

Studie 017
(CTN017-FCE20124)

Studienbericht

Pharmacia

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Reboxetine

CLINICAL STUDY
017

20 November 1995

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

(Phase III)

Final report of study
CTN017-FCE20124

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LIST OF ABBREVIATIONS AND TERMS

ANOVA	analysis of variance
b.i.d	twice daily
BUN	blood urea nitrogen
CGI	clinical global impression
CI	confidence interval
CRF	case record form
DSM-III-R	diagnostic and statistical manual - third edition - revised
ECG	electrocardiogram
ECT	electroconvulsive therapy
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
SD	standard deviation
SGOT	serum glutamic-oxaloacetic transaminase
SGPT	serum glutamic-pyruvic transaminase
T4	thyroxine
TSH	thyroid-stimulating hormone

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**REBOXETINE - PROTOCOL 20124/017
SYNOPSIS**

Name of Company: Pharmacia Spa	Individual study table referring to part IV of the dossier	(For national authority use only)
Name of finished product:	Ref.:	
Name of active ingredient(s): Reboxetine	Vol.:	
	Page:	
Title of study: Multicentre, multinational double-blind study of the activity and tolerability of reboxetine vs imipramine in patients suffering from Major Depressive Episodes		
Investigators: Dr H Berzewski, Dr M Wolfersdorf, Dr J Fischer, Dr R Uebelhack, Dr W König, Dr M Derely, Dr J Wilmotte, Dr M Van Moffaert, Dr R Spiers, Dr J Bollen, Prof CA Gagiano, Dr M Berk, Dr DAB Wilson, Dr H Hauer, Dr M El Mallah, Dr M O'Connolly, Dr P Adler, Dr K Schroter, Dr G Stumpf, Dr P Weinholz, Dr H Wiswedel, Prof A Levin.		
Study centres: Universitätsklinikum Steglitz, Freie Universität Berlin, Berlin, Germany; Abt. Psychiatric I - Univ Ulm, Ravensburg-Weissenau, Germany; Bürgerhospita, Psychiatrische Klinik, Stuttgart, Germany; Poliklinik der Charité Nervenlinik, Berlin, Germany; Psychiatrisches Landeskrankenhaus, Weinsberg, Germany; Clinique La Ramée, Neuropsychiatric Hospital, Brussels, Belgium; Hôpital Civil Vincent Van Gogh, Marchienne-au-Pont, Belgium; Universitair Ziekenhuis Gent, Psychiatrische Klinik, Gent, Belgium; St Camillus Ziekenhuis, St Denijs-Westrem, Belgium; Sancta Maria Psychiatr Ziekenhuis, Sint Truiden, Belgium; Department of Psychiatry, University of Orange Free State, Bloemfontein, South Africa; Johannesburg Medical School, Psychiatry Department, Parktown, South Africa; Department of Psychiatry, Groote Schuur Hospital, Cape Town, South Africa; An der Auerach 8, Emskirchen, Germany; Seltsamplatz 3, Forchheim, Germany; Haimendorferstrasse 4, Schwabach-Wolkersdorf, Germany; Schnieglingerstrasse 36a, Nürnberg, Germany; Altdorfer Strasse 11, Lauf/Pegnitz, Germany; Volkacher Strasse 31, Nürnberg, Germany; Brauhofgasse 1, Erlangen-Frauenaurach, Germany; Friedenstrasse 12, Fürth/Bay, Germany; Fort England Hospital, Grahamstown, South Africa.		
Publication (reference): None		
Study period: December 1990 - September 1992	Clinical Phase: III	
Objectives: To assess the activity and tolerability of reboxetine in comparison with 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 case of fluoxetine administration), after which they received reboxetine 4 mg b.i.d., or imipramine 150 mg (50 mg in the morning and 100 mg in the evening) for six weeks (imipramine was given at a dose of 50 mg b.i.d. for the first three days of the study). At the end of the initial 3 weeks of treatment, patients could be switched to a higher dose regimen, corresponding to 10 mg reboxetine and 200 mg imipramine up to the end of treatment. Patients willing to continue after completion of 6 weeks' treatment were maintained, under blind conditions, 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 using the Hamilton Depression Rating Scale (HAMD), Clinical Global Impression (CGI), and the Montgomery and Asberg Depression Rating Scale (MADRS). 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.		
Number of subjects (planned and analysed): 200 patients were to be recruited in the study. Two hundred and fifty-six patients (167 females and 89 males) from 22 centres were randomised to treatment with either reboxetine (130) or imipramine (126).		

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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)
Diagnosis and main criteria for inclusion: Patients were diagnosed according to the DSM-III-R classification. The severity of depression was quantified using the HAMD scale. Criteria for inclusion were as follows: (1) Patients of either sex, of any race, aged 18 to 65 years, with a diagnosis of Major Depressive Episode, 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 HAMD 21-item ≥ 22 .		
Test product: Capsules containing RBX methanesulphonate tablets Unit dose: 4 mg (two 2 mg tablets) or 6 mg (three 2 mg tablets) of reboxetine (free base) Mode of administration: by oral route, b.i.d. Batch no: SF1131, SF1264, SF1132, SF1291		
Duration of treatment: 6 weeks		
Reference therapy: Imipramine 25 mg tablets in indistinguishable capsules Unit Dose: 50 mg or 100 mg imipramine Mode of administration: by oral route, b.i.d. Batch no: SF1130, SF1265, SF1129, SF1151, SF1263		
Criteria for evaluation: Efficacy <i>Study end-point:</i> difference of HAMD total score at last assessment vs baseline <i>Response:</i> HAMD total score decrease equal to or greater than 50% compared to the baseline value (Visit 0) <i>Remission:</i> HAMD total score lower than or equal to 10 (absolute value) <i>Time to response:</i> number of days at onset of response confirmed at all subsequent available assessments HAMD total scores and factor scores, MADRS total scores, CGI classification Safety Adverse events, 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 > 20 mmHg from lying to standing). Clinically relevant changes of laboratory tests abnormal ECG findings according to standardised criteria.		
Statistical Method: Efficacy Mean changes of HAMD total score at last valid observation respect to baseline was the study end-point. Ninety-five per cent confidence interval (CI) of the mean changes in each treatment group and of the between treatment difference were calculated. The same sets of analyses were carried out on the subset of severe (CGI-Severity of Illness, moderately to severely ill at baseline) and melancholic patients (DSM IV criteria). Ninety-five per cent CI of the proportions of response and remission in each treatment group and of the between treatment difference were computed. The cumulative probability of the onset of response (time to response) was computed adopting the Kaplan-Maier method and the between treatment comparison was carried out by the log-rank test. Secondary efficacy variables, including HAMD and MADRS total scores and CGI were summarized by descriptive statistics at each visit and at last valid observation.		

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<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>For all 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 standardized according to a method proposed by Chuang-Stein and the 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 events or adverse event clusters during the treatment period was estimated by the Kaplan-Meier method and the difference between treatments was tested by the log-rank test.</p>		
<p>Results</p> <p>Two hundred and fifty-six patients entered the study. During the study, 130 patients received reboxetine, and 126 received imipramine. Ninety-eight reboxetine and 90 imipramine recipients completed the study while 32 (24.6%) and 36 (28.6%) patients dropped out of the study, respectively. Newly emerged adverse events or intercurrent illnesses were the main reason for discontinuation in 13 (10.0%) and 18 (14.3%) patients of the reboxetine and imipramine groups, respectively. Deterioration was the main reason for withdrawal in 8 and 7 patients of the reboxetine and imipramine groups, respectively. Remaining cases included mainly unco-operative patients (7, 5 reboxetine, imipramine). One death occurred on reboxetine (suicide).</p>		
<p>Efficacy</p> <p>The mean HAMD total score was reduced from 28.8 at Day 0 to 13.0 at last assessment, in the 127 patients treated with reboxetine who had at least one assessment in addition to baseline (3 patients had only baseline data), and to 9.6 at Day 42 in the 98 patients who completed the study. In the 121 patients treated with imipramine with at least one assessment in addition to baseline (5 patients had only baseline data), the mean HAMD total score was reduced from 28.0 at Day 0 to 13.7 at last assessment, and to 10.4 at Day 42 in the 92 patients still on treatment. The mean decrease difference between the two treatments at last assessment was 1.5 points (95% CI -1÷4).</p> <p>At last assessment, 68.5% of the reboxetine-treated patients and 56.2% of the imipramine-treated patients were classified as responders, while 52.0% and 45.5%, respectively, were seen to be in remission. The between treatment difference in the proportion of response was 12.3% (95% CI 0.3÷24.3). The cumulative probability of response (Kaplan-Meier analysis) on reboxetine was significantly higher (p=0.0126) compared to imipramine.</p> <p>At the last assessment, the percentage of patients classified as 'very much improved' or 'much improved' (CGI-Global Improvement) was 66.9% in the reboxetine group and 62.0% in the imipramine group. The percentage of much to very much deteriorated cases was higher in the imipramine group (6.6 %) than in the reboxetine group (3.1 %).</p>		

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<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 MADRS score was reduced from 17.2 at Day 0 to 7.9 at last assessment in the 127 reboxetine group patients with at least one assessment in addition to baseline, and to 5.9 at Day 42 in the 98 reboxetine patients who completed the study. In patients randomised to imipramine, values changed from 16.9 at Day 0 to 8.0 at last assessment (121 patients), and to 6.0 at Day 42 (92 assessed patients).</p> <p>The results of the additional analyses on the sub-populations of severe and melancholic patients indicate that both treatments were similarly effective in terms of improvement of the clinical picture, as seen by the decrease of HAM-D scale at the last available assessment.</p>		
<p>Safety:</p> <p>All the 256 patients who received study treatment were included in the safety analysis, i.e. 130 reboxetine, 126 imipramine.</p> <p>The occurrence of newly reported adverse events was similar in both groups during the study, 106/130 (81.5%) reboxetine group patients reported 267 adverse events compared with 103/126 (81.7%) imipramine patients who reported 303 adverse events. Discontinuation due to newly emerged adverse events was more frequent on imipramine (14.3%) than on reboxetine (10%). Most frequently reported were: dry mouth (25% reboxetine and 36% imipramine); headache/migraine (16%, 14%); hypotension and related symptoms (10%, 18%) and nausea and related symptoms (15%, 11%).</p> <p>There was a significantly higher cumulative risk on imipramine than on reboxetine of developing dry mouth, hypotension and related symptoms and tremor.</p> <p>The majority of adverse events were moderate. Adverse events were reported more frequently by men than women. The most relevant between-gender differences were related to the frequency of increased sweating, complained of mainly by male patients, and nausea and related symptoms, complained of mainly by female patients. One patient on reboxetine died (suicide) and 3 patients reported serious adverse events (parasuicide by overdose on reboxetine, supraventricular tachycardia and A-V block first degree, both on imipramine).</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 and the only difference between the two treatment groups was observed in the absolute frequency of clinically relevant decrease of both systolic and diastolic blood pressure, which was higher on imipramine than on reboxetine on standing (11% and 4% of evaluated patients, respectively). The absolute frequency of heart rate values increased to ≥ 100 beats/min was slightly higher on reboxetine than on imipramine, particularly on standing (27% and 21% of evaluated patients, respectively). However, the majority of these relevant increases occurred occasionally (reported once).</p> <p>No indication of effect on cardiac function emerged from the ECG recordings.</p>		
<p>Conclusions:</p> <p>The efficacy of reboxetine therapy in patients suffering from Major Depressive Episodes, as measured by the improvement of HAM-D, MADRS and CGI scales, was similar to that of imipramine. The cumulative probability of response ($\geq 50\%$ decrease of HAM-D total score) was significantly higher on reboxetine than on imipramine. The tolerability of reboxetine was highly acceptable, as shown in the safety profile in terms of modification of vital signs, haematology and blood chemistry tests and ECG examinations, and also in the superiority of reboxetine to imipramine in terms of the frequency of occurrence of dry mouth and hypotension and related symptoms, and the incidence of discontinuation due to adverse events.</p>		

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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 hypothesized to exert antidepressant efficacy of faster onset than the antidepressants currently available in depressed patients.

Pharmacodynamics in healthy volunteers were studied using single oral doses from 0.2 to 5 mg. The administration of 5 mg was associated with orthostatic hypotension and tachycardia [2]. Single doses of 1 and 3 mg were compared to imipramine 75 mg and placebo in a Q-EEG and psychometric study. Reboxetine induced dose-related modifications of EEG power bands and psychometric performance suggestive of psychostimulating properties, while following imipramine changes consistent with its known sedative activity were apparent [3].

The pharmacokinetic properties of reboxetine, evaluated in healthy volunteers [4], showed that average peak 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 doses of between 4 and 12 mg, showed that it was well tolerated at doses of up to 10 mg/day [5].

A double-blind, parallel, 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 (HAM-D) 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 controlled studies and to collect

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comparative evidence of reboxetine's safety and efficacy vs another tricyclic antidepressant, imipramine [7]. This comparison 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 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, administered orally for 6 weeks, in adult patients with major depressive episodes. The design of the study is shown overleaf.

A total of 200 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 diagnostic classification and the severity of depression was quantified using the Hamilton Depression Rating scale (HAMD).

After an initial wash-out period of 4-14 days, patients received one of 2 treatments: oral reboxetine 4 mg b.i.d., or imipramine 50 mg in the morning and 100 mg in the evening for 6 weeks (imipramine was given at a dose of 50 mg b.i.d. for the first 3 days of the study). 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 and 200 mg for imipramine for the remaining 3 weeks of the study.

The primary study end-point was defined as the absolute HAMD total score decrease 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 assessment were to be compared between treatment groups.

Other variables used for measuring efficacy were the Clinical Global Impression (CGI) and the Montgomery and Asberg Depression Rating Scale (MADRS).

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.

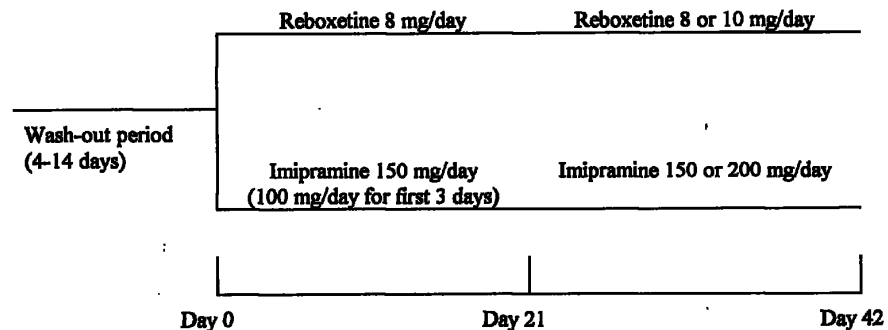
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Patients willing to continue receiving the test treatment after completion of the 6 week treatment period were maintained on the same medication under blind conditions until the completion of the last patient in the study and collection of the Case 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.



3.1.2 PROTOCOL AMENDMENTS

There was one protocol amendment, which extended the wash-out period to 3-4 weeks in case of previous fluoxetine administration.

A copy of the protocol amendment can be found in Appendix 12.1.1.

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 South Africa, while local approvals were required and obtained in Belgium, Germany and South Africa. For most centres in Germany, the approval was obtained on a draft version of the protocol,

marginally different from the final one (the most relevant differences concerned two exclusion criteria, cyclothymia and high risk of suicide, present in the final version).

The Central/IRBs 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.

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

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- The initial (pre-treatment) total score for the 21-item HAMD [9] had to be ≥ 22
 - 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 episodes associated with endocrine disorders: hypo- or hyper-thyroidism (defined as values at least 10% outside normal parameters for TSH and T₄), adrenal insufficiency, etc.
- Pregnancy (excluded by a pregnancy test at the end of the wash-out period)
- 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
- Electroconvulsive therapy (ECT) in the previous 6 months
- High risk of suicide

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3.3.3 WITHDRAWAL CRITERIA

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

- 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 10 centres participating in the study were to recruit, within a period of 1 year, a sample of 20 patients, so that a total of 200 patients was to be recruited overall.

Some of the centres which initially agreed to participate in the study never did so for logistic reasons and were replaced with other centres. During the study, 8 centres in Germany and 1 in Belgium were recruited in order to reach the foreseen patient sample.

As shown in the Principal Investigators and Affiliation list (Appendix 12.1.4), 22 centres located in 3 countries (Germany, Belgium and South Africa) participated in the study. In 17 of these centres the number of patients admitted was lower than 20, while recruitment was extended in 3 centres (nos. 9, 14/10 and 15) to above the foreseen patient sample. Recruitment was stopped after randomisation of 256 patients, slightly above the calculated sample size for an "intent to treat" analysis.

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, 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 inhibitor administration and, after the amendment, 3-4 weeks in the case of previous fluoxetine administration) patients received one of 2 possible treatments for 6 weeks: oral reboxetine 4 mg b.i.d., or imipramine 50 mg in the morning and 100 mg in the

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evening (imipramine was given at a dose of 50 mg b.i.d. for the first 3 days of the study). In the case of inefficacy or unsatisfactory response, with good tolerability, after 3 weeks of treatment, the dose of reboxetine was increased to 10 mg daily and the dose of imipramine increased to 100 mg b.i.d. for the remaining 3 weeks of the study.

3.4.2 IDENTITY OF TEST TREATMENTS

Indistinguishable capsules containing either reboxetine 4 mg (two x 2 mg tablets) (Batch No: SF1131, SF1264) or 6 mg (three x 2 mg tablets) (Batch No: SF1132, SF1291) or imipramine 50 mg (two x 25 mg tablets) (Batch No: SF1130, SF1265) plus excipients or imipramine 100 mg (four x 25 mg tablets) (Batch No: SF1129, SF1151, SF1263) 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), or one capsule of imipramine 50 mg (morning) plus one capsule imipramine 100 mg (evening) for 6 weeks. For the first 3 days of the study, imipramine was given as one 50 mg capsule in the morning and one 50 mg capsule in the evening. 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 dose of imipramine increased to 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 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] and of manufacturer recommendations [10].

3.4.4 METHOD OF ASSIGNING PATIENTS TO TREATMENT GROUPS

A randomisation list balanced within each centre and every 4 assignment was originally generated for patient allocation either to reboxetine or imipramine. In this list, in order to make the patient unequivocally identified across centres by his assignment number, a progressive number from 1 to 480 was generated. The test treatments were labelled according to the randomisation sequence number. Each randomised patient was then

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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 block of 4 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 packages.

Randomisation list was prepared by Biometrics and Data Management Department of Pharmacia, Milan by SAS PROC plan (version 5.18-6.06) and kept in a safe place until the study was completed in the last patient and the CRFs were collected.

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 4 of Appendix 12.1.1). The detachable half of the label was to be included in the appropriate place in the CRF when used.

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). An 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) 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 CGI.

3.6.1 EFFICACY

Every randomised patient 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 quantified 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.

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.

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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	(0-2)	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 6 of Appendix 12.1.1.

Factorialisation was carried out according to the ECDEU manual [11], to yield 6 factors: Anxiety/somatisation (I), Weight (II), Cognitive Disturbances (III), Diurnal Variation (IV), Retardation (V), Sleep Disturbances (VI).

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3.6.1.2 Clinical Global Impression

Severity of illness was assessed by the investigator using the CGI at screening, and 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 investigator, as described in [11], as the ratio between the subjective evaluation of improvement, scored from 1 (unchanged or worsened) to 4 (marked improvement), and the subjective evaluation of tolerability from 1 (no side effects) to 4 (side effects outweigh therapeutic effect). The Efficacy Index score ranges from 0.25 (no global benefit) to 4 (maximal global benefit). Details of the Efficacy Index can be found in Enclosure 7 of Appendix 12.1.1.

3.6.1.3 Montgomery and Asberg Depression Rating Scale

The MADRS [12] 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 [13]. The items contained in the MADRS were selected on the grounds that they were sensitive to change. The ten 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 13.

More detailed definitions of the items included in the scale can be found in Enclosure 8 of Appendix 12.1.1.

3.6.1.4 Patient Global Impression

As per protocol, each patient had to fill in the Patient Global Impression scale on Days 0, 7, 14, 21, 28, 35 and 42. The results collected were not evaluated due to the very low number of patients completing the assessments.

3.6.2 SAFETY

Every patient who received one dose of test treatment was included in the safety evaluation.

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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.

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-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; as a guideline to coding the Karch and Lasagna modified criteria were used as shown in Enclosure 11 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

* 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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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 adverse events was noted on a check list especially designed for the identification of events frequently reported in patients on antidepressant medication. The checklist is shown in Enclosure 10 of Appendix 12.1.1. These events could be either reported by the patient or observed by the investigator.

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.

ECG

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, bilirubin, total serum protein and electrophoresis, serum cholesterol and triglycerides, and at screening only, TSH and T₄.

Laboratory tests were also measured for patients who withdrew prematurely because of a serious adverse event.

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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							
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
Compliance check			x	x	x	x	x	x
Dispensing medication			x	x	x	x	x	x
Adverse events			x	x	x	x	x	x

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 measured using the HAMD scale and CGI.

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 maintained on the same medication in blind conditions until the study was completed in the last patient and the CRFs were collected. Efficacy was assessed by HAMD and CGI at monthly visits. Adverse events and vital signs were also recorded at monthly intervals and ECG and laboratory values at 3-monthly intervals. The medications were prepared as described in Section 3.4.5, but in monthly, instead of weekly, units.

3.8 GCP Compliance, Data Quality Assurance

The study was carried out before the formal adoption of GCPs by European Regulatory Authorities and in the absence of Company SOPs. 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 as stated in the declaration of Helsinki (as amended in the Venice version) and according to the procedures stated in the Attachment A 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 at which the monitor validated the content of the CRF against source documents, on the basis of the agreed procedures, were made at regular intervals. Operating procedures for study monitoring and co-ordination are described in Attachment A of Appendix 12.1.1.

Trial master file and report audits were carried out by the Company Quality Assurance Unit.

3.9 Statistical Analysis

3.9.1 SAMPLE SIZE CONSIDERATIONS

This trial mainly aimed at gathering information on the comparative effectiveness of imipramine and reboxetine additional to the information provided by a similar 3-arm placebo controlled study conducted at the same time. Ethical and the local medical practice prevented some countries (centers) from participating in the placebo controlled trial, thus rising the need of an identical separate trial excluding the placebo arm. Results of this trial were expected to be compared with the ones obtained by the 3 arm trial and joint conclusion on the reboxetine and imipramine efficacy could be eventually driven .

For the above mentioned reasons, the study had mainly estimation rather than testing purposes and therefore the number of patients made available by the participating centers was challenged against the length of the end-point variable 95% confidence interval that such a size was able to provide with.

The difference between baseline and the last postbaseline HAMD score, HAMD decrease (see below for detailed definition), was taken as the outcome variable.

From the phase II trial and from the literature [14] it seemed reasonable to assume that each treatment group showed a variability (expressed as standard deviation) of 9 points.

The participating centers were able to recruit approximately 200 patients, among which approximately 10% were expected to drop before the first postbaseline visit. Under such

assumption the expected length of the confidence interval of the between treatment difference of HAMD decrease was to be of 5.3 points of HAMD scale, 2.65 points each side.

Referring to secondary study end-points based on proportions, the same sample size allowed a length of confidence of 0.30 considering a proportion of 0.5 in each treatment group and the normal approximation method.

3.9.2 STATISTICAL AND ANALYTICAL PLANS

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 arm.

3.9.2.2 Efficacy Analyses

Definitions

The following definitions applies to the set of data analysed:

HAMD decrease	The difference between the end of treatment and baseline measurements in HAMD-21 total score. Either the last per-protocol assessment when the patient completed the study, or the last assessment before dropping out was taken as the end of treatment.
Remission	HAMD-21 total score lower than or equal to 10 (absolute value).
Response	HAMD-21 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-21 total score at entry at least equal to or greater than 22, all patients who achieved a remission (as defined above) were included into the broader category of response ($22 * 0.5 = 11$).
Time to response	Number of days elapsing between the first visit date (Baseline) and the date when the patient first achieved the response (according to the above definition) which was afterwards maintained until the end of the study or withdrawal. This definition excludes patients who achieved occasional response, but were not classified as such at the last observation.

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Severe patients	Patients scoring 5 to 6 (markedly to severely ill) on CGI-Severity of Illness scale [11] at entry.
Melancholic patients	On the basis of applicable DSM-IV criteria [15]; 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).

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 total scores of Hamilton, Montgomery and Asberg Depression Rating Scale, and CGI, were summarised by descriptive statistics (mean, median, standard deviation (-SD-), minimum, maximum, or distribution of frequency of scores) as calculated both at each visit and at the last valid observation, for the two treatment groups. In particular, in order to describe the time pattern of last valid observation values, one table reports descriptive statistics, visit by visit for only those patient who dropped out of the study at that particular time.

The frequency of patients improved, unchanged or deteriorated as for the CGI-Severity of Illness at last valid observation in comparison with baseline was also presented.

The primary end-point for efficacy analysis was HAMD decrease. Ninety-five per cent confidence interval of the between treatment difference was the basis for the efficacy conclusions [16].

Additionally, in order to allow a comparison between the results of this study and those of the above mentioned placebo controlled study, the following analyses have been carried out in both studies.

Although not strictly necessary to the analysis of differences from baseline, homogeneity of baseline HAMD-21 total scores across treatment groups was tested by ANOVA in order to assess the comparability of the disease severity within the two treatment groups.

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No transformation of the original variable was deemed necessary, as it results from the outcome variable of the difference between two random variates, and as such is known to tend to be normally distributed; homogeneity of variances was tested by F test.

ANOVA for the comparison of the HAMD decreases in the two treatment groups was performed in order to obtain a more precise estimate of the variability.

Ninety-five per cent confidence intervals of the mean difference of each treatment were computed using the standard error (SE) obtained by the ANOVA.

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-21 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. Ninety-five per cent confidence intervals of the proportions in each treatment and of the between treatment difference were computed [17].

The cumulative probability of the onset of response (time to response) was computed adopting the Kaplan-Meier method and the between treatment comparisons were carried out by the log-rank test [18].

3.9.2.3 Safety

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) change or 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 vice versa) have been displayed.

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

- frequency and percentage of patients whose values were below, equal or above the normal range at each visit. Either MacNemar test or Stuart Maxwell test [19] 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 [20], using as reference mainly the values reported on the Cecil Textbook of Medicine [21] (Appendix 12.1.8); the Wilcoxon Rank Signed test for paired data was applied in order to compare the values during treatment with those recorded at baseline [22].

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 $p < 0.01$.

Besides, abnormal values of laboratory tests defined as clinically relevant (Appendix 12.1.8) were specially considered and the frequency of patients showing them were computed according to time interval.

Clinically relevant abnormalities were judged on the basis of the concordance with other examinations evaluating the same organ function. 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, were performed both in terms of patients complaining of adverse events and the events themselves.

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 for selected aggregations of symptoms (clusters) likely to share the same underlying mechanism or described with synonyms. 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, age and diagnosis.

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 between treatment comparison was estimated by the log-rank test. 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 that anticipated into the protocol.

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 the ICD9 dictionary [23]; concomitant drugs according to the Drug Reference List [24]; adverse events according to the WHO-ART dictionary [25]. In the absence of an adequate code and preferred term, "urinary hesitancy" was coded as "micturition disorder" and "blurred vision" as "vision abnormal". The mentioned events therefore appear in the tables under the indicated terms.

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 given in Appendix 12.1.11. A selection of statistical analysis outputs is shown in Appendix 12.1.12.

4. STUDY PATIENTS

4.1 Disposition of Patients

Treatment randomisation for each patient is given in Appendix 12.1.7.

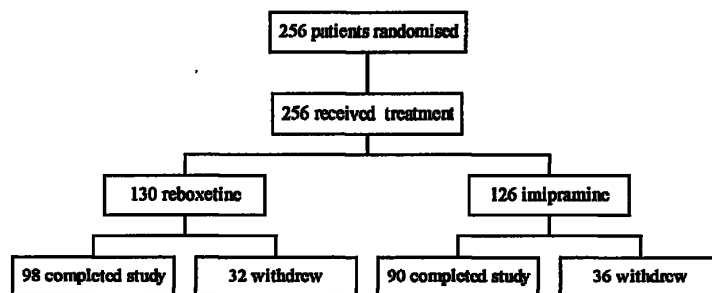
Two hundred and fifty-six patients were admitted to the study from December 1990 to September 1992 and randomised to treatment by investigators at 22 centres, as shown in Table 1.

As shown in Table 2, a total of 188 patients (73.4%) completed the study and 68 (26.6%) withdrew; 32 (24.6%) in the reboxetine group, and 36 (28.6%) in the imipramine group. Frequency and timing of withdrawal are shown as primary reason for withdrawal in Table 3.

Adverse events or intercurrent illnesses were the main reason for withdrawal in 12 and 20 patients of the reboxetine and imipramine groups, respectively. However, in two cases on imipramine, the intercurrent illness (influenza) and the event (somnolence) causing discontinuation had emerged before starting the experimental treatment. Therefore, the discontinuation rate for newly emergent adverse events is 14.3% on imipramine and 10.0% on reboxetine, including the death which occurred. Adverse events associated with discontinuation in individual cases are discussed in the Adverse Event Section (Section 8.2.3.2). Deterioration was the main reason for withdrawal in 8 and 7 patients of the reboxetine and imipramine groups, respectively. Remaining cases included mainly uncooperative patients (7 and 5 on reboxetine and imipramine, respectively).

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 (17.5% in the reboxetine group and 16.1% in the imipramine group) 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. Diagnosed endocrine disorder was present in 4 of the reboxetine and none of the imipramine group patients. Concomitant medications not allowed according to the protocol during the wash-out period were administered to 4.6% of the reboxetine group patients and 7.1% of the imipramine group patients. With the exception of thyroid function test abnormalities, non-compliance with these entry criteria was infrequent. The index episode duration was shorter than four weeks in 4 reboxetine and 2 imipramine group patients and was longer than four months only in one reboxetine group patient. In one imipramine group patient, the pregnancy test at admission was found to be positive, but treatment had already been started with administration of only one capsule of test drug.

Randomisation

Distribution and use of study medication were to be done, as previously mentioned, in blocks of 4 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.

As reported in Table 5, errors in randomisation procedures led to administration of non-randomised treatment to some patients, at a similar frequency in both treatment groups. Of the 127 patients randomised to reboxetine, 22 received imipramine; of the 129 patients randomised to imipramine, 25 received reboxetine.

Assessment intervals

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

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Concomitant medications

The frequency of administration of non-protocolled concomitant medications (because of their psychotropic properties) is given by active agent in Table 7, and by class in Table 8. Long-acting benzodiazepines were administered to five reboxetine group patients and six imipramine group patients. Overall, unprotocolled psychotropic medications were administered to 6 reboxetine group patients and to 6 imipramine group patients.

Other

One reboxetine patient had a positive pregnancy test during the study (Day 21) and was subsequently withdrawn due to this protocol violation. The patient delivered a normal healthy newborn at term.

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.

Summary of demographic data

		Reboxetine (n = 130)		Imipramine (n = 126)	
		n	(%)	n	(%)
Sex	Female	84	64.6	83	65.9
	Male	46	35.4	43	34.1
	Total	130	100	126	100
Race	Caucasian	117	90.0	118	93.7
	Black	10	7.7	8	6.3
	Other	3	2.3	0	0
	Total	130	100	126	100
		mean	SD*	mean	SD*
Age (years)		45.4	12.0	42.4	13.6
Height (cm)		167.4	8.0	167.8	8.9
Weight (kg)		68.7	11.4	69.4	13.8

*SD standard deviation

The majority of patients were female; the ratio of females to males was similar in both groups. The vast majority of patients were Caucasian. The two 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 classification, 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 (60.8% reboxetine and 54.8% imipramine). A Major Depressive Episode (DSM-III-R No 296.2) was diagnosed in all remaining cases.

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		
	n	Median (range)		n	Median (range)	
Age at onset (years)	100	40.00 (15-64)		101	39.00 (17-64)	
Number of previous episodes	72	2.00 (1-40)		66	2.00 (1-11)	
Duration of the last episode (weeks)	71	12.00 (3-128)		68	16.00 (2-60)	
Duration of the present episode (weeks)	129	7.00 (1-48)		126	8.00 (2-16)	

The treatment groups were well matched with regard to the age at onset of depression, the duration of the present episode and the number of previous episodes, while the duration of the last episode of depression was slightly higher in the imipramine group.

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 (70.0% of the reboxetine group patients, and 65.1% of the imipramine group patients). A precipitating external stress was absent more frequently in the reboxetine group (40.0%) than in the imipramine group (28.6%).

4.3.2 SEVERITY OF DEPRESSION

The severity of the depression, according to the HAMD, MADRS and CGI scales, at the various assessment intervals during the study is displayed in terms of summary statistics in Tables 19 to 37 and summarised below. 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 and MADRS scores.

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Severity of depression at Day 0

	Reboxetine			Imipramine		
	n	mean	SD*	n	mean	SD*
HAMD	127	28.8	4.8	121	28.0	5.2
MADRS	127	17.2	3.3	121	16.9	3.0

	n	(%)	n	(%)
CGI Severity				
Normal	0	(0.0%)	0	(0.0%)
Borderline mentally ill	0	(0.0%)	0	(0.0%)
Mildly ill	2	(1.6%)	1	(0.8%)
Moderately ill	26	(20.5%)	33	(27.3%)
Markedly ill	73	(57.5%)	63	(52.1%)
Severely ill	25	(19.7%)	22	(18.2%)
Extremely ill	1	(0.8%)	2	(1.7%)

*SD standard deviation

On the whole, there were no major imbalances between the two 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; mianserine and selective serotonin reuptake inhibitors were also quite common; monoamine oxidase inhibitors were infrequently mentioned. Active principles are similarly represented in both treatment groups.

4.3.4 MEDICAL HISTORY

The medical history and medical examination findings at entry of the study are summarised by single disease entity in Table 14, and by affected body system in Table 15. A minority of the patients had history or presence of diseases other than the affective disorder at admission. No imbalances between the 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, 11/130 (8.5%) of the reboxetine group patients and 20/126 (15.9%) of the imipramine group patients received half of the protocolled number of daily capsules, because they started their treatment in the evening. This resulted in a Day 1 dose of 4 mg of reboxetine and a Day 1 dose of 50 mg of imipramine. Over the next few days, a maximum of 5 and 4 patients per day, in the reboxetine and imipramine group respectively, 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. Over the same period, a maximum of one patient per day in the reboxetine and 2 in the imipramine group had their daily dose increased to 12 mg/day reboxetine and to a maximum of 300 mg/day imipramine. These were due to a mistakenly intake of double capsules in the morning and/or evening.

As summarised in Table 16.1, at the end of the initial 3 weeks of treatment, 13 patients of the reboxetine group (10% of the admitted), and 16 of the imipramine group (12.7% of the admitted) 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). Over the following period, 9 additional patients on reboxetine and 6 on imipramine were switched to level 2 dose, while a maximum of 5 patients per day in the reboxetine and 4 in the imipramine 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 sign/symptoms of intolerance. During this period, on several treatment days, 3 reboxetine group patients and 5 imipramine group patients mistakenly took both dose levels 1 and 2, corresponding to 18 mg/day reboxetine and 350 mg/day imipramine. One patient took 20 mg/day reboxetine due to a mistaken intake of double capsules of dose level 2. Signs of intolerance were reported with reboxetine and included headache, nausea and fatigue. Dry mouth, headache, dizziness, tremor, somnolence and abnormal vision were reported with imipramine (see Adverse Event Section).

Comparison of the daily dose administered (as reported in the Compliance Section of the CRF in terms of number of capsules taken per day) with the expected dose (as indicated in the Experimental Treatment Section of the CRF in terms of number of capsules foreseen per day) 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 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 64.6% of the reboxetine group patients, and 63.5% of the imipramine group patients. Only in a few cases the reported compliance was lower than

80% (2 patients in the reboxetine group and 4 in the imipramine group) or between 80% and 89% (3 patients per group in the reboxetine and imipramine groups).

6. CONCOMITANT MEDICATIONS

The absolute frequencies, of those patients who, during the treatment period, 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 both treatment groups.

7. EFFICACY RESULTS

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 28.8 at Day 0 to 13.0 at last assessment (mean decrease 15.8, 95% CI 14.0 + 17.5), in the 127 patients treated with reboxetine who had at least one assessment in addition to baseline (3 patients had only baseline data), and to 9.6 at Day 42 in the 98 patients who completed the study. In the 121 patients treated with imipramine with at least one assessment in addition to baseline (5 patients had only baseline data), the mean HAMD total score was reduced from 28.0 at Day 0 to 13.7 at last assessment (mean decrease 14.3, 95% CI 12.5 + 16.1), and to 10.4 at Day 42 in the 92 patients still on treatment. The mean decrease difference between the two treatments at last assessment was 1.5 points (95% CI -1.0 + 4.0).

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

The pattern of improvement of HAMD factors was similar in the reboxetine-treated and imipramine-treated patients. At the last assessment, small differences were seen in: Factor I Anxiety/somatisation (median difference vs Day 0 of 0.83 [reboxetine group] and 0.67 [imipramine group]); and Factor III Cognitive Disturbance (median difference vs Day 0 of 0.67 [reboxetine group] and 0.50 [imipramine 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 in comparison with the imipramine group mainly from Day 21 to Day 42: 45.5%-83.7% on reboxetine vs 38.3%-70.7% on imipramine. The percentage of

patients in remission was also slightly higher in the reboxetine group at each visit, being at Day 42, 63.3% on reboxetine and 56.5% on imipramine.

At last assessment (Table 26) 68.5% of the reboxetine-treated patients and 56.2% of the imipramine-treated patients were classified as responders, while 52.0% and 45.5%, respectively, were seen to be in remission. The between treatment difference in the proportion of response was 12.3% (95% CI 0.3 + 24.3).

The cumulative probability of response (confirmed at all available subsequent assessments) is plotted according to the Kaplan-Meier method in Figure 2. Patients on reboxetine had a cumulative rate of response significantly different ($p=0.0126$) from patients on imipramine. The time to response appears to be somewhat quicker on reboxetine than on imipramine.

Additional analyses were carried out on the sub-populations of patients classified as markedly to severely ill at admission (according to the CGI-Severity of Illness scale) and on those characterised as melancholic at admission (possible for 219 of the 256 patients admitted, 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 severely ill at admission in the two treatment groups (99 reboxetine and 87 imipramine) is shown, together with the 95% confidence interval, in Figure 3. Results are very similar to those reported for the total population (Figure 1), the mean decrease difference between the two treatments being 2.0 points (95% CI -1.0 + 5.0).

The mean decrease at last assessment of the HAMD total score in those patients which could be classified as melancholic at admission in the two treatment groups (melancholic/non-melancholic: 51/60 reboxetine, 44/64 imipramine), is shown, together with the 95% confidence interval, in Figure 4. Also in this subpopulation, the mean decrease of the HAMD total score is higher in reboxetine than in imipramine group patients and the difference is 1.6 points (95% CI -3.0 + 6.3).

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 overall distribution pattern was similar in the two treatment groups. The proportion of normal or borderline cases is somewhat higher in the reboxetine group mainly at Day 14 and Day 21 (14.5% vs 5.6% and 24.8% vs 13.1%, respectively). This proportion, at last assessment, was 44.1% with

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reboxetine and 42.1% with imipramine. Small differences between the two treatment groups were seen in the proportion of markedly ill cases (9.4% with reboxetine and 14.9% with imipramine) at last assessment.

A shift table of the last value vs Day 0 (Table 29) showed that the CGI severity of illness had decreased in 80.3% of reboxetine group patients, increased in 3.1% and remained the same for 16.5%, whereas the CGI severity of illness had decreased in 73.6% of imipramine group patients, increased in 5.8% and remained the same in 20.7%.

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 overall distribution pattern was similar in the two treatment groups. The percentage of patients who were 'very much improved' or 'much improved' at the last assessment was 66.9% in the reboxetine group and 62.0% in the imipramine group. The percentage of 'much to very much deteriorated' cases was higher in the imipramine group (6.6%) than in the reboxetine group (3.1%).

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. The most relevant difference between the two treatments is seen in the proportion of cases where marked efficacy was present in the absence of side-effects (index=4) from Day 14 to Day 42: 12.0%-41.8% of reboxetine-treated cases vs 2.8%-29.3% of imipramine-treated cases. At last assessment, side-effects were judged to outweigh efficacy in 18.1% of the reboxetine patient group and 18.2% of the imipramine patient group. Treatment group differences are seen in the proportion of cases where some advantages were seen in terms of efficacy vs side-effects (index=2): 14.2% of the reboxetine-treated cases vs 23.1% of the imipramine-treated cases; and in the proportion of cases where marked efficacy was present in the absence of side-effects (index=4): 33.9% of the reboxetine-treated cases vs 22.3% of the imipramine-treated cases.

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).

The mean total MADRS score was reduced from 17.2 at Day 0 to 7.9 at last assessment in the 127 reboxetine group patients with at least one assessment in addition to baseline,

and to 5.9 at Day 42 in the 98 reboxetine patients who completed the study. In patients treated with imipramine, values changed from 16.9 at Day 0 to 8.0 at last assessment (121 patients), and to 6.0 at Day 42 (92 assessed patients).

The pattern of improvement in MADRS items was similar in the reboxetine-treated and imipramine-treated patients.

7.4 Efficacy Conclusions

The results of the planned analysis of the study end-point, i.e. the difference vs baseline of the HAMD total score at the last assessment, prove the antidepressant efficacy of reboxetine in the treatment of major depressive episodes. The positive control, imipramine, was similar to reboxetine in terms of frequency, rate and extent of the induced clinical improvement. Patients classified as responders were somewhat more common in the reboxetine group than in the imipramine group and patients on reboxetine had a cumulative rate of response significantly greater than patients on imipramine.

Secondary efficacy assessments indicate similar improvement in both treatment groups, with a slightly higher proportion of maximal efficacy index (index=4) in the reboxetine-treated patients.

The results of the additional analyses on the sub-populations of severe and melancholic patients indicate that both treatments were similarly effective in terms of improvement of the clinical picture, as evaluated by the HAMD scale at the last available assessment.

As for the laboratory tests, vital signs and ECG, only the patients with at least one assessment in addition to baseline are evaluated.

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. 130 reboxetine patients and 126 imipramine patients.

8.1.2 TOTAL DRUG EXPOSURE

As shown in Table 16, of the 130 and 126 patients exposed to reboxetine and imipramine, 107 and 99, respectively, were treated for at least 3 weeks, while 98 and 90 were treated for 6 weeks and completed the study.

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 38, by age classes in Table 39 and by DSM-III-R diagnosis in Table 40. Eighty-one point five per cent of the reboxetine patients and 81.7% of the imipramine patients exposed had 267 and 303 adverse events and an average of 2.5 and 2.9 adverse events, respectively. Males suffered from adverse events more frequently than females on both reboxetine (87.0% vs 78.6%) and imipramine (86.0% vs 79.5%). Patients aged 18 to 30 years had adverse events more frequently than patients who were aged 31 to 45 or over 45 for reboxetine (84.2%, 83.3%, 79.7%, respectively) and for imipramine (85.3%, 73.5%, 84.5%, 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) at a similar rate in both treatment groups.

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 41 (all events) and 42 (split by body system with relevant events grouped in clusters) and by body system and sex in Table 43. Amongst the most frequently reported events (>5% of exposed patients in at least one group), the events more frequently reported on reboxetine than imipramine were: headache/migraine (16.2%, vs 14.3%), nausea and related symptoms (14.6% vs 11.1%) and urinary hesitancy/retention (7.7% vs 4.8%)

Adverse events more frequently reported on imipramine than on reboxetine were: dry mouth (35.7% vs 24.6%), hypotension and related symptoms (18.3% vs 10.0%), insomnia (11.1% vs 7.7%), tachycardia (10.3% vs 6.2%), tremor (10.3% vs 1.5%), and somnolence (7.1% vs 3.1%).

The most relevant between-gender difference was related to the frequency of increased sweating, complained of mainly by male patients (23.9% of male vs 8.3% of female patients on reboxetine; 20.9% of male vs 10.8% of female patients on imipramine), nausea and related symptoms, complained of mainly by female patients (17.9% vs 8.7% of male patients on reboxetine, 12.0% vs 9.3% of male patients on imipramine), tachycardia, complained of mainly by male patients on reboxetine (10.9% vs 3.6% of female patients), and urinary hesitancy/retention, complained of mainly by male on reboxetine (19.6% vs 1.2% of female patients).

The most frequent, therefore, were disorders of the autonomic nervous system (NS) (34.6% and 44.4% on reboxetine and imipramine, respectively) which is also the most frequently affected system in both female and male patients with adverse events,

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cardiovascular disorders (22.3%, 33.3%, respectively), gastro-intestinal (GI) system disorders (26.2%, 24.6%, respectively), central and peripheral NS disorders (20.0%, 25.4%, respectively), and psychiatric disorders (17.7%, 23.0%, respectively).

8.2.1.2 Occurrence

The occurrence of adverse events is grouped by week of onset and event/event clusters or body system in Tables 44, 45 and 46, respectively. The most frequent events on reboxetine and imipramine emerged initially during treatment, within the first week (autonomic NS disorders, 58.5%, 71.0%, respectively; cardiovascular disorders, 31.7%, 47.3%; GI system disorders, 61.9%, 52.6%; psychiatric disorders, 59.4%, 40.0%; central and peripheral NS disorders, 29.4%, 45.2%).

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 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 19. As shown in Figure 5, the risk of developing at least one adverse event in the reboxetine group is the same as that in the imipramine group. As for individual events or clusters, the cumulative risk is significantly higher on imipramine than on reboxetine for dry mouth, hypotension and related symptoms and tremor.

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 47. 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 10mg/day reboxetine and to 200 mg/day imipramine.

8.2.1.5 Maximal Severity

The maximal severity of adverse events is grouped by sex, age and DSM-III-R classification in Table 48 and by event or body system in Tables 49 and 50, respectively. Events were most frequently of moderate severity on reboxetine and imipramine (49.1% and 48.5%, respectively), particularly in females (51.5% and 50.0%), but also in males (45.0% and 45.9%), severe events being reported in 28.3% and 30.1% of the patients with at least one event on reboxetine and imipramine, respectively. The severity of adverse events for the majority of the affected body systems was moderate for both reboxetine and imipramine. However, in both groups, mildness characterised the severity of adverse events for the autonomic nervous system (46.7% reboxetine, 44.6% imipramine) and urinary system disorders (46.2% and 42.9%). There did not seem to be any effect of age or depressive illness (as diagnosed at entry) on the severity on adverse events.

8.2.1.6 Duration

Summary statistics of the duration of adverse events are described in Table 51. The median duration was 7 days for reboxetine and 8 days for imipramine. Among the most frequent events, the median duration was higher in the reboxetine group than in the imipramine group for tachycardia (8 days, 3 days) and urinary hesitancy (24 days, 3 days), and higher in the imipramine group than in the reboxetine group for increased sweating (19 days, 8 days), insomnia (17 days, 8 days), and constipation (21 days, 10 days).

8.2.1.7 Symptomatic Treatment

As shown in Table 52, 23.6% and 18.2% of the events on reboxetine and imipramine, respectively, required symptomatic treatment in 39.6% and 36.9% of the affected patients. Events most frequently requiring symptomatic treatment were insomnia on both imipramine and reboxetine (12 out of 16 and 8 out of 11 events, respectively) and hypertension on reboxetine (6 out of 7 events).

8.2.1.8 Modification of Study Medication and Patient Outcome

As shown in Table 53, no change in study medication was required for 82.0% and 77.9% of the events, in the reboxetine and imipramine groups, respectively, while the daily dose was reduced in 2.2% and 4.3% of the cases, respectively, or the treatment temporarily interrupted in 3.0% and 1.0%. According to the adverse event outcome reported by the investigators, 12.0% and 16.2% of the cases in the reboxetine and imipramine groups contributed to withdrawal. This was most frequently seen for headache/migraine on imipramine (23.8% of the 21 events) and reboxetine (14.8% of the 27 events), for urinary hesitancy/retention on imipramine (42.9% of the 7 events) and reboxetine (36.4% of the 11 events), for asthenia/fatigue on imipramine (71.4% of the 7 events) and for nausea and related symptoms on reboxetine (25.0% of the 20 events). The individual cases of patients withdrawn due to adverse events are described in Section 8.2.3.2.

As shown in Table 54, of the 46 and 65 events requiring modification of the study medication in the reboxetine and imipramine groups, the vast majority (65.2% and 75.4%, respectively) disappeared following the modification of the regimen. The patient outcome, grouped by event and action taken on study medication in Table 55, corresponds to full recovery in 69.6% and 73.8% of the reboxetine and imipramine cases following modification of the treatment regimen, and in 67.0% and 63.0% of the cases of unchanged study medication, the event being still present at last assessment in 29.4% and 34.9% of the latter cases.

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 56, 57 and 58. 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 both treatment groups, with the exception of tachycardia and urinary hesitancy in the reboxetine group, and increased sweating, insomnia and tremor in the imipramine group. In addition, in the reboxetine group, the incidence of headache increased during the early part of the study, before declining rapidly towards the end of the study.

The overall prevalence of adverse events in both treatment groups is shown in Figure 20. The proportion of patients affected by at least one adverse event during the different weeks of treatment was slightly higher on imipramine than on reboxetine, particularly during the final 3 weeks of treatment.

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 11 of Appendix 12.1.1) is described in Table 59. The majority of events on reboxetine and imipramine (39.7% and 40.9%, respectively) were judged possibly related, while 24.0% and 29.4%, respectively, were judged probably related, and 7.9% and 9.6%, respectively, were judged definitely related. Among the most frequent events, the maximal frequency of definite/probable relationship was present for dry mouth (57.6%, 68.8%) nausea and related symptoms (50.0%, 57.1%), hypotension and related symptoms (42.9%, 34.6%), insomnia (54.6%, 25.0%) on reboxetine and imipramine, respectively, as well as for urinary hesitancy/retention (54.5%) on reboxetine and asthenia/fatigue (85.7%) on imipramine.

8.2.2 ADVERSE EVENT SUMMARY

Of the 130 reboxetine patients and 126 imipramine patients who received study medication, 106 (81.5%) and 103 (81.7%) patients reported a total of 267 and 303 adverse events, respectively (2.5, 2.9 per patient) (Table 38). The cumulative risk of occurrence of the first adverse event was not significantly different between treatment groups (Figure 5). The prevalence of adverse events during the study indicates a slightly higher proportion of patients with adverse events in the imipramine than in the reboxetine group, particularly in the final 3 weeks of treatment (Figure 20).

8.2.2.1 Severity of Adverse Events

The maximum severity of adverse events is presented in Tables 48-50 and summarised as follows:

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Severity of adverse events

No. of patients					
Reboxetine			Imipramine		
Mild	Moderate	Severe	Mild	Moderate	Severe
24	52	30	22	50	31

The majority of adverse events were mild or moderate in both groups with little or no difference in the prevalence of each severity group between treatments.

8.2.2.2 Age- and Gender-Related Effects

Males suffered from adverse events more frequently than females on reboxetine (87.0% vs 78.6%) and on imipramine (86.0% vs 79.5%) (Table 38). Patients aged 18 to 30 years had adverse events more frequently than patients who were aged 31 to 45 or over 45 for reboxetine (84.2%, 83.3%, 79.7%, respectively) and for imipramine (85.3%, 73.5%, 84.5%, respectively) (Table 39). The most relevant between-gender differences were related to the frequency of increased sweating, complained of mainly by male patients (23.9% reboxetine, 20.9% imipramine), and nausea and related symptoms, complained of mainly by female patients (17.9% reboxetine, 12.0% imipramine) (Table 42).

8.2.2.3 Frequently Reported Adverse Events

Adverse events which occurred in 5% or more of the patients during the study are presented by body system in the following table:

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Adverse events occurring in 5% or more of patients

Body system	Adverse event	Reboxetine (n=130)		Imipramine (n=126)	
		No. of patients with event	% of patients exposed	No. of patients with event	% of patients exposed
GI disorders	Nausca and related symptoms	19	15	14	11
	Constipation	13	10	13	10
Psychiatric disorders	Insomnia	10	8	14	11
	Agitation / anxiety / nervousness	9	7	9	7
	Somnolence	4	3	9	7
Autonomic NS disorders	Dry mouth	32	25	45	36
	Increased sweating	18	14	18	14
General cardiovascular disorders	Hypotension and related symptoms	13	10	23	18
	Tachycardia	8	6	13	10
Central and peripheral NS disorders	Headache / migraine	21	16	18	14
	Tremor	2	2	13	10
Respiratory system disorders	Bronchitis	6	5	1	1
Body as a whole/general disorder	Asthenia/fatigue	5	4	6	5
Urinary system disorders	Urinary hesitancy/retention	10	8	6	5

The estimate of the cumulative risk of adverse events, according to the Kaplan-Meier method and log-rank test, is the same in both treatment groups. For individual events or clusters, the cumulative risk for dry mouth and tremor is significantly higher on imipramine than on reboxetine. Dry mouth was the most common adverse event with 25% of reboxetine patients and 36% of imipramine patients reporting this event.

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

8.2.3.1 Serious Adverse Events and Deaths

One patient from the reboxetine group died (suicide), and three patients suffered from serious adverse events: parasuicide by overdose (on reboxetine), supraventricular tachycardia and A-V block first degree (both on imipramine). Case histories for these patients are provided in Appendix 12.2.1.

8.2.3.2 Adverse Events Associated with Withdrawal

Thirty-one patients (13 on reboxetine, 10.0%; 18 on imipramine, 14.3%) had adverse events or intercurrent illnesses as the main reason of withdrawal from the study (Table 60). The nature of the adverse events is summarised as follows:

Adverse events leading to withdrawal

Treatment	Patient number	Adverse event	Relationship to study drug
Reboxetine	50, 51, 277, 330	Insomnia	Probable, Probable, Probable, Probable
	280, 355, 358	Dizziness	Probable, Probable, Missing
	197, 271, 355	Headache	Doubtful, Possible, Probable
	330, 355	Nausea	Probable, Probable
	277, 358	Increased sweating	Probable, Missing
	50, 353	Suicide attempt	None, Definite
	194, 237	Urinary retention	Probable, Possible
	355	Dyspopsia	Probable
	355	Abdominal pain	Probable
	280	Dry mouth	Probable
	280	Somnolence	Probable
	277	Hypothyroidism	None
	277	Agitation	Probable
	271	Hypertension	Possible
	197	Asthenia	Doubtful

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Reboxetine	129	Urinary hesitancy	Probable
	51	Delusion	Probable
	50	Hyperuricaemia	Possible
	50	Bundle branch block	Possible
Imipramine	8, 34, 209, 382, 429	Headache	Possible, None, Probable, Probable, Probable
	8, 209, 273, 379, 429	Dry mouth	Possible, Possible, Possible, Probable, Probable
	8, 273, 307, 376	Tremor	Possible, Possible, Probable, Probable
	209, 308, 429	Fatigue	Probable, Probable, Probable
	8, 357, 429	Dizziness	Possible, Probable, Probable
	196, 307, 360	Agitation	Possible, Probable, Probable
	357, 429	Asthenia	Probable, Probable
	308, 429	Nausea	Probable, Probable
	273, 379	Confusion	Possible, Probable
	196, 360	Insomnia	Possible, Probable
	8, 357	Somnolence	Possible, Probable
	8, 308	Increased sweating	Possible, Probable
	261, 273	Urinary retention	Possible, Possible
	36, 270	Tachycardia	Possible, Unknown
	429	Anorexia	Probable
	427	Oesophagitis	Possible
	379	Taste perversion	Probable
	376	Dysphagia	Probable
	360	Hot flushes	Probable
	357	Sinusitis	Possible
	308	Urinary tract infection	None
	273	Loss of taste	Possible
	196	Rash	Probable
44	Delusion	Doubtful	
34	Back pain	None	
36	Manic reaction	Definite	
8	Abnormal vision	Probable	

In addition 2 patients of the imipramine group withdrew from the study for adverse event/intercurrent illness without having a newly emerged adverse event: one patient

(No.45) dropped out due to somnolence present before the start of treatment, and a second patient (No.276) due to influenza present from one week before the start of treatment.

8.3 Laboratory tests

8.3.1 SUMMARY STATISTICS OF LABORATORY VALUES

As shown in Table 61, in the reboxetine group, compared to baseline, there was a significant ($p < 0.01$) increase after 6 weeks of treatment in platelets (median difference $18.60 \times 10^9 / \text{mm}^3$) and in uric acid (median difference 0.31 mg/dl). There was a significant decrease in serum chloride after 3 and 6 weeks of treatment (median difference -0.31 mEq/l and -0.69 mEq/l, respectively).

Similarly, in the imipramine group, compared to baseline, there was a significant increase in alkaline phosphatase after 3 and 6 weeks of treatment (median difference 4.13 U/l and 4.85 U/l, respectively).

8.3.2 URINALYSIS

Frequency of abnormal findings at baseline and during the treatment period or at last assessment are shown in Tables 62 and 63, 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 baseline to presence of albumin, sugar, WBC and RBC as compared to baseline both at the various assessment intervals (Table 64) and at last available assessment (Table 65). The same considerations hold for specific gravity (Tables 66 and 67).

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 68. There were no statistically significant shifts ($p < 0.01$) in the distribution of the frequencies (either towards the higher or lower values) in the reboxetine or imipramine groups.

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 69. Frequency of clinically relevant abnormal values was similarly low in the two treatment groups over the study period; no significantly increased frequency over baseline was present for any of the variables measured in the reboxetine and imipramine patient groups.

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 70 to 74. 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 72, 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) once, twice or more times is given in Table 73.

As shown in Table 73, the frequency of clinically relevant decrease of blood pressure, particularly the diastolic pressure, was higher than the frequency of relevant increase similarly in both groups. The only difference between the two treatment groups concerned the frequency of relevant decrease of both the systolic and diastolic pressure on standing, which was higher on imipramine than on reboxetine (13 cases vs 5, representing 11% and 4% of evaluated patients, respectively). As for heart rate, the frequency of patients with at least 20% increased values, associated with values ≥ 100 beats/min, was higher, particularly on standing, in the reboxetine group (34 cases, representing 27% of evaluated patients) compared with the imipramine group (25 cases, representing 21% of evaluated patients). Relevant increases occurred occasionally (reported once) in the majority of the cases on both groups.

The number and percentage of patients with orthostatic hypotension at each visit is presented in Table 74. At baseline the event was present in 3 patients in the reboxetine group and 1 in the imipramine group. Subsequently the event had a low frequency at all visits, affecting a maximum of 4.6% of the reboxetine patients on Day 21 and 5.8% of the imipramine patients on Day 7.

8.4.2 BODY WEIGHT

Summary statistics of the body weight values (Kg) at the various assessment intervals are given in Table 75, while the absolute and per cent frequency of patients showing higher (>2.5 Kg), lower (<2.5 Kg) or similar values vs baseline at the various assessment intervals is given in Table 76. No trends toward modification and no difference between the reboxetine and imipramine 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 77, 209 patients had their ECG recorded at baseline, 8.6% of whom showed at least one ECG abnormality (9.0% reboxetine and 8.2% imipramine). During the study, 202 patients had their ECG recorded after 3 weeks of treatment, and 177 after 6 weeks of treatment. Of these patients, 11.3% (Days 1-21) and 18.5% (Days 22 to 42) had at least one ECG abnormality recorded during treatment, in the reboxetine group. The equivalent proportions in the imipramine group were 11.5% (Days 1 to 21) and 12.9% (Days 22 to 42). In the reboxetine group, the proportion of male patients with at least one abnormality was slightly higher than the same proportion of female patients. This is due to the higher frequency of tachycardia complained of mainly by male patients on reboxetine, as already commented in section 8.2.1.1. As shown in Table 78, during the study, the frequency of at least one newly emerged abnormality in patients with normal tracing at baseline was always consistently lower than the frequency of normalisation of ECG recordings in patients with at least one abnormality at entry in both treatment groups. At the last assessment of the study (Table 79), of the 18 patients (10 reboxetine and 8 imipramine) who had had at least one abnormality at baseline, 50% on reboxetine and 50% on imipramine were reported as normal. Among the 191 patients (101 reboxetine and 90 imipramine) with normal tracings at baseline, 15.8% on reboxetine and 8.9% on imipramine 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 80. At screening, individual abnormalities are present in a maximum of 3.6% (sinus tachycardia >100) of the 111 evaluated cases of the reboxetine and in 2% (several types) of the 98 evaluated cases in the imipramine group. During the treatment, the frequencies of all observed abnormalities were not modified to any significant extent in either treatment group. As shown in Table 81, at the last assessment, for all abnormalities and both treatment groups, the proportion of newly observed cases among normal baseline cases is lower than the proportion of normalised cases among abnormal baseline cases. Newly emerged abnormalities never reported at baseline occurred with a slightly higher frequency in the reboxetine compared with the imipramine group; the most common of these was sinus tachycardia (9 reboxetine and 4 imipramine).

The frequency of randomised patients with at least one abnormality by abnormality group during the study is shown in Table 82. At screening, from 0.9% (ischaemic signs) to 5.4% (rhythm disorders) of the evaluated patients in the reboxetine group and 1.0% (ischaemic signs and other disorders) to 5.1% (rhythm disorders) in the imipramine group showed at least one abnormality of the indicated groups. During the treatment, the frequencies were not modified to any significant extent in any of the treatment

groups. As shown in Table 83, at last assessment, the proportion of newly emerged cases was similar in the two treatment groups, with the exception of newly emerged rhythm disorders in 11 cases on reboxetine and 7 on imipramine, and of newly emerged ischaemic signs in 1 case on reboxetine. In both groups, the proportion of normalised cases was consistently higher than the proportion of newly emerged cases.

8.6 Safety Conclusions

All the 256 patients who received study treatment were included in the safety analysis (130 reboxetine, 126 imipramine).

The occurrence of newly reported adverse events was similar in both groups during the study; 106/130 reboxetine group patients reported 267 adverse events compared with 103/126 imipramine patients who reported 303 adverse events. Discontinuation due to adverse event was more frequent on imipramine (14%) than on reboxetine (10%). Most frequently reported were: dry mouth (25% reboxetine and 36% imipramine); headache/migraine (16%, 14%); and nausea and related symptoms (15%, 11%). The majority of adverse events were moderate in both treatment groups. Adverse events were reported more frequently by men than women in both treatment groups. The most relevant between-gender differences were related to the frequency of increased sweating, complained of mainly by male patients, 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 is significantly higher on imipramine than reboxetine for dry mouth and tremor.

One patient of the reboxetine group died (suicide) and three patients suffered from serious adverse events: parasuicide by overdose (on reboxetine), supraventricular tachycardia and A-V block first degree (both on imipramine).

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

Vital signs were not modified to any significant extent and the only difference between the two treatment groups was observed in the absolute frequency of clinically relevant decrease of both systolic and diastolic blood pressure, which was higher on imipramine than on reboxetine on standing (11% and 4% of evaluated patients, respectively). The absolute frequency of heart rate values increased to ≥ 100 beats/min was slightly higher on reboxetine than on imipramine, particularly on standing (27% and 21% of evaluated patients, respectively). However, the majority of these relevant increases occurred occasionally (reported once).

No indication of effect on cardiac function emerged from ECG recordings.

9. DISCUSSION

Two hundred and fifty-six patients (130 reboxetine, 126 imipramine) were admitted to the study from December 1990 to September 1992 and randomised to treatment by investigators at 22 centres. A total of 188 patients (73.4%) completed the study and 68 (26.6%) withdrew; 32 (24.6%) in the reboxetine group, and 36 (28.6%) in the imipramine group.

The response to treatment was assessed using the Hamilton Depression Rating Scale (HAMD), Clinical Global Impression (CGI) and the Montgomery and Asberg Depression Rating Scale (MADRS).

The mean HAMD total score was reduced from 28.8 at Day 0 to 13.0 at last assessment (mean decrease 15.8, 95% CI 14.0 ÷ 17.5), in the 127 patients treated with reboxetine who had at least one assessment in addition to baseline, and to 9.6 at Day 42 in the 98 patients who completed the study. In the 121 patients treated with imipramine with at least one assessment in addition to baseline, the mean HAMD total score was reduced from 28.0 at Day 0 to 13.7 at last assessment (mean decrease 14.3, 95% CI 12.5 ÷ 16.1), and to 10.4 at Day 42 in the 92 patients still on treatment. The between treatment difference at last assessment was 1.5 points (95% CI -1.0 ÷ 4.0).

At last assessment, 68.5% of the reboxetine-treated patients and 56.2% of the imipramine-treated patients were classified as responders, while 52.0% and 45.5%, respectively, were seen to be in remission. The between treatment difference in the proportion of response was 12.3% (95% CI 0.3 ÷ 24.3).

In agreement with the above, the cumulative probability of response (Kaplan-Meier analysis) on reboxetine was significantly higher ($p=0.0126$) compared to imipramine.

The results of the additional analyses on the sub-populations of severe and melancholic patients indicate that both treatments were similarly effective in terms of improvement of the clinical picture, as evaluated by the HAMD scale at the last available assessment.

The results of the analysis of the secondary efficacy variables confirmed the above commented findings. At the last assessment, the percentage of patients classified as 'very much improved' or 'much improved' (CGI-Global Improvement) was somewhat higher in the reboxetine group (66.9%) than in the imipramine group (62.0%). The percentage of 'much to very much deteriorated' cases was higher in the imipramine group (6.6%) than in the reboxetine group (3.1%). In addition, the proportion of cases where efficacy outweighed side effects (CGI-Efficacy Index = 4) was higher in the reboxetine group than in the imipramine group from the second week of treatment up to the end of the study (from 12.0% to 41.8% in the reboxetine vs 2.8% to 29.3% in the imipramine group). Similarly, at last assessment, the proportion of these cases was higher on reboxetine (33.9%) than on imipramine (22.3%).

Similarly, the mean total MADRS score was reduced from 17.2 at Day 0 to 7.9 at last assessment in the 127 reboxetine group patients with at least one assessment in addition to baseline, and to 5.9 at Day 42 in the 98 reboxetine patients who completed the study.

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In patients treated with imipramine, values changed from 16.9 at Day 0 to 8.0 at last assessment (121 patients), and to 6.0 at Day 42 (92 assessed patients).

All the 256 patients who received study treatment were included in the safety analysis (130 reboxetine, 126 imipramine).

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

The occurrence of newly reported adverse events was similar in both groups during the study; 106/130 reboxetine group patients reported 267 adverse events compared with 103/126 imipramine patients who reported 303 adverse events. However, the prevalence of adverse events during the different weeks of treatment, was slightly higher on imipramine than on reboxetine mainly during the final 3 weeks of treatment. Discontinuation due to newly emerged adverse event was more frequent on imipramine (14%) than on reboxetine (10%). Most frequently reported were: dry mouth (25% reboxetine and 36% imipramine); headache/migraine (16%, 14%); hypotension and related symptoms (10%, 18%); and nausea and related symptoms (15%, 11%). The majority of adverse events were moderate and adverse events were reported more frequently by men than women in both the treatment groups. The most relevant between-gender differences were related to the frequency of increased sweating, complained of mainly by male patients, and nausea and related symptoms, complained of mainly by female patients in both treatment groups.

The estimate of the cumulative risk of adverse events according to the Kaplan-Meier method and log-rank test is significantly higher on imipramine than on reboxetine for dry mouth, hypotension and related symptoms and tremor.

One patient on the reboxetine group died (suicide) and three patients suffered from serious adverse events: parasuicide by overdose (on reboxetine), supraventricular tachycardia and A-V block first degree (both on imipramine).

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

Vital signs were not modified to any significant extent and the only difference between the two treatment groups was observed in the absolute frequency of clinically relevant decrease of both systolic and diastolic blood pressure, which was higher on imipramine than on reboxetine on standing (11% and 4% of evaluated patients, respectively). The absolute frequency of heart rate values increased to ≥ 100 beats/min was slightly higher on reboxetine than on imipramine, particularly on standing (27% and 21% of evaluated patients, respectively). However, the majority of these relevant increases occurred occasionally (reported once).

No indication of effect on cardiac function emerged from ECG recordings in either treatment group.

10. CONCLUSION

The efficacy of reboxetine therapy in patients suffering from Major Depressive Episodes, as measured by the improvement of HAMD, MADRS and CGI scales, was similar to that of imipramine. However, the cumulative probability of response ($\geq 50\%$ decrease of HAMD total score) was significantly higher on reboxetine than on imipramine.

The tolerability of reboxetine was highly acceptable, as shown in the safety profile in terms of modification of vital signs, haematology and blood chemistry tests and ECG examinations, and also in the superiority of reboxetine to imipramine in terms of the frequency of occurrence of dry mouth, hypotension and related symptoms and tremor, and of discontinuation due to adverse events.

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TABLES

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PHARMACIA CHR MSD
 REBOXETINE - PROTOCOL 20124/017
 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	Day 49			
1	6	6	6	5	5	5	5	5	5	5	5	5
	6	6	6	6	6	6	6	6	6	6	6	6
2	10	10	10	8	8	8	8	8	8	8	8	8
	10	10	10	10	10	10	10	10	10	10	10	10
3	4	4	4	4	4	4	4	4	4	4	4	4
	5	5	5	5	5	5	5	5	5	5	5	5
4	2	2	2	2	2	2	2	2	2	2	2	2
	1	1	1	1	1	1	1	1	1	1	1	1
6	2	2	2	2	2	2	2	2	2	2	2	2
	1	1	1	1	1	1	1	1	1	1	1	1
7	2	2	2	2	2	2	2	2	2	2	2	2
	1	1	1	1	1	1	1	1	1	1	1	1
8	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	4	4	4	4	4	4	4	4	4
9	23	23	23	18	18	18	18	18	18	18	18	18
	23	23	23	19	19	19	19	19	19	19	19	19
9/A	10	10	10	9	9	9	9	9	9	9	9	9
	10	10	10	10	10	10	10	10	10	10	10	10
10	6	6	6	5	5	5	5	5	5	5	5	5
	6	6	6	6	6	6	6	6	6	6	6	6
11	7	7	7	7	7	7	7	7	7	7	7	7
	6	6	6	5	5	5	5	5	5	5	5	5
12	2	2	2	2	2	2	2	2	2	2	2	2
	3	3	3	3	3	3	3	3	3	3	3	3
13	4	4	4	4	4	4	4	4	4	4	4	4

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PHARMACIA CMS R&D
REBOCETINE - PROTOCOL 20124/017
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				
13	5	5	5	4	4	4	4	2				
14	5	5	5	5	5	5	5	5				
14/1	5	5	5	5	5	5	5	5				
	2	2	2	1	1	1	1	1				
	3	3	3	2	2	2	2	2				
14/2	2	2	2	2	2	2	2	2				
14/3	4	4	4	4	4	4	4	4				
	3	3	3	3	3	3	3	3				
14/4	3	3	3	3	3	3	3	3				
	2	2	2	2	2	2	2	2				
14/7	8	8	8	8	8	8	8	8				
	6	6	6	6	6	6	6	6				
14/8	3	3	3	3	3	3	3	3				
14/10	11	11	11	11	11	11	11	11				
	14	14	14	14	14	14	14	14				
15	12	12	12	9	8	7	6	6				
	11	11	11	11	10	9	9	9				
Total	126	126	126	110	108	99	93	93				
	130	130	130	119	113	107	104	100				
Total	256	256	229	221	206	197	193	193				

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 REMOESTINE - PROTOCOL 20124/017
 TABLE No.1 2
 PATIENT DISPOSITION

	Treatment assigned						Total	
	Indipramine			Embozotiline			No.	Σ
	No.	Σ	100.00	No.	Σ	100.00		
Screened	126	100.00	100.00	130	100.00	256	100.00	
Exposed	126	100.00	100.00	130	100.00	256	100.00	
Completed	90	71.43	71.43	96	75.38	186	73.44	
Dropped	36	28.57	28.57	32	24.62	68	26.56	

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REBOXETINE - PROTOCOL 20124/017

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 7		Day 14		Day 21		Day 28		Day 35		Day 42	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%
Imipramine	ADVERSE EVENT (*)	20	100	13	65.0	1	5.0			4	20.0			2	10.0
	PROTOCOL VIOLATION	1	100	1	100										
	LOST TO FOLLOW UP	2	100					2	100						
	DETERIORATION	7	100	1	14.3	1	14.3	4	57.1					1	14.3
	PATIENT UNCOOPERATIVE	5	100	1	20.0			3	60.0	1	20.0				
	OTHER	1	100							1	100				
	Total	36	100	16	44.4	2	5.6	9	25.0	6	16.7			3	8.3
Reboxetine	ADVERSE EVENT (*)	12	100	7	58.3	2	16.7			1	8.3	2	16.7		
	DEATH	1	100											1	100
	PROTOCOL VIOLATION	3	100			2	66.7	1	33.3						
	DETERIORATION	5	100	2	25.0			3	37.5	1	12.5	2	25.0		
	PATIENT UNCOOPERATIVE	7	100	2	28.6	2	28.6	2	28.6	1	14.3				
	OTHER	1	100											1	100
	Total	32	100	11	34.4	6	18.8	6	18.8	3	9.4	4	12.5	2	6.3

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

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**PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
TABLE No.: 4
PROTOCOL VIOLATIONS AT ADMISSION**

	Imipramine		Reboxetine	
	No.	%	No.	%
Patients exposed	126	100.00	130	100.00
Age > 65 years	1	0.79		
Pregnancy	1	0.79		
Thyroid function tests abnormal*	19	•16.10	21	•17.50
Thyroid function tests missing	8	6.35	10	7.69
Evidence of Substance Use Disorder			1	0.79
Associated endocrine disorder			4	3.08
Not allowed concomitant medication °	9	7.14	6	4.62
Index episode < 4 weeks	2	1.59	4	3.08
Index episode > 4 months			1	0.79
Index episode duration: unknown			1	0.79
Clinically relevant associated pathology			1	0.79

* relative deviation from limits of normal range < 10% and > 10%

• % frequency out of assessed

° during wash-out

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REBOCETINE - PROTOCOL 20124-017
TABLE No.: 5
RANDOMIZATION: ASSIGNED TREATMENT vs RANDOMISED TREATMENT

Assigned treatment	Randomised treatment		Total
	Indipramine	Rebocetine	
Indipramine	104	22	126
Rebocetine	25	105	130
Total	129	127	256

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PHARMACIA CHR 280
 RESOMETINE - PROTOCOL 20124-017
 TABLE No.1 6
 COMPLIANCE TO SCREENING TIME AS PER PROTOCOL.

Assigned treatment: Resometine

	Success	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Assessment time								
No.	130	130	119	113	107	104	100	98
Min	-21	-1	6	13	20	27	34	40
Max	1	2	11	18	25	32	37	44
Median	-4	0	7	14	21	28	35	43
95%	1	1	8	15	22	29	36	44
Laboratory test								
No.	128				107			98
Min	-67				16			40
Max	2				25			47
Median	-3				21			43
95%	1				22			44
E.C.G.								
No.	124				102			96
Min	-41				16			40
Max	2				37			49
Median	-3				21			42
95%	1				22			44

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FEARMALIA CNS BMD
 RESCHEDULE - PROTOCOL 20124/017
 TABLE No. 1 6

COMPLIANCE TO SCHEDULE TIME AS PER PROTOCOL

Assigned treatment: Indipramine

	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
Assessment time	No.	125	110	108	99	93	93	90
	Min	-20	-4	13	20	26	33	41
	Max	1	1	17	24	31	38	46
	Median	-3	1	15	21	28	35	43
	95%	1	1	15	22	29	36	43
Laboratory test	No.	126			97			88
	Min	-20			19			40
	Max	5			28			50
	Median	-2			22			43
	95%	1			23			43
E.C.G.	No.	124			94			87
	Min	-20			14			37
	Max	2			29			49
	Median	-3			21			42
	95%	1			23			43

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PHARMACIA CSM BEO
 RESOURETINE - PROTOCOL 20124/017
 TABLE No. 1.7
 CONCOMITANT DRUGS NOT ALLOWED BY PROTOCOL, GROUPED BY ACTIVE PRINCIPLES
 NUMBER OF PATIENTS

Class / Active principle	Subcutaneous	Intravenous
NSAIDs long acting		
DITALEPAN	6	2
LORAZEPAN	1	3
LORHETAZEPAN	1	1
CLONAZEPAN ACID	1	
Total	9	6
Antidepressants		
NEURITRACEN	1	
Total	1	

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PHARMACIA CNS B2D

EBUSCETINE - PROTOCOL 2015A/017

Table No.1 8

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

	Assigned treatment	
	Trileptal	Reboxetine
At least one	6	6
Antidepressants		1
BZD long acting	6	5

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PARANACIA CHR BBD

REBORCITINE - PROTOCOL 20124/017
Table No. 1 5

DEMOGRAPHY BY ASSIGNED TREATMENT - AGE, HEIGHT, WEIGHT

Assigned treatment	Age			Height			Weight			
	Sex		Total	Sex		Total	Sex		Total	
	Female	Male		Female	Male		Female	Male		
Imipramine	No	83	43	126	83	43	126	83	42	125
	Mean	43.51	40.19	42.37	64.95	77.83	69.35	163.42	176.55	167.83
	S.D.	13.36	13.76	13.55	11.55	14.03	13.83	6.17	6.63	8.86
	Min	20.00	19.00	19.00	47.00	37.50	37.50	448.00	160.00	148.00
	Max	66.00	65.00	66.00	103.00	123.00	123.00	181.00	194.00	194.00
Reborcetine	No	84	46	130	83	46	129	83	46	129
	Mean	45.35	45.13	45.40	64.53	76.25	68.71	164.37	172.92	167.42
	S.D.	12.47	11.36	12.04	8.60	11.93	11.37	6.03	8.23	8.00
	Min	18.00	19.00	18.00	43.50	49.80	43.50	147.00	142.00	142.00
	Max	65.00	64.00	65.00	83.00	120.00	120.00	176.00	189.00	189.00
Total	No	167	89	256	166	89	255	166	88	254
	Mean	44.53	42.74	43.91	64.74	77.02	69.03	163.89	174.65	167.62
	S.D.	12.93	12.76	12.87	10.15	12.94	12.62	6.10	7.69	8.42
	Min	18.00	19.00	18.00	43.50	37.50	37.50	147.00	142.00	142.00
	Max	66.00	65.00	66.00	103.00	123.00	123.00	181.00	194.00	194.00

weight and height at screening visit

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PRAMIACIA CHE RBSD
 RESOURCING - PROTOCOL 2012A/017
 Table No.1 10
 DEMOGRAPHY BY ASSIGNED TREATMENT - RACE

Assigned treatment / Sex	Race													
	Caucasian			Black			Asian			Other			Total	
	No.	X	Z	No.	X	Z	No.	X	Z	No.	X	Z	No.	Z
Indipramine	Female	79	95.16	4	4.82								83	100.00
	Male	39	90.70	4	9.30								43	100.00
	Total	118	93.65	8	6.35								126	100.00
Reboxetine	Female	75	89.29	8	9.52	1	1.19						84	100.00
	Male	42	91.30	2	4.35	1	2.17	1	2.17				46	100.00
	Total	117	90.00	10	7.69	2	1.54	1	0.77				130	100.00
Total	Female	154	92.22	12	7.19	1	0.60						167	100.00
	Male	81	91.01	6	6.74	1	1.12	1	1.12				89	100.00
	Total	235	91.60	18	7.03	2	0.76	1	0.39				256	100.00

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PHARMACIA CHE RED
 RESOURCING - PROTOCOL 20124/017
 TABLE No. 11
 DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

	Sex											
	Female						Male					
	Isipramine	Rabonetine	Total	Isipramine	Rabonetine	Total	Isipramine	Rabonetine	Total	Isipramine	Rabonetine	Total
NR-III-E diagnosis	34	32	66	23	19	42	57	51	108	51	51	102
Age of onset (years)	43	52	101	20	27	47	69	79	148	69	79	148
No.	69	67	136	32	33	65	101	100	201	100	100	200
Mean	40.20	39.63	39.92	36.09	39.52	37.83	38.90	39.59	39.24	39.59	39.59	39.24
STD	13.87	13.54	13.66	13.60	12.79	13.20	13.85	13.23	13.52	13.23	13.23	13.52
Median	40.00	40.00	40.00	30.00	41.00	37.00	39.00	40.00	40.00	40.00	40.00	40.00
Min	18	16	16	17	15	15	17	15	15	15	15	15
Max	64	64	64	64	64	64	64	64	64	64	64	64
unknown	14	17	31	11	13	24	25	30	55	30	30	60
No.	47	47	94	19	25	44	66	72	138	72	72	144
Mean	2.57	3.62	3.10	3.53	4.24	3.93	2.85	3.83	3.36	3.83	3.83	3.36
STD	2.24	3.35	2.88	3.42	7.94	6.34	2.64	5.35	4.29	5.35	5.35	4.29
Median	2.00	3.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
Min	1	1	1	1	1	1	1	1	1	1	1	1
Max	10	15	15	11	40	40	11	40	40	40	40	40

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PARACETAMOL CME 280
 REQUESTING - PROTOCOL 2012A/017
 TABLE No. 11
 DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

	Sex													
	Female						Male						Total	
	Indipresine	Reboxetine	Total	Indipresine	Reboxetine	Total	Indipresine	Reboxetine	Total	Indipresine	Reboxetine	Total		
Duration of first episode (weeks)	No.	48	45	93	20	24	44	66	71	137				
	Mean	20.08	15.27	17.75	18.20	19.94	19.20	19.53	16.99	18.23				
	STD	14.90	10.36	13.06	14.67	24.20	20.42	14.75	16.79	15.82				
	Median	16.00	12.00	16.00	14.00	12.00	12.00	16.00	12.00	16.00				
	Min	2	3	2	4	4	4	2	3	2				
	Max	56	52	56	60	126	126	60	126	126				
Duration of present episode (weeks)	No.	83	83	166	43	46	89	126	129	255				
	Mean	8.48	8.72	8.61	8.79	7.11	7.92	8.59	8.17	8.37				
	STD	3.94	5.81	4.96	3.79	3.48	3.71	3.89	5.15	4.57				
	Median	8.08	8.00	8.00	8.00	6.00	8.00	8.00	7.00	8.00				
	Min	2	1	1	3	2	2	2	1	1				
	Max	16	48	48	16	16	16	16	48	48				

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PHARMACIA CNS RMD
 RESCHETINE - PROTOCOL 20124/017
 TABLE No. 1 12
 DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

Sex: Female

	Imipramine		Suboxetine		Total	
	No	Z	No	Z	No	Z
Character. of present episode						
Exacerbation of chronic cond.	5	6.02	11	15.10	16	9.58
Recurrence of similar prev. cond.	44	53.01	42	50.00	86	51.50
Different from any prev. cond.	1	1.20	5	5.95	6	3.59
First occurrence	53	59.76	26	30.95	59	35.33
Total	83	100.00	84	100.00	167	100.00
Onset of present episode						
Acute (< 2 weeks)	7	8.43	5	5.95	12	7.19
Subacute (>= 2 & < 12 weeks)	50	60.24	52	61.90	102	61.08
Insidious (>= 3 months)	26	31.33	26	30.95	52	31.14
Unknown			1	1.19	1	0.60
Total	83	100.00	84	100.00	167	100.00
Precipit. external stress						
Absent	23	27.71	24	40.48	57	34.13
Probably present	35	42.17	28	33.33	63	37.72
Definitely present	25	30.12	22	26.19	47	28.14
Total	83	100.00	84	100.00	167	100.00

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PHARMACIA CNS RSD
 RESOURTINE - PROTOCOL 20124/017
 TABLE No.: 12
DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

Sex: Male

	Indipramine		Reboxetine		Total		
	No	%	No	%	No	%	
Character. of present episode	Exacerbation of chronic cond.	4	9.30	4	8.70	8	8.99
	Recurrence of similar prev. cond.	16	37.21	23	50.00	39	43.82
	Different from any prev. cond.	5	11.63	1	2.17	6	6.74
	First occurrence	18	41.86	18	39.13	36	40.45
	Total	43	100.00	46	100.00	89	100.00
Onset of present episode	Acute (< 2 weeks)	4	9.30	6	13.04	10	11.24
	Subacute (>= 2 w < 12 weeks)	21	48.84	28	60.87	49	55.06
	Insidious (>= 3 months)	18	41.86	12	26.09	30	33.71
	Total	43	100.00	46	100.00	89	100.00
	Absent	13	30.23	18	39.13	31	34.85
Precipit. external stress	Probably present	16	37.21	17	36.96	33	37.08
	Definitely present	14	32.56	11	23.91	25	28.09
	Total	43	100.00	46	100.00	89	100.00

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PERANJALIA CNS RAD
 RESOURTINE - PROTOCOL 20124/017
 TABLE No. 12

DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

All patients

	Indigression		Rebozertine		Total	
	No	%	No	%	No	%
Character. of present episode						
Exacerbation of chronic cond.	9	7.14	15	11.54	24	9.38
Recurrence of similar prev. cond.	60	47.62	65	50.00	125	48.83
Different from any prev. cond.	6	4.76	6	4.62	12	4.69
First occurrence	51	40.48	44	33.85	95	37.11
Total	126	100.00	130	100.00	256	100.00
Onset of present episode						
Acute (< 2 weeks)	11	8.73	11	8.46	22	8.59
Subacute (>= 2 & < 12 weeks)	71	56.35	80	61.54	151	58.98
Insidious (>= 3 months)	44	34.92	38	29.23	82	32.03
Unknown			1	0.77	1	0.39
Total	126	100.00	130	100.00	256	100.00
Precipit. external stress						
Absent	36	28.57	52	40.00	88	34.38
Probably present	51	40.48	45	34.62	96	37.50
Definitely present	39	30.95	33	25.38	72	28.13
Total	126	100.00	130	100.00	256	100.00

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PIARMACIA CMS RBD
 REDUCTIVE - PROTOCOL 2012A/017
 TABLE No.: 13

PREVIOUS ANTIDEPRESSIVE TREATMENT BY ACTIVE PRINCIPLE

	Assigned treatment										Total	
	Raboxetine					Isiprandine					No	Σ
	No	Σ	100.0	No	Σ	No	Σ	100.0	No	Σ		
Increased patient	130		100.0	126		100.0	256		100.0	100.0		
AMITRIPTYLINE	21		16.2	16		12.7	37		14.5	14.5		
KTANBERIX	15		11.5	10		7.9	25		9.8	9.8		
DOXILEPIN	9		6.9	15		11.9	24		9.4	9.4		
MAPROTILINE	9		6.9	12		9.5	21		8.2	8.2		
CLOMIPRAMINE	8		6.2	8		6.3	16		6.3	6.3		
FLUOXETINE	9		6.9	6		4.8	15		5.9	5.9		
TRAZODONE	6		4.6	4		3.2	10		3.9	3.9		
IMIPRAMINE	6		4.6	4		3.2	10		3.9	3.9		
DOXEPIN	4		3.1	5		4.0	9		3.5	3.5		
CITALOPRAM	1		0.8	5		4.0	6		2.3	2.3		
NOCLORSETINE	3		2.3	2		1.6	5		2.0	2.0		
FLUOXANINE	3		2.3	1		0.8	4		1.6	1.6		
LITHIUM	3		2.3	1		0.8	4		1.6	1.6		
TEMPERAMINE	3		2.3	1		0.8	4		1.6	1.6		
VELTACEN	2		1.5	1		0.8	3		1.2	1.2		
VILOXAZONE	1		0.8	2		1.6	3		1.2	1.2		
NESTIPRAMINE	1		0.8	2		1.6	3		1.2	1.2		
OPIPRAMOL				2		1.6	2		0.8	0.8		
TRANTICYPROMINE	1		0.8	1		0.8	2		0.8	0.8		
NORTRIPTYLINE	1		0.8	1		0.8	2		0.8	0.8		
PHEBELZINE				1		0.8	1		0.4	0.4		
OXITRIPTAN	1		0.8				1		0.4	0.4		

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PHARMACIA CNS RBD
 PAROXETINE - PROTOCOL 20124/017
 TABLE No.: 13
 PREVIOUS ANTIDEPRESSIVE TREATMENT BY ACTIVE PRINCIPLE

	Assigned treatment							
	Paroxetine			Isipramine			Total	
	No	Z	No	Z	No	Z		
PAROXETINE	1		0.8				1	0.4

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PHARMACIA CNS BID
 RESCRIPTINE - PROTOCOL 20124/017
 TABLE No. 14
 MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS OF SCREENED PATIENTS BY SEX AND ASSIGNED TREATMENT

Previous diseases	Female						Male						Total					
	RescRIPTINE			Imipramine			Total			RescRIPTINE			Imipramine			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.
Screened patients	84	100	83	100	167	100	46	100	43	100	89	100	130	100	126	100	256	100
OTHER GU RESCRIPTIN NOS	5	6.0	2	2.4	7	4.2	1	2.2			1	1.1	6	4.6	2	1.6	8	3.1
UTERINE LEIOMYOMA	2	2.4	4	4.8	6	3.6							2	1.5	4	3.2	6	2.3
HYPERTENSION NOS	2	2.4	4	4.8	6	3.6	3	6.5	1	2.3	4	4.5	5	3.8	5	4.0	10	3.9
SPONDYLOSIS NOS	2	2.4	4	4.8	6	3.6							2	1.5	4	3.2	6	2.3
EPITHELIOMA NOS	3	3.6	1	1.2	4	2.4							3	2.3	1	0.8	4	1.6
PURE HYPERCHOLESTEROLEM	1	1.2	2	2.4	3	1.8	1	2.2			1	1.1	2	1.5	2	1.6	4	1.6
AMENIA NOS	2	2.4			2	1.2							2	1.5			2	0.8
VARICOSE VEIN OF LEG NOS	2	2.4			2	1.2							2	1.5			2	0.8
GASTRITIS/DUODENITIS NOS	2	2.4			2	1.2							2	1.5			2	0.8
CHOLELITHIASIS NOS	2	2.4	1	1.2	3	1.8	1	2.2	1	2.3	2	2.2	3	2.3	2	1.6	5	2.0
URIN TRACT INFECTION NOS	2	2.4			2	1.2							2	1.5			2	0.8
ARTROPATHY NOS	2	2.4			2	1.2							2	1.5			2	0.8
ANGINA PECTORIS									2	4.7	2	2.2			2	1.6	2	0.8
HYPERTROPHIC GOUTER NOS									2	4.3			2	2.2			2	0.8
DIABETES MELLITUS UNCOMP									2	4.3			2	2.2			2	0.8
MALIGN NEOPL BREAST NOS			1	1.2	1	0.6											1	0.4
MALIGN NEOPL OVARY			1	1.2	1	0.6											1	0.4
TRICHOCYCLOSIS			1	1.2	1	0.6											1	0.4
DIABETES MELLITUS			1	1.2	1	0.6			1	2.3	1	1.1					2	0.8
HYPERLIPIDEMIA NEC/NOS	1	1.2	1	1.2	2	1.2											1	0.8
PROBIC DISORDERS			1	1.2	1	0.6											1	0.4

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PHARMACIA CNE RSD
REBOUTINE - PROTOCOL 2014/017
TABLE No.: 14

MEDICAL HISTORY AND AMBLYOPEXAMINATION FINDINGS OF SCREENED PATIENTS BY SEX AND ASSIGNED TREATMENT

Previous diseases	Female						Male						Total					
	Subcutaneous			Total			Subcutaneous			Total			Subcutaneous			Total		
	No	X on Pt.	X on No	No	X on Pt.	X on No	No	X on Pt.	X on No	No	X on Pt.	X on No	No	X on Pt.	X on No	No	X on Pt.	
CONTACT DERMATITIS			1 1.2		1 0.6												1 0.8	1 0.4
INTERVERTEBRAL DISC DIS			1 1.2		1 0.6												1 0.8	1 0.4
LUMBAGO	1 1.2		1 1.2	2 1.2	1 0.6				1 2.2								1 0.8	3 1.2
OSTEOCHONDRODYSPLASIA NOS			1 1.2	1 0.6													1 0.8	1 0.4
OSTEOPOROSIS			1 1.2	1 0.6													1 0.8	1 0.4
URINARY SYSTEM SYMPTOMS			1 1.2	1 0.6													1 0.8	1 0.4
DIARRHEA OF INFECT ORIG	1 1.2			1 0.6													1 0.8	1 0.4
SCARLET FEVER	1 1.2			1 0.6													1 0.8	1 0.4
MAL NEO CERVIX UTERI NOS	1 1.2			1 0.6													1 0.8	1 0.4
NEOPLASM NOS, SITE NEC	1 1.2			1 0.6													1 0.8	1 0.4
MYXOMA NOS	1 1.2			1 0.6													1 0.8	1 0.4
HYPOPHYSEDENITIS NOS	1 1.2			1 0.6													1 0.8	1 0.4
IRON DEFICIENCY ANEMIAS	1 1.2			1 0.6													1 0.8	1 0.4
ALCOHOL DEPENDENCE SYND	1 1.2			1 0.6													1 0.8	1 0.4
PSYCHOGENIC SKIN DISEASE	1 1.2			1 0.6													1 0.8	1 0.4
CARPAL TUNNEL SYNDROME	1 1.2			1 0.6													1 0.8	1 0.4
ACUTE HEPTOCYCLITIS	1 1.2			1 0.6													1 0.8	1 0.4
DIS TYMPANIC MEMB NEC	1 1.2			1 0.6													1 0.8	1 0.4
SCHEURER DISEASE	1 1.2			1 0.6													1 0.8	1 0.4
OTOSCLEROSIS NOS	1 1.2			1 0.6													1 0.8	1 0.4
EROSION FRY N/O ENT INVOLV	1 1.2			1 0.6													1 0.8	1 0.4
ACUTE TONSILLITIS	1 1.2			1 0.6					1 2.2								1 1.1	2 0.8

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PHARMACIA CBS RSD
REBOCETINE - PRODUCE 2014/017
TABLE No. 1 14

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

Previous diseases	Female						Male						Total					
	Rebocetine			Imipramine			Rebocetine			Imipramine			Rebocetine			Imipramine		
	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.		
TINNITUS			1	1.2	1	0.6	1	2.2					1	1.1	1	0.8	2	0.8
TRANSIENT CEREB INCOHERIA			1	1.2	1	0.6											1	0.8
VARIKOSE VEINS, LEG			1	1.2	1	0.6											1	0.8
OSTROSTATIC HYPERTENSION			1	1.2	1	0.6											1	0.8
BRONCHITIS NOS			1	1.2	1	0.6											1	0.8
ASTHMA NOS			1	1.2	1	0.6	1	2.2	1	2.3	2	2.2	1	0.8	2	1.6	3	1.2
DUODENAL ULCER NOS	1	1.2	1	1.2	2	1.2	1	2.2			1	1.1	2	1.5	1	0.8	3	1.2
PEPTIC ULCER NOS			1	1.2	1	0.6											1	0.8
ATROPHIC GASTRITIS			1	1.2	1	0.6					1	2.3	1	1.1			2	1.6
DIAPHRAGMATIC HERNIA			1	1.2	1	0.6					1	2.3	1	1.1			2	1.6
DIVERTICULA OF COLON			1	1.2	1	0.6											1	0.8
IRRITABLE COLON			1	1.2	1	0.6											1	0.8
ANAL FISTULA			1	1.2	1	0.6											1	0.8
RECTAL PROLAPSE			1	1.2	1	0.6											1	0.8
CECUMCOLICULITIS NOS			1	1.2	1	0.6											1	0.8
ACUTE PANCREATITIS			1	1.2	1	0.6											1	0.8
FEMALE PELVIC INFLAM DIS			1	1.2	1	0.6											1	0.8
PROLAPSE OF VAGINAL WALL			1	1.2	1	0.6											1	0.8
NONINF. DIS OTI/ANTR NOS			1	1.2	1	0.6											1	0.8
EXCESSIVE MENSTRUATION			1	1.2	1	0.6											1	0.8
UNSPECIFIED ABORTION			1	1.2	1	0.6											1	0.8
CEASAREAN DELIVERY NOS	1	1.2	1	1.2	2	1.2									1	0.8	1	0.8

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PHARMACIA CRS RSD
 REBOUTINE - PROTOCOL 20124/017
 TABLE No.1 14

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

Previous diseases	Female						Male						Total		
	Rebouxetine			Indipramine			Rebouxetine			Indipramine			Total		
	No	X on Pt.	X on No	No	X on Pt.	X on No	No	X on Pt.	X on No	No	X on Pt.	X on No	No	X on Pt.	
PNEUMONIA, ORGANISM NOS	1	1.2			1	0.6								1	0.4
STOMACH ULCER NOS	1	1.2			1	0.6	1	2.2			1	1.1		2	0.8
INTESTINAL DISORDER NOS	1	1.2			1	0.6								1	0.4
HEPATITIS NOS	1	1.2			1	0.6								1	0.4
ATONY OF BLADDER	1	1.2			1	0.6								1	0.4
NONINFLAM DIS OVARI/ANNEX	1	1.2			1	0.6								1	0.4
HEMORRAGIA	1	1.2			1	0.6								1	0.4
THORAC/LUNG DISC DISPLAC	1	1.2			1	0.6	1	2.2			1	1.1		2	0.8
DISC DISPLACEMENT NOS	1	1.2			1	0.6								1	0.4
CERVICAL DISC DEGEN	1	1.2			1	0.6								1	0.4
DISC DEGENERATION NOS	1	1.2			1	0.6								1	0.4
CERVICOCANTIAL SYNDROME	1	1.2			1	0.6								1	0.4
LUMBOSACRAL NEURITIS NOS	1	1.2			1	0.6								1	0.4
JAUNDICE NOS	1	1.2			1	0.6								1	0.4
OTHER BRAIN INJURY	1	1.2			1	0.6								1	0.4
BRAIN INJURY NEC	1	1.2			1	0.6								1	0.4
UNC BENDY NEB BONE											1	2.3	1	1.1	1
SCIATIC NERVE LESION											1	2.3	1	1.1	1
OTITIS MEDIA NOS											1	2.3	1	1.1	1
ESSENTIAL HYPERTENSION											1	2.3	1	1.1	1
ATHEROSCLEROSIS NOS											1	2.3	1	1.1	1
CIRCULATORY DISEASE NOS											1	2.3	1	1.1	1

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PHARMACIA CNS RSD
 REBOXETINE - PROTOCOL 20184/017
 TABLE No. 1 14

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

Previous diseases	Female						Male						Total							
	Reboxetine			Imipramine			Total			Reboxetine			Imipramine			Total				
	No	Z on Pt.	X on Pt.	No	Z on Pt.	X on Pt.	No	Z on Pt.	X on Pt.	No	Z on Pt.	X on Pt.	No	Z on Pt.	X on Pt.	No	Z on Pt.	X on Pt.		
ALLERGIC RHINITIS NOS							1	2.3	1	1.1						1	0.8	1	0.4	
OBSTRUCTIVE CHRONIC BRONCHITIS							1	2.3	1	1.1						1	0.8	1	0.4	
STOMACH FUNCTION DIS NOS							1	2.3	1	1.1						1	0.8	1	0.4	
CHRONIC LIVER DIS/CIRRHOSIS							1	2.3	1	1.1						1	0.8	1	0.4	
CHRONIC PROSTATITIS							1	2.2	1	2.2	1	0.8	1	0.8	1	0.8	2	0.8	2	0.8
POLYARTHRITIS NOS							1	2.3	1	1.1						1	0.8	1	0.4	
ONDYMATRITIS NOS							1	2.3	1	1.1						1	0.8	1	0.4	
NEURALGIA/NEURALGIC PAIN							1	2.3	1	1.1						1	0.8	1	0.4	
OTITIS MEDIA/OTITIS EXterna							1	2.3	1	1.1						1	0.8	1	0.4	
DIZZINESS AND GIDDINESS							1	2.3	1	1.1						1	0.8	1	0.4	
OTITIS MEDIA/OTITIS EXterna							1	2.3	1	1.1						1	0.8	1	0.4	
CHEST PAIN NOS							1	2.2	1	1.1	1	0.8	1	0.8	1	0.8	1	0.8	1	0.4
HEART DISEASE NOS							1	2.2	1	1.1	1	0.8	1	0.8	1	0.8	1	0.8	1	0.4
PSYCHOSEXUAL DYSFUNCTION							1	2.2	1	1.1	1	0.8	1	0.8	1	0.8	1	0.8	1	0.4
PERIPHERAL NEUROPATHY							1	2.2	1	1.1	1	0.8	1	0.8	1	0.8	1	0.8	1	0.4
ACUTE MYOCARDIAL INFARCT							1	2.2	1	1.1	1	0.8	1	0.8	1	0.8	1	0.8	1	0.4
OLD MYOCARDIAL INFARCT							1	2.2	1	1.1	1	0.8	1	0.8	1	0.8	1	0.8	1	0.4
CHRONIC TONSILLITIS							1	2.2	1	1.1	1	0.8	1	0.8	1	0.8	1	0.8	1	0.4
ASTHMA							1	2.2	1	1.1	1	0.8	1	0.8	1	0.8	1	0.8	1	0.4
ACUTE APPENDICITIS							1	2.2	1	1.1	1	0.8	1	0.8	1	0.8	1	0.8	1	0.4
APPENDICITIS NOS							1	2.2	1	1.1	1	0.8	1	0.8	1	0.8	1	0.8	1	0.4

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PHARMACIA CNS RSD

REBOCETINE - PROTOCOL 20124/017
TABLE NO.: 14

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

Previous diseases	Female						Male						Total					
	Rebocetine			Indipramine			Total			Rebocetine			Indipramine			Total		
	No	X on Pt.	%	No	X on Pt.	%	No	X on Pt.	%	No	X on Pt.	%	No	X on Pt.	%	No	X on Pt.	%
UNUSUAL REGNIA				1	2.2					1	1.1		1	0.8		1	0.4	
MALE INFERTILITY				1	2.2					1	1.1		1	0.8		1	0.4	
OTHER PROBLIASIS				1	2.2					1	1.1		1	0.8		1	0.4	
OSTEOARTHRITIS NOS				1	2.2					1	1.1		1	0.8		1	0.4	
CERVICAL STROMOSE REC				1	2.2					1	1.1		1	0.8		1	0.4	
BACKACHE NOS				1	2.2					1	1.1		1	0.8		1	0.4	
SHOULDER REGION DIS REC				1	2.2					1	1.1		1	0.8		1	0.4	
ENTHESOPATHY OF ELBOW				1	2.2					1	1.1		1	0.8		1	0.4	
ABN BLOOD CHEMISTRY REC				1	2.2					1	1.1		1	0.8		1	0.4	
FX ANKLE NOS-CLOSED				1	2.2					1	1.1		1	0.8		1	0.4	
SPINAL CORD INJURY NOS				1	2.2					1	1.1		1	0.8		1	0.4	

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PHARMACIA CHEMIE
 RESOMETINE - PROTOCOL 2012A/017
 TABLE No.: 15
 MEDICAL HISTORY AND AMBLYOPIA EXAMINATION FINDINGS OF SCREENED PATIENTS BY BODY SYSTEM, SEX AND ASSIGNED TREATMENT

Previous diseases (body system)	Female						Male						Total					
	Rebovantine			Indapamide			Total			Rebovantine			Indapamide			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.	%
Screened Patients	84	100	83	100	167	100	46	100	43	100	89	100	130	100	126	100	256	100
HEAD/EAR	9	10.7	8	9.6	17	10.2	2	4.3	1	2.3	3	3.4	11	8.5	9	7.1	20	7.8
CIRCULATORY SYSTEM	7	8.3	7	8.4	14	8.4	5	10.9	5	11.6	10	11.2	12	9.2	12	9.5	24	9.4
MUSCULOSKELETAL SYS. AND CONNECTIVE TISSUE	8	9.5	7	8.4	15	9.0	5	10.9	3	7.0	8	9.0	13	10.0	10	7.9	23	9.0
ENDOCR., NUTRIT. AND METAB. DISEASES	4	4.8	5	6.0	9	5.4	6	13.0	1	2.3	7	7.9	10	7.7	6	4.8	16	6.3
BLOOD AND BLOOD-PUSHING ORGANS	3	3.6			3	1.8							3	2.3			3	1.2
DIGESTIVE SYSTEM	8	9.5	9	10.8	17	10.2	6	13.0	5	11.6	11	12.4	14	10.8	14	11.1	25	10.9
GENITOURINARY SYSTEM	4	4.8	4	4.8	8	4.8	2	4.3	1	2.3	3	3.4	6	4.6	5	4.0	11	4.3
MENTAL DISORDERS	2	2.4	1	1.2	3	1.8	1	2.2			1	1.1	3	2.3	1	0.8	4	1.6
NERVOUS SYSTEM AND SENSE ORGANS	5	6.0	1	1.2	6	3.6	2	4.3	2	4.7	4	4.5	7	5.4	3	2.4	10	3.9
RESPIRATORY SYSTEM	2	2.4	2	2.4	4	2.4	4	8.7	3	7.0	7	7.9	6	4.6	5	4.0	11	4.3
PREGNANCY, CELLULITE AND PUPPATOR	1	1.2	2	2.4	3	1.8							1	0.8	2	1.6	3	1.2
SKIN AND SUBCUTANEOUS TISSUE			1	1.2	1	0.6	1	2.2			1	1.1	1	0.8	1	0.8	2	0.8
SYMPTOMS, SIGNS AND ILL DEFINED CONDITIONS	1	1.2	1	1.2	2	1.2	1	2.2	1	2.3	2	2.2	2	1.5	2	1.6	4	1.6
INFECTIOUS AND PARASITIC DISEASE	2	2.4			2	1.2	1	2.2			1	1.1	3	2.3			3	1.2
INJURY AND POISONING	2	2.4			2	1.2	2	4.3			2	2.2	4	3.1			4	1.6
CONGENITAL ANOMALIES									1	2.3	1	1.1			1	0.8	1	0.4

PHARMACIA CN0560085

REBOXETINE - PROTOCOL 20124/017
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 (ng/day)																Total			
	0		4		6		8		10		12		14		18				20	
	No	X	No	X	No	X	No	X	No	X	No	X	No	X	No	X	No	X		
Day 0			11	8.5			119	91.5											130	100
1							128	100											128	100
2							124	96.9											124	100
3			4	3.1			125	99.2											124	100
4			1	0.8			121	97.6											123	100
5	1	0.8	2	1.6			120	97.6											120	100
6	2	1.6	1	0.8			116	96.7											116	100
7	1	0.8	3	2.5			1	100											1	100
8							118	99.2											119	100
Day 7	1	0.8					114	96.6											118	100
1			4	3.4			116	100											116	100
2							114	99.1											115	100
3			1	0.9			114	99.1											115	100
4			1	0.9			111	97.4			1	0.9							114	100
5			2	1.8			111	98.2											112	100
6	1	0.9	1	0.9			3	100											3	100
7							110	97.3											113	100
8			3	2.7			110	97.3											113	100
Day 14	1	0.9	2	1.8			108	95.6											113	100
1			4	3.5			109	96.5											113	100
2	1	0.9	3	2.7			110	98.2											111	100
3	1	0.9	1	0.9			108	97.3			1	0.9							108	100
4			2	1.8			105	97.2											105	100
5			3	2.8			1	100											1	100
6			1	0.9			94	87.9	9	8.4				1	0.9		1	0.9	107	100
7	1	0.9	2	1.9			92	86.8	9	8.5				1	0.9		1	0.9	106	100
8			2	1.9			93	87.7	9	8.5				1	0.9		1	0.9	106	100
Day 21	1	0.9	1	0.9			92	86.8	9	8.5			2	1.9					106	100
1			1	0.9			91	85.8	10	9.4									106	100
2			1	0.9			92	86.8	10	9.4									106	100
3			1	1.0			91	87.5	9	8.7									104	100
4							3	100											3	100
5							89	85.6	12	11.5									104	100
6			3	2.9			86	82.7	12	11.5									104	100
7			1	1.0			87	84.5	12	11.7									103	100
8			2	2.0			85	83.3	12	11.8									102	100
Day 28	1	1.0	1	1.0			85	83.3	12	11.8									102	100
1			1	1.0		1	1.0	86	84.3	11	10.8								102	100
2			2	2.0				84	83.2	12	11.9								101	100
3								83	83.0	14	14.0								100	100
4								82	82.0	13	13.0			1	1.0				100	100
5								80	80.0	12	12.0			1	1.0				100	100
6	1	1.0	4	4.0				79	79.0	14	14.0			1	1.0				100	100
7			4	4.0				79	79.0	14	14.0			1	1.0				100	100
8			1	1.0				81	81.8	14	14.1			1	1.0				99	100
9			3	3.1				80	81.6	13	13.3			1	1.0				98	100
10			8	57.1				4	28.6	2	14.3								14	100
11			1	100															1	100

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PRAXINIA CUP99085

REBOXETINE - PROTOCOL 20124/017
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 (ng/day)																Total		
	0		50		100		150		200		250		300		350				
	No	X	No	X	No	X	No	X	No	X	No	X	No	X	No	X	No	X	
Day 0	1		20	15.9	106	84.1												126	100
1			4	3.2	120	96.8												124	100
2			2	1.7	119	98.3												121	100
3			3	2.5			114	96.6				1	0.8					118	100
4			2	1.8			111	97.4										114	100
5			2	1.8	1	0.9	109	95.6	1	0.9								114	100
6	1	0.9	1	0.9			111	98.2										113	100
7	1	0.9					5	100										5	100
8							1	100										1	100
Day 7	1				1	0.9	107	97.3	2	1.8								110	100
2			3	2.7			106	96.4	1	0.9								110	100
3							108	99.1	1	0.9								109	100
4			1	0.9			107	98.2	1	0.9								109	100
5	1	0.9					107	98.2	1	0.9								109	100
6							108	99.1	1	0.9								109	100
7	1	0.9	1	0.9			104	97.2	1	0.9								107	100
8							2	100										2	100
Day 14	1				1	0.9	106	98.1			1	0.9						108	100
2			1	0.9	1	0.9	108	97.2							1	0.9		108	100
3							106	99.1							1	0.9		107	100
4					1	0.9	104	98.1							1	0.9		106	100
5			1	0.9	2	1.9	102	96.2							1	0.9		106	100
6					1	1.0	103	98.1							1	1.0		105	100
7	1	1.0	3	2.9			98	93.3			1	1.0			2	1.9		105	100
Day 21	1		1	1.0			80	80.8	13	13.1	1	1.0	1	1.0	3	3.0		99	100
2	1	1.0			1	1.0	78	79.6	13	13.3					5	5.1		98	100
3					1	1.0	79	81.4	12	12.4					5	5.2		97	100
4			1	1.0	2	2.1	78	80.4	11	11.3					5	5.2		97	100
5	2	2.1	1	1.0			75	78.1	13	13.5	1	1.0			4	4.2		96	100
6	2	2.1					76	80.0	13	13.7					4	4.2		95	100
7	1	1.1	1	1.1	1	1.1	76	80.9	11	11.7					4	4.3		94	100
8			2	100														2	100
Day 28	1	1.1					75	80.6	13	14.0					4	4.3		93	100
2			1	1.1			73	78.5	13	14.0	3	3.2			3	3.2		93	100
3			1	1.1			75	80.6	13	14.0					4	4.3		93	100
4							76	81.7	13	14.0					4	4.3		93	100
5			1	1.1	1	1.1	74	79.6	13	14.0					4	4.3		93	100
6							76	81.7	13	14.0					4	4.3		93	100
7			1	1.1	1	1.1	75	81.5	11	12.0	1	1.1			4	4.3		92	100
8			1	50.0			1	50.0										2	100
Day 35	1		1	1.1	2	2.2	73	78.5	14	15.1	2	2.2			1	1.1		93	100
2			2	2.2	2	2.2	74	80.4	13	14.1					1	1.1		92	100
3			2	2.2	1	1.1	74	80.4	14	15.2					1	1.1		92	100
4			1	1.1			75	82.4	14	15.4					1	1.1		91	100
5			1	1.1	1	1.1	74	82.2	13	14.4					1	1.1		90	100
6			1	1.1			74	82.2	14	15.6					1	1.1		90	100
7			1	1.1			73	82.0	14	15.7					1	1.1		89	100
8			7	50.0			6	42.9	1	7.1								14	100
9			1	100														1	100

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PHARMACIA CSR MSD
 REDUCING - PROTOCOL 20124/017
 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	%	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	
Indipramine	always low dose	80.16	101						
	at least one high dose	19.84	25	1	2	16	4	2	
	Total	100.00	101	1	2	16	4	2	
Suboxone	always low dose	83.03	108						
	at least one high dose	16.92	22			13	5	4	
	Total	100.00	108			13	5	4	

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PHARMACIA CRIS MSD

REBOXETINE - PROTOCOL 2012A/017

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	%		
Indipramine	4	3.2	3	2.4	8	6.3	31	24.6	80	63.5	124	100.0		
Reboxetine	2	1.5	3	2.3	10	7.7	31	23.8	84	64.6	130	100.0		
Total	6	2.3	6	2.3	18	7.0	62	24.2	164	64.1	256	100.0		

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PHARMACIA CBS 880

REGIMEN - PROTOCOL 2012A/017
TABLE No.1 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		
	Indigermine	Rebocevirine	No.	Indigermine	Rebocevirine	No.	Indigermine	Rebocevirine	No.
	No.	No.	No.	No.	No.	No.	No.	No.	No.
CHELRAL HYDRATE	17	23	10	13	27	34			
CLONITAZOLE	1	3	7	5	6	8			
PARACETAMOL			7	7	7	7			
MARVELOX	5	3			5	3			
ACETYLSALICYLIC ACID	1		2	4	3	4			
DIASIPAN			2	2	2	2			
LEVOTHYROXINE		3		1		4			
BENNA			2	2	2	2			
COFFROUNT			1	3	1	3			
LACTULOSE			2	2	2	2			
LORAZEPAN			3	1	3	1			
DICLOFENAC		2	2		2	2			
SEBROVA DESPERS		1	1	2	1	3			
VERAPAMIL	1			2	1	2			
DILTIDEMOROTAMINE		1	1	1	1	2			
ACETYLSALICYLIC ACID			1	2	1	2			
BACTRIN				3	3	3			
AMOXICILLIN	1		1	1	2	1			
LOPERAMIDE			1	2	1	2			
PICRIC ACID		1	1	1	1	2			
EMALAPREL	2	1			2	1			
NITROGLYCERINE	2	1			2	1			

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PELORACIA CIB 880
 REMOXYLINE - PROTOCOL 2015A-017
 TABLE No. 1 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		
	Indipramine		Reboxetine	Indipramine		Reboxetine	Indipramine		Reboxetine
	No.	No.	No.	No.	No.	No.	No.	No.	
ALLOPURINOL		2							2
ASCORBIC ACID					2				2
COCAINE				1		1			1
METOCLOPRAMIDE				1		1			1
DOMETICLINE					2				2
INDUPROFEN				1		1			1
SALBUTAMOL	1			1		2			2
GLYCEROL					1				1
MOORESTIC		1				1			2
NECLONETABONE	1			1					1
NIFEDIPINE					2				2
NODIUR PICOSSULFATE					1				1
BRONAZEPAN		2							2
LORHETAZEPAN	1			1					1
ACTIFED					1				1
STORCINE					1				1
TIROPYLLINE	1								1
COLASCINE	1								1
CYCLIZINE				1					1
PREDNISONONE				1					1
DOXYTORTIN					1				1
ERYTHROCYCIN				1					1

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PHARMACIA CBS MSD
 RESCRIPTINE - PROTOCOL 2012A/017
 TABLE No. 16
 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	
	Indispraline	Rescristine	Indispraline	Rescristine	Indispraline	Rescristine
	No.	No.	No.	No.	No.	No.
EPHEDRINE				1		1
EOSTRON		1				1
HYDROBIL	1				1	
PROPANOLOL			1		1	
NONPHEPRINE		1				1
HEPHEMATIC ACID				1		1
TRICLOFOS			1		1	
TRONBUTIN		1				1
CAFEBROU				1		1
SACCHARATED IRON OXIDE		1				1
ESTROGENS COMBATED			1		1	
HYDROXYPROGESTERONE	1					1
DIAXIDE	1					1
CHROMOLIC ACID	1					1
ETILEPRINE				1		1
CALCIUM CARBONATE				1		1
FLUPENTINOL		1				1
PANANERONE CO	1					1
MAGNESIUM HYDROXIDE		1				1
MAGALORATE				1		1
METAKISTINE	1					1
GALITROCLANTINE	1					1

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PHARMACIA CBS 860
 REDUCTASE - PROTOCOL 2015A/017
 TABLE No.1 18
 CONCOMITANT DRUGS BY ACTIVE PRINCIPLE: NUMBER OF PATIENTS TAKING AT LEAST ONE CONCOMITANT MEDICATION BY ABUSED TREATMENT AND INITIAL PERIOD OF ADMINISTRATION

Concomitant drugs	Before treatment		During treatment		Total	
	Indigestion	Reboosline	Indigestion	Reboosline	Indigestion	Reboosline
	No.	No.	No.	No.	No.	No.
MEFENAMIC ACID				1		1
CITRIC ACID				1		1
TIBUTALINE	1					1
TILIDINE			1			1
GIRGEO TREE LEAVES EXTRACT	1					1
COLD CAPSULES			1			1
BIOMATIN				1		1
CLONAZEPIC ACID				1		1
FLAVONATE		1				1
PENTOKSIFILLINE				1		1
CESTILPREDINION				1		1
KINONAR			1			1
COOIS				1		1
FRALDIN		1				1
BITOSTEROLS		1				1
GYNDIAN-DEPOT	1					1
HELTIRACEN		1				1
NETOPROLOL	1					1
HEMETIDINE			1			1
GLIPIZIDE		1				1
CINETHINE		1				1
CARBOCISTEINE				1		1

(CONTINUED)

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PHARMACIA CBS D&D
 REDUCTINE - PROTOCOL 2012A/017
 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	
	Indipramine	Reboxetine	Indipramine	Reboxetine	Indipramine	Reboxetine
	No.	No.	No.	No.	No.	No.
ATORVASTATIN				1		1
ESOPRANOLOL				1		1
DONPEPIDONE	1					1
CAPTROPIL			1			1
FINAVESTIN	1					1
FLUMAZETIL			1			1
DIANE			1			1
DEZALFIRAZIN	1					1
AMORFOLIN			1			1
SULFASAZOLIN				1		1
ETIDROPRID					1	1
AMANTADIN	1					1
PARIBRATAN CORP.	1					1
EFFORTIL PLUS	1					1
ACETYLCHOLIN			1			1
CLONAZEPAN				1		1
AMOXICILIN	1					1
INSULIN HUMAN			1			1
OSACEPROL	1					1
MAGNESIUM VIELA DRAGES			1			1
ONAPROFEN	1					1
PROSTATIN			1			1

(CONTINUED)

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PHARMACIA CNS DAD
 REDUCTIVE - PROTOCOL 20124/017
 TABLE No.: 16
 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		
	Indipramine		Suboxetine	Indipramine		Suboxetine	Indipramine		Suboxetine
	No.	No.	No.	No.	No.	No.	No.	No.	
CIPROFLOXACIN						1			1
CALCIUM	1							1	
HYDROXYPROPRYSOLINE			1						1
MEPREDIL	1							1	
BISOPROLOL						1			1
ZIDOVUDINE				1					1
VENALOT - SLOW RELEASE			1						1
CICAPRIDE				1					1
PRAVASTATIN			1						1
BERBERINE	1								1
RANITIDIL	1								1
LOVASTATIN						1			1
LOBATADINE						1			1
NETROSTIN			1						1
ROXITHROMYCIN								1	1
CYCLOSPORIN								1	1

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PHARMACIA CHR RED
 RESOMETTINE - PROTOCOL 20124/017
 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			
Tadipramine	No	121	121	108	107	96	93	92			
	Mean	28.27	23.75	19.64	17.06	14.15	12.49	10.36			
	Median	27	25	21	16	13	11	9			
	STD	5.00	7.03	8.38	8.17	8.57	8.17	8.19			
	Min	22	19	3	1	0	0	0			
	Max	43	45	41	39	39	37	40			
Mean diff. vs day0 (*)		4.26	8.55	11.20	14.16	15.56	17.64				
Subcutaneous	No	127	127	117	112	107	103	98			
	Mean	29.12	23.54	18.80	15.64	13.50	11.21	9.59			
	Median	28	23	19	15	13	10	8			
	STD	4.82	7.44	8.85	8.58	8.35	7.47	7.52			
	Min	22	16	0	0	0	0	0			
	Max	50	41	40	40	40	37	36			
Mean diff. vs day0 (*)		5.22	10.07	13.34	15.46	17.61	19.27				

Mean (*): mean of differences vs day0

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PAROXETIN CIBI RED

REBOSETIN - PROTOCOL 20124/017
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	121	121	108	107	96	93	92			
	Median	1.33	1.33	1.17	0.83	0.67	0.67	0.50			
	Min	0.17	0.17	0.00	0.00	0.00	0.00	0.00			
	Max	2.33	2.17	2.00	2.00	2.00	2.00	2.00			
	Median diff. vs day0 (%)		0.00	0.25	0.50	0.67	0.67	0.67			
Reboxetine	No	127	127	117	112	107	103	98			
	Median	1.50	1.17	1.00	0.83	0.83	0.67	0.50			
	Min	0.50	0.00	0.00	0.00	0.00	0.00	0.00			
	Max	2.50	2.17	2.33	2.33	2.33	1.83	1.83			
	Median diff. vs day0 (%)		0.17	0.50	0.67	0.67	0.67	0.92			

Median (%): median of differences vs day0

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PARAFACIA CHE 28D

RESUME - PROTOCOL 20124/017
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	Visit										
	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Indipramine	No	121	121	108	107	96	93	92			
	Median	1.00	0.83	0.67	0.50	0.33	0.33	0.17			
	Min	0.00	0.17	0.00	0.00	0.00	0.00	0.00			
	Max	2.50	2.50	2.00	1.83	2.17	1.83	2.00			
	Median diff. vs day0 (*)			0.17	0.33	0.33	0.50	0.50	0.67		
Suboxetine	No	127	127	117	112	107	103	98			
	Median	0.83	1.00	0.67	0.50	0.33	0.33	0.17			
	Min	0.17	0.00	0.00	0.00	0.00	0.00	0.00			
	Max	2.33	2.33	2.00	2.00	2.00	1.83	2.00			
	Median diff. vs day0 (*)			0.17	0.33	0.50	0.67	0.67			

Median (*): median of differences vs day0

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PHARMACIA CNS RSD

REBORGSTINE - PROTOCOL 20124/017
TABLE No.: 20

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

Factor: ESTABLICATION

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Indipramine	No	121	121	108	107	98	93	92			
	Median	2.00	1.75	1.50	1.25	1.00	0.75	0.50			
	Min	0.75	0.25	0.00	0.00	0.00	0.00	0.00			
	Max	3.25	3.00	3.00	3.00	3.00	3.25	3.00			
	Median diff. vs day0 (*)		0.25	0.50	0.75	1.00	1.25	1.50			
Rebortine	No	127	127	117	112	107	103	98			
	Median	2.25	2.00	1.50	1.00	0.75	0.75	0.50			
	Min	0.50	0.75	0.00	0.00	0.00	0.00	0.00			
	Max	3.25	3.25	3.00	2.75	2.75	2.25	2.00			
	Median diff. vs day0 (*)		0.25	0.50	1.00	1.25	1.25	1.50			

Median (*): median of differences vs day0

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PRAMACIA CBS RED

REBOXetine - PROTOCOL 20124/017
TABLE No.: 20

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

Factor: SLEEP DISTURBANCE

Assigned treatment	Visit										
	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63
Tigipranisone	No	121	121	108	107	98	93	92			
	Median	1.33	1.00	1.00	1.00	0.67	0.67	0.53			
	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	0.33	0.33	0.67	0.67	0.67		
Reboxetine	No	127	127	117	112	107	103	98			
	Median	1.67	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	0.33	0.67	0.67	0.67	0.67		

Median (*): median of differences vs day0

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FRANCIACA CHE 198D
 REBORENTINE - PROTOCOL 20124/017
 TABLE No. 1 21

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			
Indipramine	No	121	121	106	107	98	93	92			
	Median	3	3	2	2	1	1	1			
	Min	1	1	0	0	0	0	0			
	Max	4	4	4	4	4	4	3			
Reborentine	No	127	127	117	112	107	103	96			
	Median	3	3	2	1	1	1	1			
	Min	1	1	0	0	0	0	0			
	Max	4	4	4	4	4	4	3			

Median (*): mean of differences vs day0

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PARANACIA CHS BID

RESCHEDULE - PROTOCOL 2012A/017
TABLE No.: 21

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

Item: QUILT

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Indipramine	No	121	121	108	107	98	93	92			
	Median	2	1	1	1	1	0	0			
	Min	0	0	0	0	0	0	0			
	Max	3	3	3	3	3	3	3			
Subcutisus	No	127	127	117	112	107	103	98			
	Median	2	1	1	1	1	0	0			
	Min	0	0	0	0	0	0	0			
	Max	4	3	3	3	3	3	2			

Median (s); mean of differences vs day0

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PHARMACIA CNS 880

REBOURNE - PROTOCOL 2012A/017
TABLE No.: 21

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			
Indipramine	No	121	121	108	107	96	93	92			
	Median	1	1	1	1	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	4	4	3	3	3	3	2			
Reboune	No	127	127	117	112	107	105	98			
	Median	1	1	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	4	4	3	3	3	2	2			

Median (*): mean of differences vs day0

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PHARMACIA CNS RAD

RESPERINE - PROTOCOL 2012A/017
TABLE No.: 21

SUMMARY STATISTICS ON SCORES OF EACH ITEM ACCORDING TO THE INTERVAL BY ASSIGNED TREATMENT

Item: IMPROVING EARLY

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Imipramine	No	121	121	108	107	98	93	92			
	Median	2	1	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Reboxetine	No	127	127	117	112	107	103	98			
	Median	2	2	1	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

Median (*): mean of differences vs day0

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PARANACIA CHE RES

RESCHETTING - PROTOCOL 2012A/017
TABLE No.1 21

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 26	Day 35	Day 42			
Indipramine	No	121	121	108	107	98	93	92			
	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	127	127	117	112	107	103	98			
	Median	2	2	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

Median (x): mean of differences vs day0

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PARANACIA CNS BID

REBOCKETINE - PROTOCOL 20124/017
TABLE No. 1 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 26	Day 35	Day 42			
Insiprudine	No	121	121	108	107	98	93	92			
	Median	1	1	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Rebocketine	No	127	127	117	112	107	105	98			
	Median	2	2	1	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

Median (s): mean of differences vs day0

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PHARMACIA CHE 880

REBOGETINE - PROTOCOL 20124/017
TABLE No.: 21

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

Item: MORE AND ACTIVITIES

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Indipramine	No	121	121	108	107	98	93	92			
	Median	3	3	2	2	1	1	1			
	Min	1	0	0	0	0	0	0			
	Max	4	4	4	4	4	4	4			
Subcutisline	No	127	127	117	112	107	103	96			
	Median	3	3	2	1	1	1	1			
	Min	0	1	0	0	0	0	0			
	Max	4	4	4	4	4	4	4			

Median (M): mean of differences vs day0

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PHARMACIA CNS 880

REBORNETINE - PROTOCOL 2012A/017
TABLE No. 1 21

SUMMARY STATISTICS ON SCORES 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				
Indipramine	No	121	121	106	107	98	93	92				
	Median	1	1	1	0	0	0	0				
	Min	0	0	0	0	0	0	0				
	Max	3	3	3	3	3	3	3				
Reboksetin	No	127	127	117	112	107	103	96				
	Median	1	1	1	0	0	0	0				
	Min	0	0	0	0	0	0	0				
	Max	3	3	3	3	2	2	2				

Median (x): mean of difference vs day0

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PHARMACIA CNS DRD

REOPENING - PROTOCOL 20124/017
TABLE No.: 21

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			
Indipramine	No	121	121	106	107	96	93	92			
	Median	2	1	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	4	4	4	4	3	3	3			
Reboxetine	No	127	127	117	112	107	103	98			
	Median	2	1	1	1	1	0	0			
	Min	0	0	0	0	0	0	0			
	Max	4	3	3	3	3	2	2			

Median (n): mean of differences vs day0

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PHARMACIA CNS RBD

REBONETINE - PROTOCOL 20124/017
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			
Indipramine	No	121	121	108	107	98	93	92			
	Median	2	2	2	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	4	4	3	3	3	4	3			
Rebonetine	No	127	127	117	112	107	103	98			
	Median	2	2	1	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	4	4	4	4	4	4	4			

Median (n): mean of differences vs day0

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PHARMACIA CNS 880

REGOMETINE - PROTOCOL 20124/017
TABLE No.: 21

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

Item: ANXIETY SONATIC

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Indipramine	No	121	121	108	107	98	93	92			
	Median	2	2	1	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	4	4	3	3	3	3	3			
Subcutisus	No	127	127	117	112	107	103	98			
	Median	2	2	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	4	4	3	4	3	3	3			

Median (s): mean of differences vs day0

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PEARACIA CRIS RMD
 REGOMETINE - PROTOCOL 2012A/017
 TABLE No.: 21

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			
Isipramine	No	121	121	108	107	98	93	92			
	Median	1	1	1	1	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Subocetine	No	127	127	117	112	107	103	98			
	Median	1	1	1	1	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

Median (n): mean of differences vs day0

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PHARMACIA CHE MSD

REBOCETINE - PROTOCOL 20124/017
TABLE No.: 21

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

Item: SCWATIC GENERAL

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Indipramine	No	121	121	108	107	98	93	92			
	Median	2	2	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Rebocetine	No	127	127	117	112	107	103	98			
	Median	2	2	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

Median (n): mean of differences vs day0

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PHARMACIA CNS 880

REBOZETINE - PROTOCOL 20124-017
TABLE No.: 21

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

Item: GENITAL SYMPTOMS

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 31	Day 28	Day 35	Day 42			
Indipramine	No	121	121	108	107	96	93	92			
	Median	2	1	1	1	1	1	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Rebozetine	No	127	127	117	112	107	103	96			
	Median	1	1	1	1	1	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

Median (s): mean of differences vs day0

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PHARMACIA CSR RSD

REBOZETINE - PROTOCOL 2012A/017
TABLE No. 1 21

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

Item: HIPOCHONDRIASIS

Assigned treatment	Screen	Visit										
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
Indipramine	No	121	121	108	107	96	93	92				
	Median	1	1	1	1	0	0	0				
	Min	0	0	0	0	0	0	0				
	Max	3	3	3	3	3	3	3				
Rebozetine	No	127	127	117	112	107	105	96				
	Median	1	1	1	1	1	0	0				
	Min	0	0	0	0	0	0	0				
	Max	3	3	3	3	4	3	3				

Median (w): mean of differences vs day0

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PHARMACIA CNS RBD

REBOURNE - PROTOCOL 2012A-017
TABLE No.: 21

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

Item: LOSS OF HEIGHT

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Indipramine	No	121	121	108	107	98	93	92			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	3	3	2	2	2	2	2			
Reboxetine	No	127	127	117	112	107	103	98			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

Median (*): mean of differences vs day0

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PARANALICIA CNS 820

RESEARCHING - PROTOCOL 20124-017
TABLE No.: 21

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

Item: IMPLICIT

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Indipramine	No	121	121	108	107	98	93	92			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2	1		
Reboxetine	No	127	127	117	112	107	103	98			
	Median	1	1	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2	1		

Median (*): mean of differences vs day0

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PARANACIA CNS RSD
REGOMETINE - PROTOCOL 2012A/017
TABLE No.: 21
HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORES OF EACH ITEM ACCORDING TO THE 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			
Indipramine	No	121	121	108	107	98	93	92			
	Median	1	1	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			
Esboacetine	No	127	127	117	112	107	103	98			
	Median	1	1	1	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

Median (M): mean of differences vs day0

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PARANACIA CHS DRD

REBORELINE - PROTOCOL 20124/017
TABLE No. 11

SUMMARY STATISTICS ON SCORES 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	Day 49	Day 56	Day 63	
Indipramine	No	121	121	108	107	98	93	92				
	Median	0	0	0	0	0	0	0				
	Min	0	0	0	0	0	0	0				
	Max	3	3	3	3	3	3	3				
Reboresline	No	127	127	117	112	107	105	98				
	Median	0	0	0	0	0	0	0				
	Min	0	0	0	0	0	0	0				
	Max	3	3	3	3	3	3	3				

Median (n): mean of differences vs day0

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PARANACIA CNS 820

REMEDIATION - PROTOCOL 2012A-017
TABLE No.: 21

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

Item: PARANACIA	Assigned treatment	Screen	Visit									
			Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Indipramin	No	121	121	108	107	98	93	92				
	Median	0	0	0	0	0	0	0				
	Min	0	0	0	0	0	0	0				
	Max	2	2	2	2	2	2	2	3			
Baclofen	No	127	127	117	112	107	103	98				
	Median	0	0	0	0	0	0	0				
	Min	0	0	0	0	0	0	0				
	Max	3	3	2	2	1	1	2				

Median (s): mean of differences vs day0

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PHARMACIA CHR BBD

REBOXETINE - PROTOCOL 20124/017
TABLE No.: 21

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

Item: ORBESONAL/COMPLIATVE

Assigned treatment	Screen	Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Indipramine	No	121	121	108	107	98	93	92			
	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	127	127	117	112	107	103	98			
	Median	0	0	0	0	0	0	0			
	Min	0	0	0	0	0	0	0			
	Max	2	2	2	2	2	2	2			

Median (*): mean of differences vs day0

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PHARMACIA CHE BID
 REBORENTINE - PROTOCOL 20124/017
 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	Day 49	Day 56	Day 63	Day 70		
Indipramine												
No	12	2	9	5	1	92	121					
Mean	24.92	18.00	23.00	24.80	36.00	10.36	13.68					
Median	25	18	25	31	36	9	12					
STD	8.49	16.97	7.73	12.48		8.19	10.31					
Min	14	6	7	5	36	0	0					
Max	40	30	30	34	36	40	40					
Mean diff. vs day0 (*)	1.92	4.50	4.33	8.40	-1.00	17.64	14.34					
Reborentine												
No	10	5	5	4	5	98	127					
Mean	24.30	29.20	24.40	26.25	18.60	9.59	12.98					
Median	23	28	29	26	17	8	10					
STD	8.53	9.34	14.05	10.34	9.56	7.52	10.24					
Min	10	16	0	14	9	0	0					
Max	37	40	35	39	29	36	40					
Mean diff. vs day0 (*)	3.20	-2.60	5.20	6.00	9.60	19.27	15.78					

Mean (*): mean of differences vs day0

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PHARMACIA CHE BMD

REBOCETINE - PROTOCOL 20124/017
TABLE No.: 23

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

Factor: ANXIETY/ROMATIZATION

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	
Indipramine	No	12	2	9	5	1	92	121			
	Median	1.33	1.17	1.50	1.50	1.50	0.50	0.67			
	Min	0.83	0.67	0.00	0.50	1.50	0.00	0.00			
	Max	2.17	1.67	2.00	1.67	1.50	2.00	2.17			
	Median diff. vs day0 (*)	0.17	-0.08	0.00	0.17	0.00	0.83	0.67			
Rebocetine	No	10	5	5	4	5	98	127			
	Median	1.42	1.50	1.67	1.33	1.00	0.50	0.67			
	Min	0.83	1.17	0.00	1.00	0.33	0.00	0.00			
	Max	1.67	2.33	1.67	2.00	1.67	1.83	2.33			
	Median diff. vs day0 (*)	0.00	-0.17	0.00	0.33	0.00	0.92	0.83			

Median (*): mean of differences vs day0

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PHARMACIA CR8 BID

REBOXITINE - PROTOCOL 20124/017
TABLE No.: 25

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	Day 49	Day 56	Day 63	Day 70		
Imipramine	No	12	2	9	5	1					92	121
	Median	0.75	0.67	0.67	1.00	1.83	0.17	0.33	0.00	0.00	0.17	0.33
	Min	0.50	0.17	0.33	0.00	1.83	0.00	0.00	0.00	0.00	0.00	0.00
	Max	1.67	1.17	1.83	2.17	1.83	2.00	2.00	2.00	2.00	2.00	2.17
	Median diff. vs day0 (*)	-0.08	0.00	0.00	0.17	0.00	0.67	0.00	0.00	0.00	0.00	0.00
Reboxetine	No	10	5	5	4	5					98	127
	Median	1.00	0.67	1.00	0.92	0.33	0.17	0.17	0.17	0.17	0.17	0.17
	Min	0.17	0.33	0.00	0.67	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	1.67	1.83	1.83	1.67	1.00	2.00	2.00	2.00	2.00	2.00	2.00
	Median diff. vs day0 (*)	0.08	-0.17	0.17	0.25	0.33	0.83	0.67	0.67	0.67	0.67	0.67

Median (*): mean of differences vs day0

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PARANACIA CMS RED

REBORSTINE - PROTOCOL 20124/017
TABLE No.: 25

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		
Tandipramine	No	12	2	9	5	1					92	121
	Median	1.68	1.13	1.75	1.50	3.25					0.50	0.75
	Min	0.75	0.25	0.25	0.25	3.25					0.00	0.00
	Max	3.00	2.00	2.25	2.50	3.25					3.00	3.25
	Median diff. vs day0 (*)	0.00	0.63	0.25	0.75	-1.75					1.50	1.25
Reborstine	No	10	5	5	4	5					96	127
	Median	1.75	2.00	2.00	1.63	1.50					0.50	0.75
	Min	0.25	1.50	0.00	0.25	0.50					0.00	0.00
	Max	3.00	3.00	2.75	2.25	2.25					2.00	3.00
	Median diff. vs day0 (*)	0.38	-0.25	-0.25	0.75	0.75					1.50	1.25

Median (*): mean of differences vs day0

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PHARMACIA CNS DSD

REBORSTINE - PROTOCOL 2012A/017
TABLE No.: 23

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

Factor: SLEEP DISTURANCE

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	12	2	9	5	1	92	121				
	Median	1.00	0.63	1.00	2.00	1.00	0.33	0.67				
	Min	0.00	0.00	0.00	0.00	1.00	0.00	0.00				
	Max	2.00	1.67	2.00	2.00	1.00	2.00	2.00				
	Median diff. vs day0 (*)	0.00	0.33	0.33	0.00	1.00	0.67	0.67				
Reborstine	No	10	5	5	4	5	96	127				
	Median	1.17	1.67	1.33	1.67	1.00	0.67	0.67				
	Min	0.00	0.33	0.00	0.67	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	0.00	0.00	0.17	0.33	0.63	0.67				

Median (*): mean of differences vs day0

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PHARMACIA CBS RSD

REBOURNE - PROTOCOL 20124/017
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	Day 56	Day 63	Day 70		
Indipramine	No	12	2	9	5	1	52	121				
	Median	3	2	3	3	4	1	1				
	Min	1	0	0	0	4	0	0				
	Max	4	3	4	4	4	3	4				
Rebourne	No	10	5	5	4	5	98	127				
	Median	3	3	3	2	3	1	1				
	Min	1	2	0	1	1	0	0				
	Max	4	4	3	3	4	3	4				

Median (*): mean of differences vs day0

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PHARMACIA CNS 880

REBOCETINE - PROTOCOL 20124/017
TABLE No.: 24

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

Item: **SHIT**

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		
Indipramine	No	12	2	9	5	1					92	121
	Median	2	1	1	2	3					0	0
	Min	0	0	0	0	3					0	0
	Max	3	1	2	3	3					3	3
Rebocetine	No	10	5	5	4	5				98	127	
	Median	2	1	2	2	1				0	0	
	Min	0	0	0	2	0				0	0	
	Max	3	3	2	2	2				2	3	

Median (*): mean of differences vs day0

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PARANALIA CNS RSD

REBORENTINE - PROTOCOL 20124/017
TABLE No.: 24

SUMMARY STATISTICS ON SCORES 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		
Indipramine	No	12	2	9	5	1	92	121				
	Median	1	1	1	1	3	0	0				
	Min	0	0	0	0	3	0	0				
	Max	3	1	3	3	3	2	3				
Reboxetine	No	10	5	5	4	5	96	127				
	Median	1	1	1	1	0	0	0				
	Min	0	0	0	0	0	0	0				
	Max	2	3	2	2	2	2	3				

Median (*): mean of differences vs day0

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PHARMACIA CNS RBD

REBOCETINE - PROTOCOL 2012A/017
TABLE NO.: 24

SUMMARY STATISTICS ON SCORES 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	Day 49	Day 56	Day 63	Day 70		
Indipravine	No	12	2	9	5	1	92	121				
	Median	2	1	1	2	0	0	1				
	Min	0	0	0	0	0	0	0				
	Max	2	1	2	2	0	2	2				
Rebocetine	No	10	5	5	4	5	96	127				
	Median	1	2	1	2	1	1	1				
	Min	0	1	0	0	0	0	0				
	Max	2	2	2	2	2	2	2				

Median (x); mean of differences vs day0

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FRANCIACA CBS RBD

RESONANCE - PROTOCOL 20124/017
TABLE No. 1 24

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

Item: INDOMETIA MIDDLE

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	
Indipramine	No	12	2	9	5	1	92	121			
	Median	1	1	1	2	1	0	1			
	Min	0	0	0	0	1	0	0			
	Max	2	2	2	2	1	2	2			
Reboxetine	No	10	5	5	4	5	96	127			
	Median	2	1	1	2	1	0	1			
	Min	0	0	0	2	0	0	0			
	Max	2	2	2	2	2	2	2			

Median (*): mean of differences vs day0

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PARANACIA CNS B&D

REGORSTINE - PROTOCOL 20124/017
TABLE No. 1 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	Day 49	Day 56	Day 63	Day 70		
Imipramine	No	12	2	9	5	1					92	121
	Median	1	1	1	2	2					0	0
	Min	0	0	0	0	2					0	0
	Max	2	2	2	2	2					2	2
Bupropion	No	10	5	5	4	5					95	127
	Median	1	2	2	2	1					1	1
	Min	0	0	0	0	0					0	0
	Max	2	2	2	2	2					2	2

Median (x): mean of difference vs day0

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PARANACIA CNS RBD
REBOURNE - PROTOCOL 20124-017
TABLE No.: 24
HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORES OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: HOUS AND ACTIVITIES

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		
Indipramine	No	12	2	9	5	1	92	121				
	Median	3	2	2	2	4	1	1				
	Min	0	1	0	1	4	0	0				
	Max	4	3	4	3	4	4	4				
Reboxetine	No	10	5	5	4	5	98	127				
	Median	3	3	3	3	1	1	1				
	Min	0	2	0	0	1	0	0				
	Max	4	4	4	4	2	4	4				

Median (x): mean of differences vs day0

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PARANACIA CRB MSD

REBORSTINE - PROTOCOL 20124/017
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	Day 49	Day 56	Day 63	Day 70	
Imipramine	No	12	2	9	5	1	92				121
	Median	1	0	0	0	3	0	0	0	0	0
	Min	0	0	0	0	3	0	0	0	0	0
	Max	3	0	1	1	3	3	3	3	3	3
Reborstine	No	10	5	5	4	5	98				127
	Median	1	1	1	1	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	3	3	3	1	2	2	2	2	3	3

Median (*): mean of differences vs day0

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PARANACIA CNS RSD

ESBOMETINE - PROTOCOL 20124/017
TABLE No. 1 24

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

Item: AGITATION

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	12	2	9	5	1	92	121				
	Median	2	2	1	1	1	0	1				
	Min	0	0	0	0	1	0	0				
	Max	3	3	4	2	1	3	4				
Reboxetine	No	10	5	5	4	5	98	127				
	Median	1	1	1	1	1	0	1				
	Min	0	1	0	1	0	0	0				
	Max	3	3	3	3	2	2	3				

Median (*): mean of differences vs day0

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PHARMACIA CNS BID

REBOZETINE - PROTOCOL 20124/017
TABLE No.: 24

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

Item: ANXIETY PSYCHIC

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	12	2	9	5	1	92	121				
	Median	2	2	2	2	3	1	1				
	Min	1	1	0	1	3	0	0				
	Max	3	2	3	3	3	3	3				
Rebozetine	No	10	5	5	4	5	96	127				
	Median	2	3	2	2	1	1	1				
	Min	1	2	0	1	0	0	0				
	Max	4	4	3	3	3	4	4				

Median (*): mean of differences vs day0

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PHARMACIA CNS MSD

REBOCETINE - PROTOCOL 2012A/017
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	Day 49	Day 56	Day 63	Day 70		
Imipramine	No	12	2	9	5	1	92	121				
	Median	2	2	2	2	0	1	1				
	Min	0	1	0	1	0	0	0				
	Max	3	2	2	2	0	3	3				
Reboxetine	No	10	5	5	4	5	96	127				
	Median	2	2	2	2	1	0	1				
	Min	1	0	0	1	1	0	0				
	Max	3	2	2	3	3	3	3				

Median (s): mean of differences vs day0

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PHARMACIA CNS RED

REBOREXTINE - PROTOCOL 20124/017
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	Day 56	Day 63	Day 70		
Indipramine	No	12	2	9	5	1	92	121				
	Median	1	1	1	1	2	0	0				
	Min	0	1	0	0	2	0	0				
	Max	2	1	2	1	2	2	2	2			
Reboxetine	No	10	5	5	4	5	98	127				
	Median	1	1	1	1	1	0	0				
	Min	0	0	0	0	0	0	0				
	Max	2	2	2	1	1	2	2	2			

Median (*): mean of differences vs day0

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PHARMACIA CHE RED

REBOURNE - PROTOCOL 20124/017
TABLE No.: 24

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

Item: **SOMATIC GENERAL**

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		
Indipramine	No	12	2	9	5	1	92	121				
	Median	2	2	2	2	2	0	1				
	Min	1	1	0	0	0	0	0				
	Max	2	2	2	2	2	2	2				
Rebourne	No	10	5	5	4	5	96	127				
	Median	1	2	2	2	1	0	1				
	Min	0	1	0	1	1	0	0				
	Max	2	2	2	2	2	2	2				

Median (*): mean of differences vs day0

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PHARMACIA CNS 880

REBORNETINE - PROTOCOL 2012A/017
TABLE No.: 24

SUMMARY STATISTICS ON SCORES 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	Day 49	Day 56	Day 63	Day 70	
Indipramine	No	12	2	9	5	1	52				121
	Median	1	1	1	2	2	0				1
	Min	0	0	0	0	2	0				0
	Max	2	2	2	2	2	2				2
Reboreline	No	10	5	5	4	5	96				127
	Median	1	2	1	1	1	0				0
	Min	0	1	0	0	0	0				0
	Max	2	2	2	2	2	2				2

Median (s): mean of differences vs day0

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PARANACIA CRIS RED

REBOCETINE - PRODUCE. 2012A/017
TABLE No.: 24

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

Item: HYPOCHONDRIASIS

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	
Indipramine	No	12	2	9	5	1	92				131
	Median	1	2	2	2	0	0				0
	Min	0	0	0	0	0	0				0
	Max	3	3	3	3	3	3				3
Rebocetine	No	10	5	5	4	5	96				127
	Median	2	1	2	2	1	0				0
	Min	0	0	0	1	0	0				0
	Max	3	3	2	3	2	3				3

Median (n): mean of differences vs day0

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PARANACIA CHS 250

RESEARCHING - PROTOCOL 20124/017
TABLE No.: 24

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

Item: LOSS OF HEIGHT

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		
Indipramine	No	12	2	2	5	1					92	121
	Median	0	0	0	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0	0
	Max	2	0	2	0	0	0	0	0	0	0	2
Raboxetine	No	10	5	5	4	5	98					127
	Median	0	0	0	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0	0
	Max	1	0	0	1	0	2					2

Median (n): mean of differences vs day0

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PHARMACIA CNS 800
 RESCHEDULE - PROTOCOL 2012A-017
 TABLE No.: 24

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

Item: IMRIGANT

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	
Indipendine	No	12	2	9	5	1	92				121
	Median	1	0	0	0	2	0	0	0	0	0
	Min	0	0	0	0	2	0	0	0	0	0
	Max	2	0	1	1	2	1				2
Subcutis	No	10	5	5	4	5	98				127
	Median	0	1	0	1	1	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	1	1	1	1	1	1	1	2

Median (n): mean of differences vs day0

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PHARMACTA CHE MED

REMOSETLINE - PROTOCOL 2012A/017
TABLE No.: 24

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

Item: REVERSAL VARIATION	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		
Isiprasinas	No	12	2	9	5	1	92	121					
	Median	0	0	0	0	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0	0	0
	Max	2	0	2	2	0	2	2	2	2	2	2	2
Babozaritine	No	10	5	5	4	5	98	127					
	Median	0	0	0	1	1	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0	0	0
	Max	2	2	1	2	2	2	2	2	2	2	2	2

Median (5): mean of differences vs day0

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PHARMACIA CHE RED

REBOZETINE - PROTOCOL 20124-017
TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORES 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	Day 49	Day 56	Day 63	Day 70		
Indiprepine	No	12	2	9	5	1	92					131
	Median	0	1	0	0	3	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0	0
	Max	2	2	1	3	3	3	3	3	3	3	3
Rebozetine	No	10	5	5	4	5	96					127
	Median	1	1	1	1	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	3	3	3	3	3	3	3	3

Median (n); mean of differences vs day0

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PHARMACIA CNS MSD

REBORENTINE - PROTOCOL 2012A-017
TABLE No. 1 24

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

Item: PARANOID

	Assigned treatment							Last assessment							Total
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	
Tzipranolone	No	12	2	9	5	1	92	121							
	Median	0	0	0	0	1	0	0							
	Min	0	0	0	0	1	0	0							
	Max	1	0	1	2	1	5	3							
Reborentine	No	10	5	5	4	5	98	127							
	Median	0	0	0	1	0	0	0							
	Min	0	0	0	0	0	0	0							
	Max	2	2	1	1	1	2	2							

Median (x): mean of differences vs day0

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FRAMACIA CBS RED

ESBOMETINE - PROTOCOL 2012A-017

TABLE No.: 24

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

Item: OBSESSIONAL/COMPULSIVE

Assigned treatment	Last assessment										Total	
	Day 7	Day 14	Day 21	Day 26	Day 35	Day 42						
Tighepsaine	No	12	2	9	5	1	92					121
	Median	0	1	0	1	0	0					0
	Min	0	0	0	0	0	0					0
	Max	1	1	1	2	0	2					2
Rabozetine	No	10	5	5	4	5	98					127
	Median	0	0	1	0	0	0					0
	Min	0	0	0	0	0	0					0
	Max	2	0	1	1	1	2					2

Median (M): mean of differences vs day0

PHARMACIA C0634085

REBOXETINE - PROTOCOL 20124/017
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.	121	108	107	98	93	92
	Responders No.	9	28	41	53	59	65
	Responders %	7.4	25.9	38.3	54.1	63.4	70.7
	95% L.L.	3.5	18.0	29.1	43.7	52.8	60.2
	95% U.L.	13.7	35.2	48.2	64.2	73.2	79.7
	Remissions No.	4	18	23	40	41	52
	Remissions %	3.3	16.7	21.5	40.8	44.1	56.5
	95% L.L.	0.9	10.2	14.1	31.0	33.8	45.8
	95% U.L.	8.2	28.1	30.8	51.2	54.8	66.8
Reboxetine	Patients No.	127	117	112	107	103	98
	Responders No.	14	35	51	67	79	82
	Responders %	11.0	29.9	45.5	62.6	76.7	83.7
	95% L.L.	6.2	21.8	36.1	52.7	67.3	74.8
	95% U.L.	17.8	39.1	55.2	71.8	84.5	90.4
	Remissions No.	6	23	33	45	53	62
	Remissions %	4.7	19.7	29.5	42.1	51.5	63.3
	95% L.L.	1.8	12.9	21.2	32.6	41.4	52.9
	95% U.L.	10.0	28.0	38.8	52.0	61.4	72.8

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PHARMACIA C96 R4D
 REQUESTING - PROTOCOL 20124/017
 TABLE NO.: 24
 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	Raboxetine
Patients No.	121	127
Responders No.	63	87
Responders %	56.2	68.5
95% L.L.	46.9	59.7
95% U.L.	65.2	76.5
Remissions No.	55	66
Remissions %	45.5	52.0
95% L.L.	36.4	42.9
95% U.L.	54.8	60.9

BETWEEN TREATMENT DIFFERENCE AND 95% CONFIDENCE INTERVAL
 RESPONDERS (%): 12.3 (0.3 ; 24.3)
 REMISSIONS (%): 6.5 (-5.9 ; 18.9)

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PHARMACIA CHE MSD

REBOSIRTINE - PROTOCOL 20124/017
TABLE No. 1 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	%	
Indipromine	NORMAL				2	1.9	5	4.7	9	9.1	14	15.1	24	26.1	
	MODERATELY MENTALLY ILL														
	MILDLY ILL	1	0.8	13	10.7	22	20.6	27	25.2	26	26.3	24	25.8	18	19.6
	MODERATELY ILL	33	27.3	32	26.4	31	29.0	35	32.7	23	23.2	20	21.5	17	18.5
	MARKEDLY ILL	63	52.1	63	52.1	43	40.2	26	24.3	16	16.2	12	12.9	7	7.6
	SEVERELY ILL	22	18.2	9	7.4	5	4.7	5	4.7	5	5.1	2	2.2	1	1.1
	EXTREMELY ILL	2	1.7	1	0.8							1	1.1		
Total	121	100.0	121	100.0	107	100.0	107	100.0	99	100.0	93	100.0	92	100.0	
Subcutis	NORMAL				1	0.8	3	2.6	6	5.5	10	9.3	16	15.5	
	MODERATELY MENTALLY ILL														
	MILDLY ILL	2	1.6	20	15.7	22	18.8	23	20.4	33	30.8	34	33.0	22	22.4
	MODERATELY ILL	26	20.5	36	28.3	33	28.2	34	30.1	27	25.2	18	17.5	15	15.3
	MARKEDLY ILL	73	57.5	51	40.2	35	32.5	23	20.4	12	11.2	9	8.7	5	5.1
	SEVERELY ILL	25	19.7	15	11.8	6	5.1	5	4.4	2	1.9	1	1.0	1	1.0
	EXTREMELY ILL	1	0.8	2	1.6	1	0.9			1	0.9				
Total	127	100.0	127	100.0	117	100.0	113	100.0	107	100.0	103	100.0	98	100.0	

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PARANACIA CMS RAB
RESCKETTINE - PROTOCOL 20124/017
TABLE No.: 29
CLINICAL GLOBAL IMPRESSION: SEVERITY OF ILLNESS SHEET TABLE (LAST VALUE VS DAY 0) BY ASSIGNED TREATMENT

Assigned treatment/Shift severity	Total			Last visit																		
				Day 7			Day 14			Day 21			Day 28			Day 35			Day 42			
	No	Z	%	No	Z	%	No	Z	%	No	Z	%	No	Z	%	No	Z	%	No	Z	%	
Inipranolol	DECREASED	69	73.6	2	16.7	1	50.0	2	25.0	3	50.0								81	86.0		
	NO CHANGE	25	26.7	8	66.7			4	50.0	3	50.0								10	10.9		
	INCREASED	7	5.8	2	16.7	1	50.0	2	25.0							1	100.0		1	1.1		
	Total	121	100.0	12	100.0	2	100.0	8	100.0	6	100.0	6	100.0	1	100.0	1	100.0		92	100.0		
Rabacetam	DECREASED	102	80.3	3	30.0	2	50.0	2	33.3	3	75.0	3	75.0	3	60.0	3	60.0		69	90.8		
	NO CHANGE	21	16.5	7	70.0	1	25.0	1	25.0	2	33.3	1	25.0	1	20.0	1	20.0		9	9.2		
	INCREASED	4	3.1			1	25.0			2	33.3					1	20.0					
	Total	127	100.0	10	100.0	4	100.0	6	100.0	6	100.0	4	100.0	4	100.0	5	100.0		96	100.0		

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PHARMACIA CNS MSD

REGENERATIVE - PROTOCOL 20124/017
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	%	
Isiprasone	VERY MUCH IMPROVED	1	0.6	7	6.5	7	6.5	16	16.2	20	21.5	34	37.0
	MUCH IMPROVED	16	18.2	30	27.6	44	41.1	45	45.5	50	55.6	39	43.4
	MINIMALLY IMPROVED	36	29.8	46	43.6	58	55.5	29	29.3	15	16.1	13	14.1
	NO CHANGE	53	43.8	16	14.8	11	10.3	6	6.1	4	4.3	4	4.3
	MINIMALLY WORSE	11	9.1	6	5.6	4	3.7	1	1.0	1	1.1	2	2.2
	MUCH WORSE	3	2.5	2	1.9	3	2.8	2	2.0	2	2.2		
	VERY MUCH WORSE	1	0.8	1	0.9					1	1.1		
Total	121	100.0	108	100.0	107	100.0	99	100.0	93	100.0	92	100.0	
Rebunectine	VERY MUCH IMPROVED	2	1.6	12	10.3	17	15.0	20	18.7	30	29.1	41	41.8
	MUCH IMPROVED	23	18.1	31	26.5	51	45.1	56	52.3	49	47.6	40	40.8
	MINIMALLY IMPROVED	41	32.3	53	45.3	34	30.1	23	21.5	16	15.5	11	11.2
	NO CHANGE	50	39.4	12	10.3	6	5.3	4	3.7	5	4.9	5	5.1
	MINIMALLY WORSE	9	7.1	7	6.0	3	2.7	3	2.8	3	2.9	1	1.0
	MUCH WORSE	2	1.6	1	0.9	2	1.8	1	0.9				
	VERY MUCH WORSE												
Total	127	100.0	117	100.0	113	100.0	107	100.0	103	100.0	98	100.0	

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PHARMACIA CNS RBD
 REBOZETINE - PROTOCOL 2012A-017
 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	%	
Tolipramine	64	35.7	11	10.2	10	9.3	8	8.1	6	6.5	4	4.3	
	49	40.6	34	31.5	23	21.5	12	12.1	12	12.9	8	8.7	
	1.33 - 1.5	8	6.7	18	16.7	21	19.6	21	21.2	12	12.9	12	13.0
	2	16	13.3	32	29.6	29	27.1	32	32.3	23	24.7	25	27.2
	3	3	2.5	10	9.3	19	17.8	15	15.2	21	22.6	16	17.4
4			3	2.8	5	4.7	11	11.1	19	20.4	27	29.3	
Total	120	100	108	100	107	100	99	100	98	100	92	100	
Rebozetine	39	30.7	16	13.7	10	8.8	10	9.3	6	5.8	4	4.1	
	41	32.3	32	27.4	22	19.5	14	13.1	10	9.7	6	6.1	
	1.33 - 1.5	13	10.2	14	12.0	28	24.8	16	15.0	19	18.4	13	13.3
	2	20	15.7	29	24.8	13	11.5	12	11.2	12	11.7	17	17.3
	3	11	8.7	12	10.3	24	21.2	28	26.2	22	21.4	17	17.3
4	5	2.4	14	12.0	16	14.2	27	25.2	34	33.0	41	41.8	
Total	127	100	117	100	113	100	107	100	103	100	98	100	

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

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PHARMACIA CNS R&D

REBOSENTINE - PROTOCOL 20124/017
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	%		
Indipramine	< 1	22	18.18	10	83.33	1	50.00	2	25.00	4	66.67	1	100.0	4	4.35	
	1	15	12.40	2	16.67			5	62.50					8	8.70	
	1.33 - 1.5	12	9.92											12	13.04	
	2	28	23.14			1	50.00			2	33.33			25	27.17	
	4	17	14.05					1	12.50					16	17.39	
Total	27	22.51												27	29.35	
ReboSENTINE	Total	121	100.0	12	100.0	2	100.0	8	100.0	6	100.0	1	100.0	92	100.0	
	< 1	23	18.11	7	70.00	3	75.00	3	50.00	3	75.00	3	60.00	4	4.08	
	1	11	8.66			1	25.00	2	33.33	1	25.00	1	20.00	6	6.12	
	1.33 - 1.5	14	11.02	1	10.00									13	13.27	
	2	15	14.17	1	10.00									17	17.35	
4	15	14.17	1	10.00									17	17.35		
Total	43	35.66						1	16.67			1	20.00	41	41.84	
Total	127	100.0	10	100.0	4	100.0	4	100.0	4	100.0	4	100.0	5	100.0	98	100.0

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

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REBOUSTINE - PROTOCOL 2012A/017
TABLE No.: 34

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	Day 49	Day 56	Day 63	Day 70	
Indipramine	No	121	121	108	107	96	93	92				
	Mean	16.91	14.69	12.19	10.38	8.55	7.78	6.03				
	Median	17	16	13	10	8	7	5				
	STD	2.98	4.62	5.26	5.28	5.38	5.53	4.94				
	Min	8	5	0	0	0	0	0				
	Max	25	26	23	21	21	26	21				
Mean diff. vs day0 (s)		2.21	4.90	6.79	8.62	9.27	11.06					
Subocetone	No	127	127	117	112	107	103	98				
	Mean	17.21	14.43	11.64	9.40	8.40	7.10	5.89				
	Median	18	15	12	9	8	6	5				
	STD	3.25	4.80	5.64	5.04	5.28	4.79	4.56				
	Min	4	1	0	0	0	0	0				
	Max	28	26	27	22	24	20	20				
Mean diff. vs day0 (s)		2.78	5.66	8.02	9.07	10.39	11.62					

Mean (s): mean of differences vs day0

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PARANACIA CIB 820

RESEARCHING - PROTOCOL 20124-017
TABLE No.: 35

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

Item: REPORTED RAINBOW

Assigned treatment	Visit										
	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70
Indipromine	No	121	121	108	107	98	92				
	Median	2	2	2	1	1	1				
	Min	1	0	0	0	0	0				
	Max	3	3	3	3	3	3				
Raboctaline	No	127	127	117	112	107	103	96			
	Median	2	2	1	1	1	1	0			
	Min	1	0	0	0	0	0	0			
	Max	3	3	3	3	3	3	2			

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PARANACIA CR6 RBD

RESUMEN - PROTOCOLO 2012A/017
TABLE No. 1 35

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

Item: **INNER YENKION**

Assigned treatment	Visit											
	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70	
Indapramine	No	121	121	108	107	98	95	92				
	Median	2	2	1	1	1	1	1				
	Min	0	0	0	0	0	0	0				
	Max	3	3	3	2	3	3	3				
Suboxetina	No	127	127	117	112	107	103	98				
	Median	2	2	1	1	1	1	1				
	Min	0	0	0	0	0	0	0				
	Max	3	3	3	3	2	2	2				

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PHARMACIA CNS 888

REBOURNE - PROTOCOL 20124/017
TABLE No.: 35

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

Item: APPARENT SAUVESSE

Assigned treatment		Visit										
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
Talipramine	No	121	121	108	107	98	93	92				
	Median	2	2	1	1	1	1	0				
	Min	1	0	0	0	0	0	0				
	Max	3	3	3	3	3	3	2				
Rebourne	No	127	127	117	112	107	103	98				
	Median	2	2	1	1	1	1	0				
	Min	0	0	0	0	0	0	0				
	Max	3	3	3	3	3	3	2				

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PARANACIA CNS 800

REBOCETINE - PROTOCOL 20124/017
TABLE No.1 35

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	Day 49	Day 56	Day 63
Indipramine	No	121	121	108	107	98	93	92		
	Median	1	1	1	0	0	0	0		
	Min	0	0	0	0	0	0	0		
	Max	3	3	3	3	2	2	2		
Subocetine	No	127	127	117	112	107	103	96		
	Median	1	1	0	0	0	0	0		
	Min	0	0	0	0	0	0	0		
	Max	3	2	3	2	3	2	2		

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PHARMACIA CBS D&D

REBORSTINE - PROTOCOL 20124/017
TABLE No.: 35

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

Item: INERTIA

	Visit										
	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70
Assigned treatment											
Indipromine	No	121	121	108	107	98	93	92			
	Median	2	2	1	1	1	1	1			
	Min	1	0	0	0	0	0	0			
	Max	3	3	3	3	3	3	3			
Reborstine	No	127	127	117	112	107	103	98			
	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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PARACETAMOL 500 MG TAB

REBOCETIN - PROTOCOL 20124/017
TABLE No.: 35

SUMMARY STATISTICS ON SCORES 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	Day 49	Day 56	Day 63
Indipramine	No	121	121	108	107	96	95	92		
	Median	2	2	2	1	1	1	0		
	Min	0	0	0	0	0	0	0		
	Max	3	3	3	3	3	3	3		
Rebocetine	No	127	127	117	112	107	103	98		
	Median	2	2	1	1	1	1	1		
	Min	0	0	0	0	0	0	0		
	Max	3	3	3	3	3	3	2		

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PERMADIA CMB R4D

REBOMETINE - PROTOCOL 20124/017
TABLE No.: 35

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

Item: **PERMANENT THOUGHTS**

Assigned treatment		Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63
Indipramine	No	121	121	106	107	98	93	92			
	Median	2	1	1	1	1	1	1			
	Min	1	0	0	0	0	0	0			
	Max	3	3	2	2	3	3	2			
Reboksetin	No	127	127	117	112	107	103	98			
	Median	2	1	1	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	3	3	3	2	3	3	2			

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PHARMACIA CNS BID

REBONETINE - PROTOCOL 20124-017
TABLE No. 35

SUMMARY STATISTICS ON SCORES 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			
Indipramine	No	121	121	108	107	96	93	92			
	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	127	127	117	112	107	103	98			
	Median	2	2	1	1	1	1	1			
	Min	0	0	0	0	0	0	0			
	Max	3	3	3	2	3	2	2			

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PHARMACIA CHR 020

RESOURTINE - PROTOCOL 20124-017

TABLE No.: 35

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	Day 49	Day 56	Day 63
Indipramine	No	121	121	108	107	96	93	92		
	Median	2	2	1	1	1	1	1		
	Min	0	0	0	0	0	0	0		
	Max	3	3	3	3	3	3	2	2	
Reboxetine	No	127	127	117	112	107	105	96		
	Median	2	2	2	1	1	1	1		
	Min	0	0	0	0	0	0	0		
	Max	3	3	3	3	3	3	3	3	

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PARANACIA CHS RBD

RESONETINE - PROTOCOL 20124-017
TABLE No. 1 35

SUMMARY STATISTICS ON SCORES 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	Day 49	Day 56	Day 63	Day 70	
Indipramine	No	121	121	108	107	98	93	92				
	Median	1	1	1	1	0	0	0				
	Min	0	0	0	0	0	0	0				
	Max	3	3	2	2	3	3	2				
Suboxetine	No	127	127	117	112	107	103	98				
	Median	1	1	1	1	1	0	0				
	Min	0	0	0	0	0	0	0				
	Max	3	3	3	2	2	2	2				

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PHARMACIA CNS 880

RESEARCHING - PROTOCOL 20124-017
TABLE No.: 36

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

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		
Indipramine	No	12	2	9	5	1	92	121				
	Mean	14.42	11.00	14.11	12.40	26.00	6.03	7.98				
	Median	15	11	16	14	26	5	6				
	STD	4.42	3.90	5.37	5.03		4.94	6.12				
	Min	8	4	4	5	26	0	0				
	Max	24	18	19	18	26	21	26				
Baclofen	Mean diff. vs day0 (*)	0.92	4.50	2.33	7.00	-12.00	11.06	8.93				
	No	10	5	5	4	5	98	127				
	Mean	14.50	18.20	12.60	15.25	12.40	5.89	7.87				
	Median	15	18	17	14	13	5	7				
	STD	4.79	5.34	8.08	6.75	3.58	4.56	6.03				
	Min	9	13	0	9	7	0	0				
Max	21	27	19	24	16	20	27					
	Mean diff. vs day0 (*)	1.70	-3.60	3.60	2.00	4.60	11.62	9.35				

Mean (*): mean of differences vs day0

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PARANACIA CNS DSD

REBORETTINE - PROTOCOL 20124/017
TABLE No.: 37

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

Item: REPORTED SAUWERS

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	
Tolipramine	No	12	2	9	5	1	92				121
	Median	2	1	2	1	3	1				1
	Min	1	0	0	0	3	0				0
	Max	3	2	3	3	3	2				3
Reborettine	No	10	5	5	4	5	95				127
	Median	2	3	2	2	1	0				1
	Min	1	2	0	1	1	0				0
	Max	3	3	3	3	2	2				3

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PHARMACIA CNS 880

REBOUTINE - PROTOCOL 20124/017
TABLE No.: 37

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

Item: INNER TENSION

Assigned treatment	Last assessment										Total
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 42	Day 42	Day 42	Day 42	
Indipravine	No	12	2	9	5	1	92	121			
	Median	2	2	2	1	3	1	1			
	Min	1	1	1	1	3	0	0			
	Max	2	2	2	2	3	3	3			
Rebucetine	No	10	5	5	4	5	96	127			
	Median	1	2	2	2	1	1	1			
	Min	1	2	0	1	1	0	0			
	Max	3	3	3	2	2	2	3			

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PHARMACIA CHE RED

REBUCETINE - PROTOCOL 20124/017
TABLE No.: 37

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

Item: APPARENT SADRNESS

	Last assessment									
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Total
Indipramine	No	12	2	9	5	1	92	121		
	Median	2	1	2	2	3	0	1		
	Min	0	0	1	1	3	0	0		
	Max	3	2	3	2	3	2	3		
Rebucetine	No	10	5	5	4	5	98	127		
	Median	2	2	2	1	2	0	1		
	Min	1	1	0	1	1	0	0		
	Max	3	3	2	3	2	2	3		

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PHARMACIA CNS 220

RESUBMITTING - PROTOCOL 20124/017
TABLE No.: 37

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				
Indipravine	No	12	2	9	5	1	92	121			
	Median	1	1	1	1	2	0	0			
	Min	0	0	0	0	2	0	0			
	Max	2	1	3	2	2	2	3			
Reboxetine	No	10	5	5	4	5	98	127			
	Median	1	1	1	1	1	0	0			
	Min	1	0	0	0	0	0	0			
	Max	2	3	1	2	2	2	3			

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PHARMACIA CNS 020

RESEARCHING - PROTOCOL 20124/017
TABLE No.: 37

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				
Indipravine	No	2	2	9	5	1	92	121			
	Median	2	2	2	1	3	1	1			
	Min	1	1	0	1	3	0	0			
	Max	3	2	2	2	3	3	3			
Subcutine	No	10	5	5	4	5	98	127			
	Median	2	2	2	2	1	1	1			
	Min	0	1	0	0	1	0	0			
	Max	3	3	2	3	2	2	3			

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PHARMACIA CRIS MSD

RESEARCHING - PROTOCOL 20124-017
TABLE No.: 37

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

Item: INABILITY TO FEEL

	Last assessment:										Total	
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70		
Assigned treatment												
Indipramine												
No	12	2	9	5	1	92	121					
Median	2	2	2	1	3	0	1					
Min	0	1	0	0	3	0	0					
Max	2	2	2	2	3	3	3					
Subcutaneous												
No	10	5	5	4	5	96	127					
Median	1	2	2	2	1	1	1					
Min	1	1	0	0	1	0	0					
Max	2	3	3	2	2	2	3					

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PRAMACIA CHE RED

REBOGETINE - PROTOCOL 20124/017
TABLE No.: 37

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

Item: PERSISTENT THOUGHTS

Assigned treatment	Last assessment									
	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Total			
Imipramine	No	12	2	9	5	1	92	121		
	Median	2	1	1	2	3	1	1		
	Min	1	0	0	1	3	0	0		
	Max	2	2	2	2	3	2	3		
Bupropione	No	10	5	5	4	5	98	127		
	Median	2	1	1	2	1	1	1		
	Min	1	1	0	2	1	0	0		
	Max	2	3	2	3	1	2	3		

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PARANACIA CHS BID

REBOCETINE - PROTOCOL 2012A-017
TABLE No. 1 S7

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			
Indipramine	No	12	2	9	5	1	92	121		
	Median	1	1	1	1	2	1	1		
	Min	1	0	0	0	2	0	0		
	Max	3	2	3	2	2	3	3		
Suboxetine	No	10	5	5	4	5	98	127		
	Median	2	2	2	2	1	1	1		
	Min	0	1	0	0	0	0	0		
	Max	2	3	2	2	2	2	3		

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PHARMACIA CBS RBD
 REMONTEME - PROTOCOL 2012A-017
 TABLE No.: 37

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

Item: REDUCED SLEEP

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		
Indipramin	No	12	2	9	5	1					92	121
	Median	2	1	2	2	1					1	1
	Min	0	0	0	0	1					0	0
	Max	3	2	2	3	1					2	3
Subocetine	No	10	5	5	4	5					96	127
	Median	2	2	2	2	2					1	1
	Min	0	1	0	2	0					0	0
	Max	3	3	2	3	2					3	3

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PHARMACIA CR8 RBD

REBOURNE - PROTOCOL 20124/017
TABLE No.: 37

SUMMARY STATISTICS ON SCORES 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				
Indipramine	No	2	9	5	1	92	121				
	Median	1	1	1	3	0	0				
	Min	0	0	0	0	0	0				
	Max	3	1	2	1	3	3				
Rabornitine	No	10	5	5	4	5	98				
	Median	1	1	0	1	1	0				
	Min	0	0	0	0	0	0				
	Max	2	2	1	2	2	2				

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PEARLACIA CR6 R2D
 REDUCING - PROTOCOL 20124-017
 TABLE No. 1 36
 ADVERSE EVENTS: FREQUENCY (SEX C.I.) OF PATIENTS WHO COMPLAINED OF AT LEAST ONE ADVERSE EVENT DURING THERAPY BY SEX AND ASSIGNED TREATMENT

	Assigned treatment							
	Inipramine				Reboxetine			
	Female	Male	Total	%	Female	Male	Total	%
Pt exposed	83	43	126	84	66	40	106	81.53
Pt with adverse events	66	37	103	78.57	66	40	106	81.53
% on exposed	79.51	86.04	81.74	78.57	86.36	73.74	79.79	81.53
95% L.L.	69.24	72.07	73.86	68.26	68.78	95.06	87.80	81.53
95% U.L.	87.59	94.70	88.06	84.78	103.84	99	267	81.53
No. of adverse events	183	120	303	165	99	267	267	81.53
Ratio A.E. on Pt with A.E.	2.77	3.24	2.94	2.54	2.47	2.47	2.51	81.53

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PARACETAMOL CNS RSD
 REBOXETINE - PROTOCOL 20124/017
 TABLE No.: 39
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											
	Indipramine					Reboxetine						
	Total	18 - 30	31 - 45	> 45	Total	18 - 30	31 - 45	> 45	Total	18 - 30	31 - 45	> 45
Pt. exposed	125	34	34	58	130	19	42	69				
Pt. with adverse events	103	29	25	49	106	16	35	55				
% on exposed	81.7%	85.29	73.52	84.48	81.53	84.21	83.33	79.71				
95% L.I.	79.88	68.94	55.64	72.58	73.79	60.42	68.64	68.31				
95% U.I.	88.06	95.05	87.12	92.65	87.80	94.62	93.03	88.44				
No. of adverse events	303	80	71	152	287	35	92	140				
Ratio A.E. on Pt with A.E.	2.94	2.75	2.84	3.10	2.51	2.18	2.62	2.94				

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PRASINACIA CHS DBD
 REDUCTIVE - PROTOCOL 20124/017
 TABLE No. 1 40
 ADVERSE EVENTS, FREQUENCY (95% C.I.) OF PATIENTS WHO COMPLAINED OF AT LEAST ONE ADVERSE EVENT DURING THERAPY
 BY DBD III CLASSIFICATION AND ASSIGNED TREATMENT

	Assigned treatment					
	Indipacaine			Rebexetine		
	Total	296.2	296.3	Total	296.2	296.3
Pt exposed	126	57	69	130	51	79
Pt with adverse events	103	46	57	106	41	65
% on exposed	81.7%	80.7%	82.6%	81.5%	80.3%	82.27
95% I.I.	73.85	68.09	71.59	73.79	66.88	72.06
95% U.I.	88.06	89.95	90.68	87.80	90.18	89.96
No. of adverse events	303	152	171	267	93	174
Ratio A.E. on Pt with A.E.	2.94	2.86	3.00	2.51	2.26	2.67

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PARANACIA CNS 820

REBOCETINE - PROTOCOL 20124/017
TABLE No.: 41

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.	Z on exp. with AE	No of AE	Ratio (%)	No of Pt. exp.	Z on exp. with AE	No of AE	Ratio (%)	No of Pt. exp.	Z on exp. with AE	No of AE	Ratio (%)	
Pt exposed	83	100.0			43	100.0			126	100.0			
	84	100.0			46	100.0			130	100.0			
Pt with a.e.	66	79.5	100.0	153	2.77	37	86.0	100.0	120	3.24	103	81.7	100.0
	66	78.6	100.0	168	2.54	40	87.0	100.0	99	2.47	106	81.5	100.0
MOUTH DRY	26	31.3	39.3	26	1.00	19	44.2	51.3	22	1.15	45	35.7	43.6
	21	25.0	31.8	21	1.00	11	23.9	27.5	12	1.09	32	24.6	30.1
HEADACHE	10	12.0	15.1	11	1.10	8	18.6	21.6	10	1.25	18	14.3	17.4
	12	14.3	18.1	15	1.25	9	19.6	22.5	12	1.33	21	16.2	19.8
SWEATING INCREASED	9	10.8	13.6	9	1.00	9	20.9	24.3	11	1.22	18	14.3	17.4
	7	8.3	10.6	7	1.00	11	23.9	27.5	13	1.16	18	13.8	16.9
DIZZINESS	10	12.0	15.1	10	1.00	8	18.6	21.6	9	1.12	18	14.3	17.4
	9	10.7	13.6	9	1.00	3	6.5	7.5	4	1.33	12	9.2	11.3
NAUSEA	9	10.8	13.6	9	1.00	4	9.3	10.8	4	1.00	13	10.3	12.6
	13	15.5	19.6	13	1.00	3	6.5	7.5	3	1.00	16	12.3	15.0
CONSTIPATION	8	9.6	12.1	8	1.00	5	11.6	13.5	5	1.00	13	10.3	12.6
	9	10.7	13.6	9	1.00	4	8.7	10.0	4	1.00	13	10.0	12.2
INSOMNIA	7	8.4	10.6	7	1.00	7	16.3	18.9	9	1.28	14	11.1	13.8
	8	9.5	12.1	9	1.12	2	4.3	5.0	2	1.00	10	7.7	9.4
TACHYCARDIA	10	12.0	15.1	12	1.20	3	7.0	8.1	3	1.00	15	10.3	12.6
	3	3.6	4.5	5	1.66	5	10.9	12.5	5	1.00	8	6.2	7.5
TREMOR	8	9.6	12.1	8	1.00	5	11.6	13.5	5	1.00	13	10.3	12.6
	2	2.4	3.0	2	1.00						2	1.5	1.8

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

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PHARMACIA CHEM MED

REBONZETINE - PROTOCOL 20124/017
TABLE No.: 41

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.	Z on exp. with AE	No of AE	Ratio (x)	No of Pt. exp.	Z on exp. with AE	No of AE	Ratio (x)	No of Pt. exp.	Z on exp. with AE	No of AE	Ratio (x)	No of Pt. exp.	Z on exp. with AE	No of AE	Ratio (x)
AGITATION	6	7.2	9.0	6	1.00	3	7.0	8.1	3	1.00	9	7.1	6.7	9	1.00	
	4	4.8	6.0	4	1.00	2	4.3	5.0	4	2.00	6	4.6	5.6	8	1.33	
SOMNOLENCE	5	6.0	7.5	6	1.20	4	9.3	10.8	4	1.00	9	7.1	8.7	10	1.11	
	2	2.4	3.0	2	1.00	2	4.3	5.0	2	1.00	4	3.1	3.7	4	1.00	
MIGRAINATION DISORDER	2	2.4	3.0	2	1.00	1	2.3	2.7	1	1.00	3	2.4	2.9	3	1.00	
	1	1.2	1.5	1	1.00	7	15.2	17.5	7	1.00	8	6.2	7.5	8	1.00	
PALPITATION	3	3.6	4.5	4	1.33	2	4.7	5.4	2	1.00	5	4.0	4.8	6	1.20	
	5	6.0	7.5	5	1.00						3	3.8	4.7	3	1.00	
FATIGUE	3	3.6	4.5	3	1.00	2	4.7	5.4	2	1.00	5	4.0	4.8	5	1.00	
	3	3.6	4.5	4	1.33	1	2.2	2.5	1	1.00	4	3.1	3.7	5	1.25	
VISION ABNORMAL	1	1.2	1.5	1	1.00	3	7.0	8.1	3	1.00	4	3.2	3.8	4	1.00	
	3	3.6	4.5	3	1.00	1	2.2	2.5	1	1.00	4	3.1	3.7	4	1.00	
BRONCHITIS	1	1.2	1.5	2	2.00						1	0.8	0.9	2	2.00	
	5	6.0	7.5	5	1.00	1	2.2	2.5	1	1.00	6	4.6	5.6	6	1.00	
URINARY RETENTION	4	4.8	6.0	4	1.00						3	1.50	3.5	4	1.00	
						2	4.3	5.0	3	1.50	2	1.5	1.8	3	1.50	
HYPEREMESION						1	2.3	2.7	1	1.00	1	0.8	0.9	1	1.00	
	4	4.8	6.0	5	1.25	1	2.2	2.5	2	2.00	5	3.8	4.7	7	1.40	
INFLUENZA-LIKE SYMPTOMS	2	2.4	3.0	3	1.50						2	1.6	1.9	3	1.50	
	2	2.4	3.0	2	1.00	2	4.3	5.0	2	1.00	4	3.1	3.7	4	1.00	
RAISE	2	2.4	3.0	2	1.00						2	1.6	1.9	2	1.00	
	3	3.6	4.5	3	1.00						3	2.3	2.8	3	1.00	

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

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PARACETAMOL CNS RED

REBOCETIN - PROTOCOL 2012A/017
TABLE No. 1 41

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.	No of Pt. with AE	No of AE	Ratio (%)	No of Pt. exp.	No of Pt. with AE	No of AE	Ratio (%)	No of Pt. exp.	No of Pt. with AE	No of AE	Ratio (%)	No of Pt. exp.	No of Pt. with AE	No of AE
PARAESTHESIA	1	1.2	1.5	1	1.00	1	2.3	2.7	1	1.00	2	1.6	1.9	2	1.00
	2	2.4	3.0	2	1.00	1	2.2	2.5	2	2.00	3	2.3	2.6	4	1.33
HYPEREMION	2	2.4	3.0	2	1.00	3	7.0	8.1	4	1.33	5	4.0	4.8	6	1.20
						2	4.7	5.4	2	1.00	2	1.6	1.9	2	1.00
LIDING INCREASED						3	6.5	7.5	3	1.00	3	2.3	2.8	3	1.00
	2	2.4	3.0	2	1.00						2	1.6	1.9	2	1.00
ABDOMINAL PAIN	2	2.4	3.0	2	1.00	1	2.2	2.5	1	1.00	3	2.3	2.8	3	1.00
	2	2.4	3.0	2	1.00						2	1.6	1.9	2	1.00
FLATULENCE	2	2.4	3.0	2	1.00						2	1.6	1.9	2	1.00
	3	3.6	4.5	3	1.00						3	2.3	2.8	3	1.00
TASTE PERVERSION	2	2.4	3.0	2	1.00						2	1.6	1.9	2	1.00
	2	2.4	3.0	2	1.00						2	1.5	1.8	2	1.00
UPPER RESP TRACT INFECTION	1	1.2	1.5	1	1.00	1	2.3	2.7	2	2.00	2	1.6	1.9	3	1.50
	2	2.4	3.0	2	1.00						2	1.5	1.8	2	1.00
BACK PAIN	1	1.2	1.5	1	1.00	1	2.3	2.7	2	2.00	2	1.6	1.9	3	1.50
	2	2.4	3.0	2	1.00						2	1.5	1.8	2	1.00
ARTHRALGIA	1	1.2	1.5	1	1.00	1	2.3	2.7	2	2.00	2	1.6	1.9	3	1.50
	2	2.4	3.0	2	1.00						2	1.5	1.8	2	1.00
AMNESIA	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
	2	2.4	3.0	2	1.00						2	1.6	1.9	2	1.00
FLUSHING						1	2.2	2.5	1	1.00	1	0.8	0.9	1	1.00
	1	1.2	1.5	1	1.00	1	2.3	2.7	1	1.00	1	0.8	0.9	1	1.00
	1	1.2	1.5	1	1.00	1	2.2	2.5	1	1.00	2	1.5	1.8	2	1.00

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

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PHARMACIA CNS 080

REBOZETINE - PROTOCOL 20124/017
TABLE No. 1 41

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	Ratio (s)	No of Pt. exp.	% on exp.	No of AE with AE	Ratio (s)	No of Pt. exp.	% on exp.	No of AE with AE	Ratio (s)
EXPOSURE POSTURAL	2	2.4	3.0	2 1.00					2	1.6	1.9	2 1.00
	1	1.2	1.5	1 1.00					1	0.8	0.9	1 1.00
NEURONS	3	3.6	4.5	3 1.00					3	2.3	2.8	3 1.00
	3	3.6	4.5	3 1.00					3	2.3	2.8	3 1.00
GAMMA-GT INCREASED	2	2.4	3.0	2 1.00					2	1.6	1.9	2 1.00
	1	1.2	1.5	1 1.00					1	0.8	0.9	1 1.00
SINUSITIS	1	1.2	1.5	1 1.00					1	0.8	0.9	1 1.00
	1	1.2	1.5	1 1.00	1	2.2	2.5	1 1.00	2	1.5	1.8	2 1.00
URINARY TRACT INFECTION	1	1.2	1.5	1 1.00					1	0.8	0.9	1 1.00
	2	2.4	3.0	3 1.50					2	1.5	1.8	3 1.50
ASTHENIA	2	2.4	3.0	2 1.00					2	1.6	1.9	2 1.00
					1	2.2	2.5	1 1.00	1	0.8	0.9	1 1.00
HYPOAESTHESIA	1	1.2	1.5	1 1.00					1	0.8	0.9	1 1.00
	1	1.2	1.5	1 1.00					1	0.8	0.9	1 1.00
ACCOMMODATION ABNORMAL					2	4.7	5.4	2 1.00	2	1.6	1.9	2 1.00
	1	1.2	1.5	1 1.00					1	0.8	0.9	1 1.00
DIARRHOEA	1	1.2	1.5	1 1.00					1	0.8	0.9	1 1.00
	1	1.2	1.5	1 1.00					1	0.8	0.9	1 1.00
VOMITING	1	1.2	1.5	1 1.00					1	0.8	0.9	1 1.00
					1	2.2	2.5	1 1.00	1	0.8	0.9	1 1.00
CONFUSION	2	2.4	3.0	2 1.00					2	1.6	1.9	2 1.00
					1	2.3	2.7	1 1.00	1	0.8	0.9	1 1.00

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

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PHARMACIA CHE BBD

REBOSONTINE - PROTOCOL 20124/017
TABLE No.: 41

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	Ratio (x)	No of Pt. exp.	% on exp.	No of AE with AE	Ratio (x)	No of Pt. exp.	% on exp.	No of AE with AE	Ratio (x)			
DELAIRION	1	1.2	1.5	1	1.00				1	0.8	0.9	1	1.00		
SUICIDE ATTEMPT	1	1.2	1.5	1	1.00	1	2.2	2.5	1	1.00	2	1.5	2	1.00	
GASTROENTERITIS	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
REBOSONTINE	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
HEADACHE INCREASED	1	1.2	1.5	2	2.00						1	0.8	0.9	2	2.00
REBOSONTINE	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
HYPEROLESTEROLEMIA	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
REBOSONTINE	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
HYPERURICEMIA	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
REBOSONTINE						1	2.2	2.5	1	1.00	1	0.8	0.9	1	1.00
REBOSONTINE						2	4.3	5.0	2	1.00	2	1.5	1.6	2	1.00
ECG ABNORMAL	2	2.4	3.0	2	1.00						2	1.5	1.6	2	1.00
REBOSONTINE	1	1.2	1.5	1	1.00	1	2.3	2.7	1	1.00	2	1.6	1.9	2	1.00
REBOSONTINE	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
SPOTON INCREASED	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
REBOSONTINE	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
REBOSONTINE	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
REBOSONTINE						2	4.7	5.4	2	1.00	2	1.6	1.9	2	1.00
REBOSONTINE						1	2.3	2.7	1	1.00	1	0.8	0.9	1	1.00
REBOSONTINE						1	2.2	2.5	1	1.00	1	0.8	0.9	1	1.00
REBOSONTINE	1	1.2	1.5	1	1.00	1	2.3	2.7	1	1.00	2	1.6	1.9	2	1.00
REBOSONTINE	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
REBOSONTINE	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
REBOSONTINE	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
REBOSONTINE	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
REBOSONTINE	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00

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

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PHARMACIA CNS RSD

REBOCETINE - PROTOCOL 2012A/017
TABLE No.: 41

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.	Z on exp. with AE	No of AE	Ratio (%)	No of Pt. exp.	Z on exp. with AE	No of AE	Ratio (%)	No of Pt. exp.	Z on exp. with AE	No of AE	Ratio (%)		
ARTHRALGIA					1	2.3	2.7	1	1.00	1	0.8	0.9	1	1.00
ERYTHEMA	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00
HYPONATREMIA	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00
VERTIGO	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00
SALIVA INCREASED					1	2.3	2.7	1	1.00	1	0.8	0.9	1	1.00
TACHYCARDIA SUPRAVENTRICULAR	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00
TINNITUS	1	1.2	1.5	2	2.00					1	0.8	0.9	2	2.00
TASTE LOSS	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00
ANXIETY	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00
HALLUCINATION	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00
APPETITE INCREASED	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00
DYSPEPSIA	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00
OBESOPHAGITIS	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00
SOFT INCREASED					1	2.2	2.5	1	1.00	1	0.8	0.9	1	1.00
GLOBULINS INCREASED	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00
ERYTHROCYTES INCREASED	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00
AV BLOCK	1	1.2	1.5	1	1.00					1	2.3	2.7	1	1.00
BUNDLE BRANCH BLOCK					1	2.2	2.5	1	1.00	1	0.8	0.9	1	1.00
EXTRASTYPTILES	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00

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

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PHARMACIA CNS BID

REBOCTINE - PROTOCOL 2012A-017
TABLE No. 1 41

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.	Z on exp. with AE	No of AE	Ratio (x)	No of Pt. exp.	Z on exp. with AE	No of AE	Ratio (x)	No of Pt. exp.	Z on exp. with AE	No of AE	Ratio (x)
COUGHING					1	2.3	1	1.00	1	0.6	1	1.00
ASTHMA					1	2.3	1	1.00	1	0.6	1	1.00
LEUCOCYTOSIS	1	1.2	1.5	1.00					1	0.5	1	1.00
CYSTITIS					1	2.2	1	1.00	1	0.8	1	1.00
HAEMORRAGIC									1	0.8	1	1.00
CERVICITIS	1	1.2	1.5	1.00					1	0.8	1	1.00
PAIN	1	1.2	1.5	1.00					1	0.8	1	1.00
OTITIS MEDIA					1	2.3	1	1.00	1	0.8	1	1.00
HERPES SIMPLEX					1	2.2	1	1.00	1	0.6	1	1.00

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

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PEARLACIA CRIS DRB

REBOCETININE - PROTOCOL 20124-017
TABLE No. 1 42

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.	Ratio (x)	No of Pt	% on exp.	Ratio (x)	No of Pt	% on exp.	Ratio (x)
MOUTH DRY	26	31.3	1.00	19	44.2	1.15	45	35.7	0.8
	21	25.0	1.00	11	23.9	1.09	32	24.6	1.03
SWEATING INCREASED	9	10.8	1.00	9	20.9	1.22	18	14.3	1.11
	7	8.3	1.00	11	23.9	1.18	18	13.8	1.11
SALIVA INCREASED				1	2.3	1.00	1	0.8	1.00

(x) number of adverse events on patients who complained of adverse events (some adverse events are grouped in clusters)

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FEARNACIA CNS RBD

REBOCETININE - PROTOCOL 2012A/017
TABLE No. 1 42

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	Z on exp.	No of Pt with AE	Ratio (%)	No of Pt	Z on exp.	No of Pt with AE	Ratio (%)	No of Pt	Z on exp.	No of Pt with AE	Ratio (%)
ASTHENIA / FATIGUE	4	4.8	6.0	5 1.25	2	4.7	5.4	2 1.00	6	4.8	5.8	7 1.16
	3	3.6	4.5	4 1.33	2	4.3	5.0	2 1.00	5	3.8	4.7	6 1.20
INFLUENZA-LIKE SYMPTOMS	2	2.4	3.0	3 1.50								3 1.50
	2	2.4	3.0	2 1.00	2	4.3	5.0	2 1.00	4	3.1	3.7	4 1.00
CHEST PAIN					2	4.7	5.4	2 1.00	2	1.6	1.9	2 1.00
FEVER					1	2.3	2.7	1 1.00	1	0.8	0.9	1 1.00
PAIN					1	2.2	2.5	1 1.00	1	0.8	0.9	1 1.00
	1	1.2	1.5	1 1.00					1	0.8	0.9	1 1.00

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

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PLARNACIA CHE RED

REBOUSTINE - PROTOCOL 20124/017
TABLE No.: 42

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 event/Assigned treatment	Female			Male			Total									
	No of Pt	% on exp.	Ratio (x)	No of Pt	% on exp.	Ratio (x)	No of Pt	% on exp.	Ratio (x)							
HYPOENSION AND RELATED SYMPTOMS	Indipramine	14	16.9	21.2	14	1.00	9	20.9	24.3	13	1.44	23	16.3	22.3	27	1.17
	Reboustine	10	11.9	15.1	10	1.00	3	6.5	7.5	4	1.33	13	10.0	12.2	14	1.07
TACHYCARDIA	Indipramine	10	12.0	15.1	12	1.20	3	7.0	8.1	3	1.00	13	10.3	12.6	15	1.15
	Reboustine	3	3.6	4.5	5	1.66	5	10.9	12.5	5	1.00	8	6.2	7.5	10	1.25
PALPITATION	Indipramine	3	3.6	4.5	4	1.33	2	4.7	5.4	2	1.00	5	4.0	4.8	6	1.20
	Reboustine	5	6.0	7.5	5	1.00						5	3.8	4.7	5	1.00
HYPERTENSION	Indipramine						1	2.3	2.7	1	1.00	1	0.8	0.9	1	1.00
	Reboustine	4	4.8	6.0	5	1.25	1	2.2	2.5	2	2.00	5	3.8	4.7	7	1.40
FLASHING / HOT FLASHING	Indipramine	1	1.2	1.5	1	1.00	2	4.7	5.4	2	1.00	3	2.4	2.9	3	1.00
	Reboustine	1	1.2	1.5	1	1.00	1	2.2	2.5	1	1.00	2	1.5	1.6	2	1.00
ECG ABNORMAL	Indipramine						2	4.3	5.0	2	1.00	2	1.5	1.6	2	1.00
	Reboustine						1	2.3	2.7	1	1.00	1	0.8	0.9	1	1.00
AV BLOCK	Indipramine						1	2.2	2.5	1	1.00	1	0.8	0.9	1	1.00
	Reboustine															
BUNDLE BRANCH BLOCK	Indipramine	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
	Reboustine															
EXTRASYSTOLES	Indipramine	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
	Reboustine															
TACHYCARDIA SUPRAVENTRICULAR	Indipramine	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00
	Reboustine															

(x) number of adverse events on patients who complained of adverse events (some adverse events are grouped in clusters)

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FRANZACKA CNS 880

REBONETINE - PROTOCOL 20124/017
TABLE No.: 42

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 exp.	X on exp. with AE	No of Pt with AE	Ratio (x)	No of Pt exp.	X on exp. with AE	No of Pt with AE	Ratio (x)	No of Pt exp.	X on exp. with AE	No of Pt with AE	Ratio (x)		
HEADACHE / MIGRAINE	10	12.0	15.1	11	1.10	8	18.6	21.6	10	1.25	18	14.3	21	1.16
	12	14.3	18.1	15	1.25	9	19.6	22.5	12	1.33	21	16.2	27	1.28
TREMBOR	8	9.6	12.1	8	1.00	5	11.6	13.5	5	1.00	13	10.3	13	1.00
	2	2.4	3.0	2	1.00						2	1.5	2	1.00
PARAESTHESIA	1	1.2	1.5	1	1.00	1	2.3	2.7	1	1.00	2	1.6	2	1.00
	2	2.4	3.0	2	1.00	1	2.2	2.5	2	2.00	3	2.3	4	1.33
CONFUSION	2	2.4	3.0	2	1.00						2	1.6	2	1.00
	1	1.2	1.5	1	1.00						1	0.8	1	1.00
HYPOAESTHESIA	1	1.2	1.5	1	1.00						1	0.8	1	1.00
	1	1.2	1.5	1	1.00						1	0.8	1	1.00
HYPOKINESIA	1	1.2	1.5	1	1.00						1	0.8	1	1.00
	1	1.2	1.5	1	1.00						1	0.8	1	1.00
VERTIGO	1	1.2	1.5	1	1.00						1	0.8	1	1.00
	1	1.2	1.5	1	1.00						1	0.8	1	1.00

(x) number of adverse events on patients who complained of adverse events (some adverse events are grouped in clusters)

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PARANACIA CNS 880

REBOCETINE - PROTOCOL 20124/017
TABLE No.1 42

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

Body system: ENDOCRINE DISORDERS

Adverse events/Assigned treatment	Female			Total		
	No of Pt on exp.	No of Pt with AE	Ratio (%)	No of Pt on exp.	No of Pt with AE	Ratio (%)
HYPOHYRIDIEM	1	1.2	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 CHE RED

REBOZETINE - PROTOCOL 20124/017
TABLE No.: 42

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.	% on Pt with AE	Ratio (x)	No of Pt	% on exp.	% on Pt with AE	Ratio (x)	No of Pt	% on exp.	% on Pt with AE	Ratio (x)
HAUDREA AND RELATED SYMPTOMS	10	12.0	15.1	1.0	4	9.3	10.6	1.0	14	11.1	13.5	1.0
Indipramine												
Rebozetine	15	17.9	22.7	1.0	4	8.7	10.0	1.0	19	14.6	17.9	1.0
CONSTIPATION	8	9.6	12.1	1.0	5	11.6	13.5	1.0	13	10.3	12.6	1.0
Indipramine												
Rebozetine	9	10.7	13.6	1.0	4	8.7	10.0	1.0	13	10.0	12.2	1.0
ADDITIONAL PAIN	2	2.4	3.0	1.0					2	1.6	1.9	1.0
Indipramine												
Rebozetine	2	2.4	3.0	1.0	1	2.2	2.5	1.0	3	2.3	2.6	1.0
FLATULENCE	2	2.4	3.0	1.0					2	1.6	1.9	1.0
Indipramine												
Rebozetine	3	3.6	4.5	1.0					3	2.3	2.6	1.0
ANOREXIA	2	2.4	3.0	1.0					2	1.6	1.9	1.0
Indipramine												
Rebozetine					1	2.2	2.5	1.0	1	0.8	0.9	1.0
DIARRHOEA	1	1.2	1.5	1.0					1	0.8	0.9	1.0
Indipramine												
Rebozetine	1	1.2	1.5	1.0					1	0.8	0.9	1.0
GASTROENTERITIS	1	1.2	1.5	1.0					1	0.8	0.9	1.0
Indipramine												
Rebozetine	1	1.2	1.5	1.0					1	0.8	0.9	1.0
APPETITE INCREASED	1	1.2	1.5	1.0					1	0.8	0.9	1.0
Indipramine												
DYSPLAGIA	1	1.2	1.5	1.0					1	0.8	0.9	1.0
Indipramine												
OESOPHAGITIS	1	1.2	1.5	1.0					1	0.8	0.9	1.0
Indipramine												

(x) number of adverse events on patients who complained of adverse events (some adverse events are grouped in clusters)

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PHARMACIA CHE MSD

RESCHETINE - PROTOCOL 2012A/017
TABLE No. 1 42

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			Total		
	No of X on Pt exp.	No of Pt with AE	Ratio (s)	No of X on Pt exp.	No of Pt with AE	Ratio (s)
TINNITUS	1	1.2	1.5	2	2.00	2.00
				1	0.8	0.9
				2	2.00	2.00

(s) number of adverse events on patients who complained of adverse events (some adverse events are grouped in clusters)

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PRAMAXIA CHE DRB

RESEARCHING - PROTOCOL 20124-017
TABLE No.: 42

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 (%)	No of Pt	% on exp.	Ratio (%)
LEUKOCYTOSIS	1	1.2	1.00	1	0.8	1.00
Babesiosis	1.5	1.5	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 880

RESCUETINE - PROTOCOL 2012A-017
TABLE No.: 42

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

Body system: LIVER AND BILIAR SYSTEM DISORDERS

Adverse events/Assigned treatment	Female			Male			Total		
	No of Pt exp.	No on Pt with AE	No of AE (n)	No of Pt exp.	No on Pt with AE	No of AE (n)	No of Pt exp.	No on Pt with AE	No of AE (n)
INCREASED LIVER ENZYMES	2	2.4	4	2	2.4	4	2	2.4	4
Isipramine		3.0	4		3.0	4		3.0	4
Rescuetine	2	2.4	2	1	2.2	2.5	3	2.3	3
			1.00			1			1.00

(n) number of adverse events on patients who complained of adverse events (some adverse events are grouped in clusters)

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PHARMACIA CHE MSD

REBONETINE - PROTOCOL 20124/017
TABLE No.: 42

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 exp.	% on exp. with AE	Ratio (x)	No of Pt exp.	% on exp. with AE	Ratio (x)	No of Pt exp.	% on exp. with AE	Ratio (x)
HYPERCHOLESTEROLAEMIA	1	1.2	1.00				1	0.8	1.00
Indipramine									
Rebonetine	1	1.2	1.00				1	0.8	1.00
HYPERURICAEMIA	1	1.2	1.00				1	0.8	1.00
Indipramine									
Rebonetine				1	2.2	2.5	1	0.8	1.00
GLAUCOMA UNRECORDED	1	1.2	1.00				1	0.8	1.00
Indipramine									
Rebonetine	1	1.2	1.00				1	0.8	1.00

(x) number of adverse events on patients who complained of adverse events (some adverse events are grouped in clusters)

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PARACETAMOL 325 mg

PROTOCOL 20124/017
TABLE No.: 42

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.	Ratio (#)	No of Pt	% on exp.	Ratio (#)	No of Pt	% on exp.	Ratio (#)
BACK PAIN	1	1.2	1.00	1	2.3	2.00	2	1.6	1.50
Indipramine	1	1.2	1.00	1	2.3	2.00	2	1.6	1.50
Rohocetiline	1	1.2	1.00	1	2.3	2.00	2	1.6	1.50
ARTHRALGIA	2	2.4	2.00	2	4.6	2.00	4	3.2	2.00
Indipramine	1	1.2	1.00	1	2.3	2.00	2	1.6	1.50
Rohocetiline	1	1.2	1.00	1	2.3	2.00	2	1.6	1.50
ARTHRITIS	1	1.2	1.00	1	2.3	2.00	2	1.6	1.50
Indipramine	1	1.2	1.00	1	2.3	2.00	2	1.6	1.50

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

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PHARMACIA CHR 280

REBOCETINE - PROTOCOL 20124/017
TABLE No. 1 42

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. 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 (*)			
INSOMNIA	7	8.4	10.6	1.00	7	16.3	18.9	9	1.28	14	11.1	13.5	16	1.14	
	8	9.5	12.1	9	1.12	2	4.3	5.0	2	1.00	10	7.7	9.4	11	1.10
AGITATION / ANXIETY / NERVOUSNESS	6	7.2	9.0	7	1.16	3	7.0	8.1	3	1.00	9	7.1	8.7	10	1.11
	7	8.3	10.6	7	1.00	2	4.3	5.0	4	2.00	9	6.9	8.4	11	1.22
SOMNOLENCE	5	6.0	7.5	6	1.20	4	9.3	10.8	4	1.00	9	7.1	8.7	10	1.11
	2	2.4	3.0	2	1.00	2	4.3	5.0	2	1.00	4	3.1	3.7	4	1.00
LETHARGY INCREASED					2	4.7	5.4	2	1.00	2	1.6	1.9	2	1.00	
					3	6.5	7.5	3	1.00	3	2.3	2.8	3	1.00	
DELUSION					1	2.3	2.7	1	1.00	1	0.8	0.9	1	1.00	
	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00	
SUICIDE ATTEMPT	1	1.2	1.5	1	1.00	1	2.2	2.5	1	1.00	2	1.5	1.8	2	1.00
	1	1.2	1.5	1	1.00					1	0.8	0.9	1	1.00	

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

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PHARMACIA CHE REG

REGISTRATION - PROTOCOL 2012A/017
TABLE No.: 42

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, FEMALE

Adverse events/assigned treatment	Female			Total		
	No of Pt No of Pt exp.	No of Pt with AE	Ratio (*)	No of Pt exp.	No of Pt with AE	Ratio (*)
Menstrual disorder	1	1.5	1.00	1	0.9	1.00
Dyspareunia	1	1.5	1.00	1	0.9	1.00
Dyspareunia	1	1.5	1.00	1	0.9	1.00
Dyspareunia	1	1.5	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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PEARLACIA CNS 200

RESOURTINE - PROTOCOL 2012A/017
TABLE No.: 42

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

Body system: RESISTANCE MECHANISM DISORDERS

Adverse events/Assigned treatment	Male			Total		
	No of Pt. exp.	No of Pt. with AE	No of Pt. Ratio (%)	No of Pt. exp.	No of Pt. with AE	No of Pt. Ratio (%)
HERPES SIMPLEX	1	2.2	1 1.00	1	0.9	1 1.00
OTITIS MEDIA	1	2.3	1 1.00	1	0.9	1 1.00

(%) number of adverse events on patients who complained of adverse events (some adverse events are grouped in clusters)

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PHARMACIA CNS MSD

REBONESTINE - PROTOCOL 20024/017
TABLE No. 1 42

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 exp.	No of Pt with AE	Ratio (%)	No of Pt exp.	No of Pt with AE	Ratio (%)	No of Pt exp.	No of Pt with AE	Ratio (%)
BRONCHITIS	1	1.5	2 2.00				1	0.9	2 2.00
	5	7.5	5 1.00	1	2.5	1 1.00	6	5.6	6 1.00
UPPER RESP TRACT INFECTION	1	1.5	1 1.00	1	2.7	2 2.00	2	1.9	3 1.50
	2	3.0	2 1.00				2	1.8	2 1.00
SINUSITIS	1	1.5	1 1.00				1	0.9	1 1.00
	1	1.5	1 1.00	1	2.5	1 1.00	2	1.8	2 1.00
RHINITIS	2	3.0	2 1.00				2	1.8	2 1.00
	1	1.5	1 1.00	1	2.5	1 1.00	2	1.9	2 1.00
SPOTON INCREASED	1	1.5	1 1.00	1	2.7	1 1.00	2	1.6	2 1.00
				1	2.7	1 1.00	1	0.9	1 1.00
COUGLING				1	2.7	1 1.00	1	0.9	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 880

REGIMETINE - PROTOCOL 2012A-017
TABLE No. 1 42

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			Total		
	No of Z on Pt exp.	No of Pt with AE	No of Ratio (%)	No of Z on Pt exp.	No of Pt with AE	Ratio (%)
ERYTHEMA / RASH	2	2	1.00	2	2	1.00
	3	3	1.00	3	3	1.00
ALOPECIA	1	1	1.00	1	1	1.00
DERMATITIS FURCAL	1	1	1.00	1	1	1.00
PRURITUS	1	1	1.00	1	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 CHEM DRG

REBOUSTINE - PROTOCOL 20124/017
TABLE No.: 42

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	% on exp. with AE	Ratio (n)	No of Pt	% on exp. with AE	Ratio (n)
TASTE PERVERSION	2	2.4	1.00	2	1.6	1.00
Indipramine	2	2.4	1.00	2	1.6	1.00
Subcutaneous	2	2.4	1.00	2	1.6	1.00
TASTE LOSS	1	1.2	1.00	1	0.8	1.00
Indipramine	1	1.2	1.00	1	0.8	1.00

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

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PHARMACIA CNS MSD

REBOCETINE - PROTOCOL 20124/017
TABLE No.: 42

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 exp.	No on Pt with AE	Ratio (x)	No of Pt exp.	No on Pt with AE	Ratio (x)	No of Pt exp.	No on Pt with AE	Ratio (x)
URINARY RETENANCE / RETENTION	5	6	1.20	1	2	2.00	6	8	1.33
	1	1	1.00	9	22	2.44	10	24	2.40
URINARY TRACT INFECTION	1	1	1.00				1	1	1.00
	2	3	1.50				2	3	1.50
CYSTITIS HAEMORRHAGIC				1	2	2.00	1	2	2.00

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

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PHARMACIA CNS DSD

NEBONETINE - PROTOCOL 20124/017
TABLE No.: 42

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 event/Assigned treatment	Female				Male				Total					
	No of Pt	X on exp.	Z on exp. with AE	Pt on AE	No of Pt	X on exp.	Z on exp. with AE	Pt on AE	No of Pt	X on exp.	Z on exp. with AE	Pt on AE	Ratio (%)	
														No of AE
INDIGUNASIN	1	1.2	1.5	1	4	9.3	10.6	5	5	1.25	5	4.8	6	1.20
Rebovatinic	3	3.6	4.5	3	1	2.2	2.5	1	4	1.00	4	3.1	4	1.00

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

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PHARMACIA CHEM DRB

REBOCETININE - PROTOCOL 20124/017
TABLE No.: 43

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	Ratio (%)	No of Pt	% on exp.	No of Pt with AE	Ratio (%)	No of Pt	% on exp.	No of Pt with AE	Ratio (%)	
Pt exposed	83	100.0			43	100.0			126	100.0			
	84	100.0			46	100.0			130	100.0			
Pt with a.e.	66	79.5	100.0	183	2.77	37	86.0	100.0	120	3.24	103	81.7	100.0
	66	79.6	100.0	186	2.54	40	87.0	100.0	99	2.47	106	81.5	100.0
AUTONOMIC NERVOUS SYSTEM DISORDERS	33	39.8	50.0	35	1.06	23	53.5	62.1	34	1.47	56	44.4	54.3
	26	31.0	39.3	28	1.07	19	41.3	47.5	25	1.31	45	34.6	42.4
CARDIOVASCULAR DISORDERS, GENERAL	27	32.5	40.9	33	1.22	15	34.9	40.5	22	1.46	42	33.3	40.7
	18	21.4	27.2	26	1.44	11	25.9	27.5	15	1.36	29	22.3	27.3
GASTRO-INTESTINAL SYSTEM DISORDERS	24	28.9	36.3	29	1.20	7	16.3	18.9	9	1.28	31	24.6	30.0
	25	29.8	37.8	32	1.28	9	19.6	22.5	10	1.11	34	26.2	32.0
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO	22	26.5	33.3	26	1.18	10	23.3	27.0	16	1.60	32	25.4	31.0
	17	20.2	25.7	20	1.17	9	19.6	22.5	14	1.55	26	20.0	24.5
PSYCHIATRIC DISORDERS	14	16.9	21.2	21	1.50	15	34.9	40.5	19	1.26	29	23.0	28.1
	14	16.7	21.2	20	1.42	9	19.6	22.5	12	1.33	23	17.7	21.6
BODY AS A WHOLE- GENERAL DISORDERS	6	7.2	9.0	8	1.33	5	11.6	13.5	5	1.00	11	8.7	10.6
	6	7.1	9.0	7	1.16	5	10.9	12.5	5	1.00	11	8.5	10.3
URINARY SYSTEM DISORDERS	6	7.2	9.0	7	1.16	1	2.3	2.7	1	1.00	7	5.6	6.7
	3	3.6	4.5	4	1.33	10	21.7	25.0	11	1.10	19	10.0	12.2
RESPIRATORY SYSTEM DISORDERS	4	4.8	6.0	5	1.25	4	9.3	10.8	5	1.25	8	6.3	7.7
	9	10.7	13.6	10	1.11	2	4.3	5.0	2	1.00	11	8.5	10.3
VISION DISORDERS	1	1.2	1.5	1	1.00	4	9.3	10.8	5	1.25	5	4.0	4.8
	3	3.6	4.5	3	1.00	1	2.2	2.5	1	1.00	4	3.1	3.7

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

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PHARMACIA CNS DRD

REBOCETINE - PROTOCOL 20124/017
TABLE No. 1 43

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	Z on exp.	Z on Pt with AE	No of AE	Ratio (%)	No of Pt	Z on exp.	Z on Pt with AE	No of AE	Ratio (%)	No of Pt	Z on exp.	Z on Pt with AE	No of AE	Ratio (%)			
MUSCULO-SKELETAL SYSTEM DISORDERS	3	3.6	4.5	3	1.00	2	4.7	5.4	3	1.50	5	4.0	4.8	6	1.20			
	2	2.4	3.0	2	1.00	1	2.2	2.5	1	1.00	3	2.3	2.8	3	1.00			
SKIN AND APPENDAGES DISORDERS	2	2.4	3.0	2	1.00						2	1.6	1.9	2	1.00			
	6	7.1	9.0	6	1.00						6	4.6	5.6	6	1.00			
LIVER AND BILIAR SYSTEM DISORDERS	2	2.4	3.0	4	2.00						2	1.6	1.9	4	2.00			
	2	2.4	3.0	2	1.00	1	2.2	2.5	1	1.00	3	2.3	2.8	3	1.00			
METABOLIC AND NUTRITIONAL DISORDERS	2	2.4	3.0	3	1.50						2	1.6	1.9	3	1.50			
	2	2.4	3.0	2	1.00	1	2.2	2.5	1	1.00	3	2.3	2.8	3	1.00			
SPECIAL SENSES OTHER, DISORDERS	3	3.6	4.5	3	1.00						3	2.4	2.9	3	1.00			
	2	2.4	3.0	2	1.00						2	1.5	1.8	2	1.00			
REPRODUCTIVE DISORDERS, FEMALE	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00			
	2	2.4	3.0	2	1.00						2	1.5	1.8	2	1.00			
RESISTANCE MECHANISM DISORDERS						1	2.3	2.7	1	1.00	1	0.8	0.9	1	1.00			
						1	2.2	2.5	1	1.00	1	0.8	0.9	1	1.00			
ENDOCRINE DISORDERS	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00			
	1	1.2	1.5	2	2.00						1	0.8	0.9	2	2.00			
HEARING AND VESTIBULAR DISORDERS	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00			
	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00			
REHATOLOGY DISORDERS	1	1.2	1.5	1	1.00						1	0.8	0.9	1	1.00			

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

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PARACETAMOL CHE BRD

REBOCETIN - PROTOCOL 20124/017
TABLE No.: 44

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 %
ADVERSE EVENTS	Assigned treatment	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			46	100	36	75.0	3	6.3	3	6.3	2	4.2	3	6.3	1	2.1
HEADACHE	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			33	100	19	57.6	5	15.2	2	6.1	4	12.1	1	3.0	2	6.1
SWEATING INCREASED	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			20	100	12	60.0	1	5.0	3	15.0	1	5.0	1	5.0	2	10.0
HEADACHE	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			20	100	12	60.0	2	10.0	2	10.0	2	10.0	1	5.0	1	5.0
CONSTIPATION	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			21	100	8	38.1	4	19.0	1	4.8	3	14.3	4	19.0	1	4.8
CONSTIPATION	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			27	100	8	29.6	4	14.8	3	11.1	4	14.8	5	18.5	2	7.4
INDIGESTION	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			13	100	8	61.5	3	23.1	1	7.7	1	7.7				
INDIGESTION	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			13	100	7	53.8	2	15.4	2	15.4	1	7.7	1	7.7		
INDIGESTION	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			16	100	5	31.3	3	18.8	3	18.8	4	25.0			1	6.3
INDIGESTION	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			11	100	7	63.6	4	36.4								
INDIGESTION	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			19	100	12	63.2	3	15.8	2	10.5	2	10.5				
TACHYCARDIA	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			13	100	6	46.2			3	23.1	2	15.4	1	7.7	1	7.7
TACHYCARDIA	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			15	100	7	46.7			3	20.0	3	20.0	1	6.7	1	6.7
NAUSEA	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			10	100	2	20.0	1	10.0	1	10.0			3	30.0	2	20.0
NAUSEA	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			13	100	9	69.2	4	30.8								
TENSE	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			16	100	11	68.8	2	12.5			1	6.3			2	12.5
TENSE	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			13	100	7	53.8	3	23.1	1	7.7			1	7.7	1	7.7
DICTION DISORDER	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			2	100	1	50.0			1	50.0					2	66.7
VISION ABNORMAL	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			3	100	1	33.3										
VISION ABNORMAL	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			8	100	4	50.0	3	37.5					1	12.5		
VISION ABNORMAL	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			4	100	3	75.0					1	25.0				
VISION ABNORMAL	Rebocetine	Total	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
			4	100	4	100										

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PHARMACIA CIS D&D

REBOXETINE - PROTOCOL 20124/017
TABLE No.: 44

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	%	
ADULTATION	Isipramine	9	100	5	55.6	1	11.1	1	11.1	1	11.1	1	11.1				
	Reboxetine	8	100	6	75.0	2	25.0										
SOMNOLENCE	Isipramine	10	100	5	50.0	1	10.0			1	10.0	3	30.0				
	Reboxetine	4	100	3	75.0							1	25.0				
PALPITATION	Isipramine	6	100	1	16.7	2	33.3	1	16.7	1	16.7	1	16.7				
	Reboxetine	5	100	2	40.0	1	20.0	2	40.0								
LIBIDO DECREASED	Isipramine	2	100							1	50.0	1	50.0				
	Reboxetine	3	100	1	33.3			2	66.7								
FLATULENCE	Isipramine	2	100	1	50.0												
	Reboxetine	3	100	2	66.7	1	33.3										
HYPERSTENSION	Isipramine	1	100													1	100
	Reboxetine	7	100	1	14.3	2	28.6	1	14.3	1	14.3	1	14.3	2	28.6		
FATIGUE	Isipramine	5	100	4	80.0									1	20.0		
	Reboxetine	5	100	2	40.0	1	20.0			1	20.0					1	20.0
PARAESTHESIA	Isipramine	2	100	2	100												
	Reboxetine	4	100	1	25.0	2	50.0					1	25.0				
TASTE PERVERSION	Isipramine	2	100	2	100												
	Reboxetine	2	100	1	50.0					1	50.0						
BRONCHITIS	Isipramine	2	100							1	50.0					1	50.0
	Reboxetine	6	100			1	16.7	2	33.3			1	16.7	2	33.3		
INFLUENZA-LIKE SYMPTOMS	Isipramine	3	100			2	66.7									1	33.3
	Reboxetine	4	100			1	25.0	1	25.0			1	25.0			1	25.0

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PHARMACIA CBS RED
 REBONESTINE - PROTOCOL 20124/017
 TABLE No.: 44

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	
CANAL-OT INCREASED	Isipranisone	2	100														
	Bebocetisone	1	100			2	100										
HYPEREMESION	Isipranisone	6	100	2	33.3	1	16.7	3	50.0								
	Bebocetisone	4	100	1	25.0					2	50.0	1	25.0				
URINARY RETENTION	Isipranisone	3	100	2	66.7	1	33.3										
	Bebocetisone	1	100	1	100												
HYPERCOAGULABILITY	Isipranisone	1	100														
	Bebocetisone	1	100					1	100								
HYPEREMION POSTURAL	Isipranisone	2	100	2	100												
	Bebocetisone	1	100	1	100												
RASH	Isipranisone	2	100					1	50.0							1	50.0
	Bebocetisone	3	100	1	33.3			1	33.3			1	33.3				
UPPER RESPIRATORY TRACT INFECTION	Isipranisone	3	100														
	Bebocetisone	2	100					1	50.0			1	50.0				
HYPERURICARIA	Isipranisone	1	100														
	Bebocetisone	1	100					1	100								
SALIVA INCREASED	Isipranisone	1	100	1	100												
	Bebocetisone	3	100	1	33.3	1	33.3	1	33.3								
DIARRHEA	Isipranisone	1	100														
	Bebocetisone	3	100	1	33.3			1	33.3								
GASTROINTESTINAL INFECTION	Isipranisone	3	100	1	33.3			1	33.3								
	Bebocetisone	2	100														
HEPATIC ENZYMES INCREASED	Isipranisone	2	100														
	Bebocetisone	1	100					1	100								
BACK PAIN	Isipranisone	3	100	1	33.3												
	Bebocetisone	3	100	1	33.3												

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PHARMACIA CBS RED

REBOCETINE - PROTOCOL 2012A/017
TABLE No. 1 44

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 X	No	AE X	No	AE X	No	AE X	No	AE X	No	AE X	No	AE X	No	AE X
BACK PAIN	Rebocetine	2	100	1	50.0												
FLUERING	Isipramine	1	100					1	100								
	Rebocetine	2	100	1	50.0			1	50.0								
ABDOMINAL PAIN	Isipramine	2	100			1	50.0									1	50.0
	Rebocetine	3	100	2	66.7											1	33.3
TINNITUS	Isipramine	2	100	1	50.0			1	50.0								
ANOREXIA	Isipramine	2	100	2	100												
	Rebocetine	1	100	1	100												
TASTE LOSS	Isipramine	1	100	1	100												
	Isipramine	1	100	1	100												
	Rebocetine	2	100							1	50.0						
ASTHENIA	Isipramine	2	100	2	100												
	Rebocetine	1	100	1	100												
DIARRHOEA	Isipramine	1	100													1	100
	Rebocetine	1	100	1	100												
ARTRALGIA	Isipramine	2	100					1	50.0								
	Rebocetine	1	100													1	100
AV BLOCK	Isipramine	1	100					1	100								
BUNDLE BRANCH BLOCK	Rebocetine	1	100					1	100								
APPETITE INCREASED	Isipramine	1	100											1	100		
GLAUCOMA INCREASED	Rebocetine	1	100											1	100		
ACCOMODATION ABNORMAL	Isipramine	2	100	2	100												

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PHARMACIA CHR 282

ROBOSETINE - PROTOCOL 20124-017
TABLE No.: 44

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 %	
CONFUSION	Isipranolol	2	100	1	50.0			1	50.0								
NERVOUSNESS	Robozetina	3	100	2	66.7			1	33.3								
CERTICITIS	Robozetina	1	100	1	100												
HYPOASTHESIA	Isipranolol	1	100			1	100										
	Robozetina	1	100											1	100		
MENTAL DISORDER	Isipranolol	1	100									1	100				
	Robozetina	1	100			1	100										
FEVER	Isipranolol	1	100									1	100				
	Robozetina	1	100								1	100					
DELIRIUM	Isipranolol	1	100	1	100												
	Robozetina	1	100														
CHEST PAIN	Isipranolol	2	100	1	50.0												
	Robozetina	2	100	2	100												
HOT FLASHES	Robozetina	1	100	1	100												
PRURITUS	Isipranolol	1	100	1	100												
VOMITING	Isipranolol	1	100													1	100
	Robozetina	1	100	1	100												
PAIN	Robozetina	1	100	1	100												
	Isipranolol	1	100	1	100												
RESPIR STIMPLEX	Robozetina	1	100			1	100										
HAMIC REACTION	Isipranolol	1	100														
SPOTUM INCREASED	Isipranolol	2	100									1	50.0			1	50.0
	Robozetina	2	100									1	50.0			1	50.0
OROPHARYNGITIS	Isipranolol	1	100												1	100	

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PHARMACIA CBS RED
 REBOXETINE - PROTOCOL 20124/017
 TABLE No.: 44

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 %	
CONJUGING	Indipramine	1	100														
APYREXIA	Indipramine	1	100														
GASTROENTERITIS	Indipramine	1	100														
	Reboxetine	1	100														
ALOPECIA	Reboxetine	1	100														
DERMATITIS FUNGAL	Reboxetine	1	100														
SUICIDE ATTEMPT	Reboxetine	2	100														
ECS ABNORMAL	Reboxetine	2	100														
HYPERKINESIA	Indipramine	1	100	1	100												
ENFOTHYROIDISM	Reboxetine	1	100	1	100												
TACHYCARDIA SUPRAVENTRICULAR	Indipramine	1	100														
DYSPHAGIA	Indipramine	1	100														
HYPERLIPASIA	Indipramine	1	100														
ASTHMA	Indipramine	1	100														
OTITIS MEDIA	Indipramine	1	100														
VERTIGO	Indipramine	1	100														
ANXIETY	Indipramine	1	100														
HYPERKINESIA	Indipramine	1	100														
CYSTITIS HAEMORRHAGIC	Reboxetine	1	100														
EXTRASYSTOLES	Indipramine	1	100														
SOFT INCREASED	Reboxetine	1	100														

(CONTINUED)

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PHARMACIA CHE RED

REMOUSTINE - PROTOCOL 28124/017
TABLE No.1 44

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

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

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PARACETAMOL CRF 28D

REBOCETINE - PROTOCOL 20124/017
TABLE No.: 46

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														
		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	48	100	36	75.0	3	6.3	3	6.3	2	4.2	3	6.3	1	2.1		
	38	100	19	57.6	5	15.2	2	6.1	4	12.1	1	3.0	2	6.1		
SWEATING INCREASED	20	100	12	60.0	1	5.0	3	15.0	1	5.0	1	5.0	2	10.0		
	20	100	12	60.0	2	10.0	2	10.0	2	10.0	1	5.0	1	5.0		
SALIVA INCREASED	1	100	1	100												

(Some adverse events are grouped in clusters)

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PHARMACIA CNS 880

REBOZETINE - PROTOCOL 2012A-017

TABLE No.: 45

ADVERSE EVENTS: OCCURRENCE 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														
		0-7		8-14		15-31		22-28		29-35		36-42		> 42		
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	
ASTHENIA / FATIGUE	Indipramine	7	100	6	85.7											
	Rebozetine	6	100	3	50.0	1	16.7		1	16.7			1	14.3		
INFLUENZA-LIKE SYMPTOMS	Indipramine	3	100	2	66.7											
	Rebozetine	4	100	1	25.0	1	25.0						1	25.0		
FEVER	Indipramine	1	100													
	Rebozetine	1	100					1	100							
CHEST PAIN	Indipramine	2	100	1	50.0											
	Rebozetine	1	100	1	100											

(some adverse events are grouped in clusters)

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PHARMACIA CNS RSD
 REBOZETINE - PROTOCOL 20124/017
 TABLE No.: 46

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 %	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 %
HYPOTENSION AND RELATED SYMPTOMS	27	100	16	59.3	4	14.8	5	18.5	2	7.4						
	14	100	7	50.0			3	21.4	2	14.3	1	7.1	1	7.1		
TACHYCARDIA	15	100	7	46.7			3	20.0	3	20.0	1	6.7	1	6.7		
	10	100	2	20.0	1	10.0	1	10.0			3	30.0	2	20.0	1	10.0
PALPITATION	6	100	1	16.7	2	33.3	1	16.7	1	16.7						
	5	100	2	40.0	1	20.0	2	40.0								
HYPERTENSION	1	100												1	100	
	7	100	1	14.3	2	28.6	1	14.3	1	14.3				2	28.6	
FLASHING / HOT FLUSHES	3	100	2	66.7			1	33.3								
	2	100	1	50.0			1	50.0								
AV BLOCK	1	100														
	1	100														
BUNDLE BRANCH BLOCK	1	100														
	2	100												2	100	
ECG ABNORMAL	1	100														
	1	100			1	100										
TACHYCARDIA SUPRAVENTRICULAR	1	100														
	1	100												1	100	
EXTRASYSTOLES	1	100														

(some adverse events are grouped in clusters)

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PARALMACIA CNS EMO
 BETAHEXTINE - PROTOCOL 20124/017
 TABLE No.1 AS

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	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
HEADACHE / MIGRAINE	21	100	8	38.1	4	19.0	1	4.8	3	14.3	4	19.0	1	4.8		
	27	100	8	29.6	4	14.8	3	11.1	4	14.8	5	18.5	2	7.4	1	3.7
TREMBLE	19	100	7	36.8	3	15.8	1	5.3			1	5.3				
	2	100	1	50.0												
PARAESTHESIA	2	100	2	100												
	4	100	1	25.0	2	50.0					1	25.0				
CONFUSION	2	100	1	50.0												
	1	100			1	100										
HYPOAESTHESIA	1	100														
	1	100														
HYPERKINESIA	1	100	1	100												
	1	100														
VERTIGO	1	100														
	1	100														
HYPOKINESIA	1	100														
	1	100														

(some adverse events are grouped in cluster)

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PHARMACIA CNS 880
 REQUESTING - PROTOCOL 2012A-017
 TABLE No.1 45

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

Body system: ENDOCRINE DISORDERS

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	
HYPOTHYROIDISM	1	100	1	100													

Adverse events/Assigned treatment

Substitutes

(some adverse events are grouped in clusters)

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PHARMACIA CHE 280

REGORSTINE - PROTOCOL 20124-017
TABLE No.: 45

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

Body system: GASTRO-INTESTINAL SYSTEM DISORDERS

Adverse event/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	%
CONSTIPATION	13	100	8	61.5	3	23.1	1	7.7	1	7.7						
	13	100	7	53.8	2	15.4	2	15.4	1	7.7	1	7.7				
RASHES AND RELATED SYMPTOMS	14	100	9	64.3	4	28.6										
	20	100	13	65.0	3	15.0	1	5.0	1	5.0			2	10.0		
FLATULENCE	2	100	1	50.0	1	50.0										
	3	100	2	66.7	1	33.3										
ABDOMINAL PAIN	2	100			1	50.0										
	3	100	2	66.7							1	33.3				
ANOREXIA	2	100	2	100												
	1	100	1	100												
DIARRHOEA	1	100														
	1	100	1	100												
APPETITE INCREASED	1	100														
	1	100								1	100					
DYSPEPSIA	1	100														
	1	100														
GASTROENTERITIS	1	100														
	1	100														
DYSPEPSIA	1	100														
	1	100			1	100										

(none adverse events are grouped in clusters)

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PHARMACIA CHE 880
 REDONETINE - PROTOCOL 20124/017
 TABLE No.: 46

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

Body system: HEARING AND VESTIBULAR DISORDERS

Adverse event/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	%
TINNITUS	2	100		1	50.0				1	50.0								

(Some adverse events are grouped in clusters)

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PHARMACIA CHE DRB
 RESOMETINE - PROTOCOL 20124-017
 TABLE No.: 45

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

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

(some adverse events are grouped in cluster)

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PHARMACIA CVS RND
 RESOMITINE - PROTOCOL 20154/017
 TABLE No.: AS

ADVERSE EVENTS: OCCURRENCE 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	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 %	
INCREASED LIVER ENZYMS	4	100			3	75.0							1	25.0		
	3	100			2	66.7							1	33.3		

(some adverse events are grouped in clusters)

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PHARMACTA CIS R&D
 REBOCETIN - PROTOCOL 20124-017
 TABLE No.: 45

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													
		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 %
HYPERCHOLESTEROLAEMIA	1	100													
	1	100					1	100							
HYPERURICAEMIA	1	100					1	100							
	1	100					1	100							
GLOBULINS INCREASED	1	100											1	100	
	1	100					1	100							
HYPERLIPAEMIA	1	100					1	100							

(some adverse events are grouped in clusters)

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PHARMACIA CNS RAD
 REMOSETINE - PROTOCOL 20124/017
 TABLE No.: 45

ADVERSE EVENTS: OCCURRENCE 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 %	
BACK PAIN	3	100	1	33.3													
	2	100	1	50.0	1	50.0											
ARTHRALGIA	2	100					1	50.0	1	50.0							
	1	100															
ARTHRALGIA	1	100															
	1	100															

(same adverse events are grouped in clusters)

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PRAMIPLAXIA CNS RBD
 RESOCTINE - PROTOCOL 28124/017
 TABLE No.: 45

ADVERSE EVENTS: OCCURRENCE 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	
			No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %	No	AE %
INERTIA	16	100	5	31.3	3	18.8	3	18.8	4	25.0			1	6.3		
	11	100	7	63.6	4	36.4										
AGITATION / ANXIETY / NERVOUSNESS	10	100	5	50.0	1	10.0	1	10.0	2	20.0	1	10.0				
	11	100	8	72.7	2	18.2	1	9.1								
SOMNOLENCE	10	100	5	50.0	1	10.0			1	10.0	3	30.0				
	4	100	3	75.0							1	25.0				
LINDO DECREASED	2	100									1	50.0	1	50.0		
	3	100	1	33.3			2	66.7								
DELUSION	1	100	1	100												
	1	100			1	100										
MANIC REACTION	1	100														
	1	100					1	100								
SUICIDE ATTEMPT	2	100											1	50.0	1	50.0

(some adverse events are grouped in clusters)

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PARANACIA CRN BRD
 RESOMETINE - PROTOCOL 20124/017
 TABLE No.: 45

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

Body system: REPRODUCTIVE DISORDERS, FEMALE

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	%	No AE	%	No AE	%	No AE	%
CERVICITIS	1	100	1	100																				
Menstrual disorder	1	100																						
Menstrual disorder	1	100																						

(some adverse events are grouped in clusters)

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PHARMACIA CHE DSD

RESCHETINE - PROTOCOL 20124/017

TABLE No.: 45

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

Body system: RESISTANCE MECHANISM DISORDERS

Adverse event/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 %
HERPES SIMPLEX	1	100													
OTITIS MEDIA	1	100			1	100									

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(some adverse events are grouped in clusters)

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PHARMACIA CNS 320
 RIBOXENTINE - PROTOCOL 20124/017
 TABLE No.1.45

ADVERSE EVENTS: OCCURRENCE 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													
	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 %
BRONCHITIS	2	100			1	50.0										
UPPER RESP TRACT INFECTION	6	100			1	16.7	2	33.3						2	33.3	
SINUSITIS	2	100			1	50.0								2	66.7	
SPUTUM INCREASED	1	100	1	100												
RHINITIS	2	100							1	50.0	1	50.0				
COUGHING	2	100						1	50.0	1	50.0					
ASTHMA	1	100								1	100					

(some adverse events are grouped in clusters)

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PERMANENT CNS RBD
 RIBOXETINE - PROTOCOL 20124/017
 TABLE No.: 45

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

Body system: SKIN AND APPENDAGES DISORDERS

Adverse event/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	2	100			1	50.0								1	50.0		
PRURITUS	3	100	1	33.3			1	33.3									
ALOPECIA	1	100	1	100													
DERMATITIS FUNGAL	1	100												1	100		

(some adverse events are grouped in clusters)

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PHARMACIA CHR BBD
REBOCETINE - PROTOCOL 20124/017
TABLE No. 1 45

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

Body system: **SPECIAL SENSES OTHER, DISTURBANCES**

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 PERVERSION	2	100	2	100												
Indipramine	2	100	2	100												
TASTE LOSS	1	100	1	100					1	100.0						
Indipramine	1	100	1	100					1	100.0						

(same adverse events are grouped in cluster)

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PHARMACIA CNS RBD

REBOSINTE - PROTOCOL 2012A-017
TABLE No. 1 45

ADVERSE EVENTS: OCCURRENCE 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														
		0-7		8-14		15-21		22-28		29-35		36-42		> 42		
		No	%	No	%	No	%	No	%	No	%	No	%	No	%	
URINARY RETENTION / RETENTION	7	100	2	28.6					2	28.6	3	42.9				
	11	100	6	54.5	4	36.4					1	9.1				
URINARY TRACT INFECTION	1	100			1	100										
	3	100	1	33.3			1	33.3	1	33.3						
CYSTITIS HAEMORRHAGIC	1	100									1	100				

(some adverse events are grouped in clusters)

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PRAMAXIA CRB DDB
 REDUCTINE - PROTOCOL 20124/017
 TABLE No.: 45

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

Body system: VISION DISORDERS

Adverse events/Assigned treatment	Days of treatment															
	Total		0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
INDURSED VISION	6	100	5	83.3					1	16.7						
Behavioral	4	100	4	100												

(Some adverse events are grouped in clusters)

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PHARMACIA CHEM BSB

REQUISITE - PROTOCOL 2012A/017
TABLE No.: 46

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	%	
Body system																	
AUTONOMIC NERVOUS SYSTEM DISORDERS	Imipramine	69	100	49	71.0	4	5.8	6	8.7	3	4.3	4	5.8	3	4.3		
	Reboxetine	58	100	31	53.5	7	12.2	4	7.5	6	11.3	2	3.8	3	5.7		
CARDIOVASCULAR DISORDERS, GENERAL	Imipramine	55	100	26	47.3	7	12.7	11	20.0	6	10.9	2	3.6	3	5.5		
	Reboxetine	41	100	13	31.7	4	9.8	9	22.0	3	7.3	4	9.8	7	17.1	1	2.4
GASTRO-INTESTINAL SYSTEM DISORDERS	Imipramine	38	100	20	52.6	10	26.3	1	2.6	3	7.9	3	7.9	1	2.6		
	Reboxetine	42	100	26	61.9	6	14.3	3	7.1	2	4.8	3	7.1	2	4.8		
PSYCHIATRIC DISORDERS	Imipramine	40	100	16	40.0	5	12.5	5	12.5	6	15.0	5	12.5	1	2.5		
	Reboxetine	32	100	19	59.4	7	21.9	3	9.4					2	6.3	1	3.1
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO	Imipramine	42	100	19	45.2	8	19.0	3	7.1	4	9.5	6	14.3	2	4.8		
	Reboxetine	34	100	10	29.4	6	17.6	4	11.8	4	11.8	7	20.6	2	5.9	1	2.9
URINARY SYSTEM DISORDERS	Imipramine	8	100	2	25.0			1	12.5	2	25.0	3	37.5				
	Reboxetine	15	100	7	46.7	4	26.7	1	6.7	1	6.7	2	13.3				
BODY AS A WHOLE-GENERAL DISORDERS	Imipramine	13	100	7	53.8	3	23.1			1	7.7	1	7.7	1	7.7		
	Reboxetine	12	100	4	33.3	2	16.7	2	16.7	1	8.3	1	8.3	2	16.7		
VISION DISORDERS	Imipramine	6	100	5	83.3							1	16.7				
	Reboxetine	4	100	4	100												
RESPIRATORY SYSTEM DISORDERS	Imipramine	10	100	1	10.0	2	20.0	2	20.0	2	20.0	1	10.0	2	20.0		
	Reboxetine	12	100			1	8.3	4	33.3	2	16.7	3	25.0	2	16.7		
METABOLIC AND NUTRITIONAL DISORDERS	Imipramine	3	100	1	33.3			2	66.7								
	Reboxetine	3	100			1	33.3	2	66.7								

(CONTINUED)

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PIRAMACTA CRIS RBD

INDIPRAMINE - PROTOCOL 2012A-017
TABLE No. 1 46

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	%	No	%	No	%	No	%	No	%	No	%	No	%	
LIVER AND BILIAR SYSTEM DISORDERS	Indipramine	4	100			3	75.0							1	25.0		
	Reboxetine	3	100			2	66.7							1	33.3		
SPECIAL SENSES OTHER, DISORDERS	Indipramine	3	100														
	Reboxetine	2	100			1	50.0										
SKIN AND APPENDAGES DISORDERS	Indipramine	2	100														
	Reboxetine	6	100			2	33.3							3	50.0		
MUSCULO-SKELETAL SYSTEM DISORDERS	Indipramine	6	100			1	16.7							2	33.3		
	Reboxetine	3	100			1	33.3							1	33.3		
REPRODUCTIVE DISORDERS, FEMALE	Indipramine	1	100														
	Reboxetine	2	100			1	50.0										
HEARING AND VESTIBULAR DISORDERS	Indipramine	2	100														
	Reboxetine	1	100														
RESISTANCE MECHANISM DISORDERS	Indipramine	1	100														
	Reboxetine	1	100														
ENDOCRINE DISORDERS	Indipramine	1	100														
	Reboxetine	1	100														
HEMATOLOGY DISORDERS	Indipramine	1	100														
	Reboxetine	1	100														

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PHARMACIA CHEB RED
 REMONSTINE - PROTOCOL 2012A/017
 TABLE No.: 47

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: Rebozetine

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	
All adverse events	Mild	95	90	5		89	5	1
	Moderate	127	122	2	3	123	2	2
	Severe	43	43			43		
	Unknown	2	2			2		
	Total	267	257	7	5	257	7	3
MOUTH DRY	Mild	16	15	1		15	1	
	Moderate	12	12			12		
	Severe	5	5			5		
	Total	33	32	1		32	1	
	Mild	7	7			6		1
HEADACHE	Moderate	14	13		1	13		1
	Severe	6	6			6		
	Total	20	19		1	19		1
	Mild	10	10			10		
	Moderate	6	6			6		
SWEATING INCREASED	Mild	10	10			10		
	Moderate	6	6			6		
	Severe	3	3			3		
	Total	19	19			19		
	Mild	10	10			10		
DIZZINESS	Mild	20	20			20		
	Moderate	7	7			7		
	Severe	5	5			5		
	Total	32	32			32		
	Mild	1	1			1		

(CONTINUED)

(*) all remainder patients
 REMONSTINE - low dose <= 8 mg/day, high dose > 8 mg/day
 TILIPRANINE - low dose <= 150 mg/day, high dose > 150 mg/day

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PARALICIA CHE RED
ROBUSTINE - PROTOCOL 20124/017
TABLE No.1 47
ADVERSE EVENTS, NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THESE DAYS RESPONSE BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Robustine		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
DIZZINESS	Total	13		13				13	
	Moderate	4		4				4	
	Severe	7		7				7	
	Total	11		11				11	
TACHYCARDIA	Mild	5		3	2			3	2
	Moderate	5		5				5	
	Total	10		8	2			8	2
DYSPEPSIA	Mild	1		1				1	
	Moderate	1		1				1	
	Total	2		2				2	
CONSTIPATION	Mild	3		3				3	
	Moderate	9		9				9	
	Severe	1		1				1	
	Total	13		13				13	
NAUSEA	Mild	6		6				6	
	Moderate	5		7		1		7	1
	Severe	2		2				2	
	Total	16		15		1		15	1
SOMNOLENCE	Mild	2		2				2	
	Moderate	2		2				2	
	Total	4		4				4	

(*) all remainder patients
 ROBUSTINE - low dose <= 8 mg/day, high dose > 8 mg/day
 INIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

(CONTINUED)

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PHARMACIA CHE BHD
 REMOXETINE - PROTOCOL 2012A/017
 TABLE No.1 47
 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		
			Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
IRRITATION	Mild	1	1			1		
	Moderate	3	3			3		
	Severe	4	4			4		
	Total	8	8			8		
PALPITATION	Mild	1	1			1		
	Moderate	4	4			4		
	Total	5	5			5		
FATIGUE	Mild	1	1			1		
	Moderate	4	3	1		4		
	Total	5	4	1		5		
URINARY RETENTION	Moderate	1	1			1		
	Severe	2	2			2		
	Total	3	3			3		
VISION ABNORMAL	Mild	2	2			2		
	Moderate	1	1			1		
	Severe	1	1			1		
	Total	4	4			4		
UPPER RESPIRATORY TRACT INFECTION	Mild	2	1	1		1	1	1
	Total	2	1	1		1	1	1
NICTURITION DISORDER	Mild	6	6			6		
	Moderate	1	1			1		

(CONTINUED)

(*) all remainder patients
 REMOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
 IRIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

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PHARMACIA CHEM
 REMOXTINE - PROTOCOL 20124-017
 TABLE No.: 47
 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: Rabeprazole

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
INDIGESTION DISORDER	Severe	1	1			1		
	Total	5	5			5		
INFLUENZA-LIKE SYMPTOMS	Mild	1	1			1		
	Moderate	3	3			3		
	Total	4	4			4		
	Mild	2	2			2		
Total		2	2			2		
	Mild	2	2			2		
DASH	Moderate	1		1			1	
	Total	3	2	1		2	1	
PARASTHESIA	Mild	1	1			1		
	Moderate	3	3			3		
	Total	4	4			4		
	Moderate	2	2			2		
Severe		1	1			1		
	Total	3	3			3		
GABMA-67 INCREASED	Mild	1	1			1		
	Total	1	1			1		
HEPATIC ENZYMES INCREASED	Mild	1	1			1		
	Total	1	1			1		
ARTHRALGIA	Moderate	1	1			1		
	Total	1	1			1		

(CONTINUED)

(*) all remaining patients
 REMOXTINE - 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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PERMABACTA CHE BRD

REBONETINE - PROTOCOL 20124/017
TABLE No.1 47

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: Rebonetins

Adverse events / severity	Adverse events Number	Dose taken on onset date			Highest dose taken from 3 days before		
		Low dose (*)	High dose	Oversedose	Low dose (*)	High dose	Oversedose
ARTHRALGIA	1	1			1		
ANOREXIA	1	1			1		
	1	1			1		
HYPEREMION POSTURAL	1	1			1		
	1	1			1		
TASTE PERVERSION	1	1			1		
	1	1			1		
	2	2			2		
	3	3			3		
	3	3			3		
ABDOMINAL PAIN	1	1			1		
	2	2			2		
	3	3			3		
	6	6			6		
	6	6			6		
ASTHMA	1	1			1		
	1	1			1		
	1	1			1		
	1	1			1		
	1	1			1		
	1	1			1		

254

(CONTINUED)

(*) all remainder patients
REBONETINE - low dose <= 8 mg/day, high dose > 8 mg/day
INIPRAXINE - low dose <= 150 mg/day, high dose > 150 mg/day

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PLASMACIA CHS 820

REBUSTINE - PROTOCOL 20124-017
TABLE No. 1 47

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: Rabozastine	Adverse events / severity	Adverse events Number		Dose taken on onset date			Highest dose taken from 3 days before		
		Number	Low dose (n)	High dose	Overdose	Low dose (n)	High dose	Overdose	
FLUISHING	Total	2	2				2		
	Moderate	2	2				2		
RHINORRHOEA	Total	2	2				2		
	Mild	1	1				1		
URINARY TRACT INFECTION	Moderate	2	2				2		
	Total	3	3				3		
VOMITING	Moderate	1	1				1		
	Total	1	1				1		
GASTROENTERITIS	Moderate	1	1					1	
	Total	1	1					1	
HYPERCHOLESTEROLAEMIA	Moderate	1	1				1		
	Total	1	1				1		
HYPERTENSION	Moderate	1	1				1		
	Total	1	1				1		
FEVER	Moderate	1	1				1		
	Total	1	1				1		
DIARRHOEA	Severe	1	1				1		
	Total	1	1				1		
DELIRIUM	Severe	1	1				1		
	Total	1	1				1		
HYPERTENSION	Mild	2	1			1	1		1

(CONTINUED)

(n) all remainder patients
REBUSTINE - low dose <= 8 mg/day, high dose > 8 mg/day
TRIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

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PARACETAMOL 325 MG TAB
 RENOXETINE - PROTOCOL 2012A/017
 TABLE No.: 47

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: Rabeprazole		Adverse events Number	Dose taken on onset date			Highest dose taken from 3 days before		
Adverse events / severity			Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
HYPERTENSION	Moderate	3	3			3		
	Severe	2	2			2		
	Total	7	6	1		6	1	
NEURASTHENIA DISORDER	Moderate	1	1			1		
	Total	1	1			1		
NEUROURGES	Moderate	2	2			2		
	Severe	1	1			1		
	Total	3	3			3		
DYSPEPSIA	Moderate	3	3			3		
	Total	3	3			3		
SEX ABNORMAL	Mild	2	2			2		
	Total	2	2			2		
HEMIPYTES	Mild	2	2			2		
	Total	2	2			2		
SUICIDE ATTEMPT	Moderate	1	1			1		
	Severe	1	1			1		
	Total	2	2			2		
ALOPECIA	Mild	1	1			1		
	Total	1	1			1		
SOFT INCREASED	Mild	1	1			1		
	Total	1	1			1		

(CONTINUED)

(*) all remainder patients
 RENOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
 RABEPRAZOLE - low dose <= 150 mg/day, high dose > 150 mg/day

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PARANACIA CHS R2D

RESOUSTINE - PROTOCOL 20124-017
TABLE No.: 47

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: Rabovastatin

Adverse events / severity	Adverse events Number		Dose taken on onset date			Highest dose taken from 3 days before			
	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
GLAUCOMA INCREASED	Mild	1					1		
	Total	1					1		
LEUCOCYTOSIS	Mild	1					1		
	Total	1					1		
CERVICITIS	Mild	1					1		
	Total	1					1		
DERMATITIS FUNGAL	Moderate	1					1		
	Total	1					1		
PROBITUS	Moderate	1					1		
	Total	1					1		
MIDDLE EARACHE BLOCK	Moderate	1					1		
	Total	1					1		
CERVITIS BACTERIEMIC	Moderate	1					1		
	Total	1					1		
HYPOTENSION	Severe	1					1		
	Total	1					1		
PAIN	Severe	1					1		
	Total	1					1		
HERPES SIMPLEX	Severe	1					1		
	Total	1					1		

(*) all remainder patients
RESOUSTINE - 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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PARALACIA CR6 DMD

RESOMETINE - PROTOCOL 20154/017
TABLE No.1 47

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: Indipramine		Adverse events / severity		Dose taken on onset date			Highest dose taken from 3 days before		
		Number	Low dose (*)	High dose	Oversedose	Low dose (*)	High dose	Oversedose	
All adverse events	Mild	120	114	3	3	117	3		
	Moderate	194	128	1	5	132	1	1	
	Severe	47	46	1		47			
	Unknown	2	2			2			
	Total	303	290	5	8	298	4	1	
MOUTH DRY	Mild	21	20		1	21			
	Moderate	22	21		1	22			
	Severe	5	5			5			
	Total	48	46		2	48			
HEADACHE	Mild	5	5			5			
	Moderate	14	13		1	14			
	Severe	2	2			2			
	Total	21	20		1	21			
SWEATING INCREASED	Mild	10	10			10			
	Moderate	7	7			7			
	Severe	3	3			3			
	Total	20	20			20			
DIZZINESS	Mild	11	10		1	11			
	Moderate	6	6			6			
	Severe	2	2			2			
	Total	19	18		1	19			

(CONTINUED)

(*) all remainder patients
RESOMETINE - low dose <= 8 mg/day, high dose > 8 mg/day
INDIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

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PHARMACIA CHE 880
 REDONTEINE - PROTOCOL 20124/017
 TABLE No. 1 47
 ADVERSE EVENTS; NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THESE DAYS BEFORE
 BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Isipranine

Adverse events / severity	Adverse events Number	Dose taken on onset date			Highest dose taken from 3 days before		
		Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
INSOMNIA	Mild	4				4	
	Moderate	9				9	
	Severe	3				3	
	Total	16				16	
TACHYCARDIA	Mild	5				5	
	Moderate	9				9	
	Severe	1				1	
	Total	15				15	
TREMOR	Mild	5		1		4	1
	Moderate	5				4	1
	Severe	3				3	
	Total	13		1		11	1
CONSTIPATION	Mild	7		1		6	1
	Moderate	5				5	
	Severe	1				1	
	Total	13		1		12	1
NAUSEA	Mild	6				6	
	Moderate	6				6	
	Severe	1				1	
	Total	13				13	
SOMNOLENCE	Mild	5			1	4	
							5

(CONTINUED)

(*) all remainder patients
 REDONTEINE - low dose <= 8 mg/day, high dose > 8 mg/day
 ISIPRANINE - low dose <= 150 mg/day, high dose > 150 mg/day

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PHARMACIA CIB 820
REBORENTINE - PROTOCOL 20124-017
TABLE No.: 47
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: Isipramine

Adverse events / severity	Adverse events		Dose taken on onset date			Highest dose taken from 3 days before		
	Number		Low dose (x)	High dose	Dosedose	Low dose (*)	High dose	Dosedose
SOMNOLENCE	Moderate	3	2		1	3		
	Severe	2	2			2		
	Total	10	6		2	10		
AGITATION	Mild	3	3			3		
	Moderate	3	3			3		
	Severe	3	3			3		
Total	9	9			9			
HYPOTENSION	Mild	2	2			2		
	Moderate	4	4			4		
	Total	6	6			6		
PALPITATION	Mild	4	4			4		
	Moderate	1	1			1		
	Severe	1	1			1		
Total	6	6			6			
FATIGUE	Mild	1	1			1		
	Severe	4	4			4		
	Total	5	5			5		
URINARY RETENTION	Mild	1	1			1		
	Moderate	2	2			2		
	Severe	1	1			1		
Total	4	4			4			

(CONTINUED)

(*) all remainder patients
 REBORENTINE - low dose <= 8 mg/day, high dose > 8 mg/day
 ISIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

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PIRAMACIA CNS RMD

ESMOXETINE - PROTOCOL 20124/017
TABLE No.: 47

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 Number		Dose taken on onset date			Highest dose taken from 3 days before			
				Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
VISION ABNORMAL	MILD			2						2		
	Moderate			2			1			2		
	Total			4			1			4		
UPPER RESP TRACT INFECTION	MILD			3						3		
	Total			3						3		
	MILD			1			1			1		
MICTURITION DISORDER	Moderate			2						2		
	Total			3						3		
	MILD			2			2			2		
INFLUENZA-LIKE SYMPTOMS	Moderate			1						1		
	Total			3			3			3		
	Moderate			2			2			2		
BACK PAIN	Severe			1						1		
	Total			3			3			3		
	MILD			1			1			1		
DASH	Severe			1						1		
	Total			2			2			2		
	MILD			1			1			1		
PARASTHESIA	Severe			1						1		
	Total			2			2			2		
	MILD			2			2			2		
COORDINATION ABNORMAL	Total			2			2			2		
	MILD			2			2			2		
	Total			2			2			2		

(CONTINUED)

(*) all remainder patients
ESMOXETINE - low dose <= 5 mg/day, high dose > 5 mg/day
IMIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

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PRAMIACIA CRF BMD

REBOLIXINE - PROTOCOL 2012A/017
TABLE No.: 47

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THESE DATES BEFORE BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Isipranolol

Adverse events / severity	Adverse events Number		Dose taken on onset date			Highest dose taken from 3 days before			
	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
TINNITUS	Mild	1					1		
	Moderate	1	1				1		
	Total	2	2				2		
FLATULENCE	Mild	1	1				1		
	Moderate	1	1				1		
	Total	2	2				2		
GASTRO-ST INCREASED	Mild	1	1				1		
	Moderate	1	1				1		
	Total	2	2				2		
HEPATIC ENZYMES INCREASED	Mild	1	1				1		
	Moderate	1	1				1		
	Total	2	2				2		
SPUTUM INCREASED	Mild	1	1				1		
	Moderate	1	1				1		
	Total	2	2				2		
HOT FLASHES	Mild	1	1				1		
	Severe	1	1				1		
	Total	2	2				2		
ARTHRALGIA	Moderate	2	1				1		
	Total	2	1				1		
	Moderate	2	2				2		
ANOREXIA	Mild	2	1				1		
	Moderate	2	2				2		
	Total	4	3				3		

(CONTINUED)

(*) all remainder patients
REBOLIXINE - low dose <= 8 mg/day, high dose > 8 mg/day
ISIPRANOLOL - low dose <= 150 mg/day, high dose > 150 mg/day

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PHARMACIA CNS 020
REMOSSETINE - PROTOCOL 20124/017
TABLE No.: 47
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 Number	Dose taken on onset date			Highest dose taken from 3 days before		
			Low dose (x)	High dose	Overdose	Low dose (x)	High dose	Overdose
ANOREXIA	Total	2	2			2		
	Moderate	2	2			2		
	Total	2	2			2		
TASTE PERVERSION	Moderate	1	1			1		
	Severe	1	1			1		
	Total	2	2			2		
CONFUSION	Moderate	1	1			1		
	Severe	1	1			1		
	Total	2	2			2		
LIBIDO DECREASED	Moderate	2	2			2		
	Total	2	2			2		
	Moderate	1	1			1		
ABNORMAL PAIN	Severe	1	1			1		
	Total	2	2			2		
	Moderate	2	2			2		
BRONCHITIS	Total	2	2			2		
	Moderate	2	2			2		
	Total	2	2			2		
Chest PAIN	Moderate	2	2			2		
	Total	2	2			2		
	Severe	2	2			2		
ASTHENIA	Total	2	2			2		
	Severe	2	2			2		
	Total	2	2			2		
HYPOAESTHESIA	Mild	1	1			1		

(CONTINUED)

(x) all remainder patients
 REMOSSETINE - low dose ca 8 mg/day, high dose > 8 mg/day
 IMIPRAMINE - low dose ca 150 mg/day, high dose > 150 mg/day

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PHARMACIA CHE DED

REMOSITINE - PROTOCOL 20124/017
TABLE No.: 47

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THESE DAYS BEFORE BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Isipranidol

Adverse events / severity	Adverse events Number		Dose taken on onset date			Highest dose taken from 3 days before		
	Total	ELiD	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
HYPERTENSION	1		1					
VERTIGO	1		1					
FLUSHING	1		1					
SALIVA INCREASED	1		1					
RYTHMOPHORIA	1		1					
AV BLOCK	1		1					
EXTRABUSTRAL	1		1					
STIMULUS	1		1					
ASTHMA	1		1					
URINARY TRACT INFECTION	1		1					
OTITIS MEDIA	1		1					

(CONTINUED)

(*) all remainder patients
REMOSITINE - low dose <= 8 mg/day, high dose > 8 mg/day
TRIPRANIDOL - low dose <= 150 mg/day, high dose > 150 mg/day

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PHARMACIA CHE D&D

REMONESTINE - PROTOCOL 20124-017
TABLE No.: 47

ADVERSE EVENTS; NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THESE DAYS BEFORE
BY SEVERITY AND ASSIGNED TREATMENT

Assigned treatment: Isipramine

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
HYPERALGESIA	Moderate	1	1			1		
	Total	1	1			1		
VOMITING	Moderate	1	1			1		
	Total	1	1			1		
TACHYCARDIA SUPRAVENTRICULAR	Moderate	1	1			1		
	Total	1	1			1		
ANXIETY	Moderate	1	1			1		
	Total	1	1			1		
APPETITE INCREASED	Moderate	1	1			1		
	Total	1	1			1		
DYSPLASIA	Moderate	1	1			1		
	Total	1	1			1		
GASTROENTERITIS	Moderate	1	1			1		
	Total	1	1			1		
HYPERCHOLESTEROLA- EMIA	Moderate	1	1			1		
	Total	1	1			1		
HYPERTICARIA	Moderate	1	1			1		
	Total	1	1			1		
COUSING	Moderate	1	1			1		
	Total	1	1			1		
FEVER	Moderate	1	1			1		
	Total	1	1			1		

(CONTINUED)

(*) all remainder patients
REMONESTINE - low dose <= 8 mg/day, high dose > 8 mg/day
ISIPRAMINE - low dose <= 150 mg/day, high dose > 150 mg/day

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PHARMACIA CHE RED
 RIBOSITRINE - PROTOCOL 20124/017
 TABLE No.1 47
 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: Isiggranulose	Adverse events / severity	Adverse events Number	Dose taken on onset date			Highest dose taken from 3 days before		
			Low dose (#)	High dose	Overdose	Low dose (#)	High dose	Overdose
	FEVER	1	1				1	
	ARTHRALGIA	1	1				1	
	HYPEREMESIA	1	1				1	
	DIARRHOEA	1	1				1	
	TASTE LOSS	1	1				1	
	DELUSION	1	1				1	
	MANIC REACTION	1	1				1	
	OSOPHAGITIS	1	1				1	
	HYPERTENSION	1	1				1	
	MENTRAL DISORDER	1	1				1	
	Total	1	1				1	

(*): all remainder patients
 RIBOSITRINE - low dose <= 8 mg/day, high dose > 8 mg/day
 ISIPRAXINE - low dose <= 150 mg/day, high dose > 150 mg/day

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PRAXACTA CHE RED

REBOSONTINE - PROTOCOL 20124/017
TABLE No.: 46

ADVERSE EVENTS: NUMBER OF PATIENTS WHO COMPLAINED OF AT LEAST ONE ADVERSE EVENT BY MAXIMAL SEVERITY LEVEL, SEX, AGE, DRUG III

Assigned treatment / Severity Level	Sex						Age						DRG III									
	Total			Female			Male			18 - 30		31 - 45		> 45		296.2		296.3				
	No.	Pt.	%	No.	Pt.	%	No.	Pt.	%	No.	Pt.	%	No.	Pt.	%	No.	Pt.	%	No.	Pt.	%	
Indipromine	22	21.4	11	16.7	11	29.7	8	27.6	6	24.0	8	16.3	10	21.7	12	21.1						
	50	48.5	33	50.0	17	45.9	13	44.8	11	44.0	26	53.1	22	47.8	28	49.1						
	31	30.1	22	33.3	9	24.3	8	27.6	8	32.0	18	30.6	14	30.4	17	29.8						
Total	103	100.0	66	100.0	37	100.0	29	100.0	25	100.0	49	100.0	46	100.0	57	100.0						
Reboksetine	24	22.6	14	21.2	10	25.0	7	49.8	9	25.7	8	14.5	11	26.8	15	20.0						
	52	49.1	34	51.5	18	45.0	7	49.8	14	40.0	31	56.4	24	58.5	28	43.1						
	30	28.3	18	27.3	12	30.0	2	12.5	12	34.3	16	29.1	6	14.6	24	36.9						
Total	106	100.0	66	100.0	40	100.0	16	100.0	55	100.0	55	100.0	41	100.0	65	100.0						

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PARASACIA CMS RSD
 REDONSTINE - PROTOCOL 20124/017
 TABLE No. 1 49
 NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																			
	Indipresimine						Euboxetine													
	Female		Male		Total		Female		Male		Total									
No. Pt.	(%)	No. Pt.	(%)	No. Pt.	(%)	No. Pt.	(%)	No. Pt.	(%)	No. Pt.	(%)									
ALL adverse events	Mild	11	16.7	11	29.7	22	21.4	21.4	14	21.2	21.2	10	25.0	25.0	24	22.6	22.6			
	Moderate	39	50.0	17	45.9	56	48.5	48.5	34	51.5	51.5	18	45.0	45.0	52	49.1	49.1			
	Severe	22	28.3	33	87.3	55	48.5	48.5	10	27.3	27.3	12	30.0	30.0	30	28.3	28.3			
	Total	66	100	100	100	100	100	100	66	100	100	100	40	100	100	106	100	100		
DROUGHT MUX	Mild	11	42.3	16	7	8	42.1	21.6	19	42.2	18.4	8	38.1	12.1	8	72.7	20.0	16	50.0	15.1
	Moderate	11	42.3	16	7	10	52.6	27.0	21	46.7	20.4	8	38.1	12.1	3	27.5	7.5	11	34.4	10.4
	Severe	4	15.4	6	1	5	11.1	2.7	5	11.1	4.9	5	23.8	7.6				5	15.6	4.7
	Total	26	100	39	4	19	100	51.4	45	100	48.7	21	100	51.8	11	100	27.5	32	100	30.2
HEADACHE	Mild	2	20.0	3	0	2	25.0	5.4	4	22.2	3.9	3	25.0	4.5	2	22.2	5.0	5	25.8	4.7
	Moderate	8	80.0	12	1	4	50.0	18.8	12	56.7	11.7	7	58.3	10.6	3	33.3	7.5	10	47.6	9.4
	Severe					2	25.0	5.4	2	11.1	1.9	2	16.7	3.0	4	44.4	10.0	6	26.6	5.7
	Total	10	100	15	2	6	100	21.5	16	100	17.5	12	100	18.2	9	100	22.5	21	100	19.8
BREATHING INCREASED	Mild	5	55.6	7	6	4	44.4	10.8	9	50.0	8.7	3	42.9	4.5	6	54.5	15.0	9	50.0	8.5
	Moderate	3	33.3	4	5	3	33.3	8.1	6	33.3	5.8	2	26.6	3.0	4	36.4	10.0	6	33.3	5.7
	Severe	1	11.1	1	5	2	22.2	5.4	3	16.7	2.9	2	26.6	3.0	1	9.1	2.5	3	16.7	2.8
	Total	9	100	15	6	9	100	24.3	18	100	17.5	7	100	10.6	11	100	27.5	18	100	17.0
DIZZINESS	Mild	5	50.0	7	6	5	62.5	13.5	10	55.6	9.7	6	66.7	9.1	1	33.3	2.5	7	58.3	6.6
	Moderate	4	40.0	6	1	2	25.0	5.4	6	33.3	5.8	3	33.3	4.5	2	66.7	5.0	5	41.7	4.7
	Severe	1	10.0	1	5	1	12.5	2.7	2	11.1	1.9									
	Total	10	100	15	2	6	100	21.6	16	100	17.5	9	100	13.6	3	100	7.5	12	100	11.3

(CONTINUED)

(%) Z on all patients with adverse events

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PIAZINACIA CNS RND
 REDUCTINE - PROTOCOL 2012A-017
 TABLE No. 1 49
 NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																		
	Insipucan						Emboctine												
	Female		Male		Total		Female		Male		Total								
No. Pt.	(%) Z	No. Pt.	(%) Z	No. Pt.	(%) Z	No. Pt.	(%) Z	No. Pt.	(%) Z	No. Pt.	(%) Z								
NAUSEA	Mild	3	33.3	4.5	3	75.0	8.1	6	46.2	5.8	3	23.1	4.5	3	100	7.5	6	37.5	5.7
	Moderate	5	55.6	7.6	1	25.0	2.7	6	46.2	5.8	8	61.5	12.1				8	50.0	7.5
	Severe	1	11.1	1.5				1	7.7	1.0	2	15.4	3.0				2	12.5	1.9
	Total	9	100	13.6	4	100	10.8	13	100	12.6	13	100	19.7	3	100	7.5	16	100	15.1
CONSTIPATION	Mild	2	25.0	3.0	5	100	13.5	7	53.8	6.8	2	22.2	3.0	1	25.0	2.5	3	23.1	2.8
	Moderate	5	62.5	7.6				5	38.5	4.9	6	66.7	9.1	3	75.0	7.5	9	69.2	8.5
	Severe	1	12.5	1.5				1	7.7	1.0	1	11.1	1.5				1	7.7	0.9
	Total	8	100	12.1	5	100	13.5	13	100	12.6	9	100	15.6	4	100	10.0	13	100	12.3
INSOMNIA	Mild				2	28.6	5.4	2	14.3	1.9									
	Moderate	4	57.1	6.1	5	71.4	13.5	9	64.3	8.7	3	37.5	4.5	1	50.0	2.5	4	40.0	3.8
	Severe	3	42.9	4.5				3	21.4	2.9	5	62.5	7.6	1	50.0	2.5	6	60.0	5.7
	Total	7	100	10.6	7	100	18.9	14	100	13.6	8	100	12.1	2	100	5.0	10	100	9.4
TACHYCARDIA	Mild	2	20.0	3.0	1	33.3	2.7	3	23.1	2.9	1	33.3	1.5	2	40.0	5.0	3	37.5	2.8
	Moderate	7	70.0	10.6	2	66.7	5.4	9	69.2	8.7	2	66.7	3.0	3	60.0	7.5	5	62.5	4.7
	Severe	1	10.0	1.5				1	7.7	1.0									
	Total	10	100	15.2	3	100	8.1	13	100	12.6	3	100	4.5	5	100	12.5	8	100	7.5
TREMOR	Mild	3	37.5	4.5	2	40.0	5.4	5	38.5	4.9	1	50.0	1.5				1	50.0	0.9
	Moderate	2	25.0	3.0	3	60.0	8.1	5	36.5	4.9	1	50.0	1.5				1	50.0	0.9
	Severe	3	37.5	4.5				3	23.1	2.9									
	Total	8	100	12.1	5	100	13.5	13	100	12.6	2	100	3.0				2	100	1.9

(CONTINUED)

(%) Z on all patients with adverse events

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PHARMACIA CHEM BEE
 REPROXYLINE - PROTOCOL 20124-017
 TABLE No. 1 49
 NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																				
	Indapramine						Babozetine														
	Female			Male			Total			Female			Male			Total					
	No. Pt.	Z	(%)	No. Pt.	Z	(%)	Total	Z	(%)	No. Pt.	Z	(%)	Total	Z	(%)	No. Pt.	Z	(%)			
AGITATION	Mild	2	33.3	3.0	1	33.3	2.7	3	33.3	2.9	1	25.0	1.5					1	16.7	0.9	
	Moderate	2	33.3	3.0	1	33.3	2.7	3	33.3	2.9	1	25.0	1.5	1	50.0	2.5	2	33.3	1.9		
	Severe	2	33.3	3.0	1	33.3	2.7	3	33.3	2.9	2	50.0	3.0	1	50.0	2.5	3	50.0	2.8		
	Total	6	100	9.1	3	100	8.1	9	100	8.7	4	100	6.1	2	100	5.0	6	100	5.7		
SOMNOLENCE	Mild	2	40.0	3.0	2	50.0	5.4	4	44.4	3.9	1	50.0	1.5	1	50.0	2.5	2	50.0	1.9		
	Moderate	1	20.0	1.5	2	50.0	5.4	3	33.3	2.9	1	50.0	1.5	1	50.0	2.5	2	50.0	1.9		
	Severe	2	40.0	3.0				2	22.2	1.9											
	Total	5	100	7.6	4	100	10.8	9	100	8.7	2	100	3.0	2	100	5.0	4	100	3.8		
MICTURITION DISORDER	Mild	1	50.0	1.5				1	33.3	1.0	1	100	1.5	5	71.4	12.5	6	75.0	5.7		
	Moderate	1	50.0	1.5	1	100	2.7	2	66.7	1.9				1	14.3	2.5	1	12.5	0.9		
	Severe													1	14.3	2.5	1	12.5	0.9		
	Total	2	100	3.0	1	100	2.7	3	100	2.9	1	100	1.5	7	100	17.5	8	100	7.5		
PALPITATION	Mild	2	66.7	3.0	1	50.0	2.7	3	60.0	2.9	1	20.0	1.5					1	20.0	0.9	
	Moderate				1	50.0	2.7	1	20.0	1.0	4	80.0	6.1					4	80.0	3.5	
	Severe	1	33.3	1.5				1	20.0	1.0											
	Total	3	100	4.5	2	100	5.4	5	100	4.9	5	100	7.6					5	100	4.7	
FATIGUE	Mild				1	50.0	2.7	1	20.0	1.0								1	100	2.5	
	Moderate										3	100	4.5					3	75.0	2.8	
	Severe	3	100	4.5	1	50.0	2.7	4	80.0	3.9											
	Total	3	100	4.5	2	100	5.4	5	100	4.9	3	100	4.5	3	100	4.5	3	100	2.5	4	100

(CONTINUED)

(%) Z on all patients with adverse events

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PHARMACIA CNS B2D
 RESOURTINE - PROTOCOL 20124/017
 TABLE No.1 49
 NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																			
	Indipramine						Etaboxetine													
	Female			Male			Total			Female			Male			Total				
	No. Pt.	z	(%)	No. Pt.	z	(%)	No. Pt.	z	(%)	No. Pt.	z	(%)	No. Pt.	z	(%)	No. Pt.	z	(%)		
VISION ABNORMAL				2	66.7	5.4	2	50.0	1.9	2	66.7	3.0								
	Moderate	1	100	1.5	1	33.3	2.7	2	50.0	1.9	1	33.3	1.5							
	Severe																			
	Total	1	100	1.5	3	100	8.1	4	100	3.9	3	100	4.5	1	100	2.5	4	100	3.8	
BRONCHITIS																				
	Moderate	1	100	1.5			1	100	1.0	5	100	7.6	1	100	2.5	6	100	5.7		
	Severe																			
	Total	1	100	1.5			1	100	1.0	5	100	7.6	1	100	2.5	6	100	5.7		
URINARY RETENTION																				
	Mild	1	25.0	1.5			1	25.0	1.0											
	Moderate	2	50.0	3.0			2	50.0	1.9											
	Severe	1	25.0	1.5			1	25.0	1.0											
Total	4	100	6.1			4	100	3.9												
HYPERTENSION																				
	Mild												1	25.0	1.5					
	Moderate												2	50.0	3.0					
	Severe												1	25.0	1.5	1	100	2.5	2	40.0
Total													1	25.0	2.7	1	100	1.0		
INFLUENZA-LIKE SYMPTOMS																				
	Mild	1	50.0	1.5			1	50.0	1.0	4	100	6.1	1	100	2.5	5	100	4.7		
	Moderate	1	50.0	1.5			1	50.0	1.0	1	50.0	1.5	2	100	5.0	3	75.0	2.8		
	Total	2	100	3.0			2	100	1.9	2	100	3.0	2	100	5.0	4	100	3.8		
DASR																				
	Mild	1	50.0	1.5			1	50.0	1.0	2	66.7	3.0								
	Moderate												1	33.3	1.5					
	Total	1	100	1.5			1	100	1.0	2	66.7	3.0	1	33.3	1.5	1	100	0.9		

(*) z on all patients with adverse events

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PHARMACIA CIS RED
 BROCKETTINE - PROTOCOL 20124/017
 TABLE No.: 49

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																	
	Indipacaine									Rebuzetline								
	Female			Male			Total			Female			Male			Total		
	No. Pt.	(n) Z	(%)	No. Pt.	(n) Z	(%)	No. Pt.	(n) Z	(%)	No. Pt.	(n) Z	(%)	No. Pt.	(n) Z	(%)	No. Pt.	(n) Z	(%)
RASH	Severe	1	50.0	1.5			1	50.0	1.0									
	Total	2	100	3.0			2	100	1.9	3	100	4.5						
PARASITIC-FLU	MILD	1	100	1.5	1	100	2.7	2	100	1.9								
	Moderate																	
TOTAL	MILD	1	100	1.5	1	100	2.7	2	100	1.9	2	100	3.0	1	100	2.5	3	100
	Moderate																	
HYPOTENSION	MILD				2	66.7	5.4	2	40.0	1.9								
	Moderate	2	100	3.0	1	50.0	2.7	3	60.0	2.9								
TOTAL	MILD	2	100	3.0	3	100	8.1	5	100	4.9								
	Moderate				2	100	5.4	2	100	1.9				3	100	7.5	3	100
TOTAL	MILD				2	100	5.4	2	100	1.9				3	100	7.5	3	100
	Moderate																	
ABDOMINAL PAIN	MILD										1	50.0	1.5					
	Moderate	1	50.0	1.5							1	50.0	1.5	1	100	2.5	2	66.7
TOTAL	MILD	1	50.0	1.5							1	50.0	1.5					
	Moderate													1	100	2.5	2	66.7
FLATULENCE	MILD	1	50.0	1.5														
	Moderate	1	50.0	1.5							2	66.7	3.0					
TOTAL	MILD	2	100	3.0														
	Moderate										2	66.7	3.0					
TASTE PERCEPTION	MILD	2	100	3.0							3	100	4.5					
	Moderate										1	50.0	1.5					
TOTAL	MILD	2	100	3.0							3	100	4.5					
	Moderate	1	50.0	1.5							1	50.0	1.5					

(CONTINUED)

(*) Z on all patients with adverse events

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PIRAMACIA CMB 840
 REDOXITINE - PROTOCOL 2012A/017
 TABLE No. 1 49
 NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																				
	Indapramine						Babozetine														
	Female			Male			Total			Female			Male			Total					
	No. Pt.	(%)	Z	No. Pt.	(%)	Z	No. Pt.	(%)	Z	No. Pt.	(%)	Z	No. Pt.	(%)	Z	No. Pt.	(%)	Z			
TASTE PERVERSION	Severe	1	50.0	1.5			1	50.0	1.0												
	Total	2	100	3.0			2	100	1.9	2	100	3.0			2	100	1.9				
UPPER RESPIRATORY INFECTION	Mild	1	100	1.5	1	100	2.7	2	100	1.9	2	100	3.0								
	Total	1	100	1.5	1	100	2.7	2	100	1.9	2	100	3.0								
BACK PAIN	Mild												1	100	1.5	1	100	2.5	2	100	1.9
	Moderate	1	100	1.5																	
Severe																					
	Total	1	100	1.5	1	100	2.7	2	100	1.9	2	100	3.0	1	100	1.5	1	100	2.5	2	100
ARTRALGIA	Moderate	2	100	3.0																	
	Total	2	100	3.0																	
AMBLYOPIA	Moderate	2	100	3.0																	
	Total	2	100	3.0																	
FLUSHING	Mild																				
	Severe																				
Total																					
HYPOTENSION	Mild																				
	Moderate	2	100	3.0																	
Total																					
NEURONIA	Moderate																				
	Severe																				
Total																					

(CONTINUED)

(%) Z on all patients with adverse events

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PHARMACIA CHE 280
 BEGOMETINE - PROTOCOL 20124/017
 TABLE No.1 49

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																		
	Isipramine						Raboksetine												
	Female			Male			Total			Female			Male			Total			
	No. Pt.	(%)	Z	No. Pt.	(%)	Z	No. Pt.	(%)	Z	No. Pt.	(%)	Z	No. Pt.	(%)	Z	No. Pt.	(%)	Z	
HEADACHE- Total																			
DISPNOEA Moderate																			
DISPNOEA Total																			
GAMMA-GT INCREASED																			
MILD	1	50.0	1.5				1	50.0	1.0	1	50.0	1.0							
Moderate	1	50.0	1.5				1	50.0	1.0										
Total	2	100	3.0				2	100	1.9	1	100	1.5							
SINUSITIS																			
MILD	1	100	1.5				1	100	1.0										
Moderate																			
Total	1	100	1.5				1	100	1.0										
URINARY TRACT INFECTION																			
MILD	1	100	1.5				1	100	1.0										
Moderate																			
Total	1	100	1.5				1	100	1.0										
ASTHENIA																			
Moderate																			
Severe	2	100	3.0				2	100	1.9										
Total	2	100	3.0				2	100	1.9										
HYPOKALYCAEMIA																			
MILD	1	100	1.5				1	100	1.0										
Total	1	100	1.5				1	100	1.0										
ACCOMMODATION ABNORMAL																			
MILD				2	100	5.4													
Total				2	100	5.4													
HYPERURICAEMIA																			
Severe	1	100	1.5				1	100	1.0										

(CONTINUED)

(%) Z on all patients with adverse events

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PIRAMACIA CNS RMD
 RESOURCINE - PROTOCOL 2012A-017
 TABLE No.: 49
 NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																		
	Isipracasine									Rabonazine									
	Female			Male			Total			Female			Male			Total			
	No. Pt.	Z	(%)	No. Pt.	Z	(%)	No. Pt.	Z	(%)	No. Pt.	Z	(%)	No. Pt.	Z	(%)	No. Pt.	Z	(%)	
DIARRHEA	Total	1	100	1.5			1	100	1.0	1	100	1.5			1	100	0.9		
	Moderate	1	100	1.5									1	100	2.5	1	100	0.9	
	Total	1	100	1.5			1	100	1.0				1	100	2.5	1	100	0.9	
CONFUSION	Moderate	1	50.0	1.5			1	50.0	1.0										
	Severe	1	50.0	1.5			1	50.0	1.0										
	Total	2	100	3.0			2	100	1.9										
DELUSION	Severe				1	100	2.7	1	100	1.0	1	100	1.5			1	100	0.9	
	Total				1	100	2.7	1	100	1.0	1	100	1.5			1	100	0.9	
	Moderate																		
SUICIDE ATTEMPT	Severe																		
	Total																		
	Moderate																		
GASTROENT-ERITIS	Moderate	1	100	1.5			1	100	1.0	1	100	1.5							
	Total	1	100	1.5			1	100	1.0	1	100	1.5							
	Mild																		
HEPATIC ENZYMES INCREASED	Moderate	1	100	1.5			1	100	1.0										
	Total	1	100	1.5			1	100	1.0										
	Moderate	1	100	1.5															
HYPERTENS-ION/AR-TERIA	Moderate	1	100	1.5			1	100	1.0	1	100	1.5							
	Total	1	100	1.5			1	100	1.0	1	100	1.5							
	Moderate	1	100	1.5															
HYPERTENS-ION/AR-TERIA	Moderate	1	100	1.5															
	Total	1	100	1.5															
	Moderate	1	100	1.5															
HYPERTENS-ION/AR-TERIA	Moderate	1	100	1.5															
	Total	1	100	1.5															
	Moderate	1	100	1.5															

(*) Z on all patients with adverse events
 (CONTINUED)

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PHARMACIA CHEM
 RESOMETINER - PROTOCOL 20124-017
 TABLE No. 1 49
 NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																	
	Indipramine							Reboxetine										
	Female			Male				Female			Male							
	No. Pt.	(%) Z	(%) Pt.	No. Z	(%) Z	(%) Pt.	Total Z	(%) Z	No. Pt.	(%) Z	(%) Pt.	Total Z	(%) Z	No. Pt.	(%) Z	(%) Pt.	Total Z	
ECG ABNORMAL																		
MILD																		
Total																		
HELIOTIS																		
MILD																		
Total																		
SPOTON INCREASED																		
MILD																		
Moderate																		
Total																		
PERISTALTIC DISORDER																		
Moderate																		
Mild																		
Total																		
RYTHM																		
Mild																		
Total																		
CHEST PAIN																		
Moderate																		
Total																		
FEVER																		
Moderate																		
Total																		
HOOT FLUSHES																		
Mild																		
Severe																		
Total																		
ALOPECIA																		
Mild																		
Total																		
DERMATITIS FUNGAL																		
Moderate																		
Total																		

(CONTINUED)

(%) Z on all patients with adverse events

9550085

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PHARMACIA CHE MAD
REBONETINE - PROTOCOL 20124/017
TABLE No.: 49

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																	
	Imipramine									Rebonetine								
	Female			Male			Total			Female			Male			Total		
	No. Pt.	z	(*)	No. Pt.	z	(*)	No. Pt.	z	(*)	No. Pt.	z	(*)	No. Pt.	z	(*)	No. Pt.	z	(*)
DERMATITIS FUNGAL																		
Total																		
PRURITUS																		
Moderate																		
Total																		
ARTRODIESE																		
Severe																		
Total																		
HYPEREMIE-SIA																		
Moderate																		
Total																		
HYPOKALDEMIE																		
Severe																		
Total																		
VERTIGO																		
Mild																		
Total																		
SALIVA INCREASED																		
Mild																		
Total																		
TACHYCARDIA SUPRAVENTRICULAR																		
Moderate																		
Total																		
TINNITUS																		
Moderate																		
Total																		
TASTE LOSS																		
Severe																		
Total																		

(CONTINUED)

(*) z on all patients with adverse events

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PIAZENACIA CBS R80
 RESOMETINE - PROTOCOL 20124-017
 TABLE No.1 49
 NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment																							
	Indipacine						Rabozetine																	
	Female			Male			Total			Female			Male			Total								
	No. Pt.	(%) Z	(%) X	No. Pt.	(%) Z	(%) X	No. Pt.	(%) Z	(%) X	No. Pt.	(%) Z	(%) X	No. Pt.	(%) Z	(%) X	No. Pt.	(%) Z	(%) X						
ANXIETY	1	100	1.5				1	100	1.0															
Total	1	100	1.5				1	100	1.0															
HAMIC REACTION	1	100	1.5				1	100	1.0															
Total	1	100	1.5				1	100	1.0															
APPETITE INCREASED	1	100	1.5				1	100	1.0															
Total	1	100	1.5				1	100	1.0															
DYSPLASIA	1	100	1.5				1	100	1.0															
Total	1	100	1.5				1	100	1.0															
OROPHARYNGITIS	1	100	1.5				1	100	1.0															
Total	1	100	1.5				1	100	1.0															
SEPT INCREASED																1	100	2.5	1	100	0.9			
Total																1	100	2.5	1	100	0.9			
GLAUCOMA INCREASED																1	100	1.5			1	100	0.9	
Total																1	100	1.5			1	100	0.9	
HYPERTENSIVE CRISIS	1	100	1.5				1	100	1.0															
Total	1	100	1.5				1	100	1.0															
HYPOTHYROIDISM																1	100	1.5				1	100	0.9
Total																1	100	1.5			1	100	0.9	
AV BLOCK							1	100	2.7	1	100	1.0												
Total							1	100	2.7	1	100	1.0												

(CONTINUED)

(%) Z on all patients with adverse events

9550085

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PRANAXIA CBS BID
 RESOMETINE - PROTOCOL 2012A/017
 TABLE No.: 49
 NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

Adverse events / Severity	Assigned treatment														
	Indipramine						Reboxetine								
	Female			Male			Female			Male					
	No. Pt.	(*) Z	(*) X	No. Pt.	(*) Z	(*) X	No. Pt.	(*) Z	(*) X	No. Pt.	(*) Z	(*) X			
MIDDLE BRANCH															
Total															
EXTRASUST-OLES	1	100	1.5				1	100	1.0						
Total	1	100	1.5				1	100	1.0						
COUSLING				1	100	2.7	1	100	1.0						
Total				1	100	2.7	1	100	1.0						
ASTHMA				1	100	2.7	1	100	1.0						
Total				1	100	2.7	1	100	1.0						
LEUCOCITTO-SIB							1	100	1.5			1	100	0.9	
Total							1	100	1.5			1	100	0.9	
CYSTITIS HAEMORRHO-SIC										1	100	2.5	1	100	0.9
Total										1	100	2.5	1	100	0.9
CERVICITIS							1	100	1.5				1	100	0.9
Total							1	100	1.5				1	100	0.9
PAIN							1	100	1.5				1	100	0.9
Total							1	100	1.5				1	100	0.9
OTITIS MEDIA				1	100	2.7	1	100	1.0						
Total				1	100	2.7	1	100	1.0						
HERPES SIMPLEX													1	100	2.5
Total													1	100	2.5

(*) Z on all patients with adverse events

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FRANCIACIA CHS RED
 RESOURCING - PROTOCOL 20154/017
 TABLE No. 1 50
 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												
	Indipendence						Raboctinine						
	Female		Male		Total		Female		Male		Total		
No. Pt.	(%) Z	No. Pt.	(%) Z	No. Pt.	(%) Z	No. Pt.	(%) Z	No. Pt.	(%) Z	No. Pt.	(%) Z		
ALL adverse events	Mild	11	16.7	11	29.7	22	21.4	14	21.2	10	25.0	24	22.6
	Moderate	33	50.0	17	45.9	50	48.5	34	51.5	18	45.0	52	49.1
	Severe	22	33.3	9	24.3	31	30.1	18	27.3	12	30.0	30	28.3
	Total	66	100	37	100	103	100	66	100	40	100	106	100
AUTONOMIC NERVOUS SYSTEM DISORDERS	Mild	15	45.5	22.7	10	43.5	27.0	25	44.6	24.3	10	38.5	15.2
	Moderate	13	39.4	19.7	11	47.8	29.7	24	42.9	23.3	9	34.6	13.6
	Severe	5	15.2	7.6	2	8.7	5.4	7	12.5	6.8	7	26.9	10.6
	Total	33	100	50.0	23	100	62.2	56	100	54.4	26	100	39.4
CARDIOVASCULAR DISORDERS, GENERAL	Mild	8	29.6	12.1	9	60.0	24.3	17	40.5	16.5	8	44.4	12.1
	Moderate	15	55.6	22.7	5	33.3	13.5	20	47.6	19.4	8	44.4	12.1
	Severe	4	14.8	6.1	1	6.7	2.7	5	11.9	4.9	2	11.1	3.0
	Total	27	100	40.9	15	100	40.5	42	100	40.8	18	100	27.3
GASTRO-INTESTINAL SYSTEM DISORDERS	Mild	5	20.8	7.6	6	85.7	16.2	11	35.5	10.7	5	20.8	7.6
	Moderate	14	56.3	21.2	1	14.3	2.7	15	48.4	14.6	15	60.0	22.7
	Severe	5	20.8	7.6				5	16.1	4.9	5	20.0	7.6
	Total	24	100	36.4	7	100	18.9	31	100	30.1	25	100	37.9
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISORDERS	Mild	6	27.3	9.1	2	20.0	5.4	8	25.0	7.8	5	29.4	7.6
	Moderate	11	50.0	16.7	6	60.0	16.2	17	53.1	16.5	10	58.8	15.2
	Severe	5	22.7	7.6	2	20.0	5.4	7	21.9	6.8	2	11.8	3.0
	Total	22	100	33.3	10	100	27.0	32	100	31.1	17	100	25.6

(%) Z on all patients with adverse events
 (CONTINUED)

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PHARMACIA CHEMIE
 RESOMETIN - PROTOCOL 2012A-017
 TABLE No. 1 50
 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																		
	Indopipazine						Raboxetine												
	Female		Male		Total		Female		Male		Total								
No. Pt.	(%) Z	No. Pt.	(%) Z	No. Pt.	(%) Z	No. Pt.	(%) Z	No. Pt.	(%) Z	No. Pt.	(%) Z								
PSYCHIATRIC DISORDERS	Mild	3	21.4	4	26.7	10.8	7	24.1	6.8	2	14.3	3.0	1	11.1	2.5	3	13.0	2.8	
	Moderate	4	25.6	6.1	9	60.0	24.3	13	44.8	12.6	6	42.9	9.1	6	66.7	15.0	12	52.2	11.3
	Severe	7	50.0	10.6	2	13.3	3.4	9	31.0	8.7	6	42.9	9.1	2	22.2	5.0	8	34.8	7.5
	Total	14	100	21.2	15	100	40.5	29	100	26.2	14	100	21.2	9	100	22.5	23	100	21.7
BODY AS A WHOLE - GENERAL DISORDERS	Mild	1	16.7	1.5	1	20.0	2.7	2	18.2	1.9	1	16.7	1.5	1	20.0	2.5	2	18.2	1.9
	Moderate	1	16.7	1.5	3	60.0	8.1	4	36.4	3.9	4	66.7	6.1	4	80.0	10.0	8	72.7	7.5
	Severe	4	66.7	6.1	1	20.0	2.7	5	46.5	4.9	1	16.7	1.5				1	9.1	0.9
	Total	6	100	9.1	5	100	13.5	11	100	10.7	6	100	9.1	5	100	12.5	11	100	10.4
URINARY SYSTEM DISORDERS	Mild	3	50.0	4.5				3	42.9	2.9	1	33.3	1.5	5	50.0	12.5	6	46.2	5.7
	Moderate	2	33.3	3.0	1	100	2.7	3	42.9	2.9	2	66.7	3.0	2	20.0	5.0	4	30.8	3.8
	Severe	1	16.7	1.5				1	14.3	1.0				3	30.0	7.5	3	23.1	2.8
	Total	6	100	9.1	1	100	2.7	7	100	6.5	3	100	4.5	10	100	25.0	13	100	12.3
RESPIRATORY SYSTEM DISORDERS	Mild	2	50.0	3.0	3	75.0	8.1	5	62.5	4.9	3	33.3	4.5				3	27.3	2.8
	Moderate	2	50.0	3.0	1	25.0	2.7	3	37.5	2.9	6	66.7	9.1	2	100	5.0	8	72.7	7.5
	Severe	4	100	6.1	4	100	10.8	8	100	7.8	9	100	13.6	2	100	5.0	11	100	10.4
	Total	8	100	12.1	8	100	21.3	16	100	20.5	19	100	27.1	11	100	15.0	22	100	28.1
VISION DISORDERS	Mild				3	75.0	8.1	3	60.0	2.9	2	66.7	3.0				2	50.0	1.9
	Moderate	1	100	1.5	1	25.0	2.7	2	40.0	1.9	1	33.3	1.5				1	25.0	0.9
	Severe													1	100	2.5	1	25.0	0.9
	Total	1	100	1.5	4	100	10.8	5	100	4.9	3	100	4.5	1	100	2.5	4	100	3.8

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(%) Z on all patients with adverse events

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PRASINACTA CNS 282
 REMOXYLINE - PROTOCOL 20124/017
 TABLE No.1 50

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																	
	Indigralone						Rabozetidine											
	Female			Male			Total			Female			Male			Total		
	No. Pt.	Z	(%)	No. Pt.	Z	(%)	No. Pt.	Z	(%)	No. Pt.	Z	(%)	No. Pt.	Z	(%)	No. Pt.	Z	(%)
MUSCULO-SKELETAL DISORDERS	Mild																	
	Moderate	3	100	4.5			3	60.0	2.9	1	50.0	1.5						
	Severe																	
Total	3	100	4.5	2	100	5.4	2	40.0	1.9									
SKIN AND APPENDAGES DISORDERS	Mild	1	50.0	1.5			1	50.0	1.0	3	50.0	4.5						
	Moderate									3	50.0	4.5						
	Severe	1	50.0	1.5			1	50.0	1.0									
Total	2	100	3.0			2	100	1.9	6	100	9.1							
LIVER AND BILIAR SYSTEM DISORDERS	Mild																	
	Moderate	2	100	3.0			2	100	1.9									
	Total	2	100	3.0			2	100	1.9									
METABOLIC AND NUTRITIONAL DISORDERS	Mild																	
	Moderate	2	100	3.0			2	100	1.9	1	50.0	1.5						
	Total	2	100	3.0			2	100	1.9	2	100	3.0	1	100	2.5			
SPECIAL SENSES OTHER DISORDERS	Mild																	
	Moderate	1	50.0	1.5			1	50.0	1.0	1	50.0	1.5						
	Severe	2	100	3.0			2	66.7	1.9									
Total	3	100	4.5			3	100	2.9	2	100	3.0							
REPRODUCTIVE DISORDERS, FEMALE	Mild																	
	Moderate									1	50.0	1.5						
	Total									1	50.0	1.5						

(CONTINUED)

(%) % on all patients with adverse events

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PHARMACIA CHE DMO
ERDOXITINE - PROTOCOL 20124-017
TABLE No.: 80
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																	
	Indiprusine									Erdoxitine								
	Female			Male			Total			Female			Male			Total		
	No. Pt.	(%) Z	(%) X	No. Pt.	(%) Z	(%) X	No. Pt.	(%) Z	(%) X	No. Pt.	(%) Z	(%) X	No. Pt.	(%) Z	(%) X	No. Pt.	(%) Z	(%) X
RESPIRATORY DISORDERS, FEMALE	1	100	1.5				1	100	1.0									
Total	1	100	1.5				1	100	1.0	2	100	3.0			2	100	1.9	
RESISTANCE AGAINST ANTIBIOTICS				1	100	2.7			1.0									
Severe																		
Total				1	100	2.7			1.0						1	100	2.5	1
100	0.9																	
ENDOCRINE DISORDERS				1	100	2.7			1.0				1	100	1.5			
Severe																		
Total				1	100	2.7			1.0				1	100	1.5			1
100	0.9																	
HEARING AND VESTIBULAR DISORDERS	1	100	1.5						1.0									
Total	1	100	1.5						1.0									
HEMATOLOGY DISORDERS													1	100	1.5			
Mild																		
Total													1	100	1.5			1
100	0.9																	

(%) Z on all patients with adverse events

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PHARMACIA CNS RBD
 REBOXETINE - PROTOCOL 2012A/017
 TABLE No.: 51
 ADVERSE EVENTS: DURATION OF EPISODES (*) BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	No of Episodes	Duration of episodes (days)		
		Min	50%	Max
SUICIDE ATTEMPT	2	1	1	1
GASTROENTERITIS	1	6	6	6
HYPERCHOLESTEROLAEMIA	1	6	6	6
	1	42	42	42
HYPERURICAEMIA	1	18	18	18
	1	22	22	22
ECG ABNORMAL	1	22	22	22
	1	22	22	22
SCLERITIS	2	1	1	1
	2	2	4	6
MENSTRUAL DISORDER	2	4	4	4
	1	7	7	7
CHEST PAIN	1	7	7	7
	2	1	2	2
FEVER	1	5	5	5
	1	2	2	2
EDY FLUSHES	2	6	6	6
	1	12	12	12
DERMATITIS FUNGAL	1	5	5	5
	1	9	9	9
ARTHRALGIA	1	8	8	8
	1	1	1	1
HYPOKINAESIA	1	3	3	3
	1	3	3	3

(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

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PHARMACIA CHEM DRG
 REBOZETINE - PROTOCOL 20124/017
 TABLE No.1 51

ADVERSE EVENTS: DURATION OF EPISODES (*) BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	No of Episodes	Duration of episodes (days)		
		Min	50%	Max
VERTIGO	1	1	1	1
SALIVA INCREASED	1	42	42	42
TACHYCARDIA SUPRAVENTRICULAR	1	1	1	1
TASTE LOSS	1	21	21	21
ANXIETY	1	6	6	6
NAMIC REACTION	1	8	8	8
APPETITE INCREASED	1	23	23	23
DYSPHAGIA	1	7	7	7
OSOPHAGITIS	1	7	7	7
SOFT INCREASED	1	1	1	1
GLOBULINS INCREASED	1	22	22	22
HYPERLIPAEMIA	1	5	5	5
HYPOTHYROIDISM	1	6	6	6
AV BLOCK	1	22	22	22
BUNDLE BRANCH BLOCK	1	22	22	22
EXTRASYSTOLES	1	1	1	1
COUGHING	1	5	5	5
ASTHMA	1	1	1	1
LEUCOCYTOSIS	1	1	1	1
CYSTITIS HAEMORRHAGIC	1	7	7	7
CERVICITIS	1	10	10	10
PAIN	1	4	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

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FRANCIACA CHE RBD

REGIMETINE - PROTOCOL 20124/017

TABLE No.: 51

ADVERSE EVENTS: DURATION OF EPISODES (*) BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	No of Episodes	Duration of episodes (days)		
		Min	50%	Max
OTITIS MEDIA	1	2	2	2
HERPES SIMPLEX	1	8	8	8

(*) 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

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PHARMACIA CIB 820

REBOCETLINE - PROTOCOL 20124/017
TABLE No.: 52

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS BY SYMPTOMATIC TREATMENT AND ASSIGNED TREATMENT

Adverse events	Assigned treatment												
	Indipramine						Rebocetline						
	Symptomatic treatment						Symptomatic treatment						
	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. of pt. with A.E.	38	36.9	65	63.1	103	100.0	42	39.6	64	60.4	106	100.0	
No. of adverse events	55	18.2	243	81.8	303	100.0	63	23.6	204	76.4	267	100.0	
NAUSEA	1	2.1	47	97.9	48	100.0			23	100.0	23	100.0	
HEADACHE	5	23.8	16	76.2	21	100.0	11	40.7	16	59.3	27	100.0	
SWEATING INCREASED			20	100.0	20	100.0			20	100.0	20	100.0	
DIZZINESS	1	5.3	18	94.7	19	100.0			19	100.0	19	100.0	
INDIGESTION	2	15.4	11	84.6	13	100.0			16	100.0	16	100.0	
DIARRHOEA	12	78.0	4	25.0	16	100.0	8	72.7	3	27.3	11	100.0	
CONSTIPATION	5	38.5	8	61.5	13	100.0	2	15.4	11	84.6	13	100.0	
TACHYCARDIA	2	13.3	13	86.7	15	100.0	4	40.0	6	60.0	10	100.0	
AGITATION	2	22.2	7	77.8	9	100.0	4	50.0	4	50.0	8	100.0	
TREMBOR	1	7.7	12	92.3	13	100.0			2	100.0	2	100.0	
SOMNOLENCE			10	100.0	10	100.0			4	100.0	4	100.0	
PALPITATION			6	100.0	6	100.0			5	100.0	5	100.0	
ECTOPIC BEAT DISORDER			3	100.0	3	100.0	1	12.5	7	87.5	8	100.0	
FATIGUE			5	100.0	5	100.0			5	100.0	5	100.0	
HYPERTENSION	1	100.0			1	100.0	6	85.7	1	14.3	7	100.0	
VISION ABNORMAL			4	100.0	4	100.0			4	100.0	4	100.0	
BRONCHITIS	1	50.0	1	50.0	2	100.0	6	100.0			6	100.0	
URINARY RETENTION			4	100.0	4	100.0	1	33.3	2	66.7	3	100.0	
INFLUENZA-LIKE SYMPTOMS	1	33.3	2	66.7	3	100.0	1	25.0	3	75.0	4	100.0	

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PHARMACIA CHE ERB
 EROSCHELINE - PROTOCOL 2012A/017
 TABLE No. 1 52
 ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS BY SYMPTOMATIC TREATMENT AND ASSIGNED TREATMENT

Adverse events	Assigned treatment													
	Indipramine						Rabacetine							
	Symptomatic treatment						Symptomatic treatment							
	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	
PARAESTHESIA			2	100.0	2	100.0			4	100.0	4	100.0		
HYPOTENSION	2	33.3	4	66.7	6	100.0								
HAUSE			2	100.0	2	100.0			3	100.0	3	100.0		
ABDOMINAL PAIN			2	100.0	2	100.0	1	33.3	2	66.7	3	100.0		
FLATULENCE			2	100.0	2	100.0	1	33.3	2	66.7	3	100.0		
UPPER RESPIRATORY TRACT INFECTION	3	100.0			3	100.0	2	100.0			2	100.0		
BACK PAIN	3	100.0			3	100.0	1	50.0	1	50.0	2	100.0		
LIBIDO DECREASED	1	50.0	1	50.0	2	100.0	2	66.7	1	33.3	3	100.0		
TASTE PERVERSION			2	100.0	2	100.0					2	100.0		
URINARY TRACT INFECTION			1	100.0	1	100.0	2	66.7	1	33.3	3	100.0		
ARTRALGIA	2	100.0			2	100.0	1	100.0			1	100.0		
ANOREXIA			2	100.0	2	100.0			1	100.0	1	100.0		
FLUSHING			1	100.0	1	100.0			2	100.0	2	100.0		
HYPOTENSION POSTURAL			2	100.0	2	100.0			1	100.0	1	100.0		
NEURORRHEAS									3	100.0	3	100.0		
DYSPEPSIA									1	33.3	2	66.7	3	100.0
GAMMA-GT INCREASED			2	100.0	2	100.0			1	100.0	1	100.0		
HEPATIC ENZYMES INCREASED			2	100.0	2	100.0			1	100.0	1	100.0		
SINUSITIS			1	100.0	1	100.0	2	100.0			2	100.0		
ASTHMA			2	100.0	2	100.0					1	100.0	1	100.0
HYPOAESTHESIA			1	100.0	1	100.0			1	100.0	1	100.0		

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PHARMACIA CHE 880

RESONANCE - PROTOCOL 20124-017
TABLE No. 1 52

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS BY SYMPTOMATIC TREATMENT AND ASSIGNED TREATMENT

Adverse events	Assigned treatment											
	Indipravine						Rabovavine					
	Symptomatic treatment						Symptomatic treatment					
	YES		NO		Total		YES		NO		Total	
No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
DIARRHOEA	1	100.0	1	100.0	1	100.0	1	100.0			1	100.0
VOMITING			2	100.0	2	100.0						
TINNITUS			2	100.0	2	100.0						
CONFUSION			2	100.0	2	100.0						
DELUSION			1	100.0	1	100.0						
SUICIDE ATTEMPT												
GASTROENTERITIS	1	100.0			1	100.0	1	100.0			1	100.0
HYPERCHOLESTEROLAEMIA			1	100.0	1	100.0	1	100.0			1	100.0
HYPERURICAEMIA			1	100.0	1	100.0						
BRITANNIA												
SPUTUM INCREASED	1	50.0	1	50.0	2	100.0						
MENSTRUAL DISORDER			1	100.0	1	100.0						
HOT FLASHES			2	100.0	2	100.0						
AGGREGATION ABNORMAL			2	100.0	2	100.0						
ECG ABNORMAL												
CHEST PAIN			2	100.0	2	100.0						
FEVER	1	100.0			1	100.0						
ALOPECIA												
DERMATITIS FUNGAL												
PRURITUS							1	100.0				
HYPERKINESIA			1	100.0	1	100.0						

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PRAMAXIA CNS 880

REBOXETINE - PROTOCOL 20124/017
TABLE No.: 52

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS BY SYMPTOMATIC TREATMENT AND ASSIGNED TREATMENT

Adverse events	Assigned treatment											
	Imipramine						Reboxetine					
	Symptomatic treatment						Symptomatic treatment					
	YES	NO	Total	YES	NO	Total	YES	NO	Total	YES	NO	Total
	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z	No.	Z
HYPOKINETIA	1	100.0			1	100.0						
VERTIGO			1	100.0	1	100.0						
TACHYCARDIA SUPRAVENTRICULAR			1	100.0	1	100.0						
TASTE LOSS	1	100.0			1	100.0						
ANXIETY			1	100.0	1	100.0						
NARCIC REACTION			1	100.0	1	100.0						
APPETITE INCREASED			1	100.0	1	100.0						
DYSPLASIA			1	100.0	1	100.0						
OSOPHAGITIS			1	100.0	1	100.0						
GLUCOSINE INCREASED									1	100.0	1	100.0
HYPERLIPAEMIA			1	100.0	1	100.0						
HYPOTHYROIDISM									1	100.0	1	100.0
EXTRASYSTOLES			1	100.0	1	100.0						
LEUCOCYTOSES									1	100.0	1	100.0
CERVICITIS									1	100.0	1	100.0
PAIN									1	100.0	1	100.0
ARTERIOSIS	1	100.0			1	100.0						
SALIVA INCREASED			1	100.0	1	100.0						
SOFT INCREASED									1	100.0	1	100.0
AV BLOCK			1	100.0	1	100.0						
BUNDLE BRANCH BLOCK									1	100.0	1	100.0

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PHARMACIA CHS 820

REBOUSTINE - PROTOCOL 20124/017
TABLE No.: 52

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS BY SYMPTOMATIC TREATMENT AND ASSIGNED TREATMENT

Adverse events	Assigned treatment											
	Indigestion						Rebooustine					
	Symptomatic treatment						Symptomatic treatment					
	YES		NO		Total		YES		NO		Total	
No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
COUGHING	1	100.0			1	100.0						
ASTHMA	1	100.0			1	100.0						
CYSTITIS HAEMORRHAGIC							1	100.0			1	100.0
OTITIS MEDIA	1	100.0			1	100.0						
HERPES SIMPLEX									1	100.0	1	100.0

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PHARMACIA CHEMIE
 REBOCETIN - PROTOCOL 20154/017
 TABLE No. 1 53

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	%	
ALL adverse events	Indipramine	236	77.9	13	4.3	3	1.0	49	16.2	2	0.7	303	100.0						
	Rebocetine	219	82.0	6	2.2	6	3.0	32	12.0	2	0.7	267	100.0						
MOUTH DRY	Indipramine	42	87.5	1	2.1			5	10.4			48	100.0						
	Rebocetine	30	90.9	1	3.0	1	3.0	1	3.0			33	100.0						
HEADACHE / MIGRAINE	Indipramine	15	71.4	1	4.8			5	23.8			21	100.0						
	Rebocetine	22	81.5			1	3.7	4	14.8			27	100.0						
HYPOTENSION AND RELATED SYMPTOMS	Indipramine	23	85.2			1	3.7	3	11.1			27	100.0						
	Rebocetine	10	71.4			1	7.1	2	14.3	1	7.1	14	100.0						
BREATHING INCREASED	Indipramine	18	90.0					2	10.0			20	100.0						
	Rebocetine	14	70.0			2	10.0	3	15.0	1	5.0	20	100.0						
NAUSEA AND RELATED SYMPTOMS	Indipramine	10	71.4	1	7.1	1	7.1	2	14.3			14	100.0						
	Rebocetine	15	75.0					5	25.0			20	100.0						
INSOMNIA	Indipramine	15	93.8					1	6.3			16	100.0						
	Rebocetine	9	61.8					2	18.2			11	100.0						
CONSTIPATION	Indipramine	12	92.3	1	7.7							13	100.0						
	Rebocetine	12	92.3	1	7.7							13	100.0						
TACHYCARDIA	Indipramine	14	93.3	1	6.7							15	100.0						
	Rebocetine	10	100.0									10	100.0						
AGITATION / ANXIETY / NERVOUSNESS	Indipramine	6	80.0					2	20.0			8	100.0						
	Rebocetine	9	81.8			1	9.1	1	9.1			11	100.0						
URINARY HESITANCY / RETENTION	Indipramine	2	28.6	2	28.6			3	42.9			7	100.0						
	Rebocetine																		

(some adverse events are grouped in clusters)

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PHARMACIA CHE 880
 REBOZETINE - PROTOCOL 20124-017
 TABLE No.: S3

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.	%
URINARY RESISTANCY / RETENTION	Rebozetine	5	45.5	1	9.1	1	9.1	4	36.4						11	100.0
	Indipramine	8	61.5	1	7.7			4	30.8						13	100.0
TREMOR	Rebozetine	2	100.0												2	100.0
	Indipramine	5	50.0	3	30.0			2	20.0						10	100.0
SOMNOLENCE	Rebozetine	3	75.0					1	25.0						4	100.0
	Indipramine	1	14.3	1	14.3			5	71.4						7	100.0
ASTHENIA / FATIGUE	Rebozetine	4	66.7	1	16.7			1	16.7						6	100.0
	Indipramine	4	66.7	1	16.7	1	16.7								6	100.0
PALPITATION	Rebozetine	3	60.0			1	20.0								5	100.0
	Indipramine	5	83.3					1	16.7						6	100.0
BLURRED VISION	Rebozetine	2	50.0	2	50.0										4	100.0
	Indipramine											1	100.0		1	100.0
HYPERTENSION	Rebozetine	6	65.7					1	14.3						7	100.0
	Indipramine	2	100.0												2	100.0
BRONCHITIS	Rebozetine	6	100.0												6	100.0
	Indipramine	3	100.0												3	100.0
INFLUENZA-LIKE SYMPTOMS	Rebozetine	4	100.0												4	100.0
	Indipramine	4	100.0												4	100.0
INCREASED LIVER ENZYMES	Rebozetine	3	100.0												3	100.0
	Indipramine	2	100.0												2	100.0
PARAESTHESIA	Rebozetine	4	100.0												4	100.0
	Indipramine															

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(some adverse events are grouped in clusters)

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PLASMACIA CMS RED

REBOXETINE - PROTOCOL 20124/017
TABLE No. 1 ES

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse event/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	%
FLUSHING / HOT FLASHING	Indipramine	2	66.7									1	33.3			3	100.0	
	Reboxetine	2	100.0													2	100.0	
ABDOMINAL PAIN	Indipramine	2	100.0													2	100.0	
	Reboxetine	2	66.7									1	33.3			3	100.0	
FLATULENCE	Indipramine	1	50.0									1	50.0			2	100.0	
	Reboxetine	2	66.7									1	33.3			3	100.0	
BACK PAIN	Indipramine	2	66.7									1	33.3			3	100.0	
	Reboxetine	2	100.0													2	100.0	
LIBIDO DECREASED	Indipramine	2	100.0													2	100.0	
	Reboxetine	3	100.0													3	100.0	
UPPER RESP TRACT INFECTION	Indipramine	3	100.0													3	100.0	
	Reboxetine	2	100.0													2	100.0	
ERYTHEMA / RASH	Indipramine	1	50.0									1	50.0			2	100.0	
	Reboxetine	3	100.0													3	100.0	
TASTE PERVERSION	Indipramine	1	50.0									1	50.0			2	100.0	
	Reboxetine	1	50.0									1	50.0			2	100.0	
URINARY TRACT INFECTION	Indipramine											1	100.0			1	100.0	
	Reboxetine	3	100.0													3	100.0	
ANOREXIA	Indipramine	1	50.0									1	50.0			2	100.0	
	Reboxetine	1	100.0													1	100.0	
ARTRALGIA	Indipramine	2	100.0													2	100.0	

(CONTINUED)

(some adverse events are grouped in clusters)

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PHARMACIA CNS RSD
 RESERPTINE - PROTOCOL 20124/017
 TABLE No.: 33

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.	%
ARTHRALGIA	1	100.0									1	100.0
SINUSITIS							1	100.0			1	100.0
CHEST PAIN	2	100.0									2	100.0
FEVER	2	100.0									2	100.0
ECG ABNORMAL	1	100.0									1	100.0
HYPOASTHENIA	2	100.0									2	100.0
DIARRHEA	1	100.0									1	100.0
GASTROENTERITIS	1	100.0									1	100.0
TINNITUS	1	100.0									1	100.0
HYPERCHOLESTEROLAEMIA	2	100.0									2	100.0
HYPERURICAEMIA	1	100.0									1	100.0
SUICIDE ATTEMPT	1	50.0					1	50.0			2	100.0
HEPATIC DISORDER									1	100.0	1	100.0

(some adverse events are grouped in cluster)

(CONTINUED)

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PERAZACIA CHS RSD
 REBONETINE - PROTOCOL 20124/017
 TABLE No. 1 ES

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse event/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	%	
DIARRHEA																			
SPOTUN INCREASED																			
CONFUSION																			
DELIRIUM																			
SALIVA INCREASED																			
PAIN																			
AV BLOCK																			
BUNDLE BRANCH BLOCK																			
EXTRASYSTOLE																			
TACHYCARDIA SUPRAVENTRICULAR																			
HYPOTENSION																			
HYPOTENSION																			
VERTIGO																			
APPETITE INCREASED																			
DYSPEAGIA																			
LEUCOCYTOSIS																			
GLOBULINS INCREASED																			
HYPERTENSIA																			
ARTHRALGIA																			
CERVICITIS																			

(CONTINUED)

(some adverse events are grouped in clusters)

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PHARMACIA CBS D&D

REBOSARTINE - PROTOCOL 2012A-017
TABLE No.: 53

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. %	No.	Z	No. %	No.	Z	No. %	No.	Z	No. %	No.	Z	No.	Z	
HERPES SIMPLEX			1 100.0												1	100.0	
OTITIS MEDIA			1 100.0												1	100.0	
ASTHMA			1 100.0												1	100.0	
COUGHING			1 100.0												1	100.0	
ALOPECIA			1 100.0												1	100.0	
DERMATITIS FUNGAL			1 100.0												1	100.0	
PRURITUS			1 100.0												1	100.0	
CYSTITIS HAEMORRHAGIC			1 100.0												1	100.0	
HYPOTENSION														1	100.0	1	100.0
OROPHARYNGITIS														1	100.0	1	100.0
ORAL REACTION														1	100.0	1	100.0
TASTE LOSS														1	100.0	1	100.0

(some adverse events are grouped in clusters)

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PHARMACIA CIB 820

REBOSITINE - PROTOCOL 2012A-017
TABLE No.1 54

ADVERSE EVENTS: REAPPEARED AFTER ACTION ON STUDY DRUG AND REAPPEARED ON RESUMING TREATMENT BY ASSIGNED TREATMENT

Adverse events/assigned treatment	Modified study drug												Temporarily interrupted											
	Disappeared						Reappeared						Disappeared						Reappeared					
	NO		YES		Not applicable		Total		NO		YES		Not applicable		Total		NO		YES		Not applicable		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
ALL adverse events	15	32.6	30	65.2	1	2.2	46	100.0	3	37.5			5	62.5	8	100.0								
	14	21.5	49	75.4	2	3.1	65	100.0	1	33.3			2	66.7	3	100.0								
HEADACHE / HEADACHE	3	60.0	2	40.0			5	100.0																
	1	16.7	5	83.3			6	100.0																
UPPER RESPIRATORY / RETENTION	1	16.7	4	66.7	1	16.7	6	100.0																
	1	20.0	4	80.0			5	100.0																
MOUTH DRY	2	66.7	1	33.3			3	100.0																
	2	33.3	4	66.7			6	100.0																
NAUSEA AND RELATED SYMPTOMS	1	20.0	4	80.0			5	100.0																
	1	25.0	2	50.0	1	25.0	4	100.0																
APPETITIA / FATIGUE			2	100.0			2	100.0																
	2	33.3	4	66.7			6	100.0																
BREATHING INCREASED	1	20.0	4	80.0			5	100.0	1	50.0														
	1	50.0	1	50.0			2	100.0																
EXPOSITION AND RELATED SYMPTOMS	1	33.3	2	66.7			3	100.0	1	100.0														
	1	25.0	3	75.0			4	100.0																
SOMNOLENCE	1	100.0					1	100.0																
	2	40.0	3	60.0			5	100.0																
TREMOR	1	20.0	4	80.0			5	100.0																
			2	100.0			2	100.0	1	100.0														
PALPITATION																								

(CONTINUED)

(some adverse events are grouped in clusters)

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PHARMACIA CBS 880

REBOXETINE - PROTOCOL 20126/017
TABLE No. 1 54

ADVERSE EVENTS; REAPPEARED AFTER ACTION ON STUDY DRUG AND REAPPEARED ON RESUMING TREATMENT BY ASSIGNED TREATMENT

Adverse events/assigned treatment	Modified study drug												Temporarily interrupted													
	Disappeared						Reappeared						Disappeared													
	NO		YES		Not applicable		Total		NO		YES		Not applicable		Total		NO		YES		Not applicable		Total			
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%		
PALPITATION																										
			2	100.0					2	100.0																
			2	100.0					2	100.0																
ANXIETY / ANXIETY / RESPONSES																										
			2	100.0					2	100.0																
			2	100.0					2	100.0																
INSOMNIA																										
			2	100.0					2	100.0																
			2	100.0					2	100.0																
BLURRED VISION																										
			1	100.0					1	100.0																
			1	100.0					1	100.0																
CONFUSION																										
			2	100.0					2	100.0																
			2	100.0					2	100.0																
CONSTIPATION																										
			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																
DELUSION																										
			1	100.0					1	100.0																
			1	100.0					1	100.0																
TASTE PERVERSION																										
			1	100.0					1	100.0																
			1	100.0					1	100.0																
FLASHING / HOT FLASHES																										
			1	100.0					1	100.0																
			1	100.0					1	100.0																
SPERMATOZOA																										
			1	100.0					1	100.0																
			1	100.0					1	100.0																

(CONTINUED)

(some adverse events are grouped in cluster)

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PRANACIA CRF RSD

RESOURCING - PROTOCOL 2010A/017
TABLE No.: 54

ADVERSE EVENTS: DISAPPEARED AFTER ACTION OF STUDY DRUG AND REAPPEARED ON RESUMING TREATMENT BY ASSIGNED TREATMENT

Adverse events/Assigned treatment	Modified study drug											
	Disappeared						Temporarily interrupted					
	NO		YES		Net applicable		NO		YES		Net applicable	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
ABDOMINAL PAIN			1	100.0			1	100.0				
ANOREXIA			1	100.0			1	100.0				
CEPHALALGIA			1	100.0			1	100.0				
BACK PAIN			1	100.0			1	100.0				
HALLUCINATION			1	100.0			1	100.0				
SUICIDE ATTEMPT			1	100.0			1	100.0				
DIARRHEA / RASH	1	100.0					1	100.0				
TASTE LOSS			1	100.0			1	100.0				
URINARY TRACT INFECTION			1	100.0			1	100.0				

(Some adverse events are grouped in clusters)

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
TABLE No.: 55

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	%	No.	Z	%			
All adverse events	48	73.8		17	26.2									65	100	150	63.0	4	1.7	83	34.9				1	0.4	238	100								
	32	69.6		14	30.4									46	100	148	67.0	2	0.9	65	29.4				1	0.5	5	2.3	221	100						
MOUTH DRY	4	66.7		2	33.3								6	100	21	50.0			21	50.0																
HEADACHE / MIGRAINE	1	33.3		2	66.7								3	100	17	56.7			13	43.3																
	5	83.3		1	16.7								6	100	11	73.3			4	26.7																
HYPOTENSION AND RELATED SYMPTOMS	2	40.0		3	60.0								5	100	17	77.3			4	18.2																
	3	75.0		1	25.0								4	100	19	82.6	2	8.7	2	8.7																
SWEATING INCREASED	2	66.7		1	33.3								3	100	8	72.7			2	18.2																
	1	50.0		1	50.0								2	100	6	33.3			12	66.7																
NAUSEA AND RELATED SYMPTOMS	5	100											5	100	8	53.3			6	40.0																
	3	75.0		1	25.0								4	100	9	90.0			1	10.0																
INSOMNIA	4	80.0		1	20.0								5	100	12	80.0			3	20.0																
	1	100											1	100	6	40.0	2	13.3	7	46.7																
CONSTIPATION	2	100											2	100	3	33.3			6	66.7																
	1	100											1	100	7	58.3			5	41.7																
TACHYCARDIA				1	100								1	100	8	66.7	1	8.3	3	25.0																
	1	100											1	100	7	50.0			7	50.0																
AGITATION / ANXIETY / NERVOUSNESS	2	100											2	100	7	87.5			1	12.5																
	2	100											2	100	9	100																				

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
TABLE No.: 55

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.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
URINARY RETENCY / RETENTION	Imipramine	4	80.0			1	20.0			5	100	2	100							2	100
	Reboxetine	5	83.3			1	16.7			6	100	4	80.0			1	20.0			5	100
TREMOR	Imipramine	4	80.0			1	20.0			5	100	4	50.0			4	50.0			8	100
	Reboxetine											1	50.0			1	50.0			2	100
SOMNOLENCE	Imipramine	3	60.0			2	40.0			5	100	5	100							5	100
	Reboxetine					1	100			1	100	2	66.7			1	33.3			3	100
ASTHENIA / FATIGUE	Imipramine	4	66.7			2	33.3			6	100	1	100							1	100
	Reboxetine	2	100							2	100	3	75.0			1	25.0			4	100
PALPITATION	Imipramine	2	100							2	100	3	75.0			1	25.0			4	100
	Reboxetine	2	100							2	100	3	100							3	100
BLURRED VISION	Imipramine	1	100							1	100	3	60.0			2	40.0			5	100
	Reboxetine					2	100			2	100	1	50.0			1	50.0			2	100
HYPERTENSION	Imipramine																			1	100
	Reboxetine	1	100							1	100	4	66.7			2	33.3			6	100
BRONCHITIS	Imipramine											2	100							2	100
	Reboxetine											6	100							6	100
INFLUENZA-LIKE SYMPTOMS	Imipramine											2	66.7			1	33.3			3	100
	Reboxetine											4	100							4	100
INCREASED LIVER ENZYMES	Imipramine																			4	100
	Reboxetine											1	33.3			2	66.7			3	100

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
TABLE No.: 55

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 with sequelae		Still present		Death		Missing		Total			
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%		
PARESTHESIA	Imipramine										2	100									2	100
	Reboxetine										3	75.0			1	25.0					4	100
FLUSHING / HOT FLASHING	Imipramine	1	100					1	100	2	100										2	100
	Reboxetine									1	50.0			1	50.0						2	100
ABDOMINAL PAIN	Imipramine									2	100										2	100
	Reboxetine	1	100					1	100					2	100						2	100
FLATULENCE	Imipramine			1	100									1	100						1	100
	Reboxetine	1	100					1	100	1	50.0			1	50.0						2	100
BACK PAIN	Imipramine	1	100					1	100	2	100										2	100
	Reboxetine									2	100										2	100
LIBIDO DECREASED	Imipramine									1	50.0			1	50.0						2	100
	Reboxetine													3	100						3	100
UPPER RESP TRACT INFECTION	Imipramine									3	100										3	100
	Reboxetine									2	100										2	100
ERYTHEMA / RASH	Imipramine			1	100			1	100	1	100										1	100
	Reboxetine									1	53.3			2	66.7						3	100
TASTE PERVERSION	Imipramine	1	100					1	100	1	100										1	100
	Reboxetine	1	100					1	100	1	100										1	100
URINARY TRACT INFECTION	Imipramine	1	100					1	100													
	Reboxetine									3	100										3	100

(CONTINUED)

(some adverse events are grouped in cluster.)

