Studie 016

(CTN016-FCE20124)

Studienbericht

Pharmacia **Document 9550083**

Reboxetine	**CLINICAL STUDY 016**	**29 November 1995**

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

(Phase III)

Final report of study
CTN016-FCE20124

Authors : Dubini A, Vanoni G, Petroccione A, Massana J, Möller HJ, Burrows GD, Montenegro RM

Pharmacia **Document 9550083**

STUDY CO-ORDINATION, MANAGEMENT AND REPORTING

Study Director

Adriana Dubini Pharm.D
Pharmacia, CNS R&D
Milan, Italy

29.11.95 Adriana Dubini
date signature

Medical Research Associate

Giuliana Vanoni Biol.D
Pharmacia, CNS R&D
Milan, Italy

29.11.1995 Giuliana Vanoni
date signature

Statistics

Anna Petroccione MD
Pharmacia, Oncology R&D
Biometrics and Data Management
Milan, Italy

29.11.95 Anna Petroccione
date signature

Pharmacia **Document 9550083**

Clinical Investigator and Member of the Steering Committee:

Prof. Juan Massana

Department of Psychiatry
Hospital Clinico de Barcelona
Barcelona, Spain

8.01.96 **date** **signature**

Pharmacia **Document 9550083**

Clinical Investigator and Member of the Steering Committee:

Prof. Hans J Möller

Psychiatrische Universitätsklinik
Bonn, Germany

7.12.015
date **signature**

Pharmacia **Document 9550083**

Clinical Investigator and Member of the Steering Committee:

Prof. Graham D. Burrows

Department of Psychiatry
University of Melbourne,
Austin Hospital
Melbourne, Australia

12-12-95
date **signature**

Pharmacia **Document 9550083**

Clinical Investigator and Member of the Steering Committee:

Prof. Roger M. Montenegro

Juncal 2425 8°B
Buenos Aires, Argentina

11-12-95
date **signature**

TABLE OF CONTENTS

TABLE OF CONTENTS (continued)

TABLE OF CONTENTS (continued)

LIST OF ABBREVIATIONS AND TERMS

ANOVA	analysis of variance
AUC	area under the curve
b.i.d.	twice daily
BUN	blood urea nitrogen
CGI	clinical global impression
C.I.	confidence interval
CRF	case record form
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-Asberg depression rating scale
o.d.	once daily
PGI	Patient Global Impression
REM	rapid eye movement
SASS	social adaptation self-evaluation scale
SD	standard deviation
SGOT	serum glutamic-oxaloacetic transaminase
SGPT	serum glutamic-pyruvic transaminase
T4	thyroxine
TSH	thyroid-stimulating hormone

REBOXETINE - PROTOCOL 20124/016
SYNOPSIS

Name of Company: Pharmacia Spa **Name of finished product:** **Name of active ingredient(s):** Reboxetine	**Individual study table referring to part IV of the dossier** **Ref.:** **Vol.:** **Page:**	**(For national authority use only)**
Title of study: Multicentre, Multinational Double-Blind Study of the Activity and Tolerability of Reboxetine *vs* Fluoxetine in Patients Suffering from Major Depressive Episodes		
Investigators: Dr HJ Möller, Dr W Seeler, Dr B Ziegler, Dr B Pflug, Dr J Lopez Ibor, Dr E Alvarez, Dr J Massana, Prof GD Burrows, Dr R Gupta, Dr T George, Dr JC Ferrali, Dr R Montenegro, Dr HJ Schierle, Dr J Zehner, Prof M Hummel, Dr W Bellaire		
Study centres: Psychistrische Universitätsklinik, Bonn, Germany; Allgemeines Krankenhaus, Ochsenzoll Hamburg, Germany; Universitätsklinik im LK Homburg, Homburg/Saar, Germany; Zentrum für Psychiatrie am Klinikum der J.W. Goethe Univ, Frankfurt, Germany; Hospital Ramon y Cajal, Madrid, Spain; Hosp. de la Santa Creu y San Pau, Barcelona, Spain; Hospital Clinico de Barcelona, Barcelona, Spain; Dept. of Psychiatry, University of Melbourne, Austin Hospital, Melbourne, Australia; Phillip Health Centre, Canberra, Australia; The Prince Charles Hospital, Brisbane, Australia; Moldes 2166 8°D, Buenos Aires, Argentina; Juncal 2425 8°B, Buenos Aires, Argentina; Puiseaux Platz 2, Rodgau, Germany; Kurstrasse 9, Bad Nauheim, Germany; Psychistrische Univ. Klinik, Marburg/Lahn, Germany; Talstrasse 36, Homburg/Saar, Germany.		
Publication (reference): None		
Study period: April 1991 - May 1993	**Clinical Phase:** III	
Objectives: To assess the activity and tolerability of reboxetine in comparison with fluoxetine in patients suffering from major depressive episodes.		
Methodology: In this prospective, double-blind, randomised, parallel group, multicentre and multinational trial, patients underwent an initial wash-out period of 4-7 days (14 days in case of MAOI administration and 3-4 weeks in the case of previous fluoxetine treatment) after which they received one of two treatments: oral reboxetine 4 mg twice daily (b.i.d.) or oral fluoxetine 20 mg once daily (o.d.) for 8 weeks. After 4 weeks, the dosages could be increased if necessary as follows: reboxetine 4 mg each morning and 6 mg each afternoon or fluoxetine 20 mg b.i.d. The response to treatment was assessed using the Hamilton Depression Rating Scale (HAMD), Clinical Global Impression (CGI), the Montgomery and Asberg Depression Rating Scale (MADRS), Patient Global Impression (PGI), the Social Adaptation Self-evaluation Scale (SASS) and Quality of Sleep. Patient self-assessment results are reported separately in the Addendum 1 to the present report. 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): 220 patients were to be recruited in the study. One hundred and sixty-eight patients from 16 centres were randomised to treatment with either reboxetine (79) or fluoxetine (89).		
Diagnosis and main criteria for inclusion: Patients were diagnosed according to the DSM-III-R classification. The severity of depression was evaluated using the HAMD scale. Criteria for inclusion were as follows: (1) Patients of either sex, of any race, aged 18 to 65 years, with a diagnosis of acute Major Depressive Episodes, not accompanied by psychotic features (DSM-III-R) with the current episode having been present for 1-8 months; (2) Initial (pre-treatment) total score for the 21-item had to be ≥22.		

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)
Test product: capsules containing RBX methanesulphonate tablets **Unit dose:** 4 mg (two 2 mg tablets) or 6 mg (three 2 mg tablets) reboxetine (free base) **Mode of administration:** by oral route, b.i.d. **Batch no.:** 4 mg: SF1264; 6 mg: SF1132, SF1291		
Duration of treatment: 8 weeks		
Reference therapy: Fluoxetine 20 mg tablets in capsules **Unit dose:** 20 mg fluoxetine **Mode of administration:** by oral route o.d.(fluoxetine), with o.d. dummy placebo **Batch no.:** SF1128, SF1307, SF1340 (fluoxetine), SF1247 (dummy placebo)		
Criteria for evaluation: **Efficacy** *Study end-point:* difference of HAMD total score decrease at last assessment *vs* baseline *Response:* HAMD total score decrease equal to or greater than 50% compared to the baseline value (Visit 0). *Remission:* HAMD total score lower than or equal to 10 (absolute value). *Time to response:* no. of days to onset of response confirmed at all subsequent available assessments Other variables used for evaluating efficacy were the CGI and the MADRS. **Safety** 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. Clinically relevant modifications of blood pressure (BP) and heart rate (HR) (≥20% *vs* baseline), or such modifications associated with critical values (≥160 or ≤100 mmHg for systolic BP; ≥100 or ≤70 mmHg for diastolic BP; ≥100 or ≤50 beats/min for HR). Orthostatic hypotension (decrease of systolic BP ≥30 mmHg from lying to standing). Clinically relevant changes of laboratory tests and abnormal ECG findings according to standardised criteria.		
Statistical Method: **Efficacy** Efficacy variables, including HAMD total score, MADRS total score 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 considering the last valid observation, for both treatment groups. The number of patients showing increases, decreases or no changes in Severity of Illness score at last valid observation in comparison with baseline were also analysed. The primary end-point for efficacy analysis was the mean changes of HAMD total score at last valid observation respect to baseline. 95% confidence interval (C.I.) of the mean changes in each treatment group and of the between treatment difference were calculated. The cumulative probability of the onset of response (time to response) was computed adopting the Kaplan-Meier method and the between treatment comparison was carried out by the log-rank test.		

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)

Safety

Vital signs were summarised by descriptive statistics. Patients with orthostatic hypotension (a decrease ≥30 mmHg of systolic blood pressure from lying to standing) were described.
In addition, the frequency of patients showing clinically relevant (20% or more *vs* baseline) changes 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 were summarised in frequency tables showing normal/abnormal findings at each visit. Changes from baseline (i.e. normal to abnormal and vice versa) were displayed.

For all the laboratory tests frequency of patients shifted from values below, within or above the normal range at baseline to values below, within or above the normal range at each visit were computed. The Stuart Maxwell test was applied to test the changes in the distribution across categories at each visit *vs* baseline.

Continuous values of laboratory tests were standardised 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.

The cumulative risk of developing the first adverse event, as well as individual adverse event and adverse event clusters (newly emerged in 5% or more of patients in at least one treatment group) was estimated by Kaplan-Meier method and the difference between treatments was tested by the log-rank test.

Results:

One hundred and sixty-eight patients (121 females and 47 males) were admitted to the study and randomised to treatment. A total of 128 patients (76.2%) completed the study (59 reboxetine and 69 fluoxetine patients). Overall, 40 patients (23.8%) withdrew, 20 (25.3%) in reboxetine group and 20 (22.5%) in fluoxetine group. Newly emerged adverse events were the main reason of treatment discontinuation in 9 (11.4%) patients and 6 (6.7%) patients in the reboxetine and fluoxetine groups, while deterioration of the depression was the main reason for withdrawal in 4 and 6 patients in the two groups, respectively. Remaining cases of withdrawal were non compliance (4 patients in each treatment group) and protocol violation or being lost to follow-up (3 reboxetine and 4 fluoxetine patients).

Efficacy

The mean HAMD total score was reduced from 28.6 at Day 0 to 9.4 at last assessment, in the 76 reboxetine-treated patients who had at least one assessment in addition to baseline, and to 7.3 at Day 56 in the 59 patients who completed the study. In the 87 fluoxetine-treated patients with at least one assessment in addition to baseline, the mean HAMD total score was reduced from 27.4 at Day 0 to 10.6 at last assessment, and to 7.8 at Day 56 in the 69 patients still on treatment. The between treatment difference in HAMD total score decrease at last assessment was of 2.4 points (95% C.I.: -0.3 + 5.1).

The percentage of responders at each visit was similar in the reboxetine group and the fluoxetine group from Day 14 onwards. At last assessment, 77.6% of the reboxetine-treated patients and 73.6% of the fluoxetine-treated patients were classified as responders, while 67.1% and 66.7%, respectively, were seen to be in remission. The between treatment difference in the proportion of response was of 4.1% (95% C.I.: -9.1% + 17.2%) in favour of reboxetine.

The cumulative probability of response (confirmed at all available subsequent assessments), plotted according to the Kaplan-Meier method showed a similar pattern for patients on reboxetine and on fluoxetine (p=0.80).

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)

Efficacy (continued)

The additional analyses, carried out in the sub-populations of severe (CGI - Severity of Illness: markedly to extremely ill at the admission) and melancholic (DSM IV) patients, suggested that the reboxetine treatment was superior to the fluoxetine in both sub-populations, considering the HAMD differences at last assessment *vs* baseline. In severe cases (55 reboxetine- and 66 fluoxetine-treated patients), the between treatment difference was of 5.3 points (95% C.I.: 2.2 + 8.4), definitely different from 0, while in melancholic patients (melancholic/not melancholic: 39/29 in the reboxetine and 39/38 in the fluoxetine group) the difference was 3.6 points (95% C.I.: -0.5 + 7.7).

At last assessment, the percentage of patients who were 'much improved' and 'very much improved' (CGI) were 78.0% in the reboxetine group and 75.8% in the fluoxetine group. The proportion of the patients who had no change of the global improvement were similar in the two treatment groups (6.5% and 8.0% on reboxetine and fluoxetine, respectively), as well as the proportion of the 'minimally worse' patients (6.5% and 4.6% on reboxetine and fluoxetine, respectively). Only in the fluoxetine treatment group there were 3.4% of patients who were 'much worse' and 'very much worse'.

At last assessment, the mean total MADRS score was reduced from 17.1 at Day 0 to 5.7 in the 76 reboxetine-treated patients with at least one assessment in addition to baseline, and to 4.1 at Day 56 in the 59 reboxetine patients who completed the study. In the fluoxetine-treated patients, values changed from 16.2 at Day 0 to 6.2 at last assessment (87 patients), and to 4.3 at Day 56 (69 assessed patients).

At last assessment, side-effects were judged to outweigh efficacy in 10.4% of the reboxetine patients and 11.5% of the fluoxetine patients. A clear benefit from therapy (EI ≥ 2) was obtained in the majority of the patients in both treatment groups (approximately 64% of the reboxetine-treated patients and 72% of the fluoxetine-treated patients).

Safety: All the 168 patients who received study treatment were included in the safety analysis (79 reboxetine, 89 fluoxetine).

The occurrence of newly reported adverse events was similar in both groups during the study; 53/79 (67.1%) reboxetine group patients reported 221 adverse events compared with 60/89 (67.4%) fluoxetine patients who reported 180 adverse events. Discontinuation associated with adverse event was slightly more frequent in reboxetine patients (11.4%) than in fluoxetine patients (6.7%). More frequently reported adverse events by reboxetine-treated patients than fluoxetine-treated patients were dry mouth (34.2% *vs* 9.0%, respectively), constipation (21.5% *vs* 6.7%), hypotension and related symptoms (19.0% *vs* 7.9%), urinary hesitancy/retention (12.7% *vs* 1.1%) and paraesthesia (6.3% *vs* 1.1%). Agitation/anxiety/nervousness and diarrhoea were reported more frequently in the fluoxetine group (11.2% and 6.7%) compared with the reboxetine group (3.8% and 1.3%).

The majority of adverse events were moderate in both treatment groups. Females suffered from adverse events less than males when on reboxetine (64.9% *vs* 72.7%) and more frequently than males when on fluoxetine (75.0% *vs* 48.0%). The most relevant between-gender difference was related to the frequency of insomnia, nausea, tremor and paraesthesia, complained of mainly by female patients in both treatment groups and urinary hesitancy, complained of mainly by male patients in the reboxetine group.

The estimate cumulative risk of adverse events (according to the Kaplan-Meier method and log-rank test) is significantly higher on reboxetine than on fluoxetine for constipation, hypotension and related symptoms, dry mouth and urinary hesitancy/retention. In addition the cumulative risk is higher, but not significantly so, in reboxetine than in fluoxetine patients for paraesthesia and, conversely, it is higher in fluoxetine patients than in reboxetine patients for diarrhoea and agitation / anxiety / nervousness.

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)

Safety (continued)

There were two serious adverse events during the study: suicide attempt, occurred in one patient of each treatment group.

There was no indication of modifications in laboratory tests that were of clinical significance. Vital signs were not modified to any significant extent, with the exception of heart rate, which was more frequently increased on reboxetine and decreased on fluoxetine. A total of 6 patients in the lying position and 10 in the standing position (8.1% of the 74 and 13.9% of the 72 evaluated patients, respectively) had clinically relevant increases at least once in the reboxetine group *vs* a total of 1 patient in the lying position and 3 patients in the standing position (1.2% of the 84 and 3.7% of the 82 evaluated patients, respectively) in the fluoxetine group. No clinically relevant decreases (at least 20% *vs* baseline as well as such decreases associated with values ≤50 beats/min) were observed on both treatment groups. No indication of effect on cardiac function emerged from ECG recordings.

Conclusions

The efficacy of reboxetine and fluoxetine in patients with major depression, when administered for 8 weeks, as evaluated by HAMD, MADRS and CGI scales, were similar, in terms of frequency, rate and extent of the induced clinical improvement in the total population. Additional analyses carried out in sub-populations of severe (CGI - Severity of Illness: markedly to extremely ill at admission to the study) and melancholic patients show the reboxetine treatment to be superior to the fluoxetine treatment, in terms of mean decrease of the HAMD total score scale at the last assessment in both sub-populations. In the severely ill sub-population the 95% C.I. of the between treatment difference supports the superiority of reboxetine (C.I. 95%: 2.2 + 8.4).

The safety profiles of reboxetine and fluoxetine were also similar, as far as vital signs, haematology and blood chemistry tests and ECG examinations with the exception of heart rate which was more frequently increased on reboxetine and decreased on fluoxetine. The frequency of adverse events was slightly higher in the reboxetine group. The estimated cumulative risk of adverse events (according to the Kaplan-Meier method and log-rank test) was significantly higher on reboxetine than on fluoxetine for constipation, hypotension and related symptoms, dry mouth and urinary hesitancy/retention. In addition, the cumulative risk was higher, but not significantly so, in reboxetine patients than in fluoxetine patients for paraesthesia and, conversely, it was higher in fluoxetine patients for diarrhoea and agitation/anxiety/nervousness, but again not significantly so.

1. INTRODUCTION

Reboxetine (FCE 20124 or (2RS, αRS)-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, whereas tricyclic antidepressants were active only upon repeated administration [1]. Therefore, reboxetine was hypothesised to exert antidepressant efficacy of faster onset than the antidepressants currently available in depressed patients. In addition, comparison with imipramine 75 mg in healthy volunteers [2, 3] revealed that reboxetine does not possess the marked sedative activity of imipramine, but rather psychostimulating properties.

Pharmacokinetic studies in healthy volunteers [4], showed that average peak reboxetine levels are 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 area under the curve 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 using fixed-changing doses, at maximum 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 group, 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 ≥50% in Hamilton Depression Rating Scale (HAMD) at the end of treatment in 63% of patients compared with 36% for placebo and 46% for desipramine. These decreases were present after 14 days of treatment in 31% of reboxetine patients and 22% of desipramine patients. More reboxetine patients complained of headache and urinary retention, whereas more desipramine patients experienced dry mouth, sweating and blurred vision. Cardiovascular adverse events were relatively rare but appeared with slightly higher frequency in the desipramine group (hypotension and tachycardia).

Phase II results obtained in controlled conditions in patients suffering from major depressive disorders indicate that reboxetine is an effective antidepressant agent with a favourable therapeutic index with respect to desipramine. The present study was designed to extend information obtained from placebo-controlled studies and to collect comparative evidence of reboxetine's safety and efficacy *vs* a non-tricyclic antidepressant. Fluoxetine was chosen as it shows favourable tolerability in comparison with tricyclic antidepressants [7], and so, comparison of reboxetine with fluoxetine 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 fluoxetine 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, parallel-group, multicentre trial. Its aim was to compare the efficacy and tolerability of reboxetine with that of fluoxetine, administered orally for 8 weeks, in adult patients with major depressive episodes. The design of the study is shown overleaf.

A total of 220 patients with major depressive episodes was to be recruited in accordance with the inclusion and exclusion criteria, and an informed consent obtained from each patient prior to screening.

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

After an initial wash-out period of 4-7 days (14 days in case of MAOI administration and 3-4 weeks in the case of previous fluoxetine treatment), patients received one of two treatments: oral reboxetine 4 mg twice daily (b.i.d.) or oral fluoxetine 20 mg once daily (o.d.) plus placebo (o.d.) for 8 weeks. In case of inefficacy or unsatisfactory response, combined with good tolerability, after 4 weeks, the dose could be increased if necessary as follows: reboxetine 4 mg each morning and 6 mg each afternoon or fluoxetine 20 mg b.i.d. for the remaining 4 weeks of the study.

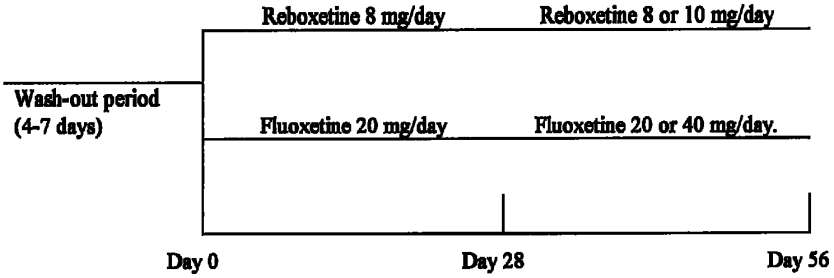
The primary study end-point was defined as the absolute HAMD total score change *vs* Day 0 at last assessment. Patients with at least a 50% decrease in the total HAMD score compared with baseline were categorised as responders and those with a total HAMD score of 10 or less were considered to be in remission. These were considered to be additional end-points and their rates at last assessment were to be estimated for each treatment groups. Other variables used for measuring efficacy were the Clinical Global Impression (CGI), the Montgomery and Asberg Depression Rating Scale (MADRS), the Social Adaptation Self-Evaluation Scale (SASS), Patient Global Impression (PGI) and Quality of Sleep.

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.

Patients willing to continue receiving the test treatment after completion of the 8 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

According to the original protocol, a run-in wash-out period of 7 days (14 days in case of MAOI administration) was to be undertaken. A protocol amendment on 24 January 1991 stipulated that a wash-out period of 4-7 days (14 days in case of MAOI administration and 3-4 weeks in the case of previous fluoxetine treatment) was to be implemented instead. For Australian country a second amendment, provided on 19 December 1991, allowed the short acting benzodiazepines (for instance temazepam) as sleep inducer during either the wash-out or the study period. The third and fourth amendments (the first only for Australian country) on 28 February 1992 stipulated that the single blind placebo treatment during the wash-out period was not required. A copy of the protocol amendments 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 or IRB. A central approval allowing the clinical evaluation of the product was required and obtained in Argentina (for the specific protocol), while local approvals were required and obtained in Germany, Australia and Spain.

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 8 months
- 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
- Resistance to antidepressant treatment (defined as lack of response to at least two previous courses of antidepressant therapy given at full doses for more than 1 month)
- History of major depressive disorder associated with endocrine disorders: hypo- or hyperthyroidism (defined as values at least 10% outside normal range values for TSH and T_4), 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/or 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/or ECG at admission
- Electroconvulsive therapy (ECT) in the previous 6 months
- High risk of suicide

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 3.6.2.2) 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 11 centres participating in the study were to recruit, within a period of 1 year, a sample of 18-20 patients, so that a total of 220 patients was to be recruited overall.

In fact, several of the centres who initially agreed to participate in the study never did so for logistical reasons, and were replaced with other centres. As shown in the Principal Investigators and Affiliation list (Appendix 12.1.4), 16 centres, located in 4 countries (Argentina, Australia, Germany and Spain) participated in the study. In 13 of these centres, the number of patients admitted was lower than 18, while recruitment was extended in centres No 15 and 16 to well above the foreseen patient sample. Recruitment was stopped after randomisation of 168 patients, approximately 24% below the expected sample size.

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 to be provided.

3.4 Treatments

3.4.1 TREATMENTS TO BE COMPARED

After the amendments and an initial wash-out period of 4-7 days (14 days in the case of monoamine oxidase inhibitors administration and, after the amendment, 3-4 weeks in the case of previous fluoxetine treatment) patients received one of two treatments for 8 weeks: oral reboxetine 4 mg b.i.d. or oral fluoxetine 20 mg o.d. plus placebo o.d.. In the case of ineffective or unsatisfactory response with good tolerability after 4 weeks of treatment, the dose could be increased if necessary as follows: reboxetine 4 mg each morning and 6 mg each afternoon or fluoxetine 20 mg b.i.d.

3.4.2 IDENTITY OF TEST TREATMENTS

Indistinguishable capsules containing either reboxetine 4 mg (two x 2 mg tablets) or 6 mg (three x 2 mg tablets) (4 mg: Batch No: SF1264; 6 mg: Batch No: SF1132, SF1291) or fluoxetine 20 mg (one tablet) (Batch No: SF1128, SF1307, SF1340) plus excipients (dummy placebo 4 mg, Batch No: SF1247) were supplied by the Pharmaceutical Development Department of Pharmacia. 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 afternoon) or one capsule of fluoxetine 20 mg o.d. (morning) plus placebo o.d. (afternoon) for 8 weeks. For patients who showed an ineffective or unsatisfactory response (worsening, no change or minimal improvement in the CGI; see Section 3.6.1.2) with good tolerability (especially non-symptomatic hypotension) after 4 weeks of treatment, the dose of reboxetine was allowed to be increased to 10 mg daily (4 mg in the morning and 6 mg in the afternoon) and the dose of fluoxetine to 20 mg b.i.d. for the remaining 4 weeks of the study. In those patients who 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 fluoxetine was selected on the basis of published evidence from controlled studies [10] and of manufacturer recommendations [11].

3.4.4 METHOD OF ASSIGNING PATIENTS TO TREATMENT GROUPS

A randomisation list balanced within each centre and every 4 assignments was originally generated for patient allocation either to reboxetine or fluoxetine. In this list, in order to make the patient unequivocally identifiable across centres by his assignment number, a progressive number from 1 to 572 was generated. The test treatments were labelled according to the randomisation sequence number. Each randomised patient was then identified by the corresponding treatment number. In spite of the anticipated break down by centre of such a sequential list, in order to minimise the waste of drug supply, the latter was shipped to the centres by complete blocks of four treatment 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 Milano 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 expire 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.

Eight cartons showing the patient number and the appropriate week of treatment (Week 1-8) were prepared for each patient. Each carton contained the medication necessary for 1 week of treatment (i.e. 16 capsules, one capsule b.i.d. and 2 additional capsules for possible losses). Additional 4 cartons showing the patient number, the appropriate week of treatment (Week 5-8) and the level of dosage (dose 2) were prepared for each patient in case of possible dose increases during the last 4 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.

3.6.1 EFFICACY

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

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

3.6.1.1 Hamilton Depression Rating Scale

The severity of depression was evaluated using the HAMD at screening, and on Days 0, 7, 14, 21, 28, 42 and 56.

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.

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

	Item	Score range	Factor
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 [12], to yield 6 factors: Anxiety/somatisation (I), Weight (II), Cognitive Disturbances (III), Diurnal Variation (IV), Retardation (V), Sleep Disturbances (VI).

3.6.1.2 Clinical Global Impression

Severity of illness was assessed by the investigator using the CGI [12] on Days 0, 7, 14, 21, 28, 42 and 56.
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 [12], 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

scored 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 [13] was measured on Days 0, 7, 14, 21, 28, 42 and 56.

This scale consists of ten items relating to depression selected from the 67 items in the Comprehensive Psychiatric Rating Scale [14]. 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 14. In a proportion of cases (24.4% of the total sample) a score of 0 to 6 was used, as in reference 13. Data have been pooled by dividing by two item scores of the latter sample.

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

3.6.1.4 Patient Self-Evaluation Scales

Each patient had to fill a "Self-Evaluation Booklet", a separate part of the CRF, on Days 7, 14, 21, 28, 42 and 56. The booklet included three rating scales: the PGI (rating the global change of the illness with reference to their general condition at the start of the

study); the Quality of Sleep (assessing sleeping time and rating sleep characteristics and quality) and the SASS (rating the patient social adjustment). The results collected with these assessments will be reported in a separate Addendum to the present report.

3.6.2 SAFETY

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

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, 42 and 56.

Any newly observed sign or symptom (including clinically relevant laboratory abnormalities), noticed by the investigators or reported by the patients were reported, regardless of presumed relationship to the study medication, in the appropriate section of the CRF (Adverse Event Report Form - Enclosure 13 of Appendix 12.1.1).

For each adverse event, the following information was entered in the CRF: description, date of onset, date of stopping, severity, drug cause-effect relationship, outcome, effect of withdrawal of treatment and rechallenge. The investigators also had to note if the double-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 12 of Appendix 12.1.1.

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

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

Adverse Events Reported through a Check-List

The presence or absence of selected adverse events was solicited through a check-list especially designed for the identification of events frequently recorded in patients on antidepressant medication. The check-list is shown in Enclosure 11 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, temperature, blood pressure and heart rate (supine and standing) were measured at screening, and on Days 0, 7, 14, 21, 28, 42 and 56.

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 28 and 56.

---

* 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.

Chest X-ray

At baseline only, where facilities were available.

Laboratory Tests

Laboratory tests were recorded at screening, on Days 28 and 56.
The laboratory tests comprised the following: full blood count, serum electrolytes, liver enzymes, urinalysis, blood sugar, serum alkaline phosphatase, blood urea nitrogen (BUN), serum creatinine, uric acid, total and direct bilirubin, total serum protein and electrophoresis, serum cholesterol and triglycerides, and, at screening only, TSH and T_4.
For patients who withdrew prematurely for any reason, all the assessments, including vital signs, ECG and laboratory tests, were to be performed.

3.7 Study Procedures and Flow Chart

3.7.1 SCHEDULE OF ASSESSMENTS

	Pre-Treatment	Treatment Day						
Assessment	Screening	0	7	14	21	28	42	56
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
SASS		x	x	x	x	x	x	x
PGI			x	x	x	x	x	x
Quality of sleep		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	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 evaluated using the HAMD.

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 8 weeks' treatment period were provided with study medication and maintained on the same medication in blind conditions until the study was completed in the last patient and 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 for the initial double-blind phase, but in monthly, instead of weekly, units (see Section 3.4.5).

3.8 GCP Compliance, Data Quality Assurance

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

The study was conducted in accordance with the Declaration of Helsinki, adopted by the 18th World Medical Assembly, Helsinki, June 1964, and amended by the 41st World Medical Assembly, Hong Kong, 1989. A copy of declaration of Helsinki can be found in Enclosure 14 of Appendix 12.1.1. Inter-rater reliability sessions with training purpose on the instrument used for the assessment of change, and particularly on the HAMD, were carried out during the investigators meetings organised by country and/or the monitoring visits by employing 4 videotaped interviews.
During the study monitoring visits, made at regular intervals, the monitor validated the content of the CRF against source documents, on the basis of the agreed procedures.

Trial master file, Data Listings 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 fluoxetine 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 fluoxetine 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 post-baseline HAMD score, HAMD decrease (see below for detailed definition), was taken as the outcome variable. From the phase II experience [6] and from the literature [7] it seemed reasonable to assume that the treatments groups would have shown a variability (expressed as standard deviation) of 9 points.

The participating centers were able to recruit approximately 200 patients, among which approximately 10% were expected to drop before the first post-baseline visit. Under such assumption the expected length of the confidence interval of HAMD decrease was to be 5.0 points of HAMD scale, 2.5 points each side.

Referring to secondary study end-points (see efficacy analyses) based on proportions, the same sample size allowed a length of confidence of 0.28 considering a proportion of 0.5 in each treatment group and the normal approximation method.

3.9.2 ANALYSES CARRIED OUT

3.9.2.1 Baseline Comparability of Treatments Groups

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

3.9.2.2 Efficacy Analyses

Definitions

The following definition apply to the set of analysed data:

HAMD decrease	The difference between the end of treatment and baseline measurements of 21-HAMD 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	21-HAMD total score lower than or equal to 10 (absolute value).
Response	21-HAMD total score decrease equal to or greater than 50% of the pre-treatment value (Baseline: visit 0). According to this definition and based on the inclusion criterion which required a 21-HAMD total score at entry at least equal 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 first the patient 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.
Severe patients	Patients scored 5 to 7 (markedly to extremely ill) on CGI-Severity of Illness scale [12] 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 HAMD and MADRS total scores, as well as 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 considering the last valid observation, in 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, only for those patients 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 conclusion [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 21-HAMD total scores across treatment groups was tested by ANOVA [17] in order to assess the comparability of the disease severity within the two treatment groups.
No transformation of the original variable was deemed necessary, as it results from the outcome variable of the difference between two random varieties, 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 21-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 [18].

The same sets of analyses were carried out on the subset of severe and melancholic patients as defined above.
Complementary to the quantitative analyses of 21-HAMD total score, the qualitative analysis classifying the patients according to the above definition as either responder or failure at last valid assessment was carried out. Ninety-five per cent confidence intervals of the proportions in each treatment and of the between treatment difference were computed [19].
The cumulative probability of the onset of response (time to response) was computed adopting the Kaplan-Meier method and the between treatment comparison was carried out by the log-rank test [20].

3.9.2.3 Safety Analyses

Vital signs as measured at each assessment time were summarised by descriptive statistics.

Patients with orthostatic hypotension (a decrease ≥30 mmHg of systolic blood pressure from lying to standing) were described. Moreover, the frequency of patients showing clinically relevant (20% or more *vs* baseline) 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.

ECGs 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 Mac Nemar test or Stuart Maxwell test [21] 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 [22], using as reference values mainly the ones reported in the Cecil Textbook of Medicine [23] (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 [24].

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 $p < 0.01$.

Moreover, abnormal values of laboratory tests defined as clinically relevant by predefined criteria (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 functionality.

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

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

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

3.9.2.4 Changes in the Conduct of the Study or Planned Analysis

No deviation of the main endpoint was introduced into the final analysis.

In general, analyses carried out were consistent with the ones anticipated in the protocol with a few exceptions:

a) subset analyses of severe and melancholic patients was introduced.

b) safety was presented in a more articulated fashion than that anticipated into the protocol.

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 for this purpose which generates listings of discrepancies between the actual value entered and predefined algorithms. Computer programs generated for this purpose are archived in Biometrics and Data Management Department.

These listings were reviewed by clinical personnel and editing of CRFs were requested at the Investigator site, whenever appropriate.

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

ECG tracings were classified and subsequently grouped according to the codes reported in Appendix 12.1.10. Previous and concomitant diseases were coded according to ICD9 dictionary [25]; concomitant drugs according to the Drug Reference List [26]; adverse events according to the WHO-ART dictionary [27].

In the absence of an adequate WHO-ART dictionary code, blurred vision was coded under the preferred term of vision abnormal and urinary hesitancy under the preferred

term of micturition disorder. In addition is to be noticed that the dictionary subsumes under the preferred term of suicide: attempt suicide, suicide attempt and suicidal tendency.

Reporting as well as statistical analyses were carried out with SAS PROCs (Version 6.07), apart from Stuart-Maxwell test and confidence interval calculation. The programs relevant to the latter are appended 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

The original randomisation list is given in Appendix 12.1.7.

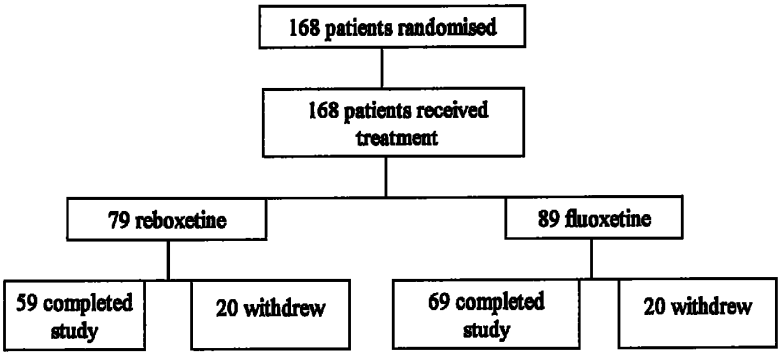
One hundred and sixty-eight patients (121 females and 47 males) were admitted to the study from April 1991 to March 1993 and randomised to treatment by investigators at 16 centres as shown in Table 1.

As shown in Table 2, a total of 128 patients (76.2%) completed the study (59 reboxetine and 69 fluoxetine patients). Overall, 40 patients (23.8%) withdrew, 20 reboxetine patients and 20 fluoxetine patients. Frequency and timing of withdrawal are shown in Table 3.

Adverse events or intercurrent illness were the main reason for withdrawal in 15 patients (reboxetine 9, fluoxetine 6). The adverse events associated with discontinuation in individual cases are discussed in the Adverse Event Section (Section 8.2.3.2). Deterioration was the reported reason for withdrawal in 10 patients (reboxetine 4, fluoxetine 6). Four patients in each treatment group were withdrawn due to non-compliance (uncooperative patients), while a total of 7 patients (reboxetine 3, fluoxetine 4) were withdrawn because of a protocol violation or being lost to follow-up visit.

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 for possible non-compliance with one of the exclusion criteria was related to abnormalities of thyroid function tests (5 (6.3%) reboxetine patients and 9 (10.1%) fluoxetine patients), possibly suggestive of an underlying, undiagnosed endocrine disorder. For 4 reboxetine patients (5.1%) and 5 fluoxetine patients (5.6%) the thyroid function tests were not available. Non-protocolled concomitant medications during the wash-out period was administered to 8.9% of the patients in the reboxetine group and 7.9% of the fluoxetine group. For 4 reboxetine patients, the duration of the present episode of major depression had not been present for between one and eight months as required by the inclusion criteria (2 patients: < 1 month and 2 patients: > 8 months); for 1 reboxetine patient the duration was missing.

Randomisation

Distribution and use of study medication were to be done, as mentioned in section 3.4.4, 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 a small number of patients, with a similar frequency in both treatment groups. Of the 78 patients randomised to reboxetine, 11 received fluoxetine instead, and of the 90 patients randomised to fluoxetine, 12 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 screen and last laboratory tests and ECG evaluations. The deviation rate was similar in both treatment groups.

Although the protocol specified that HAMD, CGI, MADRS and adverse events assessments were to be performed on Days 0, 7, 14, 21, 28, 42 and 56, these measurements were also done for some patients on Days 35 and 49. Results of these measurements have been presented in the study tables for sake of completeness, but were not be commented upon in this report as patient numbers on Days 35 and 49 were much lower than on the other assessment days.

Concomitant medications

The frequency of administration of non-protocolled (because of their psychotropic properties) concomitant medications is given by active principle in Table 7 and by class in Table 8. Long-acting benzodiazepines were administered to 2 patients of the reboxetine group and 3 of the fluoxetine group. Only one patient, from the reboxetine group, received other non-protocolled psychotropic medications. One fluoxetine patient consumed alcohol while on treatment.

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=79)		Fluoxetine (n=89)	
	n	(%)	n	(%)
Sex				
female	57	72.2	64	71.9
male	22	27.8	25	28.1
Total	79	100	89	100
Race				
Caucasian	78	98.7	89	100
Asian	1	1.3	-	-
Total	79	100	89	100
	Mean	SD	Mean	SD
Age (years)	44.0	12.6	43.6	11.8
Height (cm)	164.5	8.5	165.1	9.2
Weight (kg)	70.0	16.1	68.4	14.9

SD standard deviation

The majority of patients in both groups were female. There was only one Asian patient in the reboxetine group, all other patients were Caucasian. Both treatment groups were well matched for age, height, weight and race.

4.3.1 DIAGNOSIS AND HISTORY OF THE DEPRESSIVE DISORDER

The frequency of the DSM-III-R diagnostic classifications, the summary statistics of the history of the depressive disorder, and the characteristics of the index episode are given by treatment, and sex, in Tables 11 and 12. Recurrent Major Depressive Disorder (DSM-III-R No. 296.3) was diagnosed for the majority of patients in each treatment group (59.5% in the reboxetine group and 52.8% of the fluoxetine group), while Major Depression, Single Episode (DSM-III-R No. 296.2) was diagnosed in almost all remaining cases, with the exception of 1 reboxetine patient who was diagnosed as Schizoaffective Disorder (DSM-III-R No. 295.7), not in agreement with present episode characteristics.

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			Fluoxetine		
	n	Median	Range (min - max)	n	Median	Range (min - max)
Age of onset (years)	65	35.0	19 - 65	75	38.0	10 - 64
Number of previous episodes	43	2.0	1 - 10	42	2.0	1 - 20
Duration of the last episode (weeks)	44	16.0	4 - 104	45	16.0	3 - 52
Duration of the present episode (weeks)	78	9.5	2 - 156	89	12.0	4 - 28

The treatment groups were well matched with regard to the number of previous episodes and duration of the last episode of Depression. Whereas age at onset appears to be slightly higher in the fluoxetine group and duration of present episode appears to be longer still in the fluoxetine arm.

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 (68.4% of the reboxetine patients and 58.4% of the fluoxetine patients). A precipitating external stress was more frequently present in the reboxetine patients (50.6%) than in the fluoxetine patients (46.1%).

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, 34 and 27 and summarised for Day 0 below. There was no significant difference between the treatment groups at Day 0 with regard to the mean HAMD and MADRS total scores. Similarly, there were no relevant group differences for the initial CGI scores, except for the frequency of patients judged severely or extremely ill. At baseline, the patients judged as severe were more frequent on fluoxetine (31.0%) than on reboxetine (22.1%), while, conversely, 2.6% of the patients on reboxetine were extremely ill in comparison with 0% of the patients on fluoxetine.

Severity of Depression at Day 0

	Reboxetine			Fluoxetine		
	n	Mean	SD	n	Mean	SD
HAMD	76	28.6	5.3	87	27.4	4.1
MADRS	76	17.1	3.3	87	16.2	2.6
	n	(%)		n	(%)	
CGI severity						
Normal	0			0		
Borderline mentally ill	0			0		
Mildly ill	0			1	(1.1)	
Moderately ill	22	(28.6)		20	(23.0)	
Markedly ill	36	(46.8)		39	(44.8)	
Severely ill	17	(22.1)		27	(31.0)	
Extremely ill	2	(2.6)		0		
Total	77	(100.0)		87	(100.0)	

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; selective serotonin reuptake inhibitors and monoamine oxidase inhibitors were infrequently mentioned. Active principles were 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 among the two treatment groups were 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, with only a few exceptions. On Day 1, 12/79 (15.2%) of the reboxetine group patients and 11/89 (12.4%) of the fluoxetine group patients received half of the protocolled number of daily capsules, because they started treatment in the afternoon. This resulted in a Day 1 dose of 4 mg of reboxetine and a Day 1 dose of 0 mg of fluoxetine (as the afternoon dose corresponded to placebo). In both the reboxetine and fluoxetine treatment groups, a maximum of 3 patients per day had the number of daily capsules decreased (for the various reasons indicated in the individual data listing on the experimental treatment). These were mainly missed intake, lost medication or emergence of signs/symptoms of intolerance.

As summarised in Table 16.1, at the end of the initial 4 weeks of treatment, 12 patients of the reboxetine group (15.2% of the admitted) and 12 patients of the fluoxetine group (13.5% of the admitted), had the daily dose increased according to the protocol provisions to a dose corresponding to 10 mg of reboxetine and 40 mg of fluoxetine (60 mg for one patient), (level 2 dose). In the following days, a maximum of 3 patients in the reboxetine group and 2 patients in the fluoxetine group switched to level 2 dose, while a maximum of 3 patients per day in either treatment group had their number of daily capsules decreased (for the reasons indicated in the individual data listing on the experimental treatment). These were mainly including missed intake, lost medication or emergence of signs/symptoms of intolerance.

Comparison of the daily dose administered (as reported in the compliance section of the CRF in terms of number of capsules per day taken) with the expected dose (as indicated in the experimental treatment section of the CRF in terms of number of capsules per day foreseen) allowed calculation of the compliance with the treatment regimen. Full compliance was defined where there was full agreement between the dose prescribed by the attending physician (the per protocol dose or a lower dose mainly in case of adverse events) and the dose reported to have been taken. The total compliance over the treatment period was calculated for each patient and the patients were classified accordingly (Table 17). In 75.9% of the reboxetine patients and 59.6% of the fluoxetine patients, 100% compliance was reported.

Only in a few cases the reported compliance was lower than 80% (2 cases in the reboxetine group and 3 in the fluoxetine group) or between 80 and 89% (1 case in each group).

6. CONCOMITANT MEDICATIONS

The absolute frequencies of those patients who received concomitant medications (either as a continuation of baseline therapy or as a newly introduced medication for treatment

emergent events) during the treatment period is shown in Table 18. Chloral hydrate was the most commonly prescribed concomitant medication at a similar frequency in both treatment groups. In addition to those non-protocolled medications discussed previously in Section 3.5.1, other drugs were occasionally administered, generally following the emergence of adverse events, again at a similar frequency in both groups. The only exception to this was paracetamol, which was administered somewhat more frequently to patients in the fluoxetine group.

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 28.6 at Day 0 to 9.4 at last assessment (mean decrease 19.2, 95% C.I.: 17.3 ÷ 21.2), in the 76 patients randomised to reboxetine who had at least one assessment in addition to baseline (3 patients had only baseline data), and to 7.3 at Day 56 in the 59 patients who completed the study. In the 87 patients randomised to fluoxetine with at least one assessment in addition to baseline (2 patients had only baseline data), the mean HAMD total score was reduced from 27.4 at Day 0 to 10.6 at last assessment (mean decrease 16.8, 95% C.I.: 14.9 ÷ 18.6), and to 7.8 at Day 56 in the 69 patients still on treatment. In order to give a better appraisal of the estimated mean decrease, the two-tailed 95% C.I. for each treatment arm are shown in Figure 1. The between treatment difference in HAMD total score decrease at last assessment was of 2.4 points (95% C.I.: -0.3 ÷ 5.1).

The pattern of improvement of HAMD factors was similar in the reboxetine and fluoxetine patients. At the last assessment, the greatest treatment differences were seen in: Factor III (Cognitive disturbance) (median difference *vs* Day 0 of 0.67 [reboxetine group] and 0.50 [fluoxetine group]) and Factor VI (Sleep disturbances) (median difference *vs* Day 0 of 1.00 and 0.67 [reboxetine and fluoxetine group, respectively]).

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 was similar in the reboxetine group and the fluoxetine group from Day 14 onwards.

At last assessment (Table 26), 77.6% of the reboxetine-treated patients and 73.6% of the fluoxetine-treated patients were classified as responders, while 67.1% and 66.7%, respectively, were seen to be in remission. The between treatment difference in the proportion of response was of 4.1 % (95% C.I.: -9.1% ÷ 17.2%) in favour of reboxetine.

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 and on fluoxetine had a similar cumulative rate of response (p=0.80).

Additional analyses were carried out on the sub-populations of patients classified as markedly to extremely ill at admission (according to the CGI - Severity of Illness scale) and on those characterised as melancholic at admission (possible for 145 of the 168 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 extremely ill at admission in the two treatment groups (55 reboxetine, 66 fluoxetine) is shown, together with the 95% confidence interval, in Figure 3. Also in this sub-population, the mean decrease of the HAMD total score is higher in reboxetine than in fluoxetine group patients and the difference was of 5.3 points (95% C.I.: 2.2 ÷ 8.4). This result excludes inferiority of reboxetine compared with fluoxetine and indicates an advantage of reboxetine between 2.2 and 8.4 as measured by HAMD scale.

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: 39/29 reboxetine, 39/38 fluoxetine), is shown, together with the 95% confidence interval, in Figure 4. The between treatment difference in HAMD decrease was of 3.6 points (95% C.I.: -0.5 ÷ 7.7).

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 is provided in Table 28. The distribution pattern is clearly similar in the two treatment groups, particularly in the proportion of normal or borderline cases in the two treatment groups. This corresponds, at last assessment, to 58.5% of the cases on reboxetine and 56.3% of the cases on fluoxetine.

A shift table of the last value *vs* Day 0 (Table 29) showed that the CGI severity of illness had decreased in 87.0% of reboxetine group patients, increased in 1.3% and remained the same for 11.7% , whereas the CGI severity of illness had decreased in 89.7% of fluoxetine group patients, increased in 3.4% and remained the same in 6.9%.

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.

At last assessment, the percentage of patients who were 'much improved' and 'very much improved' were 78.0% in the reboxetine group and 75.8% in the fluoxetine group. The proportion of the patients who had no change of the global improvement were similar in the two treatment groups (6.5% and 8.0% on reboxetine and fluoxetine, respectively), as well as the proportion of the 'minimally worse' patients (6.5% and 4.6% on reboxetine and fluoxetine, respectively). Only in the fluoxetine treatment group there were 3.4% of patients who were 'much worse' and 'very much worse'.

7.2.3 EFFICACY INDEX

The CGI efficacy index, which was assessed in order to relate therapeutic efficacy and tolerability, is shown by treatment group at each visit in Table 32. The distribution of last assessment values is shown in Table 33. At last assessment, side-effects were judged to outweigh efficacy in 10.4% of the reboxetine patients and 11.5% of the fluoxetine patients. A clear benefit from therapy (EI ≥2) was obtained in the majority of the patients in both treatment groups (approximately 64% of the reboxetine-treated and 72% of the fluoxetine-treated patients).

7.3 Montgomery and Asberg Depression Rating Scale

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

The mean total MADRS score was reduced from 17.1 at Day 0 to 5.7 at last assessment in the 76 reboxetine group patients with at least one assessment in addition to baseline, and to 4.1 at Day 56 in the 59 reboxetine patients who completed the study. In patients randomised to fluoxetine, values changed from 16.2 at Day 0 to 6.2 at last assessment (87 patients), and to 4.3 at Day 56 (69 assessed 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, indicate the antidepressant efficacy of reboxetine to be similar to that of fluoxetine in the treatment of major depressive episodes. Reboxetine was found to be similar to fluoxetine in terms of frequency, rate and extent of the induced clinical improvement in the total population.

At last assessment, 77.6% of the reboxetine-treated patients and 73.6% of the fluoxetine-treated patients were classified as responders, while 67.1% and 66.7%, respectively,

were seen to be in remission. The between treatment difference in the proportion of response was of 4.1% (95% C.I.: -9.1% ÷ 17.2%) in favour of reboxetine.

Additional analyses were carried out in the sub-populations of severe (CGI- severely illness: markedly to extremely ill at the admission) and melancholic patients. In both cases, the average improvement observed on reboxetine was greater than the one seen on fluoxetine. In severe cases, the difference between treatments was of 5.3 points (95% C.I.: 2.2 + 8.4), while in melancholic patients the difference was of 3.6 points (95% C.I.: -0.5 + 7.7).

At last assessment, the percentage of patients who were 'much improved' and 'very much improved' were 78.0% in the reboxetine group and 75.8% in the fluoxetine group. The proportion of the patients who had no change of the global improvement were similar in the two treatment groups (6.5% and 8.0% on reboxetine and fluoxetine, respectively), as well as the proportion of the 'minimally worse' patients (6.5% and 4.6% on reboxetine and fluoxetine, respectively). Only in the fluoxetine treatment group there were 3.4% of patients who were 'much worse' and 'very much worse'.

At last assessment, side-effects were judged to outweigh efficacy in 10.4% of the reboxetine patients and 11.5% of the fluoxetine patients. A clear benefit from therapy (EI ≥2) was obtained in majority of the patients in both treatment groups (approximately 64% of the reboxetine-treated patients and 72% of the fluoxetine-treated patients).

The mean total MADRS score was reduced from 17.1 at Day 0 to 5.7 at last assessment in the 76 reboxetine group patients with at least one assessment in addition to baseline, and to 4.1 at Day 56 in the 59 reboxetine patients who completed the study. In patients randomised to fluoxetine, values changed from 16.2 at Day 0 to 6.2 at last assessment (87 patients), and to 4.3 at Day 56 (69 assessed patients).

8. SAFETY RESULTS

8.1 Safety Population and Extent of Exposure

8.1.1 NUMBER OF PATIENTS IN SAFETY ANALYSIS

All the patients who received study treatment were included in the safety analysis, i.e. 79 reboxetine patients and 89 fluoxetine patients. For clinical and laboratory tests were analysed only patients with at least one assessment in addition to baseline.

8.1.2 TOTAL DRUG EXPOSURE

As shown in Table 16, of the 79 and 89 patients exposed to reboxetine and fluoxetine, 74 and 82, respectively, were treated for at least 4 weeks, while 59 and 69 were treated for at least 8 weeks.

8.2 Adverse Events

8.2.1 ANALYSIS OF ADVERSE EVENTS

The number of patients with adverse events and the number of adverse events during the study are grouped by sex in Table 38, by age classes in Table 39 and by DSM-III-R diagnosis in Table 40; 67.1% of the reboxetine patients and 67.4% of the fluoxetine patients exposed had 221 and 180 adverse events, and an average of 4 and 3 adverse events per patient, respectively.

Females suffered from adverse events less than males when on reboxetine (64.9% *vs* 72.7%) and more frequently than males when on fluoxetine (75.0% *vs* 48.0%). Patients on reboxetine aged 31 to 45 years had adverse events more frequently than patients who were aged 18-30 or over 45 (72.4%, 64.3%, 63.9%, respectively). For fluoxetine, both patient groups aged 18 to 30 and 31 to 45 (69.2% and 70.3%, respectively) had adverse events more frequently than patients aged over 45 years (64.1%).

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), more so on reboxetine (58.1% *vs* 74.5%) than fluoxetine (66.7% *vs* 68.1%).

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 (adverse events split by body system, with relevant events grouped in clusters) and by body system and sex in Table 43. Among the most frequently reported events (≥5% of exposed patients in at least one group), the following were reported more frequently in the reboxetine group than in the fluoxetine group: dry mouth (34.2% *vs* 9.0%), constipation (21.5% *vs* 6.7%), hypotension and related symptoms (19.0% *vs* 7.9%), urinary hesitancy/retention (12.7% *vs* 1.1%), paraesthesia (6.3% *vs* 1.1%).

Adverse events more frequently reported in the fluoxetine group than in the reboxetine group were agitation/anxiety/nervousness (11.2% *vs* 3.8%) and diarrhoea (6.7% *vs* 1.3%).

The most relevant between-gender difference was related to the frequency of insomnia, nausea, tremor, paraesthesia and urinary hesitancy. Insomnia was reported by 14.0% of female patients *vs* 9.1% of male patients on reboxetine and 14.1% of female patients *vs* 0% of male patients on fluoxetine. Nausea was reported by 12.3% and 12.5% of female patients in the reboxetine and fluoxetine groups, respectively, compared with 9.1% of male patients in the reboxetine group and 4.0% of male patients in the fluoxetine group. Tremor was reported by 7.0% of female patients on reboxetine and 7.8% of fluoxetine *vs* 0% of male patients in both groups; paraesthesia was reported by 8.8% and 1.6% of female patients on reboxetine and fluoxetine, respectively *vs* 0% of male patients in both

treatment groups. Conversely, urinary hesitancy was reported by 27.3% of male reboxetine patients *vs* 3.5% of female reboxetine patients, while it was reported by 0% of male patients *vs* 1.6% of female patients in the fluoxetine group.

The most frequent adverse events, therefore, were disorders of the gastro-intestinal (GI) system (36.7% in the reboxetine group and 28.1% in the fluoxetine group), and nervous system (NS) disorders (27.8% and 28.1%, respectively). Autonomic NS disorders affected 38.0% and 14.6% of reboxetine and fluoxetine patients, respectively, whilst psychiatric disorders affected 20.3% and 23.6%, respectively and cardiovascular disorders were reported in 25.3% and 12.4% of reboxetine and fluoxetine patients, respectively. Urinary system disorders occurred in 15.2% of the reboxetine patients *vs* 5.6% of the fluoxetine patients (Table 43).

8.2.1.2 Occurrence

The occurrence of adverse events is grouped by week of onset and event or body system in Tables 44, 45 and 46, respectively. The majority of events in both the reboxetine and fluoxetine groups emerged initially during treatment, within the first week (autonomic NS disorders, 65.7% and 58.8%, respectively; GI disorders, 67.5%, 34.1%; central and peripheral NS disorders, 44.1%, 24.3%; psychiatric disorders, 40.0%, 22.2%; cardiovascular disorders, 33.3%, 30.8%, urinary system disorders, 64.3%, 20%).

8.2.1.3 Overall Risk

The cumulative risk of developing the first adverse event, as well as adverse event clusters or individual events reported in at least 5% of the 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 18. As shown in Figure 5, the cumulative risk of developing at least one adverse event is slightly higher in the reboxetine group compared with the fluoxetine group (particularly during the early stages of treatment), but not significantly so ($p = 0.307$). As for individual events or clusters, the cumulative risk is significantly higher on reboxetine than on fluoxetine for dry mouth ($p = 0.0001$), constipation ($p = 0.004$), urinary hesitancy/retention ($p = 0.003$) and hypotension and related symptoms ($p = 0.035$). In addition, the cumulative risk is higher, but not significantly so, in reboxetine than in fluoxetine patients for paraesthesia ($p = 0.067$) and, conversely, it is higher in fluoxetine patients for diarrhoea ($p = 0.076$) and agitation/anxiety/nervousness ($p = 0.073$).

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 is there any indication of increased frequency or severity in patients switched according to the protocol to the higher dose level, corresponding to 10 mg/day for reboxetine and to 40 mg/day for fluoxetine.

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 event or body system in Tables 49 and 50, respectively. Events on reboxetine and fluoxetine were most frequently of moderate severity (56.6% and 60.0%, respectively), severe events accounting for 24.5% and 20.0% of the occurrences of these patient groups. There were no major between-gender differences for severity of adverse events in the fluoxetine group. In the reboxetine group, the events of mild and moderate severity were more frequent in male than in female patients (25.0% *vs* 16.2% and 62.5% *vs* 54.1%, respectively), while severe events were more frequently reported in female patients (29.7% *vs* 12.5%). The severity of events for the majority of the affected body systems were moderate: 24.5% and 33.3% of the patients with events on reboxetine and fluoxetine, respectively, for central and peripheral NS disorders and 30.2% and 18.3% for GI disorders (Table 50). However, 20.0% of adverse events were also mild for GI disorders in the fluoxetine group compared with 15.1% in the reboxetine group.

8.2.1.6 Duration

Summary statistics of the duration of adverse events are described in Table 51. The median duration was 12 days for reboxetine and 9 days for fluoxetine. Among the most frequent events, the median duration was higher in the reboxetine group than in the fluoxetine group for dry mouth (reboxetine 28 days, fluoxetine 21 days), insomnia (29 days and 14 days, respectively), constipation (17 days and 13 days, respectively), blurred vision (28 days and 12 days, respectively) and agitation (19 days and 12 days, respectively). The median duration was higher in the fluoxetine group than in the reboxetine for increased sweating (reboxetine 13 days, fluoxetine 21 days), urinary hesitancy (7 days and 15 days, respectively) and paraesthesia (8 days and 35 days, respectively).

8.2.1.7 Symptomatic Treatment

As shown in Table 52, 22.2% and 30.0% of the events on reboxetine and fluoxetine, respectively, required symptomatic treatment in 56.6% and 53.3% of affected patients. Insomnia was the most frequent event leading to symptomatic treatment.

8.2.1.8 Modification of Study Medication and Patient Outcome

As shown in Table 53, no change in study medication was required for 83.7%, 86.1% of the events for reboxetine and fluoxetine patients, respectively, while the daily dose was reduced in 1.8%, 2.8% of the cases, or the treatment temporarily interrupted in 0.5%, 1.7%, respectively. According to the adverse event outcome reported by the investigator, 11.3% and 5.0% of the cases in the reboxetine and fluoxetine groups, respectively, contributed to withdrawal. 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 30 and 17 events requiring modification of the study medication in the reboxetine and fluoxetine groups, the majority (60.0% and 41.2%, respectively) did not disappear 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 44.7% (36.7% [reboxetine] and 58.8% [fluoxetine]) of the cases in both treatment groups following modification of the treatment regimen, and in 59.3% (55.0% [reboxetine] and 64.4% [fluoxetine]) of the cases of unchanged study medication. In these cases of unchanged study medication, the event was still present at last assessment in 26.7% of the reboxetine cases and 20.9% of the fluoxetine cases, or the patient had incompletely recovered (recovered with sequelae) in 0.5% of the reboxetine cases and 0.6% of the fluoxetine 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 most frequent events, in keeping with the selection of the most tolerant population over the treatment period, the proportion of affected patients tended to decrease during treatment, particularly during the last two weeks, in all treatment groups, with the exception of dry mouth and insomnia in the reboxetine group, and of insomnia, increased sweating and tremor in the fluoxetine group.

The overall prevalence of adverse events in both treatment groups is shown in Figure 19. The proportion of patients affected by at least one adverse event during the different weeks of treatment was slightly higher on reboxetine than on fluoxetine, particularly during the initial 3 weeks and last week of treatment. Only during the fourth week of treatment the proportion was slightly higher on fluoxetine than on reboxetine.

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 12 of Appendix 12.1.1) is described in Table 59. The majority of events in the reboxetine and fluoxetine groups (35.7%, 31.1%, respectively) were judged possibly related, while 28.5% and 27.2%, respectively, were judged probably related and 0.5% and 2.8%, respectively, were judged definitely related. Among the most frequent events, the maximal frequency of definite/probable relationship was present for nausea and related symptoms (31.3%, 56.5%), headache/migraine (22.7%, 21.4%), dry mouth (33.3%, 25.0%), hypotension and related symptoms (40.0%, 22.2%) and constipation (33.3%, 71.4%) for reboxetine and fluoxetine patients, respectively.

8.2.2 ADVERSE EVENT SUMMARY

Of the 79 reboxetine patients and 89 fluoxetine patients who received study medication, 53 (67.1%) and 60 (67.4%) patients, respectively, reported a total of 221 (reboxetine),

and 180 (fluoxetine) adverse events (4 and 3 events per patient, respectively) (Table 38). The cumulative risk of occurrence of adverse events was not significantly different between the two treatment groups (Figure 5). The prevalence of adverse events during the study indicates a slightly higher proportion of patients with adverse events in the reboxetine than in the fluoxetine group (Figure 19), particularly in the initial three and in the final weeks of treatment, and slightly higher on fluoxetine than on reboxetine only in the fourth week.

8.2.2.1 Severity of Adverse Events

The maximum severity of adverse events is presented in Tables 48, 49 and 50, and summarised as follows:

Severity of Adverse Events

Number of Patients					
Reboxetine			Fluoxetine*		
Mild	Moderate	Severe	Mild	Moderate	Severe
10	30	13	10	36	12

* two patients missing

The majority of adverse events were moderate in both groups.

8.2.2.2 Age- and Gender-Related Effects

Females suffered from adverse events less than males on reboxetine (64.9% *vs* 72.7%) and more frequently than males on fluoxetine (75.0% *vs* 48.0%) (Table 38). Patients on reboxetine aged 31 to 45 years had adverse events more frequently than patients who were aged 18-30 or over 45 (72.4%, 64.3%, 63.9%, respectively). In the fluoxetine group, the patients aged over 45 years had adverse events less frequently (64.1%) than both patients aged 18 to 30 and 31 to 45 (69.2% and 70.3%, respectively) (Table 39).

The most relevant between-gender difference was related to the frequency of insomnia, nausea, tremor, paraesthesia and urinary hesitancy. The adverse events complained of more frequently by female patients than male patients on reboxetine and fluoxetine, respectively were insomnia (14.0%, 14.1% [female patients] *vs* 9.1% and 0% [male patients]), nausea (12.3% on reboxetine and 12.5% on fluoxetine [female patients] *vs* 9.1% and 4.0% [male patients]), tremor (7.0%, 7.8% [female patients] *vs* 0% in both treatment groups [male patients]) and paraesthesia (8.8%, 1.6% [female patients] *vs* 0% in both treatments [male patients]). Urinary hesitancy was reported more by male patients than female patients (27.3%, *vs* 3.5%, respectively) in reboxetine-treated patients, while it was reported by 0% of male *vs* 1.6% of the female fluoxetine-treated

patients (Table 41).

8.2.2.3 Frequently Reported Adverse Events

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

Adverse Events Occurring in 5% or More of Patients in at least one Group

		Reboxetine (n=79)		Fluoxetine (n=89)	
Body system	Adverse event	No. of patients with event	% of patients exposed	No. of patients with event	% of patients exposed
GI disorders	Nausea and related symptoms	13	16.5	15	16.9
	Constipation	17	21.5	6	6.7
	Diarrhoea	1	1.3	6	6.7
Psychiatric disorders	Insomnia	10	12.7	9	10.1
	Agitation / anxiety / nervousness	3	3.8	10	11.2
Autonomic NS disorders	Dry mouth	27	34.2	8	9.0
	Increased sweating	7	8.9	7	7.9
General cardiovascular disorders	Hypotension and related symptoms	15	19.0	7	7.9
Central and peripheral NS disorders	Headache / migraine	17	21.5	20	22.5
	Tremor	4	5.1	5	5.6
	Paraesthesia	5	6.3	1	1.1
Body as a whole - General disorders	Asthenia / fatigue.	4	5.1	5	5.6
Urinary system disorders	Urinary hesitancy/retention	10	12.7	1	1.1

Headache/migraine and nausea and related symptoms were the most common adverse events in both groups, with 21.5% and 16.5% for reboxetine patients, respectively, and 22.5% and 16.9% of fluoxetine patients reporting these events. In addition, 34.2% of reboxetine patients reported dry mouth, 19.0% reported hypotension and related symptoms, 21.5% reported constipation and 12.7% reported urinary hesitancy/retention; the corresponding percentages in the fluoxetine group were 9.0%, 7.9%, 6.7% and 1.1%, respectively. Agitation/anxiety/nervousness and diarrhoea were reported more frequently in the fluoxetine group (11.2% and 6.7%) compared with the reboxetine group (3.8% and 1.3%).

As for individual events or clusters, the estimate of the cumulative risk of adverse events (according to the Kaplan-Meier method and log-rank test), is significantly higher on reboxetine than on fluoxetine for constipation, hypotension and related symptoms, dry mouth and urinary hesitancy/retention. In addition, the cumulative risk is higher, but not significantly so, in reboxetine than in fluoxetine patients for paraesthesia and, conversely, it is higher in fluoxetine than in reboxetine patients for diarrhoea and agitation/anxiety/nervousness,.

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

8.2.3.1 Serious Adverse Events and Deaths

Two patients suffered from serious adverse events during the course of this study: attempted suicide occurred in one patient of each treatment group. Case histories for these patients are provided in Appendix 12.2.1.

8.2.3.2 Adverse Events Associated with Withdrawal

Fifteen patients: 9 reboxetine (11.4%) and 6 fluoxetine (6.7%) had adverse events or intercurrent illnesses cited as the main reason for withdrawal from the study (Table 60). The nature of the adverse events present at withdrawal is summarised as follows:

Adverse Events Associated with Withdrawal

Treatment	Adverse event	Patient no.	Relationship to study drug
Reboxetine	GI disorders		
	Nausea	37	Probable
	Vomiting	129	Possible
	Constipation	196, 503	Doubtful, Possible
	Dyspepsia	387	Missing
	Psychiatric disorders		
	Insomnia	104, 4	Possible, Probable
	Somnolence	503	Possible
	Suicide attempt	335	Unknown
	Autonomic NS disorders		
	Dry mouth	34, 129, 503	Probable, Missing, Possible
	General cardiovascular disorders		
	Dizziness	196, 335, 503	Unknown, Doubtful, Possible
	Central and peripheral NS disorders		
	Headache	37	Probable
	Paraesthesia	104	Doubtful
	Body as a whole		
	Fever	37	Possible
	Rash	387	Possible
	Fatigue	503	Possible
	Liver and biliary system disorders		
	Hepatic enzymes ⇧	4, 196	Possible, Unknown
	Hepatitis infectious	196	None
	Urinary system disorders		
	Urinary retention	34	Probable
	Urinary hesitancy	503	Possible

Adverse Events Associated with Withdrawal (continued)

Treatment	Adverse event	Patient no.	Relationship to study drug
Fluoxetine	GI disorders		
	Nausea	396	Probable
	Vomiting	438	Possible
	Diarrhoea	438	Possible
	Gastritis	6	Doubtful
	Psychiatric disorders		
	Insomnia	22	Probable
	Agitation	396	Possible
	Suicide attempt	66	Doubtful
	Autonomic disorders		
	Dry mouth	66	Possible
	Increased sweating	66	Possible
	Urinary system disorders		
	Urinary hesitancy	396	Probable
	Respiratory disorders		
	Bronchitis	438	Possible
	Upper respiratory tract infection	391	Missing
	Body as a whole		
	Rash maculopapular	391	Probable

8.3 Laboratory Tests

8.3.1 SUMMARY STATISTICS OF LABORATORY VALUES

As shown in Table 61, there were no significant changes compared to baseline for any of the laboratory tests after one and two months of treatment in the reboxetine group, although after one month of treatment there was a decrease, but not significant so ($p = 0.014$) of the Cl values (median difference: -0.73 mEq/l).

A significant ($p<0.01$) decrease in gamma-GT after one month (median difference: -1.78 U/l) and two months of treatment (median difference: -3.69 U/l) was present in the fluoxetine group.

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 with baseline emerged. In fact, there was no indication of increased proportions of patients shifting from absence to presence of albumin, glucose, WBC and RBC compared with baseline, both at the various assessment intervals (Table 64) and at the last available assessment (Table 65). The same conclusions apply to the specific gravity of the urine (Table 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. A statistically significant shift in the distribution of the frequencies toward lower values was found for gamma-GT after one and two months of treatment ($p<0.01$; Maxwell's test), in the fluoxetine group and for Cl^- after one month of treatment in the reboxetine group.

8.3.4 ABNORMAL LABORATORY VALUES OF CLINICAL RELEVANCE

The distribution pattern of patients with clinically relevant abnormal values is given by variable and period of treatment in Table 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 fluoxetine 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, 71, 72, 73 and 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) at least once is given in Table 73.

The proportions of patients showing an increase and a decrease of possible clinical relevance for the systolic and diastolic blood pressure in lying and standing position were similar in both groups. For heart rate, a higher proportion of patients with at least 20%

increased values *vs* baseline, as well as such increases associated with values ≥100 beats/min was observed during all the treatment period in reboxetine- than in fluoxetine-treated patients in both positions. A total of 6 patients in the lying position and 10 in the standing position (8.1% of the 74 and 13.9% of the 72 evaluated patients, respectively) had clinically relevant increases at least once in the reboxetine group *vs* a total of 1 patients in the lying position and 3 patients in the standing position (1.2% of the 84 and 3.7% of the 82 evaluated patients, respectively) in the fluoxetine group. No clinically relevant decreases (at least 20% *vs* baseline as well as such decreases associated with values ≤50 beats/min) were observed on both treatment 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 1 fluoxetine patient and 2 reboxetine patients. Subsequently, the event had a low frequency at all visits, affecting a maximum of 7.9% of the reboxetine patients on Day 7 and 1.3% of the fluoxetine patients on Day 28.

8.4.2 BODY WEIGHT

Summary statistics of the body weight values (kg) at the various assessment intervals during the study 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 compared with baseline are given in Table 76. No trends toward modification and no difference between the reboxetine and fluoxetine groups were apparent.

8.4.3 BODY TEMPERATURE

Individual data are reported in Appendix 12.2.2 - Listing 20.0. No changes in temperature of note were apparent.

8.5 Electrocardiogram

As shown in Table 77, 146 patients (68 of the reboxetine and 78 of the fluoxetine group) had their ECG recorded at baseline, 14.4% of whom showed at least one ECG abnormality (16.2% reboxetine and 12.8% fluoxetine). During the study, 132 patients (61 reboxetine and 71 fluoxetine patients) had their ECG recorded after one month of treatment, and 120 (56 reboxetine and 64 fluoxetine patients) after two months of treatment. Of these patients, 16.4% (after one month of treatment) and 16.1% (after two months of treatment) had at least one ECG abnormality recorded during treatment in the reboxetine group. The equivalent proportions in the fluoxetine group were 9.9% (after one month) and 7.8% (after two months). As shown in Table 78, during the study, the per cent frequency of normalisation of ECG recordings in patients with at least one abnormality at entry was always consistently higher than the frequency of at least one newly emerged abnormality in patients with normal tracing at baseline in both treatment groups. At the last assessment of the study (Table 79), of the 21 patients (11 reboxetine and 10 fluoxetine) who had had at least one abnormality at baseline, 54.5% on

reboxetine and 80% on fluoxetine were reported as normal. Among the 125 patients (57 reboxetine and 68 fluoxetine) with normal tracings at baseline, 10.5% of the reboxetine- and 5.9% of the fluoxetine-treated patients showed at least one abnormality during the study.

The frequency of individual abnormalities at admission and during the study is shown by treatment group in Table 80. At screening, individual abnormalities are present in a maximum of 16.2% (several types) of the 68 evaluated cases of the reboxetine group and in 15.4% (several types) of the 78 evaluated cases in the fluoxetine group with a maximum for sinus bradycardia in both treatment groups (2.9% and 5.1% on reboxetine and fluoxetine, respectively) and conduction disorder in only the reboxetine group (2.9%). During treatment, the frequencies of all observed abnormalities were not modified to any significant extent in each treatment group. As shown in Table 81, at the last assessment, for all abnormalities and 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 in 8 reboxetine patients and 4 fluoxetine patients. The most common of these was sinus tachycardia (6 reboxetine and 0 fluoxetine) and sinus bradycardia (0 reboxetine and 2 fluoxetine).

The frequencies of randomised patients with at least one abnormality by abnormality group during the study is shown in Table 82. At screening, from 1.5% (other disorders) to 5.9% (conduction disorders, rhythm disorders) of the evaluated patients in the reboxetine group and 2.6% (ischemic signs, conduction disorder and other disorders) to 6.4% (rhythm disorders) in the fluoxetine group showed at least one abnormality of the indicated groups. During treatment, the frequencies were decreased for all groups in both treatment groups, except for "rhythm disorders" in the reboxetine group (increased to 11.5% after one month and to 10.7% after two months of treatment) and for "conduction disorder" in the fluoxetine group (increased to 4.2% after one month and to 3.1% after two months of treatment). As shown in Table 83, at last assessment, the proportion of newly emerged cases was slightly higher in the reboxetine group (7 rhythm disorders, 1 ischemic sign) than in the fluoxetine group (2 rhythm disorders, 2 conduction disorders).

8.6 Safety Conclusions

All the 168 patients who received study treatment were included in the safety analysis (79 reboxetine, 89 fluoxetine).

The occurrence of newly reported adverse events was similar in both groups during the study; 53/79 (67.1%) reboxetine group patients reported 221 adverse events compared with 60/89 (67.4%) fluoxetine patients who reported 180 adverse events. Discontinuation associated with adverse event was slightly more frequent in reboxetine patients (11.4%) than in fluoxetine patients (6.7%). More frequently reported adverse events by reboxetine-treated patients than fluoxetine-treated patients were dry mouth

(34.2% *vs* 9.0%, respectively), constipation (21.5% *vs* 6.7%), hypotension and related symptoms (19.0% *vs* 7.9%), urinary hesitancy/retention (12.7% *vs* 1.1%) and paraesthesia (6.3% *vs* 1.1%). Agitation/anxiety/nervousness and diarrhoea were reported more frequently in the fluoxetine group (11.2% and 6.7%) compared with the reboxetine group (3.8% and 1.3%).

The majority of adverse events were moderate in both treatment groups. Females suffered from adverse events less than males when on reboxetine (64.9% *vs* 72.7%) and more frequently than males when on fluoxetine (75.0% *vs* 48.0%). The most relevant between-gender difference was related to the frequency of insomnia, nausea, tremor and paraesthesia, complained of mainly by female patients in both treatment groups and urinary hesitancy, complained of mainly by male patients in the reboxetine group.

The estimate cumulative risk of adverse events (according to the Kaplan-Meier method and log-rank test) is significantly higher on reboxetine than on fluoxetine for constipation, hypotension and related symptoms, dry mouth and urinary hesitancy/retention. In addition, the cumulative risk is higher, but not significantly so, in reboxetine than in fluoxetine patients for paraesthesia and, conversely, it is higher in fluoxetine patients than in reboxetine patients for diarrhoea and agitation / anxiety / nervousness.

There were two serious adverse events (attempted suicide occurred in one patient of each treatment group) during the study.

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

Vital signs were not modified to any significant extent, with the exception of heart rate, which was more frequently increased under reboxetine and decreased under fluoxetine. A total of 6 patients in the lying position and 10 in the standing position (8.1% of the 74 and 13.9% of the 72 evaluated patients, respectively) had clinically relevant increases at least once in the reboxetine group *vs* a total of 1 patients in the lying position and 3 patients in the standing position (1.2% of the 84 and 3.7% of the 82 evaluated patients, respectively) in the fluoxetine group. No clinically relevant decreases (at least 20% *vs* baseline as well as such decreases associated with values ≤50 beats/min) were observed on both treatment groups.

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

9. DISCUSSION

One hundred and sixty-eight patients were admitted to this prospective, double-blind, randomised, parallel group, multicentre study of reboxetine (4 mg b.i.d.) and fluoxetine (20 mg o.d.), and randomised to treatment. A total of 128 patients (76.2%) completed the study (59 reboxetine and 69 fluoxetine patients). Overall, 40 patients (23.8%) withdrew, 20 reboxetine patients and 20 fluoxetine patients.

The response to treatment was assessed using the HAMD scale, the CGI and the MADRS.

The mean HAMD total score was reduced from 28.6 at Day 0 to 9.4 at last assessment, in the 76 patients randomised to reboxetine who had at least one assessment in addition to baseline, and to 7.3 at Day 56 in the 59 patients who completed the study. In the 87 patients randomised to fluoxetine with at least one assessment in addition to baseline, the mean HAMD total score was reduced from 27.4 at Day 0 to 10.6 at last assessment, and to 7.8 at Day 56 in the 69 patients still on treatment. The between treatment difference in HAMD total score decrease at last assessment was of 2.4 points (95% C.I.: -0.3 ÷ 5.1).

The percentage of responders at each visit was similar in the reboxetine group (28.0%) and the fluoxetine group (25.0%) from Day 14 onwards. At last assessment, 77.6% of the reboxetine-treated patients and 73.6% of the fluoxetine-treated patients were classified as responders, while 67.1% and 66.7%, respectively, were seen to be in remission. The between treatment difference in the proportion of response was of 4.1 % (95% C.I.: -9.1% ÷ 17.2%) in favour of reboxetine. The cumulative probability of response (confirmed at all available subsequent assessments), plotted according to the Kaplan-Meier method was a similar rate for patients on reboxetine and on fluoxetine (p=0.80) among the total population.

The additional analyses, carried out in the sub-populations of severe (CGI - Severity of Illness: markedly to extremely ill at the admission) and melancholic patients, suggested that the reboxetine treatment was superior to the fluoxetine in terms of improvement of the clinical picture, in both sub-populations, considering the HAMD differences at last assessment *vs* baseline. In severe cases (55 reboxetine- and 66 fluoxetine-treated patients), the between treatment difference was of 5.3 points (95% C.I.: 2.2 ÷ 8.4), definitely different from 0, while in melancholic patients (melancholic/not melancholic: 39/29 in the reboxetine and 39/38 in the fluoxetine group) the difference was 3.6 points (95% C.I.: -0.5 ÷ 7.7).

The percentage of patients who were 'much improved' and 'very much improved' at last assessment were 78.0% in the reboxetine group and 75.8% in the fluoxetine group. The proportion of the patients who had no change of the global improvement were similar in the two treatment groups (6.5% and 8.0% on reboxetine and fluoxetine , respectively) as well as the proportion of the 'minimally worse' patients (6.5% and 4.6% on reboxetine

and fluoxetine , respectively). Only in the fluoxetine treatment group there were 3.4% of patients who were 'much worse' and 'very much worse'.

At last assessment, side-effects were judged to outweigh efficacy in 10.4% of the reboxetine patients and 11.5% of the fluoxetine patients. A clear benefit from therapy (EI ≥2) was obtained in the majority of the patients in both treatment groups (approximately 64% of the reboxetine-treated patients and 72% of the fluoxetine-treated patients).

The mean total MADRS score was reduced from 17.1 at Day 0 to 5.7 at last assessment in the 76 reboxetine group patients with at least one assessment in addition to baseline, and to 4.1 at Day 56 in the 59 reboxetine patients who completed the study. In patients randomised to fluoxetine, values changed from 16.2 at Day 0 to 6.2 at last assessment (87 patients), and to 4.3 at Day 56 (69 assessed patients).

All the 168 patients who received study treatment were included in the safety analysis (79 reboxetine, 89 fluoxetine). For clinical and laboratory tests were analysed only patients with at least one assessment in addition to baseline.

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.

The occurrence of newly reported adverse events was similar in both groups during the study; 53/79 (67.1%) reboxetine group patients reported 221 adverse events compared with 60/89 (67.4%) fluoxetine patients who reported 180 adverse events. Discontinuation associated with adverse event was slightly more frequent in reboxetine patients (11.4%) than in fluoxetine patients (6.7%). More frequently reported adverse events on reboxetine than on fluoxetine were dry mouth (34.2% *vs* 9.0% , respectively), constipation (21.5% *vs* 6.7%), hypotension and related symptoms (19.0% *vs* 7.9%), urinary hesitancy/retention (12.7% *vs* 1.1%) and paraesthesia (6.3% *vs* 1.1%). Agitation/anxiety/nervousness and diarrhoea were reported more frequently in the fluoxetine group (11.2% and 6.7%) compared with the reboxetine group (3.8% and 1.3%).

The majority of adverse events were moderate in both treatment groups. Females suffered from adverse events less than males when on reboxetine (64.9% *vs* 72.7%) and more frequently than males when on fluoxetine (75.0% *vs* 48.0%). The most relevant between-gender difference was related to the frequency of insomnia, nausea, tremor and paraesthesia, complained of mainly by female patients in both treatment groups and urinary hesitancy, complained of mainly by male patients in the reboxetine group. The estimated cumulative risk of adverse events (according to the Kaplan-Meier method and log-rank test) is significantly higher on reboxetine than on fluoxetine for constipation, hypotension and related symptoms, dry mouth and urinary hesitancy/retention. In addition, the cumulative risk is higher, but not significantly so, in reboxetine-treated

patients than in fluoxetine-treated patients for paraesthesia and, conversely, it is higher in fluoxetine patients than in reboxetine patients for diarrhoea and agitation / anxiety / nervousness.

There were two serious adverse events (attempted suicide occurred in one patient of each treatment group) during the study.

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

Vital signs were not modified to any significant extent, with the exception of heart rate, which was more frequently increased (20% or more) under reboxetine and decreased under fluoxetine.

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

10. CONCLUSION

The efficacy of reboxetine and fluoxetine in patients with major depression, when administered for 8 weeks, as measured by HAMD, MADRS and CGI scales, were similar, in terms of frequency, rate and extent of the induced clinical improvement in the total population, but additional analyses carried out in sub-populations show reboxetine treatment to be superior to fluoxetine treatment, in terms of mean decrease of the HAMD scale at the last assessment, in melancholic and severe patients. In the latter case the C.I. of the between treatment difference supports the superiority of reboxetine.

The safety profiles of reboxetine and fluoxetine were also similar, as far as vital signs, haematology and blood chemistry tests and ECG examinations, with the exception of heart rate, which was more frequently increased on reboxetine and decreased on fluoxetine.

The frequency of patients with adverse events was similar in the two treatment groups, while the number of adverse events per patient was slightly higher in the reboxetine group. The estimated cumulative risk of any adverse events (according to the Kaplan-Meier method and log-rank test) is similar on reboxetine and fluoxetine, while it was significantly higher on reboxetine than on fluoxetine for constipation, hypotension and related symptoms, dry mouth and urinary hesitancy/retention. In addition, the cumulative risk is higher, but not significantly so, in reboxetine-treated patients than in fluoxetine-treated patients for paraesthesia and, conversely, it is higher in fluoxetine-treated patients than in reboxetine-treated patients for diarrhoea and agitation/anxiety/nervousness.

11. REFERENCES

1. Reboxetine Investigator's Brochure, Farmitalia Carlo Erba, CNS Line, July 1988.
2. Herrman WM, Schneider J, Boden S, Wagner W, Rohmel J, Grunmach J. Safety and tolerance of reboxetine in healthy male volunteers - A single rising dose tolerance study. Pharmacia Internal Report FCE 20124/602i, June 1984.
3. Herrman WM, Schneider J, Irrgang U, Rosener B, Willman J, Rohmel J, et al. Reboxetine - Quantitative pharmaco-EEG and pharmaco-psychological study. Pharmacia Internal Report FCE 20124/603i, January 1985.
4. Dubini A, Goldaniga GC, Montesanti L, Savoia L, Tamassia V, Vicario GP. Disposition and fate of ^{14}C-reboxetine administered orally to healthy volunteers. Pharmacia Internal Report FCE 20124/604i, March 1985.
5. Dubini A, Ban T. Open dose range finding study in patients hospitalised for Major Depressive Disorders. Pharmacia Internal Report FCE 20124/701i, April 1989.
6. Dubini A, Ban T, Morey LC. Phase II controlled study of the activity and tolerability of reboxetine in comparison with placebo and desipramine in patients hospitalised for Major Depressive Disorders. Pharmacia Internal Report FCE 20124/702i, February 1991.
7. Stark P, Hardison CD. A Review of Multicenter Controlled Studies of Fluoxetine *vs* Imipramine and Placebo in Outpatients with Major Depressive Disorder. J Clin Psychiatry 1985; 46(3, Sec 2): 53-58.
8. American Psychiatric Association. Mood disorders. In: Diagnostic and Statistical Manual of Mental Disorders. Third edition revised, American Psychiatric Association, Washington DC, 1987.
9. Hamilton M. A rating scale for depression. J Neurol Neurosurg Psychiatry 1960; 23: 56-62.
10. Stokes PE. Fluoxetine: A Five-Year Review. Clinical Therapeutics 1993; 15(2): 216-243.
11. Prozac. In: Physicians' Desk Reference (PDR). 43rd edition, Medical Economics Company Inc, Oradell, NJ, 1989.
12. Guy W. ECDEU Assessment Manual for Psychopharmacology. US Department of Health, Education and Welfare, Public Health Service, Alcohol, Drug Abuse, and Mental Health Administration. Rockville, Maryland: 1976.

13. Montgomery SA, Asberg M. A new depression scale designed to be sensitive to change. Br J Psychiatry 1979; 134: 382-389.

14. Asberg M, Montgomery SA, Perris C, Schalling D, Sedvall G. A comprehensive psychopathological psychiatric rating scale (CPRS). Acta Psychiatrica Scand (Suppl) 1978; 271: 5-27.

15. American Psychiatric Association. Mood disorders. In: Diagnostic and Statistical Manual of Mental Disorders. Fourth edition, American Psychiatric Association, Washington DC, 1994.

16. Gill JL. Design and Analysis of Experiments in the Animal and Medical Sciences. Ames, Iowa, USA: The Iowa State University Press, 1978: 54.

17. Gill JL. Design and Analysis of Experiments in the Animal and Medical Sciences. Ames, Iowa, USA: The Iowa State University Press, 1978: 135-150.

18. Gill JL. Design and Analysis of Experiments in the Animal and Medical Sciences. Ames, Iowa, USA: The Iowa State University Press, 1978: 52-53.

19. Peace KE. Biopharmaceutical Statistics for Drug Development. New York: Marcel Dekker, Inc, 1988: 478.

20. Kalbfleisch JD, Prentice RL. The Statistical Analysis of Failure Time Data. New York: John Wiley & Sons, 1980: 16-19.

21. Fleiss JL. Statistical Methods for Rates and Proportions. New York: John Wiley & Sons, 1973: 72-80.

22. Chuang-Stein C. Summarizing laboratory data with different reference ranges in multi-center clinical trials. Drug Information Journal 1992; 26: 77-84.

23. Wyngaarden JB, Smith LH, Bennett JC, Editors. Cecil Textbook of Medicine. Philadelphia: Saunders, 1988.

24. Hollander M, Wolfe DA. Nonparametric Statistical Methods. New York: John Wiley & Sons, 1973: 26-38.

25. Collaborating Center for International Drug Monitoring. Manual of the international statistical classification of diseases, injuries, and causes of death. Geneva: World Health Organization, 1977.

26. Collaborating Center for International Drug Monitoring. Drug Reference List. Geneva: World Health Organization, 1989.

27. Collaborating Center for International Drug Monitoring. Adverse Reactions Terminology. International monitoring of adverse reactions to drugs. Geneva: World Health Organization, 1989.

TABLES

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 1

NUMBER OF PATIENTS BY CENTRE, VISIT AND TREATMENT

Centre/Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
1	Fluoxetine	4	4	4	4	4	4	3	2	2	2
	Reboxetine	2	2	2	2	2	2	2	2	1	1
2	Fluoxetine	8	8	8	7	7	7	7	6	6	5
	Reboxetine	8	8	8	7	7	7	6	6	5	5
3	Fluoxetine	2	2	2	2	2	2	1	1	1	1
	Reboxetine	2	2	2	2	2	2	1			
4	Fluoxetine	5	5	5	5	4	4	4	4	3	3
	Reboxetine	4	4	4	3	3	3	3	3	3	2
5	Fluoxetine	1	1	1	1	1	1	1	1	1	1
	Reboxetine	1	1	1	1	1	1	1			
7	Fluoxetine	3	3	3	2	2	2	2	2	2	2
	Reboxetine	2	2	2	2	2	2	2	2	2	1
11	Fluoxetine	7	7	7	7	7	7	6	6	6	6
	Reboxetine	8	8	8	8	8	8	8	7	7	6
12	Fluoxetine	3	3	3	3	2	2	2	2	2	2
	Reboxetine	2	2	2	2	2	2	2	2	2	2
13	Fluoxetine	8	8	8	6	6	6	6	5	5	5
	Reboxetine	9	9	9	8	7	7	6	6	6	6
14	Fluoxetine	10	10	10	10	10	9	9	9	8	8
	Reboxetine	9	9	9	9	9	9	8	8	7	6
15	Fluoxetine	13	13	13	13	13	13	13	13	13	13
	Reboxetine	12	12	12	12	12	12	12	12	12	12
16	Fluoxetine	13	13	13	13	13	13	13	12	12	12
	Reboxetine	13	13	13	13	13	13	13	13	13	13

(CONTINUED)

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 1

NUMBER OF PATIENTS BY CENTRE, VISIT AND TREATMENT

Centre/Assigned treatment		Visit										
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
18	Fluoxetine	8	8	8	8	8	8	7	7	7	7
	Reboxetine	6	6	6	5	5	5	5	5	5	5
20	Fluoxetine	2	2	2	2	2	2	2	1	1	1
21	Fluoxetine	1	1	1	1	1	1	1	1	1	1
22	Fluoxetine	1	1	1	1	1					
	Reboxetine	1	1	1	1	1	1				
Total	Fluoxetine	89	89	89	85	83	81	77	72	70	69
	Reboxetine	79	79	79	75	74	74	69	66	63	59
	Total	168	168	168	160	157	155	146	138	133	128

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 2

PATIENT DISPOSITION

	Treatment assigned				Total	
	Fluoxetine		Reboxetine			
	No.	%	No.	%	No.	%
Screened	89	100.00	79	100.00	168	100.00
Exposed	89	100.00	79	100.00	168	100.00
Completed	69	77.53	59	74.68	128	76.19
Dropped	20	22.47	20	25.32	40	23.81

PHARMACIA CN2560083

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 3

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

Assigned treatment / Reasons		Total		Last visit													
				Day 7		Day 14		Day 21		Day 28		Day 35		Day 42		Day 49	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Fluoxetine	ADVERSE EVENT (*)	6	100			1	16.7			2	33.3	3	50.0				
	PROTOCOL VIOLATION	3	100	1	33.3			1	33.3	1	33.3						
	LOST TO FOLLOW UP	1	100													1	100
	DETERIORATION	6	100	1	16.7	1	16.7	1	16.7			1	16.7	2	33.3		
	PATIENT UNCOOPERATIVE	4	100	2	50.0					1	25.0	1	25.0				
	Total	20	100	4	20.0	2	10.0	2	10.0	4	20.0	5	25.0	2	10.0	1	5.0
Reboxetine	ADVERSE EVENT (*)	9	100	2	22.2					1	11.1	2	22.2	2	22.2	2	22.2
	PROTOCOL VIOLATION	2	100	1	50.0											1	50.0
	LOST TO FOLLOW UP	1	100							1	100						
	DETERIORATION	4	100			1	25.0					1	25.0	1	25.0	1	25.0
	PATIENT UNCOOPERATIVE	4	100	1	25.0					3	75.0						
	Total	20	100	4	20.0	1	5.0			5	25.0	3	15.0	3	15.0	4	20.0

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

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016

TABLE No: 4
PROTOCOL VIOLATION AT ADMISSION

	Fluoxetine		Reboxetine	
	No.	%	No.	%
Patients exposed	89	100.00	79	100.00
Age > 65 years			1	1.27
Pregnancy	1	1.12	1	1.27
Thyroid function tests abnormal*	9	10.11	5	6.33
Thyroid function tests missing	5	5.62	4	5.06
Evidence of Substance Use Disorder	1	1.12		
Associated endocrine disorder				
Not allowed concomitant medication during wash-out	7	7.87	7	8.86
Index episode < 4 weeks			2	2.53
Index episode > 8 months			2	2.53
Index episode duration: unknown			1	1.27
Clinical relevant associated pathology				

* > 10% deviation from normal range limits

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 5

RANDOMISATION: ASSIGNED TREATMENT vs RANDOMISED TREATMENT

Assigned treatment	Randomized treatment		Total
	Fluoxetine	Reboxetine	
Fluoxetine	78	11	89
Reboxetine	12	67	79
Total	90	78	168

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 6

COMPLIANCE TO SCHEDULE TIME AS PER PROTOCOL

Assigned treatment: Reboxetine

		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Assessment time	No.	79	79	75	74	74	69	66	63	59	59
	Min	-62	0	7	13	20	27	34	41	48	53
	Max	1	2	9	16	31	31	45	45	60	66
	Median	-4	1	8	15	22	29	35	43	49	56
	95th percentile	1	1	9	15	24	30	37	44	52	60
Laboratory test	No.	78					68				57
	Min	-59					15				51
	Max	2					42				76
	Median	-4					29				56
	95th percentile	1					32				60
E.C.G.	No.	78					61				57
	Min	-132					23				51
	Max	4					42				76
	Median	-4					29				56
	95th percentile	2					36				65

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 6

COMPLIANCE TO SCHEDULE TIME AS PER PROTOCOL

Assigned treatment: Fluoxetine

		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Assessment time	No.	89	89	85	83	81	77	72	70	69	69
	Min	-35	0	7	13	20	27	34	41	48	52
	Max	1	1	9	16	23	31	42	45	56	61
	Median	-4	1	8	15	22	29	36	42	49	56
	95th percentile	1	1	9	15	22	30	38	44	51	58
Laboratory test	No.	89					73				68
	Min	-35					22				50
	Max	3					45				84
	Median	-4					29				56
	95th percentile	1					35				65
E.C.G.	No.	87					70				67
	Min	-35					21				45
	Max	3					45				84
	Median	-4					29				56
	95th percentile	2					36				65

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 7

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

Class / Active principle		Fluoxetine	Reboxetine
BD2 long acting	FLUNITRAZEPAM	1	1
	NITRAZEPAM		1
	OXAZEPAM	1	
	LORAZEPAM	1	
	Total	3	2
Alcohol	ETHANOL	1	
	Total	1	
Neuroleptics	CHLORMEZANONE		1
	Total		1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Table No.: 8

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

	Assigned treatment	
	Fluoxetine	Reboxetine
At least one	4	3
Alcohol	1	
BDZ long acting	3	2
Neuroleptics		1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Table No.: 9

DEMOGRAPHY BY ASSIGNED TREATMENT - AGE, WEIGHT, HEIGHT

Assigned treatment		Age			Weight			Height		
		Sex			Sex			Sex		
		Female	Male	Total	Female	Male	Total	Female	Male	Total
Fluoxetine	No	64	25	89	64	25	89	63	25	88
	Mean	44.52	41.28	43.61	65.50	75.85	68.41	161.78	173.52	165.11
	S.D.	11.87	11.62	11.83	14.09	14.38	14.85	7.49	7.81	9.23
	Min	19.00	18.00	18.00	43.00	44.10	43.00	147.00	156.00	147.00
	Max	65.00	62.00	65.00	105.00	120.00	120.00	182.00	184.00	184.00
Reboxetine	No	57	22	79	57	22	79	57	22	79
	Mean	44.18	43.50	43.99	67.55	76.36	70.00	161.58	171.91	164.46
	S.D.	13.15	11.12	12.55	17.11	10.90	16.06	6.65	8.40	8.51
	Min	21.00	23.00	21.00	41.00	61.00	41.00	148.00	155.00	148.00
	Max	78.00	61.00	78.00	140.00	113.00	140.00	179.00	186.00	186.00
Total	No	121	47	168	121	47	168	120	47	167
	Mean	44.36	42.32	43.79	66.46	76.09	69.16	161.68	172.77	164.80
	S.D.	12.44	11.32	12.14	15.55	12.73	15.40	7.07	8.04	8.88
	Min	19.00	18.00	18.00	41.00	44.10	41.00	147.00	155.00	147.00
	Max	78.00	62.00	78.00	140.00	120.00	140.00	182.00	186.00	186.00

weight and height at screening visit

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Table No.: 10

DEMOGRAPHY BY ASSIGNED TREATMENT - RACE

Assigned treatment / Sex		Race				Total	
		Caucasian		Asian			
		No.	%	No.	%	No.	%
Fluoxetine	Female	64	100.00			64	100.00
	Male	25	100.00			25	100.00
	Total	89	100.00			89	100.00
Reboxetine	Female	56	100.00			56	100.00
	Male	22	95.65	1	4.35	23	100.00
	Total	78	98.73	1	1.27	79	100.00
Total	Female	120	100.00			120	100.00
	Male	47	97.92	1	2.08	48	100.00
	Total	167	99.40	1	0.60	168	100.00

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 11

DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

		Sex								
		Female			Male			Total		
		Fluoxetine	Reboxetine	Total	Fluoxetine	Reboxetine	Total	Fluoxetine	Reboxetine	Total
DSM-III-R diagnosis	296.2 No.	29	22	51	13	9	22	42	31	73
	296.3 No.	35	35	70	12	12	24	47	47	94
	other No.					1	1		1	1
Age of onset (years)	No.	54	48	102	21	17	38	75	65	140
	Mean	37.39	38.81	38.06	35.19	34.53	34.89	36.77	37.69	37.20
	STD	13.50	13.02	13.23	11.53	10.92	11.11	12.94	12.57	12.73
	Median	38.50	36.00	38.00	35.00	32.00	34.00	38.00	35.00	36.50
	Min	10	19	10	18	20	18	10	19	10
	Max	64	65	65	56	56	56	64	65	65
	unknown	10	9	19	4	5	9	14	14	28
Number of previous episodes	No.	30	32	62	12	11	23	42	43	85
	Mean	2.67	2.44	2.55	5.92	2.55	4.30	3.60	2.47	3.02
	STD	2.28	2.08	2.16	5.96	1.81	4.71	3.93	1.99	3.14
	Median	2.00	2.00	2.00	3.50	2.00	3.00	2.00	2.00	2.00
	Min	1	1	1	1	1	1	1	1	1
	Max	10	10	10	20	5	20	20	10	20

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 11

DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

		Sex								
		Female			Male			Total		
		Fluoxetine	Reboxetine	Total	Fluoxetine	Reboxetine	Total	Fluoxetine	Reboxetine	Total
Duration of last episode (weeks)	No.	33	32	65	12	12	24	45	44	89
	Mean	20.61	22.25	21.42	13.92	13.83	13.88	18.82	19.95	19.38
	STD	14.49	18.61	16.54	10.62	7.60	9.03	13.78	16.70	15.22
	Median	16.00	20.00	16.00	8.00	12.00	11.00	16.00	16.00	16.00
	Min	3	4	3	4	4	4	3	4	3
	Max	52	104	104	36	24	36	52	104	104
Duration of present episode (weeks)	No.	64	57	121	25	21	46	89	78	167
	Mean	13.45	14.61	14.00	10.44	11.59	10.97	12.61	13.80	13.16
	STD	6.72	20.85	15.07	6.06	7.00	6.46	6.65	18.19	13.31
	Median	12.00	10.00	12.00	8.00	8.00	8.00	12.00	9.50	12.00
	Min	4	2	2	4	4	4	4	2	2
	Max	28	156	156	24	28	28	28	156	156

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 12

DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

Sex: Female

		Fluoxetine		Reboxetine		Total	
		No	%	No	%	No	%
Charact. of present episode	Exacerbation of chronic cond.	8	12.50	6	10.53	14	11.57
	Recurrence of similar prev. cond.	28	43.75	30	52.63	58	47.93
	Different from any prev. cond.			1	1.75	1	0.83
	First occurence	28	43.75	20	35.09	48	39.67
	Total	64	100.00	57	100.00	121	100.00
Onset of present episode	Acute (< 2 weeks)	10	15.63	13	22.81	23	19.01
	Subacute (>= 2 & < 12 weeks)	23	35.94	27	47.37	50	41.32
	Insidious (>= 3 months)	31	48.44	17	29.82	48	39.67
	Total	64	100.00	57	100.00	121	100.00
Precipit. external stress	Absent	33	51.56	28	49.12	61	50.41
	Probably present	24	37.50	20	35.09	44	36.36
	Definitely present	7	10.94	9	15.79	16	13.22
	Total	64	100.00	57	100.00	121	100.00

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 12

DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

Sex: Male

		Fluoxetine		Reboxetine		Total	
		No	%	No	%	No	%
Charact. of present episode	Exacerbation of chronic cond.	4	16.00	3	13.64	7	14.89
	Recurrence of similar prev. cond.	9	36.00	10	45.45	19	40.43
	Different from any prev. cond.	1	4.00			1	2.13
	First occurence	11	44.00	9	40.91	20	42.55
	Total	25	100.00	22	100.00	47	100.00
Onset of present episode	Acute (< 2 weeks)	4	16.00	2	9.09	6	12.77
	Subacute (>= 2 & < 12 weeks)	15	60.00	12	54.55	27	57.45
	Insidious (>= 3 months)	6	24.00	8	36.36	14	29.79
	Total	25	100.00	22	100.00	47	100.00
Precipit. external stress	Absent	15	60.00	11	50.00	26	55.32
	Probably present	7	28.00	7	31.82	14	29.79
	Definitely present	3	12.00	4	18.18	7	14.89
	Total	25	100.00	22	100.00	47	100.00

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 12

DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

All patients

		Fluoxetine		Reboxetine		Total	
		No	%	No	%	No	%
Charact. of present episode	Exacerbation of chronic cond.	12	13.48	9	11.39	21	12.50
	Recurrence of similar prev. cond.	37	41.57	40	50.63	77	45.83
	Different from any prev. cond.	1	1.12	1	1.27	2	1.19
	First occurence	39	43.82	29	36.71	68	40.48
	Total	89	100.00	79	100.00	168	100.00
Onset of present episode	Acute (< 2 weeks)	14	15.73	15	18.99	29	17.26
	Subacute (>= 2 & < 12 weeks)	38	42.70	39	49.37	77	45.83
	Insidious (>= 3 months)	37	41.57	25	31.65	62	36.90
	Total	89	100.00	79	100.00	168	100.00
Precipit. external stress	Absent	48	53.93	39	49.37	87	51.79
	Probably present	31	34.83	27	34.18	58	34.52
	Definitely present	10	11.24	13	16.46	23	13.69
	Total	89	100.00	79	100.00	168	100.00

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

TABLE No.: 13

PREVIOUS ANTIDEPRESSIVE TREATMENT BY ACTIVE PRINCIPLE

	Assigned treatment				Total	
	Fluoxetine		Reboxetine			
	No	%	No	%	No	%
Screened patient	89	100.0	79	100.0	168	100.0
ANTIDEPRESSIVE	11	12.4	15	19.0	26	15.5
IMIPRAMINE	10	11.2	9	11.4	19	11.3
CLOMIPRAMINE	8	9.0	8	10.1	16	9.5
DOXEPIN	8	9.0	8	10.1	16	9.5
MOCLOBEMIDE	8	9.0	2	2.5	10	6.0
FLUOXETINE	4	4.5	6	7.6	10	6.0
TRANYLCYPROMINE	3	3.4	5	6.3	8	4.8
DOSULEPIN	5	5.6	3	3.8	8	4.8
MIANSERIN	5	5.6	2	2.5	7	4.2
TRIMIPRAMINE	2	2.2	3	3.8	5	3.0
NORTRIPTYLINE			4	5.1	4	2.4
AMINEPTINE	2	2.2	1	1.3	3	1.8
OPIPRAMOL	2	2.2	1	1.3	3	1.8
MAPROTILINE	1	1.1	1	1.3	2	1.2
FLUVOXAMINE	2	2.2			2	1.2
LITHIUM	1	1.1	1	1.3	2	1.2
VENLAFAXINE			1	1.3	1	0.6
AMOXAPINE			1	1.3	1	0.6
DIBENZEPIN			1	1.3	1	0.6

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 14

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

Previous diseases	Female						Male						Total					
	Fluoxetine		Reboxetine		Total		Fluoxetine		Reboxetine		Total		Fluoxetine		Reboxetine		Total	
	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.
Screened patients	64	100	57	100	121	100	25	100	22	100	47	100	89	100	79	100	168	100
OTHER GU NEOPLASM NOS	1	1.6	3	5.3	4	3.3							1	1.1	3	3.8	4	2.4
APPENDICITIS NOS			3	5.3	3	2.5									3	3.8	3	1.8
UTERINE LEIOMYOMA	2	3.1	2	3.5	4	3.3							2	2.2	2	2.5	4	2.4
OBESITY	2	3.1	1	1.8	3	2.5	2	8.0			2	4.3	4	4.5	1	1.3	5	3.0
VARICOSE VEIN OF LEG NOS			2	3.5	2	1.7									2	2.5	2	1.2
CHOLELITHIASIS NOS			2	3.5	2	1.7									2	2.5	2	1.2
CESAREAN DELIVERY NOS			2	3.5	2	1.7									2	2.5	2	1.2
PROSTATITIS NOS							2	8.0			2	4.3	2	2.2			2	1.2
HYPERTENSION NOS	1	1.6			1	0.8			2	9.1	2	4.3	1	1.1	2	2.5	3	1.8
TYPHOID FEVER	1	1.6			1	0.8							1	1.1			1	0.6
PULMONARY TB NEC	1	1.6			1	0.8							1	1.1			1	0.6
SEPTICEMIA NOS	1	1.6			1	0.8							1	1.1			1	0.6
GOITER NOS	1	1.6	1	1.8	2	1.7							1	1.1	1	1.3	2	1.2
MIGRAINE	1	1.6			1	0.8							1	1.1			1	0.6
RETINAL DETACH W DEFECT	1	1.6			1	0.8							1	1.1			1	0.6
DISSEMIN CHORIORETINITIS	1	1.6			1	0.8							1	1.1			1	0.6
FLU W RESP MANIFEST NEC	1	1.6			1	0.8							1	1.1			1	0.6
BRONCHITIS NOS	1	1.6			1	0.8							1	1.1			1	0.6
ASTHMA NOS	1	1.6	1	1.8	2	1.7							1	1.1	1	1.3	2	1.2
DIAPHRAGMATIC HERNIA	1	1.6			1	0.8							1	1.1			1	0.6
CHRONIC LIVER DIS NEC	1	1.6			1	0.8							1	1.1			1	0.6

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 14

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

Previous diseases	Female						Male						Total					
	Fluoxetine		Reboxetine		Total		Fluoxetine		Reboxetine		Total		Fluoxetine		Reboxetine		Total	
	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.
CHRONIC PANCREATITIS	1	1.6			1	0.8							1	1.1			1	0.6
ENDOMETRIOSIS NOS	1	1.6			1	0.8							1	1.1			1	0.6
EXCESSIVE MENSTRUATION	1	1.6	1	1.8	2	1.7							1	1.1	1	1.3	2	1.2
ECTOPIC PREGNANCY NOS	1	1.6			1	0.8							1	1.1			1	0.6
SPONTANEOUS ABORTION	1	1.6			1	0.8							1	1.1			1	0.6
DERANGEMENT OF JOINT NOS	1	1.6			1	0.8							1	1.1			1	0.6
THORAC/LUMB DISC DISPLAC	1	1.6			1	0.8							1	1.1			1	0.6
DISC DISPLACEMENT NOS	1	1.6	1	1.8	2	1.7							1	1.1	1	1.3	2	1.2
RHEUMATISM NOS	1	1.6			1	0.8							1	1.1			1	0.6
OSTEITIS DEFORMANS NOS	1	1.6			1	0.8							1	1.1			1	0.6
CYSTIC KIDNEY DISEASE	1	1.6	1	1.8	2	1.7							1	1.1	1	1.3	2	1.2
TACHYCARDIA NOS	1	1.6	1	1.8	2	1.7							1	1.1	1	1.3	2	1.2
CARDIOVAS SYS SYMP NEC	1	1.6			1	0.8							1	1.1			1	0.6
FX SACRUM/COCCYX-CLOSED	1	1.6			1	0.8							1	1.1			1	0.6
SUICIDE-PSYCHOTROPIC AGT	1	1.6			1	0.8							1	1.1			1	0.6
PULMONARY TB NOS			1	1.8	1	0.8									1	1.3	1	0.6
PURE HYPERCHOLESTEROLEM			1	1.8	1	0.8			1	4.5	1	2.1			2	2.5	2	1.2
MIXED HYPERLIPIDEMIA			1	1.8	1	0.8									1	1.3	1	0.6
HYPOPOTASSEMIA			1	1.8	1	0.8									1	1.3	1	0.6
HYPERMETROPIA			1	1.8	1	0.8									1	1.3	1	0.6
ASTIGMATISM			1	1.8	1	0.8									1	1.3	1	0.6
ALLERGIC RHINITIS NOS			1	1.8	1	0.8									1	1.3	1	0.6

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 14

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

Previous diseases	Female						Male						Total					
	Fluoxetine		Reboxetine		Total		Fluoxetine		Reboxetine		Total		Fluoxetine		Reboxetine		Total	
	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.
PNEUMONIA, ORGANISM NOS			1	1.8	1	0.8									1	1.3	1	0.6
BRONCHIECTASIS			1	1.8	1	0.8									1	1.3	1	0.6
PNEUMOTHORAX			1	1.8	1	0.8									1	1.3	1	0.6
ESOPHAGITIS			1	1.8	1	0.8									1	1.3	1	0.6
GASTRITIS/DUODENITIS NOS			1	1.8	1	0.8									1	1.3	1	0.6
INGUINAL HERNIA NOS			1	1.8	1	0.8	1	4.0			1	2.1	1	1.1	1	1.3	2	1.2
HEPATITIS IN VIRAL DIS			1	1.8	1	0.8									1	1.3	1	0.6
HYDRONEPHROSIS			1	1.8	1	0.8									1	1.3	1	0.6
CYSTITIS NOS			1	1.8	1	0.8									1	1.3	1	0.6
SALPINGO-OOPHORITIS NOS			1	1.8	1	0.8									1	1.3	1	0.6
UTERINE PROLAPSE			1	1.8	1	0.8									1	1.3	1	0.6
OVARIAN CYST NEC/NOS			1	1.8	1	0.8									1	1.3	1	0.6
NONINFL DIS OVA/ADNX NEC			1	1.8	1	0.8									1	1.3	1	0.6
INCOMPETENCE OF CERVIX			1	1.8	1	0.8									1	1.3	1	0.6
OTHER PSORIASIS			1	1.8	1	0.8									1	1.3	1	0.6
OSTEOARTHROSIS NOS			1	1.8	1	0.8									1	1.3	1	0.6
TORTICOLLIS NOS			1	1.8	1	0.8									1	1.3	1	0.6
LUMBAGO			1	1.8	1	0.8									1	1.3	1	0.6
SCIATICA			1	1.8	1	0.8									1	1.3	1	0.6
ENTHESOPATHY OF ANKLE			1	1.8	1	0.8									1	1.3	1	0.6
SCOLIOSIS			1	1.8	1	0.8									1	1.3	1	0.6
OTHER ANOMALIES OF LUNG			1	1.8	1	0.8									1	1.3	1	0.6

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 14

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

Previous diseases	Female						Male						Total					
	Fluoxetine		Reboxetine		Total		Fluoxetine		Reboxetine		Total		Fluoxetine		Reboxetine		Total	
	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.
CONGEN URETERAL OBSTRUCT			1	1.8	1	0.8									1	1.3	1	0.6
ABN BLOOD CHEMISTRY NEC			1	1.8	1	0.8	1	4.0			1	2.1	1	1.1	1	1.3	2	1.2
CLAVICLE FRACTURE			1	1.8	1	0.8									1	1.3	1	0.6
STERILIZATION			1	1.8	1	0.8									1	1.3	1	0.6
BENIGN NEO UTERUS NOS							1	4.0			1	2.1	1	1.1			1	0.6
THYROTOXICOSIS NOS							1	4.0			1	2.1	1	1.1			1	0.6
RHEUM FEV W/O HRT INVOLV							1	4.0			1	2.1	1	1.1			1	0.6
OLD MYOCARDIAL INFARCT							1	4.0			1	2.1	1	1.1			1	0.6
STOMACH ULCER NOS							1	4.0	1	4.5	2	4.3	1	1.1	1	1.3	2	1.2
ALCOHOLIC GASTRITIS							1	4.0			1	2.1	1	1.1			1	0.6
ALCOHOL LIVER DAMAGE NOS							1	4.0			1	2.1	1	1.1			1	0.6
LIVER DISORDERS NEC							1	4.0			1	2.1	1	1.1			1	0.6
ABN LIVER FUNCTION STUDY							1	4.0			1	2.1	1	1.1			1	0.6
ADV EFF PHENOTHIAZ TRANQ							1	4.0			1	2.1	1	1.1			1	0.6
DUODENAL ULCER NOS									1	4.5	1	2.1			1	1.3	1	0.6
ARTHROPATHY NOS									1	4.5	1	2.1			1	1.3	1	0.6
CONCUSSION									1	4.5	1	2.1			1	1.3	1	0.6

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 15

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

Previous diseases (body system)	Female						Male						Total					
	Fluoxetine		Reboxetine		Total		Fluoxetine		Reboxetine		Total		Fluoxetine		Reboxetine		Total	
	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.	No	% on Pt.
Screened Patients	64	100	57	100	121	100	25	100	22	100	47	100	89	100	79	100	168	100
NEOPLASM	3	4.7	5	8.8	8	6.6	1	4.0			1	2.1	4	4.5	5	6.3	9	5.4
DIGESTIVE SYSTEM	3	4.7	9	15.8	12	9.9	3	12.0	1	4.5	4	8.5	6	6.7	10	12.7	16	9.5
ENDOCR., NUTRIT. AND METAB. DISEASES	3	4.7	5	8.8	8	6.6	3	12.0	1	4.5	4	8.5	6	6.7	6	7.6	12	7.1
CIRCULATORY SYSTEM	1	1.6	2	3.5	3	2.5	2	8.0	2	9.1	4	8.5	3	3.4	4	5.1	7	4.2
PREGNANCY,CHILDBIRTH AND PUERPERIUM	2	3.1	2	3.5	4	3.3							2	2.2	2	2.5	4	2.4
GENITOURINARY SYSTEM	2	3.1	7	12.3	9	7.4	2	8.0			2	4.3	4	4.5	7	8.9	11	6.5
INFECTIOUS AND PARASITIC DISEASE	3	4.7	1	1.8	4	3.3							3	3.4	1	1.3	4	2.4
NERVOUS SYSTEM AND SENSE ORGANS	2	3.1	1	1.8	3	2.5							2	2.2	1	1.3	3	1.8
RESPIRATORY SYSTEM	3	4.7	5	8.8	8	6.6							3	3.4	5	6.3	8	4.8
MUSCOLOSKELETAL SYS. AND CONNETIVE TISSUE	4	6.3	5	8.8	9	7.4			1	4.5	1	2.1	4	4.5	6	7.6	10	6.0
CONGENITAL ANOMALIES	1	1.6	3	5.3	4	3.3							1	1.1	3	3.8	4	2.4
SYMPTOMS, SIGNS AND ILL DEFINED CONDITIONS	2	3.1	2	3.5	4	3.3	2	8.0			2	4.3	4	4.5	2	2.5	6	3.6
INJURY AND POISONING	1	1.6	1	1.8	2	1.7			1	4.5	1	2.1	1	1.1	2	2.5	3	1.8
OTHER	1	1.6	1	1.8	2	1.7	1	4.0			1	2.1	2	2.2	1	1.3	3	1.8
SKIN AND SUBCUTANEOUS TISSUE			1	1.8	1	0.8									1	1.3	1	0.6

PHARMACIA CN 95 0083

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 16

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

Assigned treatment: Reboxetine

days of treatment		Dose (mg/day)										Total	
		0		4		8		10		12			
		No	%	No	%	No	%	No	%	No	%	No	%
Day 0	1			12	15.2	67	84.8					79	100
	2			1	1.3	77	98.7					78	100
	3			1	1.3	76	98.7					77	100
	4			1	1.3	76	98.7					77	100
	5			2	2.6	74	97.4					76	100
	6	1	1.3			75	98.7					76	100
	7			1	1.4	72	98.6					73	100
	8					3	100					3	100
Day 7	1					74	98.7			1	1.3	75	100
	2					75	100					75	100
	3					75	100					75	100
	4					75	100					75	100
	5			2	2.7	73	97.3					75	100
	6			1	1.3	74	98.7					75	100
	7			1	1.4	71	98.6					72	100
	8					1	100					1	100
Day 14	1					74	100					74	100
	2			1	1.4	73	98.6					74	100
	3			1	1.4	73	98.6					74	100
	4					74	100					74	100
	5					74	100					74	100
	6					74	100					74	100
	7			1	1.4	73	98.6					74	100
	8					7	100					7	100
	9					1	100					1	100
Day 21	1					74	100					74	100
	2			1	1.4	73	98.6					74	100
	3					73	100					73	100
	4					73	100					73	100
	5			1	1.4	72	98.6					73	100
	6			1	1.4	72	98.6					73	100
	7					70	100					70	100
	8			1	16.7	5	83.3					6	100
	9			1	100							1	100
Day 28	1					57	82.6	12	17.4			69	100
	2					56	82.4	12	17.6			68	100
	3			1	1.5	55	80.9	12	17.6			68	100
	4					56	82.4	12	17.6			68	100
	5	1	1.5			54	80.6	12	17.9			67	100
	6	1	1.5			54	80.6	12	17.9			67	100
	7	1	1.6	1	1.6	49	77.8	12	19.0			63	100
	8	1	33.3			2	66.7					3	100
	9	1	100									1	100
Day 35	1			1	1.5	51	77.3	14	21.2			66	100
	2					52	78.8	14	21.2			66	100
	3					52	78.8	14	21.2			66	100
	4					52	78.8	14	21.2			66	100
	5					52	78.8	14	21.2			66	100
	6			1	1.5	52	78.8	13	19.7			66	100
	7			3	4.7	49	76.6	12	18.8			64	100
	8					2	100					2	100
Day 42	1	1	1.6			50	79.4	12	19.0			63	100
	2					51	81.0	12	19.0			63	100
	3			1	1.6	50	79.4	12	19.0			63	100
	4			1	1.6	50	79.4	12	19.0			63	100
	5			1	1.6	50	79.4	12	19.0			63	100
	6					51	81.0	12	19.0			63	100
	7			2	3.2	48	77.4	12	19.4			62	100
	8					2	66.7	1	33.3			3	100
Day 49	1					50	84.7	9	15.3			59	100
	2					50	84.7	9	15.3			59	100
	3					50	84.7	9	15.3			59	100
	4			1	1.7	50	84.7	8	13.6			59	100
	5					50	86.2	8	13.8			58	100
	6					50	86.2	8	13.8			58	100
	7					49	86.0	8	14.0			57	100
	8	1	11.1	5	55.6	3	33.3					9	100
	9			3	100							3	100

REBOXETINE - PROTOCOL 20124/016
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: Fluoxetine

days of treatment		Dose (mg/day)								Total	
		0		20		40		60			
		No	%	No	%	No	%	No	%	No	%
Day 0	1	11	12.4	78	87.6					89	100
	2			88	100					88	100
	3	1	1.1	87	98.9					88	100
	4			87	100					87	100
	5			86	100					86	100
	6			86	100					86	100
	7			86	100					86	100
	8			6	100					6	100
Day 7	1	1	1.2	84	98.8					85	100
	2	3	3.5	82	96.5					85	100
	3	1	1.2	84	98.8					85	100
	4	1	1.2	84	98.8					85	100
	5	1	1.2	83	98.8					84	100
	6	1	1.2	82	98.8					83	100
	7	2	2.5	78	97.5					80	100
Day 14	1			83	100					83	100
	2	2	2.4	81	97.6					83	100
	3	1	1.2	81	98.8					82	100
	4			82	100					82	100
	5			82	100					82	100
	6			82	100					82	100
	7			82	100					82	100
	8			3	100					3	100
Day 21	1			81	100					81	100
	2			81	100					81	100
	3			81	100					81	100
	4	2	2.5	79	97.5					81	100
	5	2	2.5	79	97.5					81	100
	6	1	1.2	79	98.8					80	100
	7			79	100					79	100
	8			5	100					5	100
Day 28	1	1	1.3	65	84.4	10	13.0	1	1.3	77	100
	2	1	1.3	67	87.0	8	10.4	1	1.3	77	100
	3	1	1.3	64	85.3	9	12.0	1	1.3	75	100
	4			65	86.7	9	12.0	1	1.3	75	100
	5	1	1.3	63	84.0	10	13.3	1	1.3	75	100
	6			64	85.3	10	13.3	1	1.3	75	100
	7	1	1.4	60	83.3	11	15.3			72	100
	8	1	33.3	2	66.7					3	100
	9			1	100					1	100
Day 35	1			60	83.3	12	16.7			72	100
	2			61	84.7	11	15.3			72	100
	3			59	83.1	12	16.9			71	100
	4	1	1.4	58	81.7	12	16.9			71	100
	5			59	83.1	12	16.9			71	100
	6			61	85.9	10	14.1			71	100
	7	1	1.5	55	84.6	9	13.8			65	100
	8			2	100					2	100
Day 42	1	1	1.4	58	82.9	11	15.7			70	100
	2	1	1.4	58	82.9	11	15.7			70	100
	3	1	1.4	58	82.9	11	15.7			70	100
	4	1	1.4	58	82.9	11	15.7			70	100
	5	1	1.4	58	82.9	11	15.7			70	100
	6	1	1.4	58	82.9	11	15.7			70	100
	7	1	1.4	58	84.1	10	14.5			69	100
	8	1	14.3	5	71.4	1	14.3			7	100
Day 49	1	1	1.4	57	82.6	11	15.9			69	100
	2	1	1.4	57	82.6	11	15.9			69	100
	3	2	2.9	56	81.2	11	15.9			69	100
	4	3	4.3	54	78.3	12	17.4			69	100
	5	1	1.5	55	80.9	12	17.6			68	100
	6	1	1.5	56	82.4	11	16.2			68	100
	7	1	1.5	52	78.8	13	19.7			66	100
	8			9	90.0	1	10.0			10	100
	9			1	100					1	100

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

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 28	Day 35	Day 49
Fluoxetine	always low dose	75	84.27	75			
	at least one high dose	14	15.73		12	1	1
	Total	89	100.00	75	12	1	1
Reboxetine	always low dose	64	81.01	64			
	at least one high dose	15	18.99		12	2	1
	Total	79	100.00	64	12	2	1

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

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 %			
	No	%	No	%	No	%	No	%	No	%	No	%
Fluoxetine	3	3.4	1	1.1	3	3.4	29	32.6	53	59.6	89	100.0
Reboxetine	2	2.5	1	1.3	3	3.8	13	16.5	60	75.9	79	100.0
Total	5	3.0	2	1.2	6	3.6	42	25.0	113	67.3	168	100.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	
	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine
	No.	No.	No.	No.	No.	No.
CHLORAL HYDRATE	8	8	9	10	17	18
TEMAZEPAM	6	6	2	4	8	10
CLOMETHIAZOLE	1	3	7	6	8	9
PARACETAMOL			10	5	10	5
ACETYLSALICYLIC ACID	1	2	3	2	4	4
METOCLOPRAMIDE			1	3	1	3
AMOXICILLIN	1		2	1	3	1
MAGALDRATE			1	2	1	2
LACTULOSE		1		2		3
DOMPERIDONE		1	2		2	1
ESTRADIOL	1	1			1	1
DOXYCYCLINE			2		2	
CHLORPHENAMINE			1	1	1	1
ESTROGENS CONJUGATED	1	1			1	1
MEDROXYPROGESTERONE	1	1			1	1
SENNA			1	1	1	1
FLUCLOXACILLIN				2		2
SODIUM PICOSULFATE			1	1	1	1
DICLOFENAC				2		2
FLUNITRAZEPAM	1			1	1	1
UREA			1	1	1	1
RANITIDINE		1	1		1	1