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
TABLE No. : 55

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		Still present		Death		Missing		Total		
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
HYPERURICAEMIA																					
DELUSION																					
SUICIDE ATTEMPT	1	100																			
MENSTRUAL DISORDER																					
RHINITIS																					
SPUTUM INCREASED																					
SEALIVA INCREASED																					
PAIN																					
AV BLOCK																					
BUNDLE BRANCH BLOCK																					
EXTRASYSTOLES																					
TACHYCARDIA SUPRAVENTRICULAR																					
HYPERKINESIA																					
HYPOKINESIA																					
VERTIGO																					
HYPOTHYROIDISM																					

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CHE BMD

REBOZETINE - PROTOCOL 20124/017
TABLE No.: 55

ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
BY ACTION OF STUDY DRUG AND ASSIGNED TREATMENT

Adverse event/Assigned treatment	Modified study drug										Unchanged study drug or Missing									
	Recovered		Still present	Death	Missing	Total	Recovered sequelae		Skill present	Death	Missing	Total	Recovered sequelae		Skill present	Death	Missing	Total		
	No.	%					No.	%					No.	%					No.	%
C3																				
C6																				
APPETITE INCREASED																				
DIARRHOEA																				
OROPHARYNGITIS																				
LEUKOCYTOSIS																				
GLOBULINS INCREASED																				
HYPERLIPAEMIA																				
ARTEROSIS																				
MANIC REACTION																				
CERVICITIS																				
HERPES SIMPLEX																				
OTITIS MEDIA																				
ASTHMA																				
COUGHING																				
ALOPECIA																				
DERMATITIS FUNGAL																				
PROLITIS																				
TASTE LOSS																				
CYSTITIS HAEMORRHAGIC																				

(Some adverse events are grouped in clusters)

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PHARMACIA CBS RSD

REBOSETTINE - PROTOCOL 2012A/017
TABLE No.: 36

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.	%		
All adverse events	194	65.3	4	1.3	100	33.0			1	0.3	303	100.0		
ROUTE DRY	180	67.4	2	0.7	79	25.6	1	0.4	5	1.5	267	100.0		
	25	85.1			23	47.9					48	100.0		
HEADACHE / HEADACHE	18	64.5			15	45.5					33	100.0		
	16	76.2			5	25.8					21	100.0		
	19	70.4			7	25.9			1	3.7	27	100.0		
HYPOTENSION AND RELATED SYMPTOMS	22	81.5	2	7.4	3	11.1					27	100.0		
	10	71.4			3	21.4			1	7.1	14	100.0		
	7	35.0			13	65.0					20	100.0		
	13	65.0			6	30.0			1	5.0	20	100.0		
NAUSEA AND RELATED SYMPTOMS	12	85.7			2	14.3					14	100.0		
	16	80.0			4	20.0					20	100.0		
	7	43.8	2	12.5	7	43.8					16	100.0		
	5	45.5			6	54.5					11	100.0		
CONSTIPATION	8	61.5			5	38.5					13	100.0		
	8	61.5	1	7.7	4	30.8					13	100.0		
TACHYCARDIA	8	55.3			7	46.7					15	100.0		
	5	50.0	1	10.0	4	40.0					10	100.0		
AGITATION / ANXIETY / NEUROPSYCHOSIS	9	90.0			1	10.0					10	100.0		
	11	100.0									11	100.0		

(CONTINUED)

(some adverse events are grouped in clusters)

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PHARMACIA CNS 020

REBOZETINE - PROTOCOL 20124/017
TABLE No.: 35

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.	%	
URINARY RESISTANCE / RETENTION	Indipramine	6	85.7			1	14.3					7	100.0
	Rebozetine	9	81.8			2	18.2					11	100.0
TENSOR	Indipramine	8	61.5			5	38.5					13	100.0
	Rebozetine	1	50.0			1	50.0					2	100.0
SOMNOLENCE	Indipramine	8	80.0			2	20.0					10	100.0
	Rebozetine	2	50.0			2	50.0					4	100.0
ASTHENIA / FATIGUE	Indipramine	5	71.4			2	28.6					7	100.0
	Rebozetine	5	83.3			1	16.7					6	100.0
PALPITATION	Indipramine	5	83.3			1	16.7					6	100.0
	Rebozetine	5	100.0									5	100.0
BLURRED VISION	Indipramine	4	66.7			2	33.3					6	100.0
	Rebozetine	1	25.0			3	75.0					4	100.0
HYPERTENSION	Indipramine									1	100.0	1	100.0
	Rebozetine	5	71.4			2	28.6					7	100.0
BRONCHITIS	Indipramine	2	100.0									2	100.0
	Rebozetine	6	100.0									6	100.0
INFLUENZA-LIKE SYMPTOMS	Indipramine	2	66.7			1	33.3					3	100.0
	Rebozetine	4	100.0									4	100.0
INCREASED LIVER ENZYMES	Indipramine					4	100.0					4	100.0
	Rebozetine	1	33.3			2	66.7					3	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

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PERANACIA CBS 260
 RIBONITRINE - PROTOCOL 20124-017
 TABLE No. 1 25

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.	%	
PAROSMIA	Indipramine	2	100.0									2	100.0
	Ribocicline	3	75.0			1	25.0					4	100.0
FLASHING / HOT FLASHING	Indipramine	3	100.0									3	100.0
	Ribocicline	1	50.0			1	50.0					2	100.0
ABDOMINAL PAIN	Indipramine	2	100.0									2	100.0
	Ribocicline	1	33.3			2	66.7					3	100.0
FLATULENCE	Indipramine					2	100.0					2	100.0
	Ribocicline	2	66.7			1	33.3					3	100.0
BACK PAIN	Indipramine	3	100.0									3	100.0
	Ribocicline	2	100.0									2	100.0
LICKING INCREASED	Indipramine	1	50.0			1	50.0					2	100.0
	Ribocicline					3	100.0					3	100.0
UPPER RESP TRACT INFECTION	Indipramine	3	100.0									3	100.0
	Ribocicline	2	100.0									2	100.0
ERYTHEMA / RASH	Indipramine	1	50.0			1	50.0					2	100.0
	Ribocicline	1	33.3			2	66.7					3	100.0
TASTE PERVERSION	Indipramine	2	100.0									2	100.0
	Ribocicline	2	100.0									2	100.0
URINARY TRACT INFECTION	Indipramine	1	100.0									1	100.0
	Ribocicline	3	100.0									3	100.0

(CONTINUED)

(Cause adverse events are grouped in cluster)

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PRASINACIA CR6 RBD

RESORPTIVE - PROTOCOL 20124-017
TABLE No.: 55

ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
BY ACTION ON STUDY DRUGS 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.	%	
ANOREXIA	Indipravine	1	50.0			1	50.0					2	100.0
	Robocetine	1	100.0									1	100.0
ARTHRALGIA	Indipravine	2	100.0									2	100.0
	Robocetine	1	100.0									1	100.0
KLINGITIS	Indipravine	1	100.0									1	100.0
	Robocetine	2	100.0									2	100.0
CHEST PAIN	Indipravine	2	100.0									2	100.0
	Robocetine	2	100.0									2	100.0
FEVER	Indipravine	1	100.0									1	100.0
	Robocetine	1	100.0									1	100.0
EYES ABNORMAL	Indipravine												
	Robocetine	2	100.0							2	100.0	2	100.0
CONFUSION	Indipravine	1	100.0									1	100.0
	Robocetine	1	100.0									1	100.0
HYPOASTHESIA	Indipravine	1	100.0									1	100.0
	Robocetine	1	100.0									1	100.0
DIARRHOEA	Indipravine	1	100.0									1	100.0
	Robocetine	1	100.0									1	100.0
GASTROENTERITIS	Indipravine	1	100.0									1	100.0
	Robocetine	1	100.0									1	100.0
TINNITUS	Indipravine	2	100.0									2	100.0
	Robocetine					1	100.0					1	100.0
HYPERCOLESTEROLEMIA	Indipravine					1	100.0					1	100.0
	Robocetine					1	100.0					1	100.0

(CONTINUED)

(some adverse events are grouped in clusters)

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PHARMACIA CHE DED

REBOSETINE - PROTOCOL 20124/017
TABLE No.: 55

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.	%	
HYPERURICAEMIA	Isipramine					1	100.0					1	100.0
	Reboksetine					1	100.0					1	100.0
DELIRIUM	Isipramine					1	100.0					1	100.0
	Reboksetine					1	100.0					1	100.0
SUICIDE ATTEMPT	Isipramine	1	50.0					1	50.0			2	100.0
	Reboksetine	1	100.0									1	100.0
MENSTRUAL DISORDER	Isipramine	1	100.0									1	100.0
	Reboksetine	1	100.0									1	100.0
HEMIPARESIS	Isipramine	2	100.0									2	100.0
	Reboksetine	2	100.0									2	100.0
SALIVA INCREASED	Isipramine											1	100.0
	Reboksetine	1	100.0									1	100.0
PAIN	Isipramine											1	100.0
	Reboksetine	1	100.0									1	100.0
AV BLOCK	Isipramine											1	100.0
	Reboksetine											1	100.0
BUNDLE BRANCH BLOCK	Isipramine											1	100.0
	Reboksetine											1	100.0
EXTRASYSTOLES	Isipramine											1	100.0
	Reboksetine											1	100.0
TACHYCARDIA SUPRAVENTRICULAR	Isipramine	1	100.0									1	100.0
	Reboksetine	1	100.0									1	100.0
HYPERKINESIA	Isipramine	1	100.0									1	100.0
	Reboksetine	1	100.0									1	100.0
VERTIGO	Isipramine	1	100.0									1	100.0
	Reboksetine											1	100.0
HYPOTHYROIDISM	Isipramine											1	100.0
	Reboksetine											1	100.0
APPETITE INCREASED	Isipramine											1	100.0
	Reboksetine											1	100.0

(CONTINUED)

(Some adverse events are grouped in clusters)

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PHARMACIA CNS RSD

REBONSTONE - PROTOCOL 20124/017

TABLE No.: 55

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	
DYSPHAGIA						1	100.0					1	100.0
OROPHARYNGITIS						1	100.0					1	100.0
LEUCOCYTOSIS						1	100.0					1	100.0
GLUCOSILINS INCREASED						1	100.0					1	100.0
HYPERLIPIDEMIA						1	100.0					1	100.0
ARTHRITIS						1	100.0					1	100.0
NAUCHE REACTION						1	100.0					1	100.0
CERVICITIS						1	100.0					1	100.0
HERPES SIMPLEX						1	100.0					1	100.0
OTITIS MEDIA						1	100.0					1	100.0
ASTHMA						1	100.0					1	100.0
COUGHING						1	100.0					1	100.0
ALOPECIA						1	100.0					1	100.0
DERMATITIS FUNGAL						1	100.0					1	100.0
PRURITUS						1	100.0					1	100.0
TASTE LOSS						1	100.0					1	100.0
CYSTITIS HAEMORRHAGIC						1	100.0					1	100.0

(rare adverse events are grouped in clusters)

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PHARMACIA CHEM BND

ROBOCETINE - PROTOCOL 2012A-017
TABLE No.: 56

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Adverse events	Days of treatment																				
	0-7		8-14		15-21		22-28		29-35		36-42		> 42								
	No Pt. exp. (n)	% on Pt. exp. (%)	No Pt. exp. (n)	% on Pt. exp. (%)	No Pt. exp. (n)	% on Pt. exp. (%)	No Pt. exp. (n)	% on Pt. exp. (%)	No Pt. exp. (n)	% on Pt. exp. (%)	No Pt. exp. (n)	% on Pt. exp. (%)	No Pt. exp. (n)	% on Pt. exp. (%)							
Assigned treatment																					
Pt. exposed	126	100	2.01	110	100	1.84	109	100	2.03	100	1.90	95	100	2.03	93	100	1.82	14	100	1.56	
ROUYE DRY																					
Indipramine	130	100	1.84	119	100	1.61	113	100	1.65	107	1.64	104	100	1.75	100	1.77	21	100	1.32		
Robocetine	36	26.6	1.00	29	26.4	1.00	26	23.9	1.00	23	23.0	1.00	24	25.3	1.04	20	21.5	1.05	11	78.6	1.09
SWEATING INCREASED																					
Indipramine	19	14.6	1.00	21	17.6	1.00	19	16.8	1.00	15	14.0	1.00	14	13.5	1.00	12	12.0	1.00	8	38.1	1.00
Robocetine	12	9.5	1.00	12	10.9	1.00	13	11.9	1.00	10	10.0	1.00	10	10.5	1.00	12	12.9	1.00	6	42.9	1.00
HEADACHE																					
Indipramine	12	9.2	1.00	9	7.6	1.00	9	8.0	1.00	7	6.5	1.00	7	6.7	1.00	6	6.0	1.00	2	9.5	1.00
Robocetine	8	6.3	1.00	6	5.5	1.00	6	5.5	1.00	8	8.0	1.00	7	7.4	1.00	5	5.4	1.00	3	21.4	1.00
CONSTIPATION																					
Indipramine	8	6.2	1.00	9	7.6	1.00	8	7.1	1.00	10	9.3	1.00	10	9.6	1.00	3	3.0	1.00	1	4.8	1.00
Robocetine	8	6.3	1.00	10	9.1	1.00	8	7.3	1.00	8	8.0	1.00	7	7.4	1.00	6	6.5	1.00	1	7.1	1.00
INSOMNIA																					
Indipramine	7	5.4	1.00	6	5.0	1.00	8	7.1	1.00	7	6.5	1.00	7	6.7	1.00	5	5.0	1.00	4	19.0	1.00
Robocetine	5	4.0	1.00	7	6.4	1.00	10	9.2	1.00	10	10.0	1.00	8	8.4	1.00	8	8.6	1.00	1	7.1	1.00
DIZZINESS																					
Indipramine	7	5.4	1.00	7	5.9	1.00	5	4.4	1.00	5	4.7	1.00	5	4.6	1.00	3	3.0	1.00	1	4.8	1.00
Robocetine	12	9.5	1.00	9	8.2	1.00	7	6.4	1.00	8	8.0	1.00	8	8.0	1.00	5	5.3	1.00	3	3.2	1.00
TACHYCARDIA																					
Indipramine	6	4.6	1.00	1	0.8	1.00	4	3.5	1.00	3	2.5	1.00	3	2.8	1.00	2	1.9	1.00	2	2.0	1.00
Robocetine	7	5.6	1.00	6	5.5	1.00	7	6.4	1.00	7	7.0	1.00	6	6.3	1.00	4	4.3	1.00			
NAUSEA																					
Indipramine	2	1.5	1.00	3	2.5	1.00	4	3.5	1.00	4	3.7	1.00	3	2.9	1.00	4	4.0	1.00	1	4.8	1.00
Robocetine	9	7.1	1.00	7	6.4	1.00	6	5.5	1.00	4	4.0	1.00	2	2.1	1.00	2	2.2	1.00			
TREMBOR																					
Indipramine	11	8.5	1.00	4	3.4	1.00	2	1.6	1.00	1	0.9	1.00	1	1.0	1.00	3	3.0	1.00	1	4.8	1.00
Robocetine	7	5.6	1.00	8	7.3	1.00	8	7.3	1.00	7	7.0	1.00	5	5.3	1.00	6	6.5	1.00	3	21.4	1.00
	1	0.8	1.00	1	0.8	1.00	2	1.6	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 D&D

REMEDIATION - PROTOCOL 20124/017
TABLE No.: 56

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. (n)	% on Pt. exp. (%)	No Pt. exp. (n)	% on Pt. exp. (%)	No Pt. exp. (n)	% on Pt. exp. (%)	No Pt. exp. (n)	% on Pt. exp. (%)	No Pt. exp. (n)	% on Pt. exp. (%)	No Pt. exp. (n)	% on Pt. exp. (%)	No Pt. exp. (n)	% on Pt. exp. (%)		
DIARRHOEA	Indipramine	1	0.8	1	0.9	1	0.9	1	1.0								
	Reboxetine	4	3.1	6	5.0	6	5.3	1	0.9	5	4.7	5	4.8	3	3.0	3	14.3
VISION ABNORMAL	Indipramine	3	2.4	2	1.8	1	0.9	1	0.9	2	2.0	2	2.1	2	2.2	2	14.3
	Reboxetine	4	3.1	4	3.4	4	3.5	4	3.5	3	2.8	3	2.9	2	2.0	2	9.5
AGITATION	Indipramine	5	4.0	3	2.7	2	1.8	2	1.8	2	2.0	2	2.1	1	1.1	1	1.0
	Reboxetine	6	4.6	4	3.4	2	1.8	1	0.9	1	0.9	1	1.0	1	1.0	1	1.0
SOMNOLENCE	Indipramine	5	4.0	4	3.6	2	1.8	2	1.8	2	2.0	2	2.0	4	4.2	2	2.2
	Reboxetine	3	2.3	1	0.8	1	0.9	1	0.9	1	1.0	1	1.0	1	1.0	1	4.8
PALPITATION	Indipramine	1	0.8	3	2.7	3	2.8	3	2.8	2	2.0	2	2.0	1	1.1	1	1.0
	Reboxetine	2	1.5	3	2.5	4	3.5	4	3.5	2	1.9	2	1.9	2	2.0	2	2.0
LIBIDO DECREASED	Indipramine																
	Reboxetine	1	0.8	1	0.8	3	2.7	3	2.7	3	2.8	3	2.9	3	3.0	3	14.3
FLATULENCE	Indipramine	1	0.8	2	1.8	2	1.8	2	1.8	1	1.0	1	1.0	1	1.1	1	1.0
	Reboxetine	2	1.5	2	1.7	2	1.8	2	1.8	2	1.9	2	1.9	2	2.0	2	2.0
REPERFUSION	Indipramine																
	Reboxetine	1	0.8	3	2.5	4	3.5	4	3.5	4	3.7	4	3.9	3	2.9	2	2.0
FATIGUE	Indipramine	4	3.2	1	0.9	1	0.9	1	0.9	1	1.0	1	1.1	1	1.1	1	1.0
	Reboxetine	2	1.5	2	1.7	1	0.9	1	0.9	2	1.9	1	1.0	1	1.0	1	4.8
PARAESTHESIA	Indipramine	2	1.6	1	0.9	1	0.9	1	0.9	1	1.0	1	1.1	1	1.1	1	1.0
	Reboxetine	1	0.8	3	2.5	1	0.9	1	0.9	1	1.0	1	1.0	1	1.0	1	4.8

(CONTINUED)

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

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PHARMACIA CIS RED
 REBOSINETE - PROTOCOL 20124-017
 TABLE No. 1 56

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	%	No	%	No	%	No	%	No	%	No	%	No	%		
TASTE PERVERSION	Indipramine	2	1.6	1	0.9	1	0.9	2	1.9	2	1.9	2	2.0	2	1.9	2	1.9
	Reboxetine	1	0.8	1	0.8	1	0.9	1	0.9	1	1.0	2	2.0	1	1.0	2	1.9
BRONCHITIS	Indipramine			1	0.9							1	1.1				
	Reboxetine			1	0.8	3	2.7	1	0.9	1	1.0	1	1.0	2	2.0	1	1.0
INFLUENZA-LIKE SYMPTOMS	Indipramine	2	1.6	1	0.8	2	1.8							1	1.1	1	1.0
	Reboxetine	1	0.8	1	0.8	2	1.8							1	1.0	1	1.0
GAMMA-GT INCREASED	Indipramine					2	1.8	2	1.8	2	1.8	2	2.0	2	2.1	2	2.2
	Reboxetine					1	0.9	1	0.9	1	1.0	1	1.0	1	1.0	1	1.0
HYPOTENSION	Indipramine	2	1.6	2	1.8	3	2.8	1	1.0	1	1.0	1	1.1	1	1.1	1	1.0
	Reboxetine	1	0.8	1	0.9							2	2.0	2	2.1		
URINARY DISTENTION	Indipramine																
	Reboxetine	2	1.5	2	1.7												
HYPERCOLESTEROLEMIA	Indipramine	1	0.8	1	0.9	1	0.9	1	0.9	1	1.0	1	1.0	1	1.1	1	1.0
	Reboxetine																
HYPOTENSION POSTURAL	Indipramine	2	1.6	2	1.8	2	1.8	2	1.8	2	1.8	1	1.0				
	Reboxetine	1	0.8	1	0.8												
BASE	Indipramine			1	0.9									1	1.1		
	Reboxetine	1	0.8	1	0.8	1	0.9	1	0.9	1	1.0	1	1.0	1	1.0	1	1.0
UPPER RESP TRACT INFECTION	Indipramine			1	0.9									2	2.2	1	1.0
	Reboxetine					1	0.9	1	0.9	1	1.0	1	1.0	1	1.0	1	1.0

(*) (CONTINUED)

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

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PHARMACIA CIS RED

REBOZITINE - PROTOCOL 20124/017
TABLE No.: 56

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	Z on Pt. exp. (x)	No	Z on Pt. exp. (x)	No	Z on Pt. exp. (x)	No	Z on Pt. exp. (x)	No	Z on Pt. exp. (x)	No	Z on Pt. exp. (x)	No	Z on Pt. exp. (x)		
EPHRAIMICARIN-IA	Indipramine																
	Baclofen																
SALIVA INCREASED	Indipramine	1	0.8 1.00	1	0.9 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
	Baclofen	1	0.8 1.00	1	0.8 1.00	1	0.9 1.00	1	0.9 1.00	1	0.9 1.00	1	1.0 1.00	1	1.0 1.00	1	4.8 1.00
URINARY TRACT INFECTION	Indipramine																
	Baclofen	1	0.8 1.00			1	0.9 1.00	2	1.9 1.00	1	1.0 1.00	1	1.0 1.00	1	1.0 1.00		
HEPATIC ENZYMES INCREASED	Indipramine																
	Baclofen																
BACK PAIN	Indipramine	1	0.8 1.00														
	Baclofen	1	0.8 1.00	2	1.7 1.00												
FLASHING	Indipramine																
	Baclofen	1	0.8 1.00	1	0.8 1.00	1	0.9 1.00	1	0.9 1.00	1	0.9 1.00	1	1.1 1.00	1	1.1 1.00		
ABDOMINAL PAIN	Indipramine																
	Baclofen	2	1.5 1.00														
TINITUS	Indipramine	1	0.8 1.00	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				
	Indipramine	2	1.6 1.00														
ANGEXIA	Baclofen	1	0.8 1.00	1	0.8 1.00												
	Indipramine	1	0.8 1.00	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				
TASTE LOSS	Indipramine	1	0.8 1.00	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				
	Indipramine	1	0.8 1.00														

(CONTINUED)

(x) number of adverse events on number of patient who complained of adverse events

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PHARMACIA CNS BID

REBOZETINE - PROTOCOL 20124/017
TABLE No. 1 56

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. (*)	% on Pt. exp. (*)	No Pt. exp. (*)	% on Pt. exp. (*)	No Pt. exp. (*)	% on Pt. exp. (*)	No Pt. exp. (*)	% on Pt. exp. (*)	No Pt. exp. (*)	% on Pt. exp. (*)	No Pt. exp. (*)	% on Pt. exp. (*)	No Pt. exp. (*)	% on Pt. exp. (*)		
SKINURITIS	Rebozetine																
ASTHENIA	Isipramine	2	1.6	1	0.9												
	Rebozetine	1	0.8														
DIARRHOEA	Isipramine																
	Rebozetine	1	0.8	1	0.8	1	0.9										
ARTRALGIA	Isipramine					1	0.9	1	1.0	1	1.0	1	1.1	1.0			
	Rebozetine																
AV BLOCK	Isipramine					1	0.9	1	1.0	1	1.0	1	1.1	1.0			
	Rebozetine																
BUNDLE BRANCH BLOCK	Isipramine					1	0.9	1	1.0	1	1.0	1	1.1	1.0			
	Rebozetine																
APPETITE INCREASED	Isipramine																
	Rebozetine																
GLOBULINS INCREASED	Isipramine																
	Rebozetine																
ACCOMMODATION ABNORMAL	Isipramine	2	1.6	1	0.9												
	Rebozetine	1	0.8														
CONFUSION	Isipramine	2	1.5	1	0.9												
	Rebozetine	1	0.8														
NEURONURGES	Isipramine	1	0.8	1	0.8	1	0.9	1	1.0	1	1.0	1	1.1	1.0			
	Rebozetine																
EPIDIDYMITIS	Isipramine																
	Rebozetine																

(CONTINUED)

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

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PARANACTA CHE RED

REPROSTINE - PROTOCOL 20124/017
TABLE No. 1 56

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	%	No	%	No	%	No	%	No	%	No	%	No	%	
HERNTRIAL DIZZINESS	Indipramine															
	Reboxetine	1	0.9	1.00	1	0.9	1.00									
FEVER	Indipramine															
	Reboxetine															
DELIRIUM	Indipramine	1	0.8	1.00												
	Reboxetine															
CHEST PAIN	Indipramine	1	0.8	1.00	1	0.8	1.00									
	Indipramine	2	1.6	1.00												
PRURITUS	Reboxetine	1	0.8	1.00	1	0.8	1.00									
	Indipramine															
VOMITING	Reboxetine	1	0.8	1.00												
	Indipramine															
PAIN	Reboxetine	1	0.8	1.00	1	0.8	1.00									
	Reboxetine	1	0.8	1.00	1	0.8	1.00									
HERPES SIMPLEX	Reboxetine															
	Indipramine															
MANIC REACTION	Indipramine															
	Indipramine															
SPUTUM INCREASED	Reboxetine															
	Indipramine															
HEMIPYRIS	Reboxetine															
	Indipramine															
COUGHING	Indipramine															
	Indipramine															

(CONTINUED)

(%) number of adverse events on number of patient who complained of adverse events

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PERANJACIA CBS RSD

REBONJACIE - PROTOCOL 2012A/017
TABLE No.: 56

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. (n)	% on Pt. exp. (x)	No Pt. exp. (n)	% on Pt. exp. (x)	No Pt. exp. (n)	% on Pt. exp. (x)	No Pt. exp. (n)	% on Pt. exp. (x)	No Pt. exp. (n)	% on Pt. exp. (x)	No Pt. exp. (n)	% on Pt. exp. (x)	No Pt. exp. (n)	% on Pt. exp. (x)
	Isipraminas									1	1.1	1	1.1	1	1.0
ARTROBRITIS	Isipraminas									1	1.1	1	1.0		
GASTRITIS-DYSPEPSIA	Isipraminas									1	1.1	1	1.0		
	Rebonjacie									1	1.0	1	1.0		
ALOPECIA	Rebonjacie									1	1.0	1	1.0		
DERMATITIS FURFURAL	Rebonjacie									1	1.0	1	1.0		
RUICIDE ATTEMPT	Rebonjacie									1	1.0	1	1.0		
ECO ABNORMAL	Rebonjacie									1	1.0	1	1.0		
HYPERKINESIA	Isipraminas	1	0.8	1.00											
HYPOHYPODYSIA	Rebonjacie	1	0.8	1.00											
TACHICARDIA SUPRAVENTRICULAR	Isipraminas									1	0.9	1.00			
DYSPNOEA	Isipraminas									1	0.9	1.00			
HYPERPALENTIA	Isipraminas									1	0.9	1.00			
ASTHMA	Isipraminas									1	0.9	1.00			
OTITIS MEDIA	Isipraminas									1	0.9	1.00			
VERTIGO	Isipraminas													1	1.0
ANKILYS	Isipraminas													1	1.0
HYPOKINESIA	Isipraminas													1	1.1

(CONTINUED)

(x) number of adverse events on number of patient who complained of adverse events

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PARANACIA CRB RED

RESCUE TIME - PROTOCOL 20124/017
TABLE No.: 56

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	% on Pt. exp. (*)	No	% on Pt. exp. (*)	No	% on Pt. exp. (*)	No	% on Pt. exp. (*)	No	% on Pt. exp. (*)	No	% on Pt. exp. (*)	No	% on Pt. exp. (*)	
CYSTITIS	Reboxetine															
HAEMORRAGIC	Reboxetine									1	1.0					
EXTRAVESICULAR	Imipramine															
SOFT INCREASED	Reboxetine												1	1.1	1.00	
LEUCOCYTOSIS	Reboxetine												1	1.0	1.00	
													1	4.8	1.00	

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

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FRAMACIA CMS R&D

REBONETINE - PROTOCOL 20154/017

TABLE No. 1 57

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: AUTONOMIC NERVOUS SYSTEM DISORDERS

Adverse event(s)/assigned treatment	Days of treatment																				
	0-7			8-14			15-21			22-28			29-35			36-42			> 42		
	No	Z on	exp. (*)	No	Z on	exp. (*)	No	Z on	exp. (*)	No	Z on	exp. (*)	No	Z on	exp. (*)	No	Z on	exp. (*)	No	Z on	exp. (*)
HOUSTE NEX	34	28.6	1.00	29	26.4	1.00	26	23.9	1.00	23	20.0	1.00	24	25.3	1.04	20	21.5	1.05	11	78.6	1.09
	19	14.6	1.00	21	17.6	1.00	19	16.8	1.00	15	14.0	1.00	14	13.5	1.00	12	12.0	1.00	8	58.1	1.00
SHRIMPING INCREASED	12	9.5	1.00	12	10.9	1.00	13	11.9	1.00	10	10.0	1.00	10	10.5	1.00	12	12.9	1.00	6	42.9	1.00
	12	9.2	1.00	9	7.6	1.00	9	8.0	1.00	7	6.5	1.00	7	6.7	1.00	6	6.0	1.00	2	9.5	1.00
SALIVA INCREASED	1	0.8	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

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in clusters)

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PARACETAMOL CHEM

REBOCETIN - PROTOCOL 20124-017
TABLE No. 1 57

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. (*)
ASTHMA / FATIGUE	5	4.0 1.20	2	1.8 1.00	1	0.9 1.00	1	1.0 1.00	1	1.1 1.00				
	3	2.3 1.00	2	1.7 1.00	1	0.9 1.00	2	1.9 1.00	1	1.0 1.00	1	1.0 1.00	1	4.8 1.00
INFLUENZA-LIKE SYMPTOMS			2	1.8 1.00	2	1.8 1.00							1	1.1 1.00
			1	0.8 1.00	2	1.8 1.00			1	1.0 1.00	1	1.0 1.00	1	4.8 1.00
FEVER									1	1.0 1.00	1	1.1 1.00		
CHEST PAIN	1	0.8 1.00	1	0.9 1.00										
	1	0.8 1.00	1	0.8 1.00										
PAIN														

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

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PRAMIPAXIA CRIS BMS

REBOZETINE - PROTOCOL 20124/017
TABLE No.: 57

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	Z on exp. (s)	No Pt	Z on exp. (s)	No Pt	Z on exp. (s)	No Pt	Z on exp. (s)	No Pt	Z on exp. (s)	No Pt	Z on exp. (s)	No Pt	Z on exp. (s)
HYPOTENSION AND RELATED SYMPTOMS	15	11.9 1.06	12	10.9 1.08	11	10.1 1.09	9	9.0 1.11	5	5.3 1.20	3	3.2 1.33	1	7.1 2.00
TACHYCARDIA	7	5.4 1.00	2	1.7 1.00	4	3.5 1.00	3	2.8 1.00	2	1.9 1.00	2	2.0 1.00	2	9.5 1.00
PALPITATION	2	1.5 1.00	3	2.5 1.00	4	3.5 1.00	4	3.7 1.00	3	2.9 1.33	4	4.3 1.00	1	4.8 1.00
HYPERTENSION	1	0.8 1.00	3	2.7 1.00	3	2.8 1.00	2	2.0 1.00	1	1.1 1.00				
FLUSHING / HOT FLASHES	2	1.5 1.00	3	2.5 1.00	4	3.5 1.00	2	1.9 1.00	2	1.9 1.00	2	2.0 1.00		
AV BLOCK													1	1.1 1.00
BUNDLE BRANCH BLOCK													1	1.0 1.00
ECG ABNORMAL													2	2.0 1.00
TACHYCARDIA SUPRAVENTRICULAR			1	0.9 1.00										
EXTRASYSTOLIC													1	1.1 1.00

(s) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in clusters)

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PHARMACIA CNS 202
 RESCHISTINE - PROTOCOL 20124/017
 TABLE No.: 57

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. (s)	No Pt	Z on exp. (s)	No Pt	Z on exp. (s)	No Pt	Z on exp. (s)	No Pt	Z on exp. (s)	No Pt	Z on exp. (s)	No Pt	Z on exp. (s)
HEADACHE / MIGRAINE	Indipramine	8 6.3 1.00	6 5.5 1.00	6 7.1 1.00	8 8.0 1.00	7 7.4 1.00	5 5.4 1.00	3 21.4 1.00						
	Reboxetine	8 6.2 1.00	9 7.6 1.00	8 7.1 1.00	10 9.3 1.00	10 9.6 1.00	3 3.0 1.00	1 4.8 1.00						
TREMBLE	Indipramine	7 5.6 1.00	8 7.3 1.00	8 7.3 1.00	7 7.0 1.00	5 5.3 1.00	6 6.5 1.00	3 21.4 1.00						
	Reboxetine	1 0.8 1.00	1 0.8 1.00	2 1.8 1.00										
PARAESTHESIA	Indipramine	2 1.6 1.00	1 0.9 1.00	1 0.9 1.00	1 1.0 1.00	1 1.1 1.00								
	Reboxetine	1 0.8 1.00	3 2.5 1.00	1 0.9 1.00			1 1.0 1.00	1 4.8 1.00						
CONFUSION	Indipramine	1 0.8 1.00		1 0.9 1.00	1 1.0 1.00									
	Indipramine		1 0.9 1.00	1 0.9 1.00										
HYPOAESTHESIA	Indipramine													
	Reboxetine					1 1.0 1.00								
HYPERKINESIA	Indipramine	1 0.8 1.00												
	Indipramine				1 1.0 1.00									
HYPOKINESIA	Indipramine													
	Indipramine				1 1.0 1.00									

(s) number of adverse events on number of patient who complained of adverse events (across adverse events are grouped in clusters)

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PHARMACIA CHE 280

REGOMETINE - PROTOCOL 20124/017
TABLE No.: 57

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: ENDOCRINE DISORDERS

Adverse events/Assigned treatment	Days of treatment													
	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No Pt exp. (n)	% on Pt exp. (s)	No Pt exp. (n)	% on Pt exp. (s)	No Pt exp. (n)	% on Pt exp. (s)	No Pt exp. (n)	% on Pt exp. (s)	No Pt exp. (n)	% on Pt exp. (s)	No Pt exp. (n)	% on Pt exp. (s)	No Pt exp. (n)	% on Pt exp. (s)
HYPOTHYROIDISM - Subcutaneous	1	0.0	1.00											

(s) number of adverse events on number of patient who complained of adverse events
(n) same adverse events are grouped in cluster

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PHARMACIA CNS 880
 REGOCHETINE - PROTOCOL 20124-017
 TABLE No.: 57

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	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. (%)
CONSTIPATION														
Indipramine	8	6.3 1.00	10	9.1 1.00	8	7.5 1.00	6	6.0 1.00	7	7.4 1.00	6	6.5 1.00	1	7.1 1.00
Rabozetina	7	5.4 1.00	6	5.0 1.00	8	7.1 1.00	7	6.5 1.00	7	6.7 1.00	5	5.0 1.00	4	19.0 1.00
NAUSEA AND RELATED SYMPTOMS														
Indipramine	9	7.1 1.00	7	6.4 1.00	6	5.5 1.00	4	4.0 1.00	3	3.2 1.00	2	2.2 1.00		
Rabozetina	12	9.2 1.00	5	4.2 1.00	3	2.7 1.00	2	1.9 1.00	2	1.9 1.00	4	4.0 1.00	2	9.5 1.00
FLATULENCE														
Indipramine	1	0.8 1.00	2	1.8 1.00	2	1.8 1.00	1	1.0 1.00	1	1.1 1.00	1	1.1 1.00		
Rabozetina	2	1.5 1.00	2	1.7 1.00	2	1.8 1.00	2	1.9 1.00	2	1.9 1.00	2	2.0 1.00		
ABDOMINAL PAIN														
Indipramine														
Rabozetina	2	1.5 1.00												
ANOREXIA														
Indipramine	2	1.6 1.00												
Rabozetina	1	0.8 1.00	1	0.8 1.00										
DIARRHEA														
Indipramine														
Rabozetina	1	0.8 1.00	1	0.8 1.00	1	0.9 1.00								
APPETITE INCREASED														
Indipramine														
Rabozetina														
CEPHALICIA														
Indipramine														
Rabozetina														
GASTROENTERITIS														
Indipramine														
Rabozetina														
DYSPEPSIA														
Indipramine														
Rabozetina														

(%) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in clusters)

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PARACETAMOL 500

RESEARCHING - PROTOCOL 20124-017
TABLE No.: 57

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	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)
TINNITUS	1	0.8	1.00	1	0.9	1.00	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)

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PHARMACIA CNS DSD

REBOSETIME - PROTOCOL 20124/017
TABLE No.: 57

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	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	
LEUCOCYTOSIS													1	4.6	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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PIRAMACIA CHS R&D

HEMOMETINE - PROTOCOL 20124/017

TABLE No. 1 57

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: LIVER AND BILIAN 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. (*)	% on Pt exp. (*)	No Pt exp. (*)	% on Pt exp. (*)	No Pt exp. (*)	% on Pt exp. (*)	No Pt exp. (*)	% on Pt exp. (*)	No Pt exp. (*)	% on Pt exp. (*)	No Pt exp. (*)	% on Pt exp. (*)	No Pt exp. (*)	% on Pt exp. (*)
INCREASED LIVER ENZYMES														
Indipramine	2	1.8	1.50	2	2.0	1.50	2	2.1	1.50	2	2.2	2.00		
Reboxetine	2	1.8	1.00	2	1.9	1.00	2	1.0	1.00	2	2.0	1.00		

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in clusters)

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PHARMACIA CNS 020

REBOCORTINE - PROTOCOL 20124/017
TABLE No.: 57

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. (*)	
HYPERCALCAEMIA- Indipramine	1	0.5	1.00	1	0.9	1.00	1	1.0	1.00	1	1.1	1.00	1	4.8	1.00
Rebocortine							1	0.9	1.00	1	1.0	1.00	1	1.0	1.00
HYPERURICAEMIA- Indipramine							1	0.9	1.00	1	1.1	1.00	1	1.1	1.00
Rebocortine							1	0.9	1.00	1	1.0	1.00	1	1.0	1.00
GLOMERULUS INCREASED													1	0.9	1.00
HYPERLIPAEMIA Indipramine													1	0.9	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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FRANZACIA CHE BID

REGIMETINE - PROTOCOL 20124/017
TABLE No.1 57

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	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)
BACK PAIN	1	0.5 1.00							1	1.1 1.00	1	1.1 1.00		
	1	0.5 1.00	2	1.7 1.00										
ARTHRALGIA					1	0.9 1.00	1	1.0 1.00	1	1.1 1.00				
									1	1.0 1.00				
ARTHRITIS									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 clusters)

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PHARMACIA CNS RED

REMOGETINE - PROTOCOL 20124/017
TABLE No.: 57

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. (*)
INSOMNIA	5	4.0 1.00	7	6.4 1.00	10	9.2 1.00	10	10.0 1.00	8	8.4 1.00	8	8.6 1.00	1	7.1 1.00
	7	5.4 1.00	7	5.9 1.00	5	4.4 1.00	5	4.7 1.00	5	4.8 1.00	3	3.0 1.00	1	1.1 1.00
AGITATION / ANXIETY / NERVOUSNESS	5	4.0 1.00	3	2.7 1.00	2	1.8 1.00	3	3.0 1.00	2	2.1 1.00	1	1.1 1.00		
	8	6.2 1.00	4	3.4 1.00	3	2.7 1.00	1	0.9 1.00	1	1.0 1.00	1	1.0 1.00		
SOMNOLENCE	5	4.0 1.00	4	3.6 1.00	2	1.8 1.00	2	2.0 1.00	4	4.2 1.00	2	2.2 1.00		
	3	2.3 1.00	1	0.8 1.00	1	0.9 1.00			1	1.0 1.00	1	1.0 1.00	1	4.8 1.00
LETHARGY / DECREASED									1	1.0 1.00	2	2.1 1.00	1	1.1 1.00
	1	0.8 1.00	1	0.8 1.00	3	2.7 1.00	3	2.8 1.00	3	2.9 1.00	3	3.0 1.00	3	14.3 1.00
DELUSION	1	0.8 1.00												
NAUTIC REACTION														
					1	0.9 1.00	1	1.0 1.00						
SUICIDE ATTEMPT													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 clusters)

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PHARMACIA CNS 820

REBOSUTIME - PROTOCOL 20124/017
TABLE No.: 57

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: REPRODUCTIVE DISORDERS, FEMALE

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. (*)
CERVICITIS	1	0.5	1.00	1	0.5	1.00	1	0.9	1.00					
MONSTRIAL DISORDER							1	1.0	1.00					
							1	0.9	1.00	1	0.9	1.00		

(*) number of adverse events on number of patient who complained of adverse events
(some adverse events are grouped in clusters)

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PARMAVIA CRB 280

REGONITING - PROTOCOL 20124/017
TABLE No. 1 57

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Body system: RESISTANCE INDICATING DISORDERS

Adverse events/Assigned treatment	Days of treatment													
	0-7		8-14		15-21		22-28		29-35		36-42		> 42	
	No Pt exp. (z)	No z on Pt exp. (x)	No z on Pt exp. (x)	No z on Pt exp. (x)	No z on Pt exp. (x)	No z on Pt exp. (x)	No z on Pt exp. (x)	No z on Pt exp. (x)	No z on Pt exp. (x)	No z on Pt exp. (x)	No z on Pt exp. (x)	No z on Pt exp. (x)	No z on Pt exp. (x)	No z on Pt exp. (x)
RESURF SKINPLEK		1	0.6	1.00	1	0.9	1.00							
OTITIS MEDIA Indipramine					1	0.9	1.00							

(x) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

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PARACETAMOL CHS RED

RESOURCING - PROTOCOL 20124/017
TABLE No.: 57

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	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)
BRONCHITIS			1	0.9	1.00					1	1.1	1.00		
			1	0.8	1.00	3	2.7	1.00	1	0.9	1.00	1	1.0	1.00
			1	0.9	1.00							2	2.0	1.00
UPPER RESP TRACT INFECTION												2	2.2	1.00
						1	0.9	1.00	1	0.9	1.00	1	1.0	1.00
SINUSITIS	1	0.8	1.00											
									1	0.9	1.00	2	1.9	1.00
SPUTUM INCREASED														
						1	0.9	1.00	1	1.0	1.00			
						1	0.9	1.00	1	0.9	1.00			
COUGHING												1	1.1	1.00
									1	1.0	1.00	1	1.0	1.00
ASTHMA						1	0.9	1.00						

(*) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in clusters)

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PHARMACIA CHE DMO

REBOZETINE - PROTOCOL 20124/017
TABLE No.: 57

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 exp. (n)	Z on Pt exp. (s)	No Pt exp. (n)	Z on Pt exp. (s)	No Pt exp. (n)	Z on Pt exp. (s)	No Pt exp. (n)	Z on Pt exp. (s)	No Pt exp. (n)	Z on Pt exp. (s)	No Pt exp. (n)	Z on Pt exp. (s)	No Pt exp. (n)	Z on Pt exp. (s)	
ERYTHEMA / TRIPYRAMINE			1	0.9	1.00										
ERYTHEMA / REBOZETINE	1	0.8	1.00	1	0.8	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00
PRURITUS / REBOZETINE	1	0.8	1.00	1	0.8	1.00									
ALOPECIA / REBOZETINE										1	1.0	1.00	1	1.0	1.00
DERMATITIS FUNGAL / REBOZETINE										1	1.0	1.00	1	1.0	1.00

(s) number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in clusters)

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PHARMACIA CHEM BRD

RESORCINOL - PROTOCOL 20124/017

TABLE No.: 57

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	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)	No Pt	% exp. (*)
TASTE PERVERSION														
Indipramine	2	1.5	1	0.9	1	1.00								
Rabozetiline	1	0.5	1	0.5	1	1.00	2	1.9	1.00	2	1.9	1.00	2	2.0
TASTE LOSS														
Indipramine	1	0.5	1	0.9	1	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)

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PHARMACIA CHR 282

NEBOSTINE - PROTOCOL 20124/017
TABLE No.: 57

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 exp. (x)	No Z on Pt exp. (x)	No Z on Pt exp. (x)	No Z on Pt exp. (x)	No Z on Pt exp. (x)	No Z on Pt exp. (x)	No Z on Pt exp. (x)	No Z on Pt exp. (x)	No Z on Pt exp. (x)	No Z on Pt exp. (x)	No Z on Pt exp. (x)	No Z on Pt exp. (x)	No Z on Pt exp. (x)									
URINARY RESISTANCE / RETENTION	2	1.6	1.00	2	1.8	1.00	1	0.9	1.00	2	2.0	1.00	3	3.2	1.00							
URINARY TRACT INFECTION	6	4.6	1.00	8	6.7	1.00	6	5.3	1.00	5	4.7	1.00	5	4.8	1.00	3	3.0	1.00	3	14.3	1.00	
CESTITIS BACTERIURAGIC	1	0.8	1.00				1	0.9	1.00	2	1.9	1.00	1	1.0	1.00	1	1.0	1.00				
													1	1.0	1.00							

(x) number of adverse events on number of patient who complained of adverse events
(some adverse events are grouped in clusters)

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PHARMACIA CHE MSD

REGORSTINE - PROTOCOL 20124-017
TABLE No.: 57

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

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. (%)	No Pt exp. (%)	No Pt exp. (%)	No Pt exp. (%)	No Pt exp. (%)	No Pt exp. (%)	No Pt exp. (%)	No Pt exp. (%)							
BLURRED VISION	4	3.2	1.25	3	2.7	1.00	1	0.9	1.00	2	2.0	1.00	2	2.1	1.00	2	2.2	1.00	2	14.3	1.00
	4	3.1	1.00	4	3.4	1.00	4	3.5	1.00	3	2.8	1.00	3	2.9	1.00	2	2.0	1.00	2	9.5	1.00

Body system: VISION DISORDERS

(*) 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 2012A/017
TABLE No.: 58

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL
BY ASSIGNED TREATMENT AND GROUPED BY BODY SYSTEM

Body system	Assignment treatment	Days of treatment																				
		0-7		8-14		15-21		22-28		29-35		36-42		> 42								
		No Pt	% on exp (x)	No Pt	% on exp (x)	No Pt	% on exp (x)	No Pt	% on exp (x)	No Pt	% on exp (x)	No Pt	% on exp (x)	No Pt	% on exp (x)							
Body system	Pt exposed	126	100	2.81	110	100	1.84	109	100	2.03	100	100	1.90	95	100	2.03	93	100	1.82	14	100	1.56
		130	100	1.64	119	100	1.61	119	100	1.45	107	100	1.64	104	100	1.75	100	1.77	21	100	1.53	
AUTONOMIC NERVOUS SYSTEM DISORDERS	Indipramine	44	34.9	1.11	37	33.6	1.23	35	32.1	1.14	31	31.0	1.09	32	33.7	1.12	29	31.2	1.17	16	146	1.18
	Reboxetine	27	20.8	1.14	26	21.8	1.15	25	22.1	1.12	22	20.6	1.00	21	20.2	1.00	17	17.0	1.05	10	47.6	1.00
CARDIOVASCULAR DISORDERS, GENERAL	Indipramine	25	19.8	1.04	22	20.0	1.04	21	19.3	1.14	18	16.0	1.16	19	11.6	1.27	9	9.7	1.22	2	14.3	1.50
	Reboxetine	12	9.2	1.08	10	8.4	1.20	14	12.4	1.28	12	11.2	1.25	8	7.7	1.50	11	11.0	1.27	3	14.3	1.00
GASTRO-INTESTINAL SYSTEM DISORDERS	Indipramine	18	14.3	1.11	19	17.8	1.10	14	12.8	1.14	15	15.0	1.00	13	13.7	1.15	11	11.8	1.00	2	14.3	1.00
	Reboxetine	22	16.9	1.18	15	12.6	1.00	13	11.5	1.07	9	8.4	1.22	11	10.6	1.18	10	10.0	1.20	5	23.8	1.20
PSYCHIATRIC DISORDERS	Indipramine	14	11.1	1.14	14	12.7	1.00	14	12.8	1.07	13	13.0	1.30	14	14.7	1.14	11	11.8	1.09	2	14.3	1.00
	Reboxetine	16	12.3	1.16	12	10.1	1.16	11	9.7	1.09	8	7.5	1.12	10	9.6	1.10	8	8.0	1.12	5	23.8	1.00
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO	Indipramine	17	13.5	1.11	15	13.6	1.06	15	13.8	1.13	16	16.0	1.12	11	11.6	1.27	9	9.7	1.22	5	35.7	1.20
	Reboxetine	10	7.7	1.00	13	10.9	1.00	11	9.7	1.00	10	9.3	1.00	12	11.5	1.00	4	4.0	1.00	2	9.5	1.00
ULINARY SYSTEM DISORDERS	Indipramine	2	1.6	1.00	2	1.8	1.00	2	1.8	1.00	2	2.0	1.00	3	3.2	1.33						
	Reboxetine	7	5.4	1.00	8	6.7	1.00	7	6.2	1.00	7	6.5	1.00	7	6.7	1.00	4	4.0	1.00	3	14.3	1.00
BODY AS A WHOLE-GENERAL DISORDERS	Indipramine	6	4.8	1.16	5	4.5	1.00	3	2.8	1.00	2	2.0	1.00	2	2.1	1.00	1	1.1	1.00	1	7.1	1.00
	Reboxetine	4	3.1	1.00	4	3.4	1.00	4	3.5	1.00	2	1.9	1.00	2	1.9	1.00	2	2.0	1.00	2	9.5	1.00
VISION DISORDERS	Indipramine	4	3.2	1.25	3	2.7	1.00	1	0.9	1.00	2	2.0	1.00	2	2.1	1.00	2	2.2	1.00	2	14.3	1.00
	Reboxetine	4	3.1	1.00	4	3.4	1.00	4	3.5	1.00	3	2.8	1.00	3	2.9	1.00	2	2.0	1.00	2	9.5	1.00

(CONTINUED)

(x) number of adverse events on number of patient who complained of adverse events

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PHARMACIA CNS BID

REPROTECTIVE - PROTOCOL 20124/017
TABLE No.: 56

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	% exp	No Pt	% exp	No Pt	% exp	No Pt	% exp	No Pt	% exp	No Pt	% exp	No Pt	% exp										
RESPIRATORY SYSTEM DISORDERS	Indipramine	1	0.8	1.00	2	1.8	1.00	2	2.0	1.00	2	2.1	1.00	2	2.2	1.00	1	7.1	1.00						
	Buboxitine				1	0.8	1.00	5	4.4	1.00	4	3.7	1.00	4	3.8	1.00	3	3.0	1.00	2	9.5	1.00			
METABOLIC AND NUTRITIONAL DISORDERS	Indipramine	1	0.8	1.00	1	0.9	1.00	2	1.8	1.50	2	2.0	1.00	2	2.1	1.00	2	2.2	1.00						
	Buboxitine							1	0.9	1.00	3	2.8	1.00	3	2.9	1.00	3	3.0	1.00	3	3.0	1.00	2	9.5	1.00
LIVER AND BILIAL SYSTEM DISORDERS	Indipramine							2	1.8	1.50	2	2.0	1.50	2	2.1	1.50	2	2.2	1.50						
	Buboxitine							2	1.8	1.00	2	1.9	1.00	2	1.9	1.00	2	2.0	1.00	2	2.0	1.00			
SPECIAL SENSES OTHER, DISORDERS	Indipramine	3	2.4	1.00	2	1.8	1.00	1	0.9	1.00	1	1.0	1.00												
	Buboxitine	1	0.8	1.00	1	0.8	1.00	1	0.9	1.00	2	1.9	1.00	2	1.9	1.00	2	2.0	1.00	2	2.0	1.00	2	9.5	1.00
SKIN AND APPENDAGES DISORDERS	Indipramine							1	0.9	1.00															
	Buboxitine	2	1.5	1.00	2	1.7	1.00	1	0.9	1.00	1	0.9	1.00	1	0.9	1.00	3	2.9	1.00	3	3.0	1.00	1	4.5	1.00
MUSCULO-SKELETAL SYSTEM DISORDERS	Indipramine	1	0.8	1.00																					
	Buboxitine	1	0.8	1.00	2	1.7	1.00																		
REPRODUCTIVE DISORDERS, FEMALE	Indipramine																								
	Buboxitine	1	0.8	1.00	1	0.8	1.00	2	1.8	1.00	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00	1	1.0	1.00			
HEARING AND VESTIBULAR DISORDERS	Indipramine	1	0.8	1.00	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						
	Buboxitine							1	0.9	1.00															
RESISTANCE MECHANISM DISORDERS	Indipramine																								
	Buboxitine							1	0.8	1.00	1	0.9	1.00	1	0.9	1.00	1	1.0	1.00						

(CONTINUED)

(*%) number of adverse events on number of patient who complained of adverse events

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PHARMACIA CHE DED
 HEMOXETINE - PROTOCOL 20124/017
 TABLE No.: 58

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL
 BY ASSIGNED TREATMENT AND GROUPED BY BODY SYSTEM

		Days of treatment													
		0-7		8-14		15-21		22-28		29-35		36-42		> 42	
Body system	Assigned treatment	No Pt	% exp (x)	No Pt	% exp (x)	No Pt	% exp (x)	No Pt	% exp (x)	No Pt	% exp (x)	No Pt	% exp (x)	No Pt	% exp (x)
ENDOCRINE DISORDERS	Reboxetine	1	0.6												
	Reboxetine		1.00												
RENATOLOGY DISORDERS	Reboxetine													1	4.6

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(x) number of adverse events on number of patient who complained of adverse events

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
TABLE No.: 59
ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL TREATMENT AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	Relationship																								
	Definito			Probable			Possible			Doubtful			None			Unknown			Missing			Total			
	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	No.	Z	%	
Total adverse events	29	9.6	89	29.4	124	40.9	27	8.9	27	8.9	27	8.9	6	2.0	1	0.3	303	100.0							
MOUTH DRY	21	7.9	64	24.0	106	39.7	42	15.7	25	9.4	6	2.2	3	1.1			267	100.0							
HEADACHE / MIGRAINE	10	20.8	23	47.9	15	31.3											48	100.0							
	7	21.2	12	36.4	13	39.4											33	100.0							
			5	23.8	10	47.6	3	14.3									21	100.0							
			2	7.4	9	33.3	13	48.1	1	3.7	1	3.7	1	3.7	1	3.7	27	100.0							
HYPOTENSION AND RELATED SYMPTOMS	3	11.1	6	22.2	15	55.6	2	7.4									27	100.0							
	2	14.3	4	28.6	4	28.6	2	14.3	1	7.1							14	100.0							
SWEATING INCREASED			9	45.0	11	55.0											20	100.0							
	1	5.0	9	45.0	7	35.0	2	10.0									20	100.0							
NAUSEA AND RELATED SYMPTOMS	4	28.6	4	28.6	5	35.7	1	7.1									14	100.0							
	6	30.0	4	20.0	7	35.0	3	15.0									20	100.0							
INSOMNIA	1	6.3	3	18.8	4	25.0	4	25.0	3	18.8	1	6.3					16	100.0							
	2	18.2	4	36.4	2	18.2	3	27.3									11	100.0							
CONSTIPATION	2	15.4	3	23.1	8	61.5											13	100.0							
			2	15.4	8	61.5	3	23.1									13	100.0							
TACHYCARDIA			4	26.7	8	53.3	2	13.3									15	100.0							
			2	20.0	8	80.0											10	100.0							
AGITATION / ANXIETY / NERVOUSNESS	2	20.0	2	20.0	6	60.0											10	100.0							
	1	9.1	2	18.2	6	54.5	1	9.1									11	100.0							
URINARY HESITANCY / RETENTION	2	28.6			5	71.4											7	100.0							
			6	54.5	5	45.5											11	100.0							

(CONTINUED)
(some adverse events are grouped in cluster)

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PHARMACIA CMS R&D
REBOXETINE - PROTOCOL 20124/017
TABLE No.: 59

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	%		
TREMOR	1	7.7	4	30.8	8	61.5																				
SOMNOLENCE	2	20.0	4	40.0	4	40.0																				
ASTHENIA / FATIGUE	1	14.3	5	71.4	1	14.3																				
PALPITATION			2	33.3	2	33.3	2	33.3																		
			3	50.0	2	33.3	1	16.7																		
BLURRED VISION					5	100.0																				
	1	25.0	1	25.0	2	50.0																				
HYPERTENSION																										
			2	28.6	4	57.1																				
BRONCHITIS																										
INCREASED LIVER ENZYMES			1	33.3	1	33.3	4	100.0																		
INFLUENZA-LIKE SYMPTOMS																										
PARAESTHESIA																										
FLUSHING / HOT FLASHING			1	25.0	3	75.0																				
			1	33.3	2	66.7																				
			1	50.0																						

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
TABLE No.: 59

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	%		
ABDOMINAL PAIN	Imipramine			1	50.0	100.0				1	50.0	100.0														
	Reboxetine			1	33.3	33.3																				
FLATULENCE	Imipramine			1	50.0	100.0																				
	Reboxetine			2	66.7	66.7																				
LIBIDO DECREASED	Imipramine			1	50.0	100.0				1	50.0	100.0														
	Reboxetine			1	33.3	33.3																				
ERYTHEMA / RASH	Imipramine			1	50.0	100.0																				
	Reboxetine			1	50.0	50.0				2	66.7	66.7				1	50.0	50.0								
BACK PAIN	Imipramine																									
	Reboxetine																									
UPPER RESP TRACT INFECTION	Imipramine																									
	Reboxetine																									
TASTE PERVERSION	Imipramine			2	100.0	100.0																				
	Reboxetine			1	50.0	50.0				1	50.0	50.0														
URINARY TRACT INFECTION	Imipramine																									
	Reboxetine																									
ANOREXIA	Imipramine			1	50.0	100.0																				
	Reboxetine																									
SINUSITIS	Imipramine																									
	Reboxetine																									
ARTHRALGIA	Imipramine																									
	Reboxetine																									

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
TABLE No.: 59

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	%		
SUICIDE ATTEMPT	1	50.0																								
CONFUSION				1	50.0	100.0																				
DELUSION																										
FEVER				1	100.0																					
ECG ABNORMAL																										
DIARRHOEA																										
TINNITUS																										
HYPERCHOLESTEROLAEMIA																										
HYPERURICAEMIA																										
MENSTRUAL DISORDER																										
CHEST PAIN																										
HYPONESTHESIA																										
RHINITIS																										
GASTROENTERITIS																										

(CONTINUED)
(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
TABLE No.: 59

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.	%		
SPUTUM INCREASED																									
MANIC REACTION	1	100.0																							
DISPHAGIA																									
PRURITUS																									
SALIVA INCREASED																									
BUNDLE BRANCH BLOCK																									
EXTRASYSTOLES																									
TACHYCARDIA SUPRAVENTRICULAR																									
HYPERKINESIA																									
VERTIGO																									
APPETITE INCREASED																									
OSOPHAGITIS																									
LEUKOCYTOSIS																									
ALOPECIA																									
TASTE LOSS																									
HYPOKINESIA																									
GLOBULINS INCREASED																									
HERPES SIMPLEX																									
OTITIS MEDIA																									
ASTHMA																									
COUGHING																									
DERMATITIS FUNGAL																									

(CONTINUED)

(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

TABLE No.: 59

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.	%	
HYPOTHYROIDISM																	
										1	100.0					1	100.0
HYPERLIPAEMIA																	
									1	100.0						1	100.0
ARTHRALGIA																	
									1	100.0						1	100.0
CYSTITIS HAEMORRHAGIC																	
									1	100.0						1	100.0
PAIN																	
											1	100.0			1	100.0	
AV BLOCK																	
												1	100.0		1	100.0	
CERVICITIS																	
												1	100.0		1	100.0	

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(some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOSETINE - PROTOCOL 20124/017
TABLE No.: 60

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	Adverse events	Relationship						Total
				Possible	Definite	Probable	Doubtful	None	Unknown	
Centre - Patient 1 - 8 (Male)	Ass. treatment Imipramine Reboxetine	3	Adverse events DIZZINESS HEADACHE TREMOR SWEATING INCREASED MOUTH DRY VISION ABNORMAL SOMNOLENCE HEADACHE BACK PAIN TACHYCARDIA MANIC REACTION DELUSION INSOMNIA SUICIDE ATTEMPT HYPERURICAEMIA BUNDLE BRANCH BLOCK DELUSION INSOMNIA	18	1	28	1	3	1	52
				5	1	18	2	2	2	30
				1						1
				1						1
				1						1
				1						1
				1						1
				1						1
				1						1
				1						1
2 - 34 (Male)	Ass. treatment Imipramine	38	Adverse events HEADACHE BACK PAIN						1	1
									1	1
										1
2 - 36 (Female)	Ass. treatment Imipramine	22	Adverse events TACHYCARDIA	1						1
										1
2 - 44 (Male)	Ass. treatment Imipramine	1	Adverse events MANIC REACTION		1					1
										1
2 - 50 (Male)	Ass. treatment Reboxetine	40	Adverse events SUICIDE ATTEMPT			1				1
										1
2 - 51 (Female)	Ass. treatment Reboxetine	12	Adverse events HYPERURICAEMIA BUNDLE BRANCH BLOCK DELUSION INSOMNIA	1						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 CMS R&D

REBOXETINE - PROTOCOL 20124/017
TABLE No.: 60

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	Definite	Probable	Doubtful	None	Unknown	Missing		
7 - 194 (Male)	4	URINARY RETENTION	Reboxetine			1						1
7 - 196 (Female)	39	INSOMNIA	Imipramine	1								1
		RASH	Imipramine			1						1
		AGITATION	Imipramine	1								1
9 - 197 (Male)	4	HEADACHE	Reboxetine				1					1
		ASTHENIA	Reboxetine				1					1
9 - 209 (Male)	4	HEADACHE	Imipramine			1						1
		MOUTH DRY	Imipramine	1								1
		FATIGUE	Imipramine			1						1
9 - 237 (Male)	10	URINARY RETENTION	Reboxetine	1								1
9 - 261 (Female)	7	URINARY RETENTION	Imipramine	1								1
9 - 270 (Female)	7	TACHYCARDIA	Imipramine						1			1
9 - 271 (Female)	22	HEADACHE	Reboxetine	1								1
		HYPERTENSION	Reboxetine	1								1
		TREMOR	Imipramine	1								1
9 - 273 (Female)	22	MOUTH DRY	Imipramine	1								1
		URINARY RETENTION	Imipramine	1								1
		TASTE LOSS	Imipramine	1								1
		CONFUSION	Imipramine	1								1
9/A - 277 (Female)	5	SWEATING INCREASED	Reboxetine				1					1
		INSOMNIA	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 20124/047
TABLE No.: 60

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	Definite	Probable	Doubtful	None	Unknown		Missing
9/A - 277 (Female)	5	AGITATION	Reboxetine			1					1
		HYPOTHYROIDISM	Reboxetine					1			1
9/A - 280 (Female)	7	DIZZINESS	Reboxetine			1					1
		MOUTH DRY	Reboxetine			1					1
		SOMNOLENCE	Reboxetine			1					1
9/A - 307 (Female)	4	TREMOR	Imipramine			1					1
		AGITATION	Imipramine			1					1
9/A - 308 (Female)	25	SWEATING INCREASED	Imipramine			1					1
		FATIGUE	Imipramine			1					1
		NAUSEA	Imipramine			1					1
		URINARY TRACT INFECTION	Imipramine						1		1
11 - 330 (Female)	3	INSOMNIA	Reboxetine			1					1
		NAUSEA	Reboxetine			1					1
13 - 353 (Female)	33	SUICIDE ATTEMPT	Reboxetine		1						1
13 - 355 (Female)	3	DIZZINESS	Reboxetine			1					1
		HEADACHE	Reboxetine			1					1
		NAUSEA	Reboxetine			1					1
		ABDOMINAL PAIN	Reboxetine			1					1
		DISPEPSIA	Reboxetine			1					1
13 - 357 (Female)	5	DIZZINESS	Imipramine			1					1
		SOMNOLENCE	Imipramine			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 20124/017
TABLE No.: 60

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	Definite	Probable	Doubtful	None	Unknown		Missing
13 - 357 (Female)	5	ASTHENIA	Imipramine			1					1
		SINUSITIS	Imipramine	1							1
13 - 358 (Male)	31	DIZZINESS	Reboxetine							1	1
		SWEATING INCREASED	Reboxetine							1	1
13 - 360 (Female)	3	INSOMNIA	Imipramine			1					1
		AGITATION	Imipramine			1					1
		HOT FLUSHES	Imipramine			1					1
14/1 - 129 (Male)	1	MICTURITION DISORDER	Reboxetine			1					1
14/1 - 429 (Female)	4	DIZZINESS	Imipramine			1					1
		HEADACHE	Imipramine			1					1
		MOUTH DRY	Imipramine			1					1
		ASTHENIA	Imipramine			1					1
		FATIGUE	Imipramine			1					1
		NAUSEA	Imipramine			1					1
		ANOREXIA	Imipramine			1					1
14/3 - 427 (Female)	28	GESOPHAGITIS	Imipramine	1							1
15 - 376 (Female)	9	TREMOR	Imipramine			1					1
		DYSPHAGIA	Imipramine			1					1
15 - 379 (Female)	2	MOUTH DRY	Imipramine			1					1
		CONFUSION	Imipramine			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 20124/017

TABLE No.: 60

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	Definite	Probable	Doubtful	None	Unknown		Missing
15 - 379 (Female)	2	TASTE PERVERSION	Imipramine			1					1
15 - 362 (Male)	2	HEADACHE	Imipramine			1					1

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(*) Only adverse events complained on the last day of treatment and still present or resulting in withdrawal

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PHARMACIA CHS 260
 REDONSTINE - PROTOCOL 20124/017
 TABLE No. 1 61
 LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment									
	Indipramine					Rebonstine				
	Days of treatment		22-42		Screen	Days of treatment		22-42		Screen
HB	Evaluated	105	103	88	115	114	114	98		
	Mean	14.47	14.48	14.40	14.46	14.67	14.34			
	STD	1.10	1.22	1.23	1.22	1.77	1.16			
	Min	11.50	10.29	10.29	11.60	11.27	11.70			
	Max	17.25	17.20	17.25	18.03	29.04	17.12			
	Median	14.50	14.56	14.44	14.40	14.50	14.51			
	Median diff.	0.00	-0.15			0.10	0.00			
	P value	0.9638	0.1223			0.4915	0.3634			
	Evaluated	105	103	88	115	113	98			
	Mean	48.90	42.91	42.62	42.86	42.93	42.18			
STD	5.34	5.87	5.38	5.10	4.96	4.22				
Min	32.67	32.67	30.24	33.30	33.50	33.50				
Max	61.50	61.75	57.50	60.80	62.30	52.60				
Median	41.50	41.64	41.90	41.60	42.29	41.63				
Median diff.	0.00	-0.16			0.06	-0.24				
P value	0.8045	0.1070			0.5886	0.0480				
BMC	Evaluated	105	103	88	115	114	98			
	Mean	4.60	4.87	4.64	4.63	4.67	4.62			
	STD	0.48	0.51	0.46	0.54	0.55	0.49			
	Min	3.28	3.52	3.72	3.52	3.38	3.66			
	Max	5.91	6.46	5.83	6.54	6.74	6.04			

(CONTINUED)
 P VALUE: PROBABILITY FROM THE WILCOXON RANK SUM TEST

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PHARMACIA CNS 282
 REDUCTINE - PROTOCOL 20124-017
 TABLE No.: 61
 LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment											
	Isipramine					Babozaline						
	Days of treatment		22-42		4-59		Days of treatment		1-21		22-42	
	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42	Screen	1-21	22-42
CBC	Median	4.49	4.49	4.59	4.56	4.65	4.65	4.65	4.65	4.65	4.65	4.65
	Median diff.		0.00	0.00		0.03		0.03		0.03		0.00
	P value		0.7502	0.8819		0.2265		0.5027				
PLATELETS	Evaluated	95	93	82	110	106	92					
	Mean	297.53	300.55	307.50	297.76	317.69	328.47					
	STD	78.10	75.16	73.18	90.33	87.50	89.36					
	Min	30.75	78.33	145.00	40.50	140.00	169.00					
	Max	486.25	481.25	582.50	598.33	585.00	640.00					
	Median	285.00	290.00	295.50	290.09	309.17	315.00					
	Median diff.		0.00	6.63		4.49	18.60					
P value		0.8127	0.1506		0.0119	0.0007						

C3
 C4
 C5

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CNS RD

REGONITINE - PROTOCOL 20124-0117
TABLE No.: 61

LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO THE INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment									
	Indipacaine					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
CBC	Evaluated	104	103	87	115	114	98			
	Mean	8.04	7.90	7.95	8.15	8.02	7.64			
	STD	1.92	1.94	2.31	2.45	2.05	2.24			
	Min	4.01	2.39	4.01	0.76	3.78	2.88			
	Max	16.53	12.56	20.91	19.02	15.33	14.90			
	Median	7.99	7.85	7.43	8.01	8.06	7.55			
	Median diff.		-0.26	-0.09		-0.13	0.00			
P value		0.2977	0.3405		0.5394	0.5072				
CBC: H	Evaluated	93	89	76	106	105	91			
	Mean	62.44	62.62	62.35	62.39	63.08	63.03			
	STD	5.33	5.62	5.63	5.52	6.79	6.34			
	Min	29.00	31.00	47.00	50.60	52.00	51.00			
	Max	77.00	78.40	91.00	91.00	99.00	115.00			
	Median	63.09	63.27	61.52	62.09	62.09	62.00			
	Median diff.		0.00	-0.67		0.29	0.00			
P value		0.5636	0.3896		0.4123	0.4942				
CBC: E	Evaluated	98	93	84	112	109	95			
	Mean	1.75	1.68	1.66	1.66	1.63	1.54			
	STD	1.32	1.32	1.47	1.32	1.22	1.42			
	Min	-1.00	-1.00	-1.00	-1.00	-1.00	-1.00			
	Max	9.00	8.00	8.33	7.40	9.00	8.33			

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P VALUE: PROBABILITY FROM THE WILCOXON RANK SUM TEST

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PEARLACIA CRIS 880
 REGOJETING - PROTOCOL 2012A/017
 TABLE No.: 61
 LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment												
	Intravenous						Subcutaneous						
	Days of treatment		22-42		1-21		Days of treatment		22-42		1-21		
	Screen	1-21	22-42	1-21	22-42	Screen	1-21	22-42	1-21	22-42	Screen	1-21	22-42
CBC: B	Median	1.51	1.54	1.61	1.61	1.50	1.60	1.68	1.60	1.68	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
	P value		0.5026	0.6247			0.6334	0.9909					
	Evaluated	97	92	82	82	110	107	95					
	Mean	0.39	0.32	0.39	0.39	0.32	0.39	0.40					
CBC: B	STD	0.49	0.46	0.46	0.46	0.41	0.48	0.49					
	Min	0.00	0.00	0.00	0.00	0.00	0.00	0.00					
	Max	3.00	3.00	2.25	2.25	2.25	2.25	1.50					
	Median	0.21	0.07	0.30	0.30	0.11	0.24	0.25					
	Median diff.		0.00	0.00	0.00		0.00	0.00					
CBC: L	P value		0.2454	0.8294			0.2267	0.1843					
	Evaluated	98	94	83	83	114	111	96					
	Mean	27.68	27.94	28.05	28.05	28.32	27.46	27.97					
	STD	4.34	4.09	4.31	4.31	5.03	5.16	5.56					
	Min	13.00	19.20	13.00	13.00	15.00	11.00	5.00					
CBC: M	Max	41.00	38.67	38.67	38.67	42.33	39.67	48.67					
	Median	27.29	27.67	28.20	28.20	26.03	27.00	27.75					
	Median diff.		-0.29	0.00	0.00		-0.30	-0.50					
	P value		0.6694	0.4812			0.1435	0.1411					
	Evaluated	98	94	83	83	114	111	96					
CBC: M	Mean	4.81	4.79	5.01	5.01	4.88	4.96	5.05					

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 P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CNS 820
 REMOXYLINE - PROTOCOL 2012A/017
 TABLE No.: 61

LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment										
	Indipramine					Rabozoline					
	Days of treatment		22-42	2.09	1.74	Days of treatment		1-21	22-42	2.09	1.98
NBC: N	Screen	1-21	1.75	2.09	Screen	1-21	2.09	22-42	1.74	2.09	1.98
	STD		1.82	2.09			1.74		1.74	2.09	1.98
	Min		1.00	0.00			-1.00		1.00	1.00	1.00
	Max		11.00	12.00			10.33		12.00	11.00	11.00
	Median		4.43	4.55			4.36		4.66	4.89	4.89
	Median diff.		0.00	0.00			0.00		0.00	0.00	0.00
	P value		0.9455	0.4900			0.7262		0.7262	0.4834	0.4834

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P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CNS RBD
 CREATININE - PROTOCOL 20124/017
 TABLE No.: 61
 LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment						
	Indapamide			Rabovotine			
	Days of treatment		Screen	Days of treatment		Screen	
CREATININE	Evaluated	103	101	69	115	113	97
	Mean	0.85	0.89	0.88	0.85	0.85	0.84
	STD	0.19	0.18	0.18	0.18	0.17	0.19
	Min	0.05	0.44	0.46	0.49	0.43	0.11
	Max	1.33	1.50	1.51	1.54	1.35	1.55
	Median	0.04	0.87	0.86	0.85	0.86	0.88
	Median diff.		0.00	0.01		0.00	0.00
	P value		0.9163	0.1277		0.7717	0.6945
	Evaluated	39	38	29	40	40	30
	Mean	24.10	23.88	24.29	23.79	25.42	23.87
UREA	STD	6.22	7.14	6.03	5.45	8.40	6.30
	Min	14.20	13.40	13.24	14.02	11.80	15.00
	Max	47.00	54.20	36.60	36.60	47.00	37.40
	Median	25.24	23.05	24.60	23.92	24.38	23.54
	Median diff.		0.44	0.48		1.48	-0.24
	P value		0.7226	0.9785		0.0803	0.5501
	Evaluated	55	54	52	61	61	55
	Mean	13.21	12.92	13.26	14.38	12.96	12.74
	STD	2.99	3.44	3.34	5.70	3.59	3.39
	Min	6.45	5.35	6.43	7.27	3.15	3.70
Max	20.20	20.20	23.50	39.45	19.65	22.40	

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SUM TEST

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PHARMACIA CHE RED
 REDOXITINE - PROTOCOL 20124/017
 TABLE No.: 61
 LABORATORY TEST: URIC ACID AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment									
	Ibuprofen					Rabozetin				
	Days of treatment		Days of treatment		Days of treatment		Days of treatment		Days of treatment	
	Screen	1-21	22-42	12-53	Screen	1-21	22-42	13-05	12-28	Screen
BUN	Median	12.50	12.42	12.53	12.53	13.60	13.05	12.28		
	Median diff.		0.00	0.00	0.00		-0.17	-0.44		
	P value		0.8198	0.9861			0.2657	0.1097		
URIC ACID	Evaluated	99	92	84	100	98	85			
	Mean	4.94	4.96	5.07	4.71	4.80	5.22			
	STD	1.41	1.37	1.50	1.51	1.43	1.31			
	Min	1.62	1.90	1.90	0.05	1.05	1.64			
	Max	8.09	8.10	10.23	7.96	8.88	7.71			
	Median	4.63	4.92	5.11	4.64	4.79	5.29			
	Median diff.		0.00	0.03			0.11	0.31		
	P value		0.6319	0.5595			0.2202	0.0010		

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PRANACTA CHE RED
 RESOMETINE - PROTOCOL 20124/017
 TABLE No. 1 61
 LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment									
	Indiparavine					Bobociclovir				
	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
TOT. PROTEINE	Evaluated	102	93	86	112	110	95			
	Mean	7.46	7.46	7.35	7.39	7.40	7.41			
	STD	0.63	0.62	0.64	0.59	0.66	0.76			
	Min	6.08	4.82	5.77	6.01	6.04	6.24			
	Max	10.49	12.10	9.19	9.25	10.63	11.06			
	Median	7.35	7.44	7.29	7.39	7.31	7.35			
	Median diff.		0.00	-0.09		0.00	0.00			
P value		0.8775	0.4049		0.6906	1.0000				
ALBUMINE	Evaluated	96	94	82	106	107	92			
	Mean	4.20	4.29	4.31	4.20	4.21	4.29			
	STD	0.64	0.47	0.63	0.57	0.61	0.55			
	Min	1.31	3.30	2.94	2.70	1.59	2.59			
	Max	5.90	5.65	6.16	5.44	5.69	5.80			
	Median	4.21	4.34	4.27	4.19	4.19	4.25			
	Median diff.		0.05	0.02		0.00	0.03			
P value		0.2977	0.2049		0.5836	0.2259				
TOT BILIRUBIN	Evaluated	101	99	88	111	110	95			
	Mean	0.54	0.52	0.55	0.57	0.58	0.55			
	STD	0.19	0.19	0.21	0.20	0.25	0.21			
	Min	0.04	0.04	0.09	0.09	0.09	-0.01			
	Max	1.09	1.09	1.00	1.06	1.86	1.08			
	Median									
	Median diff.									

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 P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CHE DED
 REDUCTINE - PROTOCOL 2014/017
 TABLE No.: 61
 LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment							
	Indipramine				Babozetine			
	Days of treatment		Screen		Days of treatment		Screen	
TOT BILIRUBIN	1-21	22-42	1-21	22-42	1-21	22-42	1-21	22-42
	0.52	0.52	0.54	0.54	0.56	0.56	0.55	0.52
	Median	Median diff.	0.00	0.00			-0.02	-0.02
	P value	0.5416	0.8288			0.8994	0.2553	
DIR BILIRUBIN	Evaluated	57	53	47	67	64	52	52
	Mean	0.07	0.07	0.07	0.06	0.07	0.06	0.06
	STD	0.06	0.06	0.07	0.05	0.05	0.05	0.06
	Min	-0.04	-0.04	-0.04	-0.04	-0.04	-0.04	-0.10
	Max	0.31	0.45	0.38	0.30	0.20	0.20	0.22
	Median	0.05	0.04	0.05	0.06	0.06	0.06	0.05
	Median diff.		0.00	0.00			0.00	0.00
	P value		0.5142	0.2766			0.7534	0.4475

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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FRAXPARACETAMOL 325 MG
 REQUESTING - PROTOCOL 20124/017
 TABLE No.: 61
 LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment											
	Indivansin						Rabacoxin					
	Days of treatment		22-42		91		Days of treatment		1-21		22-42	
SGPT	Evaluated	Screen	1-21	22-42	91	22-42	Screen	1-21	22-42	Screen	1-21	22-42
	Mean	105	103	103	91	115	115	115	97	97	97	97
	STD	18.84	20.88	19.88	19.88	18.62	18.62	19.11	19.94	19.94	19.11	19.94
	Min	6.63	25.69	6.87	6.87	6.26	6.26	7.92	6.14	6.14	7.92	6.14
	Max	-7.65	-7.65	8.82	8.82	-4.12	-4.12	8.59	11.25	11.25	8.59	11.25
	Median	42.31	271.54	45.38	45.38	39.23	39.23	76.25	40.91	40.91	76.25	40.91
	Median diff.	18.00	17.75	18.46	18.46	17.69	17.69	17.69	18.57	18.57	17.69	18.57
	P value		0.00	0.00	0.00			0.00	0.86	0.86	0.00	0.86
SGPT	Evaluated	Screen	1-21	22-42	91	22-42	Screen	1-21	22-42	Screen	1-21	22-42
	Mean	105	103	103	91	115	115	115	97	97	97	97
	STD	17.19	21.61	19.94	19.94	17.25	17.25	17.92	18.92	18.92	17.92	18.92
	Min	10.71	43.88	15.94	15.94	9.29	9.29	10.83	10.46	10.46	10.83	10.46
	Max	2.06	-0.36	2.86	2.86	3.21	3.21	0.83	0.84	0.84	0.83	0.84
	Median	65.29	450.19	113.82	113.82	65.29	65.29	56.47	55.00	55.00	56.47	55.00
	Median diff.	15.00	14.69	16.67	16.67	15.29	15.29	15.29	16.43	16.43	15.29	16.43
	P value		0.00	0.56	0.56			0.89	1.39	1.39	0.89	1.39
GAMMA GT	Evaluated	Screen	1-21	22-42	91	22-42	Screen	1-21	22-42	Screen	1-21	22-42
	Mean	105	103	103	91	115	115	112	96	96	112	96
	STD	29.50	27.96	30.47	30.47	26.13	26.13	29.52	27.91	27.91	29.52	27.91
	Min	21.00	19.41	18.94	18.94	21.28	21.28	30.25	17.03	17.03	30.25	17.03
	Max	6.90	7.95	6.90	6.90	5.27	5.27	8.00	8.00	8.00	8.00	8.00
	Median	114.97	120.91	109.33	109.33	195.34	195.34	294.14	133.84	133.84	294.14	133.84
	Median diff.											
	P value		0.9728	0.0804	0.0804			0.8638	0.0818	0.0818	0.8638	0.0818

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 P VALUE: PROBABILITY FROM THE WILCOXON RANK SUM TEST

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PHARMACIA CHEM RED
 RESORCINOL - PROTOCOL 20124/017
 TABLE No.: 61
 LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment									
	Indipromidine					Rebozotidine				
	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
GAMMA GT	Median	22.67	22.67	26.00	24.00	24.11	24.00	24.00	24.11	24.00
	Median diff.		0.00	0.00		0.00		0.00	0.00	0.00
	P value		0.2644	0.9157		0.8151		0.7998		0.7998
	Evaluated	91	88	79	100	99	84	100	99	84
LDH	Mean	315.97	310.76	309.50	310.71	302.00	319.71	302.00	319.71	319.71
	STD	80.69	89.24	85.80	108.07	84.29	109.42	84.29	109.42	109.42
	Min	128.33	96.00	65.33	0.00	79.50	10.80	79.50	10.80	10.80
	Max	664.44	636.03	565.89	632.21	632.21	718.42	632.21	718.42	718.42
	Median	316.35	304.71	305.05	310.15	287.00	324.62	287.00	324.62	324.62
	Median diff.		0.00	2.21		0.00	1.98		0.00	1.98
	P value		0.7929	0.9612		0.4527	0.7652		0.4527	0.7652
ALK. PROSPH.	Evaluated	104	101	90	113	112	95	112	112	95
	Mean	101.67	107.74	108.87	104.28	110.95	106.78	110.95	106.78	106.78
	STD	32.74	32.87	41.05	38.29	44.30	34.44	44.30	44.30	34.44
	Min	17.39	15.41	-16.31	50.60	51.05	48.58	51.05	48.58	48.58
	Max	278.60	270.05	318.50	324.20	449.60	244.40	449.60	244.40	244.40
	Median	98.17	102.62	105.72	97.24	105.08	101.17	105.08	101.17	101.17
	Median diff.		4.45	4.85		2.07	3.11		2.07	3.11
P value		0.0073	0.0032		0.0243	0.0225		0.0243	0.0225	

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CNS RBD
 RESONANCE - PROTOCOL 20124/017
 TABLE No. 1 61
 LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment														
	Indipacaine						Rabacetin								
	Days of treatment		22-42		77		Days of treatment		Screen		1-21		22-42		
Screen	1-21	22-42	77	99	84	Screen	1-21	22-42	77	99	84	Screen	1-21	22-42	
GLOBULINS ALPHA 1	Evaluated	88	84	77	99	84									
	Mean	0.18	0.17	0.18	0.18	0.18	0.18	0.17	0.18	0.18	0.17	0.17	0.18	0.17	0.19
	STD	0.07	0.08	0.08	0.08	0.09	0.09	0.09	0.10	0.10	0.10	0.10	0.09	0.10	0.09
	Min	0.03	0.02	0.04	0.04	0.01	0.01	0.00	0.00	0.00	0.00	0.00	-0.03	0.00	-0.03
	Max	0.83	0.47	0.42	0.42	0.46	0.46	0.47	0.47	0.47	0.47	0.47	0.54	0.47	0.54
	Median	0.17	0.16	0.17	0.17	0.17	0.17	0.16	0.16	0.16	0.16	0.16	0.16	0.16	0.15
	Median diff.		0.00	0.00	0.00			0.00	0.00				0.00	0.00	0.00
P value		0.0392	0.2519				0.2146	0.4481				0.2146	0.4481		
GLOBULINS ALPHA 2	Evaluated	88	84	77	99	84									
	Mean	0.83	0.80	0.84	0.84	0.84	0.84	0.84	0.84	0.84	0.84	0.84	0.84	0.84	0.82
	STD	0.16	0.16	0.20	0.20	0.15	0.15	0.16	0.16	0.16	0.16	0.16	0.16	0.16	0.16
	Min	0.50	0.48	0.51	0.47	0.53	0.53	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35
	Max	1.31	1.26	1.51	1.28	1.59	1.59	1.30	1.30	1.30	1.30	1.30	1.30	1.30	1.30
	Median	0.80	0.80	0.81	0.84	0.83	0.83	0.81	0.81	0.83	0.83	0.81	0.83	0.81	0.81
	Median diff.		-0.01	0.00	0.00			0.00	-0.04				0.00	-0.04	
P value		0.1947	0.7621				0.2272	0.2805				0.2272	0.2805		
GLOBULINS BETA	Evaluated	88	84	77	99	84									
	Mean	0.99	0.95	0.98	0.97	0.96	0.97	0.96	0.97	0.96	0.96	0.97	0.96	0.97	
	STD	0.18	0.16	0.19	0.16	0.16	0.16	0.16	0.16	0.16	0.16	0.16	0.16	0.17	
	Min	0.61	0.46	0.46	0.46	0.62	0.62	0.62	0.62	0.62	0.62	0.62	0.62	0.62	
	Max	1.59	1.36	1.61	1.46	1.58	1.58	1.46	1.46	1.58	1.58	1.58	1.58	1.46	

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 P VALUE: PROBABILITY FROM THE WILCOXON RANK SUMMED TEST

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PHARMACIA CHE 280

NEBOSTINE - PROTOCOL 20124/017
TABLE No.: 61

LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment									
	Inipressine					Eubonoptine				
	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
GLOBULINS BETA	Median	0.99	0.96	0.97	0.95	0.94	0.94	0.94	0.94	0.94
	Median diff.		-0.04	0.00		0.00		0.00	0.00	0.00
	P value		0.0274	0.8985		0.3943	0.7838			
GLOBULINS GAMMA	Evaluated	88	84	77	98	96	84	96	84	84
	Mean	1.12	1.14	1.08	1.13	1.13	1.11	1.13	1.13	1.11
	STD	0.29	0.25	0.29	0.26	0.30	0.27	0.26	0.30	0.27
	Min	0.49	0.73	0.15	0.55	0.49	0.27	0.49	0.49	0.27
	Max	2.23	1.91	1.96	1.69	2.70	1.76	1.69	2.70	1.76
	Median	1.11	1.14	1.11	1.10	1.10	1.09	1.10	1.10	1.09
	Median diff.		0.00	0.00		0.00	-0.00		0.00	-0.00
P value		0.6454	0.3397		0.8587	0.4475				

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PLAZMACIA CNS 820
 HEMOSTASIS - PROTOCOL 20124/017
 TABLE No.: 61
 LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																	
	Indiprudine						Rabostizine											
	Days of treatment		Screen		Days of treatment		Screen		Days of treatment		Screen							
TOT. CHOLEST.	Evaluated	105	100	89	112	110	93											
	Mean	253.79	253.41	264.05	272.25	270.10	271.64											
	STD	60.07	60.57	64.69	66.44	66.05	68.74											
	Min	144.56	129.66	141.45	160.44	162.77	158.84											
	Max	435.30	445.20	515.37	585.13	551.23	585.07											
	Median	247.16	251.44	258.31	264.84	255.95	258.90											
	Median diff.		0.00	12.76			-2.11											
P value		0.8247	0.0276			0.9199	0.7237											
TRIGLYCERIDES	Evaluated	100	97	85	109	107	90											
	Mean	155.65	157.05	162.44	174.36	161.37	145.90											
	STD	157.10	143.62	156.64	220.79	252.32	196.44											
	Min	-494.86	-494.86	-199.43	-136.29	-107.67	-362.86											
	Max	807.71	772.80	888.29	1040.26	2293.49	1285.10											
	Median	131.95	131.37	133.72	120.01	109.76	105.95											
	Median diff.		1.95	5.42			-9.13											
P value		0.9077	0.1943			0.1031	0.0352											
GLUCOSE	Evaluated	101	96	87	112	112	93											
	Mean	90.23	90.10	91.22	92.16	95.81	94.02											
	STD	14.53	15.79	20.86	15.76	20.50	18.04											
	Min	56.21	50.51	62.58	64.75	63.88	48.13											
	Max	142.63	172.38	221.45	157.50	242.50	181.13											
	Median																	
	P value																	

(CONTINUED)
 P VALUE: PROBABILITY FROM THE WILCOXON RANK SUM TEST

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PHARMACIA CIS RD
 REDUCTINE - PROTOCOL 20124/017
 TABLE No.: 61
 LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment								
	Indipramine				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
GLUCOSE	Median	90.00	89.25	88.48	90.19	90.65	91.70		
	Median diff.		-0.60	0.00		0.78	1.40		
	P value		0.9702	0.7151		0.4552	0.9850		

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CBS RD

RESPONSIVE - PROTOCOL 2012A/017
TABLE No.: 61

LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment									
	Indipramine					Risperidone				
	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
MA+	Evaluated	103	100	88	112	112	95			
	Mean	140.96	140.60	141.32	141.07	140.96	140.94			
	STD	2.47	2.95	3.25	2.39	2.89	2.46			
	Min	135.09	125.71	135.27	134.00	133.27	132.00			
	Max	148.00	148.73	156.63	150.00	151.00	146.00			
	Median	141.00	140.55	141.00	141.00	141.00	141.00			
	Median diff.		0.00	0.00			0.00			
	P value		0.3412	0.5378		0.2931	0.5398			
	Evaluated	90	87	75	96	96	81			
	Mean	101.84	101.48	101.96	102.09	101.40	101.06			
STD	2.44	2.50	2.28	2.74	2.83	3.19				
Min	95.60	91.60	95.60	94.80	92.67	90.00				
Max	108.67	109.20	107.60	111.33	110.44	107.78				
Median	102.00	101.56	102.00	102.31	101.67	101.73				
Median diff.		0.00	0.00			-0.31				
P value		0.1164	0.6414		0.0060	0.0002				
K+	Evaluated	99	97	83	109	108	94			
	Mean	4.16	4.30	4.17	4.17	4.28	4.11			
	STD	0.44	0.75	0.46	0.47	0.40	0.55			
	Min	3.12	2.81	3.12	3.41	3.39	1.44			
	Max	5.63	6.83	5.84	6.33	7.51	6.43			

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PHARMACIA CHE RES

REBONEXTINE - PROTOCOL 2012A/017
TABLE No.: 61

LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment												
	Indipravine						Rebonextine						
	Days of treatment		22-42		4.14		Days of treatment		22-42		4.14		
E+	Screen	1-21	4.17	4.20	4.14	4.11	Screen	1-21	4.21	4.10	4.10	22-42	4.10
	Median			0.00	0.05		Median		0.05	-0.08			
	Median diff.			0.7045	0.4966		Median diff.		0.0918	0.5478			
	P value						P value						
Ck++	Evaluated		103	99	88	114	Evaluated		111	95			
	Mean		4.69	4.87	4.89	4.95	Mean		4.95	4.92			
	STD		0.34	0.34	0.31	0.30	STD		0.40	0.32			
	Min		3.88	3.86	4.25	3.70	Min		3.54	4.00			
	Max		5.67	5.55	5.93	5.56	Max		6.64	5.85			
	Median		4.92	4.95	4.90	4.98	Median		4.96	4.95			
	Median diff.			0.00	0.00		Median diff.		0.00	0.00			
	P value			0.5996	0.9562		P value		0.9732	0.8014			
FOA--	Evaluated		85	82	72	93	Evaluated		93	75			
	Mean		1.23	1.25	1.24	1.25	Mean		1.27	1.25			
	STD		0.18	0.22	0.14	0.15	STD		0.15	0.17			
	Min		0.76	0.87	0.84	0.80	Min		0.77	0.91			
	Max		2.01	2.66	1.55	1.85	Max		1.68	1.75			
	Median		1.24	1.24	1.25	1.24	Median		1.27	1.22			
	Median diff.			0.00	0.02		Median diff.		0.02	0.01			
	P value			0.6480	0.4499		P value		0.1764	0.6667			

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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PIRAMAXIA CHS MSD
 REBOSZINIDE - PROTOCOL 20124/017
 TABLE No.: 62

ORIGINALS: NUMBER AND PERCENTAGE OF PATIENTS ACCORDING TO TIME INTERVAL, BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Rebozsinide

	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.	%	No.	%
SPECIFIC GRAVITY	Normal	39	100.0	17	100.0	56	100.0	37	94.9	16	94.1	53	94.6	33	89.2	13	92.9	46	90.2
	Not done							2	5.1	1	5.9	3	5.4	4	10.8	1	7.1	5	9.8
	Total	39	100.0	17	100.0	56	100.0	39	100.0	17	100.0	56	100.0	37	100.0	14	100.0	51	100.0
	Absent	59	95.2	29	87.9	88	92.6	59	95.2	28	94.8	87	91.6	49	90.7	19	70.4	68	84.0
ALBUMIN	Present	3	4.8	4	12.1	7	7.4	1	1.6	3	9.1	4	4.2	2	3.7	2	7.4	4	4.9
	Not done							2	3.2	2	6.1	4	4.2	3	5.6	6	22.2	9	11.1
	Total	62	100.0	33	100.0	95	100.0	62	100.0	33	100.0	95	100.0	54	100.0	27	100.0	81	100.0
	Absent	62	100.0	33	100.0	95	100.0	59	95.2	30	90.9	89	93.7	51	94.4	22	81.5	79	90.1
SUGAR	Present							1	1.6	1	3.0	2	2.1			1	3.7	1	1.2
	Not done							2	3.2	2	6.1	4	4.2	3	5.6	4	14.8	7	8.6
	Total	62	100.0	33	100.0	95	100.0	62	100.0	33	100.0	95	100.0	54	100.0	27	100.0	81	100.0
	Absent	52	82.5	28	87.5	80	84.2	51	81.0	27	84.4	78	82.1	45	83.3	19	73.1	64	80.0
BSC	Present	11	17.5	4	12.5	15	15.8	11	17.5	3	9.4	14	14.7	6	11.1	4	15.4	10	12.5
	Not done							1	1.6	2	6.3	3	3.2	3	5.6	3	11.5	6	7.5
	Total	63	100.0	32	100.0	95	100.0	63	100.0	32	100.0	95	100.0	54	100.0	26	100.0	80	100.0
	Absent	59	83.9	26	81.3	65	69.9	41	67.2	26	81.3	67	72.0	37	69.8	21	80.8	58	73.4
WBC	Present	22	36.1	6	18.8	28	30.1	19	31.1	4	12.5	23	24.7	12	22.6	2	7.7	14	17.7
	Not done							1	1.6	2	6.3	3	3.2	4	7.5	3	11.5	7	8.9
	Total	61	100.0	32	100.0	93	100.0	61	100.0	32	100.0	93	100.0	53	100.0	26	100.0	79	100.0

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PHARMACIA CNS 880
 BENDOSPINE - PROTOCOL 20124/017
 TABLE No.: 62

UTILIZATION: 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	Total	Female	Male	Total	Total	Female	Male	Total							
SPECIFIC GRAVITY	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%			
	35	100.0	15	100.0	50	100.0	34	100.0	13	86.7	47	95.9	27	90.0	15	100.0	42	93.3
	Not done																	
	Total	35	100.0	15	100.0	50	100.0	34	100.0	15	100.0	49	100.0	30	100.0	15	100.0	45
ALBUMIN	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%
	53	96.4	31	96.9	84	96.6	49	90.7	27	84.4	76	88.4	45	95.7	26	89.7	71	93.4
	Present																	
	Not done																	
TOTAL	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%
	55	100.0	32	100.0	87	100.0	54	100.0	32	100.0	86	100.0	47	100.0	29	100.0	76	100.0
	Absent																	
	Present																	
SUGAR	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%
	58	100.0	31	96.9	89	96.9	52	91.2	31	96.9	83	93.3	46	92.0	26	89.7	72	91.1
	Present																	
	Not done																	
BGC	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%
	58	100.0	33	100.0	90	100.0	57	100.0	32	100.0	89	100.0	50	100.0	29	100.0	79	100.0
	Absent																	
	Present																	
BGC	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%
	8	13.8	4	12.1	12	13.2	8	14.0	4	12.1	12	13.3	3	6.0	3	10.0	6	7.5
	Not done																	
	Total																	
BGC	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%
	58	100.0	33	100.0	91	100.0	57	100.0	33	100.0	90	100.0	50	100.0	30	100.0	80	100.0
	Absent																	
	Present																	
BGC	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%
	18	31.6	10	31.3	28	31.5	12	21.4	7	21.9	19	21.6	10	20.4	8	27.6	18	23.1
	Not done																	
	Total																	
BGC	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%	No.	X	%
	57	100.0	32	100.0	89	100.0	56	100.0	32	100.0	88	100.0	49	100.0	29	100.0	78	100.0
	Absent																	
	Present																	

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FRANZACIA CMB B&D

RESORPTIVE - PROTOCOL 20124/017
TABLE No.: 63

URINALYSIS: NUMBER AND PERCENTAGE OF PATIENTS AT LAST ASSESSMENT, BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Randomized

Urinalysis	Total												Last assessment												
	Female						Male						Female						Male						
	No.		%		Z		No.		%		Z		No.		%		Z		No.		%		Z		
	No.	%	Z	No.	%	Z	No.	%	Z	No.	%	Z	No.	%	Z	No.	%	Z	No.	%	Z	No.	%	Z	
SPECIFIC GRAVITY	Normal	35	89.7	16	94.1	51	91.1	2	100.0	3	100.0	5	100.0	33	89.2	13	92.9	46	90.2						
	Not done	4	10.3	1	5.9	5	8.9							4	10.8	1	7.1	5	9.8						
	Total	39	100.0	17	100.0	56	100.0	2	100.0	3	100.0	5	100.0	37	100.0	14	100.0	51	100.0						
ALBUMIN	Absent	57	91.9	25	75.8	82	84.3	8	100.0	6	100.0	14	100.0	49	90.7	19	70.4	68	84.0						
	Present	2	3.2	2	6.1	4	4.2							2	3.7	2	7.4	4	4.9						
	Not done	3	4.8	6	18.2	9	9.5							3	5.6	6	22.2	9	11.1						
Total	62	100.0	33	100.0	95	100.0	8	100.0	6	100.0	14	100.0	54	100.0	27	100.0	81	100.0							
	Absent	58	95.5	28	84.8	86	90.5	7	87.5	6	100.0	13	92.9	51	94.4	22	81.5	73	90.1						
	Present	1	1.6	1	3.0	2	2.1	1	12.5			1	7.1			1	3.7	1	1.2						
Total	3	4.8	4	12.1	7	7.4								3	5.6	4	14.8	7	8.6						
	62	100.0	33	100.0	95	100.0	8	100.0	6	100.0	14	100.0	54	100.0	27	100.0	81	100.0							
	Absent	52	82.6	23	71.9	75	78.9	7	77.8	4	66.7	11	73.3	45	83.3	19	73.1	64	80.0						
Total	8	12.7	6	18.8	14	14.7	2	22.2	2	33.3	4	26.7	6	11.1	4	15.4	10	12.5							
	3	4.8	3	9.4	6	6.3								3	5.6	3	11.5	6	7.5						
	63	100.0	32	100.0	95	100.0	9	100.0	6	100.0	15	100.0	54	100.0	26	100.0	80	100.0							
Total	40	65.6	25	78.1	65	69.9	3	37.5	4	66.7	7	50.0	37	69.8	21	80.8	58	73.4							
	17	27.9	4	12.5	21	22.6	5	62.5	2	33.3	7	50.0	12	22.6	2	7.7	14	17.7							
	4	6.6	3	9.4	7	7.5								4	7.8	3	11.5	7	8.9						
Total	61	100.0	32	100.0	93	100.0	8	100.0	6	100.0	14	100.0	53	100.0	26	100.0	79	100.0							

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FRANCIACA CHE MED
 RESEARCHING - PROTOCOL 20124/017
 TABLE No.1 63

URINALYSIS: NUMBER AND PERCENTAGE OF PATIENTS AT LAST ASSESSMENT, BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Indigunline

Urinalysis	Total												Last assessment											
	Female						Male						Female						Male					
	No.		%		Total		No.		%		Total		No.		%		Total		No.		%		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
SPECIFIC GRAVITY	Normal	32	91.4	15	100.0	47	94.0	5	100.0	5	100.0	27	90.0	15	100.0	42	93.3							
	Not done	3	8.6			3	6.0					3	10.0			3	6.7							
	Total	35	100.0	15	100.0	50	100.0	5	100.0	5	100.0	30	100.0	15	100.0	45	100.0							
ALBUMIN	Absent	53	96.4	29	90.6	82	94.3	8	100.0	3	100.0	11	100.0	45	95.7	26	89.7	71	95.4					
	Present	1	1.6	2	6.3	3	3.4					1	2.1	2	6.3	3	3.9							
	Not done	1	1.6	1	3.1	2	2.3					1	2.1	1	3.4	2	2.6							
Total	55	100.0	32	100.0	87	100.0	8	100.0	3	100.0	11	100.0	47	100.0	29	100.0	76	100.0						
	Absent	54	93.1	29	90.6	83	92.2	8	100.0	3	100.0	11	100.0	46	92.0	26	89.7	72	91.1					
	Present	1	1.7	1	3.1	2	2.2					1	2.0	1	3.4	2	2.5							
Not done	3	5.2	2	6.3	5	5.6							3	6.0	2	6.9	5	6.3						
	Total	58	100.0	32	100.0	90	100.0	8	100.0	3	100.0	11	100.0	50	100.0	29	100.0	79	100.0					
	Absent	50	84.2	28	84.8	78	85.7	6	75.0	3	100.0	9	81.8	44	88.0	25	83.3	69	86.3					
Present	5	8.6	3	9.1	8	8.8	2	25.0			2	18.2	3	6.0	3	10.0	6	7.5						
	Not done	3	5.2	2	6.1	5	5.5					3	6.0	2	6.7	5	6.3							
	Total	58	100.0	33	100.0	91	100.0	8	100.0	3	100.0	11	100.0	50	100.0	30	100.0	80	100.0					
Absent	41	71.9	21	65.6	62	69.7	5	62.5	2	66.7	7	63.6	36	73.5	19	65.5	55	70.5						
	Present	13	22.8	9	28.1	22	24.7	3	37.5	1	33.3	4	36.4	10	28.4	8	27.6	18	23.1					
	Not done	3	5.3	2	6.3	5	5.6					3	6.1	2	6.9	5	6.4							
Total	57	100.0	32	100.0	89	100.0	8	100.0	3	100.0	11	100.0	49	100.0	29	100.0	78	100.0						

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PHARMACIA CHE MSD
 REBOZETINE - PROTOCOL 20124/017
 TABLE No.: 64

UTILIZATION: SHEET 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: Rebozetine

Urinalysis test at baseline	Days of treatment											
	1-31 days						22-62 days					
	Absent	Present	Not done	Total	Absent	Total	Absent	Present	Not done	Total		
ALBUMIN	Absent	04	1	3	86	66	4	5	75			
	Present	3	3	1	7	2		4	6			
	Total	87	4	4	95	68	4	9	81			
SUGAR	Absent	89	2	4	95	79	1	7	81			
	Total	89	2	4	95	79	1	7	81			
	Absent	69	8	3	80	60	4	4	68			
BGC	Present	9	6		15	4	6	2	12			
	Total	76	14	3	95	64	10	6	80			
	Absent	54	10	1	65	49	5	2	56			
WBC	Present	13	13	2	28	9	9	5	23			
	Total	67	23	3	93	58	14	7	79			

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PRASINACIA CIBS 280
 RESCHEDULE - PROTOCOL 20124/017
 TABLE No.: 64

ORIGINALS; SHEET 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: Irigamulin

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	73	7	3	83	63	3	2	74	
	Present	3			3	2			2	
	Total	76	7	3	86	71	3	2	76	
SUGAR	Absent	82	2	4	88	72	1	5	78	
	Present	1			1		1		1	
	Total	83	2	4	89	72	2	5	79	
BDC	Absent	69	6	3	78	61	3	5	69	
	Present	6	6		12	8	3		11	
	Total	75	12	3	90	69	6	5	80	
WBC	Absent	51	6	3	60	44	5	5	54	
	Present	14	13	1	28	11	13		24	
	Total	65	19	4	88	55	18	5	78	

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PHARMACIA CIB 820
 RESOURCING - PROTOCOL 2012A/017
 TABLE No.: 65

URINALYSIS; SPLIT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT URINALYSIS VALUE AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Subcutaneous	Urinalysis test at baseline	Total						Last assessment					
		Total			1-21 days			22-42 days			Total		
		Absent	Present	Not done	Absent	Present	Total	Absent	Present	Total	Not done	Total	
ALSURIN	Absent	79	4	5	68	13		13			4	5	75
	Present	3		4	7	1		1		2		4	6
	Total	82	4	9	95	14		14		6		9	81
SUGAR	Absent	86	2	7	95	13		14		75	1	7	81
	Total	86	2	7	95	13		14		75	1	7	81
	Present	70	6	4	80	10	2	12	60	4	4	4	68
BSC	Present	5	8	2	15	1	2	3	4	6	2	2	12
	Total	75	14	6	95	11	4	15	64	10	6	80	
	Absent	54	9	2	65	5	4	9	49	5	2	56	
BSC	Present	11	12	5	28	2	3	5	9	9	5	23	
	Total	65	21	7	93	7	7	14	58	14	7	79	

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PHARMACIA CBS B&B
 HEMORRHETIC - PROTOCOL 20124/017
 TABLE No.: 65

URINALYSIS: SPLIT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT URINALYSIS VALUE AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Indipromin

	Total						Last assessment					
	Urinalysis test at baseline			1-31 days			22-42 days			Total		
	Absent	Present	Total	Absent	Present	Total	Absent	Present	Total	Absent	Present	Total
ALBUMIN	Absent	3	2	84	10		10	69	3	2	74	
	Present	3		3	1		1	2			2	
	Total	6	2	87	11		11	71	3	2	76	
SUGAR	Absent	1	5	89	11		11	72	1	5	78	
	Present	1		1					1		1	
	Total	2	5	90	11		11	72	2	5	79	
BEC	Absent	4	5	79	9	1	10	61	3	5	69	
	Present	4		12			1	8	3		11	
	Total	8	5	91	9	2	11	69	6	5	80	
BEC	Absent	7	5	61	5	2	7	44	5	5	54	
	Present	13	15	28	2	2	4	11	13		24	
	Total	20	20	89	7	4	11	55	18	5	78	

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PHARMACIA CHE 980
 RESORSTINE - PROTOCOL 20124/017
 TABLE No.1 66
 URINALYSIS: SHEET 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: Eboceetline

Urinalysis test at baseline	Days of treatment					
	1-21 days			22-42 days		
	Normal	Not done	Total	Normal	Not done	Total
SPECIFIC GRAVITY Normal	55	3	56	46	5	51
Total	55	3	56	46	5	51

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PHARMACIA CBS 880

REGIMENE - PROTOCOL 20154/017
TABLE No. 66

URINALYSIS: SUFF 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: Indipramine

Urinalysis test at baseline	Days of treatment					
	1-21 days			22-42 days		
	Normal	Not done	Total	Normal	Not done	Total
SPECIFIC GRAVITY Normal	47	2	49	42	3	45
Total	47	2	49	42	3	45

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PRASINACIA CRIS 820

RESEARCHING - PROTOCOL 20124-017
TABLE No.: 67

URINALYSIS: SPLIT 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: Babovertine

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	51	5	56	5	5	46	5	51
Total	51	5	56	5	5	46	5	51

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PARANACIA CHE 250

RESORPTIVE - PROTOCOL 20124/017
TABLE No.: 67

URINALYSIS: SHEET 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: Iniprandine

Urinalysis test at baseline	Total			Last assessment					
	Normal	Not done	Total	1-21 days		22-42 days		Total	Total
				Normal	Total	Normal	Not done		
SPECIFIC GRAVITY Normal	47	3	50	5	5	42	3	45	
Total	47	3	50	5	5	42	3	45	

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PHARMACIA CHE D&D

REBROUPTINE - PROTOCOL 20124/017
TABLE No.: 68

LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY - SHEET TABLE
NUMBER OF PATIENTS WITH VALUES BELOW, WITHIN OR ABOVE THE NORMAL RANGE ACCORDING TO THE INTERVAL AS COMPARED TO PRE-TREATMENT, BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																	
	Indipramine									Rabocetine								
	Days of treatment						22-42			Days of treatment						22-42		
	1-21	High	P val	Low	High	P val	Low	High	P val	Low	High	P val	Low	High	P val	Low	High	P val
RD	Low	2	1		2	1		2	2		2	2		2	2		2	
	NORMAL		98	1		85	1	104	1		104	1		104	1		88	1
	HIGH		1	0.687		1	0.687		1	0.846		1	0.846		2	0.766		
BT	Low	5	1		5	1		6	5		6	4		6	4		4	1
	NORMAL		87		2	75	1		1	93		1	79	1				
	HIGH		3	0.185		2	0.717		4	0.036		3	0.196					
RBC	Low	4	6		3	6		6	6		6	6		6	6		6	
	NORMAL		8	82	1	4	72	1		3	92	2		4	78	1		
	HIGH		1	0.867		2	0.693		1	0.513		2	0.693		2	0.693		
PLATELETS	Low		3		1	2			4			4			5			
	NORMAL		1	74	5		66	2		1	81	7		66	8			
	HIGH		7	3	0.513		4	5	0.264		5	9	0.213		4	9	0.042	

P val : probability from Maxwell's test

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PHARMACIA CHE RED

RESORCINONE - PROTOCOL 20124-017
TABLE No. 1 66

LABORATORY TEST; HAEMATOLOGY AND BLOOD CHEMISTRY - SHEET 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																	
	Inipresanina									Rebortolone								
	Days of treatment						1-21			22-42			Days of treatment			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
HSC	LOW	1		1			1	3	1				1	4				
	NORMAL	4	88	5	1	76	5	2	94	2			1	81	5			
	HIGH	3	2	0.517	3	1	0.779	7	4	0.276	1	5	2	0.582				
HSC: H	LOW	2	3	1		4	1		6	3	2		5	4	1			
	NORMAL	4	65	5	4	59	3	2	81	2		4	65	3				
	HIGH	4	5	0.617	1	3	1.000	2	7	0.466	4	5	0.945					
HSC: E	LOW	10	1		10	1		8	7		8	8						
	NORMAL	6	67	3	5	60	3	6	75	5	8	63	1					
	HIGH	1	2	0.100	2	3	0.239	1	6	1	0.846	4	3	0.407				
HSC: B	LOW																	
	NORMAL		75	8		69	5		94	5		79	10					
	HIGH	9	1	0.000	7	1	0.774	4	2	1.000	5	1	0.302					
HSC: L	LOW	3	3		2	4		7	3		3	5	1					
	NORMAL	6	67	4	4	59	5	6	76	5	6	62	4					
	HIGH	1	5	0.395	1	7	1.000	1	7	0.346	1	6	0.852					
HSC: H	LOW	3	2	1	3	3	1	5	1	1	1	5	1					
	NORMAL	1	74	6	5	57	6	6	82	5	5	71	8					
	HIGH	1	5	10.892	5	3	0.784	3	5	0.062	1	4	0.041					

P val : probability from Maxwell's test

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PHARMACIA CHEMIE

REBOURNE - PROTOCOL 20124/017
TABLE No. 1 68

LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY - SPLIT TABLE
NUMBER OF PATIENTS WITH VALUES BELOW, BETWEEN OR ABOVE THE NORMAL RANGE ACCORDING TO TIME INTERVAL AS COMPARED TO PRE-TREATMENT, BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																			
	Indipramine									Rebourline										
	Days of treatment						1-21			22-42			1-21			22-42				
	Low	Norm.	High	P val	Low	High	P val	Low	High	P val	Low	High	P val	Low	High	P val	Low	High	P val	
CREATININE	1	2			1					1										
		91	5			79	6			1	108	1			2			92		
		1	1	0.097		2		0.223			1		1	0.607			1		1	0.223
UREA	1	1			2					1										
		2	31		1	24	1			3	30	5						26	2	
		1		0.717		1		0.846					1	0.018					1	0.223
BUN	1	1								1										
		2	45		4		47	2		3	51	1			1	45			3	
		2		0.607				2	0.223				3	0.135		1	4		1	0.944
URIC ACID	2	3			3	1				3	6				3	3				
		1	71		6		1	66	4		2	75	5					66	5	
		4		0.497		3		6	0.931		1	4		2	0.603				2	4

P val : probability from Maxwell's test

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PHARMACIA CNS R&D

REBOXetine - PROTOCOL 20124/017
TABLE No. 1 68

LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY - REPT 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																		
	Indipramine									Reboxetine									
	Days of treatment						1-21			22-42			Days of treatment						
	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
TOT. PROTEINS	1	2			1	2				2	1								
	4	83	4		4	72	6			4	97	1				3	82	4	
									0.264										
ALBUMINE	2	7			3	4				4	5								
	2	71	3		5	59	2			5	78	4				4	67	4	
									0.194										
TOT BILIRUBIN	1																		
	1	94	1		1	85				2	103	2				1	86	3	
									0.223										
BIP BILIRUBIN	1	1			1	1													
		49	1			43	1				61					2	49	1	
									0.368										

386

P val : probability from Maxwell's test

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PHARMACIA CHE RED

REDUCTINE - PROTOCOL 20124-017
TABLE No.: 68

LABORATORY TEST: LABORATORY AND BLOOD CHEMISTRY - SUFFI TABLE
NUMBER OF PATIENTS WITH VALUES BELOW, WITHIN OR ABOVE THE NORMAL RANGE ACCORDING TO THE INTERVAL AS COMPARED TO PRE-TREATMENT, BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment											
	Indigermine						Rabocetine					
	Days of treatment						Days of treatment					
	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	
BOUT	LOW	1		1			1					
	NORMAL	1	91	5		80	6		103	2		
	HIGH	4	1	0.574	2	2	0.289	3	3	0.549	2	3
SUFFI	LOW	1	3		1	1			2			
	NORMAL	1	82	7	1	71	8		92	6		
	HIGH	5	4	0.513	6	2	0.664	3	5	0.290	3	3
GANDA GT	LOW	1			1				2			
	NORMAL	1	81	3	1	68	7		95	4		
	HIGH	10	7	0.092	7	6	0.607	4	7	0.363	6	3
LOW	LOW	2	3		2	3			5	6		
	NORMAL	2	70	5	1	64	3		70	3		
	HIGH	3	3	0.705	1	5	0.368	7	5	0.273	8	4
ALK. PHOSPH.	LOW	2			1	1			1	2		
	NORMAL	96	1		85				101	3		
	HIGH	2	1	0.000	2	1	0.000	1	4	0.223	2	2

P val : probability from Maxwell's test

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PHARMACIA CNS 860

REBROSTIN - PROTOCOL 20124/017
TABLE No.1 68

LABORATORY TEST: HEMATOLOGY AND BLOOD CHEMISTRY - RESULT 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																								
	Intravenous												Subcutaneous												
	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		
Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	P val	
GLUCOSYLINS ALPHA 1	5	3			4	3						9	2							6	3				
	6	64	3		5	61	3					9	65	3						3	58	3			
		1							1	0.174			1	5	3	0.051				5	4	0.779			
GLUCOSYLINS ALPHA 2	2	2			1	2	1					2	3							3	2				
	6	57	4		7	49	5					2	66	10						1	59	7			
		10	3	0.102		7	5	0.443				7	7	0.694						7	5	0.846			
GLUCOSYLINS BETA	1	2			1	1						1	1												
	2	57	5		3	49	8					3	65	10						2	59	8			
		11	6	0.325		7	8	0.887				8	9	0.943						7	6	0.967			
GLUCOSYLINS GAMMA	2	7			4	5						4	6							4	5				
	2	66	3		6	57	2					3	78	3						3	68	2			
		3	1	0.249		3	0.665					2	0.549							1	1	0.944			

P val : probability from Maxwell's test

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PHARMACIA CNS RSD

REGOUSTINE - PROTOCOL 2012A/017
TABLE No.: 65

LABORATORY TEST; HAEMATOLOGY AND BLOOD CHEMISTRY - SHEET TABLE
NUMBER OF PATIENTS WITH VALUES BELOW, WITHIN OR ABOVE THE NORMAL RANGE ACCORDING TO THE INTERVAL AS COMPARED TO PRE-TREATMENT, BY ASSIGNED TREATMENT

Laboratory test	Assigned treatment																					
	Iniprusinase									Reboxetinase												
	Days of treatment						1-21			22-42			1-21			22-42						
	Low	Nor.	High	P val	Low	High	Nor.	P val	Low	High	Nor.	P val	Low	High	Nor.	P val	Low	High	Nor.	P val		
TOT. CHOLEST.	1	1			1																	
	1	50	13		1	46	11													43	7	
				7	27	0.407		12	18	0.378		10	38	0.454		14	29	0.189				
TRIGLYCERIDES	3	3	1		2	3																
	2	58	2		2	44	7															
				9	19	0.182		6	20	1.000		5	11	0.820		4	11	0.363				
GLUCOSE	2	4			2	3	1															
	3	71	7		4	62	7															
				6	3	0.896		4	4	0.510		11	7	0.275		9	6	0.747				

P val : probability from Maxwell's test

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PHARMACIA CHEMIE

REBUCETINE - PROTOCOL 20124/017
TABLE No. 1 65

LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY - SHEET 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																	
	Indiprandine									Rebucetine								
	Days of treatment						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
HA+	LOW	1	1				2						1					
	NORMAL	1	95	2	2	75	3	5	102	2			2	90				
	HIGH	2		1.000	1	1	0.607						2	0.264				0.511
CL-	LOW	1	2				1					4						
	NORMAL	3	77	2	3	66	3	3	94	1			10	64	2			
	HIGH	2		0.905	2		0.549					3	1	0.155				0.025
E+	LOW	1	1				2						1					
	NORMAL	3	86	5	2	78	1	2	99	2			4	85	2			
	HIGH			1	0.050				0.223				3	1	0.766			0.135
Ca++	LOW	5	7				2	6				4						
	NORMAL	5	79	1	6	68	2	5	96	4			5	82	2			
	HIGH	2		0.717	2		0.867					1	0.107					0.946
PO4---	LOW	2	4				3	4				1	2					
	NORMAL	5	64	3	1	61	1	2	79	6			2	61	7			
	HIGH	4		0.881	2		0.944					3	0.607					0.249

P val : Probability from Maxwell's test

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PHARMACIA CHE MSD
 ZEPORSTINE - PROTOCOL 20124/017
 TABLE No.: 49

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	%
EB	Eval.	105	100.0	103	100.0	83	100.0
	down			1	1.0	1	1.1
BT	Eval.	105	100.0	103	100.0	86	100.0
	down					1	1.1
BSC	Eval.	115	100.0	114	100.0	96	100.0
	down	1	0.9	1	0.9	1	1.0
PLATELETS	Eval.	95	100.0	93	100.0	82	100.0
	down	1	1.1				
	up					1	1.2
BSC	Eval.	110	100.0	106	100.0	92	100.0
	down	1	0.9				
	up	1	0.9	2	1.9	2	2.2
BSC	Eval.	104	100.0	103	100.0	87	100.0
	up	1	1.0			1	1.1
	down						
BSC	Eval.	115	100.0	114	100.0	96	100.0
	down	1	0.9				
	up	2	1.7	1	0.9	1	1.0
BSC: H	Eval.	93	100.0	89	100.0	76	100.0
	down	2	2.2				
	up						
BSC: E	Eval.	108	100.0	105	100.0	91	100.0
	up					1	1.1
	down						
BSC: E	Eval.	98	100.0	93	100.0	84	100.0
	up	5	5.1	5	5.4	5	6.0
	down						

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PHARMACIA CNS 890
 REDUCTINE - PROTOCOL 2014/017
 TABLE No.: 69

LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE

Laboratory test / Assigned treatment	Eval.	Days of treatment					
		Screen		1-21		22-42	
		No	Z	No	Z	No	Z
RBC: E	Subcutaneous	112	100.0	109	100.0	95	100.0
	up	7	6.3	1	0.9	4	4.2
RBC: B	Indipramine	97	100.0	92	100.0	82	100.0
	up	7	7.2	3	3.3	4	4.9
RBC: A	Subcutaneous	110	100.0	107	100.0	95	100.0
	up	5	4.5	6	5.6	11	11.6
RBC: I	Indipramine	98	100.0	94	100.0	85	100.0
	down	3	3.1	1	1.1	1	1.2
RBC: K	Subcutaneous	114	100.0	111	100.0	96	100.0
	down	2	1.8	3	2.7	1	1.0
RBC: N	Indipramine	96	100.0	94	100.0	83	100.0
	up	4	3.5			2	2.1
UREA	Subcutaneous	114	100.0	111	100.0	96	100.0
	up	3	2.6	6	5.4	5	5.2
BUN	Indipramine	99	100.0	98	100.0	29	100.0
	up			1	2.6		
URIC ACID	Subcutaneous	61	100.0	61	100.0	55	100.0
	up	3	4.9				
RBC: L	Indipramine	95	100.0	92	100.0	84	100.0
	up	1	1.1			1	1.2
RBC: M	Subcutaneous	100	100.0	96	100.0	83	100.0
	up						

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PHARMACIA CHEM BRD
 REBOXETINE - PROTOCOL 20124/017
 TABLE No.: 69
 LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE

Laboratory test / Assigned treatment	Scores	Days of treatment					
		1-21		22-42			
		No	Z	No	Z	No	Z
URIC ACID	up	1	1.0	2	2.0		
	Eval.	102	100.0	99	100.0	68	100.0
TOT. PROTEINS	up			1	1.0		
	Eval.	111	100.0	110	100.0	93	100.0
TOT BILIRUBIN	up			1	0.9		
	Eval.	57	100.0	55	100.0	47	100.0
DEX BILIRUBIN	up			1	1.9		
	Eval.	105	100.0	103	100.0	91	100.0
SGOT	up			1	1.0		
	Eval.	115	100.0	113	100.0	97	100.0
SGPT	up			1	0.9		
	Eval.	105	100.0	103	100.0	91	100.0
GAMMA GT	up	1	1.0	1	1.0	3	3.3
	Eval.	115	100.0	113	100.0	97	100.0
ALB. PROTEIN	up	1	0.9				
	Eval.	105	100.0	103	100.0	90	100.0
ALB. PROTEIN	up	4	3.5	3	2.5	4	4.4
	Eval.	115	100.0	112	100.0	96	100.0
ALB. PROTEIN	up	2	1.7	3	2.7	1	1.0
	Eval.	113	100.0	112	100.0	95	100.0
GLUCOLIN ALPHA 1	up			1	0.9		
	Eval.	88	100.0	84	100.0	77	100.0
GLUCOLIN ALPHA 1	down			1	1.2		
	Eval.						

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PHARMACIA CNS BID
 BOBONITINE - PROTOCOL 2012A/017
 TABLE No.1 69
 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 1	Indipramine	up	1	1.1	1	1.2							
	Bobonitine	Eval.	99	100.0	97	100.0	84	100.0					
		down	1	1.0	3	3.1	2	2.4					
GLOBULINS ALPHA 2		up	1	1.0	4	4.1	1	1.2					
	Indipramine	Eval.	88	100.0	84	100.0	77	100.0					
		up					3	3.9					
GLOBULINS BETA	Bobonitine	Eval.	99	100.0	97	100.0	84	100.0					
		up	1	1.0	2	2.1	1	1.2					
	Indipramine	Eval.	85	100.0	84	100.0	77	100.0					
GLOBULINS GAMMA		up	2	2.3			2	2.6					
	Bobonitine	Eval.	99	100.0	97	100.0	84	100.0					
		up	2	2.0	1	1.0	1	1.2					
TOT. COLEST.	Indipramine	Eval.	88	100.0	84	100.0	77	100.0					
		down											
		up	1	1.1									
TRIGLYCERIDES	Bobonitine	Eval.	98	100.0	96	100.0	84	100.0					
		down			1	1.0	1	1.2					
		up			1	1.0							
TOTAL	Indipramine	Eval.	103	100.0	100	100.0	89	100.0					
		up	4	3.9	3	3.0	5	5.6					
	Bobonitine	Eval.	112	100.0	110	100.0	93	100.0					
TOTAL		up	10	8.9	11	10.0	7	7.5					
		Eval.	100	100.0	97	100.0	85	100.0					

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PHARMACIA CIS 880
 REBOXETINE - PROTOCOL 20124/017
 TABLE No.: 69
 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	%	No	Z	%
TRIGLYCERIDES	up	14	14.0	10	10.3	14	16.5					
	Eval.	109	100.0	107	100.0	90	100.0					
	up	12	11.0	8	7.5	6	6.7					
GLUCOSE	Eval.	101	100.0	96	100.0	87	100.0					
	down			1	1.0							
	up	3	3.0	2	2.1	2	2.3					
Reboxetine	Eval.	112	100.0	112	100.0	93	100.0					
	down					1	1.1					
	up	3	2.7	4	3.6	3	3.2					
MA+	Eval.	103	100.0	100	100.0	88	100.0					
	down			1	1.0							
	up					1	1.1					
E+	Eval.	99	100.0	97	100.0	83	100.0					
	down			1	1.0							
	up			3	3.1							
Reboxetine	Eval.	109	100.0	108	100.0	94	100.0					
	down					1	1.1					
	up	1	0.9	2	1.9	1	1.1					
Ca++	Eval.	114	100.0	111	100.0	95	100.0					
	up			1	0.9							
	down											
PO4--	Eval.	85	100.0	82	100.0	72	100.0					
	down	5	5.9	1	1.2	1	1.4					
	up	1	1.2	2	2.4							

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PRINACIA CBS RED
 RECHNUNG - PROTOCOL 20124/017
 TABLE No.: 69
 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	%
PO4--			93	100.0		93	100.0		75	100.0
	Subcutaneous									
			1	1.1		1	1.1		1	1.3
			1	1.1		1	1.1		2	2.7

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PHARMACIA CHR 860
 REBONETINE - PROTOCOL 20154/017
 TABLE No.: 70

BLOOD PRESSURE AND HEART RATE: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Babcockine

Vital signs	LIZING												STANDING																
	time interval						time interval						time interval						time interval										
	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70	Day 77	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 63	Day 70	Day 77					
S.B.P.	Evaluated	128	127	114	108	107	103	95	127	126	115	108	107	103	95	126.2	125.6	126.5	127.2	125.9	127.3	129.6	129.6	121.1	120.3	122.1	121.4	123.4	125.0
	Mean	17.4	18.9	15.4	16.8	14.4	15.3	15.0	17.8	17.9	16.5	17.5	16.3	16.3	16.7	17.4	18.9	15.4	16.8	14.4	15.3	15.0	17.8	17.9	16.5	17.5	16.3	16.3	16.7
	STD	120.0	120.0	125.0	125.0	125.0	125.0	130.0	120.0	120.0	120.0	121.0	120.0	120.0	120.0	120.0	120.0	125.0	125.0	125.0	125.0	130.0	120.0	120.0	121.0	120.0	120.0	120.0	120.0
	Median	95.0	85.0	95.0	90.0	95.0	90.0	90.0	90.0	90.0	80.0	85.0	80.0	90.0	85.0	95.0	85.0	95.0	90.0	95.0	90.0	90.0	90.0	80.0	85.0	80.0	90.0	90.0	85.0
	Min	210.0	210.0	160.0	190.0	160.0	200.0	165.0	210.0	200.0	160.0	170.0	160.0	160.0	170.0	210.0	210.0	160.0	190.0	160.0	200.0	165.0	210.0	200.0	160.0	170.0	160.0	160.0	170.0
D.B.P.	Evaluated	128	127	114	108	107	103	95	127	126	115	108	106	103	95	78.9	78.1	76.7	75.3	77.7	78.4	79.1	79.5	78.4	79.2	78.9	79.7	80.3	
	Mean	11.5	12.4	11.1	11.7	9.2	9.6	9.5	11.9	12.6	11.8	12.8	10.4	10.8	10.9	11.5	12.4	11.1	11.7	9.2	9.6	9.5	11.9	12.6	11.8	12.8	10.4	10.8	10.9
	STD	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	80.0
	Median	60.0	50.0	45.0	45.0	60.0	60.0	60.0	45.0	50.0	45.0	45.0	45.0	55.0	40.0	60.0	50.0	45.0	45.0	60.0	60.0	60.0	45.0	50.0	45.0	45.0	55.0	60.0	40.0
	Min	130.0	145.0	105.0	110.0	100.0	120.0	100.0	135.0	140.0	110.0	115.0	110.0	110.0	110.0	130.0	145.0	105.0	110.0	100.0	120.0	100.0	135.0	140.0	110.0	115.0	110.0	110.0	110.0
Heart Rate	Evaluated	126	124	113	107	106	101	94	125	122	112	104	106	101	93	75.7	79.4	79.0	78.1	79.5	79.8	79.2	82.2	85.9	86.6	85.2	84.3	86.1	86.1
	Mean	9.2	11.2	10.1	11.6	11.8	12.0	11.7	10.5	12.5	12.3	12.6	13.0	13.0	14.1	9.2	11.2	10.1	11.6	11.8	12.0	11.7	10.5	12.5	12.3	12.6	13.0	13.0	14.1
	STD	76.0	78.0	78.0	76.0	80.0	80.0	76.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	76.0	78.0	78.0	76.0	80.0	80.0	76.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0
	Median	54.0	60.0	60.0	56.0	60.0	60.0	60.0	56.0	60.0	60.0	60.0	60.0	60.0	60.0	54.0	60.0	60.0	56.0	60.0	60.0	60.0	56.0	60.0	60.0	60.0	60.0	60.0	60.0
	Min	100.0	108.0	110.0	116.0	126.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	124.0	100.0	108.0	110.0	116.0	126.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0

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PHARMACIA CNS 880
RESPIRATORIE - PROTOCOL 2012A/017
TABLE No. 1 70

BLOOD PRESSURE AND HEART RATE: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Injpramline

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	118	117	106	106	96	92	90	120	120	107	106	96	92	90	120	120	107	106	96	92	90	120	120	107	106	96	92	90	
	Mean	127.5	127.6	125.9	126.9	126.2	126.4	127.3	125.6	121.9	120.6	123.4	123.0	124.1	123.6	125.6	121.9	120.6	123.4	123.0	124.1	123.6	125.6	121.9	120.6	123.4	123.0	124.1	123.6	
	STD	15.8	17.5	16.7	18.2	15.0	16.9	18.0	15.5	17.7	17.1	19.3	17.2	18.4	17.5	15.5	17.7	17.1	19.3	17.2	18.4	17.5	15.5	17.7	17.1	19.3	17.2	18.4	17.5	
	Median	125.0	125.0	125.0	125.0	120.0	120.0	125.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	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
	Min	90.0	75.0	88.0	90.0	100.0	100.0	80.0	80.0	85.0	85.0	75.0	75.0	85.0	90.0	85.0	85.0	75.0	75.0	85.0	85.0	90.0	85.0	85.0	75.0	75.0	85.0	85.0	90.0	90.0
D.B.P.	Evaluated	118	117	106	106	96	92	90	120	120	107	106	96	92	90	120	120	107	106	96	92	90	120	120	107	106	96	92	90	
	Mean	77.5	78.3	77.1	79.3	77.6	79.0	78.3	79.7	78.4	77.1	79.1	79.1	80.5	80.1	79.7	78.4	77.1	79.1	79.1	80.5	80.1	79.7	78.4	77.1	79.1	79.1	80.5	80.1	
	STD	10.1	12.8	11.2	10.9	10.3	11.3	12.4	10.7	12.2	11.7	13.2	11.4	11.9	12.5	10.7	12.2	11.7	13.2	11.4	11.9	12.5	10.7	12.2	11.7	13.2	11.4	11.9	12.5	
	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	80.0	80.0
	Min	60.0	40.0	60.0	60.0	60.0	60.0	60.0	55.0	40.0	50.0	45.0	50.0	50.0	60.0	45.0	50.0	50.0	45.0	50.0	50.0	60.0	45.0	50.0	50.0	45.0	50.0	50.0	60.0	60.0
Heart Rate	Evaluated	117	116	104	106	94	90	89	117	115	103	104	92	88	87	117	115	103	104	92	88	87	117	115	103	104	92	88	87	
	Mean	76.4	79.6	79.6	80.7	80.3	79.4	78.6	82.0	87.5	86.5	88.2	87.2	85.5	85.0	82.0	87.5	86.5	88.2	87.2	85.5	85.0	82.0	87.5	86.5	88.2	87.2	85.5	85.0	
	STD	9.9	13.3	11.6	12.2	12.2	12.9	11.0	11.4	15.3	14.1	15.4	15.2	15.0	13.6	11.4	15.3	14.1	15.4	15.2	15.0	13.6	11.4	15.3	14.1	15.4	15.2	15.0	13.6	
	Median	76.0	78.0	76.0	80.0	80.0	76.0	76.0	80.0	84.0	84.0	85.0	84.0	82.5	84.0	80.0	84.0	84.0	85.0	84.0	82.5	84.0	80.0	84.0	84.0	85.0	84.0	82.5	84.0	
	Min	54.0	52.0	60.0	56.0	58.0	56.0	51.0	60.0	60.0	60.0	60.0	60.0	64.0	60.0	60.0	60.0	60.0	60.0	60.0	64.0	60.0	60.0	60.0	60.0	60.0	64.0	60.0	60.0	
Max	104.0	150.0	116.0	115.0	112.0	120.0	112.0	116.0	156.0	120.0	120.0	120.0	120.0	120.0	116.0	156.0	120.0	120.0	120.0	120.0	120.0	120.0	116.0	156.0	120.0	120.0	120.0	120.0		

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PRAXINACIA CBS RED
 RESORGINE - PROTOCOL 20124/017
 TABLE No.: 71
BLOOD PRESSURE AND HEART RATE: SUMMARY STATISTICS ON CHANGES FROM BASELINE OBSERVED DURING TREATMENT ACCORDING TO TIME INTERVAL BY ARMED TREATMENT

Assigned treatment: Raboxetine

Vital signs	LYING												STANDING												
	Time Interval						Time Interval						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	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
S.B.P.	Evaluated	127	114	108	107	103	95	126	115	108	107	103	95	127	114	108	107	103	95	126	115	108	107	103	95
	Mean	-0.9	-0.4	0.1	-0.9	0.5	2.2	-2.7	-3.8	-2.2	-2.4	-0.3	0.3	-0.9	-0.4	0.1	-0.9	0.5	2.2	-2.7	-3.8	-2.2	-2.4	-0.3	0.3
	STD	15.4	17.7	19.1	15.1	16.0	16.8	14.7	15.9	17.8	16.3	16.6	17.0	15.4	17.7	19.1	15.1	16.0	16.8	14.7	15.9	17.8	16.3	16.6	17.0
	Median	0.0	0.0	0.0	0.0	0.0	5.0	0.0	-5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5.0	0.0	-5.0	0.0	0.0	0.0	0.0
	Min	-50.0	-70.0	-85.0	-65.0	-70.0	-50.0	-50.0	-70.0	-85.0	-65.0	-65.0	-50.0	-50.0	-70.0	-85.0	-65.0	-70.0	-50.0	-50.0	-70.0	-85.0	-65.0	-65.0	-50.0
	Max	40.0	60.0	60.0	40.0	100.0	40.0	50.0	45.0	45.0	60.0	60.0	50.0	40.0	60.0	60.0	40.0	50.0	45.0	45.0	45.0	60.0	60.0	60.0	50.0
D.B.P.	Evaluated	127	114	106	107	103	95	126	115	108	106	103	95	127	114	106	107	103	95	126	115	108	106	103	95
	Mean	-0.9	-0.3	0.5	-1.0	0.1	0.5	-0.8	-1.0	-0.4	-0.3	0.7	1.1	-0.9	-0.3	0.5	-1.0	0.1	0.5	-0.8	-1.0	-0.4	-0.3	0.7	1.1
	STD	10.7	13.9	12.4	11.3	12.6	11.2	10.8	14.1	12.9	10.9	13.3	12.2	10.7	13.9	12.4	11.3	12.6	11.2	10.8	14.1	12.9	10.9	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Min	-45.0	-59.0	-45.0	-40.0	-40.0	-35.0	-35.0	-64.0	-45.0	-35.0	-40.0	-40.0	-45.0	-59.0	-45.0	-40.0	-40.0	-35.0	-35.0	-64.0	-45.0	-35.0	-40.0	-40.0
	Max	20.0	35.0	35.0	30.0	55.0	30.0	30.0	40.0	40.0	30.0	30.0	25.0	20.0	35.0	35.0	30.0	55.0	30.0	30.0	40.0	40.0	35.0	30.0	25.0
Heart Rate	Evaluated	124	113	107	106	101	94	122	112	104	106	101	93	124	113	107	106	101	94	122	112	104	106	101	93
	Mean	3.8	3.2	2.4	3.7	3.7	3.5	3.7	4.0	2.4	3.6	3.4	3.6	3.8	3.2	2.4	3.7	3.7	3.5	3.7	4.0	2.4	3.6	3.4	3.6
	STD	10.7	11.1	12.1	12.6	12.4	13.3	11.6	11.4	13.1	12.1	12.6	14.9	10.7	11.1	12.1	12.6	12.4	13.3	11.6	11.4	13.1	12.1	12.6	14.9
	Median	2.0	0.0	0.0	2.0	4.0	0.0	2.0	0.0	0.0	0.0	3.0	2.0	2.0	0.0	0.0	2.0	4.0	0.0	2.0	0.0	0.0	0.0	3.0	2.0
	Min	-26.0	-20.0	-30.0	-24.0	-23.0	-25.0	-20.0	-20.0	-40.0	-20.0	-20.0	-28.0	-26.0	-20.0	-30.0	-24.0	-23.0	-25.0	-20.0	-20.0	-40.0	-20.0	-20.0	-28.0
	Max	32.0	36.0	32.0	40.0	32.0	46.0	44.0	40.0	46.0	40.0	40.0	70.0	32.0	36.0	32.0	40.0	32.0	46.0	44.0	40.0	46.0	40.0	40.0	70.0

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PHARMACIA CIS RD

RESORSTINE - PROTOCOL 20124/017
TABLE No.: 71

BLOOD PRESSURE AND HEART RATE: SUMMARY STATISTICS ON CHANGES FROM BASELINE OBSERVED DURING TREATMENT ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Indipramine

Vital signs	LYING										STANDING									
	Time interval					Time interval					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	117	106	106	96	92	90	120	107	106	96	92	90	120	107	106	96	92	90	
	Mean	-0.0	-1.2	-0.6	-1.2	-0.1	-1.3	-3.7	-4.4	-2.1	-2.4	-2.4	-2.4	-3.7	-4.4	-2.1	-2.4	-2.4	-2.4	
	STD	13.8	16.0	14.9	11.9	15.4	15.6	15.6	17.3	16.0	14.9	15.4	16.5	15.6	17.3	16.0	14.9	15.4	16.5	
	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	-45.0	-60.0	-55.0	-35.0	-50.0	-65.0	-70.0	-50.0	-45.0	-60.0	-50.0	-50.0	-70.0	-50.0	-45.0	-60.0	-50.0	-50.0	
	Max	40.0	50.0	40.0	30.0	50.0	30.0	50.0	35.0	40.0	35.0	40.0	35.0	50.0	35.0	40.0	35.0	40.0	35.0	
D.B.P.	Evaluated	117	106	106	96	92	90	120	107	106	96	92	90	120	107	106	96	92	90	
	Mean	0.6	0.6	2.7	0.7	1.7	1.2	-1.3	-2.0	-0.2	-0.8	0.3	0.2	-1.3	-2.0	-0.2	-0.8	0.3	0.2	
	STD	10.8	10.3	11.0	9.9	11.0	11.0	11.1	11.3	11.4	11.1	11.1	11.2	11.1	11.3	11.4	11.1	11.2	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	0.0	0.0	
	Min	-45.0	-30.0	-20.0	-35.0	-20.0	-45.0	-30.0	-25.0	-40.0	-30.0	-25.0	-30.0	-45.0	-30.0	-25.0	-40.0	-30.0	-30.0	
	Max	30.0	40.0	30.0	30.0	40.0	20.0	30.0	30.0	30.0	30.0	30.0	30.0	20.0	30.0	30.0	30.0	30.0	30.0	
Heart Rate	Evaluated	116	104	104	94	90	89	115	103	104	92	88	87	115	103	104	92	88	87	
	Mean	3.4	3.5	4.3	3.9	3.1	2.7	5.5	4.4	6.1	4.7	3.3	3.1	5.5	4.4	6.1	4.7	3.3	3.1	
	STD	11.6	10.6	11.2	11.1	10.8	11.4	13.3	13.3	14.0	11.6	12.1	13.5	13.3	13.3	14.0	11.6	12.1	13.5	
	Median	1.0	4.0	4.0	2.0	2.0	2.0	4.0	2.0	4.0	2.0	4.0	4.0	4.0	2.0	4.0	2.0	4.0	4.0	
	Min	-12.0	-26.0	-20.0	-24.0	-20.0	-32.0	-22.0	-28.0	-32.0	-28.0	-20.0	-28.0	-22.0	-28.0	-32.0	-28.0	-20.0	-28.0	
	Max	78.0	38.0	46.0	38.0	40.0	36.0	84.0	48.0	49.0	44.0	50.0	56.0	48.0	48.0	49.0	44.0	50.0	56.0	

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PRAXIACIA CHE RED

REBOUSTINE - PROTOCOL 20144/017
TABLE No.: 72

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: Reboustine

Vital signs	LXING	STANDING											
		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
S.B.P.	Evaluated No	127	114	108	107	103	95	126	115	108	107	103	95
	Decrease (1) No	3	2	2	2	1	1	5	3	2	3	3	3
	Decrease (1) %	2.4	1.8	1.9	1.9	1.0	1.1	4.0	2.6	1.9	2.8	2.9	3.2
S.B.P.	Evaluated No	8	2	2	2	4	5	1	2	1	4	2	3
	Increase (2) No	6.3	1.8	1.9	1.9	3.9	5.3	0.8	1.7	0.9	3.7	1.9	3.2
	Increase (2) %	7.9	1.6	1.7	1.8	3.8	5.6	1.0	1.6	0.8	3.5	2.0	3.5
D.B.P.	Evaluated No	127	114	108	107	103	95	126	115	108	107	103	95
	Decrease (1) No	5	4	2	4	2	2	4	9	2	6	2	2
	Decrease (1) %	3.9	3.5	1.9	3.7	1.9	2.1	3.2	7.8	1.9	5.6	1.9	2.1
D.B.P.	Evaluated No	5	7	5	7	8	6	5	9	7	6	11	9
	Increase (2) No	3.9	6.1	4.6	6.5	7.8	6.3	4.0	7.8	6.5	5.6	10.7	9.5
	Increase (2) %	3.1	5.3	4.2	6.0	7.6	6.0	3.2	6.4	6.0	5.2	10.3	9.5
Both	Evaluated No	4	7	4	2	4	3	5	5	5	2	2	3
	Decrease (1) No	3.1	6.1	3.7	1.9	3.9	3.2	4.0	4.3	4.6	1.9	1.9	3.2
	Decrease (1) %	7.7	8.7	9.1	4.5	9.8	7.4	8.0	8.7	9.1	4.6	4.6	3.2
Heart rate	Evaluated No	124	113	107	106	101	94	123	113	107	106	101	94
	Decrease (1) No	3	1	4	4	1	3	1	1	2		1	3
	Decrease (1) %	2.4	0.9	3.7	3.8	1.0	3.2	0.8	0.9	1.9		1.0	3.2
Heart rate	Evaluated No	24	17	17	17	19	19	16	16	14	13	13	17
	Increase (2) No	19.4	15.0	15.9	16.0	18.8	20.2	18.0	14.2	13.1	12.3	12.9	18.1
	Increase (2) %	80.0	88.1	91.2	93.2	97.8	100.0	92.0	85.8	86.9	87.7	87.0	94.9

(1) decrease \Rightarrow 20 % of baseline value
(2) increase \Rightarrow 20 % of baseline value

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PRAMACIA CNS 820
 REPORTING - PROTOCOL 20124-017
 TABLE No.: 72

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: Indinavir

Vital signs	LIVING	STANDING											
		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
S.B.P.	Evaluated No	117	106	106	96	92	90	120	107	106	96	92	90
	Decrease (1) No	1	3	2	1	2	3	3	4	5	2	2	6
	Decrease (1) %	0.9	2.8	1.9	1.0	2.2	3.3	2.5	3.7	4.7	2.1	2.2	6.7
	Increase (2) No	3	1	2	2	2	3	2	2	3	3	3	3
	Increase (2) %	2.6	0.9	1.9	2.1	2.2	3.3	1.7	1.9	2.8	3.1	3.3	3.3
	Evaluated No	117	106	106	96	92	90	120	107	106	96	92	90
D.B.P.	Decrease (1) No	4	1	3	4	3	2	6	6	5	1	4	3
	Decrease (1) %	3.4	0.9	2.8	4.2	3.3	2.2	5.0	5.6	4.7	1.0	4.3	3.3
	Increase (2) No	6	6	10	7	5	10	6	4	8	8	10	7
	Increase (2) %	5.1	5.7	9.4	7.3	5.4	11.1	5.0	3.7	7.5	8.3	10.9	7.8
	Evaluated No	117	106	106	96	92	90	120	107	106	96	92	90
	Decrease (1) No	1	1	2			3	5	5	3	3		1
Both	Decrease (1) %	0.9	0.9	1.9			3.3	4.2	4.7	2.8	3.1		1.1
	Increase (2) No	2	1	3		2	1	1	2	3	1	3	2
	Increase (2) %	1.7	0.9	2.8		2.2	1.1	0.8	1.9	2.8	1.0	3.3	2.2
	Evaluated No	116	104	106	94	90	89	118	105	106	94	90	90
	Decrease (1) No		1	1	2		3	1	1	2	1	1	4
	Decrease (1) %		1.0	0.9	2.1		3.4	0.8	1.0	1.9	1.1	1.1	4.4
Heart rate	Increase (2) No	13	12	12	17	9	10	19	15	19	15	9	10
	Increase (2) %	11.2	11.5	11.3	18.1	10.0	11.2	16.1	14.3	17.9	16.0	10.0	11.1
	Evaluated No												

(1) decrease => 20 % of baseline value
 (2) increase => 20 % of baseline value

PHARMACIA CNS R&D

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REBOXETINE - PROTOCOL 20124/017

TABLE No.: 73

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	1			2	3	
		Increase	3					
	D.B.P. (2)	Decrease	3	2	3	9	3	2
		Increase	7	3	1	4	2	1
	BOTH (1 & 2)	Decrease	4			12	1	
		Increase	2		1	3		1
	HEART RATE (3)	Increase	10	4	2	12	5	8
Reboxetine	S.B.P. (1)	Decrease	5			4	2	1
		Increase	4			6		1
	D.B.P. (2)	Decrease	10	4	3	12	3	2
		Increase	8	1	1	7	3	1
	BOTH (1 & 2)	Decrease	3	1		3		2
		Increase	1		1	1		
	HEART RATE (3)	Increase	15	7	1	20	5	9

- (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 CIS BID
 REGONSTINE - PROTOCOL 20124-017
 TABLE No. 1 74
 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
Indipramine	Eval.	120	120	120	107	106	96	92	90		
	No.	1	1	7	4	3	2	3	4		
	Z	0.8	0.8	5.8	3.7	2.8	2.1	3.3	4.4		
	Mean	30.0	30.0	34.3	36.3	36.7	35.0	36.7	36.0		
	Max.	30.0	30.0	40.0	40.0	50.0	40.0	40.0	45.0		
Bebozetine	Eval.	128	129	128	115	108	107	103	95		
	No.	1	3	5	5	5	2	2	3		
	Z	0.8	2.3	3.9	4.3	4.6	1.9	1.9	3.2		
	Mean	30.0	31.7	35.0	42.0	36.0	35.0	36.0	30.0		
	Max.	30.0	35.0	45.0	50.0	50.0	40.0	40.0	30.0		

(*) orthostatic hypotension = decrease of systolic blood pressure in standing position \Rightarrow 30 mm hg as compared to lying position

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PEARMACTA CNS BID

RESUME - PROTOCOL 2024/017
TABLE No.: 75

BODY HEIGHT: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Subcutaneous

Sex		Time Interval										
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
Female	Evaluated	83	82	72	66	67	65	59				
	Mean	64.7	64.7	64.3	64.7	64.1	64.4	64.8				
	STD	8.7	8.7	8.3	8.6	8.5	8.9	9.0				
	Median	64.5	64.0	64.0	63.8	63.6	63.4	64.4				
	Min	44.0	44.0	43.0	42.5	43.0	43.5	43.5				
	Max	83.7	83.5	83.9	84.2	83.9	83.4	83.9				
Male	Evaluated	46	46	43	41	38	36	34				
	Mean	76.3	76.2	74.8	74.4	74.1	74.6	74.4				
	STD	12.1	12.1	10.5	10.4	10.4	10.4	10.5				
	Median	76.3	77.7	77.2	75.5	74.0	74.2	74.0				
	Min	49.6	50.0	50.0	50.0	50.0	50.0	50.0				
	Max	120.0	120.0	97.0	95.0	95.0	97.0	97.0				
Total	Evaluated	129	128	115	107	105	101	93				
	Mean	68.8	68.8	68.2	68.4	67.7	68.0	68.3				
	STD	11.4	11.5	10.5	10.4	10.4	10.4	10.6				
	Median	67.0	67.4	65.8	67.3	66.5	67.5	67.8				
	Min	44.0	44.0	43.0	42.5	43.0	43.5	43.5				
	Max	120.0	120.0	97.0	95.0	95.0	97.0	97.0				

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PHARMACIA CNS RSD

REBOUCHELINE - PROTOCOL 20124/017
TABLE No.: 75

BODY WEIGHT: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Indipramine

Sex		Time interval									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
Female	Evaluated	78	77	67	66	62	57	57			
	Mean	65.3	63.3	64.4	65.4	65.4	65.4	65.8			
	STD	11.5	11.5	9.9	11.4	11.3	11.1	11.0			
	Median	64.0	64.0	62.2	62.7	64.3	64.5	65.0			
	Min	47.0	47.0	47.0	47.5	46.5	46.0	47.0			
	Max	102.0	102.0	95.0	103.0	103.0	103.0	102.0			
Male	Evaluated	41	41	35	37	34	33	32			
	Mean	78.5	78.2	78.7	78.0	78.8	78.9	79.1			
	STD	14.3	13.9	13.6	13.6	14.6	14.7	15.2			
	Median	78.0	78.0	79.0	78.5	79.7	79.5	79.8			
	Min	37.5	36.5	38.0	38.0	37.0	35.3	36.0			
	Max	123.0	117.0	115.0	114.0	114.0	114.0	116.0			
Total	Evaluated	119	118	105	105	96	90	89			
	Mean	69.8	69.8	69.1	69.2	70.3	70.3	70.6			
	STD	14.0	13.8	13.5	13.8	14.0	14.1	14.1			
	Median	68.7	68.5	68.1	68.0	69.6	69.0	69.4			
	Min	37.5	36.5	38.0	38.0	37.0	35.3	36.0			
	Max	123.0	117.0	115.0	114.0	114.0	114.0	116.0			

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PIRAMACIA CMS RMD

REBOCETINER - PROTOCOL 2012A/017
TABLE No.1 76

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: Rebocetinas

Sex		Time interval											
		Day 7		Day 14		Day 21		Day 28		Day 35		Day 42	
		No	%	No	%	No	%	No	%	No	%	No	%
Female	Lower	1	1.2			4	6.1	4	6.0	7	10.8	7	11.9
	Same	76	95.1	68	94.4	59	89.4	59	88.1	56	86.2	49	83.1
	Higher	3	3.7	4	5.6	3	4.5	4	6.0	2	3.1	3	5.1
	Total	80	100.0	72	100.0	66	100.0	67	100.0	65	100.0	59	100.0
Male	Lower					1	2.4	2	5.3	3	8.3	3	8.8
	Same	46	100.0	41	95.3	36	92.7	34	89.5	31	84.1	26	82.4
	Higher			2	4.7	2	4.9	2	5.3	2	5.6	3	8.8
	Total	46	100.0	43	100.0	41	100.0	38	100.0	36	100.0	34	100.0
Total	Lower	1	0.8			5	4.7	6	5.7	10	9.9	10	10.8
	Same	124	96.9	109	94.5	97	90.7	93	86.6	87	84.1	77	82.8
	Higher	3	2.3	6	5.2	5	4.7	6	5.7	4	4.0	6	6.5
	Total	128	100.0	115	100.0	107	100.0	105	100.0	101	100.0	93	100.0

(*) LOWER: decrease > 2.5 Kg.
HIGHER: increase > 2.5 Kg.

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PEARADIACIA CINE RED
 REBOUSTINE - PROTOCOL 2012A/017
 TABLE No.: 76

BODY HEIGHT: NUMBER AND PERCENTAGE OF PATIENTS WITH VALUES LOWER OR HIGHER (*) THAN PRE-TREATMENT AT EACH EVALUATION TIME, BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Isigpramiso

Sex		Time interval											
		Day 7		Day 14		Day 21		Day 28		Day 35		Day 42	
		No	%	No	%	No	%	No	%	No	%	No	%
Female	Lower	4	5.2	2	3.0	5	7.4	4	6.5	4	7.0	3	5.3
	Same	69	89.6	63	84.0	60	88.2	55	88.7	47	82.5	49	86.0
	Higher	4	5.2	2	3.0	3	4.4	3	4.8	6	10.5	5	8.8
	Total	77	100.0	67	100.0	68	100.0	62	100.0	57	100.0	57	100.0
Male	Lower			1	2.6	1	2.7	2	5.9	4	12.1	3	9.4
	Same	39	95.1	36	94.7	32	86.5	29	85.3	26	78.8	26	81.5
	Higher	2	4.9	1	2.6	4	10.8	3	8.8	3	9.1	3	9.4
	Total	41	100.0	38	100.0	37	100.0	34	100.0	33	100.0	32	100.0
Total	Lower	4	3.4	3	2.9	6	5.7	6	6.3	8	8.9	6	6.7
	Same	108	91.5	99	84.3	92	87.6	84	87.5	73	81.1	75	84.3
	Higher	6	5.1	3	2.9	7	6.7	6	6.3	9	10.0	8	9.0
	Total	118	100.0	105	100.0	105	100.0	96	100.0	90	100.0	89	100.0

(*) LOWER: decrease > 2.5 Kg.
 HIGHER: increase > 2.5 Kg.

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FARMACIA CIS RAD
 REDONITINE - PROTOCOL 2012A/017
 TABLE No.: 77
 E.C.G.: NUMBER AND PERCENTAGE OF PATIENTS WITH ABNORMAL E.C.G. ACCORDING TO TIME INTERVALS, BY ASSIGNED TREATMENT AND SEX

Assigned treatment/Rox	Eval.	No.	Female			Male			Total		
			Screening	1-21 days	22-42 days	Screening	1-21 days	22-42 days	Screening	1-21 days	22-42 days
Indipramine	Eval.	No.	64	64	53	34	32	32	98	96	85
	Normal	No.	61	59	48	29	26	26	90	85	74
	Z		95.31	92.19	90.57	85.29	81.25	81.25	91.64	88.64	87.06
	Abnormal	No.	3	5	5	5	6	6	6	11	11
Reboxetine	Eval.	No.	71	71	67	40	39	38	111	106	92
	Normal	No.	67	64	54	34	30	21	101	94	75
	Z		94.37	90.14	80.45	85.00	76.92	63.64	90.99	88.68	81.52
	Abnormal	No.	4	7	13	6	9	12	10	12	17
Z		5.63	9.86	19.55	15.00	23.08	36.36	9.01	11.32	18.48	

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PFAMACIA C86 B80
 REDOXETINE - PROTOCOL 20124/017
 TABLE No.: 78
 E.C.G.: SHEET 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	No.	Time interval			
		1-21 days		22-42 days	
		Abnormal	Normal	Abnormal	Normal
Interpretative	Abnormal	3	4	4	3
	Σ	42.9	57.1	57.1	42.9
	Normal	8	81	7	71
Total	Σ	9.0	91.0	9.0	91.0
	No.	11	85	11	74
	Σ	11.5	86.5	12.9	87.1
Subocclusive	Abnormal	4	5	4	3
	Σ	44.4	55.6	57.1	42.9
	Normal	8	89	13	72
Total	Σ	8.2	91.8	16.3	84.7
	No.	12	94	17	75
	Σ	11.3	86.7	16.5	81.5

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PHARMACIA CNS 280
 REDUCING - PROTOCOL 20124/017
 TABLE No.: 79
 E.C.G.: SHEET 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.	%
Indipramine	Abnormal	4	50.0		4	50.0	8	100.0	
	Normal	8	8.9		82	91.1	90	100.0	
	Total	12	12.2		86	87.8	98	100.0	
Reboxetine	Abnormal	5	50.0		5	50.0	10	100.0	
	Normal	16	15.8		85	84.2	101	100.0	
	Total	21	18.9		90	81.1	111	100.0	

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PHARMACIA CIB 880

REBORSTINE - PROTOCOL 20124/017
TABLE No.: 50

E.C.G. NUMBER AND PERCENTAGE OF E.C.G. ABNORMALITIES OBSERVED DURING THE STUDY, BY ASSIGNED TREATMENT

E.C.G. abnormality type	Imipramine						Reborstine					
	Screening		1-21 days		22-42 days		Screening		1-21 days		22-42 days	
	No	%	No	%	No	%	No	%	No	%	No	%
Evaluated Pt	98	100.0	96	100.0	85	100.0	111	100.0	106	100.0	92	100.0
A-V BLOCK 1ST DEGREE	2	2.0	3	3.1	1	1.2	1	0.9			1	1.1
ATRIAL ECTOPIC BEATS - OCCASIONAL	1	1.0									1	1.1
CONDUCTION DISORDER											1	1.1
LEFT ANTERIOR HEMIBLOCK	1	1.0					1	0.9	1	0.9		
LEFT BUNDLE BRANCH BLOCK									2	1.9		
LEFT POSTERIOR HEMIBLOCK											1	1.1
LEFT VENTRICULAR HYPERTROPHY					1	1.2						
MYOCARDIAL ISCHEMIA	1	1.0			1	1.2						
OTHER												
PREVIOUS MYOCARDIAL INFARCTION	1	1.0	1	1.0	1	1.2	3	2.7	2	1.9	2	2.2
RIGHT BUNDLE BRANCH BLOCK					1	1.2			1	0.9	1	1.1
RIGHT INCOMPLETE BUNDLE BRANCH BLOCK			1	1.0			1	0.9				
REPOLARIZATION DISTURBANCES							1	0.9				
SINUS BRADYCARDIA (< 60)	2	2.0	1	1.0	2	2.4	1	0.9	1	0.9	1	1.1
SINUS TACHYCARDIA (> 100)	2	2.0	6	6.3	4	4.7	4	3.6	4	3.8	6	6.7
VENTRICULAR ECTOPIC BEATS - OCCASIONAL			1	1.0	3	3.5	1	0.9	1	0.9		

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PRAMIACIA CBS RED
REBOXETINE - PROTOCOL 20124/017
TABLE No.: 81

E.C.G.: MEET 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	%	
E.C.G. Abnormality	Baseline							
	A-V BLOCK 1ST DEGREE	110	100.0			110	100.0	
	Present			1	100.0	1	100.0	
ATRIAL ECTOPIC BEATS - OCCASIONAL	Baseline	110	99.1	1	0.9	111	100.0	
	Absent	110	99.1	1	0.9	111	100.0	
	Present							
CONDUCTION DISORDER	Baseline	110	99.1	1	0.9	111	100.0	
	Absent	110	99.1	1	0.9	111	100.0	
	Present							
LEFT ANTERIOR HEBILBLOCK	Baseline	110	100.0			110	100.0	
	Absent	110	100.0			110	100.0	
	Present							
LEFT BUNDLE BRANCH BLOCK	Baseline	111	100.0			111	100.0	
	Absent	111	100.0			111	100.0	
	Present							
LEFT POSTERIOR HEBILBLOCK	Baseline	110	99.1	1	0.9	111	100.0	
	Absent	110	99.1	1	0.9	111	100.0	
	Present							

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PHARMACIA CHE 250
 REDUCING TIME - PROTOCOL 20124/017
 TABLE No.: 81

E.C.G.: SKEPT 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						Total	
		Absent		Present		Total		Total	
		No	%	No	%	No	%	No	%
E.C.G. Abnormality	Baseline								
	Present								
	Total	110	99.1	1	0.9	111	100.0		
LEFT POSTERIOR HEBTBLCK	Baseline								
	Present	111	100.0			111	100.0		
	Total	111	100.0			111	100.0		
ECOCARDIAL ISCHEMIA	Baseline								
	Present	111	100.0			111	100.0		
	Total	111	100.0			111	100.0		
OTHER	Baseline								
	Present	109	98.2	2	1.8	111	100.0		
	Total	109	98.2	2	1.8	111	100.0		
PREVIOUS ECOCARDIAL INFARCTION	Baseline								
	Present	1	0.9	2	1.8	3	2.7		
	Total	1	0.9	2	1.8	3	2.7		
RIGHT BUNDLE BRANCH BLOCK	Baseline								
	Present	110	99.1	1	0.9	111	100.0		
	Total	110	99.1	1	0.9	111	100.0		

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PHARMACIA CNS RED
REBOZENTINE - PROTOCOL 2012A/017
TABLE No.: 81

E.C.G.: SIFT 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: Rebozentine

		Last assessment										
		Absent			Present			Total				
		No	Z	%	No	Z	%	No	Z	%		
E.C.G. Abnormality	Baseline											
	Absent	110	100.0					110	100.0			
	Present	1	100.0					1	100.0			
	Total	111	100.0					111	100.0			
EXPLANATION DISTURBANCES	Baseline											
	Absent	109	99.1		1	0.9		110	100.0			
	Present	1	100.0					1	100.0			
	Total	110	99.1		1	0.9		111	100.0			
SLUGS BRADYCARDIA (< 60)	Baseline											
	Absent	109	99.1		1	0.9		110	100.0			
	Present	1	100.0					1	100.0			
	Total	110	99.1		1	0.9		111	100.0			
SLUGS TACHYCARDIA (> 100)	Baseline											
	Absent	98	91.6		9	8.4		107	100.0			
	Present	3	75.0		1	25.0		4	100.0			
	Total	101	91.0		10	9.0		111	100.0			
VENTRICULAR ECTOPIC BEATS - OCCASIONAL	Baseline											
	Absent	110	100.0					110	100.0			
	Present	1	100.0					1	100.0			
	Total	111	100.0					111	100.0			

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PHARMACIA CHE EMD
 RESOGENTINE - PROTOCOL 2012A/017
 TABLE No.1 B1

E.C.G.: SHEET 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: Isipravone

		Last assessment									
		Absent			Present			Total			
		No	%	No	%	No	%	No	%		
E.C.G. Abnormality	Baseline										
	A-V BLOCK 1ST DEGREE	95	99.0	1	1.0	96	100.0				
	Total	2	100.0			2	100.0				
ATRIAL ECTOPIC BEATS - OCCASIONAL	Baseline										
	Absent	97	100.0			97	100.0				
	Total	1	100.0			1	100.0				
CONDUCTION DISORDER	Baseline										
	Absent	98	100.0			98	100.0				
	Total	98	100.0			98	100.0				
LEFT ANTERIOR HEMIBLOCK	Baseline										
	Absent	97	100.0			97	100.0				
	Total	1	100.0			1	100.0				
LEFT BUNDLE BRANCH BLOCK	Baseline										
	Absent	98	100.0			98	100.0				
	Total	98	100.0			98	100.0				
LEFT POSTERIOR HEMIBLOCK	Baseline										
	Absent	96	100.0			96	100.0				
	Total	96	100.0			96	100.0				

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PERIARACTA CHS RSD

RESOLUTION - PROTOCOL 20124/017
TABLE No.: 51

E.C.G.: SPLIT 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: Indipranolol

		Last assessment										
		Absent			Present			Total				
		No	%	z	No	%	z	No	%	z		
E.C.G. Abnormality	Baseline											
	Absent	97	99.0	1	1.0		98	100.0				
	Present											
	Total	97	99.0	1	1.0		98	100.0				
MYOCARDIAL ISCHEMIA	Baseline											
	Absent	97	100.0				97	100.0				
	Present			1	100.0		1	100.0				
	Total	97	99.0	1	1.0		98	100.0				
OTHER	Baseline											
	Absent	96	100.0				96	100.0				
	Present											
	Total	96	100.0				96	100.0				
PREVIOUS MYOCARDIAL INFARCTION	Baseline											
	Absent	96	99.0	1	1.0		97	100.0				
	Present	1	100.0				1	100.0				
	Total	97	99.0	1	1.0		98	100.0				
RIGHT BUNDLE BRANCH BLOCK	Baseline											
	Absent	97	99.0	1	1.0		98	100.0				
	Present											
	Total	97	99.0	1	1.0		98	100.0				
RIGHT INCOMPLETE BUNDLE BRANCH BLOCK	Baseline											
	Absent	96	100.0				96	100.0				
	Present											
	Total	96	100.0				96	100.0				

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PHARMACIA CIS R&D

REDOCKETING - PROTOCOL 20124/017

TABLE No.: 81

E.C.G.: SPLIT 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: Isipravastatin

	Baseline	Last assessment					
		Absent		Present		Total	
		No	%	No	%	No	%
E.C.G. Abnormality REGULARIZATION DISTURBANCES	Baseline						
	Absent	98	100.0			98	100.0
	Total	98	100.0			98	100.0
SINUS BRADYCARDIA (< 60)	Baseline						
	Absent	95	99.0	1	1.0	96	100.0
	Present	1	50.0	1	50.0	2	100.0
	Total	96	98.0	2	2.0	98	100.0
SINUS TACHYCARDIA (> 100)	Baseline						
	Absent	92	95.8	4	4.2	96	100.0
	Present	1	50.0	1	50.0	2	100.0
	Total	93	94.9	5	5.1	98	100.0
VENTRICULAR ECTOPIC BEATS - OCCASIONAL	Baseline						
	Absent	95	96.9	3	3.1	98	100.0
	Present						
Total	95	96.9	3	3.1	98	100.0	

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PHARMACIA CBS 820
 REDUCTIONS - PROTOCOL 20124-017
 TABLE No.: 82
 E.C.G.: NUMBER AND PERCENTAGE OF E.C.G. ABNORMALITIES, BY ABNORMALITY GROUP, OBSERVED DURING THE STUDY BY ASSIGNED TREATMENT

Group of abnormalities	Isiprenavir						Rabozetile					
	Screening		1-21 days		22-42 days		Screening		1-21 days		22-42 days	
	No	%	No	%	No	%	No	%	No	%	No	%
Evaluated Pt.	96	100.0	96	100.0	85	100.0	111	100.0	106	100.0	92	100.0
Rhythm disorders	5	5.1	5	5.3	5	5.4	6	5.4	6	5.7	10	10.9
Conduction disorders	3	3.1	4	4.2	2	2.4	3	2.7	4	3.8	4	4.3
Ischemic signs	1	1.0			1	1.2	1	0.9			1	1.1
Other disorders	1	1.0	1	1.0	1	1.2	3	2.7	3	2.8	3	3.3

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PARMAVIA CVS RD

REBOLIXINE - PROTUCOL 20124/017
TABLE No.: 83

E.C.G.: SCRIPT 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												
	Indipravdine						Rabocicline						
	Absent		Present		Total		Absent		Present		Total		
	No	%	No	%	No	%	No	%	No	%	No	%	
Rhythm disorders	Absent	66	92.5	7	7.5	93	100	94	89.5	11	10.5	105	100
	Present	3	60.0	2	40.0	5	100	5	83.3	1	16.7	6	100
	Total	69	90.8	9	9.2	98	100	99	89.2	12	10.8	111	100
Conduction disorders	Absent	93	97.9	2	2.1	95	100	103	97.2	3	2.8	106	100
	Present	3	100			3	100	1	33.3	2	66.7	3	100
	Total	96	98.0	2	2.0	98	100	104	95.5	5	4.5	111	100
Ischemic infarct	Absent	97	100			97	100	109	99.1	1	0.9	110	100
	Present			1	100	1	100	1	100			1	100
	Total	97	99.0	1	1.0	98	100	110	99.1	1	0.9	111	100
Other disorders	Absent	96	99.0	1	1.0	97	100	106	98.1	2	1.9	108	100
	Present	1	100			1	100	1	33.3	2	66.7	3	100
	Total	97	99.0	1	1.0	98	100	107	96.4	4	3.6	111	100

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Pharmacia

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FIGURES

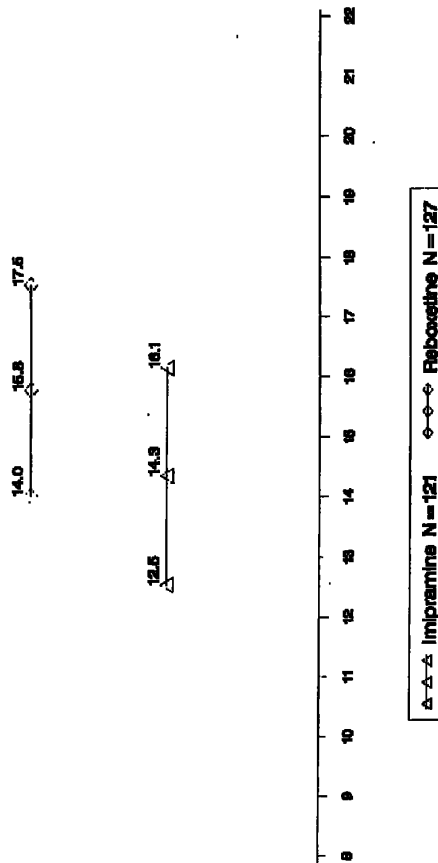
421

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
MEAN DECREASES OF HAMILTON TOTAL SCORE AT LAST ASSESSMENT
POINT ESTIMATES AND CONFIDENCE INTERVALS

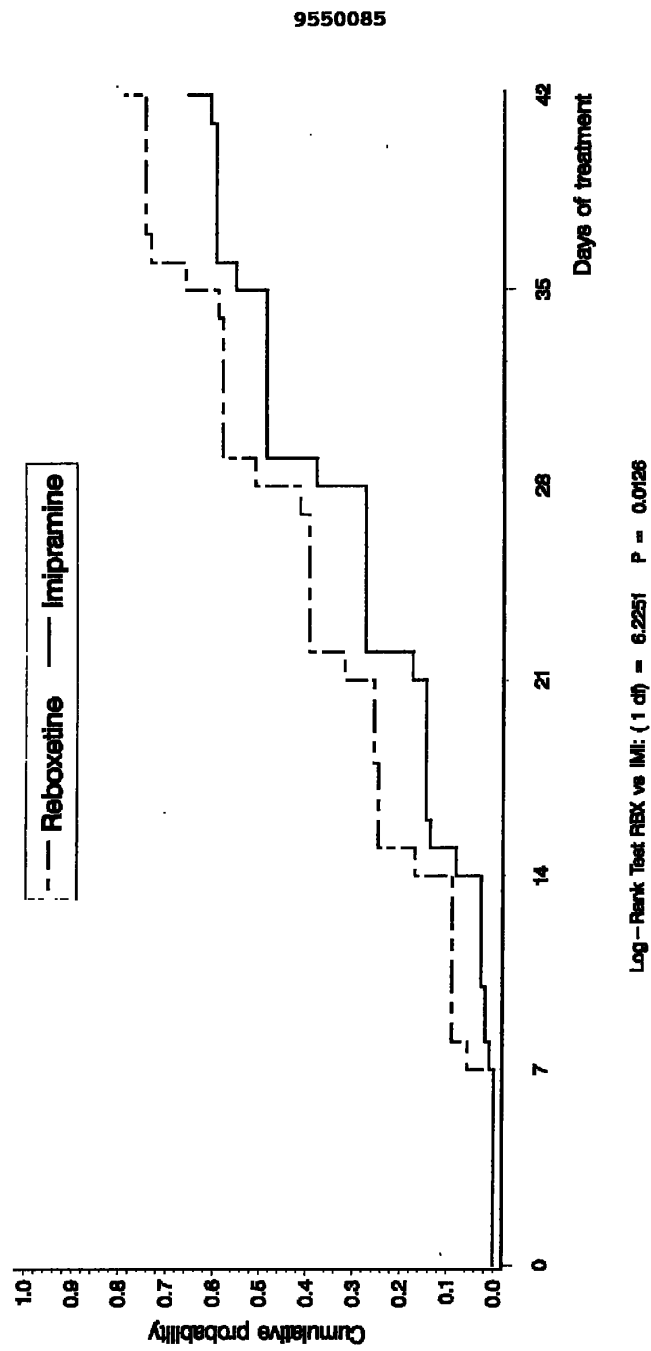
Figure No.: 1



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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
CUMULATIVE PROBABILITY OF 50% DECREASE IN HAMID TOTAL SCORE

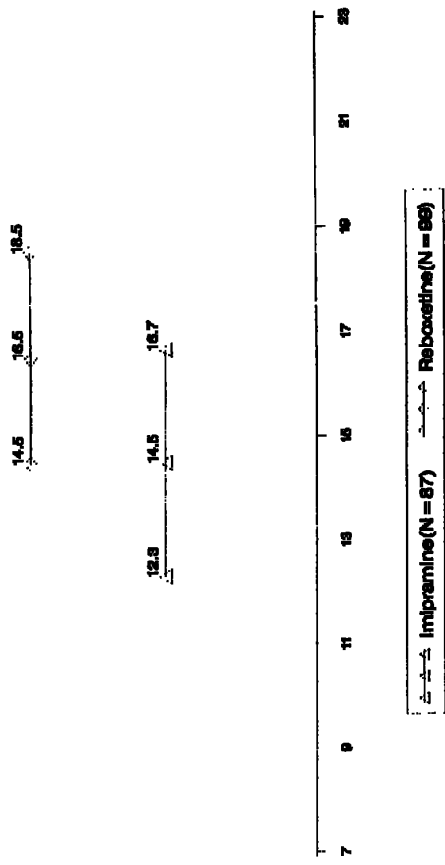
Figure No.: 2



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PHARMACIA CNS R&D
REBOXETINE -- PROTOCOL 20124/017
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



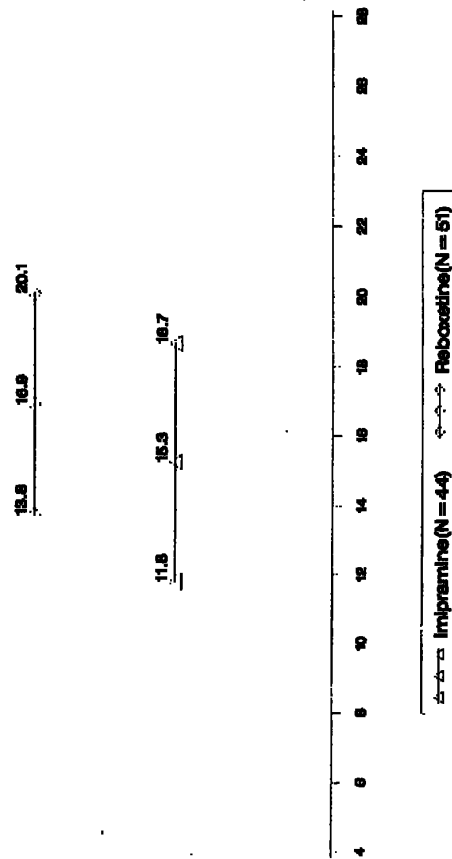
424

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
MELANCHOLIC PATIENTS MEAN DECREASES OF HAMILTON TOTAL SCORE AT LAST ASSESSMENT
POINT ESTIMATES AND 95% CONFIDENCE INTERVALS

Figure No.: 4



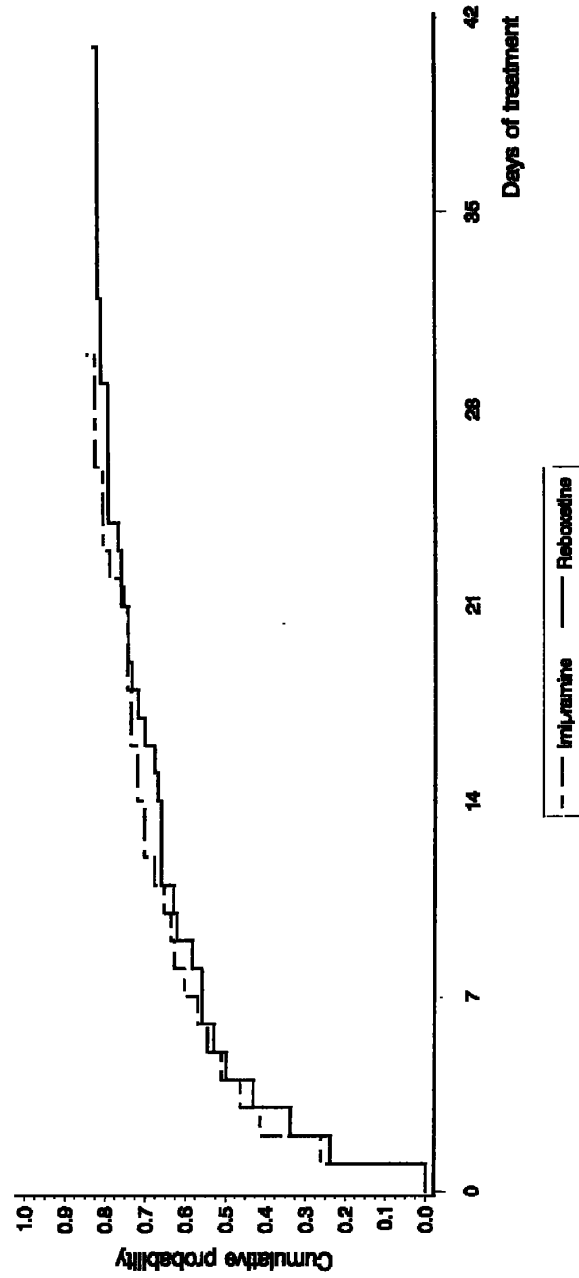
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PHARMACIA CNS RAD

REBOXETINE - PROTOCOL 20194/017

CUMULATIVE RISK OF DEVELOPING THE FIRST ADVERSE EVENT DURING TREATMENT

Figure No.: 5



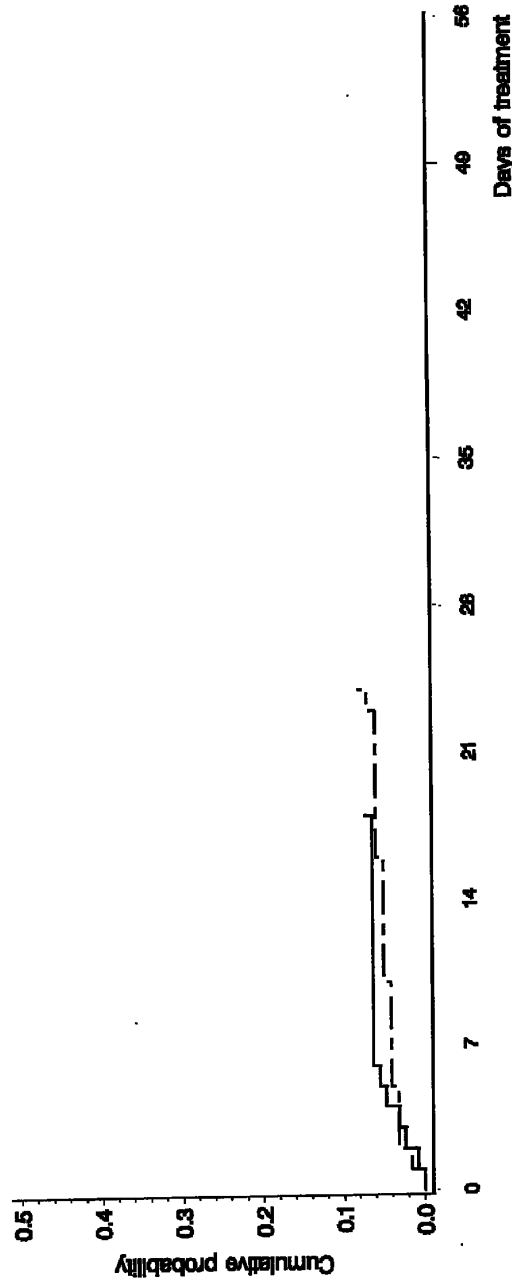
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Log-Rank Test REB vs IMP: (1 df) = 0.2667 P = 0.6147

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
CUMULATIVE RISK OF DEVELOPING AGITATION / ANXIETY / NERVOUSNESS

Figure No.: 6



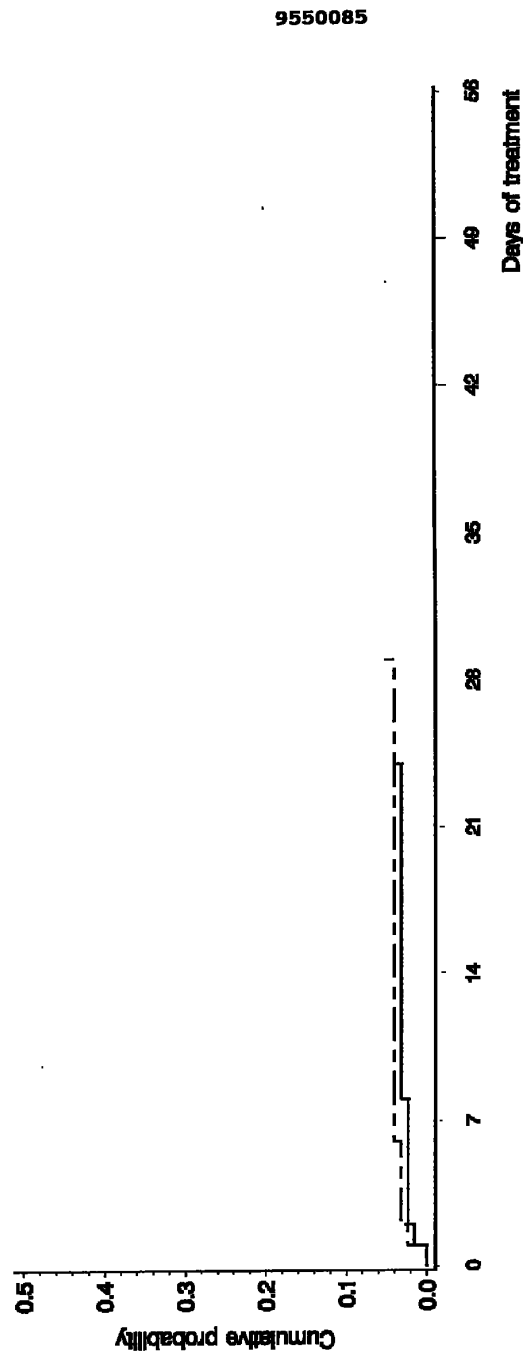
Log-Rank Test RBX vs IMI: (1 df) = 0.0109 P = 0.9167

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
CUMULATIVE RISK OF DEVELOPING ASTHENIA / FATIGUE

Figure No.: 7

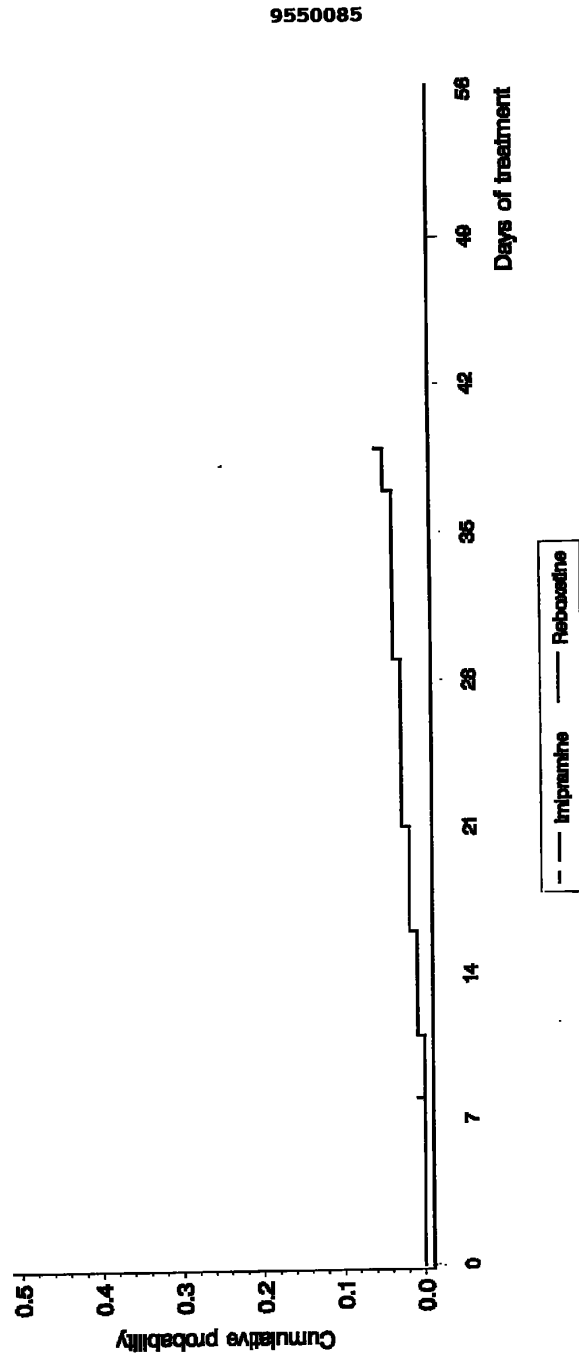


Log-Rank Test RBX vs IMI: (1 df) = 0.1474 P = 0.7010

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
CUMULATIVE RISK OF DEVELOPING BRONCHITIS

Figure No.: 8



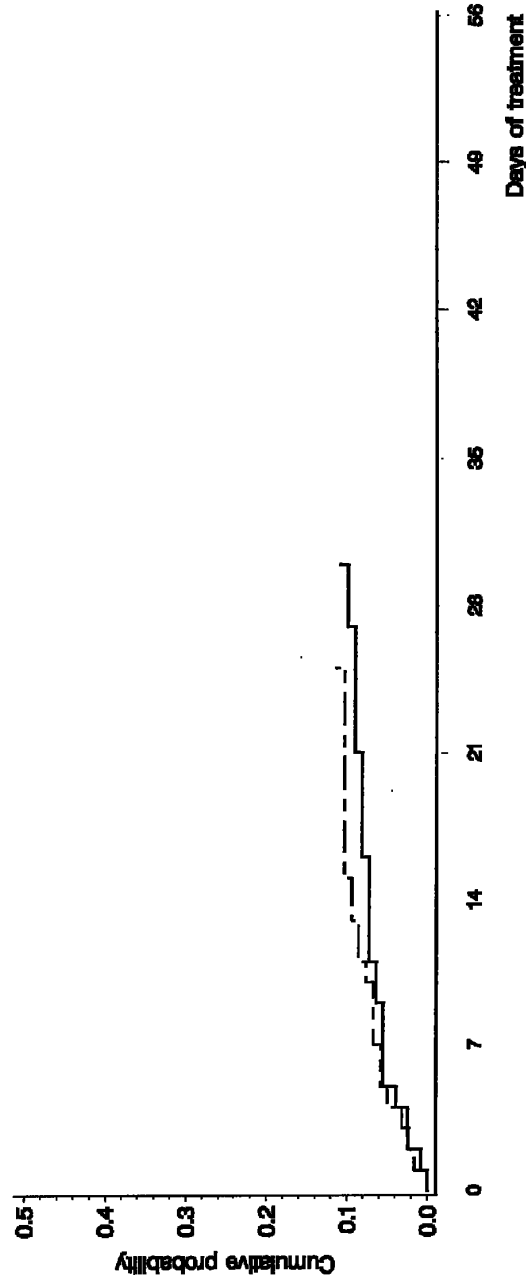
Log-Rank Test RBX vs IMI: (1 df) = 3.2913 P = 0.0696

024

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PHARMACIA CNS R&D
REBOXETINE -- PROTOCOL 20124/017
CUMULATIVE RISK OF DEVELOPING CONSTIPATION

Figure No.: 9



430

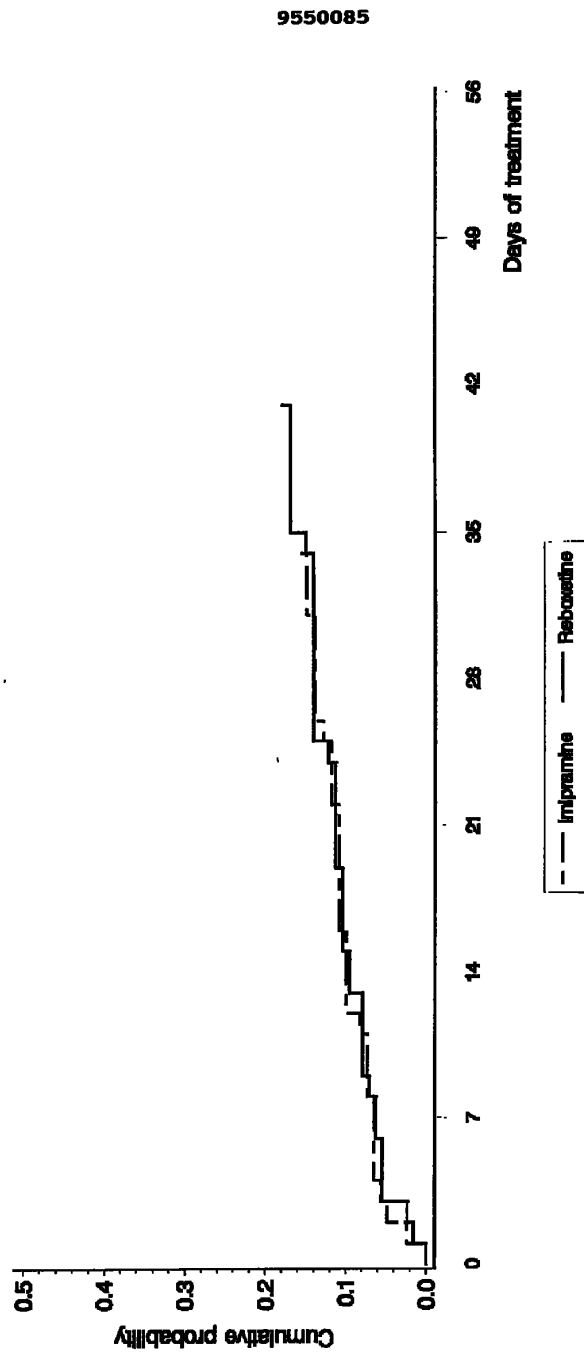
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Log-Rank Test RBX vs IMI: (1 df) = 0.0313 P = 0.8596

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
CUMULATIVE RISK OF DEVELOPING HEADACHE / MIGRAINE

Figure No.: 10



134

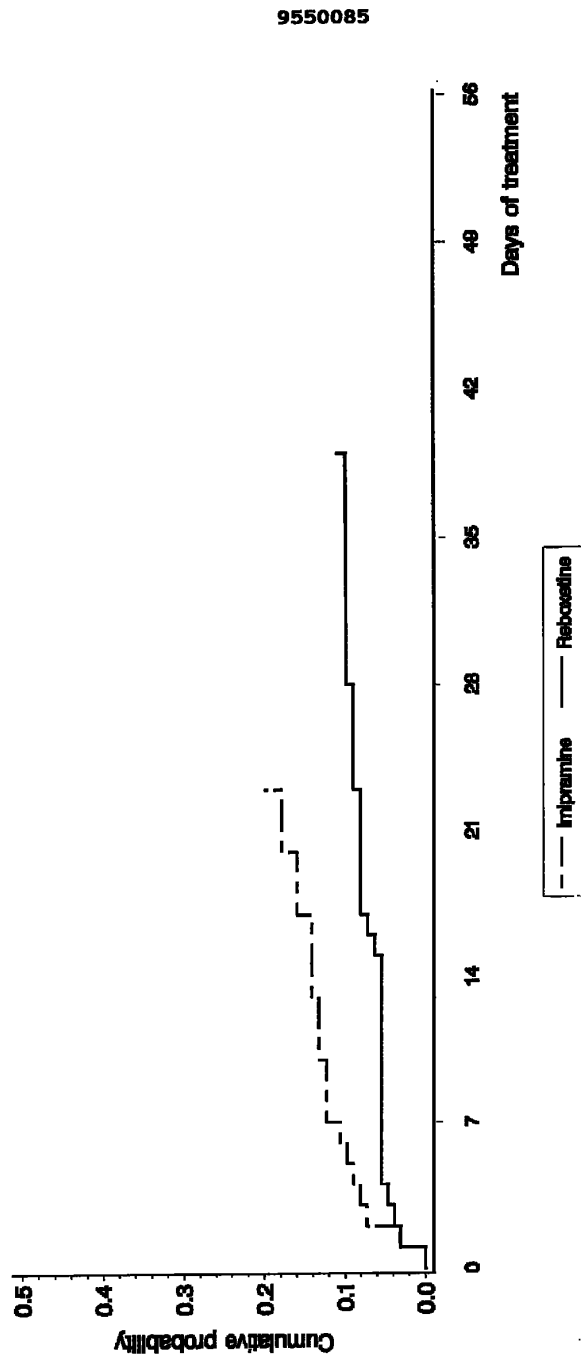
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Log-Rank Test RBX vs IMI: (1 df) = 0.0746 P = 0.7848

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
CUMULATIVE RISK OF DEVELOPING HYPOTENSION AND RELATED SYMPTOMS

Figure No.: 11

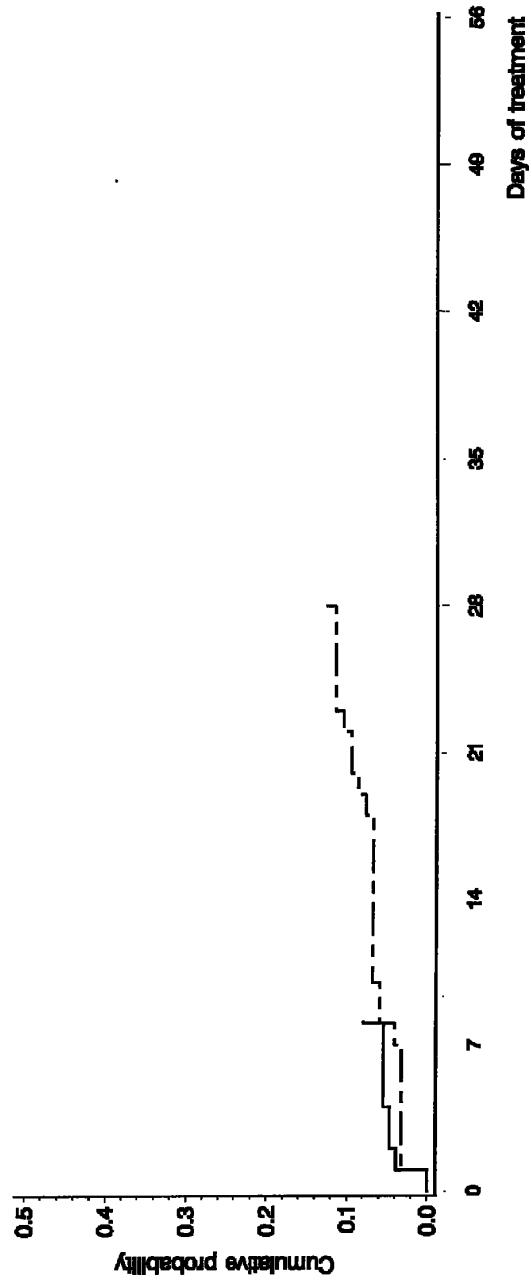


Log - Rank Test RBX vs IMI: (1 df) = 3.8965 P = 0.0484

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PHARMACIA CNS R&D
REBOXETINE – PROTOCOL 20124/017
CUMULATIVE RISK OF DEVELOPING INSOMNIA

Figure No.: 12



Log-Rank Test RBX vs IMI: (1 df) = 0.9252 P = 0.3361

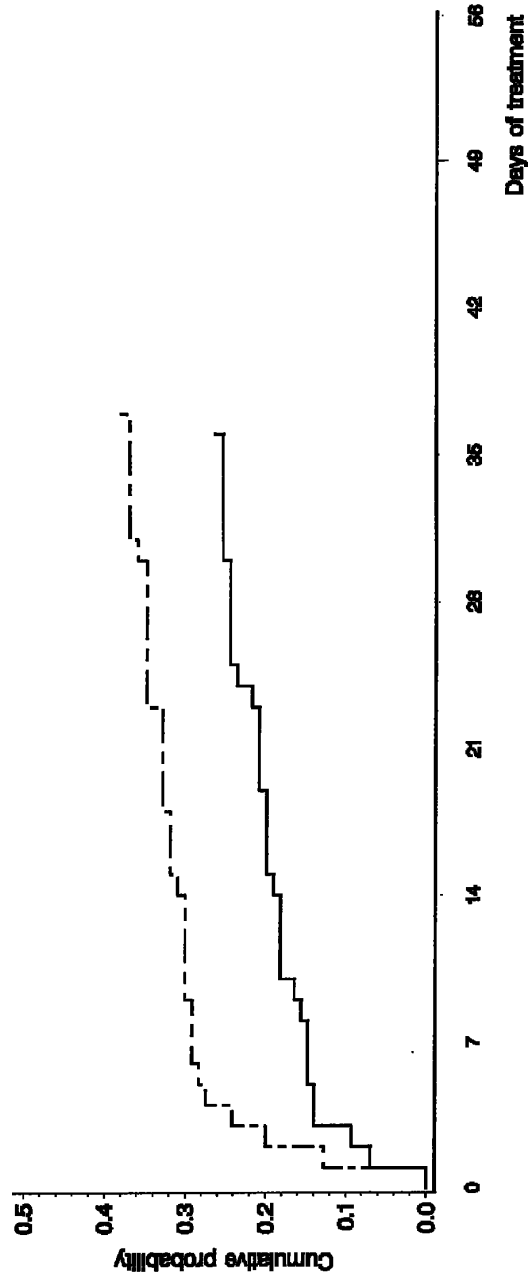
432

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
CUMULATIVE RISK OF DEVELOPING MOUTH DRY

Figure No.: 13



434

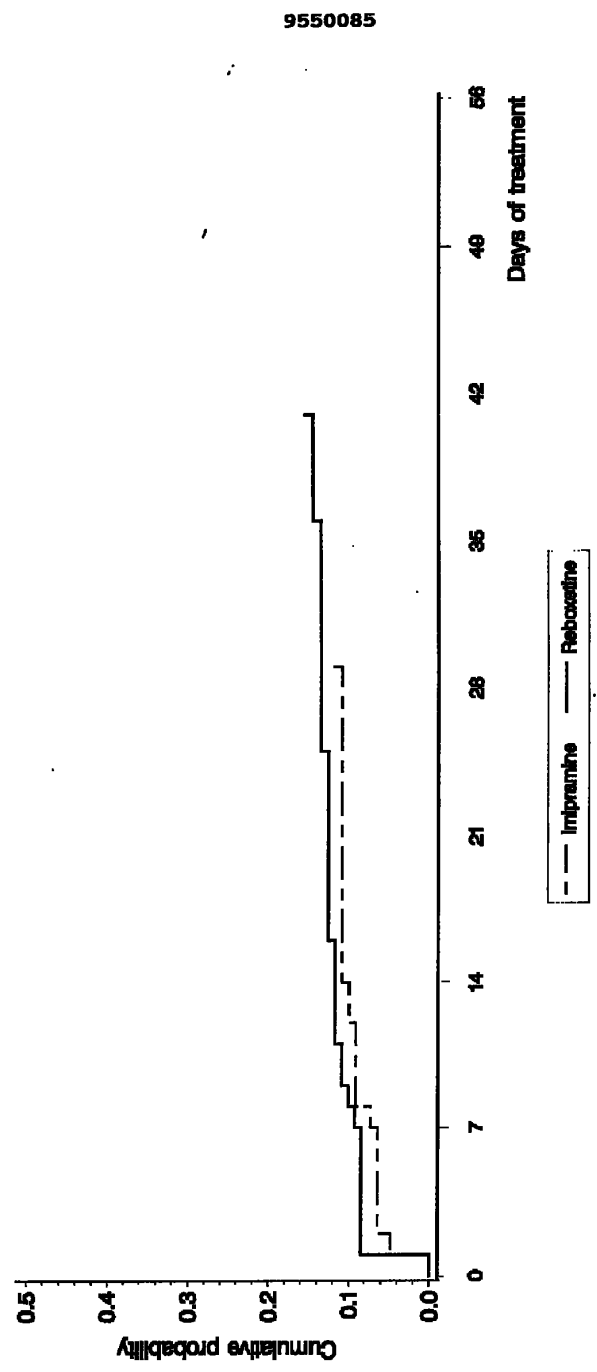
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Log-Rank Test RBX vs IMI: (1 df) = 4.6064 P = 0.0319

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
CUMULATIVE RISK OF DEVELOPING NAUSEA AND RELATED SYMPTOMS

Figure No.: 14

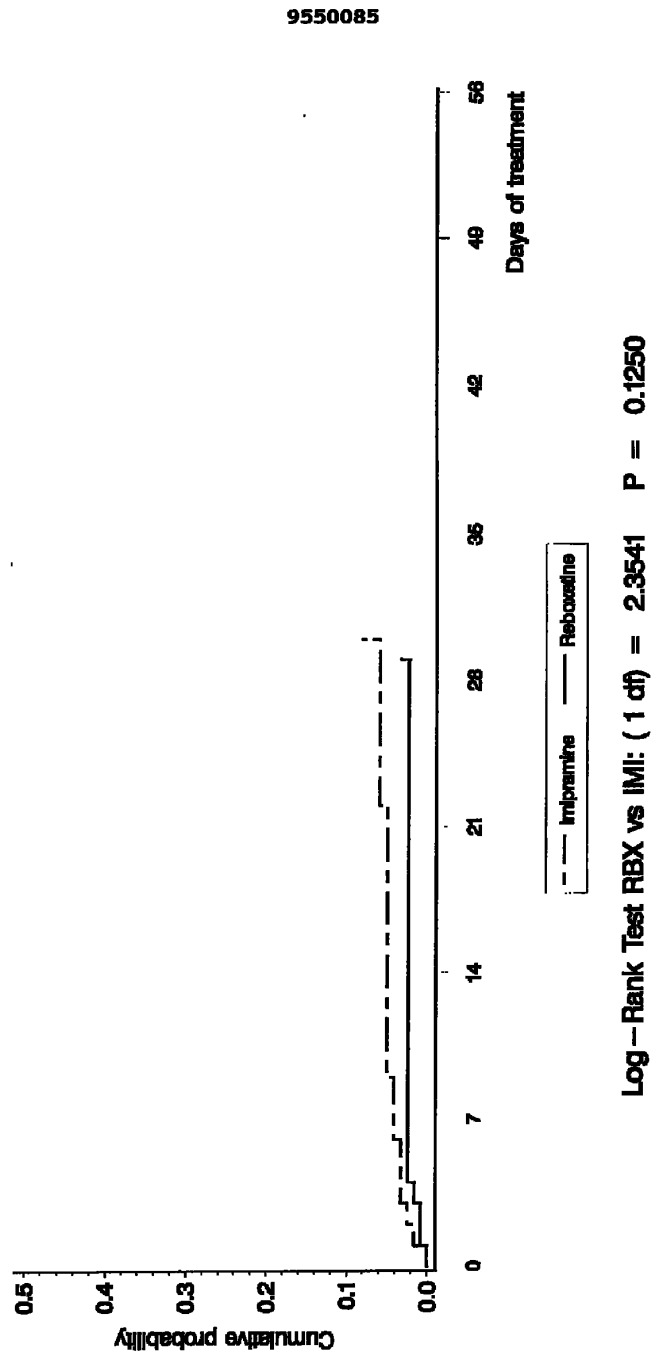


Log-Rank Test RBX vs IMI: (1 df) = 0.5755 P = 0.4481

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PHARMACIA CNS R&D
REBOXETINE – PROTOCOL 20124/017
CUMULATIVE RISK OF DEVELOPING SOMNOLENCE

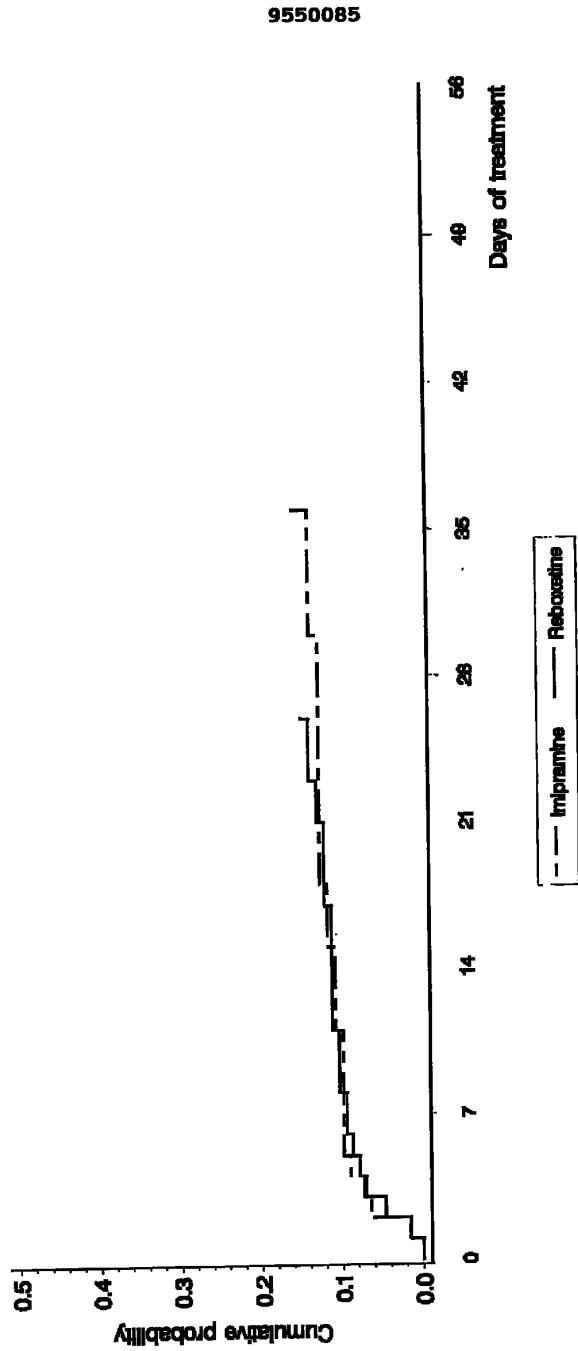
Figure No.: 15



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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
CUMULATIVE RISK OF DEVELOPING SWEATING INCREASED

Figure No.: 16



437

Log-Rank Test RBX vs IMI: (1 df) = 0.0323 P = 0.8573

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PHARMACIA CNS R&D
REBOXETINE -- PROTOCOL 20124/017
CUMULATIVE RISK OF DEVELOPING TACHYCARDIA

Figure No.: 17

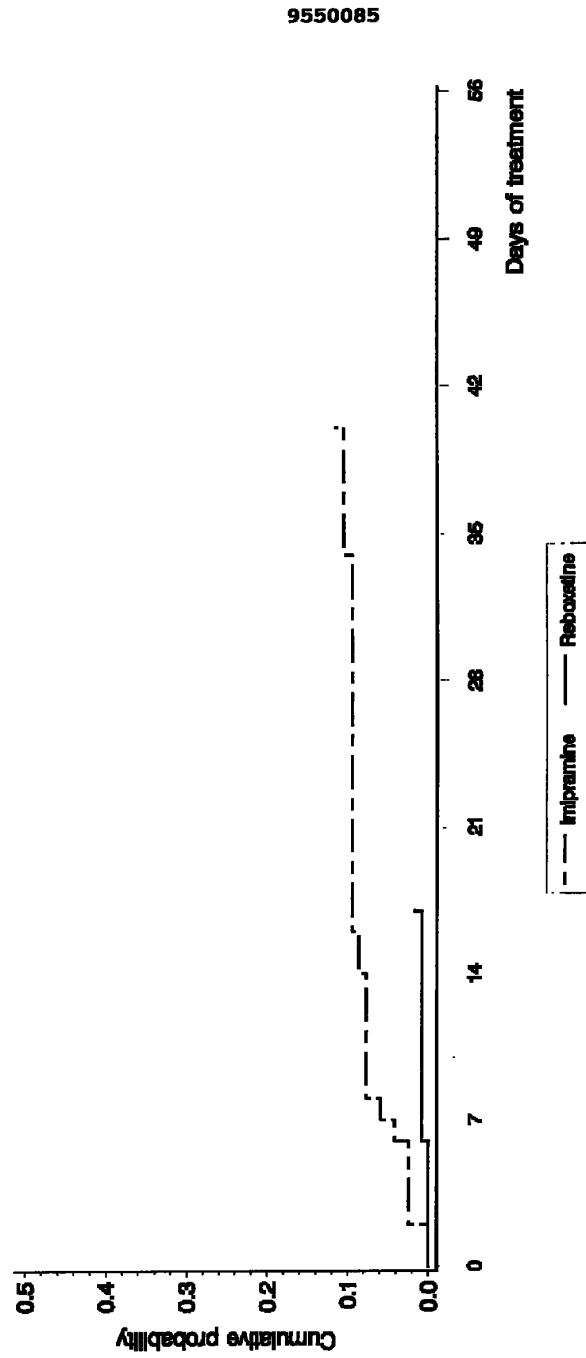


Log--Rank Test RBX vs IMI: (1 df) = 2.4496 P = 0.1176

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
CUMULATIVE RISK OF DEVELOPING TREMOR

Figure No.: 18



Log-Rank Test RBX vs IMI: (1 df) = 9.1882 P = 0.0024

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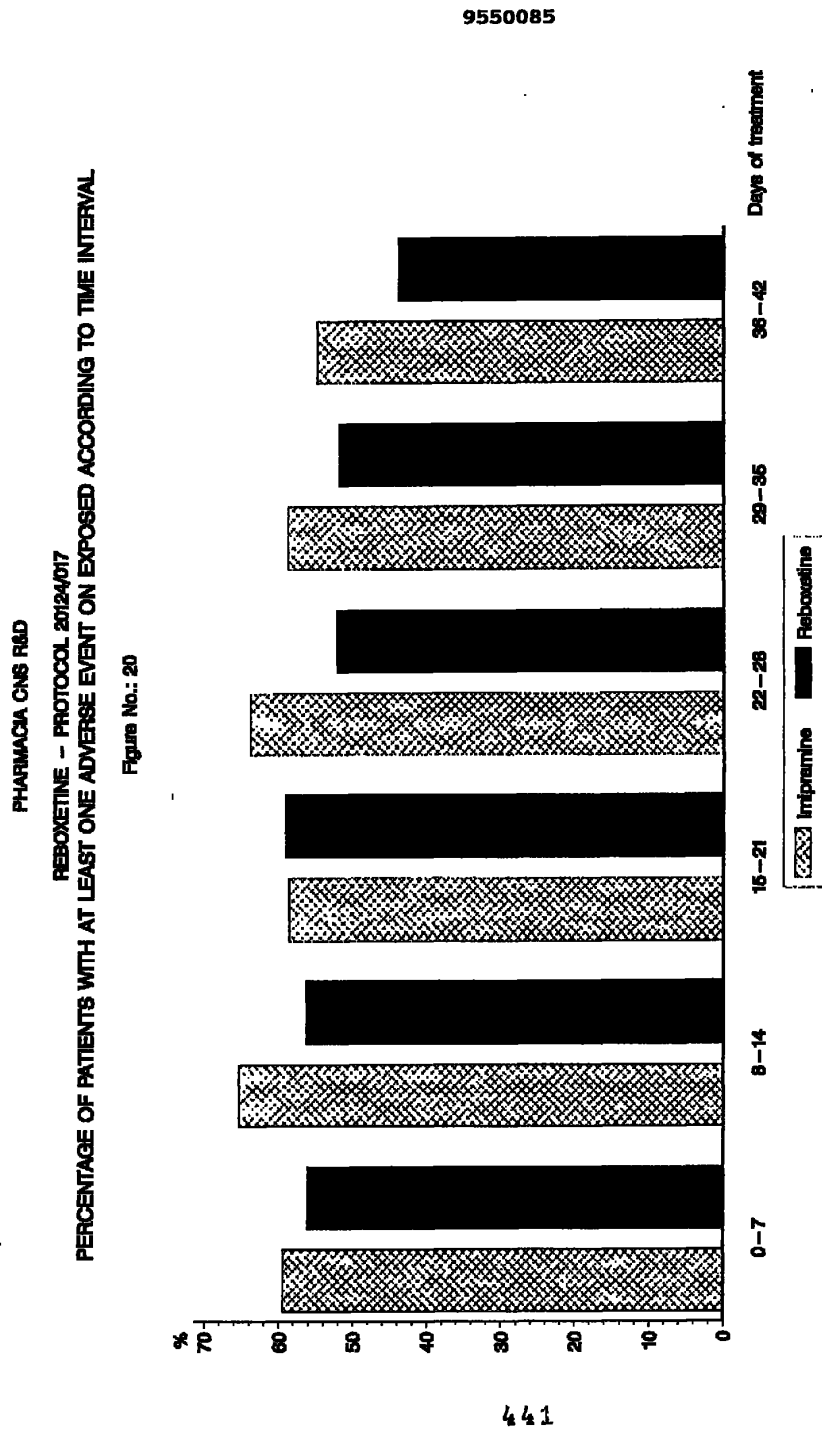
PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
CUMULATIVE RISK OF DEVELOPING URINARY HESITANCY / RETENTION

Figure No.: 19



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12. APPENDICES

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12.1 Study Information

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12.1.1 PROTOCOL AND PROTOCOL AMENDMENTS

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FARMITALIA CARLO ERBA
R&D - C.N.S. LINE

COMPOUND: REBOXETINE

PROTOCOL No. : 20124/017

VERSION : Final, September 14, 1990

PHASE : III

TITLE : Multicenter, multinational double-blind study of the activity and tolerability of reboxetine vs imipramine in patients suffering from Major Depressive Episodes.

INVESTIGATORS : see enclosure 1

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STUDY MONITOR : see 17.0

DATA MANAGEMENT CENTER: Biostatistics and 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.

20124/017

Date: September 14, 1990

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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 in patients suffering from Major Depressive Episodes, will be carried out on a multinational basis, according to a double-blind parallel group design, in 200 patients. After an initial washout period of 1-2 weeks, patients will receive either reboxetine or imipramine, 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 weeks treatment period a long-term follow-up could 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 Episodes indicate that reboxetine is an effective antidepressant agent, with a favourable therapeutic index with respect to desipramine. Consistent information from further 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 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, with random allocation of patients to one of the two treatments. The study will be organized on a multicenter, multinational basis.

5.2 Number of subjects proposed

Each center will recruit 20 patients, within a period of 12 months, for a total of 200 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.

6.2 Inclusion criteria

- Patients affected by Major Depressive Episodes (DSM-III-R see 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 21-HAMD.

- Patient's consent: informed 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 contraceptives use 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.

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- Chronic respiratory insufficiency in the physical examination and X-ray.
- History or presence of gastrointestinal, liver, or kidney 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 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 screening.
- ECT in the previous 6 months.
- 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 2 possible treatments (reboxetine, imipramine). 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 2 mg (batch N°.....) or 4 mg (batch N°.....); or imipramine 50 mg (batch N°.....) plus excipients, or imipramine 100mg (batch N°.....) 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

8.2 Labelling

The experimental treatment will be labelled by using the labels in enclosure 4. 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 this period only chloral hydrate (0.5-1.0 g night) as sleep inducer on p.r.n. basis will be allowed. Informed consent will be obtained from each patient (see 15.2).

Eligible patients will be then randomized to one of the two 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).

9.2 Treatment period

9.2.1 Dose/route of administration/treatment schedule

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 global improvement on day 21, see assessments), and in case of good tolerance, especially non-symptomatic hypotension, 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

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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:

- Patient's request.
- Unacceptable toxicity: this is defined as the occurrence of serious (see Adverse Events) adverse events.
- Lack of efficacy: this will apply to patients who will show unacceptable deterioration of the clinical picture after at least two weeks of treatment (worsening at the CGI).
- Switch to mania.

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 of events arising during the course of the study non-psychotropic 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

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hydrate (0.5-1.0 g/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.

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: October-December 1990
Duration of accrual: 12 months
Foreseen end date (date of the last visit of the last patient, excluding follow up): February 1992.

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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 6); as above plus at screening for entry and monthly during the follow-up period.
- Clinical Global Impression (enclosure 7), as above plus monthly during the follow-up period.
- Montgomery-Asberg Depression Rating Scale (enclosure 8)
- Patient Global Impression (enclosure 9)

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 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.
- ECG: at screening, day 21, day 42 and every three months during follow-up.

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- 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, 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 10).

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 11), 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 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 imipramine of the total score of the HAM-D. The comparison will be performed on the difference between baseline and the last postbaseline score for each patient regardless the length of time in the study. This analysis will take into account all the available information, reducing the potential bias due to differential drop out rates between treatment groups. All randomized patients will be included in the analysis. A 95% confidence interval will be computed.

From the phase III and from the literature (6) it seems reasonable to assume that each treatment group will show a variability (expressed as standard deviation) of 9 points. Taking into account that 200 patients are planned to be recruited and assuming that 10% of patients will drop out before first postbaseline visit, we expect a length of 5.3 scores for the confidence interval.

* 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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Referring to secondary efficacy analysis (see statistical analysis) based on proportions, the same sample size will allow for a maximum length of the confidence interval of 0.30. Maximum length is based on the hypothesis that both treatments will show a proportion of 0.5. Calculation is performed by the normal approximation method.

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 the study. Reboxetine and imipramine will be compared by computing a 95% confidence interval of the difference between treatments mean decrements vs baseline in the two groups.

Evident unbalances between baseline values in the two groups will be taken into account by means of analysis of covariance. In this case the confidence interval will refer to the corrected means.

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.

Explorative comparisons between groups will be performed. Confidence interval will be preferred to statistical test. Time course of the score of the administered rating scales will be described for the two 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 between groups.

Frequencies of patients showing maximum decrease ≥ 20 mmHg in the standing systolic blood pressure will be compared between groups.

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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 Chi-square test of the differences between 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 12)

15.1 Ethical Committee

This study will not be undertaken until approval is obtained from the Ethical Committee or 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 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 2) 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

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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:

Dr. V. Bredenkamp
FICE South Africa
P.O.Box 41111 Craighall 2024
343 Kent Av. Ferndale
Randburg 2194
phone (27-11) 7879706

Dr. S. Dasseville
FICE Belgium
Rue de l'Industrie 8
1400 Nivelles
phone: (32-67) 2672925

Dr. I. Götz-Lee
FICE GmbH Germany
Merzhauser Str.122
Postfach 480
7800 Freiburg i.Br
phone: (49-761) 4013125

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.

Operating procedures for training on assessment instruments, study monitoring and coordination are described in attachment A.

18.0 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 - see enclosure 14.

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19.0 ADMINISTRATIVE ASPECTS

19.1 Insurance policy

Farmitalia Carlo Erba Company declares to have a group insurance cover (policy NO. 4W8102 - Italia Assicurazioni - enclosure 13) 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.

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.

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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.

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.

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5. /701 - A. Dubini, T. Ban
Reboxetine: Open Dose Range Finding study in patients
hospitalized for major depressive disorders
February 1989.

6. P. Stark, D. Hardison
J. Clin. Psychiat., 1985, 46:53-58

24.0 SIGNATURES

Signatures of the:

Investigator _____

Study Monitor _____

Product Leader John Jones

Line Medical Head Adriano Dubini

Biostatisticians Richard Spear

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TABLE 1 EVALUATION SCHEDULE

DAY	SCREEN	0	4	7	14	21	28	35	42
RBX mg	8								
TREATMENT IMI mg	100-150						10		
DSM-III-R							200		
MEDICAL HISTORY									
PHYSICAL EXAMINATION									
X-RAY									
LABORATORY									
ECG									
VITAL SIGNS									
21-ITEM HAMD									
CGI									
MONTGOMERY-ASBERG DEPRESSION RS									
PATIENT GLOBAL IMPR.									
COMPLIANCE									
DISPENSING MED.									
ADR									

20124/017 Date: September 14, 1990

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LIST OF ENCLOSURES

- 1) LIST OF INVESTIGATORS
- 2) DSM-III-R CRITERIA OF MAJOR DEPRESSIVE EPISODE
- 3) CONSENT FORM
- 4) EXPERIMENTAL TREATMENT LABELLING
- 5) SCREENING FORM
- 6) HAMD: HAMILTON DEPRESSION RATING SCALE
- 7) CLINICAL GLOBAL IMPRESSION (CGI)
- 8) MADRS: MONTGOMERY ASBERG DEPRESSION RATING SCALE
- 9) PATIENT GLOBAL IMPRESSION
- 10) ADVERSE EVENTS: CHECK LIST
- 11) KARCH AND LASAGNA MODIFIED CRITERIA
- 12) DECLARATION OF HELSINKI
- 13) INSURANCE POLICY
- 14) DRUG ACCOUNTABILITY

ATTACHMENT A

PROTOCOL 20124/017: OPERATING PROCEDURES FOR TRAINING ON
ASSESSMENT INSTRUMENTS, STUDY MONITORING AND COORDINATION

ATTACHMENT B

CASE RECORD FORM

20124/017 Date: September 14, 1990

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Enclosure 1

LIST OF INVESTIGATORS

N°	Country	Name/Address	N° of patients
1.	Germany	Dr. Berzewski Department of Psychiatry University of Berlin	15
2.	"	Dr. Wolfersdorff Academic Teaching Hospital Ravensburg	25
3.	"	Dr. Täschner Academic Teaching Hospital Bürgerhospital, Stuttgart	10
4.	"	Dr. Uebhack Poliklinik der Charité Schumannstr. 20-21, 0-1040 Berlin	10
5.	"	Dr. Häuser Nervenlinik 0-1612 Teupitz	10
6.	"	Dr. König Weinsberg Psychiatric General Hospital, Weisenhof	10
7.	Belgium	Dr. Derely Clinique La Ramée Neuropsychiatric Hospital Brussels tel. (02) 3441894	20
8.	"	Dr. Wilmotte Hopital Civil et Hopital VVG Neuropsychiatric Hospital Charleroi tel. (071) 292911	20
9.	"	Dr. M. Van Moffaert Universitair Ziekenhuis Gent Psychiatrische Kliniek De Pintelaan 185, 9000 Gent tel. (091) 4043390	20
9/A	"	Dr. R. Spiers Gent	

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10. Belgium	Dr. J. Bollen Psychiatrisch Centrum Santa Maria Melverencentrum 111, 3800 Sint Truiden (011) 689911	20
11. South Africa	Prof. C.A.Gagiano Department of Psychiatry University of Orange Free State P.O.Box 339, Bloemfontein 9300	20
12. "	Prof. G. Hart, Dr. M. Berk Johannesburg Medical School Psychiatry Department 7 York Road Parktown 2193	20
13. "	Dr. D.A.B. Wilson, Dr. M. Louw Department of Psychiatry Groote Schuur Hospital Observatory 7925 (Cape Town)	20
14. Germany	Dr. Woelk Universitätsklinik Giessen	40
14.1 "	Dr. H. Hauer An der Aurach 8 8535 Emskirchen	
14.2 "	Dr. M. El Mallah Seltsamplatz 3 8550 Forchheim	
14.3 "	Dr. O' Connolly Haimendorfstr. 4 8540 Schwabach-Wolkersdorf	
14.4 "	Dr. Adler Nürnberg	
14.5 "	Dr. E. Samimi Heisterstr. 31 8500 Nürnberg	
14.6 "	Dr. E. Sarrafian Hauptstr. 28 8542 Roth	
14.7 "	Dr. K. Schröter Altdorfer Str. 11 8560 Lauf/Pegnitz	
14.8 "	Dr. G. Stumpf Volkacher Str. 31 8500 Nürnberg	

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14.9	Germany	Dr. P. Weinholz Brauhoﬀgasse 1 8520 Erlangen-Frauenaurach
14.10	"	Dr. H. Wiswedel Friedenstr. 12 8510 Fürth/Bay
15.	South Africa	Prof. A. Levin Psychiatric Hospital Grahamstown

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Date: September 14, 1990

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Protocol 20124/

Enclosure 2

DSM-III-R
Diagnostic Criteria
of the MAJOR DEPRESSIVE EPISODE

Note: All A, B, C, and D must be "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
- 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.

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Enclosure 3

REBOXETINE PROTOCOL 20124/017

Multicenter, multinational double blind study of the activity and tolerability of reboxetine vs imipramine 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. 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

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Encl.3 cont'd

possible side-effects and benefits of treatments. Blood tests, urinalysis, ECG will be undertaken bi-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 of 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 imipramine, a compound of established efficacy.

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.

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Encl. 3 cont'd

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.

_____ date
Patient Signature

I have explained all the above indicated aspects of the study to the patient, who expressed his/her consent to the participation.

_____ date
Investigator Signature

_____ date
Witness Signature

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Enclosure 4

REBOXETINE PROTOCOL 20124/017

EXPERIMENTAL TREATMENT LABELLING

TREATMENT

reboxetine protocol 20124/017

patient No.....

week 1 - 6

batch No.....

expiry.....

drug for investigational use

HIGH DOSE TREATMENT

reboxetine protocol 20124/017

patient No.....

week 5 - 6

expiry.....

drug for investigational use

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Enclosure 5

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 20124017

Centre No. [][][][][]

Pat. Initials [][][][]

Visit/cycle **S|C|R|E|E|N**

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]

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Investigator's signature _____

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Cont'd Enclosure 5

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1|7

Centre No. [][][][][][]

Pat. Initials [][][][]

Visit/cycle **S|C|R|E|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 _____

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7-scre

Investigator's signature _____

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Cont'd Enclosure 5

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No.

Centre No.

Pat. Initials

Visit/cycle

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

4-scre

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Investigator's signature _____

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Cont'd Enclosure 5

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 20124017

Centre No. [][][][][][]

Pat. Initials [][][][][]

Visit/cycle **S|C|R|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

480

5-scre

Investigator's signature _____

9550085 Cont'd Enclosure 5

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 20124018

Centre No. [][][][][]

Pat. Initials [][][][]

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 Weakly 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 [][][]

48

6-scre

Investigator's signature _____

9550085

Cont'd Enclosure 5

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1|7

Centre No. [][][][][]

Pat. Initials [][][]

Visit/cycle S|C|R|E|N|

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) _____

8-scre

482

Investigator's signature _____

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9550085 Cont'd Enclosure 5

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1|7

Centre No. [][][][][]

Pat. Initials [][][][]

Visit/cycle S|C|R|E|E|N

Date [][][][][][][]
D M Y

CONT' ECG

Please, add here the ORIGINAL TRACING AND MEDICAL REPORT



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9-scre

Investigator's signature _____

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Cont'd Enclosure 5

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 20124017

Centre No. [][][][][]

Pat. Initials [][][]

Visit/cycle **S|C|R|E|E|N**

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		
Ca ⁺⁺		<input type="checkbox"/>			
PO ₄		<input type="checkbox"/>	T ₄		
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

Observation: _____

484

10-screed Investigator's signature _____

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9550085 Cont'd Enclosure 5

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 20124012

Centre No. [][][][][]

Pat. Initials [][][]

Visit/cycle **S|C|R|E|N**

Date [][][][][][]
D M Y

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 : _____

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12-scree

Investigator's signature _____

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9550085

Cont'd Enclosure 5

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1|7

Centre No. [][][][][]

Pat. Initials [][][][]

Visit/cycle **S|C|R|E|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 no 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 [][][][] .

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13-scree

Investigator's signature _____

9550085

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1|7

Centre No. [][][][][]

Patient No. [][][][]

Initials [][][]

Visit/cycle [][][][][]

Date [][][][][][][]
D M Y

Enclosure 6

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

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Investigator's signature _____

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FARMITALIA CARLO ERBA
Erbarmont Group

Compound **REBOXETINE**

Protocol No. 20124011

Centre No. [][][][]

Patient No. [][][]

Initials [][][]

Visit/cycle [][][][]

Date [][][][][][]
D M Y

Encl. 6 cont'd

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

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Investigator's signature _____

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FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1|1

Centre No.

Patient No.

Initials

Visit/cycle

Date
D M Y

Encl. 6 cont'd

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

490

Investigator's signature _____

Enclosure 7

FARMITALIA CARLO ERBA
Erbarmont Group

9550085
Compound **REBOXETINE**

Protocol No. 2 0 1 2 4 0 1 7

Centre No. Patient No. Initials Visit cycle

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

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Investigator's signature _____

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ARMITALIA CARLO ERBA
diamond Group

Compound REBOXETINE ⁹⁵⁵⁰⁰⁸⁵

Protocol No [2][0][1][2][4][0][1][7]

Centre No. [][][][][] Patient No. [][][][] Initials [][][][] Visit/Cycle [][][][][][]

Date [][][][][][][]
D M Y

ENCLOSURE # 8

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].

Investigator's signature _____

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FARMITALIA CARLO ERBA
Erbamont Group

Compound REBOXETINE⁹⁵⁵⁰⁰⁸⁵ Protocol No. 2|0|1|2|4|0|1|7|

Centre No. [][][][] Patient No. [][][] Initials [][][] Visit/cycle [][][][][]

Date [][][][][][]
o m y

CONT. ENCLOSURE N° 8

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 [][]

Investigator's signature _____

492

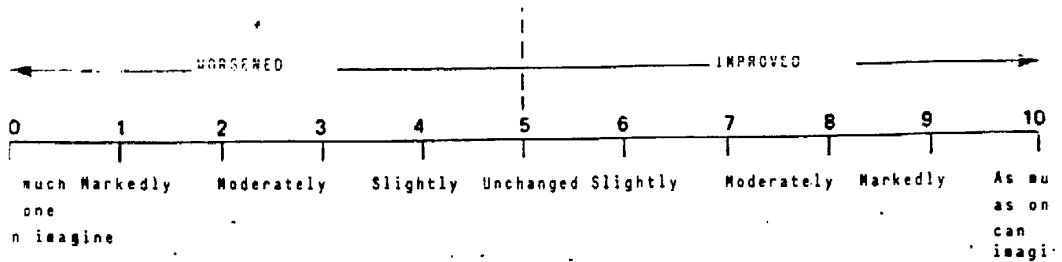
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ARMITALIA CARLO ERBA
BAMONT GROUP
S LINE

Enclosure 9

PATIENT GLOBAL IMPRESSION

FROM STUDY START MY GENERAL CONDITIONS ARE:



Using this visual-analogue scale, please indicate the number corresponding to your actual situation.

22 24

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ARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 20124017

Centre No.

Patient No.

Initials

Visit/cycle

Date
D M Y

NEWLY ADVERSE EVENTS: CHECK-LIST

Enclosure 10

1. AUTONOMIC

- Dry mouth
- Nasal congestion
- Blurred vision
- Constipation
- Urinary hesitancy
- Urinary retention
- Increased salivation
- Sweating
- Vomiting
- Diarrhoea
- Sexual disturbances

2. BEHAVIORAL TOXICITY

- Confusional reaction
- Excitement/agitation
- Increased motor activity
- Decreased motor activity
- Insomnia
- Drowsiness
- Lassitude

3. CARDIOVASCULAR

- Hypotension
- Dizziness
- Circulatory collapse
- Tachycardia
- Hypertension

4. NEUROLOGICAL

- Rigidity
- Tremor
- Akathisia
- Dystonia
- Paresthesias
- Seizures
- Myoclonus

5. OTHER

- Skin-rash
- Urticaria
- Decreased appetite
- Headache

495

30

Investigator's signature _____

Farnitalia Carlo Erba
Erbasont Group
Corporate Medical Coordination

9550085

ENCLOSURE 11

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.

9550085

Enclosure 12

DECLARATION OF HELSINKI

RECOMMENDATIONS GUIDING PHYSICIANS IN BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

ADOPTED BY THE 18TH WORLD MEDICAL ASSEMBLY, HELSINKI, FINLAND, 1964,
AMENDED BY THE 29TH WORLD MEDICAL ASSEMBLY, TOKYO, JAPAN, 1975,
AND
THE 35TH WORLD MEDICAL ASSEMBLY, VENICE, ITALY, OCTOBER 1983.

INTRODUCTION

It is the mission of the medical doctor to safeguard the health 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 doctor 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 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.

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CONT. ENCL. 12

I. 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 to a specially appointed independent committee for consideration, comment and guidance.
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 subjects unless they are satisfied that the hazards 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 hazards 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.

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CONT. ENCL.12

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.

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 to 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 (I.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.

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CONT. ENCL.12

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 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 well-being of the subject.

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Enclosure 13

 **ITALIA ASSICURAZIONI**

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



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. 65 r.d.l. 966/29-4-23) c.f. 00432690105

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Enclosure 13 cont'd

ITALIA ASSICURAZIONI

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 del
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. 94/02 P - 784 - CREDIT-RENTA

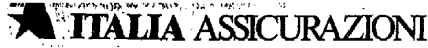
2



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. 65 r.d.l. 966/29-4-23) c.f. 00432690105

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Enclosure L3 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. 99/98 P. 7/98 - CREDITO



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. 988/29-4-23) c.f. 0043269010F



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FARMITALIA CARLO ERBA
 ERBAMONT GROUP
 OS LDM

Enclosure 14

DRUG ACCOUNTABILITY

Compound: REBOXETINE

Protocol N°: 20124/017

Title: Multicenter, multinational double-blind study of the activity and tolerability of Reboxetine vs Imipramine 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 (Please check: /_)	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.

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Attachment A

REBOXETINE PROTOCOL 20124/017: 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;
- an IRB approved blank copy of the consent form;
- the list of the laboratory normal values or ranges of the lab. tests.
- an IRB approved blank copy of the consent form;
- the list of the laboratory normal values or ranges of the lab tests.

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Prot. N° 20124/017 Cont. Attachment A

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 must immediately (within two working days) inform the Product Leader in Milan;

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Prot. N° 20124/017

Cont. Attachment A

- 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.

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Prot. N° 20124/017

Cont. 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. M. Van Moffaert and Dr. Berzewski.

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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12.1.2 CRF sample

A complete CRF sample is filed in the Study Master File

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Pharmacia

Document 9550085

**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 is 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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Document 9550085

12.1.4 CLINICAL INVESTIGATOR LIST, SIGNATURES AND CURRICULA VITAE

PRINCIPAL INVESTIGATORS AND AFFILIATIONS

- Centre 1:** Dr H Berzewski
Universitätsklinikum Steglitz, Freie Universität Berlin, Berlin, Germany
- Centre 2:** Dr M Wolfersdorf
Abt. Psychiatrie I - Univ Ulm, Ravensburg-Weissenau, Germany
- Centre 3:** Dr J Fischer
Bürgerhospital, Psychiatrische Klinik, Stuttgart, Germany
- Centre 4:** Dr R Uebelhack
Poliklinik der Charité Nervenkllinik, Berlin, Germany
- Centre 6:** Dr W König
Psychiatrisches Landeskrankenhaus Weissenhof, Weinsberg, Germany
- Centre 7:** Dr M Derely
Clinique La Raméc, Neuropsychiatric Hospital, Brussels, Belgium
- Centre 8:** Dr J Wilmotte
Hôpital Civil Vincent Van Gogh, Marchienne-au-Pont, Belgium
- Centre 9:** Dr M Van Moffaert
Universitair Ziekenhuis Gent, Psychiatrische Kliniek, Gent, Belgium
- Centre 9/a:** Dr R Spiers
St Camillus Ziekenhuis, St Denijs-Westrem, Belgium
- Centre 10:** Dr J Bollen
Sancta Maria Psychiatr Ziekenhuis, Sint Truiden, Belgium
- Centre 11:** Prof CA Gagiano
Department of Psychiatry, University of Orange Free State, Bloemfontein, South Africa

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- Centre 12:** Dr M Berk
Johannesburg Medical School, Psychiatry Department, Parktown,
South Africa
- Centre 13:** Dr DAB Wilson
Department of Psychiatry, Grootte Schuur Hospital, Cape Town, South
Africa
- Centre 14:** Dr P Weinholz
Brauhoﬀgasse 1, Erlangen-Frauenaurach, Germany
- Centre 14/1:** Dr H Hauer
An der Aurach 8, Emskirchen, Germany
- Centre 14/2:** Dr M El Mallah
Seltsamplatz 3, Forchheim, Germany
- Centre 14/3:** Dr M O'Connolly
Haimendorfstrasse 4, Schwabach-Wolkersdorf, Germany
- Centre 14/4:** Dr P Adler
Schnicglingerstrasse 36a, Nürnberg, Germany
- Centre 14/7:** Dr K Schroter
Altdorfer Strasse 11, Lauf/Pegnitz, Germany
- Centre 14/8:** Dr G Stumpf
Volkacher Strasse 31, Nürnberg, Germany
- Centre 14/10:** Dr II Wiswedel
Friedenstrasse 12, Fürth/Bay, Germany
- Centre 15:** Prof A Levin
Fort England Hospital, Grahamstown, South Africa

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, 23
20014 NERVIANO
TELEFONO (0331) 587263
TELEGRAMMI FARMITALIA CARLO ERBA NERVIANO
CASSELLA POSTALE 2
TELEX 310679 MONTEO PER FARMITALIA NERVIANO

 **FARMITALIA CARLO ERBA**

December 9th, 1992
DATA

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 

SPL SESE LLOCALE (MILANO)
CAPITALE SOC. L. 528 / 12 127 000 117
TRIBUNALE MILANO (C. F. 238246)
VCL 6366 - FACC 46 - CCIAA N. 1171077
COD. FISC. E PART. IVA N. 07608290156

GRUPPO ERBAMONT

514

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9550085

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 

6-REGISTERED TRADE MARK OF PHARMACIA SPA

515
Centro Ricerche
Farmitalia Carlo Erba srl
Via Giovanni XXIII, 23
20014 Nerviano (Mi) Italy

Telef. (0331) 58.3111 (Centralino)
Casella Postale 2

Sede Legale Milano
Capit. L. 528.732.127.000 I.V.
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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9550085

CENTRO RICERCHE
VIA GIOVANNI XXIII, 23
20014 MERVIANO
TELEFONO (0331) 597250
TELEGRAMMI FARMITALIA CARLO ERBA LERZANO
CASELLA POSTALE 2
TELETELEFONO 910679 MONTE PER FARMITALIA LERZANO

 FARMITALIA CARLO ERBA

December 9th, 1992

DATA

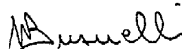
CERTIFICATE OF ANALYSIS

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 : V. Busnelli 

SPR. REDE LEGALE N. 10/1992
CAP. 145 - 145 - 145 - 145 - 145
PUBBLICAZIONE N. 145/1992
VOL. 6366 - FASC. 46 - 145/1992
COD. FISC. E PART. 145/145/145

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GRUPPO ERBAMONT

9550085

VIA CARLO MAGNATI, 24
20159 MILANO



TELEFONO (02) 69851 (CENTRALINO)
TELEGRAMMI ERBACAP MILANO
CASELLA 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	: V. Busnelli <i>Busnelli</i>

S.R.L. SEDE LEGALE IN MILANO
CAPITALE L. 538.732.127.000 I.V.
PROMUVALE DI MILANO (I.S. N. 239246
VOL. 6306 - FASC. 16 - C.C.I.A.A. N. 1171077
COD. FISC. E PART. IVA N. 07668290156

GRUPPO ERBAMONT

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VIA CARLO IMBORNATI, 24
20159 MILANO

TELEFONO (02) 8925.1 (CENTRALINO)
TELEGRAMMI ERBA-CAR-MILANO
CASELLA POSTALE 10519
C.C. POSTALE 819205
TELEX 330314 EPBA 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 <i>VB</i>

S.R.L. - SEDE LEGALE IN MILANO
CAPITALE L. 533.742.517.000 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

518 GRUPPO ERBAMONT
MONTEDISCO - CURA DELLA SALUTE

9550085

VIA CARLO IMBONATI, 24
20159 MILANO

 **FARMITALIA CARLO ERBA**

TELEFONO (02) 6985.1 (CENTRALINO)
TELEGRAMMI ERBACAR-MILANO
CASSELLA POSTALE 10519
C.C. POSTALE 619205
TELEX 330314 ERBA-I.

March 24th, 1992

DATA

VS. RIF.

NS. RIF.

TEL. 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 : V. Busnelli *Busnelli*

SRL SEDE LEGALE IN MILANO
CAPITALE L. 528.732.127.000 IV
TRIBUNALE DI MILANO R.S. N. 2382/8
VCL 8368 - FASC. 10 - C.C.I.A.A. N. 1171077
COD. FISC. E PART. IVA N. 07608290156

519

GRUPPO ERBAMONT

9550085

VIA CARLO IMBONATI, 24
20159 MILANO

TELEFONO (02) 69951 (CENTRALINO)
TELEGRAMMI ERBACAR-MILANO
CASSELLA POSTALE 10519
C.C. POSTALE 619205
TELEX 330314 ERBAI



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 Salmoneilla : absent
Approved by	: Virginio Busnelli <i>Busnelli</i>

S.R.L. - SEDE LEGALE IN MILANO
CAPITALE L. 533.742.617.000 I.V.
TRIBUNALE DI MILANO R.S. N. 238246
VOL. 6386 - FASC. 46 - C.C.I.A.A. N. 1171077
COD. FISC. E PART. IVA N. 07508290156

520

GRUPPO ERBAMONT
MONTEDISON CURA DELLA SALUTE

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VIA CARLO IMBONATI, 24
20159 MILANO



FARMITALIA CARLO ERBA

TELEFONO (02) 69951 (CENTRALINO)
TELEGRAMMI ERBACAR MILANO
CASSELLA POSTALE 10619
C.C. POSTALE 919205
TELEX 330314 ERBA I.

October 25, 1990

DATA

VS. RIF.

VS. RIF.

TEL. DIRETTO

ANALISYS 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 *VB*

S.R.L. - SEDE LEGALE IN MILANO
CAPITALE L. 333.742.017.000 IV.
TRIBUNALE DI MILANO R.S. N. 238246
VOL. 6386 - FASC. 48 - C.C.I.A.A. N. 117/077
COD. FISC. E PART. IVA N. 07608290156

521 GRUPPO ERBAMONT
MONTEDISON CURA DELLA SALUTE

9550085

VIA CARLO IMBONATI, 24
20159 MILANO

 **FARMITALIA CARLO ERBA**

TELEFONO (02) 6955.1 (CENTRALINO)
TELEGRAMMI ERBACAR-MILANO
CASELLA POSTALE 10519
C.C. POSTALE 619205
TELEX 330314 ERBA-I.

DATA **March 24th, 1992**

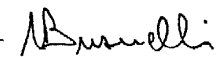
VS. RIF.

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 : V. Busnelli 

S.R.L. - SEDE LEGALE IN MILANO
CAPITALE L. 529.732.127.000 I.V.
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

522 **GRUPPO ERBAMONT**

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Pharmacia

Document 9550085

12.1.6 AUDIT CERTIFICATE

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523

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Pharmacia
Pharmaceuticals Milan R&D/GCP-QA

R&D/Q.A. AUDIT CERTIFICATE

Product **REBOXETINE**
Protocol N°: **FCE 20124/017** N° GCP: **56**
Study title: **Multicenter, multinational double-blind study of the activity and tolerability of Reboxetine vs Imipramine in patients suffering from Major Depressive Disorders.**

Type of Audit	Site	Audit date(s)	Reporting date
Draft Protocol	FICE - Milan	08.1990	28.08.1990
Final Protocol	FICE - Milan	05-09.10.1990	09.10.1990
Study Master File	Pharmacia - Milan	03-29.04.1995	02.06.1995
Data Listings vs CRFs	Pharmacia - Milan	09-17.11.1995	23.11.1995
Draft Final Report	Pharmacia - Milan	28.11-01.12.1995	04.12.1995
Final Report	Pharmacia - Milan	17.01.1996	18.01.1996

Signature of the Head of R&D/GCP-Q.A. *Alberto Kanni*

.Date: *18 Jan, 1996*

9550085

Pharmacia

Document 9550085

12.1.7 RANDOMIZATION LIST

0550085
Randomization List

Center=1

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
1	1	1	reboxetine
2	1	2	reboxetine
3	1	3	imipramine
4	1	4	imipramine
5	1	5	reboxetine
6	1	6	imipramine
7	1	7	reboxetine
8	1	8	imipramine
9	1	9	imipramine
10	1	10	imipramine
11	1	11	reboxetine
12	1	12	reboxetine
13	1	13	reboxetine
14	1	14	reboxetine
15	1	15	imipramine
16	1	16	imipramine
17	1	17	imipramine
18	1	18	reboxetine
19	1	19	imipramine
20	1	20	reboxetine
21	1	21	reboxetine
22	1	22	imipramine
23	1	23	reboxetine
24	1	24	imipramine
25	1	25	imipramine
26	1	26	reboxetine
27	1	27	reboxetine
28	1	28	imipramine
29	1	29	reboxetine
30	1	30	imipramine
31	1	31	reboxetine
32	1	32	imipramine

Center=2

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
33	2	1	reboxetine
34	2	2	imipramine
35	2	3	reboxetine
36	2	4	imipramine
37	2	5	reboxetine
38	2	6	imipramine
39	2	7	reboxetine
40	2	8	imipramine
41	2	9	reboxetine
42	2	10	imipramine
43	2	11	reboxetine
44	2	12	imipramine
45	2	13	imipramine
46	2	14	reboxetine
47	2	15	reboxetine
48	2	16	imipramine
49	2	17	imipramine
50	2	18	reboxetine
51	2	19	reboxetine
52	2	20	imipramine
53	2	21	reboxetine
54	2	22	imipramine
55	2	23	reboxetine
56	2	24	imipramine
57	2	25	reboxetine
58	2	26	imipramine
59	2	27	imipramine
60	2	28	reboxetine
61	2	29	reboxetine
62	2	30	reboxetine
63	2	31	imipramine
64	2	32	imipramine

Randomization 959085

Center=3

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
65	3	1	reboxetine
66	3	2	isipramine
67	3	3	reboxetine
68	3	4	isipramine
69	3	5	isipramine
70	3	6	reboxetine
71	3	7	isipramine
72	3	8	reboxetine
73	3	9	reboxetine
74	3	10	isipramine
75	3	11	isipramine
76	3	12	reboxetine
77	3	13	isipramine
78	3	14	reboxetine
79	3	15	reboxetine
80	3	16	isipramine
81	3	17	reboxetine
82	3	18	isipramine
83	3	19	isipramine
84	3	20	reboxetine
85	3	21	isipramine
86	3	22	isipramine
87	3	23	reboxetine
88	3	24	reboxetine
89	3	25	isipramine
90	3	26	reboxetine
91	3	27	reboxetine
92	3	28	isipramine
93	3	29	isipramine
94	3	30	reboxetine
95	3	31	reboxetine
96	3	32	isipramine

Center=4

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
97	4	1	isipramine
98	4	2	isipramine
99	4	3	reboxetine
100	4	4	reboxetine
101	4	5	isipramine
102	4	6	reboxetine
103	4	7	isipramine
104	4	8	reboxetine
105	4	9	isipramine
106	4	10	reboxetine
107	4	11	isipramine
108	4	12	reboxetine
109	4	13	isipramine
110	4	14	reboxetine
111	4	15	reboxetine
112	4	16	isipramine
113	4	17	isipramine
114	4	18	isipramine
115	4	19	reboxetine
116	4	20	reboxetine
117	4	21	isipramine
118	4	22	reboxetine
119	4	23	reboxetine
120	4	24	isipramine
121	4	25	isipramine
122	4	26	reboxetine
123	4	27	isipramine
124	4	28	reboxetine
125	4	29	reboxetine
126	4	30	isipramine
127	4	31	isipramine
128	4	32	reboxetine

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Center=5

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
129	5	1	reboxetine
130	5	2	reboxetine
131	5	3	imipramine
132	5	4	imipramine
133	5	5	imipramine
134	5	6	reboxetine
135	5	7	reboxetine
136	5	8	imipramine
137	5	9	reboxetine
138	5	10	imipramine
139	5	11	reboxetine
140	5	12	imipramine
141	5	13	reboxetine
142	5	14	imipramine
143	5	15	reboxetine
144	5	16	imipramine
145	5	17	imipramine
146	5	18	reboxetine
147	5	19	reboxetine
148	5	20	imipramine
149	5	21	imipramine
150	5	22	imipramine
151	5	23	reboxetine
152	5	24	reboxetine
153	5	25	reboxetine
154	5	26	imipramine
155	5	27	imipramine
156	5	28	reboxetine
157	5	29	imipramine
158	5	30	reboxetine
159	5	31	reboxetine
160	5	32	imipramine

Center=6

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
161	6	1	reboxetine
162	6	2	reboxetine
163	6	3	imipramine
164	6	4	imipramine
165	6	5	reboxetine
166	6	6	reboxetine
167	6	7	imipramine
168	6	8	imipramine
169	6	9	imipramine
170	6	10	reboxetine
171	6	11	reboxetine
172	6	12	imipramine
173	6	13	imipramine
174	6	14	reboxetine
175	6	15	imipramine
176	6	16	reboxetine
177	6	17	imipramine
178	6	18	reboxetine
179	6	19	reboxetine
180	6	20	imipramine
181	6	21	reboxetine
182	6	22	imipramine
183	6	23	reboxetine
184	6	24	imipramine
185	6	25	reboxetine
186	6	26	imipramine
187	6	27	imipramine
188	6	28	reboxetine
189	6	29	reboxetine
190	6	30	reboxetine
191	6	31	imipramine
192	6	32	imipramine

Kanonymisiert 9550085

----- Center=7 -----

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
193	7	1	reboxetine
194	7	2	reboxetine
195	7	3	isipramine
196	7	4	isipramine
197	7	5	reboxetine
198	7	6	isipramine
199	7	7	isipramine
200	7	8	reboxetine
201	7	9	isipramine
202	7	10	isipramine
203	7	11	reboxetine
204	7	12	reboxetine
205	7	13	isipramine
206	7	14	isipramine
207	7	15	reboxetine
208	7	16	reboxetine
209	7	17	isipramine
210	7	18	reboxetine
211	7	19	reboxetine
212	7	20	isipramine
213	7	21	isipramine
214	7	22	reboxetine
215	7	23	reboxetine
216	7	24	isipramine
217	7	25	isipramine
218	7	26	reboxetine
219	7	27	isipramine
220	7	28	reboxetine
221	7	29	isipramine
222	7	30	isipramine
223	7	31	reboxetine
224	7	32	reboxetine

----- Center=8 -----

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
225	8	1	isipramine
226	8	2	reboxetine
227	8	3	isipramine
228	8	4	reboxetine
229	8	5	isipramine
230	8	6	isipramine
231	8	7	reboxetine
232	8	8	reboxetine
233	8	9	isipramine
234	8	10	reboxetine
235	8	11	reboxetine
236	8	12	isipramine
237	8	13	reboxetine
238	8	14	isipramine
239	8	15	isipramine
240	8	16	reboxetine
241	8	17	isipramine
242	8	18	reboxetine
243	8	19	isipramine
244	8	20	reboxetine
245	8	21	isipramine
246	8	22	reboxetine
247	8	23	reboxetine
248	8	24	isipramine
249	8	25	reboxetine
250	8	26	isipramine
251	8	27	isipramine
252	8	28	reboxetine
253	8	29	isipramine
254	8	30	isipramine
255	8	31	reboxetine
256	8	32	reboxetine

Randnummer 0550085

Center=9

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
257	9	1	reboxetine
258	9	2	reboxetine
259	9	3	isipramine
260	9	4	isipramine
261	9	5	isipramine
262	9	6	reboxetine
263	9	7	reboxetine
264	9	8	isipramine
265	9	9	reboxetine
266	9	10	reboxetine
267	9	11	isipramine
268	9	12	isipramine
269	9	13	reboxetine
270	9	14	isipramine
271	9	15	reboxetine
272	9	16	isipramine
273	9	17	isipramine
274	9	18	reboxetine
275	9	19	reboxetine
276	9	20	isipramine
277	9	21	reboxetine
278	9	22	isipramine
279	9	23	isipramine
280	9	24	reboxetine
281	9	25	reboxetine
282	9	26	reboxetine
283	9	27	isipramine
284	9	28	isipramine
285	9	29	reboxetine
286	9	30	reboxetine
287	9	31	isipramine
288	9	32	isipramine

Center=10

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
289	10	1	isipramine
290	10	2	reboxetine
291	10	3	isipramine
292	10	4	reboxetine
293	10	5	reboxetine
294	10	6	isipramine
295	10	7	isipramine
296	10	8	reboxetine
297	10	9	reboxetine
298	10	10	reboxetine
299	10	11	isipramine
300	10	12	isipramine
301	10	13	isipramine
302	10	14	isipramine
303	10	15	reboxetine
304	10	16	reboxetine
305	10	17	reboxetine
306	10	18	reboxetine
307	10	19	isipramine
308	10	20	isipramine
309	10	21	reboxetine
310	10	22	isipramine
311	10	23	isipramine
312	10	24	reboxetine
313	10	25	isipramine
314	10	26	reboxetine
315	10	27	isipramine
316	10	28	reboxetine
317	10	29	reboxetine
318	10	30	reboxetine
319	10	31	isipramine
320	10	32	isipramine

REBOXETINE prot. 017
 Randomisiert 9550089

 Center=11

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
321	11	1	reboxetine
322	11	2	reboxetine
323	11	3	isipramine
324	11	4	isipramine
325	11	5	reboxetine
326	11	6	isipramine
327	11	7	reboxetine
328	11	8	isipramine
329	11	9	isipramine
330	11	10	reboxetine
331	11	11	reboxetine
332	11	12	isipramine
333	11	13	isipramine
334	11	14	isipramine
335	11	15	reboxetine
336	11	16	reboxetine
337	11	17	isipramine
338	11	18	reboxetine
339	11	19	isipramine
340	11	20	reboxetine
341	11	21	reboxetine
342	11	22	isipramine
343	11	23	reboxetine
344	11	24	isipramine
345	11	25	isipramine
346	11	26	reboxetine
347	11	27	isipramine
348	11	28	reboxetine
349	11	29	isipramine
350	11	30	reboxetine
351	11	31	reboxetine
352	11	32	isipramine

 Center=12

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
353	12	1	reboxetine
354	12	2	isipramine
355	12	3	reboxetine
356	12	4	isipramine
357	12	5	isipramine
358	12	6	reboxetine
359	12	7	reboxetine
360	12	8	isipramine
361	12	9	reboxetine
362	12	10	isipramine
363	12	11	reboxetine
364	12	12	isipramine
365	12	13	isipramine
366	12	14	reboxetine
367	12	15	isipramine
368	12	16	reboxetine
369	12	17	reboxetine
370	12	18	isipramine
371	12	19	reboxetine
372	12	20	isipramine
373	12	21	isipramine
374	12	22	reboxetine
375	12	23	reboxetine
376	12	24	isipramine
377	12	25	reboxetine
378	12	26	reboxetine
379	12	27	isipramine
380	12	28	isipramine
381	12	29	reboxetine
382	12	30	isipramine
383	12	31	isipramine
384	12	32	reboxetine

REBOXETINE p-ct. 017
Randomized 0550085

Center=13

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
385	13	1	reboxetine
386	13	2	reboxetine
387	13	3	isipramine
388	13	4	isipramine
389	13	5	isipramine
390	13	6	isipramine
391	13	7	reboxetine
392	13	8	reboxetine
393	13	9	isipramine
394	13	10	reboxetine
395	13	11	reboxetine
396	13	12	isipramine
397	13	13	reboxetine
398	13	14	isipramine
399	13	15	reboxetine
400	13	16	isipramine
401	13	17	isipramine
402	13	18	reboxetine
403	13	19	reboxetine
404	13	20	isipramine
405	13	21	reboxetine
406	13	22	isipramine
407	13	23	reboxetine
408	13	24	isipramine
409	13	25	isipramine
410	13	26	reboxetine
411	13	27	isipramine
412	13	28	reboxetine
413	13	29	reboxetine
414	13	30	isipramine
415	13	31	reboxetine
416	13	32	isipramine

Center=14

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
417	14	1	reboxetine
418	14	2	isipramine
419	14	3	reboxetine
420	14	4	isipramine
421	14	5	reboxetine
422	14	6	isipramine
423	14	7	isipramine
424	14	8	reboxetine
425	14	9	reboxetine
426	14	10	reboxetine
427	14	11	isipramine
428	14	12	isipramine
429	14	13	isipramine
430	14	14	reboxetine
431	14	15	reboxetine
432	14	16	isipramine
433	14	17	isipramine
434	14	18	reboxetine
435	14	19	isipramine
436	14	20	reboxetine
437	14	21	reboxetine
438	14	22	isipramine
439	14	23	reboxetine
440	14	24	isipramine
441	14	25	isipramine
442	14	26	isipramine
443	14	27	reboxetine
444	14	28	reboxetine
445	14	29	isipramine
446	14	30	reboxetine
447	14	31	reboxetine
448	14	32	isipramine

REMARKING - PMUJ. UL7
Randomize 0550065

----- Center=14 bis -----

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
449	14 bis	449	reboxetine
450	14 bis	450	isipramine
451	14 bis	451	isipramine
452	14 bis	452	reboxetine
453	14 bis	453	isipramine
454	14 bis	454	reboxetine
455	14 bis	455	reboxetine
456	14 bis	456	isipramine
457	14 bis	457	reboxetine
458	14 bis	458	isipramine
459	14 bis	459	reboxetine
460	14 bis	460	isipramine
461	14 bis	461	isipramine
462	14 bis	462	reboxetine
463	14 bis	463	isipramine
464	14 bis	464	reboxetine
465	14 bis	465	reboxetine
466	14 bis	466	isipramine
467	14 bis	467	reboxetine
468	14 bis	468	isipramine
469	14 bis	469	isipramine
470	14 bis	470	reboxetine
471	14 bis	471	reboxetine
472	14 bis	472	isipramine
473	14 bis	473	reboxetine
474	14 bis	474	reboxetine
475	14 bis	475	isipramine
476	14 bis	476	isipramine
477	14 bis	477	isipramine
478	14 bis	478	isipramine
479	14 bis	479	reboxetine
480	14 bis	480	reboxetine

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12.1.8 LABORATORY REFERENCE VALUES AND CRITERIA USED TO JUDGE LABORATORY ABNORMALITIES AS CLINICALLY RELEVANT

PHARMACIA C9580085

REBOXETINE - PROTOCOL 20126/017

APPENDIX No.: 12.1.8

LABORATORY REFERENCE VALUES

Laboratory test	Units	Range values			
		Female		Male	
		Min	Max	Min	Max
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 CNS MSD

REBOUSTINE - PROTOCOL 20124/017
APPENDIX No.1 12.1.6

CRITERIA USED TO JUDGE LABORATORY ABNORMALITIES AS CLINICALLY RELEVANT

Laboratory test	Percent variation above or below normal range (%)
HB	- 15
HT	- 15
ERC	- 15
PLATELETS	- 30
WBC	+ 30
WBC: N	+ 30
WBC: E	+ 30
WBC: B	+ 30
WBC: L	+ 30
WBC: M	+ 30
CRSANTINE	+ 50
UREA	+ 50
BUN	+ 50
UREIC ACID	+ 50
TOT. PROTEINS	+ 30
ALBUMINE	+ 100
TOT BILIRUBIN	+ 100
DIR BILIRUBIN	+ 100
SGOT	+ 100
SGPT	+ 100
GAMMA GT	+ 100
LVE	+ 100
ALK. PHOSPH.	+ 30
GLOBULINS ALPHA 1	+ 30
GLOBULINS ALPHA 2	+ 30
GLOBULINS BETA	+ 30
GLOBULINS GAMMA	+ 30
TOT. CHOLEST.	- 20
HDL	+ 30
TRIGLYCERIDES	+ 30
GLUCOSE	+ 10
NA+	+ 10
CL-	+ 15
K+	+ 15
Ca++	+ 15
PO4--	+ 15
ETS	not defined
T3	not defined
T4	+ 10
ESR/SEDIMENT. RATE	not defined

(*) MINUS INDICATES BELOW THE LOWER LIMIT OF NORMAL RANGE, AND PLUS ABOVE THE UPPER LIMIT OF NORMAL RANGE

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12.1.9 ADVERSE EVENTS GROUPED IN CLUSTERS

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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	2	2
		ASTHENIA	Reboxetine	1	1
		FATIGUE	Imipramine	5	5
		FATIGUE	Reboxetine	5	4
CARDIOVASCULAR DISORDERS, GENERAL	FLUSHING / HOT FLASHING	FLUSHING	Imipramine	1	1
		FLUSHING	Reboxetine	2	2
	HYPOTENSION AND RELATED SYMPTOMS	HOT FLUSHES	Imipramine	2	2
		DIZZINESS	Imipramine	19	18
		DIZZINESS	Reboxetine	13	12
		HYPOTENSION	Imipramine	6	5
		HYPOTENSION POSTURAL	Imipramine	2	2
		HYPOTENSION POSTURAL	Reboxetine	1	1
		HEADACHE	Imipramine	21	18
		HEADACHE	Reboxetine	27	21
GASTRO-INTESTINAL SYSTEM DISORDERS	NAUSEA AND RELATED SYMPTOMS	VOMITING	Imipramine	1	1
		VOMITING	Reboxetine	1	1
		DYSPEPSIA	Reboxetine	3	3
		NAUSEA	Imipramine	13	13
		NAUSEA	Reboxetine	16	16
		SOFT INCREASED GAMMA-GT INCREASED	Reboxetine	1	1
		GAMMA-GT INCREASED	Imipramine	2	2
		GAMMA-GT INCREASED	Reboxetine	1	1
		HEPATIC ENZYMES INCREASED	Imipramine	2	1
		HEPATIC ENZYMES INCREASED	Reboxetine	1	1
PSYCHIATRIC DISORDERS	AGITATION / ANXIETY / NERVOUSNESS	AGITATION	Imipramine	9	9
		AGITATION	Reboxetine	8	6
		ANXIETY	Imipramine	1	1
		NERVOUSNESS	Reboxetine	3	3
SKIN AND APPENDAGES DISORDERS	ERYTHEMA / RASH	RASH	Imipramine	2	2
		RASH	Reboxetine	3	3
URINARY SYSTEM DISORDERS	URINARY HESITANCY / RETENTION	URINARY RETENTION	Imipramine	4	4
		URINARY RETENTION	Reboxetine	3	2
		MICTURITION DISORDER	Imipramine	3	3
		MICTURITION DISORDER	Reboxetine	8	8
VISION DISORDERS	BLURRED VISION	ACCOMMODATION ABNORMAL	Imipramine	2	2

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 Appendix No.: 12.1.9
 ADVERSE EVENTS GROUPED IN CLUSTERS

Body System	Cluster	Adverse event	Treatment	No of AE	No of Pt with AE
VISION DISORDERS	BLURRED VISION	VISION ABNORMAL	Imipramine	4	4
		VISION ABNORMAL	Reboxetine	4	4

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12.1.10 ECG CODES

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REBOXETINE - PROTOCOL 20124/017

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
 - 83
 - Other (specify) _____
 - 104
 - Right axial deviation

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12.1.11 STATISTICAL ANALYSIS PROGRAMS LISTINGS

```

*
*
*          PHARMACIA CNS R&D          9550085          ;
*
*          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 :                               *
* l95 -> % LOWER LIMIT                  *
* u95 -> % UPPER LIMIT                  *
*-----*

if pct = 0 then do;
    l95=0;
    u95 = (1-exp(log(0.05)/_pop_) * 100;
end;
else
if pct = 100 then do;
    u95=100;
    l95 = 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;
    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;
    end;
    l95 = z * 100;
    if k > 100 then put '**1** convergence was not attained in 100 '
        'iterations ' k= z= pct= ls= li= ;
end;

```



```

*
*          PHARMACIA CNS R&D          9550085          ;
*
*          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 ;                               9550085
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. * (probbnm1(.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 a1 a12 a13 a21 a22 a23 a31 a32 a33;
array _a_ (9) a1 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. * probbnm1(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. * probbnm1(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. * probbnm1(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;

```

```
data maxw (keep = &var cod_trt lab_par day p_maxw_maxw_p num_ord
              dw sm up k lab_bas);;
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 9550085

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;

goptions reset=global qunit=pct /*rotate=landscape */

```

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```

rotate=portrait
device=gddmfam4 gddmtoken=fine240 gddmnickname=p3820
vsize= hsize= 7 in hpos= vpos=
vorigin=1.25 in horigin=2.25 in
ftext=swiss htitle=3 htext=2 display;
9550085
RUN;

%include pgmgen(gtitle);
%include pgmgen(qsymb4);

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 &qmaxlev 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=&qminval to &qmaxval by &qbyval;

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;
trt(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;                                     9550085
  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';
```

```

TITLE1 'PHARMACIA CNS R&D';
TITLE3 'REBOXETINE - PROTOCOL 20124/17';          9550085
TITLES 'APPENDIX NO. 12.1.11';
FOOTNOTE;

*****
*- PROGRAM .. : Y00.REBOX.PGM(CONF17)          -*
*- GOAL ..... : CONFIDENCE INTERVAL          -*
*- AUTHOR .... : N.O.                        -*
*- REFERENCE  : DESIGN AND ANALYSIS OF EXPERIM.-*
*- JOHN L.GILL, 1978 PG 51-56                -*
*-note : for each protocol introduce the requested-*
* data (supplied by ANOVA)                  -*
*****;

*****;
* MC=MEAN (CAMPION)                          ;
* MS=MEAN (STANDARD)                          ;
* NC=NUMBER OF OBSERVATION (CAMPION)          ;
* NS=NUMBER OF OBSERVATION (STANDARD)        ;
* S2E=MEAN SQUARE ERROR                      ;
* DF =DEGREES OF FREEDOM OF ERROR            ;
*****;

DATA PIPPO;INPUT
  TIT $ MC MS NC NS S2E DF ;
CARDS;
LASTTOT 15.8 14.3 127 121 101.9 246
LASTMEL 16.9 15.25 51 44 131.7 93
LASTSEV 16.5 14.5 99 87 105.3 184
;
RUN;
DATA PIPPO;SET PIPPO;
tt=abs(tinv(0.025,df));
ERR2=(1/NC+1/NS);
ERR=SQRT(ERR2*S2E);
DIFF=NC-MS;
INF=DIFF-TT*ERR;
SUP=DIFF+TT*ERR;

LABEL DIFF='BETWEEN TREATM. DIFFERENCE ' TIT='POPULATION ANALYSED'
INF='LOWER LIMIT' SUP='UPPER LIMIT'
MC='MEAN REBOXETINE ' MS='MEAN IMIPRAMINE';

PROC FORMAT ;VALUE $TIT 'LASTTOT'='TOTAL POPULATION'
'LASTMEL'='MELANCHOLIC PTS '
'LASTSEV'='SEVERE PTS ' ;

PROC PRINT LABEL NOOBS;
TITLE9 'BETWEEN TREATMENT DIFFERENCE AND 95% CONFIDENCE INTERVAL ' ;
VAR TIT MC MS DIFF INF SUP;
format tit $tit.;
RUN;

```

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Pharmacia

Document 9550085

12.1.12 SELECTION OF STATISTICAL ANALYSIS OUTPUTS

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017

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

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.)
- ANOVA according to the model : HAMD decrease = treatment
- 95% confidence interval of the between treatments difference.

Response : 50% HAMD decrease

- Log-rank test on time to response (comparison between treatments).

Analysis of Adverse events

- Log-rank test on the time to the first occurrence of either any event and selected signs-symptoms (comparison between treatments).

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1

PHARMACIA PHARMACEUTICAL MILANO - CNS
REBOXETINE - PROTOCOL 20124/017
APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON AT BASELINE

General Linear Model Procedure
Class Level Information

Class	Levels	Values
CDD_TPT	2	INI RBX

Number of observations in data set = 248

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57
33

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2

PHARMACIA PHARMACEUTICAL MILANO - CNS

REDUCING - PROTOCOL 20124/017
APPENDIX No. 1 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON AT BASELINE

General Linear Models Procedure

Dependent Variable: MAMO						
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F	
Model	1	34.59951073	34.59951073	1.38	0.2412	
Error	246	6166.88033796	25.06861922			
Corrected Total	247	6201.47985871				
R-Square		C.V.		Root MSE		MAMO Mean
	0.05579	17.68028				28.39919265
Type I SS		Mean Square		F Value		Pr > F
CS0_INT	1	34.59951073	34.59951073	1.38	0.2412	
Type III SS		Mean Square		F Value		Pr > F
CS0_INT	1	34.59951073	34.59951073	1.38	0.2412	

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PARANACIA CBS RED
RESEARCHING - PROTOCOL 20124/017
APPENDIX NO. 12.1.12
HAMILTON DEPRESSION RATING SCALE
DESCRIPTIVE STATISTICS ON LAST ASSESSMENT

TOTAL SCORE HAMILTON		BASELINE	LAST ASSESS.	DECREASE
TREATED-NT				
Treated-Int	N	121	121	121
	MEAN	26.02	15.68	14.34
Treated-Int	S.D.	5.16	10.31	9.85
	N	127	127	127
Treated-Int	MEAN	22.76	12.96	15.76
	S.D.	4.64	10.24	10.59

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PHARMACIA PHARMACEUTICAL IRLAND - CNS
RESUBMITTING - PROTOCOL 30424/017
APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSIGNMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure
Class Level Information

Class	Levels	Values
COO_TWT	2	INT MIX

Number of observations in data set = 248

556

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2

PHARMACIA PHARMACEUTICAL HILANO - CSE
 RESPOSTINE - PROTOCOL 20124/017
 APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE OF 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	1	128.61014517	128.61014517	1.26	0.2624	
Error	246	25068.93420967	101.90622662			
Corrected Total	247	25197.54435484				
R-Square		C.V.		Root MSE		DIFFN Mean
0.005104		66.93709		10.09486189		15.07661290
		Type I SS	Mean Square	F Value	Pr > F	
Source	DF	128.61014517	128.61014517	1.26	0.2624	
CSD_INT	1					
		Type III SS	Mean Square	F Value	Pr > F	
Source	DF	128.61014517	128.61014517	1.26	0.2624	
CSD_INT	1					

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PHARMACIA PHARMACEUTICAL KILKILAND - CNS

REGISTRATION - PROTOCOL 2012A/017

APPENDIX No.1 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure
Least Squares Means

COD_TRT DIFFN
LORAZAM

III 14.308430
RMS 15.7795276

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PHARMACIA CIB IND
RESEARCHING - PROTOCOL 2012A/017
APPENDIX NO. 1 12.1.12
HAMILTON IMPRESSION RATING SCALE
DESCRIPTIVE STATISTICS ON LAST ASSESSMENT
SEVERE PATIENTS JUDGED BY CGI SEVERITY AT BASELINE

TOTAL SCORE HAMILTON		BASELINE	LAST ASSESS.	DECREASE
SEVERE	TREATMENT			
NO	Isiprasone	N	34	34
		MEAN	25.24	11.29
	S.D.	3.05	9.49	
	N	28	28	
YES	Babocetine	MEAN	26.21	15.00
		S.D.	4.11	6.43
	N	87	87	
	MEAN	29.10	14.61	
S.D.	5.44	10.52		
N	99	99		
MEAN	29.48	12.96		
S.D.	4.81	10.73		

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PHARMACIA PHARMACEUTICAL MILANO - CSR
RESUBMITTAL - PROTOCOL 20154/017
APPENDIX No.1 12.1.12

SEVERE PATIENTS JUDGED BY CSF SEVERITY AT BASELINE
ANALYSIS OF VARIANCES ON TOTAL SCORE HAMILTON DEPRESSION AT LAST ASSESSMENT BY SITE RESPECT TO BASELINE VALUE

General Linear Models Procedure
Class Level Information

Class	Levels	Values
CSF_TXT	2	III NER

Number of observations in data set = 191

NOTE: Due to missing values, only 186 observations can be used in this analysis.

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PHARMACIA PHARMACEUTICAL HILAND - CNS

REMARKS - PROTOCOL 20124/017

APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE INCREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure

Dependent Variables: DIFFN					
Source	DF	Sum of Squares	Mean Square	F Value	P > F
Model	1	187.23120527	187.23120527	1.78	0.1840
Error	104	19268.49460116	185.26855762		
Corrected Total	105	19455.72580643			
R-Square					
		C.V.	Root MSE		DIFFN Mean
	0.00574	65.91791	16.25903500		15.54451613
Type III SS					
Source	DF	Sum of Squares	F Value	P > F	
COO_TRT	1	187.23120527	1.78	0.1840	
Type III SS					
Source	DF	Sum of Squares	F Value	P > F	
COO_TRT	1	187.23120527	1.78	0.1840	

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PHARMACIA PHARMACEUTICAL KILBARD - CNS

REGISTRATION - PROTOCOL 2012A/017
APPENDIX No.1 12.1.12

REVERSE PATIENTS JUDGED BY CSI SEVERITY AT BASELINE
ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure
Least Squares Means

CSO_TKT	DIFFN
III	14.4942359
REX	16.5010005

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PHARMACIA CNS 880
 REMEDIATION - PROTOCOL 2012A/017
 APPENDIX NO. 12.1.12
 HAMILTON DEPRESSION RATINGS SCALES
 DESCRIPTIVE STATISTICS ON LAST ASSESSMENT
 BIPOLAR PATIENTS

TOTAL SCORE HAMILTON		BASELINE	LAST ASSESS.	DECREASE
NO	INTEGRATED	N	64	64
	LINE	MEAN	26.00	12.27
		S.D.	3.39	9.19
		N	60	60
YES	INTEGRATED	N	44	44
	LINE	MEAN	31.50	16.25
		S.D.	5.94	11.58
		N	51	51
	INTEGRATED	MEAN	31.16	14.22
		S.D.	5.37	11.56
				12.38

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PIARMACIA PHARMACEUTICAL MILANO - CNS

REGISTRATION - PROTOCOL 20124-017

APPENDIX No.: 12.1.12

**MECHANISMIC PATIENTS
ANALYSIS OF VARIANCES ON TOTAL SCORE HAMILTON DEPRESSION AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE**

General Linear Models Procedure
Class Level Information

Class	Levels	Values
CNS_TRT	2	IMI MON

Number of observations in data set = 97

NOTE: Due to missing values, only 95 observations can be used in this analysis.

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2

PHARMACIA PHARMACEUTICAL MILANO - CHS
 RESOURTINE - PROTOCOL 2012A/017
 APPENDIX No. 1 12.1.12

HELMICOLIC PATIENTS
 ANALYSIS OF VARIANCE OF TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASKETLINE VALUE

General Linear Models Procedure

Dependent Variable: DIFF						
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F	
Model	1	67.55804954	67.55804954	0.51	0.4756	
Error	93	12245.07352941	131.67748731			
Corrected Total	94	12312.63157895				
R-Square		C.V.		Root MSE		DIFF Mean
0.005437		71.81571		11.47464410		16.18789474
Type III SS						
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F	
CMD_TXT	1	67.55804954	67.55804954	0.51	0.4756	
Type III SS						
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F	
CMD_TXT	1	67.55804954	67.55804954	0.51	0.4756	

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PHARMACIA PHARMACEUTICAL MILANO - CNS

REMOUSTINE - PROTOCOL 2012A/017
APPENDIX No.: 12.1.12

DIABETIC PATIENTS
ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Model Procedure
Least Squares Means

COD_TRT	DIFFN
	LARBA
INT	15.2500000
ERR	16.9411765

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PHARMACIA - PHARMACEUTICAL MILANO - CNS

BROMOCRIPTINE - PROTOCOL 20124/17

APPENDIX No. 12.1.12

BETWEEN TREATMENT DIFFERENCE AND 95% CONFIDENCE INTERVAL

POPULATION ANALYSED	MEAN REBOXETINE	MEAN IMIPRAMINE	BETWEEN TREATH. DIFFERENCE	LOWER LIMIT	UPPER LIMIT
TOTAL POPULATION	15.6	14.30	1.50	-1.02505	4.02505
MELANCHOLIC PTS	16.9	15.25	1.65	-3.03099	6.33099
SEVERE PTS	16.5	14.50	2.00	-0.97514	4.97514

PHARMACIA CNS 880
 RESORTING - PROTOCOL 20124/017
 APPENDIX No.: 12.1.12
 EFFICACY: KAPLAN / MEIER ANALYSIS - TIME TO ONSET OF RESPONSE (50 X HAMILTON DECREASE)

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	Uncensored
IMI	121	68	53	43.8817
EM	127	87	40	31.4961
Total	248	155	93	37.6000

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	-16.517	-2251.0
EM	16.517	2251.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	EM
IMI	33.8555	-35.8555
EM	-33.8555	35.8555

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	EM
IMI	804223	-804223
EM	-804223	804223

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	6.2251	1	0.0126
Wilcoxon	6.6837	1	0.0088
-2Log(LR)	3.4176	1	0.0645

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PHARMACIA CMO RND
 HEDONISTINE - PROTOCOL 20124/017
 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	XCensored
IMI	126	103	23	16.2540
RHX	130	106	24	15.4615
Total	256	209	47	16.3594

Testing Homogeneity of Survival Curves over Strata
 Time Variable: DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	3.6710	765.00
RHX	-3.6710	-765.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RHX
IMI	45.1117	-45.1117
RHX	-45.1117	45.1117

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	RHX
IMI	1340262	-1340262
RHX	-1340262	1340262

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	0.2907	1	0.5847
Wilcoxon	0.4364	1	0.5087
-2Log(LR)	0.7945	1	0.3728

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PHARMACIA CNS 820
 REMOUSTINE - PROTOCOL 2012A/017
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING AGITATION / ANXIETY / NERVOUSNESS

The LIFTEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
INI	126	9	117	92.8571
RSK	130	9	121	93.0769
Total	256	18	238	92.9668

Testing Homogeneity of Survival Curves over Strata
 Time Variable MAX

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
INI	0.22124	7.0000
RSK	-0.22124	-7.0000

Covariance Matrix for the Log-Rank Statistics

COD_TRT	INI	RSK
INI	4.47973	-4.47973
RSK	-4.47973	4.47973

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	INI	RSK
INI	243446	-243446
RSK	-243446	243446

Test of Equality over Strata

Test	Chi-Square	DF	Chi-Square	Pt >
Log-Rank	0.0109	1	0.9467	
Wilcoxon	0.0002	1	0.9887	
-2Log(LR)	0.0266	1	0.8744	

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PIANACCIA CHE 820
RENOVATING - PROTOCOL 2012A/017
APPENDIX No.: 12.1.12
CUMULATIVE RISK OF DEVELOPING ARTERIAL / FATIGUE

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	X-Censored
IMI	124	6	120	95.2881
EXK	150	5	125	96.1538
Total	254	11	245	95.7051

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
IMI	0.433998	160.00
EXK	-0.433998	-160.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	EXK
IMI	2.72643	-2.72643
EXK	-2.72643	2.72643

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	IMI	EXK
IMI	156746	-156746
EXK	-156746	156746

Test of Equality over Strata

Test	Chi-Square	DF	P >
Log-Rank	0.1474	1	0.7010
Wilcoxon	0.1633	1	0.6851
-2Log(LR)	0.1745	1	0.6762

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PHARMACIA CNS RSD
 RESOLUTIONS - PROTOCOL 2012A/017
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING SEIZURES

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	2Censored
IMI	126	1	125	99.2003
RSX	130	6	124	95.3946
Total	256	7	249	97.2656

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Milcoxon
IMI	-2.3969	-474.00
RSX	2.3969	474.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	RSX
IMI	1.74046	-1.74046
RSX	-1.74046	1.74046

Covariance Matrix for the Milcoxon Statistics

COD_TRT	IMI	RSX
IMI	75395.0	-75395.0
RSX	-75395.0	75395.0

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	5.2913	1	0.0696
Milcoxon	2.9639	1	0.0841
-2Log(LR)	3.6502	1	0.0561

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PHARMACIA CNS 880
 RESOUSING - PROTOCOL 20124/017
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING CONSTIPATION

The LIFETIME Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TPT	Total	Failed	Censored	ZCensored
IKI	126	13	113	89.6825
REX	150	13	117	90.0000
Total	256	26	230	89.8438

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TPT	Log-Rank	Wilcoxon
IKI	0.44940	132.00
REX	-0.44940	-132.00

Covariance Matrix for the Log-Rank Statistics

COD_TPT	IKI	REX
IKI	6.45751	-6.45751
REX	-6.45751	6.45751

Covariance Matrix for the Wilcoxon Statistics

COD_TPT	IKI	REX
IKI	322829	-322829
REX	-322829	322829

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	0.0318	1	0.8596
Wilcoxon	0.0540	1	0.8163
-2Log(LR)	0.0854	1	0.8172

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PHARMACIA CBS 82D

RESOURCING - PROTOCOL 20124/017
Appendix No.1 12.1.12

CUMULATIVE RISK OF DEVELOPING HEADACHE / MIGRAINE

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COO_TYT	Total	Failed	Censored	X-Censored
IMI	126	18	108	85.7143
EMK	130	21	109	83.8462
Total	256	39	217	84.7656

Testing Homogeneity of Survival Curves over Strata
Time Variable IMY

Rank Statistics

COO_TYT	Log-Rank	Mileston
IMI	-0.84889	-113.00
EMK	0.84889	113.00

Covariance Matrix for the Log-Rank Statistics

COO_TYT	IMI	EMK
IMI	9.68366	-9.68366
EMK	-9.68366	9.68366

Covariance Matrix for the Mileston Statistics

COO_TYT	IMI	EMK
IMI	454320	-454320
EMK	-454320	454320

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	0.8746	1	0.7843
Mileston	0.8287	1	0.8669
-2Log(LR)	0.0548	1	0.8149

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PHARMACIA CNS 280
 RESCHEDULE - PROTOCOL 2012A/017
 APPENDIX No.: 12.1.12
 CUMULATIVE RISK OF DEVELOPING EXHAUSTION AND RELATED SYMPTOMS

The LIFTEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TPT	Total	Failed	Censored	2Censored
INT	126	23	103	81.7%60
REN	130	13	117	90.0000
Total	256	36	220	85.9375

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TPT	Log-Rank	Wilcoxon
INT	5.8754	1325.0
REN	-5.8754	-1325.0

Covariance Matrix for the Log-Rank Statistics

COD_TPT	INT	REN
INT	8.85942	-8.85942
REN	-8.85942	8.85942

Covariance Matrix for the Wilcoxon Statistics

COD_TPT	INT	REN
INT	443668	-443668
REN	-443668	443668

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	3.8965	1	0.0494
Wilcoxon	3.9571	1	0.0467
-2*Log(LR)	4.7494	1	0.0295

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PIANACCIA CNS 890

RESEARCH - PROTOCOL 2012A-017
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING INSOMNIA

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COO_TPT	Total	Failed	Censored	X-Censored
IMI	126	14	112	88.8889
EM	130	10	120	92.3077
Total	256	24	232	90.6250

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COO_TPT	Log-Rank	Milozon
IMI	2.3366	403.00
EM	-2.3366	-403.00

Covariance Matrix for the Log-Rank Statistics

COO_TPT	IMI	EM
IMI	5.90078	-5.90078
EM	-5.90078	5.90078

Covariance Matrix for the Milozon Statistics

COO_TPT	IMI	EM
IMI	312368	-312368
EM	-312368	312368

Test of Equality over Strata

Test	Chi-Square	DF	P >
Log-Rank	0.9252	1	0.3361
Milozon	0.5199	1	0.4709
-2Log(LR)	1.1012	1	0.2940

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PHARMACIA CNS MSD

RESUBMITTING - PROTOCOL 2012A/017
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING MOUTH DRY

The LIFETIME Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	XCensored
IMI	126	45	61	64.2857
BNK	130	32	98	75.3046
Total	256	77	179	69.9219

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Bank Statistics

COD_TRT	Log-Bank	Milcoxon
IMI	9.1592	2117.0
BNK	-9.1592	-2117.0

Covariance Matrix for the Log-Bank Statistics

COD_TRT	IMI	BNK
IMI	10.2117	-10.2117
BNK	-10.2117	10.2117

Covariance Matrix for the Milcoxon Statistics

COD_TRT	IMI	BNK
IMI	894262	-894262
BNK	-894262	894262

Test of Equality over Strata

Test	Chi-Square	DF	Chi-Square	Pr >
Log-Bank	4.6064	1	0.0319	
Milcoxon	5.3720	1	0.0205	
-2Log(LR)	6.1999	1	0.0128	

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PEARLACIA CNS MD

RESEARCHLINE - PROTOCOL 2012A/017
APPENDIX No. 1 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	126	14	112	86.8889
BNK	130	19	111	85.3696
Total	256	33	223	87.1094

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Milcozen
IMI	-2.1412	-493.80
BNK	2.1412	493.80

Covariance Matrix for the Log-Rank Statistics

COD_TRT	IMI	BNK
IMI	7.96700	-7.96700
BNK	-7.96700	7.96700

Covariance Matrix for the Milcozen Statistics

COD_TRT	IMI	BNK
IMI	427566	-427566
BNK	-427566	427566

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	0.5755	1	0.4481
Milcozen	0.5694	1	0.4508
-2Log(LR)	0.4655	1	0.4921

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FRANGLIA CBS RSD

RESEARCH - PROTOCOL 2024/017
APPENDIX No.1 12.1.12

CUMULATIVE RISK OF DEVELOPING SEQUELAE

The LIFETIME Procedure
 Summary of the Number of Censored and Uncensored Values

COD_YR	Total	Failed	Censored	X-Censored
INI	126	9	117	92.8571
RXK	130	4	126	96.9231
Total	256	13	243	94.9219

Testing Homogeneity of Survival Curves over Strata
 Time Variable: DAY

Rank Statistics

COD_YR	Log-Rank	Milcoxon
INI	2.7587	610.00
RXK	-2.7587	-610.00

Covariance Matrix for the Log-Rank Statistics

COD_YR	INI	RXK
INI	3.25296	-3.25296
RXK	-3.25296	3.25296

Covariance Matrix for the Milcoxon Statistics

COD_YR	INI	RXK
INI	171282	-171282
RXK	-171282	171282

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	2.3041	1	0.1280
Milcoxon	2.1724	1	0.1405
-2Log(LR)	2.5436	1	0.1107

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PARACIA CNS 880
 RESUME - PROTOCOL 2014/017
 APPENDIX No.1 12.1.12
 CUMULATIVE RISK OF DEVELOPING SEVERE INCREASED

The LIFETIME Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TTT	Total	Failed	Censored	X-Censored
IMI	126	18	108	85.7143
REX	130	18	112	86.1538
Total	256	36	220	85.9375

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TTT	Log-Rank	Milcozen
IMI	0.58330	110.00
REX	-0.58330	-110.00

Covariance Matrix for the Log-Rank Statistics

COD_TTT	IMI	REX
IMI	8.86047	-8.86047
REX	-8.86047	8.86047

Covariance Matrix for the Milcozen Statistics

COD_TTT	IMI	REX
IMI	445980	-445980
REX	-445980	445980

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	0.0323	1	0.8573
Milcozen	0.0374	1	0.8482
-2Log(LR)	0.0743	1	0.7851

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PHARMACIA CHE MSD
 RESOMETIN - PROTOCOL 2012A/017
 APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING TACHYCARDIA

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TPT	Total	Failed	Censored	X-Censored
IMI	124	13	115	89.6825
RSX	130	8	122	93.8462
Total	254	21	235	91.7969

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TPT	Log-Rank	Wilcoxon
IMI	3.4861	804.00
RSX	-3.4861	-804.00

Covariance Matrix for the Log-Rank Statistics

COD_TPT	IMI	RSX
IMI	4.96120	-4.96120
RSX	-4.96120	4.96120

Covariance Matrix for the Wilcoxon Statistics

COD_TPT	IMI	RSX
IMI	231968	-231968
RSX	-231968	231968

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	2.4496	1	0.1176
Wilcoxon	2.7867	1	0.0951
-2*Log(LR)	1.6871	1	0.1698

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FRANACIA CNS DSD

RESEARCHING - PROTOCOL 2012A/017
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING THEROR

The LIFETIME Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TPT	Total	Failed	Censored	X-Censored
IMI	126	19	119	89.6825
REK	130	2	128	96.4415
Total	256	21	235	94.1406

Testing Homogeneity of Survival Curves over Strata
 Time Variable DAY

Rank Statistics

COD_TPT	Log-Rank	Wilcoxon
IMI	5.8493	1319.0
REK	-5.8493	-1319.0

Covariance Matrix for the Log-Rank Statistics

COD_TPT	IMI	REK
IMI	3.72572	-3.72572
REK	-3.72572	3.72572

Covariance Matrix for the Wilcoxon Statistics

COD_TPT	IMI	REK
IMI	190303	-190303
REK	-190303	190303

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	9.1632	1	0.0024
Wilcoxon	9.1428	1	0.0025
-2*Log(LR)	18.4402	1	0.0012

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PHARMACIA CNS RSD
 RESEARCH - PROTOCOL 20124-017
 APPENDIX No.1 12.1.12
 CUMULATIVE RISK OF DEVELOPING URBINARY RESISTANCY / RESISTION

The LIFETEST Procedure
 Summary of the Number of Censored and Uncensored Values

COD_TXT	Total	Failed	Censored	%Censored
INI	126	6	120	95.2381
RNK	130	10	120	92.3077
Total	256	16	240	93.7500

Testing Homogeneity of Survival Curves over Strata
 Time Variable: RLV

Rank Statistics

COD_TXT	Log-Rank	Milcoxon
INI	-1.8492	-511.00
RNK	1.8492	511.00

Covariance Matrix for the Log-Rank Statistics

COD_TXT	INI	RNK
INI	3.98554	-3.98554
RNK	-3.98554	3.98554

Covariance Matrix for the Milcoxon Statistics

COD_TXT	INI	RNK
INI	203568	-203568
RNK	-203568	203568

Test of Equality over Strata

Test	Chi-Square	DF	Pr >
Log-Rank	0.8590	1	0.3549
Milcoxon	1.2702	1	0.2597
-2Log(LR)	0.8521	1	0.3559

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12.2 Patient Information

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12.2.1 SERIOUS ADVERSE EVENTS - CASE HISTORIES

Narratives of serious adverse events reported on reboxetine treatment and case summaries of serious adverse events reported on reference treatment.

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Narrative of Event No. SA 0025 Protocol No. 20124/017 Patient No. 353

Center: Cape Town (South Africa)

Investigator: Wilson

Adverse event: parasuicide by overdose (date of the event: 7 July 1992).

Patient's history: the patient was a 40 years old female and was suffering from a Major Depressive Episode for 9 weeks when she entered in the 20124/017 study on 5 June 1992. She had had the onset of depressive disorder at the age of 40 years.

Baseline ECG and chest X-ray were normal. Laboratory tests did not show any clinical relevant abnormalities.

Experimental period: the patient entered the 20124/017 study on 5 June 1992 and received the experimental treatment as follows:

Treatment		Days	Dose (mg/Day)
From	To		
5 June 1992	11 June 1992	7	8
12 June 1992	14 June 1992	3	0
15 June 1992	20 June 1992	6	8
21 June 1992	21 June 1992	1	0
22 June 1992	7 July 1992	16	8

From 13 June 1992 to 15 June 1992, she was treated with mefenamic acid (250 mg/day) because of urinary pain and from 22 June 1992 to 26 June 1992 with trimethoprim/sulfamethoxazol for a urinary tract infection. The experimental treatment was temporarily interrupted for the period of the urinary tract disorder.

At the baseline visit, the Hamilton Depression Rating Scale (HAMD) was performed and the total score was of 23 points. While she was on therapy, there was a progressive improvement in the severity of the depressive syndrome until 6 July 1992 when the HAMD total score of 7 points was reported.

Suicide ideas were present at the baseline visit but they disappear during the study.

On 7 July 1992, the patient took an overdose of reboxetine following a domestic argument. She asked her sister to contact the Investigator and she was advised to come to the hospital for examination and blood sample but she refused.

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On 9 July 1992, she went to the hospital and during the medical visit she was found to be depressed, having unresolved domestic conflicts, but was not found to be suicidal. The patient claimed to have taken all tablets of the experimental treatment in her possession (a maximum of 13 tbs, equivalent to 52 mg) and was reported to be conscious at all times, able to communicate and to continue her normal tasks. The patient was definitively withdrawn from the study.

At the time of the event, the patient had been under the experimental treatment for 33 days and had received a cumulative amount of 232 mg of reboxetine, while being treated with 8 mg/day of the compound.

Comments: the Investigator judged the adverse event as drug related. However the reliability of the patient seems to be very poor because the complete absence of symptoms after a single intake of 52 mg of reboxetine which is quite unbelievable. Furthermore, on 13 July 1992 the patient's psychopathological condition was no worse (HAMD total score = 10) and no suicide feeling was present (HAMD item 3 = 0). The whole situation (family troubles, absence of suicidal thoughts, a domestic argument just before overdose was taken, refusal to attend medical care after the ingestion of the drug, no side effects after a single intake of 52 mg of reboxetine) could be interpreted as a demonstrative gesture.

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Narrative of Event No. DD 0192 Protocol No. 20124/017 Patient No. 50

Center: Ravensburg (Germany)

Investigator: Wolfersdorf

Adverse event: suicide by shooting (date of the event: 15 December 1991)

Patient's history: the patient was a 54 years old male and was suffering from a Major Depressive Episode for 1 month when he entered in the 20124/017 study on 31 October 1991. He had had the onset of depressive disorder at the age of 53 years.

His previous antidepressive treatment was mianserin which had shown poor efficacy.

Baseline ECG and chest X-ray were normal. Laboratory tests did not show any clinical relevant abnormalities.

Experimental period: the patient entered the 20124/017 study on 31 October 1991 and received the experimental treatment as follows:

Treatment		Days	Dose (mg/Day)
From	To		
6 November 1991	14 December 1991	39	8
15 December 1991	15 December 1991	1	4

From 5 November 1991 to 12 November 1991 he was treated with clomethiazole (384 mg/day) for insomnia. From 13 November 1991 to 19 November 1991, he took the above mentioned drug at the dosage of 768 mg/day. On 20 November 1991, he started treatment with chloral hydrate (2000 mg/day) for the same problem.

At the baseline visit the Hamilton Depression Rating Scale (HAMD) was performed and the total score was 24 points. While he was on therapy there was an initial deterioration in his psychopathological conditions as seen by HAMD total score of 30 points (19 November 1991). It was followed by a progressive improvement in the severity of the depressive syndrome until 10 December 1991 when the HAMD total score of 17 points was reported. At the same time no suicidal intent was detected.

On 15 December 1991, he committed suicide by shooting outside the hospital.

At the time of the event, the patient had been under the experimental treatment for 40 days and he had received a cumulative amount of reboxetine of 316 mg, while being treated with 4 mg/day of the compound.

Comments: the Investigator judged the adverse event as not drug related.

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CASE SUMMARY OF EVENT	BE 0038
PROTOCOL N°	20124/017
PT. N°	270
SEX	F
AGE AT ENTRY	43
EXPERIMENTAL TREATMENT	IMIPRAMINE
DAILY DOSE	150 MG.
TREATMENT PERIOD	11.10.91 - 17.10.91
AFTER DAYS	7
ADE (DATE OF THE EVENT)	SUPRAVENTRICULAR TACHYCARDIA (17.10.91)
DISCONTINUED	YES
COURSE	RECOVERED
RELEVANT HISTORY	EPISODES OF TACHYCARDIA
RELEVANT BASELINE CONDIT.	MAJOR DEPRESSIVE DISORDER
PREVIOUS ANTIDEPRESSIVE TREATMENTS	DOSULEPIN, MIANSERIN
RELEVANT EVENTS	NO
CONCOMITANT MEDICATIONS	NONE

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CASE SUMMARY OF EVENT	DD 0223
PROTOCOL N°	20124/017
PT. N°	451
SEX	M
AGE AT ENTRY	56
EXPERIMENTAL TREATMENT	IMIPRAMINE
DAILY DOSE	150 MG.
TREATMENT PERIOD	28.11.91 - 7.01.92
AFTER DAYS	22
ADE (DATE OF THE EVENT)	A-V BLOCK 1ST DEGREE (19.12.91)
DISCONTINUED	NO
COURSE	RECOVERED
RELEVANT HISTORY	A-V BLOCK 1ST DEGREE
RELEVANT BASELINE CONDIT.	MAJOR DEPRESSIVE DISORDER, HYPERTENSION, PERIPHERAL ARTERIAL PERFUSION DISORDER, DIABETES MELLITUS, POLYARTHROSIS
PREVIOUS ANTIDEPRESSIVE TREATMENTS	NO
RELEVANT EVENTS	NO
CONCOMITANT MEDICATIONS	DIPYRIDAMOLE/ACETYLSALICILIC ACID, ENALAPRIL

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12.2.2 INDIVIDUAL DATA LISTINGS

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 REDUCTIVNE - PROTOCOL 2012A/017
 Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Patient status In-patient / Out-patient	Hospital date	Sex	Age (years)	Height (kg)	Height (cm)	Race	DMG-III-2 (*)
1	1	Bobocetine	MD	OUT		Male	52	83.0	172.0	Caucasian	296.3
	2	Bobocetine	UKL	OUT		Female	55	70.0	170.0	Caucasian	296.3
	3	Indipramine	CFI	IN	10/04/91	Female	41	63.0	171.0	Caucasian	296.2
	4	Indipramine	JLO	OUT		Male	53	123.0	180.0	Caucasian	296.3
	5	Bobocetine	BRE	IN	15/07/91	Female	37	76.0	173.0	Caucasian	296.3
	6	Indipramine	HRB	IN	06/08/91	Female	62	67.0	168.0	Caucasian	296.2
	7	Bobocetine	G00	OUT		Male	54	85.0	186.0	Caucasian	296.3
	8	Indipramine	ALS	IN	26/10/91	Male	50	88.5	174.0	Caucasian	296.3
	9	Indipramine	IXR	OUT		Female	65	53.0	156.0	Caucasian	296.3
	10	Indipramine	ESC	IN	02/04/92	Female	46	71.0	163.0	Caucasian	296.3
	11	Bobocetine	HCA	IN	09/04/92	Male	50	71.0	159.0	Caucasian	296.3
	12	Bobocetine	J R	IN		Male	37	84.0	176.0	Caucasian	296.3
2	33	Bobocetine	VOK	IN	15/12/90	Male	45	83.0	174.0	Caucasian	296.3
	34	Indipramine	OTR	IN	27/12/90	Male	48	108.0	183.0	Caucasian	296.2
	35	Bobocetine	BEA	IN	27/12/90	Male	36	80.0	180.0	Caucasian	296.3
	36	Indipramine	BEA	IN	09/01/91	Female	39	49.0	159.0	Caucasian	296.3
	37	Bobocetine	CVA	IN	17/01/91	Male	42	80.6	177.0	Caucasian	296.3
	38	Indipramine	SKP	IN	06/12/90	Female	54	51.0	159.0	Caucasian	296.3
	39	Bobocetine	SKP	IN	24/01/91	Female	46	63.0	161.0	Caucasian	296.2
	40	Indipramine	WPE	IN	18/02/91	Male	42	72.0	182.0	Caucasian	296.2
	41	Bobocetine	WAE	IN	30/01/91	Male	30	84.0	168.0	Caucasian	296.3
	42	Indipramine	WAE	IN	06/02/91	Female	35	73.5	178.0	Caucasian	296.2
	43	Bobocetine	WAE	IN	20/03/91	Female	40	56.0	152.0	Caucasian	296.3
	44	Indipramine	PVB	IN	28/04/91	Male	34	67.0	175.0	Caucasian	296.3
45	Indipramine	J R	IN	28/04/91	Female	36	62.0	175.0	Caucasian	296.3	
46	Bobocetine	GAJ	IN	14/05/91	Female	53	66.0	160.0	Caucasian	296.3	
47	Bobocetine	GAJ	IN	17/05/91	Female	56	74.4	168.0	Caucasian	296.3	
48	Indipramine	TBB	IN	23/05/91	Female	61	80.5	159.0	Caucasian	296.3	
49	Indipramine	BEH	IN	27/05/91	Female	52	53.3	162.0	Caucasian	296.3	
50	Bobocetine	HOW	IN	31/10/91	Male	54	76.0	173.0	Caucasian	296.3	
51	Bobocetine	VQA	IN	30/10/91	Female	39	76.4	164.0	Caucasian	296.3	
52	Indipramine	BEK	IN	13/11/91	Male	25	77.0	183.0	Caucasian	296.2	
3	65	Bobocetine	EX	IN	28/03/91	Male	46	87.0	173.0	Caucasian	296.3
	66	Indipramine	H U	IN	26/04/91	Female	39	52.0	155.0	Caucasian	296.2
	67	Bobocetine	V H	IN	04/04/91	Female	56	65.0	161.0	Caucasian	296.3
	68	Indipramine	E S	IN	01/08/91	Female	52	60.8	170.0	Caucasian	296.3
	69	Indipramine	P J	IN	23/02/91	Female	22	58.5	170.0	Caucasian	296.3
	70	Bobocetine	GB	IN	31/10/91	Female	60	78.0	165.0	Caucasian	296.3
	71	Indipramine	H B	IN	11/11/91	Female	27	55.4	164.0	Caucasian	296.2
72	Bobocetine	R L	IN	24/01/92	Female	48	55.4	160.0	Caucasian	296.3	
73	Bobocetine	E P	IN	11/02/92	Female	52	88.0	189.0	Caucasian	296.3	

(*) DIAGNOSES: 296.2 Major Depressive Disorder, First Episode
 296.3 Major Depressive Disorder, Multiple Episodes
 300.4 Bipolar
 300.4 Bipolar

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PHARMACTA CNS RED

RESEARCHING - PROTOCOL 2012A/017
Listing No.1 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	In-out Hospital patient	date	Sex	Age (years)	Height (kg)	Height (cm)	Race	MM-III-R (#)
4	97	Isipramine	M H	IN	23/04/92	Male	22	60.0	175.0	Caucasian	296.3
	100	Rabocetiline	N N	IN	27/04/92	Female	34	59.0	168.0	Caucasian	296.3
	101	Isipramine	B K	IN	22/01/91	Female	54	65.0	169.0	Caucasian	296.3
6	161	Rabocetiline	A S	IN	26/03/91	Male	30	73.0	174.0	Caucasian	296.2
	162	Rabocetiline	D S	IN	31/10/91	Female	56	64.0	169.0	Caucasian	296.2
7	193	Rabocetiline	DC	IN	03/05/91	Female	56	73.0	154.0	Caucasian	296.3
	194	Rabocetiline	M G	IN	30/05/91	Male	43	120.0	174.0	Caucasian	296.2
	196	Isipramine	CL	IN	15/03/91	Female	23	51.0	153.0	Caucasian	296.3
8	225	Isipramine	B B	IN	26/02/91	Female	24	75.0	161.0	Caucasian	296.3
	226	Rabocetiline	D B	IN	26/04/91	Female	51	60.0	161.0	Caucasian	296.3
	227	Isipramine	L R	IN	27/04/91	Male	27	37.0	160.0	Caucasian	296.2
	228	Rabocetiline	V B	IN	02/05/91	Male	36	82.0	171.0	Caucasian	296.3
	229	Isipramine	B C	IN	05/10/91	Female	39	70.0	167.0	Caucasian	296.3
	230	Isipramine	A C	IN	30/10/91	Female	25	64.0	162.0	Caucasian	296.2
231	231	Rabocetiline	R R	IN	23/10/91	Female	41	37.5	162.0	Caucasian	296.3
	232	Rabocetiline	B H	IN	22/11/91	Male	41	75.0	170.0	Caucasian	296.2
9	197	Rabocetiline	VEA	OUT		Male	51	89.0	179.0	Caucasian	296.3
	198	Isipramine	VDB	OUT		Female	26	69.0	175.0	Caucasian	296.2
	199	Isipramine	T G	OUT		Male	47	84.0	174.0	Caucasian	296.3
	200	Rabocetiline	S H	OUT		Male	32	84.0	168.0	Caucasian	296.2
	201	Isipramine	DVG	OUT		Female	52	75.0	158.0	Caucasian	296.2
	202	Isipramine	DCA	OUT		Male	65	67.0	160.0	Caucasian	296.3
	203	Rabocetiline	B C	OUT		Female	34	76.0	167.0	Caucasian	296.3
	204	Rabocetiline	V A	OUT		Male	45	87.5	169.0	Caucasian	296.3
	205	Isipramine	U H	OUT		Female	41	51.0	159.0	Caucasian	296.2
	206	Isipramine	V L	OUT		Female	50	63.0	160.0	Caucasian	296.3
	207	Rabocetiline	S G	OUT		Female	64	72.0	154.0	Caucasian	296.3
	208	Rabocetiline	U H	OUT		Male	42	84.0	169.0	Caucasian	296.3
	209	Isipramine	VDB	OUT		Male	32	63.0	168.0	Caucasian	296.3
	210	Rabocetiline	VDB	OUT		Female	64	71.0	165.0	Caucasian	296.3
	211	Rabocetiline	DPH	IN	11/02/92	Female	37	63.0	163.0	Caucasian	296.3
	212	Isipramine	D I	OUT		Female	25	61.0	163.0	Caucasian	296.2
237	Rabocetiline	M E	OUT		Male	45	75.0	170.0	Caucasian	296.2	
238	Isipramine	M A	OUT		Female	54	77.0	163.0	Caucasian	296.2	
239	Isipramine	L J	OUT		Male	29	100.0	194.0	Caucasian	296.3	

(*) ILLNESS: 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 MSD
 REMEDIATION - PROTOCOL 30124/017
 Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Patient status In-out patient	Hospital date	Sex	Age (years)	Height (kg)	Weight (cm)	Race	MR-III-R (S)	
9	240	Reboxetine	V A	OUT		Female	26	62.0	174.0	Caucasian	296.2	
	241	Isipramine	ME	IN	05/05/92	Female	49	81.5	169.0	Caucasian	296.3	
	242	Reboxetine	IL	OUT		Male	50	59.0	142.0	Caucasian	296.2	
	243	Isipramine	P K	IN	07/05/92	Female	29	55.5	169.0	Caucasian	296.3	
	244	Reboxetine	I D	OUT		Male	26	90.0	183.0	Caucasian	296.2	
	245	Reboxetine	H K	OUT		Female	25	164.0	164.0	Caucasian	296.2	
	246	Isipramine	MG	OUT		Male	24	79.0	178.0	Caucasian	296.2	
	247	Isipramine	ED	OUT		Female	59	65.0	160.0	Caucasian	296.2	
	248	Isipramine	MA	OUT		Female	30	49.0	150.0	Caucasian	296.2	
	249	Isipramine	B H	IN	18/07/91	Female	34	94.0	181.0	Caucasian	296.3	
	250	Reboxetine	D H	OUT		Male	48	94.0	183.0	Caucasian	296.2	
	251	Reboxetine	H V	OUT		Female	34	53.0	145.0	Caucasian	296.2	
	252	Isipramine	H L	OUT		Female	46	74.0	169.0	Caucasian	296.3	
	253	Reboxetine	SR	OUT		Female	41	60.0	173.0	Caucasian	296.2	
	254	Isipramine	A H	OUT		Female	42	60.0	162.0	Caucasian	296.2	
	255	Isipramine	G A	IN	19/08/91	Male	48	74.5	181.0	Caucasian	296.2	
	256	Isipramine	LAP	OUT		Female	41	66.0	159.0	Caucasian	296.2	
	257	Isipramine	VB	OUT		Male	57	60.0	172.0	Caucasian	296.2	
	258	Isipramine	S E	OUT		Female	45	56.0	160.0	Caucasian	296.2	
	259	Isipramine	VD	OUT	28/10/91	Female	55	65.0	161.0	Caucasian	296.2	
	260	Isipramine	B Y	OUT	28/10/91	Male	62	84.0	186.0	Caucasian	296.2	
	261	Isipramine	K K	OUT	29/10/91	Female	25	74.0	183.0	Caucasian	296.2	
	262	Reboxetine	UM	OUT		Female	47	62.0	160.0	Caucasian	296.3	
	263	Reboxetine	V K	OUT		Female	46	52.0	163.0	Caucasian	296.2	
	264	Isipramine	MD	IN	06/03/91	Female	59	69.0	170.0	Caucasian	296.2	
	265	Isipramine	H H	OUT		Female	61	71.0	194.0	Caucasian	296.3	
	266	Isipramine	S H	OUT		Male	41	88.0	182.0	Caucasian	296.3	
	9/A	267	Isipramine	MR	OUT		Male	57	72.0	175.0	Caucasian	296.3
		268	Reboxetine	C A	IN	25/03/92	Female	31	43.5	159.0	Caucasian	296.3
		269	Reboxetine	B H	IN	22/05/92	Male	49	63.0	167.0	Caucasian	296.2
270		Isipramine	F D	IN	11/05/92	Male	38	78.0	175.0	ABAYAN	296.2	
271		Reboxetine	P H	OUT		Male	36	77.0	176.0	Caucasian	296.3	
272		Isipramine	H Y	IN	10/06/92	Female	50	54.3	162.0	Caucasian	296.3	
273		Isipramine	MA	IN	21/07/92	Male	26	78.0	184.0	Caucasian	296.3	
274		Reboxetine	VR	OUT		Female	44	70.0	169.0	Caucasian	296.3	
275		Reboxetine	HA	IN	25/08/92	Female	64	66.0	175.0	Caucasian	296.3	
276		Isipramine	S D	IN	09/07/92	Male	35	80.0	178.0	Caucasian	296.3	
277		Isipramine	S D	IN	16/09/92	Female	58	78.0	163.0	Caucasian	296.3	
278		Isipramine	CTP	IN	16/09/92	Male	35	78.0	180.0	Caucasian	296.2	
279		Isipramine	H C	OUT		Female	44	60.0	145.0	Caucasian	296.2	
280		Isipramine	P H	IN	26/02/92	Male	24	76.0	173.0	Caucasian	296.3	
281	Reboxetine	DCM	IN	07/03/92	Female	29	78.0	175.0	Caucasian	296.2		
282	Reboxetine	D H	IN	10/03/92	Female	41	65.0	161.0	Caucasian	296.3		

(S) DIAGNOSIS: 296. 2-Major Depressive Disorder, First Episode
 298. 2-Major Depressive Disorder, Multiple Episodes
 299. 2-Major Depressive Disorder, Bipolar
 300. 4-Dysthymia

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PHARMACIA CNS RED

REBOSERTINE - PROTOCOL 28-12A-017
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Patient status In-patient Hospital date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	DBP-III-2 (%)	
9/A	305	Reboxetine	H H	IN 10/12/91	Male	35	70.0	175.0	Caucasian	296.3	
	306	Reboxetine	H A	IN 24/04/92	Female	38	47.7	162.0	Caucasian	296.3	
	307	Indipramine	B C	OUT	Female	26	80.0	175.0	Caucasian	296.2	
	308	Indipramine	VD	IN 07/05/92	Female	46	62.0	168.0	Caucasian	296.3	
10	289	Indipramine	H J	IN 16/09/91	Female	56	80.0	160.0	Caucasian	296.3	
	290	Reboxetine	L J	IN 06/10/91	Male	19	76.2	179.0	Caucasian	296.3	
	291	Indipramine	SD	IN 13/02/92	Male	39	84.0	186.0	Caucasian	296.3	
	292	Reboxetine	EH	IN 05/12/91	Female	34	69.5	161.0	Caucasian	296.3	
	293	Reboxetine	EH	IN 07/11/91	Female	62	59.0	162.0	Caucasian	296.3	
	294	Reboxetine	LV	IN 20/11/91	Female	63	55.0	154.0	Caucasian	296.3	
	295	Indipramine	Y O	IN 16/12/91	Male	43	87.0	189.0	Caucasian	296.2	
	296	Reboxetine	F R	IN 14/02/92	Female	48	65.0	161.0	Caucasian	296.3	
	297	Reboxetine	E V	IN 18/03/92	Male	28	68.5	178.0	Caucasian	296.2	
	298	Reboxetine	H H	IN 18/03/92	Female	58	46.5	159.0	Caucasian	296.3	
	299	Indipramine	K L	OUT	Male	23	81.0	174.0	Caucasian	296.2	
	300	Indipramine	T B	OUT	Female	34	103.0	158.0	Caucasian	296.3	
	11	321	Reboxetine	GP	OUT	Female	48	74.0	170.0	Caucasian	296.2
		322	Reboxetine	SD	OUT	Female	35	64.0	158.0	Caucasian	296.2
		323	Indipramine	NY	OUT	Female	26	59.0	153.0	Caucasian	296.2
		324	Indipramine	FR	OUT	Male	22	70.8	180.0	Caucasian	296.2
325		Reboxetine	CR	OUT	Female	18	60.9	168.0	Caucasian	296.2	
326		Indipramine	JK	OUT	Male	29	83.7	182.0	Caucasian	296.2	
327		Reboxetine	JP	OUT	Female	38	74.0	169.0	Caucasian	296.2	
328		Indipramine	FA	OUT	Male	21	79.5	174.0	Caucasian	296.2	
329		Indipramine	JB	OUT	Female	20	77.5	164.0	Caucasian	296.2	
330		Reboxetine	JB	OUT	Female	23	75.5	174.0	Caucasian	296.2	
331		Reboxetine	JG	OUT	Male	43	74.0	180.0	Caucasian	296.3	
332		Indipramine	P T	OUT	Female	27	53.0	165.0	Caucasian	296.2	
333		Indipramine	AB	OUT	Female	47	74.0	161.0	Caucasian	296.3	
12		337	Indipramine	AB	IN 02/04/92	Female	24	73.5	164.0	Caucasian	296.3
		338	Reboxetine	AV	IN 01/06/92	Female	65	55.0	147.0	Caucasian	296.3
		339	Indipramine	LK	IN 09/06/92	Male	64	78.0	188.0	Caucasian	296.3
	340	Reboxetine	LC	IN 23/02/92	Female	44	64.0	161.0	Caucasian	296.3	
341	Reboxetine	AV	IN 13/08/92	Female	41	55.0	163.0	Caucasian	296.3		
13	353	Reboxetine	LC	OUT	Female	40	73.5	166.0	Black	296.2	
	354	Indipramine	L H	OUT	Female	34	47.0	162.0	Black	296.2	
	355	Reboxetine	J E	OUT	Female	38	54.5	162.0	Black	296.2	

(*) DIAGNOSIS: 296: Severe Depressive Disorder, First Episode
298: Severe Depressive Disorder, Multiple Episodes
299: Severe Depressive Disorder, Bipolar
300: 4-Symptoms

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PHARMACIA CNS MSD
 REMONTELINE - PROTOCOL 2012A/017
 Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Patient status In-pat Hospital	Sex	Age (years)	Height (kg)	Height (cm)	Race	DMT-III-R (%)
13	356	Indipramine	H H	OUT	Male	36	57.0	170.0	Black	296.2
	357	Indipramine	G F	OUT	Female	20	56.5	170.0	Black	296.2
	358	Reboxetine	V S	OUT	Male	50	67.0	168.0	Black	296.2
	359	Reboxetine	A B	OUT	Female	46	58.0	159.0	Black	296.2
	360	Indipramine	C B	OUT	Female	31	67.5	167.0	Black	296.2
	361	Reboxetine	E L	OUT	Female	25	51.0	159.0	Black	296.3
14	457	Reboxetine	A C	OUT	Female	59	65.0	165.0	Caucasian	296.2
	458	Indipramine	D E	OUT	Female	60	57.0	165.0	Caucasian	296.3
	459	Reboxetine	C T	OUT	Male	49	68.0	180.0	Caucasian	296.3
	460	Indipramine	G T	OUT	Male	49	66.0	174.0	Caucasian	296.3
	461	Indipramine	S H	OUT	Female	57	59.0	171.0	Caucasian	296.3
	462	Reboxetine	R H	OUT	Female	55	52.0	164.0	Caucasian	296.3
	463	Indipramine	U R	OUT	Male	62	69.0	174.0	Caucasian	296.3
	464	Reboxetine	B B	OUT	Female	64	51.0	163.0	Caucasian	296.3
	465	Reboxetine	T K	OUT	Male	51	64.0	172.0	Caucasian	296.2
	466	Indipramine	E L	OUT	Female	40	52.0	164.0	Caucasian	296.3
14/1	129	Reboxetine	H H	OUT	Male	59	74.8	189.0	Caucasian	296.2
	426	Reboxetine	H B	OUT	Female	55	81.4	176.0	Caucasian	296.3
	429	Indipramine	E E	OUT	Female	54	64.0	163.0	Caucasian	296.3
	431	Indipramine	SH	OUT	Male	56	90.2	178.0	Caucasian	296.2
432	Reboxetine	HC	OUT	Female	47	78.0	194.0	Caucasian	296.2	
14/2	126	Indipramine	HD	OUT	Female	29	56.0	165.0	Caucasian	296.3
	436	Indipramine	AK	OUT	Male	45	89.0	174.0	Caucasian	296.2
14/3	417	Reboxetine	D A	OUT	Female	27	56.0	165.0	Caucasian	296.3
	418	Indipramine	S P	OUT	Female	49	62.0	168.0	Caucasian	296.3
	419	Reboxetine	E K	OUT	Female	54	71.0	163.0	Caucasian	296.3
	420	Indipramine	R H	OUT	Female	38	50.0	160.0	Caucasian	296.3
	421	Reboxetine	E C	OUT	Female	27	64.0	170.0	Caucasian	296.3
	427	Indipramine	G H	OUT	Female	55	86.0	165.0	Caucasian	296.2
428	Indipramine	H J	OUT	Female	28	54.0	160.0	Caucasian	296.3	
14/4	131	Indipramine	PH	OUT	Female	60	72.0	164.0	Caucasian	296.3
	132	Indipramine	S R	OUT	Female	32	64.0	166.0	Caucasian	296.2
	133	Indipramine	H K	OUT	Female	38	70.0	164.0	Caucasian	296.2
	134	Reboxetine	K B	OUT	Female	26	58.0	164.0	Caucasian	296.3
	135	Reboxetine	B A	OUT	Male	58	82.0	173.0	Caucasian	296.2

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
 296.3=Major Depressive Disorder, Multiple Episodes
 300.4=Oxythryna

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PHARMACIA CNS RED

RESEARCHING - PROTOCOL 20124/017
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Patient status In-patient	Hospital date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	MM-III-R (*)
14/7	422	Indipramine	D B	OUT		Female	51	72.4	171.0	Caucasian	296.3
	423	Indipramine	S C	OUT		Female	46	68.7	178.0	Caucasian	296.3
	424	Raboxetine	K H	OUT		Male	62	83.0	167.0	Caucasian	296.3
	430	Raboxetine	K J	OUT		Female	55	70.0	165.0	Caucasian	296.3
	431	Raboxetine	K A	OUT		Male	43	63.0	165.0	Caucasian	296.2
	432	Indipramine	K H	OUT		Male	42	81.5	170.0	Caucasian	296.2
	433	Indipramine	G D	OUT		Female	51	53.0	162.0	Caucasian	296.3
	434	Raboxetine	K H	OUT		Male	40	79.0	165.0	Caucasian	296.2
	439	Raboxetine	K H	OUT		Male	64	64.0	161.0	Caucasian	296.2
	440	Indipramine	K R	OUT		Female	23	50.0	156.0	Caucasian	296.2
	441	Indipramine	S D	OUT		Male	33	78.0	180.0	Caucasian	296.2
	442	Indipramine	K H	OUT		Male	38	73.0	172.0	Caucasian	296.2
	443	Indipramine	K H	OUT		Female	48	83.0	169.0	Caucasian	296.2
	449	Raboxetine	Z G	OUT		Female	48	83.0	169.0	Caucasian	296.2
	450	Indipramine	J D	OUT		Male	54	80.0	176.0	Caucasian	296.2
14/8	130	Raboxetine	F H	OUT		Male	54	81.0	178.0	Caucasian	296.3
	425	Raboxetine	L E	OUT		Female	57	70.0	168.0	Caucasian	296.3
	447	Raboxetine	H B	OUT		Male	63	80.0	178.0	Caucasian	296.3
14/10	53	Raboxetine	L F	OUT		Male	56	66.2	169.0	Caucasian	296.3
	54	Indipramine	E F	OUT		Female	63	79.8	165.0	Caucasian	296.2
	55	Raboxetine	A E	OUT		Female	57	57.0	167.0	Caucasian	296.3
	56	Indipramine	K H	OUT		Female	62	67.2	164.0	Caucasian	296.2
	57	Raboxetine	O D	OUT		Female	58	63.3	162.0	Caucasian	296.2
	58	Raboxetine	E K	OUT		Female	56	59.2	163.0	Caucasian	296.2
	59	Indipramine	J H	OUT		Female	52	62.3	164.0	Caucasian	296.2
	60	Raboxetine	O H	OUT		Female	47	72.3	169.0	Caucasian	296.3
	137	Raboxetine	K G	OUT		Female	58	62.2	165.0	Caucasian	296.3
	138	Indipramine	S S	OUT		Female	51	59.2	164.0	Caucasian	296.2
	139	Raboxetine	S B	OUT		Female	44	67.2	168.0	Caucasian	296.2
	140	Indipramine	S E	OUT		Female	63	67.2	162.0	Caucasian	296.3
	435	Indipramine	E H	OUT		Female	61	77.2	169.0	Caucasian	296.3
	436	Raboxetine	E H	OUT		Female	49	68.2	171.0	Caucasian	296.2
	437	Raboxetine	S A	OUT		Female	44	71.3	163.0	African	296.2
	438	Indipramine	K H	OUT		Female	51	67.2	172.0	Caucasian	296.2
	443	Raboxetine	H S	OUT		Female	58	63.7	164.0	Caucasian	296.2
	444	Raboxetine	A R	OUT		Male	43	66.2	168.0	Caucasian	296.3
	445	Indipramine	E H	OUT		Female	63	72.2	169.0	Caucasian	296.2
	446	Raboxetine	E H	OUT		Female	64	63.2	166.0	Caucasian	296.2
	447	Raboxetine	H H	OUT		Male	68	69.2	167.0	Caucasian	296.3
	448	Indipramine	A K	OUT		Female	55	65.2	168.0	Caucasian	296.2

(*) DIAGNOSIS: 296.3: Major Depressive Disorder, First Episode
296.5: Major Depressive Disorder, Multiple Episodes
296.6: Major Depressive Disorder, Bipolar
300.4: Dysthymia

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Admission date	Sex	Age (years)	Height (kg)	Height (cm)	Race	MR-III-R (%)
14/10	453	Indipramine	J G	07/92	Female	55	67.2	167.0	Caucasian	296.2
	454	Reboxetine	H Z	07/92	Female	56	62.2	175.0	Caucasian	296.2
	455	Reboxetine	H H	07/92	Female	62	56.2	172.0	Caucasian	296.2
15	349	Indipramine	ES	02/09/92	Male	21	62.0	175.0	Caucasian	296.2
	351	Reboxetine	AO	02/09/92	Male	56	66.0	165.5	African	296.3
	352	Indipramine	BOA	07/92	Male	24	75.0	185.0	Black	296.3
	364	Indipramine	AJJ	29/07/92	Female	34	55.0	157.0	Caucasian	296.3
	366	Reboxetine	SK	20/08/92	Male	28	49.8	169.0	Black	296.2
	367	Indipramine	HEK	07/92	Male	32	81.0	166.0	Black	296.3
	368	Reboxetine	VR	24/07/92	Female	50	80.0	168.0	Black	296.3
	369	Reboxetine	ZS	07/92	Female	26	65.0	164.0	Black	296.3
	370	Indipramine	LAS	16/07/92	Female	30	96.0	164.0	Caucasian	296.3
	371	Reboxetine	XD	07/92	Female	23	65.0	167.0	Black	296.3
	372	Indipramine	H S	13/03/92	Male	54	37.5	167.0	Black	296.2
	373	Indipramine	BJT	25/06/92	Female	28	68.0	167.0	Caucasian	296.2
	374	Reboxetine	SLH	05/04/92	Female	48	49.0	158.0	Caucasian	296.3
	375	Reboxetine	CTB	04/06/92	Female	35	60.0	141.0	Black	296.2
	376	Indipramine	GRM	13/04/92	Female	46	59.0	154.0	Caucasian	296.3
	377	Reboxetine	DAK	08/03/92	Female	37	62.5	161.5	Caucasian	296.3
	378	Reboxetine	HEC	10/06/92	Female	34	62.0	166.0	Caucasian	296.3
	379	Indipramine	CS	07/92	Female	23	55.0	164.0	Caucasian	296.3
	380	Indipramine	WLC	29/06/92	Female	49	85.0	159.0	Black	296.3
	381	Reboxetine	WLS	21/03/92	Female	21	65.0	164.0	Caucasian	296.3
	382	Indipramine	A H	07/92	Male	19	66.0	169.0	Caucasian	296.3
	383	Indipramine	JAE	07/92	Female	36	63.0	148.0	Caucasian	296.3
	384	Reboxetine	POE	27/07/92	Female	65	47.0	165.0	Caucasian	296.3

(S) 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 20124/017

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 last episode		Best characterized	Onset was	
6	161	30	0	7 weeks	First occurrence	Subacute (>= 2 weeks)	Absent
	162	56	0	5 weeks	First occurrence	Subacute (>= 2 weeks)	Absent
7	193	Yes	Yes	1 month	Similar prev. cond.	Insidious (>= 3 months)	Definitely present
	194	Yes	Yes	1 month	First occurrence	Subacute (>= 2 weeks)	Definitely present
	196	Yes	Yes	6 weeks	Different prev. cond.	Insidious (>= 3 months)	Definitely present
8	225		5	2 months	Similar prev. cond.	Acute (< 2 weeks)	Definitely present
	226		2	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	227		0	1 month	Different prev. cond.	Acute (< 2 weeks)	Definitely present
	228		5	6 weeks	Similar prev. cond.	Acute (< 2 weeks)	Definitely present
	229		2	3 months	Chronic condition	Insidious (>= 3 months)	Probably present
	230		0	3 months	First occurrence	Insidious (>= 3 months)	Probably present
	231		1	2 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	232	Yes	1	1 month	First occurrence	Acute (< 2 weeks)	Definitely present
9	197		1	2 months	Chronic condition	Insidious (>= 3 months)	Absent
	198		0	5 weeks	First occurrence	Acute (< 2 weeks)	Probably present
	199		1	7 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	200	Yes	0	2 months	First occurrence	Subacute (>= 2 weeks)	Probably present
	201		0	2 months	First occurrence	Subacute (>= 2 weeks)	Absent
	202		0	6 weeks	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	203		3	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	204		1	24 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	205		0	14 weeks	First occurrence	Insidious (>= 3 months)	Absent
	206		1	6 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	207		2	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	208		1	1 year	Chronic condition	Insidious (>= 3 months)	Probably present
	209		1	4 months	Different prev. cond.	Insidious (>= 3 months)	Probably present
	210		0	4 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	211		0	2 weeks	First occurrence	Insidious (>= 3 months)	Probably present
	212		0				
	237	Yes					
	238	Yes					
	239	Yes					
	240	Yes					
	241	Yes					
	242	Yes					
	243	Yes					
244	Yes						
257	Yes						
258	Yes						
259	Yes						
260	Yes						
261							

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PHARMACIA CNS R&D
 REMOXETINE - PROTOCOL 20124/017
 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	
			Unknown	No. episodes	Duration of last episode			Onset was	External stress
9	262	41	Yes	1	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	263	38	Yes	2	4 months	First occurrence	Subacute (>= 2 weeks)	Probably present	
	264	38	Yes	2	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	265	38	Yes	2	4 months	First occurrence	Insidious (>= 3 months)	Absent	
	266	46	Yes	0		First occurrence	Insidious (>= 3 months)	Definitely present	
	267	21	Yes	3	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	268	26	Yes	3	3 months	First occurrence	Insidious (>= 3 months)	Probably present	
	269	27	Yes	3	3 months	First occurrence	Insidious (>= 3 months)	Probably present	
	270	27	Yes	3	3 months	First occurrence	Insidious (>= 3 months)	Probably present	
	271	54	Yes	1	2 months	Chronic condition	Insidious (>= 3 months)	Absent	
	272	35	Yes	1	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	273	35	Yes	1	2 months	First occurrence	Subacute (>= 2 weeks)	Probably present	
	274	45	Yes	0	3 weeks	Similar prev. cond.	Insidious (>= 3 months)	Probably present	
	275	45	Yes	0	3 weeks	Chronic condition	Insidious (>= 3 months)	Probably present	
	276	60	Yes	1	4 months	First occurrence	Subacute (>= 2 weeks)	Absent	
	276/A	27	Yes	3	1 year and 2 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present	
	9/A	233	56		3	12 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
234		25		4	4 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present	
235		49		0		First occurrence	Insidious (>= 3 months)	Probably present	
236		33		8	4 months	Similar prev. cond.	Insidious (>= 3 months)	Absent	
237		33		4	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
278		40		3	2 months and 3 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
279		25		2	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
280		49		3	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
281		57		3	8 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
282		25		10	5 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
283		56		2	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
284		35		0		First occurrence	Acute (< 2 weeks)	Probably present	
301		44		0		First occurrence	Subacute (>= 2 weeks)	Probably present	
302		23		2	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
303		29		2	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
304		20		4	3 months	First occurrence	Subacute (>= 2 weeks)	Definitely present	
305		22		5	6 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
306	35		3	2 months	Similar prev. cond.	Insidious (>= 3 months)	Absent		
307	26		0	10 weeks	First occurrence	Acute (< 2 weeks)	Probably present		
308	35		1	1 year	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present		
10	289	46		2	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	290	15		2	2 months	Chronic condition	Subacute (>= 2 weeks)	Probably present	
	291	30		2	2 months	Chronic condition	Insidious (>= 3 months)	Probably present	
	292	25		5	3 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	293	58		3	2 months	Chronic condition	Subacute (>= 2 weeks)	Absent	
	294	52		3	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	295	0	Yes	0	2 months	Different prev. cond.	Subacute (>= 2 weeks)	Probably present	
	296	47	Yes	2	2 months	Similar prev. cond.	Insidious (>= 3 months)	Absent	
	297	47	Yes	2	2 months	Similar prev. cond.	Acute (< 2 weeks)	Probably present	
	297	47	Yes	2	2 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present	

PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/017
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	
10	298	Yes			1 month and 2 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	299		0		2 months	Chronic condition	Insidious (>= 3 months)	Probably present	
	300		3	4 months	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
11	321		0		4 weeks	Different prev. cond.	Subacute (>= 2 weeks)	Probably present	
	322	Yes			1 month	First occurrence	Subacute (>= 2 weeks)	Definitely present	
	323		0		3 months	First occurrence	Insidious (>= 3 months)	Definitely present	
	324		0		2 months	First occurrence	Insidious (>= 3 months)	Probably present	
	325		0		3 months	First occurrence	Insidious (>= 3 months)	Probably present	
	326	Yes			3 months	First occurrence	Insidious (>= 3 months)	Probably present	
	327	Yes			3 months	First occurrence	Insidious (>= 3 months)	Definitely present	
	328	Yes			3 months	First occurrence	Insidious (>= 3 months)	Probably present	
	329	Yes			3 months	First occurrence	Insidious (>= 3 months)	Probably present	
	330	Yes		0	2 3 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present	
	331		0		3 months	First occurrence	Insidious (>= 3 months)	Definitely present	
	332		0		3 months	First occurrence	Insidious (>= 3 months)	Definitely present	
	333	Yes		1	1 year	Similar prev. cond.	Insidious (>= 3 months)	Definitely present	
12	337		1	7 months	3 months	Similar prev. cond.	Acute (< 2 weeks)	Definitely present	
	338		15	5 months	3 months and 2 weeks	Chronic condition	Acute (< 2 weeks)	Absent	
	339		2	1 year	1 month	Chronic condition	Acute (< 2 weeks)	Definitely present	
	340		12	6 months	7 weeks	Similar prev. cond.	Acute (< 2 weeks)	Probably present	
	341		4	6 months	2 months and 3 weeks	Chronic condition	Insidious (>= 3 months)	Absent	
	341		4	6 months	2 months and 3 weeks	Chronic condition	Insidious (>= 3 months)	Absent	
13	353		0		9 weeks	First occurrence	Subacute (>= 2 weeks)	Definitely present	
	354	Yes			4 months	First occurrence	Insidious (>= 3 months)	Probably present	
	355	Yes	0		4 months	Different prev. cond.	Insidious (>= 3 months)	Probably present	
	356	Yes	0		4 months	First occurrence	Acute (< 2 weeks)	Definitely present	
	357	Yes			4 months	First occurrence	Insidious (>= 3 months)	Probably present	
	358	Yes			3 months	First occurrence	Insidious (>= 3 months)	Probably present	
	359	Yes			12 months	Chronic condition	Insidious (>= 3 months)	Probably present	
	360	Yes		1	1 year	First occurrence	Subacute (>= 2 weeks)	Definitely present	
	361				4 months	Different prev. cond.	Insidious (>= 3 months)	Absent	
	361				4 months	Different prev. cond.	Insidious (>= 3 months)	Absent	
14	457		0		2 months	First occurrence	Subacute (>= 2 weeks)	Absent	
	458		5	2 months	34 days	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	459		1	3 months	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	460		3	10 weeks	6 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	461		4	8 weeks	6 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	462	Yes			7 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	463		3	6 weeks	8 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	464		6	2 months	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	465		0		2 months	First occurrence	Subacute (>= 2 weeks)	Absent	
	466		2	2 months	7 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	466		2	2 months	7 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

Centre	Patient	History of mental disorder		Duration at the time of admission	Best characterized	Present episode	External stress
		Age of onset	No. of episodes last episode				
14/1	129	58	0	6 weeks	Chronic condition	Subacute (>= 2 weeks)	Absent
	426	54	1	10 weeks	Chronic condition	Subacute (>= 2 weeks)	Absent
	429	50	1	14 months	Chronic condition	Subacute (>= 2 weeks)	Definitely present
	451	56	0	13 weeks	Chronic condition	Insidious (>= 3 months)	Probably present
452	45	0	8 weeks	Chronic condition	Subacute (>= 2 weeks)	Absent	
14/2	136	27	1	7 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	456		Yes	3 months	First occurrence	Subacute (>= 2 weeks)	Probably present
14/3	417	25	1	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	418	45	2	7 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	419	25	4	4 weeks	Different prev. cond.	Subacute (>= 2 weeks)	Absent
	420	25	10	6 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	421	24	1	6 months	Similar prev. cond.	Insidious (>= 3 months)	Absent
	427	20	2	3 months	Chronic condition	Insidious (>= 3 months)	Absent
	428		Yes	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
14/4	131	52	4	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	132		Yes	4 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present
	133	23	2	6 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	134		Yes	7 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	135		Yes	6 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present
14/7	422	39	2	1 month and 3 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	423	46	1	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	424	61	1	6 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	430		Yes	2 months and 2 weeks	First occurrence	Subacute (>= 2 weeks)	Absent
	431		Yes	1 month and 8 days	First occurrence	Subacute (>= 2 weeks)	Definitely present
	432	51	1	1 month and 8 days	First occurrence	Subacute (>= 2 weeks)	Definitely present
	433		Yes	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	434		Yes	1 month and 1 week	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	439	64	1	2 months	First occurrence	Subacute (>= 2 weeks)	Probably present
	440		Yes	6 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present
	441		Yes	2 months	First occurrence	Subacute (>= 2 weeks)	Definitely present
442		Yes	2 months and 2 weeks	First occurrence	Subacute (>= 2 weeks)	Definitely present	
449		Yes	1 month and 2 weeks	First occurrence	Subacute (>= 2 weeks)	Definitely present	
450		Yes					
14/8	130	45	3	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	425		Yes	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	467		Yes	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
14/10	53	52	2	6 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	54	63	0	7 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present

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HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

Centre	Patient	Unknown	History of mental disorder			Duration at the time of admission	Best characterized	Present episode		
			Age of onset	No. episodes	Duration of last episode			Onset was	External stress	
14/10	55		54	1	5 months	7 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	56		61	0	7 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present		
	57		58	0	8 weeks	First occurrence	Subacute (>= 2 weeks)	Definitely present		
	58		56	0	6 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present		
	59		51	0	5 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present		
	60		42	1	4 months	7 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	137		55	1	4 months	6 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	138		51	0	4 months	7 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	139		44	0	3 months	8 weeks	First occurrence	Subacute (>= 2 weeks)	Definitely present	
	140		61	1	6 months	6 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	435		56	2	6 months	4 weeks	Chronic condition	Subacute (>= 2 weeks)	Absent	
	436		49	0	4 weeks	6 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present	
	437		44	0	4 weeks	4 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present	
	438		51	0	11 weeks	5 weeks	First occurrence	Subacute (>= 2 weeks)	Probably present	
	443		49	3	4 weeks	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	444		43	0	4 weeks	4 weeks	First occurrence	Subacute (>= 2 weeks)	Definitely present	
	445		60	1	4 months	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	446		64	0	5 months	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	447		59	1	5 months	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	448		55	0	7 weeks	5 weeks	First occurrence	Subacute (>= 2 weeks)	Definitely present	
	453		55	0	6 weeks	7 weeks	First occurrence	Subacute (>= 2 weeks)	Definitely present	
	454	Yes		62	7 weeks	7 weeks	First occurrence	Subacute (>= 2 weeks)	Definitely present	
15	349		21	0	2 months	2 months	First occurrence	Subacute (>= 2 weeks)	Absent	
	351		32	40	1 month	3 weeks	Different prev. cond.	Acute (< 2 weeks)	Definitely present	
	352		23	1	3 months	3 months	Similar prev. cond.	Insidious (>= 3 months)	Definitely present	
	364		32	1	5 months	2 months and 2 weeks	Similar prev. cond.	Insidious (>= 3 months)	Definitely present	
	366		28	0	2 months	2 months	First occurrence	Insidious (>= 3 months)	Definitely present	
	367		26	11	5 months	3 months	Similar prev. cond.	Insidious (>= 3 months)	Definitely present	
	368		39	8	3 weeks	3 months and 2 weeks	Similar prev. cond.	Insidious (>= 3 months)	Definitely present	
	369		16	8	2 months and 2 weeks	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	370		20	10	3 months	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	371		16	4	3 months	1 month	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	372	Yes		28	0	3 months and 2 weeks	3 months	First occurrence	Insidious (>= 3 months)	Absent
	373		40	3	4 weeks	4 weeks	Different prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	374		34	0	3 months	3 months	First occurrence	Insidious (>= 3 months)	Definitely present	
	375		376	9	2 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present	
	377		20	6	5 months	3 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present	
	378		25	6	5 months	2 weeks	Similar prev. cond.	Insidious (>= 3 months)	Definitely present	
	379		18	2	4 months	3 months	Similar prev. cond.	Insidious (>= 3 months)	Definitely present	
	380		20	3	13 months	4 months	Similar prev. cond.	Insidious (>= 3 months)	Definitely present	
	381		20	1	2 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	382		10	1	1 month	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present	
	383		4	2	3 months	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	
	384		57	2	3 months	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent	

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MANUAL CMS 200

REDSYNE - PROTOCOL 2012A/017

Listing No.: 9.0

MS-III-B: 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.

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 3.0

DSM-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
1	1	Male	52	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	2	Female	35	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	3	Female	41	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	4	Male	53	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	5	Female	57	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	6	Male	62	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	7	Male	54	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	8	Male	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	9	Female	65	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	10	Female	46	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	11	Male	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	12	Male	27	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2	33	Male	48	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	34	Male	43	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	35	Male	34	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	36	Female	29	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	37	Male	42	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	38	Female	54	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	39	Female	46	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	40	Male	42	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	41	Male	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	42	Male	55	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	43	Female	40	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	44	Male	54	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	45	Female	36	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	46	Female	53	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	47	Female	56	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	48	Female	61	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
49	Female	52	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
50	Male	54	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
51	Female	39	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
52	Male	25	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
3	65	Male	46	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	66	Female	39	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	67	Female	56	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	68	Female	52	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	69	Female	22	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	70	Female	60	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
71	Female	27	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
72	Female	48	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
73	Female	52	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
4	97	Male	22	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	100	Female	34	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	101	Female	54	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		

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PHARMACIA CNS RSD
 REMOXETINE - PROTOCOL 20124/017
 Listing No.: 3.0
 DNS-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
6	161	Male	30	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	162	Female	56	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
7	193	Female	56	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	194	Male	43	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	196	Female	23	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
8	225	Female	24	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	226	Female	51	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	227	Male	27	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	228	Male	36	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	229	Female	39	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	230	Female	25	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	231	Female	41	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	232	Male	41	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
9	197	Male	51	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	198	Female	26	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	199	Male	47	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	200	Male	32	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	201	Female	52	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	202	Male	65	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	203	Female	34	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	204	Male	45	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	205	Female	41	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	206	Female	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	207	Female	64	296.3	X	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	X
	209	Male	32	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	210	Female	64	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	211	Female	37	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	212	Female	25	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
237	Male	45	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
238	Female	54	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
239	Male	29	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
240	Female	26	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
241	Female	49	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
242	Male	50	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
243	Female	29	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
244	Male	26	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
257	Female	25	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
258	Male	24	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
259	Female	59	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
260	Female	30	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
261	Female	34	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	

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PHARMACIA CNS RED
 REXOXYLINE - PROTOCOL 2012/4/017
 Listing No.: 3.0

DSM-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		
9	262	Male	48	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	263	Female	36	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	264	Female	46	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	265	Female	41	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	266	Female	42	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	267	Male	49	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	268	Female	41	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	269	Male	57	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	270	Female	43	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	271	Female	55	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	272	Male	62	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	273	Female	35	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	274	Female	47	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	274/A	Female	48	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	275	Female	59	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	276	Female	61	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	276/A	Male	41	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
9/A	233	Male	57	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	234	Female	31	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	235	Male	49	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	236	Male	38	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	277	Female	36	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	278	Female	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	279	Male	26	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	280	Female	44	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	281	Female	64	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	282	Male	35	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	283	Female	58	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	284	Male	35	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	301	Female	44	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	302	Male	26	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	303	Female	29	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	304	Female	41	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	305	Male	35	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
306	Female	38	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
307	Female	26	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
308	Female	46	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
10	289	Female	56	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	290	Male	19	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	291	Male	39	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	292	Female	34	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	293	Female	62	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	294	Female	63	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	295	Male	43	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	296	Female	48	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	297	Male	28	296.2	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 20124/017
 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
10	298	Female	58	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	299	Male	23	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	300	Female	34	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
11	321	Female	43	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	322	Female	35	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	323	Female	26	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	324	Male	22	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	325	Female	18	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	326	Male	29	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	327	Female	38	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	328	Male	21	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	329	Female	20	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	330	Female	23	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	331	Male	43	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
332	Female	27	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
333	Female	47	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
12	337	Female	54	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	338	Female	65	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	339	Male	64	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	340	Female	44	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	341	Female	41	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
13	353	Female	40	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	354	Female	34	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	355	Female	38	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	356	Male	36	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	357	Female	20	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	358	Male	50	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	359	Female	46	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
360	Female	31	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
361	Female	25	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
14	457	Female	59	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	458	Female	60	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	459	Male	49	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	460	Male	49	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	461	Female	57	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	462	Female	55	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	463	Male	62	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
464	Female	64	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
465	Male	51	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
466	Female	40	296.3	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 20124/017
 Listing No.: 3.0
 DNS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

Centre	Patient	Sex	Age	DSN-III-R	Present	A items									B items		C		D	
						1)	2)	3)	4)	5)	6)	7)	8)	9)	Present	1)	2)	Present	Present	Present
14/1	129	Male	59	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	426	Female	55	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	429	Female	54	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	451	Male	56	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
14/2	452	Female	47	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	136	Female	29	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
14/3	456	Male	45	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	417	Female	27	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
14/4	418	Female	49	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	419	Female	54	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	420	Female	38	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	421	Female	27	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	427	Female	55	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	428	Female	28	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
14/7	131	Female	60	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	132	Female	32	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	133	Female	38	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	134	Female	26	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
14/7	135	Male	58	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	422	Female	51	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	423	Female	46	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	424	Male	62	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	430	Female	55	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	431	Male	43	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	432	Male	42	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	433	Female	51	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	434	Male	40	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	439	Male	64	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	440	Female	23	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	14/8	441	Male	33	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
442		Male	38	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
449		Female	48	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
450		Male	54	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
14/10	130	Male	54	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	425	Female	57	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
14/10	467	Male	63	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	53	Male	58	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
14/10	54	Female	63	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

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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								
14/10	55	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	X	
	56	Female	62	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	57	Female	58	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	58	Female	56	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	59	Female	52	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	60	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	X	X
	137	Female	58	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	138	Female	51	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	139	Female	44	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	140	Female	63	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	435	Female	61	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	436	Female	49	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	437	Female	44	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	438	Female	51	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	443	Female	58	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	444	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	X	X
	445	Female	63	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
446	Female	64	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
447	Male	60	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
448	Female	55	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
453	Female	55	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
454	Female	56	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
455	Female	62	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
15	349	Male	21	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	351	Male	58	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	352	Male	24	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	384	Female	36	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	386	Male	28	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	387	Male	32	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	388	Female	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	389	Female	26	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	370	Female	30	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	371	Female	22	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	372	Male	36	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	373	Female	28	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	374	Female	48	296.3	X	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 RED

REBOXETINE - PROTOCOL 20124/017
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MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
1	4	Male	53	ESSENTIAL HYPERTENSION CHR LIVER DIS/CIRRHOSIS	
	8	Male	50	SCIATIC NERVE LESION	
	9	Female	65	MALIGN NEOPL OVARY ACUTE PANCREATITIS TRANSIENT CEREB ISCHEMIA	
	10	Female	46	DIABETES MELLITUS DUODENAL ULCER NOS	
2	33	Male	48	ACUTE APPENDICITIS ACUTE TONSILLITIS	
	34	Male	43	OTH MUSCULOSKELET ANOMAL	
	35	Male	34	CHRONIC TONSILLITIS OTH SALMONELLA INFECTION	
	39	Female	46	NONTOXIC NODULAR GOITER	
3	65	Male	46	INGUINAL HERNIA	
	67	Female	56	OTHER BRAIN INJURY NONINFLAM DIS OVAR/ADNEX	
	68	Female	52	THYROTOXICOSIS UTERINE LEIOMYOMA	
6	162	Female	56	MAL MED CERVIX UTERI NOS	
7	193	Female	56	PSYCHOGENIC SKIN DISEASE	
8	226	Female	51	PNEUMONIA, ORGANISM NOS	
	231	Female	41	DUODENAL ULCER NOS OTHER GU NEOPLASM NOS	

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MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
8	232	Male	41	ASTHMA NOS OTHER PSORIASIS	
9	201	Female	52	EXCESSIVE MENSTRUATION	
	202	Male	65	OBSTRUCT CHR BRONCHITIS	
	203	Female	34	UTERINE LEIOMYOMA	
	207	Female	64	MENIERE DISEASE	
	208	Male	42	AUTOIMMUNE DISEASE NEC	
	209	Male	32	UNC BEMV NEO BONE	
	211	Female	37	UTERINE LEIOMYOMA	
	237	Male	45	DUODENAL ULCER NOS	
	243	Female	29	CHOLELITHIASIS NOS	
	258	Male	24	ASTHMA	
	261	Female	34	CONTACT DERMATITIS	
	264	Female	46	URINARY SYSTEM SYMPTOMS	
	276	Female	61	PROLAPSE OF VAGINAL WALL	
9/A	234	Female	31	OTOSCLEROSIS NOS	
	235	Male	49	STOMACH ULCER NOS DIABETES MELLITUS UNCOMP GOUT NOS	

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MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
9/A	282	Male	35	HYPERTENSION NOS	
10	296	Female	48	GASTRITIS/DUODENITIS NOS ANEMIA NOS VARICOSE VEIN OF LEG NOS	
	300	Female	34	IRRITABLE COLON NONINFL DIS OVA/ADNX NOS ANAL FISTULA	
11	321	Female	43	BRAIN INJURY NEC OTHER GU NEOPLASM NOS	
	322	Female	35	ACUTE TONSILLITIS OTHER GU NEOPLASM NOS CESAREAN DELIVERY NOS ACUTE IRIDOCYCLITIS	
	323	Female	26	CESAREAN DELIVERY NOS	
	324	Male	22	ASTHMA NOS OTITIS MEDIA NOS	
	328	Male	21	DIAPHRAGMATIC HERNIA	
	331	Male	43	OTHER GU NEOPLASM NOS PURE HYPERCHOLESTEROLEM	
	333	Female	47	OTHER GU NEOPLASM NOS PURE HYPERCHOLESTEROLEM	
12	337	Female	54	DIAPHRAGMATIC HERNIA RECTAL PROLAPSE	
	338	Female	65	URIN TRACT INFECTION NOS OTHER GU NEOPLASM NOS ATONY OF BLADDER	

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MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
12	339	Male	64	ANGINA PECTORIS	
	341	Female	41	STOMACH ULCER NOS IRON DEFICIENCY ANEMIAS	
13	353	Female	40	METORRHAGIA	
	354	Female	34	PEPTIC ULCER NOS	
	361	Female	25	ANEMIA NOS	
14	457	Female	59	ARTHRITIS NOS DIARRHEA OF INFECT ORIG SPONDYLOSIS NOS	
	458	Female	60	ATROPHIC GASTRITIS PROSIC DISORDERS SPONDYLOSIS NOS	
	459	Male	49	NONTOX NODUL GOITER NOS	
	460	Male	49	STOMACH FUNCTION DIS NOS MONOARTHRITIS NOS	
	462	Female	55	THORAC/LUMB DISC DISPLAC	
	463	Male	62	CIRCULATORY DISEASE NOS DIZZINESS AND GIDDINESS ALLERGIC REINITIS NOS ATROPHIC GASTRITIS	
	464	Female	64	LUMBAGO ARTHRITIS NOS INTESTINAL DISORDER NOS	
	465	Male	51	CERVICAL SYNDROME NEC AUTONOMIC NERVE DIS NEC ENTHESOPATHY OF ELBOW	

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MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
14/1	429	Female	54	BRONCHITIS NOS LUMBAGO	
	451	Male	56	ATHEROSCLEROSIS NOS DIABETES MELLITUS POLYARTHRITIS NOS HYPERTENSION NOS	
	452	Female	47	DISC DISPLACEMENT NOS HEPATITIS NOS	
14/2	136	Female	29	UNSPECIFIED ABORTION	
	456	Male	45	CHOLELITHIASIS NOS	
14/3	418	Female	49	UTERINE LEIOMYOMA INTERVERTEBRAL DISC DIS	
	420	Female	38	FEMALE PELVIC INFLAM DIS	
14/4	131	Female	60	CHOLEDOCHOLITHIASIS NOS	
	135	Male	58	ACUTE MYOCARDIAL INFARCT	
14/7	422	Female	51	OTHER GU NEOPLASM NOS OSTEOPOROSIS OSTEOCHONDROPATHY NOS	
	424	Male	62	SPINAL CORD INJURY NOS OSTEOARTHRITIS NOS PSYCHOSEXUAL DYSFUNCTION	
	430	Female	55	CERVICOCRANIAL SYNDROME LUMBOSACRAL NEURITIS NOS	
	431	Male	43	MALE INFERTILITY	
	432	Male	42	NEURALGIA/NEURITIS NOS ANGINA PECTORIS	

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MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
14/7	433	Female	51	HYPERTENSION NOS	
	434	Male	40	SHOULDER REGION DIS NEC LUMBAGO	
	439	Male	64	BACKACHE NOS BREAST NEOPLASM NOS	
	441	Male	33	CHRONIC PROSTATITIS	
14/8	130	Male	54	APPENDICITIS NOS FX ANKLE NOS-CLOSED	
14/10	53	Male	58	CHRONIC PROSTATITIS THORAC/LUMB DISC DISPLAC CHOLELITHIASIS NOS TINNITUS	
	54	Female	63	HYPERTENSION NOS	
	55	Female	57	HYPOTENSION NOS SPONDYLOSIS NOS GASTRITIS/DUODENITIS NOS	
	56	Female	62	SPONDYLOSIS NOS HYPOTENSION NOS DIVERTICULA OF COLON PURE HYPERCHOLESTEROLEM	
	57	Female	58	CARPAL TUNNEL SYNDROME HYPERTENSION NOS	
	58	Female	56	SPONDYLOSIS NOS	
	60	Female	47	HYPERTENSION NOS	
	137	Female	58	NEOPLASM NOS, SITE NEC CHOLELITHIASIS NOS	

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MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
14/10	137	Female	58	HYPOTENSION NOS	
	138	Female	51	ASTHMA NOS	
	435	Female	61	HYPERTENSION NOS	
	438	Female	51	VARICOSE VEINS, LEG ORTHOSTATIC HYPOTENSION	
	443	Female	58	CERVICAL DISC DEGEN	
	444	Male	43	NONTOX NODUL GOITER NOS HYPERTENSION NOS	
	445	Female	63	MALIGN NEOPL BREAST NOS HYPERLIPIDEMIA NEC/NOS HYPERTENSION NOS	
	446	Female	64	HYPERLIPIDEMIA NEC/NOS DISC DEGENERATION NOS	
	447	Male	60	OLD MYOCARDIAL INFARCT DIABETES MELLITUS UNCOMP ABN BLOOD CHEMISTRY NEC	
	448	Female	55	TINNITUS SPONDYLOSIS NOS UTERINE LEIOMYOMA	
	454	Female	56	PURE HYPERCHOLESTEROLEM	
	455	Female	62	VARICOSE VEIN OF LEG NOS HYPOTENSION NOS	
15	351	Male	58	HYPERTENSION NOS	
	368	Female	50		ALCOHOL DEPENDENCE SYNDR

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MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
15	374	Female	48	REKUN FEV N/O HRT INVOLY SCARLET FEVER JAUNDICE NOS OTHER GU NEOPLASM NOS CHOLELITHIASIS NOS DIS TYMPANIC MEMB MEC URIN TRACT INFECTION NOS	
	380	Female	49	UTERINE LEIOMYOMA	
	384	Female	65	HYPOTHYROIDISM NOS	

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CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
1	1	Male	Screen	08/02/91	Abnormal	AORTIC ATHEROSCLEROSIS
	2	Female	Screen	05/03/91	Normal	
	3	Female	Screen	13/04/91	Normal	
	4	Male	Screen	15/04/91	Normal	
	5	Female	Screen	17/07/91	Normal	
	6	Male	Screen	06/08/91	Normal	
	7	Male	Screen		Normal	
	8	Male	Screen	29/10/91	Normal	
	9	Female	Screen	14/11/91	Normal	
	10	Female	Screen		Normal	
	11	Male	Screen	03/04/92	Normal	
	12	Male	Screen	14/04/92	Normal	
2	33	Male	Screen	27/12/90	Abnormal	BRONCHITIS NOS
	34	Male	Screen	12/90	Normal	
	35	Male	Screen	28/12/90	Normal	
	36	Female	Screen	10/01/91	Normal	
	37	Male	Screen	17/01/91	Normal	

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 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
2	38	Female	Screen	24/01/91	Abnormal	EMPHYSEMA
	39	Female	Screen	24/01/91	Normal	
	40	Male	Screen	19/02/91	Normal	
	41	Male	Screen	31/01/91	Normal	
	42	Male	Screen	08/02/91	Normal	
	43	Female	Screen	25/03/91	Normal	
	44	Male	Screen	10/04/91	Normal	
	45	Female	Screen	29/05/91	Normal	
	46	Female	Screen	15/05/91	Normal	
	47	Female	Screen	17/05/91	Normal	
	48	Female	Screen	26/08/91	Normal	
	49	Female	Screen	28/08/91	Normal	
	50	Male	Screen	04/11/91	Normal	
	51	Female	Screen	04/11/91	Normal	
3	65	Male	Screen	08/03/91	Abnormal	CORONARY ATHEROSCLEROSIS
	66	Female	Screen	02/05/91	Normal	

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 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
3	67	Female	Screen	10/04/91	Normal	
	68	Female	Screen	05/08/91	Normal	
	69	Female	Screen	19/03/91	Normal	
	70	Female	Screen	22/10/91	Normal	
	71	Female	Screen	13/11/91	Normal	
	72	Female	Screen	30/01/92	Normal	
	73	Female	Screen	12/02/92	Normal	
4	97	Male	Screen	26/05/92	Normal	
	100	Female	Screen	01/06/92	Normal	
	101	Female	Screen	06/05/91	Normal	
6	161	Male	Screen	27/03/91	Normal	
	162	Female	Screen	04/11/91	Normal	
7	193	Female	Screen		Not done	
	194	Male	Screen		Not done	
	196	Female	Screen		Not done	
8	225	Female	Screen	26/10/90	Normal	
	226	Female	Screen	03/05/91	Normal	

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 REMOXETINE - PROTOCOL 20124/017
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CHEST X-RAY

Centre	Patient	Sex	Assessment Date	Chest X-Ray Value	Pulmonary Function Abnormality
8	227	Male	Screen 03/05/91	Normal	Normal
	228	Male	Screen 08/05/91	Normal	Normal
	229	Female	Screen 18/10/91	Normal	Normal
	230	Female	Screen 04/11/91	Normal	Normal
	231	Female	Screen	Not done	Not done
	232	Male	Screen 21/10/91	Normal	Normal
9	197	Male	Screen	Not done	Not done
	198	Female	Screen	Not done	Not done
	199	Male	Screen	Not done	Not done
	200	Male	Screen	Not done	Not done
	201	Female	Screen	Not done	Not done
	202	Male	Screen	Not done	Not done
	203	Female	Screen	Not done	Not done
	204	Male	Screen	Not done	Not done
	205	Female	Screen	Not done	Not done
	206	Female	Screen	Not done	Not done
	207	Female	Screen	Not done	Not done

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 REBOXETINE - PROTOCOL 20124/017
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 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Value	Pulmonary Function Abnormality
9	208	Male	Screen		Not done	
	209	Male	Screen		Not done	
	210	Female	Screen		Not done	
	211	Female	Screen		Not done	
	212	Female	Screen		Not done	
	237	Male	Screen		Not done	
	238	Female	Screen		Not done	
	239	Male	Screen		Not done	
	240	Female	Screen		Not done	
	241	Female	Screen	07/05/92	Normal	
	242	Male	Screen		Not done	
	243	Female	Screen	12/05/92	Normal	
	244	Male	Screen		Not done	
	257	Female	Screen		Not done	
	258	Male	Screen		Not done	
	259	Female	Screen		Not done	
	260	Female	Screen		Not done	

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REBOXETINE - PROTOCOL 20124/017
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CHEST X-RAY

Centre	Patient	Sex	Assessment Date	Chest X-Ray - Pulmonary Function Value	Abnormality
9	261	Female	Screen	Not done	Not done
	262	Male	Screen	Not done	Not done
	263	Female	Screen	Not done	Not done
	264	Female	Screen	Not done	Not done
	265	Female	Screen	Not done	Not done
	266	Female	Screen	Not done	Not done
	267	Male	Screen 19/09/91	Normal	Normal
	268	Female	Screen	Not done	Not done
	269	Male	Screen	Not done	Not done
	270	Female	Screen	Not done	Not done
	271	Female	Screen	Not done	Not done
	272	Male	Screen	Not done	Not done
	273	Female	Screen	Not done	Not done
	274	Female	Screen	Not done	Not done
	274/A	Female	Screen	Not done	Not done
	275	Female	Screen	Not done	Not done
	276	Female	Screen	Not done	Not done

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 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
9	276/A	Male	Screen			Not done
9/A	233	Male	Screen			Not done
	234	Female	Screen			Not done
	235	Male	Screen			Not done
	236	Male	Screen			Not done
	277	Female	Screen			Not done
	278	Female	Screen			Not done
	279	Male	Screen			Not done
	280	Female	Screen			Not done
	281	Female	Screen			Not done
	282	Male	Screen			Not done
	283	Female	Screen			Not done
	284	Male	Screen			Not done
	301	Female	Screen			Not done
	302	Male	Screen			Not done
	303	Female	Screen			Not done
	304	Female	Screen			Not done

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 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
9/A	305	Male	Screen		Not done	
	306	Female	Screen		Not done	
	307	Female	Screen		Not done	
	308	Female	Screen		Not done	
10	289	Female	Screen	17/09/91	Normal	
	290	Male	Screen		Not done	
	291	Male	Screen	20/02/92	Abnormal	CHR AIRWAY OBSTRUCT NEC
	292	Female	Screen	12/12/91	Normal	
	293	Female	Screen	27/12/91	Normal	
	294	Female	Screen	06/01/92	Normal	
	295	Male	Screen	08/01/92	Normal	
	296	Female	Screen	24/02/92	Normal	
	297	Male	Screen	25/03/92	Normal	
	298	Female	Screen	25/03/92	Normal	
	299	Male	Screen	03/04/92	Normal	
	300	Female	Screen	07/04/92	Normal	
11	321	Female	Screen	10/06/92	Normal	

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 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Value	Pulmonary Function - Abnormality
11	322	Female	Screen	08/06/92	Normal	
	323	Female	Screen	23/06/92	Normal	
	324	Male	Screen	16/07/92	Normal	
	325	Female	Screen	24/07/92	Normal	
	326	Male	Screen	30/07/92	Normal	
	327	Female	Screen	17/08/92	Normal	
	328	Male	Screen	11/08/92	Normal	
	329	Female	Screen	18/08/92	Normal	
	330	Female	Screen	21/08/92	Normal	
	331	Male	Screen	01/09/92	Normal	
	332	Female	Screen	31/08/92	Normal	
12	333	Female	Screen	04/09/92	Normal	
	337	Female	Screen		Normal	
	338	Female	Screen		Not done	
	339	Male	Screen		Not done	
	340	Female	Screen		Not done	
	341	Female	Screen		Not done	

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CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Value	Pulmonary Function Abnormality
13	353	Female	Screen	05/06/92	Normal	
	354	Female	Screen	24/06/92	Normal	
	355	Female	Screen	11/06/92	Normal	
	356	Male	Screen	22/07/92	Normal	
	357	Female	Screen	05/08/92	Normal	
	358	Male	Screen	13/07/92	Normal	
	359	Female	Screen	19/08/92	Normal	
	360	Female	Screen	19/08/92	Normal	
	361	Female	Screen	26/08/92	Normal	
14	457	Female	Screen	26/06/92	Normal	
	458	Female	Screen	24/06/92	Normal	
	459	Male	Screen	15/07/92	Normal	
	460	Male	Screen		Not done	
	461	Female	Screen		Not done	
	462	Female	Screen		Not done	
	463	Male	Screen		Not done	
	464	Female	Screen		Not done	

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REBOXETINE - PROTOCOL 20124/017
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CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
14	465	Male	Screen		Not done	
	466	Female	Screen		Not done	
14/1	429	Male	Screen	16/12/91	Normal	
	426	Female	Screen	04/91	Normal	
	429	Female	Screen	17/09/91	Abnormal	CHR AIRWAY OBSTRUCT NEC
	451	Male	Screen	03/12/91	Normal	
	452	Female	Screen	26/11/91	Normal	
14/2	436	Female	Screen	09/01/92	Normal	
	456	Male	Screen	17/04/91	Normal	
14/3	417	Female	Screen	12/90	Normal	
	418	Female	Screen	05/91	Normal	
	419	Female	Screen	03/07/91	Normal	
	420	Female	Screen	05/07/91	Normal	
	421	Female	Screen	11/07/91	Normal	
	427	Female	Screen	06/03/91	Abnormal	EMPHISEMA
	428	Female	Screen	25/10/91	Normal	
14/4	131	Female	Screen	09/01/92	Normal	

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 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
14/4	132	Female	Screen	19/12/91	Normal	
	133	Female	Screen	10/01/92	Normal	
	134	Female	Screen	26/11/91	Normal	
	135	Male	Screen	04/11/91	Normal	
14/7	422	Female	Screen	19/04/91	Abnormal	Not relevant
	423	Female	Screen	06/11/90	Normal	
	424	Male	Screen	03/07/91	Normal	
	430	Female	Screen	07/01/91	Normal	
	431	Male	Screen	08/11/90	Normal	
	432	Male	Screen	12/04/90	Normal	
	433	Female	Screen	08/10/91	Abnormal	OSTEOCHONDROPATHY NEC
	434	Male	Screen	27/03/91	Abnormal	OSTEOCHONDROPATHY NOS
	439	Male	Screen	03/09/91	Normal	
	440	Female	Screen	06/05/91	Normal	
	441	Male	Screen	26/06/91	Normal	
	442	Male	Screen	12/06/91	Normal	
	449	Female	Screen	30/12/91	Normal	

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 CHEST X-RAY

Centre	Patient	Sex	Assessment Date	Value	Pulmonary Function Abnormality
14/7	450	Male	Screen 17/12/90	Normal	
14/8	130	Male	Screen 10/01/92	Normal	
	425	Female	Screen 06/09/91	Normal	
	467	Male	Screen 02/07/92	Normal	
14/10	53	Male	Screen 17/01/92	Normal	
	54	Female	Screen 28/01/92	Normal	
	55	Female	Screen 27/01/92	Normal	
	56	Female	Screen 03/02/92	Normal	
	57	Female	Screen 04/02/92	Normal	
	58	Female	Screen 27/03/92	Normal	
	59	Female	Screen 13/04/92	Normal	
	60	Female	Screen 06/05/92	Normal	
137		Female	Screen 25/01/92	Normal	
138		Female	Screen 07/01/92	Normal	
139		Female	Screen 13/01/92	Normal	
140		Female	Screen 15/01/92	Normal	
435		Female	Screen 24/10/91	Normal	

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 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
14/10	436	Female	Screen	22/10/91	Normal	
	437	Female	Screen	16/10/91	Normal	
	438	Female	Screen	08/10/91	Normal	
	443	Female	Screen	07/10/91	Normal	
	444	Male	Screen	18/11/91	Normal	
	445	Female	Screen	07/10/91	Normal	
	446	Female	Screen	15/11/91	Normal	
	447	Male	Screen	28/11/91	Normal	
	448	Female	Screen	26/11/91	Normal	
	453	Female	Screen	21/05/92	Normal	
	454	Female	Screen	04/06/92	Normal	
	455	Female	Screen	15/06/92	Normal	
15	349	Male	Screen		Not done	
	351	Male	Screen		Not done	
	352	Male	Screen		Not done	
	364	Female	Screen		Not done	
	366	Male	Screen		Not done	

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 CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Value	Pulmonary Function Abnormality
15	367	Male	Screen		Not done	
	368	Female	Screen		Not done	
	369	Female	Screen		Not done	
	370	Female	Screen		Not done	
	371	Female	Screen		Not done	
	372	Male	Screen		Not done	
	373	Female	Screen		Not done	
	374	Female	Screen		Not done	
	375	Female	Screen	06/06/92	Normal	
	376	Female	Screen		Not done	
	377	Female	Screen		Not done	
	378	Female	Screen		Not done	
	379	Female	Screen		Not done	
	380	Female	Screen		Not done	
	381	Female	Screen		Not done	
	382	Male	Screen		Not done	
	383	Female	Screen		Not done	

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CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Value	Abnormality
15	384	Female	Screen			Not done

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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	Male	52	CLOMIPRAMINE MAPROTILOLINE	Very good Good	Y	***	07/89	
	2	Female	55	LUDIOMIL PAROXETIN LITHIUM AMITRIPTYLINE NORTRIPTYLINE	Fair Good Poor Good Good	Y	***	07/90	
	4	Male	53	TOFRANIL	Good				
	5	Female	57	LUDIOMIL ANAFRANIL	Poor Poor				
	6	Male	62	AMITRIPTYLINE NORTRIPTYLINE	Poor Poor	Y Y	***	28/07/91	
	7	Male	54	IMIPRAMINE	Good	Y			
	9	Female	65	NOCLOBENIDE TRANALCYPRIMINE	Poor Very good		***	28/10/91	
	10	Female	46	FLUOXETINE DOXEPIN AMITRIPTYLINE	Fair Poor Poor	Y Y	***	09/91	
	11	Male	50	AMITRIPTYLINE	Fair	Y	***	01/04/92	
	12	Male	27	CLONIPRAMINE MIANSEPIN TRANALCYPRIMINE	Very good Poor Fair	Y Y	***	10/91	
2	33	Male	48	DOXEPIN	Good		***	07/90	
	34	Male	43	CLOMIPRAMINE MAPROTILOLINE	Very poor Poor	Y	***	18/12/90	
	35	Male	34	AMITRIPTYLINEOXIDE	Fair	Y	***	24/12/90	

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PHARMACIA CNS RED

REBOMETINE - PROVDCL 20124/017
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment	Efficacy	Side effects	Last taken	Last day of treat.
2	38	Female	54	MAPROTYLINE	Poor		xxx	xxx	22/01/91
	39	Female	46	AMITRIPTYLINOXIDE	Poor	Y	xxx	xxx	28/12/90
	41	Male	50	AMITRIPTYLINOXIDE	Poor		xxx	xxx	29/01/91
	42	Male	55	AMITRIPTYLINE	Poor	Y	xxx	xxx	05/02/91
	43	Female	40	MAPROTYLINE	Poor		xxx	xxx	20/03/91
	44	Male	54	FLUOXYTINE	Poor		xxx	xxx	07/04/91
	45	Female	36	DOXEPIN	Very poor		xxx	xxx	26/04/91
	48	Female	61	MAPROTYLINE	Fair	Y	xxx	xxx	22/08/91
	50	Male	54	MIANSERIN	Good				
	51	Female	39	MAPROTYLINE LITHIUM CARBONATE	Poor Poor		xxx	xxx	29/10/91
3	52	Male	25	NOCLOBEMIDE	Very poor	Y	xxx	xxx	12/11/91
	65	Male	46	APOMAL LUDIOMEL	Very poor Fair	Y	xxx	xxx	28/03/91
	66	Female	39	SAROTEN EQUILIBRIN	Poor Poor	Y	xxx	xxx	25/04/91
	67	Female	56	APOMAL SAROTEN	Fair Good		xxx	xxx	03/04/91
	68	Female	52	ANAFRANIL STANGYL	Poor Poor	Y Y	xxx xxx	xxx xxx	29/07/91

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REBOXETINE - PROTOCOL 20124/017
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment			Last day taken of treat.
					Efficacy	Side effects	Last taken	
3	70	Female	60	SAROTEN	Poor	xxx	01/91	
	72	Female	48	SAROTEN	Poor	Y	28/01/92	
	73	Female	52	AMITRIPTYLINE LUDIGMIL	Fair Good			
4	97	Male	22	MAPROTILINE	Very poor	xxx	22/04/92	
	100	Female	34	AMITRIPTYLINE	Poor			
	101	Female	54	MAPROTILINE DESIPRAMINE	Fair Poor	Y Y	29/04/91	
6	162	Female	56	AMITRIPTYLINE	Poor	Y	30/10/91	
7	193	Female	56	ANAFRANIL	Fair			
	196	Female	23	TRAZOLAN	Poor	xxx	15/03/91	
8	225	Female	24	REDOMEX TRAZOLAN PROTHIADEN	Fair Very poor Poor	Y	22/02/91	
	226	Female	51	AMITRIPTYLINE DOSULEPIN	Good Good	xxx	89	
	229	Female	39	PHENELZINE ANAFRANIL - SLOW RELEASE	Good Good	Y	01/10/91	
9	497	Male	51	DOSULEPIN NOCLOBEMIDE AMITRIPTYLINE MELITRACEN MIANSERIN	Fair Fair Poor Poor Good	xxx	01/02/92	

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PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment	Efficacy	Side effects	Last taken	Last day of treat.	
9	199	Male	47	AMITRIPTYLINE	Fair			***	24/03/92	
				MIANSEKIN	Fair					
				DOSULEPIN	Fair					
				DOXEFIN	Fair					
				VILWAZINE	Fair					
	202	Male	65	DOSULEPIN	Very good		***	08/01/92		
				MIANSEKIN	Very good					
				CLOMIPRAMINE	Very poor					
	203	Female	34	MIANSEKIN	Good					
				TRAZODONE	Fair					
	204	Male	45	DOSULEPIN	Poor		***	15/12/91		
				CLOMIPRAMINE	Fair					
				TRAZODONE	Fair					
				TRIFT-ON	Very poor					
	205	Female	41	DOSULEPIN	Good					
				LERIVON	Good					
	207	Female	64	MIANSEKIN	Poor		***	24/01/92		
				CLOMIPRAMINE	Very poor	Y				
				AMITRIPTYLINE	Good					
				MAPROTYLINE	Very good	Y				
	208	Male	42	AMITRIPTYLINE	Poor		***	01/12/91		
	237	Male	45	AMITRIPTYLINE	Good		***	91		
	239	Male	29	IMIPRAMINE	Good		***	10/04/92		
	241	Female	49	IMIPRAMINE	Good		***	05/91		
	243	Female	29	DOSULEPIN	Poor		***	10/05/92		
				MIANSEKIN	Poor					

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PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment			Last day of treat.
					Efficacy	Side effects	Last taken	
9	257	Female	25	MIANSERIN	Very poor	***	01/07/91	
	260	Female	30	DOSULEPIN	Fair			
	261	Female	34	MIANSERIN DOXEFIN	Poor Fair			
	263	Female	36	MIANSERIN	Very poor	Y	23/07/91	
	264	Female	46	MELITRACEN DOXEFIN TRAZODONE	Fair Fair Good	***	24/07/91	
	268	Female	41	INSIDON AMITRIPTYLINE	Good Good			
	270	Female	43	DOSULEPIN MIANSERIN	Very poor Poor	Y Y	11/09/91	
	272	Male	62	DOSULEPIN MIANSERIN AMITRIPTYLINE	Very poor Fair Good	***	10/10/91	
	273	Female	35	CLOMIPRAMINE DOSULEPIN	Good Good			
	274	Female	47	MIANSERIN	Very poor	***	15/09/91	
	274/A	Female	46	TRAZODONE IMIPIRAMINE DESIPRAMINE	Poor Fair Good Poor	***	21/04/92	
	275	Female	59	FLUVOXAMINE TRAZODONE	Poor Fair			
	276	Female	61	MIANSERIN DOSULEPIN	Poor Good	***	15/12/91	

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PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment	Efficacy	Side effects	Last taken	Last day of treat.
9	276/A	Male	41	FLOXYFRAL	Very good				
9/A	233	Male	57	CITALOPRAM TRAZODONE VILOXAZINE FLUOXETINE	Very poor Fair Good Poor	Y	***		20/04/92
	234	Female	31	FLUOXETINE	Poor		***		08/03/92
	236	Male	38	CITALOPRAM	Very poor		***		01/05/92
	277	Female	36	CITALOPRAM FLUOXETINE VILOXAZINE	Very poor Poor Poor		***		23/04/92
	280	Female	44	MIANSERIN	Fair	Y	***		30/03/92
	281	Female	64	TRAZODONE	Very poor	Y	***		10/08/92
	282	Male	35	DOSULEPIN DOXEPIN FLUOXETINE	Poor Poor Poor		***		14/08/92
	283	Female	58	DOSULEPIN CITALOPRAM AMITRIPTYLINE	Very good Poor Good	Y	***		01/09/92
	302	Male	26	FLUOXETINE	Poor	Y	***		11/12/91
	303	Female	29	FLUOXAMINE	Poor		***		10/02/92
	304	Female	41	PROTHIADEN	Poor				
	306	Female	38	FLUOXAMINE	Good		***		30/09/91

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PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment		Last day taken of treat.
					Efficacy	Side effects	
9/A	307	Female	26	CIPRANIL FLUOXETINE	Very poor Very poor	***	14/04/92
10	293	Female	62	ANAFRANIL - SLOW RELEASE	Fair		
	294	Female	63	DESIPRAMINE	Fair	***	29/12/91
	299	Male	23	CIPRANIL	Poor	***	02/04/92
	300	Female	34	ANAFRANIL - SLOW RELEASE	Poor	***	10/04/92
11	323	Female	26	FLUOXETINE	Fair	Y	30/04/92
	325	Female	18	FLUOXETINE	Fair	***	15/11/91
	331	Male	43	TRAZODONE NOCLOBENIDE	Fair Fair	Y	15/08/92
	333	Female	47	CLOMIPRAMINE DOTIEPIN	Fair Fair	Y	21/08/92
12	337	Female	54	CLOMIPRAMINE	Good		
	338	Female	65	DOTIEPIN	Fair	***	12/06/92
	339	Male	64	IMIPRAMINE	Very poor		
	340	Female	44	FLUOXETINE IMIPRAMINE LITHIUM	Poor Good Poor	Y	
	341	Female	41	CLOMIPRAMINE DOTIEPIN	Poor Fair		
14	458	Female	60	AMITRIPTYLINE	Fair	***	09/91

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PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment	Efficacy	Side effects	Last taken	Last day of treat.
14	459	Male	49	AMITRIPTYLINE	Good	xxx	xxx	04/91	
	460	Male	49	AMITRIPTYLINE	Fair	xxx	xxx	04/91	
	461	Female	57	OPIPRAMOL HYDROCHLORIDE	Poor	xxx	xxx	21/07/92	
	462	Female	55	MIANSERIN	Fair	xxx	xxx	24/07/92	
	463	Male	62	MAPROTIline	Fair	xxx	xxx	26/07/92	
	464	Female	64	NOCLOBEMIDE	Fair	xxx	xxx	28/07/92	
	465	Male	51	MIANSERIN	Fair	xxx	xxx	29/07/92	
	466	Female	40	AMITRIPTYLINE	Fair	xxx	xxx	30/07/92	
14/1	129	Male	59	EQUILIBRIN	Fair	xxx	xxx	10/12/91	
	426	Female	55	FLUOXETINE		xxx	xxx	25/08/91	
14/2	136	Female	29	IUDIONIL	Good	Y	xxx	02/91	
14/3	417	Female	27	FLUOXETINE	Fair	xxx	xxx	01/91	
14/4	131	Female	60	MAPROTIline	Good	xxx	xxx	20/08/88	
	134	Female	26	MIANSERIN	Good	xxx	xxx	15/02/91	
14/10	53	Male	58	MAPROTIline THIPRAHIN	Fair Good	xxx	xxx	09/90	
	55	Female	57	TRIMIPRAMINE	Fair	xxx	xxx	05/90	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment	Efficacy	Side effects	Last taken	Last day of treat.
14/10	60	Female	47	IMIPRAMINE	Fair		xxx	04/87	
	137	Female	58	MIANSERIN HYDROCHLORIDE	Fair		xxx	04/89	
	140	Female	63	MAPROTILINE HYDROCHLORIDE			xxx	09/09/89	
	435	Female	61	AMITRIPTYLINE HYDROCHLORIDE	Fair		xxx	07/89	
	443	Female	58	TRIMIPRAMINE MESILATE	Fair		xxx	04/89	
	445	Female	63	MAPROTILINE HYDROCHLORIDE	Fair		xxx	01/06/89	
	447	Male	60	TRIMIPRAMINE MALEATE	Fair		xxx	23/04/90	
15	364	Female	36	DOTHEPIN MAPROTILINE	Fair Poor	Y	xxx	20/07/92	
	367	Male	32	DOTHEPIN MAPROTILINE	Fair Poor				
	371	Female	22	DOTHEPIN AMITRIPTYLINE	Fair Poor	Y	xxx	30/06/92	
	372	Male	36	MIANSERIN AMITRIPTYLINE	Very poor Very poor		xxx xxx	07/06/92	
	374	Female	48	FLUDOXETINE AMITRIPTYLINE	Fair Good		xxx	28/03/92	
	376	Female	66	AMITRIPTYLINE LITHIUM	Good Good		xxx xxx	01/04/91	
	377	Female	37	MIANSERIN IMIPRAMIN AMITRIPTYLINE	Very poor Very good Very good		xxx	04/05/92	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Name	Previous antidepressive treatment		Last day of treat.
					Efficacy	Side effects taken	
15	380	Female	49	AMITRIPTYLINE	Good	xxx	01/06/92
	382	Male	19	MIANSERIN DOTHIEPIN	Poor Poor	xxx	15/03/92
	384	Female	65	DOTHIEPIN FLUOXETINE	Poor Poor	xxx	20/07/92

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period To (a)		Days	Start date	Treatment Randomized	
			From (*)	To (a)				
1	1	07/89	02/07/89	04/02/91	584	05/02/91	Reboxetine	
	2	07/90	02/07/90	25/02/91	240	26/02/91	Reboxetine	
	3			15/04/91		16/04/91	Imipramine	
	4			16/04/91		17/04/91	Imipramine	
	5		03/07/91	16/07/91	14	17/07/91	Reboxetine	
	6	28/07/91	29/07/91	06/08/91	9	07/08/91	Imipramine	
	7			08/10/91		09/10/91	Reboxetine	
	8			28/10/91		29/10/91	Imipramine	
	9		28/10/91	29/10/91	07/11/91	11	08/11/91	Imipramine
	10	09/91	02/09/91	18/11/91	79	19/11/91	Imipramine	
2	11	01/04/92	02/04/92	05/04/92	5	06/04/92	Reboxetine	
	12	10/91	02/10/91	14/04/92	197	15/04/92	Reboxetine	
	33	07/90	02/07/90	18/12/90	171	19/12/90	Reboxetine	
	34	18/12/90	19/12/90	27/12/90	10	28/12/90	Imipramine	
	35	24/12/90	25/12/90	27/12/90	3	28/12/90	Reboxetine	
	36		28/12/90	09/01/91	15	10/01/91	Imipramine	

(*) if missing date = last day of previous treatment + 1 day
(a) same as start treatment date - 1 day

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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)		
2	37		15/01/91	17/01/91	3	Reboxetine
	38	22/01/91	23/01/91	24/01/91	3	Imipramine
	39	28/12/90	29/12/90	24/01/91	27	Reboxetine
	40			19/02/91		Imipramine
	41	29/01/91	30/01/91	04/02/91	6	Reboxetine
	42	05/02/91	06/02/91	08/02/91	3	Imipramine
	43	20/03/91	21/03/91	25/03/91	5	Reboxetine
	44	07/04/91	08/04/91	10/04/91	3	Imipramine
	45	26/04/91	27/04/91	29/04/91	3	Imipramine
	46		13/05/91	15/05/91	3	Reboxetine
	47		17/05/91	21/05/91	5	Reboxetine
	48	22/08/91	23/08/91	26/08/91	4	Imipramine
	49		25/08/91	28/08/91	4	Imipramine
	50		31/10/91	05/11/91	6	Reboxetine
	51	29/10/91	30/10/91	05/11/91	7	Reboxetine
	52	12/11/91	13/11/91	26/11/91	14	Imipramine

(*) if missing date = last day of previous treatment + 1 day
(B) same as start treatment date - 1 day

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 REBOXETINE - PROTOCOL 20124/017
 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 (a)		Start date	Randomized
3	65	28/03/91	29/03/91	01/04/91	5	02/04/91	Reboxetine
	66	25/04/91	26/04/91	30/04/91	5	01/05/91	Imipramine
	67	03/04/91	04/04/91	09/04/91	6	10/04/91	Reboxetine
	68	29/07/91	30/07/91	02/08/91	5	03/08/91	Imipramine
	69			28/02/91		01/03/91	Imipramine
	70	01/91	17/10/91	22/10/91	6	23/10/91	Reboxetine
	71		08/11/91	13/11/91	6	14/11/91	Imipramine
	72	28/01/92	29/01/92	30/01/92	3	31/01/92	Reboxetine
	73		07/02/92	14/02/92	8	15/02/92	Reboxetine
4	97	22/04/92	23/04/92	06/05/92	14	07/05/92	Imipramine
	100		01/05/92	06/05/92	6	07/05/92	Reboxetine
	101	29/04/91	30/04/91	05/05/91	6	06/05/91	Imipramine
6	161		26/03/91	28/03/91	3	29/03/91	Reboxetine
	162	30/10/91	31/10/91	04/11/91	5	05/11/91	Reboxetine
7	193		07/06/91	10/06/91	4	11/06/91	Reboxetine
	194			02/06/91		03/06/91	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 20124/017
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 (a)		
7	196	15/03/91	16/03/91	18/03/91	4	19/03/91 Imipramine
	225	22/02/91	15/03/91	21/03/91	7	22/03/91 Imipramine
8	226	89	26/04/91	02/05/91	7	03/05/91 Reboxetine
	227		28/04/91	06/05/91	9	07/05/91 Imipramine
228	228		05/05/91	09/05/91	5	10/05/91 Reboxetine
	229	01/10/91	20/10/91	21/10/91	2	22/10/91 Imipramine
230	230		30/10/91	04/11/91	6	05/11/91 Imipramine
	231		04/11/91	04/11/91		05/11/91 Reboxetine
232	232		26/11/91	28/11/91	3	29/11/91 Reboxetine
	197	01/02/92	02/02/92	06/03/92	35	07/03/92 Reboxetine
198	198		17/03/92	17/03/92		18/03/92 Imipramine
	199	24/03/92	25/03/92	01/04/92	9	02/04/92 Imipramine
200	200		27/04/92	27/04/92		28/04/92 Reboxetine
	201		01/01/92	15/01/92	15	16/01/92 Imipramine
202	202	08/01/92	09/01/92	16/01/92	9	17/01/92 Imipramine
	203		11/91	14/01/92	75	15/01/92 Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(a) same as start treatment date - 1 day

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Centre	Patient	Last day of previous treatment	Wash out period to (a)		Days	Treatment
			From (*)	Start date		
9	204	15/12/91	16/12/91	16/01/92	33	Reboxetine
	205		15/01/92	04/02/92	21	Imipramine
	206		21/01/92	04/02/92	15	Imipramine
	207	24/01/92	25/01/92	05/02/92	13	Reboxetine
	208	01/12/91	02/12/91	14/02/92	76	Reboxetine
	209			11/02/92		Imipramine
	210		15/01/92	19/02/92	36	Reboxetine
	211		13/01/92	13/02/92	32	Reboxetine
	212			03/03/92		Imipramine
	237		02/01/91	22/04/92	478	Reboxetine
	238			19/05/92		Imipramine
	239	10/04/92	11/04/92	29/04/92	20	Imipramine
	240			27/04/92		Reboxetine
	241	05/91	05/05/92	08/05/92	4	Imipramine
	242			06/05/92		Reboxetine
	243	10/05/92	11/05/92	17/05/92	7	Imipramine

(*) if missing date = last day of previous treatment + 1 day
 (a) same as start treatment date - 1 day

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 REBOXETINE - PROTOCOL 20124/017
 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
9	244		05/06/92		16	06/06/92	Reboxetine
	257	01/07/91	02/07/91	16/07/91	16	17/07/91	Reboxetine
	258		10/07/91	16/07/91	7	17/07/91	Reboxetine
	259		10/06/91	16/07/91	37	17/07/91	Imipramine
	260		90	23/07/91	569	24/07/91	Imipramine
	261		10/07/91	22/07/91	13	23/07/91	Imipramine
	262		29/06/91	22/07/91	24	23/07/91	Reboxetine
	263	23/07/91	24/07/91	30/07/91	8	31/07/91	Reboxetine
	264	24/07/91	25/07/91	30/07/91	7	31/07/91	Imipramine
	265			22/08/91		23/08/91	Reboxetine
	266		15/08/91	17/09/91	34	18/09/91	Reboxetine
	267			01/09/91		02/09/91	Imipramine
	268		17/09/91	24/09/91	8	25/09/91	Imipramine
	269		19/09/91	24/09/91	6	25/09/91	Reboxetine
	270	11/09/91	12/09/91	10/10/91	30	11/10/91	Imipramine
	271		04/10/91	29/10/91	26	30/10/91	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
 (G) same as start treatment date - 1 day

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/017
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period (a)		Days	Treatment		
			From (*)	To (a)		Start date	Randomized	
9	272	10/10/91	11/10/91	29/10/91	20	30/10/91	Imipramine	
	273		15/10/91	29/10/91	15	30/10/91	Imipramine	
	274	15/09/91	16/09/91	30/10/91	46	31/10/91	Reboxetine	
	274/A	21/04/92	22/04/92	12/05/92	22	13/05/92	Reboxetine	
	275		01/11/91	05/11/91	5	06/11/91	Reboxetine	
	276	15/12/91	16/12/91	13/01/92	30	14/01/92	Imipramine	
	276/A		10/01/92	03/03/92	54	04/03/92	Imipramine	
	9/A	233	20/04/92	21/04/92	13/05/92	24	14/05/92	Imipramine
		234	08/03/92	09/03/92	21/05/92	74	22/05/92	Reboxetine
		235		04/05/92	25/05/92	22	26/05/92	Reboxetine
		236	01/05/92	02/05/92	26/05/92	26	27/05/92	Imipramine
		277	23/04/92	24/04/92	09/06/92	48	10/06/92	Reboxetine
		278		01/01/90	12/06/92	894	13/06/92	Imipramine
		279		15/03/92	06/08/92	145	07/08/92	Imipramine
		280	30/03/92	31/03/92	07/08/92	131	08/08/92	Reboxetine
	281	10/08/92	24/08/92	31/08/92	8	01/09/92	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 20124/017
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	From (*)	Wash out period To (‡)	Days	Start date	Treatment Randomized
9/A	282	14/08/92	15/08/92	01/09/92	19	02/09/92	Reboxetine
	283	01/09/92	02/09/92	15/09/92	15	16/09/92	Imipramine
	284			18/09/92		19/09/92	Imipramine
	301			04/03/92		05/03/92	Imipramine
	302	11/12/91	21/02/92	05/03/92	14	06/03/92	Imipramine
	303	10/02/92	11/02/92	11/03/92	31	12/03/92	Reboxetine
	304		10/03/92	25/03/92	16	26/03/92	Reboxetine
	305		25/02/92	30/03/92	35	31/03/92	Reboxetine
	306	30/09/91	01/10/91	28/04/92	212	29/04/92	Reboxetine
	307	14/04/92	15/04/92	04/05/92	21	05/05/92	Imipramine
	308			08/05/92		09/05/92	Imipramine
10	289		16/09/91	20/09/91	5	21/09/91	Imipramine
	290		07/10/91	13/10/91	7	14/10/91	Reboxetine
	291		13/02/92	16/02/92	4	17/02/92	Imipramine
	292		05/12/91	12/12/91	8	13/12/91	Reboxetine
	293		19/12/91	23/12/91	5	24/12/91	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(‡) same as start treatment date - 1 day

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PHARMACIA CNS R&D									
REBOXETINE - PROTOCOL 20124/017									
Listing No.: 6.1									
DURATION OF DRUG-FREE WASH-OUT-PERIOD									
Centre	Patient	Last day of previous treatment	From (%)	Wash out period to (%)	Days	Start date	Treatment	Start date	Randomized
10	294	29/12/91	30/12/91	02/01/92	4	03/01/92	Imipramine	03/01/92	Imipramine
	295		02/01/92	06/01/92	5	07/01/92	Imipramine	07/01/92	Imipramine
	296		14/02/92	19/02/92	6	20/02/92	Reboxetine	20/02/92	Reboxetine
	297			20/03/92		21/03/92	Reboxetine	21/03/92	Reboxetine
	298			21/03/92	6	27/03/92	Reboxetine	27/03/92	Reboxetine
	299	02/04/92	03/04/92	06/04/92	5	07/04/92	Imipramine	07/04/92	Imipramine
	300	10/04/92	11/04/92	13/04/92	4	14/04/92	Imipramine	14/04/92	Imipramine
11	321			10/06/92		11/06/92	Reboxetine	11/06/92	Reboxetine
	322		03/06/92	10/06/92	8	11/06/92	Reboxetine	11/06/92	Reboxetine
	323	30/04/92	01/05/92	23/06/92	54	24/06/92	Imipramine	24/06/92	Imipramine
	324			16/07/92		17/07/92	Imipramine	17/07/92	Imipramine
	325	15/11/91	16/11/91	29/07/92	257	30/07/92	Reboxetine	30/07/92	Reboxetine
	326			29/07/92		30/07/92	Imipramine	30/07/92	Imipramine
	327			19/08/92		20/08/92	Reboxetine	20/08/92	Reboxetine
	328			19/08/92		20/08/92	Imipramine	20/08/92	Imipramine
	329			20/08/92		21/08/92	Imipramine	21/08/92	Imipramine

(*) if missing date = last day of previous treatment + 1 day
 (B) same as start treatment date - 1 day

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REBOXETINE - PROTOCOL 20124/017
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 (a)		Start date	Randomized
11	330		14/08/92	23/08/92	10	24/08/92	Reboxetine
	331	15/08/92	16/08/92	02/09/92	19	03/09/92	Reboxetine
	332			04/09/92		05/09/92	Imipramine
	333	21/08/92	22/08/92	03/09/92	14	04/09/92	Imipramine
	337		21/05/92	25/05/92	5	26/05/92	Imipramine
12	338	12/06/92	13/06/92	19/06/92	7	20/06/92	Reboxetine
	339		16/06/92	22/06/92	7	23/06/92	Imipramine
	340		01/08/92	06/08/92	6	07/08/92	Reboxetine
	341		17/08/92	20/08/92	4	21/08/92	Reboxetine
13	353			04/06/92		05/06/92	Reboxetine
	354			23/06/92		24/06/92	Imipramine
	355		12/06/92	24/06/92	13	25/06/92	Reboxetine
	356			21/07/92		22/07/92	Imipramine
	357			04/08/92		05/08/92	Imipramine
358			05/08/92		06/08/92	Reboxetine	
359			18/08/92		19/08/92	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 20124/017
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
13	360			18/08/92		19/08/92	Imipramine
	361			25/08/92		26/08/92	Reboxetine
14	457			06/07/92		07/07/92	Reboxetine
	458	09/91	02/09/91	13/07/92	317	14/07/92	Imipramine
	459	04/91	02/04/91	15/07/92	472	16/07/92	Reboxetine
	460	04/91	02/04/91	22/07/92	479	23/07/92	Imipramine
	461	21/07/92	22/07/92	28/07/92	7	29/07/92	Imipramine
	462	24/07/92	25/07/92	30/07/92	7	31/07/92	Reboxetine
	463	26/07/92	27/07/92	02/08/92	7	03/08/92	Imipramine
	464	28/07/92	29/07/92	04/08/92	7	05/08/92	Reboxetine
	465	29/07/92	30/07/92	05/08/92	7	06/08/92	Reboxetine
	466	30/07/92	31/07/92	06/08/92	7	07/08/92	Imipramine
14/1	129	10/12/91	11/12/91	18/12/91	8	19/12/91	Reboxetine
	426	25/08/91	26/08/91	04/09/91	10	05/09/91	Reboxetine
	429			25/09/91		26/09/91	Imipramine
	451			27/11/91		28/11/91	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 RSD									
REBOXETINE - PROTOCOL 20124/017									
Listing No.: 6.1									
DURATION OF DRUG-FREE WASH-OUT-PERIOD									
Centre	Patient	Last day of previous treatment	Wash out period To (3)		Days	Start date	Treatment	Randomized	
			From (*)	To (3)					
14/1	452		27/11/91			28/11/91	Reboxetine		
14/2	136	02/91	02/02/91	14/01/92	348	15/01/92	Imipramine		
	456		14/04/92			15/04/92	Imipramine		
14/3	417	01/91	07/06/91	13/06/91	7	14/06/91	Reboxetine		
	418		17/06/91			18/06/91	Imipramine		
	419		04/07/91			05/07/91	Reboxetine		
	420		04/07/91			05/07/91	Imipramine		
	421		18/07/91			19/07/91	Reboxetine		
	427		17/09/91			18/09/91	Imipramine		
	428		24/10/91			25/10/91	Imipramine		
14/4	131	20/08/88	21/08/88	13/01/92	1242	14/01/92	Imipramine		
	132		13/01/92			14/01/92	Imipramine		
	133		15/01/92			16/01/92	Imipramine		
	134	15/02/91	16/02/91	15/01/92	335	16/01/92	Reboxetine		
	135		16/01/92			17/01/92	Reboxetine		
14/7	422		02/91	03/09/91	215	04/09/91	Imipramine		

(*) if missing date = last day of previous treatment + 1 day
 (3) same as start treatment date - 1 day

PHARMACIA CIS R&D
REBOXETINE - PROTOCOL 20124/017
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 (a)		Start date	Randomized
14/77	423		03/03/90	16/09/91	563	17/09/91	Imipramine
	424		20/11/90	18/09/91	303	19/09/91	Reboxetine
	430			06/10/91		07/10/91	Reboxetine
	431			07/10/91		08/10/91	Reboxetine
	432			07/10/91		08/10/91	Imipramine
	433		23/07/91	07/10/91	77	08/10/91	Imipramine
	434			13/10/91		14/10/91	Reboxetine
	439		04/10/91	10/11/91	38	11/11/91	Reboxetine
	440			10/11/91		11/11/91	Imipramine
	441			10/11/91		11/11/91	Imipramine
	442			10/11/91		11/11/91	Imipramine
	449			19/12/91		20/12/91	Reboxetine
	450			22/12/91		23/12/91	Imipramine
14/8	130			09/01/92		10/01/92	Reboxetine
	425			08/09/91		09/09/91	Reboxetine
	467			05/07/92		06/07/92	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(a) same as start treatment date - 1 day

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PHARMACIA CNS RSD
REBOXETINE - PROTOCOL 20124/017
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
14/10	53	09/90	17/02/92	24/02/92	8	25/02/92	Reboxetine
	54		18/02/92	25/02/92	8	26/02/92	Imipramine
	55	05/90	20/02/92	27/02/92	8	28/02/92	Reboxetine
	56		24/02/92	02/03/92	8	03/03/92	Imipramine
	57		25/02/92	03/03/92	8	04/03/92	Reboxetine
	58		02/04/92	13/04/92	12	14/04/92	Imipramine
	59		15/04/92	23/04/92	9	24/04/92	Imipramine
	60	04/87	04/05/92	12/05/92	9	13/05/92	Reboxetine
	137	04/89	20/01/92	27/01/92	8	28/01/92	Reboxetine
	138		21/01/92	28/01/92	8	29/01/92	Imipramine
	139		27/01/92	03/02/92	8	04/02/92	Reboxetine
	140	09/09/89	28/01/92	04/02/92	8	05/02/92	Imipramine
	435	07/89	04/11/91	11/11/91	8	12/11/91	Imipramine
	436		05/11/91	12/11/91	8	13/11/91	Reboxetine
	437			13/11/91		14/11/91	Reboxetine
	438		07/11/91	14/11/91	8	15/11/91	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 RD											
REBOXETINE - PROTOCOL 20124/017											
Listing No.: 6.1											
DURATION OF DRUG-FREE WASH-OUT-PERIOD											
Centre	Patient	Last day of previous treatment	Wash out period to (3)		Days	Start date	Treatment	Randomized			
			From (*)	To (3)				Start date	Treatment	Start date	Treatment
14/10	443	04/89	14/11/91	18/11/91	5	19/11/91	Reboxetine				
	444		07/11/91	15/11/91	9	16/11/91	Reboxetine				
	445	01/06/89	12/11/91	19/11/91	8	20/11/91	Imipramine				
	446		15/11/91	25/11/91	11	26/11/91	Reboxetine				
	447	23/04/90	19/11/91	26/11/91	8	27/11/91	Reboxetine				
	448		22/11/91	27/11/91	6	28/11/91	Imipramine				
	453		18/05/92	27/05/92	10	28/05/92	Imipramine				
	454		03/06/92	11/06/92	9	12/06/92	Reboxetine				
	455		11/06/92	19/06/92	9	20/06/92	Reboxetine				
15	349			19/08/92		20/08/92	Imipramine				
	351			01/09/92		02/09/92	Reboxetine				
	352			05/08/92		06/08/92	Imipramine				
	364	20/07/92	21/07/92	28/07/92	8	29/07/92	Imipramine				
	366		21/08/92	26/08/92	6	27/08/92	Reboxetine				
	367		23/08/92	30/08/92	8	31/08/92	Imipramine				
	368			03/09/92		04/09/92	Reboxetine				

(*) if missing date = last day of previous treatment + 1 day
 (3) same as start treatment date - 1 day

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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
15	369		09/07/92			10/07/92	Reboxetine
	370		15/07/92			16/07/92	Imipramine
	371	30/06/92	17/07/92		3	20/07/92	Reboxetine
	372	07/06/92	08/06/92		9	17/06/92	Imipramine
	373		24/06/92			25/06/92	Imipramine
	374	28/03/92	29/03/92		11	09/04/92	Reboxetine
	375		05/06/92			06/06/92	Reboxetine
	376	01/04/91	02/04/91		377	13/04/92	Imipramine
	377	04/05/92	05/05/92		8	13/05/92	Reboxetine
	378		14/06/92			15/06/92	Reboxetine
	379		15/04/92			16/04/92	Imipramine
	380	01/06/92	02/06/92		28	30/06/92	Imipramine
	381		20/05/92			21/05/92	Reboxetine
	382	15/03/92	16/03/92		24	09/04/92	Imipramine
	383		06/07/92			07/07/92	Imipramine
	384	20/07/92	21/07/92		8	28/07/92	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(B) 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 060085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 1

	Patient											
	1	2	3	4	5	6	7	8	9	10	11	12
	Male	Fem.	Fem.	Male	Fem.	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
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
High risk of suicide	YES	YES	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 CN9540085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 2

	Patient												
	33	34	35	36	37	38	39	40	41	42	43	44	45
	Male	Male	Male	Fem.	Male	Fem.	Fem.	Male	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	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	NO	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
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA C0520085
 REDONETINE - PROTOCOL 20124/017
 Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 2

	Patient						
	46	47	48	49	50	51	52
	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
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 2 HAND	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	N/A	N/A	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 abnorm.	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 or 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
High risk of suicide	YES	YES	YES	YES	YES	YES	YES

PHARMACIA C959085
 RESONANCE - PROTOCOL 20124/017
 Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 3

	Patient								
	65	66	67	68	69	70	71	72	73
	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
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 2 HAND	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 ?									
Dythyria, 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	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	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 abnorm.	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
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES

PHARMACIA C05E0085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 4

	Patient		
	97	100	101
	Male	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 abnorm.	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
High risk of suicide	YES	YES	YES

PHARNACIA C95E0085

REBOMETINE - PROTOCOL 2012A/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 6

	Patient	
	161	162
	Male	Female
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 of 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 abnorm.	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 of brain injury	YES	YES
Any other important clinical illness ...	YES	YES
ECT in the previous 6 months	YES	YES
High risk of suicide	YES	YES

PHARMACIA 0532085

REBONETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 7

	Patient		
	193	194	196
	Fee.	Male	Fee.
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 of above 21HAND	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?			
Dythyria, 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 haematopoietic ...	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 abnorm.	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
High risk of suicide	YES	YES	YES

PHARMACIA C05E0085

REMOMETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 8

	Patient							
	225	226	227	228	229	230	231	232
	Fem.	Fem.	Male	Male	Fem.	Fem.	Fem.	Male
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 21BAND	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 or 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
High risk of suicide	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 0550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 9

	Patient												
	197	198	199	200	201	202	203	204	205	206	207	208	209
	Male	Fem.	Male	Male	Fem.	Male	Fem.	Male	Fem.	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 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 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
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 C9540085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 9

	Patient													
	210	211	212	237	238	239	240	241	242	243	244	257	258	
	Fem.	Fem.	Fem.	Male	Fem.	Male	Fem.	Fem.	Male	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	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	YES
With a total score of 22 of above 24HAND	YES	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	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?														
Dysthymia, Cyclothymia	YES	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	YES
Pregnancy	YES	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	YES
Clinically significant hematopoietic ...	YES	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	YES
Current evidence of urinary retention	YES	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	YES
Clinically significant physical abnorma.	YES	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	YES
Evidence of substance use disorder	YES	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	YES
History of drug hypersensitivity	YES	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	YES
Any other important clinical illness ...	YES	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	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA ~~0550085~~
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 9

	Patient												
	259	260	261	262	263	264	265	266	267	268	269	270	271
	Fem.	Fem.	Fem.	Male	Fem.	Fem.	Fem.	Fem.	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	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
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA 0650085

REBOXETINE - PROTOCOL 2012A/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 9

	Patient						
	272	273	274	274/A	275	276	276/A
	Male	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
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAND	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 abnorm.	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
High risk of suicide	YES	YES	YES	YES	YES	YES	YES

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA 0550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 9/A

	Patient												
	233	234	235	236	277	278	279	280	281	282	283	284	301
	Male	Fem.	Male	Male	Fem.	Fem.	Male	Fem.	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	NO	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
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA C0500085

REBOMETINE - PROTOCOL 2012A/017
 Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 9/A

	Patient						
	302	303	304	305	306	307	308
	Male	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
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAND	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
High risk of suicide	YES	YES	YES	YES	YES	YES	YES

PHARMACIA ~~054085~~ 054085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 10

	Patient											
	289	290	291	292	293	294	295	296	297	298	299	300
	Fem.	Male	Male	Fem.	Fem.	Male	Fem.	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 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	N/A	YES	YES
Refusal of contraceptive use during	N/A	YES	YES	NO	YES	YES	YES	YES	YES	N/A	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
High risk of suicide	YES	YES	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 CN9540085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 11

	Patient													
	321	322	323	324	325	326	327	328	329	330	331	332	333	
	Fem.	Fem.	Fem.	Male	Fem.	Male	Fem.	Male	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	
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	

PHARMACIA C0560085

REBOGETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 12

	Patient				
	337	338	339	340	341
	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 21(NAND)	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	N/A	YES	N/A	YES
Refusal of contraceptive use during	N/A	N/A	YES	N/A	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 abnorm.	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
High risk of suicide	YES	YES	YES	YES	YES

PHARNACIA 0953085

REBOMETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 13

	Patient								
	353	354	355	356	357	358	359	360	361
	Fee.	Fee.	Fee.	Male	Fee.	Male	Fee.	Fee.	Fee.
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 of above 21HAND	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	YES	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	N/A	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 abnorma.	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 of 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
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES

PHARMACIA C0500085

REBOMETINE - PROTOCOL 20124/017

Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 14

	Patient									
	457	458	459	460	461	462	463	464	465	466
	Fem.	Fem.	Male	Male	Fem.	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
Affected by acute episodes of DSM-III-R.	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
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?										
Dythyria, Cyoethyria	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 of 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
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

PHARMACIA CN0380085
 RESOMETINE - PROTOCOL 2012A/017
 Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 14/1

	Patient				
	129	426	429	451	452
	Male	Female	Female	Male	Female
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 of 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 abnorms.	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 of 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
High risk of suicide	YES	YES	YES	YES	YES

PHARMACIA 2652085
 RESOMETIME - PROTOCOL 20124/017
 Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 14/2

	Patient	
	136	466
	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 of above 21RAND	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 abnorm.	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 of brain injury	YES	YES
Any other important clinical illness ...	YES	YES
ECT in the previous 6 months	YES	YES
High risk of suicide	YES	YES

PHARMACIA C05E0085
 RESOMETIN - PROTOCOL 2012A/017
 Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 14/3

	Patient						
	417	418	419	420	421	427	428
	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
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAND	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
High risk of suicide	YES	YES	YES	YES	YES	YES	YES

PHARMACIA C05E0085

REBOGETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 14/4

	Patient				
	131	132	133	134	135
	Fem.	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 21 of above 21HAMD	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?					
Dythyria, 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 abnorm.	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
High risk of suicide	YES	YES	YES	YES	YES

PHARMACIA 0955085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 14/7

	Patient												
	422	423	424	430	431	432	433	434	439	440	441	442	449
	Fem.	Fem.	Male	Fem.	Male	Male	Fem.	Male	Male	Fem.	Male	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
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA C960085

REBOMETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 14/7

	Pati- ent
	450
	Male
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 ?	
Dythyria, 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 glaucom	YES
Clinically significant physical abnorm.	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 of brain injury	YES
Any other important clinical illness ...	YES
ECT in the previous 6 months	YES
High risk of suicide	YES

PHARMACIA C0300085
 RESOMETINE - PROTOCOL 2012A/017
 Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 14/6

	Patient		
	130	425	467
	Male	Fem.	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 of above 2(HAND	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 abnorma.	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
High risk of suicide	YES	YES	YES

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA 965085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 14/10

	Patient												
	53	54	55	56	57	58	59	60	137	138	139	140	435
	Male	Fem.	Fem.	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 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	N/A	N/A	YES	YES	YES	N/A	N/A	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
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA 059085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 14/10

	Patient											
	436	437	438	443	444	445	446	447	448	453	454	455
	Fem.	Fem.	Fem.	Fem.	Male	Fem.	Fem.	Male	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	N/A	N/A	N/A
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	N/A	N/A	N/A
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
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

PHARMACIA C950085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 15

	Patient												
	349	351	352	364	366	367	368	369	370	371	372	373	374
	Male	Male	Male	Fem.	Male	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
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA C060085
 REDOXINE - PROTOCOL 20124/017
 Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 15

	Patient									
	375	376	377	378	379	380	381	382	383	384
	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Male	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?										
Aged between 18 and 65 years inclusive	YES	NO	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 of 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	N/A	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	N/A	YES	YES	N/A	NO	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	N/A	YES	YES	N/A	NO	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 abnorms.	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 of 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
High risk of suicide	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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	Male	Reboxetine	YES	DISTRANEURIN	05/02/91	Day 7	08/02/91	Day 7
					NOCTAMID	03/02/91	Screen	05/02/91	Screen
	2	Female	Reboxetine	YES	CHLORALDURAT	26/02/91	Day 7	28/02/91	Day 7
	3	Female	Imipramine	YES	MELLERIL	10/04/91	Screen	10/04/91	Screen
	4	Male	Imipramine	YES	NOCTAMID	15/04/91	Day 7	21/05/91	Day 35
					DYTIDE H	15/04/91(\$)	Screen	28/05/91(*)	Day 42
					XANEF	15/04/91(\$)	Screen	28/05/91(*)	Day 42
	6	Male	Imipramine	YES	CHLORALDURAT	29/07/91	Day 7	09/09/91	Day 35
					DIAZEPAM	16/08/91	Day 14	18/08/91	Day 14
					METOPROLOL	06/08/91(\$)	Day 7	17/09/91(*)	Day 42
	7	Male	Reboxetine	YES	CHLORALDURAT	08/10/91	Screen	20/11/91(*)	Day 42
					DIAZEPAM	14/10/91 17/10/91	Day 7 Day 14	14/10/91 19/10/91	Day 7 Day 14
	8	Male	Imipramine	NO	CHLORALDURAT	25/10/91	Screen	31/10/91(*)	Day 7
	9	Female	Imipramine	YES	ACETYLSALICYLIC ACID	10/89	Screen	19/12/91(*)	Day 42
	10	Female	Imipramine	YES	CHLORALDURAT	15/11/91	Screen	01/12/91	Day 14
					CHLORETHIAZOLE	10/12/91	Day 21	30/12/91(*)	Day 42

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 6.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
1	10	Female	Imipramine	YES	EUGLUCON	79	Screen	30/12/91(*)	Day 42
					OMEPRAZOLE	79	Screen	30/12/91(*)	Day 42
2	11	Male	Reboxetine	NO	DIAZEPAM	10/04/92	Day 7	12/04/92	Day 7
						19/04/92	Day 14	20/04/92	Day 14
						22/04/92	Day 21	22/04/92	Day 21
						24/04/92	Day 21	24/04/92	Day 21
3	12	Male	Reboxetine	NO	NOCTAMID	04/04/92	Screen	04/04/92	Screen
						14/04/92	Day 7	05/05/92(*)	Day 21
						18/12/90	Day 7	20/12/90	Day 7
						27/12/90	Screen	27/12/90	Screen
6	34	Male	Imipramine	NO	CHLORAL HYDRATE	27/12/90(§)	Screen	03/02/91	Day 42
						06/02/91	Day 42	06/02/91	Day 42
						27/12/90	Screen	09/01/91	Day 14
						27/12/90	Screen	09/01/91	Day 14
7	35	Male	Reboxetine	YES	CHLORAL HYDRATE	07/02/91	Day 42	07/02/91	Day 42
						07/02/91	Day 42	07/02/91	Day 42
						03/01/91	Day 7	03/01/91	Day 7
						09/01/91	Day 7	30/01/91	Day 21
8	37	Male	Reboxetine	YES	CHLORAL HYDRATE	17/01/91	Screen	07/02/91	Day 21
						22/01/91	Screen	28/01/91	Day 7

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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	38	Female	Imipramine	YES	DIHYDROERGOTAMINE MESILAT	28/01/91	Day 14	18/02/91	Day 21
					DISTRANEURIN	25/01/91	Day 7	07/03/91(*)	Day 7
					DISTRANEURINE	25/01/91	Day 14	07/03/91(*)	Day 42
					CYNODIAN-DEPOT	12/90	Screen	07/03/91(*)	Day 14
39	Female	Reboxetine	YES	CHLORAL HYDRATE	24/01/91	Screen	11/02/91	Day 21	Day 21
				CYCLO-MENORETTE	25/01/91	Screen	07/03/91(*)	Day 42	Day 42
				THYROKIN	25/01/91	Screen	07/03/91(*)	Day 42	Day 42
				CHLORAL HYDRATE	19/02/91	Screen	02/04/91(*)	Screen	Screen
40	Male	Imipramine	YES	CHLORALDRURAT	19/02/91	Day 7	05/03/91	Day 14	Day 14
				DISTRANEURIN	18/03/91 27/03/91	Day 28 Day 42	19/03/91 02/04/91	Day 28 Day 42	Day 28 Day 42
				ASPIRINE	08/02/91	Day 7	08/02/91	Day 7	Day 7
				CHLORAL HYDRATE	30/01/91	Screen	01/02/91	Screen	Screen
41	Male	Reboxetine	YES	CHLORALDRURAT	05/02/91	Day 7	11/02/91	Day 7	Day 7
				CHLORMETHIAZOLE	01/02/91 14/02/91 19/02/91	Screen Day 14 Day 21	11/02/91 15/02/91 08/03/91	Day 7 Day 14 Day 35	Day 7 Day 14 Day 35
				DIHYDROERGOTAMIN	11/02/91	Day 7	18/03/91	Day 42	Day 42

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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	41	Male	Reboxetine	YES	MAGALDRATE	08/09/91	Day 35	18/03/91	Day 42
	42	Male	Imipramine	YES	TYPROXIN	30/01/91	Screen	18/03/91	Day 42
	43	Female	Reboxetine	YES	CHLORAL HYDRATE	06/02/91	Screen	15/02/91	Day 7
	44	Male	Imipramine	NO	DISTRANEURIN	16/02/91	Day 14	22/03/91	Day 42
	45	Female	Imipramine	NO	CHLORAL HYDRATE	26/03/91	Day 7	15/04/91	Day 21
	46	Female	Reboxetine	YES	CHLORAL HYDRATE	08/04/91	Day 7	11/04/91	Day 7
	47	Female	Reboxetine	YES	DISTRANEURIN	08/04/91	Screen	11/04/91(*)	Screen
	48	Female	Imipramine	YES	IODINE	08/04/91	Screen	11/04/91(*)	Day 7
	49	Female	Reboxetine	YES	CHLORAL HYDRATE	26/04/91	Screen	29/04/91	Screen
	50	Male	Reboxetine	NO	CHLORAL HYDRATE	14/05/91	Screen	26/06/91	Day 42
					CHLORAL HYDRATE	17/05/91	Screen	21/05/91	Screen
					CHLORAL HYDRATE	27/05/91	Day 7	18/06/91	Day 28
					DISTRANEURIN	21/05/91	Day 7	02/07/91	Day 42
					CHLORAL HYDRATE	23/08/91	Screen	02/09/91	Day 7
					CHLORAL HYDRATE	27/08/91	Screen	08/09/91	Day 14
					CHLORAL HYDRATE	20/09/91	Day 28	20/09/91	Day 28
					CHLORAL HYDRATE	26/09/91	Day 35	02/10/91	Day 35
					CHLORAL HYDRATE	31/10/91	Screen	05/11/91	Screen

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
Listing No.: 6.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
2	50	Male	Reboxetine	NO	CHLORAL HYDRATE	20/11/91	Day 21	15/12/91	Day 42
					DISTRANEURIN	05/11/91	Day 7	19/11/91	Day 14
3	51	Female	Reboxetine	NO	CHLORAL HYDRATE	30/10/91	Screen	04/11/91	Screen
					DISTRANEURIN	06/11/91	Day 7	18/11/91	Day 14
					THYROXIN	80	Screen	17/11/91(*)	Day 14
					CHLORAL HYDRATE	27/11/91	Day 7	24/12/91	Day 28
66	65	Male	Reboxetine	YES	CHLORALDURAT	28/03/91	Screen	28/03/91	Screen
					DIGITOXIN	02/04/91	Day 7	13/05/91(*)	Day 42
					VERAPAMIL HYDROCHLORIDE	26/04/91	Day 28	13/05/91(*)	Day 42
					CHLORALDURAT	27/04/91	Screen	15/05/91	Day 21
67	66	Female	Imipramine	NO	DISTRANEURIN	02/06/91	Day 35	02/06/91	Day 35
					TAYDOR	05/06/91	Day 42	05/06/91	Day 42
					ADALAT	03/06/91	Day 35	03/06/91	Day 35
					CHLORAL HYDRATE	17/04/91	Day 14	17/04/91	Day 14
67	67	Female	Reboxetine	YES	CHLORAL HYDRATE	01/05/91	Day 28	21/05/91	Day 42
					CHLORALDURAT	04/04/91	Screen	30/04/91	Day 21
					CUNCOR	24/04/91	Day 21	21/05/91	Day 42

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/017
 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	68	Female	Imipramine	YES	CHLORALDURAT	02/08/91 17/08/91	Screen Day 21	14/08/91 13/09/91	Day 14 Day 42
					DISTRANEURIN	01/08/91 17/08/91 04/09/91	Screen Day 21 Day 35	14/08/91 02/09/91 13/09/91	Day 14 Day 35 Day 42
					EUGALAC	17/08/91 07/09/91	Day 21 Day 42	30/08/91 13/09/91	Day 28 Day 42
					CHLORALDURAT	01/03/91	Day 7	05/03/91	Day 7
					DISTRANEURIN	03/03/91	Day 7	24/03/91	Day 28
					CHLORALDURAT	21/10/91	Screen	12/11/91	Day 21
					DISTRANEURIN	23/10/91 30/10/91	Day 7 Day 14	27/10/91 19/11/91(*)	Day 7 Day 28
					TAVOR	27/10/91	Day 7	27/10/91	Day 7
					TRENTAL	05/11/91	Day 28	19/11/91(*)	Day 28
					71	Female	Imipramine	YES	DISTRANEURINE
72	Female	Reboxetine	YES	CHLORALDURAT	28/01/92	Screen	12/03/92(*)	Day 42	
73	Female	Reboxetine	YES	HEMINEURIN	13/02/92	Day 14	13/02/92	Day 14	
				CHLORAL HYDRATE	18/02/92 25/02/92 16/03/92	Day 7 Day 14 Day 35	18/02/92 25/02/92 16/03/92	Day 7 Day 14 Day 35	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First visit report	End date	Last report visit
3	73	Female	Reboxetine	YES	CHLORAL HYDRATE	19/03/92 22/03/92	Day 35 Day 42	19/03/92 22/03/92	Day 35 Day 42
		Male	Imipramine	YES	CHLORALDURAT	12/05/92 17/05/92 24/05/92 28/05/92 31/05/92 12/06/92	Day 7 Day 14 Day 21 Day 28 Day 28 Day 42	14/05/92 19/05/92 26/05/92 28/05/92 31/05/92 14/06/92	Day 14 Day 14 Day 21 Day 28 Day 28 Day 42
6	100	Female	Reboxetine	YES	NITRAZEPAN	24/04/92	Screen	01/05/92	Screen
		Female	Imipramine	NO	CHLORALDURAT	05/05/92	Screen	24/06/92(*)	Day 42
6	161	Male	Reboxetine	YES	CHLORAL HYDRATE	26/03/91	Screen	26/03/91	Screen
		Female	Imipramine	NO	CHLORAL HYDRATE	07/05/91	Day 7	23/05/91	Day 14
7	193	Female	Reboxetine	YES	NITRAZEPAN	15/04/91	Screen	05/05/91	Screen
		Female	Imipramine	NO	CHLORALDURAT	29/03/91 12/04/91	Day 7 Day 21	29/03/91 12/04/91	Day 7 Day 21
7	196	Female	Reboxetine	YES	CHLORAL HYDRATE	31/10/91 02/12/91	Screen Day 28	29/11/91 02/12/91	Day 28 Day 28
		Female	Imipramine	NO	TRANKENE	11/06/91	Screen	17/06/91(*)	Day 7
8	226	Female	Reboxetine	YES	CHLORAL HYDRATE	15/03/91	Screen	18/03/91	Screen
		Female	Imipramine	NO	LORAZEPAM	16/04/91	Day 35	16/04/91	Day 35
8	226	Female	Reboxetine	YES	RINOHAR	05/04/91	Day 21	08/04/91	Day 21
		Female	Reboxetine	YES	CHLORAL HYDRATE	26/04/91	Screen	13/06/91(*)	Day 42

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	227	Male	Imipramine	YES	CHLORAL HYDRATE	28/04/91	Screen	07/05/91	Screen
	228	Male	Reboxetine	NO	CHLORAL HYDRATE	06/05/91	Screen	17/05/91	Day 7
	229	Female	Imipramine	YES	CLANOXYL	15/10/91	Screen	24/10/91	Day 7
					LORMETAZEPAM	18/10/91(\$)	Screen	19/10/91	Screen
	230	Female	Imipramine	YES	CHLORAL HYDRATE	30/10/91	Screen	21/11/91	Day 21
	231	Female	Reboxetine	NO	BROMAZEPAM	07/91	Screen	13/11/91(*)	Day 14
					FLUPENTIXOL	07/91	Screen	13/11/91(*)	Day 14
					MELITRACEN	07/91	Screen	13/11/91(*)	Day 14
	232	Male	Reboxetine	YES	CHLORAL HYDRATE	26/11/91	Screen	09/01/92(*)	Day 42
					SURBRONC	26/11/91	Screen	30/11/91	Day 7
9	198	Female	Imipramine	YES	MARVELON	89	Screen	28/04/92(*)	Screen
	202	Male	Imipramine	YES	AMOXICILLIN	12/02/92	Day 28	26/02/92	Day 28
					BECOTIDE	23/12/88	Screen	27/02/92(*)	Screen
					THEOPHYLLINE	23/12/88	Screen	27/02/92(*)	Screen
	206	Female	Imipramine	YES	CLOTIAZEPAM	16/02/92	Day 14	16/02/92	Day 14
	207	Female	Reboxetine	NO	FELDENE	12/91	Screen	12/02/92(*)	Screen

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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	208	Male	Reboxetine	YES	BISOMATIN	02/03/92	Day 21	05/03/92	Day 21
	212	Female	Imipramine	YES	MERCILON	89	Screen	14/04/92(*)	Screen
	237	Male	Reboxetine	NO	BUSCOPAN	24/04/92	Day 7	24/04/92	Day 7
	241	Female	Imipramine	YES	MAGNESIUM HYDROXIDE	92	Screen	02/05/92(*)	Screen
	243	Female	Imipramine	YES	PREPULSID	15/05/92	Day 7	19/06/92(*)	Day 42
	257	Female	Reboxetine	YES	INDERAL	25/05/92	Day 7	25/05/92	Day 7
	263	Female	Reboxetine	NO	DIANE	90	Screen	27/08/91(*)	Screen
	266	Female	Reboxetine	YES	MARVELON	90	Screen	13/08/91(*)	Screen
	268	Female	Reboxetine	YES	BECONASE	05/08/91	Screen	01/10/91	Day 14
	271	Female	Reboxetine	NO	BROMAZEPAN	16/08/91	Screen	06/10/91	Day 21
					ACETYLSALICYLIC ACID	26/09/91	Day 7	27/09/91	Day 7
					ADALAT	13/11/91	Day 21	15/11/91	Day 21
					BRUFEN	19/11/91	Day 21	21/11/91	Day 28
						07/11/91	Day 14	10/11/91	Day 14
						13/11/91	Day 21	21/11/91	Day 28
					EPHEDRINE SULFATE	05/11/91	Day 7	15/11/91	Day 21
					LORATADINE	05/11/91	Day 7	15/11/91	Day 21

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	272	Male	Imipramine	YES	LAXOBERON	13/11/91	Day 21	10/12/91	Day 42
	273	Female	Imipramine	NO	SULFARLEN-CHOLINE	01/11/91	Day 7	21/11/91	Day 28
	275	Female	Reboxetine	YES	ASPEGIC	07/11/91 13/11/91	Day 7 Day 14	08/11/91 15/11/91	Day 7 Day 14
					DAFALGAN	18/11/91	Day 14	20/11/91	Day 21
					SIBELIUM	10/90	Screen	17/12/91(*)	Screen
	276	Female	Imipramine	NO	DIMENFORMON	90	Screen	14/01/92(*)	Screen
9/A	233	Male	Imipramine	YES	CHLORAL HYDRATE	14/05/92	Day 7	24/06/92	Day 42
	235	Male	Reboxetine	NO	ALLOPURINOL	01/01/89	Screen	29/06/92(*)	Day 35
					CHLORAL HYDRATE	26/05/92	Day 7	29/06/92(*)	Day 35
					GLIPIZIDE	01/01/89	Screen	29/06/92(*)	Day 35
	281	Female	Reboxetine	YES	CHLORAL HYDRATE	25/08/92	Screen	14/09/92	Day 14
	282	Male	Reboxetine	YES	CHLORAL HYDRATE	14/08/92	Screen	13/10/92	Day 42
					ENALAPRIL	87	Screen	13/10/92(*)	Day 42
	302	Male	Imipramine	NO	CHLORAL HYDRATE	15/03/92	Day 14	23/03/92	Day 21
	304	Female	Reboxetine	YES	MARVELON	01/01/88	Screen	06/05/92(*)	Day 42

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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/A	308	Female	Imipramine	NO	CHLORAL HYDRATE	09/05/92	Day 7	02/06/92	Day 28
					DICLOFENAC	01/01/92	Screen	09/05/92	Screen
10	289	Female	Imipramine	NO	CHLORAL HYDRATE	20/09/91	Screen	27/09/91(*)	Day 7
	291	Male	Imipramine	YES	CHLORAL HYDRATE	12/02/92	Screen	29/03/92	Day 42
					EFFORTIL	03/03/92	Day 14	29/03/92(*)	Day 42
					TREMBLEX	06/03/92	Day 21	29/03/92(*)	Day 42
295		Female	Reboxetine	YES	BUFLOMEDIL HYDROCHLORIDE	07/11/91	Screen	15/11/91	Screen
					CHLORAL HYDRATE	21/12/91	Screen	01/02/92(*)	Day 42
					URFADYN	10/01/92	Day 21	17/01/92	Day 28
294		Female	Imipramine	NO	CHLORAL HYDRATE	09/01/92	Day 14	23/01/92(*)	Day 21
					DONPERIDONE	27/12/91	Screen	23/01/92(*)	Day 21
					LACTULOSE	09/01/92	Day 14	23/01/92(*)	Day 21
					SELECTOL	20/11/91	Screen	12/91	Day 7
295		Male	Imipramine	YES	PARACETAMOL	02/01/92	Screen	04/01/92	Screen
296		Female	Reboxetine	YES	ASCORBIN	24/02/92	Day 7	01/04/92(*)	Day 42
					CHLORAL HYDRATE	14/02/92	Screen	01/04/92(*)	Day 42

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 6.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	*First report visit	End date	Last report visit
10	296	Female	Reboxetine	YES	DUPHALAC	24/02/92	Day 7	01/04/92(*)	Day 42
					FERRUM-HAUSMANN	14/02/92	Day 7	01/04/92(*)	Day 42
					SUPRADYN	23/02/92	Day 7	06/03/92	Day 14
					TAGANET	14/02/92	Day 7	01/04/92(*)	Day 42
					VENORUTON	91	Screen	01/04/92(*)	Day 42
	298	Female	Reboxetine	YES	CHLORAL HYDRATE	19/03/92	Screen	07/05/92(*)	Day 42
					PARACETANOL	20/04/92	Day 28	28/04/92	Day 42
	299	Male	Imipramine	YES	CHLORAL HYDRATE	07/04/92	Day 7	18/05/92(*)	Day 42
	300	Female	Imipramine	YES	CORDIUM	07/04/92(\$)	Screen	25/05/92(*)	Day 42
					DICEYEL	07/04/92(\$)	Screen	25/05/92(*)	Day 42
					HYDERGINE	07/04/92(\$)	Screen	25/05/92(*)	Day 42
					MERCILON	07/04/92(\$)	Screen	25/05/92(*)	Day 42
11	321	Female	Reboxetine	YES	AMOXICILLIN	23/06/92	Day 14	27/06/92	Day 21
					CARBOCISTEINE	23/06/92	Day 14	27/06/92	Day 21
					LOPERAMIDE	29/06/92	Day 21	30/06/92	Day 21
	322	Female	Reboxetine	YES	PARACETANOL	15/07/92	Day 35	15/07/92	Day 35

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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	323	Female	Imipramine	YES	COLD CAPSULES	06/07/92	Day 14	07/07/92	Day 14
	324	Male	Imipramine	YES	BRONHEXINE	11/07/92	Screen	17/07/92	Screen
	326	Male	Imipramine	YES	OXITETRACYCLIN	11/07/92	Screen	17/07/92	Screen
	327	Female	Reboxetine	YES	VENTOLINE INHALATOR	04/08/92	Day 21	04/08/92	Day 21
	329	Female	Imipramine	YES	DISPRIN	15/08/92	Day 21	16/08/92	Day 21
	330	Female	Reboxetine	NO	ERYTHROMYCIN	15/08/92	Day 21	16/08/92	Day 21
	331	Male	Reboxetine	YES	ASPIRINE	28/08/92	Day 14	01/09/92	Day 14
	337	Female	Imipramine	YES	DISPRIN	18/09/92	Day 35	20/09/92	Day 35
					HYDROXYPROGESTERONE	26/09/92	Day 42	27/09/92	Day 42
					PARACETANOL	90	Screen	02/10/92(*)	Screen
					NORDETYE	23/09/92	Day 35	23/09/92	Day 35
					CAFEGOT	01/08/92	Screen	25/08/92(*)	Screen
					CODIS	22/09/92	Day 21	23/09/92	Day 21
					CHLORAL HYDRATE	30/09/92	Day 28	01/10/92	Day 28
						25/05/92	Screen	31/05/92	Day 7
						02/06/92	Day 14	07/06/92	Day 14
						09/06/92	Day 21	10/06/92	Day 21
						12/06/92	Day 21	17/06/92	Day 28
						19/06/92	Day 28	22/06/92	Day 28
						24/06/92	Day 35	05/07/92	Day 35

(*) - start date missing = screening date
(*) - end date missing = last dose taken date

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	337	Female	Imipramine	YES	LORAZEPAM	11/06/92	Day 21	11/06/92	Day 21
					METOCLOPRAMIDE HYDROCHLOR	23/06/92	Day 35	23/06/92	Day 35
					PARACETANOL	26/05/92	Day 7	26/05/92	Day 7
						01/07/92	Day 42	02/07/92	Day 42
						04/07/92	Day 42	05/07/92	Day 42
338	Female	Reboxetine	YES	ACTIFED	07/07/92	Day 21	12/07/92	12/07/92	Day 21
					CEPACOL	25/07/92	Day 42	26/07/92	Day 42
					CHLORAL HYDRATE	20/06/92	Day 7	30/07/92	Day 42
					DUPHALAC	25/07/92	Day 42	25/07/92	Day 42
					FLAVOXATE HYDROCHLORIDE	06/91	Screen	31/07/92(*)	Day 7
					PARACETANOL	30/06/92	Day 14	30/06/92	Day 14
						04/07/92	Day 21	05/07/92	Day 21
						20/07/92	Day 35	20/07/92	Day 35
						24/07/92	Day 35	26/07/92	Day 35
					SENNA	10/07/92	Day 21	10/07/92	Day 21
						13/07/92	Day 28	13/07/92	Day 28
339	Male	Imipramine	YES	PARACETANOL	04/07/92	Day 14	Day 42	05/07/92	Day 14
						28/07/92	Day 42	28/07/92	Day 42
					SENNA	29/06/92	Day 7	29/06/92	Day 7
						12/07/92	Day 21	13/07/92	Day 21
						17/07/92	Day 28	17/07/92	Day 28
340	Female	Reboxetine	YES	BACTRIM	24/08/92	Day 21	31/08/92	31/08/92	Day 21

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(*) - start date missing = screening date
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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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	340	Female	Reboxetine	YES	CHLORAL HYDRATE	11/08/92	Day 7	11/08/92	Day 7
						16/08/92	Day 14	16/08/92	Day 14
						18/08/92	Day 14	19/08/92	Day 14
					GLYCERIN	12/08/92	Day 7	12/08/92	Day 7
					PARACETANOL	05/08/92	Screen	06/08/92	Screen
					VITAMIN C	05/08/92	Screen	05/08/92	Screen
	341	Female	Reboxetine	NO	CHLORAL HYDRATE	17/08/92	Screen	24/09/92	Day 35
					PARACETANOL	16/09/92	Day 28	16/09/92	Day 28
					BACTRIM	22/06/92	Day 14	26/06/92	Day 21
					MEFENAMIC ACID	13/06/92	Day 7	15/06/92	Day 7
					DICLOFENAC SODIUM	23/07/92	Day 35	25/07/92	Day 35
					PARACETANOL	23/07/92	Day 35	25/07/92	Day 35
35	Female	Reboxetine	NO	CODEINE PHOSPHATE	28/06/92	Day 7	29/06/92	Day 7	
				PARACETANOL	28/06/92	Day 7	29/06/92	Day 7	
				PARACETANOL	29/07/92	Day 14	01/09/92(*)	Day 14	
				ASPIRINE	05/10/92	Day 42	06/10/92	Day 42	
				C-VITAMIN	20/09/92	Day 28	21/09/92	Day 28	
				CALCIUM CARBONATE	20/09/92	Day 28	21/09/92	Day 28	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 8.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complets as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
13	361	Female	Reboxetine	YES	CITRIC ACID	20/09/92	Day 28	21/09/92	Day 28
14	460	Male	Imipramine	YES	PANKREATAN COMP.	90	Screen	06/08/92	Day 14
	464	Female	Reboxetine	YES	NOVADRAL RETARD	86	Screen	27/07/92	Screen
	465	Male	Reboxetine	YES	PANKREATAN COMP.	59	Screen	30/07/92	Screen
14/1	129	Male	Reboxetine	NO	CHLORALDURAT	11/12/91	Screen	19/12/91(*)	Screen
	426	Female	Reboxetine	YES	BACTOREDUCT	05/09/91	Day 7	10/09/91	Day 7
	429	Female	Imipramine	NO	DISTRANEURIN	25/09/91	Day 21	01/10/91	Day 28
	451	Male	Imipramine	YES	SALBUTANOL SULFATE	87	Screen	29/09/91(*)	Day 7
					TERBUTALINE	87	Screen	29/09/91(*)	Screen
					ASASANTIN	89	Screen	07/01/92(*)	Day 42
	452	Female	Reboxetine	YES	VALORON	02/01/92	Day 42	07/01/92(*)	Day 42
					XANEF	90	Screen	07/01/92(*)	Day 42
					AZUDOXAT	03/01/92	Day 42	09/01/92	Day 42
					CHLORAL HYDRATE	21/11/91	Screen	26/11/91	Screen
					ISOPTIN	23/12/91	Day 28	09/01/92(*)	Day 42
					NEVINACOR	23/12/91	Day 28	09/01/92(*)	Day 42

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
14/1	452	Female	Reboxetine	YES	PARACETAMOL	05/01/92	Day 42	09/01/92	Day 42
14/2	456	Male	Imipramine	YES	ISOPTIN	91	Screen	26/05/92(*)	Day 42
14/3	421	Female	Reboxetine	NO	GASTROSIL	27/07/91	Day 14	28/07/91	Day 14
14/4	131	Female	Imipramine	YES	SODIUM FLUORIDE	08/90	Screen	13/01/92	Screen
	132	Female	Imipramine	YES	OVIOL	06/86	Screen	24/02/92	Day 42
	133	Female	Imipramine	YES	HARVELON	84	Screen	12/06/92	Day 28
	134	Female	Reboxetine	YES	OVIOL	10/86	Screen	26/02/92	Day 42
14/7	422	Female	Imipramine	YES	BERBERINE HYDROCHLORIDE	20/05/88	Screen	15/10/91(*)	Day 42
					CALCIUM	24/08/89	Screen	15/10/91(*)	Day 42
					COLCHICINE	20/05/88	Screen	15/10/91(*)	Day 42
					HARZOL	01/08/88	Screen	30/10/91(*)	Day 42
					SERENOA REPENS	03/10/91	Day 14	30/10/91(*)	Day 42
					DURAVOLTEN - SLOW RELEASE	20/08/91	Screen	17/11/91(*)	Day 42
					SINUPRET	06/11/91	Day 35	10/11/91	Day 35
					SERENOA REPENS	13/03/91	Screen	18/11/91(*)	Day 42
					SERENOA REPENS	06/11/91	Day 35	18/11/91(*)	Day 42

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
14/7	434	Male	Reboxetine	YES	SERENOA REPENS	05/11/91	Day 28	24/11/91(*)	Day 42
439		Male	Reboxetine	YES	MAGNESIUM VERLA DRAGEES	13/08/87	Screen	22/12/91(*)	Day 42
14/10	53	Male	Reboxetine	YES	PROSTATIN	88	Screen	06/04/92(*)	Day 42
54		Female	Imipramine	YES	BAYOTENSIN	12/01/88	Screen	07/04/92(*)	Day 42
55		Female	Reboxetine	YES	CARNIGEN	14/07/88	Screen	09/04/92(*)	Day 42
					METEOZYH	17/01/92	Screen	09/04/92(*)	Day 42
					PIROXICAM	27/03/92	Day 35	31/03/92	Day 35
56		Female	Imipramine	YES	DICLOFENAC	18/03/92	Day 21	22/03/92	Day 21
					LOPERAMIDE	01/04/92	Day 35	06/04/92	Day 35
					REGULTON	18/04/84	Screen	13/04/92(*)	Day 42
57		Female	Reboxetine	YES	BRISERIN	07/11/86	Screen	25/02/92	Screen
					LOPERAMIDE HYDROCHLORIDE	02/04/92	Day 35	06/04/92	Day 35
60		Female	Reboxetine	YES	DIURSAN	04/88	Screen	14/04/92(*)	Day 42
137		Female	Reboxetine	YES	DIHYDROERGOTANIN	22/07/91	Screen	09/03/92(*)	Day 42
138		Female	Imipramine	YES	AARANE	10/90	Screen	10/03/92(*)	Day 42

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
14/10	139	Female	Reboxetine	YES	ACETYLCYSTEINE	03/03/92	Day 35	09/03/92	Day 35
					CODIPRONT	03/03/92	Day 35	09/03/92	Day 35
	435	Female	Imipramine	YES	NORFENEFINE	20/07/89	Screen	16/03/92(*)	Day 42
	436	Female	Reboxetine	YES	RAYOTENSIN	04/90	Screen	23/12/91(*)	Day 42
					CODIPRONT	23/12/91	Day 42	27/12/91	Day 42
					DOXYHEXAL TABS	22/12/91	Day 42	27/12/91	Day 42
	438	Female	Imipramine	YES	ACETYLCYSTEINE	22/11/91	Day 14	27/11/91	Day 14
					CODEINE PHOSPHATE	13/12/91	Day 35	19/12/91	Day 35
					CODIPRONT	22/11/91	Day 14	27/11/91	Day 14
					DIRYDERGOT PLUS	13/12/91	Day 35	19/12/91	Day 35
	443	Female	Reboxetine	YES	DICLOFENAC	05/87	Screen	27/12/91(*)	Day 42
	444	Male	Reboxetine	YES	ACETYLCYSTEINE	05/87	Screen	30/12/91(*)	Day 42
					CODEINE	06/12/91	Day 21	13/12/91	Day 28
					PRAZOSIN	06/12/91	Day 21	13/12/91	Day 28
					THYROXIN	03/91	Screen	27/12/91(*)	Day 42
						02/88	Screen	27/12/91(*)	Day 42

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 6.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
14/10	445	Female	Imipramine	YES	BETAHISTINE MESILATE	15/08/89	Screen	30/12/91(*)	Day 42
					BEZAFIBRATE	31/01/89	Screen	30/12/91(*)	Day 42
	446	Female	Reboxetine	YES	RANIPRIL	30/10/91	Screen	30/12/91(*)	Day 42
					CODIPRONT	11/12/91	Day 21	16/12/91	Day 21
					PRAVASTATIN	29/01/91	Screen	07/01/92(*)	Day 42
	447	Male	Reboxetine	YES	RULID	11/12/91	Day 21	16/12/91	Day 21
					ALLOPURINOL	07/11/88	Screen	07/01/92(*)	Day 42
					CIPROBAY	31/12/91	Day 42	06/01/92	Day 42
					DEPOT-H-INSULIN 'HOECHST'	08/03/91	Screen	07/01/92(*)	Day 42
					DIGYB	26/09/89	Screen	07/01/92(*)	Day 42
	448	Female	Imipramine	YES	GINKGO TREE LEAVES EXTRAC	25/10/91	Screen	07/01/92(*)	Day 42
					OXACEPROL	07/91	Screen	07/01/92(*)	Day 42
					PIROXICAM	23/12/91	Day 35	29/12/91	Day 35
	455	Female	Reboxetine	YES	VENALOT - SLOW RELEASE	04/86	Screen	31/07/92(*)	Day 42
15	349	Male	Imipramine	YES	SENNA	03/09/92	Day 14	01/10/92(*)	Day 14
	351	Male	Reboxetine	YES	AMLORETIK	02/09/92	Day 7	14/10/92(*)	Day 42

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 6.0
CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
	351	Male	Reboxetine	YES	ATENOLOL	02/09/92	Day 7	14/10/92(*)	Day 42
	352	Male	Imipramine	NO	AZIDOTHYIMIDINE	12/08/92	Day 7	27/08/92(*)	Day 21
					IBUPROFEN	12/08/92	Day 7	27/08/92(*)	Day 21
					PARACETANOL	12/08/92	Day 7	27/08/92(*)	Day 21
					VALOID	12/08/92	Day 7	27/08/92(*)	Day 21
	364	Female	Imipramine	NO	DIAZEPAM	24/08/92	Day 28	26/08/92(*)	Day 28
					PREMARIN	25/08/92	Day 28	26/08/92(*)	Day 28
	366	Male	Reboxetine	YES	CHLORAL HYDRATE	23/08/92	Screen	08/10/92(*)	Screen
	367	Male	Imipramine	YES	CAPTOPRIL	05/10/92	Day 42	11/10/92(*)	Day 42
					CHLORAL HYDRATE	27/08/92	Screen	30/08/92	Screen
	371	Female	Reboxetine	YES	CHLORAL HYDRATE	17/07/92	Screen	19/08/92	Day 35
	372	Male	Imipramine	YES	CHLORAL HYDRATE	12/06/92	Screen	29/07/92(*)	Day 42
	374	Female	Reboxetine	YES	CHLORAL HYDRATE	14/04/92	Day 7	20/05/92(*)	Day 42
	376	Female	Imipramine	NO	TRICLOXYL	14/04/92	Day 7	21/04/92(*)	Day 7
	377	Female	Reboxetine	YES	CHLORAL HYDRATE	12/05/92	Screen	25/06/92(*)	Screen
					GLYCERIN	15/05/92	Day 7	25/06/92(*)	Day 42

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 REDUCTINE - PROTOCOL 20124/017
 Listing No.: B.0
 CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complies as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
15	377	Female	Riboxetine	YES	SENA	19/05/92	Screen	25/06/92(*)	Day 42
	380	Female	Isiprandin	YES	CHELORAL HYDRATE	29/06/92	Screen	10/08/92(*)	Day 42
	381	Female	Riboxetine	YES	PREDNISON	31/07/92	Day 35	10/08/92(*)	Day 42
	382	Male	Isiprandin	NO	CHELORAL HYDRATE	09/06/92	Day 21	01/07/92	Day 42
	383	Female	Isiprandin	YES	PARACETAMOL	10/04/92	Day 7	10/04/92(*)	Day 7
	385	Female	Isiprandin	YES	CHELORAL HYDRATE	07/07/92	Day 7	18/08/92	Day 42

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

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)
1	1	Reboxetine	05/02/91	04/03/91	28	8	8	100.0	100.0		4	4	
			05/03/91	11/03/91	7	8	18	100.0	100.0		8	10	(3 - m) (3 - e)
			12/03/91	18/03/91	7	8	8	100.0	100.0		4	4	
					42								
2	2	Reboxetine	26/02/91	03/04/91	37	8	8	100.0	100.0		4	4	
			04/04/91	08/04/91	5	8	4	50.0	94.0	4m	4	4	
					42								
3	3	Imipramine	16/04/91	18/04/91	3	100	100	100.0	100.0		50	50	
			19/04/91	27/05/91	39	150	150	100.0	100.0		50	100	
								42					
4	4	Imipramine	17/04/91	19/04/91	3	100	100	100.0	100.0		50	50	
			20/04/91	07/05/91	18	150	150	100.0	100.0		50	100	
			08/05/91	14/05/91	7	150	350	100.0	100.0		150	200	(3 - m) (3 - e)
			15/05/91	28/05/91	14	150	150	100.0	100.0		50	100	
					42								
5	5	Reboxetine	17/07/91	13/08/91	28	8	8	100.0	100.0		4	4	
			14/08/91	27/08/91	14	10	10	100.0	100.0		4	6	
					42								
6	6	Imipramine	07/08/91	09/08/91	3	100	100	100.0	100.0		50	50	
			10/08/91	17/09/91	39	150	150	100.0	100.0		50	100	
					42								
7	7	Reboxetine	09/10/91	29/10/91	21	8	8	100.0	100.0		4	4	
			30/10/91	12/11/91	14	10	10	100.0	100.0		4	4	
			13/11/91	20/11/91	8	8	8	100.0	100.0		4	4	
					43								
8	8	Imipramine	29/10/91	31/10/91	3	100	100	100.0	100.0		50	50	
								3					

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(*) 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

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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 compl. day	% Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
1	9	Imipramine	08/11/91	10/11/91	3	100	100.0	100.0		50	50	
			11/11/91	19/12/91	39	150	100.0	100.0		50	100	
					42							
10	10	Imipramine	19/11/91	21/11/91	3	100	100.0	100.0		50	50	
			22/11/91	30/12/91	39	150	100.0	100.0		50	100	
					42							
11	11	Reboxetine	06/04/92	03/05/92	28	8	100.0	100.0		4	4	
					28							
12	12	Reboxetine	15/04/92	04/05/92	20	8	100.0	100.0		4	4	
			05/05/92	05/05/92	1	8	4	100.0	100.0	6e	4	4
					21							
2	33	Reboxetine	19/12/90	29/01/91	42	8	100.0	100.0		4	4	
					42							
					42							
34	34	Imipramine	28/12/90	30/12/90	3	100	100.0	100.0		50	50	
			31/12/90	02/02/91	34	150	100.0	100.0		50	100	
			03/02/91	03/02/91	1	150	50	100.0	100.0	6e	50	50
					38							
35	35	Reboxetine	28/12/90	07/02/91	42	8	100.0	100.0		4	4	
					42							
					42							
36	36	Imipramine	10/01/91	12/01/91	3	100	100.0	100.0		50	50	
			13/01/91	30/01/91	18	150	100.0	100.0		50	100	
			31/01/91	31/01/91	1	150	50	100.0	100.0	6e	50	50
					22							
37	37	Reboxetine	18/01/91	28/02/91	42	8	100.0	100.0		4	4	
					42							
					42							

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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, 6e=low daily dose in one administration
 m = morning, e = evening

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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 (**)
2	38	Imipramine	25/01/91	27/01/91	3	100	100	100.0	100.0		50	50	
			28/01/91	14/02/91	18	150	150	100.0	100.0		50	100	
			15/02/91	07/03/91	21	200	200	100.0	100.0		100	100	
				42									
39	Reboxetine	25/01/91	07/03/91	42	8	8	100.0	100.0			4	4	
				42									
40	Imipramine	20/02/91	22/02/91	3	100	100	100.0	100.0			50	50	
		23/02/91	02/04/91	39	150	150	100.0	100.0			50	100	
				42									
41	Reboxetine	05/02/91	18/03/91	42	8	8	100.0	100.0			4	4	
				42									
42	Imipramine	09/02/91	11/02/91	3	100	100	100.0	100.0			50	50	
		12/02/91	08/03/91	25	150	150	100.0	100.0			50	100	
		09/03/91	22/03/91	14	200	200	100.0	100.0			100	100	
				42									
43	Reboxetine	26/03/91	06/05/91	42	8	8	100.0	100.0			4	4	
				42									
44	Imipramine	11/04/91	11/04/91	1	100	50	100.0	100.0		3e	50		
				1									
45	Imipramine	30/04/91	02/05/91	3	100	100	100.0	100.0			50	50	
		03/05/91	03/05/91	1	150	150	100.0	100.0			50	100	
				4									
46	Reboxetine	16/05/91	26/06/91	42	8	8	100.0	100.0			4	4	
				42									
47	Reboxetine	22/05/91	02/07/91	42	8	8	100.0	100.0			4	4	
				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, 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 R6D

REBOXETINE - PROTOCOL 20124/017
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 (x)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
2	48	Imipramine	27/08/91	29/08/91	3	100	100	100.0	100.0		50	50	
			30/08/91	07/10/91	39	150	150	100.0	100.0		50	100	
					42								
49	Imipramine		29/08/91	31/08/91	3	100	100	100.0	100.0		50	50	
			01/09/91	09/10/91	39	150	150	100.0	100.0		50	100	
					42								
50	Reboxetine		06/11/91	14/12/91	39	8	8	100.0	100.0	6e	4	4	
			15/12/91	15/12/91	1	8	4	100.0	100.0		4	4	
					40								
51	Reboxetine		06/11/91	17/11/91	12	8	8	100.0	100.0		4	4	
					12								
52	Imipramine		27/11/91	29/11/91	3	100	100	100.0	100.0		50	50	
			30/11/91	07/01/92	39	150	150	100.0	100.0		50	100	
					42								
3	65	Reboxetine	02/04/91	13/05/91	42	8	8	100.0	100.0		4	4	
					42								
66	Imipramine		01/05/91	03/05/91	3	100	100	100.0	100.0		50	50	
			04/05/91	03/06/91	31	150	150	100.0	100.0		50	100	
			04/06/91	04/06/91	1	150	250	100.0	100.0		50	200	
			05/06/91	05/06/91	1	200	100	100.0	100.0	6e	100	100	(B - e)
					36								
67	Reboxetine		10/04/91	30/04/91	21	8	8	100.0	100.0		4	4	
			01/05/91	21/05/91	21	10	10	100.0	100.0		4	6	
					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
(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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PHARMACIA CNS R2D

REBOXETINE - PROTOCOL 20124/017
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	68	Imipramine	03/08/91	05/08/91	3	100	100	100.0	100.0		50	50	
			06/08/91	23/08/91	18	150	150	100.0	100.0		50	100	
			24/08/91	13/09/91	21	200	200	100.0	100.0		100	100	
					42								
69	69	Imipramine	01/03/91	03/03/91	3	100	100	100.0	100.0		50	50	
			04/03/91	11/04/91	39	150	150	100.0	100.0		50	100	
					42								
70	70	Reboxetine	23/10/91	12/11/91	21	8	8	100.0	100.0		4	4	
			13/11/91	19/11/91	7	10	10	100.0	100.0		4	6	
					28								
71	71	Imipramine	16/11/91	16/11/91	3	100	100	100.0	100.0		50	50	
			17/11/91	25/12/91	39	150	150	100.0	100.0		50	100	
					42								
72	72	Reboxetine	31/01/92	12/03/92	42	8	8	100.0	100.0		4	4	
								42					
73	73	Reboxetine	15/02/92	27/03/92	42	8	8	100.0	100.0		4	4	
								42					
97	97	Imipramine	07/05/92	09/05/92	3	100	100	100.0	100.0		50	50	
			10/05/92	18/06/92	40	150	150	100.0	100.0		50	100	
					43								
100	100	Reboxetine	07/05/92	17/06/92	42	8	8	100.0	100.0		4	4	
								42					
101	101	Imipramine	06/05/91	08/05/91	3	100	100	100.0	100.0		50	50	
			09/05/91	22/05/91	14	150	150	100.0	100.0		50	100	
					17								

(*) 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

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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)	Z Compl. day	Z Compl. cumulat.	Reason (*)	Morning dose (ng)	Evening dose (ng)	Overdose (**)
6	161	Reboxetine	29/03/91	09/05/91	42	8	8	100.0	100.0		4	4	
					42								
					42								
					42								
7	162	Reboxetine	05/11/91	16/12/91	42	8	8	100.0	100.0		4	4	
					42								
					42								
					42								
7	193	Reboxetine	11/06/91	17/06/91	7	8	8	100.0	100.0		4	4	
					7								
					7								
					7								
7	194	Reboxetine	03/06/91	06/06/91	4	8	8	100.0	100.0		4	4	
					2	8	8	100.0	100.0	3m 3e	4	4	
					6								
					6								
8	196	Imipramine	19/03/91	21/03/91	3	100	100	100.0	100.0		50	50	
					36	150	150	100.0	100.0		50	100	
					39								
					39								
8	225	Imipramine	22/03/91	22/03/91	1	100	50	100.0	100.0		50	50	
					2	100	100	100.0	100.0	9m	50	50	
					15	150	150	100.0	100.0		50	100	
					1	150	50	100.0	100.0	6e	50	50	
8	226	Reboxetine	03/05/91	30/05/91	28	8	8	100.0	100.0		4	4	
					7	8	10	100.0	100.0		4	6	
					2	10	10	100.0	100.0		4	6	
					4	10	10	100.0	98.4	1e	4	4	
8	227	Imipramine	07/05/91	09/05/91	3	100	100	100.0	100.0		50	50	
					39	150	150	100.0	100.0		50	100	
					42								
					42								
8	228	Reboxetine	10/05/91	17/05/91	8	8	8	100.0	100.0		4	4	
					8								
					8								
					8								

(*) 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
 m = morning, e = evening

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/017
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 (**)
8	229	Imipramine	22/10/91	24/10/91	3	100	100	100.0	100.0		50	50	
			25/10/91	02/12/91	39	150	150	100.0	100.0		50	100	
					42								
230	Imipramine	05/11/91	07/11/91	3	100	100	100.0	100.0			50	50	
		08/11/91	03/12/91	26	150	150	100.0	100.0			50	100	
		04/12/91	04/12/91	1	150	50	33.3	97.8	1e		50	50	
		05/12/91	06/12/91	2	150	150	100.0	97.9			50	100	
		07/12/91	07/12/91	1	150	50	33.3	96.0	1e		50	50	
		08/12/91	10/12/91	3	150	150	100.0	96.3			50	100	
		11/12/91	11/12/91	1	150	50	33.3	94.6	1e		50	50	
12/12/91	16/12/91	5	150	150	100.0	95.2			50	100			
					42								
231	Reboxetine	05/11/91	12/11/91	8	8	8	100.0	100.0			4	4	
		13/11/91	13/11/91	1	8	4	100.0	100.0	6e		4	4	
					9								
232	Reboxetine	29/11/91	09/01/92	42	8	8	100.0	100.0			4	4	
				42									
197	Reboxetine	07/03/92	10/03/92	4	8	8	100.0	100.0			4	4	
				4									
198	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								
199	Imipramine	02/04/92	04/04/92	3	100	100	100.0	100.0			50	50	
		05/04/92	23/04/92	19	150	150	100.0	100.0			50	100	
		24/04/92	24/04/92	1	150	100	66.7	98.6	1m		50	100	
		25/04/92	13/05/92	19	150	150	100.0	99.2			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, 4=double high dose, 8=double low dose, C=high daily dose in one administration, P=low daily dose in one administration
 m = morning, e = evening

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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 (**)			
9	200	Reboxetine	28/04/92	08/06/92	42	8	8	100.0	100.0		4	4				
					42											
201		Imipramine	16/01/92	16/01/92	1	100	50	50.0	50.0	1m	50	50				
			17/01/92	18/01/92	2	100	100	100.0	83.3		50	50				
			19/01/92	20/01/92	2	150	100	0.0	90.0		50	100				
			21/01/92	21/01/92	1	150	100	0.0	91.7	1m	50	150				
			22/01/92	09/02/92	19	150	150	100.0	98.0		50	100				
			10/02/92	12/02/92	3	150	100	0.0	98.2	5m 5e	50	100				
			13/02/92	26/02/92	14	150	100	0.0	98.5		50	100				
			42													
			202		Imipramine	17/01/92	19/01/92	3	100	100	100.0	100.0		50	50	
						20/01/92	20/01/92	1	150	50	33.3	83.3	1e	50	100	
21/01/92	21/01/92	1				150	100	100.0	86.7		50	100				
22/01/92	22/01/92	1				150	100	66.7	83.3	1m	100	100				
23/01/92	27/02/92	36				150	150	100.0	97.6		50	100				
42																
203		Reboxetine	15/01/92	18/01/92	4	8	8	100.0	100.0		4	4				
204		Reboxetine	17/01/92	28/02/92	43	8	8	100.0	100.0		4	4				
43																
205		Imipramine	05/02/92	07/02/92	3	100	100	100.0	100.0		50	50				
3																
206		Imipramine	05/02/92	07/02/92	3	100	100	100.0	100.0		50	50				
			08/02/92	16/02/92	9	150	150	100.0	100.0		50	100				
			17/02/92	17/02/92	1	150	0.0	0.0	92.3	1m 1e	50	100				
			18/02/92	24/02/92	7	150	150	100.0	95.0		50	100				
			25/02/92	25/02/92	1	150	100	66.7	93.7	1m	100	100				
			26/02/92	18/03/92	22	150	150	100.0	96.9		50	100				
			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, 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 20124/017
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 (%)
					43								
9	207	Reboxetine	06/02/92	07/02/92	2	8	8	100.0	100.0		4	4	
			08/02/92	08/02/92	1	8	4	50.0	83.3	1a	4	4	
			09/02/92	12/02/92	4	8	8	100.0	92.9		4	4	
					7								
208		Reboxetine	15/02/92	27/03/92	42	8	8	100.0	100.0		4	4	
					42								
209		Imipramine	12/02/92	14/02/92	3	100	100	100.0	100.0		50	50	
			15/02/92	15/02/92	1	150	150	100.0	100.0		50	100	
					4								
210		Reboxetine	20/02/92	12/03/92	22	8	8	100.0	100.0		4	4	
			13/03/92	13/03/92	1	8	4	50.0	97.8	1m	4	4	
			14/03/92	01/04/92	19	8	8	100.0	98.8		4	4	
					42								
211		Reboxetine	14/02/92	01/03/92	17	8	8	100.0	100.0		4	4	
			02/03/92	02/03/92	1	8	4	100.0	100.0		4	4	
					18								
212		Imipramine	04/03/92	06/03/92	3	100	100	100.0	100.0		50	50	
			07/03/92	14/04/92	39	150	150	100.0	100.0		50	100	
					42								
237		Reboxetine	23/04/92	26/04/92	4	8	8	100.0	100.0		4	4	
			27/04/92	27/04/92	1	8	4	100.0	100.0	3a	4	4	
			28/04/92	29/04/92	2	8	8	100.0	100.0		4	4	
			30/04/92	02/05/92	3	8	8	100.0	100.0	3m 3e	4	4	
					10								
238		Imipramine	20/05/92	22/05/92	3	100	100	100.0	100.0		50	50	
			23/05/92	30/06/92	39	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 20124/017
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 (%)
9	239	Imipramine	30/04/92	02/05/92	42	100	100	100.0	100.0		50	50	
					3								
					39								
	240	Reboxetine	28/04/92	16/05/92	42	8	8	100.0	100.0		4	4	
					19								
					19								
241	Imipramine	09/05/92	11/05/92	3	100	100	100.0	100.0		50	50		
				11									
				11									
				1									
				27									
242	Reboxetine	07/05/92	17/06/92	42	8	8	100.0	100.0		4	4		
				42									
				42									
243	Imipramine	18/05/92	20/05/92	3	100	100	100.0	100.0		50	50		
				39									
				42									
244	Reboxetine	06/06/92	03/07/92	28	8	8	100.0	100.0		4	4		
				9									
				1									
				4									
257	Reboxetine	17/07/91	27/08/91	42	8	8	100.0	100.0		4	4		
				42									
				42									
258	Reboxetine	17/07/91	06/08/91	21	8	8	100.0	100.0		4	4		
				21									

(*) 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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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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 (**)
9	259	Imipramine	17/07/91	19/07/91	3	100	100	100.0	100.0		50	50	
			20/07/91	27/08/91	39	150	150	100.0	100.0		50	100	
			42										
260	Imipramine	24/07/91	26/07/91	3	100	100	100.0	100.0			50	50	
		27/07/91	29/07/91	3	150	150	100.0	100.0			50	100	
		30/07/91	30/07/91	1	150	0.0	0.0	85.7		1m	1e		
		31/07/91	05/08/91	6	150	150	100.0	92.3			50	100	
		06/08/91	06/08/91	1	150	0.0	0.0	85.7		1m	1e		
		07/08/91	13/08/91	6	150	150	100.0	96.0			50	100	
			13/08/91										
			21										
261	Imipramine	23/07/91	24/07/91	2	100	100	100.0	100.0			50	50	
		25/07/91	25/07/91	1	100	50	50.0	83.3		1e	50	50	
		26/07/91	29/07/91	4	150	150	100.0	92.9			50	100	
			7										
262	Reboxetine	23/07/91	29/07/91	7	8	8	100.0	100.0			4	4	
		30/07/91	30/07/91	1	8	0.0	0.0	87.5			4	4	
		31/07/91	09/08/91	10	8	8	100.0	94.4			4	4	
		10/08/91	10/08/91	1	8	4	50.0	92.1		1m	4	4	
		11/08/91	15/08/91	5	8	8	100.0	93.8			4	4	
		16/08/91	16/08/91	1	8	4	50.0	92.0		1m	4	4	
		17/08/91	17/08/91	1	8	8	100.0	92.3			4	4	
		18/08/91	18/08/91	1	8	4	50.0	90.7		1e	4	4	
		19/08/91	30/08/91	12	8	8	100.0	93.6			4	4	
		31/08/91	31/08/91	1	8	4	50.0	92.5		1e	4	4	
			01/09/91										
			43										
263	Reboxetine	31/07/91	03/08/91	4	8	8	100.0	100.0			4	4	
		04/08/91	04/08/91	1	8	4	50.0	90.0		1m	4	4	
		05/08/91	13/08/91	9	8	8	100.0	96.4			4	4	
			14										
264	Imipramine	31/07/91	02/08/91	3	100	100	100.0	100.0			50	50	
		03/08/91	10/09/91	39	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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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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)							
9	265	Reboxetine	23/08/91	07/09/91	16	8	8	100.0	100.0		4	4								
							08/09/91	08/09/91	1	8	4	50.0	97.1	1e	4	4				
							09/09/91	10/09/91	2	8	8	100.0	97.4		4	4				
							11/09/91	11/09/91	1	8	4	50.0	95.0	1e	4	4				
							12/09/91	29/09/91	18	8	8	100.0	97.4		4	4				
							30/09/91	30/09/91	1	8	4	50.0	96.2	1m	4	4				
							01/10/91	03/10/91	3	8	8	100.0	96.4		4	4				
							42													
							266	Reboxetine	18/09/91	29/10/91	42	8	8	100.0	100.0			4	4	
													42							
267	Imipramine	02/09/91	04/09/91	3	100	100	100.0	100.0			50	50								
						05/09/91	05/09/91	1	150	300	100.0	100.0		100	200	(B - m) (B - e)				
						06/09/91	28/09/91	23	150	150	100.0	100.0		50	100					
						29/09/91	29/09/91	1	150	150	100.0	100.0	1m	50	150					
						30/09/91	13/10/91	14	150	150	100.0	100.0		50	100					
						42														
268	Imipramine	25/09/91	27/09/91	3	100	100	100.0	100.0			50	50								
						28/09/91	29/10/91	32	150	150	100.0	100.0		50	100					
						30/10/91	05/11/91	7	200	200	100.0	100.0		100	100					
						42														
269	Reboxetine	25/09/91	05/11/91	42	8	8	100.0	100.0			4	4								
						42														
						270	Imipramine	11/10/91	13/10/91	3	100	100	100.0	100.0		50	50			
												14/10/91	14/10/91	1	150	150	100.0	100.0		50
271	Reboxetine	30/10/91	12/11/91	14	8	8	100.0	100.0		4	4									
						7														

(*) 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
m = morning, e = evening

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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 (**)
9	271	Reboxetine	13/11/91	13/11/91	1	8	4	100.0	100.0	3e	4		
			14/11/91	17/11/91	4	8	4	100.0	100.0	3m 3e	4	4	
			18/11/91	20/11/91	3	8	8	100.0	100.0		4	4	
					22								
272	Imipramine	30/10/91	01/11/91	3	100	100	100.0	100.0			50	50	
		02/11/91	10/12/91	39	150	150	100.0	100.0			50	100	
					42								
273	Imipramine	30/10/91	01/11/91	3	100	100	100.0	100.0			50	50	
		02/11/91	20/11/91	19	150	150	100.0	100.0			50	100	
		21/11/91	21/11/91	1	150	100.0	100.0	100.0	3m 6e				
						23							
274	Reboxetine	31/10/91	31/10/91	1	8	4	100.0	100.0	6e	4			
					1								
274/A	Reboxetine	13/05/92	26/05/92	14	8	8	100.0	100.0			4	4	
		27/05/92	27/05/92	1	8	4	50.0	96.7	1m		4	4	
		28/05/92	08/06/92	12	8	8	100.0	98.1			4	4	
		09/06/92	09/06/92	1	8	4	50.0	96.4	4e		4	4	
		10/06/92	23/06/92	14	8	8	100.0	97.6			4	4	
					42								
275	Reboxetine	06/11/91	16/11/91	11	8	8	100.0	100.0			4	4	
		17/11/91	17/11/91	1	8	4	50.0	95.8	4m		4	4	
		18/11/91	07/12/91	20	8	8	100.0	98.4			4	4	
		08/12/91	08/12/91	1	8	0.0	95.5	1m 1e			4	4	
					42								
276	Imipramine	14/01/92	14/01/92	1	100	50	100.0	100.0	6e	50			
					1								
276/A	Imipramine	04/03/92	06/03/92	3	100	100	100.0	100.0			50	50	
		07/03/92	24/03/92	16	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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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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 (**)
9	276/A	Imipramine	25/03/92	14/04/92	21	200	200	100.0	100.0		100	100	
					42								
9/A	233	Imipramine	14/05/92	16/05/92	3	100	100	100.0	100.0		50	50	
			17/05/92	26/05/92	10	150	150	100.0	100.0		50	100	
			27/05/92	27/05/92	1	150	50	33.3	95.2	1e	50	50	
			28/05/92	24/06/92	28	150	150	100.0	98.4		50	100	
					42								
234	Reboxetine	22/05/92	02/07/92	42	8	8	100.0	100.0	100.0		4	4	
					42								
235	Reboxetine	26/05/92	28/06/92	34	8	8	100.0	100.0	100.0		4	4	
			29/06/92	29/06/92	1	8	4	100.0	100.0	6e	4	4	
					35								
236	Imipramine	27/05/92	29/05/92	3	100	100	100.0	100.0	100.0		50	50	
			30/05/92	07/07/92	39	150	150	100.0	100.0		50	100	
					42								
277	Reboxetine	10/06/92	14/06/92	5	8	8	100.0	100.0	100.0		4	4	
					5								
278	Imipramine	13/06/92	15/06/92	3	100	100	100.0	100.0	100.0		50	50	
			16/06/92	02/07/92	17	150	150	100.0	100.0		50	100	
			03/07/92	03/07/92	1	150	50	100.0	100.0	6e	50	50	
					21								
279	Imipramine	07/08/92	09/08/92	3	100	100	100.0	100.0	100.0		50	50	
			10/08/92	21/08/92	12	150	150	100.0	100.0		50	100	
					15								
280	Reboxetine	08/08/92	13/08/92	6	8	8	100.0	100.0	100.0		4	4	
			14/08/92	14/08/92	1	8	4	100.0	100.0	6e	4	4	

(*) 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

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PIARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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 (**)
9/A	281	Reboxetine	01/09/92	12/10/92	7	8	8	100.0	100.0		4	4	
					42								
282	Reboxetine	02/09/92	13/10/92	42	8	8	100.0	100.0			4	4	
				42									
283	Imipramine	16/09/92	16/09/92	1	100	50	100.0	100.0		9m	50	50	
				2									
				40									
				45									
284	Imipramine	19/09/92	21/09/92	3	100	100	100.0	100.0			50	50	
				18									
301	Imipramine	05/03/92	07/03/92	3	100	100	100.0	100.0			50	50	
				39									
302	Imipramine	06/03/92	08/03/92	3	100	100	100.0	100.0			50	50	
				14									
303	Reboxetine	12/03/92	30/03/92	19	8	8	100.0	100.0			4	4	
				1									
304	Reboxetine	26/03/92	06/05/92	42	8	8	100.0	100.0			4	4	
				42									
305	Reboxetine	31/03/92	11/05/92	42	8	8	100.0	100.0			4	4	
				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
 m = morning, o = evening

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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 (**)
9/A	306	Reboxetine	29/04/92	09/06/92	42	8	8	100.0	100.0		4	4	
					42								
	307	Imipramine	05/05/92	07/05/92	3	100	100	100.0	100.0	6e	50	50	
					1								
308	Imipramine	09/05/92	11/05/92	4	100	100	100.0	100.0	100.0	6e	50	100	
				3									
				21									
				1									
10	Imipramine	21/09/91	23/09/91	25	300	100	100.0	100.0	100.0	10e	50	100	
				3									
				2									
				1									
				1									
				1									
290	Reboxetine	14/10/91	25/10/91	7	8	8	100.0	100.0	100.0		4	4	(B - e)
				12									
				1									
				6									
				1									
				11									
				1									
291	Imipramine	17/02/92	19/02/92	42	100	100	100.0	100.0			50	100	
				3									
				39									
				42									
292	Reboxetine	13/12/91	20/12/91	42	8	8	100.0	100.0		10m	4	4	
				8									
				1									
				33									

(*) 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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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20324/017
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 (mg)	Evening dose (mg)	Overdose (xx)														
10	293	Reboxetine	24/12/91	29/12/91	6	8	8	100.0	100.0		4	4															
														30/12/91	30/12/91	1	8	4	50.0	92.9							
														31/12/91	04/01/92	5	8	8	100.0	95.8	1e						
														05/01/92	05/01/92	1	8	4	50.0	92.3	1e						
														06/01/92	14/01/92	9	8	8	100.0	95.5							
														15/01/92	15/01/92	1	8	14	100.0	95.7							
														16/01/92	01/02/92	17	8	18	100.0	97.5							
														40													
														294	Imipramine	03/01/92	05/01/92	3	100	100	100.0	100.0	100.0		50	50	
21																											
295	Imipramine	07/01/92	07/01/92	1	100	100	100.0	100.0	100.0		50	50															
														08/01/92	08/01/92	1	100	50	50.0	75.0							
														09/01/92	09/01/92	1	100	100	100.0	83.3	2e						
														10/01/92	31/01/92	22	150	150	100.0	98.0							
														01/02/92	02/02/92	2	150	100.0	98.1	3m							
														03/02/92	03/02/92	1	150	150	100.0	98.2	4m						
														04/02/92	04/02/92	1	150	0	0.0	94.8							
														05/02/92	07/02/92	3	150	150	100.0	95.3	4m						
														08/02/92	08/02/92	1	150	100	66.7	94.4							
														09/02/92	17/02/92	9	150	150	100.0	95.6							
42																											
296	Reboxetine	20/02/92	01/04/92	42	8	8	100.0	100.0	100.0		4	4															
														42													
297	Reboxetine	21/03/92	21/03/92	1	8	8	100.0	100.0	100.0		4	4															
														22/03/92	01/05/92	41	8	8	100.0	100.0	9n						
														02/05/92	02/05/92	1	8	4	100.0	100.0	9e						
43																											
298	Reboxetine	27/03/92	07/05/92	42	8	8	100.0	100.0	100.0		4	4															
														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, 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 8&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (ng)	% Compl. day	% Compl. cumulat.	Reason (%)	Morning dose (ng)	Evening dose (ng)	Overdose (**)	
10	299	Imipramine	07/04/92	09/04/92	3	100	100.0	100.0		50	50		
			10/04/92	18/05/92	39	150	100.0	100.0		50	100		
	300	Imipramine	14/04/92	16/04/92	3	100	100.0	100.0		50	50		
			17/04/92	17/04/92	1	150	100.0	100.0		50	100		
			18/04/92	18/04/92	1	250	100.0	100.0		50	200	(B - e)	
			19/04/92	19/04/92	1	150	100.0	100.0		100	100	(B - m)	
			20/04/92	25/05/92	36	150	100.0	100.0		50	100		
11	321	Reboxetine	11/06/92	22/07/92	42	8	100.0	100.0		4	4		
			23/07/92	23/07/92	1	8	100.0	100.0	9e	4	4		
12	322	Reboxetine	11/06/92	23/07/92	43	8	100.0	100.0		4	4		
			24/07/92	24/07/92	1	8	100.0	100.0	9e	4	4		
13	323	Imipramine	24/06/92	24/06/92	1	100	50	100.0	100.0	9m		50	
			25/06/92	26/06/92	2	100	100	100.0	100.0		50	50	
			27/06/92	28/07/92	32	150	150	100.0	100.0		50	100	
			29/07/92	29/07/92	1	150	50	33.3	98.1	1e	50	50	
			30/07/92	30/07/92	1	150	100	66.7	97.3	1m 9e	100	100	
			31/07/92	05/08/92	6	150	150	100.0	97.7	9e	50	100	
			06/08/92	06/08/92	1	150	50	100.0	97.7	50	50		
14	324	Imipramine	17/07/92	17/07/92	1	100	50	100.0	100.0	9m		50	
			18/07/92	19/07/92	2	100	100	100.0	100.0		50	50	
			20/07/92	27/08/92	39	150	150	100.0	100.0		50	100	
			28/08/92	28/08/92	1	150	50	100.0	100.0	9e	50	50	

(*) 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

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PIARNACIA CNS E2D

REBOXETINE - PROTOCOL 20124/017
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	325	Reboxetine	30/07/92	30/07/92	1	8	4	100.0	100.0	9m	4	4	
			31/07/92	09/09/92	41	8	8	100.0	100.0		4	4	
			10/09/92	10/09/92	1	8	4	100.0	100.0	9e	4	4	
					43								
	326	Imipramine	30/07/92	30/07/92	1	100	50	100.0	100.0	9m	50	50	
			31/07/92	01/08/92	2	100	100	100.0	100.0		50	50	
			02/08/92	10/09/92	40	150	150	100.0	100.0		50	100	
					43								
	327	Reboxetine	20/08/92	20/08/92	1	8	4	100.0	100.0	9m	4	4	
			21/08/92	30/09/92	41	8	8	100.0	100.0		4	4	
			01/10/92	01/10/92	1	8	4	100.0	100.0	9e	4	4	
					43								
	328	Imipramine	20/08/92	20/08/92	1	100	50	100.0	100.0	9m	50	50	
			21/08/92	22/08/92	2	100	100	100.0	100.0		50	50	
			23/08/92	16/09/92	25	150	150	100.0	100.0		50	100	
			17/09/92	17/09/92	1	150	50	100.0	100.0	9e	50	50	
								29					
	329	Imipramine	21/08/92	23/08/92	3	100	100	100.0	100.0		50	50	
			24/08/92	01/10/92	39	150	150	100.0	100.0		50	100	
			02/10/92	02/10/92	1	150	50	100.0	100.0	9e	50	50	
					43								
	330	Reboxetine	24/08/92	25/08/92	2	8	8	100.0	100.0	6e	4	4	
			26/08/92	26/08/92	1	8	4	100.0	100.0		4	4	
					3								
	331	Reboxetine	03/09/92	20/09/92	18	8	8	100.0	100.0		4	4	
			21/09/92	21/09/92	1	8	4	100.0	100.0	3m	4	4	
			22/09/92	16/10/92	23	8	8	100.0	100.0		4	4	
			15/10/92	15/10/92	1	8	4	50.0	98.8	4e	4	4	
					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, 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 RED

REBOXETINE - PROTOCOL 20124/017
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	332	Imipramine	05/09/92	05/09/92	1	100	50	100.0	100.0	9m	50	50			
			06/09/92	07/09/92	2	100	100	100.0	100.0		50	50			
			08/09/92	13/09/92	6	150	150	100.0	100.0		50	100			
			14/09/92	14/09/92	1	150	100	100.0	100.0		9m	100			
			15/09/92	19/10/92	35	150	150	100.0	100.0		9e	50			
			20/10/92	20/10/92	1	150	50	100.0	100.0			50			
			46												
			04/09/92	04/09/92	1	100	50	100.0	100.0		9m	50	50		
			05/09/92	06/09/92	2	100	100	100.0	100.0			50	50		
			07/09/92	24/09/92	18	150	150	100.0	100.0			50	100		
			25/09/92	25/09/92	1	150	250	100.0	100.0			50	200		
26/09/92	01/10/92	6	150	350	100.0	100.0			150	200	(3 - e)				
02/10/92	02/10/92	1	150	350	100.0	100.0			150	200	(3 - e)				
03/10/92	08/10/92	6	150	350	100.0	100.0			150	200	(3 - e)				
09/10/92	09/10/92	1	150	350	100.0	100.0			150	200	(3 - e)				
10/10/92	15/10/92	6	150	350	100.0	100.0			150	200	(3 - e)				
16/10/92	16/10/92	1	150	150	100.0	100.0			9e	150	200	(3 - e)			
43															
12	337	Imipramine	26/05/92	28/05/92	3	100	100	100.0	100.0		50	50			
			29/05/92	11/06/92	14	150	150	100.0	100.0		50	100			
			12/06/92	12/06/92	1	150	100	66.7	98.1	4m		100			
			13/06/92	22/06/92	10	150	150	100.0	98.8			50	100		
			23/06/92	23/06/92	1	150	150	100.0	98.9	9e		150	100	(3 - m)	
			24/06/92	24/06/92	1	150	250	100.0	98.9			150	100	(3 - m)	
			25/06/92	06/07/92	12	150	150	100.0	99.2			50	100		
			42												
			20/06/92	09/07/92	20	8	8	100.0	100.0			4	4	4	
			10/07/92	10/07/92	1	8	4	50.0	97.6	1m		4	4	4	
			11/07/92	30/07/92	20	10	10	100.0	98.8			4	4	6	
31/07/92	31/07/92	1	10	4	40.0	97.4	1e		4	4					
42															
339	339	Imipramine	23/06/92	25/06/92	3	100	100	100.0	100.0		50	50			
			26/06/92	03/08/92	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
 m = morning, e = evening

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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 (x)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)		
12	340	Reboxetine	07/08/92	10/09/92	35	8	8	100.0	100.0		4	4			
			11/09/92	17/09/92	7	10	10	100.0	100.0		4	6			
13	341	Reboxetine	21/08/92	26/08/92	6	8	8	100.0	100.0		4	4			
			27/08/92	27/08/92	1	8	4	50.0	92.9	4e	4	4			
			28/08/92	02/09/92	6	8	8	100.0	96.2	4e	4	4			
			03/09/92	03/09/92	1	8	4	50.0	92.9	4e	4	4			
			04/09/92	10/09/92	7	8	8	100.0	95.2		4	4			
			11/09/92	13/09/92	3	8	20	100.0	95.8		8	12	(A - m) (A - o)		
			14/09/92	14/09/92	1	8	14	100.0	96.0		8	6	(A - m) (A - o)		
			15/09/92	17/09/92	3	8	10	100.0	96.4		4	6	(A - m) (A - o)		
			18/09/92	24/09/92	7	10	10	100.0	97.1		4	6	(A - m) (A - o)		
							35								
			13	353	Reboxetine	05/06/92	11/06/92	7	8	8	100.0	100.0		4	4
12/06/92	14/06/92	3				8	8	0.0	70.0		4	4			
15/06/92	20/06/92	6				8	8	100.0	81.3		4	4			
21/06/92	21/06/92	1				8	8	100.0	82.4	3m	4	4			
22/06/92	06/07/92	15				8	8	100.0	90.6		4	4			
07/07/92	07/07/92	1				8	8	100.0	90.9	7e	4	4			
							33								
13	354	Imipramine	24/06/92	24/06/92	1	100	50	100.0	100.0	9m		50	50		
			25/06/92	26/06/92	2	100	100	100.0	100.0		50	50			
			27/06/92	20/07/92	24	150	150	100.0	100.0	4e	50	100			
			21/07/92	21/07/92	1	150	50	33.3	97.6		50	100			
			22/07/92	04/08/92	14	150	150	100.0	98.4		50	100			
				42											
13	355	Reboxetine	25/06/92	26/06/92	2	8	8	100.0	100.0		4	4			
			27/06/92	27/06/92	1	8	4	100.0	100.0	6e	4	4			
				3											
13	356	Imipramine	22/07/92	24/07/92	3	100	100	100.0	100.0		50	50			

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m = morning, e = evening

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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	356	Imipramine	25/07/92	01/09/92	39	150	150	100.0	100.0		50	100		
					42									
	357	Imipramine	05/08/92	07/08/92	3	100	100	100.0	100.0		50	50		
					2	150	150	100.0	100.0	3m 3a	50	100		
					1	150	100.0	100.0						
					6									
	358	Reboxetine	06/08/92	27/08/92	22	8	8	100.0	100.0			4	4	
					2	8	8	100.0	100.0	4m	8	8	(D - e)	
					2	8	8	100.0	100.0	3m 3a	4	4		
					5	8	8	100.0	100.0					
					31									
	359	Reboxetine	19/08/92	22/09/92	35	8	8	100.0	100.0		4	4		
					7	8	14	100.0	100.0		4	10	(3 - e)	
42														
360	Imipramine	19/08/92	20/08/92	2	100	100	100.0	100.0		50	50			
				1	100	50	100.0	100.0	6e	50	50			
				3										
361	Reboxetine	26/08/92	26/08/92	1	8	4	100.0	100.0			4	4		
				41	8	8	100.0	100.0	9m	4	4			
				42										
				20	8	8	100.0	100.0		4	4			
457	Reboxetine	07/07/92	26/07/92	1	8	4	50.0	97.6		4	4			
				1	8	4	100.0	98.8	1a	4	4			
				21	8	8	100.0	98.8		4	4			
				42										
458	Imipramine	14/07/92	16/07/92	3	100	100	100.0	100.0		50	50			
				4	150	150	100.0	100.0		50	100			
				7	200	200	100.0	100.0		100	100			
				21	150	150	100.0	100.0		50	100			
				7	150	50	33.3	88.9	4e	50	50			
				42										

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 m = morning, e = evening

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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 (**)	
14	459	Reboxetine	16/07/92	26/08/92	42	8	8	100.0	100.0		4	4		
														42
														42
460	Imipramine	23/07/92	26/07/92	39	100	150	100.0	100.0	100.0	4e	50	100		
														42
														42
														42
														42
461	Imipramine	29/07/92	31/07/92	42	100	150	100.0	100.0	100.0		50	50		
														42
														42
														42
														42
														42
														42
462	Reboxetine	31/07/92	10/09/92	42	8	8	100.0	100.0	100.0		4	4		
														42
														42
463	Imipramine	03/08/92	05/08/92	39	100	150	100.0	100.0	100.0		50	100		
														42
														42
464	Reboxetine	05/08/92	26/08/92	22	8	8	100.0	100.0	100.0		4	4		
														42
														42
														42
465	Reboxetine	06/08/92	16/09/92	42	8	8	100.0	100.0	100.0		4	4		
														42
														42
466	Imipramine	07/08/92	09/08/92	39	100	150	100.0	100.0	100.0		50	100		
														42
														42

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(*) 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, 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
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REBOXETINE - PROTOCOL 20124/017
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 (**)
14/1	129	Reboxetine	19/12/91	19/12/91	42 1	8	4	100.0	100.0	6e	4		
426		Reboxetine	05/09/91	17/10/91	43 1	8	8	100.0	100.0		4	4	
429		Imipramine	26/09/91	28/09/91	3	100	100	100.0	100.0		50	50	
			29/09/91	29/09/91	1	150	150	100.0	100.0		50	100	
451		Imipramine	28/11/91	30/11/91	4 3	100	100	100.0	100.0		50	50	
			01/12/91	22/12/91	22	150	150	100.0	100.0		50	100	
			23/12/91	23/12/91	1	150	150	100.0	100.0	5e	50	100	
			24/12/91	07/01/92	15	150	150	100.0	100.0		50	100	
452		Reboxetine	28/11/91	09/01/92	41 43	8	8	100.0	100.0		4	4	
14/2	136	Imipramine	15/01/92	17/01/92	3	100	100	100.0	100.0		50	50	
			18/01/92	25/02/92	39	150	150	100.0	100.0		50	100	
456		Imipramine	15/04/92	17/04/92	42 3	100	100	100.0	100.0		50	50	
			18/04/92	05/05/92	18	150	150	100.0	100.0		50	100	
			06/05/92	26/05/92	21	200	200	100.0	100.0		100	100	
14/3	417	Reboxetine	14/06/91	15/07/91	42 32	8	8	100.0	100.0		4	4	
			16/07/91	18/07/91	3	8	4	50.0	95.7	1e	4	4	
			19/07/91	26/07/91	8	10	10	100.0	96.5		4	6	

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REBOXETINE - PROTOCOL 20124/017
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 (%)
					43								
14/3	418	Imipramine	18/06/91	20/06/91	3	100	100	100.0	100.0		50	50	
			21/06/91	08/07/91	18	150	150	100.0	100.0		50	100	
			09/07/91	29/07/91	21	200	200	100.0	100.0		100	100	
					42								
419	Reboxetine	05/07/91	15/08/91	42	8	8	100.0	100.0			4	4	
					42								
420	Imipramine	05/07/91	07/07/91	3	100	100	100.0	100.0			50	50	
			08/07/91	25/07/91	18	150	150	100.0	100.0		50	100	
					21								
421	Reboxetine	19/07/91	22/08/91	35	8	8	100.0	100.0			4	4	
			23/08/91	29/08/91	7	10	10	100.0	100.0		4	8	
					42								
427	Imipramine	18/09/91	20/09/91	3	100	100	100.0	100.0			50	50	
			21/09/91	08/10/91	18	150	150	100.0	100.0		50	100	
			09/10/91	15/10/91	7	200	200	100.0	100.0		100	100	
					28								
428	Imipramine	25/10/91	27/10/91	3	100	100	100.0	100.0			50	50	
			28/10/91	08/11/91	12	150	150	100.0	100.0		50	100	
			09/11/91	09/11/91	1	150	100	66.7	97.9	1m	50	100	
			10/11/91	14/11/91	5	150	150	100.0	98.4		50	100	
			15/11/91	20/11/91	6	200	200	100.0	98.8		100	100	
			21/11/91	21/11/91	1	200	100	50.0	97.0	1m	100	100	
			22/11/91	05/12/91	14	200	200	100.0	98.0		100	100	
					42								
14/4	131	Imipramine	14/01/92	16/01/92	3	100	100	100.0	100.0		50	50	
			17/01/92	24/02/92	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, 5=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
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REBOXETINE - PROTOCOL 20124/017
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)	Z Compl. day	X Compl. cumulat.	Reason (%)	Morning dose (ng)	Evening dose (ng)	Overdose (**)
14/4	132	Imipramine	14/01/92	16/01/92	3	100	100	100.0	100.0		50	50	
			17/01/92	24/02/92	39	150	150	100.0	100.0		50	100	
133	Imipramine	16/01/92	18/01/92	3	100	100	100.0	100.0			50	50	
		19/01/92	22/01/92	4	150	150	100.0	100.0			50	100	
		23/01/92	23/01/92	1	150	200	100.0	100.0			100	100	
		24/01/92	26/02/92	34	150	150	100.0	100.0			50	100	(B - m)
134	Reboxetine	16/01/92	26/02/92	42	8	8	100.0	100.0			4	4	
				42									
135	Reboxetine	17/01/92	27/02/92	42	8	8	100.0	100.0			4	4	
				42									
14/7	422	Imipramine	04/09/91	06/09/91	3	100	100	100.0	100.0		50	50	
			07/09/91	15/10/91	39	150	150	100.0	100.0		50	100	
423	Imipramine	17/09/91	19/09/91	3	100	100	100.0	100.0			50	50	
		20/09/91	28/10/91	39	150	150	100.0	100.0			50	100	
424	Reboxetine	19/09/91	30/10/91	42	8	8	100.0	100.0			4	4	
				42									
430	Reboxetine	07/10/91	17/11/91	42	8	8	100.0	100.0			4	4	
				42									
431	Reboxetine	08/10/91	28/10/91	21	8	8	100.0	100.0			4	4	
		29/10/91	18/11/91	21	10	10	100.0	100.0			4	6	

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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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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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)
14/7	432	Imipramine	08/10/91	10/10/91	3	100	100	100.0	100.0		50	50	
			11/10/91	18/11/91	39	150	150	100.0	100.0		50	100	
					42								
433	Imipramine	08/10/91	10/10/91	3	100	100	100.0	100.0			50	50	
		11/10/91	18/11/91	39	150	150	100.0	100.0			50	100	
					42								
434	Reboxetine	14/10/91	24/11/91	42	8	8	100.0	100.0			4	4	
				42									
439	Reboxetine	11/11/91	22/12/91	42	8	8	100.0	100.0			4	4	
				42									
440	Imipramine	11/11/91	13/11/91	3	100	100	100.0	100.0			50	50	
		14/11/91	22/12/91	39	150	150	100.0	100.0			50	100	
					42								
441	Imipramine	11/11/91	13/11/91	3	100	100	100.0	100.0			50	50	
		14/11/91	22/12/91	39	150	150	100.0	100.0			50	100	
					42								
442	Imipramine	11/11/91	13/11/91	3	100	100	100.0	100.0			50	50	
		14/11/91	22/12/91	39	150	150	100.0	100.0			50	100	
					42								
449	Reboxetine	20/12/91	30/01/92	42	8	8	100.0	100.0			4	4	
				42									
450	Imipramine	23/12/91	25/12/91	3	100	100	100.0	100.0			50	50	
		26/12/91	02/02/92	39	150	150	100.0	100.0			50	100	

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(*) 1=forgot to take, 2=last 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

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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 (**)
14/8	130	Reboxetine	10/01/92	20/02/92	42	8	8	100.0	100.0		4	4	
					42								
					42								
425	Reboxetine	09/09/91	20/10/91	42	8	8	100.0	100.0			4	4	
				42									
				42									
467	Reboxetine	06/07/92	16/08/92	42	8	8	100.0	100.0			4	4	
				42									
				42									
14/10	53	Reboxetine	25/02/92	11/03/92	16	8	8	100.0	100.0		4	4	
					1								
					13								
					1								
					1								
					11								
54	Imipramine	26/02/92	26/02/92	1	100	50	50.0	50.0	1e		50	50	
				2									
				18									
				21									
				21									
				42									
55	Reboxetine	28/02/92	03/03/92	5	8	8	100.0	100.0			4	4	
				1									
				8									
				8									
				1									
				22									
				1									
				1									
				4									
				4									
				4									
				42									
56	Imipramine	05/03/92	05/03/92	3	100	100	100.0	100.0			50	100	
				15									
				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, 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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PHARMACIA CNS 880
REBOXETINE - PROTOCOL 20124/017
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.	Reasons (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
14/10	56	Imipramine	22/03/92	07/04/92	17	150	150	100.0	99.1		50	100	
			08/04/92	08/04/92	1	150	100	66.7	98.2	1m		100	
			09/04/92	13/04/92	5	150	150	100.0	98.4		50	100	
					42								
57	Reboxetine	04/03/92	24/03/92	21	8	8	100.0	100.0	100.0		4	4	
		25/03/92	31/03/92	7	10	10	100.0	100.0	100.0		4	6	
		01/04/92	01/04/92	1	8	8	100.0	100.0	100.0		4	4	
		02/04/92	02/04/92	1	8	4	50.0	98.3		1e	4	4	
		03/04/92	07/04/92	5	8	8	100.0	98.6			4	4	
					42								
58	Imipramine	16/06/92	16/06/92	3	100	100	100.0	100.0	100.0		50	50	
		17/06/92	04/05/92	18	150	150	100.0	100.0	100.0		50	100	
		05/05/92	07/05/92	3	200	200	100.0	100.0	100.0		100	100	
		08/05/92	08/05/92	1	200	300	50.0	98.0		1e	100	100	
		09/05/92	25/05/92	17	200	200	100.0	98.8			100	100	
					42								
59	Imipramine	24/04/92	26/04/92	3	100	100	100.0	100.0	100.0		50	50	
		27/04/92	13/05/92	17	150	150	100.0	100.0	100.0		50	100	
		14/05/92	14/05/92	1	150	50	33.3	96.8	1e	50	50		
					42								
60	Reboxetine	13/05/92	27/05/92	15	8	8	100.0	100.0	100.0		4	4	
		28/05/92	28/05/92	1	8	4	50.0	96.9	1m		4	4	
		29/05/92	23/06/92	26	8	8	100.0	98.8			4	4	
					42								
137	Reboxetine	28/01/92	06/02/92	10	8	8	100.0	100.0	100.0		4	4	
		07/02/92	07/02/92	1	8	4	50.0	95.5			4	4	
		08/02/92	18/02/92	11	8	8	100.0	97.7	1m		4	4	
		19/02/92	19/02/92	1	8	4	50.0	95.7			4	4	
		20/02/92	06/03/92	16	8	8	100.0	97.4	1e		4	4	
		07/03/92	07/03/92	1	8	4	50.0	96.3			4	4	
		08/03/92	09/03/92	2	8	8	100.0	96.4	1m		4	4	

(*) 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=high daily dose in one administration, 9=low daily dose in one administration, 10=high daily dose in one administration

m = morning, e = evening

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/017

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 (**)																								
14/10	138	Imipramine	29/01/92	31/01/92	42	100	100	100.0	100.0		50	50																									
														01/02/92	07/02/92	3	150	150	100.0	100.0		50	100														
														08/02/92	08/02/92	1	150	50	33.3	93.9	1e	50	50														
														09/02/92	18/02/92	10	150	100.0	96.8			50	100														
														19/02/92	21/02/92	3	200	200	100.0	97.2		100	100														
														22/02/92	22/02/92	1	200	100	50.0	95.3	1e	100	100														
														23/02/92	04/03/92	11	200	200	100.0	96.8		100	100														
														05/03/92	05/03/92	1	200	100	50.0	95.5	1e	100	100														
														06/03/92	10/03/92	5	200	200	100.0	96.0		100	100														
														139	Reboxetine	04/02/92	06/02/92	42	8	8	100.0	100.0			4	4											
07/02/92	07/02/92	1	8	50.0	87.5	1m	4	4																													
08/02/92	18/02/92	11	8	100.0	96.7		4	4																													
19/02/92	19/02/92	1	8	50.0	93.8	1m	4	4																													
20/02/92	12/03/92	22	8	100.0	97.4		4	4																													
13/03/92	13/03/92	1	8	50.0	96.2	1m	4	4																													
14/03/92	16/03/92	3	8	100.0	96.4		4	4																													
140	Imipramine	05/02/92	07/02/92	42	100	100	100.0	100.0			50	50																									
																												08/02/92	12/02/92	5	150	150	100.0	100.0		50	100
																												13/02/92	13/02/92	1	150	50	33.3	92.6	1e	50	50
														14/02/92	25/02/92	12	150	100.0	96.8		50	100															
														26/02/92	09/03/92	13	200	200	100.0	98.0		100	100														
														10/03/92	10/03/92	1	200	100	50.0	96.7	1m	100	100														
														11/03/92	17/03/92	7	200	200	100.0	97.2		100	100														
														435	Imipramine	12/11/91	14/11/91	42	100	100	100.0	100.0			50	50											
																												15/11/91	18/12/91	34	150	150	100.0	100.0		50	100
																												19/12/91	19/12/91	1	150	100	66.7	99.1	1m	50	100
20/12/91	23/12/91	4	150	150	100.0	99.2		50	100																												
436	Reboxetine	13/11/91	28/11/91	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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PHARMACIA CNS RD

REBOXETINE - PROTOCOL 20124/017
Listing No.: 9.9

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 (**)
14/10	436	Reboxetine	29/11/91	29/11/91	1	8	4	50.0	97.1	1e	4	4	
			30/11/91	18/12/91	19	8	8	100.0	98.6		4	4	
			19/12/91	19/12/91	1	8	4	50.0	97.3	1m	4	4	
			20/12/91	20/12/91	1	8	8	100.0	97.4		4	4	
			21/12/91	21/12/91	1	8	4	50.0	96.2	1e	4	4	
			22/12/91	23/12/91	2	8	8	100.0	96.3		4	4	
					41								
437	Reboxetine	14/11/91	20/11/91	7	8	8	100.0	100.0		1e	4	4	
		21/11/91	21/11/91	1	8	4	50.0	93.8		4	4		
		22/11/91	08/12/91	17	8	8	100.0	98.0		4	4		
		09/12/91	09/12/91	1	8	4	50.0	96.2	1m	4	4		
		10/12/91	23/12/91	14	8	8	100.0	97.5		4	4		
							40						
438	Imipramine	15/11/91	17/11/91	3	100	100	100.0	100.0			50	50	
		18/11/91	02/12/91	15	150	150	100.0	100.0		50	100		
		03/12/91	03/12/91	1	150	100	66.7	98.2	1m	50	100		
		04/12/91	14/12/91	11	150	150	100.0	98.9		50	100		
		15/12/91	15/12/91	1	150	50	33.3	96.8	1e	50	100		
		16/12/91	27/12/91	12	150	150	100.0	97.7		50	100		
					43								
443	Reboxetine	19/11/91	04/12/91	16	8	8	100.0	100.0			4	4	
		05/12/91	05/12/91	1	8	4	50.0	97.1	1m	4	4		
		06/12/91	17/12/91	12	8	8	100.0	98.3		4	4		
		18/12/91	18/12/91	1	8	4	50.0	96.7	1m	4	4		
		19/12/91	19/12/91	1	8	8	100.0	96.8		4	4		
		20/12/91	20/12/91	1	8	4	50.0	95.3	1e	4	4		
21/12/91	24/12/91	4	8	8	100.0	95.8		4	4				
25/12/91	25/12/91	1	8	4	50.0	94.6	1e	4	4				
26/12/91	30/12/91	5	8	8	100.0	95.2		4	4				
					42								
444	Reboxetine	16/11/91	06/12/91	21	8	8	100.0	100.0			4	4	
		07/12/91	21/12/91	15	10	10	100.0	100.0		4	6		
		22/12/91	27/12/91	5	10	6	60.0	98.3	1m	4	6		
					5	10	10	100.0	99.0		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
 (**) 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 88D

REBOXETINE - PROTOCOL 20124/017
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	Z	Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)		
14/10	445	Imipramine	20/11/91	22/11/91	3	100	100	100.0			100.0		50	50			
			23/11/91	27/11/91	5	150	150	100.0			100.0		50	100			
			28/11/91	28/11/91	1	150	50	33.3			92.6	1e	50	50			
			29/11/91	10/12/91	12	150	150	100.0			96.8		50	100			
			11/12/91	12/12/91	2	200	200	100.0			97.1		100	100			
			13/12/91	13/12/91	1	200	100	50.0			95.1	1e	100	100			
			14/12/91	27/12/91	14	200	200	100.0			96.9		100	100			
			28/12/91	28/12/91	1	200	100	50.0			95.7	1m	100	100			
			29/12/91	30/12/91	2	200	200	100.0			95.9		100	100			
							41										
446	Reboxetine	26/11/91	27/11/91	2	8	8	100.0			100.0			4	4			
		28/11/91	28/11/91	1	8	4	50.0			83.3	1m	4	4				
		29/11/91	12/12/91	14	8	8	100.0			87.1		4	4				
		13/12/91	13/12/91	1	8	4	50.0			84.4	1e	4	4				
		14/12/91	24/12/91	11	8	8	100.0			96.6		4	4				
		25/12/91	25/12/91	1	8	4	50.0			95.0	1e	4	4				
		26/12/91	07/01/92	13	8	8	100.0			96.5		4	4				
						43											
		447	Reboxetine	27/11/91	08/12/91	12	8	8	100.0			100.0			4	4	
				09/12/91	09/12/91	1	8	4	50.0			96.2	1m	4	4		
10/12/91	17/12/91			8	8	8	100.0			97.6		4	4				
18/12/91	28/12/91			11	10	10	100.0			98.4		4	6				
29/12/91	29/12/91			1	10	6	60.0			97.3	1m	6	6				
30/12/91	07/01/92			9	10	10	100.0			97.9		4	6				
						42											
448	Imipramine			28/11/91	30/11/91	3	100	100	100.0			100.0			50	50	
				01/12/91	17/12/91	17	150	150	100.0			100.0		50	100		
				18/12/91	07/01/92	21	200	200	100.0			100.0		100	100		
453	Imipramine	28/05/92	30/05/92	3	100	100	100.0			100.0			50	50			
		31/05/92	11/06/92	12	150	150	100.0			100.0		50	100				
		12/06/92	12/06/92	1	150	50	33.3			95.8	4e	50	50				
						41											

(*) 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

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

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 (**)
14/10	453	Imipramine	13/06/92	08/07/92	26	150	150	100.0	96.4		50	100	
					42								
	454	Reboxetine	12/06/92	02/07/92	21	8	8	100.0	100.0		4	4	
			03/07/92	04/07/92	2	10	10	100.0	100.0		4	6	
			05/07/92	05/07/92	1	10	4	40.0	97.5	1a	4	4	
			06/07/92	23/07/92	18	10	10	100.0	98.6		4	6	
					42								
	455	Reboxetine	20/06/92	31/07/92	42	8	8	100.0	100.0		4	4	
					42								
15	349	Imipramine	20/08/92	20/08/92	1	100	50	100.0	100.0	9m	50	50	
			21/08/92	22/08/92	2	100	100	100.0	100.0		50	100	
			23/08/92	30/09/92	39	150	150	100.0	300.0		50	100	
			01/10/92	01/10/92	1	150	50	100.0	100.0	9a	50		
					43								
	351	Reboxetine	02/09/92	02/09/92	1	8	4	100.0	100.0	9m	4	4	
			03/09/92	13/10/92	41	8	8	100.0	100.0		4	4	
			14/10/92	14/10/92	1	8	4	100.0	100.0	9a	4		
					43								
	352	Imipramine	06/08/92	08/08/92	3	100	100	100.0	100.0		50	50	
			09/08/92	26/08/92	18	150	150	100.0	100.0		50	100	
			27/08/92	27/08/92	1	150	50	100.0	100.0	6a	50		
					22								
	364	Imipramine	29/07/92	29/07/92	1	100	50	100.0	100.0	9m	50	50	
			30/07/92	31/07/92	2	100	100	100.0	100.0		50	50	
			01/08/92	25/08/92	25	150	150	100.0	100.0		50	100	
			26/08/92	26/08/92	1	150	50	100.0	100.0	9a	50		
					29								
	366	Reboxetine	27/08/92	27/08/92	1	8	4	100.0	100.0	9m	4	4	
			28/08/92	07/10/92	41	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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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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 (**)
15	366	Reboxetine	08/10/92	08/10/92	1	8	4	100.0	100.0	9e	4		
					43								
367		Imipramine	31/08/92	02/09/92	3	100	100	100.0	100.0		50	50	
			03/09/92	11/10/92	39	150	150	100.0	100.0		50	100	
					42								
368		Reboxetine	04/09/92	01/10/92	28	8	8	100.0	100.0		4	4	
			02/10/92	15/10/92	14	10	10	100.0	100.0		4	6	
					42								
369		Reboxetine	10/07/92	20/08/92	42	8	8	100.0	100.0		4	4	
					42								
370		Imipramine	16/07/92	16/07/92	1	100	50	100.0	100.0			50	
			17/07/92	18/07/92	2	100	100	100.0	100.0		50	50	
			19/07/92	04/08/92	17	150	150	100.0	100.0	9m	50	200	
			05/08/92	05/08/92	1	150	250	100.0	100.0		50	200	
			06/08/92	06/08/92	1	150	300	100.0	100.0		100	200	
			07/08/92	09/08/92	3	150	350	100.0	100.0		150	200	
			10/08/92	10/08/92	1	150	250	100.0	100.0		150	100	
			11/08/92	26/08/92	16	150	150	100.0	100.0		50	100	
			27/08/92	27/08/92	1	150	50	100.0	100.0	9e	50		
					43								
371		Reboxetine	20/07/92	26/07/92	7	8	8	100.0	100.0		4	4	
			27/07/92	27/07/92	1	8	8	0.0	87.5	4m 4e	4	4	
			28/07/92	10/08/92	14	8	8	100.0	95.5		4	4	
			11/08/92	12/08/92	2	8	8	0.0	87.5	1m 1e			
			13/08/92	13/08/92	1	8	10	100.0	88.0	1m		10	
			14/08/92	30/08/92	17	8	18	100.0	92.9		8	10	
			31/08/92	31/08/92	1	8	8	100.0	93.0	9e	8		
					43								
372		Imipramine	17/06/92	17/06/92	1	100	50	100.0	100.0			50	
			18/06/92	19/06/92	2	100	100	100.0	100.0	9m	50	100	
			20/06/92	15/07/92	26	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 20124/017

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 (x)	Morning dose (mg)	Evening dose (mg)	Overdose (xx)
15	372	Imipramine	16/07/92	16/07/92	1	150	250	100.0	100.0		50	200	(3 - e)
			17/07/92	21/07/92	5	150	350	100.0	100.0		150	200	(3 - m)
			22/07/92	22/07/92	1	150	250	100.0	100.0		150	100	(3 - m)
			23/07/92	28/07/92	6	150	150	100.0	100.0	9e	50	100	
			29/07/92	29/07/92	1	150	50	100.0	100.0		50		
			43										
373	Imipramine	25/06/92	25/06/92	1	100	50	100.0	100.0	9m		50		
		26/06/92	26/06/92	1	100	50	100.0	100.0	6e				
374	Reboxetine	09/04/92	20/05/92	42	8	8	100.0	100.0			4	4	
		42											
375	Reboxetine	06/06/92	25/06/92	20	8	8	100.0	100.0			4	4	
		20											
376	Imipramine	13/04/92	15/04/92	3	100	100	100.0	100.0			50	50	
		16/04/92	20/04/92	5	150	150	100.0	100.0	6e		50	100	
		21/04/92	21/04/92	1	150	50	100.0	100.0			50		
377	Reboxetine	13/05/92	13/05/92	1	8	4	100.0	100.0	9m		4	4	
		14/05/92	02/06/92	20	8	8	100.0	100.0			4	4	
		03/06/92	03/06/92	1	8	4	100.0	100.0	9e		4	4	
		04/06/92	04/06/92	1	8	4	100.0	100.0			4	4	
		05/06/92	24/06/92	20	8	8	100.0	100.0	9e		4	4	
		25/06/92	25/06/92	1	8	4	100.0	100.0			4	4	
			44										
378	Reboxetine	15/06/92	15/06/92	1	8	4	100.0	100.0	9m		4	4	
		16/06/92	26/07/92	41	8	8	100.0	100.0	9e		4	4	
		27/07/92	27/07/92	1	8	4	100.0	100.0			4	4	
			43										
379	Imipramine	16/04/92	16/04/92	1	100	100	100.0	100.0			50	50	

(*) 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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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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 (**)		
15	379	Imipramine	17/04/92	17/04/92	1	100	50	100.0	100.0	6e	50				
					2										
380	Imipramine	30/06/92	02/07/92	02/07/92	3	100	100	100.0	100.0		50	50			
					17	150	150	100.0	100.0		50	100			
					9	350	350	100.0	100.0		150	200	(3 - m) (3 - e)		
					1	150	250	100.0	100.0		150	100	(3 - m)		
					12	150	150	100.0	100.0		50	100	(3 - m)		
42															
381	Reboxetine	21/05/92	01/07/92	01/07/92	42	8	8	100.0	100.0		4	4			
					42										
382	Imipramine	09/04/92	09/04/92	09/04/92	1	100	50	100.0	100.0		50	50			
					1	100	50	100.0	100.0						
383	Imipramine	07/07/92	07/07/92	07/07/92	1	100	50	100.0	100.0		50	50			
					2	100	100	100.0	100.0		50	100			
384	Reboxetine	28/07/92	28/07/92	28/07/92	1	8	4	100.0	100.0		4	4			
					7	8	8	100.0	100.0		4	4			
					1	8	4	100.0	100.0						
					9										
					43										
					1	150	150	100.0	100.0		50	100			
					11	150	250	100.0	100.0		50	200			
					6	150	350	100.0	100.0		150	200			
					1	150	350	100.0	100.0		150	200			
					6	150	350	100.0	100.0		150	200			
					1	150	350	100.0	100.0		150	200			
					6	150	350	100.0	100.0		150	200			
					1	150	250	100.0	100.0		150	200			
					6	150	150	100.0	100.0		50	100			

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(*) 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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PHARMACIA CNS R80
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 10.0
 ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given		Start treat. date	Patient	Patient	Randomized		Error (*)	
	Sequen. block	Treatment				Treatment	Sequen. block		
1	1	Reboxetine	05/02/91	1	1	Reboxetine	1		
	1	Reboxetine	26/02/91	2	2	Reboxetine	1		
	1	Imipramine	16/04/91	3	3	Imipramine	1		
	1	Imipramine	17/04/91	4	4	Imipramine	1		
	2	Reboxetine	17/07/91	5	5	Reboxetine	2		
	2	Imipramine	07/08/91	6	6	Imipramine	2		
	2	Reboxetine	09/10/91	7	7	Reboxetine	2		
	3	Imipramine	29/10/91	8	8	Imipramine	2		
	3	Imipramine	08/11/91	9	9	Imipramine	3		
	3	Imipramine	19/11/91	10	10	Imipramine	3		
	3	Reboxetine	06/04/92	11	11	Reboxetine	3		
	3	Reboxetine	15/04/92	12	12	Reboxetine	3		
	2	1	Reboxetine	19/12/90	33	33	Reboxetine	1	
		1	Imipramine	28/12/90	34	34	Imipramine	1	
1		Reboxetine	28/12/90	35	35	Reboxetine	1		
2		Imipramine	10/01/91	36	36	Imipramine	1		
2		Reboxetine	18/01/91	37	37	Reboxetine	2		
2		Imipramine	25/01/91	38	38	Imipramine	2		
3		Reboxetine	25/01/91	39	39	Reboxetine	2	*	
3		Imipramine	09/02/91	41	40	Imipramine	2	*	
2		Imipramine	20/02/91	42	41	Reboxetine	3		
3		Reboxetine	26/03/91	43	42	Imipramine	3		
3		Imipramine	11/04/91	44	43	Reboxetine	3		
4		Imipramine	30/04/91	45	44	Imipramine	3		
4		Reboxetine	16/05/91	46	45	Imipramine	4		
4		Reboxetine	22/05/91	47	46	Reboxetine	4		
5	Imipramine	29/08/91	48	47	Reboxetine	4			
5	Reboxetine	06/11/91	49	48	Imipramine	4			
5	Reboxetine	06/11/91	50	49	Imipramine	5			
5	Imipramine	06/11/91	51	50	Reboxetine	5			
5	Imipramine	27/11/91	52	51	Reboxetine	5			
3	1	Imipramine	01/03/91	69	69	Imipramine	1		
	2	Reboxetine	02/04/91	65	70	Reboxetine	1		
	2	Reboxetine	10/04/91	67	71	Imipramine	1	*	
	2	Imipramine	01/05/91	66	72	Reboxetine	1	*	
	1	Reboxetine	03/08/91	68	65	Reboxetine	2	*	
	1	Reboxetine	23/10/91	70	66	Imipramine	2	*	
	1	Imipramine	14/11/91	71	67	Reboxetine	2	*	
	3	Reboxetine	31/01/92	72	68	Imipramine	2	*	
	3	Reboxetine	15/02/92	73	73	Reboxetine	3	*	
	4	1	Imipramine	06/05/91	101	101	Imipramine	1	
		2	Imipramine	07/05/92	97	102	Reboxetine	1	*

(*) Assigned treatment different from randomized

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given		Patient	Patient	Randomized	Error (*)	
	Sequen. block	Treatment					Sequen. block
4	2	Reboxetine	100	103	Imipramine	1 *	
	1	Reboxetine	161	161	Reboxetine	1	
6	1	Reboxetine	162	162	Reboxetine	1	
	1	Imipramine	196	193	Reboxetine	1 *	
7	1	Reboxetine	194	194	Reboxetine	1	
	1	Reboxetine	193	195	Imipramine	1 *	
8	1	Imipramine	225	225	Imipramine	1	
	1	Reboxetine	226	226	Reboxetine	1	
	1	Imipramine	227	227	Imipramine	1	
	1	Reboxetine	228	228	Reboxetine	1	
	2	Imipramine	229	229	Imipramine	2	
	2	Imipramine	230	230	Imipramine	2	
	2	Reboxetine	231	231	Reboxetine	2	
	2	Reboxetine	232	232	Reboxetine	2	
	9	1	Reboxetine	257	257	Reboxetine	1
		1	Reboxetine	258	258	Reboxetine	1
1		Imipramine	259	259	Imipramine	1	
2		Imipramine	261	260	Imipramine	2 *	
2		Reboxetine	262	261	Imipramine	2 *	
1		Imipramine	260	262	Reboxetine	2	
2		Reboxetine	263	263	Reboxetine	2	
2		Imipramine	264	264	Imipramine	2	
3		Reboxetine	265	265	Reboxetine	3	
3		Imipramine	267	266	Reboxetine	3 *	
3		Reboxetine	266	267	Imipramine	3 *	
3		Imipramine	268	268	Imipramine	3	
4		Reboxetine	269	269	Reboxetine	4	
4		Imipramine	270	270	Imipramine	4	
4		Reboxetine	271	271	Reboxetine	4	
4		Imipramine	272	272	Imipramine	4	
5		Imipramine	273	273	Imipramine	5	
5	Reboxetine	274	274	Reboxetine	5		
5	Reboxetine	275	275	Reboxetine	5		
6	Imipramine	276	276	Imipramine	6		
6	Reboxetine	203	201	Imipramine	6 *		
6	Imipramine	202	202	Imipramine	6		
6	Reboxetine	202	203	Reboxetine	6		
7	Imipramine	204	204	Reboxetine	7		
7	Reboxetine	205	205	Imipramine	7		
7	Imipramine	206	206	Imipramine	7		
7	Reboxetine	207	207	Reboxetine	7		

(*) Assigned treatment different from randomized

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 10.0
 ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given		Start treat. date	Patient	Patient	Randomized		Error (*)
	Sequen.	Treatment				Sequen.	Treatment	
9	8	Imipramine	12/02/92	209	208	7	Reboxetine	*
	8	Reboxetine	14/02/92	211	209	8	Imipramine	*
	7	Reboxetine	15/02/92	208	210	8	Reboxetine	*
	8	Reboxetine	20/02/92	210	211	8	Reboxetine	
	8	Imipramine	04/03/92	212	212	8	Imipramine	
	9	Reboxetine	07/03/92	197	197	9	Reboxetine	
	9	Imipramine	18/03/92	198	198	9	Imipramine	
	9	Imipramine	02/04/92	199	199	9	Imipramine	
	10	Reboxetine	23/04/92	237	200	9	Reboxetine	
	9	Reboxetine	28/04/92	200	237	10	Reboxetine	
	10	Reboxetine	28/04/92	240	238	18	Imipramine	*
	10	Imipramine	30/04/92	239	239	10	Imipramine	
	11	Reboxetine	07/05/92	242	240	10	Reboxetine	
	11	Imipramine	09/05/92	241	241	11	Imipramine	
	11	Imipramine	18/05/92	243	242	11	Reboxetine	*
	10	Imipramine	20/05/92	258	243	11	Imipramine	
	11	Reboxetine	06/06/92	244	244	11	Reboxetine	
	5	Reboxetine	13/05/92	274/A	274	5	Reboxetine	
	5	Imipramine	04/03/92	276/A	276	5	Imipramine	
	9/A	1	Imipramine	05/03/92	301	301	1	Imipramine
1		Imipramine	06/03/92	302	302	1	Imipramine	
1		Reboxetine	12/03/92	303	303	1	Reboxetine	
1		Reboxetine	26/03/92	304	304	1	Reboxetine	
2		Reboxetine	31/03/92	305	305	2	Reboxetine	
2		Reboxetine	29/04/92	306	306	2	Reboxetine	
2		Imipramine	05/05/92	307	307	2	Imipramine	
2		Imipramine	09/05/92	308	308	2	Imipramine	
3		Imipramine	14/05/92	233	233	3	Imipramine	
3		Reboxetine	22/05/92	234	234	3	Reboxetine	
3		Reboxetine	26/05/92	235	235	3	Reboxetine	
3		Imipramine	27/05/92	236	236	3	Imipramine	
4		Reboxetine	10/06/92	277	277	4	Reboxetine	
4		Imipramine	13/06/92	278	278	4	Imipramine	
4		Imipramine	07/08/92	279	279	4	Imipramine	
4		Reboxetine	08/08/92	280	280	4	Reboxetine	
5	Reboxetine	01/09/92	281	281	5	Reboxetine		
5	Reboxetine	02/09/92	282	282	5	Reboxetine		
5	Imipramine	16/09/92	283	283	5	Imipramine		
5	Imipramine	19/09/92	284	284	5	Imipramine		
10	1	Imipramine	21/09/91	289	289	1	Imipramine	
	1	Reboxetine	14/10/91	290	290	1	Reboxetine	
	1	Reboxetine	13/12/91	292	291	1	Imipramine	*
	2	Reboxetine	24/12/91	293	292	1	Reboxetine	
	2	Imipramine	03/01/92	294	294	2	Reboxetine	*
	2	Imipramine	07/01/92	295	294	2	Imipramine	

(*): Assigned treatment different from randomized

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 10.0
ASSIGNED vs RANDOMIZED TREATMENT

Centro	Given		Start treat. date	Patient	Patient	Randomized		Error (*)	
	Sequen.	block				Treatment	Treatment		Sequen.
10	1	1	17/02/92	291	295	Imipramine	2		
	2	2	20/02/92	296	296	Reboxetine	2		
	3	3	21/03/92	297	297	Reboxetine	3		
	3	3	27/03/92	298	298	Reboxetine	3		
11	1	1	07/04/92	299	299	Imipramine	3		
	2	2	14/04/92	300	300	Imipramine	3		
	1	1	11/06/92	321	321	Reboxetine	1		
	1	1	11/06/92	322	322	Reboxetine	1		
12	1	1	24/06/92	323	323	Imipramine	1		
	1	1	17/07/92	324	324	Imipramine	1		
	2	2	30/07/92	325	325	Reboxetine	2		
	2	2	30/07/92	326	326	Imipramine	2		
	2	2	20/08/92	327	327	Reboxetine	2		
	2	2	20/08/92	328	328	Imipramine	2		
	3	3	21/08/92	329	329	Imipramine	3		
	3	3	24/08/92	330	330	Reboxetine	3		
	3	3	03/09/92	331	331	Reboxetine	3		
	4	4	04/09/92	333	332	Imipramine	3		
	3	3	05/09/92	332	333	Imipramine	4		
	13	1	1	26/05/92	337	337	Imipramine	1	
		1	1	20/06/92	338	338	Reboxetine	1	
1		1	23/06/92	339	339	Imipramine	1		
2		2	07/08/92	340	340	Reboxetine	1		
14	1	1	21/08/92	341	341	Reboxetine	2		
	1	1	05/06/92	353	353	Reboxetine	1		
	1	1	24/06/92	354	354	Imipramine	1		
	1	1	25/06/92	355	355	Reboxetine	1		
	1	1	22/07/92	356	356	Imipramine	1		
	2	2	05/08/92	357	357	Imipramine	2		
	2	2	06/08/92	358	358	Reboxetine	2		
	2	2	19/08/92	359	359	Reboxetine	2		
	2	2	19/08/92	360	360	Imipramine	2		
	3	3	26/08/92	361	361	Reboxetine	3		
15	1	1	07/07/92	457	457	Reboxetine	1		
	1	1	14/07/92	458	458	Imipramine	1		
	1	1	16/07/92	459	459	Reboxetine	1		
	1	1	23/07/92	460	460	Imipramine	1		
	2	2	29/07/92	461	461	Imipramine	2		
	2	2	31/07/92	462	462	Reboxetine	2		
16	2	2	03/08/92	463	463	Imipramine	2		
	2	2	05/08/92	464	464	Reboxetine	2		

(*) Assigned treatment different from randomized

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 10.0
ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given		Start treat. date	Patient	Patient	Randomized		Error (*)
	Sequen. block	Treatment				Treatment	Sequen. block	
14	3	Reboxetine	06/08/92	465	465	Reboxetine	3	
	3	Imipramine	07/08/92	466	466	Imipramine	3	
14/1	1	Reboxetine	05/09/91	426	426	Reboxetine	1	
	2	Imipramine	26/09/91	429	427	Imipramine	1	
	3	Reboxetine	28/11/91	451	428	Imipramine	1	
	4	Reboxetine	28/11/91	452	429	Imipramine	2	*
14/2	1	Imipramine	15/01/92	136	136	Imipramine	1	
	2	Imipramine	15/04/92	456	456	Imipramine	2	
14/3	1	Reboxetine	14/06/91	417	417	Reboxetine	1	
	1	Imipramine	18/06/91	418	418	Imipramine	1	
	1	Reboxetine	05/07/91	419	419	Reboxetine	1	
	1	Imipramine	05/07/91	420	420	Imipramine	1	
	2	Reboxetine	19/07/91	421	421	Reboxetine	2	
	3	Imipramine	18/09/91	427	422	Imipramine	2	
14/4	1	Imipramine	14/01/92	131	131	Imipramine	1	
	1	Imipramine	14/01/92	132	132	Imipramine	1	
	2	Imipramine	16/01/92	133	133	Imipramine	2	
	2	Reboxetine	16/01/92	134	134	Reboxetine	2	
	2	Reboxetine	17/01/92	135	135	Reboxetine	2	
	2	Reboxetine	17/01/92	135	135	Reboxetine	2	
14/7	1	Imipramine	04/09/91	422	422	Imipramine	1	
	1	Imipramine	17/09/91	423	423	Imipramine	1	
	1	Reboxetine	19/09/91	424	424	Reboxetine	1	
	2	Reboxetine	07/10/91	430	430	Reboxetine	2	
	2	Reboxetine	08/10/91	431	431	Reboxetine	2	
	2	Imipramine	08/10/91	432	432	Imipramine	2	
	3	Imipramine	08/10/91	433	433	Imipramine	3	
	3	Reboxetine	14/10/91	434	434	Reboxetine	3	
	4	Reboxetine	11/11/91	439	435	Reboxetine	3	*
	4	Imipramine	11/11/91	440	436	Imipramine	3	*
	5	Imipramine	11/11/91	441	439	Reboxetine	4	*
	5	Imipramine	11/11/91	442	440	Reboxetine	4	*
14/8	1	Reboxetine	09/09/91	425	425	Reboxetine	1	
	2	Reboxetine	10/01/92	430	426	Reboxetine	1	

(*) Assigned treatment different from randomized

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given		Start treat. date	Patient	Patient	Randomized		Error (%)
	Sequen.	Treatment				Treatment	Sequen. block	
14/8	3	Reboxetine	06/07/92	467	427	Imipramine	1	*
14/10	1	Imipramine	12/11/91	435	435	Imipramine	1	
	1	Reboxetine	13/11/91	436	436	Reboxetine	1	
	2	Reboxetine	14/11/91	437	437	Reboxetine	2	
	2	Imipramine	15/11/91	438	438	Imipramine	2	
	3	Reboxetine	16/11/91	444	439	Reboxetine	2	*
	3	Reboxetine	19/11/91	443	440	Imipramine	2	*
	4	Imipramine	20/11/91	445	443	Reboxetine	3	*
	4	Reboxetine	26/11/91	446	444	Imipramine	3	*
	4	Reboxetine	27/11/91	447	445	Reboxetine	4	*
	4	Imipramine	28/11/91	448	446	Reboxetine	4	*
	4	Reboxetine	28/01/92	137	447	Reboxetine	4	
	5	Imipramine	29/01/92	138	448	Imipramine	4	
	5	Reboxetine	04/02/92	139	137	Reboxetine	5	
	5	Imipramine	05/02/92	140	138	Imipramine	5	
	6	Reboxetine	25/02/92	53	139	Reboxetine	5	
	6	Imipramine	26/02/92	54	140	Imipramine	5	
	6	Reboxetine	28/02/92	55	53	Reboxetine	6	
	6	Imipramine	03/03/92	56	54	Imipramine	6	
7	Reboxetine	04/03/92	57	55	Reboxetine	6		
7	Imipramine	14/04/92	58	56	Imipramine	6		
7	Reboxetine	24/04/92	59	57	Reboxetine	7	*	
7	Imipramine	13/05/92	60	58	Imipramine	7	*	
8	Reboxetine	28/05/92	453	59	Imipramine	7		
8	Imipramine	12/06/92	454	60	Reboxetine	7	*	
8	Reboxetine	20/06/92	455	453	Imipramine	8	*	
15	1	Reboxetine	09/04/92	374	373	Imipramine	1	*
	2	Imipramine	09/04/92	382	374	Reboxetine	1	*
	3	Imipramine	13/04/92	376	375	Reboxetine	1	*
	3	Imipramine	16/04/92	379	376	Imipramine	1	
	2	Reboxetine	13/05/92	377	381	Reboxetine	2	*
	2	Reboxetine	21/05/92	381	382	Imipramine	2	*
	1	Reboxetine	06/06/92	375	383	Imipramine	2	*
	3	Reboxetine	15/06/92	378	384	Reboxetine	3	*
	4	Imipramine	17/06/92	372	377	Reboxetine	3	*
	1	Imipramine	23/06/92	373	378	Reboxetine	3	*
	2	Imipramine	30/06/92	380	379	Imipramine	3	
	2	Imipramine	07/07/92	383	380	Imipramine	3	
	4	Reboxetine	10/07/92	369	369	Reboxetine	4	
	4	Imipramine	16/07/92	370	370	Imipramine	4	
	4	Reboxetine	20/07/92	371	371	Reboxetine	4	
	2	Reboxetine	28/07/92	384	372	Imipramine	4	*
	5	Imipramine	25/07/92	364	364	Imipramine	5	
	6	Imipramine	06/08/92	352	349	Imipramine	6	*
6	Imipramine	20/08/92	349	350	Reboxetine	6	*	

(*) Assigned treatment different from randomized

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124-017
Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Sequen. block	Given		Start treat. date	Patient	Patient	Randomized		Error (*)
		Treatment	Treatment				Treatment	Sequen. block	
15	7	Reboxetine		27/08/92	366	351	Reboxetine	6	
	7	Imipramine		31/08/92	367	352	Imipramine	6	
	6	Reboxetine		02/09/92	351	366	Reboxetine	7	
	7	Reboxetine		04/09/92	368	367	Imipramine	7	*

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(*) Assigned treatment different from randomized

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PHARMACIA CNS R2D
REBOXETINE - PROTOCOL 20124/017
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
1	1	Male	Day 42	18/03/91	YES			Confirmed irregularities
	2	Female	Day 42	08/04/91	YES			As prescribed
	3	Female	Day 42	27/05/91	YES			As prescribed
	4	Male	Day 42	28/05/91	YES			As prescribed
	5	Female	Day 42	27/08/91	YES			As prescribed
	6	Male	Day 42	17/09/91	YES			As prescribed
	7	Male	Day 42	20/11/91	YES			As prescribed
	8	Male	Day 7	31/10/91	NO	Adverse event Patient uncooperative	Patient	As prescribed
	9	Female	Day 42	19/12/91	YES			As prescribed
	10	Female	Day 42	30/12/91	YES			As prescribed
	11	Male	Day 28	03/05/92	NO	Deterioration	Physician	As prescribed
	12	Male	Day 21	05/05/92	NO	Deterioration	Physician	As prescribed
2	33	Male	Day 42	29/01/91	YES			As prescribed
	34	Male	Day 42	03/02/91	NO	Intercurrent medical problem	Physician	As prescribed
	35	Male	Day 42	07/02/91	YES			As prescribed
	36	Female	Day 28	31/01/91	NO	Adverse event Deterioration	Physician	As prescribed
	37	Male	Day 42	28/02/91	YES			As prescribed

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PHARMACIA CNS R8D
REBOXETINE - PROTOCOL 20124/017
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	38	Female	Day 42	07/03/91	YES			As prescribed
	39	Female	Day 42	07/03/91	YES			As prescribed
	40	Male	Day 42	02/04/91	YES			As prescribed
	41	Male	Day 42	18/03/91	YES			As prescribed
	42	Male	Day 42	22/03/91	YES			As prescribed
	43	Female	Day 42	06/05/91	YES			As prescribed
	44	Male	Day 7	11/04/91	NO	Adverse event	Physician	As prescribed
	45	Female	Day 7	03/05/91	NO	Adverse event Deterioration	Patient	As prescribed
	46	Female	Day 42	26/06/91	YES			As prescribed
	47	Female	Day 42	02/07/91	YES			As prescribed
	48	Female	Day 42	07/10/91	YES			As prescribed
	49	Female	Day 42	09/10/91	YES		Patient	As prescribed
	50	Male	Day 42	15/12/91	NO	Death	Patient	As prescribed
	51	Female	Day 14	17/11/91	NO	Adverse event Deterioration	Physician	As prescribed
	52	Male	Day 42	07/01/92	YES			As prescribed
3	65	Male	Day 42	13/05/91	YES			As prescribed

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
3	66	Female	Day 42	05/06/91	NO	Deterioration	Physician	As prescribed
	67	Female	Day 42	21/05/91	YES			As prescribed
	68	Female	Day 42	13/09/91	YES			As prescribed
	69	Female	Day 42	11/04/91	YES			As prescribed
	70	Female	Day 28	19/11/91	NO	Patient uncooperative	Patient	As prescribed
	71	Female	Day 42	25/12/91	YES		Physician Patient	As prescribed
	72	Female	Day 42	12/03/92	YES			As prescribed
	73	Female	Day 42	27/03/92	YES			As prescribed
4	97	Male	Day 42	18/06/92	YES			As prescribed
	100	Female	Day 42	24/06/92	YES			As prescribed
	101	Female	Day 21	22/05/91	NO	Deterioration	Physician Patient	As prescribed
6	161	Male	Day 42	09/05/91	YES			As prescribed
	162	Female	Day 42	16/12/91	YES			As prescribed
7	193	Female	Day 7	17/06/91	NO	Protocol violation Patient uncooperative	Patient	Unknown
	194	Male	Day 7	06/06/91	NO	Adverse event	Physician	As prescribed
	196	Female	Day 42	26/04/91	NO	Adverse event	Physician	As prescribed

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PHARMACIA CNS R&D
 RESOXETINE - PROTOCOL 20124/017
 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	225	Female	Day 21	09/04/91	NO	Lost to follow up	Patient	As prescribed	
	226	Female	Day 42	13/06/91	YES			As prescribed	
	227	Male	Day 42	17/06/91	YES			Suspected irregularities	
	228	Male	Day 14	17/05/91	NO	Patient uncooperative	Patient	As prescribed	
	229	Female	Day 42	02/12/91	YES			As prescribed	
	230	Female	Day 42	16/12/91	YES			As prescribed	
	231	Female	Day 14	13/11/91	NO	Protocol violation	Physician	As prescribed	
	232	Male	Day 42	09/01/92	YES			As prescribed	
	9	197	Male	Day 7	10/05/92	NO	Adverse event Patient uncooperative	Patient	Confirmed irregularities
		198	Female	Day 42	28/04/92	YES			As prescribed
199		Male	Day 42	13/05/92	YES			As prescribed	
200		Male	Day 42	08/06/92	YES			As prescribed	
201		Female	Day 42	26/02/92	YES			As prescribed	
202		Male	Day 42	27/02/92	YES			As prescribed	
203		Female	Day 7	18/01/92	NO	Deterioration	Patient	Suspected irregularities	
204		Male	Day 42	28/02/92	YES			As prescribed	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
9	205	Female	Day 7	07/02/92	NO	Lost to follow up Patient uncooperative	Patient	Confirmed irregularities
	206	Female	Day 42	18/03/92	YES			As prescribed
	207	Female	Day 7	12/02/92	NO	Deterioration Patient uncooperative	Physician	As prescribed
	208	Male	Day 42	27/03/92	YES			As prescribed
	209	Male	Day 7	15/02/92	NO	Adverse event Patient uncooperative	Patient	As prescribed
	210	Female	Day 42	01/04/92	YES			As prescribed
	211	Female	Day 21	02/03/92	NO	Deterioration	Physician	As prescribed
	212	Female	Day 42	14/04/92	YES			As prescribed
	237	Male	Day 14	02/05/92	NO	Adverse event	Physician	As prescribed
	238	Female	Day 42	30/06/92	YES			As prescribed
	239	Male	Day 42	10/06/92	YES			As prescribed
	240	Female	Day 21	16/05/92	NO	Patient uncooperative	Patient	Suspected irregularities
	241	Female	Day 42	19/06/92	YES			As prescribed
	242	Male	Day 42	17/06/92	YES			As prescribed
	243	Female	Day 42	28/06/92	YES			As prescribed
	244	Male	Day 42	17/07/92	YES			As prescribed

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	257	Female	Day 42	27/08/91	YES			As prescribed
	258	Male	Day 21	06/08/91	NO	Deterioration	Physician	As prescribed
	259	Female	Day 42	27/08/91	YES			As prescribed
	260	Female	Day 21	12/08/91	NO	Deterioration	Physician	As prescribed
	261	Female	Day 7	29/07/91	NO	Adverse event	Physician	As prescribed
	262	Male	Day 42	03/09/91	YES			As prescribed
	263	Female	Day 14	13/08/91	NO	Patient uncooperative	Physician	As prescribed
	264	Female	Day 42	10/09/91	YES			As prescribed
	265	Female	Day 42	03/10/91	YES			As prescribed
	266	Female	Day 42	29/10/91	YES			As prescribed
	267	Male	Day 42	13/10/91	YES			As prescribed
	268	Female	Day 42	05/11/91	YES			As prescribed
	269	Male	Day 42	05/11/91	YES			As prescribed
	270	Female	Day 7	17/10/91	NO	Adverse event	Physician	As prescribed
	271	Female	Day 28	20/11/91	NO	Adverse event	Physician	As prescribed
	272	Male	Day 42	10/12/91	YES			As prescribed
	273	Female	Day 28	20/11/91	NO	Adverse event	Physician	As prescribed

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PHARMACIA CNS RED
 REBORERINE - PROTOCOL 20124/017
 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	274	Female	Day 7	31/10/91	NO	Patient uncooperative	Physician	As prescribed
	274/A	Female	Day 42	23/06/92	YES			As prescribed
	275	Female	Day 42	17/12/91	YES			As prescribed
	276	Female	Day 7	14/01/92	NO	Intercurrent medical problem Deterioration	Patient	As prescribed
	276/A	Male	Day 42	14/04/92	YES			As prescribed
9/A	283	Male	Day 42	24/06/92	YES			As prescribed
	284	Female	Day 42	02/07/92	YES			As prescribed
	285	Male	Day 35	29/06/92	NO	Deterioration	Patient	As prescribed
	286	Male	Day 42	07/07/92	YES			As prescribed
	277	Female	Day 7	14/06/92	NO	Adverse event	Patient	Confirmed irregularities
	278	Female	Day 21	03/07/92	NO	Deterioration	Patient	As prescribed
	279	Male	Day 14	21/08/92	NO	Deterioration	Patient	As prescribed
	280	Female	Day 7	14/08/92	NO	Adverse event	Patient	As prescribed
	281	Female	Day 42	12/10/92	YES			As prescribed
	282	Male	Day 42	13/10/92	YES			As prescribed
	283	Female	Day 42	28/10/92	YES			As prescribed
	284	Male	Day 21	09/10/92	NO	Deterioration	Patient	As prescribed

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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/A	301	Female	Day 42	15/04/92	YES			As prescribed
	302	Male	Day 21	22/03/92	NO	Patient uncooperative	Patient	As prescribed
	303	Female	Day 21	31/03/92	NO	Patient uncooperative	Patient	As prescribed
	304	Female	Day 42	06/05/92	YES			As prescribed
	305	Male	Day 42	11/05/92	YES			As prescribed
	306	Female	Day 42	09/06/92	YES			As prescribed
	307	Female	Day 7	05/05/92	NO	Adverse event	Patient	As prescribed
	308	Female	Day 28	02/06/92	NO	Adverse event Deterioration	Patient	As prescribed
10	289	Female	Day 7	27/09/91	NO	Deterioration Patient uncooperative	Physician	As prescribed
	290	Male	Day 42	24/11/91	YES			As prescribed
	291	Male	Day 42	29/03/92	YES			As prescribed
	292	Female	Day 42	23/01/92	YES			As prescribed
	293	Female	Day 42	01/02/92	YES			Confirmed irregularities
	294	Female	Day 21	23/01/92	NO	Patient uncooperative	Patient Others	As prescribed
	295	Male	Day 42	17/02/92	YES			As prescribed
	296	Female	Day 42	01/04/92	YES			As prescribed

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	
10	297	Male	Day 42	02/05/92	YES			As prescribed	
	298	Female	Day 42	07/05/92	YES			As prescribed	
	299	Male	Day 42	18/05/92	YES			As prescribed	
	300	Female	Day 42	25/05/92	YES			As prescribed	
	11	321	Female	Day 42	23/07/92	YES			As prescribed
		322	Female	Day 42	24/07/92	YES			As prescribed
		323	Female	Day 42	06/08/92	YES			As prescribed
		324	Male	Day 42	28/08/92	YES			As prescribed
		325	Female	Day 42	10/09/92	YES			As prescribed
		326	Male	Day 42	10/09/92	YES			As prescribed
327		Female	Day 42	01/10/92	YES			As prescribed	
328		Male	Day 28	17/09/92	NO	Other	Physician Patient	As prescribed	
329		Female	Day 42	02/10/92	YES			As prescribed	
330		Female	Day 7	26/08/92	NO	Adverse event	Patient	As prescribed	
331	Male	Day 42	15/10/92	YES			As prescribed		
332	Female	Day 42	20/10/92	YES			As prescribed		

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PHARMACIA CNS R&D
 REBOXETINE – PROTOCOL 20124/017
 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
11	333	Female	Day 42	16/10/92	YES			As prescribed
12	337	Female	Day 42	06/07/92	YES			As prescribed
	338	Female	Day 42	31/07/92	YES			As prescribed
	339	Male	Day 42	03/08/92	YES			As prescribed
	340	Female	Day 42	17/09/92	YES			As prescribed
	341	Female	Day 35	24/09/92	NO	Protocol violation Deterioration	Physician	Confirmed irregularities
13	353	Female	Day 35	07/07/92	NO	Adverse event	Physician Patient	As prescribed
	354	Female	Day 42	04/08/92	YES			As prescribed
	355	Female	Day 7	27/06/92	NO	Adverse event	Physician Patient	As prescribed
	356	Male	Day 42	01/09/92	YES			As prescribed
	357	Female	Day 7	09/08/92	NO	Adverse event	Patient	As prescribed
	358	Male	Day 35	05/09/92	NO	Adverse event	Patient	As prescribed
	359	Female	Day 42	29/09/92	YES			As prescribed
	360	Female	Day 7	21/08/92	NO	Adverse event	Patient	As prescribed
	361	Female	Day 42	06/10/92	YES			As prescribed
14	457	Female	Day 42	17/08/92	YES			As prescribed

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PHARMACIA CHS R&D
REBORETINE - PROTOCOL 20124-017
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
14	458	Female	Day 42	24/08/92	YES			As prescribed
	459	Male	Day 42	26/08/92	YES			As prescribed
	460	Male	Day 42	02/09/92	YES			As prescribed
	461	Female	Day 42	08/09/92	YES			Confirmed irregularities
	462	Female	Day 42	10/09/92	YES			As prescribed
	463	Male	Day 42	13/09/92	YES			As prescribed
	464	Female	Day 42	16/09/92	YES			Confirmed irregularities
	465	Male	Day 42	16/09/92	YES			As prescribed
	466	Female	Day 42	17/09/92	YES			As prescribed
14/1	129	Male	Day 7	19/12/91	NO	Adverse event	Physician	As prescribed
	426	Female	Day 42	17/10/91	YES			As prescribed
	429	Female	Day 7	29/09/91	NO	Adverse event	Patient	Suspected irregularities
	451	Male	Day 42	07/01/92	YES			As prescribed
	452	Female	Day 42	09/01/92	YES			As prescribed
14/2	136	Female	Day 42	25/02/92	YES			As prescribed
	456	Male	Day 42	26/05/92	YES			As prescribed
14/3	417	Female	Day 42	26/07/91	YES			As prescribed

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
14/3	418	Female	Day 42	29/07/91	YES			As prescribed
	419	Female	Day 42	15/08/91	YES			As prescribed
	420	Female	Day 21	25/07/91	NO	Patient uncooperative	Patient	As prescribed
	421	Female	Day 42	12/09/91	NO	Other		As prescribed
	427	Female	Day 28	15/10/91	NO	Adverse event Patient uncooperative	Patient	As prescribed
	428	Female	Day 42	05/12/91	YES			As prescribed
14/4	431	Female	Day 42	24/02/92	YES			As prescribed
	432	Female	Day 42	24/02/92	YES			As prescribed
	433	Female	Day 42	26/02/92	YES			As prescribed
	434	Female	Day 42	26/02/92	YES			As prescribed
	435	Male	Day 42	27/02/92	YES			As prescribed
14/7	422	Female	Day 42	15/10/91	YES			As prescribed
	423	Female	Day 42	28/10/91	YES			As prescribed
	424	Male	Day 42	30/10/91	YES			As prescribed
	430	Female	Day 42	17/11/91	YES			As prescribed
	431	Male	Day 42	18/11/91	YES			As prescribed
	432	Male	Day 42	18/11/91	YES			As prescribed

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PHARMACIA CNS R6D
 REMOXETINE - PROTOCOL 20124/017
 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
14/7	433	Female	Day 42	18/11/91	YES			As prescribed
	434	Male	Day 42	24/11/91	YES			As prescribed
	439	Male	Day 42	22/12/91	YES			As prescribed
	440	Female	Day 42	22/12/91	YES			As prescribed
	441	Male	Day 42	22/12/91	YES			As prescribed
	442	Male	Day 42	22/12/91	YES			As prescribed
	449	Female	Day 42	30/01/92	YES			As prescribed
	450	Male	Day 42	02/02/92	YES			As prescribed
14/8	130	Male	Day 42	20/02/92	YES			As prescribed
	425	Female	Day 42	20/10/91	YES			As prescribed
	467	Male	Day 42	16/08/92	YES			As prescribed
14/10	53	Male	Day 42	06/04/92	YES			Confirmed irregularities
	54	Female	Day 42	07/04/92	YES			Confirmed irregularities
	55	Female	Day 42	09/04/92	YES			Confirmed irregularities
	56	Female	Day 42	13/04/92	YES			Confirmed irregularities
	57	Female	Day 42	14/04/92	YES			Suspected irregularities
	58	Female	Day 42	25/05/92	YES			Confirmed irregularities

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PHARMACIA CNS R&D
 REBONEXINE - PROTOCOL 20124/017
 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
14/10	59	Female	Day 42	04/06/92	YES			As prescribed
	60	Female	Day 42	23/06/92	YES			As prescribed
	137	Female	Day 42	09/03/92	YES			As prescribed
	138	Female	Day 42	10/03/92	YES			Confirmed irregularities
	139	Female	Day 42	16/03/92	YES			Confirmed irregularities
	140	Female	Day 42	17/03/92	YES			As prescribed
	435	Female	Day 42	23/12/91	YES			As prescribed
	436	Female	Day 42	23/12/91	YES			As prescribed
	437	Female	Day 42	23/12/91	YES			As prescribed
	438	Female	Day 42	27/12/91	YES			As prescribed
	443	Female	Day 42	30/12/91	YES			As prescribed
	444	Male	Day 42	27/12/91	YES			Confirmed irregularities
	445	Female	Day 42	30/12/91	YES			As prescribed
	446	Female	Day 42	07/01/92	YES			Confirmed irregularities
	447	Male	Day 42	07/01/92	YES			Confirmed irregularities
	448	Female	Day 42	07/01/92	YES			Confirmed irregularities
	453	Female	Day 42	08/07/92	YES			As prescribed

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PHARMACIA CNS R3D
 REBOXETINE - PROTOCOL 20124/017
 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
14/10	454	Female	Day 42	23/07/92	YES			As prescribed
	455	Female	Day 42	31/07/92	YES			As prescribed
15	349	Male	Day 42	01/10/92	YES			As prescribed
	351	Male	Day 42	14/10/92	YES			As prescribed
	352	Male	Day 21	27/08/92	NO	Lost to follow up	Patient	As prescribed
	364	Female	Day 28	26/08/92	NO	Patient uncooperative	Physician	As prescribed
	366	Male	Day 42	08/10/92	YES			As prescribed
	367	Male	Day 42	11/10/92	YES			As prescribed
	368	Female	Day 42	15/10/92	YES			As prescribed
	369	Female	Day 42	20/08/92	YES			As prescribed
	370	Female	Day 42	27/08/92	YES			As prescribed
	371	Female	Day 42	31/08/92	YES			As prescribed
	372	Male	Day 42	29/07/92	YES			As prescribed
	373	Female	Day 7	26/06/92	NO	Protocol violation	Physician	As prescribed
	374	Female	Day 42	20/05/92	YES			As prescribed
	375	Female	Day 21	25/06/92	NO	Protocol violation	Physician	As prescribed
	376	Female	Day 14	21/04/92	NO	Adverse event	Physician	As prescribed

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PHARMACIA CNS R&D
 REROXETINE - PROTOCOL 20124/017
 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	376	Female	Day 14	21/04/92	NO	Deterioration		
	377	Female	Day 42	25/06/92	YES			As prescribed
	378	Female	Day 42	27/07/92	YES			As prescribed
	379	Female	Day 7	17/04/92	NO	Adverse event	Patient	As prescribed
	380	Female	Day 42	10/08/92	YES			As prescribed
	381	Female	Day 42	01/07/92	YES			As prescribed
	382	Male	Day 7	10/04/92	NO	Adverse event	Patient	As prescribed
	383	Female	Day 42	18/08/92	YES			As prescribed
	384	Female	Day 14	05/08/92	NO	Protocol violation	Physician	As prescribed

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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		
1	1	Male	01. DEPRESSED MOOD	3	3	4	3	2	3	2	2		
			02. GUILT	1	1	2	0	0	0	1	1	1	
			03. SUICIDE	1	0	1	0	0	0	0	0	0	0
			04. INSOMNIA EARLY	0	0	1	0	0	0	0	0	0	0
			05. INSOMNIA MIDDLE	2	2	2	2	1	1	1	1	0	0
			06. INSOMNIA LATE	2	2	2	2	1	0	0	0	0	0
			07. WORK AND ACTIVITIES	4	4	4	4	4	4	4	4	4	3
			08. RETARDATION	2	2	2	1	0	2	2	2	2	1
			09. AGITATION	0	0	0	0	0	0	0	0	0	0
			10. ANXIETY PSYCHIC	2	1	2	1	1	1	2	1	1	1
			11. ANXIETY SOMATIC	1	2	1	1	0	2	2	2	2	0
			12. SOMATIC GASTROINTESTINAL	2	1	2	2	1	1	1	1	1	0
			13. SOMATIC GENERAL	2	1	2	0	1	1	1	2	1	0
			14. GENITAL SYMPTOMS	1	1	1	1	1	1	1	2	1	0
			15. HYPOCHONDRIASIS	1	2	1	0	0	0	0	1	1	0
			16. LOSS OF WEIGHT	1	1	1	0	0	0	0	0	0	0
			17. INSIGHT	0	0	1	0	0	0	0	0	0	0
			18. DIURNAL VARIATION	1	4	2	1	1	1	1	1	1	1
			19. DEPERSONALIZATION	1	1	2	0	0	0	2	1	1	1
			20. PARANOID	0	0	0	0	0	0	0	0	0	0
			21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	0	0
			22. Total score	27	27	34	18	14	27	19	19	13	
2	2	Female	01. DEPRESSED MOOD	3	3	3	3	2	0	0	0		
			02. GUILT	1	1	1	1	1	0	0	0	0	
			03. SUICIDE	2	2	1	1	0	0	0	0	0	0
			04. INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	0
			05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	0	0
			06. INSOMNIA LATE	1	1	2	2	2	0	1	0	0	0
			07. WORK AND ACTIVITIES	4	4	4	4	4	3	1	1	0	0
			08. RETARDATION	2	2	2	2	1	0	0	0	0	0
			09. AGITATION	1	1	1	1	1	1	0	0	0	0
			10. ANXIETY PSYCHIC	3	3	2	2	2	1	0	2	1	0
			11. ANXIETY SOMATIC	2	2	2	2	2	2	1	1	0	0
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	0	0	0	0
			13. SOMATIC GENERAL	2	2	2	2	1	1	1	1	1	1
			14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0
			15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0
			16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0
			17. INSIGHT	0	0	0	0	0	0	0	0	0	0
			18. DIURNAL VARIATION	2	2	2	2	2	1	0	0	0	0
			19. DEPERSONALIZATION	3	3	1	1	1	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	32	32	26	26	19	4	6	1		
3	3	Female	01. DEPRESSED MOOD	3	3	3	2	2	0	0	0		
			02. GUILT	2	2	0	1	0	0	0	0	0	
			03. SUICIDE	1	1	0	0	0	0	0	0	0	
			04. INSOMNIA EARLY	0	2	0	0	0	0	1	1	0	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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				
1	3	Imipramine	Female	05. INSOMNIA MIDDLE	2	2	1	0	0	1	0	0				
				06. INSOMNIA LATE	2	2	2	1	0	0	0					
				07. WORK AND ACTIVITIES	4	4	4	4	3	3	1					
				08. RETARDATION	2	1	1	1	0	0	0					
				09. AGITATION	1	0	2	1	1	0	0					
				10. ANXIETY PSYCHIC	2	3	2	2	2	1	1					
				11. ANXIETY SOMATIC	3	2	2	2	1	0	0					
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	0	0	0					
				13. SOMATIC GENERAL	2	2	2	2	1	1	0					
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	0					
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0					
				16. LOSS OF WEIGHT	2	2	2	1	0	0	0					
				17. INSIGHT	0	0	0	0	0	0	0					
				18. DIURNAL VARIATION	0	1	1	1	1	1	1					
				19. DEPERSONALIZATION	2	1	1	0	1	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	30	25	20	13	9	5	3				
				4		Imipramine	Male	01. DEPRESSED MOOD	3	3	3	3	3	2	2	0
								02. GUILT	1	1	1	2	1	0	0	
								03. SUICIDE	1	1	1	0	1	0	0	
								04. INSOMNIA EARLY	0	1	1	0	0	0	0	
05. INSOMNIA MIDDLE	1	2	2					2	1	1	0					
06. INSOMNIA LATE	2	2	2					2	2	1	1					
07. WORK AND ACTIVITIES	4	4	4					4	4	3	3					
08. RETARDATION	1	2	2					2	0	0	0					
09. AGITATION	0	0	2					2	0	0	0					
10. ANXIETY PSYCHIC	3	2	3					1	2	1	0					
11. ANXIETY SOMATIC	1	2	2					2	1	1	0					
12. SOMATIC GASTROINTESTINAL	1	1	1					1	1	1	0					
13. SOMATIC GENERAL	2	2	2					2	2	1	1					
14. GENITAL SYMPTOMS	0	0	0					0	0	0	0					
15. HYPOCHONDRIASIS	0	0	2					2	2	0	0					
16. LOSS OF WEIGHT	0	0	0					1	0	0	0					
17. INSIGHT	0	0	1					1	1	1	1					
18. DIURNAL VARIATION	1	1	1					1	1	1	0					
19. DEPERSONALIZATION	1	1	2					1	1	0	0					
20. PARANOIA	0	0	0					0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0					
22. Total score	23	26	33					28	24	13	10	2				
5		Reboxetine	Female	01. DEPRESSED MOOD	3	3	1	2	2	2	2	2				
				02. GUILT	1	2	0	1	0	1	0					
				03. SUICIDE	1	1	0	0	0	0	0					
				04. INSOMNIA EARLY	0	0	2	0	0	1	0					
				05. INSOMNIA MIDDLE	2	2	0	1	1	0	1					
				06. INSOMNIA LATE	2	2	2	2	2	2	1					
				07. WORK AND ACTIVITIES	4	4	2	4	3	4	3					
				08. RETARDATION	2	2	0	2	0	1	0					

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	1	2	2	1	2	2	0	0				
				10. ANXIETY PSYCHIC	1	1	0	1	1	1	1					
				11. ANXIETY SOMATIC	1	1	0	0	0	1	0					
				12. SOMATIC GASTROINTESTINAL	1	1	0	1	1	1	1					
				13. SOMATIC GENERAL	2	2	1	1	1	2	2					
				14. GENITAL SYMPTOMS	2	2	1	1	2	2	1					
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0					
				16. LOSS OF WEIGHT	1	1	0	1	0	0	0					
				17. INSIGHT	0	0	0	0	0	0	0					
				18. DIURNAL VARIATION	2	2	1	2	2	1	1					
				19. DEPERSONALIZATION	2	2	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	30	12	20	16	21	14					
				6	6	Imipramine	Male	01. DEPRESSED MOOD	4	4	3	2	3	2	1	1
								02. GUILT	1	1	1	1	1	0	0	
								03. SUICIDE	1	1	1	1	1	1	0	
								04. INSOMNIA EARLY	2	2	2	0	0	1	1	
								05. INSOMNIA MIDDLE	2	2	1	1	1	1	1	
								06. INSOMNIA LATE	2	2	2	2	2	2	1	
								07. WORK AND ACTIVITIES	4	4	4	4	2	1	1	
								08. RETARDATION	0	0	0	0	1	1	0	
09. AGITATION	3	2	2					3	1	1	1					
10. ANXIETY PSYCHIC	3	2	2					1	2	1	1					
11. ANXIETY SOMATIC	1	1	1					1	1	1	1					
12. SOMATIC GASTROINTESTINAL	3	2	2					1	2	2	2					
13. SOMATIC GENERAL	2	2	2					2	1	1	1					
14. GENITAL SYMPTOMS	0	0	0					0	0	0	0					
15. HYPOCHONDRIASIS	0	0	2					0	0	0	0					
16. LOSS OF WEIGHT	0	0	0					0	0	0	0					
17. INSIGHT	1	1	0					0	0	0	0					
18. DIURNAL VARIATION	2	2	2					2	2	2	2					
19. DEPERSONALIZATION	2	2	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	33	30	26					22	18	17	13					
7	7	Reboxetine	Male	01. DEPRESSED MOOD	3	3	3	3	2	3	3	2				
				02. GUILT	1	1	2	2	1	0	1					
				03. SUICIDE	2	2	2	2	1	1	1					
				04. INSOMNIA EARLY	1	1	2	0	0	1	0					
				05. INSOMNIA MIDDLE	2	2	2	1	1	1	0					
				06. INSOMNIA LATE	2	2	2	2	2	2	2					
				07. WORK AND ACTIVITIES	4	4	4	4	4	3	4					
				08. RETARDATION	1	1	0	1	0	0	0					
				09. AGITATION	0	0	0	2	1	1	2					
				10. ANXIETY PSYCHIC	0	0	3	3	2	1	2					
				11. ANXIETY SOMATIC	3	3	3	2	1	1	1					
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1					

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 REBOXETINE - PROTOCOL 20124/017
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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			
1	7	Male	13. SOMATIC GENERAL	2	2	2	2	2	2	2	2			
			14. GENITAL SYMPTOMS	2	2	1	1	1	1	2	2			
			15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0		
			16. LOSS OF HEIGHT	0	0	2	0	0	2	2	2	2		
			17. INSIGHT	0	0	0	0	0	0	0	0	1		
			18. DIURNAL VARIATION	2	2	2	2	1	1	2	2	2		
			19. DEPERSONALIZATION	2	2	2	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	0	0	0	0		
			22. Total score	31	31	34	24	19	21	25	27			
			8	8	Male	01. DEPRESSED MOOD	3	3	3					
						02. GUILT	1	2	1					
						03. SUICIDE	3	3	3					
						04. INSOMNIA EARLY	1	1	0					
						05. INSOMNIA MIDDLE	2	2	2					
						06. INSOMNIA LATE	2	2	2					
						07. WORK AND ACTIVITIES	4	4	4					
						08. RETARDATION	0	1	1					
						09. AGITATION	2	1	0					
						10. ANXIETY PSYCHIC	1	2	2					
						11. ANXIETY SOMATIC	1	1	2					
						12. SOMATIC GASTROINTESTINAL	0	0	1					
13. SOMATIC GENERAL	2	2				2								
14. GENITAL SYMPTOMS	0	0				0								
15. HYPOCHONDRIASIS	0	0				0								
16. LOSS OF HEIGHT	0	0				0								
17. INSIGHT	1	1				1								
18. DIURNAL VARIATION	1	1				1								
19. DEPERSONALIZATION	1	1				2								
20. PARANOID	0	0				0								
21. OBSESSIONAL/COMPULSIVE	0	0				0								
22. Total score	27	29				29								
9	9	Female	01. DEPRESSED MOOD	3	3	3	2	2	2	0	0			
			02. GUILT	1	1	1	0	0	0	0	0			
			03. SUICIDE	1	1	1	0	0	0	0	0			
			04. INSOMNIA EARLY	1	0	0	0	0	0	0	0			
			05. INSOMNIA MIDDLE	0	0	1	0	0	0	0	0			
			06. INSOMNIA LATE	0	0	0	0	0	0	0	0			
			07. WORK AND ACTIVITIES	4	4	4	3	2	2	1	0			
			08. RETARDATION	2	2	2	0	0	0	0	0			
			09. AGITATION	0	0	0	0	0	0	0	0			
			10. ANXIETY PSYCHIC	2	2	2	1	1	1	0	0			
			11. ANXIETY SOMATIC	2	2	1	1	0	0	0	0			
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	0	0	0	0			
			13. SOMATIC GENERAL	2	2	2	2	2	2	1	0			
			14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	1			
			15. HYPOCHONDRIASIS	0	0	1	0	0	0	0	0			
			16. LOSS OF HEIGHT	0	0	0	0	0	0	0	0			

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	Imipramine	Female	17.INSIGHT	1	1	1	1	1	1	1	1	1	1	1	0	0	0
				18.DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	2	1	0	0	0
				19.DEPERSONALIZATION	2	2	2	2	2	2	2	2	2	2	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	24	15	11	10	3	1						
10		Imipramine	Female	01.DEPRESSED MOOD	3	3	3	2	2	2	2	2	2	2	2	2	1	1
				02.GUILT	1	1	1	1	1	1	1	1	1	1	1	0	0	0
				03.SUICIDE	1	1	0	0	0	0	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	1	1	2	2	2	2	2	2	2	2	2	2
				05.INSOMNIA MIDDLE	1	2	1	1	1	1	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	2	2	2	2	2	2	2	2	2	2	2
				08.RETARDATION	2	2	1	0	0	0	0	0	0	0	0	0	0	0
				09.AGITATION	4	4	0	0	0	1	2	1	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	3	3	1	3	2	2	2	2	2	2	2	2	1	0
				11.ANXIETY SOMATIC	3	3	2	2	2	2	2	2	2	2	2	2	1	0
				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 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	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	19	16	20	24	18	13						
11		Reboxetine	Male	01.DEPRESSED MOOD	4	4	4	3	3	3	3	3	3	3	3	3	3	3
				02.GUILT	2	2	1	2	1	2	1	2	1	2	2	2	2	2
				03.SUICIDE	1	1	1	1	1	1	0	2	2	2	2	2	2	2
				04.INSOMNIA EARLY	2	2	1	2	0	2	0	2	2	2	2	2	2	2
				05.INSOMNIA MIDDLE	1	1	1	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	4	4	4	4	4	4	4	4	4	4	4	4	4	4
				08.RETARDATION	2	2	1	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
				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	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				15.HYPOCHONDRIASIS	2	2	1	2	2	2	2	2	2	2	2	2	2	2
				16.LOSS OF WEIGHT	2	2	2	0	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	0	0	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	2	2	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

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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	Reboxetine	Male	21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. total score	36	33	34	33	33	26	39							
12		Reboxetine	Male	01. DEPRESSED MOOD	3	3	2	3	3	3								
				02. GUILT	1	0	2	1	1	2								
				03. SUICIDE	0	0	1	0	1	1								
				04. INSOMNIA EARLY	2	2	2	1	1	1								
				05. INSOMNIA MIDDLE	2	2	1	1	1	1								
				06. INSOMNIA LATE	2	2	2	2	2	2								
				07. WORK AND ACTIVITIES	4	4	4	4	4	4								
				08. RETARDATION	1	1	1	0	2	2								
				09. AGITATION	0	0	1	1	0	0								
				10. ANXIETY PSYCHIC	2	2	1	1	0	2								
				11. ANXIETY SOMATIC	2	1	2	1	1	2								
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1								
				13. SOMATIC GENERAL	2	2	1	1	1	1								
				14. GENITAL SYMPTOMS	1	2	1	1	1	2								
				15. HYPOCHONDRIASIS	0	0	2	0	2	2								
				16. LOSS OF HEIGHT	2	2	0	0	0	0								
				17. INSIGHT	0	1	0	0	1	1								
				18. DIURNAL VARIATION	1	1	1	1	1	1								
				19. PERSONALIZATION	1	0	1	0	0	2								
				20. PARANOID	0	0	1	0	0	1								
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0								
				22. total score	27	26	27	18	32									
2	33	Reboxetine	Male	01. DEPRESSED MOOD	2	2	2	1	1	0								
				02. GUILT	0	0	0	0	0	0								
				03. SUICIDE	4	4	1	0	0	0								
				04. INSOMNIA EARLY	1	1	0	1	1	1								
				05. INSOMNIA MIDDLE	1	1	0	0	0	0								
				06. INSOMNIA LATE	2	2	1	1	1	0								
				07. WORK AND ACTIVITIES	2	2	2	1	0	1								
				08. RETARDATION	2	2	0	0	0	0								
				09. AGITATION	0	0	1	1	1	1								
				10. ANXIETY PSYCHIC	2	2	1	1	1	2								
				11. ANXIETY SOMATIC	2	2	1	0	0	0								
				12. SOMATIC GASTROINTESTINAL	1	1	1	0	0	1								
				13. SOMATIC GENERAL	2	2	1	0	0	1								
				14. GENITAL SYMPTOMS	1	1	0	0	0	0								
				15. HYPOCHONDRIASIS	1	1	0	0	0	0								
				16. LOSS OF HEIGHT	1	1	0	0	0	0								
				17. INSIGHT	1	1	1	1	1	1								
				18. DIURNAL VARIATION	0	0	0	0	0	0								
				19. PERSONALIZATION	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	25	25	11	6	12	8								

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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				
2	34	Male	01. DEPRESSED MOOD	3	1	3	0	2	2	2	0	2	2
			02. GUILT	0	0	0	0	0	0	0	0		
			03. SUICIDE	3	0	1	0	0	0	1	1		
			04. INSOMNIA EARLY	1	0	0	0	0	0	1	0		
			05. INSOMNIA MIDDLE	1	0	0	0	0	0	1	0		
			06. INSOMNIA LATE	1	2	0	0	0	0	1	0		
			07. WORK AND ACTIVITIES	3	1	1	1	1	2	1	1		
			08. RETARDATION	1	0	1	0	1	1	0	1		
			09. AGITATION	0	0	0	0	0	0	0	1		
			10. ANXIETY PSYCHIC	1	1	2	1	1	1	1	1		
			11. ANXIETY SOMATIC	2	1	2	0	0	1	1	0		
			12. SOMATIC GASTROINTESTINAL	1	0	2	0	0	1	1	1		
			13. SOMATIC GENERAL	2	1	1	0	1	1	1	1		
			14. GENITAL SYMPTOMS	1	0	1	0	1	1	1	1		
			15. HYPOCHONDRIASIS	3	0	2	1	2	2	2	2		
			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	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	0	0	0	0	0	0		
			22. Total score			25	9	17	5	9	17	13	
35	Reboxetine	Male	01. DEPRESSED MOOD	4	2	0	1	0	1	1	1	1	
			02. GUILT	2	1	0	0	0	0	0	0		
			03. SUICIDE	3	0	0	0	0	0	0	0		
			04. INSOMNIA EARLY	1	0	0	0	0	0	0	1		
			05. INSOMNIA MIDDLE	1	0	0	0	0	0	0	1		
			06. INSOMNIA LATE	1	2	0	0	0	0	0	0		
			07. WORK AND ACTIVITIES	4	1	0	0	0	0	0	0		
			08. RETARDATION	1	0	0	0	0	0	0	0		
			09. AGITATION	1	2	1	1	1	1	1	0		
			10. ANXIETY PSYCHIC	2	1	1	1	1	1	1	0		
			11. ANXIETY SOMATIC	0	0	0	0	0	0	0	0		
			12. SOMATIC GASTROINTESTINAL	1	1	1	0	0	0	0	0		
			13. SOMATIC GENERAL	1	1	1	0	0	0	0	1		
			14. GENITAL SYMPTOMS	1	0	0	0	0	0	0	0		
			15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0		
			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	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	11	3	5	3	5	6	
36	Imipramine	Female	01. DEPRESSED MOOD	3	4	0	0	0	0	0	0	0	
			02. GUILT	2	2	0	1	0	1	0	1		
			03. SUICIDE	0	0	1	0	0	0	0	0		
			04. INSOMNIA EARLY	2	1	1	0	0	1	0	0		

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Screening	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
2	36	Imipramine	Female	Hamilton depression rating scale	1	1	0	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	3	3	1	0	0	0					
				08. RETARDATION	2	2	0	0	0	0					
				09. AGITATION	1	1	0	0	0	0					
				10. ANXIETY PSYCHIC	2	2	0	0	0	0					
				11. ANXIETY SOMATIC	1	1	0	0	0	0					
				12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0					
				13. SOMATIC GENERAL	1	1	1	1	1	1					
				14. GENITAL SYMPTOMS	2	2	1	1	1	1					
				15. HYPOCHONDRIASIS	0	0	0	0	0	0					
				16. LOSS OF WEIGHT	2	2	0	0	0	0					
				17. INSIGHT	0	0	0	0	0	0					
				18. DIURNAL VARIATION	0	0	0	0	0	0					
				19. DEPERSONALIZATION	1	1	0	0	0	0					
				20. PARANOID	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0					
				22. Total score	25	25	23	4	7						
				37	37	Reboxetine	Male	Hamilton depression rating scale	4	3	2	2	3	2	1
								01. DEPRESSED MOOD	1	1	0	0	0	0	
								02. GUILT	3	3	0	1	0	0	
03. SUICIDE	2	2	2					2	2	1					
04. INSOMNIA EARLY	2	2	2					2	2	1					
05. INSOMNIA MIDDLE	1	1	2					2	2	1					
06. INSOMNIA LATE	4	4	2					1	1	2					
07. WORK AND ACTIVITIES	1	1	1					1	1	1					
08. RETARDATION	0	0	0					0	1	1					
09. AGITATION	0	0	0					0	1	1					
10. ANXIETY PSYCHIC	4	4	2					3	2	2					
11. ANXIETY SOMATIC	3	3	2					2	2	2					
12. SOMATIC GASTROINTESTINAL	1	1	0					0	0	0					
13. SOMATIC GENERAL	2	2	1					1	2	2					
14. GENITAL SYMPTOMS	1	1	1					1	1	1					
15. HYPOCHONDRIASIS	2	2	1					1	2	2					
16. LOSS OF WEIGHT	0	0	0					0	0	0					
17. INSIGHT	0	0	0					0	0	0					
18. DIURNAL VARIATION	1	1	0					0	1	0					
19. DEPERSONALIZATION	1	1	0					0	1	0					
20. PARANOID	0	0	0					0	0	0					
21. OBSESSIONAL/COMPULSIVE	1	1	0					0	0	0					
22. Total score	34	33	19	21	23	18									
38	38	Imipramine	Female	Hamilton depression rating scale	2	2	1	2	3	3	2				
				01. DEPRESSED MOOD	2	1	0	1	2	2					
				02. GUILT	1	1	0	1	2	1					
				03. SUICIDE	1	2	1	1	1	1					
				04. INSOMNIA EARLY	1	2	2	2	2	2					
				05. INSOMNIA MIDDLE	1	2	1	1	2	2					
				06. INSOMNIA LATE	1	2	1	1	2	2					
				07. WORK AND ACTIVITIES	3	3	3	3	3	2					
08. RETARDATION	1	2	2	2	2	2									

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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				
2	38	Imipramine	Female	09. AGITATION	1	0	0	0	0	0	0	0				
				10. ANXIETY PSYCHIC	2	2	1	2	2	2	2	2				
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2			
				12. SOMATIC GASTROINTESTINAL	0	1	1	1	1	1	1	1	1			
				13. SOMATIC GENERAL	2	2	2	2	2	2	2	2	2			
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2			
				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	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	0	0	0	0	0	0	0	0	0			
				22. Total score	22	25	20	23	27	28	27	24	24			
				39	Reboxetine	Female	01. DEPRESSED MOOD	3	3	2	2	2	1	1	1	1
							02. GUILT	2	2	2	2	2	2	2	2	
							03. SUICIDE	1	1	1	1	0	0	0	0	
							04. INSOMNIA EARLY	0	0	0	0	0	0	0	0	
							05. INSOMNIA MIDDLE	1	1	2	1	1	1	1	1	
							06. INSOMNIA LATE	2	2	1	1	0	0	0	0	
							07. WORK AND ACTIVITIES	5	5	2	2	1	1	1	1	
							08. RETARDATION	0	0	0	0	0	0	0	0	
09. AGITATION	2	2	2				2	1	1	1	1					
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	1	1	1				1	1	1	1	1					
13. SOMATIC GENERAL	2	2	2				2	2	2	2	2					
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	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	27	20				19	14	13	12	13					
40	Imipramine	Male	01. DEPRESSED MOOD	4	4	1	1	2	2	3	3	1				
			02. GUILT	2	1	1	0	0	1	1	1					
			03. SUICIDE	4	4	3	3	2	3	1	0					
			04. INSOMNIA EARLY	2	1	0	0	0	2	1	1					
			05. INSOMNIA MIDDLE	0	1	0	0	2	1	1	0					
			06. INSOMNIA LATE	2	2	2	2	2	2	2	0					
			07. WORK AND ACTIVITIES	1	2	1	2	1	2	2	0					
			08. RETARDATION	1	1	0	0	0	0	0	0					
			09. AGITATION	1	1	0	1	1	1	2	1					
			10. ANXIETY PSYCHIC	1	2	1	1	1	2	1	1					
			11. ANXIETY SOMATIC	1	1	0	1	1	1	1	1					
			12. SOMATIC GASTROINTESTINAL	1	1	0	1	1	1	1	0					

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20126/017
 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				
2	40	Male	Imipramine	13. SOMATIC GENERAL	1	1	1	1	1	1	1	0			
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	0			
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0		
				16. LOSS OF WEIGHT	1	1	1	1	1	1	1	1	1	0	
				17. INSIGHT	1	1	1	1	1	1	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	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	25	26	13	19	15	25	18	8			
				41	Reboxetine	Male	Imipramine	01. DEPRESSED MOOD	3	4	3	3	2	2	3
								02. GUILT	1	2	1	2	1	1	1
								03. SUICIDE	0	2	2	2	1	1	1
								04. INSOMNIA EARLY	2	2	2	2	1	1	2
								05. INSOMNIA MIDDLE	2	0	2	1	1	1	2
								06. INSOMNIA LATE	2	2	2	1	1	2	2
								07. WORK AND ACTIVITIES	4	3	2	3	2	2	2
								08. RETARDATION	2	1	2	1	1	1	1
								09. AGITATION	0	2	2	2	1	1	1
								10. ANXIETY PSYCHIC	1	3	3	3	2	2	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	0	1	1					1	1	1	1				
15. HYPOCHONDRIASIS	2	2	2					2	2	2	2				
16. LOSS OF WEIGHT	2	0	0					1	0	0	0				
17. INSIGHT	0	0	0					0	0	0	0				
18. DIURNAL VARIATION	1	1	0					0	1	1	2				
19. DEPERSONALIZATION	0	0	1					1	0	1	1				
20. PARANOID	0	0	0					0	0	0	0				
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0				
22. Total score	27	29	32					30	21	24	26	31			
42	Imipramine	Male	Imipramine	01. DEPRESSED MOOD	4	4	4	4	3	3	1				
				02. GUILT	1	1	2	1	2	2	1				
				03. SUICIDE	0	0	0	0	0	0	0				
				04. INSOMNIA EARLY	2	2	2	1	1	0	0				
				05. INSOMNIA MIDDLE	1	1	1	2	2	1	1				
				06. INSOMNIA LATE	4	4	3	4	4	2	0				
				07. WORK AND ACTIVITIES	2	1	1	2	2	1	1				
				08. RETARDATION	2	2	1	1	2	1	1				
				09. AGITATION	2	2	3	2	2	1	1				
				10. ANXIETY PSYCHIC	2	2	2	1	1	1	0				
				11. ANXIETY SOMATIC	2	2	2	1	1	1	0				
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	0				
				13. SOMATIC GENERAL	2	2	2	2	2	2	2				
				14. GENITAL SYMPTOMS	1	1	1	1	1	1	0				
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	0				
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0				

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	42	Imipramine	Male	17. INSIGHT	0	0	1	1	1	1	1	1				
				18. DIURNAL VARIATION	0	1	1	2	2	2	1	2				
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0			
				20. PARANOID	0	0	1	0	0	0	1	1	0			
				21. OBSESSIONAL/COMPULSIVE	0	0	1	0	0	0	1	0	1			
				22. Total score	27	27	29	30	23	19	15					
				43	Reboxetine	Female	01. DEPRESSED MOOD	3	3	1	1	0	0	0	0	1
							02. GUILT	2	2	1	1	0	1	0	1	
							03. SUICIDE	0	3	0	0	0	0	0	0	
							04. INSOMNIA EARLY	1	2	2	0	1	1	0	0	
							05. INSOMNIA MIDDLE	1	0	1	1	1	0	0	0	
							06. INSOMNIA LATE	1	1	2	1	0	0	0	0	
							07. WORK AND ACTIVITIES	4	2	0	0	0	0	0	0	
							08. RETARDATION	2	0	0	0	0	0	0	0	
							09. AGITATION	1	2	1	1	1	1	1	1	
							10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	
							11. ANXIETY SOMATIC	0	1	1	0	0	0	0	0	
							12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0	
							13. SOMATIC GENERAL	1	1	1	0	0	0	0	0	
							14. GENITAL SYMPTOMS	2	2	1	0	0	0	0	0	
							15. HYPOCHONDRIASIS	1	0	1	0	0	0	0	0	
							16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	
17. INSIGHT	0	0	1				0	0	0	0	0					
18. DIURNAL VARIATION	2	2	1				0	0	0	0	0					
19. DEPERSONALIZATION	0	0	1				0	0	0	0	0					
20. PARANOID	0	0	0				1	0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	0	0	1				0	0	0	0	0					
22. Total score	23	23	17				5	3	4	2	4					
44	Imipramine	Male	01. DEPRESSED MOOD	4	3	4	4	4	4	4	4					
			02. GUILT	2	2	2	2	2	2	2						
			03. SUICIDE	3	1	2	2	2	2	2						
			04. INSOMNIA EARLY	1	1	0	0	0	0	0						
			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	4	4	4	4	4	4						
			08. RETARDATION	2	0	2	2	2	2	2						
			09. AGITATION	1	2	2	2	2	2	2						
			10. ANXIETY PSYCHIC	3	2	2	2	2	2	2						
			11. ANXIETY SOMATIC	1	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	2	2	2	2	2	2	2						
			15. HYPOCHONDRIASIS	2	1	2	2	2	2	2						
			16. LOSS OF WEIGHT	0	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	2	0	2	2	2	2						
			20. PARANOID	2	1	2	2	2	2	2						
			21. OBSESSIONAL/COMPULSIVE	1	0	1	0	1	0	1						
			22. Total score	1	0	1	0	1	0	1						

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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	44	Imipramine	Male	21. OBSESSIONAL/COMPULSIVE 22. Total score	37	2	2	31	1	35			
	45	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. GENERAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	4	4	1	1	1	1			
	46	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. GENERAL SYMPTOMS 15. HYPOCHONDRIASIS 16. LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	4	3	3	3	2	2	2	2	2

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	
2	47	Reboxetine	Female	01. DEPRESSED MOOD	4	2	4	2	1	0	0	0	
				02. CHILL	2	2	1	1	1	0	0	0	
				03. SUICIDE	1	0	1	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	0	0	0	1	1	1	1
				05. INSOMNIA MIDDLE	2	1	2	2	2	0	0	0	0
				06. INSOMNIA LATE	0	0	2	2	2	1	0	0	0
				07. MORE AND ACTIVITIES	3	3	2	2	2	1	0	0	0
				08. RETARDATION	0	0	0	0	0	0	0	0	0
				09. AGITATION	4	3	3	3	1	1	1	1	1
				10. ANXIETY PSYCHIC	3	2	2	2	2	1	1	1	1
				11. ANXIETY SOMATIC	2	2	2	1	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	0	0	0	0	0
				13. SOMATIC GENERAL	1	1	1	1	0	0	0	0	0
				14. GENITAL SYMPTOMS	2	2	2	2	1	0	0	0	0
				15. HYPOCHONDRIASIS	2	1	1	1	0	0	0	0	0
				16. LOSS OF HEIGHT	1	1	0	0	0	0	0	0	0
				17. INSIGHT	1	1	1	1	0	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	0	0	1	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	1	0	0	0	0	0	0
				22. Total score	30	23	26	19	9	5	2	2	3
48	48	Imipramine	Female	01. DEPRESSED MOOD	3	3	3	1	1	1	1	1	
				02. CHILL	1	1	2	1	1	0	0	0	
				03. SUICIDE	2	2	0	0	0	0	0	0	
				04. INSOMNIA EARLY	1	0	1	1	0	0	0	0	
				05. INSOMNIA MIDDLE	2	2	0	0	1	1	0	0	
				06. INSOMNIA LATE	2	2	0	1	0	0	0	0	
				07. MORE AND ACTIVITIES	4	4	3	2	2	1	1	1	
				08. RETARDATION	2	1	1	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	0	0	0	0	
				13. SOMATIC GENERAL	1	1	1	1	0	0	0	0	
				14. GENITAL SYMPTOMS	2	2	2	2	1	2	2	2	
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	
				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	2	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	0	0	0	0	0	0	0	0	
				22. Total score	27	25	17	13	8	7	6	8	
49	49	Imipramine	Female	01. DEPRESSED MOOD	4	3	2	1	1	1	1	1	
				02. CHILL	2	2	0	0	1	1	0	1	
				03. SUICIDE	2	0	0	0	0	0	0	0	
				04. INSOMNIA EARLY	2	1	1	0	1	2	0	0	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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			
2	49	Female	05. INSOMNIA MIDDLE	1	1	1	0	0	1	0	0			
			06. INSOMNIA LATE	2	2	1	2	0	2	2				
			07. WORK AND ACTIVITIES	3	3	2	1	1	0	1	1			
			08. RETARDATION	0	0	0	0	0	0	0	0			
			09. AGITATION	2	1	2	1	1	1	1	1			
			10. ANXIETY PSYCHIC	2	1	1	1	1	0	1	1			
			11. ANXIETY SOMATIC	2	2	1	0	0	0	0	0			
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	1	0			
			13. SOMATIC GENERAL	1	1	1	1	1	0	0	0			
			14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	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	2	1	1	0	0	0	0			
			19. DEPERSONALIZATION	0	0	0	0	0	0	0	0			
			20. PARANOID	0	0	0	1	1	0	0	0			
			21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0			
			22. Total score	28	23	17	11	10	8	10	8	10		
			50	Reboxetine	Male	01. DEPRESSED MOOD	4	4	4	3	3	3	4	4
						02. GUILT	2	1	1	1	1	1	0	0
						03. SUICIDE	2	1	2	2	2	1	2	1
						04. INSOMNIA EARLY	2	2	2	2	2	2	1	2
05. INSOMNIA MIDDLE	2	2				2	2	2	2	1	1			
06. INSOMNIA LATE	2	1				1	1	1	1	1	1			
07. WORK AND ACTIVITIES	4	3				3	2	3	2	3	2			
08. RETARDATION	1	1				0	0	0	0	0	0			
09. AGITATION	1	1				2	2	2	2	1	1			
10. ANXIETY PSYCHIC	1	1				2	2	2	2	1	1			
11. ANXIETY SOMATIC	0	1				1	1	1	1	1	1			
12. SOMATIC GASTROINTESTINAL	1	1				1	1	1	1	1	1			
13. SOMATIC GENERAL	2	2				2	2	2	2	1	1			
14. GENITAL SYMPTOMS	0	0				1	2	2	2	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	1				1	1	1	1	1	1			
18. DIURNAL VARIATION	2	1				0	1	1	1	1	1			
19. DEPERSONALIZATION	0	0				0	0	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	28	24				27	30	26	20	26	20			
51	Reboxetine	Female	01. DEPRESSED MOOD	4	3	3	4	4	4	4	4			
			02. GUILT	2	2	2	2	2	2	2	2			
			03. SUICIDE	2	1	0	3	3	3	3	3			
			04. INSOMNIA EARLY	1	2	2	2	2	2	2	2			
			05. INSOMNIA MIDDLE	1	1	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	0	2	2	2	2	2			

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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	51	Reboxetine	Female	09. AGITATION	1	2	1	1	1	1	1	1				
				10. ANXIETY PSYCHIC	2	1	1	1	3							
				11. ANXIETY SOMATIC	2	0	1	0								
				12. SOMATIC GASTROINTESTINAL	1	1	1	2								
				13. SOMATIC GENERAL	1	1	1	2								
				14. GENITAL SYMPTOMS	2	2	2	2								
				15. HYPOCHONDRIASIS	0	1	0	0								
				16. LOSS OF WEIGHT	1	0	0	0								
				17. INSIGHT	0	0	0	2								
				18. DIURNAL VARIATION	1	2	1	2								
				19. DEPERSONALIZATION	0	1	1	2								
				20. PARANOID	0	0	0	2								
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0								
				22. Total score	28	25	23	40								
				52	52	Imipramine	Male	01. DEPRESSED MOOD	4	3	2	0	0	1	1	0
								02. GUILT	2	1	1	0	0	0	0	
								03. SUICIDE	3	2	0	0	0	0	0	
								04. INSOMNIA EARLY	1	1	1	0	1	1	0	
								05. INSOMNIA MIDDLE	1	1	1	0	0	0	0	
								06. INSOMNIA LATE	2	1	1	1	1	0	0	
								07. WORK AND ACTIVITIES	4	2	2	0	0	0	0	
								08. RETARDATION	2	0	0	0	0	0	0	
09. AGITATION	2	1	1					0	0	0	0					
10. ANXIETY PSYCHIC	1	1	0					1	0	0	0					
11. ANXIETY SOMATIC	0	1	0					0	0	0	0					
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	0	0	0					
15. HYPOCHONDRIASIS	0	0	0					0	0	0	0					
16. LOSS OF WEIGHT	2	0	0					0	0	0	0					
17. INSIGHT	0	1	0					0	0	0	0					
18. DIURNAL VARIATION	2	2	0					0	0	0	0					
19. DEPERSONALIZATION	2	2	1					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	23	12					4	2	2	2					
3	65	Reboxetine	Male	01. DEPRESSED MOOD	3	3	1	0	0	0	0	0				
				02. GUILT	0	1	0	0	0	0	0					
				03. SUICIDE	1	1	0	0	0	0	0					
				04. INSOMNIA EARLY	1	2	1	1	1	0	0					
				05. INSOMNIA MIDDLE	1	2	0	1	0	2	1					
				06. INSOMNIA LATE	1	1	1	0	0	2	1					
				07. WORK AND ACTIVITIES	4	4	4	2	1	1	0					
				08. RETARDATION	1	2	1	0	0	1	0					
				09. AGITATION	0	0	0	0	0	0	0					
				10. ANXIETY PSYCHIC	3	3	1	0	1	0	0					
				11. ANXIETY SOMATIC	3	1	1	1	2	0	0					
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0					

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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			