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	
	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine
	No.	No.	No.	No.	No.	No.
ORCIPRENALINE		1				1
AMPICILLIN				1		1
PHENOXYMETHYLPENICILLIN			1		1	
ETHANOL			1		1	
ALLOPURINOL	1				1	
ASCORBIC ACID			1		1	
PETHIDINE				1		1
ERYTHROMYCIN				1		1
HYDROCHLOROTHIAZIDE				1		1
EUGYNON				1		1
HYDROCORTISONE			1		1	
PROPRANOLOL	1				1	
POTASSIUM		1				1
NITRAZEPAM				1		1
MYLANTA				1		1
OXAZEPAM	1				1	
NORETHISTERONE	1				1	
GENTAMICIN				1		1
CHLORMEZANONE				1		1
THIAMINE				1		1
CALCIUM GLUCONATE	1				1	
DOCUSATE			1		1	

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	
	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine
	No.	No.	No.	No.	No.	No.
GASTROGEL				1		1
BACTRIM			1		1	
ETILEFRINE				1		1
IBUPROFEN				1		1
CEFALEXIN			1		1	
BECLOMETASONE		1				1
LORAZEPAM			1		1	
CALCIUM LACTATE	1				1	
KETOPROFEN		1				1
PRAZOSIN				1		1
NIFEDIPINE				1		1
ASPIRIN PLUS C			1		1	
METOPROLOL			1		1	
PIPEMIDIC ACID				1		1
CERNILTON	1				1	
DIANE	1				1	
MOLSIDOMINE	1				1	
MAGNESIUM OXIDE				1		1
MARVELON			1		1	
ENALAPRIL				1		1
TERFENADINE				1		1
EFFORTIL PLUS			1		1	

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	
	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine
	No.	No.	No.	No.	No.	No.
LINSEED		1				1
ASTEMIZOLE			1		1	
ANALGILASA			1		1	
CIPROFLOXACIN			1		1	
ESTROGEN NOS				1		1
BISOPROLOL	1				1	
VINCIGRIP			1		1	
SINVASTATIN		1				1
DEBRUNYL				1		1
LOVASTATIN		1				1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 19

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

		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Mean	27.52	27.38	22.32	18.21	15.49	12.85	11.60	9.31	8.47	7.77
	Median	26	27	23	18	15	14	11	10	7	7
	STD	3.92	4.15	5.85	6.96	6.80	6.50	7.02	5.43	6.51	5.25
	Min	22	16	9	3	2	1	0	0	0	0
	Max	36	36	39	34	31	27	31	24	25	23
	Mean diff. vs day0 (*)			5.06	9.02	11.77	14.36	17.36	17.32	19.65	19.33
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Mean	28.53	28.62	23.97	18.93	15.78	13.69	12.82	10.06	10.06	7.29
	Median	27	27	24	20	15	13	12	10	8	5
	STD	5.20	5.31	5.97	6.44	6.46	6.76	6.89	6.13	6.37	5.51
	Min	22	22	11	4	2	2	0	0	0	0
	Max	49	49	43	34	37	28	27	28	25	25
	Mean diff. vs day0 (*)			4.64	9.73	13.01	15.15	16.29	18.45	19.39	21.51

Mean (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 20

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

Factor: ANXIETY/SOMATIZATION

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	1.33	1.33	1.00	0.83	0.83	0.67	0.50	0.50	0.33	0.33
	Min	0.83	0.83	0.33	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	2.17	2.17	2.17	2.00	1.83	1.50	1.67	1.17	1.50	1.17
	Median diff. vs day0 (*)			0.00	0.33	0.50	0.67	0.92	0.83	1.00	0.83
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	1.33	1.33	1.17	0.83	0.83	0.67	0.67	0.50	0.50	0.33
	Min	0.50	0.50	0.33	0.17	0.17	0.17	0.00	0.00	0.00	0.00
	Max	2.33	2.33	2.00	2.33	2.33	1.83	1.67	1.33	1.50	1.33
	Median diff. vs day0 (*)			0.17	0.50	0.50	0.67	0.67	0.83	0.83	1.00

Median (*): median of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 20

FACTORIALISATION 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	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	1.00	0.83	0.67	0.50	0.33	0.33	0.17	0.17	0.17	0.17
	Min	0.17	0.17	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	2.00	2.00	1.67	1.33	1.33	1.33	1.17	1.00	1.50	1.17
	Median diff. vs day0 (*)			0.17	0.17	0.33	0.50	0.50	0.50	0.50	0.67
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	1.00	1.00	0.83	0.50	0.33	0.33	0.33	0.17	0.33	0.17
	Min	0.17	0.17	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Max	2.33	2.33	2.00	1.33	1.50	1.33	1.50	1.33	1.17	1.50
	Median diff. vs day0 (*)			0.17	0.33	0.50	0.50	0.50	0.67	0.67	0.67

Median (*): median of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 20

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

Factor: RETARDATION

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	2.00	2.00	1.75	1.50	1.25	1.00	0.75	0.75	0.50	0.50
	Min	1.25	1.25	0.50	0.25	0.00	0.00	0.00	0.00	0.00	0.00
	Max	3.25	3.25	3.00	2.50	2.50	2.50	2.50	2.25	2.00	2.00
	Median diff. vs day0 (*)			0.25	0.50	0.75	1.00	1.25	1.25	1.63	1.50
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	2.00	2.13	1.75	1.50	1.25	1.00	0.75	0.75	0.50	0.50
	Min	1.00	1.00	1.00	0.25	0.00	0.00	0.00	0.00	0.00	0.00
	Max	3.25	3.25	2.75	2.50	2.25	2.00	2.00	2.50	2.50	2.25
	Median diff. vs day0 (*)			0.25	0.50	0.75	1.00	1.38	1.50	1.75	1.75

Median (*): median of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 20

FACTORIALISATION HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE 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
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	1.33	1.33	1.00	1.00	0.67	0.67	0.67	0.33	0.33	0.33
	Min	0.00	0.00	0.00	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	1.67	1.67	1.67
	Median diff. vs day0 (*)			0.00	0.33	0.33	0.67	0.67	0.67	0.67	1.00
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	1.33	1.33	1.33	1.00	0.67	0.67	0.67	0.33	0.67	0.33
	Min	0.00	0.00	0.00	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	1.67	1.67	1.33	1.67
	Median diff. vs day0 (*)			0.00	0.33	0.67	0.67	0.67	0.83	1.00	1.00

Median (*): median of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: DEPRESSED MOOD

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	3	3	3	2	2	1	1	1	0	1
	Min	1	1	0	0	0	0	0	0	0	0
	Max	4	4	4	4	4	4	4	4	3	3
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	3	3	2	2	1	1	1	1	1	1
	Min	1	1	1	0	0	0	0	0	0	0
	Max	4	4	4	4	4	3	3	4	4	3

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: GUILT

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	2	2	1	1	1	1	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	3	3	3	3	3	2	1	2	2	2
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	2	2	2	1	1	1	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	3	3	3	3	2	2	2	2	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: SUICIDE

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	1	1	1	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	3	3	3	2	2	2	3	2	2	1
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	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	2	2	2	2	1	1	1

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: INSOMNIA EARLY

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	2	2	1	1	1	1	1	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	2
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	2	2	1	1	1	1	1	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: INSOMNIA MIDDLE

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	1	1	1	1	1	1	1	0	1	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	2
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	1	1	1	1	1	1	1	1	1	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: INSOMNIA LATE

Assigned treatment		Visit											
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	1	1	1	1	1	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	2
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	2	2	1	1	1	0	1	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	1

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: WORK AND ACTIVITIES

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	3	3	2	2	2	1	1	1	1	1
	Min	1	1	0	0	0	0	0	0	0	0
	Max	4	4	4	4	4	4	4	4	4	4
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	3	3	2	2	2	1	1	1	1	1
	Min	0	0	1	0	0	0	0	0	0	0
	Max	4	4	4	4	4	3	3	3	4	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: RETARDATION

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	1	1	1	1	1	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	3	3	3	2	2	2	2	2	1	2
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	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	2	2	2	2	2	2	1	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 2024/016
TABLE No.: 21

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

Item: AGITATION

Assigned treatment			Visit											
			Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No		87	87	87	84	81	80	42	69	34	69
		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	3	4	3	4	2	2	2
Reboxetine	No		76	76	76	75	73	72	34	66	31	59
		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	2	3	3	2	2	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: ANXIETY PSYCHIC

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	2	2	2	1	1	1	1	1	1	1
	Min	1	1	0	0	0	0	0	0	0	0
	Max	4	4	3	4	3	3	4	4	3	3
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	2	2	2	1	1	1	1	1	1	1
	Min	1	1	0	0	0	0	0	0	0	0
	Max	4	4	4	4	4	4	4	3	4	3

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: ANXIETY SOMATIC

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	2	2	1	1	1	1	1	1	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	4	4	3	3	3	3	4	2	2	2
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	2	2	2	1	1	1	1	1	1	1
	Min	0	0	0	0	0	0	0	0	0	0
	Max	3	3	3	3	3	2	3	3	3	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: SOMATIC GASTROINTESTINAL

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	1	1	1	1	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	1	1	1	1
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	1	1	1	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	1

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: SOMATIC GENERAL

Assigned treatment		Visit											
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	1	1	1	1	1	1	0	1	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	2
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	2	2	1	1	1	1	1	1	1	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: SOMATIC GENERAL

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	1	1	1	1	1	1	0	1	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	2
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	2	2	1	1	1	1	1	1	1	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: GENITAL SYMPTOMS

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	1	1	1	1	1	1	1	1	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	2
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	2	2	1	1	1	1	1	1	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: HYPOCHONDRIASIS

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	2	2	1	1	1	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	4	4	3	3	3	3	3	2	2	2
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	2	2	1	1	1	1	1	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	4	4	3	3	3	3	2	2	3	3

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: LOSS OF WEIGHT

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	0	0	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	1	1	2
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	1	1	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	1	1	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: INSIGHT

Assigned treatment			Visit											
			Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No		87	87	87	84	81	80	42	69	34	69
		Median	0	0	0	0	0	0	0	0	0	0
		Min	0	0	0	0	0	0	0	0	0	0
		Max	1	1	2	1	1	1	1	1	0	0
Reboxetine	No		76	76	76	75	73	72	34	66	31	59
		Median	0	0	0	0	0	0	0	0	0	0
		Min	0	0	0	0	0	0	0	0	0	0
		Max	1	1	1	1	1	1	0	0	2	0

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: DIURNAL VARIATION

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	1	1	1	1	1	1	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	2
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	1	1	1	1	1	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	1

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: DEPERSONALIZATION

Assigned treatment		Visit											
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	0	0	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	3	3	3	2	2	3	2	2	2	1
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	0	0	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	3	3	2	1	2	2	2	2	1	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: PARANOID

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	0	0	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	1	2	1	1	1	1
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	0	0	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	1	2	1	1	1	1	1	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Item: OBSESSIONAL/COMPULSIVE

Assigned treatment		Visit									
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Median	0	0	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	2
Reboxetine	No	76	76	76	75	73	72	34	66	31	59
	Median	1	1	1	1	1	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 22

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

		Last assessment									
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Mean	31.33	30.00	25.50	19.50	16.20	12.00		7.77	10.62
	Median	28	30	26	24	14	12		7	8
	STD	6.66	0.00	7.78	9.04	11.52	11.31		5.25	8.66
	Min	27	30	20	6	5	4		0	0
	Max	39	30	31	25	31	20		23	39
	Mean diff. vs day0 (*)	0.00	-2.00	2.00	5.00	14.00	17.00		19.33	16.76
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Mean	17.00	24.00	21.50	16.00	16.00	12.75	17.67	7.29	9.39
	Median	17	24	22	23	16	11	19	5	7
	STD			10.61	10.27		7.80	8.08	5.51	7.26
	Min	17	24	14	2	16	6	9	0	0
	Max	17	24	29	24	16	24	25	25	29
	Mean diff. vs day0 (*)	8.00	-1.00	3.50	17.40	12.00	13.00	9.00	21.51	19.22

Mean (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 23

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

Factor: ANXIETY/SOMATIZATION

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	1.33	1.42	1.25	1.08	1.00	0.42		0.33	0.50
	Min	1.17	1.17	0.67	0.33	0.00	0.17		0.00	0.00
	Max	1.83	1.67	1.83	1.50	1.67	0.67		1.17	1.83
	Median diff. vs day0 (*)	0.00	-0.17	0.17	0.00	0.83	0.58		0.83	0.83
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1.00	1.00	1.33	0.83	0.67	0.58	1.17	0.33	0.50
	Min	1.00	1.00	1.00	0.17	0.67	0.17	0.50	0.00	0.00
	Max	1.00	1.00	1.67	1.33	0.67	1.17	1.50	1.33	1.67
	Median diff. vs day0 (*)	0.33	-0.17	-0.08	0.67	0.50	0.33	0.00	1.00	0.83

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 23

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

Factor: COGNITIVE DISTURBANCE

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	1.33	1.08	0.58	0.42	0.17	0.33		0.17	0.17
	Min	1.17	0.83	0.50	0.17	0.00	0.17		0.00	0.00
	Max	1.67	1.33	0.67	0.83	1.17	0.50		1.17	1.67
	Median diff. vs day0 (*)	0.00	0.08	0.33	0.00	0.33	0.67		0.67	0.50
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	0.17	0.83	0.58	0.50	0.83	0.17	0.33	0.17	0.17
	Min	0.17	0.83	0.17	0.00	0.83	0.00	0.00	0.00	0.00
	Max	0.17	0.83	1.00	0.67	0.83	0.67	1.00	1.50	1.50
	Median diff. vs day0 (*)	0.17	0.00	0.50	0.50	0.17	0.33	0.50	0.67	0.67

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 23

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

Factor: RETARDATION

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2.00	2.13	2.00	2.00	1.25	1.25		0.50	0.50
	Min	2.00	2.00	1.75	0.50	0.00	0.25		0.00	0.00
	Max	2.00	2.25	2.25	2.25	2.00	2.25		2.00	2.25
	Median diff. vs day0 (*)	0.00	0.00	0.13	0.25	1.00	1.25		1.50	1.50
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1.50	1.75	1.25	1.50	1.25	1.00	1.25	0.50	0.50
	Min	1.50	1.75	1.00	0.00	1.25	0.50	0.50	0.00	0.00
	Max	1.50	1.75	1.50	2.00	1.25	2.50	2.50	2.25	2.50
	Median diff. vs day0 (*)	0.75	0.50	0.13	1.25	1.00	1.50	0.00	1.75	1.50

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 23

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

Factor: SLEEP DISTURBANCE

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	1.67	1.50	1.83	1.00	1.00	0.67		0.33	0.33
	Min	1.00	1.33	1.67	0.00	0.67	0.33		0.00	0.00
	Max	2.00	1.67	2.00	1.67	2.00	1.00		1.67	2.00
	Median diff. vs day0 (*)	0.33	-0.17	-0.67	0.00	0.00	1.00		1.00	0.67
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1.00	1.67	1.00	1.33	0.00	0.83	1.00	0.33	0.33
	Min	1.00	1.67	0.67	0.00	0.00	0.33	0.33	0.00	0.00
	Max	1.00	1.67	1.33	1.67	0.00	1.33	1.33	1.67	1.67
	Median diff. vs day0 (*)	0.33	-1.33	0.50	0.33	1.33	0.67	0.67	1.00	1.00

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	3	3	4	3	1	2		1	1
	Min	3	3	3	1	0	0		0	0
	Max	4	3	4	3	4	3		3	4
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	2	3	2	2	2	1	2	1	1
	Min	2	3	1	0	2	1	1	0	0
	Max	2	3	2	3	2	3	4	3	4

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: GUILT

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2	2	2	1	0	1		0	0
	Min	2	1	1	0	0	0		0	0
	Max	3	2	2	2	1	1		2	3
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	0	2	1	0	2	0	1	0	0
	Min	0	2	0	0	2	0	0	0	0
	Max	0	2	2	1	2	2	2	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: SUICIDE

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2	2	0	0	0	1		0	0
	Min	2	1	0	0	0	0		0	0
	Max	3	2	0	1	3	2		1	3
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1	2	0	0	1	0	1	0	0
	Min	1	2	0	0	1	0	0	0	0
	Max	1	2	0	2	1	1	1	1	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: INSOMNIA EARLY

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2	2	2	2	1	1		0	0
	Min	0	2	2	0	1	1		0	0
	Max	2	2	2	2	2	1		2	2
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	0	1	1	2	0	1	2	0	0
	Min	0	1	1	0	0	0	0	0	0
	Max	0	1	1	2	0	2	2	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: INSOMNIA MIDDLE

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2	2	2	1	1	1		0	0
	Min	1	1	2	0	0	0		0	0
	Max	2	2	2	1	2	1		2	2
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1	2	1	1	0	1	1	0	0
	Min	1	2	0	0	0	0	1	0	0
	Max	1	2	2	2	0	2	1	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: INSOMNIA LATE

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2	1	2	1	2	1		0	0
	Min	1	1	1	0	0	0		0	0
	Max	2	1	2	2	2	1		2	2
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	2	2	1	1	0	1	0	0	0
	Min	2	2	1	0	0	0	0	0	0
	Max	2	2	1	2	0	1	1	1	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: WORK AND ACTIVITIES

Assigned treatment		Last assessment									
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2	3	3	3	1	2		1	1
	Min	2	2	2	0	0	1		0	0
	Max	3	3	4	3	3	3		4	4
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1	2	3	2	2	2	2	1	1
	Min	1	2	2	0	2	1	1	0	0
	Max	1	2	3	3	2	3	4	2	4

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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									
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	1	2	1	2	1	1		0	0
	Min	0	1	0	0	0	0		0	0
	Max	2	2	1	2	2	1		2	2
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1	1	0	0	1	1	0	0	0
	Min	1	1	0	0	1	0	0	0	0
	Max	1	1	0	1	1	2	0	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: AGITATION

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	1	3	1	1	1	0		0	0
	Min	1	2	1	0	0	0		0	0
	Max	3	3	1	2	3	0		2	3
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	0	1	2	1	2	1	0	0	0
	Min	0	1	1	0	2	0	0	0	0
	Max	0	1	2	1	2	1	1	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: ANXIETY PSYCHIC

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	3	3	2	1	1	1		1	1
	Min	2	2	1	1	0	1		0	0
	Max	3	3	3	2	4	1		3	4
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1	2	2	1	1	1	2	1	1
	Min	1	2	1	0	1	0	2	0	0
	Max	1	2	2	2	1	2	2	3	3

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2	3	1	1	0	1		0	1
	Min	1	2	0	1	0	0		0	0
	Max	2	3	2	2	4	2		2	4
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1	1	2	1	1	1	1	1	1
	Min	1	1	2	1	1	0	1	0	0
	Max	1	1	2	2	1	1	3	2	3

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2	1	1	1	0	0		0	0
	Min	2	1	0	0	0	0		0	0
	Max	2	1	1	1	1	0		1	2
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	2	1	1	1	0	0	1	0	0
	Min	2	1	1	0	0	0	0	0	0
	Max	2	1	1	1	0	1	2	1	2

Median (*): mean of differences vs day0

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: SOMATIC GENERAL

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2	1	2	1	0	1		0	1
	Min	1	1	1	0	0	0		0	0
	Max	2	1	2	2	2	1		2	2
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	2	2	1	1	1	1	2	0	1
	Min	2	2	1	0	1	0	0	0	0
	Max	2	2	1	2	1	2	2	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: GENITAL SYMPTOMS

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	1	2	1	1	0	1		0	0
	Min	1	1	0	0	0	0		0	0
	Max	2	2	2	2	2	2		2	2
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	2	1	1	1	0	1	1	0	1
	Min	2	1	1	0	0	0	0	0	0
	Max	2	1	1	2	0	2	2	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: HYPOCHONDRIASIS

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	0	2	3	2	0	0		0	0
	Min	0	0	2	0	0	0		0	0
	Max	1	3	3	3	3	0		2	3
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	0	0	2	1	1	1	0	0	0
	Min	0	0	1	0	1	0	0	0	0
	Max	0	0	3	2	1	2	1	3	3

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: LOSS OF WEIGHT

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	1	2	0	0	0	0		0	0
	Min	0	1	0	0	0	0		0	0
	Max	2	2	0	0	2	0		2	2
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	0	0	1	0	1	0	0	0	0
	Min	0	0	0	0	1	0	0	0	0
	Max	0	0	2	2	1	0	0	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: INSIGHT

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	0	0	0	0	0	0		0	0
	Min	0	0	0	0	0	0		0	0
	Max	1	0	0	1	0	0		0	1
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	0	0	1	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0
	Max	0	0	1	1	0	0	0	0	1

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: DIURNAL VARIATION

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	0	1	1	1	0	1		0	0
	Min	0	0	1	1	0	0		0	0
	Max	2	1	1	2	1	1		2	2
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1	1	1	1	1	0	0	0	0
	Min	1	1	1	0	1	0	0	0	0
	Max	1	1	1	2	1	0	1	1	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: DEPERSONALIZATION

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	1	1	0	1	0	1		0	0
	Min	1	0	0	0	0	0		0	0
	Max	3	1	0	1	0	1		1	3
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	0	0	1	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0
	Max	0	0	1	0	0	0	0	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: PARANOID

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	0	1	0	0	0	0		0	0
	Min	0	0	0	0	0	0		0	0
	Max	1	1	0	0	0	0		1	1
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	0	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0
	Max	0	0	0	0	0	0	0	2	2

Median (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

TABLE No.: 24

HAMILTON DEPRESSION RATING SCALE:

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

Item: OBSESSIONAL/COMPULSIVE

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	0	0	1	0	0	0		0	0
	Min	0	0	0	0	0	0		0	0
	Max	0	0	2	1	1	0		2	2
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	0	0	1	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0
	Max	0	0	1	2	0	1	2	2	2

Median (*): mean of differences vs day0

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
Fluoxetine	Patients No.	87	84	81	80	42	69	34	69
	Responders No.	6	21	32	42	27	49	27	59
	Responders %	6.9	25.0	39.5	52.5	64.3	71.0	79.4	85.5
	95% L.L.	2.6	16.2	28.8	41.0	48.0	58.8	62.1	75.0
	95% U.L.	14.4	35.6	51.0	63.8	78.5	81.3	91.3	92.8
	Remissions No.	2	14	20	32	20	38	21	54
	Remissions %	2.3	16.7	24.7	40.0	47.6	55.1	61.8	78.3
	95% L.L.	0.3	9.4	15.8	29.2	32.0	42.6	43.6	66.7
	95% U.L.	8.1	26.4	35.5	51.6	63.6	67.1	77.8	87.3
Reboxetine	Patients No.	76	75	73	72	34	66	31	59
	Responders No.	5	21	31	39	20	49	23	53
	Responders %	6.6	28.0	42.5	54.2	58.8	74.2	74.2	89.8
	95% L.L.	2.2	18.2	31.0	42.0	40.7	62.0	55.4	79.2
	95% U.L.	14.7	39.6	54.6	66.0	75.4	84.2	88.1	96.2
	Remissions No.	0	6	15	28	14	40	20	46
	Remissions %	0.0	8.0	20.5	38.9	41.2	60.6	64.5	78.0
	95% L.L.	0.0	3.0	12.0	27.6	24.6	47.8	45.4	65.3
	95% U.L.	3.9	16.6	31.6	51.1	59.3	72.4	80.8	87.7

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 26

EFFICACY: CLASSIFICATION OF PATIENTS ACCORDING TO PROTOCOL CRITERIA ON TOTAL SCORE OF HAMILTON DEPRESSION RATING SCALE AT LAST ASSESSMENT VERSUS DAY 0 BY ASSIGNED TREATMENT

	Assigned treatment	
	Fluoxetine	Reboxetine
Patients No.	87	76
Responders No.	64	59
Responders %	73.6	77.6
95% L.L.	63.0	66.6
95% U.L.	82.4	86.4
Remissions No.	58	51
Remissions %	66.7	67.1
95% L.L.	55.7	55.4
95% U.L.	76.4	77.5

BETWEEN TREATMENT DIFFERENCE AND 95% CONFIDENCE LIMITS

RESPONDERS (%) : 4.1 (-9.1 ; 17.2)
REMISSIONS (%) : 0.4 (-14.0 ; 14.9)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 27

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

Assigned treatment/Severity of illness		Visit																	
		Day 0		Day 7		Day 14		Day 21		Day 28		Day 35		Day 42		Day 49		Day 56	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Fluoxetine	NORMAL							2	2.5	8	10.0	8	18.6	10	14.5	9	26.5	18	26.1
	BORDERLINE MENTALLY ILL			1	1.1	5	6.0	12	14.8	16	20.0	7	16.3	23	33.3	11	32.4	27	39.1
	MILDLY ILL	1	1.1	12	13.8	23	27.4	22	27.2	23	28.7	15	34.9	12	17.4	7	20.6	13	18.8
	MODERATELY ILL	20	23.0	27	31.0	25	29.8	18	22.2	15	18.8	7	16.3	19	27.5	5	14.7	8	11.6
	MARKEDLY ILL	39	44.8	35	40.2	25	29.8	22	27.2	16	20.0	5	11.6	5	7.2	2	5.9	3	4.3
	SEVERELY ILL	27	31.0	11	12.6	6	7.1	5	6.2	2	2.5								
	EXTREMELY ILL			1	1.1							1	2.3						
	Total	87	100.0	87	100.0	84	100.0	81	100.0	80	100.0	43	100.0	69	100.0	34	100.0	69	100.0
Reboxetine	NORMAL							1	1.4	4	5.6	2	5.7	7	10.6	2	6.3	13	22.0
	BORDERLINE MENTALLY ILL							6	8.2	15	20.8	9	25.7	24	36.4	15	46.9	28	47.5
	MILDLY ILL			5	6.5	17	22.7	23	31.5	19	26.4	12	34.3	18	27.3	10	31.3	15	25.4
	MODERATELY ILL	22	28.6	32	41.6	34	45.3	27	37.0	22	30.6	6	17.1	13	19.7	1	3.1	1	1.7
	MARKEDLY ILL	36	46.8	30	39.0	19	25.3	15	20.5	12	16.7	6	17.1	4	6.1	4	12.5	2	3.4
	SEVERELY ILL	17	22.1	9	11.7	5	6.7	1	1.4										
	EXTREMELY ILL	2	2.6	1	1.3														
	Total	77	100.0	77	100.0	75	100.0	73	100.0	72	100.0	35	100.0	66	100.0	32	100.0	59	100.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 28

CLINICAL GLOBAL IMPRESSION: SEVERITY OF ILLNESS AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Assigned treatment/Severity of illness		Total		Last Visit															
				Day 7		Day 14		Day 21		Day 28		Day 35		Day 42		Day 49		Day 56	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Fluoxetine	NORMAL	20	23.0									2	33.3					18	26.1
	BORDERLINE MENTALLY ILL	29	33.3							1	33.3			1	50.0			27	39.1
	MILDLY ILL	14	16.1									1	16.7					13	18.8
	MODERATELY ILL	10	11.5					1	50.0					1	50.0			8	11.6
	MARKEDLY ILL	12	13.8	2	66.7	2	100.0	1	50.0	2	66.7	2	33.3					3	4.3
	EXTREMELY ILL	2	2.3	1	33.3							1	16.7						
	Total	87	100.0	3	100.0	2	100.0	2	100.0	3	100.0	6	100.0	2	100.0			69	100.0
Reboxetine	NORMAL	14	18.2							1	25.0							13	22.0
	BORDERLINE MENTALLY ILL	31	40.3											2	66.7	1	25.0	28	47.5
	MILDLY ILL	18	23.4					1	50.0	1	25.0	1	50.0					15	25.4
	MODERATELY ILL	8	10.4	2	100.0	1	100.0	1	50.0	2	50.0			1	33.3			1	1.7
	MARKEDLY ILL	6	7.8									1	50.0			3	75.0	2	3.4
	Total	77	100.0	2	100.0	1	100.0	2	100.0	4	100.0	2	100.0	3	100.0	4	100.0	59	100.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 29

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

Assigned treatment/Shift severity		Total		Last visit															
				Day 7		Day 14		Day 21		Day 28		Day 35		Day 42		Day 49		Day 56	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Fluoxetine	DECREASED	78	89.7	2	66.7			1	50.0	1	33.3	5	83.3	2	100.0			67	97.1
	NO CHANGE	6	6.9			2	100.0			2	66.7							2	2.9
	INCREASED	3	3.4	1	33.3			1	50.0			1	16.7						
	Total	87	100.0	3	100.0	2	100.0	2	100.0	3	100.0	6	100.0	2	100.0			69	100.0
Reboxetine	DECREASED	67	87.0					1	50.0	3	75.0	1	50.0	2	66.7	2	50.0	58	98.3
	NO CHANGE	9	11.7	2	100.0	1	100.0	1	50.0	1	25.0	1	50.0	1	33.3	2	50.0		
	INCREASED	1	1.3															1	1.7
	Total	77	100.0	2	100.0	1	100.0	2	100.0	4	100.0	2	100.0	3	100.0	4	100.0	59	100.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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		Day 49		Day 56					
		No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%				
Fluoxetine	VERY MUCH IMPROVED	1	1.1	2	2.4	8	9.9	16	20.0	12	27.9	22	31.9	14	41.2	35	50.7				
	MUCH IMPROVED	12	13.8	24	28.6	29	35.8	35	43.8	16	37.2	34	49.3	14	41.2	27	39.1				
	MINIMALLY IMPROVED	26	29.9	33	39.3	31	38.3	23	28.7	12	27.9	12	17.4	5	14.7	5	7.2				
	NO CHANGE	43	49.4	19	22.6	9	11.1	5	6.3			1	1.4			2	2.9				
	MINIMALLY WORSE	4	4.6	6	7.1	4	4.9			1	2.3			1	2.9						
	MUCH WORSE	1	1.1					1	1.2	1	2.3										
	VERY MUCH WORSE									1	2.3										
	Total	87	100.0	84	100.0	81	100.0	80	100.0	43	100.0	69	100.0	34	100.0	69	100.0				
Reboxetine	VERY MUCH IMPROVED					4	5.5	14	19.4	7	20.0	22	33.3	6	18.8	30	50.8				
	MUCH IMPROVED	7	9.1	24	32.0	33	45.2	27	37.5	9	25.7	31	47.0	19	59.4	24	40.7				
	MINIMALLY IMPROVED	28	36.4	35	46.7	26	35.6	23	31.9	14	40.0	9	13.6	2	6.3	3	5.1				
	NO CHANGE	37	48.1	14	18.7	6	8.2	6	8.3	2	5.7	2	3.0	4	12.5						
	MINIMALLY WORSE	5	6.5	2	2.7	4	5.5	2	2.8	2	5.7	2	3.0	1	3.1	2	3.4				
	MUCH WORSE									1	2.9										
	Total	77	100.0	75	100.0	73	100.0	72	100.0	35	100.0	66	100.0	32	100.0	59	100.0				

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 31

CLINICAL GLOBAL IMPRESSION: GLOBAL IMPROVEMENT AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Assigned treatment/Global improvement		Total		Last visit															
				Day 7		Day 14		Day 21		Day 28		Day 35		Day 42		Day 49		Day 56	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Fluoxetine	VERY MUCH IMPROVED	37	42.5									2	33.3					35	50.7
	MUCH IMPROVED	29	33.3									1	16.7	1	50.0			27	39.1
	MINIMALLY IMPROVED	7	8.0					1	50.0	1	33.3							5	7.2
	NO CHANGE	7	8.0	1	33.3	1	50.0			2	66.7			1	50.0			2	2.9
	MINIMALLY WORSE	4	4.6	1	33.3	1	50.0	1	50.0			1	16.7						
	MUCH WORSE	2	2.3	1	33.3							1	16.7						
	VERY MUCH WORSE	1	1.1									1	16.7						
	Total	87	100.0	3	100.0	2	100.0	2	100.0	3	100.0	6	100.0	2	100.0			69	100.0
Reboxetine	VERY MUCH IMPROVED	32	41.6							1	25.0			1	33.3			30	50.8
	MUCH IMPROVED	28	36.4					1	50.0	1	25.0			1	33.3	1	25.0	24	40.7
	MINIMALLY IMPROVED	7	9.1	1	50.0							2	100.0			1	25.0	3	5.1
	NO CHANGE	5	6.5	1	50.0	1	100.0			1	25.0					2	50.0		
	MINIMALLY WORSE	5	6.5					1	50.0	1	25.0			1	33.3			2	3.4
	Total	77	100.0	2	100.0	1	100.0	2	100.0	4	100.0	2	100.0	3	100.0	4	100.0	59	100.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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		Day 49		Day 56	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Fluoxetine	< 1	20	23.0	15	17.9	9	11.1	3	3.8	2	4.7	2	2.9	1	2.9	2	2.9
	1	34	39.1	22	26.2	17	21.0	10	12.5	6	14.0	2	2.9	1	2.9	1	1.4
	1.33 - 1.5	7	8.0	8	9.5	8	9.9	14	17.5	5	11.6	11	15.9	3	8.8	5	7.2
	2	17	19.5	22	26.2	21	25.9	24	30.0	14	32.6	22	31.9	12	35.3	16	23.2
	3	7	8.0	15	17.9	21	25.9	18	22.5	10	23.3	19	27.5	8	23.5	15	21.7
	4	2	2.3	2	2.4	5	6.2	11	13.8	6	14.0	13	18.8	9	26.5	30	43.5
	Total	87	100	84	100	81	100	80	100	43	100	69	100	34	100	69	100
Reboxetine	< 1	29	37.7	9	12.0	7	9.6	7	9.7	5	14.3	4	6.1	4	12.5	1	1.7
	1	24	31.2	25	33.3	19	26.0	13	18.1	7	20.0	6	9.1	3	9.4	3	5.1
	1.33 - 1.5	5	6.5	16	21.3	14	19.2	10	13.9	3	8.6	13	19.7	7	21.9	10	16.9
	2	16	20.8	14	18.7	13	17.8	14	19.4	7	20.0	11	16.7	3	9.4	11	18.6
	3	3	3.9	11	14.7	18	24.7	14	19.4	8	22.9	11	16.7	5	15.6	5	8.5
	4					2	2.7	14	19.4	5	14.3	21	31.8	10	31.3	29	49.2
	Total	77	100	75	100	73	100	72	100	35	100	66	100	32	100	59	100

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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		Day 49		Day 56	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Fluoxetine	< 1	10	11.49	2	66.67	1	50.00	1	50.00	1	33.33	2	33.33	1	50.00			2	2.90
	1	7	8.05	1	33.33	1	50.00	1	50.00	1	33.33	2	33.33					1	1.45
	1.33 - 1.5	7	8.05							1	33.33	1	16.67					5	7.25
	2	17	19.54											1	50.00			16	23.19
	3	15	17.24															15	21.74
	4	31	35.63									1	16.67					30	43.48
	Total	87	100.0	3	100.0	2	100.0	2	100.0	3	100.0	6	100.0	2	100.0			69	100.0
Reboxetine	< 1	8	10.39	2	100.0					2	50.00			1	33.33	2	50.00	1	1.69
	1	8	10.39			1	100.0	1	50.00			1	50.00	1	33.33	1	25.00	3	5.08
	1.33 - 1.5	12	15.58					1	50.00							1	25.00	10	16.95
	2	14	18.18							1	25.00	1	50.00	1	33.33			11	18.64
	3	5	6.49															5	8.47
	4	30	38.96							1	25.00							29	49.15
	Total	77	100.0	2	100.0	1	100.0	2	100.0	4	100.0	2	100.0	3	100.0	4	100.0	59	100.0

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 34

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

Assigned treatment		Visit								
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	84	81	80	42	69	34	69
	Mean	16.2	13.6	11.3	9.4	7.7	6.6	5.9	5.2	4.3
	Median	16.0	13.5	12.0	9.0	7.5	6.0	6.0	3.5	3.0
	STD	2.6	3.7	4.4	4.5	4.3	5.0	3.4	4.1	3.3
	Min	10.0	4.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	22.0	23.0	22.0	20.0	20.0	20.0	16.0	16.0	16.0
	Mean diff. vs day0 (*)		2.63	4.84	6.78	8.50	9.85	10.18	10.96	11.68
Reboxetine	No	76	76	75	73	72	34	66	31	59
	Mean	17.1	14.6	11.7	9.3	8.2	7.8	6.1	6.0	4.1
	Median	17.0	14.3	11.0	9.0	7.0	7.3	6.0	5.0	3.0
	STD	3.3	4.2	3.8	3.8	4.5	4.4	3.9	4.5	3.3
	Min	8.5	3.0	3.0	2.0	1.0	0.0	0.0	0.0	0.0
	Max	27.0	26.0	19.0	21.0	20.0	16.0	16.5	19.0	15.0
	Mean diff. vs day0 (*)		2.47	5.40	7.74	9.01	9.01	10.95	10.82	13.10

Mean (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 35

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

Item: REPORTED SADNESS

Assigned treatment		Visit												
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	84	81	80	42	69	34	69
	Median	2.0	2.0	1.5	1.0	1.0	1.0	1.0	0.0	0.5
	Min	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	2.0
Reboxetine	No	76	76	75	73	72	34	66	31	59
	Median	2.0	2.0	1.5	1.0	1.0	1.0	1.0	0.0	0.0
	Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	3.0	3.0	3.0	3.0	2.0	2.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 35

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

Item: INNER TENSION

Assigned treatment		Visit								
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	84	81	80	42	69	34	69
	Median	2.0	2.0	1.5	1.0	1.0	1.0	1.0	1.0	1.0
	Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	2.5	2.5	2.0	2.0	2.5	2.0	2.0
Reboxetine	No	76	76	75	73	72	34	66	31	59
	Median	2.0	2.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
	Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	3.0	3.0	3.0	2.0	2.5	2.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 35

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

Item: APPARENT SADNESS

Assigned treatment		Visit								
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	84	81	80	42	69	34	69
	Median	2.0	1.5	1.0	1.0	1.0	1.0	1.0	0.0	0.0
	Min	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	3.0	3.0	3.0	3.0	2.0	2.0	2.0
Reboxetine	No	76	76	75	73	72	34	66	31	59
	Median	2.0	1.5	1.0	1.0	1.0	1.0	1.0	0.0	0.0
	Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	3.0	2.0	2.0	2.0	2.0	2.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

TABLE No.: 35

MONTGOMERY ASBERG DEPRESSION RATING SCALE

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

Item: SUICIDAL THOUGHTS

Assigned treatment		Visit										
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	84	81	80	42	69	34	69
	Median	1.0	1.0	1.0	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	0.0	0.0	0.0
	Max	3.0	2.5	3.0	3.0	2.0	2.0	1.5	1.0	1.5
Reboxetine	No	76	76	75	73	72	34	66	31	59
	Median	1.0	1.0	1.0	0.5	0.0	0.0	0.0	0.0	0.0
	Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	2.5	2.5	2.0	2.0	1.5	2.5	2.0	1.5

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 35

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

Item: INERTIA

Assigned treatment		Visit										
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	84	81	80	42	69	34	69
	Median	2.0	2.0	1.0	1.0	1.0	1.0	1.0	0.8	1.0
	Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	3.0	3.0	3.0	2.0	2.0	2.0	2.0
Reboxetine	No	76	76	75	73	72	34	66	31	59
	Median	2.0	1.5	1.0	1.0	1.0	1.0	1.0	1.0	0.0
	Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	3.0	3.0	2.0	2.0	2.0	2.0	1.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 35

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

Item: INABILITY TO FEEL

Assigned treatment		Visit										
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	84	81	80	42	69	34	69
	Median	1.5	1.0	1.0	1.0	1.0	1.0	1.0	0.0	0.0
	Min	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Reboxetine	No	76	76	75	73	72	34	66	31	59
	Median	2.0	1.5	1.0	1.0	1.0	1.0	1.0	0.0	0.0
	Min	1.0	0.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 2012A/016
TABLE No.: 35

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

Item: PESSIMISTIC THOUGHTS

Assigned treatment		Visit												
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	84	81	80	42	68	34	69
	Median	2.0	1.0	1.0	1.0	1.0	1.0	1.0	0.5	0.0
	Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	2.0	2.0	2.0	2.5	2.0	2.0	2.0	2.0	1.5
Reboxetine	No	76	76	75	73	72	34	66	31	59
	Median	2.0	1.5	1.0	1.0	1.0	1.0	1.0	1.0	0.0
	Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 35

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

Item: CONCENTRATIONS DIFFICULTIES

Assigned treatment		Visit								
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	84	81	80	42	69	34	69
	Median	2.0	1.5	1.0	1.0	1.0	1.0	1.0	1.0	0.0
	Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	3.0	3.0	3.0	2.0	2.0	2.0	2.0
Reboxetine	No	76	76	75	73	72	34	66	31	59
	Median	2.0	1.3	1.0	1.0	1.0	1.0	1.0	1.0	0.0
	Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 35

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

Item: REDUCED SLEEP

Assigned treatment		Visit									
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	84	81	80	42	69	34	69
	Median	2.0	1.5	1.0	1.0	1.0	1.0	1.0	1.0	0.5
	Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	3.0	3.0	3.0	3.0	2.0	2.0	2.0
Reboxetine	No	76	76	75	73	72	34	66	31	59
	Median	2.0	2.0	1.0	1.0	1.0	1.0	1.0	1.0	0.0
	Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Max	3.0	3.0	3.0	3.0	3.0	2.0	2.0	2.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 35

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

Item: REDUCED APPETITE

Assigned treatment		Visit								
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	84	81	80	42	69	34	69
	Median	1.0	0.5	0.0	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	0.0	0.0	0.0
	Max	2.5	3.0	3.0	3.0	1.0	1.0	1.0	2.0	1.0
Reboxetine	No	76	76	75	73	72	34	66	31	59
	Median	1.0	1.0	0.5	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	0.0	0.0	0.0
	Max	3.0	3.0	3.0	2.0	2.0	2.0	2.0	2.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 36

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

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Mean	18.7	14.8	15.3	13.5	9.9	10.5		4.3	6.2
	Median	17.0	14.8	15.3	15.0	9.0	10.5		3.0	4.0
	STD	3.3	1.1	3.2	6.8	8.9	7.8		3.3	5.5
	Min	16.5	14.0	13.0	4.0	1.0	5.0		0.0	0.0
	Max	22.5	15.5	17.5	20.0	20.0	16.0		16.0	22.5
	Mean diff. vs day0 (*)	0.17	-1.25	1.00	3.50	7.30	8.75		11.68	10.05
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Mean	13.0	14.0	11.5	11.3	13.0	9.1	13.3	4.1	5.7
	Median	13.0	14.0	11.5	13.0	13.0	7.0	13.0	3.0	4.0
	STD			3.5	7.8		4.9	5.5	3.3	4.9
	Min	13.0	14.0	9.0	3.0	13.0	6.0	8.0	0.0	0.0
	Max	13.0	14.0	14.0	20.0	13.0	16.5	19.0	15.0	20.0
	Mean diff. vs day0 (*)	4.00	2.00	1.00	7.80	4.00	7.00	3.00	13.10	11.33

Mean (*): mean of differences vs day0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 37

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

Item: REPORTED SADNESS

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2.0	2.0	2.0	2.0	1.0	1.0		0.5	1.0
	Min	2.0	2.0	2.0	1.0	0.0	0.0		0.0	0.0
	Max	3.0	2.0	2.0	3.0	2.0	2.0		2.0	3.0
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1.5	2.0	0.5	1.0	2.0	0.5	2.0	0.0	0.0
	Min	1.5	2.0	0.0	0.0	2.0	0.0	1.0	0.0	0.0
	Max	1.5	2.0	1.0	2.0	2.0	2.0	2.0	2.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 37

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

Item: INNER TENSION

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2.0	2.0	2.0	2.0	1.0	1.8		1.0	1.0
	Min	2.0	2.0	2.0	1.0	0.0	1.0		0.0	0.0
	Max	2.5	2.0	2.0	2.0	2.0	2.5		2.0	2.5
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1.5	2.0	2.0	2.0	2.0	1.0	1.0	1.0	1.0
	Min	1.5	2.0	2.0	0.0	2.0	0.0	1.0	0.0	0.0
	Max	1.5	2.0	2.0	2.5	2.0	2.5	2.0	2.0	2.5

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 37

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

Item: APPARENT SADNESS

Assigned treatment		Last assessment										
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2.0	1.3	1.5	1.5	1.0	0.8		0.0	0.0
	Min	1.5	1.0	1.0	0.0	0.0	0.0		0.0	0.0
	Max	3.0	1.5	2.0	3.0	3.0	1.5		2.0	3.0
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1.5	1.5	0.5	1.0	2.0	1.0	2.0	0.0	0.5
	Min	1.5	1.5	0.0	0.0	2.0	0.0	1.5	0.0	0.0
	Max	1.5	1.5	1.0	1.5	2.0	1.5	2.0	2.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 37

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

Item: SUICIDAL THOUGHTS

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2.0	0.8	1.5	0.0	0.5	0.8		0.0	0.0
	Min	1.5	0.0	0.0	0.0	0.0	0.0		0.0	0.0
	Max	2.5	1.5	3.0	1.0	2.0	1.5		1.5	3.0
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1.5	2.5	0.0	1.0	1.0	0.0	1.0	0.0	0.0
	Min	1.5	2.5	0.0	0.0	1.0	0.0	1.0	0.0	0.0
	Max	1.5	2.5	0.0	2.0	1.0	2.0	2.0	1.5	2.5

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20424/016
TABLE No.: 37

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

Item: INERTIA

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2.0	1.8	1.3	1.5	1.0	1.0		1.0	1.0
	Min	2.0	1.5	1.0	0.0	0.0	1.0		0.0	0.0
	Max	2.0	2.0	1.5	3.0	2.0	1.0		2.0	3.0
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1.5	1.0	1.5	1.0	1.0	1.0	1.0	0.0	0.5
	Min	1.5	1.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0
	Max	1.5	1.0	2.0	2.0	1.0	1.0	2.0	1.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 37

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

Item: INABILITY TO FEEL

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2.0	1.8	1.3	2.0	1.0	0.8		0.0	0.0
	Min	1.5	1.5	1.0	0.0	0.0	0.0		0.0	0.0
	Max	2.0	2.0	1.5	2.0	3.0	1.5		3.0	3.0
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1.0	1.5	1.5	1.0	1.0	1.3	1.0	0.0	0.5
	Min	1.0	1.5	1.0	0.5	1.0	0.0	1.0	0.0	0.0
	Max	1.0	1.5	2.0	2.0	1.0	2.0	2.0	2.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 37

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

Item: PESSIMISTIC THOUGHTS

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2.0	1.0	2.3	1.0	0.0	1.5		0.0	0.5
	Min	1.5	1.0	2.0	0.0	0.0	1.0		0.0	0.0
	Max	2.0	1.0	2.5	2.0	2.0	2.0		1.5	2.5
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1.5	1.0	1.5	1.0	2.0	1.0	2.0	0.0	0.5
	Min	1.5	1.0	1.0	0.0	2.0	0.0	1.0	0.0	0.0
	Max	1.5	1.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 37

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

Item: CONCENTRATIONS DIFFICULTIES

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	1.5	1.3	1.5	1.5	1.0	1.5		0.0	0.5
	Min	0.0	1.0	1.0	1.0	0.0	1.0		0.0	0.0
	Max	2.0	1.5	2.0	3.0	2.0	2.0		2.0	3.0
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1.0	0.5	2.0	2.0	1.0	1.5	1.0	0.0	0.5
	Min	1.0	0.5	2.0	0.0	1.0	1.0	0.0	0.0	0.0
	Max	1.0	0.5	2.0	2.0	1.0	2.0	2.0	2.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 37

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

Item: REDUCED SLEEP

Assigned treatment		Last assessment								
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	2.0	1.8	1.5	2.0	2.0	1.0		0.5	1.0
	Min	1.5	1.5	1.0	0.0	0.0	1.0		0.0	0.0
	Max	2.0	2.0	2.0	3.0	3.0	1.0		2.0	3.0
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1.0	1.0	1.0	1.0	0.0	1.5	1.0	0.0	0.5
	Min	1.0	1.0	1.0	0.0	0.0	0.0	0.5	0.0	0.0
	Max	1.0	1.0	1.0	3.0	0.0	2.0	2.0	2.0	3.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 37

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

Item: REDUCED APPETITE

Assigned treatment		Last assessment									
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	5	2		69	87
	Median	1.5	1.3	0.5	0.5	0.0	0.5		0.0	0.0
	Min	0.0	1.0	0.0	0.0	0.0	0.0		0.0	0.0
	Max	2.5	1.5	1.0	1.0	1.0	1.0		1.0	2.5
Reboxetine	No	1	1	2	5	1	4	3	59	76
	Median	1.0	1.0	1.0	1.0	1.0	0.0	1.0	0.0	0.0
	Min	1.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0
	Max	1.0	1.0	1.0	2.0	1.0	1.0	2.0	2.0	2.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 38

ADVERSE EVENTS: FREQUENCY (95% C.I.) OF PATIENTS WHO COMPLAINED OF AT LEAST ONE ADVERSE EVENT DURING THERAPY BY SEX AND ASSIGNED TREATMENT

	Assigned treatment					
	Fluoxetine			Reboxetine		
	Female	Male	Total	Female	Male	Total
Pt exposed	64	25	89	57	22	79
Pt with adverse events	48	12	60	37	16	53
% on exposed	75.00	48.00	67.41	64.91	72.72	67.08
95% L.L.	62.60	27.80	56.66	51.13	49.78	55.60
95% U.L.	84.98	68.69	76.98	77.09	89.27	77.25
No. of adverse events	156	24	180	166	55	221
Ratio A.E. on Pt with A.E.	3.25	2.00	3.00	4.48	3.43	4.16

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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							
	Fluoxetine				Reboxetine			
	Total	18 - 30	31 - 45	> 45	Total	18 - 30	31 - 45	> 45
Pt exposed	89	13	37	39	79	14	29	36
Pt with adverse events	60	9	26	25	53	9	21	23
% on exposed	67.41	69.23	70.27	64.10	67.08	64.28	72.41	63.88
95% L.L.	56.66	38.57	53.02	47.18	55.60	35.14	52.76	46.22
95% U.L.	76.98	90.91	84.13	78.80	77.25	87.24	87.27	79.18
No. of adverse events	180	37	73	70	221	37	95	89
Ratio A.E. on Pt with A.E.	3.00	4.11	2.80	2.80	4.16	4.11	4.52	3.86

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 40

ADVERSE EVENTS: FREQUENCY (95% C.I.) OF PATIENTS WHO COMPLAINED OF AT LEAST ONE ADVERSE EVENT DURING THERAPY
BY DSM III CLASSIFICATION AND ASSIGNED TREATMENT

	Assigned treatment							
	Fluoxetine			Reboxetine				
	Total	296.2	296.3	Total	295.7	296.2	296.3	
Pt exposed	89	42	47	79	1	31	47	
Pt with adverse events	60	28	32	53	0	18	35	
% on exposed	67.41	66.66	68.08	67.08	0.00	58.06	74.46	
95% L.L.	56.66	50.45	52.88	55.60	0.00	39.08	59.65	
95% U.L.	76.98	80.43	80.91	77.25	95.00	75.45	86.05	
No. of adverse events	180	84	96	221	0	69	152	
Ratio A.E. on Pt with A.E.	3.00	3.00	3.00	4.16		3.83	4.34	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)
Pt exposed	Fluoxetine	64	100.0				25	100.0				89	100.0			
	Reboxetine	57	100.0				22	100.0				79	100.0			
Pt with a.e.	Fluoxetine	48	75.0	100.0	156	3.25	12	48.0	100.0	24	2.00	60	67.4	100.0	180	3.00
	Reboxetine	37	64.9	100.0	166	4.48	16	72.7	100.0	55	3.43	53	67.1	100.0	221	4.16
HEADACHE	Fluoxetine	19	29.7	39.5	27	1.42	1	4.0	8.3	1	1.00	20	22.5	33.3	28	1.40
	Reboxetine	12	21.1	32.4	16	1.33	5	22.7	31.2	5	1.00	17	21.5	32.0	21	1.23
MOUTH DRY	Fluoxetine	6	9.4	12.5	6	1.00	2	8.0	16.6	2	1.00	8	9.0	13.3	8	1.00
	Reboxetine	20	35.1	54.0	20	1.00	7	31.8	43.7	7	1.00	27	34.2	50.9	27	1.00
CONSTIPATION	Fluoxetine	6	9.4	12.5	7	1.16						6	6.7	10.0	7	1.16
	Reboxetine	12	21.1	32.4	13	1.08	5	22.7	31.2	5	1.00	17	21.5	32.0	18	1.05
DIZZINESS	Fluoxetine	6	9.4	12.5	8	1.33						6	6.7	10.0	8	1.33
	Reboxetine	9	15.8	24.3	14	1.55	4	18.2	25.0	4	1.00	13	16.5	24.5	18	1.38
INSOMNIA	Fluoxetine	9	14.1	18.7	11	1.22						9	10.1	15.0	11	1.22
	Reboxetine	8	14.0	21.6	9	1.12	2	9.1	12.5	2	1.00	10	12.7	18.8	11	1.10
NAUSEA	Fluoxetine	8	12.5	16.6	14	1.75	1	4.0	8.3	1	1.00	9	10.1	15.0	15	1.66
	Reboxetine	7	12.3	18.9	9	1.28	2	9.1	12.5	2	1.00	9	11.4	16.9	11	1.22
SWEATING INCREASED	Fluoxetine	6	9.4	12.5	8	1.33	1	4.0	8.3	1	1.00	7	7.9	11.6	9	1.28
	Reboxetine	4	7.0	10.8	5	1.25	3	13.6	18.7	3	1.00	7	8.9	13.2	8	1.14
TREMOR	Fluoxetine	5	7.8	10.4	5	1.00						5	5.6	8.3	5	1.00
	Reboxetine	4	7.0	10.8	4	1.00						4	5.1	7.5	4	1.00
MICTURITION DISORDER	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	2	3.5	5.4	2	1.00	6	27.3	37.5	8	1.33	8	10.1	15.0	10	1.25

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)
AGITATION	Fluoxetine	5	7.8	10.4	5	1.00	2	8.0	16.6	2	1.00	7	7.9	11.6	7	1.00
	Reboxetine						1	4.5	6.2	1	1.00	1	1.3	1.8	1	1.00
FATIGUE	Fluoxetine	3	4.7	6.2	3	1.00	1	4.0	8.3	1	1.00	4	4.5	6.6	4	1.00
	Reboxetine	2	3.5	5.4	2	1.00	2	9.1	12.5	2	1.00	4	5.1	7.5	4	1.00
DIARRHOEA	Fluoxetine	4	6.3	8.3	4	1.00	2	8.0	16.6	2	1.00	6	6.7	10.0	6	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
VISION ABNORMAL	Fluoxetine	3	4.7	6.2	3	1.00	1	4.0	8.3	1	1.00	4	4.5	6.6	4	1.00
	Reboxetine	1	1.8	2.7	1	1.00	2	9.1	12.5	2	1.00	3	3.8	5.6	3	1.00
INFLUENZA-LIKE SYMPTOMS	Fluoxetine	4	6.3	8.3	5	1.25						4	4.5	6.6	5	1.25
	Reboxetine	3	5.3	8.1	3	1.00						3	3.8	5.6	3	1.00
PARAESTHESIA	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	5	8.8	13.5	5	1.00						5	6.3	9.4	5	1.00
PRURITUS	Fluoxetine	1	1.6	2.0	1	1.00	1	4.0	8.3	1	1.00	2	2.2	3.3	2	1.00
	Reboxetine	2	3.5	5.4	2	1.00	1	4.5	6.2	1	1.00	3	3.8	5.6	3	1.00
VOMITING	Fluoxetine	2	3.1	4.1	2	1.00						2	2.2	3.3	2	1.00
	Reboxetine	3	5.3	8.1	3	1.00						3	3.8	5.6	3	1.00
SOMNOLENCE	Fluoxetine	2	3.1	4.1	2	1.00	1	4.0	8.3	1	1.00	3	3.4	5.0	3	1.00
	Reboxetine	2	3.5	5.4	2	1.00						2	2.5	3.7	2	1.00
DYSPEPSIA	Fluoxetine	4	6.3	8.3	5	1.25						4	4.5	6.6	5	1.25
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
UPPER RESP TRACT INFECTION	Fluoxetine	3	4.7	6.2	3	1.00						3	3.4	5.0	3	1.00
	Reboxetine	2	3.5	5.4	2	1.00						2	2.5	3.7	2	1.00

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)
NERVOUSNESS	Fluoxetine	3	4.7	6.2	3	1.00						3	3.4	5.0	3	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
RHINITIS	Fluoxetine	1	1.6	2.0	1	1.00	2	8.0	16.6	2	1.00	3	3.4	5.0	3	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
BACK PAIN	Reboxetine	3	5.3	8.1	3	1.00						3	3.8	5.6	3	1.00
APPETITE INCREASED	Fluoxetine	3	4.7	6.2	4	1.33						3	3.4	5.0	4	1.33
ABDOMINAL PAIN	Reboxetine	3	5.3	8.1	4	1.33						3	3.8	5.6	4	1.33
HYPERCHOLESTEROLA-EMIA	Fluoxetine	1	1.6	2.0	1	1.00	1	4.0	8.3	1	1.00	2	2.2	3.3	2	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
PHARYNGITIS	Fluoxetine	2	3.1	4.1	2	1.00						2	2.2	3.3	2	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
URINARY TRACT INFECTION	Fluoxetine	2	3.1	4.1	2	1.00						2	2.2	3.3	2	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
FEVER	Fluoxetine	1	1.6	2.0	2	2.00						1	1.1	1.6	2	2.00
	Reboxetine	1	1.8	2.7	1	1.00	1	4.5	6.2	1	1.00	2	2.5	3.7	2	1.00
HOT FLUSHES	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	2	3.5	5.4	2	1.00						2	2.5	3.7	2	1.00
RASH	Reboxetine	2	3.5	5.4	2	1.00						2	2.5	3.7	2	1.00
MYALGIA	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
HYPERTONIA	Fluoxetine	1	1.6	2.0	1	1.00	1	4.0	8.3	1	1.00	2	2.2	3.3	2	1.00
VERTIGO	Reboxetine	1	1.8	2.7	1	1.00	1	4.5	6.2	2	2.00	2	2.5	3.7	3	1.50

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)
URINARY RETENTION	Reboxetine	1	1.8	2.7	1	1.00	1	4.5	6.2	1	1.00	2	2.5	3.7	2	1.00
HYPERTENSION	Fluoxetine						1	4.0	8.3	1	1.00	1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
HYPOTENSION	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
PALPITATION	Reboxetine	2	3.5	5.4	2	1.00						2	2.5	3.7	2	1.00
CONJUNCTIVITIS	Fluoxetine						1	4.0	8.3	1	1.00	1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
TINNITUS	Reboxetine	1	1.8	2.7	1	1.00	1	4.5	6.2	1	1.00	2	2.5	3.7	2	1.00
ANXIETY	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
SUICIDE ATTEMPT	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
GASTRITIS	Fluoxetine						1	4.0	8.3	1	1.00	1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
HEPATIC ENZYMES INCREASED	Reboxetine	2	3.5	5.4	2	1.00						2	2.5	3.7	2	1.00
COUGHING	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
RESPIRATORY DISORDER	Reboxetine	2	3.5	5.4	2	1.00						2	2.5	3.7	2	1.00
CYSTITIS	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)
ALLERGIC REACTION	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
ABSCESS	Reboxetine						2	9.1	12.5	2	1.00	2	2.5	3.7	2	1.00
RASH MACULO-PAPULAR	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
TENDINITIS	Reboxetine						1	4.5	6.2	1	1.00	1	1.3	1.8	1	1.00
HYPERKINESIA	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
MIGRAINE	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
ANOREXIA	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
FLUSHING	Reboxetine	1	1.8	2.7	2	2.00						1	1.3	1.8	2	2.00
HYPOTENSION POSTURAL	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
TACHYCARDIA	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
XEROPHTHALMIA	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
TASTE PERVERSION	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
EUPHORIA	Reboxetine	1	1.8	2.7	2	2.00						1	1.3	1.8	2	2.00
LIBIDO DECREASED	Reboxetine						1	4.5	6.2	1	1.00	1	1.3	1.8	1	1.00
PARONIRIA	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
FLATULENCE	Fluoxetine						1	4.0	8.3	1	1.00	1	1.1	1.6	1	1.00
HEPATITIS INFECTIOUS	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
HYPERURICAEMIA	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
ALOPECIA	Reboxetine						1	4.5	6.2	1	1.00	1	1.3	1.8	1	1.00

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)
OEDEMA GENERALISED	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
CIRCULATORY FAILURE	Reboxetine						1	4.5	6.2	1	1.00	1	1.3	1.8	1	1.00
OEDEMA LEGS	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
EPISTAXIS	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
SINUSITIS	Fluoxetine						1	4.0	8.3	1	1.00	1	1.1	1.6	1	1.00
BRONCHITIS	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
ANAEMIA	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
RENAL PAIN	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
IMPOTENCE	Fluoxetine						1	4.0	8.3	1	1.00	1	1.1	1.6	1	1.00
SPERMATORRHOEA	Reboxetine						1	4.5	6.2	1	1.00	1	1.3	1.8	1	1.00
EJACULATION DISORDER	Reboxetine						1	4.5	6.2	1	1.00	1	1.3	1.8	1	1.00
BREAST FIBROADENOSIS	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
ASTHENIA	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
CHEST PAIN PRECORDIAL	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
MALAISE	Fluoxetine						1	4.0	8.3	1	1.00	1	1.1	1.6	1	1.00
HYPERPYREXIA	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
INFECTION VIRAL	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
OTITIS MEDIA	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: AUTONOMIC NERVOUS SYSTEM DISORDERS

Adverse events/Assigned treatment		Female					Male					Total				
		No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
MOUTH DRY	Fluoxetine	6	9.4	12.5	6	1.00	2	8.0	16.6	2	1.00	8	9.0	13.3	8	1.00
	Reboxetine	20	35.1	54.0	20	1.00	7	31.8	43.7	7	1.00	27	34.2	50.9	27	1.00
SWEATING INCREASED	Fluoxetine	6	9.4	12.5	8	1.33	1	4.0	8.3	1	1.00	7	7.9	11.6	9	1.28
	Reboxetine	4	7.0	10.8	5	1.25	3	13.6	18.7	3	1.00	7	8.9	13.2	8	1.14

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: BODY AS A WHOLE-GENERAL DISORDERS

Adverse events/Assigned treatment		Female					Male					Total				
		No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
ASTHENIA / FATIGUE	Fluoxetine	4	6.3	8.3	4	1.00	1	4.0	8.3	1	1.00	5	5.6	8.3	5	1.00
	Reboxetine	2	3.5	5.4	2	1.00	2	9.1	12.5	2	1.00	4	5.1	7.5	4	1.00
INFLUENZA-LIKE SYMPTOMS	Fluoxetine	4	6.3	8.3	5	1.25						4	4.5	6.6	5	1.25
	Reboxetine	3	5.3	8.1	3	1.00						3	3.8	5.6	3	1.00
FEVER	Fluoxetine	1	1.6	2.0	2	2.00						1	1.1	1.6	2	2.00
	Reboxetine	1	1.8	2.7	1	1.00	1	4.5	6.2	1	1.00	2	2.5	3.7	2	1.00
ALLERGIC REACTION	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
HYPERPYREXIA	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
MALAISE	Fluoxetine						1	4.0	8.3	1	1.00	1	1.1	1.6	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 events/Assigned treatment		Female					Male					Total				
		No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
HYPOTENSION AND RELATED SYMPTOMS	Fluoxetine	7	10.9	14.5	9	1.28						7	7.9	11.6	9	1.28
	Reboxetine	11	19.3	29.7	16	1.45	4	18.2	25.0	4	1.00	15	19.0	28.3	20	1.33
FLUSHING / HOT FLUSHES	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	3	5.3	8.1	4	1.33						3	3.8	5.6	4	1.33
AEDEMA	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
HYPERTENSION	Fluoxetine						1	4.0	8.3	1	1.00	1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
PALPITATION	Reboxetine	2	3.5	5.4	2	1.00						2	2.5	3.7	2	1.00
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
CIRCULATORY FAILURE	Reboxetine						1	4.5	6.2	1	1.00	1	1.3	1.8	1	1.00
TACHYCARDIA	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
HEADACHE / MIGRAINE	Fluoxetine	19	29.7	39.5	27	1.42	1	4.0	8.3	1	1.00	20	22.5	33.3	28	1.40
	Reboxetine	12	21.1	32.4	17	1.41	5	22.7	31.2	5	1.00	17	21.5	32.0	22	1.29
TREMOR	Fluoxetine	5	7.8	10.4	5	1.00						5	5.6	8.3	5	1.00
	Reboxetine	4	7.0	10.8	4	1.00						4	5.1	7.5	4	1.00
PARAESTHESIA	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	5	8.8	13.5	5	1.00						5	6.3	9.4	5	1.00
HYPERTONIA	Fluoxetine	1	1.6	2.0	1	1.00	1	4.0	8.3	1	1.00	2	2.2	3.3	2	1.00
VERTIGO	Reboxetine	1	1.8	2.7	1	1.00	1	4.5	6.2	2	2.00	2	2.5	3.7	3	1.50
HYPERKINESIA	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
NAUSEA AND RELATED SYMPTOMS	Fluoxetine	13	20.3	27.0	21	1.61	2	8.0	16.6	2	1.00	15	16.9	25.0	23	1.53
	Reboxetine	11	19.3	29.7	14	1.27	2	9.1	12.5	2	1.00	13	16.5	24.5	16	1.23
CONSTIPATION	Fluoxetine	6	9.4	12.5	7	1.16						6	6.7	10.0	7	1.16
	Reboxetine	12	21.1	32.4	13	1.08	5	22.7	31.2	5	1.00	17	21.5	32.0	18	1.05
DIARRHOEA	Fluoxetine	4	6.3	8.3	4	1.00	2	8.0	16.6	2	1.00	6	6.7	10.0	6	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
ABDOMINAL PAIN	Reboxetine	3	5.3	8.1	4	1.33						3	3.8	5.6	4	1.33
APPETITE INCREASED	Fluoxetine	3	4.7	6.2	4	1.33						3	3.4	5.0	4	1.33
ANOREXIA	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
FLATULENCE	Fluoxetine						1	4.0	8.3	1	1.00	1	1.1	1.6	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: HEARING AND VESTIBULAR DISORDERS

Adverse events/Assigned treatment		Female					Male					Total				
		No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
TINNITUS	Reboxetine	1	1.8	2.7	1	1.00	1	4.5	6.2	1	1.00	2	2.5	3.7	2	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
ANEMIA	Reboxetine	1	1.8	2.7	1	1.00	1	1.3	1.8	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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					Total				
		No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
INCREASED LIVER ENZYMES	Reboxetine	2	3.5	5.4	2	1.00	2	2.5	3.7	2	1.00
HEPATITIS INFECTIOUS	Reboxetine	1	1.8	2.7	1	1.00	1	1.3	1.8	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
HYPERCHOLESTEROLA-EMIA	Fluoxetine	1	1.6	2.0	1	1.00	1	4.0	8.3	1	1.00	2	2.2	3.3	2	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
HYPERURICAEMIA	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: MUSCOLO-SKELETAL SYSTEM DISORDERS

Adverse events/Assigned treatment		Female					Male					Total				
		No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
BACK PAIN	Reboxetine	3	5.3	8.1	3	1.00						3	3.8	5.6	3	1.00
MYALGIA	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
TENDINITIS	Reboxetine						1	4.5	6.2	1	1.00	1	1.3	1.8	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: PSYCHIATRIC DISORDERS

Adverse events/Assigned treatment		Female					Male					Total				
		No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
INSOMNIA	Fluoxetine	9	14.1	18.7	11	1.22						9	10.1	15.0	11	1.22
	Reboxetine	8	14.0	21.6	9	1.12	2	9.1	12.5	2	1.00	10	12.7	18.8	11	1.10
AGITATION / ANXIETY / NERVOUSNESS	Fluoxetine	8	12.5	16.6	9	1.12	2	8.0	16.6	2	1.00	10	11.2	16.6	11	1.10
	Reboxetine	2	3.5	5.4	2	1.00	1	4.5	6.2	1	1.00	3	3.8	5.6	3	1.00
SOMNOLENCE	Fluoxetine	2	3.1	4.1	2	1.00	1	4.0	8.3	1	1.00	3	3.4	5.0	3	1.00
	Reboxetine	2	3.5	5.4	2	1.00						2	2.5	3.7	2	1.00
SUICIDE ATTEMPT	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
EUPHORIA	Reboxetine	1	1.8	2.7	2	2.00						1	1.3	1.8	2	2.00
LIBIDO DECREASED	Reboxetine						1	4.5	6.2	1	1.00	1	1.3	1.8	1	1.00
PARONIRIA	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
BREAST FIBROADENOSIS	Reboxetine	1	1.8	2.7	1	1.00	1	1.3	1.8	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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, MALE

Adverse events/Assigned treatment		Male					Total				
		No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
EJACULATION DISORDER	Reboxetine	1	4.5	6.2	1	1.00	1	1.3	1.8	1	1.00
IMPOTENCE	Fluoxetine	1	4.0	8.3	1	1.00	1	1.1	1.6	1	1.00
SPERMATORRHOEA	Reboxetine	1	4.5	6.2	1	1.00	1	1.3	1.8	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: RESISTANCE MECHANISM DISORDERS

Adverse events/Assigned treatment		Female					Male					Total				
		No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
ABSCESS	Reboxetine						2	9.1	12.5	2	1.00	2	2.5	3.7	2	1.00
INFECTION VIRAL	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
OTITIS MEDIA	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: RESPIRATORY SYSTEM DISORDERS

Adverse events/Assigned treatment		Female					Male					Total				
		No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
UPPER RESP TRACT INFECTION	Fluoxetine	3	4.7	6.2	3	1.00						3	3.4	5.0	3	1.00
	Reboxetine	2	3.5	5.4	2	1.00						2	2.5	3.7	2	1.00
RHINITIS	Fluoxetine	1	1.6	2.0	1	1.00	2	8.0	16.6	2	1.00	3	3.4	5.0	3	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
PHARYNGITIS	Fluoxetine	2	3.1	4.1	2	1.00						2	2.2	3.3	2	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
COUGHING	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
RESPIRATORY DISORDER	Reboxetine	2	3.5	5.4	2	1.00						2	2.5	3.7	2	1.00
BRONCHITIS	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
EPISTAXIS	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
SINUSITIS	Fluoxetine						1	4.0	8.3	1	1.00	1	1.1	1.6	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: SKIN AND APPENDAGES DISORDERS

Adverse events/Assigned treatment		Female					Male					Total				
		No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
PRURITUS	Fluoxetine	1	1.6	2.0	1	1.00	1	4.0	8.3	1	1.00	2	2.2	3.3	2	1.00
	Reboxetine	2	3.5	5.4	2	1.00	1	4.5	6.2	1	1.00	3	3.8	5.6	3	1.00
ERYTHEMA / RASH	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	2	3.5	5.4	2	1.00						2	2.5	3.7	2	1.00
ALOPECIA	Reboxetine						1	4.5	6.2	1	1.00	1	1.3	1.8	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
TASTE PERVERSION	Reboxetine	1	1.8	2.7	1	1.00	1	1.3	1.8	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
URINARY HESITANCY / RETENTION	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	3	5.3	8.1	3	1.00	7	31.8	43.7	9	1.28	10	12.7	18.8	12	1.20
URINARY TRACT INFECTION	Fluoxetine	2	3.1	4.1	2	1.00						2	2.2	3.3	2	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
CYSTITIS	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
RENAL PAIN	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 events/Assigned treatment		Female					Male					Total				
		No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
BLURRED VISION	Fluoxetine	3	4.7	6.2	3	1.00	1	4.0	8.3	1	1.00	4	4.5	6.6	4	1.00
	Reboxetine	1	1.8	2.7	1	1.00	2	9.1	12.5	2	1.00	3	3.8	5.6	3	1.00
CONJUNCTIVITIS	Fluoxetine						1	4.0	8.3	1	1.00	1	1.1	1.6	1	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
XEROPHTHALMIA	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
Pt exposed	Fluoxetine	64	100.0				25	100.0				89	100.0			
	Reboxetine	57	100.0				22	100.0				79	100.0			
Pt with a.e.	Fluoxetine	48	75.0	100.0	156	3.25	12	48.0	100.0	24	2.00	60	67.4	100.0	180	3.00
	Reboxetine	37	64.9	100.0	166	4.48	16	72.7	100.0	55	3.43	53	67.1	100.0	221	4.16
GASTRO-INTESTINAL SYSTEM DISORDERS	Fluoxetine	20	31.3	41.6	36	1.80	5	20.0	41.6	5	1.00	25	28.1	41.6	41	1.64
	Reboxetine	22	38.6	59.4	33	1.50	7	31.8	43.7	7	1.00	29	36.7	54.7	40	1.37
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO	Fluoxetine	23	35.9	47.9	35	1.52	2	8.0	16.6	2	1.00	25	28.1	41.6	37	1.48
	Reboxetine	16	28.1	43.2	27	1.68	6	27.3	37.5	7	1.16	22	27.8	41.5	34	1.54
AUTONOMIC NERVOUS SYSTEM DISORDERS	Fluoxetine	10	15.6	20.8	14	1.40	3	12.0	25.0	3	1.00	13	14.6	21.6	17	1.30
	Reboxetine	21	36.8	56.7	25	1.19	9	40.9	56.2	10	1.11	30	38.0	56.6	35	1.16
PSYCHIATRIC DISORDERS	Fluoxetine	18	28.1	37.5	24	1.33	3	12.0	25.0	3	1.00	21	23.6	35.0	27	1.28
	Reboxetine	13	22.8	35.1	16	1.23	3	13.6	18.7	4	1.33	16	20.3	30.1	20	1.25
CARDIOVASCULAR DISORDERS, GENERAL	Fluoxetine	10	15.6	20.8	12	1.20	1	4.0	8.3	1	1.00	11	12.4	18.3	13	1.18
	Reboxetine	15	26.3	40.5	25	1.66	5	22.7	31.2	5	1.00	20	25.3	37.7	30	1.50
BODY AS A WHOLE-GENERAL DISORDERS	Fluoxetine	9	14.1	18.7	12	1.33	2	8.0	16.6	2	1.00	11	12.4	18.3	14	1.27
	Reboxetine	7	12.3	18.9	8	1.14	3	13.6	18.7	3	1.00	10	12.7	18.8	11	1.10
RESPIRATORY SYSTEM DISORDERS	Fluoxetine	7	10.9	14.5	8	1.14	3	12.0	25.0	3	1.00	10	11.2	16.6	11	1.10
	Reboxetine	7	12.3	18.9	8	1.14						7	8.9	13.2	8	1.14
URINARY SYSTEM DISORDERS	Fluoxetine	5	7.8	10.4	5	1.00						5	5.6	8.3	5	1.00
	Reboxetine	5	8.8	13.5	5	1.00	7	31.8	43.7	9	1.28	12	15.2	22.6	14	1.16
VISION DISORDERS	Fluoxetine	3	4.7	6.2	3	1.00	2	8.0	16.6	2	1.00	5	5.6	8.3	5	1.00
	Reboxetine	3	5.3	8.1	3	1.00	2	9.1	12.5	2	1.00	5	6.3	9.4	5	1.00

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
SKIN AND APPENDAGES DISORDERS	Fluoxetine	2	3.1	4.1	2	1.00	1	4.0	8.3	1	1.00	3	3.4	5.0	3	1.00
	Reboxetine	4	7.0	10.8	4	1.00	2	9.1	12.5	2	1.00	6	7.6	11.3	6	1.00
MUSCOLO-SKELETAL SYSTEM DISORDERS	Fluoxetine	1	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	4	7.0	10.8	4	1.00	1	4.5	6.2	1	1.00	5	6.3	9.4	5	1.00
METABOLIC AND NUTRITIONAL DISORDERS	Fluoxetine	2	3.1	4.1	2	1.00	1	4.0	8.3	1	1.00	3	3.4	5.0	3	1.00
	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
RESISTANCE MECHANISM DISORDERS	Fluoxetine	2	3.1	4.1	2	1.00						2	2.2	3.3	2	1.00
	Reboxetine						2	9.1	12.5	2	1.00	2	2.5	3.7	2	1.00
REPRODUCTIVE DISORDERS, MALE	Fluoxetine						1	4.0	8.3	1	1.00	1	1.1	1.6	1	1.00
	Reboxetine						2	9.1	12.5	2	1.00	2	2.5	3.7	2	1.00
HEARING AND VESTIBULAR DISORDERS	Reboxetine	1	1.8	2.7	1	1.00	1	4.5	6.2	1	1.00	2	2.5	3.7	2	1.00
LIVER AND BILIAR SYSTEM DISORDERS	Reboxetine	2	3.5	5.4	3	1.50						2	2.5	3.7	3	1.50
HEMATOLOGY DISORDERS	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
REPRODUCTIVE DISORDERS, FEMALE	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00
SPECIAL SENSES OTHER, DISORDERS	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	1	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 44

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

		Total		Days of treatment																	
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
Adverse events	Assigned treatment																				
MOUTH DRY	Fluoxetine	8	100	6	75.0			2	25.0												
	Reboxetine	27	100	19	70.4	2	7.4	3	11.1					1	3.7	1	3.7	1	3.7		
HEADACHE	Fluoxetine	28	100	8	28.6	8	28.6			3	10.7	2	7.1	4	14.3	1	3.6	2	7.1		
	Reboxetine	21	100	7	33.3	3	14.3	3	14.3	1	4.8	4	19.0	1	4.8			2	9.5		
CONSTIPATION	Fluoxetine	7	100	2	28.6			2	28.6	1	14.3	2	28.6								
	Reboxetine	18	100	14	77.8	1	5.6	1	5.6	1	5.6							1	5.6		
INSOMNIA	Fluoxetine	11	100	2	18.2	3	27.3	2	18.2	1	9.1	1	9.1			2	18.2				
	Reboxetine	11	100	5	45.5	1	9.1	1	9.1	3	27.3			1	9.1						
SWEATING INCREASED	Fluoxetine	9	100	4	44.4	3	33.3			1	11.1					1	11.1				
	Reboxetine	8	100	4	50.0	3	37.5	1	12.5												
DIZZINESS	Fluoxetine	8	100	3	37.5	4	50.0	1	12.5												
	Reboxetine	18	100	7	38.9	3	16.7	2	11.1	1	5.6	2	11.1	1	5.6	2	11.1				
NAUSEA	Fluoxetine	15	100	6	40.0	4	26.7	2	13.3	1	6.7			1	6.7	1	6.7				
	Reboxetine	11	100	8	72.7			1	9.1			1	9.1	1	9.1						
TREMOR	Fluoxetine	5	100			1	20.0	2	40.0					1	20.0	1	20.0				
	Reboxetine	4	100	2	50.0	1	25.0	1	25.0												
MICTURITION DISORDER	Fluoxetine	1	100	1	100																
	Reboxetine	10	100	7	70.0	1	10.0			1	10.0			1	10.0						
INFLUENZA-LIKE SYMPTOMS	Fluoxetine	5	100			1	20.0			2	40.0	1	20.0			1	20.0				
	Reboxetine	3	100			2	66.7											1	33.3		
VISION ABNORMAL	Fluoxetine	4	100	1	25.0	2	50.0									1	25.0				
	Reboxetine	3	100	3	100																

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 44

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

		Total		Days of treatment																	
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
Adverse events	Assigned treatment																				
PARAESTHESIA	Fluoxetine	1	100			1	100														
	Reboxetine	5	100	5	100																
FATIGUE	Fluoxetine	4	100	2	50.0							1	25.0					1	25.0		
	Reboxetine	4	100	3	75.0			1	25.0												
PRURITUS	Fluoxetine	2	100	1	50.0							1	50.0								
	Reboxetine	3	100	1	33.3			1	33.3							1	33.3				
AGITATION	Fluoxetine	7	100	3	42.9			2	28.6	1	14.3	1	14.3								
	Reboxetine	1	100											1	100						
SOMNOLENCE	Fluoxetine	3	100	1	33.3					1	33.3			1	33.3						
	Reboxetine	2	100	1	50.0							1	50.0								
HOT FLUSHES	Fluoxetine	1	100			1	100														
	Reboxetine	2	100	1	50.0					1	50.0										
DYSPEPSIA	Fluoxetine	5	100	2	40.0			1	20.0	2	40.0										
	Reboxetine	1	100	1	100																
NERVOUSNESS	Fluoxetine	3	100			2	66.7					1	33.3								
	Reboxetine	1	100					1	100												
UPPER RESP TRACT INFECTION	Fluoxetine	3	100	1	33.3	1	33.3	1	33.3												
	Reboxetine	2	100									1	50.0			1	50.0				
APPETITE INCREASED	Fluoxetine	4	100			2	50.0			1	25.0					1	25.0				
ABSCESS	Reboxetine	2	100			2	100														
DIARRHOEA	Fluoxetine	6	100	3	50.0							2	33.3	1	16.7						
	Reboxetine	1	100	1	100																

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 44

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

		Total		Days of treatment																			
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56			
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%		
Adverse events	Assigned treatment																						
CONJUNCTIVITIS	Fluoxetine	1	100	1	100																		
	Reboxetine	1	100							1	100												
TASTE PERVERSION	Reboxetine	1	100	1	100																		
HYPERTONIA	Fluoxetine	2	100	1	50.0	1	50.0																
HYPERTENSION	Fluoxetine	1	100	1	100																		
	Reboxetine	1	100							1	100												
VOMITING	Fluoxetine	2	100	1	50.0							1	50.0										
	Reboxetine	3	100	2	66.7			1	33.3														
RHINITIS	Fluoxetine	3	100	1	33.3			1	33.3			1	33.3										
	Reboxetine	1	100															1	100				
ABDOMINAL PAIN	Reboxetine	4	100	1	25.0							2	50.0	1	25.0								
GASTRITIS	Fluoxetine	1	100			1	100																
	Reboxetine	1	100							1	100												
BREAST FIBROADENOSIS	Reboxetine	1	100			1	100																
PHARYNGITIS	Fluoxetine	2	100							1	50.0					1	50.0						
	Reboxetine	1	100					1	100														
URINARY RETENTION	Reboxetine	2	100	1	50.0									1	50.0								
PALPITATION	Reboxetine	2	100	1	50.0			1	50.0														
FEVER	Fluoxetine	2	100					1	50.0							1	50.0						
	Reboxetine	2	100	1	50.0	1	50.0																
BACK PAIN	Reboxetine	3	100			2	66.7	1	33.3														
CYSTITIS	Fluoxetine	1	100															1	100				

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 44

ADVERSE EVENTS: OCCURENCE 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		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
CYSTITIS	Reboxetine	1	100					1	100												
HEPATIC ENZYMES INCREASED	Reboxetine	2	100							1	50.0					1	50.0				
ALLERGIC REACTION	Fluoxetine	1	100											1	100						
	Reboxetine	1	100													1	100				
FLUSHING	Reboxetine	2	100	1	50.0											1	50.0				
RESPIRATORY DISORDER	Reboxetine	2	100	1	50.0							1	50.0								
EUPHORIA	Reboxetine	2	100	1	50.0	1	50.0														
URINARY TRACT INFECTION	Fluoxetine	2	100			1	50.0			1	50.0										
	Reboxetine	1	100	1	100																
EPISTAXIS	Reboxetine	1	100			1	100														
HYPERURICAEMIA	Fluoxetine	1	100							1	100										
COUGHING	Fluoxetine	1	100													1	100				
	Reboxetine	1	100															1	100		
OTITIS MEDIA	Fluoxetine	1	100			1	100														
ANXIETY	Fluoxetine	1	100					1	100												
	Reboxetine	1	100			1	100														
HYPERKINESIA	Fluoxetine	1	100									1	100								
CHEST PAIN PRECORDIAL	Fluoxetine	1	100									1	100								
RASH	Reboxetine	2	100	1	50.0							1	50.0								
MYALGIA	Fluoxetine	1	100			1	100														
	Reboxetine	1	100	1	100																

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 44

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

		Total		Days of treatment																	
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
Adverse events	Assigned treatment																				
VERTIGO	Reboxetine	3	100	1	33.3			1	33.3			1	33.3								
TINNITUS	Reboxetine	2	100	2	100																
HYPOTENSION POSTURAL	Reboxetine	1	100							1	100										
IMPOTENCE	Fluoxetine	1	100									1	100								
OEDEMA LEGS	Reboxetine	1	100									1	100								
HYPOTENSION	Fluoxetine	1	100													1	100				
	Reboxetine	1	100															1	100		
TENDINITIS	Reboxetine	1	100													1	100				
ANOREXIA	Reboxetine	1	100													1	100				
HYPERCHOLESTEROLAEMIA	Fluoxetine	2	100															1	50.0	1	50.0
	Reboxetine	1	100															1	100		
INFECTION VIRAL	Fluoxetine	1	100	1	100																
XEROPHTHALMIA	Reboxetine	1	100	1	100																
LIBIDO DECREASED	Reboxetine	1	100	1	100																
SPERMATORRHOEA	Reboxetine	1	100	1	100																
ASTHENIA	Fluoxetine	1	100			1	100														
OEDEMA GENERALISED	Fluoxetine	1	100					1	100												
SUICIDE ATTEMPT	Fluoxetine	1	100							1	100										
	Reboxetine	1	100									1	100								
FLATULENCE	Fluoxetine	1	100							1	100										
RASH MACULO-PAPULAR	Fluoxetine	1	100									1	100								
PARONIRIA	Fluoxetine	1	100													1	100				

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 44

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

		Total		Days of treatment																			
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56			
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%		
Adverse events	Assigned treatment																						
ANAEMIA	Reboxetine	1	100													1	100						
SINUSITIS	Fluoxetine	1	100															1	100				
HYPERPYREXIA	Reboxetine	1	100	1	100																		
CIRCULATORY FAILURE	Reboxetine	1	100			1	100																
EJACULATION DISORDER	Reboxetine	1	100			1	100																
MIGRAINE	Reboxetine	1	100					1	100														
RENAL PAIN	Fluoxetine	1	100							1	100												
MALAISE	Fluoxetine	1	100							1	100												
ALOPECIA	Reboxetine	1	100							1	100												
BRONCHITIS	Fluoxetine	1	100									1	100										
TACHYCARDIA	Reboxetine	1	100									1	100										
HEPATITIS INFECTIOUS	Reboxetine	1	100																	1	100		

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

ADVERSE EVENTS: OCCURENCE 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		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
MOUTH DRY	Fluoxetine	8	100	6	75.0			2	25.0												
	Reboxetine	27	100	19	70.4	2	7.4	3	11.1					1	3.7	1	3.7	1	3.7		
SWEATING INCREASED	Fluoxetine	9	100	4	44.4	3	33.3			1	11.1					1	11.1				
	Reboxetine	8	100	4	50.0	3	37.5	1	12.5												

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

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

Body system: BODY AS A WHOLE-GENERAL DISORDERS

Adverse events/Assigned treatment		Total		Days of treatment																			
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56			
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%		
INFLUENZA-LIKE SYMPTOMS	Fluoxetine	5	100			1	20.0			2	40.0	1	20.0			1	20.0						
	Reboxetine	3	100			2	66.7											1	33.3				
ASTHENIA / FATIGUE	Fluoxetine	5	100	2	40.0	1	20.0					1	20.0					1	20.0				
	Reboxetine	4	100	3	75.0			1	25.0														
FEVER	Fluoxetine	2	100					1	50.0							1	50.0						
	Reboxetine	2	100	1	50.0	1	50.0																
ALLERGIC REACTION	Fluoxetine	1	100											1	100								
	Reboxetine	1	100													1	100						
HYPERPYREXIA	Reboxetine	1	100	1	100																		
MALAISE	Fluoxetine	1	100							1	100												

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

ADVERSE EVENTS: OCCURENCE 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																			
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56			
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%		
HYPOTENSION AND RELATED SYMPTOMS	Fluoxetine	9	100	3	33.3	4	44.4	1	11.1							1	11.1						
	Reboxetine	20	100	7	35.0	3	15.0	2	10.0	2	10.0	2	10.0	1	5.0	2	10.0	1	5.0				
FLUSHING / HOT FLASHING	Fluoxetine	1	100			1	100																
	Reboxetine	4	100	2	50.0					1	25.0					1	25.0						
HYPERTENSION	Fluoxetine	1	100	1	100																		
	Reboxetine	1	100							1	100												
PALPITATION	Reboxetine	2	100	1	50.0			1	50.0														
AEDEMA	Fluoxetine	1	100					1	100														
	Reboxetine	1	100									1	100										
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	Fluoxetine	1	100									1	100										
CIRCULATORY FAILURE	Reboxetine	1	100			1	100																
TACHYCARDIA	Reboxetine	1	100									1	100										

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

ADVERSE EVENTS: OCCURENCE 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																			
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
HEADACHE / MIGRANE	Fluoxetine	28	100	8	28.6	8	28.6			3	10.7	2	7.1	4	14.3	1	3.6	2	7.1		
	Reboxetine	22	100	7	31.8	3	13.6	4	18.2	1	4.5	4	18.2	1	4.5			2	9.1		
TREMOR	Fluoxetine	5	100			1	20.0	2	40.0					1	20.0	1	20.0				
	Reboxetine	4	100	2	50.0	1	25.0	1	25.0												
PARAESTHESIA	Fluoxetine	1	100			1	100														
	Reboxetine	5	100	5	100																
HYPERTONIA	Fluoxetine	2	100	1	50.0	1	50.0														
HYPERKINESIA	Fluoxetine	1	100									1	100								
VERTIGO	Reboxetine	3	100	1	33.3			1	33.3			1	33.3								

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

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

Body system: GASTRO-INTESTINAL SYSTEM DISORDERS

Adverse events/Assigned treatment		Total		Days of treatment																			
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
CONSTIPATION	Fluoxetine	7	100	2	28.6			2	28.6	1	14.3	2	28.6										
	Reboxetine	18	100	14	77.8	1	5.6	1	5.6	1	5.6							1	5.6				
NAUSEA AND RELATED SYMPTOMS	Fluoxetine	23	100	9	39.1	5	21.7	3	13.0	3	13.0	1	4.3	1	4.3	1	4.3						
	Reboxetine	15	100	10	66.7			2	13.3	1	6.7	1	6.7	1	6.7								
APPETITE INCREASED	Fluoxetine	4	100			2	50.0			1	25.0					1	25.0						
DIARRHOEA	Fluoxetine	6	100	3	50.0							2	33.3	1	16.7								
	Reboxetine	1	100	1	100																		
ABDOMINAL PAIN	Reboxetine	4	100	1	25.0							2	50.0	1	25.0								
ANOREXIA	Reboxetine	1	100													1	100						
FLATULENCE	Fluoxetine	1	100							1	100												

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

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

Body system: HEARING AND VESTIBULAR DISORDERS

Adverse events/Assigned treatment		Total		Days of treatment																	
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
TINNITUS	Reboxetine	2	100	2	100																

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

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

Body system: HEMATOLOGY DISORDERS

Adverse events/Assigned treatment		Total		Days of treatment																	
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
ANEMIA	Reboxetine	1	100													1	100				

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

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

Body system: LIVER AND BILIAR SYSTEM DISORDERS

Adverse events/Assigned treatment		Total		Days of treatment																			
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56			
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%		
INCREASED LIVER ENZYMES	Reboxetine	2	100							1	50.0					1	50.0						
HEPATITIS INFECTIOUS	Reboxetine	1	100																	1	100		

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

ADVERSE EVENTS: OCCURENCE 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		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
HYPERURICAEMIA	Fluoxetine	1	100							1	100										
HYPERCHOLESTEROLAEMIA	Fluoxetine	2	100															1	50.0	1	50.0
	Reboxetine	1	100															1	100		

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

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

Body system: MUSCOLO-SKELETAL SYSTEM DISORDERS

Adverse events/Assigned treatment		Total		Days of treatment																			
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56			
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%		
BACK PAIN	Reboxetine	3	100			2	66.7	1	33.3														
MYALGIA	Fluoxetine	1	100			1	100																
	Reboxetine	1	100	1	100																		
TENDINITIS	Reboxetine	1	100													1	100						

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

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

Body system: PSYCHIATRIC DISORDERS

Adverse events/Assigned treatment		Total		Days of treatment																	
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
INSOMNIA	Fluoxetine	11	100	2	18.2	3	27.3	2	18.2	1	9.1	1	9.1			2	18.2				
	Reboxetine	11	100	5	45.5	1	9.1	1	9.1	3	27.3			1	9.1						
AGITATION / ANXIETY / NERVOUSNESS	Fluoxetine	11	100	3	27.3	2	18.2	3	27.3	1	9.1	2	18.2								
	Reboxetine	3	100			1	33.3	1	33.3					1	33.3						
SOMNOLENCE	Fluoxetine	3	100	1	33.3					1	33.3			1	33.3						
	Reboxetine	2	100	1	50.0							1	50.0								
EUPHORIA	Reboxetine	2	100	1	50.0	1	50.0														
LIBIDO DECREASED	Reboxetine	1	100	1	100																
SUICIDE ATTEMPT	Fluoxetine	1	100							1	100										
	Reboxetine	1	100									1	100								
PARONIRIA	Fluoxetine	1	100													1	100				

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

ADVERSE EVENTS: OCCURENCE 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																					
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56					
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%				
BREAST FIBROADENOSIS	Reboxetine	1	100			1	100																		

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

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

Body system: REPRODUCTIVE DISORDERS, MALE

Adverse events/Assigned treatment		Total		Days of treatment																	
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
IMPOTENCE	Fluoxetine	1	100									1	100								
SPERMATORRHOEA	Reboxetine	1	100	1	100																
EJACULATION DISORDER	Reboxetine	1	100			1	100														

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

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

Body system: RESISTANCE MECHANISM DISORDERS

Adverse events/Assigned treatment		Total		Days of treatment																			
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56			
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%		
ABSCESS	Reboxetine	2	100			2	100																
OTITIS MEDIA	Fluoxetine	1	100			1	100																
INFECTION VIRAL	Fluoxetine	1	100	1	100																		

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

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

Body system: RESPIRATORY SYSTEM DISORDERS

Adverse events/Assigned treatment		Total		Days of treatment																	
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
UPPER RESP TRACT INFECTION	Fluoxetine	3	100	1	33.3	1	33.3	1	33.3												
	Reboxetine	2	100									1	50.0			1	50.0				
RHINITIS	Fluoxetine	3	100	1	33.3			1	33.3			1	33.3								
	Reboxetine	1	100															1	100		
PHARYNGITIS	Fluoxetine	2	100							1	50.0					1	50.0				
	Reboxetine	1	100					1	100												
RESPIRATORY DISORDER	Reboxetine	2	100	1	50.0							1	50.0								
EPISTAXIS	Reboxetine	1	100			1	100														
COUGHING	Fluoxetine	1	100													1	100				
	Reboxetine	1	100															1	100		
SINUSITIS	Fluoxetine	1	100															1	100		
BRONCHITIS	Fluoxetine	1	100									1	100								

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

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

Body system: SKIN AND APPENDAGES DISORDERS

Adverse events/Assigned treatment		Total		Days of treatment																	
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
PRURITUS	Fluoxetine	2	100	1	50.0							1	50.0								
	Reboxetine	3	100	1	33.3			1	33.3							1	33.3				
ERYTHEMA / RASH	Fluoxetine	1	100									1	100								
	Reboxetine	2	100	1	50.0							1	50.0								
ALOPECIA	Reboxetine	1	100							1	100										

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

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

Body system: SPECIAL SENSES OTHER, DISORDERS

Adverse events/Assigned treatment		Total		Days of treatment																			
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56			
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%		
TASTE PERVERSION	Reboxetine	1	100	1	100																		

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

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

Body system: URINARY SYSTEM DISORDERS

Adverse events/Assigned treatment		Total		Days of treatment																	
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
URINARY HESITANCY / RETENTION	Fluoxetine	1	100	1	100																
	Reboxetine	12	100	8	66.7	1	8.3			1	8.3			2	16.7						
CYSTITIS	Fluoxetine	1	100															1	100		
	Reboxetine	1	100					1	100												
URINARY TRACT INFECTION	Fluoxetine	2	100			1	50.0			1	50.0										
	Reboxetine	1	100	1	100																
RENAL PAIN	Fluoxetine	1	100							1	100										

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 45

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

Body system: VISION DISORDERS

Adverse events/Assigned treatment		Total		Days of treatment																	
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
BLURRED VISION	Fluoxetine	4	100	1	25.0	2	50.0									1	25.0				
	Reboxetine	3	100	3	100																
CONJUNCTIVITIS	Fluoxetine	1	100	1	100																
	Reboxetine	1	100							1	100										
XEROPHTHALMIA	Reboxetine	1	100	1	100																

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 46

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

		Total		Days of treatment																	
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
Body system	Assigned treatment																				
AUTONOMIC NERVOUS SYSTEM DISORDERS	Fluoxetine	17	100	10	58.8	3	17.6	2	11.8	1	5.9					1	5.9				
	Reboxetine	35	100	23	65.7	5	14.3	4	11.4					1	2.9	1	2.9	1	2.9		
GASTRO-INTESTINAL SYSTEM DISORDERS	Fluoxetine	41	100	14	34.1	7	17.1	5	12.2	6	14.6	5	12.2	2	4.9	2	4.9				
	Reboxetine	40	100	27	67.5	1	2.5	3	7.5	2	5.0	3	7.5	2	5.0	1	2.5	1	2.5		
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO	Fluoxetine	37	100	9	24.3	11	29.7	2	5.4	3	8.1	3	8.1	5	13.5	2	5.4	2	5.4		
	Reboxetine	34	100	15	44.1	4	11.8	6	17.6	1	2.9	5	14.7	1	2.9			2	5.9		
PSYCHIATRIC DISORDERS	Fluoxetine	27	100	6	22.2	5	18.5	5	18.5	4	14.8	3	11.1	1	3.7	3	11.1				
	Reboxetine	20	100	8	40.0	3	15.0	2	10.0	3	15.0	2	10.0	2	10.0						
CARDIOVASCULAR DISORDERS, GENERAL	Fluoxetine	13	100	4	30.8	5	38.5	2	15.4			1	7.7			1	7.7				
	Reboxetine	30	100	10	33.3	4	13.3	3	10.0	4	13.3	4	13.3	1	3.3	3	10.0	1	3.3		
BODY AS A WHOLE-GENERAL DISORDERS	Fluoxetine	14	100	2	14.3	2	14.3	1	7.1	3	21.4	2	14.3	1	7.1	2	14.3	1	7.1		
	Reboxetine	11	100	5	45.5	3	27.3	1	9.1							1	9.1	1	9.1		
RESPIRATORY SYSTEM DISORDERS	Fluoxetine	11	100	2	18.2	1	9.1	2	18.2	1	9.1	2	18.2			2	18.2	1	9.1		
	Reboxetine	8	100	1	12.5	1	12.5	1	12.5			2	25.0			1	12.5	2	25.0		
URINARY SYSTEM DISORDERS	Fluoxetine	5	100	1	20.0	1	20.0			2	40.0							1	20.0		
	Reboxetine	14	100	9	64.3	1	7.1	1	7.1	1	7.1			2	14.3						
VISION DISORDERS	Fluoxetine	5	100	2	40.0	2	40.0									1	20.0				
	Reboxetine	5	100	4	80.0					1	20.0										
SKIN AND APPENDAGES DISORDERS	Fluoxetine	3	100	1	33.3							2	66.7								
	Reboxetine	6	100	2	33.3			1	16.7	1	16.7	1	16.7			1	16.7				

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 46

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

		Total		Days of treatment																	
				0-7		8-14		15-21		22-28		29-35		36-42		43-49		50-56		> 56	
		No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%	No AE	%
Body system	Assigned treatment																				
RESISTANCE MECHANISM DISORDERS	Fluoxetine	2	100	1	50.0	1	50.0														
	Reboxetine	2	100			2	100														
MUSCOLO-SKELETAL SYSTEM DISORDERS	Fluoxetine	1	100			1	100														
	Reboxetine	5	100	1	20.0	2	40.0	1	20.0							1	20.0				
SPECIAL SENSES OTHER, DISORDERS	Reboxetine	1	100	1	100																
REPRODUCTIVE DISORDERS, FEMALE	Reboxetine	1	100			1	100														
LIVER AND BILIAR SYSTEM DISORDERS	Reboxetine	3	100							1	33.3					1	33.3			1	33.3
METABOLIC AND NUTRITIONAL DISORDERS	Fluoxetine	3	100							1	33.3							1	33.3	1	33.3
	Reboxetine	1	100															1	100		
REPRODUCTIVE DISORDERS, MALE	Fluoxetine	1	100									1	100								
	Reboxetine	2	100	1	50.0	1	50.0														
HEARING AND VESTIBULAR DISORDERS	Reboxetine	2	100	2	100																
HEMATOLOGY DISORDERS	Reboxetine	1	100													1	100				

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Reboxetine

Adverse events / severity		Adverse events	Dose taken on onset date			Highest dose taken from 3 days before		
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
All adverse events	Mild	99	94	5		95	4	
	Moderate	98	94	4		94	4	
	Severe	17	17			17		
	Unknown	7	7			7		
	Total	221	212	9		213	8	
HEADACHE	Mild	7	6	1		6	1	
	Moderate	14	14			14		
	Total	21	20	1		20	1	
NAUSEA	Mild	2	2			2		
	Moderate	9	9			9		
	Total	11	11			11		
INSOMNIA	Mild	4	4			4		
	Moderate	6	5	1		5	1	
	Severe	1	1			1		
	Total	11	10	1		10	1	
SWEATING INCREASED	Mild	5	5			5		
	Moderate	3	3			3		
	Total	8	8			8		
DIZZINESS	Mild	13	12	1		13		
	Moderate	5	4	1		4	1	
	Total	18	16	2		17	1	

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Reboxetine

Adverse events / severity		Adverse events	Dose taken on onset date			Highest dose taken from 3 days before		
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
MOUTH DRY	Mild	17	16	1		16	1	
	Moderate	8	8			8		
	Severe	2	2			2		
	Total	27	26	1		26	1	
CONSTIPATION	Mild	7	7			7		
	Moderate	8	8			8		
	Severe	3	3			3		
	Total	18	18			18		
AGITATION	Moderate	1		1			1	
	Total	1		1			1	
DIARRHOEA	Mild	1	1			1		
	Total	1	1			1		
TREMOR	Mild	2	2			2		
	Moderate	2	2			2		
	Total	4	4			4		
DYSPEPSIA	Unknown	1	1			1		
	Total	1	1			1		
INFLUENZA-LIKE SYMPTOMS	Moderate	3	3			3		
	Total	3	3			3		
VISION ABNORMAL	Mild	2	2			2		
	Moderate	1	1			1		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Reboxetine

Adverse events / severity		Adverse events	Dose taken on onset date			Highest dose taken from 3 days before		
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
VISION ABNORMAL	Total	3	3			3		
FATIGUE	Mild	1	1			1		
	Moderate	2	2			2		
	Severe	1	1			1		
	Total	4	4			4		
NERVOUSNESS	Moderate	1	1			1		
	Total	1	1			1		
SOMNOLENCE	Mild	1	1			1		
	Moderate	1	1			1		
	Total	2	2			2		
RHINITIS	Moderate	1	1			1		
	Total	1	1			1		
UPPER RESP TRACT INFECTION	Moderate	1	1			1		
	Unknown	1	1			1		
	Total	2	2			2		
HYPERCHOLESTEROLAEMIA	Mild	1	1			1		
	Total	1	1			1		
URINARY TRACT INFECTION	Unknown	1	1			1		
	Total	1	1			1		
FEVER	Mild	1	1			1		
	Moderate	1	1			1		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Reboxetine

Adverse events / severity		Adverse events	Dose taken on onset date			Highest dose taken from 3 days before		
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
FEVER	Total	2	2			2		
PRURITUS	Mild	2	2			2		
	Moderate	1		1			1	
	Total	3	2	1		2	1	
VOMITING	Moderate	2	2			2		
	Severe	1	1			1		
	Total	3	3			3		
PHARYNGITIS	Moderate	1	1			1		
	Total	1	1			1		
MYALGIA	Moderate	1	1			1		
	Total	1	1			1		
COUGHING	Moderate	1	1			1		
	Total	1	1			1		
CYSTITIS	Severe	1	1			1		
	Total	1	1			1		
HOT FLUSHES	Mild	1	1			1		
	Moderate	1	1			1		
	Total	2	2			2		
PARAESTHESIA	Mild	3	3			3		
	Moderate	1	1			1		
	Severe	1	1			1		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Reboxetine

Adverse events / severity		Adverse events	Dose taken on onset date			Highest dose taken from 3 days before		
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
PARAESTHESIA	Total	5	5			5		
HYPERTENSION	Moderate	1	1			1		
	Total	1	1			1		
HYPOTENSION	Severe	1	1			1		
	Total	1	1			1		
CONJUNCTIVITIS	Moderate	1	1			1		
	Total	1	1			1		
GASTRITIS	Mild	1	1			1		
	Total	1	1			1		
MICTURITION DISORDER	Mild	4	4			4		
	Moderate	5	5			5		
	Severe	1	1			1		
	Total	10	10			10		
ANXIETY	Mild	1	1			1		
	Total	1	1			1		
SUICIDE ATTEMPT	Severe	1	1			1		
	Total	1	1			1		
ALLERGIC REACTION	Moderate	1	1			1		
	Total	1	1			1		
ABDOMINAL PAIN	Mild	1	1			1		
	Moderate	2	2			2		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Reboxetine

Adverse events / severity		Adverse events	Dose taken on onset date			Highest dose taken from 3 days before		
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
ABDOMINAL PAIN	Severe	1	1			1		
	Total	4	4			4		
BACK PAIN	Mild	2	2			2		
	Moderate	1	1			1		
	Total	3	3			3		
VERTIGO	Mild	3	3			3		
	Total	3	3			3		
HEPATIC ENZYMES INCREASED	Severe	1	1			1		
	Unknown	1	1			1		
	Total	2	2			2		
RASH	Mild	1	1			1		
	Severe	1	1			1		
	Total	2	2			2		
URINARY RETENTION	Mild	1		1			1	
	Severe	1	1			1		
	Total	2	1	1		1	1	
FLUSHING	Mild	1	1			1		
	Moderate	1	1			1		
	Total	2	2			2		
PALPITATION	Mild	1	1			1		
	Moderate	1	1			1		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Reboxetine

Adverse events / severity		Adverse events	Dose taken on onset date			Highest dose taken from 3 days before		
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
PALPITATION	Total	2	2			2		
TINNITUS	Mild	2	2			2		
	Total	2	2			2		
EUPHORIA	Mild	1	1			1		
	Moderate	1	1			1		
	Total	2	2			2		
RESPIRATORY DISORDER	Mild	1	1			1		
	Moderate	1	1			1		
	Total	2	2			2		
ABSCESS	Unknown	2	2			2		
	Total	2	2			2		
TACHYCARDIA	Mild	1	1			1		
	Total	1	1			1		
XEROPHTHALMIA	Mild	1	1			1		
	Total	1	1			1		
TASTE PERVERSION	Mild	1	1			1		
	Total	1	1			1		
ALOPECIA	Mild	1	1			1		
	Total	1	1			1		
CIRCULATORY FAILURE	Mild	1	1			1		
	Total	1	1			1		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Reboxetine

Adverse events / severity		Adverse events	Dose taken on onset date			Highest dose taken from 3 days before		
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
OEDEMA LEGS	Mild	1		1			1	
	Total	1		1			1	
ANAEMIA	Mild	1	1			1		
	Total	1	1			1		
SPERMATORRHOEA	Mild	1	1			1		
	Total	1	1			1		
HYPERPYREXIA	Mild	1	1			1		
	Total	1	1			1		
TENDINITIS	Moderate	1	1			1		
	Total	1	1			1		
MIGRAINE	Moderate	1	1			1		
	Total	1	1			1		
ANOREXIA	Moderate	1	1			1		
	Total	1	1			1		
HYPOTENSION POSTURAL	Moderate	1	1			1		
	Total	1	1			1		
LIBIDO DECREASED	Moderate	1	1			1		
	Total	1	1			1		
HEPATITIS INFECTIOUS	Moderate	1	1			1		
	Total	1	1			1		
EPISTAXIS	Moderate	1	1			1		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Reboxetine

Adverse events / severity		Adverse events	Dose taken on onset date			Highest dose taken from 3 days before		
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
EPISTAXIS	Total	1	1			1		
EJACULATION DISORDER	Moderate	1	1			1		
	Total	1	1			1		
BREAST FIBROADENOSIS	Unknown	1	1			1		
	Total	1	1			1		

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Fluoxetine

Adverse events / severity		Adverse events	Dose taken on onset date			Highest dose taken from 3 days before		
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
All adverse events	Mild	79	76	3		77	2	
	Moderate	79	72	7		73	6	
	Severe	14	12	2		14		
	Unknown	8	6	2		6	2	
	Total	180	166	14		170	10	
HEADACHE	Mild	8	8			8		
	Moderate	17	15	2		16	1	
	Severe	2	2			2		
	Unknown	1		1			1	
	Total	28	25	3		26	2	
NAUSEA	Mild	12	12			12		
	Moderate	1	1			1		
	Severe	1	1			1		
	Unknown	1	1			1		
	Total	15	15			15		
INSOMNIA	Mild	4	4			4		
	Moderate	4	3	1		3	1	
	Severe	2	1	1		2		
	Unknown	1	1			1		
	Total	11	9	2		10	1	
SWEATING INCREASED	Mild	3	3			3		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Fluoxetine

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
SWEATING INCREASED	Moderate	6	6			6		
	Total	9	9			9		
DIZZINESS	Mild	6	6			6		
	Moderate	1	1			1		
	Severe	1	1			1		
	Total	8	8			8		
MOUTH DRY	Mild	7	7			7		
	Moderate	1	1			1		
	Total	8	8			8		
CONSTIPATION	Mild	3	3			3		
	Moderate	4	3	1		3	1	
	Total	7	6	1		6	1	
AGITATION	Mild	2	2			2		
	Moderate	3	3			3		
	Severe	2	2			2		
	Total	7	7			7		
DIARRHOEA	Mild	4	4			4		
	Moderate	2	2			2		
	Total	6	6			6		
TREMOR	Mild	1	1			1		
	Moderate	3	3			3		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Fluoxetine

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
TREMOR	Severe	1	1			1		
	Total	5	5			5		
DYSPEPSIA	Mild	1	1			1		
	Moderate	4	4			4		
	Total	5	5			5		
INFLUENZA-LIKE SYMPTOMS	Mild	2	2			2		
	Moderate	3	2	1		2	1	
	Total	5	4	1		4	1	
APPETITE INCREASED	Mild	2	2			2		
	Moderate	2	2			2		
	Total	4	4			4		
VISION ABNORMAL	Mild	4	3	1		4		
	Total	4	3	1		4		
FATIGUE	Mild	1	1			1		
	Moderate	2	2			2		
	Severe	1		1		1		
	Total	4	3	1		4		
NERVOUSNESS	Mild	1	1			1		
	Moderate	2	1	1		1	1	
	Total	3	2	1		2	1	
SOMNOLENCE	Mild	2	2			2		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Fluoxetine

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
SOMNOLENCE	Moderate	1	1			1		
	Total	3	3			3		
RHINITIS	Mild	2	2			2		
	Moderate	1	1			1		
	Total	3	3			3		
UPPER RESP TRACT INFECTION	Mild	1	1			1		
	Unknown	2	2			2		
	Total	3	3			3		
HYPERCHOLESTEROLAEMIA	Mild	1		1			1	
	Severe	1	1			1		
	Total	2	1	1		1	1	
URINARY TRACT INFECTION	Mild	1	1			1		
	Unknown	1	1			1		
	Total	2	2			2		
FEVER	Mild	1	1			1		
	Moderate	1	1			1		
	Total	2	2			2		
PRURITUS	Moderate	2	2			2		
	Total	2	2			2		
HYPERTONIA	Moderate	2	2			2		
	Total	2	2			2		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

REBOXETINE - PROTOCOL 20124/016
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: Fluoxetine

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
VOMITING	Moderate	2	2			2		
	Total	2	2			2		
PHARYNGITIS	Moderate	2	2			2		
	Total	2	2			2		
MYALGIA	Mild	1	1			1		
	Total	1	1			1		
FLATULENCE	Mild	1	1			1		
	Total	1	1			1		
HYPERURICAEMIA	Mild	1	1			1		
	Total	1	1			1		
OEDEMA GENERALISED	Mild	1	1			1		
	Total	1	1			1		
COUGHING	Mild	1	1			1		
	Total	1	1			1		
CYSTITIS	Mild	1		1			1	
	Total	1		1			1	
RENAL PAIN	Mild	1	1			1		
	Total	1	1			1		
ASTHENIA	Mild	1	1			1		
	Total	1	1			1		
HOT FLUSHES	Mild	1	1			1		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Fluoxetine

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
HOT FLUSHES	Total	1	1			1		
INFECTION VIRAL	Mild	1	1			1		
	Total	1	1			1		
HYPERKINESIA	Moderate	1	1			1		
	Total	1	1			1		
PARAESTHESIA	Moderate	1	1			1		
	Total	1	1			1		
HYPERTENSION	Moderate	1	1			1		
	Total	1	1			1		
HYPOTENSION	Moderate	1	1				1	
	Total	1	1				1	
CONJUNCTIVITIS	Moderate	1	1			1		
	Total	1	1			1		
PARONIRIA	Moderate	1	1			1		
	Total	1	1			1		
GASTRITIS	Moderate	1	1			1		
	Total	1	1			1		
BRONCHITIS	Moderate	1	1			1		
	Total	1	1			1		
MICTURITION DISORDER	Moderate	1	1			1		
	Total	1	1			1		

(CONTINUED)

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Fluoxetine

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
IMPOTENCE	Moderate	1	1			1		
	Total	1	1			1		
CHEST PAIN PRECORDIAL	Moderate	1		1		1		
	Total	1		1		1		
MALAISE	Moderate	1	1			1		
	Total	1	1			1		
OTITIS MEDIA	Moderate	1	1			1		
	Total	1	1			1		
RASH MACULO-PAPULAR	Severe	1	1			1		
	Total	1	1			1		
ANXIETY	Severe	1	1			1		
	Total	1	1			1		
SUICIDE ATTEMPT	Severe	1	1			1		
	Total	1	1			1		
SINUSITIS	Unknown	1	1			1		
	Total	1	1			1		
ALLERGIC REACTION	Unknown	1		1			1	
	Total	1		1			1	

(*) all remainder patients
REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day
FLUOXETINE - low dose <= 20 mg/day, high dose > 20 mg/day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 48

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

Assigned treatment / Severity level		Total		Sex: Female		Sex: Male		Age: 18 - 30		Age: 31 - 45		Age: > 45		DSM III: 296.2		DSM III: 296.3	
		No. Pt	%	No. Pt	%	No. Pt	%	No. Pt	%	No. Pt	%	No. Pt	%	No. Pt	%	No. Pt	%
Fluoxetine	Missing	2	3.3	1	2.1	1	8.3			2	7.7			2	7.1		
	Mild	10	16.7	8	16.7	2	16.7	1	11.1	4	15.4	5	20.0	6	21.4	4	12.5
	Moderate	36	60.0	29	60.4	7	58.3	7	77.8	15	57.7	14	56.0	15	53.6	21	65.6
	Severe	12	20.0	10	20.8	2	16.7	1	11.1	5	19.2	6	24.0	5	17.9	7	21.9
	Total	60	100.0	48	100.0	12	100.0	9	100.0	26	100.0	25	100.0	28	100.0	32	100.0
Reboxetine	Mild	10	18.9	6	16.2	4	25.0	1	11.1	4	19.0	5	21.7	5	27.8	5	14.3
	Moderate	30	56.6	20	54.1	10	62.5	7	77.8	12	57.1	11	47.8	9	50.0	21	60.0
	Severe	13	24.5	11	29.7	2	12.5	1	11.1	5	23.8	7	30.4	4	22.2	9	25.7
	Total	53	100.0	37	100.0	16	100.0	9	100.0	21	100.0	23	100.0	18	100.0	35	100.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 49

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

Adverse events / Severity		Assigned treatment																	
		Fluoxetine									Reboxetine								
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
All adverse events	Mild	8	17.0	16.7	2	18.2	16.7	10	17.2	16.7	6	16.2	16.2	4	25.0	25.0	10	18.9	18.9
	Moderate	29	61.7	60.4	7	63.6	58.3	36	62.1	60.0	20	54.1	54.1	10	62.5	62.5	30	56.6	56.6
	Severe	10	21.3	20.8	2	18.2	16.7	12	20.7	20.0	11	29.7	29.7	2	12.5	12.5	13	24.5	24.5
	Total	47	100	97.9	11	100	91.7	58	100	96.7	37	100	100	16	100	100	53	100	100
HEADACHE	Mild	3	15.8	6.3				3	15.0	5.0	3	25.0	8.1	2	40.0	12.5	5	29.4	9.4
	Moderate	14	73.7	29.2	1	100	8.3	15	75.0	25.0	9	75.0	24.3	3	60.0	18.8	12	70.6	22.6
	Severe	2	10.5	4.2				2	10.0	3.3									
	Total	19	100	39.6	1	100	8.3	20	100	33.3	12	100	32.4	5	100	31.3	17	100	32.1
MOUTH DRY	Mild	5	83.3	10.4	2	100	16.7	7	87.5	11.7	13	65.0	35.1	4	57.1	25.0	17	63.0	32.1
	Moderate	1	16.7	2.1				1	12.5	1.7	5	25.0	13.5	3	42.9	18.8	8	29.6	15.1
	Severe										2	10.0	5.4				2	7.4	3.8
	Total	6	100	12.5	2	100	16.7	8	100	13.3	20	100	54.1	7	100	43.8	27	100	50.9
CONSTIPATION	Mild	3	50.0	6.3				3	50.0	5.0	6	50.0	16.2				6	35.3	11.3
	Moderate	3	50.0	6.3				3	50.0	5.0	3	25.0	8.1	5	100	31.3	8	47.1	15.1
	Severe										3	25.0	8.1				3	17.6	5.7
	Total	6	100	12.5				6	100	10.0	12	100	32.4	5	100	31.3	17	100	32.1
DIZZINESS	Mild	4	66.7	8.3				4	66.7	6.7	4	44.4	10.8	4	100	25.0	8	61.5	15.1
	Moderate	1	16.7	2.1				1	16.7	1.7	5	55.6	13.5				5	38.5	9.4
	Severe	1	16.7	2.1				1	16.7	1.7									
	Total	6	100	12.5				6	100	10.0	9	100	24.3	4	100	25.0	13	100	24.5

(CONTINUED)

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 49

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

Adverse events / Severity		Assigned treatment																	
		Fluoxetine									Reboxetine								
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
INSOMNIA	Mild	3	33.3	6.3				3	33.3	5.0	2	25.0	5.4	1	50.0	6.3	3	30.0	5.7
	Moderate	3	33.3	6.3				3	33.3	5.0	5	62.5	13.5	1	50.0	6.3	6	60.0	11.3
	Severe	2	22.2	4.2				2	22.2	3.3	1	12.5	2.7				1	10.0	1.9
	Missing	1	11.1	2.1				1	11.1	1.7									
	Total	9	100	18.8				9	100	15.0	8	100	21.6	2	100	12.5	10	100	18.9
NAUSEA	Mild	6	75.0	12.5				6	66.7	10.0				1	50.0	6.3	1	11.1	1.9
	Moderate	1	12.5	2.1				1	11.1	1.7	7	100	18.9	1	50.0	6.3	8	88.9	15.1
	Severe	1	12.5	2.1				1	11.1	1.7									
	Missing				1	100	8.3	1	11.1	1.7									
	Total	8	100	16.7	1	100	8.3	9	100	15.0	7	100	18.9	2	100	12.5	9	100	17.0
SWEATING INCREASED	Mild	3	50.0	6.3				3	42.9	5.0	2	50.0	5.4	2	66.7	12.5	4	57.1	7.5
	Moderate	3	50.0	6.3	1	100	8.3	4	57.1	6.7	2	50.0	5.4	1	33.3	6.3	3	42.9	5.7
	Total	6	100	12.5	1	100	8.3	7	100	11.7	4	100	10.8	3	100	18.8	7	100	13.2
TREMOR	Mild	1	20.0	2.1				1	20.0	1.7	2	50.0	5.4				2	50.0	3.8
	Moderate	3	60.0	6.3				3	60.0	5.0	2	50.0	5.4				2	50.0	3.8
	Severe	1	20.0	2.1				1	20.0	1.7									
	Total	5	100	10.4				5	100	8.3	4	100	10.8				4	100	7.5
MICTURITION DISORDER	Mild										1	50.0	2.7	2	33.3	12.5	3	37.5	5.7
	Moderate	1	100	2.1				1	100	1.7				4	66.7	25.0	4	50.0	7.5
	Severe										1	50.0	2.7				1	12.5	1.9

(CONTINUED)

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 49

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

Adverse events / Severity		Assigned treatment																		
		Fluoxetine									Reboxetine									
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
MICTURITION DISORDER	Total	1	100	2.1				1	100	1.7	2	100	5.4	6	100	37.5	8	100	15.1
AGITATION	Mild	2	40.0	4.2				2	28.6	3.3									
	Moderate	2	40.0	4.2	1	50.0	8.3	3	42.9	5.0				1	100	6.3	1	100	1.9
	Severe	1	20.0	2.1	1	50.0	8.3	2	28.6	3.3									
	Total	5	100	10.4	2	100	16.7	7	100	11.7				1	100	6.3	1	100	1.9
FATIGUE	Mild	1	33.3	2.1				1	25.0	1.7				1	50.0	6.3	1	25.0	1.9
	Moderate	2	66.7	4.2				2	50.0	3.3	2	100	5.4				2	50.0	3.8
	Severe				1	100	8.3	1	25.0	1.7				1	50.0	6.3	1	25.0	1.9
	Total	3	100	6.3	1	100	8.3	4	100	6.7	2	100	5.4	2	100	12.5	4	100	7.5
DIARRHOEA	Mild	2	50.0	4.2	2	100	16.7	4	66.7	6.7	1	100	2.7				1	100	1.9
	Moderate	2	50.0	4.2				2	33.3	3.3									
	Total	4	100	8.3	2	100	16.7	6	100	10.0	1	100	2.7				1	100	1.9
VISION ABNORMAL	Mild	3	100	6.3	1	100	8.3	4	100	6.7	1	100	2.7	1	50.0	6.3	2	66.7	3.8
	Moderate													1	50.0	6.3	1	33.3	1.9
	Total	3	100	6.3	1	100	8.3	4	100	6.7	1	100	2.7	2	100	12.5	3	100	5.7
INFLUENZA-LIKE SYMPTOMS	Mild	2	50.0	4.2				2	50.0	3.3									
	Moderate	2	50.0	4.2				2	50.0	3.3	3	100	8.1				3	100	5.7
	Total	4	100	8.3				4	100	6.7	3	100	8.1				3	100	5.7
PARAESTHESIA	Mild										3	60.0	8.1				3	60.0	5.7

(CONTINUED)

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 49

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

Adverse events / Severity		Assigned treatment																	
		Fluoxetine									Reboxetine								
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
PARAESTHESIA	Moderate	1	100	2.1				1	100	1.7	1	20.0	2.7				1	20.0	1.9
	Severe										1	20.0	2.7				1	20.0	1.9
	Total	1	100	2.1				1	100	1.7	5	100	13.5				5	100	9.4
PRURITUS	Mild										2	100	5.4				2	66.7	3.8
	Moderate	1	100	2.1	1	100	8.3	2	100	3.3				1	100	6.3	1	33.3	1.9
	Total	1	100	2.1	1	100	8.3	2	100	3.3	2	100	5.4	1	100	6.3	3	100	5.7
VOMITING	Moderate	2	100	4.2				2	100	3.3	2	66.7	5.4				2	66.7	3.8
	Severe										1	33.3	2.7				1	33.3	1.9
	Total	2	100	4.2				2	100	3.3	3	100	8.1				3	100	5.7
SOMNOLENCE	Mild	1	50.0	2.1	1	100	8.3	2	66.7	3.3	1	50.0	2.7				1	50.0	1.9
	Moderate	1	50.0	2.1				1	33.3	1.7	1	50.0	2.7				1	50.0	1.9
	Total	2	100	4.2	1	100	8.3	3	100	5.0	2	100	5.4				2	100	3.8
DYSPEPSIA	Mild	1	25.0	2.1				1	25.0	1.7									
	Moderate	3	75.0	6.3				3	75.0	5.0									
	Missing										1	100	2.7				1	100	1.9
	Total	4	100	8.3				4	100	6.7	1	100	2.7				1	100	1.9
UPPER RESP TRACT INFECTION	Mild	1	33.3	2.1				1	33.3	1.7									
	Moderate										1	50.0	2.7				1	50.0	1.9
	Missing	2	66.7	4.2				2	66.7	3.3	1	50.0	2.7				1	50.0	1.9
	Total	3	100	6.3				3	100	5.0	2	100	5.4				2	100	3.8

(CONTINUED)

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 49

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

Adverse events / Severity		Assigned treatment																	
		Fluoxetine									Reboxetine								
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
NERVOUSNESS	Mild	1	33.3	2.1				1	33.3	1.7									
	Moderate	2	66.7	4.2				2	66.7	3.3	1	100	2.7				1	100	1.9
	Total	3	100	6.3				3	100	5.0	1	100	2.7				1	100	1.9
RHINITIS	Mild				2	100	16.7	2	66.7	3.3									
	Moderate	1	100	2.1				1	33.3	1.7	1	100	2.7				1	100	1.9
	Total	1	100	2.1	2	100	16.7	3	100	5.0	1	100	2.7				1	100	1.9
BACK PAIN	Mild										2	66.7	5.4				2	66.7	3.8
	Moderate										1	33.3	2.7				1	33.3	1.9
	Total										3	100	8.1				3	100	5.7
APPETITE INCREASED	Mild	1	33.3	2.1				1	33.3	1.7									
	Moderate	2	66.7	4.2				2	66.7	3.3									
	Total	3	100	6.3				3	100	5.0									
ABDOMINAL PAIN	Mild										1	33.3	2.7				1	33.3	1.9
	Moderate										1	33.3	2.7				1	33.3	1.9
	Severe										1	33.3	2.7				1	33.3	1.9
	Total										3	100	8.1				3	100	5.7
HYPERCHOLESTEROLAEMIA	Mild				1	100	8.3	1	50.0	1.7	1	100	2.7				1	100	1.9
	Severe	1	100	2.1				1	50.0	1.7									
	Total	1	100	2.1	1	100	8.3	2	100	3.3	1	100	2.7				1	100	1.9
PHARYNGITIS	Moderate	2	100	4.2				2	100	3.3	1	100	2.7				1	100	1.9

(CONTINUED)

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 49

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

Adverse events / Severity		Assigned treatment																		
		Fluoxetine									Reboxetine									
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
PHARYNGITIS	Total	2	100	4.2				2	100	3.3	1	100	2.7				1	100	1.9
URINARY TRACT INFECTION	Mild	1	50.0	2.1				1	50.0	1.7									
	Missing	1	50.0	2.1				1	50.0	1.7	1	100	2.7				1	100	1.9
	Total	2	100	4.2				2	100	3.3	1	100	2.7				1	100	1.9
FEVER	Mild													1	100	6.3	1	50.0	1.9
	Moderate	1	100	2.1				1	100	1.7	1	100	2.7				1	50.0	1.9
	Total	1	100	2.1				1	100	1.7	1	100	2.7	1	100	6.3	2	100	3.8
HOT FLUSHES	Mild	1	100	2.1				1	100	1.7	1	50.0	2.7				1	50.0	1.9
	Moderate										1	50.0	2.7				1	50.0	1.9
	Total	1	100	2.1				1	100	1.7	2	100	5.4				2	100	3.8
RASH	Mild										1	50.0	2.7				1	50.0	1.9
	Severe										1	50.0	2.7				1	50.0	1.9
	Total										2	100	5.4				2	100	3.8
MYALGIA	Mild	1	100	2.1				1	100	1.7									
	Moderate										1	100	2.7				1	100	1.9
	Total	1	100	2.1				1	100	1.7	1	100	2.7				1	100	1.9
HYPERTONIA	Moderate	1	100	2.1	1	100	8.3	2	100	3.3									
	Total	1	100	2.1	1	100	8.3	2	100	3.3									
VERTIGO	Mild										1	100	2.7	1	100	6.3	2	100	3.8
	Total										1	100	2.7	1	100	6.3	2	100	3.8

(CONTINUED)

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 49

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

Adverse events / Severity		Assigned treatment																		
		Fluoxetine									Reboxetine									
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
URINARY RETENTION	Mild										1	100	2.7				1	50.0	1.9
	Severe													1	100	6.3	1	50.0	1.9
	Total										1	100	2.7	1	100	6.3	2	100	3.8
HYPERTENSION	Moderate				1	100	8.3	1	100	1.7	1	100	2.7				1	100	1.9
	Total				1	100	8.3	1	100	1.7	1	100	2.7				1	100	1.9
HYPOTENSION	Moderate	1	100	2.1				1	100	1.7									
	Severe										1	100	2.7				1	100	1.9
	Total	1	100	2.1				1	100	1.7	1	100	2.7				1	100	1.9
PALPITATION	Mild										1	50.0	2.7				1	50.0	1.9
	Moderate										1	50.0	2.7				1	50.0	1.9
	Total										2	100	5.4				2	100	3.8
CONJUNCTIVITIS	Moderate				1	100	8.3	1	100	1.7	1	100	2.7				1	100	1.9
	Total				1	100	8.3	1	100	1.7	1	100	2.7				1	100	1.9
TINNITUS	Mild										1	100	2.7	1	100	6.3	2	100	3.8
	Total										1	100	2.7	1	100	6.3	2	100	3.8
ANXIETY	Mild										1	100	2.7				1	100	1.9
	Severe	1	100	2.1				1	100	1.7									
	Total	1	100	2.1				1	100	1.7	1	100	2.7				1	100	1.9
SUICIDE ATTEMPT	Severe	1	100	2.1				1	100	1.7	1	100	2.7				1	100	1.9
	Total	1	100	2.1				1	100	1.7	1	100	2.7				1	100	1.9

(CONTINUED)

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 49

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

Adverse events / Severity		Assigned treatment																		
		Fluoxetine									Reboxetine									
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
GASTRITIS	Mild										1	100	2.7				1	100	1.9
	Moderate				1	100	8.3	1	100	1.7									
	Total				1	100	8.3	1	100	1.7	1	100	2.7				1	100	1.9
HEPATIC ENZYMES INCREASED	Severe										1	50.0	2.7				1	50.0	1.9
	Unknown										1	50.0	2.7				1	50.0	1.9
	Total										2	100	5.4				2	100	3.8
COUGHING	Mild	1	100	2.1				1	100	1.7									
	Moderate										1	100	2.7				1	100	1.9
	Total	1	100	2.1				1	100	1.7	1	100	2.7				1	100	1.9
RESPIRATORY DISORDER	Mild										1	50.0	2.7				1	50.0	1.9
	Moderate										1	50.0	2.7				1	50.0	1.9
	Total										2	100	5.4				2	100	3.8
CYSTITIS	Mild	1	100	2.1				1	100	1.7									
	Severe										1	100	2.7				1	100	1.9
	Total	1	100	2.1				1	100	1.7	1	100	2.7				1	100	1.9
ALLERGIC REACTION	Moderate										1	100	2.7				1	100	1.9
	Missing	1	100	2.1				1	100	1.7									
	Total	1	100	2.1				1	100	1.7	1	100	2.7				1	100	1.9
ABSCESS	Missing													2	100	12.5	2	100	3.8
	Total													2	100	12.5	2	100	3.8

(CONTINUED)

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 49

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

Adverse events / Severity		Assigned treatment																		
		Fluoxetine									Reboxetine									
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
RASH MACULO-PAPULAR	Severe	1	100	2.1				1	100	1.7									
	Total	1	100	2.1				1	100	1.7									
TENDINITIS	Moderate													1	100	6.3	1	100	1.9
	Total													1	100	6.3	1	100	1.9
HYPERKINE-SIA	Moderate	1	100	2.1				1	100	1.7									
	Total	1	100	2.1				1	100	1.7									
MIGRAINE	Moderate										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9
ANOREXIA	Moderate										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9
FLUSHING	Moderate										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9
HYPOTENSI-ON POSTURAL	Moderate										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9
TACHYCARD-IA	Mild										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9
XEROPHTHA-LMIA	Mild										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9
TASTE PERVERSION	Mild										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9

(CONTINUED)

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 49

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

Adverse events / Severity		Assigned treatment																		
		Fluoxetine									Reboxetine									
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
EUPHORIA	Moderate										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9
LIBIDO DECREASED	Moderate													1	100	6.3	1	100	1.9
	Total													1	100	6.3	1	100	1.9
PARONIRIA	Moderate	1	100	2.1				1	100	1.7									
	Total	1	100	2.1				1	100	1.7									
FLATULENCE	Mild				1	100	8.3	1	100	1.7									
	Total				1	100	8.3	1	100	1.7									
HEPATITIS INFECTIOUS	Moderate										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9
HYPERURIC-AEMIA	Mild	1	100	2.1				1	100	1.7									
	Total	1	100	2.1				1	100	1.7									
ALOPECIA	Mild													1	100	6.3	1	100	1.9
	Total													1	100	6.3	1	100	1.9
OEDEMA GENERALIS-ED	Mild	1	100	2.1				1	100	1.7									
	Total	1	100	2.1				1	100	1.7									
CIRCULATO-RY FAILURE	Mild													1	100	6.3	1	100	1.9
	Total													1	100	6.3	1	100	1.9
OEDEMA LEGS	Mild										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9

(CONTINUED)

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 49

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

Adverse events / Severity		Assigned treatment																		
		Fluoxetine									Reboxetine									
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
EPISTAXIS	Moderate										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9
SINUSITIS	Missing				1	100	8.3	1	100	1.7									
	Total				1	100	8.3	1	100	1.7									
BRONCHITIS	Moderate	1	100	2.1				1	100	1.7									
	Total	1	100	2.1				1	100	1.7									
ANAEMIA	Mild										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9
RENAL PAIN	Mild	1	100	2.1				1	100	1.7									
	Total	1	100	2.1				1	100	1.7									
IMPOTENCE	Moderate				1	100	8.3	1	100	1.7									
	Total				1	100	8.3	1	100	1.7									
SPERMATOR-RHOEA	Mild													1	100	6.3	1	100	1.9
	Total													1	100	6.3	1	100	1.9
EJACULATI-ON DISORDER	Moderate													1	100	6.3	1	100	1.9
	Total													1	100	6.3	1	100	1.9
BREAST FIBROADEN-OSIS	Missing										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9
ASTHENIA	Mild	1	100	2.1				1	100	1.7									
	Total	1	100	2.1				1	100	1.7									

(CONTINUED)

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 49

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

Adverse events / Severity		Assigned treatment																		
		Fluoxetine									Reboxetine									
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
CHEST PAIN PRECORDIAL	Moderate	1	100	2.1				1	100	1.7									
	Total	1	100	2.1				1	100	1.7									
MALAISE	Moderate				1	100	8.3	1	100	1.7									
	Total				1	100	8.3	1	100	1.7									
HYPERPYREXIA	Mild										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9
INFECTION VIRAL	Mild	1	100	2.1				1	100	1.7									
	Total	1	100	2.1				1	100	1.7									
OTITIS MEDIA	Moderate	1	100	2.1				1	100	1.7									
	Total	1	100	2.1				1	100	1.7									

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 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																	
		Fluoxetine									Reboxetine								
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
All adverse events	Mild	8	17.0	16.7	2	18.2	16.7	10	17.2	16.7	6	16.2	16.2	4	25.0	25.0	10	18.9	18.9
	Moderate	29	61.7	60.4	7	63.6	58.3	36	62.1	60.0	20	54.1	54.1	10	62.5	62.5	30	56.6	56.6
	Severe	10	21.3	20.8	2	18.2	16.7	12	20.7	20.0	11	29.7	29.7	2	12.5	12.5	13	24.5	24.5
	Total	47	100	97.9	11	100	91.7	58	100	96.7	37	100	100	16	100	100	53	100	100
GASTRO-INTESTINAL SYSTEM DISORDERS	Mild	9	45.0	18.8	3	60.0	25.0	12	48.0	20.0	7	31.8	18.9	1	14.3	6.3	8	27.6	15.1
	Moderate	10	50.0	20.8	1	20.0	8.3	11	44.0	18.3	10	45.5	27.0	6	85.7	37.5	16	55.2	30.2
	Severe	1	5.0	2.1				1	4.0	1.7	5	22.7	13.5				5	17.2	9.4
	Missing				1	20.0	8.3	1	4.0	1.7									
	Total	20	100	41.7	5	100	41.7	25	100	41.7	22	100	59.5	7	100	43.8	29	100	54.7
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO	Mild	2	8.7	4.2				2	8.0	3.3	5	31.3	13.5	3	50.0	18.8	8	36.4	15.1
	Moderate	18	78.3	37.5	2	100	16.7	20	80.0	33.3	10	62.5	27.0	3	50.0	18.8	13	59.1	24.5
	Severe	3	13.0	6.3				3	12.0	5.0	1	6.3	2.7				1	4.5	1.9
	Total	23	100	47.9	2	100	16.7	25	100	41.7	16	100	43.2	6	100	37.5	22	100	41.5
AUTONOMIC NERVOUS SYSTEM DISORDERS	Mild	6	60.0	12.5	2	66.7	16.7	8	61.5	13.3	13	61.9	35.1	6	66.7	37.5	19	63.3	35.8
	Moderate	4	40.0	8.3	1	33.3	8.3	5	38.5	8.3	6	28.6	16.2	3	33.3	18.8	9	30.0	17.0
	Severe										2	9.5	5.4				2	6.7	3.8
	Total	10	100	20.8	3	100	25.0	13	100	21.7	21	100	56.8	9	100	56.3	30	100	56.6
PSYCHIATR-IC DISORDERS	Mild	5	27.8	10.4	1	33.3	8.3	6	28.6	10.0	4	30.8	10.8	1	33.3	6.3	5	31.3	9.4
	Moderate	7	38.9	14.6	1	33.3	8.3	8	38.1	13.3	7	53.8	18.9	2	66.7	12.5	9	56.3	17.0
	Severe	5	27.8	10.4	1	33.3	8.3	6	28.6	10.0	2	15.4	5.4				2	12.5	3.8

(CONTINUED)

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 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																	
		Fluoxetine									Reboxetine								
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
PSYCHIATRIC DISORDERS	Missing	1	5.6	2.1				1	4.8	1.7									
	Total	18	100	37.5	3	100	25.0	21	100	35.0	13	100	35.1	3	100	18.8	16	100	30.2
CARDIOVASCULAR DISORDERS, GENERAL	Mild	6	60.0	12.5				6	54.5	10.0	5	33.3	13.5	5	100	31.3	10	50.0	18.9
	Moderate	3	30.0	6.3	1	100	8.3	4	36.4	6.7	9	60.0	24.3				9	45.0	17.0
	Severe	1	10.0	2.1				1	9.1	1.7	1	6.7	2.7				1	5.0	1.9
	Total	10	100	20.8	1	100	8.3	11	100	18.3	15	100	40.5	5	100	31.3	20	100	37.7
BODY AS A WHOLE-GENERAL DISORDERS	Mild	3	33.3	6.3				3	27.3	5.0	1	14.3	2.7	2	66.7	12.5	3	30.0	5.7
	Moderate	5	55.6	10.4	1	50.0	8.3	6	54.5	10.0	6	85.7	16.2				6	60.0	11.3
	Severe				1	50.0	8.3	1	9.1	1.7				1	33.3	6.3	1	10.0	1.9
	Missing	1	11.1	2.1				1	9.1	1.7									
	Total	9	100	18.8	2	100	16.7	11	100	18.3	7	100	18.9	3	100	18.8	10	100	18.9
RESPIRATORY SYSTEM DISORDERS	Mild	1	14.3	2.1	2	66.7	16.7	3	30.0	5.0	1	14.3	2.7				1	14.3	1.9
	Moderate	4	57.1	8.3				4	40.0	6.7	5	71.4	13.5				5	71.4	9.4
	Missing	2	28.6	4.2	1	33.3	8.3	3	30.0	5.0	1	14.3	2.7				1	14.3	1.9
	Total	7	100	14.6	3	100	25.0	10	100	16.7	7	100	18.9				7	100	13.2
URINARY SYSTEM DISORDERS	Mild	3	60.0	6.3				3	60.0	5.0	2	40.0	5.4	2	28.6	12.5	4	33.3	7.5
	Moderate	1	20.0	2.1				1	20.0	1.7				4	57.1	25.0	4	33.3	7.5
	Severe										2	40.0	5.4	1	14.3	6.3	3	25.0	5.7
	Missing	1	20.0	2.1				1	20.0	1.7	1	20.0	2.7				1	8.3	1.9
	Total	5	100	10.4				5	100	8.3	5	100	13.5	7	100	43.8	12	100	22.6

(CONTINUED)

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 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																	
		Fluoxetine									Reboxetine								
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
VISION DISORDERS	Mild	3	100	6.3	1	50.0	8.3	4	80.0	6.7	2	66.7	5.4	1	50.0	6.3	3	60.0	5.7
	Moderate				1	50.0	8.3	1	20.0	1.7	1	33.3	2.7	1	50.0	6.3	2	40.0	3.8
	Total	3	100	6.3	2	100	16.7	5	100	8.3	3	100	8.1	2	100	12.5	5	100	9.4
SKIN AND APPENDAGES DISORDERS	Mild										3	75.0	8.1	1	50.0	6.3	4	66.7	7.5
	Moderate	1	50.0	2.1	1	100	8.3	2	66.7	3.3				1	50.0	6.3	1	16.7	1.9
	Severe	1	50.0	2.1				1	33.3	1.7	1	25.0	2.7				1	16.7	1.9
	Total	2	100	4.2	1	100	8.3	3	100	5.0	4	100	10.8	2	100	12.5	6	100	11.3
MUSCOLO-SKELETAL SYSTEM DISORDERS	Mild	1	100	2.1				1	100	1.7	2	50.0	5.4				2	40.0	3.8
	Moderate										2	50.0	5.4	1	100	6.3	3	60.0	5.7
	Total	1	100	2.1				1	100	1.7	4	100	10.8	1	100	6.3	5	100	9.4
METABOLIC AND NUTRITION-AL DISORDERS	Mild	1	50.0	2.1	1	100	8.3	2	66.7	3.3	1	100	2.7				1	100	1.9
	Severe	1	50.0	2.1				1	33.3	1.7									
	Total	2	100	4.2	1	100	8.3	3	100	5.0	1	100	2.7				1	100	1.9
RESISTANCE MECHANISM DISORDERS	Mild	1	50.0	2.1				1	50.0	1.7									
	Moderate	1	50.0	2.1				1	50.0	1.7									
	Missing													2	100	12.5	2	100	3.8
	Total	2	100	4.2				2	100	3.3				2	100	12.5	2	100	3.8
REPRODUCT-IVE DISORDERS, MALE	Mild													1	50.0	6.3	1	50.0	1.9
	Moderate				1	100	8.3	1	100	1.7				1	50.0	6.3	1	50.0	1.9
	Total				1	100	8.3	1	100	1.7				2	100	12.5	2	100	3.8

(CONTINUED)

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 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																		
		Fluoxetine									Reboxetine									
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
HEARING AND VESTIBULAR DISORDERS	Mild										1	100	2.7	1	100	6.3	2	100	3.8
	Total										1	100	2.7	1	100	6.3	2	100	3.8
LIVER AND BILIAR SYSTEM DISORDERS	Severe										1	50.0	2.7				1	50.0	1.9
	Unknown										1	50.0	2.7				1	50.0	1.9
	Total										2	100	5.4				2	100	3.8
HEMATOLOGY DISORDERS	Mild										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9
REPRODUCT-IVE DISORDERS, FEMALE	Missing										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9
SPECIAL SENSES OTHER, DISORDERS	Mild										1	100	2.7				1	100	1.9
	Total										1	100	2.7				1	100	1.9

(*) % on all patients with adverse events

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 51

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

Adverse events/Assigned treatment		No of Episodes	Duration of episodes (days)			
			Min	50%	90%	Max
All adverse events	Fluoxetine	180	1	9	32	56
	Reboxetine	221	1	12	46	59
HEADACHE	Fluoxetine	28	1	6	24	36
	Reboxetine	21	1	9	19	32
MOUTH DRY	Fluoxetine	8	8	21	56	56
	Reboxetine	27	3	28	56	59
DIZZINESS	Fluoxetine	8	1	4	32	32
	Reboxetine	18	1	8	50	59
NAUSEA	Fluoxetine	15	1	7	15	21
	Reboxetine	11	1	9	17	25
CONSTIPATION	Fluoxetine	7	4	13	31	31
	Reboxetine	18	1	17	57	59
INSOMNIA	Fluoxetine	11	3	14	41	49
	Reboxetine	11	7	29	55	56
SWEATING INCREASED	Fluoxetine	9	9	21	53	53
	Reboxetine	8	5	13	20	20
MICTURITION DISORDER	Fluoxetine	1	15	15	15	15
	Reboxetine	10	2	7	29	35
TREMOR	Fluoxetine	5	1	13	46	46
	Reboxetine	4	4	12	42	42
AGITATION	Fluoxetine	7	1	12	21	21
	Reboxetine	1	19	19	19	19

(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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 51

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

Adverse events/Assigned treatment		No of Episodes	Duration of episodes (days)			
			Min	50%	90%	Max
FATIGUE	Fluoxetine	4	6	9	22	22
	Reboxetine	4	7	13	28	28
INFLUENZA-LIKE SYMPTOMS	Fluoxetine	5	1	17	37	37
	Reboxetine	3	5	14	18	18
DIARRHOEA	Fluoxetine	6	2	4	8	8
	Reboxetine	1	7	7	7	7
VISION ABNORMAL	Fluoxetine	4	3	12	23	23
	Reboxetine	3	5	28	40	40
PARAESTHESIA	Fluoxetine	1	35	35	35	35
	Reboxetine	5	5	8	44	44
DYSPEPSIA	Fluoxetine	5	1	4	9	9
	Reboxetine	1	25	25	25	25
PRURITUS	Fluoxetine	2	10	23	35	35
	Reboxetine	3	12	19	42	42
VOMITING	Fluoxetine	2	2	3	3	3
	Reboxetine	3	1	9	18	18
SOMNOLENCE	Fluoxetine	3	8	8	31	31
	Reboxetine	2	7	17	27	27
UPPER RESP TRACT INFECTION	Fluoxetine	3	1	6	27	27
	Reboxetine	2	5	6	7	7
APPETITE INCREASED	Fluoxetine	4	7	9	20	20
NERVOUSNESS	Fluoxetine	3	8	8	27	27

(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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 51

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

Adverse events/Assigned treatment		No of Episodes	Duration of episodes (days)			
			Min	50%	90%	Max
NERVOUSNESS	Reboxetine	1	21	21	21	21
ABDOMINAL PAIN	Reboxetine	4	1	3	32	32
RHINITIS	Fluoxetine	3	7	8	10	10
	Reboxetine	1	5	5	5	5
FEVER	Fluoxetine	2	6	10	13	13
	Reboxetine	2	2	4	6	6
BACK PAIN	Reboxetine	3	4	12	14	14
VERTIGO	Reboxetine	3	1	1	5	5
HYPERCHOLESTEROLAEMIA	Fluoxetine	2	1	1	1	1
	Reboxetine	1	6	6	6	6
PHARYNGITIS	Fluoxetine	2	10	11	11	11
	Reboxetine	1	13	13	13	13
URINARY TRACT INFECTION	Fluoxetine	2	1	4	6	6
	Reboxetine	1	15	15	15	15
HOT FLUSHES	Fluoxetine	1	9	9	9	9
	Reboxetine	2	23	38	53	53
RASH	Reboxetine	2	3	7	11	11
MYALGIA	Fluoxetine	1	10	10	10	10
	Reboxetine	1	2	2	2	2
HYPERTONIA	Fluoxetine	2	1	22	42	42
URINARY RETENTION	Reboxetine	2	3	21	39	39
FLUSHING	Reboxetine	2	14	16	17	17

(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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 51

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

Adverse events/Assigned treatment		No of Episodes	Duration of episodes (days)			
			Min	50%	90%	Max
HYPERTENSION	Fluoxetine	1	21	21	21	21
	Reboxetine	1	28	28	28	28
HYPOTENSION	Fluoxetine	1	2	2	2	2
	Reboxetine	1	8	8	8	8
PALPITATION	Reboxetine	2	3	20	36	36
CONJUNCTIVITIS	Fluoxetine	1	43	43	43	43
	Reboxetine	1	9	9	9	9
TINNITUS	Reboxetine	2	7	8	8	8
ANXIETY	Fluoxetine	1	16	16	16	16
	Reboxetine	1	1	1	1	1
EUPHORIA	Reboxetine	2	8	12	15	15
SUICIDE ATTEMPT	Fluoxetine	1	1	1	1	1
	Reboxetine	1	1	1	1	1
GASTRITIS	Fluoxetine	1	22	22	22	22
	Reboxetine	1	27	27	27	27
HEPATIC ENZYMES INCREASED	Reboxetine	2	22	25	27	27
COUGHING	Fluoxetine	1	11	11	11	11
	Reboxetine	1	5	5	5	5
RESPIRATORY DISORDER	Reboxetine	2	10	19	27	27
CYSTITIS	Fluoxetine	1	5	5	5	5
	Reboxetine	1	39	39	39	39
ALLERGIC REACTION	Fluoxetine	1	22	22	22	22

(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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 51

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

Adverse events/Assigned treatment		No of Episodes	Duration of episodes (days)			
			Min	50%	90%	Max
ALLERGIC REACTION	Reboxetine	1	15	15	15	15
ABSCESS	Reboxetine	2	9	28	46	46
RASH MACULO-PAPULAR	Fluoxetine	1	5	5	5	5
TENDINITIS	Reboxetine	1	14	14	14	14
HYPERKINESIA	Fluoxetine	1	28	28	28	28
MIGRAINE	Reboxetine	1	2	2	2	2
ANOREXIA	Reboxetine	1	11	11	11	11
HYPOTENSION POSTURAL	Reboxetine	1	15	15	15	15
TACHYCARDIA	Reboxetine	1	3	3	3	3
XEROPHTHALMIA	Reboxetine	1	8	8	8	8
TASTE PERVERSION	Reboxetine	1	56	56	56	56
LIBIDO DECREASED	Reboxetine	1	8	8	8	8
PARONIRIA	Fluoxetine	1	8	8	8	8
FLATULENCE	Fluoxetine	1	9	9	9	9
HEPATITIS INFECTIOUS	Reboxetine	1	1	1	1	1
HYPERURICAEMIA	Fluoxetine	1	29	29	29	29
ALOPECIA	Reboxetine	1	3	3	3	3
OEDEMA GENERALISED	Fluoxetine	1	8	8	8	8
CIRCULATORY FAILURE	Reboxetine	1	1	1	1	1
OEDEMA LEGS	Reboxetine	1	16	16	16	16
EPISTAXIS	Reboxetine	1	26	26	26	26
SINUSITIS	Fluoxetine	1	4	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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 51

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

Adverse events/Assigned treatment		No of Episodes	Duration of episodes (days)			
			Min	50%	90%	Max
BRONCHITIS	Fluoxetine	1	6	6	6	6
ANAEMIA	Reboxetine	1	8	8	8	8
RENAL PAIN	Fluoxetine	1	2	2	2	2
IMPOTENCE	Fluoxetine	1	13	13	13	13
SPERMATORRHOEA	Reboxetine	1	9	9	9	9
EJACULATION DISORDER	Reboxetine	1	3	3	3	3
BREAST FIBROADENOSIS	Reboxetine	1	46	46	46	46
ASTHENIA	Fluoxetine	1	8	8	8	8
CHEST PAIN PRECORDIAL	Fluoxetine	1	22	22	22	22
MALAISE	Fluoxetine	1	1	1	1	1
HYPERPYREXIA	Reboxetine	1	7	7	7	7
INFECTION VIRAL	Fluoxetine	1	6	6	6	6
OTITIS MEDIA	Fluoxetine	1	22	22	22	22

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 52

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

Adverse events	Assigned treatment											
	Fluoxetine						Reboxetine					
	Symptomatic treatment						Symptomatic treatment					
	YES		NO		Total		YES		NO		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
No. of pt. with A.E.	32	53.3	28	46.7	60	100.0	30	56.6	23	43.4	53	100.0
No. of adverse events	54	30.0	126	70.0	180	100.0	49	22.2	172	77.8	221	100.0
HEADACHE	12	42.9	16	57.1	28	100.0	5	23.8	16	76.2	21	100.0
MOUTH DRY			8	100.0	8	100.0	2	7.4	25	92.6	27	100.0
DIZZINESS			8	100.0	8	100.0	1	5.6	17	94.4	18	100.0
NAUSEA	2	13.3	13	86.7	15	100.0	3	27.3	8	72.7	11	100.0
CONSTIPATION	4	57.1	3	42.9	7	100.0	2	11.1	16	88.9	18	100.0
INSOMNIA	8	72.7	3	27.3	11	100.0	8	72.7	3	27.3	11	100.0
SWEATING INCREASED			9	100.0	9	100.0			8	100.0	8	100.0
MICTURITION DISORDER			1	100.0	1	100.0			10	100.0	10	100.0
TREMOR			5	100.0	5	100.0	1	25.0	3	75.0	4	100.0
AGITATION	4	57.1	3	42.9	7	100.0			1	100.0	1	100.0
FATIGUE			4	100.0	4	100.0			4	100.0	4	100.0
INFLUENZA-LIKE SYMPTOMS	3	60.0	2	40.0	5	100.0	2	66.7	1	33.3	3	100.0
DIARRHOEA	1	16.7	5	83.3	6	100.0			1	100.0	1	100.0
VISION ABNORMAL			4	100.0	4	100.0			3	100.0	3	100.0
PARAESTHESIA			1	100.0	1	100.0	1	20.0	4	80.0	5	100.0
DYSPEPSIA			5	100.0	5	100.0	1	100.0			1	100.0
PRURITUS	2	100.0			2	100.0	1	33.3	2	66.7	3	100.0
VOMITING	2	100.0			2	100.0	2	66.7	1	33.3	3	100.0
SOMNOLENCE			3	100.0	3	100.0			2	100.0	2	100.0

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 52

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

Adverse events	Assigned treatment											
	Fluoxetine						Reboxetine					
	Symptomatic treatment						Symptomatic treatment					
	YES		NO		Total		YES		NO		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
UPPER RESP TRACT INFECTION	2	66.7	1	33.3	3	100.0	2	100.0			2	100.0
APPETITE INCREASED			4	100.0	4	100.0						
NERVOUSNESS			3	100.0	3	100.0			1	100.0	1	100.0
ABDOMINAL PAIN							1	25.0	3	75.0	4	100.0
RHINITIS			3	100.0	3	100.0	1	100.0			1	100.0
FEVER	1	50.0	1	50.0	2	100.0	1	50.0	1	50.0	2	100.0
BACK PAIN							2	66.7	1	33.3	3	100.0
VERTIGO									3	100.0	3	100.0
HYPERCHOLESTEROLAEMIA			2	100.0	2	100.0			1	100.0	1	100.0
PHARYNGITIS	2	100.0			2	100.0			1	100.0	1	100.0
URINARY TRACT INFECTION	1	50.0	1	50.0	2	100.0	1	100.0			1	100.0
HOT FLUSHES			1	100.0	1	100.0			2	100.0	2	100.0
RASH							1	50.0	1	50.0	2	100.0
MYALGIA			1	100.0	1	100.0			1	100.0	1	100.0
HYPERTONIA			2	100.0	2	100.0						
URINARY RETENTION									2	100.0	2	100.0
FLUSHING									2	100.0	2	100.0
HYPERTENSION	1	100.0			1	100.0	1	100.0			1	100.0
HYPOTENSION	1	100.0			1	100.0			1	100.0	1	100.0
PALPITATION									2	100.0	2	100.0
CONJUNCTIVITIS	1	100.0			1	100.0			1	100.0	1	100.0

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 52

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

Adverse events	Assigned treatment											
	Fluoxetine						Reboxetine					
	Symptomatic treatment						Symptomatic treatment					
	YES		NO		Total		YES		NO		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
TINNITUS									2	100.0	2	100.0
ANXIETY	1	100.0			1	100.0			1	100.0	1	100.0
EUPHORIA									2	100.0	2	100.0
SUICIDE ATTEMPT			1	100.0	1	100.0	1	100.0			1	100.0
GASTRITIS	1	100.0			1	100.0	1	100.0			1	100.0
HEPATIC ENZYMES INCREASED							1	50.0	1	50.0	2	100.0
COUGHING	1	100.0			1	100.0	1	100.0			1	100.0
RESPIRATORY DISORDER									2	100.0	2	100.0
CYSTITIS			1	100.0	1	100.0	1	100.0			1	100.0
ALLERGIC REACTION			1	100.0	1	100.0	1	100.0			1	100.0
ABSCESS							2	100.0			2	100.0
RASH MACULO-PAPULAR			1	100.0	1	100.0						
HYPERKINESIA			1	100.0	1	100.0						
MIGRAINE									1	100.0	1	100.0
ANOREXIA									1	100.0	1	100.0
HYPOTENSION POSTURAL							1	100.0			1	100.0
TACHYCARDIA									1	100.0	1	100.0
XEROPHTHALMIA									1	100.0	1	100.0
TASTE PERVERSION									1	100.0	1	100.0
PARONIRIA			1	100.0	1	100.0						
HEPATITIS INFECTIOUS									1	100.0	1	100.0

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 52

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

Adverse events	Assigned treatment											
	Fluoxetine						Reboxetine					
	Symptomatic treatment						Symptomatic treatment					
	YES		NO		Total		YES		NO		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
HYPERURICAEMIA			1	100.0	1	100.0						
OEDEMA GENERALISED	1	100.0			1	100.0						
OEDEMA LEGS									1	100.0	1	100.0
EPISTAXIS									1	100.0	1	100.0
BRONCHITIS	1	100.0			1	100.0						
ANAEMIA									1	100.0	1	100.0
RENAL PAIN			1	100.0	1	100.0						
BREAST FIBROADENOSIS									1	100.0	1	100.0
ASTHENIA			1	100.0	1	100.0						
CHEST PAIN PRECORDIAL			1	100.0	1	100.0						
HYPERPYREXIA									1	100.0	1	100.0
INFECTION VIRAL	1	100.0			1	100.0						
OTITIS MEDIA	1	100.0			1	100.0						
TENDINITIS							1	100.0			1	100.0
LIBIDO DECREASED									1	100.0	1	100.0
FLATULENCE			1	100.0	1	100.0						
ALOPECIA									1	100.0	1	100.0
CIRCULATORY FAILURE									1	100.0	1	100.0
SINUSITIS			1	100.0	1	100.0						
IMPOTENCE			1	100.0	1	100.0						
SPERMATORRHOEA									1	100.0	1	100.0

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/046
TABLE No.: 52

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

Adverse events	Assigned treatment													
	Fluoxetine						Reboxetine							
	Symptomatic treatment						Symptomatic treatment							
	YES		NO		Total		YES		NO		Total			
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%		
EJACULATION DISORDER									1	100.0	1	100.0		
MALAISE			1	100.0	1	100.0								

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	%	No.	%	No.	%	No.	%	No.	%	No.	%
All adverse events	Fluoxetine	155	86.1	5	2.8	3	1.7	9	5.0	8	4.4	180	100.0
	Reboxetine	185	83.7	4	1.8	1	0.5	25	11.3	6	2.7	221	100.0
HEADACHE / MIGRANE	Fluoxetine	26	92.9	1	3.6					1	3.6	28	100.0
	Reboxetine	19	86.4	1	4.5			2	9.1			22	100.0
NAUSEA AND RELATED SYMPTOMS	Fluoxetine	20	87.0					2	8.7	1	4.3	23	100.0
	Reboxetine	13	81.3					2	12.5	1	6.3	16	100.0
MOUTH DRY	Fluoxetine	8	100.0									8	100.0
	Reboxetine	25	92.6					2	7.4			27	100.0
HYPOTENSION AND RELATED SYMPTOMS	Fluoxetine	8	88.9	1	11.1							9	100.0
	Reboxetine	17	85.0					3	15.0			20	100.0
CONSTIPATION	Fluoxetine	6	85.7	1	14.3							7	100.0
	Reboxetine	16	88.9					2	11.1			18	100.0
INSOMNIA	Fluoxetine	8	72.7	2	18.2					1	9.1	11	100.0
	Reboxetine	8	72.7	1	9.1			2	18.2			11	100.0
SWEATING INCREASED	Fluoxetine	9	100.0									9	100.0
	Reboxetine	8	100.0									8	100.0
AGITATION / ANXIETY / NERVOUSNESS	Fluoxetine	8	72.7					3	27.3			11	100.0
	Reboxetine	2	66.7	1	33.3							3	100.0
URINARY HESITANCY / RETENTION	Fluoxetine	1	100.0									1	100.0
	Reboxetine	10	83.3					2	16.7			12	100.0
ASTHENIA / FATIGUE	Fluoxetine	5	100.0									5	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	%	No.	%	No.	%	No.	%	No.	%	No.	%
ASTHENIA / FATIGUE	Reboxetine	3	75.0					1	25.0			4	100.0
TREMOR	Fluoxetine	5	100.0									5	100.0
	Reboxetine	4	100.0									4	100.0
INFLUENZA-LIKE SYMPTOMS	Fluoxetine	4	80.0			1	20.0					5	100.0
	Reboxetine	3	100.0									3	100.0
DIARRHOEA	Fluoxetine	5	83.3					1	16.7			6	100.0
	Reboxetine							1	100.0			1	100.0
BLURRED VISION	Fluoxetine	4	100.0									4	100.0
	Reboxetine	3	100.0									3	100.0
PARAESTHESIA	Fluoxetine	1	100.0									1	100.0
	Reboxetine	4	80.0					1	20.0			5	100.0
FLUSHING / HOT FLASHING	Fluoxetine	1	100.0									1	100.0
	Reboxetine	4	100.0									4	100.0
SOMNOLENCE	Fluoxetine	3	100.0									3	100.0
	Reboxetine	1	50.0					1	50.0			2	100.0
UPPER RESP TRACT INFECTION	Fluoxetine	1	33.3							2	66.7	3	100.0
	Reboxetine	1	50.0							1	50.0	2	100.0
PRURITUS	Fluoxetine	2	100.0									2	100.0
	Reboxetine	2	66.7	1	33.3							3	100.0
FEVER	Fluoxetine	2	100.0									2	100.0
	Reboxetine	1	50.0					1	50.0			2	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	%	No.	%	No.	%	No.	%	No.	%	No.	%
ABDOMINAL PAIN	Reboxetine	3	75.0			1	25.0					4	100.0
APPETITE INCREASED	Fluoxetine	4	100.0									4	100.0
RHINITIS	Fluoxetine	3	100.0									3	100.0
	Reboxetine	1	100.0									1	100.0
VERTIGO	Reboxetine	3	100.0									3	100.0
HYPERCHOLESTEROLAEMIA	Fluoxetine	2	100.0									2	100.0
	Reboxetine	1	100.0									1	100.0
BACK PAIN	Reboxetine	3	100.0									3	100.0
PHARYNGITIS	Fluoxetine	1	50.0			1	50.0					2	100.0
	Reboxetine	1	100.0									1	100.0
ERYTHEMA / RASH	Fluoxetine							1	100.0			1	100.0
	Reboxetine	1	50.0					1	50.0			2	100.0
URINARY TRACT INFECTION	Fluoxetine	1	50.0							1	50.0	2	100.0
	Reboxetine									1	100.0	1	100.0
ALLERGIC REACTION	Fluoxetine									1	100.0	1	100.0
	Reboxetine	1	100.0									1	100.0
AEDEMA	Fluoxetine	1	100.0									1	100.0
	Reboxetine	1	100.0									1	100.0
HYPERTENSION	Fluoxetine	1	100.0									1	100.0
	Reboxetine	1	100.0									1	100.0
PALPITATION	Reboxetine	2	100.0									2	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	%	No.	%	No.	%	No.	%	No.	%	No.	%
HYPERTONIA	Fluoxetine	2	100.0									2	100.0
TINNITUS	Reboxetine	2	100.0									2	100.0
INCREASED LIVER ENZYMES	Reboxetine	1	50.0					1	50.0			2	100.0
MYALGIA	Fluoxetine	1	100.0									1	100.0
	Reboxetine	1	100.0									1	100.0
EUPHORIA	Reboxetine	2	100.0									2	100.0
COUGHING	Fluoxetine	1	100.0									1	100.0
	Reboxetine	1	100.0									1	100.0
RESPIRATORY DISORDER	Reboxetine	2	100.0									2	100.0
CYSTITIS	Fluoxetine	1	100.0									1	100.0
	Reboxetine	1	100.0									1	100.0
CONJUNCTIVITIS	Fluoxetine	1	100.0									1	100.0
	Reboxetine	1	100.0									1	100.0
SUICIDE ATTEMPT	Fluoxetine							1	100.0			1	100.0
	Reboxetine							1	100.0			1	100.0
ABSCESS	Reboxetine									2	100.0	2	100.0
HYPERPYREXIA	Reboxetine	1	100.0									1	100.0
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	Fluoxetine	1	100.0									1	100.0
CIRCULATORY FAILURE	Reboxetine	1	100.0									1	100.0
TACHYCARDIA	Reboxetine	1	100.0									1	100.0
HYPERKINESIA	Fluoxetine	1	100.0									1	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	%	No.	%	No.	%	No.	%	No.	%	No.	%
FLATULENCE	Fluoxetine	1	100.0									1	100.0
ANEMIA	Reboxetine	1	100.0									1	100.0
HYPERURICAEMIA	Fluoxetine	1	100.0									1	100.0
LIBIDO DECREASED	Reboxetine	1	100.0									1	100.0
PARONIRIA	Fluoxetine	1	100.0									1	100.0
BREAST FIBROADENOSIS	Reboxetine	1	100.0									1	100.0
EJACULATION DISORDER	Reboxetine	1	100.0									1	100.0
IMPOTENCE	Fluoxetine	1	100.0									1	100.0
SPERMATORRHOEA	Reboxetine	1	100.0									1	100.0
INFECTION VIRAL	Fluoxetine	1	100.0									1	100.0
OTITIS MEDIA	Fluoxetine	1	100.0									1	100.0
EPISTAXIS	Reboxetine	1	100.0									1	100.0
ALOPECIA	Reboxetine	1	100.0									1	100.0
TASTE PERVERSION	Reboxetine	1	100.0									1	100.0
RENAL PAIN	Fluoxetine	1	100.0									1	100.0
XEROPHTHALMIA	Reboxetine	1	100.0									1	100.0
MALAISE	Fluoxetine					1	100.0					1	100.0
ANOREXIA	Reboxetine							1	100.0			1	100.0
TENDINITIS	Reboxetine							1	100.0			1	100.0
BRONCHITIS	Fluoxetine							1	100.0			1	100.0
HEPATITIS INFECTIOUS	Reboxetine									1	100.0	1	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	%	No.	%	No.	%	No.	%	No.	%	No.	%
SINUSITIS	Fluoxetine									1	100.0	1	100.0

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 54

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

Adverse events/Assigned treatment		Modified study drug								Temporarily interrupted							
		Disappeared								Riappeared							
		NO		YES		Not applicable		Total		NO		YES		Not applicable		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
All adverse events	Reboxetine	18	60.0	10	33.3	2	6.7	30	100.0	1	100.0					1	100.0
	Fluoxetine	7	41.2	9	52.9	1	5.9	17	100.0	2	66.7			1	33.3	3	100.0
INSOMNIA	Reboxetine	2	66.7	1	33.3			3	100.0								
	Fluoxetine	1	50.0	1	50.0			2	100.0								
HYPOTENSION AND RELATED SYMPTOMS	Reboxetine	2	66.7			1	33.3	3	100.0								
	Fluoxetine			1	100.0			1	100.0								
HEADACHE / MIGRAINE	Reboxetine	2	66.7	1	33.3			3	100.0								
	Fluoxetine			1	100.0			1	100.0								
NAUSEA AND RELATED SYMPTOMS	Reboxetine			2	100.0			2	100.0								
	Fluoxetine	1	50.0	1	50.0			2	100.0								
AGITATION / ANXIETY / NERVOUSNESS	Reboxetine			1	100.0			1	100.0								
	Fluoxetine	3	100.0					3	100.0								
CONSTIPATION	Reboxetine	2	100.0					2	100.0								
	Fluoxetine			1	100.0			1	100.0								
MOUTH DRY	Reboxetine	1	50.0	1	50.0			2	100.0								
DIARRHOEA	Reboxetine	1	100.0					1	100.0								
	Fluoxetine			1	100.0			1	100.0								
SUICIDE ATTEMPT	Reboxetine					1	100.0	1	100.0								
	Fluoxetine	1	100.0					1	100.0								
ERYTHEMA / RASH	Reboxetine	1	100.0					1	100.0								

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 54

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

Adverse events/Assigned treatment		Modified study drug								Temporarily interrupted							
		Disappeared								Riappeared							
		NO		YES		Not applicable		Total		NO		YES		Not applicable		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
ERYTHEMA / RASH	Fluoxetine	1	100.0					1	100.0								
URINARY HESITANCY / RETENTION	Reboxetine	1	50.0	1	50.0			2	100.0								
ASTHENIA / FATIGUE	Reboxetine	1	100.0					1	100.0								
FEVER	Reboxetine			1	100.0			1	100.0								
INFLUENZA-LIKE SYMPTOMS	Fluoxetine			1	100.0			1	100.0	1	100.0					1	100.0
MALAISE	Fluoxetine					1	100.0	1	100.0					1	100.0	1	100.0
PARAESTHESIA	Reboxetine	1	100.0					1	100.0								
ABDOMINAL PAIN	Reboxetine			1	100.0			1	100.0	1	100.0					1	100.0
ANOREXIA	Reboxetine			1	100.0			1	100.0								
INCREASED LIVER ENZYMES	Reboxetine	1	100.0					1	100.0								
TENDINITIS	Reboxetine	1	100.0					1	100.0								
SOMNOLENCE	Reboxetine	1	100.0					1	100.0								
BRONCHITIS	Fluoxetine			1	100.0			1	100.0								
PHARYNGITIS	Fluoxetine			1	100.0			1	100.0	1	100.0					1	100.0
PRURITUS	Reboxetine	1	100.0					1	100.0								

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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		Recovered with sequelae		Still present		Death		Missing		Total		Recovered		Recovered with sequelae		Still present		Death		Missing		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
All adverse events	Fluoxetine	10	58.8			7	41.2					17	100	105	64.4	1	0.6	34	20.9			23	14.1	163	100
	Reboxetine	11	36.7			19	63.3					30	100	105	55.0	1	0.5	51	26.7			34	17.8	191	100
HEADACHE / MIGRANE	Fluoxetine	1	100									1	100	21	77.8	1	3.7	2	7.4			3	11.1	27	100
	Reboxetine	2	66.7			1	33.3					3	100	14	73.7			3	15.8			2	10.5	19	100
NAUSEA AND RELATED SYMPTOMS	Fluoxetine	1	50.0			1	50.0					2	100	16	76.2			2	9.5			3	14.3	21	100
	Reboxetine	1	50.0			1	50.0					2	100	11	78.6			1	7.1			2	14.3	14	100
MOUTH DRY	Fluoxetine													2	25.0			3	37.5			3	37.5	8	100
	Reboxetine	1	50.0			1	50.0					2	100	8	32.0			12	48.0			5	20.0	25	100
HYPOTENSION AND RELATED SYMPTOMS	Fluoxetine	1	100									1	100	7	87.5							1	12.5	8	100
	Reboxetine					3	100					3	100	8	47.1	1	5.9	3	17.6			5	29.4	17	100
CONSTIPATION	Fluoxetine	1	100									1	100	5	83.3							1	16.7	6	100
	Reboxetine					2	100					2	100	9	56.3			6	37.5			1	6.3	16	100
INSOMNIA	Fluoxetine	1	50.0			1	50.0					2	100	4	44.4			4	44.4			1	11.1	9	100
	Reboxetine	1	33.3			2	66.7					3	100	2	25.0			4	50.0			2	25.0	8	100
SWEATING INCREASED	Fluoxetine													3	33.3			5	55.6			1	11.1	9	100
	Reboxetine													6	75.0			1	12.5			1	12.5	8	100
AGITATION / ANXIETY / NERVOUSNESS	Fluoxetine					3	100					3	100	4	50.0			4	50.0					8	100
	Reboxetine	1	100									1	100	1	50.0							1	50.0	2	100
URINARY HESITANCY / RETENTION	Fluoxetine																	1	100					1	100
	Reboxetine	1	50.0			1	50.0					2	100	8	80.0			1	10.0			1	10.0	10	100

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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		Recovered with sequelae		Still present		Death		Missing		Total		Recovered		Recovered with sequelae		Still present		Death		Missing		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
ASTHENIA / FATIGUE	Fluoxetine													4	80.0			1	20.0					5	100
	Reboxetine					1	100					1	100	3	100									3	100
TREMOR	Fluoxetine													4	80.0			1	20.0					5	100
	Reboxetine													3	75.0			1	25.0					4	100
INFLUENZA-LIKE SYMPTOMS	Fluoxetine	1	100									1	100	3	75.0							1	25.0	4	100
	Reboxetine																	2	66.7			1	33.3	3	100
DIARRHOEA	Fluoxetine	1	100									1	100	5	100									5	100
	Reboxetine					1	100					1	100												
BLURRED VISION	Fluoxetine													3	75.0			1	25.0					4	100
	Reboxetine													1	33.3			2	66.7					3	100
PARAESTHESIA	Fluoxetine													1	100									1	100
	Reboxetine					1	100					1	100	3	75.0							1	25.0	4	100
FLUSHING / HOT FLASHING	Fluoxetine													1	100									1	100
	Reboxetine													3	75.0			1	25.0					4	100
SOMNOLENCE	Fluoxetine													2	66.7							1	33.3	3	100
	Reboxetine					1	100					1	100					1	100					1	100
UPPER RESP TRACT INFECTION	Fluoxetine													2	66.7							1	33.3	3	100
	Reboxetine													1	50.0							1	50.0	2	100
PRURITUS	Fluoxetine													2	100									2	100
	Reboxetine					1	100					1	100					1	50.0			1	50.0	2	100

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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		Recovered with sequelae		Still present		Death		Missing		Total		Recovered		Recovered with sequelae		Still present		Death		Missing		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
FEVER	Fluoxetine													1	50.0							1	50.0	2	100
	Reboxetine	1	100									1	100	1	100									1	100
ABDOMINAL PAIN	Reboxetine	1	100									1	100	3	100									3	100
APPETITE INCREASED	Fluoxetine													3	75.0			1	25.0					4	100
RHINITIS	Fluoxetine													2	66.7							1	33.3	3	100
	Reboxetine																	1	100					1	100
VERTIGO	Reboxetine													3	100									3	100
HYPERCHOLESTEROL-AEMIA	Fluoxetine																	2	100					2	100
	Reboxetine																	1	100					1	100
BACK PAIN	Reboxetine													3	100									3	100
PHARYNGITIS	Fluoxetine	1	100									1	100					1	100					1	100
	Reboxetine																	1	100					1	100
ERYTHEMA / RASH	Fluoxetine					1	100					1	100												
	Reboxetine					1	100					1	100									1	100	1	100
URINARY TRACT INFECTION	Fluoxetine													1	50.0							1	50.0	2	100
	Reboxetine																					1	100	1	100
ALLERGIC REACTION	Fluoxetine																					1	100	1	100
	Reboxetine																	1	100					1	100
AEDEMA	Fluoxetine													1	100									1	100
	Reboxetine																					1	100	1	100

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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		Recovered with sequelae		Still present		Death		Missing		Total		Recovered		Recovered with sequelae		Still present		Death		Missing		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
HYPERTENSION	Fluoxetine													1	100									1	100
	Reboxetine																					1	100	1	100
PALPITATION	Reboxetine													1	50.0			1	50.0					2	100
HYPERTONIA	Fluoxetine													1	50.0			1	50.0					2	100
TINNITUS	Reboxetine													2	100									2	100
INCREASED LIVER ENZYMES	Reboxetine	1	100									1	100					1	100					1	100
MYALGIA	Fluoxetine													1	100									1	100
	Reboxetine													1	100									1	100
EUPHORIA	Reboxetine													1	50.0							1	50.0	2	100
SUICIDE ATTEMPT	Fluoxetine					1	100					1	100												
	Reboxetine	1	100									1	100												
ABSCESS	Reboxetine																					2	100	2	100
COUGHING	Fluoxetine																	1	100					1	100
	Reboxetine																	1	100					1	100
RESPIRATORY DISORDER	Reboxetine																	1	50.0			1	50.0	2	100
CYSTITIS	Fluoxetine																	1	100					1	100
	Reboxetine																	1	100					1	100
CONJUNCTIVITIS	Fluoxetine																	1	100					1	100
	Reboxetine													1	100									1	100

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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		Recovered with sequelae		Still present		Death		Missing		Total		Recovered		Recovered with sequelae		Still present		Death		Missing		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
HYPERPYREXIA	Reboxetine													1	100									1	100
MALAISE	Fluoxetine	1	100									1	100												
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	Fluoxetine																					1	100	1	100
CIRCULATORY FAILURE	Reboxetine													1	100									1	100
TACHYCARDIA	Reboxetine													1	100									1	100
HYPERKINESIA	Fluoxetine																	1	100					1	100
ANOREXIA	Reboxetine					1	100					1	100												
FLATULENCE	Fluoxetine													1	100									1	100
ANEMIA	Reboxetine																					1	100	1	100
HEPATITIS INFECTIOUS	Reboxetine																	1	100					1	100
HYPERURICAEMIA	Fluoxetine																	1	100					1	100
TENDINITIS	Reboxetine					1	100					1	100												
LIBIDO DECREASED	Reboxetine													1	100									1	100
PARONIRIA	Fluoxetine													1	100									1	100
BREAST FIBROADENOSIS	Reboxetine																	1	100					1	100
EJACULATION DISORDER	Reboxetine													1	100									1	100
IMPOTENCE	Fluoxetine													1	100									1	100

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 56

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

		Days of treatment																											
		0-7			8-14			15-21			22-28			29-35			36-42			43-49			50-56			> 56		
		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.	(*)	No Pt.	% on exp.	(*)	No Pt.	% on exp.	(*)
Adverse events	Assigned treatment																												
Pt exposed	Fluoxetine	89	100	1.62	85	100	2.00	83	100	1.69	82	100	1.57	78	100	1.70	73	100	1.56	71	100	1.71	69	100	1.59	13	100	1.33
	Reboxetine	79	100	2.42	75	100	2.50	74	100	2.30	74	100	2.22	72	100	2.27	66	100	2.26	63	100	2.21	59	100	2.00	15	100	1.88
MOUTH DRY	Fluoxetine	6	6.7	1.00	6	7.1	1.00	7	8.4	1.00	5	6.1	1.00	3	3.8	1.00	2	2.7	1.00	2	2.8	1.00	2	2.9	1.00	2	15.4	1.00
	Reboxetine	19	24.1	1.00	21	28.0	1.00	20	27.0	1.00	17	23.0	1.00	16	22.2	1.00	13	19.7	1.00	12	19.0	1.00	13	22.0	1.00	9	60.0	1.00
HEADACHE	Fluoxetine	8	9.0	1.00	15	17.6	1.00	9	10.8	1.00	7	8.5	1.00	4	5.1	1.00	7	9.6	1.00	3	4.2	1.00	2	2.9	1.00	1	7.7	1.00
	Reboxetine	7	8.9	1.00	7	9.3	1.00	8	10.8	1.00	4	5.4	1.00	6	8.3	1.00	5	7.6	1.00	3	4.8	1.00	4	6.8	1.00	2	13.3	1.00
CONSTIPATION	Fluoxetine	2	2.2	1.00	2	2.4	1.00	3	3.6	1.00	3	3.7	1.00	4	5.1	1.00	4	5.5	1.00	3	4.2	1.00	1	1.4	1.00			
	Reboxetine	14	17.7	1.00	14	18.7	1.00	11	14.9	1.00	8	10.8	1.12	7	9.7	1.00	7	10.6	1.00	7	11.1	1.00	6	10.2	1.00	3	20.0	1.00
INSOMNIA	Fluoxetine	2	2.2	1.00	5	5.9	1.00	6	7.2	1.00	6	7.3	1.00	7	9.0	1.00	5	6.8	1.00	5	7.0	1.00	4	5.8	1.00	1	7.7	1.00
	Reboxetine	5	6.3	1.00	6	8.0	1.00	6	8.1	1.00	9	12.2	1.00	8	11.1	1.00	8	12.1	1.00	7	11.1	1.00	6	10.2	1.00	2	13.3	1.00
SWEATING INCREASED	Fluoxetine	4	4.5	1.00	7	8.2	1.00	6	7.2	1.00	5	6.1	1.00	4	5.1	1.00	4	5.5	1.00	5	7.0	1.00	5	7.2	1.00	4	30.8	1.00
	Reboxetine	4	5.1	1.00	6	8.0	1.00	6	8.1	1.00	2	2.7	1.00	1	1.4	1.00												
DIZZINESS	Fluoxetine	3	3.4	1.00	5	5.9	1.00	2	2.4	1.00	2	2.4	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00						
	Reboxetine	7	8.9	1.00	8	10.7	1.00	7	9.5	1.00	4	5.4	1.00	5	6.9	1.00	6	9.1	1.00	5	7.9	1.00	4	6.8	1.00	1	6.7	1.00
NAUSEA	Fluoxetine	6	6.7	1.00	6	7.1	1.33	5	6.0	1.00	2	2.4	1.00	1	1.3	1.00	2	2.7	1.00	2	2.8	1.00	1	1.4	1.00			
	Reboxetine	8	10.1	1.00	5	6.7	1.00	4	5.4	1.00	2	2.7	1.00	2	2.8	1.00	1	1.5	1.00									
TREMOR	Fluoxetine				1	1.2	1.00	3	3.6	1.00	3	3.7	1.00	2	2.6	1.00	3	4.1	1.00	4	5.6	1.00	2	2.9	1.00	1	7.7	1.00
	Reboxetine	2	2.5	1.00	2	2.7	1.00	2	2.7	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00	1	6.7	1.00
MICTURITION DISORDER	Fluoxetine	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00																		
	Reboxetine	7	8.9	1.00	5	6.7	1.00	2	2.7	1.00	2	2.7	1.00	1	1.4	1.00	2	3.0	1.00	2	3.2	1.00	1	1.7	1.00	1	6.7	1.00

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 56

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

		Days of treatment																														
		0-7			8-14			15-21			22-28			29-35			36-42			43-49			50-56			> 56							
		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.	(*)	No Pt.	% on exp.	(*)	No Pt.	% on exp.	(*)					
Adverse events	Assigned treatment																															
INFLUENZA-LIKE SYMPTOMS	Fluoxetine				1	1.2	1.00	1	1.2	1.00	3	3.7	1.00	4	5.1	1.00	3	4.1	1.00	3	4.2	1.00	1	1.4	1.00								
	Reboxetine				2	2.7	1.00	2	2.7	1.00	2	2.7	1.00	1	1.4	1.00							1	1.7	1.00	1	6.7	1.00					
VISION ABNORMAL	Fluoxetine	1	1.1	1.00	3	3.5	1.00	2	2.4	1.00	1	1.2	1.00							1	1.4	1.00	1	1.4	1.00	1	7.7	1.00					
	Reboxetine	3	3.8	1.00	3	4.0	1.00	2	2.7	1.00	2	2.7	1.00	2	2.8	1.00	1	1.5	1.00													
PARAESTHESIA	Fluoxetine				1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00										
	Reboxetine	5	6.3	1.00	4	5.3	1.00	2	2.7	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00								
FATIGUE	Fluoxetine	2	2.2	1.00	2	2.4	1.00	1	1.2	1.00	1	1.2	1.00	1	1.3	1.00	1	1.4	1.00				1	1.4	1.00								
	Reboxetine	3	3.8	1.00	3	4.0	1.00	2	2.7	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00										
PRURITUS	Fluoxetine	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	2	2.6	1.00	1	1.4	1.00													
	Reboxetine	1	1.3	1.00	1	1.3	1.00	2	2.7	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	2	3.2	1.00	2	3.4	1.00	2	13.3	1.00					
AGITATION	Fluoxetine	3	3.4	1.00	2	2.4	1.00	4	4.8	1.00	3	3.7	1.00	2	2.6	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00								
	Reboxetine																1	1.5	1.00	1	1.6	1.00	1	1.7	1.00								
SOMNOLENCE	Fluoxetine	1	1.1	1.00	1	1.2	1.00				1	1.2	1.00	1	1.3	1.00	2	2.7	1.00	2	2.8	1.00	1	1.4	1.00								
	Reboxetine	1	1.3	1.00	1	1.3	1.00							1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00								
HOT FLUSHES	Fluoxetine				1	1.2	1.00	1	1.2	1.00																						
	Reboxetine	1	1.3	1.00	1	1.3	1.00	1	1.4	1.00	2	2.7	1.00	2	2.8	1.00	2	3.0	1.00	2	3.2	1.00	1	1.7	1.00								
DYSPEPSIA	Fluoxetine	2	2.2	1.00	1	1.2	1.00	1	1.2	1.00	3	3.7	1.00	1	1.3	1.00																
	Reboxetine	1	1.3	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00																
NERVOUSNESS	Fluoxetine				2	2.4	1.00	2	2.4	1.00				1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	7.7	1.00				
	Reboxetine							1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00													

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 56

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

		Days of treatment																											
		0-7			8-14			15-21			22-28			29-35			36-42			43-49			50-56			> 56		
		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.	(*)	No Pt.	% on exp.	(*)	No Pt.	% on exp.	(*)
Adverse events	Assigned treatment																												
UPPER RESP TRACT INFECTION	Fluoxetine	1	1.1	1.00	1	1.2	1.00	2	2.4	1.00	2	2.4	1.00	1	1.3	1.00	1	1.4	1.00										
	Reboxetine													1	1.4	1.00	1	1.5	1.00	1	1.6	1.00							
APPETITE INCREASED	Fluoxetine				2	2.4	1.00	2	2.4	1.00	1	1.2	1.00	1	1.3	1.00	1	1.4	1.00	2	2.8	1.00	1	1.4	1.00			
ABSCESS	Reboxetine				2	2.7	1.00	2	2.7	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00	1	6.7	1.00
DIARRHOEA	Fluoxetine	3	3.4	1.00	1	1.2	1.00							2	2.6	1.00	1	1.4	1.00									
	Reboxetine	1	1.3	1.00	1	1.3	1.00																					
CONJUNCTIVITIS	Fluoxetine	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00						
	Reboxetine										1	1.4	1.00	1	1.4	1.00												
TASTE PERVERSION	Reboxetine	1	1.3	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00	1	6.7	1.00
HYPERTONIA	Fluoxetine	1	1.1	1.00	2	2.4	1.00	1	1.2	1.00	1	1.2	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00						
HYPERTENSION	Fluoxetine	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00															
	Reboxetine										1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00						
VOMITING	Fluoxetine	1	1.1	1.00										1	1.3	1.00												
	Reboxetine	2	2.5	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00												
RHINITIS	Fluoxetine	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	1	1.3	1.00	1	1.4	1.00									
	Reboxetine																						1	1.7	1.00	1	6.7	1.00
ABDOMINAL PAIN	Reboxetine	1	1.3	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	3	4.2	1.00	1	1.5	1.00									
GASTRITIS	Fluoxetine				1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	1	1.3	1.00												

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 56

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

		Days of treatment																											
		0-7			8-14			15-21			22-28			29-35			36-42			43-49			50-56			> 56		
		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.	(*)	No Pt.	% on exp.	(*)	No Pt.	% on exp.	(*)
Adverse events	Assigned treatment																												
GASTRITIS	Reboxetine										1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00						
BREAST FIBROADENOSIS	Reboxetine				1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00	1	6.7	1.00
PHARYNGITIS	Fluoxetine										1	1.2	1.00	1	1.3	1.00				1	1.4	1.00	1	1.4	1.00	1	7.7	1.00
	Reboxetine							1	1.4	1.00	1	1.4	1.00	1	1.4	1.00												
URINARY RETENTION	Reboxetine	1	1.3	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	2	3.0	1.00									
PALPITATION	Reboxetine	1	1.3	1.00				1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00			
FEVER	Fluoxetine							1	1.2	1.00	1	1.2	1.00							1	1.4	1.00	1	1.4	1.00			
	Reboxetine	1	1.3	1.00	1	1.3	1.00	1	1.4	1.00																		
BACK PAIN	Reboxetine				2	2.7	1.00	3	4.1	1.00	2	2.7	1.00															
CYSTITIS	Fluoxetine																						1	1.4	1.00			
	Reboxetine							1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00			
HEPATIC ENZYMES INCREASED	Reboxetine										1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	2	3.2	1.00	1	1.7	1.00	1	6.7	1.00
ALLERGIC REACTION	Fluoxetine																1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	7.7	1.00
	Reboxetine																			1	1.6	1.00	1	1.7	1.00	1	6.7	1.00
FLUSHING	Reboxetine	1	1.3	1.00	1	1.3	1.00	1	1.4	1.00										1	1.6	1.00	1	1.7	1.00	1	6.7	1.00
RESPIRATORY DISORDER	Reboxetine	1	1.3	1.00	1	1.3	1.00							1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00			
EUPHORIA	Reboxetine	1	1.3	1.00	1	1.3	2.00	1	1.4	1.00	1	1.4	1.00															

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 56

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

		Days of treatment																														
		0-7			8-14			15-21			22-28			29-35			36-42			43-49			50-56			> 56							
		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.	(*)	No Pt.	% on exp.	(*)	No Pt.	% on exp.	(*)					
Adverse events	Assigned treatment																															
URINARY TRACT INFECTION	Fluoxetine				1	1.2	1.00				1	1.2	1.00																			
	Reboxetine	1	1.3	1.00	1	1.3	1.00	1	1.4	1.00																						
EPISTAXIS	Reboxetine				1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00													
HYPERURICAEMIA	Fluoxetine										1	1.2	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00							
COUGHING	Fluoxetine																			1	1.4	1.00	1	1.4	1.00	1	7.7	1.00				
	Reboxetine																						1	1.7	1.00	1	6.7	1.00				
OTITIS MEDIA	Fluoxetine				1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	1	1.3	1.00																
ANXIETY	Fluoxetine							1	1.2	1.00	1	1.2	1.00	1	1.3	1.00																
	Reboxetine				1	1.3	1.00																									
HYPERKINESIA	Fluoxetine													1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00							
CHEST PAIN PRECORDIAL	Fluoxetine													1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00							
RASH	Reboxetine	1	1.3	1.00	1	1.3	1.00							1	1.4	1.00																
MYALGIA	Fluoxetine				1	1.2	1.00	1	1.2	1.00																						
	Reboxetine	1	1.3	1.00																												
VERTIGO	Reboxetine	1	1.3	1.00				1	1.4	1.00				1	1.4	1.00																
TINNITUS	Reboxetine	2	2.5	1.00	1	1.3	1.00																									
HYPOTENSION POSTURAL	Reboxetine										1	1.4	1.00	1	1.4	1.00	1	1.5	1.00													
IMPOTENCE	Fluoxetine													1	1.3	1.00	1	1.4	1.00	1	1.4	1.00										

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 56

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

		Days of treatment																											
		0-7			8-14			15-21			22-28			29-35			36-42			43-49			50-56			> 56		
		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.	(*)	No Pt.	% on exp.	(*)	No Pt.	% on exp.	(*)
Adverse events	Assigned treatment																												
OEDEMA LEGS	Reboxetine													1	1.4	1.00	1	1.5	1.00	1	1.6	1.00							
HYPOTENSION	Fluoxetine																			1	1.4	1.00							
	Reboxetine																						1	1.7	1.00	1	6.7	1.00	
TENDINITIS	Reboxetine																			1	1.6	1.00	1	1.7	1.00	1	6.7	1.00	
ANOREXIA	Reboxetine																			1	1.6	1.00	1	1.7	1.00	1	6.7	1.00	
HYPERCHOLEST-EROLAEMIA	Fluoxetine																						1	1.4	1.00	1	7.7	1.00	
	Reboxetine																						1	1.7	1.00				
INFECTION VIRAL	Fluoxetine	1	1.1	1.00	1	1.2	1.00																						
XEROPHTHALMIA	Reboxetine	1	1.3	1.00	1	1.3	1.00																						
LIBIDO DECREASED	Reboxetine	1	1.3	1.00	1	1.3	1.00																						
SPERMATORRHO-EA	Reboxetine	1	1.3	1.00	1	1.3	1.00																						
ASTHENIA	Fluoxetine				1	1.2	1.00	1	1.2	1.00																				
OEDEMA GENERALISED	Fluoxetine							1	1.2	1.00	1	1.2	1.00																
SUICIDE ATTEMPT	Fluoxetine										1	1.2	1.00																
	Reboxetine													1	1.4	1.00													
FLATULENCE	Fluoxetine										1	1.2	1.00	1	1.3	1.00													
RASH MACULO-PAPULAR	Fluoxetine													1	1.3	1.00	1	1.4	1.00										

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 56

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

		Days of treatment																											
		0-7			8-14			15-21			22-28			29-35			36-42			43-49			50-56			> 56		
		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.	(*)	No Pt.	% on exp.	(*)	No Pt.	% on exp.	(*)
Adverse events	Assigned treatment																												
PARONIRIA	Fluoxetine																			1	1.4	1.00	1	1.4	1.00			
ANAEMIA	Reboxetine																			1	1.6	1.00	1	1.7	1.00			
SINUSITIS	Fluoxetine																						1	1.4	1.00	1	7.7	1.00
HYPERPYREXIA	Reboxetine	1	1.3	1.00																								
CIRCULATORY FAILURE	Reboxetine				1	1.3	1.00																					
EJACULATION DISORDER	Reboxetine				1	1.3	1.00																					
MIGRAINE	Reboxetine							1	1.4	1.00																		
RENAL PAIN	Fluoxetine										1	1.2	1.00															
MALAISE	Fluoxetine										1	1.2	1.00															
ALOPECIA	Reboxetine										1	1.4	1.00															
BRONCHITIS	Fluoxetine													1	1.3	1.00												
TACHYCARDIA	Reboxetine													1	1.4	1.00												
HEPATITIS INFECTIOUS	Reboxetine																									1	6.7	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 57

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

Body system: AUTONOMIC NERVOUS SYSTEM DISORDERS

Adverse events/Assigned treatment		Days of treatment																											
		0-7			8-14			15-21			22-28			29-35			36-42			43-49			50-56			> 56		
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)
MOUTH DRY	Fluoxetine	6	6.7	1.00	6	7.1	1.00	7	8.4	1.00	5	6.1	1.00	3	3.8	1.00	2	2.7	1.00	2	2.8	1.00	2	2.9	1.00	2	15.4	1.00
	Reboxetine	19	24.1	1.00	21	28.0	1.00	20	27.0	1.00	17	23.0	1.00	16	22.2	1.00	13	19.7	1.00	12	19.0	1.00	13	22.0	1.00	9	60.0	1.00
SWEATING INCREASED	Fluoxetine	4	4.5	1.00	7	8.2	1.00	6	7.2	1.00	5	6.1	1.00	4	5.1	1.00	4	5.5	1.00	5	7.0	1.00	5	7.2	1.00	4	30.8	1.00
	Reboxetine	4	5.1	1.00	6	8.0	1.00	6	8.1	1.00	2	2.7	1.00	1	1.4	1.00												

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 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			43-49			50-56			> 56							
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)					
INFLUENZA-LIKE SYMPTOMS	Fluoxetine				1	1.2	1.00	1	1.2	1.00	3	3.7	1.00	4	5.1	1.00	3	4.1	1.00	3	4.2	1.00	1	1.4	1.00								
	Reboxetine				2	2.7	1.00	2	2.7	1.00	2	2.7	1.00	1	1.4	1.00							1	1.7	1.00	1	6.7	1.00					
ASTHENIA / FATIGUE	Fluoxetine	2	2.2	1.00	3	3.5	1.00	2	2.4	1.00	1	1.2	1.00	1	1.3	1.00	1	1.4	1.00				1	1.4	1.00								
	Reboxetine	3	3.8	1.00	3	4.0	1.00	2	2.7	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00										
FEVER	Fluoxetine							1	1.2	1.00	1	1.2	1.00							1	1.4	1.00	1	1.4	1.00							
	Reboxetine	1	1.3	1.00	1	1.3	1.00	1	1.4	1.00																						
ALLERGIC REACTION	Fluoxetine																1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	7.7	1.00				
	Reboxetine																			1	1.6	1.00	1	1.7	1.00	1	6.7	1.00				
HYPERPYREXIA	Reboxetine	1	1.3	1.00																												
MALAISE	Fluoxetine										1	1.2	1.00																			

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56		
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)
HYPOTENSION AND RELATED SYMPTOMS	Fluoxetine	3	3.4	1.00	5	5.9	1.00	2	2.4	1.00	2	2.4	1.00	1	1.3	1.00	1	1.4	1.00	2	2.8	1.00						
	Reboxetine	7	8.9	1.00	8	10.7	1.00	7	9.5	1.00	5	6.8	1.00	6	8.3	1.00	7	10.6	1.00	5	7.9	1.00	5	8.5	1.00	2	13.3	1.00
FLUSHING / HOT FLASHING	Fluoxetine				1	1.2	1.00	1	1.2	1.00																		
	Reboxetine	2	2.5	1.00	2	2.7	1.00	2	2.7	1.00	2	2.7	1.00	2	2.8	1.00	2	3.0	1.00	3	4.8	1.00	2	3.4	1.00	1	6.7	1.00
HYPERTENSION	Fluoxetine	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00															
	Reboxetine										1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00						
PALPITATION	Reboxetine	1	1.3	1.00				1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00			
AEDEMA	Fluoxetine							1	1.2	1.00	1	1.2	1.00															
	Reboxetine													1	1.4	1.00	1	1.5	1.00	1	1.6	1.00						
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	Fluoxetine													1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00			
CIRCULATORY FAILURE	Reboxetine				1	1.3	1.00																					
TACHYCARDIA	Reboxetine													1	1.4	1.00												

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56							
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)					
HEADACHE / MIGRANE	Fluoxetine	8	9.0	1.00	15	17.6	1.00	9	10.8	1.00	7	8.5	1.00	4	5.1	1.00	7	9.6	1.00	3	4.2	1.00	2	2.9	1.00	1	7.7	1.00					
	Reboxetine	7	8.9	1.00	7	9.3	1.00	9	12.2	1.00	4	5.4	1.00	6	8.3	1.00	5	7.6	1.00	3	4.8	1.00	4	6.8	1.00	2	13.3	1.00					
TREMOR	Fluoxetine				1	1.2	1.00	3	3.6	1.00	3	3.7	1.00	2	2.6	1.00	3	4.1	1.00	4	5.6	1.00	2	2.9	1.00	1	7.7	1.00					
	Reboxetine	2	2.5	1.00	2	2.7	1.00	2	2.7	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00	1	6.7	1.00					
PARAESTHESIA	Fluoxetine				1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00										
	Reboxetine	5	6.3	1.00	4	5.3	1.00	2	2.7	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00								
HYPERTONIA	Fluoxetine	1	1.1	1.00	2	2.4	1.00	1	1.2	1.00	1	1.2	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00										
HYPERKINESIA	Fluoxetine													1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00							
VERTIGO	Reboxetine	1	1.3	1.00				1	1.4	1.00				1	1.4	1.00																

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56							
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)					
CONSTIPATION	Fluoxetine	2	2.2	1.00	2	2.4	1.00	3	3.6	1.00	3	3.7	1.00	4	5.1	1.00	4	5.5	1.00	3	4.2	1.00	1	1.4	1.00							
	Reboxetine	14	17.7	1.00	14	18.7	1.00	11	14.9	1.00	8	10.8	1.12	7	9.7	1.00	7	10.6	1.00	7	11.1	1.00	6	10.2	1.00	3	20.0	1.00				
NAUSEA AND RELATED SYMPTOMS	Fluoxetine	9	10.1	1.00	8	9.4	1.25	7	8.4	1.00	6	7.3	1.00	4	5.1	1.00	2	2.7	1.00	2	2.8	1.00	1	1.4	1.00							
	Reboxetine	10	12.7	1.10	6	8.0	1.16	6	8.1	1.00	5	6.8	1.00	5	6.9	1.00	2	3.0	1.00	1	1.6	1.00										
APPETITE INCREASED	Fluoxetine				2	2.4	1.00	2	2.4	1.00	1	1.2	1.00	1	1.3	1.00	1	1.4	1.00	2	2.8	1.00	1	1.4	1.00							
DIARRHOEA	Fluoxetine	3	3.4	1.00	1	1.2	1.00							2	2.6	1.00	1	1.4	1.00													
	Reboxetine	1	1.3	1.00	1	1.3	1.00																									
ABDOMINAL PAIN	Reboxetine	1	1.3	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	3	4.2	1.00	1	1.5	1.00													
ANOREXIA	Reboxetine																			1	1.6	1.00	1	1.7	1.00	1	6.7	1.00				
FLATULENCE	Fluoxetine										1	1.2	1.00	1	1.3	1.00																

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56							
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)					
TINNITUS	Reboxetine	2	2.5	1.00	1	1.3	1.00																									

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56		
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)
ANEMIA	Reboxetine																			1	1.6	1.00	1	1.7	1.00			

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 57

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

Body system: LIVER AND BILIAR SYSTEM DISORDERS

Adverse events/Assigned treatment		Days of treatment																											
		0-7			8-14			15-21			22-28			29-35			36-42			43-49			50-56			> 56		
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)
INCREASED LIVER ENZYMES	Reboxetine										1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	2	3.2	1.00	1	1.7	1.00	1	6.7	1.00
HEPATITIS INFECTIOUS	Reboxetine																									1	6.7	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56		
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)
HYPERURICAEMIA	Fluoxetine										1	1.2	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00			
HYPERCHOLESTEROLAEMIA	Fluoxetine																						1	1.4	1.00	1	7.7	1.00
	Reboxetine																						1	1.7	1.00			

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 57

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

Body system: MUSCOLO-SKELETAL SYSTEM DISORDERS

Adverse events/Assigned treatment		Days of treatment																														
		0-7			8-14			15-21			22-28			29-35			36-42			43-49			50-56			> 56							
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)					
BACK PAIN	Reboxetine				2	2.7	1.00	3	4.1	1.00	2	2.7	1.00																			
MYALGIA	Fluoxetine				1	1.2	1.00	1	1.2	1.00																						
	Reboxetine	1	1.3	1.00																												
TENDINITIS	Reboxetine																			1	1.6	1.00	1	1.7	1.00	1	6.7	1.00				

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56							
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)					
INSOMNIA	Fluoxetine	2	2.2	1.00	5	5.9	1.00	6	7.2	1.00	6	7.3	1.00	7	9.0	1.00	5	6.8	1.00	5	7.0	1.00	4	5.8	1.00	1	7.7	1.00					
	Reboxetine	5	6.3	1.00	6	8.0	1.00	6	8.1	1.00	9	12.2	1.00	8	11.1	1.00	8	12.1	1.00	7	11.1	1.00	6	10.2	1.00	2	13.3	1.00					
AGITATION / ANXIETY / NERVOUSNESS	Fluoxetine	3	3.4	1.00	4	4.7	1.00	7	8.4	1.00	4	4.9	1.00	3	3.8	1.33	2	2.7	1.00	2	2.8	1.00	2	2.9	1.00	1	7.7	1.00					
	Reboxetine				1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	2	3.0	1.00	1	1.6	1.00	1	1.7	1.00								
SOMNOLENCE	Fluoxetine	1	1.1	1.00	1	1.2	1.00				1	1.2	1.00	1	1.3	1.00	2	2.7	1.00	2	2.8	1.00	1	1.4	1.00								
	Reboxetine	1	1.3	1.00	1	1.3	1.00							1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00								
EUPHORIA	Reboxetine	1	1.3	1.00	1	1.3	2.00	1	1.4	1.00	1	1.4	1.00																				
LIBIDO DECREASED	Reboxetine	1	1.3	1.00	1	1.3	1.00																										
SUICIDE ATTEMPT	Fluoxetine										1	1.2	1.00																				
	Reboxetine													1	1.4	1.00																	
PARONIRIA	Fluoxetine																			1	1.4	1.00	1	1.4	1.00								

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56		
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)
BREAST FIBROADENOSIS	Reboxetine				1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00	1	6.7	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 57

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

Body system: REPRODUCTIVE DISORDERS, MALE

Adverse events/Assigned treatment		Days of treatment																											
		0-7			8-14			15-21			22-28			29-35			36-42			43-49			50-56			> 56		
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)
IMPOTENCE	Fluoxetine													1	1.3	1.00	1	1.4	1.00	1	1.4	1.00						
SPERMATORRHOEA	Reboxetine	1	1.3	1.00	1	1.3	1.00																					
EJACULATION DISORDER	Reboxetine				1	1.3	1.00																					

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 57

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

Body system: RESISTANCE MECHANISM DISORDERS

Adverse events/Assigned treatment		Days of treatment																														
		0-7			8-14			15-21			22-28			29-35			36-42			43-49			50-56			> 56							
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)					
ABSCESS	Reboxetine				2	2.7	1.00	2	2.7	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00	1	6.7	1.00					
OTITIS MEDIA	Fluoxetine				1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	1	1.3	1.00																
INFECTION VIRAL	Fluoxetine	1	1.1	1.00	1	1.2	1.00																									

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56		
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)
UPPER RESP TRACT INFECTION	Fluoxetine	1	1.1	1.00	1	1.2	1.00	2	2.4	1.00	2	2.4	1.00	1	1.3	1.00	1	1.4	1.00									
	Reboxetine													1	1.4	1.00	1	1.5	1.00	1	1.6	1.00						
RHINITIS	Fluoxetine	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	1	1.3	1.00	1	1.4	1.00									
	Reboxetine																						1	1.7	1.00	1	6.7	1.00
PHARYNGITIS	Fluoxetine										1	1.2	1.00	1	1.3	1.00				1	1.4	1.00	1	1.4	1.00	1	7.7	1.00
	Reboxetine							1	1.4	1.00	1	1.4	1.00	1	1.4	1.00												
RESPIRATORY DISORDER	Reboxetine	1	1.3	1.00	1	1.3	1.00							1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00			
EPISTAXIS	Reboxetine				1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00									
COUGHING	Fluoxetine																			1	1.4	1.00	1	1.4	1.00	1	7.7	1.00
	Reboxetine																						1	1.7	1.00	1	6.7	1.00
SINUSITIS	Fluoxetine																						1	1.4	1.00	1	7.7	1.00
BRONCHITIS	Fluoxetine													1	1.3	1.00												

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56							
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)					
PRURITUS	Fluoxetine	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	2	2.6	1.00	1	1.4	1.00													
	Reboxetine	1	1.3	1.00	1	1.3	1.00	2	2.7	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	2	3.2	1.00	2	3.4	1.00	2	13.3	1.00				
ERYTHEMA / RASH	Fluoxetine													1	1.3	1.00	1	1.4	1.00													
	Reboxetine	1	1.3	1.00	1	1.3	1.00							1	1.4	1.00																
ALOPECIA	Reboxetine										1	1.4	1.00																			

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56		
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)
TASTE PERVERSION	Reboxetine	1	1.3	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00	1	6.7	1.00

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56		
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)
URINARY HESITANCY / RETENTION	Fluoxetine	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00																			
	Reboxetine	8	10.1	1.00	6	8.0	1.00	3	4.1	1.00	3	4.1	1.00	2	2.8	1.00	4	6.1	1.00	2	3.2	1.00	1	1.7	1.00	1	6.7	1.00
CYSTITIS	Fluoxetine																						1	1.4	1.00			
	Reboxetine							1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00			
URINARY TRACT INFECTION	Fluoxetine				1	1.2	1.00				1	1.2	1.00															
	Reboxetine	1	1.3	1.00	1	1.3	1.00	1	1.4	1.00																		
RENAL PAIN	Fluoxetine										1	1.2	1.00															

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 57

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

Body system: VISION DISORDERS

Adverse events/Assigned treatment		Days of treatment																														
		0-7			8-14			15-21			22-28			29-35			36-42			43-49			50-56			> 56							
		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.	(*)	No Pt	% on exp.	(*)	No Pt	% on exp.	(*)					
BLURRED VISION	Fluoxetine	1	1.1	1.00	3	3.5	1.00	2	2.4	1.00	1	1.2	1.00							1	1.4	1.00	1	1.4	1.00	1	7.7	1.00				
	Reboxetine	3	3.8	1.00	3	4.0	1.00	2	2.7	1.00	2	2.7	1.00	2	2.8	1.00	1	1.5	1.00													
CONJUNCTIVITIS	Fluoxetine	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00										
	Reboxetine										1	1.4	1.00	1	1.4	1.00																
XEROPHTHALMIA	Reboxetine	1	1.3	1.00	1	1.3	1.00																									

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56		
		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	(*)	No Pt	% on exp	(*)	No Pt	% on exp	(*)
Body system	Assigned treatment																												
Pt exposed	Fluoxetine	89	100	1.62	85	100	2.00	83	100	1.69	82	100	1.57	78	100	1.70	73	100	1.56	71	100	1.71	69	100	1.59	13	100	1.33
	Reboxetine	79	100	2.42	75	100	2.50	74	100	2.30	74	100	2.22	72	100	2.27	66	100	2.26	63	100	2.21	59	100	2.00	15	100	1.88
AUTONOMIC NERVOUS SYSTEM DISORDERS	Fluoxetine	9	10.1	1.11	11	12.9	1.18	11	13.3	1.18	10	12.2	1.00	7	9.0	1.00	6	8.2	1.00	7	9.9	1.00	7	10.1	1.00	6	46.2	1.00
	Reboxetine	21	26.6	1.09	24	32.0	1.12	23	31.1	1.13	18	24.3	1.05	16	22.2	1.06	13	19.7	1.00	12	19.0	1.08	13	22.0	1.00	9	60.0	1.00
GASTRO-INTESTINAL SYSTEM DISORDERS	Fluoxetine	12	13.5	1.16	9	10.6	1.66	11	13.3	1.09	10	12.2	1.10	10	12.8	1.20	7	9.6	1.14	6	8.5	1.16	3	4.3	1.00			
	Reboxetine	24	30.4	1.12	21	28.0	1.09	17	23.0	1.05	14	18.9	1.07	13	18.1	1.15	9	13.6	1.11	8	12.7	1.12	6	10.2	1.16	3	20.0	1.33
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO	Fluoxetine	9	10.1	1.00	17	20.0	1.11	12	14.5	1.16	11	13.4	1.09	8	10.3	1.12	10	13.7	1.30	7	9.9	1.42	5	7.2	1.00	2	15.4	1.00
	Reboxetine	12	15.2	1.25	13	17.3	1.00	14	18.9	1.00	6	8.1	1.00	9	12.5	1.00	7	10.6	1.00	5	7.9	1.00	6	10.2	1.00	3	20.0	1.00
PSYCHIATRIC DISORDERS	Fluoxetine	6	6.7	1.00	9	10.6	1.11	13	15.7	1.00	12	14.6	1.00	10	12.8	1.20	9	12.3	1.00	9	12.7	1.11	7	10.1	1.14	2	15.4	1.00
	Reboxetine	8	10.1	1.00	10	13.3	1.10	8	10.8	1.00	11	14.9	1.00	10	13.9	1.10	10	15.2	1.10	8	12.7	1.12	7	11.9	1.14	2	13.3	1.00
CARDIOVASCULAR DISORDERS, GENERAL	Fluoxetine	4	4.5	1.00	7	8.2	1.00	5	6.0	1.00	4	4.9	1.00	2	2.6	1.00	2	2.7	1.00	3	4.2	1.00	1	1.4	1.00			
	Reboxetine	10	12.7	1.00	11	14.7	1.00	10	13.5	1.00	9	12.2	1.00	10	13.9	1.20	10	15.2	1.20	8	12.7	1.37	7	11.9	1.14	3	20.0	1.00
BODY AS A WHOLE-GENERAL DISORDERS	Fluoxetine	2	2.2	1.00	4	4.7	1.00	4	4.8	1.00	6	7.3	1.00	4	5.1	1.25	4	5.5	1.25	5	7.0	1.00	4	5.8	1.00	1	7.7	1.00
	Reboxetine	5	6.3	1.00	5	6.7	1.20	4	5.4	1.25	3	4.1	1.00	2	2.8	1.00	1	1.5	1.00	2	3.2	1.00	2	3.4	1.00	2	13.3	1.00
RESPIRATORY SYSTEM DISORDERS	Fluoxetine	2	2.2	1.00	2	2.4	1.00	3	3.6	1.00	4	4.9	1.00	4	5.1	1.00	2	2.7	1.00	1	1.4	2.00	2	2.9	1.50	2	15.4	1.50
	Reboxetine	1	1.3	1.00	2	2.7	1.00	2	2.7	1.00	2	2.7	1.00	4	5.6	1.00	3	4.5	1.00	2	3.2	1.00	2	3.4	1.50	1	6.7	2.00
URINARY SYSTEM DISORDERS	Fluoxetine	1	1.1	1.00	2	2.4	1.00	1	1.2	1.00	2	2.4	1.00										1	1.4	1.00			
	Reboxetine	9	11.4	1.00	7	9.3	1.00	5	6.8	1.00	4	5.4	1.00	3	4.2	1.00	5	7.6	1.00	3	4.8	1.00	2	3.4	1.00	1	6.7	1.00

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56							
		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	(*)	No Pt	% on exp	(*)	No Pt	% on exp	(*)					
Body system	Assigned treatment																															
VISION DISORDERS	Fluoxetine	2	2.2	1.00	4	4.7	1.00	3	3.6	1.00	2	2.4	1.00	1	1.3	1.00	1	1.4	1.00	2	2.8	1.00	1	1.4	1.00	1	7.7	1.00					
	Reboxetine	4	5.1	1.00	4	5.3	1.00	2	2.7	1.00	3	4.1	1.00	3	4.2	1.00	1	1.5	1.00													
SKIN AND APPENDAGES DISORDERS	Fluoxetine	1	1.1	1.00	1	1.2	1.00	1	1.2	1.00	1	1.2	1.00	3	3.8	1.00	2	2.7	1.00													
	Reboxetine	2	2.5	1.00	2	2.7	1.00	2	2.7	1.00	2	2.7	1.00	2	2.8	1.00	1	1.5	1.00	2	3.2	1.00	2	3.4	1.00	2	13.3	1.00					
RESISTANCE MECHANISM DISORDERS	Fluoxetine	1	1.1	1.00	2	2.4	1.00	1	1.2	1.00	1	1.2	1.00	1	1.3	1.00																
	Reboxetine				2	2.7	1.00	2	2.7	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00	1	6.7	1.00					
MUSCOLO-SKELETAL SYSTEM DISORDERS	Fluoxetine				1	1.2	1.00	1	1.2	1.00																						
	Reboxetine	1	1.3	1.00	2	2.7	1.00	3	4.1	1.00	2	2.7	1.00							1	1.6	1.00	1	1.7	1.00	1	6.7	1.00					
SPECIAL SENSES OTHER, DISORDERS	Reboxetine	1	1.3	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00	1	6.7	1.00					
REPRODUCTIVE DISORDERS, FEMALE	Reboxetine				1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	1	1.6	1.00	1	1.7	1.00	1	6.7	1.00					
LIVER AND BILIAR SYSTEM DISORDERS	Reboxetine										1	1.4	1.00	1	1.4	1.00	1	1.5	1.00	2	3.2	1.00	1	1.7	1.00	2	13.3	1.00					
METABOLIC AND NUTRITIONAL DISORDERS	Fluoxetine										1	1.2	1.00	1	1.3	1.00	1	1.4	1.00	1	1.4	1.00	2	2.9	1.00	1	7.7	1.00					
	Reboxetine																						1	1.7	1.00								
REPRODUCTIVE DISORDERS, MALE	Fluoxetine													1	1.3	1.00	1	1.4	1.00	1	1.4	1.00										
	Reboxetine	1	1.3	1.00	2	2.7	1.00																									

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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			43-49			50-56			> 56		
		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	(*)	No Pt	% on exp	(*)	No Pt	% on exp	(*)
Body system	Assigned treatment																											
HEARING AND VESTIBULAR DISORDERS	Reboxetine	2	2.5	1.00	1	1.3	1.00																					
HEMATOLOGY DISORDERS	Reboxetine																			1	1.6	1.00	1	1.7	1.00			

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	%
Total adverse events	Reboxetine	1	0.5	63	28.5	79	35.7	35	15.8	19	8.6	19	8.6	5	2.3	221	100.0
	Fluoxetine	5	2.8	49	27.2	56	31.1	31	17.2	18	10.0	14	7.8	7	3.9	180	100.0
HEADACHE / MIGRANE	Reboxetine	1	4.5	4	18.2	6	27.3	7	31.8			4	18.2			22	100.0
	Fluoxetine			6	21.4	10	35.7	10	35.7			1	3.6	1	3.6	28	100.0
NAUSEA AND RELATED SYMPTOMS	Reboxetine			5	31.3	7	43.8	3	18.8					1	6.3	16	100.0
	Fluoxetine			13	56.5	5	21.7	2	8.7			2	8.7	1	4.3	23	100.0
MOUTH DRY	Reboxetine			9	33.3	15	55.6	1	3.7			1	3.7	1	3.7	27	100.0
	Fluoxetine	1	12.5	1	12.5	5	62.5	1	12.5							8	100.0
HYPOTENSION AND RELATED SYMPTOMS	Reboxetine			8	40.0	8	40.0	3	15.0			1	5.0			20	100.0
	Fluoxetine			2	22.2	6	66.7	1	11.1							9	100.0
CONSTIPATION	Reboxetine			6	33.3	7	38.9	4	22.2	1	5.6					18	100.0
	Fluoxetine			5	71.4	1	14.3	1	14.3							7	100.0
INSOMNIA	Reboxetine			4	36.4	3	27.3	1	9.1	2	18.2	1	9.1			11	100.0
	Fluoxetine	1	9.1	4	36.4	4	36.4	1	9.1					1	9.1	11	100.0
SWEATING INCREASED	Reboxetine			5	62.5	2	25.0	1	12.5							8	100.0
	Fluoxetine			2	22.2	6	66.7	1	11.1							9	100.0
AGITATION / ANXIETY / NERVOUSNESS	Reboxetine			2	66.7			1	33.3							3	100.0
	Fluoxetine	1	9.1	1	9.1	7	63.6	2	18.2							11	100.0
URINARY HESITANCY / RETENTION	Reboxetine			5	41.7	5	41.7	1	8.3			1	8.3			12	100.0
	Fluoxetine			1	100.0											1	100.0
TREMOR	Reboxetine			1	25.0	2	50.0	1	25.0							4	100.0
	Fluoxetine			3	60.0	1	20.0					1	20.0			5	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	%
ASTHENIA / FATIGUE	Reboxetine					4	100.0									4	100.0
	Fluoxetine					2	40.0	2	40.0	1	20.0					5	100.0
INFLUENZA-LIKE SYMPTOMS	Reboxetine									2	66.7	1	33.3			3	100.0
	Fluoxetine							2	40.0	3	60.0					5	100.0
DIARRHOEA	Reboxetine									1	100.0					1	100.0
	Fluoxetine			1	16.7	2	33.3	2	33.3			1	16.7			6	100.0
BLURRED VISION	Reboxetine			2	66.7	1	33.3									3	100.0
	Fluoxetine			1	25.0	2	50.0					1	25.0			4	100.0
PARAESTHESIA	Reboxetine			1	20.0			3	60.0			1	20.0			5	100.0
	Fluoxetine					1	100.0									1	100.0
FLUSHING / HOT FLASHING	Reboxetine			1	25.0	3	75.0									4	100.0
	Fluoxetine			1	100.0											1	100.0
SOMNOLENCE	Reboxetine					2	100.0									2	100.0
	Fluoxetine			3	100.0											3	100.0
PRURITUS	Reboxetine			1	33.3	1	33.3	1	33.3							3	100.0
	Fluoxetine					2	100.0									2	100.0
UPPER RESP TRACT INFECTION	Reboxetine									2	100.0					2	100.0
	Fluoxetine									1	33.3	1	33.3	1	33.3	3	100.0
APPETITE INCREASED	Fluoxetine			2	50.0							2	50.0			4	100.0
FEVER	Reboxetine					1	50.0					1	50.0			2	100.0
	Fluoxetine											2	100.0			2	100.0
ABDOMINAL PAIN	Reboxetine					1	25.0	2	50.0			1	25.0			4	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	%
RHINITIS	Reboxetine									1	100.0					1	100.0
	Fluoxetine									3	100.0					3	100.0
VERTIGO	Reboxetine			1	33.3					2	66.7					3	100.0
BACK PAIN	Reboxetine			1	33.3					1	33.3	1	33.3			3	100.0
ERYTHEMA / RASH	Reboxetine					2	100.0									2	100.0
	Fluoxetine			1	100.0											1	100.0
HYPERCHOLESTEROLAEMIA	Reboxetine											1	100.0			1	100.0
	Fluoxetine					1	50.0					1	50.0			2	100.0
PHARYNGITIS	Reboxetine											1	100.0			1	100.0
	Fluoxetine									2	100.0					2	100.0
URINARY TRACT INFECTION	Reboxetine													1	100.0	1	100.0
	Fluoxetine									1	50.0			1	50.0	2	100.0
HYPERTONIA	Fluoxetine	1	50.0							1	50.0					2	100.0
AEDEMA	Reboxetine											1	100.0			1	100.0
	Fluoxetine			1	100.0											1	100.0
TINNITUS	Reboxetine			2	100.0											2	100.0
EUPHORIA	Reboxetine			2	100.0											2	100.0
PALPITATION	Reboxetine					1	50.0	1	50.0							2	100.0
INCREASED LIVER ENZYMES	Reboxetine					1	50.0					1	50.0			2	100.0
RESPIRATORY DISORDER	Reboxetine					1	50.0	1	50.0							2	100.0
MYALGIA	Reboxetine							1	100.0							1	100.0
	Fluoxetine							1	100.0							1	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	%
SUICIDE ATTEMPT	Reboxetine											1	100.0			1	100.0
	Fluoxetine							1	100.0							1	100.0
CONJUNCTIVITIS	Reboxetine									1	100.0					1	100.0
	Fluoxetine							1	100.0							1	100.0
ALLERGIC REACTION	Reboxetine									1	100.0					1	100.0
	Fluoxetine													1	100.0	1	100.0
COUGHING	Reboxetine									1	100.0					1	100.0
	Fluoxetine									1	100.0					1	100.0
CYSTITIS	Reboxetine									1	100.0					1	100.0
	Fluoxetine									1	100.0					1	100.0
HYPERTENSION	Reboxetine											1	100.0			1	100.0
	Fluoxetine											1	100.0			1	100.0
ABSCESS	Reboxetine													2	100.0	2	100.0
FLATULENCE	Fluoxetine	1	100.0													1	100.0
CIRCULATORY FAILURE	Reboxetine			1	100.0											1	100.0
IMPOTENCE	Fluoxetine			1	100.0											1	100.0
TASTE PERVERSION	Reboxetine			1	100.0											1	100.0
XEROPHTHALMIA	Reboxetine			1	100.0											1	100.0
TACHYCARDIA	Reboxetine					1	100.0									1	100.0
ANOREXIA	Reboxetine					1	100.0									1	100.0
ANEMIA	Reboxetine					1	100.0									1	100.0
LIBIDO DECREASED	Reboxetine					1	100.0									1	100.0

(CONTINUED)

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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.	%
EJACULATION DISORDER	Reboxetine					1	100.0									1	100.0
BRONCHITIS	Fluoxetine					1	100.0									1	100.0
EPISTAXIS	Reboxetine					1	100.0									1	100.0
HYPERPYREXIA	Reboxetine							1	100.0							1	100.0
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	Fluoxetine							1	100.0							1	100.0
HYPERKINESIA	Fluoxetine							1	100.0							1	100.0
PARONIRIA	Fluoxetine							1	100.0							1	100.0
SPERMATORRHOEA	Reboxetine							1	100.0							1	100.0
ALOPECIA	Reboxetine							1	100.0							1	100.0
MALAISE	Fluoxetine									1	100.0					1	100.0
HEPATITIS INFECTIOUS	Reboxetine									1	100.0					1	100.0
HYPERURICAEMIA	Fluoxetine									1	100.0					1	100.0
TENDINITIS	Reboxetine									1	100.0					1	100.0
BREAST FIBROADENOSIS	Reboxetine									1	100.0					1	100.0
INFECTION VIRAL	Fluoxetine									1	100.0					1	100.0
OTITIS MEDIA	Fluoxetine									1	100.0					1	100.0
RENAL PAIN	Fluoxetine											1	100.0			1	100.0
SINUSITIS	Fluoxetine													1	100.0	1	100.0

(some adverse events are grouped in cluster)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 60

340

ADVERSE EVENTS(*) PRESENT AT LAST DAY OF TREATMENT AND THEIR RELATIONSHIP TO STUDY MEDICATION
(ONLY PATIENTS WHO WITHDREW FROM THE STUDY FOR ADVERSE EVENTS)

				Relationship							Total
				Probable	Definite	Possible	Doubtful	None	Unknown	Missing	
All adverse events		Ass. treatment									
		Reboxetine		5		11	3	1	3	2	25
		Fluoxetine		4		6	2			1	13
Centre - Patient	Days of Treatment	Adverse events	Ass. treatment								
1 - 4 (Female)	42	INSOMNIA	Reboxetine	1							1
		HEPATIC ENZYMES INCREASED	Reboxetine			1					1
1 - 6 (Male)	29	GASTRITIS	Fluoxetine				1				1
2 - 34 (Male)	41	URINARY RETENTION	Reboxetine	1							1
		MOUTH DRY	Reboxetine	1							1
2 - 37 (Male)	4	HEADACHE	Reboxetine	1							1
		NAUSEA	Reboxetine	1							1
		FEVER	Reboxetine			1					1
3 - 66 (Female)	28	MOUTH DRY	Fluoxetine			1					1
		SWEATING INCREASED	Fluoxetine			1					1
		SUICIDE ATTEMPT	Fluoxetine				1				1
4 - 104 (Female)	49	INSOMNIA	Reboxetine			1					1
		PARAESTHESIA	Reboxetine				1				1
5 - 129 (Female)	31	MOUTH DRY	Reboxetine							1	1
		VOMITING	Reboxetine			1					1
7 - 196 (Female)	49	HEPATIC ENZYMES INCREASED	Reboxetine						1		1
		DIZZINESS	Reboxetine						1		1

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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)

				Relationship							
				Probable	Definite	Possible	Doubtful	None	Unknown	Missing	Total
Centre - Patient	Days of Treatment	Adverse events	Ass. treatment								
7 - 196 (Female)	49	CONSTIPATION	Reboxetine				1				1
		HEPATITIS INFECTIOUS	Reboxetine					1			1
11 - 335 (Female)	35	SUICIDE ATTEMPT	Reboxetine						1		1
		DIZZINESS	Reboxetine				1				1
12 - 396 (Female)	14	NAUSEA	Fluoxetine	1							1
		AGITATION	Fluoxetine			1					1
		MICTURITION DISORDER	Fluoxetine	1							1
13 - 387 (Female)	31	RASH	Reboxetine			1					1
		DYSPEPSIA	Reboxetine							1	1
13 - 391 (Female)	35	RASH MACULO-PAPULAR	Fluoxetine	1							1
		UPPER RESP TRACT INFECTION	Fluoxetine							1	1
13 - 503 (Female)	7	MOUTH DRY	Reboxetine			1					1
		DIZZINESS	Reboxetine			1					1
		CONSTIPATION	Reboxetine			1					1
		MICTURITION DISORDER	Reboxetine			1					1
		SOMNOLENCE	Reboxetine			1					1
		FATIGUE	Reboxetine			1					1
16 - 438 (Female)	30	VOMITING	Fluoxetine			1					1
		DIARRHOEA	Fluoxetine			1					1

(CONTINUED)

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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)

				Relationship							
				Probable	Definite	Possible	Doubtful	None	Unknown	Missing	Total
Centre - Patient	Days of Treatment	Adverse events	Ass. treatment								
16 - 438 (Female)	30	BRONCHITIS	Fluoxetine			1					1
20 - 22 (Female)	35	INSOMNIA	Fluoxetine	1							1

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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
HB	Evaluated	82	78	68	70	68	57
	Mean	14.22	14.18	14.15	13.91	14.11	14.08
	STD	1.42	1.43	1.50	1.61	2.35	1.41
	Min	11.20	10.93	11.36	9.28	10.80	10.67
	Max	18.60	18.50	18.30	19.50	29.00	18.00
	Median	14.10	13.90	14.10	13.69	13.80	14.10
	Median diff.		-0.04	0.00		-0.05	0.00
	P value		0.8059	0.3622		0.4687	0.4016
HT	Evaluated	81	78	67	70	68	57
	Mean	43.01	43.00	43.08	42.31	42.44	43.25
	STD	5.83	5.47	6.03	6.36	5.88	6.08
	Min	27.25	24.75	34.75	27.25	32.00	30.29
	Max	60.20	58.76	60.20	64.28	65.48	62.60
	Median	42.00	42.00	41.50	41.05	42.00	42.00
	Median diff.		0.00	-0.80		0.00	0.22
	P value		0.6915	0.3516		0.7094	0.4657
RBC	Evaluated	81	78	67	70	68	57
	Mean	4.92	4.89	4.96	4.89	4.92	5.03
	STD	0.77	0.75	0.88	0.84	0.86	0.82
	Min	3.81	3.77	3.88	3.58	3.20	3.75
	Max	7.02	7.07	7.53	8.21	8.49	8.00

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
RBC	Median	4.69	4.71	4.67	4.65	4.74	4.84
	Median diff.		0.00	-0.07		0.02	0.02
	P value		0.9087	0.2851		0.5086	0.3230
PLATELETS	Evaluated	81	77	67	70	68	57
	Mean	285.06	280.33	287.21	284.50	300.06	306.06
	STD	89.55	81.70	80.41	73.65	77.93	71.12
	Min	168.33	-20.00	168.97	110.00	165.00	176.67
	Max	755.00	657.50	742.50	493.33	696.67	590.00
	Median	262.50	266.67	283.33	270.50	283.33	298.00
	Median diff.		7.50	1.00		4.25	10.83
	P value		0.6377	0.6139		0.2460	0.0544

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
WBC	Evaluated	81	78	67	70	68	57
	Mean	7.84	7.56	7.67	7.47	7.50	7.38
	STD	2.71	1.86	1.95	2.24	1.94	1.92
	Min	3.96	3.53	3.57	4.27	4.21	4.59
	Max	23.19	12.60	14.09	16.36	15.39	14.41
	Median	7.64	7.44	7.53	7.18	7.56	7.24
	Median diff.		-0.09	0.04		0.16	-0.16
	P value		0.4023	0.8846		0.3690	0.5727
WBC: N	Evaluated	80	77	66	69	65	56
	Mean	63.27	62.77	63.45	63.12	63.03	63.30
	STD	3.99	3.86	3.55	4.07	4.88	4.30
	Min	54.33	53.50	55.96	53.29	46.50	51.00
	Max	72.33	72.50	71.00	71.67	75.00	71.00
	Median	63.00	63.00	63.67	63.00	62.33	63.58
	Median diff.		-0.50	-0.50		-0.48	-0.79
	P value		0.4559	0.5801		0.4898	0.2226
WBC: E	Evaluated	76	73	62	66	62	53
	Mean	1.62	1.53	1.71	1.70	1.73	1.53
	STD	0.97	0.79	0.79	1.06	1.08	0.92
	Min	-1.00	-1.00	0.00	-1.00	-1.00	-1.00
	Max	5.00	4.33	5.00	5.67	7.00	3.40

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
WBC: E	Median	1.51	1.50	1.59	1.51	1.57	1.57
	Median diff.		0.00	0.00		0.00	0.00
	P value		0.4118	0.8152		0.9037	0.2816
WBC: B	Evaluated	76	73	62	66	62	53
	Mean	0.19	0.16	0.14	0.13	0.19	0.13
	STD	0.26	0.24	0.23	0.19	0.30	0.21
	Min	0.00	0.00	0.00	0.00	0.00	0.00
	Max	0.83	0.75	1.20	0.75	1.28	0.75
	Median	0.00	0.00	0.00	0.00	0.00	0.00
	Median diff.		0.00	0.00		0.00	0.00
	P value		0.5602	0.2352		0.0682	0.2036
WBC: L	Evaluated	81	78	66	70	66	57
	Mean	26.88	26.85	26.60	27.15	27.12	26.93
	STD	4.82	5.12	4.15	4.76	5.88	4.90
	Min	14.00	11.00	14.00	17.00	12.00	19.67
	Max	42.00	39.67	38.00	44.00	45.67	49.00
	Median	26.93	26.64	27.00	26.26	26.36	26.57
	Median diff.		-0.05	-0.44		0.67	1.00
	P value		0.7357	0.9515		0.4112	0.3252
WBC: M	Evaluated	77	74	64	68	64	55
	Mean	4.68	4.83	4.77	4.56	4.40	4.39

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
WBC: M	STD	1.23	1.29	1.29	1.54	1.46	1.27
	Min	1.00	1.40	1.00	-1.00	-1.00	1.00
	Max	7.90	8.00	8.75	7.67	7.67	7.67
	Median	4.60	4.98	4.60	4.60	4.59	4.60
	Median diff.		0.48	0.00		0.00	0.00
	P value		0.2516	0.3913		0.3388	0.5538

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
CREATININE	Evaluated	82	78	67	71	69	59
	Mean	0.86	0.85	0.83	0.83	0.82	0.83
	STD	0.14	0.16	0.14	0.21	0.20	0.20
	Min	0.57	0.54	0.58	-0.19	-0.16	0.54
	Max	1.38	1.48	1.30	1.40	1.40	1.45
	Median	0.84	0.87	0.83	0.84	0.83	0.84
	Median diff.		0.00	0.00		-0.01	-0.03
	P value		0.5017	0.1165		0.2562	0.3301
UREA	Evaluated	43	41	39	40	39	39
	Mean	27.63	25.89	26.90	28.23	28.30	26.74
	STD	7.20	5.96	6.46	6.70	6.48	4.86
	Min	14.60	15.00	15.00	15.40	13.80	16.14
	Max	41.40	36.60	46.20	44.60	49.00	39.80
	Median	27.80	25.40	27.00	26.80	27.80	27.00
	Median diff.		-1.60	-0.40		0.00	-1.20
	P value		0.0492	0.3138		0.9470	0.4408
BUN	Evaluated	31	30	23	25	24	18
	Mean	12.56	11.62	13.14	10.72	10.84	10.28
	STD	3.09	2.10	2.78	3.31	3.25	3.32
	Min	7.55	7.55	8.47	4.80	3.10	4.25
	Max	18.00	14.89	19.10	17.08	16.53	15.85

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
BUN	Median	11.79	12.03	12.98	11.13	11.21	11.07
	Median diff.		-0.96	0.48		0.11	-0.84
	P value		0.0855	0.2935		0.7348	0.4749
URIC ACID	Evaluated	78	74	64	66	64	56
	Mean	4.61	4.48	4.41	4.46	4.47	4.49
	STD	1.23	1.06	1.07	1.32	1.21	1.11
	Min	2.48	2.99	2.70	1.54	2.08	2.23
	Max	9.63	7.30	7.51	7.55	8.36	7.41
	Median	4.33	4.21	4.15	4.31	4.45	4.56
	Median diff.		-0.10	-0.10		-0.04	-0.10
	P value		0.1052	0.2108		0.6784	0.3755

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
TOT. PROTEINS	Evaluated	79	74	64	69	66	57
	Mean	7.24	7.27	7.22	7.22	7.27	7.24
	STD	0.62	0.62	0.45	0.57	0.49	0.48
	Min	4.50	5.18	6.15	6.01	6.40	6.23
	Max	8.49	8.95	8.38	8.89	8.90	9.49
	Median	7.29	7.35	7.19	7.18	7.19	7.20
	Median diff.		0.00	-0.10		0.00	0.00
	P value		0.9638	0.5722		0.6136	0.5699
ALBUMINE	Evaluated	76	71	63	64	61	56
	Mean	4.27	4.25	4.17	4.14	4.14	4.11
	STD	0.50	0.59	0.49	0.52	0.58	0.47
	Min	3.00	2.44	3.13	3.10	2.19	3.38
	Max	5.20	5.54	5.33	5.31	5.94	5.56
	Median	4.30	4.29	4.19	4.10	4.13	4.01
	Median diff.		0.00	-0.03		0.06	0.00
	P value		0.9899	0.3776		0.5280	0.7012
TOT BILIRUBIN	Evaluated	78	74	63	68	66	56
	Mean	0.63	0.66	0.60	0.64	0.64	0.63
	STD	0.19	0.17	0.15	0.22	0.21	0.15
	Min	0.20	0.20	0.28	0.20	0.20	0.26
	Max	1.20	1.09	0.84	1.53	1.60	1.09

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
TOT BILIRUBIN	Median	0.63	0.68	0.62	0.64	0.64	0.61
	Median diff.		0.00	0.00		0.00	-0.00
	P value		0.0220	0.5508		0.7329	0.2626
DIR BILIRUBIN	Evaluated	40	37	37	35	33	35
	Mean	0.12	0.12	0.11	0.11	0.11	0.11
	STD	0.04	0.04	0.04	0.04	0.04	0.04
	Min	0.04	0.04	0.03	0.00	0.03	0.00
	Max	0.20	0.25	0.20	0.20	0.20	0.17
	Median	0.12	0.12	0.10	0.12	0.10	0.12
	Median diff.		0.00	0.00		0.00	0.00
	P value		0.8241	0.1008		0.8856	0.9583

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
SGOT	Evaluated	81	77	65	69	67	56
	Mean	21.99	21.59	22.04	22.43	24.11	34.22
	STD	7.09	5.85	5.83	9.12	17.67	72.76
	Min	8.00	10.00	11.33	8.46	11.33	12.00
	Max	53.75	42.00	45.00	60.00	153.75	538.00
	Median	20.00	21.67	21.67	20.29	20.29	21.67
	Median diff.		0.00	-1.14		0.57	0.00
	P value		0.7589	0.5040		0.7838	0.3371
SGPT	Evaluated	71	67	57	63	62	50
	Mean	21.17	19.08	19.19	19.85	21.74	46.05
	STD	14.05	8.99	8.20	11.40	27.13	151.01
	Min	5.00	1.67	1.67	3.21	2.50	5.00
	Max	103.53	51.43	38.82	65.71	219.29	1067.50
	Median	18.89	19.29	21.18	19.58	17.92	19.89
	Median diff.		0.00	0.00		-0.26	0.00
	P value		0.7513	0.5118		0.8599	0.5821
GAMMA GT	Evaluated	82	78	66	71	69	58
	Mean	36.54	29.34	28.46	26.94	26.51	35.37
	STD	28.77	16.90	21.05	16.90	18.07	46.08
	Min	8.00	8.00	9.83	8.00	9.45	9.45
	Max	173.00	120.61	166.17	81.89	122.67	318.86

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
GAMMA GT	Median	30.32	25.69	22.89	21.71	22.63	23.95
	Median diff.		-1.78	-3.69		0.00	-0.59
	P value		0.0013	0.0000		0.7737	0.7566
LDH	Evaluated	78	72	64	64	62	55
	Mean	310.90	317.90	309.57	300.76	307.01	317.84
	STD	62.76	92.67	72.10	76.39	70.95	74.68
	Min	192.50	203.70	183.75	128.10	159.25	166.95
	Max	445.20	878.50	594.30	572.25	548.10	504.00
	Median	313.25	309.75	301.44	292.29	302.63	301.35
	Median diff.		-12.23	-8.75		-8.75	3.50
	P value		0.2504	0.2839		0.6598	0.2588
ALK. PHOSPH.	Evaluated	80	76	63	68	64	57
	Mean	125.80	125.27	127.08	109.71	111.77	115.30
	STD	159.62	144.70	131.66	47.07	41.40	48.06
	Min	31.03	27.91	26.12	40.44	44.69	41.86
	Max	1497.21	1323.96	1114.54	294.07	257.43	274.13
	Median	105.15	108.61	106.79	106.28	109.45	110.86
	Median diff.		1.54	2.18		1.54	6.33
	P value		0.9653	0.6176		0.4682	0.2196

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
GLOBULINS ALPHA 1	Evaluated	56	49	45	44	43	39
	Mean	0.21	0.22	0.21	0.22	0.22	0.22
	STD	0.05	0.06	0.05	0.07	0.05	0.06
	Min	0.07	0.10	0.10	0.10	0.10	0.15
	Max	0.33	0.35	0.39	0.39	0.33	0.41
	Median	0.20	0.21	0.20	0.21	0.21	0.20
	Median diff.		0.00	0.00		0.00	0.00
	P value		0.4154	0.1760		0.5891	0.6994
GLOBULINS ALPHA 2	Evaluated	56	49	45	44	43	39
	Mean	0.85	0.88	0.86	0.82	0.85	0.82
	STD	0.12	0.14	0.11	0.17	0.15	0.16
	Min	0.59	0.62	0.59	0.23	0.28	0.20
	Max	1.09	1.26	1.13	1.16	1.23	1.15
	Median	0.85	0.85	0.87	0.83	0.85	0.81
	Median diff.		0.01	0.00		0.03	0.00
	P value		0.2266	0.0807		0.3532	0.8294
GLOBULINS BETA	Evaluated	56	49	45	44	43	39
	Mean	0.94	0.94	0.95	0.93	0.94	0.92
	STD	0.10	0.13	0.11	0.11	0.10	0.10
	Min	0.75	0.54	0.70	0.66	0.73	0.68
	Max	1.16	1.33	1.40	1.21	1.20	1.22

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
GLOBULINS BETA	Median	0.91	0.90	0.95	0.91	0.95	0.90
	Median diff.		0.00	0.01		0.00	0.00
	P value		0.5179	0.4268		0.6283	0.7667
GLOBULINS GAMMA	Evaluated	56	49	45	44	43	39
	Mean	1.24	1.25	1.32	1.28	1.34	1.37
	STD	0.41	0.38	0.39	0.40	0.40	0.37
	Min	0.13	0.16	0.23	0.21	0.22	0.57
	Max	1.84	1.79	1.96	1.82	2.30	1.84
	Median	1.22	1.36	1.36	1.27	1.28	1.40
	Median diff.		0.00	0.00		0.02	0.02
	P value		0.6728	0.4872		0.4283	0.1199

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
TOT. CHOLEST.	Evaluated	77	73	65	68	66	56
	Mean	253.34	247.92	256.10	253.04	240.27	247.36
	STD	64.58	62.90	71.93	74.70	59.08	66.01
	Min	108.65	103.96	129.38	99.98	142.06	122.12
	Max	438.13	435.04	595.12	504.97	430.40	435.37
	Median	259.88	239.00	246.50	239.41	239.06	239.00
	Median diff.		0.00	0.00		-10.15	-6.09
	P value		0.5897	0.8428		0.0550	0.2648
TRIGLYCERIDES	Evaluated	76	72	65	68	66	55
	Mean	129.19	124.77	141.38	130.07	121.11	135.38
	STD	83.18	74.68	140.30	92.22	93.35	79.74
	Min	-293.43	-199.43	-135.64	-70.06	-155.79	-0.34
	Max	383.42	357.86	1095.33	470.23	461.56	542.98
	Median	119.33	120.35	114.25	111.20	113.23	121.66
	Median diff.		0.00	-7.62		4.38	4.69
	P value		0.5557	0.0847		0.4725	0.3072
GLUCOSE	Evaluated	78	73	64	67	64	55
	Mean	87.07	88.36	85.21	88.64	90.01	90.12
	STD	12.05	16.83	14.22	20.77	28.56	27.59
	Min	63.88	58.63	25.20	63.00	64.75	57.40
	Max	128.33	195.13	129.57	237.67	299.53	271.05

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
GLUCOSE	Median	86.99	87.50	86.11	86.63	87.50	85.91
	Median diff.		0.00	-0.37		2.53	0.00
	P value		0.8941	0.5331		0.4987	0.8015

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
NA+	Evaluated	80	76	66	71	68	59
	Mean	140.19	139.64	140.26	140.53	140.47	141.03
	STD	2.61	3.55	3.63	3.05	2.71	2.47
	Min	132.67	118.22	129.33	126.00	132.00	136.00
	Max	146.53	145.00	150.62	147.00	147.00	148.22
	Median	140.00	140.11	140.50	141.00	141.00	141.00
	Median diff.		0.00	-0.12		0.00	0.00
	P value		0.6895	0.8364		0.7148	0.6274
CL-	Evaluated	70	67	54	61	60	53
	Mean	102.23	102.37	102.43	103.01	102.18	102.47
	STD	2.70	3.10	3.28	3.44	2.27	2.15
	Min	96.11	91.60	92.46	95.54	98.00	96.15
	Max	110.00	110.00	109.20	110.00	110.00	106.80
	Median	102.32	102.00	102.34	102.92	102.00	102.00
	Median diff.		0.00	0.80		-0.73	-0.80
	P value		0.6993	0.2651		0.0143	0.0265
K+	Evaluated	77	74	63	70	66	59
	Mean	4.29	4.43	4.37	4.28	4.42	4.33
	STD	0.42	0.56	0.49	0.41	0.47	0.47
	Min	3.18	3.27	3.50	3.14	2.86	2.27
	Max	5.26	7.66	6.06	5.42	5.26	5.21

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

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

Laboratory test		Assigned treatment					
		Fluoxetine			Reboxetine		
		Days of treatment			Days of treatment		
		Screen	1-28	29-56	Screen	1-28	29-56
K+	Median	4.30	4.38	4.30	4.30	4.41	4.30
	Median diff.		0.00	0.00		0.09	0.00
	P value		0.2274	0.7118		0.0190	0.3650
Ca++	Evaluated	80	76	66	69	65	57
	Mean	4.99	4.97	5.03	5.01	5.00	5.01
	STD	0.39	0.39	0.42	0.38	0.34	0.32
	Min	4.26	3.70	4.26	4.44	4.35	4.44
	Max	5.72	5.76	5.85	5.93	5.72	5.72
	Median	4.97	5.00	5.00	4.98	5.00	4.98
	Median diff.		0.00	0.00		0.00	0.00
	P value		0.8360	0.1610		0.4600	0.5318
PO4--	Evaluated	72	67	62	63	59	53
	Mean	1.33	1.31	1.35	1.27	1.30	1.30
	STD	0.25	0.15	0.34	0.13	0.14	0.15
	Min	1.04	1.03	0.87	1.00	0.94	0.85
	Max	3.18	1.71	3.65	1.63	1.72	1.54
	Median	1.30	1.30	1.33	1.25	1.30	1.31
	Median diff.		0.00	0.00		0.04	0.00
	P value		0.6857	0.8484		0.0299	0.4849

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 62

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

Assigned treatment: Reboxetine

Urinalysis		Days of treatment																	
		Screening						1-28 days						29-56 days					
		Female		Male		Total		Female		Male		Total		Female		Male		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
SPECIFIC GRAVITY	Normal	32	100.0	11	100.0	43	100.0	32	100.0	11	100.0	43	100.0	28	96.6	9	90.0	37	94.9
	Not done													1	3.4	1	10.0	2	5.1
	Total	32	100.0	11	100.0	43	100.0	32	100.0	11	100.0	43	100.0	29	100.0	10	100.0	39	100.0
ALBUMIN	Absent	44	100.0	15	88.2	59	96.7	42	95.5	16	94.1	58	95.1	34	91.9	13	86.7	47	90.4
	Present			2	11.8	2	3.3	1	2.3	1	5.9	2	3.3	2	5.4	1	6.7	3	5.8
	Not done							1	2.3			1	1.6	1	2.7	1	6.7	2	3.8
	Total	44	100.0	17	100.0	61	100.0	44	100.0	17	100.0	61	100.0	37	100.0	15	100.0	52	100.0
SUGAR	Absent	43	97.7	17	100.0	60	98.4	42	95.5	17	100.0	59	96.7	35	94.6	14	93.3	49	94.2
	Present	1	2.3			1	1.6	1	2.3			1	1.6	1	2.7			1	1.9
	Not done							1	2.3			1	1.6	1	2.7	1	6.7	2	3.8
	Total	44	100.0	17	100.0	61	100.0	44	100.0	17	100.0	61	100.0	37	100.0	15	100.0	52	100.0
RBC	Absent	37	84.1	11	73.3	48	81.4	36	81.8	12	80.0	48	81.4	33	89.2	8	61.5	41	82.0
	Present	7	15.9	4	26.7	11	18.6	6	13.6	2	13.3	8	13.6	3	8.1	2	15.4	5	10.0
	Not done							2	4.5	1	6.7	3	5.1	1	2.7	3	23.1	4	8.0
	Total	44	100.0	15	100.0	59	100.0	44	100.0	15	100.0	59	100.0	37	100.0	13	100.0	50	100.0
WBC	Absent	31	70.5	7	50.0	38	65.5	29	65.9	8	57.1	37	63.8	24	64.9	3	25.0	27	55.1
	Present	13	29.5	7	50.0	20	34.5	13	29.5	5	35.7	18	31.0	12	32.4	7	58.3	19	38.8
	Not done							2	4.5	1	7.1	3	5.2	1	2.7	2	16.7	3	6.1
	Total	44	100.0	14	100.0	58	100.0	44	100.0	14	100.0	58	100.0	37	100.0	12	100.0	49	100.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 62