3	65	Reboxetine	Male	13. SOMATIC GENERAL	2	2	1	1	1	0	0	0			
				14. GENITAL SYMPTOMS	2	2	1	1	1	1	0	0			
				15. HYPOCHONDRIASIS	3	3	1	0	1	0	0	0	0		
				16. LOSS OF WEIGHT	0	2	2	0	0	0	0	0	0		
				17. INSIGHT	0	0	0	0	0	0	0	0	0		
				18. DIURNAL VARIATION	2	2	1	1	1	1	1	1	1		
				19. DEPERSONALIZATION	2	2	2	0	0	0	0	0	0		
				20. PARANOID	0	0	0	0	0	0	0	0	0		
				21. OBSESSIONAL/COMPULSIVE	2	1	1	0	0	0	0	0	0		
				22. Total score	31	34	20	8	9	8	5	3			
				66	66	Imipramine	Female	01. DEPRESSED MOOD	3	1	0	0	0	1	4
								02. GUILT	4	2	2	1	0	1	3
								03. SUICIDE	4	3	0	0	0	0	3
								04. INSOMNIA EARLY	1	2	0	0	0	0	0
								05. INSOMNIA MIDDLE	1	2	0	1	0	0	1
								06. INSOMNIA LATE	0	2	2	0	0	0	2
								07. WORK AND ACTIVITIES	3	2	1	1	1	1	4
								08. RETARDATION	1	1	0	0	0	0	3
								09. AGITATION	4	2	1	0	0	1	1
								10. ANXIETY PSYCHIC	2	3	1	2	0	1	3
								11. ANXIETY SOMATIC	1	1	2	0	1	1	0
								12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	2
13. SOMATIC GENERAL	1	1	0					0	0	0	2				
14. GENITAL SYMPTOMS	2	2	1					0	0	1	0				
15. HYPOCHONDRIASIS	2	2	1					0	0	1	0				
16. LOSS OF WEIGHT	2	2	0					0	1	0	2				
17. INSIGHT	1	1	0					0	1	0	2				
18. DIURNAL VARIATION	1	1	0					0	0	0	0				
19. DEPERSONALIZATION	0	3	0					0	0	0	3				
20. PARANOID	2	1	0					0	0	0	1				
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0				
22. Total score	35	35	10					3	3	8	36				
67	67	Reboxetine	Female	01. DEPRESSED MOOD	1	1	2	2	1	1	2	3			
				02. GUILT	1	1	2	2	1	3	2				
				03. SUICIDE	4	4	1	0	1	1	2				
				04. INSOMNIA EARLY	2	2	1	0	0	0	1				
				05. INSOMNIA MIDDLE	2	2	2	1	1	1	2				
				06. INSOMNIA LATE	2	2	2	1	2	1	2				
				07. WORK AND ACTIVITIES	3	2	1	1	1	1	1				
				08. RETARDATION	1	1	0	0	1	1	0				
				09. AGITATION	2	1	1	2	2	1	2				
				10. ANXIETY PSYCHIC	4	4	2	1	2	2	2				
				11. ANXIETY SOMATIC	3	2	2	2	1	3	1				
				12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0				
				13. SOMATIC GENERAL	2	1	0	0	1	1	0				
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0				
				15. HYPOCHONDRIASIS	3	3	0	1	1	1	3				
				16. LOSS OF WEIGHT	1	1	0	0	1	0	0				

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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				
3	67	Reboxetine	Female	17.INSIGHT	0	0	1	1	0	1	1	1				
				18.DIURNAL VARIATION	0	0	1	1	0	1	1	1				
				19.DEPERSONALIZATION	2	2	1	2	2	1	1	2	2			
				20.PARANOID	1	1	1	1	1	0	1	1	1			
				21.OBSESSIONAL/COMPULSIVE	1	1	2	2	1	0	0	1	1			
				22.Total score	36	32	22	22	17	21	21	27				
				68	68	Imipramine	Female	01.DEPRESSED MOOD	3	3	3	3	3	3	3	3
								02.GUILT	2	2	3	3	2	2	2	2
								03.SUICIDE	2	2	3	1	1	1	1	1
								04.INSOMNIA EARLY	2	2	1	2	1	1	1	1
								05.INSOMNIA MIDDLE	2	2	2	1	1	1	1	1
								06.INSOMNIA LATE	2	2	2	2	1	1	1	1
								07.WORK AND ACTIVITIES	4	4	4	4	4	4	4	4
								08.RETARDATION	3	2	3	2	3	3	3	3
								09.AGIATION	2	3	2	1	3	2	2	2
								10.ANXIETY PSYCHIC	3	3	2	2	3	3	3	3
								11.ANXIETY SOMATIC	5	5	2	3	2	3	2	2
								12.SOMATIC GASTROINTESTINAL	2	2	1	0	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	1	1	1	1	1	1	1
								16.LOSS OF WEIGHT	2	2	0	0	0	0	0	0
17.INSIGHT	1	1	1					1	1	1	1	1				
18.DIURNAL VARIATION	1	1	1					0	1	1	0	0				
19.DEPERSONALIZATION	3	2	2					3	1	2	1	2				
20.PARANOID	1	0	1					1	1	1	1	1				
21.OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0	0				
22.Total score	42	41	34					33	33	33	30	32				
69	69	Imipramine	Female	01.DEPRESSED MOOD	3	3	4	1	1	0	2	1				
				02.GUILT	2	2	3	2	0	0	1	0				
				03.SUICIDE	4	2	2	2	0	0	1	0				
				04.INSOMNIA EARLY	1	2	0	0	2	1	0	0				
				05.INSOMNIA MIDDLE	1	2	0	1	0	0	0	0				
				06.INSOMNIA LATE	1	2	0	2	0	0	0	0				
				07.WORK AND ACTIVITIES	2	3	3	1	1	1	1	1				
				08.RETARDATION	2	2	2	1	0	0	0	0				
				09.AGIATION	2	2	1	1	0	1	1	1				
				10.ANXIETY PSYCHIC	4	3	4	2	1	1	1	1				
				11.ANXIETY SOMATIC	3	3	1	1	1	0	1	0				
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	0	0	1	0				
				13.SOMATIC GENERAL	1	1	2	1	1	0	1	0				
				14.GENITAL SYMPTOMS	2	2	2	2	2	1	0	1				
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	0	0				
				16.LOSS OF WEIGHT	2	2	0	1	0	0	0	0				
				17.INSIGHT	1	1	1	1	1	1	1	1				
				18.DIURNAL VARIATION	1	1	1	1	1	1	0	0				
				19.DEPERSONALIZATION	3	3	1	1	0	0	2	1				
				20.PARANOID	1	1	1	1	1	1	1	1				
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0				
				22.Total score	42	41	34	33	33	30	32					

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	69	Imipramine	Female	21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22.Total score	37	38	31	23	9	5	14	8							
70		Reboxetine	Female	01.DEPRESSED MOOD	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
				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	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	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	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
				12.SOMATIC GASTROINTESTINAL	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				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 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	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19.DEPERSONALIZATION	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
				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	29	32	39	34	30	28									
71		Imipramine	Female	01.DEPRESSED MOOD	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				02.GUILT	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				03.SUICIDE	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				04.INSOMNIA EARLY	0	1	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
				06.INSOMNIA LATE	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08.RETARDATION	1	2	1	0	0	0	0	0	0	0	0	0	0	0	0
				09.AGITATION	2	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
				11.ANXIETY SOMATIC	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12.SOMATIC GASTROINTESTINAL	2	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	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
				17.INSIGHT	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
				19.DEPERSONALIZATION	1	1	1	1	1	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	1
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				22.Total score	33	29	40	3	8	2	1								

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	72	Reboxetine	Female	01. DEPRESSED MOOD	3	2	2	3	2	2	2	1			
				02. GUILT	3	2	2	2	2	2	1	1	1		
				03. SUICIDE	3	1	1	1	1	1	1	1	1	0	
				04. INSOMNIA EARLY	0	0	1	1	1	1	1	1	1	0	
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1	
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	
				07. WORK AND ACTIVITIES	4	4	2	3	3	3	3	3	3	2	2
				08. RETARDATION	2	1	0	0	0	0	0	0	0	0	0
				09. AGITATION	2	2	2	1	1	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	3	2	2	2	2	2	2	2	2	1	1
				11. ANXIETY SOMATIC	2	2	2	1	1	1	1	1	1	1	0
				12. SOMATIC GASTROINTESTINAL	2	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	0	0	0	0	0	0	0	0	0
				15. HYPOCHONDRIASIS	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
				17. INSIGHT	2	1	1	1	1	1	1	1	1	1	1
				18. DIURNAL VARIATION	2	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1	1
				20. PARANOID	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
				22. Total score	36	30	22	21	18	19	14	11			
				4	97	Reboxetine	Female	01. DEPRESSED MOOD	2	2	2	0	0	0	1
02. GUILT	2	2	2					1	1	1	0	0	0		
03. SUICIDE	1	0	0					0	0	0	0	0	0		
04. INSOMNIA EARLY	1	1	1					1	1	0	0	0	0		
05. INSOMNIA MIDDLE	1	1	1					1	1	0	0	0	0		
06. INSOMNIA LATE	1	1	1					1	1	0	0	0	0		
07. WORK AND ACTIVITIES	4	3	2					0	1	0	1	0	0	0	
08. RETARDATION	1	2	0					0	0	0	0	0	0	0	
09. AGITATION	2	1	2					0	1	0	0	0	0	0	
10. ANXIETY PSYCHIC	2	2	1					1	1	0	0	0	0	0	
11. ANXIETY SOMATIC	3	3	0					0	0	0	0	0	0	0	
12. SOMATIC GASTROINTESTINAL	0	0	0					0	0	1	0	0	0	0	
13. SOMATIC GENERAL	1	1	0					0	0	0	0	0	0	0	
14. GENITAL SYMPTOMS	0	0	0					0	0	0	0	0	0	0	
15. HYPOCHONDRIASIS	0	0	0					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	0					0	0	0	0	0	0	0	
18. DIURNAL VARIATION	1	1	0					0	0	0	0	0	0	0	
19. DEPERSONALIZATION	1	0	1					0	0	0	0	0	0	0	
20. PARANOID	1	0	1					0	0	0	0	0	0	0	
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0	0	0	0	
22. Total score	25	22	13					5	5	6	2	0			
4	97	Imipramine	Male					01. DEPRESSED MOOD	4	4	4	4	2	2	1
				02. GUILT	0	0	0	0	0	0	0				
				03. SUICIDE	2	2	2	1	1	2	1				
04. INSOMNIA EARLY	2	2	2	1	2	2	2								

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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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	97	Imipramine	Male	05. INSOMNIA MIDDLE	2	2	2	2	2	2	1	2				
				06. INSOMNIA LATE	2	2	2	2	2	0	1					
				07. WORK AND ACTIVITIES	4	4	4	3	4	3	2					
				08. RETARDATION	1	1	0	0	1	0	0					
				09. AGITATION	0	0	0	0	0	0	0					
				10. ANXIETY PSYCHIC	2	2	1	1	1	0	2					
				11. ANXIETY SOMATIC	2	2	2	2	1	1	0					
				12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	1					
				13. SOMATIC GENERAL	1	1	1	1	1	0	1					
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	1					
				15. HYPOCHONDRIASIS	1	1	1	1	1	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	1	1	1	1	2					
				19. DEPERSONALIZATION	3	3	3	3	3	2	3					
				20. PARANOID	1	1	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	2	2	2	2	2	1	1					
				22. Total score	34	34	30	26	23	25	15	21				
				100		Reboxetine	Female	01. DEPRESSED MOOD	4	4	4	3	2	1	1	1
								02. GUILT	2	2	3	2	1	0	0	
								03. SUICIDE	3	3	3	3	2	0	0	
								04. INSOMNIA EARLY	2	2	2	2	2	2	1	
05. INSOMNIA MIDDLE	2	2	2					2	2	1	1					
06. INSOMNIA LATE	2	2	2					2	1	2	1					
07. WORK AND ACTIVITIES	4	4	4					4	3	1	0					
08. RETARDATION	3	3	3					3	0	0	0					
09. AGITATION	3	3	4					2	2	1	0					
10. ANXIETY PSYCHIC	3	3	3					2	2	1	0					
11. ANXIETY SOMATIC	3	3	3					2	2	1	0					
12. SOMATIC GASTROINTESTINAL	2	2	2					2	1	0	0					
13. SOMATIC GENERAL	1	1	1					1	0	0	0					
14. GENITAL SYMPTOMS	1	1	2					2	1	0	0					
15. HYPOCHONDRIASIS	0	0	0					0	0	0	0					
16. LOSS OF WEIGHT	2	1	1					0	0	0	0					
17. INSIGHT	1	1	0					0	0	0	0					
18. DIURNAL VARIATION	1	1	2					2	2	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	39	38	41					34	22	10	5	7				
101		Imipramine	Female	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3				
				02. GUILT	0	0	0	0	0	0	0					
				03. SUICIDE	2	2	1	3	3	3	3					
				04. INSOMNIA EARLY	2	2	0	1	2	2	2					
				05. INSOMNIA MIDDLE	2	2	1	0	0	0	0					
				06. INSOMNIA LATE	2	2	2	2	2	2	2					
				07. WORK AND ACTIVITIES	2	2	1	3	3	3	3					
				08. RETARDATION	1	1	1	1	0	0	0					

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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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	101	Imipramine	Female	09. AGITATION	0	0	1	0	0	0	0	0				
				10. ANXIETY PSYCHIC	2	2	3	1	3							
				11. ANXIETY SOMATIC	1	1	2	1	2							
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	2							
				13. SOMATIC GENERAL	0	0	1	2	2							
				14. GENITAL SYMPTOMS	2	2	2	2	2							
				15. HYPOCHONDRIASIS	0	0	0	0	0							
				16. LOSS OF WEIGHT	0	0	0	0	0							
				17. INSIGHT	1	1	0	0	0							
				18. DIURNAL VARIATION	1	1	2	2	1							
				19. DEPERSONALIZATION	0	0	0	0	0							
				20. PARANOID	0	0	0	0	0							
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0							
				22. Total score	24	24	23	23	28							
				6	161	Reboxetine	Male	01. DEPRESSED MOOD	3	3	0	1	1	0	3	1
								02. GUILT	0	0	0	0	0	0	0	
								03. SUICIDE	3	1	0	0	0	0	0	
								04. INSOMNIA EARLY	1	1	1	1	2	1	0	
								05. INSOMNIA MIDDLE	2	2	1	1	2	2	2	
								06. INSOMNIA LATE	1	2	1	1	1	1	1	
								07. WORK AND ACTIVITIES	3	3	1	0	0	2	1	
								08. RETARDATION	2	2	1	1	1	0	1	
09. AGITATION	1	1	0					0	1	0	0					
10. ANXIETY PSYCHIC	1	1	0					0	1	0	1					
11. ANXIETY SOMATIC	2	2	1					1	1	2	1					
12. SOMATIC GASTROINTESTINAL	2	2	1					0	1	0	1					
13. SOMATIC GENERAL	2	2	0					0	1	0	0					
14. GENITAL SYMPTOMS	1	1	0					0	0	0	0					
15. HYPOCHONDRIASIS	1	1	1					1	1	0	0					
16. LOSS OF WEIGHT	1	1	0					0	0	0	1					
17. INSIGHT	1	1	1					1	1	1	1					
18. DIURNAL VARIATION	2	2	0					0	0	0	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	29	28	9					8	13	7	13					
6	162	Reboxetine	Female	01. DEPRESSED MOOD	3	3	3	1	1	0	0	1				
				02. GUILT	0	0	0	0	0	0	0					
				03. SUICIDE	1	0	1	0	0	0	0					
				04. INSOMNIA EARLY	1	1	1	1	0	0	1					
				05. INSOMNIA MIDDLE	2	1	2	1	1	1	1					
				06. INSOMNIA LATE	2	1	1	0	0	1	1					
				07. WORK AND ACTIVITIES	4	4	2	2	1	1	1					
				08. RETARDATION	2	2	1	1	0	0	0					
				09. AGITATION	2	2	2	2	1	0	0					
				10. ANXIETY PSYCHIC	3	3	1	1	1	0	0					
				11. ANXIETY SOMATIC	2	2	1	1	0	0	0					
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	0	0	0					

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
6	162	Reboxetine Female		1	1	1	1	0	0	0
		13.SOMATIC GENERAL		1	1	1	1	0	0	0
		14.GENITAL SYMPTOMS		1	1	1	1	0	0	0
		15.HYPOCHONDRIASIS		1	1	1	1	0	0	0
		16.LOSS OF WEIGHT		2	0	0	0	0	0	1
		17.INSIGHT		1	1	1	1	1	1	1
		18.DIURNAL VARIATION		2	2	2	2	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		31	28	22	18	12	3	7
7	193	Reboxetine Female		3	3	3	3	3	3	3
		01.DEPRESSED MOOD		3	3	3	3	3	3	3
		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
		05.INSOMNIA MIDDLE		1	1	1	1	1	1	1
		06.INSOMNIA LATE		0	0	0	0	0	0	0
		07.WORK AND ACTIVITIES		3	3	3	3	3	3	3
		08.RETARDATION		1	1	1	1	1	1	1
		09.AGITATION		3	3	3	3	3	3	3
		10.ANXIETY PSYCHIC		3	3	3	3	3	3	3
		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		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		23	23	23	23	23	23	23
194		Reboxetine Male		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
		03.SUICIDE		3	3	3	3	3	3	3
		04.INSOMNIA EARLY		1	0	0	0	0	0	0
		05.INSOMNIA MIDDLE		1	2	2	2	2	2	2
		06.INSOMNIA LATE		0	0	0	0	0	0	0
		07.WORK AND ACTIVITIES		4	4	4	4	4	4	4
		08.RETARDATION		1	0	0	0	0	0	0
		09.AGITATION		2	0	0	0	0	0	0
		10.ANXIETY PSYCHIC		1	1	1	1	1	1	1
		11.ANXIETY SOMATIC		2	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	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

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/017
 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	194	Reboxetine Male		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	16					
			HAMILTON DEPRESSION RATING SCALE							
			01.DEPRESSED MOOD	4	4	2	2	2	2	2
			02.GUILT	1	1	0	0	0	0	0
			03.SUICIDE	2	2	0	0	1	2	2
			04.INSOMNIA EARLY	0	0	2	0	1	2	2
			05.INSOMNIA MIDDLE	1	1	0	0	1	1	1
			06.INSOMNIA LATE	0	0	0	0	1	1	1
			07.WORK AND ACTIVITIES	3	3	2	2	1	1	1
			08.RETARDATION	1	1	1	0	0	0	0
			09.AGIATION	1	1	1	1	1	1	1
			10.ANXIETY PSYCHIC	1	1	1	1	1	1	1
			11.ANXIETY SOMATIC	3	3	1	0	1	1	1
			12.SOMATIC GASTROINTESTINAL	1	1	0	0	1	0	0
			13.SOMATIC GENERAL	1	1	2	0	0	0	0
			14.GENITAL SYMPTOMS	1	1	1	0	0	0	0
			15.HYPOCHONDRIASIS	0	0	1	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	0	1	0	1	0
			19.DEPERSONALIZATION	0	0	0	0	0	0	0
			20.PARANOID	1	1	0	0	0	0	0
			21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0
			22.Total score	24	24	16	7	5	10	10
8	225	Imipramine Female		2	2	3	0	0	0	0
			01.DEPRESSED MOOD	2	2	3	0	0	0	0
			02.GUILT	1	1	1	0	0	0	0
			03.SUICIDE	1	1	2	0	0	0	0
			04.INSOMNIA EARLY	2	2	1	0	0	0	0
			05.INSOMNIA MIDDLE	1	1	0	0	0	0	0
			06.INSOMNIA LATE	1	1	0	0	0	0	0
			07.WORK AND ACTIVITIES	2	2	2	1	1	1	1
			08.RETARDATION	1	1	1	0	0	0	0
			09.AGIATION	0	0	0	0	0	0	0
			10.ANXIETY PSYCHIC	2	2	2	1	1	1	1
			11.ANXIETY SOMATIC	2	2	2	1	1	1	1
			12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1
			13.SOMATIC GENERAL	1	1	2	1	1	1	1
			14.GENITAL SYMPTOMS	1	1	1	0	1	0	0
			15.HYPOCHONDRIASIS	0	0	2	0	2	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	1	1	2	0	0	0	0
			19.DEPERSONALIZATION	0	0	0	0	0	0	0
			20.PARANOID	0	0	0	0	0	0	0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	225	Imipramine	Female	21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				22.Total score	22	22	25	6															
8	226	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	3	3	2	2	3	3	3	2	2	3	3	3	3			
				02.GUILT	0	0	0	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	0	1	2	2	2	2	2	2	2	2	2
				04.INSOMNIA EARLY	2	2	2	2	2	2	2	2	1	2	2	2	2	2	2	2	2	2	2
				05.INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
				06.INSOMNIA LATE	2	2	2	2	2	2	2	2	1	1	2	2	2	2	2	2	2	2	2
				07.WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	2
				08.RETARDATION	2	2	2	2	2	2	2	2	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	0
				10.ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	2
				11.ANXIETY SOMATIC	3	3	3	3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	2
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	0	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	0	1	1	1	1	1	1	1	1	1	1
				15.HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1
				16.LOSS OF HEIGHT	2	2	2	2	2	2	2	2	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	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
				24.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1
				22.Total score	27	25	20	16	17	18	17	17	17	17	17	17	17	17	17	17	17	17	17
8	227	Imipramine	Male	01.DEPRESSED MOOD	4	4	4	4	2	2	2	2	2	2	2	2	2	2	2	2			
				02.GUILT	2	2	2	2	2	2	2	2	1	2	2	2	2	2	2	2	2	2	
				03.SUICIDE	2	2	2	2	2	2	2	2	1	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	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	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
				09.AGITATION	4	4	4	4	4	4	4	2	2	2	2	2	2	2	2	2	2	2	
				10.ANXIETY PSYCHIC	4	4	4	4	4	4	4	2	2	2	2	2	2	2	2	2	2	2	
				11.ANXIETY SOMATIC	3	3	3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	2	
				12.SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	
				14.GENITAL SYMPTOMS	2	2	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	1	1	1	1	1	1	1	1	1	1	
				16.LOSS OF HEIGHT	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	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	
				24.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
				22.Total score	32	30	19	16	23	17	11	7											

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	228	Reboxetine	Male	01. DEPRESSED MOOD	3	3	2	2	2	2	2	2
				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	2	2	2	2	2
				05. INSOMNIA MIDDLE	2	2	1	1	1	1	1	1
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	3	3	3	2	2	2	2	2
				08. RETARDATION	2	2	2	1	1	1	1	1
				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	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	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	0	0	0	0	0	0	0	0
				22. Total score	30	28	28	28	28	28	28	28
				01. DEPRESSED MOOD	3	3	3	3	3	3	3	3
				02. GUILT	3	2	2	2	2	2	2	2
				03. SUICIDE	3	3	0	0	1	1	1	1
				04. INSOMNIA EARLY	1	2	1	0	2	1	0	0
				05. INSOMNIA MIDDLE	0	0	1	1	0	0	0	0
				06. INSOMNIA LATE	0	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	3	3	3	2	2	2	2	2
				08. RETARDATION	1	1	1	0	0	0	0	0
				09. AGITATION	1	0	0	1	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	2	1	2	1	1	2
				11. ANXIETY SOMATIC	2	2	1	0	2	1	1	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	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	1	1	0	0	1	1	1	1
				18. DIURNAL VARIATION	1	1	0	0	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	0	0	0	1	0	0	0
				22. Total score	26	24	15	8	16	8	8	11
				01. DEPRESSED MOOD	3	3	3	2	2	2	2	2
				02. GUILT	0	0	0	1	1	1	1	1
				03. SUICIDE	1	1	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	1	0	0	0	0	0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	230	Imipramine	Female	05. INSOMNIA MIDDLE	0	1	0	0	0	1	1	0				
				06. INSOMNIA LATE	2	2	0	0	0	0	0					
				07. WORK AND ACTIVITIES	4	4	3	2	1	1	0	1				
				08. RETARDATION	3	3	2	1	1	0	0	0				
				09. AGITATION	1	1	0	1	0	0	0	0				
				10. ANXIETY PSYCHIC	1	1	1	1	2	1	1	1				
				11. ANXIETY SOMATIC	0	0	0	0	0	1	1	1				
				12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0				
				13. SOMATIC GENERAL	1	2	0	1	1	0	0	0				
				14. GENITAL SYMPTOMS	2	2	2	1	1	0	0	0				
				15. HYPOCHONDRIASIS	1	2	0	1	1	0	0	0				
				16. LOSS OF WEIGHT	0	0	0	0	2	0	0	0				
				17. INSIGHT	0	0	0	0	0	0	0	0				
				18. DIURNAL VARIATION	1	1	0	0	0	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	22	25	12	15	12	5	4	5				
				231	Reboxetine	Female	01. DEPRESSED MOOD	3	3	1	1	1	1	1	1	1
							02. GUILT	2	2	1	0	0	0	0		
							03. SUICIDE	2	1	1	0	0	0	0		
							04. INSOMNIA EARLY	2	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	2	2				2	2	2	2						
08. RETARDATION	1	1	0				0	0	0	0						
09. AGITATION	0	0	0				0	0	0	0						
10. ANXIETY PSYCHIC	2	2	1				1	1	1	1						
11. ANXIETY SOMATIC	2	2	1				1	1	1	1						
12. SOMATIC GASTROINTESTINAL	0	0	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	0	0	0				0	0	0	0						
17. INSIGHT	0	0	0				0	0	0	0						
18. DIURNAL VARIATION	2	2	1				1	1	1	1						
19. DEPERSONALIZATION	0	1	0				0	0	0	0						
20. PARANOID	0	1	0				0	0	0	0						
21. OBSESSIONAL/COMPULSIVE	0	1	0				0	0	0	0						
22. Total score	25	26	14				14	11	11	11						
232	Reboxetine	Male	01. DEPRESSED MOOD	2	2	2	2	2	3	1	1	1				
			02. GUILT	3	2	0	0	0	0	0						
			03. SUICIDE	1	2	0	0	0	0	0						
			04. INSOMNIA EARLY	2	2	2	2	2	1	1						
			05. INSOMNIA MIDDLE	2	2	2	2	2	1	1						
			06. INSOMNIA LATE	0	0	1	2	1	1	1						
			07. WORK AND ACTIVITIES	2	4	3	3	3	2	2						
			08. RETARDATION	1	1	1	1	1	1	1						

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	232	Reboxetine	Male	09. AGITATION	2	2	2	2	2	1	1	1				
				10. ANXIETY PSYCHIC	3	4	2	3	3	2	1	1				
				11. ANXIETY SOMATIC	3	3	3	3	2	2	1	1				
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1				
				13. SOMATIC GENERAL	1	1	1	2	1	1	1	0				
				14. GENITAL SYMPTOMS	1	1	0	0	0	0	0	0				
				15. HYPOCHONDRIASIS	1	2	0	0	0	0	0	0				
				16. LOSS OF WEIGHT	1	0	0	0	2	0	0	0				
				17. INSIGHT	0	0	0	0	0	0	1	0				
				18. DIURNAL VARIATION	1	1	2	1	1	1	1	1				
				19. DEPERSONALIZATION	0	1	0	0	0	0	0	0				
				20. PARANOID	1	0	0	0	0	0	0	0				
				21. OBSESSIONAL/COMPULSIVE	0	1	0	1	1	1	0	0				
				22. Total score	23	34	22	23	25	16	15	11				
				9	197	Reboxetine	Male	04. DEPRESSED MOOD	2	3	3					
								02. GUILT	2	2	2					
								03. SUICIDE	1	1	1					
								04. INSOMNIA EARLY	0	0	0					
								05. INSOMNIA MIDDLE	0	0	0					
								06. INSOMNIA LATE	0	0	0					
								07. WORK AND ACTIVITIES	3	3	3					
								08. RETARDATION	0	2	2					
09. AGITATION	3	2	0													
10. ANXIETY PSYCHIC	1	2	2													
11. ANXIETY SOMATIC	2	1	3													
12. SOMATIC GASTROINTESTINAL	0	1	0													
13. SOMATIC GENERAL	1	1	2													
14. GENITAL SYMPTOMS	2	1	1													
15. HYPOCHONDRIASIS	3	3	3													
16. LOSS OF WEIGHT	0	0	0													
17. INSIGHT	0	0	0													
18. DIURNAL VARIATION	2	0	0													
19. DEPERSONALIZATION	0	1	1													
20. PARANOID	0	0	1													
21. OBSESSIONAL/COMPULSIVE	0	0	0													
22. Total score	22	23	24													
198	Imipramine	Female	01. DEPRESSED MOOD	3	2	2	2	3	2	0	0	0				
			02. GUILT	2	2	2	2	2	0	0						
			03. SUICIDE	0	2	1	1	1	0	0						
			04. INSOMNIA EARLY	2	1	2	2	2	0	0						
			05. INSOMNIA MIDDLE	0	2	0	1	0	0							
			06. INSOMNIA LATE	2	1	1	1	1	0							
			07. WORK AND ACTIVITIES	1	1	1	1	1	0							
			08. RETARDATION	0	0	0	0	0	0							
			09. AGITATION	3	2	0	0	1	0							
			10. ANXIETY PSYCHIC	2	2	2	2	1	0							
			11. ANXIETY SOMATIC	2	2	2	2	2	0							
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	0							

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	198	Imipramine	Female	13. SOMATIC GENERAL	2	2	2	2	2	0	0	0				
				14. GENITAL SYMPTOMS	2	0	0	0	0	0	0					
				15. HYPOCHONDRIASIS	1	2	2	2	2	0	0					
				16. LOSS OF HEIGHT	0	0	0	0	0	0	0					
				17. INSIGHT	2	0	0	0	0	0	0					
				18. DIURNAL VARIATION	0	2	2	2	2	0	0					
				19. DEPERSONALIZATION	1	2	1	1	0	0	0					
				20. PARANOID	0	1	1	1	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	2	0	2	2	0	0					
				22. Total score	27	29	24	25	22	1	0					
				199	199	Imipramine	Male	01. DEPRESSED MOOD	4	3	3	3	3	1	1	2
								02. GUILT	2	1	1	1	1	1	1	
								03. SUICIDE	1	2	2	2	2	0	0	
								04. INSOMNIA EARLY	1	1	1	1	1	0	0	
								05. INSOMNIA MIDDLE	1	0	0	0	1	0	0	
								06. INSOMNIA LATE	1	0	2	2	0	0	0	
								07. WORK AND ACTIVITIES	1	4	4	4	4	4	4	
								08. RETARDATION	2	1	1	1	1	1	1	
								09. AGITATION	1	2	1	1	2	2	2	
								10. ANXIETY PSYCHIC	3	2	2	2	2	2	2	
								11. ANXIETY SOMATIC	1	3	3	3	3	3	4	
								12. SOMATIC GASTROINTESTINAL	2	0	0	0	0	0	0	
13. SOMATIC GENERAL	1	2	2					2	2	2	2					
14. GENITAL SYMPTOMS	1	0	0					0	0	0	0					
15. HYPOCHONDRIASIS	3	3	3					3	3	2	3					
16. LOSS OF WEIGHT	0	0	1					0	1	0	0					
17. INSIGHT	2	1	1					1	1	1	1					
18. DIURNAL VARIATION	0	0	0					0	0	0	0					
19. DEPERSONALIZATION	1	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	29	25	27					27	27	19	24					
200	200	Reboxetine	Male	01. DEPRESSED MOOD	2	3	3	2	2	0	0	0				
				02. GUILT	3	3	3	1	0	0	0					
				03. SUICIDE	1	1	1	0	0	0	0					
				04. INSOMNIA EARLY	0	0	0	0	0	0	0					
				05. INSOMNIA MIDDLE	2	2	2	1	0	0	0					
				06. INSOMNIA LATE	1	1	1	1	0	1	0					
				07. WORK AND ACTIVITIES	3	3	3	2	1	1	1					
				08. RETARDATION	0	0	0	0	0	0	0					
				09. AGITATION	2	2	2	0	0	0	0					
				10. ANXIETY PSYCHIC	3	3	3	2	2	1	1					
				11. ANXIETY SOMATIC	3	3	3	2	1	1	1					
				12. SOMATIC GASTROINTESTINAL	2	2	1	1	1	1	1					
				13. SOMATIC GENERAL	1	1	1	1	1	0	0					
				14. GENITAL SYMPTOMS	1	1	1	1	1	0	0					
				15. HYPOCHONDRIASIS	3	3	3	3	3	1	1					
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0					

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	200	Reboxetine	Male	17.INSIGHT	1	1	1	1	0	0	0	0	0	0	0		
				18.DIURNAL VARIATION	1	1	0	0	0	0	0	0	0	0	0		
				19.DEPERSONALIZATION	0	0	1	0	0	0	0	0	0	0	0		
				20.PARANOID	0	0	0	0	0	0	0	0	0	0	0		
				21.OBSESSIONAL/COMPULSIVE	0	0	1	0	0	0	0	0	0	0	0		
				22.Total score	29	30	30	18	9	6	6	5					
				201	Imipramine	Female	01.DEPRESSED MOOD	3	3	0	0	0	0	0	0	0	0
							02.GUILT	3	2	0	0	0	0	0	1	0	0
							03.SUICIDE	0	0	0	0	0	0	0	0	0	0
							04.INSOMNIA EARLY	0	2	0	0	0	0	0	0	1	0
05.INSOMNIA MIDDLE	2	0	0				0	0	0	0	0	0	0				
06.INSOMNIA LATE	0	1	2				0	0	0	0	0	0	0				
07.WORK AND ACTIVITIES	2	4	2				0	3	2	2	0	0	0				
08.RETARDATION	1	2	0				0	1	0	1	1	1	1				
09.AGITATION	2	1	0				0	0	1	1	1	1	1				
10.ANXIETY PSYCHIC	3	3	3				3	3	1	1	0	2	2				
11.ANXIETY SOMATIC	4	5	4	2	2	0	0	0	0	0							
12.SOMATIC GASTROINTESTINAL	1	0	0	1	1	0	2	0	0	0							
13.SOMATIC GENERAL	1	0	1	1	1	1	1	0	0	0							
14.CENTRAL SYMPTOMS	0	0	1	1	1	1	1	0	0	0							
15.HYPOCHONDRIASIS	0	0	0	1	1	1	1	0	0	0							
16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0							
17.INSIGHT	0	0	1	0	0	0	0	0	0	0							
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	0	0	0	0	0	0	0	0	0	0							
22.Total score	22	22	18	11	13	9	11	6									
202	Imipramine	Male	01.DEPRESSED MOOD	3	4	3	0	1	1	3	2	2	2				
			02.GUILT	2	1	0	0	1	2	2	2	1	1				
			03.SUICIDE	0	0	2	0	1	1	1	1	1	1				
			04.INSOMNIA EARLY	2	1	1	0	0	0	0	0	0	0				
			05.INSOMNIA MIDDLE	0	1	0	1	0	0	0	0	0	0				
			06.INSOMNIA LATE	1	1	2	0	2	0	0	0	0	0				
			07.WORK AND ACTIVITIES	3	3	3	3	3	1	3	2	2	2				
			08.RETARDATION	1	2	1	1	0	0	2	2	0	0				
			09.AGITATION	3	1	2	1	0	0	2	2	1	2				
			10.ANXIETY PSYCHIC	3	1	1	1	2	1	2	1	2	3				
11.ANXIETY SOMATIC	2	1	1	1	1	1	1	1	2	3							
12.SOMATIC GASTROINTESTINAL	0	1	1	1	0	1	1	1	1	2							
13.SOMATIC GENERAL	2	0	1	1	1	1	1	1	1	2							
14.CENTRAL 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 WEIGHT	1	1	1	1	1	1	1	1	1	1							
17.INSIGHT	2	2	1	1	1	1	0	0	0	0							
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							

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	202	Imipramine	Male	21-OBSessional/COMPULSIVE 22-Total score	30	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	203	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-GENERAL SYMPTOMS 15-HYPHONDRIASIS 16-LOSS OF HEIGHT 17-INSIGHT 18-DIURNAL VARIATION 19-DEPERSONALIZATION 20-PARANOID 21-OBSessional/COMPULSIVE 22-Total score	3	4	4	2	2	4	2	4	2	4	2	4	2	4	2
	204	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-GENERAL SYMPTOMS 15-HYPHONDRIASIS 16-LOSS OF HEIGHT 17-INSIGHT 18-DIURNAL VARIATION 19-DEPERSONALIZATION 20-PARANOID 21-OBSessional/COMPULSIVE 22-Total score	3	4	4	2	2	4	2	4	2	4	2	4	2	4	2

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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		
9	205	Female	01. DEPRESSED MOOD	3	3								
			02. GUILT	0	0								
			03. SUICIDE	2	1								
			04. INSOMNIA EARLY	1	1								
			05. INSOMNIA MIDDLE	2	0								
			06. INSOMNIA LATE	3	1								
			07. WORK AND ACTIVITIES	0	0								
			08. RETARDATION	4	3								
			09. AGITATION	3	3								
			10. ANXIETY PSYCHIC	3	3								
			11. ANXIETY SOMATIC	1	2								
			12. SOMATIC GASTROINTESTINAL	2	2								
			13. SOMATIC GENERAL	3	3								
			14. GENITAL SYMPTOMS	1	1								
			15. HYPOCHONDRIASIS	0	0								
			16. LOSS OF HEIGHT	1	2								
			17. INSIGHT	0	0								
			18. DIURNAL VARIATION	0	0								
			19. DEPERSONALIZATION	0	0								
			20. PARANOID	0	0								
			21. OBSESSIONAL/COMPULSIVE	1	1								
			22. Total score			30	30						
206	Imipramine	Female	01. DEPRESSED MOOD	4	4	4	4	4	2	0	0	0	
			02. GUILT	2	2	2	2	1	0	0	0	0	
			03. SUICIDE	0	0	0	0	0	0	0	0	0	0
			04. INSOMNIA EARLY	0	0	0	0	1	1	0	0	0	0
			05. INSOMNIA MIDDLE	2	2	1	1	1	1	0	0	0	0
			06. INSOMNIA LATE	2	2	2	2	2	2	1	1	1	1
			07. WORK AND ACTIVITIES	1	1	1	1	1	0	0	0	0	0
			08. RETARDATION	3	2	1	0	0	0	0	0	0	0
			09. AGITATION	1	2	2	2	2	2	1	1	1	1
			10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1
			11. ANXIETY SOMATIC	3	3	3	3	3	3	2	1	1	1
			12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	0	0	0	0
			13. SOMATIC GENERAL	2	2	2	2	2	2	0	0	0	0
			14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0
			15. HYPOCHONDRIASIS	2	2	2	2	2	2	0	0	0	0
			16. LOSS OF HEIGHT	0	0	0	0	0	0	0	0	0	0
			17. INSIGHT	2	0	0	0	1	1	1	0	0	0
			18. DIURNAL VARIATION	0	1	1	1	0	1	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	1	0	0	0
			22. Total score			29	28	26	25	13	6	4	4
207	Reboxetine	Female	01. DEPRESSED MOOD	3	3	4							
			02. GUILT	1	0	1							
			03. SUICIDE	0	0	0							
			04. INSOMNIA EARLY	2	2	1							

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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					
9	207	Reboxetine	Female	05. INSOMNIA MIDDLE	0	2	0	0	0	0	0	0					
				06. INSOMNIA LATE	2	1	0	0	0	0	0						
				07. WORK AND ACTIVITIES	1	3	2	0	0	0	0	0					
				08. RETARDATION	1	2	0	0	0	0	0	0					
				09. AGITATION	1	2	1	1	1	1	1	1					
				10. ANXIETY PSYCHIC	1	3	2	3	2	2	2	2					
				11. ANXIETY SOMATIC	3	3	3	3	3	3	3	3					
				12. SOMATIC GASTROINTESTINAL	2	1	1	1	1	1	1	1					
				13. SOMATIC GENERAL	0	2	1	1	1	1	1	1					
				14. GENITAL SYMPTOMS	1	0	0	0	0	0	0	0					
				15. HYPOCHONDRIASIS	2	1	0	0	0	0	0	0					
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0					
				17. INSIGHT	2	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	22	26	22	22	23	15	10	15	13	18			
				208	Reboxetine	Male	01. DEPRESSED MOOD	4	5	0	0	0	0	0	0	2	
							02. GUILT	0	2	2	0	0	0	0	0	0	0
							03. SUICIDE	0	0	0	0	0	0	0	0	0	0
							04. INSOMNIA EARLY	1	1	0	0	0	0	0	0	0	0
05. INSOMNIA MIDDLE	1	0	2				0	0	0	0	0	0	0				
06. INSOMNIA LATE	1	2	2				0	0	0	0	0	0	0				
07. WORK AND ACTIVITIES	2	1	2				1	0	1	3	2	0	0				
08. RETARDATION	0	1	0				2	0	0	1	0	0	0				
09. AGITATION	2	2	1				1	1	1	0	0	1	1				
10. ANXIETY PSYCHIC	1	2	3				2	1	2	1	2	1	3				
11. ANXIETY SOMATIC	3	2	4				2	1	0	1	0	1	2				
12. SOMATIC GASTROINTESTINAL	2	2	1				1	1	1	1	1	1	2				
13. SOMATIC GENERAL	2	2	2				1	1	1	1	1	1	2				
14. GENITAL SYMPTOMS	1	1	1				2	2	2	2	2	1	0				
15. HYPOCHONDRIASIS	2	1	3				3	2	4	0	0	0	2				
16. LOSS OF WEIGHT	0	0	0				0	0	0	0	0	0	0				
17. INSIGHT	0	0	0				0	0	0	0	0	0	0				
18. DIURNAL VARIATION	0	0	0				0	0	0	0	0	0	2				
19. DEPERSONALIZATION	1	1	0				0	0	0	0	0	0	1				
20. PARANOID	1	1	0				0	0	0	0	0	0	0				
21. OBSESSIONAL/COMPULSIVE	1	2	0				0	0	0	0	0	0	1				
22. Total score	25	26	23				15	10	15	13	18						
209	Imipramine	Male	01. DEPRESSED MOOD	2	2	2	2	2	2	2	2	2					
			02. GUILT	3	2	2	2	2	2	2	2						
			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	2	2	2	2	2	2	2	2						
			07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	2						
			08. RETARDATION	0	0	0	0	0	0	0	0						

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/047
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	209	Imipramine	Male	09. AGITATION	2	2	1									
				10. ANXIETY PSYCHIC	2	4	2									
				11. ANXIETY SOMATIC	2	2	0									
				12. SOMATIC GASTROINTESTINAL	0	0	0									
				13. SOMATIC GENERAL	2	2	2									
				14. GENITAL SYMPTOMS	1	1	0									
				15. HYPOCHONDRIASIS	3	2	1									
				16. LOSS OF WEIGHT	0	0	0									
				17. INSIGHT	0	1	0									
				18. DIURNAL VARIATION	0	0	0									
				19. DEPERSONALIZATION	0	0	0									
				20. PARANOID	0	0	0									
				21. OBSESSIONAL/COMPULSIVE	1	1	1									
				22. Total score	22	23	14									
				210		Reboxetine	Female	01. DEPRESSED MOOD	4	4	3	3	0	1	0	1
								02. GUILT	0	2	2	1	1	0	0	0
								03. SUICIDE	1	1	1	1	0	0	0	
								04. INSOMNIA EARLY	2	1	0	1	1	1	1	
								05. INSOMNIA MIDDLE	0	0	0	0	0	1	0	
								06. INSOMNIA LATE	1	2	0	2	0	0	1	
								07. WORK AND ACTIVITIES	3	2	2	1	0	1	0	
								08. RETARDATION	1	1	0	0	0	0	0	
09. AGITATION	0	0	2					2	1	1	0					
10. ANXIETY PSYCHIC	3	2	1					3	3	2	1					
11. ANXIETY SOMATIC	4	2	2					2	2	2	1					
12. SOMATIC GASTROINTESTINAL	1	0	0					0	0	0	0					
13. SOMATIC GENERAL	2	0	0					0	0	0	0					
14. GENITAL SYMPTOMS	1	0	0					0	0	0	0					
15. HYPOCHONDRIASIS	2	3	3					2	3	1	2					
16. LOSS OF WEIGHT	0	0	0					0	0	0	0					
17. INSIGHT	1	1	1					0	0	0	0					
18. DIURNAL VARIATION	1	2	1					1	1	1	0					
19. DEPERSONALIZATION	0	1	0					0	0	0	0					
20. PARANOID	0	0	0					0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	1	1	2					1	1	0	0					
22. Total score	28	25	20					21	12	13	10					
211		Reboxetine	Female	01. DEPRESSED MOOD	2	3	3	3	3	0	3					
				02. GUILT	3	3	3	3	3	1						
				03. SUICIDE	3	2	2	0	2	2						
				04. INSOMNIA EARLY	2	1	1	1	1	2						
				05. INSOMNIA MIDDLE	1	1	2	1	2	3						
				06. INSOMNIA LATE	3	2	2	3	3	2						
				07. WORK AND ACTIVITIES	2	0	0	0	1	2						
				08. RETARDATION	2	2	2	2	2	2						
				09. AGITATION	3	2	3	3	3	2						
				10. ANXIETY PSYCHIC	3	2	3	3	2	2						
				11. ANXIETY SOMATIC	1	1	2	1	1	1						

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	211	Reboxetine	Female	13. SOMATIC GENERAL	1	1	2	2	1	1	1	0					
				14. GENITAL SYMPTOMS	2	0	1	1	1	1	1	1	0				
				15. HYPOCHONDRIASIS	2	1	2	2	1	1	1	1	1	0			
				16. LOSS OF WEIGHT	1	0	1	1	0	0	0	0	0	0			
				17. INSIGHT	0	0	0	0	0	0	0	0	0	0	0		
				18. DIURNAL VARIATION	1	2	1	2	0	0	0	0	0	0	0		
				19. DEPERSONALIZATION	2	3	3	3	1	0	0	0	0	0	0		
				20. PARANOID	1	1	1	1	0	0	0	0	0	0	0		
				21. OBSESSIONAL/COMPULSIVE	1	0	0	0	0	0	0	0	0	0	0		
				22. Total score	38	30	37	35	26								
				212	212	Imipramine	Female	01. DEPRESSED MOOD	3	3	2	3	2	1	1	0	
								02. GUILT	2	0	1	1	1	1	1	1	1
								03. SUICIDE	3	0	1	0	1	1	1	1	1
								04. INSOMNIA EARLY	0	1	0	1	0	0	0	0	0
								05. INSOMNIA MIDDLE	2	1	1	0	1	0	0	0	0
								06. INSOMNIA LATE	2	1	1	0	1	0	0	0	0
								07. WORK AND ACTIVITIES	3	3	3	2	1	1	1	1	1
								08. RETARDATION	0	1	0	0	0	0	0	0	0
								09. AGITATION	2	3	3	0	2	1	2	1	2
								10. ANXIETY PSYCHIC	1	1	1	2	1	2	1	1	1
								11. ANXIETY SOMATIC	2	1	1	0	1	1	1	1	1
								12. SOMATIC GASTROINTESTINAL	0	1	1	0	1	0	0	0	0
13. SOMATIC GENERAL	2	2	1					0	0	1	0	0	0				
14. GENITAL SYMPTOMS	0	1	0					0	1	0	0	0	0				
15. HYPOCHONDRIASIS	1	3	3					1	2	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	0	1	2					0	2	0	0	0	0				
19. DEPERSONALIZATION	2	0	0					1	0	1	0	0	0				
20. PARANOID	0	1	1					0	1	0	0	0	0				
21. OBSESSIONAL/COMPULSIVE	0	1	0					2	0	0	0	0	0				
22. Total score	25	35	23					17	18	10	10	2					
237	237	Reboxetine	Male	01. DEPRESSED MOOD	2	3	2	2	3								
				02. GUILT	0	0	0	0	0								
				03. SUICIDE	0	0	0	0	0								
				04. INSOMNIA EARLY	2	2	2	2	2								
				05. INSOMNIA MIDDLE	2	2	2	2	2								
				06. INSOMNIA LATE	2	2	1	2	2								
				07. WORK AND ACTIVITIES	3	3	2	4	4								
				08. RETARDATION	2	3	5	3	3								
				09. AGITATION	1	0	0	3	3								
				10. ANXIETY PSYCHIC	3	3	2	4	4								
				11. ANXIETY SOMATIC	3	2	2	2	2								
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2								
				13. SOMATIC GENERAL	2	2	2	2	2								
				14. GENITAL SYMPTOMS	2	2	2	2	2								
				15. HYPOCHONDRIASIS	3	3	3	3	3								
				16. LOSS OF WEIGHT	0	0	0	0	0								

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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	237	Reboxetine	Male	17. INSIGHT	1	1	1	1	1	1	1	1				
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0			
				19. DEPERSONALIZATION	1	1	1	1	1	1	1	1	1			
				20. PARANOID	0	0	0	0	0	0	0	0	0			
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0			
				22. Total score	33	31	27	36								
				238	Imipramine	Female	01. DEPRESSED MOOD	3	3	3	3	2	2	1	0	0
							02. GUILT	1	1	1	1	1	0	0	0	0
							03. SUICIDE	1	1	1	1	1	1	1	1	0
							04. INSOMNIA EARLY	2	2	2	2	2	1	1	1	0
							05. INSOMNIA MIDDLE	1	1	1	1	1	0	0	0	0
							06. INSOMNIA LATE	0	0	0	0	0	0	0	0	0
							07. WORK AND ACTIVITIES	4	4	4	4	2	2	2	0	0
08. RETARDATION	1	1	1				1	1	0	0	0	0				
09. AGITATION	2	2	2				2	1	1	1	0	0				
10. ANXIETY PSYCHIC	3	3	3				3	2	1	1	0	0				
11. ANXIETY SOMATIC	3	3	3				3	3	1	1	0	0				
12. SOMATIC GASTROINTESTINAL	1	1	1				1	1	2	0	0	0				
13. SOMATIC GENERAL	2	2	2				2	2	2	0	0	0				
14. CENTRAL SYMPTOMS	0	0	0	0	0	0	0	0	0							
15. HYPOCHONDRIASIS	2	2	2	2	1	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	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	0	0	0	0	0	0	0	0	0							
22. Total score	28	28	28	28	19	10	2	2	2	2						
239	Imipramine	Male	01. DEPRESSED MOOD	3	3	3	3	2	1	1	1	1				
			02. GUILT	1	1	1	1	0	0	0	0	0				
			03. SUICIDE	1	1	1	1	0	0	0	0	0				
			04. INSOMNIA EARLY	0	0	0	0	0	0	1	1	1				
			05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	1	1				
			06. INSOMNIA LATE	2	2	2	2	2	1	1	1	1				
			07. WORK AND ACTIVITIES	4	4	4	4	2	2	2	2	1				
			08. RETARDATION	2	2	2	2	1	1	1	1	0				
			09. AGITATION	1	1	1	1	2	2	2	2	1				
			10. ANXIETY PSYCHIC	3	3	3	3	3	3	2	2	1				
			11. ANXIETY SOMATIC	3	3	3	3	3	3	2	2	1				
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	0	0	0				
			13. SOMATIC GENERAL	2	2	2	2	1	1	1	1	0				
14. CENTRAL SYMPTOMS	0	0	0	0	0	0	0	0	0							
15. HYPOCHONDRIASIS	3	3	3	3	3	1	1	1	0							
16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0							
17. INSIGHT	1	1	1	1	1	1	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	0	0	0	0	0	0	0	0	0							

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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	239	Imipramine	Male	21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22.Total score	29	29	25	23	13	17	14	11						
240		Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	3										
				02.GUILT	0	0	0	0										
				03.SUICIDE	2	2	1	1										
				04.INSOMNIA EARLY	0	0	1	1										
				05.INSOMNIA MIDDLE	0	0	1	1										
				06.INSOMNIA LATE	2	2	2	2										
				07.WORK AND ACTIVITIES	3	3	3	3										
				08.RETARDATION	1	1	1	1										
				09.ACTIATION	2	2	1	1										
				10.ANXIETY PSYCHIC	4	4	3	3										
				11.ANXIETY SOMATIC	2	2	2	2										
				12.SOMATIC GASTROINTESTINAL	2	2	1	1										
				13.SOMATIC GENERAL	2	2	1	1										
				14.GENITAL SYMPTOMS	1	1	1	1										
				15.HYPOCHONDRIASIS	2	2	1	1										
				16.LOSS OF WEIGHT	2	2	1	1										
				17.INSIGHT	1	1	1	1										
				18.DIURNAL VARIATION	1	1	1	1										
				19.DEPERSONALIZATION	0	0	2	2										
				20.PARANOID	0	0	0	0										
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0										
				22.Total score	30	32	27	26										
241		Imipramine	Female	01.DEPRESSED MOOD	3	3	3	3										
				02.GUILT	1	1	1	1										
				03.SUICIDE	1	1	1	1										
				04.INSOMNIA EARLY	0	0	0	0										
				05.INSOMNIA MIDDLE	1	1	1	1										
				06.INSOMNIA LATE	1	1	1	1										
				07.WORK AND ACTIVITIES	3	2	2	1										
				08.RETARDATION	0	3	3	3										
				09.AGITATION	3	3	3	3										
				10.ANXIETY PSYCHIC	3	3	3	3										
				11.ANXIETY SOMATIC	1	1	2	1										
				12.SOMATIC GASTROINTESTINAL	0	1	1	1										
				13.SOMATIC GENERAL	1	1	1	1										
				14.GENITAL SYMPTOMS	1	1	1	1										
				15.HYPOCHONDRIASIS	0	0	0	0										
				16.LOSS OF WEIGHT	1	1	2	0										
				17.INSIGHT	0	0	0	0										
				18.DIURNAL VARIATION	1	1	1	1										
				19.DEPERSONALIZATION	0	0	0	0										
				20.PARANOID	0	0	0	0										
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0										
				22.Total score	23	26	27	20										

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	Reboxetine	Male	01. DEPRESSED MOOD	3	3	2	2	1	0	0
			02. GUILT	0	0	0	0	0	0	
			03. SUICIDE	2	2	1	1	0	0	
			04. INSOMNIA EARLY	2	2	1	1	0	0	
			05. INSOMNIA MIDDLE	2	2	2	2	0	0	
			06. INSOMNIA LATE	2	2	2	2	1	0	
			07. WORK AND ACTIVITIES	4	3	3	3	2	0	
			08. RETARDATION	0	0	0	0	0	0	
			09. AGITATION	2	2	2	2	1	0	
			10. ANXIETY PSYCHIC	2	2	2	2	2	0	
			11. ANXIETY SOMATIC	3	3	3	2	2	0	
			12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	
			13. SOMATIC GENERAL	1	1	1	1	1	0	
			14. GENITAL SYMPTOMS	0	0	0	0	0	0	
			15. HYPOCHONDRIASIS	1	1	1	1	1	0	
			16. LOSS OF WEIGHT	0	0	0	0	0	0	
			17. INSIGHT	0	0	0	0	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	24	23	21	19	18	11	0
809	Imipramine	Female	01. DEPRESSED MOOD	3	3	3	2	2	2	1
			02. GUILT	0	0	0	0	1	1	0
			03. SUICIDE	3	3	2	2	1	1	0
			04. INSOMNIA EARLY	2	2	2	1	1	1	0
			05. INSOMNIA MIDDLE	2	2	1	1	0	0	
			06. INSOMNIA LATE	1	1	1	0	0	0	
			07. WORK AND ACTIVITIES	3	3	2	1	1	0	
			08. RETARDATION	2	2	2	1	1	0	
			09. AGITATION	0	0	1	1	1	0	
			10. ANXIETY PSYCHIC	2	2	2	1	1	0	
			11. ANXIETY SOMATIC	3	3	3	2	2	2	
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	
			13. SOMATIC GENERAL	1	1	1	1	1	0	
			14. GENITAL SYMPTOMS	0	0	0	0	0	0	
			15. HYPOCHONDRIASIS	1	1	0	0	0	0	
			16. LOSS OF WEIGHT	2	2	0	0	0	0	
			17. INSIGHT	2	2	0	0	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	21	18	15	12	5
244	Reboxetine	Male	01. DEPRESSED MOOD	4	2	2	2	4	1	1
			02. GUILT	3	3	1	1	2	1	
			03. SUICIDE	0	0	0	0	1	0	
			04. INSOMNIA EARLY	0	0	0	0	2	1	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	Reboxetine	Male	05. INSOMNIA MIDDLE	1	1	1	1	0	0	0			
			06. INSOMNIA LATE	0	0	0	0	0	0	0			
			07. WORK AND ACTIVITIES	4	4	2	2	2	0	0	0		
			08. RETARDATION	3	3	1	1	1	1	1	1		
			09. AGITATION	0	0	0	0	0	0	0	0		
			10. ANXIETY PSYCHIC	3	3	2	1	1	1	1	1		
			11. ANXIETY SOMATIC	2	2	2	2	2	1	1	1		
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1		
			13. SOMATIC GENERAL	2	2	2	1	1	1	1	1		
			14. GENITAL SYMPTOMS	2	2	2	1	1	1	1	1		
			15. HYPOCHONDRIASIS	2	2	2	1	1	1	1	1		
			16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0		
			17. INSIGHT	2	2	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	29	16	14	14	21	14	14	12	
			257	Reboxetine	Female	01. DEPRESSED MOOD	3	3	2	1	0	1	0
						02. GUILT	1	1	0	0	0	0	0
						03. SUICIDE	1	1	0	0	0	0	0
						04. INSOMNIA EARLY	2	2	0	0	0	0	0
05. INSOMNIA MIDDLE	1	1				0	1	0	0	0			
06. INSOMNIA LATE	2	2				0	0	0	0	0			
07. WORK AND ACTIVITIES	3	3				1	0	0	0	0			
08. RETARDATION	3	2				1	1	0	1	0			
09. AGITATION	3	3				0	0	0	0	0			
10. ANXIETY PSYCHIC	2	2				1	1	0	0	0			
11. ANXIETY SOMATIC	3	1				2	2	1	0	2			
12. SOMATIC GASTROINTESTINAL	1	1				2	2	1	0	0			
13. SOMATIC GENERAL	2	2				2	2	0	1	1			
14. GENITAL SYMPTOMS	2	1				2	0	0	0	0			
15. HYPOCHONDRIASIS	3	1				0	0	0	1	0			
16. LOSS OF WEIGHT	0	0				0	0	0	0	0			
17. INSIGHT	1	1				1	1	0	0	1			
18. DIURNAL VARIATION	2	1				1	1	0	1	1			
19. DEPERSONALIZATION	1	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	36	30				14	12	1	15	8	7		
258	Reboxetine	Male	01. DEPRESSED MOOD	2	3	2	3	3	3	3			
			02. GUILT	2	2	2	2	2	2	2			
			03. SUICIDE	1	1	2	0	2	2	2			
			04. INSOMNIA EARLY	2	1	2	2	2	2	2			
			05. INSOMNIA MIDDLE	2	1	0	1	2	2	2			
			06. INSOMNIA LATE	2	1	0	1	2	2	2			
			07. WORK AND ACTIVITIES	1	2	2	3	3	3	3			
			08. RETARDATION	1	1	1	1	1	1	1			

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 12.0
 HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
9	258	Reboxetine	Male	09. AGITATION	2	3	0	2	1								
				10. ANXIETY PSYCHIC	3	4	4	1	2								
				11. ANXIETY SOMATIC	4	3	4	2	2								
				12. SOMATIC GASTROINTESTINAL	1	2	1	2	2								
				13. SOMATIC GENERAL	2	1	2	1	2								
				14. GENITAL SYMPTOMS	1	0	2	1	1								
				15. HYPOCHONDRIASIS	2	2	0	2	2								
				16. LOSS OF WEIGHT	0	0	0	0	0								
				17. INSIGHT	1	1	0	0	0								
				18. DIURNAL VARIATION	0	0	1	0	1								
				19. DEPERSONALIZATION	0	1	0	1	1								
				20. PARANOID	0	1	0	1	1								
				21. OBSESSIONAL/COMPULSIVE	0	1	1	2	1								
				22. Total score	29	31	29	28	35								
				259	Imipramine	Female	01. DEPRESSED MOOD	2	2	2	2	1	1	1	1	1	
							02. GUILT	0	0	0	0	0	0	0	0	0	0
							03. SUICIDE	0	0	0	0	0	0	0	0	0	0
							04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2
							05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2
							06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2
							07. MORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2
							08. RETARDATION	2	2	2	2	2	2	2	2	2	2
09. AGITATION	2	2	2				2	2	2	2	2	2	2				
10. ANXIETY PSYCHIC	3	3	3				3	3	3	3	3	3	3				
11. ANXIETY SOMATIC	3	3	3				3	3	3	3	3	3	3				
12. SOMATIC GASTROINTESTINAL	2	2	2				2	2	2	2	2	2	2				
13. SOMATIC GENERAL	2	2	2				2	2	2	2	2	2	2				
14. GENITAL SYMPTOMS	1	1	1				1	1	1	1	1	1	1				
15. HYPOCHONDRIASIS	2	2	2				2	2	2	2	2	2	2				
16. LOSS OF WEIGHT	1	1	1				1	1	1	1	1	1	1				
17. INSIGHT	0	0	0				0	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	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	29	29	29				29	13	14	15	12						
260	Imipramine	Female	01. DEPRESSED MOOD	4	1	1	2	4									
			02. GUILT	2	2	1	1										
			03. SUICIDE	0	0	0	0	3									
			04. INSOMNIA EARLY	2	2	1	2	1									
			05. INSOMNIA MIDDLE	0	0	0	0	0									
			06. INSOMNIA LATE	0	0	1	0	0									
			07. MORK AND ACTIVITIES	5	2	0	5	2									
			08. RETARDATION	0	0	0	1	0									
			09. AGITATION	4	4	4	4	4									
			10. ANXIETY PSYCHIC	4	3	3	3	2									
			11. ANXIETY SOMATIC	4	2	2	1	1									
			12. SOMATIC GASTROINTESTINAL	1	0	0	0	1									

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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			
9	260	Female	Imipramine	13.SOMATIC GENERAL	1	1	0	1	1					
				14.GENITAL SYMPTOMS	1	1	0	1	1					
				15.HYPOCHONDRIASIS	2	3	3	1	1					
				16.LOSS OF WEIGHT	0	0	1	0	0					
				17.INSIGHT	2	0	2	2	0					
				18.DIURNAL VARIATION	0	2	2	0	0					
				19.DEPERSONALIZATION	1	1	0	1	1					
				20.PARANOID	2	2	2	2	1					
				21.OBSESSIONAL/COMPULSIVE	2	0	0	1	1					
				22.Total score	35	26	24	27	25					
				261	Female	Imipramine	01.DEPRESSED MOOD	4	4	4				
							02.GUILT	3	2	3				
							03.SUICIDE	0	0	2				
							04.INSOMNIA EARLY	1	1	2				
							05.INSOMNIA MIDDLE	2	2	1				
							06.INSOMNIA LATE	2	2	1				
							07.WORK AND ACTIVITIES	1	2	3				
							08.RETARDATION	2	2	1				
							09.AGITATION	2	2	5				
							10.ANXIETY PSYCHIC	3	2	2				
							11.ANXIETY SOMATIC	1	2	2				
							12.SOMATIC GASTROINTESTINAL	0	2	2				
13.SOMATIC GENERAL	2	2	1											
14.GENITAL SYMPTOMS	1	1	2											
15.HYPOCHONDRIASIS	1	2	2											
16.LOSS OF WEIGHT	0	0	0											
17.INSIGHT	2	1	0											
18.DIURNAL VARIATION	1	1	1											
19.DEPERSONALIZATION	1	1	0											
20.PARANOID	2	1	1											
21.OBSESSIONAL/COMPULSIVE	1	1	1											
22.Total score	32	33	34											
262	Male	Reboxetine	01.DEPRESSED MOOD	4	4	2	1	2	2	3	1			
			02.GUILT	2	3	2	1	3	1	1	1	0		
			03.SUICIDE	1	2	1	0	0	0	0	0	0		
			04.INSOMNIA EARLY	2	2	2	1	1	1	1	0	0		
			05.INSOMNIA MIDDLE	2	2	1	1	1	1	0	0	0		
			06.INSOMNIA LATE	2	2	1	1	1	0	0	0	0		
			07.WORK AND ACTIVITIES	2	2	1	1	3	0	1	1	1		
			08.RETARDATION	0	1	0	0	0	0	0	0	0		
			09.AGITATION	2	1	1	1	0	1	0	1	1		
			10.ANXIETY PSYCHIC	3	1	1	1	0	1	1	1	1		
			11.ANXIETY SOMATIC	2	2	2	0	0	2	0	0	0		
			12.SOMATIC GASTROINTESTINAL	1	2	0	0	0	0	1	1	1		
			13.SOMATIC GENERAL	2	2	1	1	0	0	0	0	0		
			14.GENITAL SYMPTOMS	1	2	0	0	1	0	0	0	0		
			15.HYPOCHONDRIASIS	1	1	0	0	0	0	0	0	0		
			16.LOSS OF WEIGHT	2	1	2	0	0	0	0	0	0		

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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	262	Reboxetine	Male	17. INSIGHT	0	1	0	0	1	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	0		
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
				20. PARANOID	0	0	1	1	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	32	30	20	12	12	8	8	8	7								
				263	Reboxetine	Female	01. DEPRESSED MOOD	4	1	3	3										
							02. GUILT	2	0	2	1										
							03. SUICIDE	2	0	1	0										
							04. INSOMNIA EARLY	1	0	1	1										
05. INSOMNIA MIDDLE	2	0	1				2														
06. INSOMNIA LATE	2	0	1				0														
07. WORK AND ACTIVITIES	3	4	2				2														
08. RETARDATION	0	0	3				0														
09. AGITATION	1	0	1				1														
10. ANXIETY PSYCHIC	2	0	2				2														
11. ANXIETY SOMATIC	3	1	1	2																	
12. SOMATIC GASTROINTESTINAL	0	1	1	0																	
13. SOMATIC GENERAL	2	1	1	2																	
14. GENITAL STIMULUS	1	0	1	1																	
15. HYPOCHONDRIASIS	0	2	1	1																	
16. LOSS OF WEIGHT	2	2	0	0																	
17. INSIGHT	0	1	0	0																	
18. DIURNAL VARIATION	1	1	0	0																	
19. DEPERSONALIZATION	0	0	0	0																	
20. PARANOID	0	0	0	0																	
21. OBSESSIONAL/COMPULSIVE	0	1	0	0																	
22. Total score	28	16	23	16																	
264	Imipramine	Female	01. DEPRESSED MOOD	3	3	2	1														
			02. GUILT	2	3	1	0														
			03. SUICIDE	0	1	0	0														
			04. INSOMNIA EARLY	1	0	1	1														
			05. INSOMNIA MIDDLE	0	0	0	0														
			06. INSOMNIA LATE	0	0	1	1														
			07. WORK AND ACTIVITIES	3	3	3	2														
			08. RETARDATION	3	3	1	0														
			09. AGITATION	2	1	1	0														
			10. ANXIETY PSYCHIC	3	2	2	1														
11. ANXIETY SOMATIC	2	2	1	2																	
12. SOMATIC GASTROINTESTINAL	2	2	1	2																	
13. SOMATIC GENERAL	2	1	2	1																	
14. GENITAL STIMULUS	2	1	3	0																	
15. HYPOCHONDRIASIS	2	0	0	0																	
16. LOSS OF WEIGHT	2	1	0	0																	
17. INSIGHT	0	0	1	0																	
18. DIURNAL VARIATION	2	1	1	0																	
19. DEPERSONALIZATION	0	0	0	0																	
20. PARANOID	1	1	1	0																	

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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	264	Imipramine	Female	21.OBSESSIONAL/COMPULSIVE	2	2	1	0	0	0	0	0	0	0	0	0	0	0
				22.Total score	32	27	25	10	11	10	11	10	11	10	11	11	16	16
	265	Reboxetine	Female	01.DEPRESSED MOOD	3	2	3	1	0	0	0	0	0	3	2	2	1	0
				02.GUILT	0	0	0	0	0	0	0	0	0	0	0	1	0	0
				03.SUICIDE	0	3	3	1	1	0	0	3	1	0	3	1	0	0
				04.INSOMNIA EARLY	2	1	1	1	0	2	2	2	2	1	0	2	1	0
				05.INSOMNIA MIDDLE	1	1	1	1	2	1	2	2	2	1	2	2	0	0
				06.INSOMNIA LATE	1	1	1	1	1	0	1	0	1	1	1	0	0	0
				07.WORK AND ACTIVITIES	3	3	3	3	3	1	2	3	2	3	2	3	2	2
				08.RETARDATION	1	1	1	1	1	0	1	1	1	1	1	1	1	1
				09.AGITATION	1	1	1	1	3	1	2	2	2	2	2	2	2	1
				10.ANXIETY PSYCHIC	2	3	4	3	0	1	2	2	1	1	1	0	0	0
				11.ANXIETY SOMATIC	3	3	3	3	0	1	2	1	1	1	1	0	0	0
				12.SOMATIC GASTROINTESTINAL	2	1	1	0	1	1	1	1	1	1	1	0	0	0
				13.SOMATIC GENERAL	2	1	1	1	0	1	1	1	1	1	1	0	0	0
				14.GENITAL SYMPTOMS	0	1	1	1	1	0	1	1	1	1	1	0	0	0
				15.HYPOCHONDRIASIS	1	2	0	1	1	0	1	0	1	1	1	1	0	0
				16.LOSS OF WEIGHT	1	1	0	0	0	0	0	0	0	2	0	0	0	0
				17.INSIGHT	0	0	1	1	2	2	1	1	1	1	1	1	1	1
				18.DIURNAL VARIATION	0	0	2	2	2	1	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	0	1	1	1	0	1	1	1	1	1	1	1	1	1
				20.FARANOID	0	2	1	2	1	2	1	1	1	1	1	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	1
				22.Total score	22	30	29	22	10	22	20	10	28	20	20	9	9	9
	266	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	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
				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
				05.INSOMNIA MIDDLE	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
				07.WORK AND ACTIVITIES	3	3	2	2	1	0	1	0	1	1	1	1	1	1
				08.RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				09.AGITATION	3	3	2	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	2	0	0
				11.ANXIETY SOMATIC	3	3	3	2	2	1	1	1	1	1	2	0	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	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	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	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.FARANOID	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	23	18	14	10	14	10	14	10	14	14	14	8

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PHARMACIA CNS R&D
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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
9	267	Imipramine	Male	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	1	1	1	
				05. INSOMNIA MIDDLE	2	2	2	2	0	0	0	
				06. INSOMNIA LATE	2	2	2	2	0	0	0	
				07. WORK AND ACTIVITIES	2	2	1	0	0	0	0	
				08. RETARDATION	1	1	0	0	0	0	0	
				09. AGITATION	2	2	1	0	0	0	0	
				10. ANXIETY PSYCHIC	2	2	2	1	1	1	2	
				11. ANXIETY SOMATIC	3	3	2	2	2	1	2	
				12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	
				15. HYPOCHONDRIASIS	1	1	1	1	0	0	0	
				16. LOSS OF HEIGHT	2	2	2	0	0	0	0	
				17. INSIGHT	0	0	0	0	0	0	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	0	0	0	0	0	0	0	
				22. Total score	27	27	19	12	6	4	4	6
268	Imipramine	Female	01. DEPRESSED MOOD	4	4	0	0	1	1	1	3	2
			02. GUILT	1	1	0	1	2	2	1		
			03. SUICIDE	0	0	0	0	1	1	0		
			04. INSOMNIA EARLY	0	0	0	0	0	0	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	4	4	2	1	2	1	3		
			08. RETARDATION	3	2	2	1	1	1	2		
			09. AGITATION	1	1	2	1	1	1	1		
			10. ANXIETY PSYCHIC	3	3	1	2	2	1	4		
			11. ANXIETY SOMATIC	4	4	1	1	0	0	2		
			12. SOMATIC GASTROINTESTINAL	0	0	1	1	0	1	1		
			13. SOMATIC GENERAL	2	2	1	1	1	1	2		
			14. GENITAL SYMPTOMS	2	2	1	1	1	1	2		
			15. HYPOCHONDRIASIS	2	2	1	1	1	1	0		
			16. LOSS OF HEIGHT	0	0	0	0	0	0	0		
			17. INSIGHT	1	1	0	0	0	0	0		
			18. DIURNAL VARIATION	1	0	1	1	1	1	2		
			19. DEPERSONALIZATION	1	1	0	1	0	0	0		
			20. PARANOID	1	1	0	1	1	1	0		
			21. OBSESSIONAL/COMPULSIVE	1	1	1	0	1	0	0		
			22. Total score	31	32	14	16	14	14	25	19	
269	Reboxetine	Male	01. DEPRESSED MOOD	3	3	0	0	0	0	0	0	0
			02. GUILT	1	0	1	0	0	0	0		
			03. SUICIDE	0	0	0	0	0	0	0		
			04. INSOMNIA EARLY	2	2	2	0	0	0	0		

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REBOXETINE - PROTOCOL 20124/017
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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	269	Reboxetine	Male	05.INSOMNIA MIDDLE 06.INSOMNIA LATE 07.WORK AND ACTIVITIES 08.RETARDATION 09.AGITATION 10.ANKIETY PSYCHIC 11.ANKIETY 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 0 4 2 2 2 0 2 3 4 0 0 0 0 25	1 0 3 2 1 1 1 1 0 3 1 0 0 0	0 0 2 1 1 1 1 1 1 1 1 0 0 0	0 0 2 1 1 1 1 1 0 1 0 0 0	0 0 1 0 1 1 1 1 0 1 0 0 0	0 0 1 0 0 0 0 0 0 0 0 0	0 0 1 0 0 0 0 0 0 0 0 0
270		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.ANKIETY PSYCHIC 11.ANKIETY 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 1 0 0 1 0 0 0 4 2 3 2 1 0	4 0 0 0 0 0 4 3 0 2 1 1 1 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	3 0 0 0 0 0 0 0 0 0 0 0 0 17	
271		Reboxetine	Female	01.DEPRESSED MOOD 02.GUILT 03.SUICIDE 04.INSOMNIA EARLY 05.INSOMNIA MIDDLE 06.INSOMNIA LATE 07.WORK AND ACTIVITIES 08.RETARDATION	3 2 1 2 2 2 4 3	3 2 0 2 2 1 3 3	2 2 0 2 2 1 3 3	2 2 0 2 2 1 3 3	2 2 0 2 2 1 3 3	2 2 0 2 2 1 3 3	2 2 0 2 2 1 3 3

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PHARMACIA CSR 800
 RESONANCE - PROTOCOL 2012A/017
 Listing No.1 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	271	Rebouxine Female	09. ACTIVATION	1	3	1	1	1	1	1				
			10. ANXIETY PSYCHIC	4	3	3	1	1	1					
			11. ANXIETY SOMATIC	1	2	2	1	1	1					
			12. SOMATIC GASTROINTESTINAL	0	1	1	0	0	0					
			13. SOMATIC GENERAL	1	2	2	2	2	2					
			14. GENITAL SYMPTOMS	1	1	1	1	1	1					
			15. HYPOCHONDRIASIS	0	2	2	2	2	2					
			16. LOSS OF WEIGHT	0	2	0	0	0	0					
			17. INSIGHT	1	1	1	1	1	1					
			18. DIURNAL VARIATION	1	1	1	1	1	1					
			19. DEPERSONALIZATION	1	0	0	0	0	0					
			20. PARANOID	0	0	0	0	0	0					
			21. OBSSSSIONAL/COMPULSIVE	2	1	1	1	1	1					
			22. Total score	31	35	31	24	23	24					
			272	Indipramine Male	01. DEPRESSED MOOD	4	4	3	0	0	0	0	0	
					02. SUICID	1	2	0	0	0	0	0	0	
					03. SUICIDE	0	0	0	0	0	0	0	0	
					04. INSOMNIA EARLY	2	0	0	0	0	0	0	0	
					05. INSOMNIA MIDDLE	1	2	2	2	1	1	0	0	
					06. INSOMNIA LATE	1	2	2	1	0	0	0	0	
					07. ROSE AND ACTIVITIES	3	4	4	3	3	3	2	1	1
					08. RETARDATION	2	2	1	1	1	1	1	1	1
09. ACTIVATION	1	2			1	0	0	0	0	0	0			
10. ANXIETY PSYCHIC	2	3			3	0	0	0	1	1	1			
11. ANXIETY SOMATIC	1	4			2	0	0	0	1	1	1			
12. SOMATIC GASTROINTESTINAL	2	1			0	0	0	0	0	0	0			
13. SOMATIC GENERAL	1	2			2	2	2	2	2	2	2			
14. GENITAL SYMPTOMS	2	2			2	2	2	2	2	2	2			
15. HYPOCHONDRIASIS	1	3			3	2	2	2	2	2	2			
16. LOSS OF WEIGHT	0	2			2	1	0	0	0	0	0			
17. INSIGHT	2	1			1	0	0	0	0	0	0			
18. DIURNAL VARIATION	0	1			2	-2	1	1	0	0	1			
19. DEPERSONALIZATION	1	3			2	0	0	0	0	1	1			
20. PARANOID	1	2			2	0	0	0	0	0	0			
21. OBSSSSIONAL/COMPULSIVE	1	1			1	1	1	1	1	1	0			
22. Total score	29	45			37	17	15	13	11	9				
273	Indipramine Female	01. DEPRESSED MOOD	4	4	4	4	3	3	3	3				
		02. SUICID	1	3	3	3	3	3	3	3				
		03. SUICIDE	1	3	3	3	3	3	3	3				
		04. INSOMNIA EARLY	2	1	2	2	2	2	2	2				
		05. INSOMNIA MIDDLE	0	2	2	2	1	2	2	2				
		06. INSOMNIA LATE	1	2	1	1	1	1	1	1				
		07. ROSE AND ACTIVITIES	4	4	3	3	3	3	3	3				
		08. RETARDATION	3	2	1	1	1	1	1	1				
		09. ACTIVATION	1	4	4	3	3	3	3	3				
		10. ANXIETY PSYCHIC	1	4	4	3	3	3	3	3				
		11. ANXIETY SOMATIC	1	2	2	1	1	1	1	1				
		12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1				

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	273	Imipramine	Female	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	1	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	1	1	2	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
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				22. Total score	32	42	41	41	33	31	31	34						
274	Reboxetine	Female	01. DEPRESSED MOOD	3	3	1	1	1	1	1	1	1	1	1	1	1	1	1
			02. GUILT	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
			03. SUICIDE	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
			04. INSOMNIA EARLY	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1
			05. INSOMNIA MIDDLE	1	0	2	2	2	2	2	2	2	2	2	2	2	2	2
			06. INSOMNIA LATE	1	0	2	2	2	2	2	2	2	2	2	2	2	2	2
			07. WORK AND ACTIVITIES	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1
			08. RETARDATION	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2
			09. ACTIVATION	2	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
			11. ANXIETY SOMATIC	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1
			12. SOMATIC GASTROINTESTINAL	1	2	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	1	1
			14. GENITAL SYMPTOMS	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1
			15. HYPOCHONDRIASIS	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1
			16. LOSS OF WEIGHT	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0
			17. INSIGHT	1	2	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
			19. DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			20. PARANOID	0	1	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	29	23	23	21	21	21	21	21	21	21	21	21	21	21
274/A	Reboxetine	Female	01. DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
			02. GUILT	3	3	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	0	0	0	0	0	0	0	0	0	0	0	0	0
			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	4	4	4	4	4	4	4	4	4	4	4	4
			08. RETARDATION	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2
			09. ACTIVATION	1	1	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	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. GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
			15. HYPOCHONDRIASIS	3	3	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

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	274/A	Reboxetine	Female	17. INSIGHT	1	1	1	1	1	1	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	1	1	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	0	0			
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			
				22. Total score	31	30	24	22	15	13	11	11	13	11	13	11	13	11	13	11			
				275	Reboxetine	Female	01. DEPRESSED MOOD	3	4	2	2	3	3	2	2	2	2	2	2	2	2	1	
							02. GUILT	0	2	2	1	2	2	2	2	2	2	2	2	2	2	2	1
							03. SUICIDE	0	2	2	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	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
							06. INSOMNIA LATE	0	2	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	2
							08. RETARDATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
							09. AGITATION	1	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0
							10. ANXIETY PSYCHIC	1	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	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	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
							15. HYPOCHONDRIASIS	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
							16. LOSS OF WEIGHT	0	2	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	0	0	2				1	0	0	0	0	0	0	0	0	0	0	0	0				
19. DEPERSONALIZATION	0	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	0	0	1				1	1	1	1	1	1	1	1	1	1	1	1	1				
22. Total score	23	38	28				28	26	15	15	15	15	15	15	15	15	15	15	15				
276	Imipramine	Female	01. DEPRESSED MOOD	4	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	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	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			06. INSOMNIA LATE	1	2	1	2	1	2	1	2	1	2	1	2	1	2	1					
			07. WORK AND ACTIVITIES	3	4	3	4	3	4	3	4	3	4	3	4	3	4	3					
			08. RETARDATION	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			09. AGITATION	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			10. ANXIETY PSYCHIC	0	2	1	1	1	1	1	1	1	1	1	1	1	1	1					
			11. ANXIETY SOMATIC	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1					
			12. SOMATIC GASTROINTESTINAL	2	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	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					
			17. INSIGHT	1	2	1	2	1	2	1	2	1	2	1	2	1	2	1					
			18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
			19. DEPERSONALIZATION	1	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 20124/017
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	276	Imipramine	Female	0	1	0	23	23	23	23	23	23	23	23	23	23	23	23
	276/A	Imipramine	Male	2	2	3	4	4	3	3	2	2	2	2	2	2	2	2
				21.OBSESSIONAL/COMPULSIVE	2	2	3	4	3	3	2	2	2	2	2	2	2	2
				22.Total score	23	23	23	23	23	23	23	23	23	23	23	23	23	23
				01.DEPRESSED MOOD	2	2	3	4	3	3	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	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				08.RETARDATION	4	3	3	3	3	3	2	2	2	2	2	2	2	2
				09.ANXIETY PSYCHIC	3	3	3	3	3	3	2	2	2	2	2	2	2	2
				10.ANXIETY SOMATIC	4	4	4	4	4	4	3	3	3	3	3	3	3	3
				11.ANXIETY SOMATIC	4	4	4	4	4	4	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	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.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22.Total score	22	23	25	30	23	23	23	23	23	23	23	23	23	23
9/A	238	Imipramine	Male	3	3	3	3	3	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	1
				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	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	4	4	4	4	4	4	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.ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10.ANXIETY SOMATIC	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
				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	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	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	1	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	0	0	0	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	1	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	30	29	28	28	28	28	28	28	28	28	28	28	28

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
9/A	278	Imipramine	Female	09. AGITATION	3	2	2	1	2	2						
				10. ANXIETY PSYCHIC	2	2	2	1	2							
				11. ANXIETY SOMATIC	1	2	1	1	2							
				12. SOMATIC GASTROINTESTINAL	0	1	0	0	1							
				13. SOMATIC GENERAL	2	2	2	1	2							
				14. GENITAL SYMPTOMS	2	2	2	1	2							
				15. HYPOCHONDRIASIS	0	0	0	0	0							
				16. LOSS OF WEIGHT	0	0	0	0	0							
				17. INSIGHT	0	0	0	0	0							
				18. DIURNAL VARIATION	1	1	1	0	0							
				19. DEPERSONALIZATION	2	2	1	0	1							
				20. PARANOID	1	1	0	0	0							
				21. OBSESSIONAL/COMPULSIVE	1	1	1	0	1							
				22. Total score	29	31	21	9	24							
				279	279	Imipramine	Male	01. DEPRESSED MOOD	3	3	3	3	3			
								02. GUILT	2	2	2	2	1			
								03. SUICIDE	1	1	1	1	1			
								04. INSOMNIA EARLY	1	1	1	1	1			
								05. INSOMNIA MIDDLE	1	1	2	2	2			
								06. INSOMNIA LATE	1	1	1	1	2			
								07. WORK AND ACTIVITIES	3	3	3	3	3			
								08. RETARDATION	1	1	1	0	0			
09. AGITATION	1	1	2					2	3							
10. ANXIETY PSYCHIC	2	2	2					2	2							
11. ANXIETY SOMATIC	1	1	1					2	2							
12. SOMATIC GASTROINTESTINAL	0	0	1					1	1							
13. SOMATIC GENERAL	2	2	2					2	2							
14. GENITAL SYMPTOMS	1	1	1					1	1							
15. HYPOCHONDRIASIS	1	1	1					1	3							
16. LOSS OF WEIGHT	0	0	0					0	0							
17. INSIGHT	1	1	0					0	0							
18. DIURNAL VARIATION	0	0	0					0	0							
19. DEPERSONALIZATION	1	1	2					2	2							
20. PARANOID	0	0	0					0	0							
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0							
22. Total score	23	23	26					30								
280	280	Reboxetine	Female	01. DEPRESSED MOOD	3	3	3	3	3							
				02. GUILT	2	2	2	2	2							
				03. SUICIDE	1	1	1	1	1							
				04. INSOMNIA EARLY	1	1	1	1	1							
				05. INSOMNIA MIDDLE	2	2	2	2	2							
				06. INSOMNIA LATE	1	1	1	1	2							
				07. WORK AND ACTIVITIES	3	3	3	3	3							
				08. RETARDATION	1	1	0	0	0							
				09. AGITATION	2	2	2	2	2							
				10. ANXIETY PSYCHIC	2	2	2	2	2							
				11. ANXIETY SOMATIC	2	2	2	2	2							
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1							

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 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
9/A	280	Reboxetine 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	29	28	30					
	281	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	25	27	15	7	4	3	3	2
	282	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	4	3	3	2	2	2	1	1

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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/A	282	Reboxetine	Male	17. INSIGHT	0	0	0	1	1	0	0	0
				18. DIURNAL VARIATION	1	1	1	6	0	0	0	0
				19. DEPERSONALIZATION	1	1	1	1	0	0	1	0
				20. PARANOID	1	1	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	1	1	1	0	0	0	0	0
				22. Total score	34	33	29	22	18	15	15	12
	283	Imipramine	Female	01. DEPRESSED MOOD	3	3	3	1	1	1	1	0
				02. GUILT	1	1	1	0	0	0	0	0
				03. SUICIDE	1	0	1	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	0	1	1	0	1
				05. INSOMNIA MIDDLE	0	1	1	1	0	0	0	1
				06. INSOMNIA LATE	1	1	1	0	0	0	0	1
				07. WORK AND ACTIVITIES	2	3	2	1	1	1	1	1
				08. RETARDATION	2	2	2	1	0	0	0	0
				09. AGITATION	2	2	2	1	1	1	1	1
				10. ANXIETY PSYCHIC	2	2	2	1	0	0	0	0
				11. ANXIETY SOMATIC	2	2	1	0	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	2	2	2	1	1	1	1	1
				15. HYPOCHONDRIASIS	2	2	2	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	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	25	26	24	8	9	8	7	5
	284	Imipramine	Male	01. DEPRESSED MOOD	4	4	4	3	3	3	3	3
				02. GUILT	1	1	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	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	4	4	4	3	4	4	4	4
				08. RETARDATION	0	0	0	0	0	0	0	0
				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	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	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	1	1	1	1
				20. PARANOID	0	0	0	0	0	0	0	0

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PHARMACIA CNS R&D
 REBOMETINE - PROTOCOL 20124/017
 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/A	284	Imipramine	Male	21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	1
				22.Total score	33	30	28	24	28			
	301	Imipramine	Female	01.DEPRESSED MOOD	3	3	2	1	0	0	0	0
				02.GUILT	1	1	1	0	0	0	0	0
				03.SUICIDE	1	1	1	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	1	1	1	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	3	3	2	1	1	1	0	1
				08.RETARDATION	0	0	0	0	0	0	0	0
				09.AGITATION	2	2	2	1	1	0	0	0
				10.ANXIETY PSYCHIC	1	2	1	1	1	0	0	0
				11.ANXIETY SOMATIC	1	2	1	1	1	0	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	0	0	0
				13.SOMATIC GENERAL	2	2	2	1	1	1	1	0
				14.GENERAL SYMPTOMS	2	2	2	1	1	1	1	0
				15.HYPOCHONDRIASIS	1	2	1	0	0	0	0	0
				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	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	1	1	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	24	25	20	8	5	3	2	3
	302	Imipramine	Male	01.DEPRESSED MOOD	3	3	3	3	3	3	3	3
				02.GUILT	2	2	2	1	1	1	1	1
				03.SUICIDE	1	1	1	1	1	1	1	1
				04.INSOMNIA EARLY	0	0	1	0	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	1	1	1	1	1	1	0	0
				09.AGITATION	2	3	3	3	3	3	4	4
				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.GENERAL SYMPTOMS	2	2	2	2	2	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	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	26	27	29	28	29	28	29	29

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PHARMACIA CNS R&D
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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
9/A	303	Reboxetine	Female	01. DEPRESSED MOOD	4	4	3	3	3	3	3	3
				02. GUILT	1	2	1	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	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	4	3	3	3	3	3	3	3
				08. RETARDATION	1	1	0	0	0	0	0	0
				09. AGITATION	2	2	1	2	3	3	3	3
				10. ANXIETY PSYCHIC	2	2	1	1	1	1	1	1
				11. ANXIETY SOMATIC	2	2	1	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	2	2	1	1	1	1	1	1
				13. SOMATIC GENERAL	2	2	1	2	2	2	2	2
				14. GENITAL SYMPTOMS	1	2	1	2	2	2	2	2
				15. HYPOCHONDRIASIS	1	2	1	2	2	2	2	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	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	0	0	1	1	1	1	1	1
				22. Total score	30	29	18	26	29	26	17	29
				01. DEPRESSED MOOD	3	3	2	1	1	1	0	0
				02. GUILT	1	1	1	1	1	1	0	0
				03. SUICIDE	1	1	0	0	0	0	0	0
				04. INSOMNIA EARLY	1	1	1	1	1	1	1	1
				05. INSOMNIA MIDDLE	0	1	0	0	1	1	0	0
				06. INSOMNIA LATE	1	1	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	3	3	2	1	2	2	2	1
				08. RETARDATION	1	1	1	1	1	1	1	1
				09. AGITATION	2	3	2	2	2	1	1	0
				10. ANXIETY PSYCHIC	2	3	2	1	1	1	1	1
				11. ANXIETY SOMATIC	2	2	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0
				13. SOMATIC GENERAL	2	2	1	2	2	1	0	0
				14. GENITAL SYMPTOMS	2	2	2	1	2	2	1	1
				15. HYPOCHONDRIASIS	2	2	2	1	2	2	1	1
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17. INSIGHT	1	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	1	1	0	0	0	0	0	0
				20. PARANOID	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	1	1	1	1	0	0
				22. Total score	26	29	18	14	17	14	7	5
				01. DEPRESSED MOOD	3	3	2	1	1	1	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	1	1	1	1	1	1	1	1

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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/A	307	Imipramine	Female	09. AGITATION	2	2	2	2										
				10. ANXIETY PSYCHIC	2	2	2	2										
				11. ANXIETY SOMATIC	2	2	2	2										
				12. SOMATIC GASTROINTESTINAL	0	0	0	0										
				13. SOMATIC GENERAL	2	2	2	2										
				14. GENITAL SYMPTOMS	2	2	2	2										
				15. HYPOCHONDRIASIS	0	0	0	0										
				16. LOSS OF WEIGHT	0	0	0	0										
				17. INSIGHT	0	0	0	0										
				18. DIURNAL VARIATION	0	0	0	0										
				19. DEPERSONALIZATION	1	1	1	1										
				20. PARANOID	0	0	0	0										
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1										
				22. Total score	25	25	25	25										
				01. DEPRESSED MOOD	4	4	4	3					2					4
				02. GUILT	2	2	2	1					1					1
				03. SUICIDE	1	1	1	1					0					1
				04. INSOMNIA EARLY	2	2	2	2					2					2
				05. INSOMNIA MIDDLE	2	2	2	2					2					2
				06. INSOMNIA LATE	2	2	2	2					0					2
				07. MORE AND ACTIVITIES	3	3	3	3					2					3
				08. RETARDATION	2	2	2	2					1					1
				09. AGITATION	2	2	2	2					2					2
				10. ANXIETY PSYCHIC	2	2	2	2					2					2
				11. ANXIETY SOMATIC	2	2	2	2					1					1
				12. SOMATIC GASTROINTESTINAL	1	1	1	1					0					1
				13. SOMATIC GENERAL	2	2	2	2					2					2
				14. GENITAL SYMPTOMS	2	2	2	2					2					2
				15. HYPOCHONDRIASIS	2	2	2	2					1					2
				16. LOSS OF WEIGHT	2	2	2	2					2					2
				17. INSIGHT	0	0	0	0					0					0
				18. DIURNAL VARIATION	0	0	0	0					0					0
				19. DEPERSONALIZATION	1	1	1	1					0					1
				20. PARANOID	0	0	0	0					0					0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0					0					0
				22. Total score	35	35	28	27				15						31
10	289	Imipramine	Female	01. DEPRESSED MOOD	3	3	3	3										
				02. GUILT	0	0	0	0										
				03. SUICIDE	0	0	0	0										
				04. INSOMNIA EARLY	2	2	2	2										
				05. INSOMNIA MIDDLE	0	0	0	0										
				06. INSOMNIA LATE	2	2	2	2										
				07. MORE AND ACTIVITIES	3	3	3	3										
				08. RETARDATION	1	1	1	1										
				09. AGITATION	0	0	0	0										
				10. ANXIETY PSYCHIC	0	0	0	0										
				11. ANXIETY SOMATIC	1	1	1	1										
				12. SOMATIC GASTROINTESTINAL	2	2	2	2										

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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								
10	289	Imipramine	Female	13.SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0							
				14.GENITAL SYMPTOMS	0	0	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	2	2	2				
				16.LOSS OF WEIGHT	2	2	2	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	1	1	1				
				18.DIURNAL VARIATION	2	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	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	22	22	22	26																			
				290	Reboxetine	Male	01.DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0		
							02.GUILT	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
							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	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	0	0	0	0	0	0	0	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	4	4	4	4	4	4	4	4	4	4
							08.RETARDATION	3	2	2	2	2	2	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	0	0	0	0	0	0
							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	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
							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	0	0	0				0	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	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	0				
16.LOSS OF WEIGHT	1	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				
18.DIURNAL VARIATION	0	1	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	1	1				
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	22	22	22				17	9	6	5	4	3															
291	Imipramine	Male	01.DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0						
			02.GUILT	1	1	1	1	1	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	2	2	2	2	2					
			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	2	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	2					
			07.WORK AND ACTIVITIES	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					
			09.AGITATION	2	2	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	1	1					
			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	0	0	0	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	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					

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/017
 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
10	291	Imipramine	Male	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	1	1	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	16	5	5	2	2	2	2	2	2	2	2	2	0
	292	Reboxetine	Female	01. DEPRESSED MOOD	2	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
				03. SUICIDE	3	3	3	3	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	1
				05. INSOMNIA MIDDLE	2	2	2	2	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	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	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
				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	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16. LOSS OF WEIGHT	1	1	1	1	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
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	25	25	22	9	9	5	5	5	5	5	5	5	5	5	4
	293	Reboxetine	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	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	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	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
				09. AGITATION	1	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	4
				11. ANXIETY SOMATIC	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
				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	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	25	25	22	9	9	5	5	5	5	5	5	5	5	5	4

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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	
10	293	Reboxetine	Female	21.OBSESSIONAL/COMPULSIVE 22.Total score	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	294	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	4	2	4	4	4	4	3	3	3	3	3	3	3	3	3
	295	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

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PHARMACIA CNS RSD
REBOXETINE - PROTOCOL 20124/017
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
10	296	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	1	1	1	1
				02.GUILT	2	2	2	2	2	2	
				03.SUICIDE	1	1	1	0	0	0	
				04.INSOMNIA EARLY	1	1	1	1	1	1	
				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	2	1	
				08.RETARDATION	2	2	2	1	1	1	
				09.AGITATION	1	1	1	1	1	1	
				10.ANXIETY PSYCHIC	3	3	3	1	1	1	
				11.ANXIETY SOMATIC	1	1	1	0	0	0	
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	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	1	1	1	0	0	0	
				17.INSIGHT	0	0	0	0	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	23	23	23	17	12	11	11
33	297	Reboxetine	Male	01.DEPRESSED MOOD	3	3	3	3	2	1	0
				02.GUILT	2	2	2	1	1	1	
				03.SUICIDE	2	2	1	1	1	1	
				04.INSOMNIA EARLY	2	2	2	2	1	1	
				05.INSOMNIA MIDDLE	2	2	1	1	1	1	
				06.INSOMNIA LATE	1	1	1	1	1	1	
				07.WORK AND ACTIVITIES	3	3	3	2	1	1	
				08.RETARDATION	1	1	1	1	1	1	
				09.AGITATION	2	2	2	2	1	0	
				10.ANXIETY PSYCHIC	2	1	1	1	0	0	
				11.ANXIETY SOMATIC	1	1	1	1	0	0	
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	0	0	
				13.SOMATIC GENERAL	1	0	0	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	1	1	1	0	0	
				17.INSIGHT	1	0	0	0	0	0	
				18.DIURNAL VARIATION	1	2	2	1	0	0	
				19.DEPERSONALIZATION	0	0	0	0	0	0	
				20.PARANOID	0	1	1	0	0	0	
				21.OBSESSIONAL/COMPULSIVE	1	0	0	0	0	0	
				22.Total score	28	25	23	19	15	10	8
298	Reboxetine	Female	01.DEPRESSED MOOD	3	4	4	3	3	2	1	1
			02.GUILT	1	2	2	1	1	1	0	
			03.SUICIDE	1	2	2	1	1	1	0	
			04.INSOMNIA EARLY	2	2	2	2	2	1	1	

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PIARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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				
10	298	Reboxetine	Female	05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1				
				06. INSOMNIA LATE	2	2	2	2	2	2	2					
				07. WORK AND ACTIVITIES	3	3	3	3	2	2	2					
				08. RETARDATION	2	2	2	2	1	1	1					
				09. AGITATION	3	3	3	3	2	2	2					
				10. ANXIETY PSYCHIC	2	2	2	2	2	1	1					
				11. ANXIETY SOMATIC	2	2	2	2	2	1	1					
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1					
				13. SOMATIC GENERAL	1	1	1	1	1	1	0					
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0					
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2					
				16. LOSS OF HEIGHT	1	1	1	1	1	1	1					
				17. INSIGHT	1	1	1	1	1	1	0					
				18. DIURNAL VARIATION	0	0	0	0	0	0	0					
				19. DEPERSONALIZATION	1	2	2	2	2	2	1					
				20. PARANOID	0	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0					
				22. Total score	28	32	32	29	26	21	15	10				
				299	299	Imipramine	Male	01. DEPRESSED MOOD	3	3	3	3	3	3	2	1
								02. GUILT	0	0	0	0	0	0	0	
								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	4	4	4					4	3	3	3					
08. RETARDATION	3	3	3					3	3	3	2					
09. AGITATION	3	3	3					3	2	2	2					
10. ANXIETY PSYCHIC	3	3	3					3	1	1	1					
11. ANXIETY SOMATIC	2	2	2					2	1	1	0					
12. SOMATIC GASTROINTESTINAL	0	0	0					0	0	0	0					
13. SOMATIC GENERAL	1	1	1					1	1	1	1					
14. GENITAL SYMPTOMS	0	0	0					0	0	0	0					
15. HYPOCHONDRIASIS	2	2	2					2	2	2	2					
16. LOSS OF HEIGHT	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	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	28					31	24	24	23	11				
300	300	Imipramine	Female	01. DEPRESSED MOOD	2	2	2	2	1	1	1	2				
				02. GUILT	1	1	1	1	1	0	0					
				03. SUICIDE	1	1	1	1	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	2	2	2	2	2	2	2					
				07. WORK AND ACTIVITIES	3	3	3	3	2	2	2					
				08. RETARDATION	2	2	2	2	2	1	1					

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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
10	300	Imipramine	Female	09. AGITATION	2	2	1	1	1	1	1	1	1	1	0	0	0	0	2
				10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0
				11. ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	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
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2	1	1	1	1	1
				15. HYPOCHONDRIASIS	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
				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	22	22	21	21	21	16	15	13	12	12	12	12	19
11	321	Reboxetine	Female	01. DEPRESSED MOOD	2	3	1	0	0	0	1	1	1	1	1	0	0	0	0
				02. GUILT	1	0	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
				04. INSOMNIA EARLY	2	2	1	0	2	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	2	2	2	1	0	0	0	0	0	0	1	1	1	1	2
				06. INSOMNIA LATE	2	2	1	1	2	1	2	1	1	1	1	1	1	1	1
				07. WORK AND ACTIVITIES	2	2	2	0	1	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	0
				09. AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	3	3	1	1	1	1	1	1	1	1	1	1	1	1	1
				11. ANXIETY SOMATIC	3	3	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	1	1	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 HEIGHT	1	1	1	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	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				19. DEPERSONALIZATION	1	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	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	28	26	16	16	15	13	13	8	8	8	8	8	8	8	8
322		Reboxetine	Female	01. DEPRESSED MOOD	3	3	2	1	1	1	1	1	1	1	0	0	0	0	0
				02. GUILT	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0
				03. SUICIDE	0	1	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	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				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
				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	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	1	1	1	1	1	1	1	1	1	1	1	1	1	1

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	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	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	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	1	2	1	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	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	22	22	15	7	9	3	4	6								
				01. DEPRESSED MOOD	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0
				02. GUILT	2	1	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	0	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	2	2	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	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
				10. ANXIETY PSYCHIC	3	3	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
				12. SOMATIC GASTROINTESTINAL	1	1	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
				14. GENITAL SYMPTOMS	1	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	0	1	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	1	1	1	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	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				22. Total score	24	23	17	18	10	8	7	8								
				01. DEPRESSED MOOD	3	3	2	1	2	1	1	1	1	1	1	1	1	1	1	1
				02. GUILT	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
				03. SUICIDE	2	1	1	0	1	0	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	0
				05. INSOMNIA MIDDLE	1	1	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	0
				07. WORK AND ACTIVITIES	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
				09. AGITATION	2	1	1	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	3	3
				11. ANXIETY SOMATIC	1	1	0	0	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	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	0	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 20124/017
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	17.INSIGHT	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	2	1	1	2	1	1	1
				19.DEPERSONALIZATION	1	1	1	0	0	0	1	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	23	22	16	9	16	10	11	6
				01.DEPRESSED MOOD	3	2	2	1	1	0	0	0
				02.GUILT	1	1	1	0	0	0	0	0
				03.SUICIDE	1	1	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	0	0	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	0	0	0	0	0	0	0	0				
09.AGITATION	1	2	1	0	0	0	0	0				
10.ANXIETY PSYCHIC	2	2	2	2	2	1	0	0				
11.ANXIETY SOMATIC	2	2	2	1	1	0	0	0				
12.SOMATIC GASTROINTESTINAL	0	1	0	0	1	0	0	0				
13.SOMATIC GENERAL	2	2	2	1	1	0	0	0				
14.GENITAL SYMPTOMS	1	0	0	0	0	0	0	0				
15.HYPCHONDRIASIS	0	0	0	0	0	0	0	0				
16.LOSS OF WEIGHT	0	0	1	0	0	0	0	0				
17.INSIGHT	0	0	0	0	0	0	0	0				
18.DIURNAL VARIATION	2	2	2	1	1	0	0	0				
19.DEPERSONALIZATION	0	1	1	1	0	0	0	0				
20.PARANOID	1	0	1	1	0	0	0	0				
21.OBSESSIONAL/COMPULSIVE	1	0	0	0	0	1	0	0				
22.Total score	22	21	19	8	6	1	0	1				
11	325	Reboxetine	Female	01.DEPRESSED MOOD	3	2	2	1	1	0	0	0
				02.GUILT	1	1	1	0	0	0	0	0
				03.SUICIDE	1	1	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	0	0	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	0	0	0	0	0	0	0	0
				09.AGITATION	1	2	1	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	2	2	2	1	0	0
				11.ANXIETY SOMATIC	2	2	2	1	1	0	0	0
12.SOMATIC GASTROINTESTINAL	0	1	0	0	1	0	0	0				
13.SOMATIC GENERAL	2	2	2	1	1	0	0	0				
14.GENITAL SYMPTOMS	1	0	0	0	0	0	0	0				
15.HYPCHONDRIASIS	0	0	0	0	0	0	0	0				
16.LOSS OF WEIGHT	0	0	1	0	0	0	0	0				
17.INSIGHT	0	0	0	0	0	0	0	0				
18.DIURNAL VARIATION	2	2	2	1	1	0	0	0				
19.DEPERSONALIZATION	0	1	1	1	0	0	0	0				
20.PARANOID	1	0	1	1	0	0	0	0				
21.OBSESSIONAL/COMPULSIVE	1	0	0	0	0	1	0	0				
22.Total score	22	21	19	8	6	1	0	1				
11	326	Imipramine	Male	01.DEPRESSED MOOD	3	3	2	1	1	1	0	1
				02.GUILT	1	1	1	1	0	0	0	1
				03.SUICIDE	2	2	0	0	0	0	0	1
				04.INSOMNIA EARLY	1	2	2	0	0	0	0	0
				05.INSOMNIA MIDDLE	0	0	0	0	0	0	0	0
				06.INSOMNIA LATE	0	0	0	0	2	1	1	0
				07.WORK AND ACTIVITIES	2	2	2	1	0	0	0	0
				08.RETARDATION	2	1	1	0	0	0	0	0
				09.AGITATION	0	0	0	0	1	1	0	0
				10.ANXIETY PSYCHIC	3	3	3	2	2	1	0	0
				11.ANXIETY SOMATIC	2	2	1	0	1	0	0	1
12.SOMATIC GASTROINTESTINAL	1	1	0	0	1	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.HYPCHONDRIASIS	0	0	0	0	0	0	0	0				
16.LOSS OF WEIGHT	2	1	1	1	1	1	0	2				
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	1	1	1	0	0	0	0	0				

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	
11	326	Imipramine	Male	21.OBSESSIONAL/COMPULSIVE 22.Total score	0 22	0 21	0 14	0 6	0 9	0 6	0 1	0 8	
327	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.DENTAL SYMPTOMS 15.HYPOCHONDRIASIS 16.LOSS OF WEIGHT 17.INSIGHT 18.DIURNAL VARIATION 19.DEPERSONALIZATION 20.PARANOID 21.OBSESSIONAL/COMPULSIVE 22.Total score	3 3 1 2 1 2 0 2 3 2 0 2 1 0 0 2 2 1 1 1 1 0 26	3 1 1 2 1 2 0 2 3 2 0 2 1 0 0 2 2 1 1 1 1 0 25	3 1 2 2 1 2 0 2 5 2 0 2 1 1 0 2 2 2 2 2 1 1 0 25	0 2 1 2 1 2 0 2 2 2 1 1 1 1 0 2 2 2 2 2 1 1 0 25	0 2 1 2 1 2 0 2 2 2 1 1 1 1 0 2 2 2 2 2 1 1 0 25	2 1 0 1 1 1 0 1 1 1 0 1 1 1 0 1 1 1 1 1 1 0 18	2 1 0 1 1 1 0 1 1 1 0 1 1 1 0 1 1 1 1 1 1 0 13	1 1 0 0 1 1 0 1 1 1 0 1 1 0 1 1 1 1 1 1 0 13	1 0 0 0 1 1 0 1 1 1 0 1 1 0 1 1 1 1 1 1 0 8	
328	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.DENTAL SYMPTOMS 15.HYPOCHONDRIASIS 16.LOSS OF WEIGHT 17.INSIGHT 18.DIURNAL VARIATION 19.DEPERSONALIZATION 20.PARANOID 21.OBSESSIONAL/COMPULSIVE 22.Total score	2 1 1 2 1 2 0 2 3 3 0 2 1 0 0 2 2 1 1 1 1 0 26	2 1 1 2 1 2 0 2 3 3 0 2 1 0 0 2 2 1 1 1 1 0 26	2 1 0 1 1 2 0 2 2 3 0 2 1 0 0 2 2 1 1 1 1 0 26	1 0 0 0 0 2 0 2 2 2 1 1 1 0 0 2 2 1 1 1 1 0 26	1 0 0 0 0 2 0 2 2 2 1 1 1 0 0 2 2 1 1 1 1 0 26	1 0 0 0 0 2 0 2 2 2 1 1 1 0 0 2 2 1 1 1 1 0 26	2 1 0 1 1 2 0 2 2 2 1 1 1 0 0 2 2 1 1 1 1 0 26	2 1 0 0 0 2 0 2 2 2 1 1 1 0 0 2 2 1 1 1 1 0 26	0 0 0 0 0 2 0 2 2 2 1 1 0 0 0 2 2 1 1 1 1 0 26	0 0 0 0 0 2 0 2 2 2 1 1 0 0 0 2 2 1 1 1 1 0 26

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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		
11	329	Imipramine	Female	01..DEPRESSED MOOD	3	2	2	1	1	1	1	1		
				02..GUILT	2	2	1	1	1	1	0	0		
				03..SUICIDE	1	1	1	1	0	0	0	0	0	
				04..INSOMNIA EARLY	1	0	0	0	0	0	0	0	0	
				05..INSOMNIA MIDDLE	1	2	1	1	0	0	0	0	0	
				06..INSOMNIA LATE	1	2	2	2	1	1	1	1	1	
				07..WOK AND ACTIVITIES	2	2	2	2	2	1	1	1	1	
				08..RETARDATION	0	0	0	0	0	0	0	0	0	0
				09..AGITATION	2	1	1	0	1	1	1	1	1	
				10..ANXIETY PSYCHIC	2	2	2	3	2	1	1	1	1	
				11..ANXIETY SOMATIC	2	2	2	1	1	1	1	1	2	
				12..SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	
				13..SOMATIC GENERAL	2	2	2	2	1	1	0	0	1	
				14..GENERAL SYMPTOMS	1	1	1	6	0	0	0	0	0	
				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	1	1	1	1	1	1	
				19..DEPERSONALIZATION	1	1	1	1	1	1	1	1	0	
				20..PARAMOID	1	0	0	0	0	0	0	0	0	
				21..OBSESSIONAL/COMPULSIVE	1	0	0	0	0	0	0	0	0	
				22..Total score				25	22	19	11	10	5	6
330	330	Reboxetine	Female	01..DEPRESSED MOOD	3	3	3	3	3	3	3	3		
				02..GUILT	1	2	2	1	1	1	1	1		
				03..SUICIDE	2	2	2	1	1	1	1	1		
				04..INSOMNIA EARLY	0	0	0	1	1	1	1	1		
				05..INSOMNIA MIDDLE	1	1	1	2	2	2	2	2		
				06..INSOMNIA LATE	0	0	0	2	2	2	2	2		
				07..WOK AND ACTIVITIES	3	2	2	2	2	2	2	2		
				08..RETARDATION	1	1	1	1	1	1	1	1		
				09..AGITATION	0	0	0	0	0	0	0	0		
				10..ANXIETY PSYCHIC	3	2	2	1	1	1	1	1		
				11..ANXIETY SOMATIC	1	2	2	2	2	2	2	2		
				12..SOMATIC GASTROINTESTINAL	0	0	0	2	2	2	2	2		
				13..SOMATIC GENERAL	2	2	2	2	2	2	2	2		
				14..GENERAL SYMPTOMS	1	1	1	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	1	0	0	0	0	0	0	0		
				18..DIURNAL VARIATION	2	2	2	1	1	1	1	1		
				19..DEPERSONALIZATION	1	1	1	0	0	0	0	0		
				20..PARAMOID	0	0	0	0	0	0	0	0		
				21..OBSESSIONAL/COMPULSIVE	1	0	0	0	0	0	0	0		
				22..Total score				23	21	22	22	22	22	
331	331	Reboxetine	Male	01..DEPRESSED MOOD	3	3	2	1	1	3	0	0		
				02..GUILT	1	2	1	1	1	1	1	0		
				03..SUICIDE	2	1	0	0	1	0	0			
				04..INSOMNIA EARLY	2	2	2	2	2	2	1			

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PHARMACIA CNS R&D
 REBOXTINE - PROTOCOL 2012/017
 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
11	331	Reboxetine	Male	05.INSOMNIA MIDDLE	1	0	1	2	1	1	1	0
				06.INSOMNIA LATE	2	2	1	0	0	0	0	0
				07.WORK AND ACTIVITIES	2	2	1	1	1	2	1	0
				08.RETARDATION	1	1	0	0	0	1	0	0
				09.AGITATION	0	0	1	0	0	0	0	0
				10.ANXIETY PSYCHIC	3	3	3	2	1	2	1	1
				11.ANXIETY SOMATIC	2	2	2	1	3	2	1	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	1	1	1	0
				13.SOMATIC GENERAL	2	2	1	0	2	2	1	0
				14.GENITAL SYMPTOMS	2	2	2	1	1	2	1	0
				15.HYPOCHONDRIASIS	0	0	0	0	0	1	0	0
				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	2	2	1	1	0	1	0	0
				19.DEPERSONALIZATION	1	1	0	0	0	0	0	0
				20.PARANOID	0	1	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	1	1	0	0	0	0	0	0
				22.Total score	29	28	21	12	12	21	17	4
332		Imipramine	Female	01.DEPRESSED MOOD	3	3	2	0	0	0	0	0
				02.GUILT	1	1	0	0	0	0	0	0
				03.SUICIDE	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	1	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	0	0	0	0	0	0	0	0
				06.INSOMNIA LATE	0	0	0	1	0	0	0	0
				07.WORK AND ACTIVITIES	2	2	0	0	0	0	0	0
				08.RETARDATION	0	0	0	0	0	0	0	0
				09.AGITATION	2	2	1	0	0	0	0	0
				10.ANXIETY PSYCHIC	3	3	0	0	0	0	0	0
				11.ANXIETY SOMATIC	2	2	0	0	1	0	0	0
				12.SOMATIC GASTROINTESTINAL	0	1	0	0	0	0	0	0
				13.SOMATIC GENERAL	2	2	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	1	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	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	22	22	3	1	1	0	0	0
333		Imipramine	Female	01.DEPRESSED MOOD	3	3	3	2	3	2	1	0
				02.GUILT	2	2	2	2	2	1	0	0
				03.SUICIDE	1	1	0	1	1	1	0	0
				04.INSOMNIA EARLY	2	2	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	1	1	1	2	1	0	0	0
				06.INSOMNIA LATE	0	2	2	1	0	0	0	0
				07.WORK AND ACTIVITIES	2	2	2	2	2	1	0	0
				08.RETARDATION	0	0	0	0	0	0	0	0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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				
11	333	Imipramine	Female	09. AGITATION	2	2	2	2	1	1	1	0				
				10. ANXIETY PSYCHIC	3	3	3	3	3	1	2	0				
				11. ANXIETY SOMATIC	1	1	1	1	1	0	1	1	0			
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	1	0	0			
				13. SOMATIC GENERAL	2	2	2	2	2	0	0	0	0			
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0			
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0			
				16. LOSS OF HEIGHT	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	0	0	0	0	0	0	0	0	0			
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	0	0	0	0			
				22. Total score	24	26	25	25	22	11	9	1				
				12	337	Imipramine	Female	01. DEPRESSED MOOD	2	4	1	0	3	2	2	0
								02. GUILT	1	1	1	0	0	0	0	0
								03. SUICIDE	2	2	2	0	0	3	2	0
								04. INSOMNIA EARLY	0	0	0	0	0	1	0	0
								05. INSOMNIA MIDDLE	0	2	2	0	0	1	0	1
								06. INSOMNIA LATE	2	2	1	1	2	1	1	0
								07. WORK AND ACTIVITIES	2	3	0	0	0	0	0	0
								08. RETARDATION	0	0	0	0	0	0	0	0
09. AGITATION	0	1	0					0	0	0	0	0				
10. ANXIETY PSYCHIC	3	4	0					0	0	0	0	0				
11. ANXIETY SOMATIC	2	1	0					0	0	0	0	0				
12. SOMATIC GASTROINTESTINAL	2	1	1					0	0	0	0	0				
13. SOMATIC GENERAL	1	1	0					0	0	0	0	0				
14. GENITAL SYMPTOMS	0	3	0					0	0	0	0	0				
15. HYPOCHONDRIASIS	0	3	0					0	0	0	0	0				
16. LOSS OF HEIGHT	1	1	2					2	2	2	2	2				
17. INSIGHT	1	0	0					0	0	0	0	0				
18. DIURNAL VARIATION	2	2	1					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	0	0	0					0	0	0	0	0				
22. Total score	23	32	12					6	10	11	17	3				
338	Reboxetine	Female	01. DEPRESSED MOOD	2	4	3	0	0	1	1	2	1				
			02. GUILT	2	2	1	1	0	0	0	0					
			03. SUICIDE	3	3	2	1	0	1	0	1					
			04. INSOMNIA EARLY	0	2	2	1	2	2	2	2					
			05. INSOMNIA MIDDLE	0	1	1	0	0	0	0	2					
			06. INSOMNIA LATE	0	2	1	1	0	0	0	2					
			07. WORK AND ACTIVITIES	3	3	2	1	0	1	1	0					
			08. RETARDATION	1	1	1	1	1	1	1	1					
			09. AGITATION	2	0	0	0	0	0	0	0					
			10. ANXIETY PSYCHIC	4	4	3	1	2	1	2	1					
			11. ANXIETY SOMATIC	3	2	1	1	2	1	2	1					
			12. SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0					

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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
12	333	Female			2	2	2	1	0	0	1
			13. SOMATIC GENERAL	2	2	2	2	1	0	0	1
			14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2
			15. HYPOCHONDRIASIS	3	3	3	3	3	2	2	3
			16. LOSS OF WEIGHT	2	0	2	0	0	0	0	2
			17. INSIGHT	0	0	0	1	0	0	0	0
			18. DIURNAL VARIATION	2	1	1	2	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	0	0	0	0	0	0	0	0
			22. Total score	33	32	28	18	15	13	17	20
	339	Male			3	3	3	1	1	1	0
			01. DEPRESSED MOOD	3	3	3	3	1	1	1	0
			02. GUILT	2	2	1	2	1	1	1	0
			03. SUICIDE	2	0	0	0	0	0	0	0
			04. INSOMNIA EARLY	2	0	0	1	0	0	0	0
			05. INSOMNIA MIDDLE	2	2	1	0	2	1	1	1
			06. INSOMNIA LATE	1	1	1	0	1	1	0	0
			07. WORK AND ACTIVITIES	3	3	1	1	0	0	0	0
			08. RETARDATION	2	2	1	0	1	1	1	1
			09. AGITATION	2	1	0	2	1	2	0	0
			10. ANXIETY PSYCHIC	3	2	2	2	1	3	1	1
			11. ANXIETY SOMATIC	2	2	0	0	1	1	1	0
			12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	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	2	2	0	0	0	0	0	0
			16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0
			17. INSIGHT	2	1	2	1	2	2	1	1
			18. DIURNAL VARIATION	1	1	2	1	2	2	1	1
			19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
			20. PARANOID	1	1	0	0	0	0	0	0
			21. OBSESSIONAL/COMPULSIVE	0	1	0	0	0	0	0	0
			22. Total score	33	30	16	16	14	16	10	5
	340	Female			2	3	3	0	0	0	2
			01. DEPRESSED MOOD	2	3	3	3	0	0	0	2
			02. GUILT	1	1	1	0	0	0	0	0
			03. SUICIDE	2	0	0	0	0	0	0	0
			04. INSOMNIA EARLY	2	2	0	0	0	0	0	0
			05. INSOMNIA MIDDLE	2	2	1	1	1	0	2	1
			06. INSOMNIA LATE	1	2	2	1	1	1	1	2
			07. WORK AND ACTIVITIES	2	2	2	0	0	0	1	0
			08. RETARDATION	1	1	1	0	0	0	0	0
			09. AGITATION	1	2	0	0	0	0	0	1
			10. ANXIETY PSYCHIC	2	2	2	0	0	0	0	2
			11. ANXIETY SOMATIC	1	2	1	0	1	0	1	0
			12. SOMATIC GASTROINTESTINAL	0	1	1	0	1	0	1	0
			13. SOMATIC GENERAL	1	2	1	0	0	1	0	2
			14. GENITAL SYMPTOMS	2	2	2	1	1	0	1	0
			15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0
			16. LOSS OF WEIGHT	2	1	0	0	0	0	0	0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	340	Reboxetine	Female	17..INSIGHT	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	
				19..DEPERSONALIZATION	2	3	3	1	1	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	32	23	5	7	4	13	14								
19	341	Reboxetine	Female	01..DEPRESSED MOOD	3	2	2	2	2	2	3	0	0	0	0	0	0	0		
				02..GUILT	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1	
				03..SUICIDE	3	0	1	1	2	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	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..MORR AND ACTIVITIES	4	2	2	2	2	2	3	1	0	0	0	0	0	0	0	0
				08..RETARDATION	2	2	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
				10..ANXIETY PSYCHIC	3	2	3	2	2	2	3	1	0	0	0	0	0	0	0	0
				11..ANXIETY SOMATIC	3	2	2	2	2	2	3	1	0	0	0	0	0	0	0	0
				12..SOMATIC GASTROINTESTINAL	1	1	2	2	2	2	2	0	0	0	0	0	0	0	0	0
				13..SOMATIC GENERAL	1	2	2	2	2	2	2	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	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	2	2	2	2	2	2	2	2	2	2	2	2	2
				19..DEPERSONALIZATION	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
				21..OBSESSIONAL/COMPULSIVE	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				22..Total score	40	30	31	24	36	10	29									
19	353	Reboxetine	Female	01..DEPRESSED MOOD	3	3	2	2	1	1	1	0	0	0	0	0	0			
				02..GUILT	2	2	0	1	0	0	0	0	0	0	0	0	0	0		
				03..SUICIDE	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	
				04..INSOMNIA EARLY	2	2	0	1	1	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	1	
				06..INSOMNIA LATE	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	
				07..MORR AND ACTIVITIES	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	
				08..RETARDATION	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	
				09..AGITATION	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	
				10..ANXIETY PSYCHIC	1	0	2	2	2	1	1	0	0	0	0	0	0	0	0	
				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	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	
				14..GENITAL SYMPTOMS	2	2	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	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
				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	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 20124/017
 Listing No.: 12.0
 HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
13	353	Reboxetine	Female	21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22.Total score	23	23	17	11	9	7	10	
13	354	Imipramine	Female	01.DEPRESSED MOOD	2	2	1	1	0	0	0	0
				02.GUILT	0	0	0	0	0	0	0	
				03.SUICIDE	3	3	0	0	0	0	0	
				04.INSOMNIA EARLY	0	0	0	0	0	0	0	
				05.INSOMNIA MIDDLE	1	1	0	0	0	0	0	
				06.INSOMNIA LATE	0	0	0	0	0	0	0	
				07.WORK AND ACTIVITIES	2	2	1	1	1	1	1	
				08.RETARDATION	0	0	0	0	0	0	0	
				09.AGITATION	1	1	1	1	0	0	0	
				10.ANXIETY PSYCHIC	2	2	1	2	0	2	0	
				11.ANXIETY SOMATIC	3	3	2	1	1	1	0	
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	0	0	0	
				13.SOMATIC GENERAL	1	1	2	1	1	0	1	
				14.GENTRAL SYMPTOMS	1	1	0	0	0	0	0	
				15.HYPOCHONDRIASIS	2	2	2	1	1	0	0	
				16.LOSS OF WEIGHT	2	2	1	0	0	0	0	
				17.INSIGHT	1	1	1	0	0	0	0	
				18.DIURNAL VARIATION	1	1	2	1	0	0	0	
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	
				20.PARANOID	1	1	1	1	0	0	0	
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	
				22.Total score	24	24	15	11	5	4	3	
13	355	Reboxetine	Female	01.DEPRESSED MOOD	2	2	1	1	0	0	0	
				02.GUILT	2	2	2	1	0	0	0	
				03.SUICIDE	3	3	2	1	1	1	1	
				04.INSOMNIA EARLY	2	2	1	1	1	1	1	
				05.INSOMNIA MIDDLE	1	1	1	1	1	1	1	
				06.INSOMNIA LATE	0	0	0	0	0	0	0	
				07.WORK AND ACTIVITIES	0	0	0	0	0	0	0	
				08.RETARDATION	0	0	0	0	0	0	0	
				09.AGITATION	3	3	2	1	1	1	1	
				10.ANXIETY PSYCHIC	2	2	1	1	1	1	1	
				11.ANXIETY SOMATIC	3	3	3	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.GENTRAL SYMPTOMS	0	0	0	0	0	0	0	
				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	1	1	1	0	0	0	0	
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	
				20.PARANOID	1	1	1	1	0	0	0	
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	
				22.Total score	25	24	24	10	10	10	10	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
13	356	Imipramine	Male	01..DEPRESSED MOOD	2	2	2	1	1	1	1	1
				02..GUILT	1	1	1	1	1	1	1	0
				03..SUICIDE	2	2	1	0	0	0	0	0
				04..INSOMNIA EARLY	2	2	1	1	1	0	0	2
				05..INSOMNIA MIDDLE	2	2	1	1	0	1	1	0
				06..INSOMNIA LATE	2	2	1	1	1	1	1	1
				07..WOKK AND ACTIVITIES	3	3	3	1	1	1	1	1
				08..RETARDATION	0	0	0	0	0	0	0	0
				09..AGITATION	1	1	1	1	1	2	1	1
				10..ANXIETY PSYCHIC	4	4	3	2	1	1	1	2
				11..ANXIETY SOMATIC	3	3	3	2	1	1	1	2
				12..SOMATIC GASTROINTESTINAL	1	1	1	0	0	0	0	0
				13..SOMATIC GENERAL	2	2	2	2	2	2	2	2
				14..GENERAL SYMPTOMS	0	0	0	0	0	0	0	0
				15..HYPOCHONDRIASIS	3	3	3	2	2	2	2	2
				16..LOSS OF HEIGHT	1	1	1	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	2	2	1	1	1	1	1	1
				21..OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22..Total score	32	32	26	17	14	15	15	16
357		Imipramine	Female	01..DEPRESSED MOOD	3	3						
				02..GUILT	0	0						
				03..SUICIDE	1	1						
				04..INSOMNIA EARLY	0	0						
				05..INSOMNIA MIDDLE	1	1						
				06..INSOMNIA LATE	0	0						
				07..WOKK AND ACTIVITIES	2	2						
				08..RETARDATION	0	0						
				09..AGITATION	2	2						
				10..ANXIETY PSYCHIC	3	3						
				11..ANXIETY SOMATIC	1	1						
				12..SOMATIC GASTROINTESTINAL	2	2						
				13..SOMATIC GENERAL	0	0						
				14..GENERAL SYMPTOMS	1	1						
				15..HYPOCHONDRIASIS	0	0						
				16..LOSS OF HEIGHT	2	2						
				17..INSIGHT	0	0						
				18..DIURNAL VARIATION	2	2						
				19..DEPERSONALIZATION	0	0						
				20..PARANOID	2	2						
				21..OBSESSIONAL/COMPULSIVE	0	0						
				22..Total score	24	25						
358		Reboxetine	Male	01..DEPRESSED MOOD	3	3	2	2	1	1	1	1
				02..GUILT	1	1	1	0	0	0	0	2
				03..SUICIDE	2	2	2	0	0	0	0	0
				04..INSOMNIA EARLY	2	2	0	2	2	2	2	0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
13	358	Male	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	0	1	2	2	1	2	0	0
359	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	2	2	2	2	1	2	0	0
360	Imipramine	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSOMNIA EARLY 05. INSOMNIA MIDDLE 06. INSOMNIA LATE 07. WORK AND ACTIVITIES 08. RETARDATION	2	2	2	2	2	2	2	2

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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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	360	Imipramine	Female	09. AGITATION	2	2	2	1																			
				10. ANXIETY PSYCHIC	3	3	2																				
				11. ANXIETY SOMATIC	2	2	2																				
				12. SOMATIC GASTROINTESTINAL	1	1	0																				
				13. SOMATIC GENERAL	1	1	1																				
				14. GENITAL SYMPTOMS	2	2	1																				
				15. HYPOCHONDRIASIS	0	0	0																				
				16. LOSS OF WEIGHT	1	1	2																				
				17. INSIGHT	0	0	0																				
				18. DIURNAL VARIATION	0	0	0																				
				19. DEPERSONALIZATION	0	0	0																				
				20. PARANOID	2	2	0																				
				21. OBSESSIONAL/COMPULSIVE	0	0	0																				
				22. Total score	24	24	16																				
				361	Reboxetine	Female	01. DEPRESSED MOOD	2	2	1																	
							02. GUILT	2	2	0																	
							03. SUICIDE	3	3	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	2																	
							08. RETARDATION	0	0	0																	
09. AGITATION	1	1	0																								
10. ANXIETY PSYCHIC	2	2	1																								
11. ANXIETY SOMATIC	2	2	1																								
12. SOMATIC GASTROINTESTINAL	0	0	0																								
13. SOMATIC GENERAL	2	2	2																								
14. GENITAL SYMPTOMS	0	0	0																								
15. HYPOCHONDRIASIS	1	1	1																								
16. LOSS OF WEIGHT	0	0	2																								
17. INSIGHT	1	1	1																								
18. DIURNAL VARIATION	0	0	0																								
19. DEPERSONALIZATION	0	0	0																								
20. PARANOID	0	0	0																								
21. OBSESSIONAL/COMPULSIVE	0	0	0																								
22. Total score	25	25	17																								
14	Reboxetine	Female	01. DEPRESSED MOOD	4	4	4																					
			02. GUILT	2	2	2																					
			03. SUICIDE	1	1	1																					
			04. INSOMNIA EARLY	2	2	2																					
			05. INSOMNIA MIDDLE	1	1	1																					
			06. INSOMNIA LATE	2	2	2																					
			07. WORK AND ACTIVITIES	2	2	2																					
			08. RETARDATION	2	2	2																					
			09. AGITATION	3	3	3																					
			10. ANXIETY PSYCHIC	2	2	2																					
			11. ANXIETY SOMATIC	2	2	2																					
			12. SOMATIC GASTROINTESTINAL	1	1	1																					

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PHARMACIA CNS RSD
REBOXETINE - PROTOCOL 20124/017
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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	457	Reboxetine	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	38	36	36	36	36	36	32	32	29	25					
458	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	37	37	34	30	27	28	26	23								
459	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	2	2	2	2	2	2	2	2	2	2	2	2	2	2

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
14	Reboxetine	Male	17.INSIGHT	1	1	1	1	1	1	1	1	1		
			18. DIURNAL VARIATION	0	0	0	0	0	0	0	0	0		
			19. DEPERSONALIZATION	1	1	1	1	1	1	1	1	1		
			20. PARANOID	1	1	1	1	1	1	1	1	1		
			21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1		
			22. Total score	29	29	29	25	22	22	21	20			
			460	Imipramine	Male	01. DEPRESSED MOOD	3	2	2	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	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	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	2	2	2	2	2	2	2	2						
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	0	0	0	0	0	0	0	0						
19. DEPERSONALIZATION	1	1	1	1	1	1	1	1						
20. PARANOID	1	1	1	1	1	1	1	1						
21. OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1						
22. Total score	35	33	32	31	30	29	27	22						
461	Imipramine	Female	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	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	3	3	3	3	3	3	3			
			08. RETARDATION	2	2	2	2	2	2	2	2			
			09. AGITATION	2	3	3	3	3	3	3	3			
			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. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2						
15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2						
16. LOSS OF WEIGHT	2	0	0	1	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	2	2	2	2	2	2	2	2						
20. PARANOID	2	2	2	2	2	2	2	2						

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	461	Imipramine	Female	21.OBSESSIONAL/COMPULSIVE	2	2	2	2	2	2	2	2
				22.Total score	39	40	39	40	39	37	40	
14	462	Reboxetine	Female	01.DEPRESSED MOOD	2	2	2	2	2	2	2	2
				02.GUILT	2	2	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	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	2	2	2	2	2	2	2	
				09.AGITATION	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	1	1	1	1	1	1	1	
				13.SOMATIC GENERAL	2	2	2	2	2	2	2	
				14.GENTAL SYMPTOMS	2	2	2	2	2	2	2	
				15.HYPOCHONDRIASIS	2	2	2	2	2	2	2	
				16.LOSS OF WEIGHT	1	1	1	1	1	1	1	
				17.INSIGHT	1	1	1	1	1	1	1	
				18.DIURNAL VARIATION	0	0	0	0	0	0	0	
				19.DEPERSONALIZATION	2	2	2	2	2	2	2	
				20.PARANOID	1	1	1	1	1	1	1	
				21.OBSESSIONAL/COMPULSIVE	2	2	2	2	2	2	2	
				22.Total score	36	36	35	35	35	34	34	
14	463	Imipramine	Male	01.DEPRESSED MOOD	2	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	
				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	2	2	2	2	2	2	2	
				09.AGITATION	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	1	1	1	1	1	1	1	
				13.SOMATIC GENERAL	2	2	2	2	2	2	2	
				14.GENTAL SYMPTOMS	2	2	2	2	2	2	2	
				15.HYPOCHONDRIASIS	2	2	2	2	2	2	2	
				16.LOSS OF WEIGHT	1	1	1	1	1	1	1	
				17.INSIGHT	1	1	1	1	1	1	1	
				18.DIURNAL VARIATION	2	2	2	2	2	2	2	
				19.DEPERSONALIZATION	1	1	1	1	1	1	1	
				20.PARANOID	1	1	1	1	1	1	1	
				21.OBSESSIONAL/COMPULSIVE	2	2	2	2	2	2	2	
				22.Total score	35	34	33	30	29	29	21	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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 Day
14	466	Inipramine Female	05. INSOMNIA MIDDLE	2	2	2	1	1	1	1	0
			06. INSOMNIA LATE	2	2	2	1	1	1	1	1
			07. WORK AND ACTIVITIES	2	2	2	2	1	1	1	1
			08. RETARDATION	2	2	2	1	1	1	1	1
			09. AGITATION	2	2	1	1	1	1	1	0
			10. ANXIETY PSYCHIC	2	2	2	2	1	1	1	1
			11. ANXIETY SOMATIC	2	2	2	2	1	1	1	0
			12. SOMATIC GASTROINTESTINAL	2	2	1	1	1	1	1	0
			13. SOMATIC GENERAL	2	2	2	2	2	2	2	1
			14. GENITAL SYMPTOMS	2	2	2	2	2	1	1	1
			15. HYPOCHONDRIASIS	2	2	2	2	2	1	1	1
			16. LOSS OF WEIGHT	1	1	1	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	2	2	2	2	1	1	1	1
			20. PARANOID	1	1	1	1	1	1	1	1
			21. OBSESSIVE/COMPULSIVE	2	2	2	2	1	1	1	1
			22. Total score	35	35	34	30	22	20	20	14
14/1	429	Reboxetine Male	01. DEPRESSED MOOD	3	3						
			02. GUILTY	0	0						
			03. SUICIDE	1	1						
			04. INSOMNIA EARLY	0	0						
			05. INSOMNIA MIDDLE	2	2						
			06. INSOMNIA LATE	1	1						
			07. WORK AND ACTIVITIES	2	2						
			08. RETARDATION	1	1						
			09. AGITATION	0	0						
			10. ANXIETY PSYCHIC	3	3						
			11. ANXIETY SOMATIC	2	3						
			12. SOMATIC GASTROINTESTINAL	0	0						
			13. SOMATIC GENERAL	2	0						
			14. GENITAL SYMPTOMS	1	1						
			15. HYPOCHONDRIASIS	3	4						
			16. LOSS OF WEIGHT	0	0						
			17. INSIGHT	0	1						
			18. DIURNAL VARIATION	2	2						
			19. DEPERSONALIZATION	2	1						
			20. PARANOID	0	0						
			21. OBSESSIVE/COMPULSIVE	0	0						
			22. Total score	25	23						
14/1	426	Reboxetine Female	01. DEPRESSED MOOD	3	3	3	2	1	1	1	0
			02. GUILTY	2	2	1	0	0	0	0	0
			03. SUICIDE	1	1	1	0	1	0	0	0
			04. INSOMNIA EARLY	2	2	2	0	1	1	1	1
			05. INSOMNIA MIDDLE	2	2	2	2	2	1	0	0
			06. INSOMNIA LATE	2	0	2	2	0	0	0	0
			07. WORK AND ACTIVITIES	2	2	2	2	0	0	0	0
			08. RETARDATION	2	2	2	0	1	0	0	0
			09. AGITATION	0	1	1	0	0	0	0	0

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REBOXETINE - PROTOCOL 20124/017
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
14/1	426	Reboxetine	Female		3	0	0	1	1	0	0	0
				09. AGITATION			2	1	2	1	1	1
				10. ANXIETY PSYCHIC		3	2	1	2	1	1	1
				11. ANXIETY SOMATIC		3	2	1	2	0	0	0
				12. SOMATIC GASTROINTESTINAL		1	0	0	0	0	0	0
				13. SOMATIC GENERAL		2	2	0	0	1	0	0
				14. GENITAL SYMPTOMS		1	2	0	0	1	1	1
				15. HYPOCHONDRIASIS		0	1	0	0	1	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	0	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	25	23	8	13	6	4	3
429		Imipramine	Female		1	2	2					
				01. DEPRESSED MOOD		0	1	1				
				02. GUILT		2	2					
				03. SUICIDE		2	2					
				04. INSOMNIA EARLY		2	2					
				05. INSOMNIA MIDDLE		2	2					
				06. INSOMNIA LATE		1	2					
				07. WORK AND ACTIVITIES		1	2					
				08. RETARDATION		1	0					
				09. AGITATION		2	2					
				10. ANXIETY PSYCHIC		2	2					
				11. ANXIETY SOMATIC		2	2					
				12. SOMATIC GASTROINTESTINAL		0	2					
				13. SOMATIC GENERAL		1	1					
				14. GENITAL SYMPTOMS		3	3					
				15. HYPOCHONDRIASIS		0	0					
				16. LOSS OF WEIGHT		1	1					
				17. INSIGHT		1	1					
				18. DIURNAL VARIATION		1	1					
				19. DEPERSONALIZATION		0	0					
				20. PARANOID		0	0					
				21. OBSESSIONAL/COMPULSIVE		0	0					
				22. Total score	25	29	25					
451		Imipramine	Male		3	3	1	1	2	3	3	3
				01. DEPRESSED MOOD		1	1	1	1	1	0	0
				02. GUILT		0	1	1	1	1	1	1
				03. SUICIDE		1	1	1	0	1	1	1
				04. INSOMNIA EARLY		2	1	2	0	2	1	1
				05. INSOMNIA MIDDLE		1	0	0	1	0	0	0
				06. INSOMNIA LATE		2	2	1	2	1	2	2
				07. WORK AND ACTIVITIES		2	2	1	1	1	1	1
				08. RETARDATION		0	0	0	0	0	0	0
				09. AGITATION		3	3	1	0	1	0	1
				10. ANXIETY PSYCHIC		1	0	2	1	2	1	1
				11. ANXIETY SOMATIC		0	0	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL		0	0	0	0	0	0	0

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PHARMACIA CNS RRD
REBOXETINE - PROTOCOL 20124/017
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
14/1	451	Imipramine	Male	19. 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	2
				15. HYPOCHONDRIASIS	3	3	3	3	2	2	2	2	2	2	2	3	3	3
				16. LOSS OF WEIGHT	0	0	0	0	0	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
				18. DIURNAL VARIATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				19. DEPERSONALIZATION	0	0	0	0	1	2	1	2	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	24	20	18	19	19	20	19	20	19	20	19	20	20
452		Reboxetine	Female	01. DEPRESSED MOOD	4	4	2	2	3	3	3	3	2	2	2	2	2	3
				02. GUILT	2	2	0	0	1	0	0	0	0	0	0	0	0	0
				03. SUICIDE	1	1	0	0	0	0	0	0	0	0	0	0	0	1
				04. INSOMNIA EARLY	2	2	2	0	1	1	1	1	1	1	1	1	1	0
				05. INSOMNIA MIDDLE	0	0	0	0	1	2	0	0	0	0	0	0	0	0
				06. INSOMNIA LATE	0	0	0	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	1
				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	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				11. ANXIETY SOMATIC	1	1	0	0	0	0	0	0	0	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	1	1	0	1	0	0	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	2	2	2	2	1	1	1	1	1	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	1	1	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
				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	0	0	0	0	0	0	0	0	0	0	0
				19. DEPERSONALIZATION	1	1	1	0	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	24	24	14	12	10	10	7	7	7	7	7	7	7	7
14/2	136	Imipramine	Female	01. DEPRESSED MOOD	3	2	1	2	3	3	2	2	2	2	1	1	0	0
				02. GUILT	2	2	1	2	1	1	1	1	1	1	1	1	1	0
				03. SUICIDE	2	2	0	0	0	0	0	0	0	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	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	1	0	0	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
				08. RETARDATION	1	0	1	1	1	1	1	1	1	1	1	1	1	1
				09. AGITATION	0	4	0	2	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	2	3	2	3	1	2	2	2	2	2	2	2	2	1
				11. ANXIETY SOMATIC	1	1	2	1	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	1	1	0	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	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

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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				
14/2	136	Imipramine	Female	17-INSIGHT	0	0	0	0	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	0	0	0	0	0	0	0	0	0			
				21-OBSessional/COMPULSIVE	0	0	0	0	0	0	0	0	0			
				22-Total score	24	25	19	21	15	13	11	7				
				456	456	Imipramine	Male	01-DEPRESSED MOOD	3	3	3	1	1	1	1	1
								02-GUILT	2	2	2	1	1	0	0	0
								03-SUICIDE	1	1	1	1	1	1	1	1
								04-INSOMNIA EARLY	2	2	0	0	0	0	0	0
								05-INSOMNIA MIDDLE	0	0	0	0	0	0	0	0
								06-INSOMNIA LATE	0	0	0	1	1	0	0	0
								07-WORK AND ACTIVITIES	2	2	2	1	1	1	1	1
08-RETARDATION	3	2	2					2	1	1	1	1				
09-AGITATION	0	0	0					0	0	0	0	0				
10-ANXIETY PSYCHIC	2	1	1					1	0	1	1	1				
11-ANXIETY SOMATIC	1	1	1					1	1	0	0	0				
12-SOMATIC GASTROINTESTINAL	0	1	1					1	1	1	0	0				
13-GENITAL SYMPTOMS	1	1	1					1	1	1	1	1				
14-LOSS OF WEIGHT	0	0	0	0	0	0	0	0								
17-INSIGHT	2	3	1	1	0	0	1	1								
18-DIURNAL VARIATION	1	1	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	22	19	17	14	11	9	7	6								
14/3	417	Reboxetine	Female	01-DEPRESSED MOOD	4	4	2	2	1	1	2	1				
				02-GUILT	3	3	0	0	0	0	0	0				
				03-SUICIDE	1	1	0	0	0	0	0	0				
				04-INSOMNIA EARLY	1	1	2	2	1	0	0	0				
				05-INSOMNIA MIDDLE	2	2	2	2	1	0	0	0				
				06-INSOMNIA LATE	1	1	4	0	1	1	0	0				
				07-WORK AND ACTIVITIES	4	4	3	2	1	1	1	1				
				08-RETARDATION	0	0	0	0	0	0	0	0				
				09-AGITATION	5	3	3	1	1	1	1	1				
				10-ANXIETY PSYCHIC	4	4	3	3	1	0	0	0				
				11-ANXIETY SOMATIC	2	2	1	1	0	0	0	0				
				12-SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0				
				13-GENITAL SYMPTOMS	1	1	0	0	0	0	0	0				
				14-LOSS OF WEIGHT	2	2	1	1	0	1	1	1				
				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				

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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		
14/3	417	Reboxetine	Female	21.OBSESSIONAL/COMPULSIVE 22.Total score	30	0	0	0	0	0	0	0	0	0	0	0	0	0	9	
418		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	1	1	1	1	1	3	3	3	3	3	3	
419		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	4	4	3	3	2	2	2	1	1	1	1	1	1	1	1	1

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 2012A/017
 Listing No.: 72.0

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
14/3	420	Imipramine	Female	01. DEPRESSED MOOD	3	2	2	2	2	2	1	1	2	2	1	1	1	2
				02. GUILT	2	2	2	2	2	2	1	1	1	1	1	1	1	1
				03. SUICIDE	3	3	3	3	3	3	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	0	0	1	1	1	1	1	1
				06. INSOMNIA LATE	2	2	2	2	2	2	1	1	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	4	4	4	4	4	4	3	3	2	2	2	2	2	2
				08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				09. AGITATION	3	3	3	3	3	3	2	2	1	1	1	1	1	1
				10. ANXIETY PSYCHIC	4	4	4	4	4	4	2	2	3	3	3	3	3	3
				11. ANXIETY SOMATIC	3	3	3	3	3	3	2	2	2	2	2	2	2	2
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	0	0	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	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	1	1	1	1
				15. HYPOCHONDRIASIS	3	3	3	3	3	3	2	2	3	3	3	3	3	3
				16. LOSS OF WEIGHT	3	3	3	3	3	3	2	2	2	2	2	2	2	2
				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	35	35	31	31	15	15	22	22	22	22	22	22	22	22
421	421	Reboxetine	Female	01. DEPRESSED MOOD	4	4	4	4	4	4	2	2	2	2	2	2	2	2
				02. GUILT	2	2	2	2	2	2	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	2	2	2	2	2	2	1	1	0	0	0	0	0	0
				06. INSOMNIA LATE	2	2	2	2	2	2	1	1	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	3	3	3	3	3	3	2	2	1	1	1	1	1	1
				08. RETARDATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				09. AGITATION	4	4	4	4	4	4	3	3	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	4	4	4	4	4	4	3	3	2	2	2	2	2	2
				11. ANXIETY SOMATIC	3	3	3	3	3	3	2	2	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	1	1	0	0	0	0	0	0
				13. SOMATIC GENERAL	1	1	1	1	1	1	0	0	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	3	3	3	3	3	3	1	1	1	1	1	1	1	1
				15. HYPOCHONDRIASIS	3	3	3	3	3	3	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	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	33	31	22	11	11	9	10	9	9	9	9	9	9	9
427	427	Imipramine	Female	01. DEPRESSED MOOD	3	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
				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

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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
14/4	131	Imipramine	Female	09. ACITATION	0	0	0	0	0	1	0	0
				10. ANXIETY PSYCHIC	1	1	1	1	1	0	1	0
				11. ANXIETY SOMATIC	2	2	2	2	2	1	1	0
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1
				13. SOMATIC GENERAL	1	1	1	1	1	0	0	0
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	0	0	0
				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	1	1	0	0	0
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0
				20. PARANOID	1	1	1	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22. Total score	23	23	21	21	17	10	9	5
				01. DEPRESSED MOOD	2	2	2	2	1	1	1	1
				02. GUILT	2	2	2	2	1	1	1	0
				03. SUICIDE	1	1	1	1	0	0	0	0
				04. INSOMNIA EARLY	2	2	2	1	1	1	1	1
				05. INSOMNIA MIDDLE	2	2	2	1	1	0	0	0
				06. INSOMNIA LATE	2	2	2	1	1	1	1	0
				07. WORK AND ACTIVITIES	1	1	1	1	1	1	1	0
				08. RETARDATION	1	1	1	1	1	1	0	0
				09. ACITATION	1	1	1	1	1	0	0	0
				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	2	2	2	1	1	1	1	1
				14. GENITAL SYMPTOMS	2	2	2	1	1	1	1	1
				15. HYPOCHONDRIASIS	1	1	1	1	1	1	1	0
				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	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	0	0	0	0	0	0	0	0
				22. Total score	27	25	25	17	14	11	10	5
				01. DEPRESSED MOOD	3	3	3	2	2	2	2	1
				02. GUILT	0	0	0	1	0	0	0	0
				03. SUICIDE	1	1	1	1	1	0	0	0
				04. INSOMNIA EARLY	2	2	2	1	1	1	1	1
				05. INSOMNIA MIDDLE	2	2	2	1	1	0	0	0
				06. INSOMNIA LATE	2	2	2	1	1	1	1	0
				07. WORK AND ACTIVITIES	2	2	2	2	1	1	1	1
				08. RETARDATION	1	1	1	1	1	1	1	0
				09. ACITATION	1	1	1	1	0	0	0	0
				10. ANXIETY PSYCHIC	2	2	2	1	1	1	1	1
				11. ANXIETY SOMATIC	3	3	3	2	1	1	1	0
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
14/4	133	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	28	29	24	16	15	10	5
	134	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	34	32	33	23	18	9	9	7
	135	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	34	32	33	23	18	9	9	7

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PHARMACIA CMS R&D
REBOXETINE - PROTOCOL 20124-017
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 Day				
14/4	135	Reboxetine	Male	17.INSIGHT	0	0	0	0	0	0	0	0				
				18.DIURNAL VARIATION	2	2	2	1	1	0	0					
				19.DEPERSONALIZATION	1	1	1	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	32	32	24	16	13	7	5				
				14/7	422	Imipramine	Female	01.DEPRESSED MOOD	3	3	3	3	3	2	2	1
								02.GUILT	2	2	2	2	2	2	1	
								03.SUICIDE	0	0	0	0	0	0	0	
								04.INSOMNIA EARLY	2	2	2	1	0	0	0	
05.INSOMNIA MIDDLE	2	2	2					2	2	1	1					
06.INSOMNIA LATE	2	2	2					2	2	2	1					
07.WORK AND ACTIVITIES	2	2	2					2	2	2	2					
08.RETARDATION	1	1	1					1	1	1	1					
09.AGIATION	1	1	1					1	1	1	1					
10.ANXIETY PSYCHIC	4	4	4					4	3	2	2					
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	0					
14.GENITAL SYMPTOMS	2	2	2					2	2	2	2					
15.HYPOCHONDRIASIS	1	1	1					1	1	1	1					
16.LOSS OF WEIGHT	1	1	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	25	23	21	17	9	6							
08 07	423	Imipramine	Female	01.DEPRESSED MOOD	3	3	3	3	3	3	2	0				
				02.GUILT	2	2	2	2	2	2	2					
				03.SUICIDE	1	1	1	1	2	2	2					
				04.INSOMNIA EARLY	2	2	2	2	1	1	0					
				05.INSOMNIA MIDDLE	2	2	2	2	2	1	1					
				06.INSOMNIA LATE	1	1	1	1	1	1	1					
				07.WORK AND ACTIVITIES	2	2	2	2	2	1	1					
				08.RETARDATION	1	1	1	1	1	1	1					
				09.AGIATION	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	0	0	1					
				13.SOMATIC GENERAL	1	1	1	1	0	0	0					
				14.GENITAL SYMPTOMS	2	2	2	2	1	2	2					
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	0					
				16.LOSS OF WEIGHT	1	1	1	1	1	1	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					

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
14/7	423	Inipramine	Female	21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22.Total score	23	23	21	21	20	18	17	2						
424		Reboxetine	Male	01.DEPRESSED MOOD	3	3	3	3	1	3	1	0						
				02.GUILT	3	3	3	3	2	2	1	0						
				03.SUICIDE	1	1	1	1	1	1	1	0						
				04.INSOMNIA EARLY	2	2	2	2	2	1	1	1						
				05.INSOMNIA MIDDLE	1	1	1	1	1	1	1	1						
				06.INSOMNIA LATE	2	2	2	2	2	1	1	0						
				07.WORK AND ACTIVITIES	3	3	3	3	2	2	1	0						
				08.RETARDATION	1	1	1	1	1	1	1	0						
				09.AGITATION	3	3	3	3	2	2	1	0						
				10.ANXIETY PSYCHIC	1	1	1	1	1	1	1	1						
				11.ANXIETY SOMATIC	2	2	2	2	2	1	1	0						
				12.SOMATIC GASTROINTESTINAL	2	2	2	2	2	1	1	0						
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1						
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	1	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	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	28	28	27	27	21	19	13	4						
430		Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	3	2	1	0	0						
				02.GUILT	3	3	3	3	2	1	0	0						
				03.SUICIDE	1	1	1	1	1	0	0	0						
				04.INSOMNIA EARLY	2	2	2	2	1	0	0	0						
				05.INSOMNIA MIDDLE	2	2	2	2	1	1	1	1						
				06.INSOMNIA LATE	2	2	2	2	1	1	1	0						
				07.WORK AND ACTIVITIES	2	2	2	2	2	1	1	0						
				08.RETARDATION	1	1	1	1	1	0	0	0						
				09.AGITATION	3	3	3	3	2	1	0	0						
				10.ANXIETY PSYCHIC	2	2	2	2	2	1	1	0						
				11.ANXIETY SOMATIC	2	2	2	2	2	1	1	0						
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1						
				13.SOMATIC GENERAL	2	2	2	2	1	0	0	0						
				14.GENITAL SYMPTOMS	2	2	2	2	2	1	1	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	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	28	28	27	24	15	8	3	0						

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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
14/7	433	Imipramine	Female		1	1	1	1	1	0	0	0
				05.INSOMNIA MIDDLE	1	1	1	1	1	0	0	0
				06.INSOMNIA LATE	1	1	1	1	1	1	0	0
				07.WORK AND ACTIVITIES	3	3	2	1	1	1	1	0
				08.RETARDATION	1	1	1	0	0	0	0	0
				09.AGITATION	3	3	2	2	1	1	1	0
				10.ANXIETY PSYCHIC	2	2	2	2	1	1	1	0
				11.ANXIETY SOMATIC	2	2	2	2	1	1	1	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	0
				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	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	28	28	26	24	15	8	6	1
434		Reboxetine	Male		3	3	3	2	0	0	0	0
				01.DEPRESSED MOOD	3	3	3	2	0	0	0	0
				02.GUILT	3	3	3	2	1	1	1	0
				03.SUICIDE	1	1	1	1	1	1	1	0
				04.INSOMNIA EARLY	1	1	1	1	1	1	1	0
				05.INSOMNIA MIDDLE	1	1	1	1	1	1	1	0
				06.INSOMNIA LATE	2	2	2	1	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	3	1	1	1	1	0
				08.RETARDATION	1	1	1	0	0	0	0	0
				09.AGITATION	3	3	3	1	1	1	1	0
				10.ANXIETY PSYCHIC	1	1	1	1	1	1	1	0
				11.ANXIETY SOMATIC	2	2	2	1	1	1	1	0
				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	2	2	2	1	1	1	1	0
				15.HYPOCHONDRIASIS	1	1	1	1	1	1	1	0
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	1	1	1	1	1	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	27	27	27	16	6	6	3	0
439		Reboxetine	Male		3	3	3	2	2	1	1	0
				01.DEPRESSED MOOD	3	3	3	2	2	1	1	0
				02.GUILT	3	3	3	2	2	1	1	0
				03.SUICIDE	1	1	1	1	1	1	1	0
				04.INSOMNIA EARLY	1	1	1	1	1	1	1	0
				05.INSOMNIA MIDDLE	1	1	1	1	1	1	1	0
				06.INSOMNIA LATE	1	1	1	1	1	1	1	0
				07.WORK AND ACTIVITIES	2	2	2	2	1	1	1	0
				08.RETARDATION	1	1	1	1	1	1	1	0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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				
14/7	439	Reboxetine	Male	09. AGITATION	2	2	2	1	1	1	1				
				10. ANXIETY PSYCHIC	2	2	2	1	1	1					
				11. ANXIETY SOMATIC	2	2	2	2	1	0					
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	0					
				13. SOMATIC GENERAL	1	1	1	1	1	0					
				14. GENITAL SYMPTOMS	2	2	2	2	2	1					
				15. HYPOCHONDRIASIS	2	2	2	1	1	0					
				16. LOSS OF WEIGHT	0	0	0	0	0	0					
				17. INSIGHT	1	1	1	1	0	0					
				18. DIURNAL VARIATION	0	0	0	0	0	0					
				19. DEPERSONALIZATION	1	1	1	1	0	0					
				20. PARANOID	0	0	0	0	0	0					
				21. OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0					
				22. Total score	27	27	27	24	19	15	9	4			
				0065	440	Imipramine	Female	01. DEPRESSED MOOD	3	3	3	0	0	0	0
								02. GUILT	3	3	3	1	0	0	
								03. SUICIDE	1	1	1	0	0	0	
								04. INSOMNIA EARLY	2	2	2	1	0	0	
								05. INSOMNIA MIDDLE	2	2	2	0	0	0	
								06. INSOMNIA LATE	1	1	1	0	0	0	
								07. MORE AND ACTIVITIES	2	2	2	0	0	0	
								08. RETARDATION	1	1	1	0	0	0	
09. AGITATION	2	2	2					2	0	0					
10. ANXIETY PSYCHIC	1	1	1					1	0	0					
11. ANXIETY SOMATIC	2	2	2					2	1	0					
12. SOMATIC GASTROINTESTINAL	1	1	1					0	0	0					
13. SOMATIC GENERAL	0	0	0					0	0	0					
14. GENITAL SYMPTOMS	1	1	1					1	0	0					
15. HYPOCHONDRIASIS	0	0	0					0	0	0					
16. LOSS OF WEIGHT	0	0	0					0	0	0					
17. INSIGHT	1	1	1					1	0	0					
18. DIURNAL VARIATION	0	0	0					0	0	0					
19. DEPERSONALIZATION	1	1	1					1	0	0					
20. PARANOID	0	0	0					0	0	0					
21. OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0					
22. Total score	26	26	26					3	0	0	0				
0065	441	Imipramine	Male	01. DEPRESSED MOOD	3	3	3	1	0	0	0				
				02. GUILT	2	2	2	0	0	0					
				03. SUICIDE	2	2	2	1	0	0					
				04. INSOMNIA EARLY	2	2	2	1	0	0					
				05. INSOMNIA MIDDLE	2	2	2	0	0	0					
				06. INSOMNIA LATE	1	1	1	0	1	0					
				07. MORE AND ACTIVITIES	3	3	3	0	0	0					
				08. RETARDATION	0	0	0	0	0	0					
				09. AGITATION	2	2	2	1	0	0					
				10. ANXIETY PSYCHIC	1	1	1	1	0	0					
				11. ANXIETY SOMATIC	2	2	2	2	1	0					
12. SOMATIC GASTROINTESTINAL	1	1	1	0	0	0									

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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				
14/7	441	Imipramine	Male	13. SOMATIC GENERAL	1	1	1	1	0	0	0	0				
				14. GENITAL SYMPTOMS	2	2	2	1	0	0	0					
				15. HYPOCHONDRIASIS	1	1	1	1	0	0	0					
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0					
				17. INSIGHT	1	1	1	1	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	26	7	1	0	0				
				442	442	Imipramine	Male	01. DEPRESSED MOOD	3	3	3	2	1	0	0	0
								02. GUILT	3	2	2	1	1	0	0	
								03. SUICIDE	2	2	2	1	1	0	0	
								04. INSOMNIA EARLY	2	2	1	1	1	0	0	
								05. INSOMNIA MIDDLE	1	1	1	1	1	0	0	
								06. INSOMNIA LATE	2	2	1	1	1	0	0	
								07. WORK AND ACTIVITIES	3	3	3	2	2	0	0	
								08. RETARDATION	1	1	1	0	0	0	0	
								09. AGITATION	2	2	2	1	1	0	0	
								10. ANXIETY PSYCHIC	2	2	1	1	1	0	0	
								11. ANXIETY SOMATIC	1	1	1	1	1	0	0	
								12. SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	0	
13. SOMATIC GENERAL	2	2	2					2	2	1	1					
14. GENITAL SYMPTOMS	1	1	1					1	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	0	0	0					0	0	0	0					
19. DEPERSONALIZATION	1	1	1					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	26					17	15	6	2	1				
449	449	Reboxetine	Female	01. DEPRESSED MOOD	2	2	2	1	0	0	0	0				
				02. GUILT	3	3	2	1	1	0	0					
				03. SUICIDE	2	2	2	1	0	0	0					
				04. INSOMNIA EARLY	1	1	1	0	1	0	0					
				05. INSOMNIA MIDDLE	1	1	0	0	0	0	0					
				06. INSOMNIA LATE	1	1	0	1	0	0	0					
				07. WORK AND ACTIVITIES	2	2	2	1	1	0	0					
				08. RETARDATION	1	1	0	0	0	0	0					
				09. AGITATION	1	1	1	0	1	0	0					
				10. ANXIETY PSYCHIC	1	1	1	1	1	0	0					
				11. ANXIETY SOMATIC	1	1	2	1	1	0	0					
				12. SOMATIC GASTROINTESTINAL	0	0	1	1	0	0	0					
				13. SOMATIC GENERAL	1	1	0	0	0	0	0					
				14. GENITAL SYMPTOMS	2	2	2	2	1	0	0					
				15. HYPOCHONDRIASIS	1	1	1	0	0	0	0					
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0					

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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					
14/7	449	Reboxetine	Female	17.INSIGHT	1	1	1	1	1	1	1	1	1	1	1	1	1	1	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	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	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				22.Total score	24	24	24	23	14	7	2	2	0	0	0	0	0	0	0	0	0	0	0
				01.DEPRESSED MOOD	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0
				02.GUILT	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	0
				03.SUICIDE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0
				04.INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
05.INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0				
06.INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0				
07.WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	0				
08.RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0				
09.AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0				
10.ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0				
11.ANXIETY SOMATIC	2	2	2	2	2	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	1	1	1	1	1	0				
13.SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0				
14.CENTRAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0				
15.HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	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	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	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	26	26	26	26	26	26	26	26	22	19	10	10	10	10	10	10	10	10	0				
14/8	130	Reboxetine	Male	01.DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	0			
				02.GUILT	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	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	0
				05.INSOMNIA MIDDLE	0	0	0	0	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	1	1	1	0
				07.WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0
				08.RETARDATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
				09.AGITATION	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0
				10.ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0
11.ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0				
12.SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0				
13.SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0				
14.CENTRAL SYMPTOMS	0	0	0	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	2	2	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	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	0				
18.DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0				
19.DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0				
20.PARANOID	0	0	0	0	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 20124/017
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient Treatment	Sex	Hamilton depression rating scale	Screening Day	0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14/8	130	Male	21. OBSESSIONAL/COMPULSIVE 22. Total score	25	25	22	17	15	13	10	8
425	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	1	1	1	1	1	1	1	1
467	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 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. Total score	2	1	1	1	1	1	1	1

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
14/10 53	Male	01.DEPRESSED MOOD	3	3	2	2	1	1	1	1
		02.GUILT	0	0	1	1	1	0	0	0
		03.SUICIDE	0	0	0	0	0	0	0	0
		04.INSOMNIA EARLY	2	2	2	1	1	1	1	1
		05.INSOMNIA MIDDLE	2	2	2	2	1	1	0	0
		06.INSOMNIA LATE	2	2	2	2	2	2	1	1
		07.WORK AND ACTIVITIES	3	3	3	2	2	2	2	1
		08.RETARDATION	2	2	1	1	1	1	1	1
		09.AGITATION	2	2	1	1	1	0	0	0
		10.ANXIETY PSYCHIC	2	2	2	1	1	1	1	1
		11.ANXIETY SOMATIC	2	2	2	2	1	1	0	0
		12.SOMATIC GASTROINTESTINAL	2	2	2	2	1	0	0	0
		13.SOMATIC GENERAL	2	2	2	2	1	0	0	0
		14.GENITAL SYMPTOMS	1	1	1	1	1	1	1	1
		15.HYPOCHONDRIASIS	2	2	2	2	1	1	1	1
		16.LOSS OF HEIGHT	0	0	1	0	0	0	0	0
		17.INSIGHT	0	0	1	0	0	0	0	0
		18.DIURNAL VARIATION	0	0	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	30	28	28	22	16	11	8	8
54	Female	01.DEPRESSED MOOD	3	3	3	2	2	2	2	1
		02.GUILT	2	2	2	1	1	1	1	1
		03.SUICIDE	1	1	1	1	1	1	0	0
		04.INSOMNIA EARLY	2	2	2	1	1	2	2	2
		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	2	2	2	2	2
		08.RETARDATION	2	2	2	2	1	1	1	1
		09.AGITATION	1	2	2	2	2	1	1	1
		10.ANXIETY PSYCHIC	2	2	2	2	1	1	1	1
		11.ANXIETY SOMATIC	2	2	2	2	2	2	2	1
		12.SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	1
		13.SOMATIC GENERAL	2	2	2	2	2	2	2	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	0	0	0	0	0	0	0	0
		17.INSIGHT	1	0	0	0	0	0	0	0
		18.DIURNAL VARIATION	2	2	2	2	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	30	30	29	26	22	22	20	16
55	Female	01.DEPRESSED MOOD	2	2	2	2	2	1	1	1
		02.GUILT	2	2	1	0	0	0	0	0
		03.SUICIDE	0	0	0	0	0	0	0	0
		04.INSOMNIA EARLY	1	1	1	1	1	1	1	0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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					
14/10	55	Reboxetine	Female	05.INSOMNIA MIDDLE	2	2	2	2	2	1	1	1					
				06.INSOMNIA LATE	2	2	2	2	2	2	2	2	2				
				07.WORK AND ACTIVITIES	3	2	2	2	2	2	2	2	2	2			
				08.RETARDATION	2	2	2	2	2	2	2	2	2	2			
				09.AGITATION	3	2	2	2	2	2	2	2	2	2			
				10.ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	2	2			
				11.ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2			
				12.SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2			
				13.SOMATIC GENERAL	2	2	2	2	2	2	2	2	2	2			
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2			
				15.HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2			
				16.LOSS OF WEIGHT	1	1	1	1	1	1	1	1	1	1			
				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	2	2	2	2	2	2	2	2	2	2			
				20.PARAMOID	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	30	27	24	23	20	15	11	8					
				56	56	Imipramine	Female	01.DEPRESSED MOOD	3	3	3	2	2	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	2	2	2	2	2	2	2
05.INSOMNIA MIDDLE	1	1	1					1	1	1	1	1	1				
06.INSOMNIA LATE	2	2	2					2	2	2	2	2	2				
07.WORK AND ACTIVITIES	3	2	2					2	2	2	2	2	2				
08.RETARDATION	2	2	2					2	2	2	2	2	2				
09.AGITATION	2	2	2					2	2	2	2	2	2				
10.ANXIETY PSYCHIC	2	2	2					2	2	2	2	2	2				
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	2	2	2					2	2	2	2	2	2				
14.GENITAL SYMPTOMS	1	0	0					0	0	0	0	0	0				
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	1	1	1					1	1	1	1	1	1				
18.DIURNAL VARIATION	2	2	2					2	2	2	2	2	2				
19.DEPERSONALIZATION	0	0	0					0	0	0	0	0	0				
20.PARAMOID	0	0	0					0	0	0	0	0	0				
21.OBSESSIONAL/COMPULSIVE	0	0	0					0	0	0	0	0	0				
22.Total score	26	25	22					19	17	14	14	13					
57	57	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	2	2	1	1	1					
				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	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	2	2	2	2	2	2	2						
				08.RETARDATION	2	2	2	2	2	2	2						

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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								
14/10	57	Reboxetine	Female	09. AGITATION	2	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	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 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	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	0	0				
				17. INSIGHT	1	0	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	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	28	26	23	20	20	20	20	20	20	20	20	20	20	20	17	15	15	15	15				
				58	58	Imipramine	Female	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	1	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	2
								07. WORK AND ACTIVITIES	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
09. AGITATION	2	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	2				
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				
59	59	Imipramine	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					
				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	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	3	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 20124/017
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
14/10	59	Imipramine	Female			2	2	1	1	1	1	1
				13.SOMATIC GENERAL	2	2	2	1	1	1	1	1
				14.GENITAL SYMPTOMS	0	0	1	0	0	0	0	0
				15.HYPOCHONDRIASIS	1	1	1	1	1	0	0	0
				16.LOSS OF WEIGHT	2	0	0	0	0	0	0	0
				17.INSIGHT	1	1	1	1	1	1	1	1
				18.DIURNAL VARIATION	2	2	2	2	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	30	27	27	21	16	13	12	10
60		Reboxetine	Female			2	2	2	1	1	1	1
				01.DEPRESSED MOOD	2	2	2	2	1	1	1	1
				02.GUILT	2	3	2	1	1	0	0	0
				03.SUICIDE	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	2	2	2	2	1	1	1
				05.INSOMNIA MIDDLE	2	2	2	2	2	1	1	1
				06.INSOMNIA LATE	1	1	2	1	1	1	1	1
				07.WORK AND ACTIVITIES	2	2	2	2	2	2	2	1
				08.RETARDATION	2	2	2	2	1	0	0	0
				09.AGITATION	2	2	2	2	1	1	1	1
				10.ANXIETY PSYCHIC	2	2	2	2	2	1	1	1
				11.ANXIETY SOMATIC	2	2	2	2	1	1	1	1
				12.SOMATIC GASTROINTESTINAL	1	2	2	1	1	1	0	0
				13.SOMATIC GENERAL	2	2	2	1	1	1	1	1
				14.GENITAL SYMPTOMS	0	1	1	1	1	0	0	0
				15.HYPOCHONDRIASIS	1	2	2	2	1	1	1	1
				16.LOSS OF WEIGHT	0	2	0	0	0	0	0	0
				17.INSIGHT	1	1	1	0	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	24	31	28	23	18	14	11	10
137		Reboxetine	Female			3	3	2	2	1	1	1
				01.DEPRESSED MOOD	3	3	2	2	2	1	1	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	1	1	1	1	1	1
				05.INSOMNIA MIDDLE	2	2	2	1	1	1	1	1
				06.INSOMNIA LATE	1	1	1	1	1	1	1	1
				07.WORK AND ACTIVITIES	3	2	3	3	2	2	2	2
				08.RETARDATION	2	2	2	2	2	1	1	1
				09.AGITATION	1	1	2	2	1	1	1	1
				10.ANXIETY PSYCHIC	5	5	5	2	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	0	0	0	0	0	0	0	0

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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
14/10	137	Reboxetine	Female	17.INSIGHT	1	1	1	0	0	0	0
				18.DIURNAL VARIATION	2	2	2	2	1	1	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	29	28	29	20	17	18	18
				01.DEPRESSED MOOD	3	3	2	2	2	1	1
				02.GUILT	1	2	2	1	1	1	1
				03.SUICIDE	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	1	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	2	2	1	1
				08.RETARDATION	2	2	2	1	1	1	1
				09.AGITATION	2	2	1	1	1	1	1
				10.ANXIETY PSYCHIC	3	3	3	2	2	1	1
				11.ANXIETY SOMATIC	2	2	1	1	1	1	1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1
				13.SOMATIC GENERAL	2	2	1	1	1	1	1
				14.GENITAL SYMPTOMS	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	1	2	2	2	2	2	1
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0
				17.INSIGHT	1	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	2	2	2	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	27	28	26	21	17	14	13
				01.DEPRESSED MOOD	3	3	2	1	1	1	1
				02.GUILT	2	2	1	0	0	0	0
				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	0	0	0	0
				07.WORK AND ACTIVITIES	2	3	2	2	1	1	1
				08.RETARDATION	2	2	2	1	0	0	0
				09.AGITATION	2	2	2	1	0	0	0
				10.ANXIETY PSYCHIC	1	1	1	1	1	1	1
				11.ANXIETY SOMATIC	2	2	2	1	1	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1
				13.SOMATIC GENERAL	2	2	1	1	1	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	1	1	1	1	1	1	1
				17.INSIGHT	1	1	1	1	1	1	1
				18.DIURNAL VARIATION	2	2	2	2	1	1	1
				19.DEPERSONALIZATION	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
14/10	199	Reboxetine	Female	21.OBSESSIONAL/COMPULSIVE 22.Total score	0 26	0 28	0 24	0 18	0 11	0 8	0 8	0 8
140		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.GENTRAL SYMPTOMS 15.HYPCHONDRIASIS 16.LOSS OF WEIGHT 17.INSIGHT 18.DIURNAL VARIATION 19.DEPERSONALIZATION 20.PARANOID 21.OBSESSIONAL/COMPULSIVE 22.Total score	3 2 0 2 2 1 2 3 2 1 2 2 2 2 2 2 0 0 1 0 0 0 30	3 2 0 1 2 2 3 2 1 2 2 2 2 2 2 2 0 0 1 1 0 0 28	2 3 0 1 2 2 3 2 2 2 2 2 2 2 2 2 0 0 1 1 0 0 29	2 2 0 1 2 2 2 2 2 2 2 2 2 2 2 2 0 0 1 1 0 0 26	2 2 0 1 2 2 2 2 2 2 2 2 2 2 2 2 0 0 1 1 0 0 23	2 2 0 1 2 2 2 2 2 2 2 2 2 2 2 2 0 0 1 1 0 0 19	2 2 0 1 2 2 2 2 2 2 2 2 2 2 2 2 0 0 1 1 0 0 21	1 1 0 0 2 2 2 2 2 2 2 2 2 2 2 0 0 1 1 0 0 19
435		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.GENTRAL SYMPTOMS 15.HYPCHONDRIASIS 16.LOSS OF WEIGHT 17.INSIGHT 18.DIURNAL VARIATION 19.DEPERSONALIZATION 20.PARANOID 21.OBSESSIONAL/COMPULSIVE 22.Total score	4 2 1 2 2 1 2 1 1 2 2 2 2 2 2 0 0 1 1 0 0 30	4 2 1 2 2 1 2 1 1 2 2 2 2 2 2 0 0 1 1 0 0 28	3 2 1 2 2 1 2 1 1 2 2 2 2 2 2 0 0 1 1 0 0 29	2 2 1 2 2 1 2 1 1 2 2 2 2 2 2 0 0 1 1 0 0 26	2 2 1 2 2 1 2 1 1 2 2 2 2 2 2 0 0 1 1 0 0 23	2 2 1 2 2 1 2 1 1 2 2 2 2 2 2 0 0 1 1 0 0 19	2 2 1 2 2 1 2 1 1 2 2 2 2 2 2 0 0 1 1 0 0 21	2 2 1 2 2 1 2 1 1 2 2 2 2 2 2 0 0 1 1 0 0 19

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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		
14/10	436	Reboxetine	Female	01. DEPRESSED MOOD	3	3	3	3	2	2	2	2	1	1	1	1	1		
				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	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	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	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
				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	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				16. LOSS OF HEIGHT	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
				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	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score				30	28	28	28	22	22	16	14	12	12	12	12
437	Reboxetine	Female	01. DEPRESSED MOOD	3	3	3	3	2	2	2	2	1	1	1	1	1			
			02. GUILT	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	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	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 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	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	26	22	16	12	9	9	9	9	9		
438	Imipramine	Female	01. DEPRESSED MOOD	2	3	2	2	2	2	2	2	1	1	1	1				
			02. GUILT	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				
			04. INSOMNIA EARLY	2	1	2	2	2	2	2	2	2	2	2	2				

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	
14/10	438	Imipramine	Female	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	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
				08..RETARDATION	2	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1
				09..AGITATION	1	2	1	1	1	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	1
				11..ANXIETY SOMATIC	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				12..SOMATIC GASTROINTESTINAL	2	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1
				13..SOMATIC GENERAL	2	2	2	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	2	1	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
				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	26	23	21	18	17	15	15	15	15	15	15	15	15	15
443		Reboxetine	Female	01..DEPRESSED MOOD	4	4	4	3	2	2	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	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	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
				07..WORK AND ACTIVITIES	3	3	3	3	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	2	3	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
				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	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	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17..INSIGHT	1	1	1	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
				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	29	30	29	27	23	15	13	12	12	12	12	12	12	12	12	12
444		Reboxetine	Male	01..DEPRESSED MOOD	3	3	3	3	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
				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	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

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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
14/10	444	Reboxetine	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	29	29	29	27	26	19	15	14
445		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	3	3	3	2	2	2	1	1
446		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	2	2	1	1	1	1

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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				
14/10	446	Reboxetine	Female	13. SOMATIC GENERAL	2	2	2	1	1	1	1	1				
				14. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0			
				15. HYPOCHONDRIASIS	2	2	2	2	1	1	1					
				16. LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0			
				17. INSIGHT	2	2	0	0	0	1	1	1	1			
				18. DIURNAL VARIATION	2	2	2	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	0	0	0	0	0	0	0	0	0			
				22. Total score	30	31	27	19	16	16	15					
				447	Reboxetine	Male	01. DEPRESSED MOOD	3	3	3	2	2	2	2	1	1
							02. GUILT	1	1	1	1	1	1	0	0	
							03. SUICIDE	1	1	1	1	1	1	0	0	
04. INSOMNIA EARLY	2	2	2				2	2	1	1	1					
05. INSOMNIA MIDDLE	2	2	2				2	1	1	1	1					
06. INSOMNIA LATE	2	2	1				1	1	1	1	1					
07. WORK AND ACTIVITIES	2	2	2				2	2	2	1	1	1				
08. RETARDATION	2	2	2				1	1	1	1	1					
09. AGITATION	2	2	2				1	1	1	1	1					
10. ANXIETY PSYCHIC	3	3	2				2	2	2	2	1	1				
11. ANXIETY SOMATIC	2	2	2				2	1	1	1	1					
12. SOMATIC GASTROINTESTINAL	2	2	2				2	2	2	1	1					
13. SOMATIC GENERAL	0	0	0				0	0	0	0	0					
14. GENITAL SYMPTOMS	1	1	1	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	2	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	28	30	28	23	23	19	13									
448	Imipramine	Female	01. DEPRESSED MOOD	4	4	3	3	3	3	2	1	1				
			02. GUILT	2	2	2	2	2	2	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	1	1	1	1	1					
			06. INSOMNIA LATE	2	2	2	2	2	2	2	2					
			07. WORK AND ACTIVITIES	3	3	3	2	2	2	2	2					
			08. RETARDATION	3	3	2	2	2	2	1	1					
			09. AGITATION	2	2	2	2	2	2	2	2					
			10. ANXIETY PSYCHIC	3	3	3	3	2	2	2	2					
			11. ANXIETY SOMATIC	3	2	3	3	3	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. GENITAL SYMPTOMS	0	0	0	0	0	0	0	0								
15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2								
16. LOSS OF WEIGHT	2	2	2	2	2	2	2	2								

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PHARMACIA CNS RD
 REBOXETINE - PROTOCOL 20124/017
 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			
14/10	448	Female	17. INSIGHT	0	0	0	0	0	1	1			
			18. DIURNAL VARIATION	2	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	36	33	32	30	27	25	22	22		
			453	Imipramine	Female	01. DEPRESSED MOOD	2	2	2	1	1	1	1
						02. GUILT	1	1	1	1	1	1	1
						03. SUICIDE	0	0	0	0	0	0	0
						04. INSOMNIA EARLY	2	1	1	0	0	0	0
						05. INSOMNIA MIDDLE	2	1	1	1	1	1	1
						06. INSOMNIA LATE	2	2	1	1	1	1	1
07. WORK AND ACTIVITIES	3	3				2	2	2	2	2			
08. RETARDATION	2	2				2	1	1	1	0			
09. AGITATION	2	2				2	1	1	1	1			
10. ANXIETY PSYCHIC	3	2				2	1	1	1	1			
11. ANXIETY SOMATIC	2	2				2	1	1	1	1			
12. SOMATIC GASTROINTESTINAL	2	2				2	1	1	1	1			
13. SOMATIC GENERAL	2	2	2	1	1	1	1						
14. GENITAL SYMPTOMS	1	1	1	0	0	0	0						
15. HYPOCHONDRIASIS	1	1	1	1	1	1	1						
16. LOSS OF WEIGHT	2	2	0	0	0	0	0						
17. INSIGHT	0	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	30	30	24	17	14	17	13	12					
454	Reboxetine	Female	01. DEPRESSED MOOD	3	3	2	2	1	1	1			
			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	2	1	1	1	1	1			
			06. INSOMNIA LATE	2	2	2	2	2	2	1			
			07. WORK AND ACTIVITIES	3	2	2	2	2	2	1			
			08. RETARDATION	2	2	2	1	1	1	1			
			09. AGITATION	3	3	2	2	1	1	0			
			10. ANXIETY PSYCHIC	2	2	2	2	2	2	1			
			11. ANXIETY SOMATIC	2	2	2	1	1	1	1			
			12. SOMATIC GASTROINTESTINAL	2	2	2	1	1	1	1			
13. SOMATIC GENERAL	2	2	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	2	0	0	0	0	0	0						
17. INSIGHT	1	1	1	1	1	1	1						
18. DIURNAL VARIATION	2	2	2	2	2	2	1						
19. DEPERSONALIZATION	0	0	0	0	0	0	0						
20. PARANOID	0	0	0	0	0	0	0						

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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
14/10	454	Reboxetine	Female	21.OBSESSIONAL/COMPULSIVE	30	0	0	0	0	0	0	0
				22.Total score	30	28	25	21	19	18	14	11
	455	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	2	2	1	1	1
				02.GUILT	0	1	1	1	1	1	1	1
				03.SUICIDE	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	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	1	0
				07.WORK AND ACTIVITIES	3	3	2	2	2	2	1	1
				08.RETARDATION	2	2	2	2	1	1	1	1
				09.AGIATION	2	2	2	2	1	1	1	1
				10.ANXIETY PSYCHIC	2	2	2	2	2	1	1	1
				11.ANXIETY SOMATIC	1	1	1	1	1	1	1	1
				12.SOMATIC GASTROINTESTINAL	1	1	2	2	1	1	1	1
				13.SOMATIC GENERAL	2	2	2	1	1	1	1	1
				14.GENITAL SYMPTOMS	1	1	1	1	0	0	0	0
				15.HYPOCHONDRIASIS	1	1	1	1	1	1	1	1
				16.LOSS OF WEIGHT	2	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	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	28	24	19	16	13	14
15	349	Imipramine	Male	01.DEPRESSED MOOD	2	2	1	0	0	0	0	0
				02.GUILT	2	2	1	0	0	0	0	0
				03.SUICIDE	3	3	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	1	1	1	1	1
				05.INSOMNIA MIDDLE	0	0	0	0	1	0	0	0
				06.INSOMNIA LATE	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	2	2	1	1	0	0	0	0
				08.RETARDATION	0	0	0	0	0	0	0	0
				09.AGIATION	0	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	2	2	1	1	2	1
				11.ANXIETY SOMATIC	2	2	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	2	2	1	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	1	0	0	1	1
				14.GENITAL SYMPTOMS	2	2	2	2	1	0	0	1
				15.HYPOCHONDRIASIS	1	1	1	0	0	0	0	0
				16.LOSS OF WEIGHT	2	2	0	0	0	0	0	0
				17.INSIGHT	1	1	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	1	0	0	0	0	0
				19.DEPERSONALIZATION	3	3	1	0	0	0	0	0
				20.PARANOID	2	2	1	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0
				22.Total score	31	31	15	6	4	5	5	3

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PEARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012s/017
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				
15	351	Reboxetine	Male	Hamilton depression rating scale																		
				01.DEPRESSED MOOD	4	4	1	0	0	0	1	1	0	0	0	0	0	0	0	0	0	
				02.GUILT	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				03.SUICIDE	3	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	0	0	2	2	2	2	1	0	0	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	2	2	2	0	0	2	2	2	2	1	0	0	0	0	0	0	0	0
				06.INSOMNIA LATE	2	2	2	0	0	2	2	2	2	0	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	4	4	1	0	0	3	1	1	1	0	0	0	0	0	0	0	0	0
				08.RETARDATION	3	3	1	0	0	1	1	1	1	0	0	0	0	0	0	0	0	0
				09.AGITATION	2	2	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	3	3	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
				11.ANXIETY SOMATIC	2	2	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	2	2	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	2	2	2	0	0	2	1	1	2	1	1	1	1	0	0	0	0	0
				14.GENITAL SYMPTOMS	2	2	2	0	0	2	1	2	2	1	1	1	1	0	0	0	0	0
				15.HYPOCHONDRIASIS	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				16.LOSS OF HEIGHT	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	2	2	2	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	41	41	17	1	32	9	2	0	0	0	0	0	0	0	0	0	0	0
352	Imipramine	Male	Hamilton depression rating scale																			
			01.DEPRESSED MOOD	3	3	1	0	0	1	1	0	0	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	2	2	
			03.SUICIDE	2	2	2	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	0	0	
			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	1	1	1	2	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	3	3	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	
			11.ANXIETY SOMATIC	2	2	3	1	0	3	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	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
			14.GENITAL SYMPTOMS	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
			15.HYPOCHONDRIASIS	1	1	2	1	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	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	2	2	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	26	25	23	15	14	0	0	0	0	0	0	0	0	0	0	0	0	0	
364	Imipramine	Female	Hamilton depression rating scale																			
			01.DEPRESSED MOOD	4	4	1	1	1	2	3	0	0	0	0	0	0	0	0	0	0		
			02.GUILT	3	3	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
			03.SUICIDE	3	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
04.INSOMNIA EARLY	2	2	2	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0				

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	364	Imipramine	Female	05. INSOMNIA MIDDLE	2	2	1	2	0	2	2	2					
				06. INSOMNIA LATE	2	2	1	1	1	2	2						
				07. WORK AND ACTIVITIES	4	4	3	0	0	1	1						
				08. RETARDATION	2	2	1	0	0	0	0						
				09. AGITATION	0	0	1	1	0	1	1						
				10. ANXIETY PSYCHIC	3	3	3	2	1	3	3						
				11. ANXIETY SOMATIC	2	2	1	0	1	1	1						
				12. SOMATIC GASTROINTESTINAL	2	2	2	0	1	1	1						
				13. SOMATIC GENERAL	2	2	1	0	1	2	2						
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2						
				15. HYPOCHONDRIASIS	2	2	0	0	0	0	0						
				16. LOSS OF HEIGHT	2	2	2	2	0	0	0						
				17. INSIGHT	1	1	1	1	0	0	0						
				18. DIURNAL VARIATION	1	1	1	1	0	0	0						
				19. DEPERSONALIZATION	2	2	2	2	1	0	0						
				20. PARANOID	0	0	0	0	0	1	3						
				21. OBSESSIONAL/COMPULSIVE	2	2	1	1	1	2	2						
				22. Total score	41	41	27	16	16	34							
				366	Reboxetine	Male	01. DEPRESSED MOOD	3	3	0	0	0	0	0	0	0	
							02. GUILT	3	3	0	0	0	0	0	0	0	
							03. SUICIDE	4	4	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	2	2	1				0	0	0	0	0	0	0				
07. WORK AND ACTIVITIES	2	2	2				0	0	1	1	1	1	1				
08. RETARDATION	1	1	0				0	0	0	0	0	0	0				
09. AGITATION	0	0	0				0	0	0	0	0	0	0				
10. ANXIETY PSYCHIC	3	3	0				0	0	0	1	1	0	0				
11. ANXIETY SOMATIC	2	2	0				0	0	0	0	0	0	0				
12. SOMATIC GASTROINTESTINAL	2	2	0				0	0	0	1	2	0	0				
13. SOMATIC GENERAL	2	2	0				0	0	0	0	0	0	0				
14. GENITAL SYMPTOMS	2	2	0				0	0	0	0	0	0	0				
15. HYPOCHONDRIASIS	2	2	0				0	0	0	0	0	0	0				
16. LOSS OF HEIGHT	2	2	0				0	0	0	0	0	0	0				
17. INSIGHT	1	1	0				0	0	0	0	0	0	0				
18. DIURNAL VARIATION	1	1	0				0	0	0	0	0	0	0				
19. DEPERSONALIZATION	2	2	0				0	0	0	0	0	0	0				
20. PARANOID	2	2	0				0	0	0	0	0	0	0				
21. OBSESSIONAL/COMPULSIVE	0	0	0				0	0	0	0	0	0	0				
22. Total score	36	36	1				0	1	5	6	1						
367	Imipramine	Male	01. DEPRESSED MOOD	4	4	4	3	2	2	2	2	3					
			02. GUILT	1	1	1	2	1	1	1	1						
			03. SUICIDE	2	2	2	2	1	1	2	2						
			04. INSOMNIA EARLY	0	0	0	1	2	1	1	1						
			05. INSOMNIA MIDDLE	1	1	1	0	2	1	1	1						
			06. INSOMNIA LATE	1	1	1	1	2	0	0	0						
			07. WORK AND ACTIVITIES	4	4	4	4	4	3	4	4						
			08. RETARDATION	2	2	2	2	1	2	1	1						

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	367	Male	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	32	32	28	32	35	19	19	27
368	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	1	0	0	0	1	1
369	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	0	0	0	0	0	0

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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	369	Reboxetine	Female	13. SOMATIC GENERAL	2	2	2	1	0	0	0	0	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	2	2	1	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
				16. LOSS OF WEIGHT	0	0	0	2	0	0	0	0	0	0	0	2	0	0
				17. INSIGHT	1	1	1	0	0	0	0	0	0	0	0	0	0	0
				18. DIURNAL VARIATION	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
				20. PARANOID	3	3	0	0	0	0	0	0	0	0	0	0	0	0
				21. OBSESSIONAL/COMPULSIVE	2	2	0	0	0	0	0	0	0	0	0	0	0	0
				22. Total score	34	34	4	3	0	0	0	0	0	0	0	2	0	0
370		Imipramine	Female	01. DEPRESSED MOOD	2	2	0	1	1	2	2	0	0	1	1	1	1	1
				02. GUILT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				03. SUICIDE	3	3	1	0	2	0	0	0	1	0	1	0	0	0
				04. INSOMNIA EARLY	2	2	2	1	2	1	0	0	1	0	0	0	0	0
				05. INSOMNIA MIDDLE	2	2	1	1	1	1	1	1	0	0	0	0	0	0
				06. INSOMNIA LATE	1	1	1	1	1	1	1	1	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	2	2	2	1	1	1	1	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	1	1	2	1	2	1	2	1	2	1	2	2	2	2
				10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	0	1	0	1	0	0	0
				11. ANXIETY SOMATIC	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
				13. SOMATIC GENERAL	2	2	2	1	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	1	1	1	1	1	1	0	0	0	0	0
				17. INSIGHT	0	0	0	1	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
				19. DEPERSONALIZATION	2	2	2	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
				21. OBSESSIONAL/COMPULSIVE	1	1	1	1	0	0	0	0	0	0	0	0	0	0
				22. Total score	22	22	20	10	15	7	10	7	10	11	11	11	11	11
371		Reboxetine	Female	01. DEPRESSED MOOD	2	2	0	0	0	0	0	0	0	0	0	0	0	0
				02. GUILT	1	1	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
				04. INSOMNIA EARLY	2	2	2	2	2	1	0	0	0	0	0	0	0	0
				05. INSOMNIA MIDDLE	2	2	2	1	2	1	2	0	0	0	0	0	0	0
				06. INSOMNIA LATE	2	2	1	2	2	1	2	0	0	0	0	0	0	0
				07. WORK AND ACTIVITIES	2	2	0	0	0	0	0	0	0	0	0	0	0	0
				08. RETARDATION	1	1	0	0	0	0	0	0	0	0	0	0	0	0
				09. AGITATION	1	1	1	1	2	2	1	1	1	0	0	0	0	0
				10. ANXIETY PSYCHIC	3	3	1	1	2	2	1	1	0	0	0	0	0	0
				11. ANXIETY SOMATIC	2	2	1	0	0	0	0	0	0	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	1	1	1	0	0	0	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	2	2	2	0	2	1	1	0	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	2	2	2	1	1	1	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	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124-017
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	371	Reboxetine	Female	17.INSIGHT	1	1	0	0	0	0	0	0				
				18. DIURNAL VARIATION	2	2	1	2	1	0	1	0				
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0				
				20. PARANOID	0	0	0	2	0	0	0	0				
				21. OBSESSIONAL/COMPULSIVE	1	1	0	1	0	0	0	0				
				22. Total score	30	30	12	18	15	4	8	4				
				372	Imipramine	Male	01. DEPRESSED MOOD	4	4	3	3	3	3	3	1	2
							02. GUILT	3	3	3	1	2	2	3	2	
							03. SUICIDE	4	4	2	3	2	2	2	2	
							04. INSOMNIA EARLY	2	2	2	1	0	2	1	1	
							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	4	4	3	4	3	3	3	2	
08. RETARDATION	3	3	3				2	2	2	1	1					
09. AGITATION	0	0	0				0	0	0	0	0					
10. ANXIETY PSYCHIC	0	0	0				0	0	0	0	0					
11. ANXIETY SOMATIC	0	0	0				0	0	1	0	0					
12. SOMATIC GASTROINTESTINAL	2	2	2				2	1	1	0	2					
13. SOMATIC GENERAL	0	0	0				2	2	1	2	1					
373	Imipramine	Female	04. INSOMNIA EARLY	2	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	4	4	4	4						
			08. RETARDATION	1	1	1	1	1	1	1						
			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. GENITAL SYMPTOMS	2	2	2	2	2	2	2						
			15. HYPOCHONDRIASIS	2	2	2	2	2	2	2						
			16. LOSS OF WEIGHT	2	2	2	2	2	2	2						
17. INSIGHT	1	1	1	1	1	1	1									
18. DIURNAL VARIATION	1	1	1	1	1	1	1									
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	34	34	25	25	27	28	27									

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	373	Female	21.OBSESSIONAL/COMPULSIVE 22.Total score	1 34	1 35						
	374	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	3 2 2 0 0 0 4 2 2 3 3 2 2 1 0 0 2 2 2 2 2 2 36	3 2 2 0 0 0 2 1 2 2 3 2 2 1 0 0 1 2 2 2 2 2 56	3 1 1 2 1 1 2 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 20	1 0 0 1 1 1 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 12	0 0 0 1 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 12	0 0 0 0 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 7	0 4	
	375	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 0 3 2 2 1 4 3 1 1 0 0 0 1 1 2 2 2 2 2 2 30	4 0 3 2 2 1 1 3 3 1 0 0 0 0 0 0 0 0 0 0 0 0 52	4 0 2 1 1 2 1 1 1 2 1 1 1 1 1 1 1 1 1 1 1 12	0 0 2 1 1 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 12	0 7	0 4		

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 2012/4/017
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	376	Inipramine	Female	01. DEPRESSED MOOD	4	4	4	4	4	4	4	4		
				02. GUILT	3	3	3	3	3	3	3	3	3	
				03. SUICIDE	2	2	2	2	2	2	2	2	2	2
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2
				05. INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1
				06. INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2
				07. WORK AND ACTIVITIES	4	4	4	4	4	4	4	4	4	4
				08. RETARDATION	3	3	3	3	3	3	3	3	3	3
				09. AGITATION	2	2	2	2	2	2	2	2	2	2
				10. ANXIETY PSYCHIC	3	3	3	3	3	3	3	3	3	3
				11. ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1
				12. SOMATIC GASTROINTESTINAL	2	2	2	2	2	2	2	2	2	2
				13. SOMATIC GENERAL	0	0	0	0	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2
				15. HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	2
				16. LOSS OF HEIGHT	1	1	1	1	1	1	1	1	1	1
				17. INSIGHT	1	1	1	1	1	1	1	1	1	1
				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	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	36	36	36	40	40	40	40	40	40	40
377	377	Reboxetine	Female	01. DEPRESSED MOOD	4	4	4	4	4	4	4	4		
				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	1	1	1	1	1	1	1	1	1	
				10. ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	
				11. ANXIETY SOMATIC	4	4	4	4	4	4	4	4	4	
				12. SOMATIC GASTROINTESTINAL	3	3	3	3	3	3	3	3	3	
				13. SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	
				15. HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	
				16. LOSS OF HEIGHT	3	3	3	3	3	3	3	3	3	
				17. INSIGHT	2	2	2	2	2	2	2	2	2	
				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	2	2	2	2	2	2	2	2	2	
				22. Total score	50	50	50	25	15	8	8	8	5	4
378	378	Reboxetine	Female	01. DEPRESSED MOOD	4	4	4	4	4	4	4	4		
				02. GUILT	3	3	3	3	3	3	3	3		
				03. SUICIDE	3	3	3	3	3	3	3	3		
				04. INSOMNIA EARLY	2	2	2	2	2	2	2	2		

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	378	Reboxetine	Female	05. INSOMNIA MIDDLE	2	2	2	2	2	2	2	0	0	2	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	4	4	2	2	1	1	0	0	0	0	0	0	0	0
				08. RETARDATION	2	2	1	1	1	1	0	0	0	0	0	0	0	0
				09. AGITATION	0	0	1	1	1	1	1	0	0	0	0	0	0	0
				10. ANXIETY PSYCHIC	0	0	0	0	0	0	0	0	0	0	0	0	0	0
				11. ANXIETY SOMATIC	1	1	0	0	0	0	0	0	0	0	0	0	0	0
				12. SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0	0	0	0	0	0	0
				13. SOMATIC GENERAL	1	1	0	0	0	0	0	0	0	0	0	0	0	0
				14. GENITAL SYMPTOMS	2	2	2	2	2	2	1	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	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
				19. DEPERSONALIZATION	0	0	1	0	0	0	0	0	0	0	0	0	0	0
				20. PARANOIA	1	1	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	19	13	5	5	3	5	3	5	3	3	3	2
379		Imipramine	Female	01. DEPRESSED MOOD	4	4												
				02. GUILT	1	1												
				03. SUICIDE	3	3												
				04. INSOMNIA EARLY	2	2												
				05. INSOMNIA MIDDLE	2	2												
				06. INSOMNIA LATE	2	2												
				07. WORK AND ACTIVITIES	3	3												
				08. RETARDATION	2	2												
				09. AGITATION	0	0												
				10. ANXIETY PSYCHIC	3	3												
				11. ANXIETY SOMATIC	1	1												
				12. SOMATIC GASTROINTESTINAL	2	2												
				13. SOMATIC GENERAL	2	2												
				14. GENITAL SYMPTOMS	0	0												
				15. HYPOCHONDRIASIS	2	2												
				16. LOSS OF WEIGHT	2	2												
				17. INSIGHT	0	0												
				18. DIURNAL VARIATION	1	1												
				19. DEPERSONALIZATION	3	3												
				20. PARANOIA	1	1												
				21. OBSESSIONAL/COMPULSIVE	0	0												
				22. Total score	36	36												
380		Imipramine	Female	01. DEPRESSED MOOD	4	4	3	3	2	2	3	3	3	0	0	0	0	0
				02. GUILT	3	3	3	2	2	2	3	3	3	0	0	0	0	0
				03. SUICIDE	3	3	2	0	0	0	2	2	2	0	0	0	0	0
				04. INSOMNIA EARLY	2	2	0	0	0	0	1	1	1	0	0	0	0	0
				05. INSOMNIA MIDDLE	2	2	0	0	0	0	2	2	2	0	0	0	0	0
				06. INSOMNIA LATE	1	1	0	0	0	0	2	2	2	0	0	0	0	0
				07. WORK AND ACTIVITIES	4	4	2	2	2	2	4	4	4	1	1	1	1	1
				08. RETARDATION	2	2	2	1	1	1	2	2	2	1	1	1	1	1

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
15	380	Imipramine	Female	09. AGITATION	3	3	1	1	0	0	0	0				
				10. ANXIETY PSYCHIC	4	4	2	3	0	0	1	1				
				11. ANXIETY SOMATIC	1	1	1	1	3	0	1	1				
				12. SOMATIC GASTROINTESTINAL	1	1	1	1	2	0	1	0				
				13. SOMATIC GENERAL	1	1	1	2	2	1	0	1				
				14. GENITAL SYMPTOMS	2	2	2	2	2	0	2	2				
				15. HYPOCHONDRIASIS	2	2	2	2	1	0	2	0				
				16. LOSS OF HEIGHT	0	0	2	0	2	0	0	0				
				17. INSIGHT	0	0	1	0	1	0	0	0				
				18. DIURNAL VARIATION	1	1	1	0	2	0	0	0				
				19. DEPERSONALIZATION	0	0	0	0	0	0	0	0				
				20. PARANOID	0	0	1	0	0	0	0	0				
				21. OBSESSIONAL/COMPULSIVE	2	2	2	1	1	0	0	0				
				22. Total score	40	39	29	26	39	3	8	10				
				381	Reboxetine	Female	01. DEPRESSED MOOD	3	3	2	2	3	1	1	1	2
							02. GUILT	1	1	1	2	0	0	1	0	
							03. SUICIDE	4	4	2	2	0	1	0	1	
							04. INSOMNIA EARLY	2	2	2	0	1	0	1	0	
							05. INSOMNIA MIDDLE	1	1	1	2	2	1	0	1	
							06. INSOMNIA LATE	2	2	2	2	1	2	1	1	
							07. WORK AND ACTIVITIES	4	4	2	3	3	2	2	2	
							08. RETARDATION	1	1	1	1	1	1	1	1	
09. AGITATION	1	1	1				0	1	1	1	1					
10. ANXIETY PSYCHIC	2	2	3				2	2	2	1	2					
11. ANXIETY SOMATIC	1	1	2				2	0	1	0	0					
12. SOMATIC GASTROINTESTINAL	0	0	2				2	2	1	1	1					
13. SOMATIC GENERAL	2	2	2				0	2	1	1	1					
14. GENITAL SYMPTOMS	0	0	2				0	2	1	0	2					
15. HYPOCHONDRIASIS	0	0	2				0	2	2	2	2					
16. LOSS OF HEIGHT	0	0	2				0	1	0	0	0					
17. INSIGHT	1	1	0				0	0	0	0	0					
18. DIURNAL VARIATION	1	1	1				0	0	0	0	0					
19. DEPERSONALIZATION	2	2	2				1	2	0	1	1					
20. PARANOID	0	0	1				0	0	0	0	0					
21. OBSESSIONAL/COMPULSIVE	2	2	1				1	1	1	1	1					
22. Total score	32	32	34				21	23	19	16	21					
382	Imipramine	Male	01. DEPRESSED MOOD	3	3											
			02. GUILT	1	1											
			03. SUICIDE	1	1											
			04. INSOMNIA EARLY	1	1											
			05. INSOMNIA MIDDLE	1	1											
			06. INSOMNIA LATE	1	1											
			07. WORK AND ACTIVITIES	3	3											
			08. RETARDATION	2	2											
			09. AGITATION	3	3											
			10. ANXIETY PSYCHIC	3	3											
			11. ANXIETY SOMATIC	0	0											
			12. SOMATIC GASTROINTESTINAL	1	1											

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	382	Imipramine	Male	13. SOMATIC GENERAL	1	1										
				14. GENITAL SYMPTOMS	2	2										
				15. HYPOCHONDRIASIS	1	1										
				16. LOSS OF WEIGHT	0	0										
				17. INSIGHT	1	1										
				18. DIURNAL VARIATION	0	0										
				19. DEPERSONALIZATION	2	2										
				20. PARANOID	1	1										
				21. OBSESSIONAL/COMPULSIVE	2	2										
				22. Total score	30	30										
				383	Imipramine	Female	01. DEPRESSED MOOD	3	3	3	3	3	1	1	0	0
							02. GUILT	3	3	2	2	1	0	0	0	
							03. SUICIDE	3	3	3	3	1	0	0	0	
							04. INSOMNIA EARLY	2	2	2	2	0	0	2	1	
							05. INSOMNIA MIDDLE	2	2	2	2	0	0	0	1	
							06. INSOMNIA LATE	2	2	2	2	2	2	2	1	
							07. WORK AND ACTIVITIES	2	2	2	2	2	2	2	0	
							08. RETARDATION	1	1	1	1	2	1	0	0	
							09. AGITATION	2	2	2	2	3	2	1	0	
							10. ANXIETY PSYCHIC	3	3	2	2	3	1	1	1	
							11. ANXIETY SOMATIC	2	2	2	2	3	1	0	2	
							12. SOMATIC GASTROINTESTINAL	1	1	1	1	2	1	1	1	
13. SOMATIC GENERAL	2	2	2				2	2	2	1	2					
14. GENITAL SYMPTOMS	2	2	2				2	2	2	1	1					
15. HYPOCHONDRIASIS	2	2	2				2	1	1	1	0					
16. LOSS OF WEIGHT	2	2	2				2	1	2	0	0					
17. INSIGHT	1	1	1				1	0	1	0	0					
18. DIURNAL VARIATION	1	1	1				1	0	0	0	0					
19. DEPERSONALIZATION	3	3	2				2	0	0	0	0					
20. PARANOID	2	2	2				2	0	0	1	1					
21. OBSESSIONAL/COMPULSIVE	2	2	2				2	1	1	0	1					
22. Total score	43	43	33				34	15	17	8	9					
384	Reboxetine	Female	01. DEPRESSED MOOD	4	4	3	3									
			02. GUILT	3	3	3	3									
			03. SUICIDE	4	4	2	2									
			04. INSOMNIA EARLY	2	2	2	2									
			05. INSOMNIA MIDDLE	2	2	2	2									
			06. INSOMNIA LATE	2	2	2	2									
			07. WORK AND ACTIVITIES	4	4	4	4									
			08. RETARDATION	3	3	3	3									
			09. AGITATION	2	2	2	2									
			10. ANXIETY PSYCHIC	4	4	4	4									
			11. ANXIETY SOMATIC	0	0	1	1									
			12. SOMATIC GASTROINTESTINAL	2	2	2	2									
			13. SOMATIC GENERAL	0	0	0	0									
			14. GENITAL SYMPTOMS	2	2	2	2									
			15. HYPOCHONDRIASIS	1	1	1	1									
			16. LOSS OF WEIGHT	2	2	1	1									

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PHARMACIA CBS BHD
 REBOSETINE - PROTOCOL 2012A/017
 Listing No.1 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	384	Rebosetine	Female	17. INEARTH 18. DIURNAL VARIATION 19. PERSONALIZATION 20. PARANOID 21. OBSSERSSIONAL/COMPULSIVE 22. Total score	2	2	1	1	1	1	1
					1	0	0	0	0	0	0
					1	1	1	1	1	1	1
					1	1	1	1	1	1	1
					42	42	42	42	42	42	37

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.17	1.33	1.50	0.50	0.50	1.33	1.00	0.33	
				2. WEIGHT	1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.67	0.50	1.00	0.17	1.00	0.67	0.50		
				4. DIURNAL VARIATION	1.00	1.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	2.50	2.50	2.75	2.25	1.75	2.75	2.00	1.50	1.50
				6. SLEEP DISTURBANCE	1.33	1.33	1.67	1.33	0.67	0.33	0.00	0.33	0.00
				7. Total score	7.67	7.67	9.92	5.25	4.08	6.42	4.67	3.67	
				2	2	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	1.00	1.00	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	1.17	1.17	0.67					0.67	0.50	0.00	0.00	0.00	0.00
4. DIURNAL VARIATION	2.00	2.00	2.00					2.00	1.00	0.00	0.00	0.00	0.00
5. RETARDATION	2.75	2.75	2.75					2.75	1.75	0.50	0.50	0.25	0.25
6. SLEEP DISTURBANCE	0.67	0.67	1.00					1.00	1.00	0.33	0.33	0.00	0.00
7. Total score	9.92	9.92	7.42					7.42	5.08	1.00	1.33	0.25	
3	3	Imipramine	Female					1. ANXIETY/SOMATIZATION	1.33	1.33	1.17	1.17	0.67
				2. WEIGHT	2.00	2.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.00	0.67	0.50	0.33	0.33	0.00	0.00	0.00	0.00
				4. DIURNAL VARIATION	0.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	2.50	2.25	2.25	2.00	1.50	1.00	0.25	0.25	0.25
				6. SLEEP DISTURBANCE	1.33	2.00	1.00	0.33	0.00	0.67	0.33	0.00	0.00
				7. Total score	8.17	9.25	7.92	5.83	3.50	3.00	1.92	1.42	
				4	4	Imipramine	Male	1. ANXIETY/SOMATIZATION	1.00	1.00	1.33	1.00	1.00
2. WEIGHT	0.00	0.00	2.00					2.00	2.00	0.00	0.00	0.00	0.00
3. COGNITIVE DISTURBANCE	0.50	0.50	1.00					0.83	0.50	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
5. RETARDATION	2.50	2.75	2.75					2.50	2.25	1.50	1.50	0.25	0.25
6. SLEEP DISTURBANCE	1.00	1.67	1.67					1.33	1.00	0.67	0.33	0.33	0.33
7. Total score	6.00	6.92	9.75					8.67	7.75	3.83	3.17	0.58	
5	5	Reboxetine	Female					1. ANXIETY/SOMATIZATION	0.83	0.83	0.17	0.50	0.33
				2. WEIGHT	1.00	1.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	1.17	0.53	0.53	0.33	0.50	0.00	0.00	0.00
				4. DIURNAL VARIATION	2.00	2.00	1.00	2.00	2.00	2.00	1.00	1.00	1.00
				5. RETARDATION	2.75	2.75	1.00	2.25	1.75	2.25	1.50	1.50	1.50
				6. SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	1.00	1.00	0.67	1.00	1.00
				7. Total score	8.75	9.08	3.83	7.08	5.42	6.42	4.00	4.17	
				6	6	Imipramine	Male	1. ANXIETY/SOMATIZATION	1.67	1.33	1.33	1.00	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	1.00	0.67					0.83	0.50	0.33	0.17	0.17	0.17
4. DIURNAL VARIATION	2.00	2.00	2.00					2.00	2.00	2.00	2.00	2.00	2.00
5. RETARDATION	2.00	2.00	1.75					1.50	1.50	1.00	0.50	0.50	0.50
6. SLEEP DISTURBANCE	2.00	2.00	1.67					1.00	1.00	1.33	1.00	1.00	1.00
7. Total score	8.83	8.33	7.42					6.33	5.67	5.50	4.50	4.50	

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.50	1.50	1.33	0.83	0.83	1.00	1.17	1.17
				2. WEIGHT	0.00	0.00	2.00	0.00	0.00	2.00	2.00	2.00
				3. COGNITIVE DISTURBANCE	0.83	0.83	1.33	0.83	0.50	0.33	0.67	0.83
				4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	1.00	2.00	2.00
				5. RETARDATION	2.50	2.50	2.00	2.25	1.75	2.25	2.00	2.00
				6. SLEEP DISTURBANCE	1.67	1.67	2.00	1.00	1.00	1.00	0.67	1.00
				7. Total score	8.50	8.50	10.67	6.92	5.08	7.08	8.75	9.00
				8	8	Imipramine	Male	1. ANXIETY/SOMATIZATION	0.83	1.00	1.33	
2. WEIGHT	0.00	0.00	0.00									
3. COGNITIVE DISTURBANCE	1.17	1.17	1.00									
4. DIURNAL VARIATION	1.00	1.00	1.00									
5. RETARDATION	2.25	2.50	2.50									
6. SLEEP DISTURBANCE	1.67	1.67	1.33									
7. Total score	6.92	7.33	7.17									
9	9	Imipramine	Female					1. ANXIETY/SOMATIZATION	1.33	1.50	1.17	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	0.17	0.00	0.00	0.00	0.00
				4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	1.50	1.50	0.00
				5. RETARDATION	2.75	2.75	2.75	1.75	1.50	1.50	0.75	0.25
				6. SLEEP DISTURBANCE	0.33	0.00	0.33	0.00	0.00	0.00	0.00	0.00
				7. Total score	7.08	6.92	6.75	4.75	4.00	3.00	0.75	0.25
				10	10	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.50	1.50	1.00	1.33
2. WEIGHT	0.00	0.00	0.00					0.00	0.00	0.00	0.00	0.00
3. COGNITIVE DISTURBANCE	0.50	0.33	0.17					0.00	0.33	0.50	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	2.50	2.50	2.25					1.50	1.25	1.50	1.50	1.25
6. SLEEP DISTURBANCE	1.67	2.00	0.67					0.33	2.00	1.33	1.33	1.33
7. Total score	7.17	7.33	5.08					4.17	5.58	6.33	5.00	4.08
11	11	Reboxetine	Male					1. ANXIETY/SOMATIZATION	1.67	1.33	1.50	1.33
				2. WEIGHT	2.00	2.00	2.00	2.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	0.83	0.67	0.83	1.33	0.67	1.67		
				4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00		
				5. RETARDATION	3.00	3.00	2.75	2.25	2.25	2.25		
				6. SLEEP DISTURBANCE	1.67	1.67	1.67	2.00	1.33	2.00		
				7. Total score	11.17	10.67	10.75	8.92	7.42	9.92		
				12	12	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.17	1.17	1.17	0.50
2. WEIGHT	2.00	2.00	0.00					0.00	0.00			
3. COGNITIVE DISTURBANCE	0.33	0.00	1.00					0.33	1.00			
4. DIURNAL VARIATION	1.00	1.00	1.00					1.00	1.00			
5. RETARDATION	2.25	2.50	2.00					2.00	2.00			

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124-017
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	12	Male	6. SLEEP DISTURBANCE	2.00	2.00	1.67	1.33	1.33				
			7. Total score	8.75	8.67	6.83	5.17	7.75				
2	33	Male	1. ANXIETY/SOMATIZATION	1.50	1.50	0.83	0.33	0.33	0.83	0.50	0.33	
			2. WEIGHT	1.00	1.00	0.00	0.00	1.00	0.00	1.00	0.00	0.00
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.33	0.17	0.17	0.17	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	1.75	1.75	0.75	0.25	0.00	0.00	0.75	0.50	0.25
			6. SLEEP DISTURBANCE	1.33	1.33	0.33	0.67	0.67	0.67	0.67	0.67	0.00
			7. Total score	6.25	6.25	2.25	1.42	1.17	3.42	1.83	1.83	0.75
34	Imipramine	Male	1. ANXIETY/SOMATIZATION	1.67	1.67	0.83	1.67	0.50	0.83	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	0.67	0.67	0.00	0.17	0.00	0.00	0.00	0.17	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	2.00	2.00	0.50	1.50	0.50	1.00	1.00	1.50	1.00
			6. SLEEP DISTURBANCE	1.00	1.00	0.67	0.00	0.00	0.00	0.00	1.00	0.33
			7. Total score	5.33	5.33	2.00	3.53	1.00	1.85	3.83	2.67	
35	Reboxetine	Male	1. ANXIETY/SOMATIZATION	0.67	0.67	0.50	0.33	0.17	0.17	0.17	0.17	
			2. WEIGHT	2.00	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	0.17	0.17	0.17	0.17	0.33	0.17
			4. DIURNAL VARIATION	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			5. RETARDATION	2.50	2.50	0.75	0.00	0.00	0.00	0.00	0.25	0.50
			6. SLEEP DISTURBANCE	1.00	1.00	0.67	0.00	0.33	0.33	0.33	0.33	0.67
			7. Total score	9.17	9.17	2.42	0.50	1.17	0.67	1.08	1.50	
36	Imipramine	Female	1. ANXIETY/SOMATIZATION	0.83	0.83	0.83	0.17	0.00				
			2. WEIGHT	2.00	2.00	0.00	0.00	2.00				
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.00	0.33				
			4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00				
			5. RETARDATION	2.50	2.50	2.75	0.50	0.25				
			6. SLEEP DISTURBANCE	1.33	1.33	1.00	0.33	0.67				
			7. Total score	7.33	7.33	5.25	1.00	3.25				
37	Reboxetine	Male	1. ANXIETY/SOMATIZATION	2.00	2.00	1.17	1.17	1.33	1.50	1.33	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	0.00	0.33	0.50	0.33	0.33	0.17	0.17
			4. DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	0.00	1.00	1.00
			5. RETARDATION	2.50	2.25	1.50	1.25	1.25	1.25	1.25	1.50	1.00
			6. SLEEP DISTURBANCE	1.67	1.67	2.00	2.00	2.00	1.33	1.00	1.00	1.00
			7. Total score	8.17	7.92	4.67	5.00	6.08	4.92	4.00	3.83	
38	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.00	1.17	1.00	1.17	1.17	1.17	1.17	1.17	
			2. WEIGHT	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
			3. COGNITIVE DISTURBANCE	0.67	0.33	0.00	0.33	0.50	0.83	0.67	0.50	0.50

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	38	Imipramine	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	2.00
				5. RETARDATION	2.00	2.25	2.00	2.75	2.50	2.50	
				6. SLEEP DISTURBANCE	1.00	2.00	1.33	1.67	1.67	1.33	
				7. Total score	5.67	6.75	6.33	6.08	7.17	7.00	
				1. ANXIETY/SOMATIZATION	1.33	1.33	0.83	0.83	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	0.50	0.33	0.17	
39	Reboxetine	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	2.00
			5. RETARDATION	2.00	2.00	1.50	1.00	1.00	1.00		
			6. SLEEP DISTURBANCE	1.00	1.00	1.00	0.67	0.33	0.33		
			7. Total score	8.17	8.17	5.17	4.83	3.67	3.50		
			1. ANXIETY/SOMATIZATION	1.33	1.33	0.83	0.83	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	0.50	0.33	0.17		
40	Imipramine	Male	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	2.00
			5. RETARDATION	2.00	2.25	1.00	1.50	1.25	1.75		
			6. SLEEP DISTURBANCE	1.33	1.33	0.67	1.33	1.00	0.67		
			7. Total score	6.33	6.58	3.67	4.33	3.42	7.08		
			1. ANXIETY/SOMATIZATION	0.83	1.00	0.33	0.83	0.67	1.00		
			2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	1.17	1.00	0.67	0.67	0.50	1.00		
41	Reboxetine	Male	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	2.00
			5. RETARDATION	2.00	2.25	1.00	1.50	1.25	1.75		
			6. SLEEP DISTURBANCE	1.33	1.33	0.67	1.33	1.00	0.67		
			7. Total score	6.33	6.58	3.67	4.33	3.42	7.08		
			1. ANXIETY/SOMATIZATION	1.00	1.50	2.00	1.83	1.33	1.50		
			2. WEIGHT	2.00	0.00	0.00	1.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	0.17	1.00	1.00	0.50	0.50	0.67		
42	Imipramine	Male	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	2.00
			5. RETARDATION	2.75	2.25	2.00	2.25	1.50	1.75		
			6. SLEEP DISTURBANCE	2.00	1.33	2.00	1.00	1.00	1.33		
			7. Total score	8.92	7.08	7.00	7.08	5.33	6.08		
			1. ANXIETY/SOMATIZATION	1.33	1.33	1.50	1.17	1.33	1.00		
			2. WEIGHT	0.00	0.00	0.00	1.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	0.50	0.50	0.83	0.33	0.67	0.83		
43	Reboxetine	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	2.00
			5. RETARDATION	3.00	2.75	2.50	3.00	3.00	2.00		
			6. SLEEP DISTURBANCE	1.33	1.33	1.33	1.67	1.33	0.67		
			7. Total score	6.17	6.92	7.17	9.17	8.33	6.50		
			1. ANXIETY/SOMATIZATION	0.67	0.67	0.83	0.17	0.17	0.17		
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	0.50	1.17	0.67	0.33	0.00	0.33		
44	Imipramine	Male	4. DIURNAL VARIATION	2.00	2.00	1.00	0.00	0.00	0.00	0.00	0.25
			5. RETARDATION	2.75	1.75	0.50	0.00	0.00	0.00		
			6. SLEEP DISTURBANCE	1.00	1.00	1.67	0.67	0.67	0.33		
			7. Total score	6.92	6.58	4.67	1.17	0.83	0.83		
			1. ANXIETY/SOMATIZATION	1.50	1.33	1.83					

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PHARMACIA CNS RSD
REBOXETINE - PROTOCOL 20124/017
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		
2	44	Male	Imipramine	Hamilton depression rating scale	0.00	1.00	0.00					
				2.WEIGHT	1.83	1.33	1.67					
				3.COGNITIVE DISTURBANCE	0.00	2.00	2.00					
				4.DIURNAL VARIATION	3.00	2.25	3.00					
				5.RETARDATION	1.67	1.00	0.00					
				6.SLEEP DISTURBANCE	8.00	8.92	8.50					
				7.Total score								
45	Female	Imipramine	1.ANXIETY/SOMATIZATION	1.17	1.33	0.83						
				2.WEIGHT	0.00	0.00	0.00					
				3.COGNITIVE DISTURBANCE	0.50	0.33	0.50					
				4.DIURNAL VARIATION	0.00	0.00	0.00					
				5.RETARDATION	3.00	3.00	1.00					
				6.SLEEP DISTURBANCE	1.00	0.67	1.00					
				7.Total score	5.67	5.33	3.33					
46	Female	Reboxetine	1.ANXIETY/SOMATIZATION	0.50	0.50	0.83	0.83	0.83	0.33	0.33	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	0.67	0.17	0.50	0.17	0.17	0.17
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	0.00	0.00	2.00
				5.RETARDATION	2.50	1.75	1.50	1.75	1.25	1.25	1.25	1.25
				6.SLEEP DISTURBANCE	1.67	1.33	1.67	1.33	1.00	0.67	1.00	0.67
				7.Total score	9.50	8.25	6.67	6.08	5.58	3.42	2.75	4.00
47	Female	Reboxetine	1.ANXIETY/SOMATIZATION	1.67	1.33	1.33	1.17	0.17	0.17	0.17	0.17	
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	1.17	0.83	1.00	0.33	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	1.75	2.00	1.50	0.50	0.25	0.00	0.00
				6.SLEEP DISTURBANCE	1.00	0.67	1.33	1.33	1.33	0.67	0.33	0.67
				7.Total score	7.08	5.58	5.67	4.33	2.33	1.25	0.50	0.83
48	Female	Imipramine	1.ANXIETY/SOMATIZATION	0.67	0.67	0.67	0.50	0.17	0.17	0.33		
				2.WEIGHT	1.00	1.00	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	0.33	
				4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	0.00	0.00	
				5.RETARDATION	2.75	2.50	2.00	1.25	1.00	1.00	1.00	
				6.SLEEP DISTURBANCE	1.67	1.33	0.33	0.67	0.33	0.33	0.00	
				7.Total score	8.75	8.17	4.50	3.75	2.67	1.67	1.33	
49	Female	Imipramine	1.ANXIETY/SOMATIZATION	1.00	0.83	0.67	0.33	0.50	0.00	0.33		
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	1.00	0.50	0.50	0.33	0.33	0.33	0.17	
				4.DIURNAL VARIATION	1.00	2.00	1.00	1.00	0.00	0.00	0.00	
				5.RETARDATION	2.25	2.00	1.00	1.00	1.00	0.25	1.25	
				6.SLEEP DISTURBANCE	1.67	1.33	1.00	0.67	0.33	1.67	0.67	
				7.Total score	7.92	7.67	4.67	3.33	2.17	2.25	2.42	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	50	Reboxetine	Male	1. ANXIETY/SOMATIZATION	0.50	0.83	1.33	1.67	1.50	1.00	1.00
				2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	0.50	0.83	1.17	0.83	0.33	0.17
				4. DIURNAL VARIATION	2.00	1.00	0.00	1.00	1.00	1.00	1.00
				5. RETARDATION	2.75	2.50	2.25	1.75	1.75	1.50	1.50
				6. SLEEP DISTURBANCE	2.00	1.33	1.67	1.67	1.33	1.33	1.00
				7. Total score	9.08	7.17	6.08	7.25	6.42	6.17	4.67
					51	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.00	0.67	0.67
2. WEIGHT	1.00	0.00	0.00					0.00			
3. COGNITIVE DISTURBANCE	0.83	1.00	0.67					1.83			
4. DIURNAL VARIATION	1.00	2.00	1.00					2.00			
5. RETARDATION	2.75	2.00	2.00					3.00			
6. SLEEP DISTURBANCE	1.53	1.67	2.00					2.00			
7. Total score	7.92	7.53	6.33					10.33			
	52	Imipramine	Male					1. ANXIETY/SOMATIZATION	0.50	0.83	0.17
				2. WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.50	1.00	0.50	0.00	0.00	0.00	0.00
				4. DIURNAL VARIATION	2.00	2.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	3.00	1.75	1.25	0.25	0.00	0.25	0.25
				6. SLEEP DISTURBANCE	1.33	1.00	1.00	0.33	0.33	0.33	0.33
				7. Total score	10.33	6.58	2.92	0.92	0.50	0.58	0.58
				3	65	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.83	1.50	0.83
2. WEIGHT	0.00	2.00	2.00					0.00	0.00	0.00	0.00
3. COGNITIVE DISTURBANCE	0.83	0.83	0.50					0.00	0.00	0.00	0.00
4. DIURNAL VARIATION	2.00	2.00	1.00					1.00	1.00	1.00	1.00
5. RETARDATION	2.50	2.75	1.75					0.75	0.50	0.75	0.00
6. SLEEP DISTURBANCE	1.00	1.67	0.67					0.67	0.33	1.33	1.00
7. Total score	8.17	10.75	6.75					2.75	2.67	3.08	2.17
	66	Imipramine	Female					1. ANXIETY/SOMATIZATION	1.33	1.50	0.67
				2. WEIGHT	2.00	2.00	0.00	0.00	0.00	1.00	0.00
				3. COGNITIVE DISTURBANCE	2.17	1.83	0.50	0.17	0.00	0.33	1.83
				4. DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.25	1.50	0.25	0.25	0.25	0.50	3.25
				6. SLEEP DISTURBANCE	0.67	2.00	0.67	0.33	0.00	0.00	1.00
				7. Total score	9.42	9.83	2.08	0.75	0.58	2.33	7.58
					67	Reboxetine	Female	1. ANXIETY/SOMATIZATION	2.17	1.83	0.83
2. WEIGHT	1.00	1.00	0.00					1.00	0.00	0.00	0.00
3. COGNITIVE DISTURBANCE	1.83	1.67	1.33					1.50	1.17	1.17	1.83
4. DIURNAL VARIATION	0.00	0.00	1.00					1.00	0.00	1.00	1.00
5. RETARDATION	1.25	1.00	0.75					0.75	0.75	0.75	1.00

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/017
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	67	Female	6. SLEEP DISTURBANCE	2.00	2.00	1.67	0.67	1.00	0.67	0.67	1.67
			7. Total score	8.25	7.50	5.58	5.92	3.58	4.92	5.00	6.50
68	Imipramine	Female	1. ANXIETY/SOMATIZATION	2.00	2.00	1.50	1.17	1.67	1.67	1.33	1.50
			2. WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00
68	Imipramine	Female	3. COGNITIVE DISTURBANCE	1.67	1.67	1.50	1.33	1.33	1.33	1.33	1.33
			4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			5. RETARDATION	3.00	2.75	3.00	2.75	3.00	3.00	3.00	3.00
			6. SLEEP DISTURBANCE	2.00	2.00	1.33	2.00	1.00	1.00	0.67	1.00
			7. Total score	10.67	10.42	7.33	7.42	7.00	7.00	6.33	6.83
			1. ANXIETY/SOMATIZATION	1.67	1.50	1.50	1.00	0.50	0.50	0.17	0.67
			2. WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00
69	Imipramine	Female	3. COGNITIVE DISTURBANCE	2.00	1.67	1.33	1.17	1.00	1.00	0.50	
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	2.25	2.50	2.75	1.25	0.75	0.25	1.00	
			6. SLEEP DISTURBANCE	1.00	2.00	0.67	1.00	0.67	0.33	0.00	
			7. Total score	9.92	10.67	7.25	6.42	2.92	1.92	2.67	
			1. ANXIETY/SOMATIZATION	1.67	1.50	1.50	1.00	0.50	0.50	0.17	
			2. WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	
70	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.33	1.50	1.83	1.67	1.50	1.50	1.50	
			2. WEIGHT	0.00	0.00	0.00	1.00	0.00	1.00	0.00	
			3. COGNITIVE DISTURBANCE	1.17	1.33	1.67	1.50	1.33	1.17	1.17	
			4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00	0.00	
			5. RETARDATION	2.00	2.00	2.75	1.75	1.75	1.50	1.50	
			6. SLEEP DISTURBANCE	1.67	2.00	2.00	2.00	2.00	1.67	1.67	
			7. Total score	7.17	7.83	9.25	8.92	6.58	6.83	6.83	
71	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	0.83	0.00	0.67	0.33	0.17	
			2. WEIGHT	2.00	2.00	0.00	1.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	1.50	1.33	0.33	0.17	0.17	0.00	0.00	
			4. DIURNAL VARIATION	2.00	1.00	0.00	0.00	0.00	0.00	0.00	
			5. RETARDATION	2.00	1.75	0.75	0.25	0.75	0.00	0.25	
			6. SLEEP DISTURBANCE	1.33	1.00	0.00	0.00	0.00	0.00	0.00	
			7. Total score	10.17	8.42	1.92	1.42	1.58	0.33	0.17	
72	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.67	1.50	1.17	0.83	1.00	1.00	0.50	
			2. WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	1.67	1.17	1.17	1.17	0.67	0.67	0.50	
			4. DIURNAL VARIATION	2.00	1.00	1.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	2.50	2.25	1.00	1.50	1.25	1.25	1.25	
			6. SLEEP DISTURBANCE	0.67	0.67	1.00	0.67	1.00	0.67	0.67	
			7. Total score	10.50	8.58	5.33	5.17	3.92	4.92	3.92	
73	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.17	1.33	0.17	0.17	0.17	0.17	0.00	
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	1.17	0.50	1.00	0.17	0.17	0.33	0.00	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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			
3	Reboxetine	Female	4. DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00
			5. RETARDATION	1.75	2.00	1.00	0.00	0.25	0.25	0.50	0.00	0.00	
			6. SLEEP DISTURBANCE	1.00	0.67	0.67	1.00	0.33	0.67	0.00	0.00		
			7. Total score	6.08	5.50	2.83	1.33	1.92	1.42	0.50	0.00		
			1. ANXIETY/SOMATIZATION	1.17	1.17	0.83	0.83	0.50	0.83	0.17	0.83		
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	1.33	1.33	1.17	1.00	1.00	0.83	0.83	1.00		
4	Imipramine	Male	4. DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	1.00	2.00	1.00	1.00	
			5. RETARDATION	2.75	2.75	2.25	2.25	2.00	2.00	1.00	1.25		
			6. SLEEP DISTURBANCE	2.00	2.00	2.00	1.67	1.67	2.00	1.00	1.33		
			7. Total score	9.25	9.25	7.75	6.75	6.17	6.67	5.00	5.42		
			1. ANXIETY/SOMATIZATION	1.67	1.67	1.50	1.17	0.67	0.17	0.00	0.17		
			2. WEIGHT	2.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	1.33	1.33	1.67	1.17	0.83	0.17	0.00	0.00		
100	Reboxetine	Female	4. DIURNAL VARIATION	1.00	1.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	3.00	3.00	3.25	3.00	1.50	0.50	0.25	0.25		
			6. SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	1.67	1.67	1.00	1.33		
			7. Total score	11.00	10.00	11.42	9.33	6.67	3.50	2.25	2.75		
			1. ANXIETY/SOMATIZATION	1.67	1.67	1.50	1.17	0.67	0.17	0.00	0.17		
			2. WEIGHT	2.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	1.33	1.33	1.67	1.17	0.83	0.17	0.00	0.00		
101	Imipramine	Female	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	2.00	2.25	2.25			
			6. SLEEP DISTURBANCE	2.00	2.00	1.00	1.00	1.00	1.33	1.00			
			7. Total score	6.50	6.50	6.58	6.67	6.67	6.92	6.50			
			1. ANXIETY/SOMATIZATION	1.17	1.17	1.50	1.17	1.83	0.83	0.50			
			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	0.50	0.50	0.50	0.50			
161	Reboxetine	Male	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	0.50	0.00	0.00	0.00	0.00			
			6. SLEEP DISTURBANCE	1.33	1.67	1.00	1.00	1.67	1.33	1.00			
			7. Total score	6.75	8.75	2.17	2.00	3.17	1.83	3.17			
			1. ANXIETY/SOMATIZATION	1.50	1.50	0.67	0.50	0.83	0.50	0.67			
			2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00			
			3. COGNITIVE DISTURBANCE	0.67	0.33	0.00	0.00	0.17	0.00	0.00			
162	Reboxetine	Female	4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00			
			5. RETARDATION	2.50	2.50	1.75	1.25	0.75	0.25	0.50			
			6. SLEEP DISTURBANCE	1.67	1.00	1.33	1.00	0.33	1.00	1.00			
			7. Total score	10.17	9.33	6.58	5.58	4.08	0.75	3.42			
			1. ANXIETY/SOMATIZATION	1.50	1.50	1.00	1.00	0.83	0.17	0.17			
			2. WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00			
			3. COGNITIVE DISTURBANCE	0.50	0.33	0.50	0.33	0.17	0.00	0.17			
193	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.83	1.83								

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 12.4

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	
7	193	Reboxetine	Female	2.WEIGHT	0.00	0.00					
				3.COGNITIVE DISTURBANCE	1.33	1.33					
				4.DIURNAL VARIATION	0.00	0.00					
				5.RETARDATION	1.75	1.75					
				6.SLEEP DISTURBANCE	0.67	0.67					
				7.Total score	5.58	5.58					
				1.ANXIETY/SOMATIZATION	0.67	0.50					
				2.WEIGHT	0.00	0.00					
7	194	Reboxetine	Male	1.ANXIETY/SOMATIZATION	0.67	0.50					
				2.WEIGHT	0.00	0.00					
				3.COGNITIVE DISTURBANCE	1.17	0.83					
				4.DIURNAL VARIATION	1.00	0.00					
				5.RETARDATION	2.25	1.50					
				6.SLEEP DISTURBANCE	0.67	0.67					
				7.Total score	5.75	3.50					
				1.ANXIETY/SOMATIZATION	1.00	1.00	0.83	0.17	0.17	0.50	0.33
2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00				
3.COGNITIVE DISTURBANCE	0.83	0.83	0.17	0.17	0.17	0.33	0.17				
4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	1.00	1.00				
5.RETARDATION	2.25	2.25	1.50	1.00	0.75	0.75	0.75				
6.SLEEP DISTURBANCE	0.33	0.33	1.33	1.00	0.67	1.00	0.67				
7.Total score	7.42	7.42	3.83	2.53	1.08	2.25	3.25				
1.ANXIETY/SOMATIZATION	1.00	1.00	1.50	0.67							
2.WEIGHT	2.00	2.00	2.00	0.00							
3.COGNITIVE DISTURBANCE	0.50	0.50	0.67	0.17							
4.DIURNAL VARIATION	1.00	1.00	2.00	0.00							
5.RETARDATION	1.50	1.50	1.75	0.25							
6.SLEEP DISTURBANCE	1.33	1.33	0.33	0.00							
7.Total score	7.33	7.33	8.25	1.08							
8	225	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.50	0.67			
				2.WEIGHT	2.00	2.00	2.00	0.00			
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.67	0.17			
				4.DIURNAL VARIATION	1.00	1.00	2.00	0.00			
				5.RETARDATION	1.50	1.50	1.75	0.25			
				6.SLEEP DISTURBANCE	1.33	1.33	0.33	0.00			
				7.Total score	7.33	7.33	8.25	1.08			
				1.ANXIETY/SOMATIZATION	1.50	1.33	1.17	1.00	0.83	0.83	1.00
2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00				
3.COGNITIVE DISTURBANCE	0.33	0.33	0.17	0.17	0.33	0.50	0.50				
4.DIURNAL VARIATION	0.00	0.00	1.00	1.00	1.00	1.00	0.00				
5.RETARDATION	2.25	2.25	1.75	1.50	1.75	1.25	1.50				
6.SLEEP DISTURBANCE	1.67	1.33	1.33	0.67	1.00	1.33	0.67				
7.Total score	7.75	7.25	5.42	4.33	3.92	4.92	3.67				
7	226	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.33	0.83	0.50	0.67	0.33	
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	1.50	1.50	0.67	1.17	0.50	0.17	
				4.DIURNAL VARIATION	0.00	0.08	0.00	0.00	0.00	0.00	
				5.RETARDATION	2.50	2.50	1.75	1.50	1.25	1.25	
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00	
				7.Total score	6.67	6.33	4.25	3.67	5.08	4.67	
				1.ANXIETY/SOMATIZATION	1.67	1.33	0.83	0.50	0.83	0.67	
2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00					
3.COGNITIVE DISTURBANCE	1.50	1.50	0.67	1.17	0.50	0.17					
4.DIURNAL VARIATION	0.00	0.08	0.00	0.00	0.00	0.00					
5.RETARDATION	2.50	2.50	1.75	1.50	1.25	1.25					
6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00					
7.Total score	6.67	6.33	4.25	3.67	5.08	4.67					
7	227	Imipramine	Male	1.ANXIETY/SOMATIZATION	1.67	1.33	0.83	0.50	0.83	0.33	
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	1.50	1.50	0.67	1.17	0.50	0.17	
				4.DIURNAL VARIATION	0.00	0.08	0.00	0.00	0.00	0.00	
				5.RETARDATION	2.50	2.50	1.75	1.50	1.25	1.25	
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00	
				7.Total score	6.67	6.33	4.25	3.67	5.08	4.67	
				1.ANXIETY/SOMATIZATION	1.67	1.33	0.83	0.50	0.83	0.33	
2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00					
3.COGNITIVE DISTURBANCE	1.50	1.50	0.67	1.17	0.50	0.17					
4.DIURNAL VARIATION	0.00	0.08	0.00	0.00	0.00	0.00					
5.RETARDATION	2.50	2.50	1.75	1.50	1.25	1.25					
6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00					
7.Total score	6.67	6.33	4.25	3.67	5.08	4.67					

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PFARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	228	Male	1. ANXIETY/SOMATIZATION	1.17	1.17	1.83	1.83					
			2. WEIGHT	0.00	0.00	0.00	0.00					
			3. COGNITIVE DISTURBANCE	1.17	1.00	0.83	0.83					
			4. DIURNAL VARIATION	0.00	0.00	0.00	0.00					
			5. RETARDATION	2.50	2.50	1.75	1.75					
			6. SLEEP DISTURBANCE	2.00	1.67	1.67	1.67					
			7. Total score	6.83	6.33	6.08	6.08					
229	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	0.67	0.33	1.00	0.67	0.50	1.17	
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	1.33	0.83	0.33	0.33	0.50	0.17	0.33	0.33	0.17
			4. DIURNAL VARIATION	1.00	1.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00
			5. RETARDATION	2.00	2.00	1.25	0.75	1.00	0.50	0.75	0.50	0.50
			6. SLEEP DISTURBANCE	0.33	0.67	0.67	0.33	0.67	0.33	0.00	0.00	0.00
			7. Total score	6.00	5.83	2.92	1.75	4.17	1.67	1.58	2.83	
230	Imipramine	Female	1. ANXIETY/SOMATIZATION	0.50	0.83	0.17	0.50	0.83	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	0.00	0.33	0.17	0.17	0.00	0.00	
			4. DIURNAL VARIATION	1.00	1.00	0.00	0.00	1.00	0.00	0.00	0.00	
			5. RETARDATION	3.00	3.00	2.50	1.50	1.25	0.25	0.25	0.50	
			6. SLEEP DISTURBANCE	1.33	1.67	0.33	0.00	0.00	0.33	0.33	0.00	
			7. Total score	6.17	6.83	3.00	4.33	3.25	1.08	0.92	1.00	
231	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.17	1.33	0.83						
			2. WEIGHT	0.00	0.00	0.00						
			3. COGNITIVE DISTURBANCE	0.67	1.00	0.17						
			4. DIURNAL VARIATION	2.00	2.00	1.00						
			5. RETARDATION	2.00	1.75	1.00						
			6. SLEEP DISTURBANCE	1.33	1.00	1.00						
			7. Total score	7.17	7.08	4.00						
232	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.50	1.83	1.17	1.17	1.17	1.00	0.83	0.33	
			2. WEIGHT	1.00	2.00	0.00	0.00	2.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	1.17	1.33	0.33	0.50	0.50	0.17	0.17	0.17	
			4. DIURNAL VARIATION	1.00	1.00	2.00	1.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	1.50	2.00	1.25	1.50	1.25	1.25	1.25	1.00	
			6. SLEEP DISTURBANCE	1.33	1.33	1.67	2.00	1.67	1.00	1.00	1.00	
			7. Total score	7.50	9.50	6.67	6.17	8.08	4.42	4.25	3.50	
9	197	Male	1. ANXIETY/SOMATIZATION	1.17	1.33	1.67						
			2. WEIGHT	0.00	0.00	0.00						
			3. COGNITIVE DISTURBANCE	1.00	1.00	0.83						
			4. DIURNAL VARIATION	2.00	0.00	0.00						
			5. RETARDATION	1.75	2.25	2.25						

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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	197	Reboxetine	Male	6. SLEEP DISTURBANCE 7. Total score	0.00 5.92	0.00 4.58	0.00 4.75				
	198	Imipramine	Female	1. ANXIETY/SOMATIZATION 2. WEIGHT 3. COGNITIVE DISTURBANCE 4. DIURNAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	1.83 0.00 1.00 0.00 1.50 1.33 5.67	1.50 0.00 0.83 2.00 0.75 1.00 7.42	1.50 0.00 1.17 2.00 1.00 1.33 6.67	1.33 0.00 0.83 2.00 0.75 1.00 6.25	0.00 0.00 0.17 0.00 0.00 0.00 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 0.00 0.00
	199	Imipramine	Male	1. ANXIETY/SOMATIZATION 2. WEIGHT 3. COGNITIVE DISTURBANCE 4. DIURNAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	2.00 0.00 1.00 0.00 2.00 1.00 6.00	1.83 0.00 0.67 0.00 2.00 1.00 5.90	1.83 0.00 0.83 0.00 2.00 1.00 5.67	1.83 0.00 0.83 0.00 2.00 1.00 6.33	1.67 0.00 0.50 0.00 1.50 0.00 3.67	2.00 0.00 0.50 0.00 2.25 0.00 4.75	1.67 0.00 0.67 0.00 1.50 0.00 4.17
	200	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 1.00 1.00 1.50 1.00 6.67	2.17 0.00 1.33 0.00 1.75 1.00 6.92	2.00 0.00 0.17 0.00 1.25 0.00 6.08	1.67 0.00 0.00 0.00 0.75 0.00 5.75	1.00 0.00 0.00 0.00 0.33 0.00 1.25	0.67 0.00 0.00 0.00 0.25 0.00 1.25	0.67 0.00 0.00 0.00 0.25 0.00 1.25
	201	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 0.83 0.00 1.50 0.67 4.50	1.00 0.00 0.67 0.00 2.25 1.00 4.92	1.50 0.00 0.33 0.00 0.75 0.00 3.92	1.17 0.00 0.00 0.00 1.25 0.00 2.17	1.33 0.00 0.00 0.00 0.50 0.00 2.58	1.00 0.00 0.17 0.00 0.75 0.00 1.67	0.83 0.00 0.33 0.00 0.25 0.00 2.25
	202	Imipramine	Male	1. ANXIETY/SOMATIZATION 2. WEIGHT 3. COGNITIVE DISTURBANCE 4. DIURNAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	1.83 0.00 0.83 2.00 2.25 1.00 7.92	1.33 0.00 0.33 1.00 2.25 1.00 6.92	1.50 0.00 0.83 1.00 2.25 0.00 6.42	1.17 0.00 0.33 0.00 1.75 0.67 4.67	0.83 0.00 0.33 0.00 1.25 0.67 2.33	1.17 2.00 0.63 0.00 1.75 0.00 5.75	1.17 1.00 1.17 1.00 1.25 0.00 6.58
	203	Reboxetine	Female	1. ANXIETY/SOMATIZATION 2. WEIGHT 3. COGNITIVE DISTURBANCE	1.67 0.00 1.33	2.17 0.00 0.50	1.00 0.00 1.67	1.00 0.00 0.50	1.00 0.00 1.67	1.00 0.00 1.67	1.00 0.00 1.67

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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	203	Reboxetine	Female	4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.33
				5. RETARDATION	1.50	2.50	2.00				
				6. SLEEP DISTURBANCE	1.67	0.67	1.00				
				7. Total score	6.17	5.83	6.67				
				1. ANXIETY/SOMATIZATION	1.17	1.17	0.33	0.33	0.00	0.00	0.33
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	1.00
				3. COGNITIVE DISTURBANCE	0.83	0.33	0.17	0.00	0.17	0.00	0.00
204	Reboxetine	Male	4. DIURNAL VARIATION	0.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00
			5. RETARDATION	2.25	2.25	1.00	0.25	0.00	0.00	0.00	
			6. SLEEP DISTURBANCE	0.33	0.67	0.33	0.00	0.33	0.33	0.00	
			7. Total score	4.58	6.42	1.83	1.58	0.67	0.50	0.33	
			1. ANXIETY/SOMATIZATION	1.17	1.17	0.33	0.33	0.00	0.00	0.33	
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	1.00	
			3. COGNITIVE DISTURBANCE	0.83	0.33	0.17	0.00	0.17	0.00	0.00	
205	Imipramine	Female	1. ANXIETY/SOMATIZATION	2.17	2.50						
			2. WEIGHT	0.00	0.00						
			3. COGNITIVE DISTURBANCE	0.83	1.33						
			4. DIURNAL VARIATION	0.00	0.00						
			5. RETARDATION	1.75	1.25						
			6. SLEEP DISTURBANCE	1.67	0.67						
			7. Total score	6.42	5.75						
206	Imipramine	Female	1. ANXIETY/SOMATIZATION	2.00	1.67	1.67	1.67	0.67	0.33	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	1.00	1.00	1.00	0.67	0.17	0.17	
			4. DIURNAL VARIATION	0.00	1.00	0.00	0.00	1.00	0.00	0.00	
			5. RETARDATION	2.00	1.75	1.50	1.25	0.00	0.50	0.00	
			6. SLEEP DISTURBANCE	1.33	1.33	1.00	1.33	0.33	0.33	0.33	
			7. Total score	6.17	6.75	6.17	5.25	3.67	1.33	0.83	
207	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.67	1.67	1.67					
			2. WEIGHT	0.00	0.00	0.00					
			3. COGNITIVE DISTURBANCE	0.33	0.33	0.50					
			4. DIURNAL VARIATION	0.00	1.00	2.00					
			5. RETARDATION	1.50	2.00	1.50					
			6. SLEEP DISTURBANCE	1.33	1.67	0.33					
			7. Total score	4.83	6.67	6.00					
208	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.67	1.50	2.17	1.50	1.00	1.33	0.67	1.50
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	0.83	1.33	0.50	0.17	0.33	0.00	0.00	
			4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	2.00	
			5. RETARDATION	1.75	1.50	0.75	1.25	0.50	1.75	1.75	
			6. SLEEP DISTURBANCE	1.00	1.00	1.33	0.00	0.00	0.00	0.67	
			7. Total score	5.25	5.33	4.75	2.92	1.83	3.08	5.00	
209	Imipramine	Male	1. ANXIETY/SOMATIZATION	1.50	1.83	0.83					

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PHARMACIA CNS 8&D
REBOXETINE - PROTOCOL 20124/017
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	209	Imipramine	Male	2.WEIGHT	0.00	0.00	0.00					
				3.COGNITIVE DISTURBANCE	1.00	0.83	0.67					
				4.DIURNAL VARIATION	0.00	0.00	0.00					
				5.RETARDATION	1.25	1.25	1.25					
				6.SLEEP DISTURBANCE	0.67	0.67	0.00					
				7.Total score	4.42	4.58	2.75					
				1.ANXIETY/SOMATIZATION	2.17	1.33	1.17	1.33	1.17	1.17	0.83	0.67
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00
210	Reboxetine	Female	3.COGNITIVE DISTURBANCE	0.33	0.83	1.17	0.83	0.50	0.17	0.33	0.00	
			4.DIURNAL VARIATION	1.00	2.00	1.00	1.00	1.00	1.00	0.00	0.00	
			5.RETARDATION	2.25	1.75	1.25	1.00	0.00	0.50	0.00	0.50	
			6.SLEEP DISTURBANCE	1.00	1.00	0.00	1.00	0.33	0.67	1.00	0.00	
			7.Total score	6.75	6.92	4.98	5.17	3.00	3.50	2.17	2.17	
			1.ANXIETY/SOMATIZATION	1.67	1.17	2.00	1.83	1.17				
			2.WEIGHT	1.00	0.00	1.00	1.00	0.00				
			3.COGNITIVE DISTURBANCE	2.00	2.00	2.00	2.00	0.83				
211	Reboxetine	Female	4.DIURNAL VARIATION	1.00	2.00	1.00	0.00	0.00	0.00	0.00		
			5.RETARDATION	2.25	1.25	1.50	1.75	2.00				
			6.SLEEP DISTURBANCE	1.67	1.33	1.67	0.67	2.00				
			7.Total score	9.58	7.75	9.17	9.25	6.00				
			1.ANXIETY/SOMATIZATION	1.00	1.33	1.33	0.83	0.83	0.83	0.67	0.17	
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	1.00	0.00	
			3.COGNITIVE DISTURBANCE	1.50	0.83	1.00	1.00	0.83	0.50	0.50	0.17	
			4.DIURNAL VARIATION	0.00	1.00	2.00	0.00	2.00	0.00	0.00	0.00	
212	Imipramine	Female	5.RETARDATION	1.50	2.00	1.25	1.25	1.00	0.50	0.50	0.00	
			6.SLEEP DISTURBANCE	1.33	1.00	0.67	0.33	0.67	0.00	0.00	0.00	
			7.Total score	5.33	6.17	6.25	3.42	5.33	1.83	2.67	0.33	
			1.ANXIETY/SOMATIZATION	2.33	2.17	2.00	2.33					
			2.WEIGHT	0.00	0.00	0.00	0.00					
			3.COGNITIVE DISTURBANCE	0.67	0.17	0.17	0.67					
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00					
			5.RETARDATION	2.25	2.75	2.25	3.00					
237	Reboxetine	Male	6.SLEEP DISTURBANCE	2.00	2.00	1.67	2.00					
			7.Total score	7.25	7.08	6.08	8.00					
			1.ANXIETY/SOMATIZATION	1.83	1.83	1.83	1.83	1.33	0.33	0.17	0.17	
			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	0.67	0.33	0.33	0.00	0.00	
			4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	0.00	0.00	
			5.RETARDATION	1.00	2.00	1.00	1.00	0.75	0.75	0.00	0.00	
			6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	0.33	0.33	0.33	
238	Imipramine	Female	7.Total score	7.50	7.50	7.50	7.50	5.67	3.75	0.50	0.50	
			1.ANXIETY/SOMATIZATION	1.83	1.83	1.83	1.83	1.33	0.33	0.17	0.17	
			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	0.67	0.33	0.33	0.00	0.00	
			4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	0.00	0.00	
			5.RETARDATION	1.00	2.00	1.00	1.00	0.60	0.75	0.00	0.00	
			6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	0.33	0.33	0.33	
			7.Total score	7.50	7.50	7.50	7.50	5.67	3.75	0.50	0.50	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	239	Imipramine	Male	1.ANXIETY/SOMATIZATION	2.17	2.17	2.00	1.67	0.83	1.00	0.83	0.67
				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	0.33	0.33	0.33	0.17	
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	1.00	1.00	1.00
				5.RETARDATION	2.25	2.25	2.00	1.75	1.00	0.75	0.50	
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.33	1.00	1.33	1.00	1.00
				7.Total score	6.25	6.25	5.50	5.08	2.92	4.67	3.92	3.33
				240	Reboxetine	Female	1.ANXIETY/SOMATIZATION	2.17	2.33	1.67	1.50	
2.WEIGHT	0.00	1.00	0.00				0.00					
3.COGNITIVE DISTURBANCE	0.67	1.00	0.67				0.67					
4.DIURNAL VARIATION	1.00	1.00	1.00				1.00					
5.RETARDATION	2.00	2.00	2.00				2.00					
6.SLEEP DISTURBANCE	0.67	0.67	1.33				1.33					
7.Total score	8.50	8.00	6.67				6.50					
241	Imipramine	Female	1.ANXIETY/SOMATIZATION				1.17	1.33	1.33	1.00	1.00	1.00
			2.WEIGHT	1.00	1.00	2.00	0.00	0.00	0.00	0.00		
			3.COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.83	0.67	0.67	0.50		
			4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00		
			5.RETARDATION	1.75	2.25	2.25	1.50	1.25	1.25	1.25		
			6.SLEEP DISTURBANCE	0.67	0.67	0.67	0.67	0.67	0.67	0.67		
			7.Total score	6.42	7.08	8.08	5.00	4.58	4.58	4.58		
			242	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.17	1.17	1.17	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	0.67	0.67				0.50	0.50	0.50	0.17	0.00		
4.DIURNAL VARIATION	0.00	0.00				0.00	0.00	0.00	0.00	0.00		
5.RETARDATION	1.75	1.50				1.50	1.25	1.00	0.75	0.00		
6.SLEEP DISTURBANCE	2.00	2.00				1.67	1.67	1.67	0.33	0.00		
7.Total score	5.58	5.33				4.83	4.42	4.17	2.25	0.00		
243	Imipramine	Female				1.ANXIETY/SOMATIZATION	1.67	1.67	1.17	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	0.50	0.50	0.50	0.50	0.33	0.50	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	1.75	1.25	1.00	0.75	0.25		
			6.SLEEP DISTURBANCE	1.67	1.67	1.33	1.00	0.33	0.33	0.33		
			7.Total score	7.83	7.83	4.75	3.92	2.50	2.67	2.42		
			244	Reboxetine	Male	1.ANXIETY/SOMATIZATION	2.00	2.00	1.33	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	0.50	0.50				0.17	0.17	0.17	0.83	0.50		
4.DIURNAL VARIATION	0.00	0.00				0.00	0.00	0.00	0.00	0.00		
5.RETARDATION	3.25	3.25				1.50	1.50	1.50	1.75	1.00		

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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	244	Male	6.SLEEP DISTURBANCE 7.Total score	0.33 6.08	0.33 3.33	0.33 3.00	0.33 3.00	0.67 4.42	0.33 3.58	0.00 2.33
	257	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	2.00 0.00 1.00 2.00 1.67 9.42	1.33 0.00 1.17 1.00 0.00 3.67	1.00 0.00 1.00 0.50 0.33 4.83	0.17 0.00 0.00 0.00 0.00 0.17	1.17 0.00 0.17 2.00 0.75 4.08	0.83 0.00 0.00 2.00 0.25 3.08	0.83 0.00 0.00 0.00 0.00 0.00 2.83
	258	Male	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	2.17 0.00 0.83 0.00 1.25 2.00 6.25	1.83 0.00 1.00 0.00 1.50 1.00 6.17	1.33 0.00 1.17 0.00 2.25 1.35 6.08	1.67 0.00 1.17 0.00 2.50 0.67 6.58	0.83 0.00 0.17 0.00 2.00 1.33 6.08	1.00 0.00 0.00 0.00 2.50 0.67 6.08	0.00 0.00 0.00 0.00 2.00 1.33 6.58
	259	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	2.00 1.00 0.33 1.00 1.75 2.00 8.08	2.00 1.00 0.33 1.00 1.75 2.00 8.08	2.00 1.00 0.33 1.00 1.75 2.00 8.08	0.67 0.00 0.17 1.00 0.75 1.33 3.92	0.83 0.00 0.00 0.00 0.50 1.67 3.33	1.00 0.60 0.50 0.00 0.50 1.33 3.33	0.67 0.80 0.00 0.00 0.50 1.33 2.83
	260	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	2.33 0.00 1.83 0.00 2.00 6.83	1.50 0.00 1.33 2.00 0.25 6.67	1.67 0.00 1.50 0.00 0.67 6.92	1.50 0.00 1.50 0.00 0.67 5.42	1.00 0.00 1.83 0.00 0.33 4.92	1.00 0.00 1.83 0.00 0.33 4.92	1.00 0.00 0.00 0.00 0.33 4.92
	261	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.50 0.00 1.50 1.00 2.00 1.67 7.67	1.83 0.00 1.17 1.00 2.25 1.67 7.92	1.50 0.00 1.33 0.00 0.25 1.33 8.00	1.50 0.00 1.33 0.00 0.67 1.33 8.00	1.50 0.00 1.67 2.50 1.67 1.33 8.00	1.50 0.00 1.67 2.50 1.67 1.33 8.00	1.50 0.00 1.67 2.50 1.67 1.33 8.00
	262	Male	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE	1.50 2.00 0.83	1.50 0.00 1.00	0.67 2.00 0.83	0.50 0.00 0.63	0.50 0.00 0.50	0.33 0.00 0.33	0.33 0.00 0.17

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PHARMACIA CNS RBD
REBOXETINE - PROTOCOL 20124/017
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	262	Male	4. DIURNAL VARIATION	2.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			5. RETARDATION	2.00	2.25	1.00	0.50	1.50	0.50	1.00	0.50	1.00	0.50
			6. SLEEP DISTURBANCE	2.00	2.00	1.33	1.33	1.00	0.33	0.33	0.33	0.33	0.33
			7. Total score	10.33	6.75	6.83	2.83	3.00	1.67	1.83	1.50		
			1. ANXIETY/SOMATIZATION	1.17	1.00	1.00	1.17						
			2. HEIGHT	2.00	2.00	0.00	0.00						
			3. COGNITIVE DISTURBANCE	0.83	0.17	0.67	0.33						
263	Reboxetine	Female	4. DIURNAL VARIATION	1.00	1.00	0.00	0.00						
			5. RETARDATION	2.00	1.25	2.25	1.50						
			6. SLEEP DISTURBANCE	1.67	0.33	1.33	0.33						
			7. Total score	8.67	5.75	5.25	3.33						
			1. ANXIETY/SOMATIZATION	2.17	1.50	1.67	0.83	0.67	0.50	0.50	1.50		
			2. HEIGHT	0.00	0.00	0.00	0.00	1.00	1.00	1.00	0.00		
			3. COGNITIVE DISTURBANCE	1.17	1.33	0.67	0.17	0.00	0.00	0.33	0.17		
264	Imipramine	Female	4. DIURNAL VARIATION	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	
			5. RETARDATION	2.75	2.50	2.00	0.75	2.00	0.00	2.00	0.00	1.00	
			6. SLEEP DISTURBANCE	0.33	0.00	0.67	0.33	1.33	1.33	1.00	0.67		
			7. Total score	6.42	5.33	6.00	2.08	5.00	4.83	4.83	3.53		
			1. ANXIETY/SOMATIZATION	2.17	1.50	1.67	0.83	0.67	0.50	0.50	1.50		
			2. HEIGHT	0.00	0.00	0.00	0.00	1.00	1.00	1.00	0.00		
			3. COGNITIVE DISTURBANCE	1.17	1.33	0.67	0.17	0.00	0.00	0.33	0.17		
265	Reboxetine	Female	4. DIURNAL VARIATION	0.00	2.00	2.00	2.00	1.00	0.00	0.00	0.00	0.00	
			5. RETARDATION	1.75	1.75	2.00	1.50	2.00	1.00	0.00	0.00	0.00	
			6. SLEEP DISTURBANCE	1.33	1.00	1.00	1.33	0.33	1.67	1.67	0.33		
			7. Total score	5.75	8.58	7.67	6.50	2.75	7.75	4.67	2.00		
			1. ANXIETY/SOMATIZATION	1.50	1.67	1.67	0.67	0.67	1.17	0.83	0.33		
			2. HEIGHT	1.00	1.00	0.00	0.00	0.00	2.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	0.17	1.17	1.00	1.00	0.50	1.17	0.67	0.33		
266	Reboxetine	Female	4. DIURNAL VARIATION	1.00	1.00	2.00	1.00	1.00	0.00	0.00	0.00	0.00	
			5. RETARDATION	1.50	1.50	1.00	0.25	0.50	0.50	0.50	0.25		
			6. SLEEP DISTURBANCE	1.67	2.00	2.00	2.00	1.00	1.67	1.67	1.67		
			7. Total score	6.50	6.83	6.83	6.58	4.33	2.33	3.33	2.25		
			1. ANXIETY/SOMATIZATION	1.83	1.83	1.50	1.17	0.67	0.67	1.00	0.17		
			2. HEIGHT	0.00	0.00	0.00	2.00	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		
267	Imipramine	Male	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00	
			5. RETARDATION	1.50	1.50	1.00	0.00	0.00	0.00	0.00	0.00		
			6. SLEEP DISTURBANCE	1.67	2.00	2.00	2.00	1.00	1.67	1.67	1.67		
			7. Total score	6.50	6.83	6.83	6.58	4.33	2.33	3.33	2.25		
			1. ANXIETY/SOMATIZATION	1.33	1.33	1.00	0.83	0.67	0.67	0.50	0.83		
			2. HEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00		
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.33	0.17	0.00	0.00	0.00	0.00		
268	Imipramine	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00	
			5. RETARDATION	1.50	1.50	1.00	0.00	0.00	0.00	0.00	0.00		
			6. SLEEP DISTURBANCE	2.00	2.00	2.00	1.67	0.33	0.33	0.33	0.33		
			7. Total score	8.50	8.50	6.83	3.67	2.00	0.83	0.83	1.17		
			1. ANXIETY/SOMATIZATION	2.00	2.17	0.83	1.00	0.67	0.67	1.50	1.17		

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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	268	Imipramine	Female	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	1.17	0.50	0.83	1.00	0.67	0.50	0.67	
				4.DIURNAL VARIATION	1.00	0.00	1.00	1.00	1.00	1.00	2.00	2.00	
				5.RETARDATION	3.25	3.00	1.25	0.75	1.25	1.00	2.50	1.50	
				6.SLEEP DISTURBANCE	0.00	0.00	0.00	0.33	0.00	0.33	0.00	0.00	
				7.Total score	7.08	6.33	3.58	3.92	3.92	3.67	6.83	5.33	
				1.ANXIETY/SOMATIZATION	1.50	1.50	0.83	0.83	0.33	0.50	0.17	0.17	
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
269	Reboxetine	Male	3.COGNITIVE DISTURBANCE	0.50	0.33	0.33	0.17	0.17	0.00	0.00	0.50		
			4.DIURNAL VARIATION	0.00	1.00	0.00	0.00	0.00	1.00	0.00	1.00		
			5.RETARDATION	2.50	2.00	0.75	0.50	0.25	0.25	0.75	0.25		
			6.SLEEP DISTURBANCE	1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00		
			7.Total score	5.50	5.83	2.92	1.50	0.75	1.92	0.92	1.92		
			1.ANXIETY/SOMATIZATION	1.67	1.17	1.33							
			2.WEIGHT	0.00	0.00	0.00							
			3.COGNITIVE DISTURBANCE	0.17	0.50	0.50							
270	Imipramine	Female	4.DIURNAL VARIATION	0.00	0.00	0.00							
			5.RETARDATION	3.00	3.00	1.50							
			6.SLEEP DISTURBANCE	0.33	0.33	0.00							
			7.Total score	5.17	5.00	3.33							
			1.ANXIETY/SOMATIZATION	1.67	1.17	1.33							
			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							
271	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.83	1.83	1.17	1.17	1.17	1.17	1.17		
			2.WEIGHT	0.00	2.00	0.00	0.00	0.00	0.00	0.00			
			3.COGNITIVE DISTURBANCE	1.17	1.00	0.67	0.67	0.67	0.67	0.67			
			4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00			
			5.RETARDATION	2.75	2.50	2.50	1.75	1.75	1.75	1.75			
			6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.33	1.67	1.67			
			7.Total score	7.75	10.00	7.67	6.25	5.92	6.25	6.25			
			1.ANXIETY/SOMATIZATION	1.50	2.33	1.83	0.67	0.67	0.50	0.67			
272	Imipramine	Male	2.WEIGHT	0.00	2.00	2.00	1.00	0.00	0.00	0.00	0.00		
			3.COGNITIVE DISTURBANCE	0.83	2.00	1.33	0.17	0.17	0.17	0.17			
			4.DIURNAL VARIATION	0.00	1.00	2.00	2.00	1.00	1.00	0.00			
			5.RETARDATION	2.75	3.00	2.50	1.50	1.50	1.50	1.25			
			6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	0.33	0.33	0.00			
			7.Total score	6.42	11.67	11.00	6.33	3.67	3.50	2.42			
			1.ANXIETY/SOMATIZATION	1.50	2.00	2.00	1.00	0.00	0.00	0.00			
			2.WEIGHT	0.00	2.00	2.00	1.00	0.00	0.00	0.00			
273	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.33	2.00	2.00	1.67	1.50	1.50	1.67			
			2.WEIGHT	1.00	0.00	0.00	0.00	0.00	0.00	0.00			
			3.COGNITIVE DISTURBANCE	1.00	1.83	2.00	1.33	1.17	1.17	1.17			
			4.DIURNAL VARIATION	1.00	2.00	2.00	0.00	0.00	2.00	2.00			
			5.RETARDATION	3.25	3.00	3.00	2.50	2.50	2.25	2.25			
			6.SLEEP DISTURBANCE	1.00	1.67	1.67	1.67	1.33	1.33	2.00			
			7.Total score	8.58	10.50	10.17	7.17	8.25	9.08	9.08			
			1.ANXIETY/SOMATIZATION	1.33	2.00	2.00	1.67	1.50	1.50	1.67			

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 2012A/017
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	274	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.67	0.83					
				2.WEIGHT	0.00	2.00	0.00					
				3.COGNITIVE DISTURBANCE	0.67	0.67	1.33					
				4.DIURNAL VARIATION	1.00	0.00	0.00					
				5.RETARDATION	2.75	2.25	1.00					
				6.SLEEP DISTURBANCE	1.00	1.33	1.33					
				7.Total score	6.75	7.92	4.50					
274/A	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.50	0.67	0.83	1.00	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	1.00	1.00	0.33	0.33	0.50	0.67	0.33	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	2.25	2.50	2.25	1.50	0.75	1.25	1.25	1.25
			6.SLEEP DISTURBANCE	1.67	1.67	0.67	0.67	0.33	0.00	0.00	0.00	0.00
			7.Total score	7.58	6.58	5.17	4.75	3.33	2.58	2.08	2.58	2.58
275	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.83	1.67	1.67	0.33	0.33	0.17	0.17	
			2.WEIGHT	0.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			3.COGNITIVE DISTURBANCE	0.17	1.33	1.00	0.67	0.67	0.67	0.50	0.50	0.33
			4.DIURNAL VARIATION	0.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			5.RETARDATION	2.50	2.75	2.50	2.50	2.00	2.00	1.25	1.00	1.00
			6.SLEEP DISTURBANCE	1.00	1.33	0.67	0.67	0.33	0.33	0.33	0.33	0.33
			7.Total score	5.17	11.25	5.83	5.50	3.33	3.33	2.25	1.83	1.83
276	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.00						
			2.WEIGHT	0.00	0.00	1.00						
			3.COGNITIVE DISTURBANCE	0.33	0.50	0.83						
			4.DIURNAL VARIATION	0.00	0.00	0.00						
			5.RETARDATION	2.50	2.25	2.00						
			6.SLEEP DISTURBANCE	1.00	1.00	1.00						
			7.Total score	5.17	5.08	5.83						
276/A	Imipramine	Male	1.ANXIETY/SOMATIZATION	1.67	1.67	1.83	1.67	1.33	0.83	0.83	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	1.33	1.50	0.50	1.50	1.17	0.17	0.17	0.17	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	0.75	0.50	2.25	2.25	1.50	0.25	0.25	0.25	0.25
			6.SLEEP DISTURBANCE	0.00	0.33	1.33	0.67	0.67	0.33	0.33	0.33	0.00
			7.Total score	4.75	5.00	5.42	6.08	4.67	1.58	1.58	0.75	0.75
9/A	233	Imipramine	Male	1.ANXIETY/SOMATIZATION	1.67	1.50	1.50	0.67	0.83	0.67	1.00	
				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	0.67	0.33	0.17	0.17	0.17	0.33
				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	2.50	2.50	2.00	1.75	1.75	2.00

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
9/A	233	Imipramine	Male	Hamilton depression rating scale	1.67	1.67	1.67	1.00	1.00	1.00	1.00
				6.SLEEP DISTURBANCE	8.67	8.33	6.50	6.33	4.00	3.75	3.58
				7.Total score							4.33
	234	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.50	1.67	1.17	0.83	1.00	0.83
				2.WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	0.83	0.67	0.50	0.33	0.33	0.33
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.50	2.50	2.50	2.25	1.50	1.50	1.25
				6.SLEEP DISTURBANCE	1.33	1.67	1.33	1.00	1.00	0.33	0.67
				7.Total score	8.17	6.50	6.17	4.92	3.67	3.17	2.75
											2.92
	235	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.50	1.50	1.17	0.67	0.67	0.83	1.50
				2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.50	0.00	0.17	0.17	1.00
				4.DIURNAL VARIATION	0.00	1.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.75	2.50	1.75	1.50	1.00	1.50	1.75
				6.SLEEP DISTURBANCE	2.00	2.00	1.00	1.00	1.00	1.00	2.00
				7.Total score	9.08	9.83	4.42	3.17	2.83	3.50	6.25
	236	Imipramine	Male	1.ANXIETY/SOMATIZATION	1.50	1.50	1.50	1.33	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	1.33	1.33	1.50	1.33	0.67	0.67	0.17
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	0.00
				5.RETARDATION	2.50	2.25	2.25	2.00	1.00	1.25	1.00
				6.SLEEP DISTURBANCE	0.67	0.67	0.33	0.33	0.33	0.67	0.33
				7.Total score	7.00	6.75	6.58	6.00	4.00	4.58	4.17
											1.25
	277	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.50	1.67				
				2.WEIGHT	0.00	0.00	0.00				
				3.COGNITIVE DISTURBANCE	1.00	1.17	1.33				
				4.DIURNAL VARIATION	1.00	0.00	0.00				
				5.RETARDATION	2.50	2.50	2.75				
				6.SLEEP DISTURBANCE	0.67	0.67	2.00				
				7.Total score	6.83	5.83	7.75				
	278	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.17	1.50	1.00	0.67	1.50		
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	1.50	1.50	1.00	0.17	0.83		
				4.DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.00		
				5.RETARDATION	2.25	2.25	1.50	0.75	1.75		
				6.SLEEP DISTURBANCE	1.00	1.00	0.67	0.33	4.00		
				7.Total score	6.92	7.25	5.17	1.92	5.08		
	279	Imipramine	Male	1.ANXIETY/SOMATIZATION	1.17	1.17	1.33	1.67			
				2.WEIGHT	0.00	0.00	0.00	0.00			
				3.COGNITIVE DISTURBANCE	0.83	0.83	1.17	1.17			

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124-017
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
9/A	279	Imipramine	Male	Hamilton depression rating scale	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				4. DIURNAL VARIATION	2.00	2.00	1.75	2.00			
				5. RETARDATION	1.00	1.00	1.33	1.67			
				6. SLEEP DISTURBANCE	5.00	5.00	5.58	6.50			
				7. Total score							
	280	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.50	1.50	1.67				
				2. HEIGHT	0.00	0.00	0.00				
				3. COGNITIVE DISTURBANCE	1.17	1.17	1.17				
				4. DIURNAL VARIATION	0.00	0.00	0.00				
				5. RETARDATION	2.25	2.00	2.00				
				6. SLEEP DISTURBANCE	1.33	1.33	1.67				
				7. Total score	6.25	6.00	6.50				
	281	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.50	1.50	0.67	0.50	0.17	0.00	0.00
				2. HEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.50	0.67	0.33	0.17	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	1.50	0.75	0.50	0.50	0.50	0.25
				6. SLEEP DISTURBANCE	1.33	1.67	1.00	0.00	0.00	0.00	0.00
				7. Total score	5.58	6.08	3.50	1.42	0.83	0.67	0.42
	282	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.50	1.50	1.33	1.17	1.00	0.83	0.67
				2. HEIGHT	0.00	0.00	0.00	1.00	2.00	2.00	0.00
				3. COGNITIVE DISTURBANCE	1.33	1.17	0.83	0.50	0.17	0.17	0.33
				4. DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.00	0.00	0.00
				5. RETARDATION	3.00	2.50	2.25	2.00	1.50	1.25	1.00
				6. SLEEP DISTURBANCE	1.33	2.00	2.00	1.00	1.00	0.67	1.00
				7. Total score	8.17	8.17	7.42	5.67	5.67	4.92	3.42
	283	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.50	1.50	1.17	0.50	0.50	0.50	0.00
				2. HEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.00	0.83	1.00	0.17	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	2.25	2.00	0.75	0.75	0.75	0.50
				6. SLEEP DISTURBANCE	0.67	1.00	1.00	0.33	0.67	0.33	0.67
				7. Total score	5.17	5.58	5.17	1.75	2.08	1.75	1.58
	284	Imipramine	Male	1. ANXIETY/SOMATIZATION	1.67	1.50	1.50	1.33	1.50		
				2. HEIGHT	2.00	2.00	0.00	0.00	0.00		
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.67	1.00		
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00		
				5. RETARDATION	2.50	2.50	2.50	2.00	2.25		
				6. SLEEP DISTURBANCE	2.00	1.33	1.33	1.33	1.33		
				7. Total score	9.00	8.17	6.17	5.33	6.08		
	301	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.00	1.50	1.00	0.50	0.33	0.00	0.00

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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/A	301	Isipramine	Female	2.WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.17	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
				5.RETARDATION	2.00	2.00	1.50	0.75	0.50	0.50	0.25	0.25	0.25
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	0.33	0.33	0.33	0.33	0.33	0.67
				7.Total score	6.83	5.33	4.33	1.75	1.17	0.83	0.58	0.58	0.92
				1.ANXIETY/SOMATIZATION	1.50	1.50	1.50	1.67	1.50				
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00				
302	Imipramine	Male	3.COGNITIVE DISTURBANCE	1.00	1.17	1.33	1.17	1.50					
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00					
			5.RETARDATION	2.25	2.25	2.25	2.25	2.00					
			6.SLEEP DISTURBANCE	0.67	0.67	1.00	0.67	1.00					
			7.Total score	5.42	5.58	6.08	5.75	6.00					
			1.ANXIETY/SOMATIZATION	1.33	1.50	0.83	1.67	1.67					
			2.WEIGHT	2.00	0.00	0.00	0.00	0.00					
			3.COGNITIVE DISTURBANCE	1.00	1.17	0.50	1.00	1.33					
303	Reboxetine	Female	4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00					
			5.RETARDATION	2.75	2.50	2.00	2.00	2.00					
			6.SLEEP DISTURBANCE	1.00	1.00	0.67	0.67	1.00					
			7.Total score	8.08	6.17	4.00	5.33	6.00					
			1.ANXIETY/SOMATIZATION	1.33	1.50	0.83	1.67	1.67					
			2.WEIGHT	2.00	0.00	0.00	0.00	0.00					
			3.COGNITIVE DISTURBANCE	1.00	1.17	0.50	1.00	1.33					
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00					
304	Reboxetine	Female	5.RETARDATION	2.25	2.25	1.75	1.00	1.25					
			6.SLEEP DISTURBANCE	0.67	1.00	0.33	0.33	0.67					
			7.Total score	5.42	6.08	3.75	2.83	3.58					
			1.ANXIETY/SOMATIZATION	1.67	1.67	1.00	0.83	1.00					
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00					
			3.COGNITIVE DISTURBANCE	0.83	1.17	0.67	0.67	0.67					
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00					
			5.RETARDATION	2.25	2.25	1.75	1.00	1.25					
305	Reboxetine	Male	6.SLEEP DISTURBANCE	0.67	0.67	0.33	0.33	0.67					
			7.Total score	8.92	7.08	5.33	2.08	1.75					
			1.ANXIETY/SOMATIZATION	1.67	1.83	0.83	0.67	0.50					
			2.WEIGHT	2.00	0.00	0.00	0.00	0.00					
			3.COGNITIVE DISTURBANCE	1.33	1.33	0.67	0.33	0.17					
			4.DIURNAL VARIATION	1.00	1.00	2.00	0.00	0.00					
			5.RETARDATION	2.25	2.25	1.50	0.75	0.75					
			6.SLEEP DISTURBANCE	0.67	0.67	0.33	0.33	0.33					
306	Reboxetine	Female	7.Total score	7.67	7.83	8.00	2.17	0.75					
			1.ANXIETY/SOMATIZATION	1.17	1.33	1.50	0.67	0.00					
			2.WEIGHT	2.00	2.00	2.00	0.00	0.00					
			3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	0.17	0.00					
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00					
			5.RETARDATION	2.50	2.50	2.50	1.00	0.75					
			6.SLEEP DISTURBANCE	1.00	1.00	1.00	0.33	0.00					
			7.Total score	7.67	7.83	8.00	2.17	0.75					

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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/A	307	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33				
				2.WEIGHT	0.00	0.00	0.00				
				3.COGNITIVE DISTURBANCE	1.17	1.17	1.17				
				4.DIURNAL VARIATION	0.00	0.00	0.00				
				5.RETARDATION	2.25	2.25	2.25				
				6.SLEEP DISTURBANCE	0.33	0.33	0.33				
				7.Total score	5.08	5.08	5.08				
308	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.17	1.33	0.67	1.50		
			2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00		
			3.COGNITIVE DISTURBANCE	1.17	1.17	0.83	0.67	0.33	1.00		
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00		
			5.RETARDATION	2.75	2.75	2.50	2.25	1.75	2.50		
			6.SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	0.67	2.00		
			7.Total score	9.42	9.42	6.50	6.25	3.42	7.00		
10	289	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.17	1.00	1.47				
				2.WEIGHT	2.00	2.00	2.00				
				3.COGNITIVE DISTURBANCE	0.00	0.17	0.50				
				4.DIURNAL VARIATION	2.00	1.00	1.00				
				5.RETARDATION	1.75	1.75	1.75				
				6.SLEEP DISTURBANCE	1.33	1.67	2.00				
				7.Total score	8.25	7.58	8.42				
290	Reboxetine	Male	1.ANXIETY/SOMATIZATION	0.67	0.83	0.50	0.17	0.00	0.00	0.00	0.00
			2.WEIGHT	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			3.COGNITIVE DISTURBANCE	1.00	1.00	1.17	0.67	0.50	0.33	0.33	
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			5.RETARDATION	2.25	2.00	1.50	1.00	0.75	0.50	0.25	
			6.SLEEP DISTURBANCE	0.67	0.67	0.33	0.00	0.00	0.00	0.00	
			7.Total score	5.58	5.50	3.50	1.83	1.25	1.08	0.83	0.58
291	Imipramine	Male	1.ANXIETY/SOMATIZATION	0.50	0.50	0.50	0.17	0.17	0.00	0.00	0.00
			2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
			3.COGNITIVE DISTURBANCE	1.00	1.00	0.50	0.33	0.17	0.17	0.00	
			4.DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.00	0.00	0.00	
			5.RETARDATION	1.50	1.50	1.00	0.50	0.25	0.25	0.00	
			6.SLEEP DISTURBANCE	1.67	1.67	1.67	0.00	0.00	0.00	0.00	
			7.Total score	6.67	6.67	4.67	1.00	0.42	0.42	0.00	
292	Reboxetine	Female	1.ANXIETY/SOMATIZATION	0.50	0.50	0.50	0.33	0.33	0.17	0.17	0.17
			2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	1.17	1.17	0.83	0.33	0.17	0.17	0.17	
			4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	0.00	0.00	
			5.RETARDATION	1.75	1.75	1.75	0.50	0.50	0.50	0.50	

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PHARMACIA CHS RSD
REBOXETINE - PROTOCOL 20124/017
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
10	292	Reboxetine	Female	6. SLEEP DISTURBANCE	1.67	1.67	0.67	0.67	0.33	0.33	0.00
				7. Total score	8.08	8.08	2.83	2.83	1.17	1.17	0.83
	293	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				2. WEIGHT	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				3. COGNITIVE DISTURBANCE	0.50	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
				5. RETARDATION	1.25	1.25	1.25	1.25	1.25	1.00	1.00
				6. SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	2.00
				7. Total score	6.75	6.75	7.00	6.75	6.75	5.33	5.33
	294	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.17	1.17	1.67	1.50			
				2. WEIGHT	1.00	2.00	2.00	2.00			
				3. COGNITIVE DISTURBANCE	1.00	0.67	1.00	0.83	0.67		
				4. DIURNAL VARIATION	2.00	2.00	2.00	2.00			
				5. RETARDATION	2.00	1.25	2.25	2.00	1.75		
				6. SLEEP DISTURBANCE	2.00	1.00	2.00	2.00			
				7. Total score	9.17	8.08	10.92	10.50	9.92		
	295	Imipramine	Male	1. ANXIETY/SOMATIZATION	0.83	0.83	0.50	0.50	0.33	0.33	0.33
				2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	1.17	1.00	0.50	0.50	0.33	0.33
				4. DIURNAL VARIATION	1.00	1.00	2.00	2.00	2.00	2.00	2.00
				5. RETARDATION	1.75	1.50	1.50	1.25	1.00	0.75	0.50
				6. SLEEP DISTURBANCE	1.33	1.67	2.00	2.00	1.67	1.00	0.67
				7. Total score	6.75	6.17	6.00	6.25	5.50	4.42	3.83
	296	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.00	1.00	1.00	0.50	0.33	0.33	0.33
				2. WEIGHT	1.00	1.00	1.00	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	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	1.75	1.75	1.75	1.50	1.00	0.75	0.75
				6. SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.00	1.00	1.00
				7. Total score	6.88	6.88	6.08	4.17	2.83	2.58	2.58
	297	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.00	0.50	0.50	0.50	0.17	0.00	0.00
				2. WEIGHT	2.00	1.00	1.00	1.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.17	1.17	1.00	0.67	0.50	0.33	0.33
				4. DIURNAL VARIATION	1.00	2.00	2.00	1.00	0.00	0.00	0.00
				5. RETARDATION	1.75	1.75	1.75	1.50	1.00	0.75	0.25
				6. SLEEP DISTURBANCE	1.67	1.67	1.33	1.33	1.00	1.00	1.00
				7. Total score	8.58	8.08	7.58	6.00	5.25	2.50	2.08
	298	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.33	1.00	0.67	0.50
				2. WEIGHT	1.00	1.00	1.00	1.00	1.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	1.17	1.17	0.83	0.67	0.50	0.33

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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		
10	Reboxetine	Female	4. DIURNAL VARIATION	1.00	2.00	2.00	2.00	2.00	2.00	1.00	0.00	
			5. RETARDATION	2.00	2.25	2.25	2.00	1.50	1.25	1.00	0.75	
			6. SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.33	1.33	1.00	1.00	
			7. Total score	7.83	9.42	9.42	8.83	8.17	7.08	4.33	2.42	
			1. ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.33	0.83	0.83	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	0.67	0.67	0.50	1.00	0.50	0.50	0.50	0.50	0.17
299	Imipramine	Male	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	
			5. RETARDATION	2.50	2.50	2.50	2.25	2.25	2.25	2.00	2.00	
			6. SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	
			7. Total score	7.50	7.50	7.33	7.83	6.58	6.58	6.33	3.17	
			1. ANXIETY/SOMATIZATION	0.83	0.83	0.83	0.67	0.50	0.33	0.33	0.33	0.17
			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	0.50	1.00	0.33	0.08	0.08	0.00	1.00
300	Imipramine	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	1.75	1.75	1.75	1.75	1.00	0.75	0.75	1.25	
			6. SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	
			7. Total score	6.25	6.25	6.08	5.92	4.83	4.08	4.08	5.42	
			1. ANXIETY/SOMATIZATION	0.83	0.83	0.83	0.67	0.50	0.33	0.33	0.33	0.17
			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	0.50	1.00	0.33	0.08	0.08	0.00	1.00
11	Reboxetine	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	1.25	1.50	0.25	0.75	0.25	0.25	0.00	0.00	
			6. SLEEP DISTURBANCE	2.00	1.67	1.00	1.33	1.00	1.33	1.33	1.67	
			7. Total score	7.75	7.33	5.75	5.08	3.58	4.58	2.00	2.17	
			1. ANXIETY/SOMATIZATION	1.50	1.33	1.00	0.83	1.17	0.67	0.50	0.50	
			2. WEIGHT	1.00	1.00	2.00	2.00	0.00	2.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	1.00	0.83	0.50	0.17	0.17	0.33	0.17	0.00	
322	Reboxetine	Female	4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	1.25	1.25	0.75	0.50	0.50	0.00	0.25	0.25	
			6. SLEEP DISTURBANCE	1.33	1.33	1.33	0.67	0.67	0.33	0.67	1.33	
			7. Total score	6.42	5.58	5.08	2.50	3.67	0.67	1.08	2.58	
			1. ANXIETY/SOMATIZATION	1.00	1.17	0.50	0.17	0.33	0.33	0.17	0.00	
			2. WEIGHT	0.00	0.00	0.00	0.00	2.00	0.00	0.00	1.00	
			3. COGNITIVE DISTURBANCE	0.83	0.83	0.50	0.17	0.17	0.00	0.00	0.00	
323	Imipramine	Female	4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	
			5. RETARDATION	1.25	1.00	0.75	0.50	0.50	0.25	0.25	0.25	
			6. SLEEP DISTURBANCE	1.33	1.33	1.33	0.67	0.67	0.33	0.67	1.33	
			7. Total score	6.42	5.58	5.08	2.50	3.67	0.67	1.08	2.58	
			1. ANXIETY/SOMATIZATION	1.33	1.33	1.00	1.00	0.67	0.50	0.50	0.67	
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	
			3. COGNITIVE DISTURBANCE	1.00	0.83	0.50	0.67	0.50	0.33	0.17	0.00	
324	Imipramine	Male	4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	
			5. RETARDATION	1.25	1.00	0.75	0.50	0.50	0.25	0.25	0.25	
			6. SLEEP DISTURBANCE	1.00	1.00	1.00	0.67	0.67	0.33	0.33	0.33	
			7. Total score	6.58	7.17	5.25	4.67	2.08	2.42	2.25	3.25	
			1. ANXIETY/SOMATIZATION	1.17	1.17	1.00	1.00	1.17	0.83	0.83	0.33	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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			
11	324	Imipramine	Male	2.WEIGHT	1.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.17	0.83	0.50	0.00	0.33	0.33	0.33	0.00	0.00	
				4.DIURNAL VARIATION	1.00	2.00	1.00	1.00	2.00	1.00	1.00	1.00	0.00	
				5.RETARDATION	1.50	1.75	1.00	0.50	1.25	0.50	0.50	1.00	0.00	
				6.SLEEP DISTURBANCE	0.33	0.33	0.00	0.00	0.00	0.00	0.33	0.33	0.00	
				7.Total score	6.17	6.08	4.83	2.50	4.75	2.67	3.00	2.17		
				1.ANXIETY/SOMATIZATION	1.00	1.17	1.00	0.67	0.50	0.00	0.00	0.00	0.00	
				2.WEIGHT	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00	1.00	
325	Reboxetine	Female	3.COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.17	0.00	0.17	0.00	0.00	0.00	0.00	
			4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	0.00	0.00	0.00	0.00		
			5.RETARDATION	1.50	1.00	1.00	0.50	0.50	0.00	0.00	0.00	0.00		
			6.SLEEP DISTURBANCE	1.00	1.00	0.67	0.00	0.00	0.00	0.00	0.00	0.00		
			7.Total score	6.33	6.00	6.33	2.33	2.00	0.17	0.00	1.00			
			1.ANXIETY/SOMATIZATION	1.00	1.17	1.00	0.67	0.50	0.00	0.00	0.00	0.00		
			2.WEIGHT	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00	1.00		
			3.COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.17	0.00	0.17	0.00	0.00	0.00		
326	Imipramine	Male	2.WEIGHT	1.17	1.17	0.67	0.33	0.67	0.33	0.00	0.33	0.00	0.33	
			3.COGNITIVE DISTURBANCE	2.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	2.00		
			4.DIURNAL VARIATION	0.83	0.83	0.33	0.17	0.17	0.17	0.00	0.00	0.50		
			5.RETARDATION	1.75	1.50	1.25	0.50	0.25	0.25	0.00	0.25	0.25		
			6.SLEEP DISTURBANCE	0.33	0.67	0.67	0.00	0.67	0.53	0.33	0.00	0.00		
			7.Total score	6.08	5.17	3.92	2.00	2.75	2.08	0.33	3.08			
			1.ANXIETY/SOMATIZATION	1.17	1.17	0.67	0.33	0.67	0.33	0.00	0.33	0.00		
			2.WEIGHT	2.00	1.00	1.00	1.00	1.00	1.00	0.00	0.00	2.00		
327	Reboxetine	Female	3.COGNITIVE DISTURBANCE	0.83	0.83	0.33	0.17	0.17	0.17	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	0.00	0.00		
			5.RETARDATION	1.75	1.50	1.25	0.50	0.25	0.25	0.00	0.25	0.25		
			6.SLEEP DISTURBANCE	0.33	0.67	0.67	0.00	0.67	0.53	0.33	0.00	0.00		
			7.Total score	6.08	5.17	3.92	2.00	2.75	2.08	0.33	3.08			
			1.ANXIETY/SOMATIZATION	1.17	1.17	0.67	0.33	0.67	0.33	0.00	0.33	0.00		
			2.WEIGHT	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00	1.00		
			3.COGNITIVE DISTURBANCE	1.00	0.83	0.33	0.17	0.17	0.17	0.33	0.17	0.00		
328	Imipramine	Male	2.WEIGHT	1.17	1.33	0.67	1.17	0.50	0.50	0.00	0.00	0.00		
			3.COGNITIVE DISTURBANCE	1.00	1.00	0.33	0.00	0.00	0.00	0.00	0.00			
			4.DIURNAL VARIATION	2.00	2.00	1.00	2.00	1.00	1.00	1.00	1.00	0.00		
			5.RETARDATION	1.00	1.00	0.75	0.75	0.25	0.25	0.25	0.25	0.00		
			6.SLEEP DISTURBANCE	1.67	1.33	0.67	0.00	0.33	0.00	0.00	0.00	0.00		
			7.Total score	6.83	6.67	5.25	4.25	2.08	1.75					
			1.ANXIETY/SOMATIZATION	1.17	1.33	0.67	1.17	0.50	0.50	0.00	0.00	0.00		
			2.WEIGHT	0.00	0.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00		
329	Imipramine	Female	2.WEIGHT	1.00	1.00	1.17	0.67	0.50	0.33	0.50	0.50	0.67		
			3.COGNITIVE DISTURBANCE	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
			4.DIURNAL VARIATION	1.33	0.83	0.67	0.50	0.50	0.00	0.00	0.17	0.00		
			5.RETARDATION	1.50	1.25	1.00	0.75	0.50	0.50	0.50	0.50	0.50		
			6.SLEEP DISTURBANCE	1.00	1.33	1.00	0.33	0.33	0.33	0.33	0.33	0.33		
			7.Total score	6.83	6.42	4.83	2.25	2.83	1.17	2.00	2.67			
			1.ANXIETY/SOMATIZATION	1.00	1.00	1.17	0.67	0.50	0.33	0.50	0.50	0.67		
			2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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	330	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.17	1.00	1.33						
				2. WEIGHT	0.00	0.00	0.00						
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.33						
				4. DIURNAL VARIATION	2.00	2.00	1.00						
				5. RETARDATION	2.00	1.75	1.50						
				6. SLEEP DISTURBANCE	0.33	0.33	1.67						
				7. Total score	6.33	5.92	5.83						
12	331	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.33	1.33	1.17	0.50	1.17	1.33	0.33	0.33	
				2. WEIGHT	1.00	0.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	1.00	0.33	0.17	0.17	0.33	0.17	0.00	0.00
				4. DIURNAL VARIATION	2.00	2.00	1.00	1.00	0.00	1.00	0.00	0.00	0.00
				5. RETARDATION	2.00	2.00	1.25	0.75	0.75	2.00	0.50	0.25	0.25
				6. SLEEP DISTURBANCE	1.67	1.33	1.33	1.33	0.33	0.67	0.67	0.33	0.33
				7. Total score	8.83	7.67	7.08	3.75	2.42	5.33	1.67	0.92	0.92
11	332	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.17	1.33	0.00	0.00	0.17	0.00	0.00	0.00	
				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	0.17	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	1.50	1.25	0.50	0.00	0.00	0.00	0.00	0.00	
				6. SLEEP DISTURBANCE	0.67	0.67	0.00	0.33	0.00	0.00	0.00	0.00	
				7. Total score	5.33	5.25	0.67	0.33	0.17	0.00	0.00	0.00	
12	333	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.17	1.17	1.17	1.17	1.00	0.33	0.50	0.00	
				2. WEIGHT	0.00	0.00	2.00	2.00	0.00	0.00	0.00	0.00	
				3. COGNITIVE DISTURBANCE	1.00	1.00	0.83	1.00	0.83	0.67	0.33	0.00	
				4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00	1.00	
				5. RETARDATION	1.50	1.50	1.50	1.25	1.50	0.75	0.50	0.00	
				6. SLEEP DISTURBANCE	1.00	1.67	1.00	1.00	0.33	0.00	0.00	0.00	
				7. Total score	6.67	7.33	8.50	8.42	7.67	3.75	3.33	1.00	
12	337	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.50	1.67	0.17	0.00	0.17	0.17	0.83	0.00	
				2. WEIGHT	1.00	1.00	2.00	2.00	0.00	0.00	2.00	0.00	
				3. COGNITIVE DISTURBANCE	0.50	0.67	0.17	0.00	0.00	0.50	0.33	0.00	
				4. DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	1.00	1.00	0.00	
				5. RETARDATION	1.50	2.25	0.75	0.50	1.25	1.00	1.25	0.50	
				6. SLEEP DISTURBANCE	0.67	2.00	1.33	0.33	1.00	0.67	0.67	0.33	
				7. Total score	7.17	9.58	5.42	3.83	3.42	3.33	6.68	0.83	
11	338	Reboxetine	Female	1. ANXIETY/SOMATIZATION	2.00	1.83	1.67	1.33	1.17	0.67	1.50	1.00	
				2. WEIGHT	2.00	0.00	2.00	0.00	0.00	0.00	0.00	2.00	
				3. COGNITIVE DISTURBANCE	1.17	0.83	0.50	0.17	0.00	0.17	0.00	0.17	
				4. DIURNAL VARIATION	2.00	1.00	1.00	2.00	1.00	1.00	1.00	1.00	
				5. RETARDATION	2.00	2.50	2.00	1.00	1.00	1.25	1.50	1.00	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
12	336	Reboxetine	Female	Hamilton depression rating scale							
				6.SLEEP DISTURBANCE	0.67	1.67	1.33	1.00	1.00	0.67	0.67
				7.Total score	9.83	7.83	8.50	4.17	3.75	3.67	7.17
339	Imipramine	Male	1.ANXIETY/SOMATIZATION	1.33	1.17	0.50	0.67	0.50	0.83	0.50	0.17
			2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00
			3.COGNITIVE DISTURBANCE	1.33	1.17	0.33	1.00	0.33	0.50	0.17	0.00
			4.DIURNAL VARIATION	2.00	1.00	2.00	1.00	2.00	2.00	1.00	1.00
			5.RETARDATION	2.50	2.50	1.75	1.00	1.00	1.00	1.00	0.50
			6.SLEEP DISTURBANCE	1.00	1.00	0.67	0.33	1.00	0.67	0.33	0.33
			7.Total score	10.17	8.83	5.25	4.00	4.83	5.00	3.00	2.00
340	Reboxetine	Female	1.ANXIETY/SOMATIZATION	0.67	1.33	0.83	0.00	0.33	0.00	0.67	0.50
			2.WEIGHT	2.00	2.00	2.00	0.00	0.00	2.00	0.00	1.00
			3.COGNITIVE DISTURBANCE	1.00	1.00	0.67	0.17	0.00	0.00	0.17	0.33
			4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00
			5.RETARDATION	1.75	2.00	2.00	0.25	0.00	0.00	1.00	1.00
			6.SLEEP DISTURBANCE	1.67	2.00	1.00	0.67	0.67	0.33	1.00	1.00
			7.Total score	9.08	10.33	7.50	2.08	2.42	3.33	3.83	4.83
341	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.17	1.50	1.17	1.33	0.50	1.67	
			2.WEIGHT	2.00	2.00	0.00	0.00	2.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	1.50	0.83	1.17	0.83	1.00	0.17	0.67	
			4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	0.00	1.00	2.00	
			5.RETARDATION	2.75	2.00	1.75	2.00	1.75	2.50	2.25	
			6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.00	1.33	0.67	1.33	
			7.Total score	11.92	10.00	8.42	5.75	8.17	3.08	7.92	
353	Reboxetine	Female	1.ANXIETY/SOMATIZATION	0.50	0.50	0.83	0.83	0.50	0.33	0.33	
			2.WEIGHT	2.00	2.00	2.00	2.00	0.00	2.00	0.00	
			3.COGNITIVE DISTURBANCE	1.17	1.17	0.33	0.17	0.00	0.17	0.00	
			4.DIURNAL VARIATION	1.00	1.00	1.00	0.00	1.00	1.00	1.00	
			5.RETARDATION	1.75	1.75	1.25	0.50	0.50	0.25	1.25	
			6.SLEEP DISTURBANCE	1.00	1.00	0.67	1.00	1.00	0.00	0.67	
			7.Total score	7.42	7.42	6.08	2.50	3.00	3.75	3.25	
354	Imipramine	Female	1.ANXIETY/SOMATIZATION	1.67	1.67	1.50	1.00	0.50	0.50	0.33	
			2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	0.83	0.83	0.33	0.33	0.00	0.00	0.00	
			4.DIURNAL VARIATION	1.00	1.00	2.00	1.00	0.00	0.00	0.00	
			5.RETARDATION	1.25	1.25	0.50	0.50	0.25	0.25	0.00	
			6.SLEEP DISTURBANCE	0.33	0.33	0.00	0.00	0.33	0.00	0.33	
			7.Total score	7.08	7.08	4.33	2.83	1.08	0.75	0.38	
355	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	0.83					
			2.WEIGHT	2.00	2.00	0.00					
			3.COGNITIVE DISTURBANCE	1.50	1.17	0.33					

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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	355	Reboxetine	Female	4. DIURNAL VARIATION	1.00	1.00	0.00					
				5. RETARDATION	0.50	0.75	0.25					
				6. SLEEP DISTURBANCE	1.00	1.00	0.67					
				7. Total score	7.33	7.25	2.08					
				1. ANXIETY/SOMATIZATION	2.33	2.33	2.17	1.50	1.17	1.00	1.33	1.50
				2. WEIGHT	1.00	1.00	0.00	0.00	0.00	1.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.00	1.00	0.67	0.50	0.50	0.67	0.50	0.33
356	Imipramine	Male	4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			5. RETARDATION	1.25	1.25	1.25	0.50	0.50	0.50	0.50	0.50	
			6. SLEEP DISTURBANCE	2.00	2.00	1.00	1.00	0.67	0.67	0.67	1.00	
			7. Total score	7.58	7.58	6.08	3.50	2.83	3.83	3.00	3.33	
			1. ANXIETY/SOMATIZATION	1.50	1.67							
			2. WEIGHT	2.00	2.00							
			3. COGNITIVE DISTURBANCE	0.83	0.83							
357	Imipramine	Female	4. DIURNAL VARIATION	2.00	2.00							
			5. RETARDATION	1.25	1.25							
			6. SLEEP DISTURBANCE	0.33	0.33							
			7. Total score	7.92	8.08							
			1. ANXIETY/SOMATIZATION	1.83	1.83	1.00	1.17	0.50	1.00			
			2. WEIGHT	2.00	2.00	0.00	2.00	0.00	0.00			
			3. COGNITIVE DISTURBANCE	1.00	1.00	1.00	0.17	0.17	0.67			
358	Reboxetine	Male	4. DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	1.00			
			5. RETARDATION	1.25	1.25	1.00	0.50	0.25	0.25			
			6. SLEEP DISTURBANCE	1.00	1.00	0.67	1.33	1.00	0.67			
			7. Total score	9.08	9.08	4.67	6.17	2.92	3.58			
			1. ANXIETY/SOMATIZATION	1.67	1.67	1.83	1.00	0.50	0.83	0.50	0.50	
			2. WEIGHT	0.00	0.00	0.00	1.00	0.00	0.00	2.00	0.00	
			3. COGNITIVE DISTURBANCE	1.17	1.17	1.00	0.67	0.17	0.17	0.00	0.00	
359	Reboxetine	Female	4. DIURNAL VARIATION	0.00	0.00	1.00	1.00	1.00	1.00	1.00		
			5. RETARDATION	1.00	1.00	0.75	0.50	0.25	0.00	0.00		
			6. SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.67	1.33	1.33	1.00	
			7. Total score	5.50	5.50	6.25	5.83	3.58	3.58	3.83	2.50	
			1. ANXIETY/SOMATIZATION	1.17	1.17	0.83						
			2. WEIGHT	1.00	1.00	2.00						
			3. COGNITIVE DISTURBANCE	1.17	1.17	0.50						
360	Imipramine	Female	4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
			5. RETARDATION	1.50	1.50	0.90						
			6. SLEEP DISTURBANCE	1.00	1.00	1.00						
			7. Total score	5.83	5.83	5.08						
			1. ANXIETY/SOMATIZATION	1.17	1.17	0.83						
			2. WEIGHT	1.00	1.00	2.00						
			3. COGNITIVE DISTURBANCE	1.17	1.17	0.50						
361	Reboxetine	Female	4. DIURNAL VARIATION	1.33	1.33	0.83	0.50	0.33	0.67	0.17	0.33	
			5. RETARDATION	1.00	1.00	1.00						
			6. SLEEP DISTURBANCE	1.00	1.00	1.00						
			7. Total score	5.83	5.83	5.08						
			1. ANXIETY/SOMATIZATION	1.33	1.33	0.83	0.50	0.33	0.67	0.17	0.33	
			2. WEIGHT	1.00	1.00	2.00						
			3. COGNITIVE DISTURBANCE	1.17	1.17	0.50						

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	361	Female	2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	1.00	0.00	
			3.COGNITIVE DISTURBANCE	1.00	1.00	0.17	0.00	0.00	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	1.25	1.25	0.75	0.25	0.25	0.00	0.25	0.25	0.25
			6.SLEEP DISTURBANCE	2.00	2.00	2.00	0.33	0.00	0.00	0.00	0.00	0.00
			7.Total score	5.58	5.58	5.75	1.08	0.58	0.67	1.42	0.75	
			1.ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.67	1.50	1.50	1.67	1.50	
			2.WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
14	457	Female	3.COGNITIVE DISTURBANCE	1.67	1.67	1.67	1.67	1.50	1.50	1.33	1.00	
			4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	0.00	0.00	
			5.RETARDATION	2.50	2.50	2.50	2.25	2.25	1.50	1.25		
			6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.33	1.33	1.67	1.67		
			7.Total score	10.50	8.50	8.50	8.50	7.58	7.58	6.17	5.42	
			1.ANXIETY/SOMATIZATION	1.83	1.83	1.50	1.67	1.50	1.50	1.33	1.33	
			2.WEIGHT	1.00	1.00	1.00	0.00	0.00	1.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	1.50	1.50	1.53	1.00	1.00	1.00	1.00	0.83	
14	458	Female	4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	
			5.RETARDATION	2.25	2.25	2.25	2.00	1.75	1.75	1.75	1.25	
			6.SLEEP DISTURBANCE	2.00	2.00	1.67	1.33	1.33	1.33	1.33	1.33	
			7.Total score	9.58	9.58	9.08	7.33	6.58	7.58	6.42	5.75	
			1.ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.50	1.17	1.17	1.17	1.17	
			2.WEIGHT	1.00	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	0.83	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	
14	459	Male	5.RETARDATION	2.00	2.00	2.00	1.75	1.50	1.50	1.25	1.25	
			6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.33	1.33	1.33	1.33	1.00	
			7.Total score	7.17	7.17	7.17	5.42	4.83	4.83	4.58	4.25	
			1.ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.50	1.17	1.17	1.17	1.17	
			2.WEIGHT	1.00	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	0.83	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	
			5.RETARDATION	2.00	2.00	2.00	1.75	1.50	1.50	1.25	1.25	
14	460	Male	6.SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	2.00	1.00	
			7.Total score	8.50	7.33	7.08	6.83	6.67	6.42	6.00	4.58	
			1.ANXIETY/SOMATIZATION	1.67	1.50	1.50	1.50	1.50	1.50	1.50	1.33	
			2.WEIGHT	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3.COGNITIVE DISTURBANCE	1.33	1.33	1.33	1.17	1.17	1.17	1.00	1.00	
			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	2.50	2.00	2.00	1.75	1.50	1.25	
			6.SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	2.00	1.00	
14	461	Female	7.Total score	8.50	7.33	7.08	6.83	6.67	6.42	6.00	4.58	
			1.ANXIETY/SOMATIZATION	1.83	2.00	2.00	2.00	2.00	2.00	1.83	2.00	
			2.WEIGHT	2.00	0.00	0.00	1.00	0.80	0.80	0.80	0.80	
			3.COGNITIVE DISTURBANCE	1.83	2.00	1.83	1.83	1.83	1.83	1.67	2.00	
			4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			5.RETARDATION	2.25	2.50	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	2.00	
			7.Total score	9.92	8.50	8.33	9.33	8.33	8.33	8.00	8.50	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	462	Female	1. ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.67	1.67	1.67	1.67	1.67	
			2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			3. COGNITIVE DISTURBANCE	1.83	1.83	1.83	1.83	1.83	1.83	1.83	1.83	1.83
			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	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	2.00	2.00	2.00
			7. Total score	8.50	8.50	7.50	7.50	7.50	7.50	7.50	7.33	7.33
			1. ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.67	1.67	1.67	1.67	1.50	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	1.50	1.50	1.50	1.17	1.00	1.00	1.00	1.00	1.00			
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	2.00	1.75	1.75	1.75	1.75	1.75	1.00			
6. SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	2.00	2.00	2.00	1.33	1.00			
7. Total score	9.17	8.17	7.17	6.58	6.42	6.42	6.42	4.83	4.33			
464	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.83	1.83	2.00	2.00	1.83	1.67	1.83	1.67	
			2. WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	2.00	2.00	2.00	2.00	2.00	1.83	1.83	2.00	
			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	2.25	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	
			7. Total score	10.08	10.08	8.25	8.25	8.08	7.75	7.92	7.67	
			1. ANXIETY/SOMATIZATION	1.83	1.83	1.83	1.67	1.67	1.50	0.83	0.50	
2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00				
3. COGNITIVE DISTURBANCE	1.83	2.00	1.83	1.50	1.00	1.00	0.67	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	2.50	2.00	1.75	1.50	1.25	1.00	0.75				
6. SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	1.33	1.33	1.00	0.33				
7. Total score	8.92	9.33	7.67	6.92	5.50	5.08	3.50	1.58				
466	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.83	1.83	1.67	1.50	1.33	1.17	1.17	0.67	
			2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	1.83	1.83	1.67	1.67	1.17	1.00	1.00	0.67	
			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	1.75	1.00	1.00	1.00	1.00	
			6. SLEEP DISTURBANCE	2.00	2.00	2.00	1.33	1.00	1.00	1.00	0.67	
			7. Total score	8.92	8.92	7.33	6.25	4.50	4.17	4.17	3.00	
			1. ANXIETY/SOMATIZATION	1.67	1.50							
2. WEIGHT	0.00	0.00										
3. COGNITIVE DISTURBANCE	0.50	0.33										
4. DIURNAL VARIATION	2.00	2.00										
5. RETARDATION	1.75	1.75										

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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	
14/1	129	Reboxetine	Male	6. SLEEP DISTURBANCE 7. Total score	1.00 6.92	1.00 6.58						
426		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 1.00 1.00 1.50 2.00 6.83	1.50 0.00 0.50 1.00 2.00 1.33 6.33	1.17 0.00 0.33 0.00 0.50 0.67 6.25	0.33 0.00 0.33 1.00 0.50 1.00 3.67	0.33 0.00 0.00 0.00 0.50 0.67 1.50	0.17 0.00 0.00 0.00 0.25 0.33 0.75	0.17 0.00 0.00 0.00 0.25 0.33 0.75	
429		Imipramine	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 1.00 1.00 2.00 6.33	2.17 0.00 0.83 1.00 1.25 1.67 6.92	1.83 0.00 0.50 1.00 1.00 2.00 6.33					
451		Imipramine	Male	1. ANXIETY/SOMATIZATION 2. WEIGHT 3. COGNITIVE DISTURBANCE 4. DIURNAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	1.67 0.00 0.17 2.00 1.33 1.33 7.17	1.50 0.00 0.17 2.00 3.00 1.33 7.00	1.33 0.00 0.50 2.00 2.00 0.67 5.75	0.83 0.00 0.67 1.00 1.50 1.00 5.50	1.17 0.00 0.50 2.00 1.50 0.33 6.00	0.83 0.00 0.67 2.00 1.75 1.00 4.08	1.50 0.00 0.17 0.00 2.00 0.67 4.33	
452		Reboxetine	Female	1. ANXIETY/SOMATIZATION 2. WEIGHT 3. COGNITIVE DISTURBANCE 4. DIURNAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	0.83 0.00 0.67 1.00 3.00 0.67 6.17	0.83 0.00 0.67 1.00 3.00 0.67 6.17	0.33 0.00 0.00 2.00 2.00 1.00 3.67	0.17 0.00 0.17 0.00 1.75 1.00 3.08	0.00 0.00 0.17 0.00 1.50 1.00 2.67	0.17 0.00 0.33 1.00 1.00 0.33 2.50	0.00 0.00 0.00 0.00 1.25 0.00 1.58	
14/2	136	Imipramine	Female	1. ANXIETY/SOMATIZATION 2. WEIGHT 3. COGNITIVE DISTURBANCE 4. DIURNAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	1.17 1.00 0.67 2.25 1.00 6.08	1.33 1.00 1.17 1.75 0.67 5.92	1.17 0.00 0.50 2.00 0.00 3.92	0.83 0.00 0.83 1.25 0.00 4.17	0.83 0.00 0.67 1.00 0.00 2.92	0.67 0.00 0.67 1.00 0.00 2.67	0.83 0.00 0.33 0.50 0.75 2.08	0.50 0.00 0.33 0.50 0.00 1.33
456		Imipramine	Male	1. ANXIETY/SOMATIZATION 2. WEIGHT 3. COGNITIVE DISTURBANCE	1.17 0.00 0.50	0.83 0.00 0.50	0.83 0.00 0.33	0.50 0.00 0.33	0.67 0.00 0.33	0.67 0.00 0.17	0.50 0.00 0.17	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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	
14/2	456	Imipramine	Male	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	
				4. DIURNAL VARIATION	2.25	2.00	1.25	1.00	1.00	1.00	0.75	0.75
				5. RETARDATION	0.67	0.67	0.33	0.67	0.67	0.67	0.00	0.00
				6. SLEEP DISTURBANCE	5.58	5.00	3.67	3.08	2.50	1.83	1.42	1.25
				7. Total score								
				1. ANXIETY/SOMATIZATION	1.67	1.67	0.83	0.83	0.17	0.17	0.33	0.50
				2. WEIGHT	1.00	1.00	0.00	0.00	1.00	1.00	0.00	0.00
14/3	417	Reboxetine	Female	1.17	1.17	0.50	0.17	0.17	0.17	0.33	0.17	
				3. COGNITIVE DISTURBANCE	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				4. DIURNAL VARIATION	2.00	2.00	1.25	1.00	0.50	1.00	0.75	0.75
				5. RETARDATION	1.33	1.33	1.33	1.00	0.33	0.00	0.67	0.67
				6. SLEEP DISTURBANCE	7.17	7.17	3.92	4.67	1.83	2.17	1.67	2.08
				7. Total score								
				1. ANXIETY/SOMATIZATION	2.00	2.00	1.00	1.17	1.00	1.17	0.83	1.17
2. WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	2.00	0.00				
4/8	418	Imipramine	Female	1.00	1.00	1.00	0.67	0.67	1.17	0.67	0.67	
				3. COGNITIVE DISTURBANCE	1.00	1.00	1.00	0.67	0.67	0.67	0.67	0.67
				4. DIURNAL VARIATION	1.25	1.25	1.00	0.75	0.75	1.75	1.75	1.75
				5. RETARDATION	0.67	0.67	0.00	0.00	0.00	0.00	0.00	0.67
				6. SLEEP DISTURBANCE	7.92	7.92	4.00	2.58	2.42	4.08	5.25	4.25
				7. Total score								
				1. ANXIETY/SOMATIZATION	0.83	0.83	0.83	0.67	0.67	0.67	0.83	0.67
2. WEIGHT	0.00	0.00	0.00	2.00	0.00	0.00	0.00	2.00				
4/9	419	Reboxetine	Female	1.17	1.17	0.83	0.67	0.33	0.33	0.33	0.17	
				3. COGNITIVE DISTURBANCE	2.00	2.00	2.00	1.00	0.00	0.00	0.00	0.00
				4. DIURNAL VARIATION	2.00	2.00	1.75	1.50	1.00	0.75	0.75	0.50
				5. RETARDATION	0.67	0.67	0.67	1.00	0.33	0.00	0.67	0.00
				6. SLEEP DISTURBANCE	6.67	6.67	6.08	6.83	2.33	1.75	2.58	3.33
				7. Total score								
				1. ANXIETY/SOMATIZATION	2.17	2.17	2.17	1.17	1.17	2.00	2.00	2.00
2. WEIGHT	3.00	3.00	1.00	0.00	0.00	0.33	0.33	0.33				
4/20	420	Imipramine	Female	1.33	1.33	1.33	0.50	0.33	0.33	0.33	0.33	
				3. COGNITIVE DISTURBANCE	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				4. DIURNAL VARIATION	2.00	2.00	1.75	1.25	1.25	1.25	1.25	1.25
				5. RETARDATION	1.00	1.00	0.67	0.00	0.33	0.33	0.33	0.33
				6. SLEEP DISTURBANCE	9.50	9.50	6.92	2.92	2.92	5.92	5.92	5.92
				7. Total score								
				1. ANXIETY/SOMATIZATION	2.33	2.17	1.83	0.83	0.67	0.83	0.67	0.83
2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00				
4/21	421	Reboxetine	Female	1.00	0.83	0.50	0.33	0.33	0.33	0.33	0.33	
				3. COGNITIVE DISTURBANCE	2.00	2.00	1.00	1.00	0.60	0.60	0.60	0.60
				4. DIURNAL VARIATION	1.75	1.75	1.25	0.75	0.75	0.75	0.75	0.50
				5. RETARDATION	1.33	1.33	0.67	0.00	0.00	0.00	0.00	0.00
				6. SLEEP DISTURBANCE	8.42	8.08	5.25	2.92	1.75	1.92	1.67	1.67
				7. Total score								
				1. ANXIETY/SOMATIZATION	1.67	1.67	1.33	1.83	1.83	1.83	1.67	1.67
2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00				
4/27	427	Imipramine	Female	1.00	0.83	0.50	0.33	0.33	0.33	0.33	0.33	
				3. COGNITIVE DISTURBANCE	2.00	2.00	1.00	1.00	0.60	0.60	0.60	0.60
				4. DIURNAL VARIATION	1.75	1.75	1.25	0.75	0.75	0.75	0.75	0.50
				5. RETARDATION	1.33	1.33	0.67	0.00	0.00	0.00	0.00	0.00
				6. SLEEP DISTURBANCE	8.42	8.08	5.25	2.92	1.75	1.92	1.67	1.67
				7. Total score								
				1. ANXIETY/SOMATIZATION	1.67	1.67	1.33	1.83	1.83	1.83	1.67	1.67
2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00				

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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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					
14/3	427	Imipramine	Female	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	0.50	0.50	0.50	0.67	0.67	0.67	0.67	0.67	0.67	0.67
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				6.SLEEP DISTURBANCE	1.00	1.00	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.67
				7.Total score	5.17	5.17	3.50	4.17	4.17	4.17	4.17	4.17	4.17	4.00
				1.ANXIETY/SOMATIZATION	1.33	1.33	1.17	1.33	0.83	0.83	0.83	0.83	0.83	0.83
				2.WEIGHT	0.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00
14/4	131	Imipramine	Female	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	0.17	0.67	0.50	0.33	0.33	0.33	
				4.DIURNAL VARIATION	1.00	1.00	0.00	1.00	1.00	0.00	0.00	0.00	0.00	
				5.RETARDATION	2.00	2.00	1.75	1.25	1.00	1.50	1.00	1.00	1.00	
				6.SLEEP DISTURBANCE	1.67	1.67	1.00	0.33	0.33	0.00	0.00	0.00	0.00	
				7.Total score	6.83	6.83	4.58	4.08	4.83	2.83	2.17	2.17	2.17	2.17
				1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	1.00	0.83	0.33	0.33	0.50	0.17	0.17
				2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
132	132	Imipramine	Female	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	0.17	0.17	0.17	0.17	0.17	0.17	
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00	
				5.RETARDATION	2.00	2.00	2.25	1.75	1.50	1.50	1.25	1.25	0.75	
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	0.33	0.33	0.33	0.33	0.33	
				7.Total score	7.67	7.67	5.67	5.75	4.75	2.33	2.08	1.25	1.25	1.25
				1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.00	0.83	0.67	0.67	0.67	0.67	0.33
				2.WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
133	133	Imipramine	Female	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	0.67	0.67	0.17	0.17	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	0.00	
				5.RETARDATION	1.50	1.50	1.50	1.00	1.25	1.00	0.75	0.50	0.50	
				6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.00	1.00	0.67	0.67	0.67	0.33	
				7.Total score	8.50	6.50	6.50	3.67	3.25	2.50	2.25	1.17	1.17	1.17
				1.ANXIETY/SOMATIZATION	1.50	1.50	1.50	1.17	0.83	0.83	0.50	0.50	0.33	
				2.WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
134	134	Reboxetine	Female	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	0.83	0.83	0.33	0.50	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	2.00	1.50	1.25	0.50	0.50	0.25	0.25	
				6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.00	1.00	0.67	0.67	0.67	0.67	
				7.Total score	9.00	7.00	8.00	4.83	3.92	2.00	2.00	1.58	1.58	1.58
				1.ANXIETY/SOMATIZATION	2.17	2.17	2.17	1.50	1.17	0.57	0.83	0.83	0.67	
				2.WEIGHT	2.00	0.00	1.00	0.80	0.60	0.00	0.00	0.00	0.00	

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REBOXETINE - PROTOCOL 20124/017
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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
14/4	135	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.50	1.50	1.50	1.00	0.83	0.50	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	0.50	0.33	0.17	0.17	0.17
				4. DIURNAL VARIATION	2.00	2.00	1.00	1.00	0.00	0.00	0.00
				5. RETARDATION	2.25	2.25	1.75	1.00	1.00	0.50	0.25
				6. SLEEP DISTURBANCE	2.00	2.00	1.33	1.00	1.00	0.33	0.33
				7. Total score	8.75	8.75	6.08	4.33	3.00	1.50	1.08
14/7	422	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	1.17	1.00	0.67	0.33	0.33
				2. WEIGHT	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	0.17
				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	2.00	1.75	0.75	0.25
				6. SLEEP DISTURBANCE	2.00	2.00	1.67	1.33	1.00	0.67	0.67
				7. Total score	6.83	6.83	5.83	4.83	3.92	2.08	1.42
423		Imipramine	Female	1. ANXIETY/SOMATIZATION	0.67	0.67	0.33	0.33	0.33	0.50	0.00
				2. WEIGHT	1.00	1.00	1.00	1.00	1.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	0.83	0.83	0.83	1.00	1.00	1.00	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	2.00	1.75	1.75	1.25	0.25
				6. SLEEP DISTURBANCE	1.67	1.67	1.67	1.33	1.00	1.00	0.33
				7. Total score	6.17	6.17	5.83	5.42	4.08	3.75	0.58
424		Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.00	1.00	1.00	0.83	0.67	0.67	0.17
				2. WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.17	1.17	1.17	0.83	0.83	0.50	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	1.50	1.75	0.75	0.25
				6. SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.00	1.00	0.67
				7. Total score	7.08	7.08	6.08	4.83	4.25	2.92	1.08
430		Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.17	1.17	1.00	0.50	0.33	0.17	0.00
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.17	1.17	1.17	0.83	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	2.00	2.00	2.00	1.75	1.00	0.50	0.00
				6. SLEEP DISTURBANCE	2.00	2.00	2.00	1.33	1.00	0.67	0.00
				7. Total score	6.53	6.53	6.17	5.25	3.33	1.83	0.83
431		Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.33	1.33	1.50	2.33	2.33	1.00	0.17
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.17	1.17	1.50	1.50	1.50	0.50	0.00
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	1.75	1.75	2.00	2.75	2.75	1.25	0.50

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
14/7	431	Reboxetine	Male	6. SLEEP DISTURBANCE	1.67	1.67	1.67	2.00	2.00	1.00	0.67
				7. Total score	5.92	5.92	6.67	8.58	8.58	3.75	1.33
432		Imipramine	Male	1. ANXIETY/SOMATIZATION	1.33	1.33	1.17	1.00	0.83	0.50	0.17
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.33	1.33	1.17	1.00	0.83	0.50	0.17
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.25	2.25	2.00	1.75	1.75	0.75	0.00
				6. SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00	0.00
				7. Total score	5.92	5.92	5.00	4.42	2.75	1.33	0.17
433		Imipramine	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	1.50	1.33	0.83	0.33	0.33
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.33	1.33	1.17	0.83	0.67	0.33	0.33
				4. DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5. RETARDATION	2.25	2.25	2.00	1.75	0.75	0.50	0.25
				6. SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	0.33	0.00	0.00
				7. Total score	5.92	5.92	5.17	3.25	1.75	1.17	0.25
434		Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.17	1.17	1.17	0.83	0.17	0.33	0.17
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.17	1.17	1.17	0.67	0.50	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	1.00	0.50	0.75	0.25
				6. SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	0.67	0.33	0.00
				7. Total score	5.92	5.92	5.50	1.83	1.42	0.75	0.00
439		Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.50	1.50	1.33	1.00	0.83	0.17	0.00
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.17	1.17	1.17	0.67	0.50	0.33	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	1.75	1.50	1.00	1.00	0.50
				6. SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	0.67	0.33
				7. Total score	5.67	5.67	5.08	4.17	3.33	2.17	1.00
440		Imipramine	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.33	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	1.17	1.17	1.17	1.17	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	1.50	1.50	1.50	0.00	0.00	0.00	0.00
				6. SLEEP DISTURBANCE	1.67	1.67	1.67	0.33	0.00	0.00	0.00
				7. Total score	5.67	5.67	5.67	0.67	0.00	0.00	0.00
441		Imipramine	Male	1. ANXIETY/SOMATIZATION	1.17	1.17	1.17	1.17	0.33	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	1.00	1.00	0.33	0.00	0.00

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 12.1

Centro	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 Day
14/7	441	Imipramine	Male	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	2.00	0.50	0.00	0.00	0.00	0.00
				7. Total score	1.67	1.67	1.67	0.33	0.33	0.33	0.00	0.00
				7. Total score	5.83	5.83	5.83	1.50	0.33	0.00	0.00	0.00
442		Imipramine	Male	1. ANXIETY/SOMATIZATION	1.00	1.00	1.00	0.83	0.67	0.33	0.00	0.00
				2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3. COGNITIVE DISTURBANCE	1.33	1.33	1.33	0.67	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	0.00
				5. RETARDATION	2.25	2.25	2.25	1.25	1.25	0.25	0.25	0.25
				6. SLEEP DISTURBANCE	1.67	1.67	1.00	1.00	1.00	0.33	0.33	0.00
				7. Total score	6.25	6.25	5.58	3.75	3.42	1.25	0.58	0.25
449		Reboxetine	Female	1. ANXIETY/SOMATIZATION	0.83	0.83	1.00	0.67	0.17	0.00	0.00	0.00
				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	1.33	0.83	0.50	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	1.75	1.75	1.75	1.00	0.50	0.25	0.00	0.00
				6. SLEEP DISTURBANCE	1.00	1.00	0.67	0.33	0.33	0.00	0.00	0.00
				7. Total score	5.08	5.08	4.75	2.83	1.50	0.42	0.00	0.00
450		Imipramine	Male	1. ANXIETY/SOMATIZATION	1.17	1.17	1.17	1.00	1.00	0.33	0.00	0.00
				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	1.17	1.00	0.67	0.50	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	2.00	1.75	1.50	0.75	0.00	0.00
				6. SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	1.00	0.67	0.00	0.00
				7. Total score	5.67	5.67	5.67	4.75	4.17	2.25	0.00	0.00
14/8	150	Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.83	1.83	1.50	1.00	0.83	0.67	0.50	0.50
				2. WEIGHT	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	0.67	0.67	0.67	0.50	0.33
				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	1.00	0.75	0.75	0.50	0.25
				6. SLEEP DISTURBANCE	0.67	0.67	0.67	0.67	0.67	0.33	0.33	0.33
				7. Total score	5.83	5.83	5.25	4.33	3.92	3.42	2.83	2.42
425		Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.83	1.83	1.83	1.83	1.67	1.67	1.67	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	0.67	0.67	0.67	0.67	0.67	0.67
				4. DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	1.25	1.25	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	1.00	1.00	1.00
				7. Total score	6.08	6.08	6.08	5.50	5.33	5.33	5.33	5.33
467		Reboxetine	Male	1. ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.67	1.67	1.67	1.67	1.67

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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					
14/8	467	Male	Reboxetine	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	0.83	0.83	0.83	0.83	0.83	0.83	0.83	0.83	0.67	0.67
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	1.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.00
				7.Total score	6.58	5.75	5.75	5.25	5.08	5.58	5.58	5.42	4.75	
14/10	53	Male	Reboxetine	1.ANXIETY/SOMATIZATION	1.83	1.83	1.83	1.50	0.83	0.50	0.33	0.33	0.33	
				2.WEIGHT	2.00	0.00	1.00	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	0.00	0.00	0.00	0.00	
				4.DIURNAL VARIATION	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	
				5.RETARDATION	2.25	2.25	1.75	1.50	1.25	1.25	1.25	1.00	1.00	
				6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.67	1.33	1.00	0.67	1.00	0.67	
				7.Total score	8.42	6.42	7.32	5.00	3.75	2.75	2.75	2.00	2.00	
54		Female	Imipramine	1.ANXIETY/SOMATIZATION	1.50	1.33	1.33	1.17	1.17	1.17	1.17	1.17	0.67	
				2.WEIGHT	0.60	1.00	0.60	0.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	0.67	0.83	0.83	0.67	0.50	0.33	0.33	0.33	0.33	
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	1.00	0.00	0.00	0.00	
				5.RETARDATION	2.25	2.00	2.25	1.75	1.50	1.50	1.50	1.50	1.25	
				6.SLEEP DISTURBANCE	2.00	2.00	1.67	1.67	1.33	1.67	1.67	1.67	1.67	
				7.Total score	8.42	9.17	8.08	7.42	5.67	5.83	4.67	3.92		
55		Female	Reboxetine	1.ANXIETY/SOMATIZATION	1.50	1.50	1.33	1.33	1.33	0.83	0.67	0.67	0.67	
				2.WEIGHT	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	0.83	0.67	0.50	0.83	0.17	0.17	0.17	0.00	0.00	
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	1.00	1.00	0.00	0.00	
				5.RETARDATION	1.75	1.50	1.50	1.25	1.25	1.00	0.50	0.50	0.50	
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.33	1.67	1.33	1.00	0.67	1.83	
				7.Total score	9.75	8.33	7.00	5.75	5.42	4.33	2.67	1.83		
56		Female	Imipramine	1.ANXIETY/SOMATIZATION	1.33	1.33	1.00	1.00	1.00	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	0.00	
				3.COGNITIVE DISTURBANCE	0.33	0.50	0.33	0.33	0.17	0.17	0.17	0.00	0.00	
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00	
				5.RETARDATION	2.25	1.75	1.75	1.25	1.25	1.00	0.75	0.75	0.75	
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.33	1.00	1.33	1.33	1.33	1.33	
				7.Total score	7.58	7.25	6.75	5.92	5.42	4.00	4.08	3.92		
57		Female	Reboxetine	1.ANXIETY/SOMATIZATION	1.50	1.33	1.17	0.83	1.00	0.83	0.83	0.83	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	0.50	0.33	0.33	0.33	0.33	0.33	0.33	0.17	0.33	
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00	1.00	1.00	
				5.RETARDATION	2.25	2.25	2.00	1.75	1.50	1.00	1.00	1.00	1.00	
				6.SLEEP DISTURBANCE	1.67	1.67	1.33	1.33	1.33	1.33	1.33	1.33	1.33	
				7.Total score	7.92	7.58	6.83	6.25	6.17	5.50	4.33	4.33		

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PHARMACIA CMS R&D
REBOXETINE - PROTOCOL 20124-017
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	
14/10	58	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.33	0.83	1.00	1.00	
				2. WEIGHT	0.00	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	2.00	2.00	2.00	2.00	4.00	1.00	0.00	
				5. RETARDATION	2.00	1.75	1.50	1.25	4.00	0.75	0.75	
				6. SLEEP DISTURBANCE	1.67	2.00	1.33	1.00	1.00	1.00	1.33	
				7. Total score	7.67	8.75	7.42	6.50	5.92	4.17	4.00	3.42
59	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.67	1.50	1.50	1.33	1.17	0.83	0.83	0.83	
			2. WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	0.67	0.50	0.50	0.17	0.17	0.17	0.17	0.17	
			4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	1.50	1.75	2.00	1.50	1.00	0.75	0.50	0.50	
			6. SLEEP DISTURBANCE	2.00	2.00	1.67	1.33	1.00	0.67	0.67	0.33	
			7. Total score	9.83	7.75	7.67	6.33	4.33	3.67	3.42	2.83	
60	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.50	1.83	1.83	1.33	1.00	1.00	0.83	0.83	
			2. WEIGHT	0.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	0.67	0.83	0.50	0.33	0.33	0.17	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	1.50	1.75	1.75	1.25	1.25	0.75	0.50	0.50	
			6. SLEEP DISTURBANCE	1.33	1.67	2.00	1.67	1.33	1.00	0.67	0.67	
			7. Total score	6.00	9.08	7.08	6.08	4.92	3.92	3.17	3.00	
137	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.50	1.00	1.00	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	0.50	0.50	0.67	0.50	0.33	0.33	0.50	0.33	
			4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	1.00	0.00	
			5. RETARDATION	2.25	2.00	2.25	2.00	1.75	1.25	1.25	1.25	
			6. SLEEP DISTURBANCE	1.67	1.67	1.33	1.00	1.00	1.00	1.00	1.00	
			7. Total score	8.08	7.83	7.92	7.00	6.08	4.58	4.75	5.58	
138	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.17	1.17	0.83	0.83	0.67	
			2. WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
			3. COGNITIVE DISTURBANCE	0.50	0.67	0.50	0.33	0.33	0.33	0.33	0.33	
			4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00	1.00	
			5. RETARDATION	2.00	2.00	1.75	1.75	1.25	1.25	0.75	0.75	
			6. SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	1.33	1.00	1.00	1.00	
			7. Total score	7.50	7.67	7.25	6.25	6.08	5.42	3.92	3.75	
139	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.33	1.50	1.17	1.00	0.67	0.50	0.50	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	0.67	0.67	0.33	0.00	0.00	0.00	0.00	
			4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	2.00	2.25	1.75	1.25	1.00	0.50	0.50	0.50	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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
14/70	139	Reboxetine	Female	6.SLEEP DISTURBANCE 7.Total score	1.33 7.33	1.33 7.33	1.00 5.58	0.67 3.33	0.67 2.67	0.67 2.67	0.67 2.67
140		Imipramine	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 1.00 2.50 1.67 9.17	1.50 0.00 0.83 1.00 2.25 1.67 7.17	1.50 0.00 0.83 1.00 2.00 1.67 7.25	1.33 0.00 0.33 1.00 2.00 1.33 6.00	1.17 0.00 0.33 1.00 1.50 1.00 5.00	1.33 0.00 0.33 1.00 1.25 1.00 5.42	1.17 0.00 0.33 1.00 1.25 1.00 5.08
435		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 2.00 1.33 7.50	1.50 0.00 0.83 2.00 2.00 1.33 7.67	1.50 0.00 0.83 2.00 2.00 1.33 7.75	1.17 0.00 0.33 1.00 1.50 1.00 5.83	1.17 0.00 0.33 1.00 1.25 1.00 4.92	1.00 0.00 0.33 1.00 1.25 1.00 4.25	0.83 0.00 0.33 1.00 1.25 1.00 4.08
436		Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.17 1.00 0.83 2.00 2.25 2.00 9.25	1.00 1.00 0.50 2.00 2.25 2.00 8.83	1.17 1.00 0.50 2.00 2.25 2.00 8.92	1.00 0.00 0.17 1.00 1.75 1.33 4.50	1.00 0.00 0.17 1.00 1.75 1.00 3.92	1.00 0.00 0.17 1.00 1.75 1.00 3.42	0.83 0.00 0.17 1.00 1.75 1.00 3.42
437		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 0.83 2.00 2.00 1.67 7.17	1.17 0.00 0.50 1.75 1.50 1.67 7.75	1.33 0.00 0.33 1.50 2.00 1.67 7.58	1.00 0.00 0.33 1.00 1.00 1.00 4.33	0.83 0.00 0.33 1.00 1.00 1.00 3.50	0.50 0.00 0.00 1.00 1.00 1.00 2.83	0.50 0.00 0.00 1.00 1.00 1.00 2.83
438		Imipramine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.33 1.00 0.50 1.50 1.75 1.67 7.25	1.33 1.00 0.50 1.50 1.75 1.67 7.68	1.67 0.00 0.50 1.00 1.50 1.33 6.00	1.17 0.00 0.50 1.00 1.50 1.33 5.50	1.00 0.00 0.50 1.00 1.25 1.00 4.75	0.83 0.00 0.17 1.00 1.25 1.00 4.58	0.83 0.00 0.17 1.00 1.25 1.00 4.25
443		Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE	1.33 0.00 0.83	1.50 0.00 0.83	1.17 0.00 0.83	1.33 0.00 0.67	1.17 0.00 0.67	0.83 0.00 0.67	0.83 0.00 0.67

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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				
14/10	443	Female	Reboxetine	Hamilton depression rating scale										