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

Assigned treatment: Fluoxetine

Urinalysis		Days of treatment																	
		Screening						1-28 days						29-56 days					
		Female		Male		Total		Female		Male		Total		Female		Male		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
SPECIFIC GRAVITY	Normal	33	100.0	11	100.0	44	100.0	30	93.8	10	100.0	40	95.2	30	96.8	11	100.0	41	97.6
	Not done							2	6.3			2	4.8	1	3.2			1	2.4
	Total	33	100.0	11	100.0	44	100.0	32	100.0	10	100.0	42	100.0	31	100.0	11	100.0	42	100.0
ALBUMIN	Absent	45	90.0	16	100.0	61	92.4	43	87.8	15	100.0	58	90.6	39	86.7	14	100.0	53	89.8
	Present	5	10.0			5	7.6	2	4.1			2	3.1	3	6.7			3	5.1
	Not done							4	8.2			4	6.3	3	6.7			3	5.1
	Total	50	100.0	16	100.0	66	100.0	49	100.0	15	100.0	64	100.0	45	100.0	14	100.0	59	100.0
SUGAR	Absent	50	100.0	16	100.0	66	100.0	45	91.8	15	100.0	60	93.8	42	93.3	14	100.0	56	94.9
	Not done							4	8.2			4	6.3	3	6.7			3	5.1
	Total	50	100.0	16	100.0	66	100.0	49	100.0	15	100.0	64	100.0	45	100.0	14	100.0	59	100.0
RBC	Absent	44	88.0	16	94.1	60	89.6	39	79.6	15	93.8	54	83.1	34	73.9	12	85.7	46	76.7
	Present	6	12.0	1	5.9	7	10.4	4	8.2	1	6.3	5	7.7	9	19.6	2	14.3	11	18.3
	Not done							6	12.2			6	9.2	3	6.5			3	5.0
	Total	50	100.0	17	100.0	67	100.0	49	100.0	16	100.0	65	100.0	46	100.0	14	100.0	60	100.0
WBC	Absent	32	66.7	13	76.5	45	69.2	27	57.4	14	87.5	41	65.1	21	48.8	11	78.6	32	56.1
	Present	16	33.3	4	23.5	20	30.8	16	34.0	2	12.5	18	28.6	18	41.9	3	21.4	21	36.8
	Not done							4	8.5			4	6.3	4	9.3			4	7.0
	Total	48	100.0	17	100.0	65	100.0	47	100.0	16	100.0	63	100.0	43	100.0	14	100.0	57	100.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 63

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

Assigned treatment: Reboxetine

Urinalysis		Total						Last assessment											
								1-28 days						29-56 days					
		Female		Male		Total		Female		Male		Total		Female		Male		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
SPECIFIC GRAVITY	Normal	31	96.9	10	90.9	41	95.3	3	100.0	1	100.0	4	100.0	28	96.6	9	90.0	37	94.9
	Not done	1	3.1	1	9.1	2	4.7							1	3.4	1	10.0	2	5.1
	Total	32	100.0	11	100.0	43	100.0	3	100.0	1	100.0	4	100.0	29	100.0	10	100.0	39	100.0
ALBUMIN	Absent	41	93.2	15	88.2	56	91.8	7	100.0	2	100.0	9	100.0	34	91.9	13	86.7	47	90.4
	Present	2	4.5	1	5.9	3	4.9							2	5.4	1	6.7	3	5.8
	Not done	1	2.3	1	5.9	2	3.3							1	2.7	1	6.7	2	3.8
	Total	44	100.0	17	100.0	61	100.0	7	100.0	2	100.0	9	100.0	37	100.0	15	100.0	52	100.0
SUGAR	Absent	42	95.5	16	94.1	58	95.1	7	100.0	2	100.0	9	100.0	35	94.6	14	93.3	49	94.2
	Present	1	2.3			1	1.6							1	2.7			1	1.9
	Not done	1	2.3	1	5.9	2	3.3							1	2.7	1	6.7	2	3.8
	Total	44	100.0	17	100.0	61	100.0	7	100.0	2	100.0	9	100.0	37	100.0	15	100.0	52	100.0
RBC	Absent	39	88.6	10	66.7	49	83.1	6	85.7	2	100.0	8	88.9	33	89.2	8	61.5	41	82.0
	Present	4	9.1	2	13.3	6	10.2	1	14.3			1	11.1	3	8.1	2	15.4	5	10.0
	Not done	1	2.3	3	20.0	4	6.8							1	2.7	3	23.1	4	8.0
	Total	44	100.0	15	100.0	59	100.0	7	100.0	2	100.0	9	100.0	37	100.0	13	100.0	50	100.0
WBC	Absent	28	63.6	5	35.7	33	56.9	4	57.1	2	100.0	6	66.7	24	64.9	3	25.0	27	55.1
	Present	15	34.1	7	50.0	22	37.9	3	42.9			3	33.3	12	32.4	7	58.3	19	38.8
	Not done	1	2.3	2	14.3	3	5.2							1	2.7	2	16.7	3	6.1
	Total	44	100.0	14	100.0	58	100.0	7	100.0	2	100.0	9	100.0	37	100.0	12	100.0	49	100.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 63

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

Assigned treatment: Fluoxetine

Urinalysis		Total						Last assessment											
								1-28 days						29-56 days					
		Female		Male		Total		Female		Male		Total		Female		Male		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
SPECIFIC GRAVITY	Normal	32	97.0	11	100.0	43	97.7	2	100.0			2	100.0	30	96.8	11	100.0	41	97.6
	Not done	1	3.0			1	2.3							1	3.2			1	2.4
	Total	33	100.0	11	100.0	44	100.0	2	100.0			2	100.0	31	100.0	11	100.0	42	100.0
ALBUMIN	Absent	44	88.0	16	100.0	60	90.9	5	100.0	2	100.0	7	100.0	39	86.7	14	100.0	53	89.8
	Present	3	6.0			3	4.5							3	6.7			3	5.1
	Not done	3	6.0			3	4.5							3	6.7			3	5.1
	Total	50	100.0	16	100.0	66	100.0	5	100.0	2	100.0	7	100.0	45	100.0	14	100.0	59	100.0
SUGAR	Absent	47	94.0	16	100.0	63	95.5	5	100.0	2	100.0	7	100.0	42	93.3	14	100.0	56	94.9
	Not done	3	6.0			3	4.5							3	6.7			3	5.1
	Total	50	100.0	16	100.0	66	100.0	5	100.0	2	100.0	7	100.0	45	100.0	14	100.0	59	100.0
RBC	Absent	38	76.0	15	88.2	53	79.1	4	100.0	3	100.0	7	100.0	34	73.9	12	85.7	46	76.7
	Present	9	18.0	2	11.8	11	16.4							9	19.6	2	14.3	11	18.3
	Not done	3	6.0			3	4.5							3	6.5			3	5.0
	Total	50	100.0	17	100.0	67	100.0	4	100.0	3	100.0	7	100.0	46	100.0	14	100.0	60	100.0
WBC	Absent	23	47.9	14	82.4	37	56.9	2	40.0	3	100.0	5	62.5	21	48.8	11	78.6	32	56.1
	Present	21	43.8	3	17.6	24	36.9	3	60.0			3	37.5	18	41.9	3	21.4	21	36.8
	Not done	4	8.3			4	6.2							4	9.3			4	7.0
	Total	48	100.0	17	100.0	65	100.0	5	100.0	3	100.0	8	100.0	43	100.0	14	100.0	57	100.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 64

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT URINALYSIS VALUE AT EACH EVALUATION TIME AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Urinalysis test at baseline		Days of treatment							
		1-28 days				29-56 days			
		Absent	Present	Not done	Total	Absent	Present	Not done	Total
ALBUMIN	Absent	57	1	1	59	46	2	2	50
	Present	1	1		2	1	1		2
	Total	58	2	1	61	47	3	2	52
SUGAR	Absent	59		1	60	49		2	51
	Present		1		1		1		1
	Total	59	1	1	61	49	1	2	52
RBC	Absent	43	3	2	48	37	2	2	41
	Present	5	5	1	11	4	3	2	9
	Total	48	8	3	59	41	5	4	50
WBC	Absent	32	4	2	38	24	5	1	30
	Present	5	14	1	20	3	14	2	19
	Total	37	18	3	58	27	19	3	49

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 64

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT URINALYSIS VALUE AT EACH EVALUATION TIME AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Fluoxetine

Urinalysis test at baseline		Days of treatment							
		1-28 days				29-56 days			
		Absent	Present	Not done	Total	Absent	Present	Not done	Total
ALBUMIN	Absent	55		4	59	51	1	3	55
	Present	3	2		5	2	2		4
	Total	58	2	4	64	53	3	3	59
SUGAR	Absent	60		4	64	56		3	59
	Total	60		4	64	56		3	59
RBC	Absent	52	1	5	58	45	5	3	53
	Present	2	4	1	7	1	6		7
	Total	54	5	6	65	46	11	3	60
WBC	Absent	38	4	3	45	31	3	4	38
	Present	3	14	1	18	1	18		19
	Total	41	18	4	63	32	21	4	57

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 65

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

Assigned treatment: Reboxetine

Urinalysis test at baseline		Total				Last assessment						
						1-28 days			29-56 days			
		Absent	Present	Not done	Total	Absent	Present	Total	Absent	Present	Not done	Total
ALBUMIN	Absent	55	2	2	59	9		9	46	2	2	50
	Present	1	1		2				1	1		2
	Total	56	3	2	61	9		9	47	3	2	52
SUGAR	Absent	58		2	60	9		9	49		2	51
	Present		1		1					1		1
	Total	58	1	2	61	9		9	49	1	2	52
RBC	Absent	43	3	2	48	6	1	7	37	2	2	41
	Present	6	3	2	11	2		2	4	3	2	9
	Total	49	6	4	59	8	1	9	41	5	4	50
WBC	Absent	29	8	1	38	5	3	8	24	5	1	30
	Present	4	14	2	20	1		1	3	14	2	19
	Total	33	22	3	58	6	3	9	27	19	3	49

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 65

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

Assigned treatment: Fluoxetine

Urinalysis test at baseline		Total				Last assessment						
						1-28 days			29-56 days			
		Absent	Present	Not done	Total	Absent	Present	Total	Absent	Present	Not done	Total
ALBUMIN	Absent	57	1	3	61	6		6	51	1	3	55
	Present	3	2		5	1		1	2	2		4
	Total	60	3	3	66	7		7	53	3	3	59
SUGAR	Absent	63		3	66	7		7	56		3	59
	Total	63		3	66	7		7	56		3	59
RBC	Absent	52	5	3	60	7		7	45	5	3	53
	Present	1	6		7				1	6		7
	Total	53	11	3	67	7		7	46	11	3	60
WBC	Absent	36	5	4	45	5	2	7	31	3	4	38
	Present	1	19		20		1	1	1	18		19
	Total	37	24	4	65	5	3	8	32	21	4	57

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 66

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABNORMAL OR NORMAL URINALYSIS VALUE AT EACH EVALUATION TIME AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT (SPECIFIC GRAVITY)

Assigned treatment: Reboxetine

Urinalysis test at baseline		Days of treatment				
		1-28 days		29-56 days		
		Normal	Total	Normal	Not done	Total
SPECIFIC GRAVITY	Normal	43	43	37	2	39
	Total	43	43	37	2	39

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 66

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABNORMAL OR NORMAL URINALYSIS VALUE AT EACH EVALUATION TIME AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT (SPECIFIC GRAVITY)

Assigned treatment: Fluoxetine

Urinalysis test at baseline		Days of treatment					
		1-28 days			29-56 days		
		Normal	Not done	Total	Normal	Not done	Total
SPECIFIC GRAVITY	Normal	40	2	42	41	1	42
	Total	40	2	42	41	1	42

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 67

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABNORMAL OR NORMAL URINALYSIS VALUE AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT (SPECIFIC GRAVITY)

Assigned treatment: Reboxetine

Urinalysis test at baseline		Total			Last assessment					
					1-28 days			29-56 days		
		Normal	Not done	Total	Normal	Total	Normal	Not done	Total
SPECIFIC GRAVITY	Normal	41	2	43	4	4	37	2	39
	Total	41	2	43	4	4	37	2	39

PHARMACIA CORP R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 67

URINALYSIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABNORMAL OR NORMAL URINALYSIS VALUE AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT (SPECIFIC GRAVITY)

Assigned treatment: Fluoxetine

Urinalysis test at baseline		Total			Last assessment				
					1-28 days		29-56 days		
		Normal	Not done	Total	Normal	Total	Normal	Not done	Total
SPECIFIC GRAVITY	Normal	43	1	44	2	2	41	1	42
	Total	43	1	44	2	2	41	1	42

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 68

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

Laboratory test		Assigned treatment															
		Fluoxetine								Reboxetine							
		Days of treatment								Days of treatment							
		1-28				29-56				1-28				29-56			
		Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val
HB	LOW		2				3			2	1			1	2		
	NORMAL	2	71	2		5	57	2		3	58	1		1	49	1	
	HIGH			1	0.368			1	0.287		1	2	0.607		2	1	0.717
HT	LOW	1	2				2			3	4			2	5		
	NORMAL		66	2		4	50	4		2	52	1			40	4	
	HIGH		2	5	0.368		4	3	0.717		3	3	0.435		4	2	0.082
RBC	LOW	4	4			3	3			2	4			1	4		
	NORMAL	3	48	2		3	37	3		2	40	4		1	34	1	
	HIGH		2	15	0.931		3	15	1.000		1	15	0.291		1	15	0.407
PLATELETS	LOW										2				1		
	NORMAL	1	70	1			62				58	4			50	3	
	HIGH		2	3	0.513		3	2	0.250		2	2	0.264		2	1	0.549

P val : probability from Maxwell's test

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 68

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

Laboratory test		Assigned treatment															
		Fluoxetine								Reboxetine							
		Days of treatment								Days of treatment							
		1-28				29-56				1-28				29-56			
		Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val
WBC	LOW	2	1			2	1				1						
	NORMAL	1	64	2		1	56	1		3	59	1			53	1	
	HIGH		6	2	0.368		4	2	0.407		2	2	0.513		1	2	1.000
WBC: N	LOW	1	3				3			2	1			1			
	NORMAL	5	50	5		1	45	5		2	44	7		3	35	7	
	HIGH		11	2	0.253	1	7	4	0.607		2	7	0.211		7	3	0.223
WBC: E	LOW	4	3			2	2			2	1	1		2			
	NORMAL	1	61	1			54	1		2	50	1		2	43	1	
	HIGH	1	2		0.479		3		0.223		2	3	1.000		5		0.097
WBC: B	LOW																
	NORMAL		72				61	1			60	2			53		
	HIGH		1		1.000				1.000				0.500				1.000
WBC: L	LOW	4	7			3	6			5	3			2	5	1	
	NORMAL	6	50	4		5	44	3		6	42	4		4	42	1	
	HIGH		3	4	0.896		4	1	0.890	1	2	3	0.390		1	1	0.733
WBC: M	LOW		1	1			1			3	1			1	2		
	NORMAL	4	65			2	58	1		3	54	1		1	48	1	
	HIGH		1	2	0.695		2		0.717		2		0.513		2		0.717

P val : probability from Maxwell's test

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 68

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

Laboratory test		Assigned treatment															
		Fluoxetine								Reboxetine							
		Days of treatment								Days of treatment							
		1-28				29-56				1-28				29-56			
		Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val
CREATININE	LOW									1	1				2		
	NORMAL		77				65	1			63	1			52	2	
	HIGH			1	1.000			1	1.000		1	2	0.607		1	2	0.311
UREA	LOW		1														
	NORMAL		33				29	3		1	29	1			31		
	HIGH		6	1	0.030		7		0.344		6	2	0.102		7	1	0.016
BUN	LOW									1	2			2	1		
	NORMAL		30				22	1		2	19			1	14		
	HIGH				1.000				1.000				1.000				1.000
URIC ACID	LOW	1				1	1			2	1			1	1		
	NORMAL		64	3			57				56	1		2	46	2	
	HIGH		4	2	1.000		2	3	0.223		1	3	0.607		3	1	0.766

P val : probability from Maxwell's test

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 68

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

Laboratory test		Assigned treatment															
		Fluoxetine								Reboxetine							
		Days of treatment								Days of treatment							
		1-28				29-56				1-28				29-56			
		Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val
TOT. PROTEINS	LOW	3	3			3	1				3	1			2		
	NORMAL	3	59	4		2	56	1			61			2	52		
	HIGH		2		0.717		1		0.846		1		0.102			1	1.000
ALBUMINE	LOW	1	3			1	2			2	3				6		
	NORMAL	4	54	3		3	48	2		4	45	2		1	44	1	
	HIGH		3	3	0.931		4	3	0.648		3	2	0.842		4		0.068
TOT BILIRUBIN	LOW																
	NORMAL		72	1			62				63	2			55		
	HIGH		1		1.000		1		1.000		1		1.000			1	1.000
DIR BILIRUBIN	LOW																
	NORMAL		36	1			37				33				35		
	HIGH				1.000				1.000				1.000				1.000

P val : probability from Maxwell's test

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 68

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

Laboratory test		Assigned treatment															
		Fluoxetine								Reboxetine							
		Days of treatment								Days of treatment							
		1-28				29-56				1-28				29-56			
		Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val
SGOT	LOW		1								2				1		
	NORMAL		65	4			56	3			51	7			48	2	
	HIGH		6	1	0.497		5	1	0.727		5	2	0.311		3	2	0.549
SGPT	LOW										2				1		
	NORMAL	1	54	3		1	47	2		1	48	6			40	4	
	HIGH		7	2	0.273		5	2	0.319		3	2	0.513		3	2	0.565
GAMMA GT	LOW																
	NORMAL		54	1			46	1			57				45	2	
	HIGH		12	11	0.003		13	6	0.002		5	7	0.063		5	6	0.453
LDH	LOW	1					1				5			1	5		
	NORMAL	1	62	4		3	55	2		3	49	2			43	3	
	HIGH		3	1	0.565		2	1	0.607		2	1	0.779		2	1	0.074
ALK. PHOSPH.	LOW	3				2				3	4			2	4		
	NORMAL	1	65	1		2	54				49	1		1	40	4	
	HIGH		2	4	0.513		1	4	0.223		3	4	0.082		4	2	0.407

P val : probability from Maxwell's test

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 68

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

Laboratory test		Assigned treatment															
		Fluoxetine								Reboxetine							
		Days of treatment								Days of treatment							
		1-28				29-56				1-28				29-56			
		Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val
GLOBULINS ALPHA 1	LOW		1				1										
	NORMAL		46	1			42	1			39				36	1	
	HIGH		1		0.607			1	0.368		2	2	0.500		1	1	1.000
GLOBULINS ALPHA 2	LOW		1			1				1	1			1	1		
	NORMAL		40	4			39	2			35	2		1	31	1	
	HIGH		2	2	0.435		2	1	1.000		2	2	0.607		4		0.407
GLOBULINS BETA	LOW										1				1		
	NORMAL	1	44	1			41				37	2		1	34		
	HIGH		1	2	0.607		2	2	0.500		2	1	0.607		2	1	0.368
GLOBULINS GAMMA	LOW	4				3				4				3			
	NORMAL	1	30	2		1	25	3			22	6			22	3	
	HIGH		5	7	0.319		5	8	0.472		3	8	0.508		1	10	0.625

P val : probability from Maxwell's test

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 68

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

Laboratory test		Assigned treatment															
		Fluoxetine								Reboxetine							
		Days of treatment								Days of treatment							
		1-28				29-56				1-28				29-56			
		Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val
TOT. CHOLEST.	LOW	2				1					1			1			
	NORMAL		36	6			33	8		1	40	6		1	33	3	
	HIGH		12	17	0.238		5	18	0.581	1	7	10	0.765		6	12	0.368
TRIGLYCERI-DES	LOW	2	2				2			3	3			1	3		
	NORMAL	1	54	4		1	50	3			49	5			43	4	
	HIGH		7	2	0.562		6	3	0.513	1	3	2	0.598		1	3	0.091
GLUCOSE	LOW	1	2			2	1			1	2				2	1	
	NORMAL	4	58	3		3	54	2		3	54	2		2	44	4	
	HIGH		3	2	0.717		1	1	0.513		1	1	0.766		1	1	0.261

P val : probability from Maxwell's test

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 68

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

Laboratory test		Assigned treatment															
		Fluoxetine								Reboxetine							
		Days of treatment								Days of treatment							
		1-28				29-56				1-28				29-56			
		Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val
NA+	LOW		5			1	4				2				2		
	NORMAL	5	65			5	54	2		3	61	1			54	2	
	HIGH		1		0.607				0.348		1		0.905		1		0.311
CL-	LOW	2	2			1	1				3				3		
	NORMAL	1	54	4		4	41	5			48			1	40	1	
	HIGH		3	1	0.788		2		0.214		7	2	0.007		6	2	0.102
K+	LOW		4				2				1				1		
	NORMAL	1	65	3			57	3			61	3		1	55	1	
	HIGH		1		0.247		1		0.223	1			0.565		1		1.000
Ca++	LOW	3	4			3	4			1	1				2		
	NORMAL	4	55	3		3	45	4		4	51	2		2	46	1	
	HIGH		4	3	0.931		1	6	0.379		4	2	0.291		3	3	0.607
PO4--	LOW																
	NORMAL		58	4		2	51	4		1	54	2		3	45	1	
	HIGH		3	2	1.000		2	3	0.264		2		0.607		3	1	0.135

P val : probability from Maxwell's test

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 69

LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE

Laboratory test / Assigned treatment			Days of treatment					
			Screen		1-28		29-56	
			No	%	No	%	No	%
HT	Fluoxetine	Eval.	81	100.0	78	100.0	67	100.0
		down	1	1.2	1	1.3		
	Reboxetine	Eval.	70	100.0	68	100.0	57	100.0
		down	1	1.4				
RBC	Reboxetine	Eval.	70	100.0	68	100.0	57	100.0
		down			1	1.5		
PLATELETS	Fluoxetine	Eval.	81	100.0	77	100.0	67	100.0
		down			1	1.3		
		up	1	1.2	1	1.3	1	1.5
	Reboxetine	Eval.	70	100.0	68	100.0	57	100.0
		down	1	1.4				
		up			1	1.5	1	1.8
WBC	Fluoxetine	Eval.	81	100.0	78	100.0	67	100.0
		up	1	1.2				
	Reboxetine	Eval.	70	100.0	68	100.0	57	100.0
		up	2	2.9				
WBC: N	Reboxetine	Eval.	69	100.0	65	100.0	56	100.0
		down			1	1.5		
WBC: E	Fluoxetine	Eval.	76	100.0	73	100.0	62	100.0
		up	3	3.9	1	1.4	1	1.6
	Reboxetine	Eval.	66	100.0	62	100.0	53	100.0
		up	4	6.1	4	6.5		
WBC: B	Fluoxetine	Eval.	76	100.0	73	100.0	62	100.0

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 69

LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE

Laboratory test / Assigned treatment			Days of treatment					
			Screen		1-28		29-56	
			No	%	No	%	No	%
WBC: B	Fluoxetine	up					1	1.6
	Reboxetine	Eval.	66	100.0	62	100.0	58	100.0
		up			2	3.2		
WBC: L	Fluoxetine	Eval.	81	100.0	78	100.0	66	100.0
		down	1	1.2	2	2.6		
	Reboxetine	Eval.	70	100.0	66	100.0	57	100.0
		down	1	1.4	2	3.0	1	1.8
		up	1	1.4	2	3.0	1	1.8
WBC: M	Fluoxetine	Eval.	77	100.0	74	100.0	64	100.0
		up					1	1.6
URIC ACID	Fluoxetine	Eval.	78	100.0	74	100.0	64	100.0
		up	1	1.3				
SGOT	Reboxetine	Eval.	69	100.0	67	100.0	56	100.0
		up	1	1.4	1	1.5	2	3.6
SGPT	Fluoxetine	Eval.	71	100.0	67	100.0	57	100.0
		up	2	2.8				
	Reboxetine	Eval.	63	100.0	62	100.0	50	100.0
		up	1	1.6	1	1.6	2	4.0
GAMMA GT	Fluoxetine	Eval.	82	100.0	78	100.0	66	100.0
		up	4	4.9	1	1.3	1	1.5
	Reboxetine	Eval.	71	100.0	69	100.0	58	100.0
		up			1	1.4	4	6.9
LDH	Fluoxetine	Eval.	78	100.0	72	100.0	64	100.0

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 69

LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE

Laboratory test / Assigned treatment			Days of treatment					
			Screen		1-28		29-56	
			No	%	No	%	No	%
LDH	Fluoxetine	up			1	1.4		
ALK. PHOSPH.	Fluoxetine	Eval.	80	100.0	76	100.0	63	100.0
		up	1	1.2	1	1.3	1	1.6
GLOBULINS ALPHA 1	Fluoxetine	Eval.	56	100.0	49	100.0	45	100.0
		down	1	1.8				
		up					1	2.2
	Reboxetine	Eval.	44	100.0	43	100.0	39	100.0
		up	1	2.3			1	2.6
GLOBULINS ALPHA 2	Reboxetine	Eval.	44	100.0	43	100.0	39	100.0
		down	1	2.3				
GLOBULINS GAMMA	Fluoxetine	Eval.	56	100.0	49	100.0	45	100.0
		down	3	5.4	2	4.1	2	4.4
	Reboxetine	Eval.	44	100.0	43	100.0	39	100.0
		down	1	2.3	1	2.3		
		up			1	2.3		
TOT. CHOLEST.	Fluoxetine	Eval.	77	100.0	73	100.0	65	100.0
		up	3	3.9	2	2.7	3	4.6
	Reboxetine	Eval.	68	100.0	66	100.0	56	100.0
		up	5	7.4	2	3.0	5	8.9
TRIGLYCERIDES	Fluoxetine	Eval.	76	100.0	72	100.0	65	100.0
		up	5	6.6	1	1.4	3	4.6
	Reboxetine	Eval.	68	100.0	66	100.0	55	100.0
		up	3	4.4	3	4.5	1	1.8

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 69

LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE

Laboratory test / Assigned treatment			Days of treatment					
			Screen		1-28		29-56	
			No	%	No	%	No	%
GLUCOSE	Fluoxetine	Eval.	78	100.0	73	100.0	64	100.0
		down					1	1.6
		up			1	1.4		
	Reboxetine	Eval.	67	100.0	64	100.0	55	100.0
		up	1	1.5	1	1.6	1	1.8
NA+	Fluoxetine	Eval.	80	100.0	76	100.0	66	100.0
		down			1	1.3		
K+	Fluoxetine	Eval.	77	100.0	74	100.0	63	100.0
		up			1	1.4	1	1.6
	Reboxetine	Eval.	70	100.0	66	100.0	59	100.0
		down					1	1.7
Ca++	Fluoxetine	Eval.	80	100.0	76	100.0	66	100.0
		down			1	1.3		
PO4--	Fluoxetine	Eval.	72	100.0	67	100.0	62	100.0
		down					1	1.6
		up	1	1.4	2	3.0	1	1.6
	Reboxetine	Eval.	63	100.0	59	100.0	53	100.0
		up			1	1.7		

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 70

BLOOD PRESSURE AND HEART RATE: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Vital signs		LYING									STANDING								
		time interval									time interval								
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
S.B.P.	Evaluated	77	77	75	73	71	37	66	31	57	77	76	75	73	71	37	66	31	57
	Mean	122.6	122.7	121.9	124.1	124.0	115.7	123.5	120.4	122.3	119.6	115.6	115.2	118.9	117.7	114.1	118.6	117.0	118.6
	STD	16.1	18.8	16.9	16.8	19.4	18.7	15.6	15.7	16.5	17.4	18.2	17.5	17.3	20.3	18.0	15.7	18.7	17.0
	Median	120.0	120.0	120.0	120.0	120.0	115.0	121.0	120.0	124.0	120.0	120.0	120.0	120.0	120.0	110.0	120.0	120.0	120.0
	Min	80.0	70.0	80.0	90.0	70.0	80.0	70.0	70.0	80.0	70.0	70.0	70.0	80.0	70.0	80.0	70.0	70.0	80.0
	Max	160.0	160.0	165.0	180.0	180.0	165.0	170.0	145.0	170.0	160.0	160.0	145.0	180.0	180.0	145.0	145.0	140.0	160.0
D.B.P.	Evaluated	77	77	75	73	71	37	66	31	57	77	76	75	73	71	37	66	31	57
	Mean	78.3	78.9	79.1	80.0	80.8	76.5	80.9	78.1	79.7	77.8	77.5	77.7	79.7	79.8	77.0	79.6	78.3	79.8
	STD	13.2	14.0	11.7	11.6	12.4	13.8	10.9	9.9	11.4	12.4	12.6	12.0	11.1	11.9	12.7	12.2	11.9	12.3
	Median	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0
	Min	40.0	40.0	50.0	60.0	50.0	50.0	50.0	50.0	50.0	40.0	40.0	40.0	50.0	45.0	55.0	45.0	45.0	50.0
	Max	125.0	115.0	110.0	115.0	120.0	115.0	110.0	90.0	110.0	110.0	110.0	110.0	110.0	110.0	105.0	115.0	95.0	110.0
Heart Rate	Evaluated	76	74	73	70	70	37	65	31	56	73	72	71	68	69	36	64	31	54
	Mean	77.0	78.9	78.9	79.3	79.0	80.2	79.8	81.5	79.9	83.8	84.7	85.1	83.9	85.2	87.5	84.5	87.1	84.7
	STD	8.0	8.9	7.9	8.5	8.0	10.4	8.4	7.8	9.4	11.7	12.0	11.7	11.2	12.9	14.1	10.3	10.1	11.6
	Median	78.0	78.0	80.0	79.0	78.0	78.0	80.0	80.0	77.0	82.0	82.0	82.0	80.0	81.0	84.0	82.0	84.0	80.0
	Min	52.0	60.0	60.0	62.0	65.0	60.0	62.0	68.0	63.0	63.0	65.0	65.0	64.0	65.0	62.0	66.0	71.0	65.0
	Max	96.0	116.0	100.0	112.0	100.0	112.0	115.0	100.0	112.0	124.0	120.0	120.0	116.0	124.0	132.0	116.0	110.0	124.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 70

BLOOD PRESSURE AND HEART RATE: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Fluoxetine

Vital signs		LYING									STANDING								
		time interval									time interval								
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
S.B.P.	Evaluated	86	86	82	80	77	43	67	36	68	86	86	82	81	78	44	68	37	69
	Mean	123.4	123.5	122.8	122.1	122.2	120.7	121.3	118.1	121.4	121.2	120.9	120.2	119.5	121.0	119.3	120.3	116.5	119.6
	STD	17.0	14.5	15.8	15.9	16.2	18.6	16.0	15.6	15.0	17.1	16.2	18.7	17.2	17.6	19.9	16.5	17.9	15.5
	Median	120.0	122.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0	120.0
	Min	80.0	90.0	80.0	85.0	85.0	80.0	80.0	85.0	85.0	80.0	80.0	70.0	80.0	80.0	80.0	80.0	70.0	80.0
	Max	170.0	170.0	170.0	175.0	170.0	160.0	180.0	140.0	160.0	170.0	170.0	190.0	170.0	165.0	160.0	165.0	145.0	150.0
D.B.P.	Evaluated	86	86	82	80	77	43	67	36	68	86	86	82	81	78	44	68	37	69
	Mean	78.6	79.9	77.9	78.6	78.2	76.4	78.1	74.4	78.0	79.5	80.0	78.7	79.3	79.7	78.1	78.1	76.1	77.4
	STD	9.3	9.5	8.6	9.2	8.9	12.5	10.8	11.5	8.5	9.4	10.5	9.9	10.0	9.9	13.7	10.4	11.8	9.2
	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
	Min	50.0	50.0	60.0	60.0	50.0	40.0	40.0	45.0	50.0	50.0	50.0	50.0	50.0	50.0	40.0	40.0	50.0	50.0
	Max	105.0	100.0	100.0	100.0	100.0	100.0	105.0	100.0	100.0	105.0	105.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Heart Rate	Evaluated	85	84	77	77	76	40	62	33	67	84	82	76	77	75	40	62	35	67
	Mean	79.0	76.8	76.3	75.5	75.0	75.5	74.8	73.5	73.9	83.3	81.2	80.8	80.3	80.6	81.7	78.9	77.8	77.7
	STD	9.5	9.0	9.4	8.3	9.0	8.0	8.5	6.3	6.8	9.3	9.2	10.7	8.3	9.6	10.6	8.3	7.9	7.0
	Median	78.0	76.0	76.0	76.0	74.0	76.0	76.0	72.0	74.0	82.0	80.0	80.0	80.0	78.0	80.0	80.0	78.0	76.0
	Min	60.0	60.0	56.0	52.0	59.0	60.0	56.0	63.0	52.0	66.0	60.0	60.0	56.0	63.0	64.0	60.0	58.0	56.0
	Max	120.0	108.0	108.0	96.0	120.0	96.0	105.0	88.0	86.0	106.0	108.0	124.0	100.0	116.0	112.0	100.0	96.0	96.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Reboxetine

Vital signs		LYING								STANDING							
		Time interval								Time interval							
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
S.B.P.	Evaluated	77	75	73	71	37	66	31	57	76	75	73	71	37	66	31	57
	Mean	0.1	-0.6	1.9	1.6	-4.1	0.7	-1.5	-0.7	-3.6	-4.3	0.0	-1.7	-2.5	-1.4	-2.9	-0.6
	STD	10.0	10.4	12.9	12.2	14.9	12.3	12.9	12.1	12.7	12.8	13.4	15.0	17.8	13.0	14.3	12.8
	Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Min	-25.0	-30.0	-40.0	-30.0	-40.0	-30.0	-30.0	-30.0	-30.0	-50.0	-35.0	-35.0	-40.0	-35.0	-40.0	-25.0
	Max	30.0	40.0	45.0	35.0	30.0	40.0	30.0	45.0	50.0	20.0	30.0	65.0	40.0	30.0	20.0	50.0
D.B.P.	Evaluated	77	75	73	71	37	66	31	57	76	75	73	71	37	66	31	57
	Mean	0.6	0.8	1.9	2.5	0.4	2.2	1.3	1.7	-0.1	-0.0	2.3	2.1	1.8	1.5	1.9	2.3
	STD	7.8	8.5	7.9	8.5	8.3	8.7	9.9	8.6	8.9	8.7	8.4	9.2	10.8	9.9	11.4	8.3
	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	5.0	0.0
	Min	-10.0	-25.0	-15.0	-15.0	-15.0	-16.0	-20.0	-20.0	-30.0	-20.0	-20.0	-25.0	-20.0	-25.0	-25.0	-10.0
	Max	30.0	30.0	30.0	24.0	31.0	35.0	30.0	25.0	20.0	20.0	20.0	22.0	28.0	25.0	25.0	30.0
Heart Rate	Evaluated	74	73	70	70	37	65	31	56	72	71	68	69	36	64	31	54
	Mean	2.1	1.9	2.4	1.7	2.2	2.4	2.7	2.8	1.0	1.4	0.1	1.9	2.3	1.4	2.6	2.4
	STD	9.5	8.3	8.9	8.8	10.7	9.6	10.6	10.7	11.3	8.3	8.2	12.9	12.2	9.1	11.9	11.5
	Median	0.0	0.0	0.0	0.0	0.0	1.0	4.0	0.0	0.0	0.0	0.0	0.0	-1.0	0.0	2.0	-0.5
	Min	-36.0	-24.0	-16.0	-29.0	-18.0	-18.0	-28.0	-18.0	-38.0	-32.0	-25.0	-46.0	-20.0	-20.0	-22.0	-14.0
	Max	29.0	26.0	38.0	28.0	25.0	41.0	24.0	38.0	40.0	30.0	30.0	36.0	38.0	34.0	28.0	44.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Fluoxetine

Vital signs		LYING								STANDING							
		Time interval								Time interval							
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
S.B.P.	Evaluated	86	82	80	77	43	67	36	68	86	82	81	78	44	68	37	69
	Mean	0.1	0.1	-1.5	-1.8	-3.4	-2.1	-5.8	-2.0	-0.3	-0.5	-2.0	-0.7	-2.6	0.2	-3.4	-0.5
	STD	9.7	13.0	11.2	12.5	14.3	13.9	16.1	11.5	9.1	13.2	12.8	11.6	13.3	12.9	16.0	12.4
	Median	0.0	0.0	0.0	0.0	0.0	0.0	-2.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Min	-30.0	-50.0	-40.0	-40.0	-40.0	-45.0	-45.0	-45.0	-20.0	-40.0	-50.0	-30.0	-35.0	-35.0	-50.0	-40.0
	Max	30.0	30.0	28.0	30.0	32.0	50.0	25.0	25.0	25.0	50.0	30.0	40.0	25.0	45.0	22.0	30.0
D.B.P.	Evaluated	86	82	80	77	43	67	36	68	86	82	81	78	44	68	37	69
	Mean	1.3	-0.5	0.3	-0.5	-1.4	-0.3	-2.6	0.0	0.4	-0.5	-0.1	0.1	-1.9	-0.9	-2.3	-1.3
	STD	7.5	8.3	9.7	8.0	10.7	8.5	9.3	8.4	7.5	8.3	8.5	8.3	10.2	6.8	8.8	8.0
	Median	0.0	0.0	0.0	0.0	0.0	0.0	-2.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Min	-20.0	-25.0	-25.0	-25.0	-40.0	-20.0	-20.0	-20.0	-20.0	-30.0	-20.0	-30.0	-40.0	-14.0	-30.0	-20.0
	Max	20.0	30.0	30.0	20.0	20.0	30.0	20.0	30.0	25.0	25.0	30.0	30.0	25.0	20.0	20.0	25.0
Heart Rate	Evaluated	84	77	77	76	40	62	33	67	82	76	77	75	40	62	35	67
	Mean	-2.3	-2.1	-3.7	-4.4	-4.3	-3.5	-4.0	-4.6	-2.4	-2.2	-3.0	-3.0	-1.9	-3.6	-5.7	-4.8
	STD	9.8	11.0	10.1	8.8	10.4	8.0	9.4	10.4	7.9	10.3	9.1	8.7	12.1	8.5	10.4	9.5
	Median	-2.0	-2.0	-2.0	-3.5	-4.0	-2.5	-4.0	-4.0	0.0	-2.0	0.0	-2.0	-3.0	-2.0	-4.0	-4.0
	Min	-32.0	-40.0	-36.0	-36.0	-36.0	-33.0	-28.0	-44.0	-28.0	-40.0	-32.0	-36.0	-28.0	-30.0	-31.0	-36.0
	Max	40.0	40.0	20.0	16.0	18.0	14.0	12.0	16.0	18.0	36.0	12.0	16.0	44.0	20.0	20.0	14.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Reboxetine

Vital signs			LYING								STANDING							
			time intervals								time intervals							
			Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
S.B.P.	Evaluated	No	77	75	73	71	37	66	31	57	76	75	73	71	37	66	31	57
	Decrease (1)	No	2	1	2	2	3	1	1	1	1	3	2	4	4	2	1	
		%	2.6	1.3	2.7	2.8	8.1	1.5	3.2	1.8	1.3	4.0	2.7	5.6	10.8	3.0	3.2	
	Increase (2)	No		2	2	1	1	1		1	1		3	1	1	2	1	2
		%		2.7	2.7	1.4	2.7	1.5		1.8	1.3		4.1	1.4	2.7	3.0	3.2	3.5
D.B.P.	Evaluated	No	77	75	73	71	37	66	31	57	76	75	73	71	37	66	31	57
	Decrease (1)	No										2			1	1		
		%										2.7			2.7	1.5		
	Increase (2)	No	2	3	5	6	1	4	1	5	2	5	7	7	3	5	3	3
		%	2.6	4.0	6.8	8.5	2.7	6.1	3.2	8.8	2.6	6.7	9.6	9.9	8.1	7.6	9.7	5.3
Both	Evaluated	No	77	75	73	71	37	66	31	57	76	75	73	71	37	66	31	57
	Decrease (1)	No									3	1		1		2	1	
		%									3.9	1.3		1.4		3.0	3.2	
	Increase (2)	No	2	2	2	1	1	2	1	1	1		2	1	1	2		1
		%	2.6	2.7	2.7	1.4	2.7	3.0	3.2	1.8	1.3		2.7	1.4	2.7	3.0		1.8
Heart rate	Evaluated	No	74	73	70	70	37	65	31	56	72	71	68	69	36	64	31	54
	Decrease (1)	No	1	2		1			1		3	1	1	3	1		1	
		%	1.4	2.7		1.4			3.2		4.2	1.4	1.5	4.3	2.8		3.2	
	Increase (2)	No	6	6	5	3	7	5	4	7	3	3	3	7	4	4	5	6
		%	8.1	8.2	7.1	4.3	18.9	7.7	12.9	12.5	4.2	4.2	4.4	10.1	11.1	6.3	16.1	11.1

(1) decrease => 20 % of baseline value
(2) increase => 20 % of baseline value

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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: Fluoxetine

Vital signs			LYING								STANDING							
			time intervals								time intervals							
			Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
S.B.P.	Evaluated	No	86	82	80	77	43	67	36	68	86	82	81	78	44	68	37	69
	Decrease (1)	No		2	1	4	3	3	3	2		4	3		2	1	2	1
		%		2.4	1.2	5.2	7.0	4.5	8.3	2.9		4.9	3.7		4.5	1.5	5.4	1.4
	Increase (2)	No	1	2	1	2	1	2	1	1	1	1	3	1	1	3	1	1
		%	1.2	2.4	1.2	2.6	2.3	3.0	2.8	1.5	1.2	1.2	3.7	1.3	2.3	4.4	2.7	1.4
D.B.P.	Evaluated	No	86	82	80	77	43	67	36	68	86	82	81	78	44	68	37	69
	Decrease (1)	No	1	2	3	2	4	2	1		2	2	1	1	2		1	2
		%	1.2	2.4	3.8	2.6	9.3	3.0	2.8		2.3	2.4	1.2	1.3	4.5		2.7	2.9
	Increase (2)	No	4		4	5	3	2	2	3	3	3	1	2		1	1	2
		%	4.7		5.0	6.5	7.0	3.0	5.6	4.4	3.5	3.7	1.2	2.6		1.5	2.7	2.9
Both	Evaluated	No	86	82	80	77	43	67	36	68	86	82	81	78	44	68	37	69
	Decrease (1)	No		1	1				1				1				1	1
		%		1.2	1.2				2.8				1.2				2.7	1.4
	Increase (2)	No		3	1	1						1	1	1	1			1
		%		3.7	1.2	1.3						1.2	1.2	1.3	2.3			1.4
Heart rate	Evaluated	No	84	77	77	76	40	62	33	67	82	76	77	75	40	62	35	67
	Decrease (1)	No	5	4	7	7	3	2	4	7	5	4	5	3	3	2	5	5
		%	6.0	5.2	9.1	9.2	7.5	3.2	12.1	10.4	6.1	5.3	6.5	4.0	7.5	3.2	14.3	7.5
	Increase (2)	No	2	4	1		2	1		2	1	2		1	2	1	1	
		%	2.4	5.2	1.3		5.0	1.6		3.0	1.2	2.6		1.3	5.0	1.6	2.9	

(1) decrease => 20 % of baseline value
(2) increase => 20 % of baseline value

PHARMACIA CNS R&D 9590083

REBOXETINE - PROTOCOL 20124/016
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
Fluoxetine	S.B.P. (1)	Decrease	4			5		1
		Increase	1			2		
	D.B.P. (2)	Decrease	6	1	1	2	2	1
		Increase	1	1			2	
	BOTH (1 & 2)	Decrease	1			1		
	HEART RATE (3)	Increase		1		3		
Reboxetine	S.B.P. (1)	Decrease	2		2	2	1	2
		Increase		2		1	1	
	D.B.P. (2)	Decrease				1	2	
		Increase	3	1		4		2
	BOTH (1 & 2)	Decrease				1	1	1
	HEART RATE (3)	Increase	4	1	1	4	3	3

(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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 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
Fluoxetine	Eval.	85	86	86	82	80	77	42	67	36	68
	No.	1	1				1	1			
	%	1.2	1.2				1.3	2.4			
	Mean	30.0	30.0				40.0	30.0			
	Max.	30.0	30.0				40.0	30.0			
Reboxetine	Eval.	75	77	76	75	73	71	37	66	31	57
	No.	1	2	6	4	1	5		3	1	
	%	1.3	2.6	7.9	5.3	1.4	7.0		4.5	3.2	
	Mean	30.0	30.0	34.2	33.8	30.0	38.0		30.0	30.0	
	Max.	30.0	30.0	40.0	45.0	30.0	60.0		30.0	30.0	

(*) orthostatic hypotension = decrease of systolic blood pressure in standing position => 30 mm hg as compared to lying position

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 75

BODY WEIGHT: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Reboxetine

Sex		Time interval								
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Female	Evaluated	56	56	53	54	53	30	47	24	42
	Mean	67.4	66.9	67.1	67.3	67.5	66.3	67.7	66.2	68.4
	STD	17.3	17.2	17.7	17.4	17.4	17.8	18.0	18.6	18.7
	Median	64.8	64.3	64.0	64.3	64.4	64.3	64.8	63.6	65.0
	Min	41.0	41.1	41.5	42.8	42.9	43.7	43.8	44.0	44.0
	Max	140.0	140.0	140.0	140.0	140.0	140.0	140.0	140.0	140.0
Male	Evaluated	20	20	20	19	18	7	18	7	15
	Mean	76.9	76.8	76.7	77.2	77.0	80.1	77.1	80.4	77.8
	STD	11.1	11.0	11.2	11.4	11.4	15.9	11.4	15.8	12.7
	Median	74.0	73.5	72.5	75.0	74.5	78.5	74.5	78.3	74.5
	Min	61.0	61.0	60.0	61.0	61.0	66.5	62.0	66.0	62.0
	Max	113.0	113.0	113.0	113.0	112.0	113.0	113.0	113.0	115.0
Total	Evaluated	76	76	73	73	71	37	65	31	57
	Mean	69.9	69.5	69.8	69.9	69.9	68.9	70.3	69.4	70.9
	STD	16.4	16.4	16.7	16.5	16.6	18.1	16.9	18.7	17.7
	Median	68.4	67.1	67.5	67.0	67.5	66.3	67.4	66.1	69.0
	Min	41.0	41.1	41.5	42.8	42.9	43.7	43.8	44.0	44.0
	Max	140.0	140.0	140.0	140.0	140.0	140.0	140.0	140.0	140.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 75

BODY WEIGHT: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND SEX

Assigned treatment: Fluoxetine

Sex		Time interval								
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Female	Evaluated	64	64	60	60	57	36	49	30	51
	Mean	65.7	65.7	65.6	66.4	66.6	67.4	66.1	67.9	65.7
	STD	14.2	14.2	14.5	14.4	14.5	14.8	14.7	15.7	13.6
	Median	62.0	62.0	62.0	62.0	62.0	63.5	62.5	64.6	62.5
	Min	43.0	42.0	42.0	41.5	41.0	43.2	42.0	42.6	41.8
	Max	105.0	105.0	105.0	105.0	105.0	105.0	105.0	105.0	105.0
Male	Evaluated	22	22	22	21	20	9	18	7	18
	Mean	78.0	77.5	77.2	76.6	75.9	79.6	76.7	84.2	77.0
	STD	13.6	13.2	13.0	13.2	13.4	17.1	13.1	17.0	13.1
	Median	73.0	73.0	73.3	73.0	72.5	74.0	72.5	77.5	73.5
	Min	61.0	61.0	61.0	60.0	59.3	58.2	61.0	71.9	61.0
	Max	120.0	118.0	117.0	118.0	119.0	119.0	119.0	120.0	119.0
Total	Evaluated	86	86	82	81	77	45	67	37	69
	Mean	68.9	68.7	68.7	69.1	69.0	69.9	68.9	71.0	68.6
	STD	15.0	14.8	15.0	14.7	14.7	15.8	15.0	17.0	14.3
	Median	64.8	64.4	64.5	65.2	65.2	67.1	67.0	68.0	67.3
	Min	43.0	42.0	42.0	41.5	41.0	43.2	42.0	42.6	41.8
	Max	120.0	118.0	117.0	118.0	119.0	119.0	119.0	120.0	119.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 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: Reboxetine

Sex		Time interval															
		Day 7		Day 14		Day 21		Day 28		Day 35		Day 42		Day 49		Day 56	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Female	Lower					1	1.9	1	1.9	1	3.3	2	4.3	3	12.5	4	9.5
	Same	54	96.4	51	96.2	52	96.3	49	92.5	27	90.0	41	87.2	16	66.7	34	81.0
	Higher	2	3.6	2	3.8	1	1.9	3	5.7	2	6.7	4	8.5	5	20.8	4	9.5
	Total	56	100.0	53	100.0	54	100.0	53	100.0	30	100.0	47	100.0	24	100.0	42	100.0
Male	Lower	1	5.0	1	5.0	2	10.5	2	11.1	1	14.3	2	11.1	1	14.3	2	13.3
	Same	18	90.0	17	85.0	14	73.7	13	72.2	5	71.4	13	72.2	5	71.4	12	80.0
	Higher	1	5.0	2	10.0	3	15.8	3	16.7	1	14.3	3	16.7	1	14.3	1	6.7
	Total	20	100.0	20	100.0	19	100.0	18	100.0	7	100.0	18	100.0	7	100.0	15	100.0
Total	Lower	1	1.3	1	1.4	3	4.1	3	4.2	2	5.4	4	6.2	4	12.9	6	10.5
	Same	72	94.7	68	93.2	66	90.4	62	87.3	32	86.5	54	83.1	21	67.7	46	80.7
	Higher	3	3.9	4	5.5	4	5.5	6	8.5	3	8.1	7	10.8	6	19.4	5	8.8
	Total	76	100.0	73	100.0	73	100.0	71	100.0	37	100.0	65	100.0	31	100.0	57	100.0

(*) LOWER: decrease > 2.5 Kg.
HIGHER: increase > 2.5 Kg.

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 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: Fluoxetine

Sex		Time interval															
		Day 7		Day 14		Day 21		Day 28		Day 35		Day 42		Day 49		Day 56	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%	No	%
Female	Lower	1	1.6	3	5.0	2	3.3	2	3.5	1	2.8	3	6.1	1	3.3	5	9.8
	Same	62	96.9	56	93.3	55	91.7	48	84.2	30	83.3	40	81.6	24	80.0	39	76.5
	Higher	1	1.6	1	1.7	3	5.0	7	12.3	5	13.9	6	12.2	5	16.7	7	13.7
	Total	64	100.0	60	100.0	60	100.0	57	100.0	36	100.0	49	100.0	30	100.0	51	100.0
Male	Same	21	95.5	19	86.4	20	95.2	17	85.0	6	66.7	16	88.9	5	71.4	16	88.9
	Higher	1	4.5	3	13.6	1	4.8	3	15.0	3	33.3	2	11.1	2	28.6	2	11.1
	Total	22	100.0	22	100.0	21	100.0	20	100.0	9	100.0	18	100.0	7	100.0	18	100.0
Total	Lower	1	1.2	3	3.7	2	2.5	2	2.6	1	2.2	3	4.5	1	2.7	5	7.2
	Same	83	96.5	75	91.5	75	92.6	65	84.4	36	80.0	56	83.6	29	78.4	55	79.7
	Higher	2	2.3	4	4.9	4	4.9	10	13.0	8	17.8	8	11.9	7	18.9	9	13.0
	Total	86	100.0	82	100.0	81	100.0	77	100.0	45	100.0	67	100.0	37	100.0	69	100.0

(*) LOWER: decrease > 2.5 Kg.
HIGHER: increase > 2.5 Kg.

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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/Sex			Female			Male			Total		
			Screening	1-28 days	29-56 days	Screening	1-28 days	29-56 days	Screening	1-28 days	29-56 days
Fluoxetine	Eval.	No.	58	51	48	20	20	16	78	71	64
	Normal	No.	52	45	45	16	19	14	68	64	59
		%	89.66	88.24	93.75	80.00	95.00	87.50	87.18	90.14	92.19
	Abnormal	No.	6	6	3	4	1	2	10	7	5
		%	10.34	11.76	6.25	20.00	5.00	12.50	12.82	9.86	7.81
Reboxetine	Eval.	No.	51	47	41	17	14	15	68	61	56
	Normal	No.	42	40	34	15	11	13	57	51	47
		%	82.35	85.11	82.93	88.24	78.57	86.67	83.82	83.61	83.93
	Abnormal	No.	9	7	7	2	3	2	11	10	9
		%	17.65	14.89	17.07	11.76	21.43	13.33	16.18	16.39	16.07

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 78

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH NORMAL OR ABNORMAL E.C.G. VALUE AT EACH EVALUATION TIME AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment/E.C.G. at Baseline			Time interval			
			1-28 days		29-56 days	
			Abnormal	Normal	Abnormal	Normal
Fluoxetine	Abnormal	No.	3	6	2	6
		%	33.3	66.7	25.0	75.0
	Normal	No.	4	58	3	53
		%	6.5	93.5	5.4	94.6
	Total	No.	7	64	5	59
		%	9.9	90.1	7.8	92.2
Reboxetine	Abnormal	No.	4	6	5	4
		%	40.0	60.0	55.6	44.4
	Normal	No.	6	45	4	43
		%	11.8	88.2	8.5	91.5
	Total	No.	10	51	9	47
		%	16.4	83.6	16.1	83.9

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 79

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH NORMAL OR ABNORMAL E.C.G. VALUE AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment/E.C.G. at Baseline		Last assessment				Total	
		Abnormal		Normal			
		No.	%	No.	%	No.	%
Fluoxetine	Abnormal	2	20.0	8	80.0	10	100.0
	Normal	4	5.9	64	94.1	68	100.0
	Total	6	7.7	72	92.3	78	100.0
Reboxetine	Abnormal	5	45.5	6	54.5	11	100.0
	Normal	6	10.5	51	89.5	57	100.0
	Total	11	16.2	57	83.8	68	100.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 80

E.C.G.: NUMBER AND PERCENTAGE OF E.C.G. ABNORMALITIES OBSERVED DURING THE STUDY, BY ASSIGNED TREATMENT

E.C.G. abnormality type	Fluoxetine						Reboxetine					
	Screening		1-28 days		29-56 days		Screening		1-28 days		29-56 days	
	No	%	No	%	No	%	No	%	No	%	No	%
Evaluated Pt	78	100.0	71	100.0	64	100.0	68	100.0	61	100.0	56	100.0
ATRIAL ECTOPIC BEATS - OCCASIONAL									1	1.6		
CONDUCTION DISORDER							2	2.9	1	1.6	1	1.8
LEFT ANTERIOR HEMIBLOCK			1	1.4	1	1.6						
LEFT VENTRICULAR HYPERTROPHY	1	1.3										
MYOCARDIAL ISCHEMIA	1	1.3					1	1.5				
NON SPECIFIC ST-T WAVE CHANGES	1	1.3					1	1.5				
PREVIOUS MYOCARDIAL INFARCTION	1	1.3	1	1.4	1	1.6	1	1.5	1	1.6	1	1.8
RIGHT BUNDLE BRANCH BLOCK	1	1.3					1	1.5	1	1.6	1	1.8
RIGHT INCOMPLETE BUNDLE BRANCH BLOCK	1	1.3	2	2.8	1	1.6	1	1.5				
RIPOLARIZATION DISTURBANCES									1	1.6		
SINUS BRADYCARDIA (< 60)	4	5.1	3	4.2	2	3.1	2	2.9				
SINUS TACHYCARDIA (> 100)	1	1.3					1	1.5	6	9.8	6	10.7
VENTRICULAR ECTOPIC BEATS - OCCASIONAL	1	1.3					1	1.5				

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 81

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

		Last assessment				Total	
		Absent		Present			
		No	%	No	%	No	%
E.C.G. Abnormality	Baseline						
ATRIAL ECTOPIC BEATS - OCCASIONAL	Absent	67	98.5	1	1.5	68	100.0
	Present						
	Total	67	98.5	1	1.5	68	100.0
CONDUCTION DISORDER	Baseline						
	Absent	66	100.0			66	100.0
	Present	1	50.0	1	50.0	2	100.0
	Total	67	98.5	1	1.5	68	100.0
LEFT ANTERIOR HEMIBLOCK	Baseline						
	Absent	68	100.0			68	100.0
	Total	68	100.0			68	100.0
LEFT VENTRICULAR HYPERTROPHY	Baseline						
	Absent	68	100.0			68	100.0
	Total	68	100.0			68	100.0
MYOCARDIAL ISCHEMIA	Baseline						
	Absent	67	100.0			67	100.0
	Present	1	100.0			1	100.0
	Total	68	100.0			68	100.0
NON SPECIFIC ST-T WAVE CHANGES	Baseline						
	Absent	67	100.0			67	100.0
	Present	1	100.0			1	100.0
	Total	68	100.0			68	100.0

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 81

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

		Last assessment				Total	
		Absent		Present			
		No	%	No	%	No	%
E.C.G. Abnormality	Baseline						
PREVIOUS MYOCARDIAL INFARCTION	Absent	67	100.0			67	100.0
	Present			1	100.0	1	100.0
	Total	67	98.5	1	1.5	68	100.0
RIGHT BUNDLE BRANCH BLOCK	Baseline						
	Absent	67	100.0			67	100.0
	Present			1	100.0	1	100.0
	Total	67	98.5	1	1.5	68	100.0
RIGHT INCOMPLETE BUNDLE BRANCH BLOCK	Baseline						
	Absent	67	100.0			67	100.0
	Present	1	100.0			1	100.0
	Total	68	100.0			68	100.0
RIPOLARIZATION DISTURBANCES	Baseline						
	Absent	67	98.5	1	1.5	68	100.0
	Present						
	Total	67	98.5	1	1.5	68	100.0
SINUS BRADYCARDIA (< 60)	Baseline						
	Absent	66	100.0			66	100.0
	Present	2	100.0			2	100.0
	Total	68	100.0			68	100.0
SINUS TACHYCARDIA (> 100)	Baseline						
	Absent	61	91.0	6	9.0	67	100.0

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 81

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

		Last assessment				Total	
		Absent		Present			
		No	%	No	%	No	%
E.C.G. Abnormality	Baseline						
SINUS TACHYCARDIA (> 100)	Present			1	100.0	1	100.0
	Total	61	89.7	7	10.3	68	100.0
VENTRICULAR ECTOPIC BEATS - OCCASIONAL	Baseline						
	Absent	67	100.0			67	100.0
	Present	1	100.0			1	100.0
	Total	68	100.0			68	100.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 81

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Fluoxetine

		Last assessment				Total	
		Absent		Present			
		No	%	No	%	No	%
E.C.G. Abnormality	Baseline						
ATRIAL ECTOPIC BEATS - OCCASIONAL	Absent	78	100.0			78	100.0
	Total	78	100.0			78	100.0
CONDUCTION DISORDER	Baseline						
	Absent	78	100.0			78	100.0
	Total	78	100.0			78	100.0
LEFT ANTERIOR HEMIBLOCK	Baseline						
	Absent	77	98.7	1	1.3	78	100.0
	Present						
	Total	77	98.7	1	1.3	78	100.0
LEFT VENTRICULAR HYPERTROPHY	Baseline						
	Absent	77	100.0			77	100.0
	Present	1	100.0			1	100.0
	Total	78	100.0			78	100.0
MYOCARDIAL ISCHEMIA	Baseline						
	Absent	77	100.0			77	100.0
	Present	1	100.0			1	100.0
	Total	78	100.0			78	100.0
NON SPECIFIC ST-T WAVE CHANGES	Baseline						
	Absent	77	100.0			77	100.0
	Present	1	100.0			1	100.0
	Total	78	100.0			78	100.0

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 81

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Fluoxetine

		Last assessment				Total	
		Absent		Present			
		No	%	No	%	No	%
E.C.G. Abnormality	Baseline						
PREVIOUS MYOCARDIAL INFARCTION	Absent	77	100.0			77	100.0
	Present			1	100.0	1	100.0
	Total	77	98.7	1	1.3	78	100.0
RIGHT BUNDLE BRANCH BLOCK	Baseline						
	Absent	77	100.0			77	100.0
	Present	1	100.0			1	100.0
	Total	78	100.0			78	100.0
RIGHT INCOMPLETE BUNDLE BRANCH BLOCK	Baseline						
	Absent	76	98.7	1	1.3	77	100.0
	Present	1	100.0			1	100.0
	Total	77	98.7	1	1.3	78	100.0
RIPOLARIZATION DISTURBANCES	Baseline						
	Absent	78	100.0			78	100.0
	Total	78	100.0			78	100.0
SINUS BRADYCARDIA (< 60)	Baseline						
	Absent	72	97.3	2	2.7	74	100.0
	Present	3	75.0	1	25.0	4	100.0
	Total	75	96.2	3	3.8	78	100.0
SINUS TACHYCARDIA (> 100)	Baseline						
	Absent	77	100.0			77	100.0
	Present	1	100.0			1	100.0

(CONTINUED)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 81

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Assigned treatment: Fluoxetine

		Last assessment				Total	
		Absent		Present			
		No	%	No	%	No	%
E.C.G. Abnormality	Total						
SINUS TACHYCARDIA (> 100)		78	100.0			78	100.0
VENTRICULAR ECTOPIC BEATS - OCCASIONAL	Baseline						
	Absent	77	100.0			77	100.0
	Present	1	100.0			1	100.0
	Total	78	100.0			78	100.0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Fluoxetine						Reboxetine					
	Screening		1-28 days		29-56 days		Screening		1-28 days		29-56 days	
	No	%	No	%	No	%	No	%	No	%	No	%
Evaluated Pt.	78	100.0	71	100.0	64	100.0	68	100.0	61	100.0	56	100.0
Rhythm disorders	5	6.4	3	4.2	2	3.1	4	5.9	7	11.5	6	10.7
Conduction disorders	2	2.6	3	4.2	2	3.1	4	5.9	2	3.3	2	3.6
Ischemic signs	2	2.6					2	2.9	1	1.6		
Other disorders	2	2.6	1	1.4	1	1.6	1	1.5	1	1.6	1	1.8

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
TABLE No.: 83

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES, BY ABNORMALITY GROUP, AT LAST ASSESSMENT AS COMPARED TO PRETREATMENT EVALUATION, BY ASSIGNED TREATMENT

E.C.G. Abnormality / Baseline		Last assessment													
		Fluoxetine						Reboxetine							
		Absent		Present		Total		Absent		Present		Total			
		No	%	No	%	No	%	No	%	No	%	No	%		
Rhythm disorders	Absent	71	97.3	2	2.7	73	100	57	89.1	7	10.9	64	100		
	Present	4	80.0	1	20.0	5	100	3	75.0	1	25.0	4	100		
	Total	75	96.2	3	3.8	78	100	60	88.2	8	11.8	68	100		
Conduction disorders	Absent	74	97.4	2	2.6	76	100	64	100			64	100		
	Present	2	100			2	100	2	50.0	2	50.0	4	100		
	Total	76	97.4	2	2.6	78	100	66	97.1	2	2.9	68	100		
Ischemic signs	Absent	76	100			76	100	65	98.5	1	1.5	66	100		
	Present	2	100			2	100	2	100			2	100		
	Total	78	100			78	100	67	98.5	1	1.5	68	100		
Other disorders	Absent	76	100			76	100	67	100			67	100		
	Present	1	50.0	1	50.0	2	100			1	100	1	100		
	Total	77	98.7	1	1.3	78	100	67	98.5	1	1.5	68	100		

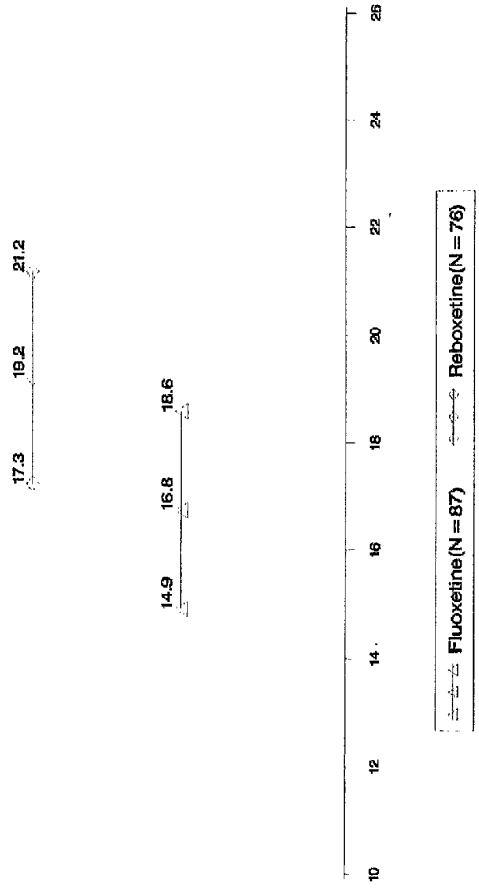
FIGURES

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

MEAN DECREASES OF HAMILTON TOTAL SCORE AT LAST ASSESSMENT
POINT ESTIMATES AND CONFIDENCE INTERVALS

Figure No.: 1



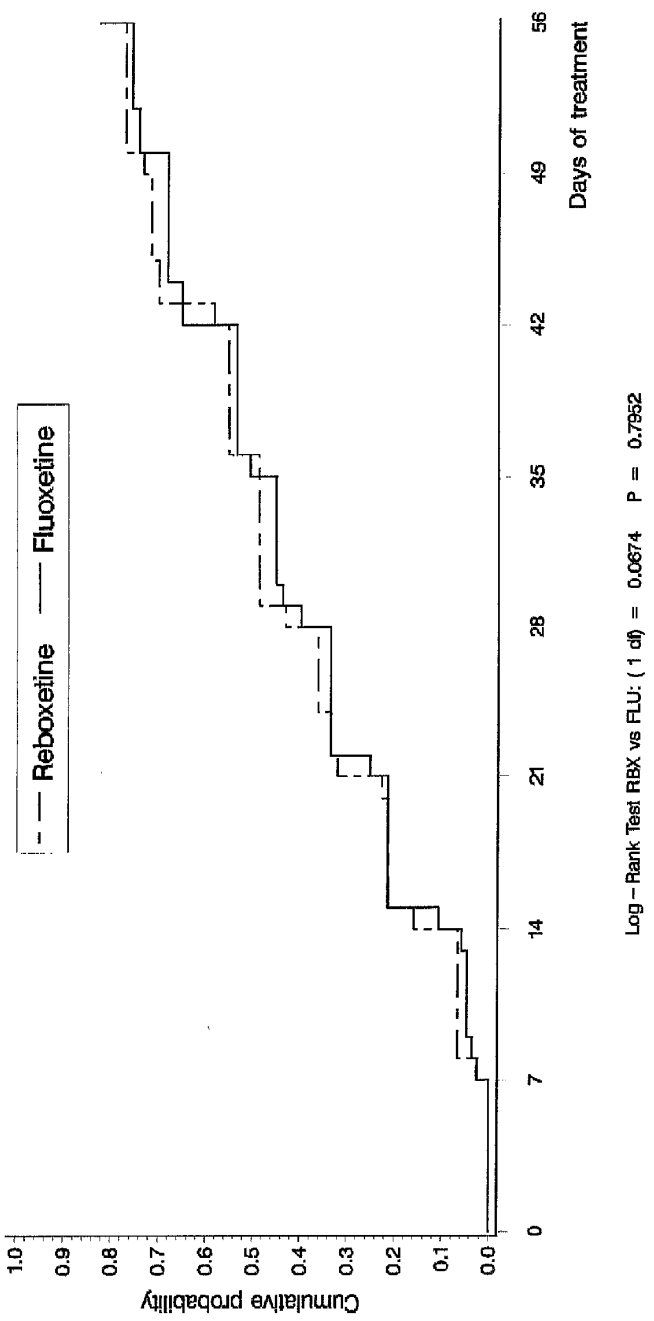
9550083

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

CUMULATIVE PROBABILITY OF 50% DECREASE IN HAMD TOTAL SCORE

Figure No.: 2



Log – Rank Test RBX vs FLU: (1 df) = 0.0674 P = 0.7952

9550083

PHARMACIA CNS R&D

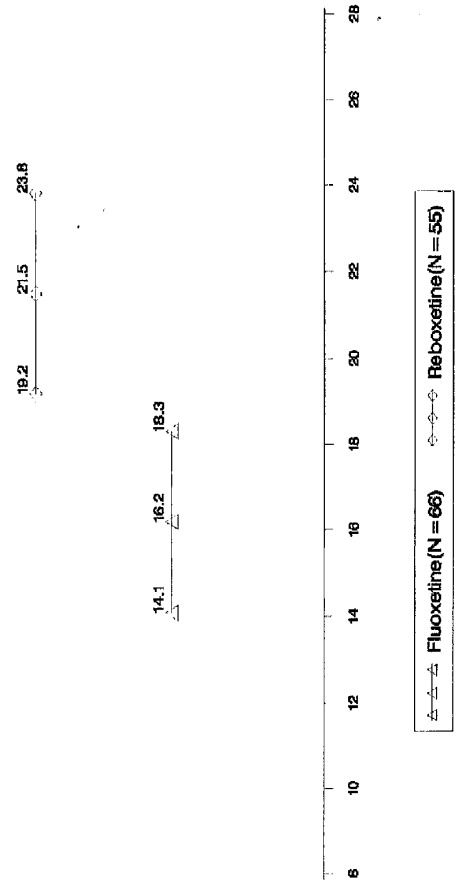
REBOXETINE – PROTOCOL 20124/016

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



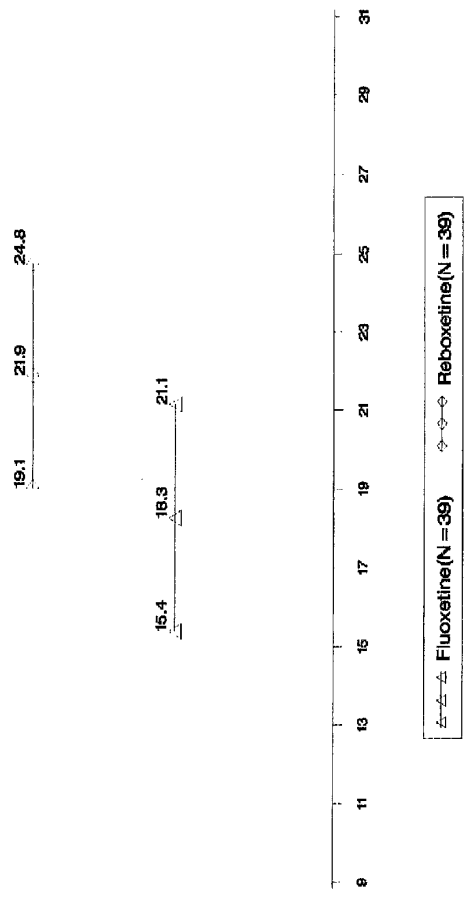
PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

MELANCHOLIC PATIENTS MEAN DECREASES OF HAMILTON TOTAL SCORE AT LAST ASSESSMENT

POINT ESTIMATES AND 95% CONFIDENCE INTERVALS

Figure No.: 4



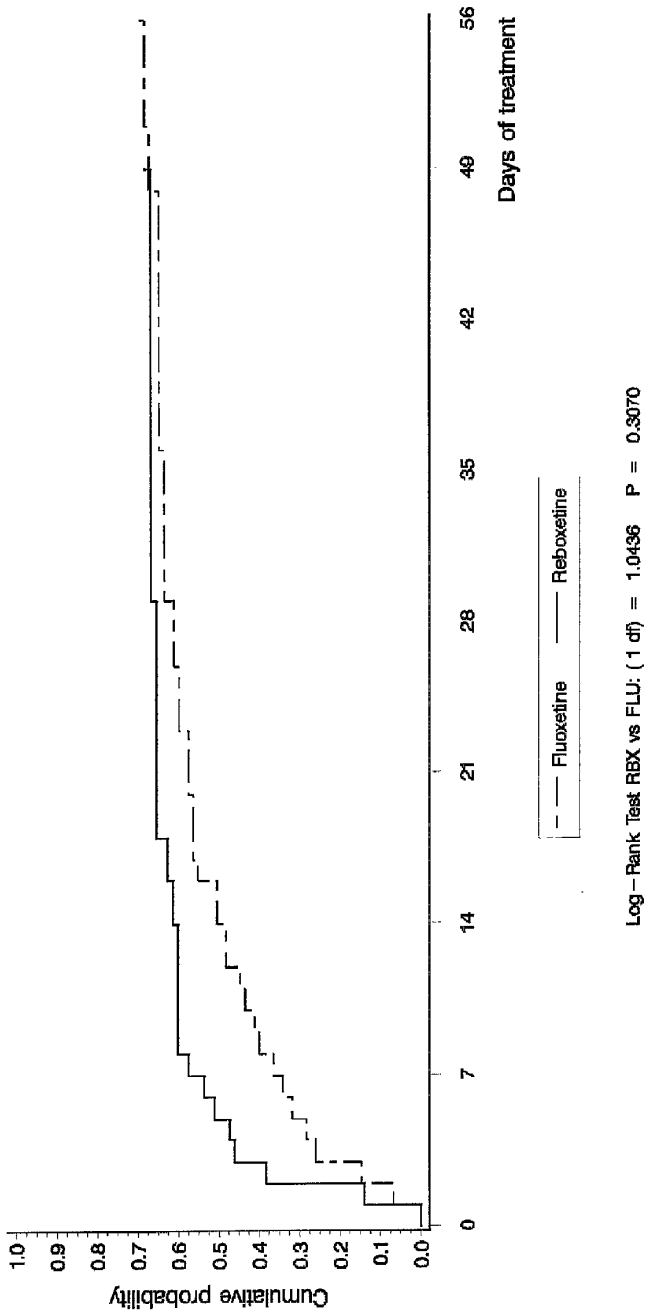
9550083

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

CUMULATIVE RISK OF DEVELOPING THE FIRST ADVERSE EVENT DURING TREATMENT

Figure No.: 5



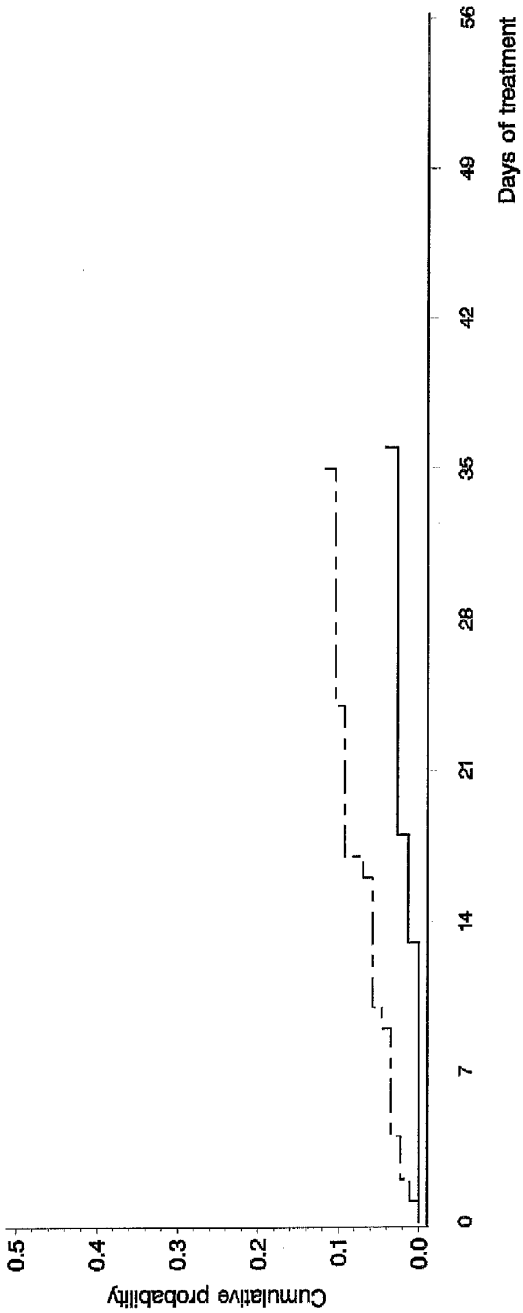
9550083

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

CUMULATIVE RISK OF DEVELOPING AGITATION / ANXIETY / NERVOUSNESS

Figure No.: 6



Log–Rank Test RBX vs FLU: (1 df) = 3.2024 P = 0.0735

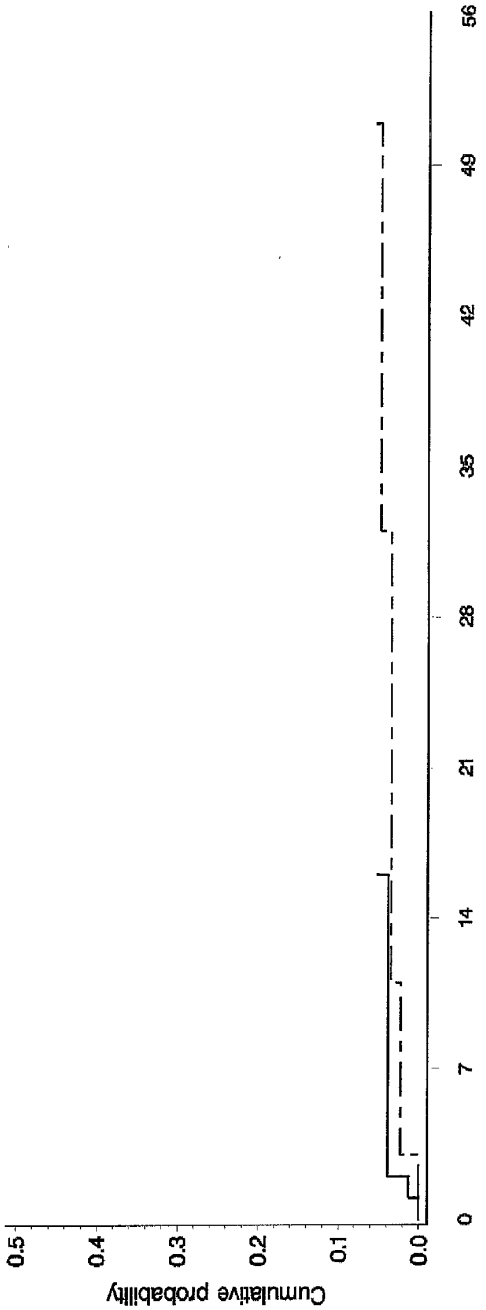
9550083

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

CUMULATIVE RISK OF DEVELOPING ASTHENIA / FATIGUE

Figure No.: 7



Log–Rank Test RBX vs FLU: (1 df) = 0.0159 P = 0.8997

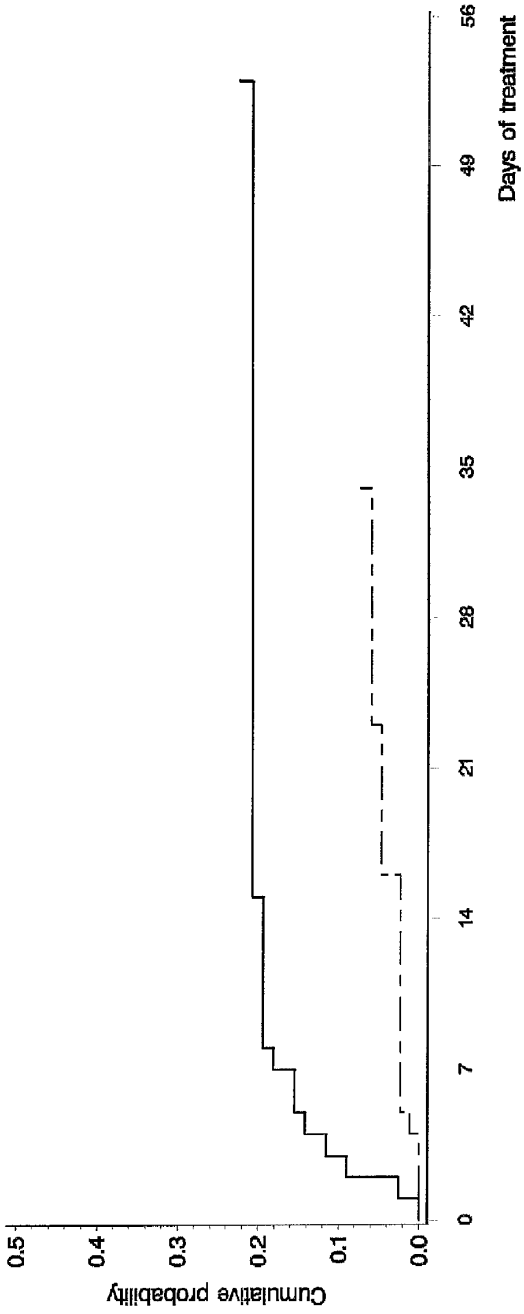
9550083

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

CUMULATIVE RISK OF DEVELOPING CONSTIPATION

Figure No.: 8



Log – Rank Test RBX vs FLU: (1 df) = 8.2765 P = 0.0040

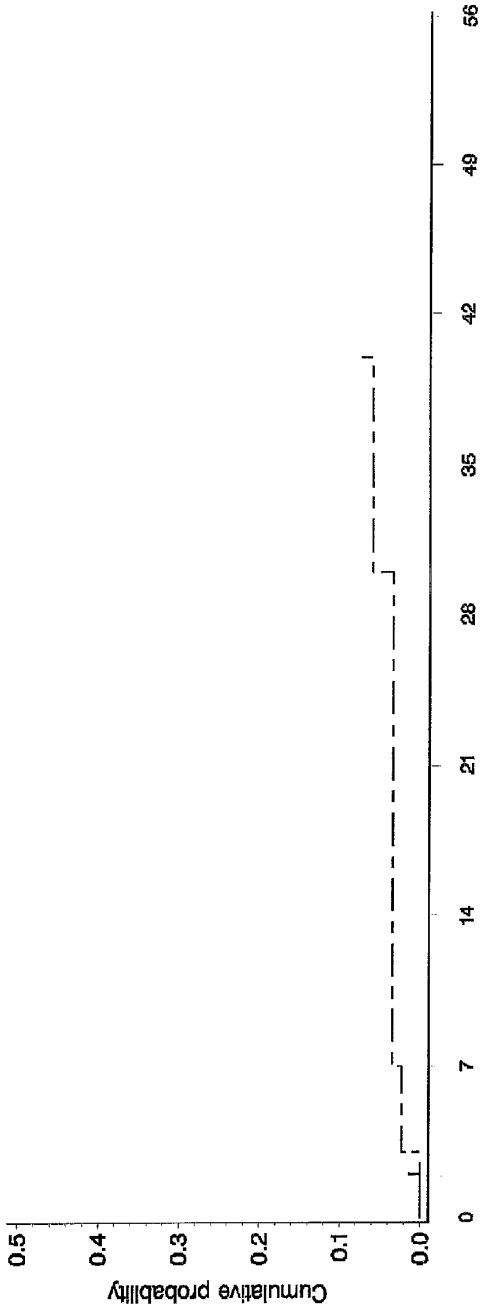
9550083

PHARMACIA CNS R&D

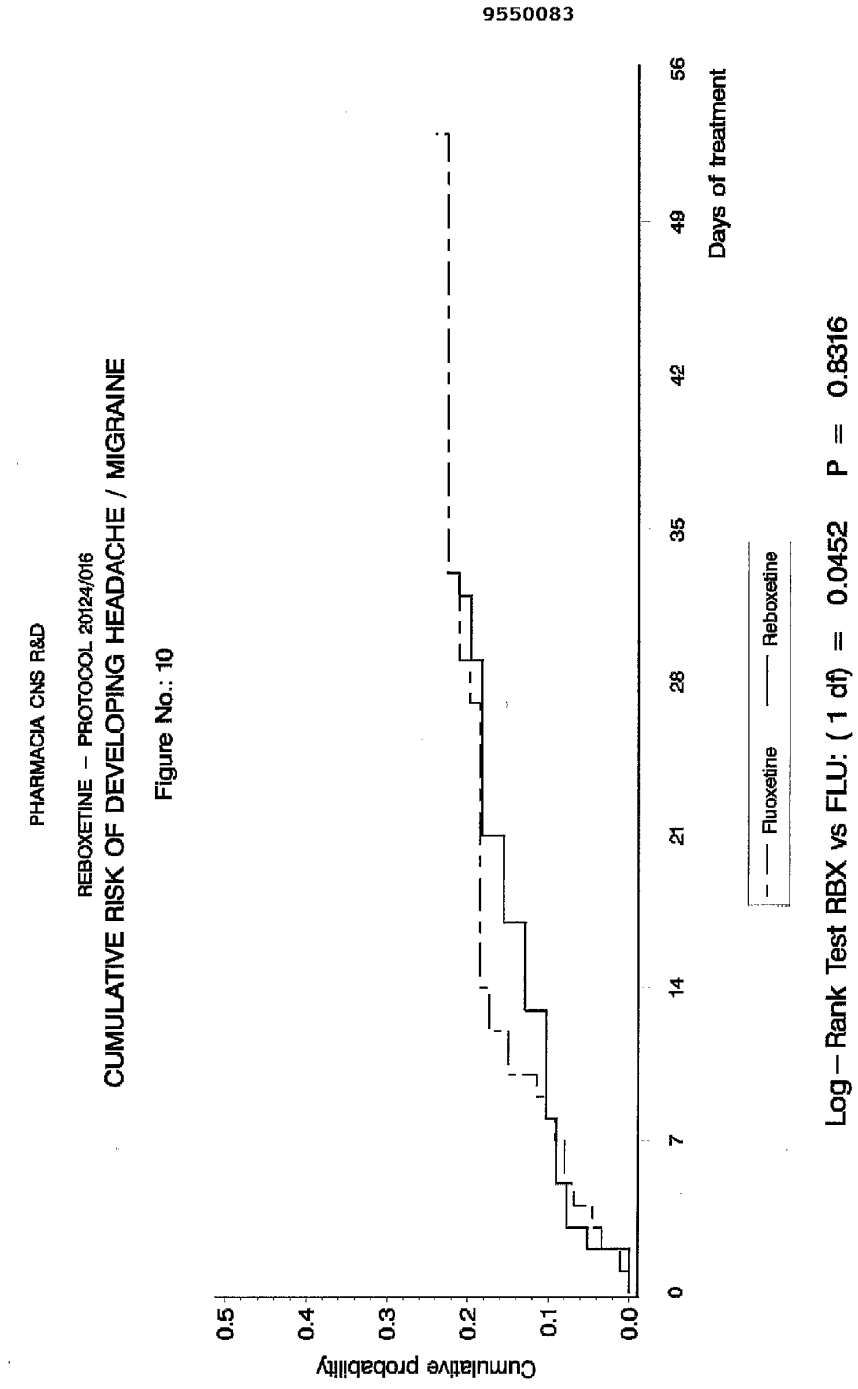
REBOXETINE – PROTOCOL 20124/016

CUMULATIVE RISK OF DEVELOPING DIARRHOEA

Figure No.: 9



Log – Rank Test RBX vs FLU: (1 df) = 3.1385 P = 0.0765



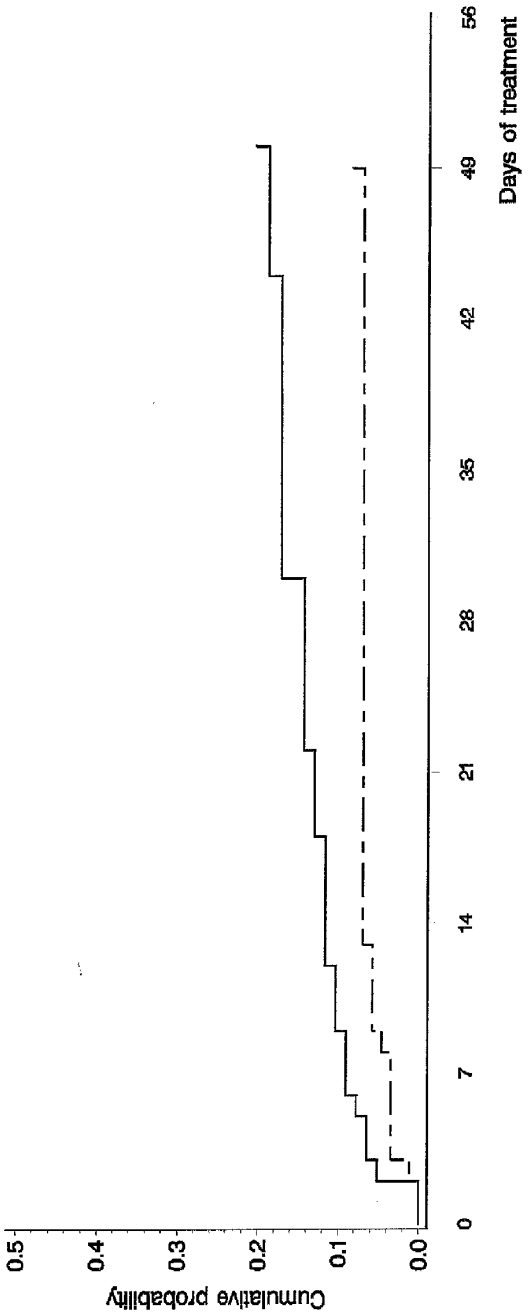
9550083

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

CUMULATIVE RISK OF DEVELOPING HYPOTENSION AND RELATED SYMPTOMS

Figure No.: 11



Log–Rank Test RBX vs FLU: (1 df) = 4.4644 P = 0.0346

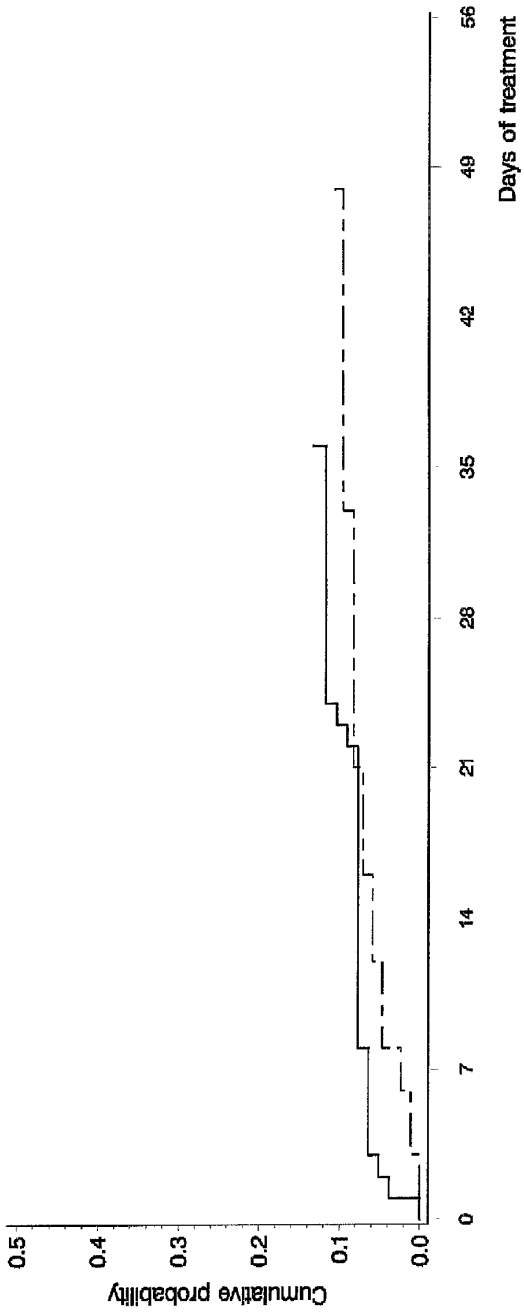
9550083

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

CUMULATIVE RISK OF DEVELOPING INSOMNIA

Figure No.: 12



Log – Rank Test RBX vs FLU: (1 df) = 0.2966 P = 0.5860

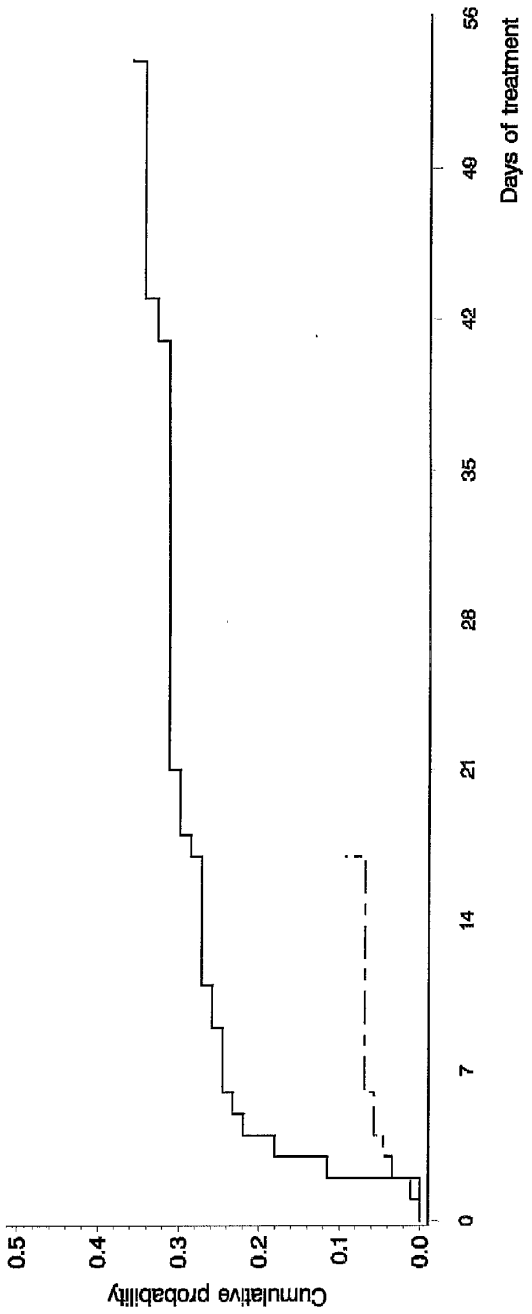
9550083

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

CUMULATIVE RISK OF DEVELOPING MOUTH DRY

Figure No.: 13



Log – Rank Test RBX vs FLU: (1 df) = 15.9783 P = 0.0001

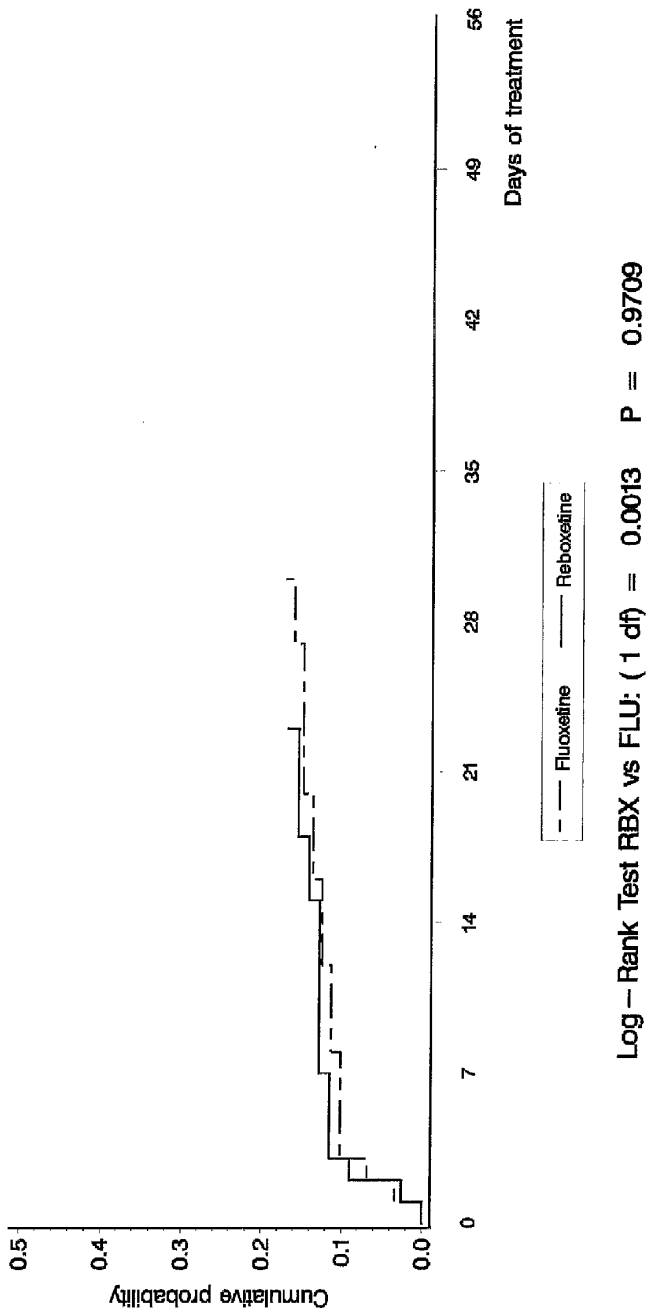
9550083

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

CUMULATIVE RISK OF DEVELOPING NAUSEA AND RELATED SYMPTOMS

Figure No.: 14



Log – Rank Test RBX vs FLU: (1 df) = 0.0013 P = 0.9709

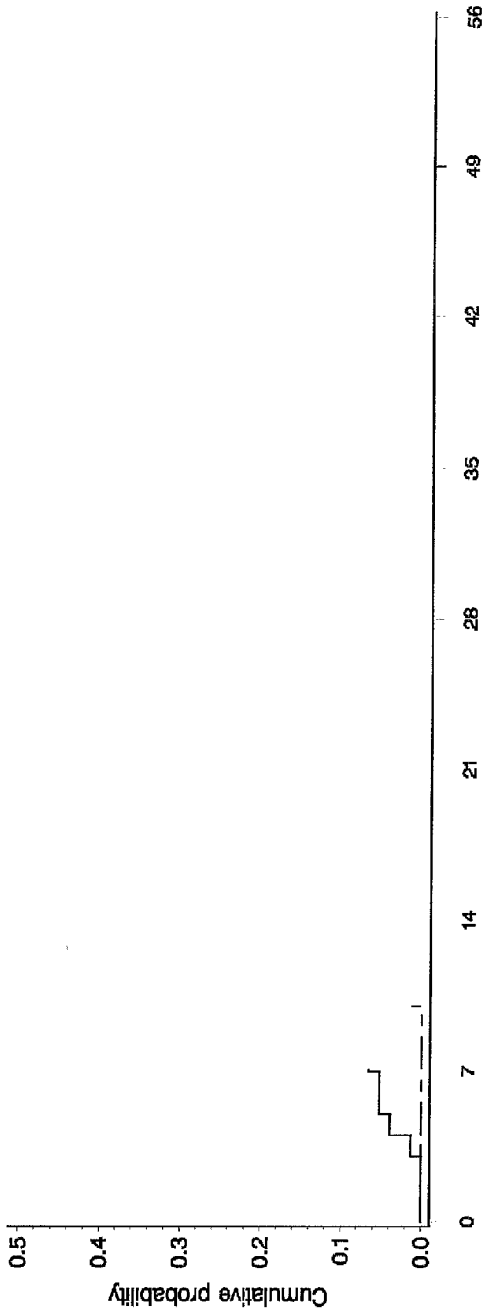
9550083

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

CUMULATIVE RISK OF DEVELOPING PARAESTHESIA

Figure No.: 15



Log – Rank Test RBX vs FLU: (1 df) = 3.3562 P = 0.0670

9550083

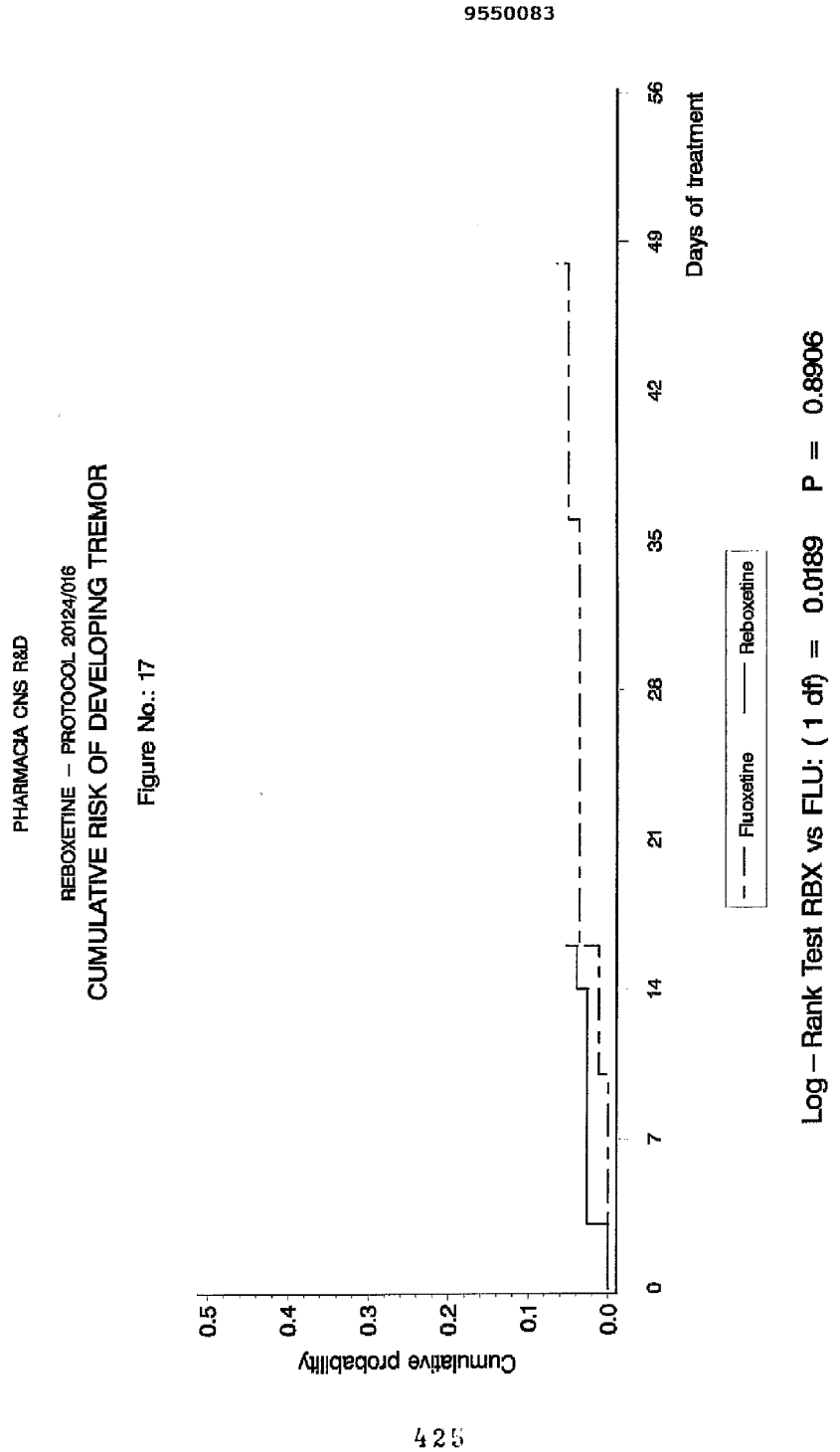
PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

CUMULATIVE RISK OF DEVELOPING SWEATING INCREASED

Figure No.: 16

Log – Rank Test RBX vs FLU: (1 df) = 0.0671 P = 0.7956



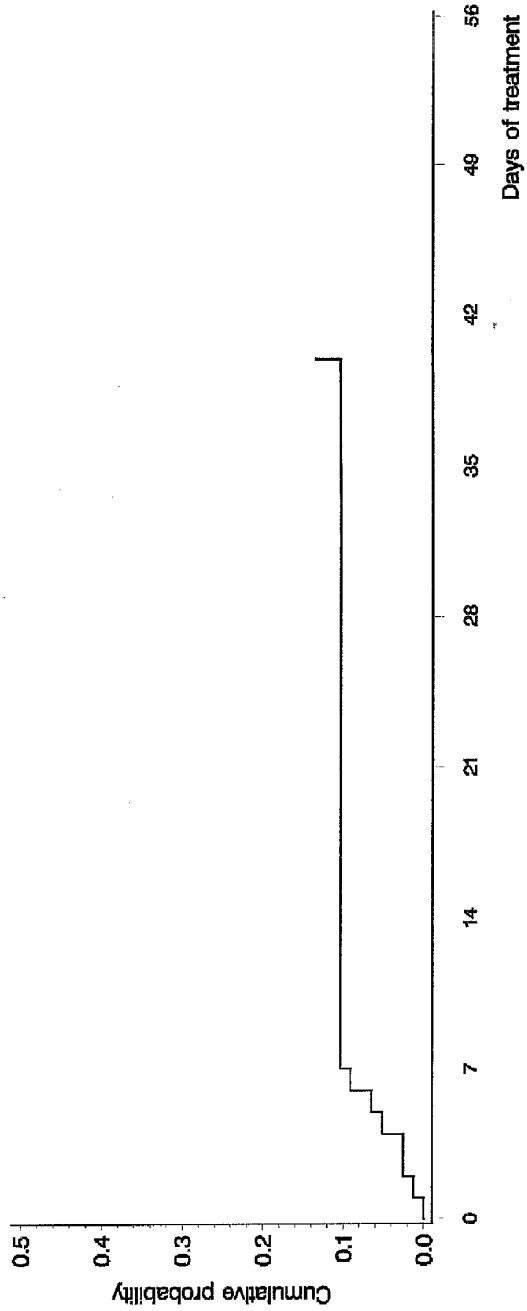
9550083

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

CUMULATIVE RISK OF DEVELOPING URINARY HESITANCY / RETENTION

Figure No.: 18



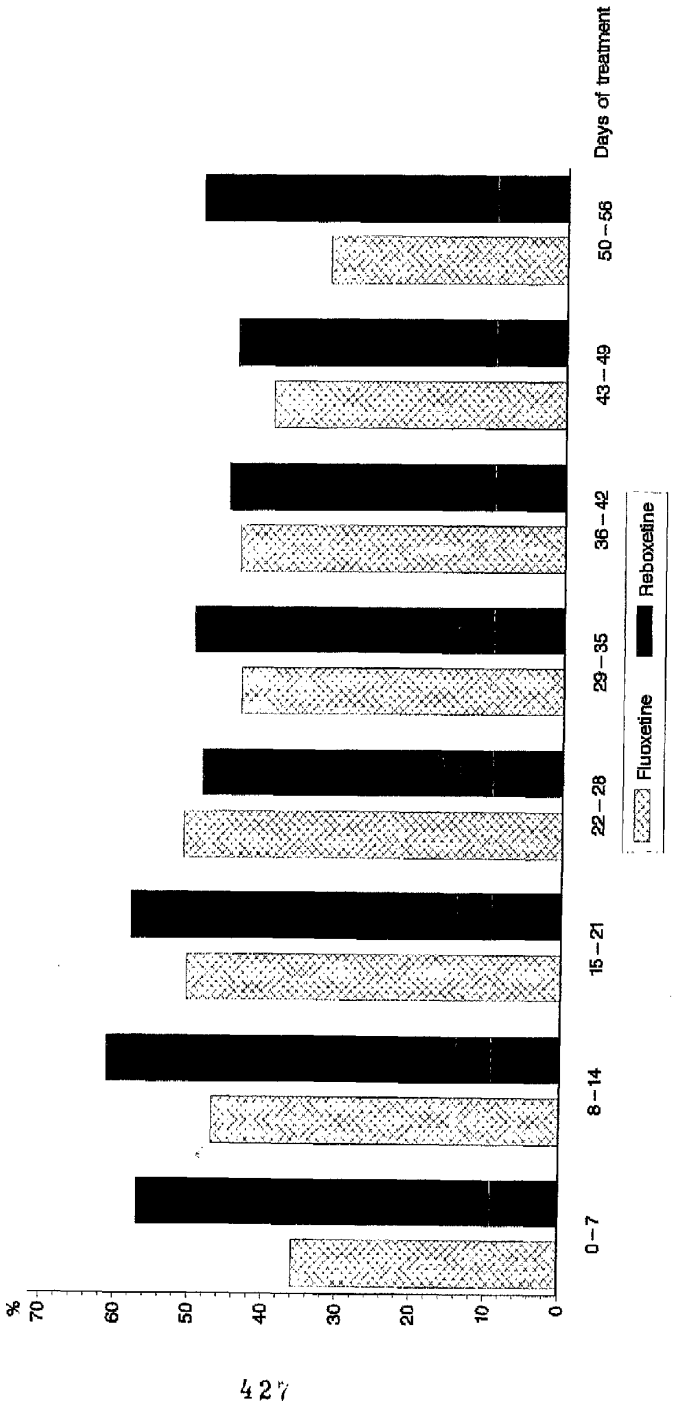
Log–Rank Test RBX vs FLU: (1 df) = 8.9520 P = 0.0028

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/016

PERCENTAGE OF PATIENTS WITH AT LEAST ONE ADVERSE EVENT ON EXPOSED ACCORDING TO TIME INTERVAL

Figure No.: 19



12. APPENDICES

12.1 Study Information

12.1.1 PROTOCOL AND PROTOCOL AMENDMENTS

FARMITALIA CARLO ERBA
ERBAMONT GROUP
CNS LINE

AMENDMENT 1 to the
REBOXETINE PROTOCOL 20124/016

The paragraph 9.1 will be as follow:

9.1. Pre-treatment period

Patients will be checked for eligibility according to the inclusion and exclusion criteria. A washout period of 4-7 days (14 days in case of MAOI administration, and 3-4 weeks in case of previous fluoxetine treatment) will then be undertaken,during which single blind placebo will be adminstered. During this period chlormethiazole (Heminevrin, caps 192 mg) as sleep inducer on p.r.n. basis will be allowed. Informed consent will be obtained - 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).

Signatures:

Investigator _____

Study Monitor _____

Product Leader _____

Line Medical Head _____

Biostatisticians _____

FARMITALIA CARLO ERBA
EBRAMONT GRUOP
CNS LINE

9550083

AMENDMENT 2 to the
REBOXETINE PROTOCOL 20124/016
for AUSTRALIA

The paragraph 9.1 will be as follow:

Patients will be checked for eligibility according to the inclusion and exclusion criteria. A washout period of 4-7 days (14 days in case of MAOI administration and 3 - 4 weeks in case of previous fluoxetine treatment) will then be undertaken, during which single blind placebo will be administered. During this period chlormethiazole (Heminevrin, caps 192 mg) as sleep inducer on p.r.n. basis will be allowed. Alternatively the short acting benzodiazepines (for instance temazepam 10 mg tablet) as sleep inducer on the p.r.n. basis will be allowed. Informed consent will be obtained - 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 screening form.

The paragraph 9.2.5 will be as follow:

No concomitant medications other than hypnotic on p.r.n. basis (see 9.1.) are allowed at entry into the study. Concomitant medication should be avoided throughout the study. In case of events arising during the course of the study nonpsychotropic medications which are considered necessary for the patient's welfare may be administered and will not be considered violation to the protocol. The drugs, dosage and frequency of administration will be recorded. Short acting benzodiazepines (for instance temazepam 10mg tablet) as sleep inducer on p.r.n. basis at bed-time are allowed.

Signatures:

Investigator_____

Study Monitor_____

Product Leader_____

Line Medical Head_____

9550083

FARMITALIA CARLO ERBA
EBRAMONT GRUOP
CNS LINE

AMENDMENT 3 to the
REBOXETINE PROTOCOL 20124/016
for Australia

The paragraph 9.1 will be as follow:

Patients will be checked for eligibility according to the inclusion and exclusion criteria. A washout period of 4-7 days (14 days in case of MAOI administration and 3 - 4 weeks in case of previous fluoxetine treatment) will then be undertaken. During this period chlormethiazole (Heminevrin, caps 192 mg) as sleep inducer on p.r.n. basis will be allowed. Alternatively the short acting benzodiazepines (for instance temazepam 10 mg tablet) as sleep inducer on the p.r.n. basis will be allowed. Informed consent will be obtained - 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 screening form.

The paragraph 9.2.5 will be as follow:

No concomitant medications other than hypnotic on p.r.n. basis (see 9.1.) are allowed at entry into the study. Concomitant medication should be avoided throughout the study. In case of events arising during the course of the study nonpsychotropic medications which are considered necessary for the patient's welfare may be administered and will not be considered violation to the protocol. The drugs, dosage and frequency of administration will be recorded. Short acting benzodiazepines (for instance temazepam 10mg tablet) as sleep inducer on p.r.n. basis at bed-time are allowed.

Signatures:

Investigator_____

Study Monitor_____

Product Leader_____

Line Medical Head_____

9550083

FARMITALIA CARLO ERBA
EBRAMONT GRUOP
CNS LINE

AMENDMENT 4 to the
REBOXETINE PROTOCOL 20124/016

The paragraph 9.1 will be as follow:

Patients will be checked for eligibility according to the inclusion and exclusion criteria. A washout period of 4-7 days (14 days in case of MAOI administration and 3 - 4 weeks in case of previous fluoxetine treatment) will then be undertaken. During this period chlormethiazole (Heminevrin, caps 192 mg) as sleep inducer on p.r.n. basis will be allowed. Informed consent will be obtained - 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 screening form.

Signatures:

Investigator_____

Study Monitor_____

Product Leader_____

Line Medical Head_____

FARMITALIA CARLO ERBA
R&D - C.N.S. LINE

COMPOUND: REBOXETINE

PROTOCOL No. : 20124/016

VERSION : Final: September 24, 1990

PHASE : III

TITLE : **Multicenter, multinational double-blind study of the activity and tolerability of reboxetine vs fluoxetine in patients suffering from Major Depressive Episodes.**

INVESTIGATORS : see enclosure 1

PRODUCT LEADER : Dr. Marek Jarema
Farmitalia Carlo Erba
CNS Dpt
Via Carlo Imbonati, 24
20159 Milano
Phone: (39-2) 69952749
Fax: (39-2) 69952249

STUDY MONITOR : see 17.0

DATA MANAGEMENT CENTER: Biostatistics and Data Management
FICE Milan

TABLE OF CONTENTS

1.0 PROTOCOL SUMMARY

The study, aimed at the evaluation of the efficacy and tolerability of reboxetine in comparison with fluoxetine in patients suffering from Major Depressive Episodes, will be carried out on a multinational basis, according to a double-blind parallel group design, in 220 patients. After an initial washout period of 1-2 weeks, patients will receive either reboxetine or fluoxetine , administered according to a fixed-flexible dose regimen, for 8 weeks. Efficacy (Clinical Global Impression, Hamilton Depression Rating Scale, Montgomery-Asberg Depression Rating Scale, Patient Global Impression and Social Adjustement Scale) and tolerability (newly observed signs and symptoms, lab tests and ECG) will be assessed every 1-2 weeks. At the end of the 8 weeks treatment period a long-term follow-up can 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 α2 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.

The comparison with the positive control, imipramine 75 mg, associated with similar EEG modifications in the fronto-central derivative, with modifications indicative of sedative activity in the occipito-temporal derivative and with 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 was 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.

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 the ventricular extrasystoles present before study start and hypertensive episodes respectively and 1 of the placebo group due to a cutaneous rash); in 5 cases (2, 1 and 2 in the RBX, DMI and P group respectively) for reasons unrelated to the experimental treatment.

Of the 80, 82 and 81 cases evaluable for efficacy in the RBX, DMI and P group (after exclusion of protocol violations, mainly related to associated treatments) 63%, 46% and 36% respectively showed a decrease >50% of the HAMD total score at the end of treatment; in 31%, 22% and 21% of these patients respectively the decrease was present within the 14th day of treatment. As to within-center results, the highest frequency of response was observed in the RBX group in all but 3 of the participating centers. After 2 and 4 weeks of treatment an average decrease of 23% and 34% of the HAMD was present in the P group; the corresponding figures were 34% and 49% in the DMI group and 39% and 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 and 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. Comparative evidence vs non-tricyclic antidepressants, and particularly vs fluoxetine, a selective 5HT-uptake inhibitor of established antidepressant efficacy and of favourable tolerability in comparison with tricyclic antidepressants 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 fluoxetine in patients suffering from Major Depressive Disorders.

5.0 DESIGN

5.1 Description

This phase III study will be carried out according to a double blind parallel group design, controlled vs fluoxetine, with random allocation of patients to one of the two treatments. The study will be organized on a multicentre, multinational basis.

5.2 Number of subjects proposed

Each center will recruit 20 patients, within a period of 12 months, for a total of 220 patients overall.

5.3 Logistics

The centers participating in the study are listed in enclusure 1.

6.0 STUDY POPULATION

6.1 Source of subjects

Adult patients selected from the population under in-patient care or attending out-patient or day-hospital clinics of the participating centers will be studied. These latter can be hospitalized for the study.

6.2 Inclusion criteria

- Patients affected by of Major Depressive Episodes (DSM III R -enclosure 2) not accompanied by psychotic features with presence of illness for at least one month and for less than 8 months.

- 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

- Resistance to antidepressive treatment (lack of response to at least two courses of previous antidepressants given at full doses for more than 1 month).

- History of Major Depressive Disorders associated to Endocrine Disorders: hypo and hyper-thyroidism tested by TSH and T4 at screen 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 to use efficient contraceptive measures during the study period.

- Past history of any drug hypersensitivity.

- Participation in any clinical study with an investigational compound in the 4 weeks preceding the study.

- Evidence of Substance Use Disorder (DSM-III-R) within past 6 months or currently.

- Chronic respiratory insufficiency in the physical examination (and X-ray in case of availability of facilities).

- Progressive illness or systematic disease of the digestive system, liver, or kidneys, or other conditions known to interfere with the absorption, distribution, metabolism and excretion of drugs.

- History of seizures or brain injury; current evidence of clinically important hematopoietic or cardiovascular diseases. Current evidence of urinary retention, or glaucoma.

- Symptoms of any other important clinical illness in the 4 weeks preceding the study.

- Clinically relevant abnormal findings in the physical examination, laboratory tests and ECG at admission.

- ECT in the previous 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 or fluoxetine). On this basis the experimental treatments will be prepared and labelled with the corresponding patient number.

Patient allocation to treatment will be done at the end of the pre-treatment period by the main Investigator on the basis of the patient's temporal entry into the study.

8.0 EXPERIMENTAL TREATMENTS

8.1 Test preparation

Indistinguishable capsules containing reboxetine 4 mg (2 tabl of 2 mg, batch no.....) or 6 mg (3 tabl of 2 mg, batch no.....) or fluoxetine 20 mg (1 caps of 20mg, batch no.....) or excipients only (batch no....) will be used. The experimental treatments will be administered according to fixed-flexible dose schedules as indicated under Study Conduct . Test preparations will consist of:

	morning	afternoon
-reboxetine	1 cps 4 mg	1 cps 4 mg
-reboxetine dose 2 (last 4 weeks)	as above	1 cps 6 mg
-fluoxetine	1 cps 20 mg	1 cps placebo
-fluoxetine dose 2 (last 4 weeks)	as above	1 cps 20 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 8 cartons labelled with the patient number and the indication "week 1" to "week 8" will be prepared. Each carton will contain the medication necessary for 1 week plus 2 capsules for possible losses, prepared according to the b.i.d. regimen with 1 cps for the "morning" and 1 cps for the "afternoon" dose. In addition for each patient 4 cartons labelled with the patient number

and the indication "week 5-dose 2", "week 6-dose 2", "week 7-dose 2" and "week 8-dose 2"will be provided, for the possible dosage increase during the last 4 weeks of treatment (see Study Conduct).

8.4 Drug supplies storage

Drug supplies will be stored at room temperature. All drug supplies will be handled under the direct responsibility of the Investigator and held by the Hospital Pharmacy. The study Monitor will check drug storage conditions during site visits.

The Investigator will be also responsible for drug accountability and will keep a record of the test compounds received from the Sponsor as well as of the dispensed drug.

8.5 Dispensing, use and disposal of the test preparation 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 run-in washout period of 7 days (14 days in case of MAOI administration) will then be undertaken, during which single blind placebo will be administered. During this period chlormethiazole (Heminevrin, caps 192mg) as a sleep inducer on p.r.n. basis will be allowed. Informed consent will be obtained - 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 56. In case of inefficacy or unsatisfactory response (worsening or no change or minimal improvement at the CGI on day 28, see assessments), and ine the case of good tolerance, especially non-symptomatic hypotension, the dose can be increased to (see 8.0 Experimental Treatments) "dose 2" from day 29 to day 56, i.e. up to the end of treatment. In case of intolerance the dose will be reduced to the previously well tolerated lower dosage level.

The treatments will be administered in the morning and in the afternoon, at least 2 hours before or after meals.

9.2.2 Duration of treatment

The experimental treatment will be administered for 8 weeks.

9.2.3 Indications for early termination of test therapy

Termination of test therapy prior to completion of the 8 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 deterioration 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 chormethiazole (Heminevrin , caps 192 mg) as a hypnotic on p.r.n. basis is allowed at entry into the study. Concomitant medication should be avoided throughout 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. Chlormethiazole (0,5 - 1,0g) 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 a copy of 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 (see section 17.0) 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 8 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 fluoxetine, Prozac will be prescribed.

9.4 Study timetable

Foreseen start date: December 1990
Duration of accrual: 12 months
Foreseen end date (date of the last visit of the last patient): February 1992.

10.0 EFFICACY ASSESSMENTS

10.1 Variables to be measured for efficacy assessment

On days 0, 7, 14, 21, 28, 42, 56 :

- 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).

- Social Adaptation Self-evaluation Scale (enclosure 9).

- Patients Global Impression - excluding day 0 (enclosure 10).

- Quality of Sleep (enclosure 11).

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 28, day 56 and every three months during follow-up

- Chest x-ray: at baseline in case of availability of facilities

- Laboratory: TSH and T4 at screen; full blood count, sodium, potassium, chlorine, BUN, creatinine, glucose, bilirubin, calcium, phosphorus, SGOT, SGPT, gammaGT, alkaline phosphatase, LDH, total proteins, albumin, cholesterol, uric acid, triglycerides, globulins - α_1, α_2, ß, gamma -, urinalysis - at admission, day 28, day 56 and every three months during follow-up.

- Adverse events: a check-list will be administered at each visit (enclosure 10).

11.2 Criteria for safety 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, 2 = moderate, 3 = severe, 4 = unknown), drug cause-effect relationship (according to Karch and Lasagna modified criteria; see enclosure 13), outcome, dechallenge (what happened to the adverse event when the drug was stopped or the dose decreased?) rechallenge (what

happened when the drug was restarted after the adverse event had disappeared?). The Investigator will also note if the double-blind code has been opened, the action taken regarding the test drug (none, discontinued, dosage reduced) and any treatment applied because of the adverse reactions.

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 fluoxetine of the total score of the HAMD. The comparision will be performed on the difference between baseline and the last postbaseline score for each patient regardless of length of time in the study. This analysis will take into account all the avaiable information, reducing the potential bias due to differential drop-out rates between groups. All randomized patients will be included in the analysis. A 95% confidence interval will be computed.

---

* 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 Committe on the Safety of Medicines. Br.J. Clin. Pharmac. (1988), **26**, 679-689.

From the phase II trial 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 220 patients are planned to be recruited and assuming that 10% of patients will drop out before the first postbaseline visit, we expect a lenght of 5 points for the confidence interval.

Refering to secondary efficacy analysis (see statistical analysis) based on proportions, the same sample size will allow for a maximum lenght of the confidence interval of 0.28. Maximum lenght 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 lenght of time in the study. Reboxetine and fluoxetine will be compared by computing a 95% confidence interval of the difference between treatments mean decrements vs baseline in the two groups.

Evident unbalences between baseline values in the two groups will be taken into account by means of analysis of covariance. In this case the confidence intervall 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 performed 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 eight weeks treatment period. In order to evaluate the onset of antidepressive effectiveness, time to responsewill be analysed. A non parametric test (Wilcoxon) will be performed for the comparison of the two treatment groups.

Dropouts will be classified by reasons for study termination and proportions of patients dropped out compared between groups.

Frequencies of patients showing maximum decrease ≥ 20mmHg in the standing systolic blood pressure will be compared between groups.

Adverse events will be presented by patient-by-patient listing and tabulated by treatment both on a patient basis and on an event basis. If clinically significant differences arise, they will be submitted to non parametric test of the differences between treatment groups.

Descritpive 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 and Hong-Kong revision, enclosure 14).

15.1 Ethical Committee

This study will not be undertaken until approval is obtained from the Ethical Commettee 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 FICE Subsidiary 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 3) will be signed by the patient or by the next of kin, and/or by the Investigator. In the latter case, the signature of a witness will testify that full information was given to the patient.

16.0 PROTOCOL AMENDMENTS

After the protocol has been signed, no changes will be made without the agreement of the Investigator the Steering Committee and the Sponsor. Any change will be recorded on a written agreement which will be signed and dated by both parties and attached to the original protocol. No protocol change will be implemented without Regulatory approval, where required.

17.0 STUDY MONITORING

The monitors of the study are:

Dr. J. Sastre (Antibioticos Pharma, c. Antonio Lopez 109, 28026 Madrid, Spain, phone: +341-5895100, fax: 4765798).

Dr. I. Götz-Lee (Farmitalia Carlo Erba GmbH, Merzhauser Str. 112, Postfach 480, Freiburg i. Br. - Germany, phone: +49761-4013115, fax: 40133200).

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 preparations will be supplied by Farmitalia Carlo Erba as 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 16.

19.0 ADMINISTRATIVE ASPECTS

19.1 Insurance policy

Farmitalia Carlo Erba Company declares to have a group insurance cover (policy N0. 4W8102 - Italia Assicurazioni) which provides indemnity to the Investigator, to the co-Investigators and to the subjects participating in the trial (enclosure 15).

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 expressely permitted.
The Investigator agrees that FICE R&D maintains the right to utilize the results of this study, in their original form and/or in a global report, for submission to the governmental and regulatory authorities of any country.

20.0 STUDY REPORT

20.1 Clinical Study Final Report

The final Medical Study Report will be written by the Product Leader and will be submitted to the Investigator for approval and signature.

20.2 Use and publication of study results

The Investigators, whilst free to use the data resulting from this study, are asked to discuss any paper with Farmitalia Carlo Erba prior to publication; to this purpose copy of manuscript/abstract has 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 may 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 ^{14}C-reboxetine administered orally to healthy volunteers.
March, 1985.

5. /118i - Strolin Benedetti et al.
A new HPLC method for the determination of FCE 20124 and its metabolite FCE 22930 in human plasma
September, 1987

6. P. Stark and D. Hardison
J. Clin. Psychiat. 46:53-58, 1985

24.0 SIGNATURES

Signatures of the:

Investigator _____

Study Monitor _____

Product Leader _____

Line Medical Head _____

Biostatisticians _____

TABLE 1

EVALUATION SCHEDULE

SCREEN		Screen	0	7	14	21	28	42	56	DAY
TREATMENT	RBX mg		8----------							->
							10----------			->
	FLU mg		20----------							->
							40----------			->
DIAGNOSIS : DSM III R		■								
MEDICAL HISTORY		■								
PHYSICAL EXAMINATION		■								
X-RAY		■								
ECG		■					■		■	
LABORATORY		■					■		■	
VITAL SIGNS		■	■	■	■	■	■	■	■	
21-ITEM HAMD		■	■	■	■	■	■	■	■	
CGI			■	■	■	■	■	■	■	
MADRS		■	■	■	■	■	■	■	■	
PGI			■	■	■	■	■	■	■	
SAS			■	■	■	■	■	■	■	
QUALITY OF SLEEP			■	■	■	■	■	■	■	
ADVERSE EVENTS			■	■	■	■	■	■	■	■

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) CGI: CLINICAL GLOBAL IMPRESSION
8) MADRS: MONTGOMERY ASBERG DEPRESSION RATING SCALE
9) SASS: SOCIAL ADAPTATION SELF-EVALUATION SCALE
10) PGI: PATIENTS GLOBAL IMPRESSION
11) QUALITY OF SLEEP
12) ADVERSE EVENTS: CHECK LIST
13) KARCH AND LASAGNA MODIFIED CRITERIA
14) DECLARATION OF HELSINKI
15) INSURANCE POLICY
16) DRUG ACCOUNTABILITY

ATTACHMENT A

PROTOCOL 20124/016: OPERATING PROCEDURES FOR TRAINING ON ASSESSMENT INSTRUMENTS, STUDY MONITORING AND COORDINATION

ATTACHMENT B

CASE RECORD FORM

Enclosure 1

LIST OF INVESTIGATORS

No.	Country	Principal Investigator (Name, Address)	No. of patients
1.	Germany	Dr. Moeller Dept. of Psychiatry University of Bonn	20
2.	"	Dr. Seeler Ochsenzoll Academic Teaching Hospital Hamburg	20
3.	"	Dr. Ziegler Academic Teaching Hospital Saar	20
4.	"	Dr. Pflug Dept. of Psychiatry University of Frankfurt	20
5.	Spain	Dr. J. Lopez Ibor (Coordinator) Hospital Ramon y Cajal Ctra. Colmenar Km. 9 28034 Madrid	20
6.	"	Dr. Jose Luis Ayuso Hospital Universitario San Carlos c/ Dr. Martin Lago s/n 28040 Madrid	20
7.	"	Dr. Enrique Alvarez Hosp. de la Santa Creu y San Pau San Antonio M. Claret, 167 08025 Barcelona	20
8.	"	Dra. Carmen Leal Hosp. Clinico Universitario Avda. Blasco Ibanez, 17 46010 Valencia	20

FARMITALIA CARLO ERBA
ERBAMONT GROUP
CNS LINE

9.	Spain	Dr. Miguel Gutierrez Hosp. Santiago Apostol Av. Olaguibel s/n 01004 Victoria	20
10.	"	Dr. J. Giner Ubago/Dr. Camacho Hosp. Clinico Universitario Avda. Dr. Fedriani, s/n 41009 Sevilla	20
11.	"	Prof. Ballus/Dr. J. Massana/ Dra. Aurora Otero/Dr. Gatell Hosp. Clinico de Barcelona Casanova, 143 08036 Barcelona	20
12.	Australia	Prof. G.D. Burrows Department of Psychiatry University of Melbourne Austin Hospital Heidelberg, Vic 3084 phone: 4505111	4
13.	"	Dr. Ramesh Gupta Phillip Health Centre Woden, Canberra	10
14.	"	Dr. Tom George Prince Charles Hospital Brisbane	10
15.	Argentina	Dr. J. C. Ferrali Moldes 2166 8° D Buenos Aires phone: (+541)7860533	30
16.	"	Dr. R. Montenegro Juncal 2425 8°B Buenos Aires phone and fax: (+541) 848381	30
17.	Germany	Dr Kuhn Schillerstrasse 3 W-7858 Weil	8
18.	"	Dr H.J. Schierle Puiseaux Platz 2 6054 Rodgau 3	8
19.	"	Dr Seichter Spiegelgassa 1 W-7407 Rottenburg	8

FARMITALIA CARLO ERBA
ERBAMONT GROUP
CNS LINE

20.	Germany	Dr J. Zehner Kurstrasse 9 6350 Bad Nauheim	8
21.	"	Dr M.M.Hummel Zentrum für Nervenheilkunde Prychiatr. Universitätsklinik Rudolf-Bultmann Strasse 8 3550 Marburg/Lahn	8
22	"	Dr W. Bellaire Talstrasse 36 6650 Homburg/Saar	16

Protocol 20124/016 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 allmost 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, neraly 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.

9550083

Enclosure 3

REBOXETINE PROTOCOL 20124/016

Multicenter, multinational double blind study of the activity and tolerability of reboxetine vs fluoxetine 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 fluoxetine, 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 untill 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 eight 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

possible side-effects and benefits of treatments. Blood tests, urinalysis, ECG will be undertaken be-weekly. Blood pressure and pulse will be taken every week, on the occasion of each visit.

Possible discomforts and risks

Antidepressant drugs can cause dry mouth, blurred vision, dizziness, mild difficulty in voiding urine, postural hypotension and electrocardiographic changes. After fluoxetine these side-effects are rarely reported, whereas nausea, nervousness, headache, and insomnia occur more frequently than with classic antidepressants.

Reboxetine has been so far administered for 28 days to about 180 patients and was well tolerated up to the dose of 5 mg twice daily. In the dose range of 3-5 mg twice daily clinically relevant improvement of depressive condition was present in the majority of patients; symptoms complained off by patients were mainly mild and transient and included most frequently headache, sweating, lassitude, nasal congestion, constipation and urinary hesitancy. At higher doses orthostatic hypotension, tachycardia, dizziness, blurred vision and nausea were reported.

Patients participating in the study will be carefully monitored to detect early signs of such side-effects.

Possible benefits

Other drugs are available for treatment of depressive disorders but none has been of proven value in all cases. This study will allow the evaluation of the antidepressant activity of reboxetine in comparison with fluoxetine, a compound of established favourable therapeutic index.

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.

Problems and questions

Should any problem or question arise with regard to the study, patients can contact the Principal Investigator:

.....
or the other staff members also involved in the study:

.....

.....

.....

In addition any problem or question can be discussed with a member of the Institutional Review Board (.....
.....), the Committee which has evaluated the potential risks and possible benefits of the study.

Payments and policy regarding research-related injuries.

Patients will not be paid for the participation in the study. The Clinical Center will provide short-term medical care for any physical injury resulting from participation in the study. No long-term medical care or financial compensation for such injuries will be provided except as it may be through whatever remedies are normally available under law. Insurance coverage is granted through the Sponsor Company.

PATIENTS CONSENT

I have read the explanation about this study and I have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

_____ _____
Patient Signature date

I have explained all the above indicated aspects of the study to the patient, who expressed his/her consent to the participation.

_____ _____
Investigator Signature date

_____ _____
Wittness Signature date

9550083

Enclosure 4

REBOXETINE PROTOCOL 20124/016

EXPERIMENTAL TREATMENT LABELLING

TREATMENT

reboxetine protocol 20124/016
patient No.....
week 1 - 8
batch No.....
expiry.....
drug for investigational use

HIGH DOSE TREATMENT

reboxetine protocol 20124/016
patient No.....
week 5 - 8
expiry.....
drug for investigational use

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1|

Centre No. ____ Patient No. ____ Initials ____ Visit/cycle ____

Investigator's name _____ Monitor's name _____ Date ____ D M Y

PRE-STUDY CHECKLIST

Enclosure 5

IN THE PATIENT:

ARE THE FOLLOWING CONDITIONS PRESENT?	YES	NO
– Aged between 18 and 65 years inclusive?	☐	☐
– Affected by Acute Recurrences of Mayor Depressive Disorders (DSM-III-R), not compained by psycothic features with the presence of illness for at least one month and not for less than 8 months?	☐	☐
– With a total score of 22 or above in the 21-HAMD?	☐	☐
– Able and willing (he or the next of kin) to give Informed Consent?	☐	☐
ARE THE FOLLOWING CONDITIONS ABSENT?		
– Dysthymic Disorders?	☐	☐
– Resistance to antidepressant treatment?	☐	☐
– History of Major Depressive Disorders, associated to Endocrine Disorders?	☐	☐
– Pregnancy? (if applicable)	☐	☐
– Refusal of contraceptive use during the study period?	☐	☐
– Clinically significant hematopoietic abnormality?	☐	☐
– Clinically significant lab values abnormality?	☐	☐
– Current evidence of urinary retention?	☐	☐
– Current evidence of thyroid disease (tested by TSH and T4)	☐	☐
– Current evidence of glaucoma?	☐	☐
– Clinically significant physical abnormality?	☐	☐

If NO, please cross and detail:

– Hepatic function ☐: _____

– Renal function ☐: _____

– Gastrointestinal function ☐: _____

– Cardiovascular function ☐: _____

Investigator's signature _____

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1|

Centre No. ____ Patient No. ____ Initials ____ Visit/cycle ____

Date ____ D M Y

(CONT') Cont'd EncL.5

	YES	NO
– Participation in a clinical trial with an investigational compound in the 4 weeks preceding the study?	☐	☐
– Evidence of substance use disorder within past 6 months or currently?	☐	☐
– Chronic respiratory insufficienty?	☐	☐
– History of drug hypersensitivity?	☐	☐
– Any history of seizures or brain injury?	☐	☐
– Any other important clinical illness in the 4 weeks preceding the study?	☐	☐
– ECT in the previous 6 months?	☐	☐

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.

Investigator's signature _____

9550083

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2 0 1 2 4 0 1 ;

Centre No. ⌊⌊⌊⌊⌋ Patient No. ⌊⌊⌊⌋ Initials ⌊⌊⌊⌋ Visit/cycle ⌊⌊⌊⌊⌊⌋

Date ⌊⌊⌊⌊⌊⌋ D M Y

LABORATORY TESTS Cont'd Encl. 5

Tests	Value	Clinically Significant abnormality*	Tests	Value*	Clinically Significant abnormality*
BLOOD TESTS			BUN		☐
HGB		☐	Creatinine		☐
MCT		☐	Uric acid		☐
RBC		☐	Total bilirubin		☐
WBC		☐	Direct bilirubin		☐
Neutrophils		☐	Total protein		☐
Lymphocytes		☐	Blood albumin		☐
Eosinophils		☐	Cholesterol		☐
Monocytes		☐	Triglycerides		☐
Basophils		☐	Globulins: α 1		☐
Platelets		☐	α 2		☐
Na^+		☐	β		☐
K^+		☐	γ		☐
CL^-		☐	rT_3		☐
Ca^{++}		☐	T_3		☐
PO_4		☐	T_4		☐
SGOT		☐	**URINALYSIS**		
SGPT		☐	Specific gravity		☐
γ-GT		☐	Albumin		☐
			Sugar		☐
BLOOD SUGAR		☐	RBC		☐
Alkaline phosphatase		☐	WBC		☐

Observation: _____

* Cross in case of clinically significant abnormality

Investigator's signature _____

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1

Centre No. | | | | Patient No. | | | Initials | | | Visit/cycle | | | | | |

Date | | | | | | | | D M Y

ADMISSION EXAMINATION

Cont'd EncL. 5

CHEST X-RAY taken on | | | | | | | | D M Y normal ☐ abnormal ☐

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 _____

Investigator's signature _____

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2 0 1 2 4 0 1

Centre No. ____ Patient No. ____ Initials ____ Visit/cycle ____

Date ____ D M Y

DIAGNOSIS

Cont'd EncL.5

– DSM III-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

Investigator's signature ____

9550083

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|

Centre No. | | | | | Patient No. | | | Initials | | | Visit/cycle | | | | |

Date | | | | | D. M

Cont'd Encl. 5

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 w
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 throughts 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 ½ 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 slepp
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

Investigator's signature _____

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2 0 1 2 4 0 1

Centre No. ___ Patient No. ___ Initials ___ Visit/cycle ___

Date ___ D M

Cont'd Encl. 5

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 mirror 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 feeelings 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 Hypocondriacal delusions

Investigator's signature _____

9550083

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2 0 1 2 4 0 1

Centre No. | | | | Patient No. | | | Initials | | | Visit/cycle | | | | |

Date | | | | | | D M

Cont'd Encl. 5

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 |__|

Investigator's signature _____

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

Cont'd Encl. 5

PREVIOUS TREATMENTS

NAME*	EFFICACY (Very poor, Poor, Fair, Good, Very good)	SIDE EFFECTS (if any)
	VP P F G VG	
	VP P F G VG	
	VP P F G VG	
	VP P F G VG	
	VP P F G VG	

Last treatment taken; name* _____ Last day of treatment | | | | | | D M Y

Drug free, Wash-Out Period: from | | | | | | D M Y to | | | | | | D M Y

CONCOMITANT DRUGS (during the drug free, wash-out period)

NAME*	Daily Dose (mg)	Started on (date)			Discontinued on (date)			Reason for the administration
		D	M	Y	D	M	Y	

* Whenever possible use non-proprietary name instead of trade name

Observations: _____

_____

_____

_____

Investigator's signature _____

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2 0 1 2 4 0 1

Centre No. ____ Patient No. ____ Initials ____ Visit/cycle ____

Date ____ D M Y

Cont'd Encl.5

ECG

HEART RATE ____

- Normal .... ☐
- Abnormal .... ☐

if abnormal check one or more boxes as appropriate:

- Sinus bradycardia (<60) .... ☐
- Sinus tachycardia (>100) .... ☐
- 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) ____________________

Investigator's signature ____________

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2 0 1 2 4 0 1 6

Centre No. | | | |

Patient No. | | |

Initials | | |

Visit/cycle | | | | | |

Date | | | | | | (D M Y)

CONT' ECG

Cont'd Encl. 5

Please, add here the ORIGINAL TRACING AND MEDICAL REPORT

Investigator's signature _____

9550083

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2 0 1 2 4 0 1 6

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 wee
[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 throughts 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 ½ 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 slepp
[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

Investigator's signature _____

9550083

FARMITALIA CARLO ERBA Erbamont Group | Compound **REBOXETINE** | Protocol No. 2 0 1 2 4 0 1

Centre No. | Patient No. | Initials | Visit/cycle | Date D M Y

Cont'd EncL.6

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 mirror 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 feeelings 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] Hypocondriacal delusions

Investigator's signature _____

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2 0 1 2 4 0 1 [illegible]

Centre No. | | | | Patient No. | | | Initials | | | Visit/cycle | | | | |

Date | | | | | | D M Y

Cont'd Encl. 6

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 |

Investigator's signature _____

FARMITALIA CARLO ERBA Erbamont Group

Compound REBOXETINE 9550083

Protocol No. 2|0|1|2|4|0|1|6

Centre No. | | | | | Patient No. | | | Initials | | | Visit/cycle | | | | | | |

Date | | | | | | | | | D M Y

CLINICAL GLOBAL IMPRESSION (CGI)

ENCLOSURE N° 7

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] Severily 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)

	Tolerability: side effects			
Activity	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

Investigator's signature _____

ARMITALIA CARLO ERBA
Erbamont Group

Compound REBOXETINE

Protocol No. 2 0 1 2 4 0 1 0

Centre No. | | | | Patient No. | | | Initials | | | Visit/cycle | | | |

Date | | | | | | (D M Y)

ENCLOSURE N° 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 fatiguability.

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 481

FARMITALIA CARLO ERBA
Erbamont Group

Compound REBOXETINE

Protocol No. 2 0 1 2 4 0 1 6

Centre No. | | | | Patient No. | | | | Initials | | | Visit/cycle | | | | |

Date | | | | | | D 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 mounting 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]. ☐

0. 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 tastless. Need to force oneself to eat [2]; Must be forced to eat. Food refusal [3]. ☐

Total score | |

Investigator's signature _____

9550083

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1|6

Centre No. | | | | Patient No. | | | Initials | | | Visit/cycle D|A|Y| | |

Investigator's name _____ Monitor's name _____ Date | | | . | | | | D M Y

Enclosure 9

SASS: SOCIAL ADAPTATION SELF-EVALUATION SCALE

We would like you to answer a set of simple questions, expressing your actual opinion. Please answer ALL questions; please circle one answer for each question. Thank you.

1. Are you professionally active? YES NO
   If "yes":
   A. Are you interested in your professional activities?
   3 - very 2 - moderately 1 - a little 0 - not at all
   If "no":
   B. Are you interested in your home activities?
   3 - very 2 - moderately 1 - a little 0 - not at all

2. Do you exercise these activities with:
   3 - much pleasure 2 - quite a pleasure 1 - a little pleasure 0 - no pleasure at all

3. Are you interested in hobbies/leisures?
   3 - very 2 - moderately 1 - a little 0 - not at all

4. The quality of your spare time is:
   3 - very good 2 - good 1 - moderate 0 - unsatisfactory

5. How frequently do you seek contacts with the members of your family (spouse, children, parents, etc.)?
   3 - very frequently 2 - frequently 1 - rarely 0 - never

6. How is the quality of the social relationship in your family?
   3 - very good 2 - good 1 - fair 0 - unsatisfactory

7. Outside your family, do you establish social relationship with:
   3 - many person 2 - quite a few persons 1 - only a few persons 0 - none

8. Do you try to develop social relationship with others:
   3 - very actively 2 - actively 1 - with moderate activity 0 - not actively at all

9. How do you estimate - in general - the social relationships you have with the other people?
   3 - very good 2 - good 1 - fair 0 - unsatisfactory

10. Do the relationships with the others appear to you to be:
    3 - very valuable 2 - valuable 1 - of a little value 0 - no valuable at all

Investigator's signature _____

9550083

FARMITALIA CARLO ERBA
Erbamont Group

Compound **REBOXETINE**

Protocol No. 2|0|1|2|4|0|1|6

Centre No. | | | | Patient No. | | | | Initials | | | Visit/cycle D|A|Y| | |

Investigator's name _____ Monitor's name _____ Date | | | | | | D M Y

Cont'd Encl. 9

11. How often do the persons from your social circle seek the contact with you?
3 - very often 2 - often 1 - rarely 0 - never

12. Do you observe the social rules, good manner, politeness, etc.?
3 - always 2 - most of the time 1 - rarely 0 - never

13. To what extend do you participate in the social life activities (such as club, church, etc.)?
3 - fully 2 - moderately 1 - slightly 0 - not at all

14. Do you like to search for informations in order to better understand things, situations, subjects, etc.?
3 - very much 2 - moderately 1 - not much 0 - not at all

15. Are you interested in scientific, technical or cultural informations?
3 - very much 2 - moderately 1 - a little 0 - not at all

16. Do you have difficulties in expressing to people around you your personal opinions?
0 - always 1 - often 2 - sometimes 3 - never

17. Do you feel rejected, expelled from your social circle?
0 - always 1 - often 2 - sometimes 3 - never

18. Do you consider your physical outlook to be important?
3 - very 2 - moderately 1 - not very much 0 - not at all

19. Do you have difficulties in managing your resources and incomes?
0 - always 1 - often 2 - sometimes 3 - never

20. Do you feel you could (or you can) arrange your environment according to your wishes and needs?
3 - very 2 - moderately 1 - a little 0 - not at all

That's all. Thank you for answering the questions.

For official use: Total score: |__|__|

Investigator's signature _____

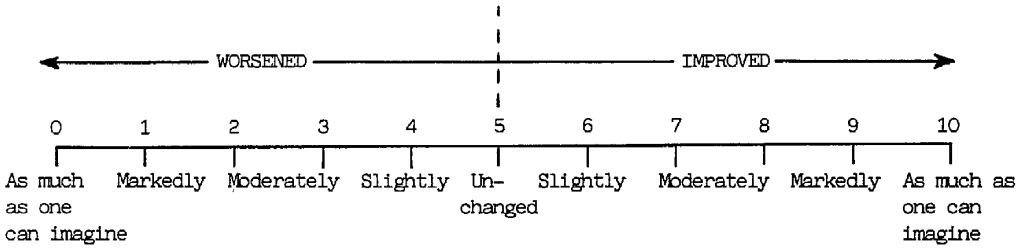
9550083

FARMITALIA CARLO ERBA
Erbamount group
R & D, CNS Line

Enclosure 10

PATIENT GLOBAL IMPRESSION

FROM STUDY START MY GENERAL CONDITIONS ARE:



By using this visual-analogue scale, please write the number corresponding to your actual situation.....

9550083

20124/014 Enclosure 11

QUALITY OF SLEEP

(Self-evaluation Scale)

Instruction: Please answer all questions A - E by crossing out the appropriate answer.
Please check only 1 answer for each question.

Time of falling asleep /__/__/ (h m) Time of waking up /__/__/ (h m)

Regarding your last 1-2 nights, do you consider that:

A. After having turn off the light you have fallen asleep:

[1] Immediately
[2] After about 15-30 minutes
[3] After one hour or more
[4] Not at all

B. Have you been dreaming during the night?

[1] Not at all
[2] A little bit
[3] Moderately
[4] All the night

C. How many times have you been awakeing during the night?

[1] No times
[2] 1 - 2 times for a short period of time
[3] 1 - 2 times for a long period of time
[4] 3 times or more

D. Do you wake up in the morning:

[1] Fully rested and fresh
[2] Quite rested
[3] A little bit tired
[4] Tired and fatiqued

E. Generally, do you think that your sleep was:

[1] Very good
[2] Good
[3] Fair
[4] Poor

9550083

ARMITALIA CARLO ERBA rbamont Group | Compound **REBOXETINE** | Protocol No. 2|0|1|2|4|0|1|6

entre No. | Patient No. | Initials | Visit/cycle | Date D M Y

Enclosure 12

NEWLY ADVERSE EVENTS: CHECK-LIST

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

Investigator's signature _____

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 tha the aetiology is unrelated to the study drug.

Enclosure 14

Declaration of Helsinki IV (Hong Kong - September 1989)

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

Recommendations guiding physicians
in biomedical research involving human subjects

Adopted by the 18th World Medical Assembly,
Helsinki, Finland, June 1964,

and amended by the
29th World Medical Assembly,
Tokyo, Japan, October 1975,
35th World Medical Assembly,
Venice, Italy, October 1983
and the
41st World Medical Assembly
Hong Kong, September 1989

INTRODUCTION

It is the mission of the physician to safeguard the healthy of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient." The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.
In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognized between medica research in which the aim is essentially diagnostic or therapeutic for a patient, and medica research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

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 for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.
3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research , even though the subject has given his or her consent.
4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.
6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
7. Physicians should abstain from engaging in research projects involving human subject unless they are satisfied that the hazard involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.
8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazard of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.
10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.
11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation. Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.
12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE
(Clinical research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, reestablishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method.

4. The refusal of the patient of participate in a study must never interfere with the physician-patient relationship.

5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (1, 2).

6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Non-clinical biomedical research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers - either healthy persons or patients for whom the experimental design is not related to the patient's illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject.

ITALIA ASSICURAZIONI 9550083

Enclosure 15

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 comoresa "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 thausand 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 healt workers for clinical trials and

Mod. 89/182 P - 7/88 - CRESTA-GENOVA

9550083

Enclosure 15 Cont'd

ITALIA ASSICURAZIONI

prove cliniche, nonche'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 gia' 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 attivita' 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 responsabilita' civile che possa derivare personalmente
- damage relating to third party liability which may result personally

agli esperimentatori 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,

prevarra', 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 Rischi

493

9550083

FARMITALIA CARLO ERBA
ERBAMONT GROUP
CNS LINE

Enclosure 16

DRUG ACCOUNTABILITY

Compound: REBOXETINE

Protocol N°: 20124/016

Title: Multicenter, multinational double-blind study of the activity and tolerability of Reboxetine vs Fluoxetine in patients suffering from Major Depressive Episodes

Centre N°/City________________

Investigator:____________________

Treatm. received: |__|__|__| (d m y) for patient N°____ to patient N°____ Receipt N°____________

Cartons per patient received: 16 + 8 (dose 2)

Pat N°	Pat. Init.	Date Start	Weekly treatment given (Please check: ✓)	N° of remaining cartons per pat.	N° of remaining caps. per pat.
			1__ 2__ 3__ 4__ 5__ 6__ 7__ 8__ Dose 2 : 5__ 6__ 7__ 8__	└─┘ + └─┘ (dose 2)	└─┴─┘ + └─┴─┘ (dose 2)
			1__ 2__ 3__ 4__ 5__ 6__ 7__ 8__ Dose 2 : 5__ 6__ 7__ 8__	└─┘ + └─┘ (dose 2)	└─┴─┘ + └─┴─┘ (dose 2)
			1__ 2__ 3__ 4__ 5__ 6__ 7__ 8__ Dose 2 : 5__ 6__ 7__ 8__	└─┘ + └─┘ (dose 2)	└─┴─┘ + └─┴─┘ (dose 2)
			1__ 2__ 3__ 4__ 5__ 6__ 7__ 8__ Dose 2 : 5__ 6__ 7__ 8__	└─┘ + └─┘ (dose 2)	└─┴─┘ + └─┴─┘ (dose 2)
			1__ 2__ 3__ 4__ 5__ 6__ 7__ 8__ Dose 2 : 5__ 6__ 7__ 8__	└─┘ + └─┘ (dose 2)	└─┴─┘ + └─┴─┘ (dose 2)
			1__ 2__ 3__ 4__ 5__ 6__ 7__ 8__ Dose 2 : 5__ 6__ 7__ 8__	└─┘ + └─┘ (dose 2)	└─┴─┘ + └─┴─┘ (dose 2)
			1__ 2__ 3__ 4__ 5__ 6__ 7__ 8__ Dose 2 : 5__ 6__ 7__ 8__	└─┘ + └─┘ (dose 2)	└─┴─┘ + └─┴─┘ (dose 2)
			1__ 2__ 3__ 4__ 5__ 6__ 7__ 8__ Dose 2 : 5__ 6__ 7__ 8__	└─┘ + └─┘ (dose 2)	└─┴─┘ + └─┴─┘ (dose 2)
			1__ 2__ 3__ 4__ 5__ 6__ 7__ 8__ Dose 2 : 5__ 6__ 7__ 8__	└─┘ + └─┘ (dose 2)	└─┴─┘ + └─┴─┘ (dose 2)
			1__ 2__ 3__ 4__ 5__ 6__ 7__ 8__ Dose 2 : 5__ 6__ 7__ 8__	└─┘ + └─┘ (dose 2)	└─┴─┘ + └─┴─┘ (dose 2)

N° of total caps. to be returned: __________

N° of total cartons 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.

Attachment A

REBOXETINE PROTOCOL 20124/016: 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 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.

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 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;

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 from (form D) will be filled in and copy of it sent to FICE Milan.

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 to defined.

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.

12.1.2 CRF SAMPLE

A complete CRF is filed in the Study Master File.

12.1.3 ETHIC COMMITTEES OR INVESTIGATIONAL REVIEW BOARDS: APPROVALS, LIST OF MEMBERS, PATIENT INFORMATION AND CONSENT FORMS

Investigational Review Board and Ethics Committees approvals were obtained according to local regulations and laws: copy of approval documents and, in case of Ethics Committees, list of members is filed in the Study Master File.

The proposed Consent Forms 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.

12.1.4 CLINICAL INVESTIGATOR LIST, SIGNATURES AND CURRICULA VITAE

Centre 1: Dr H.J. Möller (Principal investigator)
Dr G Höflich, Dr J.Fuger, Dr C. Krappel, I.Maurer (Co-investigators)
Psychiatrische Universitätsklinik
Bonn, Germany

Centre 2: Dr W. Seeler (Principal investigator)
Dr R. Wittgens, Dr D. Moehrs , U. Janzen, S. Srna, C.Hebell Siewers (Co-investigators)
Allgemeines Krankenhaus
Ochsenzoll
Hamburg, Germany

Centre 3: Dr B. Ziegler (Principal investigator)
Dr Trabert, Dr I. Rentschler (Co-investigators)
Universitätsklinik im LK Homburg
Homburg/Saar, Germany

Centre 4: Prof B. Pflug (Principal investigator)
Dr Flett , T. Holzmann (Co-investigators)
Zentrum für Psychiatrie am Klinikum der J.W. Goethe Univ.
Frankfurt, Germany

Centre 5: Dr J. Lopez Ibor (Principal investigator)
Dr J. Saiz-Ruiz, Dr A. Ciudad Herrera (Co-investigators)
Hospital Ramon y Cajal
Madrid, Spain

Centre 7: Dr E. Alvarez Martinez (Principal investigator)
Dr J. Perez Blanco, Dr J. Soriano (Co-investigators)
Hosp. de la Santa Creu y San Pau
Barcelona, Spain

Centre 11: Dr J. Massana (Principal investigator)
Dr L. Risueño, Dr A. Otero, Dr Gatell (Co-investigators)
Hospital Clinico de Barcelona
Barcelona, Spain

Centre 12	Prof G.D. Burrows (Principal investigator) Dr S. Gyorki (Co-investigator) Dept. of Psychiatry University of Melbourne, Austin Hospital, Melbourne, Australia
Centre 13:	Dr R. Gupta (Principal investigator) Phillip Health Centre Canberra, Australia
Centre 14:	Dr T. George (Principal investigator) The Prince Charles Hospital Brisbane, Australia
Centre 15:	Dr J.C. Ferrali (Principal investigator) Moldes 2166 8°D Buenos Aires, Argentina
Centre 16:	Dr R. Montenegro (Principal investigator) Juncal 2425 8°B Buenos Aires, Argentina
Centre 18:	Dr H.J. Schierle (Principal investigator) Puiseaux Platz 2 Rodgau, Germany
Centre 20:	Dr J. Zehner (Principal investigator) Kurstrasse 9 Bad Nauheim, Germany
Centre 21:	Prof M. Hummel (Principal investigator) Dr T. Reuster, Dr H. Berger, Dr Winkler (Co-investigators) Psychiatrische Univ. Klinik Marburg/Lahn, Germany
Centre 22:	Dr W. Bellaire (Principal investigator) Talstrasse 36 Homburg/Saar, Germany

Investigators signatures and Curricula vitae are filed in the Study Master File.

Pharmacia Document 9550083

12.1.5. CERTIFICATES OF ANALYSIS

9550083

Pharmacia
Farmitalia Carlo Erba

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

504

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

9550083

CENTRO RICERCHE
VIA GIOVANNI XXIII, 23
20014 NERVIANO
TELEFONO (0331) 587250
TELEGRAMMI FARMITAL A CARLO ERBA NERVIANO
CASELLA POSTALE 2
TELEX 310679 MONTED PER FARMITAL A NERVIANO

FARMITALIA CARLO ERBA

DATA December 9th, 1992

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

505

GRUPPO ERBAMONT

9550083

VIA CARLO IMBONATI, 24
20159 MILANO

TELEFONO (02) 6995,1 (CENTRALINO)
TELEGRAMMI ERBACAR MILANO
CASELLA POSTALE 10519
C.C. POSTALE 819205
TELEX 330314 ERBA I-

FARMITALIA CARLO ERBA

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

506

9550083

VIA CARLO IMBONATI, 24
20159 MILANO

TELEFONO (02) 6995.1 (CENTRALINO)
TELEGRAMMI ERBACAR-MILANO
CASELLA POSTALE 10519
C.C. POSTALE 619705
TELEX 330314 ERBA I-

FARMITALIA CARLO ERBA

DATA October 22, 1990

VS. RIF.

NS. RIF.

TEL. DIRETTO

CERTIFICATE OF ANALYSIS

Fluoxetine hydrochloride 20 mg capsules

Batch SF 1128

Manufacturing date	: September 1990
Expiry date	: April 1993
Description	: hard-gelatin capsule, opaque red-brown, size No. 0, containing a 20 mg PROZAC opaque white body, light green cap capsule (LILLY, batch No. N9708Y1)
Uniformity of mass	: complies, according to Eur. Ph., 2nd Ed., requirements
Disintegration time	: 14 minutes
Microbial contamination	: total viable aerobic count < 1000 moulds and yeasts < 100 E. Coli and Salmonella : absent
Approved by	: Virginio Busnelli

507

9550083

VIA CARLO IMBONATI, 24
20159 MILANO

TELEFONO (02) 6995.1 (CENTRALINO)
TELEGRAMMI ERBACAR-MILANO
CASELLA POSTALE 10519
C.C. POSTALE 619205
TELEX 330314 ERBA I-

FARMITALIA CARLO ERBA

DATA May 25th, 1992

VS. RIF.

NS. RIF.

TEL. DIRETTO

CERTIFICATE OF ANALYSIS

Fluoxetine hydrochloride 20 mg capsules

Batch SF 1307

Manufacturing date	: May, 1992
Expiry date	: November, 1994
Description	: red-brown, hard-gelatin capsule, snap-fit, size No. 0, containing a 20 mg PROZAC opaque-white body, light green cap capsule (LILLY batch P0901Y1)
Uniformity of mass	: within the limits, according to Ph. Eur. 2nd Ed., Section V.5.2.1
Disintegration	: 15 minutes
Microbial contamination	: total viable aerobic counts < 1000 moulds and yeasts < 100 E. Coli and Salmonellae : absent
Approved by	: Virginio Busnelli

508

9550083

VIA CARLO IMBONATI, 24
20159 MILANO

TELEFONO (02) 6895.1 (CENTRALINO)
TELEGRAMMI ERBACAR-MILANO
CASELLA POSTALE 10519
C.C. POSTALE 619205
TELEX 330314 ERBA-I-

FARMITALIA CARLO ERBA

DATA November 18th, 1992

VS. RIF.

NS. RIF.

TEL. DIRETTO

CERTIFICATE OF ANALYSIS

Fluoxetine hydrochloride 20 mg capsules

Batch SF 1340

Manufacturing date	: October, 1992
Expiry date	: April, 1995
Description	: red-brown, hard-gelatin capsule, snap-fit, size No. 0, containing a 20 mg PROZAC opaque-white body, light green cap capsule (LILLY batch P1304Y1)
Uniformity of mass	: within the limits, according to Ph. Eur. 2nd Ed., Section V.5.2.1
Disintegration	: 15 minutes
Microbial contamination	: total viable aerobic counts < 1000 moulds and yeasts < 100 E. Coli and Salmonellae : absent
Approved by	: Virginio Busnelli

509

GRUPPO ERBAMONT

VIA CARLO IMBONATI, 24
20159 MILANO

TELEFONO (02) 6093.1 (CEN.TRALINO)
TELEGRAMMI ERBADAR MILANO
CASELLA POSTALE 10519
C.C. POSTALE 619205
TELEX 330314 ERBA I-

9550083

FARMITALIA CARLO ERBA

DATA December 11th, 1991

VS. RIF.

NS. RIF

TEL. DIRETTO

CERTIFICATE OF ANALYSIS

PLACEBO for Reboxetine capsules

Batch SF 1247

Manufacturing date	: October, 1991
Appearance	: red-brown, hard-gelatin capsule, snap-fit, size No. 0, containing two round, convex, 6 mm diameter, white tablets, marked S.F. on a side (batch SF 1205)
Identification	: negative
Average weight	: mg 199.76
Uniformity of weight	: within the limits, according to Ph. Eur. 2nd Ed., Section V.5.2.1
Disintegration	: 10 minutes
Microbial contamination	: total viable aerobic count < 1000 moulds and yeasts < 100 E. Coli and Salmonellae : absent
Approved by	: Virginio Busnelli

510

CAPITALE ... I.V.
TRIBUNALE DI MILANO n.s. ... 38246
VOL. 6966 - FASC. 46 - C.C.I.A.A. N. 1171077
COD. FISC. E PART. IVA N. 07605290156

GRUPPO ERBAMONT

Pharmacia Document 9550083

12.1.6 AUDIT CERTIFICATE

9550083

Pharmacia
Pharmaceuticals Milan R&D/GCP-QA

R&D/Q.A. AUDIT CERTIFICATE

Product **REBOXETINE**

Protocol N°: **FCE 20124/016** N° GCP: **55**

Study title: Multicenter, Multinational Double-Blind Study of the activity and Tolerability of Reboxetine vs Fluoxetine in Patients suffering from Major Depressive Episodes.

Type of Audit	Site	Audit date(s)	Reporting date
Study Master File	Pharmacia - Milan	02-10.02.1995	14.02.1995
Data Listings vs CRFs	Pharmacia - Milan	02.-17.11.1995	20.11.1995
Final Draft Report	Pharmacia - Milan	28.11-04.12.1995	05.12.1995
Final Report	Pharmacia - Milan	27-29.01.1996	30.01.1996

Signature of the Head of R&D/GCP-Q.A.: Dr: Alberto Nava

Date: Jan 30th, 1996

512

12.1.7 RANDOMISATION LIST

REBOXETINE - 016

Randomization List 9550083

---------- Center=1 ----------

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
1	1	1	fluoxetine
2	1	2	reboxetine
3	1	3	fluoxetine
4	1	4	reboxetine
5	1	5	fluoxetine
6	1	6	fluoxetine
7	1	7	reboxetine
8	1	8	reboxetine
9	1	9	fluoxetine
10	1	10	reboxetine
11	1	11	reboxetine
12	1	12	fluoxetine
13	1	13	reboxetine
14	1	14	fluoxetine
15	1	15	reboxetine
16	1	16	fluoxetine
17	1	17	reboxetine
18	1	18	reboxetine
19	1	19	fluoxetine
20	1	20	fluoxetine
21	1	21	fluoxetine
22	1	22	fluoxetine
23	1	23	reboxetine
24	1	24	reboxetine
25	1	25	fluoxetine
26	1	26	reboxetine
27	1	27	reboxetine
28	1	28	fluoxetine
29	1	29	reboxetine
30	1	30	fluoxetine
31	1	31	reboxetine
32	1	32	fluoxetine

---------- Center=2 ----------

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
33	2	1	fluoxetine
34	2	2	reboxetine
35	2	3	reboxetine
36	2	4	fluoxetine
37	2	5	reboxetine
38	2	6	fluoxetine
39	2	7	fluoxetine
40	2	8	reboxetine
41	2	9	fluoxetine
42	2	10	reboxetine
43	2	11	reboxetine
44	2	12	fluoxetine
45	2	13	reboxetine
46	2	14	fluoxetine
47	2	15	fluoxetine
48	2	16	reboxetine
49	2	17	reboxetine
50	2	18	reboxetine
51	2	19	fluoxetine
52	2	20	fluoxetine
53	2	21	fluoxetine
54	2	22	fluoxetine
55	2	23	reboxetine
56	2	24	reboxetine
57	2	25	fluoxetine
58	2	26	fluoxetine
59	2	27	reboxetine
60	2	28	reboxetine
61	2	29	fluoxetine
62	2	30	reboxetine
63	2	31	reboxetine
64	2	32	fluoxetine

Centers 19,20,21 and 22,23,24 are enlargement of centers 12,13,14
Centers 25,26 are enlargement of centers 15,16

REBOXETINE - 016

Randomization 2550083

Center=3

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
65	3	1	fluoxetine
66	3	2	fluoxetine
67	3	3	reboxetine
68	3	4	reboxetine
69	3	5	reboxetine
70	3	6	reboxetine
71	3	7	fluoxetine
72	3	8	fluoxetine
73	3	9	reboxetine
74	3	10	reboxetine
75	3	11	fluoxetine
76	3	12	fluoxetine
77	3	13	reboxetine
78	3	14	reboxetine
79	3	15	fluoxetine
80	3	16	fluoxetine
81	3	17	fluoxetine
82	3	18	fluoxetine
83	3	19	reboxetine
84	3	20	reboxetine
85	3	21	fluoxetine
86	3	22	fluoxetine
87	3	23	reboxetine
88	3	24	reboxetine
89	3	25	reboxetine
90	3	26	fluoxetine
91	3	27	reboxetine
92	3	28	fluoxetine
93	3	29	fluoxetine
94	3	30	fluoxetine
95	3	31	reboxetine
96	3	32	reboxetine

Center=4

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
97	4	1	reboxetine
98	4	2	fluoxetine
99	4	3	fluoxetine
100	4	4	reboxetine
101	4	5	reboxetine
102	4	6	fluoxetine
103	4	7	fluoxetine
104	4	8	reboxetine
105	4	9	fluoxetine
106	4	10	reboxetine
107	4	11	reboxetine
108	4	12	fluoxetine
109	4	13	fluoxetine
110	4	14	fluoxetine
111	4	15	reboxetine
112	4	16	reboxetine
113	4	17	fluoxetine
114	4	18	fluoxetine
115	4	19	reboxetine
116	4	20	reboxetine
117	4	21	fluoxetine
118	4	22	reboxetine
119	4	23	fluoxetine
120	4	24	reboxetine
121	4	25	reboxetine
122	4	26	fluoxetine
123	4	27	reboxetine
124	4	28	fluoxetine
125	4	29	fluoxetine
126	4	30	reboxetine
127	4	31	fluoxetine
128	4	32	reboxetine

Centers 19,20,21 and 22,23,24 are enlargement of centers 12,13,14
Centers 25,26 are enlargement of centers 15,16

REBOXETINE - 016

Randomization 9550083

Center=5

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
129	5	1	reboxetine
130	5	2	fluoxetine
131	5	3	fluoxetine
132	5	4	reboxetine
133	5	5	fluoxetine
134	5	6	reboxetine
135	5	7	fluoxetine
136	5	8	reboxetine
137	5	9	fluoxetine
138	5	10	reboxetine
139	5	11	reboxetine
140	5	12	fluoxetine
141	5	13	reboxetine
142	5	14	fluoxetine
143	5	15	fluoxetine
144	5	16	reboxetine
145	5	17	fluoxetine
146	5	18	reboxetine
147	5	19	fluoxetine
148	5	20	reboxetine
149	5	21	fluoxetine
150	5	22	fluoxetine
151	5	23	reboxetine
152	5	24	reboxetine
153	5	25	fluoxetine
154	5	26	fluoxetine
155	5	27	reboxetine
156	5	28	reboxetine
157	5	29	reboxetine
158	5	30	fluoxetine
159	5	31	fluoxetine
160	5	32	reboxetine

Center=6

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
161	6	1	fluoxetine
162	6	2	reboxetine
163	6	3	fluoxetine
164	6	4	reboxetine
165	6	5	fluoxetine
166	6	6	fluoxetine
167	6	7	reboxetine
168	6	8	reboxetine
169	6	9	fluoxetine
170	6	10	fluoxetine
171	6	11	reboxetine
172	6	12	reboxetine
173	6	13	reboxetine
174	6	14	fluoxetine
175	6	15	fluoxetine
176	6	16	reboxetine
177	6	17	reboxetine
178	6	18	reboxetine
179	6	19	fluoxetine
180	6	20	fluoxetine
181	6	21	reboxetine
182	6	22	fluoxetine
183	6	23	fluoxetine
184	6	24	reboxetine
185	6	25	fluoxetine
186	6	26	fluoxetine
187	6	27	reboxetine
188	6	28	reboxetine
189	6	29	fluoxetine
190	6	30	reboxetine
191	6	31	fluoxetine
192	6	32	reboxetine

Centers 19,20,21 and 22,23,24 are enlargement of centers 12,13,14
Centers 25,26 are enlargement of centers 15,16

REBOXETINE - 016

Randomization: 9550083

Center=7

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
193	7	1	reboxetine
194	7	2	fluoxetine
195	7	3	fluoxetine
196	7	4	reboxetine
197	7	5	fluoxetine
198	7	6	reboxetine
199	7	7	reboxetine
200	7	8	fluoxetine
201	7	9	fluoxetine
202	7	10	fluoxetine
203	7	11	reboxetine
204	7	12	reboxetine
205	7	13	fluoxetine
206	7	14	reboxetine
207	7	15	fluoxetine
208	7	16	reboxetine
209	7	17	fluoxetine
210	7	18	reboxetine
211	7	19	fluoxetine
212	7	20	reboxetine
213	7	21	reboxetine
214	7	22	fluoxetine
215	7	23	fluoxetine
216	7	24	reboxetine
217	7	25	fluoxetine
218	7	26	reboxetine
219	7	27	fluoxetine
220	7	28	reboxetine
221	7	29	reboxetine
222	7	30	fluoxetine
223	7	31	fluoxetine
224	7	32	reboxetine

Center=8

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
225	8	1	fluoxetine
226	8	2	reboxetine
227	8	3	reboxetine
228	8	4	fluoxetine
229	8	5	fluoxetine
230	8	6	reboxetine
231	8	7	fluoxetine
232	8	8	reboxetine
233	8	9	fluoxetine
234	8	10	reboxetine
235	8	11	reboxetine
236	8	12	fluoxetine
237	8	13	fluoxetine
238	8	14	fluoxetine
239	8	15	reboxetine
240	8	16	reboxetine
241	8	17	fluoxetine
242	8	18	fluoxetine
243	8	19	reboxetine
244	8	20	reboxetine
245	8	21	reboxetine
246	8	22	reboxetine
247	8	23	fluoxetine
248	8	24	fluoxetine
249	8	25	fluoxetine
250	8	26	reboxetine
251	8	27	fluoxetine
252	8	28	reboxetine
253	8	29	fluoxetine
254	8	30	reboxetine
255	8	31	fluoxetine
256	8	32	reboxetine

Centers 19,20,21 and 22,23,24 are enlargement of centers 12,13,14
Centers 25,26 are enlargement of centers 15,16

REBOXETINE - 016

Randomization 9550083

Center=9

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
257	9	1	fluoxetine
258	9	2	fluoxetine
259	9	3	reboxetine
260	9	4	reboxetine
261	9	5	reboxetine
262	9	6	fluoxetine
263	9	7	reboxetine
264	9	8	fluoxetine
265	9	9	reboxetine
266	9	10	fluoxetine
267	9	11	fluoxetine
268	9	12	reboxetine
269	9	13	fluoxetine
270	9	14	fluoxetine
271	9	15	reboxetine
272	9	16	reboxetine
273	9	17	fluoxetine
274	9	18	fluoxetine
275	9	19	reboxetine
276	9	20	reboxetine
277	9	21	reboxetine
278	9	22	fluoxetine
279	9	23	reboxetine
280	9	24	fluoxetine
281	9	25	fluoxetine
282	9	26	reboxetine
283	9	27	fluoxetine
284	9	28	reboxetine
285	9	29	fluoxetine
286	9	30	fluoxetine
287	9	31	reboxetine
288	9	32	reboxetine

Center=10

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
289	10	1	reboxetine
290	10	2	reboxetine
291	10	3	fluoxetine
292	10	4	fluoxetine
293	10	5	fluoxetine
294	10	6	fluoxetine
295	10	7	reboxetine
296	10	8	reboxetine
297	10	9	reboxetine
298	10	10	fluoxetine
299	10	11	reboxetine
300	10	12	fluoxetine
301	10	13	reboxetine
302	10	14	reboxetine
303	10	15	fluoxetine
304	10	16	fluoxetine
305	10	17	fluoxetine
306	10	18	reboxetine
307	10	19	fluoxetine
308	10	20	reboxetine
309	10	21	fluoxetine
310	10	22	reboxetine
311	10	23	fluoxetine
312	10	24	reboxetine
313	10	25	fluoxetine
314	10	26	fluoxetine
315	10	27	reboxetine
316	10	28	reboxetine
317	10	29	fluoxetine
318	10	30	reboxetine
319	10	31	fluoxetine
320	10	32	reboxetine

Centers 19,20,21 and 22,23,24 are enlargement of centers 12,13,14
Centers 25,26 are enlargement of centers 15,16

REBOXETINE - 016

9550083

Randomization List

Center=11

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
321	11	1	fluoxetine
322	11	2	reboxetine
323	11	3	fluoxetine
324	11	4	reboxetine
325	11	5	reboxetine
326	11	6	reboxetine
327	11	7	fluoxetine
328	11	8	fluoxetine
329	11	9	reboxetine
330	11	10	reboxetine
331	11	11	fluoxetine
332	11	12	fluoxetine
333	11	13	reboxetine
334	11	14	fluoxetine
335	11	15	reboxetine
336	11	16	fluoxetine
337	11	17	reboxetine
338	11	18	fluoxetine
339	11	19	fluoxetine
340	11	20	reboxetine
341	11	21	fluoxetine
342	11	22	reboxetine
343	11	23	reboxetine
344	11	24	fluoxetine
345	11	25	reboxetine
346	11	26	fluoxetine
347	11	27	fluoxetine
348	11	28	reboxetine
349	11	29	fluoxetine
350	11	30	reboxetine
351	11	31	reboxetine
352	11	32	fluoxetine

Center=12

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
353	12	1	fluoxetine
354	12	2	fluoxetine
355	12	3	reboxetine
356	12	4	reboxetine
357	12	5	fluoxetine
358	12	6	reboxetine
359	12	7	reboxetine
360	12	8	fluoxetine
361	12	9	fluoxetine
362	12	10	reboxetine
363	12	11	reboxetine
364	12	12	fluoxetine
365	12	13	fluoxetine
366	12	14	reboxetine
367	12	15	fluoxetine
368	12	16	reboxetine
369	12	17	reboxetine
370	12	18	reboxetine
371	12	19	fluoxetine
372	12	20	fluoxetine
373	12	21	fluoxetine
374	12	22	fluoxetine
375	12	23	reboxetine
376	12	24	reboxetine
377	12	25	fluoxetine
378	12	26	fluoxetine
379	12	27	reboxetine
380	12	28	reboxetine
381	12	29	reboxetine
382	12	30	fluoxetine
383	12	31	fluoxetine
384	12	32	reboxetine

Centers 19,20,21 and 22,23,24 are enlargement of centers 12,13,14
Centers 25,26 are enlargement of centers 15,16

REBOXETINE - 016

Randomization List 9550083

Center=13

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
385	13	1	fluoxetine
386	13	2	fluoxetine
387	13	3	reboxetine
388	13	4	reboxetine
389	13	5	fluoxetine
390	13	6	reboxetine
391	13	7	fluoxetine
392	13	8	reboxetine
393	13	9	fluoxetine
394	13	10	reboxetine
395	13	11	reboxetine
396	13	12	fluoxetine

Center=14

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
397	14	1	fluoxetine
398	14	2	reboxetine
399	14	3	reboxetine
400	14	4	fluoxetine
401	14	5	fluoxetine
402	14	6	reboxetine
403	14	7	reboxetine
404	14	8	fluoxetine
405	14	9	fluoxetine
406	14	10	fluoxetine
407	14	11	reboxetine
408	14	12	reboxetine

Center=15

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
409	15	1	reboxetine
410	15	2	fluoxetine
411	15	3	reboxetine
412	15	4	fluoxetine
413	15	5	reboxetine
414	15	6	fluoxetine
415	15	7	reboxetine
416	15	8	fluoxetine
417	15	9	reboxetine
418	15	10	reboxetine
419	15	11	fluoxetine
420	15	12	fluoxetine
421	15	13	reboxetine
422	15	14	fluoxetine
423	15	15	fluoxetine
424	15	16	reboxetine
425	15	17	reboxetine
426	15	18	fluoxetine
427	15	19	reboxetine
428	15	20	fluoxetine

Center=16

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
429	16	1	fluoxetine
430	16	2	reboxetine
431	16	3	reboxetine
432	16	4	fluoxetine
433	16	5	reboxetine
434	16	6	fluoxetine
435	16	7	reboxetine
436	16	8	fluoxetine
437	16	9	reboxetine
438	16	10	fluoxetine
439	16	11	fluoxetine

Centers 19,20,21 and 22,23,24 are enlargement of centers 12,13,14
Centers 25,26 are enlargement of centers 15,16

REBOXETINE - 016

Randomization List 9550083

Center=16

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
440	16	12	reboxetine
441	16	13	fluoxetine
442	16	14	reboxetine
443	16	15	fluoxetine
444	16	16	reboxetine
445	16	17	reboxetine
446	16	18	fluoxetine
447	16	19	fluoxetine
448	16	20	reboxetine

Center=17

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
449	17	1	reboxetine
450	17	2	fluoxetine
451	17	3	fluoxetine
452	17	4	reboxetine
453	17	5	reboxetine
454	17	6	fluoxetine
455	17	7	fluoxetine
456	17	8	reboxetine
457	17	9	fluoxetine
458	17	10	fluoxetine
459	17	11	reboxetine
460	17	12	reboxetine
461	17	13	fluoxetine
462	17	14	reboxetine
463	17	15	fluoxetine
464	17	16	reboxetine
465	17	17	reboxetine
466	17	18	fluoxetine
467	17	19	reboxetine
468	17	20	fluoxetine

Center=18

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
469	18	1	reboxetine
470	18	2	fluoxetine
471	18	3	reboxetine
472	18	4	fluoxetine
473	18	5	fluoxetine
474	18	6	reboxetine
475	18	7	fluoxetine
476	18	8	reboxetine
477	18	9	fluoxetine
478	18	10	reboxetine
479	18	11	reboxetine
480	18	12	fluoxetine
481	18	13	fluoxetine
482	18	14	reboxetine
483	18	15	reboxetine
484	18	16	fluoxetine
485	18	17	reboxetine
486	18	18	reboxetine
487	18	19	fluoxetine
488	18	20	fluoxetine

Centers 19,20,21 and 22,23,24 are enlargement of centers 12,13,14
Centers 25,26 are enlargement of centers 15,16

REBOXETINE - 016

Randomization List 9550083

Center=19

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
489	19	1	reboxetine
490	19	2	fluoxetine
491	19	3	reboxetine
492	19	4	fluoxetine
493	19	5	fluoxetine
494	19	6	reboxetine
495	19	7	reboxetine
496	19	8	fluoxetine

Center=20

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
497	20	1	fluoxetine
498	20	2	reboxetine
499	20	3	fluoxetine
500	20	4	reboxetine
501	20	5	reboxetine
502	20	6	fluoxetine
503	20	7	reboxetine
504	20	8	fluoxetine

Center=21

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
505	21	1	reboxetine
506	21	2	fluoxetine
507	21	3	fluoxetine
508	21	4	reboxetine
509	21	5	fluoxetine
510	21	6	fluoxetine
511	21	7	reboxetine
512	21	8	reboxetine

Center=22

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
513	22	1	fluoxetine
514	22	2	reboxetine
515	22	3	fluoxetine
516	22	4	reboxetine
517	22	5	fluoxetine
518	22	6	reboxetine
519	22	7	reboxetine
520	22	8	fluoxetine

Center=23

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
521	23	1	reboxetine
522	23	2	fluoxetine
523	23	3	reboxetine
524	23	4	fluoxetine
525	23	5	reboxetine
526	23	6	fluoxetine
527	23	7	reboxetine
528	23	8	fluoxetine
529	23	9	reboxetine
530	23	10	fluoxetine
531	23	11	reboxetine
532	23	12	fluoxetine
533	23	13	fluoxetine
534	23	14	reboxetine
535	23	15	reboxetine
536	23	16	fluoxetine

522

Centers 19,20,21 and 22,23,24 are enlargement of centers 12,13,14
Centers 25,26 are enlargement of centers 15,16

REBOXETINE - 016

Randomization list 9550083

---------- Center=24 ----------

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
537	24	1	reboxetine
538	24	2	fluoxetine
539	24	3	fluoxetine
540	24	4	reboxetine
541	24	5	reboxetine
542	24	6	fluoxetine
543	24	7	fluoxetine
544	24	8	reboxetine
545	24	9	fluoxetine
546	24	10	reboxetine
547	24	11	reboxetine
548	24	12	fluoxetine
549	24	13	fluoxetine
550	24	14	fluoxetine
551	24	15	reboxetine
552	24	16	reboxetine

---------- Center=25 ----------

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
553	25	1	fluoxetine
554	25	2	fluoxetine
555	25	3	reboxetine
556	25	4	reboxetine
557	25	5	reboxetine
558	25	6	fluoxetine
559	25	7	fluoxetine
560	25	8	reboxetine
561	25	9	reboxetine
562	25	10	reboxetine
563	25	11	fluoxetine
564	25	12	fluoxetine

---------- Center=26 ----------

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
565	26	1	fluoxetine
566	26	2	reboxetine
567	26	3	fluoxetine
568	26	4	reboxetine
569	26	5	fluoxetine
570	26	6	reboxetine
571	26	7	reboxetine
572	26	8	fluoxetine

Centers 19,20,21 and 22,23,24 are enlargement of centers 12,13,14
Centers 25,26 are enlargement of centers 15,16

12.1.8 LABORATORY REFERENCE VALUES AND CRITERIA USED TO JUDGE LABORATORY ABNORMALITIES AS CLINICALLY RELEVANT

PHARMACIA CNS R&D 9550083

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.8
LABORATORY REFERENCE VALUES

		Range values			
		Female		Male	
Laboratory test	Units	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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.8

CRITERIA USED TO JUDGE LABORATORY ABNORMALITIES AS CLINICALLY RELEVANT

Laboratory test	Percent variation above or below normal range (*)
HB	- 15
HT	- 15
RBC	- 15
PLATELETS	-+ 30
WBC	-+ 30
WBC: N	-+ 30
WBC: E	+ 30
WBC: B	+ 30
WBC: L	-+ 30
WBC: M	+ 30
CREATININE	+ 50
UREA	+ 50
BUN	+ 50
URIC ACID	+ 30
TOT. PROTEINS	-+ 30
ALBUMINE	-+ 30
TOT BILIRUBIN	+ 100
DIR BILIRUBIN	+ 100
SGOT	+ 100
SGPT	+ 100
GAMMA GT	+ 100
LDH	+ 100
ALK. PHOSPH.	+ 100
GLOBULINS ALPHA 1	-+ 30
GLOBULINS ALPHA 2	-+ 30
GLOBULINS BETA	-+ 30
GLOBULINS GAMMA	-+ 30
TOT. CHOLEST.	+ 30
HDL	- 20
TRIGLYCERIDES	+ 30
GLUCOSE	-+ 30
NA+	-+ 10
CL-	-+ 10
K+	-+ 15
Ca++	-+ 15
PO4--	-+ 15
RT3	not defined
T3	not defined
T4	-+ 10
TSH	-+ 10
ESR/SEDIMENT. RATE	not defined

(*) MINUS INDICATES BELOW THE LOWER LIMIT OF NORMAL RANGE, AND PLUS ABOVE THE UPPER LIMIT OF NORMAL RANGE

12.1.9 ADVERSE EVENTS GROUPED IN CLUSTERS

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Appendix No.: 12.1.9

ADVERSE EVENTS GROUPED IN CLUSTERS

	Cluster	Adverse event	Treatment	No of AE	No o: witl
GENERAL DISORDERS	ASTHENIA / FATIGUE	ASTHENIA	Fluoxetine	1	
		FATIGUE	Fluoxetine	4	
		FATIGUE	Reboxetine	4	
ISORDERS, GENERAL	AEDEMA	OEDEMA GENERALISED	Fluoxetine	1	
		OEDEMA LEGS	Reboxetine	1	
	CARDIAC ISCHEMIA AND RELATED SYMPTOMS	CHEST PAIN PRECORDIAL	Fluoxetine	1	
	FLUSHING / HOT FLASHING	FLUSHING	Reboxetine	2	
		HOT FLUSHES	Fluoxetine	1	
		HOT FLUSHES	Reboxetine	2	
	HYPOTENSION AND RELATED SYMPTOMS	DIZZINESS	Fluoxetine	8	
		DIZZINESS	Reboxetine	18	
		HYPOTENSION	Fluoxetine	1	
		HYPOTENSION	Reboxetine	1	
		HYPOTENSION POSTURAL	Reboxetine	1	
ERAL NERVOUS SYSTEM DISO	HEADACHE / MIGRAINE	HEADACHE	Fluoxetine	28	
		HEADACHE	Reboxetine	21	
		MIGRAINE	Reboxetine	1	
L SYSTEM DISORDERS	NAUSEA AND RELATED SYMPTOMS	VOMITING	Fluoxetine	2	
		VOMITING	Reboxetine	3	
		DYSPEPSIA	Fluoxetine	5	
		DYSPEPSIA	Reboxetine	1	
		GASTRITIS	Fluoxetine	1	
		GASTRITIS	Reboxetine	1	
		NAUSEA	Fluoxetine	15	
		NAUSEA	Reboxetine	11	
DERS	ANEMIA	ANAEMIA	Reboxetine	1	
SYSTEM DISORDERS	INCREASED LIVER ENZYMES	HEPATIC ENZYMES INCREASED	Reboxetine	2	
RDERS	AGITATION / ANXIETY / NERVOUSNESS	AGITATION	Fluoxetine	7	
		AGITATION	Reboxetine	1	
		ANXIETY	Fluoxetine	1	
		ANXIETY	Reboxetine	1	
		NERVOUSNESS	Fluoxetine	3	
		NERVOUSNESS	Reboxetine	1	
GES DISORDERS	ERYTHEMA / RASH	RASH	Reboxetine	2	
		RASH MACULO-PAPULAR	Fluoxetine	1	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Appendix No.: 12.1.9

ADVERSE EVENTS GROUPED IN CLUSTERS

Body System	Cluster	Adverse event	Treatment	No of AE	No of Pt with AE
URINARY SYSTEM DISORDERS	URINARY HESITANCY / RETENTION	URINARY RETENTION	Reboxetine	2	2
		MICTURITION DISORDER	Fluoxetine	1	1
		MICTURITION DISORDER	Reboxetine	10	8
VISION DISORDERS	BLURRED VISION	VISION ABNORMAL	Fluoxetine	4	4
		VISION ABNORMAL	Reboxetine	3	3

12.1.10 ECG CODES

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 29124/016

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 - - Mobitz 2
- Complete

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 • Ripolarization disturbances

107 • Non specific ST-T changes

82 • Myocardial ischemia

84 • Acute Myocardial Infarction

4 Other

80 • Left ventricular hypertrophy

81 • Right ventricular hypertrophy

83 • Previous Myocardial infarction

93 • Other (specify)_____

104 • Right axial deviation

12.1.11 STATISTICAL ANALYSIS PROGRAMS LISTINGS

```
*                                                                       ;
*                    PHARMACIA CNS R&D          9550083                 ;
*                   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;
     u95 = z * 100;
     if k > 100 then put '**l** 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;
    l95 = z * 100;
    if k > 100 then put '**l** convergence was not attained in 100 '
                        'iterations ' k= z= pct= ls= li= ;
end;
```

```
*                                                                       ;
*                      PHARMACIA CNS R&D        9550083                 ;
*                     APPENDIX No.: 12.1.11                             ;
*                                                                       ;
 *---------------------------------------------------------------------*
 *                                                                     *
 *  PGM NAME: LAB003                                                   *
 *  CREATED:  07.12.93                                                 *
 *  AIM     :  Stuart-Maxwell test                                     *
 *                                                                     *
 *                                                                     *
 *  BY CORTESI - PANSID MI                                             *
 *---------------------------------------------------------------------*;

 %macro labstat(var= );

proc sort data = labst;
 by centre patient lab_par day;


data stat(keep = lab_par  day  lab_ind  lab_dif  &var
                 cod_trt  bas  nr_paz   nvis     num_ord)

     shift(keep = lab_par  day      &var  cod_trt   num_ord
                  lab_bas  lab_now  k    up   down  same  nvis)

     maxw  (keep = lab_par  day     &var   cod_trt
                   indice   k       nvis   num_ord);

 set labst;
 by centre patient lab_par day ;
 retain bas lab_bas 0;

 if first.patient then nr_paz = 1;
 else nr_paz = 0;

 if first.lab_par then do;
                     bas = lab_ind;
                     lab_bas = lab_uid;
                     lab_dif = .;
                  end;
 else do;
        k = 1;
        lab_now = lab_uid;
        lab_dif =lab_ind - bas;
        up = 0;
        down = 0;
        same = 0;
        if lab_dif > 0 then up = 1;
        else if lab_dif < 0 then down = 1;
        else same = 1;
        output shift;
        indice = (lab_bas-1) * 3 + (lab_now);
        output maxw;
      end;
 output stat;


               * proc univariate * ;

proc sort data = stat;
 by &var cod_trt lab_par day;

proc univariate data = stat noprint;
 by &var cod_trt lab_par  day;
 var lab_ind lab_dif bas;
 id num_ord;
 output out   =stat (drop=x2-x8 y1-y5)
        mean  =lab_mean x2       bas_mean
        median=lab_medi dif_medi  bas_medi
        std   =lab_std  x3        bas_std
        min   =lab_min  x4        y1
        max   =lab_max  x5        y2
        n     =lab_frq  x6        y3
        probt =x7       t_prob    y4
        probs =x8       s_prob    y5;


proc sort data = shift ;
 by &var cod_trt lab_par day lab_bas lab_now;

proc means data = shift noprint;
 by  &var cod_trt lab_par day;
 var up down same;
 id num_ord;
 output out=shifts
        sum=up down same;
```

```
data stat  ;
 merge stat (in=a) shifts(in=b);                    9550083
 by  &var cod_trt lab_par day;
 if a = 1 or b = 1;
 if b=1 then do;
        if up = down then p_value = 1;
        else p_value = 2. * (probbnml(.5,sum(up,down),min(up,down)));
 end;

 p_test = s_prob;

          *--------------------------------------*
          * MAXWELL TEST                         *
          *--------------------------------------*;

proc sort data = maxw  ;
 by  &var cod_trt lab_par  day indice;

proc means data = maxw noprint;
 by  &var cod_trt lab_par  day indice;
 var k;
 id num_ord;
 output out=maxw
        sum=k;

 data maxw(keep = &var cod_trt lab_par  day  p_maxw num_ord);
  set maxw;
 by  &var cod_trt lab_par  day indice;
  retain  a11 a12 a13 a21 a22 a23 a31 a32 a33;
  array _a_ (9) a11 a12 a13 a21 a22 a23 a31 a32 a33;

  if first.day then do i=1 to 9; _a_(i) = 0 ; end;

  _a_(indice)=k;
  if last.day then do;
       n12=(a12+a21)/2;
       n13=(a13+a31)/2;
       n23=(a23+a32)/2;

       d1=a12+a13-a21-a31;
       d2=a21+a23-a12-a32;
       d3=a31+a32-a13-a23;

       d1=d1*d1;
       d2=d2*d2;
       d3=d3*d3;

       numx2=n23*d1+n13*d2+n12*d3;
       denx2=(n12*(n13+n23)+n13*n23)*2;
       if denx2 > 0 then do;
                          x2=numx2/denx2;
                          p_maxw = 1 - probchi(x2,2);
                        end;
        else do;
              if a32 > 0 or a23 > 0 then do;
                    if a32 = a23 then p_maxw = 1;
                         else do;
                                denx2=a32+a23;
                                numx2=min(a32,a23);
                                p_maxw = 2. * probbnml(0.5,denx2,numx2);
                              end;
                   end; * if a32 > 0 ..... ;
              else if a21 > 0 or a12 > 0 then do;
                    if a21 = a12 then p_maxw = 1;
                         else do;
                                denx2=a21+a12;
                                numx2=min(a21,a12);
                                p_maxw = 2. * probbnml(0.5,denx2,numx2);
                              end;
                   end; * if a21 > 0 ..... ;
              else if a31 > 0 or a13 > 0 then do;
                    if a31 = a13 then p_maxw = 1;
                         else do;
                                denx2=a31+a13;
                                numx2=min(a31,a13);
                                p_maxw = 2. * probbnml(0.5,denx2,numx2);
                              end;
                    end; * if a31 > 0 ..... ;
              else p_maxw = 1;  * tutti gli elementi no su diag.;
       end; * if denx2 <= 0 ..... ;
       output;
       end; * if last day ..... ;

proc means data = shift noprint;
 by &var cod_trt lab_par day lab_bas lab_now;
 var k ;
 id num_ord;
 output out=shift
        sum=k;
```

```
                                                                    9550083
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                9550083

             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;                          537
  by level;
RUN;

goptions reset=global gunit=pct  /*rotate=landscape */
```

```
          rotate=portrait                                    9550083
          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;
RUN;


%include pgmgen(gtitle);
%include pgmgen(gsymb4);

title5 f=swiss  h=2.5
       'MEAN DECREASES OF HAMILTON TOTAL SCORE AT LAST ASSESSMENT';
TITLE6 F=SWISS  H=2.5  'POINT ESTIMATES AND CONFIDENCE INTERVALS';
title7 ' ' ;

data b;
 set graf;
 format function $8. text $8. x y 8.4 ;
   function='label';
   position='3';
   size=3  ;
   style='swiss';
   hsys = '1';
   xsys ='2';
   ysys = '2' ;
   when= 'a';

   x=value;
   y=level;
   text=put(value,4.1);
RUN;

axis1 label =(a=90 '          ')
      style=0
      offset=(2  )
      order=0 to &gmaxlev by 0.1
      value=none
      minor=none
      major=none;

axis2 label =(f=swiss h=1.8 '   ')
      value=(f=swiss h=1.5)
      minor=none
      order=&gminval to &gmaxval by &gbyval;

legend1 label =none
        frame
        value=(f=swiss h=2.0)
        position=(bottom center outside);

* legend1 label =(position=top  f=swiss h=1.8 'Treatments:')
        down=5
        value=(f=swiss h=2.0);

proc gplot data=graf;
plot level*value=cod_trt /
    annotate=b
    vaxis=axis1
    haxis=axis2
    legend=legend1;
format cod_trt $ftrt.;
run;


proc sort data = med;
 by descending cod_trt;

data med1(keep=trt_con dif ls li er);
 set med end=fine;
 retain m1-m10 st1-st10 i 0 ;
 format trt1-trt10 $8. trt_con $30.;
 retain trt1-trt10;
 array tmean (10) m1-m10;
 array tstd (10) st1-st10;
 array ttrt (10) trt1-trt10;
 i = i + 1;
 file print;
 if i > 10 then
    put 'MORE THAN 10 TREATMENTS  '
        ' delle array ' i= trt1= trt2= trt3= trt4= trt5= trt6=
         trt7= trt8= trt9= trt10=;

 else do;
       ttrt(i) = cod_trt;
       tmean(i) = lsmean;                    538
       tstd(i) = stderr;
      end;
 if fine=1 then do;
    da = 0;
    DO K = 1 TO I - 1; *        MAX NUMBER OF TREATMENTS     ;
```

```
      do da = k + 1 to i;                                    9550083
         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;
end;
label trt_con='Treatments'
      dif='means difference'
       li='lower confidence limit'
       ls='upper confidence limit';
```

```
TITLE1  'PHARMACIA  CNS R&D';
TITLE3  'REBOXETINE _ PROTOCOL 20124/16';        9550083
TITLE5  'APPENDIX NO. 12.1.11';
FOOTNOTE;

      ***************************************************
      *-  PROGRAM .. : Y00.REBOX.PGM(CONF16)           -*
      *-  GOAL ..... : CONFIDENCE INTERVAL             -*
      *-  AUTHOR ... : N.O.                           -*
      *-  REFERENCE  : DESIGN ANA ANALYSIS OF EXPERIMENTS*
      *-               JOHN L. GILL, 1978 PG 51-56    -*
      *-                                              -*
      *-  note : for each protocol to introduce the   -*
      *-           requested data                     -*
      *-  these data are supplied by ANOVA            -*
      *************************************************** ;


*********************************************;
* MC=MEAN (CAMPION)                          ;
* MS=MEAN (STANDARD)                         ;
* NC=NUMBER OF OBSERVATION (CAMPION)         ;
* NS=NUMBER OF OBSERVATION (STANDARD)        ;
* S2E=MEAN SQUARE ERROR                      ;
* DF =DEGREE OF FREADOM OF ERROR             ;
*********************************************;

DATA PIPPO;INPUT
 TIT $ MC  MS  NC NS S2E  DF ;
CARDS;
LASTTOT   19.2 16.8 76 87 75.88 161
LASTMEL   21.9 18.3 39 39 80.85 76
LASTSEV   21.5 16.2 55 66 75.65 119
;
RUN;
DATA PIPPO;SET PIPPO;
tt=abs(tinv(0.025,df));
ERR2=(1/NC+1/NS);
ERR=SQRT(ERR2*S2E);
DIFF=MC-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 FLUOXETINE';

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;
```

12.1.12 SELECTION OF STATISTICAL ANALYSIS OUTPUTS

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016

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).

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON AT BASELINE

General Linear Models Procedure
Class Level Information

Class	Levels	Values
COD_TRT	2	FLU REX

Number of observations in data set = 163

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.4.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON AT BASELINE

General Linear Models Procedure

Dependent Variable: HAM0

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	62.28241736	62.28241736	2.79	0.0966
Error	161	3590.41696915	22.30072652		
Corrected Total	162	3652.69938650			

R-Square	C.V.	Root MSE	HAM0 Mean
0.017051	16.89149	4.72236450	27.95705521

Source	DF	Type I SS	Mean Square	F Value	Pr > F
COD_TRT	1	62.28241736	62.28241736	2.79	0.0966

Source	DF	Type III SS	Mean Square	F Value	Pr > F
COD_TRT	1	62.28241736	62.28241736	2.79	0.0966

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX NO.:12.1.12
HAMILTON DEPRESSION RATING SCALE
DESCRIPTIVE STATISTICS ON LAST ASSESSMENT

TOTAL SCORE HAMILTON		BASELINE	LAST ASSESS.	DECREASE
TREATMENT				
Fluoxetine	N	87	87	87
	MEAN	27.38	10.62	16.76
	S.D.	4.15	8.66	8.89
Reboxetine	N	76	76	76
	MEAN	28.62	9.39	19.22
	S.D.	5.31	7.26	8.50

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure
Class Level Information

Class	Levels	Values
COD_TRT	2	FLU REX

Number of observations in data set = 163

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure

Dependent Variable: DIFFN

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	246.49122900	246.49122900	3.25	0.0734
Error	161	12217.12840290	75.88278511		
Corrected Total	162	12463.61963190			

R-Square	C.V.	Root MSE	DIFFN Mean
0.019777	48.64354	8.71107256	17.90797546

Source	DF	Type I SS	Mean Square	F Value	Pr > F
COD_TRT	1	246.49122900	246.49122900	3.25	0.0734

Source	DF	Type III SS	Mean Square	F Value	Pr > F
COD_TRT	1	246.49122900	246.49122900	3.25	0.0734

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure
Least Squares Means

COD_TRT	DIFFN LSMEAN
FLU	16.7586207
REX	19.2236842

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX NO.: 12.1.12
HAMILTON DEPRESSION 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	Fluoxetine	N	21	21	21
		MEAN	24.71	6.24	18.48
		S.D.	3.08	6.56	5.90
	Reboxetine	N	21	21	21
		MEAN	25.43	12.24	13.19
		S.D.	1.63	8.29	8.31
YES	Fluoxetine	N	66	66	66
		MEAN	28.23	12.02	16.21
		S.D.	4.10	8.82	9.63
	Reboxetine	N	55	55	55
		MEAN	29.84	8.31	21.53
		S.D.	5.71	6.58	7.42

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

SEVERE PATIENTS JUDGED BY CGI SEVERITY AT BASELINE
ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure
Class Level Information

Class	Levels	Values
COD_TRT	2	FLU RBX

Number of observations in data set = 123

NOTE: Due to missing values, only 121 observations can be used in this analysis.

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

SEVERE PATIENTS JUDGED BY CGI SEVERITY AT BASELINE
ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure

Dependent Variable: DIFFN

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	1	847.52506887	847.52506887	11.20	0.0011
Error	119	9002.73939394	75.65327222		
Corrected Total	120	9850.26446281			

R-Square	C.V.	Root MSE	DIFFN Mean
0.086041	46.69231	8.69788895	18.62809917

Source	DF	Type I SS	Mean Square	F Value	Pr > F
COD_TRT	1	847.52506887	847.52506887	11.20	0.0011

Source	DF	Type III SS	Mean Square	F Value	Pr > F
COD_TRT	1	847.52506887	847.52506887	11.20	0.0011

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

SEVERE PATIENTS JUDGED BY CGI SEVERITY AT BASELINE

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure
Least Squares Means

COD_TRT	DIFFN LSMEAN
FLU	16.2121212
RBX	21.5272727

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX NO.: 12.1.12
HAMILTON DEPRESSION RATING SCALE
DESCRIPTIVE STATISTICS ON LAST ASSESSMENT
MELANCHOLIC PATIENTS

TOTAL SCORE HAMILTON			BASELINE	LAST ASSESS.	DECREASE
MELANCH-OLIC	TREATME-NT				
NO	Fluoxet-ine	N	38	38	38
		MEAN	26.21	11.32	14.89
		S.D.	4.48	8.74	8.26
	Reboxet-ine	N	29	29	29
		MEAN	26.79	10.66	16.14
		S.D.	3.43	8.33	8.28
YES	Fluoxet-ine	N	39	39	39
		MEAN	28.74	10.46	18.28
		S.D.	3.87	8.71	9.46
	Reboxet-ine	N	39	39	39
		MEAN	30.67	8.74	21.92
		S.D.	6.11	6.85	8.50

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12
MELANCHOLIC PATIENTS

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENTN WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure
Class Level Information

Class	Levels	Values
COD_TRT	2	FLU REX

Number of observations in data set = 80

NOTE: Due to missing values, only 78 observations can be used in this analysis.

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12
MELANCHOLIC PATIENTS

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENTN 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	258.51282051	258.51282051	3.20	0.0777
Error	76	6144.66666667	80.85087719		
Corrected Total	77	6403.17948718			

R-Square	C.V.	Root MSE	DIFFN Mean
0.040373	44.72918	8.99171158	20.10256410

Source	DF	Type I SS	Mean Square	F Value	Pr > F
COD_TRT	1	258.51282051	258.51282051	3.20	0.0777

Source	DF	Type III SS	Mean Square	F Value	Pr > F
COD_TRT	1	258.51282051	258.51282051	3.20	0.0777

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

MELANCHOLIC PATIENTS

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENTN WITH RESPECT TO BASELINE VALUE

General Linear Models Procedure
Least Squares Means

COD_TRT	DIFFN LSMEAN
FLU	18.2820513
REX	21.9230769

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

APPENDIX No.: 12.1.12

BETWEEN TREATMENT DIFFERENCE AND 95% CONFIDENCE INTERVAL

POPULATION ANALYSED	MEAN REBOXETINE	MEAN FLUOXETINE	BETWEEN TREATM. DIFFERENCE	LOWER LIMIT	UPPER LIMIT
TOTAL POPULATION	19.2	16.8	2.4	-0.30095	5.10095
MELANCHOLIC PTS	21.9	18.3	3.6	-0.45546	7.65546
SEVERE PTS	21.5	16.2	5.3	2.15565	8.44435

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

EFFICACY: KAPLAN / MEIER ANALYSIS - TIME TO ONSET OF RESPONSE (50 % HAMILTON DECREASE)

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
FLU	87	64	23	26.4368
RBX	76	59	17	22.3684
Total	163	123	40	24.5399

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	-1.3551	-227.00
RBX	1.3551	227.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	27.2588	-27.2588
RBX	-27.2588	27.2588

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	299728	-299728
RBX	-299728	299728

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.0674	1	0.7952
Wilcoxon	0.1719	1	0.6784
-2Log(LR)	0.1147	1	0.7349

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	%Censored
FLU	89	60	29	32.5843
RBX	79	53	26	32.9114
Total	168	113	55	32.7381

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	-5.1212	-1289.0
RBX	5.1212	1289.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	25.1296	-25.1296
RBX	-25.1296	25.1296

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	359527	-359527
RBX	-359527	359527

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	1.0436	1	0.3070
Wilcoxon	4.6214	1	0.0316
-2Log(LR)	0.8914	1	0.3451

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING AGITATION / ANXIETY / NERVOUSNESS

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
FLU	89	10	79	88.7640
RBX	79	3	76	96.2025
Total	168	13	155	92.2619

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	3.2214	514.00
RBX	-3.2214	-514.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	3.24045	-3.24045
RBX	-3.24045	3.24045

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	76089.6	-76089.6
RBX	-76089.6	76089.6

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	3.2024	1	0.0735
Wilcoxon	3.4722	1	0.0624
-2Log(LR)	3.4226	1	0.0643

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING ASTHENIA / FATIGUE

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
FLU	89	5	84	94.3820
RBX	79	4	75	94.9367
Total	168	9	159	94.6429

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	0.18839	-4.0000
RBX	-0.18839	4.0000

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	2.23278	-2.23278
RBX	-2.23278	2.23278

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	53566.5	-53566.5
RBX	-53566.5	53566.5

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.0159	1	0.8997
Wilcoxon	0.0003	1	0.9862
-2Log(LR)	0.0278	1	0.8676

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING CONSTIPATION

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
FLU	89	6	83	93.2584
RBX	79	17	62	78.4810
Total	168	23	145	86.3095

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	-6.8156	-1085.0
RBX	6.8156	1085.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	5.61253	-5.61253
RBX	-5.61253	5.61253

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	128783	-128783
RBX	-128783	128783

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	8.2765	1	0.0040
Wilcoxon	9.1411	1	0.0025
-2Log(LR)	8.8755	1	0.0029

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING DIARRHOEA

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
FLU	89	6	83	93.2584
RBX	79	1	78	98.7342
Total	168	7	161	95.8333

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	2.3363	348.00
RBX	-2.3363	-348.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	1.73909	-1.73909
RBX	-1.73909	1.73909

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	41632.4	-41632.4
RBX	-41632.4	41632.4

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	3.1385	1	0.0765
Wilcoxon	2.9089	1	0.0881
-2Log(LR)	3.6144	1	0.0573

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING HEADACHE / MIGRANE

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
FLU	89	20	69	77.5281
RBX	79	17	62	78.4810
Total	168	37	131	77.9762

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	0.64242	93.000
RBX	-0.64242	-93.000

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	9.12765	-9.12765
RBX	-9.12765	9.12765

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	188081	-188081
RBX	-188081	188081

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.0452	1	0.8316
Wilcoxon	0.0460	1	0.8302
-2Log(LR)	0.0641	1	0.8001

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING HYPOTENSION AND RELATED SYMPTOMS

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
FLU	89	7	82	92.1348
RBX	79	15	64	81.0127
Total	168	22	146	86.9048

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	-4.9161	-712.00
RBX	4.9161	712.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	5.41364	-5.41364
RBX	-5.41364	5.41364

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	120071	-120071
RBX	-120071	120071

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	4.4644	1	0.0346
Wilcoxon	4.2220	1	0.0399
-2Log(LR)	4.7096	1	0.0300

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING INSOMNIA

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
FLU	89	9	80	89.8876
RBX	79	10	69	87.3418
Total	168	19	149	88.6905

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	-1.1811	-213.00
RBX	1.1811	213.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	4.70280	-4.70280
RBX	-4.70280	4.70280

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	105541	-105541
RBX	-105541	105541

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.2966	1	0.5860
Wilcoxon	0.4299	1	0.5121
-2Log(LR)	0.2853	1	0.5933

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING MOUTH DRY

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
FLU	89	8	81	91.0112
RBX	79	27	52	65.8228
Total	168	35	133	79.1667

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	-11.555	-1661.0
RBX	11.555	1661.0

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	8.35602	-8.35602
RBX	-8.35602	8.35602

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	182465	-182465
RBX	-182465	182465

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	15.9783	1	0.0001
Wilcoxon	15.1203	1	0.0001
-2Log(LR)	18.7290	1	0.0001

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING NAUSEA AND RELATED SYMPTOMS

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
FLU	89	15	74	83.1461
RBX	79	13	66	83.5443
Total	168	28	140	83.3333

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	0.09527	-7.0000
RBX	-0.09527	7.0000

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	6.82025	-6.82025
RBX	-6.82025	6.82025

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	158582	-158582
RBX	-158582	158582

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.0013	1	0.9709
Wilcoxon	0.0003	1	0.9860
-2Log(LR)	0.0029	1	0.9574

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING PARAESTHESIA

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
FLU	89	1	88	98.8764
RBX	79	5	74	93.6709
Total	168	6	162	96.4286

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	-2.2344	-364.00
RBX	2.2344	364.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	1.48756	-1.48756
RBX	-1.48756	1.48756

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	38338.4	-38338.4
RBX	-38338.4	38338.4

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	3.3562	1	0.0670
Wilcoxon	3.4560	1	0.0630
-2Log(LR)	3.6177	1	0.0572

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING SWEATING INCREASED

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
FLU	89	7	82	92.1348
RBX	79	7	72	91.1392
Total	168	14	154	91.6667

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	-0.48254	-85.000
RBX	0.48254	85.000

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	3.47097	-3.47097
RBX	-3.47097	3.47097

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	85336.6	-85336.6
RBX	-85336.6	85336.6

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.0671	1	0.7956
Wilcoxon	0.0847	1	0.7711
-2Log(LR)	0.0508	1	0.8216

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING TREMOR

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
FLU	89	5	84	94.3820
RBX	79	4	75	94.9367
Total	168	9	159	94.6429

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	0.20534	-3.0000
RBX	-0.20534	3.0000

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	2.22732	-2.22732
RBX	-2.22732	2.22732

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	51339.6	-51339.6
RBX	-51339.6	51339.6

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.0189	1	0.8906
Wilcoxon	0.0002	1	0.9894
-2Log(LR)	0.0250	1	0.8743

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.12

CUMULATIVE RISK OF DEVELOPING URINARY HESITANCY / RETENTION

The LIFETEST Procedure
Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
FLU	89	1	88	98.8764
RBX	79	10	69	87.3418
Total	168	11	157	93.4524

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
FLU	-4.9337	-751.00
RBX	4.9337	751.00

Covariance Matrix for the Log-Rank Statistics

COD_TRT	FLU	RBX
FLU	2.71913	-2.71913
RBX	-2.71913	2.71913

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	FLU	RBX
FLU	65786.4	-65786.4
RBX	-65786.4	65786.4

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	8.9520	1	0.0028
Wilcoxon	8.5732	1	0.0034
-2Log(LR)	10.5227	1	0.0012

12.2 Patient Information

12.2.1 SERIOUS ADVERSE EVENTS - CASE HISTORIES

Narrative of serious adverse event reported on reboxetine treatment and case summary of serious adverse event reported on reference treatment.

Pharmacia Document 9550083

Narrative of Event N. ES 0062 **Protocol N. 20124/ 016** **Patient N. 335**

Center: Barcelona (Spain) **Investigator: Lopez-Ibor**

Adverse event: attempted suicide (date of the event: 16 November 1992).

Patient's history: the patient was a 33 year old female and was suffering from a Major Depressive Episode for 3 months when she entered Study 20124/016 on 29 September 1992. Details regarding her previous history of mental disorders are unknown.

The patient had been suffering from bronchiectasis, which was confirmed by chest X-ray.

Baseline ECG was normal. Laboratory tests did not show any clinical relevant abnormalities.

Experimental period: the patient entered Study 20124/016 on 29 September 1992 and received the experimental treatment as follows:

Treatment		Days	Dose (mg/day)	Remarks
From	To			
13 October 1992	16 November 1992	35	8	

At the baseline visit, the Hamilton Depression Rating Scale (HAMD) was performed and the total score was 28 points. After 22 days of treatment (03 November 1992), a clinical improvement has been noticed with a HAMD total score of 14 points. On 10 November 1992 a HAMD total score of 20 points was reported. During this time no suicidal intent was detected.

On 16 November 1992 the patient took 10-12 tablets (1 mg each) of alprazolam, with full recovery afterwards. The experimental treatment was definitively discontinued.

At the time of the event the patient had been under the experimental treatment for 35 days and she had received a cumulative amount of 280 mg of reboxetine, while being treated with 8 mg/day of the compound.

Comments: the Investigator considered the relationship between the adverse event and the experimental treatment as not known.

Pharmacia Document 9550083

CLINICAL REPORT

ADE ID	**DD 0184**
PROTOCOL N°	20124/016
PT. N°	66
SEX	F
AGE AT ENTRY	27
EXPERIMENTAL TREATMENT	Fluoxetine
DAILY DOSE	20 mg
TREATMENT PERIOD	16 October 1991 - 12 November 1991
AFTER DAYS	28
ADE (DATE OF THE EVENT)	Attempted Suicide (12 November 1991)
CODE	0500
DISCONTINUED	Y
COURSE	Under Treatment
RELEVANT HISTORY	Attempted Suicide
RELEVANT BASELINE CONDIT.	Major Depressive Disorder
PREVIOUS ANTIDEPRESSIVE TREATMENTS	Amitriptyline, Clomipramine, Imipramine, Mianserin
RELEVANT EVENTS	No
CONCOMITANT MEDICATIONS	Chloral Hydrate

12.2.2. INDIVIDUAL DATA LISTINGS

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Patient status In-out patient	Hospital date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	DSM-III-R (*)
1	1	Fluoxetine	CBS	IN	08/11/91	Male	21	72.0	184.0	Caucasian	296.2
	2	Reboxetine	NE	IN	16/06/92	Male	51	85.0	168.0	Caucasian	296.2
	3	Fluoxetine	ED	IN	22/06/92	Female	42	74.2	164.0	Caucasian	296.3
	4	Reboxetine	JT	IN	07/08/92	Female	61	73.0	160.0	Caucasian	296.3
	5	Fluoxetine	AM	IN	05/10/92	Female	65	89.5	174.0	Caucasian	296.3
	6	Fluoxetine	SO	IN	09/01/93	Male	44	90.0	178.0	Caucasian	296.2
2	33	Fluoxetine	GE	IN	02/05/91	Female	52	60.0	168.0	Caucasian	296.3
	34	Reboxetine	BP	IN	29/04/91	Male	38	67.0	178.0	Caucasian	296.3
	35	Reboxetine	SD	IN	05/04/91	Female	64	65.0	156.0	Caucasian	296.3
	36	Fluoxetine	PA	IN	25/04/91	Male	45	77.0	180.0	Caucasian	296.3
	37	Reboxetine	SA	IN	01/10/91	Male	28	65.5	173.0	Caucasian	296.3
	38	Fluoxetine	SL	IN	18/06/91	Male	51	62.5	168.0	Caucasian	296.3
	39	Fluoxetine	WP	IN	12/06/91	Male	43	68.0	174.0	Caucasian	296.3
	40	Reboxetine	RP	IN	02/06/91	Male	54	78.0	184.0	Caucasian	296.3
	41	Fluoxetine	AK	IN	10/02/92	Male	58	72.0	163.0	Caucasian	296.3
	42	Reboxetine	WA	IN	02/03/92	Female	50	64.0	168.0	Caucasian	296.3
	43	Reboxetine	GK	IN	13/11/91	Female	42	72.1	158.0	Caucasian	296.3
	44	Fluoxetine	FS	IN	10/12/91	Male	46	73.0	171.0	Caucasian	296.3
	45	Reboxetine	SP	IN	09/09/92	Female	37	63.5	168.0	Caucasian	296.3
	47	Fluoxetine	KA	IN	24/03/92	Female	40	78.5	169.0	Caucasian	296.3
	48	Reboxetine	DB	IN	09/03/92	Female	65	52.3	156.0	Caucasian	296.2
	80	Fluoxetine	AH	IN	08/01/93	Male	44	120.0	178.0	Caucasian	296.3
3	65	Fluoxetine	NG	IN	01/10/91	Female	63	64.5	166.0	Caucasian	296.2
	66	Fluoxetine	US	IN	11/10/91	Female	27	65.8	166.0	Caucasian	296.3
	67	Reboxetine	MFS	IN	28/10/92	Female	56	72.1	160.0	Caucasian	296.2
	68	Reboxetine	CZ	IN	26/11/92	Female	29	57.0	163.0	Caucasian	296.3
4	97	Reboxetine	BC	IN	17/04/91	Female	62	61.5	156.0	Caucasian	296.2
	98	Fluoxetine	BP	IN	23/05/91	Female	35	80.5	160.0	Caucasian	296.3
	99	Fluoxetine	KF	IN	10/10/91	Female	46	53.0	153.0	Caucasian	296.2
	100	Reboxetine	RS	IN	07/05/92	Male	23	76.3	175.0	Caucasian	295.7
	101	Reboxetine	EM	IN	01/07/92	Female	45	54.0	158.0	Caucasian	296.3
	102	Fluoxetine	IS	IN	07/07/92	Female	65	66.0	157.0	Caucasian	296.3
	103	Fluoxetine	LM	IN	06/07/92	Female	58	58.9	160.0	Caucasian	296.3
	104	Reboxetine	KM	IN	12/08/92	Female	55	51.2	163.0	Caucasian	296.2
	105	Fluoxetine	KR	IN	18/08/92	Male	40	79.0	176.0	Caucasian	296.2
5	129	Reboxetine	JMS	OUT		Female	56	64.0	162.0	Caucasian	296.3
	130	Fluoxetine	IMU	OUT		Female	31	47.0	150.0	Caucasian	296.2

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode
296.5=Major Depressive Disorder, Bipolar
300.4=Dysthymia

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Patient status: In-out patient	Hospital date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	DSM-III-R (*)
7	193	Reboxetine	MMG	IN	01/12/91	Female	25	41.0	157.0	Caucasian	296.3
	194	Fluoxetine	JAM	OUT		Female	26	49.0	158.0	Caucasian	296.2
	195	Fluoxetine	MBV	OUT		Male	34	88.0	181.0	Caucasian	296.2
	196	Reboxetine	CAB	OUT		Female	50	85.0	156.0	Caucasian	296.3
	197	Fluoxetine	LA	IN	27/10/92	Male	43	44.1	156.0	Caucasian	296.3
11	321	Fluoxetine	RPB	OUT		Female	56	79.0	167.0	Caucasian	296.2
	322	Reboxetine	MFC	OUT		Female	21	45.0	157.0	Caucasian	296.2
	323	Fluoxetine	CML	OUT		Female	62	79.0	154.0	Caucasian	296.2
	324	Reboxetine	ESS	OUT		Female	34	48.0	152.0	Caucasian	296.3
	325	Reboxetine	MFN	OUT		Female	27	65.9	156.0	Caucasian	296.3
	326	Reboxetine	TPB	OUT		Female	52	86.5	148.0	Caucasian	296.2
	327	Fluoxetine	SMC	OUT		Female	34	65.0	159.0	Caucasian	296.3
	328	Fluoxetine	FRM	OUT		Female	55	49.8	147.0	Caucasian	296.3
	329	Reboxetine	CGB	OUT		Female	44	66.8	150.0	Caucasian	296.2
	330	Reboxetine	AJG	OUT		Male	51	82.0	165.0	Caucasian	296.3
	331	Fluoxetine	DTM	OUT		Female	38	55.0	160.0	Caucasian	296.3
	332	Fluoxetine	MSG	OUT		Female	20	55.5	166.0	Caucasian	296.2
	333	Reboxetine	CMF	OUT		Female	40	64.7	165.0	Caucasian	296.3
	334	Fluoxetine	EFG	OUT		Female	49	72.3	152.0	Caucasian	296.3
	335	Reboxetine	MMC	OUT		Female	33	58.0	162.0	Caucasian	296.2
12	393	Fluoxetine	NB	OUT		Female	19	44.0	160.0	Caucasian	296.3
	394	Reboxetine	PB	OUT		Male	45	77.0	155.0	Caucasian	296.3
	395	Reboxetine	FMT	OUT		Male	45	67.5	169.0	Caucasian	296.3
	396	Fluoxetine	KG	OUT		Female	39	47.0	157.0	Caucasian	296.3
	497	Fluoxetine	IH	OUT		Female	43	68.0	155.0	Caucasian	296.3
13	385	Fluoxetine	MH	OUT		Female	47	71.0	163.0	Caucasian	296.3
	386	Fluoxetine	MO	IN	22/04/92	Male	62	70.7	165.0	Caucasian	296.3
	387	Reboxetine	IC	IN	14/04/92	Female	78	76.2	161.0	Caucasian	296.3
	388	Reboxetine	MK	IN	15/03/92	Male	50	68.7	170.0	Caucasian	296.3
	389	Fluoxetine	MS	IN	18/07/92	Female	22	59.3	165.0	Caucasian	296.2
	390	Reboxetine	GG	OUT		Male	56	84.0	174.0	Caucasian	296.2
	391	Fluoxetine	DS	OUT		Female	32	56.0	158.0	Caucasian	296.2
	392	Reboxetine	VS	IN	10/08/92	Female	38	78.0	164.0	Caucasian	296.3
	501	Reboxetine	QL	OUT		Male	39	61.0	173.0	Asian	296.2
	502	Fluoxetine	LT	OUT		Female	43	82.0		Caucasian	296.2
	503	Reboxetine	CC	OUT		Female	48	57.0	165.0	Caucasian	296.3
	504	Fluoxetine	RL	OUT		Female	30	59.0	175.0	Caucasian	296.2

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode
296.5=Major Depressive Disorder, Bipolar
300.4=Dysthymia

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Patient status: In-out patient	Patient status: Hospital date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	DSM-III-R (*)
13	505	Reboxetine	LR	OUT		Female	41	84.0	170.0	Caucasian	296.3
	506	Fluoxetine	LL	OUT		Male	38	67.0	169.0	Caucasian	296.2
	507	Fluoxetine	VV	OUT		Female	49	62.0	157.0	Caucasian	296.3
	508	Reboxetine	RF	OUT		Female	25	90.5	160.0	Caucasian	296.2
	521	Reboxetine	IPK	OUT		Male	50	72.0	166.0	Caucasian	296.3
14	397	Fluoxetine	LM	OUT		Female	63	58.0	151.0	Caucasian	296.3
	398	Reboxetine	JP	OUT		Female	41	44.0	158.0	Caucasian	296.3
	399	Reboxetine	JB	OUT		Female	43	55.0	171.0	Caucasian	296.3
	400	Fluoxetine	RH	OUT		Male	31	79.0	160.0	Caucasian	296.2
	401	Fluoxetine	EC	OUT		Female	40	51.5	171.0	Caucasian	296.3
	402	Reboxetine	JT	IN	21/05/92	Female	48	99.0	173.0	Caucasian	296.2
	403	Reboxetine	CA	IN	26/05/92	Female	43	71.0	179.0	Caucasian	296.3
	404	Fluoxetine	AA	OUT		Female	61	57.0	151.0	Caucasian	296.2
	405	Fluoxetine	JR	OUT		Female	40	51.0	163.0	Caucasian	296.2
	406	Fluoxetine	DA	OUT		Female	50	60.0	165.0	Caucasian	296.2
	407	Reboxetine	VJ	OUT		Male	37	75.0	165.0	Caucasian	296.3
	408	Reboxetine	LO	OUT		Female	22	106.0	156.0	Caucasian	296.2
	509	Fluoxetine	WL	IN	17/09/92	Female	29	102.0	176.0	Caucasian	296.3
	510	Fluoxetine	GN	OUT		Female	40	55.5	155.0	Caucasian	296.3
	511	Reboxetine	TO	OUT		Female	28	64.0	160.0	Caucasian	296.3
	512	Reboxetine	LB	IN	01/11/92	Female	32	57.5	175.0	Caucasian	296.2
	537	Reboxetine	DR	IN	27/10/92	Female	34	56.0	165.0	Caucasian	296.2
	538	Fluoxetine	CG	OUT		Female	40	70.0	160.0	Caucasian	296.2
	539	Fluoxetine	JH	OUT	29/03/93	Female	40	43.0	153.0	Caucasian	296.2
15	409	Reboxetine	JL	OUT		Male	56	78.0	180.0	Caucasian	296.3
	410	Fluoxetine	EB	OUT		Female	51	60.0	167.0	Caucasian	296.3
	411	Reboxetine	BA	OUT		Female	61	52.0	152.0	Caucasian	296.3
	412	Fluoxetine	RL	OUT		Female	51	59.0	160.0	Caucasian	296.2
	413	Reboxetine	RF	OUT		Female	51	93.0	165.0	Caucasian	296.3
	414	Fluoxetine	HB	OUT		Male	38	83.0	178.0	Caucasian	296.2
	415	Reboxetine	BM	OUT		Female	43	58.0	150.0	Caucasian	296.3
	416	Fluoxetine	TR	OUT		Female	42	61.0	158.0	Caucasian	296.2
	417	Reboxetine	NF	OUT		Female	54	62.0	164.0	Caucasian	296.3
	418	Reboxetine	MP	OUT		Female	34	52.0	165.0	Caucasian	296.3
	419	Fluoxetine	CG	OUT		Female	56	59.0	161.0	Caucasian	296.3
	420	Fluoxetine	AGG	OUT		Male	61	72.0	175.0	Caucasian	296.3
	421	Reboxetine	CB	OUT		Female	62	87.0	158.0	Caucasian	296.3
	422	Fluoxetine	RCR	OUT		Male	41	61.0	163.0	Caucasian	296.3
	423	Fluoxetine	FG	OUT		Female	27	58.0	173.0	Caucasian	296.2
	424	Reboxetine	ARP	OUT		Male	32	71.0	176.0	Caucasian	296.3
	425	Reboxetine	ABO	OUT		Female	58	72.0	157.0	Caucasian	296.3

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode
296.5=Major Depressive Disorder, Bipolar
300.4=Dysthymia

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Patient status: In-out patient	Patient status: Hospital date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	DSM-III-R (*)
15	426	Fluoxetine	AD	OUT		Male	18	64.0	179.0	Caucasian	296.2
	427	Reboxetine	RE	OUT		Female	47	84.0	167.0	Caucasian	296.3
	428	Fluoxetine	PF	OUT		Male	38	69.0	167.0	Caucasian	296.2
	449	Reboxetine	GN	OUT		Female	33	70.0	161.0	Caucasian	296.3
	450	Fluoxetine	JP	OUT		Male	33	91.0	183.0	Caucasian	296.2
	451	Fluoxetine	NP	OUT		Female	49	68.0	167.0	Caucasian	296.3
	452	Reboxetine	AMS	OUT		Female	30	65.0	168.0	Caucasian	296.2
	454	Fluoxetine	OM	OUT		Male	51	67.0	173.0	Caucasian	296.3
16	429	Fluoxetine	LBA	OUT		Female	48	62.0	155.0	Caucasian	296.3
	430	Reboxetine	JRE	OUT		Male	51	71.0	164.0	Caucasian	296.3
	431	Reboxetine	EW	OUT		Female	58	80.0	171.0	Caucasian	296.3
	432	Fluoxetine	IHC	OUT		Female	64	73.0	160.0	Caucasian	296.3
	433	Reboxetine	DDQ	OUT		Female	39	62.0	155.0	Caucasian	296.3
	434	Fluoxetine	MG	OUT		Female	48	63.0	158.0	Caucasian	296.3
	435	Reboxetine	CCC	OUT		Female	48	67.0	165.0	Caucasian	296.2
	436	Fluoxetine	MJM	OUT		Female	40	51.0	163.0	Caucasian	296.3
	437	Reboxetine	MVP	OUT		Female	22	54.5	163.0	Caucasian	296.2
	438	Fluoxetine	SC	OUT		Female	64	62.0	151.0	Caucasian	296.2
	439	Fluoxetine	BF	OUT		Female	51	105.0	169.0	Caucasian	296.2
	440	Reboxetine	ER	OUT		Female	41	65.0	168.0	Caucasian	296.3
	441	Fluoxetine	ML	OUT		Female	52	59.0	165.0	Caucasian	296.2
	442	Reboxetine	MLG	OUT		Female	55	52.0	160.0	Caucasian	296.3
	443	Fluoxetine	BM	OUT		Male	23	73.0	174.0	Caucasian	296.2
	444	Reboxetine	MBV	OUT		Female	27	48.0	155.0	Caucasian	296.2
	445	Reboxetine	FV	OUT		Male	45	84.0	162.0	Caucasian	296.2
	446	Fluoxetine	BK	OUT		Female	31	54.0	165.0	Caucasian	296.2
	447	Fluoxetine	CAD	OUT		Male	30	73.0	179.0	Caucasian	296.2
	448	Reboxetine	AR	OUT		Female	42	59.0	157.0	Caucasian	296.2
	455	Fluoxetine	SSV	OUT		Female	40	58.0	150.0	Caucasian	296.2
	456	Reboxetine	MT	OUT		Male	49	71.0	173.0	Caucasian	296.2
	457	Fluoxetine	OP	OUT		Female	52	74.0	176.0	Caucasian	296.3
	458	Fluoxetine	MA	OUT		Female	55	62.0	163.0	Caucasian	296.2
	459	Reboxetine	VCN	OUT		Male	46	90.0	185.0	Caucasian	296.2
	460	Reboxetine	CP	OUT		Male	61	70.0	160.0	Caucasian	296.2
18	25	Fluoxetine	AG	OUT		Female	59	87.0	159.0	Caucasian	296.3
	26	Reboxetine	GK	OUT		Female	33	69.0	169.0	Caucasian	296.2
	27	Reboxetine	EK	OUT		Female	35	140.0	174.0	Caucasian	296.2
	28	Fluoxetine	JE	OUT		Female	47	62.0	161.0	Caucasian	296.3
	29	Reboxetine	MW	OUT		Male	24	113.0	181.0	Caucasian	296.2
	30	Fluoxetine	EL	OUT		Female	51	62.0	158.0	Caucasian	296.3
	31	Reboxetine	MK	OUT		Female	56	58.0	154.0	Caucasian	296.2

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode
296.5=Major Depressive Disorder, Bipolar
300.4=Dysthymia

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Patient status: In-out patient	Hospital date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	DSM-III-R (*)
18	32	Fluoxetine	GP	OUT		Female	36	62.0	168.0	Caucasian	296.2
	49	Reboxetine	K-P	OUT		Female	57	82.0	164.0	Caucasian	296.2
	50	Reboxetine	TW	OUT		Female	63	70.0	160.0	Caucasian	296.3
	51	Fluoxetine	LV	OUT		Female	36	92.0	170.0	Caucasian	296.2
	52	Fluoxetine	JG	OUT		Female	47	105.0	170.0	Caucasian	296.3
	53	Fluoxetine	NG	OUT		Female	41	90.0	150.0	Caucasian	296.2
	54	Fluoxetine	HS	OUT		Male	56	87.0	180.0	Caucasian	296.2
20	21	Fluoxetine	FR	OUT		Female	52	64.0	165.0	Caucasian	296.3
	22	Fluoxetine	DH	OUT		Female	41	62.0	163.0	Caucasian	296.2
21	9	Fluoxetine	OB	OUT		Female	27	79.0	182.0	Caucasian	296.3
22	113	Fluoxetine	TS	OUT		Male	43	94.0	184.0	Caucasian	296.3
	115	Reboxetine	SS	OUT		Male	26	73.0	186.0	Caucasian	296.2

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode
296.5=Major Depressive Disorder, Bipolar
300.4=Dysthymia

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

		History of mental disorder				Present episode			
Centre	Patient	Unknown	Age of onset	No episodes	Duration of last episode	Duration at the time of admission	Best characterized	Onset was	External stress
1	1		21	0		4 months	First occurence	Insidious (>= 3 months)	Definitely present
	2		50	0		6 months	First occurence	Insidious (>= 3 months)	Absent
	3		27	8	5 months	5 months	Similar prev. cond.	Insidious (>= 3 months)	Absent
	4		46	1	3 months	5 months	Similar prev. cond.	Insidious (>= 3 months)	Absent
	5		46	7	2 months	4 months	Similar prev. cond.	Insidious (>= 3 months)	Absent
	6		44	0		4 months	First occurence	Subacute (>= 2 weeks)	Probably present
2	33		25	5	6 weeks	2 months	Similar prev. cond.	Acute (< 2 weeks)	Absent
	34		32	1	1 month	4 months	Similar prev. cond.	Insidious (>= 3 months)	Absent
	35		62	3	1 year	3 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	36		22	20	4 weeks	4 weeks	Chronic condition	Subacute (>= 2 weeks)	Absent
	37		23	2	6 months	5 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	38		25	15	6 weeks	6 months	Similar prev. cond.	Acute (< 2 weeks)	Probably present
	39		33	9	8 weeks	5 weeks	Similar prev. cond.	Acute (< 2 weeks)	Probably present
	40		35	2	2 months	1 month	Similar prev. cond.	Acute (< 2 weeks)	Probably present
	41		56	3	6 months	2 months	Chronic condition	Subacute (>= 2 weeks)	Absent
	42		46	1	8 weeks	4 months	Similar prev. cond.	Insidious (>= 3 months)	Definitely present
	43		40	3	1 month	1 month	Chronic condition	Subacute (>= 2 weeks)	Probably present
	44		26	4	1 month	4 weeks	Chronic condition	Subacute (>= 2 weeks)	Absent
	45	583	32	2	1 year	7 weeks	Chronic condition	Subacute (>= 2 weeks)	Probably present
	47		38	3	3 weeks	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	48		65	0		4 months	First occurence	Insidious (>= 3 months)	Definitely present
	80		35	5	5 weeks	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
3	65		62	0		4 months	First occurence	Insidious (>= 3 months)	Probably present
	66		16	1	1 year	6 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	67		56	0		7 months	First occurence	Insidious (>= 3 months)	Definitely present
	68		21	2	5 months	5 weeks	Chronic condition	Subacute (>= 2 weeks)	Definitely present
4	97	Yes	62			4 weeks	First occurence	Subacute (>= 2 weeks)	Absent
	98		34	1	3 weeks	4 weeks	Similar prev. cond.	Acute (< 2 weeks)	Probably present
	99	Yes	46			3 months	First occurence	Insidious (>= 3 months)	Definitely present
	100		20	1	2 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	101		43	1	3 months	6 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	102		60	10	4 weeks	6 months	Similar prev. cond.	Insidious (>= 3 months)	Definitely present
	103		51		1 year	7 months	Chronic condition	Insidious (>= 3 months)	Absent
	104	Yes				6 months	Different prev. cond.	Insidious (>= 3 months)	Definitely present
	105	Yes				6 months	Different prev. cond.	Insidious (>= 3 months)	Probably present
5	129		56	1	2 months and 2 weeks	3 months and 3 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	130		31	0		2 months	First occurence	Insidious (>= 3 months)	Probably present
7	193		19	4	5 months	8 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	194	Yes				8 weeks	First occurence	Subacute (>= 2 weeks)	Absent
	195	Yes				6 weeks	First occurence	Insidious (>= 3 months)	Absent

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

		History of mental disorder				Present episode			
Centre	Patient	Unknown	Age of onset	No episodes	Duration of last episode	Duration at the time of admission	Best characterized	Onset was	External stress
7	196		24	2	3 months	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	197		20	6	2 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
11	321	Yes				3 months	First occurence	Insidious (>= 3 months)	Probably present
	322	Yes				6 months	First occurence	Insidious (>= 3 months)	Probably present
	323	Yes				4 months	First occurence	Insidious (>= 3 months)	Definitely present
	324		32	1	2 months	6 weeks	Similar prev. cond.	Acute (< 2 weeks)	Absent
	325	Yes				3 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	326	Yes				3 months	First occurence	Insidious (>= 3 months)	Probably present
	327		16	1	9 months	3 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	328	Yes				3 months	Similar prev. cond.	Insidious (>= 3 months)	Definitely present
	329	Yes				3 months	First occurence	Subacute (>= 2 weeks)	Absent
	330		24	1	1 month	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	331		10	4	3 months	4 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	332	Yes				4 months	First occurence	Insidious (>= 3 months)	Probably present
	333		22	1	6 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	334		25	1	1 year	3 months	Similar prev. cond.	Insidious (>= 3 months)	Absent
	335	Yes				3 months	First occurence	Insidious (>= 3 months)	Definitely present
12	393		14		6 months	3 months	Chronic condition	Subacute (>= 2 weeks)	Absent
	394		42	5	6 months	2 months	Chronic condition	Subacute (>= 2 weeks)	Absent
	395		29		3 months	1 month	Chronic condition	Subacute (>= 2 weeks)	Absent
	396		18		2 months	3 months	Chronic condition	Insidious (>= 3 months)	Absent
	497		20	3	3 months	2 months	Chronic condition	Insidious (>= 3 months)	Absent
13	385		32	1	6 months	10 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	386		50	1	9 months	5 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	387		58		6 months	3 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	388		44	5	10 weeks	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	389		22	0		6 months	First occurence	Insidious (>= 3 months)	Probably present
	390		56	0		4 months	First occurence	Insidious (>= 3 months)	Definitely present
	391		32	0		6 months	First occurence	Insidious (>= 3 months)	Probably present
	392		25	3	4 weeks	2 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	501	Yes				3 months	First occurence	Insidious (>= 3 months)	Probably present
	502		43	0		8 weeks	First occurence	Subacute (>= 2 weeks)	Definitely present
	503	Yes		1		1 year	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	504		30	0		6 months	First occurence	Insidious (>= 3 months)	Definitely present
	505		39			3 years	Chronic condition	Insidious (>= 3 months)	Probably present
	506		38	0		5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	507		43	1	12 weeks	4 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Definitely present
	508		25			5 weeks	Chronic condition	Insidious (>= 3 months)	Probably present
	521		44				Chronic condition	Subacute (>= 2 weeks)	Probably present
14	397		57	2	3 months	6 weeks	Similar prev. cond.	Acute (< 2 weeks)	Absent
	398		37	2	8 months	6 weeks	Similar prev. cond.	Acute (< 2 weeks)	Absent
	399		33	1	2 years	5 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent

584

9550083

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

		History of mental disorder				Present episode			
Centre	Patient	Unknown	Age of onset	No episodes	Duration of last episode	Duration at the time of admission	Best characterized	Onset was	External stress
14	400		31			6 weeks	First occurence	Acute (< 2 weeks)	Definitely present
	401		23	2	14 weeks	8 weeks	Similar prev. cond.	Acute (< 2 weeks)	Absent
	402		48			6 weeks	First occurence	Acute (< 2 weeks)	Probably present
	403		20	1	10 weeks	8 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	404		61	0		6 months	First occurence	Subacute (>= 2 weeks)	Absent
	405		39	0		6 months	First occurence	Subacute (>= 2 weeks)	Probably present
	406		49			25 weeks	First occurence	Subacute (>= 2 weeks)	Absent
	407		26	5	3 months	5 weeks	Similar prev. cond.	Acute (< 2 weeks)	Absent
	408		22	0		5 weeks	First occurence	Acute (< 2 weeks)	Definitely present
	509		26	1	1 year	4 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	510		34	1	2 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	511		20	3	4 months	9 weeks	Similar prev. cond.	Acute (< 2 weeks)	Absent
	512		31	0		6 months	First occurence	Subacute (>= 2 weeks)	Absent
	537		34	0		4 weeks	First occurence	Acute (< 2 weeks)	Absent
	538		39	0		4 months	First occurence	Subacute (>= 2 weeks)	Absent
	539		40	0		4 months	First occurence	Subacute (>= 2 weeks)	Probably present
15	409		41	4	5 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	410	585	38	2	3 months	3 months	Similar prev. cond.	Acute (< 2 weeks)	Absent
	411		47	3	6 months	1 month	Similar prev. cond.	Acute (< 2 weeks)	Absent
	412		51			2 months	First occurence	Acute (< 2 weeks)	Probably present
	413		36	5	6 months	5 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	414		37			3 months	First occurence	Subacute (>= 2 weeks)	Absent
	415		24	4	4 months	3 months	Similar prev. cond.	Acute (< 2 weeks)	Absent
	416	Yes				2 months	First occurence	Acute (< 2 weeks)	Absent
	417		50	1	6 months	2 months	Similar prev. cond.	Acute (< 2 weeks)	Absent
	418		31	1	3 months	3 months	Similar prev. cond.	Acute (< 2 weeks)	Absent
	419		40	3	4 months	2 months	Similar prev. cond.	Acute (< 2 weeks)	Absent
	420		50	2	6 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	421		42	8	5 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	422		38	1	4 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	423		27			2 months	First occurence	Acute (< 2 weeks)	Absent
	424		26	1	4 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	425		34	10	4 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	426		18			10 weeks	First occurence	Acute (< 2 weeks)	Absent
	427		45	2	6 months	3 months	Similar prev. cond.	Acute (< 2 weeks)	Absent
	428		38			2 months	First occurence	Subacute (>= 2 weeks)	Absent
	449		30	2	4 months	3 months	Similar prev. cond.	Acute (< 2 weeks)	Probably present
	450		33			3 months	First occurence	Subacute (>= 2 weeks)	Absent
	451		47	1	4 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	452		30			2 months	First occurence	Subacute (>= 2 weeks)	Probably present
	454		42	2	6 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
16	429		38	2	3 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	430		45	1	6 months	45 days	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	431		52	1	3 months	2 months and 2 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	432		60	1	5 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	433		35	1	5 months	2 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

		History of mental disorder				Present episode			
Centre	Patient	Unknown	Age of onset	No episodes	Duration of last episode	Duration at the time of admission	Best characterized	Onset was	External stress
16	434		20	3	4 months	3 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	435		48			1 month and 2 weeks	First occurence	Subacute (>= 2 weeks)	Absent
	436		33	1	6 months	5 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	437		22			4 months	First occurence	Insidious (>= 3 months)	Absent
	438		64			2 months	First occurence	Subacute (>= 2 weeks)	Absent
	439	Yes				5 months	First occurence	Insidious (>= 3 months)	Probably present
	440		36	1	6 months	3 months	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	441		52			3 months	First occurence	Insidious (>= 3 months)	Probably present
	442		50	2	6 months	6 months	Similar prev. cond.	Insidious (>= 3 months)	Absent
	443	Yes				3 months	First occurence	Insidious (>= 3 months)	Absent
	444	Yes				5 months	First occurence	Insidious (>= 3 months)	Absent
	445	Yes				4 months	First occurence	Insidious (>= 3 months)	Probably present
	446	Yes				2 months	First occurence	Subacute (>= 2 weeks)	Absent
	447	Yes				1 month	First occurence	Subacute (>= 2 weeks)	Absent
	448	Yes				5 months	First occurence	Insidious (>= 3 months)	Absent
	455	Yes				6 months	First occurence	Insidious (>= 3 months)	Absent
	456	Yes				7 months	First occurence	Insidious (>= 3 months)	Absent
	457		48	1	6 months	6 months	Similar prev. cond.	Insidious (>= 3 months)	Absent
	458	Yes				3 months	First occurence	Insidious (>= 3 months)	Absent
	459	Yes				2 months	First occurence	Subacute (>= 2 weeks)	Absent
	460	Yes				5 months	First occurence	Insidious (>= 3 months)	Absent
18	25		51	4	5 months	3 months	Chronic condition	Insidious (>= 3 months)	Absent
	26		33			6 weeks	First occurence	Subacute (>= 2 weeks)	Probably present
	27		35			8 weeks	First occurence	Acute (< 2 weeks)	Absent
	28		42	3	4 months	4 weeks	Chronic condition	Acute (< 2 weeks)	Absent
	29		24			6 weeks	First occurence	Subacute (>= 2 weeks)	Probably present
	30		44	2	6 months and 6 weeks	8 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Absent
	31		56	0		8 weeks	First occurence	Subacute (>= 2 weeks)	Absent
	32		36	0		6 weeks	First occurence	Subacute (>= 2 weeks)	Absent
	49		57	0		6 weeks	First occurence	Subacute (>= 2 weeks)	Probably present
	50		52	4	8 months	7 weeks	Chronic condition	Subacute (>= 2 weeks)	Absent
	51		36	0		5 weeks	First occurence	Subacute (>= 2 weeks)	Absent
	52		44	1	9 months	5 weeks	Similar prev. cond.	Subacute (>= 2 weeks)	Probably present
	53		41	0		8 weeks	First occurence	Subacute (>= 2 weeks)	Absent
	54		56	0		4 months	First occurence	Insidious (>= 3 months)	Absent
20	21		40			6 months	Similar prev. cond.	Insidious (>= 3 months)	Probably present
	22		41			6 months	Chronic condition	Insidious (>= 3 months)	Absent
21	9		17	4	6 months	3 months	Chronic condition	Insidious (>= 3 months)	Probably present
22	113		26	3	2 months	5 weeks	Chronic condition	Subacute (>= 2 weeks)	Absent
	115		26	0		6 weeks	First occurence	Subacute (>= 2 weeks)	Absent

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 3.0
DMS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

A. At least five of the following symptoms have been present during the same two-week period and represent a change from previous functioning: at least one of the symptoms is either 1) depressed mood or 2) loss of interest or pleasure.

1) depressed mood most of day, nearly every day, as indicated by subjective account or observation by others

2) markedly diminished interest or pleasure in all, or almost all, activites 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.