				4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00
				5. RETARDATION	2.25	2.25	2.25	1.75	1.50	0.75	0.75	0.75	0.75	0.75
				6. SLEEP DISTURBANCE	1.67	1.67	2.00	2.00	1.67	1.00	0.67	0.67	0.67	0.67
				7. Total score	8.08	8.25	8.25	7.75	6.00	4.08	3.58	3.58	3.42	
				1. ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.33	0.63	0.63	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	0.00	0.00
444	Reboxetine	Male	Hamilton depression rating scale											
			3. COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.50	0.33	0.33	0.33	0.17	0.17	0.17	
			4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	2.25	2.25	2.25	2.00	1.75	1.75	1.00	1.00	1.00	1.00	
			6. SLEEP DISTURBANCE	1.67	1.67	2.00	2.00	2.00	1.00	1.00	1.00	1.00	1.00	
			7. Total score	8.08	8.08	8.25	7.83	7.58	5.92	4.17	4.17	4.00		
			1. ANXIETY/SOMATIZATION	1.83	1.83	1.67	1.50	1.50	1.17	1.17	1.17	1.17	1.00	
2. WEIGHT	2.00	2.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00				
445	Imipramine	Female	Hamilton depression rating scale											
			3. COGNITIVE DISTURBANCE	1.00	1.00	0.83	0.67	0.67	0.50	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	1.00	
			5. RETARDATION	1.75	1.75	1.50	1.50	1.50	1.50	1.25	1.25	1.25	1.25	
			6. SLEEP DISTURBANCE	2.00	2.00	2.00	1.67	1.67	1.33	1.00	1.00	1.00	1.00	
			7. Total score	9.58	9.58	9.25	7.33	6.53	5.50	4.75	4.75	4.42		
			1. ANXIETY/SOMATIZATION	1.83	1.83	1.67	1.50	1.50	1.17	1.17	1.17	1.17	1.00	
2. WEIGHT	2.00	2.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00				
446	Reboxetine	Female	Hamilton depression rating scale											
			3. COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.33	0.33	0.33	0.33	0.17	0.17	0.17	
			4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	1.75	1.75	1.25	1.00	0.75	0.75	0.75	0.75	0.75	0.75	
			6. SLEEP DISTURBANCE	1.67	2.00	2.00	1.33	1.33	1.00	1.00	1.00	1.00	1.00	
			7. Total score	8.08	8.42	7.58	5.00	4.42	4.25	4.08	4.08	3.75	3.25	
			1. ANXIETY/SOMATIZATION	1.67	1.67	1.50	1.33	1.33	1.00	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	0.00	0.00				
447	Reboxetine	Male	Hamilton depression rating scale											
			3. COGNITIVE DISTURBANCE	0.67	0.83	0.83	0.67	0.67	0.50	0.17	0.17	0.17	0.17	
			4. DIURNAL VARIATION	1.00	2.00	2.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	1.75	1.75	1.25	1.25	1.25	1.25	0.75	0.75	0.75	0.75	
			6. SLEEP DISTURBANCE	2.00	2.00	1.67	1.33	1.33	1.00	1.00	1.00	1.00	1.00	
			7. Total score	7.08	8.25	7.75	6.58	6.58	5.75	3.75	3.75	3.25		
			1. ANXIETY/SOMATIZATION	1.67	1.67	1.50	1.33	1.33	1.00	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	0.00	0.00				
448	Imipramine	Female	Hamilton depression rating scale											
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.50	0.50	0.50	
			4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	2.50	2.50	2.00	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	1.33	1.33	1.33	1.33	
			7. Total score	11.17	9.00	8.67	8.08	5.92	5.50	4.67	4.67	4.67		
			1. ANXIETY/SOMATIZATION	2.00	1.83	2.00	2.00	1.83	1.67	1.83	1.83	1.83	1.83	
2. WEIGHT	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00				
453	Imipramine	Female	Hamilton depression rating scale											
			3. COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.50	0.50	0.50	
			4. DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00	
			5. RETARDATION	2.50	2.50	2.00	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	1.33	1.33	1.33	1.33	
			7. Total score	11.17	9.00	8.67	8.08	5.92	5.50	4.67	4.67	4.67		
			1. ANXIETY/SOMATIZATION	1.67	1.67	1.50	1.00	1.00	1.00	0.83	0.83	0.83	0.83	
2. WEIGHT	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00				

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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			
14/10	453	Imipramine	Female	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	0.50	0.33	0.17	0.33	0.17	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	2.25	1.75	1.25	1.00	1.25	1.00	0.50
				6.SLEEP DISTURBANCE	2.00	1.67	1.33	1.00	0.67	1.00	0.67	0.67
				7.Total score	9.17	9.08	6.08	4.58	3.83	4.58	3.67	3.33
				1.ANXIETY/SOMATIZATION	1.50	1.50	1.50	1.00	1.00	1.00	1.17	0.83
2.WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00				
3.COGNITIVE DISTURBANCE	0.67	0.67	0.50	0.33	0.33	0.33	0.17	0.00				
4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	1.00	1.00	1.00				
5.RETARDATION	2.00	1.75	1.50	1.25	1.00	1.00	1.00	1.00				
6.SLEEP DISTURBANCE	1.67	2.00	1.67	1.33	1.33	1.33	1.00	0.67				
7.Total score	9.83	7.92	7.17	6.50	5.92	4.83	4.00	3.33				
455	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.50	1.33	1.17	1.00	1.00	1.00	
			2.WEIGHT	2.00	0.00	0.00	0.00	0.00	0.00	0.00		
			3.COGNITIVE DISTURBANCE	0.33	0.67	0.50	0.33	0.33	0.33	0.17		
			4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	1.00	1.00		
			5.RETARDATION	2.25	2.25	2.00	1.75	1.85	1.00	0.75		
			6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.67	1.33	1.00	0.67		
			7.Total score	9.92	8.25	8.00	7.08	5.08	4.33	3.58		
15	349	Imipramine	Male	1.ANXIETY/SOMATIZATION	1.50	1.50	0.83	0.33	0.17	0.33	0.50	
				2.WEIGHT	2.00	2.00	0.00	0.00	0.00	2.00	0.00	
				3.COGNITIVE DISTURBANCE	1.67	1.67	0.50	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	
				5.RETARDATION	1.50	1.50	1.00	0.75	0.25	0.00	0.25	
				6.SLEEP DISTURBANCE	0.67	0.67	0.67	0.33	0.67	0.33	0.33	
				7.Total score	9.33	9.33	4.00	1.42	1.08	2.67	1.08	
351	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.83	1.83	0.50	0.00	1.33	0.33	0.00		
			2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00		
			3.COGNITIVE DISTURBANCE	1.33	1.33	0.17	0.00	1.58	0.33	0.00		
			4.DIURNAL VARIATION	2.00	2.00	2.00	0.00	2.00	0.00	0.00		
			5.RETARDATION	3.25	3.25	1.25	0.25	1.75	0.75	0.50		
			6.SLEEP DISTURBANCE	2.00	2.00	0.00	0.00	2.00	0.67	0.00		
			7.Total score	11.42	11.42	5.92	0.25	8.58	2.08	0.50		
352	Imipramine	Male	1.ANXIETY/SOMATIZATION	1.67	1.67	1.67	0.83	1.33	0.00			
			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	0.67	0.50			
			4.DIURNAL VARIATION	2.00	1.00	1.00	1.00	1.00	0.75			
			5.RETARDATION	2.00	2.00	1.50	1.00	0.75	0.00			
			6.SLEEP DISTURBANCE	0.67	0.67	0.67	0.33	0.00	0.00			
			7.Total score	7.00	6.00	5.50	3.83	2.58	0.00			

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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	364	Imipramine	Female	1. ANXIETY/SOMATIZATION	1.67	1.67	1.33	0.33	0.67	1.50										
				2. WEIGHT	2.00	2.00	2.00	0.00	0.00	0.00	0.00									
				3. COGNITIVE DISTURBANCE	1.50	1.50	1.00	0.83	1.17	2.17										
				4. DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	0.00	0.00									
				5. RETARDATION	3.00	3.00	1.75	1.00	1.50											
				6. SLEEP DISTURBANCE	2.00	2.00	0.67	1.67	0.33	2.00										
				7. Total score	12.17	12.17	8.75	4.58	3.17	7.17										
366	Reboxetine	Male	1. ANXIETY/SOMATIZATION	2.00	2.00	0.00	0.00	0.00	0.00	0.50	0.83	0.00								
			2. WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00							
			3. COGNITIVE DISTURBANCE	1.83	1.83	0.00	0.00	0.00	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	0.00	0.00							
			5. RETARDATION	2.00	2.00	0.00	0.00	0.25	0.25	0.25	0.25	0.25	0.25							
			6. SLEEP DISTURBANCE	0.67	0.67	0.33	0.00	0.00	0.33	0.00	0.33	0.00	0.33							
			7. Total score	9.50	9.50	0.33	0.00	0.25	1.08	1.08	0.83	0.67	1.17							
367	Imipramine	Male	1. ANXIETY/SOMATIZATION	1.67	1.67	1.33	1.33	1.83	0.83	0.83	0.67	1.17								
			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	1.17	1.17	0.83	1.67	1.33	0.50	0.67	0.83									
			4. DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00							
			5. RETARDATION	3.00	3.00	3.00	2.50	2.50	2.00	2.50	2.00	2.00	2.50							
			6. SLEEP DISTURBANCE	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.67							
			7. Total score	7.50	7.50	6.83	8.17	7.67	5.00	5.00	5.00	5.00	5.00							
368	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	0.67	0.17	0.83	0.67	0.67	0.83									
			2. WEIGHT	0.00	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	0.00	0.33	0.33	0.17	0.00	0.00								
			4. DIURNAL VARIATION	2.00	2.00	1.00	0.00	0.00	0.00	1.00	0.00	0.00								
			5. RETARDATION	2.50	2.50	0.75	0.50	0.75	0.75	0.75	0.75	0.75								
			6. SLEEP DISTURBANCE	2.00	2.00	0.33	0.33	0.33	0.33	0.33	0.33	0.33								
			7. Total score	8.67	8.67	5.42	1.00	2.25	2.08	2.58	1.58									
369	Reboxetine	Female	1. ANXIETY/SOMATIZATION	1.33	1.33	0.17	0.17	0.00	0.00	0.00	0.00									
			2. WEIGHT	0.00	0.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00								
			3. COGNITIVE DISTURBANCE	1.50	1.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00								
			4. DIURNAL VARIATION	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00								
			5. RETARDATION	2.50	2.50	0.75	0.00	0.00	0.00	0.00	0.00	0.00								
			6. SLEEP DISTURBANCE	1.67	1.67	0.00	0.00	0.00	0.00	0.00	0.00	0.00								
			7. Total score	9.00	9.00	0.92	2.17	0.00	0.00	0.00	0.00	0.00								
370	Imipramine	Female	1. ANXIETY/SOMATIZATION	0.17	0.17	0.33	0.50	0.33	0.17	0.50	0.33									
			2. WEIGHT	0.00	0.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00								
			3. COGNITIVE DISTURBANCE	1.33	1.33	1.17	0.67	0.17	0.67	0.17	0.67	0.67								
			4. DIURNAL VARIATION	2.00	2.00	2.00	0.00	1.00	1.00	0.00	0.00	0.00								
			5. RETARDATION	1.50	1.50	1.00	0.50	0.75	0.00	0.75	0.00	0.75								

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PHARMACIA CHS RD
REBOXETINE - PROTOCOL 20124/017
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	370	Imipramine	Female	6.SLEEP DISTURBANCE 7.Total score	1.67 6.67	1.33 6.83	1.00 3.17	1.33 5.08	1.00 3.33	0.00 1.92	0.67 2.42
371	Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.83 0.00 0.67 2.00 1.75 2.00 8.25	0.33 2.00 0.17 1.00 0.25 1.67 5.42	0.83 0.00 0.83 2.00 0.25 1.67 6.00	0.50 2.00 0.33 1.00 0.50 1.67 6.00	0.33 0.00 0.17 1.00 0.00 0.33 6.00	0.67 0.00 0.17 1.00 0.00 0.67 6.00	0.17 0.00 0.00 1.00 0.00 0.67 6.00	
372	Imipramine	Male	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	0.67 2.00 1.50 0.00 3.23 2.00 9.42	0.50 0.00 1.17 0.00 2.75 1.33 5.75	0.83 0.00 1.00 0.00 2.75 1.00 5.58	1.00 0.00 1.50 0.00 2.50 0.67 5.67	0.67 2.00 1.17 0.00 2.50 1.33 5.50	1.00 0.00 1.17 0.00 2.50 1.00 5.92		
373	Imipramine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.17 2.00 1.50 1.00 2.50 1.67 9.83	1.33 2.00 1.50 1.00 2.50 1.67 10.00	1.33 2.00 1.50 1.00 2.50 1.67 10.00	1.33 2.00 1.50 1.00 2.50 1.67 10.00	1.33 2.00 1.50 1.00 2.50 1.67 10.00	1.33 2.00 1.50 1.00 2.50 1.67 10.00		
374	Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.83 0.00 2.00 2.00 2.75 0.00 8.58	0.83 0.00 0.67 1.00 1.25 0.67 5.42	0.50 0.00 0.67 1.00 0.75 1.33 3.00	0.50 0.00 0.67 1.00 0.75 1.33 3.00	0.00 0.00 0.17 0.00 0.00 0.67 3.00	0.00 0.00 0.17 0.00 0.00 0.33 3.00	0.67 0.00 0.17 0.00 0.00 0.33 3.00	
375	Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	0.83 0.00 1.50 0.00 2.75 1.67 6.75	1.17 0.00 0.33 0.00 0.92 1.67 7.08	0.50 0.00 0.33 0.00 0.75 0.33 1.92	0.00 0.00 0.00 0.00 0.00 0.00 0.00	0.00 0.00 0.33 0.00 0.00 0.33 1.92	0.00 0.00 0.00 0.00 0.00 0.33 1.92	0.00 0.00 0.00 0.00 0.00 0.33 1.92	
376	Imipramine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE	1.83 1.00 1.17	1.83 1.00 1.17	2.17 1.00 1.17	2.17 1.00 1.17	2.17 1.00 1.17	2.17 1.00 1.17	2.17 1.00 1.17	2.17 1.00 1.17

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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									
15	376	Imipramine	Female		1.00	1.00	0.00													
				4. DIURNAL VARIATION	2.75	2.75	2.75													
				5. RETARDATION	1.67	1.67	2.00													
				6. SLEEP DISTURBANCE	9.42	9.42	10.25													
				7. Total score																
377		Reboxetine	Female		2.50	2.50	1.83	1.17	0.67	0.67	0.50	0.33								
				1. ANXIETY/SOMATIZATION	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00								
				2. WEIGHT	2.33	2.33	0.83	0.33	0.33	0.33	0.00	0.17								
				3. COGNITIVE DISTURBANCE	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00								
				4. DIURNAL VARIATION	2.75	2.75	1.00	0.75	0.25	0.25	0.25	0.00								
				5. RETARDATION	2.00	2.00	1.00	1.00	0.33	0.33	0.33	0.33								
				6. SLEEP DISTURBANCE	13.58	13.58	6.67	3.25	1.58	1.58	1.08	0.83								
				7. Total score																
378		Reboxetine	Female		0.67	0.67	0.33	0.17	0.00	0.17	0.17	0.00								
				1. ANXIETY/SOMATIZATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00								
				2. WEIGHT	1.17	1.17	0.83	0.50	0.33	0.33	0.00	0.17								
				3. COGNITIVE DISTURBANCE	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00								
				4. DIURNAL VARIATION	3.00	3.00	1.50	1.00	0.50	0.50	0.00	0.25								
				5. RETARDATION	1.67	1.67	1.67	1.67	1.67	1.67	1.00	0.33								
				6. SLEEP DISTURBANCE	6.50	6.50	5.33	3.33	1.17	2.17	0.67	0.58								
				7. Total score																
379		Imipramine	Female		1.67	1.67														
				1. ANXIETY/SOMATIZATION	2.00	2.00														
				2. WEIGHT	1.33	1.33														
				3. COGNITIVE DISTURBANCE	1.00	1.00														
				4. DIURNAL VARIATION	2.25	2.25														
				5. RETARDATION	2.00	2.00														
				6. SLEEP DISTURBANCE	10.25	10.25														
				7. Total score																
380		Imipramine	Female		1.50	1.50	1.17	1.50	2.00	0.17	0.83	0.83								
				1. ANXIETY/SOMATIZATION	2.00	2.00	2.00	0.00	2.00	0.00	0.00	0.00								
				2. WEIGHT	1.83	1.83	1.50	1.17	1.17	0.00	0.00	0.00								
				3. COGNITIVE DISTURBANCE	1.00	1.00	1.00	0.00	2.00	0.00	0.00	0.00								
				4. DIURNAL VARIATION	3.00	3.00	2.00	1.75	2.50	0.50	0.75	1.00								
				5. RETARDATION	1.67	1.33	0.67	1.00	2.00	0.00	0.00	0.33								
				6. SLEEP DISTURBANCE	11.00	10.67	8.33	5.42	11.67	0.67	1.58	2.17								
				7. Total score																
381		Reboxetine	Female		1.00	1.00	1.83	1.00	1.17	1.17	0.83	1.00								
				1. ANXIETY/SOMATIZATION	0.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00								
				2. WEIGHT	1.67	1.67	1.33	0.67	0.67	0.50	0.67	1.00								
				3. COGNITIVE DISTURBANCE	1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00								
				4. DIURNAL VARIATION	2.50	2.50	1.75	1.75	1.25	1.00	1.75	1.00								
				5. RETARDATION	1.67	1.67	1.33	1.33	1.33	1.33	1.00	0.67								
				6. SLEEP DISTURBANCE	7.83	7.83	9.58	4.75	5.92	4.25	3.50	4.42								
				7. Total score																
382		Imipramine	Male		1.17	1.17														
				1. ANXIETY/SOMATIZATION																

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	382	Imipramine	Male	2.WEIGHT	0.00	0.00						
				3.COGNITIVE DISTURBANCE	1.67	1.67						
				4.DIURNAL VARIATION	0.00	0.00						
				5.RETARDATION	2.50	2.50						
				6.SLEEP DISTURBANCE	1.00	1.00						
				7.Total score	6.93	6.93						
								1.83	1.83	2.00	2.00	0.67
383	Imipramine	Female	1.ANXIETY/SOMATIZATION	2.00	2.00	1.00	1.00	2.00	2.00	0.00	0.00	
			2.WEIGHT	2.50	2.50	1.67	1.17	0.83	0.67	0.17	0.33	
			3.COGNITIVE DISTURBANCE	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	
			4.DIURNAL VARIATION	2.00	2.00	2.00	2.25	1.25	1.00	0.25	0.00	
			5.RETARDATION	2.00	2.00	2.00	1.33	0.00	1.67	1.00	0.67	
			6.SLEEP DISTURBANCE	11.33	11.33	8.00	6.75	2.92	4.00	1.92	1.83	
			7.Total score									
384	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50							
			2.WEIGHT	2.00	2.00							
			3.COGNITIVE DISTURBANCE	1.83	1.83							
			4.DIURNAL VARIATION	1.00	1.00							
			5.RETARDATION	3.25	3.25							
			6.SLEEP DISTURBANCE	2.00	2.00							
			7.Total score	11.58	11.58							

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REBOXETINE - PROTOCOL 20124/017
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
1	1	Reboxetine	Male	01.REPORTED SADNESS	2	3	2	1	2	2	1
				02.INNER TENSION	1	2	1	1	1	1	1
				03.APPARENT SADNESS	2	2	2	1	3	2	1
				04.SUICIDAL THOUGHTS	1	1	0	0	1	1	1
				05.INERTIA	2	2	2	2	3	2	1
				06.INABILITY TO FEEL	2	4	1	2	2	2	1
				07.PESSIMISTIC THOUGHTS	2	1	1	1	1	1	1
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2
				09.REDUCED SLEEP	1	3	2	1	1	1	1
				10.REDUCED APPETITE	1	2	2	1	2	1	0
				11.Total score	16	20	15	12	19	15	10
2	2	Reboxetine	Female	01.REPORTED SADNESS	3	2	2	1	0	0	0
				02.INNER TENSION	2	1	1	1	0	0	0
				03.APPARENT SADNESS	2	2	2	1	0	0	0
				04.SUICIDAL THOUGHTS	2	1	1	1	0	0	0
				05.INERTIA	3	2	2	1	0	0	0
				06.INABILITY TO FEEL	2	2	2	1	0	0	0
				07.PESSIMISTIC THOUGHTS	2	1	1	1	0	0	0
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	2	2
				09.REDUCED SLEEP	1	1	1	1	1	1	0
				10.REDUCED APPETITE	2	1	1	1	0	0	0
				11.Total score	21	15	15	10	2	3	2
3	3	Imipramine	Female	01.REPORTED SADNESS	2	2	2	1	0	0	0
				02.INNER TENSION	1	1	1	1	1	0	0
				03.APPARENT SADNESS	2	1	1	0	0	0	0
				04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0
				05.INERTIA	2	2	2	2	2	1	0
				06.INABILITY TO FEEL	2	1	2	1	1	0	0
				07.PESSIMISTIC THOUGHTS	2	1	2	0	0	0	0
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2
				09.REDUCED SLEEP	3	1	1	1	1	1	0
				10.REDUCED APPETITE	2	1	1	0	0	0	0
				11.Total score	19	12	13	8	7	4	2
4	4	Imipramine	Male	01.REPORTED SADNESS	2	2	3	2	2	1	0
				02.INNER TENSION	2	2	1	1	1	1	0
				03.APPARENT SADNESS	2	2	2	2	1	0	0
				04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0
				05.INERTIA	2	2	3	2	2	2	0
				06.INABILITY TO FEEL	2	2	2	2	2	2	0
				07.PESSIMISTIC THOUGHTS	2	1	2	2	1	1	0
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	1
				09.REDUCED SLEEP	2	2	2	1	1	1	1
				10.REDUCED APPETITE	2	2	2	1	0	0	0
				11.Total score	19	18	18	15	11	10	2

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
1	5	Reboxetine	Female	01. REPORTED SADNESS	2	1	2	1	2	2	2	2	
				02. INNER TENSION	2	2	1	1	1	1	1	1	1
				03. APPARENT SADNESS	2	1	2	1	2	2	2	2	2
				04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0	0
				05. INERTIA	3	2	2	2	2	2	2	2	2
				06. INABILITY TO FEEL	2	1	1	1	2	2	1	0	0
				07. PESSIMISTIC THOUGHTS	1	0	1	0	1	1	0	0	0
				08. CONCENTRATIONS DIFFICULTIES	3	1	2	1	2	2	2	2	2
				09. REDUCED SLEEP	2	2	2	2	2	2	2	2	2
				10. REDUCED APPETITE	2	0	1	1	1	1	1	1	1
				11. Total score	19	10	14	11	15	13	11	13	11
6	6	Imipramine	Male	01. REPORTED SADNESS	3	2	2	2	2	1	0	0	
				02. INNER TENSION	2	2	1	2	2	2	1	1	
				03. APPARENT SADNESS	2	2	2	2	2	2	1	1	
				04. SUICIDAL THOUGHTS	1	1	1	1	1	1	0	0	
				05. INERTIA	2	2	2	2	1	1	0	0	
				06. INABILITY TO FEEL	2	1	2	0	0	0	0	0	
				07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	0	0	
				08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	1	1	1	
				09. REDUCED SLEEP	3	2	2	2	2	2	1	1	
				10. REDUCED APPETITE	1	1	1	1	0	1	1	1	
				11. Total score	19	16	16	13	12	5	6	6	
7	7	Reboxetine	Male	01. REPORTED SADNESS	2	3	2	2	1	2	2	2	
				02. INNER TENSION	2	2	2	1	1	1	1	2	
				03. APPARENT SADNESS	2	2	2	2	2	2	2	2	
				04. SUICIDAL THOUGHTS	2	2	2	2	2	1	1	1	
				05. INERTIA	2	2	2	2	2	2	2	2	
				06. INABILITY TO FEEL	2	2	2	2	1	1	2	2	
				07. PESSIMISTIC THOUGHTS	1	2	2	2	1	2	2	2	
				08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2	2	
				09. REDUCED SLEEP	2	3	2	2	2	1	2	1	
				10. REDUCED APPETITE	2	1	2	1	1	1	1	1	
				11. Total score	18	21	19	15	15	17	17		
8	8	Imipramine	Male	01. REPORTED SADNESS	3	2	2	2	2	2	2	2	
				02. INNER TENSION	2	1	1	1	1	1	1	1	
				03. APPARENT SADNESS	2	2	2	2	2	2	2	2	
				04. SUICIDAL THOUGHTS	2	2	2	2	2	2	2	2	
				05. INERTIA	3	2	2	2	2	2	2	2	
				06. INABILITY TO FEEL	2	2	2	2	1	2	2	2	
				07. PESSIMISTIC THOUGHTS	1	1	2	2	2	2	2	2	
				08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2	2	
				09. REDUCED SLEEP	2	2	2	2	2	1	2	2	
				10. REDUCED APPETITE	2	2	2	2	2	2	2	2	
				11. Total score	23	21	21	21	21	21	21		

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 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
1	8	Imipramine	Male	11.Total score	19	17					
9	Imipramine	Female	01.REPORTED SADNESS	2	2	2	2	1	1	0	0
			02.INNER TENSION	1	1	1	1	1	1	0	0
			03.APPARENT SADNESS	2	2	1	0	0	0	0	0
			04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0	0
			05.INERTIA	2	2	2	2	2	2	0	0
			06.INABILITY TO FEEL	2	1	2	2	1	0	0	0
			07.PESSIMISTIC THOUGHTS	1	1	0	0	0	0	0	0
			08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	2	2	2	0
			09.REDUCED SLEEP	0	1	0	0	0	0	0	0
			10.REDUCED APPETITE	1	1	1	0	0	0	0	0
			11.Total score	14	14	11	6	6	6	2	0
10	Imipramine	Female	01.REPORTED SADNESS	2	2	2	2	1	2	2	1
			02.INNER TENSION	1	0	1	1	1	2	1	0
			03.APPARENT SADNESS	2	2	1	1	1	1	1	0
			04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0
			05.INERTIA	2	2	2	2	2	2	2	0
			06.INABILITY TO FEEL	2	1	2	2	1	1	1	0
			07.PESSIMISTIC THOUGHTS	1	1	0	0	0	1	0	0
			08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2	2
			09.REDUCED SLEEP	3	2	1	3	3	3	2	2
			10.REDUCED APPETITE	1	1	1	0	1	1	1	0
			11.Total score	17	13	12	11	15	15	12	8
11	Reboxetine	Male	01.REPORTED SADNESS	3	3	3	3	2	3	3	
			02.INNER TENSION	1	2	2	2	1	2	2	
			03.APPARENT SADNESS	3	2	2	2	2	3	3	
			04.SUICIDAL THOUGHTS	1	1	1	0	0	2	2	
			05.INERTIA	2	2	2	2	2	3	3	
			06.INABILITY TO FEEL	2	2	2	1	2	2	2	
			07.PESSIMISTIC THOUGHTS	1	1	2	1	1	3	3	
			08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	3	
			09.REDUCED SLEEP	3	2	3	2	2	3	3	
			10.REDUCED APPETITE	2	1	1	1	1	1	1	
			11.Total score	20	18	20	14	14	24	24	
12	Reboxetine	Male	01.REPORTED SADNESS	2	2	2	1	2	2	2	
			02.INNER TENSION	1	1	1	1	1	1	1	
			03.APPARENT SADNESS	2	2	2	2	2	2	2	
			04.SUICIDAL THOUGHTS	0	1	1	1	1	1	1	
			05.INERTIA	2	2	2	2	2	2	2	
			06.INABILITY TO FEEL	0	1	1	1	1	1	1	
			07.PESSIMISTIC THOUGHTS	0	1	1	1	1	2	2	
			08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2	
			09.REDUCED SLEEP	3	2	2	2	2	2	2	

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
1	12	Reboxetine	Male	10. REDUCED APPETITE	1	1	1	1	1	1	1	1
				11. Total score	14	15	14	17	17	17	17	
				01. REPORTED SADNESS	1	1	0	0	0	0	0	
				02. INNER TENSION	2	1	1	1	1	1	1	
				03. APPARENT SADNESS	2	1	1	1	1	1	1	
				04. SUICIDAL THOUGHTS	3	0	0	0	0	0	0	
				05. INERTIA	1	0	0	0	0	0	0	
				06. INABILITY TO FEEL	2	1	0	0	1	1	1	
				07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	
				08. CONCENTRATIONS DIFFICULTIES	0	0	0	0	0	0	0	
				09. REDUCED SLEEP	2	1	1	1	1	1	1	
10. REDUCED APPETITE	1	1	0	0	1	0	0					
11. Total score	15	7	4	3	8	6	2					
2	33	Reboxetine	Male	01. REPORTED SADNESS	1	1	0	0	1	1	0	
				02. INNER TENSION	2	1	1	1	1	1	1	
				03. APPARENT SADNESS	2	1	1	1	2	1	0	
				04. SUICIDAL THOUGHTS	3	0	0	0	0	0	0	
				05. INERTIA	1	0	0	0	0	0	0	
				06. INABILITY TO FEEL	2	1	0	0	1	1	1	
				07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	
				08. CONCENTRATIONS DIFFICULTIES	0	0	0	0	0	0	0	
				09. REDUCED SLEEP	2	1	1	1	1	1	1	
				10. REDUCED APPETITE	1	1	0	0	1	0	0	
				11. Total score	15	7	4	3	8	6	2	
34	34	Imipramine	Male	01. REPORTED SADNESS	2	0	1	0	1	1	1	
				02. INNER TENSION	2	1	1	1	1	1	1	
				03. APPARENT SADNESS	4	1	1	0	1	1	1	
				04. SUICIDAL THOUGHTS	2	0	0	0	0	1	1	
				05. INERTIA	2	1	0	0	0	1	1	
				06. INABILITY TO FEEL	1	0	0	0	0	0	0	
				07. PESSIMISTIC THOUGHTS	1	1	1	1	1	2	1	
				08. CONCENTRATIONS DIFFICULTIES	1	1	1	0	0	0	0	
				09. REDUCED SLEEP	1	1	0	0	0	1	1	
				10. REDUCED APPETITE	1	0	0	0	0	0	0	
				11. Total score	14	5	5	2	5	8	7	
35	35	Reboxetine	Male	01. REPORTED SADNESS	3	1	0	0	0	0	1	
				02. INNER TENSION	2	1	1	1	1	1	0	
				03. APPARENT SADNESS	2	1	0	1	1	1	1	
				04. SUICIDAL THOUGHTS	2	1	0	0	0	0	0	
				05. INERTIA	2	1	0	0	0	0	0	
				06. INABILITY TO FEEL	2	0	0	0	0	0	0	
				07. PESSIMISTIC THOUGHTS	2	1	0	1	1	1	0	
				08. CONCENTRATIONS DIFFICULTIES	2	1	0	0	0	0	0	
				09. REDUCED SLEEP	1	0	0	1	0	1	1	
				10. REDUCED APPETITE	2	0	0	0	0	0	0	
				11. Total score	20	7	1	4	3	4	3	
36	36	Imipramine	Female	01. REPORTED SADNESS	2	2	0	0	0	0	0	
				02. INNER TENSION	2	2	0	1	1	1	1	
				03. APPARENT SADNESS	2	2	1	0	1	1	1	
				04. SUICIDAL THOUGHTS	0	1	0	0	0	0	0	
				05. INERTIA	2	2	1	0	0	0	0	
				06. INABILITY TO FEEL	1	1	0	0	0	0	0	
				07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	
				08. CONCENTRATIONS DIFFICULTIES	2	2	0	0	0	0	0	

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 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
2	36	Imipramine	Female	09. REDUCED SLEEP	2	1	1	1				
				10. REDUCED APPETITE	2	2	0	0				
				11. Total score	16	16	4	4				
37	Reboxetine	Male	01. REPORTED SADNESS	2	1	2	1	1	2	1	1	
			02. INNER TENSION	3	2	2	2	2	1	1	1	
			03. APPARENT SADNESS	2	1	1	1	2	1	1	1	
			04. SUICIDAL THOUGHTS	3	0	1	1	0	1	0	1	0
			05. INERTIA	2	0	0	1	1	1	1	1	0
			06. INABILITY TO FEEL	2	1	1	1	1	1	1	1	1
			07. PESSIMISTIC THOUGHTS	1	0	1	0	1	1	1	1	1
			08. CONCENTRATIONS DIFFICULTIES	1	2	1	1	2	1	1	2	1
			09. REDUCED SLEEP	2	3	2	2	2	1	1	1	1
			10. REDUCED APPETITE	1	1	0	0	1	1	1	1	0
			11. Total score	19	11	11	10	12	10	10	12	10
38	Imipramine	Female	01. REPORTED SADNESS	1	1	2	2	2	3	3	2	
			02. INNER TENSION	2	1	2	2	2	2	2	2	2
			03. APPARENT SADNESS	1	1	2	2	2	2	2	2	1
			04. SUICIDAL THOUGHTS	1	1	1	2	2	2	2	2	1
			05. INERTIA	2	1	1	2	2	2	2	2	2
			06. INABILITY TO FEEL	2	2	2	2	2	2	2	2	2
			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	3	2	2	2	2	2	2	2	2
			10. REDUCED APPETITE	1	1	2	2	2	2	2	2	2
			11. Total score	16	13	17	19	20	19	16	19	16
39	Reboxetine	Female	01. REPORTED SADNESS	3	2	2	1	1	1	1	1	
			02. INNER TENSION	2	2	2	1	1	1	1	1	1
			03. APPARENT SADNESS	3	2	1	1	1	1	1	1	1
			04. SUICIDAL THOUGHTS	2	1	1	0	0	0	0	0	0
			05. INERTIA	2	2	2	1	1	1	1	1	1
			06. INABILITY TO FEEL	2	1	1	1	1	1	1	1	0
			07. PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1	1	1
			08. CONCENTRATIONS DIFFICULTIES	3	2	2	2	2	1	1	1	1
			09. REDUCED SLEEP	2	2	2	2	1	1	1	1	1
			10. REDUCED APPETITE	2	1	1	1	1	1	1	1	1
			11. Total score	23	17	15	10	9	9	8	9	8
40	Imipramine	Male	01. REPORTED SADNESS	2	1	2	1	1	3	2	1	
			02. INNER TENSION	1	1	1	1	2	2	1	1	
			03. APPARENT SADNESS	2	1	1	1	1	1	1	1	
			04. SUICIDAL THOUGHTS	2	2	2	2	2	2	2	2	
			05. INERTIA	2	1	1	1	1	1	1	1	
			06. INABILITY TO FEEL	1	1	1	1	1	1	1	1	
			07. PESSIMISTIC THOUGHTS	2	1	1	1	1	1	1	1	

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
2	40	Imipramine	Male	08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	0
				09. REDUCED SLEEP	2	1	1	1	1	1	1
				10. REDUCED APPETITE	1	1	1	1	1	0	
				11. Total score	16	11	13	12	18	15	5
				01. REPORTED SADNESS	2	2	1	1	1	2	1
				02. INNER TENSION	2	2	2	2	2	1	2
				03. APPARENT SADNESS	2	2	1	1	1	1	2
				04. SUICIDAL THOUGHTS	1	1	2	1	1	1	1
				05. INERTIA	1	2	2	1	1	2	1
				06. INABILITY TO FEEL	2	2	2	1	1	2	1
				07. PESSIMISTIC THOUGHTS	2	2	2	1	1	1	1
41	Reboxetine	Male	08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	2	1	3	
			09. REDUCED SLEEP	2	1	2	1	1	1	2	
			10. REDUCED APPETITE	1	1	2	1	1	1	2	
			11. Total score	16	17	16	10	12	14	15	
			01. REPORTED SADNESS	2	2	2	2	2	2	1	
			02. INNER TENSION	2	2	2	2	2	2	1	
			03. APPARENT SADNESS	2	2	2	2	2	2	1	
			04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0	
			05. INERTIA	2	2	1	1	2	1	1	
			06. INABILITY TO FEEL	2	2	2	2	2	2	1	
			07. PESSIMISTIC THOUGHTS	1	2	1	2	2	2	1	
42	Imipramine	Male	08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	1	
			09. REDUCED SLEEP	2	3	2	2	2	0	1	
			10. REDUCED APPETITE	1	1	1	1	2	1	0	
			11. Total score	16	18	15	17	14	11	6	
			01. REPORTED SADNESS	2	2	2	2	2	2	1	
			02. INNER TENSION	2	2	2	2	2	2	1	
			03. APPARENT SADNESS	2	2	2	2	2	2	1	
			04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0	
			05. INERTIA	2	2	2	1	2	1	1	
			06. INABILITY TO FEEL	2	2	2	2	2	2	1	
			07. PESSIMISTIC THOUGHTS	1	2	1	2	2	2	1	
43	Reboxetine	Female	08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	0	
			09. REDUCED SLEEP	2	3	2	2	2	0	1	
			10. REDUCED APPETITE	1	1	1	1	2	1	0	
			11. Total score	16	18	15	17	14	11	6	
			01. REPORTED SADNESS	2	1	1	1	1	1	1	
			02. INNER TENSION	2	1	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	1	1	0	0	0	0	0	
			06. INABILITY TO FEEL	1	1	1	1	1	1	1	
			07. PESSIMISTIC THOUGHTS	2	2	0	0	0	0	0	
44	Imipramine	Male	08. CONCENTRATIONS DIFFICULTIES	1	2	1	1	1	1	0	
			09. REDUCED SLEEP	1	0	0	0	0	0	0	
			10. REDUCED APPETITE	1	0	0	0	0	0	0	
			11. Total score	13	9	3	3	3	2	3	
			01. REPORTED SADNESS	2	2	2	2	2	2	2	
			02. INNER TENSION	2	2	2	2	2	2	2	
			03. APPARENT SADNESS	1	1	2	2	2	2	2	
			04. SUICIDAL THOUGHTS	1	1	2	2	2	2	2	
			05. INERTIA	1	2	2	2	2	2	2	
			06. INABILITY TO FEEL	2	2	2	2	2	2	2	

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PHARMACIA CNS RED
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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
2	44	Imipramine	Male	07.PESSIMISTIC THOUGHTS	2	2									
				08.CONCENTRATIONS DIFFICULTIES	2	1									
				09.REDUCED SLEEP	2	1									
				10.REDUCED APPETITE	1	2									
				11.Total score	17	18									
				45	Imipramine	Female	01.REPORTED SADNESS	2	1						
							02.INNER TENSION	2	1						
							03.APPARENT SADNESS	2	1						
							04.SUICIDAL THOUGHTS	1	0						
							05.INERTIA	1	1						
							06.INABILITY TO FEEL	1	0						
07.PESSIMISTIC THOUGHTS	2	1													
08.CONCENTRATIONS DIFFICULTIES	1	1													
09.REDUCED SLEEP	1	1													
10.REDUCED APPETITE	1	1													
11.Total score	14	8													
46	Reboxetine	Female	01.REPORTED SADNESS	2	1	2	1	1	1	1	1	1			
			02.INNER TENSION	1	2	1	1	1	1	1	1	1			
			03.APPARENT SADNESS	2	2	2	2	2	2	2	2	2			
			04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0	0			
			05.INERTIA	1	1	1	1	1	1	1	1	1			
			06.INABILITY TO FEEL	1	2	2	2	2	2	2	2	2			
			07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	1	1			
			08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1	1	1			
			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	12	13	13	10	7	6	6	6	6			
47	Reboxetine	Female	01.REPORTED SADNESS	2	3	1	1	1	1	0	0				
			02.INNER TENSION	2	2	2	2	2	2	2	2	2			
			03.APPARENT SADNESS	2	2	2	2	2	2	2	2	2			
			04.SUICIDAL THOUGHTS	0	1	0	0	0	0	0	0	0			
			05.INERTIA	1	1	1	1	1	1	1	1	1			
			06.INABILITY TO FEEL	1	1	1	1	1	1	1	1	1			
			07.PESSIMISTIC THOUGHTS	2	2	2	2	2	2	2	2	2			
			08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1	1	1			
			09.REDUCED SLEEP	2	3	2	2	2	2	2	2	2			
			10.REDUCED APPETITE	1	1	1	1	1	1	1	1	1			
			11.Total score	14	17	9	5	3	2	2	2	2			
48	Imipramine	Female	01.REPORTED SADNESS	2	2	1	1	1	0	0	1				
			02.INNER TENSION	1	2	1	1	1	1	1	1				
			03.APPARENT SADNESS	2	2	2	2	2	2	2	2				
			04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0				
			05.INERTIA	2	2	2	2	2	2	2	2				

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
2	48	Imipramine	Female	06. INABILITY TO FEEL	2	2	0	0	0	0	0				
				07. PESSIMISTIC THOUGHTS	1	1	1	0	0	1	1				
				08. CONCENTRATIONS DIFFICULTIES	2	1	1	0	0	0	1				
				09. REDUCED SLEEP	2	0	1	1	0	0	0				
				10. REDUCED APPETITE	1	1	0	0	0	0	0				
				11. Total score	16	13	7	4	2	4	5				
				49	Imipramine	Female	01. REPORTED SADNESS	2	1	1	0	0	1	1	1
							02. INNER TENSION	2	1	1	1	1	1	1	
							03. APPARENT SADNESS	2	1	1	1	0	1	1	
							04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0	
							05. INERTIA	2	1	1	1	0	1	0	
06. INABILITY TO FEEL	2	1	1				1	0	0	0					
07. PESSIMISTIC THOUGHTS	2	1	1				1	1	1	0					
08. CONCENTRATIONS DIFFICULTIES	1	0	1				0	1	0	0					
09. REDUCED SLEEP	2	1	1				1	2	2	1					
10. REDUCED APPETITE	1	1	1				1	0	1	0					
11. Total score	16	8	9				7	6	8	4					
50	Reboxetine	Male	01. REPORTED SADNESS	2	3	3	2	2	2	2	2				
			02. INNER TENSION	1	2	2	2	1	2	2					
			03. APPARENT SADNESS	2	2	2	2	2	2	2					
			04. SUICIDAL THOUGHTS	1	1	2	1	1	1	1					
			05. INERTIA	2	1	1	1	1	1	1					
			06. INABILITY TO FEEL	2	1	2	1	1	1	1					
			07. PESSIMISTIC THOUGHTS	2	2	2	2	2	1	1					
			08. CONCENTRATIONS DIFFICULTIES	2	1	2	1	1	1	0					
			09. REDUCED SLEEP	2	3	3	3	2	2	2					
			10. REDUCED APPETITE	1	1	1	1	1	1	1					
			11. Total score	17	17	20	15	14	13						
51	Reboxetine	Female	01. REPORTED SADNESS	2	2	3	2	2	2	2	2				
			02. INNER TENSION	2	2	2	2	2	2	2					
			03. APPARENT SADNESS	1	2	3	2	2	2	2					
			04. SUICIDAL THOUGHTS	1	1	3	1	1	1	1					
			05. INERTIA	2	2	3	2	2	2	2					
			06. INABILITY TO FEEL	3	2	3	2	2	2	2					
			07. PESSIMISTIC THOUGHTS	2	2	3	2	2	2	2					
			08. CONCENTRATIONS DIFFICULTIES	2	1	2	2	1	1	1					
			09. REDUCED SLEEP	2	3	3	3	2	2	2					
			10. REDUCED APPETITE	1	1	1	1	1	1	1					
			11. Total score	19	17	27	15	14	13						
52	Imipramine	Male	01. REPORTED SADNESS	2	1	0	0	0	0	1	0				
			02. INNER TENSION	1	1	1	1	0	0	0					
			03. APPARENT SADNESS	2	1	0	0	0	1	0					
			04. SUICIDAL THOUGHTS	2	0	0	0	0	0	0					

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
2	52	Imipramine	Male	05. INERTIA	2	1	1	0	0	0	0	0				
				06. INABILITY TO FEEL	2	1	0	0	0	0	0					
				07. PESSIMISTIC THOUGHTS	2	1	0	0	1	0	0					
				08. CONCENTRATIONS DIFFICULTIES	1	0	0	0	0	0	0					
				09. REDUCED SLEEP	2	1	1	1	1	0	0					
				10. REDUCED APPETITE	1	1	0	0	0	0	0					
				11. Total score	17	8	3	2	2	2	0					
				3	65	Reboxetine	Male	01. REPORTED SADNESS	2	1	0	0	1	0	0	0
								02. INNER TENSION	2	1	0	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	1	1	0					0	0	0	0					
06. INABILITY TO FEEL	1	1	0					0	1	0	0					
07. PESSIMISTIC THOUGHTS	1	0	0					1	0	0	0					
08. CONCENTRATIONS DIFFICULTIES	1	1	1					0	0	0	0					
09. REDUCED SLEEP	2	1	2					1	2	2	1					
10. REDUCED APPETITE	1	2	0					0	0	0	0					
11. Total score	12	10	3					4	4	2	1					
66	66	Imipramine	Female	01. REPORTED SADNESS	1	0	0	0	1	3						
				02. INNER TENSION	1	0	1	0	1	3						
				03. APPARENT SADNESS	1	0	0	0	1	3						
				04. SUICIDAL THOUGHTS	2	0	0	0	0	2						
				05. INERTIA	2	1	0	0	0	3						
				06. INABILITY TO FEEL	2	0	0	0	0	3						
				07. PESSIMISTIC THOUGHTS	1	1	0	0	0	3						
				08. CONCENTRATIONS DIFFICULTIES	1	0	0	0	1	2						
				09. REDUCED SLEEP	2	2	0	0	0	1						
				10. REDUCED APPETITE	1	0	0	0	0	3						
				11. Total score	14	4	1	0	4	26						
67	67	Reboxetine	Female	01. REPORTED SADNESS	1	0	2	1	2	1	2					
				02. INNER TENSION	3	1	1	1	1	2						
				03. APPARENT SADNESS	1	2	1	1	1	2						
				04. SUICIDAL THOUGHTS	1	1	0	0	0	1						
				05. INERTIA	2	1	1	1	0	2						
				06. INABILITY TO FEEL	3	2	2	1	1	2						
				07. PESSIMISTIC THOUGHTS	3	2	2	1	1	2						
				08. CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	2						
				09. REDUCED SLEEP	3	2	1	2	1	2						
				10. REDUCED APPETITE	1	0	0	0	0	0						
				11. Total score	18	12	11	9	9	13	15					
68	68	Imipramine	Female	01. REPORTED SADNESS	3	2	3	2	2	2	2					
				02. INNER TENSION	3	1	2	2	3	3						
				03. APPARENT SADNESS	2	2	2	2	2	2						

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
3	68	Imipramine	Female	04. SUICIDAL THOUGHTS	1	2	1	1	1	1	1
				05. INERTIA	2	3	3	3	3	3	
				06. INABILITY TO FEEL	3	3	3	3	3	3	
				07. PESSIMISTIC THOUGHTS	3	2	2	1	2	2	
				08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	
				09. REDUCED SLEEP	3	2	3	2	1	1	
				10. REDUCED APPETITE	3	2	0	2	1	2	
				11. Total score	25	21	21	20	20	20	
				01. REPORTED SADNESS	2	3	1	1	0	1	
				02. INNER TENSION	2	3	2	1	0	1	
				03. APPARENT SADNESS	2	2	1	1	0	1	
69	Imipramine	Female	04. SUICIDAL THOUGHTS	2	2	1	1	0	1	1	0
			05. INERTIA	2	2	1	1	0	1	1	
			06. INABILITY TO FEEL	2	2	1	1	0	1	1	
			07. PESSIMISTIC THOUGHTS	2	2	2	1	1	1	0	
			08. CONCENTRATIONS DIFFICULTIES	2	2	2	1	0	1	1	
			09. REDUCED SLEEP	2	2	2	2	1	0	2	
			10. REDUCED APPETITE	3	2	2	2	1	0	0	
			11. Total score	22	21	15	8	1	11	4	
			01. REPORTED SADNESS	2	3	2	2	2	2		
			02. INNER TENSION	2	3	2	2	2	2		
			03. APPARENT SADNESS	2	2	2	1	1	1		
70	Reboxetine	Female	04. SUICIDAL THOUGHTS	2	2	1	1	1	1	1	1
			05. INERTIA	2	3	2	2	2	2		
			06. INABILITY TO FEEL	2	3	3	2	2	2		
			07. PESSIMISTIC THOUGHTS	2	2	2	2	2	2		
			08. CONCENTRATIONS DIFFICULTIES	1	2	1	1	1	1		
			09. REDUCED SLEEP	2	3	3	3	3	2		
			10. REDUCED APPETITE	1	2	2	1	2	2		
			11. Total score	17	25	20	17	17	17		
			01. REPORTED SADNESS	2	3	2	2	2	2		
			02. INNER TENSION	2	3	2	2	2	2		
			03. APPARENT SADNESS	2	2	2	1	1	1		
71	Imipramine	Female	04. SUICIDAL THOUGHTS	1	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	0	0	1	0	0	0	
			08. CONCENTRATIONS DIFFICULTIES	2	1	0	0	0	0	0	
			09. REDUCED SLEEP	1	0	0	0	0	0	0	
			10. REDUCED APPETITE	1	0	0	0	0	0	0	
			11. Total score	15	5	0	0	0	0	0	
			01. REPORTED SADNESS	1	0	0	1	0	0	0	
			02. INNER TENSION	2	1	0	0	0	0	0	
			03. APPARENT SADNESS	1	1	0	1	0	0	0	
72	Reboxetine	Female	01. REPORTED SADNESS	2	1	1	1	1	1	2	1
			02. INNER TENSION	2	2	2	2	2	2	1	

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REBOXETINE - PROTOCOL 20124-017
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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
3	72	Reboxetine	Female	03.APPARENT SADNESS	2	1	1	1	1	1	2	1				
				04.SUICIDAL THOUGHTS	1	1	1	1	1	2	1	0				
				05.INERTIA	2	2	2	2	1	2	1	1				
				06.INABILITY TO FEEL	1	1	2	2	1	1	0	1				
				07.PESSIMISTIC THOUGHTS	2	1	1	1	1	2	1	1				
				08.CONCENTRATIONS DIFFICULTIES	1	0	1	0	1	1	0	0				
				09.REDUCED SLEEP	1	2	1	1	1	1	1	1				
				10.REDUCED APPETITE	2	1	2	2	1	1	0	1				
				11.Total score	16	13	15	12	13	10	8					
				73	Reboxetine	Female	01.REPORTED SADNESS	2	1	1	1	0	0	0	0	0
							02.INNER TENSION	1	1	1	1	1	0	0	0	0
03.APPARENT SADNESS	1	1	0				0	0	0	0	0					
04.SUICIDAL THOUGHTS	1	0	0				0	0	0	0	0					
05.INERTIA	2	2	1				1	1	0	1	0					
06.INABILITY TO FEEL	3	1	0				0	0	0	0	0					
07.PESSIMISTIC THOUGHTS	2	1	1				1	1	1	1	0					
08.CONCENTRATIONS DIFFICULTIES	1	0	1				1	1	1	0	0					
09.REDUCED SLEEP	1	1	1				1	1	1	0	0					
10.REDUCED APPETITE	0	0	0				1	0	0	0	0					
11.Total score	14	8	6				5	3	2	0						
4	97	Imipramine	Male	01.REPORTED SADNESS	2	2	2	2	2	2	1	1				
				02.INNER TENSION	1	1	1	1	2	1	2	2				
				03.APPARENT SADNESS	2	2	2	2	2	2	2	2				
				04.SUICIDAL THOUGHTS	1	1	1	1	1	1	1	1				
				05.INERTIA	2	2	1	2	2	2	2	3				
				06.INABILITY TO FEEL	3	3	2	3	2	2	3	3				
				07.PESSIMISTIC THOUGHTS	1	2	1	2	2	0	0	0				
				08.CONCENTRATIONS DIFFICULTIES	2	2	1	2	2	2	3	3				
				09.REDUCED SLEEP	2	2	2	2	2	2	2	2				
				10.REDUCED APPETITE	2	1	1	1	0	1	2	2				
				11.Total score	18	18	15	18	17	15	18					
100	Reboxetine	Female	01.REPORTED SADNESS	3	3	2	2	2	0	0	0					
			02.INNER TENSION	2	3	2	1	1	1	1	0					
			03.APPARENT SADNESS	2	2	2	2	1	1	0	0					
			04.SUICIDAL THOUGHTS	2	2	2	2	1	1	1	1					
			05.INERTIA	3	3	3	3	1	1	0	0					
			06.INABILITY TO FEEL	3	3	3	3	1	1	0	1					
			07.PESSIMISTIC THOUGHTS	2	2	2	1	1	1	0	1					
			08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	1	0					
			09.REDUCED SLEEP	3	3	3	2	2	2	2	2					
			10.REDUCED APPETITE	3	3	3	0	0	0	0	0					
			11.Total score	25	26	23	14	9	5	5						
101	Imipramine	Female	01.REPORTED SADNESS	2	2	2	2	3	0	0	0					

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 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
4	101	Imipramine	Female	02.INNER TENSION	1	2	2	2	0	0	0	1	
				03.APPARENT SADNESS	1	1	2	2	0	0	2	1	
				04.SUICIDAL THOUGHTS	2	2	2	3	0	0	2	1	
				05.ENERGIA	2	2	1	1	0	0	1	1	
				06.INABILITY TO FEEL	1	1	2	2	0	0	1	1	
				07.PESSIMISTIC THOUGHTS	1	1	0	0	0	0	0	0	
				08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	0	0	1	1	
				09.REDUCED SLEEP	2	2	2	2	0	0	2	2	
				10.REDUCED APPETITE	1	2	2	2	0	0	2	2	
				11.Total score	14	16	16	19					
				6	161	Reboxetine	Male	01.REPORTED SADNESS	2	0	0	0	0
02.INNER TENSION	2	1	1					1	0	0	2	1	
03.APPARENT SADNESS	2	1	0					1	0	0	1	1	
04.SUICIDAL THOUGHTS	1	0	0					0	0	0	0	0	
05.ENERGIA	2	1	0					0	0	0	1	1	
06.INABILITY TO FEEL	2	0	0					0	0	0	1	1	
07.PESSIMISTIC THOUGHTS	1	0	0					1	0	0	1	1	
08.CONCENTRATIONS DIFFICULTIES	2	1	0					0	0	0	0	0	
09.REDUCED SLEEP	3	2	2					2	0	0	1	2	
10.REDUCED APPETITE	3	1	1					1	0	0	1	2	
11.Total score	20	7	5					6	2	10	9		
162	Reboxetine	Female	01.REPORTED SADNESS	2	1	0	0	0	0	0	0	0	
			02.INNER TENSION	2	2	1	1	0	0	0	1		
			03.APPARENT SADNESS	2	1	1	1	0	0	0	0		
			04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0	0		
			05.ENERGIA	2	1	1	1	0	0	1	1		
			06.INABILITY TO FEEL	2	2	1	1	0	0	0	0		
			07.PESSIMISTIC THOUGHTS	2	1	0	0	0	0	0	0		
			08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	1	1		
			09.REDUCED SLEEP	2	2	2	2	1	1	1	1		
			10.REDUCED APPETITE	2	1	1	1	1	1	0	0		
			11.Total score	18	13	8	5	2	2	4			
7	193	Reboxetine	Female	01.REPORTED SADNESS	0								
				02.INNER TENSION	3								
				03.APPARENT SADNESS	2								
				04.SUICIDAL THOUGHTS	2								
				05.ENERGIA	2								
				06.INABILITY TO FEEL	2								
				07.PESSIMISTIC THOUGHTS	1								
				08.CONCENTRATIONS DIFFICULTIES	2								
				09.REDUCED SLEEP	0								
				10.REDUCED APPETITE	0								
				11.Total score	13								

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
7	194	Reboxetine	Male	01. REPORTED SADNESS	1								
				02. INNER TENSION	1								
				03. APPARENT SADNESS	1								
				04. SUICIDAL THOUGHTS	2								
				05. INERTIA	2								
				06. INABILITY TO FEEL	1								
				07. PESSIMISTIC THOUGHTS	1								
				08. CONCENTRATIONS DIFFICULTIES	1								
				09. REDUCED SLEEP	1								
				10. REDUCED APPETITE	0								
				11. Total score	11								
B	196	Imipramine	Female	01. REPORTED SADNESS	2	1	0	1	1	1	1	1	
				02. INNER TENSION	1	1	1	1	1	1	1	1	1
				03. APPARENT SADNESS	2	1	1	1	1	1	1	1	1
				04. SUICIDAL THOUGHTS	2	0	0	0	0	0	0	0	0
				05. INERTIA	2	1	1	1	1	1	1	1	1
				06. INABILITY TO FEEL	2	1	1	0	0	0	0	0	0
				07. PESSIMISTIC THOUGHTS	1	0	0	0	0	0	0	0	0
				08. CONCENTRATIONS DIFFICULTIES	2	1	1	0	0	0	0	0	0
				09. REDUCED SLEEP	1	0	0	0	0	0	0	0	0
				10. REDUCED APPETITE	1	0	0	0	0	0	0	0	0
				11. Total score	16	6	5	4	4	4	4	4	6
B	225	Imipramine	Female	01. REPORTED SADNESS	2	2	0						
				02. INNER TENSION	2	2	1						
				03. APPARENT SADNESS	2	2	0						
				04. SUICIDAL THOUGHTS	1	2	0						
				05. INERTIA	2	1	1						
				06. INABILITY TO FEEL	2	2	1						
				07. PESSIMISTIC THOUGHTS	1	1	0						
				08. CONCENTRATIONS DIFFICULTIES	1	2	0						
				09. REDUCED SLEEP	2	0	0						
				10. REDUCED APPETITE	2	1	1						
				11. Total score	17	15	4						
7	226	Reboxetine	Female	01. REPORTED SADNESS	2	2	1	2	1	2	2	2	
				02. INNER TENSION	2	2	2	2	1	2	1	2	1
				03. APPARENT SADNESS	2	2	1	2	2	2	2	2	2
				04. SUICIDAL THOUGHTS	1	1	0	1	1	1	2	1	1
				05. INERTIA	2	2	2	2	2	2	1	1	1
				06. INABILITY TO FEEL	2	2	1	2	1	2	1	2	2
				07. PESSIMISTIC THOUGHTS	2	2	0	2	1	2	1	2	2
				08. CONCENTRATIONS DIFFICULTIES	0	1	1	1	1	1	0	0	0
				09. REDUCED SLEEP	2	2	1	2	2	2	2	1	1
				10. REDUCED APPETITE	1	1	1	1	1	1	1	1	0
				11. Total score	16	17	10	17	13	15	12		

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
8	227	Imipramine	Male	01.REPORTED SADNESS	2	1	1	2	1	1	1	1
				02.INNER TENSION	3	1	1	2	1	1	1	1
				03.APPARENT SADNESS	3	1	1	2	1	1	1	0
				04.SUICIDAL THOUGHTS	1	1	1	1	1	1	0	0
				05.INERTIA	1	1	1	1	1	1	1	0
				06.INABILITY TO FEEL	1	1	1	2	1	1	1	0
				07.PESSIMISTIC THOUGHTS	2	1	1	2	1	1	1	1
				08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	1	0
				09.REDUCED SLEEP	1	1	1	2	1	1	1	1
				10.REDUCED APPETITE	1	1	0	0	1	1	1	1
				11.Total score	17	11	9	16	10	9	5	
228	Reboxetine	Male	01.REPORTED SADNESS	2	2	2	2	1	1	1	1	
			02.INNER TENSION	2	3	3	1	1	1	1		
			03.APPARENT SADNESS	2	1	1	1	1	1	1		
			04.SUICIDAL THOUGHTS	2	1	1	1	1	1	1		
			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	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	1	2	2	1	1	1	1		
			11.Total score	19	18	18	18	18	18	18		
229	Imipramine	Female	01.REPORTED SADNESS	2	2	2	2	1	1	1	1	
			02.INNER TENSION	2	2	2	1	1	1	1		
			03.APPARENT SADNESS	2	1	1	2	1	1	1		
			04.SUICIDAL THOUGHTS	3	1	0	1	0	1	0		
			05.INERTIA	2	2	1	1	1	1	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	1	0	0	1		
			09.REDUCED SLEEP	1	1	0	1	1	1	0		
			10.REDUCED APPETITE	1	0	0	0	0	0	0		
			11.Total score	17	12	7	9	6	5	6		
230	Imipramine	Female	01.REPORTED SADNESS	3	2	2	1	1	0	0	0	
			02.INNER TENSION	2	1	1	1	1	1	1		
			03.APPARENT SADNESS	2	2	1	1	1	0	0		
			04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0		
			05.INERTIA	3	2	1	1	0	0	0		
			06.INABILITY TO FEEL	2	1	1	1	1	0	0		
			07.PESSIMISTIC THOUGHTS	2	1	1	1	1	1	1		
			08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	0	0	0		
			09.REDUCED SLEEP	2	1	1	0	0	1	0		
			10.REDUCED APPETITE	0	0	0	0	0	0	0		

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REBOXETINE - PROTOCOL 20124/017
Listing No.: 15.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
8	230	Imipramine	Female	11.Total score	19	11	7	5	3	2	2
	231	Reboxetine	Female	01.REPORTED SADNESS	2	1					
				02.INNER TENSION	2	1					
				03.APPARENT SADNESS	2	1					
				04.SUICIDAL THOUGHTS	1	1					
				05.INERTIA	2	1					
				06.INABILITY TO FEEL	1	1					
				07.PESSIMISTIC THOUGHTS	2	1					
				08.CONCENTRATIONS DIFFICULTIES	2	2					
				09.REDUCED SLEEP	2	2					
				10.REDUCED APPETITE	0	0					
				11.Total score	16	10					
	232	Reboxetine	Male	01.REPORTED SADNESS	2	2	2	2	1	1	1
				02.INNER TENSION	2	1	2	1	1	1	1
				03.APPARENT SADNESS	2	1	2	1	1	1	1
				04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0
				05.INERTIA	2	2	1	2	1	1	1
				06.INABILITY TO FEEL	2	2	2	2	1	1	1
				07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	0
				08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	2	2	1
				09.REDUCED SLEEP	3	3	2	2	1	1	2
				10.REDUCED APPETITE	2	1	1	1	2	1	1
				11.Total score	18	14	14	14	10	10	9
9	197	Reboxetine	Male	01.REPORTED SADNESS	3	2					
				02.INNER TENSION	2	1					
				03.APPARENT SADNESS	2	2					
				04.SUICIDAL THOUGHTS	0	1					
				05.INERTIA	2	2					
				06.INABILITY TO FEEL	0	1					
				07.PESSIMISTIC THOUGHTS	1	2					
				08.CONCENTRATIONS DIFFICULTIES	1	0					
				09.REDUCED SLEEP	0	0					
				10.REDUCED APPETITE	0	1					
				11.Total score	12	14					
	198	Imipramine	Female	01.REPORTED SADNESS	1	1	1	1	0	0	0
				02.INNER TENSION	2	1	1	1	0	0	0
				03.APPARENT SADNESS	1	1	1	1	0	0	0
				04.SUICIDAL THOUGHTS	2	1	2	1	0	0	0
				05.INERTIA	2	1	1	1	0	0	0
				06.INABILITY TO FEEL	1	2	2	1	0	0	0
				07.PESSIMISTIC THOUGHTS	2	1	1	1	0	0	0
				08.CONCENTRATIONS DIFFICULTIES	2	2	1	2	0	0	0
				09.REDUCED SLEEP	2	2	1	2	0	0	0

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20426/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
9	198	Imipramine	Female	10. REDUCED APPETITE	0	1	2	0	0	0	0	
				11. Total score	15	15	13	11	0	0	0	
	199	Imipramine	Male	01. REPORTED SADNESS	2	2	2	2	2	1	2	1
				02. INNER TENSION	2	2	2	2	1	2	2	
				03. APPARENT SADNESS	2	2	2	2	1	2	2	
				04. SUICIDAL THOUGHTS	1	1	1	1	1	1	1	
				05. INERTIA	2	2	2	2	1	2	2	
				06. INABILITY TO FEEL	2	2	2	2	1	2	2	
				07. PESSIMISTIC THOUGHTS	2	2	2	2	1	2	2	
				08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	2	2	
				09. REDUCED SLEEP	1	2	2	1	1	1	1	
10. REDUCED APPETITE				0	1	0	0	0	0	0		
11. Total score	16	18	16	15	10	16	14					
200	Reboxetine	Male	01. REPORTED SADNESS	3	3	2	2	1	1	1	1	
			02. INNER TENSION	2	2	1	1	1	1	1		
			03. APPARENT SADNESS	2	2	1	1	0	0	0		
			04. SUICIDAL THOUGHTS	1	1	0	0	0	0	0		
			05. INERTIA	2	1	1	0	0	0	0		
			06. INABILITY TO FEEL	2	2	1	0	0	0	0		
			07. PESSIMISTIC THOUGHTS	3	3	2	1	0	0	0		
			08. CONCENTRATIONS DIFFICULTIES	1	1	0	0	0	0	0		
			09. REDUCED SLEEP	2	2	2	2	0	0	0		
			10. REDUCED APPETITE	1	1	1	1	0	0	0		
			11. Total score	19	18	11	5	2	2	2		
201	Imipramine	Female	01. REPORTED SADNESS	1	2	0	0	0	0	1	0	
			02. INNER TENSION	1	2	2	2	1	1	1	0	
			03. APPARENT SADNESS	1	1	0	0	0	0	0		
			04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0		
			05. INERTIA	2	1	2	1	1	1	0		
			06. INABILITY TO FEEL	0	0	0	0	1	0	0		
			07. PESSIMISTIC THOUGHTS	1	1	1	0	1	0	0		
			08. CONCENTRATIONS DIFFICULTIES	1	1	0	0	1	1	1		
			09. REDUCED SLEEP	1	1	0	0	0	0	0		
			10. REDUCED APPETITE	0	0	0	0	0	0	0		
			11. Total score	8	9	5	5	6	4	1		
202	Imipramine	Male	01. REPORTED SADNESS	2	3	0	0	0	2	2	1	
			02. INNER TENSION	2	1	1	1	2	2	1		
			03. APPARENT SADNESS	2	2	0	0	1	1	1		
			04. SUICIDAL THOUGHTS	0	1	0	0	1	1	1		
			05. INERTIA	1	1	1	0	1	2	2		
			06. INABILITY TO FEEL	1	2	0	0	1	1	1		
			07. PESSIMISTIC THOUGHTS	3	2	1	1	1	2	1		
			08. CONCENTRATIONS DIFFICULTIES	3	1	1	0	0	1	1		

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9	202	Imipramine	Male	09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 0 16	1 0 14	1 0 5	1 0 4	0 1 10	0 1 13	0 0 10
	203	Reboxetine	Female	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 1 1 0 11	3 2 3 0 1 1 2 1 1 1 17					
	204	Reboxetine	Male	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	1 2 1 0 1 2 1 1 1 0 11	1 1 1 0 0 0 1 1 1 0 5	0 0 0 0 0 2 1 1 0 0 4	0 0 0 0 0 0 0 0 1 0 1	0 0 0 0 0 0 0 0 1 0 1	0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0
	205	Imipramine	Female	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 0 0 1 0 0 1 0 7						
	206	Imipramine	Female	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS	2 2 0 0 1 2 2	2 1 0 0 1 1 2	2 2 0 1 1 1 1	0 0 0 1 0 1 1	0 1 0 1 1 1 1	0 1 0 0 0 1 1	0 1 0 0 0 0 0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9	206	Imipramine	Female	08. CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	1
				09. REDUCED SLEEP	1	1	1	1	0	0	0
				10. REDUCED APPETITE	0	0	0	0	0	0	
				11. Total score	13	13	10	5	4	2	
				01. REPORTED SADNESS	2	1	1	1	1	1	
				02. INNER TENSION	2	1	1	1	0	0	
				03. APPARENT SADNESS	2	1	1	1	0	0	
				04. SUICIDAL THOUGHTS	0	0	0	0	0	0	
				05. INERTIA	1	1	1	1	0	0	
				06. INABILITY TO FEEL	2	2	2	2	2	2	
				07. PESSIMISTIC THOUGHTS	2	2	2	2	2	2	
207	Reboxetine	Female	08. CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	1	1
			09. REDUCED SLEEP	1	1	1	1	0	0	0	
			10. REDUCED APPETITE	0	0	0	0	0	0		
			11. Total score	13	13	10	5	4	2		
			01. REPORTED SADNESS	2	1	1	1	1	1		
			02. INNER TENSION	2	1	1	1	0	0		
			03. APPARENT SADNESS	2	1	1	1	0	0		
			04. SUICIDAL THOUGHTS	0	0	0	0	0	0		
			05. INERTIA	1	1	1	1	0	0		
			06. INABILITY TO FEEL	2	2	2	2	2	2		
			07. PESSIMISTIC THOUGHTS	2	2	2	2	2	2		
208	Reboxetine	Male	08. CONCENTRATIONS DIFFICULTIES	2	2	2	0	0	1	1	1
			09. REDUCED SLEEP	1	1	1	1	2	1	1	
			10. REDUCED APPETITE	1	1	1	1	0	0	0	
			11. Total score	17	17	10	4	6	11		
			01. REPORTED SADNESS	2	2	2	0	1	1		
			02. INNER TENSION	2	1	1	1	2	1		
			03. APPARENT SADNESS	2	1	1	0	0	1		
			04. SUICIDAL THOUGHTS	0	0	0	0	1	0		
			05. INERTIA	0	0	1	0	0	2		
			06. INABILITY TO FEEL	0	0	0	0	0	1		
			07. PESSIMISTIC THOUGHTS	1	1	1	1	1	3		
08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	0	1					
209	Imipramine	Male	08. CONCENTRATIONS DIFFICULTIES	1	1	1	0	0	0	1	0
			09. REDUCED SLEEP	1	1	1	0	0	1	0	
			10. REDUCED APPETITE	0	0	0	0	0	0		
			11. Total score	9	8	4	1	6	11		
			01. REPORTED SADNESS	1	1	1	0	1	0		
			02. INNER TENSION	2	2	2	1	2	1		
			03. APPARENT SADNESS	1	1	1	0	0	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		
210	Reboxetine	Female	01. REPORTED SADNESS	1	1	1	0	1	1	0	0
			02. INNER TENSION	1	1	1	1	2	1	1	
			03. APPARENT SADNESS	2	1	1	0	1	0	0	
			04. SUICIDAL THOUGHTS	1	1	0	0	0	0		
			05. INERTIA	2	1	1	0	1	0		
			06. INABILITY TO FEEL	2	1	1	0	1	0		

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
9	210	Reboxetine	Female	07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	0	0			
				08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	1				
				09. REDUCED SLEEP	1	0	0	0	1	1	1				
				10. REDUCED APPETITE	0	0	0	0	0	0	0				
				11. Total score	13	9	8	3	3	3	3				
				211	Reboxetine	Female	01. REPORTED SADNESS	2	3	3	3	1			
							02. INNER TENSION	2	2	2	2	2			
							03. APPARENT SADNESS	2	2	2	2	1			
							04. SUICIDAL THOUGHTS	2	2	2	2	1			
							05. INERTIA	1	2	2	2	1			
							06. INABILITY TO FEEL	2	2	2	2	1			
07. PESSIMISTIC THOUGHTS	2	2	2				2	1							
08. CONCENTRATIONS DIFFICULTIES	2	2	2				2	1							
09. REDUCED SLEEP	1	2	2				2	1							
10. REDUCED APPETITE	1	2	2				2	0							
11. Total score	17	21	20				9								
212	Imipramine	Female	01. REPORTED SADNESS	2	1	2	1	1	1	1	1	0			
			02. INNER TENSION	2	1	1	1	1	1	1	1	1			
			03. APPARENT SADNESS	2	1	1	0	0	0	0	0	0			
			04. SUICIDAL THOUGHTS	1	1	0	1	1	1	1	1	1			
			05. INERTIA	1	2	1	0	0	0	0	0	0			
			06. INABILITY TO FEEL	1	1	0	0	0	0	0	0	0			
			07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	1	1	1		
			08. CONCENTRATIONS DIFFICULTIES	1	1	0	0	0	0	0	0	0	0		
			09. REDUCED SLEEP	1	1	0	1	0	0	0	0	0	0		
			10. REDUCED APPETITE	1	1	0	1	0	0	0	0	0	0		
			11. Total score	13	11	6	6	4	4	4	2				
237	Reboxetine	Male	01. REPORTED SADNESS	2	2	3									
			02. INNER TENSION	2	2	2									
			03. APPARENT SADNESS	1	1	1									
			04. SUICIDAL THOUGHTS	0	0	0									
			05. INERTIA	2	2	2									
			06. INABILITY TO FEEL	1	1	1									
			07. PESSIMISTIC THOUGHTS	1	1	1									
			08. CONCENTRATIONS DIFFICULTIES	1	1	1									
			09. REDUCED SLEEP	2	2	2									
			10. REDUCED APPETITE	0	0	1									
			11. Total score	12	12	15									
238	Imipramine	Female	01. REPORTED SADNESS	2	2	2	2	1	1	0	0				
			02. INNER TENSION	2	2	2	2	1	1	0	0				
			03. APPARENT SADNESS	2	2	2	2	0	0	0	0				
			04. SUICIDAL THOUGHTS	1	1	1	1	1	1	0	0				
			05. INERTIA	2	2	2	2	1	1	0	0				

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REBOXETINE - PROTOCOL 20124/017
Listing No.: 15.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42			
9	238	Imipramine	Female	06. INABILITY TO FEEL	2	2	2	1	0	0	0			
				07. PESSIMISTIC THOUGHTS	1	1	1	1	0	0				
				08. CONCENTRATIONS DIFFICULTIES	2	2	2	1	0	0				
				09. REDUCED SLEEP	2	2	2	2	1	1				
				10. REDUCED APPETITE	1	1	1	1	0	0				
				11. Total score	17	17	17	10	6	1				
				239	Imipramine	Male	01. REPORTED SADNESS	2	2	2	1	1	1	1
							02. INNER TENSION	2	2	1	1	1	1	
							03. APPARENT SADNESS	2	2	2	1	1	1	
							04. SUICIDAL THOUGHTS	1	1	0	0	0	0	
							05. INERTIA	2	3	2	1	1	1	
06. INABILITY TO FEEL	2	2	2				1	1	1					
07. PESSIMISTIC THOUGHTS	2	2	2				0	0	0					
08. CONCENTRATIONS DIFFICULTIES	2	2	2				1	1	1					
09. REDUCED SLEEP	2	2	1				1	1	1					
10. REDUCED APPETITE	0	1	1				0	0	0					
11. Total score	17	19	15				7	7	7					
240	Reboxetine	Female	01. REPORTED SADNESS	2	2	2	2	2	2	2				
			02. INNER TENSION	3	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	3	3	3	3	3	3					
			09. REDUCED SLEEP	2	2	2	2	2	2					
			10. REDUCED APPETITE	1	1	1	1	1	1					
			11. Total score	19	18	18	15	15	15					
241	Imipramine	Female	01. REPORTED SADNESS	2	2	2	1	1	1	1				
			02. INNER TENSION	2	2	2	2	2	2					
			03. APPARENT SADNESS	2	2	1	1	1	1					
			04. SUICIDAL THOUGHTS	1	1	1	1	1	1					
			05. INERTIA	2	2	1	1	1	1					
			06. INABILITY TO FEEL	2	2	2	2	2	2					
			07. PESSIMISTIC THOUGHTS	2	2	1	1	1	1					
			08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2					
			09. REDUCED SLEEP	1	2	2	2	2	2					
			10. REDUCED APPETITE	1	2	2	2	2	2					
			11. Total score	17	19	15	15	15	10					
242	Reboxetine	Male	01. REPORTED SADNESS	2	2	2	2	1	0	0				
			02. INNER TENSION	2	2	2	2	1	0					
			03. APPARENT SADNESS	2	2	2	2	1	0					
			04. SUICIDAL THOUGHTS	2	1	1	1	0	0					

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
9	242	Reboxetine	Male	05. INERTIA	2	2	2	2	2	0	0				
				06. INABILITY TO FEEL	2	1	1	1	1	0	0				
				07. PESSIMISTIC THOUGHTS	2	2	1	1	1	0	0				
				08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	1	0				
				09. REDUCED SLEEP	2	2	2	2	2	1	0				
				10. REDUCED APPETITE	1	1	1	1	1	0	0				
				11. Total score	19	17	16	16	11	1	1				
				243	Imipramine	Female	01. REPORTED SADNESS	2	2	1	2	1	1	1	0
							02. INNER TENSION	2	2	2	2	2	2	1	
							03. APPARENT SADNESS	2	2	1	1	1	1	1	
							04. SUICIDAL THOUGHTS	2	1	1	1	1	1	0	
05. INERTIA	2	2	1				1	1	1	0					
06. INABILITY TO FEEL	2	2	2				2	1	1	1					
07. PESSIMISTIC THOUGHTS	2	2	1				1	1	1	1					
08. CONCENTRATIONS DIFFICULTIES	2	2	2				2	1	1	0					
09. REDUCED SLEEP	2	2	2				2	1	1	0					
10. REDUCED APPETITE	1	1	1				1	1	1	1					
11. Total score	19	18	15				11	11	10	4					
244	Reboxetine	Male	01. REPORTED SADNESS	3	2	2	2	2	1	1	1				
			02. INNER TENSION	2	1	1	1	1	2	2					
			03. APPARENT SADNESS	2	2	2	2	2	1	1					
			04. SUICIDAL THOUGHTS	0	0	0	0	0	1	0					
			05. INERTIA	2	1	1	1	2	1	1					
			06. INABILITY TO FEEL	2	1	1	1	1	2	1					
			07. PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1					
			08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	1	0					
			09. REDUCED SLEEP	1	1	1	1	1	2	1					
			10. REDUCED APPETITE	0	0	0	0	0	1	0					
			11. Total score	16	11	11	11	14	8	7					
257	Reboxetine	Female	01. REPORTED SADNESS	2	2	1	0	0	1	0	0				
			02. INNER TENSION	2	1	0	0	1	0	1					
			03. APPARENT SADNESS	2	2	1	0	1	0	0					
			04. SUICIDAL THOUGHTS	1	0	0	0	0	0	0					
			05. INERTIA	2	2	0	1	1	1	1					
			06. INABILITY TO FEEL	2	1	1	0	0	0	0					
			07. PESSIMISTIC THOUGHTS	2	2	0	0	0	0	0					
			08. CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	0					
			09. REDUCED SLEEP	2	2	1	1	1	1	0					
			10. REDUCED APPETITE	2	2	0	0	0	0	0					
			11. Total score	18	13	6	3	5	1	2					
258	Reboxetine	Male	01. REPORTED SADNESS	2	2	2	2	3	2	3					
			02. INNER TENSION	2	3	3	3	3	2	2					
			03. APPARENT SADNESS	2	2	2	2	2	2						

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
9	258	Reboxetine	Male	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 1 1 2 0 13	2 2 2 2 2 1 21	1 2 2 2 2 1 17	1 2 2 2 2 1 15	0 0 0 0 0 0 0	0 0 0 0 0 0 0	0 0 0 0 0 0 0	
259		Imipramine	Female	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 1 18	2 2 2 2 2 2 18	2 2 2 2 2 2 18	1 1 0 0 0 0 7	0 2 0 0 0 0 6	0 1 0 0 0 0 4	0 1 0 0 0 0 4	
260		Imipramine	Female	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 16	1 3 1 0 0 3 9	2 1 2 2 1 2 13	2 1 2 2 2 2 18	3 2 2 2 1 2 6	2 1 2 2 2 2 4	3 2 2 2 2 2 4	
261		Imipramine	Female	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 1 0 2 2 16	1 1 1 2 2 2 15	2 2 2 2 2 2 15	2 2 2 2 2 2 15	2 1 2 2 2 2 15	2 1 2 2 2 2 15	2 1 2 2 2 2 15	
262		Reboxetine	Male	01. REPORTED SADNESS 02. INNER TENSION	2 2	2 1	2 1	2 0	2 2	0 0	1 0	1 1

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
9	262	Reboxetine	Male	03. APPARENT SADNESS	1	2	2	1	0	1	0	0			
				04. SUICIDAL THOUGHTS	1	1	1	0	0	0	0				
				05. INERTIA	1	2	1	0	0	0	0				
				06. INABILITY TO FEEL	2	2	1	0	0	1	1				
				07. PESSIMISTIC THOUGHTS	2	1	2	1	1	0	0				
				08. CONCENTRATIONS DIFFICULTIES	2	1	2	1	1	0	0				
				09. REDUCED SLEEP	0	0	0	0	0	0	0				
				10. REDUCED APPETITE	14	14	12	4	4	4	4				
				11. Total score											
				263	Reboxetine	Female	01. REPORTED SADNESS	1	2	3	0	0	0	0	0
							02. INNER TENSION	0	2	2	0	0	0	0	
03. APPARENT SADNESS	0	1	0				0	0	0	0					
04. SUICIDAL THOUGHTS	0	1	1				0	0	0	0					
05. INERTIA	0	1	1				0	0	0	0					
06. INABILITY TO FEEL	0	1	1				0	0	0	0					
07. PESSIMISTIC THOUGHTS	0	1	1				0	0	0	0					
08. CONCENTRATIONS DIFFICULTIES	1	1	1				0	0	0	0					
09. REDUCED SLEEP	1	1	1				0	0	0	0					
10. REDUCED APPETITE	1	0	0				0	0	0	0					
11. Total score	4	12	13				0	0	0	0					
264	Imipramine	Female	01. REPORTED SADNESS	2	2	0	0	0	0	0	0				
			02. INNER TENSION	2	1	1	0	0	0	0					
			03. APPARENT SADNESS	2	2	1	0	0	0	0					
			04. SUICIDAL THOUGHTS	1	0	0	0	0	0	0					
			05. INERTIA	2	2	1	0	0	0	0					
			06. INABILITY TO FEEL	2	2	0	0	0	0	0					
			07. PESSIMISTIC THOUGHTS	1	1	1	0	0	0	0					
			08. CONCENTRATIONS DIFFICULTIES	1	2	1	0	0	0	0					
			09. REDUCED SLEEP	0	0	1	1	1	1	1					
			10. REDUCED APPETITE	0	0	0	0	0	0	0					
			11. Total score	13	12	6	1	1	1	8					
265	Reboxetine	Female	01. REPORTED SADNESS	2	2	2	1	3	2	1	1				
			02. INNER TENSION	3	3	1	1	2	1	1					
			03. APPARENT SADNESS	3	3	1	0	2	1	1					
			04. SUICIDAL THOUGHTS	2	2	1	0	3	1	0					
			05. INERTIA	2	3	0	0	2	0	0					
			06. INABILITY TO FEEL	3	3	1	1	4	2	1					
			07. PESSIMISTIC THOUGHTS	1	1	0	0	1	1	1					
			08. CONCENTRATIONS DIFFICULTIES	1	1	2	2	2	1	1					
			09. REDUCED SLEEP	1	1	1	0	3	2	1					
			10. REDUCED APPETITE	0	0	1	0	2	2	0					
			11. Total score	18	19	10	5	21	16	7					
266	Reboxetine	Female	01. REPORTED SADNESS	1	1	0	0	0	0	0	0				

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		MONTGOMERY ASBERG DEPRESSION RATING SCALE											
		Montgomery Asberg Depression Rating Scale											
Centre	Patient Treatment	Sex	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
9	Reboxetine	Female	02. INNER TENSION	2	2	1	1	1	2	1			
			03. APPARENT SADNESS	1	0	0	0	0	0	0	0		
			04. SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0		
			05. INERTIA	2	1	1	1	1	1	1	0		
			06. INABILITY TO FEEL	1	1	1	1	0	0	0	0		
			07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	1		
			08. CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	1	1		
			09. REDUCED SLEEP	3	3	3	3	3	3	3	2		
			10. REDUCED APETITE	2	1	0	0	0	0	0	0		
			11. Total score	16	12	8	7	4	4	6	4		
			267	Imipramine	Male	01. REPORTED SADNESS	2	1	0	0	0	0	0
02. INNER TENSION	2	1				1	1	1	1	2			
03. APPARENT SADNESS	2	1				0	0	0	0	0	0		
04. SUICIDAL THOUGHTS	0	0				0	0	0	0	0	0		
05. INERTIA	2	1				0	0	0	0	0	0		
06. INABILITY TO FEEL	2	1				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	3	3				2	2	1	1	1	1		
10. REDUCED APETITE	1	1				0	0	0	0	0	0		
11. Total score	18	11				5	3	3	3	3	4		
268	Imipramine	Female	01. REPORTED SADNESS	3	0	2	1	1	2	2			
			02. INNER TENSION	2	1	1	1	1	1	2	2		
			03. APPARENT SADNESS	3	0	1	1	2	2	2	1		
			04. SUICIDAL THOUGHTS	1	0	1	1	0	0	0	0		
			05. INERTIA	2	1	1	1	1	1	2	2		
			06. INABILITY TO FEEL	2	1	0	1	1	1	1	1		
			07. PESSIMISTIC THOUGHTS	3	0	1	1	1	1	1	1		
			08. CONCENTRATIONS DIFFICULTIES	2	0	1	1	1	1	1	1		
			09. REDUCED SLEEP	0	0	1	0	1	1	1	1		
			10. REDUCED APETITE	1	0	1	0	1	0	1	0		
			11. Total score	19	3	10	8	10	10	12	10		
269	Reboxetine	Male	01. REPORTED SADNESS	2	1	0	0	0	0	0			
			02. INNER TENSION	1	0	1	1	1	1	0	0		
			03. APPARENT SADNESS	1	0	1	0	1	0	0	0		
			04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0		
			05. INERTIA	1	1	0	0	0	0	1	1		
			06. INABILITY TO FEEL	2	1	0	0	0	0	0	0		
			07. PESSIMISTIC THOUGHTS	1	1	0	0	0	0	0	0		
			08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	0	0	0	0		
			09. REDUCED SLEEP	1	1	0	0	0	0	0	0		
			10. REDUCED APETITE	0	0	0	0	0	0	0	0		
			11. Total score	10	7	3	2	1	1	1	1		

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
9	270	Imipramine	Female	D1.REPORTED SADNESS	3	2							
				D2.INNER TENSION	3	2							
				D3.APPARENT SADNESS	3	0							
				D4.SUICIDAL THOUGHTS	0	0							
				D5.INERTIA	2	1							
				D6.INABILITY TO FEEL	2	1							
				D7.PESSIMISTIC THOUGHTS	2	1							
				D8.CONCENTRATIONS DIFFICULTIES	2	1							
				D9.REDUCED SLEEP	1	0							
				D10.REDUCED APPETITE	0	0							
				D11.Total score	18	8							
	271	Reboxetine	Female	D1.REPORTED SADNESS	2	1	1	1	1	1	1	1	
				D2.INNER TENSION	2	2	1	1	1	1	1	1	1
				D3.APPARENT SADNESS	1	1	1	1	1	1	1	1	1
				D4.SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0	0
				D5.INERTIA	2	1	1	1	1	1	1	1	1
				D6.INABILITY TO FEEL	2	2	2	2	2	2	2	2	2
				D7.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	1	1
				D8.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2	2	2
				D9.REDUCED SLEEP	2	2	2	2	2	2	2	2	2
				D10.REDUCED APPETITE	2	2	2	2	2	2	2	2	2
				D11.Total score	17	14	11	11	11	11	11	11	11
	272	Imipramine	Male	D1.REPORTED SADNESS	2	1	1	1	0	0	0	0	
				D2.INNER TENSION	2	1	1	1	1	1	0	0	0
				D3.APPARENT SADNESS	3	2	0	0	0	0	0	0	0
				D4.SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0	0
				D5.INERTIA	2	1	1	1	1	1	1	1	1
				D6.INABILITY TO FEEL	2	2	0	0	0	0	0	0	0
				D7.PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1	1	1
				D8.CONCENTRATIONS DIFFICULTIES	3	3	2	2	1	1	1	1	1
				D9.REDUCED SLEEP	2	2	2	2	2	2	2	2	2
				D10.REDUCED APPETITE	2	2	2	2	2	2	2	2	2
				D11.Total score	22	16	6	6	4	4	2	2	2
	273	Imipramine	Female	D1.REPORTED SADNESS	2	3	2	1	1	1	1		
				D2.INNER TENSION	2	2	1	1	1	1	1		
				D3.APPARENT SADNESS	2	2	2	1	1	1	1		
				D4.SUICIDAL THOUGHTS	2	2	2	2	2	2	2		
				D5.INERTIA	2	2	1	1	1	1	1		
				D6.INABILITY TO FEEL	2	2	2	2	2	2	2		
				D7.PESSIMISTIC THOUGHTS	2	2	2	2	2	2	2		
				D8.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2		
				D9.REDUCED SLEEP	2	2	2	2	2	2	2		
				D10.REDUCED APPETITE	2	2	2	2	2	2	2		
				D11.Total score	20	21	16	14	14	14	14		

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
9	274	Reboxetine	Female	01.REPORTED SADNESS	2	2							
				02.INNER TENSION	2	1							
				03.APPARENT SADNESS	1	1							
				04.SUICIDAL THOUGHTS	1	1							
				05.INERTIA	1	0							
				06.INABILITY TO FEEL	1	1							
				07.PESSIMISTIC THOUGHTS	1	1							
				08.CONCENTRATIONS DIFFICULTIES	2	1							
				09.REDUCED SLEEP	2	1							
				10.REDUCED APPETITE	0	0							
				11.Total score	13	9							
274/A	Reboxetine	Female	01.REPORTED SADNESS	2	2	2	1	1	0	0	1	1	
			02.INNER TENSION	2	2	1	1	1	1	1	1	1	
			03.APPARENT SADNESS	2	1	1	1	1	1	1	1	1	
			04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0	0	
			05.INERTIA	3	3	3	1	1	1	1	1	1	
			06.INABILITY TO FEEL	2	0	0	0	0	0	0	0	0	
			07.PESSIMISTIC THOUGHTS	2	1	1	1	1	1	1	1	1	
			08.CONCENTRATIONS DIFFICULTIES	2	1	2	1	1	1	1	1	1	
			09.REDUCED SLEEP	2	1	1	1	1	1	1	1	1	
			10.REDUCED APPETITE	1	0	0	0	0	0	0	0	0	
			11.Total score	18	11	11	7	6	6	7	7	7	
275	Reboxetine	Female	01.REPORTED SADNESS	3	1	1	1	1	1	1	1	1	
			02.INNER TENSION	2	1	1	1	0	0	0	0	0	
			03.APPARENT SADNESS	2	1	1	1	1	1	1	1	1	
			04.SUICIDAL THOUGHTS	2	2	2	1	1	0	0	0	0	
			05.INERTIA	2	2	2	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	2	2	2	1	1	1	1	1	1	
			09.REDUCED SLEEP	2	2	2	1	1	1	1	1	1	
			10.REDUCED APPETITE	2	1	1	0	0	0	0	0	0	
			11.Total score	21	16	16	8	7	7	4	4	3	
276	Imipramine	Female	01.REPORTED SADNESS	2	2								
			02.INNER TENSION	1	2								
			03.APPARENT SADNESS	2	2								
			04.SUICIDAL THOUGHTS	0	1								
			05.INERTIA	1	3								
			06.INABILITY TO FEEL	1	1								
			07.PESSIMISTIC THOUGHTS	1	2								
			08.CONCENTRATIONS DIFFICULTIES	1	2								
			09.REDUCED SLEEP	1	1								
			10.REDUCED APPETITE	1	1								

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9	276	Imipramine	Female	11.Total score	11	17					
	276/A	Imipramine	Male	01.REPORTED SADNESS	2	2	3	2	0	0	0
				02.INNER TENSION	2	2	2	2	1	1	1
				03.APPARENT SADNESS	1	2	2	2	0	0	0
				04.SUICIDAL THOUGHTS	0	0	1	1	0	0	0
				05.INERTIA	1	1	0	1	0	0	0
				06.INABILITY TO FEEL	1	1	1	2	0	0	0
				07.PESSIMISTIC THOUGHTS	1	1	1	2	1	1	1
				08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	0	0	0
				09.REDUCED SLEEP	1	1	1	1	1	1	1
				10.REDUCED APPETITE	1	0	0	0	0	0	0
				11.Total score	11	11	12	13	3	3	2
9/A	233	Imipramine	Male	01.REPORTED SADNESS	2	2	2	1	1	1	1
				02.INNER TENSION	2	2	2	2	1	1	1
				03.APPARENT SADNESS	2	2	2	1	1	1	1
				04.SUICIDAL THOUGHTS	1	1	1	0	0	0	0
				05.INERTIA	3	3	3	2	2	2	2
				06.INABILITY TO FEEL	2	2	2	1	1	1	1
				07.PESSIMISTIC THOUGHTS	1	1	2	2	1	0	1
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	1
				09.REDUCED SLEEP	2	2	2	2	2	2	2
				10.REDUCED APPETITE	2	2	2	2	0	0	0
				11.Total score	19	19	20	10	10	9	10
234		Reboxetine	Female	01.REPORTED SADNESS	3	2	2	1	1	1	1
				02.INNER TENSION	2	2	1	1	1	1	1
				03.APPARENT SADNESS	2	2	2	1	1	1	1
				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	1	1	1
				07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	0
				08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1
				09.REDUCED SLEEP	2	2	1	1	1	1	1
				10.REDUCED APPETITE	2	2	2	1	1	1	1
				11.Total score	18	17	15	9	10	9	8
235		Reboxetine	Male	01.REPORTED SADNESS	3	2	1	1	1	1	2
				02.INNER TENSION	1	1	1	1	1	1	1
				03.APPARENT SADNESS	3	1	1	1	1	1	1
				04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0
				05.INERTIA	2	2	1	1	2	2	2
				06.INABILITY TO FEEL	2	1	1	1	0	1	2
				07.PESSIMISTIC THOUGHTS	1	1	1	1	0	1	1
				08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1
				09.REDUCED SLEEP	3	2	2	2	2	2	2

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
9/A	235	Reboxetine	Male	10. REDUCED APPETITE 11. Total score	2 19	1 13	0 9	0 7	0 9	1 15		
	236	Imipramine	Male	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 1 0 16	2 2 2 1 2 2 2 2 1 0 15	2 1 2 1 2 1 1 1 1 0 13	1 1 1 0 1 1 1 1 1 0 8	1 1 1 0 1 1 1 1 1 0 9	1 1 1 0 1 1 1 1 1 0 9	0 1 0 0 1 1 0 0 1 0 3	
	277	Reboxetine	Female	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 2 2 1 1 19	2 2 3 1 2 2 2 2 1 1 21	3 2 3 1 2 2 2 2 1 1 19	3 2 3 1 2 2 2 2 1 1 21	2 2 3 1 2 2 2 2 1 1 19	2 2 3 1 2 2 2 2 1 1 21	2 2 3 1 2 2 2 2 1 1 21	3 2 3 1 2 2 2 2 1 1 21
	278	Imipramine	Female	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 1 0 17	1 1 1 1 2 1 1 1 1 0 11	1 1 1 0 2 0 0 0 1 0 5	2 1 1 1 2 1 1 1 1 0 11	1 1 1 0 2 1 1 1 1 0 14	2 2 2 1 2 1 1 1 1 0 14	2 2 2 0 2 0 0 0 2 1 14	
	279	Imipramine	Male	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 1	2 2 2 1 2 2 2 1	2 2 2 1 2 2 2 1	2 2 2 1 2 2 2 1	2 2 2 1 2 2 2 1	2 2 2 1 2 2 2 1	2 2 2 1 2 2 2 1	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9/A	279	Imipramine	Male	09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	1 0 14	2 1 16	2 1 18				
	280	Reboxetine	Female	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 1 18	2 2 2 1 2 2 2 2 2 1 18					
	281	Reboxetine	Female	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 1 2 1 14	1 1 1 0 1 1 1 0 0 0 7	0 1 1 0 1 0 0 0 0 0 4	0 0 0 1 1 0 0 0 0 2	0 0 0 0 0 0 0 0 0 1	0 1 0 0 0 0 0 0 0 1	
	282	Reboxetine	Male	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 2 2 2 2 2 1 19	2 2 2 1 2 2 2 2 2 1 18	1 1 1 0 2 1 1 1 2 1 13	1 1 1 0 1 2 1 1 1 1 10	1 1 1 0 1 1 1 1 1 1 9	1 1 1 0 1 1 1 0 1 1 6	
	283	Imipramine	Female	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS	2 1 2 1 2 2 1	2 1 2 1 2 2 1	1 1 1 0 1 0 0	1 1 1 0 1 1 0	0 0 0 0 0 0 0	0 1 0 0 0 0 0	

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9/A	283	Imipramine	Female	08. CONCENTRATIONS DIFFICULTIES	1	1	0	0	0	0	0
				09. REDUCED SLEEP	1	1	1	1	1	1	1
				10. REDUCED APPETITE	1	1	0	0	0	0	0
				11. Total score	14	14	6	6	3	3	3
	284	Imipramine	Male	01. REPORTED SADNESS	3	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	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	1	1	1	1	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	2	1	1	1	1	1	1
				11. Total score	19	16	15	16	16	16	16
	301	Imipramine	Female	01. REPORTED SADNESS	2	1	1	1	0	0	0
				02. INNER TENSION	1	1	1	1	1	1	1
				03. APPARENT SADNESS	2	1	1	1	0	0	0
				04. SUICIDAL THOUGHTS	1	1	0	0	0	0	0
				05. INERTIA	2	1	1	1	1	1	1
				06. INABILITY TO FEEL	2	1	1	1	0	0	0
				07. PESSIMISTIC THOUGHTS	2	1	1	1	0	0	0
				08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	0	0	0
				09. REDUCED SLEEP	1	1	1	1	1	1	1
				10. REDUCED APPETITE	2	1	1	1	0	0	0
				11. Total score	16	10	9	3	3	3	2
	302	Imipramine	Male	01. REPORTED SADNESS	2	2	2	2	3	3	3
				02. INNER TENSION	2	2	2	2	2	2	2
				03. APPARENT SADNESS	1	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	1	1	1	1	1	1	1
				10. REDUCED APPETITE	1	1	1	1	1	1	1
				11. Total score	17	17	16	17	17	17	17
	303	Reboxetine	Female	01. REPORTED SADNESS	3	2	2	2	2	2	2
				02. INNER TENSION	1	1	2	2	2	2	2
				03. APPARENT SADNESS	3	2	2	2	2	2	2
				04. SUICIDAL THOUGHTS	1	1	1	1	1	1	1
				05. INERTIA	3	2	2	2	2	2	2
				06. INABILITY TO FEEL	2	2	2	2	2	2	2

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9/A	303	Reboxetine	Female	07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 2 1 2 20	1 2 1 1 15	1 2 1 1 16	2 2 2 1 18	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0
	304	Reboxetine	Female	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 1 1 1 1 15	1 1 1 1 1 0 0 0 0 9	1 1 1 1 1 0 0 0 0 8	1 1 1 1 1 1 1 1 0 7	0 0 0 0 0 0 0 0 0 6	0 0 0 0 0 0 0 0 0 2	0 0 0 0 0 0 0 0 0 3
	305	Reboxetine	Male	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	1 1 1 0 1 1 1 1 1 1 9	1 1 1 0 1 0 0 0 0 0 7	0 1 1 0 1 0 0 0 0 0 6	0 0 0 0 0 0 0 0 0 0 5	0 0 0 0 0 0 0 0 0 0 3	
	306	Reboxetine	Female	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 20	3 2 3 1 2 2 2 2 2 2 20	1 1 1 0 1 1 1 1 1 1 7	1 0 0 0 1 1 1 1 1 1 4	0 1 0 0 0 0 0 0 0 0 3	0 0 0 0 0 0 0 0 0 0 3	
	307	Imipramine	Female	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

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
9/A	307	Imipramine	Female	06. INABILITY TO FEEL	2	2										
				07. PESSIMISTIC THOUGHTS	1	1										
				08. CONCENTRATIONS DIFFICULTIES	1	1										
				09. REDUCED SLEEP	1	1										
				10. REDUCED APPETITE	0	0										
				11. Total score	14	15										
				308	Imipramine	Female	01. REPORTED SADNESS	3	3	2	2	1	3			
							02. INNER TENSION	2	2	2	2	1	2			
							03. APPARENT SADNESS	3	2	2	1	2				
							04. SUICIDAL THOUGHTS	1	1	1	1	1				
							05. INERTIA	2	2	2	2	2				
06. INABILITY TO FEEL	2	2	2				2	2								
07. PESSIMISTIC THOUGHTS	2	1	1				1	1								
08. CONCENTRATIONS DIFFICULTIES	2	1	1				1	1								
09. REDUCED SLEEP	2	2	2				2	1	3							
10. REDUCED APPETITE	2	1	1				1	1								
11. Total score	21	17	16				12	18								
10	289	Imipramine	Female	01. REPORTED SADNESS	1	1										
				02. INNER TENSION	0	1										
				03. APPARENT SADNESS	1	1										
				04. SUICIDAL THOUGHTS	0	0										
				05. INERTIA	2	2										
				06. INABILITY TO FEEL	1	1										
				07. PESSIMISTIC THOUGHTS	1	1										
				08. CONCENTRATIONS DIFFICULTIES	1	2										
				09. REDUCED SLEEP	1	2										
				10. REDUCED APPETITE	1	2										
				11. Total score	9	13										
290	Reboxetine	Male	01. REPORTED SADNESS	3	1	1	1	1	1	0	0	0				
			02. INNER TENSION	1	1	1	1	0	0	0	0	0				
			03. APPARENT SADNESS	2	2	1	0	0	0	0	0	0				
			04. SUICIDAL THOUGHTS	2	2	1	1	1	1	1	1	1				
			05. INERTIA	0	0	0	0	0	0	0	0	0				
			06. INABILITY TO FEEL	3	2	1	1	1	1	1	1	1				
			07. PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1	1	1				
			08. CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	1	1	1				
			09. REDUCED SLEEP	1	1	0	0	0	0	0	0	0				
			10. REDUCED APPETITE	1	1	0	0	0	0	0	0	0				
			11. Total score	17	14	7	5	5	2	5	2	5				
291	Imipramine	Male	01. REPORTED SADNESS	3	1	0	0	0	0	0	0					
			02. INNER TENSION	1	1	1	1	0	0	0	0					
			03. APPARENT SADNESS	3	2	0	0	0	0	0	0					
			04. SUICIDAL THOUGHTS	2	1	0	0	0	0	0	0					

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
10	291	Imipramine	Male	05. INERTIA	2	1	0	0	0	0	0
				06. INABILITY TO FEEL	2	2	1	1	1	0	0
				07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	0
				08. CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	0
				09. REDUCED SLEEP	2	2	0	0	0	0	0
				10. REDUCED APPEITE	1	1	0	0	0	0	0
				11. Total score	18	13	4	4	2	2	0
292	Reboxetine	Female	01. REPORTED SADNESS	1	1	1	1	1	0	0	0
			02. INNER TENSION	2	1	1	1	1	1	1	1
			03. APPARENT SADNESS	2	2	1	1	1	0	0	0
			04. SUICIDAL THOUGHTS	2	1	0	0	0	0	0	0
			05. INERTIA	1	1	0	0	0	0	0	0
			06. INABILITY TO FEEL	2	1	0	0	0	0	0	0
			07. PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1	1
			08. CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	1	0
			09. REDUCED SLEEP	2	2	1	1	1	1	1	0
			10. REDUCED APPEITE	1	1	0	0	0	0	0	0
			11. Total score	17	13	6	6	4	4	4	2
293	Reboxetine	Female	01. REPORTED SADNESS	2	2	2	2	2	2	1	1
			02. INNER TENSION	2	2	2	2	2	2	2	2
			03. APPARENT SADNESS	2	2	2	2	2	2	2	2
			04. SUICIDAL THOUGHTS	1	1	1	1	1	1	0	0
			05. INERTIA	2	2	2	2	2	2	2	2
			06. INABILITY TO FEEL	2	2	2	2	2	2	2	2
			07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	1
			08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2	2
			09. REDUCED SLEEP	2	2	2	2	2	2	2	2
			10. REDUCED APPEITE	1	1	1	1	1	1	1	1
			11. Total score	17	17	17	17	17	17	15	15
294	Imipramine	Female	01. REPORTED SADNESS	1	3	3	3	2	2	2	0
			02. INNER TENSION	1	2	2	2	2	2	2	2
			03. APPARENT SADNESS	2	3	2	2	1	1	1	1
			04. SUICIDAL THOUGHTS	1	1	1	1	1	1	1	1
			05. INERTIA	2	2	2	2	2	2	2	2
			06. INABILITY TO FEEL	2	2	2	2	2	2	2	2
			07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	1
			08. CONCENTRATIONS DIFFICULTIES	1	1	2	2	2	2	2	2
			09. REDUCED SLEEP	2	3	2	2	2	2	2	2
			10. REDUCED APPEITE	1	2	2	2	2	2	2	2
			11. Total score	14	21	19	17	17	17	15	15
295	Imipramine	Male	01. REPORTED SADNESS	2	2	1	1	1	1	1	0
			02. INNER TENSION	2	2	2	2	1	1	1	1
			03. APPARENT SADNESS	2	1	1	1	1	1	1	0

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
10	295	Imipramine	Male	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	1	1	1	1	1	1
				08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	0	0	0
				09.REDUCED SLEEP	2	2	2	2	2	2	2
				10.REDUCED APPETITE	1	1	0	0	0	0	0
				11.Total score	17	15	13	10	7	7	5
	296	Reboxetine	Female	01.REPORTED SADNESS	3	3	3	3	3	3	3
				02.INNER TENSION	2	2	2	2	2	2	2
				03.APPARENT SADNESS	3	3	3	3	3	3	3
				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	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	20	20	15	9	9	9	9
	297	Reboxetine	Male	01.REPORTED SADNESS	2	2	2	2	2	2	2
				02.INNER TENSION	1	1	1	1	1	1	1
				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	1	1	1	1	1	1	1
				07.PESSIMISTIC THOUGHTS	1	1	1	1	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	2	2	2	2	2	2	2
				11.Total score	17	17	12	9	5	4	2
	298	Reboxetine	Female	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	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	16	16	15	13	10	7	5
	299	Imipramine	Male	01.REPORTED SADNESS	3	3	3	3	3	3	3
				02.INNER TENSION	2	2	2	2	2	2	2

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 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
10	299	Imipramine	Male	03..APPARENT SADNESS	3	1	2	2	2	2	2	1			
				04..SUICIDAL THOUGHTS	1	1	3	1	1	1	0				
				05..INERTIA	2	2	3	3	3	2	1				
				06..INABILITY TO FEEL	2	2	2	2	2	2	1				
				07..PESSIMISTIC THOUGHTS	2	2	2	2	2	2	1				
				08..CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2				
				09..REDUCED SLEEP	2	2	2	2	2	2	2				
				10..REDUCED APPETITE	0	0	1	0	0	0	0				
				11..Total score	19	19	23	19	19	16	7				
				300	Imipramine	Female	01..REPORTED SADNESS	2	2	2	1	1	1	1	2
							02..INNER TENSION	1	1	1	1	1	1	1	
03..APPARENT SADNESS	2	2	2				1	1	2	2					
04..SUICIDAL THOUGHTS	1	1	0				0	0	0	1					
05..INERTIA	3	3	3				2	1	2	2					
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	1				1	1	1	1					
09..REDUCED SLEEP	2	2	2				2	2	2	2					
10..REDUCED APPETITE	0	0	0				0	0	0	0					
11..Total score	16	16	14				10	9	9	13					
11	321	Reboxetine	Female	01..REPORTED SADNESS	2	4	1	1	1	0	0	0			
				02..INNER TENSION	2	1	1	1	1	1	1				
				03..APPARENT SADNESS	2	0	0	0	1	0	0				
				04..SUICIDAL THOUGHTS	1	0	0	0	0	0	0				
				05..INERTIA	1	0	1	0	0	0	0				
				06..INABILITY TO FEEL	1	0	0	1	0	0	0				
				07..PESSIMISTIC THOUGHTS	2	0	0	0	1	0	0				
				08..CONCENTRATIONS DIFFICULTIES	2	0	1	1	0	0	0				
				09..REDUCED SLEEP	3	2	2	2	2	2	2				
				10..REDUCED APPETITE	2	1	2	1	1	1	1				
				11..Total score	18	5	8	7	6	4	4				
322	Reboxetine	Female	01..REPORTED SADNESS	2	1	1	0	0	0	0	0				
			02..INNER TENSION	2	1	0	1	1	1	1					
			03..APPARENT SADNESS	1	2	0	1	0	0	0					
			04..SUICIDAL THOUGHTS	1	0	0	0	0	0	0					
			05..INERTIA	2	0	1	1	1	1	1					
			06..INABILITY TO FEEL	2	1	0	1	1	1	1					
			07..PESSIMISTIC THOUGHTS	1	1	0	0	0	0	0					
			08..CONCENTRATIONS DIFFICULTIES	1	0	1	1	0	1	1					
			09..REDUCED SLEEP	2	2	2	2	2	1	1					
			10..REDUCED APPETITE	0	1	0	0	0	0	1					
			11..Total score	14	9	5	7	4	5	5					
323	Imipramine	Female	01..REPORTED SADNESS	2	1	1	0	0	0	0	0				

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
11	323	Imipramine	Female	02. INNER TENSION	2	2	2	1	1	1	1	1
				03. APPARENT SADNESS	1	0	1	0	0	0	0	0
				04. SUICIDAL THOUGHTS	2	2	2	1	1	1	1	
				05. INERTIA	2	2	2	1	1	1	1	
				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	1	1	1	1	
				09. REDUCED SLEEP	2	2	2	1	1	1	1	
				10. REDUCED APPETITE	2	0	0	0	0	0	0	
				11. Total score	18	12	12	7	6	5	5	
				324	Imipramine	Male	01. REPORTED SADNESS	2	2	1	2	2
02. INNER TENSION	1	2	2				1	1	1	1		
03. APPARENT SADNESS	2	2	1				2	1	1	1		
04. SUICIDAL THOUGHTS	1	1	0				1	1	1	1		
05. INERTIA	2	1	1				2	1	1	1		
06. INABILITY TO FEEL	2	1	1				1	0	1	1		
07. PESSIMISTIC THOUGHTS	1	1	1				1	1	1	1		
08. CONCENTRATIONS DIFFICULTIES	2	1	0				1	1	1	1		
09. REDUCED SLEEP	1	1	1				0	0	0	0		
10. REDUCED APPETITE	1	1	1				1	1	1	1		
11. Total score	15	13	8				12	8	7	5		
325	Reboxetine	Female	01. REPORTED SADNESS	1	1	1	0	0	0	0	0	
			02. INNER TENSION	2	2	1	1	1	0	0		
			03. APPARENT SADNESS	1	1	0	1	0	0	0		
			04. SUICIDAL THOUGHTS	1	0	0	0	0	0	0		
			05. INERTIA	2	2	1	1	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	1	1	1	1	1		
			09. REDUCED SLEEP	1	1	0	0	0	0	0		
			10. REDUCED APPETITE	1	0	0	0	0	0	0		
			11. Total score	13	11	4	4	1	0	0		
326	Imipramine	Male	01. REPORTED SADNESS	2	2	1	1	1	0	0	1	
			02. INNER TENSION	2	1	1	1	1	1	0		
			03. APPARENT SADNESS	1	2	1	1	1	1	0		
			04. SUICIDAL THOUGHTS	2	0	0	0	0	0	0		
			05. INERTIA	2	1	1	0	0	0	0		
			06. INABILITY TO FEEL	2	2	1	1	0	0	0		
			07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1		
			08. CONCENTRATIONS DIFFICULTIES	1	2	1	1	0	1	1		
			09. REDUCED SLEEP	1	1	0	2	0	0	0		
			10. REDUCED APPETITE	1	0	0	1	1	1	1		
			11. Total score	15	12	7	9	4	1	6		

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
11	327	Reboxetine	Female	01.REPORTED SADNESS	2	2	1	1	1	1	1	0	
				02.INNER TENSION	2	2	2	1	1	1	1	1	1
				03.APPARENT SADNESS	2	2	2	1	1	1	1	1	1
				04.SUICIDAL THOUGHTS	1	1	1	0	0	0	0	0	0
				05.INERTIA	2	2	1	1	1	1	1	1	0
				06.INABILITY TO FEEL	2	2	1	1	1	1	1	1	0
				07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	1	1
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	0	1	1	1	1
				09.REDUCED SLEEP	2	2	2	1	1	1	1	1	1
				10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
				11.Total score	16	16	12	8	7	8	7	8	6
328	Imipramine	Male	01.REPORTED SADNESS	2	1	1	1	0	0	0	0		
			02.INNER TENSION	2	1	1	1	1	1	1	1		
			03.APPARENT SADNESS	1	1	1	0	0	0	0	0		
			04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0		
			05.INERTIA	2	1	1	1	1	1	1	1		
			06.INABILITY TO FEEL	2	1	1	0	0	0	0	0		
			07.PESSIMISTIC THOUGHTS	1	0	1	1	1	1	1	1		
			08.CONCENTRATIONS DIFFICULTIES	2	1	2	1	1	1	1	1		
			09.REDUCED SLEEP	2	1	0	1	0	0	0	0		
			10.REDUCED APPETITE	0	0	1	0	0	0	0	0		
			11.Total score	15	7	9	4	5	5	5	5		
329	Imipramine	Female	01.REPORTED SADNESS	1	2	1	1	1	0	1	1		
			02.INNER TENSION	1	1	1	1	1	1	1	1		
			03.APPARENT SADNESS	2	2	1	0	0	0	0	0		
			04.SUICIDAL THOUGHTS	1	1	1	0	0	0	0	0		
			05.INERTIA	2	2	1	1	1	1	1	1		
			06.INABILITY TO FEEL	2	1	1	1	1	1	1	1		
			07.PESSIMISTIC THOUGHTS	1	1	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	0	0	0	0	0	0	0	0		
			11.Total score	14	14	9	7	7	5	5	5		
330	Reboxetine	Female	01.REPORTED SADNESS	2	2	2	1	1	0	1	1		
			02.INNER TENSION	1	1	1	1	1	1	1	1		
			03.APPARENT SADNESS	2	2	1	0	0	0	0	0		
			04.SUICIDAL THOUGHTS	2	1	1	0	0	0	0	0		
			05.INERTIA	2	2	1	1	1	1	1	1		
			06.INABILITY TO FEEL	2	1	1	1	1	1	1	1		
			07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	1		
			08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1	1		
			09.REDUCED SLEEP	0	0	0	0	0	0	0	0		
			10.REDUCED APPETITE	0	0	0	0	0	0	0	0		
			11.Total score	13	13	13	13	13	13	13	13		

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 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
11	331	Reboxetine	Male	01.REPORTED SADNESS	2	1	0	0	2	0	0
				02.INNER TENSION	2	2	1	1	1	1	1
				03.APPARENT SADNESS	2	1	1	1	2	0	0
				04.SUICIDAL THOUGHTS	1	0	0	0	1	0	0
				05.INERTIA	2	1	1	1	2	1	1
				06.INABILITY TO FEEL	2	2	1	1	2	1	1
				07.PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	1
				09.REDUCED SLEEP	2	2	2	1	1	1	1
				10.REDUCED APPETITE	1	1	0	1	1	0	1
				11.Total score	18	13	9	8	14	5	6
352	Imipramine	Female	01.REPORTED SADNESS	2	1	0	0	0	0	0	0
			02.INNER TENSION	2	0	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	2	0	0	0	0	0	0	
			06.INABILITY TO FEEL	2	1	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	1	0	1	0	0	0	0	
			10.REDUCED APPETITE	1	0	0	0	0	0	0	
			11.Total score	13	3	1	0	0	0	0	
333	Imipramine	Female	01.REPORTED SADNESS	2	2	1	2	2	1	1	0
			02.INNER TENSION	2	2	2	2	1	1	0	
			03.APPARENT SADNESS	2	2	2	2	1	1	0	
			04.SUICIDAL THOUGHTS	1	0	1	1	1	0	0	
			05.INERTIA	2	2	2	2	1	1	0	
			06.INABILITY TO FEEL	2	2	2	2	1	1	1	
			07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	
			08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	1	
			09.REDUCED SLEEP	2	2	1	1	0	0	0	
			10.REDUCED APPETITE	0	2	1	1	0	0	0	
			11.Total score	16	16	15	16	8	7	2	
12	Imipramine	Female	01.REPORTED SADNESS	2	0	0	0	2	1	1	0
			02.INNER TENSION	2	0	0	0	0	1	1	
			03.APPARENT SADNESS	2	1	0	2	1	1	0	
			04.SUICIDAL THOUGHTS	2	0	0	0	1	0	0	
			05.INERTIA	1	0	0	0	0	0	0	
			06.INABILITY TO FEEL	0	0	0	0	0	0	0	
			07.PESSIMISTIC THOUGHTS	1	1	0	1	0	0	0	
			08.CONCENTRATIONS DIFFICULTIES	0	0	0	0	0	0	0	
			09.REDUCED SLEEP	0	2	1	0	2	1	1	
			10.REDUCED APPETITE	2	0	0	0	0	0	0	
			11.Total score	2	0	0	2	0	0	0	

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Listing No.: 13-0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
12	337	Imipramine	Female	11.Total score	14	3	0	7	5	5	2
			Female	01.REPORTED SADNESS	3	2	1	1	1	1	1
			Female	02.INNER TENSION	2	2	2	1	1	2	1
			Female	03.APPARENT SADNESS	2	1	1	1	1	1	1
			Female	04.SUICIDAL THOUGHTS	2	1	1	1	1	0	1
			Female	05.INERTIA	2	2	1	0	1	2	1
			Female	06.INABILITY TO FEEL	1	2	1	0	1	1	1
			Female	07.PESSIMISTIC THOUGHTS	2	1	1	0	0	0	0
			Female	08.CONCENTRATIONS DIFFICULTIES	0	0	1	1	1	1	1
			Female	09.REDUCED SLEEP	2	1	1	1	2	2	3
			Female	10.REDUCED APPETITE	0	1	1	0	0	1	0
			Female	11.Total score	16	13	11	7	9	11	10
339		Imipramine	Male	01.REPORTED SADNESS	2	1	1	1	0	0	0
			Male	02.INNER TENSION	2	2	2	1	2	1	1
			Male	03.APPARENT SADNESS	1	1	1	0	0	0	0
			Male	04.SUICIDAL THOUGHTS	1	1	1	0	0	0	0
			Male	05.INERTIA	2	1	1	0	0	0	0
			Male	06.INABILITY TO FEEL	2	2	1	1	0	0	0
			Male	07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	0
			Male	08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1
			Male	09.REDUCED SLEEP	1	1	1	1	1	1	1
			Male	10.REDUCED APPETITE	2	2	1	2	2	2	1
			Male	11.Total score	15	13	11	8	7	5	2
340		Reboxetine	Female	01.REPORTED SADNESS	2	2	0	0	0	0	1
			Female	02.INNER TENSION	2	1	0	0	0	1	1
			Female	03.APPARENT SADNESS	1	1	0	0	0	0	1
			Female	04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0
			Female	05.INERTIA	2	2	0	0	0	1	1
			Female	06.INABILITY TO FEEL	1	1	0	0	0	0	1
			Female	07.PESSIMISTIC THOUGHTS	1	1	0	0	0	1	1
			Female	08.CONCENTRATIONS DIFFICULTIES	2	2	0	1	0	1	1
			Female	09.REDUCED SLEEP	2	2	1	2	1	1	2
			Female	10.REDUCED APPETITE	2	2	1	1	1	1	1
			Female	11.Total score	15	15	2	4	1	8	10
341		Reboxetine	Female	01.REPORTED SADNESS	1	2	1	2	0	1	1
			Female	02.INNER TENSION	2	2	2	2	0	1	2
			Female	03.APPARENT SADNESS	1	1	1	1	0	0	1
			Female	04.SUICIDAL THOUGHTS	0	1	1	2	0	2	2
			Female	05.INERTIA	2	1	1	2	1	1	1
			Female	06.INABILITY TO FEEL	2	2	2	2	1	0	2
			Female	07.PESSIMISTIC THOUGHTS	2	2	2	2	2	1	1
			Female	08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2
			Female	09.REDUCED SLEEP	3	3	2	2	2	2	2

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Listing No.: 15.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
12	341	Reboxetine	Female	10. REDUCED APPETITE 11. Total score	1 16	2 18	1 15	2 19	1 7	2 16	
13	353	Reboxetine	Female	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 2 2 2 2 2 2 2 17	1 1 2 2 1 1 1 1 2 2 14	1 1 1 0 1 3 1 1 1 2 10	1 1 1 1 1 0 1 1 1 0 6	0 1 1 0 1 0 1 1 0 4	1 1 2 1 1 1 1 1 1 1 11	
354		Imipramine	Female	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 1 1 1 1 2 15	1 1 1 0 2 1 1 1 0 2 7	1 1 1 0 1 0 0 1 1 0 5	0 0 0 1 1 0 0 1 1 0 3	0 0 0 0 0 0 0 0 0 0 2	0 0 0 0 0 0 0 0 0 0 2	
355		Reboxetine	Female	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	1 2 1 2 1 2 2 1 1 2 15	1 1 1 1 1 1 0 1 1 1 9	1 1 1 1 1 1 1 1 1 0 5	1 1 1 1 1 1 1 1 1 0 3	1 1 1 1 1 1 1 1 1 0 2	1 1 1 1 1 1 1 1 1 0 1	
356		Imipramine	Male	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 2 2 2 2 2	2 2 1 1 1 2 2 2	2 2 1 1 1 1 1 1	1 1 0 1 1 1 1 1	1 1 0 0 1 0 1 1	0 1 1 1 1 1 1 1	1 2 1 0 1 1 1 1

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 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
13	356	Imipramine	Male	09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 1 18	1 1 15	1 0 10	1 0 6	1 0 8	1 0 8	2 0 10
	357	Imipramine	Female	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 1 2 2 2 1 15						
	358	Reboxetine	Male	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 1 0 2 1 15	1 2 1 2 1 1 1 0 2 1 11	2 2 1 0 1 1 0 0 2 1 10	0 1 1 0 0 1 1 0 2 1 7	1 2 1 0 0 1 2 0 2 1 9	0 1 0 0 0 0 0 0 2 0 9	0 1 0 0 0 0 0 0 2 0 9
	359	Reboxetine	Female	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	1 2 1 2 1 1 1 2 2 2 15	1 2 1 2 2 1 2 1 2 2 16	1 2 1 1 1 1 0 0 2 0 10	1 1 1 0 1 0 0 0 2 0 7	0 1 1 0 0 0 0 0 2 0 9	0 0 0 0 0 0 0 0 2 0 9	0 1 0 0 0 0 0 0 2 0 9
	360	Imipramine	Female	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS	2 2 1 1 1 1 2	1 2 1 1 1 1 2	1 2 1 1 1 1 2	1 1 1 0 0 0 2	1 2 1 0 0 0 5	0 1 1 1 1 1 2	2 1 1 1 1 1 2

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 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
13	360	Imipramine	Female	08. CONCENTRATIONS DIFFICULTIES	1	1	0	0	0	0	0
				09. REDUCED SLEEP	2	2	0	0	0	0	
				10. REDUCED APPETITE	1	1	0	0	0	0	
				11. Total score	15	12					
				01. REPORTED SADNESS	2	1	0	0	0	0	
				02. INNER TENSION	1	1	0	0	0	0	
				03. APPARENT SADNESS	2	1	0	0	0	0	
				04. SUICIDAL THOUGHTS	2	1	0	0	0	0	
				05. INERTIA	2	2	0	0	0	0	
				06. INABILITY TO FEEL	2	1	0	0	0	0	
				07. PESSIMISTIC THOUGHTS	2	1	0	0	0	0	
14	457	Reboxetine	Female	08. CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	0	2
				09. REDUCED SLEEP	2	2	1	1	0	0	
				10. REDUCED APPETITE	0	0	0	0	0	0	
				11. Total score	17	11	2	1	2	1	
				01. REPORTED SADNESS	3	3	3	2	2	1	
				02. INNER TENSION	2	2	2	2	2	1	
				03. APPARENT SADNESS	1	1	1	1	1	1	
				04. SUICIDAL THOUGHTS	1	1	1	1	1	1	
				05. INERTIA	1	1	1	1	1	1	
				06. INABILITY TO FEEL	2	2	2	2	2	1	
				07. PESSIMISTIC THOUGHTS	2	2	2	2	2	1	
458	458	Imipramine	Female	08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	1
				09. REDUCED SLEEP	2	2	2	2	2	2	
				10. REDUCED APPETITE	2	2	2	2	2	2	
				11. Total score	18	18	18	18	17	15	
				01. REPORTED SADNESS	2	2	2	2	2	2	
				02. INNER TENSION	2	2	2	2	2	2	
				03. APPARENT SADNESS	3	3	3	3	2	1	
				04. SUICIDAL THOUGHTS	2	2	2	2	2	2	
				05. INERTIA	2	2	2	2	2	2	
				06. INABILITY TO FEEL	2	2	2	2	2	1	
				07. PESSIMISTIC THOUGHTS	2	2	2	2	1	1	
459	459	Reboxetine	Male	08. CONCENTRATIONS DIFFICULTIES	2	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	20	20	20	17	16	16	
				01. REPORTED SADNESS	2	2	2	2	1	1	
				02. INNER TENSION	2	2	2	2	2	1	
				03. APPARENT SADNESS	2	2	2	2	1	1	
				04. SUICIDAL THOUGHTS	1	1	1	1	1	1	
				05. INERTIA	2	2	2	2	1	1	
				06. INABILITY TO FEEL	2	2	2	1	1	1	
				07. PESSIMISTIC THOUGHTS	2	2	2	2	1	1	

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14	459	Reboxetine	Male	07. PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1
				08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	
				09. REDUCED SLEEP	2	2	1	1	1	1	
				10. REDUCED APPETITE	1	1	1	1	1	1	
				11. Total score	18	18	14	11	11	10	
				01. REPORTED SADNESS	2	2	2	2	2	1	
				02. INNER TENSION	2	2	2	2	2	2	
				03. APPARENT SADNESS	1	1	1	1	1	1	
				04. SUICIDAL THOUGHTS	2	2	2	2	1	1	
				05. INERTIA	2	2	2	2	1	1	
				06. INABILITY TO FEEL	1	1	1	1	1	1	
14	460	Imipramine	Male	01. REPORTED SADNESS	2	2	2	2	2	2	1
				02. INNER TENSION	2	2	2	2	2	2	
				03. APPARENT SADNESS	2	2	2	2	2	1	
				04. SUICIDAL THOUGHTS	1	1	1	1	1	1	
				05. INERTIA	2	2	2	2	2	1	
				06. INABILITY TO FEEL	2	2	2	2	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	2	2	2	2	2	1	
				11. Total score	18	18	18	18	16	13	
14	461	Imipramine	Female	01. REPORTED SADNESS	2	2	2	2	2	2	2
				02. INNER TENSION	2	2	2	2	2	2	
				03. APPARENT SADNESS	2	2	2	2	2	2	
				04. SUICIDAL THOUGHTS	2	2	2	2	2	2	
				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	3	3	3	3	3	2	
				09. REDUCED SLEEP	2	2	2	2	2	2	
				10. REDUCED APPETITE	2	2	2	2	2	2	
				11. Total score	21	21	21	21	21	20	
14	462	Reboxetine	Female	01. REPORTED SADNESS	2	2	2	2	2	2	2
				02. INNER TENSION	2	2	2	2	2	2	
				03. APPARENT SADNESS	2	2	2	2	2	2	
				04. SUICIDAL THOUGHTS	2	2	2	2	2	2	
				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	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	20	20	20	20	20	20	
14	463	Imipramine	Male	01. REPORTED SADNESS	2	2	1	1	1	1	1
				02. INNER TENSION	2	2	2	1	1	1	
				03. APPARENT SADNESS	2	2	1	1	1	1	
				04. SUICIDAL THOUGHTS	2	1	1	1	1	1	
				05. INERTIA	1	1	1	1	1	1	

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 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
14	463	Imipramine	Male	06. INABILITY TO FEEL	2	2	2	2	1	1	1	1			
				07. PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1				
				08. CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	1				
				09. REDUCED SLEEP	2	2	2	2	2	2	2				
				10. REDUCED APPETITE	2	2	1	1	1	1	1				
				11. Total score	19	18	14	12	11	11	10				
				464	Reboxetine	Female	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	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					
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	20	20	20				20	20	20	20					
465	Reboxetine	Male	01. REPORTED SADNESS	3	2	1	1	1	1	1	0				
			02. INNER TENSION	3	2	1	1	1	1	1					
			03. APPARENT SADNESS	2	2	1	1	1	1	1					
			04. SUICIDAL THOUGHTS	1	1	1	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	1	1	1	1	0					
			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	1	1	1	1	0					
			11. Total score	21	19	14	11	10	8	2					
466	Imipramine	Female	01. REPORTED SADNESS	2	2	1	1	1	1	1	0				
			02. INNER TENSION	2	2	1	1	1	1	1					
			03. APPARENT SADNESS	2	2	1	1	1	1	1					
			04. SUICIDAL THOUGHTS	2	2	1	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	2	2	1	1	1	1					
			08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	1	1					
			09. REDUCED SLEEP	2	2	1	1	1	1	1					
			10. REDUCED APPETITE	2	2	1	1	1	1	0					
			11. Total score	20	20	13	11	11	10	6					
14/1	129	Reboxetine	Male	01. REPORTED SADNESS	1										
				02. INNER TENSION	1										
				03. APPARENT SADNESS	2										
				04. SUICIDAL THOUGHTS	1										

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REBOXETINE - PROTOCOL 20124/017

Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
14/1	129	Reboxetine	Male	05. INERTIA	1										
				06. INABILITY TO FEEL	1										
				07. PESSIMISTIC THOUGHTS	1										
				08. CONCENTRATIONS DIFFICULTIES	2										
				09. REDUCED SLEEP	2										
				10. REDUCED APPETITE	0										
				11. Total score	12										
				426	Reboxetine	Female	01. REPORTED SADNESS	2	2	1	1	1	1	1	0
							02. INNER TENSION	2	1	1	1	1	1	1	
							03. APPARENT SADNESS	2	2	1	1	1	0	0	
							04. SUICIDAL THOUGHTS	1	1	1	1	0	0	0	
05. INERTIA	2	1	0				0	0	0						
06. INABILITY TO FEEL	2	1	0				0	0	0						
07. PESSIMISTIC THOUGHTS	2	1	0				1	0	0						
08. CONCENTRATIONS DIFFICULTIES	2	1	0				1	1	1						
09. REDUCED SLEEP	2	3	2				2	1	1						
10. REDUCED APPETITE	0	0	0				0	0	0						
11. Total score	16	14	6				8	5	4						
429	Imipramine	Female	01. REPORTED SADNESS	2	2										
			02. INNER TENSION	2	2										
			03. APPARENT SADNESS	1	1										
			04. SUICIDAL THOUGHTS	1	1										
			05. INERTIA	1	1										
			06. INABILITY TO FEEL	1	1										
			07. PESSIMISTIC THOUGHTS	1	1										
			08. CONCENTRATIONS DIFFICULTIES	2	1										
			09. REDUCED SLEEP	2	3										
			10. REDUCED APPETITE	2	1										
			11. Total score	15	14										
451	Imipramine	Male	01. REPORTED SADNESS	2	1	1	1	1	2	1	2				
			02. INNER TENSION	2	1	1	1	1	1	1					
			03. APPARENT SADNESS	2	1	2	2	2	2	2					
			04. SUICIDAL THOUGHTS	1	1	1	1	1	1	1					
			05. INERTIA	2	1	1	1	1	1	1					
			06. INABILITY TO FEEL	1	1	1	2	1	1	2					
			07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1					
			08. CONCENTRATIONS DIFFICULTIES	1	2	1	0	1	2	2					
			09. REDUCED SLEEP	2	2	2	1	2	1	2					
			10. REDUCED APPETITE	0	0	0	0	0	0	0					
			11. Total score	13	11	11	10	12	11	14					
452	Reboxetine	Female	01. REPORTED SADNESS	2	2	2	2	2	2	2	2				
			02. INNER TENSION	1	1	0	0	1	1	0					
			03. APPARENT SADNESS	3	2	2	2	1	0	2					

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 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
14/1	452	Reboxetine	Female	04.SUICIDAL THOUGHTS	2	0	0	0	0	0	0	0				
				05.INERTIA	2	2	2	2	2	2	2	1				
				06.INABILITY TO FEEL	3	3	3	2	2	2	2	1				
				07.PESSIMISTIC THOUGHTS	2	1	0	1	1	1	1	1				
				08.CONCENTRATIONS DIFFICULTIES	3	2	2	2	2	2	1	2				
				09.REDUCED SLEEP	2	1	2	2	2	1	1	0				
				10.REDUCED APPETITE	2	1	1	0	0	0	0	0				
				11.Total score	22	15	14	11	12	10	9					
				14/2	136	Imipramine	Female	01.REPORTED SADNESS	2	2	2	2	2	2	1	1
								02.INNER TENSION	2	2	2	1	1	1	1	
								03.APPARENT SADNESS	4	2	2	1	1	1	0	
04.SUICIDAL THOUGHTS	1	1	1					1	1	1	0					
05.INERTIA	2	2	2					1	1	1	0					
06.INABILITY TO FEEL	2	2	2					2	2	1	1					
07.PESSIMISTIC THOUGHTS	1	1	2					2	1	1	1					
08.CONCENTRATIONS DIFFICULTIES	2	1	1					1	1	1	1					
09.REDUCED SLEEP	1	0	0					0	0	0	0					
10.REDUCED APPETITE	1	0	0					0	0	0	0					
11.Total score	15	14	14					10	12	8	5					
14/3	417	Reboxetine	Female	01.REPORTED SADNESS	3	1	1	1	1	0	1	1				
				02.INNER TENSION	2	1	1	1	1	1	1					
				03.APPARENT SADNESS	2	1	1	1	1	0	1					
				04.SUICIDAL THOUGHTS	2	0	0	0	0	0	0					
				05.INERTIA	2	1	1	1	1	1	1					
				06.INABILITY TO FEEL	2	1	0	0	1	1	1					
				07.PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1					
				08.CONCENTRATIONS DIFFICULTIES	1	2	1	1	1	1	1					
				09.REDUCED SLEEP	1	1	1	1	1	1	1					
				10.REDUCED APPETITE	0	0	0	0	0	0	0					
				11.Total score	13	11	9	8	5	4	4					
14/3	418	Imipramine	Female	01.REPORTED SADNESS	3	2	1	1	1	2	2	2				
				02.INNER TENSION	2	2	2	2	2	2	2					

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 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
14/3	418	Imipramine	Female	03.APPARENT SADNESS	2	2	2	1	2	2	2	2				
				04.SUICIDAL THOUGHTS	1	2	1	1	1	1	1	1				
				05.INERTIA	2	1	1	1	1	1	1	1				
				06.INABILITY TO FEEL	2	2	2	2	2	2	2	2				
				07.PESSIMISTIC THOUGHTS	2	2	2	2	2	2	2	2				
				08.CONCENTRATIONS DIFFICULTIES	1	3	1	1	2	2	2	2				
				09.REDUCED SLEEP	0	0	0	0	0	0	0	0				
				10.REDUCED APPETITE	0	1	0	0	0	1	1	1				
				11.Total score	15	17	12	10	13	14	14					
				419	Reboxetine	Female	01.REPORTED SADNESS	2	2	1	1	1	1	1	1	1
							02.INNER TENSION	2	2	1	1	1	1	1	1	
03.APPARENT SADNESS	2	2	2				1	1	1	1	1					
04.SUICIDAL THOUGHTS	1	1	1				0	0	0	0	0					
05.INERTIA	1	1	1				1	1	1	1	1					
06.INABILITY TO FEEL	2	2	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	0	1	2				2	2	2	2	2					
10.REDUCED APPETITE	1	0	0				0	0	0	0	0					
11.Total score	15	15	11				9	7	7	6						
420	Imipramine	Female	01.REPORTED SADNESS	3	3	2	2	2	2	2	2					
			02.INNER TENSION	2	2	2	2	2	2	2						
			03.APPARENT SADNESS	1	1	1	0	0	0	0						
			04.SUICIDAL THOUGHTS	3	3	2	2	2	2	2						
			05.INERTIA	2	2	1	1	1	1	1						
			06.INABILITY TO FEEL	2	2	1	1	1	1	1						
			07.PESSIMISTIC THOUGHTS	3	3	2	2	2	2	2						
			08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	2						
			09.REDUCED SLEEP	1	1	0	0	1	1	1						
			10.REDUCED APPETITE	1	2	0	2	2	2	2						
			11.Total score	20	21	11	16	16	16							
421	Reboxetine	Female	01.REPORTED SADNESS	2	2	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	0	0	0	0	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	2	1	1	1	1	1	1						
			08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	1						
			09.REDUCED SLEEP	2	1	0	0	0	0	0						
			10.REDUCED APPETITE	2	1	0	0	0	0	0						
			11.Total score	16	12	7	7	7	7							
427	Imipramine	Female	01.REPORTED SADNESS	2	1	1	1	1	1	1	1					

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REBOXETINE - PROTOCOL 20124/017
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
14/3	427	Imipramine	Female	01.REPORTED SADNESS	2	1	1	1	1	1	1	1
				02.INNER TENSION	2	2	2	2	2	2	2	
				03.APPARENT SADNESS	1	0	1	1	1	1		
				04.SUICIDAL THOUGHTS	2	1	1	1	1	1		
				05.INERTIA	2	1	1	1	1	1		
				06.INABILITY TO FEEL	2	2	2	2	2	2		
				07.PESSIMISTIC THOUGHTS	2	2	2	2	2	2		
				08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1		
				09.REDUCED SLEEP	1	0	0	0	0	0		
				10.REDUCED APPETITE	1	0	1	1	1	1		
				11.Total score	17	9	11	11	10	10		
428	Imipramine	Female	01.REPORTED SADNESS	3	2	1	2	1	1	1	1	
			02.INNER TENSION	2	2	1	1	1	1			
			03.APPARENT SADNESS	2	2	2	2	1	1			
			04.SUICIDAL THOUGHTS	2	2	0	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	1	2	1	1	1			
			08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1			
			09.REDUCED SLEEP	1	1	1	1	0	0			
			10.REDUCED APPETITE	1	1	1	1	1	1			
			11.Total score	19	17	13	14	11	10			
14/4	131	Imipramine	Female	01.REPORTED SADNESS	2	2	2	2	2	1	1	
				02.INNER TENSION	1	1	1	1	1	1		
				03.APPARENT SADNESS	2	2	1	1	0	0		
				04.SUICIDAL THOUGHTS	1	1	1	1	0	0		
				05.INERTIA	1	1	1	1	1	1		
				06.INABILITY TO FEEL	1	1	1	1	1	1		
				07.PESSIMISTIC THOUGHTS	1	1	1	1	0	0		
				08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	0	0		
				09.REDUCED SLEEP	2	2	2	2	1	1		
				10.REDUCED APPETITE	1	1	1	1	1	1		
				11.Total score	13	13	12	9	7	7		
132	Imipramine	Female	01.REPORTED SADNESS	3	3	2	1	1	1	0	0	
			02.INNER TENSION	2	2	1	1	1	1			
			03.APPARENT SADNESS	2	2	1	1	1	1			
			04.SUICIDAL THOUGHTS	1	1	1	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	1	1			
			08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1			
			09.REDUCED SLEEP	2	2	1	1	1	1			
			10.REDUCED APPETITE	2	2	1	1	1	1			
			11.Total score	18	18	11	9	9	5			

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		PHARMACIA CNS RED								
		REBOXETINE - PROTOCOL 20124/017								
		Listing No.: 13.0								
		MONTGOMERY ASBERG DEPRESSION RATING SCALE								
Centre	Patient Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14/4	133	Female	01.REPORTED SADNESS	2	2	2	2	2	1	1
			02.INNER TENSION	2	2	2	1	1	0	0
			03.APPARENT SADNESS	2	2	1	1	1	1	0
			04.SUICIDAL THOUGHTS	1	1	1	1	1	0	0
			05.INERTIA	2	2	2	1	1	1	1
			06.INABILITY TO FEEL	1	1	1	1	1	0	0
			07.PESSIMISTIC THOUGHTS	1	1	1	1	1	0	0
			08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	0
			09.REDUCED SLEEP	2	2	2	2	2	1	1
			10.REDUCED APPETITE	2	2	2	1	1	1	0
			11.Total score	16	16	15	12	12	7	3
134	Reboxetine	Female	01.REPORTED SADNESS	3	3	2	2	1	1	0
			02.INNER TENSION	2	2	2	1	1	1	1
			03.APPARENT SADNESS	2	2	1	1	1	1	0
			04.SUICIDAL THOUGHTS	1	1	1	1	0	0	0
			05.INERTIA	2	2	2	1	1	1	0
			06.INABILITY TO FEEL	2	2	1	1	1	1	0
			07.PESSIMISTIC THOUGHTS	1	1	1	1	1	0	0
			08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	0	0
			09.REDUCED SLEEP	2	2	2	2	1	1	1
			10.REDUCED APPETITE	2	2	2	1	1	1	1
			11.Total score	19	19	16	11	8	7	4
135	Reboxetine	Male	01.REPORTED SADNESS	3	3	2	1	1	0	0
			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	2	2	2	1	1	0
			06.INABILITY TO FEEL	1	1	1	1	1	1	1
			07.PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1
			08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	0	0
			09.REDUCED SLEEP	2	2	2	1	1	1	1
			10.REDUCED APPETITE	1	1	1	1	1	0	0
			11.Total score	19	19	13	10	9	5	4
14/7	422	Female	01.REPORTED SADNESS	2	2	2	2	2	1	1
			02.INNER TENSION	2	2	2	2	1	1	0
			03.APPARENT SADNESS	1	1	1	1	1	1	1
			04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0
			05.INERTIA	2	2	1	0	0	0	0
			06.INABILITY TO FEEL	2	2	2	2	2	0	0
			07.PESSIMISTIC THOUGHTS	1	1	2	2	2	1	0
			08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	0
			09.REDUCED SLEEP	2	2	2	2	2	1	0
			10.REDUCED APPETITE	1	1	1	1	0	0	0
			11.Total score	15	16	14	12	10	6	2

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 15.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		
14/7	423	Imipramine	Female	01.REPORTED SADNESS	2	2	2	2	2	2	2	0	
				02.INNER TENSION	2	2	2	2	2	2	2	2	0
				03.APPARENT SADNESS	2	2	2	2	2	1	1	1	0
				04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0	0
				05.INERTIA	2	2	2	2	2	1	1	1	1
				06.INABILITY TO FEEL	2	1	1	1	1	1	1	1	1
				07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	1	0
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	1	1	1	1
				09.REDUCED SLEEP	2	2	2	2	2	2	2	1	1
				10.REDUCED APPETITE	3	2	2	2	2	1	1	1	0
				11.Total score	18	16	16	14	11	9	2	2	2
	424	Reboxetine	Male	01.REPORTED SADNESS	2	2	2	2	1	2	0	0	
				02.INNER TENSION	2	2	2	2	1	1	0	0	
				03.APPARENT SADNESS	1	1	1	1	1	1	2	0	
				04.SUICIDAL THOUGHTS	1	1	1	1	1	0	0	0	
				05.INERTIA	2	2	2	2	2	2	1	1	
				06.INABILITY TO FEEL	2	2	2	2	2	2	0	0	
				07.PESSIMISTIC THOUGHTS	2	2	2	2	2	1	1	0	
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	0	0	
				09.REDUCED SLEEP	2	2	2	2	1	1	1	1	
				10.REDUCED APPETITE	2	2	2	2	1	1	1	0	
				11.Total score	18	17	17	14	13	6	4	4	
	430	Reboxetine	Female	01.REPORTED SADNESS	2	2	2	2	1	1	0	0	
				02.INNER TENSION	2	2	2	2	1	1	0	0	
				03.APPARENT SADNESS	2	2	2	2	1	0	0	0	
				04.SUICIDAL THOUGHTS	1	1	1	1	1	0	0	0	
				05.INERTIA	2	2	2	2	1	1	0	0	
				06.INABILITY TO FEEL	2	2	2	2	1	1	1	1	
				07.PESSIMISTIC THOUGHTS	2	2	2	2	1	0	0	0	
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	1	1	
				09.REDUCED SLEEP	2	1	1	1	1	0	0	0	
				10.REDUCED APPETITE	1	1	0	0	0	0	0	0	
				11.Total score	18	17	15	9	5	3	0	0	
	431	Reboxetine	Male	01.REPORTED SADNESS	2	2	2	2	2	3	1	0	
				02.INNER TENSION	2	2	2	2	2	2	1	0	
				03.APPARENT SADNESS	2	2	2	2	2	2	1	0	
				04.SUICIDAL THOUGHTS	1	2	3	2	2	2	1	0	
				05.INERTIA	1	1	2	2	2	2	1	1	
				06.INABILITY TO FEEL	2	2	2	2	3	3	1	1	
				07.PESSIMISTIC THOUGHTS	2	2	2	2	2	2	1	0	
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	1	1	
				09.REDUCED SLEEP	2	2	2	2	2	2	1	1	
				10.REDUCED APPETITE	1	1	2	2	2	2	1	0	

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14/7	431	Reboxetine	Male	11.Total score	17	18	21	22	22	10	5
				01.REPORTED SADNESS	2	2	2	2	1	1	0
				02.INNER TENSION	2	2	2	2	1	0	0
				03.APPARENT SADNESS	2	2	2	2	1	0	0
				04.SUICIDAL THOUGHTS	1	1	1	1	1	0	0
				05.INERTIA	2	2	2	2	1	0	0
				06.INABILITY TO FEEL	2	2	2	2	1	1	0
				07.PESSIMISTIC THOUGHTS	1	1	1	1	0	0	0
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	0	0
				09.REDUCED SLEEP	2	2	2	2	1	0	1
				10.REDUCED APPETITE	2	2	2	2	1	1	1
				11.Total score	18	18	16	14	7	4	2
				01.REPORTED SADNESS	2	2	2	2	1	1	0
				02.INNER TENSION	3	2	2	2	1	1	0
				03.APPARENT SADNESS	2	3	2	2	1	1	0
				04.SUICIDAL THOUGHTS	1	1	1	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	2	2	2	2	1	0	0
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	0	0
				09.REDUCED SLEEP	2	2	2	2	1	1	1
				10.REDUCED APPETITE	2	2	2	2	1	1	0
				11.Total score	20	20	15	9	6	4	1
				01.REPORTED SADNESS	2	2	1	0	0	0	0
				02.INNER TENSION	2	2	1	1	0	0	0
				03.APPARENT SADNESS	2	2	1	1	0	0	0
				04.SUICIDAL THOUGHTS	2	2	1	0	0	0	0
				05.INERTIA	2	2	1	0	0	0	0
				06.INABILITY TO FEEL	2	2	1	1	1	1	0
				07.PESSIMISTIC THOUGHTS	2	2	0	0	0	0	0
				08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	0	0	0
				09.REDUCED SLEEP	2	2	1	1	1	1	0
				10.REDUCED APPETITE	2	2	1	1	0	1	0
				11.Total score	20	20	9	6	2	3	0
				01.REPORTED SADNESS	3	3	2	2	1	1	0
				02.INNER TENSION	2	2	2	2	1	0	0
				03.APPARENT SADNESS	3	3	2	2	1	0	0
				04.SUICIDAL THOUGHTS	1	1	1	1	1	0	0
				05.INERTIA	2	2	2	2	1	1	1
				06.INABILITY TO FEEL	2	2	2	2	1	1	0
				07.PESSIMISTIC THOUGHTS	2	2	2	2	1	1	0
				08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	0
				09.REDUCED SLEEP	2	2	2	2	1	1	0

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 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14/7	439	Reboxetine	Male	10. REDUCED APPETITE 11. Total score	3 22	3 22	2 16	1 14	1 10	5 5	2 2
440		Imipramine	Female	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 2 2 2 2 2 2 20	2 2 3 1 2 2 2 2 2 2 20	2 2 3 1 2 2 2 2 2 2 20	1 1 1 0 0 0 0 0 1 3	0 0 0 0 0 0 0 0 1 1	0 0 0 0 0 0 0 0 1 1	0 0 0 0 0 0 0 0 0 0
441		Imipramine	Male	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 20	2 2 2 2 2 2 2 2 2 2 20	0 0 1 0 0 0 0 0 1 1 4	0 0 0 0 0 0 0 0 0 0 2	0 0 0 0 0 0 0 0 0 0 1	0 0 0 0 0 0 0 0 0 0 0
442		Imipramine	Male	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	1 2 2 1 2 2 2 2 2 2 18	2 2 1 2 2 1 2 2 2 2 16	1 1 1 1 2 1 1 1 1 1 9	0 0 0 0 0 0 0 0 0 0 6	0 0 0 0 0 0 0 0 0 0 2	0 0 0 0 0 0 0 0 0 0 1	0 0 0 0 0 0 0 0 0 0 0
449		Reboxetine	Female	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 1 2 2 1 2 2 2	2 1 2 1 2 2 2 2	1 1 1 0 0 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

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Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14/7	449	Reboxetine	Female	09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	2 2 18	2 2 18	1 1 9	2 1 5	1 0 1	1 0 1	0 0 0
450		Imipramine	Male	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 2 2 2 2 2 2 2 2 22	2 2 1 1 1 1 1 1 1 1 19	2 2 1 1 1 1 1 1 1 1 13	1 1 0 0 0 0 0 0 0 0 5	0 0 0 0 0 0 0 0 0 0 0	
14/8	130	Reboxetine	Male	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 2 2 1 1 15	2 1 2 2 2 2 2 2 1 1 14	1 1 1 0 1 1 1 1 1 1 11	1 1 1 0 1 1 1 1 1 1 10	1 1 1 0 1 1 1 1 1 1 9	1 1 1 0 1 1 1 1 1 1 6	
425		Reboxetine	Female	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 3 3 1 3 2 2 1 18	2 2 2 0 3 4 5 3 2 1 18	2 2 2 0 3 2 1 3 2 1 18	2 2 2 0 2 2 2 2 2 1 16	2 2 2 0 2 2 2 2 2 1 16	2 2 2 0 2 2 2 2 2 1 16	
467		Reboxetine	Male	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUICIDAL THOUGHTS 05. INERTIA 06. INABILITY TO FEEL 07. PESSIMISTIC THOUGHTS	2 2 2 0 3 2 2	2 2 2 0 2 1 2	2 2 2 0 1 1 2	2 2 1 0 1 1 2	2 2 1 0 1 1 2	1 1 0 0 1 1 2	

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REBOXETINE - PROTOCOL 20124/017
Listing No.: 13.0
MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14/8	467	Reboxetine	Male	08..CONCENTRATIONS DIFFICULTIES	3	3	2	1	3	2	2
				09..REDUCED SLEEP	3	3	3	2	3	3	2
				10..REDUCED APPETITE	1	1	1	1	1	1	1
				11..Total score	19	18	15	13	18	14	12
14/10	53	Reboxetine	Male	01..REPORTED SADNESS	2	1	1	1	0	0	0
				02..INNER TENSION	2	2	2	1	1	1	1
				03..APPARENT SADNESS	2	2	1	1	0	0	0
				04..SUICIDAL THOUGHTS	0	0	0	0	0	0	0
				05..INERTIA	2	2	2	1	1	0	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	3	2	2	2	1	1	1
				09..REDUCED SLEEP	2	2	2	1	1	1	1
				10..REDUCED APPETITE	2	2	2	1	1	1	0
				11..Total score	19	17	15	10	7	6	5
54		Imipramine	Female	01..REPORTED SADNESS	2	2	2	2	2	2	1
				02..INNER TENSION	2	2	2	2	2	2	2
				03..APPARENT SADNESS	2	2	2	1	2	2	1
				04..SUICIDAL THOUGHTS	1	1	1	1	1	0	0
				05..INERTIA	2	2	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	2	2	2	1	1	1
				09..REDUCED SLEEP	2	2	2	2	1	1	1
				10..REDUCED APPETITE	2	2	2	1	1	1	1
				11..Total score	20	19	17	15	15	14	12
55		Reboxetine	Female	01..REPORTED SADNESS	2	2	1	1	1	0	0
				02..INNER TENSION	3	2	2	1	1	1	1
				03..APPARENT SADNESS	2	2	1	1	1	0	0
				04..SUICIDAL THOUGHTS	0	0	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	3	2	2	2	2	1	1
				09..REDUCED SLEEP	2	2	2	1	1	0	0
				10..REDUCED APPETITE	2	2	1	1	1	1	0
				11..Total score	20	18	14	13	9	6	5
56		Imipramine	Female	01..REPORTED SADNESS	2	2	1	1	1	1	1
				02..INNER TENSION	2	2	2	1	1	1	1
				03..APPARENT SADNESS	2	2	1	1	1	1	1
				04..SUICIDAL THOUGHTS	0	0	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

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14/10	56	Imipramine	Female	07.PESSIMISTIC THOUGHTS	2	2	2	2	1	1	1
				08.CONCENTRATIONS DIFFICULTIES	3	2	2	2	1	1	1
				09.REDUCED SLEEP	2	2	1	1	1	1	
				10.REDUCED APPETITE	1	1	1	2	1	1	
				11.Total score	18	17	14	14	9	9	
				01.REPORTED SADNESS	2	2	2	2	2	1	
				02.INNER TENSION	2	2	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	1	1	
				06.INABILITY TO FEEL	3	2	2	2	2	1	
57	Reboxetine	Female	07.PESSIMISTIC THOUGHTS	2	2	2	2	2	2	1	1
			08.CONCENTRATIONS DIFFICULTIES	3	2	2	2	2	1		
			09.REDUCED SLEEP	2	2	2	2	2	2		
			10.REDUCED APPETITE	2	2	1	1	1	1		
			11.Total score	19	17	15	14	13	10		
			01.REPORTED SADNESS	2	2	2	2	2	1		
			02.INNER TENSION	2	2	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	1	1		
			06.INABILITY TO FEEL	3	2	2	2	2	1		
58	Imipramine	Female	07.PESSIMISTIC THOUGHTS	2	2	2	2	2	1	1	
			08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	1		
			09.REDUCED SLEEP	2	2	2	2	2	1		
			10.REDUCED APPETITE	2	2	1	1	1	1		
			11.Total score	18	16	15	13	11	8		
			01.REPORTED SADNESS	2	2	2	1	1	1		
			02.INNER TENSION	2	2	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	1	1		
			06.INABILITY TO FEEL	2	2	2	2	2	1		
59	Imipramine	Female	07.PESSIMISTIC THOUGHTS	2	2	2	2	2	1	1	
			08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	1		
			09.REDUCED SLEEP	2	2	2	2	2	1		
			10.REDUCED APPETITE	2	2	1	1	1	1		
			11.Total score	18	16	15	13	11	8		
			01.REPORTED SADNESS	2	2	2	1	1	1		
			02.INNER TENSION	2	2	1	1	0	0		
			03.APPARENT SADNESS	2	2	2	1	0	0		
			04.SUICIDAL THOUGHTS	0	0	0	0	0	0		
			05.INERTIA	2	2	1	1	1	1		
			06.INABILITY TO FEEL	2	2	2	2	2	1		
60	Reboxetine	Female	07.PESSIMISTIC THOUGHTS	2	2	2	2	2	1	1	
			08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	1		
			09.REDUCED SLEEP	2	2	2	2	2	1		
			10.REDUCED APPETITE	2	2	1	1	1	1		
			11.Total score	17	17	14	11	8	7		
			01.REPORTED SADNESS	2	2	2	2	1	1		
			02.INNER TENSION	3	2	2	1	1	0		
			03.APPARENT SADNESS	2	2	2	1	1	0		
			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	2	1		

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 13.0
 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42					
14/10	140	Imipramine	Female	05. INERTIA	2	2	2	2	2	2	2	2				
				06. INABILITY TO FEEL	1	1	1	1	1	1	1	1	1			
				07. PESSIMISTIC THOUGHTS	2	2	2	2	2	2	2	2	2			
				08. CONCENTRATIONS DIFFICULTIES	3	3	2	2	2	2	2	2	2			
				09. REDUCED SLEEP	2	2	2	2	1	2	1	2	1			
				10. REDUCED APPETITE	2	2	2	2	1	2	1	2	1			
				11. Total score	18	18	17	17	14	16	14	16	14			
				435	Imipramine	Female	01. REPORTED SADNESS	2	2	2	2	1	1	1	1	1
							02. INNER TENSION	2	2	2	2	1	1	1	1	1
							03. APPARENT SADNESS	2	2	2	2	1	1	1	1	1
							04. SUICIDAL THOUGHTS	0	1	1	0	0	0	0	0	0
05. INERTIA	2	2	1				1	1	1	1	1	1				
06. INABILITY TO FEEL	2	2	2				2	2	2	2	2	2				
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	1	1	1	1	1				
10. REDUCED APPETITE	1	1	1				1	1	1	1	1	1				
11. Total score	16	17	16				11	11	11	11	8					
436	Reboxetine	Female	01. REPORTED SADNESS	2	2	2	1	1	1	1	1	1				
			02. INNER TENSION	2	2	2	1	1	1	1	1	1				
			03. APPARENT SADNESS	2	2	1	1	1	1	1	1	1				
			04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0	0				
			05. INERTIA	1	2	2	2	1	1	1	1	1				
			06. INABILITY TO FEEL	2	2	2	2	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	2	2	2	1	1	1	1	1	1				
			10. REDUCED APPETITE	2	2	2	1	1	1	1	0	0				
			11. Total score	16	17	14	10	9	8	8	8					
437	Reboxetine	Female	01. REPORTED SADNESS	2	2	1	1	1	1	1	1	1				
			02. INNER TENSION	2	2	1	1	1	1	1	1	1				
			03. APPARENT SADNESS	2	2	1	1	1	1	1	1	1				
			04. SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0	0				
			05. INERTIA	1	1	1	1	1	1	1	1	1				
			06. INABILITY TO FEEL	2	2	2	1	1	1	1	1	1				
			07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	1	1				
			08. CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	1	1	1				
			09. REDUCED SLEEP	2	2	2	1	1	1	1	1	1				
			10. REDUCED APPETITE	2	2	1	1	1	1	1	0	0				
			11. Total score	17	16	11	9	8	6	6						
438	Imipramine	Female	01. REPORTED SADNESS	2	3	2	1	1	1	1	1					
			02. INNER TENSION	2	2	2	2	1	1	1	1					
			03. APPARENT SADNESS	2	2	2	2	1	1	1	1					

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42				
14/10	438	Imipramine	Female	04. SUICIDAL THOUGHTS	1	1	1	1	1	1	1	1			
				05. INERTIA	2	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	2	2	2	2	2	2	2				
				09. REDUCED SLEEP	2	2	2	2	2	2	2				
				10. REDUCED APPETITE	2	2	1	1	1	1	1				
				11. Total score	19	19	17	14	12	10	10				
				443	Reboxetine	Female	01. REPORTED SADNESS	3	3	2	2	2	1	0	0
							02. INNER TENSION	2	2	2	2	1	1	1	
							03. APPARENT SADNESS	3	3	2	2	1	1	1	
04. SUICIDAL THOUGHTS	1	1	1				1	1	0	0					
05. INERTIA	3	3	3				2	1	1	1					
06. INABILITY TO FEEL	2	2	2				2	1	1	1					
07. PESSIMISTIC THOUGHTS	3	3	3				2	1	1	1					
08. CONCENTRATIONS DIFFICULTIES	3	3	2				2	1	1	1					
09. REDUCED SLEEP	2	2	2				2	2	1	1					
10. REDUCED APPETITE	2	2	2				2	2	1	1					
11. Total score	24	24	21				18	11	8	8					
444	Reboxetine	Male	01. REPORTED SADNESS	3	3	3	3	3	2	1	1				
			02. INNER TENSION	2	2	2	2	1	1	1					
			03. APPARENT SADNESS	2	2	2	2	2	1	1					
			04. SUICIDAL THOUGHTS	0	0	0	0	0	0	0					
			05. INERTIA	1	1	1	1	1	1	1					
			06. INABILITY TO FEEL	2	2	2	2	2	2	2					
			07. PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1					
			08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	1	1					
			09. REDUCED SLEEP	2	2	2	2	2	1	1					
			10. REDUCED APPETITE	2	2	2	2	2	1	1					
			11. Total score	17	17	17	16	13	10	9					
445	Imipramine	Female	01. REPORTED SADNESS	3	3	2	2	2	1	1	1				
			02. INNER TENSION	3	2	2	2	2	1	1					
			03. APPARENT SADNESS	1	1	1	1	1	0	0					
			04. SUICIDAL THOUGHTS	2	2	2	2	2	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	1	1	1	1	1	1	1					
			08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	1	1					
			09. REDUCED SLEEP	2	2	2	2	2	2	2					
			10. REDUCED APPETITE	2	2	2	2	2	2	2					
			11. Total score	20	19	18	18	15	14	10					
446	Reboxetine	Female	01. REPORTED SADNESS	2	2	1	1	1	1	1	1				
			02. INNER TENSION	2	1	1	1	1	1	1					

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14/10	446	Reboxetine	Female	03. APPARENT SADNESS	2	2	1	1	1	1	1
				04. SUICIDAL THOUGHTS	1	1	1	1	1	1	
				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	2	2	2	2	2	2	
				11. Total score	18	17	14	14	12	10	
				01. REPORTED SADNESS	2	2	2	2	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	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	19	19	16	16	14	8					
448	448	Imipramine	Female	01. REPORTED SADNESS	2	2	2	2	2	2	2
				02. INNER TENSION	2	2	2	2	2	2	
				03. APPARENT SADNESS	2	2	2	2	2	2	
				04. SUICIDAL THOUGHTS	0	0	0	0	0	0	
				05. INERTIA	2	2	2	2	2	2	
				06. INABILITY TO FEEL	3	3	2	2	2	2	
				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	19	19	17	18	16	15	
453	453	Imipramine	Female	01. REPORTED SADNESS	2	2	1	0	1	0	0
				02. INNER TENSION	3	2	1	1	1	1	
				03. APPARENT SADNESS	2	2	1	0	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	2	1	1	1	
				07. PESSIMISTIC THOUGHTS	2	2	2	2	2	2	
				08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	
				09. REDUCED SLEEP	2	2	1	1	1	1	
				10. REDUCED APPETITE	2	2	1	0	1	0	
				11. Total score	19	18	12	7	11	6	
454	454	Reboxetine	Female	01. REPORTED SADNESS	2	2	2	2	2	2	2

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14/10	454	Reboxetine	Female	02. INNER TENSION	2	2	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	1	1	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	2	2	
				09. REDUCED SLEEP	2	2	2	2	1	1	
				10. REDUCED APPETITE	2	2	2	1	1	1	
				11. Total score	18	18	16	14	11	10	
				455	Reboxetine	Female	01. REPORTED SADNESS	2	2	2	1
02. INNER TENSION	3	2	1				1	1	1		
03. APPARENT SADNESS	2	2	2				2	1	1		
04. SUICIDAL THOUGHTS	0	0	0				0	0	0		
05. INERTIA	2	2	1				1	1	1		
06. INABILITY TO FEEL	3	1	1				1	1	1		
07. PESSIMISTIC THOUGHTS	2	2	2				1	1	1		
08. CONCENTRATIONS DIFFICULTIES	2	3	2				2	1	1		
09. REDUCED SLEEP	2	2	2				1	1	1		
10. REDUCED APPETITE	1	2	2				1	0	0		
11. Total score	19	18	15				11	8	7		
15	349	Imipramine	Male	01. REPORTED SADNESS	1	0	0	0	0	0	
				02. INNER TENSION	1	1	0	1	1	1	
				03. APPARENT SADNESS	1	0	0	0	0	0	
				04. SUICIDAL THOUGHTS	2	0	0	0	0	0	
				05. INERTIA	1	1	1	0	0	0	
				06. INABILITY TO FEEL	2	1	2	1	1	0	
				07. PESSIMISTIC THOUGHTS	1	1	0	0	0	0	
				08. CONCENTRATIONS DIFFICULTIES	1	1	1	0	0	0	
				09. REDUCED SLEEP	1	1	1	1	1	1	
				10. REDUCED APPETITE	1	0	0	0	1	1	
				11. Total score	12	6	5	3	4	3	
351	Reboxetine	Male	01. REPORTED SADNESS	2	0	0	1	1	0	0	
			02. INNER TENSION	2	1	0	1	0	0		
			03. APPARENT SADNESS	2	0	0	1	0	0		
			04. SUICIDAL THOUGHTS	2	0	0	1	0	0		
			05. INERTIA	3	1	0	1	1	0		
			06. INABILITY TO FEEL	2	2	0	1	1	0		
			07. PESSIMISTIC THOUGHTS	2	0	0	1	0	0		
			08. CONCENTRATIONS DIFFICULTIES	3	1	0	2	1	1		
			09. REDUCED SLEEP	3	2	0	2	1	0		
			10. REDUCED APPETITE	3	1	0	1	0	0		
			11. Total score	24	8	0	12	4	2		

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 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	
15	352	Imipramine	Male	01.REPORTED SADNESS	2	1	0	0	0	0	0	0
				02.INNER TENSION	2	1	1	1	1	1	1	
				03.APPARENT SADNESS	2	1	0	1	1	1		
				04.SUICIDAL THOUGHTS	1	1	0	0	0	0		
				05.INERTIA	1	2	1	1	1	1		
				06.INABILITY TO FEEL	2	2	2	1	1	1		
				07.PESSIMISTIC THOUGHTS	2	0	0	1	1	1		
				08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	0	0		
				09.REDUCED SLEEP	1	1	1	1	1	1		
				10.REDUCED APPETITE	1	2	1	1	1	1		
				11.Total score	15	12	8	6	6	6		
364	Imipramine	Female	01.REPORTED SADNESS	3	1	0	0	0	2	2	0	0
			02.INNER TENSION	2	1	1	1	1	2	2		
			03.APPARENT SADNESS	3	1	1	1	1	2	2		
			04.SUICIDAL THOUGHTS	2	1	1	1	1	2	2		
			05.INERTIA	3	2	0	1	1	1	1		
			06.INABILITY TO FEEL	3	2	1	1	1	1	1		
			07.PESSIMISTIC THOUGHTS	2	1	1	1	1	2	2		
			08.CONCENTRATIONS DIFFICULTIES	2	2	1	0	1	0	0		
			09.REDUCED SLEEP	2	2	2	2	2	2	2		
			10.REDUCED APPETITE	2	2	2	0	1	1	1		
			11.Total score	24	14	7	9	15	15			
366	Reboxetine	Male	01.REPORTED SADNESS	1	0	0	0	0	0	0	0	
			02.INNER TENSION	2	0	0	0	1	1	0		
			03.APPARENT SADNESS	1	0	0	0	0	0	0		
			04.SUICIDAL THOUGHTS	2	0	0	0	0	0	0		
			05.INERTIA	2	0	0	1	1	1	0		
			06.INABILITY TO FEEL	2	0	0	1	1	1	0		
			07.PESSIMISTIC THOUGHTS	1	0	0	1	1	0	1		
			08.CONCENTRATIONS DIFFICULTIES	1	0	0	1	1	0	1		
			09.REDUCED SLEEP	2	1	0	0	1	0	1		
			10.REDUCED APPETITE	2	0	0	0	0	0	0		
			11.Total score	16	1	0	3	5	4	2		
367	Imipramine	Male	01.REPORTED SADNESS	2	2	2	2	2	1	2	2	
			02.INNER TENSION	1	0	2	1	1	1	1		
			03.APPARENT SADNESS	2	2	3	2	2	2	2		
			04.SUICIDAL THOUGHTS	1	1	1	1	1	1	1		
			05.INERTIA	3	3	3	3	2	2	2		
			06.INABILITY TO FEEL	3	3	3	2	1	1	1		
			07.PESSIMISTIC THOUGHTS	1	1	1	2	1	1	1		
			08.CONCENTRATIONS DIFFICULTIES	3	3	3	3	1	2	2		
			09.REDUCED SLEEP	1	1	1	1	1	1	1		
			10.REDUCED APPETITE	0	0	0	0	2	0	1		
			11.Total score	17	16	20	21	10	15	14		

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 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
15	368	Reboxetine	Female	01.REPORTED SADNESS	3	1	0	0	0	0	0
				02.INNER TENSION	0	0	0	1	1	0	1
				03.APPARENT SADNESS	3	1	0	0	0	0	0
				04.SUICIDAL THOUGHTS	2	1	0	0	0	0	0
				05.INERTIA	3	1	1	1	1	1	1
				06.INABILITY TO FEEL	3	1	1	2	2	2	1
				07.PESSIMISTIC THOUGHTS	0	1	0	0	0	0	0
				08.CONCENTRATIONS DIFFICULTIES	0	0	0	0	0	1	0
				09.REDUCED SLEEP	2	1	1	1	1	1	0
				10.REDUCED APPETITE	0	0	0	0	0	0	0
				11.Total score	16	7	3	5	5	5	3
	369	Reboxetine	Female	01.REPORTED SADNESS	2	0	0	0	0	0	0
				02.INNER TENSION	1	0	1	0	0	0	0
				03.APPARENT SADNESS	3	1	0	0	0	0	0
				04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0
				05.INERTIA	3	1	1	0	0	0	0
				06.INABILITY TO FEEL	3	1	1	0	0	0	0
				07.PESSIMISTIC THOUGHTS	2	0	0	0	0	0	0
				08.CONCENTRATIONS DIFFICULTIES	2	1	1	0	0	0	0
				09.REDUCED SLEEP	2	0	0	0	0	0	0
				10.REDUCED APPETITE	0	0	0	0	0	0	0
				11.Total score	19	4	4	0	0	0	0
	370	Imipramine	Female	01.REPORTED SADNESS	1	1	0	1	0	0	0
				02.INNER TENSION	2	2	1	1	1	1	1
				03.APPARENT SADNESS	1	1	1	1	0	0	0
				04.SUICIDAL THOUGHTS	2	1	1	1	0	0	0
				05.INERTIA	1	2	1	1	0	0	0
				06.INABILITY TO FEEL	2	2	1	1	0	0	0
				07.PESSIMISTIC THOUGHTS	1	1	1	0	0	2	1
				08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	0	0	0
				09.REDUCED SLEEP	2	2	2	2	1	0	1
				10.REDUCED APPETITE	0	0	0	0	0	0	0
				11.Total score	14	13	9	9	2	4	3
	371	Reboxetine	Female	01.REPORTED SADNESS	1	0	0	0	0	0	0
				02.INNER TENSION	1	1	1	1	1	1	0
				03.APPARENT SADNESS	1	0	0	0	0	0	0
				04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0
				05.INERTIA	1	0	0	0	0	0	0
				06.INABILITY TO FEEL	1	0	0	1	1	0	0
				07.PESSIMISTIC THOUGHTS	1	0	0	0	0	0	0
				08.CONCENTRATIONS DIFFICULTIES	1	0	0	1	1	0	0
				09.REDUCED SLEEP	3	2	2	2	1	1	0
				10.REDUCED APPETITE	2	0	0	0	0	2	0

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
15	371	Reboxetine	Female	11.Total score	13	3	3	5	4	3	2
	372	Imipramine	Male	01.REPORTED SADNESS	2	3	2	1	2	2	1
				02.INNER TENSION	0	0	0	0	0	0	1
				03.APPARENT SADNESS	3	3	2	1	2	2	1
				04.SUICIDAL THOUGHTS	2	3	2	2	2	1	2
				05.INERTIA	3	3	2	2	2	2	2
				06.INABILITY TO FEEL	3	3	3	3	3	2	2
				07.PESSIMISTIC THOUGHTS	3	3	2	2	2	2	1
				08.CONCENTRATIONS DIFFICULTIES	3	3	2	2	2	2	1
				09.REDUCED SLEEP	3	2	1	1	2	2	2
				10.REDUCED APPETITE	3	3	2	2	3	3	2
				11.Total score	25	26	15	16	20	18	15
	373	Imipramine	Female	01.REPORTED SADNESS	2						
				02.INNER TENSION	1						
				03.APPARENT SADNESS	1						
				04.SUICIDAL THOUGHTS	1						
				05.INERTIA	2						
				06.INABILITY TO FEEL	2						
				07.PESSIMISTIC THOUGHTS	2						
				08.CONCENTRATIONS DIFFICULTIES	2						
				09.REDUCED SLEEP	2						
				10.REDUCED APPETITE	2						
				11.Total score	17						
	374	Reboxetine	Female	01.REPORTED SADNESS	2	0	0	0	0	0	0
				02.INNER TENSION	2	1	1	0	0	0	1
				03.APPARENT SADNESS	1	1	0	0	0	0	0
				04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0
				05.INERTIA	3	1	0	1	1	0	0
				06.INABILITY TO FEEL	3	0	0	1	1	0	0
				07.PESSIMISTIC THOUGHTS	2	1	0	0	0	0	1
				08.CONCENTRATIONS DIFFICULTIES	3	2	1	1	1	0	0
				09.REDUCED SLEEP	0	2	2	3	1	1	1
				10.REDUCED APPETITE	2	0	0	0	0	1	0
				11.Total score	19	8	4	6	4	2	3
	375	Reboxetine	Female	01.REPORTED SADNESS	2	0	0	0	0	0	
				02.INNER TENSION	1	1	0	0	0	0	
				03.APPARENT SADNESS	2	0	0	0	0	0	
				04.SUICIDAL THOUGHTS	2	0	0	0	0	0	
				05.INERTIA	3	1	0	0	0	0	
				06.INABILITY TO FEEL	2	1	0	0	0	0	
				07.PESSIMISTIC THOUGHTS	1	0	0	0	0	0	
				08.CONCENTRATIONS DIFFICULTIES	2	1	0	0	0	0	
				09.REDUCED SLEEP	2	1	0	0	0	0	

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
15	375	Reboxetine	Female	10. REDUCED APPETITE 11.Total score	0 17	0 5	0 0	0 0	0 0	0 0	0 0
376		Imipramine	Female	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 3 2 2 3 2 2 22	3 2 3 1 3 2 2 3 2 2 24					
377		Reboxetine	Female	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 3 2 2 2 3 2 22	1 2 2 1 1 0 1 1 1 1 11	0 1 1 0 0 0 0 0 1 1 7	0 1 0 0 0 0 0 0 1 1 4	0 0 0 0 0 0 0 0 0 0 2	0 0 0 0 0 0 0 0 0 0 3	
378		Reboxetine	Female	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 0 3 2 3 2 2 2 2 1 21	0 1 1 1 0 2 1 1 1 1 9	0 1 0 0 0 2 2 1 1 1 7	0 1 0 0 0 0 0 0 0 1 4	0 0 0 0 0 0 0 0 0 1 2	0 0 0 0 0 0 0 0 0 0 1	
379		Imipramine	Female	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 3 2 2 3 2 2	2 2 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

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
15	379	Female	Imipramine	2 2 21	2	1	3	0	0	0
					09. REDUCED SLEEP	1	1	0	0	0
					10. REDUCED APPETITE	1	1	0	0	0
					11. Total score	2	2	0	0	0
					01. REPORTED SADNESS	2	1	1	0	1
					02. INNER TENSION	2	1	1	0	0
					03. APPARENT SADNESS	3	2	3	0	0
					04. SUICIDAL THOUGHTS	2	2	2	0	0
					05. INERTIA	3	2	2	1	0
					06. INABILITY TO FEEL	1	3	2	0	1
					07. PESSIMISTIC THOUGHTS	2	2	2	1	0
					08. CONCENTRATIONS DIFFICULTIES	3	1	1	0	1
					09. REDUCED SLEEP	2	2	2	0	1
					10. REDUCED APPETITE	2	2	1	2	1
					11. Total score	23	19	14	3	4
					01. REPORTED SADNESS	2	1	2	0	0
					02. INNER TENSION	2	1	2	2	1
					03. APPARENT SADNESS	2	1	1	0	0
					04. SUICIDAL THOUGHTS	3	1	1	0	1
					05. INERTIA	3	2	2	1	1
					06. INABILITY TO FEEL	3	2	2	1	1
					07. PESSIMISTIC THOUGHTS	1	1	1	2	1
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	1	1
					09. REDUCED SLEEP	3	1	3	2	2
					10. REDUCED APPETITE	0	2	2	2	1
					11. Total score	21	14	18	10	10
					01. REPORTED SADNESS	3	2	2	0	0
					02. INNER TENSION	2	2	2	1	2
					03. APPARENT SADNESS	3	1	2	0	0
					04. SUICIDAL THOUGHTS	1	1	1	0	0
					05. INERTIA	2	2	2	1	1
					06. INABILITY TO FEEL	2	2	2	1	1
					07. PESSIMISTIC THOUGHTS	2	2	2	1	1
					08. CONCENTRATIONS DIFFICULTIES	2	2	2	2	2
					09. REDUCED SLEEP	1	2	2	2	1
					10. REDUCED APPETITE	1	1	1	1	0
					11. Total score	20	14	14	10	10
					01. REPORTED SADNESS	2	2	2	1	0
					02. INNER TENSION	2	1	2	1	2
					03. APPARENT SADNESS	3	1	2	0	0
					04. SUICIDAL THOUGHTS	2	2	2	1	0
					05. INERTIA	2	2	2	1	0
					06. INABILITY TO FEEL	3	2	2	2	1
					07. PESSIMISTIC THOUGHTS	3	2	2	1	0

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
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 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
15	383	Imipramine	Female	08. CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	0	0
				09. REDUCED SLEEP	3	3	2	0	2	1	1
				10. REDUCED APPETITE	2	2	2	1	1	0	
				11. Total score	24	19	17	8	7	5	
384	Reboxetine	Female	01. REPORTED SADNESS	3	2						
			02. INNER TENSION	3	2						
			03. APPARENT SADNESS	3	2						
			04. SUICIDAL THOUGHTS	3	2						
			05. INERTIA	3	3						
			06. INABILITY TO FEEL	3	2						
			07. PESSIMISTIC THOUGHTS	2	2						
			08. CONCENTRATIONS DIFFICULTIES	2	2						
			09. REDUCED SLEEP	3	2						
			10. REDUCED APPETITE	3	2						
			11. Total score	28	21						

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REBOXETINE - PROTOCOL 20124/017
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	Reboxetine	Male	Severity of illness	5.00	6.00	4.00	4.00	6.00	4.00	3.00
				Global improvement		5.00	3.00	2.00	4.00	3.00	2.00
				Efficacy index		14.00	6.00	6.00	14.00	10.00	6.00
				Efficacy index (*)		0.50	1.50	1.50	0.50	1.00	1.50
2	2	Reboxetine	Female	Severity of illness	6.00	5.00	5.00	4.00	1.00	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	3.00
				Efficacy index (*)		1.00	1.00	1.50	2.00	2.00	1.33
3	3	Imipramine	Female	Severity of illness	6.00	5.00	5.00	4.00	3.00	2.00	2.00
				Global improvement		3.00	3.00	2.00	2.00	2.00	1.00
				Efficacy index		10.00	10.00	6.00	6.00	1.00	1.00
				Efficacy index (*)		1.00	1.00	1.50	1.50	4.00	4.00
4	4	Imipramine	Male	Severity of illness	6.00	6.00	6.00	6.00	4.00	3.00	2.00
				Global improvement		5.00	4.00	3.00	3.00	2.00	1.00
				Efficacy index		14.00	14.00	10.00	6.00	6.00	2.00
				Efficacy index (*)		0.50	0.50	1.00	1.50	1.50	2.00
5	5	Reboxetine	Female	Severity of illness	6.00	3.00	5.00	4.00	5.00	4.00	4.00
				Global improvement		2.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		2.00	10.00	6.00	6.00	5.00	5.00
				Efficacy index (*)		2.00	1.00	1.50	1.00	1.50	3.00
6	6	Imipramine	Male	Severity of illness	6.00	6.00	6.00	5.00	4.00	4.00	4.00
				Global improvement		4.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		14.00	10.00	10.00	10.00	6.00	6.00
				Efficacy index (*)		0.50	1.00	1.00	1.00	1.50	1.50
7	7	Reboxetine	Male	Severity of illness	6.00	6.00	6.00	5.00	5.00	6.00	6.00
				Global improvement		5.00	4.00	3.00	3.00	3.00	4.00
				Efficacy index		14.00	14.00	10.00	10.00	10.00	14.00
				Efficacy index (*)		0.50	0.50	1.00	1.00	0.67	0.50
8	8	Imipramine	Male	Severity of illness	6.00	6.00	6.00	6.00	5.00	6.00	6.00
				Global improvement		4.00	4.00	3.00	3.00	3.00	4.00
				Efficacy index		15.00	14.00	10.00	10.00	11.00	14.00
				Efficacy index (*)		0.33	0.50	1.00	0.67	0.50	0.50

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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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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	Imipramine	Female	Severity of illness	6.00	6.00	4.00	3.00	3.00	2.00	1.00
				Global improvement		4.00	2.00	2.00	2.00	1.00	
				Efficacy index		14.00	6.00	2.00	2.00	2.00	
				Efficacy index (*)		0.50	1.50	2.00	2.00	2.00	2.00
10	10	Imipramine	Female	Severity of illness	6.00	5.00	4.00	5.00	6.00	5.00	4.00
				Global improvement		3.00	3.00	3.00	4.00	3.00	
				Efficacy index		11.00	6.00	11.00	15.00	10.00	
				Efficacy index (*)		0.67	1.50	0.67	0.33	1.00	1.50
11	11	Reboxetine	Male	Severity of illness	7.00	7.00	6.00	6.00	7.00		
				Global improvement		4.00	5.00	3.00	6.00		
				Efficacy index		14.00	14.00	10.00	13.00		
				Efficacy index (*)		0.50	0.50	1.00	1.00		
12	12	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	6.00			
				Global improvement		4.00	3.00	5.00			
				Efficacy index		14.00	10.00	14.00			
				Efficacy index (*)		0.50	1.00	0.50			
2	33	Reboxetine	Male	Severity of illness	5.00	4.00	2.00	2.00	4.00	3.00	1.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	
				Efficacy index		10.00	1.00	1.00	5.00	5.00	
				Efficacy index (*)		1.00	4.00	4.00	3.00	3.00	4.00
34	34	Imipramine	Male	Severity of illness	5.00	3.00	4.00	2.00	4.00	3.00	4.00
				Global improvement		2.00	5.00	2.00	2.00	2.00	
				Efficacy index		6.00	6.00	2.00	5.00	7.00	
				Efficacy index (*)		1.50	1.50	2.00	3.00	1.00	1.50
35	35	Reboxetine	Male	Severity of illness	6.00	4.00	2.00	2.00	2.00	2.00	2.00
				Global improvement		2.00	1.00	1.00	1.00	2.00	
				Efficacy index		5.00	1.00	1.00	1.00	1.00	
				Efficacy index (*)		3.00	4.00	4.00	4.00	4.00	4.00
36	36	Imipramine	Female	Severity of illness	6.00	5.00	4.00	2.00	6.00		
				Global improvement		3.00	1.00	2.00	6.00		
				Efficacy index		10.00	2.00	1.00	16.00		
				Efficacy index (*)		1.00	2.00	4.00	0.25		

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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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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	37	Reboxetine	Male	Severity of illness	6.00	4.00	4.00	4.00	4.00	4.00	3.00
				Global improvement		2.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		6.00	9.00	10.00	6.00	6.00	5.00
				Efficacy index (*)		1.50	2.00	1.00	1.50	3.00	
	38	Imipramine	Female	Severity of illness	5.00	5.00	5.00	6.00	6.00	6.00	5.00
				Global improvement		3.00	3.00	4.00	6.00	6.00	3.00
				Efficacy index		9.00	10.00	14.00	14.00	14.00	9.00
				Efficacy index (*)		2.00	1.00	0.50	0.50	2.00	
	39	Reboxetine	Female	Severity of illness	6.00	5.00	5.00	4.00	4.00	3.00	3.00
				Global improvement		3.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	9.00	5.00	5.00	5.00	1.00
				Efficacy index (*)		2.00	2.00	3.00	3.00	4.00	
	40	Imipramine	Male	Severity of illness	5.00	5.00	4.00	3.00	3.00	4.00	3.00
				Global improvement		2.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		5.00	5.00	9.00	5.00	5.00	5.00
				Efficacy index (*)		3.00	3.00	3.00	2.00	3.00	
	41	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	4.00	5.00	5.00	5.00
				Global improvement		2.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		5.00	5.00	7.00	10.00	10.00	4.00
				Efficacy index (*)		0.33	0.25	1.00	1.00	1.00	
	42	Imipramine	Male	Severity of illness	6.00	5.00	5.00	5.00	5.00	5.00	3.00
				Global improvement		5.00	4.00	4.00	3.00	3.00	2.00
				Efficacy index		14.00	10.00	14.00	6.00	9.00	5.00
				Efficacy index (*)		0.50	1.00	0.50	1.50	2.00	
	43	Reboxetine	Female	Severity of illness	5.00	4.00	2.00	2.00	2.00	1.00	2.00
				Global improvement		2.00	1.00	2.00	2.00	2.00	2.00
				Efficacy index		6.00	2.00	2.00	1.00	1.00	1.00
				Efficacy index (*)		1.50	2.00	2.00	4.00	4.00	
	44	Imipramine	Male	Severity of illness	6.00	6.00					
				Global improvement		6.00					
				Efficacy index		13.00					
				Efficacy index (*)		1.00					

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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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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/017

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	45	Imipramine	Female	Severity of illness	5.00	4.00						
				Global improvement		3.00						
				Efficacy index		12.00						
				Efficacy index (*)		0.50						
	46	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	3.00	3.00	3.00	
				Global improvement		3.00	3.00	2.00	2.00	2.00	2.00	
				Efficacy index		11.00	10.00	6.00	6.00	6.00	6.00	
				Efficacy index (*)		0.67	1.00	1.50	1.50	1.50	1.50	
	47	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	3.00	2.00	1.00	1.00	
				Global improvement		5.00	2.00	2.00	1.00	1.00	1.00	
				Efficacy index		15.00	7.00	6.00	6.00	2.00	2.00	
				Efficacy index (*)		0.33	1.00	1.50	2.00	2.00	2.00	
	48	Imipramine	Female	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	2.00	2.00	2.00	
				Efficacy index		10.00	5.00	6.00	1.00	1.00	6.00	
				Efficacy index (*)		1.00	3.00	1.50	4.00	4.00	1.50	
	49	Imipramine	Female	Severity of illness	6.00	5.00	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		10.00	6.00	6.00	3.00	3.00	6.00	
				Efficacy index (*)		1.00	1.50	1.50	1.33	2.00	1.50	
	50	Reboxetine	Male	Severity of illness	6.00	6.00	6.00	5.00	5.00	5.00	5.00	
				Global improvement		4.00	6.00	4.00	3.00	3.00	3.00	
				Efficacy index		14.00	15.00	15.00	11.00	11.00	11.00	
				Efficacy index (*)		0.50	0.33	0.33	0.67	0.67	0.67	
	51	Reboxetine	Female	Severity of illness	6.00	6.00	7.00					
				Global improvement		4.00	7.00					
				Efficacy index		14.00	15.00					
				Efficacy index (*)		0.50	0.33					
	52	Imipramine	Male	Severity of illness	6.00	4.00	3.00	2.00	1.00	2.00	1.00	
				Global improvement		2.00	2.00	1.00	1.00	1.00	1.00	
				Efficacy index		6.00	2.00	2.00	2.00	2.00	1.00	
				Efficacy index (*)		1.50	2.00	2.00	2.00	2.00	4.00	

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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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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	65	Reboxetine	Male	Severity of illness	5.00	3.00	2.00	2.00	2.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		6.00	6.00	7.00	2.00	3.00	3.00
				Efficacy index (*)		1.50	1.50	1.00	2.00	1.33	1.33
	66	Imipramine	Female	Severity of illness	6.00	2.00	1.00	1.00	2.00	7.00	
				Global improvement		2.00	2.00	1.00	2.00	7.00	
				Efficacy index		2.00	2.00	2.00	2.00	14.00	
				Efficacy index (*)		2.00	2.00	2.00	2.00	0.50	
	67	Reboxetine	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	4.00	
				Efficacy index		10.00	10.00	10.00	11.00	10.00	14.00
				Efficacy index (*)		1.00	1.00	1.00	0.67	1.00	0.50
	68	Imipramine	Female	Severity of illness	6.00	6.00	6.00	6.00	6.00	6.00	6.00
				Global improvement		3.00	3.00	3.00	3.00	3.00	
				Efficacy index		10.00	10.00	10.00	10.00	10.00	10.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	1.00
	69	Imipramine	Female	Severity of illness	6.00	6.00	5.00	3.00	2.00	4.00	2.00
				Global improvement		4.00	3.00	2.00	2.00	3.00	2.00
				Efficacy index		14.00	10.00	10.00	1.00	5.00	1.00
				Efficacy index (*)		0.50	1.00	2.00	4.00	3.00	4.00
	70	Reboxetine	Female	Severity of illness	6.00	7.00	5.00	5.00	5.00	5.00	
				Global improvement		6.00	3.00	3.00	3.00	3.00	
				Efficacy index		15.00	11.00	11.00	11.00	11.00	
				Efficacy index (*)		0.33	0.67	0.67	0.67		
	71	Imipramine	Female	Severity of illness	5.00	2.00	1.00	2.00	1.00	1.00	1.00
				Global improvement		2.00	1.00	2.00	1.00	1.00	1.00
				Efficacy index		2.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		2.00	2.00	2.00	2.00	2.00	2.00
	72	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	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	10.00	6.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	1.50

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
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 R&D
REBOXETINE - PROTOCOL 20124/017
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	73	Reboxetine	Female	Severity of illness	5.00	3.00	2.00	2.00	2.00	2.00	1.00
				Global improvement		2.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		2.00	2.00	2.00	2.00	2.00	2.00
4	97	Imipramine	Male	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	4.00	4.00	4.00
				Efficacy index		13.00	9.00	13.00	13.00	13.00	13.00
4	97	Imipramine	Male	Severity of illness (*)	1.00	2.00	2.00	1.00	1.00	1.00	1.00
				Global improvement		4.00	3.00	4.00	4.00	4.00	4.00
				Efficacy index		13.00	9.00	13.00	13.00	13.00	13.00
100		Reboxetine	Female	Severity of illness	6.00	6.00	5.00	4.00	3.00	3.00	2.00
				Global improvement		4.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		13.00	9.00	5.00	1.00	1.00	1.00
100		Reboxetine	Female	Severity of illness (*)	1.00	2.00	2.00	3.00	4.00	4.00	4.00
				Global improvement		4.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		13.00	9.00	5.00	1.00	1.00	1.00
101		Imipramine	Female	Severity of illness	4.00	4.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		4.00	6.00	6.00	6.00	6.00	6.00
				Efficacy index		15.00	14.00	14.00	14.00	14.00	14.00
101		Imipramine	Female	Severity of illness (*)	0.33	0.33	0.50	0.50	0.50	0.50	0.50
				Global improvement		4.00	5.00	5.00	5.00	5.00	5.00
				Efficacy index		15.00	14.00	14.00	14.00	14.00	14.00
6	161	Reboxetine	Male	Severity of illness	5.00	4.00	3.00	4.00	2.00	4.00	3.00
				Global improvement		2.00	1.00	2.00	2.00	1.00	3.00
				Efficacy index		6.00	1.00	6.00	2.00	6.00	6.00
6	161	Reboxetine	Male	Severity of illness (*)	1.50	4.00	4.00	1.50	2.00	1.50	1.50
				Global improvement		2.00	1.00	2.00	2.00	1.00	3.00
				Efficacy index		6.00	1.00	6.00	2.00	6.00	6.00
7	193	Reboxetine	Female	Severity of illness	5.00	4.00	3.00	2.00	1.00	1.00	2.00
				Global improvement		3.00	2.00	2.00	1.00	1.00	2.00
				Efficacy index		9.00	5.00	5.00	1.00	1.00	1.00
7	193	Reboxetine	Female	Severity of illness (*)	2.00	3.00	3.00	4.00	4.00	4.00	4.00
				Global improvement		2.00	1.00	2.00	2.00	1.00	1.00
				Efficacy index		6.00	1.00	6.00	2.00	6.00	6.00
7	193	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		4.00	3.00	2.00	2.00	1.00	2.00
				Efficacy index		9.00	5.00	5.00	1.00	1.00	1.00
7	193	Reboxetine	Female	Severity of illness (*)	4.00	2.00	3.00	4.00	4.00	4.00	4.00
				Global improvement		2.00	1.00	2.00	2.00	1.00	1.00
				Efficacy index		6.00	1.00	6.00	2.00	6.00	6.00
194		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	4.00	4.00	4.00	4.00
				Efficacy index		13.00	9.00	13.00	13.00	13.00	13.00
194		Reboxetine	Male	Severity of illness (*)	1.00	2.00	2.00	1.00	1.00	1.00	1.00
				Global improvement		4.00	3.00	4.00	4.00	4.00	4.00
				Efficacy index		13.00	9.00	13.00	13.00	13.00	13.00

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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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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	196	Imipramine	Female	Severity of illness	5.00	3.00	3.00	3.00	3.00	3.00	4.00
				Global improvement		2.00	2.00	2.00	2.00	2.00	3.00
				Efficacy index		7.00	7.00	7.00	7.00	7.00	8.00
				Efficacy index (*)	1.00	1.00	1.00	1.00	1.00	1.00	0.75
8	225	Imipramine	Female	Severity of illness	4.00	4.00	2.00				
				Global improvement		5.00	1.00				
				Efficacy index		15.00	2.00				
				Efficacy index (*)	0.33	2.00					
	226	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	5.00	4.00	4.00	4.00
				Global improvement		4.00	3.00	5.00	3.00	5.00	3.00
				Efficacy index		13.00	9.00	10.00	9.00	13.00	9.00
				Efficacy index (*)	1.00	2.00	1.00	2.00	1.00	2.00	
	227	Imipramine	Male	Severity of illness	5.00	3.00	3.00	3.00	2.00	2.00	2.00
				Global improvement		2.00	2.00	3.00	2.00	2.00	2.00
				Efficacy index		2.00	2.00	6.00	2.00	2.00	2.00
				Efficacy index (*)	2.00	2.00	1.50	2.00	2.00	2.00	
	228	Reboxetine	Male	Severity of illness	5.00	4.00	4.00	4.00			
				Global improvement		3.00	3.00	3.00			
				Efficacy index		11.00	12.00				
				Efficacy index (*)	0.67	0.50					
	229	Imipramine	Female	Severity of illness	5.00	4.00	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		6.00	2.00	10.00	6.00	6.00	6.00
				Efficacy index (*)	1.50	2.00	1.00	1.50	1.50	1.50	
	230	Imipramine	Female	Severity of illness	5.00	4.00	3.00	3.00	2.00	2.00	2.00
				Global improvement		2.00	2.00	2.00	1.00	1.00	1.00
				Efficacy index		5.00	5.00	5.00	1.00	1.00	1.00
				Efficacy index (*)	3.00	3.00	3.00	4.00	4.00	4.00	
	231	Reboxetine	Female	Severity of illness	4.00	3.00	3.00	3.00	3.00	3.00	4.00
				Global improvement		2.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		5.00	5.00	5.00	1.00	1.00	1.00
				Efficacy index (*)	3.00	3.00	3.00	4.00	4.00	4.00	

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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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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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	232	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	4.00	3.00	3.00	2.00
				Global improvement		3.00	4.00	3.00	2.00	2.00	2.00
				Efficacy index		9.00	13.00	9.00	5.00	5.00	5.00
				Efficacy index (*)	2.00	1.00	2.00	3.00	3.00	3.00	
9	197	Reboxetine	Male	Severity of illness	4.00	4.00					
				Global improvement		5.00					
				Efficacy index		16.00					
				Efficacy index (*)	0.25						
198	198	Imipramine	Female	Severity of illness	5.00	5.00	5.00	4.00	1.00	1.00	1.00
				Global improvement		4.00	4.00	3.00	1.00	1.00	1.00
				Efficacy index		14.00	14.00	6.00	2.00	2.00	1.00
				Efficacy index (*)	0.50	0.50	1.50	2.00	2.00	4.00	
199	199	Imipramine	Male	Severity of illness	4.00	4.00	5.00	5.00	4.00	5.00	4.00
				Global improvement		5.00	5.00	5.00	3.00	3.00	3.00
				Efficacy index		14.00	14.00	14.00	10.00	14.00	10.00
				Efficacy index (*)	0.50	0.50	0.50	1.00	0.50	1.00	
200	200	Reboxetine	Male	Severity of illness	5.00	5.00	3.00	2.00	1.00	1.00	1.00
				Global improvement		4.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		14.00	6.00	2.00	1.00	1.00	1.00
				Efficacy index (*)	0.50	1.50	2.00	4.00	4.00	4.00	
201	201	Imipramine	Female	Severity of illness	6.00	5.00	2.00	2.00	2.00	2.00	1.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	3.00	1.00	1.00	1.00	1.00
				Efficacy index (*)	2.00	1.33	4.00	4.00	4.00	2.00	
202	202	Imipramine	Male	Severity of illness	5.00	5.00	4.00	3.00	4.00	4.00	4.00
				Global improvement		4.00	3.00	2.00	5.00	3.00	4.00
				Efficacy index		15.00	10.00	2.00	15.00	10.00	14.00
				Efficacy index (*)	0.33	1.00	2.00	0.33	1.00	0.50	
203	203	Reboxetine	Female	Severity of illness	6.00	6.00					
				Global improvement		6.00					
				Efficacy index		15.00					
				Efficacy index (*)	0.33						

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 R&D
REBOXETINE - PROTOCOL 20124/017
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	204	Reboxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 2.00 2.00 2.00	2.00 2.00 1.00 2.00	2.00 2.00 1.00 4.00	1.00 1.00 1.00 4.00	2.00 2.00 1.00 4.00	2.00 2.00 1.00 4.00	1.00 1.00 1.00 4.00
	205	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00	3.00	3.00	2.00	2.00	1.00
	206	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 13.00 1.00	3.00 9.00 2.00	3.00 6.00 1.50	2.00	2.00	1.00
	207	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 3.00 11.00 0.67	5.00	2.00	2.00	2.00	1.00
	208	Reboxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 14.00 0.50	2.00 2.00 2.00	2.00 1.00 3.00 1.33	2.00	2.00	4.00
	209	Imipramine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	3.00	3.00 4.00 16.00 0.25	3.00	2.00	2.00	2.00	2.00
	210	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	3.00	3.00 9.00 2.00	3.00 3.00 1.00	2.00 2.00 1.50	2.00	2.00	2.00
	211	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 3.00 10.00 1.00	5.00 3.00 6.00 1.50	5.00 3.00 5.00 3.00	5.00 3.00 5.00 3.00

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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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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	212	Imipramine	Female	Severity of illness	4.00	4.00	4.00	3.00	2.00	2.00	1.00
				Global improvement		3.00	3.00	3.00	2.00	2.00	1.00
				Efficacy index		11.00	6.00	6.00	2.00	2.00	2.00
				Efficacy index (*)	0.67	1.50	1.50	2.00	2.00	2.00	
	237	Reboxetine	Male	Severity of illness	5.00	5.00	4.00				
				Global improvement		3.00	4.00				
				Efficacy index		11.00	15.00				
				Efficacy index (*)	0.67	0.33					
	238	Imipramine	Female	Severity of illness	5.00	5.00	5.00	3.00	3.00	1.00	1.00
				Global improvement		4.00	4.00	3.00	3.00	1.00	1.00
				Efficacy index		13.00	13.00	9.00	5.00	4.00	1.00
				Efficacy index (*)	1.00	1.00	2.00	3.00	4.00	4.00	
	239	Imipramine	Male	Severity of illness	5.00	5.00	5.00	3.00	3.00	3.00	3.00
				Global improvement		4.00	2.00	2.00	2.00	2.00	2.00
				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	
	240	Reboxetine	Female	Severity of illness	6.00	6.00	6.00	6.00			
				Global improvement		4.00	4.00	4.00			
				Efficacy index		14.00	14.00	14.00			
				Efficacy index (*)	0.50	0.50	0.50				
	241	Imipramine	Female	Severity of illness	6.00	5.00	4.00	4.00	4.00	4.00	3.00
				Global improvement		5.00	3.00	3.00	3.00	3.00	2.00
				Efficacy index		14.00	10.00	10.00	10.00	10.00	6.00
				Efficacy index (*)	0.50	1.00	1.00	1.00	1.00	1.50	
	242	Reboxetine	Male	Severity of illness	5.00	5.00	4.00	4.00	4.00	1.00	1.00
				Global improvement		4.00	3.00	3.00	3.00	1.00	1.00
				Efficacy index		14.00	10.00	10.00	10.00	1.00	1.00
				Efficacy index (*)	0.50	1.00	1.00	1.00	4.00	4.00	
	243	Imipramine	Female	Severity of illness	5.00	5.00	5.00	3.00	3.00	3.00	2.00
				Global improvement		3.00	3.00	2.00	2.00	2.00	1.00
				Efficacy index		11.00	9.00	5.00	5.00	5.00	1.00
				Efficacy index (*)	0.67	2.00	3.00	3.00	3.00	4.00	

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=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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PHARMACIA CNS RD
REBOXETINE - PROTOCOL 20124/017
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	244	Reboxetine	Male	Severity of illness	5.00	4.00	4.00	4.00	4.00	3.00	3.00
				Global improvement		3.00	3.00	3.00	3.00	3.00	3.00
				Efficacy index		6.00	10.00	10.00	6.00	9.00	9.00
				Efficacy index (*)		1.50	1.00	1.00	1.50	2.00	2.00
	257	Reboxetine	Female	Severity of illness	5.00	3.00	3.00	2.00	3.00	2.00	2.00
				Global improvement		3.00	3.00	1.00	2.00	2.00	2.00
				Efficacy index		5.00	5.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		3.00	3.00	2.00	2.00	2.00	2.00
	258	Reboxetine	Male	Severity of illness	4.00	5.00	5.00	6.00	6.00		
				Global improvement		5.00	4.00	5.00			
				Efficacy index		15.00	13.00	13.00			
				Efficacy index (*)		0.33	1.00	1.00			
	259	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	2.00	2.00	2.00	2.00
				Efficacy index		14.00	14.00	6.00	2.00	2.00	2.00
				Efficacy index (*)		0.50	0.50	1.50	2.00	2.00	2.00
	260	Imipramine	Female	Severity of illness	4.00	4.00	4.00	5.00			
				Global improvement		3.00	3.00	5.00			
				Efficacy index		9.00	9.00	13.00			
				Efficacy index (*)		2.00	2.00	1.00			
	261	Imipramine	Female	Severity of illness	5.00	5.00					
				Global improvement		5.00					
				Efficacy index		16.00					
				Efficacy index (*)		0.25					
	262	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	3.00	3.00	2.00	2.00	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
	263	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	4.00			
				Global improvement		4.00	5.00				
				Efficacy index		13.00	13.00				
				Efficacy index (*)		1.00	1.00				

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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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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	264	Imipramine	Female	Severity of illness	5.00	5.00	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		10.00	7.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		1.00	1.00	2.00	2.00	2.00	2.00
	265	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	3.00	3.00	3.00	2.00
				Global improvement		4.00	3.00	2.00	5.00	3.00	2.00
				Efficacy index		13.00	9.00	5.00	13.00	9.00	1.00
				Efficacy index (*)		1.00	2.00	3.00	1.00	2.00	4.00
	266	Reboxetine	Female	Severity of illness	4.00	3.00	2.00	2.00	2.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	1.00
				Efficacy index		10.00	6.00	6.00	6.00	6.00	2.00
				Efficacy index (*)		1.00	1.50	1.50	1.50	1.50	2.00
	267	Imipramine	Male	Severity of illness	5.00	4.00	3.00	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	6.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		1.50	1.50	2.00	2.00	2.00	2.00
	268	Imipramine	Female	Severity of illness	5.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		2.00	2.00	2.00	2.00	2.00	4.00
				Efficacy index		6.00	6.00	6.00	6.00	6.00	13.00
				Efficacy index (*)		1.50	1.50	1.50	1.50	1.00	1.00
	269	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00	1.00	1.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	1.00
				Efficacy index		6.00	6.00	6.00	6.00	5.00	1.00
				Efficacy index (*)		1.50	1.50	1.50	3.00	4.00	4.00
	270	Imipramine	Female	Severity of illness	5.00	5.00					
				Global improvement		5.00					
				Efficacy index		16.00					
				Efficacy index (*)		0.25					
	271	Reboxetine	Female	Severity of illness	4.00	3.00	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		11.00	11.00	12.00	12.00	12.00	12.00
				Efficacy index (*)		0.67	0.67	0.50	0.50	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
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 20124/017
Listing No.: 16.0

CLINICAL GLOBAL IMPRESSION

Contro	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
9	272	Imipramine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00 3.00 10.00 1.00	3.00 3.00 6.00 1.50	3.00 3.00 6.00 1.50	3.00 3.00 6.00 1.50	3.00 2.00 2.00 2.00	3.00 2.00 2.00 2.00	3.00 2.00 2.00 2.00
	273	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 4.00 15.00 0.33	5.00 3.00 11.00 0.67	4.00 3.00 12.00 0.50	4.00 3.00 12.00 0.50	4.00 3.00 12.00 0.50	4.00 3.00 12.00 0.50	4.00 3.00 12.00 0.50
	274	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00 4.00 16.00 0.25	4.00 4.00 16.00 0.25	4.00 4.00 16.00 0.25	4.00 4.00 16.00 0.25	4.00 4.00 16.00 0.25	4.00 4.00 16.00 0.25	4.00 4.00 16.00 0.25
	274/A	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00 3.00 10.00 1.00	6.00 3.00 10.00 1.00	6.00 3.00 10.00 1.00	6.00 3.00 10.00 1.00	6.00 3.00 10.00 1.00	6.00 3.00 10.00 1.00	6.00 3.00 10.00 1.00
	275	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 3.00 6.00 1.50	3.00 3.00 6.00 1.50	3.00 3.00 6.00 1.50	3.00 3.00 6.00 1.50	3.00 2.00 4.00 4.00	3.00 2.00 4.00 4.00	3.00 2.00 4.00 4.00
	276	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00 5.00 13.00 1.00	5.00 5.00 13.00 1.00	5.00 5.00 13.00 1.00	5.00 5.00 13.00 1.00	5.00 5.00 13.00 1.00	5.00 5.00 13.00 1.00	5.00 5.00 13.00 1.00
	276/A	Imipramine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00 5.00 13.00 1.00	5.00 5.00 13.00 1.00	5.00 5.00 13.00 1.00	5.00 5.00 13.00 1.00	5.00 5.00 13.00 1.00	5.00 5.00 13.00 1.00	5.00 5.00 13.00 1.00
9/A	283	Imipramine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 4.00 13.00 1.00	5.00 4.00 13.00 1.00	5.00 4.00 13.00 1.00	5.00 4.00 13.00 1.00	5.00 4.00 13.00 1.00	5.00 4.00 13.00 1.00	5.00 4.00 13.00 1.00

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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=mainly 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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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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/A	234	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	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	10.00	6.00	6.00	6.00	6.00	6.00
				Efficacy index (*)	1.00	1.00	1.00	1.50	1.50	1.50	1.50
	235	Reboxetine	Male	Severity of illness	6.00	4.00	3.00	3.00	3.00	3.00	5.00
				Global improvement		2.00	2.00	2.00	2.00	4.00	4.00
				Efficacy index	5.00	5.00	5.00	5.00	6.00	14.00	14.00
				Efficacy index (*)	3.00	3.00	3.00	3.00	1.50	0.50	0.50
	236	Imipramine	Male	Severity of illness	5.00	5.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		4.00	3.00	2.00	2.00	2.00	1.00
				Efficacy index	13.00	10.00	6.00	6.00	6.00	6.00	6.00
				Efficacy index (*)	1.00	1.00	1.00	1.50	1.50	4.00	4.00
	277	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	16.00	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	0.25
	278	Imipramine	Female	Severity of illness	5.00	3.00	3.00	3.00	4.00	4.00	4.00
				Global improvement		2.00	1.00	4.00	4.00	4.00	4.00
				Efficacy index	6.00	6.00	1.00	13.00	13.00	13.00	13.00
				Efficacy index (*)	1.50	4.00	4.00	1.00	1.00	1.00	1.00
	279	Imipramine	Male	Severity of illness	4.00	4.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		4.00	5.00	5.00	5.00	5.00	5.00
				Efficacy index	15.00	15.00	15.00	15.00	15.00	15.00	15.00
				Efficacy index (*)	0.33	0.33	0.33	0.33	0.33	0.33	0.33
	280	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		5.00	5.00	5.00	5.00	5.00	5.00
				Efficacy index	16.00	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	0.25
	281	Reboxetine	Female	Severity of illness	4.00	3.00	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	5.00	4.00	4.00	4.00	4.00	4.00
				Efficacy index (*)	3.00	4.00	4.00	4.00	4.00	4.00	4.00

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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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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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/A	282	Reboxetine	Male	Severity of illness	6.00	6.00	4.00	4.00	3.00	3.00	3.00
				Global improvement		4.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		14.00	6.00	6.00	5.00	5.00	5.00
				Efficacy index (*)	0.50	1.50	1.50	3.00	3.00	3.00	
	283	Imipramine	Female	Severity of illness	4.00	4.00	3.00	3.00	2.00	1.00	1.00
				Global improvement		4.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		13.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index (*)	1.00	4.00	4.00	4.00	4.00	4.00	
	284	Imipramine	Male	Severity of illness	5.00	5.00	4.00	4.00	5.00		
				Global improvement		4.00	3.00	4.00			
				Efficacy index		14.00	10.00	13.00			
				Efficacy index (*)	0.50	1.00	1.00				
	301	Imipramine	Female	Severity of illness	4.00	3.00	3.00	1.00	1.00	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	2.00
				Efficacy index (*)	1.00	1.50	2.00	2.00	2.00	2.00	
	302	Imipramine	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00		
				Global improvement		4.00	4.00	4.00			
				Efficacy index		14.00	14.00	14.00			
				Efficacy index (*)	0.50	0.50	0.50				
	303	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	4.00	4.00		
				Global improvement		3.00	4.00	4.00			
				Efficacy index		10.00	14.00	14.00			
				Efficacy index (*)	1.00	0.50	0.50				
	304	Reboxetine	Female	Severity of illness	4.00	3.00	3.00	3.00	3.00	1.00	1.00
				Global improvement		2.00	2.00	2.00	2.00	1.00	1.00
				Efficacy index		6.00	6.00	6.00	2.00	2.00	1.00
				Efficacy index (*)	1.50	1.50	1.50	1.50	2.00	4.00	
	305	Reboxetine	Male	Severity of illness	5.00	3.00	2.00	2.00	2.00	1.00	1.00
				Global improvement		2.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		6.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index (*)	1.50	4.00	4.00	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

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 2012A/017
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/A	306	Reboxetine	Female	Severity of illness	5.00	5.00	3.00	1.00	1.00	1.00	1.00
				Global improvement		4.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index	15.00	2.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index (*)	0.33	2.00	4.00	4.00	4.00	4.00	4.00
	307	Imipramine	Female	Severity of illness	4.00	4.00					
				Global improvement		4.00					
				Efficacy index	16.00						
				Efficacy index (*)	0.25						
	308	Imipramine	Female	Severity of illness	6.00	5.00	5.00	4.00	4.00	6.00	
				Global improvement		3.00	3.00	2.00	4.00		
				Efficacy index	10.00	10.00	10.00	6.00	15.00		
				Efficacy index (*)	1.00	1.00	1.50	0.33			
10	289	Imipramine	Female	Severity of illness	5.00	5.00					
				Global improvement		6.00					
				Efficacy index	14.00						
				Efficacy index (*)	0.50						
	290	Reboxetine	Male	Severity of illness	6.00	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	10.00	6.00	6.00	5.00	5.00	5.00	
				Efficacy index (*)	1.00	1.50	3.00	3.00	3.00	3.00	
	291	Imipramine	Male	Severity of illness	5.00	5.00	4.00	4.00	2.00	2.00	1.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	1.00
				Efficacy index	10.00	7.00	7.00	2.00	2.00	2.00	
				Efficacy index (*)	1.00	1.00	1.00	2.00	2.00	2.00	
	292	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	1.00
				Efficacy index	9.00	1.00	1.00	1.00	1.00	1.00	
				Efficacy index (*)	2.00	4.00	4.00	4.00	4.00	4.00	
	293	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				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	

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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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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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
10	294	Imipramine	Female	Severity of illness	5.00	6.00	6.00	5.00			
				Global improvement		7.00	7.00	6.00			
				Efficacy index		15.00	13.00	13.00			
				Efficacy index (*)		0.33	1.00	1.00			
	295	Imipramine	Male	Severity of illness	5.00	5.00	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		13.00	9.00	9.00	6.00	5.00	5.00
				Efficacy index (*)		1.00	2.00	2.00	1.50	3.00	3.00
	296	Reboxetine	Female	Severity of illness	6.00	6.00	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		14.00	7.00	5.00	5.00	5.00	5.00
				Efficacy index (*)		0.50	1.00	3.00	3.00	3.00	3.00
	297	Reboxetine	Male	Severity of illness	6.00	6.00	4.00	3.00	2.00	2.00	1.00
				Global improvement		4.00	3.00	2.00	2.00	2.00	1.00
				Efficacy index		13.00	9.00	5.00	5.00	1.00	1.00
				Efficacy index (*)		1.00	2.00	3.00	3.00	3.00	4.00
	298	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	4.00	3.00	2.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	2.00
				Efficacy index		13.00	9.00	10.00	6.00	6.00	6.00
				Efficacy index (*)		1.00	2.00	1.00	1.50	1.50	1.50
	299	Imipramine	Male	Severity of illness	5.00	5.00	6.00	6.00	5.00	5.00	3.00
				Global improvement		4.00	6.00	4.00	3.00	3.00	3.00
				Efficacy index		14.00	14.00	14.00	10.00	10.00	10.00
				Efficacy index (*)		0.50	0.50	0.50	1.00	1.00	1.00
	300	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	3.00	2.00	2.00	3.00
				Efficacy index		13.00	13.00	9.00	6.00	6.00	10.00
				Efficacy index (*)		1.00	1.00	2.00	1.50	1.50	1.00
11	321	Reboxetine	Female	Severity of illness	4.00	3.00	3.00	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	5.00	6.00	5.00	5.00	4.00
				Efficacy index (*)		1.50	3.00	3.00	4.00	4.00	4.00

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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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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	322	Reboxetine	Female	Severity of illness	4.00	4.00	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	1.00	1.00	1.00
				Efficacy index (*)		2.00	1.50	3.00	4.00	4.00	4.00
	323	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	1.00	2.00	1.00
				Efficacy index		10.00	10.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		1.00	1.00	2.00	2.00	2.00	2.00
	324	Imipramine	Male	Severity of illness	4.00	4.00	3.00	4.00	2.00	2.00	2.00
				Global improvement		3.00	3.00	3.00	2.00	2.00	2.00
				Efficacy index		10.00	6.00	10.00	6.00	6.00	6.00
				Efficacy index (*)		1.00	1.50	1.00	1.50	1.50	2.00
	325	Reboxetine	Female	Severity of illness	4.00	4.00	2.00	2.00	2.00	1.00	1.00
				Global improvement		3.00	2.00	2.00	1.00	1.00	1.00
				Efficacy index		10.00	2.00	2.00	1.00	1.00	1.00
				Efficacy index (*)		1.00	2.00	2.00	4.00	4.00	4.00
	326	Imipramine	Male	Severity of illness	4.00	4.00	3.00	3.00	2.00	1.00	2.00
				Global improvement		3.00	2.00	2.00	2.00	4.00	2.00
				Efficacy index		10.00	6.00	6.00	2.00	2.00	2.00
				Efficacy index (*)		1.00	1.50	1.50	2.00	2.00	4.00
	327	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	3.00	3.00	3.00	2.00
				Global improvement		3.00	3.00	3.00	2.00	2.00	2.00
				Efficacy index		10.00	6.00	6.00	6.00	6.00	6.00
				Efficacy index (*)		1.00	1.50	1.50	1.50	1.50	2.00
	328	Imipramine	Male	Severity of illness	4.00	3.00	3.00	2.00	2.00	2.00	2.00
				Global improvement		2.00	2.00	2.00	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
	329	Imipramine	Female	Severity of illness	4.00	4.00	3.00	3.00	3.00	2.00	2.00
				Global improvement		4.00	3.00	2.00	2.00	1.00	1.00
				Efficacy index		10.00	6.00	6.00	6.00	6.00	6.00
				Efficacy index (*)		1.00	1.50	1.50	1.50	4.00	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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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	330	Reboxetine	Female	Severity of illness	4.00	4.00					
				Global improvement		4.00					
				Efficacy index	16.00	0.25					
	331	Reboxetine	Male	Severity of illness	4.00	4.00	3.00	3.00	4.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	3.00	2.00	2.00
				Efficacy index	10.00	6.00	6.00	10.00	6.00	6.00	6.00
	332	Imipramine	Female	Severity of illness	4.00	2.00	1.00	1.00	1.00	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	4.00	4.00	4.00	4.00
	333	Imipramine	Female	Severity of illness	4.00	4.00	4.00	4.00	3.00	3.00	1.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	1.00
				Efficacy index	13.00	9.00	9.00	6.00	6.00	2.00	2.00
12	337	Imipramine	Female	Severity of illness	4.00	3.00	2.00	3.00	3.00	4.00	1.00
				Global improvement		2.00	1.00	3.00	3.00	5.00	1.00
				Efficacy index	6.00	2.00	6.00	6.00	15.00	2.00	2.00
	338	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	3.00	3.00	4.00	4.00
				Global improvement		4.00	3.00	2.00	2.00	3.00	3.00
				Efficacy index	14.00	0.50	1.00	1.50	1.50	1.00	1.00
	339	Imipramine	Male	Severity of illness	4.00	4.00	4.00	3.00	3.00	2.00	1.00
				Global improvement		3.00	3.00	2.00	2.00	2.00	1.00
				Efficacy index	10.00	10.00	6.00	6.00	6.00	2.00	2.00
	340	Reboxetine	Female	Severity of illness	5.00	5.00	2.00	2.00	1.00	3.00	4.00
				Global improvement		4.00	1.00	1.00	1.00	2.00	3.00
				Efficacy index	14.00	0.50	2.00	2.00	1.00	5.00	5.00

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=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

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PRARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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	341	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	4.00	5.00	
				Global improvement		4.00	3.00	4.00	3.00	4.00	4.00
				Efficacy index (*)		14.00	10.00	14.00	11.00	14.00	14.00
13	353	Reboxetine	Female	Severity of illness	3.00	3.00	3.00	2.00	2.00	4.00	
				Global improvement		3.00	2.00	2.00	2.00	5.00	5.00
				Efficacy index (*)		9.00	6.00	5.00	6.00	13.00	13.00
13	354	Imipramine	Female	Severity of illness	4.00	3.00	3.00	1.00	1.00	1.00	1.00
				Global improvement		2.00	2.00	1.00	1.00	1.00	2.00
				Efficacy index (*)		3.00	5.00	1.00	1.00	1.00	4.00
13	355	Reboxetine	Female	Severity of illness	4.00	3.00	3.00	3.00	4.00	4.00	4.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		3.00	3.00	3.00	3.00	3.00	3.00
13	356	Imipramine	Male	Severity of illness	5.00	4.00	3.00	3.00	3.00	4.00	4.00
				Global improvement		3.00	2.00	2.00	2.00	3.00	3.00
				Efficacy index (*)		10.00	6.00	6.00	6.00	10.00	6.00
13	357	Imipramine	Female	Severity of illness	4.00	4.00	4.00	3.00	3.00	3.00	1.50
				Global improvement		3.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		3.00	3.00	2.00	2.00	2.00	2.00
13	358	Reboxetine	Male	Severity of illness	5.00	4.00	4.00	3.00	3.00	3.00	2.00
				Global improvement		3.00	5.00	5.00	5.00	5.00	5.00
				Efficacy index (*)		10.00	14.00	6.00	6.00	15.00	15.00
13	359	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	2.00	3.00	3.00	2.00
				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	1.00

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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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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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	360	Imipramine	Female	Severity of illness	4.00	4.00					
				Global improvement	3.00	3.00					
				Efficacy index	12.00	0.50					
	361	Reboxetine	Female	Severity of illness	5.00	4.00	3.00	2.00	3.00	2.00	1.00
				Global improvement	2.00	1.00	1.00	1.00	2.00	1.00	1.00
				Efficacy index	6.00	1.00	1.00	1.00	5.00	1.00	1.00
14	457	Reboxetine	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	2.00	2.00
				Efficacy index	13.00	14.00	14.00	10.00	10.00	6.00	6.00
	458	Imipramine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	4.00	4.00
				Global improvement	4.00	4.00	4.00	3.00	3.00	3.00	2.00
				Efficacy index	14.00	14.00	14.00	10.00	10.00	6.00	6.00
	459	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	3.00	3.00	3.00	3.00
				Global improvement	4.00	4.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index	13.00	9.00	9.00	5.00	5.00	5.00	5.00
	460	Imipramine	Male	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	4.00	3.00	2.00	2.00
				Efficacy index	13.00	13.00	13.00	13.00	9.00	5.00	5.00
	461	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	3.00	3.00
				Efficacy index	13.00	13.00	14.00	14.00	14.00	11.00	14.00
	462	Reboxetine	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	4.00
				Efficacy index	13.00	14.00	14.00	14.00	14.00	14.00	14.00

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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 R&D
REBOXETINE - PROTOCOL 20124/017
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
14	463	Imipramine	Male	Severity of illness	5.00	5.00	4.00	4.00	4.00	3.00	2.00
				Global improvement		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	3.00	3.00		
	464	Reboxetine	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	
				Efficacy index	13.00	13.00	13.00	14.00	14.00	14.00	
				Efficacy index (*)	1.00	1.00	1.00	0.50	0.50	0.50	
	465	Reboxetine	Male	Severity of illness	5.00	5.00	4.00	3.00	3.00	3.00	1.00
				Global improvement		3.00	3.00	2.00	2.00	2.00	
				Efficacy index	10.00	10.00	6.00	6.00	5.00	1.00	
				Efficacy index (*)	1.00	1.00	1.50	1.50	3.00	4.00	
	466	Imipramine	Female	Severity of illness	5.00	5.00	4.00	3.00	3.00	3.00	2.00
				Global improvement		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	
14/1	129	Reboxetine	Male	Severity of illness	5.00						
				Global improvement							
				Efficacy index							
				Efficacy index (*)							
	426	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	2.00	2.00	2.00
				Global improvement		4.00	3.00	3.00	1.00	1.00	
				Efficacy index	13.00	10.00	10.00	10.00	2.00	2.00	
				Efficacy index (*)	1.00	1.00	1.00	2.00	2.00	2.00	
	429	Imipramine	Female	Severity of illness	5.00	4.00					
				Global improvement		5.00					
				Efficacy index	16.00	16.00					
				Efficacy index (*)	0.25						
	451	Imipramine	Male	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	4.00	
				Efficacy index	10.00	13.00	7.00	9.00	14.00	14.00	
				Efficacy index (*)	1.00	1.00	1.00	2.00	0.50	0.50	

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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 R&D
REBOXETINE - PROTOCOL 20124/017
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CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14/1	452	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		9.00	10.00	10.00	6.00	6.00	10.00
				Efficacy index (*)		2.00	1.00	1.00	1.50	1.00	1.00
14/2	136	Imipramine	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00	3.00	2.00
				Global improvement		5.00	4.00	3.00	3.00	2.00	1.00
				Efficacy index		14.00	13.00	9.00	9.00	5.00	1.00
				Efficacy index (*)		0.50	1.00	2.00	2.00	3.00	4.00
14/3	456	Imipramine	Male	Severity of illness	5.00	5.00	4.00	4.00	3.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		10.00	6.00	5.00	2.00	1.00	1.00
				Efficacy index (*)		1.00	1.50	3.00	2.00	4.00	4.00
14/3	417	Reboxetine	Female	Severity of illness	5.00	3.00	3.00	3.00	3.00	3.00	3.00
				Global improvement		2.00	2.00	2.00	1.00	2.00	2.00
				Efficacy index		1.00	1.00	6.00	1.00	1.00	1.00
				Efficacy index (*)		4.00	4.00	1.50	4.00	4.00	4.00
14/8	418	Imipramine	Female	Severity of illness	4.00	4.00	4.00	4.00	5.00	5.00	5.00
				Global improvement		3.00	3.00	3.00	4.00	3.00	5.00
				Efficacy index		9.00	9.00	9.00	13.00	9.00	13.00
				Efficacy index (*)		2.00	2.00	2.00	1.00	2.00	1.00
14/9	419	Reboxetine	Female	Severity of illness	4.00	4.00	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	13.00	6.00	2.00	2.00	6.00
				Efficacy index (*)		2.00	1.00	1.50	2.00	1.50	4.00
14/20	420	Imipramine	Female	Severity of illness	5.00	5.00	4.00	4.00	5.00		
				Global improvement		3.00	2.00	6.00			
				Efficacy index		9.00	1.00	13.00			
				Efficacy index (*)		2.00	4.00	1.00			
14/21	421	Reboxetine	Female	Severity of illness	5.00	4.00	3.00	3.00	3.00	3.00	3.00
				Global improvement		2.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		5.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		3.00	2.00	4.00	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

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PHARMACIA CNS R&D
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CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
14/3	427	Imipramine	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement	3.00	3.00	4.00	4.00	4.00	4.00	
				Efficacy index	10.00	10.00	13.00	13.00	15.00	15.00	
				Efficacy index (*)	1.00	1.00	1.00	1.00	0.53		
428	428	Imipramine	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	2.00	2.00	
				Efficacy index	9.00	6.00	5.00	5.00	5.00	5.00	
				Efficacy index (*)	2.00	1.50	3.00	3.00	3.00	3.00	
14/4	131	Imipramine	Female	Severity of illness	5.00	5.00	5.00	4.00	3.00	3.00	2.00
				Global improvement	4.00	3.00	2.00	2.00	2.00	1.00	
				Efficacy index	14.00	10.00	5.00	5.00	5.00	1.00	
				Efficacy index (*)	0.50	1.00	3.00	3.00	3.00	4.00	
132	132	Imipramine	Female	Severity of illness	5.00	5.00	4.00	4.00	4.00	3.00	3.00
				Global improvement	4.00	4.00	2.00	2.00	2.00	1.00	
				Efficacy index	13.00	5.00	5.00	5.00	5.00	1.00	
				Efficacy index (*)	1.00	3.00	3.00	3.00	3.00	4.00	
133	133	Imipramine	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	2.00	2.00	1.00	
				Efficacy index	13.00	9.00	5.00	6.00	5.00	1.00	
				Efficacy index (*)	1.00	2.00	3.00	1.50	3.00	4.00	
134	134	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00	3.00	2.00
				Global improvement	4.00	3.00	3.00	2.00	2.00	1.00	
				Efficacy index	13.00	9.00	5.00	6.00	5.00	1.00	
				Efficacy index (*)	1.00	2.00	3.00	3.00	3.00	4.00	
135	135	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	4.00	4.00	3.00	2.00
				Global improvement	4.00	2.00	2.00	2.00	2.00	1.00	
				Efficacy index	14.00	5.00	5.00	5.00	5.00	1.00	
				Efficacy index (*)	0.50	3.00	3.00	3.00	3.00	4.00	
14/7	422	Imipramine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	3.00	2.00
				Global improvement	4.00	3.00	3.00	3.00	3.00	2.00	
				Efficacy index	13.00	10.00	10.00	6.00	6.00	2.00	
				Efficacy index (*)	1.00	1.00	1.00	1.50	1.50	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=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 20124/017
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
14/7	423	Imipramine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	1.00
				Global improvement		4.00	3.00	3.00	3.00	3.00	3.00
				Efficacy index		13.00	10.00	10.00	10.00	10.00	9.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	2.00	2.00
	424	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	4.00	3.00	1.00
				Global improvement		3.00	5.00	3.00	3.00	3.00	3.00
				Efficacy index		9.00	10.00	10.00	6.00	6.00	6.00
				Efficacy index (*)		2.00	1.00	1.00	1.50	1.50	2.00
	430	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	4.00	3.00	3.00	1.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	1.00
				Efficacy index		13.00	9.00	6.00	5.00	6.00	2.00
				Efficacy index (*)		1.00	2.00	1.50	3.00	1.50	2.00
	431	Reboxetine	Male	Severity of illness	6.00	6.00	6.00	6.00	6.00	5.00	3.00
				Global improvement		4.00	5.00	6.00	4.00	3.00	2.00
				Efficacy index		13.00	13.00	13.00	14.00	10.00	6.00
				Efficacy index (*)		1.00	1.00	0.50	0.50	1.00	1.50
	432	Imipramine	Male	Severity of illness	5.00	5.00	5.00	5.00	3.00	3.00	3.00
				Global improvement		4.00	4.00	4.00	2.00	2.00	2.00
				Efficacy index		13.00	13.00	13.00	6.00	6.00	6.00
				Efficacy index (*)		1.00	1.00	1.00	1.50	1.50	1.50
	433	Imipramine	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00	3.00	1.00
				Global improvement		4.00	3.00	3.00	3.00	2.00	1.00
				Efficacy index		13.00	9.00	10.00	10.00	6.00	2.00
				Efficacy index (*)		1.00	2.00	1.00	1.00	1.50	2.00
	434	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	4.00	3.00	3.00	1.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	1.00
				Efficacy index		13.00	10.00	6.00	6.00	6.00	2.00
				Efficacy index (*)		1.00	1.00	1.50	1.50	1.50	2.00
	439	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00	4.00	3.00
				Global improvement		4.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		13.00	10.00	10.00	10.00	6.00	2.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.50	2.00

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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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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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
14/7	440	Imipramine	Female	Severity of illness	4.00	4.00	4.00	3.00	3.00	1.00	1.00
				Global improvement		4.00	3.00	2.00	1.00	1.00	1.00
				Efficacy index		13.00	9.00	6.00	1.00	1.00	1.00
				Efficacy index (*)		1.00	2.00	1.50	4.00	4.00	4.00
	441	Imipramine	Male	Severity of illness	5.00	5.00	5.00	4.00	1.00	1.00	1.00
				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
	442	Imipramine	Male	Severity of illness	5.00	5.00	5.00	5.00	3.00	3.00	1.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	1.00
				Efficacy index		13.00	3.00	5.00	6.00	1.00	1.00
				Efficacy index (*)		1.00	2.00	3.00	1.50	4.00	4.00
	449	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	4.00	3.00	1.00	1.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	1.00
				Efficacy index		13.00	9.00	5.00	6.00	1.00	1.00
				Efficacy index (*)		1.00	2.00	3.00	4.00	4.00	4.00
	450	Imipramine	Male	Severity of illness	4.00	5.00	5.00	5.00	3.00	1.00	1.00
				Global improvement		4.00	3.00	3.00	2.00	1.00	1.00
				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
14/8	130	Reboxetine	Male	Severity of illness	5.00	5.00	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	5.00	5.00	5.00	6.00	2.00
				Efficacy index (*)		2.00	3.00	3.00	3.00	1.50	2.00
	425	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	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
	467	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	10.00	10.00	10.00	10.00	10.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	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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PHARMACIA CNS R&D		REBOXETINE - PROTOCOL 2012/4/017		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				
14/10	53	Reboxetine	Male	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 3.00	4.00 2.00 5.00 3.00	3.00 2.00 4.00 3.00	2.00 1.00 1.00 4.00	2.00 1.00 1.00 4.00				
	54	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 4.00 14.00 0.50	5.00 4.00 13.00 0.50	5.00 4.00 13.00 1.00	5.00 4.00 9.00 2.00	5.00 3.00 9.00 2.00	5.00 3.00 9.00 2.00	5.00 3.00 9.00 2.00				
	55	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 4.00 13.00 1.00	5.00 4.00 13.00 1.00	5.00 4.00 5.00 3.00	4.00 2.00 6.00 1.50	4.00 2.00 5.00 3.00	3.00 2.00 5.00 4.00	2.00 1.00 1.00 4.00				
	56	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	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				
	57	Reboxetine	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	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				
	58	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 3.00 10.00 1.00	5.00 3.00 10.00 1.00	4.00 3.00 9.00 2.00	4.00 2.00 5.00 3.00	3.00 2.00 5.00 3.00				
	59	Imipramine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 3.00 10.00 1.00	5.00 3.00 10.00 1.00	4.00 2.00 6.00 1.50	4.00 2.00 6.00 1.50	2.00 1.00 4.00 4.00				
	60	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00 4.00 13.00 1.00	5.00 4.00 13.00 1.00	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	2.00 1.00 1.00 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

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/017
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
14/10	137	Reboxetine	Female	Severity of illness	5.00	6.00	5.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		14.00	10.00	6.00	5.00	5.00	5.00
				Efficacy index (*)		0.50	1.00	1.50	3.00	3.00	3.00
	138	Imipramine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	4.00	4.00
				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 (*)		0.50	2.00	2.00	2.00	3.00	3.00
	139	Reboxetine	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	1.00	1.00	1.00
				Efficacy index		10.00	5.00	5.00	1.00	1.00	1.00
				Efficacy index (*)		1.00	3.00	3.00	4.00	4.00	4.00
	140	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	3.00	3.00	4.00	3.00
				Efficacy index		14.00	13.00	9.00	9.00	13.00	9.00
				Efficacy index (*)		0.50	1.00	2.00	2.00	1.00	2.00
	435	Imipramine	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00	4.00	4.00
				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
	436	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		14.00	10.00	5.00	5.00	5.00	5.00
				Efficacy index (*)		0.50	1.00	3.00	3.00	3.00	3.00
	437	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00	4.00	2.00
				Global improvement		3.00	3.00	2.00	2.00	1.00	1.00
				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
	438	Imipramine	Female	Severity of illness	5.00	5.00	5.00	4.00	3.00	3.00	3.00
				Global improvement		4.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		14.00	9.00	5.00	5.00	5.00	5.00
				Efficacy index (*)		0.50	2.00	3.00	3.00	3.00	3.00

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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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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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
14/70	443	Reboxetine	Female	Severity of illness	6.00	6.00	5.00	5.00	4.00	3.00	3.00
				Global improvement	4.00	4.00	3.00	3.00	2.00	2.00	
				Efficacy index	14.00	9.00	9.00	9.00	5.00	5.00	
				Efficacy index (*)	0.50	2.00	2.00	3.00	3.00	3.00	
444	444	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	4.00	3.00	3.00
				Global improvement	4.00	4.00	3.00	3.00	2.00	2.00	
				Efficacy index	14.00	13.00	9.00	9.00	5.00	5.00	
				Efficacy index (*)	0.50	1.00	2.00	3.00	3.00	3.00	
445	445	Imipramine	Female	Severity of illness	5.00	5.00	5.00	5.00	4.00	4.00	4.00
				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 (*)	0.50	2.00	2.00	2.00	3.00	3.00	
446	446	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	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	
447	447	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	3.00	3.00	2.00	
				Efficacy index	14.00	9.00	9.00	9.00	9.00	5.00	
				Efficacy index (*)	0.50	2.00	2.00	2.00	3.00	3.00	
448	448	Imipramine	Female	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	3.00	3.00	3.00	
				Efficacy index	14.00	9.00	9.00	9.00	9.00	9.00	
				Efficacy index (*)	0.50	2.00	2.00	2.00	2.00	2.00	
453	453	Imipramine	Female	Severity of illness	5.00	5.00	4.00	3.00	4.00	3.00	2.00
				Global improvement	4.00	2.00	2.00	2.00	2.00	1.00	
				Efficacy index	14.00	5.00	5.00	5.00	5.00	1.00	
				Efficacy index (*)	0.50	3.00	3.00	3.00	3.00	4.00	
454	454	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	4.00	3.00	2.00
				Global improvement	4.00	3.00	3.00	3.00	2.00	1.00	
				Efficacy index	13.00	9.00	9.00	9.00	5.00	1.00	
				Efficacy index (*)	1.00	2.00	2.00	3.00	3.00	4.00	

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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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PHARMACIA CMS RED

REBOXETINE - PROTOCOL 20124/017
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
14/10	455	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00	3.00	3.00
				Global improvement		4.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		14.00	9.00	5.00	5.00	5.00	5.00
				Efficacy index (*)		0.50	2.00	3.00	3.00	3.00	3.00
15	349	Imipramine	Male	Severity of illness	4.00	3.00	2.00	2.00	1.00	1.00	1.00
				Global improvement		2.00	2.00	2.00	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
351	351	Reboxetine	Male	Severity of illness	6.00	4.00	1.00	5.00	2.00	1.00	1.00
				Global improvement		2.00	1.00	3.00	2.00	1.00	1.00
				Efficacy index		5.00	1.00	5.00	1.00	1.00	1.00
				Efficacy index (*)		3.00	4.00	3.00	4.00	4.00	4.00
352	352	Imipramine	Male	Severity of illness	4.00	4.00	3.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	2.00	3.00	3.00	3.00	3.00
				Efficacy index		10.00	5.00	5.00	5.00	5.00	5.00
				Efficacy index (*)		1.00	3.00	3.00	3.00	3.00	3.00
364	364	Imipramine	Female	Severity of illness	6.00	5.00	3.00	4.00	5.00	3.00	3.00
				Global improvement		3.00	2.00	3.00	3.00	3.00	3.00
				Efficacy index		3.00	5.00	5.00	9.00	9.00	9.00
				Efficacy index (*)		3.00	3.00	3.00	2.00	2.00	2.00
366	366	Reboxetine	Male	Severity of illness	5.00	1.00	1.00	1.00	1.00	2.00	1.00
				Global improvement		1.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		2.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		2.00	2.00	4.00	4.00	4.00	4.00
367	367	Imipramine	Male	Severity of illness	5.00	5.00	5.00	6.00	4.00	4.00	5.00
				Global improvement		4.00	5.00	5.00	3.00	3.00	4.00
				Efficacy index		13.00	13.00	14.00	6.00	5.00	13.00
				Efficacy index (*)		1.00	1.00	0.50	1.50	3.00	1.00
368	368	Reboxetine	Female	Severity of illness	5.00	3.00	2.00	2.00	2.00	2.00	2.00
				Global improvement		2.00	1.00	1.00	2.00	2.00	2.00
				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

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 R&D
REBOXETINE - PROTOCOL 20124-017
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	369	Reboxetine	Female	Severity of illness	5.00	2.00	2.00	1.00	1.00	1.00	1.00
				Global improvement		1.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		1.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index (*)	4.00	4.00	4.00	4.00	4.00	4.00	4.00
370	370	Imipramine	Female	Severity of illness	4.00	4.00	4.00	4.00	3.00	4.00	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	
371	371	Reboxetine	Female	Severity of illness	4.00	3.00	3.00	3.00	2.00	2.00	1.00
				Global improvement		2.00	2.00	2.00	1.00	1.00	1.00
				Efficacy index		1.00	2.00	6.00	1.00	1.00	2.00
				Efficacy index (*)	4.00	4.00	2.00	1.50	4.00	4.00	
372	372	Imipramine	Male	Severity of illness	7.00	6.00	5.00	5.00	5.00	5.00	4.00
				Global improvement		3.00	3.00	3.00	3.00	3.00	3.00
				Efficacy index		9.00	9.00	5.00	9.00	10.00	5.00
				Efficacy index (*)	2.00	2.00	2.00	3.00	2.00	1.00	
373	373	Imipramine	Female	Severity of illness	5.00						
				Global improvement							
				Efficacy index							
				Efficacy index (*)							
374	374	Reboxetine	Female	Severity of illness	6.00	3.00	3.00	2.00	1.00	1.00	1.00
				Global improvement		2.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		6.00	6.00	6.00	2.00	2.00	2.00
				Efficacy index (*)	1.50	1.50	1.50	2.00	2.00	2.00	
375	375	Reboxetine	Female	Severity of illness	5.00	3.00	1.00	1.00			
				Global improvement		2.00	1.00	1.00			
				Efficacy index		5.00	1.00	1.00			
				Efficacy index (*)	3.00	4.00	4.00				
376	376	Imipramine	Female	Severity of illness	6.00	7.00					
				Global improvement		6.00					
				Efficacy index		14.00					
				Efficacy index (*)	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
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 R&D
REBOXETINE - PROTOCOL 20124/017
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	377	Reboxetine	Female	Severity of illness	6.00	4.00	3.00	2.00	2.00	2.00	2.00
				Global improvement		2.00	2.00	2.00	2.00	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
	378	Reboxetine	Female	Severity of illness	5.00	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		5.00	1.00	1.00	2.00	2.00	2.00
				Efficacy index (*)		3.00	4.00	4.00	2.00	2.00	
	379	Imipramine	Female	Severity of illness	6.00						
				Global improvement							
				Efficacy index							
				Efficacy index (*)							
	380	Imipramine	Female	Severity of illness	6.00	5.00	4.00	5.00	2.00	3.00	3.00
				Global improvement		3.00	3.00	3.00	1.00	2.00	2.00
				Efficacy index		9.00	9.00	9.00	2.00	2.00	2.00
				Efficacy index (*)		2.00	2.00	2.00	2.00	2.00	
	381	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	4.00	3.00	3.00	4.00
				Global improvement		3.00	3.00	3.00	2.00	2.00	3.00
				Efficacy index		10.00	11.00	11.00	7.00	7.00	7.00
				Efficacy index (*)		1.00	0.67	0.67	1.00	1.00	
	382	Imipramine	Male	Severity of illness	5.00						
				Global improvement							
				Efficacy index							
				Efficacy index (*)							
	383	Imipramine	Female	Severity of illness	7.00	5.00	5.00	3.00	3.00	2.00	2.00
				Global improvement		3.00	4.00	2.00	2.00	1.00	1.00
				Efficacy index		9.00	13.00	1.00	5.00	1.00	1.00
				Efficacy index (*)		2.00	1.00	4.00	3.00	4.00	
	384	Reboxetine	Female	Severity of illness	6.00	5.00					
				Global improvement		4.00					
				Efficacy index		9.00					
				Efficacy index (*)		2.00					

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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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PHARMACIA CNS RSD

REBOXETINE - PROTOCOL 28126/017
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 rfty	Hist	Rel	Stud	Symp	Dis	Re	Out	Still	Present (c)															
1	1	Reboxetine	18/03/91	18/03/91	COMSTIPATION		25/01/91	Detail	0			2										3	Y													
								Detail	42								42	2									3	Y								
								Summary																						MO						
								Detail	7																					3						
								Detail	14																						3					
								Detail	21																						3					
								Detail	28																							3				
								Detail	35																								3			
								Detail	42																								3			
								Summary																									Y			
								Summary						19/03/91(*)				42	3	2	2	1	2	2	3	3	3	3	3	3	3	Y				
2	2	Reboxetine	08/04/91	CONSTIPATION			28/02/91	Detail	7																2	3										
								Detail	14																						3					
								Detail	21																								3			
								Detail	28																									3		
								Detail	35																									3		
								Detail	42																									3		
								Summary																										Y		
								Summary						09/04/91(*)				42	3	1	2	2	2	1	5	5	5	5	5	5	5	Y				
								Summary						28/02/91				7	2	1	4	1	YES	3	3	3	3	3	3	3	3	1	YES			
								Summary						28/02/91				7	2	1	4	1	YES	3	3	3	3	3	3	3	3	1	YES			
									MOUTH DRY	21/02/91				21/02/91	Detail	0																				
	Detail	7																															3			
	Detail	14																																	3	
	Detail	28																																		3
	Detail	35																																		3
	Detail	42																																		3
	Summary																																		Y	
	Summary													09/04/91(*)				42	3	1	1	2	2	1	2	2	1	2	2	1	2	2	1	3	Y	
	Summary													28/02/91				7	2	1	4	1	YES	3	3	3	3	3	3	3	3	1	YES			
	Summary													28/02/91				7	2	1	4	1	YES	3	3	3	3	3	3	3	3	1	YES			
		RASH	14/05/91											14/05/91	Detail	21																				
								Detail	28																											
								Detail	35																											
								Detail	42																											
								Summary																												
								Summary						19/03/91				21	1	2	6	1	3	6	1	3	6	1	3	6	1	3	6	1	YES	
								Summary						01/03/91				7	1	2	2	1	2	3	3	3	3	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. withdrawn, 4=stop, 5=stop.
 Hospital: 1=required, 2=not req.; 3=not appl. -- Outcome: 1=recovered, 2=rel. with seq., 3=still present, 4=death
 Disapp./Resp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=unlikely, 2=probable, 3=possible, 4=definite, 5=unknown, 6=none
 Symptomatic treatment: 1=no, 2=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 ONS R&D
 REDOMETINE - PROTOCOL 2024/917
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Onset date	Adverse event	Type record	Visit No	Enc No	Last report		Dis app.	Re app.	Out app.	Skill present (c)								
											report rity	visit rity												
1	2	Redometine	26/02/91	08/04/91	VISION ABNORMAL	01/03/91		Detail	14			1	2	2	1	3	3	3						
								Detail	21			1	2	2	1	3	3	3						
								Detail	28			1	2	2	1	3	3	3						
								Detail	35			1	1	5	1	3	3	3						
								Detail	42			2	2	1	2	2	1	3	3					
								Summary				99/04/91(*)	42	2	1	2	2	1	3	3	3	Y		
								YES																
3	3	Imipramine	16/04/91	27/05/91	HEADACHE	11/04/91(2)		Detail	0			2	1	4	1	3	3	3						
								Detail	7			22/04/91	7	2	1	4	1	3	3	3	1			
								Summary				22/04/91												NO
4	4	Imipramine	17/04/91	28/05/91	TACHYCARDIA	21/04/91		Detail	7			2	2	3	1	3	3	3						
								Detail	14			1	2	5	1	3	3	3	3					
								Detail	21			2	2	3	1	3	3	3	3					
								Detail	28			1	2	3	1	3	3	3	3					
								Detail	35			1	2	3	1	3	3	3	3					
								Summary				18/05/91	35	1	2	3	1	3	3	3	1	YES		
4	4	Imipramine	17/04/91	28/05/91	AGITATION	21/04/91		Detail	7			1	2	4	1	3	3	3						
								Detail	14			1	1	3	1	3	3	3	1					
								Summary				28/04/91	14	1	1	3	1	3	3	3	1	YES		
								4	4	Imipramine	17/04/91	28/05/91	AGITATION	21/04/91		Detail	7			1	2	4	1	3
Detail	14			2	2	3	1									3	3	3	3					
Detail	21			2	2	3	1									3	3	3	3					
Detail	28			1	2	3	1									3	3	3	3					
Detail	35			1	2	3	1									3	3	3	3					
Summary				29/05/91(*)	42	2	2									5	1	3	3	3	3	Y		
YES																								

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 reqd, 3=not appl. -- Outcomes: 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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PHARMACIA CNS RD
 REMOXYLINE - PROTOCOL 20124/017
 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	Saves rcty	Hist dry	Rel ship	Stud drug	Somp app.	Dis app.	Re app.	Out app.	Still present (c)			
			Start date	End date																		
1	6	Imipramine	07/08/91	17/09/91	10/08/91	SWEATING INCREASED	Detail	28		2	2	3	1	3	3	3	3	3	3	3		
			Detail	35		2	2	3	1	3	3	3	2									
			Detail	42		2	1	3	1	3	3	3	3	2								
			Summary		18/09/91(*)	42	2	1	3	1	3	3	3	3	3	3	3	3	3	3	3	Y
			Detail	7	14/10/91		3	2	3	1	YES	3	3	3	3	3	3	3	3	3	3	1
			Summary		14/10/91	7	3	2	3	1	YES	3	3	3	3	3	3	3	3	3	3	1
			Detail	14	19/10/91		3	2	3	1	YES	3	3	3	3	3	3	3	3	3	3	1
			Summary		19/10/91	14	3	2	3	1	YES	3	3	3	3	3	3	3	3	3	3	1
			Detail	7	18/10/91		1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3
			Summary		18/10/91	7	1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3
7	Reboxetine	09/10/91	20/11/91	14/10/91	AGITATION	Detail	16		1	2	3	1	3	3	3	3	3	3	3	3		
		Detail	21		1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3		
		Detail	28		1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3		
		Detail	35		1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3		
		Detail	42		1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3		
		Summary		21/11/91(*)	42	1	2	3	2	3	1	3	2	3	3	3	3	3	3	3	Y	
		Detail	9	07/10/91(c)		0	2														NO	
		Summary		21/11/91(*)	9	0	2														NO	
		Detail	7	14/10/91		1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	
		Summary		14/10/91	7	1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	
8	Imipramine	29/10/91	31/10/91	30/10/91	CHEST PAIN	Detail	7		2	2	4	1	3	3	3	3	3	3	3	1		
		Summary		31/10/91	7	2	2	4	1	3	3	3	3	3	3	3	3	3	3	1		
		Detail	7	01/11/91		1	2	3	3	3	3	3	3	3	3	3	3	3	3	3	1	
		Summary		01/11/91	7	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3	1	

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
 Study drug: 1=on change, 2=dose reduced, 3=drug withdrawn, 4=temp. inter., 5=permanent
 Hospital: 1=required, 2=not req., 3=not appl.
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl.
 Somp app.: 1=not appl., 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
 (b) onset date missing; start treatment date of report visit

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PHARMACIA CNS RBD
 REMOETIME - PROTOCOL 20126/017
 Listing No.: 17.0
 ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Adverse event	Types	No data	Last report visit	See rity	Hist	Rel	Stud	Symb	Dis	Ra	Dat	Still	
			Start date	End date															
1	6	Imipramine	29/10/91	31/10/91	30/10/91	HEADACHE	Detail	7	01/11/91	7	2	2	3	3	3	2	3	1	Y
							Summary		01/11/91	7	2	2	3	3	3	2	3	1	Y
							Detail	7	01/11/91	7	2	2	3	3	3	2	3	1	Y
							Summary		01/11/91	7	2	2	3	3	3	2	3	1	Y
							Detail	7	01/11/91	7	1	2	3	3	3	2	3	1	Y
							Summary		01/11/91	7	1	2	3	3	3	2	3	1	Y
							Detail	7	01/11/91	7	1	2	3	3	3	2	3	1	Y
							Summary		01/11/91	7	1	2	3	3	3	2	3	1	Y
							Detail	7	01/11/91	7	1	2	3	3	3	2	3	1	Y
							Summary		01/11/91	7	1	2	3	3	3	2	3	1	Y
							Detail	7	01/11/91	7	1	2	3	3	3	2	3	1	Y
							Summary		01/11/91	7	1	2	3	3	3	2	3	1	Y
9	Imipramine	06/11/91	19/12/91	19/12/91	CONSTIPATION	Detail	7		7	2	2	3	1	3	3	3	3		
						Detail	14		2	1	3	1	3	3	3	3			
						Detail	21		1	2	3	1	3	3	3	3			
						Detail	28		1	2	3	1	3	3	3	3			
						Detail	35		1	2	3	1	3	3	3	3			
						Detail	42		1	2	3	1	3	3	3	3			
						Summary		19/12/91(*)	42	2	1	3	1	3	3	3	3	3	Y
						Detail	35	09/12/91	35	3	1	6	1	3	3	3	3	1	Y
						Summary		09/12/91	35	3	1	6	1	3	3	3	3	1	Y
						Detail	0		2	1	6	1	3	3	3	3	3		
						Detail	7		2	1	6	1	3	3	3	3	3		

Severely: 0=unknown, 1=mild, 2=moderate, 3=severe,
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. h/chr.
 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
 (*) adverse event used for statistical analysis
 (1) 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 CNS R0D

REBOXETINE - PROTOCOL 20184/017
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	List report	Sae r1cy	Hist dry	Med app.	Rel. Dis	Stad	Sym	Hesp	App.	Comp	Present	(c)			
			Start date	End date																		
1	9	Imipramine	05/11/91	19/12/91	SWEATING INCREASED	Detail	14	1	1	1	6	1	5	3	3	3	3	3				
			Detail	21		1	1	6	1	5	3	3	3									
			Detail	28		1	1	6	1	5	3	3	3									
			Detail	35		1	1	6	1	5	3	3	3									
			Detail	42		1	1	6	1	5	3	3	3									
			05/11/91(8)	19/12/91(8)	Summary	42	2	1	4	1	5	3	3	3	3	3	3	3	NO			
10	10	Imipramine	15/11/91	30/12/91	INSOMNIA	Detail	0															
			Summary	30/12/91(8)		0	3	1	3	1	YES	3	3	3	3	3	3	3	3	3	NO	
			Detail	21		2	1	4	1	YES	3	3	3	3	3	3	3	3	3	3		
			Detail	28		1	1	4	1	YES	3	3	3	3	3	3	3	3	3	3		
			Detail	35		1	1	4	1	YES	3	3	3	3	3	3	3	3	3	3	3	Y
			30/12/91(8)	Summary	42	3	1	3	1	YES	3	3	3	3	3	3	3	3	3	Y		
			22/11/91		MOUTH DRY	Detail	7	3	2	2	1	3	3	3	3	3	3	3	3			
			Detail	14		1	2	3	1	3	3	3	3	3	3	3	3	3	3			
			Detail	21		2	2	3	1	3	3	3	3	3	3	3	3	3	3			
			Detail	28		1	2	3	1	3	3	3	3	3	3	3	3	3	3	3		
			Detail	35		20/12/91	1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	
			20/12/91	Summary	35	3	2	2	1	3	3	3	3	3	3	3	3	3	3	1		
			27/11/91		SOMNOLENCE	Detail	14	1	2	3	1	3	3	3	3	3	3	3	3			
			Detail	21		09/12/91	1	2	3	1	3	3	3	3	3	3	3	3	3	3		
			Detail	28		09/12/91	21	1	2	3	1	3	3	3	3	3	3	3	3	3	3	1
			Detail	35																		
			Summary																			
			23/11/91		TINNITUS	Detail	7	2	2	3	1	3	3	3	3	3	3	3	3			
			Detail	14		29/11/91	14	2	2	3	1	3	3	3	3	3	3	3	3	3		
			Detail	21		29/11/91	14	2	2	3	1	3	3	3	3	3	3	3	3	3	1	
			Detail	28																		
			Detail	35		22/12/91	1	2	4	1	3	3	3	3	3	3	3	3	3	3	3	3
			22/12/91	Summary	35	1	2	4	1	3	3	3	3	3	3	3	3	3	3	1		
			10/04/92	03/05/92	AGITATION	Detail	7	12/04/92	2	2	3	1	YES	3	3	3	3	3	3	3	3	
			Detail	14		12/04/92	7	2	2	3	1	YES	3	3	3	3	3	3	3	3	3	1
			Detail	21																		
			Detail	28																		
			Detail	35																		

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawal, 4=stop.
 Hospital: 1=required, 2=not req., 3=not app.
 Disapp./Resp.: 1=no, 2=yes, 3=not app.
 Outcome: 1=recovered, 2=rec. with seq., 3=kill present, 4=death
 Symptomatic treatment: 1=no, 2=yes
 (c) adverse event used for statistical analysis
 (r) adverse event still present: end date = visit date
 (8) onset data missing: first report visit date used
 (18) onset data missing: start treatment date of report visit

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PHARMACIA CNS 98D
REBOXETINE - PROTOCOL 20124/017
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	Sere	Hst	Rel	Std	Sym	Dis	Re	Out	Still			
			Start date	End date																		
1	11	Reboxetine	84/06/92	05/05/92	AGITATION	Detail	14			21	2	2	4	1	YES	3	3	3	3			
						Detail	21	24/04/92			2	2	4	1	YES	3	3	3	3	1		
						Summary	25/04/92				21	2	2	4	1	YES	3	3	3	3	1	YES
12	Reboxetine	15/06/92	05/05/92	INSOMNIA	Detail	7				21	2	1	4	1	YES	3	3	3	3			
					Detail	16				2	1	4	1	YES	3	3	3	3	3	3	Y	
					Detail	21				1	1	4	1	YES	3	3	3	3	3	3	Y	
					Summary	05/05/92(*)			21	2	1	4	1	YES	3	3	3	3	Y	NO		
2	35	Reboxetine	19/12/98	29/01/91	ECG ABNORMAL	Detail	7				42	1	2	3	1	3	3	3	3	3		
						Detail	14				1	2	3	1	3	3	3	3	3	3	3	Y
						Detail	21				1	2	3	1	3	3	3	3	3	3	3	Y
					Summary	05/05/92(*)			21	1	2	3	1	3	3	3	3	3	Y	YES		
					Summary	17/04/92			42	1	2	3	1	3	3	3	3	3	3	Y	YES	
2	35	Reboxetine	19/12/98	29/01/91	ECG ABNORMAL	Detail	7				42	1	2	3	1	3	3	3	3	3		
						Detail	14				1	2	3	1	3	3	3	3	3	3	3	Y
						Detail	21				1	2	3	1	3	3	3	3	3	3	3	Y
					Summary	05/05/92(*)			21	1	2	3	1	3	3	3	3	3	Y	YES		
					Summary	17/04/92			42	1	2	3	1	3	3	3	3	3	3	Y	YES	
2	35	Reboxetine	19/12/98	29/01/91	ECG ABNORMAL	Detail	0				42	2	1	6	1	3	3	3	3	1		
						Detail	42	29/01/91			42	2	1	6	1	3	3	3	3	3	1	NO
						Summary	29/01/91			42	2	1	6	1	3	3	3	3	3	3	1	NO
					Summary	17/12/98(D)																
2	35	Reboxetine	19/12/98	29/01/91	ECG ABNORMAL	Detail	7				7	2	2	1	1	3	3	3	1			
						Detail	25/12/90				7	2	2	1	1	3	3	3	1	YES		
						Summary	25/12/90				7	2	2	1	1	3	3	3	1	YES		
					Summary	25/12/90																
2	35	Reboxetine	19/12/98	29/01/91	ECG ABNORMAL	Detail	7				7	2	2	1	1	3	3	3	1			
						Detail	25/12/90				7	2	2	1	1	3	3	3	1	YES		
						Summary	25/12/90				7	2	2	1	1	3	3	3	1	YES		
					Summary	25/12/90																
2	35	Reboxetine	19/12/98	29/01/91	ECG ABNORMAL	Detail	7				7	2	2	1	1	3	3	3	1			
						Detail	25/12/90				7	2	2	1	1	3	3	3	1	YES		
						Summary	25/12/90				7	2	2	1	1	3	3	3	1	YES		
					Summary	25/12/90																
2	35	Reboxetine	19/12/98	29/01/91	ECG ABNORMAL	Detail	7				7	2	2	1	1	3	3	3	1			
						Detail	25/12/90				7	2	2	1	1	3	3	3	1	YES		
						Summary	25/12/90				7	2	2	1	1	3	3	3	1	YES		
					Summary	25/12/90																
2	35	Reboxetine	19/12/98	29/01/91	ECG ABNORMAL	Detail	7				7	2	2	1	1	3	3	3	1			
						Detail	25/12/90				7	2	2	1	1	3	3	3	1	YES		
						Summary	25/12/90				7	2	2	1	1	3	3	3	1	YES		
					Summary	25/12/90																
2	35	Reboxetine	19/12/98	29/01/91	ECG ABNORMAL	Detail	7				7	2	2	1	1	3	3	3	1			
						Detail	25/12/90				7	2	2	1	1	3	3	3	1	YES		
						Summary	25/12/90				7	2	2	1	1	3	3	3	1	YES		
					Summary	25/12/90																
2	35	Reboxetine	19/12/98	29/01/91	ECG ABNORMAL	Detail	7				7	2	2	1	1	3	3	3	1			
						Detail	25/12/90				7	2	2	1	1	3	3	3	1	YES		
						Summary	25/12/90				7	2	2	1	1	3	3	3	1	YES		
					Summary	25/12/90																

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./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
 (w) 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

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PHARMACIA CNS R&D
REBORNETINE - PROTOCOL 20126/917
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	Sv	Rt	St	Dis	Re	O	C	Still	Sympt	Trea	Hosp	app.	case	present	(c)	
																										25/12/98
2	54	Imipramine	25/12/98	02/01/91	ACCOMMODATION ABNORMAL	25/12/98	Summary	02/01/91	7	1	2	3	1	3	3	3	1	YES								
					BACK PAIN	31/12/98	Detail	31/12/98	7	3	1	6	1	YES	3	3	3	1	YES							
						02/02/91	Summary	02/02/91	7	2	1	6	1	YES	3	3	3	1	YES							
						02/02/91	Detail	02/02/91	42	3	1	6	3	YES	3	2	3	1	YES							
						02/02/91	Summary	02/02/91	42	3	1	6	3	YES	3	2	3	1	YES							
					DIZZINESS	31/12/98	Detail	31/12/98	7	2	3	1	3	3	3	3	1	YES								
						02/01/91	Summary	02/01/91	7	1	2	3	1	3	3	3	1	YES								
						09/01/91	Detail	16/01/91	14	2	2	3	1	3	3	3	1	YES								
						10/01/91	Summary	10/01/91	14	2	2	3	1	3	3	3	1	YES								
					HEADACHE	31/12/98	Detail	31/12/98	7	2	1	6	1	YES	3	3	3	1	YES							
						31/12/98	Summary	31/12/98	7	2	1	6	1	YES	3	3	3	1	YES							
						26/01/91	Detail	31/01/91	35	1	2	2	1	3	3	3	1	YES								
						02/02/91	Summary	02/02/91	42	2	1	6	3	2	5	2	5	1	YES							
						02/02/91	Detail	02/02/91	42	2	1	6	3	2	5	2	5	1	YES							
						02/02/91	Summary	02/02/91	42	2	1	6	3	2	5	2	5	1	YES							
					HYPOTENSION	31/12/98	Detail	02/01/91	7	2	2	1	1	3	3	3	1	YES								
						02/01/91	Summary	02/01/91	7	2	2	1	1	3	3	3	1	YES								
						09/01/91	Detail	10/01/91	14	2	2	5	1	3	3	3	1	YES								
						10/01/91	Summary	10/01/91	14	2	2	5	1	3	3	3	1	YES								
					MOUTH DRY	28/12/98	Detail	7	2	2	1	1	3	3	3	3	1	YES								
						28/12/98	Detail	7	2	2	1	1	3	3	3	3	1	YES								
						28/12/98	Summary	28/12/98	7	2	2	1	1	3	3	3	1	YES								
						02/01/91	Detail	14	2	2	2	1	1	3	3	3	1	YES								
						02/01/91	Summary	02/01/91	21	2	2	1	1	3	3	3	1	YES								
					PARAESTHESIA	31/12/98	Detail	02/01/91	7	1	2	6	1	3	3	3	1	YES								
						31/12/98	Summary	02/01/91	7	1	2	6	1	3	3	3	1	YES								
					SOMNOLENCE	26/01/91	Detail	30/01/91	35	2	2	2	1	3	3	3	1	YES								
						26/01/91	Summary	30/01/91	35	2	2	2	1	3	3	3	1	YES								

Severity: 1=unknown, 2=mild, 3=moderate, 4=severe, 5=life threatening, 6=death
 Study drug: 1=no change, 2=dose reduced, 3=stop, 4=intermittent, 5=stop, 6=withdrawn, 7=intermittent
 Hospital: 1=required, 2=not req, 3=not app. -- Outcome: 1=recovered, 2=rec. with set, 3=still present, 4=death
 Disapp./Reapp.: 1=no, 2=yes, 3=not app. -- Relationships: 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
 (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 DIS RSD

REBOXETINE - PROTOCOL 20124/017
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Adverse event	Dnsst date	Type record	Visit No	End date	Last report visit	Save rity	Hist dry	Rel shld	Stud Symp	Dis app.	Re come	Out Still											
			Start date	End date																									
2	34	Isipramine	25/12/90	05/02/91	VISION ABNORMAL	25/12/90	Detail	7	14	05/01/91	14	1	2	2	1	3	3	3	3										
																				Detail	7	1	2	2	1	3	3	3	1
																				Summary	14	1	2	2	1	3	3	3	1
35	Reboxetine	25/12/90	07/02/91	ECG ABNORMAL	07/02/91	Detail	42	07/02/91	42	1	2	4	1	3	3	3	3	3	3										
																				Summary	42	1	2	4	1	3	3	3	3
																				Summary	42	1	2	4	1	3	3	3	3
36	Isipramine	15/01/91	31/01/91	CONSTIPATION	15/01/91	Detail	7	14	22/01/91	14	2	2	1	1	3	3	3	3	3										
																				Detail	7	2	2	1	1	3	3	3	3
																				Summary	14	2	2	1	1	3	3	3	1
37	Reboxetine	16/01/91	26/02/91	HEADACHE	16/01/91	Detail	0	31/01/91	0	31/01/91	0	1	1	1	3	3	3	3	3										
																				Summary	0	31/01/91	0	1	1	3	3	3	3
																				Summary	0	31/01/91	0	1	1	3	3	3	3

INSOMNIA
 HALLUCINATION
 MOUTH DRY
 TACHYCARDIA

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Severely: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening
 Study drug: 1=none change, 2=dose reduced, 3=stop, 4=withdrewn, 5=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
 (D) onset date missing; first report visit date used

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PHARMACIA CNS RD
REBOXETINE - PROTOCOL 20124/017
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Onset date	End date	Adverse event	Type record	Visit No	Last report visit	Sav	R1	Stu	Sym	Dis	Re	Out	Still	Last report visit				
																	visit	city			
2	37	Reboxetine	18/01/91	28/02/91	INSOMNIA	Detail	0														
						Detail	21	07/02/91	1	2	3	1	3	3	3	1					
						Summary		07/02/91	21	1	2	3	1	3	3	3	1				
38	Imipramine	25/01/91	07/03/91	HYPERCHOLESTEROLEMIA	Detail	42															
					Summary		07/03/91 (*)	42	2	1	3	1	3	3	3	3	Y				
					Detail	21	14/02/91	1	2	5	1	3	3	3	1						
40	Imipramine	20/02/91	02/06/91	INSOMNIA	Detail	0															
					Detail	14	02/02/91	2	2	5	1	YES	3	3	3	1					
					Summary		03/02/91	14	2	2	5	1	YES	3	3	3	1				
41	Reboxetine	05/02/91	18/05/91	ABDOMINAL PAIN	Detail	35															
					Detail	21	02/02/91	2	2	2	1	1	YES	3	3	3	Y				
					Summary		02/02/91 (*)	20	2	2	1	1	YES	3	3	3	Y				
41	Reboxetine	05/02/91	18/05/91	ABDOMINAL PAIN	Detail	35															
					Detail	42	18/03/91 (*)	2	2	6	1	YES	3	3	3	3	Y				
					Summary		18/03/91 (*)	42	2	2	6	1	YES	3	3	3	Y				
41	Reboxetine	05/02/91	18/05/91	HEADACHE	Detail	7															
					Detail	14	07/02/91	3	1	3	1	YES	2	3	3	3					
					Detail	21	07/02/91	3	1	3	1	YES	3	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: and date = visit date
(*) onset date missing: first report visit date used

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PHARMACIA CNS RBD

REBORETTINE - PROTOCOL 28124/917
Listing No.: 17.8

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 dry	Hist dry	Rel. Stude	Symp	Dis app.	Re app.	Det	Still								
2	41	Reborettine	06/02/91 - 16/02/91	16/02/91	16/02/91	HEADACHE	07/02/91	Detail	35	42	2	1	0	1	YES	3	3	3	3							
								Detail	42	18/02/91(*)	42	3	1	3	1	YES	2	3	5	3	Y	YES				
								Summary																		
								Detail	7		1	2	3	1	2	3	1	2	3	3	3	3	3	3	3	
								Detail	14		1	2	5	1	5	3	3	3	3	3	3	3	3	3	3	
								Detail	21		1	2	5	1	5	3	3	3	3	3	3	3	3	3	3	
								Detail	28		1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	
								Detail	35		1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	
								Detail	42		1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	
								Summary			35	1	2	3	1	2	3	3	3	3	3	3	3	3	3	
																										YES
							62	Insipiramine	09/02/91 - 22/03/91	22/03/91	18/03/91	18/03/91	TACHYCARDIA	05/02/91	Detail	7	42	1	2	3	1	3	3	3	3	3
	Detail	14		1	2	3								1	3	3	3	3	3	3	3	3	3			
	Detail	21		1	2	3								1	3	3	3	3	3	3	3	3	3	3		
	Detail	28		1	2	3								1	3	3	3	3	3	3	3	3	3	3		
	Detail	35		1	2	3								1	3	3	3	3	3	3	3	3	3	3	3	
	Detail	42		1	2	3								1	3	3	3	3	3	3	3	3	3	3	3	
	Summary			42	1	2								3	1	3	3	3	3	3	3	3	3	3	3	
	Detail	42		18/03/91(*)	42	1								2	3	1	3	3	3	3	3	3	3	3	3	
	Summary																									YES
62	Insipiramine	09/02/91 - 22/03/91	22/03/91	18/03/91	18/03/91	TACHYCARDIA								02/03/91	Detail	28	28	2	2	4	1	3	3	3	3	3
								Summary			28	2	2	4	1	3	3	3	3	3	3	3	3			
								Detail	7		13/02/91	7	1	2	3	1	3	3	3	3	3	3	3	3		
								Summary			13/02/91														YES	
								Detail	14		22/02/91	14	1	2	2	1	3	3	3	3	3	3	3	3	3	
								Detail	21		1	2	2	1	3	3	3	3	3	3	3	3	3	3	3	
								Detail	28		1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	
								Detail	35		15/02/91	35	1	2	1	1	3	3	3	3	3	3	3	3	3	
								Detail	42		15/02/91	42	1	2	1	1	3	3	3	3	3	3	3	3	3	
								Summary																		YES
							62	Insipiramine	09/02/91 - 22/03/91	22/03/91	18/03/91	18/03/91	TACHYCARDIA	01/02/91	Detail	21	21	2	2	2	1	3	3	3	3	3
	Summary			21	2	2								2	1	3	3	3	3	3	3	3	3			

Severity: 1=unknown, 2=mild, 3=moderate, 4=severe, 5=life threatening
 Study drug: 1=none, 2=decreased, 3=stopped, 4=withdrewn, 5=other
 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 still present; end date = visit date
 (*) onset date missing; first report visit date used
 -- History: 1=present 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

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PHARMACIA CNS RBD

REBOXETINE - PROTOCOL 20124/017
Listing No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit record	Last report visit	Save Hist	Rel ship	Re Stud	Dis app.	Re Out	Still present (C)				
2	45	Reboxetine	26/03/91	06/05/91	INSOMNIA		25/03/91	Detail	7	2	1	6	1	YES	5	3	3			
								Detail	14	2	1	6	1	YES	3	5	3	3		
								Detail	21	2	1	6	1	YES	3	3	3	3		
								Detail	28	2	1	6	1	YES	3	3	3	1		
								Summary	27/04/91	28	2	1	6	1	YES	3	3	3	1	
								Detail	7	1	2	3	1	3	3	3	1			
								Detail	14	1	2	3	1	3	3	3	1			
								Summary	05/04/91	14	1	2	3	1	3	3	1			
								Detail	7	5	2	4	3	3	3	3	3			
								Summary	11/06/91(*)	7	5	2	4	3	3	3	3			
44		Imipramine	11/04/91	11/04/91	DELUSION		11/04/91	Detail	7	2	1	3	1	3	3	3				
								Detail	14	1	2	3	1	3	3	3	1			
								Summary	05/04/91	14	1	2	3	1	3	3	3	1		
								Summary	11/06/91(*)	7	5	2	4	3	3	3	3	3		
45		Imipramine	30/04/91	03/05/91	SOMNOLENCE		06/04/91	Detail	7	2	1	3	1	YES	3	3	1			
								Detail	14	2	1	3	1	YES	3	3	3	1		
								Summary	11/06/91	7	2	1	3	1	YES	3	3	3	1	
								Summary	03/05/91(*)	7	3	2	1	3	3	1	3	3	Y	
46		Reboxetine	16/05/91	26/06/91	INSOMNIA		16/05/91	Detail	7	2	2	3	1	YES	3	3	3			
								Detail	14	2	2	3	1	YES	3	3	3	3		
								Detail	21	2	2	3	1	YES	3	3	3	3		
								Detail	28	2	2	1	1	YES	3	3	3	3		
								Detail	35	2	2	3	1	YES	3	3	3	3		
								Detail	42	2	2	1	1	YES	3	3	3	3	Y	
								Summary	26/06/91(*)	42	3	2	1	1	YES	3	3	3	3	Y
								Detail	7	3	2	1	1	3	3	3	1			
								Summary	27/05/91	7	3	2	1	1	3	3	3	1		
								46		TACHYCARDIA					16/05/91	Detail	42	2	2	1
Summary	16/05/91	42	2	2	1	3	2									3	1			

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=rec. with seq., 3=still present, 4=not reach
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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PHARMACIA CMS RBD

REBOWETINE - PROTOCOL 20124/017
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Onset date	End date	Adverse event	Type record	Visit No	Last report visit	Save	Hist	Rel	Stud	Symp	Dis	Re	Out	Still		
2	66	Rebowetina	16/05/91	26/06/91	TACHYCARDIA	Summary	26/06/91	42	1	2	2	1	3	2	3	1	YES		
47		Rebowetina	22/05/91	02/07/91	INSOMNIA	Detail Summary	0 7 27/05/91 27/05/91	2 3 1 3 1 1	3	1	3	1	YES	3	3	3	1	YES	
			29/05/91			Detail Detail Detail Detail Detail Summary	16 21 25 35 42	7 3 2 1 1 1 2 2 5 1 2 2 3 1	3	2	3	1	YES	3	3	3	3	3	3
			22/05/91		NERVOUSNESS	Detail Summary	7 20/05/91 20/05/91	2 2 2 3 1	3	2	3	1	3	3	3	3	1	YES	
48		Imipramine	27/06/91	07/10/91	ENTRASYSTOLES	Detail Summary	42	42	1	2	3	1	3	3	3	3	3	YES	
			16/09/91		GAMMA-GT INCREASED	Detail Summary	21	21 2 1 5 1	2	1	3	1	3	3	3	3	3	YES	
			16/09/91		HYPERURICAEHIA	Detail Summary	21 07/10/91	21 2 2 3 1	2	2	3	1	3	3	3	3	3	YES	
			25/06/91		INSOMNIA	Detail Detail Summary	0 7 02/08/91 02/08/91	2 1 1 6 1	2	1	6	1	YES	3	3	3	1	NO	
			16/09/91		TACHYCARDIA	Detail Summary Detail Summary	21 16/09/91 16/09/91 42 07/10/91	21 2 1 4 1 2 1 2 3 1 42 1 2 3 1	2 2 42	2	1	4	1	3	3	3	3	1	YES

Severity: 0=unknown, 1= mild, 2= moderate, 3= severe, 4= life threatening
 Study drug: 1= no change, 2= dose reduced, 3= dose withdrawn, 4= temp. inter.
 Hospital: 1= required, 2= not req., 3= not appl. -- Outcome: 1= recovered, 2= rec. with seq., 3= still present, 4= search
 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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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20126/017
 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	Sere city	Hist app.	Rel. drug	Stud. app.	Sympt. app.	Dis. app.	Re. app.	Out. app.	Still. app.																																																																																																																	
																				09/10/91	09/10/91	09/10/91	09/10/91	09/10/91	09/10/91	09/10/91	09/10/91	09/10/91	09/10/91	09/10/91	09/10/91	09/10/91	09/10/91	09/10/91	09/10/91	09/10/91																																																																																																
2	49	Imipramine	29/08/91	09/10/91	AGITATION	26/09/91	Detail	35	02/10/91	35	02/10/91	2	2	1	1	3	3	3	1	YES																																																																																																																
																					Summary	35	2	2	1	1	3	3	1	YES																																																																																																						
																															28/09/91	Detail	28	25/09/91	28	2	2	1	1	3	3	3	1	YES																																																																																								
																																													Summary	28	2	2	1	1	3	3	1	YES																																																																														
																																																							09/10/91	Detail	0	09/10/91	0	2	1	6	1	YES	3	3	3	NO																																																																
																																																																					Summary	7	1	6	1	YES	3	3	1	NO																																																						
																																																																															27/08/91	Detail	16	08/09/91	16	2	2	1	6	1	YES	3	3	3	NO																																							
																																																																																														Summary	16	2	2	1	6	1	YES	3	3	3	NO																											
																																																																																																										20/09/91	Detail	28	08/09/91	28	2	2	1	6	1	YES	3	3	3	NO												
																																																																																																																									Summary	28	2	2	1	6	1	YES	3	3	3	NO
Summary	42	2	2	1	1	YES	3	3	3	3	Y																																																																																																																									
												12/09/91	Detail	21	18/09/91	21	1	2	2	1	3	3	3	1	YES																																																																																																											
																										Summary	21	1	2	2	1	3	3	1	YES																																																																																																	
																																				11/09/91	Detail	14	11/09/91	14	2	2	3	1	3	3	3	1	YES																																																																																			
																																																		Summary	14	2	2	3	1	3	3	1	YES																																																																									
																																																												15/12/91	Detail	21	17/12/91	21	2	3	1	3	3	3	3	Y																																																												
																																																																									Summary	21	2	3	1	3	3	3	Y																																																			
																																																																																		31/10/91	Detail	6	31/10/91	6	2	1	3	1	YES	3	3	3																																						
																																																																																															Summary	6	2	1	3	1	YES	3	3	3																												
																																																																																																									15/12/91	Detail	14	15/12/91	14	2	2	1	YES	3	3	3	3															
																																																																																																																						Summary	14	2	2	1	YES	3	3	3	3					
26/11/91	Detail	28	26/11/91	28	2	2	1	YES	3	3	3																																																																																																																					3				
												Summary	28	2	2	1	YES	3	3	3	3																																																																																																															
																						09/10/91	Detail	35	09/10/91	35	2	2	1	YES	3	3	3	3																																																																																																		
																																			Summary	35	2	2	1	YES	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=stop, 4=stop, 5=continue, 6=stop, 7=withdrawn, 8=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
 IC: adverse event used for statistical analysis
 (a) adverse event still present: end date = visit date
 (b) onset date missing: first report visit date used
 (c) onset date missing: start treatment date of report visit

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/017
 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 rty	Hist dry	Rel ship	Stud drug	Symp app.	Dis Hosp	Re app.	Re come	Dis Still			
																			Summary	Detail	Summary
2	50	Reboxetine	06/11/91	15/12/91	INSOMNIA	31/10/91	Summary	10/12/91(*)	35	5	1	2	1	YES	3	3	3	3	5	YES	
			15/12/91		SUICIDE ATTEMPT	15/12/91	Detail	42	15/12/91	42	3	6	1	3	3	3	3	3	4	YES	
			10/11/91		SWEATING INCREASED	10/11/91	Detail	7		1	2	3	1	3	3	3	3	3	3	3	YES
			14	18/11/91		14	1	2	3	1	3	3	3	1	3	3	3	3	1	YES	
			18/11/91			18/11/91	Summary	14		1	2	3	1	3	3	3	3	3	1	YES	
			18/12/91		TACHYCARDIA	18/12/91	Detail	35	10/12/91	35	1	2	3	1	3	3	3	3	1	YES	
			10/12/91			10/12/91	Summary	35		1	2	3	1	3	3	3	3	1	YES		
			06/11/91	17/11/91	CONSTIPATION	06/11/91	Detail	7	12/11/91	7	2	2	3	1	3	3	3	3	1	YES	
			12/11/91			12/11/91	Summary	7		2	2	3	1	3	3	3	3	1	YES		
			18/11/91		DELUSION	18/11/91	Detail	14		19/11/91(*)	14	3	2	2	3	3	3	3	3	3	YES
51	Reboxetine	INSOMNIA	30/10/91			30/10/91	Detail	6		2											
			7			7		2	1	3	1	YES	3	3	3	3	3	3	3	3	
			14			14		3	2	2	1	YES	3	3	3	3	3	3	3	3	
			19/11/91(*)			19/11/91(*)	Summary	14		3	1	2	1	YES	3	3	3	3	3	3	3
			27/11/91	07/01/92	ACCOMMODATION ABNORMAL	27/11/91	Detail	7		1	2	2	1	3	3	3	3	3	3	3	3
			14	18/12/91		14	1	2	2	1	3	3	3	1	3	3	3	3	1	YES	
			27/11/91		INSOMNIA	27/11/91	Detail	7		1	2	3	1	YES	3	3	3	3	3	3	3
			14			14	1	2	2	1	YES	3	3	3	3	3	3	3	3	3	
			21			21	1	2	1	YES	3	3	3	3	3	3	3	3	3	3	
			28			28	1	2	1	YES	3	3	3	3	3	3	3	3	3	3	
35	30/12/91		35	1	2	1	YES	3	3	3	3	3	3	3	3	3	3	3			
30/12/91			30/12/91	Summary	35		1	2	2	1	YES	3	3	3	3	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. withdrawal, 4=temp. intr.
 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: and date = visit date
 (D) onset date missing: first report visit date used

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PHARMACIA CNS RED
 REMOXTINE - PROTOCOL 20124/917
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment		Onset date	Type record	Visit No	Last report	Saw	Hist	Rel	Stud	Somp	Dis	Re	Duc	Still		
		Start date	End date														city	drug
2	Jalspramlone	27/11/91	07/01/92	27/11/91	Detail	7	30/11/91	1	2	2	1	3	3	3	1	YES		
					Summary	30/11/91	7	1	2	2	1	3	3	3	1	YES		
					Detail	28	23/12/91	28	1	2	6	1	3	3	3	1	YES	
					Summary	23/12/91	28	1	2	6	1	3	3	3	3	1	YES	
					Detail	14	03/12/91	14	1	2	2	1	3	3	3	3	3	3
					Detail	21		21	1	2	1	3	3	3	3	3	3	
					Detail	26		26	1	2	1	3	3	3	3	3	3	
					Detail	35		31/12/91	35	1	2	1	3	3	3	3	3	
					Summary	31/12/91		35	1	2	2	1	3	3	3	3	3	
					Detail	7		05/06/91	7	1	2	5	1	3	3	3	3	3
		Detail	14	14	1	2			4	1	3	3	3	3	1			
		Summary	11/06/91	14	2	2			3	1	3	3	3	3	1			
		Detail	35	01/05/91	35	1			1	4	1	3	3	3	3	3		
		Detail	42		42	1			1	4	1	3	3	3	3	1		
		Summary	18/05/91		42	1	1		4	1	3	3	3	3	1			
		Detail	21		15/04/91	21	3		1	3	1	3	3	3	3	3		
		Detail	28			28	2		1	2	1	YES	3	3	3	3		
		Detail	35			05/05/91	35		3	1	2	1	YES	3	3	3	1	
		Summary	05/05/91			35	3		1	2	1	YES	3	3	3	1		
		Detail	42			09/05/91	42	2	1	2	1	YES	3	3	3	3		
		Summary	13/05/91(4)				42	2	1	2	1	YES	3	3	3	3		
		Detail	0				27/02/91(2)	0	2									NO
		Summary	12/05/91(4)	0				2										NO
		Detail	42	13/05/91				42	1	2	2	1	3	3	3	3	3	3
		Summary	13/05/91(4)					42	1	2	2	1	3	3	3	3	3	3

SAVERBY: 0=unknown, 1=mild, 2=moderate, 3=severe,
 Study drug: 1=none change, 2=dose reduced, 3=stop, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Dissep./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
 (f) onset date missing: first report visit date used

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PHARMACIA CNS RED
 RENOMETINE - PROTOCOL 20124/017
 Listing No.: 17.0
 ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment		Onset date	Type record	Visit No	End date	Last report visit	Save visit	Hist ory	Rel ship	Rel Stud	Symp	Dis app.	Re case	Out still							
		Start date	End date																				
5	Raboxetina	02/04/91	13/05/91	13/05/91	SWEATING INCREASED	7			2	2	3	1		5	3	3							
						14			2	2	3	1	5	3	3								
						21			2	1	3	1	5	3	3								
						28			2	2	4	1	5	3	3								
						35			2	2	3	1	5	3	3								
						42			2	2	2	1	5	3	3								
						Summary			13/05/91(*)	42	2	1	2	1	3	3	3	3	3	3	Y	YES	
						Detail			14/15/04/91	1	1	3	1	3	3	3	3	3	3	3	1		
						Detail			21	1	1	3	1	3	3	3	3	3	3	3	3		
						Detail			28	1	1	3	1	3	3	3	3	3	3	3	3		
						Detail			35	2	1	3	1	YES	3	3	3	3	3	3	3		
						Detail			42	2	1	4	1	3	3	3	3	3	3	3	3	Y	
						Summary			13/05/91(*)	42	2	1	5	1	YES	3	3	3	3	3	3	Y	YES
						Detail			15/06/91	TACHYCARDIA				1	1	3	1		3	3	3	1	
Detail			21					1	1	3	1		3	3	3	3							
Detail			28					1	1	3	1		3	3	3	3							
Detail			35					2	1	3	1	YES	3	3	3	3							
Detail			42					2	1	4	1	3	3	3	3	3	Y						
Summary			13/05/91(*)					42	2	1	5	1	YES	3	3	3	Y	YES					
Detail			27/02/91(*)	VISION ABNORMAL				1	1	6	1		3	3	3	1							
Detail			05/04/91					1	1	6	1		3	3	3	1							
Summary			05/04/91					7	1	6	1		3	3	3	1							
Detail			02/08/91					3	2	4	1	YES	3	3	3	1							
Summary			06/08/91					35	3	2	4	1	YES	3	3	3	1	YES					
Detail			01/04/91					1	1	2	1		3	3	3	3							
Detail			14/11/05/91					1	1	2	1		3	3	3	3							
Summary			11/05/91					14	2	1	2	1	3	3	3	1							
Detail			05/06/91(*)					0	1	1	1		3	3	3	1							
Detail			18/05/91					1	2	3	1		3	3	3	3							
Detail			28					1	2	2	1		3	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=stop, 4=withdrawn, 5=temp. increase
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Kospp.: 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 of report visit

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PHARMACIA DNS RBD

REBOVETINE - PROTOCOL 20126/017
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Start date	End date	Treatment	Onset date	Type of record	Visit No	Last report visit	SASP	Hosp	Recep	Disapp	Recep	Disapp	Still present (c)								
																	Adverse event	Adverse event	Adverse event	Adverse event	Adverse event	Adverse event	Adverse event	Adverse event
3	66	Imipramine	05/05/91	05/06/91	MOUTH DRY	18/05/91	Detail	35	05/06/91(*)	35	1	2	3	1	3	3	3	Y						
							Summary																	
						07/05/91	Detail	7	07/05/91	7	1	2	3	1	3	3	3	3	3	3	3	3	Y	
							Summary																	
						22/05/91	Detail	28	21/05/91	28	1	2	5	1	3	3	3	3	3	3	3	3	Y	
							Summary																	
						05/06/91	Detail	35	05/06/91(*)	35	1	2	2	1	3	3	3	3	3	3	3	3	Y	
							Summary																	
						07/05/91	Detail	7	07/05/91	7	1	2	2	1	3	3	3	3	3	3	3	3	3	Y
							Summary																	
67	Rebovetine	19/04/91	21/05/91	HYPERTENSION	15/06/91	Detail	7	15/06/91	7	2	2	3	1	3	3	3	3	Y						
						Summary																		
					14/06/91	Detail	14	14/06/91	14	2	1	5	1	3	3	3	3	3	3	3	3	Y		
						Summary																		
					21/06/91	Detail	21	21/06/91	21	2	1	3	1	3	3	3	3	3	3	3	3	Y		
						Summary																		
					15/05/91	Detail	28	15/05/91	28	2	1	3	1	3	3	3	3	3	3	3	3	Y		
						Summary																		
					15/05/91	Detail	35	15/05/91	35	2	1	5	1	3	3	3	3	3	3	3	3	Y		
						Summary																		
18/05/91	Detail	42	21/05/91(*)	42	1	1	3	1	3	3	3	3	3	3	3	3	Y							
	Summary																							
67	Rebovetine	19/04/91	21/05/91	HYPERTENSION	23/05/91	Detail	42	23/05/91	42	1	2	3	1	3	3	3	3	Y						
						Summary																		
67	Rebovetine	19/04/91	21/05/91	HYPERTENSION	12/06/91	Detail	7	12/06/91	7	2	2	3	1	3	3	3	3	Y						
						Summary																		
					14/06/91	Detail	14	14/06/91	14	2	1	5	1	3	3	3	3	3	3	3	Y			
						Summary																		
					21/06/91	Detail	21	21/06/91	21	2	1	3	1	3	3	3	3	3	3	3	3	Y		
						Summary																		
67	Rebovetine	19/04/91	21/05/91	HYPERTENSION	15/05/91	Detail	28	15/05/91	28	2	1	3	1	3	3	3	3	Y						
						Summary																		
					15/05/91	Detail	35	15/05/91	35	2	1	5	1	3	3	3	3	3	3	3	Y			
						Summary																		
					21/05/91	Detail	42	21/05/91(*)	42	1	1	3	1	3	3	3	3	3	3	3	Y			
						Summary																		
67	Rebovetine	19/04/91	21/05/91	HYPERTENSION	23/05/91	Detail	42	23/05/91	42	1	2	3	1	3	3	3	3	Y						
						Summary																		
67	Rebovetine	19/04/91	21/05/91	HYPERTENSION	12/06/91	Detail	7	12/06/91	7	2	2	3	1	3	3	3	3	Y						
						Summary																		
					14/06/91	Detail	14	14/06/91	14	2	1	5	1	3	3	3	3	3	3	3	Y			
						Summary																		
					21/06/91	Detail	21	21/06/91	21	2	1	3	1	3	3	3	3	3	3	3	3	Y		
						Summary																		

Severity: 1=unknown, 2=mild, 3=moderate, 4=severe.
 Study drug: 1=none, 2=dose reduced, 3=def. withdrawal, 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
 (3) onset date missing; first report visit date used

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PHARMACIA CNS RED
REBEXETINE - PROTOCOL 20124/017
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	Sev	Hist rity	Rel drug	Stud app.	Symp	Dis app.	Re case	Out	Still present (c)								
3	67	Rebexetine	10/04/91	21/05/91		TACHYCARDIA	10/04/91	Detail	7			2	2	2	1			3	3	3	3							
					Detail	14		2	2	2	1			3	3	3	3											
					Detail	21		1	2	3	1				3	3	3	3										
					Detail	28	02/05/91		1	2	3	1	YES		3	3	3	2										
					Summary	28	02/05/91		2	2	2	1	YES		3	3	3	2						YES				
					Detail	35	12/05/91		1	2	3	1	YES		3	3	3	1							YES			
					Summary	35	12/05/91		1	2	3	1	YES		3	3	3	1							YES			
					Detail	42			1	2	3	1	YES		3	3	3	3							Y			
					Summary	42	21/05/91(*)		1	2	3	1	YES		3	3	3	3							Y			
56	Isipremine	02/08/91	15/09/91		CONSTIPATION	17/02/91	Detail	21			3	2	3	1				3	3	3	3							
				Detail	28		2	2	3	1	YES		3	3	3	3												
				Detail	35		2	2	3	1	YES		3	3	3	3												
				Detail	42		1	2	2	1	YES		3	3	3	3							Y					
				Summary	42	13/09/91(*)		3	2	2	1	YES		3	3	3	3							Y				
				Detail	21			1	2	3	1			3	3	3	1							Y				
				Summary	21	13/09/91(*)		1	2	3	1			3	3	3	1							Y				
				Detail	42			2	2	3	1			3	3	3	1							Y				
				Summary	42	13/09/91(*)		2	2	3	1			3	3	3	1							Y				
						GAMMA-GT INCREASED	23/08/91	Detail	21			1	2	3	1				3	3	3	3						
								Summary	21	13/09/91(*)		1	2	3	1			3	3	3	1						Y	
								Detail	42			2	2	3	1			3	3	3	1						Y	
								Summary	42	13/09/91(*)		2	2	3	1			3	3	3	1							Y
								Detail	42			1	2	3	1			3	3	3	1							Y
								Summary	42	13/09/91(*)		1	2	3	1			3	3	3	1							Y
								Detail	42			3	1	4	1			3	3	3	1							Y
								Summary	42	13/09/91(*)		3	1	4	1			3	3	3	1							Y
						HYPERTENSION POSTURAL	09/08/91	Detail	7			2	2	3	1				3	3	3	3						
								Detail	14		1	2	3	1			3	3	3	3								
								Detail	21		2	2	3	1			3	3	3	3								
								Detail	28	30/08/91		1	2	3	1			3	3	3	2							
								Summary	28	30/08/91		2	2	3	1			3	3	3	2							YES
								Summary	30/08/91		28	2	2	3	1			3	3	3	2							YES

Severity: 0=unknown, 1= mild, 2= moderate, 3= severe, 4= life threatening
 Study drug: lmo change, 2=dose reduced, 3= safe, 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./Resp.: 1=lmo, 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
 (*) onset date missing: first report visit date used

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PHARMACIA CNS RD
 REMOXTINE - PROTOCOL 20124/917
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Dentra Patient D-ug	3	68	Enpramine	03/08/91	13/09/91	INSOMNIA	Onset date	Treatment		Type record	Visit No	End No data	Last visit	Save Rety	Hist dry	Rel Stud Sym	Dis app.	Re Hosp	Out app.	Still some present (c)	
								Start date	End date												
							31/07/91(D)	Detail	0			0	3								NO
							31/07/91(D)	Summary	0			0	3								NO
							31/07/91(D)	Detail	0			0	2								NO
							31/07/91(D)	Summary	0			0	2								NO
							05/08/91	Detail	7			1	2	3	1	3	3	3	3	3	3
							05/08/91	Detail	14			2	2	1	3	3	3	3	3	3	3
							21/08/91	Detail	21			2	2	1	3	3	3	3	3	3	2
							20/03/91	Summary	21			2	2	2	1	3	3	3	3	2	YES
							10/02/91	Detail	0			2									NO
							24/03/91	Detail	28			1	1	6	1	YES	3	3	3	1	NO
							24/03/91	Summary	28			2	1	6	1	YES	3	3	3	1	NO
								Detail	6			2									
								Detail	7			2	1	4	1	3	3	3	3	3	
								Detail	14			1	1	4	1	3	3	3	3	3	
								Detail	21			1	1	4	1	3	3	3	3	3	
								Detail	28			1	1	4	1	3	3	3	3	3	
								Detail	35			1	1	4	1	3	3	3	3	3	
								Detail	42			1	1	4	1	3	3	3	3	2	
							05/04/91	Detail	42			2	1	4	1	3	3	3	3	2	NO
							05/04/91	Summary	42			2	1	4	1	3	3	3	3	2	NO
							08/11/91	Detail	21			3	1	5	1	3	3	3	3	3	
							19/11/91	Detail	28			3	1	5	1	3	3	3	3	3	Y
							19/11/91(*)	Summary	28			3	1	5	1	3	3	3	3	3	Y
							04/11/91	Detail	14			3	2	3	1	YES	3	3	3	1	YES
							04/11/91	Summary	14			3	2	3	1	YES	3	3	3	1	YES
							12/11/91	Detail	21			1	2	3	1	3	3	3	3	3	Y
							19/11/91(*)	Summary	21			1	2	3	1	3	3	3	3	3	Y

Severity: 0=unknown, 1= mild, 2= moderate, 3= severe, 4= 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
 (E) onset date missing: start treatment date of report visit

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PHARMACIA CNS RBD

REBOXETINE - PROTOCOL 20126/917
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	End date	report visit	Sev	Hist ary	Rel	Stud	Disp	Re	Out	Still	
3	70	Reboxetine	28/10/91	19/11/91	PAIN	28/10/91	Detail	7		3	1	5	1	3	3	3	3		
							Detail	14	31/10/91	2	1	5	1	3	3	3	3		
							Summary	31/10/91	14	3	1	5	1	3	3	3	3	1	YES
					PALPITATION	19/10/91	Detail	7		3	1	5	1	3	3	3	3		
							Detail	14		3	1	5	1	3	3	3	3		
							Detail	21		3	1	5	1	3	3	3	3		
							Detail	28		3	1	5	1	3	3	3	3		
							Summary	19/11/91(*)	28	3	1	5	1	3	3	3	3	5	NO
					TACHYCARDIA	29/10/91	Detail	7		2	2	3	1	3	5	3	3		
							Detail	14		1	2	3	1	3	5	3	3		
							Summary	19/11/91(*)	14	2	2	3	1	3	5	3	3	Y	
					TINNITUS		Detail	0		3									
							Detail	7		5	1	6	1	3	3	3	3		
							Detail	28		3	1	5	1	YES	3	3	3	Y	
							Summary	19/11/91(*)	28	3	1	5	1	YES	3	3	3	3	NO
71		Indipramine	14/11/91	25/12/91	CONSTIPATION	11/11/91	Detail	0		2	2	2	5	1	3	3	3	1	
							Detail	7	15/11/91	2	2	2	5	1	3	3	3	1	
							Summary	15/11/91	7	2	2	2	5	1	3	3	3	1	
					DIZZINESS	03/12/91	Detail	21		2	1	4	1	3	3	3	3		
							Detail	28		1	1	4	1	3	3	3	3		
							Detail	35	12/12/91	1	1	4	1	3	3	3	3		
							Summary	12/12/91	35	2	1	4	1	3	3	3	3	1	YES
					INSOMNIA	11/11/91 (D)	Detail	0		2									
							Summary	25/12/91(*)	0	2									
					MOUTH DRY	15/11/91	Detail	7		2	2	5	1	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. withdrawal, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=resolved, 2=rec. with seq., 3=still present, 4=search
 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
 (*) adverse event used for statistical analysis
 (C) adverse event still present: end date = visit date
 (D) onset date missing: first report visit date used
 (E) ...

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PHARMACIA DAS R&D

REBOXETINE - PROTOCOL 20124/D17
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 app.	Re app.	Det	Still		
											visit rity	dry ship						
5	71	Imipramine	14/11/91	25/12/91	MOUTH DRV	15/11/91	Detail	14	1	2	3	1	3	3	3	3		
							Detail	21	2	2	3	1	3	3	3	3		
							Detail	28	1	2	3	1	3	3	3	3		
							Detail	35	1	2	3	1	3	3	3	3		
							Detail	42	1	2	3	1	3	3	3	1		
							Summary	19/12/91	42	2	2	3	1	3	3	3	1	
																	YES	
						TACHYCARDIA	14/11/91	Detail	0	1	1	3	1	3	3	3	3	
							Detail	7	1	1	3	1	3	3	3	3	3	
							Detail	14	1	1	3	1	3	3	3	3	3	
							Detail	21	1	1	3	1	3	3	3	3	3	
							Detail	28	1	1	3	1	3	3	3	3	3	
							Detail	35	1	1	3	1	3	3	3	3	3	
							Detail	42	1	1	3	1	3	3	3	3	3	
							Summary	25/12/91(*)	42	2	1	3	1	2	3	3	3	3
																	YES	
						TREMOR	11/11/91	Detail	0	3	1	5	1	3	3	3	1	
							Detail	7	15/11/91	2	1	5	1	3	3	3	1	
							Summary	15/11/91	7	3	1	5	1	3	3	3	1	
																	NO	
72		Reboxetine	31/01/92	12/03/92	AGITATION	05/02/92	Detail	7	1	2	3	1	3	3	3	3	3	
							Detail	14	2	2	3	1	3	3	3	3	3	
							Detail	21	2	2	3	1	3	3	3	3	3	
							Detail	28	1	2	2	1	3	3	3	3	3	
							Detail	35	1	2	3	1	3	3	3	3	3	
							Summary	06/03/92(*)	35	2	2	2	1	3	3	3	1	
																	YES	
						CONSTIPATION	26/02/92	Detail	20	20/02/92	2	1	4	1	3	3	1	
							Summary	20/02/92	20	2	1	4	1	3	3	3	1	
						DIZZINESS	09/05/92	Detail	42	1	1	4	1	3	3	3	3	
							Summary	13/05/92(*)	42	1	1	4	1	3	3	3	3	
																	YES	
						INSOMNIA		Detail	0	2	1	5	1	YES	3	3	3	
							Detail	7	2	1	5	1	YES	3	3	3	3	

Severity: 1=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=one 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=yes, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=no
 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 R3D

REBOXETINE - PROTOCOL 20126/017
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	End date	Last visit rcty	Sae	Hist rcty	Rel. to drug	Stued	Simp	Dis app.	Re app.	In app.	Out app.	Still app.	Present (c)										
																						report	visit rcty	dry	ship	drug	trea	Hosp	app.	app.	come
3	72	Reboxetine	31/01/92	12/03/92	INSOMNIA	27/01/92(0)	14	1	5	1	YES	3	1	5	1	YES	3	3	3	3	3	3	3								
							21	3	1	5	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3					
							28	1	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3			
							28	1	1	4	1	YES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3		
							28	1	1	4	1	YES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
							Summary	35	3	1	4	1	YES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
							Summary	13/03/92(1*)																							
							0	2																							
							7	1	1	5	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
							14	1	1	5	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
3	73	Reboxetine	15/02/92	27/03/92	CONSTIPATION	06/03/92	35	2	2	5	1	3	3	3	3	3	3	3	3	3	3	3	3	3							
							42	1	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3				
							Summary	42	2	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3		
							7	2	2	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3		
							Summary	15/02/92																							
							13/03/92																								
							28	1	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
							Summary	28	1	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
							14	1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
							21	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
28	1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3								
Summary	28	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3								
3	72	Reboxetine	31/01/92	12/03/92	INSOMNIA	27/01/92(0)	8	1	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3							
							7	1	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3					
							14	1	1	4	1	YES	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3			
							Summary	14	1	1	4	1	YES	3	3	3	3	3	3	3	3	3	3	3	3	3	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=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./Keapp.: 1=y, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=suspected, 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
 (0) onset date missing: first report visit date used
 (8) onset date missing: start treatment date of report visit

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PHARMACIA CNS RSD
 REMOXETINE - PROTOCOL 20124/017
 Listing No.: 17.9
 ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient ID	Drug	Treatment		Onset date	Type	Visit	End No date	Last report visit	Saw r/cy	Hist r/cy	Rel. Hasp	RSD	Sympt	Disapp.	Re app.	Out app.	Still		
			Start date	End date																
3	75	Reboxetine	15/02/92	27/03/92	TASTE PERVERSION	Detail	28		1	2	4	1	3	3	3	3	3	3		
			Detail	35			1	2	4	1	3	3	3	3	3	3	3	3	3	
			Summary	42		26/03/92	42	1	2	4	1	3	3	3	3	3	3	3	3	3
4	97	Imipramine	07/05/92	18/06/92	DIZZINESS	Detail	0		1	1	6	1	3	3	3	3	3	3	Y	
			Detail	42			1	1	6	1	3	3	3	3	3	3	3	3	3	Y
			Summary	42		18/06/92(*)	42	1	1	6	1	3	3	3	3	3	3	3	3	3
		HEADACHE	23/04/92		Detail	0		2	1	1	6	1	3	3	3	3	3	3	Y	
			Detail	42		1	1	6	1	3	3	3	3	3	3	3	3	3	3	Y
			Summary	42	18/06/92(*)	42	2	1	6	1	3	3	3	3	3	3	3	3	3	Y
		INSOMNIA	25/04/92		Detail	0		2	1	1	6	1	3	3	3	3	3	3	3	
			Detail	7		1	1	6	1	3	3	3	3	3	3	3	3	3	3	3
			Summary	14	19/05/92	14	2	1	6	1	3	3	3	3	3	3	3	3	3	2
		HEADACHE	24/05/92		Detail	21	26/05/92	21	1	1	6	1	3	3	3	3	3	3	2	
			Detail	21		1	1	6	1	3	3	3	3	3	3	3	3	3	2	
			Summary	26	26/05/92	26	1	1	6	1	3	3	3	3	3	3	3	3	3	2
		FLATULENCE	26/05/92		Detail	26	31/05/92	26	1	1	6	1	3	3	3	3	3	3	1	
			Detail	26		1	1	6	1	3	3	3	3	3	3	3	3	3	1	
			Summary	42	14/06/92	42	1	1	6	1	3	3	3	3	3	3	3	3	3	2
100	Reboxetine	07/05/92	24/06/92	HEADACHE	Detail	0		2	1	1	6	1	3	3	3	3	3	3	Y	
		Detail	42			1	1	6	1	3	3	3	3	3	3	3	3	3	3	Y
		Summary	42		17/06/92(*)	42	2	1	6	1	3	3	3	3	3	3	3	3	3	Y
		INSOMNIA	27/04/92		Detail	0		3	1	1	6	1	3	3	3	3	3	3	Y	
			Detail	42		1	1	6	1	3	3	3	3	3	3	3	3	3	3	Y
			Summary	42	17/06/92(*)	42	3	1	6	1	3	3	3	3	3	3	3	3	3	Y
101	Imipramine	06/05/91	22/05/91	FLATULENCE	Detail	14		2	2	3	1	3	1	3	1	3	1	3	3	
		Detail	21			2	2	3	3	3	3	3	3	3	3	3	3	3	3	Y
		Summary	23		23/05/91(*)	21	2	2	3	3	3	3	3	3	3	3	3	3	3	Y

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
 Study drug: 1=none, 2=dose reduced, 3=withdrewn, 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
 (‡) onset date missing: start treatment date of report visit

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PHARMACIA CNS RSD
 REMOXETINE - PROTOCOL 20124/017
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit record	Last visit	Save rty	Hosp app.	Med drug	Rel app.	Med app.	Still present (c)	Dis app.	Re app.	Out app.	Still present (c)									
																					report	city	ofy	slip	trns	Hosp	app.	app.	same
4	101	Imipramine	06/05/91	22/05/91	HEADACHE	05/05/91(2)	0	Detail	7	1	1	4	1	3	3	3	3	3	3	3	3	Y							
							7	Summary	23/05/91(4)	7	2	1	4	1	3	3	3	3	3	3	3	3	3	3	Y				
							MICTURITION DISORDER	7	Detail	7	1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	Y		
								14	Detail	14	1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	Y	
								21	Detail	21	1	2	3	3	1	3	3	3	3	3	3	3	3	3	3	3	3	Y	
								23/05/91(4)	Summary	23/05/91(4)	21	1	2	3	3	1	3	3	3	3	3	3	3	3	3	3	3	Y	
							NAUSEA	0	Detail	0	1	1	4	3	3	1	3	3	3	3	3	3	3	3	3	3	3	Y	
								21	Detail	21	1	1	4	3	3	1	3	3	3	3	3	3	3	3	3	3	3	Y	
								23/05/91(4)	Summary	23/05/91(4)	21	1	1	4	3	3	1	3	3	3	3	3	3	3	3	3	3	Y	
								NO	Summary	23/05/91(4)	21	1	1	4	3	3	1	3	3	3	3	3	3	3	3	3	3	Y	
							RUSH	14	Detail	14	1	2	5	1	3	3	3	3	3	3	3	3	3	3	3	3	3	Y	
								15/05/91	Detail	15/05/91	14	1	2	5	1	3	3	3	3	3	3	3	3	3	3	3	3	Y	
23/05/91(4)	Summary	23/05/91(4)	7	2	1	5		1	3	3	3	3	3	3	3	3	3	3	3	3	Y								
NO	Summary	23/05/91(4)	7	2	1	5		1	3	3	3	3	3	3	3	3	3	3	3	3	Y								
TACHYCARDIA	21	Detail	21	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	Y								
	28	Detail	28	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	Y								
	28/04/91	Detail	28/04/91	20	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	Y								
	YES	Summary	28/04/91	20	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	Y								
6	101	Remoxetine	29/05/91	09/05/91	CONSTIPATION	28/04/91	21	Detail	21	2	2	3	1	3	3	3	3	3	3	3	3	3							
							28	Detail	28	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3			
							28/04/91	Detail	28/04/91	20	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3		
							YES	Summary	28/04/91	20	2	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3		
							HEADACHE	7	Detail	7	2	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
								05/06/91	Detail	05/06/91	7	2	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3
								16/04/91	Detail	16/04/91	21	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
								YES	Summary	16/04/91	21	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
							HEADACHE	20	Detail	20	2	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
								26/06/91	Detail	26/06/91	21	2	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3
								26/06/91	Detail	26/06/91	21	2	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3
								YES	Summary	26/06/91	21	2	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3
HEADACHE	35	Detail	35	2	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3							
	29/04/91	Detail	29/04/91	35	2	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3							
	29/04/91	Detail	29/04/91	35	2	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3							
	YES	Summary	29/04/91	35	2	1	4	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3							

Severity: 1=unknown, 2=mild, 3=moderate, 4=severe, 5=critical
 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
 (*) adverse event still present: end date = visit date
 (d) end date missing: first report visit date used
 (e) end date missing: start treatment date of report visit

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PHARMACIA CIS RBD
 REBOXETINE - PROTOCOL 20124/91/7
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit	Last report	Sev	Hist	Rel	Stud	Somp	Dis	Re	Out	Still						
			Start date	End date																			
6	161	Reboxetine	29/02/91	09/05/91	INSOMNIA	SWEATING INCREASED	0	03/06/91	7	1	2	4	1	2	4	1	3	3	1				
							Summary	03/06/91	7	1	2	4	1	3	3	1	3	3	1	YES			
							Detail	0	3	1	4	1	YES	3	3	3	3	3	3	3	3	3	3
							Detail	7	2	1	4	1	YES	3	3	3	3	3	3	3	3	3	3
							Detail	14	2	1	4	1	YES	3	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	3
							Detail	28	2	1	4	1	YES	3	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	3
							Detail	42	2	1	4	1	YES	3	3	3	3	3	3	3	3	3	3
							Summary	09/05/91(*)	42	3	1	4	1	YES	3	3	3	3	3	3	3	3	3
7	162	Reboxetine	05/11/91	16/12/91	HEADACHE	SWEATING INCREASED	0	03/06/91	7	1	2	4	1	2	4	1	3	3	1				
							Summary	03/06/91	7	1	2	4	1	3	3	1	3	3	1	YES			
							Detail	0	3	1	4	1	YES	3	3	3	3	3	3	3	3	3	
							Detail	7	2	1	4	1	YES	3	3	3	3	3	3	3	3	3	
							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	28	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	2	1	4	1	YES	3	3	3	3	3	3	3	3	3	
							Summary	16/12/91(*)	42	3	1	4	1	YES	3	3	3	3	3	3	3	3	3
7	194	Reboxetine	03/06/91	06/06/91	URINARY RETENTION	SWEATING INCREASED	0	25/11/91	21	2	2	4	1	2	4	1	3	3	1				
							Summary	25/11/91	21	2	2	4	1	3	3	1	3	3	1	YES			
							Detail	0	3	1	4	1	YES	3	3	3	3	3	3	3	3		
							Detail	7	2	1	4	1	YES	3	3	3	3	3	3	3	3		
							Detail	14	2	1	4	1	YES	3	3	3	3	3	3	3	3		
							Detail	21	2	1	4	1	YES	3	3	3	3	3	3	3	3		
							Detail	28	2	1	4	1	YES	3	3	3	3	3	3	3	3		
							Detail	35	2	1	4	1	YES	3	3	3	3	3	3	3	3		
							Detail	42	2	1	4	1	YES	3	3	3	3	3	3	3	3		
							Summary	16/12/91(*)	42	3	1	4	1	YES	3	3	3	3	3	3	3	3	
7	196	Imipramine	19/03/91	25/04/91	ABIATATION	SWEATING INCREASED	0	11/04/91	21	2	2	4	1	2	4	1	3	3	1				
							Summary	11/04/91	21	2	2	4	1	3	3	1	3	3	1	YES			
							Detail	0	3	1	4	1	YES	3	3	3	3	3	3	3			
							Detail	7	2	1	4	1	YES	3	3	3	3	3	3	3			
							Detail	14	2	1	4	1	YES	3	3	3	3	3	3	3			
							Detail	21	2	1	4	1	YES	3	3	3	3	3	3	3			
							Detail	28	2	1	4	1	YES	3	3	3	3	3	3	3			
							Detail	35	2	1	4	1	YES	3	3	3	3	3	3	3			
							Detail	42	2	1	4	1	YES	3	3	3	3	3	3	3			
							Summary	25/04/91	42	3	1	4	1	YES	3	3	3	3	3	3	3		

Severity: 1=none, 2=mild, 3=moderate, 4=severe, 5=critical
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawal, 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
 (M) adverse event still present: end date = visit date
 (3) onset date missing: first report visit date used

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PHARMACIA CNS RSD

REBOKETINE - PROTOCOL 28126/017
Listing No.: 17.6

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No date	Last report visit	Sine rity	Hist dry	Rel treat	Sine Hosp	Dis app.	Re app.	Out come	Still present (C)			
			Start date	End date															
7	196	Imipramine	19/05/91	21/06/91	AGITATION	Summary	27/06/91(1*)	42	2	1	3	1	YES	2	3	5	Y		
			07/06/91	07/06/91	HYPOTENSION	Detail	21	07/06/91	21	2	3	3	1	2	3	3	1	YES	
						Summary	07/06/91	21	2	3	3	1	2	3	3	1	YES		
			15/06/91	15/06/91	INSOMNIA	Detail	35			2	2	3	1	2	3	3	3	Y	
						Detail	42			2	2	3	1	2	3	3	3	Y	
						Summary	27/06/91(1*)	42	2	2	3	1	2	3	3	3	Y	YES	
			21/05/91	21/05/91	MOUTH DRY	Detail	7			2	2	3	1	3	3	3	3		
						Detail	14			2	2	3	1	2	3	3	3		
						Detail	21			3	2	3	1	2	3	3	3		
						Detail	28			1	2	3	1	2	3	3	3		
						Detail	35			1	2	3	1	2	3	3	3		
						Summary	19/06/91			55	3	2	3	1	2	3	3	1	YES
						Summary	19/06/91			55	3	2	3	1	2	3	3	1	YES
			8	225	Imipramine	24/06/91	27/06/91(1*)	RASH	Detail	42		3	2	2	3	2	1	3	3
						Summary	27/06/91(1*)	42	3	2	2	3	2	1	3	3	Y		
21/05/91	21/05/91	SOMNOLENCE				Detail	7			2	2	3	1	3	3	3			
						Detail	14			2	2	3	1	2	3	3	3		
						Detail	21			1	2	3	1	2	3	3	3		
						Detail	28			1	2	3	1	2	3	3	1	YES	
						Summary	19/06/91			28	2	2	3	1	2	3	3	1	YES
05/06/91	05/06/91	SPUTUM INCREASED				Detail	21			2	2	6	1	YES	2	3	3		
						Detail	28			2	2	6	1	YES	2	3	3		
						Summary	05/06/91			28	2	2	6	1	YES	2	3	3	1
8	225	Imipramine	22/05/91	09/06/91	DIZZINESS	Detail	7		2	1	2	1	3	3	3				
						Detail	14			1	1	4	1	3	3	3	1		
						Summary	03/06/91	14	2	1	2	1	3	3	3	1	YES		

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
Study drug: 1=no change, 2=dose reduced, 3=def. 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./Reapp.: 1=no, 2=yes, 3=not appl. --- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
Symptomatic treatment: 1=yes
(C) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(*) onset data missing: first report visit date used
(*) onset data missing: start treatment date of report visit

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PHARMACIA CNS RED
 REBOCETLINE - PROTOCOL 20126/017
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	Last report	Save rity	Hist ary	Rel shlp	Stud drug	Symp trea	Dis app.	Re app.	Out come	Still present (c)
			Start date	End date													
8	225	Imipramine	22/03/91	05/06/91	MOUTH DRY	Detail	7	1	1	2	1	3	3	3	3	3	
			Detail	14		1	1	3	1	3	3	3	3	Y			
			Summary	11/06/91(*)		14	1	1	2	1	3	3	3	Y			
	226	Reboacetline	29/08/91	11/06/91(*)	TREMOR	Detail	14	1	2	3	1	3	3	3	3	3	Y
			Summary	20/05/91		21	2	1	6	1	3	3	3	1			
			Summary	23/05/91		21	2	1	6	1	3	3	3	1			
	227	Imipramine	06/06/91	17/05/91	MOUTH DRY	Detail	55	2	2	4	1	2	3	3	3	3	Y
			Detail	42		1	2	4	1	3	3	3	3	Y			
			Summary	14/06/91(*)		42	2	2	4	1	2	3	3	3	Y		
	228	Reboacetline	10/05/91	17/05/91	HEADACHE	Detail	7	1	2	3	1	3	3	3	3	3	
			Detail	14		1	2	3	1	3	3	3	3				
			Detail	21		1	2	3	1	3	3	3	3				
	229	Imipramine	22/10/91	02/12/91	BRONCHITIS	Detail	28	1	2	2	1	3	3	3	3	3	
			Detail	35		1	2	3	1	3	3	3	3				
			Detail	42		1	2	3	1	2	3	3	3	Y			
	228	Reboacetline	12/05/91	17/05/91	HEADACHE	Detail	7	2	1	3	1	3	3	3	3	3	
			Detail	14		2	1	3	1	3	3	3	1	3	Y		
			Summary	10/05/91(*)		14	3	1	3	3	3	3	1	3	Y		
	229	Imipramine	14/10/91	02/12/91	BRONCHITIS	Detail	7	2	1	6	1	YES	3	3	3	1	NO
			Detail	42		2	2	2	1	2	3	3	3	3	Y		
			Summary	03/12/91(*)		42	2	2	2	1	2	3	3	3	Y		

Severid: 0=unknown, 1=mild, 2=moderate, 3=severe.
 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=pro. with seq., 3=still present, 4=search
 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
 (c) onset date missing: first report visit date used
 (c) onset date missing: first report visit date used

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20126/917
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment		Onset date	Adverse event	Chast date	Type record	Visit No	End date	Last report visit	Save rity	HIST dry	Rat ship	Rat Stud	Symp app.	Dis app.	Re	Out	Skill		
		Start date	End date																		
0	251	Reboxetine	05/11/91	13/11/91	HEADACHE	07/11/91	Detail	7		13/11/91(*)	7	1	1	4	1	2	5	3	3	Y	
								Summary					1	1	4	1	2	5	3	3	Y
														7	1	4	1	2	5	3	3
9	197	Reboxetine	07/03/92	10/03/92	ASTHENIA	08/03/92	Detail	7		13/11/91(*)	7	1	3	4	1	2	3	3	3	Y	
								Summary					1	3	4	1	2	3	3	3	Y
														7	1	3	4	1	2	3	3
9	197	Reboxetine	07/03/92	10/03/92	ASTHENIA	08/03/92	Detail	7		11/03/92	7	2	2	4	3	2	2	3	1		
								Summary					2	2	4	3	2	2	3	1	
														7	2	4	3	2	2	3	1
9	197	Reboxetine	08/03/92	10/03/92	HEADACHE	08/03/92	Detail	7		11/03/92	7	3	2	4	3	2	2	3	1		
								Summary					3	2	4	3	2	2	3	1	
														7	3	2	4	3	2	2	3
9	198	Isipramine	16/03/92	28/04/92	MOUTH DRY	17/03/92	Detail	7		27/03/92	14	3	2	3	1	3	3	3			
								Summary					3	2	3	1	3	3	3		
														14	3	2	3	1	2	3	1
9	198	Isipramine	31/03/92			31/03/92	Detail	21			1	2	3	1	3	3	3				
								Summary					1	2	3	1	3	3			
														28	1	2	3	1	3	3	1
9	199	Isipramine	02/04/92	13/05/92	CONSTIPATION	17/03/92	Detail	7		26/03/92	14	2	2	3	1	3	3	1			
								Summary					2	2	3	1	3	3	1		
														14	2	3	1	3	3	1	NO
9	199	Isipramine	02/04/92	13/05/92	CONSTIPATION	05/04/92	Detail	7		11/04/92	14	1	2	3	1	3	3	1			
								Summary						1	2	3	1	3	3	1	
														14	1	2	3	1	3	3	1

Serious: 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=amp. 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=non
 Symptomatic treatment: 1=no, 2=yes
 (c) adverse event used for statistical analysis
 (4) adverse event still present: end date = visit date
 (5) onset date missing: first report visit date used
 (8) onset date missing: start treatment date of report visit

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PHARMACIA CNS MSD
 REBOQUETINE - PROTOCOL 20124/017
 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	Save rity	Hist dry	Re ship	Stud drug	Sym tras	Dis app.	Re app.	Dat some	Still Present (c)				
			Start date	End date																		
9	199	Imipramine	02/04/92	13/05/92	30/04/92	LIPOIDO DECREASED	Detail	58	01/05/92	35	2	3	4	1	2	3	3	1	YES			
							Summary		01/05/92		35	2	3	4	1	2	3	3	1	YES		
							03/04/92	MICTURITION DISORDER	Detail	35	02/05/92	35	2	1	3	1	2	3	3	1	YES	
							02/05/92		Summary		02/05/92		35	2	1	3	1	2	3	3	1	YES
							06/06/92	MOUTH DRY	Detail	7			1	2	2	1	3	3	3	3		
									Detail	14			1	2	1	2	3	3	3	3		
									Detail	21			1	2	1	2	3	3	3	3		
									Detail	26			1	2	1	2	3	3	3	3		
									Detail	35			1	2	1	2	3	3	3	3		
									Detail	42			1	2	1	2	3	3	3	3		
						Summary		13/05/92(*)	42	1	2	2	1	3	3	3	3	3	Y			
200	Reboquetine	MOUTH DRY	26/04/92	06/05/92	28/04/92		Detail	7		1	2	3	1	3	3	3	3					
							Detail	14		1	2	3	1	3	3	3	3	3				
							Detail	21		1	2	3	1	3	3	3	3	3				
							Detail	28		1	2	3	1	3	3	3	3	3				
							Summary		13/05/92		28	1	2	3	1	3	3	3	3	1	YES	
							Summary		13/05/92		28	1	2	3	1	3	3	3	3	1	YES	
201	Imipramine	ABDOMINAL PAIN	16/01/92	26/02/92	27/01/92		Detail	14		3	2	3	1	3	3	3	3	1	YES			
							Summary		27/01/92		14	3	2	3	1	3	3	3	1	YES		
							06/02/92(B)	MENSTRUAL DISORDER	Detail	28		12/02/92		6								
							Summary		12/02/92		28		6								YES	
202	Imipramine	COUGHING	17/01/92	27/02/92	20/02/92		Detail	42		1	2	3	1	3	3	3	3	3	Y			
							Summary		26/02/92(*)		42	1	2	3	1	3	3	3	3	Y		
							Detail	28		2	2	4	1	YES	2	3	3	3				
							Summary		15/02/92		35	2	2	4	1	YES	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. 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
 (d) onset date missing: first report visit date used
 (e) onset date missing: start treatment date of report visit

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20126/017
 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	Sav	Hist	Rel	Stud	Symp	Dis	Re	Out	Still	app.	come	present	(c)										
																								visit	city	dry	shp	drug	traa	hosp	app.	come	present
9	Zolopramine	17/01/92	27/02/92	FEVER	11/02/92	26	Detail	35	15/02/92	2	2	4	1	YES	2	3	3																
							Detail	35	15/02/92	2	2	4	1	YES	2	3	3	1															
							Summary	55	15/02/92	2	2	4	1	YES	2	3	3	1															
							Detail	7		3	2	3	1		3	3	3	3															
							Detail	14		2	1	3	1		3	3	3	3															
							Detail	21		2	1	3	1		3	3	3	3															
							Detail	28		2	1	4	1		3	3	3	3															
							Detail	35		3	1	2	1		3	3	3	3															
							Detail	42		3	1	2	1		3	3	3	3															
							Summary	42	27/02/92(*)	42	3	1	2	1		3	3	3															
							208	Reboxetine	15/01/92	16/01/92	AGITATION	17/01/92	7	Detail	14	29/01/92	2	2	3	1		3	3	3									
Detail	14	29/01/92	2	2	3	1									3	3	3	1															
Summary	21	05/02/92	1	2	3	1									3	3	3	1															
Detail	28		1	2	3	1									3	3	3	1															
Detail	35		5	2	3	1									3	3	3	3															
Detail	42		2	2	4	1									3	3	3	3															
Summary	42	27/02/92(*)	42	3	2	3								1		3	3	3															
Detail	7	17/01/92	3	2	3	4									3	2	3	1															
Summary	7	17/01/92	7	3	2	3								4		3	2	3	1														
204	Reboxetine	17/01/92	28/02/92	HERPES SIMPLEX	28/01/92	14								Detail	14	04/02/92	3	2	4	1		2	3	3									
														Detail	14	04/02/92	3	2	4	1		2	3	3	1								
							Summary	21	02/02/92	2	2	4	1		2	3	3	1															
							Detail	14		2	2	4	1		2	3	3	3															
							Detail	21		2	2	4	1		2	3	3	1															
							Summary	21	02/02/92	2	2	4	1		2	3	3	1															
							Detail	35	28/02/92	1	2	3	1		3	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=stop, 4=stop with treatment, 5=stop with treatment and follow-up
 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
 (D) onset date missing: first report visit date used
 (S) start treatment date missing: start treatment date of report visit

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PHARMACIA CNS RBD
 REBOXETINE - PROTOCOL 2024/R17
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Onset date	Type record	Visit No	Last report	Save rity	Hist	Rea	Stud	Sump	Dis app.	Re app.	Out come	Skill present
3	204	Reboxetine	17/01/92	28/02/92	MOUTH DRY	Summary	20/02/92	35	1	2	3	1	3	3	3	1	YES
						Detail	7	2	2	5	1	3	3	3	3	3	
						Detail	14	2	2	3	1	3	3	3	3	3	
						Detail	21	1	2	3	1	3	3	3	3	3	
	206	Etiopramine	05/02/92	18/05/92	HEADACHE	Summary	04/02/92	14	1	2	3	1	3	3	3	3	NO
						Detail	21	2	3	1	3	3	3	3	3		
						Detail	21	1	2	3	1	3	3	3	3	3	
						Summary	24/02/92	21	1	2	3	1	3	3	3	3	
	207	Reboxetine	06/02/92	12/02/92	FATIGUE	Summary	16/02/92	14	3	2	3	4	2	2	2	1	YES
						Detail	14	3	2	3	4	2	2	2	1	1	
						Detail	14	3	2	3	4	2	2	2	1	1	
						Summary	17/02/92	14	3	2	3	4	2	2	2	1	
	208	Reboxetine	02/03/92	02/03/92	VERTIGO	Summary	02/03/92	28	1	2	3	1	2	3	3	1	YES
						Detail	28	1	2	3	1	2	3	3	1		
						Detail	28	1	2	3	1	2	3	3	1		
						Summary	02/03/92	28	1	2	3	1	2	3	3	1	
	209	Reboxetine	06/02/92	12/02/92	FATIGUE	Summary	06/02/92	7	2	2	3	1	3	3	3	1	YES
						Detail	7	2	2	3	1	3	3	3	1		
						Detail	7	2	2	3	1	3	3	3	1		
						Summary	11/02/92	7	2	2	3	1	3	3	3	1	
	200	Reboxetine	15/02/92	27/03/92	BACK PAIN	Summary	16/02/92	7	1	1	3	1	3	3	3	3	YES
						Detail	7	1	1	3	1	3	3	3	3		
						Detail	14	2	2	3	1	3	3	3	3		
						Summary	27/02/92	14	1	1	3	1	3	3	3	1	
	207	Reboxetine	01/03/92	05/03/92	CONSTIPATION	Summary	01/03/92	21	2	2	3	1	3	3	3	1	YES
						Detail	21	2	2	3	1	3	3	3	1		
						Detail	21	2	2	3	1	3	3	3	1		
						Summary	05/03/92	21	2	2	3	1	3	3	3	1	
	200	Reboxetine	17/02/92	24/02/92	MOUTH DRY	Summary	17/02/92	7	2	2	3	1	3	3	3	3	YES
						Detail	7	2	2	3	1	3	3	3	3		
						Detail	14	2	1	3	1	3	3	3	3		
						Summary	24/02/92	14	2	1	3	1	3	3	3	1	
	200	Reboxetine	24/02/92	27/03/92	MOUTH DRY	Summary	24/02/92	42	2	2	3	1	3	3	3	3	YES
						Detail	42	2	2	3	1	3	3	3	3		
						Detail	42	2	2	3	1	3	3	3	3		
						Summary	27/03/92	42	2	2	3	1	3	3	3	3	

-- History: 1=represent 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. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=prob. 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) adverse date missing: first report visit date used
 (b) adverse date missing: first report visit date used

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PHARMACIA CNS RMD

REBOXETINE - PROTOCOL 20124/R17
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	Rety	Sav	Hist	Rel	Stud	Somp	Dis	Re	Out	Skill	Last									
																				visit	report								
9	208	Reboxetine	15/02/92	27/03/92	SWEATING INCREASED	14/02/92	Detail	7																					
							Summary	14	22/02/92	1	2	3	1	3	3	3	1												
							Detail	62		14	1	2	3	1	3	3	3	1											
							Summary	42	27/03/92(*)	42	1	2	3	1	3	3	3	3	1										
209	Isipramine	12/02/92	15/02/92	FATIGUE	12/02/92	Detail	7	16/02/92																					
						Summary	7	16/02/92	7	3	2	2	3	2	2	3	1												
						Detail	7		7	3	2	2	3	2	1	3	3	1											
						Summary	7	16/02/92(*)	7	3	2	2	3	2	1	3	3	1											
210	Reboxetine	20/02/92	01/04/92	MOUTH DRY	27/02/92	Detail	14																						
						Summary	21	09/02/92	1	2	3	1	3	3	3	1													
						Detail	21		21	1	2	3	1	3	3	3	1												
						Summary	21	09/02/92	21	1	2	3	1	3	3	3	1												
211	Reboxetine	14/02/92	02/03/92	MOUTH DRY	01/03/92	Detail	0																						
						Summary	14	02/03/92	1	2	3	1	2	3	3	1													
						Detail	7		7	2	1	3	1	3	3	3	3												
						Summary	21	09/02/92	21	3	1	3	1	3	3	3	3	1											
211	Reboxetine	14/02/92	02/03/92	NAUSEA	22/02/92	Detail	14																						
						Summary	21	02/03/92	14	1	2	3	1	2	3	3	1												
						Detail	21		21	2	2	3	1	3	3	3	3												
						Summary	21	02/03/92(*)	21	2	2	3	1	3	3	3	3	1											

Serious: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=stop, 4=temp. inter.
 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
 (D) adverse event still present; end date = visit date
 (E) onset date missing; first report visit date used
 -- History: 1=present before, 2=not observed bef., 3=unknown

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20126/017
 Listing No.: 17-0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit	End No data	Last report visit	Sew	Hst	Rel	Stud	Symp	Dis	Re	Out	Still				
			Start date	End date																		
9	211	Reboxetine	14/02/92	02/03/92	TREMOR	Detail	7		1	2	5	1	2	5	3	3	3					
						Detail	14		1	2	5	1	3	3	3	3	3					
						Detail	21		1	2	3	1	3	3	3	3	3	3	Y			
						Summary	05/03/92(*)	21	1	2	3	1	2	5	3	3	3	3	Y	YES		
						Detail	7		3	2	2	1	3	3	3	3	3	3				
						Detail	14		2	2	2	1	3	3	3	3	3	3				
						Detail	21		1	2	2	1	3	3	3	3	3	3				
						Detail	28		1	2	2	1	3	3	3	3	3	3				
						Detail	35		1	2	2	1	3	3	3	3	3	3				
						Summary	02/06/92	42	5	2	2	1	3	3	3	3	3	3	1		NO	
	212	Isoprenaline	06/04/92	14/06/92	MOUTH DRY	Detail	7		3	2	2	1	3	3	3	3						
						Detail	14		2	2	2	1	3	3	3	3	3					
						Detail	21		1	2	2	1	3	3	3	3	3					
						Detail	28		1	2	2	1	3	3	3	3	3					
						Detail	35		1	2	2	1	3	3	3	3	3					
						Detail	42		08/06/92													
						Summary	08/06/92	42	5	2	2	1	3	3	3	3	3	3	1		NO	
				237	Reboxetine	23/04/92	02/05/92	MOUTH DRY	Detail	7		1	3	1	4	3	2	3	1			
									Summary	28/04/92	7	1	3	1	4	3	2	3	1			YES
									Detail	7		3	2	2	1	3	3	3	3	3		
						Detail	14		3	2	2	1	3	3	3	3	3					
						Detail	21		3	2	2	1	3	3	3	3	3					
						Detail	28		2	2	2	1	3	3	3	3	3					
						Summary	29/03/92	28	3	2	2	1	3	3	3	3	3	1		NO		
						Summary	29/03/92	28	3	2	2	1	3	3	3	3	3	1		NO		
						Detail	7		1	3	1	4	3	2	3	1				YES		
						Summary	28/04/92	7	1	3	1	4	3	2	3	1				YES		
	237	Reboxetine	23/04/92	02/05/92	MOUTH DRY	Detail	7		2	3	1	4	2	1	3	1						
						Summary	29/04/92	7	2	3	1	4	2	1	3	1			YES			
				239	Isoprenaline	30/04/92	16/06/92	MOUTH DRY	Detail	7		2	2	3	1	3	3	3	3			
									Detail	14		2	2	2	1	3	3	3	3			
									Detail	21		2	2	2	1	3	3	3	3			

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=stop, 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 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
 (*) 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

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PHARMACIA CNS RBD
 REBOXETINE - PROTOCOL 28134/017
 Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Adverse event	Typs record	Visit No	End date	Last report visit	Save rcty	Hist drv	Rel. Stud	Symp	Dis app.	Re app.	Out come	Still Present (c)			
			Start date	End date																	
9	239	Imipramine	30/04/92	19/05/92	30/04/92	MOUTH DRY	Detail	26			2	2	3	1	3	3	3	3			
							Detail	35			2	2	3	1	3	3	3	3	3		
							Detail	42			2	2	3	1	3	3	3	3	3	3	
							Summary				10/06/92(*)	42	2	2	2	1	3	3	3	3	Y
							Detail	7					2	2	3	1	3	3	3	3	
							Detail	14					3	2	2	1	3	3	3	3	
							Detail	21					3	2	2	1	3	3	3	3	
							Detail	28					2	2	3	1	3	3	3	3	
							Detail	35					2	2	3	1	3	3	3	3	
							Detail	42				10/06/92(*)	42	3	2	2	1	3	3	3	Y
240	Reboxetine	MOUTH DRY	28/04/92	16/05/92	28/04/92		Detail	7			1	2	3	1	3	3	3	3			
							Detail	14			16/05/92		1	2	3	1	3	3	3		
							Summary				16/05/92	14	1	2	3	1	3	3	3	1	
							Detail	21					1	2	3	1	3	3	3	1	
							Summary				15/05/92	21	1	2	3	1	3	3	3	1	
							Detail	7					1	2	3	1	3	3	3	3	
							Detail	14					1	2	3	1	3	3	3	3	
							Detail	21					1	2	3	1	3	3	3	3	
							Summary				16/05/92	21	1	2	3	1	3	3	3	3	1
							Detail	42				15/06/92	42	2	2	4	4	3	3	3	1
241	Imipramine	NAUSEA	09/05/92	19/05/92	15/05/92		Detail	7			2	2	4	4	3	3	3	3			
							Detail	14				2	2	4	1	3	3	3	3		
							Detail	21					2	2	4	1	3	3	3		
							Detail	28					2	2	4	1	3	3	3		
							Detail	35					2	2	4	1	3	3	3		
							Detail	42				15/06/92	42	2	2	4	4	3	3	3	1
							Summary				15/06/92	42	2	2	4	4	3	3	3	1	
							Detail	7					2	2	2	1	3	3	3	3	
							Detail	14				15/05/92	14	2	2	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. withdrawn, 4=temp. inter.
 Hospital: 1=referred, 2=not ref., 3=not app. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Resp.: 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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PHARMACIA CNS R0D

REBOXETINE - PROTOCOL 20126/017
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	End date	Last visit rity	Swp	Rel	Hes	Drug	Hes	App.	Some	Present	(C)
			Start date	End date														
9	241	Imipramine	09/05/92	19/05/92	13/05/92	Summary	14	2	2	2	2	1	3	3	3	3	1	YES
	242	Reboxetine	07/05/92	17/06/92	08/05/92	Detail	7	2	2	3	1	2	3	3	3	3	3	3
						Detail	14	2	2	3	1	2	3	3	3	3	3	3
						Detail	21	2	2	3	1	2	3	3	3	3	3	3
						Detail	28	2	2	3	1	2	3	3	3	3	3	3
						Detail	35	2	2	3	1	2	3	3	3	3	3	3
						Summary	35	2	2	3	1	2	3	3	3	3	3	3
	243	Imipramine	16/05/92	26/06/92	23/05/92	Detail	7	2	1	3	1	YES	3	3	3	3	1	YES
						Summary	7	2	1	3	1	YES	3	3	3	3	1	YES
	244	Reboxetine	06/06/92	17/07/92	06/06/92	Detail	7	1	2	3	1	5	3	3	3	3	3	3
						Detail	14	1	2	3	1	5	3	3	3	3	3	3
						Detail	21	1	2	3	1	5	3	3	3	3	3	3
						Detail	28	1	2	3	1	5	3	3	3	3	3	3
						Summary	28	1	2	3	1	5	3	3	3	3	3	3
	257	Reboxetine	17/07/91	27/08/91	01/08/91	Detail	21	1	2	3	1	2	3	3	3	3	3	3
						Detail	28	1	2	3	1	2	3	3	3	3	3	3
						Detail	35	1	2	3	1	2	3	3	3	3	3	3
						Detail	42	1	2	3	1	2	3	3	3	3	3	3
						Summary	28/08/91(*)	42	1	2	3	1	2	3	3	3	3	3
	258	Reboxetine	17/07/91	06/08/91	19/07/91	Detail	7	2	2	3	1	2	3	3	3	3	3	3
						Summary	7	2	2	3	1	2	3	3	3	3	3	3
	259	Imipramine	17/07/91	27/08/91	31/07/91	Detail	14	2	2	3	1	2	3	3	3	3	3	3
						Detail	21	2	2	3	1	2	3	3	3	3	3	3
						Detail	28	2	2	3	1	2	3	3	3	3	3	3

Serality: 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./reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=name
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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PHARMACIA CNS 820
 REBORETIME - PROTOCOL 20124/017
 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	Save rity	Hist ary	Re chlp	Stud Sym	Dis app	Re come	Out Still			
			Start date	End date																
Y	259	Imipramine	17/07/91	27/08/91	31/07/91	MOUTH DRY	Detail	35		2	2	3	1	2	3	3	3	3		
							Summary	42	28/08/91(*)	42	2	2	3	1	2	3	3	3	3	
							Detail	7		1	2	3	1	2	3	3	3	3	3	3
							Detail	14		1	2	3	1	2	3	3	3	3	3	3
							Detail	21		1	2	3	1	2	3	3	3	3	3	3
							Detail	28		1	2	3	1	2	3	3	3	3	3	3
							Detail	35		1	2	3	1	2	3	3	3	3	3	3
							Detail	42		1	2	3	1	2	3	3	3	3	3	3
							Summary	28/08/91(*)	42	1	2	3	1	2	3	3	3	3	3	3
Y	261	Imipramine	25/07/91	29/07/91	24/07/91	URINARY RETENTION	Detail	28		1	2	3	1	2	3	3	3	3		
							Detail	35	19/06/91	35	1	2	3	1	2	3	3	3		
							Summary	19/06/91	35	1	2	3	1	2	3	3	3	3		
							Detail	7	01/06/91	7	3	2	3	3	3	2	3	3	3	
Y	264	Imipramine	31/07/91	10/09/91	01/08/91	DIZZINESS	Detail	7		1	2	3	1	2	3	3	3	3		
							Detail	14	09/08/91	14	1	2	3	1	2	3	3	3		
							Summary	09/08/91	14	1	2	3	1	2	3	3	3			
							Detail	7		2	2	3	1	3	3	3	3			
Y			03/08/91		12/08/91	MOUTH DRY	Detail	7		2	2	3	1	2	3	3	3	3		
							Detail	14	12/08/91	14	2	2	3	1	2	3	3	3		
							Summary	12/08/91	14	2	2	3	1	2	3	3	3			
							Detail	14		2	2	3	1	2	3	3	3			
Y			10/09/91		10/09/91	SWEATING INCREASED	Detail	14		2	2	3	1	2	3	3	3	3		
							Detail	21		2	2	3	1	2	3	3	3			
							Detail	28		2	2	3	1	2	3	3	3			
							Detail	35		1	2	3	1	2	3	3	3			
				Detail	42	10/09/91	42	1	2	3	1	3	3	3	3					
				Summary	10/09/91	42	2	2	3	1	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= stop, 4= withdrawal, 5= temporary
 Hospital: 1= required, 2= not req., 3= not appl., 4= none
 Disapp./Reapp.: 1= no, 2= yes, 3= not appl., 4= 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

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PHARACIA CMS RD
REBOXetine - PROTOCOL 2012/017
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	Sympt	Rel	Stud	Symp	Dis	Re	Out	Still													
9	266	Reboxetine	18/09/91	29/10/91	MENSTRUAL DISORDER	06/10/91	Detail	21		1	2	5	1		2	3	5	3													
							Detail	28	10/10/91	2	2	5	1		2	3	5	1													
							Summary	10/10/91	28	2	2	5	1		2	3	5	1							YES						
							PALPITATION	Detail	7		2	1	6	1		2	5	5	5												
								Detail	14		1	1	3	1		2	5	3	5												
								Detail	21		1	1	3	1		2	5	3	5												
								Detail	28		1	1	3	1		2	5	3	5												
								Detail	35		1	1	3	1		2	5	3	5												
								Detail	42	25/10/91	1	1	3	1		2	5	3	5												
							Summary	25/10/91	42	2	1	3	1		2	5	3	5								YES					
							267	Imipramine	02/09/91	15/10/91	SALIVA INCREASED	01/05/91	Detail	0		2	1	3	1		2	5	3	3							
													Detail	7		2	1	3	1		2	5	3	3							
													Detail	14		2	1	6	1	YES	2	5	3	3							
													Detail	21	06/10/91	2	1	6	1		2	5	3	1							
													Summary	06/10/91	21	2	1	3	1	YES	2	5	3	1							NO
													Detail	7		1	2	5	1		5	5	3	3							
													Summary	14/10/91(*)	42	1	2	3	1		3	5	3	3							
267	Imipramine	02/09/91	15/10/91	SWEATING INCREASED	Detail	0		3																							
					Summary	14/10/91(*)	0	3															NO								
9	266	Reboxetine	18/09/91	29/10/91	MENSTRUAL DISORDER	06/10/91	Detail	7		1	2	3	1		2	3	5	3													
							Detail	14		1	2	5	1		2	3	5	3													
							Detail	21		1	2	5	1		2	3	5	3													
							Detail	28		1	2	5	1		2	3	5	3													
							Detail	35		1	2	5	1		2	3	5	3													
							Detail	42	14/10/91(*)	1	2	5	1		2	3	5	3								Y					
Summary	14/10/91(*)	42	1	2	3	1		3	5	3	3								YES												
267	Imipramine	02/09/91	15/10/91	SWEATING INCREASED	Detail	0		3																							
					Summary	14/10/91(*)	0	3															NO								
9	266	Reboxetine	18/09/91	29/10/91	MENSTRUAL DISORDER	06/10/91	Detail	7		1	2	3	1		2	3	5	3													
							Detail	14		1	2	3	1		2	3	5	3													
							Detail	21		1	2	3	1		2	3	5	3													
							Detail	28		1	2	5	1		2	3	5	3													
							Detail	35		1	2	5	1		2	3	5	3													
							Detail	42	14/10/91(*)	1	2	5	1		2	3	5	3								Y					
Summary	14/10/91(*)	42	1	2	5	1		2	3	5	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. -- 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: and date = visit date
 (D) onset date missing: first report visit date used
 (P) report date missing: start treatment date of report visit

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PHARMACIA CNS RBD

REBOMETINE - PROTOCOL 20126/017
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Contra Patient Drug	Treatment	Start date	End date	Onset date	Type of Adverse event	Last report visit	Save Hist	Rel ship	Steady state	Sympt	Dis app.	Re app.	Out app.	Still present (C)						
															report	No date	visit	rity	ery	ship
9	Inipramine	02/09/91	13/10/91	02/09/91	VISION ABNORMAL	Detail	7	1	2	2	1	3	3	3	3					
						Detail	14	1	2	5	1	3	3	3	3					
						Detail	21	1	2	5	1	3	3	3	3					
						Detail	20	1	2	5	1	3	3	3	3					
						Detail	35	1	2	5	1	3	3	3	3					
						Detail	42	1	2	5	1	3	3	3	3					
						Summary	146/10/91(*)	42	1	2	2	1	3	3	3	3	3	3	Y	YES
						Detail	7	1	2	3	1	2	3	3	3	3	3	3	3	
						Detail	14	1	2	3	1	2	3	3	3	3	3	3	3	
						Detail	21	1	2	3	1	2	3	3	3	3	3	3	1	
Summary	10/10/91	21	1	2	3	1	2	3	3	3	3	3	1	YES						
286	Inipramine	25/09/91	05/11/91	AGITATION	Detail	7	1	3	3	1	YES	2	3	3	3					
					Detail	14	1	3	3	1	2	3	3	3	3					
					Detail	21	1	3	3	1	2	3	3	3	3	1				
					Summary	10/10/91	21	1	3	3	1	2	3	3	3	1	YES			
					Detail	7	29/09/91	1	3	3	1	YES	2	3	3	3	1			
					Summary	29/09/91	7	1	3	3	1	YES	2	3	3	3	1	YES		
					289	Reboxetine	25/09/91	05/11/91	MICTURITION DISORDER	Detail	7	1	2	3	1	2	3	3	3	3
										Detail	14	1	2	3	1	2	3	3	3	3
										Detail	21	1	2	3	1	2	3	3	3	3
										Detail	20	1	2	3	1	2	3	3	3	3
Detail	35	1	2	3						1	2	3	3	3	3					
Detail	42	1	2	3						1	2	3	3	3	3					
Summary	05/11/91(*)	42	1	2						3	1	2	3	3	3	3	3	Y	YES	
Detail	42	04/11/91	1	2						3	1	3	3	3	3	3	3	1		
Summary	04/11/91	42	1	2						3	1	3	3	3	3	3	3	1	YES	
289	Reboxetine	25/09/91	05/11/91	MICTURITION DISORDER						Detail	14	2	2	3	1	2	3	3	3	3
					Detail	21	2	2	3	1	2	3	3	3	3	1				
					Summary	10/10/91	21	2	2	3	1	2	3	3	3	1	YES			
					Detail	7	29/09/91	1	2	3	1	2	3	3	3	3	1			
					Summary	29/09/91	7	1	2	3	1	2	3	3	3	3	1	YES		

Severity: 1=unknown, 2=mild, 3=moderate, 4=severe, 5=critical
 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=search
 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
 (3) onset date missing: first report visit date used

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20126/017