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 3.0

DMS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

						A items								B items		C	D
Centre	Patient	Sex	Age	DSM-III-R	Present	1)	2)	3)	4)	5)	6)	7)	8)	9)	Present	1)	2)	Present	Present
1	1	Male	21	296.2	x	x	x	x	x	x		x	x		x	x	x	x	x
	2	Male	51	296.2	x	x	x		x	x	x		x		x	x	x	x	x
	3	Female	42	296.3	x	x	x		x	x	x		x		x	x	x	x	x
	4	Female	61	296.3	x	x	x	x	x	x	x	x	x		x	x	x	x	x
	5	Female	65	296.3	x	x	x		x	x	x		x		x	x	x	x	x
	6	Male	44	296.2	x	x	x		x	x	x		x		x	x	x	x	x
2	33	Female	52	296.3	x	x	x	x	x	x	x		x	x	x	x	x	x	x
	34	Male	38	296.3	x	x	x		x		x	x	x	x	x	x	x	x	x
	35	Female	64	296.3	x	x	x			x	x	x	x		x	x	x	x	x
	36	Male	45	296.3	x	x	x			x	x		x	x	x	x	x	x	x
	37	Male	28	296.3	x	x	x		x	x	x	x	x	x	x	x	x	x	x
	38	Male	51	296.3	x	x	x			x	x		x	x	x	x	x	x	x
	39	Male	43	296.3	x	x	x	x		x			x		x	x	x	x	x
	40	Male	54	296.3	x	x	x		x	x	x				x	x	x	x	x
	41	Male	58	296.3	x	x	x		x	x	x		x	x	x	x	x	x	x
	42	Female	50	296.3	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	43	Female	42	296.3	x	x	x		x	x	x		x	x	x	x	x	x	x
	44	Male	46	296.3	x	x	x			x	x	x	x	x	x	x	x	x	x
	45	Female	37	296.3	x	x	x			x	x		x	x	x	x	x	x	x
	47	Female	40	296.3	x	x	x		x		x	x	x		x	x	x	x	x
	48	Female	65	296.2	x	x	x		x	x	x		x		x	x	x	x	x
	80	Male	44	296.3	x	x	x		x	x	x	x	x	x	x	x	x	x	x
3	65	Female	63	296.2	x	x	x		x	x	x		x	x	x	x	x	x	x
	66	Female	27	296.3	x	x	x		x	x	x		x	x	x	x	x	x	x
	67	Female	56	296.2	x	x	x		x	x	x		x	x	x	x	x	x	x
	68	Female	29	296.3	x	x	x		x	x	x		x	x	x	x	x	x	x
4	97	Female	62	296.2	x	x	x		x	x	x		x		x	x	x	x	x
	98	Female	35	296.3	x	x	x	x	x		x			x	x	x	x	x	x
	99	Female	46	296.2	x	x	x		x	x	x			x	x	x	x	x	x
	100	Male	23	295.7	x	x	x		x	x	x	x	x	x	x	x	x	x	x
	101	Female	45	296.3	x	x	x		x	x	x		x	x	x	x	x	x	x
	102	Female	65	296.3	x	x	x		x	x	x	x	x	x	x	x	x	x	x
	103	Female	58	296.3	x	x	x		x	x	x		x	x	x	x	x	x	x
	104	Female	55	296.2	x	x	x		x	x	x		x	x	x	x	x	x	x
	105	Male	40	296.2	x	x	x		x		x	x	x		x	x	x	x	x
5	129	Female	56	296.3	x	x	x		x	x			x	x	x	x	x	x	x
	130	Female	31	296.2	x	x	x		x	x			x	x	x	x	x	x	x
7	193	Female	25	296.3	x	x	x		x	x	x		x	x	x	x	x	x	x
	194	Female	26	296.2	x	x	x		x	x			x	x	x	x	x	x	x
	195	Male	34	296.2	x	x	x		x	x			x	x	x	x	x	x	x

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 3.0

DMS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

Centre	Patient	Sex	Age	DSM-III-R	A items 1)	2)	3)	4)	5)	6)	7)	8)	9)	Present	B items 1)	2)	C Present	D Present
7	196	Female	50	296.3	X	X	X	X		X	X	X			X	X	X	X
	197	Male	43	296.3	X	X	X	X	X	X	X	X		X	X	X	X	X
11	321	Female	56	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	322	Female	21	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	323	Female	62	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	324	Female	34	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	325	Female	27	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	326	Female	52	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	327	Female	34	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	328	Female	55	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	329	Female	44	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	330	Male	51	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	331	Female	38	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	332	Female	20	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	333	Female	40	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	334	Female	49	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	335	Female	33	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
12	393	Female	19	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	394	Male	45	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	395	Male	45	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	396	Female	39	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	497	Female	43	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
13	385	Female	47	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	386	Male	62	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	387	Female	78	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	388	Male	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	389	Female	22	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	390	Male	56	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	391	Female	32	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	392	Female	38	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	501	Male	39	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	502	Female	43	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	503	Female	48	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	504	Female	30	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	505	Female	41	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	506	Male	38	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	507	Female	49	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	508	Female	25	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	521	Male	50	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X
14	397	Female	63	296.3	X	X		X	X	X	X	X		X	X	X	X	X
	398	Female	41	296.3	X	X	X	X		X	X	X		X	X	X	X	X
	399	Female	43	296.3	X	X	X	X		X		X		X	X	X	X	X

PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/016
Listing No.: 3.0

DMS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

Centre	Patient	Sex	Age	DSM-III-R	Present	A items 1)	2)	3)	4)	5)	6)	7)	8)	9)	B Present	B items 1)	2)	C Present	D Present
14	400	Male	31	296.2	x	x	x	x	x		x		x		x	x	x	x	x
	401	Female	40	296.3	x	x	x		x		x	x	x		x	x	x	x	x
	402	Female	48	296.2	x	x	x		x	x	x		x		x	x	x	x	x
	403	Female	43	296.3	x	x	x			x	x	x	x		x	x	x	x	x
	404	Female	61	296.2	x	x	x			x	x	x	x	x	x	x	x	x	x
	405	Female	40	296.2	x	x	x		x		x	x	x		x	x	x	x	x
	406	Female	50	296.2	x	x	x		x	x	x		x		x	x	x	x	x
	407	Male	37	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	408	Female	22	296.2	x	x	x		x	x	x	x	x	x	x	x	x	x	x
	509	Female	29	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	510	Female	40	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	511	Female	28	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	512	Female	32	296.2	x	x	x		x	x	x	x	x		x	x	x	x	x
	537	Female	34	296.2	x	x	x		x	x	x	x	x		x	x	x	x	x
	538	Female	40	296.2	x	x	x		x	x	x	x	x		x	x	x	x	x
	539	Female	40	296.2	x	x	x		x	x	x	x	x		x	x	x	x	x
15	409	Male	56	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	410	Female	51	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	411	Female	61	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	412	Female	51	296.2	x	x	x		x	x	x	x	x		x	x	x	x	x
	413	Female	51	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	414	Male	38	296.2	x	x	x		x	x	x	x	x		x	x	x	x	x
	415	Female	43	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	416	Female	42	296.2	x	x	x		x	x	x	x	x		x	x	x	x	x
	417	Female	54	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	418	Female	34	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	419	Female	56	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	420	Male	61	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	421	Female	62	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	422	Male	41	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	423	Female	27	296.2	x	x	x		x	x	x	x	x		x	x	x	x	x
	424	Male	32	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	425	Female	58	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	426	Male	18	296.2	x	x	x		x	x	x	x	x		x	x	x	x	x
	427	Female	47	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	428	Male	38	296.2	x	x	x		x	x	x	x	x		x	x	x	x	x
	449	Female	33	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	450	Male	33	296.2	x	x	x		x	x	x	x	x		x	x	x	x	x
	451	Female	49	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	452	Female	30	296.2	x	x	x		x	x	x	x	x		x	x	x	x	x
	454	Male	51	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
16	429	Female	48	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	430	Male	51	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	431	Female	58	296.3	x	x	x		x	x	x	x	x	x	x	x	x	x	x
	432	Female	64	296.3	x	x	x		x	x	x	x	x		x	x	x	x	x
	433	Female	39	296.3	x	x	x			x	x	x	x		x	x	x	x	x

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 3.0

DMS-III-R: DIAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE

					A										B			C	D
						items										items			
Centre	Patient	Sex	Age	DSM-III-R	Present	1)	2)	3)	4)	5)	6)	7)	8)	9)	Present	1)	2)	Present	Present
16	434	Female	48	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	435	Female	48	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	436	Female	40	296.3	X	X	X	X	X	X		X			X	X	X	X	X
	437	Female	22	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	438	Female	64	296.2	X	X	X		X	X	X	X	X	X	X	X	X	X	X
	439	Female	51	296.2	X	X	X	X	X	X	X	X	X		X	X	X	X	X
	440	Female	41	296.3	X	X	X	X	X	X	X	X	X		X	X	X	X	X
	441	Female	52	296.2		X	X	X	X	X	X	X	X			X	X	X	X
	442	Female	55	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	443	Male	23	296.2	X	X	X		X	X	X		X		X	X	X	X	X
	444	Female	27	296.2	X	X	X	X	X	X	X	X	X		X	X	X	X	X
	445	Male	45	296.2	X	X	X	X	X	X	X	X	X		X	X	X	X	X
	446	Female	31	296.2	X	X	X	X	X	X	X	X	X		X	X	X	X	X
	447	Male	30	296.2	X	X	X	X	X	X	X		X		X	X	X	X	X
	448	Female	42	296.2	X	X	X		X	X	X	X	X		X	X	X	X	X
	455	Female	40	296.2	X	X	X		X	X	X	X	X		X	X	X	X	X
	456	Male	49	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	457	Female	52	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	458	Female	55	296.2	X	X	X		X	X	X	X	X		X	X	X	X	X
	459	Male	46	296.2	X	X	X		X	X	X		X		X	X	X	X	X
	460	Male	61	296.2	X	X	X		X	X	X	X	X		X	X	X	X	X
18	25	Female	59	296.3	X	X	X		X		X	X	X		X	X	X	X	X
	26	Female	33	296.2	X	X	X		X	X	X	X	X		X	X	X	X	X
	27	Female	35	296.2	X	X	X		X		X	X	X		X	X	X	X	X
	28	Female	47	296.3	X	X	X		X	X	X	X	X		X	X	X	X	X
	29	Male	24	296.2	X	X	X		X		X		X		X	X	X	X	X
	30	Female	51	296.3	X	X	X		X		X	X	X		X	X	X	X	X
	31	Female	56	296.2	X	X	X		X	X	X	X	X		X	X	X	X	X
	32	Female	36	296.2	X	X	X		X		X	X	X		X	X	X	X	X
	49	Female	57	296.2	X	X	X		X	X	X	X	X		X	X	X	X	X
	50	Female	63	296.3	X	X	X		X		X	X	X	X	X	X	X	X	X
	51	Female	36	296.2	X	X	X		X	X	X	X	X	X	X	X	X	X	X
	52	Female	47	296.3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	53	Female	41	296.2	X	X	X		X	X	X	X	X		X	X	X	X	X
	54	Male	56	296.2	X	X	X		X	X	X	X	X		X	X	X	X	X
20	21	Female	52	296.3	X	X	X		X	X	X		X	X	X	X	X	X	X
	22	Female	41	296.2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
21	9	Female	27	296.3	X	X	X		X	X		X	X		X	X	X	X	X
22	113	Male	43	296.3	X	X	X	X		X	X		X		X	X	X	X	X
	115	Male	26	296.2	X	X	X		X	X	X	X	X		X	X	X	X	X

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 4.0

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
1	3	Female	42	SEPTICEMIA NOS GOITER NOS	
	4	Female	61	PURE HYPERCHOLESTEROLEM CHOLELITHIASIS NOS	
2	34	Male	38	DUODENAL ULCER NOS STOMACH ULCER NOS	HYPERTENSION NOS
	35	Female	64	TORTICOLLIS NOS	
	39	Male	43	STOMACH ULCER NOS PROSTATITIS NOS	
	41	Male	58	INGUINAL HERNIA NOS	
	42	Female	50	UTERINE PROLAPSE GASTRITIS/DUODENITIS NOS	
	45	Female	37	SALPINGO-OOPHORITIS NOS UTERINE LEIOMYOMA	MIXED HYPERLIPIDEMIA
	47	Female	40		TACHYCARDIA NOS
	80	Male	44	OLD MYOCARDIAL INFARCT	OBESITY ABN BLOOD CHEMISTRY NEC
3	65	Female	63	PULMONARY TB NEC	
	67	Female	56	APPENDICITIS NOS STERILIZATION VARICOSE VEIN OF LEG NOS UTERINE LEIOMYOMA	
	68	Female	29	CLAVICLE FRACTURE	
4	97	Female	62	HYDRONEPHROSIS	HYDRONEPHROSIS HYPOPOTASSEMIA CONGEN URETERAL OBSTRUCT

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 4.0

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
4	99	Female	46	OTHER GU NEOPLASM NOS CHRONIC PANCREATITIS	SUICIDE-PSYCHOTROPIC AGT
	100	Male	23	CONCUSSION	
	101	Female	45	CESAREAN DELIVERY NOS NONINFL DIS OVA/ADNX NEC HEPATITIS IN VIRAL DIS OVARIAN CYST NEC/NOS	
	102	Female	65	ECTOPIC PREGNANCY NOS	CARDIOVAS SYS SYMP NEC
	103	Female	58	CYSTIC KIDNEY DISEASE FX SACRUM/COCCYX-CLOSED SPONTANEOUS ABORTION	
7	193	Female	25	INGUINAL HERNIA NOS PNEUMONIA, ORGANISM NOS ASTIGMATISM HYPERMETROPIA	
	197	Male	43	RHEUM FEV W/O HRT INVOLV BENIGN NEO UTERUS NOS	THYROTOXICOSIS NOS
11	323	Female	62	TYPHOID FEVER	
	324	Female	34	SCOLIOSIS	
	326	Female	52		CYSTITIS NOS ABN BLOOD CHEMISTRY NEC
	329	Female	44		TACHYCARDIA NOS
	331	Female	38	UTERINE LEIOMYOMA	
	334	Female	49	DISSEMIN CHORIORETINITIS DIAPHRAGMATIC HERNIA RETINAL DETACH W DEFECT	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 4.0

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
11	335	Female	33	OTHER ANOMALIES OF LUNG	
13	386	Male	62		ABN LIVER FUNCTION STUDY ADV EFF PHENOTHIAZ TRANQ
	387	Female	78	ESOPHAGITIS	
	388	Male	50	ARTHROPATHY NOS	
	392	Female	38	OTHER GU NEOPLASM NOS ALLERGIC RHINITIS NOS	
	503	Female	48	OTHER GU NEOPLASM NOS ASTHMA NOS	
	521	Male	50	HYPERTENSION NOS	
14	397	Female	63	OSTEITIS DEFORMANS NOS	
	398	Female	41	BRONCHIECTASIS	
	399	Female	43	PULMONARY TB NOS PNEUMOTHORAX EXCESSIVE MENSTRUATION OTHER PSORIASIS OSTEOARTHROSIS NOS	
	404	Female	61	UTERINE LEIOMYOMA	
	405	Female	40		BRONCHITIS NOS
	406	Female	50	ASTHMA NOS	
	408	Female	22	CHOLELITHIASIS NOS INCOMPETENCE OF CERVIX CESAREAN DELIVERY NOS	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 4.0

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
14	510	Female	40	MIGRAINE DERANGEMENT OF JOINT NOS	
	511	Female	28	CYSTIC KIDNEY DISEASE	
	538	Female	40	DISC DISPLACEMENT NOS THORAC/LUMB DISC DISPLAC	
	539	Female	40	ENDOMETRIOSIS NOS	
16	430	Male	51	PURE HYPERCHOLESTEROLEM	
	438	Female	64	HYPERTENSION NOS	
18	26	Female	33	GOITER NOS	
	27	Female	35		OBESITY
	49	Female	57	VARICOSE VEIN OF LEG NOS OTHER GU NEOPLASM NOS DISC DISPLACEMENT NOS APPENDICITIS NOS	
	50	Female	63	ENTHESOPATHY OF ANKLE LUMBAGO SCIATICA APPENDICITIS NOS	
	52	Female	47	RHEUMATISM NOS OBESITY	
	53	Female	41	EXCESSIVE MENSTRUATION CHRONIC LIVER DIS NEC OBESITY	CHRONIC LIVER DIS NEC OBESITY
	54	Male	56	ALCOHOLIC GASTRITIS PROSTATITIS NOS ALCOHOL LIVER DAMAGE NOS	LIVER DISORDERS NEC

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 4.0

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
18	54	Male	56	OBESITY	
20	22	Female	41		FLU W RESP MANIFEST NEC

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Chest X-Ray - Pulmonary Function			
			Assessment	Date	Value	Abnormality
1	1	Male	Screen	19/11/91	Normal	
	2	Male	Screen	26/06/92	Normal	
	3	Female	Screen	25/06/92	Normal	
	4	Female	Screen	12/08/92	Normal	
	5	Female	Screen	06/10/92	Normal	
	6	Male	Screen	11/01/93	Normal	
2	33	Female	Screen	07/05/91	Normal	
	34	Male	Screen	08/05/91	Normal	
	35	Female	Screen	16/04/91	Normal	
	36	Male	Screen	26/04/91	Normal	
	37	Male	Screen		Not done	
	38	Male	Screen	28/06/91	Abnormal	ABN FINDINGS-LUNG FIELD
	39	Male	Screen	19/06/91	Normal	
	40	Male	Screen	02/91	Normal	
	41	Male	Screen	14/02/92	Normal	
	42	Female	Screen	09/03/92	Normal	
	43	Female	Screen	19/11/91	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Chest X-Ray - Assessment	Date	Pulmonary Function Value	Abnormality
2	44	Male	Screen	12/12/91	Normal	
	45	Female	Screen	14/09/92	Normal	
	47	Female	Screen	27/03/92	Abnormal	PLEURISY W/O EFFUS OR TB
	48	Female	Screen	27/04/92	Abnormal	VIRAL PNEUMONIA
	80	Male	Screen	11/92	Normal	
3	65	Female	Screen	02/10/91	Abnormal	PULMONARY TB NEC
	66	Female	Screen	22/10/91	Normal	
	67	Female	Screen	30/10/92	Normal	
	68	Female	Screen	27/11/92	Normal	
4	97	Female	Screen	18/04/91	Normal	
	98	Female	Screen	29/05/91	Normal	
	99	Female	Screen	14/10/91	Normal	
	100	Male	Screen	07/05/92	Normal	
	101	Female	Screen	02/07/92	Normal	
	102	Female	Screen	08/07/92	Normal	
	103	Female	Screen	07/07/92	Normal	
	104	Female	Screen	17/08/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Assessment	Date	Chest X-Ray - Pulmonary Function Abnormality Value
4	105	Male	Screen	26/08/92	Normal
5	129	Female	Screen		Not done
	130	Female	Screen	23/02/92	Normal
7	193	Female	Screen		Not done
	194	Female	Screen		Not done
	195	Male	Screen	14/02/92	Normal
	196	Female	Screen	22/05/92	Normal
	197	Male	Screen	16/11/92	Normal
11	321	Female	Screen	25/10/91	Normal
	322	Female	Screen	08/09/91	Normal
	323	Female	Screen	30/10/91	Normal
	324	Female	Screen	10/12/91	Normal
	325	Female	Screen	16/01/92	Normal
	326	Female	Screen	12/91	Normal
	327	Female	Screen	15/01/92	Normal
	328	Female	Screen	21/12/91	Normal
	329	Female	Screen	12/01/92	Normal

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Chest X-Ray - Pulmonary Function			
			Assessment	Date	Value	Abnormality
11	330	Male	Screen	20/01/92	Normal	
	331	Female	Screen	20/04/92	Normal	
	332	Female	Screen	14/06/92	Normal	
	333	Female	Screen	07/06/92	Normal	
	334	Female	Screen	07/08/92	Normal	
	335	Female	Screen	15/08/92	Abnormal	OTHER ANOMALIES OF LUNG
12	393	Female	Screen		Normal	
	394	Male	Screen		Normal	
	395	Male	Screen		Normal	
	396	Female	Screen		Normal	
	497	Female	Screen		Normal	
13	385	Female	Screen	13/03/92	Normal	
	386	Male	Screen	23/04/92	Normal	
	387	Female	Screen		Not done	
	388	Male	Screen	15/03/92	Normal	
	389	Female	Screen	20/07/92	Normal	
	390	Male	Screen	28/05/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Chest X-Ray - Pulmonary Function			
			Assessment	Date	Value	Abnormality
13	391	Female	Screen	05/06/92	Normal	
	392	Female	Screen	12/08/92	Normal	
	501	Male	Screen	30/10/92	Normal	
	502	Female	Screen	04/11/92	Normal	
	503	Female	Screen	12/11/92	Normal	
	504	Female	Screen	25/11/92	Normal	
	505	Female	Screen	15/04/92	Normal	
	506	Male	Screen		Not done	
	507	Female	Screen	11/09/92	Normal	
	508	Female	Screen	30/10/92	Normal	
	521	Male	Screen	01/12/93	Normal	
14	397	Female	Screen	30/01/92	Normal	
	398	Female	Screen	15/04/92	Normal	
	399	Female	Screen	13/04/92	Abnormal	PULMONARY TB NOS
	400	Male	Screen	14/05/92	Normal	
	401	Female	Screen	02/12/91	Normal	
	402	Female	Screen	25/05/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Chest X-Ray - Pulmonary Function			
			Assessment	Date	Value	Abnormality
14	403	Female	Screen	29/05/92	Normal	
	404	Female	Screen	16/06/92	Normal	
	405	Female	Screen	19/06/92	Normal	
	406	Female	Screen	30/06/92	Normal	
	407	Male	Screen	17/06/91	Normal	
	408	Female	Screen	04/08/92	Normal	
	509	Female	Screen	28/09/92	Normal	
	510	Female	Screen	30/09/92	Normal	
	511	Female	Screen	22/10/92	Normal	
	512	Female	Screen	02/11/92	Normal	
	537	Female	Screen	29/10/92	Abnormal	FX RIB/STERN/LARYN/TRACH
	538	Female	Screen	12/02/93	Normal	
	539	Female	Screen	10/03/93	Normal	
15	409	Male	Screen	01/04/92	Normal	
	410	Female	Screen	28/03/92	Normal	
	411	Female	Screen	15/04/92	Normal	
	412	Female	Screen	15/04/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Chest X-Ray - Pulmonary Function			
			Assessment	Date	Value	Abnormality
15	413	Female	Screen	20/04/92	Normal	
	414	Male	Screen	20/05/92	Normal	
	415	Female	Screen	05/06/92	Normal	
	416	Female	Screen	23/06/92	Normal	
	417	Female	Screen	17/06/92	Normal	
	418	Female	Screen	12/08/92	Normal	
	419	Female	Screen	17/07/92	Normal	
	420	Male	Screen	12/07/92	Normal	
	421	Female	Screen	19/08/92	Normal	
	422	Male	Screen	18/08/92	Normal	
	423	Female	Screen	16/08/92	Normal	
	424	Male	Screen	13/08/92	Normal	
	425	Female	Screen	24/09/92	Normal	
	426	Male	Screen	20/10/92	Normal	
	427	Female	Screen	19/11/92	Normal	
	428	Male	Screen	18/11/92	Normal	
	449	Female	Screen	05/12/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Chest X-Ray - Pulmonary Function Assessment	Date	Value	Abnormality
15	450	Male	Screen	27/11/92	Normal	
	451	Female	Screen	25/11/92	Normal	
	452	Female	Screen	12/12/92	Normal	
	454	Male	Screen	04/01/93	Normal	
16	429	Female	Screen	09/03/92	Normal	
	430	Male	Screen	26/03/92	Normal	
	431	Female	Screen	01/04/92	Normal	
	432	Female	Screen	08/04/92	Normal	
	433	Female	Screen	30/03/92	Normal	
	434	Female	Screen	06/04/92	Normal	
	435	Female	Screen	09/04/92	Normal	
	436	Female	Screen	20/04/92	Normal	
	437	Female	Screen	22/04/92	Normal	
	438	Female	Screen	15/05/92	Normal	
	439	Female	Screen	15/05/92	Normal	
	440	Female	Screen	30/06/92	Normal	
	441	Female	Screen	13/07/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Chest X-Ray - Pulmonary Function			
			Assessment	Date	Value	Abnormality
16	442	Female	Screen	03/07/92	Normal	
	443	Male	Screen	20/08/92	Normal	
	444	Female	Screen	20/08/92	Normal	
	445	Male	Screen	12/09/92	Normal	
	446	Female	Screen	12/09/92	Normal	
	447	Male	Screen	12/09/92	Normal	
	448	Female	Screen	14/09/92	Normal	
	455	Female	Screen	14/09/92	Normal	
	456	Male	Screen	08/12/92	Normal	
	457	Female	Screen	08/12/92	Normal	
	458	Female	Screen	01/10/92	Normal	
	459	Male	Screen	16/12/92	Normal	
	460	Male	Screen	17/12/92	Normal	
18	25	Female	Screen	29/09/92	Normal	
	26	Female	Screen	29/09/92	Normal	
	27	Female	Screen	29/09/92	Normal	
	28	Female	Screen	29/09/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 5.0

CHEST X-RAY

Centre	Patient	Sex	Chest X-Ray - Pulmonary Function Assessment	Date	Value	Abnormality
18	29	Male	Screen	29/09/92	Normal	
	30	Female	Screen	30/09/92	Normal	
	31	Female	Screen	13/10/92	Normal	
	32	Female	Screen	05/10/92	Normal	
	49	Female	Screen	10/11/92	Normal	
	50	Female	Screen	10/11/92	Normal	
	51	Female	Screen	10/11/91	Normal	
	52	Female	Screen	10/11/92	Normal	
	53	Female	Screen	29/12/92	Normal	
	54	Male	Screen	05/01/93	Normal	
20	21	Female	Screen	30/10/92	Abnormal	GENERAL SYMPTOMS NEC
	22	Female	Screen	13/11/92	Normal	
21	9	Female	Screen		Not done	
22	113	Male	Screen		Normal	
	115	Male	Screen		Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

				Previous antidepressant treatment				
Centre	Patient	Sex	Age	Name	Efficacy	Side effects	Last taken	Last day of treat.
1	3	Female	42	LUDIOMIL	Poor		***	24/06/92
				AMITRIPTYLINE HYDROCHLORIDE	Poor			
				AURORIX	Very poor			
	4	Female	61	TOLVIN	Poor		***	06/08/92
	5	Female	65	ANAFRANIL	Poor		***	06/10/92
	6	Male	44	FEVARIN	Poor		***	01/01/93
2	33	Female	52	FLUOXETINE	Very poor		***	03/91
	34	Male	38	SAROTEN	Very poor		***	30/04/91
	35	Female	64	APONAL	Poor		***	11/04/91
				AMITRIPTYLINE HYDROCHLORIDE	Poor	Y		
	36	Male	45	SAROTEN	Poor	Y	***	26/04/91
	37	Male	28	ANAFRANIL	Very poor		***	30/09/91
				INSIDON	Very poor		***	
				AMITRIPTYLINE	Very poor		***	
				AMITRIPTYLINE	Good		***	
	39	Male	43	STANGYL	Fair		***	11/06/91
				APONAL	Very poor	Y		
	40	Male	54	APONAL	Poor	Y	***	04/06/91
	41	Male	58	EQUILIBRIN	Poor		***	09/02/92
				AURORIX	Poor			
	42	Female	50	SAROTEN - SLOW RELEASE	Very poor	Y	***	03/03/92
	43	Female	42	SAROTEN	Poor		***	12/11/91

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

				Previous antidepressant treatment				
Centre	Patient	Sex	Age	Name	Efficacy	Side effects	Last taken	Last day of treat.
2	44	Male	46	SAROTEN	Poor		***	09/12/91
	45	Female	37	SAROTEN	Very poor	Y	***	26/08/92
	47	Female	40	INSIDON	Very poor		***	22/03/92
	48	Female	65	SAROTEN RETARD	Fair	Y	***	15/05/92
	80	Male	44	SAROTEN TOLVIN	Poor Poor	Y	***	11/92
3	65	Female	63	TOFRANIL MITE APONAL	Very poor Very poor		***	11/10/91
	66	Female	27	SAROTEN ANAFRANIL TOFRANIL TOLVIN	Fair Poor Poor Poor			
	67	Female	56	APONAL	Very poor		***	13/11/92
	68	Female	29	AMITRIPTYLINE	Fair		***	25/11/92
4	97	Female	62	SAROTEN RETARD	Very poor	Y	***	16/04/91
	99	Female	46	DOXEPIN			***	09/10/91
	102	Female	65	AURORIX ANAFRANIL	Good Poor		***	29/06/92
	103	Female	58	FEVARIN FLUOXETINE	Poor Fair	 Y	***	08/07/92
	105	Male	40	APONAL	Very poor		***	14/08/92
5	129	Female	56	TRYPTIZOL	Very good	Y	***	05/91

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Previous antidepressant treatment				
				Name	Efficacy	Side effects	Last taken	Last day of treat.
7	193	Female	25	ANAFRANIL TRYPTIZOL	Fair Good	Y Y	***	25/11/91
	197	Male	43	ANAFRANIL	Poor	Y	***	28/10/92
11	324	Female	34	CLOMIPRAMINE	Very good	Y	***	15/01/91
12	394	Male	45	AURORIX	Fair	Y	***	27/06/92
	395	Male	45	AMITRIPTYLINE	Fair	Y	***	15/07/92
	396	Female	39	MOCLOBEMIDE PARNATE ANAFRANIL LITHIUM	Poor Good Poor Fair		***	15/07/92
	497	Female	43	PROTHIADEN PROZAC AURORIX	Fair Fair Poor	Y Y		
13	385	Female	47	DOXEPIN	Fair	Y	***	25/01/92
	386	Male	62	MIANSERIN	Good			
	387	Female	78	PROTHIADEN TRIMIPRAMINE	Fair Good		*** ***	14/04/92
	388	Male	50	PROTHIADEN	Good		***	02/03/92
	390	Male	56	DOXEPIN	Poor		***	25/05/92
	391	Female	32	PROTHIADEN	Poor		***	03/06/92
	505	Female	41	NORTRIPTYLINE LITHIUM	Poor Good		***	25/08/92

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Previous antidepressant treatment: Name	Efficacy	Side effects	Last taken	Last day of treat.
13	505	Female	41	IMIPRAMINE FLUOXETINE	Poor Good			
	506	Male	38	ANAFRANIL	Fair	Y	***	22/10/92
	507	Female	49	PROTHIADEN	Fair		***	09/09/92
	521	Male	50	PROZAC SURMONTIL	Fair Fair	Y Y	***	14/10/92
14	398	Female	41	DOTHIEPIN	Very good	Y	***	29/08/91
	405	Female	40	DOTHIEPIN		Y	***	12/06/92
	407	Male	37	VENLAFAXINE				
	509	Female	29	DOTHIEPIN	Poor	Y	***	20/09/92
	510	Female	40	DOXEPIN	Fair	Y	***	86
	511	Female	28	DOXEPIN	Fair	Y	***	02/09/92
	539	Female	40	DOXEPIN	Poor	Y		
15	409	Male	56	DEMOLOX PARNATE NORTRIPTYLINE	Fair Good Very good		***	20/03/92
	410	Female	51	TOFRANIL	Fair		***	08/04/92
	411	Female	61	ANAFRANIL TRANYLCYPROMINE	Very good Fair		***	31/12/88
	413	Female	51	FLUOXETINE TOFRANIL SURVECTOR	Good Very good Good		***	30/06/91

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

Centre	Patient	Sex	Age	Previous antidepressant treatment: Name	Efficacy	Side effects	Last taken	Last day of treat.
15	415	Female	43	FLUOXETINE TOFRANIL PARNATE LERIVON	Fair Good Good Poor		***	10/05/92
	417	Female	54	NORTRIPTYLINE	Very good		***	20/11/88
	418	Female	34	ANAFRANIL	Very good		***	31/07/89
	419	Female	56	SURVECTOR TOFRANIL PARNATE	Good Very good Good		***	30/10/89
	420	Male	61	AURORIX TOFRANIL PARNATE	Poor Good Good		***	15/07/92
	421	Female	62	TRYPTANOL TOFRANIL NORTRIPTYLINE FLUOXETINE	Very good Good Good Fair		***	31/08/90
	422	Male	41	FLUOXETINE	Very good		***	30/06/90
	424	Male	32	TOFRANIL	Very good		***	31/03/87
	425	Female	58	FLUOXETINE TOFRANIL TRYPTANOL PARNATE	Fair Very good Very good Good		***	01/09/92
	427	Female	47	ANAFRANIL PARNATE	Very good Good		***	30/04/92
	449	Female	33	AURORIX ANAFRANIL	Fair Good		***	18/11/92

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

				Previous antidepressant treatment				
Centre	Patient	Sex	Age	Name	Efficacy	Side effects	Last taken	Last day of treat.
15	450	Male	33	TOFRANIL	Fair	Y	***	30/11/92
	451	Female	49	SURVECTOR	Fair		***	07/12/92
				ANAFRANIL	Good	Y		
	454	Male	51	TOFRANIL	Good		***	30/01/90
16	429	Female	48	TRYPTANOL	Good	Y	***	20/04/91
	431	Female	58	TOFRANIL	Good	Y	***	05/10/86
	432	Female	64	TOFRANIL	Good	Y	***	19/05/89
	433	Female	39	TOFRANIL	Good	Y	***	05/11/88
	434	Female	48	LERIVON	Good	Y	***	19/03/92
				TOFRANIL	Fair	Y		
	436	Female	40	LERIVON	Very poor	Y	***	25/07/91
	440	Female	41	SURMONTIL	Very good	Y	***	05/04/88
	442	Female	55	ANAFRANIL	Poor	Y	***	05/03/92
				TOFRANIL	Poor	Y		
				AMITRIPTYLINE	Poor	Y		
18	26	Female	33	APONAL	Poor		***	23/09/92
	29	Male	24	NOVERIL - SLOW RELEASE	Poor		***	28/09/92
	30	Female	51	EQUILIBRIN	Poor		***	30/09/92
	31	Female	56	SINQUAN	Poor		***	12/10/92
	32	Female	36	INSIDON	Poor		***	30/09/92

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

				Previous antidepressant treatment				
Centre	Patient	Sex	Age	Name	Efficacy	Side effects	Last taken	Last day of treat.
18	49	Female	57	SINQUAN	Poor		***	10/11/92
	50	Female	63	MAPROTILINE	Poor		***	09/11/92
	51	Female	36	EQUILIBRIN	Poor		***	07/11/92
	52	Female	47	TOFRANIL	Poor		***	10/11/92
	54	Male	56	AURORIX	Poor		***	31/12/92
20	21	Female	52	STANGYL	Fair		***	10/10/92
	22	Female	41	EQUILIBRIN	Very poor		***	05/11/92
21	9	Female	27	MOCLOBEMIDE CLOMIPRAMINE	Poor Poor		***	08/10/92
22	113	Male	43	AMITRIPTYLINE DOXEPIN	Fair Fair	Y	***	15/11/92

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period			Treatment	
			From (*)	To (a)	Days	Start date	Randomized
1	1			14/11/91		15/11/91	Fluoxetine
	2			25/06/92		26/06/92	Reboxetine
	3	24/06/92	25/06/92	30/06/92	7	01/07/92	Fluoxetine
	4	06/08/92	07/08/92	13/08/92	7	14/08/92	Reboxetine
	5	06/10/92	07/10/92	12/10/92	6	13/10/92	Fluoxetine
	6	01/01/93	06/01/93	13/01/93	8	14/01/93	Fluoxetine
2	33	03/91	02/03/91	03/05/91	64	04/05/91	Fluoxetine
	34	30/04/91	01/05/91	02/05/91	3	03/05/91	Reboxetine
	35	11/04/91	12/04/91	15/04/91	5	16/04/91	Reboxetine
	36	26/04/91	27/04/91	01/05/91	5	02/05/91	Fluoxetine
	37	30/09/91	01/10/91	06/10/91	7	07/10/91	Reboxetine
	38			19/06/91		20/06/91	Fluoxetine
	39	11/06/91	12/06/91	18/06/91	8	19/06/91	Fluoxetine
	40	04/06/91	05/06/91	05/06/91	2	06/06/91	Reboxetine
	41	09/02/92	10/02/92	12/02/92	3	13/02/92	Fluoxetine
	42	03/03/92	04/03/92	04/03/92	2	05/03/92	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(a) same as start treatment date - 1 day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period			Treatment	
			From (*)	To (@)	Days	Start date	Randomized
2	43	12/11/91	13/11/91	18/11/91	6	19/11/91	Reboxetine
	44	09/12/91	10/12/91	12/12/91	3	13/12/91	Fluoxetine
	45	26/08/92	27/08/92	09/09/92	15	10/09/92	Reboxetine
	47	22/03/92	23/03/92	24/03/92	3	25/03/92	Fluoxetine
	48	15/05/92	16/05/92	18/05/92	4	19/05/92	Reboxetine
	80	11/92	02/11/92	14/01/93	75	15/01/93	Fluoxetine
3	65	11/10/91	12/10/91	15/10/91	4	16/10/91	Fluoxetine
	66		12/10/91	15/10/91	4	16/10/91	Fluoxetine
	67	13/11/92	14/11/92	17/11/92	4	18/11/92	Reboxetine
	68	25/11/92	26/11/92	29/11/92	4	30/11/92	Reboxetine
4	97	16/04/91	17/04/91	21/04/91	5	22/04/91	Reboxetine
	98		24/05/91	29/05/91	6	30/05/91	Fluoxetine
	99	09/10/91	11/10/91	14/10/91	4	15/10/91	Fluoxetine
	100			07/05/92		08/05/92	Reboxetine
	101			01/07/92		02/07/92	Reboxetine
	102	29/06/92	30/06/92	09/07/92	10	10/07/92	Fluoxetine

(*) if missing date = last day of previous treatment + 1 day
(@) same as start treatment date - 1 day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period			Treatment	
			From (*)	To (@)	Days	Start date	Randomized
4	103	08/07/92	09/07/92	12/07/92	4	13/07/92	Fluoxetine
	104		10/08/92	17/08/92	8	18/08/92	Reboxetine
	105	14/08/92	15/08/92	20/08/92	7	21/08/92	Fluoxetine
5	129	05/91	02/05/91	28/11/91	212	29/11/91	Reboxetine
	130			27/02/92		28/02/92	Fluoxetine
7	193	25/11/91	30/11/91	05/12/91	6	06/12/91	Reboxetine
	194			09/01/92		10/01/92	Fluoxetine
	195			13/02/92		14/02/92	Fluoxetine
	196			28/05/92		29/05/92	Reboxetine
	197	28/10/92	29/10/92	10/11/92	13	11/11/92	Fluoxetine
11	321			13/11/91		14/11/91	Fluoxetine
	322			13/11/91		14/11/91	Reboxetine
	323			18/11/91		19/11/91	Fluoxetine
	324	15/01/91	16/01/91	23/01/92	373	24/01/92	Reboxetine
	325			11/02/92		12/02/92	Reboxetine
	326			11/02/92		12/02/92	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(@) same as start treatment date - 1 day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period			Treatment	
			From (*)	To (@)	Days	Start date	Randomized
11	327			13/02/92		14/02/92	Fluoxetine
	328			18/02/92		19/02/92	Fluoxetine
	329			30/03/92		31/03/92	Reboxetine
	330			20/04/92		21/04/92	Reboxetine
	331			25/05/92		26/05/92	Fluoxetine
	332			27/07/92		28/07/92	Fluoxetine
	333			14/09/92		15/09/92	Reboxetine
	334			21/09/92		22/09/92	Fluoxetine
	335			12/10/92		13/10/92	Reboxetine
12	393			24/06/92		25/06/92	Fluoxetine
	394	27/06/92	28/06/92	05/07/92	9	06/07/92	Reboxetine
	395	15/07/92	16/07/92	23/07/92	9	24/07/92	Reboxetine
	396	15/07/92	16/07/92	03/08/92	20	04/08/92	Fluoxetine
	497		13/02/93	23/02/93	11	24/02/93	Fluoxetine
13	385	25/01/92	26/01/92	13/03/92	49	14/03/92	Fluoxetine
	386		01/04/92	23/04/92	23	24/04/92	Fluoxetine

(*) if missing date = last day of previous treatment + 1 day
(@) same as start treatment date - 1 day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period			Treatment	
			From (*)	To (@)	Days	Start date	Randomized
13	387	14/04/92	15/04/92	17/04/92	3	18/04/92	Reboxetine
	388	02/03/92	03/03/92	15/03/92	14	16/03/92	Reboxetine
	389			20/07/92		21/07/92	Fluoxetine
	390	25/05/92	26/05/92	27/05/92	3	28/05/92	Reboxetine
	391	03/06/92	04/06/92	10/06/92	7	11/06/92	Fluoxetine
	392		10/08/92	13/08/92	4	14/08/92	Reboxetine
	501		30/10/92	01/11/92	3	02/11/92	Reboxetine
	502			02/11/92		03/11/92	Fluoxetine
	503			11/11/92		12/11/92	Reboxetine
	504			25/11/92		26/11/92	Fluoxetine
	505	25/08/92	26/08/92	30/08/92	5	31/08/92	Reboxetine
	506	22/10/92	23/10/92	26/10/92	4	27/10/92	Fluoxetine
	507	09/09/92	10/09/92	10/09/92	2	11/09/92	Fluoxetine
	508		29/10/92	01/11/92	4	02/11/92	Reboxetine
	521	14/10/92	15/10/92	29/11/92	47	30/11/92	Reboxetine
14	397		12/03/92	13/04/92	33	14/04/92	Fluoxetine

(*) if missing date = last day of previous treatment + 1 day
(@) same as start treatment date - 1 day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period			Treatment	
			From (*)	To (@)	Days	Start date	Randomized
14	398	29/08/91	30/08/91	14/04/92	229	15/04/92	Reboxetine
	399			20/04/92		21/04/92	Reboxetine
	400			14/05/92		15/05/92	Fluoxetine
	401		14/01/92	21/05/92	129	22/05/92	Fluoxetine
	402			26/05/92		27/05/92	Reboxetine
	403			28/05/92		29/05/92	Reboxetine
	404			15/06/92		16/06/92	Fluoxetine
	405	12/06/92	13/06/92	21/06/92	10	22/06/92	Fluoxetine
	406			29/06/92		30/06/92	Fluoxetine
	407		03/03/92	13/07/92	133	14/07/92	Reboxetine
	408			03/08/92		04/08/92	Reboxetine
	509	20/09/92	21/09/92	28/09/92	9	29/09/92	Fluoxetine
	510	86	02/01/86	29/09/92	2464	30/09/92	Fluoxetine
	511	02/09/92	03/09/92	22/10/92	50	23/10/92	Reboxetine
	512			02/11/92		03/11/92	Reboxetine
	537			02/11/92		03/11/92	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(@) same as start treatment date - 1 day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period			Treatment	
			From (*)	To (@)	Days	Start date	Randomized
14	538			11/02/93		12/02/93	Fluoxetine
	539		23/02/93	09/03/93	15	10/03/93	Fluoxetine
15	409	20/03/92	21/03/92	07/04/92	19	08/04/92	Reboxetine
	410	08/04/92	09/04/92	16/04/92	8	17/04/92	Fluoxetine
	411	31/12/88	01/01/89	21/04/92	1207	22/04/92	Reboxetine
	412			22/04/92		23/04/92	Fluoxetine
	413	30/06/91	01/07/91	29/04/92	304	30/04/92	Reboxetine
	414			01/06/92		02/06/92	Fluoxetine
	415	10/05/92	11/05/92	11/06/92	33	12/06/92	Reboxetine
	416			22/06/92		23/06/92	Fluoxetine
	417	20/11/88	21/11/88	18/06/92	1306	19/06/92	Reboxetine
	418	31/07/89	01/08/89	16/07/92	1081	17/07/92	Reboxetine
	419	30/10/89	31/10/89	15/07/92	989	16/07/92	Fluoxetine
	420	15/07/92	16/07/92	19/08/92	35	20/08/92	Fluoxetine
	421	31/08/90	01/09/90	31/07/92	700	01/08/92	Reboxetine
	422	30/06/90	01/07/90	18/08/92	780	19/08/92	Fluoxetine

(*) if missing date = last day of previous treatment + 1 day
(@) same as start treatment date - 1 day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period			Treatment	
			From (*)	To (@)	Days	Start date	Randomized
15	423			20/08/92		21/08/92	Fluoxetine
	424	31/03/87	01/04/87	20/08/92	1969	21/08/92	Reboxetine
	425	01/09/92	02/09/92	01/10/92	31	02/10/92	Reboxetine
	426			27/10/92		28/10/92	Fluoxetine
	427	30/04/92	01/05/92	02/12/92	216	03/12/92	Reboxetine
	428			02/12/92		03/12/92	Fluoxetine
	449	18/11/92	19/11/92	07/12/92	19	08/12/92	Reboxetine
	450	30/11/92	01/12/92	09/12/92	9	10/12/92	Fluoxetine
	451	07/12/92	08/12/92	17/12/92	10	18/12/92	Fluoxetine
	452			22/12/92		23/12/92	Reboxetine
	454	30/01/90	31/01/90	18/01/93	1084	19/01/93	Fluoxetine
16	429	20/04/91	21/04/91	25/03/92	340	26/03/92	Fluoxetine
	430			29/03/92		30/03/92	Reboxetine
	431	05/10/86	06/10/86	30/03/92	2003	31/03/92	Reboxetine
	432	19/05/89	20/05/89	30/03/92	1046	31/03/92	Fluoxetine
	433	05/11/88	06/11/88	01/04/92	1243	02/04/92	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(@) same as start treatment date - 1 day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period			Treatment	
			From (*)	To (@)	Days	Start date	Randomized
16	434	19/03/92	20/03/92	06/04/92	18	07/04/92	Fluoxetine
	435			13/04/92		14/04/92	Reboxetine
	436	25/07/91	26/07/91	23/04/92	273	24/04/92	Fluoxetine
	437			29/04/92		30/04/92	Reboxetine
	438			19/05/92		20/05/92	Fluoxetine
	439			19/05/92		20/05/92	Fluoxetine
	440	05/04/88	06/04/88	30/06/92	1547	01/07/92	Reboxetine
	441			21/07/92		22/07/92	Fluoxetine
	442	05/03/92	06/03/92	21/07/92	139	22/07/92	Reboxetine
	443			24/08/92		25/08/92	Fluoxetine
	444			24/08/92		25/08/92	Reboxetine
	445			17/09/92		18/09/92	Reboxetine
	446			17/09/92		18/09/92	Fluoxetine
	447			17/09/92		18/09/92	Fluoxetine
	448			18/09/92		19/09/92	Reboxetine
	455			18/09/92		19/09/92	Fluoxetine

(*) if missing date = last day of previous treatment + 1 day
(@) same as start treatment date - 1 day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period			Treatment	
			From (*)	To (@)	Days	Start date	Randomized
16	456			15/12/92		16/12/92	Reboxetine
	457			15/12/92		16/12/92	Fluoxetine
	458			15/12/92		16/12/92	Fluoxetine
	459			21/12/92		22/12/92	Reboxetine
	460			21/12/92		22/12/92	Reboxetine
18	25		23/09/92	05/10/92	13	06/10/92	Fluoxetine
	26	23/09/92	24/09/92	05/10/92	13	06/10/92	Reboxetine
	27			05/10/92		06/10/92	Reboxetine
	28		23/09/92	05/10/92	13	06/10/92	Fluoxetine
	29	28/09/92	29/09/92	05/10/92	7	06/10/92	Reboxetine
	30	30/09/92	01/10/92	06/10/92	7	07/10/92	Fluoxetine
	31	12/10/92	13/10/92	19/10/92	7	20/10/92	Reboxetine
	32	30/09/92	01/10/92	06/10/92	6	07/10/92	Fluoxetine
	49	10/11/92	11/11/92	16/11/92	7	17/11/92	Reboxetine
	50	09/11/92	10/11/92	16/11/92	8	17/11/92	Reboxetine
	51	07/11/92	09/11/92	16/11/92	8	17/11/92	Fluoxetine

(*) if missing date = last day of previous treatment + 1 day
(@) same as start treatment date - 1 day

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 6.1

DURATION OF DRUG-FREE WASH-OUT-PERIOD

Centre	Patient	Last day of previous treatment	Wash out period			Treatment	
			From (*)	To (@)	Days	Start date	Randomized
18	52	10/11/92	11/11/92	16/11/92	7	17/11/92	Fluoxetine
	53			14/01/93		15/01/93	Fluoxetine
	54	31/12/92	05/01/93	11/01/93	7	12/01/93	Fluoxetine
20	21	10/10/92	11/10/92	05/11/92	27	06/11/92	Fluoxetine
	22	05/11/92	06/11/92	11/11/92	6	12/11/92	Fluoxetine
21	9	08/10/92	09/10/92	18/10/92	10	19/10/92	Fluoxetine
22	113	15/11/92	24/11/92	02/12/92	9	03/12/92	Fluoxetine
	115			28/12/92		29/12/92	Reboxetine

(*) if missing date = last day of previous treatment + 1 day
(@) same as start treatment date - 1 day

PHARMACIA CNS 9990083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 1

	Patient					
	1	2	3	4	5	6
	Male	Male	Fem.	Fem.	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?						
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?						
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficienty	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES
Resistence to previous antidepres. treat	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES

PHARMACIA CNS R&D 5590083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 2

	Patient												
	33	34	35	36	37	38	39	40	41	42	43	44	45
	Fem.	Male	Fem.	Male	Male	Male	Male	Male	Male	Fem.	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 insufficienty	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
Resistence to previous antidepres. treat	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 2

	Patient		
	47	48	80
	Fem.	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 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 abnorma.	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES
Chronic respiratory insufficienty	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
Resistence to previous antidepres. treat	YES	YES	YES
High risk of suicide	YES	YES	YES

PHARMACIA CNS R&D 9990083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 3

	Patient			
	65	66	67	68
	Fem.	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?				
Aged between 18 and 65 years inclusive	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?				
Dysthymia, Cyclothymia	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES
Chronic respiratory insufficienty	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES
Resistence to previous antidepres. treat	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES

PHARMACIA CNS R&D 9590083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 4

	Patient								
	97	98	99	100	101	102	103	104	105
	Fem.	Fem.	Fem.	Male	Fem.	Fem.	Fem.	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?									
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES
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 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?									
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	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 abnorma.	NO	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 insufficienty	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
Resistence to previous antidepres. treat	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES

PHARMACIA CN 9990083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 5

	Patient	
	129	130
	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?		
Aged between 18 and 65 years inclusive	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES
With a total score of 22 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 abnorma.	YES	YES
Participation in a clinical trial with .	YES	YES
Evidence of substance use disorder	YES	YES
Chronic respiratory insufficienty	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
Resistence to previous antidepres. treat	YES	YES
High risk of suicide	YES	YES

PHARMACIA CNS R&D 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 7

	Patient				
	193	194	195	196	197
	Fem.	Fem.	Male	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?					
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES
With a total score of 22 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	NO
Current evidence of urinary retention	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	NO
Participation in a clinical trial with .	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES
Chronic respiratory insufficienty	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
Resistence to previous antidepres. treat	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES

PHARMACIA CNS R&D 9990083

REBOXETINE - PROTOCOL 20124/016
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.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Male	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?													
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?													
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	NO	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 insufficienty	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
Resistence to previous antidepres. treat	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA CNS R&D 9990083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 11

	Patient	
	334	335
	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?		
Aged between 18 and 65 years inclusive	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES
With a total score of 22 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 abnorma.	YES	YES
Participation in a clinical trial with .	YES	YES
Evidence of substance use disorder	YES	YES
Chronic respiratory insufficienty	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
Resistence to previous antidepres. treat	YES	YES
High risk of suicide	YES	YES

PHARMACIA CNS R&D 9990083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 12

	Patient				
	393	394	395	396	497
	Fem.	Male	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 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 abnorma.	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES
Chronic respiratory insufficienty	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
Resistence to previous antidepres. treat	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES

PHARMACIA CNS R&D 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 13

	Patient												
	385	386	387	388	389	390	391	392	501	502	503	504	505
	Fem.	Male	Fem.	Male	Fem.	Male	Fem.	Fem.	Male	Fem.	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?													
Aged between 18 and 65 years inclusive	YES	YES	NO	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 insufficienty	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
Resistence to previous antidepres. treat	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 CN9350083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 13

	Patient			
	506	507	508	521
	Male	Fem.	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?				
Aged between 18 and 65 years inclusive	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?				
Dysthymia, Cyclothymia	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES
Chronic respiratory insufficienty	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES
Resistence to previous antidepres. treat	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES

PHARMACIA CNS 0350083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 14

	Patient												
	397	398	399	400	401	402	403	404	405	406	407	408	509
	Fem.	Fem.	Fem.	Male	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Male	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?													
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 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 insufficienty	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
Resistence to previous antidepres. treat	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA CN 9990083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 14

	Patient					
	510	511	512	537	538	539
	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?						
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES	YES	YES	YES	YES
With a total score of 22 of above 21HAMD	YES	YES	YES	YES	YES	YES
Able and willing to give Informed Cons..	YES	YES	YES	YES	YES	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?						
Dysthymia, Cyclothymia	YES	YES	YES	YES	YES	YES
History of DSM-III-R, associated to	YES	YES	YES	YES	YES	YES
Pregnancy	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES
Clinically significant hematopoietic ...	YES	YES	YES	YES	YES	YES
Clinically significant lab values abnor.	YES	YES	YES	YES	YES	YES
Current evidence of urinary retention	YES	YES	YES	YES	YES	YES
Current evidence of glaucoma	YES	YES	YES	YES	YES	YES
Clinically significant physical abnorma.	YES	YES	YES	YES	YES	YES
Participation in a clinical trial with .	YES	YES	YES	YES	YES	YES
Evidence of substance use disorder	YES	YES	YES	YES	YES	YES
Chronic respiratory insufficienty	YES	YES	YES	YES	YES	YES
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES
Any history of seizures of brain injury	YES	YES	YES	YES	YES	YES
Any other important clinical illness ...	YES	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES
Resistence to previous antidepres. treat	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES

PHARMACIA CNS R&D 9590083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 15

	Patient												
	409	410	411	412	413	414	415	416	417	418	419	420	421
	Male	Fem.	Fem.	Fem.	Fem.	Male	Fem.	Fem.	Fem.	Fem.	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 insufficienty	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
Resistence to previous antidepres. treat	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA CNS SSR 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 15

	Patient											
	422	423	424	425	426	427	428	449	450	451	452	454
	Male	Fem.	Male	Fem.	Male	Fem.	Male	Fem.	Male	Fem.	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?												
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
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 insufficienty	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
Resistence to previous antidepres. treat	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 CN9350083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 16

	Patient												
	429	430	431	432	433	434	435	436	437	438	439	440	441
	Fem.	Male	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	N/A	N/A	YES	YES	YES	YES	YES	YES	YES	YES	YES
Refusal of contraceptive use during	YES	YES	N/A	N/A	YES	YES	N/A	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 insufficienty	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
Resistence to previous antidepres. treat	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 16

	Patient												
	442	443	444	445	446	447	448	455	456	457	458	459	460
	Fem.	Male	Fem.	Male	Fem.	Male	Fem.	Fem.	Male	Fem.	Fem.	Male	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?													
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	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 insufficienty	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
Resistance to previous antidepres. treat	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 CNS [illegible] 9990083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 18

	Patient												
	25	26	27	28	29	30	31	32	49	50	51	52	53
	Fem.	Fem.	Fem.	Fem.	Male	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?													
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	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 insufficienty	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
Resistence to previous antidepres. treat	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

PHARMACIA CNS 9590083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 18

	Patient
	54
	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 ?	
Dysthymia, Cyclothymia	YES
History of DSM-III-R, associated to	YES
Pregnancy	YES
Refusal of contraceptive use during	YES
Clinically significant hematopoietic ...	YES
Clinically significant lab values abnor.	YES
Current evidence of urinary retention	YES
Current evidence of glaucoma	YES
Clinically significant physical abnorma.	YES
Participation in a clinical trial with .	YES
Evidence of substance use disorder	YES
Chronic respiratory insufficienty	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
Resistence to previous antidepres. treat	YES
High risk of suicide	YES

PHARMACIA CNS 9590083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 20

	Patient	
	21	22
	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?		
Aged between 18 and 65 years inclusive	YES	YES
Affected by acute episodes of DSM-III-R.	YES	YES
With a total score of 22 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 abnorma.	YES	YES
Participation in a clinical trial with .	YES	YES
Evidence of substance use disorder	YES	YES
Chronic respiratory insufficienty	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
Resistence to previous antidepres. treat	YES	YES
High risk of suicide	YES	YES

PHARMACIA CN2 88D 9990083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 21

	Patient
	9
	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?	
Aged between 18 and 65 years inclusive	YES
Affected by acute episodes of DSM-III-R.	YES
With a total score of 22 of above 21HAMD	YES
Able and willing to give Informed Cons..	YES
ARE THE FOLLOWING CONDITIONS ABSENT ?	
Dysthymia, Cyclothymia	YES
History of DSM-III-R, associated to	YES
Pregnancy	YES
Refusal of contraceptive use during	YES
Clinically significant hematopoietic ...	YES
Clinically significant lab values abnor.	YES
Current evidence of urinary retention	YES
Current evidence of glaucoma	YES
Clinically significant physical abnorma.	YES
Participation in a clinical trial with .	YES
Evidence of substance use disorder	YES
Chronic respiratory insufficienty	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
Resistence to previous antidepres. treat	YES
High risk of suicide	YES

PHARMACIA CNS 5550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 7.0

INCLUSION / EXCLUSION CRITERIA

Centre: 22

	Patient	
	113	115
	Male	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 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 abnorma.	YES	YES
Participation in a clinical trial with .	YES	YES
Evidence of substance use disorder	YES	YES
Chronic respiratory insufficienty	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
Resistence to previous antidepres. treat	YES	YES
High risk of suicide	YES	YES

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	2	Male	Reboxetine	YES	ASPIRINE	25/06/92($)	Day 7	20/08/92(*)	Day 56
					CHLORAL HYDRATE	01/07/92	Day 7	31/07/92	Day 35
					DISTRANEURIN	02/07/92	Day 7	02/07/92	Day 7
					MUSKEL TRANCOPAL	12/08/92	Day 49	20/08/92(*)	Day 56
					VOLTAREN	13/08/92	Day 49	20/08/92(*)	Day 56
	3	Female	Fluoxetine	YES	CHLORAL HYDRATE	03/07/92	Day 7	09/08/92	Day 42
	4	Female	Reboxetine	NO	CHLORAL HYDRATE	18/08/92	Day 7	25/09/92	Day 42
					SIMVASTATIN	12/08/92($)	Screen	24/09/92(*)	Day 42
	5	Female	Fluoxetine	NO	CHLORAL HYDRATE	14/10/92	Day 7	11/11/92(*)	Day 35
					DISTRANEURINE	30/10/92	Day 21	11/11/92(*)	Day 35
	6	Male	Fluoxetine	NO	CHLORAL HYDRATE	09/01/93	Screen	14/01/93	Screen
					PASPERTIN	04/02/93	Day 28	11/02/93	Day 28
					RIOPAN	21/01/93	Day 14	26/01/93	Day 14
					ZANTIC	26/01/93	Day 14	04/02/93	Day 21
2	33	Female	Fluoxetine	YES	CHLORALDURAT	02/05/91 13/06/91	Screen Day 42	10/05/91 28/06/91(*)	Day 7 Day 56
					DISTRANEURIN	10/05/91	Day 7	12/06/91	Day 42

($) - start date missing = screening date
(*) - end date missing = last dose taken date

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	34	Male	Reboxetine	NO	CHLORALDURAT	30/04/91	Screen	06/06/91	Day 35
					REMESTAN	30/04/91	Screen	01/05/91	Screen
	37	Male	Reboxetine	NO	ASPIRIN 'BAYER'	11/10/91	Day 7	10/10/91(*)	Day 7
	38	Male	Fluoxetine	NO	ALCOHOL	15/07/91	Day 28	15/07/91	Day 28
					CHLORALDURAT	25/06/91	Day 7	15/07/91	Day 28
	39	Male	Fluoxetine	NO	CERNILTON	01/91	Day 7	22/06/91(*)	Day 7
					DISTRANEURIN	22/06/91	Day 7	22/06/91(*)	Day 7
					MOTILIUM	21/06/91	Day 7	22/06/91(*)	Day 7
					TAVOR	12/06/91	Screen	18/06/91	Screen
	40	Male	Reboxetine	NO	CHLORALDURAT	05/06/91	Screen	20/06/91	Day 21
					DISTRANEURIN	04/06/91	Screen	06/06/91	Screen
	42	Female	Reboxetine	YES	ASPIRINE	12/03/92	Day 14	25/03/92	Day 21
					CHLORAL HYDRATE	02/03/92 05/03/92	Screen Day 7	03/03/92 23/03/92	Screen Day 21
					DISTRANEURINE	24/03/92	Day 21	26/03/92	Day 28
					EFFORTIL	26/03/92	Day 28	29/04/92(*)	Day 56

($) - start date missing = screening date
(*) - end date missing = last dose taken date

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	42	Female	Reboxetine	YES	REFOBACIN	31/03/92	Day 28	08/04/92	Day 28
					TELDANE	09/04/92	Day 42	29/04/92(*)	Day 56
	43	Female	Reboxetine	YES	ASPIRIN 'BAYER'	14/11/91	Screen	24/11/91	Day 7
					ATARAX	08/01/91	Day 56	12/01/91	Day 56
					BASODEXAN	04/12/91	Day 35	08/01/92	Day 56
					CHLORALDURAT	13/11/91	Screen	13/01/92(*)	Day 56
					IBUPROFEN	28/11/91	Day 14	13/01/92(*)	Day 56
					MOTILIUM	15/11/91	Screen	06/12/91	Day 21
					RIOPAN	11/12/91	Day 28	06/01/92	Day 49
	44	Male	Fluoxetine	NO	BASODEXAN	23/12/91	Day 14	16/01/92	Day 42
					BELOC	19/12/91	Day 7	08/01/92	Day 28
					CHLORAL HYDRATE	10/12/91	Screen	10/01/92	Day 35
					HYDRODEXAN	23/12/91	Day 14	16/01/92	Day 42
	45	Female	Reboxetine	YES	CHLORALDURAT	09/09/92	Day 7	25/09/92	Day 21
					MEDROXYPROGESTERONE ACETA	89	Screen	04/11/92(*)	Day 56
					PROGYNOVA	89	Screen	04/11/92(*)	Day 56

($) - start date missing = screening date
(*) - end date missing = last dose taken date

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	47	Female	Fluoxetine	YES	CHLORAL HYDRATE	24/03/92	Screen	08/04/92	Day 21
					COTRIMSTADA	02/04/92	Day 14	07/04/92	Day 14
					INDOBLOC	24/03/92($)	Screen	26/03/92	Day 7
					MOTILIUM	27/03/92	Day 7	07/04/92	Day 14
					VITAMIN C	27/03/92	Day 7	01/04/92	Day 7
	48	Female	Reboxetine	YES	BETABION	21/05/92	Day 7	25/05/92	Day 7
					CHLORALDURAT	24/04/92	Screen	18/05/92	Screen
					DISTRANEURIN	19/05/92	Day 7	13/07/92(*)	Day 56
					LAXOBERAL	22/05/92	Day 7	22/05/92	Day 7
					TAVOR	24/04/92	Screen	17/05/92	Screen
	80	Male	Fluoxetine	YES	ALLOPURINOL	93	Screen	11/03/93(*)	Day 56
					ASPIRIN 'BAYER'	89	Screen	11/03/93(*)	Day 56
					CONCOR	89	Screen	11/03/93(*)	Day 56
					CORVATON	89	Screen	11/03/93(*)	Day 56
3	65	Female	Fluoxetine	YES	CHLORALDURAT	11/10/91 02/12/91	Screen Day 49	27/11/91 10/12/91	Day 56 Day 56
	66	Female	Fluoxetine	NO	CHLORAL HYDRATE	11/10/91 23/10/91	Screen Day 14	15/10/91 12/11/91	Day 7 Day 28

($) - start date missing = screening date
(*) - end date missing = last dose taken date

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	66	Female	Fluoxetine	NO	MARVELON	17/10/91	Day 7	07/11/91	Day 28
	67	Female	Reboxetine	NO	CHLORAL HYDRATE	13/11/92	Screen	15/12/92(*)	Day 28
	68	Female	Reboxetine	NO	CHLORAL HYDRATE	26/11/92	Screen	28/12/92(*)	Day 35
					RIOPAN	04/12/92	Day 7	20/12/92	Day 21
4	97	Female	Reboxetine	YES	CHLORALDURAT	17/04/91	Screen	16/06/91(*)	Day 56
					DISTRANEURIN	18/04/91	Screen	19/04/91	Day 7
					EUGALAC	03/05/91	Day 14	28/05/91	Day 35
					KALINOR	20/04/91	Screen	26/04/91	Day 7
					LINSEED	17/04/91	Screen	02/05/91	Day 14
					SENNA LEAF	29/05/91	Day 42	16/06/91(*)	Day 56
	98	Female	Fluoxetine	YES	CHLORALDURAT	28/05/91 11/07/91	Day 7 Day 49	05/07/91 24/07/91	Day 42 Day 56
	99	Female	Fluoxetine	NO	CHLORAL HYDRATE	11/10/91	Day 14	25/10/91	Day 7
	101	Female	Reboxetine	YES	CHLORAL HYDRATE	01/07/92	Day 7	26/08/92(*)	Day 56
					EUGALAC	06/07/92	Day 7	26/08/92(*)	Day 56
					VOLTAREN	13/08/92	Day 56	04/09/92	Day 56

($) - start date missing = screening date
(*) - end date missing = last dose taken date

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 8.0

CONCOMITANT DRUGS

Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	report
Female	Fluoxetine	YES	CHLORAL HYDRATE	13/07/92	Day 7	04/09/92	D
			LAXOBERAL	07/08/92	Day 28	07/08/92	D
Female	Fluoxetine	NO	ASPIRINE	22/07/92	Day 14	22/07/92	D
			CHLORAL HYDRATE	09/07/92 27/07/92	Screen Day 21	19/07/92 17/08/92	D D
			DISTRANEURINE	20/07/92	Day 14	17/08/92	D
Female	Reboxetine	NO	CHLORAL HYDRATE	08/09/92	Day 28	05/10/92(*)	D
Male	Fluoxetine	YES	CHLORAL HYDRATE	18/08/92	Screen	15/10/92(*)	D
Female	Reboxetine	NO	DISTRANEURINE	22/11/91	Day 7	29/12/91(*)	D
			VALIUM	19/11/91	Day 14	22/11/91	D
Female	Reboxetine	YES	DISTRANEURINE	04/12/91	Screen	31/01/92	D
			LACTULOSE	04/12/91	Day 7	31/01/92(*)	D
			MAGNESIA	19/12/91	Day 14	25/12/91	D
Female	Fluoxetine	YES	ANALGILASA	21/01/92	Day 14	23/01/92	D
			DISTRANEURINE	19/01/92 24/01/92 09/02/92	Day 14 Day 28 Day 35	21/01/92 25/01/92 10/02/92	D D D
			VINCIGRIP	22/01/92	Day 49	26/02/92	D

($) - start date missing = screening date
(*) - end date missing = last dose taken date

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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
7	195	Male	Fluoxetine	YES	DISTRANEURINE	11/02/92	Screen	24/03/92	Day 42
	196	Female	Reboxetine	NO	ADALAT	25/06/92	Day 28	10/07/92	Day 49
					DISTRANEURINE	22/05/92	Screen	16/07/92(*)	Day 49
					HIDROSALURETIL	10/07/92	Day 49	16/07/92	Day 49
	197	Male	Fluoxetine	NO	DISTRANEURINE	08/11/92	Screen	10/11/92	Day 7
11	321	Female	Fluoxetine	YES	PARACETAMOL	25/11/91	Day 14	27/12/91	Day 42
	322	Female	Reboxetine	YES	DISTRANEURINE	28/11/91	Day 14	09/01/92(*)	Day 56
					PARACETAMOL	18/11/91	Day 7	27/11/91	Day 14
	324	Female	Reboxetine	YES	DENUBIL	07/02/92	Day 14	14/02/92	Day 21
	325	Female	Reboxetine	YES	DISTRANEURINE	18/02/92	Day 7	10/03/92	Day 28
	326	Female	Reboxetine	YES	PIPEMIDIC ACID	29/02/92	Day 21	07/04/92(*)	Day 56
	332	Female	Fluoxetine	YES	DISTRANEURINE	04/08/92	Day 14	17/09/92	Day 56
	333	Female	Reboxetine	YES	DISTRANEURINE	06/10/92	Day 28	04/11/92	Day 56
	334	Female	Fluoxetine	YES	AMOXICILLIN	05/10/92	Day 14	26/10/92	Day 35
12	394	Male	Reboxetine	YES	ROHYPNOL	90 13/07/92	Screen Day 14	04/07/92 31/08/92(*)	Screen Day 56
					TEMAZEPAM	06/07/92	Day 7	13/07/92	Day 7

($) - start date missing = screening date
(*) - end date missing = last dose taken date

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 8.8

CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
12	396	Female	Fluoxetine	NO	ROHYPNOL	89	Screen	17/08/92(*)	Day 7
	497	Female	Fluoxetine	YES	KEFLEX	18/03/93	Day 35	03/04/93	Day 35
					PANADOL	22/03/93	Day 28	23/03/93	Day 28
					SEREPAX	72	Screen	21/04/93(*)	Day 56
13	385	Female	Fluoxetine	YES	PROVERA	90	Screen	08/05/92(*)	Day 56
	386	Male	Fluoxetine	NO	TEMAZEPAM	23/04/92	Screen	30/04/92(*)	Day 7
	387	Female	Reboxetine	NO	FLUCLOXACILLIN	16/05/92	Day 28	21/05/92	Day 28
					MYLANTA	24/04/92	Day 7	06/05/92	Day 21
					NOCTEC	07/05/92	Day 21	17/05/92	Day 28
					RANITIDINE	14/04/92	Screen	18/05/92(*)	Day 28
					TEMAZEPAM	14/04/92	Screen	07/05/92	Day 14
	388	Male	Reboxetine	YES	CHLORAL HYDRATE	27/03/92	Day 14	11/05/92(*)	Day 56
					FLUCLOXACILLIN	24/03/92	Day 14	01/04/92	Day 14
					MOGADON	17/03/92	Day 7	18/03/92	Day 7
					ORUDIS - SLOW RELEASE	15/03/92	Screen	11/05/92(*)	Day 56
					TEMAZEPAM	14/03/92	Screen	26/03/92	Day 14

($) - start date missing = screening date
(*) - end date missing = last dose taken date

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 8.0

CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
13	389	Female	Fluoxetine	NO	TEMAZEPAM	20/07/92	Screen	23/07/92(*)	Day 7
	390	Male	Reboxetine	YES	ERYTHROMYCIN	09/06/92	Day 14	18/06/92	Day 21
					MAXOLON	15/06/92	Day 21	15/06/92	Day 21
					PETHIDINE	15/06/92	Day 21	15/06/92	Day 21
					TEMAZEPAM	03/06/92	Day 7	22/07/92(*)	Day 56
	391	Female	Fluoxetine	NO	PANADOL	24/06/92	Day 14	24/06/92	Day 14
					SQUIBB-BC	16/07/92	Day 35	15/07/92(*)	Day 35
					TELDANE	16/07/92	Day 35	15/07/92(*)	Day 35
					TEMAZEPAM	04/06/92 23/06/92	Screen Day 14	16/06/92 24/06/92	Day 7 Day 14
	392	Female	Reboxetine	NO	NOCTEC	20/08/92	Day 7	27/08/92(*)	Day 14
					TEMAZEPAM	10/08/92	Screen	20/08/92	Day 7
	502	Female	Fluoxetine	YES	PARACETAMOL	09/11/92	Day 7	09/11/92	Day 7
	503	Female	Reboxetine	NO	ALUPENT	85	Screen	18/11/92(*)	Day 7
					BECONASE	85	Screen	18/11/92(*)	Day 7
					ESTROGEN NOS	12/11/92($)	Screen	18/11/92(*)	Day 7

($) - start date missing = screening date
(*) - end date missing = last dose taken date

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 8.0

CONCOMITANT DRUGS

Centre	Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
13	504	Female	Fluoxetine	YES	PANADOL	24/12/92	Day 28	25/12/92	Day 42
	505	Female	Reboxetine	YES	GASTROGEL	31/08/92	Day 7	01/09/92	Day 7
	506	Male	Fluoxetine	YES	PANADOL	26/10/92	Screen	27/10/92	Screen
					VIBRAMYCIN	21/12/92	Day 56	23/12/92(*)	Day 56
	507	Female	Fluoxetine	YES	PANADOL	20/10/92	Day 42	20/10/92	Day 42
					TEMAZEPAM	10/09/92	Screen	06/11/92(*)	Day 56
	508	Female	Reboxetine	YES	PANADOL	14/12/92	Day 56	20/12/92	Day 56
	521	Male	Reboxetine	YES	MINIPRESS	30/11/92($)	Screen	26/01/93(*)	Day 56
					RENITEC	30/11/92($)	Screen	26/01/93(*)	Day 56
14	397	Female	Fluoxetine	YES	ASTEMIZOLE	15/05/92	Day 35	21/05/92	Day 42
					CALCIUM GLUCONATE	71	Screen	09/06/92(*)	Day 56
					CALCIUM LACTATE	71	Day 7	09/06/92(*)	Screen
					PARACETAMOL	22/04/92	Day 14	27/04/92	Day 14
					SENOKOT	18/04/92	Day 7	20/04/92	Day 7
					TEMAZEPAM	16/10/89	Screen	09/06/92(*)	Day 56
	398	Female	Reboxetine	YES	CHLORPHENIRAMINE	07/06/92	Day 56	10/06/92(*)	Day 56

($) - start date missing = screening date
(*) - end date missing = last dose taken date

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	398	Female	Reboxetine	YES	PARACETAMOL	07/06/92	Day 56	10/06/92(*)	Day 56
	399	Female	Reboxetine	YES	ESTROGENS CONJUGATED	10/91	Screen	16/06/92(*)	Day 56
	402	Female	Reboxetine	YES	PARACETAMOL	16/06/92	Day 21	20/06/92	Day 28
					TEMAZEPAM	21/05/92	Screen	02/07/92	Day 42
	403	Female	Reboxetine	YES	TEMAZEPAM	14/04/92	Screen	24/07/92(*)	Day 56
	404	Female	Fluoxetine	YES	CHLORPHENIRAMINE MALEATE	17/07/92	Day 35	20/07/92	Day 35
					PARACETAMOL	17/07/92	Day 35	20/07/92	Day 35
						28/07/92	Day 42	28/07/92	Day 42
						08/08/92	Day 56	11/08/92(*)	Day 56
	405	Female	Fluoxetine	YES	AMOXICILLIN	17/06/92	Screen	23/06/92	Day 7
	406	Female	Fluoxetine	NO	NORETHISTERONE	04/92	Screen	21/07/92(*)	Day 21
					OESTRADIOL	04/92	Screen	21/07/92(*)	Day 21
					TEMAZEPAM	30/06/92	Screen	21/07/92(*)	Day 21
	407	Male	Reboxetine	NO	TEMAZEPAM	13/07/92	Screen	24/08/92(*)	Day 42
	509	Female	Fluoxetine	NO	TEMAZEPAM	17/09/92	Screen	10/11/92(*)	Day 42
	510	Female	Fluoxetine	YES	DOXYCYCLINE	17/11/92	Day 49	22/11/92	Day 56
					PARACETAMOL	25/10/92	Day 28	25/10/92	Day 28
	511	Female	Reboxetine	NO	METOCLOPRAMIDE	26/10/92	Day 7	26/10/92	Day 7

($) - start date missing = screening date
(*) - end date missing = last dose taken date

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	511	Female	Reboxetine	NO	TEMAZEPAM	27/10/92	Day 7	08/11/92	Day 21
	512	Female	Reboxetine	NO	AMPICILLIN	16/11/92	Day 14	23/11/92	Day 21
					ASPIRIN 'BAYER'	17/11/92	Day 21	28/11/92	Day 28
					PARACETAMOL	16/11/92	Day 14	16/11/92	Day 14
					TEMAZEPAM	17/11/92	Day 21	02/12/92(*)	Day 28
	537	Female	Reboxetine	YES	AMOXICILLIN	04/11/92	Day 7	18/11/92	Day 21
					MICROGYNON	07/11/92	Day 7	22/12/92	Day 56
	538	Female	Fluoxetine	YES	PARACETAMOL	13/02/93	Day 7	14/02/93	Day 7
	539	Female	Fluoxetine	YES	COLOXYL	30/03/93	Day 21	03/05/93	Day 56
					ESTROGENS CONJUGATED	91	Screen	05/05/93(*)	Day 56
					TEMAZEPAM	30/03/93	Day 21	10/04/93	Day 35
15	450	Male	Fluoxetine	YES	ASPIRIN 'BAYER'	12/12/92	Day 7	04/01/93	Day 28
	451	Female	Fluoxetine	YES	ASPIRIN 'BAYER'	31/12/92	Day 14	14/01/93	Day 28
	452	Female	Reboxetine	YES	METOCLOPRAMIDE	24/12/92	Day 7	29/12/92	Day 7
16	430	Male	Reboxetine	YES	LOVASTATIN	88	Screen	25/05/92(*)	Day 56
	434	Female	Fluoxetine	YES	CHLORAL HYDRATE	27/04/92	Day 21	01/06/92(*)	Day 56

($) - start date missing = screening date
(*) - end date missing = last dose taken date

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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
16	435	Female	Reboxetine	YES	CHLORAL HYDRATE	21/04/92	Day 14	08/06/92(*)	Day 56
	436	Female	Fluoxetine	YES	EFFORTIL PLUS	11/06/92	Day 49	12/06/92	Day 49
	438	Female	Fluoxetine	NO	AMOXICILLIN	17/06/92	Day 35	23/06/92	Day 35
					ASPIRINA C	17/06/92	Day 35	20/06/92	Day 35
	442	Female	Reboxetine	YES	CHLORAL HYDRATE	29/07/92	Day 14	14/09/92(*)	Day 56
	455	Female	Fluoxetine	YES	CHLORAL HYDRATE	26/09/92	Day 14	13/11/92(*)	Day 56
	456	Male	Reboxetine	YES	CHLORAL HYDRATE	23/12/92	Day 14	09/02/93(*)	Day 56
	457	Female	Fluoxetine	YES	CHLORAL HYDRATE	23/12/92	Day 14	28/01/93	Day 49
20	21	Female	Fluoxetine	YES	DISTRANEURINE	11/11/92 27/11/92	Day 7 Day 28	13/11/92 29/11/92	Day 7 Day 28
	22	Female	Fluoxetine	NO	CHLORAL HYDRATE	26/11/92	Day 14	16/12/92(*)	Day 35
21	9	Female	Fluoxetine	YES	ARCASIN	10/11/92	Day 28	17/11/92	Day 35
					CIPROBAY	18/11/92	Day 35	26/11/92	Day 42
					DIANE	80	Screen	13/12/92(*)	Day 56
22	113	Male	Fluoxetine	NO	TAVOR	18/12/92	Day 21	18/12/92(*)	Day 21

($) - start date missing = screening date
(*) - end date missing = last dose taken date

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	% Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
1	1	Fluoxetine	15/11/91	09/01/92	56	20	20	100.0	100.0		20	0	
					56								
	2	Reboxetine	26/06/92	20/08/92	56	8	8	100.0	100.0		4	4	
					56								
	3	Fluoxetine	01/07/92	24/08/92	55	20	20	100.0	100.0		20	0	
			25/08/92	25/08/92	1	20	20	100.0	100.0	9e	20		
					56								
	4	Reboxetine	14/08/92	10/09/92	28	8	8	100.0	100.0		4	4	
			11/09/92	24/09/92	14	10	10	100.0	100.0		4	6	
					42								
	5	Fluoxetine	13/10/92	09/11/92	28	20	20	100.0	100.0		20	0	
			10/11/92	10/11/92	1	40	40	100.0	100.0		20	20	
			11/11/92	11/11/92	1	40	20	100.0	100.0	6e	20		
					30								
	6	Fluoxetine	14/01/93	10/02/93	28	20	20	100.0	100.0		20	0	
			11/02/93	11/02/93	1	20	20	100.0	100.0	6e	20		
					29								
2	33	Fluoxetine	04/05/91	18/05/91	15	20	20	100.0	100.0		20	0	
			19/05/91	19/05/91	1	20	0	0.0	93.8	4m		0	
			20/05/91	31/05/91	12	20	20	100.0	96.4		20	0	
			01/06/91	28/06/91	28	40	40	100.0	98.2		20	20	
					56								
	34	Reboxetine	03/05/91	12/06/91	41	8	8	100.0	100.0		4	4	
					41								
	35	Reboxetine	16/04/91	10/06/91	56	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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 (**)
					56								
2	36	Fluoxetine	02/05/91	26/06/91	56	20	20	100.0	100.0		20	0	
					56								
	37	Reboxetine	07/10/91	07/10/91	1	8	4	100.0	100.0	9m		4	
			08/10/91	08/10/91	1	8	8	100.0	100.0		4	4	
			09/10/91	09/10/91	1	8	4	100.0	100.0	3m		4	
			10/10/91	10/10/91	1	8	4	100.0	100.0	6e	4		
					4								
	38	Fluoxetine	20/06/91	20/06/91	1	20	0	100.0	100.0	9m		0	
			21/06/91	14/07/91	24	20	20	100.0	100.0		20	0	
			15/07/91	15/07/91	1	20	0	0.0	96.2	1m		0	
			16/07/91	24/07/91	9	20	20	100.0	97.1		20	0	
			25/07/91	25/07/91	1	20	20	100.0	97.2	9e	20		
					36								
	39	Fluoxetine	19/06/91	21/06/91	3	20	20	100.0	100.0		20	0	
			22/06/91	22/06/91	1	20	20	100.0	100.0	6e	20		
					4								
	40	Reboxetine	06/06/91	04/07/91	29	8	8	100.0	100.0		4	4	
					29								
	41	Fluoxetine	13/02/92	08/04/92	56	20	20	100.0	100.0		20	0	
					56								
	42	Reboxetine	05/03/92	29/04/92	56	8	8	100.0	100.0		4	4	
					56								
	43	Reboxetine	19/11/91	13/01/92	56	8	8	100.0	100.0		4	4	
					56								

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

reatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	% Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
loxetine	19/12/91	30/01/92	49	20	20	100.0	100.0		20	0	
			49								
oxetine	18/09/92	04/11/92	56	8	8	100.0	100.0		4	4	
			56								
loxetine	25/03/92	19/05/92	56	20	20	100.0	100.0		20	0	
			56								
oxetine	19/05/92	15/06/92	28	8	8	100.0	100.0		4	4	
	16/06/92	13/07/92	28	10	10	100.0	100.0		4	6	
			56								
loxetine	15/01/92	11/03/92	56	20	20	100.0	100.0		20	0	
			56								
loxetine	15/10/91	10/12/91	56	20	20	100.0	100.0		20	0	
			56								
loxetine	16/10/91	11/11/91	27	20	20	100.0	100.0		20	0	
	12/11/91	12/11/91	1	20	20	100.0	100.0	3e	20		
			28								
oxetine	18/11/92	15/12/92	28	8	8	100.0	100.0		4	4	
			28								
oxetine	30/11/92	28/12/92	29	8	8	100.0	100.0		4	4	
			29								
oxetine	22/04/91	16/06/91	56	8	8	100.0	100.0		4	4	
			56								
loxetine	28/05/91	24/07/91	56	20	20	100.0	100.0		20	0	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 (**)
					56								
4	99	Fluoxetine	15/10/91	24/10/91	10	20	20	100.0	100.0		20	0	
			25/10/91	25/10/91	1	20	20	100.0	100.0	6e	20		
					11								
	100	Reboxetine	08/05/92	08/05/92	1	8	4	100.0	100.0	6e	4		
					1								
	101	Reboxetine	02/07/92	26/08/92	56	8	8	100.0	100.0		4	4	
					56								
	102	Fluoxetine	10/07/92	10/08/92	32	20	20	100.0	100.0		20	0	
			11/08/92	18/08/92	8	20	40	100.0	100.0		20	20	
			19/08/92	03/09/92	16	20	20	100.0	100.0		20	0	
					56								
	103	Fluoxetine	13/07/92	17/08/92	36	20	20	100.0	100.0		20	0	
			18/08/92	18/08/92	1	20	20	100.0	100.0	6e	20		
					37								
	104	Reboxetine	18/08/92	04/10/92	48	8	8	100.0	100.0		4	4	
			05/10/92	05/10/92	1	8	4	100.0	100.0	6e	4		
					49								
	105	Fluoxetine	21/08/92	15/10/92	56	20	20	100.0	100.0		20	0	
					56								
5	129	Reboxetine	29/11/91	29/12/91	31	8	8	100.0	100.0		4	4	
					31								
	130	Fluoxetine	28/02/92	23/04/92	56	20	20	100.0	100.0		20	0	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient,
5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening,
10=reason unknown

(**) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 (**)
					56								
7	193	Reboxetine	06/12/91	10/01/92	36	8	8	100.0	100.0		4	4	
			11/01/92	31/01/92	21	10	10	100.0	100.0		4	6	
					57								
	194	Fluoxetine	10/01/92	10/02/92	32	20	20	100.0	100.0		20	0	
			11/02/92	11/02/92	1	20	0	0.0	97.0	1m		0	
			12/02/92	16/02/92	5	20	20	100.0	97.4		20	0	
			17/02/92	17/02/92	1	20	0	0.0	94.9	1m		0	
			18/02/92	28/02/92	11	20	20	100.0	96.0		20	0	
			29/02/92	29/02/92	1	20	20	100.0	96.1	1e	20		
			01/03/92	05/03/92	5	20	20	100.0	96.4		20	0	
					56								
	195	Fluoxetine	14/02/92	19/03/92	35	20	20	100.0	100.0		20	0	
			20/03/92	02/04/92	14	40	40	100.0	100.0		20	20	
			03/04/92	03/04/92	1	40	20	50.0	99.0	1m		20	
			04/04/92	04/04/92	1	40	40	100.0	99.0		20	20	
			05/04/92	05/04/92	1	40	20	50.0	98.1	1e	20		
			06/04/92	07/04/92	2	40	40	100.0	98.1		20	20	
			08/04/92	08/04/92	1	40	20	50.0	97.3	1e	20		
			09/04/92	09/04/92	1	40	40	100.0	97.3		20	20	
					56								
	196	Reboxetine	29/05/92	25/06/92	28	8	8	100.0	100.0		4	4	
			26/06/92	16/07/92	21	10	10	100.0	100.0		4	6	
					49								
	197	Fluoxetine	11/11/92	11/11/92	1	20	20	100.0	100.0	6e	20		
					1								
11	321	Fluoxetine	14/11/91	09/01/92	57	20	20	100.0	100.0		20	0	
					57								
	322	Reboxetine	14/11/91	09/01/92	57	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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 (**)
					57								
11	323	Fluoxetine	19/11/91	13/01/92	56	20	20	100.0	100.0		20	0	
					56								
	324	Reboxetine	24/01/92	30/01/92	7	8	8	100.0	100.0		4	4	
			31/01/92	31/01/92	1	8	12	100.0	100.0		8	4	(8 - m)
			01/02/92	12/03/92	41	8	8	100.0	100.0		4	4	
			13/03/92	19/03/92	7	10	10	100.0	100.0		4	6	
					56								
	325	Reboxetine	12/02/92	10/03/92	28	8	8	100.0	100.0		4	4	
			11/03/92	31/03/92	21	10	10	100.0	100.0		4	6	
			01/04/92	07/04/92	7	8	8	100.0	100.0		4	4	
					56								
999	326	Reboxetine	12/02/92	07/04/92	56	8	8	100.0	100.0		4	4	
					56								
	327	Fluoxetine	14/02/92	26/02/92	13	20	20	100.0	100.0		20	0	
			27/02/92	27/02/92	1	20	0	0.0	92.9	1m		0	
			28/02/92	12/03/92	14	20	20	100.0	96.4		20	0	
					28								
	328	Fluoxetine	19/02/92	26/02/92	8	20	20	100.0	100.0		20	0	
			27/02/92	27/02/92	1	20		0.0	88.9	1m 1e			
			28/02/92	17/03/92	19	20	20	100.0	96.4		20	0	
			18/03/92	14/04/92	28	40	40	100.0	98.2		20	20	
					56								
	329	Reboxetine	31/03/92	01/05/92	32	8	8	100.0	100.0		4	4	
			02/05/92	06/05/92	5	8		100.0	100.0	3m 3e			
			07/05/92	27/05/92	21	8	8	100.0	100.0		4	4	
					58								

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	330	Reboxetine	21/04/92	18/05/92	28	8	8	100.0	100.0		4	4	
			19/05/92	08/06/92	21	10	10	100.0	100.0		4	6	
					49								
	331	Fluoxetine	26/05/92	18/06/92	24	20	20	100.0	100.0		20	0	
			19/06/92	19/06/92	1	20	0	100.0	100.0	3m		0	
			20/06/92	22/06/92	3	20	20	100.0	100.0		20	0	
			23/06/92	23/06/92	1	20	40	100.0	100.0		40	0	(B - m)
			24/06/92	20/07/92	27	20	20	100.0	100.0		20	0	
					56								
	332	Fluoxetine	28/07/92	31/08/92	35	20	20	100.0	100.0		20	0	
			01/09/92	01/09/92	1	20		0.0	97.2	1m 1e			
			02/09/92	24/09/92	23	20	20	100.0	98.3		20	0	
					59								
	333	Reboxetine	15/09/92	12/10/92	28	8	8	100.0	100.0		4	4	
			13/10/92	09/11/92	28	10	10	100.0	100.0		4	6	
					56								
	334	Fluoxetine	22/09/92	19/10/92	28	20	20	100.0	100.0		20	0	
			20/10/92	16/11/92	28	40	40	100.0	100.0		20	20	
					56								
	335	Reboxetine	13/10/92	16/11/92	35	8	8	100.0	100.0		4	4	
					35								
12	393	Fluoxetine	25/06/92	21/07/92	27	20	20	100.0	100.0		20	0	
			22/07/92	12/08/92	22	40	40	100.0	100.0		20	20	
			13/08/92	13/08/92	1	40	20	50.0	99.0	1m		20	
			14/08/92	18/08/92	5	40	40	100.0	99.1		20	20	
					55								
	394	Reboxetine	06/07/92	02/08/92	28	8	8	100.0	100.0		4	4	
			03/08/92	24/08/92	22	10	10	100.0	100.0		4	6	
			25/08/92	31/08/92	7	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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 (**)
					57								
12	395	Reboxetine	24/07/92	19/08/92	27	8	8	100.0	100.0		4	4	
			20/08/92	16/09/92	28	10	10	100.0	100.0		4	6	
					55								
	396	Fluoxetine	04/08/92	10/08/92	7	20	20	100.0	100.0		20	0	
			11/08/92	17/08/92	7	20		0.0	50.0				
					14								
	497	Fluoxetine	24/02/93	23/03/93	28	20	20	100.0	100.0		20	0	
			24/03/93	21/04/93	29	40	40	100.0	100.0		20	20	
					57								
13	385	Fluoxetine	14/03/92	24/04/92	42	20	20	100.0	100.0		20	0	
			25/04/92	08/05/92	14	20		0.0	75.0				
					56								
	386	Fluoxetine	24/04/92	29/04/92	6	20	20	100.0	100.0		20	0	
			30/04/92	30/04/92	1	20	20	100.0	100.0	6e	20		
					7								
	387	Reboxetine	18/04/92	17/05/92	30	8	8	100.0	100.0		4	4	
			18/05/92	18/05/92	1	8	4	100.0	100.0	6e	4		
					31								
	388	Reboxetine	16/03/92	19/03/92	4	8	8	100.0	100.0		4	4	
			20/03/92	20/03/92	1	8	4	50.0	90.0	10e	4		
			21/03/92	21/03/92	1	8		0.0	75.0	10m 10e			
			22/03/92	10/05/92	50	8	8	100.0	97.3		4	4	
			11/05/92	11/05/92	1	8		0.0	95.6	10m 10e			
					57								
	389	Fluoxetine	21/07/92	23/07/92	3	20	20	100.0	100.0		20	0	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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								
13	390	Reboxetine	28/05/92	08/07/92	42	8	8	100.0	100.0		4	4	
			09/07/92	09/07/92	1	8		0.0	97.7	10m 10e			
			10/07/92	22/07/92	13	8	8	100.0	98.2		4	4	
					56								
	391	Fluoxetine	11/06/92	15/07/92	35	20	20	100.0	100.0		20	0	
			16/07/92	16/07/92	1	20		100.0	100.0	3m 6e			
					36								
	392	Reboxetine	14/08/92	26/08/92	13	8	8	100.0	100.0		4	4	
			27/08/92	27/08/92	1	8	4	100.0	100.0	6e	4		
					14								
	501	Reboxetine	02/11/92	12/11/92	11	8	8	100.0	100.0		4	4	
			13/11/92	13/11/92	1	8	4	50.0	95.8	10e	4		
			14/11/92	21/11/92	8	8	8	100.0	97.5		4	4	
			22/11/92	22/11/92	1	8	4	50.0	95.2	10e	4		
			23/11/92	05/12/92	13	8	8	100.0	97.1		4	4	
			06/12/92	06/12/92	1	8	4	50.0	95.7	10e	4		
			07/12/92	12/12/92	6	8	8	100.0	96.3		4	4	
			13/12/92	13/12/92	1	8	4	50.0	95.2	10e	4		
			14/12/92	28/12/92	15	8	8	100.0	96.5		4	4	
			29/12/92	30/12/92	2	8	4	50.0	94.9	10e	4		
					59								
	502	Fluoxetine	03/11/92	14/11/92	12	20	20	100.0	100.0		20	0	
			15/11/92	15/11/92	1	20	20	100.0	100.0	10e	20		
			16/11/92	25/11/92	10	20	20	100.0	100.0		20	0	
			26/11/92	26/11/92	1	20	20	100.0	100.0	10e	20		
			27/11/92	24/12/92	28	20	20	100.0	100.0		20	0	
					52								
	503	Reboxetine	12/11/92	12/11/92	1	8	4	100.0	100.0	9m		4	
			13/11/92	18/11/92	6	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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	% Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
					7								
13	504	Fluoxetine	26/11/92	29/12/92	34	20	20	100.0	100.0		20	0	
			30/12/92	30/12/92	1	20	20	100.0	100.0	10e	20		
			31/12/92	20/01/93	21	20	20	100.0	100.0		20	0	
					56								
	505	Reboxetine	31/08/92	05/10/92	36	8	8	100.0	100.0		4	4	
			06/10/92	10/10/92	5	10	10	100.0	100.0		4	6	
			11/10/92	11/10/92	1	10	4	40.0	98.6	10e	4		
			12/10/92	21/10/92	10	10	10	100.0	98.8		4	6	
			22/10/92	22/10/92	1	10	4	100.0	98.9	6e	4		
					53								
	506	Fluoxetine	27/10/92	02/11/92	7	20	20	100.0	100.0		20	0	
			03/11/92	03/11/92	1	20	20	100.0	100.0	10e	20		
			04/11/92	23/12/92	50	20	20	100.0	100.0		20	0	
					58								
	507	Fluoxetine	11/09/92	08/10/92	28	20	20	100.0	100.0		20	0	
			09/10/92	21/10/92	13	40	40	100.0	100.0		20	20	
			22/10/92	22/10/92	1	40		0.0	97.6	10m 10e			
			23/10/92	06/11/92	15	40	40	100.0	98.2		20	20	
					57								
	508	Reboxetine	02/11/92	07/11/92	6	8	8	100.0	100.0		4	4	
			08/11/92	08/11/92	1	8	4	50.0	92.9	10e	4		
			09/11/92	14/11/92	6	8	8	100.0	96.2		4	4	
			15/11/92	15/11/92	1	8	4	50.0	92.9	10e	4		
			16/11/92	07/12/92	22	8	8	100.0	97.2		4	4	
			08/12/92	08/12/92	1	8	4	50.0	95.9	1m		4	
			09/12/92	13/12/92	5	8	8	100.0	96.4		4	4	
			14/12/92	14/12/92	1	8	4	50.0	95.3	1e	4		
			15/12/92	29/12/92	15	8	8	100.0	96.6		4	4	
					58								
	521	Reboxetine	30/11/92	26/01/93	58	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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

reatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	% Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
			58								
luoxetine	14/04/92	14/04/92	1	20	0	100.0	100.0	9m		0	
	15/04/92	08/06/92	55	20	20	100.0	100.0		20	0	
	09/06/92	09/06/92	1	20	20	100.0	100.0	9e	20		
			57								
eboxetine	15/04/92	15/04/92	1	8	4	100.0	100.0	9m		4	
	16/04/92	14/05/92	29	8	8	100.0	100.0		4	4	
	15/05/92	15/05/92	1	8	4	100.0	100.0	3e	4		
	16/05/92	09/06/92	25	8	8	100.0	100.0		4	4	
	10/06/92	10/06/92	1	8	4	100.0	100.0	9e	4		
			57								
eboxetine	21/04/92	21/04/92	1	8	4	100.0	100.0	9m		4	
	22/04/92	06/05/92	15	8	8	100.0	100.0		4	4	
	07/05/92	07/05/92	1	8	4	100.0	100.0	3e	4		
	08/05/92	03/06/92	27	8	8	100.0	100.0		4	4	
	04/06/92	04/06/92	1	8	4	50.0	98.9	1e	4		
	05/06/92	15/06/92	11	8	8	100.0	99.1		4	4	
	16/06/92	16/06/92	1	8	4	100.0	99.1	9e	4		
			57								
luoxetine	15/05/92	15/05/92	1	20	0	100.0	100.0	9m		0	
	16/05/92	10/07/92	56	20	20	100.0	100.0		20	0	
	11/07/92	11/07/92	1	20	20	100.0	100.0	9e	20		
			58								
luoxetine	22/05/92	22/05/92	1	20	0	100.0	100.0	9m		0	
	23/05/92	20/06/92	29	20	20	100.0	100.0		20	0	
	21/06/92	21/06/92	1	20	0	0.0	96.8	1m		0	
	22/06/92	16/07/92	25	20	20	100.0	98.2		20	0	
	17/07/92	17/07/92	1	20	20	100.0	98.2	9e	20		
			57								
eboxetine	27/05/92	27/05/92	1	8	4	100.0	100.0	9m		4	
	28/05/92	21/07/92	55	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

REBOXETINE - PROTOCOL 20124/016
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	402	Reboxetine	22/07/92	22/07/92	1	8	4	100.0	100.0	9e	4		
					57								
	403	Reboxetine	29/05/92	29/05/92	1	8	4	100.0	100.0	9m		4	
			30/05/92	23/07/92	55	8	8	100.0	100.0		4	4	
			24/07/92	24/07/92	1	8	4	100.0	100.0	9e	4		
					57								
	404	Fluoxetine	16/06/92	16/06/92	1	20	0	100.0	100.0	9m		0	
			17/06/92	10/08/92	55	20	20	100.0	100.0		20	0	
			11/08/92	11/08/92	1	20	20	100.0	100.0	9e	20		
					57								
	405	Fluoxetine	22/06/92	22/06/92	1	20	0	100.0	100.0	9m		0	
			23/06/92	30/07/92	38	20	20	100.0	100.0		20	0	
			31/07/92	31/07/92	1	20	20	100.0	100.0	10e	20		
			01/08/92	17/08/92	17	20	20	100.0	100.0		20	0	
			18/08/92	18/08/92	1	20	20	100.0	100.0	9e	20		
					58								
	406	Fluoxetine	30/06/92	30/06/92	1	20	0	100.0	100.0	9m		0	
			01/07/92	20/07/92	20	20	20	100.0	100.0		20	0	
			21/07/92	21/07/92	1	20	20	100.0	100.0	6e	20		
					22								
	407	Reboxetine	14/07/92	10/08/92	28	8	8	100.0	100.0		4	4	
			11/08/92	23/08/92	13	10	10	100.0	100.0		4	6	
			24/08/92	24/08/92	1	10	4	100.0	100.0	6e	4		
					42								
	408	Reboxetine	04/08/92	04/08/92	1	8	4	100.0	100.0	9m		4	
			05/08/92	07/08/92	3	8	8	100.0	100.0		4	4	
			08/08/92	08/08/92	1	8	4	50.0	90.0	2e	4		
			09/08/92	14/08/92	6	8	8	100.0	95.5		4	4	
			15/08/92	15/08/92	1	8	4	50.0	91.7	2e	4		
			16/08/92	29/08/92	14	8	8	100.0	96.2		4	4	
			30/08/92	31/08/92	2	8	4	50.0	92.9	2e	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

672

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	408	Reboxetine	01/09/92	18/09/92	18	8	8	100.0	95.7		4	4	
			19/09/92	19/09/92	1	8	4	50.0	94.7	2e	4		
			20/09/92	29/09/92	10	8	8	100.0	95.6		4	4	
			30/09/92	30/09/92	1	8	4	100.0	95.7	9e	4		
					58								
	509	Fluoxetine	29/09/92	29/09/92	1	20	0	100.0	100.0	9m		0	
			30/09/92	30/09/92	1	20	20	100.0	100.0		20	0	
			01/10/92	01/10/92	1	20	20	100.0	100.0		20	0	(D - e)
			02/10/92	09/11/92	39	20	20	100.0	100.0		20	0	
			10/11/92	10/11/92	1	20	20	100.0	100.0	6e	20		
					43								
	510	Fluoxetine	30/09/92	30/09/92	1	20	0	100.0	100.0	9m		0	
			01/10/92	16/10/92	16	20	20	100.0	100.0		20	0	
			17/10/92	17/10/92	1	20	0	0.0	94.4	1m		0	
			18/10/92	25/11/92	39	20	20	100.0	98.2		20	0	
			26/11/92	26/11/92	1	20	20	100.0	98.3	9e	20		
					58								
	511	Reboxetine	23/10/92	23/10/92	1	8	4	100.0	100.0	9m		4	
			24/10/92	09/12/92	47	8	8	100.0	100.0		4	4	
			10/12/92	10/12/92	1	8	4	100.0	100.0	6e	4		
					49								
	512	Reboxetine	03/11/92	03/11/92	1	8	4	100.0	100.0	9m		4	
			04/11/92	01/12/92	28	8	8	100.0	100.0		4	4	
			02/12/92	02/12/92	1	8	4	100.0	100.0	6e	4		
					30								
	537	Reboxetine	03/11/92	03/11/92	1	8	4	100.0	100.0	9m		4	
			04/11/92	28/12/92	55	8	8	100.0	100.0		4	4	
			29/12/92	29/12/92	1	8	4	100.0	100.0	9e	4		
					57								
	538	Fluoxetine	12/02/93	12/02/93	1	20	0	100.0	100.0	9m		0	
			13/02/93	19/02/93	7	20	20	100.0	100.0		20	0	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	538	Fluoxetine	20/02/93	20/02/93	1	20	0	0.0	88.9	1m		0	
			21/02/93	26/02/93	6	20	20	100.0	93.3		20	0	
			27/02/93	27/02/93	1	20	0	0.0	87.5	1m		0	
			28/02/93	04/04/93	36	20	20	100.0	96.2		20	0	
			05/04/93	05/04/93	1	20		0.0	94.3	1m 1e			
			06/04/93	08/04/93	3	20	20	100.0	94.6		20	0	
			09/04/93	09/04/93	1	20	20	100.0	94.7	9e	20		
					57								
	539	Fluoxetine	10/03/93	10/03/93	1	20	0	100.0	100.0	9m		0	
			11/03/93	06/04/93	27	20	20	100.0	100.0		20	0	
			07/04/93	04/05/93	28	40	40	100.0	100.0		20	20	
			05/05/93	05/05/93	1	40	20	100.0	100.0	9e	20		
					57								
15	409	Reboxetine	08/04/92	05/05/92	28	8	8	100.0	100.0		4	4	
			06/05/92	02/06/92	28	10	10	100.0	100.0		4	6	
					56								
	410	Fluoxetine	17/04/92	11/06/92	56	20	20	100.0	100.0		20	0	
					56								
	411	Reboxetine	22/04/92	16/06/92	56	8	8	100.0	100.0		4	4	
					56								
	412	Fluoxetine	23/04/92	17/06/92	56	20	20	100.0	100.0		20	0	
					56								
	413	Reboxetine	30/04/92	24/06/92	56	8	8	100.0	100.0		4	4	
					56								
	414	Fluoxetine	02/06/92	20/07/92	49	20	20	100.0	100.0		20	0	
			21/07/92	27/07/92	7	40	40	100.0	100.0		20	20	
					56								

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.8

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	415	Reboxetine	12/06/92	06/08/92	56	8	8	100.0	100.0		4	4	
					56								
	416	Fluoxetine	23/06/92	17/08/92	56	20	20	100.0	100.0		20	0	
					56								
	417	Reboxetine	19/06/92	13/08/92	56	8	8	100.0	100.0		4	4	
					56								
	418	Reboxetine	17/07/92	10/09/92	56	8	8	100.0	100.0		4	4	
					56								
	419	Fluoxetine	16/07/92	09/09/92	56	20	20	100.0	100.0		20	0	
					56								
	420	Fluoxetine	20/08/92	14/10/92	56	20	20	100.0	100.0		20	0	
					56								
	421	Reboxetine	01/08/92	25/09/92	56	8	8	100.0	100.0		4	4	
					56								
	422	Fluoxetine	19/08/92	13/10/92	56	20	20	100.0	100.0		20	0	
					56								
	423	Fluoxetine	21/08/92	17/09/92	28	20	20	100.0	100.0		20	0	
			18/09/92	15/10/92	28	40	40	100.0	100.0		20	20	
					56								
	424	Reboxetine	21/08/92	15/10/92	56	8	8	100.0	100.0		4	4	
					56								
	425	Reboxetine	02/10/92	26/11/92	56	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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 (**)
					56								
15	426	Fluoxetine	28/10/92	22/12/92	56	20	20	100.0	100.0		20	0	
					56								
	427	Reboxetine	03/12/92	27/01/93	56	8	8	100.0	100.0		4	4	
					56								
	428	Fluoxetine	03/12/92	27/01/93	56	20	20	100.0	100.0		20	0	
					56								
	449	Reboxetine	08/12/92	04/01/93	28	8	8	100.0	100.0		4	4	
			05/01/93	01/02/93	28	10	10	100.0	100.0		4	6	
					56								
	450	Fluoxetine	10/12/92	03/02/93	56	20	20	100.0	100.0		20	0	
					56								
	451	Fluoxetine	18/12/92	11/02/93	56	20	20	100.0	100.0		20	0	
					56								
	452	Reboxetine	23/12/92	16/02/93	56	8	8	100.0	100.0		4	4	
					56								
	454	Fluoxetine	19/01/93	15/03/93	56	20	20	100.0	100.0		20	0	
					56								
16	429	Fluoxetine	26/03/92	20/05/92	56	20	20	100.0	100.0		20	0	
					56								
	430	Reboxetine	30/03/92	30/03/92	1	8	4	100.0	100.0	9m		4	
			31/03/92	25/05/92	56	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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 (**)
					57								
16	431	Reboxetine	31/03/92	25/05/92	56	8	8	100.0	100.0		4	4	
					56								
	432	Fluoxetine	31/03/92	25/05/92	56	20	20	100.0	100.0		20	0	
					56								
	433	Reboxetine	02/04/92	27/05/92	56	8	8	100.0	100.0		4	4	
					56								
	434	Fluoxetine	07/04/92	01/06/92	56	20	20	100.0	100.0		20	0	
					56								
	435	Reboxetine	14/04/92	08/06/92	56	8	8	100.0	100.0		4	4	
					56								
	436	Fluoxetine	24/04/92	21/05/92	28	20	20	100.0	100.0		20	0	
			22/05/92	23/05/92	2	40	20	50.0	96.7	4e	20		
			24/05/92	29/05/92	6	40	40	100.0	97.2		20	20	
			30/05/92	30/05/92	1	40	20	50.0	95.9	1m		20	
			31/05/92	02/06/92	3	40	40	100.0	96.3		20	20	
			03/06/92	03/06/92	1	40	20	50.0	95.1	1m		20	
			04/06/92	10/06/92	7	40	40	100.0	95.8		20	20	
			11/06/92	11/06/92	1	40	20	100.0	95.9	3e	20		
			12/06/92	18/06/92	7	40	40	100.0	96.4		20	20	
					56								
	437	Reboxetine	30/04/92	24/06/92	56	8	8	100.0	100.0		4	4	
					56								
	438	Fluoxetine	20/05/92	17/06/92	29	20	20	100.0	100.0		20	0	
			18/06/92	18/06/92	1	20	20	100.0	100.0	3e	20		

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 (**)
					30								
16	439	Fluoxetine	20/05/92	14/07/92	56	20	20	100.0	100.0		20	0	
					56								
	440	Reboxetine	01/07/92	25/08/92	56	8	8	100.0	100.0		4	4	
					56								
	441	Fluoxetine	22/07/92	14/09/92	55	20	20	100.0	100.0		20	0	
					55								
	442	Reboxetine	22/07/92	17/08/92	27	8	8	100.0	100.0		4	4	
			18/08/92	14/09/92	28	10	10	100.0	100.0		4	6	
					55								
	443	Fluoxetine	25/08/92	18/10/92	55	20	20	100.0	100.0		20	0	
					55								
	444	Reboxetine	25/08/92	19/10/92	56	8	8	100.0	100.0		4	4	
					56								
	445	Reboxetine	18/09/92	12/11/92	56	8	8	100.0	100.0		4	4	
					56								
	446	Fluoxetine	18/09/92	12/11/92	56	20	20	100.0	100.0		20	0	
					56								
	447	Fluoxetine	18/09/92	19/09/92	2	20	20	100.0	100.0		20	0	
			20/09/92	20/09/92	1	20	0	0.0	66.7	1m		0	
			21/09/92	13/10/92	23	20	20	100.0	96.2		20	0	
			14/10/92	14/10/92	1	20	0	0.0	92.6	1m		0	
			15/10/92	12/11/92	29	20	20	100.0	96.4		20	0	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 (**)
					56								
16	448	Reboxetine	19/09/92	03/10/92	15	8	8	100.0	100.0		4	4	
			04/10/92	04/10/92	1	8	4	50.0	96.9	1m		4	
			05/10/92	02/11/92	29	8	8	100.0	98.9		4	4	
			03/11/92	03/11/92	1	8	4	50.0	97.8	1e	4		
			04/11/92	13/11/92	10	8	8	100.0	98.2		4	4	
					56								
	455	Fluoxetine	19/09/92	13/11/92	56	20	20	100.0	100.0		20	0	
					56								
	456	Reboxetine	16/12/92	09/02/93	56	8	8	100.0	100.0		4	4	
					56								
	457	Fluoxetine	16/12/92	09/02/93	56	20	20	100.0	100.0		20	0	
					56								
	458	Fluoxetine	16/12/92	09/02/93	56	20	20	100.0	100.0		20	0	
					56								
	459	Reboxetine	22/12/92	15/02/93	56	8	8	100.0	100.0		4	4	
					56								
	460	Reboxetine	22/12/92	15/02/93	56	8	8	100.0	100.0		4	4	
					56								
18	25	Fluoxetine	06/10/92	07/11/92	33	20	20	100.0	100.0		20	0	
			08/11/92	08/11/92	1	20	20	100.0	100.0		20	0	(B - e)
			09/11/92	30/11/92	22	20	20	100.0	100.0		20	0	
					56								
	26	Reboxetine	06/10/92	30/11/92	56	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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 (**)
					56								
18	27	Reboxetine	06/10/92	30/11/92	56	8	8	100.0	100.0		4	4	
					56								
	28	Fluoxetine	06/10/92	02/11/92	28	20	20	100.0	100.0		20	0	
					28								
	29	Reboxetine	06/10/92	30/11/92	56	8	8	100.0	100.0		4	4	
					56								
	30	Fluoxetine	07/10/92	03/11/92	28	20	20	100.0	100.0		20	0	
			04/11/92	09/11/92	6	20	60	100.0	100.0		40	20	(3 - m) (3 - e)
			10/11/92	10/11/92	1	20	40	100.0	100.0		20	20	
			11/11/92	23/11/92	13	40	40	100.0	100.0		20	20	
			24/11/92	24/11/92	1	40		0.0	98.0	1m 1e			
			25/11/92	01/12/92	7	40	40	100.0	98.2		20	20	
					56								
680	31	Reboxetine	20/10/92	14/12/92	56	8	8	100.0	100.0		4	4	
					56								
	32	Fluoxetine	07/10/92	29/11/92	54	20	20	100.0	100.0		20	0	
			30/11/92	30/11/92	1	20	40	100.0	100.0		40	0	(B - m) (B - e)
					55								
	49	Reboxetine	17/11/92	11/01/93	56	8	8	100.0	100.0		4	4	
					56								
	50	Reboxetine	17/11/92	17/11/92	1	8	8	100.0	100.0		4	4	
			18/11/92	18/11/92	1	8	4	100.0	100.0	6e	4		
					2								
	51	Fluoxetine	17/11/92	11/01/93	56	20	20	100.0	100.0		20	0	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 (**)
					56								
18	52	Fluoxetine	17/11/92	11/01/93	56	20	20	100.0	100.0		20	0	
					56								
	53	Fluoxetine	15/01/93	11/03/93	56	20	20	100.0	100.0		20	0	
					56								
	54	Fluoxetine	12/01/93	08/03/93	56	20	20	100.0	100.0		20	0	
					56								
20	21	Fluoxetine	06/11/92	30/12/92	55	20	20	100.0	100.0		20	0	
					55								
	22	Fluoxetine	12/11/92	16/12/92	35	20	20	100.0	100.0		20	0	
					35								
21	9	Fluoxetine	19/10/92	24/10/92	6	20	20	100.0	100.0		20	0	
			25/10/92	25/10/92	1	20	20	100.0	100.0	1e	20		
			26/10/92	11/11/92	17	20	20	100.0	100.0		20	0	
			12/11/92	13/11/92	2	20		100.0	100.0	3m 3e			
			14/11/92	15/11/92	2	20	20	100.0	100.0		20	0	
			16/11/92	17/11/92	2	20	0	100.0	100.0	3m		0	
			18/11/92	25/11/92	8	20	20	100.0	100.0		20	0	
			26/11/92	26/11/92	1	20	20	100.0	100.0	1e	20		
			27/11/92	09/12/92	13	20	20	100.0	100.0		20	0	
			10/12/92	11/12/92	2	20	0	0.0	96.3	1m		0	
			12/12/92	12/12/92	1	20	20	100.0	96.4	1e	20		
			13/12/92	13/12/92	1	20	20	100.0	96.4		20	0	
					56								
22	113	Fluoxetine	03/12/92	17/12/92	15	20	20	100.0	100.0		20	0	
			18/12/92	18/12/92	1	20	20	100.0	100.0	6e	20		
					16								

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.8

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 (**)
22	115	Reboxetine	29/12/92	19/01/93	22	8	8	100.0	100.0		4	4	
			20/01/93	20/01/93	1	8	4	100.0	100.0	6e	4		
					23								

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 1=low dose, 2=high dose, 3=low dose + high dose, 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
1	1	Fluoxetine	15/11/91	09/01/92	56	2	2	100.0	100.0	1	1		
					56								
	2	Reboxetine	26/06/92	20/08/92	56	2	2	100.0	100.0	1	1		
					56								
	3	Fluoxetine	01/07/92	24/08/92	55	2	2	100.0	100.0	1	1		
			25/08/92	25/08/92	1	2	1	100.0	100.0	1	0	9e	
					56								
	4	Reboxetine	14/08/92	24/09/92	42	2	2	100.0	100.0	1	1		
					42								
	5	Fluoxetine	13/10/92	10/11/92	29	2	2	100.0	100.0	1	1		
			11/11/92	11/11/92	1	2	1	50.0	98.3	1		6e	
					30								
	6	Fluoxetine	14/01/93	10/02/93	28	2	2	100.0	100.0	1	1		
			11/02/93	11/02/93	1	2	1	50.0	98.3	1		6e	
					29								
2	33	Fluoxetine	04/05/91	18/05/91	15	2	2	100.0	100.0	1	1		
			19/05/91	19/05/91	1	2	1	50.0	96.9		1	4m	
			20/05/91	28/06/91	40	2	2	100.0	99.1	1	1		
					56								
	34	Reboxetine	03/05/91	12/06/91	41	2	2	100.0	100.0	1	1		
					41								
	35	Reboxetine	16/04/91	10/06/91	56	2	2	100.0	100.0	1	1		
					56								
	36	Fluoxetine	02/05/91	26/06/91	56	2	2	100.0	100.0	1	1		

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
					56								
2	37	Reboxetine	07/10/91	07/10/91	1	2	1	100.0	100.0	0	1	9m	
			08/10/91	08/10/91	1	2	2	100.0	100.0	1	1		
			09/10/91	09/10/91	1	2	1	100.0	100.0		1	3m	
			10/10/91	10/10/91	1	2	1	50.0	87.5	1		6e	
					4								
	38	Fluoxetine	20/06/91	20/06/91	1	2	1	100.0	100.0	0	1	9m	
			21/06/91	14/07/91	24	2	2	100.0	100.0	1	1		
			15/07/91	15/07/91	1	2	1	50.0	98.1		1	1m	
			16/07/91	24/07/91	9	2	2	100.0	98.6	1	1		
			25/07/91	25/07/91	1	2	1	100.0	98.6	1	0	9e	
					36								
	39	Fluoxetine	19/06/91	21/06/91	3	2	2	100.0	100.0	1	1		
			22/06/91	22/06/91	1	2	1	50.0	87.5	1		6e	
					4								
	40	Reboxetine	06/06/91	04/07/91	29	2	2	100.0	100.0	1	1		
					29								
	41	Fluoxetine	13/02/92	08/04/92	56	2	2	100.0	100.0	1	1		
					56								
	42	Reboxetine	05/03/92	29/04/92	56	2	2	100.0	100.0	1	1		
					56								
	43	Reboxetine	19/11/91	13/01/92	56	2	2	100.0	100.0	1	1		
					56								
	44	Fluoxetine	13/12/91	30/01/92	49	2	2	100.0	100.0	1	1		
					49								

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
2	45	Reboxetine	10/09/92	04/11/92	56	2	2	100.0	100.0	1	1		
					56								
	47	Fluoxetine	25/03/92	19/05/92	56	2	2	100.0	100.0	1	1		
					56								
	48	Reboxetine	19/05/92	13/07/92	56	2	2	100.0	100.0	1	1		
					56								
	80	Fluoxetine	15/01/93	11/03/93	56	2	2	100.0	100.0	1	1		
					56								
3	65	Fluoxetine	16/10/91	10/12/91	56	2	2	100.0	100.0	1	1		
					56								
	66	Fluoxetine	16/10/91	11/11/91	27	2	2	100.0	100.0	1	1		
			12/11/91	12/11/91	1	2	1	100.0	100.0	1		3e	
					28								
	67	Reboxetine	18/11/92	15/12/92	28	2	2	100.0	100.0	1	1		
					28								
	68	Reboxetine	30/11/92	28/12/92	29	2	2	100.0	100.0	1	1		
					29								
4	97	Reboxetine	22/04/91	16/06/91	56	2	2	100.0	100.0	1	1		
					56								
	98	Fluoxetine	30/05/91	24/07/91	56	2	2	100.0	100.0	1	1		
					56								
	99	Fluoxetine	15/10/91	24/10/91	10	2	2	100.0	100.0	1	1		
			25/10/91	25/10/91	1	2	1	50.0	95.5	1		6e	

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
					11								
4	100	Reboxetine	08/05/92	08/05/92	1	2	1	50.0	50.0	1		6e	
					1								
	101	Reboxetine	02/07/92	26/08/92	56	2	2	100.0	100.0	1	1		
					56								
	102	Fluoxetine	10/07/92	03/09/92	56	2	2	100.0	100.0	1	1		
					56								
	103	Fluoxetine	13/07/92	17/08/92	36	2	2	100.0	100.0	1	1		
			18/08/92	18/08/92	1	2	1	50.0	98.6	1		6e	
					37								
	104	Reboxetine	18/08/92	04/10/92	48	2	2	100.0	100.0	1	1		
			05/10/92	05/10/92	1	2	1	50.0	99.0	1		6e	
					49								
	105	Fluoxetine	21/08/92	15/10/92	56	2	2	100.0	100.0	1	1		
					56								
5	129	Reboxetine	29/11/91	29/12/91	31	2	2	100.0	100.0	1	1		
					31								
	130	Fluoxetine	28/02/92	23/04/92	56	2	2	100.0	100.0	1	1		
					56								
7	193	Reboxetine	06/12/91	31/01/92	57	2	2	100.0	100.0	1	1		
					57								
	194	Fluoxetine	10/01/92	10/02/92	32	2	2	100.0	100.0	1	1		
			11/02/92	11/02/92	1	2	1	50.0	98.5		1	1m	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
7	194	Fluoxetine	12/02/92	16/02/92	5	2	2	100.0	98.7	1	1		
			17/02/92	17/02/92	1	2	1	50.0	97.4		1	1m	
			18/02/92	28/02/92	11	2	2	100.0	98.0	1	1		
			29/02/92	29/02/92	1	2	1	50.0	97.1	1		1e	
			01/03/92	05/03/92	5	2	2	100.0	97.3	1	1		
					56								
	195	Fluoxetine	14/02/92	02/04/92	49	2	2	100.0	100.0	1	1		
			03/04/92	03/04/92	1	2	1	50.0	99.0		1	1m	
			04/04/92	04/04/92	1	2	2	100.0	99.0	1	1		
			05/04/92	05/04/92	1	2	1	50.0	98.1	1		1e	
			06/04/92	07/04/92	2	2	2	100.0	98.1	1	1		
			08/04/92	08/04/92	1	2	1	50.0	97.3	1		1e	
			09/04/92	09/04/92	1	2	2	100.0	97.3	1	1		
					56								
47	196	Reboxetine	29/05/92	16/07/92	49	2	2	100.0	100.0	1	1		
					49								
	197	Fluoxetine	11/11/92	11/11/92	1	2	1	50.0	50.0	1		6e	
					1								
11	321	Fluoxetine	14/11/91	09/01/92	57	2	2	100.0	100.0	1	1		
					57								
	322	Reboxetine	14/11/91	09/01/92	57	2	2	100.0	100.0	1	1		
					57								
	323	Fluoxetine	19/11/91	13/01/92	56	2	2	100.0	100.0	1	1		
					56								
	324	Reboxetine	24/01/92	30/01/92	7	2	2	100.0	100.0	1	1		
			31/01/92	31/01/92	1	2	3	75.0	96.9	2	1		(B - m)
			01/02/92	19/03/92	48	2	2	100.0	99.6	1	1		

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
					56								
11	325	Reboxetine	12/02/92	07/04/92	56	2	2	100.0	100.0	1	1		
					56								
	326	Reboxetine	12/02/92	07/04/92	56	2	2	100.0	100.0	1	1		
					56								
	327	Fluoxetine	14/02/92	26/02/92	13	2	2	100.0	100.0	1	1		
			27/02/92	27/02/92	1	2	1	50.0	96.4		1	1m	
			28/02/92	12/03/92	14	2	2	100.0	98.2	1	1		
					28								
	328	Fluoxetine	19/02/92	26/02/92	8	2	2	100.0	100.0	1	1		
			27/02/92	27/02/92	1	2		0.0	88.9			1m 1e	
			28/02/92	14/04/92	47	2	2	100.0	98.2	1	1		
					56								
	329	Reboxetine	31/03/92	01/05/92	32	2	2	100.0	100.0	1	1		
			02/05/92	06/05/92	5	2		100.0	100.0			3m 3e	
			07/05/92	27/05/92	21	2	2	100.0	100.0	1	1		
					58								
	330	Reboxetine	21/04/92	08/06/92	49	2	2	100.0	100.0	1	1		
					49								
	331	Fluoxetine	26/05/92	18/06/92	24	2	2	100.0	100.0	1	1		
			19/06/92	19/06/92	1	2	1	100.0	100.0		1	3m	
			20/06/92	22/06/92	3	2	2	100.0	100.0	1	1		
			23/06/92	23/06/92	1	2	3	75.0	99.1	2	1		(B - m)
			24/06/92	20/07/92	27	2	2	100.0	99.6	1	1		
					56								
	332	Fluoxetine	28/07/92	31/08/92	35	2	2	100.0	100.0	1	1		
			01/09/92	01/09/92	1	2		0.0	97.2			1m 1e	

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
11	332	Fluoxetine	02/09/92	24/09/92	23	2	2	100.0	98.3	1	1		
					59								
	333	Reboxetine	15/09/92	09/11/92	56	2	2	100.0	100.0	1	1		
					56								
	334	Fluoxetine	22/09/92	16/11/92	56	2	2	100.0	100.0	1	1		
					56								
	335	Reboxetine	13/10/92	16/11/92	35	2	2	100.0	100.0	1	1		
					35								
12	393	Fluoxetine	25/06/92	12/08/92	49	2	2	100.0	100.0	1	1		
			13/08/92	13/08/92	1	2	1	50.0	99.0		1	1m	
			14/08/92	18/08/92	5	2	2	100.0	99.1	1	1		
					55								
	394	Reboxetine	06/07/92	31/08/92	57	2	2	100.0	100.0	1	1		
					57								
	395	Reboxetine	24/07/92	16/09/92	55	2	2	100.0	100.0	1	1		
					55								
	396	Fluoxetine	04/08/92	10/08/92	7	2	2	100.0	100.0	1	1		
			11/08/92	17/08/92	7	2		0.0	50.0				
					14								
	497	Fluoxetine	24/02/93	21/04/93	57	2	2	100.0	100.0	1	1		
					57								
13	385	Fluoxetine	14/03/92	24/04/92	42	2	2	100.0	100.0	1	1		
			25/04/92	08/05/92	14	2		0.0	75.0				