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit record	End No date	Last report visit	Sava rity	Hist ary	Rel ship	Stud area	Sump Hoop	Dis app.	Re come	Out Skill										
			Start date	End date																							
9	270	Imipramine	11/10/91	17/10/91	TACHYCARDIA	17/10/91	Detail	7	17/10/91(*)	7	3	1	5	1	2	3	3	3	Y								
							Summary																				
							Detail	14	10/11/91	14	1	2	3	1	YES	3	5	5	1								
							Summary																				
							Detail	0		0	2																
							Summary																				
							Detail	7		7	1	3	1	YES	3	3	3	3	3								
							Summary																				
							Detail	14		14	1	3	1	YES	3	3	3	3	3								
							Summary																				
271	Reboxetine	30/10/91	20/11/91	BACK PAIN	10/11/91	Detail	14	10/11/91	14	1	2	3	1	YES	3	5	5	1									
						Summary																					
						Detail	0		0	2																	
						Summary																					
						Detail	7		7	1	3	1	YES	3	3	3	3										
						Summary																					
						Detail	14		14	1	3	1	YES	3	3	3	3										
						Summary																					
						Detail	21		21	15/11/91	21	2	1	3	4	YES	3	2	1	1							
						Summary																					
				EARACHE	21/10/91(D)	Detail	0		0	2																	
						Summary																					
						Detail	7		7	1	3	1	YES	3	3	3	3										
						Summary																					
						Detail	14		14	1	3	1	YES	3	3	3	3										
						Summary																					
						Detail	21		21	15/11/91	21	2	1	3	4	YES	3	2	1	1							
						Summary																					
										HEADACHE	18/11/91	Detail	21		21	5	2	3	4	YES	3	1	3	3			
												Summary															
Detail	28		28	21/11/91	28							5	2	3	3	YES	3	2	3	1							
Summary																											
Detail	21		21	13/11/91	21							5	2	3	4	YES	3	2	2	3							
Summary																											
Detail	28		28	21/11/91	28							5	2	3	3	YES	3	2	3	1							
Summary																											
				MOUTH DRY	01/10/91							Detail	9		9	2											
												Summary															
						Detail	7		7	1	3	1	3	1	3	3	3										
						Summary																					
						Detail	14		14	1	3	1	3	1	3	3	3										
						Summary																					
						Detail	21		21	1	3	4	3	1	3	3	3										
						Summary																					
						Detail	28		28	26/11/91(*)	28	2	1	3	3	5	1	3	3	Y							
						Summary																					
				PALPITATION	18/11/91	Detail	21		21	2	2	3	4	3	2	1	1										
						Summary																					
						Detail	16		16	16/11/91	16	2	2	3	4	3	2	1	1								
						Summary																					
						Detail	0		0	27/10/91	0	3															
						Summary																					

Severity: Unknown, Mild, Moderate, 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
 (Y) adverse event still present: end date = visit date
 (D) onset date missing: first report visit date used
 (*) onset date missing: start treatment date of report visit

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PHARMACIA CHS RED

REMOSSETINE - PROTOCOL 20124/017
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	Sera	Hist	Rel	Stad	Sym	Dis	Re	Out	Still	come	Present	(c)								
																							visit	15	15	15	15	15	15	15
9	271	Reboxetine	30/10/91	29/11/91	RHINITIS	27/10/91	Detail	7			1	1	3	1	3	1	3	3	3	3										
							Detail	14		1	1	5	1	3	3	3	3	3												
							Detail	21	15/11/91	1	1	5	4	3	2	1	1													
							Summary		15/11/91	21	3	1	5	4	3	2	1	1										NO		
					SNEATING INCREASED		Detail	0		3																				
							Detail	7		2	1	3	1	3	3	3	3													
							Detail	14		2	1	3	1	3	3	3	3													
							Detail	21		2	1	3	4	3	1	3	3													
						21/10/91(0)	Detail	20		2	1	3	3	3	3	1	3	3	3	3	3									
							Summary		20/11/91(0)	20	3	1	3	3	3	1	3	3	3	3	3	3	3	3	3	3			NO	
							Detail	16		1	2	3	1	3	3	3	3													
							Detail	21		1	2	3	1	3	3	3	3													
	272	Imipramine	30/10/91	10/12/91	CONSTIPATION	09/11/91	Detail	16		1	2	3	1	3	1	3	3	3	3	3										
							Detail	21		1	2	3	1	3	3	3	3													
							Detail	28		1	2	3	1	3	3	3	3													
							Detail	35		1	2	3	1	3	3	3	3													
						42 05/12/91	Detail	42	05/12/91	1	2	3	1	3	3	3	3	3	3	3	3									
							Summary		05/12/91	42	1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3		YES	
							Detail	21	17/11/91	1	2	3	1	3	3	3	3													
							Summary		17/11/91	21	1	2	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3		YES
	273	Imipramine	30/10/91	20/11/91	CONFUSION	14/11/91	Detail	21		2	2	3	1	3	3	3	3	3	3	3										
							Detail	28	20/11/91	2	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3			
							Detail	35	20/11/91	2	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3		
							Summary		20/11/91	28	2	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3		YES

Severity: 1=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.
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl.
 Relationship: 1=definite, 2=suspect, 3=possible, 4=doubtful, 5=unknown, 6=none
 Supplemental 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 RBD
 REDOMETINE - PROTOCOL 20124/017
 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 rft	Hist rft	Rea rft	Stud rft	Sump rft	Dis app.	Xa app.	Out app.	Skill present (c)								
																				date	date	date	date	date	date	date	date
9	273	Imipramine	30/10/91	20/11/91	MOUTH DRY		01/11/91	Detail	7																		
								Detail	14																		
								Detail	21																		
								Detail	28	21/11/91																	
								Summary	31/11/91																		
								Detail	28	21/11/91																	
								Summary	21/11/91																		
								Detail	21																		
								Detail	28	23/11/91																	
								Summary	23/11/91																		
	274	Reboxetine	31/10/91	31/10/91	NAUSEA		20/11/91	Detail	28	21/11/91																	
								Summary	21/11/91																		
								Detail	7	31/10/91																	
								Summary	31/10/91																		
								Detail	7	10/05/92																	
								Detail	14	20/05/92																	
								Summary	20/05/92																		
								Detail	9																		
								Detail	7																		
								Detail	14																		

Severly: 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=none, 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 R2D
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient ID	Treatment	Start date	End date	Onset date	Type	Visit No	Rel	Hist	Rat	Stud	Sym	Dis	Ra	Out	Still	Last		
																	report	visit	
9	275	Reboxetine	06/11/91	17/12/91	30/10/91(2)	Summary	21	20/11/91	21	3	1	3	1	3	3	1	NO		
						Detail	21	20/11/91	21	3	1	3	1	3	3	1	NO		
						Summary	21	20/11/91	21	3	1	3	1	3	3	1	NO		
276	Imipramine	14/01/92	14/01/92	07/01/92	Summary	7	15/01/92	7	1	1	6	3	2	2	3	1	NO		
					Detail	7	15/01/92	7	1	1	6	3	2	2	3	1	NO		
					Summary	7	15/01/92	7	1	1	6	3	2	2	3	1	NO		
9/A	233	Imipramine	14/05/92	24/06/92	18/01/92	Summary	7	15/01/92	7	2	2	3	3	2	3	1	NO		
						Detail	7	15/01/92	7	2	2	3	3	2	3	1	NO		
						Summary	7	15/01/92	7	2	2	3	3	2	3	1	NO		
234	Reboxetine	22/05/92	02/07/92	01/06/92	Summary	42	24/06/92	42	2	2	4	1	YES	2	3	3	YES		
					Detail	42	24/06/92	42	2	2	4	1	YES	2	3	3	YES		
					Summary	42	24/06/92	42	2	2	4	1	YES	2	3	3	YES		
235	Reboxetine	26/05/92	29/06/92	26/05/92	Summary	42	04/07/92	42	1	2	2	3	2	2	3	1	YES		
					Detail	42	04/07/92	42	1	2	2	3	2	2	3	1	YES		
					Summary	42	04/07/92	42	1	2	2	3	2	2	3	1	YES		

Severity: 0=unknown, 1= mild, 2=moderate, 3=severe.
 Study drug: 1= no change, 2=dose reduced, 3=def. withdrawn, 4=stop. 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
 (f) onset date missing; first report visit date used
 (g) onset date missing; start treatment date of report visit

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PHARMACIA CNS RMD

RESOMETINE - PROTOCOL 20126/817
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Types record	Visit No	End date	Last report visit	Save rity	Hist any ship	Rel. Stud Sympt	Dis app.	Re app.	Out come	Skill Present (C)			
			Start date	End date															
9/A	256	Imipramine	27/05/92	07/07/92	MOUTH DRY	Detail	16			1	2	2	1	2	3	3			
						Detail	21		1	2	2	1	2	3	3	3			
						Detail	28		1	2	2	1	2	3	3	3			
						Detail	35		1	2	2	1	2	3	3	3			
						Detail	42	03/07/92	1	2	2	1	2	3	3	3			
		Summary	03/07/92	42	1	2	2	1	2	3	3	1	2	3	3	1	YES		
277	Reboxetine	10/06/92	16/06/92	AGITATION	Detail	7	16/06/92		3	2	2	3	2	2	3	1			
					Summary	16/06/92	7	3	2	2	3	2	2	3	1	YES			
		HYPOHYDRIISM	06/06/92(3)	11/06/92		Detail	8	16/06/92(*)		0	3	1	6	3	2	1	3	3	Y
						Summary	16/06/92	8	3	1	6	3	2	1	3	3	Y		
						Detail	7	16/06/92(*)		7	5	1	6	3	2	1	3	3	Y
						Summary	16/06/92(*)	7	5	1	6	3	2	1	3	3	Y		
		INSOMNIA	11/06/92			Detail	7	16/06/92		3	2	2	3	2	2	3	1	YES	
						Summary	16/06/92	7	3	2	2	3	2	2	3	1	YES		
		SWEATING INCREASED	11/06/92			Detail	7	16/06/92		3	2	2	3	2	2	3	1	YES	
						Summary	16/06/92	7	3	2	2	3	2	2	3	1	YES		
278	Imipramine	19/06/92	03/07/92	HYPERKINESIA		Detail	7	17/06/92		2	2	3	1	2	3	3	1	YES	
						Summary	17/06/92	7	2	2	3	1	2	3	3	1	YES		
279	Imipramine	07/08/92	21/08/92	NAUSEA		Detail	7	10/08/92		2	2	2	1	2	3	3	1	YES	
						Summary	10/08/92	7	2	2	2	1	2	3	3	1	YES		
		PALPITATION	19/08/92			Detail	7			2	2	2	1	2	3	3	3		
						Detail	14		2	2	2	1	2	3	3	3	Y		
						Summary	21/08/92(*)	14	2	2	2	1	2	3	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. -- Outcome: 1=recovered, 2=erro. 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
 (c) 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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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 201204/017
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit End No date	Last visit rfty	report save	Hist rly	Hst dry	Hst drug	Hst app.	Dis	Re	Dut	Still	
			Start date	End date														
9/A	280	Reboxetine	08/08/92	16/08/92	DIZZINESS	Detail	7	14/08/92(*)	2	2	2	3	2	1	3	3	Y	
			Summary	7	2	2	3	2	1	3	3	Y						
			08/08/92		MOUTH DRY	Detail	7	14/08/92(*)	7	3	2	2	3	2	1	3	3	Y
			Summary	7	3	2	3	2	1	3	3	Y						
			08/08/92		SOMNOLENCE	Detail	7	14/08/92(*)	7	2	2	2	3	2	1	3	3	Y
			Summary	7	2	2	3	2	1	3	3	Y						
	281	Reboxetine	01/09/92	12/10/92	INSOMNIA	Detail	7		2	2	4	1	YES	2	3	3	3	
			Summary	14	14	09/92	14	2	2	4	1	YES	2	3	3	1	NO	
	282	Reboxetine	02/09/92	15/10/92	MOUTH DRY	Detail	7		1	2	2	1	2	3	3	3	3	
			Detail	14	1	2	1	2	3	3								
			Summary	21	28/09/92	21	1	2	1	2	3	1	YES					
	284	Imipramine	19/09/92	09/10/92	MOUTH DRY	Detail	7		1	2	2	1	2	3	3	3	3	
Summary			14	30/09/92	14	1	2	1	2	3	1	YES						
301	Imipramine	05/03/92	15/04/92	MOUTH DRY	Detail	7		1	2	2	1	2	3	3	3	3		
		Detail	14	1	2	1	2	3	3									
		Detail	21	1	2	1	2	3	3									
		Detail	28	1	2	1	2	3	3									
		Detail	35	1	2	1	2	3	3									
		Summary	42	15/04/92(*)	42	1	2	1	2	3	3	Y						
		PALPITATION	14/03/92			Detail	14		1	2	1	2	3	3	3	3		
			Detail	21	1	2	1	2	3	3								
			Detail	28	27/03/92	28	1	2	1	2	3	1	YES					
			Summary	27/03/92	28	1	2	1	2	3	1	YES						

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
Study drug: 1=not changed, 2=dose reduced, 3=def. withdrawn, 4=comp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Naspp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=not known, 5=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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REBOXETINE - PROTOCOL 20126/017
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Center	Patient	Drug	Treatment		Onset date	Type record	Visit No	End date	Last report	Sweat	Rel. Stud	Hosp	Drug	Appr.	Dis	Rt	Out	Still	Present (c)																																																				
			Start date	End date																																																																			
9/A	302	Imipramin	05/05/92	22/03/92	INSOMNIA		14	15/05/92	Detail	2	2	4	1	YES	2	3	3	3	3	3	YES																																																		
							21															28/03/92	2	2	4	1	YES	2	3	3	1																																								
							Summary															28/03/92	21	2	2	4	1	YES	2	3	3	1																																							
							7															07/05/92	MOUTH DRY		Detail	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	YES																														
							14																																			1	2	2	1	2	3	3	3	3																					
							21																																			23/03/92(*)	21	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3										
							Summary																																			23/03/92(*)	21	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3										
							7																																			07/05/92	SWEATING INCREASED		Detail	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	YES									
							14																																																								1	2	2	1	2	3	3	3	3
							21																																																								23/03/92(*)	21	1	2	2	1	2	3	3
Summary	23/03/92(*)	21	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3																																																		
7	14/05/92	MOUTH DRY		Detail	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	YES																																																		
14																																																															1	2	2	1	2	3	3	3	3
21																						31/03/92(*)	21	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3																														
Summary																						31/03/92(*)	21	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3																						3								
7																						14/05/92	SWEATING INCREASED		Detail	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3																						YES								
14																																																																1	2	2	1	2	3	3	3
21																																										31/03/92(*)	21	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3										
Summary																																										31/03/92(*)	21	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3									
7																																										28/05/92	MOUTH DRY		Detail	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	YES									
14																																																																1	2	2	1	2	3	3	3
21	31/03/92(*)	21	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3																																																			
Summary	31/03/92(*)	21	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3																																																		
7	02/06/92	MOUTH DRY		Detail	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	YES																																																		
14																																																																1	2	2	1	2	3	3	3
21																						14/10/04/92	21	1	2	2	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3																														
Summary																						14/10/04/92	21	1	2	2	1	2	3	3	3	3	3	3	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. 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./Reappl: 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
(*) onset date missing; start treatment date of report visit

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 17.8

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	Std	Sump	Dis	Re	Dut	Still	Last report visit		
																				only	drug	area
9/A	305	Reboxetine	31/05/92	11/05/92	11/05/92	MOUTH DRY	02/06/92	Summary	14	1	2	2	1			2	3	3	1	YES		
	306	Reboxetine	29/06/92	09/06/92	09/06/92	FATIGUE	29/06/92	Detail	7		2	2	1			2	3	3	3			
								Summary	14	2	2	2	1			2	3	3	1	YES		
								Detail	7		2	2	1			2	3	3	3			
								Summary	14	2	2	2	1			2	3	3	1	YES		
	367	Imipramine	05/05/92	06/05/92	06/05/92	AGITATION	06/05/92	Detail	7		5	2	2	3		2	2	3	1	YES		
								Summary	10/05/92	7	3	2	2	3		2	2	3	1	YES		
								Detail	7		3	2	2	3		2	2	5	1	YES		
								Summary	10/05/92	7	3	2	2	3		2	2	5	1	YES		
	368	Imipramine	09/05/92	02/06/92	02/06/92	FATIGUE	10/05/92	Detail	7		2	2	2	1		2	3	3	3			
								Detail	14		2	2	1			2	5	3	3			
								Detail	21		1	2	1			2	3	3	3			
								Detail	28		3	2	3			2	1	3	3	Y		
								Summary	02/06/92(*)	28	3	2	2	3		2	1	3	3	Y		
								Detail	7		2	2	4	1	YES	2	3	3	3			
								Summary	02/06/92	28	2	2	4	1	YES	2	3	3	1	YES		
								Detail	7		1	2	2	1		2	3	3	3			
								Detail	14		2	2	1			2	3	3	3			
								Detail	21		1	2	1			2	3	3	3			
								Detail	28		1	2	2	3		2	1	3	3	Y		
								Summary	02/06/92(*)	28	2	2	2	3		2	1	3	3	Y		
								Detail	7		2	2	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
 (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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PHARMACIA CNS RSD
 REMOETINE - PROTOCOL 20126/017
 Listing No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Onset date	Adverse event	Start date	End date	Type	Visit No	Last report visit	Searched	Hist rity	Rel. to drug	Simp. app.	Dis. app.	Re. app.	Out. app.	Still present	(c)		
																				report visit	dry
9/A	588	Imipramine	89/05/92	02/06/92	SWEATING INCREASED	10/05/92	14	Detail	1	2	2	1	2	3	3						
									21	1	2	1	2	3	3						
									28	3	2	3	2	1	3	3	Y				
									Summary	02/06/92(*)	28	3	2	3	2	1	3	3	Y		
10	289	Imipramine	21/05/91	27/09/91	URINARY TRACT INFECTION	29/05/92	21	Detail	1	2	6	1	2	3	3						
									28	1	2	6	3	2	2	3	1				
									Summary	31/05/92	28	1	2	6	3	2	2	3	1		
									Detail	7	2	4	1	3	5	3	3	Y			
290	Reboetine	14/10/91	24/11/91	FATIGUE	20/09/91	7	Detail	1	3	3	1	3	3	3	3	Y					
								21	1	3	4	1	2	3	3	1					
								Summary	04/11/91	21	1	3	3	1	2	3	3	1			
								Detail	7	2	3	3	1	3	3	3	Y				
291	Imipramine	17/02/92	29/05/92	DIZZINESS	17/10/91	7	Detail	1	2	3	1	2	3	3	3						
								14	1	3	1	3	3	3	3	1					
								Summary	28/10/91	14	1	2	3	1	2	3	3	1			
								Detail	14	1	2	3	1	YES	2	3	3	3			
9/A	588	Imipramine	17/02/92	29/05/92	DIZZINESS	21/02/92	14	Detail	1	2	3	1	YES	2	3	3	3				
									21	1	2	3	1	YES	2	3	3	3			
									28	1	2	3	1	2	3	3	3	3			
									Summary	30/05/92(*)	42	1	2	3	1	YES	2	3	3	3	Y
9/A	588	Imipramine	17/02/92	29/05/92	DIZZINESS	02/03/92	14	Detail	1	2	3	1	YES	3	3	3	3				
									21	1	2	3	1	YES	3	3	3	3	Y		
									28	1	2	3	1	YES	3	3	3	3	Y		
									Summary	30/05/92(*)	42	1	2	3	1	YES	3	3	3	3	Y

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
 Study drug: 1=none, 2=dose reduced, 3=def. withdrawn, 4=temp. held, 5=permanent withdrawal
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcomes: 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
 (P) onset date missing: first report visit date used
 (S) onset date missing: start treatment date of report visit

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	Sae	Hst	Rst	Stud	Sympt	Disapp	Re	Out	Still		
		Start date	End date																	
10	Imipramine	17/02/92	25/03/92	22/02/92	TREMOR	Detail	7		2	2	3	1				2	3	3	3	
		Detail	14				2	2	3	1				2	3	3	3	3	3	
		Detail	21				2	2	3	1				2	3	3	3	3	3	3
		Summary	28			14/03/92	2	2	3	1				2	3	3	3	3	3	3
292	Reboxetine	15/12/91	25/01/92	13/12/91	SWEATING INCREASED	Detail	7		1	2	3	1				3	3	3	1	
		Summary	13/12/91			7	1	2	3	1				3	3	3	1			
293	Reboxetine	24/12/91	01/02/92	10/01/92	URINARY TRACT INFECTION	Detail	21		2	2	3	1				3	3	3	3	
		Detail	28			17/01/92	2	2	3	1				3	3	3	3	1		
		Summary	17/01/92			28	2	2	3	1				3	3	3	3	1		
294	Imipramine	03/01/92	25/01/92	09/01/92	CONSTIPATION	Detail	14		2	2	3	1				3	3	3	3	
		Detail	21				2	2	3	1				3	3	3	3	3	3	
		Summary	23/01/92(*)			21	2	2	3	1				3	3	3	3	3	3	3
294	Imipramine	03/01/92	25/01/92	09/01/92	INSOMNIA	Detail	14		2	2	3	1				3	3	3	3	
		Detail	21				2	2	3	1				3	3	3	3	3	3	
		Summary	23/01/92(*)			21	2	2	3	1				3	3	3	3	3	3	3
294	Imipramine	03/01/92	25/01/92	09/01/92	NAUSEA	Detail	14		2	2	3	1				3	3	3	3	
		Detail	21				2	2	3	1				3	3	3	3	3	3	
		Summary	23/01/92(*)			21	2	2	3	1				3	3	3	3	3	3	3
295	Imipramine	07/01/92	17/02/92	25/01/92	DIZZINESS	Detail	7		2	1	4	1				3	3	3	3	
		Detail	14			14/01/92	1	1	4	1				3	3	3	3	3	1	
		Summary	14/01/92			14	2	1	4	1				3	3	3	3	3	1	
295	Imipramine	07/01/92	17/02/92	25/01/92	DIZZINESS	Detail	28	01/02/92	3	2	2	4				3	2	3	1	
		Summary	01/02/92			28	3	2	2	4				3	2	3	1			

Sae: 1=Blank, 2=moderate, 3=severe, 4=life threatening, 5=death, 6=unknown
 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
 (E) adverse event still present; end date = visit date
 (D) onset date missing; first report visit date used

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PHARMACIA CNS RBD

REBOSETLINE - PROTOCOL 20124/817
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit record	End No date	Last report visit	Sae rity	Hst	Hst	Rel	Stud	Syp	Dis app.	Re app.	Out	Still	
			Start date	End date																
10	296	Reboxetine	29/02/92	01/06/92	AGITATION		Detail	7	1	2	3	1	2	3	1	2	3	3	3	
								Detail	14	05/03/92	1	2	3	1	2	3	3	1		
								Summary	05/03/92	14	1	2	3	1	2	3	3	1	YES	
								Detail	7	1	3	5	1	2	3	3	3			
								Detail	14	05/03/92	1	3	5	1	2	3	3	1	YES	
								Summary	05/03/92	14	1	3	5	1	2	3	3	1	YES	
								Detail	7	2	2	3	1	YES	3	3	3	3		
								Detail	42	2	2	3	1	YES	3	3	3	3	Y	
								Summary	02/04/92(*)	42	2	2	3	1	YES	3	3	3	Y	
								Summary												
295	Reboxetine	27/03/92	07/05/92	HEADACHE		Detail	28	1	2	3	1	YES	3	3	3	3	3	3		
							Detail	35	28/04/92	1	2	3	1	YES	3	3	3	1	YES	
							Summary	28/04/92	35	1	2	3	1	YES	3	3	3	1	YES	
							Detail	21	2	2	2	1	3	3	3	3	3			
							Detail	28	2	2	2	1	3	3	3	3	3			
							Detail	35	2	2	2	1	3	3	3	3	3			
							Detail	42	3	2	2	1	3	3	3	3	3	Y		
							Summary	07/05/92(*)	42	3	2	2	1	3	3	3	3	Y		
							Summary													
							299	Imipramine	07/06/92	18/05/92	INSOMNIA		Detail	7	2	3	5	1	YES	3
Detail	42	19/05/92(*)	2	3	5	1								YES	3	3	3	3	Y	
Summary	19/05/92(*)	42	2	3	5	1								YES	3	3	3	3	Y	
Detail	7	2	3	5	1	2								3	3	3	3			
Detail	14	2	3	5	1	2								3	3	3	3			
Detail	21	2	3	5	1	2								3	3	3	3			
Detail	28	2	3	5	1	2								3	3	3	3			
Detail	35	1	3	5	1	2								3	3	3	3			
Detail	42	1	3	5	1	2								3	3	3	3	Y		
Summary	19/05/92(*)	42	2	3	5	1								2	3	3	3	Y		

Severities: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
 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=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
 (a) onset date missing: first report visit date used
 (b) onset date missing: start treatment date of report visit

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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	End date	Last report visit	Sae	Rty	Hst	Hosp	Rel. app.	Stud. app.	Dis. app.	Re. app.	Out. app.	Skill	Present (C)																											
																						report	visit	date	date	date	date	date	date	date	date	date	date	date	date	date	date	date	date	date								
10	299	Imipramine	07/04/92	16/05/92	NAUSEA	16/04/92	Detail	14			1	3	3	1	2	3	3	3	3	3	3	3	YES																									
																								Detail	21	1	3	3	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3					
																								Detail	20	1	3	3	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3		
																								Detail	35	1	3	3	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3		
																								Summary	42	1	3	3	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
300	Imipramine	16/04/92	25/05/92	HEADACHE	12/05/92	Detail	42			42	1	3	3	1	2	3	3	3	3	3	3	3	YES																									
																								Summary	19/05/92(1*)	42	1	3	3	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3			
																								Detail	28	11/05/92	28	2	3	3	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
																								Summary	35	11/05/92	35	2	3	3	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
																								Detail	42	26/05/92(1*)	42	2	3	3	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
11	321	Reboxetine	11/06/92	23/07/92	BRONCHITIS	13/05/92	Detail	95			1	3	3	1	2	3	3	3	3	3	3	3	YES																									
																								Detail	42	26/05/92(1*)	42	1	3	3	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3			
																								Summary	26/05/92(1*)	42	1	3	3	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
																								Detail	14	21/06/92	14	2	2	6	1	YES	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
																								Summary	26/06/92	21	2	2	6	1	YES	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
322	Reboxetine	11/06/92	24/07/92	HEADACHE	13/06/92	Detail	7				2	2	3	1	2	3	3	3	3	3	3	3	YES																									
																								Detail	21	30/06/92	21	3	2	3	1	YES	2	3	3	3	3	3	3	3	3	3	3	3	3			
																								Summary	30/06/92	21	3	2	3	1	YES	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
																								Detail	35	15/07/92	35	2	1	4	1	YES	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
																								Summary	15/07/92	35	2	1	4	1	YES	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
					MOUTH DRY	24/06/92	Detail	14	01/07/92		2	2	3	1	2	3	3	3	3	3	3	3	3																									
																								Summary	14	01/07/92	2	2	3	1	2	3	3	3	3	3	3	3	3	3	3	3	3	3				

Severity: 1=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.
 Disapp./Comp.: 1=no, 2=yes, 3=not appl.
 Relationship: 1=definite, 2=probable, 3=possible, 4=undetectable, 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
 (E) onset date missing: start treatment date of report visit

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PHARMACIA CNS RED
 REMOXETINE - PROTOCOL 20124/017
 Listing No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

Center	Patient Drug	Treatment		Onset date	Adverse event	Type record	Visit End No data	Last report visit	Sere rity	Hist ory	Hist ship	Rel drug	Stu app.	Sym treat	Dis app.	Re app.	Dut app.	Still app.	
		Start date	End date																
11	322	Reboxetine	11/06/92	24/07/92	MOUTH DRY	Summary	01/07/92	14	2	2	3	1	2	1	2	3	1	YES	
	323	Imipramine	26/06/92	04/08/92	APPETITE INCREASED	Detail 26 Detail 42 Summary		2 1 42	2	2	3	1	2	3	3	3	3	3	Y
					INFLUENZA-LIKE SYMPTOMS	Detail 14 Summary	04/07/92 09/07/92	14 14	1	1	4	1	YES	2	3	3	1	YES	
					MOUTH DRY	Detail 7 Detail 26 Detail 42 Summary		2 1 2 42	2	2	2	1	2	3	3	3	3	3	Y
					TREMOR	Detail 7 Detail 26 Detail 42 Summary		2 1 2 42	2	2	3	1	2	3	3	3	3	3	Y
	324	Imipramine	17/07/92	28/08/92	ASTHMA	Detail 21 Summary	04/08/92 04/08/92	21 21	1	1	4	1	YES	2	3	3	1	YES	
					DIZZINESS	Detail 7 Detail 14 Detail 21 Detail 42 Summary		1 1 2 42	1	2	3	1	2	3	3	3	3	3	Y
					MOUTH DRY	Detail 7 Detail 14 Summary		2 1 42	2	2	3	1	2	3	3	3	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. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=search
 Disapp./Kepp.: 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
 (3) onset date missing: start treatment date of report visit

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PHARMACIA CNS RD
 REBOXETINE - PROTOCOL 28126/017
 Listings No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type	Visit record	No data	Last report visit	rcty	Mist	Rel	Stud	Samp	Dis app.	Re app.	Out	Still								
			Start date	End date																						
11	325	Reboxetine	30/07/92	18/09/92	DIZZINESS	01/08/92	Detail	7		1	2	3	1	2	3	1	2	3	3							
							Detail	14	10/08/92	1	2	3	1	2	3	3	1	2	3	3	1	2	3	3		
							Detail	21	15/08/92	1	2	3	1	2	3	3	1	2	3	3	1	2	3	3	1	
							Summary	15	08/92	21	1	2	3	1	2	3	3	1	2	3	3	1	2	3	3	1
							INFLUENZA-LIKE SYMPTOMS																			
							Detail	21	10/08/92	1	1	4	1	2	3	3	1	2	3	3	1	2	3	3	1	
							Summary	10	08/92	21	1	1	4	1	2	3	3	1	2	3	3	1	2	3	3	1
							HOT FLUSHES																			
							Detail	7	05/08/92	1	2	3	1	2	3	3	1	2	3	3	1	2	3	3	1	
							Summary	05	08/92	7	1	2	3	1	2	3	3	1	2	3	3	1	2	3	3	1
							326	Empiramine	30/07/92	10/09/92	HOT FLUSHES	31/07/92	Detail	7	05/08/92	1	2	3	1	2	3	3	1	2	3	3
Summary	05	08/92	7	1	2	3							1	2	3	3	1	2	3	3	1	2	3	3		
TINSOMNIA																										
Detail	21	10/08/92	2	2	2	1							2	3	3	1	2	3	3	1	2	3	3	1		
Summary	10	08/92	21	2	2	2							1	2	3	3	1	2	3	3	1	2	3	3	1	
MOUTH DRY																										
Detail	7	07/92	2	2	2	1							2	3	3	1	2	3	3	1	2	3	3	1		
Detail	21	07/92	1	2	2	1							2	3	3	1	2	3	3	1	2	3	3	1		
Detail	42	07/92	1	2	3	1							3	3	3	1	2	3	3	1	2	3	3	1		
Summary	10	07/92	42	2	2	2							1	2	3	3	1	2	3	3	1	2	3	3	1	
327	Reboxetine	20/08/92	01/10/92	CONSTIPATION	21/08/92	Detail							7			2	2	3	1	2	3	1	2	3	3	
						Summary	01	10/92	7	2	2	3	1	2	3	3	1	2	3	3	1	2	3			
						OTITIS MEDIA																				
						Detail	21	16/08/92	1	2	4	1	2	3	3	1	2	3	3	1	2	3	3	1		
						Summary	16	08/92	21	1	2	4	1	2	3	3	1	2	3	3	1	2	3	3		
						PALPITATION																				
						Detail	14	15/08/92	1	2	4	1	2	3	3	1	2	3	3	1	2	3	3	1		
						Summary	15	08/92	14	1	2	4	1	2	3	3	1	2	3	3	1	2	3	3		
						SWEATING INCREASED																				
						Detail	7	07/92	2	2	2	1	2	3	3	1	2	3	3	1	2	3	3	1		
						Detail	14	07/92	1	2	3	1	2	3	3	1	2	3	3	1	2	3	3	1		
Detail	21	19/08/92	1	2	3	1	2	3	3	1	2	3	3	1	2	3	3	1								
Summary	19	08/92	21	2	2	2	1	2	3	3	1	2	3	3	1	2	3	3								

Severity: 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=search
 Disapp./Appr.: 1=no, 2=yes, 3=not app. -- Relationship: 1=unlikely, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (4) adverse event still present: end date = visit
 (4) onset date missing: first report visit date used
 (8) onset date missing: start treatment date of report visit

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PHARMACIA CNS REG
 REMONETINE - PROTOCOL 20124/017
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	End date	Last report visit	Shave rity	Hist dry	Rel. Stud drug	Sym treat	Dis Hosp	Re app.	Re some	Out present	Skill (C)				
			Start date	End date																		
11	527	Reboxetine	20/06/92	01/10/92	CONSTIPATION	Detail	28		1	2	3	1	2	3	3	3	3					
			Detail	35			1	2	3	1	2	3	3	3								
			Detail	42			1	2	3	1	2	3	3	3	Y							
			Summary			01/10/92(*)	42	2	2	3	1	2	3	3	3	Y						
			Detail	21			2	1	3	1	2	3	3	3								
			Detail	42			1	1	3	1	2	3	3	3	Y							
			Summary			01/10/92(*)	42	2	1	3	1	2	3	3	3	Y						
			Detail	14		01/09/92		2	1	4	1	YES	2	3	3	1						
			Summary			01/09/92	14	2	1	4	1	YES	2	3	3	1						
			Detail	35		18/09/92		2	1	4	1	YES	2	3	3	1						
			Summary			18/09/92	35	2	1	4	1	YES	2	3	3	1						
528	Imipramine	20/08/92	17/09/92	MOUTH DRY	Detail	7		2	1	3	1	2	3	3	3							
					Detail	26		1	2	3	1	2	3	3	3							
					Detail	35		1	2	3	1	2	3	3	3							
					Detail	42		1	2	3	1	2	3	3	3	Y						
					Summary		01/10/92(*)	42	2	1	3	1	2	3	3	3	Y					
					Detail	7		2	1	2	1	2	3	3	3							
					Detail	21		1	1	3	1	2	3	3	3							
					Detail	28		1	1	3	1	2	3	3	3	Y						
					Summary		17/09/92(*)	28	2	1	2	1	2	3	3	3	Y					
					329	Imipramine	21/08/92	02/10/92	ABDOMINAL PAIN	Detail	42		01/10/92	2	1	4	1	2	3	3	1	
										Summary		01/10/92	42	2	1	4	1	2	3	3	1	
Detail	7	27/08/92		2						1	3	1	2	3	3	1						
Summary		27/08/92	7	2						1	3	1	2	3	3	1						
Detail	7	22/08/92		2						1	3	1	2	3	3							
Summary		22/08/92	7	2						1	3	1	2	3	3							
Detail	7	22/08/92		2						1	3	1	2	3	3							
Summary		22/08/92	7	2						1	3	1	2	3	3							
Detail	7	22/08/92		2						1	3	1	2	3	3							
Summary		22/08/92	7	2						1	3	1	2	3	3							

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=def. withdrawn, 4=stop. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcomes: 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
 (E) onset date missing: start treatment date of report visit

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PHARMACIA CNS RBD
 REBOXETINE - PROTOCOL 20124/917
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	Last visit rity	Sympt	Rel	Drug	Hosp	Dis	Re	Out	Skill
			Start date	End date												
11	329	Imipramine	21/08/92	02/10/92	DIZZINESS	Detail	14	1	1	3	1			2	3	3
						Detail	21	1	1	4	1		2	3	3	3
						Summary	28	2	1	3	1		2	3	3	1
330	Reboxetine	24/08/92	26/08/92	HEADACHE	Detail	42	2	1	4	1	YES			2	3	1
					Summary	62	2	1	4	1	YES		2	3	1	
					Detail	7	2	2	3			2	2	3	1	
331	Reboxetine	05/09/92	15/10/92	CONSTIPATION	Detail	14	2	2	3	1				2	3	3
					Detail	21	1	2	3	1		2	3	3	3	
					Summary	28	2	2	3	1		2	3	3	1	
332	Imipramine	05/09/92	20/10/92	MOUTH DRY	Detail	42	1	2	3	1				2	3	3
					Summary	62	1	2	3	1		2	3	3	Y	
					Detail	7	1	2	2	1		2	3	3	Y	

ADVERSE EVENTS: DETAIL AND SUMMARY

Severities: 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=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
 (e) onset date missing: start treatment date of report visit

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PHARMACIA CIS RBD

REBOMETINE - PROTOCOL 20124/917
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	Save ery	Hist ship	Re app.	Dis app.	Re pres	Out Skill					
																visit	freq	freq	freq	freq
11	532	Imipramine	05/09/92	20/10/92	MOUTH DRY	05/09/92	Detail	21	25/09/92	1	2	3	1	2	3	3	1			
						Summary	21	25/09/92	1	2	2	1	2	3	3	1	YES			
						26/09/92	Detail	20	1	2	3	1	2	3	3	3				
							Detail	35	1	2	2	1	2	3	3	3				
							Detail	42	1	2	3	1	2	3	3	3				
							Detail	42	1	2	3	1	2	3	3	3				
							Summary	42	1	2	2	1	2	3	3	3	1	YES		
						26/09/92	Detail	20	1	2	2	1	2	3	3	3				
							Detail	42	1	2	3	1	2	3	3	3		Y		
							Summary	42	1	2	2	1	2	3	3	3	Y	YES		
							25/09/92	Detail	20	2	2	2	1	2	3	3	3			
Detail	42	1	2	2	1			3	3	3	3		Y							
25/09/92	Summary	42	2	2	2	1	2	3	3	3	Y	YES								
	10/05/92(2)	Detail	8	06/07/92(1)	0	3														
Summary		8	06/07/92(1)	0	3										NO					
12	537	Imipramine	26/05/92	06/07/92	AGITATION	10/05/92(2)	Detail	8	06/07/92(1)	0	3									
						Summary	8	06/07/92(1)	0	3										
						23/06/92	Detail	35	23/06/92	5	2	1	2	3	2	1	1			
							Summary	35	23/06/92	5	2	1	2	3	2	1	1		YES	
						26/05/92	Detail	7	06/07/92(1)	1	2	2	1	3	3	3	Y			
							Summary	7	06/07/92(1)	1	2	2	1	3	3	3	Y		YES	
						26/05/92	Detail	8	26/05/92	2	1	4	1	YES	3	3	3	1		
							Summary	7	26/05/92	2	1	4	1	YES	3	3	3	1	NO	
						10/05/92(2)	Detail	8	06/07/92(1)	0	2									
							Summary	8	06/07/92(1)	0	2									

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening
 Study drug: 1=no change, 2=dose reduced, 3=discontinued, 4=withdrawn, 5=other
 Hospital: 1=required, 2=not req, 3=not appl.
 Disapp./Resp.: 1=no, 2=yes, 3=not appl.
 Symptomatic treatment: 1=no, 2=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

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PHARMACIA CNS R&D
 REBROSETIME - PROTOCOL 20124/017
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Adverse event	Type record	Visit No	End date	Last visit	report	Sae	Hst	Rel	Stud	Sym	Dis	Re	Out	Skill		
			Start date	End date																		
12	337	Imbruvina	26/05/92	06/07/92	25/06/92	HECTURITION DISORDER	Detail	85	25/06/92	35	2	2	1	2	3	2	1	2	1	1	YES	
							Summary		23/06/92													
			20/06/92			PALPITATION	Detail	28	28/06/92	28	1	2	3	1	3	3	3	1				YES
							Summary		28/06/92													
			23/06/92				Detail	35	25/06/92	35	1	2	2	2	3	2	1	1				YES
							Summary		25/06/92													
			26/05/92			SOMNOLENCE	Detail	7	06/06/92	7	1	2	2	1	3	3	3	1				YES
							Summary		06/06/92													
			25/06/92				Detail	35	23/06/92	35	3	2	1	2	3	2	1	1				YES
							Summary		23/06/92													
			25/06/92			TACHYCARDIA	Detail	35	25/06/92	35	1	2	2	2	3	2	1	1				YES
							Summary		25/06/92													
			01/07/92			UPPER RESP TRACT INFECTED	Detail	42	05/07/92	42	1	1	6	1	YES	3	3	1				YES
							Summary		05/07/92													
			25/06/92			URINARY RETENTION	Detail	35	23/06/92	35	2	2	1	2	3	2	1	1				YES
							Summary		23/06/92													
			23/06/92			VOMITING	Detail	35	23/06/92	35	2	2	1	2	YES	2	2	1	1			YES
							Summary		23/06/92													
336	Rebasectine	20/06/92	31/07/92		31/07/92	CONSTIPATION	Detail	0	31/07/92(*)	0	2											NO
							Summary															
			25/06/92			FLATULENCE	Detail	7	31/07/92(*)	7	2	2	5	1	3	3	3	3	3	3	3	Y
							Summary		31/07/92(*)													
			17/06/92			HEADACHE	Detail	0		1												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. -- 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
 (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 RED
 REMOXETINE - PROTOCOL 20126/917
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment		Onset date	Type record	Visit End No data	Last report visit	Sev	Hist	Rel	Stu	Sym	DLE	Re	Out	Still	
		Start date	End date														
12	336	Reboxetine	20/06/92	31/07/92	HEADACHE	Summary	31/07/92(*)	0	1								NO
					INSOMNIA	Detail 0 Detail 21 Summary		3	1	4	1	YES	3	3	3	3	Y
					MOUTH DRY	Detail 0 Detail 21 Summary	18/07/92(*)	21	1	4	1	YES	3	3	3	3	Y
						Detail 0 Detail 21 Summary	18/07/92(*)	21	1	4	1		3	3	3	3	NO
					PALPITATION	Detail 0 Summary	21/07/92(*)	0	1								NO
					RHINITIS	Detail 21 Summary	09/07/92	21	1	6	1	YES	3	3	3	3	YES
					UPPER RESP TRACT INFECTION	Detail 85 Summary	26/07/92	35	1	6	1	YES	3	3	3	3	YES
						Detail 14 Summary	05/07/92	14	2	1	4	1		3	3	3	YES
					CONSTIPATION	Detail 7 Summary	03/08/92(*)	7	1	2	1	YES	3	3	3	3	YES
					HEADACHE	Detail 14 Summary	16/07/92	14	1	2	3	1		3	3	3	YES
					MOUTH DRY	Detail 7 Summary	05/08/92(*)	7	1	2	2	1		3	3	3	YES

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
 Study drug: 1=no change, 2=dose reduced, 3=stop, 4=withdrewn, 5=temp. inter.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=pro. with seq., 3=still present, 4=severe
 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
 (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 of report visit

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PHARMACIA CNS RBD
 REMOXETINE - PROTOCOL 20124/017
 Listing No.: 17.9

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	Sev	Hist	Rel	Stud	Symp	Dis	Re	Out	Still
			date	date	date	adverse event			visit rity	0	1	2	3	4	5	6	7	8
12	539	Imipramine	23/06/92	03/08/92	03/07/92	TRACT INFECTION	Detail	14	06/07/92	1	1	6	1	YES	3	3	3	1
					30/07/92	UPPER RESP TRACT	Summary	66/07/92	14	1	1	6	1	YES	3	3	3	1
							Detail	62	04/08/92	1	1	6	1	YES	2	3	3	1
							Summary	04/08/92	02	1	1	6	1	YES	2	3	3	1
340	Raboxetine	07/08/92	17/09/92	ABDOMINAL PAIN	10/08/92	Detail	7	13/08/92(4)	7	1	2	3	1	3	3	3	3	3
						Summary	13/08/92(4)	7	1	2	3	1	3	3	3	3	3	3
					11/08/92	CONSTIPATION	Detail	7	12/08/92	2	2	2	1	YES	3	3	3	1
						Summary	12/08/92	7	2	2	2	1	YES	3	3	3	1	
					10/08/92	FLATULENCE	Detail	7	13/08/92	2	2	2	1	YES	3	3	3	1
						Summary	13/08/92	7	2	2	2	1	YES	3	3	3	1	
					02/07/92	INSOMNIA	Detail	0	28/08/92	0	1	6	1	3	3	3	1	NO
						Summary	28/08/92	28	1	6	1	1	3	3	3	1	NO	
					05/08/92	NAUSEA	Detail	0	30/08/92	0	1	6	1	3	3	3	1	NO
						Summary	30/08/92	28	1	6	1	1	3	3	3	1	NO	
					18/08/92	PARAESTHESIA	Detail	14	20/08/92	2	2	3	1	3	3	3	1	YES
						Summary	20/08/92	14	2	2	3	1	3	3	3	1	YES	
					25/08/92	UPPER RESP TRACT INFECTION	Detail	21	31/08/92	1	1	6	1	YES	3	3	3	1
						Summary	31/08/92	21	1	1	6	1	YES	3	3	3	1	
541	Raboxetine	21/08/92	24/09/92	FLATULENCE	28/08/92	Detail	14	27/09/92	3	2	2	3	3	3	2	3	1	YES
						Summary	27/09/92	14	3	2	2	3	3	3	2	3	1	YES
					14/09/92	HEADACHE	Detail	28	14/09/92	2	1	5	1	YES	3	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=treated, 2=not treated, 3=not applicable -- 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
 (2) onset date missing: first report visit date used

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PHARMACIA CNS RSD
REBOXETINE - PROTOCOL 20124/017
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	Save r.f.y	Hist ofy	Rel. to drug	Simp	Hosp	Dis. app.	Re. app.	Out. app.	Still Present (c)												
		Start date	End date																											
12	341	Reboxetine	21/08/92	24/09/92	HEADACHE	Summary		24/09/92(*)	28	2	1	5	1	YES	3	3	3	3	Y	YES										
						Detail		28/09/92	2	2	2	3	3	2	3	1	YES													
						Summary		28/09/92	28	2	2	2	3	3	2	3	1	YES												
						Detail		07/09/92	21	2	2	3	3	3	2	3	1	YES												
						Summary		30/09/92	21	2	2	3	3	3	2	3	1	YES												
						Detail		24/08/92	7	01/09/92	2	2	2	1	3	3	3	1	YES											
						Summary		01/09/92	7	2	2	2	1	3	3	3	1	YES												
						Detail		23/08/92	7	24/09/92(*)	7	1	2	3	1	3	3	3	Y	YES										
						Summary		24/09/92(*)	7	1	2	3	1	3	3	3	3	Y	YES											
						13	353	Reboxetine	05/08/92	07/07/92	MICTURITION DISORDER	Detail		7	1	1	6	1	YES	2	3	3	3	3	3	Y	YES			
												Detail		14	1	1	2	1	YES	2	3	3	3	3	3	3	3	3	3	3
												Detail		28/03/92	28	03/07/92	28	1	1	2	1	YES	2	3	3	3	3	3	3	3
Summary		03/07/92	28	1	1							2	1	YES	2	3	3	3	3	3	3	3	3	3	3					
Detail		07/07/92	55	07/07/92	55							2	1	3	2	2	3	1	YES											
Summary		07/07/92	55	2	1							3	2	2	2	3	1	YES												
Detail		23/07/92	55	25/07/92	55							2	1	6	1	YES	2	3	3	1	YES									
Summary		25/07/92	55	2	1							6	1	YES	2	3	3	1	YES											
Detail		25/08/92	7	27/06/92	7							2	1	2	3	2	2	3	1	YES										
Summary		27/06/92	7	2	1							2	3	2	2	3	1	YES												
14	355	Reboxetine	25/06/92	27/06/92	ABDOMINAL PAIN							Detail		7	27/06/92	7	2	2	3	2	2	3	1	YES						
												Summary		27/06/92	7	2	2	3	2	2	3	1	YES							
						Detail		25/08/92	7	27/06/92	7	2	2	3	2	2	3	1	YES											
						Summary		27/06/92	7	2	2	3	2	2	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. 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
 (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 RBD
 REBORETINE - PROTOCOL 20124/017
 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	Samp	Rel	Hist	Trea	Hosp	Dis app.	Re com.	Out	Still												
			Start date	End date																											
13	355	Reboretine	25/06/92	27/06/92	DYSPEPSIA		Detail	7	29/06/92	7	2	1	2	3	2	2	2	3	1	YES											
			Summary	29/06/92			7	2	1	2	3	2	2	2	3	1	YES														
			25/06/92				HEADACHE		Detail	7	01/07/92(*)	7	2	2	2	3	2	1	3	3	3	Y	YES								
			Summary	01/07/92(*)					7	2	2	3	2	1	3	3	Y	YES													
			25/06/92						NAUSEA		Detail	7	01/07/92(*)	7	2	1	2	3	2	1	3	3	Y	YES							
			Summary	01/07/92(*)							7	2	1	2	3	2	1	3	3	Y	YES										
			29/07/92								HEADACHE		Detail	14	02/08/92(*)	14	1	1	6	1	YES	2	3	3	3	Y	YES				
			Summary	02/08/92(*)									14	1	1	6	1	YES	2	3	3	3	Y	YES							
			28/07/92										TREMBL		Detail	7		7	2	2	1	2	3	2	3	3	3	3	Y		
			Detail	14												14	1	2	1	2	3	3	3	3	3	3	3	3	3	Y	
			Detail	21												21	1	2	1	2	3	3	3	3	3	3	3	3	3	3	Y
			Detail	35												35	1	2	4	1	2	5	3	3	3	3	3	3	3	3	Y
			Detail	42												42	1	2	3	1	2	3	3	3	3	3	3	3	3	3	Y
Summary	02/08/92(*)	42	2	2	2	1									2	3	3	3	3	3	3	3	3	3	3	Y					
10/08/92		ASTHENIA		Detail	7										7	3	1	2	3	2	1	3	3	3	3	Y					
Summary	12/08/92(*)			7	3	1	2	3							2	1	3	3	3	Y											
18/08/92				DIZZINESS		Detail	7								7	3	2	2	3	2	1	3	3	3	Y						
Summary	12/08/92(*)					7	3	2	2	3					2	1	3	3	Y												
05/08/92						SINUSITIS		Detail	7	06/08/92					7	1	2	3	3	2	2	3	3	3	1	YES					
Summary	06/08/92							7	1	2	3	3			2	2	3	3	1	YES											
18/08/92								SOMNOLENCE		Detail	7				7	3	2	2	3	2	1	3	3	3	Y						
Summary	12/08/92(*)									7	3	2	2	3	2	1	3	3	Y												
26/08/92										DIZZINESS		Detail	26	30/08/92	26	2	2	4	2	2	4	2	2	1	1	1					

Severity: 1=unknown, 2=mild, 3=moderate, 4=severe, 5=critical
 Study drug: 1=none, 2=drug, 3=drug+placebo, 4=drug+placebo+control, 5=drug+placebo+control+placebo
 Hospital: 1=required, 2=not req., 3=not appl., 4=not appl., 5=not appl.
 Disapp./Reapp.: 1=none, 2=yes, 3=not appl., 4=not appl., 5=not appl.
 Relationship: 1=definite, 2=probable, 3=possible, 4=definite, 5=unknown, 6=none
 Symptomatic treatment: 0=no, 1=yes
 (C) adverse event used for statistical analysis
 (4) adverse event still present: end date = visit date
 (5) onset date missing: first report visit date used

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/917
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit	End No	Last report visit	Save	Hist	Rel	Stud	Symp	Dis	Re	Out	Still		
				data	data		data	records		data	visit	city	ary	ship	drug	traa	Hosp	app.	app.	come	present	(c)
13	358	Reboxetine	06/08/92	05/09/92	05/09/92	DIZZINESS	28/08/92	Summary	30/08/92	28	2	2	2	2	4	2	2	2	1	1	YES	
							05/09/92	Summary	06/09/92	35											YES	
						MOUTH DRY	05/08/92	Detail	7	1	2	2	1	2	3	3						
								Detail	16	1	2	1	2	3	3							
								Detail	21	1	2	1	2	3	3							Y
								Summary	06/09/92	21	1	2	2	1	2	3	3					NO
						SWEATING INCREASED	26/08/92	Detail	28	2	2	2	4	2	2	1	1					YES
								Summary	30/08/92	28	2	2	4	2	2	1	1					YES
							05/09/92	Detail	35													YES
								Summary	06/09/92	35												YES
359		Reboxetine	19/08/92	29/09/92	29/09/92	HYPOAESTHESIA	18/09/92	Detail	55	22/09/92	1	2	4	1	2	3	1	1				YES
								Summary	22/09/92	55	1	2	4	1	2	3	1	1				YES
360		Imipramine	19/08/92	21/08/92	21/08/92	AGITATION	19/08/92	Detail	7	24/08/92	3	2	2	3	2	2	3	1				YES
								Summary	24/08/92	7	3	2	2	3	2	2	3	1				YES
						HOT FLUSHES	19/08/92	Detail	7	24/08/92	3	2	2	3	2	2	3	1				YES
								Summary	24/08/92	7	3	2	2	3	2	2	3	1				YES
						INSOMNIA	19/08/92	Detail	7	24/08/92	3	2	2	3	2	2	3	1				YES
								Summary	24/08/92	7	3	2	2	3	2	2	3	1				YES
361		Reboxetine	26/08/92	06/10/92	06/10/92	HEADACHE	05/10/92	Detail	42	06/10/92	2	3	4	1	YES	2	3	3	1			YES
								Summary	06/10/92	42	2	3	4	1	YES	2	3	3	1			YES
						HYPOTENSION POSTURAL	29/08/92	Detail	7	05/09/92	1	2	1	2	3	3	1					YES
								Detail	14	05/09/92	1	2	1	2	3	3	1					YES
								Summary	05/09/92	14	1	2	2	1	2	3	3	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=stems. 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
 (d) adverse event still present: end date = visit data
 (e) onset date missing: first report visit date used

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/917
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment		Onset date	Type	Visit	End	Last report	Save	Hist	Rel	Stu	Somp	Dis	Re	Out	Still		
		Start date	End date															visit	city
13	361	Reboxetine	26/08/92	06/10/92	RHINITIS	20	21/09/92	20	21/09/92	1	2	4	1	2	3	3	1	YES	
						Summary	25	21/09/92	25	1	2	4	1	2	3	3	1		
						Detail	20	21/09/92	20	1	2	4	1	2	3	3	1		
14	457	Reboxetine	07/07/92	17/08/92	MOUTH DRY	14		14		1	2	2	1	2	3	3	3	Y	
						Summary	28	18/08/92(*)	28	1	2	2	1	2	3	3	3		Y
						Detail	14		14	1	2	2	1	2	3	3	3		Y
458	Imipramine	14/07/92	24/08/92	CONSTIPATION	7		7		1	3	3	1	2	3	3	3	Y		
					Summary	42	25/08/92(*)	42	1	3	3	1	2	3	3	3		Y	
					Detail	7		7	1	3	3	1	2	3	3	3		Y	
461	Imipramine	29/07/92	06/09/92	CONSTIPATION	14		14		1	3	3	1	3	3	3	3	Y		
					Summary	42	09/09/92(*)	42	2	3	3	2	3	1	3	3		Y	
					Detail	14		14	1	3	3	1	3	3	3	3		Y	
462	Reboxetine	31/07/92	10/09/92	CONSTIPATION	14		14		1	3	3	1	3	3	3	3	Y		
					Summary	42	09/09/92(*)	42	2	3	3	2	3	1	3	3		Y	
					Detail	14		14	1	3	3	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=stam. inter.
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
(*) onset date missing; first report visit date used

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PHARMACIA CNS RBD
REBOXETINE -- PROTOCOL 20124/917
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 city	Hist	Rel	Stud	Symp	Dis	Re	Out	Still		
14	464	Reboxetine	05/08/92	16/09/92	FATIGUE	26/08/92	Detail 26	2	2	2	1	3	3	3	3	3	3	3	3	3		
							Detail 35	2	2	2	2	3	2	3	1							
							Summary 08/09/92	35	2	2	2	3	2	3	1						YES	
							Detail 42	2	1	4	1	3	3	3	3	3	3	3	3	3	Y	
							Summary 17/09/92(*)	42	2	1	4	1	3	3	3	3	3	3	3	3	Y	
							Detail 42	2	2	4	1	3	3	3	3	3	3	3	3	3	Y	
							Summary 17/09/92(*)	42	2	2	4	1	3	3	3	3	3	3	3	3	Y	
							Detail 7	1	2	3	1	3	3	3	3	3	3	3	3	3	3	
							Detail 14	1	2	3	1	3	3	3	3	3	3	3	3	3	3	
							Detail 21	1	3	3	1	3	3	3	3	3	3	3	3	3	3	
							Detail 28	1	3	3	1	3	3	3	3	3	3	3	3	3	3	
							Detail 35	1	3	3	1	3	3	3	3	3	3	3	3	3	3	
							Detail 42	1	3	3	1	3	3	3	3	3	3	3	3	3	3	
							Summary 30/08/92	28	1	2	5	1	3	3	3	3	3	3	3	3	1	
							Summary 30/08/92	28	1	2	5	1	3	3	3	3	3	3	3	3	1	
14/1	129	Reboxetine	19/12/91	19/12/91	MICTURITION DISORDER	19/12/91	Detail 7	5	2	2	3	2	2	3	1						YES	
							Summary 19/12/91	7	5	2	3	2	2	3	1							YES
							Detail 14	2	2	2	1	3	3	3	3	3	3	3	3	3	3	
							Detail 21	2	1	4	1	3	3	3	3	3	3	3	3	3	3	
							Summary 24/09/91	21	2	1	2	1	3	3	3	3	3	3	3	3	1	
							Detail 14	2	2	2	1	3	3	3	3	3	3	3	3	3	3	
							Detail 21	2	2	2	1	3	3	3	3	3	3	3	3	3	3	
							Detail 28	1	2	2	1	3	3	3	3	3	3	3	3	3	3	
							Detail 35	1	2	2	1	3	3	3	3	3	3	3	3	3	3	
							Detail 42	1	2	2	1	3	3	3	3	3	3	3	3	3	3	
							Summary 17/10/91(*)	42	2	2	2	1	3	3	3	3	3	3	3	3	3	
							Summary 17/10/91(*)	42	2	2	2	1	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	
							Detail 21	2	1	4	1	3	3	3	3	3	3	3	3	3	3	
							Summary 24/09/91	21	2	1	2	1	3	3	3	3	3	3	3	3	1	
							Detail 7	2	1	6	1	YES	3	3	3	3	3	3	3	3	1	
							Summary 10/09/91	7	2	1	6	1	YES	3	3	3	3	3	3	3	1	
							Detail 28	1	1	6	1	3	3	3	3	3	3	3	3	3	3	
							Detail 35	1	1	6	1	3	3	3	3	3	3	3	3	3	3	
							Detail 42	1	1	6	1	3	3	3	3	3	3	3	3	3	3	
							Summary 11/10/91	42	1	1	6	1	3	3	3	3	3	3	3	3	1	
							Summary 11/10/91	42	1	1	6	1	3	3	3	3	3	3	3	3	1	

Severely: 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./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 DMS RED
 REDDENTINE - PROTOCOL 20124/917
 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 Pcty	HIST ary	Rel ship	Stud Sym	Dis Hosp	Re app.	Out come	Still present (C)	
147	429	Imipramine	26/09/91	26/09/91	ANOREXIA	27/09/91	Detail	7	02/10/91	7	2	2	2	3	2	2	3	1	YES
							Summary												
			26/09/91		ASTHENIA	26/09/91	Detail	7	30/09/91	7	3	2	2	3	2	2	3	1	YES
							Summary												
			26/09/91		DIZZINESS	26/09/91	Detail	7	30/09/91	7	2	2	2	3	2	2	3	1	YES
							Summary												
			26/09/91		FATIGUE	26/09/91	Detail	7	30/09/91	7	5	2	2	3	2	2	3	1	YES
							Summary												
			26/09/91		HEADACHE	26/09/91	Detail	7	30/09/91	7	2	1	2	3	2	2	3	1	YES
							Summary												
			26/09/91		MOUTH DRY	26/09/91	Detail	7	30/09/91	7	2	2	2	3	2	2	3	1	YES
							Summary												
			26/09/91		NAUSEA	26/09/91	Detail	7	30/09/91	7	2	2	2	3	2	2	3	1	YES
							Summary												
451		Imipramine	28/11/91	07/01/92	ARTHRITIS	01/01/92	Detail	42	06/01/92(*)	42	3	1	6	1	YES	3	3	3	Y
							Summary												
			10/12/91		AV BLOCK	10/12/91	Detail	21			1	2	5	1	3	3	3	3	Y
							Detail	42			1	2	5	1	3	3	3	3	Y
							Summary				42	1	2	5	1	3	3	3	Y
			26/11/91(CD)		CIRCULATORY FAILURE	26/11/91(CD)	Detail	0			2								NO
							Summary												

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=as 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=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
 (CD) onset date missing; first report visit date used

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PHARMACIA DNS 103D

REBOMETINE - PROTOCOL 20124/017
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment	Start date	End date	Onset date	Type	Visit record	Last report visit	Save rity	Hist dry	Rel ship	Re Stud	Dis app.	Re Out	Still presen		
14/1	451	Insipiramide	25/11/91	07/01/92	DIABETES MELLITUS	24/11/91(3)	Detail 0 Summary 0	08/01/92(*)	0	1						NO		
					HYPERTENSION	24/11/91(2)	Detail 0 Summary 0	08/01/92(*)	0	2						NO		
					MOUTH DRY	25/11/91	Detail 7 Summary 21	02/12/91 02/12/91	7	2	3	1	3	3	3	1	YES	
						16/12/91	Detail 21 Summary 28		2	2	3	1	3	3	3	3		
						Detail 35 Summary 42			2	2	3	1	3	3	3	3	Y	
						08/01/92(*)			42	2	2	3	3	3	3	3	Y	
452	Reboxetine	28/11/91	09/01/92	BRONCHITIS	02/01/92	Detail 42 Summary 42	09/01/92		42	2	3	6	1	YES	3	3	1	
						09/01/92			42	2	3	6	1	YES	3	3	1	
					HYPERCHESTEROLAEMIA	23/12/91	Detail 28 Summary 28	09/01/92(*)	28	2	3	5	1	YES	3	3	3	Y
						23/12/91	Detail 28 Summary 28		28	1	1	5	1	YES	3	3	1	
					HYPERTENSION	23/12/91	Detail 28 Summary 28	27/12/91	28	1	1	5	1	YES	3	3	1	
					MOUTH DRY	21/12/91	Detail 28 Summary 35		2	1	3	1	3	3	3	3		
						06/01/92	Detail 42 Summary 42	06/01/92	42	2	1	3	1	3	3	3	1	
						06/01/92			42	2	1	3	1	3	3	3	1	
					PALEPTATION	08/12/91	Detail 14 Summary 21	16/12/91	21	2	2	3	1	3	3	3	1	

-- 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. 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
(3) onset date missing: first report visit date used

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PHARMACIA CNS RFD
REBOXETINE - PROTOCOL 20124/017
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient Drug	Treatment	Start date	End date	Adverse event	Onset date	Type	Visit record	Enc No	Last report visit	Save rity	Hist ary	Re al stud	St ud	St ill	Dis app.	Re com	St ill	
14/1	452	Reboxetine	20/11/91	09/01/92	PARAESTHESIA	08/12/91	Detail	14		21	2	2	3	1	3	3	3	3	3
							Summary		18/12/91		2	2	2	3	1	3	3	3	1
14/2	134	Imipramine	15/01/92	25/02/92	AGITATION	15/01/92	Detail	7		14	1	2	3	1	2	3	3	3	3
							Summary		19/01/92		1	2	3	1	2	3	3	3	1
					CONSTIPATION	15/01/92	Detail	7		14	1	2	2	1	2	3	3	3	3
							Summary		24/01/92		1	2	2	1	2	3	3	3	1
					MOUTH DRY	15/01/92	Detail	7		14	1	2	2	1	2	3	3	3	3
							Summary		24/01/92		1	2	2	1	2	3	3	3	1
454		Imipramine	15/06/92	26/05/92	CONSTIPATION	09/05/92	Detail	28		28	1	2	3	1	2	3	3	3	1
							Summary		09/05/92		1	2	3	1	2	3	3	3	1
					DIZZINESS	21/04/92	Detail	7		21	1	2	3	1	2	3	3	3	1
							Summary		21/04/92		1	2	3	1	2	3	3	3	1
					MOUTH DRY	16/06/92	Detail	7		7	1	2	3	1	2	3	3	3	1
							Summary		19/06/92		1	2	3	1	2	3	3	3	1
					NAUSEA	22/04/92	Detail	14		14	1	1	3	1	2	3	3	3	1
							Summary		22/04/92		1	1	3	1	2	3	3	3	1
14/3	417	Reboxetine	14/06/91	26/07/91	DERMATITIS FUNGAL	16/07/91	Detail	35		42	2	1	4	1	1	1	1	1	3
							Summary		29/07/91		2	1	4	1	1	1	1	1	3

Severity: 0=unknown, 1= mild, 2= moderate, 3= severe, 4= life threatening
 Study drug: 1= no change, 2= dose reduced, 3= stop, 4= withdrawn, 5= other
 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
 (Q) onset date missing: first report visit date used

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PHARMACIA CNS RBD
REBOXETINE - PROTOCOL 20126/017
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	Re-visit	His-ory	Sue-cess	Rel-ated	Stu-dy	Sym-p-oms	Dis-appe-ared	Re-appe-ared	App-rop-ri-ate	Some-thing	Still	Present	(C)	
			Start date	End date																				
14/3	417	Reboxetine	14/06/91	24/07/91	30/06/91	DIZZINESS	Detail	21	04/07/91	21	2	2	3	1	3	3	3	1	3	3	3	1	YES	
							Summary	04/07/91	21	2	2	3	1	3	3	3	3	1	3	3	3	1	YES	
							Detail	05/07/91	21	26/07/91(*)	21	1	2	4	1	3	3	3	3	3	3	3	3	Y
							Summary	05/07/91	21	26/07/91(*)	21	1	2	4	1	3	3	3	3	3	3	3	3	Y
419	Reboxetine	05/07/91				BLOBULINES INCREASED	Detail	21	04/07/91	21	2	2	3	1	2	3	3	1	2	3	3	1	YES	
						Summary	04/07/91	21	2	2	3	1	2	3	3	3	1	2	3	3	3	1	YES	
						Detail	30/06/91																	
						Summary	30/06/91																	
421	Reboxetine	15/07/91	15/08/91	19/07/91	MOUTH DRY	Detail	21				2	2	2	1	3	3	3	3	3	3	3	3	3	
						Detail	28				2	2	2	1	3	3	3	3	3	3	3	3	3	
						Detail	35	05/08/91				2	2	2	1	3	3	3	3	3	3	3	3	3
						Summary	05/08/91				35	2	2	2	1	3	3	3	3	3	3	3	3	3
422	Reboxetine	19/07/91	12/09/91	26/07/91	DYSPEPSIA	Detail	14	26/07/91	14	2	1	4	1	YES	3	3	1	1	1	1	1	1	YES	
						Summary	26/07/91	14	2	1	4	1	YES	3	3	1	1	1	1	1	1	1	1	YES
427	Imipramine	10/10/91	15/10/91	10/10/91	DESOPHAGITIS	Detail	26	16/10/91(*)	26	3	2	3	3	2	2	3	3	3	2	2	3	3	Y	
						Summary	16/10/91(*)	26	3	2	3	3	2	2	3	3	3	2	2	3	3	3	Y	
428	Imipramine	15/09/91		15/09/91	TASTE PERVERSION	Detail	7				2	2	2	1	2	3	3	3	2	2	3	3	3	
						Detail	14	27/09/91	14	2	2	2	1	2	2	1	2	3	3	1	1	1	1	YES
						Summary	27/09/91	14	2	2	2	1	2	2	1	2	3	3	1	1	1	1	1	YES
						Detail	14																	
429	Imipramine	06/11/91	05/12/91	06/11/91	HYPOMESTHESIA	Detail	14				1	2	5	1	2	3	3	3	2	2	3	3	3	
						Summary	12/11/91	21	1	2	5	1	2	3	3	1	2	3	3	1	1	1	1	YES
14/4	Imipramine	14/01/92	26/02/92	14/01/92	HEADACHE	Detail	7	26/01/92	7	2	2	3	1	3	3	3	3	3	2	2	3	3	3	1
						Summary	26/01/92	7	2	2	3	1	3	3	3	3	3	3	3	2	2	3	3	3

Serivity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
 Study drug: 1=no change, 2=dose reduced, 3=stop, 4=withdrewn, 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
 (D) onset date missing: first report visit date used
 (S) onset date missing: start treatment date of report visit

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PHARMACIA CNS RSD

REBOXETINE - PROTOCOL 20126/017
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit End No data	LabC report visit r1cy	Saw Hist	Rel. Stud Sympt	Dis Hosp	Re app.	Out app.	Still			
			Start date	End date													
16/4	131	Imipramine	14/01/92	24/02/92	MOUTH DRY	Detail	7			1	2	2	1	3	3	3	
			Detail	14		25/01/92	1	2	2	1	3	3	3	1			
			Summary	25		01/92	14	1	2	2	1	3	3	3	1	YES	
135	Imipramine	16/01/92	26/02/92	HEADACHE	Detail	28	10/02/92			2	1	4	1	3	3	1	
		Summary	30		02/92	28	2	1	4	1	3	3	3	1	YES		
135	Reboxetine	17/01/92	27/02/92	DIZZINESS	Detail	7	22/01/92			2	2	3	1	3	3	1	
		Summary	22		01/92	7	2	2	3	1	3	3	3	1	YES		
16/7	422	Imipramine	01/09/91	15/10/91	ARTHRALGIA	Detail	0	18/10/91(*)		3						NO	
			Summary	18		10/91(*)	0	3								NO	
423	Imipramine	17/09/91	28/10/91	HEADACHE	Detail	14				1	2	3	1	2	3	3	
					Detail	21											
					Detail	26											
					Detail	35											
					Detail	42											
Summary	16	10/91(*)	42	2	2	3	1	2	3	3	3	1	YES				
423	Imipramine	17/09/91	28/10/91	HEADACHE	Detail	14				2	2	3	1	2	3	3	
					Summary	28	12/10/91	28	2	2	3	1	2	3	3	1	YES
423	Imipramine	17/09/91	28/10/91	MOUTH DRY	Detail	42				1	2	3	1	2	3	3	
					Summary	29	10/91(*)	42	1	2	3	1	2	3	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= dose withdrawn, 4= comp. inc. acc.
 Hospital: 1= required, 2= not req., 3= not appl. -- Outcome: 1= recovered, 2= prev. with seq., 3= still present, 4= reach
 Disapp./Repp.: 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
 [4] adverse event still present: end date = visit date
 [6] onset date missing: first report visit date used
 [8] onset date missing: start treatment date of report visit

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PHARMACIA CNS RSD
 REBOXETINE - PROTOCOL 20124/417
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No date	Last report visit	Save rity	Hist ery	Rel ship	Rea drug	Dis app.	Re come	Out app.	Skill Present (C)							
			Start date	End date																			
14/7	424	Reboxetine	19/09/91	30/10/91	HEADACHE	Detail	35	25/10/91	35	1	2	4	1	2	3	3	1						
						Summary													YES				
						Detail	0																
						Detail	7							1	6	1	2	3	3	3			
						Detail	14							2	1	3	1	2	3	3			
						Detail	21							2	1	3	1	YES	2	3	3		
						Summary								2	1	3	1	YES	2	3	3		
						Detail	31/10/91(*)							2	1	3	1	YES	2	3	3		
						Summary								2	1	3	1	YES	2	3	3		
						Detail	04/11/91							2	1	3	1	2	3	3	1		
						Summary								2	1	3	1	2	3	3	1		
						Detail	06/11/91							2	1	3	1	2	3	3	1		
						Summary								2	1	3	1	2	3	3	1		
			430	Reboxetine	07/10/91	17/11/91	INFLUENZA-LIKE SYMPTOMS	06/11/91	Detail	35	19/11/91	35	2	2	6	1	2	3	3	1			
	Summary																			YES			
								Detail	21														
								Detail	28							1	2	1	1	2	3	3	
								Detail	35							2	2	1	1	2	3	3	
								Detail	42							1	2	1	1	2	3	3	
								Summary								2	2	1	1	2	3	3	
								Detail	18/11/91(*)							4	2	2	1	1	2	3	3
								Summary								4	2	2	1	1	2	3	3
								Detail	06/11/91							2	2	6	1	YES	2	3	3
								Summary								3	2	6	1	YES	2	3	3
								Detail	25/10/91							1	2	1	1	2	3	3	
								Summary								1	2	1	1	2	3	3	
431	Reboxetine	06/10/91						18/11/91	FEVER	25/10/91	Detail	21	26/10/91	21	2	2	3	1	2	3	3	1	
				Summary																YES			
						Detail	0																
						Summary										1	1	1	1	2	3	3	
						Detail	23/10/91									2	3	3	1	2	3	3	
						Detail	26									1	3	3	1	2	3	3	
						Detail	35									1	3	3	1	2	3	3	
						Summary										1	3	3	1	2	3	3	
						Detail	07/10/91(*)									1	1	1	1	2	3	3	
						Summary										1	1	1	1	2	3	3	
						Detail	23/10/91									2	3	3	1	2	3	3	
						Summary										2	3	3	1	2	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=dose withdrawn, 4=temp. incar.
 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
 (P) onset date missing: first report visit date used
 (S) onset date missing: start treatment date of report visit

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PHARMACIA CNS RBD

REBOMETINE - PROTOCOL 20124/017
Listing No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Adverse event	Type record	Visit No	End date	List report	Save Hist	Rel. Ship	Drug	Tras	Hosp	App.	Dis	Re	Out	Skill										
			Start date	End date																										
1477	431	Rebometine	08/10/91	18/11/91	25/10/91	LIBIDO DECREASED	Detail	42	19/11/91(*)	42	2	3	3	1	2	3	3	3	3	3	3	Y								
			Summary																											
			Detail	20			01/11/91	1	2	3	1	2	3	3																
			Detail	35				1	2	2	1	2	3	3																
			Detail	42				1	2	2	1	2	3	3																
			Summary				19/11/91(*)	42	1	2	2	1	2	3	3														Y	
			Detail	21			24/10/91	2	3	3	1	2	3	3																
			Detail	26			01/11/91	2	3	3	1	2	3	3																
			Summary				01/11/91	26	2	3	3	1	2	3	3															Y
			Detail	21			23/10/91	2	3	3	1	2	3	3																
			Detail	26			02/11/91	2	3	3	1	2	3	3																
			Summary				02/11/91	26	2	3	3	1	2	3	3															Y
			Detail	28			01/11/91	1	2	3	1	2	3	3																
			Detail	35				2	2	2	1	2	3	3																
Detail	42		1	2	2	1	2	3	3																					
Summary		19/11/91(*)	42	2	2	2	1	2	3	3															Y					
Detail	28	30/10/91	2	2	1	1	2	3	3																					
Detail	35		2	2	1	1	2	3	3																					
Detail	42		1	2	1	1	2	3	3																					
Summary		19/11/91(*)	42	2	2	1	1	2	3	3																Y				
Detail	21	24/10/91	1	2	3	1	2	3	3																					
Summary		24/10/91	21	1	2	3	1	2	3	3																Y				
Detail	21	25/10/91	1	2	3	1	2	3	3																					
Detail	26		1	2	3	1	2	3	3																					
Detail	35	09/11/91	1	3	3	1	2	3	3																					
Summary		09/11/91	35	1	2	3	1	2	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. withdrawal, 4= temp. inter.
 Hospital: 1= required, 2= not req., 3= not appl. -- Outcome: 1= recovered, 2= rel. with seq., 3= still present, 4= search
 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, 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

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PHARMACIA CNS R&D
 REMOXETINE - PROTOCOL 20184/017
 Listing No.: 17.0
 ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	End date	Last visit	report	Sue	Hist	Rel	Stud	Symp	Dis	Re	Out	Still	present (c)				
			Start date	End date																				
14/7	433	Imipramine	05/10/91	16/11/91	06/11/91	MOUTH DRY	35		19/11/91(*)	42	2	2	1	1	1	2	3	3	3	3	Y			
			42																					
			Summary																					
434	Reboxetine	14/10/91	24/11/91	22/10/91	HEADACHE	14																		
		21																						
		28																						
435	Reboxetine	11/11/91	22/12/91	20/11/91	MOUTH DRY	14																		
		21																						
		28																						
439	Reboxetine	11/11/91	22/12/91	20/11/91	MOUTH DRY	14																		
		21																						
		28																						
440	Imipramine	11/11/91	22/12/91	02/12/91	TACHYCARDIA	21		02/12/91	21	2	1	3	1	1	2	3	3	1			YES			
		28																						
		Summary																						
442	Imipramine	11/11/91	22/12/91	05/12/91	HEADACHE	28		06/12/91	28	2	2	3	1	1	2	3	3	1			YES			
		42																						
		Summary																						
449	Imipramine	11/11/91	22/12/91	02/12/91	TACHYCARDIA	21		02/12/91	21	2	1	3	1	1	2	3	3	1			YES			
		28																						
		Summary																						

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe.
 Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inacc.
 Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
 Disapp./Kapp.: 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
 (9) onset date missing: first report visit date used
 (8) onset date missing: start treatment date of report visit

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Adverse event	Type record	Visit No	Last report visit date	Saves	Hist	Rel	Stu	Sym	Dis	Re	Out	Skill
			Start date	End date														
14/8	139	Reboxetine	10/01/92	28/02/92	18/02/92	MICTURITION DISORDER	Detail	35	21/02/92(*)	1	2	2	1	2	3	3	3	3
							Summary	42		42	1	2	2	1	2	3	3	3
467		Reboxetine	06/07/92	16/08/92	16/07/92	MICTURITION DISORDER	Detail	14	17/08/92	1	2	2	3	2	2	3	3	3
							Summary	42		42	1	2	3	1	2	3	3	3
14/10	83	Reboxetine	25/02/92	06/06/92	16/02/92(*)	PROSTATIC DISORDER	Detail	0	06/06/92(*)	2								
							Summary	0		0	2							
54		Imipramine	26/02/92	07/04/92	17/02/92(*)	HYPERTENSION	Detail	0	07/04/92(*)	2								
							Summary	0		0	2							
55		Reboxetine	26/02/92	09/04/92	26/02/92	NAUSEA	Detail	7	02/03/92	1	2	1	1	3	3	3	3	3
							Summary	82/03/92	7		7	1	2	1	1	3	3	3
55		Reboxetine	26/02/92	09/04/92	27/03/92	ARTHRALGIA	Detail	35	31/03/92	2	2	6	1	YES	3	3	3	3
							Summary	31/03/92	35		35	2	2	6	1	YES	3	3
56		Imipramine	17/01/92		17/01/92	FLATULENCE	Detail	0	09/04/92(*)	2								
							Summary	0		0	2							
56		Imipramine	19/03/92		19/03/92	BAMBA-CT INCREASED	Detail	21	09/04/92	1	2	4	1	3	3	3	3	3
							Summary	09/04/92	21		21	1	2	4	1	3	3	3
56		Imipramine	14/07/88		14/07/88	HYPOTENSION	Detail	0	09/04/92(*)	2								
							Summary	0		0	2							
56		Imipramine	10/03/92	15/04/92	10/03/92	ARTHRALGIA	Detail	21	22/03/92	2	2	6	1	YES	3	3	3	3
							Summary	22/03/92	21		21	2	2	6	1	YES	3	3

Severity: 1=unknown, 2=mild, 3=moderate, 4=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
(*) adverse event still present: end date = visit date
(*) onset date missing: first report visit date used

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PHARMACIA CNS RED
REBORETTINE - PROCTON 20126/017
Listing No.: 17.9

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	End date	Last report visit	Sev	MIST	Rel. ship	Stud. Sympt	Dis. app.	Re. app.	Out. app.	Still present (C)					
			Start date	End date																		
14/10	54	Imipramine	03/03/92	13/04/92	03/03/92	Detail	7	08/03/92	7	1	2	1	1	2	3	3	1					
						Summary			08/03/92	7	1	2	1	1	2	3	3	1				
57	Reborettine	06/03/92	14/04/92	GASTROENTERITIS	01/04/92	08/04/92	01/04/92	Detail	35	2	2	6	1	YES	3	3	3	1				
								Summary			08/04/92	35	2	2	6	1	YES	3	3	3	1	
58	Imipramine	14/04/92	25/05/92	MOUTH DRY	24/02/92(C)	13/04/92(1*)	24/02/92(C)	Detail	0	0	1											
								Summary			13/04/92(1*)	0	1									
59	Imipramine	14/04/92	06/06/92	NAUSEA	03/03/92	14/04/92	03/03/92	Detail	7	0	2	1	1	2	3	3	1					
								Summary			14/04/92	7	0	2	1	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
 (*) 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

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20126/017
Listing No.: 17.6

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient ID	Drug	Treatment	Start date	End date	Adverse event	Onset date	Type record	Visit No	End No data	Last report visit	Sae	Hst	Rat	Stud	Sym	Dis app.	Re	Ra	Out	Still	(c)																					
																							visit rcty	ory	ship	drug	tra	Hosp	app.	come	present												
14/10	137	Reboxetine	28/01/92	09/03/92	MOUTH DRY	28/01/92	Detail	7	1	2	1	1	1	1	1	1	3	3	3	3	3	3	3																				
																								21	14/02/92	21	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
185	185	Imipramine	29/01/92	19/03/92	SOMNOLENCE	28/01/92	Detail	7	2	2	1	1	1	1	1	1	3	3	3	3	3	3	3																				
																								Summary	30/01/92	7	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
139	139	Reboxetine	04/02/92	16/03/92	BRONCHITIS	03/02/92	Detail	95	2	2	6	1	YES	3	3	1	3	3	3	3	3	3	3																				
																								Summary	09/03/92	95	2	2	6	1	YES	3	3	1	3	3	1	3	3	3	3	3	3
140	140	Imipramine	05/02/92	17/03/92	MOUTH DRY	04/02/92	Detail	7	1	2	1	1	1	1	1	1	3	3	3	3	3	3	3																				
																								Summary	11/02/92	7	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
405	405	Imipramine	12/11/91	25/12/91	HYPERTENSION	05/11/91(d)	Detail	0	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2																				
																								Summary	23/12/91(e)	0	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
456	456	Reboxetine	13/11/91	25/12/91	BRONCHITIS	21/12/91	Detail	42	2	2	6	1	YES	2	2	1	2	2	2	2	2	2	2																				
																								Summary	27/12/91	42	2	2	6	1	YES	2	2	1	2	2	1	2	2	2	2	2	2
							15/11/91	Detail	7	1	2	1	1	1	1	1	3	3	3	3	3	3	3																				
																								Summary	16/11/91	7	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

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=covered, 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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PHARMACIA DNS RSD

REBOXETINE - PROTOCOL 20124/017
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	Sae	rity	dry	slip	drug	treat	Hosp	app.	Dis	Re	Out	Still	app. come present (c)										
																									report	visit	dry	slip	drug	treat	Hosp	app.	Dis	Re
14/10	438	Imipramine	15/11/91	27/12/91	BRONCHITIS	22/11/91	Detail	14	27/11/91		14	2	2	6	1	2	3	3	1															
							Summary	27/11/91		14	2	2	6	1	2	3	3	1																
							Detail	85	19/12/91		85	2	2	6	1	YES	2	3	3	1														
							Summary	19/12/91		35	2	2	6	1	YES	2	3	3	1															
							Detail	7	18/11/91		7	1	2	1	1	2	3	3	1															
							Summary	18/11/91		7	1	2	1	1	2	3	3	1																
							Detail	0	27/12/91(0)		0	1																						
							Summary	27/12/91(0)		0	1																							
							443	Reboxetine	19/11/91	30/12/91	MOUTH DRY	18/11/91	Detail	7					2	2	1	1	2	3	3	1								
													Detail	14	01/12/91		14	2	2	1	1	2	3	3	1									
Summary	01/12/91		14	2	2	1							1	2	3	3	1																	
Summary			14	2	2	1							1	2	3	3	1																	
444	Reboxetine	16/11/91	27/12/91	BRONCHITIS	19/11/91	Detail	7	23/11/91		7	2	2	1	1	2	3	3	1																
						Summary	23/11/91		7	2	2	1	1	2	3	3	1																	
						Detail	21	13/12/91		21	2	2	6	1	YES	2	3	3	1															
						Summary	13/12/91		28	2	2	6	1	YES	2	3	3	1																
				DIZZINESS	16/11/91	Detail	7	21/11/91		7	1	2	1	1	2	3	3	1																
						Summary	21/11/91		7	1	2	1	1	2	3	3	1																	
						Detail	0	27/12/91(0)		0	1																							
						Summary	27/12/91(0)		0	1																								
				HYPERTENSION	16/11/91	Detail	7	21/11/91		7	1	2	1	1	2	3	3	1																
						Summary	21/11/91		7	1	2	1	1	2	3	3	1																	
						Detail	0	27/12/91(0)		0	1																							
						Summary	27/12/91(0)		0	1																								

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=def. withdrawn, 4=temp. inter.
 Hospital: 1=required, 2=no req., 3=not appl.
 Disapp./Reapp.: 1=no, 2=yes, 3=not appl.
 Outcome: 1=recovered, 2=rec. with ser., 3=still present, 4=death
 Symptomatic treatment: 0=no, 1=yes
 -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none

(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 DNS RED
 REMOXETINE - PROTOCOL 20126/017
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	End date	Lest report visit	Saves	Mist	Rel	Stud	Sympt	Dis	Re	Out	Still	(c)										
			Start date	End date																									
14/10	445	Imipramine	20/11/91	30/12/91	HYPERLIPAEMIA	Detail	0													NO									
						Summary	0	2	2																				
						Detail	0	2																					
						Summary	0	2																					
						Detail	7	26/11/91																					
						Summary	7	26/11/91																					
						Detail	0	30/12/91																					
						Summary	0	30/12/91																					
						Detail	21	16/12/91																					
						Summary	21	16/12/91																					
446	Reboxetine	26/11/91	07/01/92	BRONCHITIS	Detail	2	2	6	1	YES	2	6	1	YES	2	6	1	YES	2	6	1	YES							
					Summary	2	2	6	1	YES	2	6	1	YES	2	6	1	YES	2	6	1	YES	2	6	1	YES			
447	Reboxetine	27/11/91	07/01/92	ATHEROSCLEROSIS	Detail	0	2																						
					Summary	0	2																						
		31/12/91		CVSTITIS HAEMORRHOIC	Detail	42	06/01/92																						
					Summary	42	06/01/92																						
		25/11/91		DIABETES MELLITUS	Detail	0	07/01/92																						
					Summary	0	07/01/92																						
		25/11/91		HYPERURICAEMIA	Detail	0	07/01/92																						
					Summary	0	07/01/92																						
		27/11/91		NAUSEA	Detail	7	02/12/91																						
					Summary	7	02/12/91																						

Serious: unknown, 1= mild, 2= moderate, 3= severe,
 Study drug: 1= no change, 2= dose reduced, 3= drug withdrawn, 4= temp. inter.
 Hospital: 1= treated, 2= not resp., 3= not appl. -- Outcome: 1= recovered, 2= rec. with seq., 3= still present, 4= death
 Disapp./Recap.: 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
 (8) onset date missing: start treatment date of report visit

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/817
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit End No date	Last report visit	Sev rty	Hst	Rel. ship	Stud. app.	Sym. app.	Dis. app.	Re. app.	Dut. app.	Skill		
			Start date	End date															
14/10	448	Imipramine	28/11/91	07/01/92	23/12/91	Detail	35	29/12/91	2	2	6	1	YES	2	3	3	1		
			Summary				35	29/12/91	2	2	6	1	YES	2	3	3	1		
455	Imipramine	28/05/92	06/07/92	MOUTH DRY	28/05/92	Detail	7	02/06/92	1	2	1	1		3	3	3	1		
							Summary		7	02/06/92	1	2	1	1		3	3	3	1
455	Reboxetine	20/06/92	31/07/92	NAUSEA	28/06/92	Detail	7	25/06/92	2	2	1	1		3	3	3	1		
							Summary		7	25/06/92	2	2	1	1		3	3	3	1
15	349	Imipramine	20/08/92	01/10/92	CONSTIPATION	01/09/92	Detail	14		1	1	3	1	YES	2	3	3	3	
								Detail		21		1	3	1	2	3	3	3	3
								Detail		28		1	3	1	2	3	3	3	3
								Detail		35	21/09/92	1	3	1	2	3	3	3	3
								Summary		35	21/09/92	1	3	1	YES	2	3	3	3
352	Imipramine	06/08/92	27/08/92	FATIGUE	27/08/92	Detail	7	27/08/92	1	1	4	1		2	3	3	1		
							Detail		14	05/09/92	1	2	5	1	2	3	3	1	
							Summary		14	05/09/92	1	1	5	1	2	3	3	1	
352	Imipramine	06/08/92	27/08/92	NAUSEA	06/08/92	Detail	7	06/08/92	1	2	3	1		2	3	3	1		
							Summary		7	06/08/92	1	2	3	1	2	3	3	1	
346	Reboxetine	27/08/92	08/10/92	FLUSHING	01/09/92	Detail	7		1	2	2	1		3	3	3	3		
							Detail		14	04/09/92	1	2	2	1	3	3	3	1	
							Summary		14	04/09/92	1	2	2	1	3	3	3	1	
347	Imipramine	31/08/92	11/10/92	DIZZINESS	09/09/92	Detail	28	26/09/92	1	1	4	1		2	3	3	1		
							Summary		28	26/09/92	1	1	4	1	2	3	3	1	
																		14/09/92	26/09/92

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.
 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
 (S) onset date missing; first report visit date used
 (8) onset date missing; start treatment date of report visit

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PHARMACIA CNS MSD
 REBOMETINE - PROTOCOL 20124/017
 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	Sav rity	Hist ary	Rel drug	Rea trea	Stu app.	Symp	Dis Hosp	Re app.	Onc Still	
			Start date	End date																
15	367	Imipramine	31/08/92	11/10/92	16/09/92	FLUSHING	Summary	26	09/92	26	1	1	3	1	2	3	3	1	YES	
					05/10/92	HYPERTENSION	Detail 35		12/10/92(*)	35					YES				Y	
							Summary								YES				Y	
371	Reboxetine	20/07/92	31/08/92	HEADACHE	27/07/92	Detail 14		2	1	3	1	2	3	3	3	3				
						Detail 21	10/08/92		1	3	1	2	3	3	3	3	1			YES
						Summary	10/08/92	21	1	3	1	2	3	3	3	3	1			
						Detail 42	31/08/92		1	4	1	2	3	3	3	3	Y			YES
						Summary	31/08/92(*)	42	1	4	1	2	3	3	3	3	Y			YES
372	Imipramine	17/06/92	29/07/92	HEADACHE	17/07/92	Detail 35		2	1	2	1	2	3	3	3	3				
						Detail 42	24/07/92		1	2	2	2	3	2	3	1				YES
						Summary	24/07/92	42	2	1	2	2	3	2	3	1				YES
						Detail 35	16/07/92		2	2	1	1	3	3	3	3				
						Detail 42	22/07/92		1	2	2	2	3	2	3	1				YES
						Summary	22/07/92	42	2	2	1	2	3	2	3	1				YES
						Detail 35	29/07/92		2	2	1	1	3	3	3	3				
						Detail 42	22/07/92		1	2	2	2	3	2	3	1				YES
						Summary	22/07/92	42	2	2	1	2	3	2	3	1				YES
374	Reboxetine	09/06/92	20/06/92	DIZZINESS	23/06/92	Detail 14	23/06/92		1	6	1	3	3	3	1					YES
						Summary	23/06/92	14	1	6	1	3	3	3	1					YES
						Detail 7	09/06/92		2	1	3	1	3	3	3	3				
						Detail 14	27/06/92		2	1	2	1	3	3	3	3				
						Detail 21	27/06/92		2	1	3	1	3	3	3	1				YES
						Summary	27/06/92	21	2	1	2	1	3	3	3	1				YES
						Detail 7	15/06/92		2	2	2	1	3	3	3	3				
						Detail 14	15/06/92		1	2	2	1	3	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
 (C) adverse event used for statistical analysis
 (a) adverse event still present; end date = visit date
 (b) onset date missing; first report visit date used

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PHARMACIA DNS RED
 REBOXETINE - PROTOCOL 20124/117
 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment		Onset date	Type record	Visit No	Last report										
			Start date	End date				Save	Visit	dry	shlp	drug	area	hosp	Dis app.	Re app.	Out app.	Still present (c)
374	Reboxetine	09/04/92	28/05/92	TASTE PERVERSION	13/04/92	Detail	21	1	2	2	1	3	3	3	3	3	3	3
						Detail	26	1	2	3	1	3	3	3	3	3	3	
						Detail	35	1	2	2	1	3	3	3	3	3	3	
						Detail	42	1	2	2	1	3	3	3	3	3	3	
						Summary	99	2	2	2	3	3	2	3	1	3	3	1
376	Isipramine	13/04/92	21/04/92	DYSPHAGIA	20/04/92	Detail	14	2	2	2	1	3	3	3	3	3	3	
						Summary	26	2	2	2	1	3	3	3	3	3	3	
377	Reboxetine	13/05/92	25/06/92	ANXIETY	29/04/92	Detail	14	3	2	2	3	3	1	3	3	3	3	
						Summary	26	3	2	2	3	3	1	3	3	3	3	
						Detail	0	3	3	3	3	3	3	3	3	3	3	
378	Reboxetine	15/06/92	27/07/92	ALDPECIA	12/05/92(2)	Detail	0	3	3	3	3	3	3	3	3	3	3	
						Summary	25	0	3	3	3	3	3	3	3	3	3	
						Detail	25	1	2	3	1	3	3	3	3	3	3	
						Detail	42	1	2	4	1	2	3	3	1	2	3	3
						Summary	25	1	2	3	1	2	3	3	1	2	3	3
379	Reboxetine	15/06/92	27/07/92	MOUTH DRY	12/05/92(0)	Detail	0	3	3	3	3	3	3	3	3	3		
						Summary	25	0	3	3	3	3	3	3	3	3	3	
380	Reboxetine	15/06/92	27/07/92	SONNLENZE	12/05/92(0)	Detail	25	1	2	1	1	2	3	3	1	2	3	
						Summary	17	1	2	1	1	2	3	3	1	2	3	
381	Reboxetine	15/06/92	27/07/92	SONNLENZE	13/07/92	Detail	42	1	2	2	1	2	3	3	3	3		
						Summary	27	1	2	2	1	2	3	3	3	3		
382	Reboxetine	15/06/92	27/07/92	TINNITUS	15/05/92	Detail	35	1	1	4	1	3	3	3	3			
						Summary	29	1	1	4	1	3	3	3	3			

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=life threatening, 5=death
 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=still present, 4=death
 Disapp./Resp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=doubtful, 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

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	Sev	Hist	Rel	Stud	Area	Hosp	Dis app.	Re app.	Out come	Still present (C)	
379	Imipramine	16/06/92	17/06/92	CONFUSION	17/06/92	Detail	7	16/06/92	7	3	2	3	2	3	2	2	2	2	1	YES
						Summary		16/06/92		3	2	3	2	3	2	2	2	2	1	
					MOUTH DRY	17/06/92	Detail	7	16/06/92	3	2	3	2	3	2	2	2	3	1	YES
						Summary		16/06/92		3	2	3	2	3	2	2	2	3	1	
					TASTE PERVERSION	17/06/92	Detail	7	16/06/92	3	2	3	2	3	2	2	2	3	1	YES
						Summary		16/06/92		3	2	3	2	3	2	2	2	3	1	
380	Imipramine	30/06/92	10/06/92	SOMNOLENCE	21/07/92	Detail	28	10/06/92(*)	28	1	2	3	2	2	2	1	3	3	Y	YES
						Summary		10/06/92(*)		1	2	3	2	2	2	1	3	3	Y	
381	Reboxetine	21/05/92	01/07/92	MOUTH DRY	25/05/92	Detail	7		5	2	1	1	1	3	5	3	3	3	3	
						Detail	14		5	2	1	1	1	3	5	3	3	3	3	
						Detail	21		5	2	1	1	1	3	5	3	3	3	3	
						Detail	28		5	2	1	1	1	2	3	3	3	3	3	
						Detail	35		5	2	1	1	1	2	3	3	3	3	3	
						Detail	42		5	2	1	1	1	2	3	3	3	3	3	
						Summary		02/07/92(*)	42	3	2	1	1	2	3	3	3	3	3	Y
382	Imipramine	09/06/92	10/06/92	HEADACHE	10/06/92	Detail	7	17/06/92	7	5	2	2	3	YES	2	2	2	3	1	YES
						Summary		17/06/92		5	2	2	3	YES	2	2	2	3	1	
383	Imipramine	07/02/92	16/08/92	INFLUENZA-LIKE SYMPTOMS	14/07/92	Detail	14		2	1	6	1	2	3	3	3	3	3		
						Detail	21	26/07/92	1	1	6	1	2	3	3	1	2	3	3	1
						Summary		26/07/92	21	2	1	6	1	2	3	1	2	3	3	Y
						Detail	42		1	1	6	1	2	3	3	3	3	3	3	Y
						Summary		16/08/92(*)	42	1	1	6	1	2	3	3	3	3	3	Y
					INSOMNIA	01/05/92	Detail	7		5	1	6	1	YES	2	3	3	3	3	Y
						Detail	42		1	1	6	1	YES	2	3	3	3	3	3	Y
						Summary		16/06/92(*)	42	3	1	6	1	YES	2	3	3	3	3	Y

Severity: 1=unknown, 2=mild, 3=moderate, 4=severe, 5=life threatening
 Study drug: 1=no change, 2=dose reduced, 3=drug 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 a visit
 (P) onset date missing; first report visit date used
 (U) onset date missing; start treatment date of report visit

PHARMACIA CNS 9930085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 1 Patient: 1 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/02/91		26/02/91		19/03/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13.4-18.5 (G/DL)	01/01/91	15.80		15.50		16.60	
HT	40-48 (%)	01/01/91	45.20		45.20		47.60	
RBC	4.15-5.9 (10 ⁶ /MMS)	01/01/91						
			5.28		5.18		5.56	
HBC	4-10.7 (10 ³ /MMS)	01/01/91	5.90		5.90		6.90	
HBC: N	40-75 (%)	01/01/91	59.00		53.00		70.00	
HBC: L	20-45 (%)	01/01/91	34.00		38.00		26.00	
HBC: E	1-6 (%)	01/01/91	2.00		4.00		3.00	
HBC: H	2-10 (%)	01/01/91	5.00		5.00		0.00 <	
HBC: B	0-1 (%)	01/01/91	0.00		0.00		1.00	
PLATELETS	100-300 (10 ³ /MMS)	01/01/91			203.00		195.00	
NA+	130-149 (MMOL/L)	01/01/91	139.00		143.00		143.00	
K+	3.66-5.35 (MMOL/L)	01/01/91	5.70 >		5.10		4.10	
CL-	94-109 (MMOL/L)	01/01/91	111.00 >		102.00		101.00	
Ca++	2.24-2.78 (MMOL/L)	01/01/91	2.35		2.15 <<		2.48	
PO4--	0.87-1.45 (MMOL/L)	01/01/91	1.09		0.60 <<		0.89	
SGOT	5-19 (U/L)	01/01/91	11.00		7.00		8.00	
SGPT	5-23 (U/L)	01/01/91	15.00		17.00		20.00	
GAMMA GT	6-28 (U/L)	01/01/91	4.00 <		9.00		13.00	
LDH	120-240 (U/L)	01/01/91	232.00		159.00		207.00	
ALK. PHOSPH.	60-170 (U/L)	01/01/91	65.00		65.00		87.00	
GLUCOSE	3.54-5.68 (MMOL/L)	01/01/91	8.80 >>		8.65 >>		6.97 >	
BUN	1.7-8.3 (MMOL/L)	01/01/91	3.90		4.00		4.40	
UREA	()	01/01/91						
CREATININE	58-110 (UMOL/L)	01/01/91	82.00		87.00		82.00	
URIC ACID	202-416 (UMOL/L)	01/01/91	292.00		299.00		328.00	
TOT BILIRUBIN	3.6-21.9 (UMOL/L)	01/01/91	8.80		7.70		5.30	
DIR BILIRUBIN	0-4.3 (UMOL/L)	01/01/91						
TOT. PROTEINS	65.6-86.5 (G/L)	01/01/91	76.40		67.70		79.10	
ALBUMINE	58-70 (%)	01/01/91	67.00		66.20		67.00	
TOT. CHOLEST.	4-5.2 (MMOL/L)	01/01/91			5.97 >		7.04 >>	
TRIGLYCERIDES	1.7-2.3 (MMOL/L)	01/01/91			1.27 <		1.68 <	
GLOBULINS ALPHA 1	1.5-4 (%)	01/01/91	2.60		2.80		2.70	
GLOBULINS ALPHA 2	5-10 (%)	01/01/91	7.00		7.50		6.90	
GLOBULINS BETA	7-13 (%)	01/01/91	9.00		9.60		9.70	
GLOBULINS GAMMA	10-19 (%)	01/01/91	14.40		13.90		13.70	
TSH	0.3-4 (MU/L)	01/01/91	1.20					
T4	50-115 (UG/L)	01/01/91	110.00					

(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 589
990085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 1 Patient: 11 Treatment: Reboxetine Sex: Male

Laboratory test	Range value	Range date	Visit number / Laboratory date	
			Screen	Day 21
			03/04/92	28/04/92
			value (⊕)	value (⊕)
HB	13.4-18.5 (G/DL)	01/01/91	16.30	16.20
HT	40-48 (X)	01/01/91	49.60 >	49.40 >
RBC	4.15-5.9 (10 ⁶ /MM ³)	01/01/91		
MBC	4-10.7 (10 ³ /MM ³)	01/01/91	5.31	5.25
MBC: N	40-75 (X)	01/01/91	7.70	7.10
MBC: L	20-45 (X)	01/01/91	56.00	50.00
MBC: E	1-6 (X)	01/01/91	30.00	43.00
MBC: M	2-10 (X)	01/01/91	5.00	3.00
MBC: B	0-1 (X)	01/01/91	8.00	4.00
PLATELETS	100-300 (10 ³ /MM ³)	01/01/91	1.00	0.00
NA+	130-149 (MMOL/L)	01/01/91	244.00	237.00
K+	3.66-5.35 (MMOL/L)	01/01/91	142.00	
CL-	94-109 (MMOL/L)	01/01/91	4.90	
Ca++	2.24-2.78 (MMOL/L)	01/01/91	109.00	2.48
PO4--	0.87-1.48 (MMOL/L)	01/01/91	2.38	1.10
SGOT	5-19 (U/L)	01/01/91	1.21	6.00
SGPT	5-23 (U/L)	01/01/91	6.00	12.00
GAMMA GT	6-28 (U/L)	01/01/91	9.00	14.00
LDH	120-240 (U/L)	01/01/91	16.00	118.00 <
ALK. PHOSPH.	60-170 (U/L)	01/01/91	118.00 <	120.00 <
GLUCOSE	3.54-5.68 (MMOL/L)	01/01/91	134.00	
BUN	1.7-8.3 (MMOL/L)	01/01/91	5.02	7.10
UREA	()	01/01/91	4.70	
CREATININE	58-110 (UMOL/L)	01/01/91	86.00	78.00
URIC ACID	202-416 (UMOL/L)	01/01/91	2.74 <	311.00
TOT BILIRUBIN	3.6-21.9 (UMOL/L)	01/01/91	8.40	18.60
DIR BILIRUBIN	0-4.3 (UMOL/L)	01/01/91		
TOT. PROTEINS	65.6-86.5 (G/L)	01/01/91	75.00	74.80
ALBUMINE	58-70 (X)	01/01/91	60.90	64.30
TOT. CHOLEST.	4-5.2 (MMOL/L)	01/01/91	5.51 >	5.38 >
TRIGLYCERIDES	1.7-2.3 (MMOL/L)	01/01/91	2.25	1.63 <
GLOBULINS ALPHA 1	1.5-4 (X)	01/01/91	1.80	1.40 <
GLOBULINS ALPHA 2	5-10 (X)	01/01/91	8.10	7.00
GLOBULINS BETA	7-13 (X)	01/01/91	12.00	10.90
GLOBULINS GAMMA	10-19 (X)	01/01/91	17.20	16.40
TSH	0.3-4 (MU/L)	01/01/91	2.30	
T4	50-115 (UG/L)	01/01/91	98.00	

(⊕) << 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 30085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 1 Patient: 12 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date	
			Screen	Day 21
			13/04/92	05/05/92
			value (†)	value (†)
Laboratory test	Range value	Range date		
HB	13.4-18.5 (G/DL)	01/01/91	17.80	18.20
HT	40-48 (X)	01/01/91	53.20 >	54.20 >
RBC	4.15-5.9 (10 ⁶ /MM3)	01/01/91		
			6.12 >	6.30 >
WBC	4-10.7 (10 ³ /MM3)	01/01/91	5.80	7.00
WBC: N	40-75 (X)	01/01/91	62.00	68.00
WBC: L	20-45 (X)	01/01/91	28.00	24.00
WBC: E	1-6 (X)	01/01/91	2.00	1.00
WBC: M	2-10 (X)	01/01/91	7.00	7.00
WBC: B	0-1 (X)	01/01/91	1.00	0.00
PLATELETS	100-300 (10 ³ /MM3)	01/01/91	145.00	226.00
NA+	130-149 (MMOL/L)	01/01/91	144.00	140.00
K+	3.66-5.35 (MMOL/L)	01/01/91	4.10	3.80
CL-	94-109 (MMOL/L)	01/01/91	119.00 >	95.00
Ca++	2.24-2.78 (MMOL/L)	01/01/91	2.34	2.53
PO4--	0.87-1.45 (MMOL/L)	01/01/91	0.91	0.93
SGOT	5-19 (U/L)	01/01/91	8.00	7.00
SGPT	5-23 (U/L)	01/01/91	15.00	16.00
GAMMA GT	6-28 (U/L)	01/01/91	8.00	13.00
LDH	120-240 (U/L)	01/01/91	150.00	146.00
ALK. PHOSPH.	60-170 (U/L)	01/01/91	105.00	102.00
GLUCOSE	3.54-5.68 (MMOL/L)	01/01/91	5.51	
BUN	1.7-8.3 (MMOL/L)	01/01/91	7.50	6.30
UREA	()	01/01/91		
CREATININE	58-110 (UMOL/L)	01/01/91	87.00	99.00
URIC ACID	202-416 (UMOL/L)	01/01/91	258.00	267.00
TOT BILIRUBIN	3.6-21.9 (UMOL/L)	01/01/91	23.20 >	34.70 >
DIR BILIRUBIN	0-4.3 (UMOL/L)	01/01/91		
TOT. PROTEINS	65.6-86.5 (G/L)	01/01/91	69.40	73.70
ALBUMINE	58-70 (X)	01/01/91	71.90 >	71.00 >
TOT. CHOLEST.	4-5.2 (MMOL/L)	01/01/91	4.34	4.60
TRIGLYCERIDES	1.7-2.3 (MMOL/L)	01/01/91	1.91	1.33 <
GLOBULINS ALPHA 1	1.5-4 (X)	01/01/91	2.50	2.60
GLOBULINS ALPHA 2	5-10 (X)	01/01/91	6.80	6.90
GLOBULINS BETA	7-13 (X)	01/01/91	8.40	8.60
GLOBULINS GAMMA	10-19 (X)	01/01/91	10.40	10.90
TSH	0.3-4 (MU/L)	01/01/91	1.90	
T4	50-115 (UG/L)	01/01/91	101.00	

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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 1 Patient: 2 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			26/02/91		19/03/91		09/04/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.7-16.6 (G/DL)	01/01/91	15.00		14.10		14.90	
HT	36-42 (%)	01/01/91	42.70 >		39.70		42.30 >	
RBC	3.6-5.3 (10 ⁶ /MM ³)	01/01/91	4.63		4.31		4.56	
WBC	4-10.7 (10 ³ /MM ³)	01/01/91	5.50		6.80		4.90	
WBC: N	40-75 (%)	01/01/91	68.00		69.00		65.00	
WBC: L	20-45 (%)	01/01/91	20.00		26.00		27.00	
WBC: E	1-6 (%)	01/01/91	1.00		1.00		2.00	
WBC: M	2-10 (%)	01/01/91	10.00		4.00		4.00	
WBC: B	0-1 (%)	01/01/91	1.00		0.00		2.00 >>	
PLATELETS	100-300 (10 ³ /MM ³)	01/01/91	358.00 >		328.00 >		337.00 >	
NA+	130-149 (MMOL/L)	01/01/91	141.00		140.00		142.00	
K+	3.66-5.35 (MMOL/L)	01/01/91	4.66		4.40		4.39	
CL-	94-109 (MMOL/L)	01/01/91	105.00		104.00		106.00	
Ca++	2.24-2.78 (MMOL/L)	01/01/91	2.31		2.60		2.58	
PO4--	0.87-1.45 (MMOL/L)	01/01/91	1.05		1.09		0.85 <	
SGOT	5-18 (U/L)	01/01/91	4.00 <		7.00		10.00	
SGPT	5-18 (U/L)	01/01/91	10.00		11.00		17.00	
GAMMA GT	4-18 (U/L)	01/01/91	18.00		19.00 >		19.00 >	
LDH	120-240 (U/L)	01/01/91	120.00		164.00		171.00	
ALK. PHOSPH.	60-170 (U/L)	01/01/91	110.00		108.00		118.00	
GLUCOSE	3.54-5.68 (MMOL/L)	01/01/91	5.16		4.92		4.94	
BUN	1.7-8.3 (MMOL/L)	01/01/91	2.70		3.80		4.50	
UREA	()	01/01/91						
CREATININE	50-98 (UMOL/L)	01/01/91	75.00		69.00		77.00	
URIC ACID	142-339 (UMOL/L)	01/01/91	244.00		239.00		316.00	
TOT. BILIRUBIN	3.6-21.5 (UMOL/L)	01/01/91	6.30		6.50		8.20	
DIR. BILIRUBIN	0-4.3 (UMOL/L)	01/01/91						
TOT. PROTEINS	65.6-86.5 (G/L)	01/01/91						
ALBUMINE	58-70 (%)	01/01/91						
TOT. CHOLEST.	4-5.2 (MMOL/L)	01/01/91	77.70		76.50		83.00	
TRIGLYCERIDES	1.7-2.3 (MMOL/L)	01/01/91						
GLOBULINS ALPHA 1	1.5-4 (%)	01/01/91						
GLOBULINS ALPHA 2	5-10 (%)	01/01/91						
GLOBULINS BETA	7-13 (%)	01/01/91						
GLOBULINS GAMMA	10-19 (%)	01/01/91						
TSH	0.3-4 (MU/L)	01/01/91	1.10		13.10		13.70	
T4	50-115 (UG/L)	01/01/91	96.00					

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PHARMACIA CNS 990
9390085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 1 Patient: 5 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			17/07/91		07/08/91		28/08/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.7-16.6 (G/DL)	01/01/91	14.10		14.30		14.60	
HT	36-42 (%)	01/01/91	42.70 >	43.80 >		43.20 >		
RBC	3.6-5.3 (10 ⁶ /MM ³)	01/01/91	4.68	4.82		4.77		
WBC	4-10.7 (10 ³ /MM ³)	01/01/91	6.60	8.50		7.00		
WBC: N	40-75 (%)	01/01/91	61.00	71.00		60.00		
WBC: L	20-45 (%)	01/01/91	34.00	25.00		32.00		
WBC: E	1-6 (%)	01/01/91	1.00	1.00		1.00		
WBC: M	2-10 (%)	01/01/91	4.00	3.00		6.00		
WBC: B	0-1 (%)	01/01/91	0.00	0.00		1.00		
PLATELETS	100-300 (10 ³ /MM ³)	01/01/91	333.00 >	361.00 >		353.00 >		
NA+	130-149 (MMOL/L)	01/01/91	146.00	148.00		142.00		
K+	3.66-5.35 (MMOL/L)	01/01/91	4.23	4.80		4.49		
CL-	94-109 (MMOL/L)	01/01/91		105.00		101.00		
Ca++	2.24-2.78 (MMOL/L)	01/01/91	2.16 <					
PO4--	0.87-1.45 (MMOL/L)	01/01/91	1.20	1.47 >		1.09		
SGOT	5-18 (U/L)	01/01/91	10.00	7.00		12.00		
SGPT	5-18 (U/L)	01/01/91	13.00	8.00		17.00		
GAMMA GT	4-18 (U/L)	01/01/91	11.00	10.00		11.00		
LDH	120-240 (U/L)	01/01/91	130.00	134.00		230.00		
ALK. PHOSPH.	60-170 (U/L)	01/01/91	103.00	91.00		135.00		
GLUCOSE	3.54-5.68 (MMOL/L)	01/01/91		5.92 >		5.02		
BUN	1.7-8.3 (MMOL/L)	01/01/91	5.10	4.70		8.70 >		
UREA	()	01/01/91						
CREATININE	50-98 (UMOL/L)	01/01/91	78.00	86.00		86.00		
URIC ACID	142-339 (UMOL/L)	01/01/91	218.00	231.00		438.00 >		
TOT BILIRUBIN	3.6-21.5 (UMOL/L)	01/01/91	8.10	6.80		6.90		
DIR BILIRUBIN	0-4.3 (UMOL/L)	01/01/91						
TOT. PROTEINS	65.6-86.5 (G/L)	01/01/91	67.80			69.40		
ALBUMINE	58-70 (%)	01/01/91	66.70			67.80		
TOT. CHOLEST.	4-5.2 (MMOL/L)	01/01/91	5.62 >	6.62 >		5.47 >		
TRIGLYCERIDES	1.7-2.3 (MMOL/L)	01/01/91	1.37 <	1.45 <		0.95 <		
GLOBULINS ALPHA 1	1.5-4 (%)	01/01/91				2.90		
GLOBULINS ALPHA 2	5-10 (%)	01/01/91	6.50			4.90 <		
GLOBULINS BETA	7-13 (%)	01/01/91	10.50			11.20		
GLOBULINS GAMMA	10-19 (%)	01/01/91	13.70			13.20		
TSH	0.3-4 (MU/L)	01/01/91	0.56					
T4	50-115 (UG/L)	01/01/91	111.00					

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PHARMACIA CN 9550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 1 Patient: 7 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			08/10/91		30/10/91		21/11/91	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	13.4-18.5 (G/DL)	01/01/91	15.70		14.70		15.00	
HT	40-48 (X)	01/01/91	45.40		43.40		43.10	
RBC	4.15-5.9 (10 ⁶ /MM ³)	01/01/91						
			4.93		4.70		4.71	
			8.00		5.10		5.60	
WBC	4-10.7 (10 ³ /MM ³)	01/01/91						
WBC: N	40-75 (X)	01/01/91						
			75.00		54.00			
WBC: L	20-45 (X)	01/01/91						
			16.00 <		30.00			
WBC: E	1-6 (X)	01/01/91						
			1.00		5.00			
WBC: M	2-10 (X)	01/01/91						
			8.00		10.00			
WBC: B	0-1 (X)	01/01/91						
			0.00		1.00			
PLATELETS	100-300 (10 ³ /MM ³)	01/01/91	289.00		262.00		263.00	
NA+	130-149 (MMOL/L)	01/01/91	145.00		142.00		146.00	
K+	3.66-5.35 (MMOL/L)	01/01/91	5.00		4.50		4.61	
CL-	94-109 (MMOL/L)	01/01/91	104.00		102.00		105.00	
Ca++	2.24-2.78 (MMOL/L)	01/01/91	2.33		2.46		2.36	
PO4--	0.87-1.45 (MMOL/L)	01/01/91	0.64 <<		0.80 <		0.77 <	
SGOT	5-19 (U/L)	01/01/91	9.00		8.00		13.00	
SGPT	5-23 (U/L)	01/01/91	10.00		8.00		11.00	
GAMMA GT	6-28 (U/L)	01/01/91	19.00		13.00		12.00	
LDH	120-240 (U/L)	01/01/91	164.00		164.00		207.00	
ALK. PHOSPH.	60-170 (U/L)	01/01/91	138.00		124.00		120.00	
GLUCOSE	3.54-5.68 (MMOL/L)	01/01/91	6.41 >		5.35		5.56	
BUN	1.7-8.3 (MMOL/L)	01/01/91	5.00		6.20		4.60	
UREA	()	01/01/91						
CREATININE	58-110 (UMOL/L)	01/01/91	104.00		97.00		85.00	
URIC ACID	202-416 (UMOL/L)	01/01/91	315.00		350.00		374.00	
TOT BILIRUBIN	3.6-21.9 (UMOL/L)	01/01/91	7.00		7.80		7.70	
DIR BILIRUBIN	0-4.3 (UMOL/L)	01/01/91						
TOT. PROTEINS	65.6-86.5 (G/L)	01/01/91	70.10		73.30		68.00	
ALBUMINE	58-70 (X)	01/01/91	67.50		69.70		70.50 >	
TOT. CHOLEST.	4-5.2 (MMOL/L)	01/01/91	6.50 >		4.60		5.07	
TRIGLYCERIDES	1.7-2.3 (MMOL/L)	01/01/91	1.75		1.30 <		1.27 <	
GLOBULINS ALPHA 1	1.5-4 (X)	01/01/91	2.40		2.20		2.40	
GLOBULINS ALPHA 2	5-10 (X)	01/01/91	6.60		5.60		5.20	
GLOBULINS BETA	7-13 (X)	01/01/91	10.50		9.20		8.90	
GLOBULINS GAMMA	10-19 (X)	01/01/91	13.00		13.30		13.00	
TSH	0.3-4 (MU/L)	01/01/91						
T4	50-115 (UG/L)	01/01/91	110.00					

(¢) << 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 550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 33 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			19/12/90		08/01/91		29/01/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/11/90	15.70		16.10		16.20	
HT	0.38-0.57 (L/L)	01/11/90	0.47		0.47		0.47	
RBC	4.5-5.8 (10 ⁶ /MM ³)	01/11/90	5.00		4.91		5.10	
WBC	4000-9000 (/MM ³)	01/11/90	7500.00		7100.00		8200.00	
WBC: N	55-60 (%)	01/11/90	56.00				59.00	
WBC: L	30-40 (%)	01/11/90	39.00				28.00 <	
WBC: E	1-3 (%)	01/11/90	0.00	<			3.00	
WBC: M	3-7 (%)	01/11/90	5.00				10.00 >>	
WBC: B	0-1 (%)	01/11/90	0.00				0.00	
PLATELETS	150000-300000 (/MM ³)	01/11/90					196000	
NA+	136-147 (MMOL/L)	01/11/90	141.00		143.00		143.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	4.70		4.00		4.30	
CL-	95-108 (MMOL/L)	01/11/90						
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.60		2.40		2.40	
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	15.00		13.00		17.00	
SGPT	5-22 (U/L)	01/11/90	18.00		19.00		27.00 >	
GAMMA GT	6-28 (U/L)	01/11/90	20.00		20.00		20.00	
LDH	()	01/11/90						
ALK. PHOSPH.	60-170 (U/L)	01/11/90			114.00		122.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	81.00		96.00		94.00	
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90						
CREATININE	0.5-1.1 (MG/DL)	01/11/90	0.90		0.90		0.80	
URIC ACID	0.4-7 (MG/DL)	01/11/90			4.80		4.40	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90			0.60		0.40	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90						
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	6.90		6.90		6.70	
ALBUMINE	53-63 (%)	01/11/90	65.00	>	62.90		64.70 >	
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	279.00	>	313.00 >>		325.00 >>	
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	166.00		102.00		104.00	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	3.00		2.90	<	3.10	
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	7.70		8.10		7.00	
GLOBULINS BETA	10-13 (%)	01/11/90	10.20		11.30		10.90	
GLOBULINS GAMMA	14-20 (%)	01/11/90	14.10		14.80		14.30	
TSH	0.3-4 (UU/ML)	01/11/90	1.20				1.60	
T4	5-12 (UG/DL)	01/11/90	8.40		8.40		7.30	

(€) << 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 ~~CPS 19085~~

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 35 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			28/12/90		17/01/91		07/02/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/11/90	15.20		15.70		16.30	
HT	0.38-0.57 (L/L)	01/11/90	0.45		0.50		0.48	
RBC	4.5-5.8 (10 ⁶ /MM ³)	01/11/90	5.00		4.87		5.30	
WBC	4000-9000 (/MM ³)	01/11/90	7000.00		8700.00		5400.00	
WBC: N	55-60 (%)	01/11/90	64.00	>			72.90	
WBC: L	30-40 (%)	01/11/90	26.00	<			21.00	
WBC: E	1-3 (%)	01/11/90	1.00	<			1.00	
WBC: M	3-7 (%)	01/11/90	7.00				6.00	
WBC: B	0-1 (%)	01/11/90	0.00				0.00	
PLATELETS	150000-300000 (/MM ³)	01/11/90			302000	>	302000	
NA+	136-147 (MMOL/L)	01/11/90	141.00		144.00		145.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	3.80		4.20		4.90	
CL-	95-108 (MMOL/L)	01/11/90						
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.50		2.70	>	2.70	
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	24.00	>			22.00	
SGPT	5-22 (U/L)	01/11/90	46.00	>>			35.00	
GAMMA GT	6-28 (U/L)	01/11/90	22.00				19.00	
LDH	()	01/11/90						
ALK. PHOSPH.	60-170 (U/L)	01/11/90	79.00		81.00		79.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	88.00		84.00		73.00	
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90						
CREATININE	0.5-1.1 (MG/DL)	01/11/90	0.80				1.00	
URIC ACID	0.4-7 (MG/DL)	01/11/90	4.30		4.10		5.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90			0.40		0.30	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90						
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	7.20		7.60		8.00	
ALBUMINE	53-63 (%)	01/11/90	64.30	>	62.10		62.70	
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90			319.00	>>	319.00	
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90			146.00		83.00	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	2.20	<	2.70	<	2.70	
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	6.90	<	6.50	<	8.30	
GLOBULINS BETA	10-13 (%)	01/11/90	10.50		11.40		9.90	
GLOBULINS GAMMA	14-20 (%)	01/11/90	16.10		17.30		16.40	
TSH	0.3-4 (UU/ML)	01/11/90	1.80				1.50	
T4	5-12 (UG/DL)	01/11/90	1.80		8.20		8.90	

(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 C9560085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 37 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			17/01/91		07/02/91		28/02/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/11/90	16.40		15.20		15.40	
HT	0.38-0.57 (L/L)	01/11/90	0.48		0.44		0.45	
RBC	4.5-5.8 (10 ⁶ /MM ³)	01/11/90	5.60		5.10		5.30	
WBC	4000-9000 (/MM ³)	01/11/90	6800.00		6700.00		6000.00	
WBC: N	55-60 (%)	01/11/90	62.00	>	63.00	>	69.00	>
WBC: L	30-40 (%)	01/11/90	30.00		21.00	<	23.00	<
WBC: E	1-3 (%)	01/11/90	1.00		3.00		1.00	
WBC: M	3-7 (%)	01/11/90	6.00		12.00	>>	7.00	
WBC: B	0-1 (%)	01/11/90	1.00		1.00		0.00	
PLATELETS	150000-300000 (/MM ³)	01/11/90			260000		270000	
NA+	136-147 (MMOL/L)	01/11/90	144.00		143.00		142.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	3.90		4.30		4.30	
CL-	95-108 (MMOL/L)	01/11/90						
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.40		2.60			
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	9.00		16.00		10.00	
SGPT	5-22 (U/L)	01/11/90	25.00	>	40.00	>	17.00	
GAMMA GT	6-28 (U/L)	01/11/90	106.00	>>	159.00	>>	73.00	>>
LDH	()	01/11/90						
ALK. PHOSPH.	60-170 (U/L)	01/11/90	90.00		126.00		104.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	81.00		75.00			
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90						
CREATININE	0.5-1.1 (MG/DL)	01/11/90	0.90				0.80	
URIC ACID	0.4-7 (MG/DL)	01/11/90	4.90		4.80		4.30	
TOT. BILIRUBIN	0-1 (MG/DL)	01/11/90	0.90		0.90		1.00	
DIR. BILIRUBIN	0-0.25 (MG/DL)	01/11/90						
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	7.60		7.20		7.40	
ALBUMINE	53-63 (%)	01/11/90	64.60	>	63.20	>	62.60	
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	200.00		242.00	>	197.00	
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	821.00	>>	1010.00	>>	330.00	>>
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	2.70	<	2.70	<	2.70	<
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	7.70		7.30		7.10	
GLOBULINS BETA	10-13 (%)	01/11/90	10.10		10.80		11.30	
GLOBULINS GAMMA	14-20 (%)	01/11/90	14.90		16.00		16.30	
TSH	0.3-4 (UU/ML)	01/11/90	1.90					
T4	5-12 (UG/DL)	01/11/90	12.00					

(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 C9530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 39 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			24/01/91		14/02/91		07/03/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/11/90	13.60		14.40		13.70	
HT	0.37-0.46 (L/L)	01/11/90	0.41		0.43		0.40	
RBC	4-5 (10 ⁶ /MM3)	01/11/90	4.40		4.70		4.30	
WBC	4000-9000 (/MM3)	01/11/90	5700.00		7300.00		6000.00	
WBC: N	55-60 (%)	01/11/90	67.00 >		69.00 >		56.00	
WBC: L	30-40 (%)	01/11/90	23.00 <		18.00 <<		31.00	
WBC: E	1-3 (%)	01/11/90	4.00 >>		2.00		2.00	
WBC: M	3-7 (%)	01/11/90	5.00		9.00 >		10.00 >>	
WBC: B	0-1 (%)	01/11/90	1.00		2.00 >>		2.00 >>	
PLATELETS	150000-300000 (/MM3)	01/11/90	345000 >		331000 >		302000 >	
NA+	136-147 (MMOL/L)	01/11/90	143.00		142.00		141.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	4.00		4.30		4.10	
CL-	95-108 (MMOL/L)	01/11/90						
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.40		2.40		2.40	
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	6.00		6.00		7.00	
SGPT	5-22 (U/L)	01/11/90	11.00		8.00		9.00	
GAMMA GT	6-28 (U/L)	01/11/90	8.00		9.00		8.00	
LDH	()	01/11/90						
ALK. PHOSPH.	60-170 (U/L)	01/11/90	72.00		76.00		80.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	81.00		77.00		45.00 <<	
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90						
CREATININE	0.5-1.3 (MG/DL)	01/11/90	0.80		0.80		0.80	
URIC ACID	2.4-5.7 (MG/DL)	01/11/90	4.20		3.30		3.10	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	0.90		0.60		0.60	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90						
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	6.70		7.30		6.50	
ALBUMINE	53-63 (%)	01/11/90	65.80 >		62.10		61.50	
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	182.00		215.00		186.00	
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	67.00 <		75.00		56.00 <	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	2.70 <		2.50 <		2.80 <	
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	6.60 <		7.50		7.50	
GLOBULINS BETA	10-13 (%)	01/11/90	9.70 <		11.10		10.40	
GLOBULINS GAMMA	14-20 (%)	01/11/90	15.20		16.80		17.80	
TSH	0.3-4 (UU/ML)	01/11/90	0.60		0.30		0.50	
T4	5-12 (UG/DL)	01/11/90	12.10		10.00		7.20	

(€) << 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 and laboratory not done () missing range value

PHARMACIA CNS 5590085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 41 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/02/91		25/02/91		18/03/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/11/90	17.00		17.00		17.10	
HT	0.38-0.57 (L/L)	01/11/90	0.49		0.50		0.49	
RBC	4.5-5.8 (10 ⁶ /MM3)	01/11/90	5.20		5.30		5.20	
WBC	4000-9000 (/MM3)	01/11/90	7700.00		7600.00		8900.00	
WBC: N	55-60 (%)	01/11/90	67.00 >		72.00 >		84.00 >>	
WBC: L	30-40 (%)	01/11/90	24.00 <		19.00 <<		12.00 <<	
WBC: E	1-3 (%)	01/11/90	2.00		1.00		0.00 <	
WBC: M	3-7 (%)	01/11/90	7.00		6.00		4.00	
WBC: B	0-1 (%)	01/11/90	0.00		2.00 >>		0.00	
PLATELETS	150000-300000 (/MM3)	01/11/90	282000		313000 >		330000 >	
NA+	136-147 (MMOL/L)	01/11/90	142.00		139.00		141.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	3.90		4.20		3.90	
CL-	95-108 (MMOL/L)	01/11/90						
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.40				2.30	
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	7.00		7.00		7.00	
SGPT	5-22 (U/L)	01/11/90	14.00		18.00		22.00	
GAMMA GT	6-28 (U/L)	01/11/90	16.00		16.00		22.00	
LDH	()	01/11/90						
ALK. PHOSPH.	60-170 (U/L)	01/11/90	66.00		64.00		75.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	85.00		87.00		107.00	
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90						
CREATININE	0.5-1.1 (MG/DL)	01/11/90	0.90		1.00		1.10	
URIC ACID	0.4-7 (MG/DL)	01/11/90	4.10		3.70		4.10	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	0.90		0.70		0.50	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90					0.20	
TOT. PROTEINE	6.5-8.5 (G/DL)	01/11/90	6.70		6.90		6.90	
ALBUMINE	53-63 (%)	01/11/90	65.10 >		63.50 >		68.30 >	
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	190.00		195.00		186.00	
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	62.00 <		56.00 <		53.00 <	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	3.10		3.00		2.60 <	
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	6.30 <		8.30		6.50 <	
GLOBULINS BETA	10-13 (%)	01/11/90	11.80		11.10		12.60	
GLOBULINS GAMMA	14-20 (%)	01/11/90	13.70 <		14.30		10.00 <	
TSH	0.3-4 (UU/ML)	01/11/90	0.20					
T4	5-12 (UG/DL)	01/11/90	8.60					

(€) << 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 5590085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 43 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/03/91		15/04/91		06/05/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/11/90	14.30		12.60		13.20	
HT	0.37-0.46 (L/L)	01/11/90	0.41		0.37		0.39	
RBC	4-5 (10 ⁶ /MM3)	01/11/90	4.80		4.30		4.60	
HBC	4000-9000 (/MM3)	01/11/90	9400.00 >		7800.00		8700.00	
HBC: N	55-60 (%)	01/11/90	53.00 <		56.00		69.00 >	
HBC: L	30-40 (%)	01/11/90	41.00 >		32.00		23.00 <	
HBC: E	1-3 (%)	01/11/90	2.00		3.00		2.00	
HBC: M	3-7 (%)	01/11/90	4.00		8.00 >		5.00	
HBC: B	0-1 (%)	01/11/90	0.00		1.00		1.00	
PLATELETS	150000-300000 (/MM3)	01/11/90	419000 >>		411000 >>		444000 >>	
NA+	136-147 (MMOL/L)	01/11/90	139.00		140.00		143.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	4.10		4.10		4.00	
CL-	95-108 (MMOL/L)	01/11/90						
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.40		2.30		2.30	
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	10.00		7.00		16.00	
SGPT	5-22 (U/L)	01/11/90	10.00		12.00		34.00 >	
GAMMA GT	6-28 (U/L)	01/11/90	7.00		9.00		14.00	
LDH	()	01/11/90						
ALK. PHOSPH.	60-170 (U/L)	01/11/90	84.00		82.00		89.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	72.00		79.00		80.00	
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90						
CREATININE	0.5-1.3 (MG/DL)	01/11/90	0.70		0.60		0.50	
URIC ACID	2.4-5.7 (MG/DL)	01/11/90	0.60 <		3.60		4.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	0.60		0.40		0.50	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90						
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	6.70		6.30 <		6.90	
ALBUMINE	53-63 (%)	01/11/90	64.00 >		61.90		62.20	
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	218.00		172.00 <		279.00 >	
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	55.00 <		66.00 <		87.00	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	3.60		4.30		3.90	
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	8.80		11.10 >		9.10	
GLOBULINS BETA	10-13 (%)	01/11/90	10.60		10.80		12.20	
GLOBULINS GAMMA	14-20 (%)	01/11/90	12.60 <		11.90 <		14.60	
TSH	0.3-4 (UU/ML)	01/11/90	0.10		0.10		0.10	
T4	5-12 (UG/DL)	01/11/90	12.40		9.90		8.40	

(€) << 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)

PHARMACTA CN558085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 46 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			15/05/91		05/06/91		26/06/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/11/90	14.30		14.30		14.50	
HT	0.37-0.46 (L/L)	01/11/90	0.42		0.42		0.43	
RBC	4-5 (10 ⁶ /MM ³)	01/11/90	4.70		4.60		4.83	
WBC	4000-9000 (/MM ³)	01/11/90	5800.00		6400.00		5100.00	
WBC: N	55-60 (%)	01/11/90	54.00 <		76.00 >		52.00 <	
WBC: L	30-40 (%)	01/11/90	41.00 >		18.00 <<		43.00 >	
WBC: E	1-3 (%)	01/11/90	1.00		1.00		0.00 <	
WBC: M	3-7 (%)	01/11/90	4.00		3.00		4.00	
WBC: B	0-1 (%)	01/11/90	0.00		2.00 >>		1.00	
PLATELETS	150000-300000 (/MM ³)	01/11/90	322000 >		308000 >		339000 >	
NA+	136-147 (MMOL/L)	01/11/90	144.00		145.00		142.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	4.30		4.10		4.10	
CL-	95-108 (MMOL/L)	01/11/90						
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.50				2.39	
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	10.00		14.00		13.00	
SGPT	5-22 (U/L)	01/11/90	13.00		18.00		15.00	
GAMMA GT	6-28 (U/L)	01/11/90	12.00		11.00		11.00	
LDH	()	01/11/90						
ALK. PHOSPH.	60-170 (U/L)	01/11/90	80.00		76.00		80.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	93.00		97.00		97.00	
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90						
CREATININE	0.5-1.3 (MG/DL)	01/11/90	0.90		0.90		1.00	
URIC ACID	2.4-5.7 (MG/DL)	01/11/90	5.80 >		0.90 <		7.20 >	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	0.40		0.50		0.70	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90						
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	8.10		8.10		7.80	
ALBUMINE	53-63 (%)	01/11/90	64.70 >		64.10 >		64.90 >	
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	271.00 >		252.00 >		268.00 >	
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	252.00 >>		222.00 >		201.00 >	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	2.20 <		2.20 <		2.30 <	
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	6.90 <		6.90 <		5.10 <	
GLOBULINS BETA	10-13 (%)	01/11/90	9.40 <		9.40 <		10.00	
GLOBULINS GAMMA	14-20 (%)	01/11/90	16.80		16.80		17.70	
TSH	0.3-4 (UU/ML)	01/11/90	0.70		1.70		0.90	
T4	5-12 (UG/DL)	01/11/90			8.20		8.50	

(€) << 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 C0550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 47 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			21/05/91		11/06/91		02/07/91	
			value	(†)	value	(†)	value	(†)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/11/90	14.70		14.10		13.80	
HT	0.37-0.46 (L/L)	01/11/90	0.42		0.43		0.42	
RBC	4-5 (10 ⁶ /MM ³)	01/11/90	5.10 >		5.10 >		5.10 >	
HBC	4000-9000 (/MM ³)	01/11/90	6700.00		6300.00		5800.00	
HBC: N	55-60 (%)	01/11/90	72.00 >		70.00 >		67.00 >	
HBC: L	30-40 (%)	01/11/90	22.00 <		22.00 <		27.00 <	
HBC: E	1-3 (%)	01/11/90	2.00		0.00 <		0.00 <	
HBC: M	3-7 (%)	01/11/90	3.00		7.00		5.00	
HBC: B	0-1 (%)	01/11/90	1.00		0.00		1.00	
PLATELETS	150000-300000 (/MM ³)	01/11/90						
NA+	136-147 (MMOL/L)	01/11/90	322000 >		339000 >		379000 >	
K+	3.6-5.1 (MMOL/L)	01/11/90	145.00		142.00		142.00	
CL-	95-108 (MMOL/L)	01/11/90	4.40		4.20		4.31	
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.40				2.15 <	
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	10.00		10.00		9.00	
SGPT	5-22 (U/L)	01/11/90	15.00		18.00		21.00	
GAMMA GT	6-28 (U/L)	01/11/90	20.00		12.00		17.00	
LDH	()	01/11/90						
ALK. PHOSPH.	60-170 (U/L)	01/11/90	138.00		123.00		135.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	85.00		91.00		91.00	
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90						
CREATININE	0.5-1.3 (MG/DL)	01/11/90	0.90		1.10		1.10	
URIC ACID	2.4-5.7 (MG/DL)	01/11/90	5.30		5.00		5.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	0.50		0.50		0.60	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90						
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	7.60		7.20		7.00	
ALBUMINE	53-63 (%)	01/11/90	63.90 >		62.70		61.30	
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	302.00 >>		320.00 >>		343.00 >>	
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	169.00		118.00		160.00	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	2.80 <		2.60 <		3.40	
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	8.20		8.00		7.90	
GLOBULINS BETA	10-13 (%)	01/11/90	13.00		12.90		10.80	
GLOBULINS GAMMA	14-20 (%)	01/11/90	12.10 <		13.80 <		16.60	
TSH	0.3-4 (UU/ML)	01/11/90	0.10					
T4	5-12 (UG/DL)	01/11/90	11.30				9.70	

(†) << 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 550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 50 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date	
			Screen	Day 21
			04/11/91	26/11/91
			value (†)	value (‡)
Laboratory test	Range value	Range date		
HB	14-18 (G/DL)	01/11/90	16.00	15.60
HT	0.38-0.57 (L/L)	01/11/90	0.48	0.47
RBC	4.5-5.8 (10 ⁶ /MM ³)	01/11/90	5.00	4.90
WBC	4000-9000 (/MM ³)	01/11/90	10900.0 >	7900.00
WBC: N	55-60 (%)	01/11/90	51.80 <	53.10 <
WBC: L	30-40 (%)	01/11/90	35.10	33.50
WBC: E	1-3 (%)	01/11/90	2.10	2.90
WBC: M	3-7 (%)	01/11/90	10.20 >>	9.60 >>
WBC: B	0-1 (%)	01/11/90	0.90	0.90
PLATELETS	150000-300000 (/MM ³)	01/11/90	193000	184000
NA+	136-147 (MMOL/L)	01/11/90	140.00	138.00
K+	3.6-5.1 (MMOL/L)	01/11/90	4.33	4.50
CL-	95-108 (MMOL/L)	01/11/90		
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.40	2.41
PO4--	()	01/11/90		
SGOT	5-18 (U/L)	01/11/90	11.00	14.00
SGPT	5-22 (U/L)	01/11/90	24.00 >	25.00 >
GAMMA GT	6-28 (U/L)	01/11/90	24.00	22.00
LDH	()	01/11/90		
ALK. PHOSPH.	60-170 (U/L)	01/11/90	94.00	88.00
GLUCOSE	70-110 (MG/DL)	01/11/90	81.00	89.00
BUN	20-40 (MG/DL)	01/11/90		23.00
UREA	()	01/11/90		
CREATININE	0.5-1.1 (MG/DL)	01/11/90	1.10	1.20 >
URIC ACID	0.4-7 (MG/DL)	01/11/90	5.80	10.00 >>
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	0.40	0.60
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90		
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	7.00	7.20
ALBUMINE	53-63 (%)	01/11/90	61.50	65.60 >
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	215.00	205.00
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	143.00	134.00
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	3.10	3.00
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	8.30	7.20
GLOBULINS BETA	10-13 (%)	01/11/90	10.90	10.10
GLOBULINS GAMMA	14-20 (%)	01/11/90	16.20	14.10
TSH	0.3-4 (UU/ML)	01/11/90	2.60	
T4	5-12 (UG/DL)	01/11/90	8.30	

(†) << 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 9590085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 51 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			04/11/91
			value (c)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	01/11/90	13.10
HT	0.37-0.46 (L/L)	01/11/90	0.40
RBC	4-5 (10 ⁶ /MM3)	01/11/90	4.00
WBC	4000-9000 (/MM3)	01/11/90	7100.00
WBC: N	55-60 (%)	01/11/90	70.00 >
WBC: L	30-40 (%)	01/11/90	22.30 <
WBC: E	1-3 (%)	01/11/90	1.30
WBC: M	3-7 (%)	01/11/90	5.10
WBC: B	0-1 (%)	01/11/90	1.20 >
PLATELETS	150000-300000 (/MM3)	01/11/90	276000
NA+	136-147 (MMOL/L)	01/11/90	139.00
K+	3.6-5.1 (MMOL/L)	01/11/90	4.05
CL-	95-108 (MMOL/L)	01/11/90	
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.28 <
PO4--	()	01/11/90	
SGOT	5-18 (U/L)	01/11/90	7.00
SGPT	5-22 (U/L)	01/11/90	10.00
GAMMA GT	6-28 (U/L)	01/11/90	12.00
LDH	()	01/11/90	
ALK. PHOSPH.	60-170 (U/L)	01/11/90	82.00
GLUCOSE	70-110 (MG/DL)	01/11/90	76.00
BUN	20-40 (MG/DL)	01/11/90	
UREA	()	01/11/90	
CREATININE	0.5-1.3 (MG/DL)	01/11/90	0.80
URIC ACID	2.4-5.7 (MG/DL)	01/11/90	2.20 <
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	0.40
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90	
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	
ALBUMINE	53-63 (%)	01/11/90	58.50
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	254.00 >
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	104.00
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	2.70 <
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	9.10
GLOBULINS BETA	10-13 (%)	01/11/90	10.40
GLOBULINS GAMMA	14-20 (%)	01/11/90	19.30
TSH	0.3-4 (UU/ML)	01/11/90	0.50
T4	5-12 (UG/DL)	01/11/90	8.70

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS 888
9530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 3 Patient: 65 Treatment: Roboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			29/03/91		22/04/91		13/05/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/02/91	16.80		17.20		16.80	
HT	42-52 (X)	01/02/91	48.00		49.50		47.00	
RBC	4.6-6.2 (10 ⁶ /MM ³)	01/02/91	5.42		5.47		5.34	
WBC	4.8-10.8 (10 ³ /MM ³)	01/02/91						
WBC: N	45-78 (X)	01/02/91	7.40		9.40		10.80	
WBC: L	18-45 (X)	01/02/91	56.30		63.30		63.80	
WBC: E	0-5 (X)	01/02/91	31.30		24.80		24.50	
WBC: M	2-12 (X)	01/02/91	3.80		2.10		3.00	
WBC: B	0-1 (X)	01/02/91	4.80		5.48		5.30	
PLATELETS	125-400 (10 ³ /MM ³)	01/02/91	0.70		0.90		0.80	
NA+	135-150 (MMOL/L)	01/02/91	265.00		301.00		283.00	
K+	3.6-5.3 (MMOL/L)	01/02/91	142.00		151.00 >		147.00	
CL-	97-108 (MMOL/L)	01/02/91	3.60		4.50		4.30	
Ca ⁺⁺	2.1-2.7 (MMOL/L)	01/02/91	97.00		100.00		95.00 <	
PO ₄ ⁻⁻	2-4.9 (MG/DL)	01/02/91	2.40		2.60		2.50	
SGOT	5-22 (U/L)	01/02/91	4.00		3.90		4.00	
SGPT	5-22 (U/L)	01/02/91	12.00		9.00		10.00	
GAMMA GT	0-28 (U/L)	01/02/91	32.00 >		23.00 >		31.00 >	
LDH	150-240 (U/L)	01/02/91	13.00		15.00		14.00	
ALK. PHOSPH.	40-200 (U/L)	01/02/91	193.00		177.00		165.00	
GLUCOSE	70-110 (MG/DL)	01/02/91	91.00		102.00		109.00	
BUN	0-25 (MG/DL)	01/02/91	114.00 >		140.00 >		197.00 >>	
UREA	()	01/02/91	14.00		12.00		15.00	
CREATININE	0-1.3 (MG/DL)	01/02/91	()		()		()	
URIC ACID	2.5-7 (MG/DL)	01/02/91	1.10		1.00		1.00	
TOT BILIRUBIN	0-1.3 (MG/DL)	01/02/91	5.10		6.30		5.70	
DIR BILIRUBIN	()	01/02/91	1.10		0.90		0.70	
TOT. PROTEINS	6.2-8.2 (G/DL)	01/02/91	7.90		7.80		7.60	
ALBUMINE	58-72 (X)	01/02/91	62.10		54.40 <		62.10	
TOT. CHOLEST.	120-200 (MG/DL)	01/02/91	310.00 >>		233.00 >		243.00 >	
TRIGLYCERIDES	75-200 (MG/DL)	01/02/91	271.00 >>		165.00 >		364.00 >>	
GLOBULINS ALPHA 1	2-4.2 (X)	01/02/91	3.80		3.50		3.80	
GLOBULINS ALPHA 2	6.5-10.3 (X)	01/02/91	8.60		10.10		8.60	
GLOBULINS BETA	6.7-11.2 (X)	01/02/91	9.30		11.40 >		9.30	
GLOBULINS GAMMA	11.8-20.5 (X)	01/02/91	16.10		19.00		16.10	
TSH	0.1-4 (UU/ML)	01/02/91	2.00					
T4	0.92-1.82 (NG/DL)	01/02/91	1.18					

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CN9590085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 3 Patient: 67 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/04/91		30/04/91		23/05/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/02/91	14.30		15.20		14.60	
HT	37-47 (Z)	01/02/91	43.10		45.30		43.80	
RBC	4.2-5.4 (10 ⁶ /MM ³)	01/02/91	4.54		4.82		4.73	
WBC	4.8-10.8 (10 ³ /MM ³)	01/02/91			7.60		8.00	
WBC: N	45-78 (%)	01/02/91			63.80		73.80	
WBC: L	18-45 (%)	01/02/91			28.60		27.30	
WBC: E	0-5 (%)	01/02/91			1.10		1.06	
WBC: M	2-12 (%)	01/02/91			4.40		5.20	
WBC: B	0-1 (%)	01/02/91			0.50		0.60	
PLATELETS	125-400 (10 ³ /MM ³)	01/02/91	242.00		257.00		301.00	
NA+	135-150 (MMOL/L)	01/02/91	144.00		143.00		142.00	
K+	3.6-5.3 (MMOL/L)	01/02/91	3.60		5.10		4.10	
CL-	97-108 (MMOL/L)	01/02/91	102.00		101.00		95.00	
Ca++	2.1-2.7 (MMOL/L)	01/02/91	2.60		2.70		2.50	
PO4--	2.4-4.9 (MG/DL)	01/02/91	4.30		4.40		4.40	
SGOT	5-18 (U/L)	01/02/91	5.00		6.00		6.00	
SGPT	5-22 (U/L)	01/02/91	7.00		7.00		6.00	
GAMMA GT	0-18 (U/L)	01/02/91	10.00		9.00		8.00	
LDH	150-240 (U/L)	01/02/91	75.00	<	131.00	<	164.00	
ALK. PHOSPH.	40-200 (U/L)	01/02/91	72.00		75.00		78.00	
GLUCOSE	70-110 (MG/DL)	01/02/91	119.00	>	105.00		168.00	
BUN	0-25 (MG/DL)	01/02/91	13.00		14.00		12.00	
UREA	()	01/02/91						
CREATININE	0-1.3 (MG/DL)	01/02/91	0.90		0.90		0.90	
URIC ACID	2.5-5.7 (MG/DL)	01/02/91	4.40		6.20	>	5.10	
TOT BILIRUBIN	0-1.3 (MG/DL)	01/02/91	0.70		0.60		0.60	
DIR BILIRUBIN	()	01/02/91						
TOT. PROTEINS	6.2-8.2 (G/DL)	01/02/91	7.10		7.50		7.00	
ALBUMINE	58-72 (Z)	01/02/91	62.60		63.40		59.60	
TOT. CHOLEST.	120-200 (MG/DL)	01/02/91	270.00	>>	305.00	>>	288.00	
TRIGLYCERIDES	75-200 (MG/DL)	01/02/91	199.00		178.00		177.00	
GLOBULINS ALPHA 1	2-4.2 (Z)	01/02/91	3.80		3.60		4.00	
GLOBULINS ALPHA 2	6.5-10.3 (Z)	01/02/91	8.70		8.60		9.70	
GLOBULINS BETA	6.7-11.2 (Z)	01/02/91	10.30		10.90		11.40	
GLOBULINS GAMMA	11.8-20.5 (Z)	01/02/91	13.30		13.30		15.00	
TSH	0.1-4 (UU/ML)	01/02/91	5.20					
T4	0.92-1.82 (NG/DL)	01/02/91	1.36					

(€) << 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 CN930085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 3 Patient: 70 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 21
			22/10/91	12/11/91
			value (€)	value (€)
Laboratory test	Range value	Range date		
HB	12-16 (G/DL)	01/02/91	15.30	14.60
HT	37-47 (X)	01/02/91	43.60	41.30
RBC	4.2-5.4 (10 ⁶ /MM ³)	01/02/91	5.06	4.89
MBC	4.8-10.8 (10 ³ /MM ³)	01/02/91		
			6.50	5.40
MBC: N	45-78 (X)	01/02/91	59.40	64.10
MBC: L	18-45 (X)	01/02/91	33.50	24.00
MBC: E	0-5 (X)	01/02/91	1.40	3.70
MBC: M	2-12 (X)	01/02/91	3.50	4.60
MBC: B	0-1 (X)	01/02/91	0.70	1.10 >
PLATELETS	125-400 (10 ³ /MM ³)	01/02/91	268.00	230.00
NA+	135-150 (MMOL/L)	01/02/91	141.00	142.00
K+	3.6-5.3 (MMOL/L)	01/02/91	3.60	4.40
CL-	97-108 (MMOL/L)	01/02/91	99.00	103.00
Ca++	2.1-2.7 (MMOL/L)	01/02/91	2.50	2.50
PO4--	2-4.9 (MG/DL)	01/02/91	3.60	4.30
SGOT	5-18 (U/L)	01/02/91	11.00	13.00
SGPT	5-22 (U/L)	01/02/91	15.00	31.00 >
GAMMA GT	0-18 (U/L)	01/02/91	25.00 >	37.00 >>
LDH	150-240 (U/L)	01/02/91	135.00 <	152.00
ALK. PHOSPH.	40-200 (U/L)	01/02/91	109.00	118.00
GLUCOSE	70-110 (MG/DL)	01/02/91	159.00 >>	159.00 >>
BUN	0-25 (MG/DL)	01/02/91	16.00	13.00
UREA	()	01/02/91		
CREATININE	0-1.3 (MG/DL)	01/02/91	0.80	0.80
URIC ACID	2.5-5.7 (MG/DL)	01/02/91	4.10	3.50
TOT BILIRUBIN	0-1.3 (MG/DL)	01/02/91	0.80	0.70
DIR BILIRUBIN	()	01/02/91		
TOT. PROTEINS	6.2-8.2 (G/DL)	01/02/91	7.30	7.20
ALBUMINE	58-72 (X)	01/02/91	51.30 <	50.80 <
TOT. CHOLEST.	120-200 (MG/DL)	01/02/91	271.00 >>	238.00 >
TRIGLYCERIDES	75-200 (MG/DL)	01/02/91	220.00 >	168.00
GLOBULINS ALPHA 1	2-4.2 (X)	01/02/91	4.10	5.10 >
GLOBULINS ALPHA 2	6.5-10.3 (X)	01/02/91	9.60	10.50 >
GLOBULINS BETA	6.7-11.2 (X)	01/02/91	15.20 >>	16.60 >>
GLOBULINS GAMMA	11.8-20.5 (X)	01/02/91	19.60	16.70
TSH	0.1-4 (UU/ML)	01/02/91	0.70	
T4	0.92-1.82 (NG/DL)	01/02/91	1.24	

(€) << 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 880
9330085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 3 Patient: 72 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			28/01/92		21/02/92		13/03/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/02/91	13.50		14.10		12.90	
HT	37-47 (%)	01/02/91	40.10		41.20		37.20	
RBC	4.2-5.4 (10 ⁶ /MM ³)	01/02/91	4.63		4.89		4.53	
WBC	4.8-10.8 (10 ³ /MM ³)	01/02/91						
WBC: N	45-78 (%)	01/02/91	7.20		8.10		6.80	
WBC: L	18-45 (%)	01/02/91	61.10		67.10		66.30	
WBC: E	0-5 (%)	01/02/91	25.80		23.30		26.40	
WBC: M	2-12 (%)	01/02/91	1.00		1.50		0.80	
WBC: B	0-1 (%)	01/02/91	4.90		6.20		4.50	
PLATELETS	125-400 (10 ³ /MM ³)	01/02/91	0.50		0.60		0.60	
NA+	135-150 (MMOL/L)	01/02/91	332.00		303.00		296.00	
K+	3.6-5.3 (MMOL/L)	01/02/91	141.00		140.00		139.00	
CL-	97-108 (MMOL/L)	01/02/91	3.50	<	3.80		3.30	
Ca++	2.1-2.7 (MMOL/L)	01/02/91	103.00		102.00		102.00	
PO4--	2-4.9 (MG/DL)	01/02/91	2.20		2.20		2.10	
SGOT	5-22 (U/L)	01/02/91	2.70		3.50		3.30	
SGPT	5-22 (U/L)	01/02/91	7.00		9.00		14.00	
GAMMA GT	0-18 (U/L)	01/02/91	10.00		14.00		14.00	
LDH	150-240 (U/L)	01/02/91	16.00		12.00		10.00	
ALK. PHOSPH.	40-200 (U/L)	01/02/91	100.00	<	131.00	<	122.00	
GLUCOSE	70-110 (MG/DL)	01/02/91	80.00		128.00		113.00	
BUN	0-25 (MG/DL)	01/02/91	130.00	>	97.00		97.00	
UREA	()	01/02/91	15.00		15.00		11.00	
CREATININE	0-1.3 (MG/DL)	01/02/91	1.00		0.80		0.80	
URIC ACID	2.5-5.7 (MG/DL)	01/02/91	3.50		4.90		4.30	
TOT BILIRUBIN	0-1.3 (MG/DL)	01/02/91	0.40		0.50		0.50	
DIR BILIRUBIN	()	01/02/91						
TOT. PROTEINS	6.2-8.2 (G/DL)	01/02/91	7.20		7.10		7.40	
ALBUMINE	58-72 (%)	01/02/91	54.00	<	61.40		61.40	
TOT. CHOLEST.	120-200 (MG/DL)	01/02/91	202.00	>	197.00		198.00	
TRIGLYCERIDES	75-200 (MG/DL)	01/02/91	230.00	>	154.00		134.00	
GLOBULINS ALPHA 1	2-4.2 (%)	01/02/91	5.10	>	3.40		3.40	
GLOBULINS ALPHA 2	6.5-10.3 (%)	01/02/91	9.60		7.90		7.90	
GLOBULINS BETA	6.7-11.2 (%)	01/02/91	10.60		10.10		10.10	
GLOBULINS GAMMA	11.8-20.5 (%)	01/02/91	16.70		16.70		16.70	
TSH	0.1-4 (UU/ML)	01/02/91	1.10					
T4	0.92-1.82 (NG/DL)	01/02/91	1.37					

(€) << 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 880
530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 3 Patient: 73 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/02/92		06/03/92		27/03/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/02/91	14.20		13.70		13.90	
HT	37-47 (X)	01/02/91	38.50		38.80		39.80	
RBC	4.2-5.4 (10 ⁶ /MM ³)	01/02/91	4.57		4.52		4.62	
WBC	4.8-10.8 (10 ³ /MM ³)	01/02/91						
WBC: N	45-78 (X)	01/02/91	4.50	<	5.10		6.30	
WBC: L	45-78 (X)	01/02/91	61.90		65.60		67.70	
WBC: E	18-45 (X)	01/02/91	28.60		24.20		24.00	
WBC: M	0-5 (X)	01/02/91	1.50		2.80		1.50	
WBC: N	2-12 (X)	01/02/91	6.80		5.60		5.20	
WBC: B	0-1 (X)	01/02/91	0.20		0.30		0.30	
PLATELETS	125-400 (10 ³ /MM ³)	01/02/91	199.00		211.00		242.00	
NA+	135-150 (MMOL/L)	01/02/91	141.00		143.00		141.00	
K+	3.6-5.3 (MMOL/L)	01/02/91	3.70		5.10		4.60	
CL-	97-108 (MMOL/L)	01/02/91	107.00		105.00		106.00	
Ca++	2.1-2.7 (MMOL/L)	01/02/91	2.30		2.40		2.40	
PO4--	2-4.9 (MG/DL)	01/02/91	3.70		3.90		3.50	
SGOT	5-18 (U/L)	01/02/91	13.00		17.00		13.00	
SGPT	5-22 (U/L)	01/02/91	14.00		24.00	>	17.00	
GAMMA GT	0-18 (U/L)	01/02/91	20.00	>	22.00	>	23.00	
LDH	150-240 (U/L)	01/02/91	159.00		190.00		207.00	
ALK. PHOSPH.	40-200 (U/L)	01/02/91	88.00		109.00		106.00	
GLUCOSE	70-110 (MG/DL)	01/02/91	87.00		108.00		101.00	
BUN	0-25 (MG/DL)	01/02/91	24.00		21.00		22.00	
UREA	()	01/02/91						
CREATININE	0-1.3 (MG/DL)	01/02/91	0.70		0.70		0.80	
URIC ACID	2.5-5.7 (MG/DL)	01/02/91	5.30		6.30	>	7.00	
TOT. BILIRUBIN	0-1.3 (MG/DL)	01/02/91	0.80		0.80		0.70	
DIR. BILIRUBIN	()	01/02/91						
TOT. PROTEINS	6.2-8.2 (G/DL)	01/02/91	7.40		7.50		8.20	
ALBUMINE	58-72 (X)	01/02/91	56.30	<	62.40		62.40	
TOT. CHOLEST.	120-200 (MG/DL)	01/02/91	154.00		179.00		164.00	
TRIGLYCERIDES	75-200 (MG/DL)	01/02/91	96.00		99.00		102.00	
GLOBULINS ALPHA 1	2-4.2 (X)	01/02/91	4.00		2.90		2.90	
GLOBULINS ALPHA 2	6.5-10.3 (X)	01/02/91	8.20		7.10		7.10	
GLOBULINS BETA	6.7-11.2 (X)	01/02/91	9.90		9.50		9.50	
GLOBULINS GAMMA	11.8-20.5 (X)	01/02/91	21.50	>	18.10		18.10	
TSH	0.1-4 (UU/ML)	01/02/91	0.40					
T4	0.92-1.82 (NG/DL)	01/02/91	1.54					

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS 330085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 4 Patient: 100 Treatment: Reboxetina Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			01/05/92		27/05/92		17/06/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	7.4-10.5 (MMOL/L)	01/04/91	7.90		7.60		8.00	
HT	0.36-0.45 (L/L)	01/04/91	0.39		0.41		0.37	
RBC	4.2-5.4 (10 ⁶ /MM ³)	01/04/91	4.28		4.20		4.21	
HBC	3.8-9.8 (10 ³ /MM ³)	01/04/91	5.25		6.00		7.17	
HBC: N	36-84 (%)	01/04/91	69.00		68.50		68.70	
HBC: L	20-42 (%)	01/04/91	21.20		21.70		24.00	
HBC: E	0-5 (%)	01/04/91	1.10		1.00		0.80	
HBC: M	0-9.5 (%)	01/04/91	7.20		7.40		6.00	
HBC: B	0-1 (%)	01/04/91	0.30		0.20		0.40	
PLATELETS	150-300 (10 ³ /MM ³)	01/04/91	287.00		270.00		271.00	
NA+	136-152 (MMOL/L)	01/04/91	140.00		141.50		142.00	
K+	3.8-5.5 (MMOL/L)	01/04/91	4.04		4.20		4.10	
CL-	97-108 (MMOL/L)	01/04/91	93.00 <		96.00 <		94.00 <	
Ca++	2.4-2.65 (MMOL/L)	01/04/91	2.20 <		2.16 <		2.41	
PO4--	0.8-1.3 (MMOL/L)	01/04/91	1.14		1.20		1.24	
SGOT	0.32-0.49 (MMOL/L/S)	01/04/91	0.20 <		0.24 <		0.39	
SGPT	0.17-0.4 (MMOL/L/S)	01/04/91	0.17		0.28		0.27	
GAMMA GT	0-0.4 (MMOL/L/S)	01/04/91	0.45 >		0.52 >		0.22	
LDH	0-6.6 (MMOL/L)	01/04/91	4.00		4.12		4.85	
ALK. PHOSPH.	1.45-3.65 (MMOL/L/S)	01/04/91	2.27		2.17		2.07	
GLUCOSE	3.33-5.55 (MMOL/L)	01/04/91	3.90		4.10		3.40	
BUN	3.6-7.1 (MMOL/L)	01/04/91						
UREA	()	01/04/91						
CREATININE	0-88 (UMOL/L)	01/04/91	53.00		61.00		63.00	
URIC ACID	140-340 (UMOL/L)	01/04/91	266.00		265.00		364.00 >	
TOT BILIRUBIN	0-16 (UMOL/L)	01/04/91	12.00		11.80		16.50 >	
DIR BILIRUBIN	()	01/04/91						
TOT. PROTEINS	65-85 (G/L)	01/04/91	72.00		71.80		76.30	
ALBUMINE	55-65 (%)	01/04/91	60.40		60.10		63.80	
TOT. CHOLEST.	3.5-6.6 (MMOL/L)	01/04/91	6.32		6.80 >		5.42	
TRIGLYCERIDES	1.75-2.1 (MMOL/L)	01/04/91	1.25 <		1.75		0.60 <	
GLOBULINS ALPHA 1	3-6 (%)	01/04/91	2.50 <		2.50 <		2.40 <	
GLOBULINS ALPHA 2	5-10 (%)	01/04/91	7.20		7.40		6.40	
GLOBULINS BETA	9-14 (%)	01/04/91	11.90		11.70		10.40	
GLOBULINS GAMMA	12-20 (%)	01/04/91	18.00		17.90		17.00	
TSH	0.24-2.9 (MU/L)	01/04/91	0.88					
T4	65-155 (NMOL/L)	01/04/91	74.00					

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PHARMACIA CNG 950085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 6 Patient: 161 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			27/03/91		18/04/91		08/05/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	26/03/91	16.10		15.20		15.70	
HT	40-52 (%)	26/03/91	47.90		44.30		45.30	
RBC	4.5-5.9 (10 ⁶ /MM ³)	26/03/91	5.30		4.93		5.06	
WBC	4000-10000 (/MM ³)	26/03/91	5800.00		8100.00		9100.00	
WBC: N	45-80 (%)	26/03/91	65.00		50.00		62.00	
WBC: L	20-40 (%)	26/03/91	32.00		38.00		31.00	
WBC: E	0-4 (%)	26/03/91	0.00		5.00	>	4.00	
WBC: M	2-8 (%)	26/03/91	2.00		6.00		3.00	
WBC: B	0-1 (%)	26/03/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	26/03/91	278.00		242.00		291.00	
NA+	134-147 (MMOL/L)	26/03/91	141.00		143.00		144.00	
K+	3.6-5.5 (MMOL/L)	26/03/91	3.87		4.01		4.37	
CL-	98-109 (MMOL/L)	26/03/91	103.00		103.00		103.00	
Ca++	2.1-2.6 (MMOL/L)	26/03/91	2.44		2.42		2.56	
PO4--	0.8-1.6 (MMOL/L)	26/03/91	1.10		1.20		1.20	
SGOT	5-18 (U/L)	26/03/91	8.00		8.00		8.00	
SGPT	5-22 (U/L)	26/03/91	14.00		12.00		12.00	
GAMMA GT	0-28 (U/L)	26/03/91	17.00		13.00		15.00	
LDH	120-140 (U/L)	26/03/91	101.00	<	107.00	<	110.00	
ALK. PHOSPH.	50-170 (U/L)	26/03/91	97.00		88.00		96.00	
GLUCOSE	50-100 (MG/DL)	26/03/91	81.00		84.00		80.00	
BUN	10-50 (MG/DL)	26/03/91	26.00		24.00		36.00	
UREA	()	26/03/91						
CREATININE	0.6-1.2 (MG/DL)	26/03/91	1.30	>	0.99		1.07	
URIC ACID	3.4-7 (MG/DL)	26/03/91	4.70		4.95		5.30	
TOT BILIRUBIN	0-1 (MG/DL)	26/03/91	0.62		0.36		0.59	
DIR BILIRUBIN	0-0.3 (MG/DL)	26/03/91	0.20		0.10		0.10	
TOT. PROTEINS	6-8.2 (G/DL)	26/03/91	7.30		7.90		7.60	
ALBUMINE	58-70 (%)	26/03/91	67.00		71.80	>	69.00	
TOT. CHOLEST.	120-260 (MG/DL)	26/03/91	176.00		251.00		197.00	
TRIGLYCERIDES	74-172 (MG/DL)	26/03/91	195.00	>	173.00	>	116.00	
GLOBULINS ALPHA 1	1.5-4 (%)	26/03/91	2.00		2.30		4.00	
GLOBULINS ALPHA 2	5-10 (%)	26/03/91	9.00		5.90		7.00	
GLOBULINS BETA	8-13 (%)	26/03/91	8.00		9.10		9.00	
GLOBULINS GAMMA	10-19 (%)	26/03/91	14.00		10.90		11.00	
TSH	0.2-3.9 (MU/L)	26/03/91	0.70					
T4	4.5-12 (UG/DL)	26/03/91	10.80					

(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 530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 6 Patient: 162 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/11/91		25/11/91		16/12/91	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	02/02/91	13.80		14.00		13.30	
HT	36-46 (%)	02/02/91	41.50		42.00		39.80	
RBC	4-5.3 (10 ⁶ /MM ³)	02/02/91	4.40		4.54		4.33	
WBC	4000-10000 (/MM ³)	02/02/91	6100.00		4600.00		4300.00	
WBC: N	45-80 (%)	02/02/91	68.00		73.00		71.00	
WBC: L	20-40 (%)	02/02/91	24.00		19.00	<	<	
WBC: E	0-4 (%)	02/02/91	1.00		3.00		2.00	
WBC: M	2-8 (%)	02/02/91	7.00		5.00		7.00	
WBC: B	0-1 (%)	02/02/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	02/02/91	212.00		222.00		227.00	
NA+	134-147 (MMOL/L)	02/02/91	149.00	>	143.00		141.00	
K+	3.6-5.5 (MMOL/L)	02/02/91	4.40		3.90		3.70	
CL-	98-109 (MMOL/L)	02/02/91	107.00		106.00		104.00	
Ca++	2.1-2.6 (MMOL/L)	02/02/91	2.50		2.50		2.40	
PO4--	0.8-1.6 (MMOL/L)	02/02/91	0.90		1.20		1.10	
SGOT	5-15 (U/L)	02/02/91	7.00		9.00		9.00	
SGPT	5-17 (U/L)	02/02/91	8.00		11.00		9.00	
GAMMA GT	0-18 (U/L)	02/02/91	13.00		16.00		12.00	
LDH	120-140 (U/L)	02/02/91	100.00	<	124.00		121.00	
ALK. PHOSPH.	50-170 (U/L)	02/02/91	100.00	<	98.00		132.00	
GLUCOSE	50-100 (MG/DL)	02/02/91	91.00		77.00		82.00	
BUN	10-50 (MG/DL)	02/02/91	39.00		37.00		26.00	
UREA	()	02/02/91						
CREATININE	0.5-1 (MG/DL)	02/02/91	0.66		0.72		0.59	
URIC ACID	2.4-5.7 (MG/DL)	02/02/91	2.30	<	3.85		3.60	
TOT BILIRUBIN	0-1 (MG/DL)	02/02/91	0.30		0.30		0.50	
DIR BILIRUBIN	0-0.3 (MG/DL)	02/02/91	0.10		0.30		0.10	
TOT. PROTEINS	6-8.2 (G/DL)	02/02/91	7.30		7.70		7.40	
ALBUMINE	58-70 (%)	02/02/91	59.00		59.00		63.00	
TOT. CHOLEST.	120-260 (MG/DL)	02/02/91	252.00		257.00		253.00	
TRIGLYCERIDES	74-172 (MG/DL)	02/02/91	123.00		82.00		105.00	
GLOBULINS ALPHA 1	1.5-4 (%)	02/02/91	4.00		4.00		4.00	
GLOBULINS ALPHA 2	5-10 (%)	02/02/91	10.00		10.00		8.00	
GLOBULINS BETA	8-13 (%)	02/02/91	11.00		11.00		11.00	
GLOBULINS GAMMA	10-19 (%)	02/02/91	16.00		16.00		14.00	
TSH	0.2-3.9 (MU/L)	02/02/91	0.10					
T4	0.7-2 (NG/DL)	02/02/91	2.60					

(⊕) << 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 950085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 7 Patient: 193 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			04/04/91
			value (€)
Laboratory test	Range value	Range date	
HB	12-18 (G/DL)	03/02/91	13.70
HT	37-56 (%)	03/02/91	41.90
RBC	4200-6200 (10 ³ /MM3)	03/02/91	4690.00
WBC	4000-10000 (/MM3)	03/02/91	5380.00
WBC: N	50-70 (%)	03/02/91	58.40
WBC: L	20-40 (%)	03/02/91	20.50
WBC: E	0-5 (%)	03/02/91	11.10 >>
WBC: M	2-10 (%)	03/02/91	7.90
WBC: B	0-2 (%)	03/02/91	0.70
PLATELETS	150-400 (10 ³ /MM3)	03/02/91	211.00
NA+	136-146 (MMOL/L)	03/02/91	147.00 >
K+	3.5-5 (MMOL/L)	03/02/91	5.10 >
CL-	95-105 (MMOL/L)	03/02/91	106.00 >
Ca++	2-2.6 (MMOL/L)	03/02/91	2.27
PO4--	0.79-1.56 (MMOL/L)	03/02/91	1.49
SGOT	5-25 (U/L)	03/02/91	43.00 >
SGPT	5-20 (U/L)	03/02/91	82.00 >>
GAMMA GT	0-38 (U/L)	03/02/91	561.00 >>
LDH	138-276 (U/L)	03/02/91	
ALK. PHOSPH.	0-207 (U/L)	03/02/91	400.00 >
GLUCOSE	0.6-1.2 (G/L)	03/02/91	0.76
BUN	0.1-0.5 (G/L)	03/02/91	0.27
UREA	()	03/02/91	
CREATININE	0-1.4 (MG/DL)	03/02/91	1.06
URIC ACID	2.4-7 (MG/DL)	03/02/91	4.40
TOT BILIRUBIN	0-1.5 (MG/DL)	03/02/91	0.27
DIR BILIRUBIN	0-0.5 (MG/DL)	03/02/91	0.10
TOT. PROTEINS	6.3-8.5 (G/DL)	03/02/91	
ALBUMINE	53-70 (%)	03/02/91	
TOT. CHOLEST.	1.5-2.5 (G/L)	03/02/91	3.07 >
TRIGLYCERIDES	0.4-1.72 (G/L)	03/02/91	1.23
GLOBULINS ALPHA 1	1.5-5.5 (%)	03/02/91	
GLOBULINS ALPHA 2	8-12 (%)	03/02/91	
GLOBULINS BETA	8-14 (%)	03/02/91	
GLOBULINS GAMMA	9-18 (%)	03/02/91	
TSH	0.2-5 (MU/L)	03/02/91	
T4	0.8-1.9 (NG/DL)	03/02/91	

(◊) << 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 880
9550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 7 Patient: 194 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date
			Screen
			31/05/91
			value (±)
Laboratory test	Range value	Range date	
HB	12-18 (G/DL)	03/02/91	14.90
HT	37-56 (%)	03/02/91	43.00
RBC	4200-6200 (10 ³ -3/MM3)	03/02/91	5110.00
WBC	4000-10000 (/MM3)	03/02/91	5970.00
WBC: N	50-70 (%)	03/02/91	43.70 <
WBC: L	20-40 (%)	03/02/91	39.30
WBC: E	0-5 (%)	03/02/91	4.00
WBC: M	2-10 (%)	03/02/91	10.00
WBC: B	0-2 (%)	03/02/91	1.00
PLATELETS	150-400 (10 ³ -3/MM3)	03/02/91	184.00
NA+	136-146 (MMOL/L)	03/02/91	146.00
K+	3.5-5 (MMOL/L)	03/02/91	3.90
CL-	95-105 (MMOL/L)	03/02/91	106.00 >
Ca++	2-2.6 (MMOL/L)	03/02/91	2.20
PO4--	0.79-1.56 (MMOL/L)	03/02/91	1.19
SGOT	5-25 (U/L)	03/02/91	18.00
SGPT	5-20 (U/L)	03/02/91	36.00 >
GAMMA GT	0-38 (U/L)	03/02/91	21.00
LDH	138-276 (U/L)	03/02/91	261.00
ALK. PHOSPH.	0-207 (U/L)	03/02/91	127.00
GLUCOSE	0.6-1.2 (G/L)	03/02/91	0.87
BUH	0.1-0.5 (G/L)	03/02/91	0.37
UREA	()	03/02/91	
CREATININE	0-1.4 (MG/DL)	03/02/91	1.15
URIC ACID	2.4-7 (MG/DL)	03/02/91	7.40 >
TOT BILIRUBIN	0-1.5 (MG/DL)	03/02/91	0.67
DIR BILIRUBIN	0-0.5 (MG/DL)	03/02/91	0.10
TOT. PROTEINS	6.3-8.5 (G/DL)	03/02/91	6.88
ALBUMINE	53-70 (%)	03/02/91	69.98
TOT. CHOLEST.	1.5-2.5 (G/L)	03/02/91	1.67
TRIGLYCERIDES	0.4-1.72 (G/L)	03/02/91	1.16
GLOBULINS ALPHA 1	1.5-5.5 (%)	03/02/91	4.40
GLOBULINS ALPHA 2	8-12 (%)	03/02/91	6.40 <
GLOBULINS BETA	8-14 (%)	03/02/91	9.60
GLOBULINS GAMMA	9-18 (%)	03/02/91	9.70
TSH	0.2-5 (MU/L)	03/02/91	0.80
T4	0.8-1.9 (NG/DL)	03/02/91	1.50

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PHARMACIA CNS 9530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 8 Patient: 226 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			02/05/91		24/05/91		14/06/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	04/02/91	13.30		13.40		13.40	
HT	32-36 (X)	04/02/91	40.20 >		40.30 >		38.50 >	
RBC	4-5 (10 ⁶ /MM ³)	04/02/91	4.33		4.36		4.13	
WBC	4.5-9 (10 ³ /MM ³)	04/02/91	4.30 <		4.00 <		4.60	
WBC: N	45-70 (X)	04/02/91	40.00 <		47.00 <		39.00 <	
WBC: L	20-40 (X)	04/02/91	51.00 >		44.00 >		50.00 >	
WBC: E	1-3 (X)	04/02/91	2.00		2.00		3.00	
WBC: M	3-7 (X)	04/02/91	5.00		4.00		7.00	
WBC: B	0-1 (X)	04/02/91	2.00 >>		3.00 >>		1.00	
PLATELETS	150-400 (10 ³ /MM ³)	04/02/91	322.00		298.00		350.00	
NA+	135-146 (MEQ/L)	04/02/91	143.00		140.00		140.00	
K+	3.5-5 (MEQ/L)	04/02/91	4.50		4.20		4.20	
CL-	95-106 (MEQ/L)	04/02/91	97.00		98.00		92.00 <	
Ca++	4.2-5.3 (MEQ/L)	04/02/91	4.80		4.80		5.20	
PO4--	2.7-4.5 (MG/DL)	04/02/91	4.30		4.10		4.40	
SGOT	5-21 (U/L)	04/02/91	13.00		13.00		13.00	
SGPT	5-22 (U/L)	04/02/91	14.00		14.00		14.00	
GAMMA GT	5-25 (U/L)	04/02/91	11.00		11.00		13.00	
LDH	160-320 (U/L)	04/02/91	217.00		212.00		217.00	
ALK. PHOSPH.	73-207 (U/L)	04/02/91	162.00		153.00		165.00	
GLUCOSE	80-110 (MG/DL)	04/02/91	80.00		89.00		73.00 <	
BUN	10-50 (MG/DL)	04/02/91	42.00		50.00		38.00	
UREA	()	04/02/91						
CREATININE	0.5-0.9 (MG/DL)	04/02/91	0.90		0.80		0.80	
URIC ACID	2.4-5.7 (MG/DL)	04/02/91	3.10		1.90 <		3.20	
TOT BILIRUBIN	0-1 (MG/DL)	04/02/91	0.40		0.40		0.30	
DIR BILIRUBIN	0-0.3 (MG/DL)	04/02/91	0.30		0.20		0.20	
TOT. PROTEINS	66-70 (G/L)	04/02/91	71.90 >		74.90 >		75.80 >	
ALBUMINE	56-70 (X)	04/02/91	64.10		72.30 >		70.30 >	
TOT. CHOLEST.	150-250 (MG/DL)	04/02/91	240.00		291.00 >		299.00 >	
TRIGLYCERIDES	35-185 (MG/DL)	04/02/91	135.00		75.00		108.00	
GLOBULINS ALPHA 1	1.8-4.5 (X)	04/02/91	6.60 >>		2.50		2.50	
GLOBULINS ALPHA 2	4-13 (X)	04/02/91	7.80		6.80		7.30	
GLOBULINS BETA	9-14 (X)	04/02/91	11.00		9.90		10.60	
GLOBULINS GAMMA	8-16 (X)	04/02/91	10.50		8.50		9.40	
TSH	0.4-3.7 (UUI/ML)	04/02/91	1.10					
T4	6.1-11.5 (UG/DL)	04/02/91	8.50					

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PHARMACIA CN 9550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 8 Patient: 228 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date
			Screen
			08/05/91
			value (φ)
Laboratory test	Range value	Range date	
HB	13-17 (G/DL)	02/04/91	14.60
HT	35-50 (%)	02/04/91	41.00
RBC	4-5.5 (10 ⁶ /MM ³)	02/04/91	4.70
WBC	4-10 (10 ³ /MM ³)	02/04/91	8.30
WBC: N	25-75 (%)	02/04/91	59.00
WBC: L	10-40 (%)	02/04/91	30.00
WBC: E	0-4 (%)	02/04/91	2.00
WBC: M	2-10 (%)	02/04/91	8.00
WBC: B	0-1 (%)	02/04/91	0.00
PLATELETS	150-400 (10 ³ /MM ³)	02/04/91	212.00
NA+	137-150 (MEQ/L)	02/04/91	139.00
K+	3.5-5.2 (MEQ/L)	02/04/91	4.50
CL-	90-110 (MEQ/L)	02/04/91	101.00
Ca++	4.5-5.5 (MEQ/L)	02/04/91	4.70
PO4--	25-45 (MG/L)	02/04/91	29.00
SGOT	5-25 (U/L)	02/04/91	20.00
SGPT	5-25 (U/L)	02/04/91	32.00 >
GAMMA GT	0-40 (U/L)	02/04/91	30.00
LDH	160-320 (U/L)	02/04/91	198.00
ALK. PHOSPH.	40-210 (U/L)	02/04/91	104.00
GLUCOSE	0.6-1.1 (G/L)	02/04/91	1.07
BUN	0.1-0.45 (G/L)	02/04/91	0.20
UREA	()	02/04/91	
CREATININE	5-12 (MG/L)	02/04/91	10.60
URIC ACID	30-65 (MG/L)	02/04/91	67.00 >
TOT BILIRUBIN	0-10 (MG/L)	02/04/91	5.20
DIR BILIRUBIN	0-3 (MG/L)	02/04/91	1.70
TOT. PROTEINS	65-80 (G/L)	02/04/91	65.00
ALBUMINE	55-70 (%)	02/04/91	63.50
TOT. CHOLEST.	1.5-2.5 (G/L)	02/04/91	2.16
TRIGLYCERIDES	0.7-1.5 (G/L)	02/04/91	2.99 >>
GLOBULINS ALPHA 1	2-4 (%)	02/04/91	2.80
GLOBULINS ALPHA 2	6-10 (%)	02/04/91	8.00
GLOBULINS BETA	9-13 (%)	02/04/91	12.10
GLOBULINS GAMMA	11-15 (%)	02/04/91	13.60
TSH	0.1-4 (MU/L)	02/04/91	1.20
T4	7.3-20.1 (PG/NL)	02/04/91	12.00

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PHARMACIA CNS 550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 8 Patient: 231 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date	
			Screen	
			29/10/91	
			value	(*)
Laboratory test	Range value	Range date		
HB	12-16 (G/DL)	04/02/91	12.50	
HT	32-36 (%)	04/02/91	36.30	>
RBC	4-5 (10 ⁶ /MM ³)	04/02/91	3.87	<
WBC	4.5-9 (10 ³ /MM ³)	04/02/91	6.30	<
WBC: N	45-70 (%)	04/02/91	33.00	<
WBC: L	20-40 (%)	04/02/91	60.00	>>
WBC: E	1-3 (%)	04/02/91	3.00	
WBC: M	3-7 (%)	04/02/91	4.00	
WBC: B	0-1 (%)	04/02/91	0.00	
PLATELETS	150-400 (10 ³ /MM ³)	04/02/91	197.00	
NA+	135-146 (MEQ/L)	04/02/91	148.00	>
K+	3.5-5 (MEQ/L)	04/02/91	4.40	
CL-	95-106 (MEQ/L)	04/02/91	99.00	
Ca++	4.2-5.3 (MEQ/L)	04/02/91	4.80	
PO4--	2.7-4.5 (MG/DL)	04/02/91	4.00	
SGOT	5-21 (U/L)	04/02/91	10.00	
SGPT	5-22 (U/L)	04/02/91	9.00	
GAMMA GT	5-25 (U/L)	04/02/91	7.00	
LDH	160-320 (U/L)	04/02/91	177.00	
ALK. PHOSPH.	73-207 (U/L)	04/02/91	75.00	
GLUCOSE	80-110 (MG/DL)	04/02/91	79.00	<
BUN	10-50 (MG/DL)	04/02/91	25.00	
UREA	()	04/02/91		
CREATININE	0.5-0.9 (MG/DL)	04/02/91	0.90	
URIC ACID	2.4-5.7 (MG/DL)	04/02/91	3.90	
TOT BILIRUBIN	0-1 (MG/DL)	04/02/91		
DIR BILIRUBIN	0-0.3 (MG/DL)	04/02/91		
TOT. PROTEINS	66-70 (G/L)	04/02/91	77.40	>
ALBUMINE	56-70 (%)	04/02/91	62.00	
TOT. CHOLEST.	150-250 (MG/DL)	04/02/91	278.00	>
TRIGLYCERIDES	35-185 (MG/DL)	04/02/91	150.00	
GLOBULINS ALPHA 1	1.8-4.5 (%)	04/02/91	2.70	
GLOBULINS ALPHA 2	4-13 (%)	04/02/91	7.80	
GLOBULINS BETA	9-14 (%)	04/02/91	12.00	
GLOBULINS GAMMA	8-16 (%)	04/02/91	14.60	
TSH	0.4-3.7 (UUI/ML)	04/02/91	9.10	
T4	6.1-11.5 (UG/DL)	04/02/91	11.90	

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PHARMACIA CNS 880
080085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 8 Patient: 232 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			27/11/91		20/12/91		08/01/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-17 (G/DL)	02/04/91	13.20		13.50		13.60	
HT	35-50 (%)	02/04/91	41.00		38.00		46.00	
RBC	4-5.5 (10 ⁶ /MM ³)	02/04/91	4.20		4.10		4.90	
WBC	4-10 (10 ³ /MM ³)	02/04/91	12.40	>	7.80		13.60 >>	
WBC: N	25-75 (%)	02/04/91	72.00		51.00		72.00	
WBC: L	10-40 (%)	02/04/91	21.00		38.00		24.00	
WBC: E	0-4 (%)	02/04/91	2.00		5.00	>	1.00	
WBC: M	2-10 (%)	02/04/91	5.00		4.00		2.00	
WBC: B	0-1 (%)	02/04/91	0.00		1.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	02/04/91	346.00		379.00		491.00 >	
NA+	137-150 (MEQ/L)	02/04/91	145.00		139.00		145.00	
K+	3.5-5.2 (MEQ/L)	02/04/91	4.70		4.90		4.30	
CL-	90-110 (MEQ/L)	02/04/91	110.00		104.00		108.00	
Ca++	4.5-5.5 (MEQ/L)	02/04/91	4.80		4.90		4.80	
PO4--	25-45 (MG/L)	02/04/91	34.00		31.00		28.00	
SGOT	5-25 (U/L)	02/04/91	23.00		11.00		13.00	
SGPT	5-25 (U/L)	02/04/91	20.00		10.00		11.00	
GAMMA GT	0-40 (U/L)	02/04/91	78.00	>	27.00		19.00	
LDH	160-320 (U/L)	02/04/91	193.00		197.00		231.00	
ALK. PHOSPH.	40-210 (U/L)	02/04/91	64.00		62.00		75.00	
GLUCOSE	0.6-1.1 (G/L)	02/04/91	1.09		1.05		0.97	
BUN	0.1-0.45 (G/L)	02/04/91	0.16		0.20		0.22	
UREA	()	02/04/91						
CREATININE	5-12 (MG/L)	02/04/91	10.40		9.70		10.50	
URIC ACID	30-65 (MG/L)	02/04/91	70.00	>			68.00 >	
TOT BILIRUBIN	0-10 (MG/L)	02/04/91	5.40		5.80		3.90	
DIR BILIRUBIN	0-3 (MG/L)	02/04/91	2.20		2.40		1.50	
TOT. PROTEINS	65-80 (G/L)	02/04/91	74.00				78.00	
ALBUMINE	55-70 (%)	02/04/91					61.10	
TOT. CHOLEST.	1.5-2.5 (G/L)	02/04/91	1.78		2.13			
TRIGLYCERIDES	0.7-1.5 (G/L)	02/04/91	0.80		0.96			
GLOBULINS ALPHA 1	2-4 (%)	02/04/91					2.70	
GLOBULINS ALPHA 2	6-10 (%)	02/04/91					9.40	
GLOBULINS BETA	9-13 (%)	02/04/91					12.20	
GLOBULINS GAMMA	11-15 (%)	02/04/91					14.60	
TSH	0.1-4 (MU/L)	02/04/91	1.80					
T4	7.3-20.1 (PG/ML)	02/04/91	11.10					

(€) << 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 399085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 197 Treatment: Reboxetine Sex: Male

Laboratory test	Range value	Range date	Visit number / Laboratory date	
			Screen	Day 7
			27/02/92	17/03/92
			value (†)	value (‡)
HB	13-18 (G/DL)	01/06/91	16.60	16.80
HT	37-54 (X)	01/06/91	50.00	49.50
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	5.40	5.44
WBC	4-10 (10 ³ /MM ³)	01/06/91	9.80	11.00 >
WBC: N	40-70 (X)	01/06/91	62.10	65.00
WBC: L	19-48 (X)	01/06/91	33.90	26.40
WBC: E	0-7 (X)	01/06/91	0.70	0.62
WBC: M	3.4-9 (X)	01/06/91	4.00	7.53
WBC: B	0-1.5 (X)	01/06/91	0.20	0.43
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	223.00	214.00
NA+	135-145 (MMOL/L)	01/06/91	140.00	143.00
K+	3.5-5 (MMOL/L)	01/06/91		4.49
CL-	98-108 (MMOL/L)	01/06/91	98.00	98.00
Ca++	8.5-10.5 (MG/DL)	01/06/91	8.99	9.00
PO4--	2.1-4 (MG/DL)	01/06/91	2.58	2.18
SGOT	11-33 (U/L)	01/06/91	19.00	20.00
SGPT	11-39 (U/L)	01/06/91	22.00	23.00
GAMMA GT	15-85 (U/L)	01/06/91	28.00	27.00
LDH	200-450 (U/L)	01/06/91	325.00	324.00
ALK. PHOSPH.	34-154 (U/L)	01/06/91	122.00	141.00
GLUCOSE	0.6-1 (G/L)	01/06/91	0.54 <	0.78
BUN	()	01/06/91		
UREA	0.18-0.43 (G/L)	01/06/91	0.29	0.30
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.96	1.08
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.40	4.10
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.67	0.41
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.08	0.11
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	6.80	7.20
ALBUMINE	52-68 (X)	01/06/91	59.80	57.20
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	239.00	258.00
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	145.00	180.00 >
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	2.80	3.10
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	7.60	9.50
GLOBULINS BETA	9.5-14 (X)	01/06/91	14.90 >	13.80
GLOBULINS GAMMA	12-21 (X)	01/06/91	14.90	16.40
TSH	1-5 (UU/ML)	01/06/91		
T4	4.5-13 (UG/DL)	01/06/91	8.90	

(†) << 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 889
930085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 200 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			21/04/92		18/05/92		08/06/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	10/04/92	15.10		14.90		15.40	
HT	37-54 (%)	10/04/92	45.10		43.40		45.30	
RBC	4-6.2 (10 ⁶ /MM ³)	10/04/92	4.92		4.81		4.98	
HBC	4-10 (10 ³ /MM ³)	10/04/92	4.65		5.37		4.74	
HBC: N	40-70 (%)	10/04/92	48.20		49.10		48.30	
HBC: L	19-48 (%)	10/04/92	34.00		34.70		34.20	
HBC: E	0-7 (%)	10/04/92	5.50		6.32		6.04	
HBC: M	3.4-9 (%)	10/04/92	11.60	>	9.07	>	10.07	
HBC: B	0-1.5 (%)	10/04/92	0.59		0.86		0.86	
PLATELETS	150-350 (10 ³ /MM ³)	10/04/92	276.00		316.00		318.00	
NA+	135-145 (MMOL/L)	10/04/92	143.00		140.00		139.00	
K+	3.5-5 (MMOL/L)	10/04/92	4.45		7.19	>>	4.52	
CL-	98-108 (MMOL/L)	10/04/92	103.00		98.00		100.00	
Ca++	8.5-10.5 (MG/DL)	10/04/92	10.10		9.51		10.10	
PO4--	2.1-4 (MG/DL)	10/04/92	2.67		3.29		2.24	
SGOT	11-33 (U/L)	10/04/92	21.00		21.00		28.00	
SGPT	11-39 (U/L)	10/04/92	25.00		31.00		42.00	
GAMMA GT	15-85 (U/L)	10/04/92	44.00		29.00		60.00	
LDH	200-450 (U/L)	10/04/92	336.00		536.00	>	367.00	
ALK. PHOSPH.	34-154 (U/L)	10/04/92	92.00		86.00		113.00	
GLUCOSE	0.6-1 (G/L)	10/04/92	0.69		0.84		0.68	
BUN	()	10/04/92						
UREA	0.18-0.43 (G/L)	10/04/92	0.34		0.26		0.36	
CREATININE	0.7-1.3 (MG/DL)	10/04/92	0.97		1.01		0.99	
URIC ACID	3.4-7.3 (MG/DL)	10/04/92	4.60		3.90		4.20	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	10/04/92	0.72		0.69		0.62	
DIR BILIRUBIN	0-0.36 (MG/DL)	10/04/92	0.15				0.10	
TOT. PROTEINS	6.7-7.9 (G/DL)	10/04/92	7.70		7.70		7.50	
ALBUMINE	3.8-4.8 (G/DL)	10/04/92	4.70				4.40	
	52-68 (%)	10/05/92			58.50			
TOT. CHOLEST.	155-280 (MG/DL)	10/04/92	272.00		257.00		259.00	
TRIGLYCERIDES	62-162 (MG/DL)	10/04/92	74.00		121.00		119.00	
GLOBULINS ALPHA 1	2.5-4.8 (%)	10/04/92	2.50		2.00	<	4.00	
GLOBULINS ALPHA 2	6.2-11 (%)	10/04/92	8.60		12.30	>	11.30	
GLOBULINS BETA	9.5-14 (%)	10/04/92	12.60		12.40		15.60	
GLOBULINS GAMMA	12-21 (%)	10/04/92	14.90		14.90		10.10	
TSH	1-5 (UU/ML)	10/04/92	1.05					
T4	4.5-13 (UG/DL)	10/04/92	62.00					

(€) << 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 889
9390085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 203 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 7	
			10/01/92		28/01/92	
			value	(φ)	value	(φ)
Laboratory test	Range value	Range date				
HB	11-16 (G/DL)	01/06/91	15.60		15.90	
HT	37-54 (X)	01/06/91	46.50		47.10	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	5.10		5.24	
MBC	4-10 (10 ³ /MM ³)	01/06/91	10.50	>	9.27	
MBC: N	40-70 (X)	01/06/91	63.00		59.60	
MBC: L	19-48 (X)	01/06/91	30.00		30.00	
MBC: E	0-7 (X)	01/06/91	3.00		3.05	
MBC: M	3.4-9 (X)	01/06/91	5.00		6.73	
MBC: B	0-1.5 (X)	01/06/91	0.00		0.62	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	352.00	>	315.00	
NA+	135-145 (MMOL/L)	01/06/91	142.00		140.00	
K+	3.5-5 (MMOL/L)	01/06/91	6.06	>>	4.08	
CL-	98-108 (MMOL/L)	01/06/91	102.00		100.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.68		9.33	
PO4--	2.1-4 (MG/DL)	01/06/91	4.04	>	3.33	
SGOT	11-33 (U/L)	01/06/91	38.00	>	39.00	
SGPT	11-39 (U/L)	01/06/91	50.00	>	53.00	
GAMMA GT	5-55 (U/L)	01/06/91	40.00		36.00	
LDH	200-450 (U/L)	01/06/91	357.00		333.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	70.00		78.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.87		0.89	
BUN	()	01/06/91				
UREA	0.18-0.43 (G/L)	01/06/91	0.20		0.25	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.95		0.95	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	6.20		5.80	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.52		0.40	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.06		0.11	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.50		7.30	
ALBUMINE	52-68 (X)	01/06/91	58.60		59.40	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	273.00		228.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	281.00	>>	155.00	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	3.60		3.30	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	11.00		10.20	
GLOBULINS BETA	9.5-14 (X)	01/06/91	13.80		12.50	
GLOBULINS GAMMA	12-21 (X)	01/06/91	13.00		14.50	
TSH	1-5 (UV/NL)	01/06/91	1.24			
T4	4.5-13 (UG/DL)	01/06/91	8.50			

(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)
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CN030085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 204 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			09/01/92		06/02/92		28/02/92	
			value	(*)	value	(*)	value	(*)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/06/91	15.10		13.90		13.40	
HT	37-54 (%)	01/06/91	45.90		40.90		39.90	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	5.03		4.53		4.32	
WBC	4-10 (10 ³ /MM ³)	01/06/91	8.83		7.75		9.00	
WBC: N	40-70 (%)	01/06/91	62.90		59.60		44.90	
WBC: L	19-48 (%)	01/06/91	26.20		29.50		49.20 >	
WBC: E	0-7 (%)	01/06/91	2.71		4.13		0.70	
WBC: M	3.4-9 (%)	01/06/91	7.77		6.60		5.90	
WBC: B	0-1.5 (%)	01/06/91	0.41		0.21		0.20	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	385.00 >		469.00 >>		459.00 >>	
NA+	135-145 (MMOL/L)	01/06/91	141.00		143.00		143.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.19		4.75		3.85	
CL-	98-108 (MMOL/L)	01/06/91	98.00		101.00		100.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.64		9.90		9.39	
PO4--	2.1-4 (MG/DL)	01/06/91	2.91		3.54		3.72	
SGOT	11-38 (U/L)	01/06/91	27.00		24.00		35.00 >	
SGPT	11-39 (U/L)	01/06/91	33.00		26.00		36.00	
GAMMA GT	15-85 (U/L)	01/06/91	40.00		40.00		52.00	
LDH	200-450 (U/L)	01/06/91	367.00		359.00		338.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	127.00		111.00		121.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.91		0.53 <		0.81	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.28		0.34		0.26	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.94		1.14		0.92	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.40		5.40		3.70	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.70		0.65		0.56	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.15		0.14		0.11	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.90		7.20		7.30	
ALBUMINE	52-68 (%)	01/06/91	55.50		52.60		57.10	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	227.00		210.00		202.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	78.00		93.00		75.00	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	2.20 <		2.90		2.90	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	8.70		10.50		8.10	
GLOBULINS BETA	9.5-14 (%)	01/06/91	14.00		11.70		13.30	
GLOBULINS GAMMA	12-21 (%)	01/06/91	19.60		22.30 >		18.70	
TSH	1-5 (UU/ML)	01/06/91	7.90					
T4	4.5-13 (UG/DL)	01/06/91	0.52					

(*) << 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 888
9330085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 207 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			27/01/92
			value (c)
Laboratory test	Range value	Range date	
HB	11-16 (G/DL)	01/06/91	12.90
HT	37-54 (%)	01/06/91	39.40
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.43
WBC	4-10 (10 ³ /MM ³)	01/06/91	4.76
WBC: N	40-70 (%)	01/06/91	
WBC: L	19-48 (%)	01/06/91	
WBC: E	0-7 (%)	01/06/91	
WBC: M	3.4-9 (%)	01/06/91	
WBC: B	0-1.5 (%)	01/06/91	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	310.00
NA+	135-145 (MMOL/L)	01/06/91	144.00
K+	3.5-5 (MMOL/L)	01/06/91	4.16
CL-	98-108 (MMOL/L)	01/06/91	106.00
Ca ⁺⁺	8.5-10.5 (MG/DL)	01/06/91	9.67
PO ₄ ⁻⁻	2.1-4 (MG/DL)	01/06/91	3.26
SGOT	11-33 (U/L)	01/06/91	15.00
SGPT	11-39 (U/L)	01/06/91	13.00
GAMMA GT	5-55 (U/L)	01/06/91	
LDH	200-450 (U/L)	01/06/91	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.84
BUN	()	01/06/91	
UREA	0.18-0.43 (G/L)	01/06/91	0.53 >
CREATININE	0.7-1.3 (MG/DL)	01/06/91	1.15
URIC ACID	3.4-7.9 (MG/DL)	01/06/91	6.00
TOT. BILIRUBIN	0.04-1.15 (MG/DL)	01/06/91	0.40
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	6.60 <
ALBUMINE	52-68 (%)	01/06/91	49.00 <
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	253.00
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	303.00 >>
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	3.30
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	8.20
GLOBULINS BETA	9.5-14 (%)	01/06/91	14.90 >
GLOBULINS GAMMA	12-21 (%)	01/06/91	16.90
TSH	1-5 (UU/ML)	01/06/91	0.50
T4	4.5-13 (UG/DL)	01/06/91	8.60

(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 () missing range value

PHARMACIA CNS 888
9330085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 208 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/02/92		06/03/92		30/03/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/06/91	15.30		14.50		15.10	
HT	37-54 (%)	01/06/91	43.90		41.40		43.80	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.51		4.29		4.53	
HBC	4-10 (10 ³ /MM ³)	01/06/91	6.39		5.69		5.88	
HBC: N	40-70 (%)	01/06/91	64.00		40.50			
HBC: L	19-48 (%)	01/06/91	26.00		44.10			
HBC: E	0-7 (%)	01/06/91	2.00		3.08			
HBC: M	3.4-9 (%)	01/06/91	8.00		11.90	>>		
HBC: B	0-1.5 (%)	01/06/91	0.00		0.48			
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	218.00		205.00		191.00	
NA+	135-145 (MMOL/L)	01/06/91			139.00			
K+	3.5-5 (MMOL/L)	01/06/91			3.86			
CL-	98-108 (MMOL/L)	01/06/91			98.00			
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.23		9.33		9.59	
PO4--	2.1-4 (MG/DL)	01/06/91	3.46		3.67		4.27 >	
SGOT	11-33 (U/L)	01/06/91	37.00 >		40.00 >		45.00 >	
SGPT	11-39 (U/L)	01/06/91	45.00 >		55.00 >		67.00 >	
GAMMA GT	15-85 (U/L)	01/06/91	56.00		50.00		61.00	
LDH	200-450 (U/L)	01/06/91	377.00		318.00		367.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	72.00		65.00		67.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.71		0.85			
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.38		0.55 >		0.46 >	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	1.15		1.11		1.09	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	5.70		4.00		4.70	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.79		0.84		1.24 >	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.20		0.18		0.23	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.30		7.00		7.30	
ALBUMINE	52-68 (%)	01/06/91	60.10		61.80		51.40 <	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	244.00		240.00		263.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	78.00		74.00		80.00	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	2.00 <		2.20 <		2.30 <	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	10.00		8.00		12.40 >	
GLOBULINS BETA	9.5-14 (%)	01/06/91	13.50		12.40		15.80 >	
GLOBULINS GAMMA	12-21 (%)	01/06/91	14.30		15.60		18.00	
TSH	1-5 (UU/ML)	01/06/91	6.20					
T4	4.5-13 (UG/DL)	01/06/91	1.61					

(€) << 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 20124/017

Listing No.: 18.0

LABORATORY DATA 0550085

Centre: 9 Patient: 210 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/02/92		11/03/92		01/04/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	12.80		13.10		12.70	
HT	37-54 (%)	01/06/91	36.70 <		37.90		37.80	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.21		4.35		4.34	
WBC	4-10 (10 ³ /MM ³)	01/06/91	7.32		7.61		7.41	
WBC: N	40-70 (%)	01/06/91	57.40		50.50		50.00	
WBC: L	19-48 (%)	01/06/91	28.70		37.30		36.70	
WBC: E	0-7 (%)	01/06/91	2.25		2.04		2.42	
WBC: M	3.4-9 (%)	01/06/91	9.49 >		9.68 >		10.20 >	
WBC: B	0-1.5 (%)	01/06/91	2.20 >>		0.53		0.73	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	283.00		280.00		296.00	
NA+	135-145 (MMOL/L)	01/06/91	143.00		145.00		144.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.51		4.48		4.27	
CL-	98-108 (MMOL/L)	01/06/91	100.00		100.00		101.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.56		9.79		9.39	
PO4--	2.1-4 (MG/DL)	01/06/91	3.49		3.51		3.67	
SGOT	11-33 (U/L)	01/06/91	14.00		16.00		16.00	
SGPT	11-39 (U/L)	01/06/91	12.00		12.00		13.00	
GAMMA GT	5-55 (U/L)	01/06/91	14.00		13.00		13.00	
LDH	200-450 (U/L)	01/06/91	279.00		329.00		305.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	92.00		103.00		106.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	1.11 >		1.06 >		0.94	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.31		0.39		0.31	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.90		1.05		1.13	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.50		4.40		4.40	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.39		0.37		0.22	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.07		0.05		0.05	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.40		7.60		7.40	
ALBUMINE	52-68 (%)	01/06/91			57.80		63.20	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	241.00		250.00		250.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	158.00		109.00		139.00	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91			2.70		2.60	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91			8.60		7.50	
GLOBULINS BETA	9.5-14 (%)	01/06/91			14.40 >		12.50	
GLOBULINS GAMMA	12-21 (%)	01/06/91			16.60		14.20	
TSH	1-5 (UU/ML)	01/06/91	0.87					
T4	4.5-13 (UG/DL)	01/06/91	2.10					

(€) << 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 20124/017
Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 211 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			11/02/92		03/03/92	
			value	(c)	value	(c)
Laboratory test	Range value	Range date				
HB	11-16 (G/DL)	01/06/91	14.40		13.80	
HT	37-54 (X)	01/06/91	42.00		39.60	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.18		4.09	
MBC	4-10 (10 ³ /MM ³)	01/06/91	6.70		6.67	
MBC: N	40-70 (X)	01/06/91			67.60	
MBC: L	19-48 (X)	01/06/91	33.70		22.20	
MBC: E	0-7 (X)	01/06/91			1.09	
MBC: M	3.4-9 (X)	01/06/91	5.10		8.90	
MBC: B	0-1.5 (X)	01/06/91			0.18	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	262.00		237.00	
NA+	135-145 (MMOL/L)	01/06/91	140.00		137.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.07		4.53	
CL-	98-108 (MMOL/L)	01/06/91	100.00		98.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.60		9.71	
PO4--	2.1-4 (MG/DL)	01/06/91	3.70		3.48	
SGOT	11-33 (U/L)	01/06/91	13.00		12.00	
SGPT	11-39 (U/L)	01/06/91	11.00		9.00 <	
GAMMA GT	5-55 (U/L)	01/06/91	13.00		11.00	
LDH	200-450 (U/L)	01/06/91	279.00		282.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	58.00		57.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.82		0.79	
BUN	()	01/06/91				
UREA	0.18-0.43 (G/L)	01/06/91	0.30		0.23	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.96		0.92	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	2.65 <		2.90 <	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.37		0.76	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.09		0.15	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91			7.20	
ALBUMINE	52-68 (X)	01/06/91	54.10		59.90	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	219.00		187.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	110.00		68.00	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	3.30		2.70	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	11.10		9.50	
GLOBULINS BETA	9.5-14 (X)	01/06/91	14.30 >		12.20	
GLOBULINS GAMMA	12-21 (X)	01/06/91	14.40		15.70	
TSH	1-5 (UU/ML)	01/06/91	0.61			
T4	4.5-13 (UG/DL)	01/06/91	7.80			

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

0550085

LABORATORY DATA

Centre: 9 Patient: 237 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date	
			Screen	Day 14
			15/04/92	06/05/92
			value (€)	value (€)
Laboratory test	Range value	Range date		
HB	13-18 (G/DL)	01/06/91	16.00	15.60
HT	37-54 (%)	01/06/91	46.40	46.70
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.91	4.90
WBC	4-10 (10 ³ /MM ³)	01/06/91	6.88	7.76
WBC: N	40-70 (%)	01/06/91	51.30	60.00
WBC: L	19-48 (%)	01/06/91	37.50	30.20
WBC: E	0-7 (%)	01/06/91	1.41	1.27
WBC: M	3.4-9 (%)	01/06/91	9.08 >	7.89
WBC: B	0-1.5 (%)	01/06/91	0.67	0.59
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	233.00	256.00
NA+	135-145 (MMOL/L)	01/06/91	144.00	145.00
K+	3.5-5 (MMOL/L)	01/06/91	5.03 >	5.04 >
CL-	98-108 (MMOL/L)	01/06/91	102.00	106.00
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.91	10.30
PO4--	2.1-4 (MG/DL)	01/06/91	2.67	3.13
SGOT	11-33 (U/L)	01/06/91	23.00	19.00
SGPT	11-39 (U/L)	01/06/91	36.00	24.00
GAMMA GT	15-85 (U/L)	01/06/91	20.00	20.00
LDH	200-450 (U/L)	01/06/91	261.00	259.00
ALK. PHOSPH.	34-154 (U/L)	01/06/91	93.00	103.00
GLUCOSE	0.6-1 (G/L)	01/06/91	0.86	1.03 >
BUN	()	01/06/91		
UREA	0.18-0.43 (G/L)	01/06/91	0.41	0.49 >
CREATININE	0.7-1.3 (MG/DL)	01/06/91	1.12	1.18
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.60	5.10
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.55	0.22
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.09	0.05
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.50	7.30
ALBUMINE	52-68 (%)	01/06/91	54.70	56.60
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	267.00	206.00
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	77.00	123.00
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	2.80	2.40 <
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	10.10	9.20
GLOBULINS BETA	9.5-14 (%)	01/06/91	15.30 >	14.60 >
GLOBULINS GAMMA	12-21 (%)	01/06/91		17.20
TSH	1-5 (UU/ML)	01/06/91	0.94	
T4	4.5-13 (UG/DL)	01/06/91	7.70	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 240 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			23/04/92
			value (€)
Laboratory test	Range value	Range date	
HB	11-16 (G/DL)	01/06/91	14.60
HT	37-54 (Z)	01/06/91	43.30
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.64
WBC	4-10 (10 ³ /MM ³)	01/06/91	5.81
WBC: N	40-70 (Z)	01/06/91	63.48
WBC: L	19-48 (Z)	01/06/91	27.38
WBC: E	0-7 (Z)	01/06/91	0.78
WBC: M	3.4-9 (Z)	01/06/91	8.23
WBC: B	0-1.5 (Z)	01/06/91	0.23
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	345.00
NA+	135-145 (MMOL/L)	01/06/91	143.00
K+	3.5-5 (MMOL/L)	01/06/91	4.47
CL-	98-108 (MMOL/L)	01/06/91	103.00
Ca++	8.5-10.5 (MG/DL)	01/06/91	10.60
PO4--	2.1-4 (MG/DL)	01/06/91	1.86 <
SGOT	11-33 (U/L)	01/06/91	21.00
SGPT	11-39 (U/L)	01/06/91	17.00
GAMMA GT	5-55 (U/L)	01/06/91	29.00
LDH	200-450 (U/L)	01/06/91	335.00
ALK. PHOSPH.	34-154 (U/L)	01/06/91	83.00
GLUCOSE	0.6-1 (G/L)	01/06/91	0.68
BUN	()	01/06/91	
UREA	0.18-0.43 (G/L)	01/06/91	0.31
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.94
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.90
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.47
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.11
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	8.60 >
ALBUMINE	52-68 (Z)	01/06/91	57.80
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	264.00
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	66.00
GLOBULINS ALPHA 1	2.5-4.8 (Z)	01/06/91	2.80
GLOBULINS ALPHA 2	6.2-11 (Z)	01/06/91	10.90
GLOBULINS BETA	9.5-14 (Z)	01/06/91	14.20 >
GLOBULINS GAMMA	12-21 (Z)	01/06/91	14.20
TSH	1-5 (UU/ML)	01/06/91	1.26
T4	4.5-13 (UG/DL)	01/06/91	13.80

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 9 Patient: 242 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			30/04/92		27/05/92		17/06/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/06/91	15.20		14.70		13.80	
HT	37-54 (%)	01/06/91	45.30		44.20		40.70	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.80		4.71		4.41	
WBC	4-10 (10 ³ /MM ³)	01/06/91	9.04		4.53		4.21	
WBC: N	40-70 (%)	01/06/91	78.00 >		57.40		52.10	
WBC: L	19-48 (%)	01/06/91	13.00 <<		32.70		36.80	
WBC: E	0-7 (%)	01/06/91	0.00		0.79		1.10	
WBC: M	3.4-9 (%)	01/06/91	8.00		8.79		9.01 >	
WBC: B	0-1.5 (%)	01/06/91	1.00		0.27		0.99	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	380.00 >		336.00		328.00	
NA+	135-145 (MMOL/L)	01/06/91	140.00		139.00		140.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.39		3.91		3.94	
CL-	98-108 (MMOL/L)	01/06/91	94.00 <		95.00 <		98.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	10.30		9.93		9.69	
PO4--	2.1-4 (MG/DL)	01/06/91	3.05		2.39		2.66	
SGOT	11-33 (U/L)	01/06/91	23.00		18.00		21.00	
SGPT	11-39 (U/L)	01/06/91	32.00		11.00		13.00	
GAMMA GT	15-85 (U/L)	01/06/91	60.00		30.00		24.00	
LDH	200-450 (U/L)	01/06/91	356.00		305.00		301.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	115.00		92.00		86.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	1.05 >		0.97		0.92	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.41		0.45 >		0.45 >	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.98		0.89		0.89	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.80		4.00		4.70	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.43		0.37		0.39	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.07		0.06		0.07	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.60		7.40		7.10	
ALBUMINE	52-68 (%)	01/06/91	53.50		53.80		52.60	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	290.00 >		245.00		229.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	144.00		160.00		75.00	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	3.10		2.50		2.80	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	13.50 >		11.50 >		11.80 >	
GLOBULINS BETA	9.5-14 (%)	01/06/91	14.70 >		15.00 >		15.40 >	
GLOBULINS GAMMA	12-21 (%)	01/06/91	15.30		17.20		17.40	
TSH	1-5 (UU/ML)	01/06/91	1.64					
T4	4.5-19 (UG/DL)	01/06/91	11.50					

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 9 Patient: 244 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/05/92		26/06/92		16/07/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/06/91	14.90		15.40		14.90	
HT	37-54 (X)	01/06/91	44.00		46.00		43.80	
RBC	4-6.2 (10~6/MM3)	01/06/91	5.17		5.40		5.20	
WBC	4-10 (10~3/MM3)	01/06/91	5.86		5.99		5.43	
WBC: N	40-70 (X)	01/06/91	50.00		49.10		55.60	
WBC: L	19-48 (X)	01/06/91	42.00		48.70	>	35.80	
WBC: E	0-7 (X)	01/06/91	0.00		2.49		1.55	
WBC: M	3.4-9 (X)	01/06/91	6.00		4.75		6.82	
WBC: B	0-1.5 (X)	01/06/91	0.00		1.00		0.21	
PLATELETS	150-350 (10~3/MM3)	01/06/91	244.00		328.00		350.00	
NA+	135-145 (MMOL/L)	01/06/91	143.00		138.00			
K+	3.5-5 (MMOL/L)	01/06/91						
CL-	98-108 (MMOL/L)	01/06/91	100.00		98.00			
Ca++	8.5-10.5 (MG/DL)	01/06/91	10.40		10.40			
PO4--	2.1-4 (MG/DL)	01/06/91	2.87		4.01	>		
SGOT	11-33 (U/L)	01/06/91	24.00		23.00			
SGPT	11-39 (U/L)	01/06/91	41.00	>	29.00			
GAMMA GT	15-85 (U/L)	01/06/91	36.00		35.00			
LDH	200-450 (U/L)	01/06/91	322.00		327.00			
ALK. PHOSPH.	34-154 (U/L)	01/06/91	81.00		81.00			
GLUCOSE	0.6-1 (G/L)	01/06/91	0.57	<	0.82			
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.34		0.35			
CREATININE	0.7-1.3 (MG/DL)	01/06/91	1.19		1.24			
URIC ACID	3.4-7.9 (MG/DL)	01/06/91	8.10	>	6.90			
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.44		0.44			
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.06		0.07			
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	8.10	>	8.10	>		
ALBUMINE	52-68 (X)	01/06/91	59.10		60.70			
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	246.00		237.00			
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	284.00	>>	182.00	>		
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	2.70		1.60	<<		
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	9.10		7.60			
GLOBULINS BETA	9.5-14 (X)	01/06/91	13.60		14.90	>		
GLOBULINS GAMMA	12-21 (X)	01/06/91	15.50		15.20			
TSH	1-5 (UU/ML)	01/06/91	0.78					
T4	4.5-13 (UG/DL)	01/06/91	7.90					

(€) << 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 20124/017

Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 9 Patient: 257 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/07/91		07/08/91		28/08/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	13.90		13.30		13.30	
HT	37-54 (X)	01/06/91	40.10		39.90		39.50	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.35		4.37		4.32	
WBC	4-10 (10 ³ /MM ³)	01/06/91	9.65		9.11		8.08	
WBC: N	40-70 (X)	01/06/91	47.00		65.00		55.50	
WBC: L	19-48 (X)	01/06/91	38.10		28.10		34.90	
WBC: E	0-7 (X)	01/06/91			2.54		4.52	
WBC: M	3.4-9 (X)	01/06/91	8.00		4.01		3.58	
WBC: B	0-1.5 (X)	01/06/91			0.41		1.56 >	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	275.00		288.00		312.00	
NA+	135-145 (MMOL/L)	01/06/91			140.00		143.00	
K+	3.5-5 (MMOL/L)	01/06/91			4.02		3.66	
CL-	98-108 (MMOL/L)	01/06/91			98.00		103.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.80		9.20		9.40	
PO4--	2.1-4 (MG/DL)	01/06/91	3.60		4.20 >		4.00	
SGOT	11-33 (U/L)	01/06/91	15.00		15.00		15.00	
SGPT	11-39 (U/L)	01/06/91	21.00		12.00		15.00	
GAMMA GT	5-55 (U/L)	01/06/91	41.00		38.00		31.00	
LDH	200-450 (U/L)	01/06/91	319.00		282.00		264.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	77.00		76.00		73.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.91		0.87		1.11 >	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.29					
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.77		0.86		0.84	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91			4.10		5.10	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.40		2.30 >>		0.20	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91			0.08			
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91			7.80		7.80	
ALBUMINE	52-68 (X)	01/06/91						
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91			226.00		258.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91			122.00		100.00	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91						
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91						
GLOBULINS BETA	9.5-14 (X)	01/06/91						
GLOBULINS GAMMA	12-21 (X)	01/06/91						
TSH	1-5 (UU/ML)	01/06/91	2.07					
T4	4.5-13 (UG/DL)	01/06/91	12.90					

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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 258 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date
			Screen
			10/07/91
			value (†)
Laboratory test	Range value	Range date	
HB	13-18 (G/DL)	01/06/91	15.50
HT	37-54 (%)	01/06/91	44.10
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	5.03
HBC	4-10 (10 ³ /MM ³)	01/06/91	5.48
HBC: N	40-70 (%)	01/06/91	56.10
HBC: L	19-48 (%)	01/06/91	36.10
HBC: E	0-7 (%)	01/06/91	0.96
HBC: M	3.4-9 (%)	01/06/91	4.79
HBC: B	0-1.5 (%)	01/06/91	2.09 >>
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	211.00
NA+	135-145 (MMOL/L)	01/06/91	
K+	3.5-5 (MMOL/L)	01/06/91	
CL-	98-108 (MMOL/L)	01/06/91	
Ca ⁺⁺	8.5-10.5 (MG/DL)	01/06/91	9.20
PO ₄ ⁻⁻	2.1-4 (MG/DL)	01/06/91	2.70
SGOT	11-33 (U/L)	01/06/91	20.00
SGPT	11-39 (U/L)	01/06/91	18.00
GAMMA GT	15-85 (U/L)	01/06/91	16.00
LDH	200-450 (U/L)	01/06/91	306.00
ALK. PHOSPH.	34-154 (U/L)	01/06/91	84.00
GLUCOSE	0.6-1 (G/L)	01/06/91	0.88
BUN	()	01/06/91	
UREA	0.18-0.43 (G/L)	01/06/91	0.39
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.88
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.76
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	
ALBUMINE	52-68 (%)	01/06/91	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	
GLOBULINS BETA	9.5-14 (%)	01/06/91	
GLOBULINS GAMMA	12-21 (%)	01/06/91	
TSH	1-5 (UU/HL)	01/06/91	1.29
T4	4.5-13 (UG/DL)	01/06/91	7.80

(†) << 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)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 9 Patient: 262 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			16/07/91		13/08/91		03/09/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/06/91	16.20		16.70		16.30	
HT	37-54 (%)	01/06/91	45.50		47.60		47.90	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.85		5.11		5.09	
HBC	4-10 (10 ³ /MM ³)	01/06/91	11.90 >		12.60 >		12.00 >	
HBC: N	40-70 (%)	01/06/91	74.40 >		77.00 >		72.70 >	
HBC: L	19-48 (%)	01/06/91	19.50		17.00 <		20.20	
HBC: E	0-7 (%)	01/06/91	1.88		1.00		2.30	
HBC: M	3.4-9 (%)	01/06/91	3.58		4.00		4.46	
HBC: B	0-1.5 (%)	01/06/91	0.64		1.00		0.36	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	226.00		213.00		211.00	
NA+	135-145 (MMOL/L)	01/06/91	143.00		140.00		140.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.25		4.17		3.59	
CL-	98-108 (MMOL/L)	01/06/91	107.00		97.00 <		98.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	8.80		9.10		9.10	
PO4--	2.1-4 (MG/DL)	01/06/91	2.90		2.20		2.80	
SGOT	11-33 (U/L)	01/06/91	32.00		33.00		24.00	
SGPT	11-39 (U/L)	01/06/91	37.00		27.00		43.00 >	
GAMMA GT	15-85 (U/L)	01/06/91	37.00		33.00		28.00	
LDH	200-450 (U/L)	01/06/91	286.00		388.00		298.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	82.00		102.00		83.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.99		0.94		1.02 >	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.22		0.15 <		0.18	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	1.12		1.00		1.15	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	6.60		6.80		5.90	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.44		0.37		0.50	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91			0.11		0.13	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.79		7.80		7.50	
ALBUMINE	52-68 (%)	01/06/91	59.80		49.90 <		64.30	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	220.00		214.00		230.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	349.00 >>		380.00 >>		384.00 >>	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	1.50 <<		2.10 <<		1.00 <<	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	8.10		6.90		7.30	
GLOBULINS BETA	9.5-14 (%)	01/06/91	14.90 >		14.40 >		12.70	
GLOBULINS GAMMA	12-21 (%)	01/06/91	15.70		17.20		14.70	
TSH	1-5 (UU/ML)	01/06/91	0.78					
T4	4.5-13 (UG/DL)	01/06/91	10.00					

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

LABORATORY DATA 0550085

Centre: 9 Patient: 263 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 14	
			24/07/91		14/08/91	
			value	(€)	value	(€)
Laboratory test	Range value	Range date				
HB	11-16 (G/DL)	01/06/91	13.50		13.40	
HT	37-54 (%)	01/06/91	39.90		39.40	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.23		4.19	
MBC	4-10 (10 ³ /MM ³)	01/06/91	5.08		5.16	
MBC: N	40-70 (%)	01/06/91	62.00		54.80	
MBC: L	19-48 (%)	01/06/91	19.00		33.80	
MBC: E	0-7 (%)	01/06/91	5.00		4.46	
MBC: M	3.4-9 (%)	01/06/91	12.00	>>	6.46	
MBC: B	0-1.5 (%)	01/06/91			0.51	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	173.00		153.00	
NA+	135-145 (MMOL/L)	01/06/91	139.00		142.00	
K+	3.5-5 (MMOL/L)	01/06/91			4.35	
CL-	98-108 (MMOL/L)	01/06/91	100.00		100.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.50		9.70	
PO4--	2.1-4 (MG/DL)	01/06/91	3.50		4.70 >>	
SGOT	11-33 (U/L)	01/06/91	19.00		13.00	
SGPT	11-39 (U/L)	01/06/91	14.00		12.00	
GAMMA GT	5-55 (U/L)	01/06/91	14.00		11.00	
LDH	200-450 (U/L)	01/06/91	354.00		305.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	66.00		56.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.89		0.75	
BUN	()	01/06/91				
UREA	0.18-0.43 (G/L)	01/06/91	0.30			
CREATININE	0.7-1.3 (MG/DL)	01/06/91	1.16		0.85	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91			5.50	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.30		0.39	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91			0.07	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.39		7.30	
ALBUMINE	52-68 (%)	01/06/91	62.20			
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	243.00		247.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	79.00		47.00 <	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	2.70			
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	10.10			
GLOBULINS BETA	9.5-14 (%)	01/06/91	9.40	<		
GLOBULINS GAMMA	12-21 (%)	01/06/91	15.60			
TSH	1-5 (UV/ML)	01/06/91	0.52			
T4	4.5-13 (UG/DL)	01/06/91	7.20			

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 265 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			13/08/91		12/09/91		03/10/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	14.10		14.60		15.50	
HT	37-54 (%)	01/06/91	42.00		42.80		45.90	
RBC	4-6.2 (10 ⁶ /MM3)	01/06/91	4.42		4.59		4.92	
WBC	4-10 (10 ³ /MM3)	01/06/91	6.68		6.05		7.48	
WBC: N	40-70 (%)	01/06/91	60.50		54.50		58.70	
WBC: L	19-48 (%)	01/06/91	31.00		36.70		32.50	
WBC: E	0-7 (%)	01/06/91	0.97		2.11		1.81	
WBC: M	3.4-9 (%)	01/06/91	6.40		6.24		6.42	
WBC: B	0-1.5 (%)	01/06/91	1.16		0.49		0.58	
PLATELETS	150-350 (10 ³ /MM3)	01/06/91	311.00		340.00		401.00 >	
NA+	135-145 (MMOL/L)	01/06/91	142.00		142.00		137.00	
K+	3.5-5 (MMOL/L)	01/06/91	5.30 >		4.19		4.58	
CL-	98-108 (MMOL/L)	01/06/91	105.00		101.00		95.00 <	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.90		9.70		11.20 >	
PO4--	2.1-4 (MG/DL)	01/06/91	2.20		3.10		2.70	
SGOT	11-33 (U/L)	01/06/91	20.00		16.00		23.00	
SGPT	11-39 (U/L)	01/06/91	9.00 <		13.00		6.00 <	
GAMMA GT	5-55 (U/L)	01/06/91	10.00		12.00		14.00	
LDH	200-450 (U/L)	01/06/91	510.00 >		254.00		398.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	45.00		41.00		52.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.70		0.65		0.84	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.20		0.14 <		0.33	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.76		0.85		0.83	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.70		3.70		4.90	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.64		0.60		0.48	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91			0.11			
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.60		7.60		9.00 >	
ALBUMINE	52-68 (%)	01/06/91	60.40		63.60		53.10	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	178.00		167.00		212.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	82.00		73.00		120.00	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	1.90 <		1.50 <<		1.70 <<	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	10.20		7.70		11.10 >	
GLOBULINS BETA	9.5-14 (%)	01/06/91	10.70		10.90		12.80	
GLOBULINS GAMMA	12-21 (%)	01/06/91	16.80		16.40		19.60	
TSH	1-5 (UU/ML)	01/06/91	1.31					
T4	4.5-13 (UG/DL)	01/06/91	6.70					

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 266 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/09/91		08/10/91		28/10/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	14.40		13.60		15.00	
HT	37-54 (X)	01/06/91	42.90		40.20		43.40	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.32		4.12		4.52	
WBC	4-10 (10 ³ /MM ³)	01/06/91	7.57		7.15		9.63	
WBC: N	40-70 (X)	01/06/91	67.80		61.90		75.00 >	
WBC: L	19-48 (X)	01/06/91	26.30		31.50		20.80	
WBC: E	0-7 (X)	01/06/91	0.66		0.68		0.81	
WBC: M	3.4-9 (X)	01/06/91	5.19		5.45		2.75 <	
WBC: B	0-1.5 (X)	01/06/91	0.12		0.47		0.66	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	382.00 >		419.00 >		359.00 >	
NA+	135-145 (MMOL/L)	01/06/91	140.00		139.00		141.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.52		4.60		4.46	
CL-	98-108 (MMOL/L)	01/06/91	103.00		103.00		101.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.70		9.50		9.70	
PO4--	2.1-4 (MG/DL)	01/06/91	3.20		3.30		3.50	
SGOT	11-33 (U/L)	01/06/91	21.00		20.00		27.00	
SGPT	11-39 (U/L)	01/06/91	27.00		22.00		28.00	
GAMMA GT	5-55 (U/L)	01/06/91	39.00		32.00		29.00	
LDH	200-450 (U/L)	01/06/91	375.00		277.00		341.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	65.00		71.00		81.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.90		0.84		0.90	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.18		0.22		0.18	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.69 <		0.68 <		0.68 <	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.30		3.90		3.80	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.63		0.59		0.67	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.04		0.08			
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.70		7.00		8.00 >	
ALBUMINE	52-68 (X)	01/06/91	62.60		55.50		57.40	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	241.00		238.00		247.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	140.00		249.00 >>		225.00 >>	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	2.40 <		3.10		3.10	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	10.70		12.20 >		12.10 >	
GLOBULINS BETA	9.5-14 (X)	01/06/91	13.30		14.30 >		13.10	
GLOBULINS GAMMA	12-21 (X)	01/06/91	11.00 <		14.80		14.20	
TSH	1-5 (UU/ML)	01/06/91	2.98					
T4	4.5-13 (UG/DL)	01/06/91	8.90					

(€) << 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 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 269 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			19/09/91		15/10/91		05/11/91	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/06/91	16.40		16.30		16.30	
HT	37-54 (X)	01/06/91	46.60		46.50		45.60	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.73		4.79		4.70	
WBC	4-10 (10 ³ /MM ³)	01/06/91	8.27		7.64		8.82	
WBC: N	40-70 (X)	01/06/91	62.40		46.00		52.00	
WBC: L	19-48 (X)	01/06/91	28.80		41.80		36.20	
WBC: E	0-7 (X)	01/06/91	1.45		3.33		2.94	
WBC: M	3.4-9 (X)	01/06/91	6.76		8.03		8.49	
WBC: B	0-1.5 (X)	01/06/91	0.64		0.85		0.45	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	62.40	<<	289.00		282.00	
NA+	135-145 (MMOL/L)	01/06/91	137.00		141.00		142.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.95		4.90		4.70	
CL-	98-108 (MMOL/L)	01/06/91	104.00		104.00		101.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.60		10.10		9.30	
PO4--	2.1-4 (MG/DL)	01/06/91	3.20		4.10	>	3.70	
SDOT	11-33 (U/L)	01/06/91	32.00		24.00		28.00	
SGPT	11-39 (U/L)	01/06/91	31.00		27.00		40.00	
GAMMA GT	15-85 (U/L)	01/06/91	97.00	>	79.00		102.00	
LDH	200-450 (U/L)	01/06/91	699.00	>	320.00		357.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	65.00		68.00		75.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.85		0.76		0.81	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.25		0.23		0.21	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.87		0.89		0.99	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	5.70		5.60		5.10	
TOT. BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.76		0.32		0.67	
DIR. BILIRUBIN	0-0.36 (MG/DL)	01/06/91			0.15		0.14	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.70		7.10		7.30	
ALBUMINE	52-68 (X)	01/06/91	55.00		57.60		53.70	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	315.00	>	330.00	>	364.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	404.00	>>	450.00	>>	588.00	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	2.70		2.70		2.50	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	11.30	>	12.00	>	10.60	
GLOBULINS BETA	9.5-14 (X)	01/06/91	14.60	>	12.30		18.10	
GLOBULINS GAMMA	12-21 (X)	01/06/91	16.40		15.50		14.90	
TSH	1-5 (UU/ML)	01/06/91	1.25					
T4	4.5-13 (UG/DL)	01/06/91	8.70					

(⊕) << 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 20124/017
Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 9 Patient: 271 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			22/10/91		19/11/91	
			value	(c)	value	(c)
Laboratory test	Range value	Range date				
HB	11-16 (G/DL)	01/06/91	12.90		12.50	
HT	37-54 (X)	01/06/91	39.60		37.10	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.23		3.97 <	
MBC	4-10 (10 ³ /MM ³)	01/06/91	5.81		6.75	
MBC: N	40-70 (X)	01/06/91	55.20		64.90	
MBC: L	19-48 (X)	01/06/91	35.20		26.90	
MBC: E	0-7 (X)	01/06/91	2.95		1.47	
MBC: M	3.4-9 (X)	01/06/91	5.91		6.19	
MBC: B	0-1.5 (X)	01/06/91	0.77		0.42	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	327.00		413.00 >	
NA+	135-145 (MMOL/L)	01/06/91	138.00		138.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.81		4.32	
CL-	98-108 (MMOL/L)	01/06/91	94.00 <		96.00 <	
Ca++	8.5-10.5 (MG/DL)	01/06/91	10.40		10.40	
PO4--	2.1-4 (MG/DL)	01/06/91	3.30		3.70	
SGOT	11-33 (U/L)	01/06/91	25.00		26.00	
SGPT	11-39 (U/L)	01/06/91	26.00		14.00	
GAMMA GT	5-55 (U/L)	01/06/91	36.00		37.00	
LDH	200-450 (U/L)	01/06/91	344.00		363.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	88.00		100.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.83		0.71	
BUN	()	01/06/91				
UREA	0.18-0.43 (G/L)	01/06/91	0.38		0.58 >	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	1.15		1.27	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	5.60		6.00	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.40		0.32	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.12		0.11	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	8.00 >		8.10 >	
ALBUMINE	52-68 (X)	01/06/91	54.50		46.00 <	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	344.00 >		284.00 >	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	434.00 >>		309.00 >>	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	2.80		2.90	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	13.10 >		11.40 >	
GLOBULINS BETA	9.5-14 (X)	01/06/91	12.50		12.60	
GLOBULINS GAMMA	12-21 (X)	01/06/91	17.10		16.40	
TSH	1-5 (UU/ML)	01/06/91	9.30			
T4	4.5-13 (UG/DL)	01/06/91	1.62			

(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 20124/017
Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 274 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory data			
			Screen		Day 7	
			23/10/91		06/11/91	
			value	(e)	value	(e)
Laboratory test	Range value	Range date				
HB	11-16 (G/DL)	01/06/91	14.40		32.30 >	
HT	37-54 (X)	01/06/91	41.70		42.20	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.46		4.51	
MBC	4-10 (10 ³ /MM ³)	01/06/91	5.10		6.24	
MBC: N	40-70 (X)	01/06/91	54.50		55.40	
MBC: L	19-48 (X)	01/06/91	36.00		36.10	
MBC: E	0-7 (X)	01/06/91	3.73		2.24	
MBC: M	3.4-9 (X)	01/06/91	5.00		5.18	
MBC: B	0-1.5 (X)	01/06/91	0.87		1.16	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	242.00		254.00	
NA+	135-145 (MMOL/L)	01/06/91	139.00		144.00	
K+	3.5-5 (MMOL/L)	01/06/91	3.99		3.85	
CL-	98-108 (MMOL/L)	01/06/91	99.00		101.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.80		9.20	
PO4--	2.1-4 (MG/DL)	01/06/91	3.20		3.30	
SGOT	11-33 (U/L)	01/06/91	18.00		17.00	
SGPT	11-39 (U/L)	01/06/91	31.00		33.00	
GAMMA GT	5-55 (U/L)	01/06/91	36.00		36.00	
LDH	200-450 (U/L)	01/06/91	308.00		285.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	73.00		70.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	1.06 >		1.08 >	
BUN	()	01/06/91				
UREA	0.18-0.43 (G/L)	01/06/91	0.32		0.44 >	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.72		0.74	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	2.50 <		2.70 <	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.50		0.43	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.10		0.08	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.30		7.20	
ALBUMINE	52-68 (X)	01/06/91				
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	312.00 >		302.00 >	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	80.00		69.00	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91				
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91				
GLOBULINS BETA	9.5-14 (X)	01/06/91				
GLOBULINS GAMMA	12-21 (X)	01/06/91				
TSH	1-5 (UU/ML)	01/06/91				
T4	4.5-13 (UG/DL)	01/06/91				

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 274/A Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			21/04/92		02/06/92		24/06/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	13.50		13.90		13.90	
HT	37-54 (%)	01/06/91	40.20		41.20		41.60	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.03		4.15		4.20	
HBC	4-10 (10 ³ /MM ³)	01/06/91	9.33		8.59		10.10 >	
HBC: N	40-70 (%)	01/06/91	58.20		58.10		61.60	
HBC: L	19-48 (%)	01/06/91	28.40		27.40		23.40	
HBC: E	0-7 (%)	01/06/91	1.30		1.74		1.51	
HBC: M	3,4-9 (%)	01/06/91	10.80 >		12.70 >>		12.80 >>	
HBC: B	0-1.5 (%)	01/06/91	1.40		0.13		0.75	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	329.00		312.00		395.00 >	
NA+	135-145 (MMOL/L)	01/06/91	140.00		141.00		139.00	
K+	3,5-5 (MMOL/L)	01/06/91	3.60		3.46 <		3.26 <	
CL-	98-108 (MMOL/L)	01/06/91	99.00		95.00 <		96.00 <	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.60		9.50		9.13	
PO4--	2.1-4 (MG/DL)	01/06/91	3.83		2.64		2.71	
SGOT	11-33 (U/L)	01/06/91	21.00		22.00		20.00	
SGPT	11-39 (U/L)	01/06/91	11.00		11.00		10.00 <	
GAMMA GT	5-55 (U/L)	01/06/91	9.00		9.00		8.00	
LDH	200-450 (U/L)	01/06/91	364.00		401.00		375.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	68.00		65.00		71.00	
GLUCOSE	0,6-1 (G/L)	01/06/91	0.77		0.88		0.86	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.24		0.25		0.30	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.87		0.83		0.85	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.50		4.10		5.10	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.40		0.28		0.29	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.08		0.07		0.06	
TOT. PROTEINS	6,7-7.9 (G/DL)	01/06/91	6.90		6.60 <		6.60 <	
ALBUMINE	52-68 (%)	01/06/91	59.60		63.30		58.20	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	255.00		245.00		250.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	67.00		66.00		81.00	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	2.90		3.00		3.00	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	11.30 >		9.20		10.20	
GLOBULINS BETA	9,5-14 (%)	01/06/91	12.50		11.40		12.60	
GLOBULINS GAMMA	12-21 (%)	01/06/91	13.70		13.10		16.00	
TSH	1-5 (UU/ML)	01/06/91	1.57					
T4	4.5-13 (UG/DL)	01/06/91	8.40					

(€) << 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 20124/017

Listing No.: 18.0

LABORATORY DATA 0550085

Centre: 9 Patient: 275 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			31/10/91		26/11/91		18/12/91	
			value	(e)	value	(e)	value	(e)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	13.30		12.80		12.60	
HT	37-54 (X)	01/06/91	38.30		38.40		36.30 <	
RBC	4-6.2 (10 ⁶ /MM3)	01/06/91	4.48		4.44		4.21	
WBC	4-10 (10 ³ /MM3)	01/06/91	5.62		5.65		5.46	
WBC: N	40-70 (X)	01/06/91	56.80		54.10		63.40	
WBC: L	19-48 (X)	01/06/91	31.40		28.70		22.50	
WBC: E	0-7 (X)	01/06/91	5.09		8.03 >		5.15	
WBC: M	3.4-9 (X)	01/06/91	5.27		8.82		8.44	
WBC: B	0-1.5 (X)	01/06/91	1.47		0.44		0.52	
PLATELETS	150-350 (10 ³ /MM3)	01/06/91	273.00		328.00		298.00	
NA+	135-145 (MMOL/L)	01/06/91	142.00		145.00		142.00	
K+	3.5-5 (MMOL/L)	01/06/91	3.72		3.62		4.41	
CL-	98-108 (MMOL/L)	01/06/91	102.00		101.00		100.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.90		10.00		9.80	
PO4--	2.1-4 (MG/DL)	01/06/91	3.20		3.40		3.20	
SGOT	11-33 (U/L)	01/06/91	35.00 >		17.00		24.00	
SGPT	11-39 (U/L)	01/06/91	24.00		14.00		22.00	
GAMMA GT	5-55 (U/L)	01/06/91	20.00		16.00		18.00	
LDH	200-450 (U/L)	01/06/91	315.00		269.00		289.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	158.00 >		152.00		151.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.79		0.89		0.83	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.45 >		0.50 >		0.44 >	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.84		0.86		0.73	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	1.80 <		2.60 <		2.30 <	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.47		0.43		0.51	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.07		0.09		0.08	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.10		7.00		7.10	
ALBUMINE	52-68 (X)	01/06/91	56.80		58.90		59.00	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	295.00 >		242.00		254.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	79.00		122.00		146.00	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	2.70		2.10 <		2.70	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	11.60 >		11.90 >		12.10 >	
GLOBULINS BETA	9.5-14 (X)	01/06/91	15.80 >		14.30 >		15.60 >	
GLOBULINS GAMMA	12-21 (X)	01/06/91	13.10		11.70 <		12.40	
TSH	1-5 (U/ML)	01/06/91						
T4	4.5-13 (UG/DL)	01/06/91						

(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 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9/A Patient: 234 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/05/92		11/06/92		02/07/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/01/92	13.10		14.50		14.20	
HT	37-47 (%)	01/01/92	37.60		40.50		42.30	
RBC	4-5.8 (10 ⁶ /MM3)	01/01/92	3.70 <		4.13		4.20	
WBC	4000-10000 (/MM3)	01/01/92	7900.00		8400.00		8900.00	
WBC: N	40-70 (%)	01/01/92	39.10 <		35.90 <		46.20	
WBC: L	20-50 (%)	01/01/92	50.50 >		50.90 >		46.40	
WBC: E	0-8 (%)	01/01/92	5.20		6.00		4.50	
WBC: M	0-13 (%)	01/01/92	4.70		6.70		2.00	
WBC: B	0-3 (%)	01/01/92	0.60		0.50		1.00	
PLATELETS	150-400 (10 ³ /MM3)	01/01/92			256.00		287.00	
NA+	136-147 (MMOL/L)	01/01/92	139.00		138.00		140.00	
K+	3.6-5.5 (MMOL/L)	01/01/92	4.30				4.50	
CL-	95-110 (MMOL/L)	01/01/92	105.00		99.00		102.00	
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.58		9.94		10.15	
PO4--	2.4-4.8 (MG/DL)	01/01/92			4.10		4.00	
SGOT	5-40 (U/L)	01/01/92	15.00		27.00		22.00	
SGPT	5-40 (U/L)	01/01/92	16.00		30.00		18.00	
GAMMA GT	0-40 (U/L)	01/01/92	11.00		23.00		24.00	
LDH	150-460 (U/L)	01/01/92			339.00		282.00	
ALK. PHOSPH.	40-350 (U/L)	01/01/92			105.00		122.00	
GLUCOSE	50-120 (MG/DL)	01/01/92	76.00		79.00		71.00	
BUN	()	01/01/92						
UREA	8-48 (MG/DL)	01/01/92	18.00		27.00		25.00	
CREATININE	0.3-1.25 (MG/DL)	01/01/92	1.00		0.96		1.00	
URIC ACID	2-6.5 (MG/DL)	01/01/92						
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.53		0.43		0.60	
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.15		0.09		0.17	
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	6.62		7.39		7.19	
ALBUMINE	55-72 (%)	01/01/92	65.70		68.20		69.00	
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	177.00		179.00		171.00	
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	58.00		65.00		46.00	
GLOBULINS ALPHA 1	2-6 (%)	01/01/92	4.10		2.80		2.40	
GLOBULINS ALPHA 2	6-11 (%)	01/01/92	7.60		7.50		6.80	
GLOBULINS BETA	9-14 (%)	01/01/92	10.10		8.70 <		7.20 <	
GLOBULINS GAMMA	10-20 (%)	01/01/92	12.50		12.80		14.60	
TSH	0.1-4 (UU/ML)	01/01/92	1.49					
T4	4.8-12.8 (UG/DL)	01/01/92	8.30					

(€) << 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)

PHARMACTA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9/A Patient: 235 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date	
			Screen	Day 21
			22/05/92	16/06/92
			value (♣)	value (♣)
Laboratory test	Range value	Range date		
HB	14-18 (G/DL)	01/01/92	16.10	15.20
HT	42-53 (X)	01/01/92	46.40	43.80
RBC	4.5-6.2 (10 ⁶ /MM ³)	01/01/92	5.32	5.08
WBC	4000-10000 (/MM ³)	01/01/92	6600.00	8000.00
WBC: N	40-70 (X)	01/01/92	63.10	66.20
WBC: L	20-50 (X)	01/01/92	27.50	26.60
WBC: E	0-8 (X)	01/01/92	3.80	4.00
WBC: M	0-13 (X)	01/01/92	5.00	2.80
WBC: B	0-3 (X)	01/01/92	0.50	0.40
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	264.00	317.00
NA+	136-147 (MMOL/L)	01/01/92	143.00	140.00
K+	3.6-5.5 (MMOL/L)	01/01/92	4.00	4.20
CL-	95-110 (MMOL/L)	01/01/92	100.00	104.00
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.61	8.85
PO4--	2-4.5 (MG/DL)	01/01/92	3.50	3.50
SGOT	5-40 (U/L)	01/01/92	14.00	25.00
SGPT	5-40 (U/L)	01/01/92	17.00	25.00
GAMMA GT	0-40 (U/L)	01/01/92	14.00	18.00
LDH	150-460 (U/L)	01/01/92	134.00	281.00
ALK. PHOSPH.	40-350 (U/L)	01/01/92	117.00	182.00
GLUCOSE	50-120 (MG/DL)	01/01/92		118.00
BUN	()	01/01/92		
UREA	8-50 (MG/DL)	01/01/92	28.00	39.00
CREATININE	0.3-1.38 (MG/DL)	01/01/92	1.21	1.07
URIC ACID	2-7.5 (MG/DL)	01/01/92	6.39	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.64	0.43
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.17	0.12
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	6.70	6.74
ALBUMINE	55-72 (X)	01/01/92	66.80	66.20
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	160.00	180.00
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	88.00	59.00
GLOBULINS ALPHA 1	2-6 (X)	01/01/92	2.90	2.80
GLOBULINS ALPHA 2	6-11 (X)	01/01/92	9.10	8.50
GLOBULINS BETA	9-14 (X)	01/01/92	10.70	11.40
GLOBULINS GAMMA	10-20 (X)	01/01/92	10.50	11.10
TSH	0.1-4 (UU/ML)	01/01/92	1.20	
T4	4.8-12.8 (UG/DL)	01/01/92	8.20	

(♣) << 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 and laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9/A Patient: 277 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			11/06/92
			value (c)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	01/01/92	15.10
HT	37-47 (X)	01/01/92	44.30
RBC	4-5.8 (10 ⁶ /MM ³)	01/01/92	4.87
WBC	4000-10000 (/MM ³)	01/01/92	6100.00
WBC: N	40-70 (X)	01/01/92	71.60 >
WBC: L	20-50 (X)	01/01/92	24.00
WBC: E	0-8 (X)	01/01/92	0.90
WBC: M	0-13 (X)	01/01/92	2.60
WBC: B	0-3 (X)	01/01/92	0.80
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	175.00
NA+	136-147 (MMOL/L)	01/01/92	136.00
K+	3.6-5.5 (MMOL/L)	01/01/92	
CL-	95-110 (MMOL/L)	01/01/92	104.00
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.84
PO4--	2.4-4.8 (MG/DL)	01/01/92	4.10
SGOT	5-40 (U/L)	01/01/92	21.00
SGPT	5-40 (U/L)	01/01/92	18.00
GAMMA GT	0-40 (U/L)	01/01/92	12.00
LDH	150-460 (U/L)	01/01/92	339.00
ALK. PHOSPH.	40-350 (U/L)	01/01/92	101.00
GLUCOSE	50-120 (MG/DL)	01/01/92	78.00
BUN	()	01/01/92	
UREA	8-48 (MG/DL)	01/01/92	41.00
CREATININE	0.3-1.25 (MG/DL)	01/01/92	1.10
URIC ACID	2-6.5 (MG/DL)	01/01/92	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.60
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.16
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	7.77
ALBUMINE	55-72 (X)	01/01/92	63.60
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	202.00
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	64.00
GLOBULINS ALPHA 1	2-6 (X)	01/01/92	2.30
GLOBULINS ALPHA 2	6-11 (X)	01/01/92	7.00
GLOBULINS BETA	9-14 (X)	01/01/92	9.60
GLOBULINS GAMMA	10-20 (X)	01/01/92	17.50
TSH	0.1-4 (UU/ML)	01/01/92	59.20
T4	4.8-12.8 (UG/DL)	01/01/92	3.10

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9/A Patient: 280 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			07/08/92
			value (c)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	01/01/92	14.90
HT	37-47 (Z)	01/01/92	43.60
RBC	4-5.8 (10 ⁶ /MM ³)	01/01/92	5.03
WBC	4000-10000 (/MM ³)	01/01/92	10800.0 >
WBC: N	40-70 (Z)	01/01/92	78.70 >
WBC: L	20-50 (Z)	01/01/92	19.00 <
WBC: E	0-8 (Z)	01/01/92	0.70
WBC: M	0-13 (Z)	01/01/92	1.10
WBC: B	0-3 (Z)	01/01/92	0.60
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	230.00
NA+	136-147 (MMOL/L)	01/01/92	131.00 <
K+	3.6-5.5 (MMOL/L)	01/01/92	
CL-	95-110 (MMOL/L)	01/01/92	89.00 <
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.91
PO4--	2.4-4.8 (MG/DL)	01/01/92	
SGOT	5-40 (U/L)	01/01/92	20.00
SGPT	5-40 (U/L)	01/01/92	14.00
GAMMA GT	0-40 (U/L)	01/01/92	9.00
LDH	150-460 (U/L)	01/01/92	356.00
ALK. PHOSPH.	40-350 (U/L)	01/01/92	167.00
GLUCOSE	50-120 (MG/DL)	01/01/92	79.00
BUN	()	01/01/92	
UREA	8-48 (MG/DL)	01/01/92	35.00
CREATININE	0.3-1.25 (MG/DL)	01/01/92	1.03
URIC ACID	2-6.5 (MG/DL)	01/01/92	2.45
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.61
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.09
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	8.24 >
ALBUMINE	55-72 (Z)	01/01/92	64.30
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	327.00 >>
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	81.00
GLOBULINS ALPHA 1	2-6 (Z)	01/01/92	2.70
GLOBULINS ALPHA 2	6-11 (Z)	01/01/92	7.80
GLOBULINS BETA	9-14 (Z)	01/01/92	10.70
GLOBULINS GAMMA	10-20 (Z)	01/01/92	14.50
TSH	0.1-4 (UU/ML)	01/01/92	2.40
T4	4.8-12.8 (UG/DL)	01/01/92	11.00

(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)

PHARNACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9/A Patient: 281 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/08/92		21/09/92		12/10/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/01/92	15.20		15.00		15.50	
HT	37-47 (X)	01/01/92	44.70		44.40		47.30 >	
RBC	4-5.8 (10 ⁶ /MM ³)	01/01/92	4.70		4.77		5.05	
WBC	4000-10000 (/MM ³)	01/01/92	5900.00		6300.00		5500.00	
WBC: N	40-70 (X)	01/01/92	46.60		47.50		47.20	
WBC: L	20-50 (X)	01/01/92	44.30		42.30		41.60	
WBC: E	0-8 (X)	01/01/92	2.60		4.50		5.70	
WBC: M	0-13 (X)	01/01/92	6.10		5.40		5.20	
WBC: B	0-3 (X)	01/01/92	0.50		0.30		0.30	
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	223.00		231.00		224.00	
NA+	136-147 (MMOL/L)	01/01/92	141.00		143.00		145.00	
K+	3.6-5.5 (MMOL/L)	01/01/92	4.90		4.10		4.60	
CL-	95-110 (MMOL/L)	01/01/92	96.00		101.00		104.00	
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.73		9.28		9.49	
PO4--	2.4-4.8 (MG/DL)	01/01/92			3.50		3.40	
SGOT	5-40 (U/L)	01/01/92	36.00		28.00		25.00	
SGPT	5-40 (U/L)	01/01/92	26.00		34.00		21.00	
GAMMA GT	0-40 (U/L)	01/01/92	29.00		37.00		33.00	
LDH	150-460 (U/L)	01/01/92	541.00 >		252.00		242.00	
ALK. PHOSPH.	40-350 (U/L)	01/01/92	156.00		237.00		220.00	
GLUCOSE	50-120 (MG/DL)	01/01/92	99.00		82.00		102.00	
BUN	()	01/01/92						
UREA	8-48 (MG/DL)	01/01/92	24.00		27.00		27.00	
CREATININE	0.3-1.25 (MG/DL)	01/01/92	0.85		1.01		1.00	
URIC ACID	2-6.5 (MG/DL)	01/01/92	9.07 >>		8.01 >		7.83 >	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.84		0.50		0.61	
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.05		0.17		0.20	
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	7.53		7.62		7.39	
ALBUMINE	55-72 (X)	01/01/92	59.60		69.20		63.60	
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	220.00		206.00		203.00	
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	162.00		128.00		123.00	
GLOBULINS ALPHA 1	2-6 (X)	01/01/92	3.50		2.50		3.30	
GLOBULINS ALPHA 2	6-11 (X)	01/01/92	10.30		6.40		7.50	
GLOBULINS BETA	9-14 (X)	01/01/92	11.90		10.30		11.70	
GLOBULINS GAMMA	10-20 (X)	01/01/92	14.70		11.60		13.90	
TSH	0.1-4 (UU/ML)	01/01/92						
T4	4.8-12.8 (UG/DL)	01/01/92	9.50					

(c) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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 () 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9/A Patient: 282 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			01/09/92		22/09/92		13/10/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/01/92	12.10	<	14.60		14.80	
HT	42-53 (%)	01/01/92	39.50	<	45.30		46.30	
RBC	4.5-6.2 (10 ⁶ /MM ³)	01/01/92	4.70		5.25		5.33	
WBC	4000-10000 (/MM ³)	01/01/92	8200.00		10900.0	>	11500.0	>
WBC: N	40-70 (%)	01/01/92	56.90		50.80		67.40	
WBC: L	20-50 (%)	01/01/92	35.80		39.30		26.50	
WBC: E	0-13 (%)	01/01/92	2.20		3.90		2.50	
WBC: M	0-13 (%)	01/01/92	4.80		5.60		3.50	
WBC: B	0-3 (%)	01/01/92	0.30		0.40		0.10	
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	149.00	<	334.00		334.00	
NA+	136-147 (MMOL/L)	01/01/92	139.00		140.00		139.00	
K+	3.6-5.5 (MMOL/L)	01/01/92	4.40		4.10		4.70	
CL-	95-110 (MMOL/L)	01/01/92	102.00		102.00		100.00	
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.44		9.73		9.48	
PO4--	2-4.5 (MG/DL)	01/01/92	3.90		4.30		3.10	
SGOT	5-40 (U/L)	01/01/92	21.00		17.00		20.00	
SGPT	5-40 (U/L)	01/01/92	42.00	>	10.00		17.00	
GAMMA GT	0-40 (U/L)	01/01/92	26.00		17.00		17.00	
LDH	150-460 (U/L)	01/01/92	367.00		375.00		344.00	
ALK. PHOSPH.	40-350 (U/L)	01/01/92	147.00		156.00		167.00	
GLUCOSE	50-120 (MG/DL)	01/01/92	61.00		75.00		77.00	
BUN	()	01/01/92						
UREA	8-50 (MG/DL)	01/01/92	27.00		26.00		26.00	
CREATININE	0.3-1.38 (MG/DL)	01/01/92	1.11		1.36		1.25	
URIC ACID	2-7.5 (MG/DL)	01/01/92	7.74	>	6.87		5.26	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.22		0.35		0.52	
DIER BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.03		0.01		0.16	
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	7.40		7.61		7.65	
ALBUMINE	55-72 (%)	01/01/92	65.90		62.60		68.80	
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	265.00	>	218.00		206.00	
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	266.00	>>	134.00		140.00	
GLOBULINS ALPHA 1	2-6 (%)	01/01/92	2.70		2.50		2.60	
GLOBULINS ALPHA 2	6-11 (%)	01/01/92	9.30		7.70		8.00	
GLOBULINS BETA	9-14 (%)	01/01/92	11.30		8.70	<	10.00	
GLOBULINS GAMMA	10-20 (%)	01/01/92	10.80		18.50		10.60	
TSH	0.1-4 (UU/ML)	01/01/92	0.96					
T4	4.8-12.8 (UG/DL)	01/01/92	6.90					

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9/A Patient: 303 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			06/03/92		31/03/92	
			value	(e)	value	(e)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	01/01/92	14.40		14.80	
HT	37-47 (%)	01/01/92	40.50		43.40	
RBC	4-5.8 (10 ⁶ /MM3)	01/01/92	4.25		4.47	
WBC	4000-10000 (/MM3)	01/01/92	17400.0	>>	14000.0	
WBC: N	40-70 (%)	01/01/92	76.00	>	74.40	
WBC: L	20-50 (%)	01/01/92	8.00	<<	15.60	
WBC: E	0-8 (%)	01/01/92	0.00		1.20	
WBC: M	0-13 (%)	01/01/92	2.00		2.50	
WBC: B	0-3 (%)	01/01/92	0.00		0.30	
PLATELETS	150-400 (10 ³ /MM3)	01/01/92	372.00		426.00	
NA+	136-147 (MMOL/L)	01/01/92	142.00		139.00	
K+	3.6-5.5 (MMOL/L)	01/01/92	4.70		4.60	
CL-	95-110 (MMOL/L)	01/01/92	102.00		101.00	
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.30		9.87	
PO4--	2.4-4.8 (MG/DL)	01/01/92	4.50		5.00	
SGOT	5-40 (U/L)	01/01/92	19.00		25.00	
SGPT	5-40 (U/L)	01/01/92	21.00		34.00	
GAMMA GT	0-40 (U/L)	01/01/92	44.00	>	40.00	
LDH	150-460 (U/L)	01/01/92			265.00	
ALK. PHOSPH.	40-350 (U/L)	01/01/92	70.00		76.00	
GLUCOSE	50-120 (MG/DL)	01/01/92	76.00		76.00	
BUN	()	01/01/92				
UREA	8-48 (MG/DL)	01/01/92	22.00		36.00	
CREATININE	0.3-1.25 (MG/DL)	01/01/92	0.92		0.95	
URIC ACID	2-6.5 (MG/DL)	01/01/92	3.06		3.17	
TOT. BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.24		0.78	
DIR. BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.07		0.05	
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	6.85		7.42	
ALBUMINE	55-72 (%)	01/01/92	59.90		60.50	
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	202.00		243.00	
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	141.00		168.00	
GLOBULINS ALPHA 1	2-6 (%)	01/01/92	5.00		5.40	
GLOBULINS ALPHA 2	6-11 (%)	01/01/92	10.20		10.60	
GLOBULINS BETA	9-14 (%)	01/01/92	12.50		11.40	
GLOBULINS GAMMA	10-20 (%)	01/01/92	12.40		12.10	
TSH	0.1-4 (UU/ML)	01/01/92	2.19			
T4	4.8-12.8 (UG/DL)	01/01/92	8.40			

(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 20124/017
Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9/A Patient: 304 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			12/03/92		15/04/92		06/05/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range data						
HB	12-16 (G/DL)	01/01/92	13.80		13.20		15.40	
HT	37-47 (%)	01/01/92	39.10		39.40		43.80	
RBC	4-5.8 (10 ⁶ /MM ³)	01/01/92	4.39		4.31		4.82	
HBC	4000-10000 (/MM ³)	01/01/92	9400.00		6500.00		7200.00	
HBC: N	40-70 (%)	01/01/92	46.00		61.00		59.60	
HBC: L	20-50 (%)	01/01/92	48.00		31.70		32.00	
HBC: E	0-8 (%)	01/01/92	2.00		1.00		3.00	
HBC: M	0-13 (%)	01/01/92	4.00		5.70		4.90	
HBC: B	0-3 (%)	01/01/92	0.00		0.70		0.50	
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	131.00	<	288.00		271.00	
NA+	136-147 (MMOL/L)	01/01/92	145.00		141.00		142.00	
K+	3.6-5.5 (MMOL/L)	01/01/92	4.30		4.00		4.10	
CL-	95-110 (MMOL/L)	01/01/92	102.00		102.00		102.00	
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.59		8.65		9.42	
PO4--	2.4-4.8 (MG/DL)	01/01/92	3.50		3.40		2.80	
SGOT	5-40 (U/L)	01/01/92	27.00		15.00		18.00	
SGPT	5-40 (U/L)	01/01/92	29.00		14.00		13.00	
GAMMA GT	0-40 (U/L)	01/01/92	15.00		15.00		17.00	
LDH	150-460 (U/L)	01/01/92			322.00		392.00	
ALK. PHOSPH.	40-350 (U/L)	01/01/92	138.00		144.00		165.00	
GLUCOSE	50-120 (MG/DL)	01/01/92	90.00		87.00		83.00	
BUN	()	01/01/92						
UREA	8-48 (MG/DL)	01/01/92	36.00		25.00		32.00	
CREATININE	0.3-1.25 (MG/DL)	01/01/92	0.94		0.91		1.00	
URIC ACID	2-6.5 (MG/DL)	01/01/92	6.09					
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.72		0.35		0.33	
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.11		0.03		0.01	
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	7.35		6.88		7.63	
ALBUMINE	55-72 (%)	01/01/92	67.10		66.10		65.40	
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	300.00	>	308.00	>	307.00	
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	128.00		126.00		87.00	
GLOBULINS ALPHA 1	2-6 (%)	01/01/92	3.00		3.40		3.60	
GLOBULINS ALPHA 2	6-11 (%)	01/01/92	6.90		7.00		7.30	
GLOBULINS BETA	9-14 (%)	01/01/92	10.90		11.50		11.70	
GLOBULINS GAMMA	10-20 (%)	01/01/92	12.10		12.00		12.00	
TSH	0.1-4 (UU/ML)	01/01/92	4.12					
T4	4.8-12.8 (UG/DL)	01/01/92	11.00					

(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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 9/A Patient: 305 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/03/92		20/04/92		11/05/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/01/92	15.90		16.00		16.20	
HT	42-53 (X)	01/01/92	47.70		45.70		43.90	
RBC	4.5-6.2 (10 ⁶ /MM ³)	01/01/92	4.87		4.71		4.56	
WBC	4000-10000 (/MM ³)	01/01/92	7100.00		6900.00		7700.00	
WBC: N	40-70 (X)	01/01/92	47.80		53.90		56.30	
WBC: L	20-50 (X)	01/01/92	40.70		36.80		36.80	
WBC: E	0-8 (X)	01/01/92	7.00		5.40		4.60	
WBC: M	0-13 (X)	01/01/92	3.60		3.50		2.20	
WBC: B	0-3 (X)	01/01/92	0.90		0.30		0.20	
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	295.00		284.00		303.00	
NA+	136-147 (MMOL/L)	01/01/92	138.00		142.00		143.00	
K+	3.6-5.5 (MMOL/L)	01/01/92	4.90		4.40		4.30	
CL-	95-110 (MMOL/L)	01/01/92	98.00		98.00		103.00	
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.77		9.83		9.40	
PO4--	2-4.5 (MG/DL)	01/01/92	3.20		3.80		3.90	
SGOT	5-40 (U/L)	01/01/92	17.00		20.00		15.00	
SGPT	5-40 (U/L)	01/01/92	12.00		20.00		11.00	
GAMMA GT	0-40 (U/L)	01/01/92	12.00		16.00		18.00	
LDH	150-460 (U/L)	01/01/92			378.00			
ALK. PHOSPH.	40-350 (U/L)	01/01/92	190.00		202.00		199.00	
GLUCOSE	50-120 (MG/DL)	01/01/92	80.00		79.00		83.00	
BUN	()	01/01/92						
UREA	8-50 (MG/DL)	01/01/92	18.00		22.00		16.00	
CREATININE	0.3-1.38 (MG/DL)	01/01/92	1.24		1.08		1.12	
URIC ACID	2-7.5 (MG/DL)	01/01/92	5.96				6.20	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.70		0.52		0.47	
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.04		0.01		0.12	
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	7.12		7.29		7.27	
ALBUMINE	55-72 (X)	01/01/92			68.70		69.50	
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	206.00		217.00		190.00	
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	123.00		118.00		115.00	
GLOBULINS ALPHA 1	2-6 (X)	01/01/92	2.90		2.90		3.10	
GLOBULINS ALPHA 2	6-11 (X)	01/01/92	7.00		7.00		7.10	
GLOBULINS BETA	9-14 (X)	01/01/92	10.40		10.40		10.30	
GLOBULINS GAMMA	10-20 (X)	01/01/92	11.00		11.00		10.00	
TSH	0.1-4 (UU/ML)	01/01/92	1.58					
T4	4.8-12.8 (UG/DL)	01/01/92	7.70					

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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 20124/017

Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 9/A Patient: 306 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			28/04/92		19/05/92		09/06/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/01/92	14.40		15.90		15.40	
HT	37-47 (X)	01/01/92	39.80		45.80		43.90	
RBC	4-5.8 (10 ⁶ /MM ³)	01/01/92	4.38		5.09		4.91	
WBC	4000-10000 (/MM ³)	01/01/92	12400.0	>	7600.00		9700.00	
WBC: N	40-70 (X)	01/01/92	64.20		51.30		66.10	
WBC: L	20-50 (X)	01/01/92	32.70		41.20		28.70	
WBC: E	0-8 (X)	01/01/92	1.10		3.00		1.60	
WBC: M	0-13 (X)	01/01/92	1.60		4.10		3.40	
WBC: B	0-3 (X)	01/01/92	0.40		0.50		0.20	
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	105.00	<	225.00		248.00	
NA+	136-147 (MMOL/L)	01/01/92	140.00		140.00		139.00	
E+	3.6-5.5 (MMOL/L)	01/01/92	4.40		4.90		4.10	
CL-	95-110 (MMOL/L)	01/01/92	106.00		105.00		102.00	
Ca++	8.3-10.5 (MG/DL)	01/01/92	8.65		9.13		8.28	<
PO4--	2.4-4.8 (MG/DL)	01/01/92	3.50		4.30		3.70	
SGOT	5-40 (U/L)	01/01/92	18.00		19.00		21.00	
SGPT	5-40 (U/L)	01/01/92	12.00		15.00		12.00	
GAMMA GT	0-40 (U/L)	01/01/92	13.00		12.00		12.00	
LDH	150-460 (U/L)	01/01/92	496.00	>	411.00		453.00	
ALK. PHOSPH.	40-350 (U/L)	01/01/92	144.00		154.00		165.00	
GLUCOSE	50-120 (MG/DL)	01/01/92	71.00		74.00		85.00	
BUN	()	01/01/92						
UREA	8-48 (MG/DL)	01/01/92	30.00		31.00		37.00	
CREATININE	0.3-1.25 (MG/DL)	01/01/92	0.84		0.91		0.91	
URIC ACID	2-6.5 (MG/DL)	01/01/92	2.96					
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.52		0.44		0.35	
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.01		0.04		0.02	
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	6.75		6.91		6.38	
ALBUMINE	55-72 (X)	01/01/92	63.80		63.90		67.30	
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	186.00		213.00		183.00	
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	72.00		80.00		120.00	
GLOBULINS ALPHA 1	2-6 (X)	01/01/92	3.30		3.30		3.40	
GLOBULINS ALPHA 2	6-11 (X)	01/01/92	10.60		8.50		7.70	
GLOBULINS BETA	9-14 (X)	01/01/92	11.10		11.50		9.90	
GLOBULINS GAMMA	10-20 (X)	01/01/92	11.20		12.80		11.70	
TSH	0.1-4 (U/ML)	01/01/92			2.98			
T4	4.8-12.8 (UG/DL)	01/01/92			6.70			

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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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 10 Patient: 290 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			07/10/91		04/11/91		25/11/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	21/09/91	15.80		16.30		13.70 <	
HT	36-54 (%)	21/09/91	48.10		51.70		44.20	
RBC	4-5 (10 ⁶ /MM ³)	21/09/91	5.46 >		5.53 >		4.78	
WBC	4000-10000 (/MM ³)	21/09/91	7700.00		6400.00		5500.00 <	
WBC: N	40-70 (%)	21/09/91	36.00 <		74.00 >		32.00 <	
WBC: L	20-40 (%)	21/09/91	56.00 >>		20.00		56.00 >>	
WBC: E	1-4 (%)	21/09/91	4.00		0.00 <		4.00	
WBC: M	4-8 (%)	21/09/91	4.00		6.00		6.00	
WBC: B	0-1 (%)	21/09/91	0.00		0.00		2.00 >>	
PLATELETS	150000-400000 (/MM ³)	21/09/91	193000		220000		199000	
NA+	135-155 (MEQ/L)	21/09/91	140.80		140.50		141.30	
K+	3.1-5.5 (MEQ/L)	21/09/91	3.77		4.47		4.58	
CL-	98-107 (MEQ/L)	21/09/91	103.00		100.00		100.00	
Ca++	88-102 (MG/DL)	21/09/91	98.00		104.00 >		102.00	
PO4--	2.5-4.8 (MG/DL)	21/09/91	4.77		4.70		5.46 >	
SCOT	5-18 (U/L)	21/09/91	8.00		10.00		9.00	
SGPT	5-22 (U/L)	21/09/91	7.00		11.00		8.00	
GAMMA GT	0-25 (U/L)	21/09/91	7.00		7.00		5.00	
LDH	150-240 (U/L)	21/09/91	119.00 <		197.00		128.00 <	
ALK. PHOSPH.	40-90 (U/L)	21/09/91	107.00 >		101.00 >		69.00	
GLUCOSE	76-120 (MG/DL)	21/09/91	97.00		97.00		99.00	
BUN	10-50 (MG/DL)	21/09/91	18.00		22.80		29.00	
UREA	()	21/09/91						
CREATININE	0.7-1.35 (MG/DL)	21/09/91	0.83		0.82		0.83	
URIC ACID	2.5-7 (MG/DL)	21/09/91	2.92		3.41		2.89	
TOT BILIRUBIN	0-1 (MG/DL)	21/09/91	0.50		0.65		0.58	
DIR BILIRUBIN	0-0.25 (MG/DL)	21/09/91	0.08		0.02		0.01	
TOT. PROTEINS	6.6-8.7 (G/DL)	21/09/91	7.20		6.58 <		6.58 <	
ALBUMINE	3.97-5.34 (G/DL)	21/09/91	4.25		4.01		4.28	
TOT. CHOLEST.	120-260 (MG/DL)	21/09/91	142.00		138.00		121.00	
TRIGLYCERIDES	65-172 (MG/DL)	21/09/91	62.00 <		68.00		55.00 <	
GLOBULINS ALPHA 1	1.8-5 (%)	21/09/91	5.30 >					
	0.11-0.32 (G/DL)	03/11/91			0.28		0.37 >	
GLOBULINS ALPHA 2	7-12 (%)	21/09/91	13.50 >					
	0.42-0.87 (G/DL)	03/11/91			0.92 >		0.92 >	
GLOBULINS BETA	6-15 (%)	21/09/91	13.10					
	0.53-1.12 (G/DL)	03/11/91			0.81		0.87	
GLOBULINS GAMMA	7.8-18.2 (%)	21/09/91	9.80					
	0.53-1.97 (G/DL)	03/11/91			0.56		0.72	
TSH	0.15-5.5 (MU/L)	21/09/91	1.80					
T4	5-12 (UG/DL)	21/09/91	8.40					
	5-12 (MG/DL)	03/11/91						

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 10 Patient: 292 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/12/91		03/01/92		25/01/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	22/09/91	14.20		14.60		13.70	
HT	36-54 (%)	22/09/91	39.90		42.60		40.20	
RBC	4-5 (10 ⁶ /MM3)	22/09/91	4.48		4.40		4.60	
HBC	4000-10000 (/MM3)	22/09/91	5800.00		6900.00		6000.00	
HBC: N	40-70 (%)	22/09/91	64.00		70.00		46.00	
HBC: L	20-40 (%)	22/09/91	28.00		26.00		38.00	
HBC: E	1-4 (%)	22/09/91	6.00	>>	2.00		10.00	>>
HBC: M	4-8 (%)	22/09/91	2.00	<	2.00	<	4.00	
HBC: B	0-1 (%)	22/09/91	0.00		0.00		2.00	>>
PLATELETS	150000-400000 (/MM3)	22/09/91	321000		214000		361000	
NA+	135-155 (MEQ/L)	22/09/91	140.10		141.80		141.70	
K+	3.1-5.5 (MEQ/L)	22/09/91	4.20		3.78		4.25	
CL-	98-107 (MEQ/L)	22/09/91	105.00		112.00	>	93.00	<
Ca++	88-102 (MG/L)	22/09/91	100.00		93.00		93.00	
PO4--	2.5-4.8 (MG/DL)	22/09/91	4.40		3.83		3.77	
SGOT	5-15 (U/L)	22/09/91	6.00		7.00		7.00	
SGPT	5-17 (U/L)	22/09/91	15.00		3.00	<	11.00	
GAMMA GT	0-18 (U/L)	22/09/91	7.00		4.00		5.00	
LDH	150-240 (U/L)	22/09/91	176.00		132.00	<	181.00	>
ALK. PHOSPH.	40-90 (U/L)	22/09/91	81.00		77.00		97.00	>
GLUCOSE	76-120 (MG/DL)	22/09/91	96.00		99.00		112.00	
BUN	10-50 (MG/DL)	22/09/91	30.80		25.00		29.20	
UREA	()	22/09/91						
CREATININE	0.55-1.1 (MG/DL)	22/09/91	0.76		0.72		0.55	
URIC ACID	2.5-5.7 (MG/DL)	22/09/91	2.31	<	2.57		1.79	<
TOT BILIRUBIN	0-1 (MG/DL)	22/09/91	1.03	>	0.71		0.30	
DIR BILIRUBIN	0-0.25 (MG/DL)	22/09/91	0.12		0.08		0.02	
TOT. PROTEINS	6.6-8.7 (G/DL)	22/09/91	7.62		7.50		7.60	
ALBUMINE	56-72 (%)	22/09/91	48.90	<				
TOT. CHOLEST.	3.97-5.34 (G/DL)	02/01/92			4.10		4.80	
TRIGLYCERIDES	120-260 (MG/DL)	22/09/91	156.00		133.00		171.00	
GLOBULINS ALPHA 1	65-172 (MG/DL)	22/09/91	108.00		73.00		60.00	<
GLOBULINS ALPHA 2	1.8-5 (%)	22/09/91	3.90					
GLOBULINS BETA	0.11-0.32 (G/DL)	02/01/92			0.30		0.20	
GLOBULINS GAMMA	7-12 (%)	22/09/91	12.20	>	0.80		0.70	
TSH	0.42-0.87 (G/DL)	02/01/92			0.80		0.70	
T4	6-15 (%)	22/09/91	18.20	>	1.10		0.90	
TSH	0.53-1.12 (G/DL)	02/01/92			1.10		0.90	
T4	7.8-18.2 (%)	22/09/91	17.30		1.30		1.00	
TSH	0.15-5.5 (MU/L)	22/09/91	0.90					
T4	5-12 (UG/DL)	22/09/91						
T4	5-12 (MG/DL)	02/01/92						

(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 20124/017

Listing No.: 18.0

LABORATORY DATA 0550085

Centre: 10 Patient: 293 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			16/12/91		14/01/92		04/02/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	22/09/91	13.60		12.90		12.20	
HT	36-54 (X)	22/09/91	44.90				39.50	
RBC	4-5 (10 ⁶ /MM ³)	22/09/91	4.56		4.11		4.01	
HBC	4000-10000 (/MM ³)	22/09/91	6500.00		5000.00		4900.00	
HBC: N	40-70 (X)	22/09/91	82.00	>	82.00	>	46.00	
HBC: L	20-40 (X)	22/09/91	14.00	<	14.00	<	42.00	
HBC: E	1-4 (X)	22/09/91	2.00		2.00		2.00	
HBC: H	4-8 (X)	22/09/91	2.00	<	2.00	<	10.00	
HBC: B	0-1 (X)	22/09/91	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM ³)	22/09/91	323000		396000		392000	
NA+	135-155 (MEQ/L)	22/09/91	140.90		141.40		142.20	
K+	3.1-5.5 (MEQ/L)	22/09/91	4.28		4.58		4.63	
CL-	98-107 (MEQ/L)	22/09/91	102.00		102.00		92.00	
Ca++	88-102 (MG/DL)	22/09/91	93.00		95.00		97.00	
PO4--	2.5-4.8 (MG/DL)	22/09/91	4.16		4.33		3.90	
SGOT	5-15 (U/L)	22/09/91	16.00	>	6.00		6.00	
SGPT	5-17 (U/L)	22/09/91	14.00		3.00	<	7.00	
GAMMA GT	0-18 (U/L)	22/09/91	17.00		11.00		7.00	
LDH	150-240 (U/L)	22/09/91	184.00		172.00		138.00	
ALK. PHOSPH.	40-90 (U/L)	22/09/91	129.00	>	116.00	>	97.00	
GLUCOSE	76-120 (MG/DL)	22/09/91	123.00	>	95.00		99.00	
BUN	10-50 (MG/DL)	22/09/91	40.00		39.00		52.00	
UREA	()	22/09/91						
CREATININE	0.55-1.1 (MG/DL)	22/09/91	0.75		0.66		0.69	
URIC ACID	2.5-5.7 (MG/DL)	22/09/91	1.45	<	3.12		3.30	
TOT BILIRUBIN	0-1 (MG/DL)	22/09/91	0.57		0.49		0.49	
DIR BILIRUBIN	0-0.25 (MG/DL)	22/09/91	0.07		0.05		0.03	
TOT. PROTEINS	6.6-8.7 (G/DL)	22/09/91	7.13		7.10		7.55	
ALBUMINE	56-72 (X)	22/09/91	59.70					
TOT. CHOLEST.	3.97-5.34 (G/DL)	13/01/92			3.80	<	4.30	
TRIGLYCERIDES	120-260 (MG/DL)	22/09/91	190.00		195.00		260.00	
GLOBULINS ALPHA 1	65-172 (MG/DL)	22/09/91	75.00		105.00		104.00	
GLOBULINS ALPHA 2	1.8-5 (X)	22/09/91	3.80					
GLOBULINS BETA	0.11-0.32 (G/DL)	13/01/92			0.50	>>	0.20	
GLOBULINS GAMMA	7-12 (X)	22/09/91	12.90	>				
TSH	0.42-0.87 (G/DL)	13/01/92			0.90	>	0.60	
T4	6-15 (X)	22/09/91	12.40					
T4	0.53-1.12 (G/DL)	13/01/92			1.20	>	0.80	
T4	7.8-18.2 (X)	22/09/91	11.20					
T4	0.53-1.97 (G/DL)	13/01/92			0.80		0.50	
T4	0.15-5.5 (MU/L)	22/09/91	0.50					
T4	5-12 (UG/DL)	22/09/91	7.20					
T4	5-12 (MG/DL)	13/01/92						

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 10 Patient: 296 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			15/02/92		12/03/92		02/04/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	31/12/91	12.00		15.30		11.70 <	
HT	36-54 (X)	31/12/91	34.60 <		38.70		36.80	
RBC	4-5 (10 ⁶ /MM3)	31/12/91	4.22		4.68		4.13	
WBC	4000-10000 (/MM3)	31/12/91	12700.0 >		11300.0 >		4300.00	
WBC: N	40-70 (X)	31/12/91	52.00		52.00		46.00	
WBC: L	20-40 (X)	31/12/91	40.00		36.00		32.00	
WBC: E	1-4 (X)	31/12/91	8.00 >>		0.00 <		12.00 >>	
WBC: M	4-8 (X)	31/12/91	0.00 <		12.00 >>		8.00	
WBC: B	0-1 (X)	31/12/91	0.00		0.00		2.00 >>	
PLATELETS	150000-400000 (/MM3)	31/12/91	276000		304000		249000	
NA+	135-155 (MEQ/L)	31/12/91	139.80		139.50		140.40	
K+	3.1-5.5 (MEQ/L)	31/12/91	4.48		4.30		4.12	
CL-	98-107 (MEQ/L)	31/12/91	100.00		98.00		97.00 <	
Ca++	88-102 (MG/L)	31/12/91	90.00		97.00		100.00	
PO4--	2.5-4.8 (MG/DL)	31/12/91	3.90		4.10		5.09 >	
SGOT	5-15 (U/L)	31/12/91	9.00		6.00		8.00	
SGPT	5-17 (U/L)	31/12/91	6.00		6.00		9.00	
GAMMA GT	0-18 (U/L)	31/12/91	5.00		4.00		5.00	
LDH	150-240 (U/L)	31/12/91	201.00		188.00		129.00 <	
ALK. PHOSPH.	40-90 (U/L)	31/12/91	51.00		49.00		39.00 <	
GLUCOSE	76-120 (MG/DL)	31/12/91	93.00		185.00 >>		98.00	
BUN	10-50 (MG/DL)	31/12/91	19.90		26.00		19.60	
UREA	()	31/12/91						
CREATININE	0.55-1.1 (MG/DL)	31/12/91	0.74		1.05		0.89	
URIC ACID	2.5-5.7 (MG/DL)	31/12/91	2.67		5.27		5.62	
TOT BILIRUBIN	0-1 (MG/DL)	31/12/91	0.36		0.24		0.23	
DIR BILIRUBIN	0-0.25 (MG/DL)	31/12/91	0.05		0.02		0.01	
TOT. PROTEINS	6.6-8.7 (G/DL)	31/12/91	8.06		6.80		7.00	
ALBUMINE	3.97-5.34 (G/DL)	31/12/91	4.30		4.30		4.50	
TOT. CHOLEST.	120-260 (MG/DL)	31/12/91	157.90		147.00		165.00	
TRIGLYCERIDES	65-172 (MG/DL)	31/12/91	101.00		85.00		86.00	
GLOBULINS ALPHA 1	0.11-0.32 (G/DL)	31/12/91	0.30		0.20		0.20	
GLOBULINS ALPHA 2	0.42-0.87 (G/DL)	31/12/91	0.70		0.60		0.60	
GLOBULINS BETA	0.53-1.12 (G/DL)	31/12/91	0.90		0.80		0.80	
GLOBULINS GAMMA	0.53-1.97 (G/DL)	31/12/91	1.10		0.90		0.80	
TSH	0.2-6 (MUI/L)	31/12/91	2.20				3.70	
T4	45-135 (NG/ML)	31/12/91	76.00				76.00	

(€) << 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 RSD

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 10 Patient: 297 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			19/03/92		10/04/92		01/05/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	31/12/91	15.30		16.50		15.70	
HT	36-54 (%)	31/12/91	49.50		50.00		47.00	
RBC	4-5 (10 ⁶ /MM ³)	31/12/91	4.87		5.60 >		5.10 >	
WBC	4000-10000 (/MM ³)	31/12/91	8500.00		8700.00		7900.00	
WBC: N	40-70 (%)	31/12/91	56.00		65.00		64.00	
WBC: L	20-40 (%)	31/12/91	30.00		30.00		30.00	
WBC: E	1-4 (%)	31/12/91	8.00 >>		2.00		2.00	
WBC: M	4-8 (%)	31/12/91	6.00		3.00 <		4.00	
WBC: B	0-1 (%)	31/12/91	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM ³)	31/12/91						
			311000		288000		315000	
NA+	135-155 (MEQ/L)	31/12/91	139.60		143.00		141.00	
K+	3.1-5.5 (MEQ/L)	31/12/91	4.28		5.20		4.20	
CL-	98-107 (MEQ/L)	31/12/91	99.00		102.00		99.00	
Ca++	88-102 (MG/L)	31/12/91	102.00		95.00		93.00	
PO4--	2.5-4.8 (MG/DL)	31/12/91	4.85 >		3.70		3.50	
SGOT	5-18 (U/L)	31/12/91	6.00		8.00		21.00 >	
SGPT	5-22 (U/L)	31/12/91	9.00		10.00		17.00	
GAMMA GT	0-25 (U/L)	31/12/91	8.00		12.00		21.00	
LDH	150-240 (U/L)	31/12/91	194.00		162.00		162.00	
ALK. PHOSPH.	40-90 (U/L)	31/12/91	47.00		91.00 >		120.00 >	
GLUCOSE	76-120 (MG/DL)	31/12/91	90.00		105.00		77.00	
BUN	10-50 (MG/DL)	31/12/91	12.90		23.00		28.00	
UREA	()	31/12/91						
CREATININE	0.7-1.35 (MG/DL)	31/12/91	0.90		1.10		1.00	
URIC ACID	2.5-7 (MG/DL)	31/12/91	5.40		6.20		5.70	
TOT BILIRUBIN	0-1 (MG/DL)	31/12/91	0.49		0.60		1.10 >	
DIR BILIRUBIN	0-0.25 (MG/DL)	31/12/91	0.10		0.20		0.20	
TOT. PROTEINS	6.6-8.7 (G/DL)	31/12/91	6.55 <		6.30 <		6.70	
ALBUMINE	3.97-5.34 (G/DL)	31/12/91	4.60		4.40		4.70	
TOT. CHOLEST.	120-260 (MG/DL)	31/12/91	196.00		211.00		226.00	
TRIGLYCERIDES	65-172 (MG/DL)	31/12/91	79.00		91.00		93.00	
GLOBULINS ALPHA 1	0.11-0.32 (G/DL)	31/12/91	0.20		0.20		0.10 <	
GLOBULINS ALPHA 2	0.42-0.87 (G/DL)	31/12/91	0.60		0.70		0.70	
GLOBULINS BETA	0.53-1.12 (G/DL)	31/12/91	0.70		1.00		0.90	
GLOBULINS GAMMA	0.53-1.97 (G/DL)	31/12/91	0.50 <		0.30 <<		0.30 <<	
TSH	0.2-6 (MUI/L)	31/12/91	1.60					
T4	45-135 (NG/HL)	31/12/91	76.00					

(⊕) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 10 Patient: 298 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			19/03/92		16/04/92		11/05/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	31/12/91	14.50		15.90		13.60	
HT	36-54 (X)	31/12/91	48.40		51.00		48.50	
RBC	4-5 (10 ⁶ /MM ³)	31/12/91	4.81		5.20 >		4.37	
WBC	4000-10000 (/MM ³)	31/12/91	7900.00		7300.00		9300.00	
WBC: N	40-70 (X)	31/12/91	51.00		69.00		58.00	
WBC: L	20-40 (X)	31/12/91	33.00		27.00		34.00	
WBC: E	1-4 (X)	31/12/91	5.00	>	1.00		1.00	
WBC: M	4-8 (X)	31/12/91	6.00		2.00 <		2.00 <	
WBC: B	0-1 (X)	31/12/91	1.00		0.00		2.00 >>	
PLATELETS	150000-400000 (/MM ³)	31/12/91	313000		367000		138.70	
NA+	135-155 (MEQ/L)	31/12/91	141.10		141.00		4.23	
K+	3.1-5.5 (MEQ/L)	31/12/91	4.47		4.90		89.00 <	
CL-	98-107 (MEQ/L)	31/12/91	100.00		100.00		89.00	
Ca++	88-102 (MG/L)	31/12/91	98.00		93.00		89.00	
PO4--	2.5-4.8 (MG/DL)	31/12/91	3.60		3.60			
SGOT	5-15 (U/L)	31/12/91	12.00		18.00 >		11.00	
SGPT	5-17 (U/L)	31/12/91	9.00		29.00 >		19.00 >	
GAMMA GT	0-18 (U/L)	31/12/91	7.00		15.00		13.00	
LDH	150-240 (U/L)	31/12/91	203.00		238.00		201.00	
ALK. PHOSPH.	40-90 (U/L)	31/12/91	70.00		132.00 >		93.00 >	
GLUCOSE	76-120 (MG/DL)	31/12/91	108.00		81.00		105.00	
BUN	10-50 (MG/DL)	31/12/91	29.70		30.00			
UREA	()	31/12/91						
CREATININE	0.55-1.1 (MG/DL)	31/12/91	0.99		0.80		0.66	
URIC ACID	2.5-5.7 (MG/DL)	31/12/91	4.80		5.80 >		6.31 >	
TOT BILIRUBIN	0-1 (MG/DL)	31/12/91	0.55		0.56		0.79	
DIR BILIRUBIN	0-0.25 (MG/DL)	31/12/91	0.10		0.10		0.02	
TOT. PROTEINS	6.6-8.7 (G/DL)	31/12/91	7.21		7.70		7.36	
ALBUMINE	3.97-5.34 (G/DL)	31/12/91	4.60		4.60		4.90	
TOT. CHOLEST.	120-260 (MG/DL)	31/12/91	224.00		197.00		189.00	
TRIGLYCERIDES	65-172 (MG/DL)	31/12/91	116.00		168.00		86.00	
GLOBULINS ALPHA 1	0.11-0.32 (G/DL)	31/12/91	0.30		0.30		0.20	
GLOBULINS ALPHA 2	0.42-0.87 (G/DL)	31/12/91	0.70		0.70		0.80	
GLOBULINS BETA	0.53-1.12 (G/DL)	31/12/91	0.90		0.90		0.80	
GLOBULINS GAMMA	0.53-1.97 (G/DL)	31/12/91	0.90		0.90		1.00	
TSH	0.2-6 (MUI/L)	31/12/91	1.80					
T4	45-135 (NG/ML)	31/12/91	83.00					

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 11 Patient: 321 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/06/92		02/07/92		22/07/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12.5-16.5 (G/DL)	01/05/92	14.50		14.90		14.60	
HT	0.37-0.49 (L/L)	01/05/92	0.42		0.44		0.43	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/05/92	4.80		4.90		4.72	
HBC	4-11 (10 ³ /MM ³)	01/05/92	6.60		8.10		7.50	
HBC: N	1.6-8 (10 ³ /MM ³)	01/05/92	3.70		4.50		4.40	
HBC: L	1-4.5 (10 ³ /MM ³)	01/05/92	2.90		3.10		2.60	
HBC: E	0-0.4 (10 ³ /MM ³)	01/05/92	0.10		0.10		0.10	
HBC: M	0.2-0.8 (10 ³ /MM ³)	01/05/92	0.30		0.40		0.50	
HBC: B	0-0.1 (10 ³ /MM ³)	01/05/92	0.10		0.10		0.10	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/92	244.00		326.00		258.00	
NA+	136-147 (MMOL/L)	01/05/92	139.00		136.00		138.00	
K+	3.5-5.1 (MMOL/L)	01/05/92	4.80		4.20		5.10	
CL-	98-108 (MMOL/L)	01/05/92	107.00		102.00		107.00	
Ca++	2.2-2.6 (MMOL/L)	01/05/92	2.37		2.28		2.31	
PO4--	0.8-1.45 (MMOL/L)	01/05/92	0.85		1.30		0.98	
SGOT	5-40 (U/L)	01/05/92	18.00		27.00		21.00	
SGPT	5-35 (U/L)	01/05/92	28.00		20.00		19.00	
GAMMA GT	4-18 (U/L)	01/05/92	17.00		18.00		22.00 >	
LDH	100-350 (U/L)	01/05/92	181.00		330.00		256.00	
ALK. PHOSPH.	25-160 (U/L)	01/05/92	88.00		142.00		107.00	
GLUCOSE	3.5-6.8 (MMOL/L)	01/05/92	4.42		4.60		4.30	
BUN	()	01/05/92						
UREA	2.6-6.7 (MMOL/L)	01/05/92	5.00		4.50		4.30	
CREATININE	47-88 (UMOL/L)	01/05/92	54.00		86.00		71.00	
URIC ACID	0.12-0.4 (MMOL/L)	01/05/92	0.35		0.34		0.40	
TOT BILIRUBIN	4-21 (UMOL/L)	01/05/92	4.50		2.00 <		4.00	
DIR BILIRUBIN	0-4 (UMOL/L)	01/05/92					2.00	
TOT. PROTEINS	65-80 (G/L)	01/05/92	75.00		78.00		72.00	
ALBUMINE	38-52 (G/L)	01/05/92	40.00		43.00		45.00	
TOT. CHOLEST.	2-6.5 (MMOL/L)	01/05/92	9.42 >>		9.90 >>		7.91 >	
TRIGLYCERIDES	0-1.7 (MMOL/L)	01/05/92	3.59 >>		2.50 >>		2.00 >	
GLOBULINS ALPHA 1	2-4 (G/L)	01/05/92	2.11		2.84		2.28	
GLOBULINS ALPHA 2	5-9 (G/L)	01/05/92	7.51		10.32 >		8.82	
GLOBULINS BETA	7-11 (G/L)	01/05/92	10.59		12.10 >		10.43	
GLOBULINS GAMMA	7-16 (G/L)	01/05/92	6.50 <		9.48		7.75	
TSH	0.4-5 (MUI/L)	01/05/92	1.60					
T4	9-20.9 (PMOL/L)	01/05/92	13.30					

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 11 Patient: 322 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			08/06/92		03/07/92		27/07/92	
			value	(ø)	value	(ø)	value	(ø)
Laboratory test	Range value	Range date						
HB	12.5-16.5 (G/DL)	01/05/92	14.20		15.60		14.20	
HT	0.37-0.49 (L/L)	01/05/92	0.43		0.46		0.43	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/05/92	5.40		5.80		5.40	
HBC	4-11 (10 ³ /MM ³)	01/05/92	6.50		4.70		4.40	
HBC: N	1.6-8 (10 ³ /MM ³)	01/05/92	3.40		2.00		2.00	
HBC: L	1-4.5 (10 ³ /MM ³)	01/05/92	2.20		2.10		1.60	
HBC: E	0-0.4 (10 ³ /MM ³)	01/05/92	0.30		0.20		0.40	
HBC: M	0.2-0.8 (10 ³ /MM ³)	01/05/92	0.40		0.40		0.40	
HBC: B	0-0.1 (10 ³ /MM ³)	01/05/92	0.10		0.00		0.10	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/92	208.00		140.00 <		169.00	
NA+	136-147 (MMOL/L)	01/05/92	139.00		133.00 <		140.00	
K+	3.5-5.1 (MMOL/L)	01/05/92	4.40		4.80		4.20	
CL-	98-108 (MMOL/L)	01/05/92	106.00		99.00		109.00 >	
Ca++	2.2-2.6 (MMOL/L)	01/05/92	2.39		1.91 <		2.31	
PO4--	0.8-1.45 (MMOL/L)	01/05/92	1.08		1.06		1.10	
SGOT	5-40 (U/L)	01/05/92	17.00		13.00		9.00	
SGPT	5-35 (U/L)	01/05/92	16.00		10.00		8.00	
GAMMA GT	4-18 (U/L)	01/05/92	7.00		8.00		6.00	
LDH	100-350 (U/L)	01/05/92	230.00		286.00		273.00	
ALK. PHOSPH.	25-160 (U/L)	01/05/92	59.00		68.00		63.00	
GLUCOSE	3.5-6.8 (MMOL/L)	01/05/92	6.29		5.40		4.20	
BUN	()	01/05/92						
UREA	2.6-6.7 (MMOL/L)	01/05/92	5.20		5.70		6.00	
CREATININE	47-88 (UMOL/L)	01/05/92	68.00		78.00		80.00	
URIC ACID	0.12-0.4 (MMOL/L)	01/05/92	0.22		0.26		0.30	
TOT. BILIRUBIN	4-21 (UMOL/L)	01/05/92	7.40		5.00		7.00	
DIR. BILIRUBIN	0-4 (UMOL/L)	01/05/92	75.00		77.00		72.00	
TOT. PROTEINS	65-80 (G/L)	01/05/92	43.60		43.00		39.00	
ALBUMINE	38-52 (G/L)	01/05/92	5.62		5.60		5.20	
TOT. CHOLEST.	2-6.5 (MMOL/L)	01/05/92	5.62		0.60		0.40	
TRIGLYCERIDES	0-1.7 (MMOL/L)	01/05/92	1.03		2.40		2.55	
GLOBULINS ALPHA 1	2-4 (G/L)	01/05/92	2.27		7.26		7.97	
GLOBULINS ALPHA 2	5-9 (G/L)	01/05/92	9.72		14.21 >		9.41	
GLOBULINS BETA	7-11 (G/L)	01/05/92	12.11		11.69		12.65	
GLOBULINS GAMMA	7-16 (G/L)	01/05/92	12.11		11.69		12.65	
TSH	0.4-5 (MUI/L)	01/05/92	2.70					
T4	9-20.9 (PMOL/L)	01/05/92	14.80					

(ø) << clinically relevant (value lower than min range)
 < out of range (value lower than min range)
 ** missing laboratory test value and laboratory not done

>> clinically relevant (value higher than max range)
 > out of range (value higher than max range)
 () 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 11 Patient: 325 Treatment: Roboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			24/07/92		21/08/92		11/09/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12.5-16.5 (G/DL)	01/05/92	15.00		15.40		14.50	
HT	0.37-0.49 (L/L)	01/05/92	0.46		0.49		0.45	
RBC	4.2-5.8 (10 ³ /MM ³)	01/05/92	4.90		5.20		4.80	
WBC	4-11 (10 ³ /MM ³)	01/05/92	4.30		10.10		4.50	
WBC: N	1.6-8 (10 ³ /MM ³)	01/05/92	2.20		7.10		2.10	
WBC: L	1-4.5 (10 ³ /MM ³)	01/05/92	1.40		1.80		1.50	
WBC: E	0-0.4 (10 ³ /MM ³)	01/05/92	0.40		0.50	>	0.70 >>	
WBC: M	0.2-0.8 (10 ³ /MM ³)	01/05/92	0.30		0.60		0.20	
WBC: B	0-0.1 (10 ³ /MM ³)	01/05/92	0.00		0.10		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/92	226.00		260.00		260.00	
NA+	136-147 (MMOL/L)	01/05/92	137.00		142.00		139.00	
K+	3.5-5.1 (MMOL/L)	01/05/92	4.00		3.90		4.70	
CL-	98-108 (MMOL/L)	01/05/92	105.00		104.00		105.00	
Ca++	2.2-2.6 (MMOL/L)	01/05/92	2.42		2.24		2.26	
PO4--	0.8-1.45 (MMOL/L)	01/05/92	1.22		1.05		1.11	
SGOT	5-40 (U/L)	01/05/92	23.00		23.00		22.00	
SGPT	5-35 (U/L)	01/05/92	34.00		28.00		22.00	
GAMMA GT	4-18 (U/L)	01/05/92	7.00		15.00		8.00	
LDH	100-350 (U/L)	01/05/92	290.00		153.00		144.00	
ALK. PHOSPH.	25-160 (U/L)	01/05/92	93.00		97.00		93.00	
GLUCOSE	3.5-6.8 (MMOL/L)	01/05/92	3.60		4.30		4.10	
BUN	()	01/05/92						
UREA	2.6-6.7 (MMOL/L)	01/05/92	5.20		3.50		3.00	
CREATININE	47-88 (UMOL/L)	01/05/92	64.00		61.00		56.00	
URIC ACID	0.42-0.4 (MMOL/L)	01/05/92	0.22		0.22		0.34	
TOT BILIRUBIN	4-21 (UMOL/L)	01/05/92	4.00		6.00		10.00	
DIR BILIRUBIN	0-4 (UMOL/L)	01/05/92						
TOT. PROTEINS	65-80 (G/L)	01/05/92	75.00		76.00		74.00	
ALBUMINE	38-52 (G/L)	01/05/92	43.15		42.50		49.80	
TOT. CHOLEST.	2-6.5 (MMOL/L)	01/05/92	3.90		4.90		4.40	
TRIGLYCERIDES	0-1.7 (MMOL/L)	01/05/92	0.60		0.50		0.70	
GLOBULINS ALPHA 1	2-4 (G/L)	01/05/92	2.91		2.82		2.10	
GLOBULINS ALPHA 2	5-9 (G/L)	01/05/92	7.39		8.09		5.60	
GLOBULINS BETA	7-11 (G/L)	01/05/92	9.23		10.21		7.00	
GLOBULINS GAMMA	7-16 (G/L)	01/05/92	12.33		12.29		9.50	
TSH	0.4-5 (MUI/L)	01/05/92	2.50					
T4	9-20.9 (PMOL/L)	01/05/92	11.50					

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 11 Patient: 327 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/08/92		09/09/92		01/10/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12.5-16.5 (G/DL)	01/05/92	13.70		13.20		13.10	
HT	0.37-0.49 (L/L)	01/05/92	0.42		0.40		0.43	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/05/92	4.70		4.50		4.60	
WBC	4-11 (10 ³ /MM ³)	01/05/92	4.30		3.60 <		4.10	
WBC: N	1.6-8 (10 ³ /MM ³)	01/05/92	2.10		2.00		1.90	
WBC: L	1-4.5 (10 ³ /MM ³)	01/05/92	1.90		1.30		1.80	
WBC: E	0-0.4 (10 ³ /MM ³)	01/05/92	0.10		0.10		0.10	
WBC: M	0.2-0.8 (10 ³ /MM ³)	01/05/92	0.20		0.20		0.30	
WBC: B	0-0.1 (10 ³ /MM ³)	01/05/92	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/92	247.00		231.00		235.00	
NA+	136-147 (MMOL/L)	01/05/92	141.00		137.00		136.00	
K+	3.5-5.1 (MMOL/L)	01/05/92	4.80		4.60		3.60	
CL-	98-108 (MMOL/L)	01/05/92	107.00		106.00		104.00	
Ca++	2.2-2.6 (MMOL/L)	01/05/92	2.60		2.21		2.20	
PO4--	0.8-1.45 (MMOL/L)	01/05/92	1.00		0.87		0.92	
SGOT	5-40 (U/L)	01/05/92	14.00		15.00		19.00	
SGPT	5-35 (U/L)	01/05/92	11.00		12.00		16.00	
GAMMA GT	5-35 (U/L)	01/05/92	6.00		9.00		16.00	
LDH	100-350 (U/L)	01/05/92	122.00		128.00		140.00	
ALK. PHOSPH.	25-160 (U/L)	01/05/92	35.00		40.00		48.00	
GLUCOSE	3.5-6.8 (MMOL/L)	01/05/92	4.10		4.10		4.60	
BUN	()	01/05/92						
UREA	2.6-6.7 (MMOL/L)	01/05/92	4.90		3.30		4.00	
CREATININE	47-88 (UMOL/L)	01/05/92	85.00		73.00		77.00	
URIC ACID	0.12-0.4 (MMOL/L)	01/05/92	0.17		0.13		0.20	
TOT BILIRUBIN	4-21 (UMOL/L)	01/05/92	12.00		13.00		8.00	
DIR BILIRUBIN	0-4 (UMOL/L)	01/05/92						
TOT. PROTEINS	65-80 (G/L)	01/05/92	75.00		71.00		71.00	
ALBUMINE	38-52 (G/L)	01/05/92	41.45		46.30		44.20	
TOT. CHOLEST.	2-6.5 (MMOL/L)	01/05/92	5.90		5.60		5.10	
TRIGLYCERIDES	0-1.7 (MMOL/L)	01/05/92	0.50		0.50		0.50	
GLOBULINS ALPHA 1	2-4 (G/L)	01/05/92	2.59		1.70 <		2.00	
GLOBULINS ALPHA 2	5-9 (G/L)	01/05/92	6.47		4.30 <		5.30	
GLOBULINS BETA	7-11 (G/L)	01/05/92	10.07		8.40		9.40	
GLOBULINS GAMMA	7-16 (G/L)	01/05/92	14.42		10.30		10.10	
TSH	0.4-5 (MUI/L)	01/05/92	2.50					
T4	9-20.9 (PMOL/L)	01/05/92	17.10					

1188

(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 20124/017

Listing No.: 18.0

0150085

LABORATORY DATA

Centre: 11 Patient: 330 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 7
			22/08/92	31/08/92
			value (ø)	value (ø)
Laboratory test	Range value	Range date		
HB	12.5-16.5 (G/DL)	01/05/92	14.30	14.20
HT	0.37-0.49 (L/L)	01/05/92	0.45	0.43
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/05/92	5.00	4.80
WBC	4-11 (10 ³ /MM ³)	01/05/92	9.70	8.30
WBC: N	1.6-8 (10 ³ /MM ³)	01/05/92	5.90	4.80
WBC: L	1-4.5 (10 ³ /MM ³)	01/05/92	3.10	3.10
WBC: E	0-0.4 (10 ³ /MM ³)	01/05/92	0.10	0.10
WBC: M	0.2-0.8 (10 ³ /MM ³)	01/05/92	0.40	0.30
WBC: B	0-0.1 (10 ³ /MM ³)	01/05/92	0.10	0.10
PLATELETS	150-400 (10 ³ /MM ³)	01/05/92	228.00	218.00
NA+	136-147 (MMOL/L)	01/05/92	137.00	134.00 <
K+	3.5-5.1 (MMOL/L)	01/05/92	3.60	3.60
CL-	98-108 (MMOL/L)	01/05/92	108.00	107.00
Ca++	2.2-2.6 (MMOL/L)	01/05/92	2.22	2.20
PO4--	0.8-1.45 (MMOL/L)	01/05/92	1.07	1.03
SGOT	5-40 (U/L)	01/05/92	17.00	17.00
SGPT	5-35 (U/L)	01/05/92	15.00	13.00
GAMMA GT	4-18 (U/L)	01/05/92	16.00	9.00
LDH	100-350 (U/L)	01/05/92	191.00	163.00
ALK. PHOSPH.	25-160 (U/L)	01/05/92	49.00	50.00
GLUCOSE	3.5-6.8 (MMOL/L)	01/05/92	4.40	5.50
BUN	()	01/05/92		
UREA	2.6-6.7 (MMOL/L)	01/05/92	3.90	5.00
CREATININE	47-88 (UMOL/L)	01/05/92	61.00	56.00
URIC ACID	0.12-0.4 (MMOL/L)	01/05/92	0.26	0.27
TOT BILIRUBIN	4-21 (UMOL/L)	01/05/92	13.00	25.00 >
DIR BILIRUBIN	0-4 (UMOL/L)	01/05/92		
TOT. PROTEINS	65-80 (G/L)	01/05/92	70.00	71.00
ALBUMINE	38-52 (G/L)	01/05/92	37.80 <	40.00
TOT. CHOLEST.	2-6.5 (MMOL/L)	01/05/92	5.60	6.00
TRIGLYCERIDES	0-1.7 (MMOL/L)	01/05/92	1.50	1.00
GLOBULINS ALPHA 1	2-4 (G/L)	01/05/92	2.93	2.10
GLOBULINS ALPHA 2	5-9 (G/L)	01/05/92	6.71	4.80 <
GLOBULINS BETA	7-11 (G/L)	01/05/92	9.30	7.90
GLOBULINS GAMMA	7-16 (G/L)	01/05/92	13.20	11.30
TSH	0.4-5 (MUI/L)	01/05/92	3.10	
T4	9-20.9 (PMOL/L)	01/05/92	13.00	

1180

(ø) << clinically relevant (value lower than min range)
 < out of range (value lower than min range)
 ** missing laboratory test value nd laboratory not done

>> clinically relevant (value higher than max rang
 > out of range (value higher than max rang
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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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 11 Patient: 331 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			01/09/92		24/09/92		15/10/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	14.5-18.5 (G/DL)	01/05/92	15.00		14.60		14.30 <	
HT	0.42-0.54 (L/L)	01/05/92	0.47		0.44		0.42	
RBC	4.8-6.4 (10 ⁶ /MM ³)	01/05/92	4.80		4.62 <		4.50 <	
WBC	4-11 (10 ³ /MM ³)	01/05/92	5.00		7.30		6.30	
WBC: N	1.6-8 (10 ³ /MM ³)	01/05/92	2.40		4.40		3.60	
WBC: L	1-4.5 (10 ³ /MM ³)	01/05/92	1.90		2.10		2.10	
WBC: E	0-0.4 (10 ³ /MM ³)	01/05/92	0.20		0.20		0.20	
WBC: M	0.2-0.8 (10 ³ /MM ³)	01/05/92	0.60		0.60		0.40	
WBC: B	0-0.1 (10 ³ /MM ³)	01/05/92	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/92	291.00		298.00		250.00	
NA+	136-147 (MMOL/L)	01/05/92	139.00		141.00		136.00	
K+	3.5-5.1 (MMOL/L)	01/05/92	4.30		4.80		4.00	
CL-	98-108 (MMOL/L)	01/05/92	105.00		105.00		104.00	
Ca++	2.2-2.6 (MMOL/L)	01/05/92	2.31		2.47		2.27	
PO4--	0.8-1.45 (MMOL/L)	01/05/92	0.79	<	0.94		0.97	
SGOT	5-40 (U/L)	01/05/92	19.00		14.00		15.00	
SGPT	5-35 (U/L)	01/05/92	21.00		16.00		14.00	
GAMMA GT	0-28 (U/L)	01/05/92	26.00		39.00 >		20.00	
LDH	100-350 (U/L)	01/05/92	141.00		158.00		120.00	
ALK. PHOSPH.	25-160 (U/L)	01/05/92	38.00		43.00		36.00	
GLUCOSE	3.5-6.8 (MMOL/L)	01/05/92	3.50		4.00		4.00	
BUN	()	01/05/92						
UREA	2.6-6.7 (MMOL/L)	01/05/92	5.50		5.60		5.40	
CREATININE	60-115 (UMOL/L)	01/05/92	90.00		77.00		92.00	
URIC ACID	0.48-0.45 (MMOL/L)	01/05/92	0.39		0.38		0.37	
TOT BILIRUBIN	4-21 (UMOL/L)	01/05/92	9.00		9.00		8.00	
DIR BILIRUBIN	0-4 (UMOL/L)	01/05/92						
TOT. PROTEINS	65-80 (G/L)	01/05/92	74.00		76.00		72.00	
ALBUMINE	38-52 (G/L)	01/05/92	48.70		47.10		48.40	
TOT. CHOLEST.	2-6.5 (MMOL/L)	01/05/92	8.00	>	7.40 >		6.70 >	
TRIGLYCERIDES	0-1.7 (MMOL/L)	01/05/92	0.80		1.30		1.50	
GLOBULINS ALPHA 1	2-4 (G/L)	01/05/92	2.40		2.70		2.10	
GLOBULINS ALPHA 2	5-9 (G/L)	01/05/92	7.40		9.30 >		6.80	
GLOBULINS BETA	7-11 (G/L)	01/05/92	8.80		10.10		8.20	
GLOBULINS GAMMA	7-16 (G/L)	01/05/92	6.70	<	6.70 <		6.60 <	
TSH	0.4-5 (MUI/L)	01/05/92	1.50					
T4	9-20.9 (PMOL/L)	01/05/92	14.60					

1190

(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 20124/017
Listing No.: 950085

LABORATORY DATA

Centre: 12 Patient: 338 Treatment: Roboetine Sex: Female

Laboratory test			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			15/06/92		10/07/92		31/07/92	
			value	(€)	value	(€)	value	(€)
Range value	Range date							
HB	12.3-16.7 (G/DL) 01/04/92	16.00		16.40		15.50		
HT	36-50 (X) 01/04/92	46.00		48.00		45.00		
RBC	3.7-5.7 (10 ⁶ /MM ³) 01/04/92	5.00		5.40		5.00		
WBC	3.9-11.5 (10 ³ /MM ³) 01/04/92							
WBC: N	2-7.5 (10 ³ /MM ³) 01/04/92	10.20		8.10		8.90		
WBC: L	1-4 (10 ³ /MM ³) 01/04/92	5.92		4.37		4.46		
WBC: E	0.2-0.45 (10 ³ /MM ³) 01/04/92	3.37		2.75		3.07		
WBC: M	0.2-0.8 (10 ³ /MM ³) 01/04/92	0.10	<	0.16	<	0.18	<	
WBC: B	0-0.1 (10 ³ /MM ³) 01/04/92	0.82	>	0.81	>	1.01	>	
PLATELETS	150-400 (10 ³ /MM ³) 01/04/92	0.00		0.00		0.19	>>	
NA+	135-150 (MMOL/L) 01/04/92	363.00		355.00		327.00		
K+	3.6-5.7 (MMOL/L) 01/04/92	142.00		138.00		141.00		
CL-	99-110 (MMOL/L) 01/04/92	4.30		5.00		5.20		
Ca++	2.15-2.65 (MMOL/L) 01/04/92	109.00		109.00		107.00		
PO4--	0.8-1.5 (MMOL/L) 01/04/92	2.35		2.40		2.47		
SCOT	5-45 (U/L) 01/04/92	1.07		1.42		1.59	>	
SCPT	5-50 (U/L) 01/04/92	24.00		19.00		21.00		
GAMMA GT	0-50 (U/L) 01/04/92	18.00		15.00		14.00		
LDH	120-230 (U/L) 01/04/92	19.00		26.00		23.00		
ALK. PHOSPH.	21-91 (IU/L) 01/04/92	161.00		205.00		171.00		
GLUCOSE	4.5-7.8 (MMOL/L) 01/04/92	78.00		63.00		45.00		
BUN	2.5-6.6 (MMOL/L) 01/04/92	4.10	<	4.00	<	4.60		
UREA	() 01/04/92	4.40		3.20		3.80		
CREATININE	62-115 (UMOL/L) 01/04/92	78.00		87.00		97.00		
URIC ACID	0.09-0.35 (MMOL/L) 01/04/92	0.16		0.29		0.22		
TOT. BILIRUBIN	2-26 (UMOL/L) 01/04/92	15.00		12.00		7.00		
DIR. BILIRUBIN	0-7 (UMOL/L) 01/04/92	2.00		1.00		1.00		
TOT. PROTEINS	60-80 (G/L) 01/04/92	80.00		77.00		70.00		
ALBUMINE	35-50 (G/L) 01/04/92	48.00		47.00		41.00		
TOT. CHOLEST.	3.5-5.1 (MMOL/L) 01/04/92	7.36	>>	7.84	>>	7.82	>>	
TRIGLYCERIDES	0.28-2.3 (MMOL/L) 01/04/92	1.97		1.95		1.16		
GLOBULINS ALPHA 1	1-4 (G/L) 01/04/92	2.00		3.00		2.00		
GLOBULINS ALPHA 2	4-9 (G/L) 01/04/92	8.00		8.00		7.00		
GLOBULINS BETA	5-10 (G/L) 01/04/92	9.00		9.00		9.00		
GLOBULINS GAMMA	6-15 (G/L) 01/04/92	13.00		10.00		11.00		
TSH	0.4-5 (UU/ML) 01/04/92	0.56						
T4	11-24 (PMOL/L) 01/04/92	19.50						

1191

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 12 Patient: 340 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/08/92		27/08/92		17/09/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12.3-16.7 (G/DL)	01/04/92	13.50		14.50		14.60	
HT	36-50 (%)	01/04/92	40.00		42.00		44.00	
RBC	3.7-5.7 (10 ⁶ /MM ³)	01/04/92	4.40		4.70		4.80	
WBC	3.9-11.5 (10 ³ /MM ³)	01/04/92	4.50		4.10		5.00	
WBC: N	2-7.5 (10 ³ /MM ³)	01/04/92	2.57		2.46		3.33	
WBC: L	1-4 (10 ³ /MM ³)	01/04/92	1.36		1.19		1.12	
WBC: E	0.2-0.45 (10 ³ /MM ³)	01/04/92	0.03	<	0.08	<	0.04	
WBC: M	0.2-0.8 (10 ³ /MM ³)	01/04/92	0.51		0.33		0.47	
WBC: B	0-0.1 (10 ³ /MM ³)	01/04/92	0.03		0.04		0.05	
PLATELETS	150-400 (10 ³ /MM ³)	01/04/92	325.00		308.00		275.00	
NA+	135-150 (MMOL/L)	01/04/92	143.00		139.00		138.00	
K+	3.6-5.7 (MMOL/L)	01/04/92	4.00		5.00		3.90	
CL-	99-110 (MMOL/L)	01/04/92	109.00		106.00		109.00	
Ca++	2.15-2.65 (MMOL/L)	01/04/92	2.32		2.38		2.29	
PO4--	0.8-1.5 (MMOL/L)	01/04/92	0.90		1.20		1.15	
SGOT	5-45 (U/L)	01/04/92	29.00		36.00		26.00	
SGPT	5-50 (U/L)	01/04/92	14.00		21.00		14.00	
GAMMA GT	0-50 (U/L)	01/04/92	38.00		12.00		15.00	
LDH	120-230 (U/L)	01/04/92	198.00		195.00		149.00	
ALK. PHOSPH.	21-91 (IU/L)	01/04/92	40.00		69.00		44.00	
GLUCOSE	4.5-7.8 (MMOL/L)	01/04/92	5.50		4.90		5.40	
BUN	2.5-6.6 (MMOL/L)	01/04/92	2.60		3.70		3.60	
UREA	()	01/04/92						
CREATININE	62-115 (UMOL/L)	01/04/92	75.00		78.00		98.00	
URIC ACID	0.09-0.35 (MMOL/L)	01/04/92	0.20		0.12		0.18	
TOT BILIRUBIN	0.2-2.6 (UMOL/L)	01/04/92	6.00		5.00		10.00	
DIR BILIRUBIN	0-7 (UMOL/L)	01/04/92	1.00		1.00		2.00	
TOT. PROTEINS	60-80 (G/L)	01/04/92	70.00		74.00		73.00	
ALBUMINE	35-50 (G/L)	01/04/92	44.00		44.00		37.00	
TOT. CHOLEST.	3.5-5.1 (MMOL/L)	01/04/92	5.89	>	5.41	>	4.96	
TRIGLYCERIDES	0.28-2.3 (MMOL/L)	01/04/92	0.86		0.79		0.93	
GLOBULINS ALPHA 1	1-4 (G/L)	01/04/92	2.00		2.00		3.00	
GLOBULINS ALPHA 2	4-9 (G/L)	01/04/92	5.00		7.00		8.00	
GLOBULINS BETA	5-10 (G/L)	01/04/92	8.00		9.00		10.00	
GLOBULINS GAMMA	6-15 (G/L)	01/04/92	11.00		12.00		15.00	
TSH	0.4-5 (UU/ML)	01/04/92	1.20					
T4	11-24 (PMOL/L)	01/04/92	11.20					

(€) << 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

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 12 Patient: 341 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			18/08/92		10/09/92	
			value (€)	value (€)	value (€)	value (€)
Laboratory test	Range value	Range date				
HB	12.3-16.7 (G/DL)	01/04/92	11.90 <	11.50 <		
HT	36-50 (%)	01/04/92	36.00	36.00		
RBC	3.7-5.7 (10 ⁶ /MM ³)	01/04/92	4.60	4.60		
WBC	3.9-11.5 (10 ³ /MM ³)	01/04/92	7.40	5.80		
WBC: N	2-7.5 (10 ³ /MM ³)	01/04/92	3.92	2.55		
WBC: L	1-4 (10 ³ /MM ³)	01/04/92	2.22	2.61		
WBC: E	0.2-0.45 (10 ³ /MM ³)	01/04/92	0.74 >>	0.41		
WBC: M	0.2-0.8 (10 ³ /MM ³)	01/04/92	0.52	0.17 <		
WBC: B	0-0.1 (10 ³ /MM ³)	01/04/92	0.00	0.06		
PLATELETS	150-400 (10 ³ /MM ³)	01/04/92	477.00 >	368.00		
NA+	135-150 (MMOL/L)	01/04/92	142.00	140.00		
K+	3.6-5.7 (MMOL/L)	01/04/92	4.90	4.70		
CL-	99-110 (MMOL/L)	01/04/92	105.00	107.00		
Ca++	2.15-2.65 (MMOL/L)	01/04/92	2.37	2.19		
PO4--	0.8-1.5 (MMOL/L)	01/04/92	1.34	1.30		
SGOT	5-45 (U/L)	01/04/92	47.00 >	26.00		
SGPT	5-50 (U/L)	01/04/92	16.00	16.00		
GAMMA GT	0-50 (U/L)	01/04/92	9.00	9.00		
LDH	120-230 (U/L)	01/04/92	226.00	156.00		
ALK. PHOSPH.	21-91 (IU/L)	01/04/92	33.00	74.00		
GLUCOSE	4.5-7.8 (MMOL/L)	01/04/92	4.90	5.00		
BUN	2.5-6.6 (MMOL/L)	01/04/92	4.10	4.40		
UREA	()	01/04/92				
CREATININE	62-115 (UMOL/L)	01/04/92	79.00	114.00		
URIC ACID	0.09-0.35 (MMOL/L)	01/04/92	0.20	0.25		
TOT BILIRUBIN	2-26 (UMOL/L)	01/04/92	7.00	6.00		
DIR BILIRUBIN	0-7 (UMOL/L)	01/04/92	1.00	1.00		
TOT. PROTEINS	60-80 (G/L)	01/04/92	71.00	60.00		
ALBUMINE	35-50 (G/L)	01/04/92	47.00	35.00		
TOT. CHOLEST.	3.5-5.1 (MMOL/L)	01/04/92	5.29 >	5.62 >		
TRIGLYCERIDES	0.28-2.3 (MMOL/L)	01/04/92	0.60	0.70		
GLOBULINS ALPHA 1	1-4 (G/L)	01/04/92	2.00	2.00		
GLOBULINS ALPHA 2	4-9 (G/L)	01/04/92	5.00	5.00		
GLOBULINS BETA	5-10 (G/L)	01/04/92	8.00	7.00		
GLOBULINS GAMMA	6-15 (G/L)	01/04/92	9.00	11.00		
TSH	0.4-5 (UU/ML)	01/04/92	0.85			
T4	11-24 (PMOL/L)	01/04/92	24.40			

(€) << clinically relevant (value lower than min range)
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 ** missing laboratory test value nd laboratory not done

>> clinically relevant (value higher than max range)
 > out of range (value higher than max range)
 () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA 09530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 13 Patient: 353 Treatment: Reboxetine Sex: Female

Laboratory test	Range value	Range date	Visit number / Laboratory date	
			Screen	Day 21
			05/06/92	29/06/92
			value (†)	value (‡)
HB	11.6-15.6 (G/DL)	01/06/92	13.50	13.90
HT	0.35-0.45 (L/L)	01/06/92	0.43	0.44
RBC	3.7-5.3 (10 ⁶ /MM ³)	01/06/92	5.31 >	5.65 >
WBC	4-11 (10 ³ /MM ³)	01/06/92	6.03	6.39
WBC: N	40-75 (%)	01/06/92	52.00	68.00
WBC: L	20-45 (%)	01/06/92	38.00	16.00 <
WBC: E	1-6 (%)	01/06/92	1.00	1.00
WBC: M	2-10 (%)	01/06/92	7.00	12.00 >
WBC: B	0-1 (%)	01/06/92	1.00	1.00
PLATELETS	140-420 (10 ³ /MM ³)	01/06/92	196.00	187.00
NA+	135-145 (MMOL/L)	01/06/92	137.00	133.00 <
K+	3.5-5.5 (MMOL/L)	01/06/92	4.80	5.00
CL-	97-107 (MMOL/L)	01/06/92		104.00
Ca++	2.1-2.6 (MMOL/L)	01/06/92	2.28	2.38
PO4--	0.8-1.3 (MMOL/L)	01/06/92	1.12	1.09
SGOT	0-53 (U/L)	01/06/92	9.00	9.00
SGPT	1-25 (U/L)	01/06/92	9.00	7.00
GAMMA GT	0-40 (U/L)	01/06/92	10.00	5.00
LDR	175-350 (U/L)	01/06/92	186.00	153.00 <
ALK. PHOSPH.	30-70 (U/L)	01/06/92	63.00	59.00
GLUCOSE	3.7-5.6 (MMOL/L)	01/06/92	4.80	4.70
BUN	1.7-6.7 (MMOL/L)	01/06/92	3.30	3.90
UREA	()	01/06/92		
CREATININE	75-115 (UMOL/L)	01/06/92	79.00	85.00
URIC ACID	0.09-0.36 (MMOL/L)	01/06/92	0.25	0.23
TOT BILIRUBIN	1-17 (UMOL/L)	01/06/92	9.00	5.00
DIR BILIRUBIN	1.7-5.1 (UMOL/L)	01/06/92	1.00 <	1.00 <
TOT. PROTEINS	60-80 (G/L)	01/06/92	69.00	72.00
ALBUMINE	35-50 (G/L)	01/06/92	43.00	45.00
TOT. CHOLEST.	0-5.1 (MMOL/L)	01/06/92	4.10	4.60
TRIGLYCERIDES	0.3-2.3 (MMOL/L)	01/06/92		
GLOBULINS ALPHA 1	1-5 (%)	01/06/92	1.88	1.82
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/06/92	7.88	10.74 >
GLOBULINS BETA	11-16 (%)	01/06/92	13.35	10.09 <
GLOBULINS GAMMA	12-22 (%)	01/06/92	11.55 <	13.04
TSH	0.4-4 (MU/L)	01/06/92	0.76	
T4	6.3-22.8 (PMOL/L)	01/06/92		

(†) << 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 RD
 9550085
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 18.0

LABORATORY DATA
 Centre: 13 Patient: 355 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			17/06/92
			value (c)
Laboratory test	Range value	Range date	
HB	11.6-15.6 (G/DL)	02/05/92	13.50
HT	0.35-0.45 (L/L)	02/05/92	0.46 >
RBC	3.7-5.3 (10 ⁶ /MM ³)	02/05/92	5.40 >
WBC	4-11 (10 ³ /MM ³)	02/05/92	3.42 <
WBC: N	40-75 (%)	02/05/92	49.00
WBC: L	20-45 (%)	02/05/92	40.00
WBC: E	1-6 (%)	02/05/92	2.00
WBC: M	2-10 (%)	02/05/92	5.00
WBC: B	0-1 (%)	02/05/92	1.00
PLATELETS	140-420 (10 ³ /MM ³)	02/05/92	309.00
NA+	135-145 (MMOL/L)	02/05/92	138.00
K+	3.5-5.5 (MMOL/L)	02/05/92	4.70
CL-	97-107 (MMOL/L)	02/05/92	107.00
Ca++	2.1-2.6 (MMOL/L)	02/05/92	2.24
PO4--	0.8-1.3 (MMOL/L)	02/05/92	1.09
SGOT	0-53 (U/L)	02/05/92	16.00
SGPT	1-25 (U/L)	02/05/92	17.00
GAMMA GT	0-40 (U/L)	02/05/92	3.00
LDH	175-350 (U/L)	02/05/92	191.00
ALK. PHOSPH.	30-70 (U/L)	02/05/92	78.00 >
GLUCOSE	3.7-5.6 (MMOL/L)	02/05/92	4.40
BUN	1.7-6.7 (MMOL/L)	02/05/92	4.60
UREA	()	02/05/92	
CREATININE	75-115 (UMOL/L)	02/05/92	76.00
URIC ACID	0.09-0.36 (MMOL/L)	02/05/92	0.14
TOT. BILIRUBIN	1-17 (UMOL/L)	02/05/92	7.00
DIR BILIRUBIN	1.7-5.1 (UMOL/L)	02/05/92	1.00 <
TOT. PROTEINS	60-80 (G/L)	02/05/92	66.00
ALBUMINE	35-50 (G/L)	02/05/92	45.00
TOT. CHOLEST.	0-5.1 (MMOL/L)	02/05/92	6.10 >
TRIGLYCERIDES	0.3-2.3 (MMOL/L)	02/05/92	
GLOBULINS ALPHA 1	1-3 (G/L)	02/05/92	4.07 >>
GLOBULINS ALPHA 2	5-9 (G/L)	02/05/92	8.83
GLOBULINS BETA	4-10 (G/L)	02/05/92	11.66 >
GLOBULINS GAMMA	7-20 (G/L)	02/05/92	3.93 <<
TSH	0.4-4 (MU/L)	02/05/92	
T4	6.3-22.8 (PMOL/L)	02/05/92	

(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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 13 Patient: 358 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date			
			Screen		Day 21	
			06/08/92		27/08/92	
			value	(†)	value	(†)
Laboratory test	Range value	Range date				
HB	13.3-17.3 (G/DL)	01/08/92	17.40 >		17.60 >	
HT	0.4-0.5 (L/L)	01/08/92	0.49		0.49	
RBC	4.5-5.9 (10 ⁶ /MM ³)	01/08/92	5.44		5.71	
MBC	4-11 (10 ³ /MM ³)	01/08/92	10.20		7.68	
MBC: N	40-75 (%)	01/08/92			64.00	
MBC: L	20-45 (%)	01/08/92			27.00	
MBC: E	1-6 (%)	01/08/92			1.00	
MBC: M	2-10 (%)	01/08/92			7.00	
MBC: B	0-1 (%)	01/08/92			1.00	
PLATELETS	140-420 (10 ³ /MM ³)	01/08/92	297.00		344.00	
NA+	135-145 (MMOL/L)	01/08/92	145.00		141.00	
K+	3.5-5.5 (MMOL/L)	01/08/92	5.00		4.20	
CL-	97-107 (MMOL/L)	01/08/92	109.00 >		104.00	
Ca ⁺⁺	2.1-2.6 (MMOL/L)	01/08/92	2.48		2.40	
PO ₄ ⁻⁻	0.8-1.3 (MMOL/L)	01/08/92	1.28		1.28	
SGOT	0-53 (U/L)	01/08/92	17.00		21.00	
SGPT	1-25 (U/L)	01/08/92	19.00		18.00	
GAMMA GT	0-40 (U/L)	01/08/92	0.00		0.00	
LDH	175-350 (U/L)	01/08/92	151.00 <		188.00	
ALK. PHOSPH.	30-70 (U/L)	01/08/92	122.00 >		166.00 >>	
GLUCOSE	3.7-5.6 (MMOL/L)	01/08/92	4.60		4.70	
BUN	1.7-6.7 (MMOL/L)	01/08/92	5.10			
UREA	()	01/08/92				
CREATININE	75-115 (UMOL/L)	01/08/92	89.00		86.00	
URIC ACID	0.15-0.48 (MMOL/L)	01/08/92	0.25		0.26	
TOT BILIRUBIN	1-17 (UMOL/L)	01/08/92	10.00		15.00	
DIR BILIRUBIN	1.7-5.1 (UMOL/L)	01/08/92	1.00 <		2.00	
TOT. PROTEINS	60-80 (G/L)	01/08/92	74.00		75.00	
ALBUMINE	35-50 (G/L)	01/08/92	44.00		45.00	
TOT. CHOLEST.	0-5.1 (MMOL/L)	01/08/92	4.10		4.00	
TRIGLYCERIDES	0.3-2.3 (MMOL/L)	01/08/92				
GLOBULINS ALPHA 1	1-5 (%)	01/08/92	2.84		9.40	
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/08/92	13.04		19.83	
GLOBULINS BETA	11-16 (%)	01/08/92	19.83		0.82	
GLOBULINS GAMMA	12-22 (%)	01/08/92	0.82			
TSH	0.4-4 (MU/L)	01/08/92				
T4	6.3-22.8 (PMOL/L)	01/08/92				

(†) << 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 20124/017
Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 13 Patient: 359 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			19/08/92		09/09/92		30/09/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.6-15.6 (G/DL)	10/08/92	14.90		15.10		15.20	
HT	0.35-0.45 (L/L)	10/08/92	0.43		0.43		0.44	
RBC	3.7-5.3 (10 ⁶ /MM ³)	10/08/92	4.86		4.72		4.72	
WBC	4-11 (10 ³ /MM ³)	10/08/92	10.60		7.11		5.87	
WBC: N	40-75 (%)	10/08/92	75.00		76.00 >		70.00	
WBC: L	20-45 (%)	10/08/92	16.00 <		17.00 <		22.00	
WBC: E	1-6 (%)	10/08/92	1.00		1.00		1.00	
WBC: M	2-10 (%)	10/08/92	6.00		4.00		6.00	
WBC: B	0-1 (%)	10/08/92	1.00		1.00		1.00	
PLATELETS	140-420 (10 ³ /MM ³)	10/08/92	278.00		220.00		233.00	
NA+	135-145 (MMOL/L)	10/08/92	141.00		139.00		141.00	
K+	3.5-5.5 (MMOL/L)	10/08/92	4.60		5.20			
CL-	97-107 (MMOL/L)	10/08/92	108.00 >		108.00 >		107.00	
Ca++	2.1-2.6 (MMOL/L)	10/08/92	2.63 >		2.48		2.42	
PO4--	0.8-1.3 (MMOL/L)	10/08/92	0.96		0.96			
SGOT	0-53 (U/L)	10/08/92	12.00		10.00		11.00	
SGPT	1-25 (U/L)	10/08/92	5.00		7.00		7.00	
GAMMA GT	0-40 (U/L)	10/08/92	0.00				0.00	
LDH	175-350 (U/L)	10/08/92	238.00		166.00 <		9.00 <	
ALK. PHOSPH.	30-70 (U/L)	10/08/92	93.00 >		90.00 >		95.00 >	
GLUCOSE	3.7-5.6 (MMOL/L)	10/08/92	5.10		4.60		4.40	
BUN	1.7-6.7 (MMOL/L)	10/08/92	4.00		3.90		3.00	
UREA	()	10/08/92						
CREATININE	75-115 (UMOL/L)	10/08/92	85.00		76.00		86.00	
URIC ACID	0.09-0.36 (MMOL/L)	10/08/92	0.30		0.28		0.27	
TOT BILIRUBIN	1-17 (UMOL/L)	10/08/92	10.00		5.00		5.00	
DIR BILIRUBIN	1.7-5.1 (UMOL/L)	10/08/92	2.00		2.00		1.00 <	
TOT. PROTEINS	60-80 (G/L)	10/08/92	77.00		76.00		74.00	
ALBUMINE	35-50 (G/L)	10/08/92	44.00		48.00		46.00	
TOT. CHOLEST.	0-5.1 (MMOL/L)	10/08/92	5.70 >		4.80		4.70	
TRIGLYCERIDES	0.3-2.3 (MMOL/L)	10/08/92	1.00					
GLOBULINS ALPHA 1	1-5 (%)	10/08/92	3.32					
GLOBULINS ALPHA 2	4.5-9.5 (%)	10/08/92	10.98 >					
GLOBULINS BETA	11-16 (%)	10/08/92	10.51 <					
GLOBULINS GAMMA	12-22 (%)	10/08/92	14.85					
TSH	0.4-4 (MU/L)	10/08/92	1.11					
T4	6.3-22.8 (PMOL/L)	10/08/92						

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< 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 13 Patient: 361 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			26/08/92		16/09/92		07/10/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11.6-15.6 (G/DL)	15/08/92	11.50	<	12.60		12.60	
HT	0.35-0.45 (L/L)	15/08/92	0.38		0.37		0.38	
RBC	3.7-5.3 (10 ⁶ /MM ³)	15/08/92	4.81		4.50		4.58	
HBC	4-11 (10 ³ /MM ³)	15/08/92	8.27		6.12		6.22	
HBC: N	40-75 (%)	15/08/92	66.00		51.00		57.00	
HBC: L	20-45 (%)	15/08/92	23.00		35.00		35.00	
HBC: E	1-6 (%)	15/08/92	2.00		2.00		2.00	
HBC: H	2-10 (%)	15/08/92	7.00		8.00		4.00	
HBC: B	0-1 (%)	15/08/92	0.00		1.00		1.00	
PLATELETS	140-420 (10 ³ /MM ³)	15/08/92	238.00		210.00		248.00	
NA+	135-145 (MMOL/L)	15/08/92	139.00		139.00		139.00	
K+	3.5-5.5 (MMOL/L)	15/08/92	4.40		4.80		5.30	
CL-	97-107 (MMOL/L)	15/08/92	106.00		106.00		102.00	
Ca++	2.1-2.6 (MMOL/L)	15/08/92	2.35		2.35		2.38	
PO4--	0.8-1.3 (MMOL/L)	15/08/92	1.28		1.28		1.38 >	
SGOT	0-53 (U/L)	15/08/92	15.00		12.00		13.00	
SGPT	1-25 (U/L)	15/08/92	13.00		8.00		7.00	
GAMMA GT	0-40 (U/L)	15/08/92	0.00		0.00		12.00	
LDH	175-350 (U/L)	15/08/92	158.00	<	149.00	<	182.00	
ALK. PHOSPH.	30-70 (U/L)	15/08/92	57.00		50.00		39.00	
GLUCOSE	3.7-5.6 (MMOL/L)	15/08/92	4.80		4.20		5.60	
BUN	1.7-6.7 (MMOL/L)	15/08/92	5.60		6.20		3.70	
UREA	()	15/08/92						
CREATININE	75-115 (UMOL/L)	15/08/92	75.00		70.00	<	86.00	
URIC ACID	0.09-0.36 (MMOL/L)	15/08/92	0.23		0.25		0.24	
TOT BILIRUBIN	1-17 (UMOL/L)	15/08/92	5.00		3.00		4.00	
DIR BILIRUBIN	1.7-5.1 (UMOL/L)	15/08/92	2.00		2.00		0.00 <	
TOT. PROTEINS	60-80 (G/L)	15/08/92	77.00		77.00		83.00 >	
ALBUMINE	35-50 (G/L)	15/08/92	48.00		47.00		49.00	
TOT. CHOLEST.	0-5.1 (MMOL/L)	15/08/92	5.20	>	5.10		6.05 >	
TRIGLYCERIDES	0.3-2.3 (MMOL/L)	15/08/92	0.50		0.60			
GLOBULINS ALPHA 1	1-5 (%)	15/08/92	1.83				3.70	
GLOBULINS ALPHA 2	4.5-9.5 (%)	15/08/92	9.13				11.97 >	
GLOBULINS BETA	11-16 (%)	15/08/92	13.90				13.20	
GLOBULINS GAMMA	12-22 (%)	15/08/92	20.67				17.42	
TSH	0.4-4 (MU/L)	15/08/92	0.63					
T4	6.3-22.8 (PHOL/L)	15/08/92						

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 < 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14 Patient: 457 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			07/07/92		28/07/92		18/08/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/06/92	13.80		13.90		13.80	
HT	42-54 (X)	01/06/92	41.00 <		40.80 <		40.60 <	
RBC	4.2-5.8 (10 ⁶ /MM3)	01/06/92	4.10 <		4.20		4.10 <	
WBC	4000-9000 (/MM3)	01/06/92	6800.00		6600.00		6800.00	
WBC: N	50-70 (X)	01/06/92						
WBC: L	25-40 (X)	01/06/92	38.00		39.00		38.00	
WBC: E	1-4 (X)	01/06/92	2.00		2.00		2.00	
WBC: M	4-8 (X)	01/06/92	5.00		5.00		4.00	
WBC: B	0-1 (X)	01/06/92	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM3)	01/06/92	270000		270000		270000	
NA+	134-148 (MMOL/L)	01/06/92	140.00		141.00		140.00	
K+	3.8-5.2 (MMOL/L)	01/06/92	3.90		4.00		4.00	
CL-	1.8-2.2 (MG/DL)	01/06/92	2.10		2.10		2.20	
Ca++	2-2.6 (MMOL/L)	01/06/92	2.10		2.30		2.30	
PO4--	()	01/06/92						
SGOT	5-18 (U/L)	01/06/92	8.00		8.00		10.00	
SGPT	5-22 (U/L)	01/06/92	8.00		8.00		10.00	
GAMMA GT	4-28 (U/L)	01/06/92	10.00		11.00		16.00	
LDH	120-240 (U/L)	01/06/92	164.00		161.00		156.00	
ALK. PHOSPH.	60-170 (U/L)	01/06/92	119.00		104.00		111.00	
GLUCOSE	60-110 (MG/DL)	01/06/92	92.00		96.00		89.00	
BUN	10-50 (MG/DL)	01/06/92	19.00		20.00		21.00	
UREA	()	01/06/92						
CREATININE	0.3-1.2 (MG/DL)	01/06/92	0.80		0.80		0.80	
URIC ACID	2.4-7 (MG/DL)	01/06/92	5.80		6.10		5.90	
TOT BILIRUBIN	0-1 (MG/DL)	01/06/92	0.80		0.80		0.80	
DIR BILIRUBIN	0-0.2 (MG/DL)	01/06/92						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/06/92	7.30		7.20		7.10	
ALBUMINE	57-68 (X)	01/06/92	62.00		61.00		62.00	
TOT. CHOLEST.	0-200 (MG/DL)	01/06/92	256.00 >		281.00 >>		167.00	
TRIGLYCERIDES	50-180 (MG/DL)	01/06/92	184.00 >		196.00 >		188.00 >	
GLOBULINS ALPHA 1	2-4.5 (X)	01/06/92	3.20		3.30		3.40	
GLOBULINS ALPHA 2	5-9 (X)	01/06/92	7.10		7.40		7.70	
GLOBULINS BETA	9-13 (X)	01/06/92	10.40		10.20		10.10	
GLOBULINS GAMMA	10-20 (X)	01/06/92	16.20		16.90		16.20	
TSH	0.2-3.1 (UU/ML)	01/06/92	0.20					
T4	5-11.5 (UG/DL)	01/06/92	7.60					

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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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14 Patient: 459 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			13/07/92		06/08/92		27/08/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/06/92	14.40		14.20		14.30	
HT	42-54 (X)	01/06/92	41.00 <		41.00 <		40.00 <	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/06/92	4.30		4.20		4.30	
HBC	4000-9000 (/MM ³)	01/06/92	7400.00		7000.00		7200.00	
HBC: N	50-70 (X)	01/06/92						
HBC: L	25-40 (X)	01/06/92	36.00		35.00		37.00	
HBC: E	1-4 (X)	01/06/92	3.00		3.00		3.00	
HBC: M	4-8 (X)	01/06/92	6.00		5.00		4.00	
HBC: B	0-1 (X)	01/06/92	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM ³)	01/06/92	290000		290000		290000	
NA+	134-148 (MMOL/L)	01/06/92	140.00		140.00		141.00	
K+	3.8-5.2 (MMOL/L)	01/06/92	3.90		4.10		4.00	
CL-	1.8-2.2 (MG/DL)	01/06/92	2.10		2.00		2.00	
Ca++	2-2.6 (MMOL/L)	01/06/92	2.30		2.20		2.10	
PO4--	()	01/06/92						
SGOT	5-18 (U/L)	01/06/92	16.00		16.00		16.00	
SGPT	5-22 (U/L)	01/06/92	18.00		19.00		18.00	
GAMMA GT	4-28 (U/L)	01/06/92	21.00		23.00		22.00	
LDH	120-240 (U/L)	01/06/92	211.00		209.00		212.00	
ALK. PHOSPH.	60-170 (U/L)	01/06/92	158.00		156.00		161.00	
GLUCOSE	60-110 (MG/DL)	01/06/92	101.00		99.00		96.00	
BUN	10-50 (MG/DL)	01/06/92	42.00		41.00		42.00	
UREA	()	01/06/92						
CREATININE	0.3-1.2 (MG/DL)	01/06/92	0.80		0.80		0.80	
URIC ACID	2.4-7 (MG/DL)	01/06/92	6.10		6.40		6.20	
TOT BILIRUBIN	0-1 (MG/DL)	01/06/92	0.70		0.80		0.80	
DIR BILIRUBIN	0-0.2 (MG/DL)	01/06/92						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/06/92	7.90		7.80		7.70	
ALBUMINE	57-68 (X)	01/06/92	62.00		61.00		62.00	
TOT. CHOLEST.	0-200 (MG/DL)	01/06/92	216.00 >		236.00 >		216.00 >	
TRIGLYCERIDES	50-180 (MG/DL)	01/06/92	211.00 >		198.00 >		192.00 >	
GLOBULINS ALPHA 1	2-4.5 (X)	01/06/92	3.60		3.70		3.90	
GLOBULINS ALPHA 2	5-9 (X)	01/06/92	7.80		7.60		7.40	
GLOBULINS BETA	9-13 (X)	01/06/92	11.20		11.30		11.80	
GLOBULINS GAMMA	10-20 (X)	01/06/92	18.90		18.70		17.90	
TSH	0.2-3.1 (UU/ML)	01/06/92	1.40					
T4	5-11.5 (UG/DL)	01/06/92	7.10					

(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 20124/017
Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 14 Patient: 462 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			24/07/92		21/08/92		11/09/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/06/92	13.30		13.50		13.40	
HT	42-54 (X)	01/06/92	39.00 <		39.00 <		39.00 <	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/06/92	4.10 <		4.10 <		4.00 <	
WBC	4000-9000 (/MM ³)	01/06/92	7000.00		6800.00		7000.00	
WBC: N	50-70 (X)	01/06/92						
WBC: L	25-40 (X)	01/06/92	37.00		38.00		39.00	
WBC: E	1-4 (X)	01/06/92	3.00		3.00		3.00	
WBC: M	4-8 (X)	01/06/92	3.00 <		2.00 <		2.00 <	
WBC: B	0-1 (X)	01/06/92	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM ³)	01/06/92	270000		270000		270000	
NA+	134-148 (MMOL/L)	01/06/92	139.00		140.00		141.00	
K+	3.8-5.2 (MMOL/L)	01/06/92	4.10		4.20		4.10	
CL-	1.8-2.2 (MG/DL)	01/06/92	2.00		2.00		2.00	
Ca++	2-2.6 (MMOL/L)	01/06/92	2.10		2.20		2.10	
PO4--	()	01/06/92						
SCOT	5-18 (U/L)	01/06/92	8.00		9.00		9.00	
SCPT	5-22 (U/L)	01/06/92	8.00		8.00		9.00	
GAMMA GT	4-28 (U/L)	01/06/92	12.00		13.00		12.00	
LDH	120-240 (U/L)	01/06/92	146.00		139.00		140.00	
ALK. PHOSPH.	60-170 (U/L)	01/06/92	98.00		99.00		100.00	
GLUCOSE	60-110 (MG/DL)	01/06/92	84.00		90.00		91.00	
BUN	10-50 (MG/DL)	01/06/92	29.00		31.00		31.00	
UREA	()	01/06/92						
CREATININE	0.3-1.2 (MG/DL)	01/06/92	0.70		0.80		0.80	
URIC ACID	2.4-7 (MG/DL)	01/06/92	4.90		5.20		5.40	
TOT. BILIRUBIN	0-1 (MG/DL)	01/06/92	0.80		0.80		0.80	
DIR. BILIRUBIN	0-0.2 (MG/DL)	01/06/92						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/06/92	7.40		7.60		7.40	
ALBUMINE	57-68 (X)	01/06/92	64.00		66.00		64.00	
TOT. CHOLEST.	0-200 (MG/DL)	01/06/92	198.00		201.00 >		204.00 >	
TRIGLYCERIDES	50-180 (MG/DL)	01/06/92	114.00		112.00		112.00	
GLOBULINS ALPHA 1	2-4.5 (X)	01/06/92	3.80		3.90		3.80	
GLOBULINS ALPHA 2	5-9 (X)	01/06/92	7.40		7.50		7.60	
GLOBULINS BETA	9-13 (X)	01/06/92	11.90		12.10		12.40	
GLOBULINS GAMMA	10-20 (X)	01/06/92	18.20		13.90		18.00	
TSH	0.2-3.1 (UU/ML)	01/06/92	1.80					
T4	5-11.5 (UG/DL)	01/06/92	6.40					

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14 Patient: 464 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			29/07/92		27/08/92		17/09/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/06/92	12.80		13.00		13.10	
HT	42-54 (%)	01/06/92	39.00 <		39.00 <		39.00 <	
RBC	4.2-5.8 (10 ⁶ /MM3)	01/06/92	4.00 <		4.10 <		4.20	
WBC	4000-9000 (/MM3)	01/06/92	5600.00		6000.00		6600.00	
WBC: N	50-70 (%)	01/06/92						
WBC: L	25-40 (%)	01/06/92	39.00		38.00		38.00	
WBC: E	1-4 (%)	01/06/92	3.00		3.00		2.00	
WBC: M	4-8 (%)	01/06/92	6.00		5.00		5.00	
WBC: B	0-1 (%)	01/06/92	1.00		1.00		1.00	
PLATELETS	150000-400000 (/MM3)	01/06/92	270000		270000		270000	
NA+	134-148 (MMOL/L)	01/06/92	138.00		137.00		139.00	
K+	3.8-5.2 (MMOL/L)	01/06/92	3.90		3.70 <		3.80	
CL-	1.8-2.2 (MG/DL)	01/06/92	2.00		1.90		1.90	
Ca++	2-2.6 (MMOL/L)	01/06/92	2.30		2.10		2.10	
PO4--	()	01/06/92						
SGOT	5-18 (U/L)	01/06/92	12.00		12.00		12.00	
SGPT	5-22 (U/L)	01/06/92	12.00		12.00		12.00	
GAMMA GT	4-28 (U/L)	01/06/92	21.00		18.00		16.00	
LDH	120-240 (U/L)	01/06/92	194.00		190.00		189.00	
ALK. PHOSPH.	60-170 (U/L)	01/06/92	98.00		100.00		99.00	
GLUCOSE	60-110 (MG/DL)	01/06/92	112.00 >		109.00		104.00	
BUN	10-50 (MG/DL)	01/06/92	39.00		40.00		42.00	
UREA	()	01/06/92						
CREATININE	0.3-1.2 (MG/DL)	01/06/92	0.80		0.80		0.80	
URIC ACID	2.4-7 (MG/DL)	01/06/92	5.70		5.80		5.90	
TOT BILIRUBIN	0-1 (MG/DL)	01/06/92	0.80		0.80		0.80	
DIR BILIRUBIN	0-0.2 (MG/DL)	01/06/92						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/06/92	7.20		7.10		7.00	
ALBUMINE	57-68 (%)	01/06/92	61.00		62.00		60.00	
TOT. CHOLEST.	0-200 (MG/DL)	01/06/92	246.00 >		251.00 >		247.00 >	
TRIGLYCERIDES	50-180 (MG/DL)	01/06/92	118.00		121.00		119.00	
GLOBULINS ALPHA 1	2-4.5 (%)	01/06/92	3.60		3.70		3.80	
GLOBULINS ALPHA 2	5-9 (%)	01/06/92	11.80 >>		11.90 >>		12.00 >>	
GLOBULINS BETA	9-13 (%)	01/06/92	10.60		10.20		10.40	
GLOBULINS GAMMA	10-20 (%)	01/06/92	18.40		18.70		18.60	
TSH	0.2-3.1 (UU/ML)	01/06/92	2.30					
T4	5-11.5 (UG/DL)	01/06/92	7.80					

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14 Patient: 465 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			30/07/92		27/08/92		17/09/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/06/92	14.20		14.40		14.20	
HT	42-54 (%)	01/06/92	41.00	<	41.00	<	42.00	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/06/92	4.30		4.40		4.40	
WBC	4000-9000 (/MM ³)	01/06/92	7200.00		7000.00		6800.00	
WBC: N	50-70 (%)	01/06/92						
WBC: L	25-40 (%)	01/06/92	40.00		39.00		38.00	
WBC: E	1-4 (%)	01/06/92	2.00		2.00		2.00	
WBC: H	4-8 (%)	01/06/92	7.00		6.00		5.00	
WBC: B	0-1 (%)	01/06/92	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM ³)	01/06/92						
NA+	134-148 (MMOL/L)	01/06/92	290000		290000		290000	
K+	3.8-5.2 (MMOL/L)	01/06/92	142.00		140.00		139.00	
CL-	1.8-2.2 (MG/DL)	01/06/92	4.20		4.10		2.00	<<
Ca++	2-2.6 (MMOL/L)	01/06/92	2.00		2.00		2.10	
PO4--	()	01/06/92	2.10		2.10		2.00	
SGOT	5-18 (U/L)	01/06/92	16.00		14.00		12.00	
SGPT	5-22 (U/L)	01/06/92	16.00		16.00		12.00	
GAMMA GT	4-28 (U/L)	01/06/92	28.00		26.00		20.00	
LDH	120-240 (U/L)	01/06/92	164.00		168.00		171.00	
ALK. PHOSPH.	60-170 (U/L)	01/06/92	112.00		114.00		112.00	
GLUCOSE	60-110 (MG/DL)	01/06/92	96.00		99.00		96.00	
BUN	10-50 (MG/DL)	01/06/92	36.00		38.00		39.00	
UREA	()	01/06/92						
CREATININE	0.3-1.2 (MG/DL)	01/06/92	0.80		0.80		0.80	
URIC ACID	2.4-7 (MG/DL)	01/06/92	6.20		6.60		6.40	
TOT BILIRUBIN	0-1 (MG/DL)	01/06/92	0.70		0.80		0.80	
DIR BILIRUBIN	0-0.2 (MG/DL)	01/06/92						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/06/92	7.60		7.50		7.40	
ALBUMINE	57-68 (%)	01/06/92	64.00		66.00		64.00	
TOT. CHOLEST.	0-200 (MG/DL)	01/06/92	257.00	>	263.00	>>	246.00	>
TRIGLYCERIDES	50-180 (MG/DL)	01/06/92	173.00		191.00	>	174.00	
GLOBULINS ALPHA 1	2-4.5 (%)	01/06/92	4.20		4.20		4.10	
GLOBULINS ALPHA 2	5-9 (%)	01/06/92	8.60		7.80		7.90	
GLOBULINS BETA	9-13 (%)	01/06/92	12.20		13.10	>	13.60	>
GLOBULINS GAMMA	10-20 (%)	01/06/92	19.70		19.00		18.40	
TSH	0.2-3.1 (UU/ML)	01/06/92	2.60					
T4	5-11.5 (UG/DL)	01/06/92	8.20					

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/1 Patient: 129 Treatment: Roboxetine Sex: Male

			Visit number / Laboratory data
			Screen
			11/12/91
			value (⊕)
Laboratory test	Range value	Range date	
HB	13-18 (G/DL)	01/07/91	15.40
HT	40-54 (Z)	01/07/91	46.90
RBC	4.1-6 (10 ⁶ /MM ³)	01/07/91	5.30
WBC	4000-9000 (/MM ³)	01/07/91	6200.00
WBC: N	50-70 (Z)	01/07/91	66.00
WBC: L	20-40 (Z)	01/07/91	31.00
WBC: E	0-3 (Z)	01/07/91	0.00
WBC: M	0-8 (Z)	01/07/91	3.00
WBC: B	0-2 (Z)	01/07/91	0.00
PLATELETS	150-400 (10 ³ /MM ³)	01/07/91	282.00
NA+	135-145 (MMOL/L)	01/07/91	139.00
K+	3.7-5 (MMOL/L)	01/07/91	4.30
CL-	()	01/07/91	
Ca++	4.5-5.2 (MEQ/L)	01/07/91	4.61
PO4--	()	01/07/91	
SGOT	5-18 (U/L)	01/07/91	8.00
SGPT	5-22 (U/L)	01/07/91	16.00
GAMMA GT	0-28 (U/L)	01/07/91	12.00
LDH	120-240 (U/L)	01/07/91	172.00
ALK. PHOSPH.	40-190 (U/L)	01/07/91	92.00
GLUCOSE	60-100 (MG/DL)	01/07/91	89.00
BUN	10-50 (MG/DL)	01/07/91	30.00
UREA	()	01/07/91	
CREATININE	0-1.2 (MG/DL)	01/07/91	1.09
URIC ACID	2.5-7 (MG/DL)	01/07/91	5.00
TOT BILIRUBIN	0-1 (MG/DL)	01/07/91	0.40
DIR BILIRUBIN	0-0.25 (MG/DL)	01/07/91	0.10
TOT. PROTEINS	6.5-8 (G/DL)	01/07/91	6.93
ALBUMINE	57-68 (Z)	01/07/91	65.40
TOT. CHOLEST.	130-200 (MG/DL)	01/07/91	208.00 >
TRIGLYCERIDES	65-170 (MG/DL)	01/07/91	69.00
GLOBULINS ALPHA 1	2-4 (Z)	01/07/91	2.30
GLOBULINS ALPHA 2	5-9 (Z)	01/07/91	5.10
GLOBULINS BETA	8-12 (Z)	01/07/91	12.10 >
GLOBULINS GAMMA	12-19 (Z)	01/07/91	14.90
TSH	0.2-4 (MU/L)	01/07/91	0.24
T4	10-25 (PMOL/L)	01/07/91	31.70

(⊕) << 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 20124/017
Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 14/1 Patient: 426 Treatment: Reboxetine Sex: Female

Laboratory test			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			29/08/91		24/09/91		17/10/91	
			value	(€)	value	(€)	value	(€)
Range value		Range date						
HB	12-16 (G/DL)	10/08/91	13.30		14.00		12.90	
HT	37-47 (%)	10/08/91	38.40		41.10		39.00	
RBC	3.9-5.3 (10 ⁶ /MM ³)	10/08/91	4.00		4.30		4.00	
WBC	4000-9000 (/MM ³)	10/08/91	5100.00		5700.00		6000.00	
WBC: N	50-70 (%)	10/08/91	49.00	<	41.00	<	49.00	
WBC: L	20-40 (%)	10/08/91	51.00	>	52.00	>	47.00	
WBC: E	0-3 (%)	10/08/91	0.00		0.00		0.00	
WBC: M	0-8 (%)	10/08/91	6.00		7.00		4.00	
WBC: B	0-2 (%)	10/08/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	10/08/91	291.00		265.00		387.00	
NA+	135-145 (MMOL/L)	10/08/91	142.00		141.00		140.00	
K+	3.7-5 (MMOL/L)	10/08/91	4.40		3.89		5.19	
CL-	()	10/08/91						
Ca++	2.2-2.6 (MMOL/L)	10/08/91	2.52					
	4.5-5.2 (MEQ/L)	10/09/91			4.66		4.32	
PO4--	()	10/08/91						
SGOT	5-18 (U/L)	10/08/91	9.00		9.00		16.00	
SGPT	5-22 (U/L)	10/08/91	9.00		10.00		31.00	
GAMMA GT	0-28 (U/L)	10/08/91	9.00		10.00		11.00	
LDH	120-240 (U/L)	10/08/91			198.00		258.00	
ALK. PHOSPH.	40-190 (U/L)	10/08/91	147.00		128.00		123.00	
GLUCOSE	60-100 (MG/DL)	10/08/91	114.00	>	90.00		92.00	
BUN	10-50 (MG/DL)	10/08/91	28.00		33.00		4.10	
UREA	()	10/08/91						
CREATININE	0-1.2 (MG/DL)	10/08/91	0.80		0.91		0.81	
URIC ACID	2.5-5.8 (MG/DL)	10/08/91	5.90	>	5.00			
TOT BILIRUBIN	0-1 (MG/DL)	10/08/91			0.50		0.50	
DIR BILIRUBIN	0-0.25 (MG/DL)	10/08/91	0.18		0.20		0.20	
TOT. PROTEINS	6.5-8 (G/DL)	10/08/91	7.10		7.20		7.02	
ALBUMINE	57-68 (%)	10/08/91	65.90		64.90		61.20	
TOT. CHOLEST.	130-200 (MG/DL)	10/08/91	233.00	>	226.00	>	177.00	
TRIGLYCERIDES	65-170 (MG/DL)	10/08/91	96.00		111.00			
GLOBULINS ALPHA 1	2-4 (%)	10/08/91	2.50		2.80		3.80	
GLOBULINS ALPHA 2	5-9 (%)	10/08/91	7.40		7.60		9.00	
GLOBULINS BETA	8-12 (%)	10/08/91	10.80		11.60		11.70	
GLOBULINS GAMMA	12-19 (%)	10/08/91	13.40		12.90		14.10	
TSH	0.2-4 (MU/L)	10/08/91	0.98					
T4	10-25 (PNOL/L)	10/08/91	8.00					

(€) << 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 20124/017
Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 14/1 Patient: 452 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			26/11/91		19/12/91		09/01/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/07/91	12.50		12.80		12.70	
HT	37-47 (X)	01/07/91	34.30 <		35.80 <		34.90 <	
RBC	3.9-5.3 (10 ⁶ /MM ³)	01/07/91	4.00		4.10		4.10	
WBC	4000-9000 (/MM ³)	01/07/91	6900.00		6800.00		8100.00	
WBC: N	50-70 (X)	01/07/91	55.00		58.00		58.00	
WBC: L	20-40 (X)	01/07/91	41.00 >		40.00		41.00 >	
WBC: E	0-3 (X)	01/07/91	0.00		0.00		0.00	
WBC: M	0-8 (X)	01/07/91	4.00		2.00		1.00	
WBC: B	0-2 (X)	01/07/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/07/91	345.00		349.00		344.00	
NA+	135-145 (MMOL/L)	01/07/91	142.00		139.00		139.00	
K+	3.7-5 (MMOL/L)	01/07/91	3.70		4.10		4.20	
CL-	()	01/07/91						
Ca++	4.5-5.2 (MEQ/L)	01/07/91	4.25 <		4.59		4.77	
PO4--	()	01/07/91						
SGOT	5-18 (U/L)	01/07/91	8.00		10.00		14.00	
SGPT	5-22 (U/L)	01/07/91	10.00		12.00		18.00	
GAMMA GT	0-28 (U/L)	01/07/91	24.00		15.00		15.00	
LDH	120-240 (U/L)	01/07/91	137.00		161.00		152.00	
ALK. PHOSPH.	40-190 (U/L)	01/07/91	103.00		132.00		108.00	
GLUCOSE	60-100 (MG/DL)	01/07/91	101.00 >		89.00		83.00	
BUN	10-50 (MG/DL)	01/07/91	17.00		24.00		29.00	
UREA	()	01/07/91						
CREATININE	0-1.2 (MG/DL)	01/07/91	0.70		0.66		0.78	
URIC ACID	2.5-5.8 (MG/DL)	01/07/91	3.80		3.90		2.70	
TOT BILIRUBIN	0-1 (MG/DL)	01/07/91	0.40		0.40		0.30	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/07/91	0.10		0.10			
TOT. PROTEINS	6.5-8 (G/DL)	01/07/91	6.92		7.06		6.82	
ALBUMINE	57-68 (X)	01/07/91	61.10		60.80		63.60	
TOT. CHOLEST.	130-200 (MG/DL)	01/07/91	294.00 >>		160.00		196.00	
TRIGLYCERIDES	65-170 (MG/DL)	01/07/91	119.00		56.00 <		50.00 <	
GLOBULINS ALPHA 1	2-4 (X)	01/07/91	2.40		2.80		1.90 <	
GLOBULINS ALPHA 2	5-9 (X)	01/07/91	8.10		8.50		6.50	
GLOBULINS BETA	8-12 (X)	01/07/91	10.60		10.30		10.10	
GLOBULINS GAMMA	12-19 (X)	01/07/91	17.60		17.40		17.60	
TSH	0.2-4 (MU/L)	01/07/91	0.56					
T4	10-25 (PMOL/L)	01/07/91	24.30					

(€) << clinically relevant (value lower than min range)
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>> clinically relevant (value higher than max range)
> out of range (value higher than max range)
() 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 20124/017
Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/3 Patient: 417 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			07/06/91		05/07/91		26/07/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/05/91	14.00		12.80		12.50	
HT	36-48 (X)	01/05/91	42.70		39.70		39.20	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/05/91	4.60		4.20		4.00 <	
WBC	4000-9000 (/MM ³)	01/05/91	7000.00		6900.00		8700.00 <	
WBC: N	50-70 (%)	01/05/91	55.00		52.00		46.00 <	
WBC: L	25-40 (%)	01/05/91	41.00	>	40.00		40.00	
WBC: E	0-1 (%)	01/05/91	1.00		1.00		0.00	
WBC: M	4-8 (%)	01/05/91	1.00	<	2.00	<	6.00	
WBC: B	0-1 (%)	01/05/91	2.00	>>	1.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/91	270.00		290.00		275.00	
NA+	134-148 (MMOL/L)	01/05/91	140.10		144.50		139.80	
K+	3.8-5.2 (MMOL/L)	01/05/91	3.80		7.31	>>	4.00	
CL-	96-111 (MMOL/L)	01/05/91	103.00		104.20		103.10	
Ca++	2-2.6 (MMOL/L)	01/05/91	2.50		2.50		2.50	
PO4--	0.8-1.6 (MMOL/L)	01/05/91	1.14		1.15		1.13	
SGOT	5-18 (U/L)	01/05/91	7.00		6.00		7.00	
SGPT	5-22 (U/L)	01/05/91	8.00		6.00		10.00	
GAMMA GT	4-28 (U/L)	01/05/91	9.00		8.00		13.00	
LDH	120-240 (U/L)	01/05/91	148.00		127.00		140.00	
ALK. PHOSPH.	60-170 (U/L)	01/05/91	74.00		68.00		84.00	
GLUCOSE	60-110 (MG/DL)	01/05/91	103.80		103.10		85.40	
BUN	10-50 (MG/DL)	01/05/91	36.00		36.00		31.00	
UREA	()	01/05/91						
CREATININE	0.3-1.2 (MG/DL)	01/05/91	0.80		1.10		0.90	
URIC ACID	2.4-7 (MG/DL)	01/05/91	5.10		5.40		5.70	
TOT BILIRUBIN	0-1 (MG/DL)	01/05/91	0.20		0.30		0.20	
DIR BILIRUBIN	0-0.2 (MG/DL)	01/05/91	0.10		0.10		0.10	
TOT. PROTEINS	6.6-8.7 (G/DL)	01/05/91	7.70		8.20		7.70	
ALBUMINE	57-68 (X)	01/05/91	51.10	<	43.00	<	50.30 <	
TOT. CHOLEST.	120-200 (MG/DL)	01/05/91	235.00	>	217.00	>	289.00 >>	
TRIGLYCERIDES	50-180 (MG/DL)	01/05/91	115.00		119.00		161.00	
GLOBULINS ALPHA 1	2-4.5 (X)	01/05/91	5.60	>	3.30		4.20	
GLOBULINS ALPHA 2	5-9 (X)	01/05/91	11.00	>	8.10		8.70	
GLOBULINS BETA	9-13 (X)	01/05/91	14.00	>	11.80		14.80 >	
GLOBULINS GAMMA	10-20 (X)	01/05/91	18.30		33.80	>>	22.00 >	
TSH	0.2-3.1 (UU/ML)	01/05/91	0.61					
T4	5-11.5 (UG/DL)	01/05/91	12.60					

(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 20124/017
Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/3 Patient: 419 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/07/91		25/07/91		15/08/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/05/91	13.70		13.50		13.80	
HT	36-48 (%)	01/05/91	39.70		39.00		41.80	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/05/91	4.40		4.20		4.50	
WBC	4000-9000 (/MM ³)	01/05/91	4000.00		5200.00		4000.00	
WBC: N	50-70 (%)	01/05/91	39.00	<	40.00	<	40.00	
WBC: L	25-40 (%)	01/05/91	54.00	>>	50.00	>	56.00	
WBC: E	0-1 (%)	01/05/91	2.00	>>	1.00		2.00	
WBC: M	4-8 (%)	01/05/91	5.00		6.00		2.00	
WBC: B	0-1 (%)	01/05/91	0.00		1.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/91	216.00		220.00		202.00	
NA+	134-148 (MMOL/L)	01/05/91	145.00		145.00		141.70	
K+	3.6-5.2 (MMOL/L)	01/05/91	4.00		4.40		4.10	
CL-	96-111 (MMOL/L)	01/05/91	103.80		105.40		103.60	
Ca ⁺⁺	2-2.6 (MMOL/L)	01/05/91	2.40		2.50		2.50	
PO ₄ ⁻⁻⁻	0.8-1.6 (MMOL/L)	01/05/91	1.20		1.22		1.44	
SGOT	5-18 (U/L)	01/05/91	8.00		12.00		8.00	
SGPT	5-22 (U/L)	01/05/91	6.00		10.00		6.00	
GAMMA GT	4-28 (U/L)	01/05/91	8.00		9.00		6.00	
LDH	120-240 (U/L)	01/05/91	201.00		209.00		201.00	
ALK. PHOSPH.	60-170 (U/L)	01/05/91	90.00		94.00		84.00	
GLUCOSE	60-110 (MG/DL)	01/05/91	101.00		123.10	>	89.20	
BUN	10-50 (MG/DL)	01/05/91	36.00		34.00		33.00	
UREA	()	01/05/91						
CREATININE	0.3-1.2 (MG/DL)	01/05/91	0.90		1.00		1.00	
URIC ACID	2.4-7 (MG/DL)	01/05/91	5.70		5.10		5.80	
TOT. BILIRUBIN	0-1 (MG/DL)	01/05/91	0.60		0.30		0.30	
DIR. BILIRUBIN	0-0.2 (MG/DL)	01/05/91	0.30	>	0.10		0.10	
TOT. PROTEINS	6.6-8.7 (G/DL)	01/05/91	7.60		7.50		7.60	
ALBUMINE	57-68 (%)	01/05/91	66.70		60.50	>	68.50	
TOT. CHOLEST.	120-200 (MG/DL)	01/05/91	264.00	>>	311.00	>>	246.00	
TRIGLYCERIDES	50-180 (MG/DL)	01/05/91	93.00		110.00		124.00	
GLOBULINS ALPHA 1	2-4.5 (%)	01/05/91	2.90		2.80		3.40	
GLOBULINS ALPHA 2	5-9 (%)	01/05/91	8.00		7.80		7.20	
GLOBULINS BETA	9-13 (%)	01/05/91	9.30		9.80		10.80	
GLOBULINS GAMMA	10-20 (%)	01/05/91	13.10		19.10		9.70	
TSH	0.2-3.1 (UU/ML)	01/05/91	1.37					
T4	5-11.5 (UG/DL)	01/05/91	7.94					

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/3 Patient: 421 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/07/91		08/08/91		22/08/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/05/91	13.40		13.70		12.70	
HT	36-48 (%)	01/05/91	39.50		41.10		40.10	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/05/91	4.60		4.50		4.10 <	
HBC	4000-9000 (/MM ³)	01/05/91	3600.00 <		5300.00		4500.00	
HBC: N	50-70 (%)	01/05/91	54.80		58.00		47.00 <	
HBC: L	25-40 (%)	01/05/91	30.80		27.00		40.00	
HBC: E	0-1 (%)	01/05/91	3.20 >>		4.00 >>		1.00	
HBC: H	4-8 (%)	01/05/91	7.70		10.00 >		12.00 >>	
HBC: B	0-1 (%)	01/05/91	1.20 >		1.00		0.00	
PLATELETS	150-400 (10 ³ -3/MM ³)	01/05/91	263.00		228.00		242.00	
NA+	134-148 (MMOL/L)	01/05/91	141.00		140.10		138.40	
K+	3.8-5.2 (MMOL/L)	01/05/91	3.90		4.10		3.70 <	
CL-	96-114 (MMOL/L)	01/05/91	102.40		102.00		103.00	
Ca++	2-2.6 (MMOL/L)	01/05/91	2.20		2.40		2.30	
PO4--	0.8-1.6 (MMOL/L)	01/05/91	1.10		1.12		1.11	
SGOT	5-18 (U/L)	01/05/91	7.00		7.00		7.00	
SGPT	5-22 (U/L)	01/05/91	11.00		10.00		9.00	
GAMMA GT	4-28 (U/L)	01/05/91	5.00		5.00		4.00	
LDH	120-240 (U/L)	01/05/91	100.00 <		124.00		130.00	
ALK. PHOSPH.	60-170 (U/L)	01/05/91	54.00 <		81.00		61.00	
GLUCOSE	60-110 (MG/DL)	01/05/91	73.50		111.50 >		124.10 >	
BUN	10-50 (MG/DL)	01/05/91	34.00		22.00		23.00	
UREA	()	01/05/91						
CREATININE	0.3-1.2 (MG/DL)	01/05/91	0.91		1.00		1.00	
URIC ACID	2.4-7 (MG/DL)	01/05/91	1.80 <		2.40		2.20 <	
TOT BILIRUBIN	0-1 (MG/DL)	01/05/91	0.37		0.30		0.20	
DIR BILIRUBIN	0-0.2 (MG/DL)	01/05/91	0.10		0.10		0.00	
TOT. PROTEINS	6.6-8.7 (G/DL)	01/05/91	7.00		7.60		7.30	
ALBUMINE	57-68 (%)	01/05/91	63.30		66.50		56.90 <	
TOT. CHOLEST.	120-200 (MG/DL)	01/05/91	140.00		170.00		154.00	
TRIGLYCERIDES	50-180 (MG/DL)	01/05/91	34.00 <		68.00		52.00	
GLOBULINS ALPHA 1	2-4.5 (%)	01/05/91	2.50		1.50 <		4.40	
GLOBULINS ALPHA 2	5-9 (%)	01/05/91	5.50		5.50		7.30	
GLOBULINS BETA	9-13 (%)	01/05/91	10.10		10.10		11.40	
GLOBULINS GAMMA	10-20 (%)	01/05/91	18.60		16.40		20.00	
TSH	0.2-3.1 (U/ML)	01/05/91	0.42					
T4	5-11.5 (UG/DL)	01/05/91	9.00					

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/4 Patient: 134 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			13/01/92		06/02/92		27/02/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	02/12/91	13.20		13.80		14.20	
HT	95.8-45.4 (%)	02/12/91	46.00 >	42.00	45.00		45.00	
RBC	3.9-5.6 (10 ⁶ /MM ³)	02/12/91	4.80		5.10		5.20	
WBC	5-9 (10 ³ /MM ³)	02/12/91	8.30		7.80		7.60	
WBC: N	50-70 (%)	02/12/91	62.00		57.00		57.00	
WBC: L	25-40 (%)	02/12/91	34.00		38.00		39.00	
WBC: E	2-4 (%)	02/12/91	3.00		4.00		2.00	
WBC: M	2-8 (%)	02/12/91	3.00		1.00 <		1.00 <	
WBC: B	0-1 (%)	02/12/91	1.00		0.00		1.00	
PLATELETS	200-350 (10 ³ /MM ³)	02/12/91	240.00		270.00		265.00	
NA+	137-147 (MMOL/L)	02/12/91	144.00		140.00		139.00	
K+	3.6-5.5 (MMOL/L)	02/12/91	4.10		3.90		3.80	
CL-	101-111 (MMOL/L)	02/12/91	109.00		108.00		102.00	
Ca++	2.25-2.6 (MMOL/L)	02/12/91	2.46		2.32		2.48	
PO4--	0.8-1.6 (MMOL/L)	02/12/91	0.90		1.40		0.95	
SGOT	5-17 (U/L)	02/12/91	16.00		14.00		15.00	
SGPT	5-23 (U/L)	02/12/91	18.00		20.00		21.00	
GAMMA GT	6-28 (U/L)	02/12/91	24.00		21.00		24.00	
LDH	80-240 (U/L)	02/12/91	160.00		221.00		218.00	
ALK. PHOSPH.	40-190 (U/L)	02/12/91	140.00		113.00		160.00	
GLUCOSE	70-115 (MG/DL)	02/12/91	84.00		91.00		102.00	
BUN	20-40 (MG/DL)	02/12/91	36.00		32.00		39.00	
UREA	()	02/12/91						
CREATININE	0.6-1.1 (MG/DL)	02/12/91	0.90		0.90		0.80	
URIC ACID	2.4-5.7 (MG/DL)	02/12/91	3.60		3.50		5.60	
TOT BILIRUBIN	0-1.1 (MG/DL)	02/12/91	0.80		0.90		0.90	
DIR BILIRUBIN	()	02/12/91						
TOT. PROTEINS	6.7-8.2 (G/DL)	02/12/91	6.90		6.70		7.40	
ALBUMINE	53-70 (%)	02/12/91	69.00		58.00		56.00	
TOT. CHOLEST.	140-240 (MG/DL)	02/12/91	201.00		233.00		240.00	
TRIGLYCERIDES	0-200 (MG/DL)	02/12/91	184.00		192.00		185.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	02/12/91	3.40		3.20		4.20	
GLOBULINS ALPHA 2	9-14 (%)	02/12/91	10.20		10.40		9.30	
GLOBULINS BETA	8-12 (%)	02/12/91	11.20		11.40		14.60 >	
GLOBULINS GAMMA	10-18 (%)	02/12/91	11.80		10.90		11.20	
TSH	0.16-3.2 (MU/L)	02/12/91	2.41					
T4	48-120 (UG/L)	02/12/91	102.00					

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/4 Patient: 135 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/01/92		06/02/92		28/02/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	02/12/91	15.30		15.60		15.80	
HT	43.2-49.2 (X)	02/12/91	46.40		48.00		49.00	
RBC	4.6-6.2 (10 ⁶ /MM ³)	02/12/91	5.30		5.40		5.60	
WBC	5-9 (10 ³ /MM ³)	02/12/91	8.20		7.60		8.40	
WBC: N	50-70 (%)	02/12/91	59.00		55.00		64.00	
WBC: L	25-40 (%)	02/12/91	33.00		39.00		30.00	
WBC: E	2-4 (%)	02/12/91	3.00		4.00		2.00	
WBC: M	3-5 (%)	02/12/91	3.00		2.00 <		4.00	
WBC: B	0-1 (%)	02/12/91	1.00		0.00		0.00	
PLATELETS	200-350 (10 ³ /MM ³)	02/12/91	320.00		316.00		290.00	
NA+	137-142 (MMOL/L)	02/12/91	139.00		142.00		140.00	
K+	3.6-5.5 (MMOL/L)	02/12/91	3.90		4.90		4.70	
CL-	101-111 (MMOL/L)	02/12/91	109.00		109.00		109.00	
Ca++	2.25-2.6 (MMOL/L)	02/12/91	2.34		2.43		2.58	
PO4--	0.8-1.6 (MMOL/L)	02/12/91	0.91		1.30		1.40	
SGOT	5-17 (U/L)	02/12/91	19.00 >		20.00 >		21.00 >	
SGPT	5-23 (U/L)	02/12/91	20.00		24.00 >		25.00 >	
GAMMA GT	6-28 (U/L)	02/12/91	24.00		32.00 >		34.00 >	
LDH	80-240 (U/L)	02/12/91	160.00		180.00		225.00	
ALK. PHOSPH.	50-190 (U/L)	02/12/91	154.00		144.00		165.00	
GLUCOSE	50-100 (MG/DL)	02/12/91	102.00 >		98.00		104.00 >	
BUN	20-40 (MG/DL)	02/12/91	43.00 >		41.00 >		42.00 >	
UREA	()	02/12/91						
CREATININE	0.7-1.3 (MG/DL)	02/12/91	1.12		1.20		0.91	
URIC ACID	3.7-7 (MG/DL)	02/12/91	6.50		6.20		6.50	
TOT BILIRUBIN	0-1.1 (MG/DL)	02/12/91	1.00		0.90		1.00	
DIR BILIRUBIN	()	02/12/91						
TOT. PROTEINS	6.7-8.2 (G/DL)	02/12/91	7.20		7.40		7.60	
ALBUMINE	53-70 (%)	02/12/91	56.00		58.00		61.00	
TOT. CHOLEST.	140-250 (MG/DL)	02/12/91	246.00		233.00		248.00	
TRIGLYCERIDES	0-200 (MG/DL)	02/12/91	184.00		201.00 >		222.00 >	
GLOBULINS ALPHA 1	2.5-4.5 (%)	02/12/91	3.30		3.60		4.20	
GLOBULINS ALPHA 2	9-14 (%)	02/12/91	9.20		9.80		11.20	
GLOBULINS BETA	8-12 (%)	02/12/91	10.40		12.20 >		11.80	
GLOBULINS GAMMA	10-18 (%)	02/12/91	14.60		15.20		14.80	
TSH	0.16-3.2 (MU/L)	02/12/91	2.28					
T4	48-120 (UG/L)	02/12/91	116.00					

(€) << 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

1211

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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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/7 Patient: 424 Treatment: Roboxtine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/09/91		10/10/91		31/10/91	
			value	(±)	value	(±)	value	(±)
Laboratory test	Range value	Range date						
HB	12.8-16 (G/DL)	01/08/91	14.00		13.50		15.40	
HT	37-47 (X)	01/08/91	45.00		47.00		37.80	
RBC	4.5-5 (10 ⁶ /MM ³)	01/08/91	4.30 <		4.60		4.70	
WBC	3500-9000 (/MM ³)	01/08/91	6500.00		7200.00		6200.00	
WBC: N	37-73 (%)	01/08/91	62.00		48.00		43.00	
WBC: L	20-55 (%)	01/08/91	32.00		32.00		25.00	
WBC: E	0.5-11 (%)	01/08/91	2.00		2.00		6.00	
WBC: M	2.5-10 (%)	01/08/91	2.00 <		2.00 <		3.50	
WBC: B	0-2 (%)	01/08/91	1.00		0.00		1.00	
PLATELETS	150000-400000 (/MM ³)	01/08/91	290000		325000		395000	
NA+	134-148 (MMOL/L)	01/08/91	140.00		142.00		148.00	
K+	3.8-5.2 (MMOL/L)	01/08/91	4.20		4.40		3.70 <	
CL-	84-110 (MMOL/L)	01/08/91	99.00		96.00		98.00	
Ca++	4.2-5.5 (MEQ/L)	01/08/91	4.30		4.40		5.00	
PO4--	23.3-49.8 (NG/L)	01/08/91	42.00		38.00		28.50	
SGOT	5-18 (U/L)	01/08/91	12.00		13.00		16.00	
SGPT	5-22 (U/L)	01/08/91	10.00		11.00		20.00	
GAMMA GT	4-28 (U/L)	01/08/91	20.00		18.00		26.00	
LDH	120-240 (U/L)	01/08/91	180.00		184.00		185.00	
ALK. PHOSPH.	60-170 (U/L)	01/08/91	140.00		145.00		160.00	
GLUCOSE	60-110 (MG/DL)	01/08/91	69.30		72.40		115.00 >	
BUN	10-50 (MG/DL)	01/08/91	46.00		42.00		25.80	
UREA	()	01/08/91						
CREATININE	0.3-1.2 (MG/DL)	01/08/91	0.90		0.80		1.00	
URIC ACID	2.4-7 (MG/DL)	01/08/91	5.40		5.20		6.70	
TOT BILIRUBIN	0-1 (MG/DL)	01/08/91	0.80		0.80		0.40	
DIR BILIRUBIN	()	01/08/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/08/91	6.90		6.80		8.00	
ALBUMINE	3.7-5.5 (G/DL)	01/08/91	4.30		5.20		5.10	
TOT. CHOLEST.	120-200 (MG/DL)	01/08/91	222.00 >		254.00 >		254.00 >	
TRIGLYCERIDES	50-180 (MG/DL)	01/08/91	162.00		148.00		190.00 >	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/08/91	0.30		0.10		0.20	
GLOBULINS ALPHA 2	0.4-0.8 (G/DL)	01/08/91	0.60		0.50		0.70	
GLOBULINS BETA	0.4-0.9 (G/DL)	01/08/91	0.80		0.70		0.80	
GLOBULINS GAMMA	0.7-1.4 (G/DL)	01/08/91	1.20		0.90		1.20	
TSH	0.2-4 (UU/ML)	01/08/91	2.40					
T4	5-11.5 (UG/DL)	01/08/91	7.80					

(±) << 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

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/7 Patient: 430 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			07/10/91		28/10/91		18/11/91	
			value	(e)	value	(e)	value	(e)
Laboratory test	Range value	Range date						
HB	12.8-16 (G/DL)	05/10/91	14.30		14.50		15.20	
HT	37-47 (X)	05/10/91	44.80		45.20		42.80	
RBC	4.5-5 (10 ⁶ /MM ³)	05/10/91	4.30	<	4.50		4.60	
WBC	3500-9000 (/MM ³)	05/10/91	7800.00		8200.00		7400.00	
WBC: N	37-73 (X)	05/10/91	48.00		47.00		53.00	
WBC: L	20-55 (X)	05/10/91	32.00		33.00		32.00	
WBC: E	0.5-11 (X)	05/10/91	5.80		5.70		0.90	
WBC: M	2.5-10 (X)	05/10/91	8.40		8.20		7.40	
WBC: B	0-2 (X)	05/10/91	1.20		1.00		0.00	
PLATELETS	150000-400000 (/MM ³)	05/10/91	320000		400000		290000	
NA+	134-148 (MMOL/L)	05/10/91	140.00		145.00		143.00	
K+	3.8-5.2 (MMOL/L)	05/10/91	4.20		4.50		4.80	
CL-	84-110 (MMOL/L)	05/10/91	98.00		97.00		97.00	
Ca++	4.2-5.5 (MEQ/L)	05/10/91	4.30		4.50		4.80	
PO4--	2.5-4.5 (MG/DL)	05/10/91	3.20		3.30			
	23.3-49.8 (MG/L)	17/11/91					42.40	
SGOT	5-18 (U/L)	05/10/91	8.00		10.00		16.00	
SGPT	5-22 (U/L)	05/10/91	7.00		12.00		18.00	
GAMMA GT	4-28 (U/L)	05/10/91	7.00		8.00		12.00	
LDH	120-240 (U/L)	05/10/91	127.00		135.00		195.00	
ALK. PHOSPH.	60-170 (U/L)	05/10/91	140.00		142.00		136.00	
GLUCOSE	60-110 (MG/DL)	05/10/91	94.20		97.20		96.40	
BUN	10-50 (MG/DL)	05/10/91	39.80		35.20		21.40	
UREA	()	05/10/91						
CREATININE	0.3-1.2 (MG/DL)	05/10/91	1.00		0.90		1.00	
URIC ACID	2.4-7 (MG/DL)	05/10/91	4.50		4.70		6.20	
TOT BILIRUBIN	0-1 (MG/DL)	05/10/91	0.29		0.30		0.10	
DIR BILIRUBIN	()	05/10/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	05/10/91	7.52		8.20		7.40	
ALBUMINE	3.7-5.5 (G/DL)	05/10/91	3.90		4.10		5.20	
TOT. CHOLEST.	120-200 (MG/DL)	05/10/91	240.00	>	238.00	>	225.00	
TRIGLYCERIDES	50-180 (MG/DL)	05/10/91	183.00	>	169.00		154.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	05/10/91	0.10		0.20		0.10	
GLOBULINS ALPHA 2	0.4-0.8 (G/DL)	05/10/91	0.50		0.40		0.50	
GLOBULINS BETA	0.4-0.9 (G/DL)	05/10/91	0.70		0.80		0.70	
GLOBULINS GAMMA	0.7-1.4 (G/DL)	05/10/91	0.90		1.20		1.20	
TSH	0.2-4 (UU/ML)	05/10/91	2.30					
T4	5-11.5 (UG/DL)	05/10/91	10.80					

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/7 Patient: 431 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			08/10/91		29/10/91		19/11/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12.8-16 (G/DL)	05/10/91	14.70		14.30		14.20	
HT	37-47 (%)	05/10/91	43.40		42.20		41.00	
RBC	4.5-5 (10 ⁶ /MM ³)	05/10/91	4.30 <		4.10 <		4.20 <	
HBC	3500-9000 (/MM ³)	05/10/91	7500.00		8200.00		4900.00	
HBC: N	37-73 (%)	05/10/91	45.00		43.00		57.00	
HBC: L	20-55 (%)	05/10/91	32.00		30.00		35.00	
HBC: E	0.5-11 (%)	05/10/91	0.80		0.70		0.60	
HBC: M	2.5-10 (%)	05/10/91	3.40		3.40		7.20	
HBC: B	0-2 (%)	05/10/91	1.50		1.50		0.00	
PLATELETS	150000-400000 (/MM ³)	05/10/91						
			420000 >		375000		325000	
NA+	134-148 (MMOL/L)	05/10/91	143.00		142.00		142.00	
K+	3.8-5.2 (MMOL/L)	05/10/91	4.20		3.80		4.20	
CL-	84-110 (MMOL/L)	05/10/91	101.00		100.00		98.00	
Ca++	4.2-5.5 (MEQ/L)	05/10/91	4.14 <		4.00 <		4.80	
PO4--	2.5-4.5 (MG/DL)	05/10/91	3.50		3.20			
							37.20	
							12.00	
SGOT	5-18 (U/L)	05/10/91	8.00		12.00		12.00	
SGPT	5-22 (U/L)	05/10/91	10.00		14.00		21.00	
GAMMA GT	4-28 (U/L)	05/10/91	9.00		12.00		26.00	
LDH	120-240 (U/L)	05/10/91	146.00		152.00		186.00	
ALK. PHOSPH.	60-170 (U/L)	05/10/91	70.70		78.40		154.00	
GLUCOSE	60-110 (MG/DL)	05/10/91	78.60		72.40		78.40	
BUN	10-50 (MG/DL)	05/10/91	32.00		28.30		18.40	
UREA	()	05/10/91						
CREATININE	0.3-1.2 (MG/DL)	05/10/91	1.20		1.00		0.90	
URIC ACID	2.4-7 (MG/DL)	05/10/91	6.64		6.70		6.40	
TOT BILIRUBIN	0-1 (MG/DL)	05/10/91	0.24		0.10		0.20	
DIR BILIRUBIN	()	05/10/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	05/10/91	6.50 <		6.20 <		6.80	
ALBUMINE	3.7-5.5 (G/DL)	05/10/91	4.30		4.10		4.70	
TOT. CHOLEST.	120-200 (MG/DL)	05/10/91	195.00		182.00		202.00 >	
TRIGLYCERIDES	50-180 (MG/DL)	05/10/91	98.60		82.40		84.30	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	05/10/91	0.20		0.10		0.20	
GLOBULINS ALPHA 2	0.4-0.8 (G/DL)	05/10/91	0.70		0.50		0.40	
GLOBULINS BETA	0.4-0.9 (G/DL)	05/10/91	0.60		0.60		0.50	
GLOBULINS GAMMA	0.7-1.4 (G/DL)	05/10/91	1.10		1.30		1.20	
TSH	0.2-4 (UU/ML)	05/10/91	3.20					
T4	5-11.5 (UG/DL)	05/10/91	10.20					

(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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/7 Patient: 434 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/10/91		04/11/91		25/11/91	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	12.8-16 (G/DL)	05/10/91	14.80		14.20		13.40	
HT	37-47 (%)	05/10/91	44.00		43.00		42.00	
RBC	4.5-5 (10 ⁶ /MM ³)	05/10/91	4.80		4.60		4.80	
WBC	3500-9000 (/MM ³)	05/10/91	7800.00		8200.00		7600.00	
WBC: N	37-73 (%)	05/10/91	69.00		72.00		55.00	
WBC: L	20-55 (%)	05/10/91	35.00		36.00		32.00	
WBC: E	0.5-11 (%)	05/10/91	2.40		2.30		4.50	
WBC: M	2.5-10 (%)	05/10/91	6.80		6.40		4.20	
WBC: B	0-2 (%)	05/10/91	0.00		0.00		1.00	
PLATELETS	150000-400000 (/MM ³)	05/10/91	240000		315000		295000	
NA+	134-148 (MMOL/L)	05/10/91	145.00		144.00		132.00 <	
K+	3.8-5.2 (MMOL/L)	05/10/91	4.30		4.10		3.80	
CL-	84-110 (MMOL/L)	05/10/91	98.00		96.00		97.00	
Ca++	4.2-5.5 (MEQ/L)	05/10/91	4.80		4.60		4.40	
PO4--	2.5-4.5 (MG/DL)	05/10/91	3.70		3.60		30.20	
	23.3-49.8 (MG/L)	24/11/91					16.00	
SGOT	5-18 (U/L)	05/10/91	9.00		12.00		20.00	
SGPT	5-22 (U/L)	05/10/91	10.00		14.00		28.00	
GAMMA GT	4-28 (U/L)	05/10/91	18.00		22.00		140.00	
LDH	120-240 (U/L)	05/10/91	180.00		176.00		125.00	
ALK. PHOSPH.	60-170 (U/L)	05/10/91	130.00		145.00		72.40	
GLUCOSE	60-110 (MG/DL)	05/10/91	72.80		68.40		23.20	
BUN	10-50 (MG/DL)	05/10/91	22.00		21.40			
UREA	()	05/10/91						
CREATININE	0.3-1.2 (MG/DL)	05/10/91	0.90		0.70		0.80	
URIC ACID	2.4-7 (MG/DL)	05/10/91	6.20		6.00		6.80	
TOT BILIRUBIN	0-1 (MG/DL)	05/10/91	0.90		0.80		0.40	
DIR BILIRUBIN	()	05/10/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	05/10/91	6.80		6.40 <		6.90	
ALBUMINE	3.7-5.5 (G/DL)	05/10/91	4.90		4.80		4.70	
TOT. CHOLEST.	120-200 (MG/DL)	05/10/91	320.00 >>		310.00 >>		295.00 >>	
TRIGLYCERIDES	50-180 (MG/DL)	05/10/91	175.00		105.00		128.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	05/10/91	0.20		0.10		0.20	
GLOBULINS ALPHA 2	0.4-0.8 (G/DL)	05/10/91	0.80		0.60		0.50	
GLOBULINS BETA	0.4-0.9 (G/DL)	05/10/91	0.70		0.70		0.40	
GLOBULINS GAMMA	0.7-1.4 (G/DL)	05/10/91	1.30		1.20		1.00	
TSH	0.2-4 (UU/ML)	05/10/91	3.40					
T4	5-11.5 (UG/DL)	05/10/91	10.10					

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/7 Patient: 439 Treatment: Roboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/11/91		02/12/91		23/12/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12.8-16 (G/DL)	01/08/91	14.50		14.70		15.20	
HT	37-47 (%)	01/08/91	42.00		45.00		42.00	
RBC	4.5-5 (10 ⁶ /MM ³)	01/08/91	4.60		4.90		4.70	
WBC	3500-9000 (/MM ³)	01/08/91	6400.00		7200.00		6800.00	
WBC: N	37-73 (%)	01/08/91	56.00		53.00		48.00	
WBC: L	20-55 (%)	01/08/91	35.00		40.00		32.00	
WBC: E	0.5-11 (%)	01/08/91	0.60		0.80		7.40	
WBC: M	2.5-10 (%)	01/08/91	8.00		8.50		6.20	
WBC: B	0-2 (%)	01/08/91	1.00		1.00		0.00	
PLATELETS	150000-400000 (/MM ³)	01/08/91	157000		232000		325000	
NA+	134-148 (MMOL/L)	01/08/91	141.40		140.20		141.00	
K+	3.8-5.2 (MMOL/L)	01/08/91	4.53		4.40		4.30	
CL-	84-110 (MMOL/L)	01/08/91	96.00		103.00		97.00	
Ca ⁺⁺	4.2-5.5 (MEQ/L)	01/08/91	4.30		4.20		4.90	
PO ₄ ⁻⁻⁻	23.3-49.8 (MG/L)	01/08/91	32.40		23.80		32.40	
SGOT	5-18 (U/L)	01/08/91	11.00		14.60		18.40 >	
SGPT	5-22 (U/L)	01/08/91	8.00		20.30		20.60	
GAMMA GT	4-28 (U/L)	01/08/91	3.00 <		24.80		32.40 >	
LDH	120-240 (U/L)	01/08/91	184.00		192.00		204.00	
ALK. PHOSPH.	60-170 (U/L)	01/08/91	106.00		112.00		152.00	
GLUCOSE	60-110 (MG/DL)	01/08/91	90.50		79.40		92.00	
BUN	10-50 (MG/DL)	01/08/91	61.00 >		53.00 >		45.80	
UREA	()	01/08/91						
CREATININE	0.3-1.2 (MG/DL)	01/08/91	0.90		0.70		0.90	
URIC ACID	2.4-7 (MG/DL)	01/08/91	4.40		4.30		5.60	
TOT BILIRUBIN	0-1 (MG/DL)	01/08/91	0.48		0.74		0.00	
DIR BILIRUBIN	()	01/08/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/08/91	6.86		7.20		6.90	
ALBUMINE	3.7-5.5 (G/DL)	01/08/91	4.60		5.10		4.20	
TOT. CHOLEST.	120-200 (MG/DL)	01/08/91	257.00 >		268.00 >>		254.00 >	
TRIGLYCERIDES	50-180 (MG/DL)	01/08/91	51.00		78.00		68.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/08/91	0.20		0.10		0.20	
GLOBULINS ALPHA 2	0.4-0.8 (G/DL)	01/08/91	0.60		0.80		0.50	
GLOBULINS BETA	0.4-0.9 (G/DL)	01/08/91	0.80		0.80		0.70	
GLOBULINS GAMMA	0.7-1.4 (G/DL)	01/08/91	1.20		1.20		1.00	
TSH	0.2-4 (UU/ML)	01/08/91	2.80					
T4	5-11.5 (UG/DL)	01/08/91	8.40					

(€) << 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 20124/017
Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/7 Patient: 449 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			16/12/91		10/01/92		31/01/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	12.8-16 (G/DL)	01/08/91	14.20		14.80		13.20	
HT	37-47 (X)	01/08/91	41.80		42.40		40.60	
RBC	4.5-5 (10 ⁶ /MM ³)	01/08/91	4.80		4.90		4.90	
WBC	3500-9000 (/MM ³)	01/08/91	7200.00		8400.00		8600.00	
WBC: N	37-73 (X)	01/08/91	45.00		52.00		50.00	
WBC: L	20-55 (X)	01/08/91	35.00		48.00		45.00	
WBC: E	0.5-11 (X)	01/08/91	4.50		5.70		7.40	
WBC: M	2.5-10 (X)	01/08/91	3.50		2.90		4.80	
WBC: B	0-2 (X)	01/08/91	0.00		0.00		0.80	
PLATELETS	150000-400000 (/MM ³)	01/08/91	193000		232000		287000	
NA+	134-148 (MMOL/L)	01/08/91	138.00		135.00		142.00	
K+	3.8-5.2 (MMOL/L)	01/08/91	3.90		4.80		4.20	
CL-	84-110 (MMOL/L)	01/08/91	98.00		96.00		97.00	
Ca++	4.2-5.5 (MEQ/L)	01/08/91	4.50		4.80		4.90	
PO4--	23.3-49.8 (MG/L)	01/08/91	36.20		39.20		42.40	
SGOT	5-18 (U/L)	01/08/91	9.00		8.00		10.00	
SGPT	5-22 (U/L)	01/08/91	9.00		8.00		8.00	
GAMMA GT	4-28 (U/L)	01/08/91	9.00		9.00		8.00	
LDH	120-240 (U/L)	01/08/91	166.00		172.00		148.00	
ALK. PHOSPH.	60-170 (U/L)	01/08/91	107.00		118.00		123.00	
GLUCOSE	60-110 (MG/DL)	01/08/91	103.00		100.00		89.00	
BUN	10-50 (MG/DL)	01/08/91	31.00		30.80		29.40	
UREA	()	01/08/91						
CREATININE	0.3-1.2 (MG/DL)	01/08/91	0.80		0.70		0.80	
URIC ACID	2.4-7 (MG/DL)	01/08/91	5.90		6.20		4.90	
TOT BILIRUBIN	0-1 (MG/DL)	01/08/91	0.28		0.42		0.62	
DIR BILIRUBIN	()	01/08/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/08/91	6.62		6.84		7.02	
ALBUMINE	3.7-5.5 (G/DL)	01/08/91	4.80		5.10		5.00	
TOT. CHOLEST.	120-200 (MG/DL)	01/08/91	216.00 >		220.00 >		214.00 >	
TRIGLYCERIDES	50-180 (MG/DL)	01/08/91	121.00		112.00		98.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/08/91	0.20		0.20		0.20	
GLOBULINS ALPHA 2	0.4-0.8 (G/DL)	01/08/91	0.40		0.50		0.60	
GLOBULINS BETA	0.4-0.9 (G/DL)	01/08/91	0.50		0.60		0.50	
GLOBULINS GAMMA	0.7-1.4 (G/DL)	01/08/91	0.80		0.70		0.80	
TSH	0.2-4 (UU/ML)	01/08/91	0.30					
T4	5-11.5 (UG/DL)	01/08/91	7.40					

(⊕) << 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 20124/017
Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/8 Patient: 130 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/01/92		31/01/92		21/02/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	02/08/91	12.90	<	12.80	<	12.90	<
HT	38-52 (%)	02/08/91	43.00		44.00		43.00	
RBC	4.5-6 (10 ⁶ /MM ³)	02/08/91	4.10	<	4.20	<	4.20	<
WBC	4000-10000 (/MM ³)	02/08/91	7600.00		8400.00		7600.00	
WBC: N	63-73 (%)	02/08/91	63.00		67.00		63.00	
WBC: L	19-52 (%)	02/08/91	31.00		32.00		33.00	
WBC: E	0-4 (%)	02/08/91	2.00		0.00		1.00	
WBC: M	0-8 (%)	02/08/91	3.00		1.00		2.00	
WBC: B	0-2 (%)	02/08/91	1.00		0.00		1.00	
PLATELETS	140000-440000 (/MM ³)	02/08/91	225000		220000		175000	
NA+	135-145 (MMOL/L)	02/08/91	149.00	>	145.00		141.00	
K+	3.8-5 (MMOL/L)	02/08/91	3.90		4.10		4.00	
CL-	()	02/08/91						
Ca++	2.2-2.75 (MMOL/L)	02/08/91	2.59		2.61		2.49	
PO4--	()	02/08/91						
SGOT	5-18 (U/L)	02/08/91	11.00		10.00		9.00	
SGPT	5-22 (U/L)	02/08/91	9.00		11.00		13.00	
GAMMA GT	0-28 (U/L)	02/08/91	13.00		15.00		14.00	
LDH	120-240 (U/L)	02/08/91	126.00		131.00		129.00	
ALK. PHOSPH.	60-170 (U/L)	02/08/91	154.00		156.00		154.00	
GLUCOSE	60-110 (MG/DL)	02/08/91	96.00		102.00		107.00	
BUN	10-50 (MG/DL)	02/08/91	36.00		40.00		40.00	
UREA	()	02/08/91						
CREATININE	0.6-1.1 (MG/DL)	02/08/91	1.00		0.90		1.00	
URIC ACID	3.4-7 (MG/DL)	02/08/91	5.40		5.60		5.40	
TOT BILIRUBIN	0-1.1 (MG/DL)	02/08/91	0.70		0.70		0.70	
DIR BILIRUBIN	()	02/08/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	02/08/91	6.80		6.70		6.70	
ALBUMINE	55-70 (%)	02/08/91	63.00		63.00		64.00	
TOT. CHOLEST.	120-200 (MG/DL)	02/08/91	205.00	>	209.00	>	212.00	>
TRIGLYCERIDES	65-200 (MG/DL)	02/08/91	174.00		170.00		181.00	
GLOBULINS ALPHA 1	1.5-4 (%)	02/08/91	5.00	>	6.00	>>	5.00	>
GLOBULINS ALPHA 2	5-10 (%)	02/08/91	7.00		7.00		7.00	
GLOBULINS BETA	8-13 (%)	02/08/91	12.00		11.00		11.00	
GLOBULINS GAMMA	10-19 (%)	02/08/91	13.00		13.00		13.00	
TSH	0.25-3.1 (UU/ML)	02/08/91	2.90					
T4	5-11.5 (UG/DL)	02/08/91	9.00					

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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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/8 Patient: 425 Treatment: Roboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/09/91		30/09/91		21/10/91	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	02/08/91	13.10		13.20		12.90	
HT	36-46 (%)	02/08/91	43.00		42.00		41.00	
RBC	4.1-5.4 (10 ⁶ /MM ³)	02/08/91	3.90 <		3.80 <		3.80 <	
HBC	4000-10000 (/MM ³)	02/08/91	8400.00		7600.00		7800.00	
HBC: N	63-73 (%)	02/08/91	67.00		62.00 <		62.00 <	
HBC: L	19-52 (%)	02/08/91	30.00		32.00		34.00	
HBC: E	0-4 (%)	02/08/91	1.00		4.00		1.00	
HBC: M	0-8 (%)	02/08/91	2.00		1.00		2.00	
HBC: B	0-2 (%)	02/08/91	0.00		1.00		0.00	
PLATELETS	140000-440000 (/MM ³)	02/08/91	325000		330000		350000	
NA+	135-145 (MMOL/L)	02/08/91	141.00		144.00		142.00	
K+	3.8-5 (MMOL/L)	02/08/91	3.90		3.90		3.90	
CL-	()	02/08/91						
Ca++	2.2-2.75 (MMOL/L)	02/08/91	2.61		2.56		2.62	
PO4--	()	02/08/91						
SGOT	5-15 (U/L)	02/08/91	12.00		14.00		13.00	
SGPT	5-17 (U/L)	02/08/91	14.00		11.00		12.00	
GAMMA GT	0-18 (U/L)	02/08/91	17.00		16.00		15.00	
LDH	120-240 (U/L)	02/08/91	125.00		127.00		137.00	
ALK. PHOSPH.	60-170 (U/L)	02/08/91	154.00		157.00		156.00	
GLUCOSE	60-110 (MG/DL)	02/08/91	94.00		88.00		78.00	
BUN	10-50 (MG/DL)	02/08/91	40.00		40.00		40.00	
UREA	()	02/08/91						
CREATININE	0.5-1 (MG/DL)	02/08/91	1.00		1.00		0.90	
URIC ACID	2.4-5.7 (MG/DL)	02/08/91	5.20		5.40		5.60	
TOT BILIRUBIN	0-1.1 (MG/DL)	02/08/91	0.70		0.70		0.60	
DIR BILIRUBIN	()	02/08/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	02/08/91	7.30		7.40		7.40	
ALBUMINE	53-68 (%)	02/08/91	62.00		65.00		63.00	
TOT. CHOLEST.	120-200 (MG/DL)	02/08/91	207.00 >		211.00 >		219.00 >	
TRIGLYCERIDES	65-200 (MG/DL)	02/08/91	169.00		161.00		174.00	
GLOBULINS ALPHA 1	1.5-4 (%)	02/08/91	5.00 >		6.00 >>		5.00 >	
GLOBULINS ALPHA 2	5-10 (%)	02/08/91	8.00		8.00		9.00	
GLOBULINS BETA	8-13 (%)	02/08/91	10.00		9.00		10.00	
GLOBULINS GAMMA	10-19 (%)	02/08/91	15.00		12.00		13.00	
TSH	0.25-3.1 (UU/ML)	02/08/91	2.70					
T4	5-11.5 (UG/DL)	02/08/91	8.00					

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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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/8 Patient: 467 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			02/07/92		27/07/92		17/08/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	02/08/91	13.00	<	12.90	<	12.80	<
HT	98-52 (%)	02/08/91	41.00		41.00		42.00	
RBC	4.5-6 (10~6/HMS)	02/08/91	3.80	<<	3.70	<<	3.80	<<
WBC	4000-10000 (/HMS)	02/08/91	7600.00		8400.00		7600.00	
WBC: N	63-73 (%)	02/08/91	62.00	<	60.00	<	64.00	
WBC: L	19-52 (%)	02/08/91	30.00		29.00		26.00	
WBC: E	0-4 (%)	02/08/91	3.00		5.00	>	4.00	
WBC: M	0-8 (%)	02/08/91	4.00		4.00		6.00	
WBC: B	0-2 (%)	02/08/91	1.00		2.00		0.00	
PLATELETS	140000-440000 (/HMS)	02/08/91	275000		225000		250000	
NA+	135-145 (MMOL/L)	02/08/91	139.00		134.00	<	131.00	<
K+	3.8-5 (MMOL/L)	02/08/91	4.00		3.80		3.90	
CL-	()	02/08/91						
Ca++	2.2-2.75 (MMOL/L)	02/08/91	2.48		2.51		2.54	
PO4--	()	02/08/91						
SGOT	5-18 (U/L)	02/08/91	11.00		12.00		13.00	
SGPT	5-22 (U/L)	02/08/91	13.00		13.00		11.00	
GAMMA GT	0-28 (U/L)	02/08/91	9.00		17.00		16.00	
LDH	120-240 (U/L)	02/08/91	122.00		124.00		127.00	
ALK. PHOSPH.	60-170 (U/L)	02/08/91	151.00		154.00		150.00	
GLUCOSE	60-110 (MG/DL)	02/08/91	88.00		92.00		101.00	
BUN	10-50 (MG/DL)	02/08/91	36.00		40.00		40.00	
UREA	()	02/08/91						
CREATININE	0.6-1.1 (MG/DL)	02/08/91	1.00		1.00		0.90	
URIC ACID	3.4-7 (MG/DL)	02/08/91	5.60		5.70		5.90	
TOT BILIRUBIN	0-1.1 (MG/DL)	02/08/91	0.60		0.70		0.70	
DIR BILIRUBIN	()	02/08/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	02/08/91	7.20		7.10		7.00	
ALBUMINE	55-70 (%)	02/08/91	63.00		62.00		61.00	
TOT. CHOLEST.	120-200 (MG/DL)	02/08/91	211.00	>	217.00	>	229.00	>
TRIGLYCERIDES	65-200 (MG/DL)	02/08/91	181.00		192.00		174.00	
GLOBULINS ALPHA 1	1.5-4 (%)	02/08/91	5.00	>	6.00	>>	7.00	>>
GLOBULINS ALPHA 2	5-10 (%)	02/08/91	7.00		8.00		9.00	
GLOBULINS BETA	8-13 (%)	02/08/91	11.00		10.00		11.00	
GLOBULINS GAMMA	10-19 (%)	02/08/91	14.00		14.00		12.00	
TSH	0.25-3.1 (UU/ML)	02/08/91	2.60					
T4	5-11.5 (UG/DL)	02/08/91	9.00					

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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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/10 Patient: 53 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			17/02/92		16/03/92		06/04/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/10/91	15.20		13.10		14.10	
HT	40-54 (X)	01/10/91	44.20		37.60 <		40.50	
RBC	4.6-6.2 (10 ⁶ /MM ³)	01/10/91	4.85		4.95		4.25 <	
HBC	5000-9000 (/MM ³)	01/10/91	12700.0 >>		7200.00		6400.00 <	
HBC: N	50-70 (X)	01/10/91	72.00 >		68.00		58.00 <	
HBC: L	25-40 (X)	01/10/91	18.00 <		20.00 <		33.00 <	
HBC: E	2-4 (X)	01/10/91	2.00 <		0.00 <		0.00 <	
HBC: M	2-8 (X)	01/10/91	7.00		12.00 >>		8.00	
HBC: B	0-1 (X)	01/10/91	1.00		0.00		1.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	316.00 >		299.00		236.00	
NA+	137-147 (MMOL/L)	01/10/91	144.00		142.00		141.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.40		5.10		4.10	
CL-	85-120 (MMOL/L)	01/10/91	111.00		101.00		99.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.26		2.31		2.39	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.05		0.73 <		1.07	
SGOT	4-20 (U/L)	01/10/91	7.00		6.60		5.80	
SGPT	4-20 (U/L)	01/10/91	7.00		4.60		8.00	
GAMMA GT	4-18 (U/L)	01/10/91	7.50		5.90		9.40	
LDH	55-150 (U/L)	01/10/91	140.00		124.00		149.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	99.00		70.00		76.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	73.00		89.00		109.00	
BUN	20-40 (MG/DL)	01/10/91	25.00		21.00		48.00 >	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.84		0.81		1.07	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	2.86		2.06 <		5.59	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.55		0.12		0.47	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.05		0.08		0.05	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	6.33 <		7.36		7.76 >	
ALBUMINE	56-66 (X)	01/10/91	58.50		58.20		69.80 >	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	228.00		220.00		258.00 >	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	94.00		114.00		100.00	
GLOBULINS ALPHA 1	2.5-4.5 (X)	01/10/91	4.40		4.10		5.20 >	
GLOBULINS ALPHA 2	6.5-10 (X)	01/10/91	10.10 >		8.90		10.80 >	
GLOBULINS BETA	8.5-14 (X)	01/10/91	16.20 >		15.50 >		10.40	
GLOBULINS GAMMA	11-19 (X)	01/10/91	10.80 <		13.30		17.80	
TSH	0.16-3.2 (MU/L)	01/10/91	0.73					
T4	48-120 (UG/L)	01/10/91	73.00					

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1221

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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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/10 Patient: 55 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			20/02/92		19/03/92		07/04/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	17.30	>	16.40	>	15.20	
HT	36-47 (X)	01/10/91	47.10	>	45.20		43.80	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	5.10		5.07		4.25	
WBC	5000-9000 (/MM ³)	01/10/91	8800.00		7500.00		7300.00	
WBC: N	50-70 (%)	01/10/91	62.00		66.00		62.00	
WBC: L	25-40 (%)	01/10/91	22.00	<	26.00		31.00	
WBC: E	2-4 (%)	01/10/91	2.00		3.00		1.00	<
WBC: M	2-8 (%)	01/10/91	13.00	>>	4.00		6.00	
WBC: B	0-1 (%)	01/10/91	1.00		1.00		0.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	250.00		249.00		177.00	
NA+	137-147 (MMOL/L)	01/10/91	145.00		145.00		142.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.40		5.00		3.90	
CL-	85-120 (MMOL/L)	01/10/91	105.00		106.00		102.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.40		2.49		2.30	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.01		1.05		1.02	
SGOT	4-20 (U/L)	01/10/91	7.20		12.00		7.90	
SGPT	4-20 (U/L)	01/10/91	10.20		28.00	>	4.90	
GAMMA GT	4-18 (U/L)	01/10/91	22.60	>	60.00	>>	5.00	
LDH	55-150 (U/L)	01/10/91	142.00		117.00		117.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	137.00		82.00		49.00	<
GLUCOSE	70-120 (MG/DL)	01/10/91	109.00		100.00		123.00	>
BUN	20-40 (MG/DL)	01/10/91	33.00		28.00		22.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.96		1.07		0.87	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	5.13		7.22	>	5.01	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.29		0.61		0.39	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.06		0.05		0.14	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.37		7.10		6.58	<
ALBUMINE	56-66 (X)	01/10/91	68.90	>	62.80		70.40	>
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	276.00	>	278.00	>	244.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	167.00		222.00	>	144.00	
GLOBULINS ALPHA 1	2.5-4.5 (X)	01/10/91	2.60		2.90		2.60	
GLOBULINS ALPHA 2	6.5-10 (X)	01/10/91	5.40	<	6.60		6.30	<
GLOBULINS BETA	8.5-14 (X)	01/10/91	14.30	>	14.70	>	11.30	
GLOBULINS GAMMA	11-19 (X)	01/10/91	8.70	<	13.00		9.30	<
TSH	0.16-3.2 (MU/L)	01/10/91	0.47					
T4	48-120 (UG/L)	01/10/91	91.00					

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 < 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 20124/017

Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 14/10 Patient: 57 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/02/92		24/03/92		14/04/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	15.80		15.60		13.30	
HT	36-47 (%)	01/10/91	43.80		43.90		38.90	
RBC	3.9-5.6 (10 ⁶ /MMS)	01/10/91	4.69		4.44		4.02	
WBC	5000-9000 (/MMS)	01/10/91	4900.00 <		8100.00		4900.00 <	
WBC: N	50-70 (%)	01/10/91	61.00		62.00		54.00	
WBC: L	25-40 (%)	01/10/91	53.00 >>		30.00		33.00	
WBC: E	2-4 (%)	01/10/91	0.00 <		1.00 <		1.00 <	
WBC: M	2-8 (%)	01/10/91	6.00		6.00		11.00 >>	
WBC: B	0-1 (%)	01/10/91	0.00		1.00		1.00	
PLATELETS	150-300 (10 ³ /MMS)	01/10/91	261.00		367.00 >		322.00 >	
NA+	137-147 (MMOL/L)	01/10/91	138.00		141.00		137.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.10		4.70		4.40	
CL-	85-120 (MMOL/L)	01/10/91	106.00		111.00		104.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.32		2.43		2.56	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	2.16 >>		1.21		1.16	
SGOT	4-20 (U/L)	01/10/91	6.00		9.40		8.80	
SGPT	4-20 (U/L)	01/10/91	4.90		7.70		7.30	
GAMMA GT	4-18 (U/L)	01/10/91	7.80		12.80		8.30	
LDH	55-150 (U/L)	01/10/91	88.00		70.00		188.00 >	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	95.00		137.00		87.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	87.00		97.00		99.00	
BUN	20-40 (MG/DL)	01/10/91	32.00		36.00		25.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	1.08		0.97		0.80	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	3.42		5.40		4.34	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.17		0.42		0.22	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.06		0.08		0.27 >	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.38		8.33 >		7.08	
ALBUMINE	56-66 (%)	01/10/91	58.90		52.50 <		58.50	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	148.00		226.00		191.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	50.00		122.00		89.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	3.30		4.90 >		4.10	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	9.40		15.20 >>		9.50	
GLOBULINS BETA	8.5-14 (%)	01/10/91	16.10 >		15.60 >		12.40	
GLOBULINS GAMMA	11-19 (%)	01/10/91	12.40		11.80		15.20	
TSH	0.16-3.2 (MU/L)	01/10/91	0.72					
T4	48-120 (UG/L)	01/10/91	88.00					

(€) << 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

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 14/10 Patient: 60 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/05/92		02/06/92		23/06/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	13.40		14.10		13.50	
HT	36-47 (%)	01/10/91	39.00		41.50		37.90	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	3.96		4.52		4.39	
WBC	5000-9000 (/MM ³)	01/10/91	10200.0	>	10400.0	>	5200.00	<
WBC: N	50-70 (%)	01/10/91	60.00		51.00		39.00	<
WBC: L	25-40 (%)	01/10/91	34.00		44.00	>	52.00	>
WBC: E	2-4 (%)	01/10/91	3.00		0.00	<	0.00	<
WBC: M	2-8 (%)	01/10/91	3.00		5.00		8.00	
WBC: B	0-1 (%)	01/10/91	0.00		0.00		1.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	246.00		171.00		318.00	>
NA+	137-147 (MMOL/L)	01/10/91	145.00		141.00		144.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.20		3.90		4.30	
CL-	85-120 (MMOL/L)	01/10/91	101.00		104.00		107.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.42		2.34		2.37	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.43		1.01		1.26	
SGOT	4-20 (U/L)	01/10/91	4.30		57.00	>>	7.80	
SGPT	4-20 (U/L)	01/10/91	3.80	<	6.20		8.20	
GAMMA GT	4-18 (U/L)	01/10/91	8.20		11.10		5.70	
LDH	55-150 (U/L)	01/10/91	123.00		153.00	>	124.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	71.00		67.00		58.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	89.00		94.00		99.00	
BUN	20-40 (MG/DL)	01/10/91	29.00		15.00	<	32.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.80		0.75		0.76	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	4.17		3.29		4.53	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.25		0.44		0.31	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.21		0.14		0.05	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.04		7.17		7.55	
ALBUMINE	56-66 (%)	01/10/91	59.10		63.90		58.40	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	252.00	>	207.00		289.00	>
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	147.00		149.00		161.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	5.40	>	2.90		4.30	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	10.30	>	7.90		8.50	
GLOBULINS BETA	8.5-14 (%)	01/10/91	13.40		10.70		12.30	
GLOBULINS GAMMA	11-19 (%)	01/10/91	11.80		14.60		16.50	
TSH	0.16-3.2 (MU/L)	01/10/91	1.58					
T4	48-120 (UG/L)	01/10/91	95.00					

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/10 Patient: 137 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			20/01/92		17/02/92		09/03/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	12.80		13.20		13.60	
HT	36-47 (%)	01/10/91	37.80		36.40		38.20	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	3.93		4.53		4.51	
WBC	5000-9000 (/MM ³)	01/10/91	6000.00		8800.00		4000.00 <	
WBC: N	50-70 (%)	01/10/91	51.00		58.00		59.00	
WBC: L	25-40 (%)	01/10/91	40.00		33.00		30.00	
WBC: E	2-4 (%)	01/10/91	1.00	<	0.00	<	2.00	
WBC: M	2-8 (%)	01/10/91	7.00		8.00		30.00	
WBC: B	0-1 (%)	01/10/91	1.00		1.00		2.00 >>	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	200.00		246.00		270.00	
NA+	137-147 (MMOL/L)	01/10/91	144.00		152.00 >		146.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.40		5.30		4.10	
CL-	85-120 (MMOL/L)	01/10/91	95.00		99.00		101.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.34		2.78 >		2.40	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	0.96		1.45		1.07	
SGOT	4-20 (U/L)	01/10/91	11.30		6.50		5.20	
SGPT	4-20 (U/L)	01/10/91	18.20		8.20		6.90	
GAMMA GT	4-18 (U/L)	01/10/91	11.30		12.60		10.00	
LDH	55-150 (U/L)	01/10/91	175.00 >		185.00 >		206.00 >	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	61.00		104.00		71.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	90.00		114.00		100.00	
BUN	20-40 (MG/DL)	01/10/91	33.00		13.00 <		21.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.82		0.97		0.94	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	2.81		2.74		3.92	
TOT. BILIRUBIN	0-1 (MG/DL)	01/10/91	0.29		0.49		0.57	
DIR. BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.05		0.07		0.05	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.00		6.96		7.41	
ALBUMINE	56-66 (%)	01/10/91	68.50 >		60.80		63.60	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	279.00 >		279.00 >		277.00 >	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	120.00		153.00		118.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	2.50		3.00		3.10	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	6.80		11.60 >		8.40	
GLOBULINS BETA	8.5-14 (%)	01/10/91	11.20		16.80 >		11.90	
GLOBULINS GAMMA	11-19 (%)	01/10/91	11.00		7.90 <		12.80	
TSH	0.16-3.2 (MU/L)	01/10/91	1.08					
T4	48-120 (UG/L)	01/10/91	77.00					

(¢) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/10 Patient: 139 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			27/01/92		24/02/92		16/03/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	13.50		14.00		14.00	
HT	36-47 (Z)	01/10/91	38.40		39.80		40.30	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.42		4.45		5.21	
WBC	5000-9000 (/MM ³)	01/10/91	5400.00		6200.00		6400.00	
WBC: N	50-70 (Z)	01/10/91	45.00 <		55.00		58.00	
WBC: L	25-40 (Z)	01/10/91	48.00 >		40.00		34.00	
WBC: E	2-4 (Z)	01/10/91	2.00		1.00 <		1.00 <	
WBC: M	2-8 (Z)	01/10/91	5.00		3.00		6.00	
WBC: B	0-1 (Z)	01/10/91	1.00		1.00		1.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	236.00		184.00		296.00	
NA+	137-147 (MMOL/L)	01/10/91	145.00		142.00		144.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.30		4.30		3.60	
CL-	85-120 (MMOL/L)	01/10/91	105.00		100.00		93.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.45		3.00 >>		2.36	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.11		1.26		2.00 >>	
SGOT	4-20 (U/L)	01/10/91	9.90		11.70		12.10	
SGPT	4-20 (U/L)	01/10/91	7.20		22.70 >		14.00	
GAMMA GT	4-18 (U/L)	01/10/91	8.80		31.70 >		4.90	
LDH	55-150 (U/L)	01/10/91	206.00 >		246.00 >		285.00 >	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	104.00		191.00 >		122.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	102.00		106.00		128.00 >	
BUN	20-40 (MG/DL)	01/10/91			33.00		40.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.87		0.89		0.31 <	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	3.59		3.93		6.03 >	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.48		0.40		0.53	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.05		0.05		0.05	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.02		6.98		7.51	
ALBUMINE	56-66 (Z)	01/10/91	61.10		60.40		55.40 <	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	228.00		285.00 >		261.00 >	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	233.00 >		145.00		242.00 >	
GLOBULINS ALPHA 1	2.5-4.5 (Z)	01/10/91	2.70		1.50 <<		3.60	
GLOBULINS ALPHA 2	6.5-10 (Z)	01/10/91	9.90		10.30 >		8.50	
GLOBULINS BETA	8.5-14 (Z)	01/10/91	9.70		13.90		15.10 >	
GLOBULINS GAMMA	11-19 (Z)	01/10/91	16.60		13.90		17.50	
TSH	0.16-3.2 (MU/L)	01/10/91	0.55					
T4	48-120 (UG/L)	01/10/91	103.00					

(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

090177e1803f157a\Approved\Approved On: 13-Nov-2002 02:36

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/10 Patient: 436 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/11/91		03/12/91		23/12/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	14.10		13.90		13.60	
HT	36-47 (%)	01/10/91	40.90		39.60		38.20	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.36		5.06		4.29	
WBC	5000-9000 (/MM ³)	01/10/91	7100.00		5800.00		7200.00	
WBC: N	50-70 (%)	01/10/91	60.00		70.00		68.00	
WBC: L	25-40 (%)	01/10/91	34.00		23.00	<	23.00	
WBC: E	2-4 (%)	01/10/91	0.08	<	2.00		2.00	
WBC: M	2-8 (%)	01/10/91	5.00		3.00		5.00	
WBC: B	0-1 (%)	01/10/91	0.00		1.00		2.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	128.00	<	333.00	>	216.00	
NA+	137-147 (MMOL/L)	01/10/91	145.00		142.00		141.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.60		4.40		4.30	
CL-	85-120 (MMOL/L)	01/10/91	112.00		100.00		103.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.41		2.35		2.43	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.21		1.01		1.96	
SGOT	4-20 (U/L)	01/10/91	6.10		8.20		5.00	
SGPT	4-20 (U/L)	01/10/91	5.70		16.10		8.00	
GAMMA GT	4-18 (U/L)	01/10/91	14.80		15.00		9.20	
LDH	55-150 (U/L)	01/10/91	194.00	>	154.00	>	116.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	67.00		108.00		121.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	98.00		128.00	>	109.00	
BUN	20-40 (MG/DL)	01/10/91	70.00	>>	34.00		34.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.95		1.00		0.66	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	7.08	>	7.43	>>	5.23	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.23		0.46		0.37	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.08		0.13		0.10	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.43		7.58		6.68	
ALBUMINE	56-66 (%)	01/10/91	59.00		61.50		58.30	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	253.00	>	290.00	>	201.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	145.00		451.00	>>	139.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	2.90		3.00		5.40	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	7.40		6.80		10.20	
GLOBULINS BETA	8.5-14 (%)	01/10/91	14.20	>	14.20	>	14.00	
GLOBULINS GAMMA	11-19 (%)	01/10/91	16.50		14.40		12.20	
TSH	0.16-3.2 (MU/L)	01/10/91	0.33					
T4	48-120 (UG/L)	01/10/91	63.00					

(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 20124/017
Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 14/10 Patient: 437 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/11/91		03/12/91		23/12/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	15.70		15.30		14.20	
HT	36-47 (X)	01/10/91	43.50		42.70		38.60	
RBC	3.9-5.6 (10 ⁶ /MMS)	01/10/91	4.46		4.73		4.78	
HBC	5000-9000 (/MMS)	01/10/91	7500.00		4600.00 <		7700.00	
HBC: N	50-70 (X)	01/10/91	55.00		51.00		54.00	
HBC: L	25-40 (X)	01/10/91	42.00 >		31.00		38.00	
HBC: E	2-4 (X)	01/10/91	0.00 <		3.00		0.00 <	
HBC: M	2-8 (X)	01/10/91	0.00 <		6.00		6.00	
HBC: B	0-1 (X)	01/10/91	3.00 >>		3.00 >>		2.00 >>	
PLATELETS	150-300 (10 ³ -3/MMS)	01/10/91	183.00		231.00		257.00	
NA+	137-147 (MMOL/L)	01/10/91	143.00		139.00		145.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.00		4.70		4.40	
CL-	85-120 (MMOL/L)	01/10/91	105.00		99.00		103.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.26		2.33		2.31	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	0.90		1.04		0.83	
SGOT	4-20 (U/L)	01/10/91	8.60		16.00		11.50	
SGPT	4-20 (U/L)	01/10/91	18.70		34.80 >		14.70	
GAMMA GT	4-18 (U/L)	01/10/91	29.00 >		25.80 >		11.40	
LDH	55-150 (U/L)	01/10/91	189.00 >		150.00		206.00 >	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	76.00		70.00		133.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	101.00		112.00		123.00 >	
BUN	20-40 (MG/DL)	01/10/91	31.00		39.00		27.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.83		1.01		1.02	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	3.38		4.22		5.27	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.37		0.73		0.24	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.08				0.06	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.89		7.60		7.53	
ALBUMINE	56-66 (X)	01/10/91	59.20		63.10		57.90	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	238.00		218.00		259.00 >	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	141.00		133.00		212.00 >	
GLOBULINS ALPHA 1	2.5-4.5 (X)	01/10/91	2.80		3.10		2.60	
GLOBULINS ALPHA 2	6.5-10 (X)	01/10/91	7.40		8.90		7.60	
GLOBULINS BETA	8.5-14 (X)	01/10/91	14.10 >		12.90		19.00 >>	
GLOBULINS GAMMA	11-19 (X)	01/10/91	16.50		12.00		12.90	
TSH	0.16-3.2 (MU/L)	01/10/91	1.09					
T4	48-120 (UG/L)	01/10/91	124.00					

(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

1228

090177e1803f157a\Approved\Approved On: 13-Nov-2002 02:36

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/10 Patient: 443 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			15/11/91		09/12/91		30/12/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	14.40		14.20		14.00	
HT	36-47 (X)	01/10/91	40.50		40.60		42.10	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.61		4.49		4.42	
WBC	5000-9000 (/MM ³)	01/10/91	10500.0	>	5700.00		4900.00 <	
WBC: N	50-70 (%)	01/10/91	60.00		62.00		75.00 >	
WBC: L	25-40 (%)	01/10/91	32.00		32.00		21.00 <	
WBC: E	2-4 (%)	01/10/91	1.00	<	0.00	<	1.00 <	
WBC: M	2-8 (%)	01/10/91	7.00		6.00		2.00	
WBC: B	0-1 (%)	01/10/91	0.00		0.00		1.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	333.00	>	355.00	>	270.00	
NA+	137-147 (MMOL/L)	01/10/91	143.00		140.00		146.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	3.90		4.00		4.10	
CL-	85-120 (MMOL/L)	01/10/91	99.00		98.00		96.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.47		2.38		2.29	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.43		1.26		1.11	
SGOT	4-20 (U/L)	01/10/91	10.70		8.50		7.80	
SGPT	4-20 (U/L)	01/10/91	18.90		13.30		7.70	
GAMMA GT	4-18 (U/L)	01/10/91	7.30		8.70		6.40	
LDH	55-150 (U/L)	01/10/91	148.00		160.00	>	209.00 >	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	98.00		106.00		69.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	97.00		96.00		106.00	
BUN	20-40 (MG/DL)	01/10/91	42.00	>	37.00		24.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	1.15		1.05		0.84	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	4.90		4.93		4.34	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.52		0.80		0.66	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.13		0.08		0.05	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.18		7.51		7.31	
ALBUMINE	56-66 (%)	01/10/91	53.50	<	58.70		64.00	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	324.00	>	268.00	>	233.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	82.00		90.00		64.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	5.80	>	2.20	<	3.50	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	9.60		8.60		8.10	
GLOBULINS BETA	8.5-14 (%)	01/10/91	18.60	>>	11.10		10.60	
GLOBULINS GAMMA	11-19 (%)	01/10/91	12.50		19.30	>	13.80	
TSH	0.16-3.2 (MU/L)	01/10/91	2.34					
T4	48-120 (UG/L)	01/10/91	87.00					

(€) << 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 20124/017
Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/10 Patient: 444 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			15/11/91		06/12/91		27/12/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/10/91	14.00		14.50		13.60	
HT	40-54 (X)	01/10/91	39.80	<	41.00		37.80	<
RBC	4.6-6.2 (10 ⁶ /MM ³)	01/10/91	4.34	<	4.83		4.89	
WBC	5000-9000 (/MM ³)	01/10/91	7000.00		6900.00		5800.00	
WBC: N	50-70 (X)	01/10/91	60.00		67.00		64.00	
WBC: L	25-40 (X)	01/10/91	36.00		26.00		30.00	
WBC: E	2-4 (X)	01/10/91	0.00	<	2.00		2.00	
WBC: M	2-8 (X)	01/10/91	4.00		2.00		3.00	
WBC: B	0-1 (X)	01/10/91	0.00		3.00	>>	1.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	253.00		319.00	>	350.00	>
NA+	137-147 (MMOL/L)	01/10/91	144.00		143.00		144.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.50		4.80		4.00	
CL-	85-120 (MMOL/L)	01/10/91	109.00		93.00		99.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.35		2.45		2.30	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.27		1.09		1.32	
SCOT	4-20 (U/L)	01/10/91	7.30		9.00		5.10	
SGPT	4-20 (U/L)	01/10/91	8.10		9.20		6.60	
GAMMA GT	4-18 (U/L)	01/10/91	18.90	>	12.20		8.80	
LDH	55-150 (U/L)	01/10/91	168.00	>	169.00	>	150.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	94.00		136.00		65.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	104.00		112.00		107.00	
BUN	20-40 (MG/DL)	01/10/91	79.00	>>	43.00	>	14.00	<
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	1.02		0.90		1.03	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	4.15		4.40		3.11	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.49		0.60		0.56	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.14		0.14		0.08	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.44		7.23		6.90	
ALBUMINE	56-66 (X)	01/10/91	52.90	<	54.80	<	62.70	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	206.00		229.00		195.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	147.00		81.00		127.00	
GLOBULINS ALPHA 1	2.5-4.5 (X)	01/10/91	3.90		4.00		2.80	
GLOBULINS ALPHA 2	6.5-10 (X)	01/10/91	9.10		9.00		7.60	
GLOBULINS BETA	8.5-14 (X)	01/10/91	16.90	>	10.30		15.10	>
GLOBULINS GAMMA	11-19 (X)	01/10/91	17.10		17.90		12.00	
TSH	0.16-3.2 (MU/L)	01/10/91	3.18					
T4	48-120 (UG/L)	01/10/91	89.00					

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/10 Patient: 446 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/11/91		16/12/91		07/01/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	12.30		14.20		17.40 >	
HT	36-47 (%)	01/10/91	34.00 <		39.40		47.10 >	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	3.50 <		4.52		4.98 >	
WBC	5000-9000 (/MM ³)	01/10/91	2700.00 <<		10700.0 >		5300.00 >	
WBC: N	50-70 (%)	01/10/91	64.00		49.00 <		62.00 >	
WBC: L	25-40 (%)	01/10/91	28.00		44.00 >		28.00 <	
WBC: E	2-4 (%)	01/10/91	1.00 <		2.00		1.00 <	
WBC: M	2-8 (%)	01/10/91	7.00		4.00		9.00 >	
WBC: B	0-1 (%)	01/10/91	0.00		1.00		0.00 >	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	170.00		231.00		197.00 >	
NA+	137-147 (MMOL/L)	01/10/91	141.00		145.00		145.00 >	
K+	3.6-5.5 (MMOL/L)	01/10/91	5.10		5.00		4.90 >	
CL-	85-120 (MMOL/L)	01/10/91	104.00		102.00		102.00 >	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.48		2.59		2.46 >	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	0.99		1.04		1.06 >	
SGOT	4-20 (U/L)	01/10/91	8.10		6.90		9.50 >	
SGPT	4-20 (U/L)	01/10/91	11.60		5.90		12.10 >	
GAMMA GT	4-18 (U/L)	01/10/91	15.90		8.80		22.60 >	
LDH	55-150 (U/L)	01/10/91	246.00 >		137.00		168.00 >	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	68.00		78.00		103.00 >	
GLUCOSE	70-120 (MG/DL)	01/10/91	114.00		111.00		114.00 >	
BUN	20-40 (MG/DL)	01/10/91	69.00 >>		31.00		33.00 >	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	1.11		1.00		0.99 >	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	4.60		4.79		4.92 >	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.44		0.85		0.75 >	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.10		0.07		0.10 >	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.89		7.45		7.21 >	
ALBUMINE	56-66 (%)	01/10/91	55.00 <		55.40 <		62.00 >	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	262.00 >		191.00		234.00 >	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	74.00		73.00		76.00 >	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	3.40		4.20		3.60 >	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	8.50		9.80		8.00 >	
GLOBULINS BETA	8.5-14 (%)	01/10/91	13.50		17.10 >		17.70 >	
GLOBULINS GAMMA	11-19 (%)	01/10/91	19.70 >		13.50		8.20 <	
TSH	0.16-3.2 (MU/L)	01/10/91	1.19					
T4	48-120 (UG/L)	01/10/91	80.00					

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/10 Patient: 447 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			26/11/91		17/12/91		07/01/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/10/91	14.60		15.40		14.90	
HT	40-54 (%)	01/10/91	40.70		42.60		40.20	
RBC	4.6-6.2 (10 ⁶ /MM ³)	01/10/91	4.60		4.45 <		4.91	
HBC	5000-9000 (/MM ³)	01/10/91	5100.00		5400.00		5500.00	
WBC: N	50-70 (%)	01/10/91	54.00		66.00		71.00 >	
WBC: L	25-40 (%)	01/10/91	38.00		30.00		22.00 <	
WBC: E	2-4 (%)	01/10/91	2.00		1.00 <		0.00 <	
WBC: M	2-8 (%)	01/10/91	4.00		2.00		7.00	
WBC: B	0-1 (%)	01/10/91	2.00	>>	1.00		0.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	276.00		229.00		210.00	
NA+	137-147 (MMOL/L)	01/10/91	141.00		147.00		139.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	3.70		4.20		4.50	
CL-	85-120 (MMOL/L)	01/10/91	96.00		106.00		97.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.38		2.26		2.26	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.09		1.13		1.00	
SGOT	4-20 (U/L)	01/10/91	9.20		8.60		8.60	
SGPT	4-20 (U/L)	01/10/91	10.90		8.50		12.90	
GAMMA GT	4-18 (U/L)	01/10/91	6.70		8.50		8.70	
LDH	55-150 (U/L)	01/10/91	175.00 >		194.00 >		135.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	90.00		118.00		93.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	106.00		99.00		101.00	
BUN	20-40 (MG/DL)	01/10/91	32.00		42.00 >		32.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.79		0.79		0.95	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	5.63		3.52		4.82	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.93		0.49		0.18	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.05		0.06		0.10	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.64		7.70		6.84	
ALBUMINE	56-66 (%)	01/10/91	61.50		63.30		58.60	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	210.00		236.00		181.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	69.00		81.00		54.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	2.80		2.80		4.60 >	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	11.00 >		8.50		9.80	
GLOBULINS BETA	8.5-14 (%)	01/10/91	12.00		12.30		15.70 >	
GLOBULINS GAMMA	11-19 (%)	01/10/91	12.70		13.10		11.30	
TSH	0.16-3.2 (MU/L)	01/10/91	1.00					
T4	48-120 (UG/L)	01/10/91	97.00					

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 14/10 Patient: 454 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/06/92		02/07/92		23/07/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	14.60		14.60		14.80	
HT	36-47 (X)	01/10/91	41.40		42.50		44.40	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.20		5.07		4.79	
WBC	5000-9000 (/MM ³)	01/10/91	6700.00		7700.00		5300.00	
WBC: N	50-70 (%)	01/10/91	56.00		76.00 >		55.00	
WBC: L	25-40 (%)	01/10/91	37.00		24.00 <		33.00	
WBC: E	2-4 (%)	01/10/91	1.00 <		0.00 <		0.00 <	
WBC: M	2-8 (%)	01/10/91	6.00		5.00		10.00 >	
WBC: B	0-1 (%)	01/10/91	0.00		1.00		2.00 >>	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	269.00		306.00 >		277.00	
NA+	137-147 (MMOL/L)	01/10/91	135.00 <		143.00		142.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.50		5.00		4.40	
CL-	85-120 (MMOL/L)	01/10/91	107.00		102.00		104.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.32		2.44		2.26	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.08		1.32		1.09	
SGOT	4-20 (U/L)	01/10/91	6.00		5.50		7.60	
SGPT	4-20 (U/L)	01/10/91	7.00		4.70		8.40	
GAMMA GT	4-18 (U/L)	01/10/91	12.80		6.70		9.10	
LDH	55-150 (U/L)	01/10/91	138.00		79.00		138.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	73.00		97.00		66.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	126.00 >		98.00		98.00	
BUN	20-40 (MG/DL)	01/10/91	38.00		20.00		35.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.82		0.80		1.10	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	3.99		3.31		4.68	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.39		0.32		0.35	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.10		0.14		0.15	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.50		6.63		7.81	
ALBUMINE	56-66 (%)	01/10/91	59.90		70.60 >		52.70 <	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	218.00		199.00		230.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	45.00		94.00		61.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	3.20		2.80		3.80	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	8.70		7.10		10.50 >	
GLOBULINS BETA	8.5-14 (%)	01/10/91	13.30		11.30		13.90	
GLOBULINS GAMMA	11-19 (%)	01/10/91	15.00		8.30 <		19.10 >	
TSH	0.16-3.2 (MU/L)	01/10/91	1.21					
T4	48-120 (UG/L)	01/10/91	82.00					

(€) << 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 20124/017
Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 14/10 Patient: 455 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			12/06/92		10/07/92		31/07/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	14.80		14.40		14.50	
HT	36-47 (X)	01/10/91	44.20		41.80		41.80	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.71		4.82		4.96	
WBC	5000-9000 (/MM ³)	01/10/91	5100.00		5300.00		6600.00	
WBC: N	50-70 (X)	01/10/91	44.00	<	43.00	<	63.00	
WBC: L	25-40 (X)	01/10/91	48.00	>	46.00	>	32.00	
WBC: E	2-4 (X)	01/10/91	0.00	<	1.00	<	0.00	
WBC: M	2-8 (X)	01/10/91	7.00		10.00	>	5.00	
WBC: B	0-1 (X)	01/10/91	1.00		0.00		0.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	204.00		351.00	>	250.00	
NA+	137-147 (MMOL/L)	01/10/91	142.00		136.00	<	143.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.30		4.10		4.20	
CL-	85-120 (MMOL/L)	01/10/91	104.00		104.00		106.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.45		2.41		2.41	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.10		1.09		0.85	
SGOT	4-20 (U/L)	01/10/91	8.20		7.80		7.10	
SGPT	4-20 (U/L)	01/10/91	8.70		10.30		15.50	
GAMMA GT	4-18 (U/L)	01/10/91	10.50		7.70		22.70	
LDH	55-150 (U/L)	01/10/91	166.00	>	112.00		112.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	94.00		104.00		111.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	101.00		110.00		101.00	
BUN	20-40 (MG/DL)	01/10/91	33.00		19.00	<	36.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.85		0.75		0.74	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	6.01	>	3.19		6.41	
TOT. BILIRUBIN	0-1 (MG/DL)	01/10/91	0.56		0.51		0.95	
DIR. BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.05		0.14		0.05	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.62		7.50		6.72	
ALBUMINE	56-66 (X)	01/10/91	59.70		57.60		63.00	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	248.00		177.00		176.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	72.00		60.00		81.00	
GLOBULINS ALPHA 1	2.5-4.5 (X)	01/10/91	4.10		3.60		3.90	
GLOBULINS ALPHA 2	6.5-10 (X)	01/10/91	7.20		7.50		8.70	
GLOBULINS BETA	8.5-14 (X)	01/10/91	12.10		12.70		12.40	
GLOBULINS GAMMA	11-19 (X)	01/10/91	16.90		18.70		12.10	
TSH	0.16-3.2 (MU/L)	01/10/91	0.51					
T4	48-120 (UG/L)	01/10/91	72.00					

(⊕) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 15 Patient: 351 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			02/09/92		23/09/92		14/10/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13.5-18 (G/DL)	01/03/92	18.60 >	16.70	17.00			
HT	0.4-0.54 (L/L)	01/03/92	0.58 >	0.49	0.49			
RBC	4.4-6 (10 ⁶ /MM ³)	01/03/92	6.68 >	5.77	5.87			
HBC	4-11 (10 ³ /MM ³)	01/03/92	7.80	6.30	9.40			
HBC: N	20-75 (%)	01/03/92	52.00	50.00	45.00			
HBC: L	10-40 (%)	01/03/92	35.00	46.00 >	38.00			
HBC: E	1-6 (%)	01/03/92	6.00	1.00	4.00			
HBC: M	2-10 (%)	01/03/92	7.00	3.00	12.00 >			
HBC: B	0-2 (%)	01/03/92	0.00	0.00	1.00			
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	245.00	250.00	285.00			
NA+	136-148 (MMOL/L)	01/03/92	143.00	139.00	145.00			
K+	3.8-5 (MMOL/L)	01/03/92	4.50	4.40	5.00			
CL-	97-106 (MMOL/L)	01/03/92	94.00 <	91.00 <	94.00 <			
Ca++	2.25-2.75 (MMOL/L)	01/03/92	2.54	2.58	2.57			
PO4--	0.6-1.8 (MMOL/L)	01/03/92	1.33	0.66	1.24			
SGOT	5-37 (U/L)	01/03/92	19.00	27.00	28.00			
SGPT	5-40 (U/L)	01/03/92	20.00	41.00 >	31.00			
GAMMA GT	11-50 (U/L)	01/03/92	22.00	19.00	19.00			
LDH	230-460 (U/L)	01/03/92	291.00	274.00	271.00			
ALK. PHOSPH.	40-120 (U/L)	01/03/92	82.00	72.00	69.00			
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	10.30 >>	17.10 >>	11.30 >>			
BUN	()	01/03/92						
UREA	2.5-6.6 (MMOL/L)	01/03/92	3.50	4.80	4.90			
CREATININE	44-120 (UMOL/L)	01/03/92	162.70 >	139.00 >	163.90 >			
URIC ACID	0.19-0.43 (MMOL/L)	01/03/92						
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	10.00	9.00	9.00			
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	3.00	5.00	5.00			
TOT. PROTEINS	62-82 (G/L)	01/03/92	92.00 >	85.00 >	80.00			
ALBUMINE	35-57 (G/L)	01/03/92	39.00	39.00	45.00			
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	6.90 >	7.30 >	8.00 >			
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	4.37 >>	3.58 >>	3.13 >>			
GLOBULINS ALPHA 1	1-5 (%)	01/03/92						
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92						
GLOBULINS BETA	11-16 (%)	01/03/92						
GLOBULINS GAMMA	()	01/03/92						
TSH	0.4-4 (MU/L)	01/03/92			4.20			
T4	8-25 (PMOL/L)	01/03/92			15.20			

(€) << 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

1235

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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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 15 Patient: 366 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			27/08/92		17/09/92		08/10/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13.5-18 (G/DL)	01/03/92	15.10		13.40 <	15.60		
HT	0.4-0.54 (L/L)	01/03/92	0.47		0.41	0.45		
RBC	4.4-6 (10 ⁶ /MM ³)	01/03/92	5.24		4.61	5.06		
HBC	4-11 (10 ³ /MM ³)	01/03/92	4.70		9.60	5.50		
HBC: N	20-75 (%)	01/03/92	38.00		43.00	43.00		
HBC: L	10-40 (%)	01/03/92	57.00 >>		51.00 >	47.00 >		
HBC: E	1-6 (%)	01/03/92	0.00 <		4.00	2.00		
HBC: M	2-10 (%)	01/03/92	5.00		1.00 <	8.00		
HBC: B	0-2 (%)	01/03/92	0.00		1.00	0.00		
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	237.00			340.00		
NA+	136-148 (MMOL/L)	01/03/92	141.00		145.00	148.00		
K+	3.8-5 (MMOL/L)	01/03/92	4.10		3.90	4.20		
CL-	97-106 (MMOL/L)	01/03/92	101.00		101.00	100.00		
Ca++	2.25-2.75 (MMOL/L)	01/03/92	2.69		2.18 <	2.20 <		
PO4--	0.6-1.8 (MMOL/L)	01/03/92	0.55 <		1.14	1.14		
SGOT	5-37 (U/L)	01/03/92	27.00		23.00	30.00		
SGPT	5-40 (U/L)	01/03/92	43.00 >		36.00	38.00		
GAMMA GT	11-50 (U/L)	01/03/92	30.00		29.00	73.00 >		
LDH	230-460 (U/L)	01/03/92	320.00		360.00	309.00		
ALK. PHOSPH.	40-120 (U/L)	01/03/92	72.00		76.00	81.00		
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	5.90		4.30	5.00		
BUN	()	01/03/92						
UREA	2.5-6.6 (MMOL/L)	01/03/92	3.70		3.60	3.00		
CREATININE	44-120 (UMOL/L)	01/03/92	75.00		81.40	68.70		
URIC ACID	0.19-0.43 (MMOL/L)	01/03/92						
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	3.00 <		5.00	9.00		
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	2.00		5.00	5.00		
TOT. PROTEINS	62-82 (G/L)	01/03/92	78.00		82.00	82.00		
ALBUMINE	35-57 (G/L)	01/03/92	39.00		39.00	44.00		
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	3.50		3.40	4.60		
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	1.04		0.87	1.03		
GLOBULINS ALPHA 1	1-5 (%)	01/03/92						
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92						
GLOBULINS BETA	11-16 (%)	01/03/92						
GLOBULINS GAMMA	()	01/03/92						
TSH	0.4-4 (MU/L)	01/03/92	0.90		1.50	1.00		
T4	8-25 (PMOL/L)	01/03/92	15.40		15.30	15.40		

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 15 Patient: 368 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/09/92		24/09/92		15/10/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/03/92	12.60				12.60	
HT	0.35-0.49 (L/L)	01/03/92	0.41				0.36	
RRC	3.9-5.6 (10-6/MM3)	01/03/92	4.75				4.35	
WBC	4-11 (10-3/MM3)	01/03/92	6.00				6.70	
WBC: N	20-75 (%)	01/03/92	46.00				51.00	
WBC: L	10-40 (%)	01/03/92	45.00	>			43.00	
WBC: E	1-6 (%)	01/03/92	1.00				2.00	
WBC: M	2-10 (%)	01/03/92	8.00				4.00	
WBC: B	0-2 (%)	01/03/92	0.00				0.00	
PLATELETS	140-400 (10-3/MM3)	01/03/92	510.00	>			453.00	
NA+	136-148 (MMOL/L)	01/03/92	143.00		144.00		144.00	
K+	3.8-5 (MMOL/L)	01/03/92	4.40		4.50		4.30	
CL-	97-106 (MMOL/L)	01/03/92	99.00		99.00		100.00	
Ca++	2.25-2.75 (MMOL/L)	01/03/92	2.31		2.25		2.34	
PO4--	0.6-1.8 (MMOL/L)	01/03/92	1.09		0.88		0.97	
SGOT	5-31 (U/L)	01/03/92	16.00				16.00	
SGPT	5-31 (U/L)	01/03/92	17.00				21.00	
GAMMA GT	7-32 (U/L)	01/03/92	21.00				19.00	
LDH	230-460 (U/L)	01/03/92	372.00				358.00	
ALK. PHOSPH.	40-120 (U/L)	01/03/92	68.00				65.00	
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	6.40	>	7.80	>	6.40	
BUN	()	01/03/92						
UREA	2.5-6.6 (MMOL/L)	01/03/92	3.30		3.60		2.90	
CREATININE	44-120 (UMOL/L)	01/03/92	90.20		88.00		70.70	
URIC ACID	0.14-0.33 (MMOL/L)	01/03/92			0.24			
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	3.00	<			6.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	2.00				5.00	
TOT. PROTEINS	62-82 (G/L)	01/03/92			81.00		83.00	
ALBUMINE	35-57 (G/L)	01/03/92	40.00		50.00		45.00	
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	6.50				6.40	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	3.09	>>			2.25	
GLOBULINS ALPHA 1	1-5 (%)	01/03/92						
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92						
GLOBULINS BETA	11-16 (%)	01/03/92						
GLOBULINS GAMMA	()	01/03/92						
TSH	0.4-4 (MU/L)	01/03/92			1.90		1.50	
T4	8-25 (PMOL/L)	01/03/92			25.10		16.40	

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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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 15 Patient: 369 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/07/92		30/07/92		20/08/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/03/92	14.00		13.80		14.50	
HT	0.35-0.49 (L/L)	01/03/92	0.42		0.41		0.45	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/03/92	4.43		4.48		4.96	
WBC	4-11 (10 ³ /MM ³)	01/03/92	9.30		8.20		7.80	
WBC: N	20-75 (%)	01/03/92	58.00		65.00		50.00	
WBC: L	10-40 (%)	01/03/92	38.00		31.00		46.00 >	
WBC: E	1-6 (%)	01/03/92	0.00 <		0.00 <		1.00	
WBC: M	2-10 (%)	01/03/92	3.00		3.00		3.00	
WBC: B	0-2 (%)	01/03/92	1.00		1.00		0.00	
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	363.00		347.00		478.00 >	
NA+	136-148 (MMOL/L)	01/03/92	146.00		146.00		139.00	
K+	3.8-5 (MMOL/L)	01/03/92	4.50		4.30		4.50	
CL-	97-106 (MMOL/L)	01/03/92	99.00		102.00		94.00 <	
Ca++	2.25-2.75 (MMOL/L)	01/03/92	2.44		2.29		2.63	
PO4--	0.6-1.8 (MMOL/L)	01/03/92	1.70		1.37		1.11	
SGOT	5-31 (U/L)	01/03/92	22.00		24.00		22.00	
SGPT	5-31 (U/L)	01/03/92	21.00		16.00		18.00	
GAMMA GT	7-32 (U/L)	01/03/92	21.00		16.00		23.00	
LDH	230-460 (U/L)	01/03/92	325.00		269.00			
ALK. PHOSPH.	40-120 (U/L)	01/03/92	37.00 <		36.00 <		36.00 <	
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	4.60		4.90		4.70	
BUN	()	01/03/92						
UREA	2.5-6.6 (MMOL/L)	01/03/92	5.00		5.80		4.10	
CREATININE	44-120 (UMOL/L)	01/03/92	82.00		89.00		89.00	
URIC ACID	0.14-0.33 (MMOL/L)	01/03/92						
TOT. BILIRUBIN	5-20 (UMOL/L)	01/03/92	6.00		5.00		9.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	2.00		1.80		2.00	
TOT. PROTEINS	62-82 (G/L)	01/03/92	89.00 >		85.00 >		90.00 >	
ALBUMINE	35-57 (G/L)	01/03/92	40.00		41.00		39.00	
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	5.70				5.90	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	1.02				1.52	
GLOBULINS ALPHA 1	1-5 (%)	01/03/92						
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92						
GLOBULINS BETA	11-16 (%)	01/03/92						
GLOBULINS GAMMA	()	01/03/92						
TSH	0.4-4 (MU/L)	01/03/92	1.10		1.30			
T4	8-25 (PMOL/L)	01/03/92	11.70		12.70			

(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

1238

090177e1803f157a\Approved\Approved On: 13-Nov-2002 02:36

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 15 Patient: 371 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			20/07/92		10/08/92		31/08/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/03/92	13.40		14.50		13.30	
HT	0.35-0.49 (L/L)	01/03/92	0.40		0.44		0.39	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/03/92	4.36		4.83		4.34	
WBC	4-11 (10 ³ /MM ³)	01/03/92	9.00		6.60		6.30	
WBC: N	20-75 (%)	01/03/92	56.00		55.00		51.00	
WBC: L	10-40 (%)	01/03/92	39.00		40.00		40.00	
WBC: E	1-6 (%)	01/03/92	0.00	<	2.00		1.00	
WBC: M	2-10 (%)	01/03/92	5.00		3.00		8.00	
WBC: B	0-2 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	325.00		342.00		397.00	
NA+	136-148 (MMOL/L)	01/03/92	143.00		144.00		143.00	
K+	3.8-5 (MMOL/L)	01/03/92	4.20		4.50		4.10	
CL-	97-106 (MMOL/L)	01/03/92	104.00		102.00		108.00	
Ca++	2.25-2.75 (MMOL/L)	01/03/92	2.20	<	2.15	<	2.31	
PO4--	0.6-1.8 (MMOL/L)	01/03/92	0.80		1.12		0.49	
SGOT	5-31 (U/L)	01/03/92	28.00		28.00		19.00	
SGPT	5-31 (U/L)	01/03/92	18.00		30.00		13.00	
GAMMA GT	7-32 (U/L)	01/03/92	26.00		22.00		21.00	
LDH	230-460 (U/L)	01/03/92	432.00		341.00		366.00	
ALK. PHOSPH.	40-120 (U/L)	01/03/92	81.00		96.00		86.00	
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	4.80		4.60		5.10	
BUN	()	01/03/92						
UREA	2.5-6.6 (MMOL/L)	01/03/92	2.30	<	2.00	<	3.10	
CREATININE	44-120 (UMOL/L)	01/03/92	67.00		69.00		82.00	
URIC ACID	0.14-0.33 (MMOL/L)	01/03/92						
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	11.00		5.00		1.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	2.00		2.00		1.00	
TOT. PROTEINS	62-82 (G/L)	01/03/92	76.00		78.00		77.00	
ALBUMINE	35-57 (G/L)	01/03/92	38.00		37.00		39.00	
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	4.20		3.60		3.70	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	0.82	<	0.76	<	0.78	
GLOBULINS ALPHA 1	1-5 (%)	01/03/92						
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92						
GLOBULINS BETA	11-16 (%)	01/03/92						
GLOBULINS GAMMA	()	01/03/92						
TSH	0.4-4 (MU/L)	01/03/92	0.90		0.60		0.40	
T4	8-25 (PMOL/L)	01/03/92	15.40		17.30		16.70	

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 15 Patient: 374 Treatment: Reboxetine Sex: Female

Laboratory test	Range value	Range date	Visit number / Laboratory data			
			Day 21		Day 42	
			24/04/92		20/05/92	
			value	(#)	value	(#)
HB	11.5-16.5 (G/DL)	01/03/92	14.30		13.70	
HT	0.35-0.49 (L/L)	01/03/92	0.41		0.40	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/03/92	4.55		4.45	
WBC	4-11 (10 ³ /MM ³)	01/03/92	4.80		6.60	
WBC: N	20-75 (%)	01/03/92	62.00		55.00	
WBC: L	10-40 (%)	01/03/92	27.00		36.00	
WBC: E	1-6 (%)	01/03/92	4.00		6.00	
WBC: M	2-10 (%)	01/03/92	6.00		3.00	
WBC: B	0-2 (%)	01/03/92	1.00		0.00	
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	275.00		393.00	
NA+	136-148 (MMOL/L)	01/03/92	139.00		142.00	
K+	3.8-5 (MMOL/L)	01/03/92	5.00		3.70	<
CL-	97-106 (MMOL/L)	01/03/92	99.00		100.00	
Ca ⁺⁺	2.25-2.75 (MMOL/L)	01/03/92	2.45		2.33	
PO ₄ ⁻⁻	0.6-1.8 (MMOL/L)	01/03/92	1.30		1.20	
SGOT	5-31 (U/L)	01/03/92	26.00		24.00	
SGPT	5-31 (U/L)	01/03/92	22.00		26.00	
GAMMA GT	7-32 (U/L)	01/03/92	36.00	>	23.00	
LDH	230-460 (U/L)	01/03/92	409.00			
ALK. PHOSPH.	40-120 (U/L)	01/03/92	57.00		49.00	
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	5.10		4.70	
BUN	()	01/03/92				
UREA	2.5-6.6 (MMOL/L)	01/03/92	4.60		4.50	
CREATININE	44-120 (UMOL/L)	01/03/92	79.00		65.00	
URIC ACID	0.14-0.33 (MMOL/L)	01/03/92				
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	6.00		6.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	2.00		1.00	
TOT. PROTEINS	62-82 (G/L)	01/03/92	79.00		80.00	
ALBUMINE	35-57 (G/L)	01/03/92	38.00		40.00	
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	5.20		5.90	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	0.77	<	1.03	
GLOBULINS ALPHA 1	1-5 (%)	01/03/92				
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92				
GLOBULINS BETA	11-16 (%)	01/03/92				
GLOBULINS GAMMA	()	01/03/92				
TSH	0.4-4 (MU/L)	01/03/92				
T4	8-25 (PMOL/L)	01/03/92				

(#) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 15 Patient: 375 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Day 21
			25/06/92
			value (c)
Laboratory test	Range value	Range date	
HB	11.5-16.5 (G/DL)	01/03/92	13.70
HT	0.35-0.49 (L/L)	01/03/92	0.40
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/03/92	4.49
WBC	4-11 (10 ³ /MM ³)	01/03/92	8.00
WBC: N	20-75 (%)	01/03/92	50.00
WBC: L	10-40 (%)	01/03/92	42.00 >
WBC: E	1-6 (%)	01/03/92	1.00
WBC: M	2-10 (%)	01/03/92	6.00
WBC: B	0-2 (%)	01/03/92	1.00
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	377.00
NA+	136-148 (MMOL/L)	01/03/92	134.00 <
K+	3.8-5 (MMOL/L)	01/03/92	4.60
CL-	97-106 (MMOL/L)	01/03/92	103.00
Ca++	2.25-2.75 (MMOL/L)	01/03/92	2.26
PO4--	0.6-1.8 (MMOL/L)	01/03/92	1.20
SGOT	5-31 (U/L)	01/03/92	26.00
SGPT	5-31 (U/L)	01/03/92	18.00
GAMMA GT	7-32 (U/L)	01/03/92	9.00
LDH	230-460 (U/L)	01/03/92	612.00 >
ALK. PHOSPH.	40-120 (U/L)	01/03/92	31.00 <
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	7.30 >
BUN	()	01/03/92	
UREA	2.5-6.6 (MMOL/L)	01/03/92	3.20
CREATININE	44-120 (UMOL/L)	01/03/92	59.00
URIC ACID	0.14-0.33 (MMOL/L)	01/03/92	
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	8.00
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	4.00
TOT. PROTEINS	62-82 (G/L)	01/03/92	77.00
ALBUMINE	35-57 (G/L)	01/03/92	38.00
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	6.00
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	1.00
GLOBULINS ALPHA 1	1-5 (%)	01/03/92	
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92	
GLOBULINS BETA	11-16 (%)	01/03/92	
GLOBULINS GAMMA	()	01/03/92	
TSH	0.4-4 (MU/L)	01/03/92	0.80
T4	8-25 (PMOL/L)	01/03/92	16.10

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 15 Patient: 377 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			13/05/92		03/06/92		24/06/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/03/92	15.60		15.90		14.40	
HT	0.35-0.49 (L/L)	01/03/92	0.48		0.46		0.43	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/03/92	5.43		5.33		5.04	
HBC	4-11 (10 ⁹ /MM ³)	01/03/92	9.60		8.10		6.80	
HBC: N	20-75 (%)	01/03/92	65.00		52.00		52.00	
HBC: L	10-40 (%)	01/03/92	26.00		36.00		37.00	
HBC: E	1-6 (%)	01/03/92	3.00		1.00		1.00	
HBC: M	2-10 (%)	01/03/92	6.00		10.00		4.00	
HBC: B	0-2 (%)	01/03/92	0.00		1.00		1.00	
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	358.00		346.00		297.00	
NA+	136-148 (MMOL/L)	01/03/92	140.00		140.00		138.00	
K+	3.8-5 (MMOL/L)	01/03/92	4.60		4.50		4.30	
CL-	97-106 (MMOL/L)	01/03/92	103.00		100.00		103.00	
Ca++	2.25-2.75 (MMOL/L)	01/03/92	2.29		2.18 <		2.18 <	
PO4--	0.6-1.8 (MMOL/L)	01/03/92	1.10		0.90		0.80	
SGOT	5-31 (U/L)	01/03/92	30.00		17.00		19.00	
SGPT	5-31 (U/L)	01/03/92	31.00		24.00		25.00	
GAMMA GT	7-32 (U/L)	01/03/92	66.00 >>		38.00 >		28.00	
LDH	230-460 (U/L)	01/03/92	424.00		328.00		321.00	
ALK. PHOSPH.	40-120 (U/L)	01/03/92	67.00		73.00		64.00	
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	5.10		5.60		5.30	
BUN	()	01/03/92						
UREA	2.5-6.6 (MMOL/L)	01/03/92	2.70		2.10 <		2.70	
CREATININE	44-120 (UMOL/L)	01/03/92	77.00		54.00		57.00	
URIC ACID	0.14-0.33 (MMOL/L)	01/03/92						
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	6.00		6.00		7.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	1.00		1.00		2.00	
TOT. PROTEINS	62-82 (G/L)	01/03/92	68.00		79.00		77.00	
ALBUMINE	35-57 (G/L)	01/03/92	43.00		40.00		40.00	
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	6.40		6.90 >		5.40	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	1.81		1.43		1.05	
GLOBULINS ALPHA 1	1-5 (X)	01/03/92						
GLOBULINS ALPHA 2	4.5-9.5 (X)	01/03/92						
GLOBULINS BETA	11-16 (X)	01/03/92						
GLOBULINS GAMMA	()	01/03/92						
TSH	0.4-4 (MU/L)	01/03/92	0.60		1.10		0.60	
T4	8-25 (PMOL/L)	01/03/92	16.90		21.00		31.80	

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 15 Patient: 378 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			15/06/92		06/07/92		27/07/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/03/92	13.90		13.90		14.60	
HT	0.35-0.49 (L/L)	01/03/92	0.42		0.42		0.41	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/03/92	4.36		4.40		4.37	
WBC	4-11 (10 ³ /MM ³)	01/03/92	7.40		7.10		9.40	
WBC: N	20-75 (%)	01/03/92	51.00		70.00		48.00	
WBC: L	10-40 (%)	01/03/92	36.00		22.00		41.00 >	
WBC: E	1-6 (%)	01/03/92	4.00		1.00		5.00	
WBC: M	2-10 (%)	01/03/92	9.00		6.00		6.00	
WBC: B	0-2 (%)	01/03/92	0.00		1.00		0.00	
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	240.00		300.00		277.00	
NA+	136-148 (MMOL/L)	01/03/92	138.00		141.00		145.00	
K+	3.8-5 (MMOL/L)	01/03/92	4.70		3.80		6.00 >>	
CL-	97-106 (MMOL/L)	01/03/92	99.00		96.00 <		100.00	
Ca++	2.25-2.75 (MMOL/L)	01/03/92	2.22 <		2.20 <		2.56	
PO4--	0.6-1.8 (MMOL/L)	01/03/92	1.10		1.10		0.90	
SGOT	5-31 (U/L)	01/03/92	18.00		23.00		38.00 >	
SGPT	5-31 (U/L)	01/03/92	12.00		24.00		33.00 >	
GAMMA GT	7-32 (U/L)	01/03/92	11.00		14.00			
LDH	230-460 (U/L)	01/03/92	288.00		235.00		786.00 >	
ALK. PHOSPH.	40-120 (U/L)	01/03/92	79.00		92.00		72.00	
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	6.90 >		5.80		4.90	
BUN	()	01/03/92						
UREA	2.5-6.6 (MMOL/L)	01/03/92	2.80		4.10		4.40	
CREATININE	44-120 (UMOL/L)	01/03/92	86.00		77.00		49.00	
URIC ACID	0.14-0.33 (MMOL/L)	01/03/92					5.00	
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	5.00		3.00 <		2.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	2.00		1.00		2.00	
TOT. PROTEINS	62-82 (G/L)	01/03/92	76.00		81.00		95.00 >	
ALBUMINE	35-57 (G/L)	01/03/92	39.00		38.00		40.00	
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	5.10		5.90		6.00	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	1.84		0.89		0.67 <	
GLOBULINS ALPHA 1	1-5 (%)	01/03/92						
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92						
GLOBULINS BETA	11-16 (%)	01/03/92						
GLOBULINS GAMMA	()	01/03/92						
TSH	0.4-4 (MU/L)	01/03/92	2.00					
T4	8-25 (PMOL/L)	01/03/92	16.80					

(⊕) << 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

PHARMACTIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 15 Patient: 381 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			21/05/92		11/06/92		02/07/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/03/92	13.00		12.60		12.30	
HT	0.35-0.49 (L/L)	01/03/92	0.39		0.37		0.38	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/03/92	4.29		4.09		4.14	
WBC	4-11 (10 ³ /MM ³)	01/03/92	7.30		6.20		8.10	
WBC: N	20-75 (%)	01/03/92	63.00		48.00		60.00	
WBC: L	10-40 (%)	01/03/92	34.00		44.00	>	34.00	
WBC: E	1-6 (%)	01/03/92	0.00	<	2.00		1.00	
WBC: M	2-10 (%)	01/03/92	3.00		4.00		5.00	
WBC: B	0-2 (%)	01/03/92	0.00		2.00		0.00	
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	377.00		324.00		400.00	
NA+	136-148 (MMOL/L)	01/03/92	137.00		138.00		143.00	
K+	3.8-5 (MMOL/L)	01/03/92	4.20		3.90		4.30	
CL-	97-106 (MMOL/L)	01/03/92	102.00		98.00		103.00	
Ca++	2.25-2.75 (MMOL/L)	01/03/92	2.29		2.16	<	2.26	
PO4--	0.6-1.8 (MMOL/L)	01/03/92	1.10		1.10		1.00	
SGOT	5-31 (U/L)	01/03/92	11.00		20.00		15.00	
SGPT	5-31 (U/L)	01/03/92	12.00		21.00		12.00	
GAMMA GT	7-32 (U/L)	01/03/92	13.00		11.00		7.00	
LDH	230-460 (U/L)	01/03/92	188.00	<	233.00		270.00	
ALK. PHOSPH.	40-120 (U/L)	01/03/92	39.00	<	47.00		34.00	
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	4.80		5.20		5.90	
BUN	()	01/03/92						
UREA	2.5-6.6 (MMOL/L)	01/03/92	3.60		3.20		3.50	
CREATININE	44-120 (UMOL/L)	01/03/92	58.00		46.00		56.00	
URIC ACID	0.14-0.33 (MMOL/L)	01/03/92						
TOT. BILIRUBIN	5-20 (UMOL/L)	01/03/92	14.00		13.00		12.00	
DIR. BILIRUBIN	0-5 (UMOL/L)	01/03/92	2.00		3.00		2.00	
TOT. PROTEINS	62-82 (G/L)	01/03/92	77.00		77.00		77.00	
ALBUMINE	35-57 (G/L)	01/03/92	40.00		41.00		37.00	
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	6.00		5.80		5.60	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	1.04		1.01		0.70	
GLOBULINS ALPHA 1	1-5 (%)	01/03/92						
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92						
GLOBULINS BETA	11-16 (%)	01/03/92						
GLOBULINS GAMMA	()	01/03/92						
TSH	0.4-4 (MU/L)	01/03/92			0.40			
T4	8-25 (PMOL/L)	01/03/92			17.20			

(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 20124/017

Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 15 Patient: 384 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date
			Screen
			28/07/92
			value (€)
Laboratory test	Range value	Range date	
HB	11.5-16.5 (G/DL)	01/03/92	13.10
HT	0.35-0.49 (L/L)	01/03/92	0.38
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/03/92	4.28
WBC	4-11 (10 ³ /MM ³)	01/03/92	13.10 >
WBC: N	20-75 (%)	01/03/92	75.00
WBC: L	10-40 (%)	01/03/92	20.00
WBC: E	1-6 (%)	01/03/92	0.00 <
WBC: M	2-10 (%)	01/03/92	5.00
WBC: B	0-2 (%)	01/03/92	0.00
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	275.00
NA+	136-148 (MMOL/L)	01/03/92	138.00
K+	3.8-5 (MMOL/L)	01/03/92	4.60
CL-	97-106 (MMOL/L)	01/03/92	96.00 <
Ca++	2.25-2.75 (MMOL/L)	01/03/92	2.05 <
PO4--	0.6-1.8 (MMOL/L)	01/03/92	0.40 <<
SGOT	5-31 (U/L)	01/03/92	20.00
SGPT	5-31 (U/L)	01/03/92	21.00
GAMMA GT	7-32 (U/L)	01/03/92	72.00 >>
LDH	230-460 (U/L)	01/03/92	330.00
ALK. PHOSPH.	40-120 (U/L)	01/03/92	116.00
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	8.00 >>
BUN	()	01/03/92	
UREA	2.5-6.6 (MMOL/L)	01/03/92	4.80
CREATININE	44-120 (UMOL/L)	01/03/92	61.00
URIC ACID	0.14-0.33 (MMOL/L)	01/03/92	
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	11.00
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	4.00
TOT. PROTEINS	62-82 (G/L)	01/03/92	82.00
ALBUMINE	35-57 (G/L)	01/03/92	37.00
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	4.40
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	0.75 <
GLOBULINS ALPHA 1	1-5 (%)	01/03/92	
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92	
GLOBULINS BETA	11-16 (%)	01/03/92	
GLOBULINS GAMMA	()	01/03/92	
TSH	0.4-4 (MU/L)	01/03/92	4.50
T4	8-25 (PMOL/L)	01/03/92	16.80

(€) << 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

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 1 Patient: 3 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			16/04/91		07/05/91		28/05/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.7-16.6 (G/DL)	01/01/91	14.50		14.20		13.50	
HT	36-42 (%)	01/01/91	42.00		41.80		37.80	
RBC	3.6-5.3 (10 ⁶ /MM ³)	01/01/91	4.58		4.58		4.28	
WBC	4-10.7 (10 ³ /MM ³)	01/01/91	7.80		6.90		7.00	
WBC: N	40-75 (%)	01/01/91	79.00 >		56.00		55.00	
WBC: L	20-45 (%)	01/01/91	14.00 <		35.00		33.00	
WBC: E	1-6 (%)	01/01/91	2.00		3.00		3.00	
WBC: M	2-10 (%)	01/01/91	4.00		5.00		6.00	
WBC: B	0-1 (%)	01/01/91	1.00		1.00		0.00	
PLATELETS	100-300 (10 ³ /MM ³)	01/01/91	369.00 >		365.00 >		350.00 >	
NA+	130-149 (MMOL/L)	01/01/91	139.00		142.00		141.00	
K+	3.66-5.35 (MMOL/L)	01/01/91	4.10		5.60 >		4.30	
CL-	94-109 (MMOL/L)	01/01/91	109.00		100.00			
Ca++	2.24-2.78 (MMOL/L)	01/01/91	2.72		2.50			
PO4--	0.87-1.45 (MMOL/L)	01/01/91	1.05		1.03		1.06	
SGOT	5-18 (U/L)	01/01/91	8.00		7.00		7.00	
SGPT	5-18 (U/L)	01/01/91	11.00		8.00		10.00	
GAMMA GT	4-18 (U/L)	01/01/91	17.00		11.00		13.00	
LDH	120-240 (U/L)	01/01/91	134.00		121.00		141.00	
ALK. PHOSPH.	60-170 (U/L)	01/01/91	126.00		121.00		124.00	
GLUCOSE	3.54-5.68 (MMOL/L)	01/01/91	7.09 >		5.08		5.42	
BUN	1.7-8.3 (MMOL/L)	01/01/91	3.90		3.40		5.30	
UREA	()	01/01/91						
CREATININE	50-98 (UMOL/L)	01/01/91	67.00		77.00		77.00	
URIC ACID	142-339 (UMOL/L)	01/01/91	256.00		221.00		259.00	
TOT BILIRUBIN	3.6-21.5 (UMOL/L)	01/01/91	4.60		8.90		7.90	
DIR BILIRUBIN	0-4.3 (UMOL/L)	01/01/91						
TOT. PROTEINS	65.6-86.5 (G/L)	01/01/91			78.60		77.80	
ALBUMINE	58-70 (%)	01/01/91			65.80		66.30	
TOT. CHOLEST.	4-5.2 (MMOL/L)	01/01/91			5.74 >		5.49 >	
TRIGLYCERIDES	1.7-2.3 (MMOL/L)	01/01/91			0.95 <		1.17 <	
GLOBULINS ALPHA 1	1.5-4 (%)	01/01/91			2.20		2.30	
GLOBULINS ALPHA 2	5-10 (%)	01/01/91			7.10		6.90	
GLOBULINS BETA	7-13 (%)	01/01/91			10.50		10.30	
GLOBULINS GAMMA	10-19 (%)	01/01/91			14.40		14.20	
TSH	0.3-4 (MU/L)	01/01/91	1.20					
T4	50-115 (UG/L)	01/01/91	124.00					

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 1 Patient: 4 Treatment: Imipramine Sex: Male

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			17/04/91		07/05/91		29/05/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	13.4-18.5 (G/DL)	01/01/91	16.80		16.50		16.00	
HT	40-48 (X)	01/01/91	48.60	>	47.50		46.30	
RBC	4.15-5.9 (10 ⁶ /MM ³)	01/01/91	5.33		5.13		5.10	
HBC	4-10.7 (10 ³ /MM ³)	01/01/91	7.80		6.50		6.40	
HBC: N	40-75 (X)	01/01/91	67.00		64.00		59.00	
HBC: L	20-45 (X)	01/01/91	28.00		29.00		33.00	
HBC: E	1-6 (X)	01/01/91	1.00		2.00		1.00	
HBC: M	2-10 (X)	01/01/91	4.00		5.00		7.00	
HBC: B	0-1 (X)	01/01/91	0.00		0.00		0.00	
PLATELETS	100-300 (10 ³ /MM ³)	01/01/91	270.00		257.00		281.00	
NA+	130-149 (MMOL/L)	01/01/91	145.00		141.00		142.00	
K+	3.66-5.35 (MMOL/L)	01/01/91	4.00		4.10		3.90	
CL-	94-109 (MMOL/L)	01/01/91			103.00		102.00	<
Ca++	2.24-2.78 (MMOL/L)	01/01/91	2.45		2.13	<	2.11	<
PO4--	0.87-1.45 (MMOL/L)	01/01/91	0.98		1.01		0.88	
SGOT	5-19 (U/L)	01/01/91	7.00		7.00		9.00	
SGPT	5-19 (U/L)	01/01/91	12.00		12.00		16.00	
GAMMA GT	5-23 (U/L)	01/01/91	30.00	>	30.00	>	36.00	>
LDH	6-28 (U/L)	01/01/91	134.00		112.00	<	127.00	>
ALK. PHOSPH.	120-240 (U/L)	01/01/91	124.00		98.00		96.00	
GLUCOSE	60-170 (U/L)	01/01/91	124.00		98.00		96.00	
BUN	3.54-5.68 (MMOL/L)	01/01/91	5.83	>	4.83		6.15	>
UREA	1.7-8.3 (MMOL/L)	01/01/91	7.20		7.40		6.30	
UREA	()	01/01/91						
CREATININE	58-110 (UMOL/L)	01/01/91	84.00		82.00		82.00	
URIC ACID	202-416 (UMOL/L)	01/01/91	325.00		278.00		322.00	
TOT BILIRUBIN	3.6-21.9 (UMOL/L)	01/01/91	9.10		5.70		7.20	
DIR BILIRUBIN	0-4.3 (UMOL/L)	01/01/91						
TOT. PROTEINS	65.6-86.5 (G/L)	01/01/91	73.80		70.10		77.00	
ALBUMINE	58-70 (X)	01/01/91	65.60		65.00		56.60	<
TOT. CHOLEST.	4-5.2 (MMOL/L)	01/01/91	5.76	>	5.16		5.98	>
TRIGLYCERIDES	1.7-2.3 (MMOL/L)	01/01/91	2.49	>	2.68	>		
GLOBULINS ALPHA 1	1.5-4 (X)	01/01/91	1.60		1.60		3.00	
GLOBULINS ALPHA 2	5-10 (X)	01/01/91	6.80		7.60		7.40	
GLOBULINS BETA	7-13 (X)	01/01/91	12.00		11.80		10.00	
GLOBULINS GAMMA	10-19 (X)	01/01/91	14.00		14.00		23.00	>
TSH	0.3-4 (MU/L)	01/01/91	0.69					
T4	50-115 (UG/L)	01/01/91	133.00					

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 1 Patient: 6 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/08/91		28/08/91		18/09/91	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	13.4-18.5 (G/DL)	01/01/91	14.80		14.40		14.40	
HT	40-48 (X)	01/01/91	44.70		42.00		42.80	
RBC	4.15-5.9 (10 ⁶ /MM ³)	01/01/91						
			4.73		4.55		4.57	
WBC	4-10.7 (10 ³ /MM ³)	01/01/91	7.20		8.60		8.00	
WBC: N	40-75 (X)	01/01/91	60.00		53.00			
WBC: L	20-45 (X)	01/01/91	31.00		33.00			
WBC: E	1-6 (X)	01/01/91	3.00		4.00			
WBC: M	2-10 (X)	01/01/91	6.00		10.00			
WBC: B	0-1 (X)	01/01/91	0.00		0.00			
PLATELETS	100-300 (10 ³ /MM ³)	01/01/91	290.00		284.00		286.00	
NA+	130-149 (MMOL/L)	01/01/91	143.00		143.00		132.00	
K+	3.66-5.35 (MMOL/L)	01/01/91	4.20		5.15		4.77	
CL-	94-109 (MMOL/L)	01/01/91			103.00			
Ca++	2.24-2.78 (MMOL/L)	01/01/91	2.16 <		2.49		2.48	
PO4--	0.87-1.45 (MMOL/L)	01/01/91	0.72 <<		1.17		0.80 <	
SGOT	5-19 (U/L)	01/01/91	9.00		8.00		12.00	
SGPT	5-23 (U/L)	01/01/91	10.00		9.00		10.00	
GAMMA GT	6-28 (U/L)	01/01/91	13.00		9.00		13.00	
LDH	120-240 (U/L)	01/01/91	264.00 >		123.00		284.00 >	
ALK. PHOSPH.	60-170 (U/L)	01/01/91	151.00		100.00		152.00	
GLUCOSE	3.54-5.68 (MMOL/L)	01/01/91			4.35		4.82	
BUN	1.7-8.3 (MMOL/L)	01/01/91	4.30		3.80		7.40	
UREA	()	01/01/91						
CREATININE	58-110 (UMOL/L)	01/01/91	76.00		78.00		76.00	
URIC ACID	202-416 (UMOL/L)	01/01/91	281.00		215.00		356.00	
TOT BILIRUBIN	3.6-21.9 (UMOL/L)	01/01/91	7.90		6.30		9.20	
DIR BILIRUBIN	0-4.3 (UMOL/L)	01/01/91						
TOT. PROTEINS	65.6-86.5 (G/L)	01/01/91	74.50		69.40		74.10	
ALBUMINE	58-70 (X)	01/01/91	66.80		67.80		68.20	
TOT. CHOLEST.	4-5.2 (MMOL/L)	01/01/91	5.01		6.03 >		4.80	
TRIGLYCERIDES	1.7-2.3 (MMOL/L)	01/01/91	0.80 <		2.25			
GLOBULINS ALPHA 1	1.5-4 (X)	01/01/91	2.80		2.90		2.80	
GLOBULINS ALPHA 2	5-10 (X)	01/01/91	5.00		4.90 <		4.90 <	
GLOBULINS BETA	7-13 (X)	01/01/91	11.80		11.20		11.20	
GLOBULINS GAMMA	10-19 (X)	01/01/91	13.60		13.20		12.90	
TSH	0.3-4 (MU/L)	01/01/91	0.28					
T4	50-115 (UG/L)	01/01/91	118.00					

(⊕) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 1 Patient: 8 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date
			Screen
			29/10/91
			value (†)
Laboratory test	Range value	Range date	
HB	13.4-18.5 (G/DL)	01/01/91	17.20
HT	40-48 (%)	01/01/91	48.70 >
RBC	4.15-5.9 (10 ⁶ /MM ³)	01/01/91	5.26
WBC	4-10.7 (10 ³ /MM ³)	01/01/91	9.60
WBC: N	40-75 (%)	01/01/91	68.00
WBC: L	20-45 (%)	01/01/91	23.00
WBC: E	1-6 (%)	01/01/91	4.00
WBC: M	2-10 (%)	01/01/91	5.00
WBC: B	0-1 (%)	01/01/91	0.00
PLATELETS	100-300 (10 ³ /MM ³)	01/01/91	288.00
NA+	130-149 (MMOL/L)	01/01/91	143.00
K+	3.66-5.35 (MMOL/L)	01/01/91	4.70
CL-	94-109 (MMOL/L)	01/01/91	83.00 <<
Ca++	2.24-2.78 (MMOL/L)	01/01/91	2.53
PO4--	0.87-1.45 (MMOL/L)	01/01/91	0.81 <
SGOT	5-19 (U/L)	01/01/91	8.00
SGPT	5-23 (U/L)	01/01/91	12.00
GAMMA GT	6-28 (U/L)	01/01/91	15.00
LDH	120-240 (U/L)	01/01/91	165.00
ALK. PHOSPH.	60-170 (U/L)	01/01/91	94.00
GLUCOSE	3.54-5.68 (MMOL/L)	01/01/91	7.44 >>
BUN	1.7-8.3 (MMOL/L)	01/01/91	6.30
UREA	()	01/01/91	
CREATININE	58-110 (UMOL/L)	01/01/91	133.00 >
URIC ACID	202-416 (UMOL/L)	01/01/91	426.00 >
TOT BILIRUBIN	3.6-21.9 (UMOL/L)	01/01/91	17.00
DIR BILIRUBIN	0-4.3 (UMOL/L)	01/01/91	
TOT. PROTEINS	65.6-86.5 (G/L)	01/01/91	73.90
ALBUMINE	58-70 (%)	01/01/91	67.10
TOT. CHOLEST.	4-5.2 (MMOL/L)	01/01/91	4.81
TRIGLYCERIDES	1.7-2.3 (MMOL/L)	01/01/91	0.93 <
GLOBULINS ALPHA 1	1.5-4 (%)	01/01/91	2.60
GLOBULINS ALPHA 2	5-10 (%)	01/01/91	7.50
GLOBULINS BETA	7-13 (%)	01/01/91	11.50
GLOBULINS GAMMA	10-19 (%)	01/01/91	11.30
TSH	0.3-4 (MU/L)	01/01/91	1.30
T4	50-115 (UG/L)	01/01/91	143.00

(†) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 1 Patient: 9 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/11/91		28/11/91		19/12/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.7-16.6 (G/DL)	01/01/91	14.60		13.80		13.70	
HT	36-42 (%)	01/01/91	42.80 >		41.20		40.60	
RBC	3.6-5.3 (10 ⁶ /MM ³)	01/01/91	4.67		4.42		4.36	
HBC	4-10.7 (10 ³ /MM ³)	01/01/91	9.10		7.30		7.80	
HBC: N	40-75 (%)	01/01/91	64.00		68.00		70.00	
HBC: L	20-45 (%)	01/01/91	27.00		23.00		20.00	
HBC: E	1-6 (%)	01/01/91	1.00		1.00		1.00	
HBC: M	2-10 (%)	01/01/91	6.00		7.00		8.00	
HBC: B	0-1 (%)	01/01/91	2.00	>>	1.00		1.00	
PLATELETS	100-300 (10 ³ /MM ³)	01/01/91	322.00 >>		336.00 >		366.00 >	
NA+	130-149 (MMOL/L)	01/01/91	142.00		142.00		142.00	
K+	3.66-5.35 (MMOL/L)	01/01/91	4.90		4.80		5.20	
CL-	94-109 (MMOL/L)	01/01/91	100.00		96.00		98.00	
Ca++	2.24-2.78 (MMOL/L)	01/01/91	2.65		2.45		2.35	
PO4--	0.87-1.45 (MMOL/L)	01/01/91	1.22		1.44		1.43	
SGOT	5-18 (U/L)	01/01/91	7.00		6.00		7.00	
SGPT	5-18 (U/L)	01/01/91	7.00		9.00		12.00	
GAMMA GT	4-18 (U/L)	01/01/91	15.00		14.00		24.00 >	
LDH	120-240 (U/L)	01/01/91	207.00		137.00		141.00	
ALK. PHOSPH.	60-170 (U/L)	01/01/91	107.00		110.00		126.00	
GLUCOSE	3.54-5.68 (MMOL/L)	01/01/91	5.50		4.87		4.32	
BUN	1.7-8.3 (MMOL/L)	01/01/91	6.20		7.30		3.80	
UREA	()	01/01/91						
CREATININE	50-98 (UMOL/L)	01/01/91	73.00		75.00		78.00	
URIC ACID	142-339 (UMOL/L)	01/01/91	271.00		251.00		248.00	
TOT BILIRUBIN	3.6-21.5 (UMOL/L)	01/01/91	9.70		8.60		8.10	
DIR BILIRUBIN	0-4.3 (UMOL/L)	01/01/91						
TOT. PROTEINS	65.6-86.5 (G/L)	01/01/91	74.00				69.00	
ALBUMINE	58-70 (%)	01/01/91	63.80				62.30	
TOT. CHOLEST.	4-5.2 (MMOL/L)	01/01/91	6.46		6.05 >		6.04 >	
TRIGLYCERIDES	1.7-2.3 (MMOL/L)	01/01/91	2.44	>	2.76 >		2.66 >	
GLOBULINS ALPHA 1	1.5-4 (%)	01/01/91	3.00				3.40	
GLOBULINS ALPHA 2	5-10 (%)	01/01/91	7.60				8.20	
GLOBULINS BETA	7-13 (%)	01/01/91	11.50				12.20	
GLOBULINS GAMMA	10-19 (%)	01/01/91	14.10				13.90	
TSH	0.3-4 (MU/L)	01/01/91	0.60					
T4	50-115 (UG/L)	01/01/91	157.00					

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 1 Patient: 10 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			15/11/91		10/12/91		30/12/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.7-16.6 (G/DL)	01/01/91	15.70		15.80			
HT	36-42 (X)	01/01/91	45.00 >		45.20 >			
RBC	3.6-5.3 (10 ⁶ /MM ³)	01/01/91	4.75		4.76			
WBC	4-10.7 (10 ³ /MM ³)	01/01/91	9.80		6.90			
WBC: N	40-75 (X)	01/01/91	81.00 >					
WBC: L	20-45 (X)	01/01/91	13.00 <<					
WBC: E	1-6 (X)	01/01/91	1.00					
WBC: M	2-10 (X)	01/01/91	3.00					
WBC: B	0-1 (X)	01/01/91						
PLATELETS	100-300 (10 ³ /MM ³)	01/01/91	283.00		258.00			
NA+	130-149 (MMOL/L)	01/01/91			141.00	146.00		
K+	3.66-5.35 (MMOL/L)	01/01/91			3.70	3.90		
CL-	94-109 (MMOL/L)	01/01/91			99.00	99.00		
Ca++	2.24-2.78 (MMOL/L)	01/01/91	2.50		2.29	2.37		
PO4--	0.87-1.45 (MMOL/L)	01/01/91	0.65 <<		0.79 <	0.69 <<		
SGOT	5-18 (U/L)	01/01/91	8.00		7.00	7.00		
SGPT	5-18 (U/L)	01/01/91	8.00		7.00	11.00		
GAMMA GT	4-18 (U/L)	01/01/91	20.00 >		18.00	26.00 >		
LDH	120-240 (U/L)	01/01/91	179.00		121.00	152.00		
ALK. PHOSPH.	60-170 (U/L)	01/01/91	149.00		122.00	116.00		
GLUCOSE	3.54-5.68 (MMOL/L)	01/01/91	7.53 >>		9.80 >>	12.80 >>		
BUN	1.7-8.3 (MMOL/L)	01/01/91	3.90		4.60	4.90		
UREA	()	01/01/91						
CREATININE	50-98 (UMOL/L)	01/01/91	75.00		74.00	70.00		
URIC ACID	142-339 (UMOL/L)	01/01/91	460.00 >>		374.00 >	365.00 >		
TOT BILIRUBIN	3.6-21.5 (UMOL/L)	01/01/91	6.90		6.00	7.30		
DIR BILIRUBIN	0-4.3 (UMOL/L)	01/01/91						
TOT. PROTEINS	65.6-86.5 (G/L)	01/01/91	78.00		78.00	77.00		
ALBUMINE	58-70 (X)	01/01/91	62.90		64.00	62.00		
TOT. CHOLEST.	4-5.2 (MMOL/L)	01/01/91	5.68 >		5.90 >	6.37 >		
TRIGLYCERIDES	1.7-2.3 (MMOL/L)	01/01/91	2.81 >		3.62 >>	4.33 >>		
GLOBULINS ALPHA 1	1.5-4 (X)	01/01/91	3.40		2.80	3.30		
GLOBULINS ALPHA 2	5-10 (X)	01/01/91	9.00		8.70	9.50		
GLOBULINS BETA	7-13 (X)	01/01/91	10.50		9.50	10.10		
GLOBULINS GAMMA	10-19 (X)	01/01/91	14.20		15.00	15.10		
TSH	0.3-4 (MU/L)	01/01/91	0.45					
T4	50-115 (UG/L)	01/01/91	138.00					

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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 2 Patient: 34 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			27/12/90		17/01/91		07/02/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/11/90	15.80		15.90		16.30	
HT	0.38-0.57 (L/L)	01/11/90	0.48		0.47		0.48	
RBC	4.5-5.8 (10 ⁶ /MM ³)	01/11/90	5.30		5.14		5.20	
WBC	4000-9000 (/MM ³)	01/11/90	8400.00		5900.00		6700.00	
WBC: N	55-60 (%)	01/11/90	65.00 >				66.00 >	
WBC: L	30-40 (%)	01/11/90	20.00 <<				20.00 <<	
WBC: E	1-3 (%)	01/11/90	5.00 >>				5.00 >>	
WBC: M	3-7 (%)	01/11/90	10.00 >>				8.00 >	
WBC: B	0-1 (%)	01/11/90	0.00				1.00	
PLATELETS	150000-300000 (/MM ³)	01/11/90					307000 >	
NA+	136-147 (MMOL/L)	01/11/90	143.00		150.00 >		146.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	4.40		4.70		4.70	
CL-	95-108 (MMOL/L)	01/11/90						
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.50		2.60		2.60	
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	26.00 >		18.00		21.00 >	
SGPT	5-22 (U/L)	01/11/90	46.00 >>		38.00 >		58.00 >>	
GAMMA GT	6-28 (U/L)	01/11/90	17.00		17.00		21.00	
LDH	()	01/11/90						
ALK. PHOSPH.	60-170 (U/L)	01/11/90	84.00		76.00		81.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	100.00				90.00	
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90						
CREATININE	0.5-1.1 (MG/DL)	01/11/90	1.20 >		1.20 >		1.10	
URIC ACID	0.4-7 (MG/DL)	01/11/90	6.60		5.90		7.50 >	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90			1.00		0.40	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90						
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	7.40		6.90		7.20	
ALBUMINE	53-63 (%)	01/11/90	63.60 >		64.40 >		64.80 >	
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	179.00		157.00		230.00 >	
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	156.00		116.00		193.00 >	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	2.80 <		2.70 <		2.50 <	
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	6.90 <		6.70 <		6.30 <	
GLOBULINS BETA	10-13 (%)	01/11/90	12.00		11.70		11.40	
GLOBULINS GAMMA	14-20 (%)	01/11/90	14.70		14.50		15.00	
TSH	0.3-4 (UU/ML)	01/11/90	1.00				1.50	
T4	5-12 (UG/DL)	01/11/90	9.20		8.40		9.30	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 2 Patient: 36 Treatment: Imipramine Sex: Female

Laboratory test	Range value	Range date	Visit number / Laboratory date			
			Screen		Day 21	
			09/01/91		30/01/91	
			value	(€)	value	(€)
HB	12-16 (G/DL)	01/11/90	12.70		14.10	
HT	0.37-0.46 (L/L)	01/11/90	0.37		0.41	
RBC	4-5 (10 ⁶ /MM ³)	01/11/90	4.20		4.60	
WBC	4000-9000 (/MM ³)	01/11/90	7100.00		6300.00	
WBC: N	55-60 (%)	01/11/90	41.00	<	42.00	<
WBC: L	30-40 (%)	01/11/90	48.00	>	42.00	>
WBC: E	1-3 (%)	01/11/90	4.00	>>	8.00	>>
WBC: M	3-7 (%)	01/11/90	6.00		4.00	
WBC: B	0-1 (%)	01/11/90	1.00		4.00	>>
PLATELETS	150000-300000 (/MM ³)	01/11/90			275000	
NA+	136-147 (MMOL/L)	01/11/90	140.00		140.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	4.30		4.40	
CL-	95-108 (MMOL/L)	01/11/90				
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.50		2.30	
PO4--	()	01/11/90				
SGOT	5-18 (U/L)	01/11/90	7.00		8.00	
SGPT	5-22 (U/L)	01/11/90	3.00	<	5.00	
GAMMA GT	6-28 (U/L)	01/11/90	10.00		8.00	
LDH	()	01/11/90				
ALK. PHOSPH.	60-170 (U/L)	01/11/90	104.00		115.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	72.00		89.00	
BUN	20-40 (MG/DL)	01/11/90				
UREA	()	01/11/90				
CREATININE	0.5-1.3 (MG/DL)	01/11/90	0.90		0.90	
URIC ACID	2.4-5.7 (MG/DL)	01/11/90	4.00		5.40	
TOT. BILIRUBIN	0-1 (MG/DL)	01/11/90				
DIR. BILIRUBIN	0-0.25 (MG/DL)	01/11/90				
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90				
ALBUMINE	53-63 (%)	01/11/90	61.70		65.80	>
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	221.00	>	261.00	>
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	89.00		49.00	<
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	3.10		2.40	<
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	7.80		6.10	<
GLOBULINS BETA	10-13 (%)	01/11/90	9.80	<	9.00	<
GLOBULINS GAMMA	14-20 (%)	01/11/90	17.60		16.70	
TSH	0.3-4 (UU/ML)	01/11/90	0.40		1.30	
T4	5-12 (UG/DL)	01/11/90	9.40		7.70	

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PHARMACIA CNS 880
9550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 38 Treatment: Imipramine Sex: Female

Laboratory test	Range value	Range date	Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/01/91		14/02/91		07/03/91	
			value	(€)	value	(€)	value	(€)
HB	12-16 (G/DL)	01/11/90	13.40		13.70		12.90	
HT	0.37-0.46 (L/L)	01/11/90	0.39		0.40		0.38	
RBC	4-5 (10 ⁶ /MM ³)	01/11/90	3.92	<	4.10		3.80	<
HBC	4000-9000 (/MM ³)	01/11/90	6400.00		5600.00		5600.00	
HBC: N	55-60 (%)	01/11/90			66.00	>	68.00	>
HBC: L	30-40 (%)	01/11/90			24.00	<	21.00	<
HBC: E	1-3 (%)	01/11/90			1.00		1.00	
HBC: M	3-7 (%)	01/11/90			9.00	>	10.00	>>
HBC: B	0-1 (%)	01/11/90			0.00		0.00	
PLATELETS	150000-300000 (/MM ³)	01/11/90			276000		272000	
NA+	136-147 (MMOL/L)	01/11/90	142.00		139.00		141.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	4.20		3.70		4.60	
CL-	95-108 (MMOL/L)	01/11/90						
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.20	<	2.20	<	2.30	
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	14.00		8.00		7.00	
SGPT	5-22 (U/L)	01/11/90	21.00		10.00		7.00	
GAMMA GT	6-28 (U/L)	01/11/90	7.00		7.00		8.00	
LDH	()	01/11/90						
ALK. PHOSPH.	60-170 (U/L)	01/11/90	81.00		72.00		74.00	
GLUCOSE	70-110 (MG/DL)	01/11/90			144.00	>>	92.00	
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90						
CREATININE	0.5-1.3 (MG/DL)	01/11/90			1.00		1.00	
URIC ACID	2.4-5.7 (MG/DL)	01/11/90	3.50		4.10		3.70	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	0.50		0.50		0.40	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90						
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	7.00		7.00		6.70	
ALBUMINE	53-63 (%)	01/11/90	63.30	>	60.80		61.20	>>
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	333.00	>>	356.00	>>	308.00	>>
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	114.00		131.00		93.00	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90			2.30	<	2.70	<
GLOBULINS ALPHA 2	7-10 (%)	01/11/90			7.80		8.10	
GLOBULINS BETA	10-13 (%)	01/11/90			9.30	<	9.60	<
GLOBULINS GAMMA	14-20 (%)	01/11/90			17.30		18.40	
TSH	0.3-4 (UU/ML)	01/11/90			0.30		0.20	
T4	5-12 (UG/DL)	01/11/90	9.20		8.40		5.90	

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS 880
9550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 40 Treatment: Imipramine Sex: Male

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			20/02/91		19/03/91		02/04/91	
			value	(ø)	value	(ø)	value	(ø)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/11/90	15.70		16.70		15.40	
HT	0.38-0.57 (L/L)	01/11/90	0.46		0.49		0.45	
RBC	4.5-5.8 (10 ⁶ /MM ³)	01/11/90	4.47 <		4.90		4.60	
WBC	4000-9000 (/MM ³)	01/11/90	9400.00 >		10200.0 >		9600.00 >	
WBC: N	55-60 (%)	01/11/90			59.00 <		50.00 <	
WBC: L	30-40 (%)	01/11/90			28.00 <		37.00 <	
WBC: E	1-3 (%)	01/11/90			4.00 >>		4.00 >>	
WBC: M	3-7 (%)	01/11/90			9.00 >		8.00 >	
WBC: B	0-1 (%)	01/11/90			0.00		1.00	
PLATELETS	150000-300000 (/MM ³)	01/11/90			376000 >		353000 >	
NA+	136-147 (MMOL/L)	01/11/90	145.00		143.00		140.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	4.70		4.60		3.90	
CL-	95-108 (MMOL/L)	01/11/90						
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.20 <		2.60			
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	7.00		7.00		10.00	
SGPT	5-22 (U/L)	01/11/90	9.00		8.00		14.00	
GAMMA GT	6-28 (U/L)	01/11/90	11.00		9.00		12.00	
LDH	()	01/11/90						
ALK. PHOSPH.	60-170 (U/L)	01/11/90	94.00		111.00		86.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	83.00		86.00		68.00 <	
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90						
CREATININE	0.5-1.1 (MG/DL)	01/11/90	1.10		1.40 >		1.10	
URIC ACID	0.4-7 (MG/DL)	01/11/90	7.10 >		8.60 >		7.80 >	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	0.70		0.40		0.50	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90						
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	7.60		7.30		7.20	
ALBUMINE	53-63 (%)	01/11/90	59.30		63.70 >		62.70	
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	251.00 >		209.00		261.00 >	
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	233.00 >>		156.00		305.00 >>	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	3.70		2.90 <		3.10	
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	9.10		8.10		8.50	
GLOBULINS BETA	10-13 (%)	01/11/90	13.00		10.50		11.70	
GLOBULINS GAMMA	14-20 (%)	01/11/90	14.90		14.80		14.00	
TSH	0.3-4 (UU/ML)	01/11/90	0.30		1.30		1.70	
T4	5-12 (UG/DL)	01/11/90	9.90		7.20		9.40	

(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

PHARMACIA CNS 890
9550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 42 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			08/02/91		01/03/91		22/03/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/11/90	15.70		15.30		14.70	
HT	0.38-0.57 (L/L)	01/11/90	0.46		0.46		0.43	
RBC	4.5-5.8 (10 ⁶ /MM ³)	01/11/90	5.00		4.90		4.60	
HBC	4000-9000 (/MM ³)	01/11/90	5900.00		6300.00		5600.00	
HBC: N	55-60 (%)	01/11/90	58.00		64.00 >		56.00	
HBC: L	30-40 (%)	01/11/90	36.00		28.00 <		37.00	
HBC: E	1-3 (%)	01/11/90	2.00		2.00		3.00	
HBC: M	3-7 (%)	01/11/90	4.00		6.00		5.00	
HBC: B	0-1 (%)	01/11/90	0.00		0.00		1.00	
PLATELETS	150000-300000 (/MM ³)	01/11/90	184000		212000		229000	
NA+	136-147 (MMOL/L)	01/11/90	141.00		141.00		142.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	3.90		4.10		4.00	
CL-	95-108 (MMOL/L)	01/11/90						
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.50				2.40	
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	8.00		6.00		7.00	
SGPT	5-22 (U/L)	01/11/90	12.00		12.00		8.00	
GAMMA GT	6-28 (U/L)	01/11/90	37.00 >		27.00		26.00	
LDH	()	01/11/90						
ALK. PHOSPH.	60-170 (U/L)	01/11/90	85.00		104.00		95.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	88.00		90.00		78.00	
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90						
CREATININE	0.5-1.1 (MG/DL)	01/11/90	0.90		0.90		0.90	
URIC ACID	0.4-7 (MG/DL)	01/11/90	4.10		3.60		4.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	0.50		0.60		0.80	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90						
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	7.00		8.00		7.10	
ALBUMINE	53-63 (%)	01/11/90	65.50 >		63.70 >		66.00 >	
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	328.00 >>		300.00 >>		337.00 >>	
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	214.00 >		97.00		174.00 >	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	2.30 <		2.50 <		2.40 <	
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	8.00		8.50		8.70	
GLOBULINS BETA	10-13 (%)	01/11/90	10.20		11.30		11.40	
GLOBULINS GAMMA	14-20 (%)	01/11/90	14.00		14.00		11.50 <	
TSH	0.3-4 (UU/ML)	01/11/90	0.60		1.00			
T4	5-12 (UG/DL)	01/11/90	8.70		8.30			

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max rang)
 < out of range (value lower than min range) > out of range (value higher than max rang)
 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 080
9530085

REBOMETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 44 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date	
			Screen	
			10/04/91	
			value	(*)
Laboratory test	Range value	Range date		
HB	14-18 (G/DL)	01/11/90	16.00	
HT	0.38-0.57 (L/L)	01/11/90	0.47	
RBC	4.5-5.8 (10 ⁶ /MM ³)	01/11/90	4.90	
WBC	4000-9000 (/MM ³)	01/11/90	6500.00	
WBC: N	55-60 (%)	01/11/90	68.00	>
WBC: L	30-40 (%)	01/11/90	20.00	<<
WBC: E	1-3 (%)	01/11/90	1.00	
WBC: M	3-7 (%)	01/11/90	11.00	>>
WBC: B	0-1 (%)	01/11/90	0.00	
PLATELETS	150000-300000 (/MM ³)	01/11/90	268000	
NA+	136-147 (MMOL/L)	01/11/90	135.00	<
K+	3.6-5.1 (MMOL/L)	01/11/90	4.30	
CL-	95-108 (MMOL/L)	01/11/90		
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.60	
PO4--	()	01/11/90		
SGOT	5-18 (U/L)	01/11/90	12.00	
SGPT	5-22 (U/L)	01/11/90	18.00	
GAMMA GT	6-28 (U/L)	01/11/90	12.00	
LDH	()	01/11/90		
ALK. PHOSPH.	60-170 (U/L)	01/11/90	72.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	100.00	
BUN	20-40 (MG/DL)	01/11/90		
UREA	()	01/11/90		
CREATININE	0.5-1.1 (MG/DL)	01/11/90	0.80	
URIC ACID	0.4-7 (MG/DL)	01/11/90	3.70	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	1.10	>
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90		
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	7.10	
ALBUMINE	53-63 (%)	01/11/90	67.40	>
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	266.00	>
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	99.00	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	2.70	<
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	7.60	
GLOBULINS BETA	10-13 (%)	01/11/90	9.10	<
GLOBULINS GAMMA	14-20 (%)	01/11/90	13.20	<
TSH	0.3-4 (UU/ML)	01/11/90	0.90	
T4	5-12 (UG/DL)	01/11/90	7.80	

(*) << 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 880
9330085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 45 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			29/04/91
			value (⊕)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	01/11/90	12.80
HT	0.37-0.46 (L/L)	01/11/90	0.39
RBC	4-5 (10 ⁶ /MM ³)	01/11/90	4.40
MBC	4000-9000 (/MM ³)	01/11/90	4600.00
MBC: N	55-60 (%)	01/11/90	57.00
MBC: L	30-40 (%)	01/11/90	36.00
MBC: E	1-3 (%)	01/11/90	2.00
MBC: M	3-7 (%)	01/11/90	4.00
MBC: B	0-1 (%)	01/11/90	1.00
PLATELETS	150000-300000 (/MM ³)	01/11/90	189000
NA+	136-147 (MMOL/L)	01/11/90	145.00
K+	3.6-5.1 (MMOL/L)	01/11/90	4.40
CL-	95-108 (MMOL/L)	01/11/90	
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.40
PO4--	()	01/11/90	
SGOT	5-18 (U/L)	01/11/90	8.00
SGPT	5-22 (U/L)	01/11/90	12.00
GAMMA GT	6-28 (U/L)	01/11/90	7.00
LDH	()	01/11/90	
ALK. PHOSPH.	60-170 (U/L)	01/11/90	65.00
GLUCOSE	70-110 (MG/DL)	01/11/90	89.00
BUN	20-40 (MG/DL)	01/11/90	
UREA	()	01/11/90	
CREATININE	0.5-1.3 (MG/DL)	01/11/90	0.60
URIC ACID	2.4-5.7 (MG/DL)	01/11/90	3.20
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	0.50
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90	
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	7.30
ALBUMINE	53-63 (%)	01/11/90	65.00 >
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	181.00
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	75.00
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	2.20 <
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	5.60 <
GLOBULINS BETA	10-13 (%)	01/11/90	8.80 <
GLOBULINS GAMMA	14-20 (%)	01/11/90	18.40
TSH	0.3-4 (UU/ML)	01/11/90	1.30
T4	5-12 (UG/DL)	01/11/90	7.20

(⊕) << 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

PHARMACIA CNS 880
 9330085
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 18.0

LABORATORY DATA
 Centre: 2 Patient: 48 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			26/08/91		16/09/91		07/10/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/11/90	14.90		14.80		14.40	
HT	0.37-0.46 (L/L)	01/11/90	0.45		0.45		0.44	
RBC	4-5 (10 ⁶ /MM ³)	01/11/90	5.14 >		5.00		4.90	
WBC	4000-9000 (/MM ³)	01/11/90	5600.00		5300.00		5400.00	
WBC: N	55-60 (%)	01/11/90	58.00		47.00 <		50.00 <	
WBC: L	30-40 (%)	01/11/90	34.00		41.00 >		40.00	
WBC: E	1-3 (%)	01/11/90	1.00		2.00		2.00	
WBC: M	3-7 (%)	01/11/90	6.00		8.00 >		7.00	
WBC: B	0-1 (%)	01/11/90	1.00		2.00 >>		1.00	
PLATELETS	150000-300000 (/MM ³)	01/11/90	177000		177000		241000	
NA+	136-147 (MMOL/L)	01/11/90	143.00		140.00		146.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	3.98		4.34		4.90	
CL-	95-108 (MMOL/L)	01/11/90						
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.20 <		2.20 <		2.27 <	
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	15.00		19.00 >		17.00	
SGPT	5-22 (U/L)	01/11/90	15.00		18.00		15.00	
GAMMA GT	6-28 (U/L)	01/11/90	32.00 >		38.00 >		31.00 >	
LDH	()	01/11/90						
ALK. PHOSPH.	60-170 (U/L)	01/11/90	136.00		147.00		145.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	99.00		85.00		85.00	
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90			1.10		1.00	
CREATININE	0.5-1.3 (MG/DL)	01/11/90						
URIC ACID	2.4-5.7 (MG/DL)	01/11/90	5.60		6.40 >		5.80 >	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	0.70		0.80		0.70	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90						
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	7.10		7.20		7.20	
ALBUMINE	53-63 (%)	01/11/90	57.90		58.80		57.80	
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	201.00		222.00 >		214.00	
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	124.00		149.00		160.00	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	3.40		3.20		3.40	
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	7.90		8.80		9.00	
GLOBULINS BETA	10-13 (%)	01/11/90	10.70		10.00		10.80	
GLOBULINS GAMMA	14-20 (%)	01/11/90	20.10 >		19.20		18.80	
TSH	0.3-4 (UU/ML)	01/11/90			2.50			
T4	5-12 (UG/DL)	01/11/90	10.50		10.10			

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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 880
9330085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: 49 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			28/08/91		18/09/91		09/10/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/11/90	13.80		13.20		13.30	
HT	0.37-0.46 (L/L)	01/11/90	0.39		0.41		0.40	
RBC	4-5 (10 ⁶ /MM ³)	01/11/90	4.40		4.30		4.20	
WBC	4000-9000 (/MM ³)	01/11/90	7600.00		7100.00		10400.0 >	
WBC: N	55-60 (%)	01/11/90	49.90 <		65.70 >		72.00 >	
WBC: L	30-40 (%)	01/11/90	40.80 >		26.20 <		22.00 <	
WBC: E	1-3 (%)	01/11/90	1.10		0.80 <		0.00 <	
WBC: M	3-7 (%)	01/11/90	7.20 >		6.80		5.00	
WBC: B	0-1 (%)	01/11/90	1.00		0.50		1.00	
PLATELETS	150000-300000 (/MM ³)	01/11/90	232000		231000		227000	
NA+	136-147 (MMOL/L)	01/11/90	144.00		139.00		143.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	4.67		4.35		4.49	
CL-	95-108 (MMOL/L)	01/11/90					109.00 >	
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.30		2.31		2.39	
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	20.00 >		12.00		12.00	
SGPT	5-22 (U/L)	01/11/90	28.00 >		18.00		15.00	
GAMMA GT	6-28 (U/L)	01/11/90	35.00 >		30.00 >		17.00	
LDH	()	01/11/90						
ALK. PHOSPH.	60-170 (U/L)	01/11/90	71.00		106.00			
GLUCOSE	70-110 (MG/DL)	01/11/90	80.00		81.00		74.00	
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90						
CREATININE	0.5-1.3 (MG/DL)	01/11/90	0.90		0.90		0.80	
URIC ACID	2.4-5.7 (MG/DL)	01/11/90	3.50		3.70		4.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	0.50		0.30		0.40	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90						
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	7.10		7.20		7.10	
ALBUMINE	53-63 (%)	01/11/90	65.60 >		62.20		70.70 >	
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	223.00 >		262.00 >		257.00 >	
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	74.00		78.00		89.00	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	3.20		2.20 <		3.70	
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	7.60		7.80		8.30	
GLOBULINS BETA	10-13 (%)	01/11/90	10.40		11.00		8.20 <	
GLOBULINS GAMMA	14-20 (%)	01/11/90	13.20 <		13.80 <		9.10 <<	
TSH	0.3-4 (UU/ML)	01/11/90	0.60		1.00		0.70	
T4	5-12 (UG/DL)	01/11/90	9.00		6.60		9.20	

(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 5530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 2 Patient: S2 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			15/11/91		17/12/91		07/01/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/11/90	14.40		14.50		15.10	
HT	0.38-0.57 (L/L)	01/11/90	0.44		0.44		0.46	
RBC	4.5-5.8 (10 ⁶ /MM ³)	01/11/90	4.80		4.80		5.10	
WBC	4000-9000 (/MM ³)	01/11/90	7600.00		6500.00		7000.00	
WBC: N	55-60 (%)	01/11/90	58.20		51.10	<	50.00	
WBC: L	30-40 (%)	01/11/90	30.10		36.70		35.00	
WBC: E	1-3 (%)	01/11/90	3.40	>	4.40	>>	5.00	
WBC: M	3-7 (%)	01/11/90	7.30	>	6.70		8.00	
WBC: B	0-1 (%)	01/11/90	1.00		1.10	>	2.00	
PLATELETS	150000-300000 (/MM ³)	01/11/90	200000		206000		212000	
NA+	136-147 (MMOL/L)	01/11/90	142.00		140.00		138.00	
K+	3.6-5.1 (MMOL/L)	01/11/90	4.40		4.33		4.08	
CL-	95-108 (MMOL/L)	01/11/90						
Ca++	2.3-2.6 (MMOL/L)	01/11/90	2.47		2.48		2.52	
PO4--	()	01/11/90						
SGOT	5-18 (U/L)	01/11/90	11.00		13.00		14.00	
SGPT	5-22 (U/L)	01/11/90	14.00		10.00		11.00	
GAMMA GT	6-28 (U/L)	01/11/90	8.00		7.00		8.00	
LDH	()	01/11/90						
ALK. PROSPH.	60-170 (U/L)	01/11/90	88.00		99.00		108.00	
GLUCOSE	70-110 (MG/DL)	01/11/90	70.00		76.00		88.00	
BUN	20-40 (MG/DL)	01/11/90						
UREA	()	01/11/90						
CREATININE	0.5-1.1 (MG/DL)	01/11/90	1.10		1.10		1.00	
URIC ACID	0.4-7 (MG/DL)	01/11/90	4.90		5.80		4.90	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/90	0.60		0.60		0.80	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/90						
TOT. PROTEINS	6.5-8.5 (G/DL)	01/11/90	7.10		7.10		7.70	
ALBUMINE	53-63 (%)	01/11/90	69.00	>	67.30	>	65.30	
TOT. CHOLEST.	140-220 (MG/DL)	01/11/90	201.00		185.00		210.00	
TRIGLYCERIDES	74-172 (MG/DL)	01/11/90	78.00		93.00		97.00	
GLOBULINS ALPHA 1	3-5 (%)	01/11/90	2.70	<	2.70	<	3.20	
GLOBULINS ALPHA 2	7-10 (%)	01/11/90	6.50	<	6.70	<	7.60	
GLOBULINS BETA	10-13 (%)	01/11/90	10.10		8.20	<	9.60	
GLOBULINS GAMMA	14-20 (%)	01/11/90	11.70	<	15.10		14.30	
TSH	0.3-4 (UU/ML)	01/11/90	0.80		1.60		2.80	
T4	5-12 (UG/DL)	01/11/90	8.10		5.80		7.00	

(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 841
530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 3 Patient: 66 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			27/04/91		23/05/91	
			value	(c)	value	(c)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	01/02/91	12.90		14.00	
HT	37-47 (%)	01/02/91	38.60		40.50	
RBC	4.2-5.4 (10 ⁶ /MM ³)	01/02/91	4.14	<	4.41	
WBC	4.8-10.8 (10 ³ /MM ³)	01/02/91	6.50		5.70	
WBC: N	45-78 (%)	01/02/91	62.80		67.10	
WBC: L	18-45 (%)	01/02/91	26.70		24.10	
WBC: E	0-5 (%)	01/02/91	2.50		2.70	
WBC: M	2-12 (%)	01/02/91	4.50		3.90	
WBC: B	0-1 (%)	01/02/91	0.60		0.90	
PLATELETS	125-400 (10 ³ /MM ³)	01/02/91	330.00		390.00	
NA+	135-150 (MMOL/L)	01/02/91	140.00		138.00	
K+	3.6-5.3 (MMOL/L)	01/02/91	4.40		4.00	
CL-	97-108 (MMOL/L)	01/02/91	97.00		98.00	
Ca++	2.1-2.7 (MMOL/L)	01/02/91	2.50		2.40	
PO4--	2-4.9 (MG/DL)	01/02/91	3.70		4.30	
SGOT	5-18 (U/L)	01/02/91	7.00		9.00	
SGPT	5-22 (U/L)	01/02/91	7.00		11.00	
GAMMA GT	0-18 (U/L)	01/02/91	13.00		13.00	
LDH	150-240 (U/L)	01/02/91	161.00		152.00	
ALK. PHOSPH.	40-200 (U/L)	01/02/91	88.00		95.00	
GLUCOSE	70-110 (MG/DL)	01/02/91	94.00		123.00 >	
BUN	0-25 (MG/DL)	01/02/91	21.00		21.00	
UREA	()	01/02/91				
CREATININE	0-1.3 (MG/DL)	01/02/91	0.90		0.90	
URIC ACID	2.5-5.7 (MG/DL)	01/02/91	5.50		5.10	
TOT BILIRUBIN	0-1.3 (MG/DL)	01/02/91	0.70		0.50	
DIR BILIRUBIN	()	01/02/91				
TOT. PROTEINS	6.2-8.2 (G/DL)	01/02/91	8.10		7.20	
ALBUMINE	58-72 (%)	01/02/91	63.70		62.90	
TOT. CHOLEST.	120-200 (MG/DL)	01/02/91	253.00	>	228.00 >	
TRIGLYCERIDES	75-200 (MG/DL)	01/02/91	114.00		116.00	
GLOBULINS ALPHA 1	2-4.2 (%)	01/02/91	3.30		2.80	
GLOBULINS ALPHA 2	6.5-10.3 (%)	01/02/91	8.50		7.30	
GLOBULINS BETA	6.7-11.2 (%)	01/02/91	9.30		9.10	
GLOBULINS GAMMA	11.8-20.5 (%)	01/02/91	14.80		17.00	
TSH	0.1-4 (UU/ML)	01/02/91	0.60			
T4	0.92-1.82 (NG/DL)	01/02/91	1.52			

(+) << 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-880
9330085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 3 Patient: 68 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			02/08/91		23/08/91		13/09/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/02/91	13.60		13.70		12.90	
HT	37-47 (X)	01/02/91	39.50		38.90		38.40	
RBC	4.2-5.4 (10 ⁶ /MM ³)	01/02/91	4.92		4.66		4.51	
WBC	4.8-10.8 (10 ³ /MM ³)	01/02/91						
WBC: N	45-78 (%)	01/02/91	6.60		7.10		6.90	
WBC: L	18-45 (%)	01/02/91	65.90		63.90		60.50	
WBC: E	0-5 (%)	01/02/91	27.80		28.20		32.30	
WBC: M	2-12 (%)	01/02/91	0.90		0.70		1.00	
WBC: B	0-1 (%)	01/02/91	3.90		5.30		4.90	
PLATELETS	125-400 (10 ³ /MM ³)	01/02/91	0.20		0.30		0.30	
NA+	135-150 (MMOL/L)	01/02/91	218.00		276.00		261.00	
K+	3.6-5.3 (MMOL/L)	01/02/91	143.00		145.00		144.00	
CL-	97-108 (MMOL/L)	01/02/91	3.60		3.70		3.80	
Ca++	2.1-2.7 (MMOL/L)	01/02/91	105.00		98.00		98.00	
PO4--	2-4.9 (MG/DL)	01/02/91	2.40		2.50		2.40	
SGOT	5-18 (U/L)	01/02/91	4.40		3.70		4.10	
SGPT	5-22 (U/L)	01/02/91	6.00		7.00		28.00	
GAMMA GT	0-18 (U/L)	01/02/91	4.00	<	11.00	>	79.00	
LDH	150-240 (U/L)	01/02/91	10.00		25.00	>	57.00	
ALK. PHOSPH.	40-200 (U/L)	01/02/91	131.00	<	157.00	>	165.00	
GLUCOSE	70-110 (MG/DL)	01/02/91	141.00		162.00		185.00	
BUN	0-25 (MG/DL)	01/02/91	61.00	<	101.00	>	129.00	
UREA	()	01/02/91	24.00		19.00		17.00	
CREATININE	0-1.3 (MG/DL)	01/02/91	0.80		1.00		0.80	
URIC ACID	2.5-5.7 (MG/DL)	01/02/91	4.60		4.40		4.90	
TOT. BILIRUBIN	0-1.3 (MG/DL)	01/02/91	0.80		0.60		0.40	
DIR. BILIRUBIN	()	01/02/91						
TOT. PROTEINS	6.2-8.2 (G/DL)	01/02/91	7.20		7.80		7.50	
ALBUMINE	58-72 (%)	01/02/91	57.90	<	57.90	<	64.10	
TOT. CHOLEST.	120-200 (MG/DL)	01/02/91	247.00	>	236.00	>	270.00	
TRIGLYCERIDES	75-200 (MG/DL)	01/02/91	251.00	>	231.00	>	612.00	
GLOBULINS ALPHA 1	2-4.2 (%)	01/02/91	3.60		3.60		3.40	
GLOBULINS ALPHA 2	6.5-10.3 (%)	01/02/91	9.50		9.50		8.40	
GLOBULINS BETA	6.7-11.2 (%)	01/02/91	9.10		9.10		8.40	
GLOBULINS GAMMA	11.8-20.5 (%)	01/02/91	19.60		19.60		15.50	
TSH	0.1-4 (UU/ML)	01/02/91	1.40					
T4	0.92-1.82 (NG/DL)	01/02/91	0.81					

(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 990085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 3 Patient: 69 Treatment: Imipramine Sex: Female

Laboratory test	Range value	Range date	Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			01/03/91		22/03/91		11/04/91	
			value	(†)	value	(†)	value	(†)
HB	12-16 (G/DL)	01/02/91	14.50		14.90		13.50	
HT	37-47 (X)	01/02/91	42.70		44.30		37.50	
RBC	4.2-5.4 (10 ⁶ /MM ³)	01/02/91	4.28		4.40		3.92	<
HBC	4.8-10.8 (10 ³ /MM ³)	01/02/91						
WBC: N	45-78 (X)	01/02/91	8.10		6.20		7.00	
WBC: L	18-45 (X)	01/02/91	65.10		56.80		64.10	
WBC: E	0-5 (X)	01/02/91	23.40		32.30		21.90	
WBC: M	2-12 (X)	01/02/91	3.00		4.50		3.40	
WBC: B	0-1 (X)	01/02/91	6.00		4.60		7.60	
PLATELETS	125-400 (10 ³ /MM ³)	01/02/91	0.70		1.10	>	0.40	
NA+	135-150 (MMOL/L)	01/02/91	281.00		313.00		300.00	
K+	3.6-5.3 (MMOL/L)	01/02/91	145.00		143.00		143.00	
CL-	97-108 (MMOL/L)	01/02/91	3.80		4.50		4.30	
Ca++	2.1-2.7 (MMOL/L)	01/02/91	103.00		98.00		102.00	
PO4--	2-4.9 (MG/DL)	01/02/91	2.50		2.60		2.50	
SGOT	5-18 (U/L)	01/02/91	4.30		3.80		4.50	
SGPT	5-22 (U/L)	01/02/91	6.00		6.00		5.00	
GAMMA GT	0-18 (U/L)	01/02/91	8.00		6.00		6.00	
LDH	150-240 (U/L)	01/02/91	7.00		7.00		7.00	
ALK. PHOSPH.	40-200 (U/L)	01/02/91	115.00	<	121.00	<	88.00	<
GLUCOSE	70-110 (MG/DL)	01/02/91	80.00		88.00		81.00	
BUN	0-25 (MG/DL)	01/02/91	81.00		80.00		94.00	
UREA	()	01/02/91	8.00		7.00		6.00	
CREATININE	0-1.3 (MG/DL)	01/02/91						
URIC ACID	2.5-5.7 (MG/DL)	01/02/91	0.80		0.70		0.80	
TOT BILIRUBIN	0-1.3 (MG/DL)	01/02/91	2.20	<	2.20	<	2.30	<
DIR BILIRUBIN	()	01/02/91	0.60		0.80		0.40	
TOT. PROTEINS	6.2-8.2 (G/DL)	01/02/91	7.20		7.30		6.40	
ALBUMINE	58-72 (X)	01/02/91	64.60		68.40		68.30	
TOT. CHOLEST.	120-200 (MG/DL)	01/02/91	231.00	>	186.00		179.00	
TRIGLYCERIDES	75-200 (MG/DL)	01/02/91	76.00		84.00		84.00	<
GLOBULINS ALPHA 1	2-4.2 (X)	01/02/91	4.28		4.10		4.30	>
GLOBULINS ALPHA 2	6.5-10.3 (X)	01/02/91	8.20		6.50		6.30	<
GLOBULINS BETA	6.7-11.2 (X)	01/02/91	8.80		8.10		7.90	<
GLOBULINS GAMMA	11.8-20.5 (X)	01/02/91	14.00		12.90		12.40	
TSH	0.1-4 (UU/ML)	01/02/91	1.47					
T4	0.92-1.82 (NG/DL)	01/02/91	1.31					

(†) << 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

1264

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS 5990085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 3 Patient: 71 Treatment: Imipramine Sex: Female

Laboratory test	Range value	Range date	Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			12/11/91		04/12/91		25/12/91	
			value	(€)	value	(€)	value	(€)
HB	12-16 (G/DL)	01/02/91	13.70		14.60		13.40	
HT	37-47 (%)	01/02/91	38.60		42.10		37.70	
RBC	4.2-5.4 (10 ⁶ /MM ³)	01/02/91	4.21		4.55		4.03	<
WBC	4.8-10.8 (10 ³ /MM ³)	01/02/91	6.60		6.70		6.50	
WBC: N	45-78 (%)	01/02/91	69.60		64.80		59.80	
WBC: L	18-45 (%)	01/02/91	21.60		22.50		26.20	
WBC: E	0-5 (%)	01/02/91	1.90		2.50		3.30	
WBC: M	2-12 (%)	01/02/91	4.80		6.30		6.60	
WBC: B	0-1 (%)	01/02/91	0.60		1.30	>	0.70	
PLATELETS	125-400 (10 ³ /MM ³)	01/02/91	235.00		198.00		179.00	
NA+	135-150 (MMOL/L)	01/02/91	140.00		141.00		140.00	
K+	3.6-5.3 (MMOL/L)	01/02/91	3.20	<	3.60		3.20	<
CL-	97-108 (MMOL/L)	01/02/91	102.00		99.00		104.00	
Ca++	2.1-2.7 (MMOL/L)	01/02/91	2.40		2.30		2.30	
PO4--	2-4.9 (MG/DL)	01/02/91	3.30		3.70		3.00	
SGOT	5-18 (U/L)	01/02/91	10.00		9.00		10.00	
SGPT	5-22 (U/L)	01/02/91	6.00		10.00		16.00	
GAMMA GT	0-18 (U/L)	01/02/91	6.00		6.00		9.00	
LDH	150-240 (U/L)	01/02/91	125.00	<	102.00	<	112.00	<
ALK. PROSPH.	40-200 (U/L)	01/02/91	62.00		68.00		81.00	
GLUCOSE	70-110 (MG/DL)	01/02/91	76.00		77.00			
BUN	0-25 (MG/DL)	01/02/91	11.00		10.00		9.00	
UREA	()	01/02/91						
CREATININE	0-1.3 (MG/DL)	01/02/91	0.80		0.80		0.70	
URIC ACID	2.5-5.7 (MG/DL)	01/02/91	2.60		2.60		4.20	
TOT BILIRUBIN	0-1.3 (MG/DL)	01/02/91	0.60		0.60		0.60	
DIR BILIRUBIN	()	01/02/91						
TOT. PROTEINS	6.2-8.2 (G/DL)	01/02/91	7.10		6.90		6.70	
ALBUMINE	58-72 (%)	01/02/91	52.20	<	58.90		56.00	<
TOT. CHOLEST.	120-200 (MG/DL)	01/02/91	180.00		160.00		192.00	
TRIGLYCERIDES	75-200 (MG/DL)	01/02/91	72.00	<	52.00	<	78.00	
GLOBULINS ALPHA 1	2-4.2 (Z)	01/02/91	6.70	>>	3.70		5.30	>
GLOBULINS ALPHA 2	6.5-10.3 (Z)	01/02/91	10.80	>	10.10		9.90	
GLOBULINS BETA	6.7-11.2 (Z)	01/02/91	11.10		10.40		10.10	
GLOBULINS GAMMA	11.8-20.5 (Z)	01/02/91	18.90		16.30		18.40	
TSH	0.1-4 (UU/ML)	01/02/91	1.50					
T4	0.92-1.82 (NG/DL)	01/02/91	1.26					

(€) << 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

1265

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS 880
9530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 4 Patient: 97 Treatment: Imipramine Sex: Male

Laboratory test	Range value	Range date	Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/05/92		27/05/92		17/06/92	
			value	(€)	value	(€)	value	(€)
HB	8.6-12 (MMOL/L)	01/04/91	10.30		10.70		10.00	
HT	0.43-0.49 (L/L)	01/04/91	0.49		0.49		0.45	
RBC	4.6-6.2 (10 ⁶ /MM ³)	01/04/91	5.21		5.30		4.90	
WBC	3.8-9.8 (10 ³ /MM ³)	01/04/91	5.80		5.70		5.52	
WBC: N	36-84 (%)	01/04/91	60.60		61.00		53.20	
WBC: L	20-42 (%)	01/04/91	29.40		28.80		34.80	
WBC: E	0-5 (%)	01/04/91	3.30		3.10		5.00	
WBC: M	0-9.5 (%)	01/04/91	3.50		3.70		4.50	
WBC: B	0-1 (%)	01/04/91	1.00		1.00		1.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/04/91	212.00		205.00		227.00	
NA+	136-152 (MMOL/L)	01/04/91	141.00		142.00		141.00	
K+	3.8-5.5 (MMOL/L)	01/04/91	4.59		4.57		4.86	
CL-	97-108 (MMOL/L)	01/04/91	98.00		98.00		100.00	
Ca++	2.4-2.65 (MMOL/L)	01/04/91	2.29 <		2.28 <		2.60	
PO4--	0.8-1.3 (MMOL/L)	01/04/91	1.03		1.03		1.08	
SGOT	0.32-0.49 (MMOL/L/S)	01/04/91	0.17 <		0.17 <		0.31 <	
SGPT	0.22-0.57 (MMOL/L/S)	01/04/91	0.18 <		0.18 <		0.19 <	
GAMMA GT	0-0.57 (MMOL/L/S)	01/04/91	0.19		0.19		0.19	
LDH	0-6.6 (MMOL/L)	01/04/91	3.73		3.73		4.48	
ALK. PHOSPH.	3.7-4.85 (MMOL/L/S)	01/04/91	3.25 <		3.23 <		2.91 <	
GLUCOSE	3.33-5.55 (MMOL/L)	01/04/91	3.70		4.10		3.70	
BUN	5.3-8.9 (MMOL/L)	01/04/91						
UREA	()	01/04/91						
CREATININE	0-102 (UMOL/L)	01/04/91	75.00		69.00		76.00	
URIC ACID	140-340 (UMOL/L)	01/04/91	349.00 >		349.00 >		504.00 >>	
TOT BILIRUBIN	0-16 (UMOL/L)	01/04/91	11.00		11.00		12.00	
DIR BILIRUBIN	()	01/04/91						
TOT. PROTEINS	65-85 (G/L)	01/04/91	71.60		71.60		70.80	
ALBUMINE	55-65 (%)	01/04/91	65.70 >		65.50 >		65.70 >	
TOT. CHOLEST.	3.5-6.6 (MMOL/L)	01/04/91	5.70		5.59		6.99 >	
TRIGLYCERIDES	1.75-2.1 (MMOL/L)	01/04/91	0.94 <		0.94 <		1.38 <	
GLOBULINS ALPHA 1	3-6 (%)	01/04/91	3.30		3.50		3.30	
GLOBULINS ALPHA 2	5-10 (%)	01/04/91	8.60		8.50		8.60	
GLOBULINS BETA	9-14 (%)	01/04/91	10.20		10.20		10.20	
GLOBULINS GAMMA	12-20 (%)	01/04/91	12.20		12.30		12.20	
TSH	0.24-2.9 (MU/L)	01/04/91	0.59					
T4	65-155 (NMOL/L)	01/04/91	83.00					

(€) << 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 550085
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 18.0

LABORATORY DATA
 Centre: 4 Patient: 101 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			06/05/91		23/05/91	
			value	(€)	value	(€)
Laboratory test	Range value	Range date				
HB	7.4-10.5 (MMOL/L)	01/04/91	8.70		8.80	
HT	0.36-0.45 (L/L)	01/04/91	0.40		0.40	
RBC	4.2-5.4 (10 ⁶ /MM ³)	01/04/91	4.36		4.26	
WBC	3.8-9.8 (10 ³ /MM ³)	01/04/91	6.90		6.83	
WBC: N	36-84 (%)	01/04/91			62.20	
WBC: L	20-42 (%)	01/04/91			27.60	
WBC: E	0-5 (%)	01/04/91			1.70	
WBC: M	0-9.5 (%)	01/04/91			5.10	
WBC: B	0-1 (%)	01/04/91			1.20 >	
PLATELETS	150-300 (10 ³ /MM ³)	01/04/91			293.00	
NA+	136-152 (MMOL/L)	01/04/91	143.00		140.00	
K+	3.8-5.5 (MMOL/L)	01/04/91	4.71		4.25	
CL-	97-108 (MMOL/L)	01/04/91	108.00		110.00 >	
Ca ⁺⁺	2.4-2.65 (MMOL/L)	01/04/91	2.47			
PO ₄ ⁻⁻	0.8-1.3 (MMOL/L)	01/04/91				
SGOT	0.32-0.49 (MMOL/L/S)	01/04/91	0.35		0.27 <	
SGPT	0.17-0.4 (MMOL/L/S)	01/04/91	0.33		0.33	
GAMMA GT	0-0.4 (MMOL/L/S)	01/04/91	0.57 >		0.50 >	
LDH	0-6.6 (MMOL/L)	01/04/91			4.95	
ALK. PHOSPH.	1.45-3.65 (MMOL/L/S)	01/04/91				
GLUCOSE	3.33-5.55 (MMOL/L)	01/04/91	4.20		4.30	
BUN	3.6-7.1 (MMOL/L)	01/04/91	5.50		7.40 >	
UREA	()	01/04/91				
CREATININE	0-88 (UMOL/L)	01/04/91	83.00		90.00 >	
URIC ACID	140-340 (UMOL/L)	01/04/91	333.00		341.00 >	
TOT BILIRUBIN	0-16 (UMOL/L)	01/04/91	9.00		9.00	
DIR BILIRUBIN	()	01/04/91				
TOT. PROTEINS	65-85 (G/L)	01/04/91				
ALBUMINE	55-65 (%)	01/04/91				
TOT. CHOLEST.	3.5-6.6 (MMOL/L)	01/04/91				
TRIGLYCERIDES	1.75-2.1 (MMOL/L)	01/04/91				
GLOBULINS ALPHA 1	3-6 (%)	01/04/91				
GLOBULINS ALPHA 2	5-10 (%)	01/04/91				
GLOBULINS BETA	9-14 (%)	01/04/91				
GLOBULINS GAMMA	12-20 (%)	01/04/91				
TSH	0.24-2.9 (MU/L)	01/04/91	0.30			
T4	65-155 (NMOL/L)	01/04/91	64.00			

(€) << 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 9850085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 7 Patient: 196 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/03/91		06/04/91		04/05/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	03/02/91	14.90		13.80		14.70	
HT	37-56 (X)	03/02/91	43.20		39.40		43.00	
RBC	4200-6200 (10 ³ -3/MM3)	03/02/91	4850.00		4500.00		4730.00	
WBC	4000-10000 (/MM3)	03/02/91	7320.00		7920.00		6970.00	
WBC: N	50-70 (X)	03/02/91	54.10		52.40		56.40	
WBC: L	20-40 (X)	03/02/91	36.10		31.20		31.80	
WBC: E	0-5 (X)	03/02/91	3.50		2.20		3.50	
WBC: M	2-10 (X)	03/02/91	4.00		2.00		4.70	
WBC: B	0-2 (X)	03/02/91	0.60		0.50		0.90	
PLATELETS	150-400 (10 ³ -3/MM3)	03/02/91	284.00		346.00		364.00	
NA+	136-146 (MMOL/L)	03/02/91	141.00		139.00		145.00	
K+	3.5-5 (MMOL/L)	03/02/91	4.40		3.80		3.70	
CL-	95-105 (MMOL/L)	03/02/91	105.00		102.00		103.00	
Ca++	2-2.6 (MMOL/L)	03/02/91	2.31		2.40		2.35	
PO4--	0.79-1.56 (MMOL/L)	03/02/91	1.19		1.03		0.92	
SGOT	5-25 (U/L)	03/02/91	13.00		14.00		14.00	
SGPT	5-20 (U/L)	03/02/91	21.00	>	23.00	>	13.00	
GAMMA GT	0-38 (U/L)	03/02/91	27.00		38.00		22.00	
LDH	138-276 (U/L)	03/02/91	114.00		236.00		291.00	
ALK. PHOSPH.	0-207 (U/L)	03/02/91	141.00		141.00		139.00	
GLUCOSE	0.6-1.2 (G/L)	03/02/91	0.82		1.01		1.11	
BUN	0.1-0.5 (G/L)	03/02/91	0.26		0.31		0.29	
UREA	()	03/02/91						
CREATININE	0-1.4 (NG/DL)	03/02/91	0.79		0.94		0.85	
URIC ACID	2.4-7 (NG/DL)	03/02/91	4.30		4.40		4.30	
TOT BILIRUBIN	0-1.5 (NG/DL)	03/02/91	0.18		0.16		0.27	
DIR BILIRUBIN	0-0.5 (NG/DL)	03/02/91	0.08		0.08		0.06	
TOT. PROTEINS	6.3-8.5 (G/DL)	03/02/91	7.80		8.10		7.90	
ALBUMINE	53-70 (X)	03/02/91	65.80		63.80		59.30	
TOT. CHOLEST.	1.5-2.5 (G/L)	03/02/91	2.57	>	2.52	>	2.44	
TRIGLYCERIDES	0.4-1.72 (G/L)	03/02/91	2.71	>>	2.09	>	1.40	
GLOBULINS ALPHA 1	1.5-5.5 (X)	03/02/91	5.00		4.60		3.80	
GLOBULINS ALPHA 2	8-12 (X)	03/02/91	7.90	<	8.40		12.70	
GLOBULINS BETA	8-14 (X)	03/02/91	7.70	<	8.90		8.80	
GLOBULINS GAMMA	9-18 (X)	03/02/91	13.60		14.30		15.30	
TSH	0.2-5 (MU/L)	03/02/91						
T4	0.8-1.9 (NG/DL)	03/02/91	1.40					

(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 950085
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 18.0

LABORATORY DATA
 Centre: 8 Patient: 225 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			22/03/91
			value (€)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	04/02/91	15.40
HT	32-36 (%)	04/02/91	44.50 >
RBC	4-5 (10 ⁶ /MM ³)	04/02/91	5.17 >
WBC	4.5-9 (10 ³ /MM ³)	04/02/91	9.60 >
WBC: N	45-70 (%)	04/02/91	49.00
WBC: L	20-40 (%)	04/02/91	37.00
WBC: E	1-3 (%)	04/02/91	4.00 >>
WBC: M	3-7 (%)	04/02/91	10.00 >>
WBC: B	0-1 (%)	04/02/91	0.00
PLATELETS	150-400 (10 ³ /MM ³)	04/02/91	318.00
NA+	135-146 (MEQ/L)	04/02/91	
K+	3.5-5 (MEQ/L)	04/02/91	
CL-	95-106 (MEQ/L)	04/02/91	
Ca++	4.2-5.3 (MEQ/L)	04/02/91	
PO4--	2.7-4.5 (MG/DL)	04/02/91	
SGOT	5-21 (U/L)	04/02/91	17.00
SGPT	5-22 (U/L)	04/02/91	33.00 >
GAMMA GT	5-25 (U/L)	04/02/91	21.00
LDH	160-320 (U/L)	04/02/91	
ALK. PHOSPH.	73-207 (U/L)	04/02/91	
GLUCOSE	80-110 (MG/DL)	04/02/91	
BUN	10-50 (MG/DL)	04/02/91	
UREA	()	04/02/91	
CREATININE	0.5-0.9 (MG/DL)	04/02/91	
URIC ACID	2.4-5.7 (MG/DL)	04/02/91	
TOT BILIRUBIN	0-1 (MG/DL)	04/02/91	
DIR BILIRUBIN	0-0.3 (MG/DL)	04/02/91	
TOT. PROTEINS	66-70 (G/L)	04/02/91	
ALBUMINE	56-70 (%)	04/02/91	
TOT. CHOLEST.	150-250 (MG/DL)	04/02/91	
TRIGLYCERIDES	35-185 (MG/DL)	04/02/91	
GLOBULINS ALPHA 1	1.8-4.5 (%)	04/02/91	
GLOBULINS ALPHA 2	4-13 (%)	04/02/91	
GLOBULINS BETA	9-14 (%)	04/02/91	
GLOBULINS GAMMA	8-16 (%)	04/02/91	
TSH	0.4-3.7 (UUI/ML)	04/02/91	
T4	6.1-11.5 (UG/DL)	04/02/91	

(€) << 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 CUS 860
9530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 8 Patient: 227 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/05/91		29/05/91		18/06/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	13-17 (G/DL)	02/04/91	15.40		16.40		16.40	
HT	35-50 (%)	02/04/91	45.00		48.00		49.00	
RBC	4-5.5 (10 ⁶ /MM ³)	02/04/91	4.50		4.90		5.00	
HBC	4-10 (10 ⁹ /MM ³)	02/04/91	9.70		10.30	>	9.70	
HBC: N	25-75 (%)	02/04/91	52.00		60.00		82.00 >	
HBC: L	10-40 (%)	02/04/91	39.00		33.00		17.00	
HBC: E	0-4 (%)	02/04/91	1.00		2.00		0.00	
HBC: M	2-10 (%)	02/04/91	8.00		5.00		1.00 <	
HBC: B	0-1 (%)	02/04/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	02/04/91	247.00		284.00		305.00	
NA+	137-150 (MEQ/L)	02/04/91	140.00		147.00		143.00	
K+	3.5-5.2 (MEQ/L)	02/04/91	4.80		5.20		5.20	
CL-	90-110 (MEQ/L)	02/04/91	112.00	>	104.00		104.00	
Ca++	4.5-5.5 (MEQ/L)	02/04/91	4.90		5.20		5.10	
PO4--	25-45 (MG/L)	02/04/91	39.00		32.00		33.00	
SGOT	5-25 (U/L)	02/04/91	13.00		15.00		12.00	
SGPT	5-25 (U/L)	02/04/91	14.00		19.00		12.00	
GAMMA GT	0-40 (U/L)	02/04/91	103.00	>>	29.00			
LDH	160-320 (U/L)	02/04/91	202.00					
ALK. PHOSPH.	40-210 (U/L)	02/04/91	103.00				125.00	
GLUCOSE	0.6-1.1 (G/L)	02/04/91	0.95				0.92	
BUN	0.1-0.45 (G/L)	02/04/91	0.17		0.17		0.15	
UREA	()	02/04/91						
CREATININE	5-12 (MG/L)	02/04/91	9.70		12.10	>	12.10 >	
URIC ACID	30-65 (MG/L)	02/04/91	47.00		54.00		47.00	
TOT BILIRUBIN	0-10 (MG/L)	02/04/91	4.50		6.60		5.70	
DIR BILIRUBIN	0-3 (MG/L)	02/04/91	1.80		2.10		1.90	
TOT. PROTEINS	65-80 (G/L)	02/04/91	64.00	<	80.00		75.00	
ALBUMINE	55-70 (%)	02/04/91	65.10		62.40		65.90	
TOT. CHOLEST.	1.5-2.5 (G/L)	02/04/91	1.88		2.62	>	2.48	
TRIGLYCERIDES	0.7-1.5 (G/L)	02/04/91	1.17		0.85		1.26	
GLOBULINS ALPHA 1	2-4 (%)	02/04/91	3.10		3.60		3.30	
GLOBULINS ALPHA 2	6-10 (%)	02/04/91	8.80		9.80		8.30	
GLOBULINS BETA	9-13 (%)	02/04/91	12.10		12.60		11.10	
GLOBULINS GAMMA	11-15 (%)	02/04/91	11.00		11.50		11.40	
TSH	0.1-4 (MU/L)	02/04/91	1.20					
T4	7.3-20.1 (PG/ML)	02/04/91	9.30		14.80			

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CUC 890
9550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 8 Patient: 229 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/10/91		12/11/91		03/12/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	04/02/91	14.00		14.00		13.88	
HT	32-36 (X)	04/02/91	40.60 >		40.90 >		40.60 >	
RBC	4-5 (10 ⁶ /MM ³)	04/02/91	4.36		4.40		4.38	
HBC	4.5-9 (10 ³ /MM ³)	04/02/91	8.30		8.90		7.00	
HBC: N	45-70 (X)	04/02/91	60.00		72.00 >		55.00	
HBC: L	20-40 (X)	04/02/91	30.00		19.00 <		34.00	
HBC: E	1-3 (X)	04/02/91	2.00		0.00 <		2.00	
HBC: H	3-7 (X)	04/02/91	6.00		9.00 >		6.00	
HBC: B	0-1 (X)	04/02/91	2.00 >>		0.00		3.00 >>	
PLATELETS	150-400 (10 ³ /MM ³)	04/02/91	298.00		274.00		298.00	
NA+	135-146 (MEQ/L)	04/02/91	141.00		141.00		141.00	
K+	3.5-5 (MEQ/L)	04/02/91	4.60		4.60		4.10	
CL-	95-106 (MEQ/L)	04/02/91	102.00		103.00		99.00	
Ca++	4.2-5.3 (MEQ/L)	04/02/91	4.60		4.60		4.40	
PO4--	2.7-4.5 (NG/DL)	04/02/91	4.70 >		3.70		3.90	
SGOT	5-21 (U/L)	04/02/91	13.00		10.00		11.00	
SGPT	5-22 (U/L)	04/02/91	14.00		10.00		11.00	
GAMMA GT	5-25 (U/L)	04/02/91	13.00		6.00		11.00	
LDH	160-320 (U/L)	04/02/91	199.00		176.00		173.00	
ALK. PHOSPH.	73-207 (U/L)	04/02/91	135.00		120.00		124.00	
GLUCOSE	80-110 (MG/DL)	04/02/91	90.00		95.00		93.00	
BUN	10-50 (MG/DL)	04/02/91	24.00		28.00		32.00	
UREA	()	04/02/91						
CREATININE	0.5-0.9 (NG/DL)	04/02/91	0.80		0.90		0.90	
URIC ACID	2.4-5.7 (NG/DL)	04/02/91	3.60		3.60		3.10	
TOT BILIRUBIN	0-1 (MG/DL)	04/02/91	0.30		0.30		0.40	
DIR BILIRUBIN	0-0.3 (MG/DL)	04/02/91	0.10				0.20	
TOT. PROTEINS	66-70 (G/L)	04/02/91	66.70		71.60 >		70.30 >	
ALBUMINE	56-70 (X)	04/02/91	62.50		71.50 >		66.70	
TOT. CHOLEST.	150-250 (MG/DL)	04/02/91	238.00		249.00		269.00 >	
TRIGLYCERIDES	35-185 (MG/DL)	04/02/91	109.00		136.00		133.00	
GLOBULINS ALPHA 1	1.8-4.5 (X)	04/02/91	3.90		2.60		2.80	
GLOBULINS ALPHA 2	4-13 (X)	04/02/91	10.10		7.20		8.10	
GLOBULINS BETA	9-14 (X)	04/02/91	12.20		10.30		12.70	
GLOBULINS GAMMA	8-16 (X)	04/02/91	11.30		8.40		9.80	
TSH	0.4-3.7 (UUI/ML)	04/02/91	1.60					
T4	6.1-11.5 (UG/DL)	04/02/91	7.60					

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CUS 890
9530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 8 Patient: 230 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/11/91		26/11/91		17/12/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	04/02/91	14.60		14.50		13.70	
HT	32-36 (%)	04/02/91	42.20 >	42.30 >			40.40 >	
RBC	4-5 (10 ⁶ /MM ³)	04/02/91	4.59		4.58		4.32	
WBC	4.5-9 (10 ³ /MM ³)	04/02/91	6.40		7.30		5.70	
WBC: N	45-70 (%)	04/02/91	54.00		48.00		52.00	
WBC: L	20-40 (%)	04/02/91	39.00		44.00 >		39.00	
WBC: E	1-3 (%)	04/02/91	2.00		2.00		2.00	
WBC: M	3-7 (%)	04/02/91	5.00		6.00		5.00	
WBC: B	0-1 (%)	04/02/91	0.00		0.00		1.00	
PLATELETS	150-400 (10 ³ /MM ³)	04/02/91	327.00		380.00		349.00	
NA+	135-146 (MEQ/L)	04/02/91	142.00		138.00		144.00	
K+	3.5-5 (MEQ/L)	04/02/91	4.40		4.30		4.50	
CL-	95-106 (MEQ/L)	04/02/91	102.00		98.00		106.00	
Ca++	4.2-5.3 (MEQ/L)	04/02/91	4.60		4.70		4.80	
PO4--	2.7-4.5 (MG/DL)	04/02/91	3.40		3.70		3.60	
SGOT	5-21 (U/L)	04/02/91	12.00		11.00		9.00	
SGPT	5-22 (U/L)	04/02/91	25.00 >		20.00		19.00	
GAMMA GT	5-25 (U/L)	04/02/91	14.00		12.00		12.00	
LDH	160-320 (U/L)	04/02/91	190.00		196.00		231.00	
ALK. PHOSPH.	73-207 (U/L)	04/02/91	89.00		95.00		89.00	
GLUCOSE	80-110 (MG/DL)	04/02/91	82.00		87.00		93.00	
BUN	10-50 (MG/DL)	04/02/91	25.00		32.00		32.00	
UREA	()	04/02/91						
CREATININE	0.5-0.9 (MG/DL)	04/02/91	0.90		0.90		1.00 >	
URIC ACID	2.4-5.7 (MG/DL)	04/02/91	4.60		4.30		3.90	
TOT BILIRUBIN	0-1 (MG/DL)	04/02/91	1.10 >		0.70		0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	04/02/91			0.30		0.20	
TOT. PROTEINS	66-70 (G/L)	04/02/91	71.90 >		71.30 >		71.40 >	
ALBUMINE	56-70 (G/L)	04/02/91	66.00		63.40		64.20	
TOT. CHOLEST.	150-250 (MG/DL)	04/02/91	250.00		228.00		247.00	
TRIGLYCERIDES	35-185 (MG/DL)	04/02/91	217.00 >		224.00 >		189.00 >	
GLOBULINS ALPHA 1	1.8-4.5 (%)	04/02/91	3.40		4.30		3.30	
GLOBULINS ALPHA 2	4-13 (%)	04/02/91	9.10		10.50		8.80	
GLOBULINS BETA	9-14 (%)	04/02/91	12.60		12.00		12.50	
GLOBULINS GAMMA	8-16 (%)	04/02/91	8.90		9.90		11.10	
TSH	0.4-3.7 (UUI/ML)	04/02/91	3.10					
T4	6.1-11.5 (UG/DL)	04/02/91	11.10					

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS 800
9550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 198 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/03/92		07/04/92		28/04/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	15.00		14.00		14.90	
HT	37-54 (X)	01/06/91	43.80		41.30		43.30	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.60		4.40		4.60	
WBC	4-10 (10 ³ /MM ³)	01/06/91	8.13		7.00		5.61	
WBC: N	40-70 (X)	01/06/91	69.50		54.60		35.30 <	
WBC: L	19-48 (X)	01/06/91	23.50		35.90		50.40 >	
WBC: E	0-7 (X)	01/06/91	0.71		1.90		2.47	
WBC: M	3.4-9 (X)	01/06/91	6.26		6.22		10.50 >	
WBC: B	0-1.5 (X)	01/06/91	0.02		1.38		1.08	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	274.00		283.00		291.00	
NA+	135-145 (MMOL/L)	01/06/91	141.00		135.00			
K+	3.5-5 (MMOL/L)	01/06/91	4.00		6.80	>>		
CL-	98-108 (MMOL/L)	01/06/91	98.00		96.00	<		
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.31		9.50		9.38	
PO4--	2.1-4 (MG/DL)	01/06/91	3.09		3.85		3.91	
SGOT	11-33 (U/L)	01/06/91	16.00		17.00		16.00	
SGPT	11-39 (U/L)	01/06/91	13.00		13.00		12.00	
GAMMA GT	5-55 (U/L)	01/06/91	11.00		11.00		13.00	
LDH	200-450 (U/L)	01/06/91	336.00		347.00		345.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	62.00		67.00		70.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.85		1.06	>	0.74	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.36		0.38		0.30	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.73		0.83		0.82	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	2.70	<	3.50		2.60 <	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.35		0.19		0.46	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.05		0.05		0.05	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.50		7.30		7.20	
ALBUMINE	52-68 (X)	01/06/91	56.60		54.80		56.50	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	179.00		169.00		230.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	58.00	<	59.00	<	52.00 <	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	3.10		3.20		2.90	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	9.90		11.00		9.90	
GLOBULINS BETA	9.5-14 (X)	01/06/91	13.20		16.10	>	14.50 >	
GLOBULINS GAMMA	12-21 (X)	01/06/91	17.20		14.90		16.40	
TSH	1-5 (U/ML)	01/06/91	1.01					
T4	4.5-13 (UG/DL)	01/06/91	10.90					

(€) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max rang
< out of range (value lower than min range) > out of range (value higher than max rang)
** 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 QNS 860
9550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 199 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date	
			Screen	Day 21
			30/03/92	22/04/92
			value (c)	value (c)
Laboratory test	Range value	Range date		
HB	13-18 (G/DL)	01/06/91	15.10	15.60
HT	37-54 (Z)	01/06/91	45.40	46.50
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	5.05	5.30
MBC	4-10 (10 ³ /MM ³)	01/06/91	6.28	8.01
MBC: N	40-70 (Z)	01/06/91		47.70
MBC: L	19-48 (Z)	01/06/91		40.60
MBC: E	0-7 (Z)	01/06/91		2.91
MBC: M	3.4-9 (Z)	01/06/91		10.30 >
MBC: B	0-1.5 (Z)	01/06/91		0.56
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	341.00	364.00 >
NA+	135-145 (MMOL/L)	01/06/91		141.00
K+	3.5-5 (MMOL/L)	01/06/91		4.62
CL-	98-108 (MMOL/L)	01/06/91		102.00
Ca++	8.5-10.5 (MG/DL)	01/06/91	10.10	9.48
PO4--	2.1-4 (MG/DL)	01/06/91	>>	5.92 >
SGOT	11-33 (U/L)	01/06/91	23.00	25.00
SGPT	11-39 (U/L)	01/06/91		37.00
GAMMA GT	15-85 (U/L)	01/06/91	23.00	21.00
LDH	200-450 (U/L)	01/06/91	333.00	312.00
ALK. PHOSPH.	34-154 (U/L)	01/06/91	116.00	104.00
GLUCOSE	0.6-1 (G/L)	01/06/91		0.81
BUN	()	01/06/91		
UREA	0.18-0.43 (G/L)	01/06/91	0.29	0.28
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.99	0.98
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.50	5.20
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.35	0.59
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.06	0.12
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.80	7.70
ALBUMINE	52-68 (Z)	01/06/91	54.40	61.20
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	305.00 >	285.00 >
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	314.00 >>	201.00 >
GLOBULINS ALPHA 1	2.5-4.8 (Z)	01/06/91	2.60	1.70 <<
GLOBULINS ALPHA 2	6.2-11 (Z)	01/06/91	11.50 >	9.40 >
GLOBULINS BETA	9.5-14 (Z)	01/06/91	16.50 >	14.40 >
GLOBULINS GAMMA	12-21 (Z)	01/06/91	15.10	13.20
TSH	1-5 (UU/ML)	01/06/91	4.88	
T4	4.5-13 (UG/DL)	01/06/91	9.50	

(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

1274

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PHARMACIA CHE 800
9530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 201 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			07/01/92		05/02/92		26/02/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	14.70		14.80		14.40	
HT	37-54 (X)	01/06/91	45.70		44.70		42.90	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.95		4.72		4.71	
WBC	4-10 (10 ³ /MM ³)	01/06/91	8.12		5.70		7.08	
WBC: N	40-70 (X)	01/06/91					65.10	
WBC: L	19-48 (X)	01/06/91			36.30		23.50	
WBC: E	0-7 (X)	01/06/91	2.83				2.32	
WBC: M	3.4-9 (X)	01/06/91			5.16		8.22	
WBC: B	0-1.5 (X)	01/06/91					0.90	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	113.00	<	244.00		321.00	
NA+	135-145 (MMOL/L)	01/06/91	137.00		142.00		142.00	
K+	3.5-5 (MMOL/L)	01/06/91			4.24		4.73	
CL-	98-108 (MMOL/L)	01/06/91	101.00		103.00		97.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	8.69		9.50		9.86	
PO4--	2.1-4 (MG/DL)	01/06/91	3.37		3.63		3.54	
SGOT	11-33 (U/L)	01/06/91	33.00		13.00		19.00	
SGPT	11-39 (U/L)	01/06/91	14.00		14.00		23.00	
GAMMA GT	5-55 (U/L)	01/06/91	6.00		15.00		24.00	
LDH	200-450 (U/L)	01/06/91	741.00	>	258.00		315.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	72.00		81.00		82.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.67		1.01	>	0.76	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.26		0.21		0.29	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.83		1.05		1.01	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	5.20		3.57		5.20	
TOT. BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91			0.30		0.13	
DIR. BILIRUBIN	0-0.36 (MG/DL)	01/06/91			0.07			
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	6.80		6.74		7.20	
ALBUMINE	52-68 (X)	01/06/91	54.70				58.70	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	245.00				258.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	191.00	>	228.00	>>	280.00	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	3.20				3.20	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	12.90	>			12.20	
GLOBULINS BETA	9.5-14 (X)	01/06/91	15.90	>			14.90	
GLOBULINS GAMMA	12-21 (X)	01/06/91	13.20				11.00	
TSH	1-5 (UU/ML)	01/06/91	1.46					
T4	4.5-13 (UG/DL)	01/06/91	5.70					

(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 9550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 202 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			09/01/92		06/02/92		27/02/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/06/91	15.90		15.40		16.10	
HT	37-54 (X)	01/06/91	47.60		43.60		47.40	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	5.10		4.73		5.05	
WBC	4-10 (10 ³ /MM ³)	01/06/91	6.24		7.09		5.50	
WBC: N	40-70 (X)	01/06/91	79.30	>	75.00	>	67.00	
WBC: L	19-48 (X)	01/06/91	11.80	<<	13.00	<<	16.00	<
WBC: E	0-7 (X)	01/06/91	0.92		1.00		1.00	
WBC: M	3.4-9 (X)	01/06/91	7.70		11.00	>	15.00	>>
WBC: B	0-1.5 (X)	01/06/91	0.23		0.00			
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	178.00		150.00		199.00	
Na+	135-145 (MMOL/L)	01/06/91	140.00		141.00		143.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.42		4.43			
CL-	98-108 (MMOL/L)	01/06/91	100.00		100.00		98.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.71		9.28		9.42	
PO4--	2.1-4 (MG/DL)	01/06/91	1.75	<<	2.87		2.15	
SGOT	11-33 (U/L)	01/06/91	21.00		33.00		21.00	
SGPT	11-39 (U/L)	01/06/91	26.00		26.00		15.00	
GAMMA GT	15-85 (U/L)	01/06/91	25.00		14.00	<	21.00	
LDH	200-450 (U/L)	01/06/91	358.00		644.00	>	344.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	119.00		91.00		97.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.97		0.77		0.57	<
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.41		0.45	>	0.43	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.98		1.10		0.95	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	6.30		6.80		6.60	
TOT. BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.48		0.62		0.62	
DIR. BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.09				0.11	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	6.50	<	6.40	<	6.30	<
ALBUMINE	52-68 (X)	01/06/91	57.90		55.80		64.40	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	172.00		190.00		205.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	66.00		59.00	<	54.00	<
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	2.70		3.40		2.90	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	7.40		14.10	>	7.20	
GLOBULINS BETA	9.5-14 (X)	01/06/91	12.70		13.40		14.00	
GLOBULINS GAMMA	12-21 (X)	01/06/91	19.30		13.30		11.40	<
TSH	1-5 (UU/ML)	01/06/91	0.79					
T4	4.5-13 (UG/DL)	01/06/91	9.30					

(€) << 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 958085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 205 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			27/01/92
			value (€)
Laboratory test	Range value	Range date	
HB	11-16 (G/DL)	01/06/91	14.20
HT	37-54 (X)	01/06/91	43.60
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.73
WBC	4-10 (10 ³ /MM ³)	01/06/91	8.34
WBC: N	40-70 (%)	01/06/91	67.00
WBC: L	19-48 (%)	01/06/91	24.00
WBC: E	0-7 (%)	01/06/91	2.00
WBC: M	3.4-9 (%)	01/06/91	7.00
WBC: B	0-1.5 (%)	01/06/91	0.00
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	250.00
NA+	135-145 (MMOL/L)	01/06/91	139.00
K+	3.5-5 (MMOL/L)	01/06/91	
CL-	98-108 (MMOL/L)	01/06/91	99.00
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.68
PO4--	2.1-4 (MG/DL)	01/06/91	2.73
SGPT	11-33 (U/L)	01/06/91	16.00
SGPT	11-39 (U/L)	01/06/91	14.00
GAMMA GT	5-55 (U/L)	01/06/91	14.00
LDH	200-450 (U/L)	01/06/91	350.00
ALK. PHOSPH.	34-154 (U/L)	01/06/91	67.00
GLUCOSE	0.6-1 (G/L)	01/06/91	0.79
BUN	()	01/06/91	
UREA	0.18-0.43 (G/L)	01/06/91	0.31
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.85
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	3.50
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.22
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.04
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	8.00 >
ALBUMINE	52-68 (%)	01/06/91	55.80
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	262.00
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	113.00
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	2.60
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	11.90 >
GLOBULINS BETA	9.5-14 (%)	01/06/91	13.80
GLOBULINS GAMMA	12-21 (%)	01/06/91	15.80
TSH	1-5 (UU/ML)	01/06/91	
T4	4.5-13 (UG/DL)	01/06/91	

(€) << 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 800~~ 9580085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centro: 9 Patient: 206 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			28/01/92		26/02/92		18/03/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	10.70	<	8.86	<<	8.86 <<	
HT	37-54 (X)	01/06/91	34.30	<	32.20	<	27.20 <<	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	5.14		4.20		4.18	
WBC	4-10 (10 ³ /MM ³)	01/06/91	8.40		6.52		6.52	
WBC: N	40-70 (X)	01/06/91	66.30					
WBC: L	19-48 (X)	01/06/91	27.20					
WBC: E	0-7 (X)	01/06/91	0.37					
WBC: M	3.4-9 (X)	01/06/91	5.77					
WBC: B	0-1.5 (X)	01/06/91	0.36					
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	369.00	>	313.00		313.00	
NA+	135-145 (MMOL/L)	01/06/91	141.00		141.00		141.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.00		5.10	>	5.69 >	
CL-	98-108 (MMOL/L)	01/06/91	100.00		101.00		101.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.06		8.80		8.80	
PO4--	2.1-4 (MG/DL)	01/06/91	3.40		2.84		2.84	
SGOT	11-33 (U/L)	01/06/91	14.00		14.00		14.00	
SGPT	11-39 (U/L)	01/06/91	14.00		13.00		13.00	
GAMMA GT	5-55 (U/L)	01/06/91	10.00		11.00		9.00	
LDH	200-450 (U/L)	01/06/91	265.00		269.00		44.00 <	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	70.00		67.00		67.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.94		0.78		0.78	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.38		0.28		0.28	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.98		1.00		1.00	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	2.50	<	2.60	<	2.60 <	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.37		0.16		0.16	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.09		0.04		0.04	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.50		6.40	<	6.40 <	
ALBUMINE	52-68 (X)	01/06/91	53.40		60.00		60.00	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	213.00		183.00		183.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	100.00		97.00		97.00	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	3.00		2.90		2.90	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	11.20	>	8.70		8.70	
GLOBULINS BETA	9.5-14 (X)	01/06/91	15.50	>	13.20		13.20	
GLOBULINS GAMMA	12-21 (X)	01/06/91	17.00		16.20		15.20	
TSH	1-5 (UU/ML)	01/06/91	0.26					
T4	4.5-13 (UG/DL)	01/06/91	6.60					

(€) << 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 880~~
3530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 209 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date
			Screen
			04/02/92
			value (⊕)
Laboratory test	Range value	Range date	
HB	13-18 (G/DL)	01/06/91	15.40
HT	37-54 (X)	01/06/91	44.60
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	5.16
WBC	4-10 (10 ³ /MM ³)	01/06/91	5.09
WBC: N	40-70 (X)	01/06/91	57.30
WBC: L	19-48 (X)	01/06/91	29.90
WBC: E	0-7 (X)	01/06/91	1.92
WBC: M	3.4-9 (X)	01/06/91	10.80 >
WBC: B	0-1.5 (X)	01/06/91	0.09
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	281.00
NA+	135-145 (MMOL/L)	01/06/91	145.00
K+	3.5-5 (MMOL/L)	01/06/91	4.30
CL-	98-108 (MMOL/L)	01/06/91	103.00
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.36
PO4--	2.1-4 (MG/DL)	01/06/91	2.66
SGOT	11-33 (U/L)	01/06/91	27.00
SGPT	11-39 (U/L)	01/06/91	36.00
GAMMA GT	15-85 (U/L)	01/06/91	42.00
LDH	200-450 (U/L)	01/06/91	285.00
ALK. PHOSPH.	34-154 (U/L)	01/06/91	103.00
GLUCOSE	0.6-1 (G/L)	01/06/91	0.80
BUN	()	01/06/91	
UREA	0.18-0.43 (G/L)	01/06/91	0.31
CREATININE	0.7-1.3 (MG/DL)	01/06/91	1.11
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	6.00
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.94
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.19
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.50
ALBUMINE	52-68 (X)	01/06/91	63.70
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	187.00
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	86.00
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	1.90 <
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	7.40
GLOBULINS BETA	9.5-14 (X)	01/06/91	11.30
GLOBULINS GAMMA	12-21 (X)	01/06/91	15.80
TSH	1-5 (UU/ML)	01/06/91	0.58
T4	4.5-13 (UG/DL)	01/06/91	8.10

(⊕) << 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 840
9530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 212 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/02/92		24/03/92		14/04/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	13.40		13.70		14.10	
HT	37-54 (X)	01/06/91	38.80		40.00		41.80	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.35		4.53		4.71	
HBC	4-10 (10 ³ /MM ³)	01/06/91	8.56		8.64		8.62	
HBC: N	40-70 (X)	01/06/91	52.30		52.60		55.60	
HBC: L	19-48 (X)	01/06/91	35.20		37.20		34.60	
HBC: E	0-7 (X)	01/06/91	1.03		0.85		1.36	
HBC: M	3.4-9 (X)	01/06/91	9.95	>	6.47		6.60	
HBC: B	0-1.5 (X)	01/06/91	1.47		2.94	>>	1.87	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	255.00		307.00		260.00	
NA+	135-145 (MMOL/L)	01/06/91	141.00		135.00		139.00	
K+	3.5-5 (MMOL/L)	01/06/91			3.56		4.59	
CL-	98-108 (MMOL/L)	01/06/91	98.00		90.00	<	99.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	10.00		9.64		9.71	
PO4--	2.1-4 (MG/DL)	01/06/91	2.91		2.88		2.80	
SGOT	11-33 (U/L)	01/06/91	17.00		21.00		23.00	
SGPT	11-39 (U/L)	01/06/91	12.00		16.00		16.00	
GAMMA GT	5-55 (U/L)	01/06/91	11.00		15.00		13.00	
LDH	200-450 (U/L)	01/06/91	327.00		328.00		432.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	64.00		70.00		74.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.84		0.82		0.71	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.22		0.16	<	0.20	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.88		0.90		0.98	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	3.60		3.60		3.60	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.27		0.31		0.28	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.06		0.06			
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.80		7.90		7.60	
ALBUMINE	52-68 (X)	01/06/91	57.70		53.40		50.00	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	240.00		263.00		259.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	112.00		115.00		208.00	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	3.20		3.20		3.60	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	12.10	>	13.60	>	13.90	
GLOBULINS BETA	9.5-14 (X)	01/06/91	12.60		15.20	>	14.60	
GLOBULINS GAMMA	12-21 (X)	01/06/91	14.20		14.70		18.00	
TSH	1-5 (UU/ML)	01/06/91	0.55					
T4	4.5-13 (UG/DL)	01/06/91	13.90					

(€) << 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)

PHARNACIA 095 58085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centro: 9 Patient: 238 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			12/05/92		09/06/92		30/06/92	
			value	(ø)	value	(ø)	value	(ø)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	15.10		14.80		14.40	
HT	37-54 (%)	01/06/91	44.70		43.60		43.20	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.65		4.56		4.38	
HBC	4-10 (10 ³ /MM ³)	01/06/91	9.27		9.82		12.90 >	
HBC: N	40-70 (%)	01/06/91	64.70		64.30		77.00 >	
HBC: L	19-48 (%)	01/06/91	23.60		27.70		16.00 <	
HBC: E	0-7 (%)	01/06/91	0.94		1.17		1.00	
HBC: H	3.4-9 (%)	01/06/91	10.40 >		6.15		5.00	
HBC: B	0-1.5 (%)	01/06/91	0.41		0.63		1.00	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	231.00		359.00 >		290.00	
NA+	135-145 (MMOL/L)	01/06/91	143.00		138.00		142.00	
K+	3.5-5 (MMOL/L)	01/06/91	3.75		4.28		4.17	
CL-	98-108 (MMOL/L)	01/06/91	102.00		101.00		101.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.70		10.60 >		10.10	
PO4--	2.1-4 (MG/DL)	01/06/91	2.99		4.01 >		3.96	
SGOT	11-33 (U/L)	01/06/91	20.00		21.00		18.00	
SGPT	11-39 (U/L)	01/06/91	25.00		34.00		16.00	
GAMMA GT	5-55 (U/L)	01/06/91	36.00		48.00		40.00	
LDH	200-450 (U/L)	01/06/91	367.00		355.00		375.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	54.00		52.00		46.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.65		0.86		1.03 >	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.34		0.35		0.45 >	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	1.09		1.27		1.05	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.60		4.20		4.60	
TOT BILLIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.26		0.48		0.61	
DIR BILLIRUBIN	0-0.36 (MG/DL)	01/06/91	0.05		0.10		0.11	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	6.90		7.40		7.20	
ALBUMINE	52-68 (%)	01/06/91	51.10 <		54.40		52.60	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	293.00 >		307.00 >		278.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	150.00		133.00		112.00	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	4.20		3.50		3.50	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	13.30 >		12.90 >		13.40 >	
GLOBULINS BETA	9.5-14 (%)	01/06/91	15.20 >		14.50 >		14.60 >	
GLOBULINS GAMMA	12-21 (%)	01/06/91	16.20		14.70		15.90	
TSH	1-5 (UU/ML)	01/06/91	1.37					
T4	4.5-13 (UG/DL)	01/06/91	9.80					

(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

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CHEMIE 9530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 239 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/04/92		20/05/92		10/06/92	
			value	(ϕ)	value	(ϕ)	value	(ϕ)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/06/91	14.50		14.90		14.60	
HT	37-54 (%)	01/06/91	43.20		45.30		43.60	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	5.16		5.34		5.50	
HBC	4-10 (10 ³ /MM ³)	01/06/91	6.43		6.75		6.53	
HBC: N	40-70 (%)	01/06/91	49.50		55.20		47.90	
HBC: L	19-48 (%)	01/06/91	40.00		35.20		41.70	
HBC: E	0-7 (%)	01/06/91	2.14		3.21		3.19	
HBC: H	3.4-9 (%)	01/06/91	7.51		6.35		7.13	
HBC: B	0-1.5 (%)	01/06/91	0.84				0.16	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	252.00		216.00		210.00	
NA+	135-145 (MMOL/L)	01/06/91	143.00		144.00		140.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.34		4.06		4.27	
CL-	98-108 (MMOL/L)	01/06/91	104.00		101.00		101.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.54		9.33		9.31	
PO4--	2.1-4 (MG/DL)	01/06/91	4.08 >		3.39		3.70	
SGOT	11-33 (U/L)	01/06/91	33.00		36.00 >		32.00	
SGPT	11-39 (U/L)	01/06/91	30.00		55.00 >		43.00 >	
GAMMA GT	15-85 (U/L)	01/06/91	21.00		26.00		26.00	
LDH	200-450 (U/L)	01/06/91	328.00		313.00		325.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	102.00		109.00		93.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	1.02 >		1.04 >		0.99	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.32		0.29		0.30	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	1.04		1.15		1.07	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	8.10 >		8.20 >		8.20 >	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.47		0.29		0.97	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.08		0.12		0.12	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.60		7.50		7.20	
ALBUMINE	52-68 (%)	01/06/91	59.90		61.80		58.40	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	193.00		207.00		203.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	195.00 >		317.00 >>		187.00 >	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	2.90		2.40 <		2.10 <	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	8.90		6.20		8.10	
GLOBULINS BETA	9.5-14 (%)	01/06/91	14.10 >		12.80		19.70 >>	
GLOBULINS GAMMA	12-21 (%)	01/06/91	14.20		16.80		10.60 <	
TSH	1-5 (U/ML)	01/06/91	1.31					
T4	4.5-13 (UG/DL)	01/06/91	8.10					

(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 (ϕ) missing range value

1282

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS 840
3530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9 Patient: 241 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/05/92		29/05/92		17/06/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HR	11-16 (G/DL)	01/06/91	14.10		12.40		14.10	
HT	37-54 (X)	01/06/91	42.60		37.40		42.50	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.62		4.04		4.60	
WBC	4-10 (10 ³ /MM ³)	01/06/91	6.91		6.28		6.06	
WBC: N	40-70 (X)	01/06/91	64.00		67.10		66.70	
WBC: L	19-48 (X)	01/06/91	24.00		23.10		22.10	
WBC: E	0-7 (X)	01/06/91	1.00		1.83		2.87	
WBC: M	3.4-9 (X)	01/06/91	5.00		7.53		7.46	
WBC: B	0-1.5 (X)	01/06/91	3.00	>>	0.42		0.85	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	54.60	<<	173.00		146.00 <	
NA+	135-145 (MMOL/L)	01/06/91	142.00		142.00		142.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.37		3.98		3.92	
CL-	98-108 (MMOL/L)	01/06/91	102.00		103.00		103.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.61		8.43 <		9.08	
PO4--	2.1-4 (MG/DL)	01/06/91	2.30		2.07 <		3.11	
SGOT	11-33 (U/L)	01/06/91	15.00		11.00		13.00	
SGPT	11-39 (U/L)	01/06/91	17.00		13.00		18.00	
GAMMA GT	5-55 (U/L)	01/06/91	25.00		25.00		40.00	
LDH	200-450 (U/L)	01/06/91	272.00		218.00		242.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	59.00		53.00		63.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.91		0.87		1.01 >	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.34		0.27		0.37	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.92		0.97		1.00	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	3.90		4.90		4.70	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.83		0.30		0.79	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91			0.08			
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	6.90		5.70 <		6.50 <	
ALBUMINE	52-68 (X)	01/06/91	62.70		61.00		63.20	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	261.00		184.00		285.00 >	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	72.00		91.00		99.00	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	2.10	<	2.50		2.20 <	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	8.50		12.60 >		8.80	
GLOBULINS BETA	9.5-14 (X)	01/06/91	12.90		12.60		14.60 >	
GLOBULINS GAMMA	12-21 (X)	01/06/91	13.90		11.20 <		11.20 <	
TSH	1-5 (UU/ML)	01/06/91	0.22					
T4	4.5-13 (UG/DL)	01/06/91	7.50					

(€) << 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 20124/017

Listing No.: 18.0

LABORATORY DATA 0550085

Centre: 9 Patient: 243 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/05/92		08/06/92		29/06/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	13.70		14.00		14.20	
HT	37-54 (%)	01/06/91	40.40		41.10		42.10	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.52		4.58		4.69	
WBC	4-10 (10 ³ /MM ³)	01/06/91	8.99		8.47		9.31	
WBC: N	40-70 (%)	01/06/91	74.50 >		74.00 >		68.00	
WBC: L	19-48 (%)	01/06/91	16.80 <		16.00 <		21.50	
WBC: E	0-7 (%)	01/06/91	1.22		3.57		4.87	
WBC: M	3.4-9 (%)	01/06/91	6.96		5.82		4.90	
WBC: B	0-1.5 (%)	01/06/91	0.47		0.56		0.77	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	376.00 >		397.00 >		456.00 >>	
NA+	135-145 (MMOL/L)	01/06/91	138.00		139.00		140.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.72		4.47		4.43	
CL-	98-108 (MMOL/L)	01/06/91	96.00 <		96.00 <		100.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.53		9.67		9.45	
PO4--	2.1-4 (MG/DL)	01/06/91	2.85		3.52		3.88	
SGOT	11-33 (U/L)	01/06/91	15.00		13.00		17.00	
SGPT	11-39 (U/L)	01/06/91	16.00		15.00		16.00	
GAMMA GT	5-55 (U/L)	01/06/91	45.00		32.00		40.00	
LDH	200-450 (U/L)	01/06/91	275.00		257.00		295.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	82.00		84.00		114.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.76		0.82		1.29 >	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.17 <		0.17 <		0.19	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.77		0.77		0.84	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	3.20 <		3.60		3.60	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.59		0.76		0.40	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.13		0.16		0.08	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.70		7.40		7.40	
ALBUMINE	52-68 (%)	01/06/91	53.30		55.50		50.20 <	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	201.00		263.00		247.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	187.00 >		182.00 >		308.00 >>	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	3.70		6.70 >>		3.20	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	10.10		8.60		11.80 >	
GLOBULINS BETA	9.5-14 (%)	01/06/91	14.50 >		11.70		16.30 >	
GLOBULINS GAMMA	12-21 (%)	01/06/91	18.40		17.50		18.50	
TSH	1-5 (UU/ML)	01/06/91	0.84					
T4	4.5-13 (UG/DL)	01/06/91	13.80					

(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

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 259 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			05/07/91		07/08/91		28/08/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	13.90		16.00		13.90	
HT	37-54 (%)	01/06/91	37.30		38.20		38.10	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.12		4.18		4.19	
WBC	4-10 (10 ³ /MM ³)	01/06/91	6.91		7.15		8.14	
WBC: N	40-70 (%)	01/06/91	66.70		58.80		57.20	
WBC: L	19-48 (%)	01/06/91	28.40		34.80		36.80	
WBC: E	0-7 (%)	01/06/91	0.25		0.91		1.02	
WBC: M	3.4-9 (%)	01/06/91	4.47		5.07		3.63	
WBC: B	0-1.5 (%)	01/06/91	0.19		0.41		1.30	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	297.00		340.00		349.00	
NA+	135-145 (MMOL/L)	01/06/91	147.00	>	142.00		145.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.13		4.05		4.25	
CL-	98-108 (MMOL/L)	01/06/91	104.00		99.00		105.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	10.00		8.80		9.40	
PO4--	2.1-4 (MG/DL)	01/06/91	2.60		3.60		3.60	
SGOT	11-33 (U/L)	01/06/91	22.00		20.00		25.00	
SGPT	11-39 (U/L)	01/06/91	8.00	<	11.00		18.00	
GAMMA GT	5-55 (U/L)	01/06/91	27.00		26.00		59.00	
LDH	200-450 (U/L)	01/06/91	306.00		315.00		323.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	60.00		72.00		87.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.91		0.88		1.01	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.38					
CREATININE	0.7-1.3 (NG/DL)	01/06/91	0.94		1.07		1.31	
URIC ACID	3.4-7.3 (NG/DL)	01/06/91	4.30		3.10	<	3.50	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.69		0.19		0.33	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.11		0.09			
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.90		6.80		7.20	
ALBUMINE	52-68 (%)	01/06/91	58.50					
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	147.00	<	154.00	<	170.00	
TRIGLICERIDES	68-162 (MG/DL)	01/06/91	68.00		253.00	>>	230.00	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	3.50					
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	9.60					
GLOBULINS BETA	9.5-14 (%)	01/06/91	12.10					
GLOBULINS GAMMA	12-21 (%)	01/06/91	17.30					
TSH	1-5 (UU/ML)	01/06/91						
T4	4.5-13 (UG/DL)	01/06/91						

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 260 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			17/07/91		14/08/91	
			value	(φ)	value	(φ)
Laboratory test	Range value	Range date				
HB	11-16 (G/DL)	01/06/91	14.70		15.90	
HT	37-54 (Z)	01/06/91	42.10		43.70	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.59		4.78	
MBC	4-10 (10 ³ /MM ³)	01/06/91	10.10 >		9.83	
MBC: N	40-70 (Z)	01/06/91	73.00 >		66.00	
MBC: L	19-48 (Z)	01/06/91	10.00 <<		18.00 <	
MBC: E	0-7 (Z)	01/06/91	3.00		2.00	
MBC: M	3.4-9 (Z)	01/06/91	12.00 >>		9.00	
MBC: B	0-1.5 (Z)	01/06/91	2.00 >>		1.00	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	270.00		279.00	
NA+	135-145 (MMOL/L)	01/06/91			143.00	
K+	3.5-5 (MMOL/L)	01/06/91			3.84	
CL-	98-108 (MMOL/L)	01/06/91			99.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91			9.40	
PO4--	2.1-4 (MG/DL)	01/06/91			4.40 >	
SGOT	11-33 (U/L)	01/06/91			47.00 >	
SGPT	11-39 (U/L)	01/06/91			54.00 >	
GAMMA GT	5-55 (U/L)	01/06/91			33.00	
LDH	200-450 (U/L)	01/06/91			509.00 >	
ALK. PHOSPH.	34-154 (U/L)	01/06/91			75.00	
GLUCOSE	0.6-1 (G/L)	01/06/91			1.09 >	
BUN	()	01/06/91				
UREA	0.18-0.43 (G/L)	01/06/91				
CREATININE	0.7-1.3 (MG/DL)	01/06/91			0.85	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91			6.10	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91			0.43	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91			0.03	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91			7.90	
ALBUMINE	52-68 (Z)	01/06/91				
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	157.00		185.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	76.00		98.00	
GLOBULINS ALPHA 1	2.5-4.8 (Z)	01/06/91				
GLOBULINS ALPHA 2	6.2-11 (Z)	01/06/91				
GLOBULINS BETA	9.5-14 (Z)	01/06/91				
GLOBULINS GAMMA	12-21 (Z)	01/06/91				
TSH	1-5 (UU/ML)	01/06/91	0.91			
T4	4.5-13 (UG/DL)	01/06/91	9.40			

(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 (φ) 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 261 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 7	
			19/07/91		30/07/91	
			value	(€)	value	(€)
Laboratory test	Range value	Range date				
HB	11-16 (G/DL)	01/06/91	14.40		14.30	
HT	37-54 (X)	01/06/91	41.80		42.10	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.61		4.57	
MBC	4-10 (10 ³ /MM ³)	01/06/91	6.98		5.70	
MBC: N	40-70 (X)	01/06/91	46.20		39.70 <	
MBC: L	19-48 (X)	01/06/91	40.80		47.00	
MBC: E	0-7 (X)	01/06/91	5.09		4.60	
MBC: M	3.4-9 (X)	01/06/91	7.28		8.04	
MBC: B	0-1.5 (X)	01/06/91	0.71		0.74	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	241.00		279.00	
NA+	135-145 (MMOL/L)	01/06/91	138.00		141.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.37		4.42	
CL-	98-108 (MMOL/L)	01/06/91	104.00		102.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.10		9.40	
PO4--	2.1-4 (MG/DL)	01/06/91	3.60			
SGOT	11-33 (U/L)	01/06/91	31.00		17.00	
SGPT	11-39 (U/L)	01/06/91	39.00		18.00	
GAMMA GT	5-55 (U/L)	01/06/91	60.00 >		35.00	
LDH	200-450 (U/L)	01/06/91	432.00		355.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	96.00		81.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.96		0.88	
BUN	()	01/06/91				
UREA	0.18-0.43 (G/L)	01/06/91	0.22		0.26	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.98		0.86	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.30		4.30	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.68		0.58	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.14		0.14	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.49		7.10	
ALBUMINE	52-68 (X)	01/06/91	51.50 <		52.40	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	200.00		179.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	181.00 >			
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	2.20 <		2.30 <	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	8.20		7.90	
GLOBULINS BETA	9.5-14 (X)	01/06/91	14.40 >		13.00	
GLOBULINS GAMMA	12-21 (X)	01/06/91	23.70 >		24.50 >	
TSH	1-5 (UU/ML)	01/06/91	3.13			
T4	4.5-13 (UG/DL)	01/06/91	8.60			

(€) << 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 20124/017
Listing No.: 18.0

0550085

LABORATORY DATA

Centre: 9 Patient: 264 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			24/07/91		21/08/91		11/09/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	12.60		12.20		12.40	
HT	37-54 (%)	01/06/91	37.10		36.00 <		36.60 <	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.21		4.14		4.19	
WBC	4-10 (10 ³ /MM ³)	01/06/91	5.23		7.55		4.69	
WBC: N	40-70 (%)	01/06/91	52.80		66.70		63.80	
WBC: L	19-48 (%)	01/06/91	38.80		24.70		28.90	
WBC: E	0-7 (%)	01/06/91	1.93		1.57		0.84	
WBC: M	3.4-9 (%)	01/06/91	5.23		6.49		5.41	
WBC: B	0-1.5 (%)	01/06/91	1.96 >>		0.55		1.06	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	201.00		211.00		217.00	
NA+	135-145 (MMOL/L)	01/06/91	142.00		143.00		146.00 >	
K+	3.5-5 (MMOL/L)	01/06/91	4.22		3.86		4.49	
CL-	98-108 (MMOL/L)	01/06/91	102.00		101.00		106.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.70		9.30		9.50	
PO4--	2.1-4 (MG/DL)	01/06/91	3.10		3.50		3.30	
SGOT	11-33 (U/L)	01/06/91	14.00		13.00		11.00	
SGPT	11-39 (U/L)	01/06/91	15.00		5.00 <		9.00 <	
GAMMA GT	5-55 (U/L)	01/06/91	21.00		18.00		18.00	
LDH	200-450 (U/L)	01/06/91	333.00		268.00		269.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	40.00		56.00		57.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.97		1.19 >		0.88	
BUN	()	01/06/91					0.36	
UREA	0.18-0.43 (G/L)	01/06/91					0.87	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.93		0.92		3.40	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91			4.00		0.43	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.60		0.33		0.10	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.05		0.09		6.90	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.60		7.90			
ALBUMINE	52-68 (%)	01/06/91						
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	215.00		195.00		232.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	81.00		74.00		75.00	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91						
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91						
GLOBULINS BETA	9.5-14 (%)	01/06/91						
GLOBULINS GAMMA	12-21 (%)	01/06/91						
TSH	1-5 (UU/ML)	01/06/91	1.60					
T4	4.5-13 (UG/DL)	01/06/91	10.80					

(€) << 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 20124/017
Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 9 Patient: 267 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			30/08/91		23/09/91		14/10/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/06/91	16.40		16.00		16.70	
HT	37-54 (X)	01/06/91	47.40		49.50		49.30	
RBC	4-6.2 (10 ⁶ /MM3)	01/06/91	5.04		5.26		5.29	
WBC	4-10 (10 ³ /MM3)	01/06/91	6.93		8.22		7.28	
WBC: N	40-70 (X)	01/06/91	61.10		60.70		62.20	
WBC: L	19-48 (X)	01/06/91	31.10		29.10		28.20	
WBC: E	0-7 (X)	01/06/91	2.48		2.87		3.02	
WBC: M	3.4-9 (X)	01/06/91	5.04		6.53		4.94	
WBC: B	0-1.5 (X)	01/06/91	1.32		0.82		1.71	
PLATELETS	150-350 (10 ³ /MM3)	01/06/91	343.00		266.00		284.00	
NA+	135-145 (MMOL/L)	01/06/91	143.00		144.00		144.00	
K+	3.5-5 (MMOL/L)	01/06/91	3.91		3.82		4.31	
CL-	98-108 (MMOL/L)	01/06/91	105.00		103.00		100.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.80		10.20		10.60	
PO4--	2.1-4 (MG/DL)	01/06/91	3.90		4.80	>>	4.20	
SGOT	11-33 (U/L)	01/06/91	27.00		33.00		26.00	
SGPT	11-39 (U/L)	01/06/91	53.00	>	37.00		27.00	
GAMMA GT	15-85 (U/L)	01/06/91	77.00		53.00		28.00	
LDH	200-450 (U/L)	01/06/91	330.00				348.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	69.00		79.00		73.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	1.43	>>	0.93		0.97	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.58	>	0.29		0.39	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.80		1.02		0.92	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.10		4.00		5.40	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.63		0.58		0.76	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.16		0.10		0.02	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.00		7.30		7.20	
ALBUMINE	52-68 (X)	01/06/91	66.20		63.40		63.40	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	179.00		125.00	<	224.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	106.00		115.00		95.00	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	2.20	<	2.60		3.00	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	8.30		9.30		8.80	
GLOBULINS BETA	9.5-14 (X)	01/06/91	11.00		10.90		11.60	
GLOBULINS GAMMA	12-21 (X)	01/06/91	12.20		13.90		13.40	
TSH	1-5 (UU/ML)	01/06/91	1.35					
T4	4.5-13 (UG/DL)	01/06/91	9.70					

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 268 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			17/09/91		15/10/91		05/11/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/06/91	14.70		14.90		14.40	
HT	37-54 (%)	01/06/91	43.00		43.00		42.40	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.74		4.79		4.66	
WBC	4-10 (10 ³ /MM ³)	01/06/91	6.56		6.69		6.32	
WBC: N	40-70 (%)	01/06/91	61.00		58.80		50.70	
WBC: L	19-48 (%)	01/06/91	31.10		34.10		41.30	
WBC: E	0-7 (%)	01/06/91	1.82		1.16		2.02	
WBC: M	3.4-9 (%)	01/06/91	5.08		4.48		5.06	
WBC: B	0-1.5 (%)	01/06/91	1.07		1.56	>	0.88	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	321.00		342.00		378.00 >	
NA+	135-145 (MMOL/L)	01/06/91	140.00		141.00		140.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.49		3.86		4.77	
CL-	98-108 (MMOL/L)	01/06/91	103.00		100.00		99.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.70		9.70		9.30	
PO4--	2.1-4 (MG/DL)	01/06/91	2.80		3.30		3.40	
SGOT	11-33 (U/L)	01/06/91	22.00		18.00		20.00	
SGPT	11-39 (U/L)	01/06/91	33.00		22.00		27.00	
GAMMA GT	5-55 (U/L)	01/06/91	17.00		18.00		26.00	
LDH	200-450 (U/L)	01/06/91	349.00		327.00		381.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	66.00		72.00		82.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.89		0.75		0.64	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.29		0.30		0.34	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.89		0.98		0.93	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	6.40		5.60		5.30	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.35		0.33		0.43	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.04		0.08		0.05	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.70		7.80		7.90	
ALBUMINE	52-68 (%)	01/06/91	54.20		62.80		52.40	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	183.00		215.00		218.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	53.00 <		179.00 >		123.00	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	3.30		1.80 <		2.50	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	10.10		6.10 <		10.20	
GLOBULINS BETA	9.5-14 (%)	01/06/91	14.90 >		14.20 >		16.40 >	
GLOBULINS GAMMA	12-21 (%)	01/06/91	17.60		15.10		18.40	
TSH	1-5 (UU/ML)	01/06/91	1.48					
T4	4.5-13 (UG/DL)	01/06/91	8.20					

(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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 270 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			02/10/91
			value (†)
Laboratory test	Range value	Range date	
HB	11-16 (G/DL)	01/06/91	13.30
HT	37-54 (%)	01/06/91	39.40
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.35
WBC	4-10 (10 ³ /MM ³)	01/06/91	5.12
WBC: N	40-70 (%)	01/06/91	34.20 <
WBC: L	19-48 (%)	01/06/91	57.90 >
WBC: E	0-7 (%)	01/06/91	0.85
WBC: M	3.4-9 (%)	01/06/91	6.47
WBC: B	0-1.5 (%)	01/06/91	0.56
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	272.00
NA+	135-145 (MMOL/L)	01/06/91	141.00
K+	3.5-5 (MMOL/L)	01/06/91	4.23
CL-	98-108 (MMOL/L)	01/06/91	100.00
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.20
PO4--	2.1-4 (MG/DL)	01/06/91	3.20
SGOT	11-33 (U/L)	01/06/91	18.00
SGPT	11-39 (U/L)	01/06/91	15.00
GAMMA GT	5-55 (U/L)	01/06/91	22.00
LDH	200-450 (U/L)	01/06/91	192.00 <
ALK. PHOSPH.	34-154 (U/L)	01/06/91	36.00
GLUCOSE	0.6-1 (G/L)	01/06/91	1.29 >
BUN	()	01/06/91	
UREA	0.18-0.43 (G/L)	01/06/91	0.26
CREATININE	0.7-1.3 (MG/DL)	01/06/91	1.02
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	3.20 <
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.36
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.11
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.30
ALBUMINE	52-68 (%)	01/06/91	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	
GLOBULINS BETA	9.5-14 (%)	01/06/91	
GLOBULINS GAMMA	12-21 (%)	01/06/91	
TSH	1-5 (UU/ML)	01/06/91	10.60
T4	4.5-13 (UG/DL)	01/06/91	1.09

(†) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 272 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/10/91		19/11/91		10/12/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/06/91	16.10		16.30		16.70	
HT	37-54 (%)	01/06/91	48.80		47.70		51.30	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	5.26		5.21		5.47	
HBC	4-10 (10 ³ /MM ³)	01/06/91	7.63		7.76		7.01	
HBC: N	40-70 (%)	01/06/91	64.10		65.40		69.00	
HBC: L	19-48 (%)	01/06/91	24.50		20.90		18.00 <	
HBC: E	0-7 (%)	01/06/91	3.55		7.90 >		6.00	
HBC: M	3.4-9 (%)	01/06/91	4.43		4.67		7.00	
HBC: B	0-1.5 (%)	01/06/91	3.51 >>		1.17		0.00	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	279.00		259.00		266.00	
NA+	135-145 (MMOL/L)	01/06/91	143.00		140.00		143.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.84		4.49		3.88	
CL-	98-108 (MMOL/L)	01/06/91	100.00		98.00		95.00 <	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.50		9.80		10.00	
PO4--	2.1-4 (MG/DL)	01/06/91	1.20 <<		1.60 <<		2.30	
SGOT	11-33 (U/L)	01/06/91	22.00		17.00		24.00	
SGPT	11-39 (U/L)	01/06/91	16.00		14.00		21.00	
GAMMA GT	15-85 (U/L)	01/06/91	30.00		19.00		23.00	
LDH	200-450 (U/L)	01/06/91	343.00		296.00		308.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	78.00		68.00		83.00 >	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.84		0.81		1.14 >	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.34		0.67 >>		0.37	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	1.23		1.37 >		1.41 >	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.60		5.40		5.10	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.44		0.60		0.56	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.11		0.10		0.12	
ALB.	6.7-7.9 (G/DL)	01/06/91	7.60		7.10		7.80	
TOT. PROTEINS								
ALBUMINE	52-68 (%)	01/06/91	56.30		63.80		52.50	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	232.00		174.00		246.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	228.00 >>		142.00		162.00	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	3.50		2.50		2.50	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	11.60 >		8.60		12.10 >	
GLOBULINS BETA	9.5-14 (%)	01/06/91	14.30 >		13.00		18.40 >>	
GLOBULINS GAMMA	12-21 (%)	01/06/91	14.30		12.10		14.40	
TSH	1-5 (UU/ML)	01/06/91	7.70					
T4	4.5-13 (UG/DL)	01/06/91	3.28					

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 273 Treatment: Imipramine Sex: Female

Laboratory test	Range value	Range date	Visit number / Laboratory date			
			Screen		Day 21	
			24/10/91		19/11/91	
			value	(€)	value	(€)
HB	11-16 (G/DL)	01/06/91	14.90		14.70	
HT	37-54 (X)	01/06/91	42.60		43.10	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.60		4.65	
WBC	4-10 (10 ³ /MM ³)	01/06/91	6.87		8.46	
WBC: N	40-70 (X)	01/06/91	65.00		63.80	
WBC: L	19-48 (X)	01/06/91	28.10		25.40	
WBC: E	0-7 (X)	01/06/91	2.00		4.58	
WBC: M	3.4-9 (X)	01/06/91	4.44		4.97	
WBC: B	0-1.5 (X)	01/06/91	0.42		1.28	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	322.00		318.00	
NA+	135-145 (MMOL/L)	01/06/91	140.00		141.00	
K+	3.5-5 (MMOL/L)	01/06/91	4.60		4.23	
CL-	98-108 (MMOL/L)	01/06/91	101.00		100.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.20		9.70	
PO4--	2.1-4 (MG/DL)	01/06/91	3.00		2.50	
SGOT	11-33 (U/L)	01/06/91	17.00		16.00	
SGPT	11-39 (U/L)	01/06/91	21.00		14.00	
GAMMA GT	5-55 (U/L)	01/06/91	14.00		13.00	
LDH	200-450 (U/L)	01/06/91	353.00		334.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	55.00		60.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.85		0.65	
BUN	()	01/06/91				
UREA	0.18-0.43 (G/L)	01/06/91	0.36		0.28	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.83		0.89	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	3.10	<	3.70	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.57		0.42	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.11		0.08	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.90		7.90	
ALBUMINE	52-68 (X)	01/06/91	55.00		53.10	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	232.00		205.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	52.00	<	93.00	
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	3.00		3.30	
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	10.80		9.60	
GLOBULINS BETA	9.5-14 (X)	01/06/91	13.80		11.50	
GLOBULINS GAMMA	12-21 (X)	01/06/91	17.40		14.20	
TSH	1-5 (UU/ML)	01/06/91	1.72			
T4	4.5-13 (UG/DL)	01/06/91	7.60			

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PHARNACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9 Patient: 276 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 7
			24/12/91	16/01/92
			value (⊕)	value (⊕)
Laboratory test	Range value	Range date		
HB	11-16 (G/DL)	01/06/91	13.70	11.80
HT	37-54 (X)	01/06/91	42.10	35.60 <
RBC	4-6.2 (10 ⁶ /MM3)	01/06/91	4.38	3.74 <
MBC	4-10 (10 ³ /MM3)	01/06/91	8.17	7.11
MBC: N	40-70 (X)	01/06/91	69.90	61.50
MBC: L	19-48 (X)	01/06/91	24.00	30.10
MBC: E	0-7 (X)	01/06/91	0.06	1.73
MBC: M	3.4-9 (X)	01/06/91	5.13	5.62
MBC: B	0-1.5 (X)	01/06/91	0.06	1.73 >
PLATELETS	150-350 (10 ³ /MM3)	01/06/91	275.00	278.00
NA+	135-145 (MMOL/L)	01/06/91	140.00	141.00
K+	3.5-5 (MMOL/L)	01/06/91	4.25	4.63
CL-	98-108 (MMOL/L)	01/06/91	95.00 <	102.00
Ca++	8.5-10.5 (MG/DL)	01/06/91	10.00	8.48 <
PO4--	2.1-4 (MG/DL)	01/06/91	4.20 >	3.71
SGOT	11-33 (U/L)	01/06/91	18.00	16.00
SGPT	11-39 (U/L)	01/06/91	16.00	12.00
GAMMA GT	5-55 (U/L)	01/06/91	14.00	11.00
LDH	200-450 (U/L)	01/06/91	281.00	282.00
ALK. PHOSPH.	34-154 (U/L)	01/06/91	48.00	53.00
GLUCOSE	0.6-1 (G/L)	01/06/91	0.81	0.82
BUN	()	01/06/91		
UREA	0.18-0.43 (G/L)	01/06/91	0.20	0.19
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.64 <	0.73
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	4.20	3.80
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.49	0.39
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.10	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.30	6.50 <
ALBUMINE	52-68 (X)	01/06/91	58.10	60.90
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	243.00	186.00
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	111.00	125.00
GLOBULINS ALPHA 1	2.5-4.8 (X)	01/06/91	3.30	3.00
GLOBULINS ALPHA 2	6.2-11 (X)	01/06/91	11.30 >	8.70
GLOBULINS BETA	9.5-14 (X)	01/06/91	11.20	11.50
GLOBULINS GAMMA	12-21 (X)	01/06/91	16.10	15.90
TSH	1-5 (UV/ML)	01/06/91	0.69	
T4	4.5-13 (UG/DL)	01/06/91	11.90	

(⊕) << 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 20124/017

Listing No.: 18.0

0550085

LABORATORY DATA

Centre: 9 Patient: 276/A Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			24/02/92		24/03/92		14/04/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/06/91	14.60		14.60		14.10	
HT	37-54 (%)	01/06/91	42.70		43.10		40.70	
RBC	4-6.2 (10 ⁶ /MM ³)	01/06/91	4.80		4.76		4.64	
WBC	4-10 (10 ³ /MM ³)	01/06/91	9.95		7.89		6.22	
WBC: N	40-70 (%)	01/06/91	57.00				53.70	
WBC: L	19-48 (%)	01/06/91	34.00				32.70	
WBC: E	0-7 (%)	01/06/91	5.00				4.12	
WBC: M	3.4-9 (%)	01/06/91	3.00	<			5.76	
WBC: B	0-1.5 (%)	01/06/91	1.00				3.70	
PLATELETS	150-350 (10 ³ /MM ³)	01/06/91	205.00		151.00		226.00 >>	
NA+	135-145 (MMOL/L)	01/06/91	144.00				138.00	
K+	3.5-5 (MMOL/L)	01/06/91	6.26	>>				
CL-	98-108 (MMOL/L)	01/06/91	99.00				102.00	
Ca++	8.5-10.5 (MG/DL)	01/06/91	9.56		9.59		9.13	
PO4--	2.1-4 (MG/DL)	01/06/91	3.93		8.42 >>		3.12	
SGOT	11-33 (U/L)	01/06/91	18.00		17.00		20.00	
SGPT	11-39 (U/L)	01/06/91	20.00		19.00		19.00	
GAMMA GT	15-85 (U/L)	01/06/91	16.00		17.00		14.00 <	
LDH	200-450 (U/L)	01/06/91	407.00		442.00		383.00	
ALK. PHOSPH.	34-154 (U/L)	01/06/91	80.00		102.00		93.00	
GLUCOSE	0.6-1 (G/L)	01/06/91	0.95				0.64	
BUN	()	01/06/91						
UREA	0.18-0.43 (G/L)	01/06/91	0.31		0.25		0.21	
CREATININE	0.7-1.3 (MG/DL)	01/06/91	0.88		1.12		1.00	
URIC ACID	3.4-7.3 (MG/DL)	01/06/91	6.50		5.40		6.20	
TOT BILIRUBIN	0.04-1.13 (MG/DL)	01/06/91	0.39		0.18		0.21	
DIR BILIRUBIN	0-0.36 (MG/DL)	01/06/91	0.08		0.03		0.04	
TOT. PROTEINS	6.7-7.9 (G/DL)	01/06/91	7.10		7.10		7.00	
ALBUMINE	52-68 (%)	01/06/91	68.40 >		55.90		65.70	
TOT. CHOLEST.	155-280 (MG/DL)	01/06/91	181.00		203.00		175.00	
TRIGLYCERIDES	62-162 (MG/DL)	01/06/91	242.00 >>		370.00 >>		237.00 >>	
GLOBULINS ALPHA 1	2.5-4.8 (%)	01/06/91	2.30 <		2.70		3.30	
GLOBULINS ALPHA 2	6.2-11 (%)	01/06/91	6.70		10.40		5.60 <	
GLOBULINS BETA	9.5-14 (%)	01/06/91	10.90		14.90 >		11.90	
GLOBULINS GAMMA	12-21 (%)	01/06/91	11.80 <		16.10		13.50	
TSH	1-5 (UU/ML)	01/06/91	0.57					
T4	4.5-13 (UG/DL)	01/06/91	6.60					

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9/A Patient: 233 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			13/05/92		03/06/92		24/06/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range data						
HB	14-18 (G/DL)	01/01/92	16.70		17.70		17.70	
HT	42-53 (%)	01/01/92	49.70		49.10		53.10 >	
RBC	4.5-6.2 (10 ⁶ /MM ³)	01/01/92	5.21		5.22		5.43	
WBC	4000-10000 (/MM ³)	01/01/92	10100.0 >		8400.00		8200.00 >	
WBC: N	40-70 (%)	01/01/92	70.30 >		66.40		79.90 >	
WBC: L	20-50 (%)	01/01/92	25.20		23.50		15.10 <	
WBC: E	0-8 (%)	01/01/92	1.50		3.60		1.30	
WBC: M	0-13 (%)	01/01/92	2.70		5.40		3.60	
WBC: B	0-3 (%)	01/01/92	0.30		1.10		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	403.00 >		386.00		350.00 >	
NA+	136-147 (MMOL/L)	01/01/92	135.00 <		135.00 <		136.00	
K+	3.6-5.5 (MMOL/L)	01/01/92						
CL-	95-110 (MMOL/L)	01/01/92	100.00		100.00		102.00	
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.32		8.94		9.45	
PO4--	2-4.5 (MG/DL)	01/01/92	3.10		3.40		3.20	
SGOT	5-40 (U/L)	01/01/92	22.00		27.00		28.00	
SGPT	5-40 (U/L)	01/01/92	26.00		34.00		48.00 >	
GAMMA GT	0-60 (U/L)	01/01/92	36.00		42.00 >		39.00	
LDH	150-460 (U/L)	01/01/92	254.00		293.00		268.00	
ALK. PHOSPH.	40-350 (U/L)	01/01/92	279.00		309.00		261.00	
GLUCOSE	50-120 (MG/DL)	01/01/92	97.00		95.00		107.00	
BUN	()	01/01/92						
UREA	8-50 (MG/DL)	01/01/92	33.00		34.00		34.00	
CREATININE	0.3-1.38 (MG/DL)	01/01/92	0.95		0.89		0.89	
URIC ACID	2-7.5 (MG/DL)	01/01/92						
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.30		0.23		0.22	
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.11		0.01		0.09	
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	7.90		7.33		6.93	
ALBUMINE	55-72 (G)	01/01/92	59.50		62.60		65.70	
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	209.00		208.00		225.00	
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	124.00		228.00 >>		259.00 >>	
GLOBULINS ALPHA 1	2-6 (%)	01/01/92	3.20		2.50		2.60	
GLOBULINS ALPHA 2	6-11 (%)	01/01/92	9.00		7.90		7.40	
GLOBULINS BETA	9-14 (%)	01/01/92	11.60		9.50		10.60	
GLOBULINS GAMMA	10-20 (%)	01/01/92	16.70		17.50		13.70	
TSH	0.1-4 (U/ML)	01/01/92	0.42					
T4	4.8-12.8 (UG/DL)	01/01/92	7.50					

1296

(€) << 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 20124/017

Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 9/A Patient: 236 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			12/05/92		16/06/92		07/07/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/01/92	15.50		15.30		15.20	
HT	42-53 (Z)	01/01/92	42.80		45.50		44.10	
RBC	4.5-6.2 (10 ⁶ /MM ³)	01/01/92	4.82		5.13		5.04	
WBC	4000-10000 (/MM ³)	01/01/92	8200.00		7700.00		6500.00	
WBC: N	40-70 (%)	01/01/92	58.80		63.30		61.30	
WBC: L	20-50 (%)	01/01/92	31.00		30.80		31.60	
WBC: E	0-8 (%)	01/01/92	2.50		2.00		1.90	
WBC: M	0-13 (%)	01/01/92	7.50		3.60		5.10	
WBC: B	0-3 (%)	01/01/92	0.30		0.30		0.20	
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	288.00		324.00		295.00	
NA+	136-147 (MMOL/L)	01/01/92	138.00		140.00		140.00	
K+	3.6-5.5 (MMOL/L)	01/01/92	3.80		3.80		4.40	
CL-	95-110 (MMOL/L)	01/01/92	100.00		98.00		103.00	
Ca++	8.3-10.5 (MG/DL)	01/01/92	8.90		8.90		9.10	
PO4--	2-4.5 (MG/DL)	01/01/92	3.40				2.80	
SGOT	5-40 (U/L)	01/01/92	51.00 >		28.00		29.00	
SGPT	5-40 (U/L)	01/01/92	61.00 >		48.00 >		44.00 >	
GAMMA GT	0-40 (U/L)	01/01/92	30.00		30.00		31.00	
LDH	150-460 (U/L)	01/01/92	419.00		333.00		360.00	
ALK. PHOSPH.	40-350 (U/L)	01/01/92	174.00		191.00		199.00	
GLUCOSE	50-120 (MG/DL)	01/01/92	79.00		73.00		76.00	
BUN	()	01/01/92						
UREA	8-50 (MG/DL)	01/01/92	31.00		32.00		18.00	
CREATININE	0.3-1.38 (MG/DL)	01/01/92	0.98		1.04		1.02	
URIC ACID	2-7.5 (MG/DL)	01/01/92	4.99		4.13		3.83	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.68		0.55		0.33	
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.14		0.16		0.04	
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	7.02		7.10		6.85	
ALBUMINE	55-72 (%)	01/01/92	65.10		63.50		62.70	
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	222.00		203.00		203.00	
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	143.00		119.00		116.00	
GLOBULINS ALPHA 1	2-6 (%)	01/01/92	3.00		2.30		2.50	
GLOBULINS ALPHA 2	6-11 (%)	01/01/92	6.40		6.60		7.10	
GLOBULINS BETA	9-14 (%)	01/01/92	12.70		12.20		12.70	
GLOBULINS GAMMA	10-20 (%)	01/01/92	12.80		15.40		15.00	
TSH	0.1-4 (UU/ML)	01/01/92	1.51					
T4	4.8-12.8 (UG/DL)	01/01/92	1.16					

1297

(€) << 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 20124/017

Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 9/A Patient: 278 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 21
			12/06/92	03/07/92
			value (€)	value (€)
Laboratory test	Range value	Range date		
HB	12-16 (G/DL)	01/01/92	13.90	13.10
HT	37-47 (X)	01/01/92	40.80	40.80
RBC	4-5.8 (10 ⁶ /MM ³)	01/01/92	4.77	4.78
MBC	4000-10000 (/MM ³)	01/01/92	8300.00	7400.00
MBC: N	40-70 (X)	01/01/92	71.60	75.90
MBC: L	20-50 (X)	01/01/92	22.40	20.30
MBC: E	0-8 (X)	01/01/92	1.50	1.10
MBC: M	0-13 (X)	01/01/92	3.90	2.20
MBC: B	0-3 (X)	01/01/92	0.60	0.60
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	410.00	339.00
NA+	136-147 (MMOL/L)	01/01/92	139.00	140.00
K+	3.6-5.5 (MMOL/L)	01/01/92	4.50	4.90
CL-	95-110 (MMOL/L)	01/01/92	99.00	102.00
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.30	9.57
PO4--	2.4-4.8 (MG/DL)	01/01/92	3.40	3.00
SGOT	5-40 (U/L)	01/01/92	30.00	23.00
SGPT	5-40 (U/L)	01/01/92	15.00	12.00
GAMMA GT	0-40 (U/L)	01/01/92	10.00	10.00
LDH	150-460 (U/L)	01/01/92	337.00	279.00
ALK. PHOSPH.	40-350 (U/L)	01/01/92	147.00	131.00
GLUCOSE	50-120 (MG/DL)	01/01/92	80.00	87.00
BUN	()	01/01/92		
UREA	8-48 (MG/DL)	01/01/92	30.00	35.00
CREATININE	0.3-1.25 (MG/DL)	01/01/92	1.09	0.89
URIC ACID	2-6.5 (MG/DL)	01/01/92		3.62
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.40	0.44
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.14	0.14
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	7.60	7.76
ALBUMINE	55-72 (X)	01/01/92	64.60	66.70
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	220.00	182.00
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	68.00	48.00
GLOBULINS ALPHA 1	2-6 (X)	01/01/92	3.40	3.00
GLOBULINS ALPHA 2	6-11 (X)	01/01/92	7.20	5.90
GLOBULINS BETA	9-14 (X)	01/01/92	11.20	9.90
GLOBULINS GAMMA	10-20 (X)	01/01/92	13.60	14.50
TSH	0.1-4 (UU/ML)	01/01/92	0.76	
T4	4.8-12.8 (UG/DL)	01/01/92	12.60	

(e) << clinically relevant (value lower than min range) 1298 >> clinically relevant (value higher than max range)
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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9/A Patient: 279 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date
			Screen
			05/08/92
			value (€)
Laboratory test	Range value	Range date	
HB	14-18 (G/DL)	01/01/92	17.10
HT	42-53 (%)	01/01/92	48.80
RBC	4.5-6.2 (10 ⁶ /MM ³)	01/01/92	5.06
WBC	4000-10000 (/MM ³)	01/01/92	8300.00
WBC: N	40-70 (%)	01/01/92	58.10
WBC: L	20-50 (%)	01/01/92	34.50
WBC: E	0-8 (%)	01/01/92	1.50
WBC: M	0-13 (%)	01/01/92	5.60
WBC: B	0-3 (%)	01/01/92	0.30
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	280.00
NA+	136-147 (MMOL/L)	01/01/92	142.00
K+	3.6-5.5 (MMOL/L)	01/01/92	3.90
CL-	95-110 (MMOL/L)	01/01/92	101.00
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.21
PO4--	2-4.5 (MG/DL)	01/01/92	3.60
SGOT	5-40 (U/L)	01/01/92	19.00
SGPT	5-40 (U/L)	01/01/92	18.00
GAMMA GT	0-40 (U/L)	01/01/92	18.00
LDH	150-460 (U/L)	01/01/92	273.00
ALK. PHOSPH.	40-350 (U/L)	01/01/92	146.00
GLUCOSE	50-120 (MG/DL)	01/01/92	75.00
BUN	()	01/01/92	
UREA	8-50 (MG/DL)	01/01/92	29.00
CREATININE	0.3-1.38 (MG/DL)	01/01/92	1.21
URIC ACID	2-7.5 (MG/DL)	01/01/92	4.37
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.50
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.11
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	7.42
ALBUMINE	55-72 (%)	01/01/92	65.80
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	205.00
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	94.00
GLOBULINS ALPHA 1	2-6 (%)	01/01/92	2.70
GLOBULINS ALPHA 2	6-11 (%)	01/01/92	7.00
GLOBULINS BETA	9-14 (%)	01/01/92	10.40
GLOBULINS GAMMA	10-20 (%)	01/01/92	14.10
TSH	0.1-4 (UU/ML)	01/01/92	1.20
T4	4.8-12.8 (UG/DL)	01/01/92	7.50

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9/A Patient: 283 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/09/92		07/10/92		28/10/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/01/92	13.80		14.40		15.20	
HT	37-47 (%)	01/01/92	41.60		44.00		44.10	
RBC	4-5.8 (10 ⁶ /MM ³)	01/01/92	4.45		4.77		4.83	
WBC	4000-10000 (/MM ³)	01/01/92	5400.00		6500.00		6300.00	
WBC: N	40-70 (%)	01/01/92	51.80		66.80		53.00	
WBC: L	20-50 (%)	01/01/92	41.70		29.30		40.80	
WBC: E	0-8 (%)	01/01/92	1.50		1.00		0.40	
WBC: M	0-13 (%)	01/01/92	4.50		2.70		5.70	
WBC: B	0-3 (%)	01/01/92	0.60		0.30		0.10	
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	236.00		210.00		201.00	
NA+	136-147 (MMOL/L)	01/01/92	143.00		141.00		140.00	
K+	3.6-5.5 (MMOL/L)	01/01/92	4.50		4.20		4.60	
CL-	95-110 (MMOL/L)	01/01/92	105.00		107.00		101.00	
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.23		9.20		9.00	
PO4--	2.4-4.8 (MG/DL)	01/01/92	2.70		2.60			
SGOT	5-40 (U/L)	01/01/92	24.00		22.00		21.00	
SGPT	5-40 (U/L)	01/01/92	30.00		23.00		22.00	
GAMMA GT	0-40 (U/L)	01/01/92	20.00		20.00		19.00	
LDH	150-460 (U/L)	01/01/92	234.00		296.00		205.00	
ALK. PHOSPH.	40-350 (U/L)	01/01/92	208.00		232.00		230.00	
GLUCOSE	50-120 (MG/DL)	01/01/92	83.00		78.00		71.00	
BUN	()	01/01/92						
UREA	8-48 (MG/DL)	01/01/92	24.00		28.00		31.00	
CREATININE	0.3-1.25 (MG/DL)	01/01/92	1.03		1.01		1.04	
URIC ACID	2-6.5 (MG/DL)	01/01/92	5.48		4.95		4.77	
TOT BILIRUBIN	0-1.1 (MG/DL)	01/01/92	0.31		0.47		0.53	
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.10		0.12		0.13	
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	6.99		7.42		7.52	
ALBUMINE	55-72 (%)	01/01/92	68.10		59.00		62.50	
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	210.00		219.00		216.00	
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	67.00		100.00		88.00	
GLOBULINS ALPHA 1	2-6 (%)	01/01/92	3.10		2.80		2.80	
GLOBULINS ALPHA 2	6-11 (%)	01/01/92	6.40		7.20		8.60	
GLOBULINS BETA	9-14 (%)	01/01/92	11.20		14.20		11.90	
GLOBULINS GAMMA	10-20 (%)	01/01/92	11.20		16.80		14.20	
TSH	0.1-4 (UU/ML)	01/01/92	3.64					
T4	4.8-12.8 (UG/DL)	01/01/92	6.70					

(€) << 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 20124/017

Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9/A Patient: 284 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date			
			Screen		Day 21	
			16/09/92		09/10/92	
			value	(±)	value	(±)
Laboratory test	Range value	Range date				
HB	14-18 (G/DL)	01/01/92	16.90		16.80	
HT	42-53 (Z)	01/01/92	52.00		50.60	
RBC	4.5-6.2 (10 ⁶ /MM3)	01/01/92	5.26		5.11	
WBC	4000-10000 (/MM3)	01/01/92	9600.00		11300.0	
WBC: N	40-70 (%)	01/01/92	71.20	>	77.10 >	
WBC: L	20-50 (%)	01/01/92	22.80		19.60 <	
WBC: E	0-8 (%)	01/01/92	1.70		0.80	
WBC: M	0-13 (%)	01/01/92	4.10		2.40	
WBC: B	0-3 (%)	01/01/92	0.30		0.10	
PLATELETS	150-400 (10 ³ /MM3)	01/01/92	215.00		300.00	
NA+	136-147 (MMOL/L)	01/01/92	140.00		140.00	
K+	3.6-5.5 (MMOL/L)	01/01/92	4.00		4.30	
CL-	95-110 (MMOL/L)	01/01/92	100.00		101.00	
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.88		9.39	
PO4--	2-4.5 (MG/DL)	01/01/92	4.00		3.60	
SGOT	5-40 (U/L)	01/01/92	37.00		21.00	
SGPT	5-40 (U/L)	01/01/92	34.00		23.00	
GAMMA GT	0-40 (U/L)	01/01/92	20.00		13.00	
LDH	150-460 (U/L)	01/01/92	307.00		385.00	
ALK. PHOSPH.	40-350 (U/L)	01/01/92	191.00		177.00	
GLUCOSE	50-120 (MG/DL)	01/01/92	75.00		74.00	
BUN	()	01/01/92				
UREA	8-50 (MG/DL)	01/01/92	23.00		25.00	
CREATININE	0.3-1.38 (MG/DL)	01/01/92	0.95		0.95	
URIC ACID	2-7.5 (MG/DL)	01/01/92	4.47		4.43	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.65		0.59	
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.25			
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	7.17		7.43	
ALBUMINE	55-72 (Z)	01/01/92	68.00		67.80	
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	209.00		154.00	
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	177.00	>	129.00	
GLOBULINS ALPHA 1	2-6 (Z)	01/01/92	3.50		3.70	
GLOBULINS ALPHA 2	6-11 (Z)	01/01/92	6.60		8.50	
GLOBULINS BETA	9-14 (Z)	01/01/92	9.80		10.00	
GLOBULINS GAMMA	10-20 (Z)	01/01/92	12.10		10.00	
TSH	0.1-4 (UU/ML)	01/01/92	3.45			
T4	4.8-12.8 (UG/DL)	01/01/92	5.70			

(±) << 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 20124/017

Listing No.: 18.0

LABORATORY DATA 9550085

Centre: 9/A Patient: 301 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			28/02/92		25/03/92		15/04/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/01/92	13.50		14.40		14.20	
HT	37-47 (Z)	01/01/92	40.90		43.20		42.20	
RBC	4-5.8 (10 ⁶ /MM ³)	01/01/92	4.32		4.58		4.44	
WBC	4000-10000 (/MM ³)	01/01/92	6100.00		6400.00		4900.00	
WBC: N	40-70 (Z)	01/01/92	38.80 <		63.80		59.10	
WBC: L	20-50 (Z)	01/01/92	54.90 >		30.90		33.70	
WBC: E	0-8 (Z)	01/01/92	0.40		1.20		0.60	
WBC: M	0-13 (Z)	01/01/92	5.30		3.30		5.90	
WBC: B	0-3 (Z)	01/01/92	0.50		0.80		0.60	
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92			233.00		239.00	
NA+	136-147 (MMOL/L)	01/01/92	146.00		140.00		140.00	
K+	3.6-5.5 (MMOL/L)	01/01/92	4.40		3.80		4.10	
CL-	95-110 (MMOL/L)	01/01/92	108.00		100.00		101.00	
Ca++	8.3-10.5 (MG/DL)	01/01/92	7.98 <		9.20		8.97	
PO4--	2.4-4.8 (MG/DL)	01/01/92			3.30		3.70	
SGOT	5-40 (U/L)	01/01/92	21.00		19.00		19.00	
SGPT	5-40 (U/L)	01/01/92	15.00		12.00		15.00	
GAMMA GT	0-40 (U/L)	01/01/92	12.00		11.00		13.00	
LDH	150-460 (U/L)	01/01/92			276.00		282.00	
ALK. PHOSPH.	40-350 (U/L)	01/01/92	83.00		91.00		101.00	
GLUCOSE	50-120 (MG/DL)	01/01/92	81.00		127.00 >		83.00	
BUN	()	01/01/92						
UREA	8-48 (MG/DL)	01/01/92	31.00		34.00		38.00	
CREATININE	0.3-1.25 (MG/DL)	01/01/92	0.89		0.95		0.90	
URIC ACID	2-6.5 (MG/DL)	01/01/92	4.84		4.02		4.36	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.38		0.91		0.79	
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.07		0.19		0.20	
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	6.66		7.53		7.51	
ALBUMINE	55-72 (Z)	01/01/92			61.00		64.50	
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	164.00		202.00		210.00	
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	230.00 >>		196.00 >		142.00	
GLOBULINS ALPHA 1	2-6 (Z)	01/01/92			4.50		4.20	
GLOBULINS ALPHA 2	6-11 (Z)	01/01/92			10.60		7.40	
GLOBULINS BETA	9-14 (Z)	01/01/92			10.90		9.10	
GLOBULINS GAMMA	10-20 (Z)	01/01/92			20.00		14.80	
TSH	0.1-4 (UU/ML)	01/01/92	2.09					
T4	4.8-12.8 (UG/DL)	01/01/92	6.40					

(€) << 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 20124/017

Listing No.: 18.0

LABORATORY DATA 0550085

Centre: 9/A Patient: 302 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date
			Screen
			02/03/92
			value (c)
Laboratory test	Range value	Range date	
HB	14-18 (G/DL)	01/01/92	17.00
HT	42-53 (%)	01/01/92	50.60
RBC	4.5-6.2 (10 ⁶ /MM ³)	01/01/92	5.73
WBC	4000-10000 (/MM ³)	01/01/92	6100.00
WBC: N	40-70 (%)	01/01/92	50.40
WBC: L	20-50 (%)	01/01/92	37.30
WBC: E	0-8 (%)	01/01/92	6.00
WBC: M	0-13 (%)	01/01/92	5.50
WBC: B	0-3 (%)	01/01/92	0.80
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	315.00
NA+	136-147 (MMOL/L)	01/01/92	140.00
K+	3.6-5.5 (MMOL/L)	01/01/92	4.80
CL-	95-110 (MMOL/L)	01/01/92	99.00
Ca++	8.3-10.5 (MG/DL)	01/01/92	10.34
PO4--	2-4.5 (MG/DL)	01/01/92	3.60
SGOT	5-40 (U/L)	01/01/92	23.00
SGPT	5-40 (U/L)	01/01/92	26.00
GAMMA GT	0-40 (U/L)	01/01/92	14.00
LDH	150-460 (U/L)	01/01/92	279.00
ALK. PROSPH.	40-350 (U/L)	01/01/92	147.00
GLUCOSE	50-120 (MG/DL)	01/01/92	69.00
BUN	()	01/01/92	
UREA	8-50 (MG/DL)	01/01/92	
CREATININE	0.3-1.38 (MG/DL)	01/01/92	1.11
URIC ACID	2-7.5 (MG/DL)	01/01/92	4.33
TOT. BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.64
DIR. BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.12
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	8.71 >
ALBUMINE	55-72 (%)	01/01/92	57.90
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	149.00
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	59.00
GLOBULINS ALPHA 1	2-6 (%)	01/01/92	2.60
GLOBULINS ALPHA 2	6-11 (%)	01/01/92	7.50
GLOBULINS BETA	9-14 (%)	01/01/92	9.60
GLOBULINS GAMMA	10-20 (%)	01/01/92	22.40 >
TSH	0.1-4 (UU/HL)	01/01/92	1.49
T4	4.8-12.8 (UG/DL)	01/01/92	8.80

(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 20124/017
Listing No.: 18.0

9550085

LABORATORY DATA

Centre: 9/A Patient: 307 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			05/05/92
			value (c)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	01/01/92	15.70
HT	37-47 (X)	01/01/92	45.20
RBC	4-5.8 (10 ⁶ /MM ³)	01/01/92	4.64
WBC	4000-10000 (/MM ³)	01/01/92	6200.00
WBC: N	40-70 (X)	01/01/92	49.80
WBC: L	20-50 (X)	01/01/92	39.20
WBC: E	0-8 (X)	01/01/92	5.30
WBC: M	0-13 (X)	01/01/92	5.20
WBC: B	0-3 (X)	01/01/92	0.50
PLATELETS	150-400 (10 ³ /MM ³)	01/01/92	253.00
NA+	136-147 (MMOL/L)	01/01/92	141.00
K+	3.6-5.5 (MMOL/L)	01/01/92	4.80
CL-	95-110 (MMOL/L)	01/01/92	102.00
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.21
PO4--	2.4-4.8 (MG/DL)	01/01/92	3.80
SGOT	5-40 (U/L)	01/01/92	21.00
SGPT	5-40 (U/L)	01/01/92	17.00
GAMMA GT	0-40 (U/L)	01/01/92	11.00
LDH	150-460 (U/L)	01/01/92	284.00
ALK. PHOSPH.	40-350 (U/L)	01/01/92	174.00
GLUCOSE	50-120 (MG/DL)	01/01/92	77.00
BUN	()	01/01/92	
UREA	8-48 (MG/DL)	01/01/92	27.00
CREATININE	0.3-1.25 (MG/DL)	01/01/92	0.95
URIC ACID	2-6.5 (MG/DL)	01/01/92	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.26
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.08
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	7.28
ALBUMINE	55-72 (X)	01/01/92	66.20
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	236.00
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	74.00
GLOBULINS ALPHA 1	2-6 (X)	01/01/92	4.00
GLOBULINS ALPHA 2	6-11 (X)	01/01/92	6.00
GLOBULINS BETA	9-14 (X)	01/01/92	10.60
GLOBULINS GAMMA	10-20 (X)	01/01/92	13.20
TSH	0.1-4 (UU/ML)	01/01/92	0.48
T4	4.8-12.8 (UG/DL)	01/01/92	9.70

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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 R4D
9530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 9/A Patient: 308 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 21
			09/05/92	29/05/92
			value (†)	value (‡)
Laboratory test	Range value	Range date		
HB	12-16 (G/DL)	01/01/92	14.50	14.20
HT	37-47 (X)	01/01/92	41.60	41.30
RBC	4-5.8 (10 ⁶ /MM3)	01/01/92	4.46	4.53
WBC	4000-10000 (/MM3)	01/01/92	4000.00	4200.00
WBC: N	40-70 (X)	01/01/92	50.40	59.10
WBC: L	20-50 (X)	01/01/92	39.40	34.90
WBC: E	0-8 (X)	01/01/92	6.40	1.90
WBC: M	0-13 (X)	01/01/92	3.50	3.70
WBC: B	0-3 (X)	01/01/92	0.30	0.30
PLATELETS	150-400 (10 ³ /MM3)	01/01/92	264.00	262.00
NA+	136-147 (MMOL/L)	01/01/92	142.00	144.00
K+	3.6-5.5 (MMOL/L)	01/01/92	5.10	4.40
CL-	95-110 (MMOL/L)	01/01/92	97.00	102.00
Ca++	8.3-10.5 (MG/DL)	01/01/92	9.77	9.36
PO4--	2.4-4.8 (MG/DL)	01/01/92	3.60	3.60
SGOT	5-40 (U/L)	01/01/92	21.00	18.00
SGPT	5-40 (U/L)	01/01/92	15.00	10.00
GAMMA GT	0-40 (U/L)	01/01/92	12.00	11.00
LDH	150-460 (U/L)	01/01/92	419.00	342.00
ALK. PHOSPH.	40-350 (U/L)	01/01/92	188.00	171.00
GLUCOSE	50-120 (MG/DL)	01/01/92	75.00	67.00
BUN	()	01/01/92		
UREA	8-48 (MG/DL)	01/01/92	27.00	23.00
CREATININE	0.3-1.25 (MG/DL)	01/01/92	0.97	0.94
URIC ACID	2-6.5 (MG/DL)	01/01/92	3.98	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.57	0.46
DIR BILIRUBIN	0-0.9 (MG/DL)	01/01/92	0.01	0.01
TOT. PROTEINS	6.1-8 (G/DL)	01/01/92	7.89	6.72
ALBUMINE	55-72 (X)	01/01/92	63.10	65.50
TOT. CHOLEST.	120-250 (MG/DL)	01/01/92	281.00 >	232.00
TRIGLYCERIDES	40-170 (MG/DL)	01/01/92	99.00	71.00
GLOBULINS ALPHA 1	2-6 (X)	01/01/92	3.90	3.70
GLOBULINS ALPHA 2	6-11 (X)	01/01/92	7.80	6.90
GLOBULINS BETA	9-14 (X)	01/01/92	11.40	11.00
GLOBULINS GAMMA	10-20 (X)	01/01/92	13.80	12.90
TSH	0.1-4 (UU/ML)	01/01/92	1.39	
T4	4.8-12.8 (UG/DL)	01/01/92	9.70	

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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 10 Patient: 289 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			23/09/91
			value (⚡)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	22/09/91	12.80
HT	36-54 (%)	22/09/91	48.10
RBC	4-5 (10 ⁶ /MM ³)	22/09/91	4.35
HBC	4000-10000 (/MM ³)	22/09/91	4500.00
HBC: N	40-70 (%)	22/09/91	
HBC: L	20-40 (%)	22/09/91	35.00
HBC: E	1-4 (%)	22/09/91	2.00
HBC: M	4-8 (%)	22/09/91	2.00 <
HBC: B	0-1 (%)	22/09/91	0.00
PLATELETS	150000-400000 (/MM ³)	22/09/91	159000
NA+	135-155 (MEQ/L)	22/09/91	140.30
K+	3.1-5.5 (MEQ/L)	22/09/91	3.77
CL-	98-107 (MEQ/L)	22/09/91	103.00
Ca++	88-102 (MG/L)	22/09/91	98.00
PD4--	2.5-4.8 (MG/DL)	22/09/91	4.77
SGOT	5-15 (U/L)	22/09/91	8.00
SGPT	5-17 (U/L)	22/09/91	7.00
GAMMA GT	0-18 (U/L)	22/09/91	7.00
LDH	150-240 (U/L)	22/09/91	119.00 <
ALK. PHOSPH.	40-90 (U/L)	22/09/91	101.00 >
GLUCOSE	76-120 (MG/DL)	22/09/91	108.00
BUN	10-50 (MG/DL)	22/09/91	18.00
UREA	()	22/09/91	
CREATININE	0.55-1.1 (MG/DL)	22/09/91	0.83
URIC ACID	2.5-5.7 (MG/DL)	22/09/91	2.92
TOT BILIRUBIN	0-1 (MG/DL)	22/09/91	0.54
DIR BILIRUBIN	0-0.25 (MG/DL)	22/09/91	0.12
TOT. PROTEINS	6.6-8.7 (G/DL)	22/09/91	7.30
ALBUMINE	56-72 (%)	22/09/91	62.90
TOT. CHOLEST.	120-260 (MG/DL)	22/09/91	148.00
TRIGLYCERIDES	65-172 (MG/DL)	22/09/91	
GLOBULINS ALPHA 1	1.8-5 (%)	22/09/91	3.00
GLOBULINS ALPHA 2	7-12 (%)	22/09/91	6.80 <
GLOBULINS BETA	6-15 (%)	22/09/91	13.10
GLOBULINS GAMMA	7.8-18.2 (%)	22/09/91	14.20
TSH	0.15-5.5 (MU/L)	22/09/91	1.20
T4	5-12 (UG/DL)	22/09/91	8.60

(⚡) << 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 CN 550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 10 Patient: 291 Treatment: Imipramine Sex: Male

Laboratory test			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			13/02/92		09/03/92		30/03/92	
			value	(φ)	value	(φ)	value	(φ)
Range value	Range date							
HB	14-18 (G/DL)	12/02/92	15.10		15.40		14.80	
HT	36-54 (X)	12/02/92	45.50		49.10		47.20	
RBC	4-5 (10 ⁶ /MM3)	12/02/92	5.01	>	5.40	>	4.95	
MBC	4000-10000 (/MM3)	12/02/92	7300.00		6300.00		10100.0	
MBC: N	40-70 (X)	12/02/92	40.00		66.00		74.00	
MBC: L	20-40 (X)	12/02/92	48.00	>	24.00		20.00	
MBC: E	1-4 (X)	12/02/92	4.00		4.00		4.00	
MBC: M	4-8 (X)	12/02/92	4.00		6.00		2.00	
MBC: B	0-1 (X)	12/02/92	4.00	>>	0.00		0.00	
PLATELETS	150000-400000 (/MM3)	12/02/92	318000		235000		259000	
NA+	135-155 (MEQ/L)	12/02/92	134.70	<	139.10		139.80	
K+	3.1-5.5 (MEQ/L)	12/02/92	4.23		4.69		4.25	
CL-	98-107 (MEQ/L)	12/02/92	98.00		102.00		100.00	
Ca++	88-102 (MG/L)	12/02/92	99.00		79.00	<	108.00	
PO4--	2.5-4.8 (MG/DL)	12/02/92	4.20		3.96		3.22	
SGOT	5-18 (U/L)	12/02/92	10.00		11.00		11.00	
SGPT	5-22 (U/L)	12/02/92	15.00		20.00		22.00	
GAMMA GT	0-25 (U/L)	12/02/92	28.00	>	17.00		27.00	
LDH	150-240 (U/L)	12/02/92	120.00	<	201.00		176.00	
ALK. PHOSPH.	40-90 (U/L)	12/02/92	63.00		63.00		70.00	
GLUCOSE	76-120 (MG/DL)	12/02/92	102.00		80.00		114.00	
BUN	10-50 (MG/DL)	12/02/92	31.20		9.60	<	34.90	
UREA	()	12/02/92						
CREATININE	0.7-1.35 (MG/DL)	12/02/92	0.79		0.76		0.90	
URIC ACID	2.5-7 (MG/DL)	12/02/92	5.10		4.74		6.90	
TOT BILIRUBIN	0-1 (MG/DL)	12/02/92	0.33		0.26		0.47	
DIR BILIRUBIN	0-0.25 (MG/DL)	12/02/92	0.09		0.02		0.05	
TOT. PROTEINS	6.6-8.7 (G/DL)	12/02/92	7.70		7.50		7.60	
ALBUMINE	3.97-5.34 (G/DL)	12/02/92	4.80		5.00			
TOT. CHOLEST.	120-260 (MG/DL)	12/02/92	190.00		169.00		258.00	
TRIGLYCERIDES	65-172 (MG/DL)	12/02/92	139.00		139.00		170.00	
GLOBULINS ALPHA 1	0.11-0.32 (G/DL)	12/02/92	0.20		0.20			
GLOBULINS ALPHA 2	0.42-0.87 (G/DL)	12/02/92	0.90	>	0.70			
GLOBULINS BETA	0.53-1.12 (G/DL)	12/02/92	1.00		1.10			
GLOBULINS GAMMA	0.53-1.97 (G/DL)	12/02/92	0.80		0.70			
TSH	0.15-5.5 (MU/L)	12/02/92						
T4	5-12 (MG/DL)	12/02/92						

(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 CN 6-888
9530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 10 Patient: 294 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			07/01/92
			value (◊)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	06/01/92	14.30
HT	36-54 (X)	06/01/92	40.90
RBC	4-5 (10 ⁶ /MM ³)	06/01/92	4.57
WBC	4000-10000 (/MM ³)	06/01/92	8800.00
WBC: N	40-70 (X)	06/01/92	68.00
WBC: L	20-40 (X)	06/01/92	20.00
WBC: E	1-4 (X)	06/01/92	8.00 >>
WBC: M	4-8 (X)	06/01/92	4.00
WBC: B	0-1 (X)	06/01/92	0.00
PLATELETS	150000-400000 (/MM ³)	06/01/92	380000
NA+	135-155 (MEQ/L)	06/01/92	141.80
K+	3.1-5.5 (MEQ/L)	06/01/92	4.94
CL-	98-107 (MEQ/L)	06/01/92	101.00
Ca++	88-102 (MG/L)	06/01/92	104.00 >
PO4--	2.5-4.8 (MG/DL)	06/01/92	4.70
SGOT	5-15 (U/L)	06/01/92	17.00 >
SGPT	5-17 (U/L)	06/01/92	9.00
GAMMA GT	0-18 (U/L)	06/01/92	9.00
LDH	150-240 (U/L)	06/01/92	172.00
ALK. PHOSPH.	40-90 (U/L)	06/01/92	79.00
GLUCOSE	76-120 (MG/DL)	06/01/92	113.00
BUH	10-50 (MG/DL)	06/01/92	40.50
UREA	()	06/01/92	
CREATININE	0.55-1.1 (MG/DL)	06/01/92	0.91
URIC ACID	2.5-5.7 (MG/DL)	06/01/92	5.52
TOT BILIRUBIN	0-1 (MG/DL)	06/01/92	0.66
DIR BILIRUBIN	0-0.25 (MG/DL)	06/01/92	0.06
TOT. PROTEINS	6.6-8.7 (G/DL)	06/01/92	8.01
ALBUMINE	56-72 (X)	06/01/92	52.40 <
TOT. CHOLEST.	120-260 (MG/DL)	06/01/92	191.20
TRIGLYCERIDES	65-172 (MG/DL)	06/01/92	200.00 >
GLOBULINS ALPHA 1	1.8-5 (X)	06/01/92	3.70
GLOBULINS ALPHA 2	7-12 (X)	06/01/92	11.10
GLOBULINS BETA	6-15 (X)	06/01/92	19.00 >
GLOBULINS GAMMA	7.8-18.2 (X)	06/01/92	17.90
TSH	0.2-6 (MUI/L)	06/01/92	2.30
T4	45-135 (NG/ML)	06/01/92	92.00

(◊) << 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

PHARMACIA CNS 0085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 10 Patient: 295 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			02/01/92		27/01/92		24/02/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	31/12/91	14.70		14.70		12.60 <	
HT	36-54 (X)	31/12/91	43.40		43.40		43.60	
RBC	4-5 (10 ⁶ /MM3)	31/12/91	4.66		4.66		4.26	
WBC	4000-10000 (/MM3)	31/12/91	11500.0	>	11000.0	>	4300.00	
WBC: N	40-70 (X)	31/12/91	66.00		66.00		56.00	
WBC: L	20-40 (X)	31/12/91	30.00		30.00		24.00	
WBC: E	1-4 (X)	31/12/91	2.00		2.00		12.00 >>	
WBC: M	4-8 (X)	31/12/91	2.00	<	2.00	<	8.00	
WBC: B	0-1 (X)	31/12/91	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM3)	31/12/91	305000		305000		263000	
NA+	135-155 (MEQ/L)	31/12/91	141.90		141.90		140.40	
K+	3.1-5.5 (MEQ/L)	31/12/91	4.58		4.58		4.68	
CL-	98-107 (MEQ/L)	31/12/91	101.00		101.00		97.00 <	
Ca++	88-102 (MG/DL)	31/12/91	98.00		98.00		102.00	
PO4--	2.5-4.8 (MG/DL)	31/12/91	3.52		3.52		3.06	
SGOT	5-18 (U/L)	31/12/91	10.00		10.00		12.00	
SGPT	5-22 (U/L)	31/12/91	15.00		15.00		22.00	
GAMMA GT	0-25 (U/L)	31/12/91	21.00		21.00		10.00	
LDH	150-240 (U/L)	31/12/91	159.00		159.00		160.00	
ALK. PHOSPH.	40-90 (U/L)	31/12/91	38.00	<	38.00	<	52.00	
GLUCOSE	76-120 (MG/DL)	31/12/91	94.00		94.00		92.00	
BUN	10-50 (MG/DL)	31/12/91	25.60		25.60		20.60	
UREA	()	31/12/91						
CREATININE	0.7-1.35 (MG/DL)	31/12/91	1.06		1.06		1.07	
URIC ACID	2.5-7 (MG/DL)	31/12/91	6.63		6.63		6.16	
TOT BILIRUBIN	0-1 (MG/DL)	31/12/91	0.52		0.52		0.02	
DIR BILIRUBIN	0-0.25 (MG/DL)	31/12/91	0.07		0.07		0.34 >	
TOT. PROTEINS	6.6-8.7 (G/DL)	31/12/91	7.20		7.20		7.98	
ALBUMINE	3.97-5.34 (G/DL)	31/12/91	4.40		4.40		4.20	
TOT. CHOLEST.	120-260 (MG/DL)	31/12/91	138.00		138.00		122.00	
TRIGLYCERIDES	65-172 (MG/DL)	31/12/91	247.00	>>	247.00	>>	232.00 >>	
GLOBULINS ALPHA 1	0.11-0.32 (G/DL)	31/12/91	0.30		0.30		0.20	
GLOBULINS ALPHA 2	0.42-0.87 (G/DL)	31/12/91	0.60		0.60		0.50	
GLOBULINS BETA	0.53-1.12 (G/DL)	31/12/91	1.10		0.90		0.70	
GLOBULINS GAMMA	0.53-1.97 (G/DL)	31/12/91	0.90		2.20	>	0.60	
TSH	0.2-6 (MUI/L)	31/12/91	2.20				2.30	
T4	45-135 (NG/ML)	31/12/91	71.00				57.00	

(€) << 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 CN550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 10 Patient: 299 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			02/04/92		28/04/92		19/05/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	31/12/91	15.00		15.70		14.80	
HT	36-54 (X)	31/12/91	47.20		53.40		46.20	
RBC	4-5 (10 ⁶ /MM3)	31/12/91	4.89		5.17	>	4.52	
WBC	4000-10000 (/MM3)	31/12/91	6100.00		10500.0	>	4800.00	
WBC: N	40-70 (X)	31/12/91	61.00		72.00	>	42.00	
WBC: L	20-40 (X)	31/12/91	30.00		24.00		>	
WBC: E	1-4 (X)	31/12/91	7.00	>>	0.00	<	2.00	
WBC: M	4-8 (X)	31/12/91	2.00	<	4.00		>	
WBC: B	0-1 (X)	31/12/91	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM3)	31/12/91	359000		368000		368000	
NA+	135-155 (MEQ/L)	31/12/91	140.50		139.70		135.60	
K+	3.1-5.5 (MEQ/L)	31/12/91	4.47		4.65		4.96	
CL-	98-107 (MEQ/L)	31/12/91	100.00		103.00		100.00	
Ca++	88-102 (MG/L)	31/12/91	101.00		101.00		96.00	
PO4--	2.5-4.8 (MG/DL)	31/12/91	4.02		4.08		3.34	
SGOT	5-18 (U/L)	31/12/91	13.00		14.00		14.00	
SGPT	5-22 (U/L)	31/12/91	5.00		21.00		>	
GAMMA GT	0-25 (U/L)	31/12/91	51.00	>>	68.00	>>	14.00	
LDH	150-240 (U/L)	31/12/91	216.00		151.00		153.00	
ALK. PHOSPH.	40-90 (U/L)	31/12/91	88.00		85.00		87.00	
GLUCOSE	76-120 (MG/DL)	31/12/91	110.00		118.00		82.00	
BUN	10-50 (MG/DL)	31/12/91	20.40		33.70		18.20	
UREA	()	31/12/91						
CREATININE	0.7-1.35 (MG/DL)	31/12/91	0.82		0.96		0.84	
URIC ACID	2.5-7 (MG/DL)	31/12/91	5.72		5.17		6.63	
TOT BILIRUBIN	0-1 (MG/DL)	31/12/91	0.61		0.18		0.19	
DIR BILIRUBIN	0-0.25 (MG/DL)	31/12/91	0.03		0.01		0.06	
TOT. PROTEINS	6.6-8.7 (G/DL)	31/12/91	7.40		7.33		8.17	
ALBUMINE	3.97-5.34 (G/DL)	31/12/91	5.50	>	5.30			
	56-72 (X)	18/05/92					69.50	
TOT. CHOLEST.	120-260 (MG/DL)	31/12/91	161.00		214.00		241.00	
TRIGLYCERIDES	65-172 (MG/DL)	31/12/91	107.00		151.00		264.00	
LOBULINS ALPHA 1	0.11-0.32 (G/DL)	31/12/91	0.20		0.10	<		
	1.8-5 (X)	18/05/92					2.60	
LOBULINS ALPHA 2	0.42-0.87 (G/DL)	31/12/91	0.50		0.70			
	7-12 (X)	18/05/92					9.60	
LOBULINS BETA	0.53-1.12 (G/DL)	31/12/91	0.70		0.60			
	6-15 (X)	18/05/92					9.10	
LOBULINS GAMMA	0.53-1.97 (G/DL)	31/12/91	0.50	<	0.70			
	7.8-18.2 (X)	18/05/92					9.10	
TSH	0.2-6 (MUI/L)	31/12/91	1.10					
	0.2-6 (IE)	18/05/92						
T4	45-135 (NG/NL)	31/12/91	195.00					
	45-135 (NG/NL)	18/05/92						

(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 550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 10 Patient: 300 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			07/04/92		05/05/92		26/05/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	06/04/92	13.20		12.90		13.90	
HT	36-54 (Z)	06/04/92	45.00		43.90		47.50	
RBC	4-5 (10 ⁶ /MM ³)	06/04/92	4.80		4.51		4.66	
WBC	4000-10000 (/MM ³)	06/04/92	4900.00		8100.00		5000.00	
WBC: N	40-70 (Z)	06/04/92	64.00		68.00		48.00	
WBC: L	20-40 (Z)	06/04/92	32.00		20.00		44.00	>
WBC: E	1-4 (Z)	06/04/92	2.00		0.00	<>	0.00	<
WBC: M	4-8 (Z)	06/04/92	2.00	<	12.00	>>	8.00	
WBC: B	0-1 (Z)	06/04/92	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM ³)	06/04/92	259000		265000		268000	
NA+	135-155 (MEQ/L)	06/04/92	142.10		141.00		141.70	
K+	3.1-5.5 (MEQ/L)	06/04/92	3.90		4.03		3.61	
CL-	98-107 (MEQ/L)	06/04/92	110.00	>	103.00		105.00	
Ca++	88-102 (MG/L)	06/04/92	100.00		102.00		100.00	
PO4--	2.5-4.8 (MG/DL)	06/04/92	4.08		3.96		3.97	
SGOT	5-15 (U/L)	06/04/92	7.00		7.00		9.00	
SGPT	5-17 (U/L)	06/04/92	9.00		10.00		12.00	
GAMMA GT	0-18 (U/L)	06/04/92	5.00		13.00		11.00	
LDH	150-240 (U/L)	06/04/92	201.00		203.00		200.00	
ALK. PHOSPH.	40-90 (U/L)	06/04/92	45.00		59.00		40.00	
GLUCOSE	76-120 (MG/DL)	06/04/92	91.00		121.00	>	94.00	
BUN	10-50 (MG/DL)	06/04/92	22.80		19.50		15.20	
UREA	()	06/04/92						
CREATININE	0.55-1.1 (MG/DL)	06/04/92	0.67		0.89		0.62	
URIC ACID	2.5-5.7 (MG/DL)	06/04/92	2.60		5.19		2.33	<
TOT BILIRUBIN	0-1 (MG/DL)	06/04/92	0.46		0.30		0.19	
DIR BILIRUBIN	0-0.25 (MG/DL)	06/04/92	0.01		0.01		0.03	
TOT. PROTEINS	6.6-8.7 (G/DL)	06/04/92	7.60		7.50		7.71	
ALBUMINE	56-72 (Z)	06/04/92	64.80				50.00	<
TOT. CHOLEST.	3.97-5.34 (G/DL)	04/05/92			5.10			
TRIGLYCERIDES	120-260 (MG/DL)	06/04/92	245.00		266.00	>	225.00	>
GLOBULINS ALPHA 1	65-172 (MG/DL)	06/04/92	224.00	>>			196.00	>
GLOBULINS ALPHA 2	1.8-5 (Z)	06/04/92	3.70				5.00	
GLOBULINS BETA	0.11-0.32 (G/DL)	04/05/92			0.30			
GLOBULINS GAMMA	7-12 (Z)	06/04/92	9.50				17.10	>>
TSH	0.42-0.87 (G/DL)	04/05/92			0.70			
T4	6-15 (Z)	06/04/92	14.10				16.70	>
	0.53-1.12 (G/DL)	04/05/92			0.90			
	7.8-18.2 (Z)	06/04/92	7.90				11.20	
	0.53-1.97 (G/DL)	04/05/92			0.60			
	0.2-6 (MUI/L)	06/04/92	1.30					
	45-135 (NG/ML)	06/04/92	105.00					

(€) << 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 330085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 11 Patient: 323 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/06/92		15/07/92		06/08/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12.5-16.5 (G/DL)	01/05/92	14.60		14.60		15.10	
HT	0.37-0.49 (L/L)	01/05/92	0.43		0.45		0.47	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/05/92	4.90		5.00		5.10	
WBC	4-11 (10 ³ /MM ³)	01/05/92	4.90		5.10		6.00	
WBC: N	1.6-8 (10 ³ /MM ³)	01/05/92	2.80		3.00		3.80	
WBC: L	1-4.5 (10 ³ /MM ³)	01/05/92	1.70		1.60		1.60	
WBC: E	0-0.4 (10 ³ /MM ³)	01/05/92	0.00		0.10		0.10	
WBC: M	0.2-0.8 (10 ³ /MM ³)	01/05/92	0.30		0.50		0.50	
WBC: B	0-0.1 (10 ³ /MM ³)	01/05/92	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/92	269.00		314.00		265.00	
NA+	136-147 (MMOL/L)	01/05/92	141.00		138.00		143.00	
K+	3.5-5.1 (MMOL/L)	01/05/92	4.40		4.40		4.90	
CL-	98-108 (MMOL/L)	01/05/92	107.00		105.00		106.00	
Ca++	2.2-2.6 (MMOL/L)	01/05/92	2.27		2.36		2.26	
PO4--	0.8-1.45 (MMOL/L)	01/05/92	0.88		0.95		1.21	
SGOT	5-40 (U/L)	01/05/92	20.00		21.00		19.00	
SGPT	5-35 (U/L)	01/05/92	17.00		13.00		19.00	
GAMMA GT	4-18 (U/L)	01/05/92	6.00		11.00		17.00	
LDH	100-350 (U/L)	01/05/92	216.00		416.00 >		203.00	
ALK. PHOSPH.	25-160 (U/L)	01/05/92	44.00		56.00		51.00	
GLUCOSE	3.5-6.8 (MMOL/L)	01/05/92	3.67		4.00		3.90	
BUN	()	01/05/92						
UREA	2.6-6.7 (MMOL/L)	01/05/92	5.60		5.10		5.40	
CREATININE	47-88 (UMOL/L)	01/05/92	65.00		78.00		73.00	
URIC ACID	0.12-0.4 (MMOL/L)	01/05/92	0.16		0.20		0.17	
TOT BILIRUBIN	4-21 (UMOL/L)	01/05/92	11.00		6.00		8.00	
DIR BILIRUBIN	0-4 (UMOL/L)	01/05/92			75.00		79.00	
TOT. PROTEINS	65-80 (G/L)	01/05/92	75.00		45.00		49.55	
ALBUMINE	38-52 (G/L)	01/05/92	45.00		5.40		4.50	
TOT. CHOLEST.	2-6.5 (MMOL/L)	01/05/92	5.59		1.30		1.10	
TRIGLYCERIDES	0-1.7 (MMOL/L)	01/05/92	0.89		3.30		2.61	
GLOBULINS ALPHA 1	2-4 (G/L)	01/05/92	3.30		6.97		6.59	
GLOBULINS ALPHA 2	5-9 (G/L)	01/05/92	6.97		10.20		9.69	
GLOBULINS BETA	7-11 (G/L)	01/05/92	10.20		9.05		10.56	
GLOBULINS GAMMA	7-11 (G/L)	01/05/92	9.05		4.10			
TSH	0.4-5 (MUI/L)	01/05/92	4.10					
T4	9-20.9 (PMOL/L)	01/05/92	13.70					

(€) << 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 ~~CP550~~ 085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 11 Patient: 324 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			17/07/92		07/08/92		28/08/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14.5-18.5 (G/DL)	01/05/92	14.90		15.60		15.50	
HT	0.42-0.54 (L/L)	01/05/92	0.45		0.46		0.47	
RBC	4.8-6.4 (10 ⁶ /MM ³)	01/05/92	4.70	<	4.80		4.84	
WBC	4-11 (10 ³ /MM ³)	01/05/92	6.60		6.50		9.15	
WBC: N	1.6-8 (10 ³ /MM ³)	01/05/92	3.30		3.50		6.22	
WBC: L	1-4.5 (10 ³ /MM ³)	01/05/92	2.50		2.30		1.92	
WBC: E	0-0.4 (10 ³ /MM ³)	01/05/92	0.30		0.30		0.46	
WBC: M	0.2-0.8 (10 ³ /MM ³)	01/05/92	0.60		0.30		0.46	
WBC: B	0-0.1 (10 ³ /MM ³)	01/05/92	0.00		0.00		0.09	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/92	283.00		259.00		290.00	
NA+	136-147 (MMOL/L)	01/05/92	139.00		137.00		136.00	
K+	3.5-5.1 (MMOL/L)	01/05/92	3.90		3.70		4.10	
CL-	98-108 (MMOL/L)	01/05/92	106.00		104.00		104.00	
Ca++	2.2-2.6 (MMOL/L)	01/05/92	2.30		2.46		2.15	
PO4--	0.8-1.45 (MMOL/L)	01/05/92	1.03		1.06		0.88	
SGOT	5-40 (U/L)	01/05/92	20.00		20.00		20.00	
SGPT	5-35 (U/L)	01/05/92	42.00	>	29.00		30.00	
GAMMA GT	0-28 (U/L)	01/05/92	21.00		10.00		29.00	
LDH	100-350 (U/L)	01/05/92	285.00		122.00		142.00	
ALK. PHOSPH.	25-160 (U/L)	01/05/92	52.00		55.00		20.00	
GLUCOSE	3.5-6.8 (MMOL/L)	01/05/92	3.60		4.60		3.30	
BUN	()	01/05/92						
UREA	2.6-6.7 (MMOL/L)	01/05/92	3.40		3.80		3.10	
CREATININE	60-115 (UMOL/L)	01/05/92	79.00		76.00		65.00	
URIC ACID	0.18-0.45 (MMOL/L)	01/05/92	0.34		0.28		0.31	
TOT BILIRUBIN	4-21 (UMOL/L)	01/05/92	13.00		16.00		12.00	
DIR BILIRUBIN	0-4 (UMOL/L)	01/05/92						
TOT. PROTEINS	65-80 (G/L)	01/05/92	77.00		77.00		77.00	
ALBUMINE	38-52 (G/L)	01/05/92	46.18		41.20		51.30	
TOT. CHOLEST.	2-6.5 (MMOL/L)	01/05/92	3.20		3.90		4.00	
TRIGLYCERIDES	0-1.7 (MMOL/L)	01/05/92	0.50		0.70		0.50	
GLOBULINS ALPHA 1	2-4 (G/L)	01/05/92	2.46		2.66		2.00	
GLOBULINS ALPHA 2	5-9 (G/L)	01/05/92	6.48		5.67		4.30	
GLOBULINS BETA	7-11 (G/L)	01/05/92	7.60		9.83		12.60	
GLOBULINS GAMMA	7-16 (G/L)	01/05/92	14.28		17.63	>	17.20	
TSH	0.4-5 (MUI/L)	01/05/92	2.30					
T4	9-20.9 (PMOL/L)	01/05/92	17.60					

(€) << 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 955085

REBOXETINE - PROTOCOL 2D124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 11 Patient: 326 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			30/07/92		20/08/92		10/09/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	14.5-18.5 (G/DL)	01/05/92	16.00		15.60		15.90	
HT	0.42-0.54 (L/L)	01/05/92	0.50		0.49		0.49	
RBC	4.8-6.4 (10 ⁶ /MM ³)	01/05/92	5.60		5.40		5.40	
WBC	4-11 (10 ³ /MM ³)	01/05/92	6.90		5.50		6.80	
WBC: N	1.6-8 (10 ³ /MM ³)	01/05/92	4.40		3.40		4.50	
WBC: L	1-4.5 (10 ³ /MM ³)	01/05/92	2.10		1.60		1.90	
WBC: E	0-0.4 (10 ³ /MM ³)	01/05/92	0.10		0.10		0.10	
WBC: M	0.2-0.8 (10 ³ /MM ³)	01/05/92	0.30		0.40		0.30	
WBC: B	0-0.1 (10 ³ /MM ³)	01/05/92	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/92	199.00		156.00		183.00	
NA+	136-147 (MMOL/L)	01/05/92	139.00		142.00		141.00	
K+	3.5-5.1 (MMOL/L)	01/05/92	4.20		4.00		4.30	
CL-	98-108 (MMOL/L)	01/05/92	104.00		106.00		105.00	
Ca++	2.2-2.6 (MMOL/L)	01/05/92	2.54		2.21		2.24	
PO4--	0.8-1.45 (MMOL/L)	01/05/92	1.08		0.73	<	0.86	
SGOT	5-40 (U/L)	01/05/92	23.00		32.00		16.00	
SGPT	5-35 (U/L)	01/05/92	23.00		57.00	>	18.00	
GAMMA GT	0-28 (U/L)	01/05/92	13.00		26.00		15.00	
LDH	100-350 (U/L)	01/05/92	315.00		137.00		144.00	
ALK. PHOSPH.	25-160 (U/L)	01/05/92	47.00		52.00		53.00	
GLUCOSE	3.5-6.8 (MMOL/L)	01/05/92	4.30		3.20	<	3.50	
BUN	()	01/05/92						
UREA	2.6-6.7 (MMOL/L)	01/05/92	4.90		3.80		4.10	
CREATININE	60-115 (UMOL/L)	01/05/92	96.00		100.00		93.00	
URIC ACID	0.18-0.45 (MMOL/L)	01/05/92	0.39		0.49	>	0.33	
TOT BILIRUBIN	4-21 (UMOL/L)	01/05/92	13.00		10.00		15.00	
DIR BILIRUBIN	0-4 (UMOL/L)	01/05/92			72.00		72.00	
TOT. PROTEINS	65-80 (G/L)	01/05/92	72.00		73.00		72.00	
ALBUMINE	38-52 (G/L)	01/05/92	43.00		43.30		54.70 >	
TOT. CHOLEST.	2-6.5 (MMOL/L)	01/05/92	4.30		4.10		4.60	
TRIGLYCERIDES	0-1.7 (MMOL/L)	01/05/92	0.80		0.50		0.60	
GLOBULINS ALPHA 1	2-4 (G/L)	01/05/92	2.38		2.86		1.70 <	
GLOBULINS ALPHA 2	5-9 (G/L)	01/05/92	7.07		8.52		4.50 <	
GLOBULINS BETA	7-11 (G/L)	01/05/92	9.88		9.48		6.30 <	
GLOBULINS GAMMA	7-16 (G/L)	01/05/92	8.77		8.76		4.80 <<	
TSH	0.4-5 (MUI/L)	01/05/92	1.60					
T4	9-20.9 (PMOL/L)	01/05/92	14.10					

(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 480085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 11 Patient: 328 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 28	
			19/08/92		10/09/92		18/09/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14.5-18.5 (G/DL)	01/05/92	14.10	<	17.00		16.50	
HT	0.42-0.54 (L/L)	01/05/92	0.44		0.51		0.52	
RBC	4.8-6.4 (10 ⁶ /MM ³)	01/05/92	5.10		5.70		5.60	
WBC	4-11 (10 ³ /MM ³)	01/05/92	4.80		5.50		6.60	
WBC: N	1.6-8 (10 ³ /MM ³)	01/05/92	0.91	<<	3.10		4.00	
WBC: L	1-4.5 (10 ³ /MM ³)	01/05/92	2.40		1.90		2.10	
WBC: E	0-0.4 (10 ³ /MM ³)	01/05/92	0.38		0.10		0.10	
WBC: M	0.2-0.8 (10 ³ /MM ³)	01/05/92	0.62		0.40		0.40	
WBC: B	0-0.1 (10 ³ /MM ³)	01/05/92	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/92	260.00		233.00		257.00	
NA+	136-147 (MMOL/L)	01/05/92	140.00		137.00		137.00	
K+	3.5-5.1 (MMOL/L)	01/05/92	3.80		3.90		3.40 <	
CL-	98-108 (MMOL/L)	01/05/92	102.00		100.00		99.00	
Ca++	2.2-2.6 (MMOL/L)	01/05/92	2.37		2.31		2.35	
PO4--	0.8-1.45 (MMOL/L)	01/05/92	1.06		0.71 <		1.06	
SGOT	5-40 (U/L)	01/05/92	23.00		18.00		19.00	
SGPT	5-35 (U/L)	01/05/92	26.00		18.00		21.00	
GAMMA GT	0-28 (U/L)	01/05/92	24.00		21.00		22.00	
LDH	100-350 (U/L)	01/05/92	126.00		139.00		135.00	
ALK. PHOSPH.	25-160 (U/L)	01/05/92	69.00		71.00		77.00	
GLUCOSE	3.5-6.8 (MMOL/L)	01/05/92	4.90		4.30		3.80	
BUN	()	01/05/92						
UREA	2.6-6.7 (MMOL/L)	01/05/92	4.70		4.30		4.20	
CREATININE	60-115 (UMOL/L)	01/05/92	83.00		85.00		72.00	
URIC ACID	0.18-0.45 (MMOL/L)	01/05/92	0.38		0.34		0.32	
TOT BILIRUBIN	4-21 (UMOL/L)	01/05/92	11.00		11.00		12.00	
DIR BILIRUBIN	0-4 (UMOL/L)	01/05/92						
TOT. PROTEINS	65-80 (G/L)	01/05/92	80.00		72.00		79.00	
ALBUMINE	38-52 (G/L)	01/05/92	47.90		50.10		57.00 >	
TOT. CHOLEST.	2-6.5 (MMOL/L)	01/05/92	5.40		4.70		5.50	
TRIGLYCERIDES	0-1.7 (MMOL/L)	01/05/92	1.40		1.20		1.80 >	
GLOBULINS ALPHA 1	2-4 (G/L)	01/05/92	2.54		1.80		1.70 <	
GLOBULINS ALPHA 2	5-9 (G/L)	01/05/92	6.90		4.50		4.40 <	
GLOBULINS BETA	7-11 (G/L)	01/05/92	11.26	>	7.70		7.90	
GLOBULINS GAMMA	7-16 (G/L)	01/05/92	11.51		7.80		8.00	
TSH	0.4-5 (MUI/L)	01/05/92	1.60					
T4	9-20.9 (PMOL/L)	01/05/92	16.60					

(€) << 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 CN538085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 11 Patient: 329 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/08/92		11/09/92		02/10/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12.5-16.5 (G/DL)	01/05/92	13.60		12.60		13.20	
HT	0.37-0.49 (L/L)	01/05/92	0.41		0.39		0.43	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/05/92	4.80		4.40		4.70	
WBC	4-11 (10 ³ /MM ³)	01/05/92	4.80		4.70		5.30	
WBC: N	1.6-8 (10 ³ /MM ³)	01/05/92	0.82	<<	2.00		2.20	
WBC: L	1-4.5 (10 ³ /MM ³)	01/05/92	2.83		2.00		2.30	
WBC: E	0-0.4 (10 ³ /MM ³)	01/05/92	0.43	>	0.30		0.30	
WBC: M	0.2-0.8 (10 ³ /MM ³)	01/05/92	0.43		0.30		0.40	
WBC: B	0-0.1 (10 ³ /MM ³)	01/05/92	0.00		0.10		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/92	215.00		257.00		308.00	
NA+	136-147 (MMOL/L)	01/05/92	143.00		140.00		141.00	
K+	3.5-5.1 (MMOL/L)	01/05/92	4.10		4.60		4.20	
CL-	98-108 (MMOL/L)	01/05/92	108.00		108.00		108.00	
Ca++	2.2-2.6 (MMOL/L)	01/05/92	2.21		2.29		2.10 <	
PO4--	0.8-1.45 (MMOL/L)	01/05/92	1.00		1.09		1.05 <	
SGOT	5-40 (U/L)	01/05/92	30.00		28.00		23.00	
SGPT	5-35 (U/L)	01/05/92	43.00	>	35.00		21.00	
GAMMA GT	4-18 (U/L)	01/05/92	49.00	>>	26.00	>	38.00 >>	
LDH	100-350 (U/L)	01/05/92	203.00		177.00		165.00	
ALK. PHOSPH.	25-160 (U/L)	01/05/92	106.00		113.00		97.00	
GLUCOSE	3.5-6.8 (MMOL/L)	01/05/92	3.40	<	3.80		3.80	
BUN	()	01/05/92						
UREA	2.6-6.7 (MMOL/L)	01/05/92	3.30		3.60		2.30 <	
CREATININE	47-88 (UMOL/L)	01/05/92	74.00		68.00		60.00	
URIC ACID	0.12-0.4 (MMOL/L)	01/05/92	0.29		0.31		0.26	
TOT. BILIRUBIN	4-21 (UMOL/L)	01/05/92	23.00	>	5.00		18.00	
DIR. BILIRUBIN	0-4 (UMOL/L)	01/05/92						
TOT. PROTEINS	65-80 (G/L)	01/05/92	79.00		73.00		73.00	
ALBUMINE	38-52 (G/L)	01/05/92	47.30		46.00		44.60	
TOT. CHOLEST.	2-6.5 (MMOL/L)	01/05/92	4.90		4.70		4.80	
TRIGLYCERIDES	0-1.7 (MMOL/L)	01/05/92			1.30		1.00	
GLOBULINS ALPHA 1	2-4 (G/L)	01/05/92	2.46		2.10		2.10	
GLOBULINS ALPHA 2	5-9 (G/L)	01/05/92	6.97		5.90		6.80	
GLOBULINS BETA	7-11 (G/L)	01/05/92	9.66		8.20		8.80	
GLOBULINS GAMMA	7-16 (G/L)	01/05/92	12.58		10.70		10.70	
TSH	0.4-5 (MUI/L)	01/05/92	2.00					
T4	9-20.9 (PMOL/L)	01/05/92	14.90					

(€) << 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 350085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 11 Patient: 332 Treatment: Imipramine Sex: Female

Laboratory test			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			03/09/92		28/09/92		15/10/92	
			value	(c)	value	(c)	value	(c)
Range value	Range date							
HB	12.5-16.5 (G/DL) 01/05/92	12.00	<	11.30	<	11.40	<	
HT	0.37-0.49 (L/L) 01/05/92	0.38		0.36	<	0.35	<	
RBC	4.2-5.8 (10 ⁶ /MM ³) 01/05/92	4.30		4.10	<	4.00	<	
WBC	4-11 (10 ³ /MM ³) 01/05/92	9.50		7.80		6.90		
WBC: N	1.6-8 (10 ³ /MM ³) 01/05/92	7.30		5.30		4.10		
WBC: L	1-4.5 (10 ³ /MM ³) 01/05/92	1.80		1.70		2.20		
WBC: E	0-0.4 (10 ³ /MM ³) 01/05/92	0.10		0.40		0.30		
WBC: M	0.2-0.8 (10 ³ /MM ³) 01/05/92	0.30		0.40		0.40		
WBC: B	0-0.1 (10 ³ /MM ³) 01/05/92	0.10		0.10		0.00		
PLATELETS	150-400 (10 ³ /MM ³) 01/05/92	372.00		361.00		360.00		
NA+	136-147 (MMOL/L) 01/05/92	138.00		141.00		133.00	<	
K+	3.5-5.1 (MMOL/L) 01/05/92	4.00		4.20		4.00		
CL-	98-108 (MMOL/L) 01/05/92	105.00		107.00		106.00		
Ca++	2.2-2.6 (MMOL/L) 01/05/92	2.38		2.26		2.22		
PO4--	0.8-1.45 (MMOL/L) 01/05/92	1.24		1.13		1.06		
SGOT	5-40 (U/L) 01/05/92	19.00		26.00		22.00		
SGPT	5-35 (U/L) 01/05/92	14.00		13.00		20.00		
GAMMA GT	4-18 (U/L) 01/05/92	19.00	>	11.00		16.00		
LDH	100-350 (U/L) 01/05/92	156.00		144.00		146.00		
ALK. PHOSPH.	25-160 (U/L) 01/05/92	77.00		74.00		72.00		
GLUCOSE	3.5-6.8 (MMOL/L) 01/05/92	3.80		2.90	<	2.80	<	
BUN	() 01/05/92							
UREA	2.6-6.7 (MMOL/L) 01/05/92	2.70		3.80		3.80		
CREATININE	47-88 (UMOL/L) 01/05/92	81.00		67.00		99.00	>	
URIC ACID	0.12-0.4 (MMOL/L) 01/05/92	0.29		0.17		0.18		
TOT BILIRUBIN	4-21 (UMOL/L) 01/05/92	8.00		6.00		6.00		
DIR BILIRUBIN	0-4 (UMOL/L) 01/05/92							
TOT. PROTEINS	65-80 (G/L) 01/05/92	76.00		77.00		75.00		
ALBUMINE	38-52 (G/L) 01/05/92	49.40		46.30		48.10		
TOT. CHOLEST.	2-6.5 (MMOL/L) 01/05/92	4.60		4.60		4.60		
TRIGLYCERIDES	0-1.7 (MMOL/L) 01/05/92	1.00		1.00		1.10		
GLOBULINS ALPHA 1	2-4 (G/L) 01/05/92	2.40		2.70		2.10		
GLOBULINS ALPHA 2	5-9 (G/L) 01/05/92	5.60		6.90		5.40		
GLOBULINS BETA	7-11 (G/L) 01/05/92	7.40		8.30		8.00		
GLOBULINS GAMMA	7-16 (G/L) 01/05/92	11.20		12.90		11.30		
TSH	0.4-5 (MUI/L) 01/05/92	2.20						
T4	9-20.9 (PMOL/L) 01/05/92	15.80						

(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 0085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 11 Patient: 333 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/09/92		25/09/92		16/10/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12.5-16.5 (G/DL)	01/05/92	13.60		13.70		13.10	
HT	0.37-0.49 (L/L)	01/05/92	0.42		0.42		0.41	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/05/92	4.32		4.40		4.12 <	
WBC	4-11 (10 ³ /MM ³)	01/05/92	4.60		6.90		4.50	
WBC: N	1.6-8 (10 ³ /MM ³)	01/05/92	1.80		5.00		2.20	
WBC: L	1-4.5 (10 ³ /MM ³)	01/05/92	2.30		1.50		1.80	
WBC: E	0-0.4 (10 ³ /MM ³)	01/05/92	0.10		0.00		0.10	
WBC: M	0.2-0.8 (10 ³ /MM ³)	01/05/92	0.30		0.30		0.30	
WBC: B	0-0.1 (10 ³ /MM ³)	01/05/92	0.00		0.00		0.10	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/92	329.00		261.00		296.00	
NA+	136-147 (MMOL/L)	01/05/92	138.00		141.00		138.00	
K+	3.5-5.1 (MMOL/L)	01/05/92	4.50		3.80		4.20	
CL-	98-108 (MMOL/L)	01/05/92	103.00		104.00		105.00	
Ca++	2.2-2.6 (MMOL/L)	01/05/92	2.31		2.20		2.26	
PO4--	0.8-1.45 (MMOL/L)	01/05/92	1.32		0.91		1.01	
SGOT	5-40 (U/L)	01/05/92	22.00		21.00		17.00	
SGPT	5-35 (U/L)	01/05/92	23.00		18.00		19.00	
GAMMA GT	4-18 (U/L)	01/05/92	19.00 >		7.00		17.00	
LDH	100-350 (U/L)	01/05/92	155.00		142.00		132.00	
ALK. PHOSPH.	25-160 (U/L)	01/05/92	57.00		49.00		59.00	
GLUCOSE	3.5-6.8 (MMOL/L)	01/05/92	4.40		4.60		3.80	
BUN	()	01/05/92						
UREA	2.6-6.7 (MMOL/L)	01/05/92	3.00		2.30 <		3.40	
CREATININE	47-88 (UMOL/L)	01/05/92	82.00		71.00		69.00	
URIC ACID	0.12-0.4 (MMOL/L)	01/05/92	0.13		0.23		0.19	
TOT BILIRUBIN	4-21 (UMOL/L)	01/05/92	5.00		6.00		7.00	
DIR BILIRUBIN	0-4 (UMOL/L)	01/05/92						
TOT. PROTEINS	65-80 (G/L)	01/05/92	75.00		69.00		70.00	
ALBUMINE	38-52 (G/L)	01/05/92	51.20		47.30		47.20	
TOT. CHOLEST.	2-6.5 (MMOL/L)	01/05/92	7.90 >		4.80		6.40	
TRIGLYCERIDES	0-1.7 (MMOL/L)	01/05/92	0.70		0.90		0.70	
GLOBULINS ALPHA 1	2-4 (G/L)	01/05/92	2.60		2.10		2.00	
GLOBULINS ALPHA 2	5-9 (G/L)	01/05/92	6.70		6.10		7.10	
GLOBULINS BETA	7-11 (G/L)	01/05/92	8.10		7.00		7.30	
GLOBULINS GAMMA	7-16 (G/L)	01/05/92	6.50 <		6.30 <		6.40 <	
TSH	0.4-5 (MUI/L)	01/05/92	2.90					
T4	9-20.9 (PMOL/L)	01/05/92	9.50					

(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

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS 990085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 12 Patient: 337 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			11/05/92		15/06/92		06/07/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12.3-16.7 (G/DL)	01/04/92	15.30		14.20		14.90	
HT	36-50 (%)	01/04/92	45.00		42.00		44.00	
RBC	3.7-5.7 (10 ⁶ /MM ³)	01/04/92	5.00		4.60		5.00	
WBC	3.9-11.5 (10 ³ /MM ³)	01/04/92	8.80		8.00		5.60	
WBC: N	2-7.5 (10 ³ /MM ³)	01/04/92	5.96		4.80		2.58	
WBC: L	1-4 (10 ³ /MM ³)	01/04/92	2.02		2.40		2.31	
WBC: E	0.2-0.45 (10 ³ /MM ³)	01/04/92	0.08	<	0.08	<	0.08	
WBC: M	0.2-0.8 (10 ³ /MM ³)	01/04/92	0.68		0.72		0.54	
WBC: B	0-0.1 (10 ³ /MM ³)	01/04/92	0.06		0.00		0.08	
PLATELETS	150-400 (10 ³ /MM ³)	01/04/92	416.00	>	386.00		384.00	
NA+	135-150 (MMOL/L)	01/04/92	141.00		141.00		138.00	
K+	3.6-5.7 (MMOL/L)	01/04/92	5.10		4.50		4.90	
CL-	99-110 (MMOL/L)	01/04/92	105.00		106.00		104.00	
Ca++	2.15-2.65 (MMOL/L)	01/04/92	2.42		2.34		2.48	
PO4--	0.8-1.5 (MMOL/L)	01/04/92	1.04		1.02		1.27	
SGOT	5-45 (U/L)	01/04/92	24.00		24.00		46.00	
SGPT	5-50 (U/L)	01/04/92	18.00		17.00		36.00	
GAMMA GT	0-50 (U/L)	01/04/92	15.00		17.00		7.00	
LDH	120-230 (U/L)	01/04/92	188.00		162.00		184.00	
ALK. PHOSPH.	21-91 (IU/L)	01/04/92	81.00		78.00		59.00	
GLUCOSE	4.5-7.8 (MMOL/L)	01/04/92	3.20	<	2.70	<<	4.00	
BUN	2.5-6.6 (MMOL/L)	01/04/92	4.50		4.30		4.00	
UREA	()	01/04/92						
CREATININE	62-115 (UMOL/L)	01/04/92	101.00		88.00		112.00	
URIC ACID	0.09-0.35 (MMOL/L)	01/04/92	0.23		0.26		0.34	
TOT BILIRUBIN	2-26 (UMOL/L)	01/04/92	5.00		6.00		4.00	
DIR BILIRUBIN	0-7 (UMOL/L)	01/04/92	1.00		2.00		1.00	
TOT. PROTEINS	60-80 (G/L)	01/04/92	73.00		79.00		71.00	
ALBUMINE	35-50 (G/L)	01/04/92	43.00		48.00		46.00	
TOT. CHOLEST.	3.5-5.1 (MMOL/L)	01/04/92	6.30	>	6.52	>	5.86	
TRIGLYCERIDES	0.28-2.3 (MMOL/L)	01/04/92	2.55	>	2.57	>	1.16	
GLOBULINS ALPHA 1	1-4 (G/L)	01/04/92	3.00		3.00		3.00	
GLOBULINS ALPHA 2	4-9 (G/L)	01/04/92	7.00		7.00		7.00	
GLOBULINS BETA	5-10 (G/L)	01/04/92	11.00	>	11.00	>	8.00	
GLOBULINS GAMMA	6-15 (G/L)	01/04/92	9.00		10.00		7.00	
TSH	0.4-5 (UU/ML)	01/04/92	1.46					
T4	11-24 (PMOL/L)	01/04/92	15.00					

(¢) << 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 990085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 12 Patient: 339 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			02/06/92		13/07/92		03/08/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14.1-18.5 (G/DL)	01/04/92	14.70		15.30		15.00	
HT	41-56 (%)	01/04/92	43.00		44.00		44.00	
RBC	4-6.5 (10 ⁶ /MM ³)	01/04/92	4.50		4.80		4.80	
WBC	3.9-11.5 (10 ³ /MM ³)	01/04/92	8.90		11.60 >		8.90	
WBC: N	2-7.5 (10 ³ /MM ³)	01/04/92	4.68		6.24		3.77	
WBC: L	1-4 (10 ³ /MM ³)	01/04/92	3.07		3.48		3.75	
WBC: E	0.2-0.45 (10 ³ /MM ³)	01/04/92	0.27		0.15 <		0.43	
WBC: M	0.2-0.8 (10 ³ /MM ³)	01/04/92	0.76		1.02 >		0.86 >	
WBC: B	0-0.1 (10 ³ /MM ³)	01/04/92	0.12 >		0.10		0.09	
PLATELETS	150-400 (10 ³ /MM ³)	01/04/92	398.00		409.00 >		389.00	
NA+	135-150 (MMOL/L)	01/04/92	142.00		141.00		140.00	
K+	3.6-5.7 (MMOL/L)	01/04/92	4.40		5.30		4.20	
CL-	99-110 (MMOL/L)	01/04/92	109.00		105.00		103.00	
Ca++	2.15-2.65 (MMOL/L)	01/04/92	2.44		2.38		2.25	
PO4--	0.8-1.5 (MMOL/L)	01/04/92	1.15		1.13		1.03	
SGOT	5-45 (U/L)	01/04/92	20.00		37.00		22.00	
SGPT	5-50 (U/L)	01/04/92	9.00		17.00		10.00	
GAMMA GT	0-50 (U/L)	01/04/92	24.00		24.00		18.00	
LDH	120-230 (U/L)	01/04/92	156.00		182.00		152.00	
ALK. PHOSPH.	21-91 (IU/L)	01/04/92	62.00		70.00		48.00	
GLUCOSE	4.5-7.8 (MMOL/L)	01/04/92	4.00 <		3.90 <		4.20 <	
BUN	2.5-6.6 (MMOL/L)	01/04/92	6.60		6.10		3.90	
UREA	()	01/04/92						
CREATININE	62-115 (UMOL/L)	01/04/92	109.00		113.00		98.00	
URIC ACID	0.15-0.41 (MMOL/L)	01/04/92	0.30		0.30		0.23	
TOT BILIRUBIN	2-26 (UMOL/L)	01/04/92	10.00		12.00		3.00	
DIR BILIRUBIN	0-7 (UMOL/L)	01/04/92	1.00		1.00		1.00	
TOT. PROTEINS	60-80 (G/L)	01/04/92	70.00		71.00		61.00	
ALBUMINE	35-50 (G/L)	01/04/92	38.00		44.00		37.00	
TOT. CHOLEST.	3.5-5.1 (MMOL/L)	01/04/92	3.81		3.94		3.73	
TRIGLYCERIDES	0.28-2.3 (MMOL/L)	01/04/92	0.66		0.79		1.57	
GLOBULINS ALPHA 1	1-4 (G/L)	01/04/92	3.00		2.00		2.00	
GLOBULINS ALPHA 2	4-9 (G/L)	01/04/92	7.00		6.00		6.00	
GLOBULINS BETA	5-10 (G/L)	01/04/92	10.00		8.00		8.00	
GLOBULINS GAMMA	6-15 (G/L)	01/04/92	12.00		11.00		8.00	
TSH	0.4-5 (UU/ML)	01/04/92	1.89					
T4	11-24 (PMOL/L)	01/04/92	14.50					

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS 350085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 13 Patient: 354 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			24/06/92		15/07/92		12/08/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.6-15.6 (G/DL)	02/05/92	12.70		12.70		13.40	
HT	0.35-0.45 (L/L)	02/05/92	0.36		0.39		0.38	
RBC	3.7-5.3 (10 ⁶ /MM ³)	02/05/92	4.02		4.44		4.37	
WBC	4-11 (10 ³ /MM ³)	02/05/92	6.99		6.86		5.44	
WBC: N	40-75 (%)	02/05/92	54.00		52.00		48.00	
WBC: L	20-45 (%)	02/05/92	38.00		36.00		35.00	
WBC: E	1-6 (%)	02/05/92	1.00		3.00		5.00	
WBC: M	2-10 (%)	02/05/92	6.00		7.00		9.00	
WBC: B	0-1 (%)	02/05/92	0.00		0.00		1.00	
PLATELETS	140-420 (10 ³ /MM ³)	02/05/92	250.00		299.00		293.00	
NA+	135-145 (MMOL/L)	02/05/92	140.00		142.00		140.00	
K+	3.5-5.5 (MMOL/L)	02/05/92	3.90		4.20		4.30	
CL-	97-107 (MMOL/L)	02/05/92	106.00		111.00 >		109.00 >	
Ca++	2.1-2.6 (MMOL/L)	02/05/92	2.29		2.32		2.34	
PO4--	0.8-1.3 (MMOL/L)	02/05/92	1.28		1.12		1.09	
SGOT	0-53 (U/L)	02/05/92	12.00		25.00		78.00 >	
SGPT	1-25 (U/L)	02/05/92	7.00		29.00 >		19.00	
GAMMA GT	0-40 (U/L)	02/05/92	21.00		25.00		27.00	
LDH	175-350 (U/L)	02/05/92	195.00		207.00		206.00	
ALK. PHOSPH.	30-70 (U/L)	02/05/92	91.00 >		86.00 >		129.00 >	
GLUCOSE	3.7-5.6 (MMOL/L)	02/05/92	4.80		3.70		4.00	
BUN	1.7-6.7 (MMOL/L)	02/05/92	3.70		4.00		4.00	
UREA	()	02/05/92						
CREATININE	75-115 (UMOL/L)	02/05/92	72.00 <		71.00 <		72.00 <	
URIC ACID	0.09-0.36 (MMOL/L)	02/05/92	0.19		0.20		0.25	
TOT BILIRUBIN	1-17 (UMOL/L)	02/05/92	5.00		7.00		5.00	
DIR BILIRUBIN	1.7-5.1 (UMOL/L)	02/05/92	1.00 <		2.00		1.00 <	
TOT. PROTEINS	60-80 (G/L)	02/05/92	71.00		72.00		76.00	
ALBUMINE	35-50 (G/L)	02/05/92	43.00		41.00		44.00	
TOT. CHOLEST.	0-5.1 (MMOL/L)	02/05/92	4.40		5.20 >		5.00	
TRIGLYCERIDES	0.3-2.3 (MMOL/L)	02/05/92						
GLOBULINS ALPHA 1	1-3 (G/L)	02/05/92			1.66			
GLOBULINS ALPHA 2	5-9 (G/L)	02/05/92			5.62			
GLOBULINS BETA	4-10 (G/L)	02/05/92			7.96			
GLOBULINS GAMMA	7-20 (G/L)	02/05/92			12.84			
TSH	0.4-4 (MU/L)	02/05/92	1.07					
T4	6.3-22.8 (PNOL/L)	02/05/92						

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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 5590085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centro: 13 Patient: 356 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/07/92		12/08/92		02/09/92	
			value	(*)	value	(*)	value	(*)
Laboratory test	Range value	Range date						
HB	13.3-17.3 (G/DL)	10/07/92			15.20		15.70	
HT	0.4-0.5 (L/L)	10/07/92			0.46		0.46	
RBC	4.5-5.9 (10 ⁶ /MM ³)	10/07/92			5.24		5.24	
WBC	4-11 (10 ³ /MM ³)	10/07/92			7.40		11.82	>
WBC: N	40-75 (%)	10/07/92			66.00		71.00	
WBC: L	20-45 (%)	10/07/92			21.00		14.00	<
WBC: E	1-6 (%)	10/07/92			5.00		7.00	>
WBC: M	2-10 (%)	10/07/92			7.00		6.00	
WBC: B	0-1 (%)	10/07/92			1.00		1.00	
PLATELETS	140-420 (10 ³ /MM ³)	10/07/92			343.00		385.00	
NA+	135-145 (MMOL/L)	10/07/92	139.00		139.00		137.00	
K+	3.5-5.5 (MMOL/L)	10/07/92	4.80		4.90		4.40	
CL-	97-107 (MMOL/L)	10/07/92	105.00		105.00		103.00	
Ca++	2.1-2.6 (MMOL/L)	10/07/92	2.32		2.41		2.35	
PO4--	0.8-1.3 (MMOL/L)	10/07/92	1.04		0.77	<	1.06	
SGOT	0-53 (U/L)	10/07/92	29.00		26.00		31.00	
SGPT	1-25 (U/L)	10/07/92	17.00		31.00	>	39.00	>
GAMMA GT	0-40 (U/L)	10/07/92	0.00		0.00		11.00	
LDH	175-350 (U/L)	10/07/92	233.00		171.00	<	211.00	
ALK. PHOSPH.	30-70 (U/L)	10/07/92	106.00	>	103.00	>	120.00	>
GLUCOSE	3.7-5.6 (MMOL/L)	10/07/92	4.50		3.20	<	4.30	
BUN	1.7-6.7 (MMOL/L)	10/07/92	4.30		3.50		3.80	
UREA	()	10/07/92						
CREATININE	75-115 (UMOL/L)	10/07/92	83.00		80.00		87.00	
URIC ACID	0.15-0.48 (MMOL/L)	10/07/92	0.23		0.25		0.25	
TOT BILIRUBIN	1-17 (UMOL/L)	10/07/92	9.00		7.00		5.00	
DIR BILIRUBIN	1.7-5.1 (UMOL/L)	10/07/92	1.00	<	1.00	<	2.00	
TOT. PROTEINS	60-80 (G/L)	10/07/92	74.00		72.00		71.00	
ALBUMINE	35-50 (G/L)	10/07/92	46.00		44.00		41.00	
TOT. CHOLEST.	0-5.1 (MMOL/L)	10/07/92	5.50	>	5.00		5.10	
TRIGLYCERIDES	0.3-2.3 (MMOL/L)	10/07/92	0.90		1.10		1.20	
GLOBULINS ALPHA 1	1-5 (%)	10/07/92			2.11			
GLOBULINS ALPHA 2	4.5-9.5 (%)	10/07/92			12.32	>		
GLOBULINS BETA	11-16 (%)	10/07/92			11.93			
GLOBULINS GAMMA	12-22 (%)	10/07/92			13.34			
TSH	0.4-4 (MU/L)	10/07/92	1.47					
T4	6.3-22.8 (PMOL/L)	10/07/92						

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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 090085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 13 Patient: 357 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	
			05/08/92	
			value	(*)
Laboratory test	Range value	Range date		
HB	11.6-15.6 (G/DL)	03/08/92	11.40	<
HT	0.35-0.45 (L/L)	03/08/92	0.33	<
RBC	3.7-5.3 (10 ⁶ /MM ³)	03/08/92	4.24	
WBC	4-11 (10 ³ /MM ³)	03/08/92	5.51	
WBC: N	40-75 (%)	03/08/92	59.00	
WBC: L	20-45 (%)	03/08/92	33.00	
WBC: E	1-6 (%)	03/08/92	0.00	<
WBC: M	2-10 (%)	03/08/92	6.00	
WBC: B	0-1 (%)	03/08/92	0.00	
PLATELETS	140-420 (10 ³ /MM ³)	03/08/92	348.00	
NA+	135-145 (MMOL/L)	03/08/92	140.00	
K+	3.5-5.5 (MMOL/L)	03/08/92	4.30	
CL-	97-107 (MMOL/L)	03/08/92	103.00	
Ca++	2.1-2.6 (MMOL/L)	03/08/92	2.35	
PO4--	0.8-1.3 (MMOL/L)	03/08/92	1.27	
SGOT	0-53 (U/L)	03/08/92	13.00	
SGPT	1-25 (U/L)	03/08/92	12.00	
GAMMA GT	0-40 (U/L)	03/08/92	11.00	
LDH	175-350 (U/L)	03/08/92	198.00	
ALK. PHOSPH.	30-70 (U/L)	03/08/92		
GLUCOSE	3.7-5.6 (MMOL/L)	03/08/92	4.40	
BUN	1.7-6.7 (MMOL/L)	03/08/92	6.10	
UREA	()	03/08/92		
CREATININE	75-115 (UMOL/L)	03/08/92	64.00	<
URIC ACID	0.09-0.36 (MMOL/L)	03/08/92	0.19	
TOT BILIRUBIN	1-17 (UMOL/L)	03/08/92	8.00	
DIR BILIRUBIN	1.7-5.1 (UMOL/L)	03/08/92	2.00	
TOT. PROTEINS	60-80 (G/L)	03/08/92	83.00	>
ALBUMINE	55-75 (%)	03/08/92	51.00	<
TOT. CHOLEST.	0-5.1 (MMOL/L)	03/08/92	4.10	
TRIGLYCERIDES	0.3-2.3 (MMOL/L)	03/08/92		
GLOBULINS ALPHA 1	1-5 (%)	03/08/92	1.87	
GLOBULINS ALPHA 2	4.5-9.5 (%)	03/08/92	7.88	
GLOBULINS BETA	11-16 (%)	03/08/92	15.44	
GLOBULINS GAMMA	12-22 (%)	03/08/92	23.32	>
TSH	0.4-4 (MU/L)	03/08/92	0.78	
T4	6.3-22.8 (PMOL/L)	03/08/92		

(*) << 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 9890085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 13 Patient: 360 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			19/08/92
			value (⊕)
Laboratory test	Range value	Range date	
HB	11.6-15.6 (G/DL)	02/05/92	13.00
HT	0.35-0.45 (L/L)	02/05/92	0.39
RBC	3.7-5.3 (10 ⁶ /MM ³)	02/05/92	4.59
WBC	4-11 (10 ³ /MM ³)	02/05/92	5.30
WBC: N	40-75 (%)	02/05/92	57.00
WBC: L	20-45 (%)	02/05/92	32.00
WBC: E	1-6 (%)	02/05/92	1.00
WBC: M	2-10 (%)	02/05/92	7.00
WBC: B	0-1 (%)	02/05/92	
PLATELETS	140-420 (10 ³ /MM ³)	02/05/92	184.00
NA+	135-145 (MMOL/L)	02/05/92	140.00
K+	3.5-5.5 (MMOL/L)	02/05/92	4.00
CL-	97-107 (MMOL/L)	02/05/92	108.00 >
Ca++	2.1-2.6 (MMOL/L)	02/05/92	2.33
PO4--	0.8-1.3 (MMOL/L)	02/05/92	0.96
SGOT	0-53 (U/L)	02/05/92	10.00
SGPT	1-25 (U/L)	02/05/92	17.00
GAMMA GT	0-40 (U/L)	02/05/92	2.00
LDH	175-350 (U/L)	02/05/92	171.00 <
ALK. PHOSPH.	30-70 (U/L)	02/05/92	77.00 >
GLUCOSE	3.7-5.6 (MMOL/L)	02/05/92	4.10
BUN	1.7-6.7 (MMOL/L)	02/05/92	2.70
UREA	()	02/05/92	
CREATININE	75-115 (UMOL/L)	02/05/92	68.00 <
URIC ACID	0.09-0.36 (MMOL/L)	02/05/92	0.14
TOT BILIRUBIN	1-17 (UMOL/L)	02/05/92	3.00
DIR BILIRUBIN	1.7-5.1 (UMOL/L)	02/05/92	1.00 <
TOT. PROTEINS	60-80 (G/L)	02/05/92	69.00
ALBUMINE	35-50 (G/L)	02/05/92	43.00
TOT. CHOLEST.	0-5.1 (MMOL/L)	02/05/92	4.90
TRIGLYCERIDES	0.3-2.3 (MMOL/L)	02/05/92	
GLOBULINS ALPHA 1	1-3 (G/L)	02/05/92	
GLOBULINS ALPHA 2	5-9 (G/L)	02/05/92	
GLOBULINS BETA	4-10 (G/L)	02/05/92	
GLOBULINS GAMMA	7-20 (G/L)	02/05/92	
TSH	0.4-4 (MU/L)	02/05/92	0.57
T4	6.3-22.8 (PMOL/L)	02/05/92	

(⊕) << 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 950085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14 Patient: 458 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/07/92		04/08/92		25/08/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/06/92	13.10		13.20		13.30	
HT	42-54 (%)	01/06/92	39.00 <		39.00 <		40.00 <	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/06/92	4.00 <		4.10 <		4.20 <	
WBC	4000-9000 (/MM ³)	01/06/92	7200.00		7000.00		6800.00	
WBC: N	50-70 (%)	01/06/92						
WBC: L	25-40 (%)	01/06/92	39.00		39.00		38.00	
WBC: E	1-4 (%)	01/06/92	3.00		4.00		3.00	
WBC: M	4-8 (%)	01/06/92	4.00		3.00 <		2.00 <	
WBC: B	0-1 (%)	01/06/92	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM ³)	01/06/92	280000		280000		280000	
NA+	134-148 (MMOL/L)	01/06/92	136.00		139.00		138.00	
K+	3.8-5.2 (MMOL/L)	01/06/92	3.80		3.70 <		3.60 <	
CL-	1.8-2.2 (MG/DL)	01/06/92	2.10		2.00		1.90	
Ca++	2-2.6 (MMOL/L)	01/06/92	1.90 <		1.90 <		2.00	
PO4--	()	01/06/92						
SGOT	5-18 (U/L)	01/06/92	10.00		10.00		11.00	
SGPT	5-22 (U/L)	01/06/92	10.00		10.00		15.00	
GAMMA GT	4-28 (U/L)	01/06/92	12.00		14.00		19.00	
LDH	120-240 (U/L)	01/06/92	171.00		170.00		172.00	
ALK. PHOSPH.	60-170 (U/L)	01/06/92	134.00		126.00		131.00	
GLUCOSE	60-110 (MG/DL)	01/06/92	88.00		94.00		96.00	
BUN	10-50 (MG/DL)	01/06/92	21.00		22.00		26.00	
UREA	()	01/06/92						
CREATININE	0.3-1.2 (MG/DL)	01/06/92	0.80		0.80		0.80	
URIC ACID	2.4-7 (MG/DL)	01/06/92	5.20		5.10		5.60	
TOT BILIRUBIN	0-1 (MG/DL)	01/06/92	0.70		0.70		0.70	
DIR BILIRUBIN	0-0.2 (MG/DL)	01/06/92						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/06/92	8.00		7.00		7.10	
ALBUMINE	57-68 (%)	01/06/92	61.00		62.00		64.00	
TOT. CHOLEST.	0-200 (MG/DL)	01/06/92	241.00 >		236.00 >		251.00 >	
TRIGLYCERIDES	50-180 (MG/DL)	01/06/92	116.00		120.00		141.00	
GLOBULINS ALPHA 1	2-4.5 (%)	01/06/92	2.90		2.80		3.00	
GLOBULINS ALPHA 2	5-9 (%)	01/06/92	6.80		6.70		6.80	
GLOBULINS BETA	9-13 (%)	01/06/92	11.70		11.90		12.40	
GLOBULINS GAMMA	10-20 (%)	01/06/92	12.30		12.80		16.60	
TSH	0.2-3.1 (UU/ML)	01/06/92	1.10					
T4	5-11.5 (UG/DL)	01/06/92	7.20					

(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 CN9590085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14 Patient: 460 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			20/07/92		13/08/92		03/09/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/06/92	14.20		14.20		14.40	
HT	42-54 (X)	01/06/92	39.00	<	39.00	<	39.00	<
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/06/92	4.40		4.30		4.40	
WBC	4000-9000 (/MM ³)	01/06/92	6800.00		6600.00		6900.00	
WBC: N	50-70 (%)	01/06/92						
WBC: L	25-40 (%)	01/06/92	36.00		38.00		38.00	
WBC: E	1-4 (%)	01/06/92	3.00		3.00		2.00	
WBC: M	4-8 (%)	01/06/92	2.00	<	2.00	<	2.00	<
WBC: B	0-1 (%)	01/06/92	1.00		0.00		0.00	
PLATELETS	150000-400000 (/MM ³)	01/06/92	260000		260000		260000	
NA+	134-148 (MMOL/L)	01/06/92	141.00		140.00		139.00	
K+	3.8-5.2 (MMOL/L)	01/06/92	3.90		3.80		3.80	
CL-	1.8-2.2 (MG/DL)	01/06/92	2.00		1.90		2.00	
Ca++	2-2.6 (MMOL/L)	01/06/92	2.40		2.30		2.40	
PO4--	()	01/06/92						
SGOT	5-18 (U/L)	01/06/92	10.00		10.00		10.00	
SGPT	5-22 (U/L)	01/06/92	11.00		10.00		10.00	
GAMMA GT	4-28 (U/L)	01/06/92	14.00		12.00		14.00	
LDH	120-240 (U/L)	01/06/92	161.00		158.00		156.00	
ALK. PHOSPH.	60-170 (U/L)	01/06/92	102.00		101.00		102.00	
GLUCOSE	60-110 (MG/DL)	01/06/92	84.00		92.00		94.00	
BUN	10-50 (MG/DL)	01/06/92	42.00		40.00		41.00	
UREA	()	01/06/92						
CREATININE	0.3-1.2 (MG/DL)	01/06/92	0.90		0.90		0.80	
URIC ACID	2.4-7 (MG/DL)	01/06/92	6.40		6.20		6.40	
TOT BILIRUBIN	0-1 (MG/DL)	01/06/92	0.80		0.80		0.80	
DIR BILIRUBIN	0-0.2 (MG/DL)	01/06/92						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/06/92	8.40		7.20		7.40	
ALBUMINE	57-68 (%)	01/06/92	62.00		63.00		64.00	
TOT. CHOLEST.	0-200 (MG/DL)	01/06/92	207.00	>	113.00		202.00	>
TRIGLYCERIDES	50-180 (MG/DL)	01/06/92	113.00		119.00		176.00	
GLOBULINS ALPHA 1	2-4.5 (%)	01/06/92	3.80		3.90		3.80	
GLOBULINS ALPHA 2	5-9 (%)	01/06/92	7.40		7.60		7.40	
GLOBULINS BETA	9-13 (%)	01/06/92	12.10		12.40		12.90	
GLOBULINS GAMMA	10-20 (%)	01/06/92	16.40		16.80		16.60	
TSH	0.2-3.1 (UU/ML)	01/06/92	2.20					
T4	5-11.5 (UG/DL)	01/06/92	8.30					

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 ** missing laboratory test value and laboratory not done () missing range value

PHARMACIA CNS 990085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14 Patient: 461 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			22/07/92		19/08/92		09/09/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/06/92	12.80		13.00		13.10	
HT	42-54 (%)	01/06/92	39.00	<	39.00	<	39.00	<
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/06/92	4.00	<	4.10	<	4.10	<
WBC	4000-9000 (/MM ³)	01/06/92	6800.00		6600.00		6800.00	
WBC: N	50-70 (%)	01/06/92						
WBC: L	25-40 (%)	01/06/92	35.00		36.00		35.00	
WBC: E	1-4 (%)	01/06/92	2.00		2.00		2.00	
WBC: M	4-8 (%)	01/06/92	4.00		4.00		4.00	
WBC: B	0-1 (%)	01/06/92	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM ³)	01/06/92	260000		260000		260000	
NA+	134-148 (MMOL/L)	01/06/92	141.00		138.00		139.00	
K+	3.8-5.2 (MMOL/L)	01/06/92	3.90		4.00		4.10	
CL-	1.8-2.2 (MG/DL)	01/06/92	2.00		2.10		2.00	
Ca++	2-2.6 (MMOL/L)	01/06/92	2.10		2.00		2.10	
PO4--	()	01/06/92						
SGOT	5-18 (U/L)	01/06/92	12.00		12.00		12.00	
SGPT	5-22 (U/L)	01/06/92	12.00		12.00		12.00	
GAMMA GT	4-28 (U/L)	01/06/92	16.00		17.00		16.00	
LDH	120-240 (U/L)	01/06/92	198.00		196.00		194.00	
ALK. PHOSPH.	60-170 (U/L)	01/06/92	112.00		116.00		121.00	
GLUCOSE	60-110 (MG/DL)	01/06/92	108.00		98.00		94.00	
BUN	10-50 (MG/DL)	01/06/92	41.00		42.00		41.00	
UREA	()	01/06/92						
CREATININE	0.3-1.2 (MG/DL)	01/06/92	0.70		0.70		0.70	
URIC ACID	2.4-7 (MG/DL)	01/06/92	5.80		5.90		6.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/06/92	0.70		0.70		0.70	
DIR BILIRUBIN	0-0.2 (MG/DL)	01/06/92						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/06/92	7.60		7.40		7.20	
ALBUMINE	57-68 (%)	01/06/92	61.00		62.00		61.00	
TOT. CHOLEST.	0-200 (MG/DL)	01/06/92	212.00	>	216.00	>	198.00	
TRIGLYCERIDES	50-180 (MG/DL)	01/06/92	108.00		112.00		107.00	
GLOBULINS ALPHA 1	2-4.5 (%)	01/06/92	3.70		3.80		3.90	
GLOBULINS ALPHA 2	5-9 (%)	01/06/92	7.90		7.60		7.50	
GLOBULINS BETA	9-13 (%)	01/06/92	11.70		12.40		12.70	
GLOBULINS GAMMA	10-20 (%)	01/06/92	17.60		17.90		19.00	
TSH	0.2-3.1 (UU/ML)	01/06/92	1.30					
T4	5-11.5 (UG/DL)	01/06/92	7.00					

(€) << 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 CN9590085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14 Patient: 463 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			27/07/92		24/08/92		14/09/92	
			value	(*)	value	(*)	value	(*)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/06/92	14.80		14.90		14.70	
HT	42-54 (%)	01/06/92	42.00		42.00		42.00	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/06/92	4.40		4.40		4.40	
HBC	4000-9000 (/MM ³)	01/06/92	6900.00		7000.00		6900.00	
HBC: N	50-70 (%)	01/06/92						
HBC: L	25-40 (%)	01/06/92	38.00		39.00		39.00	
HBC: E	1-4 (%)	01/06/92	4.00		4.00		4.00	
HBC: M	4-8 (%)	01/06/92	2.00	<	2.00	<	2.00	
HBC: B	0-1 (%)	01/06/92	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM ³)	01/06/92	290000		290000		290000	
NA+	134-148 (MMOL/L)	01/06/92	142.00		140.00		141.00	
K+	3.8-5.2 (MMOL/L)	01/06/92	4.10		4.00		3.90	
CL-	1.8-2.2 (MG/DL)	01/06/92	2.00		2.00		2.10	
Ca++	2-2.6 (MMOL/L)	01/06/92	2.20		2.00		1.90	
PO4--	()	01/06/92						
SGOT	5-18 (U/L)	01/06/92	12.00		10.00		10.00	
SGPT	5-22 (U/L)	01/06/92	12.00		11.00		11.00	
GAMMA GT	4-28 (U/L)	01/06/92	19.00		17.00		16.00	
LDH	120-240 (U/L)	01/06/92	152.00		156.00		154.00	
ALK. PHOSPH.	60-170 (U/L)	01/06/92	101.00		102.00		100.00	
GLUCOSE	60-110 (MG/DL)	01/06/92	103.00		99.00		106.00	
BUN	10-50 (MG/DL)	01/06/92	39.00		40.00		41.00	
UREA	()	01/06/92						
CREATININE	0.3-1.2 (MG/DL)	01/06/92	0.80		0.80		0.80	
URIC ACID	2.4-7 (MG/DL)	01/06/92	6.20		6.10		6.20	
TOT. BILIRUBIN	0-1 (MG/DL)	01/06/92	0.80		0.80		0.80	
DIR. BILIRUBIN	0-0.2 (MG/DL)	01/06/92						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/06/92	6.80		7.00		7.10	
ALBUMINE	57-68 (%)	01/06/92	62.00		61.00		62.00	
TOT. CHOLEST.	0-200 (MG/DL)	01/06/92	221.00	>	213.00	>	41.00	
TRIGLYCERIDES	50-180 (MG/DL)	01/06/92	198.00	>	180.00		182.00	
GLOBULINS ALPHA 1	2-4.5 (%)	01/06/92	3.90		3.80		3.90	
GLOBULINS ALPHA 2	5-9 (%)	01/06/92	7.60		7.40		7.60	
GLOBULINS BETA	9-13 (%)	01/06/92	12.80		12.90		13.10	
GLOBULINS GAMMA	10-20 (%)	01/06/92	17.90		18.20		18.40	
TSH	0.2-3.1 (UU/ML)	01/06/92	1.70					
T4	5-11.5 (UG/DL)	01/06/92	6.20					

(*) << 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

PHARMACIA CNS 849
3390085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14 Patient: 466 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			31/07/92		28/08/92		18/09/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/06/92	12.20		12.40		12.50	
HT	42-54 (X)	01/06/92	38.00 <		38.00 <		38.00 <	
RBC	4.2-5.8 (10 ⁶ /MM3)	01/06/92	4.00 <		4.10 <		4.10 <	
WBC	4000-9000 (/MM3)	01/06/92	6800.00		7000.00		6900.00	
WBC: N	50-70 (%)	01/06/92						
WBC: L	25-40 (%)	01/06/92	37.00		38.00		39.00	
WBC: E	1-4 (%)	01/06/92	3.00		3.00		2.00	
WBC: M	4-8 (%)	01/06/92	4.00		5.00		5.00	
WBC: B	0-1 (%)	01/06/92	1.00		1.00		0.00	
PLATELETS	150000-400000 (/MM3)	01/06/92	280000		280000		280000	
NA+	134-148 (MMOL/L)	01/06/92	136.00		138.00		139.00	
K+	3.8-5.2 (MMOL/L)	01/06/92	3.80		3.80		3.80	
CL-	1.8-2.2 (MG/DL)	01/06/92	1.90		2.00		2.00	
Ca++	2-2.6 (MMOL/L)	01/06/92	2.10		2.00		2.00	
PO4--	()	01/06/92						
SGOT	5-18 (U/L)	01/06/92	12.00		12.00		12.00	
SGPT	5-22 (U/L)	01/06/92	12.00		12.00		12.00	
GAMMA GT	4-28 (U/L)	01/06/92	16.00		17.00		16.00	
LDH	120-240 (U/L)	01/06/92	172.00		174.00		176.00	
ALK. PHOSPH.	60-170 (U/L)	01/06/92	102.00		100.00		96.00	
GLUCOSE	60-110 (MG/DL)	01/06/92	89.00		93.00		92.00	
BUN	10-50 (MG/DL)	01/06/92	41.00		40.00		41.00	
UREA	()	01/06/92						
CREATININE	0.3-1.2 (MG/DL)	01/06/92	0.80		0.80		0.80	
URIC ACID	2.4-7 (MG/DL)	01/06/92	5.80		5.90		6.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/06/92	0.70		0.70		0.70	
DIR BILIRUBIN	0-0.2 (MG/DL)	01/06/92						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/06/92	7.20		7.10		7.00	
ALBUMINE	57-68 (%)	01/06/92	62.00		63.00		64.00	
TOT. CHOLEST.	0-200 (MG/DL)	01/06/92	212.00 >		232.00 >		221.00 >	
TRIGLYCERIDES	50-180 (MG/DL)	01/06/92	134.00		156.00		119.00	
GLOBULINS ALPHA 1	2-4.5 (%)	01/06/92	3.70		3.80		3.90	
GLOBULINS ALPHA 2	5-9 (%)	01/06/92	7.80		8.00		7.80	
GLOBULINS BETA	9-13 (%)	01/06/92	12.10		12.30		11.90	
GLOBULINS GAMMA	10-20 (%)	01/06/92	16.60		16.80		16.70	
TSH	0.2-3.1 (UU/ML)	01/06/92	1.70					
T4	5-11.5 (UG/DL)	01/06/92	8.30					

(€) << 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 9990085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centro: 14/1 Patient: 429 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			18/09/91
			value (†)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	01/07/91	13.50
HT	37-47 (X)	01/07/91	38.10
RBC	3.9-5.3 (10 ⁶ /MM ³)	01/07/91	4.50
WBC	4000-9000 (/MM ³)	01/07/91	11600.0 >
WBC: N	50-70 (X)	01/07/91	63.00
WBC: L	20-40 (X)	01/07/91	36.00
WBC: E	0-3 (X)	01/07/91	0.00
WBC: M	0-8 (X)	01/07/91	1.00
WBC: B	0-2 (X)	01/07/91	0.00
PLATELETS	150-400 (10 ³ /MM ³)	01/07/91	387.00
NA+	135-145 (MMOL/L)	01/07/91	141.00
K+	3.7-5 (MMOL/L)	01/07/91	4.12
CL-	()	01/07/91	
Ca++	4.5-5.2 (MEQ/L)	01/07/91	4.62
PO4--	()	01/07/91	
SGOT	5-18 (U/L)	01/07/91	4.00 <
SGPT	5-22 (U/L)	01/07/91	6.00
GAMMA GT	0-28 (U/L)	01/07/91	15.00
LDH	120-240 (U/L)	01/07/91	120.00
ALK. PHOSPH.	40-190 (U/L)	01/07/91	112.00
GLUCOSE	60-100 (MG/DL)	01/07/91	100.00
BUN	10-50 (MG/DL)	01/07/91	3.60 <
UREA	()	01/07/91	
CREATININE	0-1.2 (MG/DL)	01/07/91	0.76
URIC ACID	2.5-5.8 (MG/DL)	01/07/91	3.60
TOT BILIRUBIN	0-1 (MG/DL)	01/07/91	0.30
DIR BILIRUBIN	0-0.25 (MG/DL)	01/07/91	
TOT. PROTEINS	6.5-8 (G/DL)	01/07/91	7.09
ALBUMINE	57-68 (X)	01/07/91	67.80
TOT. CHOLEST.	130-200 (MG/DL)	01/07/91	245.00 >
TRIGLYCERIDES	65-170 (MG/DL)	01/07/91	
GLOBULINS ALPHA 1	2-4 (X)	01/07/91	1.90 <
GLOBULINS ALPHA 2	5-9 (X)	01/07/91	4.30 <
GLOBULINS BETA	8-12 (X)	01/07/91	7.70 <
GLOBULINS GAMMA	12-19 (X)	01/07/91	22.90 >
TSH	0.2-4 (MU/L)	01/07/91	1.38
T4	10-25 (PMOL/L)	01/07/91	14.70

(†) << 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 1830 () missing range value

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PHARNACIA CNS 990085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/1 Patient: 451 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			14/11/91		19/12/91		08/01/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/07/91	45.60		15.20		14.80	
HT	40-54 (X)	01/07/91	46.60		42.40		41.90	
RBC	4.1-6 (10 ⁶ /MM ³)	01/07/91	5.20		5.00		5.00	
WBC	4000-9000 (/MM ³)	01/07/91	7900.00		7400.00		9100.00 >	
WBC: N	50-70 (X)	01/07/91	73.00 >		79.00 >		76.00 >	
WBC: L	20-40 (X)	01/07/91	22.00		20.00		20.00	
WBC: E	0-3 (X)	01/07/91	0.00		0.00		0.00	
WBC: M	0-8 (X)	01/07/91	5.00		1.00		4.00	
WBC: B	0-2 (X)	01/07/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/07/91	283.00		298.00		328.00 <	
NA+	135-145 (MMOL/L)	01/07/91	138.00		136.00		134.00 <	
K+	3.7-5 (MMOL/L)	01/07/91	5.00		4.90		4.50	
CL-	()	01/07/91						
Ca++	4.5-5.2 (MEQ/L)	01/07/91	4.67		4.80		4.75	
PO4--	()	01/07/91						
SGOT	5-18 (U/L)	01/07/91	5.00		5.00		6.00	
SGPT	5-22 (U/L)	01/07/91	6.00		6.00		10.00	
GAMMA GT	0-28 (U/L)	01/07/91	22.00		22.00		26.00	
LDH	120-240 (U/L)	01/07/91					128.00	
ALK. PHOSPH.	40-190 (U/L)	01/07/91	125.00		132.00		123.00	
GLUCOSE	60-100 (MG/DL)	01/07/91	113.00 >		155.00 >>		161.00 >>	
BUN	10-50 (MG/DL)	01/07/91	41.00		48.00		39.00	
UREA	()	01/07/91						
CREATININE	0-1.2 (MG/DL)	01/07/91	1.13		1.01		1.11	
URIC ACID	2.5-7 (MG/DL)	01/07/91	4.10		4.80		4.80	
TOT BILIRUBIN	0-1 (MG/DL)	01/07/91	0.40		0.40		0.50	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/07/91	0.10		0.10		0.10	
TOT. PROTEINS	6.5-8 (G/DL)	01/07/91	7.23		7.35		7.36	
ALBUMINE	57-68 (X)	01/07/91					65.30	
TOT. CHOLEST.	130-200 (MG/DL)	01/07/91	285.00 >>		305.00 >>		342.00 >>	
TRIGLYCERIDES	65-170 (MG/DL)	01/07/91	404.00 >>		309.00 >>		440.00 >>	
GLOBULINS ALPHA 1	2-4 (X)	01/07/91					2.50	
GLOBULINS ALPHA 2	5-9 (X)	01/07/91					8.90	
GLOBULINS BETA	8-12 (X)	01/07/91					10.30	
GLOBULINS GAMMA	12-19 (X)	01/07/91					12.80	
TSH	0.2-4 (MU/L)	01/07/91						
T4	10-25 (PMOL/L)	01/07/91	6.40					

(€) << 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 990085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centro: 14/2 Patient: 136 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			08/01/92		11/02/92		25/02/92	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/12/91	13.00		12.50			
HT	36-46 (X)	01/12/91	38.60		36.50			
RBC	4.2-5.4 (10 ⁶ /MM ³)	01/12/91	4.23		4.09 <			
WBC	4-9.4 (10 ³ /MM ³)	01/12/91	8.00		9.40			
WBC: N	50-70 (X)	01/12/91	67.80		69.60			
WBC: L	25-40 (X)	01/12/91	25.50		24.10 <			
WBC: E	0-4 (X)	01/12/91	1.30		0.50			
WBC: M	2-13 (X)	01/12/91	4.70		4.80			
WBC: B	0-1 (X)	01/12/91	0.70		0.90			
PLATELETS	150-440 (10 ³ /MM ³)	01/12/91	299.00		282.00			
NA+	134-150 (MMOL/L)	01/12/91	138.00		139.00	139.00		
K+	3.5-5.6 (MMOL/L)	01/12/91	4.29		4.00	4.00		
CL-	94-111 (MMOL/L)	01/12/91	94.00		105.00	106.00		
Ca++	2.05-2.55 (MMOL/L)	01/12/91	2.51		2.30	2.20		
PO4--	2.5-4.8 (MG/DL)	01/12/91	2.50		3.02			
SGOT	5-15 (U/L)	01/12/91	10.00		10.00	9.00		
SGPT	5-22 (U/L)	01/12/91	16.00		15.00	8.00		
GAMMA GT	0-18 (U/L)	01/12/91	12.00		8.00	8.00		
LDH	120-240 (U/L)	01/12/91	153.00		148.00	153.00		
ALK. PHOSPH.	50-170 (U/L)	01/12/91	101.00		120.00	87.00		
GLUCOSE	60-110 (MG/DL)	01/12/91	57.00 <		103.00	82.00		
BUN	10-50 (MG/DL)	01/12/91	25.00		38.00	22.00		
UREA	()	01/12/91						
CREATININE	0-1.2 (MG/DL)	01/12/91	0.79		0.73	0.80		
URIC ACID	2.5-5.7 (MG/DL)	01/12/91	3.70		3.60	3.60		
TOT BILIRUBIN	0-1 (MG/DL)	01/12/91	0.69		0.73	0.71		
DIR BILIRUBIN	0-0.25 (MG/DL)	01/12/91	0.21		0.38 >	0.21		
TOT. PROTEINS	6.2-8.5 (G/DL)	01/12/91	6.80					
ALBUMINE	3500-5500 (MG/DL)	01/12/91	3740.00		4090.00			
TOT. CHOLEST.	120-200 (MG/DL)	01/12/91	229.00 >		210.00 >	183.00		
TRIGLYCERIDES	65-175 (MG/DL)	01/12/91	92.20		94.80	94.20		
GLOBULINS ALPHA 1	1.5-4 (X)	01/12/91	3.20			3.80		
GLOBULINS ALPHA 2	5-12 (X)	01/12/91	6.20			6.80		
GLOBULINS BETA	7-13 (X)	01/12/91	9.80			10.40		
GLOBULINS GAMMA	10-19 (X)	01/12/91	13.40			13.80		
TSH	0.16-3.2 (UU/HL)	01/12/91	0.48					
T4	5-13 (UG/DL)	01/12/91	7.80					

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 ** missing laboratory test value () laboratory not done () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS 9890085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/2 Patient: 456 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			09/04/92		07/05/92		29/05/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/12/91	15.80		16.00		16.20	
HT	38-52 (%)	01/12/91	45.60		48.20		48.10	
RBC	4.5-6.3 (10 ⁶ /MM ³)	01/12/91	5.39		5.44		5.53	
WBC	4-9.4 (10 ³ /MM ³)	01/12/91	7.70		5.70		8.70	
WBC: N	50-70 (%)	01/12/91	53.10		52.80		52.30	
WBC: L	25-40 (%)	01/12/91	39.70		37.40		39.30	
WBC: E	0-4 (%)	01/12/91	1.00		1.50		1.30	
WBC: M	2-13 (%)	01/12/91	5.20		8.20		6.70	
WBC: B	0-1 (%)	01/12/91	1.10	>	0.10		0.40	
PLATELETS	150-440 (10 ³ /MM ³)	01/12/91	258.00		252.00		272.00	
NA+	134-150 (MMOL/L)	01/12/91	138.00		143.00		167.00 >>	
K+	3.5-5.6 (MMOL/L)	01/12/91	3.60		4.30		4.69	
CL-	94-111 (MMOL/L)	01/12/91			111.00		121.00 >	
Ca++	2.05-2.55 (MMOL/L)	01/12/91	2.20		2.20		2.43	
PO4--	2.5-4.8 (MG/DL)	01/12/91			3.49			
SGOT	5-18 (U/L)	01/12/91	10.00		9.00		12.00	
SGPT	5-24 (U/L)	01/12/91	24.00		16.00		17.00	
GAMMA GT	0-28 (U/L)	01/12/91	15.00		14.00		20.00	
LDH	120-240 (U/L)	01/12/91	173.00		152.00		185.00	
ALK. PHOSPH.	60-170 (U/L)	01/12/91	95.00		101.00		157.00	
GLUCOSE	60-110 (MG/DL)	01/12/91	98.00		97.00		102.00	
BUN	10-50 (MG/DL)	01/12/91	27.00		31.00		34.00	
UREA	()	01/12/91						
CREATININE	0-1.4 (MG/DL)	01/12/91	1.00		0.95		1.44 >	
URIC ACID	2.5-7 (MG/DL)	01/12/91	7.70 >		6.80		8.11 >	
TOT BILIRUBIN	0-1 (MG/DL)	01/12/91			2.11 >>		1.37 >	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/12/91	0.39 >		0.56 >>		0.47 >	
TOT. PROTEINS	6.2-8.5 (G/DL)	01/12/91	7.20		7.70		9.50 >	
ALBUMINE	3500-5500 (MG/DL)	01/12/91	4580.00					
TOT. CHOLEST.	120-200 (MG/DL)	01/12/91	160.00		202.00 >		251.00 >	
TRIGLYCERIDES	65-175 (MG/DL)	01/12/91	91.40		128.00		204.00 >	
GLOBULINS ALPHA 1	1.5-4 (%)	01/12/91			2.90		2.60	
GLOBULINS ALPHA 2	5-12 (%)	01/12/91			7.20		6.20	
GLOBULINS BETA	7-13 (%)	01/12/91			12.40		11.70	
GLOBULINS GAMMA	10-19 (%)	01/12/91			15.00		15.90	
TSH	0.16-3.2 (UU/ML)	01/12/91	0.77					
T4	5-13 (UG/DL)	01/12/91	12.10					

(€) << 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 9590085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/3 Patient: 418 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/06/91		08/07/91		29/07/91	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/05/91	14.20		13.90		13.20	
HT	36-48 (%)	01/05/91	41.30		41.30		40.00	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/05/91	4.30		4.20		4.40	
HBC	4000-9000 (/MM ³)	01/05/91	5800.00		9300.00	>	6000.00	
HBC: N	50-70 (%)	01/05/91	68.00		56.00		56.00	
HBC: L	25-40 (%)	01/05/91	23.00	<	38.00		40.00	
HBC: E	0-1 (%)	01/05/91	1.00		2.00	>>	2.00	
HBC: M	4-8 (%)	01/05/91	6.00		4.00		1.00	
HBC: B	0-1 (%)	01/05/91	1.00		0.00		1.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/91	240.00		246.00		280.00	
NA+	134-148 (MMOL/L)	01/05/91	140.20		143.60		141.70	
K+	3.8-5.2 (MMOL/L)	01/05/91	4.20		4.00		4.30	
CL-	96-111 (MMOL/L)	01/05/91	99.50		99.80		107.10	
Ca++	2-2.6 (MMOL/L)	01/05/91	2.30		2.30		2.40	
PO4--	0.8-1.6 (MMOL/L)	01/05/91	1.20		1.22		1.15	
SGOT	5-18 (U/L)	01/05/91	6.00		6.00		8.00	
SGPT	5-22 (U/L)	01/05/91	6.00		6.00		6.00	
GAMMA GT	4-28 (U/L)	01/05/91	9.00		8.00		11.00	
LDH	120-240 (U/L)	01/05/91	157.00		165.00		190.00	
ALK. PHOSPH.	60-170 (U/L)	01/05/91	95.00		92.00		94.00	
GLUCOSE	60-110 (MG/DL)	01/05/91	95.50		110.20	>	114.40	
BUN	10-50 (MG/DL)	01/05/91	38.00		34.00		47.00	
UREA	()	01/05/91						
CREATININE	0.3-1.2 (MG/DL)	01/05/91	0.90		0.80		1.00	
URIC ACID	2.4-7 (MG/DL)	01/05/91	4.30		4.20		4.80	
TOT BILIRUBIN	0-1 (MG/DL)	01/05/91	0.20		0.30		0.20	
DIR BILIRUBIN	0-0.2 (MG/DL)	01/05/91	0.10		0.10		0.10	
TOT. PROTEINS	6.6-8.7 (G/DL)	01/05/91	6.50	<	6.90		7.00	
ALBUMINE	57-68 (%)	01/05/91	65.70		56.20	<	57.30	
TOT. CHOLEST.	120-200 (MG/DL)	01/05/91	265.00	>>	219.00	>	337.00	
TRIGLYCERIDES	50-180 (MG/DL)	01/05/91	78.00		64.00		58.00	
GLOBULINS ALPHA 1	2-4.5 (%)	01/05/91	4.50		4.50		3.80	
GLOBULINS ALPHA 2	5-9 (%)	01/05/91	8.50		11.10	>	10.50	
GLOBULINS BETA	9-13 (%)	01/05/91	10.70		11.60		11.70	
GLOBULINS GAMMA	10-20 (%)	01/05/91	10.60		16.60		16.70	
TSH	0.2-3.1 (UU/ML)	01/05/91	0.85					
T4	5-11.5 (UG/DL)	01/05/91	8.22					

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 ** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 0085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/3 Patient: 420 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			04/07/91
			value (c)
Laboratory test	Range value	Range date	
HB	12-16 (G/DL)	01/05/91	15.00
HT	36-48 (X)	01/05/91	43.60
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/05/91	4.70
WBC	4000-9000 (/MM ³)	01/05/91	5000.00
WBC: N	50-70 (X)	01/05/91	50.00
WBC: L	25-40 (X)	01/05/91	46.00 >
WBC: E	0-1 (X)	01/05/91	2.00 >>
WBC: M	4-8 (X)	01/05/91	2.00 <
WBC: B	0-1 (X)	01/05/91	0.00
PLATELETS	150-400 (10 ³ /MM ³)	01/05/91	265.00
NA+	134-148 (MMOL/L)	01/05/91	145.40
K+	3.8-5.2 (MMOL/L)	01/05/91	3.70 <
CL-	96-111 (MMOL/L)	01/05/91	103.60
Ca++	2-2.6 (MMOL/L)	01/05/91	2.50
PO4--	0.8-1.6 (MMOL/L)	01/05/91	1.09
SGOT	5-18 (U/L)	01/05/91	8.00
SGPT	5-22 (U/L)	01/05/91	7.00
GAMMA GT	4-28 (U/L)	01/05/91	7.00
LDH	120-240 (U/L)	01/05/91	152.00
ALK. PHOSPH.	60-170 (U/L)	01/05/91	96.00
GLUCOSE	60-110 (MG/DL)	01/05/91	112.00 >
BUN	10-50 (MG/DL)	01/05/91	18.00
UREA	()	01/05/91	
CREATININE	0.3-1.2 (MG/DL)	01/05/91	0.80
URIC ACID	2.4-7 (MG/DL)	01/05/91	3.80
TOT BILIRUBIN	0-1 (MG/DL)	01/05/91	0.50
DIR BILIRUBIN	0-0.2 (MG/DL)	01/05/91	0.10
TOT. PROTEINS	6.6-8.7 (G/DL)	01/05/91	8.00
ALBUMINE	57-68 (X)	01/05/91	59.10
TOT. CHOLEST.	120-200 (MG/DL)	01/05/91	183.00
TRIGLYCERIDES	50-180 (MG/DL)	01/05/91	76.00
GLOBULINS ALPHA 1	2-4.5 (X)	01/05/91	2.70
GLOBULINS ALPHA 2	5-9 (X)	01/05/91	5.60
GLOBULINS BETA	9-13 (X)	01/05/91	8.60 <
GLOBULINS GAMMA	10-20 (X)	01/05/91	24.10 >
TSH	0.2-3.1 (UU/ML)	01/05/91	1.60
T4	5-11.5 (UG/DL)	01/05/91	6.92

(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 CN9390085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/3 Patient: 427 Treatment: Imipramine Sex: Female

Laboratory test	Range value	Range date	Visit number / Laboratory date			
			Screen		Day 21	
			18/09/91		09/10/91	
			value (φ)	value (φ)	value (φ)	value (φ)
HB	12-16 (G/DL)	01/05/91	14.20		14.10	
HT	36-48 (%)	01/05/91	40.90		41.10	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/05/91	4.70		4.70	
WBC	4000-9000 (/MM ³)	01/05/91	5000.00		3900.00	<
WBC: N	50-70 (%)	01/05/91	59.00		56.00	
WBC: L	25-40 (%)	01/05/91	34.00		38.00	
WBC: E	0-1 (%)	01/05/91	2.00	>>	2.00	>>
WBC: M	4-8 (%)	01/05/91	5.00		4.00	
WBC: B	0-1 (%)	01/05/91	0.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/91	261.00		240.00	
NA+	134-148 (MMOL/L)	01/05/91	144.20		145.50	
K+	3.8-5.2 (MMOL/L)	01/05/91	4.40		4.30	
CL-	96-111 (MMOL/L)	01/05/91	107.00		108.30	
Ca++	2-2.6 (MMOL/L)	01/05/91	2.40		2.40	
PO4--	0.8-1.6 (MMOL/L)	01/05/91	1.56		1.57	
SGOT	5-18 (U/L)	01/05/91	9.00		15.00	
SGPT	5-22 (U/L)	01/05/91	9.00		23.00	>
GAMMA GT	4-28 (U/L)	01/05/91	11.00		16.00	
LDH	120-240 (U/L)	01/05/91	182.00		215.00	
ALK. PHOSPH.	60-170 (U/L)	01/05/91	129.00		129.00	
GLUCOSE	60-110 (MG/DL)	01/05/91	108.30		106.40	
BUN	10-50 (MG/DL)	01/05/91	40.00		43.00	
UREA	()	01/05/91				
CREATININE	0.3-1.2 (MG/DL)	01/05/91	1.10		1.00	
URIC ACID	2.4-7 (MG/DL)	01/05/91	5.10		4.70	
TOT BILIRUBIN	0-1 (MG/DL)	01/05/91	0.20		0.40	
DIR BILIRUBIN	0-0.2 (MG/DL)	01/05/91	0.20		0.00	
TOT. PROTEINS	6.6-8.7 (G/DL)	01/05/91	7.40		7.20	