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
					56								
13	386	Fluoxetine	24/04/92	29/04/92	6	2	2	100.0	100.0	1	1		
			30/04/92	30/04/92	1	2	1	50.0	92.9	1		6e	
					7								
	387	Reboxetine	18/04/92	17/05/92	30	2	2	100.0	100.0	1	1		
			18/05/92	18/05/92	1	2	1	50.0	98.4	1		6e	
					31								
	388	Reboxetine	16/03/92	19/03/92	4	2	2	100.0	100.0	1	1		
			20/03/92	20/03/92	1	2	1	50.0	90.0	1		10e	
			21/03/92	21/03/92	1	2		0.0	75.0			10m 10e	
			22/03/92	10/05/92	50	2	2	100.0	97.3	1	1		
			11/05/92	11/05/92	1	2		0.0	95.6			10m 10e	
					57								
	389	Fluoxetine	21/07/92	23/07/92	3	2	2	100.0	100.0	1	1		
					3								
	390	Reboxetine	28/05/92	08/07/92	42	2	2	100.0	100.0	1	1		
			09/07/92	09/07/92	1	2		0.0	97.7			10m 10e	
			10/07/92	22/07/92	13	2	2	100.0	98.2	1	1		
					56								
	391	Fluoxetine	11/06/92	15/07/92	35	2	2	100.0	100.0	1	1		
			16/07/92	16/07/92	1	2		50.0	98.6			3m 6e	
					36								
	392	Reboxetine	14/08/92	26/08/92	13	2	2	100.0	100.0	1	1		
			27/08/92	27/08/92	1	2	1	50.0	96.4	1		6e	
					14								
	501	Reboxetine	02/11/92	12/11/92	11	2	2	100.0	100.0	1	1		
			13/11/92	13/11/92	1	2	1	50.0	95.8	1		10e	

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 1=low dose, 2=high dose, 3=low dose + high dose, 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
13	501	Reboxetine	14/11/92	21/11/92	8	2	2	100.0	97.5	1	1		
			22/11/92	22/11/92	1	2	1	50.0	95.2	1		10e	
			23/11/92	05/12/92	13	2	2	100.0	97.1	1	1		
			06/12/92	06/12/92	1	2	1	50.0	95.7	1		10e	
			07/12/92	12/12/92	6	2	2	100.0	96.3	1	1		
			13/12/92	13/12/92	1	2	1	50.0	95.2	1		10e	
			14/12/92	28/12/92	15	2	2	100.0	96.5	1	1		
			29/12/92	30/12/92	2	2	1	50.0	94.9	1		10e	
					59								
	502	Fluoxetine	03/11/92	14/11/92	12	2	2	100.0	100.0	1	1		
			15/11/92	15/11/92	1	2	1	50.0	96.2	1		10e	
			16/11/92	25/11/92	10	2	2	100.0	97.8	1	1		
			26/11/92	26/11/92	1	2	1	50.0	95.8	1		10e	
			27/11/92	24/12/92	28	2	2	100.0	98.1	1	1		
					52								
	503	Reboxetine	12/11/92	12/11/92	1	2	1	100.0	100.0	0	1	9m	
			13/11/92	18/11/92	6	2	2	100.0	100.0	1	1		
					7								
	504	Fluoxetine	26/11/92	29/12/92	34	2	2	100.0	100.0	1	1		
			30/12/92	30/12/92	1	2	1	50.0	98.6	1		10e	
			31/12/92	20/01/93	21	2	2	100.0	99.1	1	1		
					56								
	505	Reboxetine	31/08/92	10/10/92	41	2	2	100.0	100.0	1	1		
			11/10/92	11/10/92	1	2	1	50.0	98.8	1		10e	
			12/10/92	21/10/92	10	2	2	100.0	99.0	1	1		
			22/10/92	22/10/92	1	2	1	50.0	98.1	1		6e	
					53								
	506	Fluoxetine	27/10/92	02/11/92	7	2	2	100.0	100.0	1	1		
			03/11/92	03/11/92	1	2	1	50.0	93.8	1		10e	
			04/11/92	23/12/92	50	2	2	100.0	99.1	1	1		
					58								

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
13	507	Fluoxetine	11/09/92	21/10/92	41	2	2	100.0	100.0	1	1		
			22/10/92	22/10/92	1	2		0.0	97.6			10m 10e	
			23/10/92	06/11/92	15	2	2	100.0	98.2	1	1		
					57								
	508	Reboxetine	02/11/92	07/11/92	6	2	2	100.0	100.0	1	1		
			08/11/92	08/11/92	1	2	1	50.0	92.9	1		10e	
			09/11/92	14/11/92	6	2	2	100.0	96.2	1	1		
			15/11/92	15/11/92	1	2	1	50.0	92.9	1		10e	
			16/11/92	07/12/92	22	2	2	100.0	97.2	1	1		
			08/12/92	08/12/92	1	2	1	50.0	95.9		1	1m	
			09/12/92	13/12/92	5	2	2	100.0	96.4	1	1		
			14/12/92	14/12/92	1	2	1	50.0	95.3	1		1e	
			15/12/92	29/12/92	15	2	2	100.0	96.6	1	1		
					58								
	521	Reboxetine	30/11/92	26/01/93	58	2	2	100.0	100.0	1	1		
					58								
14	397	Fluoxetine	14/04/92	14/04/92	1	2	1	100.0	100.0	0	1	9m	
			15/04/92	08/06/92	55	2	2	100.0	100.0	1	1		
			09/06/92	09/06/92	1	2	1	100.0	100.0	1	0	9e	
					57								
	398	Reboxetine	15/04/92	15/04/92	1	2	1	100.0	100.0	0	1	9m	
			16/04/92	14/05/92	29	2	2	100.0	100.0	1	1		
			15/05/92	15/05/92	1	2	1	100.0	100.0	1		3e	
			16/05/92	09/06/92	25	2	2	100.0	100.0	1	1		
			10/06/92	10/06/92	1	2	1	100.0	100.0	1	0	9e	
					57								
	399	Reboxetine	21/04/92	21/04/92	1	2	1	100.0	100.0	0	1	9m	
			22/04/92	06/05/92	15	2	2	100.0	100.0	1	1		
			07/05/92	07/05/92	1	2	1	100.0	100.0	1		3e	
			08/05/92	03/06/92	27	2	2	100.0	100.0	1	1		
			04/06/92	04/06/92	1	2	1	50.0	98.9	1		1e	
			05/06/92	15/06/92	11	2	2	100.0	99.1	1	1		
			16/06/92	16/06/92	1	2	1	100.0	99.1	1	0	9e	

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
					57								
14	400	Fluoxetine	15/05/92	15/05/92	1	2	1	100.0	100.0	0	1	9m	
			16/05/92	10/07/92	56	2	2	100.0	100.0	1	1		
			11/07/92	11/07/92	1	2	1	100.0	100.0	1	0	9e	
					58								
	401	Fluoxetine	22/05/92	22/05/92	1	2	1	100.0	100.0	0	1	9m	
			23/05/92	20/06/92	29	2	2	100.0	100.0	1	1		
			21/06/92	21/06/92	1	2	1	50.0	98.4		1	1m	
			22/06/92	16/07/92	25	2	2	100.0	99.1	1	1		
			17/07/92	17/07/92	1	2	1	100.0	99.1	1	0	9e	
					57								
	402	Reboxetine	27/05/92	27/05/92	1	2	1	100.0	100.0	0	1	9m	
			28/05/92	21/07/92	55	2	2	100.0	100.0	1	1		
			22/07/92	22/07/92	1	2	1	100.0	100.0	1	0	9e	
					57								
	403	Reboxetine	29/05/92	29/05/92	1	2	1	100.0	100.0	0	1	9m	
			30/05/92	23/07/92	55	2	2	100.0	100.0	1	1		
			24/07/92	24/07/92	1	2	1	100.0	100.0	1	0	9e	
					57								
	404	Fluoxetine	16/06/92	16/06/92	1	2	1	100.0	100.0	0	1	9m	
			17/06/92	10/08/92	55	2	2	100.0	100.0	1	1		
			11/08/92	11/08/92	1	2	1	100.0	100.0	1	0	9e	
					57								
	405	Fluoxetine	22/06/92	22/06/92	1	2	1	100.0	100.0	0	1	9m	
			23/06/92	30/07/92	38	2	2	100.0	100.0	1	1		
			31/07/92	31/07/92	1	2	1	50.0	98.8	1		10e	
			01/08/92	17/08/92	17	2	2	100.0	99.1	1	1		
			18/08/92	18/08/92	1	2	1	100.0	99.1	1	0	9e	
					58								

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
14	406	Fluoxetine	30/06/92	30/06/92	1	2	1	100.0	100.0	0	1	9m	
			01/07/92	20/07/92	20	2	2	100.0	100.0	1	1		
			21/07/92	21/07/92	1	2	1	50.0	97.7	1		6e	
					22								
	407	Reboxetine	14/07/92	23/08/92	41	2	2	100.0	100.0	1	1		
			24/08/92	24/08/92	1	2	1	50.0	98.8	1		6e	
					42								
	408	Reboxetine	04/08/92	04/08/92	1	2	1	100.0	100.0	0	1	9m	
			05/08/92	07/08/92	3	2	2	100.0	100.0	1	1		
			08/08/92	08/08/92	1	2	1	50.0	90.0	1		2e	
			09/08/92	14/08/92	6	2	2	100.0	95.5	1	1		
			15/08/92	15/08/92	1	2	1	50.0	91.7	1		2e	
			16/08/92	29/08/92	14	2	2	100.0	96.2	1	1		
			30/08/92	31/08/92	2	2	1	50.0	92.9	1		2e	
			01/09/92	18/09/92	18	2	2	100.0	95.7	1	1		
			19/09/92	19/09/92	1	2	1	50.0	94.7	1		2e	
			20/09/92	29/09/92	10	2	2	100.0	95.6	1	1		
			30/09/92	30/09/92	1	2	1	100.0	95.7	1	0	9e	
					58								
	509	Fluoxetine	29/09/92	29/09/92	1	2	1	100.0	100.0	0	1	9m	
			30/09/92	30/09/92	1	2	2	100.0	100.0	1	1		
			01/10/92	01/10/92	1	2	3	50.0	83.3	1	2		(D - e)
			02/10/92	09/11/92	39	2	2	100.0	98.8	1	1		
			10/11/92	10/11/92	1	2	1	50.0	97.7	1		6e	
					43								
	510	Fluoxetine	30/09/92	30/09/92	1	2	1	100.0	100.0	0	1	9m	
			01/10/92	16/10/92	16	2	2	100.0	100.0	1	1		
			17/10/92	17/10/92	1	2	1	50.0	97.2		1	1m	
			18/10/92	25/11/92	39	2	2	100.0	99.1	1	1		
			26/11/92	26/11/92	1	2	1	100.0	99.1	1	0	9e	
					58								
	511	Reboxetine	23/10/92	23/10/92	1	2	1	100.0	100.0	0	1	9m	
			24/10/92	09/12/92	47	2	2	100.0	100.0	1	1		

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
14	511	Reboxetine	10/12/92	10/12/92	1	2	1	50.0	99.0	1		6e	
					49								
	512	Reboxetine	03/11/92	03/11/92	1	2	1	100.0	100.0	0	1	9m	
			04/11/92	01/12/92	28	2	2	100.0	100.0	1	1		
			02/12/92	02/12/92	1	2	1	50.0	98.3	1		6e	
					30								
	537	Reboxetine	03/11/92	03/11/92	1	2	1	100.0	100.0	0	1	9m	
			04/11/92	28/12/92	55	2	2	100.0	100.0	1	1		
			29/12/92	29/12/92	1	2	1	100.0	100.0	1	0	9e	
					57								
	538	Fluoxetine	12/02/93	12/02/93	1	2	1	100.0	100.0	0	1	9m	
			13/02/93	19/02/93	7	2	2	100.0	100.0	1	1		
			20/02/93	20/02/93	1	2	1	50.0	94.4		1	1m	
			21/02/93	26/02/93	6	2	2	100.0	96.7	1	1		
			27/02/93	27/02/93	1	2	1	50.0	93.8		1	1m	
			28/02/93	04/04/93	36	2	2	100.0	98.1	1	1		
			05/04/93	05/04/93	1	2		0.0	96.2			1m 1e	
			06/04/93	08/04/93	3	2	2	100.0	96.4	1	1		
			09/04/93	09/04/93	1	2	1	100.0	96.5	1	0	9e	
					57								
	539	Fluoxetine	10/03/93	10/03/93	1	2	1	100.0	100.0	0	1	9m	
			11/03/93	04/05/93	55	2	2	100.0	100.0	1	1		
			05/05/93	05/05/93	1	2	1	100.0	100.0	1	0	9e	
					57								
15	409	Reboxetine	08/04/92	02/06/92	56	2	2	100.0	100.0	1	1		
					56								
	410	Fluoxetine	17/04/92	11/06/92	56	2	2	100.0	100.0	1	1		
					56								
	411	Reboxetine	22/04/92	16/06/92	56	2	2	100.0	100.0	1	1		

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
					56								
15	412	Fluoxetine	23/04/92	17/06/92	56	2	2	100.0	100.0	1	1		
					56								
	413	Reboxetine	30/04/92	24/06/92	56	2	2	100.0	100.0	1	1		
					56								
	414	Fluoxetine	02/06/92	27/07/92	56	2	2	100.0	100.0	1	1		
					56								
	415	Reboxetine	12/06/92	06/08/92	56	2	2	100.0	100.0	1	1		
					56								
	416	Fluoxetine	23/06/92	17/08/92	56	2	2	100.0	100.0	1	1		
					56								
	417	Reboxetine	19/06/92	13/08/92	56	2	2	100.0	100.0	1	1		
					56								
	418	Reboxetine	17/07/92	10/09/92	56	2	2	100.0	100.0	1	1		
					56								
	419	Fluoxetine	16/07/92	09/09/92	56	2	2	100.0	100.0	1	1		
					56								
	420	Fluoxetine	20/08/92	14/10/92	56	2	2	100.0	100.0	1	1		
					56								
	421	Reboxetine	01/08/92	25/09/92	56	2	2	100.0	100.0	1	1		
					56								

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
15	422	Fluoxetine	19/08/92	13/10/92	56	2	2	100.0	100.0	1	1		
					56								
	423	Fluoxetine	21/08/92	15/10/92	56	2	2	100.0	100.0	1	1		
					56								
	424	Reboxetine	21/08/92	15/10/92	56	2	2	100.0	100.0	1	1		
					56								
	425	Reboxetine	02/10/92	26/11/92	56	2	2	100.0	100.0	1	1		
					56								
	426	Fluoxetine	28/10/92	22/12/92	56	2	2	100.0	100.0	1	1		
					56								
	427	Reboxetine	03/12/92	27/01/93	56	2	2	100.0	100.0	1	1		
					56								
	428	Fluoxetine	03/12/92	27/01/93	56	2	2	100.0	100.0	1	1		
					56								
	449	Reboxetine	08/12/92	01/02/93	56	2	2	100.0	100.0	1	1		
					56								
	450	Fluoxetine	10/12/92	03/02/93	56	2	2	100.0	100.0	1	1		
					56								
	451	Fluoxetine	18/12/92	11/02/93	56	2	2	100.0	100.0	1	1		
					56								
	452	Reboxetine	23/12/92	16/02/93	56	2	2	100.0	100.0	1	1		

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient,
5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening,
10=reason unknown

(**) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
					56								
15	454	Fluoxetine	19/01/93	15/03/93	56	2	2	100.0	100.0	1	1		
					56								
16	429	Fluoxetine	26/03/92	20/05/92	56	2	2	100.0	100.0	1	1		
					56								
	430	Reboxetine	30/03/92	30/03/92	1	2	1	100.0	100.0	0	1	9m	
			31/03/92	25/05/92	56	2	2	100.0	100.0	1	1		
					57								
	431	Reboxetine	31/03/92	25/05/92	56	2	2	100.0	100.0	1	1		
					56								
	432	Fluoxetine	31/03/92	25/05/92	56	2	2	100.0	100.0	1	1		
					56								
	433	Reboxetine	02/04/92	27/05/92	56	2	2	100.0	100.0	1	1		
					56								
	434	Fluoxetine	07/04/92	01/06/92	56	2	2	100.0	100.0	1	1		
					56								
	435	Reboxetine	14/04/92	08/06/92	56	2	2	100.0	100.0	1	1		
					56								
	436	Fluoxetine	24/04/92	21/05/92	28	2	2	100.0	100.0	1	1		
			22/05/92	23/05/92	2	2	1	50.0	96.7	1		4e	
			24/05/92	29/05/92	6	2	2	100.0	97.2	1	1		
			30/05/92	30/05/92	1	2	1	50.0	95.9		1	1m	
			31/05/92	02/06/92	3	2	2	100.0	96.3	1	1		
			03/06/92	03/06/92	1	2	1	50.0	95.1		1	1m	
			04/06/92	10/06/92	7	2	2	100.0	95.8	1	1		

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
16	436	Fluoxetine	11/06/92	11/06/92	1	2	1	100.0	95.9	1		3e	
			12/06/92	18/06/92	7	2	2	100.0	96.4	1	1		
					56								
	437	Reboxetine	30/04/92	24/06/92	56	2	2	100.0	100.0	1	1		
					56								
	438	Fluoxetine	20/05/92	17/06/92	29	2	2	100.0	100.0	1	1		
			18/06/92	18/06/92	1	2	1	100.0	100.0	1		3e	
					30								
	439	Fluoxetine	20/05/92	14/07/92	56	2	2	100.0	100.0	1	1		
					56								
	440	Reboxetine	01/07/92	25/08/92	56	2	2	100.0	100.0	1	1		
					56								
	441	Fluoxetine	22/07/92	14/09/92	55	2	2	100.0	100.0	1	1		
					55								
	442	Reboxetine	22/07/92	14/09/92	55	2	2	100.0	100.0	1	1		
					55								
	443	Fluoxetine	25/08/92	18/10/92	55	2	2	100.0	100.0	1	1		
					55								
	444	Reboxetine	25/08/92	19/10/92	56	2	2	100.0	100.0	1	1		
					56								
	445	Reboxetine	18/09/92	12/11/92	56	2	2	100.0	100.0	1	1		
					56								
	446	Fluoxetine	18/09/92	12/11/92	56	2	2	100.0	100.0	1	1		

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
					56								
16	447	Fluoxetine	18/09/92	19/09/92	2	2	2	100.0	100.0	1	1		
			20/09/92	20/09/92	1	2	1	50.0	83.3		1	1m	
			21/09/92	13/10/92	23	2	2	100.0	98.1	1	1		
			14/10/92	14/10/92	1	2	1	50.0	96.3		1	1m	
			15/10/92	12/11/92	29	2	2	100.0	98.2	1	1		
					56								
	448	Reboxetine	19/09/92	03/10/92	15	2	2	100.0	100.0	1	1		
			04/10/92	04/10/92	1	2	1	50.0	96.9		1	1m	
			05/10/92	02/11/92	29	2	2	100.0	98.9	1	1		
			03/11/92	03/11/92	1	2	1	50.0	97.8	1		1e	
			04/11/92	13/11/92	10	2	2	100.0	98.2	1	1		
					56								
700	455	Fluoxetine	19/09/92	13/11/92	56	2	2	100.0	100.0	1	1		
					56								
	456	Reboxetine	16/12/92	09/02/93	56	2	2	100.0	100.0	1	1		
					56								
	457	Fluoxetine	16/12/92	09/02/93	56	2	2	100.0	100.0	1	1		
					56								
	458	Fluoxetine	16/12/92	09/02/93	56	2	2	100.0	100.0	1	1		
					56								
	459	Reboxetine	22/12/92	15/02/93	56	2	2	100.0	100.0	1	1		
					56								
	460	Reboxetine	22/12/92	15/02/93	56	2	2	100.0	100.0	1	1		
					56								

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
18	25	Fluoxetine	06/10/92	07/11/92	33	2	2	100.0	100.0	1	1		
			08/11/92	08/11/92	1	2	3	50.0	98.5	1	2		(B - e)
			09/11/92	30/11/92	22	2	2	100.0	99.1	1	1		
					56								
	26	Reboxetine	06/10/92	30/11/92	56	2	2	100.0	100.0	1	1		
					56								
	27	Reboxetine	06/10/92	30/11/92	56	2	2	100.0	100.0	1	1		
					56								
	28	Fluoxetine	06/10/92	02/11/92	28	2	2	100.0	100.0	1	1		
					28								
	29	Reboxetine	06/10/92	30/11/92	56	2	2	100.0	100.0	1	1		
					56								
	30	Fluoxetine	07/10/92	03/11/92	28	2	2	100.0	100.0	1	1		
			04/11/92	09/11/92	6	2	4	100.0	100.0	2	2		(3 - m) (3 - e)
			10/11/92	23/11/92	14	2	2	100.0	100.0	1	1		
			24/11/92	24/11/92	1	2		0.0	98.0			1m 1e	
			25/11/92	01/12/92	7	2	2	100.0	98.2	1	1		
					56								
	31	Reboxetine	20/10/92	14/12/92	56	2	2	100.0	100.0	1	1		
					56								
	32	Fluoxetine	07/10/92	29/11/92	54	2	2	100.0	100.0	1	1		
			30/11/92	30/11/92	1	2	4	0.0	98.2	2	2		(B - m) (B - e)
					55								
	49	Reboxetine	17/11/92	11/01/93	56	2	2	100.0	100.0	1	1		
					56								

(*) 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
18	50	Reboxetine	17/11/92	17/11/92	1	2	2	100.0	100.0	1	1		
			18/11/92	18/11/92	1	2	1	50.0	75.0	1		6e	
					2								
	51	Fluoxetine	17/11/92	11/01/93	56	2	2	100.0	100.0	1	1		
					56								
	52	Fluoxetine	17/11/92	11/01/93	56	2	2	100.0	100.0	1	1		
					56								
	53	Fluoxetine	15/01/93	11/03/93	56	2	2	100.0	100.0	1	1		
					56								
	54	Fluoxetine	12/01/93	08/03/93	56	2	2	100.0	100.0	1	1		
					56								
20	21	Fluoxetine	06/11/92	30/12/92	55	2	2	100.0	100.0	1	1		
					55								
	22	Fluoxetine	12/11/92	16/12/92	35	2	2	100.0	100.0	1	1		
					35								
21	9	Fluoxetine	19/10/92	24/10/92	6	2	2	100.0	100.0	1	1		
			25/10/92	25/10/92	1	2	1	50.0	92.9	1		1e	
			26/10/92	11/11/92	17	2	2	100.0	97.9	1	1		
			12/11/92	13/11/92	2	2		100.0	98.1			3m 3e	
			14/11/92	15/11/92	2	2	2	100.0	98.2	1	1		
			16/11/92	17/11/92	2	2	1	100.0	98.3		1	3m	
			18/11/92	25/11/92	8	2	2	100.0	98.7	1	1		
			26/11/92	26/11/92	1	2	1	50.0	97.4	1		1e	
			27/11/92	09/12/92	13	2	2	100.0	98.1	1	1		
			10/12/92	11/12/92	2	2	1	50.0	96.3		1	1m	
			12/12/92	12/12/92	1	2	1	50.0	95.5	1		1e	
			13/12/92	13/12/92	1	2	2	100.0	95.5	1	1		

(*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown

(**) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration
m = morning, e = evening

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Patient	Treatment	From date	To date	Treat. days	Cps prescribed	Daily Cps	% Compl. day	% Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (**)
					56								
22	113	Fluoxetine	03/12/92	17/12/92	15	2	2	100.0	100.0	1	1		
			18/12/92	18/12/92	1	2	1	50.0	96.9	1		6e	
					16								
	115	Reboxetine	29/12/92	19/01/93	22	2	2	100.0	100.0	1	1		
			20/01/93	20/01/93	1	2	1	50.0	97.8	1		6e	
					23								

703

(*) 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

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given: Sequen. block	Given: Treatment	Given: Start treat. date	Given: Patient	Randomized: Patient	Randomized: Treatment	Randomized: Sequen. block	Error (*)
1	1	Fluoxetine	15/11/91	1	1	Fluoxetine	1	
	1	Reboxetine	26/06/92	2	2	Reboxetine	1	
	1	Fluoxetine	01/07/92	3	3	Fluoxetine	1	
	1	Reboxetine	14/08/92	4	4	Reboxetine	1	
	2	Fluoxetine	13/10/92	5	5	Fluoxetine	2	
	2	Fluoxetine	14/01/93	6	6	Fluoxetine	2	
2	1	Reboxetine	16/04/91	35	33	Fluoxetine	1	*
	1	Fluoxetine	02/05/91	36	34	Reboxetine	1	*
	1	Reboxetine	03/05/91	34	35	Reboxetine	1	
	1	Fluoxetine	04/05/91	33	36	Fluoxetine	1	
	2	Reboxetine	06/06/91	40	37	Reboxetine	2	
	2	Fluoxetine	19/06/91	39	38	Fluoxetine	2	
	2	Fluoxetine	20/06/91	38	39	Fluoxetine	2	
	2	Reboxetine	07/10/91	37	40	Reboxetine	2	
	3	Reboxetine	19/11/91	43	41	Fluoxetine	3	*
	3	Fluoxetine	13/12/91	44	42	Reboxetine	3	*
	3	Fluoxetine	13/02/92	41	43	Reboxetine	3	*
	3	Reboxetine	05/03/92	42	44	Fluoxetine	3	*
	4	Fluoxetine	25/03/92	47	45	Reboxetine	4	*
	4	Reboxetine	19/05/92	48	46	Fluoxetine	4	*
	4	Reboxetine	10/09/92	45	47	Fluoxetine	4	*
	5	Fluoxetine	15/01/93	80	48	Reboxetine	4	*
3	1	Fluoxetine	16/10/91	65	65	Fluoxetine	1	
	1	Fluoxetine	16/10/91	66	66	Fluoxetine	1	
	1	Reboxetine	18/11/92	67	67	Reboxetine	1	
	1	Reboxetine	30/11/92	68	68	Reboxetine	1	
4	1	Reboxetine	22/04/91	97	97	Reboxetine	1	
	1	Fluoxetine	30/05/91	98	98	Fluoxetine	1	
	1	Fluoxetine	15/10/91	99	99	Fluoxetine	1	
	1	Reboxetine	08/05/92	100	100	Reboxetine	1	
	2	Reboxetine	02/07/92	101	101	Reboxetine	2	
	2	Fluoxetine	10/07/92	102	102	Fluoxetine	2	
	2	Fluoxetine	13/07/92	103	103	Fluoxetine	2	
	2	Reboxetine	18/08/92	104	104	Reboxetine	2	
	3	Fluoxetine	21/08/92	105	105	Fluoxetine	3	
5	1	Reboxetine	29/11/91	129	129	Reboxetine	1	
	1	Fluoxetine	28/02/92	130	130	Fluoxetine	1	

(*) Assigned treatment different from randomized

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given: Sequen. block	Given: Treatment	Given: Start treat. date	Given: Patient	Randomized: Patient	Randomized: Treatment	Randomized: Sequen. block	Error (*)
7	1	Reboxetine	06/12/91	193	193	Reboxetine	1	
	1	Fluoxetine	10/01/92	194	194	Fluoxetine	1	
	1	Fluoxetine	14/02/92	195	195	Fluoxetine	1	
	1	Reboxetine	29/05/92	196	196	Reboxetine	1	
	2	Fluoxetine	11/11/92	197	197	Fluoxetine	2	
11	1	Fluoxetine	14/11/91	321	321	Fluoxetine	1	
	1	Reboxetine	14/11/91	322	322	Reboxetine	1	
	1	Fluoxetine	19/11/91	323	323	Fluoxetine	1	
	1	Reboxetine	24/01/92	324	324	Reboxetine	1	
	2	Reboxetine	12/02/92	325	325	Reboxetine	2	
	2	Reboxetine	12/02/92	326	326	Reboxetine	2	
	2	Fluoxetine	14/02/92	327	327	Fluoxetine	2	
	2	Fluoxetine	19/02/92	328	328	Fluoxetine	2	
	3	Reboxetine	31/03/92	329	329	Reboxetine	3	
	3	Reboxetine	21/04/92	330	330	Reboxetine	3	
	3	Fluoxetine	26/05/92	331	331	Fluoxetine	3	
	3	Fluoxetine	28/07/92	332	332	Fluoxetine	3	
	4	Reboxetine	15/09/92	333	333	Reboxetine	4	
	4	Fluoxetine	22/09/92	334	334	Fluoxetine	4	
	4	Reboxetine	13/10/92	335	335	Reboxetine	4	
12	1	Fluoxetine	25/06/92	393	393	Fluoxetine	1	
	1	Reboxetine	06/07/92	394	394	Reboxetine	1	
	1	Reboxetine	24/07/92	395	395	Reboxetine	1	
	1	Fluoxetine	04/08/92	396	396	Fluoxetine	1	
	2	Fluoxetine	24/02/93	497	497	Fluoxetine	2	
13	1	Fluoxetine	14/03/92	385	385	Fluoxetine	1	
	1	Reboxetine	16/03/92	388	386	Fluoxetine	1	*
	1	Reboxetine	18/04/92	387	387	Reboxetine	1	
	1	Fluoxetine	24/04/92	386	388	Reboxetine	1	*
	2	Reboxetine	28/05/92	390	389	Fluoxetine	2	*
	2	Fluoxetine	11/06/92	391	390	Reboxetine	2	*
	2	Fluoxetine	21/07/92	389	391	Fluoxetine	2	
	2	Reboxetine	14/08/92	392	392	Reboxetine	2	
	3	Reboxetine	31/08/92	505	505	Reboxetine	3	
	3	Fluoxetine	11/09/92	507	506	Fluoxetine	3	
	3	Fluoxetine	27/10/92	506	507	Fluoxetine	3	
	3	Reboxetine	02/11/92	508	508	Reboxetine	3	

(*) Assigned treatment different from randomized

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given Sequen. block	Given Treatment	Given Start treat. date	Given Patient	Randomized Patient	Randomized Treatment	Randomized Sequen. block	Error (*)
13	4	Reboxetine	02/11/92	501	501	Reboxetine	4	
	4	Fluoxetine	03/11/92	502	502	Fluoxetine	4	
	4	Reboxetine	12/11/92	503	503	Reboxetine	4	
	4	Fluoxetine	26/11/92	504	504	Fluoxetine	4	
	5	Reboxetine	30/11/92	521	521	Reboxetine	5	
14	1	Fluoxetine	14/04/92	397	397	Fluoxetine	1	
	1	Reboxetine	15/04/92	398	398	Reboxetine	1	
	1	Reboxetine	21/04/92	399	399	Reboxetine	1	
	1	Fluoxetine	15/05/92	400	400	Fluoxetine	1	
	2	Fluoxetine	22/05/92	401	401	Fluoxetine	2	
	2	Reboxetine	27/05/92	402	402	Reboxetine	2	
	2	Reboxetine	29/05/92	403	403	Reboxetine	2	
	2	Fluoxetine	16/06/92	404	404	Fluoxetine	2	
	3	Fluoxetine	22/06/92	405	405	Fluoxetine	3	
	3	Fluoxetine	30/06/92	406	406	Fluoxetine	3	
	3	Reboxetine	14/07/92	407	407	Reboxetine	3	
	3	Reboxetine	04/08/92	408	408	Reboxetine	3	
	4	Fluoxetine	29/09/92	509	509	Fluoxetine	4	
	4	Fluoxetine	30/09/92	510	510	Fluoxetine	4	
	4	Reboxetine	23/10/92	511	511	Reboxetine	4	
	4	Reboxetine	03/11/92	512	512	Reboxetine	4	
	5	Reboxetine	03/11/92	537	537	Reboxetine	5	
	5	Fluoxetine	12/02/93	538	538	Fluoxetine	5	
	5	Fluoxetine	10/03/93	539	539	Fluoxetine	5	
15	1	Reboxetine	08/04/92	409	409	Reboxetine	1	
	1	Fluoxetine	17/04/92	410	410	Fluoxetine	1	
	1	Reboxetine	22/04/92	411	411	Reboxetine	1	
	1	Fluoxetine	23/04/92	412	412	Fluoxetine	1	
	2	Reboxetine	30/04/92	413	413	Reboxetine	2	
	2	Fluoxetine	02/06/92	414	414	Fluoxetine	2	
	2	Reboxetine	12/06/92	415	415	Reboxetine	2	
	3	Reboxetine	19/06/92	417	416	Fluoxetine	2	*
	2	Fluoxetine	23/06/92	416	417	Reboxetine	3	*
	3	Fluoxetine	16/07/92	419	418	Reboxetine	3	*
	3	Reboxetine	17/07/92	418	419	Fluoxetine	3	*
	4	Reboxetine	01/08/92	421	420	Fluoxetine	3	*
	4	Fluoxetine	19/08/92	422	421	Reboxetine	4	*
	3	Fluoxetine	20/08/92	420	422	Fluoxetine	4	
	4	Fluoxetine	21/08/92	423	423	Fluoxetine	4	
	4	Reboxetine	21/08/92	424	424	Reboxetine	4	
	5	Reboxetine	02/10/92	425	425	Reboxetine	5	

(*) Assigned treatment different from randomized

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Centre	Given: Sequen. block	Given: Treatment	Given: Start treat. date	Given: Patient	Randomized: Patient	Randomized: Treatment	Randomized: Sequen. block	Error (*)
15	5	Fluoxetine	28/10/92	426	426	Fluoxetine	5	
	5	Reboxetine	03/12/92	427	427	Reboxetine	5	
	5	Fluoxetine	03/12/92	428	428	Fluoxetine	5	
	6	Reboxetine	08/12/92	449	449	Reboxetine	6	
	6	Fluoxetine	10/12/92	450	450	Fluoxetine	6	
	6	Fluoxetine	18/12/92	451	451	Fluoxetine	6	
	6	Reboxetine	23/12/92	452	452	Reboxetine	6	
	7	Fluoxetine	19/01/93	454	454	Fluoxetine	7	
16	1	Fluoxetine	26/03/92	429	429	Fluoxetine	1	
	1	Reboxetine	30/03/92	430	430	Reboxetine	1	
	1	Reboxetine	31/03/92	431	431	Reboxetine	1	
	1	Fluoxetine	31/03/92	432	432	Fluoxetine	1	
	2	Reboxetine	02/04/92	433	433	Reboxetine	2	
	2	Fluoxetine	07/04/92	434	434	Fluoxetine	2	
	2	Reboxetine	14/04/92	435	435	Reboxetine	2	
	2	Fluoxetine	24/04/92	436	436	Fluoxetine	2	
	3	Reboxetine	30/04/92	437	437	Reboxetine	3	
	3	Fluoxetine	20/05/92	438	438	Fluoxetine	3	
	3	Fluoxetine	20/05/92	439	439	Fluoxetine	3	
	3	Reboxetine	01/07/92	440	440	Reboxetine	3	
	4	Fluoxetine	22/07/92	441	441	Fluoxetine	4	
	4	Reboxetine	22/07/92	442	442	Reboxetine	4	
	4	Fluoxetine	25/08/92	443	443	Fluoxetine	4	
	4	Reboxetine	25/08/92	444	444	Reboxetine	4	
	5	Reboxetine	18/09/92	445	445	Reboxetine	5	
	5	Fluoxetine	18/09/92	446	446	Fluoxetine	5	
	5	Fluoxetine	18/09/92	447	447	Fluoxetine	5	
	5	Reboxetine	19/09/92	448	448	Reboxetine	5	
	6	Fluoxetine	19/09/92	455	455	Fluoxetine	6	
	6	Reboxetine	16/12/92	456	456	Reboxetine	6	
	7	Fluoxetine	16/12/92	457	457	Fluoxetine	7	
	7	Fluoxetine	16/12/92	458	458	Fluoxetine	7	
	7	Reboxetine	22/12/92	459	459	Reboxetine	7	
	7	Reboxetine	22/12/92	460	460	Reboxetine	7	
18	1	Fluoxetine	06/10/92	25	25	Fluoxetine	1	
	1	Reboxetine	06/10/92	26	26	Reboxetine	1	
	1	Reboxetine	06/10/92	27	27	Reboxetine	1	
	1	Fluoxetine	06/10/92	28	28	Fluoxetine	1	
	2	Reboxetine	06/10/92	29	29	Reboxetine	2	
	2	Fluoxetine	07/10/92	30	30	Fluoxetine	2	
	2	Fluoxetine	07/10/92	32	31	Reboxetine	2	*

(*) Assigned treatment different from randomized

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

	Given				Randomized			Error
Centre	Sequen. block	Treatment	Start treat. date	Patient	Patient	Treatment	Sequen. block	(*)
18	2	Reboxetine	20/10/92	31	32	Fluoxetine	2	*
	3	Reboxetine	17/11/92	49	49	Reboxetine	3	
	3	Reboxetine	17/11/92	50	50	Reboxetine	3	
	3	Fluoxetine	17/11/92	51	51	Fluoxetine	3	
	3	Fluoxetine	17/11/92	52	52	Fluoxetine	3	
	4	Fluoxetine	12/01/93	54	53	Fluoxetine	4	
	4	Fluoxetine	15/01/93	53	54	Fluoxetine	4	
20	1	Fluoxetine	06/11/92	21	21	Fluoxetine	1	
	1	Fluoxetine	12/11/92	22	22	Fluoxetine	1	
21	1	Fluoxetine	19/10/92	9	9	Fluoxetine	1	
22	1	Fluoxetine	03/12/92	113	113	Fluoxetine	1	
	1	Reboxetine	29/12/92	115	114	Fluoxetine	1	*

(*) Assigned treatment different from randomized

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
1	1	Male	Day 56	09/01/92	YES			As prescribed
	2	Male	Day 56	20/08/92	YES			As prescribed
	3	Female	Day 56	25/08/92	YES			As prescribed
	4	Female	Day 42	24/09/92	NO	Adverse event	Physician Patient	As prescribed
	5	Female	Day 35	11/11/92	NO	Deterioration	Physician Patient	As prescribed
	6	Male	Day 28	11/02/93	NO	Adverse event Deterioration	Physician Patient	As prescribed
2	33	Female	Day 56	28/06/91	YES			As prescribed
	34	Male	Day 42	12/06/91	NO	Adverse event	Patient	As prescribed
	35	Female	Day 56	10/06/91	YES			As prescribed
	36	Male	Day 56	26/06/91	YES			As prescribed
	37	Male	Day 7	10/10/91	NO	Adverse event	Physician Patient	As prescribed
	38	Male	Day 35	25/07/91	NO	Patient uncooperative	Patient	As prescribed
	39	Male	Day 7	22/06/91	NO	Patient uncooperative	Patient	As prescribed
	40	Male	Day 28	04/07/91	NO	Patient uncooperative	Patient	As prescribed
	41	Male	Day 56	08/04/92	YES			As prescribed
	42	Female	Day 56	29/04/92	YES			As prescribed

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	43	Female	Day 56	13/01/92	YES			As prescribed
	44	Male	Day 49	30/01/92	NO	Lost to follow up	Patient	As prescribed
	45	Female	Day 56	04/11/92	YES			As prescribed
	47	Female	Day 56	19/05/92	YES			As prescribed
	48	Female	Day 56	13/07/92	YES			As prescribed
	80	Male	Day 56	11/03/93	YES			As prescribed
3	65	Female	Day 56	10/12/91	YES			As prescribed
	66	Female	Day 28	12/11/91	NO	Adverse event	Physician	As prescribed
	67	Female	Day 28	15/12/92	NO	Patient uncooperative	Patient	As prescribed
	68	Female	Day 35	28/12/92	NO	Deterioration	Physician	As prescribed
4	97	Female	Day 56	16/06/91	YES			As prescribed
	98	Female	Day 56	24/07/91	YES			As prescribed
	99	Female	Day 14	25/10/91	NO	Deterioration	Physician	As prescribed
	100	Male	Day 7	08/05/92	NO	Protocol violation	Physician	As prescribed
	101	Female	Day 56	26/08/92	YES			As prescribed
	102	Female	Day 56	03/09/92	YES			As prescribed
	103	Female	Day 42	18/08/92	NO	Deterioration	Physician	As prescribed

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
4	104	Female	Day 49	05/10/92	NO	Adverse event	Patient	As prescribed
	105	Male	Day 56	15/10/92	YES			As prescribed
5	129	Female	Day 35	29/12/91	NO	Adverse event	Physician	As prescribed
	130	Female	Day 56	23/04/92	YES			As prescribed
7	193	Female	Day 56	31/01/92	YES			As prescribed
	194	Female	Day 56	05/03/92	YES			As prescribed
	195	Male	Day 56	09/04/92	YES			As prescribed
	196	Female	Day 49	16/07/92	NO	Intercurrent medical problem	Physician	As prescribed
	197	Male	Day 7	11/11/92	NO	Protocol violation	Physician	As prescribed
11	321	Female	Day 56	09/01/92	YES			As prescribed
	322	Female	Day 56	09/01/92	YES			As prescribed
	323	Female	Day 56	13/01/92	YES			As prescribed
	324	Female	Day 56	19/03/92	YES			As prescribed
	325	Female	Day 56	07/04/92	YES			As prescribed
	326	Female	Day 56	07/04/92	YES			As prescribed
	327	Female	Day 28	12/03/92	NO	Protocol violation	Physician	As prescribed
	328	Female	Day 56	14/04/92	YES			As prescribed

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
LISTING No.: 11.0

REASONS FOR DISCONTINUATION OF THE TREATMENT

Centre	Patient	Sex	Last visit	Date of last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
11	329	Female	Day 56	27/05/92	YES			As prescribed
	330	Male	Day 49	08/06/92	NO	Deterioration	Physician	As prescribed
	331	Female	Day 56	20/07/92	YES			As prescribed
	332	Female	Day 56	24/09/92	YES			As prescribed
	333	Female	Day 56	09/11/92	YES			As prescribed
	334	Female	Day 56	16/11/92	YES			As prescribed
	335	Female	Day 35	16/11/92	NO	Adverse event	Physician	As prescribed
12	393	Female	Day 56	18/08/92	YES			As prescribed
	394	Male	Day 56	31/08/92	YES			As prescribed
	395	Male	Day 56	16/09/92	YES			As prescribed
	396	Female	Day 14	17/08/92	NO	Adverse event Protocol violation	Patient	Unknown
	497	Female	Day 56	21/04/93	YES		Physician Patient	As prescribed
13	385	Female	Day 56	08/05/92	YES			As prescribed
	386	Male	Day 7	30/04/92	NO	Deterioration	Physician	As prescribed
	387	Female	Day 28	18/05/92	NO	Adverse event	Physician	As prescribed
	388	Male	Day 56	11/05/92	YES			As prescribed

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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
13	389	Female	Day 7	23/07/92	NO	Patient uncooperative	Patient	As prescribed
	390	Male	Day 56	22/07/92	YES			As prescribed
	391	Female	Day 35	15/07/92	NO	Adverse event	Physician	As prescribed
	392	Female	Day 14	27/08/92	NO	Deterioration	Physician	As prescribed
	501	Male	Day 56	30/12/92	YES			As prescribed
	502	Female	Day 56	24/12/92	YES			As prescribed
	503	Female	Day 7	18/11/92	NO	Adverse event	Patient	As prescribed
	504	Female	Day 56	20/01/93	YES			As prescribed
	505	Female	Day 56	22/10/92	YES			As prescribed
	506	Male	Day 56	23/12/92	YES			As prescribed
	507	Female	Day 56	06/11/92	YES	Improvement	Physician Patient	As prescribed
	508	Female	Day 56	29/12/92	YES			As prescribed
	521	Male	Day 56	26/01/93	YES			As prescribed
14	397	Female	Day 56	09/06/92	YES			As prescribed
	398	Female	Day 56	10/06/92	YES			As prescribed
	399	Female	Day 56	16/06/92	YES			As prescribed

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	400	Male	Day 56	11/07/92	YES			As prescribed
	401	Female	Day 56	17/07/92	YES			As prescribed
	402	Female	Day 56	22/07/92	YES			As prescribed
	403	Female	Day 56	24/07/92	YES			As prescribed
	404	Female	Day 56	11/08/92	YES			As prescribed
	405	Female	Day 56	18/08/92	YES			As prescribed
	406	Female	Day 21	21/07/92	NO	Deterioration	Physician	As prescribed
	407	Male	Day 42	24/08/92	NO	Deterioration	Patient	As prescribed
	408	Female	Day 56	30/09/92	YES			As prescribed
	509	Female	Day 42	10/11/92	NO	Deterioration	Patient	As prescribed
	510	Female	Day 56	26/11/92	YES			As prescribed
	511	Female	Day 49	10/12/92	NO	Protocol violation	Physician	As prescribed
	512	Female	Day 28	02/12/92	NO	Patient uncooperative	Patient	As prescribed
	537	Female	Day 56	29/12/92	YES			As prescribed
	538	Female	Day 56	09/04/93	YES			As prescribed
	539	Female	Day 56	05/05/93	YES			As prescribed
15	409	Male	Day 56	02/06/92	YES			As prescribed

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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
15	410	Female	Day 56	11/06/92	YES			As prescribed
	411	Female	Day 56	16/06/92	YES			As prescribed
	412	Female	Day 56	17/06/92	YES			As prescribed
	413	Female	Day 56	24/06/92	YES			As prescribed
	414	Male	Day 56	27/07/92	YES			As prescribed
	415	Female	Day 56	06/08/92	YES			As prescribed
	416	Female	Day 56	17/08/92	YES			As prescribed
	417	Female	Day 56	13/08/92	YES			As prescribed
	418	Female	Day 56	10/09/92	YES			As prescribed
	419	Female	Day 56	09/09/92	YES			As prescribed
	420	Male	Day 56	14/10/92	YES			As prescribed
	421	Female	Day 56	25/09/92	YES			As prescribed
	422	Male	Day 56	13/10/92	YES			As prescribed
	423	Female	Day 56	15/10/92	YES			As prescribed
	424	Male	Day 56	15/10/92	YES			As prescribed
	425	Female	Day 56	26/11/92	YES			As prescribed
	426	Male	Day 56	22/12/92	YES			As prescribed

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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
15	427	Female	Day 56	27/01/93	YES			As prescribed
	428	Male	Day 56	27/01/93	YES			As prescribed
	449	Female	Day 56	01/02/93	YES			As prescribed
	450	Male	Day 56	03/02/93	YES			As prescribed
	451	Female	Day 56	11/02/93	YES			As prescribed
	452	Female	Day 56	16/02/93	YES			As prescribed
	454	Male	Day 56	15/03/93	YES			As prescribed
16	429	Female	Day 56	20/05/92	YES			As prescribed
	430	Male	Day 56	25/05/92	YES			As prescribed
	431	Female	Day 56	25/05/92	YES			As prescribed
	432	Female	Day 56	25/05/92	YES			As prescribed
	433	Female	Day 56	27/05/92	YES			As prescribed
	434	Female	Day 56	01/06/92	YES			As prescribed
	435	Female	Day 56	08/06/92	YES			As prescribed
	436	Female	Day 56	18/06/92	YES			As prescribed
	437	Female	Day 56	24/06/92	YES			As prescribed
	438	Female	Day 35	18/06/92	NO	Intercurrent medical problem Other	Physician	As prescribed

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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
16	439	Female	Day 56	14/07/92	YES			As prescribed
	440	Female	Day 56	25/08/92	YES			As prescribed
	441	Female	Day 56	14/09/92	YES			As prescribed
	442	Female	Day 56	14/09/92	YES			As prescribed
	443	Male	Day 56	18/10/92	YES			As prescribed
	444	Female	Day 56	19/10/92	YES			As prescribed
	445	Male	Day 56	12/11/92	YES			As prescribed
	446	Female	Day 56	12/11/92	YES			As prescribed
	447	Male	Day 56	12/11/92	YES			As prescribed
	448	Female	Day 56	13/11/92	YES			As prescribed
	455	Female	Day 56	13/11/92	YES			As prescribed
	456	Male	Day 56	09/02/93	YES			As prescribed
	457	Female	Day 56	09/02/93	YES			As prescribed
	458	Female	Day 56	09/02/93	YES			As prescribed
	459	Male	Day 56	15/02/93	YES			As prescribed
	460	Male	Day 56	15/02/93	YES			As prescribed
18	25	Female	Day 56	30/11/92	YES			As prescribed

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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
18	26	Female	Day 56	30/11/92	YES			As prescribed
	27	Female	Day 56	30/11/92	YES			As prescribed
	28	Female	Day 28	02/11/92	NO	Patient uncooperative	Patient	As prescribed
	29	Male	Day 56	30/11/92	YES			As prescribed
	30	Female	Day 56	01/12/92	YES			As prescribed
	31	Female	Day 56	14/12/92	YES			As prescribed
	32	Female	Day 56	30/11/92	YES			As prescribed
	49	Female	Day 56	11/01/93	YES			As prescribed
	50	Female	Day 7	18/11/92	NO	Patient uncooperative	Patient	Confirmed irregularities
	51	Female	Day 56	11/01/93	YES			As prescribed
	52	Female	Day 56	11/01/93	YES			As prescribed
	53	Female	Day 56	11/03/93	YES			As prescribed
	54	Male	Day 56	08/03/93	YES			As prescribed
20	21	Female	Day 56	30/12/92	YES			Suspected irregularities
	22	Female	Day 35	16/12/92	NO	Adverse event	Physician Patient	As prescribed
21	9	Female	Day 56	13/12/92	YES			As prescribed

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 2012A/016
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
22	113	Male	Day 21	18/12/92	NO	Protocol violation	Physician	As prescribed
	115	Male	Day 28	20/01/93	NO	Lost to follow up	Patient	As prescribed

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
1	1	Fluoxetine	Male	01.DEPRESSED MOOD	3	3	2	1	1	0	0	0	0	0
				02.GUILT	1	1	0	0	0	0	0	0	0	0
				03.SUICIDE	1	1	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	1	1	0	0	0	0	0
				05.INSOMNIA MIDDLE	2	2	1	0	0	0	0	0	0	0
				06.INSOMNIA LATE	1	1	1	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	2	2	1	1	1	1	0	0	0	0
				08.RETARDATION	2	2	1	1	1	0	0	0	0	0
				09.AGITATION	0	0	0	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	1	1	0	0	0	0	0	0
				11.ANXIETY SOMATIC	1	1	1	0	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	0	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	1	1	1	1	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	1	1	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	1	1	1	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	1	1	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0
				22.Total score	23	23	14	7	4	1	0	0	0	0
	2	Reboxetine	Male	01.DEPRESSED MOOD	4	4	2	4	2	0	0	0	0	0
				02.GUILT	1	0	0	0	0	0	0	0	0	0
				03.SUICIDE	1	1	1	1	0	0	0	0	0	0
				04.INSOMNIA EARLY	0	0	0	0	1	0	0	0	0	0
				05.INSOMNIA MIDDLE	1	1	1	2	2	2	0	1	1	1
				06.INSOMNIA LATE	2	2	2	2	1	1	1	1	1	1
				07.WORK AND ACTIVITIES	4	4	3	2	2	1	1	0	0	0
				08.RETARDATION	3	3	2	2	2	1	0	1	1	0
				09.AGITATION	1	2	2	2	1	0	0	0	1	1
				10.ANXIETY PSYCHIC	2	3	3	1	2	1	1	1	1	1
				11.ANXIETY SOMATIC	1	1	2	2	2	1	0	0	1	0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	1
				13.SOMATIC GENERAL	1	1	1	2	1	2	1	1	1	1
				14.GENITAL SYMPTOMS	0	0	0	1	1	0	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	2	0	1	0	1	1	1	1
				16.LOSS OF WEIGHT	0	0	1	2	0	0	0	0	0	0
				17.INSIGHT	0	0	1	0	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	1	1	0	1	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	2	2	1	2	1	1	0	0	0	0
				22.Total score	26	27	24	26	20	11	5	7	6	7
	3	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	1	1	0	1			0
				02.GUILT	0	0	0	0	0	0	0			0
				03.SUICIDE	1	1	1	0	0	0	0			0
				04.INSOMNIA EARLY	2	2	2	1	1	2	1			0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
1	3	Fluoxetine	Female	05.INSOMNIA MIDDLE	1	1	2	0	1	0	1			1
				06.INSOMNIA LATE	1	1	1	1	1	0	1			1
				07.WORK AND ACTIVITIES	2	2	2	1	1	1	1			1
				08.RETARDATION	0	0	0	0	0	0	0			0
				09.AGITATION	2	1	1	0	0	0	0			0
				10.ANXIETY PSYCHIC	2	2	2	2	2	0	1			1
				11.ANXIETY SOMATIC	0	0	2	0	0	0	0			0
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0			0
				13.SOMATIC GENERAL	2	2	2	2	1	1	1			1
				14.GENITAL SYMPTOMS	2	2	2	2	2	1	1			1
				15.HYPOCHONDRIASIS	2	2	2	0	0	1	0			0
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0			0
				17.INSIGHT	0	0	0	0	0	0	0			0
				18.DIURNAL VARIATION	2	2	2	1	1	1	1			1
				19.DEPERSONALIZATION	0	0	0	1	0	0	0			0
				20.PARANOID	0	0	0	0	0	0	0			0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	0	0			0
				22.Total score	24	23	25	13	12	7	9			7
	4	Reboxetine	Female	01.DEPRESSED MOOD	4	4	4	4	3	2	1	1		
				02.GUILT	2	2	2	2	1	1	0	0		
				03.SUICIDE	0	0	0	0	0	0	0	0		
				04.INSOMNIA EARLY	1	1	2	2	2	2	2	2		
				05.INSOMNIA MIDDLE	1	0	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	2	1	1	1		
				08.RETARDATION	1	1	1	0	0	0	0	0		
				09.AGITATION	2	2	2	1	1	1	1	1		
				10.ANXIETY PSYCHIC	4	4	4	3	3	2	1	1		
				11.ANXIETY SOMATIC	2	2	2	2	2	2	1	1		
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0		
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1		
				14.GENITAL SYMPTOMS	1	1	0	0	0	0	0	0		
				15.HYPOCHONDRIASIS	2	2	2	2	2	2	1	1		
				16.LOSS OF WEIGHT	2	2	0	0	0	0	0	0		
				17.INSIGHT	0	0	0	0	0	0	0	0		
				18.DIURNAL VARIATION	1	1	1	1	0	0	0	0		
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0		
				20.PARANOID	0	0	0	0	0	0	0	0		
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0		
				22.Total score	28	27	26	23	19	16	11	11		
	5	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	2	3	2	3				
				02.GUILT	1	1	1	1	1	0				
				03.SUICIDE	0	0	0	0	1	1				
				04.INSOMNIA EARLY	1	1	1	1	2	2				
				05.INSOMNIA MIDDLE	1	1	1	1	1	1				
				06.INSOMNIA LATE	1	1	1	2	0	2				
				07.WORK AND ACTIVITIES	4	4	4	3	1	3				
				08.RETARDATION	1	1	1	2	2	2				

721

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
1	5	Fluoxetine	Female	09.AGITATION	1	1	1	1	1	2				
				10.ANXIETY PSYCHIC	2	2	2	1	1	2				
				11.ANXIETY SOMATIC	2	2	2	3	3	2				
				12.SOMATIC GASTROINTESTINAL	0	0	0	1	1	1				
				13.SOMATIC GENERAL	2	2	2	1	1	1				
				14.GENITAL SYMPTOMS	1	1	1	0	0	0				
				15.HYPOCHONDRIASIS	0	0	0	1	1	1				
				16.LOSS OF WEIGHT	0	0	0	0	0	0				
				17.INSIGHT	0	0	0	0	0	0				
				18.DIURNAL VARIATION	2	2	2	1	1	1				
				19.DEPERSONALIZATION	0	0	0	0	0	0				
				20.PARANOID	0	0	0	0	0	0				
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0				
				22.Total score	22	22	21	22	19	24				
	6	Fluoxetine	Male	01.DEPRESSED MOOD	3	3	3	3	3	3				
				02.GUILT	0	1	1	1	1	1				
				03.SUICIDE	0	0	0	0	0	0				
				04.INSOMNIA EARLY	1	2	2	2	2	2				
				05.INSOMNIA MIDDLE	1	1	1	1	1	1				
				06.INSOMNIA LATE	1	0	0	0	0	0				
				07.WORK AND ACTIVITIES	3	3	2	2	2	2				
				08.RETARDATION	2	2	2	2	2	2				
				09.AGITATION	0	0	0	0	0	0				
				10.ANXIETY PSYCHIC	1	1	1	1	1	1				
				11.ANXIETY SOMATIC	1	1	1	1	1	1				
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1				
				13.SOMATIC GENERAL	1	2	2	2	2	2				
				14.GENITAL SYMPTOMS	2	2	2	2	2	2				
				15.HYPOCHONDRIASIS	3	3	3	3	3	3				
				16.LOSS OF WEIGHT	1	0	0	0	0	0				
				17.INSIGHT	1	1	1	1	1	1				
				18.DIURNAL VARIATION	2	2	2	2	2	2				
				19.DEPERSONALIZATION	1	1	1	1	1	1				
				20.PARANOID	0	0	0	0	0	0				
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0				
				22.Total score	25	26	25	25	25	25				
2	33	Fluoxetine	Female	01.DEPRESSED MOOD	4	4	0	3	3	2	3	3	3	3
				02.GUILT	1	1	0	0	0	0	0	0	0	0
				03.SUICIDE	2	2	0	1	0	1	1	1	1	1
				04.INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2
				05.INSOMNIA MIDDLE	2	2	2	1	2	1	1	1	1	1
				06.INSOMNIA LATE	2	2	2	2	2	2	2	2	2	2
				07.WORK AND ACTIVITIES	4	4	0	3	2	2	2	1	2	1
				08.RETARDATION	3	3	0	2	1	0	1	1	0	1
				09.AGITATION	0	0	0	2	2	1	2	2	2	2
				10.ANXIETY PSYCHIC	3	3	0	4	3	1	3	1	3	3
				11.ANXIETY SOMATIC	0	0	0	0	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1

722

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
2	33	Fluoxetine	Female	13.SOMATIC GENERAL	1	1	0	0	1	0	0	0	0	0
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0
				16.LOSS OF WEIGHT	2	2	0	0	0	0	0	0	0	0
				17.INSIGHT	0	0	2	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	1	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	3	3	0	1	1	1	0	0	0	0
				20.PARANOID	0	0	0	1	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0
				22.Total score	33	33	11	25	22	16	20	17	19	19
	34	Reboxetine	Male	01.DEPRESSED MOOD	4	4	2	1	1	1	0	1		
				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	2	2	0	2	0		
				05.INSOMNIA MIDDLE	2	2	2	1	2	1	1	1		
				06.INSOMNIA LATE	2	2	1	1	1	1	1	1		
				07.WORK AND ACTIVITIES	4	4	3	2	1	1	0	1		
				08.RETARDATION	1	1	0	0	0	0	0	0		
				09.AGITATION	0	0	1	1	0	1	0	1		
				10.ANXIETY PSYCHIC	1	1	1	0	1	0	1	1		
				11.ANXIETY SOMATIC	1	1	1	2	1	0	1	0		
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0		
				13.SOMATIC GENERAL	1	1	1	0	0	1	1	0		
				14.GENITAL SYMPTOMS	1	1	0	0	1	0	0	0		
				15.HYPOCHONDRIASIS	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	1	1	0	0	0	0		
				19.DEPERSONALIZATION	0	0	1	0	0	0	0	0		
				20.PARANOID	0	0	0	0	0	0	0	0		
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0		
				22.Total score	26	26	18	11	10	6	7	6		
	35	Reboxetine	Female	01.DEPRESSED MOOD	4	4	3	3	1	2	2	2	2	2
				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	0	0	0	0	0	0	2	0	0	0
				05.INSOMNIA MIDDLE	0	0	2	0	0	2	2	2	2	2
				06.INSOMNIA LATE	0	0	0	1	1	0	0	0	0	0
				07.WORK AND ACTIVITIES	4	4	3	2	2	1	1	1	1	1
				08.RETARDATION	3	3	1	1	1	1	1	1	1	1
				09.AGITATION	2	2	0	0	1	2	2	2	2	2
				10.ANXIETY PSYCHIC	4	4	1	1	2	4	1	2	2	4
				11.ANXIETY SOMATIC	3	3	3	2	2	2	1	1	0	2
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	1	0	0	1
				13.SOMATIC GENERAL	2	2	2	1	1	1	1	1	1	0
				14.GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	1
				15.HYPOCHONDRIASIS	4	4	1	1	0	3	1	2	1	0
				16.LOSS OF WEIGHT	0	0	1	2	2	1	0	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56 Day
2	35	Reboxetine	Female	17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	2	2	2	1	1	1	2	1
				19.DEPERSONALIZATION	0	0	0	0	2	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	1	0	0	0	0	0
				22.Total score	29	29	20	17	19	20	16	15	18	15
	36	Fluoxetine	Male	01.DEPRESSED MOOD	2	1	1	1	1	0	0	0	0	0
				02.GUILT	0	0	0	0	0	0	0	0	0	0
				03.SUICIDE	1	0	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	0	1	0	1	1	0	0	0	0	0
				05.INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	0
				06.INSOMNIA LATE	0	0	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	4	2	3	2	2	0	0	0	0	0
				08.RETARDATION	2	2	1	1	0	0	0	0	0	0
				09.AGITATION	2	0	0	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	0	0	0	0	0	0	0	0
				11.ANXIETY SOMATIC	3	2	1	1	1	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	1	1	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	2	2	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	2	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	23	16	13	13	10	1	0	0	0	0
	37	Reboxetine	Male	01.DEPRESSED MOOD	2	2								
				02.GUILT	1	1								
				03.SUICIDE	4	1								
				04.INSOMNIA EARLY	0	1								
				05.INSOMNIA MIDDLE	0	1								
				06.INSOMNIA LATE	0	0								
				07.WORK AND ACTIVITIES	3	3								
				08.RETARDATION	1	1								
				09.AGITATION	2	3								
				10.ANXIETY PSYCHIC	2	2								
				11.ANXIETY SOMATIC	2	2								
				12.SOMATIC GASTROINTESTINAL	1	1								
				13.SOMATIC GENERAL	1	1								
				14.GENITAL SYMPTOMS	1	1								
				15.HYPOCHONDRIASIS	3	3								
				16.LOSS OF WEIGHT	3	3								
				17.INSIGHT	1	1								
				18.DIURNAL VARIATION	0	0								
				19.DEPERSONALIZATION	0	0								
				20.PARANOID	1	1								

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
2	37	Reboxetine	Male	21.OBSESSIONAL/COMPULSIVE	1	1								
				22.Total score	29	29								
	38	Fluoxetine	Male	01.DEPRESSED MOOD	2	2	1	2	1	0	0			
				02.GUILT	2	2	0	0	0	0	0			
				03.SUICIDE	3	3	1	1	1	0	0			
				04.INSOMNIA EARLY	2	2	1	1	1	1	1			
				05.INSOMNIA MIDDLE	1	1	0	0	0	0	0			
				06.INSOMNIA LATE	2	2	2	1	1	1	2			
				07.WORK AND ACTIVITIES	2	2	2	1	1	0	0			
				08.RETARDATION	1	1	1	1	1	0	0			
				09.AGITATION	2	2	2	2	2	1	0			
				10.ANXIETY PSYCHIC	3	3	1	1	1	0	0			
				11.ANXIETY SOMATIC	2	2	0	0	0	0	0			
				12.SOMATIC GASTROINTESTINAL	0	0	1	1	1	0	0			
				13.SOMATIC GENERAL	1	1	1	1	0	0	0			
				14.GENITAL SYMPTOMS	1	1	0	0	1	1	0			
				15.HYPOCHONDRIASIS	2	2	2	1	1	1	0			
				16.LOSS OF WEIGHT	1	1	1	2	2	0	2			
				17.INSIGHT	1	1	0	0	0	0	0			
				18.DIURNAL VARIATION	1	1	1	1	0	0	0			
				19.DEPERSONALIZATION	1	1	1	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	31	31	18	16	14	5	5			
	39	Fluoxetine	Male	01.DEPRESSED MOOD	3	3								
				02.GUILT	2	2								
				03.SUICIDE	1	1								
				04.INSOMNIA EARLY	0	0								
				05.INSOMNIA MIDDLE	2	2								
				06.INSOMNIA LATE	0	0								
				07.WORK AND ACTIVITIES	2	2								
				08.RETARDATION	2	2								
				09.AGITATION	2	2								
				10.ANXIETY PSYCHIC	2	2								
				11.ANXIETY SOMATIC	3	3								
				12.SOMATIC GASTROINTESTINAL	2	2								
				13.SOMATIC GENERAL	1	1								
				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	2	2								
				20.PARANOID	0	0								
				21.OBSESSIONAL/COMPULSIVE	1	1								
				22.Total score	30	30								

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56 Day
2	40	Reboxetine	Male	01.DEPRESSED MOOD	2	2	2	1	1					
				02.GUILT	2	2	2	0	0					
				03.SUICIDE	2	2	1	0	0					
				04.INSOMNIA EARLY	2	2	2	1	1					
				05.INSOMNIA MIDDLE	2	2	1	1	0					
				06.INSOMNIA LATE	2	2	2	1	1					
				07.WORK AND ACTIVITIES	2	2	2	2	2					
				08.RETARDATION	0	0	0	0	0					
				09.AGITATION	1	1	1	1	1					
				10.ANXIETY PSYCHIC	1	1	1	1	1					
				11.ANXIETY SOMATIC	2	2	2	1	2					
				12.SOMATIC GASTROINTESTINAL	0	0	0	1	1					
				13.SOMATIC GENERAL	1	1	2	1	1					
				14.GENITAL SYMPTOMS	1	1	2	1	1					
				15.HYPOCHONDRIASIS	1	1	2	1	1					
				16.LOSS OF WEIGHT	0	0	0	0	0					
				17.INSIGHT	0	0	1	0	0					
				18.DIURNAL VARIATION	1	1	1	2	1					
				19.DEPERSONALIZATION	1	1	1	1	0					
				20.PARANOID	0	0	0	0	0					
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0					
				22.Total score	23	23	25	16	14					
	41	Fluoxetine	Male	01.DEPRESSED MOOD	4	4	4	4	3	3	0	1	0	0
				02.GUILT	1	1	1	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	1	0	0	0	0
				05.INSOMNIA MIDDLE	2	2	0	2	0	0	0	0	1	0
				06.INSOMNIA LATE	2	2	1	2	2	2	0	0	1	0
				07.WORK AND ACTIVITIES	4	4	4	1	3	3	2	2	1	0
				08.RETARDATION	2	2	2	2	1	1	1	1	1	0
				09.AGITATION	0	0	0	0	0	0	0	1	1	0
				10.ANXIETY PSYCHIC	4	4	0	0	0	0	0	0	0	0
				11.ANXIETY SOMATIC	4	4	3	2	1	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	2	1	1	1	2	1	1
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	1
				15.HYPOCHONDRIASIS	1	1	1	2	1	1	1	1	1	1
				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	1	0	0	0	1	0	0	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	30	30	23	21	16	14	8	10	7	6
	42	Reboxetine	Female	01.DEPRESSED MOOD	4	4	2	1	1	1	1	2	1	1
				02.GUILT	3	3	2	1	1	0	0	1	0	0
				03.SUICIDE	2	2	2	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	0	0	2	2	2	2	1	0	0	1

726

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
2	42	Reboxetine	Female	05.INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	0
				06.INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1
				07.WORK AND ACTIVITIES	4	4	2	1	1	1	0	1	1	1
				08.RETARDATION	1	1	1	0	0	0	0	0	0	0
				09.AGITATION	0	0	1	0	0	2	0	0	0	2
				10.ANXIETY PSYCHIC	3	3	2	0	1	1	1	0	1	1
				11.ANXIETY SOMATIC	2	2	1	1	1	1	1	1	0	1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1
				14.GENITAL SYMPTOMS	2	2	2	1	2	1	1	1	1	1
				15.HYPOCHONDRIASIS	2	2	2	0	0	0	1	1	0	0
				16.LOSS OF WEIGHT	2	2	0	0	0	0	0	0	0	0
				17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	1	1	2	1	1	1	1	1	1
				19.DEPERSONALIZATION	1	1	1	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	0	0	0	0	0	0	0
				22.Total score	33	33	28	15	15	16	11	12	9	11
	43	Reboxetine	Female	01.DEPRESSED MOOD	3	3	1	1	1	1	1	1	1	1
				02.GUILT	3	3	1	1	1	0	0	0	0	0
				03.SUICIDE	2	2	1	1	1	1	1	1	1	1
				04.INSOMNIA EARLY	2	2	2	1	1	1	2	1	2	1
				05.INSOMNIA MIDDLE	1	1	2	1	1	1	2	1	1	1
				06.INSOMNIA LATE	1	1	1	0	1	0	1	1	0	0
				07.WORK AND ACTIVITIES	4	4	4	3	2	2	3	3	3	2
				08.RETARDATION	3	3	2	2	0	0	0	0	0	0
				09.AGITATION	0	0	0	0	0	0	0	1	0	0
				10.ANXIETY PSYCHIC	2	2	2	1	2	1	1	2	0	1
				11.ANXIETY SOMATIC	3	3	2	1	1	1	2	1	1	1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	0	0	0	1	0	0
				13.SOMATIC GENERAL	1	1	2	1	1	1	1	1	1	1
				14.GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1
				15.HYPOCHONDRIASIS	3	3	2	2	2	2	2	2	2	2
				16.LOSS OF WEIGHT	0	0	0	1	1	2	1	1	0	0
				17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	1	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	0	0	1	0	1	0	0	1	0	0
				20.PARANOID	0	0	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	2	2	2	2	2	2	2	2	2	2
				22.Total score	33	33	27	20	19	16	20	21	15	14
	44	Fluoxetine	Male	01.DEPRESSED MOOD	4	4	1	1	0	0	1	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	0	1	0	1	0	1		
				05.INSOMNIA MIDDLE	2	2	0	1	0	0	0	0		
				06.INSOMNIA LATE	1	1	1	1	0	0	0	0		
				07.WORK AND ACTIVITIES	3	3	4	3	3	1	1	1		
				08.RETARDATION	1	1	0	1	0	0	0	0		

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
2	44	Fluoxetine	Male	09.AGITATION	0	0	0	1	0	0	0	0		
				10.ANXIETY PSYCHIC	2	2	1	1	1	1	1	1		
				11.ANXIETY SOMATIC	2	2	2	1	1	0	0	0		
				12.SOMATIC GASTROINTESTINAL	0	0	1	1	0	0	0	0		
				13.SOMATIC GENERAL	1	1	0	1	1	1	1	0		
				14.GENITAL SYMPTOMS	2	2	0	0	0	0	0	0		
				15.HYPOCHONDRIASIS	1	1	0	0	0	0	0	0		
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0		
				17.INSIGHT	0	0	0	0	0	0	0	0		
				18.DIURNAL VARIATION	2	2	2	2	1	1	0	0		
				19.DEPERSONALIZATION	2	2	3	1	2	1	1	1		
				20.PARANOID	0	0	0	0	0	0	0	0		
				21.OBSESSIONAL/COMPULSIVE	1	1	1	0	0	0	0	0		
				22.Total score	31	31	17	16	9	6	5	4		
	45	Reboxetine	Female	01.DEPRESSED MOOD	3	3	1	0	1	1	0	0	0	0
				02.GUILT	3	3	1	1	1	1	0	0	0	0
				03.SUICIDE	1	1	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	0	0	0	0	0	1	0	0
				05.INSOMNIA MIDDLE	0	0	0	0	0	0	1	0	0	0
				06.INSOMNIA LATE	1	1	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	2	2	1	1	0	1	0	0
				08.RETARDATION	1	1	0	0	0	0	0	0	0	0
				09.AGITATION	1	1	0	0	0	0	0	1	0	0
				10.ANXIETY PSYCHIC	2	2	0	0	1	1	0	1	1	1
				11.ANXIETY SOMATIC	3	3	1	1	0	0	1	0	1	1
				12.SOMATIC GASTROINTESTINAL	1	1	0	1	0	0	0	1	0	0
				13.SOMATIC GENERAL	2	2	1	1	1	1	1	1	0	0
				14.GENITAL SYMPTOMS	2	2	1	1	2	2	2	1	0	0
				15.HYPOCHONDRIASIS	2	2	1	1	1	1	0	0	0	0
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	1	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	1	1	0	0	0	0	0	0
				19.DEPERSONALIZATION	2	2	1	1	1	1	1	1	0	0
				20.PARANOID	1	1	0	0	0	0	1	1	1	1
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	2	2	1	1	1	1
				22.Total score	33	33	12	11	11	11	8	9	7	7
	47	Fluoxetine	Female	01.DEPRESSED MOOD	3	4	2	1	1	1	0	0	0	0
				02.GUILT	0	0	0	0	0	0	0	0	0	0
				03.SUICIDE	2	1	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	1
				05.INSOMNIA MIDDLE	2	2	1	1	1	0	0	0	0	1
				06.INSOMNIA LATE	2	2	2	1	1	1	1	1	0	1
				07.WORK AND ACTIVITIES	2	2	1	1	0	0	0	0	0	0
				08.RETARDATION	0	1	0	0	0	0	0	0	0	0
				09.AGITATION	1	1	0	1	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	4	3	1	2	0	1	1	1	1	0
				11.ANXIETY SOMATIC	2	3	2	2	1	2	1	1	1	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	0	0	0	0	0

728

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
2	47	Fluoxetine	Female	13.SOMATIC GENERAL	1	1	1	0	0	1	0	0	0	0
				14.GENITAL SYMPTOMS	2	2	1	1	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	1	2	3	1	0	1	0	0	0	0
				16.LOSS OF WEIGHT	2	2	1	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	1	1	2	1	1	1	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	27	29	18	12	5	9	4	4	4	4
	48	Reboxetine	Female	01.DEPRESSED MOOD	3	4	4	3	4	3	3	3	3	3
				02.GUILT	2	2	0	0	0	0	0	0	0	0
				03.SUICIDE	2	2	1	1	1	1	1	0	1	1
				04.INSOMNIA EARLY	2	2	2	1	1	0	0	1	1	1
				05.INSOMNIA MIDDLE	1	1	1	1	1	1	2	1	1	1
				06.INSOMNIA LATE	1	2	1	1	2	2	2	2	2	1
				07.WORK AND ACTIVITIES	3	3	3	2	2	2	2	2	2	2
				08.RETARDATION	1	1	2	1	1	0	0	0	0	0
				09.AGITATION	1	1	0	0	0	1	0	0	1	1
				10.ANXIETY PSYCHIC	4	3	3	1	2	1	1	1	1	3
				11.ANXIETY SOMATIC	2	2	2	2	1	1	2	1	1	1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1
				13.SOMATIC GENERAL	1	2	1	1	1	1	1	1	1	1
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2
				15.HYPOCHONDRIASIS	2	3	3	3	3	3	2	2	2	2
				16.LOSS OF WEIGHT	2	2	0	0	1	0	2	0	0	2
				17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	0	0	1	1	1	2	1	1	1	1
				20.PARANOID	0	0	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	1	1	0	0	0	0	0	0	0	0
				22.Total score	31	34	27	21	24	21	22	18	20	23
	80	Fluoxetine	Male	01.DEPRESSED MOOD	3	3	2	1	0	0	0	0	0	0
				02.GUILT	2	2	0	0	0	0	0	0	0	0
				03.SUICIDE	3	3	1	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	2	2	2	2	1	1	1
				05.INSOMNIA MIDDLE	2	2	2	2	2	1	1	1	1	1
				06.INSOMNIA LATE	2	2	1	2	2	2	1	1	1	0
				07.WORK AND ACTIVITIES	4	4	2	2	2	1	1	1	1	1
				08.RETARDATION	1	1	0	0	0	0	0	0	0	0
				09.AGITATION	2	2	2	1	1	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	0	0	0	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	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	0	0	0
				14.GENITAL SYMPTOMS	1	1	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	2	1	0	0	0	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
2	80	Fluoxetine	Male	17.INSIGHT	1	1	1	1	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	1	1	1	0	0	0	0	0
				19.DEPERSONALIZATION	0	0	0	0	1	0	0	0	0	0
				20.PARANOID	1	1	1	1	1	1	1	1	1	0
				21.OBSESSIONAL/COMPULSIVE	2	2	1	1	2	1	1	1	1	1
				22.Total score	34	34	19	16	15	9	8	6	6	4
3	65	Fluoxetine	Female	01.DEPRESSED MOOD	4	4	4	4	4	2	1	1	2	1
				02.GUILT	0	0	0	0	0	0	0	0	0	0
				03.SUICIDE	1	1	1	1	1	0	0	0	0	0
				04.INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	1	1	2	1	1	1	1	1	1	2
				06.INSOMNIA LATE	2	2	2	2	2	2	1	1	1	1
				07.WORK AND ACTIVITIES	2	2	2	2	2	1	1	2	2	1
				08.RETARDATION	1	1	0	0	0	0	0	0	1	0
				09.AGITATION	0	0	0	0	0	3	0	0	0	0
				10.ANXIETY PSYCHIC	4	4	3	2	2	2	2	1	1	1
				11.ANXIETY SOMATIC	1	1	0	0	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	1	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	0	0	0	0	0	1	0
				14.GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	2	2	2	2	1	1	0	0
				16.LOSS OF WEIGHT	2	2	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	1	1	2	2	2	2	2	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	24	24	19	15	17	15	9	9	11	5
	66	Fluoxetine	Female	01.DEPRESSED MOOD	4	4	4	4	4					
				02.GUILT	2	2	2	2	2					
				03.SUICIDE	2	1	1	1	0					
				04.INSOMNIA EARLY	0	1	2	2	2					
				05.INSOMNIA MIDDLE	2	1	2	2	2					
				06.INSOMNIA LATE	0	1	2	2	1					
				07.WORK AND ACTIVITIES	3	3	2	2	2					
				08.RETARDATION	1	1	1	1	1					
				09.AGITATION	1	0	3	2	1					
				10.ANXIETY PSYCHIC	4	4	3	2	1					
				11.ANXIETY SOMATIC	0	0	1	2	0					
				12.SOMATIC GASTROINTESTINAL	0	0	1	0	0					
				13.SOMATIC GENERAL	1	1	1	1	1					
				14.GENITAL SYMPTOMS	1	1	0	0	0					
				15.HYPOCHONDRIASIS	2	2	2	2	2					
				16.LOSS OF WEIGHT	0	0	2	0	0					
				17.INSIGHT	0	0	0	0	0					
				18.DIURNAL VARIATION	1	1	0	1	1					
				19.DEPERSONALIZATION	2	2	0	0	0					
				20.PARANOID	0	0	0	0	0					

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
3	66	Fluoxetine	Female	21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0					
				22.Total score	26	25	29	26	20					
	67	Reboxetine	Female	01.DEPRESSED MOOD	4	4	3	3	1	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	1	1	0				
				06.INSOMNIA LATE	2	2	1	2	1	0				
				07.WORK AND ACTIVITIES	2	2	2	2	0	0				
				08.RETARDATION	1	2	2	1	0	0				
				09.AGITATION	2	3	2	2	2	0				
				10.ANXIETY PSYCHIC	4	4	3	1	1	0				
				11.ANXIETY SOMATIC	3	3	3	3	2	1				
				12.SOMATIC GASTROINTESTINAL	2	2	1	0	0	0				
				13.SOMATIC GENERAL	2	2	1	0	0	0				
				14.GENITAL SYMPTOMS	2	2	2	2	1	1				
				15.HYPOCHONDRIASIS	3	3	2	2	2	0				
				16.LOSS OF WEIGHT	0	0	1	0	0	0				
				17.INSIGHT	0	0	0	0	0	0				
				18.DIURNAL VARIATION	2	2	2	1	1	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	38	40	33	22	12	2				
	68	Reboxetine	Female	01.DEPRESSED MOOD	4	4	3	1	1	2				
				02.GUILT	2	2	2	2	2	1				
				03.SUICIDE	1	1	1	0	1	0				
				04.INSOMNIA EARLY	2	2	2	2	2	2				
				05.INSOMNIA MIDDLE	2	2	2	2	2	2				
				06.INSOMNIA LATE	1	1	1	2	1	1				
				07.WORK AND ACTIVITIES	4	4	2	2	2	2				
				08.RETARDATION	2	2	2	1	1	1				
				09.AGITATION	1	1	2	0	1	1				
				10.ANXIETY PSYCHIC	4	4	4	4	3	1				
				11.ANXIETY SOMATIC	3	3	3	1	1	1				
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1				
				13.SOMATIC GENERAL	1	1	1	0	1	0				
				14.GENITAL SYMPTOMS	1	1	1	1	1	1				
				15.HYPOCHONDRIASIS	3	3	3	2	0	1				
				16.LOSS OF WEIGHT	2	2	2	1	0	2				
				17.INSIGHT	0	0	0	0	0	0				
				18.DIURNAL VARIATION	2	2	0	2	1	2				
				19.DEPERSONALIZATION	0	0	0	0	0	0				
				20.PARANOID	0	0	0	0	0	0				
				21.OBSESSIONAL/COMPULSIVE	2	2	2	2	2	2				
				22.Total score	38	38	34	26	23	23				

731

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
4	97	Reboxetine	Female	01.DEPRESSED MOOD	1	1	3	3	2	0	0	0	0	0
				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	0	2	2	0	2	0	0	2
				05.INSOMNIA MIDDLE	2	2	2	2	1	1	2	2	2	2
				06.INSOMNIA LATE	2	2	2	2	1	0	0	0	1	1
				07.WORK AND ACTIVITIES	2	2	2	3	1	0	0	0	0	0
				08.RETARDATION	1	1	1	1	0	0	0	0	0	0
				09.AGITATION	0	1	0	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	3	3	3	1	0	0	0	0	0
				11.ANXIETY SOMATIC	2	0	0	3	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	2	2	1	2	0	2	2	2	0	0
				13.SOMATIC GENERAL	2	2	0	2	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	0	3	1	3	0	0	0	0	0	0
				16.LOSS OF WEIGHT	2	2	0	0	0	0	0	0	0	0
				17.INSIGHT	0	0	0	1	1	0	0	0	2	0
				18.DIURNAL VARIATION	2	1	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	1	1	2	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	23	25	17	27	9	3	6	4	5	5
	98	Fluoxetine	Female	01.DEPRESSED MOOD	3	4	3	2	3	4	0	0	0	0
				02.GUILT	0	0	0	0	0	0	0	0	0	0
				03.SUICIDE	3	0	0	0	0	2	2	0	0	0
				04.INSOMNIA EARLY	1	1	2	2	2	1	0	1	2	0
				05.INSOMNIA MIDDLE	0	0	0	2	2	1	0	0	0	0
				06.INSOMNIA LATE	0	0	2	1	1	1	0	0	0	0
				07.WORK AND ACTIVITIES	4	4	3	1	3	3	0	0	0	0
				08.RETARDATION	1	1	0	0	0	0	0	0	0	0
				09.AGITATION	0	2	0	2	4	2	4	0	0	0
				10.ANXIETY PSYCHIC	3	3	3	0	0	0	0	0	0	0
				11.ANXIETY SOMATIC	3	1	2	0	1	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	0	1	1	2	1	0	0	1	1	0
				13.SOMATIC GENERAL	2	2	2	1	2	2	0	0	0	0
				14.GENITAL SYMPTOMS	2	2	0	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	3	2	1	0	0	0	0	0	0	0
				16.LOSS OF WEIGHT	2	2	2	0	2	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	0
				19.DEPERSONALIZATION	3	0	0	0	0	3	0	0	0	0
				20.PARANOID	0	0	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	1	1	1	1	1	0
				22.Total score	30	25	21	13	22	20	7	3	4	0
	99	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	4							
				02.GUILT	1	1	2							
				03.SUICIDE	2	2	2							
				04.INSOMNIA EARLY	2	2	0							

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 12.6

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Day	21 Day	28 Day	35 Day	42 Day	49 Day	56
4	99	Fluoxetine	Female	05.INSOMNIA MIDDLE	2	2	2							
				06.INSOMNIA LATE	0	0	1							
				07.WORK AND ACTIVITIES	2	2	2							
				08.RETARDATION	1	1	1							
				09.AGITATION	3	3	1							
				10.ANXIETY PSYCHIC	3	3	3							
				11.ANXIETY SOMATIC	2	2	1							
				12.SOMATIC GASTROINTESTINAL	0	0	2							
				13.SOMATIC GENERAL	1	1	2							
				14.GENITAL SYMPTOMS	0	0	1							
				15.HYPOCHONDRIASIS	2	2	0							
				16.LOSS OF WEIGHT	1	1	0							
				17.INSIGHT	0	0	0							
				18.DIURNAL VARIATION	0	0	0							
				19.DEPERSONALIZATION	2	2	3							
				20.PARANOID	0	0	0							
				21.OBSESSIONAL/COMPULSIVE	0	0	0							
				22.Total score	27	27	27							
	100	Reboxetine	Male	01.DEPRESSED MOOD	3	4								
				02.GUILT	3	3								
				03.SUICIDE	2	2								
				04.INSOMNIA EARLY	2	2								
				05.INSOMNIA MIDDLE	2	2								
				06.INSOMNIA LATE	2	2								
				07.WORK AND ACTIVITIES	4	4								
				08.RETARDATION	1	1								
				09.AGITATION	0	0								
				10.ANXIETY PSYCHIC	4	3								
				11.ANXIETY SOMATIC	2	2								
				12.SOMATIC GASTROINTESTINAL	2	2								
				13.SOMATIC GENERAL	2	2								
				14.GENITAL SYMPTOMS	1	1								
				15.HYPOCHONDRIASIS	3	2								
				16.LOSS OF WEIGHT	2	2								
				17.INSIGHT	0	0								
				18.DIURNAL VARIATION	0	0								
				19.DEPERSONALIZATION	0	0								
				20.PARANOID	0	0								
				21.OBSESSIONAL/COMPULSIVE	0	0								
				22.Total score	35	34								
	101	Reboxetine	Female	01.DEPRESSED MOOD	2	2	1	2	1	3	3	1	1	3
				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	1	2	0	0	1
				05.INSOMNIA MIDDLE	2	2	2	2	2	1	2	2	0	1
				06.INSOMNIA LATE	0	0	2	0	0	0	1	1	0	0
				07.WORK AND ACTIVITIES	4	4	4	2	0	2	1	0	0	1
				08.RETARDATION	1	1	2	1	0	1	0	0	0	0

733

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
4	101	Reboxetine	Female	09.AGITATION	0	0	0	0	0	3	0	0	0	0
				10.ANXIETY PSYCHIC	1	1	4	3	1	4	4	3	0	3
				11.ANXIETY SOMATIC	3	3	2	2	2	2	2	1	2	1
				12.SOMATIC GASTROINTESTINAL	1	1	2	1	0	1	1	1	1	1
				13.SOMATIC GENERAL	2	2	2	2	0	2	2	1	0	1
				14.GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	1	0	0	2	1	0	0	0
				16.LOSS OF WEIGHT	2	2	0	0	0	2	1	0	0	0
				17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	0	0	0	1	0	0	0	1	2	0
				19.DEPERSONALIZATION	2	2	0	0	0	0	0	0	0	0
				20.PARANOID	1	1	1	1	0	1	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0
				22.Total score	25	25	25	19	8	25	20	11	6	12
	102	Fluoxetine	Female	01.DEPRESSED MOOD	1	1	0	0	3	0	3	2	3	0
				02.GUILT	2	2	0	2	0	0	0	2	2	0
				03.SUICIDE	2	2	0	0	0	0	0	0	2	0
				04.INSOMNIA EARLY	2	2	0	0	0	1	2	1	0	1
				05.INSOMNIA MIDDLE	0	0	2	0	0	0	0	0	0	0
				06.INSOMNIA LATE	2	2	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	4	4	2	1	3	0	3	1	2	3
				08.RETARDATION	1	1	2	0	1	0	1	0	1	0
				09.AGITATION	3	3	0	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	4	4	0	0	3	0	4	4	3	0
				11.ANXIETY SOMATIC	1	1	1	0	1	0	1	0	0	1
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	2	1	0	0	0
				13.SOMATIC GENERAL	2	2	0	0	1	1	2	1	2	1
				14.GENITAL SYMPTOMS	0	0	0	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	1	1	2	0	0	0	0	0	0	0
				16.LOSS OF WEIGHT	0	2	0	0	0	0	0	0	0	0
				17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	1	0	0	0	1	2	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	26	28	9	3	12	5	19	12	16	10
	103	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	4	2	4	4			
				02.GUILT	0	0	0	0	0	0	0			
				03.SUICIDE	2	2	2	2	1	2	2			
				04.INSOMNIA EARLY	2	2	2	2	2	2	2			
				05.INSOMNIA MIDDLE	2	2	2	1	2	2	2			
				06.INSOMNIA LATE	2	2	2	2	1	2	2			
				07.WORK AND ACTIVITIES	4	4	4	4	3	4	3			
				08.RETARDATION	2	2	1	2	1	0	1			
				09.AGITATION	3	3	3	3	0	0	3			
				10.ANXIETY PSYCHIC	3	3	3	3	3	3	4			
				11.ANXIETY SOMATIC	2	2	1	2	1	0	0			
				12.SOMATIC GASTROINTESTINAL	2	2	1	2	1	0	0			

734

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
4	103	Fluoxetine	Female	13.SOMATIC GENERAL	2	2	2	2	2	2	2			
				14.GENITAL SYMPTOMS	2	2	2	0	0	0	0			
				15.HYPOCHONDRIASIS	3	3	3	3	1	0	0			
				16.LOSS OF WEIGHT	0	0	0	2	0	0	0			
				17.INSIGHT	1	1	1	0	0	0	0			
				18.DIURNAL VARIATION	0	0	0	0	0	0	0			
				19.DEPERSONALIZATION	0	0	3	0	1	0	0			
				20.PARANOID	0	0	0	0	0	0	0			
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0			
				22.Total score	35	35	35	34	21	21	25			
	104	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	3	2	2	1	1		
				02.GUILT	0	0	0	0	0	0	0	0		
				03.SUICIDE	1	1	1	1	0	0	0	0		
				04.INSOMNIA EARLY	1	1	0	0	0	1	1	1		
				05.INSOMNIA MIDDLE	0	0	0	0	0	0	0	0		
				06.INSOMNIA LATE	2	2	2	0	0	0	0	0		
				07.WORK AND ACTIVITIES	3	3	3	3	3	3	2	2		
				08.RETARDATION	3	3	2	2	1	1	1	1		
				09.AGITATION	0	0	1	0	0	0	0	0		
				10.ANXIETY PSYCHIC	2	2	2	0	0	0	0	0		
				11.ANXIETY SOMATIC	0	0	1	0	0	0	0	0		
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0		
				13.SOMATIC GENERAL	2	2	2	2	2	2	2	2		
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2	2		
				15.HYPOCHONDRIASIS	0	0	1	1	1	2	1	1		
				16.LOSS OF WEIGHT	2	2	0	0	0	0	0	0		
				17.INSIGHT	0	0	0	0	0	0	0	0		
				18.DIURNAL VARIATION	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	22	20	14	11	13	10	10		
	105	Fluoxetine	Male	01.DEPRESSED MOOD	3	3	4	4	4	3	4	4	3	3
				02.GUILT	1	1	2	1	1	1	1	1	1	1
				03.SUICIDE	1	1	1	1	2	1	1	1	1	1
				04.INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	2
				05.INSOMNIA MIDDLE	1	1	1	1	1	0	0	0	0	0
				06.INSOMNIA LATE	2	2	2	0	2	2	1	0	0	2
				07.WORK AND ACTIVITIES	3	3	3	3	3	3	3	2	2	2
				08.RETARDATION	2	2	1	1	1	1	1	1	1	1
				09.AGITATION	0	0	1	0	1	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	2	0	1	0	0	0	0	0
				11.ANXIETY SOMATIC	3	3	0	0	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	1	0	0	0
				13.SOMATIC GENERAL	1	1	2	2	2	2	2	2	2	2
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	1	2
				15.HYPOCHONDRIASIS	1	1	1	1	1	1	0	1	0	1
				16.LOSS OF WEIGHT	0	0	1	0	1	0	0	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
4	105	Fluoxetine	Male	17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	0	0	0	0	1	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	27	27	25	18	24	18	19	16	13	17
5	129	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	2	2	2				
				02.GUILT	0	1	0	0	0	0				
				03.SUICIDE	3	3	1	1	0	2				
				04.INSOMNIA EARLY	2	2	1	1	1	2				
				05.INSOMNIA MIDDLE	2	2	1	1	0	1				
				06.INSOMNIA LATE	2	2	1	1	0	2				
				07.WORK AND ACTIVITIES	4	4	4	4	4	3				
				08.RETARDATION	0	0	0	0	0	0				
				09.AGITATION	1	1	1	1	1	1				
				10.ANXIETY PSYCHIC	2	2	2	2	2	1				
				11.ANXIETY SOMATIC	3	3	2	2	2	2				
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1				
				13.SOMATIC GENERAL	2	2	2	2	2	1				
				14.GENITAL SYMPTOMS	2	2	2	2	2	2				
				15.HYPOCHONDRIASIS	2	2	2	2	2	2				
				16.LOSS OF WEIGHT	2	2	2	2	0	0				
				17.INSIGHT	0	0	0	0	0	1				
				18.DIURNAL VARIATION	1	1	1	1	1	1				
				19.DEPERSONALIZATION	0	0	0	0	0	0				
				20.PARANOID	0	0	0	0	0	0				
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	0				
				22.Total score	33	34	26	26	21	24				
	130	Fluoxetine	Female	01.DEPRESSED MOOD	4	4	2	3	2	2	3	2	1	0
				02.GUILT	1	2	1	2	1	1	1	1	0	0
				03.SUICIDE	1	1	1	0	0	0	1	0	0	0
				04.INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	0	0	0	1	0	0	0	0	0	0
				06.INSOMNIA LATE	0	0	0	1	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	4	4	4	4	4	4	4	4	4	4
				08.RETARDATION	1	1	1	1	0	1	1	1	0	0
				09.AGITATION	1	1	0	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	1	2	2	2	1	1	2	1	1	0
				11.ANXIETY SOMATIC	2	2	1	1	1	1	1	1	1	1
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	0	0	0	0	1
				13.SOMATIC GENERAL	2	2	1	1	1	1	1	1	1	1
				14.GENITAL SYMPTOMS	2	2	1	1	1	1	1	1	0	0
				15.HYPOCHONDRIASIS	2	2	1	1	1	1	1	1	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	1	1	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	1	1	0	0	0	0	1	0	0	0
				20.PARANOID	1	1	1	1	1	1	1	1	1	1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
5	130	Fluoxetine	Female	21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1
				22.Total score	26	28	18	20	14	15	19	15	11	9
7	193	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	3	2	3	3	2	2	3
				02.GUILT	1	1	1	1	1	1	1	1	1	1
				03.SUICIDE	3	3	2	1	0	1	2	1	1	1
				04.INSOMNIA EARLY	0	0	1	1	1	1	0	1	1	0
				05.INSOMNIA MIDDLE	1	1	1	1	0	0	1	0	0	1
				06.INSOMNIA LATE	2	2	2	1	1	0	0	1	0	0
				07.WORK AND ACTIVITIES	2	2	2	2	2	3	3	2	2	2
				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	2	2	2	2	2	2	1	1	1	1
				11.ANXIETY SOMATIC	1	1	1	1	1	0	1	1	0	1
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	1	1	1	1	0
				13.SOMATIC GENERAL	2	2	1	1	1	1	1	1	1	0
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2
				15.HYPOCHONDRIASIS	2	2	2	1	1	0	0	0	0	1
				16.LOSS OF WEIGHT	1	1	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	0	0	2	2	2	2	1	1	0	0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	0	1	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	1	0	0	1	1
				22.Total score	24	24	22	19	16	19	17	15	13	14
	194	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	3	2	1	2	1	0	0
				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	1	0	1	1	0	0	0
				05.INSOMNIA MIDDLE	0	0	1	1	0	2	1	1	1	0
				06.INSOMNIA LATE	0	0	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	2	3	3	2	2	1	0	0
				08.RETARDATION	0	0	0	0	0	0	0	0	0	0
				09.AGITATION	0	0	0	0	0	1	1	1	0	1
				10.ANXIETY PSYCHIC	1	1	1	2	1	1	2	2	1	0
				11.ANXIETY SOMATIC	3	3	2	2	1	0	1	0	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	1	0	1	0
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1	2	0
				14.GENITAL SYMPTOMS	1	1	1	1	1	0	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	1	1	1	0	0	0	0	0
				16.LOSS OF WEIGHT	1	1	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	1	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	1	1	2	2	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	1	1	0	0	0	0	0	0	0	0
				22.Total score	22	22	17	17	13	11	12	7	5	1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
7	195	Fluoxetine	Male	01.DEPRESSED MOOD	4	4	4	3	3	4	3	4	0	0
				02.GUILT	1	1	1	0	0	1	1	1	1	0
				03.SUICIDE	1	1	1	0	0	1	1	1	0	0
				04.INSOMNIA EARLY	0	0	0	1	1	1	0	1	1	1
				05.INSOMNIA MIDDLE	2	2	1	2	1	1	1	1	1	2
				06.INSOMNIA LATE	1	1	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	4	4	4	4	3	4	3	4	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	2	2	2	0	0	2	1	2	1	1
				11.ANXIETY SOMATIC	1	1	1	0	0	1	1	0	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1
				13.SOMATIC GENERAL	1	1	1	1	0	1	1	1	0	0
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2	1	1	1
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	0
				16.LOSS OF WEIGHT	0	0	0	0	0	0	2	0	0	0
				17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	1	0	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	0	0	0	0	0	0	0	0	0	0
				22.Total score	22	22	18	15	11	20	17	17	7	7
	196	Reboxetine	Female	01.DEPRESSED MOOD	4	4	3	3	3	3	3	4	4	
				02.GUILT	2	2	2	1	1	1	1	1	1	
				03.SUICIDE	2	2	2	2	2	2	1	0	1	
				04.INSOMNIA EARLY	2	2	2	2	2	2	2	2	2	
				05.INSOMNIA MIDDLE	0	1	2	2	2	2	0	0	1	
				06.INSOMNIA LATE	2	2	2	2	2	2	2	1	1	
				07.WORK AND ACTIVITIES	3	3	3	3	3	3	3	3	4	
				08.RETARDATION	1	0	0	0	0	0	0	0	0	
				09.AGITATION	0	0	0	1	1	0	0	0	0	
				10.ANXIETY PSYCHIC	3	3	3	3	3	3	2	2	2	
				11.ANXIETY SOMATIC	3	3	3	2	2	2	3	3	3	
				12.SOMATIC GASTROINTESTINAL	2	1	1	1	1	1	1	1	2	
				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	1	0	0	
				16.LOSS OF WEIGHT	0	0	1	1	0	0	0	1	0	
				17.INSIGHT	0	0	0	0	0	0	0	0	0	
				18.DIURNAL VARIATION	0	0	0	0	1	1	1	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	1	0	1	0	0	0	
				22.Total score	28	27	28	28	27	27	24	22	25	
	197	Fluoxetine	Male	01.DEPRESSED MOOD	3	3								
				02.GUILT	2	2								
				03.SUICIDE	1	1								
				04.INSOMNIA EARLY	1	1								

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
7	197	Fluoxetine	Male	05.INSOMNIA MIDDLE	1	1								
				06.INSOMNIA LATE	1	0								
				07.WORK AND ACTIVITIES	3	3								
				08.RETARDATION	1	1								
				09.AGITATION	2	1								
				10.ANXIETY PSYCHIC	2	2								
				11.ANXIETY SOMATIC	1	2								
				12.SOMATIC GASTROINTESTINAL	1	1								
				13.SOMATIC GENERAL	2	2								
				14.GENITAL SYMPTOMS	1	1								
				15.HYPOCHONDRIASIS	2	1								
				16.LOSS OF WEIGHT	2	0								
				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	27	23								
11	321	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	3	3	2	2	1	0	1
				02.GUILT	2	2	1	3	3	2	0	0	0	0
				03.SUICIDE	2	2	1	2	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	1	1	1	0	0	0	0
				05.INSOMNIA MIDDLE	2	2	2	2	1	1	1	1	0	1
				06.INSOMNIA LATE	2	1	1	0	1	1	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	3	2	2	3	1	1	0	1
				08.RETARDATION	2	2	2	2	0	0	0	0	0	0
				09.AGITATION	0	0	0	0	2	3	2	1	0	0
				10.ANXIETY PSYCHIC	3	3	3	2	2	1	1	0	0	0
				11.ANXIETY SOMATIC	1	1	1	2	0	2	2	0	0	0
				12.SOMATIC GASTROINTESTINAL	2	2	2	1	2	1	1	1	0	0
				13.SOMATIC GENERAL	2	2	2	2	2	2	2	0	0	0
				14.GENITAL SYMPTOMS	2	2	1	1	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	2	2	2	2	1	0	0	0
				16.LOSS OF WEIGHT	0	0	0	1	1	1	1	0	0	0
				17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	2	1	1	1	1	1	0	0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	1	1	1	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	1	1	1	1	1	0	0	0
				22.Total score	32	31	30	29	25	24	16	6	2	7
	322	Reboxetine	Female	01.DEPRESSED MOOD	4	4	3	3	3	2	1	1	1	1
				02.GUILT	2	2	2	2	2	1	2	2	1	2
				03.SUICIDE	2	3	2	1	2	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	1	2	1	1	1	1	1
				05.INSOMNIA MIDDLE	2	2	2	2	2	2	1	1	1	1
				06.INSOMNIA LATE	2	2	2	1	2	2	1	1	1	1
				07.WORK AND ACTIVITIES	3	3	4	2	3	3	1	1	1	1
				08.RETARDATION	2	2	1	2	1	1	0	1	0	1

739

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
11	322	Reboxetine	Female	09.AGITATION	0	0	2	0	2	1	1	1	1	1
				10.ANXIETY PSYCHIC	3	3	1	1	3	2	3	1	1	1
				11.ANXIETY SOMATIC	2	2	2	2	3	1	2	1	1	1
				12.SOMATIC GASTROINTESTINAL	2	2	2	2	2	1	1	2	1	1
				13.SOMATIC GENERAL	2	2	2	2	2	2	1	1	1	1
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2
				15.HYPOCHONDRIASIS	2	2	2	2	2	3	2	2	3	3
				16.LOSS OF WEIGHT	2	2	2	1	0	0	0	0	0	0
				17.INSIGHT	1	1	0	0	1	0	0	0	0	0
				18.DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	2	2	0	1	1	1	1	1	1	1
				20.PARANOID	1	1	1	2	1	1	1	1	1	1
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1
				22.Total score	39	40	35	30	37	27	22	21	19	21
	323	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	1	1	0	0				0
				02.GUILT	3	3	2	1	0	0				0
				03.SUICIDE	2	2	0	0	0	0				0
				04.INSOMNIA EARLY	2	2	1	0	0	0				0
				05.INSOMNIA MIDDLE	2	2	1	1	0	0				0
				06.INSOMNIA LATE	2	2	0	1	0	0				0
				07.WORK AND ACTIVITIES	2	3	1	0	0	0				0
				08.RETARDATION	1	2	1	0	0	0				0
				09.AGITATION	0	0	0	0	0	0				0
				10.ANXIETY PSYCHIC	1	1	1	0	0	0				0
				11.ANXIETY SOMATIC	2	3	1	0	0	0				0
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	0				0
				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	0	0	0				0
				16.LOSS OF WEIGHT	1	1	1	0	0	0				0
				17.INSIGHT	1	1	0	0	0	0				0
				18.DIURNAL VARIATION	1	1	0	0	0	0				0
				19.DEPERSONALIZATION	0	0	0	0	0	0				0
				20.PARANOID	1	1	1	0	0	0				0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	0	0				0
				22.Total score	30	33	17	7	2	2				2
	324	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	3	3	3	1	2	1	1
				02.GUILT	2	2	2	3	1	2	1	0	1	1
				03.SUICIDE	1	1	1	1	0	1	0	0	0	0
				04.INSOMNIA EARLY	2	2	1	2	1	1	1	0	1	0
				05.INSOMNIA MIDDLE	2	2	1	2	0	1	1	1	0	0
				06.INSOMNIA LATE	2	2	2	2	2	1	1	0	1	0
				07.WORK AND ACTIVITIES	2	2	1	3	1	1	1	0	1	0
				08.RETARDATION	0	0	1	1	0	0	0	0	0	0
				09.AGITATION	2	2	2	1	3	3	2	1	2	0
				10.ANXIETY PSYCHIC	3	3	3	4	4	4	1	0	2	2
				11.ANXIETY SOMATIC	2	2	1	2	3	2	1	0	2	1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	0	0	1	1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
11	324	Reboxetine	Female	13.SOMATIC GENERAL	2	2	1	2	2	2	2	0	2	0
				14.GENITAL SYMPTOMS	2	2	1	1	1	1	1	0	0	1
				15.HYPOCHONDRIASIS	3	3	3	3	3	1	1	0	1	2
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	0	0	1	1	1	0	0	0	0	0
				18.DIURNAL VARIATION	1	1	1	1	1	2	1	1	2	1
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	1	1	0	0	1	0	0	0	1	0
				21.OBSESSIONAL/COMPULSIVE	1	1	2	1	1	2	1	1	2	1
				22.Total score	32	32	28	34	29	28	16	6	20	12
	325	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	3	2	1	1	1	0	0
				02.GUILT	2	2	1	1	2	1	1	1	0	2
				03.SUICIDE	1	1	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	1	1	0	1	0	0	0	0
				05.INSOMNIA MIDDLE	2	2	2	1	2	2	0	1	1	1
				06.INSOMNIA LATE	1	2	2	1	2	0	0	0	0	0
				07.WORK AND ACTIVITIES	2	2	3	2	2	1	1	1	0	1
				08.RETARDATION	2	2	2	2	2	1	1	1	1	0
				09.AGITATION	0	0	0	0	1	0	0	0	0	0
				10.ANXIETY PSYCHIC	3	3	3	3	0	1	1	0	2	0
				11.ANXIETY SOMATIC	2	2	2	2	1	2	1	2	0	2
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	0	1	0	0	0	0
				13.SOMATIC GENERAL	2	2	2	2	2	1	1	2	2	0
				14.GENITAL SYMPTOMS	1	1	1	1	0	0	1	0	0	0
				15.HYPOCHONDRIASIS	2	2	1	1	1	1	0	0	1	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	1	1	0	0	1	0	0	0	0	0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	1	1	1	1	1	1	0	0	0	1
				21.OBSESSIONAL/COMPULSIVE	1	2	1	1	2	1	1	1	1	1
				22.Total score	29	31	26	23	21	15	9	10	8	9
	326	Reboxetine	Female	01.DEPRESSED MOOD	2	2	1	0	0	0	0	0	0	0
				02.GUILT	2	2	2	1	0	0	0	0	0	0
				03.SUICIDE	3	3	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	0	0	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	2	2	2	2	0	0	0	0	0	0
				06.INSOMNIA LATE	2	2	2	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	2	2	2	3	1	0	0	0	0	0
				08.RETARDATION	1	1	0	0	0	0	0	0	0	0
				09.AGITATION	1	2	2	2	0	1	0	0	0	0
				10.ANXIETY PSYCHIC	2	3	2	0	0	1	0	0	0	0
				11.ANXIETY SOMATIC	3	3	2	1	2	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	0	0	1	1	0	0	0	0	0	0
				13.SOMATIC GENERAL	2	2	2	2	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	1	1	1	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	1	1	1	1	0	0	0	0
				16.LOSS OF WEIGHT	0	0	0	1	1	0	0	0	0	0

741

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
11	326	Reboxetine	Female	17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	1	1	2	1	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	1	1	1	1	2	1	0	0	0	0
				22.Total score	29	31	22	17	8	4	0	0	0	0
	327	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	1	2	1	1				
				02.GUILT	1	1	2	2	1	0				
				03.SUICIDE	1	1	0	0	0	0				
				04.INSOMNIA EARLY	0	0	0	0	0	0				
				05.INSOMNIA MIDDLE	1	1	2	0	0	0				
				06.INSOMNIA LATE	2	2	0	0	0	0				
				07.WORK AND ACTIVITIES	2	3	2	2	1	0				
				08.RETARDATION	2	2	2	1	1	0				
				09.AGITATION	0	0	0	1	0	0				
				10.ANXIETY PSYCHIC	2	2	1	1	1	1				
				11.ANXIETY SOMATIC	1	1	1	0	0	1				
				12.SOMATIC GASTROINTESTINAL	0	0	1	1	1	0				
				13.SOMATIC GENERAL	2	2	2	0	0	0				
				14.GENITAL SYMPTOMS	0	0	0	0	1	1				
				15.HYPOCHONDRIASIS	3	3	1	1	1	0				
				16.LOSS OF WEIGHT	0	0	0	0	0	0				
				17.INSIGHT	1	1	0	0	0	0				
				18.DIURNAL VARIATION	1	1	1	1	1	1				
				19.DEPERSONALIZATION	0	0	0	0	0	0				
				20.PARANOID	2	2	1	2	1	0				
				21.OBSESSIONAL/COMPULSIVE	2	2	2	2	1	1				
				22.Total score	26	27	19	16	11	6				
	328	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	2	3	2	1	1	0	0	0
				02.GUILT	2	2	1	2	2	0	1	0	0	0
				03.SUICIDE	1	1	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	0	1	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	2	2	1	1	1	1	1	2	1	1
				06.INSOMNIA LATE	2	2	0	1	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	2	2	2	2	3	1	0	0	0	0
				08.RETARDATION	1	1	2	1	2	1	0	0	0	0
				09.AGITATION	1	1	0	0	1	0	1	1	0	0
				10.ANXIETY PSYCHIC	2	2	2	2	1	1	0	0	0	0
				11.ANXIETY SOMATIC	2	2	0	1	1	1	2	0	1	0
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	1	0	0	0	0	0
				13.SOMATIC GENERAL	2	2	2	2	2	2	0	0	0	0
				14.GENITAL SYMPTOMS	1	1	0	1	1	1	1	0	0	0
				15.HYPOCHONDRIASIS	2	2	1	1	1	1	2	1	0	1
				16.LOSS OF WEIGHT	0	0	0	0	1	0	0	0	0	0
				17.INSIGHT	1	1	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	2	2	2	0	1	0	0	0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	1	1	1	1	1	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
11	328	Fluoxetine	Female	21.OBSESSIONAL/COMPULSIVE	2	2	1	2	2	1	1	1	1	0
				22.Total score	30	30	17	23	24	12	12	5	3	2
	329	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	1	2	0	2	1	0	0
				02.GUILT	2	2	2	1	2	0	2	0	1	0
				03.SUICIDE	3	3	1	1	1	0	1	0	0	0
				04.INSOMNIA EARLY	2	2	2	2	1	0	1	0	0	0
				05.INSOMNIA MIDDLE	2	2	2	2	1	0	1	0	0	0
				06.INSOMNIA LATE	2	2	2	1	1	0	2	0	0	0
				07.WORK AND ACTIVITIES	2	2	1	1	0	0	1	0	0	0
				08.RETARDATION	1	1	1	0	0	0	1	0	0	0
				09.AGITATION	2	2	1	2	0	0	0	0	2	0
				10.ANXIETY PSYCHIC	2	2	4	2	2	0	1	0	1	1
				11.ANXIETY SOMATIC	1	1	1	1	2	1	1	1	2	1
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	1	0	1	0
				13.SOMATIC GENERAL	2	2	2	1	1	0	2	0	0	1
				14.GENITAL SYMPTOMS	1	1	1	1	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	1	1	1	1	2	1	2	0	1	1
				16.LOSS OF WEIGHT	0	0	0	0	0	1	1	0	0	0
				17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	2	2	2	2	2	1	0	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	1	1	1	1	2	0	2	0	0	0
				22.Total score	30	30	27	20	19	5	23	3	8	5
	330	Reboxetine	Male	01.DEPRESSED MOOD	3	3	3	2	3	2	2	2	2	
				02.GUILT	3	3	2	3	1	2	2	2	2	
				03.SUICIDE	2	2	0	0	1	1	1	1	1	
				04.INSOMNIA EARLY	1	1	2	1	0	0	0	0	0	
				05.INSOMNIA MIDDLE	2	2	2	1	1	1	1	1	1	
				06.INSOMNIA LATE	2	2	2	1	1	1	1	0	0	
				07.WORK AND ACTIVITIES	0	0	2	1	1	1	1	2	2	
				08.RETARDATION	0	0	1	0	1	1	1	0	0	
				09.AGITATION	3	3	0	2	0	0	0	1	1	
				10.ANXIETY PSYCHIC	3	3	3	1	3	2	1	2	2	
				11.ANXIETY SOMATIC	0	0	1	1	1	2	1	1	1	
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	
				13.SOMATIC GENERAL	0	0	2	2	1	1	1	2	2	
				14.GENITAL SYMPTOMS	2	2	1	2	1	2	2	1	1	
				15.HYPOCHONDRIASIS	2	2	2	1	2	2	2	1	1	
				16.LOSS OF WEIGHT	0	0	0	1	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	1	1	0	0	0	0	0	0	0	
				21.OBSESSIONAL/COMPULSIVE	2	2	1	2	1	2	2	2	2	
				22.Total score	27	27	25	22	19	21	19	19	19	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
11	331	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	1	1	0	0	0	0	0
				02.GUILT	2	2	2	1	1	0	0	0	0	0
				03.SUICIDE	1	1	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	0	0	0	0	0	0	0	1
				05.INSOMNIA MIDDLE	2	2	1	1	0	0	0	0	0	0
				06.INSOMNIA LATE	2	2	1	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	2	1	1	0	1	1	0	0
				08.RETARDATION	1	1	2	0	0	0	0	0	0	0
				09.AGITATION	2	2	0	1	1	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	2	1	1	0	0	0	0	0
				11.ANXIETY SOMATIC	2	2	1	2	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	0	0	0	0
				13.SOMATIC GENERAL	2	2	2	0	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	2	2	1	1	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	1	1	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	1	1	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	1	2	1	1	0	0	0	0	0	0
				22.Total score	32	33	22	13	7	2	1	1	0	1
	332	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	1	1	0	0	0	0	0
				02.GUILT	2	2	2	1	1	1	0	0	0	0
				03.SUICIDE	0	0	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	1	1	1	1	1	1	1
				05.INSOMNIA MIDDLE	2	2	2	1	0	0	1	1	0	0
				06.INSOMNIA LATE	0	0	1	0	1	1	1	0	0	0
				07.WORK AND ACTIVITIES	3	3	2	1	1	1	0	0	1	0
				08.RETARDATION	2	2	2	1	2	1	1	0	1	0
				09.AGITATION	1	1	0	0	0	0	0	1	0	0
				10.ANXIETY PSYCHIC	2	2	1	1	0	0	0	1	0	0
				11.ANXIETY SOMATIC	2	2	1	0	0	0	1	2	0	0
				12.SOMATIC GASTROINTESTINAL	2	2	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	2	2	2	1	1	0	0	0	0	0
				14.GENITAL SYMPTOMS	1	1	1	0	0	1	1	0	0	0
				15.HYPOCHONDRIASIS	1	1	1	1	1	0	0	0	0	0
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	1	0	0
				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	1	1	1	0	0	0	0	0
				22.Total score	26	26	22	11	11	7	7	8	4	2
	333	Reboxetine	Female	01.DEPRESSED MOOD	3	2	3	2	2	1	0	1	0	0
				02.GUILT	3	3	3	3	1	2	1	1	1	1
				03.SUICIDE	1	1	1	1	0	0	0	0	0	0
				04.INSOMNIA EARLY	0	0	2	0	0	0	0	0	0	0

744

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
11	333	Reboxetine	Female	05.INSOMNIA MIDDLE	2	2	2	2	2	0	0	0	0	0
				06.INSOMNIA LATE	2	2	2	2	0	1	0	0	0	0
				07.WORK AND ACTIVITIES	2	2	2	2	1	1	1	0	0	0
				08.RETARDATION	1	1	1	1	0	0	1	0	0	0
				09.AGITATION	0	0	1	1	1	2	0	1	1	0
				10.ANXIETY PSYCHIC	1	2	2	0	1	1	0	0	1	0
				11.ANXIETY SOMATIC	2	2	2	1	2	2	2	1	2	1
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	1	0
				13.SOMATIC GENERAL	2	2	2	2	2	2	2	1	1	0
				14.GENITAL SYMPTOMS	1	2	1	1	1	1	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	1	1	1	2	1	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	2	2	2	1	1	1	2	1	1	0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	1	0	0	0	1	0	0	0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	0	1	1	0	0	1
				22.Total score	26	27	29	21	15	17	12	6	8	5
743	334	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	1	1	1	1	1	1	1
				02.GUILT	2	2	2	0	0	0	1	1	1	1
				03.SUICIDE	1	1	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	0	0	0	1	0	0	0	0
				05.INSOMNIA MIDDLE	2	2	1	0	2	1	0	1	0	1
				06.INSOMNIA LATE	2	2	1	0	1	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	3	2	2	2	1	0	1	0
				08.RETARDATION	0	0	1	0	0	0	0	0	0	0
				09.AGITATION	2	2	0	2	2	2	2	1	1	0
				10.ANXIETY PSYCHIC	2	2	1	0	2	2	0	0	0	0
				11.ANXIETY SOMATIC	3	3	3	2	2	2	1	2	2	2
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	1	0	0	0
				13.SOMATIC GENERAL	2	2	2	1	0	2	0	2	2	1
				14.GENITAL SYMPTOMS	1	1	1	1	0	1	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	2	1	1	2	1	0	2	1
				16.LOSS OF WEIGHT	0	0	0	0	1	0	1	0	0	0
				17.INSIGHT	1	1	1	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	2	2	0	1	1	1	1	0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	0	0	1	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	1	1	1	1	1	1	1	1
				22.Total score	30	30	24	13	16	18	11	10	12	10
	335	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	2	2	2	2			
				02.GUILT	3	2	2	2	1	2	2			
				03.SUICIDE	1	1	0	1	0	1	1			
				04.INSOMNIA EARLY	1	1	1	0	0	0	0			
				05.INSOMNIA MIDDLE	2	1	0	0	0	0	0			
				06.INSOMNIA LATE	2	2	2	1	0	2	0			
				07.WORK AND ACTIVITIES	2	2	1	1	2	2	2			
				08.RETARDATION	1	2	2	2	1	1	1			

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
11	335	Reboxetine	Female	09.AGITATION	0	1	1	1	0	1	2			
				10.ANXIETY PSYCHIC	2	2	1	1	1	2	1			
				11.ANXIETY SOMATIC	2	1	2	2	1	1	1			
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	0			
				13.SOMATIC GENERAL	2	2	2	1	2	2	1			
				14.GENITAL SYMPTOMS	1	2	1	0	1	0	0			
				15.HYPOCHONDRIASIS	2	1	1	1	0	0	1			
				16.LOSS OF WEIGHT	1	1	1	1	0	1	1			
				17.INSIGHT	0	0	0	0	0	0	0			
				18.DIURNAL VARIATION	1	1	1	1	1	1	1			
				19.DEPERSONALIZATION	0	0	0	0	0	0	0			
				20.PARANOID	1	1	1	1	0	0	0			
				21.OBSESSIONAL/COMPULSIVE	2	1	1	1	1	1	0			
				22.Total score	30	28	24	20	14	20	16			
12	393	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	2	2	2	1	1	2	0	1
				02.GUILT	1	1	1	1	0	0	0	0	0	0
				03.SUICIDE	2	2	1	0	1	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	1	2	0	1	1	0	1	1
				05.INSOMNIA MIDDLE	2	2	2	1	1	1	1	2	2	1
				06.INSOMNIA LATE	1	1	2	1	2	1	0	2	1	1
				07.WORK AND ACTIVITIES	3	3	2	2	2	2	2	2	1	2
				08.RETARDATION	2	2	2	1	1	1	1	2	1	1
				09.AGITATION	1	1	0	1	2	2	1	2	1	2
				10.ANXIETY PSYCHIC	3	3	2	2	1	2	2	2	1	1
				11.ANXIETY SOMATIC	0	0	1	0	0	0	1	1	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	0	1	0	0
				13.SOMATIC GENERAL	1	1	1	1	0	1	1	1	1	1
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	1	2
				15.HYPOCHONDRIASIS	4	4	0	1	1	1	0	1	0	0
				16.LOSS OF WEIGHT	0	0	0	0	1	0	0	0	0	1
				17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	0	0	2	2	2	3	2	2	2	1
				20.PARANOID	0	0	0	1	1	0	1	0	0	0
				21.OBSESSIONAL/COMPULSIVE	2	2	2	2	2	2	2	2	2	2
				22.Total score	29	29	24	23	22	20	18	24	15	17
	394	Reboxetine	Male	01.DEPRESSED MOOD	3	3	3	2	1	2	2	3	1	3
				02.GUILT	1	1	0	1	0	1	1	1	1	1
				03.SUICIDE	1	1	1	1	0	1	1	1	1	1
				04.INSOMNIA EARLY	2	2	2	2	2	2	2	2	1	2
				05.INSOMNIA MIDDLE	1	1	1	1	1	1	1	2	1	1
				06.INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1
				07.WORK AND ACTIVITIES	2	2	2	2	1	2	2	2	2	2
				08.RETARDATION	2	2	2	1	1	1	2	2	1	2
				09.AGITATION	1	1	2	1	2	2	2	2	2	1
				10.ANXIETY PSYCHIC	2	2	2	1	2	3	3	1	1	3
				11.ANXIETY SOMATIC	0	0	1	1	0	1	1	2	1	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	1	0	1	0	0

9550083

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
12	394	Reboxetine	Male	13.SOMATIC GENERAL	2	2	1	1	0	0	1	1	1	0
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2
				15.HYPOCHONDRIASIS	1	1	0	0	1	0	1	1	0	0
				16.LOSS OF WEIGHT	1	1	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	0
				19.DEPERSONALIZATION	0	0	2	0	1	2	2	2	1	2
				20.PARANOID	1	1	1	1	1	0	1	0	0	2
				21.OBSESSIONAL/COMPULSIVE	2	2	2	2	2	2	2	2	2	2
				22.Total score	26	26	26	20	18	24	27	28	19	25
	395	Reboxetine	Male	01.DEPRESSED MOOD	2	2	2	2	1	1	1	1	1	1
				02.GUILT	1	1	1	1	0	0	0	1	1	1
				03.SUICIDE	1	1	1	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	1	1	1	0	0	0	0	1
				05.INSOMNIA MIDDLE	1	1	1	1	0	0	1	1	0	1
				06.INSOMNIA LATE	1	1	1	0	0	0	0	1	0	0
				07.WORK AND ACTIVITIES	2	2	2	1	1	2	2	2	2	1
				08.RETARDATION	1	1	1	0	0	1	0	1	1	0
				09.AGITATION	2	2	2	1	1	1	1	1	1	2
				10.ANXIETY PSYCHIC	2	2	2	1	1	1	2	1	1	1
				11.ANXIETY SOMATIC	2	2	1	1	1	1	2	2	0	1
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	0	1	0	0	0
				13.SOMATIC GENERAL	2	2	1	1	0	1	0	1	1	0
				14.GENITAL SYMPTOMS	2	2	1	1	1	1	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	1	0	0	1	0	0	1	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	1	1	0	0	1	1	1	1
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0	0	0
				20.PARANOID	0	0	1	0	0	0	0	0	1	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	1	1	1	0
				22.Total score	25	25	21	12	7	10	12	14	12	10
	396	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	3						
				02.GUILT	2	2	2	2						
				03.SUICIDE	2	2	2	2						
				04.INSOMNIA EARLY	2	2	2	2						
				05.INSOMNIA MIDDLE	1	1	1	2						
				06.INSOMNIA LATE	1	1	2	1						
				07.WORK AND ACTIVITIES	2	2	2	2						
				08.RETARDATION	2	2	1	2						
				09.AGITATION	2	2	2	2						
				10.ANXIETY PSYCHIC	1	1	3	3						
				11.ANXIETY SOMATIC	0	0	2	2						
				12.SOMATIC GASTROINTESTINAL	1	1	1	1						
				13.SOMATIC GENERAL	1	1	1	1						
				14.GENITAL SYMPTOMS	2	2	2	2						
				15.HYPOCHONDRIASIS	2	2	0	0						
				16.LOSS OF WEIGHT	0	0	0	1						