ALBUMINE	57-68 (%)	01/05/91	58.10		56.70	<
TOT. CHOLEST.	120-200 (MG/DL)	01/05/91	234.00	>	244.00	>
TRIGLYCERIDES	50-180 (MG/DL)	01/05/91	158.00		144.00	
GLOBULINS ALPHA 1	2-4.5 (%)	01/05/91	3.50		2.90	
GLOBULINS ALPHA 2	5-9 (%)	01/05/91	6.80		7.20	
GLOBULINS BETA	9-13 (%)	01/05/91	13.10	>	12.20	
GLOBULINS GAMMA	10-20 (%)	01/05/91	18.50		21.00	>
TSH	0.2-3.1 (UU/ML)	01/05/91	2.46			
T4	5-11.5 (UG/DL)	01/05/91	7.71			

(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

PHARNACIA CNS 5590085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/3 Patient: 428 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			25/10/91		14/11/91		05/12/91	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/05/91	13.60		13.80		13.80	
HT	36-48 (%)	01/05/91	40.60		39.00		38.10	
RBC	4.2-5.8 (10 ⁶ /MM ³)	01/05/91	4.50		4.60		4.50	
WBC	4000-9000 (/MM ³)	01/05/91	7500.00		5000.00		6500.00	
WBC: N	50-70 (%)	01/05/91	50.00		67.00		66.00	
WBC: L	25-40 (%)	01/05/91	34.00		30.00		30.00	
WBC: E	0-1 (%)	01/05/91	4.00	>>	1.00		2.00 >>	
WBC: M	4-8 (%)	01/05/91	12.00	>>	2.00	<	6.00	
WBC: B	0-1 (%)	01/05/91	0.00		0.00		0.00	
PLATELETS	150-400 (10 ³ /MM ³)	01/05/91	234.00		260.00		234.00	
NA+	134-148 (MMOL/L)	01/05/91	138.60		116.80	<<	138.60	
K+	3.8-5.2 (MMOL/L)	01/05/91	3.70	<	3.20	<<	3.70 <	
CL-	96-111 (MMOL/L)	01/05/91					107.60	
Ca++	2-2.6 (MMOL/L)	01/05/91	2.30		2.00		2.20	
PO4--	0.8-1.6 (MMOL/L)	01/05/91					1.16	
SGOT	5-18 (U/L)	01/05/91	8.00		10.00		8.00	
SGPT	5-22 (U/L)	01/05/91	6.00		9.00		8.00	
GAMMA GT	4-28 (U/L)	01/05/91	10.00		8.00		11.00	
LDH	120-240 (U/L)	01/05/91	148.00		193.00		187.00	
ALK. PHOSPH.	60-170 (U/L)	01/05/91	79.00		108.00		108.00	
GLUCOSE	60-110 (MG/DL)	01/05/91	68.40		80.00		89.50	
BUN	10-50 (MG/DL)	01/05/91	30.00		34.00		19.00	
UREA	()	01/05/91						
CREATININE	0.3-1.2 (MG/DL)	01/05/91	0.70		0.70		0.80	
URIC ACID	2.4-7 (MG/DL)	01/05/91	3.60		4.10		3.70	
TOT BILIRUBIN	0-1 (MG/DL)	01/05/91	0.10		0.20		0.40	
DIR BILIRUBIN	0-0.2 (MG/DL)	01/05/91	0.00		0.10		0.10	
TOT. PROTEINS	6.6-8.7 (G/DL)	01/05/91	7.60		8.10		7.80	
ALBUMINE	57-68 (%)	01/05/91	52.40	<	64.40		58.40	
TOT. CHOLEST.	120-200 (MG/DL)	01/05/91	162.00		178.00		172.00	
TRIGLYCERIDES	50-180 (MG/DL)	01/05/91	68.00		73.00		73.00	
GLOBULINS ALPHA 1	2-4.5 (%)	01/05/91	4.40		2.90		3.30	
GLOBULINS ALPHA 2	5-9 (%)	01/05/91	7.00		6.70		7.60	
GLOBULINS BETA	9-13 (%)	01/05/91	10.90		10.50		12.70	
GLOBULINS GAMMA	10-20 (%)	01/05/91	25.30	>	15.50		18.00	
TSH	0.2-3.1 (UU/ML)	01/05/91	1.74					
T4	5-11.5 (UG/DL)	01/05/91	6.25					

(⊕) << 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 CN9390085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/4 Patient: 131 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			09/01/92		03/02/92		24/02/92	
			value	(*)	value	(*)	value	(*)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	02/12/91	14.80		14.20		13.90	
HT	35.8-45.4 (%)	02/12/91	37.00		38.00		40.00	
RBC	3.9-5.6 (10 ⁶ /MM ³)	02/12/91	4.80		4.60		4.50	
WBC	5-9 (10 ³ /MM ³)	02/12/91	7.80		7.30		7.80	
WBC: N	50-70 (%)	02/12/91	66.00		64.00		59.00	
WBC: L	25-40 (%)	02/12/91	31.00		32.00		36.00	
WBC: E	2-4 (%)	02/12/91	2.00		2.00		2.00	
WBC: M	2-8 (%)	02/12/91	1.00	<	2.00		1.00	
WBC: B	0-1 (%)	02/12/91	0.00		0.00		0.00	
PLATELETS	200-350 (10 ³ /MM ³)	02/12/91	270.00		254.00		220.00	
NA+	137-147 (MMOL/L)	02/12/91	142.00		143.00		140.00	
K+	3.6-5.5 (MMOL/L)	02/12/91	3.90		4.70		4.20	
CL-	101-111 (MMOL/L)	02/12/91	104.00		102.00		112.00	
Ca++	2.25-2.6 (MMOL/L)	02/12/91	2.30		2.43		2.48	
PO4--	0.8-1.6 (MMOL/L)	02/12/91	1.30		1.40		1.30	
SGOT	5-17 (U/L)	02/12/91	16.00		18.00	>	18.00	
SGPT	5-23 (U/L)	02/12/91	20.00		22.00		22.00	
GANMA GT	6-28 (U/L)	02/12/91	28.00		20.00		19.00	
LDH	80-240 (U/L)	02/12/91	195.00		220.00		210.00	
ALK. PHOSPH.	40-190 (U/L)	02/12/91	80.00		105.00		145.00	
GLUCOSE	70-115 (MG/DL)	02/12/91	104.00		98.00		101.00	
BUN	20-40 (MG/DL)	02/12/91	44.00	>	36.00		44.00	
UREA	()	02/12/91						
CREATININE	0.6-1.1 (MG/DL)	02/12/91	0.80		1.10		0.90	
URIC ACID	2.4-5.7 (MG/DL)	02/12/91	5.20		5.40		5.20	
TOT BILIRUBIN	0-1.1 (MG/DL)	02/12/91	0.80		0.60		0.80	
DIR BILIRUBIN	()	02/12/91						
TOT. PROTEINS	6.7-8.2 (G/DL)	02/12/91	7.70		7.40		7.70	
ALBUMINE	53-70 (%)	02/12/91	56.00		59.00		65.00	
TOT. CHOLEST.	140-240 (MG/DL)	02/12/91	213.00		244.00	>	224.00	
TRIGLYCERIDES	0-200 (MG/DL)	02/12/91	164.00		193.00		186.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	02/12/91	3.20		3.30		3.80	
GLOBULINS ALPHA 2	9-14 (%)	02/12/91	10.40		9.90		8.40	
GLOBULINS BETA	8-12 (%)	02/12/91	9.30		10.40		11.10	
GLOBULINS GAMMA	10-18 (%)	02/12/91	13.40		13.20		13.30	
TSH	0.16-3.2 (MU/L)	02/12/91	1.84					
T4	48-120 (UG/L)	02/12/91	116.00					

(*) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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PHARMACIA CN9350085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/4 Patient: 132 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			09/01/92		03/02/92		24/02/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	02/12/91	13.60		13.40		13.20	
HT	35.8-45.4 (X)	02/12/91	37.00		38.00		37.00	
RBC	3.9-5.6 (10 ⁶ /MM ³)	02/12/91	4.80		4.70		4.50	
WBC	5-9 (10 ³ /MM ³)	02/12/91	8.40		7.90		8.20	
WBC: N	50-70 (X)	02/12/91	64.00		58.00		60.00	
WBC: L	25-40 (X)	02/12/91	34.00		38.00		35.00	
WBC: E	2-4 (X)	02/12/91	0.00	<	0.00	<	1.00	
WBC: M	2-8 (X)	02/12/91	2.00		3.00		2.00	
WBC: B	0-1 (X)	02/12/91	0.00		0.00		2.00	
PLATELETS	200-350 (10 ³ /MM ³)	02/12/91	295.00		270.00		260.00	
NA+	137-147 (MMOL/L)	02/12/91	142.00		140.00		141.00	
K+	3.6-5.5 (MMOL/L)	02/12/91	3.70		3.90		3.60	
CL-	101-111 (MMOL/L)	02/12/91	109.00		104.00		109.00	
Ca++	2.25-2.6 (MMOL/L)	02/12/91	2.36		2.40		2.50	
PO4--	0.8-1.6 (MMOL/L)	02/12/91	1.10		1.10		1.30	
SGOT	5-17 (U/L)	02/12/91	18.00	>	17.00		18.00	
SGPT	5-23 (U/L)	02/12/91	16.00		18.00		20.00	
GANMA GT	6-28 (U/L)	02/12/91	24.00		27.00		24.00	
LDH	80-240 (U/L)	02/12/91	195.00		210.00		195.00	
ALK. PHOSPH.	40-190 (U/L)	02/12/91	165.00		180.00		160.00	
GLUCOSE	70-115 (MG/DL)	02/12/91	93.00		88.00		76.00	
BUN	20-40 (MG/DL)	02/12/91	36.00		44.00	>	36.00	
UREA	()	02/12/91						
CREATININE	0.6-1.4 (MG/DL)	02/12/91	0.92		0.80		1.10	
URIC ACID	2.4-5.7 (MG/DL)	02/12/91	4.60		4.70		4.60	
TOT BILIRUBIN	0-1.1 (MG/DL)	02/12/91	0.90		0.80		0.90	
DIR BILIRUBIN	()	02/12/91						
TOT. PROTEINS	6.7-8.2 (G/DL)	02/12/91	7.30		7.40		7.30	
ALBUMINE	53-70 (X)	02/12/91	56.00		66.00		70.00	
TOT. CHOLEST.	140-240 (MG/DL)	02/12/91	193.00		214.00		195.00	
TRIGLYCERIDES	0-200 (MG/DL)	02/12/91	160.00		184.00		165.00	
GLOBULINS ALPHA 1	2.5-4.5 (X)	02/12/91	3.20		3.80		3.10	
GLOBULINS ALPHA 2	9-14 (X)	02/12/91	13.20		10.40		9.40	
GLOBULINS BETA	8-12 (X)	02/12/91	9.20		11.40		11.20	
GLOBULINS GAMMA	10-18 (X)	02/12/91	14.00		13.50		12.80	
TSH	0.16-3.2 (MU/L)	02/12/91	2.80					
T4	48-120 (UG/L)	02/12/91	116.00					

(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 CN9390085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/4 Patient: 133 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			09/01/92		06/02/92		27/02/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	02/12/91	11.40		11.90		11.80	
HT	35.8-45.4 (X)	02/12/91	37.00		40.20		38.00	
RBC	3.9-5.6 (10 ⁶ /MM ³)	02/12/91	4.10		4.80		4.60	
WBC	5-9 (10 ³ /MM ³)	02/12/91	6.50		6.30		6.80	
WBC: N	50-70 (%)	02/12/91	51.00		54.00		56.00	
WBC: L	25-40 (%)	02/12/91	42.00	>	40.00		38.00	
WBC: E	2-4 (%)	02/12/91	4.00		3.00		3.00	
WBC: M	2-8 (%)	02/12/91	2.00		3.00		2.00	
WBC: B	0-1 (%)	02/12/91	0.00		0.00		1.00	
PLATELETS	200-350 (10 ³ /MM ³)	02/12/91	190.00	<	240.00		210.00	
NA+	137-147 (MMOL/L)	02/12/91	140.00		141.00		140.00	
K+	3.6-5.5 (MMOL/L)	02/12/91	3.90		4.10		3.90	
CL-	101-111 (MMOL/L)	02/12/91	109.00		111.00		112.00	
Ca++	2.25-2.6 (MMOL/L)	02/12/91	2.30		2.45		2.50	
PO4--	0.8-1.6 (MMOL/L)	02/12/91	0.80		0.90		1.30	
SGOT	5-17 (U/L)	02/12/91	17.00		19.00	>	16.00	
SGPT	5-23 (U/L)	02/12/91	20.00		23.00		20.00	
GAMMA GT	6-28 (U/L)	02/12/91	12.00		24.00		30.00	
LDH	80-240 (U/L)	02/12/91	199.00		230.00		210.00	
ALK. PHOSPH.	40-190 (U/L)	02/12/91	93.00		120.00		145.00	
GLUCOSE	70-115 (MG/DL)	02/12/91	99.00		83.00		101.00	
BUN	20-40 (MG/DL)	02/12/91	36.00		44.00	>	41.00	
UREA	()	02/12/91						
CREATININE	0.6-1.1 (MG/DL)	02/12/91	0.82		1.00		1.10	
URIC ACID	2.4-5.7 (MG/DL)	02/12/91	4.30		4.80		4.90	
TOT BILIRUBIN	0-1.1 (MG/DL)	02/12/91	0.60		0.80		0.90	
DIR BILIRUBIN	()	02/12/91						
TOT. PROTEINS	6.7-8.2 (G/DL)	02/12/91	6.90		7.20		7.40	
ALBUMINE	53-70 (%)	02/12/91	61.00		64.00		58.00	
TOT. CHOLEST.	140-240 (MG/DL)	02/12/91	224.00		254.00	>	241.00	
TRIGLYCERIDES	0-200 (MG/DL)	02/12/91	201.00	>	224.00	>	218.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	02/12/91	3.80		3.20		3.80	
GLOBULINS ALPHA 2	9-14 (%)	02/12/91	9.80		10.20		11.40	
GLOBULINS BETA	8-12 (%)	02/12/91	11.40		14.60	>	11.80	
GLOBULINS GAMMA	10-18 (%)	02/12/91	16.20		15.20		14.80	
TSH	0.16-3.2 (MU/L)	02/12/91	2.80					
T4	48-120 (UG/L)	02/12/91	99.00					

(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 950085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/7 Patient: 422 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			02/09/91		25/09/91		16/10/91	
			value	(ϕ)	value	(ϕ)	value	(ϕ)
Laboratory test	Range value	Range date						
HB	12.8-16 (G/DL)	05/08/91	12.80		13.20		13.20	
HT	37-47 (%)	05/08/91	49.20	>	45.70		48.40 >	
RBC	4.5-5 (10 ⁶ /MM ³)	05/08/91	4.20	<	4.30	<	4.50	
HBC	3500-9000 (/MM ³)	05/08/91	5200.00		6300.00		6800.00	
HBC: N	37-73 (%)	05/08/91	62.00		44.00		52.00	
HBC: L	20-55 (%)	05/08/91	31.00		28.00		30.00	
HBC: E	0.5-11 (%)	05/08/91	2.00		3.00		2.00	
HBC: M	2.5-10 (%)	05/08/91	3.00		6.00		3.00	
HBC: B	0-2 (%)	05/08/91	0.00		1.00		0.00	
PLATELETS	150000-400000 (/MM ³)	05/08/91	295000		325000		325000	
NA+	134-148 (MMOL/L)	05/08/91	144.80		140.30		145.20	
K+	3.8-5.2 (MMOL/L)	05/08/91	3.80		4.50		4.20	
CL-	84-110 (MMOL/L)	05/08/91	96.00		96.80		98.00	
Ca++	2.2-2.6 (MMOL/L)	05/08/91	2.30		2.30		2.30	
PO4--	2.5-4.5 (MG/DL)	05/08/91	3.20		3.70		3.70	
SGOT	5-18 (U/L)	05/08/91	9.00		9.00		8.00	
SGPT	5-22 (U/L)	05/08/91	12.00		12.00		10.00	
GAMMA GT	4-28 (U/L)	05/08/91	23.00		26.00		21.00	
LDH	120-240 (U/L)	05/08/91	168.00		177.00		170.00	
ALK. PHOSPH.	60-170 (U/L)	05/08/91	146.00		145.00		148.00	
GLUCOSE	60-110 (MG/DL)	05/08/91	85.90		93.20		92.40	
BUN	10-50 (MG/DL)	05/08/91	25.40		24.50		23.40	
UREA	()	05/08/91						
CREATININE	0.3-1.2 (MG/DL)	05/08/91	1.00		1.10		0.90	
URIC ACID	2.4-7 (MG/DL)	05/08/91	6.10		6.90		5.70	
TOT BILIRUBIN	0-1 (MG/DL)	05/08/91	0.30		0.20		0.20	
DIR BILIRUBIN	()	05/08/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	05/08/91	7.70		7.60		6.40 <	
ALBUMINE	3.7-5.5 (G/DL)	05/08/91	6.40	>	4.20		6.80 >	
TOT. CHOLEST.	120-200 (MG/DL)	05/08/91	260.00	>	239.00	>	245.00 >	
TRIGLYCERIDES	50-180 (MG/DL)	05/08/91	230.00	>	134.00		195.00 >	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	05/08/91	0.30		0.10		0.20	
GLOBULINS ALPHA 2	0.4-0.8 (G/DL)	05/08/91	0.70		0.60		0.80	
GLOBULINS BETA	0.4-0.9 (G/DL)	05/08/91	0.80		0.70		0.50	
GLOBULINS GAMMA	0.7-1.4 (G/DL)	05/08/91	1.20		1.00		1.20	
TSH	0.2-4 (UU/ML)	05/08/91	1.40					
T4	5-11.5 (UG/DL)	05/08/91	7.20					

(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 550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/7 Patient: 423 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			10/09/91		08/10/91		29/10/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12.8-16 (G/DL)	01/08/91	17.00	>	16.00		15.80	
HT	37-47 (X)	01/08/91	50.20	>	48.80	>	48.40 >	
RBC	4.5-5 (10 ⁶ /MM ³)	01/08/91	4.80		4.60		5.20 >	
WBC	3500-9000 (/MM ³)	01/08/91	7200.00		8400.00		7600.00	
WBC: N	37-73 (X)	01/08/91	68.00		62.00		60.00	
WBC: L	20-55 (X)	01/08/91	25.00		20.00		23.00	
WBC: E	0.5-11 (X)	01/08/91	3.00		2.00		1.00	
WBC: M	2.5-10 (X)	01/08/91	3.00		3.00		0.00 <	
WBC: B	0-2 (X)	01/08/91	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM ³)	01/08/91	375000		320000		295000	
NA+	134-148 (MMOL/L)	01/08/91	139.30		142.00		145.00	
K+	3.8-5.2 (MMOL/L)	01/08/91	4.30		4.50		4.10	
CL-	84-110 (MMOL/L)	01/08/91	87.00		97.00		96.00	
Ca++	4.2-5.5 (MEQ/L)	01/08/91	4.30		4.40		4.50	
PO4--	23.3-49.8 (MG/L)	01/08/91	40.00		34.00		40.00	
SGOT	5-18 (U/L)	01/08/91	12.00		9.00		13.00	
SGPT	5-22 (U/L)	01/08/91	9.00		10.00		15.00	
GAMMA GT	4-28 (U/L)	01/08/91	4.00		4.00		8.00	
LDH	120-240 (U/L)	01/08/91	191.00		185.00		196.00	
ALK. PHOSPH.	60-170 (U/L)	01/08/91	144.00		145.00		142.00	
GLUCOSE	60-110 (MG/DL)	01/08/91	96.60		89.40		78.30	
BUN	10-50 (MG/DL)	01/08/91	28.00		22.80		20.80	
UREA	()	01/08/91						
CREATININE	0.3-1.2 (MG/DL)	01/08/91	0.80		0.70		0.80	
URIC ACID	2.4-7 (MG/DL)	01/08/91	5.40		5.30		5.10	
TOT BILIRUBIN	0-1 (MG/DL)	01/08/91	0.50		0.60		0.80	
DIR BILIRUBIN	()	01/08/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/08/91	7.20		6.80		6.40 <	
ALBUMINE	3.7-5.5 (G/DL)	01/08/91	4.80		4.30		4.40	
TOT. CHOLEST.	120-200 (MG/DL)	01/08/91	215.00	>	228.00	>	232.00 >	
TRIGLYCERIDES	50-180 (MG/DL)	01/08/91	61.00		72.00		105.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/08/91	0.10		0.10		0.10	
GLOBULINS ALPHA 2	0.4-0.8 (G/DL)	01/08/91	0.50		0.40		0.50	
GLOBULINS BETA	0.4-0.9 (G/DL)	01/08/91	0.70		0.80		0.90	
GLOBULINS GAMMA	0.7-1.4 (G/DL)	01/08/91	1.00		1.20		1.00	
TSH	0.2-4 (UU/ML)	01/08/91	2.40					
T4	5-11.5 (UG/DL)	01/08/91	7.30					

(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 C9530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/7 Patient: 432 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			08/10/91		29/10/91		19/11/91	
			value	(ϕ)	value	(ϕ)	value	(ϕ)
Laboratory test	Range value	Range date						
HB	12.8-16 (G/DL)	01/08/91	14.60		14.00		14.60	
HT	37-47 (%)	01/08/91	46.20		43.80		42.70	
RBC	4.5-5 (10 ⁶ /MM ³)	01/08/91	4.40	<	4.60		4.70	
HBC	3500-9000 (/MM ³)	01/08/91	8600.00		7400.00		5700.00	
HBC: N	37-73 (%)	01/08/91	68.00		66.00		64.00	
HBC: L	20-55 (%)	01/08/91	32.00		30.00		37.00	
HBC: E	0.5-11 (%)	01/08/91	7.40		7.20		1.40	
HBC: M	2.5-10 (%)	01/08/91	8.00		6.00		6.80	
HBC: B	0-2 (%)	01/08/91	1.00		0.00		0.00	
PLATELETS	150000-400000 (/MM ³)	01/08/91	425000	>	395000		345000	
NA+	134-148 (MMOL/L)	01/08/91	145.00		140.00		142.00	
K+	3.8-5.2 (MMOL/L)	01/08/91	4.40		4.70		4.20	
CL-	84-110 (MMOL/L)	01/08/91	98.00		96.00		102.00	
Ca++	4.2-5.5 (MEQ/L)	01/08/91	4.57		4.80		4.70	
PO4--	23.3-49.8 (MG/L)	01/08/91	42.00		40.00		32.40	
SGOT	5-18 (U/L)	01/08/91	9.00		12.30		14.20	
SGPT	5-22 (U/L)	01/08/91	17.00		19.40		20.40	
GAMMA GT	4-28 (U/L)	01/08/91	19.00		18.70		26.80	
LDH	120-240 (U/L)	01/08/91	190.00		210.00		194.00	
ALK. PHOSPH.	60-170 (U/L)	01/08/91	63.50		98.40		102.80	
GLUCOSE	60-110 (MG/DL)	01/08/91	74.80		88.30		86.40	
BUN	10-50 (MG/DL)	01/08/91	33.00		31.20		29.40	
UREA	()	01/08/91						
CREATININE	0.3-1.2 (MG/DL)	01/08/91	1.19		1.10		1.00	
URIC ACID	2.4-7 (MG/DL)	01/08/91	6.13		6.70		6.30	
TOT BILIRUBIN	0-1 (MG/DL)	01/08/91	0.26		0.40		0.60	
DIR BILIRUBIN	()	01/08/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/08/91	6.80		6.40	<	7.20	
ALBUMINE	3.7-5.5 (G/DL)	01/08/91	5.10		4.90		5.40	
TOT. CHOLEST.	120-200 (MG/DL)	01/08/91	240.00	>	253.00	>	249.00	>
TRIGLYCERIDES	50-180 (MG/DL)	01/08/91	116.00		102.00		98.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/08/91	0.20		0.10		0.20	
GLOBULINS ALPHA 2	0.4-0.8 (G/DL)	01/08/91	0.60		0.70		0.60	
GLOBULINS BETA	0.4-0.9 (G/DL)	01/08/91	0.60		0.30	<	0.70	
GLOBULINS GAMMA	0.7-1.4 (G/DL)	01/08/91	1.00		1.20		0.90	
TSH	0.2-4 (UU/NL)	01/08/91	3.10					
T4	5-11.5 (UG/DL)	01/08/91	7.20					

(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 950085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/7 Patient: 433 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			08/10/91		29/10/91		19/11/91	
			value	(†)	value	(†)	value	(†)
Laboratory test	Range value	Range date						
HB	12.8-16 (G/DL)	01/10/91	13.80		14.00		15.20	
HT	37-47 (%)	01/10/91	42.00		46.00		38.40	
RBC	4.5-5 (10 ⁶ /MM ³)	01/10/91	4.70		4.40	<	4.80	
WBC	3500-9000 (/MM ³)	01/10/91	8700.00		7900.00		8200.00	
WBC: N	37-73 (%)	01/10/91	68.00		62.00		58.00	
WBC: L	20-55 (%)	01/10/91	35.00		34.00		37.00	
WBC: E	0.5-11 (%)	01/10/91	7.50		7.30		6.40	
WBC: M	2.5-10 (%)	01/10/91	8.40		6.20		6.00	
WBC: B	0-2 (%)	01/10/91	1.00		0.00		0.00	
PLATELETS	150000-400000 (/MM ³)	01/10/91	370000		290000		320000	
NA+	134-148 (MMOL/L)	01/10/91	145.10		142.00		146.00	
K+	3.8-5.2 (MMOL/L)	01/10/91	4.96		4.80		5.00	
CL-	84-110 (MMOL/L)	01/10/91	96.00		97.00		99.00	
Ca++	4.2-5.5 (MEQ/L)	01/10/91	4.50		4.40		4.00	
PO4--	23.3-49.8 (MG/L)	01/10/91	37.00				42.00	
	2.5-4.5 (MG/DL)	20/10/91			3.80			
SGOT	5-18 (U/L)	01/10/91	8.00		12.00		14.00	
SGPT	5-22 (U/L)	01/10/91	9.00		13.40		16.80	
GAMMA GT	4-28 (U/L)	01/10/91	8.00		12.80		22.40	
LDH	120-240 (U/L)	01/10/91	135.00		142.50		154.80	
ALK. PHOSPH.	60-170 (U/L)	01/10/91	98.00		168.30		145.20	
GLUCOSE	60-110 (MG/DL)	01/10/91	91.80		82.40		79.80	
BUN	10-50 (MG/DL)	01/10/91	28.00		26.00		23.00	
UREA	()	01/10/91						
CREATININE	0.3-1.2 (MG/DL)	01/10/91	0.63		0.80		0.90	
URIC ACID	2.4-7 (MG/DL)	01/10/91	3.65		4.30		5.80	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.46		0.70		0.10	
DIR BILIRUBIN	()	01/10/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/10/91	7.46		8.20		8.50	
ALBUMINE	3.7-5.5 (G/DL)	01/10/91	5.00		5.40		4.80	
TOT. CHOLEST.	120-200 (MG/DL)	01/10/91	252.00	>	248.00	>	253.00	
TRIGLYCERIDES	50-180 (MG/DL)	01/10/91	90.00		82.00		102.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/10/91	0.10		0.10		0.30	
GLOBULINS ALPHA 2	0.4-0.8 (G/DL)	01/10/91	0.60		0.70		0.80	
GLOBULINS BETA	0.4-0.9 (G/DL)	01/10/91	0.70		0.80		0.70	
GLOBULINS GAMMA	0.7-1.4 (G/DL)	01/10/91	0.90		1.00		1.20	
TSH	0.2-4 (UU/ML)	01/10/91	1.40					
T4	5-11.5 (UG/DL)	01/10/91	6.90					

(†) << 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 530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/7 Patient: 440 Treatment: Imipranine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			07/11/91		02/12/91		23/12/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12.8-16 (G/DL)	01/08/91	14.20		14.60		13.80	
HT	37-47 (%)	01/08/91	41.30		40.20		41.60	
RBC	4.5-5 (10 ⁶ /MM ³)	01/08/91	4.80		4.60		4.70	
WBC	3500-9000 (/MM ³)	01/08/91	4800.00		8400.00		8200.00	
WBC: N	37-73 (%)	01/08/91	51.00		67.00		53.00	
WBC: L	20-55 (%)	01/08/91	37.00		45.00		42.00	
WBC: E	0.5-11 (%)	01/08/91	0.90		10.10		7.30	
WBC: M	2.5-10 (%)	01/08/91	7.40		8.40		8.20	
WBC: B	0-2 (%)	01/08/91	0.00		1.00		0.00	
PLATELETS	150000-400000 (/MM ³)	01/08/91	263000		282000		380000	
NA+	134-148 (MMOL/L)	01/08/91	141.60		145.80		142.00	
K+	3.8-5.2 (MMOL/L)	01/08/91	4.70		4.80		4.10	
CL-	84-110 (MMOL/L)	01/08/91	99.00		104.00		95.00	
Ca++	4.2-5.5 (MEQ/L)	01/08/91	4.30		4.40		4.90	
PO4--	23.3-49.8 (NG/L)	01/08/91	38.40		39.20		34.70	
SGOT	5-18 (U/L)	01/08/91	7.00		8.00		7.00	
SGPT	5-22 (U/L)	01/08/91	7.00		7.00		8.00	
GAMMA GT	4-28 (U/L)	01/08/91	8.00		12.00		11.00	
LDH	120-240 (U/L)	01/08/91	174.00		178.00		196.00	
ALK. PHOSPH.	60-170 (U/L)	01/08/91	75.00		79.00		124.00	
GLUCOSE	60-110 (MG/DL)	01/08/91	85.80		82.40		72.60	
BUH	10-50 (NG/DL)	01/08/91	24.00		23.00		24.00	
UREA	()	01/08/91						
CREATININE	0.3-1.2 (MG/DL)	01/08/91	1.00		0.70		0.80	
URIC ACID	2.4-7 (MG/DL)	01/08/91	5.40		4.80		4.30	
TOT BILIRUBIN	0-1 (MG/DL)	01/08/91	0.20		0.20		0.80	
DIR BILIRUBIN	()	01/08/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/08/91	8.20		8.40		7.20	
ALBUMINE	3.7-5.5 (G/DL)	01/08/91	5.50		4.80		4.30	
TOT. CHOLEST.	120-200 (MG/DL)	01/08/91	223.00	>	202.00	>	179.00	
TRIGLYCERIDES	50-180 (MG/DL)	01/08/91	134.00		102.00		82.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/08/91	0.20		0.10		0.20	
GLOBULINS ALPHA 2	0.4-0.8 (G/DL)	01/08/91	0.50		0.50		0.60	
GLOBULINS BETA	0.4-0.9 (G/DL)	01/08/91	0.70		0.60		0.70	
GLOBULINS GAMMA	0.7-1.4 (G/DL)	01/08/91	1.00		1.00		0.70	
TSH	0.2-4 (UU/NL)	01/08/91	2.40					
T4	5-11.5 (UG/DL)	01/08/91	7.80					

(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 ~~CMS 530~~ 085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/7 Patient: 441 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			08/11/91		02/12/91		23/12/91	
			value	(ϕ)	value	(ϕ)	value	(ϕ)
Laboratory test	Range value	Range date						
HB	12.8-16 (G/DL)	01/08/91	14.20		14.60		13.80	
HT	37-47 (%)	01/08/91	42.00		45.00		42.00	
RBC	4.5-5 (10 ⁶ /MM ³)	01/08/91	4.80		4.20	<	4.70	
WBC	3500-9000 (/MM ³)	01/08/91	6300.00		7200.00		8000.00	
WBC: N	37-73 (%)	01/08/91	52.00		58.00		49.00	
WBC: L	20-55 (%)	01/08/91	35.00		45.00		42.00	
WBC: E	0.5-11 (%)	01/08/91	8.00		7.20		6.80	
WBC: M	2.5-10 (%)	01/08/91	2.80		5.80		4.30	
WBC: B	0-2 (%)	01/08/91	1.00		1.00		0.00	
PLATELETS	150000-400000 (/MM ³)	01/08/91	268000		270000		320000	
NA+	134-148 (MMOL/L)	01/08/91	143.10		142.80		147.20	
K+	3.8-5.2 (MMOL/L)	01/08/91	4.70		4.60		4.80	
CL-	84-110 (MMOL/L)	01/08/91	99.00		104.00		105.00	
Ca++	4.2-5.5 (MEQ/L)	01/08/91	4.50		4.80		4.90	
PO4--	23.3-49.8 (NG/L)	01/08/91	26.80		46.20		43.40	
SGOT	5-18 (U/L)	01/08/91	10.00		12.00		13.40	
SGPT	5-22 (U/L)	01/08/91	8.00		16.00		18.00	
GAMMA GT	4-28 (U/L)	01/08/91	12.00		24.00		22.20	
LDH	120-240 (U/L)	01/08/91	127.00		138.00		134.00	
ALK. PHOSPH.	60-170 (U/L)	01/08/91	112.00		167.00		142.00	
GLUCOSE	60-110 (MG/DL)	01/08/91	108.30		98.40		89.00	
BUN	10-50 (MG/DL)	01/08/91	41.00		41.80		30.20	
UREA	()	01/08/91						
CREATININE	0.3-1.2 (MG/DL)	01/08/91	1.20		0.90		0.70	
URIC ACID	2.4-7 (MG/DL)	01/08/91	5.00		6.20		6.40	
TOT BILIRUBIN	0-1 (MG/DL)	01/08/91	0.50		0.10		0.10	
DIR BILIRUBIN	()	01/08/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/08/91	7.50		7.80		7.40	
ALBUMINE	3.7-5.5 (G/DL)	01/08/91	4.20		5.00		5.40	
TOT. CHOLEST.	120-200 (MG/DL)	01/08/91	196.00		202.00	>	210.00	
TRIGLYCERIDES	50-180 (MG/DL)	01/08/91	101.00		97.00		92.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/08/91	0.20		0.10		0.10	
GLOBULINS ALPHA 2	0.4-0.8 (G/DL)	01/08/91	0.60		0.70		0.60	
GLOBULINS BETA	0.4-0.9 (G/DL)	01/08/91	0.50		0.80		0.50	
GLOBULINS GAMMA	0.7-1.4 (G/DL)	01/08/91	0.90		1.30		1.00	
TSH	0.2-4 (UU/ML)	01/08/91	3.80					
T4	5-11.5 (UG/DL)	01/08/91	8.40					

(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

1346

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PHARMACIA CNS 390085

REBOXETINE - PROTOCOL 20124/017

Listing No.: 18.0

LABORATORY DATA

Centre: 14/7 Patient: 442 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			08/11/91		02/12/91		23/12/91	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12.8-16 (G/DL)	01/08/91	14.20		15.30		15.80	
HT	37-47 (X)	01/08/91	45.00		43.00		46.00	
RBC	4.5-5 (10 ⁶ /MM ³)	01/08/91	4.70		4.30	<	4.70	
WBC	3500-9000 (/MM ³)	01/08/91	4700.00		8500.00		8700.00	
WBC: N	37-73 (X)	01/08/91	43.00		68.00		60.00	
WBC: L	20-55 (X)	01/08/91	35.00		50.00		40.00	
WBC: E	0.5-11 (X)	01/08/91	1.40		8.20		7.40	
WBC: M	2.5-10 (X)	01/08/91	8.40		5.40		8.40	
WBC: B	0-2 (X)	01/08/91	0.00		2.00		1.00	
PLATELETS	150000-400000 (/MM ³)	01/08/91	320000		210000		295000	
NA+	134-148 (MMOL/L)	01/08/91	148.00		141.00		144.00	
K+	3.8-5.2 (MMOL/L)	01/08/91	4.20		4.20		4.80	
CL-	84-110 (MMOL/L)	01/08/91	104.00		106.00		95.00	
Ca++	4.2-5.5 (MEQ/L)	01/08/91	4.40		4.90		4.90	
PO4--	23.3-49.8 (MG/L)	01/08/91	32.40		34.30		32.80	
SGOT	5-18 (U/L)	01/08/91	16.00		18.00		26.00 >	
SGPT	5-22 (U/L)	01/08/91	18.00		17.00		24.00 >	
GAMMA GT	4-28 (U/L)	01/08/91	20.00		24.00		56.00 >>	
LDH	120-240 (U/L)	01/08/91	175.00		192.00		175.00	
ALK. PHOSPH.	60-170 (U/L)	01/08/91	125.00		162.00		148.00	
GLUCOSE	60-110 (MG/DL)	01/08/91	84.70		92.40		72.00	
BUN	10-50 (MG/DL)	01/08/91	22.80		20.40		30.20	
UREA	()	01/08/91						
CREATININE	0.3-1.2 (MG/DL)	01/08/91	0.70		0.80		1.00	
URIC ACID	2.4-7 (MG/DL)	01/08/91	5.40		5.20		4.50	
TOT BILIRUBIN	0-1 (MG/DL)	01/08/91	0.40		0.50		1.00	
DIR BILIRUBIN	()	01/08/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/08/91	7.50		8.00		6.80	
ALBUMINE	3.7-5.5 (G/DL)	01/08/91	4.30		4.80		4.20	
TOT. CHOLEST.	120-200 (MG/DL)	01/08/91	196.00		202.00 >		212.00 >	
TRIGLYCERIDES	50-180 (MG/DL)	01/08/91	102.00		100.00		98.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/08/91	0.10		0.20		0.20	
GLOBULINS ALPHA 2	0.4-0.8 (G/DL)	01/08/91	0.40		0.60		0.70	
GLOBULINS BETA	0.4-0.9 (G/DL)	01/08/91	0.70		0.60		0.60	
GLOBULINS GAMMA	0.7-1.4 (G/DL)	01/08/91	1.00		0.90		1.20	
TSH	0.2-4 (UU/ML)	01/08/91	2.80					
T4	5-11.5 (UG/DL)	01/08/91	7.80					

(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 () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARNACIA CNS 330085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/7 Patient: 450 Treatment: Inipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			06/12/91		13/01/92		03/02/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	12.8-16 (G/DL)	01/08/91	14.00		13.80		15.20	
HT	37-47 (Z)	01/08/91	45.00		42.00		46.80	
RBC	4.5-5 (10 ⁶ /MM ³)	01/08/91	4.70		4.80		4.70	
WBC	3500-9000 (/MM ³)	01/08/91	8400.00		7600.00		8200.00	
WBC: N	37-73 (Z)	01/08/91	45.00		63.00		65.00	
WBC: L	20-55 (Z)	01/08/91	35.00		48.00		32.00	
WBC: E	0.5-11 (Z)	01/08/91	10.10		7.20		6.40	
WBC: M	2.5-10 (Z)	01/08/91	8.40		6.80		7.30	
WBC: B	0-2 (Z)	01/08/91	0.80		1.00		0.80	
PLATELETS	150000-400000 (/MM ³)	01/08/91	325000		358000		324000	
NA+	134-148 (MMOL/L)	01/08/91	142.00		141.00		145.00	
K+	3.8-5.2 (MMOL/L)	01/08/91	4.40		4.60		4.40	
CL-	84-110 (MMOL/L)	01/08/91	100.00		99.00		104.00	
Ca++	4.2-5.5 (MEQ/L)	01/08/91	4.70		4.80		5.00	
PO4--	23.3-49.8 (MG/L)	01/08/91	36.80		42.40		46.80	
SGOT	5-18 (U/L)	01/08/91	10.00		9.00		12.00	
SGPT	5-22 (U/L)	01/08/91	11.00		11.00		14.00	
GAMMA GT	4-28 (U/L)	01/08/91	8.00		12.00		11.00	
LDH	120-240 (U/L)	01/08/91	194.00		186.00		145.00	
ALK. PHOSPH.	60-170 (U/L)	01/08/91	121.00		142.00		164.00	
GLUCOSE	60-110 (MG/DL)	01/08/91	54.00	<	87.40		102.00	
BUN	10-50 (MG/DL)	01/08/91	21.00	<	22.40		21.00	
UREA	()	01/08/91						
CREATININE	0.3-1.2 (MG/DL)	01/08/91	1.40	>	1.20		1.10	
URIC ACID	2.4-7 (MG/DL)	01/08/91	7.40	>	6.80		6.70	
TOT BILIRUBIN	0-1 (MG/DL)	01/08/91	0.30		0.70		0.80	
DIR BILIRUBIN	()	01/08/91						
TOT. PROTEINS	6.6-8.7 (G/DL)	01/08/91	7.00		7.40		6.90	
ALBUMINE	3.7-5.5 (G/DL)	01/08/91	4.80		5.20		4.80	
TOT. CHOLEST.	120-200 (MG/DL)	01/08/91	197.00		184.00		186.00	
TRIGLYCERIDES	50-180 (MG/DL)	01/08/91	110.00		102.00		84.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/08/91	0.10		0.20		0.30	
GLOBULINS ALPHA 2	0.4-0.8 (G/DL)	01/08/91	0.30	<	0.40		0.50	
GLOBULINS BETA	0.4-0.9 (G/DL)	01/08/91	0.90		0.70		0.50	
GLOBULINS GAMMA	0.7-1.4 (G/DL)	01/08/91	1.20		1.00		1.10	
TSH	0.2-4 (UU/ML)	01/08/91	3.80					
T4	5-11.5 (UG/DL)	01/08/91	6.70					

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PHARNACIA CNS 350085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/10 Patient: 54 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/02/92		17/03/92		07/04/92	
			value	(⊕)	value	(⊕)	value	(⊕)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	14.60		14.80		15.00	
HT	36-47 (%)	01/10/91	41.50		42.20		43.50	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.28		4.26		4.68	
WBC	5000-9000 (/MM ³)	01/10/91	5200.00		3700.00	<	6100.00	
WBC: N	50-70 (%)	01/10/91	51.00		53.00		61.00	
WBC: L	25-40 (%)	01/10/91	43.00	>	41.00	>	31.00	
WBC: E	2-4 (%)	01/10/91	1.00	<	1.00	<	0.00	
WBC: M	2-8 (%)	01/10/91	4.00		5.00		7.00	
WBC: B	0-1 (%)	01/10/91	1.00		0.00		1.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	256.00		107.00	<	305.00	
NA+	137-147 (MMOL/L)	01/10/91	141.00		141.00		142.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.50		4.40		4.60	
CL-	85-120 (MMOL/L)	01/10/91	106.00		109.00		106.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.64	>	2.43		2.50	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.13		1.01		1.23	
SGOT	4-20 (U/L)	01/10/91	8.10		12.60		5.70	
SGPT	4-20 (U/L)	01/10/91	5.60		9.10		5.90	
GAMMA GT	4-18 (U/L)	01/10/91	9.70		9.60		9.10	
LDH	55-150 (U/L)	01/10/91	105.00		97.00		116.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	60.00		96.00		130.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	96.00		94.00		100.00	
BUN	20-40 (MG/DL)	01/10/91	38.00		24.00		40.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	1.03		0.93		0.84	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	5.08		4.19		3.62	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.33		0.61		0.30	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.07		0.17		0.06	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.54		6.83		7.70	
ALBUMINE	56-66 (%)	01/10/91	41.40	<	62.80		55.50	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	220.00		195.00		239.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	327.00	>>	303.00	>>	344.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	3.60		3.70		2.10	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	10.80	>	8.30		9.80	
GLOBULINS BETA	8.5-14 (%)	01/10/91	20.70	>>	13.30		14.90	
GLOBULINS GAMMA	11-19 (%)	01/10/91	25.30	>>	11.90		17.70	
TSH	0.16-3.2 (MU/L)	01/10/91	3.35					
T4	48-120 (UG/L)	01/10/91	79.00					

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PHARMACIA CNS 9390085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/10 Patient: 56 Treatment: Imipramine Sex: Female

			Visit number / Laboratory data					
			Screen		Day 21		Day 42	
			24/02/92		23/03/92		13/04/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	15.90		16.20 >	14.20		
HT	36-47 (%)	01/10/91	43.30		44.00	41.60		
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.74		4.35	4.59		
WBC	5000-9000 (/MM ³)	01/10/91	5900.00		7200.00	6100.00		
WBC: N	50-70 (%)	01/10/91	67.00		71.00 >	48.00 <		
WBC: L	25-40 (%)	01/10/91	26.00		24.00 <	40.00		
WBC: E	2-4 (%)	01/10/91	0.00 <		1.00 <	0.00 <		
WBC: M	2-8 (%)	01/10/91	7.00		3.00	11.00 >>		
WBC: B	0-1 (%)	01/10/91	0.00		1.00	1.00		
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	302.00 >		195.00	322.00 >		
NA+	137-147 (MMOL/L)	01/10/91	139.00		137.00	141.00		
K+	3.6-5.5 (MMOL/L)	01/10/91	4.40		3.90	4.00		
CL-	85-120 (MMOL/L)	01/10/91	104.00		95.00	101.00		
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.44		2.39	2.45		
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.16		0.77 <	1.31		
SGOT	4-20 (U/L)	01/10/91	6.80		10.20	8.70		
SGPT	4-20 (U/L)	01/10/91	6.80		12.30	9.30		
GAMMA GT	4-18 (U/L)	01/10/91	15.60		4.20	12.00		
LDH	55-150 (U/L)	01/10/91	118.00		132.00	178.00 >		
ALK. PHOSPH.	50-190 (U/L)	01/10/91	112.00		78.00	96.00		
GLUCOSE	70-120 (MG/DL)	01/10/91	101.00		104.00	116.00		
BUN	20-40 (MG/DL)	01/10/91	39.00		26.00	36.00		
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.94		0.81	0.90		
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	6.61 >		5.25	4.97		
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.29		0.38	0.44		
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.05		0.05	0.13		
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.32		7.60	7.93 >		
ALBUMINE	56-66 (%)	01/10/91	64.30		64.40	54.50 <		
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	217.00		264.00 >	290.00 >		
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	409.00 >>		347.00 >>	359.00 >>		
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	3.50		2.60	4.60 >		
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	9.00		5.60 <	13.60 >>		
GLOBULINS BETA	8.5-14 (%)	01/10/91	14.00		12.90	17.00 >		
GLOBULINS GAMMA	11-19 (%)	01/10/91	9.20 <		14.50	10.30 <		
TSH	0.16-3.2 (MU/L)	01/10/91	0.85					
T4	48-120 (UG/L)	01/10/91	103.00					

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 < 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 CN 580085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/10 Patient: 58 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			02/04/92		04/05/92		25/05/92	
			value	(ϕ)	value	(ϕ)	value	(ϕ)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	15.80		15.40		15.70	
HT	36-47 (%)	01/10/91	46.30		44.90		45.60	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.13		4.54		5.04	
WBC	5000-9000 (/MM ³)	01/10/91	8000.00		4900.00	<	5850.00	
WBC: N	50-70 (%)	01/10/91	62.00		45.00	<	54.00	
WBC: L	25-40 (%)	01/10/91	29.00		48.00	>	40.00	
WBC: E	2-4 (%)	01/10/91	1.00	<	1.00	<	0.00	
WBC: M	2-8 (%)	01/10/91	7.00		6.00		6.00	
WBC: B	0-1 (%)	01/10/91	1.00		0.00		0.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	156.00		211.00		223.00	
UA+	137-147 (MMOL/L)	01/10/91	139.00		142.00		139.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.40		4.20		4.30	
CL-	85-120 (MMOL/L)	01/10/91	101.00		100.00		105.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.39		2.39		2.43	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.06		0.97		0.84	
SGOT	4-20 (U/L)	01/10/91	7.50		8.30		14.30	
SGPT	4-20 (U/L)	01/10/91	9.20		9.70		32.00	
GAMMA GT	4-18 (U/L)	01/10/91	21.20	>	9.80		26.20	
LDH	55-150 (U/L)	01/10/91	102.00		153.00	>	150.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	93.00		80.00		102.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	98.00		120.00		108.00	
BUN	20-40 (MG/DL)	01/10/91	19.00	<	24.00		50.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.81		0.93		1.12	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	4.25		4.90		4.80	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.22		0.37		0.89	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.05		0.11		0.07	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.53		7.44		7.33	
ALBUMINE	56-66 (%)	01/10/91	59.50		61.60		65.30	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	207.00		267.00	>	264.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	221.00	>	192.00		320.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	2.70		2.70		2.40	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	8.30		7.10		8.40	
GLOBULINS BETA	8.5-14 (%)	01/10/91	18.80	>>	14.80	>	11.10	
GLOBULINS GAMMA	11-19 (%)	01/10/91	10.70	<	13.80		9.90	
TSH	0.16-3.2 (MU/L)	01/10/91	0.56					
T4	48-120 (UG/L)	01/10/91	52.00					

(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 CN59085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/10 Patient: 59 Treatment: Imipramino Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			16/04/92		14/05/92		05/06/92	
			value	(c)	value	(c)	value	(c)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	15.20		15.00		15.20	
HT	36-47 (%)	01/10/91	44.80		43.90		44.60	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.48		5.08		4.88	
WBC	5000-9000 (/MM ³)	01/10/91	12400.0	>>	5700.00		8200.00	
WBC: N	50-70 (%)	01/10/91	73.00	>	61.00		46.00	<
WBC: L	25-40 (%)	01/10/91	18.00	<	34.00		40.00	
WBC: E	2-4 (%)	01/10/91	1.00	<	0.00	<	0.00	<
WBC: M	2-8 (%)	01/10/91	8.00		5.00		9.00	>
WBC: B	0-1 (%)	01/10/91	0.00		0.00		1.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	185.00		327.00	>	299.00	
NA+	137-147 (MMOL/L)	01/10/91	141.00		141.00		143.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.40		4.40		4.60	
CL-	85-120 (MMOL/L)	01/10/91	110.00		103.00		99.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.20	<	2.37		2.46	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.24		1.02		1.57	
SGOT	4-20 (U/L)	01/10/91	5.70		7.30		7.30	
SGPT	4-20 (U/L)	01/10/91	7.80		7.60		15.30	
GAMMA GT	4-18 (U/L)	01/10/91	9.10		10.40		8.10	
LDH	55-150 (U/L)	01/10/91	136.00		106.00		151.00	>
ALK. PHOSPH.	50-190 (U/L)	01/10/91	56.00		101.00		82.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	110.00		90.00		101.00	
BUN	20-40 (MG/DL)	01/10/91	36.00		38.00		26.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.97		1.15		0.84	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	4.26		5.93	>	3.59	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.88		1.11	>	0.40	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.20		0.05		0.21	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.19		7.31		7.05	
ALBUMINE	56-66 (%)	01/10/91	65.50		60.50		64.00	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	142.00		181.00		219.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	92.00		81.00		60.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	3.20		2.50		2.80	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	7.60		7.40		8.70	
GLOBULINS BETA	8.5-14 (%)	01/10/91	9.80		13.50		12.90	
GLOBULINS GAMMA	11-19 (%)	01/10/91	13.80		16.00		11.60	
TSH	0.16-3.2 (MU/L)	01/10/91	0.26					
T4	48-120 (UG/L)	01/10/91	74.00					

(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 330085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/10 Patient: 138 Treatment: Imipramino 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	11-16 (G/DL)	01/10/91	13.80		13.80		13.90	
HT	36-47 (%)	01/10/91	39.80		39.10		38.90	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.39		4.29		5.00	
HBC	5000-9000 (/MM ³)	01/10/91	4700.00	<	5400.00		7000.00	
HBC: N	50-70 (%)	01/10/91	54.00		63.00		59.00	
HBC: L	25-40 (%)	01/10/91	37.00		30.00		32.00	
HBC: E	2-4 (%)	01/10/91	0.00	<	0.00	<	1.00	
HBC: M	2-8 (%)	01/10/91	8.00		7.00		7.00	
HBC: B	0-1 (%)	01/10/91	1.00		0.00		1.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	263.00		200.00		180.00	
NA+	137-147 (MMOL/L)	01/10/91	141.00		142.00		142.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.90		4.80		4.10	
CL-	85-120 (MMOL/L)	01/10/91	95.00		104.00		96.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.49		2.53		2.31	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.18		1.34		0.74	
SGOT	4-20 (U/L)	01/10/91	7.40		10.50		11.20	
SGPT	4-20 (U/L)	01/10/91	15.80		26.50	>	20.60	
GAMMA GT	4-18 (U/L)	01/10/91	34.60	>	53.40	>>	14.30	
LDH	55-150 (U/L)	01/10/91	135.00		172.00	>	185.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	98.00		134.00		87.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	107.00		101.00		106.00	
BUN	20-40 (MG/DL)	01/10/91	42.00	>	27.00		42.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.25	<	0.80		1.10	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	5.30		5.90	>	5.84	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.70		0.78		0.72	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.08		0.05		0.10	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.40		7.44		7.26	
ALBUMINE	56-66 (%)	01/10/91	61.50		61.60		63.50	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	231.00		204.00		197.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	118.00		177.00		154.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	2.90		2.90		3.00	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	8.70		9.50		8.50	
GLOBULINS BETA	8.5-14 (%)	01/10/91	13.70		12.00		13.70	
GLOBULINS GAMMA	11-19 (%)	01/10/91	13.20		13.00		11.20	
TSH	0.16-3.2 (MU/L)	01/10/91	1.42					
T4	48-120 (UG/L)	01/10/91	66.00					

(*) << 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 590085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/10 Patient: 140 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			28/01/92		25/02/92		17/03/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	15.00		15.50		15.60	
HT	36-47 (%)	01/10/91	42.20		44.30		42.70	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.81		4.35		4.37	
WBC	5000-9000 (/MM ³)	01/10/91	6600.00		8700.00		6000.00	
WBC: N	50-70 (%)	01/10/91	66.00		52.00		51.00	
WBC: L	25-40 (%)	01/10/91	29.00		41.00	>	42.00	
WBC: E	2-4 (%)	01/10/91	2.00		1.00	<	0.00	
WBC: M	2-8 (%)	01/10/91	2.00		5.00		6.00	
WBC: B	0-1 (%)	01/10/91	1.00		1.00		1.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	258.00		252.00		201.00	
NA+	137-147 (MMOL/L)	01/10/91	140.00		142.00		142.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.30		3.50	<	3.60	
CL-	85-120 (MMOL/L)	01/10/91	101.00		96.00		96.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.66	>	2.49		2.43	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.31		1.06		1.11	
SGOT	4-20 (U/L)	01/10/91	5.30		9.00		6.60	
SGPT	4-20 (U/L)	01/10/91	6.10		7.20		5.90	
GAMMA GT	4-18 (U/L)	01/10/91	6.00		6.50		5.50	
LDH	55-150 (U/L)	01/10/91	215.00	>	248.00	>	216.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	68.00		101.00		101.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	93.00		101.00		93.00	
BUN	20-40 (MG/DL)	01/10/91	26.00		17.00	<	30.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.84		0.86		0.92	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	4.25		5.01		6.09	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.24		0.62		0.57	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.05		0.05		0.05	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	6.80		7.07		7.32	
ALBUMINE	56-66 (%)	01/10/91	55.30	<	60.10		58.20	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	243.00		247.00		235.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	119.00		124.00		60.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	3.90		5.60	>	4.10	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	11.70	>	10.10	>	9.60	
GLOBULINS BETA	8.5-14 (%)	01/10/91	16.00	>	13.30		13.90	
GLOBULINS GAMMA	11-19 (%)	01/10/91	13.10		10.90	<	14.10	
TSH	0.16-3.2 (MU/L)	01/10/91	1.10					
T4	48-120 (UG/L)	01/10/91	109.00					

(€) << 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 CN 550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/10 Patient: 435 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			04/11/91		02/12/91		23/12/91	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	14.50		14.60		14.10	
HT	36-47 (%)	01/10/91	42.50		40.70		39.30	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.53		4.81		5.10	
HBC	5000-9000 (/MM ³)	01/10/91	6100.00		4900.00	<	6800.00	
HBC: N	50-70 (%)	01/10/91	40.00	<	45.00	<	54.00	
HBC: L	25-40 (%)	01/10/91	46.00	>	40.00		37.00	
HBC: E	2-4 (%)	01/10/91	1.00	<	1.00	<	3.00	
HBC: M	2-8 (%)	01/10/91	11.00	>>	12.00	>>	5.00	
HBC: B	0-1 (%)	01/10/91	1.00		1.00		1.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	254.00		300.00		246.00	
NA+	137-147 (MMOL/L)	01/10/91	140.00		139.00		148.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.00		3.30	<	4.40	
CL-	85-120 (MMOL/L)	01/10/91	99.00		99.00		103.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.55		2.43		2.39	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.00		1.11		1.06	
SGOT	4-20 (U/L)	01/10/91	11.00		11.50		9.60	
SGPT	4-20 (U/L)	01/10/91	11.00		11.10		15.20	
GAMMA GT	4-18 (U/L)	01/10/91	11.00		8.90		13.10	
LDH	55-150 (U/L)	01/10/91	181.00	>	206.00	>	162.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	153.00		176.00		99.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	125.00	>	99.00		121.00	
BUN	20-40 (MG/DL)	01/10/91	37.00		20.00		25.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.98		0.80		0.87	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	6.76	>	4.43		5.32	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.53		0.27		0.54	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.03		0.05		0.13	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.89		8.22	>	7.42	
ALBUMINE	56-66 (%)	01/10/91	52.10	<	57.70		54.80	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	269.00	>	279.00	>	233.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	163.00		70.00		130.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	4.00		3.30		3.70	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	11.90	>	7.20		12.40	
GLOBULINS BETA	8.5-14 (%)	01/10/91	16.70	>	17.20	>	14.50	
GLOBULINS GAMMA	11-19 (%)	01/10/91	15.20		14.60		14.60	
TSH	0.16-3.2 (MU/L)	01/10/91	0.18					
T4	48-120 (UG/L)	01/10/91	72.00					

(¢) << 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 0959085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/10 Patient: 438 Treatment: Inipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			07/11/91		05/12/91		27/12/91	
			value	(φ)	value	(φ)	value	(φ)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	12.80		13.30		13.70	
HT	36-47 (%)	01/10/91	35.90	<	37.30		39.00	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	3.68	<	4.03		5.12	
WBC	5000-9000 (/MM ³)	01/10/91	7600.00		5900.00		15100.0	>>
WBC: N	50-70 (%)	01/10/91	65.00		62.00		61.00	
WBC: L	25-40 (%)	01/10/91	26.00		32.00		33.00	
WBC: E	2-4 (%)	01/10/91	1.00	<	1.00	<	0.00	<
WBC: M	2-8 (%)	01/10/91	6.00		5.00		6.00	
WBC: B	0-1 (%)	01/10/91	1.00		0.00		0.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	290.00		249.00		285.00	
NA+	137-147 (MMOL/L)	01/10/91	144.00		142.00		143.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.70		4.30		4.20	
CL-	85-120 (MMOL/L)	01/10/91	108.00		99.00		97.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.36		2.47		2.29	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.18		1.10		1.37	
SGOT	4-20 (U/L)	01/10/91	6.10		8.00		12.70	
SGPT	4-20 (U/L)	01/10/91	10.10		10.20		7.40	
GAMMA GT	4-18 (U/L)	01/10/91	12.40		7.60		4.10	
LDH	55-150 (U/L)	01/10/91	178.00	>	173.00	>	177.00	>
ALK. PHOSPH.	50-190 (U/L)	01/10/91	79.00		99.00		103.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	111.00		98.00		85.00	
BUN	20-40 (MG/DL)	01/10/91	39.00		35.00		32.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.76		1.04		0.89	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	4.64		5.89	>	5.29	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.28		0.25		0.05	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.10		0.05		0.05	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.01		7.48		7.72	
ALBUMINE	56-66 (%)	01/10/91	63.60		56.30		60.00	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	187.00		218.00		130.00	<
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	81.00		116.00		98.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	3.30		2.80		2.80	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	12.70	>	8.70		9.60	
GLOBULINS BETA	8.5-14 (%)	01/10/91	11.50		12.80		14.10	>
GLOBULINS GAMMA	11-19 (%)	01/10/91	8.90	<	17.40		13.50	
TSH	0.16-3.2 (MU/L)	01/10/91	0.93					
T4	48-120 (UG/L)	01/10/91	113.00					

(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 50085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/10 Patient: 445 Treatment: Imipramine Sex: Female

Laboratory test	Range value	Range date	Visit number / Laboratory date			
			Screen		Day 42	
			15/11/91		30/12/91	
			value (€)	value (€)	value (€)	value (€)
HB	11-16 (G/DL)	01/10/91	15.60		14.70	
HT	36-47 (X)	01/10/91	43.50		40.60	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.33		4.44	
WBC	5000-9000 (/MM ³)	01/10/91	7100.00		5900.00	
WBC: N	50-70 (X)	01/10/91	66.00		62.00	
WBC: L	25-40 (X)	01/10/91	29.00		33.00	
WBC: E	2-4 (X)	01/10/91	1.00	<	1.00	<
WBC: M	2-8 (X)	01/10/91	3.00		3.00	
WBC: B	0-1 (X)	01/10/91	1.00		1.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	249.00		249.00	
NA+	137-147 (MMOL/L)	01/10/91	137.00		146.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	3.90		4.80	
CL-	85-120 (MMOL/L)	01/10/91	95.00		105.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.39		2.44	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	0.77	<	1.26	
SGOT	4-20 (U/L)	01/10/91	10.20		7.10	
SGPT	4-20 (U/L)	01/10/91	12.30		14.60	
GAMMA GT	4-18 (U/L)	01/10/91	4.20		37.80	>>
LDH	55-150 (U/L)	01/10/91	132.00		98.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	78.00		122.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	100.00		85.00	
BUN	20-40 (MG/DL)	01/10/91	26.00		30.00	
UREA	()	01/10/91				
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.81		0.83	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	5.25		3.80	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.38		0.54	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.15		0.08	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.78		8.01	>
ALBUMINE	56-66 (X)	01/10/91	60.70		61.80	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	264.00	>	221.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	347.00	>>	172.00	
GLOBULINS ALPHA 1	2.5-4.5 (X)	01/10/91	2.50		3.10	
GLOBULINS ALPHA 2	6.5-10 (X)	01/10/91	10.30	>	7.60	
GLOBULINS BETA	8.5-14 (X)	01/10/91	11.00		13.60	
GLOBULINS GAMMA	11-19 (X)	01/10/91	15.50		13.90	
TSH	0.16-3.2 (MU/L)	01/10/91	0.60			
T4	48-120 (UG/L)	01/10/91	132.00			

(€) << 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 09550085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centro: 14/10 Patient: 448 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date		
			Screen	Day 21	Day 42
			22/11/91	17/12/91	08/01/92
			value (⊕)	value (⊕)	value (⊕)
Laboratory test	Range value	Range date			
HB	11-16 (G/DL)	01/10/91	15.50	14.60	14.10
HT	36-47 (X)	01/10/91	42.90	40.50	39.00
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.27	4.64	3.94
WBC	5000-9000 (/MM ³)	01/10/91	7100.00	6200.00	4700.00 <
WBC: N	50-70 (X)	01/10/91	63.00	72.00 >	67.00
WBC: L	25-40 (X)	01/10/91	30.00	23.00 <	28.00
WBC: E	2-4 (X)	01/10/91	1.00 <	1.00 <	1.00 <
WBC: M	2-8 (X)	01/10/91	5.00	4.00	4.00
WBC: B	0-1 (X)	01/10/91	1.00	0.00	1.00
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	230.00	330.00 >	252.00
NA+	137-147 (MMOL/L)	01/10/91	145.00	147.00	144.00
K+	3.6-5.5 (MMOL/L)	01/10/91	4.40	4.60	4.10
CL-	85-120 (MMOL/L)	01/10/91	98.00	102.00	106.00
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.44	2.53	2.24 <
PO4--	0.8-1.6 (MMOL/L)	01/10/91	0.74 <	1.00	0.77 <
SGOT	4-20 (U/L)	01/10/91	9.10	5.90	7.60
SGPT	4-20 (U/L)	01/10/91	12.60	6.50	6.60
GAMMA GT	4-18 (U/L)	01/10/91	50.80 >>	9.30	17.80
LDH	55-150 (U/L)	01/10/91	165.00 >	135.00	171.00 >
ALK. PHOSPH.	50-190 (U/L)	01/10/91	78.00	67.00	77.00
GLUCOSE	70-120 (MG/DL)	01/10/91	111.00	111.00	138.00 >
BUN	20-40 (MG/DL)	01/10/91	34.00	43.00 >	45.00 >
UREA	()	01/10/91			
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.89	0.94	1.06
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	6.46 >	6.02 >	7.24 >
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.27	0.64	0.47
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.15	0.05	0.05
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.16	7.86	7.94 >
ALBUMINE	56-66 (X)	01/10/91	63.00	56.50	58.40
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	308.00 >	260.00 >	202.00
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	342.00 >>	216.00 >	233.00 >
GLOBULINS ALPHA 1	2.5-4.5 (X)	01/10/91	2.90	5.00 >	3.60
GLOBULINS ALPHA 2	6.5-10 (X)	01/10/91	6.70	11.20 >	14.50 >>
GLOBULINS BETA	8.5-14 (X)	01/10/91	16.50 >	13.30	12.00
GLOBULINS GAMMA	11-19 (X)	01/10/91	10.90 <	13.90	11.40
TSH	0.16-3.2 (MU/L)	01/10/91	1.12		
T4	48-120 (UG/L)	01/10/91	70.00		

(⊕) << 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 549 085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 14/10 Patient: 453 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			18/05/92		17/06/92		08/07/92	
			value	(*)	value	(*)	value	(*)
Laboratory test	Range value	Range date						
HB	11-16 (G/DL)	01/10/91	13.60		13.50		13.50	
HT	36-47 (%)	01/10/91	40.30		39.90		40.50	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/10/91	4.23		4.79		4.25	
WBC	5000-9000 (/MM ³)	01/10/91	5000.00		8500.00		6100.00	
WBC: N	50-70 (%)	01/10/91	60.00		61.00		70.00	
WBC: L	25-40 (%)	01/10/91	31.00		32.00		20.00	
WBC: E	2-4 (%)	01/10/91	3.00		0.00	<	1.00	
WBC: M	2-8 (%)	01/10/91	6.00		6.00		8.00	
WBC: B	0-1 (%)	01/10/91	0.00		1.00		1.00	
PLATELETS	150-300 (10 ³ /MM ³)	01/10/91	298.00		254.00		234.00	
NA+	137-147 (MMOL/L)	01/10/91	140.00		139.00		143.00	
K+	3.6-5.5 (MMOL/L)	01/10/91	4.40		4.10		4.00	
CL-	85-120 (MMOL/L)	01/10/91	104.00		104.00		105.00	
Ca++	2.25-2.6 (MMOL/L)	01/10/91	2.35		2.26		2.30	
PO4--	0.8-1.6 (MMOL/L)	01/10/91	1.21		0.97		1.11	
SGOT	4-20 (U/L)	01/10/91	6.80		8.10		9.00	
SGPT	4-20 (U/L)	01/10/91	7.00		10.20		9.20	
GAMMA GT	4-18 (U/L)	01/10/91	7.80		17.00		8.30	
LDH	55-150 (U/L)	01/10/91	102.00		145.00		62.00	
ALK. PHOSPH.	50-190 (U/L)	01/10/91	98.00		85.00		105.00	
GLUCOSE	70-120 (MG/DL)	01/10/91	81.00		101.00		102.00	
BUN	20-40 (MG/DL)	01/10/91	22.00		23.00		34.00	
UREA	()	01/10/91						
CREATININE	0.7-1.3 (MG/DL)	01/10/91	0.98		0.94		0.76	
URIC ACID	2.4-5.7 (MG/DL)	01/10/91	4.01		4.61		5.66	
TOT BILIRUBIN	0-1 (MG/DL)	01/10/91	0.38		0.52		0.48	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/10/91	0.07		0.20		0.07	
TOT. PROTEINS	6.6-7.9 (G/DL)	01/10/91	7.17		6.91		6.90	
ALBUMINE	56-66 (%)	01/10/91	56.70		64.00		61.30	
TOT. CHOLEST.	140-250 (MG/DL)	01/10/91	184.00		189.00		218.00	
TRIGLYCERIDES	20-200 (MG/DL)	01/10/91	131.00		131.00		196.00	
GLOBULINS ALPHA 1	2.5-4.5 (%)	01/10/91	3.10		3.40		5.70	
GLOBULINS ALPHA 2	6.5-10 (%)	01/10/91	11.10	>	9.70		7.40	
GLOBULINS BETA	8.5-14 (%)	01/10/91	16.30	>	11.00		12.80	
GLOBULINS GAMMA	11-19 (%)	01/10/91	12.70		11.10		12.80	
TSH	0.16-3.2 (MU/L)	01/10/91	0.32		0.67		0.30	
T4	48-120 (UG/L)	01/10/91	98.00		112.00		85.00	

(*) << 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 CNF-898
5590085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 15 Patient: 349 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			20/08/92		10/09/92		01/10/92	
			value	(*)	value	(*)	value	(*)
Laboratory test	Range value	Range date						
HB	13.5-18 (G/DL)	01/03/92	15.80		15.40		15.20	
HT	0.4-0.54 (L/L)	01/03/92	0.49		0.45		0.44	
RBC	4.4-6 (10 ⁶ /MM ³)	01/03/92	5.47		4.96		4.97	
WBC	4-11 (10 ³ /MM ³)	01/03/92	8.20		5.70		6.40	
WBC: N	20-75 (%)	01/03/92	46.00		49.00		59.00	
WBC: L	10-40 (%)	01/03/92	48.00	>	46.00	>	32.00	
WBC: E	1-6 (%)	01/03/92	1.00		2.00		1.00	
WBC: M	2-10 (%)	01/03/92	4.00		3.00		8.00	
WBC: B	0-2 (%)	01/03/92	1.00		0.00		0.00	
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	293.00		266.00		253.00	
NA+	136-148 (MMOL/L)	01/03/92	140.00		142.00		143.00	
K+	3.8-5 (MMOL/L)	01/03/92	3.80		3.90		4.70	
CL-	97-106 (MMOL/L)	01/03/92	98.00		100.00		103.00	
Ca++	2.25-2.75 (MMOL/L)	01/03/92	2.23	<	2.26		2.26	
PO4--	0.6-1.8 (MMOL/L)	01/03/92	1.04		0.93		1.35	
SGOT	5-37 (U/L)	01/03/92	18.00		17.00		17.00	
SGPT	5-40 (U/L)	01/03/92	12.00		12.00		11.00	
GAMMA GT	11-50 (U/L)	01/03/92	9.00	<	10.00	<	9.00	
LDH	230-460 (U/L)	01/03/92	215.00	<	251.00		284.00	
ALK. PHOSPH.	40-120 (U/L)	01/03/92	80.00		78.00		79.00	
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	4.90		5.80		5.80	
BUN	()	01/03/92						
UREA	2.5-6.6 (MMOL/L)	01/03/92	3.60		2.50		4.80	
CREATININE	44-120 (UMOL/L)	01/03/92	85.00		91.60		103.00	
URIC ACID	0.19-0.43 (MMOL/L)	01/03/92						
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	18.00		12.00		11.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	3.00		5.00		5.00	
TOT. PROTEINS	62-82 (G/L)	01/03/92	84.00	>	79.00		70.00	
ALBUMINE	35-57 (G/L)	01/03/92	39.00		40.00		43.00	
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	4.10		3.80		3.90	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	1.43		0.95		1.53	
GLOBULINS ALPHA 1	1-5 (%)	01/03/92						
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92						
GLOBULINS BETA	11-16 (%)	01/03/92						
GLOBULINS GAMMA	()	01/03/92						
TSH	0.4-4 (MU/L)	01/03/92	1.00		1.70			
T4	8-25 (PMOL/L)	01/03/92	14.90		12.10			

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PHARMACIA CNS 540
5930085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 15 Patient: 352 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date			
			Screen		Day 21	
			06/08/92		27/08/92	
			value	(€)	value	(€)
Laboratory test	Range value	Range date				
HB	13.5-18 (G/DL)	01/03/92	15.80		16.80	
HT	0.4-0.54 (L/L)	01/03/92	0.50		0.51	
RBC	4.4-6 (10 ⁶ /MM ³)	01/03/92	5.62		5.66	
WBC	4-11 (10 ³ /MM ³)	01/03/92	6.50		8.10	
WBC: N	20-75 (%)	01/03/92	65.00		57.00	
WBC: L	10-40 (%)	01/03/92	26.00		38.00	
WBC: E	1-6 (%)	01/03/92	0.00	<	1.00	
WBC: M	2-10 (%)	01/03/92	9.00		3.00	
WBC: B	0-2 (%)	01/03/92	0.00		1.00	
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	299.00			
NA+	136-148 (MMOL/L)	01/03/92	145.00		139.00	
K+	3.8-5 (MMOL/L)	01/03/92	5.00		4.90	
CL-	97-106 (MMOL/L)	01/03/92	101.00		96.00 <	
Ca ⁺⁺	2.25-2.75 (MMOL/L)	01/03/92	2.22	<	2.51	
PO ₄ ⁻⁻	0.6-1.8 (MMOL/L)	01/03/92	1.01		1.31	
SGOT	5-37 (U/L)	01/03/92	25.00		20.00	
SGPT	5-40 (U/L)	01/03/92	29.00		35.00	
GANMA GT	11-50 (U/L)	01/03/92	19.00		31.00	
LDH	230-460 (U/L)	01/03/92	259.00		244.00	
ALK. PHOSPH.	40-120 (U/L)	01/03/92	93.00		100.00	
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92			6.50 >	
BUN	()	01/03/92				
UREA	2.5-6.6 (MMOL/L)	01/03/92	4.60		5.90	
CREATININE	44-120 (UMOL/L)	01/03/92	106.00		132.40 >	
URIC ACID	0.19-0.43 (MMOL/L)	01/03/92				
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	6.00		5.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	2.00		2.00	
TOT. PROTEINS	62-82 (G/L)	01/03/92	73.00		87.00 >	
ALBUMINE	35-57 (G/L)	01/03/92	37.00		42.00	
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	4.50		6.00	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	0.64	<	1.26	
GLOBULINS ALPHA 1	1-5 (%)	01/03/92				
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92				
GLOBULINS BETA	11-16 (%)	01/03/92				
GLOBULINS GAMMA	()	01/03/92				
TSH	0.4-4 (MU/L)	01/03/92	0.80		0.80	
T4	8-25 (PMOL/L)	01/03/92	21.50		18.30	

(€) << 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 240~~ 5530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 15 Patient: 364 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			29/07/92		19/08/92	
			value	(€)	value	(€)
Laboratory test	Range value	Range date				
HB	11.5-16.5 (G/DL)	01/03/92	14.20		14.00	
HT	0.35-0.49 (L/L)	01/03/92	0.43		0.42	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/03/92	4.54		4.55	
WBC	4-11 (10 ³ /MM ³)	01/03/92	7.20		5.20	
WBC: N	20-75 (%)	01/03/92	55.00		51.00	
WBC: L	10-40 (%)	01/03/92	38.00		39.00	
WBC: E	1-6 (%)	01/03/92	2.00		5.00	
WBC: M	2-10 (%)	01/03/92	4.00		5.00	
WBC: B	0-2 (%)	01/03/92	1.00		0.00	
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92			278.00	
NA+	136-148 (MMOL/L)	01/03/92	149.00	>	146.00	
K+	3.8-5 (MMOL/L)	01/03/92	5.40	>	5.80	
CL-	97-106 (MMOL/L)	01/03/92	102.00		98.00	
Ca++	2.25-2.75 (MMOL/L)	01/03/92	2.27		2.58	
PO4--	0.6-1.8 (MMOL/L)	01/03/92	1.20		1.19	
SGOT	5-31 (U/L)	01/03/92	19.00		345.00	
SGPT	5-31 (U/L)	01/03/92	18.00		468.00	
GAMMA GT	7-32 (U/L)	01/03/92	18.00		79.00	
LDH	230-460 (U/L)	01/03/92	342.00		551.00	
ALK. PHOSPH.	40-120 (U/L)	01/03/92	80.00		132.00	
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	4.70		4.60	
BUN	()	01/03/92				
UREA	2.5-6.6 (MMOL/L)	01/03/92	3.90		4.90	
CREATININE	44-120 (UMOL/L)	01/03/92	72.00		91.10	
URIC ACID	0.14-0.33 (MMOL/L)	01/03/92				
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	5.00		6.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	2.00		2.00	
TOT. PROTEINS	62-82 (G/L)	01/03/92	84.00	>	83.00	
ALBUMINE	35-57 (G/L)	01/03/92	41.00		38.00	
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	6.00		6.70	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	1.66		1.29	
GLOBULINS ALPHA 1	1-5 (%)	01/03/92				
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92				
GLOBULINS BETA	11-16 (%)	01/03/92				
GLOBULINS GAMMA	()	01/03/92				
TSH	0.4-4 (MU/L)	01/03/92	0.90		1.50	
T4	8-25 (PMOL/L)	01/03/92	20.60		12.10	

(€) << 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 360
9330085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centro: 15 Patient: 367 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			31/08/92		21/09/92		12/10/92	
			value	(†)	value	(†)	value	(†)
Laboratory test	Range value	Range date						
HB	13.5-18 (G/DL)	01/03/92	14.80		14.70		14.20	
HT	0.4-0.54 (L/L)	01/03/92	0.43		0.45		0.43	
RBC	4.4-6 (10 ⁶ /MM ³)	01/03/92	4.94		4.04 <		4.73	
WBC	4-11 (10 ³ /MM ³)	01/03/92	5.10		4.60		8.00	
WBC: N	20-75 (%)	01/03/92	48.00		35.00		74.00	
WBC: L	10-40 (%)	01/03/92	41.00 >		57.00 >>		21.00	
WBC: E	1-6 (%)	01/03/92	6.00		3.00		2.00	
WBC: M	2-10 (%)	01/03/92	5.00		4.00		3.00	
WBC: B	0-2 (%)	01/03/92	0.00		1.00		0.00	
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92			362.00		242.00	
NA+	136-148 (MMOL/L)	01/03/92	146.00		146.00		146.00	
K+	3.8-5 (MMOL/L)	01/03/92	3.80		7.80 >>		4.80	
CL-	97-106 (MMOL/L)	01/03/92	104.00		102.00		101.00	
Ca ⁺⁺	2.25-2.75 (MMOL/L)	01/03/92	2.22 <		2.26		2.22 <	
PO ₄ ⁻	0.6-1.8 (MMOL/L)	01/03/92	0.38 <<		0.67		0.61	
SGOT	5-37 (U/L)	01/03/92	20.00		18.00		19.00	
SGPT	5-40 (U/L)	01/03/92	19.00		13.00		13.00	
GAMMA GT	11-50 (U/L)	01/03/92	17.00		18.00		17.00	
LDH	230-460 (U/L)	01/03/92	380.00		398.00		418.00	
ALK. PHOSPH.	40-120 (U/L)	01/03/92	87.00		92.00		89.00	
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	8.00 >>		5.80		5.10	
BUN	()	01/03/92						
UREA	2.5-6.6 (MMOL/L)	01/03/92	3.60		3.70		3.40	
CREATININE	44-120 (UMOL/L)	01/03/92	90.90		81.30		81.30	
URIC ACID	0.19-0.43 (MMOL/L)	01/03/92			6.00		6.00	
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	7.00		6.00		5.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	3.00		5.00		5.00	
TOT. PROTEINS	62-82 (G/L)	01/03/92	83.00 >		83.00 >		74.00	
ALBUMINE	35-57 (G/L)	01/03/92	40.00		39.00		44.00	
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	4.60		3.80		4.30	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	3.16 >>		1.06		0.73 <	
GLOBULINS ALPHA 1	1-5 (%)	01/03/92						
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92						
GLOBULINS BETA	11-16 (%)	01/03/92						
GLOBULINS GAMMA	()	01/03/92						
TSH	0.4-4 (MU/L)	01/03/92	1.50		0.80		1.30	
T4	8-25 (PMOL/L)	01/03/92	12.20		22.70		21.70	

(†) << 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 CN 539085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 15 Patient: 370 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date	
			Screen	Day 42
			16/07/92	27/08/92
			value (€)	value (€)
Laboratory test	Range value	Range date		
HB	11.5-16.5 (G/DL)	01/03/92	13.60	14.30
HT	0.35-0.49 (L/L)	01/03/92	0.41	0.39
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/03/92	4.59	5.19
WBC	4-11 (10 ³ /MM ³)	01/03/92	5.90	
WBC: N	20-75 (%)	01/03/92	46.00	44.00
WBC: L	10-40 (%)	01/03/92	40.00	41.00 >
WBC: E	1-6 (%)	01/03/92	2.00	1.00
WBC: M	2-10 (%)	01/03/92	11.00 >	13.00 >
WBC: B	0-2 (%)	01/03/92	1.00	1.00
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	283.00	330.00
NA+	136-148 (MMOL/L)	01/03/92	149.00 >	149.00 >
K+	3.8-5 (MMOL/L)	01/03/92	3.90	4.10
CL-	97-106 (MMOL/L)	01/03/92	103.00	101.00
Ca ⁺⁺	2.25-2.75 (MMOL/L)	01/03/92	2.23 <	2.32
PO ₄ ⁻⁻	0.6-1.8 (MMOL/L)	01/03/92	1.30	1.01
SGOT	5-31 (U/L)	01/03/92	24.00	43.00 >>
SGPT	5-31 (U/L)	01/03/92	28.00	76.00 >>
GAMMA GT	7-32 (U/L)	01/03/92	18.00	17.00
LDH	230-460 (U/L)	01/03/92	414.00	399.00
ALK. PHOSPH.	40-120 (U/L)	01/03/92	82.00	95.00
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	5.50	5.70
BUN	()	01/03/92		
UREA	2.5-6.6 (MMOL/L)	01/03/92	4.70	5.20
CREATININE	44-120 (UMOL/L)	01/03/92	77.00	88.20
URIC ACID	0.14-0.33 (MMOL/L)	01/03/92		
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	5.00	7.00
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	1.00	1.00
TOT. PROTEINS	62-82 (G/L)	01/03/92	78.00	84.00 >
ALBUMINE	35-57 (G/L)	01/03/92	40.00	39.00
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	6.70 >	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	1.42	
GLOBULINS ALPHA 1	1-5 (%)	01/03/92		
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92		
GLOBULINS BETA	11-16 (%)	01/03/92		
GLOBULINS GAMMA	()	01/03/92		
TSH	0.4-4 (MU/L)	01/03/92	1.40	1.00
T4	8-25 (PMOL/L)	01/03/92	11.40	13.70

(€) << 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-298~~
5530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 15 Patient: 372 Treatment: Imipramine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			17/06/92		08/07/92		29/07/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	13.5-18 (G/DL)	01/03/92	16.00		14.20		14.60	
HT	0.4-0.54 (L/L)	01/03/92	0.49		0.44		0.45	
RBC	4.4-6 (10 ⁶ /MM ³)	01/03/92	5.06		4.59		4.72	
WBC	4-11 (10 ³ /MM ³)	01/03/92	6.90		6.80		8.90	
WBC: N	20-75 (%)	01/03/92	45.00		41.00		39.00	
WBC: L	10-40 (%)	01/03/92	45.00 >		51.00 >		57.00 >>	
WBC: E	1-6 (%)	01/03/92	4.00		2.00		0.00 <	
WBC: M	2-10 (%)	01/03/92	6.00		6.00		4.00	
WBC: B	0-2 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92						
NA+	136-148 (MMOL/L)	01/03/92	139.00		150.00 >			
K+	3.8-5 (MMOL/L)	01/03/92	5.00		5.60 >			
CL-	97-106 (MMOL/L)	01/03/92	96.00 <		100.00			
Ca++	2.25-2.75 (MMOL/L)	01/03/92						
PO4--	0.6-1.8 (MMOL/L)	01/03/92						
SGOT	5-37 (U/L)	01/03/92	30.00		31.00		35.00	
SGPT	5-40 (U/L)	01/03/92	23.00		25.00		31.00	
GAMMA GT	11-50 (U/L)	01/03/92	18.00		18.00		17.00	
LDH	230-460 (U/L)	01/03/92						
ALK. PHOSPH.	40-120 (U/L)	01/03/92	91.00		84.00		70.00	
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	6.00		4.00		4.30	
BUN	()	01/03/92						
UREA	2.5-6.6 (MMOL/L)	01/03/92	5.40		4.50		5.40	
CREATININE	44-120 (UMOL/L)	01/03/92	54.00		70.00		49.00	
URIC ACID	0.19-0.43 (MMOL/L)	01/03/92						
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	7.00		7.00		8.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	4.00		2.00		2.00	
TOT. PROTEINS	62-82 (G/L)	01/03/92	70.00		84.00 >			
ALBUMINE	35-57 (G/L)	01/03/92	46.00		38.00			
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	5.00				4.60	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	0.62 <				0.87	
GLOBULINS ALPHA 1	1-5 (%)	01/03/92						
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92						
GLOBULINS BETA	11-16 (%)	01/03/92						
GLOBULINS GAMMA	()	01/03/92						
TSH	0.4-4 (MU/L)	01/03/92	0.30		0.30		0.80	
T4	8-25 (PMOL/L)	01/03/92	15.30		12.50		15.40	

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PHARMACIA CNS 530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 15 Patient: 373 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date
			Screen
			25/06/92
			value (⊕)
Laboratory test	Range value	Range date	
HB	11.5-16.5 (G/DL)	01/03/92	14.30
HT	0.35-0.49 (L/L)	01/03/92	0.43
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/03/92	4.74
MBC	4-11 (10 ³ /MM ³)	01/03/92	8.90
MBC: N	20-75 (%)	01/03/92	56.00
MBC: L	10-40 (%)	01/03/92	36.00
MBC: E	1-6 (%)	01/03/92	0.00 <
MBC: M	2-10 (%)	01/03/92	8.00
MBC: B	0-2 (%)	01/03/92	0.00
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	213.00
NA+	136-148 (MMOL/L)	01/03/92	143.00
K+	3.8-5 (MMOL/L)	01/03/92	4.20
CL-	97-106 (MMOL/L)	01/03/92	106.00
Ca++	2.25-2.75 (MMOL/L)	01/03/92	2.29
PO4--	0.6-1.8 (MMOL/L)	01/03/92	1.00
SGOT	5-31 (U/L)	01/03/92	19.00
SGPT	5-31 (U/L)	01/03/92	36.00 >
GAMMA GT	7-32 (U/L)	01/03/92	16.00
LDH	230-460 (U/L)	01/03/92	283.00
ALK. PHOSPH.	40-120 (U/L)	01/03/92	51.00
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	5.00
BUN	()	01/03/92	
UREA	2.5-6.6 (MMOL/L)	01/03/92	2.90
CREATININE	44-120 (UMOL/L)	01/03/92	78.00
URIC ACID	0.14-0.33 (MMOL/L)	01/03/92	
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	13.00
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	3.00
TOT. PROTEINS	62-82 (G/L)	01/03/92	84.00 >
ALBUMINE	35-57 (G/L)	01/03/92	40.00
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	4.10
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	0.85
GLOBULINS ALPHA 1	1-5 (%)	01/03/92	
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92	
GLOBULINS BETA	11-16 (%)	01/03/92	
GLOBULINS GAMMA	()	01/03/92	
TSH	0.4-4 (MU/L)	01/03/92	0.50
T4	8-25 (PMOL/L)	01/03/92	25.00

(⊕) << 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 380
9530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 15 Patient: 380 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			30/06/92		20/07/92	
			value	(€)	value	(€)
Laboratory test	Range value	Range date				
HB	11.5-16.5 (G/DL)	01/03/92	13.40		13.20	
HT	0.35-0.49 (L/L)	01/03/92	0.40		0.39	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/03/92	3.91		3.76 <	
WBC	4-11 (10 ³ /MM ³)	01/03/92	5.90		5.10	
WBC: N	20-75 (%)	01/03/92	33.00		46.00	
WBC: L	10-40 (%)	01/03/92	54.00 >>		36.00	
WBC: E	1-6 (%)	01/03/92			6.00	
WBC: M	2-10 (%)	01/03/92	8.00		11.00 >	
WBC: B	0-2 (%)	01/03/92			1.00	
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	195.00		389.00	
NA+	136-148 (MMOL/L)	01/03/92	137.00		143.00	
K+	3.8-5 (MMOL/L)	01/03/92	4.60		5.00	
CL-	97-106 (MMOL/L)	01/03/92	98.00		100.00	
Ca ⁺⁺	2.25-2.75 (MMOL/L)	01/03/92	1.94 <		2.00 <	
PO ₄ ⁻⁻	0.6-1.8 (MMOL/L)	01/03/92	1.00		1.40	
SGOT	5-31 (U/L)	01/03/92	47.00 >		35.00 >	
SGPT	5-31 (U/L)	01/03/92	59.00 >		49.00 >	
GAMMA GT	7-32 (U/L)	01/03/92	45.00 >		30.00	
LDH	230-460 (U/L)	01/03/92	305.00		294.00	
ALK. PHOSPH.	40-120 (U/L)	01/03/92	81.00		79.00	
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	7.00 >		4.10	
BUN	()	01/03/92				
UREA	2.5-6.6 (MMOL/L)	01/03/92	2.60		4.60	
CREATININE	44-120 (UMOL/L)	01/03/92	78.00		90.00	
URIC ACID	0.14-0.33 (MMOL/L)	01/03/92				
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	2.00 <		3.00 <	
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	2.00		2.00	
TOT. PROTEINS	62-82 (G/L)	01/03/92	105.00 >		122.00 >>	
ALBUMINE	35-57 (G/L)	01/03/92	29.00 <		32.00 <	
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	3.00 <		4.40	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	1.04		1.32	
GLOBULINS ALPHA 1	1-5 (%)	01/03/92				
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92				
GLOBULINS BETA	11-16 (%)	01/03/92				
GLOBULINS GAMMA	()	01/03/92				
TSH	0.4-4 (MU/L)	01/03/92	2.10			
T4	8-25 (PMOL/L)	01/03/92	23.30			

(€) << 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

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS 888
9530085

REBOXETINE - PROTOCOL 20124/017
Listing No.: 18.0

LABORATORY DATA

Centre: 15 Patient: 383 Treatment: Imipramine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 21		Day 42	
			07/07/92		28/07/92		18/08/92	
			value	(€)	value	(€)	value	(€)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/03/92	15.60		13.50		13.30	
HT	0.35-0.49 (L/L)	01/03/92	0.47		0.42		0.40	
RBC	3.9-5.6 (10 ⁶ /MM ³)	01/03/92	4.92		4.45		4.71	
WBC	4-11 (10 ³ /MM ³)	01/03/92	8.30		6.90		8.50	
WBC: N	20-75 (%)	01/03/92	58.00		58.00		44.00	
WBC: L	10-40 (%)	01/03/92	34.00		21.00		35.00	
WBC: E	1-6 (%)	01/03/92	2.00		8.00	>>	1.00	
WBC: M	2-10 (%)	01/03/92	4.00		15.00	>	20.00 >>	
WBC: B	0-2 (%)	01/03/92	2.00		0.00		0.00	
PLATELETS	140-400 (10 ³ /MM ³)	01/03/92	471.00 >		357.00		483.00 >	
NA+	136-148 (MMOL/L)	01/03/92	144.00		145.00		148.00	
K+	3.8-5 (MMOL/L)	01/03/92	4.60		4.50		4.20	
CL-	97-106 (MMOL/L)	01/03/92	100.00		101.00		100.00	
Ca++	2.25-2.75 (MMOL/L)	01/03/92	2.26		2.04	<	2.25	
PO4--	0.6-1.8 (MMOL/L)	01/03/92	1.00		1.20		1.49	
SGOT	5-31 (U/L)	01/03/92	19.00		18.00		16.00	
SGPT	5-31 (U/L)	01/03/92	25.00		17.00		13.00	
GAMMA GT	7-32 (U/L)	01/03/92	23.00		19.00		21.00	
LDH	230-460 (U/L)	01/03/92	350.00		386.00		353.00	
ALK. PHOSPH.	40-120 (U/L)	01/03/92	76.00		82.00		67.00	
GLUCOSE	3.3-6.1 (MMOL/L)	01/03/92	5.60		4.90		4.80	
BUH	()	01/03/92						
UREA	2.5-6.6 (MMOL/L)	01/03/92	2.40 <		3.40		2.70	
CREATININE	44-120 (UMOL/L)	01/03/92	84.00		75.00		61.50	
URIC ACID	0.14-0.33 (MMOL/L)	01/03/92						
TOT BILIRUBIN	5-20 (UMOL/L)	01/03/92	5.00		2.00	<	3.00 <	
DIR BILIRUBIN	0-5 (UMOL/L)	01/03/92	5.00		1.00		1.00	
TOT. PROTEINS	62-82 (G/L)	01/03/92	78.00		79.00		82.00	
ALBUMINE	35-57 (G/L)	01/03/92	37.00		37.00		39.00	
TOT. CHOLEST.	3.1-6.5 (MMOL/L)	01/03/92	5.90		6.00		6.80 >	
TRIGLYCERIDES	0.84-1.94 (MMOL/L)	01/03/92	2.21 >		1.79		1.23	
GLOBULINS ALPHA 1	1-5 (%)	01/03/92						
GLOBULINS ALPHA 2	4.5-9.5 (%)	01/03/92						
GLOBULINS BETA	11-16 (%)	01/03/92						
GLOBULINS GAMMA	()	01/03/92						
TSH	0.4-4 (MU/L)	01/03/92			0.80		1.40	
T4	8-25 (PMOL/L)	01/03/92			11.10		10.20	

(€) << 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

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PHARMACIA CNS RED
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 URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test						
					Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC
1	1	Reboxetine	Male	Evaluated	05/02/91	18/03/91	42	Screen Day 21 Day 42	05/02/91	1 Not done 22 Not done 43 Not done	Absent Absent Present	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	2	Reboxetine	Female	Evaluated	26/02/91	08/04/91	42	Screen Day 21 Day 42	26/02/91	1 Not done 22 Not done 43 Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	3	Imipramine	Female	Evaluated	16/04/91	27/05/91	42	Screen Day 21 Day 42	16/04/91	1 Not done 22 Not done 43 Not done	Absent Absent Present	Absent Absent Absent	Absent Absent Present	Absent Absent Present
	4	Imipramine	Male	Evaluated	17/04/91	28/05/91	42	Screen Day 21 Day 42	17/04/91	1 Not done 21 Not done 43 Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Present Absent
	5	Reboxetine	Female	Evaluated	17/07/91	27/08/91	42	Screen Day 21 Day 42	17/07/91	1 Not done 22 Not done 43 Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Absent Absent
	6	Imipramine	Male	Evaluated	07/08/91	17/09/91	42	Screen Day 21 Day 42	06/08/91	0 Not done 22 Not done 43 Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Absent Absent
	7	Reboxetine	Male	Evaluated	09/10/91	20/11/91	43	Screen Day 21 Day 42	08/10/91	0 Not done 22 Not done 44 Not done	Absent Absent Present	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	8	Imipramine	Male	Only screening	29/10/91	31/10/91	3	Screen	29/10/91	1 Not done	Absent	Absent	Absent	Absent
	9	Imipramine	Female	Evaluated	08/11/91	19/12/91	42	Screen Day 21 Day 42	06/11/91	0 Not done 21 Not done 42 Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Absent Present
	10	Imipramine	Female	Evaluated	19/11/91	30/12/91	42	Screen Day 21 Day 42	15/11/91	0 Not done 22 Not done 42 Not done	Absent Absent Present	Absent Present Present	Absent Present Present	Present Present Absent

(*) days of treatment

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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test						
										Specific gravity	Albumin	Sugar	RBC	MBC	(*)	(*)
1	11	Reboxetine	Male	Evaluated	06/04/92	03/05/92	28	Screen	03/04/92	0 Not done	Absent	Absent	Absent	Absent	Absent	
									28/04/92	23 Not done	Absent	Absent	Absent	Absent	Absent	
2	12	Reboxetine	Male	Evaluated	15/04/92	05/05/92	21	Screen	13/04/92	0 Not done	Present	Absent	Absent	Absent	Absent	
									05/05/92	21 Not done	Absent	Absent	Absent	Absent	Absent	
2	33	Reboxetine	Male	Evaluated	19/12/90	29/01/91	42	Screen	19/12/90	1 Normal	Absent	Absent	Absent	Absent	Absent	
									08/01/91	21 Normal	Absent	Absent	Absent	Absent	Absent	
2	34	Imipramine	Male	Evaluated	28/12/90	03/02/91	38	Screen	27/12/90	0 Normal	Absent	Absent	Absent	Absent	Absent	
									17/01/91	21 Not done	Not done	Not done	Not done	Not done	Not done	
2	35	Reboxetine	Male	Evaluated	28/12/90	07/02/91	42	Screen	28/12/90	1 Normal	Absent	Absent	Absent	Absent	Absent	
									07/02/91	42 Not done	Absent	Absent	Absent	Absent	Absent	
2	36	Imipramine	Female	Evaluated	10/01/91	31/01/91	22	Screen	09/01/91	0 Normal	Absent	Absent	Absent	Absent	Absent	
									30/01/91	21 Normal	Absent	Absent	Absent	Absent	Absent	
2	37	Reboxetine	Male	Evaluated	18/01/91	28/02/91	42	Screen	17/01/91	0 Normal	Absent	Absent	Absent	Absent	Absent	
									07/02/91	21 Not done	Not done	Not done	Not done	Not done	Not done	
2	38	Imipramine	Female	Without screen	25/01/91	07/03/91	42	Screen	25/01/91	1 Normal	Not done	Not done	Not done	Not done	Not done	
									14/02/91	21 Normal	Absent	Absent	Absent	Absent	Absent	
2	39	Reboxetine	Female	Without screen	25/01/91	07/03/91	42	Screen	24/01/91	0 Not done	Not done	Not done	Not done	Not done	Not done	
									16/02/91	21 Normal	Not done	Not done	Not done	Not done	Not done	
2	40	Imipramine	Male	Evaluated	20/02/91	02/04/91	42	Screen	20/02/91	1 Normal	Absent	Absent	Absent	Absent	Absent	
									19/03/91	28 Normal	Absent	Absent	Absent	Absent	Absent	
2	41	Reboxetine	Male	Without screen	05/02/91	18/03/91	42	Screen	04/02/91	0 Not done	Not done	Not done	Not done	Not done	Not done	
									18/03/91	42 Normal	Not done	Not done	Not done	Not done	Not done	

(*) days of treatment

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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test						
					Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC
2	41	Reboxetine	Male	Without screen	05/02/91	18/03/91	42	Day 21 Day 42	25/02/91 18/03/91	21 Normal 42 Not done	Absent Absent	Absent Absent	Absent Present	Absent Present
	42	Imipramine	Male	Evaluated	09/02/91	22/03/91	42	Screen Day 21 Day 42	08/02/91 01/03/91 22/03/91	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Absent Present
	43	Reboxetine	Female	Evaluated	26/03/91	06/05/91	42	Screen Day 21 Day 42	25/03/91 15/04/91 06/05/91	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Present Present
	44	Imipramine	Male	Only screening	11/04/91	11/04/91	1	Screen	10/04/91	0 Normal	Absent	Absent	Absent	Present
	45	Imipramine	Female	Only screening	30/04/91	03/05/91	4	Screen	29/04/91	0 Normal	Absent	Absent	Absent	Present
	46	Reboxetine	Female	Evaluated	16/05/91	26/06/91	42	Screen Day 21 Day 42	15/05/91 05/06/91 26/06/91	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Present Present	Absent Present Present
	47	Reboxetine	Female	Evaluated	22/05/91	02/07/91	42	Screen Day 21 Day 42	21/05/91 11/06/91 02/07/91	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Present Present
	48	Imipramine	Female	Evaluated	27/08/91	07/10/91	42	Screen Day 21 Day 42	26/08/91 16/09/91 07/10/91	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Present Present
	49	Imipramine	Female	Evaluated	29/08/91	09/10/91	42	Screen Day 21 Day 42	28/08/91 18/09/91 09/10/91	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Present Present	Absent Present Present
	50	Reboxetine	Male	Evaluated	06/11/91	15/12/91	40	Screen Day 21	04/11/91 26/11/91	0 Normal 21 Normal	Absent Absent	Absent Absent	Absent Present	Present Present
	51	Reboxetine	Female	Only screening	06/11/91	17/11/91	12	Screen	04/11/91	0 Normal	Absent	Absent	Present	
	52	Imipramine	Male	Evaluated	27/11/91	07/01/92	42	Screen	15/11/91	0 Normal	Absent	Absent	Present	

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(*) days of treatment

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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Assessment			Urinalysis test			
					Start date	End date	Days	Days	Date	Specific gravity	Albumin	Sugar	RBC	RBC
2	52	Imipramine	Male	Evaluated	27/11/91	07/01/92	42	Day 21 Day 42	17/12/91 07/01/92	21 Normal 42 Normal	Present Absent	Absent Absent	Absent Present	Present Present
3	65	Reboxetine	Male	Evaluated	02/04/91	13/05/91	42	Screen Day 21 Day 42	29/03/91 22/04/91 13/05/91	0 Not done 21 Not done 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	66	Imipramine	Female	Evaluated	01/05/91	05/06/91	36	Screen Day 21	27/04/91 23/05/91	0 Not done 23 Not done	Absent Absent	Absent Absent	Absent Absent	
	67	Reboxetine	Female	Evaluated	10/04/91	21/05/91	42	Screen Day 21 Day 42	05/04/91 30/04/91 23/05/91	0 Not done 21 Not done 44 Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	68	Imipramine	Female	Evaluated	03/08/91	13/09/91	42	Screen Day 21 Day 42	02/08/91 23/08/91 13/09/91	0 Not done 21 Not done 42 Not done	Absent Absent Absent	Absent Absent Absent	Absent Present Absent	
	69	Imipramine	Female	Evaluated	01/03/91	11/04/91	42	Screen Day 21 Day 42	01/03/91 22/03/91 11/04/91	1 Not done 22 Not done 42 Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	70	Reboxetine	Female	Evaluated	23/10/91	19/11/91	28	Screen Day 21	22/10/91 12/11/91	0 Not done 21 Not done	Absent Absent	Absent Present	Absent Present	
	71	Imipramine	Female	Evaluated	14/11/91	25/12/91	42	Screen Day 21 Day 42	12/11/91 04/12/91 25/12/91	0 Not done 21 Not done 42 Not done	Absent Absent Absent	Absent Absent Absent	Present Absent Present	
	72	Reboxetine	Female	Evaluated	31/01/92	12/03/92	42	Screen Day 21 Day 42	28/01/92 21/02/92 13/03/92	0 Not done 22 Not done 43 Not done	Absent Absent Absent	Absent Absent Absent	Present Present Present	
	73	Reboxetine	Female	Evaluated	15/02/92	27/03/92	42	Screen Day 21 Day 42	11/02/92 06/03/92 27/03/92	0 Not done 21 Not done 42 Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
4	97	Imipramine	Male	Evaluated	07/05/92	18/06/92	43	Screen	06/05/92	0 Not done	Absent	Absent	Present	

(*) days of treatment

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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	97	Imipramine	Male	Evaluated	07/05/92	18/06/92	43	Day 21	27/05/92	21 Normal	Absent	Absent	Absent	Absent	Absent
								Day 42	17/06/92	42 Not done	Absent	Absent	Absent	Absent	
100	Reboxetine	Female	Evaluated	07/05/92	24/06/92	49	Screen	01/05/92	0 Normal	Absent	Absent	Absent	Present	Present	
							Day 21	27/05/92	21 Normal	Absent	Absent	Absent	Absent		
101	Imipramine	Female	Evaluated	06/05/91	22/05/91	17	Screen	06/05/91	1 Not done	Present	Absent	Present	Present		
							Day 21	23/05/91	18 Not done	Absent	Absent	Present	Present		
6	161	Reboxetine	Male	Evaluated	29/03/91	09/05/91	42	Screen	27/03/91	0 Normal	Absent	Absent	Absent	Absent	
								Day 21	18/04/91	21 Normal	Absent	Absent	Absent	Absent	
162	Reboxetine	Female	Evaluated	05/11/91	16/12/91	42	Screen	04/11/91	0 Normal	Absent	Absent	Absent	Present		
							Day 21	25/11/91	21 Normal	Absent	Absent	Absent	Absent		
193	Reboxetine	Female	Without Urinal	11/06/91	17/06/91	7	Screen	04/04/91	0 Not done	Not done	Not done	Not done	Not done		
							Screen	31/05/91	0 Not done	Absent	Absent	Present	Present		
196	Imipramine	Female	Evaluated	19/03/91	26/04/91	39	Screen	18/03/91	0 Not done	Absent	Absent	Absent	Present		
							Day 21	06/04/91	19 Not done	Not done	Not done	Present	Present		
225	Imipramine	Female	Without Urinal	22/03/91	09/04/91	19	Screen	04/05/91	47 Not done	Absent	Absent	Present	Present		
							Screen	22/03/91	1 Not done	Not done	Not done	Not done	Not done		
226	Reboxetine	Female	Evaluated	03/05/91	13/06/91	42	Screen	02/05/91	0 Not done	Absent	Absent	Absent	Present		
							Day 21	24/05/91	22 Not done	Not done	Not done	Not done	Not done		
227	Imipramine	Male	Evaluated	07/05/91	17/06/91	42	Screen	14/06/91	43 Not done	Absent	Absent	Absent	Present		
							Day 21	03/05/91	0 Not done	Not done	Not done	Absent	Absent		
228	Reboxetine	Male	Without Urinal	10/05/91	17/05/91	8	Screen	29/05/91	23 Not done	Absent	Absent	Absent	Not done		
							Day 42	18/06/91	43 Not done	Not done	Not done	Absent	Absent		

(*) days of treatment

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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	229	Imipramine	Female	Evaluated	22/10/91	02/12/91	42	Screen	22/10/91	1 Normal	Absent	Absent	Absent	Absent	Absent	Absent			
								Day 21	12/11/91	22 Not done	Not done	Absent	Absent	Absent	Absent				
	230	Imipramine	Female	Evaluated	05/11/91	16/12/91	42	Screen	04/11/91	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent			
								Day 21	26/11/91	22 Not done	Absent	Absent	Absent	Absent	Absent				
9	231	Reboxetine	Female	Only screening	05/11/91	13/11/91	9	Screen	29/10/91	0 Not done	Absent	Absent	Absent	Absent	Absent	Absent			
								Day 21	27/11/91	0 Not done	Absent	Absent	Absent	Absent	Absent	Absent			
	232	Reboxetine	Male	Only screening	29/11/91	09/01/92	42	Screen	20/12/91	22 Not done	Not done	Not done	Not done	Not done	Not done	Not done			
								Day 42	08/01/92	41 Not done	Not done	Not done	Not done	Not done	Not done				
197	Reboxetine	Male	Evaluated	07/03/92	10/03/92	4	Screen	27/02/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent			
							Day 7	17/03/92	11 Normal	Absent	Absent	Absent	Absent	Absent	Absent				
	198	Imipramine	Female	Evaluated	18/03/92	28/04/92	42	Screen	10/03/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent			
								Day 21	07/04/92	21 Normal	Absent	Absent	Absent	Absent	Absent	Absent			
199	Imipramine	Male	Evaluated	02/04/92	13/05/92	42	Screen	28/04/92	42 Not done	Not done	Not done	Not done	Not done	Not done	Not done				
							Day 21	30/03/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent				
200	Reboxetine	Male	Evaluated	28/04/92	08/06/92	42	Screen	21/04/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent			
							Day 21	18/05/92	21 Not done	Absent	Absent	Absent	Absent	Absent	Absent				
	201	Imipramine	Female	Evaluated	16/01/92	26/02/92	42	Screen	07/01/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent			
								Day 21	05/02/92	21 Normal	Absent	Absent	Absent	Absent	Absent	Absent			
202	Imipramine	Male	Evaluated	17/01/92	27/02/92	42	Screen	09/01/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent				
							Day 21	06/02/92	21 Normal	Absent	Absent	Absent	Absent	Absent	Absent				

(*) days of treatment

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Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test			
										Specific gravity	Albumin	Sugar	MBC
9	203	Reboxetine	Female	Evaluated	15/01/92	18/01/92	4	Screen Day 7	10/01/92 28/01/92	0 Normal 14 Normal	Absent Absent	Absent Absent	Absent Absent
	204	Reboxetine	Male	Without screen	17/01/92	28/02/92	43	Screen Day 21 Day 42	09/01/92 06/02/92 28/02/92	0 Not done 21 Normal 43 Normal	Not done Absent Absent	Not done Absent Absent	Not done Absent Absent
	205	Imipramine	Female	Only screening	05/02/92	07/02/92	3	Screen	27/01/92	0 Normal	Absent	Absent	Absent
	206	Imipramine	Female	Evaluated	05/02/92	18/03/92	43	Screen Day 21 Day 42	28/01/92 28/02/92 18/03/92	0 Normal 22 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Present Absent Absent
	207	Reboxetine	Female	Only screening	06/02/92	12/02/92	7	Screen	27/01/92	0 Normal	Absent	Absent	Absent
	208	Reboxetine	Male	Evaluated	15/02/92	27/03/92	42	Screen Day 21 Day 42	10/02/92 06/03/92 30/03/92	0 Normal 21 Normal 45 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	209	Imipramine	Male	Only screening	12/02/92	15/02/92	4	Screen	04/02/92	0 Normal	Absent	Absent	Absent
	210	Reboxetine	Female	Evaluated	20/02/92	01/04/92	42	Screen Day 21 Day 42	05/02/92 11/03/92 01/04/92	0 Not done 21 Not done 42 Normal	Present Absent Absent	Present Present Present	Present Present Present
	211	Reboxetine	Female	Evaluated	14/02/92	02/03/92	18	Screen Day 21	11/02/92 03/03/92	0 Normal 19 Normal	Absent Absent	Absent Absent	Present Absent
	212	Imipramine	Female	Evaluated	04/03/92	14/04/92	42	Screen Day 21 Day 42	25/02/92 24/03/92 14/04/92	0 Not done 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Present Absent Absent
	237	Reboxetine	Male	Evaluated	23/04/92	02/05/92	10	Screen Day 14	15/04/92 06/05/92	0 Not done 14 Not done	Absent Absent	Absent Absent	Absent Present
	238	Imipramine	Female	Evaluated	20/05/92	30/06/92	42	Screen Day 21	12/05/92 09/06/92	0 Not done 21 Not done	Absent Not done	Absent Not done	Absent Not done

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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Days	Assessment	Date (*)	Urinalysis test					
					Start date	End date	End date				Specific gravity	Albumin	Sugar	RBC	HBC	
9	238	Imipramine	Female	Evaluated	20/05/92	30/06/92	30/06/92	42	Day 42	30/06/92	42	Not done	Not done	Absent	Absent	Absent
	239	Imipramine	Male	Evaluated	30/04/92	10/06/92	10/06/92	42	Screen Day 21	22/04/92	0	Not done	Absent	Absent	Absent	Absent
	240	Reboxetine	Female	Only screening	28/04/92	16/05/92	16/05/92	19	Screen	10/06/92	42	Not done	Absent	Absent	Absent	Absent
	241	Imipramine	Female	Without Urinal	09/05/92	19/06/92	19/06/92	42	Screen Day 21	06/05/92	0	Not done	Not done	Not done	Not done	Not done
	242	Reboxetine	Male	Evaluated	07/05/92	17/06/92	17/06/92	42	Screen Day 21	29/05/92	21	Not done	Not done	Not done	Not done	Not done
	243	Imipramine	Female	Evaluated	18/05/92	28/06/92	28/06/92	42	Screen Day 21	17/06/92	42	Normal	Present	Absent	Present	Absent
	244	Reboxetine	Male	Only screening	06/06/92	17/07/92	17/07/92	42	Screen Day 21	27/05/92	21	Not done	Absent	Present	Absent	Absent
	257	Reboxetine	Female	Evaluated	17/07/91	27/08/91	27/08/91	42	Screen Day 21	11/05/92	0	Not done	Absent	Absent	Absent	Absent
	258	Reboxetine	Male	Only screening	17/07/91	06/08/91	06/08/91	21	Screen Day 21	08/06/92	22	Not done	Not done	Not done	Not done	Not done
	259	Imipramine	Female	Evaluated	17/07/91	27/08/91	27/08/91	42	Screen Day 21	26/06/92	21	Not done	Not done	Not done	Not done	Not done
	260	Imipramine	Female	Without screen	24/07/91	12/08/91	12/08/91	20	Screen Day 21	16/07/92	41	Not done	Not done	Not done	Not done	Not done

(*) days of treatment

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 19.0
URINALYSIS

Centro	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test		
										Specific gravity	Albumin	Sugar
9	261	Imipramine	Female	Without Urinal	23/07/91	29/07/91	7	Screen Day 7	19/07/91 30/07/91	0 Not done 8 Not done	Not done Not done	Not done Not done
	262	Reboxetine	Male	Evaluated	23/07/91	03/09/91	43	Screen Day 21 Day 42	16/07/91 13/08/91 03/09/91	0 Not done 22 Not done 43 Not done	Absent Absent Present	Absent Absent Absent
	263	Reboxetine	Female	Without screen	31/07/91	13/08/91	14	Screen Day 14	24/07/91 14/08/91	0 Not done 15 Not done	Not done Absent	Not done Present
	264	Imipramine	Female	Evaluated	31/07/91	10/09/91	42	Screen Day 21 Day 42	24/07/91 21/08/91 11/09/91	0 Not done 22 Not done 43 Not done	Absent Absent Absent	Present Absent Present
	265	Reboxetine	Female	Evaluated	23/08/91	03/10/91	42	Screen Day 21 Day 42	13/08/91 12/09/91 03/10/91	0 Not done 21 Not done 42 Not done	Absent Absent Present	Present Present Present
	266	Reboxetine	Female	Evaluated	18/09/91	29/10/91	42	Screen Day 21 Day 42	10/09/91 08/10/91 28/10/91	0 Not done 21 Not done 41 Not done	Absent Absent Not done	Present Present Not done
	267	Imipramine	Male	Evaluated	02/09/91	13/10/91	42	Screen Day 21 Day 42	30/08/91 23/09/91 14/10/91	0 Not done 22 Not done 43 Not done	Absent Present Absent	Absent Present Absent
	268	Imipramine	Female	Evaluated	25/09/91	05/11/91	42	Screen Day 21 Day 42	17/09/91 15/10/91 05/11/91	0 Not done 21 Not done 42 Not done	Absent Absent Absent	Absent Absent Absent
	269	Reboxetine	Male	Evaluated	25/09/91	05/11/91	42	Screen Day 21 Day 42	19/09/91 15/10/91 05/11/91	0 Not done 21 Not done 42 Normal	Absent Absent Absent	Absent Absent Absent
	270	Imipramine	Female	Only screening	11/10/91	17/10/91	7	Screen	02/10/91	0 Not done	Absent	Absent

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(*) days of treatment

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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						
9	271	Reboxetine	Female	Evaluated	30/10/91	20/11/91	22	Screen Day 21	22/10/91	19/11/91	0	Not done	Absent	Absent	Absent	Absent	Absent	Absent	Present	Absent	
	272	Imipramine	Male	Evaluated	30/10/91	10/12/91	42	Screen Day 21 Day 42	22/10/91	19/11/91	0	Not done	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	
	273	Imipramine	Female	Evaluated	30/10/91	20/11/91	22	Screen Day 21	24/10/91	19/11/91	0	Not done	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Present	Absent
	274	Reboxetine	Female	Evaluated	31/10/91	31/10/91	1	Screen Day 7	23/10/91	06/11/91	0	Not done	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Present
	274/A	Reboxetine	Female	Only screening	13/05/92	23/06/92	42	Screen Day 21 Day 42	21/04/92	02/06/92	0	Not done	Absent	Absent	Absent	Absent	Absent	Absent	Present	Present	Not done
	275	Reboxetine	Female	Evaluated	06/11/91	17/12/91	42	Screen Day 21 Day 42	26/11/91	18/12/91	0	Not done	Absent	Absent	Absent	Absent	Absent	Absent	Present	Present	Not done
	276	Imipramine	Female	Evaluated	14/01/92	14/01/92	1	Screen Day 7	24/12/91	16/01/92	0	Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
	276/A	Imipramine	Male	Evaluated	04/03/92	14/04/92	42	Screen Day 21 Day 42	24/02/92	24/03/92	0	Not done	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
9/A	233	Imipramine	Male	Evaluated	14/05/92	24/06/92	42	Screen Day 21 Day 42	13/05/92	03/06/92	0	Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
	234	Reboxetine	Female	Evaluated	22/05/92	02/07/92	42	Screen Day 21 Day 42	11/06/92	02/07/92	0	Not done	Absent	Absent	Absent	Absent	Absent	Absent	Present	Present	Absent
	235	Reboxetine	Male	Only screening	26/05/92	29/06/92	35	Screen Day 21	22/05/92	16/06/92	0	Normal	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Not done

(*) days of treatment

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PHARMACIA CNS R&D
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 URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test								
					Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC	
9/A	236	Imipramine	Male	Evaluated	27/05/92	07/07/92	42	Screen Day 21	12/05/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent
								Day 42	16/06/92	21 Normal	Absent	Absent	Absent	Absent	Absent	Absent
									07/07/92	42 Normal	Absent	Absent	Absent	Absent	Absent	Absent
	277	Reboxetine	Female	Only screening	10/06/92	14/06/92	5	Screen	11/06/92	2 Normal	Absent	Absent	Absent	Absent	Absent	Absent
	278	Imipramine	Female	Evaluated	13/06/92	03/07/92	21	Screen Day 21	12/06/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent
									03/07/92	21 Normal	Absent	Absent	Absent	Present	Present	Present
	279	Imipramine	Male	Only screening	07/08/92	21/08/92	15	Screen	05/08/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent
	280	Reboxetine	Female	Only screening	08/08/92	14/08/92	7	Screen	07/08/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent
	281	Reboxetine	Female	Evaluated	01/09/92	12/10/92	42	Screen Day 21	25/08/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent
								Day 42	21/09/92	21 Normal	Absent	Absent	Absent	Absent	Present	Present
									12/10/92	42 Normal	Absent	Absent	Absent	Absent	Present	Present
	282	Reboxetine	Male	Evaluated	02/09/92	13/10/92	42	Screen Day 21	01/09/92	0 Normal	Absent	Absent	Absent	Absent	Present	Present
								Day 42	22/09/92	21 Normal	Absent	Absent	Absent	Absent	Absent	Absent
									13/10/92	42 Not done	Not done	Not done	Not done	Not done	Not done	Not done
	283	Imipramine	Female	Evaluated	16/09/92	28/10/92	43	Screen Day 21	11/09/92	0 Normal	Absent	Absent	Absent	Absent	Absent	Absent
								Day 42	07/10/92	22 Normal	Absent	Absent	Absent	Absent	Absent	Absent
									28/10/92	43 Not done	Absent	Absent	Absent	Absent	Absent	Absent
	284	Imipramine	Male	Evaluated	19/09/92	09/10/92	21	Screen Day 21	16/09/92	0 Not done	Absent	Absent	Absent	Absent	Absent	Absent
									09/10/92	21 Not done	Absent	Absent	Absent	Absent	Absent	Absent
	301	Imipramine	Female	Evaluated	05/03/92	15/04/92	42	Screen Day 21	28/02/92	0 Not done	Absent	Absent	Absent	Absent	Present	Present
								Day 42	25/03/92	21 Normal	Absent	Absent	Absent	Absent	Present	Present
									15/04/92	42 Normal	Absent	Absent	Absent	Absent	Absent	Absent
	302	Imipramine	Male	Only screening	06/03/92	22/03/92	17	Screen Day 21	02/03/92	0 Not done	Absent	Absent	Absent	Absent	Absent	Absent
									23/03/92	18 Not done	Not done	Not done	Not done	Not done	Not done	Not done

(*) days of treatment

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PHARMACIA CNS RSD
 REBOXETINE - PROTOCOL 20124/017
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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Days	Assessment	Date (*)	Urinalysis test				
					Start date	End date	End date				Specific gravity	Albumin	Sugar	RBC	WBC
9/A	303	Reboxetine	Female	Evaluated	12/03/92	31/03/92	20	Screen Day 21	06/03/92 31/03/92	0 Not done 20 Normal	Absent Absent	Absent Absent	Absent Absent	Present Present	Present Present
	304	Reboxetine	Female	Evaluated	26/03/92	06/05/92	42	Screen Day 21 Day 42	12/03/92 15/04/92 06/05/92	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	305	Reboxetine	Male	Evaluated	31/03/92	11/05/92	42	Screen Day 21 Day 42	25/03/92 20/04/92 11/05/92	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	306	Reboxetine	Female	Evaluated	29/04/92	09/06/92	42	Screen Day 21 Day 42	28/04/92 19/05/92 09/06/92	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Present Absent	Absent Absent Absent
	307	Imipramine	Female	Only screening	05/05/92	08/05/92	4	Screen	05/05/92	1 Normal	Absent	Absent	Absent	Absent	Absent
	308	Imipramine	Female	Evaluated	09/05/92	02/06/92	25	Screen Day 21	09/05/92 29/05/92	1 Normal 21 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Present Present
10	289	Imipramine	Female	Only screening	21/09/91	27/09/91	7	Screen	23/09/91	3 Normal	Absent	Absent	Absent	Absent	Absent
	290	Reboxetine	Male	Evaluated	14/10/91	24/11/91	42	Screen Day 21 Day 42	07/10/91 04/11/91 25/11/91	0 Normal 22 Not done 43 Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Absent Absent	Present Absent Absent
	291	Imipramine	Male	Evaluated	17/02/92	29/03/92	42	Screen Day 21 Day 42	13/02/92 09/03/92 30/03/92	0 Normal 22 Not done 43 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present
	292	Reboxetine	Female	Evaluated	13/12/91	23/01/92	42	Screen Day 21 Day 42	06/12/91 03/01/92 25/01/92	0 Normal 22 Normal 44 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Absent Absent
	293	Reboxetine	Female	Evaluated	24/12/91	01/02/92	40	Screen Day 21 Day 42	16/12/91 14/01/92 04/02/92	0 Not done 22 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Absent Absent

(*) days of treatment

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 URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period		Days	Assessment	Date	Urinalysis test					
					Start date	End date				Specific gravity	Albumin	Sugar	RBC	MBC	
10	294	Imipramine	Female	Only screening	03/01/92	23/01/92	21	Screen Day 21	07/01/92 23/01/92	5 Normal 21 Not done	Absent Not done	Absent Not done	Present	Absent	Not done
	295	Imipramine	Male	Evaluated	07/01/92	17/02/92	42	Screen Day 21 Day 42	02/01/92 27/01/92 24/02/92	0 Normal 21 Normal 49 Normal	Absent Absent Absent	Absent Absent Absent	Absent	Present	Present
	296	Reboxetine	Female	Evaluated	20/02/92	01/04/92	42	Screen Day 21 Day 42	15/02/92 12/03/92 02/04/92	0 Normal 22 Not done 43 Normal	Absent Absent Absent	Absent Absent Absent	Absent	Absent	Absent
	297	Reboxetine	Male	Evaluated	21/03/92	02/05/92	43	Screen Day 21 Day 42	19/03/92 10/04/92 01/05/92	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent	Present	Present
	298	Reboxetine	Female	Evaluated	27/03/92	07/05/92	42	Screen Day 21 Day 42	19/03/92 16/04/92 11/05/92	0 Normal 21 Normal 46 Normal	Absent Absent Absent	Absent Absent Absent	Absent	Absent	Present
	299	Imipramine	Male	Evaluated	07/04/92	18/05/92	42	Screen Day 21 Day 42	02/04/92 28/04/92 19/05/92	0 Not done 22 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Absent	Absent	Absent
	300	Imipramine	Female	Without screen	14/04/92	25/05/92	42	Screen Day 21 Day 42	07/04/92 05/05/92 26/05/92	0 Not done 22 Normal 43 Normal	Not done Absent Absent	Not done Absent Absent	Not done	Absent	Absent
11	321	Reboxetine	Female	Evaluated	11/06/92	23/07/92	43	Screen Day 21 Day 42	11/06/92 02/07/92 22/07/92	1 Normal 22 Not done 42 Normal	Present Not done Absent	Absent Not done Absent	Absent	Present	Absent
	322	Reboxetine	Female	Evaluated	11/06/92	24/07/92	44	Screen Day 21 Day 42	08/06/92 03/07/92 27/07/92	0 Normal 23 Normal 47 Normal	Absent Absent Absent	Absent Absent Absent	Absent	Absent	Present
	323	Imipramine	Female	Evaluated	24/06/92	06/08/92	44	Screen Day 21	18/06/92 15/07/92	0 Normal 22 Normal	Absent Absent	Absent Absent	Absent	Absent	Absent

(*): days of treatment

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PHARMACIA CNS R&D
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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test					
										Specific gravity	Albumin	Sugar	RBC		
11	323	Imipramine	Female	Evaluated	24/06/92	06/08/92	44	Day 42	06/08/92	44	Normal	Absent	Absent	Absent	Absent
	324	Imipramine	Male	Evaluated	17/07/92	28/08/92	43	Screen Day 21 Day 42	17/07/92 07/08/92 28/08/92	1 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Present Absent Absent	
	325	Reboxetine	Female	Evaluated	30/07/92	10/09/92	43	Screen Day 21 Day 42	24/07/92 21/08/92 11/09/92	0 23 44	Normal Normal Normal	Absent Absent Present	Absent Present Absent	Present Present Absent	
	326	Imipramine	Male	Evaluated	30/07/92	10/09/92	43	Screen Day 21 Day 42	30/07/92 20/08/92 10/09/92	1 22 43	Normal Normal Normal	Absent Absent Present	Absent Absent Absent	Present Absent Absent	
	327	Reboxetine	Female	Evaluated	20/08/92	01/10/92	43	Screen Day 21 Day 42	18/08/92 09/09/92 01/10/92	0 21 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Present Absent Absent	
	328	Imipramine	Male	Evaluated	20/08/92	17/09/92	29	Screen Day 21 Day 28	19/08/92 18/09/92 18/09/92	0 22 30	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Present Absent Absent	
	329	Imipramine	Female	Evaluated	21/08/92	02/10/92	43	Screen Day 21 Day 42	18/08/92 11/09/92 02/10/92	0 22 43	Normal Normal Normal	Absent Present Absent	Absent Absent Absent	Present Absent Absent	
	330	Reboxetine	Female	Evaluated	24/08/92	26/08/92	3	Screen Day 7	22/08/92 31/08/92	0 8	Normal Not done	Absent Not done	Absent Not done	Present Present	
	331	Reboxetine	Male	Evaluated	03/09/92	15/10/92	43	Screen Day 21 Day 42	01/09/92 24/09/92 15/10/92	0 22 43	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Present Present Present	
	332	Imipramine	Female	Evaluated	05/09/92	20/10/92	46	Screen Day 21 Day 42	03/09/92 28/09/92 15/10/92	0 24 41	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	333	Imipramine	Female	Evaluated	04/09/92	16/10/92	43	Screen	04/09/92	1	Normal	Absent	Absent	Absent	Present

(*): days of treatment

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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test			
										Specific Gravity	Albumin	Sugar	RBC
11	333	Imipramine	Female	Evaluated	04/09/92	16/10/92	43	Day 21 Day 42	25/09/92 16/10/92	22 Normal 43 Normal	Present Absent	Present Absent	Present Present
12	337	Imipramine	Female	Evaluated	26/05/92	06/07/92	42	Screen Day 21 Day 42	11/05/92 15/05/92 06/07/92	0 Not done 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
13	338	Reboxetine	Female	Evaluated	20/06/92	31/07/92	42	Screen Day 21 Day 42	15/06/92 10/07/92 31/07/92	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Present Absent
	339	Imipramine	Male	Evaluated	23/06/92	03/08/92	42	Screen Day 21 Day 42	02/06/92 13/07/92 03/08/92	0 Not done 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Present Present Present
	340	Reboxetine	Female	Evaluated	07/08/92	17/09/92	42	Screen Day 21 Day 42	04/08/92 27/08/92 17/09/92	0 Normal 21 Normal 42 Not done	Absent Absent Present	Absent Absent Absent	Absent Absent Absent
	341	Reboxetine	Female	Evaluated	21/08/92	24/09/92	35	Screen Day 21	18/08/92 10/09/92	0 Not done 21 Normal	Absent Absent	Absent Absent	Absent Present
	353	Reboxetine	Female	Without Urinal	05/06/92	07/07/92	33	Screen Day 21	05/06/92 29/06/92	1 Not done 25 Not done	Absent Absent	Absent Absent	Not done Not done
	354	Imipramine	Female	Without screen	24/06/92	04/08/92	42	Screen Day 21 Day 42	24/06/92 15/07/92 12/08/92	1 Not done 22 Not done 50 Normal	Absent Absent Absent	Absent Absent Absent	Not done Not done Absent
	355	Reboxetine	Female	Only screening	25/06/92	27/06/92	3	Screen	17/06/92	0 Not done	Present	Absent	Absent
	356	Imipramine	Male	Without Urinal	22/07/92	01/09/92	42	Screen Day 21 Day 42	22/07/92 12/08/92 02/09/92	1 Normal 22 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Not done Not done Not done
	357	Imipramine	Female	Without Urinal	05/08/92	09/08/92	5	Screen	05/08/92	1 Not done	Absent	Absent	Not done

(*) days of treatment

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Centre	Patient	Treatment	Sex	Patient type	Treatment period			Assessment	Date	(*)	Urinalysis test				
					Start date	End date	Days				Specific gravity	Albumin	Sugar	RBC	MBC
13	358	Reboxetine	Male	Evaluated	06/08/92	05/09/92	31	Screen	06/08/92	1	Absent	Absent	Absent	Absent	Absent
								Day 21	27/08/92	22	Normal	Absent	Absent	Absent	Absent
								Day 42							
359	Reboxetine	Female	Evaluated	19/08/92	29/09/92	42	Screen	19/08/92	1	Absent	Absent	Absent	Absent	Absent	
							Day 21	09/09/92	22	Normal	Absent	Absent	Absent	Absent	
							Day 42	30/09/92	43	Normal	Absent	Absent	Absent	Not done	
360	Imipramine	Female	Without Urinal	19/08/92	21/08/92	3	Screen	19/08/92	1	Not done	Absent	Absent	Absent	Not done	
361	Reboxetine	Female	Without screen	26/08/92	06/10/92	42	Screen	26/08/92	1	Normal	Absent	Absent	Absent	Not done	
							Day 21	16/09/92	22	Normal	Absent	Absent	Absent	Not done	
							Day 42	07/10/92	43	Not done	Absent	Absent	Absent	Absent	
14	457	Reboxetine	Female	Evaluated	07/07/92	17/08/92	42	Screen	07/07/92	1	Normal	Absent	Absent	Absent	Absent
								Day 21	28/07/92	22	Normal	Absent	Absent	Absent	Absent
								Day 42	18/08/92	43	Normal	Absent	Absent	Absent	Absent
458	Imipramine	Female	Evaluated	14/07/92	24/08/92	42	Screen	10/07/92	0	Normal	Absent	Absent	Absent	Absent	
							Day 21	04/08/92	22	Normal	Absent	Absent	Absent	Absent	
							Day 42	25/08/92	43	Normal	Absent	Absent	Absent	Absent	
459	Reboxetine	Male	Evaluated	16/07/92	26/08/92	42	Screen	13/07/92	0	Normal	Absent	Absent	Absent	Absent	
							Day 21	06/08/92	22	Normal	Absent	Absent	Absent	Absent	
							Day 42	27/08/92	43	Normal	Absent	Absent	Absent	Absent	
460	Imipramine	Male	Evaluated	23/07/92	02/09/92	42	Screen	20/07/92	0	Normal	Absent	Absent	Absent	Absent	
							Day 21	13/08/92	22	Normal	Absent	Absent	Absent	Absent	
							Day 42	03/09/92	43	Normal	Absent	Absent	Absent	Absent	
461	Imipramine	Female	Evaluated	29/07/92	08/09/92	42	Screen	22/07/92	0	Normal	Absent	Absent	Absent	Absent	
							Day 21	19/08/92	22	Normal	Absent	Absent	Absent	Absent	
							Day 42	09/09/92	43	Normal	Absent	Absent	Absent	Absent	
462	Reboxetine	Female	Evaluated	31/07/92	10/09/92	42	Screen	24/07/92	0	Normal	Absent	Absent	Absent	Absent	
							Day 21	21/08/92	22	Normal	Absent	Absent	Absent	Absent	
							Day 42	11/09/92	43	Normal	Absent	Absent	Absent	Absent	
463	Imipramine	Male	Evaluated	03/08/92	13/09/92	42	Screen	27/07/92	0	Normal	Absent	Absent	Absent	Absent	

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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test								
					Start date	End date	Days	Assessment	Date	(*) Gravity	Albumin	Sugar	RBC	MBC		
14	463	Imipramine	Male	Evaluated	03/08/92	13/09/92	42	Day 21 Day 42	24/08/92 14/09/92	22 Normal 43 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent	
	464	Reboxetine	Female	Evaluated	05/08/92	16/09/92	43	Screen Day 21 Day 42	29/07/92 27/08/92 17/09/92	0 Normal 23 Normal 44 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	465	Reboxetine	Male	Evaluated	06/08/92	16/09/92	42	Screen Day 21 Day 42	30/07/92 27/08/92 17/09/92	0 Normal 22 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	466	Imipramine	Female	Evaluated	07/08/92	17/09/92	42	Screen Day 21 Day 42	31/07/92 28/08/92 18/09/92	0 Normal 22 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
14/1	429	Reboxetine	Male	Only screening	19/12/91	19/12/91	1	Screen	11/12/91	0 Not done	Absent	Absent	Absent	Absent	Absent	
14/2	426	Reboxetine	Female	Evaluated	05/09/91	17/10/91	43	Screen Day 21 Day 42	29/08/91 24/09/91 17/10/91	0 Not done 20 Not done 43 Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	429	Imipramine	Female	Only screening	26/09/91	29/09/91	4	Screen	18/09/91	0 Not done	Absent	Absent	Absent	Absent	Absent	Absent
	451	Imipramine	Male	Evaluated	28/11/91	07/01/92	41	Screen Day 21 Day 42	14/11/91 19/12/91 08/01/92	0 Not done 22 Not done 42 Not done	Absent Absent Absent	Present Absent Present	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
14/2	452	Reboxetine	Female	Evaluated	28/11/91	09/01/92	43	Screen Day 21 Day 42	26/11/91 19/12/91 09/01/92	0 Not done 22 Not done 43 Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	456	Imipramine	Female	Evaluated	15/01/92	25/02/92	42	Screen Day 21 Day 42	08/01/92 11/02/92 25/02/92	0 Not done 28 Not done 42 Not done	Absent Not done Absent	Absent Not done Absent	Absent Not done Absent	Absent Not done Absent	Absent Not done Absent	Absent Not done Absent
	456	Imipramine	Male	Evaluated	15/04/92	26/05/92	42	Screen Day 21 Day 42	09/04/92 07/05/92 29/05/92	0 Not done 23 Not done 45 Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent

(*) days of treatment

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	WBC
14/3	417	Reboxetine	Female	Evaluated	14/06/91	26/07/91	43	Screen	07/06/91	0 Normal	Absent	Absent	Absent	Absent
								Day 21	05/07/91	22 Normal	Absent	Absent	Absent	Absent
								Day 42	26/07/91	43 Normal	Absent	Absent	Absent	Absent
418	418	Imipramine	Female	Evaluated	18/06/91	29/07/91	42	Screen	10/06/91	0 Normal	Absent	Absent	Absent	
							Day 21	08/07/91	21 Normal	Absent	Absent	Absent	Absent	
							Day 42	29/07/91	42 Normal	Absent	Absent	Absent	Absent	
419	419	Reboxetine	Female	Evaluated	05/07/91	15/08/91	42	Screen	03/07/91	0 Normal	Absent	Absent	Absent	
							Day 21	25/07/91	21 Normal	Absent	Absent	Absent	Absent	
							Day 42	15/08/91	42 Normal	Absent	Absent	Absent	Absent	
420	420	Imipramine	Female	Only screening	05/07/91	25/07/91	21	Screen	04/07/91	0 Normal	Absent	Absent	Absent	
							Day 21	19/08/91	46 Not done	Not done	Not done	Not done	Not done	
421	421	Reboxetine	Female	Evaluated	19/07/91	12/09/91	56	Screen	11/07/91	0 Normal	Absent	Absent	Absent	
							Day 21	08/08/91	21 Normal	Absent	Absent	Absent	Absent	
							Day 42	22/08/91	35 Normal	Absent	Absent	Absent	Absent	
427	427	Imipramine	Female	Evaluated	18/09/91	15/10/91	28	Screen	18/09/91	1 Normal	Absent	Absent	Absent	
							Day 21	09/10/91	22 Normal	Absent	Absent	Absent	Absent	
428	428	Imipramine	Female	Evaluated	25/10/91	05/12/91	42	Screen	25/10/91	1 Normal	Absent	Absent	Absent	
							Day 21	14/11/91	21 Normal	Absent	Absent	Absent	Absent	
							Day 42	05/12/91	42 Normal	Absent	Absent	Absent	Absent	
14/4	131	Imipramine	Female	Evaluated	14/01/92	24/02/92	42	Screen	09/01/92	0 Normal	Absent	Absent	Absent	
							Day 21	03/02/92	21 Normal	Absent	Absent	Absent	Absent	
							Day 42	24/02/92	42 Normal	Absent	Absent	Absent	Absent	
132	132	Imipramine	Female	Evaluated	14/01/92	24/02/92	42	Screen	09/01/92	0 Normal	Absent	Absent	Absent	
							Day 21	03/02/92	21 Normal	Absent	Absent	Absent	Absent	
							Day 42	24/02/92	42 Normal	Absent	Absent	Absent	Absent	
133	133	Imipramine	Female	Evaluated	16/01/92	26/02/92	42	Screen	09/01/92	0 Normal	Absent	Absent	Absent	
							Day 21	06/02/92	22 Normal	Absent	Absent	Absent	Absent	
							Day 42	27/02/92	43 Normal	Absent	Absent	Absent	Absent	

(*) days of treatment

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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test							
					Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	MBC
14/4	134	Reboxetine	Female	Evaluated	16/01/92	26/02/92	42	Screen Day 21 Day 42	13/01/92 06/02/92 27/02/92	0 Normal 22 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
135	135	Reboxetine	Male	Evaluated	17/01/92	27/02/92	42	Screen Day 21 Day 42	10/01/92 06/02/92 28/02/92	0 Normal 21 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
14/7	422	Imipramine	Female	Without Urinal	04/09/91	15/10/91	42	Screen	02/09/91	0 Normal	Net done	Net done	Net done	Net done	Net done
423	423	Imipramine	Female	Without screen	17/09/91	28/10/91	42	Screen Day 21 Day 42	10/09/91 08/10/91 29/10/91	0 Not done 22 Not done 43 Not done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done
424	424	Reboxetine	Male	Without Urinal	19/09/91	30/10/91	42	Screen Day 21 Day 42	06/09/91 10/10/91 31/10/91	0 Not done 22 Not done 43 Not done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done
430	430	Reboxetine	Female	Without Urinal	07/10/91	17/11/91	42	Screen Day 21 Day 42	07/10/91 28/10/91 18/11/91	1 Not done 22 Not done 43 Not done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done
431	431	Reboxetine	Male	Without Urinal	08/10/91	18/11/91	42	Screen Day 21 Day 42	08/10/91 29/10/91 19/11/91	1 Not done 22 Not done 43 Not done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done
432	432	Imipramine	Male	Without Urinal	08/10/91	18/11/91	42	Screen Day 21 Day 42	08/10/91 29/10/91 19/11/91	1 Not done 22 Not done 43 Not done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done
433	433	Imipramine	Female	Without Urinal	08/10/91	18/11/91	42	Screen Day 21 Day 42	08/10/91 29/10/91 19/11/91	1 Not done 22 Not done 43 Not done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done
434	434	Reboxetine	Male	Without screen	14/10/91	24/11/91	42	Screen Day 21 Day 42	10/10/91 04/11/91 25/11/91	0 Not done 22 Not done 43 Not done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done	Net done Net done Net done	Net done Present Net done

(*) days of treatment

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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Assessment	Date	Urinalysis test					
					Start date	End date	Days			Specific gravity	Albumin	Sugar	RBC	NBC	
14/7	439	Reboxetine	Male	Without Urinal	11/11/91	22/12/91	42	Screen Day 21 Day 42	06/11/91 02/12/91 23/12/91	0	Not done	Present	Not done	Present	Not done
										22	Not done	Present	Not done	Not done	Not done
										43	Not done	Not done	Not done	Not done	Not done
440	440	Imipramine	Female	Evaluated	11/11/91	22/12/91	42	Screen Day 21 Day 42	07/11/91 02/12/91 23/12/91	0	Not done	Present	Absent	Present	
										22	Not done	Absent	Absent	Absent	Absent
										43	Not done	Absent	Absent	Absent	Absent
441	441	Imipramine	Male	Without Urinal	11/11/91	22/12/91	42	Screen Day 21 Day 42	08/11/91 02/12/91 23/12/91	0	Not done	Not done	Not done	Not done	
										22	Not done	Not done	Not done	Not done	
										43	Not done	Not done	Not done	Not done	
442	442	Imipramine	Male	Without Urinal	11/11/91	22/12/91	42	Screen Day 21 Day 42	08/11/91 02/12/91 23/12/91	0	Not done	Not done	Not done	Not done	
										22	Not done	Not done	Not done	Not done	
										43	Not done	Not done	Not done	Not done	
449	449	Reboxetine	Female	Without Urinal	20/12/91	30/01/92	42	Screen Day 21 Day 42	16/12/91 10/01/92 31/01/92	0	Not done	Not done	Not done	Not done	
										22	Not done	Not done	Not done	Not done	
										43	Not done	Present	Not done	Not done	Not done
450	450	Imipramine	Male	Evaluated	23/12/91	02/02/92	42	Screen Day 21 Day 42	06/12/91 13/01/92 03/02/92	0	Not done	Present	Absent	Absent	
										22	Not done	Absent	Absent	Absent	Absent
										43	Not done	Absent	Absent	Absent	Absent
14/8	130	Reboxetine	Male	Evaluated	10/01/92	20/02/92	42	Screen Day 21 Day 42	10/01/92 31/01/92 21/02/92	1	Not done	Absent	Absent	Absent	
										22	Not done	Absent	Absent	Absent	Absent
										43	Not done	Absent	Absent	Absent	Absent
425	425	Reboxetine	Female	Evaluated	09/09/91	20/10/91	42	Screen Day 21 Day 42	06/09/91 30/09/91 21/10/91	0	Not done	Absent	Absent	Present	
										22	Not done	Absent	Absent	Absent	Present
										43	Not done	Absent	Absent	Absent	Present
467	467	Reboxetine	Male	Evaluated	06/07/92	16/08/92	42	Screen Day 21 Day 42	02/07/92 27/07/92 17/08/92	0	Not done	Absent	Absent	Absent	
										22	Not done	Absent	Absent	Absent	Absent
										43	Not done	Absent	Absent	Absent	Absent
14/10	53	Reboxetine	Male	Evaluated	25/02/92	06/04/92	42	Screen	17/02/92	0	Normal	Absent	Absent	Absent	

(*) days of treatment

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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Urinalysis test									
					Start date	End date	Days	Assessment	Date	Specific gravity (*)	Albumin	Sugar	RBC	WBC			
14/10	53	Reboxetine	Male	Evaluated	25/02/92	06/04/92	42	Day 21 Day 42	16/03/92 06/04/92	21 Normal 42 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent		
	54	Imipramine	Female	Evaluated	26/02/92	07/04/92	42	Screen Day 21 Day 42	18/02/92 17/03/92 07/04/92	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent		
	55	Reboxetine	Female	Evaluated	28/02/92	09/04/92	42	Screen Day 21 Day 42	20/02/92 19/03/92 07/04/92	0 Normal 21 Normal 40 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent		
	56	Imipramine	Female	Evaluated	03/03/92	13/04/92	42	Screen Day 21 Day 42	24/02/92 23/03/92 13/04/92	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent		
	57	Reboxetine	Female	Evaluated	04/03/92	14/04/92	42	Screen Day 21 Day 42	25/02/92 24/03/92 14/04/92	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent		
	58	Imipramine	Female	Evaluated	14/04/92	25/05/92	42	Screen Day 21 Day 42	02/04/92 04/05/92 25/05/92	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent		
	59	Imipramine	Female	Evaluated	24/04/92	04/06/92	42	Screen Day 21 Day 42	16/04/92 14/05/92 05/06/92	0 Normal 21 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent		
	60	Reboxetine	Female	Evaluated	13/05/92	23/06/92	42	Screen Day 21 Day 42	06/05/92 02/06/92 23/06/92	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent		
	137	Reboxetine	Female	Evaluated	28/01/92	09/03/92	42	Screen Day 21 Day 42	20/01/92 17/02/92 09/03/92	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent		
	138	Imipramine	Female	Evaluated	29/01/92	10/03/92	42	Screen Day 21 Day 42	21/01/92 18/02/92 10/03/92	0 Normal 21 Normal 42 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent		

(*) days of treatment

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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test			
										Specific gravity	Albumin	Sugar	RBC
14/40	139	Reboxetine	Female	Evaluated	04/02/92	16/03/92	42	Screen	27/01/92	0 Normal	Absent	Absent	Absent
								Day 21	24/02/92	21 Normal	Absent	Absent	Absent
								Day 42	16/03/92	42 Normal	Absent	Absent	Absent
140	140	Imipramine	Female	Evaluated	05/02/92	17/03/92	42	Screen	28/01/92	0 Normal	Absent	Absent	Absent
								Day 21	25/02/92	21 Normal	Absent	Absent	Absent
								Day 42	17/03/92	42 Normal	Absent	Absent	Absent
435	435	Imipramine	Female	Evaluated	12/11/91	23/12/91	42	Screen	04/11/91	0 Normal	Absent	Absent	Absent
								Day 21	02/12/91	24 Normal	Absent	Absent	Absent
								Day 42	23/12/91	42 Normal	Absent	Absent	Absent
436	436	Reboxetine	Female	Evaluated	13/11/91	23/12/91	41	Screen	06/11/91	0 Normal	Absent	Absent	Absent
								Day 21	03/12/91	21 Normal	Absent	Absent	Absent
								Day 42	23/12/91	41 Normal	Absent	Absent	Absent
437	437	Reboxetine	Female	Evaluated	14/11/91	23/12/91	40	Screen	05/11/91	0 Normal	Absent	Absent	Absent
								Day 21	03/12/91	20 Normal	Absent	Absent	Absent
								Day 42	23/12/91	40 Normal	Absent	Absent	Absent
438	438	Imipramine	Female	Evaluated	15/11/91	27/12/91	43	Screen	07/11/91	0 Normal	Absent	Absent	Absent
								Day 21	05/12/91	21 Normal	Absent	Absent	Absent
								Day 42	27/12/91	43 Normal	Absent	Absent	Absent
443	443	Reboxetine	Female	Evaluated	19/11/91	30/12/91	42	Screen	15/11/91	0 Normal	Absent	Absent	Absent
								Day 21	09/12/91	21 Normal	Absent	Absent	Absent
								Day 42	30/12/91	42 Normal	Absent	Absent	Absent
444	444	Reboxetine	Male	Evaluated	16/11/91	27/12/91	42	Screen	15/11/91	0 Normal	Absent	Absent	Absent
								Day 21	06/12/91	21 Normal	Absent	Absent	Absent
								Day 42	27/12/91	42 Normal	Absent	Absent	Absent
445	445	Imipramine	Female	Evaluated	20/11/91	30/12/91	41	Screen	15/11/91	0 Normal	Absent	Absent	Absent
								Day 21	30/12/91	41 Normal	Absent	Absent	Absent
								Day 42	30/12/91	41 Normal	Absent	Absent	Absent
446	446	Reboxetine	Female	Evaluated	26/11/91	07/01/92	43	Screen	22/11/91	0 Normal	Absent	Absent	Absent
								Day 21	16/12/91	21 Normal	Absent	Absent	Absent
								Day 42	16/12/91	21 Normal	Absent	Absent	Absent

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(*) days of treatment

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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	Urinalysis test								
										Specific Gravity	Albumin	Sugar	RBC	MBC	(*)			
14/10	446	Reboxetine	Female	Evaluated	26/11/91	07/01/92	43	Day 42	07/01/92	43	Normal	Absent	Absent	Absent	Absent	Absent	Absent	
	447	Reboxetine	Male	Evaluated	27/11/91	07/01/92	42	Screen Day 21 Day 42	26/11/91 17/12/91 07/01/92	0 21 42	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	448	Imipramine	Female	Evaluated	28/11/91	07/01/92	41	Screen Day 21 Day 42	22/11/91 17/12/91 08/01/92	0 20 42	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	453	Imipramine	Female	Evaluated	28/05/92	08/07/92	42	Screen Day 21 Day 42	18/05/92 17/06/92 08/07/92	0 21 42	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
15	349	Imipramine	Male	Evaluated	12/06/92	23/07/92	42	Screen Day 21 Day 42	03/06/92 02/07/92 23/07/92	0 21 42	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	455	Reboxetine	Female	Evaluated	20/06/92	31/07/92	42	Screen Day 21 Day 42	12/06/92 10/07/92 31/07/92	0 21 42	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	351	Reboxetine	Male	Evaluated	20/08/92	01/10/92	43	Screen Day 21 Day 42	20/08/92 10/09/92 01/10/92	1 22 43	Not done Not done Not done	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Present	Absent Absent Present	Absent Absent Present	
	352	Imipramine	Male	Evaluated	02/09/92	14/10/92	43	Screen Day 21 Day 42	02/09/92 23/09/92 14/10/92	1 22 43	Not done Not done Not done	Present Present Not done	Absent Absent Not done	Absent Absent Not done	Absent Absent Not done	Present Present Not done	Present Present Not done	
	364	Imipramine	Female	Evaluated	06/08/92	27/08/92	22	Screen Day 21	06/08/92 27/08/92	1 22	Not done Not done	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent
	366	Reboxetine	Male	Without screen	29/07/92	26/08/92	29	Screen Day 21	29/07/92 19/08/92	1 22	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

(*) days of treatment

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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Days	Assessment	Date (*)	Urinalysis test				
					Start date	End date	End date				Specific gravity	Albumin	Sugar	RBC	NBC
15	366	Reboxetine	Male	Without screen	27/08/92	08/10/92	43	Day 42	08/10/92	43	Not done	Absent	Absent	Absent	Absent
	367	Imipramine	Male	Evaluated	31/08/92	11/10/92	42	Screen Day 21 Day 42	31/08/92 21/09/92 12/10/92	1 22 43	Not done Not done Not done	Absent Present Not done	Absent Present Not done	Absent Present Not done	
	368	Reboxetine	Female	Without Urinal	04/09/92	15/10/92	42	Screen Day 21 Day 42	04/09/92 24/09/92 15/10/92	1 21 42	Normal Not done Not done	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	
	369	Reboxetine	Female	Without screen	10/07/92	20/08/92	42	Screen Day 21 Day 42	10/07/92 30/07/92 20/08/92	1 21 42	Not done Not done Not done	Not done Present Present	Not done Present Present	Not done Present Present	
	370	Imipramine	Female	Without screen	16/07/92	27/08/92	43	Screen Day 42	16/07/92 27/08/92	1 43	Not done Not done	Not done Absent	Not done Absent	Not done Absent	
	371	Reboxetine	Female	Evaluated	20/07/92	31/08/92	43	Screen Day 21 Day 42	20/07/92 10/08/92 31/08/92	1 22 43	Not done Not done Not done	Present Present Not done	Absent Present Not done	Present Present Not done	
	372	Imipramine	Male	Without Urinal	17/06/92	29/07/92	43	Screen Day 21 Day 42	17/06/92 08/07/92 29/07/92	1 22 43	Not done Not done Normal	Not done Not done Not done	Not done Not done Not done	Not done Not done Not done	
	373	Imipramine	Female	Without Urinal	25/06/92	26/06/92	2	Screen	25/06/92	1	Not done	Not done	Not done	Not done	
	374	Reboxetine	Female	Without Urinal	09/04/92	20/05/92	42	Day 21 Day 42	24/04/92 20/05/92	16 42	Not done Normal	Not done Not done	Not done Not done	Not done Not done	
	375	Reboxetine	Female	Without Urinal	06/06/92	25/06/92	20	Day 21	25/06/92	20	Not done	Not done	Not done	Not done	
	376	Imipramine	Female	Without Urinal	13/04/92	21/04/92	9								
	377	Reboxetine	Female	Only screening	13/05/92	25/06/92	44	Screen	13/05/92	1	Not done	Absent	Absent	Present	

(*) days of treatment

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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URINALYSIS

Centre	Patient	Treatment	Sex	Patient type	Treatment period			Assessment	Date	Urinalysis test			
					Start date	End date	Days			(*)	Specific gravity	Albumin	Sugar
15	378	Reboxetine	Female	Without screen	15/06/92	27/07/92	43	Screen Day 21 Day 42	15/06/92 06/07/92 27/07/92	1 Not done 22 Not done 43 Not done	Not done Absent Absent	Not done Absent Absent	Not done Present Present
	379	Imipramine	Female	Without Urinal	16/04/92	17/04/92	2	Screen	16/04/92	1 Not done	Not done	Not done	Not done
	380	Imipramine	Female	Without Urinal	30/06/92	10/08/92	42	Screen Day 21	30/06/92 20/07/92	1 Not done 21 Not done	Not done Not done	Not done Not done	Not done Not done
	381	Reboxetine	Female	Without screen	21/05/92	01/07/92	42	Screen Day 21 Day 42	21/05/92 11/06/92 02/07/92	1 Normal 22 Not done 43 Not done	Not done Absent Present	Not done Absent Present	Not done Present Present
	382	Imipramine	Male	Without Urinal	09/04/92	10/04/92	2	Screen	09/04/92	1 Not done	Not done	Not done	Not done
15	383	Imipramine	Female	Evaluated	07/07/92	18/08/92	43	Screen Day 21 Day 42	07/07/92 28/07/92 18/08/92	1 Not done 22 Not done 43 Not done	Absent Absent Absent	Absent Present Absent	Present Present Absent
15	384	Reboxetine	Female	Without Urinal	28/07/92	05/08/92	9	Screen	28/07/92	1 Normal	Not done	Not done	Not done

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(*) days of treatment

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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	1	Reboxetine	Male	Screen	05/02/91				160	100	64	140	80	76			
				Day 0	05/02/91	83.00	160	100	64	140	80	76					
				Day 7	12/02/91	82.00	140	90	76	125	80	96					
				Day 14	20/02/91	83.00	140	90	88	125	70	88					
				Day 21	26/02/91	83.00	140	90	72	125	70	84					
				Day 28	05/03/91	82.00	140	90	72	120	90	88					
				Day 35	12/03/91	82.00	140	90	72	120	80	80					
				Day 42	19/03/91	82.00	130	85	76	110	85	80					
				2	2	Reboxetine	Female	Screen	26/02/91			160	100	88	150	95	88
								Day 0	26/02/91	70.00	160	100	88	150	95	88	
Day 7	05/03/91	70.00	155					95	62	130	100	76					
Day 14	12/03/91	70.00	140					80	72	120	90	80					
Day 21	19/03/91	70.00	120					75	70	110	75	80					
Day 28	26/03/91	83.00	140					80	70	120	75	76					
Day 35	02/04/91	83.00	140					85	72	130	80	72					
Day 42	09/04/91	83.00	160					85	82	160	100	82					
3	3	Imipramine	Female					Screen	12/04/91			110	75	92	105	80	96
								Day 0	12/04/91	63.00	130	80	80	125	80	80	
				Day 7	23/04/91	63.00	140	90	108	120	80	116					
				Day 14	30/04/91	62.00	140	90	88	120	70	88					
				Day 21	07/05/91	62.00	120	75	92	100	75	112					
				Day 28	14/05/91	62.30	130	75	104	105	80	120					
				Day 35	22/05/91	62.30	120	70	80	100	70	92					
				Day 42	28/05/91	63.00	110	80	92	105	70	100					
				4	4	Imipramine	Male	Screen	15/04/91			170	100	76	170	100	84
								Day 0	15/04/91	123.00	160	95	76	150	100	76	
Day 7	23/04/91	117.00	160					110	76	130	95	92					
Day 14	30/04/91	115.00	160					100	72	140	95	92					
Day 21	07/05/91	114.00	160					110	72	160	110	88					
Day 28	14/05/91	114.00	150					105	76	160	110	76					
Day 35	21/05/91	114.00	160					105	72	150	105	84					
Day 42	29/05/91	116.00	160					110	76	145	110	88					
5	5	Reboxetine	Female					Screen	16/07/91			110	70	80	120	80	88
								Day 0	16/07/91	70.30	120	80	60	110	70	80	
				Day 7	24/07/91	70.00	110	80	60	110	70	96					
				Day 14	31/07/91	69.50	120	80	76	110	70	92					
				Day 21	07/08/91	69.50	115	90	76	100	80	92					
				Day 28	14/08/91	71.00	115	75	72	100	70	84					
				Day 35	21/08/91	69.00	105	70	80	90	60	92					
				Day 42	28/08/91	69.50	120	80	76	100	70	88					

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 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)	
1	6	Imipramine	Male	Screen	06/08/91				155	85	88	165	105	92
				Day 0	07/08/91	67.00		67.00	160	95	76	160	100	84
				Day 7	14/08/91			67.00	150	90	75	120	75	92
				Day 14	21/08/91			68.00	140	80	76	68.00	90	88
				Day 21	28/08/91			68.00	180	120	72	150	100	88
7	7	Reboxetine	Male	Day 28	03/09/91	36.30			135	90	92	140	100	96
				Day 35	10/09/91			130	85	76	130	90	100	
				Day 42	18/09/91			129	85	76	125	95	88	
				Screen	08/10/91			150	90	80	140	85	80	
				Day 0	09/10/91	85.00		85.00	150	90	80	140	85	80
8	8	Imipramine	Male	Day 7	16/10/91			83.00	120	80	72	100	85	96
				Day 14	23/10/91			83.00	120	80	72	100	85	100
				Day 21	30/10/91			85.00	115	85	80	95	80	92
				Day 28	06/11/91			80.00	80	65	125	85	80	
				Day 35	13/11/91			79.00	130	80	105	75	80	
9	9	Imipramine	Female	Day 42	21/11/91			78.00	120	80	74	110	80	
				Screen	25/10/91			120	70	88	110	70	92	
				Day 0	28/10/91	88.50		120	70	88	110	70	92	
				Day 7	31/10/91			88.00	110	80	84	120	80	84
				Screen	06/11/91			140	80	72	140	85	84	
10	10	Imipramine	Female	Day 0	06/11/91			53.00	165	80	84	165	85	84
				Day 7	15/11/91			53.00	120	75	80	100	70	92
				Day 14	21/11/91			53.00	110	70	88	95	60	96
				Day 21	28/11/91			53.00	130	80	80	120	80	88
				Day 28	05/12/91			53.00	120	70	76	105	70	80
11	11	Reboxetine	Male	Day 35	12/12/91			53.28	130	75	88	115	75	88
				Day 42	19/12/91			53.20	130	75	88	115	75	88
				Screen	15/11/91			130	80	88	125	80	88	
				Day 0	19/11/91	71.00		130	80	72	130	85	72	
				Day 7	26/11/91			71.00	130	70	88	120	80	104
11	11	Reboxetine	Male	Day 14	03/12/91			71.00	120	80	88	120	80	92
				Day 21	10/12/91			70.00	150	90	80	130	90	88
				Day 28	17/12/91			70.00	150	100	72	145	105	80
				Day 35	24/12/91			71.00	170	76	165	165	76	
				Day 42	30/12/91			71.00	150	100	72	150	95	80
11	11	Reboxetine	Male	Screen	02/04/92			150	95	88	150	100	92	
				Day 0	06/04/92	71.80		140	100	76	130	80	80	

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PHARMACIA CNS RED
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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	11	Reboxetine	Male	Day 7	13/04/92			71.00	120	80	84	110	75	92
				Day 14	20/04/92			73.00	155	100	80	140	90	92
				Day 21	27/04/92			73.00	160	100	84	120	75	96
				Day 28	04/05/92			74.00	150	90	72	130	80	88
2	12	Reboxetine	Male	Screen	13/04/92			84.80	160	90	84	160	90	84
				Day 0	14/04/92			86.00	140	90	68	130	90	88
				Day 7	21/04/92			85.80	140	90	68	110	70	88
				Day 14	28/04/92			85.80	150	100	60	100	70	88
				Day 21	05/05/92			86.50	190	110	60	140	110	92
				Screen	18/12/90			83.50	120	70	56	100	70	60
				Day 0	18/12/90			83.00	120	70	56	100	70	
				Day 7	25/12/90		32	83.00	110	90	72	110	80	
				Day 14	01/01/91			84.00	130	80	76	110	75	
				Day 21	08/01/91			83.00	120	70	64	105	70	
				Day 28	15/01/91			82.70	130	60	76	160	70	
				Day 35	22/01/91			84.80	125	80	76	110	70	
				Day 42	29/01/91			84.00	110	70	76	150	85	
34	34	Imipramine	Male	Screen	27/12/90			36.80	125	70	88	130	70	92
				Day 0	27/12/90			36.80	108.00	70	88	130	70	92
				Day 7	03/01/91		26	37.40	108.00	70	88	120	75	116
				Day 14	10/01/91			37.10	106.00	65	100	130	70	104
				Day 21	17/01/91			37.30	100.00	90	80	110	90	100
				Day 28	24/01/91			35.30	108.00	70	84	110	70	104
				Day 35	31/01/91			36.20	105.00	100	80	120	90	112
				Day 42	07/02/91			36.50	108.00	80	60	120	85	64
				Screen	27/12/90			36.20	130	80	72	130	90	80
				Day 0	27/12/90			36.20	130	80	72	130	90	80
				Day 7	03/01/91			80.00	130	90	72	120	90	
				Day 14	10/01/91			81.80	110	70	76	110	70	
				Day 21	17/01/91			82.80	110	70	92	120	90	
				Day 28	24/01/91			83.90	120	80	84	130	80	
				Day 35	31/01/91			83.50	140	90	96	120	80	
				Day 42	07/02/91			82.50	140	90	72	110	80	
36	36	Imipramine	Female	Screen	09/01/91			37.40	110	70	76	120	80	84
				Day 0	09/01/91		18	37.40	110	70	76	120	80	84
				Day 7	16/01/91			37.70	49.80	100	68	100	70	100
				Day 14	23/01/91			37.20	49.50	120	70	100	110	120
				Day 21	30/01/91			37.20	47.80	130	80	72	130	95

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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)	
2	37	Reboxetine	Male	Screen	17/01/91	36.70	24	80	110	80	84	130	90	100
				Day 0	17/01/91	36.70		80.60	110	80	84	130	90	100
				Day 7	24/01/91	36.30		80.50	140	80	108	145	95	100
				Day 14	31/01/91	35.80		81.50	120	75	76	120	80	88
				Day 21	07/02/91	35.20		81.50	140	90	100	130	90	108
				Day 28	14/02/91	36.60		80.80	100	100	88	135	105	96
	38	Imipramine	Female	Screen	23/01/91	37.30	25	80	140	80	68	120	90	88
				Day 0	24/01/91	37.30		50.90	140	80	68	120	90	88
				Day 7	31/01/91	36.90		50.00	140	70	72	120	80	100
				Day 14	07/02/91	37.00		49.30	120	70	60	80	80	100
				Day 21	14/02/91	37.20		49.50	110	80	78	100	80	100
				Day 28	21/02/91	37.30		48.60	120	80	76	120	80	84
	39	Reboxetine	Female	Screen	24/01/91	37.90	22	80	120	80	86	120	80	86
				Day 0	24/01/91	37.90		64.70	120	80	86	120	80	86
				Day 7	31/01/91	36.50		66.00	120	80	84	130	80	84
				Day 14	07/02/91	35.90		65.80	120	80	80	120	80	80
				Day 21	14/02/91	36.80		68.00	120	80	68	135	80	76
				Day 28	21/02/91	35.90		69.60	120	80	76	120	80	84
	40	Imipramine	Male	Screen	18/02/91	36.50	27	85	120	85	84	125	90	76
				Day 0	18/02/91	36.50		73.00	120	85	76	125	90	76
				Day 7	26/02/91	37.00		74.00	130	85	92	110	85	100
				Day 14	05/03/91	36.80		74.20	115	70	92	110	80	100
				Day 21	12/03/91	36.30		75.00	105	70	88	120	90	100
				Day 28	19/03/91	36.80		73.00	120	80	108	120	80	120
	41	Reboxetine	Male	Screen	31/01/91	37.00	23	80	120	80	72	130	90	88
				Day 0	04/02/91	37.00		78.50	120	80	72	130	90	88
				Day 7	11/02/91	36.80		77.30	140	90	88	120	90	120
				Day 14	18/02/91	36.60		77.20	140	90	84	115	85	80
				Day 21	25/02/91	37.00		78.50	140	100	96	130	100	92
				Day 28	04/03/91	36.10		77.00	125	90	88	120	90	100
	42	Imipramine	Male	Screen	11/03/91	36.40		100	140	100	100	125	100	116
				Day 0	11/03/91	36.40		76.00	140	100	100	125	100	116
				Day 7	18/03/91	36.40		76.10	110	75	104	110	85	132
				Day 14	25/03/91	36.50		76.10	110	75	104	110	85	132
				Day 21	01/04/91	36.50		76.10	110	75	104	110	85	132
				Day 28	08/04/91	36.50		76.10	110	75	104	110	85	132

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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	41	Reboxetine	Male	Day 42	18/03/91	36.80		77.10	150	90	120	130	90	108
	42	Imipramine	Male	Screen	06/02/91	36.20	16		120	80	92	120	90	116
				Day 0	08/02/91	36.20		75.50	120	80	92	120	90	116
				Day 7	15/02/91	36.70		75.70	140	80	84	120	80	104
				Day 14	22/02/91	36.00		75.00	135	90	96	120	80	100
				Day 21	01/03/91	37.20		75.20	140	85	100	120	85	120
				Day 28	08/03/91	36.50		75.10	110	70	84	85	70	120
				Day 35	15/03/91	36.70		75.00	150	80	120	110	80	120
				Day 42	22/03/91	36.80		74.60	130	70	84	110	80	112
	43	Reboxetine	Female	Screen	20/03/91	36.50	15		110	80	72	110	80	80
				Day 0	25/03/91	36.50		56.00	110	80	72	110	80	80
				Day 7	01/04/91	36.70		55.80	115	70	88	115	70	92
				Day 14	08/04/91	36.60		58.00	120	75	85	100	65	92
				Day 21	15/04/91	36.80		59.00	110	80	72	115	80	120
				Day 28	22/04/91	36.50		59.00	100	70	64	110	70	80
				Day 35	29/04/91	36.00		59.00	110	80	60	110	90	80
				Day 42	06/05/91	36.60		63.50	140	90	68	110	80	120
	44	Imipramine	Male	Screen	08/04/91	36.50	19		125	80	88	130	80	92
				Day 0	10/04/91	36.50		67.50	125	80	88	130	80	92
	45	Imipramine	Female	Screen	26/04/91	37.10	25		110	75	84	110	80	88
				Day 0	29/04/91	37.10		62.60	110	75	84	110	80	88
	46	Reboxetine	Female	Screen	14/05/91	36.10	18		120	80	68	125	85	80
				Day 0	15/05/91	36.10		67.00	120	80	68	125	85	80
				Day 7	22/05/91	36.40		65.70	155	95	72	125	85	100
				Day 14	29/05/91	36.00		65.60	125	85	80	115	85	100
				Day 21	05/06/91	36.30		65.00	125	95	88	105	85	100
				Day 28	12/06/91	35.50		64.30	140	80	115	120	80	112
				Day 35	19/06/91	36.00		64.90	120	80	80	110	80	96
				Day 42	26/06/91	35.50		63.70	130	80	86	120	80	94
	47	Reboxetine	Female	Screen	17/05/91	37.00	16		120	85	60	115	85	64
				Day 0	21/05/91	37.00		73.50	120	85	60	115	85	64
				Day 7	28/05/91	36.60		72.30	120	80	84	115	85	100
				Day 14	04/06/91	36.30		72.20	135	90	76	120	90	94
				Day 21	11/06/91	37.10		72.00	135	90	76	130	90	94
				Day 28	18/06/91	36.20		72.00	130	80	80	120	85	100
				Day 35	25/06/91	36.50		71.00	120	80	88	110	70	88
				Day 42	02/07/91	36.40		70.00	130	90	84	120	90	88

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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)		
2	48	Imipramine	Female	Screen	23/08/91	36.10	22		160	90	92	130	90	116
				Day 0	26/08/91	36.10		80.50	160	90	92	130	90	116
				Day 7	02/09/91	36.20		83.30	130	70	96	120	80	120
				Day 14	09/09/91	37.00		82.50	100	60	88	130	70	96
				Day 21	16/09/91	37.00		83.50	105	70	88	110	70	96
				Day 28	23/09/91	37.50		83.50	125	80	68	140	90	88
				Day 35	30/09/91	37.40		82.50	160	90	96	120	90	120
				Day 42	07/10/91	36.00		83.00	135	65	60	110	85	90
				Screen	27/08/91	36.50	18		130	90	78	125	80	82
				Day 0	28/08/91	36.50		53.50	130	90	78	125	80	82
Day 7	04/09/91	36.00		52.50	150	90	96	130	90	120				
Day 14	11/09/91	36.90		55.00	185	60	100	100	60	120				
Day 21	18/09/91	36.50		54.70	120	70	92	115	70	104				
Day 28	25/09/91	37.30		54.50	120	65	96	110	75	100				
Day 35	02/10/91	37.00		54.70	130	70	92	130	70	96				
Day 42	09/10/91	37.00		55.00	125	70	80	130	70	96				
50	Reboxetine	Male	Screen	31/10/91	36.50			120	60	68	120	65	104	
			Day 0	05/11/91	36.40	21	78.00	95	65	96	100	70	108	
			Day 7	12/11/91	35.70		78.00	120	75	92	120	80	110	
			Day 14	19/11/91	35.80		79.50	110	80	100	90	70	100	
			Day 21	26/11/91	36.20		77.30	115	80	92	110	70	96	
			Day 28	03/12/91	36.00		77.50	100	75	90	100	70	112	
			Day 35	10/12/91	37.10		78.50	130	80	104	110	80	115	
			Screen	30/10/91	36.20	16		120	90	92	110	70	100	
			Day 0	05/11/91	36.80		74.50	95	60	92	105	80	104	
			Day 7	12/11/91	36.90		75.50	130	70	100	110	65	88	
52	Imipramine	Male	Screen	13/11/91	36.70			110	85	80	125	70	80	
			Day 0	26/11/91	37.00	24	78.00	110	60	64	115	80	84	
			Day 7	03/12/91	36.90		77.60	105	65	88	95	60	120	
			Day 14	10/12/91	37.30		79.00	110	60	64	110	70	108	
			Day 21	17/12/91	36.40		77.30	110	70	80	120	70	100	
			Day 28	24/12/91	37.10		77.70	115	75	84	85	80	120	
			Day 35	31/12/91	37.50		78.80	125	80	64	130	80	84	
			Day 42	07/01/92	37.00		77.10	110	60	88	120	70	100	
			Screen	28/03/91	37.20	16		135	90	104	150	95	100	
			Day 0	01/04/91	37.40		86.40	145	95	84	135	90	96	
Day 7	08/04/91	36.40		85.50	140	90	100	135	90	88				

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PHARMACIA CNS RD

REBOXETINE - PROTOCOL 20124/017
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	65	Reboxetine	Male	Day 14	15/04/91	36.00		86.50	145	95	96	135	90	116	
				Day 21	22/04/91	36.00		85.50	152	110	116	145	115	120	120
				Day 28	29/04/91	36.10		85.50	130	90	128	125	90	124	100
				Day 35	06/05/91	36.20		85.50	135	90	96	135	95	100	104
				Day 42	13/05/91	36.40		84.50	140	100	104	145	105	104	
66		Imipramine	Female	Screen	27/04/91	37.40	12		120	70	80	120	80	96	
				Day 0	30/04/91	37.50		52.00	125	75	80	135	85	100	100
				Day 7	07/05/91	37.20		52.00	120	70	90	130	90	116	116
				Day 14	14/05/91	37.00		52.50	120	75	88	120	80	100	100
				Day 21	21/05/91	37.50		53.80	130	90	72	160	90	96	96
				Day 28	28/05/91	37.20		53.00	130	75	104	130	80	112	112
				Day 35	04/06/91	37.10		52.60	118	80	120	110	80	124	
67		Reboxetine	Female	Screen	05/04/91	37.00	11		160	90	76	170	100	96	
				Day 0	10/04/91	36.90		65.00	150	85	72	165	90	100	100
				Day 7	16/04/91	37.30		64.70	160	105	104	145	110	116	116
				Day 14	23/04/91	37.20		64.10	140	100	104	155	110	120	120
				Day 21	30/04/91	36.90		64.80	120	85	84	130	95	108	108
				Day 28	07/05/91	37.00		64.20	145	90	84	160	105	104	104
				Day 35	14/05/91	36.70		64.40	140	90	84	145	90	112	112
								Day 42	21/05/91	37.40		64.40	145	90	160
68		Imipramine	Female	Screen	01/08/91	37.20	12		120	90	68	105	75	88	
				Day 0	03/08/91	37.00		60.50	130	80	80	90	60	93	93
				Day 7	09/08/91	37.00		62.00	120	80	92	90	60	120	120
				Day 14	16/08/91	37.20		62.50	110	80	116	105	60	120	120
				Day 21	23/08/91	36.90		64.00	120	80	92	95	60	116	116
				Day 28	30/08/91	37.10		64.20	110	80	100	105	80	120	120
				Day 35	06/09/91	36.80		64.50	115	75	88	110	80	104	104
								Day 42	13/09/91	37.00		65.00	120	80	115
69		Imipramine	Female	Screen	28/02/91	37.10	12		120	70	80	130	78	88	
				Day 0	01/03/91	37.10		58.50	125	70	84	130	70	96	96
				Day 7	07/03/91	36.80		60.50	125	80	96	110	85	112	112
				Day 14	14/03/91	36.30		60.00	110	80	88	125	85	100	100
				Day 21	21/03/91	36.40		59.00	120	85	100	125	95	112	112
				Day 28	28/03/91	36.50		60.00	120	80	96	125	90	116	116
				Day 35	04/04/91	36.50		60.00	130	80	125	95	120		
				Day 42	11/04/91	36.50		60.00	125	85	115	95	112		
70		Reboxetine	Female	Screen	21/10/91	36.90	8		120	80	60	125	90	76	
				Day 0	23/10/91	37.00		78.00	130	80	64	130	80	88	88
				Day 7	29/10/91	36.80		80.00	160	90	115	80	132		

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	70	Reboxetine	Female	Day 14	05/11/91	37.00		79.00	130	85	88	115	80	108
				Day 21	12/11/91	37.00		79.40	125	80	88	120	80	96
				Day 28	19/11/91	36.80		77.00	125	75	100	110	85	120
4	71	Imipramine	Female	Screen	12/11/91	36.60	12		130	70	80	125	80	88
				Day 0	14/11/91	36.60		55.40	120	75	76	125	85	102
				Day 7	20/11/91	36.80		55.40	110	75	80	120	80	106
				Day 14	27/11/91	36.80		54.00	120	80	88	130	85	104
				Day 21	04/12/91	37.00		55.00	115	80	100	120	85	128
				Day 28	11/12/91	37.00		54.70	120	85	100	125	85	116
				Day 35	18/12/91	36.80		55.10	125	75	104	120	85	134
Day 42	25/12/91	36.80		55.00	125	80	112	115	80	128				
4	72	Reboxetine	Female	Screen	28/01/92	37.00	12		130	70	80	120	80	92
				Day 0	31/01/92	36.80		55.80	120	80	76	120	80	92
				Day 7	07/02/92	36.80		56.00	100	70	84	100	70	96
				Day 14	14/02/92	36.80		56.00	130	80	86	123	80	84
				Day 21	21/02/92	36.80		56.30	120	80	86	125	88	92
				Day 28	28/02/92	37.00		56.60	115	85	84	105	85	100
				Day 35	06/03/92	36.60		55.70	100	70	84	95	70	100
Day 42	13/03/92	37.00		55.80	100	70	84	95	65	100				
4	97	Isipramine	Male	Screen	11/02/92	36.90	12		120	70	80	130	80	84
				Day 0	13/02/92	36.80		82.00	120	70	80	125	80	88
				Day 7	21/02/92	36.80		82.00	110	80	80	110	80	96
				Day 14	28/02/92	37.60		83.90	140	95	72	145	100	84
				Day 21	06/03/92	38.00		82.80	145	105	64	150	110	76
				Day 28	13/03/92	36.60		83.90	130	90	68	140	85	72
				Day 35	21/03/92	36.60		83.20	140	90	70	130	85	74
Day 42	28/03/92	36.70		83.90	150	95	92	145	90	92				
4	97	Isipramine	Male	Screen	06/05/92	36.40	14		145	90	70	150	90	70
				Day 0	07/05/92	36.50		60.00	130	60	70	130	80	70
				Day 7	13/05/92	36.20		60.20	145	90	65	150	100	72
				Day 14	20/05/92	36.20		60.10	130	80	65	135	90	70
				Day 21	27/05/92	36.10		60.00	130	90	66	130	95	67
				Day 28	03/06/92	36.20		60.60	180	80	66	130	80	66
				Day 35	10/06/92	36.30		60.40	140	95	68	140	100	72
Day 42	18/06/92	36.40		59.80	125	80	65	135	85	70				
4	100	Reboxetine	Female	Screen	01/05/92	36.50	20		130	80	65	130	90	72
				Day 0	07/05/92	36.80		59.00	130	80	65	130	90	72
				Day 7	13/05/92	36.40		59.00	130	85	70	135	90	70
4	100	Reboxetine	Female	Day 14	20/05/92	36.40		59.50	120	80	70	120	85	

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PHARMACIA CNS RAD
REBOXETINE - PROTOCOL 20124/017
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	100	Reboxetine	Female	Day 21	27/05/92	36.50	21	60.00	125	85	75	130	90	90	70				
				Day 28	03/06/92	36.50		60.20		68	130	80	68	130	80	80			
				Day 35	10/06/92	36.40		60.50		85	130	85	75	130	90	80			
				Day 42	17/06/92	36.30		60.80		80	125	80	68	130	80	70			
6	101	Imipramine	Female	Screen	06/05/91	36.50	21	66.50	125	80	84	130	90	120	88				
				Day 0	06/05/91	36.50		67.00		84	125	80	84	130	90	100			
				Day 7	13/05/91	37.00		67.00		85	140	85	84	140	100	94			
				Day 14	21/05/91	36.50		67.00		80	140	80	80	130	80	88			
				Day 21	23/05/91	36.50		67.00		90	130	90	80	130	90	88			
				Screen	26/03/91	36.60	19	73.00		70	130	90	70	100	80	102			
7	161	Reboxetine	Male	Day 0	28/03/91	36.60		73.00	130	90	68	100	80	100	80				
				Day 7	04/04/91	36.80		73.50		84	105	70	100	80	100				
				Day 14	11/04/91	36.30		73.50		88	100	70	84	100	80	84			
				Day 21	18/04/91	36.00		73.50		100	110	70	100	110	70	100			
				Day 28	25/04/91	36.00		73.00		80	130	80	100	110	80	92			
				Day 35	02/05/91	36.10		73.50		65	110	76	72	120	80	88			
				Day 42	09/05/91	36.40		72.00		80	130	80	68	120	90	72			
				Screen	02/11/91	36.90	20	65.00		80	120	60	80	130	70	96			
				Day 0	04/11/91	36.70		66.00		100	120	80	100	120	80	100			
				Day 7	11/11/91	36.50		66.00		84	120	80	84	120	90	88			
7	162	Reboxetine	Female	Day 14	18/11/91	36.40		65.50	110	80	80	110	80	100					
				Day 21	25/11/91	36.70		66.00		80	120	80	120	85	84				
				Day 28	02/12/91	36.80		66.00		80	100	70	80	110	80	92			
				Day 35	09/12/91	36.60		66.00		84	110	80	84	110	85	80			
				Day 42	16/12/91	36.20		66.00		82	115	80	82	120	80	80			
				Screen	07/06/91	37.00	20	73.50		60	100	60	76	95	60	76			
				Day 0	11/06/91	38.00		73.50		60	110	60	88	100	60	88			
				7	193	Reboxetine	Female	Screen	30/05/91	37.00	20	120.00	140	100	76	140	100	82	
								Day 0	01/06/91	37.00		120.00		76	140	100	140	100	82
								Day 7	10/06/91	37.00		120.00		86	160	100	140	100	86
Screen	18/03/91	36.80	20					61.00		70	110	70	88	110	65	88			
7	194	Reboxetine	Male	Day 0	19/03/91	36.80		61.00	110	70	88	110	65	88					
				Day 7	25/03/91	36.30		61.00		108	100	60	100	60	112				
				Day 14	01/04/91	36.80		61.00		65	110	60	96	110	60	100			
				Day 21	08/04/91	36.80		61.00		96	105	70	96	130	70	100			
				Day 28	15/04/91	37.00		61.00		70	110	70	100	100	80	112			
				Day 35	22/04/91	37.00		61.50		70	110	70	96	120	80	100			

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/017
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)		
7	196	Imipramine	Female	Day 42	27/04/91	37.80		61.00	110	70	92	110	110	60	96	
8	225	Imipramine	Female	Screen	22/03/91	36.80							105	55	92	
				Day 0	22/03/91	36.80		75.00						105	55	92
				Day 7	29/03/91	36.80		75.00		60				90	60	98
				Day 14	05/04/91	37.20		76.00						110	60	120
226	Reboxetine	Female	Screen	02/05/91	36.40											
			Day 0	03/05/91	36.60	17										
			Day 7	10/05/91	36.20		60.00						130	70	76	
			Day 14	17/05/91	36.00		60.00						130	70	72	
			Day 21	24/05/91	36.00		60.00						100	60	72	
			Day 28	31/05/91	36.00		60.00						120	80	80	
			Day 35	07/06/91	36.70		60.00						110	80	76	
			Day 42	14/06/91	36.70		60.50						120	80	84	
227	Imipramine	Male	Screen	28/04/91	36.40											
			Day 0	07/05/91	36.50	20										
			Day 7	14/05/91	36.20		96.00						130	90	80	
			Day 14	21/05/91	36.60		95.00						130	80	76	
			Day 21	28/05/91	36.50		95.00						125	75	72	
			Day 28	04/06/91	36.40		95.00						130	90	72	
			Day 35	11/06/91	36.50		94.00						120	80	70	
			Day 42	18/06/91	36.40		94.00						130	80	72	
228	Reboxetine	Male	Screen	06/05/91	36.50											
			Day 0	10/05/91	36.40	14										
			Day 7	17/05/91	36.40		82.50						120	80	75	
			Day 14	18/05/91	36.50		82.00						120	80	78	
229	Imipramine	Female	Screen	18/10/91	37.00											
			Day 0	22/10/91	36.50	16										
			Day 7	29/10/91	35.50		68.50						120	80	88	
			Day 14	05/11/91	36.00		69.00						135	80	85	
			Day 21	12/11/91	36.50		69.00						120	80	88	
			Day 28	19/11/91	37.00		70.00						120	80	88	
			Day 35	26/11/91	37.00		70.00						120	80	92	
			Day 42	03/12/91	35.70		69.00						130	80	96	
230	Imipramine	Female	Screen	31/10/91	36.50											
			Day 0	05/11/91	37.10	20										
			Day 7	12/11/91	36.70		64.00						105	60	88	
			Day 14	19/11/91	35.80		62.50						110	70	92	

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/017
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)			
8	230	Imipramine	Female	Day 21	26/11/91	35.80		63.00	100	60	92	95	60	120			
				Day 28	03/12/91	35.30		62.80	120	80	92	110	70	96			
				Day 35	10/12/91	35.80		63.00	110	70	96	120	70	104			
				Day 42	17/12/91	36.20		64.00	115	80		120	80	112			
	231	Reboxetine	Female	Screen	28/10/91	36.30		115	60	80	110	60	84				
				Day 0	05/11/91	36.60		57.50	115	80	80	100	80	88			
	232	Reboxetine	Male	Screen	26/11/91	36.60	15	74.00	130	90	80	120	85	82			
				Day 0	29/11/91	36.40		74.00	140	80	80	100	60	80			
				Day 7	06/12/91	35.00		74.00	120	70	84	115	70	84			
				Day 14	13/12/91	35.40		74.00	130	75	68	105	70	92			
				Day 21	20/12/91	35.70		73.00	140	70	92	115	60	104			
				Day 28	27/12/91	36.20		73.00	130	70	90	115	70	96			
Day 35				03/01/92	36.60		73.00	130	70	82	120	75	84				
Day 42				10/01/92	36.40		73.50	130	70	86	120	70	90				
9				197	Reboxetine	Male	Screen	27/02/92	36.50	16	90.00	150	100	75	145	100	75
							Day 0	06/03/92	36.00		92.00	130	85	76	130	90	76
							Day 7	13/03/92	36.30			170	100	70	175	100	74
							Screen	10/03/92	35.80			100	60	85	110	70	92
198	Imipramine	Female	Day 0	17/03/92	36.20		63.00	140	90	78	130	90	78				
			Day 7	24/03/92	36.30		62.00	130	100	72	128	98	72				
			Day 14	31/03/92	35.90		61.00	135	100	90	130	95	90				
			Day 21	07/04/92	36.50		62.00	130	70	84	130	70	90				
			Day 28	14/04/92	36.30		62.00	130	90	76	120	90	80				
			Day 35	21/04/92	36.50		62.00	120	80	72	120	80	80				
			Day 42	28/04/92	36.50		62.00	130	90	84	130	90	92				
			199	Imipramine	Male	Screen	24/03/92	36.30	13	86.00	130	100	80	125	95	80	
						Day 0	01/04/92	36.30		85.00	120	80	92	125	85	86	
						Day 7	08/04/92	36.10		85.00	160	100	100	165	105	108	
						Day 14	15/04/92	36.30		85.00	135	100	78	125	90	84	
						Day 21	22/04/92	36.50		83.00	130	90	104	110	90	108	
Day 28	29/04/92	36.80					83.00	130	90	96	125	90	104				
Day 35	06/05/92	36.40					85.00	130	90	88	110	80	92				
Day 42	13/05/92	36.60					84.00	110	65	94	115	80	104				
200	Reboxetine	Male				Screen	21/04/92	36.50	18	84.00	140	90	68	145	100	78	
						Day 0	27/04/92	36.50		84.00	120	80	72	120	80	80	
						Day 7	04/05/92	36.50		84.00	140	90	72	120	80	80	
						Screen	10/03/92	35.80			100	60	85	110	70	92	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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)
9	200	Reboxetine	Male	Day 14	11/05/92	36.50		84.00	130	90	72	120	80	80
				Day 21	18/05/92	36.70		84.00	145	100	90	140	100	86
				Day 28	25/05/92	36.50		84.00	140	80	80	120	80	80
				Day 35	01/06/92	36.70		84.00	120	80	72	120	80	76
	Day 42	08/06/92	36.50		84.00	130	80	72	120	75	78			
201	201	Imipramine	Female	Screen	07/01/92	36.30			140	75	68	180	95	80
				Day 0	15/01/92	36.80		71.00	135	95	84	130	100	80
				Day 7	22/01/92	36.40		71.00	145	95	84	140	90	84
				Day 14	29/01/92	36.30		71.00	150	85	72	140	80	72
				Day 21	05/02/92	36.30		71.00	155	85	80	145	80	80
				Day 28	12/02/92	36.50		70.80	135	90	80	130	90	72
				Day 35	19/02/92	36.70			120	80	84	120	80	68
				Day 42	26/02/92	36.70		69.50	135	95	92	135	90	84
202	202	Imipramine	Male	Screen	09/01/92	36.30			150	100	70	155	95	76
				Day 0	16/01/92	36.30	18	67.00	150	70	76	150	75	76
				Day 7	23/01/92	36.10		67.00	135	80	88	140	85	96
				Day 14	30/01/92	36.30			180	110	80	160	100	80
				Day 21	06/02/92	36.60		66.00	160	100	72	150	100	72
				Day 28	13/02/92	35.80		66.00	165	95	88	170	100	92
				Day 35	20/02/92	36.30		66.00	180	110	90	170	105	90
				Day 42	27/02/92	36.40		64.00	160	95	76	155	95	76
203	203	Reboxetine	Female	Screen	09/01/92	36.70			110	80	68	110	80	68
				Day 0	14/01/92	36.70	18	78.00	135	100	80	140	95	84
				Day 7	28/01/92	36.30		78.00	95	55	80	110	60	84
				Screen	09/01/92	36.30			150	100	62	155	110	76
204	204	Reboxetine	Male	Day 0	16/01/92	36.00		88.00	210	130	88	210	135	88
				Day 7	23/01/92	36.70		86.50	210	145	92	200	140	92
				Day 14	30/01/92	36.70		86.00	140	71	74	140	71	78
				Day 21	06/02/92	36.70		86.00	125	85	71	125	90	73
				Day 28	14/02/92	36.30		87.00	68	68	68	165	100	72
				Day 35	21/02/92	36.20		87.00	140	90	66	145	100	72
				Day 42	28/02/92	36.70		85.00	160	95	80	165	95	80
				Screen	27/01/92	36.90			130	90	76	140	90	76
Day 0	03/02/92	36.70	18	51.00	150	90	76	135	80	76				
206	206	Imipramine	Female	Screen	28/01/92	36.30			115	75	66	125	90	72
				Day 0	04/02/92	36.40		64.80	125	80	68	125	80	72
				Day 7	12/02/92	36.20			160	90	64	130	85	72

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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	206	Imipramine	Female	Day 14	19/02/92	36.30		65.00	120	80	90	115	80	120
				Day 21	26/02/92	36.60		64.50	110	80	90	110	80	112
				Day 28	04/03/92	36.30		64.50	110	85	86	115	80	92
				Day 35	11/03/92	36.50		64.60	120	90	84	120	95	90
				Day 42	18/03/92	36.20		65.00	120	90	84	120	95	88
207	Reboxetine	Female	Screen	27/01/92	36.40									
			Day 0	05/02/92	36.70	24	72.00	120	80	84	145	65	84	
			Day 7	12/02/92	36.70		72.00	125	90	90	115	90	80	
208	Reboxetine	Male	Screen	10/02/92	36.60									
			Day 0	14/02/92	36.10	18	84.00	150	90	66	150	100	72	
			Day 7	21/02/92	36.40		84.00	110	75	76	105	65	76	
			Day 14	28/02/92	36.50		84.00	130	80	80	135	85	68	
			Day 21	06/03/92	36.30		82.00	145	105	72	130	105	72	
			Day 28	13/03/92	36.70		84.00	130	70	76	145	100	76	
			Day 35	20/03/92	36.50		83.50	130	60	80	120	70	84	
			Day 42	27/03/92	36.20		82.00	150	100	63	140	90	63	
209	Imipramine	Male	Screen	04/02/92	36.70									
			Day 0	11/02/92	36.10	15	65.00	120	90	60	125	100	60	
			Day 7	18/02/92	36.00		65.00	135	80	78	135	85	80	
210	Reboxetine	Female	Screen	05/02/92										
			Day 0	19/02/92	36.30	18	71.00	130	80	80	130	80	80	
			Day 7	26/02/92	36.60		72.00	145	90	66	140	95	72	
			Day 14	04/03/92	36.50		65.50	120	80	92	130	100	90	
			Day 21	11/03/92	36.70		72.30	160	90	84	130	90	84	
			Day 28	18/03/92	36.20		71.50	130	80	80	120	75	84	
Day 35	25/03/92	36.30		71.00	140	90	92	150	90	90				
Day 42	01/04/92	36.50		71.00	130	90	88	120	85	92				
211	Reboxetine	Female	Screen	11/02/92	36.80									
			Day 0	14/02/92	36.80	18	63.00	110	70	63	110	80	63	
			Day 7	21/02/92	36.30		61.40	110	75	84	115	80	84	
			Day 14	28/02/92	36.60		60.30	120	60	72	120	60	76	
Day 21	03/03/92	36.20		60.00	120	65	72	135	65	78				
212	Imipramine	Female	Screen	24/02/92	36.90									
			Day 0	03/03/92	36.30	17	61.00	150	90	70	140	90	70	
			Day 7	10/03/92	36.70		61.00	135	85	84	130	80	84	
			Day 14	17/03/92	36.20		61.00	130	80	82	130	80	84	
Day 21	24/03/92	36.90		61.00	130	70	80	135	75	84				

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Centro	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)
9	212	Imipramine	Female	Day 28	31/03/92	37.10		62.00	140	80	76	145	85	82
				Day 35	07/04/92	36.30		61.00	135	80	92	140	85	96
				Day 42	14/04/92	36.50		61.00	160	90	94	140	80	94
	237	Reboxetine	Male	Screen	15/04/92	36.20	17		135	75	76	145	90	76
				Day 0	22/04/92	36.50		75.00	135	95	76	145	90	76
				Day 7	29/04/92	36.70		75.00	135	90	80	140	90	80
				Day 14	06/05/92	37.00		75.00	135	90	100	135	90	100
				Screen	12/05/92	36.20	18		110	75	78	115	80	82
				Day 0	19/05/92	36.40		77.00	120	80	80	115	80	80
239	Imipramine	Male	Day 7	26/05/92	36.70		74.00	140	80	64	125	90	92	
			Day 14	02/06/92	36.50		74.00	150	80	72	150	80	76	
			Day 21	09/06/92	36.70		74.00	130	90	72	120	80	76	
			Day 28	16/06/92	36.70		74.00	120	80	80	130	80	84	
			Day 35	23/06/92	36.80		74.00	135	90	80	130	80	86	
			Day 42	30/06/92	36.80		74.00	140	80	78	120	70	86	
			Screen	22/04/92	36.20	19		130	85	52	140	90	69	
			Day 0	29/04/92	36.20		103.00	130	85	64	140	90	68	
			Day 7	06/05/92	36.50		103.00	110	70	60	110	70	60	
			Day 14	13/05/92	36.50		103.00	130	90	72	120	70	76	
			Day 21	20/05/92	36.50		103.00	120	90	68	110	70	72	
			Day 28	27/05/92	36.70		103.00	120	85	66	120	70	68	
Day 35	03/06/92	36.60		103.00	130	85	70	130	70	68				
Day 42	10/06/92	36.50		103.00	130	90	60	130	80	64				
240	Reboxetine	Female	Screen	23/04/92	36.40	18		120	80	70	125	85	78	
			Day 0	28/04/92	36.50		61.00	120	80	70	120	80	78	
			Day 7	05/05/92	36.30		62.00	120	80	76	110	70	80	
			Day 14	12/05/92	37.00		62.00	125	85	72	115	80	80	
			Screen	05/05/92	37.30	18		130	100	96	125	95	100	
			Day 0	08/05/92	36.50		80.30	120	90	84	130	100	92	
241	Imipramine	Female	Day 7	15/05/92	37.40		79.50	125	80	80	120	80	92	
			Day 14	22/05/92	36.80		79.70	140	100	76	105	70	84	
			Day 21	29/05/92	36.70		79.90	140	70	76	155	75	76	
			Day 28	05/06/92	36.70		82.80	130	70	76	100	70	84	
			Day 35	12/06/92	36.80		82.80	120	75	76	110	70	88	
			Day 42	19/06/92	36.50		82.00	120	75	76	120	75	76	
			Screen	30/04/92	36.10	19		135	95	89	145	100	96	
			Day 0	07/05/92	36.30		50.00	140	90	92	140	90	100	

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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)		
9	242	Reboxetine	Male	Day 7	14/05/92	36.10		50.00	105	80	92	110	80	104		
				Day 14	21/05/92	35.90		50.00	110	65	96	115	70	104		
				Day 21	27/05/92	35.90		50.00	105	55	89	90	45	84		
				Day 28	03/06/92	35.70		50.00	110	60	92	100	60	100		
				Day 35	10/06/92	36.10		50.00	110	60	100	110	60	100		
	Day 42	17/06/92	36.60		50.00	100	68	102	90	70	102					
	243	Imipramine	Female	Screen	11/05/92	36.50	20		120	70	80	130	80	80		
				Day 0	18/05/92	36.60		54.50	125	75	84	130	85	104		
				Day 7	25/05/92	36.70		53.50	140	80	88	100	90	108		
				Day 14	01/06/92	36.90		53.60	100	70	80	75	60	88		
Day 21				08/06/92	36.80		53.60	100	75	76	95	75	80			
Day 28	15/06/92	36.80		53.30	110	70	80	115	80	96						
Day 35	22/06/92	36.50		53.00	120	85	76	120	80	84						
Day 42	29/06/92	36.60		53.30	105	75	76	110	85	80						
244	Reboxetine	Male	Screen	25/05/92	36.30			120	70	82	140	90	82			
			Day 0	05/06/92	36.70		90.00	120	90	72	130	90	80			
			Day 7	12/06/92	36.50		90.00	130	80	76	120	70	82			
			Day 14	19/06/92	36.70		90.00	130	80	80	130	70	84			
			Day 21	26/06/92	36.60		90.00	130	80	76	130	80	80			
			Day 28	03/07/92	36.50		90.00	140	90	80	140	90	88			
			Day 35	11/07/92	36.50		90.00	140	80	80	140	80	80			
			Day 42	17/07/92	36.80		90.00	130	70	100	130	70	100			
			257	Reboxetine	Female	Screen	10/07/91	36.70	22		115	95	76	120	80	88
						Day 0	17/07/91	36.60		79.00	110	70	80	120	80	80
Day 7	24/07/91	37.10					79.00	115	85	115	115	90	80			
Day 14	31/07/91	37.20					76.00	120	80	84	140	100	92			
Day 21	07/08/91	36.30					78.50	120	80	96	115	85	98			
Day 28	14/08/91	36.30		76.30	130	85	84	120	80	88						
Day 35	21/08/91	36.30		80.00	120	90	76	120	90	78						
Day 42	28/08/91	36.90		76.00	120	85	74	120	85	74						
258	Reboxetine	Male	Screen	10/07/91	36.70	21		130	80	76	135	80	80			
			Day 0	17/07/91	36.70		79.00	140	90	84	150	90	86			
			Day 7	24/07/91	36.40		79.00	130	80	84	155	95	84			
			Day 14	31/07/91	36.40		78.00	130	75	96	135	70	96			
			Day 21	07/08/91	36.90		77.50	125	100	72	130	105	72			
259	Imipramine	Female	Screen	10/07/91	36.40	22		130	50	60	135	75	68			
			Day 0	17/07/91	36.30		65.00	135	85	80	130	85	86			
			Day 7	24/07/91	36.50		65.00	130	85	82	125	80	86			
			Day 14	31/07/91	36.50		65.00	125	80	76	120	80	82			

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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)		
9	259	Imipramine	Female	Day 21	07/08/91			65.00	125	80	84	125	80	86
				Day 28	14/08/91			65.00	130	80	76	130	80	78
				Day 35	21/08/91			65.00	120	80	80	120	80	80
				Day 42	28/08/91	36.30		65.00	125	80	84	125	80	86
260	Imipramine	Female	Screen	17/07/91		36.70	20	49.50	120	65	64	110	60	86
			Day 0	24/07/91		36.80		49.50	110	80	88	110	73	80
			Day 7	31/07/91										
			Day 14	07/08/91		36.70		49.00	130	75	96	105	65	92
			Day 21	14/08/91		36.80		49.90	115	95	72	115	60	72
261	Imipramine	Female	Screen	19/07/91		36.40	24	94.00	145	80	76	145	80	76
			Day 0	23/07/91		36.70		94.00	135	95	80	140	90	76
			Day 7	30/07/91		36.90		97.00	150	90	96	160	95	92
262	Reboxetine	Male	Screen	16/07/91		36.40	20	96.00	150	100	72	145	105	80
			Day 0	23/07/91		36.70		97.00	140	100	84	140	95	92
			Day 7	30/07/91		36.20		97.00	150	80	76	140	70	78
			Day 14	06/08/91		36.60		97.00	130	80	88	135	85	92
			Day 21	13/08/91		36.30		95.00	160	90	110	170	100	112
			Day 28	20/08/91		36.30		95.00	150	75	88	155	80	92
			Day 35	27/08/91		36.30		97.00	110	70	100	130	90	108
Day 42	03/09/91		36.30		97.00	150	90	88	135	100	94			
263	Reboxetine	Female	Screen	24/07/91		36.90	18	59.00	115	90	76	130	90	72
			Day 0	31/07/91		36.90		59.00	115	70	80	110	70	86
			Day 7	07/08/91		36.80		59.00	115	90	82	120	85	92
			Day 14	14/08/91		36.30		59.00	110	80	80	115	85	84
264	Imipramine	Female	Screen	21/07/91		36.90	21	69.00	135	65	80	130	80	88
			Day 0	31/07/91		36.90		68.00	140	90	72	150	80	68
			Day 7	07/08/91		36.70		68.00	130	60	96	95	60	92
			Day 14	14/08/91		36.70		68.00	130	90	80	100	90	80
			Day 21	21/08/91		65.00		65.00	100	70	99	100	70	99
			Day 28	28/08/91		65.00		65.00	120	70	110	110	70	70
			Day 35	04/09/91		63.00		63.00	120	70	70	120	70	70
Day 42	11/09/91		36.70		66.00	110	70	68	110	70	68			
265	Reboxetine	Female	Screen	13/08/91		36.70	20	60.00	130	70	76	135	80	84
			Day 0	22/08/91		36.30		60.00	130	70	76	135	80	84
			Day 7	29/08/91		36.80		60.00	100	60	90	85	45	94
			Day 14	05/09/91		36.40		60.00	95	45	74	60.00	95	50
Day 21	12/09/91		36.30		60.00	120	70	82	115	75	86			

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REBOXETINE - PROTOCOL 20124/017
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)				
9	265	Reboxetine	Female	Day 28	19/09/91	36.40		57.50	120	80	84	115	75	96			
				Day 35	26/09/91	36.10		58.00	110	75	88	105	70	91			
				Day 42	03/10/91	36.30		58.50	90	45	76	85	40	86			
	266	Reboxetine	Female	Screen	10/09/91	36.30	20		130	75	76	135	80	84			
				Day 0	17/09/91	35.90		59.00	110	70	72	105	60	78			
				Day 7	24/09/91	35.90		60.50	110	65	74	105	70	104			
				Day 14	01/10/91	36.00		59.50	95	45	96	95	55	104			
				Day 21	08/10/91	36.30		59.50	90	45	85	90	50	90			
				Day 28	15/10/91	36.30		61.00	105	70	86	110	75	90			
267	Imipramine	Male	Day 35	22/10/91	36.30		60.00	120	90	90	125	95	103				
			Day 42	29/10/91	36.30		61.00	120	80	96	115	85	104				
267	Imipramine	Male	Screen	30/08/91	37.30	24		105	65	73	100	70	100				
			Day 0	30/08/91	36.00		72.00	120	80	80	100	80	89				
			Day 7	09/09/91	35.90		69.00	120	80	84	110	80	100				
			Day 14	16/09/91	36.50		73.90	130	80	78	120	90	80				
			Day 21	23/09/91	36.40		74.50	120	75	90	120	80	85				
			Day 28	30/09/91	36.70		74.00	130	85	112	135	90	110				
			Day 35	07/10/91	36.30		78.00	120	75	100	125	90	96				
			Day 42	14/10/91	36.50		80.00	140	90	92	130	90	96				
			268	Imipramine	Female	Screen	17/09/91	36.10	20		130	80	80	140	70	84	
						Day 0	24/09/91	36.70		92.00	145	75	102	125	80	112	
						Day 7	01/10/91	36.70		91.00	120	85	108	125	85	112	
						Day 14	08/10/91	36.30		90.50	120	80	110	130	95	114	
Day 21	15/10/91	36.30					90.50	155	95	112	160	100	120				
Day 28	22/10/91	36.40					90.50	130	80	104	135	85	120				
268	Imipramine	Female	Day 35	29/10/91	36.40		90.00	135	90	96	120	85	96				
			Day 42	05/11/91	35.30		91.00	130	80	80	140	100	84				
			Screen	19/09/91	36.80	18		160	85	90	150	80	85				
			Day 0	26/09/91	36.40		81.50	115	75	85	110	70	90				
			Day 7	01/10/91	36.40		82.00	130	80	88	125	75	96				
			Day 14	08/10/91	36.30		82.00	115	80	88	120	85	88				
269	Reboxetine	Male	Day 21	15/10/91	36.00		82.50	135	80	70	140	85	82				
			Day 28	22/10/91	36.40		83.00	135	75	84	135	80	92				
			Day 35	29/10/91	36.20		84.00	120	70	96	120	80	96				
			Day 42	05/11/91	36.20		85.00	120	75	76	116	80	80				
			Screen	02/10/91	36.90	22		145	100	72	130	90	76				
			Day 0	10/10/91	36.40		52.00	110	85	72	115	85	72				
270	Imipramine	Female	Day 7	17/10/91	36.30		57.00	75	40	150	65	40	156				

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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 Heart Rate (beats/min)			
9	271	Reboxetine	Female	Screen	22/10/91	36.30	20	64.90	160	100	60	150	55	64	
				Day 0	29/10/91	36.00		64.90	130	80	72	140	80	80	80
				Day 7	05/11/91	36.40		62.50	120	80	60	130	90	90	60
				Day 14	12/11/91	36.20		66.50	110	80	72	120	80	76	76
	272	Imipramine	Male	Screen	22/10/91	36.40	21	84.00	150	75	88	140	90	92	
				Day 0	29/10/91	36.30		84.00	120	90	54	140	60	60	60
				Day 7	05/11/91	37.00		86.00	125	90	60	145	90	62	62
				Day 14	12/11/91	36.30		81.50	120	90	64	130	90	60	60
	273	Imipramine	Female	Screen	24/10/91	36.60	20	73.00	130	70	88	135	75	92	
				Day 0	29/10/91	36.90		72.00	100	65	76	110	70	88	88
				Day 7	05/11/91	35.90		71.60	110	65	84	120	80	92	92
				Day 14	12/11/91	36.20		72.50	100	70	76	110	70	80	80
274	Reboxetine	Female	Screen	23/10/91	36.40	21	62.50	130	65	88	130	55	88		
			Day 0	30/10/91	36.90		61.00	130	90	84	130	95	72	72	
			Day 7	06/11/91	36.30		61.00	110	65	72	115	65	87	87	
			Day 28	26/11/91	36.70		61.00	100	70	72	90	65	76	76	
274/A	Reboxetine	Female	Screen	21/04/92	35.80	18	52.00	120	80	64	125	85	68		
			Day 0	12/05/92	36.30		52.00	120	80	72	120	80	76	76	
			Day 7	19/05/92	36.30		50.00	100	65	72	95	65	76	76	
			Day 14	26/05/92	36.50		52.00	130	80	80	120	80	86	86	
	275	Reboxetine	Female	Screen	31/10/91	36.00	18	69.50	160	100	88	150	100	80	
				Day 0	05/11/91	37.00		69.50	120	75	68	130	65	72	72
				Day 7	12/11/91	36.80		69.40	130	80	76	120	70	80	80
				Day 14	19/11/91	36.90		68.80	130	80	80	120	80	88	88
	275	Reboxetine	Female	Screen	03/12/91	36.70		68.50	110	70	68	120	80	72	
				Day 0	10/12/91	36.70		68.50	110	75	70	125	85	85	85
				Day 7	17/12/91	36.70		68.50	110	75	70	125	85	85	85
				Day 28	03/12/91	36.70		68.50	110	75	70	125	85	85	85

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PHARMACIA CHS R&D

REBOXETINE - PROTOCOL 20124/017
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	275	Reboxetine	Female	Day 35	10/12/91	36.70		68.50	115	75	75	130	85	75
				Day 42	17/12/91	37.00		68.50	115	70	70	125	75	74
	276	Imipramine	Female	Screen	24/12/91	36.40	20	71.50	160	105	96	140	110	96
				Day 0	09/01/92	37.20		68.50	145	90	68	150	95	72
	276/A	Imipramine	Male	Day 7	16/01/92	36.30		68.50	145	80	68	135	75	74
				Screen	24/02/92	36.30	18	88.00	130	100	73	130	95	73
	276/B	Imipramine	Male	Day 0	03/03/92	36.90		88.00	120	80	72	130	80	72
				Day 7	10/03/92	36.70		88.00	130	90	76	130	75	84
	276/C	Imipramine	Male	Day 14	17/03/92	36.30		88.50	120	70	80	120	70	80
				Day 21	24/03/92	36.30		88.00	130	90	82	135	90	84
	276/D	Imipramine	Male	Day 28	31/03/92	36.70		88.00	120	70	80	120	70	80
				Day 35	07/04/92	36.20		84.00	125	70	84	125	75	86
	276/E	Imipramine	Male	Day 42	14/04/92	36.50		87.00	150	90	86	150	80	86
				Screen	11/05/92	36.50	20	72.00	140	70	76	130	70	76
9/A	253	Imipramine	Male	Day 0	13/05/92	36.50		72.00	130	70	76	130	70	76
				Day 7	20/05/92	36.80		72.00	120	60	76	110	50	84
	253/A	Imipramine	Male	Day 14	27/05/92	36.50		72.00	115	60	72	100	50	80
				Day 21	03/06/92	36.80		72.50	110	60	80	100	50	84
	253/B	Imipramine	Male	Day 28	10/06/92	36.70		73.00	120	70	76	110	70	80
				Day 35	17/06/92	36.70		72.00	110	60	76	110	50	84
	253/C	Imipramine	Male	Day 42	24/06/92	36.80		72.50	120	70	76	110	65	76
				Screen	18/05/92	36.60	18	44.00	115	75	76	108	70	80
	253/D	Reboxetine	Female	Day 0	21/05/92	36.50		44.00	115	75	72	105	70	76
				Day 7	29/05/92	36.40		44.00	110	75	72	100	70	76
	253/E	Reboxetine	Female	Day 14	04/06/92	36.50		43.00	120	70	76	105	75	72
				Day 21	11/06/92	36.40		42.50	115	85	72	100	80	76
	253/F	Reboxetine	Female	Day 28	18/06/92	36.70		43.00	110	80	80	100	75	76
				Day 35	25/06/92	36.50		43.50	115	80	80	105	75	80
	253/G	Reboxetine	Female	Day 42	02/07/92	36.80		43.50	110	70	80	110	65	84
				Screen	22/05/92	36.80	18	63.00	120	80	96	95	70	104
	255	Reboxetine	Male	Day 0	26/05/92	36.50		63.00	120	80	92	100	70	96
				Day 7	01/06/92	36.70		63.00	120	80	90	110	70	94
	255/A	Reboxetine	Male	Day 14	08/06/92	36.80		65.00	110	70	88	95	70	86
				Day 21	16/06/92	36.80		64.00	110	65	80	105	65	100
	255/B	Reboxetine	Male	Day 28	22/06/92	36.70		65.00	115	80	88	110	80	108
				Day 35	29/06/92	36.80		65.00	125	70	90	110	70	100
	256	Imipramine	Male	Screen	12/05/92	36.80	18	120	120	70	76	120	70	80

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PHARMACIA CNS R&D

REBOXETINE - PROTUDOL 20124/017
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/A	236	Imipramine	Male	Day 0	26/05/92	36.70		78.00	120	70	72	115	70	76
				Day 7	02/06/92	36.80		78.50	110	70	68	110	70	68
				Day 14	10/06/92	36.70		79.00	125	80	96	100	80	100
				Day 21	16/06/92	36.50		79.50	125	80	96	105	60	90
				Day 28	23/06/92	36.70		79.00	130	80	76	115	70	80
	277	Reboxetine	Female	Day 35	30/06/92	36.50		79.00	140	70	72	120	70	76
				Day 42	07/07/92	36.80		79.50	125	65	76	120	65	76
				Screen	05/06/92	36.20	16		110	70	60	110	70	60
	278	Imipramine	Female	Day 0	09/06/92	36.40		77.00	115	65	64	100	60	64
				Day 7	16/06/92	36.50		77.00	120	70	66	110	60	70
				Screen	10/06/92	36.80	16		150	70	76	140	70	80
				Day 0	12/06/92	36.70		56.30	160	80	80	160	80	80
				Day 7	19/06/92	36.50		57.20	140	80	96	125	80	100
	279	Imipramine	Male	Day 14	28/06/92	36.60		59.00	130	80	84	120	80	80
				Day 21	05/07/92	36.50		59.00	135	80	80	120	80	80
				Screen	03/08/92	36.70	20		125	80	64	120	80	68
	280	Reboxetine	Female	Day 0	06/08/92	36.80		78.00	125	80	60	120	90	68
				Day 7	14/08/92	36.60		78.00	130	90	72	120	95	76
				Day 14	21/08/92	36.50		77.50	140	90	76	135	90	80
	281	Reboxetine	Female	Screen	04/08/92	36.50	18	70.00	120	70	72	110	65	80
				Day 0	07/08/92	36.50		70.00	130	70	76	125	70	84
				Day 7	14/08/92	36.60		70.00	135	70	76	130	70	88
				Screen	25/08/92	36.20	18		150	100	68	140	100	68
				Day 0	31/08/92	36.50		66.00	150	100	72	135	90	76
	282	Reboxetine	Male	Day 7	07/09/92	36.70		80.00	110	70	88	100	70	88
				Day 14	14/09/92	36.80		80.00	110	60	84	105	60	88
				Day 21	21/09/92	36.80		68.50	110	60	84	105	60	88
				Day 28	28/09/92	36.80		69.00	140	90	88	110	80	88
				Day 35	05/10/92	36.50		68.00	135	70	96	110	70	100
	282	Reboxetine	Male	Day 42	12/10/92	36.80		70.00	130	80	100	120	80	100
				Screen	14/08/92	36.50	20		130	80	80	105	60	88
				Day 0	01/09/92	36.80		80.00	140	80	76	110	60	84
				Day 7	08/09/92	36.70		80.00	110	80	60	100	80	68
				Day 14	15/09/92	36.80		78.50	125	70	76	135	95	80
	282	Reboxetine	Male	Day 21	22/09/92	36.50		75.50	100	80	108	100	70	112
				Day 28	29/09/92	36.50		74.00	120	80	88	100	70	100
				Day 35	06/10/92	36.70		74.00	130	80	76	120	80	100

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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/A	282	Reboxetine	Male	Day 42	13/10/92	36.50		74.00	120	80	64	110	80	80	80
	283	Imipramine	Female	Screen	11/09/92	36.50	16		130	70	72	110	65	76	76
				Day 0	16/09/92	36.70		73.00	140	80	68	130	75	72	72
				Day 7	23/09/92	36.80		73.00	145	85	72	140	85	76	76
				Day 14	30/09/92	36.70		73.00	140	80	72	130	80	72	72
				Day 21	07/10/92	36.70		74.00	120	70	80	110	60	84	84
				Day 28	14/10/92	36.50		74.00	125	75	76	110	65	80	80
				Day 35	21/10/92	36.80		74.00	120	70	76	120	70	76	76
				Day 42	28/10/92	36.70		74.50	110	60	76	110	60	84	84
	284	Imipramine	Male	Screen	16/09/92	36.80	20		140	75	68	130	70	72	72
				Day 0	18/09/92	36.80		78.00	130	70	72	125	70	72	72
				Day 7	25/09/92	36.80		78.00	105	60	68	100	60	72	72
				Day 14	02/10/92	36.90		79.00	110	70	72	100	60	72	72
				Day 21	09/10/92	36.70		78.50	110	70	68	110	60	76	76
	301	Imipramine	Female	Screen	28/02/92	36.50	20		120	70	72	120	70	76	76
				Day 0	04/03/92	36.80		60.00	125	75	76	120	65	72	72
				Day 7	12/03/92	36.50		60.00	105	70	76	100	65	80	80
				Day 14	18/03/92	36.80		60.50	118	60	72	105	60	76	76
				Day 21	25/03/92	36.50		61.00	100	70	68	100	60	76	76
				Day 28	01/04/92	36.80		61.00	110	70	72	100	70	72	72
				Day 35	08/04/92	36.80		61.00	100	70	72	100	60	80	80
				Day 42	15/04/92	36.80		62.00	110	70	72	100	60	84	84
	302	Imipramine	Male	Screen	02/03/92	36.80	24		140	75	80	125	70	76	76
				Day 0	05/03/92	36.80		76.00	140	70	72	130	70	72	72
				Day 7	13/03/92	36.70		76.00	120	70	72	110	60	76	76
				Day 14	20/03/92	36.70		76.00	120	70	76	110	70	84	84
				Day 21	23/03/92	36.70		76.80	130	70	80	120	70	84	84
	303	Reboxetine	Female	Screen	06/03/92	36.80	22		120	80	76	110	80	100	100
				Day 0	11/03/92	36.50		77.50	110	70	72	110	70	80	80
				Day 7	18/03/92	36.80		77.00	100	70	72	100	60	76	76
				Day 14	25/03/92	36.50		77.00	95	70	72	90	60	80	80
				Day 21	31/03/92	36.80		77.00	100	70	72	90	60	84	84
	304	Reboxetine	Female	Screen	11/03/92	36.80	20		120	70	72	120	70	72	72
				Day 0	25/03/92	36.50		65.50	120	70	72	130	80	72	72
				Day 7	01/04/92	36.80		64.50	120	80	64	120	80	68	68
				Day 14	08/04/92	36.60		64.00	125	80	80	115	70	88	88
				Day 21	15/04/92	36.50		64.00	105	65	92	95	60	96	96

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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)		
9/A	304	Reboxetine	Female	Day 28	22/04/92	36.50		64.00	95	70	72	90	70	76
				Day 35	29/04/92	36.80			120	80	80	110	70	80
				Day 42	06/05/92	36.70			120	80	88	110	70	92
305	Reboxetine	Male	Screen	25/03/92	36.50	18			120	70	64	100	60	72
			Day 0	30/03/92			70.00	115	75	64	95	60	96	
			Day 7	06/04/92	36.80		70.00	100	70	84	95	75	104	
			Day 14	13/04/92	36.50		69.80	130	80	72	120	70	104	
			Day 21	20/04/92	36.80		68.50	100	70	80	90	60	92	
			Day 28	27/04/92	36.50		70.50	125	70	84	110	70	108	
			Day 35	04/05/92	36.80		70.50	120	70	80	110	70	100	
Day 42	11/05/92	36.50		70.50	110	75	76	110	70	84				
306	Reboxetine	Female	Screen	24/04/92	36.60	20			100	70	96	90	60	100
			Day 0	28/04/92	36.70		48.00	110	70	96	100	60	96	
			Day 7	05/05/92	36.70		48.00	120	70	96	110	70	96	
			Day 14	12/05/92	36.80		49.20	120	80	88	110	70	96	
			Day 21	19/05/92	36.50		49.20	120	70	88	100	55	90	
			Day 28	26/05/92	36.40		49.50	120	70	84	100	55	88	
			Day 35	02/06/92	36.60		49.50	115	65	80	100	60	88	
Day 42	09/06/92	36.80		50.00	120	70	80	110	60	88				
307	Imipramine	Female	Screen	30/04/92	36.90	16			120	70	76	110	70	80
			Day 0	05/05/92	36.50		80.00	120	70	76	120	70	80	
			Day 7	11/05/92	36.50		80.00	130	80	72	120	70	80	
308	Imipramine	Female	Screen	07/05/92	36.80	20			115	70	96	115	65	100
			Day 0	09/05/92	36.50		62.00	110	70	104	115	70	100	
			Day 7	15/05/92	36.80		61.00	120	60	100	105	70	96	
			Day 14	22/05/92	36.50		61.00	110	70	96	110	70	96	
			Day 21	29/05/92	36.80		61.00	120	65	110	115	60	100	
Day 28	02/06/92	36.80		61.00	120	70	90	120	80	120				
10	289	Imipramine	Female	Screen	16/09/91	36.40	14		150	110	64	140	90	64
				Day 0	28/09/91	36.60		79.50	150	110	64	140	90	64
				Day 7	27/09/91	36.40		79.00	145	80	60	140	90	64
290	Reboxetine	Male	Screen	07/10/91	36.70	24			120	70	80	120	80	100
			Day 0	14/10/91	37.00		75.80	130	80	68	100	70	64	
			Day 7	21/10/91	36.00		76.00	105	60	68	90	60	68	
			Day 14	28/10/91	36.00		76.30	110	50	88	76.00	90	92	
			Day 21	04/11/91	36.80		75.20	130	70	64	105	60	64	
Day 28	11/11/91	36.30		75.30	110	85	84	100	70	80				

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATAS

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		
10	290	Reboxetine	Male	Day 35	18/11/91	36.60		74.40	120	90	80	110	85	76
				Day 42	25/11/91	36.00		74.00	100	70	100	120	70	134
291	291	Imipramine	Male	Screen	13/02/92	36.20	14		120	70	72	120	75	72
				Day 0	17/02/92	36.00		84.00	120	70	72	120	75	72
				Day 7	24/02/92	36.60		86.00	142	75	68	120	80	88
				Day 14	02/03/92	36.60		86.00	110	70	76	110	65	68
				Day 21	09/03/92	36.00		86.60	120	80	76	90	60	80
				Day 28	16/03/92	36.20		88.40	140	80	80	100	70	88
				Day 35	23/03/92	36.00		88.80	120	80	76	90	70	80
				Day 42	30/03/92	36.00		90.50	130	70	80	100	60	88
292	292	Reboxetine	Female	Screen	06/12/91	36.60	20		90	60	52	120	80	60
				Day 0	13/12/91	36.00		70.00	110	60	88	110	70	80
				Day 7	20/12/91	36.60		69.00	100	60	72	120	70	80
				Day 14	27/12/91	36.50		67.90	140	80	80	125	70	84
				Day 21	03/01/92	37.10		68.30	120	75	72	110	70	68
				Day 28	10/01/92	36.60		67.00	115	70	72	110	70	68
				Day 35	18/01/92	36.00		68.00	120	80	74	110	75	72
				Day 42	25/01/92	36.00		68.60	120	80	72	110	70	72
293	293	Reboxetine	Female	Screen	16/12/91	35.70	28		150	100	80	150	100	100
				Day 0	24/12/91	36.80		57.50	120	70	96	100	60	120
				Day 7	31/12/91	36.30		57.80	140	80	104	150	90	104
				Day 14	07/01/92	36.30		58.00	140	80	88	120	90	112
				Day 21	14/01/92	36.40		57.00	140	70	100	145	80	80
				Day 28	21/01/92	36.50		57.40	160	80	100	145	90	96
				Day 35	28/01/92	36.60		57.00	110	70	88	130	90	108
				Day 42	04/02/92	37.20		57.00	130	70	108	120	60	120
294	294	Imipramine	Female	Screen	30/12/91	36.50	20		130	80	84	130	80	84
				Day 0	02/01/92	36.00		55.00	130	80	80	130	80	86
				Day 7	09/01/92	36.80		54.50	150	100	72	150	85	100
				Day 14	16/01/92	36.30		54.50	150	100	72	135	85	100
				Day 21	23/01/92	36.60		54.00	140	70	80	150	80	88
295	295	Imipramine	Male	Screen	02/01/92	36.00	16		120	80	64	120	100	84
				Day 0	06/01/92	36.00		87.00	120	80	64	120	100	84
				Day 7	14/01/92	36.50		86.00	100	100	100	130	80	96
				Day 14	20/01/92	36.80		86.90	100	70	72	100	70	72
				Day 21	27/01/92	36.40		86.90	100	100	72	100	85	100
				Day 28	03/02/92	36.00		86.50	110	70	68	100	100	100
				Day 35	10/02/92	36.20		84.50	120	70	80	130	80	80
				Day 42	17/02/92	36.50		85.00	95	60	76	95	70	80

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PIARNACIA CNS 8&D
REBOXETINE - PROTOCOL 20124/017
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		
10	296	Reboxetine	Female	Screen	15/02/92	36.40	18	64.50	110	70	76	90	65	76
				Day 0	20/02/92	36.40		67.00	110	70	76	90	65	76
				Day 7	27/02/92	36.40		67.00	85	50	100	80	60	100
				Day 14	05/03/92	36.20		65.50	140	80	72	100	60	68
				Day 21	12/03/92	36.40		66.00	120	80	76	90	60	76
				Day 28	19/03/92	36.10		67.50	130	80	76	90	60	88
				Day 35	26/03/92	36.60		67.50	140	80	72	110	70	72
				Day 42	02/04/92	36.20		67.80	120	70	72	110	70	76
				Screen	19/03/92	37.00	20	68.50	105	70	60	110	85	100
				Day 0	20/03/92	37.00		68.50	105	70	76	110	85	80
Day 7	28/03/92	36.80		68.00	110	75	76	100	80	80				
Day 14	04/04/92	36.60		68.50	105	70	76	100	70	80				
Day 21	11/04/92	36.20		68.60	120	86	68	110	70	76				
Day 28	18/04/92	36.40		71.00	130	80	83	100	60	96				
Day 35	25/04/92	36.60		71.00	130	80	83	100	60	92				
Day 42	02/05/92	36.60		72.00	130	80	84	100	80	92				
298	298	Reboxetine	Female	Day 0	26/03/92	36.50		66.50	100	65	80	120	60	72
				Day 7	02/04/92	36.50		64.80	105	50	100	105	50	100
				Day 14	09/04/92	36.70		65.00	160	100	80	120	90	100
				Day 21	16/04/92	36.40		65.50	160	100	80	160	90	96
				Day 28	23/04/92	36.50		65.00	100	65	80	120	60	72
				Day 35	30/04/92	36.30		68.50	200	120	100	200	120	100
				Day 42	07/05/92	36.70		65.00	130	65	72	125	70	80
				Screen	02/04/92	36.60		82.50	160	80	75	140	80	85
				Day 0	07/04/92	36.60		82.50	160	90	80	160	100	80
				Day 7	14/04/92	36.40		83.00	160	90	84	160	80	80
Day 14	21/04/92	36.50		83.00	120	80	76	120	90	80				
Day 21	28/04/92	36.60		83.00	150	90	84	150	100	84				
Day 28	05/05/92	36.40		82.50	140	80	105	120	80	98				
Day 35	12/05/92	36.00		83.50	110	80	80	130	90	80				
Day 42	19/05/92	36.40		83.00	160	110	98	160	120	90				
300	300	Imipramine	Female	Screen	07/04/92	37.00	20	102.00	160	90	84	150	80	86
				Day 0	14/04/92	37.20		102.00	160	100	104	160	90	100
				Day 7	21/04/92	36.80		102.00	180	120	92	160	100	92
				Day 14	05/05/92	36.80		103.00	180	100	84	200	120	84
				Day 21	12/05/92	36.40		103.00	165	100	84	160	90	84
				Day 28	19/05/92	36.40		103.00	160	90	84	140	80	86
				Day 35	26/05/92	36.80		102.00	180	100	94	180	100	98

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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)	Standing D.B.P. (mmHg)	Heart Rate (beats/min)
11	321	Reboxetine	Female	Screen	09/06/92	36.50	19	76.00	120	90	90	110	80	80
				Day 0	10/06/92	37.40		75.00	115	80	74	120	85	80
				Day 7	18/06/92	36.50		75.00	120	90	90	110	80	80
				Day 14	25/06/92	36.00		74.00	105	80	104	105	80	120
				Day 21	02/07/92	36.70		74.50	120	80	80	105	80	84
				Day 28	09/07/92	36.80		73.20	125	90	72	120	90	80
				Day 35	16/07/92	37.00		73.20	120	90	98	120	80	102
Day 42	23/07/92	36.80		73.00	130	90	88	120	85	90				
322	322	Reboxetine	Female	Screen	08/06/92	36.60	20	63.50	115	80	90	110	85	96
				Day 0	11/06/92	36.80		63.50	115	80	94	110	85	100
				Day 7	18/06/92	36.50		63.80	115	85	96	110	80	106
				Day 14	25/06/92	35.80		64.00	120	85	98	130	90	110
				Day 21	02/07/92	36.70		62.90	120	85	84	110	80	86
				Day 28	09/07/92	37.50		63.60	120	95	96	120	95	98
				Day 35	16/07/92	37.00		63.40	120	85	104	115	80	110
Day 42	24/07/92	35.50		62.80	125	85	82	115	80	86				
323	323	Imipramine	Female	Screen	18/06/92	36.80	20	58.70	120	80	76	115	80	84
				Day 0	23/06/92	37.20		58.70	120	80	78	115	75	88
				Day 7	01/07/92	36.50		59.30	115	82	86	100	75	84
				Day 14	08/07/92	35.00		60.00	125	80	82	115	80	84
				Day 21	15/07/92	36.40		60.40	115	70	88	110	70	98
				Day 28	22/07/92	37.00		61.10	110	75	88	105	70	92
				Day 35	30/07/92	36.50		61.40	120	75	90	115	70	98
Day 42	06/08/92	36.20		60.60	115	80	90	110	80	92				
324	324	Imipramine	Male	Screen	06/07/92	36.50	18	70.80	120	80	64	120	90	70
				Day 0	17/07/92	36.50		70.80	120	80	64	120	90	70
				Day 7	24/07/92	36.70		69.40	130	85	78	115	80	84
				Day 14	31/07/92	36.20		70.00	130	85	80	125	90	100
				Day 21	07/08/92	36.20		70.00	125	90	84	125	85	98
				Day 28	14/08/92	36.50		70.50	115	85	80	115	90	88
				Day 35	21/08/92	37.00		70.50	135	85	98	125	80	120
Day 42	28/08/92	36.80		72.50	135	75	90	130	80	112				
325	325	Reboxetine	Female	Screen	23/07/92	37.00	20	60.90	120	80	72	120	90	80
				Day 0	30/07/92	37.40		60.90	120	80	72	120	90	80
				Day 7	06/08/92	36.80		60.10	125	80	96	120	80	118
				Day 14	13/08/92	36.30		60.20	130	85	80	120	90	92
				Day 21	20/08/92	36.60		60.00	130	75	94	115	75	126
				Day 28	27/08/92	36.00		60.40	120	80	98	105	80	102
				Day 35	03/09/92	36.50		61.00	150	80	72	135	100	82

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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		
11	325	Reboxetine	Female	Day 42	10/09/92	36.30		59.00	130	80	84	110	85	100
	326	Imipramine	Male	Screen	24/07/92	36.50	18	83.70	135	80	82	125	90	90
				Day 0	30/07/92	36.50		82.80	135	85	82	125	90	88
				Day 7	06/08/92	36.40		82.00	135	75	76	125	85	86
				Day 14	13/08/92	36.00		81.40	120	70	93	125	80	126
				Day 21	20/08/92	36.40		80.80	130	80	88	120	85	102
				Day 28	27/08/92	35.80		81.50	160	100	92	135	90	102
				Day 35	03/09/92	37.00		80.00	125	90	88	110	90	96
				Day 42	10/09/92	36.50								
	327	Reboxetine	Female	Screen	18/08/92	36.40	20	74.60	140	90	68	130	90	72
				Day 0	20/08/92	36.40		74.80	120	80	72	120	85	75
				Day 7	27/08/92	36.00		75.00	130	85	74	125	90	82
				Day 14	03/09/92	36.00		73.50	120	100	62	125	100	65
				Day 21	10/09/92	36.70		74.90	125	85	68	105	85	92
				Day 28	17/09/92	35.40		74.30	110	70	85	110	80	98
				Day 35	24/09/92	35.60		75.60	115	80	88	110	80	98
				Day 42	01/10/92	35.60			120	80	72	120	80	80
	328	Imipramine	Male	Screen	18/08/92	36.00	18	79.50	140	80	64	130	80	72
				Day 0	20/08/92	36.60		78.50	125	85	68	125	90	80
				Day 7	27/08/92	36.70		79.00	130	85	76	125	90	86
				Day 14	03/09/92	36.00		78.50	140	70	80	140	80	96
				Day 21	10/09/92	36.00		78.50	160	80	76	150	100	84
				Day 28	17/09/92	36.40		79.30	135	85	88	130	90	100
	329	Imipramine	Female	Screen	18/08/92	36.50	18	76.30	110	70	70	115	70	78
				Day 0	21/08/92	36.40		76.30	125	65	86	115	65	96
				Day 7	28/08/92	36.00		79.40	115	65	88	115	70	92
				Day 14	04/09/92	36.00		78.00	140	60	80	120	80	84
				Day 21	11/09/92	36.00		77.50	125	90	68	120	90	64
				Day 28	18/09/92	36.60		77.40	110	70	96	110	75	114
				Day 35	25/09/92	37.00		77.70	115	75	88	115	85	115
				Day 42	02/10/92	36.00		77.50	115	75	88	115	80	96
	330	Reboxetine	Female	Screen	21/08/92	36.80	18	75.50	120	70	68	110	75	76
				Day 0	24/08/92	36.50		74.50	115	70	64	110	80	72
				Day 7	31/08/92	36.00			100	80	80	110	80	78
	331	Reboxetine	Male	Screen	01/09/92	36.00	20	74.00	125	90	84	130	100	106
				Day 0	03/09/92	36.20		73.00	140	100	80	140	90	98
				Day 7	10/09/92	36.30			140	100	78	140	100	88

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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)
11	331	Reboxetine	Male	Day 14	17/09/92	36.00		73.30	130	85	88	130	100	102
				Day 21	24/09/92	36.60		73.20	130	90	72	135	90	80
				Day 28	02/10/92	36.50		72.80	120	95	72	115	95	116
				Day 35	09/10/92	36.60		73.60	130	85	84	125	90	92
	Day 42	15/10/92	36.40		73.20	130	90	80	125	90	98			
	332	Imipramine	Female	Screen	31/08/92	36.50	18							
				Day 0	04/09/92	36.20		55.00	120	70	64	115	80	68
				Day 7	14/09/92	36.40		55.00	115	80	58	115	80	64
				Day 14	21/09/92	36.50		54.70	110	80	80	100	70	92
				Day 21	28/09/92	36.60		54.90	110	80	88	100	80	92
				Day 28	05/10/92	36.70		55.00	110	75	88	105	80	94
Day 35				12/10/92	36.70		54.80	105	80	80	110	80	92	
Day 42	20/10/92	36.80		54.70	105	85	82	95	75	100				
12	333	Imipramine	Female	Screen	04/09/92	36.00	20							
				Day 0	04/09/92	36.00		74.00	110	90	74	120	85	80
				Day 7	11/09/92	36.70		72.00	135	100	76	140	100	80
				Day 14	18/09/92	36.80		70.60	120	80	82	120	85	98
	Day 21	25/09/92	36.00		69.20	110	80	92	105	80	98			
	Day 28	02/10/92	36.20		69.10	120	80	82	110	75	90			
	Day 35	09/10/92	36.50		69.10	120	80	86	115	80	90			
	Day 42	16/10/92	36.60		69.50	120	80	80	115	80	88			
	337	Imipramine	Female	Screen	11/05/92	35.80	24							
				Day 0	25/05/92	36.00		72.00	130	80	76	110	80	88
				Day 7	01/06/92	36.00		71.00	120	70	72	110	90	86
Day 14				08/06/92	35.80		70.00	140	80	80	130	90	81	
Day 21				15/06/92	37.00		71.00	140	80	96	130	90	96	
Day 28				22/06/92	36.00		71.00	120	80	80	120	75	75	
Day 35				29/06/92	36.00		69.00	115	85	80	120	80	100	
Day 42	06/07/92	35.50		70.00	140	80	94	120	90	94				
338	Reboxetine	Female	Screen	11/06/92	37.00	21								
			Day 0	19/06/92	36.00		56.00	120	80	75	110	75	75	
			Day 7	26/06/92	36.40		53.00	110	70	78	110	70	76	
			Day 14	03/07/92	36.00		53.00	110	60	94	100	70	98	
			Day 28	17/07/92	36.20		54.00	140	90	110	90	70	108	
Day 35	24/07/92	36.10		55.20	120	80	100	130	85	78				
339	Imipramine	Male	Screen	19/06/92	37.00	21								
			Day 0	22/06/92	36.40		77.00	130	90	89	135	90	90	
			Day 7	29/06/92	35.60		77.00	150	90	78	110	75	80	
			Day 14	06/07/92	36.40		78.00	140	80	76	100	70	96	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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)
12	339	Imipramine	Male	Day 28	20/07/92	36.20		80.00	150	100	92	130	80	90
				Day 35	27/07/92	35.00		80.00	135	90	94	130	80	84
1421	340	Reboxetine	Female	Screen	04/08/92	35.80	24		100	64	98	84	62	104
				Day 0	06/08/92	35.60		65.00	120	70	74	110	70	84
				Day 7	13/08/92	35.30		64.00	130	78	92	120	70	100
				Day 14	20/08/92	35.20		65.00	138	90	84	110	70	72
				Day 21	27/08/92	34.80		64.00	110	70	80	110	60	84
				Day 28	03/09/92	34.80		63.00	110	60	84	120	80	86
				Day 35	10/09/92	33.70		63.00	120	80	82	110	90	82
Day 42	17/09/92	36.00		64.50	130	80	76	110	80	110				
13	341	Reboxetine	Female	Screen	17/08/92	37.00	18		120	70	92	130	90	86
				Day 0	20/08/92	36.00		56.00	140	80	82	130	90	86
				Day 7	27/08/92	36.50		55.00	130	80	96	130	90	96
				Day 14	03/09/92	36.60		54.90	110	60	84	120	70	96
				Day 21	10/09/92	36.60		53.70	130	70	86	120	70	88
				Day 28	17/09/92	36.00		53.80	128	70	94	120	68	90
				Day 35	24/09/92	36.00		54.00	120	80	100	120	80	96
13	353	Reboxetine	Female	Screen	05/06/92	37.00	19		122	70	66	118	80	68
				Day 0	05/06/92	37.00		73.50	122	70	66	118	80	68
				Day 7	15/06/92	37.00		70.00	110	70	68	90	70	68
				Day 14	22/06/92	37.00		71.00	140	90	96	90	70	68
				Day 21	29/06/92	37.00		71.50	140	95	62	120	90	64
				Day 28	06/07/92	37.00		70.00	122	80	60	95	70	68
				Day 35	13/07/92	37.00		70.00	120	85	60	105	85	72
13	354	Imipramine	Female	Screen	24/06/92	37.00			140	90	76	140	90	
				Day 0	24/06/92	37.00		47.00	140	90	76	140	90	
				Day 7	01/07/92	36.70		47.00	145	80	72	140	85	74
				Day 14	09/07/92	36.70		47.00	140	80	80	160	110	
				Day 21	16/07/92	37.00		47.50	160	88	72	140	95	80
				Day 28	22/07/92	36.70		46.50	130	90	80	130	95	86
				Day 35	29/07/92	36.70		49.50	143	80	82	115	90	70
Day 42	05/08/92	36.70		47.00	142	80	72	105	92	76				
13	355	Reboxetine	Female	Screen	17/06/92	37.00			90	65	58	85	60	
				Day 0	24/06/92	37.00		56.00	95	70	54	90	70	56
13	356	Imipramine	Male	Screen	22/07/92	36.30			105	60	58	105	70	
				Day 0	22/07/92	36.30		56.00	105	60	58	105	70	68

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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		
13	356	Imipramine	Male	Day 7	29/07/92	36.30		56.00	105	75	84	90	75	104
				Day 14	05/08/92	36.40		56.40	95	60	96	105	80	100
				Day 21	12/08/92	36.70		55.50	90	60	88	110	80	112
				Day 28	19/08/92	36.70		55.00	118	90	68	115	95	72
				Day 35	26/08/92	36.50		57.50	105	70	84	100	70	96
				Day 42	02/09/92			57.50	80	50	88	90	60	88
	357	Imipramine	Female	Screen	05/08/92	37.20	16		150	70	84	130	73	92
				Day 0	05/08/92	37.20		56.50	150	70	84	130	73	92
				Day 7	12/08/92	36.30								
	358	Reboxetine	Male	Screen	06/08/92	36.70	14		115	85	64	105	93	72
				Day 0	06/08/92	36.70		67.00	115	85	64	105	93	72
				Day 7	13/08/92	36.40		67.50	114	75	72	102	84	102
				Day 14	20/08/92	36.80		64.00	110	75	64	105	85	68
				Day 21	27/08/92	36.70		66.00	118	73	66	105	76	68
				Day 28	03/09/92	36.60		65.50	120	75	64	105	88	
	359	Reboxetine	Female	Screen	19/08/92	37.00			130	70	80	120	80	84
				Day 0	19/08/92	37.00		58.00	130	70	80	120	80	84
				Day 7	26/08/92	36.10		59.00	150	85	64	130	80	76
				Day 14	02/09/92	36.40		57.00	130	70	64	110	70	88
				Day 21	09/09/92	36.60		60.00	118	72	60	122	84	68
				Day 28	16/09/92	37.10		58.00	125	80	110	80	80	
				Day 35	23/09/92	35.90		56.00	140	80	64	125	64	
				Day 42	30/09/92	36.40		58.00	108	72	60	110	80	64
	360	Imipramine	Female	Screen	19/08/92	36.60	16		115	88	60	110	85	68
				Day 0	19/08/92	36.60		67.50	115	88	60	110	85	68
				Day 7	26/08/92	36.60		63.50	120	95				
	361	Reboxetine	Female	Screen	26/08/92	36.60			120	80	70	125	80	82
				Day 0	26/08/92	36.60		51.00	120	80	70	125	80	82
				Day 7	02/09/92	36.30		49.00	150	100	68	115	80	76
				Day 14	09/09/92	36.30		50.00	120	85	76	105	70	92
				Day 21	16/09/92	35.50		50.00	130	90	80	120	90	96
				Day 28	23/09/92	36.50		52.00	120	80	110	80	98	
				Day 35	30/09/92	36.30		50.00	130	85	80	120	96	
				Day 42	07/10/92	36.50		50.00	130	80	92	120	80	104
14	457	Reboxetine	Female	Screen	07/07/92	36.20	18		120	80	60	120	70	64
				Day 0	07/07/92	36.20		62.00	120	80	64	120	70	68
				Day 7	14/07/92	36.40		62.30	115	75	64	120	70	66

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

Contine	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)		
14	457	Reboxetine	Female	Day 14	21/07/92	36.30		62.20	120	80	64	120	70	68
				Day 21	28/07/92	36.50		61.70	120	80	64	115	70	64
				Day 28	04/08/92	36.60		62.80	120	80	64	120	78	64
				Day 35	11/08/92	36.20		62.70	120	80	60	115	70	64
				Day 42	18/08/92	36.30		62.90	120	80	64	115	70	68
14	458	Imipramine	Female	Screen	10/07/92	36.20	15		140	90	64	150	90	68
				Day 0	14/07/92	36.40		56.80	130	80	64	140	90	68
				Day 7	21/07/92	36.80		56.40	140	90	64	150	100	68
				Day 14	28/07/92	36.30		56.70	140	90	64	140	95	64
				Day 21	04/08/92	36.70		57.80	140	90	64	150	95	68
				Day 28	11/08/92	36.30		57.30	140	90	64	145	100	68
				Day 35	18/08/92	36.20		57.60	135	90	60	140	90	64
				Day 42	25/08/92	36.40		57.90	140	90	64	150	90	68
14	459	Reboxetine	Male	Screen	13/07/92	36.20	16		130	80	64	130	80	68
				Day 0	16/07/92	36.40		68.00	130	80	64	140	90	68
				Day 7	23/07/92	36.50		67.50	120	80	64	130	90	68
				Day 14	30/07/92	36.20		67.80	130	80	64	130	90	68
				Day 21	06/08/92	36.40		68.00	130	80	64	130	80	64
				Day 28	13/08/92	36.20		67.60	130	80	60	130	80	64
				Day 35	20/08/92	36.40		67.90	130	80	60	130	80	64
				Day 42	27/08/92	36.50		68.20	130	80	64	130	90	68
14	460	Imipramine	Male	Screen	20/07/92	35.80	14		110	70	56	100	70	60
				Day 0	23/07/92	36.00		66.00	110	70	60	100	60	72
				Day 7	30/07/92	36.10		65.70	100	70	60	90	60	68
				Day 14	06/08/92	36.20		65.50	105	70	60	100	60	64
				Day 21	13/08/92	36.30		65.40	110	70	56	100	60	60
				Day 28	20/08/92	36.80		65.50	110	80	60	110	70	64
				Day 35	27/08/92	36.20		65.70	110	70	60	110	60	64
				Day 42	03/09/92	36.30		66.00	110	70	60	105	60	60
14	461	Imipramine	Female	Screen	22/07/92	36.00	17		110	70	64	110	80	68
				Day 0	29/07/92	36.20		59.00	110	70	68	105	70	68
				Day 7	05/08/92	36.00		58.60	110	70	60	110	80	64
				Day 14	12/08/92	36.20		58.00	110	70	60	110	80	64
				Day 21	19/08/92	36.30		58.40	115	70	68	110	70	68
				Day 28	26/08/92	36.10		58.00	110	80	64	110	60	68
				Day 35	02/09/92	36.30		58.20	115	70	64	110	70	64
				Day 42	09/09/92	36.30		58.00	110	70	68	110	70	68
14	462	Reboxetine	Female	Screen	24/07/92	36.20	15		120	80	64	130	90	68
				Day 0	31/07/92	36.00		51.00	115	70	60	120	80	64

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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)		
14	462	Reboxetine	Female	Day 7	07/08/92	36.10		50.70	120	80	60	130	80	68
				Day 14	14/08/92	36.20		50.50	120	80	60	130	80	64
				Day 21	21/08/92	36.40		50.40	120	80	60	130	80	64
				Day 28	28/08/92	36.20		50.40	120	80	60	130	90	64
				Day 35	04/09/92	36.40		50.60	120	80	64	130	80	68
	Day 42	11/09/92	36.30		50.80	120	80	60	130	80	64			
	463	Imipramine	Male	Screen	27/07/92	35.90	15		120	80	64	110	70	64
				Day 0	03/08/92	36.40		68.70	120	80	64	120	80	64
				Day 7	10/08/92	36.80		68.50	120	70	64	120	80	68
				Day 14	17/08/92	36.80		68.10	130	80	64	130	80	68
				Day 21	24/08/92	36.20		68.30	120	80	64	120	80	64
	Day 28	31/08/92	36.40		68.70	120	80	64	130	80	68			
	Day 35	07/09/92	36.50		69.00	120	80	64	120	80	68			
	Day 42	14/09/92	36.30		69.40	120	80	64	130	90	68			
	464	Reboxetine	Female	Screen	29/07/92	36.70	15		100	70	64	90	60	68
				Day 0	05/08/92	36.40		50.60	100	70	64	90	60	68
				Day 7	13/08/92	36.40		50.20	100	70	64	100	60	64
				Day 14	20/08/92	36.20		50.00	100	70	60	100	60	60
				Day 21	27/08/92	36.30		50.10	100	70	64	100	60	64
	Day 28	03/09/92	36.70		50.00	100	70	64	100	60	64			
	Day 35	10/09/92	36.30		50.20	100	70	60	100	60	64			
	Day 42	17/09/92	36.60		50.70	110	70	64	110	80	64			
	465	Reboxetine	Male	Screen	30/07/92	36.80	14		130	90	68	130	80	68
				Day 0	06/08/92	36.60		63.80	120	90	60	130	90	64
				Day 7	13/08/92	36.20		63.70	120	80	64	130	90	64
				Day 14	20/08/92	36.10		63.70	120	80	64	130	80	64
				Day 21	27/08/92	36.10		64.00	120	80	60	130	80	64
	Day 28	03/09/92	36.30		64.30	120	80	60	130	80	64			
	Day 35	10/09/92	36.50		64.70	120	70	64	130	80	64			
	Day 42	17/09/92	36.20		65.00	120	70	64	130	80	64			
	466	Imipramine	Female	Screen	31/07/92	36.40	15		120	80	64	120	70	64
				Day 0	07/08/92	36.70		51.40	110	70	64	120	80	64
				Day 7	14/08/92	36.40		51.50	115	70	64	130	80	68
				Day 14	21/08/92	36.20		51.80	110	70	60	120	80	64
				Day 21	28/08/92	36.40		52.00	110	70	60	120	80	64
	Day 28	04/09/92	36.70		52.30	115	70	60	120	80	64			
	Day 35	11/09/92	36.20		52.40	115	70	60	125	80	64			
	Day 42	18/09/92	36.40		52.70	120	70	64	130	60	68			
14/1	129	Reboxetine	Male	Screen	11/12/91				170	100	68	170	105	76

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/017
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)			
14/1	129	Reboxetine	Male	Day 0	18/12/91	36.70		75.10	165	95	72	170	100	76	
				Day 7	19/12/91			75.00	160	100	96				
426	Reboxetine	Female	Screen	28/08/91		36.20	21		160	110	55	140	110	52	
			Day 0	04/09/91		36.20		81.70	150	105	55	140	110	52	
			Day 7	11/09/91		36.20		83.50	130	85	56	140	105	68	
			Day 14	18/09/91		36.70		82.50	160	105	76	145	110	96	
			Day 21	25/09/91		36.20		83.00	160	100	72	145	85	75	
			Day 28	02/10/91		35.90		82.60	140	95	76	150	110	96	
			Day 35	09/10/91		36.60		83.00	145	95	84	160	100	92	
Day 42	17/10/91		36.70		81.10	135	95	72	145	105	92				
429	Imipramine	Female	Screen	18/09/91			24		150	90	72	155	95	80	
			Day 0	25/09/91	36.70		65.00		130	90	92	135	100	92	
Day 7	02/10/91	36.90		64.20		110	75	92	125	85	88				
451	Imipramine	Male	Screen	25/11/91		36.50	20		150	95	68	160	100	80	
			Day 0	27/11/91		36.80		89.00	170	105	76	150	105	88	
			Day 7	04/12/91			89.90	170	105	64	160	100	72		
			Day 14	11/12/91		36.50		90.00	130	90	80	120	95	92	
			Day 21	18/12/91		36.50		90.00	160	100	88	170	100	88	
			Day 28	25/12/91		36.90		89.10	150	90	68	165	100	76	
			Day 35	30/12/91		36.70		89.70	155	105	68	150	100	76	
Day 42	08/01/92		36.60		90.00	160	105	80	160	110	84				
452	Reboxetine	Female	Screen	26/11/91		36.20	20		120	85	64	120	90	76	
			Day 0	27/11/91		36.70		78.20	120	85	64	120	90	76	
			Day 7	04/12/91		36.40		78.00	150	90	75	140	100	80	
			Day 14	12/12/91		36.90		77.80	150	100	80	120	90	84	
			Day 21	19/12/91		36.50		78.20	160	70	68	120	90	88	
			Day 28	27/12/91		36.80		78.00	130	85	76	130	100	84	
			Day 35	02/01/92		36.90		78.40	145	90	72	140	95	72	
Day 42	09/01/92		36.80		78.40	140	100	88	145	110	96				
14/2	136	Imipramine	Female	Screen	08/01/92		36.90	22		115	80	88	105	75	92
				Day 0	14/01/92		37.10		56.00	115	80	88	105	80	88
				Day 7	21/01/92		37.20		56.00	110	70	88	105	70	88
				Day 14	28/01/92		37.40		56.50	135	90	92	140	90	96
				Day 21	04/02/92		37.30		56.00	120	80	92	120	75	88
				Day 28	11/02/92		37.50		57.00	125	85	96	120	75	92
				Day 35	18/02/92		36.90		55.00	120	85	88	120	80	88
Day 42	25/02/92		37.20		55.50	110	80	76	125	85	84				

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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			
14/2	456	Imipramine	Male	Screen	09/04/92	37.40	16		145	95	88	155	95	92	
				Day 0	14/04/92	37.20		89.20	155	90	80	155	95	80	84
				Day 7	21/04/92	37.60		89.00	142	95	84	150	95	92	84
				Day 14	28/04/92	37.20		89.00	145	85	84	150	85	80	80
				Day 21	05/05/92	36.80		89.20	142	90	96	155	95	88	88
14/3	417	Reboxetine	Female	Screen	07/06/91	37.00	17		120	80	74	115	80	88	
				Day 0	14/06/91	37.20		56.00	120	80	74	115	80	88	
				Day 7	21/06/91	37.00		57.00	100	60	64	110	70	72	
				Day 14	28/06/91	37.00		55.00	120	80	84	110	80	84	
				Day 21	05/07/91	37.00		56.00	115	80	80	100	70	88	
418	418	Imipramine	Female	Screen	10/06/91	37.00	16		120	80	70	115	80	74	
				Day 0	17/06/91	37.00		62.50	125	80	70	118	80	72	
				Day 7	24/06/91	37.00		62.50	115	85	80	105	80	84	
				Day 14	01/07/91	37.00		63.00	115	80	76	95	70	80	
				Day 21	08/07/91	37.20		63.40	120	80	70	115	80	74	
419	419	Reboxetine	Female	Screen	03/07/91	37.00	16		130	95	78	100	80	83	
				Day 0	04/07/91	37.00		69.50	110	80	76	125	85	80	
				Day 7	11/07/91	37.10		72.00	115	80	74	120	80	80	
				Day 14	18/07/91	37.20		70.00	130	85	78	100	70	82	
				Day 21	25/07/91	37.00		70.60	120	80	80	130	90	94	
420	420	Imipramine	Female	Screen	04/07/91	37.00	20		100	70	80	90	60	88	
				Day 0	04/07/91	37.00		50.40	100	70	80	90	60	88	
				Day 7	11/07/91	37.00		49.00	110	70	76	115	75	80	
				Day 14	18/07/91	37.20		50.00	115	75	80	110	75	84	
				Day 21	25/07/91	37.20		50.60	125	80	84	110	70	92	
421	421	Reboxetine	Female	Screen	11/07/91	37.00	16		120	80	80	105	75	86	
				Day 0	18/07/91	37.20		64.20	120	80	78	105	75	84	

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REBOXETINE - PROTOCOL 20124/017
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)		
14/3	421	Reboxetine	Female	Day 7	25/07/91	37.00		65.00	115	80	78	110	70	82	
				Day 14	01/08/91	37.00		63.50	120	80	80	100	70	80	88
				Day 21	08/08/91	37.30		63.50	110	80	90	105	70	70	82
				Day 28	15/08/91	37.10		63.50	110	75	80	105	70	78	78
	Day 35	22/08/91	37.00		63.00	110	70	74	105	75	75	78			
427	427	Imipramine	Female	Screen	18/09/91	37.00	15		130	80	76	145	90	80	
				Day 0	18/09/91	37.00		85.00	135	80	72	130	85	76	80
				Day 7	25/09/91	37.00		85.40	115	80	75	120	80	74	74
				Day 21	09/10/91	37.20		86.40	120	80	72	135	85	75	75
	Day 28	16/10/91	37.00		86.00	145	80	76	130	85	80	80			
14/4	428	Imipramine	Female	Screen	25/10/91	37.00	16		120	80	72	115	80	80	
				Day 0	25/10/91	37.00		54.00	120	80	80	115	80	84	84
				Day 7	01/11/91	37.00		56.00	115	75	74	110	80	82	82
				Day 14	08/11/91	37.00		58.00	115	80	76	110	80	80	80
	Day 21	15/11/91	37.20		57.00	100	70	80	90	60	88	88			
	Day 28	22/11/91	37.00		57.20	125	80	78	115	82	80	80			
	Day 35	29/11/91	37.00		57.60	105	70	84	100	80	86	86			
	Day 42	05/12/91	37.20		58.00	100	80	82	95	80	86	86			
14/4	131	Imipramine	Female	Screen	07/01/92	36.70	20		145	70	82	140	90	86	
				Day 0	14/01/92	37.00		72.00	140	60	72	130	70	76	76
				Day 7	21/01/92	37.20		72.00	145	70	78	140	70	82	82
				Day 14	28/01/92	36.40		71.50	150	85	74	140	80	78	78
	Day 21	04/02/92	36.60		71.50	140	70	70	130	80	78	78			
	Day 28	11/02/92	36.30		71.00	140	60	72	145	70	74	74			
	Day 35	18/02/92	37.00		71.30	145	70	70	135	80	72	72			
	Day 42	25/02/92	36.80		71.00	140	75	70	135	80	68	68			
132	132	Imipramine	Female	Screen	07/01/92	36.50	28		110	60	84	115	80	92	
				Day 0	14/01/92	36.50		64.00	105	60	80	115	70	88	88
				Day 7	21/01/92	37.10		64.50	100	60	76	110	70	84	84
				Day 14	28/01/92	36.40		65.00	110	70	74	110	80	78	78
	Day 21	04/02/92	36.10		65.00	110	70	68	105	85	78	78			
	Day 28	11/02/92	36.70		65.00	115	70	70	110	70	74	74			
	Day 35	18/02/92	36.40		65.00	115	60	64	110	70	68	68			
	Day 42	25/02/92	36.30		65.00	115	60	72	110	70	78	78			
133	133	Imipramine	Female	Screen	09/01/92	36.80	18		125	70	72	120	70	76	
				Day 0	16/01/92	36.90		70.00	120	70	80	115	60	84	84
				Day 7	23/01/92	36.50		69.50	110	60	78	115	60	84	84
				Day 14	30/01/92	36.20		70.00	115	80	68	125	70	72	72
	Day 21	06/02/92	36.40		70.00	120	75	64	130	80	80	80			

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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)
14/4	133	Imipramine	Female	Day 28	13/02/92	36.10		70.00	120	60	70	120	70	74
				Day 35	20/02/92	36.20		70.00	125	80	74	128	80	76
				Day 42	27/02/92	36.10		70.00	120	70	68	115	70	72
134	Reboxetine	Female	Screen	09/01/92	36.70	20								
			Day 0	16/01/92	36.90		58.00	125	70	84	120	70	88	
			Day 7	23/01/92	37.10		57.30	115	60	84	115	70	88	
			Day 14	30/01/92	36.60		57.00	110	70	82	120	75	86	
			Day 21	06/02/92	36.30		56.70	120	70	84	110	80	88	
			Day 28	13/02/92	36.20		57.00	125	70	80	115	80	84	
			Day 35	20/02/92	36.40		57.00	120	70	74	115	65	84	
Day 42	27/02/92	36.70		57.50	130	70	92	120	85	98				
14/7	135	Reboxetine	Male	Screen	10/01/92	36.90	22							
				Day 0	17/01/92	36.20		85.00	150	70	84	155	90	86
				Day 7	24/01/92	36.40		85.00	145	70	87	150	85	90
				Day 14	31/01/92	36.40		85.00	135	70	82	145	75	88
				Day 21	07/02/92	36.10		85.00	140	70	70	135	70	74
				Day 28	14/02/92	36.40		85.00	145	70	76	135	70	80
				Day 35	21/02/92	36.30		85.00	140	80	70	140	70	72
Day 42	28/02/92	36.40		85.00	145	70	62	140	80	68				
14/7	422	Imipramine	Female	Screen	02/09/91	37.40	12							
				Day 0	04/09/91	36.80		74.00	120	75	62	125	75	68
				Day 7	11/09/91	37.40		72.80	125	70	62	130	75	72
				Day 14	18/09/91	36.80		73.20	120	70	68	130	80	74
				Day 21	25/09/91	37.10		72.80	125	75	68	130	65	76
				Day 28	02/10/91	36.80		71.80	125	70	69	125	75	77
				Day 35	09/10/91	36.90		70.80	130	70	68	130	80	74
Day 42	16/10/91	36.80		70.60	125	75	70	125	75	74				
14/7	423	Imipramine	Female	Screen	10/09/91	37.20	16							
				Day 0	17/09/91	36.40		70.20	130	80	66	130	75	82
				Day 7	24/09/91	37.10		70.20	140	75	66	140	75	73
				Day 14	01/10/91	36.40		69.80	125	75	68	125	70	76
				Day 21	08/10/91	36.30		70.00	120	70	72	125	75	78
				Day 28	15/10/91	36.80		70.20	110	70	68	120	70	76
				Day 35	22/10/91	37.00		69.60	115	70	76	120	75	80
Day 42	29/10/91	36.80		70.60	130	80	72	130	75	78				
14/7	424	Reboxetine	Male	Screen	06/09/91	37.10	24							
				Day 0	19/09/91	37.20		63.00	130	65	69	130	70	78
				Day 7	26/09/91	37.00		63.20	130	70	73	130	75	82
				Day 14	03/10/91	37.40		62.80	125	70	68	130	85	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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)		
14/7	424	Reboxetine	Male	Day 21	10/10/91	36.90		63.30	120	70	74	125	75	80	
				Day 28	17/10/91	36.40		62.40	120	70	69	125	75	75	76
				Day 35	24/10/91	36.80		62.60	120	70	68	120	75	75	75
				Day 42	31/10/91	37.20		63.00	165	80	103	170	80	105	
430	Reboxetine	Female	Screen	07/10/91	37.20	22		110	115	80	70	115	80	75	
			Day 0	07/10/91	37.20		70.40	120	65	68	125	65	65	74	
			Day 7	14/10/91	36.80		70.40	110	60	68	115	65	65	76	
			Day 14	21/10/91	36.80		69.80	120	70	64	125	75	70	78	
			Day 21	28/10/91	36.90		70.80	130	70	69	130	80	80	78	
			Day 28	04/11/91	37.00		70.10	125	65	68	130	70	74	74	
			Day 35	11/11/91	36.70		70.00	120	65	62	130	70	78	78	
Day 42	18/11/91	37.00		79.40	125	70	77	125	75	75	85				
431	Reboxetine	Male	Screen	08/10/91	37.30	22		120	125	60	68	125	65	76	
			Day 0	08/10/91	36.40		62.80	100	60	70	115	65	62	82	
			Day 7	15/10/91	37.10		63.20	110	65	62	120	70	72	72	
			Day 14	22/10/91	36.80		62.10	140	85	82	160	95	93	93	
			Day 21	29/10/91	36.40		58.20	110	60	58	125	65	75	75	
			Day 28	05/11/91	37.40		61.00	120	70	98	125	70	102	102	
			Day 35	12/11/91	36.80		62.80	115	60	87	120	65	98	98	
Day 42	19/11/91	38.10		61.40	115	70	67	125	75	75	83				
432	Imipramine	Male	Screen	08/10/91	37.20	18		120	125	70	72	125	80	78	
			Day 0	08/10/91	36.80		80.90	110	65	66	115	70	72	72	
			Day 7	15/10/91	37.00		80.50	115	65	68	125	70	74	74	
			Day 14	22/10/91	36.80		80.80	120	65	62	125	65	70	70	
			Day 21	29/10/91	36.80		80.20	125	80	59	130	80	73	73	
			Day 28	05/11/91	37.00		81.00	115	70	68	120	75	76	76	
			Day 35	12/11/91	37.10		81.20	120	70	62	120	70	78	78	
Day 42	19/11/91	36.60		80.80	130	65	70	135	70	84	84				
433	Imipramine	Female	Screen	08/10/91	37.20	18		120	125	65	68	125	70	74	
			Day 0	08/10/91	37.20		53.00	120	65	68	125	70	74	74	
			Day 7	15/10/91	36.80		53.10	115	65	64	120	65	72	72	
			Day 14	22/10/91	36.80		53.10	115	70	68	125	75	78	78	
			Day 21	29/10/91	36.90		53.10	115	70	80	120	70	92	92	
			Day 28	05/11/91	36.20		53.30	125	75	68	135	68	78	78	
			Day 35	12/11/91	36.60		53.80	120	70	70	125	75	78	78	
Day 42	19/11/91	37.20		53.20	120	75	78	125	80	89	89				
434	Reboxetine	Male	Screen	10/10/91	37.20	21		120	130	75	82	130	80	87	
			Day 0	14/10/91	37.60		79.40	130	80	84	130	85	92	92	
				Day 7	21/10/91	36.80		78.20	125	75	86	125	80	90	

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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)
14/7	434	Reboxetine	Male	Day 14	25/10/91	36.90		80.20	115	60	65	120	60	72
				Day 21	04/11/91	37.00		79.30	110	60	54	125	75	72
				Day 28	11/11/91	36.80		80.20	110	60	64	120	65	74
				Day 35	18/11/91	37.00		80.60	120	75	68	125	75	76
				Day 42	25/11/91	36.80		80.20	125	70	64	125	75	78
439	Reboxetine	Male	Screen	06/11/91	36.90	20		120	70	70	140	80	82	
			Day 0	11/11/91	37.20		65.20	120	65	74	125	70	86	
			Day 7	18/11/91	36.80		65.10	130	65	76	130	70	82	
			Day 14	25/11/91	37.00		64.90	125	75	74	125	70	80	
			Day 21	02/12/91	37.20		63.20	130	70	82	130	75	84	
440	Imipramine	Female	Day 28	09/12/91	36.50		63.40	120	65	72	120	70	80	
			Day 35	16/12/91	37.00		63.80	115	60	68	120	65	76	
			Day 42	23/12/91	35.20		64.20	130	80	98	140	85	120	
			Screen	07/11/91	37.20	22		90	60	87	105	60	98	
			Day 0	11/11/91	37.00		50.20	120	60	82	120	65	82	
441	Imipramine	Male	Day 7	18/11/91	36.80		50.10	110	60	68	115	60	74	
			Day 14	25/11/91	36.80		50.30	125	60	68	125	65	76	
			Day 21	02/12/91	37.50		51.20	115	80	115	125	80	120	
			Day 28	09/12/91	37.20		50.10	120	60	68	120	65	78	
			Day 35	16/12/91	36.60		50.10	110	60	72	115	65	78	
442	Imipramine	Male	Day 42	23/12/91	37.20		51.20	115	70	74	120	70	78	
			Screen	08/11/91	36.80	20		120	70	56	135	80	68	
			Day 0	11/11/91	36.80		78.20	120	70	58	125	70	64	
			Day 7	18/11/91	36.70		79.10	110	60	52	120	60	68	
			Day 14	25/11/91	37.20		79.00	120	60	62	125	65	76	
444	Imipramine	Male	Day 21	02/12/91	37.40		78.20	125	65	66	125	70	78	
			Day 28	09/12/91	36.90		79.20	120	65	58	120	70	64	
			Day 35	16/12/91	37.00		79.10	125	65	62	125	70	74	
			Day 42	23/12/91	37.20		78.40	115	65	51	120	65	62	
			Screen	08/11/91	36.90	25		130	75	77	135	75	82	
449	Reboxetine	Female	Day 0	11/11/91	36.80		73.20	120	60	68	125	68	72	
			Day 7	18/11/91	37.40		73.40	125	70	62	125	75	68	
			Day 14	25/11/91	37.20		72.80	125	70	68	125	75	74	
			Day 21	02/12/91	37.80		72.40	145	90	114	145	90	121	
			Day 28	09/12/91	36.90		72.80	120	65	68	125	65	72	
449	Reboxetine	Female	Day 35	16/12/91	37.20		72.40	120	65	68	125	65	76	
			Day 42	23/12/91	37.40		72.80	140	85	96	145	90	99	
449	Reboxetine	Female	Screen	16/12/91	36.90	22		125	70	78	130	80	87	
			Day 0	20/12/91	36.80		83.70	130	75	68	135	75	73	

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 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			
14/7	449	Reboxetine	Female	Day 7	27/12/91	37.20		83.40	125	75	92	136	78	98	
				Day 14	03/01/92	36.70		83.80	130	70	82	130	78	91	91
				Day 21	10/01/92	37.20		84.20	130	70	67	135	75	72	72
				Day 28	17/01/92	37.10		83.90	120	70	62	130	75	74	74
				Day 35	24/01/92	36.80		83.40	125	65	62	130	70	76	76
Day 42	31/01/92	37.30		82.00	120	70	72	125	75	75	75	78			
450	450	Imipramine	Male	Screen	06/12/91	37.80	24		140	90	59	140	90	68	
				Day 0	23/12/91	36.80		80.20	140	80	59	145	80	68	68
				Day 7	30/12/91	37.20		80.20	135	80	65	135	80	72	72
				Day 14	06/01/92	37.40		80.40	130	75	68	130	80	74	74
				Day 21	13/01/92	37.20		80.00	130	85	68	140	85	68	68
Day 28	20/01/92	36.80		80.20	130	70	68	130	75	72	72				
Day 35	27/01/92	37.00		80.60	130	70	62	130	70	62	68	68			
Day 42	03/02/92	37.20		80.40	130	70	59	140	80	59	140	80			
14/8	130	Reboxetine	Male	Screen	10/01/92	37.10	17		130	75	78	145	85	84	
				Day 0	10/01/92	37.20		81.00	130	75	78	145	85	85	84
				Day 7	17/01/92	37.40		81.00	135	80	76	140	80	84	84
				Day 14	24/01/92	37.20		81.00	145	80	72	140	95	84	84
				Day 21	31/01/92	37.30		81.00	140	75	76	145	70	88	88
Day 28	07/02/92	37.20		145	80	78	135	85	84	84	84				
Day 35	14/02/92	37.30		140	85	74	140	85	80	84	84				
Day 42	21/02/92	37.20		150	80	78	145	85	80	84	84				
425	425	Reboxetine	Female	Screen	06/09/91	37.10	17		145	80	84	140	85	88	
				Day 0	09/09/91	37.10		68.00	150	75	76	145	75	78	78
				Day 7	16/09/91	37.20		68.00	145	80	70	140	85	80	80
				Day 14	23/09/91	37.20		68.00	140	85	72	140	90	80	80
				Day 21	30/09/91	37.20		68.00	140	80	84	145	85	88	88
Day 28	07/10/91	37.10		68.00	145	85	80	140	80	84	84				
Day 35	14/10/91	37.20		68.00	150	90	88	145	95	88	88				
Day 42	21/10/91	37.10		68.00	150	85	74	155	90	74	74	74			
467	467	Reboxetine	Male	Screen	02/07/92	37.00	18		145	80	78	140	85	80	
				Day 0	06/07/92	37.00		80.00	145	80	78	145	75	74	74
				Day 7	13/07/92	37.10		80.00	150	80	84	150	85	88	88
				Day 14	20/07/92	37.20		80.00	145	90	80	150	85	84	84
				Day 21	27/07/92	37.10		80.00	140	80	76	140	75	80	80
Day 28	03/08/92	37.20		80.00	140	80	74	145	75	74	74				
Day 35	10/08/92	37.10		80.50	135	80	78	130	75	74	74				
Day 42	17/08/92	37.10		80.00	140	80	74	135	85	78	78	78			
14/10	53	Reboxetine	Male	Screen	17/02/92	37.20	17		150	80	80	140	85	84	
				Day 0	17/02/92	37.20		80.00	150	80	80	140	85	84	84

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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)
14/10	53	Reboxetine	Male	Day 0	24/02/92	37.20		68.00	155	85	76	150	90	84
				Day 7	02/03/92	37.20		66.90	145	75	76	150	80	84
				Day 14	09/03/92	37.40		67.20	150	75	70	145	70	84
				Day 21	16/03/92	37.00		67.30	140	80	84	155	90	80
				Day 28	23/03/92	36.90		67.80	140	75	76	135	80	80
Day 35	30/03/92	37.20		68.10	145	75	72	150	80	76				
Day 42	06/04/92	37.10		68.50	150	80	82	140	80	86				
54	54	Imipramine	Female	Screen	18/02/92	37.20	14		160	85	84	155	90	88
				Day 0	25/02/92	37.10		72.90	155	80	76	150	85	84
				Day 7	03/03/92	37.00		73.00	160	80	70	150	85	84
				Day 14	10/03/92	37.50		73.20	160	85	76	155	90	84
				Day 21	17/03/92	37.20		73.00	150	80	80	150	85	84
Day 28	24/03/92	37.10		71.80	145	68	68	150	75	72				
Day 35	31/03/92	37.20		72.20	145	75	72	140	80	76				
Day 42	07/04/92	37.00		72.50	150	80	72	105	85	80				
55	55	Reboxetine	Female	Screen	20/02/92	37.40	17		125	70	88	120	75	92
				Day 0	27/02/92	36.90		55.10	130	75	72	125	80	80
				Day 7	05/03/92	37.10		55.30	130	70	76	120	75	84
				Day 14	12/03/92	37.40		55.10	125	75	70	130	70	84
				Day 21	19/03/92	37.10		55.30	130	65	80	120	75	88
Day 28	26/03/92	37.10		55.60	125	75	76	120	80	80				
Day 35	02/04/92	36.90		55.40	130	75	72	125	80	80				
Day 42	09/04/92	37.10		55.80	120	60	72	125	65	76				
56	56	Imipramine	Female	Screen	24/02/92	37.60	14		125	70	76	120	80	84
				Day 0	02/03/92	37.20		67.00	130	75	76	125	80	80
				Day 7	09/03/92	37.00		66.80	125	65	80	120	75	84
				Day 14	16/03/92	36.90		67.10	130	75	76	120	80	80
				Day 21	23/03/92	36.80		67.40	130	75	72	120	80	80
Day 28	30/03/92	37.10		67.10	125	75	76	120	80	84				
Day 35	06/04/92	37.00		66.80	135	75	76	125	80	80				
Day 42	13/04/92	37.20		67.40	130	70	82	125	75	86				
57	57	Reboxetine	Female	Screen	25/02/92	37.20	14		150	75	72	145	85	76
				Day 0	03/03/92	37.10		61.90	155	60	76	150	85	80
				Day 7	10/03/92	37.30		61.50	135	80	80	150	85	84
				Day 14	17/03/92	37.20		61.90	160	85	76	150	90	80
				Day 21	24/03/92	36.90		62.20	155	80	72	150	85	80
Day 28	31/03/92	37.20		62.80	160	85	80	150	85	84				
Day 35	07/04/92	36.90		62.70	150	75	80	155	80	84				
Day 42	14/04/92	37.10		62.20	150	75	76	152	80	84				

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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)		
14/10	58	Imipramine	Female	Screen	02/04/92	36.80	16	58.30	140	85	84	130	75	88
				Day 0	13/04/92	37.10		58.30	135	75	80	130	70	84
				Day 7	21/04/92	36.80		58.40	145	85	76	135	80	80
				Day 14	27/04/92	37.10		58.50	135	70	72	130	75	80
				Day 21	04/05/92	37.10		58.30	135	75	76	130	70	80
				Day 28	11/05/92	37.10		58.00	145	80	72	140	75	76
				Day 35	18/05/92	37.10		58.50	150	80	84	140	75	80
				Day 42	25/05/92	37.20		58.90	155	85	88	140	70	80
				Screen	15/04/92	37.00	15	62.00	140	80	76	135	85	80
				Day 0	23/04/92	37.20		61.70	135	75	72	130	70	80
Day 7	30/04/92	37.00		62.20	145	70	76	135	75	80				
Day 14	07/05/92	36.80		62.90	135	70	72	130	75	80				
Day 21	14/05/92	37.20		62.10	145	75	72	140	80	80				
Day 28	21/05/92	37.20		62.40	140	75	76	140	80	80				
Day 35	28/05/92	36.90		62.60	150	80	76	150	75	80				
Day 42	05/06/92	37.00		62.60	130	65	76	135	70	80				
60	Reboxetine	Female	Screen	04/05/92	36.90	15	71.20	150	80	76	145	85	80	
			Day 0	12/05/92	37.10		70.90	155	75	76	150	80	84	
			Day 7	19/05/92	37.30		72.10	155	80	76	145	85	80	
			Day 14	26/05/92	37.00		71.20	150	75	72	150	80	76	
			Day 21	02/06/92	37.10		71.60	145	70	72	150	75	80	
			Day 28	09/06/92	37.10		71.30	155	80	76	150	75	80	
			Day 35	16/06/92	37.00		71.00	160	80	76	150	75	80	
			Day 42	23/06/92	36.80									
			Screen	20/01/92	36.20	16	62.10	115	65	80	110	70	88	
			Day 0	27/01/92	37.20		61.60	120	80	76	110	85	84	
Day 7	03/02/92	37.10		61.90	125	75	72	120	85	81				
Day 14	10/02/92	37.20		62.20	130	75	76	120	80	84				
Day 21	17/02/92	37.20		62.20	135	80	76	125	75	80				
Day 28	24/02/92	37.20		61.90	130	75	72	120	80	80				
Day 35	02/03/92	37.20		61.90	125	75	80	120	80	84				
Day 42	09/03/92	37.20		62.20	135	80	72	125	85	80				
137	Reboxetine	Female	Screen	21/01/92	36.90	15	58.60	130	70	76	120	75	80	
			Day 0	28/01/92	37.10		58.30	135	80	72	130	80	80	
			Day 7	04/02/92	37.20		58.30	130	75	72	120	80	80	
			Day 14	11/02/92	37.20		58.60	125	70	72	120	75	84	
			Day 21	18/02/92	37.20		58.30	130	75	72	120	80	80	
			Day 28	25/02/92	37.30		59.20	140	80	72	130	85	84	
			Day 35	03/03/92	37.10		59.90	140	80	72	130	85	80	
			Day 42	10/03/92	37.20		60.20	130	65	76	120	75	80	
			Screen	21/01/92	36.90	15	58.60	130	70	76	120	75	80	
			Day 0	28/01/92	37.10		58.30	135	80	72	130	80	80	
Day 7	04/02/92	37.20		58.30	130	75	72	120	80	80				
Day 14	11/02/92	37.20		58.60	125	70	72	120	75	84				
Day 21	18/02/92	37.20		58.30	130	75	72	120	80	80				
Day 28	25/02/92	37.30		59.20	140	80	72	130	85	84				
Day 35	03/03/92	37.10		59.90	140	80	72	130	85	80				
Day 42	10/03/92	37.20		60.20	130	65	76	120	75	80				

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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)
14/10	139	Reboxetine	Female	Screen	27/01/92	37.10	16	66.90	120	75	76	115	80	84
				Day 0	03/02/92	37.20		66.90	120	75	84	115	80	88
				Day 7	10/02/92	37.10		66.60	125	75	76	120	80	84
				Day 14	17/02/92	37.20		66.30	130	75	72	125	80	80
				Day 21	24/02/92	37.20		66.20	130	75	76	120	80	84
				Day 28	02/03/92	37.10		66.10	130	70	72	125	75	80
Day 35	09/03/92	37.20		66.80	130	70	72	120	75	80				
Day 42	16/03/92	37.20		66.20	135	70	76	130	75	84				
140	140	Imipramine	Female	Screen	28/01/92	37.20	16	67.00	135	80	72	130	85	76
				Day 0	04/02/92	37.20		67.00	140	80	68	130	80	76
				Day 7	11/02/92	37.20		67.20	140	80	72	130	85	76
				Day 14	18/02/92	37.20		66.90	135	75	80	130	80	84
				Day 21	25/02/92	37.20		67.50	140	80	72	135	75	80
				Day 28	03/03/92	37.20		67.60	150	80	84	135	75	80
Day 35	10/03/92	37.20		67.20	140	75	72	135	80	76				
Day 42	17/03/92	37.20		67.10	135	75	80	130	75	84				
435	435	Imipramine	Female	Screen	04/11/91	36.80	18	77.00	155	80	84	150	85	88
				Day 0	11/11/91	36.80		77.00	160	80	80	155	85	84
				Day 7	18/11/91	36.90		77.40	150	80	72	150	85	76
				Day 14	25/11/91	36.70		77.20	155	85	68	150	80	72
				Day 21	02/12/91	36.20		77.00	155	80	76	150	85	84
				Day 28	09/12/91	36.30		77.50	160	80	80	150	75	84
Day 35	16/12/91	36.70		77.30	155	80	68	150	85	72				
Day 42	23/12/91	36.90		77.10	150	80	68	145	80	72				
436	436	Reboxetine	Female	Screen	05/11/91	36.70	16	67.90	120	75	76	115	80	84
				Day 0	12/11/91	36.90		67.90	125	75	76	120	80	84
				Day 7	19/11/91	36.30		67.30	130	75	72	120	80	76
				Day 14	26/11/91	36.00		67.80	135	70	76	130	80	76
				Day 21	03/12/91	36.20		67.30	140	80	74	130	85	80
				Day 28	09/12/91	36.30		67.30	145	75	72	140	80	76
Day 35	16/12/91	36.80		67.50	140	65	68	130	70	72				
Day 42	23/12/91	36.50		67.10	145	80	72	140	85	80				
437	437	Reboxetine	Female	Screen	05/11/91	36.20	15	70.80	125	70	76	120	75	80
				Day 0	12/11/91	36.60		70.80	130	70	72	120	75	80
				Day 7	19/11/91	36.80		69.90	130	70	72	125	80	80
				Day 14	26/11/91	36.60		69.10	135	75	76	125	80	80
				Day 21	03/12/91	36.70		68.90	130	70	80	130	75	84
				Day 28	10/12/91	36.50		69.10	140	80	72	130	85	80
Day 35	17/12/91	36.90		68.70	145	85	72	140	80	76				

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/017
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)		
14/10	437	Reboxetine	Female	Day 42	23/12/91	37.10		68.80	150	80	68	145	83	72
	438	Imipramine	Female	Screen	07/11/91	36.20	13	67.90	130	70	80	120	75	81
				Day 0	14/11/91	36.20		67.90	125	70	76	120	75	80
				Day 7	21/11/91	36.70		67.60	125	65	80	120	70	84
				Day 14	28/11/91	36.90		67.50	120	65	72	125	70	80
				Day 21	05/12/91	36.20		67.30	125	70	76	120	75	80
				Day 28	12/12/91	36.70		67.50	125	65	76	120	70	80
				Day 35	19/12/91	37.50		67.40	120	65	80	120	70	83
				Day 42	27/12/91	36.90		67.60	125	60	72	120	70	80
	443	Reboxetine	Female	Screen	14/11/91	36.60	14	63.60	150	85	82	145	85	88
				Day 0	18/11/91	36.70		63.40	155	80	80	150	85	84
				Day 7	25/11/91	36.70		63.20	150	75	82	150	80	86
				Day 14	02/12/91	36.50		63.50	155	80	80	150	80	84
				Day 21	09/12/91	36.70		63.20	150	75	76	150	80	84
				Day 28	16/12/91	37.00		63.80	145	80	80	140	80	84
				Day 35	23/12/91	37.10		63.20	145	80	76	145	85	80
				Day 42	30/12/91	36.20		63.60	150	75	72	140	80	76
	444	Reboxetine	Male	Screen	15/11/91	36.70	15	66.30	140	85	72	135	85	76
				Day 0	15/11/91	36.70		66.30	150	75	72	140	80	76
				Day 7	22/11/91	36.70		66.00	145	75	76	140	80	80
				Day 14	29/11/91	36.30		60.20	145	75	72	150	80	76
				Day 21	06/12/91	36.40		66.50	150	75	68	145	80	76
				Day 28	13/12/91	36.90		66.50	135	70	72	130	75	76
				Day 35	20/12/91	37.10		66.20	160	80	68	160	85	72
				Day 42	27/12/91	36.70		66.50	145	75	76	140	80	76
	445	Imipramine	Female	Screen	15/11/91	36.80	16	71.90	155	80	84	150	85	88
				Day 0	19/11/91	36.90		71.90	160	80	80	150	85	84
				Day 7	26/11/91	36.70		70.50	155	75	76	150	80	80
				Day 14	03/12/91	36.50		70.20	165	80	76	160	90	84
				Day 21	10/12/91	36.50		70.30	160	85	78	155	80	84
				Day 28	17/12/91	36.80		70.80	150	80	72	155	85	76
				Day 35	23/12/91	36.50		70.70	155	85	72	150	80	76
				Day 42	30/12/91	36.50		70.90	150	80	76	145	85	80
	446	Reboxetine	Female	Screen	22/11/91	36.10	15	63.00	125	70	80	120	75	84
				Day 0	25/11/91	36.60		63.00	130	70	72	120	75	80
				Day 7	02/12/91	37.00		62.90	130	70	76	120	75	84
				Day 14	09/12/91	36.50		63.10	125	70	76	125	80	84
				Day 21	16/12/91	36.50		63.40	130	65	72	120	79	76
				Day 28	23/12/91	36.90		63.20	120	60	76	120	65	80

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PHARMACIA CRS R&D

REBOXETINE - PROTOCOL 20124/017
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)		
14/10	446	Reboxetine	Female	Day 35	30/12/91	36.90		64.00	130	70	68	125	75	72
				Day 42	07/01/92	36.20		64.10	140	80	72	130	85	76
447	Reboxetine	Male	Screen	26/11/91	36.90	16		150	80	72	150	85	76	76
			Day 0	26/11/91	36.90		64.20	150	80	72	150	85	76	76
			Day 7	03/12/91	36.80		64.00	155	85	76	150	85	84	84
			Day 14	10/12/91	36.50		64.30	160	80	80	150	85	83	83
			Day 21	17/12/91	36.20		64.10	150	80	72	140	85	76	76
			Day 28	23/12/91	36.90		69.10	150	80	68	150	80	76	76
			Day 35	30/12/91	37.10		69.30	155	75	72	145	80	80	80
			Day 42	07/01/92	36.70		63.90	150	75	76	145	80	84	84
448	Imipramine	Female	Screen	22/11/91	37.10	17		145	75	76	140	80	84	84
			Day 0	27/11/91	37.10		65.00	150	80	76	140	90	84	84
			Day 7	04/12/91	36.90		64.80	150	80	72	145	85	80	80
			Day 14	10/12/91	36.90		64.70	145	75	80	150	80	88	88
			Day 21	17/12/91	36.80		64.50	150	80	76	140	85	80	80
			Day 28	23/12/91	36.20		64.40	145	75	72	140	80	80	80
			Day 35	30/12/91	36.50		64.60	150	80	76	145	90	80	80
			Day 42	07/01/92	36.50		65.00	150	80	72	140	85	76	76
453	Imipramine	Female	Screen	18/05/92	37.20	14		135	70	88	130	75	88	88
			Day 0	27/05/92	37.00		66.10	140	75	72	135	80	76	76
			Day 7	03/06/92	36.90		66.30	135	80	76	130	85	84	84
			Day 14	10/06/92	37.20		66.00	150	75	72	140	80	76	76
			Day 21	17/06/92	37.20		66.30	140	70	80	135	75	84	84
			Day 28	24/06/92	37.20		66.70	145	70	72	140	75	80	80
			Day 35	01/07/92	37.20		66.30	145	70	76	140	75	84	84
			Day 42	08/07/92	36.88		66.90	135	65	72	130	70	80	80
454	Reboxetine	Female	Screen	02/06/92	37.30	13		145	80	76	140	85	80	80
			Day 0	11/06/92	37.00		61.90	140	75	72	145	80	80	80
			Day 7	17/06/92	36.70		61.80	135	65	68	140	70	76	76
			Day 14	25/06/92	37.10		62.30	145	70	72	140	80	84	84
			Day 21	02/07/92	37.00		62.20	150	75	76	160	80	84	84
			Day 28	09/07/92	36.50		62.50	145	65	72	160	70	80	80
			Day 35	16/07/92	36.80		62.20	140	65	76	135	75	80	80
			Day 42	23/07/92	37.10		62.30	145	70	72	140	75	76	76
455	Reboxetine	Female	Screen	11/06/92	37.20	14		125	65	84	120	70	88	88
			Day 0	19/06/92	36.50		57.90	130	65	72	120	70	80	84
			Day 7	26/06/92	36.40		58.10	125	60	80	120	75	84	84
			Day 14	03/07/92	36.70		58.20	125	65	76	115	70	84	84
			Day 21	10/07/92	36.70		58.00	135	70	72	125	80	80	80

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 2012A/017
 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)
14/10	455	Reboxetine	Female	Day 28	17/07/92	37.10		58.20	140	75	76	125	80	80
				Day 35	24/07/92	36.70		58.40	135	70	72	130	75	80
				Day 42	31/07/92	36.80		58.20	140	75	64	130	60	68
15	349	Imipramine	Male	Screen	18/08/92	36.40	20		110	70	84	120	70	88
				Day 0	26/08/92	36.40		62.00	110	70	84	120	70	88
				Day 7	27/08/92	36.00		62.00	106	70	72	110	70	74
				Day 14	03/09/92	36.00		62.00	110	70	68	110	70	72
				Day 21	10/09/92	35.70		62.00	120	80	84	100	70	86
				Day 28	17/09/92	36.00		61.00	108	60	84	110	70	80
				Day 35	24/09/92	36.60		61.00	110	80	68	110	90	72
Day 42	01/10/92	36.00		61.00	90	70	70	100	80	80				
351	351	Reboxetine	Male	Screen	02/09/92	36.50	20		170	110	88	160	95	92
				Day 0	02/09/92	36.50		60.00	170	110	88	160	102	92
				Day 7	09/09/92	39.00		60.00	120	80	80	120	80	84
				Day 14	16/09/92	36.60		61.00	120	80	78	120	80	84
				Day 21	23/09/92	36.60		61.00	120	80	78	120	80	84
				Day 28	30/09/92	36.60		61.00	130	90	80	130	80	84
				Day 35	07/10/92	37.00		61.00	130	90	80	130	90	86
Day 42	14/10/92	37.00		61.00	130	90	74	130	90	80				
352	352	Imipramine	Male	Screen	06/08/92	36.30	22		130	70	60	130	80	60
				Day 0	06/08/92	36.30		75.00	130	70	60	130	80	64
				Day 7	12/08/92	37.00		75.00	130	80	84	130	90	84
				Day 14	20/08/92	36.60		79.00	130	80	76	120	70	84
				Day 21	27/08/92	36.40		76.00	120	80	76	120	90	82
364	364	Imipramine	Female	Screen	29/07/92	36.80	20		110	70	88	100	70	92
				Day 0	29/07/92	36.80		55.00	110	70	88	100	70	92
				Day 7	05/08/92	36.60		53.00	120	80	84	110	80	88
				Day 14	12/08/92	36.40		55.00	110	70	80	100	70	88
				Day 21	19/08/92	36.40		55.00	110	70	88	100	70	92
366	366	Reboxetine	Male	Screen	27/08/92	35.90	18		100	60	62	110	70	62
				Day 0	27/08/92	35.70		49.80	100	60	62	110	70	60
				Day 7	03/09/92	36.00		50.00	100	55	64	120	75	68
				Day 14	10/09/92	35.60		50.00	120	80	60	100	60	60
				Day 21	17/09/92	35.40		51.00	130	80	70	130	80	88
				Day 28	24/09/92	36.20		50.00	120	90	68	120	80	70
Day 35	01/10/92	36.60		53.00	90	70	80	110	90	90				
Day 42	08/10/92	36.00		53.00	110	90	88	120	90	70				

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PHARMACIA CNS RSD

REBOXETINE - PROTOCOL 20124/017
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)				
45	367	Imipramine	Male	Screen	31/08/92	36.60	18		120	90	80	125	90	86				
				Day 0	31/08/92	36.60		81.00	120	90	80	125	90	86				
				Day 7	07/09/92	36.80		81.00	140	120	86	145	110	80				
				Day 14	14/09/92	36.20		79.00	170	120	96	160	120	90				
				Day 21	21/09/92	37.40		80.00	160	110	88	160	120	86				
				Day 28	28/09/92	36.80		80.00	150	100	88	150	120	86				
				Day 35	05/10/92	36.00		79.50	170	120	74	165	140	72				
				Day 42	12/10/92	36.40		79.00	170	120	72	160	118	74				
				368	368	Reboxetine	Female	Screen	04/09/92	36.50	15		150	100	84	130	100	106
								Day 0	04/09/92	36.50		80.00	150	100	84	130	100	106
Day 7	10/09/92	37.00						78.00	160	110	102	140	100	96				
Day 14	17/09/92	36.00						78.40	155	90	84	160	100	86				
Day 21	24/09/92	36.40						76.00	130	100	85	130	100	86				
Day 28	01/10/92	36.80						78.40	130	90	84	160	100	86				
Day 35	08/10/92	36.50						78.40	150	90	84	160	90	86				
Day 42	15/10/92	37.00						79.00	150	90	84	150	90	94				
369	369	Reboxetine	Female					Screen	10/07/92	36.00	16		120	80	80	110	70	84
								Day 0	10/07/92	36.00		63.00	120	80	80	120	70	84
				Day 7	16/07/92	36.40		63.50	130	70	88	110	60	90				
				Day 14	23/07/92	36.60		62.50	120	85	82	110	75	88				
				Day 28	06/08/92	36.00		63.00	110	80	100	110	70	110				
				Day 35	13/08/92	36.50		62.00	115	85	80	120	90	80				
				Day 42	20/08/92	36.50		62.00	140	100	108	130	90	116				
				370	370	Imipramine	Female	Screen	16/07/92	36.00	16		120	60	100	100	60	100
								Day 0	16/07/92	36.00		96.00	120	60	100	100	60	100
								Day 7	23/07/92	36.00		95.50	130	70	88	130	60	98
Day 14	30/07/92	36.50						100.00	130	70	96	130	60	104				
Day 21	06/08/92	36.40						100.00	120	70	90	130	70	100				
Day 28	13/08/92	36.20						101.00	110	70	90	120	80	112				
Day 35	20/08/92	36.00						100.00	100	60	84	110	90	80				
Day 42	27/08/92	36.00						100.00	100	60	84	110	90	80				
371	371	Reboxetine	Female					Screen	17/07/92	37.30	18		120	70	68	120	80	74
								Day 0	17/07/92	37.30		65.00	120	70	68	120	80	74
				Day 7	24/07/92	36.60		65.00	100	70	88	95	70	84				
				Day 14	03/08/92	36.80		64.50	130	80	106	110	60	112				
				Day 28	17/08/92	36.00		63.00	130	90	100	120	80	114				
				Day 35	24/08/92	36.50		63.00	125	85	98	120	80	106				
372	372	Imipramine	Male	Screen	17/06/92	35.20		90	60	88	85	60	88					
				Day 0	17/06/92	35.20		37.50	90	60	88	85	60	88				

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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)
15	372	Imipramine	Male	Day 7	24/06/92	35.00		36.50	85	60	90	85	60	96
				Day 14	01/07/92	35.00		38.00	88	60	96	80	60	98
				Day 21	08/07/92	35.80		38.00	90	60	88	85	60	92
				Day 28	15/07/92	36.20		37.00	100	65	78	110	60	88
				Day 35	22/07/92	35.60		35.30	118	65	78	110	60	80
Day 42	29/07/92	36.50		36.00	130	70	76	120	70	78				
373	Imipramine	Female	Screen	25/06/92	37.00	18	68.00	120	80	84	110	70	82	
			Day 0	25/06/92	37.00			120	80	84	110	70	82	
374	Reboxetine	Female	Screen	09/06/92	36.70	18	50.00	100	60	96	110	70	94	
			Day 0	08/06/92	36.00		50.00	100	60	88	100	60	92	
			Day 28	06/05/92	36.60		51.00	110	60	80	100	70	92	
			Day 35	13/05/92	36.50		50.00	120	60	80	100	60	96	
			Day 42	20/05/92	36.50		51.00	120	60	80	100	60	96	
375	Reboxetine	Female	Screen	06/06/92	36.20	20	60.00	110	70	88	120	80	90	
			Day 0	06/06/92	36.00		60.00	110	70	88	120	80	90	
			Day 7	13/06/92	36.40		60.50	110	70	88	100	70	88	
			Day 14	20/06/92	36.50		61.00	110	80	84	100	80	86	
			Day 21	27/06/92	36.60		63.50	120	80	85	110	70	84	
376	Imipramine	Female	Screen	13/04/92	36.00	22	59.00	130	80	72	130	80	76	
			Day 0	13/04/92	36.00		58.00	140	80	80	100	60	96	
Day 7	20/04/92	36.00												
	27/04/92	36.60												
377	Reboxetine	Female	Screen	13/05/92	36.60	28	63.50	120	80	88	115	70	70	
			Day 0	13/05/92	36.60		63.50	120	80	88	115	70	94	
			Day 7	20/05/92	36.50		62.00	125	80	86	135	90	104	
			Day 14	27/05/92	36.60		62.00	120	80	84	130	70	88	
			Day 21	03/06/92	36.60		62.00	110	60	88	100	60	84	
Day 28	11/06/92	35.00		62.00	110	60	88	100	60	84				
Day 35	18/06/92	36.80		65.00	125	70	120	138	70	125				
378	Reboxetine	Female	Screen	15/06/92	36.60	20	62.00	100	60	86	100	50	80	
			Day 0	15/06/92	36.60		62.00	100	60	86	100	50	80	
			Day 7	22/06/92	36.00		64.00	100	70	68	110	70	72	
			Day 14	29/06/92	37.00		64.00	100	60	78	85	60	82	
			Day 21	06/07/92	37.00		62.00	100	60	78	80	60	80	
Day 28	13/07/92	37.30		65.00	110	80	88	110	80	104				
Day 35	20/07/92	36.50		66.50	110	70	70	110	70	70				
Day 42	27/07/92	36.60		67.00	110	80	84	110	70	92				

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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)
15	379	Imipramine	Female	Screen	16/04/92	36.20	18	55.00	130	70	60	120	60	68
				Day 0	16/04/92	36.20			130	70	60	120	60	68
380	380	Imipramine	Female	Screen	30/06/92		22		100	60	80	90	60	84
				Day 0	30/06/92	36.60		53.00	100	60	80	90	60	84
				Day 7	06/07/92	36.80		51.50	100	60	84	105	70	88
				Day 14	13/07/92	37.00		51.50	95	60	88	100	65	94
				Day 21	20/07/92	37.00		51.00	100	70	86	100	75	84
Day 28	27/07/92	36.00		55.00	100	50	80	100	50	80				
381	381	Reboxetine	Female	Screen	21/05/92	36.70	20		110	60	96	100	70	94
				Day 0	21/05/92	36.70		65.00	110	60	96	100	70	94
				Day 7	28/05/92	36.50		63.00	110	70	78	120	80	84
				Day 14	04/06/92	37.00		62.00	100	60	84	110	70	92
				Day 21	11/06/92	36.60		62.00	100	60	86	100	70	104
				Day 28	18/06/92	36.00		63.00	100	60	84	100	70	92
				Day 35	25/06/92	36.00		63.00	100	70	78	110	80	88
Day 42	02/07/92	36.00			100	70	80	110	80	84				
382	382	Imipramine	Male	Screen	09/04/92	36.60	24		100	80	60	90	88	60
				Day 0	09/04/92	36.00		66.00	100	60	80	90	60	88
383	383	Imipramine	Female	Screen	07/07/92	36.00	20		110	65	92	110	60	96
				Day 0	07/07/92	36.00		63.00	110	65	92	110	60	96
				Day 7	14/07/92	36.80		60.00	100	60	84	100	50	86
				Day 14	21/07/92	36.90		61.00	120	80	100	110	70	105
				Day 21	28/07/92	37.00		61.00	125	85	102	115	80	104
				Day 28	04/08/92	36.80		61.00	120	70	88	120	70	100
				Day 35	11/08/92	36.30		63.00	128	70	102	119	80	110
Day 42	18/08/92	36.40		63.00	120	80	92	130	70	90				
384	384	Reboxetine	Female	Screen	28/07/92	35.80	18		130	85	78	140	90	88
				Day 0	29/07/92	35.80		47.00	130	88	78	140	90	88
				Day 7	04/08/92	36.00		46.60				110	70	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	Reboxetine	Male	05/02/91	18/03/91	Screen Day 21 Day 42	0 21 42	0 - Screening 1-21 days 22-42 days	05/02/91 26/02/91 19/03/91	Normal Normal Normal	
2	2	Reboxetine	Female	26/02/91	08/04/91	Screen Day 21 Day 42	0 21 42	0 - Screening 1-21 days 22-42 days	26/02/91 19/03/91 09/04/91	Normal Normal Normal	
3	3	Imipramine	Female	16/04/91	27/05/91	Screen Day 21 Day 42	-4 21 42	0 - Screening 1-21 days 22-42 days	12/04/91 07/05/91 28/05/91	Normal Normal Normal	
4	4	Imipramine	Male	17/04/91	28/05/91	Screen Day 21 Day 42	-2 20 42	0 - Screening 1-21 days 22-42 days	15/04/91 07/05/91 29/05/91	Normal Normal Normal	
5	5	Reboxetine	Female	17/07/91	27/08/91	Screen Day 21 Day 42	0 21 42	0 - Screening 1-21 days 22-42 days	17/07/91 07/08/91 28/08/91	Normal Normal Normal	
6	6	Imipramine	Male	07/08/91	17/09/91	Screen Day 21 Day 42	-1 21 42	0 - Screening 1-21 days 22-42 days	06/08/91 28/08/91 18/09/91	Normal Normal Normal	
7	7	Reboxetine	Male	09/10/91	20/11/91	Screen Day 21 Day 42	-1 21 43	0 - Screening 1-21 days 22-42 days	08/10/91 30/10/91 21/11/91	Abnormal Abnormal Abnormal	LEFT ANTERIOR HEMIBLOCK LEFT BUNDLE BRANCH BLOCK LEFT POSTERIOR HEMIBLOCK
8	8	Imipramine	Male	29/10/91	31/10/91	Screen	-1	0 - Screening	28/10/91	Normal	
9	9	Imipramine	Female	08/11/91	19/12/91	Screen Day 21 Day 42	-2 20 41	0 - Screening 1-21 days 22-42 days	06/11/91 28/11/91 19/12/91	Normal Normal Normal	
10	10	Imipramine	Female	19/11/91	30/12/91	Screen Day 21 Day 42	-4 21 41	0 - Screening 1-21 days 22-42 days	15/11/91 10/12/91 30/12/91	Normal Abnormal Normal	RIGHT INCOMPLETE BUNDLE BRANCH BLOCK
11	11	Reboxetine	Male	06/04/92	03/05/92	Screen Day 21	-3 29	0 - Screening 1-21 days	03/04/92 05/05/92	Abnormal Abnormal	SINUS TACHYCARDIA (> 100) SINUS TACHYCARDIA (> 100)

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 21.0

E.C.G. TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
1	12	Reboxetine	Male	15/04/92	05/05/92	Screen Day 21	-2 15	0 - Screening 1-21 days	13/04/92 30/04/92	Abnormal Normal	SINUS TACHYCARDIA (> 100)
2	33	Reboxetine	Male	19/12/90	29/01/91	Screen Day 21 Day 42	-1 20 41	0 - Screening 1-21 days 22-42 days	18/12/90 08/01/91 29/01/91	Normal Normal Abnormal	OTHER
24	34	Imipramine	Male	28/12/90	03/02/91	Screen Day 21 Day 42	-1 20 41	0 - Screening 1-21 days 22-42 days	27/12/90 17/01/91 07/02/91	Normal Normal Normal	
35	35	Reboxetine	Male	28/12/90	07/02/91	Screen Day 21 Day 42	-1 20 41	0 - Screening 1-21 days 22-42 days	27/12/90 17/01/91 07/02/91	Normal Normal Abnormal	RIPOLARIZATION DISTURBANCES
36	36	Imipramine	Female	10/01/91	31/01/91	Screen Day 21	-1 20	0 - Screening 1-21 days	09/01/91 30/01/91	Normal Abnormal	SINUS TACHYCARDIA (> 100)
37	37	Reboxetine	Male	18/01/91	28/02/91	Screen Day 21 Day 42	-1 20 41	0 - Screening 1-21 days 22-42 days	17/01/91 07/02/91 28/02/91	Normal Abnormal Normal	SINUS TACHYCARDIA (> 100)
38	38	Imipramine	Female	25/01/91	07/03/91	Screen Day 21 Day 42	-2 20 41	0 - Screening 1-21 days 22-42 days	23/01/91 14/02/91 07/03/91	Normal Normal Normal	
39	39	Reboxetine	Female	25/01/91	07/03/91	Screen Day 21 Day 42	-1 20 41	0 - Screening 1-21 days 22-42 days	24/01/91 14/02/91 07/03/91	Normal Normal Normal	
40	40	Imipramine	Male	20/02/91	02/04/91	Screen Day 21 Day 42	-1 20 41	0 - Screening 1-21 days 22-42 days	19/02/91 12/03/91 02/04/91	Normal Normal Abnormal	SINUS TACHYCARDIA (> 100) RIGHT BUNDLE BRANCH BLOCK
41	41	Reboxetine	Male	05/02/91	18/03/91	Screen Day 21 Day 42	-5 20 41	0 - Screening 1-21 days 22-42 days	31/01/91 25/02/91 18/03/91	Normal Normal Abnormal	SINUS TACHYCARDIA (> 100)

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 21.0

E.C.G.
ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
2	42	Imipramine	Male	09/02/91	22/03/91	Screen Day 21 Day 42	-1 0 - Screening 20 1-21 days	08/02/91 01/03/91	Normal Abnormal	SINUS TACHYCARDIA (> 100) A-V BLOCK 1ST DEGREE SINUS TACHYCARDIA (> 100)	
	43	Reboxetine	Female	26/03/91	06/05/91	Screen Day 21 Day 42	-1 0 - Screening 20 1-21 days 41 22-42 days	25/03/91 15/04/91 06/05/91	Normal Normal Normal		
	44	Imipramine	Male	11/04/91	11/04/91	Screen	-1 0 - Screening	10/04/91	Normal		
	45	Imipramine	Female	30/04/91	03/05/91	Screen	-1 0 - Screening	29/04/91	Normal		
	46	Reboxetine	Female	16/05/91	26/06/91	Screen Day 21 Day 42	-1 0 - Screening 20 1-21 days 41 22-42 days	15/05/91 05/06/91 26/06/91	Normal Normal Abnormal	SINUS TACHYCARDIA (> 100)	
1440	47	Reboxetine	Female	22/05/91	02/07/91	Screen Day 21 Day 42	-1 0 - Screening 22 1-21 days 41 22-42 days	21/05/91 13/06/91 02/07/91	Normal Normal Normal		
	48	Imipramine	Female	27/08/91	07/10/91	Screen Day 21 Day 42	-1 0 - Screening 20 1-21 days 41 22-42 days	26/08/91 16/09/91 07/10/91	Abnormal Abnormal Abnormal	SINUS TACHYCARDIA (> 100) A-V BLOCK 1ST DEGREE SINUS TACHYCARDIA (> 100) A-V BLOCK 1ST DEGREE SINUS TACHYCARDIA (> 100) VENTRICULAR ECTOPIC BEATS - OCCASIONAL	
	49	Imipramine	Female	29/08/91	09/10/91	Screen Day 21 Day 42	-1 0 - Screening 20 1-21 days 41 22-42 days	28/08/91 18/09/91 09/10/91	Normal Normal Normal		
	50	Reboxetine	Male	06/11/91	15/12/91	Screen Day 21	-2 0 - Screening 20 1-21 days	06/11/91 26/11/91	Normal Abnormal	LEFT BUNDLE BRANCH BLOCK	
	51	Reboxetine	Female	06/11/91	17/11/91	Screen	-2 0 - Screening	06/11/91	Normal		
	52	Imipramine	Male	27/11/91	07/01/92	Screen	-13 0 - Screening	14/11/91	Normal		

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		PRARMACIA CNS R&D		REBOXETINE - PROTOCOL 20124/017		Listing No.: 21.0		ECC TRACINGS		E.C.G.	
Centre	Patient	Treatment	Sex	Start date	End date	Visit	days of treat.	Assessment	Date	Value	Abnormality
2	52	Imipramine	Male	27/11/91	07/01/92	Day 21 Day 42	20 41	1-21 days 22-42 days	17/12/91 07/01/92	Normal Normal	
3	65	Reboxetine	Male	02/04/91	13/05/91	Screen Day 21 Day 42	-5 20 41	0 - Screening 1-21 days 22-42 days	28/03/91 22/04/91 13/05/91	Abnormal Abnormal Abnormal	PREVIOUS MYOCARDIAL INFARCTION SINUS TACHYCARDIA (> 100) PREVIOUS MYOCARDIAL INFARCTION SINUS TACHYCARDIA (> 100) PREVIOUS MYOCARDIAL INFARCTION
	66	Imipramine	Female	01/05/91	05/06/91	Screen Day 21	-4 20	0 - Screening 1-21 days	27/04/91 21/05/91	Normal Normal	
	67	Reboxetine	Female	10/04/91	21/05/91	Screen Day 21 Day 42	-2 20 41	0 - Screening 1-21 days 22-42 days	08/04/91 30/04/91 21/05/91	Normal Normal Abnormal	SINUS TACHYCARDIA (> 100)
	68	Imipramine	Female	03/08/91	13/09/91	Screen Day 21 Day 42	-2 23 41	0 - Screening 1-21 days 22-42 days	01/08/91 26/08/91 13/09/91	Abnormal Normal Abnormal	MYOCARDIAL ISCHEMIA MYOCARDIAL ISCHEMIA
	69	Imipramine	Female	01/03/91	11/04/91	Screen Day 21 Day 42	0 20 41	0 - Screening 1-21 days 22-42 days	01/03/91 21/03/91 11/04/91	Normal Normal Normal	
	70	Reboxetine	Female	23/10/91	19/11/91	Screen Day 21	-1 20	0 - Screening 1-21 days	22/10/91 12/11/91	Normal Normal	
	71	Imipramine	Female	14/11/91	25/12/91	Screen Day 21 Day 42	-2 20 41	0 - Screening 1-21 days 22-42 days	12/11/91 04/12/91 25/12/91	Normal Normal Abnormal	SINUS TACHYCARDIA (> 100)
	72	Reboxetine	Female	31/01/92	12/03/92	Screen Day 21 Day 42	-3 21 42	0 - Screening 1-21 days 22-42 days	28/01/92 21/02/92 13/03/92	Normal Normal Normal	
	73	Reboxetine	Female	15/02/92	27/03/92	Screen Day 21 Day 42	-4 20 42	0 - Screening 1-21 days 22-42 days	11/02/92 06/03/92 28/03/92	Normal Normal Normal	
4	97	Imipramine	Male	07/05/92	18/06/92	Screen	-1	0 - Screening	06/05/92	Normal	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
Listing No.: 21.0

ECC TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
4	97	Imipramine	Male	07/05/92	18/06/92	Day 21	20	1-21 days	27/05/92	Normal	
						Day 42	46	22-42 days	22/06/92	Normal	
	100	Reboxetine	Female	07/05/92	24/06/92	Screen	-6	0 - Screening	01/05/92	Normal	
						Day 21	20	1-21 days	27/05/92	Normal	
						Day 42	41	22-42 days	17/06/92	Normal	
						Screen	0	0 - Screening	06/05/91	Normal	
6	101	Imipramine	Female	06/05/91	22/05/91	Day 21	17	1-21 days	23/05/91	Normal	
						Screen	-2	0 - Screening	27/03/91	Normal	
	161	Reboxetine	Male	29/03/91	09/05/91	Day 21	20	1-21 days	18/04/91	Normal	
						Day 42	40	22-42 days	08/05/91	Abnormal	SINUS TACHYCARDIA (> 100)
7	162	Reboxetine	Female	05/11/91	16/12/91	Screen	-1	0 - Screening	04/11/91	Normal	
						Day 21	20	1-21 days	25/11/91	Normal	
8	193	Reboxetine	Female	11/06/91	17/06/91	Day 42	41	22-42 days	16/12/91	Abnormal	CONDUCTION DISORDER
						Screen	-3	0 - Screening	08/06/91	Normal	
4	194	Reboxetine	Male	03/06/91	06/06/91	Screen	-4	0 - Screening	30/05/91	Normal	
						Screen	-1	0 - Screening	18/03/91	Normal	
8	225	Imipramine	Female	19/03/91	26/04/91	Screen	0	0 - Screening	03/05/91	Normal	
						Screen	0	0 - Screening	24/05/91	Normal	
	226	Reboxetine	Female	03/05/91	13/06/91	Day 21	24	1-21 days	24/05/91	Normal	
						Day 42	45	22-42 days	17/06/91	Normal	
	227	Imipramine	Male	07/05/91	17/06/91	Screen	-4	0 - Screening	03/05/91	Normal	
						Screen	-7	0 - Screening	03/05/91	Normal	
	228	Reboxetine	Male	10/05/91	17/05/91	Screen	-5	0 - Screening	17/10/91	Normal	
						Screen	13	1-21 days	04/11/91	Normal	
	229	Imipramine	Female	22/10/91	02/12/91	Day 21	42	22-42 days	03/12/91	Normal	
						Day 42	42	22-42 days	03/12/91	Normal	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
8	230	Imipramine	Female	05/11/91	16/12/91	Screen	-5	0 - Screening	31/10/91	Normal	
						Day 21	20	1-21 days	25/11/91	Normal	
	231	Reboxetine	Female	05/11/91	13/11/91	Screen	0	0 - Screening	05/11/91	Normal	
						Day 42	41	22-42 days	16/12/91	Normal	
9	232	Reboxetine	Male	29/11/91	09/01/92	Screen	-3	0 - Screening	26/11/91	Normal	
						Day 21	21	1-21 days	20/12/91	Abnormal	SINUS TACHYCARDIA (> 100)
	197	Reboxetine	Male	07/03/92	10/03/92	Screen	-9	0 - Screening	27/02/92	Normal	
						Day 7	6	1-21 days	13/03/92	Normal	
1446	198	Imipramine	Female	18/03/92	28/04/92	Screen	-8	0 - Screening	10/03/92	Normal	
						Day 21	20	1-21 days	07/04/92	Normal	
	199	Imipramine	Male	02/04/92	13/05/92	Screen	-9	0 - Screening	24/03/92	Normal	
						Day 21	20	1-21 days	22/04/92	Normal	
200	Reboxetine	Male	25/04/92	08/06/92	Screen	-7	0 - Screening	21/04/92	Normal		
					Day 21	20	1-21 days	18/05/92	Normal		
	201	Imipramine	Female	16/01/92	26/02/92	Screen	-9	0 - Screening	07/01/92	Normal	
						Day 21	20	1-21 days	05/02/92	Normal	
202	Imipramine	Male	17/01/92	27/02/92	Screen	-8	0 - Screening	09/01/92	Normal		
					Day 21	20	1-21 days	06/02/92	Normal		
	203	Reboxetine	Female	15/01/92	18/01/92	Screen	-6	0 - Screening	09/01/92	Normal	
						Day 7	13	1-21 days	28/01/92	Normal	
204	Reboxetine	Male	17/01/92	28/02/92	Screen	-8	0 - Screening	09/01/92	Normal		
					Day 21	20	1-21 days	06/02/92	Normal		
						Day 42	42	22-42 days	28/02/92	Normal	

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 REBOXETINE - PROTOCOL 20124/017
 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	205	Imipramine	Female	05/02/92	07/02/92	Screen	-9	0 - Screening	27/01/92	Normal	
	206	Imipramine	Female	05/02/92	18/03/92	Screen Day 21 Day 42	-8 21 42	0 - Screening 1-21 days 22-42 days	28/01/92 26/02/92 18/03/92	Normal Normal Normal	
	207	Reboxetine	Female	06/02/92	12/02/92	Screen Day 7	-1 6	0 - Screening 1-21 days	05/02/92 12/02/92	Normal Normal	
	208	Reboxetine	Male	15/02/92	27/03/92	Screen Day 21 Day 42	-5 20 41	0 - Screening 1-21 days 22-42 days	10/02/92 08/03/92 27/03/92	Normal Normal Normal	
	209	Imipramine	Male	12/02/92	15/02/92	Screen	-8	0 - Screening	04/02/92	Normal	
1447	210	Reboxetine	Female	20/02/92	01/04/92	Screen Day 42	-15 41	0 - Screening 22-42 days	05/02/92 01/04/92	Normal Normal	
	211	Reboxetine	Female	14/02/92	02/03/92	Screen Day 21	-3 18	0 - Screening 1-21 days	11/02/92 03/03/92	Normal Normal	
	212	Imipramine	Female	04/03/92	14/04/92	Screen Day 21 Day 42	-9 20 41	0 - Screening 1-21 days 22-42 days	24/02/92 24/03/92 14/04/92	Normal Normal Normal	
	237	Reboxetine	Male	23/04/92	02/05/92	Screen	-1	0 - Screening	22/04/92	Normal	
	238	Imipramine	Female	20/05/92	30/06/92	Screen Day 21 Day 42	-8 20 41	0 - Screening 1-21 days 22-42 days	12/05/92 09/06/92 30/06/92	Normal Normal Normal	
	239	Imipramine	Male	30/04/92	10/06/92	Screen Day 21 Day 42	-8 20 41	0 - Screening 1-21 days 22-42 days	22/04/92 20/05/92 10/06/92	Normal Normal Normal	
	240	Reboxetine	Female	28/04/92	16/05/92	Screen	-5	0 - Screening	23/04/92	Normal	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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	241	Imipramine	Female	09/05/92	19/06/92	Screen	-3	0 - Screening	06/05/92	Normal	
	242	Reboxetine	Male	07/05/92	17/06/92	Screen Day 21 Day 42	-7 20 41	0 - Screening 1-21 days 22-42 days	30/04/92 27/05/92 17/06/92	Normal Normal Normal	
	243	Imipramine	Female	18/05/92	28/06/92	Screen Day 21 Day 42	-7 21 42	0 - Screening 1-21 days 22-42 days	11/05/92 08/06/92 29/06/92	Normal Normal Normal	
	244	Reboxetine	Male	06/06/92	17/07/92	Screen Day 21 Day 42	-12 20 40	0 - Screening 1-21 days 22-42 days	25/05/92 26/06/92 16/07/92	Normal Normal Normal	
	257	Reboxetine	Female	17/07/91	27/08/91	Screen Day 21 Day 42	0 21 42	0 - Screening 1-21 days 22-42 days	17/07/91 07/08/91 28/08/91	Normal Normal Normal	
	258	Reboxetine	Male	17/07/91	06/08/91	Screen	-7	0 - Screening	10/07/91	Normal	
	259	Imipramine	Female	17/07/91	27/08/91	Screen Day 21 Day 42	-12 21 42	0 - Screening 1-21 days 22-42 days	05/07/91 07/08/91 28/08/91	Normal Normal Normal	
	260	Imipramine	Female	24/07/91	12/08/91	Screen Day 21	0 21	0 - Screening 1-21 days	24/07/91 14/08/91	Normal Normal	
	261	Imipramine	Female	23/07/91	29/07/91	Screen Day 7	-4 7	0 - Screening 1-21 days	19/07/91 30/07/91	Normal Normal	
	262	Reboxetine	Male	23/07/91	03/09/91	Screen Day 21 Day 42	-7 21 42	0 - Screening 1-21 days 22-42 days	16/07/91 19/08/91 03/09/91	Normal Normal Normal	
	263	Reboxetine	Female	31/07/91	13/08/91	Screen Day 14	-10 14	0 - Screening 1-21 days	21/07/91 14/08/91	Normal Normal	

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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	264	Imipramine	Female	31/07/91	10/09/91	Screen	1	0 - Screening	01/08/91	Normal	
						Day 21	21	1-21 days	21/08/91	Normal	
						Day 42	42	22-42 days	11/09/91	Normal	
	265	Reboxetine	Female	23/08/91	03/10/91	Screen	-10	0 - Screening	13/08/91	Normal	
						Day 21	20	1-21 days	12/09/91	Normal	
						Day 42	41	22-42 days	03/10/91	Normal	
	266	Reboxetine	Female	18/09/91	29/10/91	Screen	-8	0 - Screening	10/09/91	Normal	
						Day 21	20	1-21 days	08/10/91	Normal	
						Day 42	41	22-42 days	29/10/91	Normal	
	267	Imipramine	Male	02/09/91	13/10/91	Screen	-3	0 - Screening	30/08/91	Normal	
						Day 21	21	1-21 days	23/09/91	Normal	
						Day 42	42	22-42 days	14/10/91	Normal	
268	Imipramine	Female	25/09/91	05/11/91	Screen	-8	0 - Screening	17/09/91	Normal		
					Day 21	20	1-21 days	15/10/91	Normal		
					Day 42	41	22-42 days	05/11/91	Normal		
269	Reboxetine	Male	25/09/91	05/11/91	Screen	-6	0 - Screening	19/09/91	Normal		
					Day 21	20	1-21 days	15/10/91	Normal		
					Day 42	41	22-42 days	05/11/91	Normal		
270	Imipramine	Female	11/10/91	17/10/91	Screen	-9	0 - Screening	02/10/91	Normal		
					Screen	-8	0 - Screening	22/10/91	Normal		
					Day 21	20	1-21 days	19/11/91	Normal		
272	Imipramine	Male	30/10/91	10/12/91	Screen	-8	0 - Screening	22/10/91	Normal		
					Day 21	20	1-21 days	19/11/91	Abnormal	VENTRICULAR ECTOPIC BEATS - OCCASIONAL	
					Day 42	41	22-42 days	10/12/91	Abnormal	VENTRICULAR ECTOPIC BEATS - OCCASIONAL	
273	Imipramine	Female	30/10/91	20/11/91	Screen	-6	0 - Screening	24/10/91	Normal		
					Day 21	20	1-21 days	19/11/91	Normal		
					Screen	-8	0 - Screening	23/10/91	Normal		
274	Reboxetine	Female	31/10/91	31/10/91	Screen	-8	0 - Screening	23/10/91	Normal		
					Day 7	6	1-21 days	06/11/91	Normal		

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/017
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
9	274/A	Reboxetine	Female	13/05/92	23/06/92	Screen Day 21 Day 42	-22 0 - Screening 20 1-21 days 42 22-42 days		21/04/92 02/06/92 24/06/92	Normal Normal Normal
	275	Reboxetine	Female	06/11/91	17/12/91	Screen Day 21 Day 42	-6 0 - Screening 20 1-21 days 41 22-42 days		31/10/91 26/11/91 17/12/91	Normal Normal Normal
	276	Imipramine	Female	14/01/92	14/01/92	Screen Day 7	-21 0 - Screening 2 1-21 days		24/12/91 16/01/92	Normal Normal
	276/A	Imipramine	Male	04/03/92	14/04/92	Screen Day 21 Day 42	-9 0 - Screening 20 1-21 days 41 22-42 days		24/02/92 24/03/92 14/04/92	Normal Normal Normal
9/A	233	Imipramine	Male	14/05/92	24/06/92	Screen Day 21 Day 42	-3 0 - Screening 20 1-21 days 41 22-42 days		11/05/92 03/06/92 24/06/92	Normal Normal Normal
	234	Reboxetine	Female	22/05/92	02/07/92	Screen Day 21 Day 42	-4 0 - Screening 20 1-21 days 41 22-42 days		18/05/92 11/06/92 02/07/92	Normal Normal Normal
	235	Reboxetine	Male	26/05/92	29/06/92	Screen Day 21	-4 0 - Screening 21 1-21 days		22/05/92 16/06/92	Normal Normal
	236	Imipramine	Male	27/05/92	07/07/92	Screen Day 21 Day 42	-15 0 - Screening 21 1-21 days 41 22-42 days		12/05/92 17/06/92 07/07/92	Normal Normal Normal
	277	Reboxetine	Female	10/06/92	14/06/92	Screen	-1 0 - Screening		09/06/92	Normal
	278	Imipramine	Female	13/06/92	03/07/92	Screen	-3 0 - Screening		10/06/92	Normal
	279	Imipramine	Male	07/08/92	21/08/92	Screen	-4 0 - Screening		03/08/92	Normal
	280	Reboxetine	Female	08/08/92	14/08/92	Screen	-4 0 - Screening		04/08/92	Normal

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		PHARMACIA CNS R&D				E. C. G.					
		REBOXETINE - PROTOCOL 20124/017									
		Listing No.: 21.0									
		ECG TRACINGS									
Centre	Patient	Treatment	Sex	Treatment period Start date	End date	Visit	days of treat.	Assessment	Date	Value	Abnormality
9/A	281	Reboxetine	Female	01/09/92	12/10/92	Screen Day 21 Day 42	-7 0 20 41	0 - Screening 1-21 days 22-42 days	25/08/92 21/09/92 12/10/92	Normal Normal Abnormal	SINUS TACHYCARDIA (> 100)
	282	Reboxetine	Male	02/09/92	13/10/92	Screen Day 21 Day 42	-19 0 20 41	0 - Screening 1-21 days 22-42 days	14/08/92 22/09/92 13/10/92	Normal Normal Normal	
	283	Imipramine	Female	16/09/92	28/10/92	Screen Day 21 Day 42	-5 0 21 42	0 - Screening 1-21 days 22-42 days	11/09/92 07/10/92 28/10/92	Normal Normal Normal	
	284	Imipramine	Male	19/09/92	09/10/92	Screen Day 21	-3 0 20	0 - Screening 1-21 days	16/09/92 09/10/92	Normal Normal	
	301	Imipramine	Female	05/03/92	15/04/92	Screen Day 21 Day 42	-6 0 20 41	0 - Screening 1-21 days 22-42 days	28/02/92 25/03/92 15/04/92	Normal Normal Normal	
	302	Imipramine	Male	06/03/92	22/03/92	Screen	-4 0	0 - Screening	02/03/92	Normal	
	303	Reboxetine	Female	12/03/92	31/03/92	Screen Day 21	-2 0 19	0 - Screening 1-21 days	10/03/92 31/03/92	Normal Normal	
	304	Reboxetine	Female	26/03/92	06/05/92	Screen Day 21 Day 42	-9 0 20 41	0 - Screening 1-21 days 22-42 days	17/03/92 15/04/92 06/05/92	Normal Normal Normal	
	305	Reboxetine	Male	31/03/92	11/05/92	Screen Day 21 Day 42	-6 0 20 41	0 - Screening 1-21 days 22-42 days	25/03/92 20/04/92 11/05/92	Normal Normal Normal	
	306	Reboxetine	Female	29/04/92	09/06/92	Screen Day 21 Day 42	-1 0 20 41	0 - Screening 1-21 days 22-42 days	28/04/92 19/05/92 09/06/92	Normal Normal Normal	
	307	Imipramine	Female	05/05/92	08/05/92	Screen	0 0	0 - Screening	05/05/92	Normal	
	308	Imipramine	Female	09/05/92	02/06/92	Screen	-1 0	0 - Screening	08/05/92	Normal	

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REBOXETINE - PROTOCOL 20124/017
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ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
9/A	308	Imipramine	Female	09/05/92	02/06/92	Day 21	20	1-21 days	29/05/92	Normal	
10	289	Imipramine	Female	21/09/91	27/09/91	Screen	-2	0 - Screening	19/09/91	Normal	
	290	Reboxetine	Male	14/10/91	24/11/91	Screen	-7	0 - Screening	07/10/91	Normal	
						Day 21	21	1-21 days	04/11/91	Normal	
						Day 42	42	22-42 days	25/11/91	Normal	
	291	Imipramine	Male	17/02/92	29/03/92	Screen	-4	0 - Screening	13/02/92	Normal	
						Day 21	21	1-21 days	09/03/92	Normal	
						Day 42	42	22-42 days	30/03/92	Normal	
	292	Reboxetine	Female	13/12/91	23/01/92	Screen	-7	0 - Screening	06/12/91	Normal	
						Day 21	21	1-21 days	03/01/92	Normal	
						Day 42	43	22-42 days	25/01/92	Normal	
	293	Reboxetine	Female	24/12/91	01/02/92	Screen	0	0 - Screening	24/12/91	Abnormal	SINUS TACHYCARDIA (> 100) PREVIOUS MYOCARDIAL INFARCTION BIPOLARIZATION DISTURBANCES
						Day 21	21	1-21 days	14/01/92	Normal	
						Day 42	42	22-42 days	04/02/92	Normal	
	294	Imipramine	Female	03/01/92	23/01/92	Screen	-4	0 - Screening	30/12/91	Normal	
	295	Imipramine	Male	07/01/92	17/02/92	Screen	-5	0 - Screening	02/01/92	Normal	
						Day 21	20	1-21 days	27/01/92	Normal	
						Day 42	41	22-42 days	17/02/92	Normal	
	296	Reboxetine	Female	20/02/92	01/04/92	Screen	-5	0 - Screening	15/02/92	Normal	
						Day 21	21	1-21 days	12/03/92	Normal	
						Day 42	42	22-42 days	02/04/92	Normal	
	297	Reboxetine	Male	21/03/92	02/05/92	Screen	-2	0 - Screening	19/03/92	Normal	
						Day 21	20	1-21 days	10/04/92	Normal	
						Day 42	48	22-42 days	08/05/92	Normal	
	298	Reboxetine	Female	27/03/92	07/05/92	Screen	-8	0 - Screening	19/03/92	Normal	
						Day 21	20	1-21 days	16/04/92	Normal	
						Day 42	41	22-42 days	07/05/92	Normal	

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 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 21.0
 ECG TRACINGS

Centre	Patient	Treatment	Sex	_Treatment period_		Visit	days of treat.	Assessment	Date Value	Abnormality
				Start date	End date					
10	299	Imipramine	Male	07/04/92	18/05/92	Screen	-5	0 - Screening	02/04/92	Normal
						Day 21	28	1-21 days	05/05/92	Abnormal
						Day 42	42	22-42 days	19/05/92	Normal
11	300	Imipramine	Female	14/04/92	25/05/92	Screen	-7	0 - Screening	07/04/92	Normal
						Day 21	21	1-21 days	05/05/92	Normal
						Day 42	42	22-42 days	26/05/92	Normal
11	321	Reboxetine	Female	11/06/92	23/07/92	Screen	-6	0 - Screening	05/06/92	Normal
						Day 21	17	1-21 days	28/06/92	Normal
						Day 42	41	22-42 days	22/07/92	Normal
11	322	Reboxetine	Female	11/06/92	24/07/92	Screen	-7	0 - Screening	04/06/92	Normal
						Day 21	21	1-21 days	02/07/92	Normal
						Day 42	43	22-42 days	24/07/92	Normal
11	323	Imipramine	Female	24/06/92	06/08/92	Screen	-1	0 - Screening	23/06/92	Normal
						Day 21	21	1-21 days	15/07/92	Normal
						Day 42	43	22-42 days	06/08/92	Normal
11	324	Imipramine	Male	17/07/92	28/08/92	Screen	0	0 - Screening	17/07/92	Normal
						Day 21	21	1-21 days	07/08/92	Normal
						Day 42	42	22-42 days	28/08/92	Normal
11	325	Reboxetine	Female	30/07/92	10/09/92	Screen	0	0 - Screening	30/07/92	Normal
						Day 21	21	1-21 days	20/08/92	Normal
						Day 42	42	22-42 days	10/09/92	Normal
11	326	Imipramine	Male	30/07/92	10/09/92	Screen	-2	0 - Screening	23/07/92	Normal
						Day 21	21	1-21 days	20/08/92	Normal
						Day 42	42	22-42 days	10/09/92	Normal
11	327	Reboxetine	Female	20/08/92	01/10/92	Screen	-3	0 - Screening	17/08/92	Normal
						Day 21	21	1-21 days	10/09/92	Normal
						Day 42	42	22-42 days	01/10/92	Normal
11	328	Imipramine	Male	20/08/92	17/09/92	Screen	-1	0 - Screening	19/08/92	Normal
						Day 21	21	1-21 days	10/09/92	Normal
						Day 28	29	22-42 days	18/09/92	Normal

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/017
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
11	329	Imipramine	Female	21/08/92	02/10/92	Screen Day 21	-3	0 - Screening	18/08/92	Normal	
						Day 42	21	1-21 days	11/09/92	Normal	
	330	Reboxetine	Female	24/08/92	26/08/92	Screen Day 7	-42	0 - Screening	13/07/92	Normal	
						Day 7	7	1-21 days	31/08/92	Normal	
	331	Reboxetine	Male	03/09/92	15/10/92	Screen Day 21	-2	0 - Screening	01/09/92	Normal	
						Day 42	21	1-21 days	24/09/92	Abnormal	RIGHT BUNDLE BRANCH BLOCK
	332	Imipramine	Female	05/09/92	20/10/92	Screen Day 21	-2	0 - Screening	15/10/92	Abnormal	RIGHT BUNDLE BRANCH BLOCK
						Day 42	42	22-42 days	15/10/92	Abnormal	RIGHT BUNDLE BRANCH BLOCK
	333	Imipramine	Female	04/09/92	16/10/92	Screen Day 21	-23	0 - Screening	08/09/92	Normal	
						Day 42	40	22-42 days	28/09/92	Normal	
	12	337	Imipramine	Female	26/05/92	06/07/92	Screen Day 21	0	0 - Screening	04/09/92	Abnormal
Day 42							21	1-21 days	29/09/92	Normal	
338		Reboxetine	Female	20/06/92	31/07/92	Screen Day 21	-15	0 - Screening	11/05/92	Normal	
						Day 42	20	1-21 days	15/06/92	Normal	
339		Imipramine	Male	23/06/92	03/08/92	Screen Day 21	0	0 - Screening	06/07/92	Normal	
						Day 42	41	22-42 days	16/10/92	Normal	
340		Reboxetine	Female	07/08/92	17/09/92	Screen Day 21	20	1-21 days	27/08/92	Normal	
						Day 42	41	22-42 days	17/09/92	Normal	
341		Reboxetine	Female	21/08/92	24/09/92	Screen Day 21	-4	0 - Screening	17/08/92	Abnormal	SINUS TACHYCARDIA (> 100) RIGHT INCOMPLETE BUNDLE BRANCH BLOCK
						Day 21	20	1-21 days	10/09/92	Normal	
353		Reboxetine	Female	05/06/92	07/07/92	Screen Day 21	0	0 - Screening	05/06/92	Normal	
						Day 21	24	1-21 days	29/06/92	Normal	

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/017
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 ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
13	354	Imipramine	Female	24/06/92	04/08/92	Screen Day 21 Day 42	0 0 - Screening 21 1-21 days 42 22-42 days	24/06/92 15/07/92 05/08/92	Normal Abnormal Abnormal	PREVIOUS MYOCARDIAL INFARCTION LEFT VENTRICULAR HYPERTROPHY PREVIOUS MYOCARDIAL INFARCTION	
	355	Reboxetine	Female	25/06/92	27/06/92	Screen	-8 0 - Screening	17/06/92	Abnormal	Not relevant	
	356	Imipramine	Male	22/07/92	01/09/92	Screen Day 21 Day 42	0 0 - Screening 21 1-21 days 42 22-42 days	22/07/92 12/08/92 02/09/92	Normal Normal Normal		
	357	Imipramine	Female	05/08/92	09/08/92	Screen	0 0 - Screening	05/08/92	Abnormal	ATEIAL ECTOPIC BEATS - OCCASIONAL	
	358	Reboxetine	Male	06/08/92	05/09/92	Screen Day 21	0 0 - Screening 21 1-21 days	06/08/92 27/08/92	Normal Normal		
	359	Reboxetine	Female	19/08/92	29/09/92	Screen Day 21 Day 42	0 0 - Screening 21 1-21 days 42 22-42 days	19/08/92 09/09/92 30/09/92	Abnormal Normal Normal	SINUS BRADYCARDIA (< 60)	
	360	Imipramine	Female	19/08/92	21/08/92	Screen	0 0 - Screening	19/08/92	Normal		
	361	Reboxetine	Female	25/08/92	06/10/92	Screen Day 21 Day 42	0 0 - Screening 21 1-21 days 42 22-42 days	26/08/92 16/09/92 07/10/92	Normal Normal Normal		
	457	Reboxetine	Female	07/07/92	17/08/92	Screen Day 21 Day 42	0 0 - Screening 21 1-21 days 42 22-42 days	07/07/92 28/07/92 18/08/92	Normal Normal Normal		
	458	Imipramine	Female	14/07/92	24/08/92	Screen Day 21 Day 42	-4 0 - Screening 21 1-21 days 42 22-42 days	10/07/92 04/08/92 25/08/92	Normal Normal Normal		
	459	Reboxetine	Male	16/07/92	26/08/92	Screen Day 21 Day 42	-3 0 - Screening 21 1-21 days 42 22-42 days	13/07/92 06/08/92 27/08/92	Normal Normal Normal		
	460	Imipramine	Male	23/07/92	02/09/92	Screen	-3 0 - Screening	20/07/92	Abnormal	SINUS BRADYCARDIA (< 60)	

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 21.0
 ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality	
				Start date	End date							
14	460	Imipramine	Male	23/07/92	02/09/92	Day 21 Day 42	21 41	1-21 days 22-42 days	13/08/92 02/09/92	Abnormal Normal	SINUS BRADYCARDIA (< 60)	
	461	Imipramine	Female	29/07/92	08/09/92	Screen Day 21 Day 42	-7 21 42	0 - Screening 1-21 days 22-42 days	22/07/92 19/08/92 09/09/92	Normal Normal Normal		
	462	Reboxetine	Female	31/07/92	10/09/92	Screen Day 21 Day 42	-7 21 42	0 - Screening 1-21 days 22-42 days	26/07/92 21/08/92 11/09/92	Normal Normal Normal		
	463	Imipramine	Male	03/08/92	13/09/92	Screen Day 21 Day 42	-7 21 42	0 - Screening 1-21 days 22-42 days	27/07/92 24/08/92 14/09/92	Normal Normal Normal		
	464	Reboxetine	Female	05/08/92	16/09/92	Screen Day 21 Day 42	-7 22 43	0 - Screening 1-21 days 22-42 days	29/07/92 27/08/92 17/09/92	Normal Normal Normal		
	465	Reboxetine	Male	06/08/92	16/09/92	Screen Day 21 Day 42	-7 21 42	0 - Screening 1-21 days 22-42 days	30/07/92 27/08/92 17/09/92	Normal Normal Normal		
	466	Imipramine	Female	07/08/92	17/09/92	Screen Day 21 Day 42	-7 21 42	0 - Screening 1-21 days 22-42 days	31/07/92 28/08/92 18/09/92	Normal Normal Normal		
	14/1	129	Reboxetine	Male	19/12/91	19/12/91	Screen	-8	0 - Screening	11/12/91	Normal	
	426	Reboxetine	Female	05/09/91	17/10/91	Screen Day 21 Day 42	-8 19 42	0 - Screening 1-21 days 22-42 days	28/08/91 24/09/91 17/10/91	Abnormal Normal Normal	VENTRICULAR ECTOPIC BEATS - OCCASIONAL	
	429	Imipramine	Female	26/09/91	29/09/91	Screen	-8	0 - Screening	18/09/91	Normal		
	451	Imipramine	Male	28/11/91	07/01/92	Screen Day 21 Day 42	-1 20 41	0 - Screening 1-21 days 22-42 days	27/11/91 18/12/91 08/01/92	Abnormal Abnormal Abnormal	ATRIAL ECTOPIC BEATS - OCCASIONAL A-V BLOCK 1ST DEGREE A-V BLOCK 1ST DEGREE	

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PHARMACIA CNS RED
 REBOXETINE - PROTOCOL 20124/017
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 ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
14/1	452	Reboxetine	Female	28/11/91	09/01/92	Screen Day 21 Day 42	-2 0 - Screening 21 1-21 days 41 22-42 days	26/11/91 19/12/91 08/01/92	Normal Normal Normal		
14/2	136	Imipramine	Female	15/01/92	25/02/92	Screen Day 21 Day 42	-6 0 - Screening 27 1-21 days 41 22-42 days	09/01/92 11/02/92 25/02/92	Normal Normal Normal		
	456	Imipramine	Male	15/04/92	26/05/92	Screen Day 21 Day 42	-6 0 - Screening 22 1-21 days 44 22-42 days	09/04/92 07/05/92 29/05/92	Normal Normal Normal		
14/3	417	Reboxetine	Female	14/06/91	26/07/91	Screen Day 21 Day 42	-4 0 - Screening 21 1-21 days 42 22-42 days	10/06/91 05/07/91 26/07/91	Normal Normal Normal		
	418	Imipramine	Female	18/06/91	29/07/91	Screen Day 21 Day 42	-8 0 - Screening 20 1-21 days 41 22-42 days	10/06/91 08/07/91 29/07/91	Normal Normal Normal		
	419	Reboxetine	Female	05/07/91	15/08/91	Screen Day 21 Day 42	-2 0 - Screening 20 1-21 days 41 22-42 days	03/07/91 25/07/91 15/08/91	Normal Normal Normal		
	420	Imipramine	Female	05/07/91	25/07/91	Screen Day 21	-1 0 - Screening 45 1-21 days	04/07/91 19/08/91	Normal Normal		
	421	Reboxetine	Female	19/07/91	12/09/91	Screen Day 21 Day 42	-8 0 - Screening 20 1-21 days 34 22-42 days	11/07/91 08/08/91 22/08/91	Normal Normal Normal		
	427	Imipramine	Female	18/09/91	15/10/91	Screen Day 21	0 0 - Screening 21 1-21 days	18/09/91 09/10/91	Normal Normal		
	428	Imipramine	Female	25/10/91	05/12/91	Screen Day 21 Day 42	0 0 - Screening 20 1-21 days 41 22-42 days	25/10/91 14/11/91 05/12/91	Normal Normal Normal		
14/4	131	Imipramine	Female	14/01/92	24/02/92	Screen Day 21	-7 0 - Screening 21 1-21 days	07/01/92 04/02/92	Normal Normal		

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REBOXETINE - PROTOCOL 20124/017
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	_Treatment period_		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
14/4	131	Imipramine	Female	14/01/92	24/02/92	Day 42	42	22-42 days	25/02/92	Normal	
	132	Imipramine	Female	14/01/92	24/02/92	Screen Day 21	-7	0 - Screening	07/01/92	Normal	
						Day 42	21	1-21 days	04/02/92	Normal	
							42	22-42 days	25/02/92	Normal	
	133	Imipramine	Female	16/01/92	26/02/92	Screen Day 21	-7	0 - Screening	09/01/92	Normal	
						Day 42	21	1-21 days	06/02/92	Normal	
							42	22-42 days	27/02/92	Normal	
	134	Reboxetine	Female	16/01/92	26/02/92	Screen Day 21	-7	0 - Screening	09/01/92	Normal	
						Day 42	21	1-21 days	06/02/92	Normal	
							42	22-42 days	27/02/92	Normal	
	135	Reboxetine	Male	17/01/92	27/02/92	Screen Day 21	-7	0 - Screening	10/01/92	Abnormal	PREVIOUS MYOCARDIAL INFARCTION
						Day 42	21	1-21 days	07/02/92	Abnormal	PREVIOUS MYOCARDIAL INFARCTION
							42	22-42 days	28/02/92	Abnormal	PREVIOUS MYOCARDIAL INFARCTION
14/7	422	Imipramine	Female	04/09/91	15/10/91	Screen Day 21	-2	0 - Screening	02/09/91	Normal	
						Day 42	21	1-21 days	25/09/91	Normal	
							48	22-42 days	22/10/91	Normal	
	423	Imipramine	Female	17/09/91	28/10/91	Screen Day 21	-7	0 - Screening	10/09/91	Normal	
						Day 42	21	1-21 days	08/10/91	Normal	
							42	22-42 days	29/10/91	Normal	
	424	Reboxetine	Male	19/09/91	30/10/91	Screen Day 21	-13	0 - Screening	06/09/91	Normal	
						Day 42	21	1-21 days	10/10/91	Normal	
							42	22-42 days	31/10/91	Abnormal	SINUS TACHYCARDIA (> 100)
	430	Reboxetine	Female	07/10/91	17/11/91	Screen Day 21	0	0 - Screening	07/10/91	Normal	
						Day 42	21	1-21 days	28/10/91	Normal	
							42	22-42 days	18/11/91	Normal	
	431	Reboxetine	Male	08/10/91	18/11/91	Screen Day 21	0	0 - Screening	08/10/91	Normal	
						Day 42	21	1-21 days	29/10/91	Normal	
							42	22-42 days	19/11/91	Normal	
	432	Imipramine	Male	08/10/91	18/11/91	Screen Day 21	0	0 - Screening	08/10/91	Normal	
							21	1-21 days	29/10/91	Normal	

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Listing No.: 21.0
ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
14/7	432	Imipramine	Male	08/10/91	18/11/91	Day 42	42	22-42 days	19/11/91	Normal	
	433	Imipramine	Female	08/10/91	18/11/91	Screen Day 21	0	0 - Screening	08/10/91	Normal	
						Day 42	21	1-21 days	29/10/91	Normal	
						Day 42	42	22-42 days	19/11/91	Normal	
	434	Reboxetine	Male	14/10/91	24/11/91	Screen Day 21	-4	0 - Screening	10/10/91	Normal	
						Day 42	21	1-21 days	04/11/91	Normal	
						Day 42	42	22-42 days	25/11/91	Normal	
	439	Reboxetine	Male	11/11/91	22/12/91	Screen Day 21	-5	0 - Screening	06/11/91	Normal	
						Day 42	36	1-21 days	17/12/91	Normal	
						Day 42	42	22-42 days	23/12/91	Abnormal	SINUS TACHYCARDIA (> 100)
	440	Imipramine	Female	11/11/91	22/12/91	Screen Day 21	-4	0 - Screening	07/11/91	Normal	
						Day 42	21	1-21 days	02/12/91	Abnormal	SINUS TACHYCARDIA (> 100)
						Day 42	42	22-42 days	23/12/91	Normal	
	441	Imipramine	Male	11/11/91	22/12/91	Screen Day 21	-3	0 - Screening	08/11/91	Normal	
						Day 42	21	1-21 days	02/12/91	Normal	
						Day 42	42	22-42 days	23/12/91	Abnormal	SINUS BRADYCARDIA (< 60)
	442	Imipramine	Male	11/11/91	22/12/91	Screen Day 21	-3	0 - Screening	08/11/91	Normal	
						Day 42	21	1-21 days	02/12/91	Abnormal	SINUS TACHYCARDIA (> 100)
						Day 42	36	22-42 days	17/12/91	Normal	
	449	Reboxetine	Female	20/12/91	30/01/92	Screen Day 21	-4	0 - Screening	16/12/91	Normal	
						Day 42	21	1-21 days	10/01/92	Normal	
						Day 42	42	22-42 days	31/01/92	Normal	
	450	Imipramine	Male	23/12/91	02/02/92	Screen Day 21	-17	0 - Screening	06/12/91	Abnormal	SINUS BRADYCARDIA (< 60)
						Day 42	21	1-21 days	13/01/92	Normal	
						Day 42	42	22-42 days	03/02/92	Abnormal	SINUS BRADYCARDIA (< 60)
14/8	130	Reboxetine	Male	10/01/92	20/02/92	Screen Day 21	0	0 - Screening	10/01/92	Normal	
						Day 42	21	1-21 days	31/01/92	Normal	
						Day 42	42	22-42 days	21/02/92	Normal	
	425	Reboxetine	Female	09/09/91	20/10/91	Screen Day 21	-3	0 - Screening	06/09/91	Normal	
						Day 21	21	1-21 days	30/09/91	Abnormal	LEFT ANTERIOR HEMIBLOCK

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ECG TRACINGS

Centre	Patient	Treatment	Sex	_Treatment period_		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
14/8	425	Reboxetine	Female	09/09/91	20/10/91	Day 42	42	22-42 days	21/10/91	Normal	
	467	Reboxetine	Male	06/07/92	16/08/92	Screen Day 21 Day 42	-4 21 42	0 - Screening 1-21 days 22-42 days	02/07/92 27/07/92 17/08/92	Normal Normal Normal	
14/10	53	Reboxetine	Male	25/02/92	06/04/92	Screen Day 21 Day 42	-8 20 41	0 - Screening 1-21 days 22-42 days	17/02/92 16/03/92 06/04/92	Normal Normal Normal	
	54	Imipramine	Female	26/02/92	07/04/92	Screen Day 21 Day 42	-8 20 41	0 - Screening 1-21 days 22-42 days	18/02/92 17/03/92 07/04/92	Normal Normal Normal	
	55	Reboxetine	Female	28/02/92	09/04/92	Screen Day 21 Day 42	-8 20 41	0 - Screening 1-21 days 22-42 days	20/02/92 19/03/92 09/04/92	Normal Normal Normal	
	56	Imipramine	Female	03/03/92	13/04/92	Screen Day 21 Day 42	-8 20 41	0 - Screening 1-21 days 22-42 days	24/02/92 23/03/92 13/04/92	Normal Normal Normal	
	57	Reboxetine	Female	04/03/92	14/04/92	Screen Day 21 Day 42	-8 20 41	0 - Screening 1-21 days 22-42 days	25/02/92 24/03/92 14/04/92	Normal Normal Normal	
	58	Imipramine	Female	14/04/92	25/05/92	Screen Day 21 Day 42	-12 20 41	0 - Screening 1-21 days 22-42 days	02/04/92 04/05/92 25/05/92	Normal Normal Normal	
	59	Imipramine	Female	24/04/92	04/06/92	Screen Day 21 Day 42	-9 20 42	0 - Screening 1-21 days 22-42 days	15/04/92 14/05/92 05/06/92	Normal Normal Normal	
	60	Reboxetine	Female	13/05/92	23/06/92	Screen Day 21 Day 42	-9 20 41	0 - Screening 1-21 days 22-42 days	04/05/92 02/06/92 23/06/92	Normal Abnormal Normal	SINUS BRADYCARDIA (< 60)
	137	Reboxetine	Female	28/01/92	09/03/92	Screen Day 21	-8 20	0 - Screening 1-21 days	20/01/92 17/02/92	Normal Normal	

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PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 Listing No.: 21.0
 ECG TRACINGS

Centre	Patient	Treatment	Sex	_Treatment period_		Visit	days of treat.	Assessment	Date	Value	Abnormality
				Start date	End date						
14/10	137	Reboxetine	Female	28/01/92	09/03/92	Day 42	41	22-42 days	09/03/92	Normal	
	138	Imipramine	Female	29/01/92	10/03/92	Screen Day 21	-8	0 - Screening	21/01/92	Normal	
						Day 42	20	1-21 days	18/02/92	Normal	
	139	Reboxetine	Female	04/02/92	16/03/92	Screen Day 21	-8	0 - Screening	27/01/92	Normal	
						Day 42	20	1-21 days	24/02/92	Normal	
	140	Imipramine	Female	05/02/92	17/03/92	Screen Day 21	-8	0 - Screening	28/01/92	Normal	
						Day 42	20	1-21 days	25/02/92	Normal	
	435	Imipramine	Female	12/11/91	23/12/91	Screen Day 21	-8	0 - Screening	04/11/91	Normal	
						Day 42	20	1-21 days	03/12/91	Normal	
	436	Reboxetine	Female	13/11/91	23/12/91	Screen Day 21	-8	0 - Screening	05/11/91	Normal	
						Day 42	20	1-21 days	03/12/91	Normal	
	437	Reboxetine	Female	14/11/91	23/12/91	Screen Day 21	-9	0 - Screening	05/11/91	Normal	
						Day 42	39	22-42 days	03/12/91	Normal	
	438	Imipramine	Female	15/11/91	27/12/91	Screen Day 21	-8	0 - Screening	07/11/91	Normal	
						Day 42	20	1-21 days	05/12/91	Normal	
	443	Reboxetine	Female	19/11/91	30/12/91	Screen Day 21	-5	0 - Screening	14/11/91	Normal	
						Day 42	20	1-21 days	09/12/91	Normal	
	444	Reboxetine	Male	16/11/91	27/12/91	Screen Day 21	-1	0 - Screening	15/11/91	Normal	
						Day 42	20	1-21 days	06/12/91	Normal	
	445	Imipramine	Female	20/11/91	30/12/91	Screen Day 21	-5	0 - Screening	15/11/91	Normal	
						Day 21	20	1-21 days	10/12/91	Normal	

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ECG TRACINGS

Centre	Patient	Treatment	Sex	_Treatment period_		Visit	days of treat.	Assessment	E.C.G.		
				Start date	End date				Date	Value	Abnormality
14/10	445	Imipramine	Female	20/11/91	30/12/91	Day 42	40	22-42 days	30/12/91	Abnormal	VENTRICULAR ECTOPIC BEATS - OCCASIONAL
	446	Reboxetine	Female	26/11/91	07/01/92	Screen Day 21 Day 42	-4 20 42	0 - Screening 1-21 days 22-42 days	22/11/91 16/12/91 07/01/92	Normal Normal Normal	
	447	Reboxetine	Male	27/11/91	07/01/92	Screen Day 21 Day 42	-1 20 41	0 - Screening 1-21 days 22-42 days	26/11/91 17/12/91 07/01/92	Normal Abnormal Abnormal	VENTRICULAR ECTOPIC BEATS - OCCASIONAL ATRIAL ECTOPIC BEATS - OCCASIONAL
	448	Imipramine	Female	28/11/91	07/01/92	Screen Day 21 Day 42	-6 19 40	0 - Screening 1-21 days 22-42 days	22/11/91 17/12/91 07/01/92	Normal Normal Normal	
	453	Imipramine	Female	28/05/92	08/07/92	Screen Day 21 Day 42	-10 20 41	0 - Screening 1-21 days 22-42 days	18/05/92 17/06/92 08/07/92	Normal Normal Normal	
	454	Reboxetine	Female	12/06/92	23/07/92	Screen Day 21 Day 42	-10 20 41	0 - Screening 1-21 days 22-42 days	02/06/92 02/07/92 23/07/92	Normal Normal Normal	
	455	Reboxetine	Female	20/06/92	31/07/92	Screen Day 21 Day 42	-9 20 41	0 - Screening 1-21 days 22-42 days	11/06/92 10/07/92 31/07/92	Normal Normal Abnormal	SINUS BRADYCARDIA (< 60)
15	349	Imipramine	Male	20/08/92	01/10/92	Screen Day 42	0 42	0 - Screening 22-42 days	20/08/92 01/10/92	Abnormal Normal	A-V BLOCK 1ST DEGREE
	351	Reboxetine	Male	02/09/92	14/10/92	Screen Day 42	0 42	0 - Screening 22-42 days	02/09/92 14/10/92	Abnormal Abnormal	A-V BLOCK 1ST DEGREE A-V BLOCK 1ST DEGREE
	352	Imipramine	Male	06/08/92	27/08/92	Screen	0	0 - Screening	06/08/92	Abnormal	SINUS BRADYCARDIA (< 60)
	364	Imipramine	Female	29/07/92	26/08/92			0 - Screening			
	366	Reboxetine	Male	27/08/92	08/10/92	Day 42	42	22-42 days	08/10/92	Normal	

1462

9550085

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23

PHARMACIA CNS RD
 REBOXETINE - PROTOCOL 20124/017
 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
15	367	Imipramine	Male	31/08/92	11/10/92	Screen Day 42	0 0 - Screening 42 22-42 days	0	31/08/92	Normal
	368	Reboxetine	Female	04/09/92	15/10/92	Screen Day 42	0 0 - Screening 41 22-42 days	0	04/09/92	Normal
	369	Reboxetine	Female	10/07/92	20/08/92		0 - Screening	0	15/10/92	Normal
	370	Imipramine	Female	16/07/92	27/08/92	Screen	0 0 - Screening	0	16/07/92	Normal
	371	Reboxetine	Female	20/07/92	31/08/92		0 - Screening	0		
	372	Imipramine	Male	17/06/92	29/07/92	Screen Day 21	0 0 - Screening 18 1-21 days	0	17/06/92	Abnormal
	373	Imipramine	Female	25/06/92	26/06/92	Screen	0 0 - Screening	0	05/07/92	Normal
	374	Reboxetine	Female	09/04/92	20/05/92	Screen Day 42	0 0 - Screening 41 22-42 days	0	17/06/92	Abnormal
	375	Reboxetine	Female	06/06/92	25/06/92	Screen Day 21	0 0 - Screening 19 1-21 days	0	05/07/92	Normal
	376	Imipramine	Female	13/04/92	21/04/92	Screen	0 0 - Screening	0	25/06/92	Normal
	377	Reboxetine	Female	13/05/92	25/06/92	Day 21 Day 42	21 1-21 days 42 22-42 days	0	09/04/92	Normal
	378	Reboxetine	Female	15/06/92	27/07/92	Screen Day 21 Day 42	0 0 - Screening 21 1-21 days 42 22-42 days	0	20/05/92	Normal
	379	Imipramine	Female	16/04/92	17/04/92		0 - Screening	0	06/06/92	Abnormal
	380	Imipramine	Female	30/06/92	10/08/92	Screen Day 21	0 0 - Screening 20 1-21 days	0	13/04/92	Normal

1468

SINUS TACHYCARDIA (> 100)
 LEFT ANTERIOR HEMIBLOCK

SINUS TACHYCARDIA (> 100)
 OTHER

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24

PHARMACIA CNS R&D
 REBOXETINE - PROTOCOL 20124/017
 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						
15	381	Reboxetine	Female	21/05/92	01/07/92	Screen Day 42	1	0 - Screening	22/05/92	Normal	
							42	22-42 days	02/07/92	Normal	
	382	Imipramine	Male	09/04/92	18/04/92			0 - Screening			
	383	Imipramine	Female	07/07/92	18/08/92	Screen	0	0 - Screening	07/07/92	Normal	
	384	Reboxetine	Female	28/07/92	05/08/92			0 - Screening			

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1464

Pharmacia

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12.2.3 CRFS

Individual Patient CRFs are filed in the Study Master File

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