747

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
12	396	Fluoxetine	Female	17.INSIGHT	0	0	0	0						
				18.DIURNAL VARIATION	1	1	1	0						
				19.DEPERSONALIZATION	2	2	1	1						
				20.PARANOID	1	1	1	1						
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0						
				22.Total score	28	28	29	30						
	497	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	3	3	3	3	3	3	3
				02.GUILT	2	2	2	1	2	2	1	1	2	1
				03.SUICIDE	2	2	1	2	1	2	1	1	1	1
				04.INSOMNIA EARLY	1	1	1	0	2	1	2	0	2	2
				05.INSOMNIA MIDDLE	2	2	0	2	1	1	1	0	1	1
				06.INSOMNIA LATE	1	1	0	1	1	0	0	1	0	1
				07.WORK AND ACTIVITIES	2	2	2	2	2	2	2	2	2	2
				08.RETARDATION	2	2	1	2	2	2	1	1	1	1
				09.AGITATION	2	2	2	2	2	2	2	1	2	2
				10.ANXIETY PSYCHIC	2	2	2	3	2	1	2	2	2	1
				11.ANXIETY SOMATIC	2	2	2	1	1	1	1	2	2	1
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	1	0	0
				13.SOMATIC GENERAL	2	2	1	1	1	2	1	1	1	1
				14.GENITAL SYMPTOMS	1	1	2	2	2	2	2	1	2	2
				15.HYPOCHONDRIASIS	2	2	2	2	2	1	0	0	0	1
				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	0
				19.DEPERSONALIZATION	2	2	0	0	1	0	0	1	1	0
				20.PARANOID	2	2	1	1	1	1	1	1	1	1
				21.OBSESSIONAL/COMPULSIVE	2	2	1	2	1	0	0	1	2	2
				22.Total score	32	32	23	27	27	23	20	20	25	23
13	385	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	2	1	1		1		1
				02.GUILT	1	1	1	1	0	0		1		0
				03.SUICIDE	2	2	2	1	0	0		0		0
				04.INSOMNIA EARLY	1	1	1	1	1	0		0		1
				05.INSOMNIA MIDDLE	1	1	1	1	0	1		1		0
				06.INSOMNIA LATE	0	0	0	0	0	0		1		0
				07.WORK AND ACTIVITIES	3	3	3	2	2	2		2		0
				08.RETARDATION	2	2	2	2	0	1		0		0
				09.AGITATION	2	2	0	0	2	0		0		1
				10.ANXIETY PSYCHIC	2	2	2	2	2	1		0		1
				11.ANXIETY SOMATIC	2	2	2	2	1	1		0		1
				12.SOMATIC GASTROINTESTINAL	1	1	2	1	1	0		1		0
				13.SOMATIC GENERAL	2	2	2	2	1	2		2		0
				14.GENITAL SYMPTOMS	1	1	0	0	1	0		1		0
				15.HYPOCHONDRIASIS	1	1	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	0	0	0	0	0	0		0		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	1	1	1	1	0	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
13	385	Fluoxetine	Female	21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0		0		0
				22.Total score	25	25	23	18	12	9		10		5
	386	Fluoxetine	Male	01.DEPRESSED MOOD	3	3	3							
				02.GUILT	2	2	3							
				03.SUICIDE	2	2	3							
				04.INSOMNIA EARLY	2	2	2							
				05.INSOMNIA MIDDLE	2	2	2							
				06.INSOMNIA LATE	2	2	2							
				07.WORK AND ACTIVITIES	3	3	3							
				08.RETARDATION	1	1	0							
				09.AGITATION	3	3	3							
				10.ANXIETY PSYCHIC	3	2	3							
				11.ANXIETY SOMATIC	2	2	2							
				12.SOMATIC GASTROINTESTINAL	2	2	2							
				13.SOMATIC GENERAL	2	2	2							
				14.GENITAL SYMPTOMS	2	2	2							
				15.HYPOCHONDRIASIS	0	0	1							
				16.LOSS OF WEIGHT	2	2	2							
				17.INSIGHT	0	0	1							
				18.DIURNAL VARIATION	1	1	2							
				19.DEPERSONALIZATION	0	0	1							
				20.PARANOID	0	0	0							
				21.OBSESSIONAL/COMPULSIVE	0	0	0							
				22.Total score	34	33	39							
	387	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	1	1	0				
				02.GUILT	2	1	2	1	1	0				
				03.SUICIDE	2	2	1	0	1	0				
				04.INSOMNIA EARLY	2	2	2	1	1	0				
				05.INSOMNIA MIDDLE	2	1	1	1	1	1				
				06.INSOMNIA LATE	2	2	2	2	0	1				
				07.WORK AND ACTIVITIES	2	3	2	1	1	0				
				08.RETARDATION	1	1	1	1	0	0				
				09.AGITATION	2	2	1	1	1	1				
				10.ANXIETY PSYCHIC	2	2	2	1	1	1				
				11.ANXIETY SOMATIC	1	3	1	2	1	1				
				12.SOMATIC GASTROINTESTINAL	2	1	1	2	1	1				
				13.SOMATIC GENERAL	2	1	1	1	1	1				
				14.GENITAL SYMPTOMS	2	1	0	0	1	0				
				15.HYPOCHONDRIASIS	2	2	1	1	2	1				
				16.LOSS OF WEIGHT	2	1	1	0	0	0				
				17.INSIGHT	0	0	0	0	0	0				
				18.DIURNAL VARIATION	1	1	2	1	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	32	29	23	17	14	8				

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
13	388	Reboxetine	Male	01.DEPRESSED MOOD	3	3	3	2	2	2		1		1
				02.GUILT	1	1	2	1	0	1		1		1
				03.SUICIDE	2	2	3	1	1	1		1		1
				04.INSOMNIA EARLY	2	2	2	1	1	1		1		1
				05.INSOMNIA MIDDLE	1	1	2	1	1	1		1		0
				06.INSOMNIA LATE	2	2	2	1	1	1		1		1
				07.WORK AND ACTIVITIES	2	2	3	2	1	2		2		1
				08.RETARDATION	0	0	1	0	0	0		0		0
				09.AGITATION	2	2	3	2	1	2		2		1
				10.ANXIETY PSYCHIC	2	2	3	2	1	2		1		1
				11.ANXIETY SOMATIC	2	2	2	1	1	2		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	0	0		1		0
				13.SOMATIC GENERAL	1	1	2	1	1	1		1		1
				14.GENITAL SYMPTOMS	1	1	0	1	1	1		1		1
				15.HYPOCHONDRIASIS	0	0	0	0	0	0		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	1	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	0	0	0	0	0	0		0		0
				22.Total score	24	24	30	17	13	17		15		11
	389	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3							
				02.GUILT	2	2	2							
				03.SUICIDE	3	3	2							
				04.INSOMNIA EARLY	2	2	2							
				05.INSOMNIA MIDDLE	2	2	1							
				06.INSOMNIA LATE	2	2	2							
				07.WORK AND ACTIVITIES	2	2	2							
				08.RETARDATION	2	2	2							
				09.AGITATION	2	2	1							
				10.ANXIETY PSYCHIC	2	2	2							
				11.ANXIETY SOMATIC	2	2	2							
				12.SOMATIC GASTROINTESTINAL	2	2	2							
				13.SOMATIC GENERAL	2	2	1							
				14.GENITAL SYMPTOMS	1	1	1							
				15.HYPOCHONDRIASIS	0	0	0							
				16.LOSS OF WEIGHT	2	2	1							
				17.INSIGHT	0	0	0							
				18.DIURNAL VARIATION	0	0	0							
				19.DEPERSONALIZATION	2	2	1							
				20.PARANOID	1	1	1							
				21.OBSESSIONAL/COMPULSIVE	0	0	0							
				22.Total score	34	34	28							
	390	Reboxetine	Male	01.DEPRESSED MOOD	3	3	2	2	1	1		1		1
				02.GUILT	2	2	2	1	1	1		1		0
				03.SUICIDE	3	3	2	1	1	0		0		0
				04.INSOMNIA EARLY	1	1	2	1	2	2		2		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
13	390	Reboxetine	Male	05.INSOMNIA MIDDLE	1	1	1	1	2	2		1		1
				06.INSOMNIA LATE	1	1	1	1	2	2		1		1
				07.WORK AND ACTIVITIES	2	2	2	2	3	2		2		0
				08.RETARDATION	2	2	1	1	0	0		0		0
				09.AGITATION	1	1	1	0	1	1		1		0
				10.ANXIETY PSYCHIC	1	1	1	2	1	1		1		1
				11.ANXIETY SOMATIC	1	1	1	0	1	1		1		0
				12.SOMATIC GASTROINTESTINAL	2	2	2	1	1	1		1		0
				13.SOMATIC GENERAL	1	1	2	1	1	0		1		1
				14.GENITAL SYMPTOMS	2	2	2	1	1	1		2		0
				15.HYPOCHONDRIASIS	0	0	0	0	0	0		0		0
				16.LOSS OF WEIGHT	1	1	1	0	1	2		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	0	0	1	1	2	1		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	0	0	0	0		0		0
				22.Total score	25	25	24	16	21	18		15		5
	391	Fluoxetine	Female	01.DEPRESSED MOOD	2	3	1	1	0	0	0			
				02.GUILT	2	1	0	0	0	0	0			
				03.SUICIDE	2	1	0	0	0	0	0			
				04.INSOMNIA EARLY	2	1	2	1	2	2	1			
				05.INSOMNIA MIDDLE	2	1	1	2	2	1	1			
				06.INSOMNIA LATE	1	1	0	0	0	0	1			
				07.WORK AND ACTIVITIES	2	2	3	1	0	1	1			
				08.RETARDATION	2	2	0	0	0	0	0			
				09.AGITATION	0	1	0	1	0	0	1			
				10.ANXIETY PSYCHIC	2	2	1	0	0	0	1			
				11.ANXIETY SOMATIC	2	2	1	0	1	1	0			
				12.SOMATIC GASTROINTESTINAL	2	1	0	0	0	0	0			
				13.SOMATIC GENERAL	2	1	1	0	0	0	0			
				14.GENITAL SYMPTOMS	2	1	1	2	2	1	0			
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	0			
				16.LOSS OF WEIGHT	1	1	0	0	2	0	0			
				17.INSIGHT	0	0	0	0	0	0	0			
				18.DIURNAL VARIATION	1	1	1	0	0	0	0			
				19.DEPERSONALIZATION	0	0	0	0	0	0	0			
				20.PARANOID	0	0	0	0	0	0	0			
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0			
				22.Total score	27	22	12	8	9	6	6			
	392	Reboxetine	Female	01.DEPRESSED MOOD	4	4	2	3						
				02.GUILT	2	2	2	2						
				03.SUICIDE	1	1	2	2						
				04.INSOMNIA EARLY	1	1	2	1						
				05.INSOMNIA MIDDLE	1	0	2	2						
				06.INSOMNIA LATE	2	0	2	2						
				07.WORK AND ACTIVITIES	3	3	2	2						
				08.RETARDATION	2	2	2	1						

751

9550083

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
13	392	Reboxetine	Female	09.AGITATION	0	0	0	1						
				10.ANXIETY PSYCHIC	3	3	2	2						
				11.ANXIETY SOMATIC	0	0	2	1						
				12.SOMATIC GASTROINTESTINAL	1	1	1	1						
				13.SOMATIC GENERAL	1	1	1	2						
				14.GENITAL SYMPTOMS	0	0	1	1						
				15.HYPOCHONDRIASIS	0	0	0	0						
				16.LOSS OF WEIGHT	2	2	0	0						
				17.INSIGHT	0	0	0	0						
				18.DIURNAL VARIATION	0	1	1	1						
				19.DEPERSONALIZATION	1	0	0	0						
				20.PARANOID	0	1	0	0						
				21.OBSESSIONAL/COMPULSIVE	1	1	0	0						
				22.Total score	25	23	24	24						
	501	Reboxetine	Male	01.DEPRESSED MOOD	3	3	2	2	1	1	1			1
				02.GUILT	1	1	1	1	1	1	0			1
				03.SUICIDE	1	1	1	1	1	1	0			1
				04.INSOMNIA EARLY	2	1	1	1	1	0	0			2
				05.INSOMNIA MIDDLE	2	2	2	1	1	2	1			0
				06.INSOMNIA LATE	2	2	2	1	2	0	1			0
				07.WORK AND ACTIVITIES	2	2	2	1	2	1	1			1
				08.RETARDATION	2	2	2	1	2	1	1			1
				09.AGITATION	0	0	0	0	0	0	0			0
				10.ANXIETY PSYCHIC	2	2	2	1	2	1	1			1
				11.ANXIETY SOMATIC	1	1	2	1	1	1	1			0
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	1	0	0			0
				13.SOMATIC GENERAL	1	1	2	1	1	1	1			0
				14.GENITAL SYMPTOMS	2	2	2	1	2	1	1			0
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	0			0
				16.LOSS OF WEIGHT	1	1	0	0	0	0	0			0
				17.INSIGHT	0	0	0	0	0	0	0			0
				18.DIURNAL VARIATION	1	1	2	1	0	1	1			0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0			0
				20.PARANOID	1	1	0	0	0	0	0			0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0			0
				22.Total score	25	24	23	14	18	12	10			8
	502	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	2	3	1	2	1			1
				02.GUILT	1	1	1	1	1	1	1			0
				03.SUICIDE	3	3	0	1	1	1	1			0
				04.INSOMNIA EARLY	0	0	0	1	1	1	0			0
				05.INSOMNIA MIDDLE	2	2	1	1	1	1	1			1
				06.INSOMNIA LATE	2	2	1	1	1	1	2			1
				07.WORK AND ACTIVITIES	2	2	1	2	2	1	0			0
				08.RETARDATION	0	0	1	1	0	2	1			0
				09.AGITATION	1	1	1	2	2	0	0			0
				10.ANXIETY PSYCHIC	2	2	1	2	2	1	1			0
				11.ANXIETY SOMATIC	2	2	1	1	2	1	0			0
				12.SOMATIC GASTROINTESTINAL	1	1	2	1	1	1	1			0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
13	502	Fluoxetine	Female	13.SOMATIC GENERAL	1	1	1	1	1	2		1		0
				14.GENITAL SYMPTOMS	2	2	1	1	1	2		1		2
				15.HYPOCHONDRIASIS	0	0	0	0	0	0		0		0
				16.LOSS OF WEIGHT	0	0	1	0	0	0		0		2
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	1	0	0	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	23	16	19	17	18		12		7
	503	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2							
				02.GUILT	1	1	0							
				03.SUICIDE	1	1	1							
				04.INSOMNIA EARLY	1	1	0							
				05.INSOMNIA MIDDLE	1	1	1							
				06.INSOMNIA LATE	2	2	2							
				07.WORK AND ACTIVITIES	2	2	1							
				08.RETARDATION	2	2	1							
				09.AGITATION	0	0	0							
				10.ANXIETY PSYCHIC	2	2	1							
				11.ANXIETY SOMATIC	2	2	1							
				12.SOMATIC GASTROINTESTINAL	2	2	2							
				13.SOMATIC GENERAL	2	2	2							
				14.GENITAL SYMPTOMS	2	2	2							
				15.HYPOCHONDRIASIS	0	0	0							
				16.LOSS OF WEIGHT	1	1	0							
				17.INSIGHT	0	0	0							
				18.DIURNAL VARIATION	1	1	1							
				19.DEPERSONALIZATION	0	0	0							
				20.PARANOID	0	0	0							
				21.OBSESSIONAL/COMPULSIVE	0	0	0							
				22.Total score	25	25	17							
	504	Fluoxetine	Female	01.DEPRESSED MOOD	2	2	2	1		1		1		1
				02.GUILT	2	2	1	1		2		0		1
				03.SUICIDE	2	2	1	1		0		0		0
				04.INSOMNIA EARLY	1	1	1	1		1		1		2
				05.INSOMNIA MIDDLE	2	2	1	0		1		1		0
				06.INSOMNIA LATE	2	2	1	1		1		1		1
				07.WORK AND ACTIVITIES	2	2	2	1		1		1		1
				08.RETARDATION	0	0	1	0		0		0		1
				09.AGITATION	2	2	2	1		1		0		0
				10.ANXIETY PSYCHIC	2	2	2	2		2		1		1
				11.ANXIETY SOMATIC	1	1	1	2		1		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1		1		1		0
				13.SOMATIC GENERAL	2	2	1	1		0		1		1
				14.GENITAL SYMPTOMS	2	2	2	1		1		1		0
				15.HYPOCHONDRIASIS	0	0	0	0		0		0		0
				16.LOSS OF WEIGHT	0	0	1	0		0		1		0

453

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
13	504	Fluoxetine	Female	17.INSIGHT	0	0	0	0		0		0		0
				18.DIURNAL VARIATION	1	1	1	0		2		1		0
				19.DEPERSONALIZATION	0	0	0	0		0		0		0
				20.PARANOID	0	0	0	0		2		0		0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0		1		0		0
				22.Total score	24	24	21	14		18		12		10
	505	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	2	2	2		1		1
				02.GUILT	2	2	2	2	1	1		1		1
				03.SUICIDE	2	2	2	1	1	1		1		0
				04.INSOMNIA EARLY	0	1	1	1	1	1		1		1
				05.INSOMNIA MIDDLE	2	2	1	1	1	1		0		0
				06.INSOMNIA LATE	2	2	1	1	2	1		0		0
				07.WORK AND ACTIVITIES	2	2	1	0	1	2		1		0
				08.RETARDATION	1	1	0	2	0	0		0		0
				09.AGITATION	2	2	2	0	1	2		1		1
				10.ANXIETY PSYCHIC	2	2	2	2	1	2		1		1
				11.ANXIETY SOMATIC	2	2	1	2	1	2		1		0
				12.SOMATIC GASTROINTESTINAL	1	1	1	2	1	1		0		0
				13.SOMATIC GENERAL	1	1	1	1	1	2		0		0
				14.GENITAL SYMPTOMS	2	1	1	2	2	1		1		0
				15.HYPOCHONDRIASIS	0	0	0	0	0	0		0		0
				16.LOSS OF WEIGHT	1	1	1	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	1	1	0	0		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	26	26	20	20	16	19		10		5
	506	Fluoxetine	Male	01.DEPRESSED MOOD	2	2	2	1	0	1		0		0
				02.GUILT	1	2	0	1	0	1		0		0
				03.SUICIDE	1	1	0	0	0	0		0		0
				04.INSOMNIA EARLY	1	2	1	0	1	0		0		0
				05.INSOMNIA MIDDLE	1	1	0	1	1	0		0		0
				06.INSOMNIA LATE	1	1	0	0	1	0		0		0
				07.WORK AND ACTIVITIES	2	2	1	1	1	1		0		0
				08.RETARDATION	1	1	0	0	0	0		0		0
				09.AGITATION	2	1	1	1	0	0		0		0
				10.ANXIETY PSYCHIC	1	2	1	1	0	1		0		0
				11.ANXIETY SOMATIC	2	2	1	0	1	1		0		0
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	0	0		0		0
				13.SOMATIC GENERAL	2	2	0	1	0	1		1		0
				14.GENITAL SYMPTOMS	2	2	1	1	1	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	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	0	1	0	0		0		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	1	1	1	0	0	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
13	506	Fluoxetine	Male	21.OBSESSIONAL/COMPULSIVE	1	1	0	0	0	0		0		0
				22.Total score	25	26	9	9	6	6		1		0
	507	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	2	2	2		1		1
				02.GUILT	2	2	2	1	1	1		1		0
				03.SUICIDE	1	1	1	1	1	1		1		0
				04.INSOMNIA EARLY	2	2	1	1	1	1		1		0
				05.INSOMNIA MIDDLE	1	1	0	1	1	0		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	0	0	0	0	0	1		0		0
				09.AGITATION	2	2	1	2	1	0		1		0
				10.ANXIETY PSYCHIC	2	2	2	1	1	1		1		0
				11.ANXIETY SOMATIC	2	2	1	2	1	1		1		0
				12.SOMATIC GASTROINTESTINAL	1	1	0	1	1	0		1		0
				13.SOMATIC GENERAL	1	1	2	2	0	0		1		1
				14.GENITAL SYMPTOMS	0	0	1	1	0	0		0		1
				15.HYPOCHONDRIASIS	0	0	1	1	0	0		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	1	1	0	0		0		0
				19.DEPERSONALIZATION	1	1	1	0	0	0		0		0
				20.PARANOID	1	1	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0		0		0
				22.Total score	23	23	20	20	12	10		12		4
	508	Reboxetine	Female	01.DEPRESSED MOOD	2	2	2	2	1	1		0		1
				02.GUILT	1	1	1	1	1	0		0		0
				03.SUICIDE	1	1	1	2	1	0		0		0
				04.INSOMNIA EARLY	2	2	1	2	1	0		0		0
				05.INSOMNIA MIDDLE	2	2	1	2	1	1		1		0
				06.INSOMNIA LATE	2	2	1	2	0	0		0		0
				07.WORK AND ACTIVITIES	2	2	1	1	1	1		0		0
				08.RETARDATION	2	2	1	1	0	1		0		0
				09.AGITATION	2	2	1	0	0	1		0		1
				10.ANXIETY PSYCHIC	2	2	1	2	1	1		1		1
				11.ANXIETY SOMATIC	2	2	1	0	1	0		0		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	0	0		1		0
				13.SOMATIC GENERAL	2	2	2	2	1	1		1		1
				14.GENITAL SYMPTOMS	2	2	2	2	1	1		0		0
				15.HYPOCHONDRIASIS	0	0	0	0	0	0		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	2	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	26	26	19	21	11	8		4		5

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
13	521	Reboxetine	Male	01.DEPRESSED MOOD	2	3	2	2		1		1		1
				02.GUILT	2	2	2	1		1		0		0
				03.SUICIDE	2	2	2	1		1		1		0
				04.INSOMNIA EARLY	1	2	1	0		1		0		0
				05.INSOMNIA MIDDLE	1	1	1	1		0		0		0
				06.INSOMNIA LATE	1	1	1	0		1		0		0
				07.WORK AND ACTIVITIES	3	2	2	1		1		1		0
				08.RETARDATION	2	2	1	1		1		1		0
				09.AGITATION	0	0	2	1		0		0		1
				10.ANXIETY PSYCHIC	1	2	1	1		0		1		1
				11.ANXIETY SOMATIC	2	1	1	0		0		0		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	0		0		0		0
				13.SOMATIC GENERAL	1	1	1	1		1		0		0
				14.GENITAL SYMPTOMS	1	2	2	0		0		0		0
				15.HYPOCHONDRIASIS	1	0	0	0		0		0		0
				16.LOSS OF WEIGHT	1	1	0	0		0		0		0
				17.INSIGHT	0	0	0	0		0		0		0
				18.DIURNAL VARIATION	1	1	1	1		0		0		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	25	21	11		8		5		4
14	397	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	3	1	1		1		1
				02.GUILT	1	1	1	1	1	1		1		1
				03.SUICIDE	1	1	1	1	0	0		0		0
				04.INSOMNIA EARLY	2	2	2	2	1	1		1		1
				05.INSOMNIA MIDDLE	1	1	1	1	1	1		1		0
				06.INSOMNIA LATE	2	2	1	1	1	1		0		1
				07.WORK AND ACTIVITIES	3	3	3	2	1	0		1		0
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	1	1	1	1	0	0		0		0
				10.ANXIETY PSYCHIC	2	2	1	2	1	2		0		2
				11.ANXIETY SOMATIC	1	1	1	1	1	1		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	1	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	0	0		0		1
				14.GENITAL 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	1	1	0	1	0	0		0		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0		0		0
				22.Total score	23	23	20	20	11	10		8		10
	398	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	2	2	1		1		1
				02.GUILT	2	2	2	1	1	1		1		0
				03.SUICIDE	1	1	1	0	0	0		0		0
				04.INSOMNIA EARLY	2	2	2	1	0	1		0		1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
14	398	Reboxetine	Female	05.INSOMNIA MIDDLE	1	1	1	1	2	1		0		0
				06.INSOMNIA LATE	1	1	1	1	1	1		0		0
				07.WORK AND ACTIVITIES	2	2	2	2	1	1		1		1
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	1	1	1	0	0	0		1		0
				10.ANXIETY PSYCHIC	2	2	2	1	2	1		1		1
				11.ANXIETY SOMATIC	1	1	1	1	2	1		1		0
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	1	1	0		1		2
				14.GENITAL SYMPTOMS	2	2	2	1	1	1		1		2
				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	2	2	1	0	1	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	0	0	0	0		0		0
				22.Total score	26	26	22	12	14	9		8		8
	399	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	3	2	2		1		1
				02.GUILT	1	1	1	1	1	1		0		0
				03.SUICIDE	1	1	1	1	0	0		0		0
				04.INSOMNIA EARLY	2	2	1	1	1	1		2		1
				05.INSOMNIA MIDDLE	2	2	2	1	2	2		2		1
				06.INSOMNIA LATE	2	2	2	2	2	2		1		0
				07.WORK AND ACTIVITIES	3	3	3	2	2	1		1		0
				08.RETARDATION	0	0	0	1	0	0		0		0
				09.AGITATION	2	2	2	1	0	1		0		0
				10.ANXIETY PSYCHIC	2	2	2	1	2	2		2		1
				11.ANXIETY SOMATIC	2	2	2	2	1	2		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	1	0		0		1
				13.SOMATIC GENERAL	2	2	2	1	2	1		1		1
				14.GENITAL SYMPTOMS	2	2	2	2	2	1		1		1
				15.HYPOCHONDRIASIS	1	1	1	1	0	0		0		0
				16.LOSS OF WEIGHT	1	1	0	0	1	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	1	1	1	1		1		0
				19.DEPERSONALIZATION	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		1
				22.Total score	28	28	26	21	20	17		13		10
	400	Fluoxetine	Male	01.DEPRESSED MOOD	3	3	2	1	1	1		0		0
				02.GUILT	2	2	1	1	1	1		1		0
				03.SUICIDE	1	1	0	0	0	0		0		0
				04.INSOMNIA EARLY	2	2	1	0	1	1		1		1
				05.INSOMNIA MIDDLE	1	1	1	0	0	0		0		0
				06.INSOMNIA LATE	2	2	0	1	0	0		0		0
				07.WORK AND ACTIVITIES	2	2	2	1	1	1		1		0
				08.RETARDATION	0	0	0	0	0	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
14	400	Fluoxetine	Male	09.AGITATION	2	2	1	0	0	0		0		0
				10.ANXIETY PSYCHIC	2	2	2	1	1	1		1		1
				11.ANXIETY SOMATIC	1	1	2	1	0	1		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	1	1		0		0
				13.SOMATIC GENERAL	2	2	1	0	0	0		1		0
				14.GENITAL SYMPTOMS	1	1	1	0	0	1		0		0
				15.HYPOCHONDRIASIS	0	0	0	0	0	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	0	0	1	0	0	0		0		0
				19.DEPERSONALIZATION	0	0	1	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	2	1		1		1
				22.Total score	25	25	18	7	8	9		7		4
	401	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	2	2	1	1		1		0
				02.GUILT	1	1	1	1	0	1		1		1
				03.SUICIDE	1	1	0	0	0	0		0		0
				04.INSOMNIA EARLY	2	2	0	0	0	1		1		1
				05.INSOMNIA MIDDLE	1	1	0	1	1	0		0		0
				06.INSOMNIA LATE	1	1	0	1	0	0		0		0
				07.WORK AND ACTIVITIES	3	3	2	2	1	1		0		1
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	2	2	1	0	0	0		1		0
				10.ANXIETY PSYCHIC	3	3	2	2	1	1		1		1
				11.ANXIETY SOMATIC	2	2	1	1	1	1		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0		1		0
				13.SOMATIC GENERAL	2	2	0	1	0	1		1		0
				14.GENITAL SYMPTOMS	2	2	2	2	2	1		2		1
				15.HYPOCHONDRIASIS	0	0	0	0	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	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	1	0	0	1		0		0
				22.Total score	27	27	14	14	9	9		10		6
	402	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	2	2	2		1		0
				02.GUILT	1	1	1	1	1	1		0		0
				03.SUICIDE	1	1	0	0	0	0		0		0
				04.INSOMNIA EARLY	2	2	2	1	1	1		0		1
				05.INSOMNIA MIDDLE	1	1	1	1	1	1		1		0
				06.INSOMNIA LATE	1	1	0	0	1	0		1		0
				07.WORK AND ACTIVITIES	2	2	2	1	2	2		1		1
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	2	2	1	0	1	1		0		0
				10.ANXIETY PSYCHIC	3	3	2	2	2	2		1		1
				11.ANXIETY SOMATIC	2	2	2	2	1	1		1		0
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	1		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
14	402	Reboxetine	Female	13.SOMATIC GENERAL	2	2	1	1	2	2		0		0
				14.GENITAL SYMPTOMS	2	2	2	1	2	2		1		1
				15.HYPOCHONDRIASIS	1	1	1	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	2	2	2	1	0	1		0		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		1
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	2	2	2	1	1	1		1		1
				22.Total score	29	29	23	14	17	18		8		6
	403	Reboxetine	Female	01.DEPRESSED MOOD	3	3	1	2	2	1		1		0
				02.GUILT	2	2	1	1	1	0		0		0
				03.SUICIDE	1	1	0	0	0	0		0		0
				04.INSOMNIA EARLY	2	2	1	1	1	1		1		1
				05.INSOMNIA MIDDLE	1	1	0	1	1	0		1		1
				06.INSOMNIA LATE	1	1	1	0	0	1		0		0
				07.WORK AND ACTIVITIES	3	3	2	2	2	1		1		0
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	1	1	0	0	0	0		0		0
				10.ANXIETY PSYCHIC	1	1	2	1	2	1		1		1
				11.ANXIETY SOMATIC	1	1	1	1	2	1		0		0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0		1		0
				13.SOMATIC GENERAL	1	1	1	0	1	1		1		0
				14.GENITAL SYMPTOMS	2	2	1	1	2	1		1		0
				15.HYPOCHONDRIASIS	0	0	0	0	1	0		0		0
				16.LOSS OF WEIGHT	2	2	0	0	1	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				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	1	1	1	1	0		0		1
				22.Total score	24	24	13	12	19	8		8		5
	404	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	2	1	1		1		0
				02.GUILT	1	1	2	1	0	0		0		0
				03.SUICIDE	0	0	0	0	0	0		0		0
				04.INSOMNIA EARLY	1	1	1	1	1	1		1		1
				05.INSOMNIA MIDDLE	1	1	1	1	0	1		1		0
				06.INSOMNIA LATE	0	0	0	0	0	0		0		0
				07.WORK AND ACTIVITIES	3	3	3	1	1	1		1		0
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	0	0	0	0	0	0		0		0
				10.ANXIETY PSYCHIC	2	2	2	1	2	0		2		2
				11.ANXIETY SOMATIC	2	2	2	1	1	1		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	1	1	0		2		2
				14.GENITAL SYMPTOMS	2	2	2	2	2	1		1		1
				15.HYPOCHONDRIASIS	1	1	1	0	0	0		0		0
				16.LOSS OF WEIGHT	2	2	0	0	0	0		0		0

459

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
14	404	Fluoxetine	Female	17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	1	1	1	0		0		0
				19.DEPERSONALIZATION	1	1	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	2	2	2	1	1	1		1		0
				22.Total score	25	25	23	14	11	7		11		8
	405	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	1	1	0	0		0		0
				02.GUILT	2	2	1	1	0	0		0		0
				03.SUICIDE	1	1	0	0	0	0		0		0
				04.INSOMNIA EARLY	2	2	0	0	1	1		0		0
				05.INSOMNIA MIDDLE	1	1	0	1	0	0		1		0
				06.INSOMNIA LATE	0	0	1	0	0	0		0		0
				07.WORK AND ACTIVITIES	2	2	1	0	1	0		0		1
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	2	2	1	0	0	0		0		0
				10.ANXIETY PSYCHIC	2	2	1	1	1	1		1		1
				11.ANXIETY SOMATIC	1	1	1	1	1	1		0		0
				12.SOMATIC GASTROINTESTINAL	2	2	0	0	1	0		0		0
				13.SOMATIC GENERAL	2	2	1	0	1	1		0		0
				14.GENITAL SYMPTOMS	0	0	2	0	0	0		0		0
				15.HYPOCHONDRIASIS	0	0	0	0	0	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	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	1	1	1	1	1	1		1		0
				22.Total score	25	25	12	7	7	5		3		2
	406	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	2	2	3					
				02.GUILT	1	1	1	1	1					
				03.SUICIDE	1	1	0	0	0					
				04.INSOMNIA EARLY	2	2	1	2	2					
				05.INSOMNIA MIDDLE	1	1	2	2	2					
				06.INSOMNIA LATE	1	1	2	2	2					
				07.WORK AND ACTIVITIES	3	3	3	3	4					
				08.RETARDATION	0	0	0	0	0					
				09.AGITATION	3	3	2	2	1					
				10.ANXIETY PSYCHIC	3	3	2	3	3					
				11.ANXIETY SOMATIC	2	2	2	2	2					
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1					
				13.SOMATIC GENERAL	2	2	2	2	2					
				14.GENITAL SYMPTOMS	2	2	2	2	2					
				15.HYPOCHONDRIASIS	2	2	2	3	3					
				16.LOSS OF WEIGHT	1	1	0	1	0					
				17.INSIGHT	0	0	0	0	0					
				18.DIURNAL VARIATION	1	1	2	1	1					
				19.DEPERSONALIZATION	0	0	1	0	0					
				20.PARANOID	0	0	0	0	0					

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
14	406	Fluoxetine	Female	21.OBSESSIONAL/COMPULSIVE	1	1	1	2	2					
				22.Total score	30	30	28	31	31					
	407	Reboxetine	Male	01.DEPRESSED MOOD	3	3	3	3	3	3		3		
				02.GUILT	1	1	2	2	2	2		2		
				03.SUICIDE	1	1	1	1	1	1		1		
				04.INSOMNIA EARLY	2	2	2	1	1	1		0		
				05.INSOMNIA MIDDLE	2	2	1	2	2	1		2		
				06.INSOMNIA LATE	1	1	2	2	1	1		1		
				07.WORK AND ACTIVITIES	3	3	3	3	3	2		3		
				08.RETARDATION	2	2	1	1	1	1		2		
				09.AGITATION	0	0	0	0	0	0		0		
				10.ANXIETY PSYCHIC	2	2	3	2	2	2		2		
				11.ANXIETY SOMATIC	2	2	2	2	2	2		1		
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1		1		
				13.SOMATIC GENERAL	2	2	2	1	1	2		1		
				14.GENITAL SYMPTOMS	2	2	2	2	2	2		2		
				15.HYPOCHONDRIASIS	1	1	2	2	2	2		2		
				16.LOSS OF WEIGHT	1	1	2	2	2	1		0		
				17.INSIGHT	0	0	0	0	0	0		0		
				18.DIURNAL VARIATION	0	0	0	0	0	1		0		
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		
				20.PARANOID	1	1	0	0	0	0		0		
				21.OBSESSIONAL/COMPULSIVE	1	1	0	0	0	1		1		
				22.Total score	28	28	29	27	26	26		24		
	408	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	2	2	1		1		0
				02.GUILT	2	2	2	1	1	1		1		0
				03.SUICIDE	1	1	1	0	1	0		0		0
				04.INSOMNIA EARLY	1	1	1	1	0	1		0		1
				05.INSOMNIA MIDDLE	0	0	1	0	0	0		1		0
				06.INSOMNIA LATE	1	1	1	0	1	0		0		0
				07.WORK AND ACTIVITIES	3	3	2	2	2	2		0		0
				08.RETARDATION	1	1	1	0	0	0		0		0
				09.AGITATION	0	0	0	0	0	0		0		0
				10.ANXIETY PSYCHIC	2	2	2	2	2	2		1		0
				11.ANXIETY SOMATIC	2	2	2	1	1	1		0		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	1	1		1		0
				13.SOMATIC GENERAL	2	2	2	2	1	1		0		1
				14.GENITAL SYMPTOMS	2	2	2	1	1	1		1		0
				15.HYPOCHONDRIASIS	1	1	0	0	0	0		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	1	1	1	1		0		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1		1		1
				22.Total score	24	24	22	14	15	13		7		6

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
14	509	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	2	2	2		3		
				02.GUILT	2	2	1	1	1	1		1		
				03.SUICIDE	1	1	1	1	1	0		2		
				04.INSOMNIA EARLY	2	2	2	2	1	1		1		
				05.INSOMNIA MIDDLE	1	1	1	1	1	2		1		
				06.INSOMNIA LATE	2	2	1	1	0	1		1		
				07.WORK AND ACTIVITIES	3	3	3	3	3	2		3		
				08.RETARDATION	2	2	2	2	2	1		1		
				09.AGITATION	0	0	0	0	0	0		0		
				10.ANXIETY PSYCHIC	2	2	2	2	2	2		1		
				11.ANXIETY SOMATIC	2	2	2	2	2	2		2		
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	0		0		
				13.SOMATIC GENERAL	1	1	2	2	2	2		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	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	1	1	1	1	1	1		0		
				22.Total score	27	27	26	24	22	20		20		
	510	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	2	2	2	2		1		0
				02.GUILT	1	1	1	1	0	1		0		1
				03.SUICIDE	1	1	1	0	0	0		0		0
				04.INSOMNIA EARLY	2	2	2	0	0	0		1		0
				05.INSOMNIA MIDDLE	1	1	1	0	0	1		0		0
				06.INSOMNIA LATE	0	0	0	1	1	0		0		0
				07.WORK AND ACTIVITIES	3	3	2	1	2	2		1		1
				08.RETARDATION	1	1	1	1	0	0		0		1
				09.AGITATION	0	0	0	0	0	1		0		1
				10.ANXIETY PSYCHIC	2	2	2	2	2	2		2		1
				11.ANXIETY SOMATIC	2	2	2	2	2	1		1		0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0		0		0
				13.SOMATIC GENERAL	2	2	1	2	2	1		1		2
				14.GENITAL SYMPTOMS	2	2	2	2	1	1		1		1
				15.HYPOCHONDRIASIS	1	1	2	0	0	0		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	1	1	1	1		0		1
				19.DEPERSONALIZATION	0	0	1	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	2	1	1	1	0	0		0		0
				22.Total score	26	25	23	17	14	13		8		8
	511	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	1	3	2		1	1	
				02.GUILT	1	1	1	1	1	0		1	0	
				03.SUICIDE	1	1	0	0	0	0		0	0	
				04.INSOMNIA EARLY	2	2	2	0	1	1		2	2	

762

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
14	511	Reboxetine	Female	05.INSOMNIA MIDDLE	1	1	1	0	1	1		1	1	
				06.INSOMNIA LATE	2	2	1	1	1	1		1	0	
				07.WORK AND ACTIVITIES	3	3	3	2	2	2		1	1	
				08.RETARDATION	1	1	1	0	1	1		0	0	
				09.AGITATION	1	1	1	1	1	0		0	0	
				10.ANXIETY PSYCHIC	3	3	2	2	2	2		2	2	
				11.ANXIETY SOMATIC	2	2	2	1	1	1		2	1	
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	1	1		0	0	
				13.SOMATIC GENERAL	2	2	2	0	1	1		1	0	
				14.GENITAL SYMPTOMS	2	2	2	1	2	2		1	0	
				15.HYPOCHONDRIASIS	0	0	0	0	0	0		0	0	
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0	0	
				17.INSIGHT	0	0	0	0	0	0		0	0	
				18.DIURNAL VARIATION	1	1	1	1	1	0		0	1	
				19.DEPERSONALIZATION	0	0	0	0	0	0		0	0	
				20.PARANOID	0	0	0	0	0	0		0	0	
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0		1	0	
				22.Total score	26	26	22	11	19	15		14	9	
14	512	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	2	1	3				
				02.GUILT	1	1	1	1	1	1				
				03.SUICIDE	1	1	0	0	0	1				
				04.INSOMNIA EARLY	2	2	0	2	1	2				
				05.INSOMNIA MIDDLE	1	1	2	1	0	1				
				06.INSOMNIA LATE	2	2	2	1	0	1				
				07.WORK AND ACTIVITIES	3	3	2	2	2	3				
				08.RETARDATION	1	1	0	0	0	0				
				09.AGITATION	0	0	1	0	0	1				
				10.ANXIETY PSYCHIC	2	2	2	2	1	2				
				11.ANXIETY SOMATIC	1	1	0	1	1	1				
				12.SOMATIC GASTROINTESTINAL	1	1	0	1	0	1				
				13.SOMATIC GENERAL	2	2	2	2	2	2				
				14.GENITAL SYMPTOMS	2	2	2	1	1	2				
				15.HYPOCHONDRIASIS	0	0	0	0	0	0				
				16.LOSS OF WEIGHT	1	1	0	0	0	0				
				17.INSIGHT	0	0	0	0	0	1				
				18.DIURNAL VARIATION	2	2	1	1	0	1				
				19.DEPERSONALIZATION	0	0	0	0	0	0				
				20.PARANOID	0	0	0	0	0	0				
				21.OBSESSIONAL/COMPULSIVE	1	1	1	0	0	0				
				22.Total score	26	26	18	17	10	23				
	537	Reboxetine	Female	01.DEPRESSED MOOD	3	3	1	0	0	0		0		0
				02.GUILT	1	1	1	1	1	0		0		0
				03.SUICIDE	1	1	0	0	0	0		0		0
				04.INSOMNIA EARLY	2	2	0	0	1	0		0		0
				05.INSOMNIA MIDDLE	1	1	1	1	1	1		1		0
				06.INSOMNIA LATE	2	2	1	0	0	0		0		0
				07.WORK AND ACTIVITIES	3	3	2	1	0	1		1		0
				08.RETARDATION	0	0	0	0	0	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
14	537	Reboxetine	Female	09.AGITATION	1	1	0	1	0	0		0		0
				10.ANXIETY PSYCHIC	2	2	1	1	1	1		0		0
				11.ANXIETY SOMATIC	2	2	1	1	0	1		0		0
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	0	0		0		0
				13.SOMATIC GENERAL	2	2	1	1	0	0		1		0
				14.GENITAL SYMPTOMS	1	1	1	1	1	0		0		0
				15.HYPOCHONDRIASIS	1	1	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	2	2	1	0	0	0		0		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0		0		0
				22.Total score	26	26	11	8	5	4		3		0
	538	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	1	1	0	0		0		0
				02.GUILT	2	2	1	0	0	0		0		0
				03.SUICIDE	1	1	0	0	0	0		0		0
				04.INSOMNIA EARLY	2	2	0	0	0	0		0		0
				05.INSOMNIA MIDDLE	2	2	0	1	1	0		0		1
				06.INSOMNIA LATE	0	0	0	0	0	0		0		0
				07.WORK AND ACTIVITIES	3	3	2	0	1	1		1		0
				08.RETARDATION	1	1	0	0	0	0		1		0
				09.AGITATION	0	0	1	0	0	0		0		0
				10.ANXIETY PSYCHIC	2	2	2	2	1	2		1		0
				11.ANXIETY SOMATIC	1	1	1	1	1	1		0		0
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	1	0	0		1		0
				14.GENITAL SYMPTOMS	1	1	1	0	0	1		1		1
				15.HYPOCHONDRIASIS	1	1	0	0	0	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	2	2	1	1	0	0		0		0
				19.DEPERSONALIZATION	0	0	1	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	0	0	1	0		0		0
				22.Total score	27	27	14	7	5	5		5		4
	539	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	2	3	2		1		1
				02.GUILT	2	2	2	1	1	1		1		1
				03.SUICIDE	1	1	1	0	1	0		0		0
				04.INSOMNIA EARLY	2	2	1	1	1	1		2		2
				05.INSOMNIA MIDDLE	2	2	2	1	2	1		1		1
				06.INSOMNIA LATE	1	1	1	1	1	1		1		1
				07.WORK AND ACTIVITIES	3	3	3	2	3	2		2		2
				08.RETARDATION	1	1	1	1	0	0		0		0
				09.AGITATION	2	2	2	2	2	1		1		1
				10.ANXIETY PSYCHIC	3	3	3	3	2	3		1		2
				11.ANXIETY SOMATIC	3	3	3	2	3	2		2		2
				12.SOMATIC GASTROINTESTINAL	2	2	2	1	1	1		1		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
14	539	Fluoxetine	Female	13.SOMATIC GENERAL	2	2	2	2	2	1		1		1
				14.GENITAL SYMPTOMS	2	2	2	1	2	2		0		0
				15.HYPOCHONDRIASIS	2	2	3	3	3	2		2		2
				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	0	0	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	1	0	1		1		1
				22.Total score	33	33	32	25	28	22		18		18
15	409	Reboxetine	Male	01.DEPRESSED MOOD	3	3	3	3	3	2		1		1
				02.GUILT	2	2	2	2	2	2		2		1
				03.SUICIDE	2	2	2	2	2	2		1		1
				04.INSOMNIA EARLY	0	0	0	0	0	0		0		0
				05.INSOMNIA MIDDLE	1	1	1	1	0	0		0		0
				06.INSOMNIA LATE	2	2	2	2	0	0		0		0
				07.WORK AND ACTIVITIES	3	3	3	3	3	2		2		1
				08.RETARDATION	1	1	1	1	1	1		1		0
				09.AGITATION	0	0	0	0	0	0		0		0
				10.ANXIETY PSYCHIC	3	3	3	3	3	3		2		1
				11.ANXIETY SOMATIC	2	2	2	2	2	2		2		1
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	2	2		2		1
				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	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	1	2	2	2	2		2		1
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	2	2	2	2	2	2		2		1
				22.Total score	27	27	27	27	24	22		19		10
	410	Fluoxetine	Female	01.DEPRESSED MOOD	2	2	2	2	2	2		1		1
				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	1	1		0		0
				05.INSOMNIA MIDDLE	2	2	2	2	1	1		1		0
				06.INSOMNIA LATE	1	1	1	1	1	1		1		0
				07.WORK AND ACTIVITIES	2	2	2	2	2	2		2		1
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	1	1	1	1	0	0		0		0
				10.ANXIETY PSYCHIC	2	2	2	2	2	1		1		1
				11.ANXIETY SOMATIC	2	2	2	2	2	2		2		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	2	2		1		1
				14.GENITAL SYMPTOMS	1	1	1	1	1	1		0		0
				15.HYPOCHONDRIASIS	2	2	2	2	2	2		1		1
				16.LOSS OF WEIGHT	2	2	2	2	0	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
15	410	Fluoxetine	Female	17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	1	1	1	1		0		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0		0		0
				22.Total score	25	25	25	25	19	18		12		9
	411	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	1	1	0		0		0
				02.GUILT	2	2	2	1	1	0		0		0
				03.SUICIDE	3	3	3	0	0	0		0		0
				04.INSOMNIA EARLY	1	1	1	0	0	0		0		0
				05.INSOMNIA MIDDLE	1	1	1	1	0	0		0		0
				06.INSOMNIA LATE	2	2	2	1	1	1		0		0
				07.WORK AND ACTIVITIES	2	2	3	1	1	1		1		0
				08.RETARDATION	1	1	2	0	0	0		0		0
				09.AGITATION	1	1	1	0	0	0		0		0
				10.ANXIETY PSYCHIC	3	3	3	1	1	1		1		1
				11.ANXIETY SOMATIC	2	2	3	1	1	1		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	0		0		0
				13.SOMATIC GENERAL	1	1	2	2	1	1		1		0
				14.GENITAL SYMPTOMS	1	1	2	1	1	1		1		0
				15.HYPOCHONDRIASIS	2	2	3	2	1	1		0		0
				16.LOSS OF WEIGHT	2	2	2	0	0	0		0		0
				17.INSIGHT	0	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	2	2	2	2	1	1		1		0
				22.Total score	32	32	38	16	11	9		6		3
	412	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	2	2	1		1		1
				02.GUILT	2	2	2	1	1	1		1		1
				03.SUICIDE	1	1	1	1	1	0		0		0
				04.INSOMNIA EARLY	2	2	2	1	1	1		0		0
				05.INSOMNIA MIDDLE	1	1	1	1	0	0		0		0
				06.INSOMNIA LATE	1	1	1	1	1	1		0		0
				07.WORK AND ACTIVITIES	2	2	2	2	1	1		1		0
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	1	1	1	0	0	0		0		0
				10.ANXIETY PSYCHIC	2	2	2	2	1	1		1		1
				11.ANXIETY SOMATIC	2	2	2	2	2	1		1		0
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	0		0		0
				13.SOMATIC GENERAL	0	0	0	0	0	0		0		0
				14.GENITAL SYMPTOMS	0	0	0	0	0	0		0		0
				15.HYPOCHONDRIASIS	1	1	1	1	1	0		0		0
				16.LOSS OF WEIGHT	2	2	2	2	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	2	2	1		0		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
15	412	Fluoxetine	Female	21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	0		0		0
				22.Total score	24	24	24	19	14	8		5		5
	413	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	2	2	1		1		0
				02.GUILT	2	2	2	1	1	1		1		0
				03.SUICIDE	3	3	3	2	2	1		0		0
				04.INSOMNIA EARLY	0	0	0	0	0	0		0		0
				05.INSOMNIA MIDDLE	2	2	1	0	0	0		0		0
				06.INSOMNIA LATE	2	2	1	1	0	0		0		0
				07.WORK AND ACTIVITIES	2	2	2	2	2	1		1		0
				08.RETARDATION	1	1	1	0	0	0		0		0
				09.AGITATION	1	1	1	0	0	0		0		0
				10.ANXIETY PSYCHIC	3	3	3	1	1	1		1		1
				11.ANXIETY SOMATIC	2	2	2	1	1	1		0		0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	1	1		1		0
				14.GENITAL SYMPTOMS	2	2	2	2	1	1		0		0
				15.HYPOCHONDRIASIS	0	0	0	0	0	0		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	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	1	1	1	1	0	0		0		0
				22.Total score	28	28	26	17	12	9		5		1
	414	Fluoxetine	Male	01.DEPRESSED MOOD	3	3	3	3	2	2		2		3
				02.GUILT	2	2	2	2	2	1		1		2
				03.SUICIDE	1	1	1	1	1	1		1		1
				04.INSOMNIA EARLY	2	2	2	2	2	1		1		2
				05.INSOMNIA MIDDLE	1	1	1	1	1	1		1		1
				06.INSOMNIA LATE	2	2	2	2	2	1		1		2
				07.WORK AND ACTIVITIES	2	2	2	2	2	2		2		2
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	1	1	1	1	1	1		1		1
				10.ANXIETY PSYCHIC	2	2	2	2	2	1		1		1
				11.ANXIETY SOMATIC	2	2	2	2	2	2		2		2
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0
				13.SOMATIC GENERAL	1	1	1	1	1	1		1		1
				14.GENITAL SYMPTOMS	1	1	1	1	1	1		1		1
				15.HYPOCHONDRIASIS	0	0	0	0	0	0		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	2	2	2		2		2
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	2	2	2	2	2	2		2		2
				22.Total score	24	24	24	24	23	19		19		23

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
15	415	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	3	2	1		0		0
				02.GUILT	2	2	2	2	1	1		0		0
				03.SUICIDE	2	2	2	2	1	0		0		0
				04.INSOMNIA EARLY	2	2	2	1	0	0		0		0
				05.INSOMNIA MIDDLE	2	2	2	1	1	0		0		0
				06.INSOMNIA LATE	2	2	2	1	1	0		0		0
				07.WORK AND ACTIVITIES	4	4	4	4	3	2		1		1
				08.RETARDATION	1	1	1	1	0	0		0		0
				09.AGITATION	2	2	2	1	0	0		0		0
				10.ANXIETY PSYCHIC	3	3	3	1	1	1		1		1
				11.ANXIETY SOMATIC	3	3	3	2	1	0		0		0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	2	1		1		0
				14.GENITAL SYMPTOMS	2	2	2	2	2	1		1		0
				15.HYPOCHONDRIASIS	1	1	1	1	1	1		1		0
				16.LOSS OF WEIGHT	2	2	2	2	2	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	2	2	1		0		0
				19.DEPERSONALIZATION	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	36	36	29	20	9		5		3
	416	Fluoxetine	Female	01.DEPRESSED MOOD	2	2	2	2	2	2		1		1
				02.GUILT	1	1	1	1	1	1		1		0
				03.SUICIDE	1	1	1	1	1	1		0		0
				04.INSOMNIA EARLY	2	2	2	2	1	1		1		0
				05.INSOMNIA MIDDLE	1	1	1	1	1	0		0		0
				06.INSOMNIA LATE	2	2	2	2	2	1		0		0
				07.WORK AND ACTIVITIES	3	3	3	3	3	2		2		1
				08.RETARDATION	1	1	1	1	1	0		0		0
				09.AGITATION	1	1	1	1	1	1		1		1
				10.ANXIETY PSYCHIC	2	2	2	2	2	1		1		1
				11.ANXIETY SOMATIC	2	2	2	2	2	2		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0		0		1
				13.SOMATIC GENERAL	1	1	1	1	1	1		1		1
				14.GENITAL SYMPTOMS	1	1	1	1	1	1		1		1
				15.HYPOCHONDRIASIS	2	2	2	2	2	2		1		0
				16.LOSS OF WEIGHT	2	2	2	2	2	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	1	1	1	2		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	26	26	26	26	25	18		12		9
	417	Reboxetine	Female	01.DEPRESSED MOOD	2	2	2	1	0	0		0		0
				02.GUILT	2	2	2	1	0	0		0		0
				03.SUICIDE	1	1	1	1	0	0		0		0
				04.INSOMNIA EARLY	2	2	1	0	0	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
15	417	Reboxetine	Female	05.INSOMNIA MIDDLE	2	2	1	1	0	0		0		0
				06.INSOMNIA LATE	2	2	1	1	1	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	1	1	1	0	0		0		0
				10.ANXIETY PSYCHIC	3	3	2	1	0	0		0		0
				11.ANXIETY SOMATIC	2	2	2	1	1	1		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	1	1		0		0
				14.GENITAL SYMPTOMS	1	1	1	1	1	1		1		1
				15.HYPOCHONDRIASIS	1	1	1	1	0	0		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	1	0	0		0		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1		1		0
				22.Total score	27	27	22	15	6	4		3		2
	418	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	2	1	1		0		0
				02.GUILT	2	2	2	2	1	0		0		0
				03.SUICIDE	1	1	1	1	1	0		0		0
				04.INSOMNIA EARLY	1	1	1	0	0	0		0		0
				05.INSOMNIA MIDDLE	2	2	2	1	0	0		0		0
				06.INSOMNIA LATE	2	2	2	1	1	0		0		0
				07.WORK AND ACTIVITIES	4	4	4	4	2	2		1		0
				08.RETARDATION	1	1	1	1	1	1		0		0
				09.AGITATION	2	2	2	1	1	1		1		0
				10.ANXIETY PSYCHIC	3	3	3	2	1	1		1		0
				11.ANXIETY SOMATIC	3	3	3	3	2	2		1		0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	2	1		1		0
				14.GENITAL SYMPTOMS	2	2	2	2	2	2		2		0
				15.HYPOCHONDRIASIS	2	2	2	2	2	2		2		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	2	2	2	2	2	1		1		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	0	0	0		0		0
				22.Total score	35	35	35	28	19	14		10		4
	419	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	3	3	2		1		1
				02.GUILT	2	2	2	2	2	1		1		1
				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		0
				06.INSOMNIA LATE	2	2	2	2	2	1		0		0
				07.WORK AND ACTIVITIES	2	2	2	2	2	2		2		1
				08.RETARDATION	1	1	1	1	1	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
15	419	Fluoxetine	Female	09.AGITATION	1	1	1	1	1	1		1		1
				10.ANXIETY PSYCHIC	2	2	2	2	2	2		1		1
				11.ANXIETY SOMATIC	2	2	2	2	2	2		2		2
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0
				13.SOMATIC GENERAL	1	1	1	1	1	1		1		1
				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	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		0		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1		1		1
				22.Total score	24	24	24	24	24	19		15		11
	420	Fluoxetine	Male	01.DEPRESSED MOOD	3	3	3	2	2	1		1		1
				02.GUILT	2	2	2	2	1	1		1		1
				03.SUICIDE	1	1	1	1	1	0		0		0
				04.INSOMNIA EARLY	1	1	1	1	1	1		0		0
				05.INSOMNIA MIDDLE	2	2	2	1	0	0		0		0
				06.INSOMNIA LATE	2	2	2	1	0	0		0		0
				07.WORK AND ACTIVITIES	2	2	2	2	2	2		2		1
				08.RETARDATION	1	1	1	1	1	1		0		0
				09.AGITATION	1	1	1	1	1	0		0		0
				10.ANXIETY PSYCHIC	1	1	1	1	1	1		1		1
				11.ANXIETY SOMATIC	2	2	2	1	1	1		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	2	2		2		1
				14.GENITAL SYMPTOMS	1	1	1	1	1	1		1		1
				15.HYPOCHONDRIASIS	2	2	2	2	1	1		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	1	1	1	1		1		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	2	2	2	2	2	1		1		1
				22.Total score	27	27	27	23	18	14		11		8
	421	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	3	2	2		1		0
				02.GUILT	2	2	2	2	2	1		1		0
				03.SUICIDE	2	2	2	2	1	1		0		0
				04.INSOMNIA EARLY	1	1	1	2	1	1		1		0
				05.INSOMNIA MIDDLE	1	1	1	1	1	1		0		0
				06.INSOMNIA LATE	2	2	2	2	1	1		0		0
				07.WORK AND ACTIVITIES	3	3	3	4	3	3		1		0
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	2	2	2	2	1	0		0		0
				10.ANXIETY PSYCHIC	3	3	3	3	2	1		0		0
				11.ANXIETY SOMATIC	2	2	3	3	2	1		0		0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
15	421	Reboxetine	Female	13.SOMATIC GENERAL	2	2	2	2	2	2		1		0
				14.GENITAL SYMPTOMS	0	0	0	0	0	0		0		0
				15.HYPOCHONDRIASIS	2	2	2	2	2	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	2	2	2	2	2	2		1		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	2	2	1	1		0		0
				22.Total score	28	28	30	32	23	18		7		3
	422	Fluoxetine	Male	01.DEPRESSED MOOD	2	2	2	2	2	1		1		1
				02.GUILT	2	2	2	2	1	1		1		0
				03.SUICIDE	1	1	1	1	1	0		0		0
				04.INSOMNIA EARLY	1	1	1	1	1	1		0		0
				05.INSOMNIA MIDDLE	1	1	1	1	1	1		0		0
				06.INSOMNIA LATE	2	2	2	2	0	0		0		0
				07.WORK AND ACTIVITIES	3	3	3	3	3	2		1		0
				08.RETARDATION	2	2	2	2	1	1		0		0
				09.AGITATION	0	0	0	0	0	0		0		0
				10.ANXIETY PSYCHIC	3	3	3	2	2	1		1		1
				11.ANXIETY SOMATIC	3	3	3	2	2	1		1		1
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	1	1		1		0
				14.GENITAL SYMPTOMS	1	1	1	1	1	1		0		0
				15.HYPOCHONDRIASIS	2	2	2	2	1	1		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	1	1	1	1		0		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	0	0		0		0
				22.Total score	27	27	27	25	18	13		6		4
	423	Fluoxetine	Female	01.DEPRESSED MOOD	2	2	2	2	2	2		1		1
				02.GUILT	2	2	2	2	2	2		1		1
				03.SUICIDE	2	2	2	2	2	1		0		0
				04.INSOMNIA EARLY	1	1	1	1	1	1		1		0
				05.INSOMNIA MIDDLE	1	1	1	1	1	1		0		0
				06.INSOMNIA LATE	1	1	1	1	1	0		0		0
				07.WORK AND ACTIVITIES	2	2	2	2	2	2		1		0
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	2	2	2	2	2	1		0		0
				10.ANXIETY PSYCHIC	2	2	2	2	2	2		1		1
				11.ANXIETY SOMATIC	2	2	2	2	2	2		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1		0		0
				13.SOMATIC GENERAL	1	1	1	1	1	1		1		1
				14.GENITAL SYMPTOMS	1	1	1	1	1	1		1		1
				15.HYPOCHONDRIASIS	2	2	2	2	2	2		1		1
				16.LOSS OF WEIGHT	2	2	2	2	2	2		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
15	423	Fluoxetine	Female	17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	1	1	1	1		1		1
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0		0		0
				22.Total score	25	25	25	25	25	22		10		9
	424	Reboxetine	Male	01.DEPRESSED MOOD	2	2	2	2	1	1		1		1
				02.GUILT	2	2	2	2	1	1		1		1
				03.SUICIDE	2	2	1	1	0	0		0		0
				04.INSOMNIA EARLY	1	1	1	1	1	0		0		0
				05.INSOMNIA MIDDLE	1	1	1	1	1	0		0		0
				06.INSOMNIA LATE	2	2	2	1	0	0		0		0
				07.WORK AND ACTIVITIES	2	2	2	2	2	2		1		1
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	1	1	1	0	0	0		0		0
				10.ANXIETY PSYCHIC	3	3	3	2	1	1		1		0
				11.ANXIETY SOMATIC	2	2	2	1	1	1		0		0
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	1	1		1		0
				14.GENITAL SYMPTOMS	1	1	1	1	1	1		1		1
				15.HYPOCHONDRIASIS	2	2	2	2	1	0		0		0
				16.LOSS OF WEIGHT	2	2	2	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	1	1	1	1		1		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	0		0		0
				22.Total score	28	28	27	20	13	9		7		4
	425	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	3	2	1		0		0
				02.GUILT	2	2	2	2	2	1		0		0
				03.SUICIDE	2	2	2	2	1	0		0		0
				04.INSOMNIA EARLY	1	1	1	1	1	1		0		0
				05.INSOMNIA MIDDLE	2	2	2	1	0	0		0		0
				06.INSOMNIA LATE	1	1	1	1	1	0		0		0
				07.WORK AND ACTIVITIES	4	4	4	3	2	1		0		0
				08.RETARDATION	1	1	1	1	0	0		0		0
				09.AGITATION	0	0	0	0	0	0		0		0
				10.ANXIETY PSYCHIC	3	3	3	3	2	1		1		1
				11.ANXIETY SOMATIC	2	2	2	2	1	1		0		0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	1	0		0		0
				14.GENITAL SYMPTOMS	0	0	0	0	0	0		0		0
				15.HYPOCHONDRIASIS	2	2	2	2	1	0		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	2	1	0		0		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
15	425	Reboxetine	Female	21.OBSESSIONAL/COMPULSIVE	1	1	1	1	0	0		0		0
				22.Total score	28	28	28	26	15	6		1		1
	426	Fluoxetine	Male	01.DEPRESSED MOOD	3	3	3	2	2	1		1		1
				02.GUILT	2	2	2	2	2	1		0		0
				03.SUICIDE	3	3	3	2	1	1		0		0
				04.INSOMNIA EARLY	1	1	1	1	1	1		1		0
				05.INSOMNIA MIDDLE	1	1	1	1	1	1		1		1
				06.INSOMNIA LATE	2	2	2	1	1	0		0		0
				07.WORK AND ACTIVITIES	3	3	3	3	3	2		1		1
				08.RETARDATION	2	2	2	2	2	0		0		0
				09.AGITATION	0	0	0	0	0	0		0		0
				10.ANXIETY PSYCHIC	3	3	3	2	2	2		1		1
				11.ANXIETY SOMATIC	2	2	2	2	2	2		2		2
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	0		0		0
				13.SOMATIC GENERAL	1	1	1	1	1	1		1		1
				14.GENITAL SYMPTOMS	0	0	0	0	0	0		0		0
				15.HYPOCHONDRIASIS	3	3	3	3	3	3		2		2
				16.LOSS OF WEIGHT	2	2	2	0	0	0		0		0
				17.INSIGHT	1	1	1	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	2	2	1		1		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	2	2	2	2	2	2		1		1
				22.Total score	34	34	34	26	25	18		12		11
	427	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	2	2	1		1		1
				02.GUILT	1	1	1	1	1	1		0		0
				03.SUICIDE	0	1	1	1	1	0		0		0
				04.INSOMNIA EARLY	1	0	0	0	0	0		0		0
				05.INSOMNIA MIDDLE	2	1	1	1	1	0		0		0
				06.INSOMNIA LATE	1	2	2	1	1	1		1		0
				07.WORK AND ACTIVITIES	2	2	2	2	2	2		2		2
				08.RETARDATION	1	1	1	1	1	1		0		0
				09.AGITATION	0	0	0	0	0	0		0		0
				10.ANXIETY PSYCHIC	3	3	3	2	2	2		1		1
				11.ANXIETY SOMATIC	2	2	2	2	2	2		2		1
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		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	2		1		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	2	2	1		1		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	0		0		0
				22.Total score	25	25	25	22	22	16		12		7

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 12.8

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	49 Day	56
15	428	Fluoxetine	Male	01.DEPRESSED MOOD	2	2	2	2	2	1		1		1
				02.GUILT	2	2	2	2	1	1		1		1
				03.SUICIDE	1	1	1	1	1	0		0		0
				04.INSOMNIA EARLY	1	1	1	1	0	0		0		0
				05.INSOMNIA MIDDLE	1	1	1	1	1	1		1		1
				06.INSOMNIA LATE	1	1	1	1	1	1		0		0
				07.WORK AND ACTIVITIES	1	1	1	1	1	1		1		1
				08.RETARDATION	1	1	1	1	1	0		0		0
				09.AGITATION	0	0	0	0	0	0		0		0
				10.ANXIETY PSYCHIC	2	2	2	2	1	1		1		1
				11.ANXIETY SOMATIC	2	2	2	2	1	1		1		1
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	2	2		2		2
				14.GENITAL SYMPTOMS	1	1	1	1	1	1		1		0
				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	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	2	2	2	2	1	1		1		1
				22.Total score	22	22	22	22	17	14		13		12
	449	Reboxetine	Female	01.DEPRESSED MOOD	2	2	3	3	3	3		3		1
				02.GUILT	1	1	1	1	1	1		1		1
				03.SUICIDE	1	1	1	1	1	1		1		0
				04.INSOMNIA EARLY	1	1	1	1	1	1		0		0
				05.INSOMNIA MIDDLE	1	1	1	1	1	1		0		0
				06.INSOMNIA LATE	1	1	1	1	1	1		1		0
				07.WORK AND ACTIVITIES	3	3	3	3	3	3		3		1
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	1	1	1	1	1	1		1		0
				10.ANXIETY PSYCHIC	3	3	3	3	3	3		3		1
				11.ANXIETY SOMATIC	2	2	2	2	2	2		2		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0		0		0
				13.SOMATIC GENERAL	1	1	1	1	1	1		1		1
				14.GENITAL SYMPTOMS	1	1	1	1	1	1		1		0
				15.HYPOCHONDRIASIS	1	1	1	1	1	1		1		0
				16.LOSS OF WEIGHT	1	1	1	1	1	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	2	2	2	2	2	2		2		1
				22.Total score	23	23	24	24	24	22		20		7
	450	Fluoxetine	Male	01.DEPRESSED MOOD	3	3	3	3	2	2		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	1	1	1	1	0	0		0		0

774

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
15	450	Fluoxetine	Male	05.INSOMNIA MIDDLE	1	1	1	1	1	0		0		0
				06.INSOMNIA LATE	2	2	2	2	1	1		0		0
				07.WORK AND ACTIVITIES	4	4	4	4	4	3		2		2
				08.RETARDATION	2	2	2	1	1	1		0		0
				09.AGITATION	0	0	0	0	0	0		0		0
				10.ANXIETY PSYCHIC	1	1	1	1	1	1		1		1
				11.ANXIETY SOMATIC	2	2	2	2	2	2		2		2
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	2	2		2		2
				14.GENITAL SYMPTOMS	2	2	2	2	2	2		2		2
				15.HYPOCHONDRIASIS	2	2	2	2	2	2		2		2
				16.LOSS OF WEIGHT	2	2	2	1	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	1	1	1	1	1	1		1		1
				22.Total score	29	29	29	27	22	19		15		15
	451	Fluoxetine	Female	01.DEPRESSED MOOD	2	2	2	2	2	1		1		1
				02.GUILT	2	2	2	2	2	1		1		1
				03.SUICIDE	1	1	1	1	0	0		0		0
				04.INSOMNIA EARLY	1	1	1	1	0	0		1		0
				05.INSOMNIA MIDDLE	1	1	1	1	1	1		1		1
				06.INSOMNIA LATE	1	1	1	1	1	0		0		0
				07.WORK AND ACTIVITIES	3	3	3	3	2	2		1		1
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	1	1	1	1	2	1		1		1
				10.ANXIETY PSYCHIC	3	3	3	3	3	2		2		1
				11.ANXIETY SOMATIC	2	2	2	3	2	2		2		2
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	1	1		0		0
				14.GENITAL SYMPTOMS	2	2	2	2	1	0		0		0
				15.HYPOCHONDRIASIS	0	0	0	0	0	0		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	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	23	23	23	24	18	12		11		9
	452	Reboxetine	Female	01.DEPRESSED MOOD	2	2	2	2	1	1		1		0
				02.GUILT	2	2	2	2	1	1		0		0
				03.SUICIDE	1	1	1	1	1	0		0		0
				04.INSOMNIA EARLY	0	0	0	0	0	0		0		0
				05.INSOMNIA MIDDLE	1	1	1	1	0	0		0		0
				06.INSOMNIA LATE	0	0	0	0	0	0		0		0
				07.WORK AND ACTIVITIES	3	3	3	3	2	2		1		1
				08.RETARDATION	0	0	0	0	0	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56 Day
15	452	Reboxetine	Female	09.AGITATION	1	1	1	1	0	0		0		0
				10.ANXIETY PSYCHIC	2	2	2	1	1	1		1		0
				11.ANXIETY SOMATIC	2	2	2	2	2	1		1		0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	0	2		1		1
				14.GENITAL SYMPTOMS	1	1	1	1	1	0		0		0
				15.HYPOCHONDRIASIS	2	2	2	2	1	1		1		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	1	1	1		2		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	0		0		0
				22.Total score	22	22	22	20	12	10		8		2
	454	Fluoxetine	Male	01.DEPRESSED MOOD	2	2	2	2	2	2		2		1
				02.GUILT	2	2	2	2	2	2		1		1
				03.SUICIDE	1	1	1	1	1	1		1		0
				04.INSOMNIA EARLY	1	1	1	1	0	0		0		0
				05.INSOMNIA MIDDLE	1	1	1	1	1	1		1		0
				06.INSOMNIA LATE	1	1	1	1	0	0		0		0
				07.WORK AND ACTIVITIES	2	2	2	2	2	2		2		2
				08.RETARDATION	0	0	0	0	0	0		0		0
				09.AGITATION	1	1	1	1	1	0		0		0
				10.ANXIETY PSYCHIC	3	3	3	3	3	1		1		1
				11.ANXIETY SOMATIC	2	2	2	2	2	1		1		1
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0
				13.SOMATIC GENERAL	2	2	2	2	2	2		2		2
				14.GENITAL SYMPTOMS	1	1	1	1	1	1		1		1
				15.HYPOCHONDRIASIS	2	2	2	2	2	2		2		2
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	1	1	1	1		1		1
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1		1		0
				22.Total score	23	23	23	23	21	17		16		13
16	429	Fluoxetine	Female	01.DEPRESSED MOOD	4	4	2	1	1	1	0	0	0	0
				02.GUILT	3	3	1	0	0	0	0	0	0	0
				03.SUICIDE	1	1	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	1	0	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	1	1	0	0	0	0	0	0	0	0
				06.INSOMNIA LATE	1	1	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	2	2	2	1	0	1	1	2	2	1
				08.RETARDATION	2	2	1	1	1	0	0	1	1	1
				09.AGITATION	3	3	2	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	3	3	1	1	1	1	1	1	1	1
				11.ANXIETY SOMATIC	2	2	1	1	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	0	0	0	0	0

776

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 12.8

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	49 Day	56
16	429	Fluoxetine	Female	13.SOMATIC GENERAL	1	1	1	0	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	1	1	0	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	2	1	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	0	0	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	2	2	1	0	0	0	0	0	0	0
				20.PARANOID	1	1	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	0	0	0	0	0	0	0
				22.Total score	33	33	17	6	3	3	2	4	4	3
	430	Reboxetine	Male	01.DEPRESSED MOOD	4	4	2	1	1	1	2	2	1	1
				02.GUILT	2	2	1	1	1	1	1	1	0	0
				03.SUICIDE	0	0	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1
				05.INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1
				06.INSOMNIA LATE	1	1	1	1	1	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	1	1	1	1	1	1	1	1
				08.RETARDATION	2	2	1	1	1	1	1	1	0	0
				09.AGITATION	0	0	0	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	0	0
				11.ANXIETY SOMATIC	2	2	1	1	1	1	1	1	1	0
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	0	0	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	1	1	0	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	2	2	0	0	2	2	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	2	2	1	1	0	0	0	0	0	0
				19.DEPERSONALIZATION	3	3	1	1	1	1	1	1	0	0
				20.PARANOID	1	1	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	1	1	0	0	0	0	0	0	0	0
				22.Total score	30	30	14	13	10	9	12	12	5	5
	431	Reboxetine	Female	01.DEPRESSED MOOD	4	4	1	1	1	1	1	1	1	1
				02.GUILT	2	2	1	0	1	0	0	0	0	0
				03.SUICIDE	1	1	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	1	0	0	0	0	0	0	0	0
				06.INSOMNIA LATE	2	2	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	1	1	0	0	1	1	1	0
				08.RETARDATION	1	1	0	0	0	0	0	0	0	0
				09.AGITATION	3	3	2	2	2	2	2	2	2	2
				10.ANXIETY PSYCHIC	3	3	1	1	1	1	1	1	1	1
				11.ANXIETY SOMATIC	2	2	1	1	1	1	2	2	1	1
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	1	1	0	0	0	0	0
				14.GENITAL SYMPTOMS	2	2	2	2	2	1	1	1	1	1
				15.HYPOCHONDRIASIS	2	2	2	1	1	0	0	0	0	0
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56 Day
16	431	Reboxetine	Female	17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	1	1	1	1	1	0	0	0	0	0
				20.PARANOID	2	2	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	2	2	1	1	1	1	1	2	1	1
				22.Total score	33	33	14	12	12	7	9	10	8	9
	432	Fluoxetine	Female	01.DEPRESSED MOOD	4	4	2	1	0	0	0	0	0	0
				02.GUILT	3	3	1	0	0	0	0	0	0	0
				03.SUICIDE	1	1	1	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	0	0	0	0	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	0	0	0	0	0	0	0	0	0	0
				06.INSOMNIA LATE	0	0	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	4	4	2	1	1	1	1	1	1	1
				08.RETARDATION	3	3	1	1	1	1	1	1	1	1
				09.AGITATION	1	1	0	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	1	1	1	1	0	0	0	0	0	0
				11.ANXIETY SOMATIC	2	2	1	0	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	0	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	2	2	1	0	0	0	1	1	1	1
				15.HYPOCHONDRIASIS	2	2	2	0	0	0	0	0	0	0
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	1	1	1	0	0	0	0	0	0
				19.DEPERSONALIZATION	2	2	0	0	0	0	0	0	0	0
				20.PARANOID	1	1	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	1	1	0	0	0	0	0	0	0	0
				22.Total score	30	30	14	5	2	2	3	3	3	3
	433	Reboxetine	Female	01.DEPRESSED MOOD	4	4	2	1	0	0	0	0	0	0
				02.GUILT	3	3	1	0	0	0	0	0	0	0
				03.SUICIDE	0	0	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1
				05.INSOMNIA MIDDLE	0	0	1	0	0	0	0	0	0	0
				06.INSOMNIA LATE	0	0	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	1	0	0	0	0	0	0	0
				08.RETARDATION	2	2	1	0	0	0	0	0	0	0
				09.AGITATION	2	2	1	0	0	0	0	0	1	1
				10.ANXIETY PSYCHIC	3	3	1	1	1	1	1	1	1	1
				11.ANXIETY SOMATIC	1	1	0	0	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	0	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	1	1	0	0	0	0	0	0	0	1
				15.HYPOCHONDRIASIS	3	3	2	0	0	0	0	0	0	0
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	1	1	0	0	0	0	0	0
				19.DEPERSONALIZATION	2	2	1	0	0	0	0	0	0	0
				20.PARANOID	1	1	0	0	0	0	0	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
16	433	Reboxetine	Female	21.OBSESSIONAL/COMPULSIVE	1	1	0	0	0	1	1	1	1	1
				22.Total score	31	31	14	4	2	3	3	3	4	5
	434	Fluoxetine	Female	01.DEPRESSED MOOD	4	4	2	1	1	1	1	1	1	1
				02.GUILT	2	2	1	0	1	0	0	0	1	1
				03.SUICIDE	2	2	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	1	1	2	1	1	1	1	1
				05.INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1
				06.INSOMNIA LATE	1	1	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	2	0	0	0	0	0	0	0
				08.RETARDATION	2	2	1	0	0	0	0	0	0	0
				09.AGITATION	2	2	1	0	1	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	1	1	1	1	1	1	1	1
				11.ANXIETY SOMATIC	2	2	1	0	1	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	0	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	2	2	2	1	1	1	1	1	1	1
				15.HYPOCHONDRIASIS	2	2	2	0	0	0	0	0	0	0
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	2	2	1	0	0	0	0	0	0	0
				20.PARANOID	1	1	1	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	2	2	1	1	1	1	1	1	1	1
				22.Total score	34	34	19	6	10	6	6	6	7	7
	435	Reboxetine	Female	01.DEPRESSED MOOD	4	4	2	1	1	1	1	1	1	1
				02.GUILT	2	2	1	1	0	0	0	0	0	0
				03.SUICIDE	1	1	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	1	1	1	1	1	1	1
				05.INSOMNIA MIDDLE	2	2	2	1	1	1	1	1	1	1
				06.INSOMNIA LATE	2	2	2	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	2	1	0	0	0	0	0	0
				08.RETARDATION	3	3	2	2	1	1	1	1	1	1
				09.AGITATION	2	2	1	1	1	0	0	0	0	0
				10.ANXIETY PSYCHIC	4	4	3	1	1	1	1	1	0	0
				11.ANXIETY SOMATIC	3	3	2	1	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	1	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	1	1	1	1	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	3	3	2	2	0	0	0	0	0	0
				16.LOSS OF WEIGHT	1	1	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	1	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	3	3	2	1	0	0	0	0	0	0
				20.PARANOID	1	1	1	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	2	2	1	1	1	1	0	0	0	0
				22.Total score	44	44	28	16	7	6	5	5	4	4

779

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
16	436	Fluoxetine	Female	01.DEPRESSED MOOD	4	4	3	1	1	1	1	1	2	1
				02.GUILT	2	2	1	1	1	1	0	0	1	1
				03.SUICIDE	1	1	1	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1
				05.INSOMNIA MIDDLE	1	1	1	0	0	0	0	0	1	1
				06.INSOMNIA LATE	0	0	0	0	0	0	0	0	1	0
				07.WORK AND ACTIVITIES	2	2	2	1	1	1	1	0	1	1
				08.RETARDATION	1	1	1	1	1	1	0	0	1	1
				09.AGITATION	2	2	1	1	1	0	0	0	1	0
				10.ANXIETY PSYCHIC	4	4	3	1	1	1	1	1	3	1
				11.ANXIETY SOMATIC	2	2	2	2	2	2	1	0	2	2
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	1
				13.SOMATIC GENERAL	1	1	0	0	0	0	0	0	1	0
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2	2	2	2
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	2	0
				16.LOSS OF WEIGHT	1	1	0	0	0	0	0	0	1	0
				17.INSIGHT	1	1	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	0	0	1	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	3	3	1	1	1	1	1	0	1	1
				20.PARANOID	2	2	2	1	1	1	1	0	1	1
				21.OBSESSIONAL/COMPULSIVE	2	2	2	1	1	1	1	1	1	1
				22.Total score	33	33	25	15	15	14	11	7	24	15
	437	Reboxetine	Female	01.DEPRESSED MOOD	4	4	2	1	1	1	1	1	1	1
				02.GUILT	2	2	1	0	0	0	0	0	0	0
				03.SUICIDE	3	3	2	1	1	1	1	0	0	0
				04.INSOMNIA EARLY	2	2	2	1	1	1	1	1	1	1
				05.INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	1
				06.INSOMNIA LATE	1	1	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	2	1	1	1	1	1	1	1
				08.RETARDATION	1	1	0	0	0	0	0	0	0	0
				09.AGITATION	2	2	2	1	1	1	1	0	0	0
				10.ANXIETY PSYCHIC	3	3	1	1	1	1	1	1	1	1
				11.ANXIETY SOMATIC	1	1	1	0	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	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	2	2	0	0	0	0	0	0	0	0
				16.LOSS OF WEIGHT	1	1	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	3	3	2	1	1	1	1	0	0	0
				20.PARANOID	1	1	1	1	1	1	1	1	0	0
				21.OBSESSIONAL/COMPULSIVE	2	2	2	1	1	1	1	1	1	1
				22.Total score	36	36	19	10	10	10	10	7	6	6
	438	Fluoxetine	Female	01.DEPRESSED MOOD	4	4	1	1	1	1	1			
				02.GUILT	3	3	1	1	0	0	0			
				03.SUICIDE	2	2	1	1	0	0	0			
				04.INSOMNIA EARLY	2	2	1	1	1	1	1			

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
16	438	Fluoxetine	Female	05.INSOMNIA MIDDLE	2	2	1	1	1	1	1			
				06.INSOMNIA LATE	1	1	0	0	0	0	0			
				07.WORK AND ACTIVITIES	2	2	1	1	1	1	1			
				08.RETARDATION	1	1	0	0	0	0	1			
				09.AGITATION	2	2	0	0	0	0	0			
				10.ANXIETY PSYCHIC	3	3	1	1	1	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	1	1	0	0	0	0	1			
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	2			
				15.HYPOCHONDRIASIS	3	3	2	2	2	2	2			
				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	2	2	1	0	0	0	0			
				20.PARANOID	0	0	0	0	0	0	0			
				21.OBSESSIONAL/COMPULSIVE	2	2	1	1	1	1	1			
				22.Total score	36	36	15	14	12	12	14			
	439	Fluoxetine	Female	01.DEPRESSED MOOD	4	4	2	1	1	0	0	0	0	0
				02.GUILT	2	2	1	0	0	0	0	0	0	0
				03.SUICIDE	1	1	1	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	0	0	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	1	1	1	1	1	0	0	0	0	0
				06.INSOMNIA LATE	1	1	1	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	2	1	1	0	0	0	0	0
				08.RETARDATION	2	2	1	0	0	0	0	0	0	0
				09.AGITATION	2	2	1	0	0	0	0	0	0	1
				10.ANXIETY PSYCHIC	3	3	1	1	1	1	0	0	0	1
				11.ANXIETY SOMATIC	2	2	1	0	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	0	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	1	2	2	2
				15.HYPOCHONDRIASIS	2	2	2	1	1	1	1	1	1	1
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	1	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	2	2	1	1	1	0	0	0	0	0
				19.DEPERSONALIZATION	3	3	2	1	1	0	0	0	0	0
				20.PARANOID	2	2	2	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1	1	1
				22.Total score	36	36	24	10	10	5	3	4	4	6
	440	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	1	1	1	1	1	1	0
				02.GUILT	2	2	1	0	0	0	0	0	0	0
				03.SUICIDE	1	1	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	1	1	0	0	0	0	0
				05.INSOMNIA MIDDLE	1	1	0	0	0	0	0	0	0	0
				06.INSOMNIA LATE	1	1	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	2	1	1	0	0	0	0	0
				08.RETARDATION	2	2	1	0	0	0	0	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
16	440	Reboxetine	Female	09.AGITATION	2	2	1	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	3	3	1	1	1	1	1	1	1	1
				11.ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	0	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	1	1	1	0	0	0	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	1	1	1	0	0	0	0	0
				16.LOSS OF WEIGHT	1	1	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	1	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	2	2	1	0	0	0	0	0	0	0
				20.PARANOID	1	1	1	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	2	2	1	1	1	1	1	1	1	1
				22.Total score	34	34	18	7	7	4	4	4	4	3
	441	Fluoxetine	Female	01.DEPRESSED MOOD	2	2	1	1	1	1		1		1
				02.GUILT	2	2	1	0	0	0		0		0
				03.SUICIDE	1	1	1	1	1	0		0		0
				04.INSOMNIA EARLY	2	2	1	0	0	0		0		0
				05.INSOMNIA MIDDLE	1	1	1	0	0	0		0		0
				06.INSOMNIA LATE	1	1	0	0	0	0		0		0
				07.WORK AND ACTIVITIES	3	3	2	1	1	0		0		1
				08.RETARDATION	2	2	2	1	1	1		0		0
				09.AGITATION	2	2	1	1	1	0		0		0
				10.ANXIETY PSYCHIC	3	3	1	1	1	1		1		1
				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	1	1	1	0	0	0		0		0
				14.GENITAL SYMPTOMS	2	2	2	2	2	1		1		0
				15.HYPOCHONDRIASIS	2	2	2	1	1	0		0		0
				16.LOSS OF WEIGHT	2	2	1	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	1	0	0	0		0		0
				19.DEPERSONALIZATION	1	1	1	0	0	0		0		0
				20.PARANOID	1	1	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1		1		1
				22.Total score	34	34	22	10	10	5		4		4
	442	Reboxetine	Female	01.DEPRESSED MOOD	4	4	3	2	1	1		2		1
				02.GUILT	3	3	3	2	1	1		1		1
				03.SUICIDE	3	3	2	1	1	1		1		1
				04.INSOMNIA EARLY	2	2	2	2	1	1		1		1
				05.INSOMNIA MIDDLE	2	2	2	1	1	1		1		1
				06.INSOMNIA LATE	2	2	2	1	1	1		1		1
				07.WORK AND ACTIVITIES	4	4	4	3	2	1		1		1
				08.RETARDATION	3	3	2	1	1	1		1		1
				09.AGITATION	2	2	2	1	1	1		1		1
				10.ANXIETY PSYCHIC	4	4	3	3	1	1		1		1
				11.ANXIETY SOMATIC	3	3	3	2	2	1		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	0	0		1		1

782

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
16	442	Reboxetine	Female	13.SOMATIC GENERAL	1	1	1	1	0	0		1		1
				14.GENITAL SYMPTOMS	2	2	2	2	2	2		1		1
				15.HYPOCHONDRIASIS	3	3	3	2	1	1		1		1
				16.LOSS OF WEIGHT	2	2	1	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	2	1	1		1		1
				19.DEPERSONALIZATION	3	3	2	1	1	1		1		1
				20.PARANOID	1	1	1	1	1	1		1		1
				21.OBSESSIONAL/COMPULSIVE	2	2	2	2	1	1		1		1
				22.Total score	49	49	43	31	20	18		20		19
	443	Fluoxetine	Male	01.DEPRESSED MOOD	2	2	2	1	1	1		1		1
				02.GUILT	0	0	0	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		1
				05.INSOMNIA MIDDLE	1	1	1	1	0	0		0		0
				06.INSOMNIA LATE	1	1	0	0	0	0		0		0
				07.WORK AND ACTIVITIES	2	2	2	1	1	1		0		1
				08.RETARDATION	1	1	1	1	1	1		1		1
				09.AGITATION	2	2	2	1	0	0		0		0
				10.ANXIETY PSYCHIC	1	1	1	1	1	1		1		1
				11.ANXIETY SOMATIC	1	1	1	0	0	0		0		0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0
				13.SOMATIC GENERAL	1	1	1	0	0	0		0		0
				14.GENITAL SYMPTOMS	1	1	1	1	0	0		0		0
				15.HYPOCHONDRIASIS	1	1	1	0	0	0		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	1	1	1	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	1	1	0		0		0
				19.DEPERSONALIZATION	1	1	1	0	0	0		0		0
				20.PARANOID	2	2	1	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1		1		1
				22.Total score	22	22	20	10	7	6		5		6
	444	Reboxetine	Female	01.DEPRESSED MOOD	2	2	2	2	1	1		0		0
				02.GUILT	1	1	1	1	0	0		0		0
				03.SUICIDE	1	1	1	1	0	0		0		0
				04.INSOMNIA EARLY	1	1	0	0	0	0		0		0
				05.INSOMNIA MIDDLE	1	1	1	1	1	0		0		0
				06.INSOMNIA LATE	1	1	1	1	0	0		0		0
				07.WORK AND ACTIVITIES	2	2	1	1	0	0		0		0
				08.RETARDATION	2	2	1	1	1	1		0		0
				09.AGITATION	0	0	0	0	0	0		0		0
				10.ANXIETY PSYCHIC	1	1	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	1	1	1	1	0	0		0		0
				14.GENITAL SYMPTOMS	2	2	2	2	2	2		0		0
				15.HYPOCHONDRIASIS	2	2	2	1	1	1		1		1
				16.LOSS OF WEIGHT	2	2	0	0	0	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
16	444	Reboxetine	Female	17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	2	1	1		0		0
				19.DEPERSONALIZATION	1	1	1	1	1	1		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1		0		0
				22.Total score	26	26	20	19	12	11		4		4
	445	Reboxetine	Male	01.DEPRESSED MOOD	2	2	2	1	1	1		1		1
				02.GUILT	1	1	0	0	0	0		0		0
				03.SUICIDE	0	0	0	0	0	0		0		0
				04.INSOMNIA EARLY	1	1	1	1	0	0		0		0
				05.INSOMNIA MIDDLE	1	1	1	0	0	0		0		0
				06.INSOMNIA LATE	1	1	0	0	0	0		0		0
				07.WORK AND ACTIVITIES	2	2	2	1	1	1		1		1
				08.RETARDATION	2	2	2	1	1	1		1		1
				09.AGITATION	0	0	0	0	0	0		0		0
				10.ANXIETY PSYCHIC	1	1	1	0	0	0		0		0
				11.ANXIETY SOMATIC	1	1	1	0	0	1		0		0
				12.SOMATIC GASTROINTESTINAL	1	1	1	0	0	1		1		0
				13.SOMATIC GENERAL	1	1	1	0	0	0		0		0
				14.GENITAL SYMPTOMS	1	1	1	1	1	1		1		1
				15.HYPOCHONDRIASIS	2	2	2	1	1	1		1		1
				16.LOSS OF WEIGHT	2	2	2	0	0	0		0		0
				17.INSIGHT	1	1	0	0	0	0		0		0
				18.DIURNAL VARIATION	1	1	1	1	0	0		0		0
				19.DEPERSONALIZATION	1	1	1	0	0	0		0		0
				20.PARANOID	1	1	1	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1		1		1
				22.Total score	24	24	21	8	6	8		7		7
	446	Fluoxetine	Female	01.DEPRESSED MOOD	2	2	2	1	1	1		1		1
				02.GUILT	1	1	1	1	0	0		0		0
				03.SUICIDE	1	1	1	1	0	0		0		0
				04.INSOMNIA EARLY	1	1	1	0	0	0		0		0
				05.INSOMNIA MIDDLE	1	1	1	1	1	1		0		0
				06.INSOMNIA LATE	1	1	1	1	0	0		0		0
				07.WORK AND ACTIVITIES	2	2	2	1	1	1		1		1
				08.RETARDATION	1	1	1	1	1	1		1		1
				09.AGITATION	1	0	0	0	0	0		0		0
				10.ANXIETY PSYCHIC	1	1	1	1	1	1		1		1
				11.ANXIETY SOMATIC	1	1	1	1	1	1		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0		0		0
				13.SOMATIC GENERAL	1	1	1	1	0	0		0		0
				14.GENITAL SYMPTOMS	2	2	2	2	2	1		1		1
				15.HYPOCHONDRIASIS	2	2	2	1	1	1		1		1
				16.LOSS OF WEIGHT	1	1	1	1	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	1	1	0		0		0
				19.DEPERSONALIZATION	1	1	1	1	0	0		0		0
				20.PARANOID	1	1	1	1	1	1		1		1

784

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
16	446	Fluoxetine	Female	21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0		0		0
				22.Total score	24	23	23	18	12	9		8		8
	447	Fluoxetine	Male	01.DEPRESSED MOOD	2	2	2	2	1	1		1		1
				02.GUILT	0	0	0	0	0	0		0		0
				03.SUICIDE	1	1	0	0	0	0		0		0
				04.INSOMNIA EARLY	0	0	0	0	0	0		0		0
				05.INSOMNIA MIDDLE	1	1	1	1	0	0		0		0
				06.INSOMNIA LATE	1	1	1	1	1	1		1		1
				07.WORK AND ACTIVITIES	3	3	2	2	1	1		1		1
				08.RETARDATION	1	1	1	1	1	1		1		1
				09.AGITATION	1	1	1	1	0	0		0		0
				10.ANXIETY PSYCHIC	1	1	1	1	1	1		1		1
				11.ANXIETY SOMATIC	1	1	1	1	1	1		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	0	0		1		0
				13.SOMATIC GENERAL	1	1	0	0	0	0		0		0
				14.GENITAL SYMPTOMS	1	1	1	1	0	0		1		0
				15.HYPOCHONDRIASIS	2	2	2	1	1	1		1		1
				16.LOSS OF WEIGHT	2	2	0	0	0	0		0		0
				17.INSIGHT	1	1	1	1	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	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	1	1	1	1	1	1		1		1
				22.Total score	23	23	18	17	9	9		11		9
	448	Reboxetine	Female	01.DEPRESSED MOOD	2	2	2	1	1	1		1		1
				02.GUILT	1	1	1	1	1	1		1		0
				03.SUICIDE	0	0	0	0	0	0		0		0
				04.INSOMNIA EARLY	1	1	1	1	1	1		1		1
				05.INSOMNIA MIDDLE	1	1	1	1	1	0		0		0
				06.INSOMNIA LATE	1	1	1	1	0	0		0		0
				07.WORK AND ACTIVITIES	2	2	1	1	1	1		1		1
				08.RETARDATION	1	1	1	1	1	1		1		1
				09.AGITATION	2	2	2	1	1	1		1		0
				10.ANXIETY PSYCHIC	1	1	1	1	0	0		0		0
				11.ANXIETY SOMATIC	1	1	1	0	0	0		0		0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0
				13.SOMATIC GENERAL	1	1	1	1	1	1		1		0
				14.GENITAL SYMPTOMS	2	2	2	2	2	2		2		2
				15.HYPOCHONDRIASIS	1	1	1	0	0	0		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	1	1	1	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	2	1	1		1		1
				19.DEPERSONALIZATION	1	1	1	1	1	1		1		0
				20.PARANOID	2	2	1	1	1	1		1		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1		1		1
				22.Total score	24	24	22	17	14	13		13		8

485

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
16	455	Fluoxetine	Female	01.DEPRESSED MOOD	4	4	4	2	2	1		1		1
				02.GUILT	2	2	2	2	2	1		1		1
				03.SUICIDE	1	1	0	0	0	0		0		0
				04.INSOMNIA EARLY	2	2	2	2	2	2		2		1
				05.INSOMNIA MIDDLE	1	1	1	1	1	0		0		0
				06.INSOMNIA LATE	1	1	1	0	0	0		0		0
				07.WORK AND ACTIVITIES	3	3	3	2	2	1		1		1
				08.RETARDATION	2	2	2	2	1	1		1		1
				09.AGITATION	2	2	2	1	1	1		1		1
				10.ANXIETY PSYCHIC	3	3	3	1	1	1		1		1
				11.ANXIETY SOMATIC	1	1	1	1	1	1		1		1
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0
				13.SOMATIC GENERAL	1	1	1	1	1	1		1		1
				14.GENITAL SYMPTOMS	2	2	2	2	2	1		2		1
				15.HYPOCHONDRIASIS	2	2	2	2	2	1		1		1
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	1	1	1	1	1	0		0		0
				18.DIURNAL VARIATION	2	2	2	2	2	1		1		1
				19.DEPERSONALIZATION	1	1	1	1	1	1		1		0
				20.PARANOID	1	1	1	1	1	0		0		0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0		0		0
				22.Total score	32	32	31	24	23	14		15		12
	456	Reboxetine	Male	01.DEPRESSED MOOD	4	4	3	1	1	1		1		1
				02.GUILT	1	1	1	0	0	0		0		0
				03.SUICIDE	1	1	1	0	0	0		0		0
				04.INSOMNIA EARLY	2	2	2	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	2	2	2	2	1	1		1		1
				08.RETARDATION	2	2	1	1	1	1		1		1
				09.AGITATION	1	1	1	0	0	0		0		0
				10.ANXIETY PSYCHIC	3	3	1	1	1	1		1		1
				11.ANXIETY SOMATIC	3	3	2	2	1	1		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1		1		1
				13.SOMATIC GENERAL	1	1	1	0	0	0		0		0
				14.GENITAL SYMPTOMS	2	2	2	2	2	2		2		2
				15.HYPOCHONDRIASIS	3	3	2	2	1	1		1		1
				16.LOSS OF WEIGHT	2	2	2	1	0	0		0		0
				17.INSIGHT	1	1	1	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	2	1	1		1		1
				19.DEPERSONALIZATION	2	2	1	1	1	1		1		1
				20.PARANOID	1	1	1	1	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	2	2	1	1	1	1		1		1
				22.Total score	38	38	30	19	13	13		13		13
	457	Fluoxetine	Female	01.DEPRESSED MOOD	2	2	2	1	1	1	1	1		1
				02.GUILT	2	2	2	1	1	1	0	0		0
				03.SUICIDE	1	1	1	0	0	0	0	0		0
				04.INSOMNIA EARLY	2	2	2	1	1	1	0	0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
16	457	Fluoxetine	Female	05.INSOMNIA MIDDLE	1	1	1	1	0	0	0	0		0
				06.INSOMNIA LATE	1	1	1	0	0	0	0	0		0
				07.WORK AND ACTIVITIES	2	2	2	2	2	2	1	1		1
				08.RETARDATION	2	2	2	1	1	1	1	1		1
				09.AGITATION	1	1	1	1	1	1	0	0		0
				10.ANXIETY PSYCHIC	3	3	3	1	1	1	0	0		0
				11.ANXIETY SOMATIC	2	2	2	1	1	1	0	0		0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	0	0		0
				13.SOMATIC GENERAL	1	1	1	1	1	1	0	0		0
				14.GENITAL SYMPTOMS	2	2	2	2	2	2	1	1		1
				15.HYPOCHONDRIASIS	2	2	2	1	1	1	0	0		0
				16.LOSS OF WEIGHT	1	1	1	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	0	0		0
				19.DEPERSONALIZATION	0	0	0	0	0	0	0	0		0
				20.PARANOID	1	1	1	0	0	0	0	0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1	1	1		1
				22.Total score	30	30	30	17	16	16	5	5		5
	458	Fluoxetine	Female	01.DEPRESSED MOOD	4	4	4	2	2	2		2		2
				02.GUILT	1	1	1	0	0	0		0		0
				03.SUICIDE	1	1	0	0	0	0		0		0
				04.INSOMNIA EARLY	0	0	0	0	0	0		0		0
				05.INSOMNIA MIDDLE	0	0	0	0	0	0		0		0
				06.INSOMNIA LATE	0	0	0	0	0	0		0		0
				07.WORK AND ACTIVITIES	3	3	3	2	2	2		2		2
				08.RETARDATION	2	2	2	2	2	2		2		2
				09.AGITATION	0	0	0	0	0	0		0		0
				10.ANXIETY PSYCHIC	3	3	3	1	1	1		1		1
				11.ANXIETY SOMATIC	3	3	3	2	1	1		1		1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1		1		1
				13.SOMATIC GENERAL	1	1	1	1	1	1		1		1
				14.GENITAL SYMPTOMS	2	2	2	2	2	2		2		2
				15.HYPOCHONDRIASIS	3	3	3	2	2	2		2		2
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	1	1	1	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	1	1	1		1		1
				19.DEPERSONALIZATION	1	1	1	1	1	1		1		1
				20.PARANOID	1	1	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1		1		1
				22.Total score	30	30	28	18	17	17		17		17
	459	Reboxetine	Male	01.DEPRESSED MOOD	2	2	2	1	1	1		0		0
				02.GUILT	0	0	0	0	0	0		0		0
				03.SUICIDE	0	0	0	0	0	0		0		0
				04.INSOMNIA EARLY	2	2	1	1	1	1		0		0
				05.INSOMNIA MIDDLE	1	1	0	0	0	0		0		0
				06.INSOMNIA LATE	1	1	0	0	0	0		0		0
				07.WORK AND ACTIVITIES	2	2	2	1	1	0		0		0
				08.RETARDATION	2	2	2	1	1	1		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
16	459	Reboxetine	Male	09.AGITATION	1	1	1	1	1	1		0		0
				10.ANXIETY PSYCHIC	3	3	1	1	1	1		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	1	1	1	0	0	0		0		0
				14.GENITAL SYMPTOMS	2	2	2	2	2	1		0		0
				15.HYPOCHONDRIASIS	2	2	2	1	1	1		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	0	0	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	1	1	1		0		0
				19.DEPERSONALIZATION	0	0	0	0	0	0		0		0
				20.PARANOID	0	0	0	0	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1		0		0
				22.Total score	25	25	19	11	11	9		0		0
	460	Reboxetine	Male	01.DEPRESSED MOOD	4	4	3	2	1	1		0		0
				02.GUILT	2	2	1	1	0	0		0		0
				03.SUICIDE	1	1	1	1	0	0		0		0
				04.INSOMNIA EARLY	2	2	2	2	1	1		0		0
				05.INSOMNIA MIDDLE	0	0	0	0	0	0		0		0
				06.INSOMNIA LATE	0	0	0	0	0	0		0		0
				07.WORK AND ACTIVITIES	3	3	3	3	2	2		0		0
				08.RETARDATION	2	2	2	2	1	1		1		1
				09.AGITATION	2	2	2	1	0	0		0		0
				10.ANXIETY PSYCHIC	3	3	2	2	1	1		0		0
				11.ANXIETY SOMATIC	2	2	2	2	1	1		0		0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0		0		0
				13.SOMATIC GENERAL	1	1	1	1	0	0		0		0
				14.GENITAL SYMPTOMS	2	2	2	2	1	1		1		1
				15.HYPOCHONDRIASIS	3	3	2	2	1	1		0		0
				16.LOSS OF WEIGHT	0	0	0	0	0	0		0		0
				17.INSIGHT	1	1	0	0	0	0		0		0
				18.DIURNAL VARIATION	2	2	2	2	1	1		0		0
				19.DEPERSONALIZATION	2	2	1	1	0	0		0		0
				20.PARANOID	1	1	1	1	0	0		0		0
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1	1		1		0
				22.Total score	34	34	28	26	11	11		3		2
18	25	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	2	1	1	1	1	0	0
				02.GUILT	2	2	2	1	1	1	1	1	0	0
				03.SUICIDE	1	1	1	1	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	1	1	1	1	1	1	0	0
				05.INSOMNIA MIDDLE	2	2	2	1	1	1	1	1	0	1
				06.INSOMNIA LATE	2	2	0	0	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	2	2	2	2	1	1	1	1	0	0
				08.RETARDATION	1	1	1	1	1	1	1	1	0	0
				09.AGITATION	0	0	0	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	2	2	2	2	2	2	1	1
				11.ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	0	0	0	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56 Day
18	25	Fluoxetine	Female	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	1	1	1	1	1	1	1	1	1	1
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	1	1	1	1	1	1	1	1	0	0
				18.DIURNAL VARIATION	1	1	1	1	1	1	1	1	1	1
				19.DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1
				20.PARANOID	0	0	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0
				22.Total score	24	24	20	17	14	14	14	14	7	7
	26	Reboxetine	Female	01.DEPRESSED MOOD	3	3	3	2	1	1	1	0	0	0
				02.GUILT	2	2	2	1	1	0	0	0	0	0
				03.SUICIDE	0	0	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	1	1	1	0	0	0	0	0
				05.INSOMNIA MIDDLE	2	2	2	2	1	1	1	1	1	1
				06.INSOMNIA LATE	2	2	2	2	1	1	1	1	1	1
				07.WORK AND ACTIVITIES	2	2	2	2	1	0	0	0	0	0
				08.RETARDATION	1	1	1	1	1	1	1	1	0	0
				09.AGITATION	2	2	2	2	2	2	2	1	1	1
				10.ANXIETY PSYCHIC	1	1	1	1	1	1	1	2	1	0
				11.ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1	0	0
				14.GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	0	0
				15.HYPOCHONDRIASIS	1	1	1	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	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	1	1	1	1	1	1	1	0	0
				19.DEPERSONALIZATION	1	1	1	1	1	1	1	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	22	20	16	13	13	10	6	4
	27	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	1	1	1	1	0	0	0
				02.GUILT	2	2	2	1	0	0	0	0	0	0
				03.SUICIDE	1	1	1	1	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	2	1	0	0	0	0	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	0	0
				07.WORK AND ACTIVITIES	2	2	2	1	1	0	0	0	0	0
				08.RETARDATION	2	2	2	2	2	2	2	1	0	0
				09.AGITATION	1	1	1	1	1	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	2	2	2	2	2	1	0	0
				11.ANXIETY SOMATIC	2	2	2	2	2	2	2	2	2	2
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	0	0	0
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	0	0	0
				14.GENITAL SYMPTOMS	1	1	1	1	1	1	1	0	0	0
				15.HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	0
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
18	27	Reboxetine	Female	17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	0	0	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	1	1	1	1	1	1	1	1	0	0
				20.PARANOID	0	0	0	0	0	0	0	0	0	0
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0
				22.Total score	24	24	23	20	17	14	14	8	4	3
	28	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	3	3	3				
				02.GUILT	2	2	2	2	2	2				
				03.SUICIDE	0	0	0	0	0	0				
				04.INSOMNIA EARLY	1	1	1	1	1	1				
				05.INSOMNIA MIDDLE	1	1	1	1	1	1				
				06.INSOMNIA LATE	1	1	1	1	1	1				
				07.WORK AND ACTIVITIES	3	3	3	3	3	3				
				08.RETARDATION	1	1	1	1	1	1				
				09.AGITATION	2	2	2	2	2	2				
				10.ANXIETY PSYCHIC	1	1	1	1	1	1				
				11.ANXIETY SOMATIC	1	1	1	1	1	1				
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1				
				13.SOMATIC GENERAL	1	1	1	1	1	1				
				14.GENITAL SYMPTOMS	1	1	1	1	1	1				
				15.HYPOCHONDRIASIS	2	2	2	2	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	1	1	1	1				
				19.DEPERSONALIZATION	1	1	1	1	1	1				
				20.PARANOID	0	0	0	0	0	0				
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0				
				22.Total score	23	23	23	23	23	23				
	29	Reboxetine	Male	01.DEPRESSED MOOD	3	3	3	2	2	1	0	1	0	0
				02.GUILT	1	1	1	1	1	0	1	0	0	0
				03.SUICIDE	0	0	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	1	1	1	1	0	1	0	0
				05.INSOMNIA MIDDLE	1	1	1	1	1	1	0	1	0	0
				06.INSOMNIA LATE	1	1	1	1	1	1	0	1	1	0
				07.WORK AND ACTIVITIES	3	3	3	2	2	1	1	0	1	0
				08.RETARDATION	2	2	2	2	2	2	0	2	1	0
				09.AGITATION	2	2	2	2	2	1	0	1	1	0
				10.ANXIETY PSYCHIC	2	2	2	2	2	1	1	1	1	1
				11.ANXIETY SOMATIC	2	2	2	2	2	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1	0	1
				14.GENITAL SYMPTOMS	1	1	1	1	1	0	0	0	0	0
				15.HYPOCHONDRIASIS	1	1	1	1	1	1	0	1	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	0	0	0	0	0	0	0	0	0	0
				19.DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	0
				20.PARANOID	0	0	0	0	0	0	0	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
18	29	Reboxetine	Male	21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	0	0
				22.Total score	23	23	23	21	21	12	6	11	7	5
	30	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	2	1	1	1	1	1	1
				02.GUILT	3	3	3	2	1	1	1	1	1	1
				03.SUICIDE	1	1	1	1	0	0	0	0	1	1
				04.INSOMNIA EARLY	1	1	1	1	1	1	1	1	1	1
				05.INSOMNIA MIDDLE	2	2	2	2	1	1	1	1	1	1
				06.INSOMNIA LATE	2	2	2	2	1	1	1	1	1	1
				07.WORK AND ACTIVITIES	3	3	3	2	1	1	1	1	1	1
				08.RETARDATION	1	1	1	1	1	1	1	1	0	0
				09.AGITATION	1	1	1	1	1	1	1	1	0	0
				10.ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	0	0
				11.ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	0	0
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1
				14.GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	0	0
				15.HYPOCHONDRIASIS	1	1	1	1	1	1	1	1	1	1
				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	1	1	1	1	1	1	1	1	0	0
				19.DEPERSONALIZATION	1	1	0	1	1	1	1	1	1	1
				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	25	24	22	16	16	16	16	11	11
	31	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	2	2	2	2	1	1	1
				02.GUILT	3	3	2	2	2	2	2	1	0	0
				03.SUICIDE	1	1	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	1	1	1	1	1	0	0	0
				05.INSOMNIA MIDDLE	1	1	2	2	2	2	2	1	1	1
				06.INSOMNIA LATE	1	1	1	1	1	1	1	1	1	1
				07.WORK AND ACTIVITIES	2	2	1	1	1	1	1	1	1	1
				08.RETARDATION	2	2	2	2	2	2	2	1	1	1
				09.AGITATION	1	1	1	1	1	1	1	1	1	1
				10.ANXIETY PSYCHIC	1	1	1	1	1	1	1	0	0	0
				11.ANXIETY SOMATIC	1	1	1	1	1	1	1	0	0	0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	1	2	2	2	2	2	2	1	1	1
				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	0	0	0	0	0	0	0	0	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	1	1	1	1	1	1	1	1	0	0
				20.PARANOID	0	0	0	0	0	0	0	0	1	1
				21.OBSESSIONAL/COMPULSIVE	0	0	0	0	0	0	0	0	1	1
				22.Total score	24	25	21	21	21	21	21	13	14	14

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
18	32	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	3	2	1	1	1	1	1
				02.GUILT	2	2	2	2	1	0	0	0	0	0
				03.SUICIDE	1	1	1	1	1	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	2	1	0	0	0	0	0
				05.INSOMNIA MIDDLE	2	2	2	2	1	1	1	0	0	0
				06.INSOMNIA LATE	2	2	2	2	2	2	1	0	0	0
				07.WORK AND ACTIVITIES	2	2	2	2	2	1	1	1	0	0
				08.RETARDATION	2	1	1	1	1	1	0	0	0	0
				09.AGITATION	1	1	1	1	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	2	2	1	1	0	0	1	1
				11.ANXIETY SOMATIC	2	2	2	2	1	1	2	0	1	1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	0	0
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1	0	0
				14.GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	0	0
				15.HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	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	1	1	1	1	1	1	1	1	0	0
				19.DEPERSONALIZATION	1	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	28	26	26	26	19	14	12	8	3	3
	49	Reboxetine	Female	01.DEPRESSED MOOD	3	3	2	1	1	1	0	0	0	0
				02.GUILT	3	3	2	1	1	1	1	1	0	0
				03.SUICIDE	0	0	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	1	1	1	1	1	1	1	0
				05.INSOMNIA MIDDLE	1	1	0	0	0	0	0	1	0	0
				06.INSOMNIA LATE	1	1	1	1	1	1	1	1	0	0
				07.WORK AND ACTIVITIES	3	3	3	1	1	1	0	0	0	0
				08.RETARDATION	2	2	0	0	0	0	0	0	0	0
				09.AGITATION	1	1	1	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	0	0	0	0	0	0	0	0
				11.ANXIETY SOMATIC	2	2	1	0	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	2	2	1	1	1	1	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	1
				14.GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1
				15.HYPOCHONDRIASIS	1	1	1	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	1	1	1	1	1	1	1	1	1	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	26	26	16	9	9	9	6	6	4	4
	50	Reboxetine	Female	01.DEPRESSED MOOD	3	3								
				02.GUILT	3	3								
				03.SUICIDE	1	1								
				04.INSOMNIA EARLY	2	2								

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56 Day
18	50	Reboxetine	Female	05.INSOMNIA MIDDLE	1	1								
				06.INSOMNIA LATE	1	1								
				07.WORK AND ACTIVITIES	3	3								
				08.RETARDATION	2	2								
				09.AGITATION	0	0								
				10.ANXIETY PSYCHIC	2	2								
				11.ANXIETY SOMATIC	2	2								
				12.SOMATIC GASTROINTESTINAL	1	1								
				13.SOMATIC GENERAL	1	1								
				14.GENITAL SYMPTOMS	1	1								
				15.HYPOCHONDRIASIS	2	2								
				16.LOSS OF WEIGHT	0	0								
				17.INSIGHT	0	0								
				18.DIURNAL VARIATION	0	0								
				19.DEPERSONALIZATION	1	1								
				20.PARANOID	0	0								
				21.OBSESSIONAL/COMPULSIVE	0	0								
				22.Total score	26	26								
793	51	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	2	1	1	1	1	1	1	0
				02.GUILT	3	3	1	1	1	1	1	1	1	0
				03.SUICIDE	1	1	1	1	1	1	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	1	1	1	1	1	1	0
				05.INSOMNIA MIDDLE	1	1	1	1	1	1	1	1	1	0
				06.INSOMNIA LATE	1	1	1	1	1	1	1	1	1	0
				07.WORK AND ACTIVITIES	2	2	2	1	1	1	2	2	2	1
				08.RETARDATION	1	1	1	1	1	1	1	1	1	0
				09.AGITATION	2	2	2	1	1	1	1	1	1	0
				10.ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	0
				11.ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	0
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	0
				14.GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	0
				15.HYPOCHONDRIASIS	2	2	2	1	1	1	1	1	1	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	1	1	1	1	1	1	1	0	1	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	24	24	21	16	16	16	16	16	16	8
	52	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	2	1	1	1	1	1	1
				02.GUILT	1	1	1	1	1	1	1	1	1	1
				03.SUICIDE	1	1	1	1	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	1	1	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	2	2	2	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	4	4	2	2	2	2	2	1
				08.RETARDATION	3	3	3	2	1	1	1	1	1	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
18	52	Fluoxetine	Female	09.AGITATION	1	1	1	1	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	1	1	1	1	1	1	1	1	1	0
				11.ANXIETY SOMATIC	1	1	1	1	1	1	1	1	1	0
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	1	1	1	1	0
				13.SOMATIC GENERAL	1	1	1	1	1	1	1	1	1	0
				14.GENITAL SYMPTOMS	1	1	1	1	1	1	1	1	1	1
				15.HYPOCHONDRIASIS	2	2	2	2	2	2	2	2	2	1
				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	1	1	1	1	1	1	1	1	1	0
				19.DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1
				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	26	26	26	23	16	16	16	16	16	8
	53	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	3	3	3	2	2	2	2	1
				02.GUILT	2	2	2	2	2	1	1	1	1	1
				03.SUICIDE	0	0	0	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	2	2	2	2	2	1	1	1	1	0
				05.INSOMNIA MIDDLE	2	2	2	2	2	2	2	2	2	1
				06.INSOMNIA LATE	1	1	1	1	1	0	0	0	0	0
				07.WORK AND ACTIVITIES	3	3	3	3	3	1	1	1	1	0
				08.RETARDATION	1	1	1	1	1	1	1	1	1	1
				09.AGITATION	1	2	2	2	2	2	2	2	2	1
				10.ANXIETY PSYCHIC	2	2	2	2	2	1	1	1	1	1
				11.ANXIETY SOMATIC	2	2	2	2	2	1	1	1	1	1
				12.SOMATIC GASTROINTESTINAL	1	1	1	1	1	0	0	0	0	0
				13.SOMATIC GENERAL	1	1	1	1	1	0	0	0	0	0
				14.GENITAL SYMPTOMS	1	1	1	1	1	0	0	0	0	0
				15.HYPOCHONDRIASIS	2	2	2	0	0	0	0	0	0	0
				16.LOSS OF WEIGHT	0	0	0	0	0	0	0	0	0	0
				17.INSIGHT	0	0	0	0	0	0	0	0	0	0
				18.DIURNAL VARIATION	1	1	1	1	1	0	0	0	0	0
				19.DEPERSONALIZATION	1	1	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	26	27	27	25	25	12	12	12	12	7
	54	Fluoxetine	Male	01.DEPRESSED MOOD	3	3	3	2	1	1	1	1	1	1
				02.GUILT	2	2	2	1	1	1	1	0	0	0
				03.SUICIDE	1	1	1	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	1	0	0	0	0	0	0	0
				05.INSOMNIA MIDDLE	2	2	2	1	1	1	1	0	0	0
				06.INSOMNIA LATE	2	2	2	1	1	1	1	1	1	1
				07.WORK AND ACTIVITIES	3	3	3	2	1	1	1	0	0	0
				08.RETARDATION	1	1	1	0	0	0	0	0	0	0
				09.AGITATION	1	1	1	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	2	1	1	1	1	1	1	1
				11.ANXIETY SOMATIC	1	1	1	0	0	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	2	2	2	1	1	1	1	1	1	1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
18	54	Fluoxetine	Male	13.SOMATIC GENERAL	1	1	1	1	1	1	1	0	0	0
				14.GENITAL SYMPTOMS	1	1	1	1	1	1	1	0	0	0
				15.HYPOCHONDRIASIS	1	1	1	1	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	1	1	1	1	1	1	1	1	1	1
				19.DEPERSONALIZATION	1	1	1	1	1	1	1	1	1	1
				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	26	26	26	14	11	11	11	6	6	6
20	21	Fluoxetine	Female	01.DEPRESSED MOOD	3	3	1	1	1	1	0	0	0	0
				02.GUILT	3	3	0	0	0	0	0	0	0	0
				03.SUICIDE	2	2	1	0	0	0	0	0	0	0
				04.INSOMNIA EARLY	0	0	2	1	2	1	2	1	1	1
				05.INSOMNIA MIDDLE	2	2	2	2	1	1	1	1	1	1
				06.INSOMNIA LATE	0	0	1	2	0	0	0	0	0	0
				07.WORK AND ACTIVITIES	1	1	0	0	0	0	0	0	0	0
				08.RETARDATION	2	2	1	0	0	0	0	0	0	0
				09.AGITATION	2	2	2	3	0	1	0	0	0	0
				10.ANXIETY PSYCHIC	2	2	0	2	0	2	0	1	0	0
				11.ANXIETY SOMATIC	3	3	3	3	2	2	1	0	0	0
				12.SOMATIC GASTROINTESTINAL	2	2	0	0	0	0	0	0	0	0
				13.SOMATIC GENERAL	2	2	1	1	0	0	0	0	0	0
				14.GENITAL SYMPTOMS	2	2	2	2	2	0	0	2	2	2
				15.HYPOCHONDRIASIS	2	2	1	0	0	0	0	0	0	0
				16.LOSS OF WEIGHT	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	2	2	2	1	0	0	1	0	1	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	1	1	0	0	0	0	0	0	0	0
				22.Total score	34	34	19	18	8	8	5	5	5	4
	22	Fluoxetine	Female	01.DEPRESSED MOOD	4	4	4	3	3	3	2			
				02.GUILT	2	2	2	2	1	1	1			
				03.SUICIDE	2	2	3	2	2	2	3			
				04.INSOMNIA EARLY	0	0	1	0	0	0	2			
				05.INSOMNIA MIDDLE	1	1	1	2	0	2	2			
				06.INSOMNIA LATE	2	2	2	2	2	2	2			
				07.WORK AND ACTIVITIES	2	2	3	3	3	3	3			
				08.RETARDATION	2	2	2	1	2	1	2			
				09.AGITATION	2	2	2	2	1	1	3			
				10.ANXIETY PSYCHIC	3	3	3	1	3	3	3			
				11.ANXIETY SOMATIC	0	0	1	3	3	3	4			
				12.SOMATIC GASTROINTESTINAL	0	0	1	0	0	0	0			
				13.SOMATIC GENERAL	2	2	2	2	0	2	0			
				14.GENITAL SYMPTOMS	1	1	2	0	0	2	0			
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	3			
				16.LOSS OF WEIGHT	0	0	0	0	2	0	0			

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56 Day
20	22	Fluoxetine	Female	17.INSIGHT	0	0	0	0	0	0	0			
				18.DIURNAL VARIATION	1	2	2	0	2	2	1			
				19.DEPERSONALIZATION	0	0	0	0	0	0	0			
				20.PARANOID	0	0	0	0	0	0	0			
				21.OBSESSIONAL/COMPULSIVE	2	2	2	0	1	0	0			
				22.Total score	26	27	33	23	25	27	31			
21	9	Fluoxetine	Female	01.DEPRESSED MOOD	4	4	4	4	4	3	2	1	1	1
				02.GUILT	2	2	2	1	1	1	1	1	1	1
				03.SUICIDE	2	2	2	2	0	0	0	0	0	0
				04.INSOMNIA EARLY	1	1	0	0	0	2	1	1	1	0
				05.INSOMNIA MIDDLE	1	1	0	0	0	2	0	0	0	0
				06.INSOMNIA LATE	2	2	2	1	1	1	1	1	1	0
				07.WORK AND ACTIVITIES	2	2	2	2	2	2	1	1	0	0
				08.RETARDATION	2	2	2	1	1	2	0	0	0	0
				09.AGITATION	1	1	1	0	0	0	0	0	0	0
				10.ANXIETY PSYCHIC	3	3	3	2	2	1	1	1	1	1
				11.ANXIETY SOMATIC	2	2	2	1	1	0	0	0	0	0
				12.SOMATIC GASTROINTESTINAL	0	0	0	0	0	1	0	0	0	0
				13.SOMATIC GENERAL	2	2	2	1	1	1	1	1	1	1
				14.GENITAL SYMPTOMS	2	2	2	2	2	1	0	0	0	0
				15.HYPOCHONDRIASIS	0	0	0	0	0	0	0	0	0	1
				16.LOSS OF WEIGHT	0	0	0	0	0	2	0	0	0	1
				17.INSIGHT	0	0	0	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	26	26	24	17	15	19	8	7	6	6
22	113	Fluoxetine	Male	01.DEPRESSED MOOD	3	3	3	3						
				02.GUILT	1	1	1	1						
				03.SUICIDE	1	1	1	1						
				04.INSOMNIA EARLY	2	2	2	2						
				05.INSOMNIA MIDDLE	1	1	1	1						
				06.INSOMNIA LATE	2	1	1	1						
				07.WORK AND ACTIVITIES	3	3	3	3						
				08.RETARDATION	1	1	1	1						
				09.AGITATION	2	3	3	3						
				10.ANXIETY PSYCHIC	3	3	2	2						
				11.ANXIETY SOMATIC	3	3	3	3						
				12.SOMATIC GASTROINTESTINAL	1	1	1	1						
				13.SOMATIC GENERAL	1	1	1	1						
				14.GENITAL SYMPTOMS	1	1	1	1						
				15.HYPOCHONDRIASIS	2	2	2	3						
				16.LOSS OF WEIGHT	2	0	0	2						
				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						

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	49 Day	56
22	113	Fluoxetine	Male	21.OBSESSIONAL/COMPULSIVE	0	0	0	0						
				22.Total score	30	28	27	30						
	115	Reboxetine	Male	01.DEPRESSED MOOD	1	2	2	2	2					
				02.GUILT	2	2	2	2	2					
				03.SUICIDE	1	1	1	0	0					
				04.INSOMNIA EARLY	1	1	1	1	1					
				05.INSOMNIA MIDDLE	1	1	1	1	2					
				06.INSOMNIA LATE	1	1	1	1	1					
				07.WORK AND ACTIVITIES	3	3	3	3	3					
				08.RETARDATION	1	0	0	0	0					
				09.AGITATION	2	2	2	2	2					
				10.ANXIETY PSYCHIC	2	2	1	1	2					
				11.ANXIETY SOMATIC	2	2	2	2	2					
				12.SOMATIC GASTROINTESTINAL	1	1	0	0	1					
				13.SOMATIC GENERAL	1	1	1	1	1					
				14.GENITAL SYMPTOMS	1	1	1	1	1					
				15.HYPOCHONDRIASIS	3	3	3	3	3					
				16.LOSS OF WEIGHT	1	1	1	0	2					
				17.INSIGHT	1	1	1	1	1					
				18.DIURNAL VARIATION	0	0	0	1	1					
				19.DEPERSONALIZATION	1	1	1	1	1					
				20.PARANOID	0	0	0	0	0					
				21.OBSESSIONAL/COMPULSIVE	1	1	1	1	1					
				22.Total score	27	27	25	24	29					

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
1	1	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.00	1.00	0.67	0.33	0.00	0.00	0.00	0.00	0.00	0.00
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.00	2.00	1.25	1.00	0.75	0.25	0.00	0.00	0.00	0.00
				6.SLEEP DISTURBANCE	1.67	1.67	1.33	0.33	0.33	0.00	0.00	0.00	0.00	0.00
				7.Total score	6.17	6.17	4.25	1.67	1.08	0.25	0.00	0.00	0.00	0.00
	2	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.00	1.17	1.50	0.83	1.17	0.83	0.50	0.67	0.50	0.67
				2.WEIGHT	0.00	0.00	1.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.67	1.00	0.33	0.17	0.00	0.00	0.00	0.17
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.75	2.75	1.75	2.25	1.75	0.50	0.25	0.25	0.25	0.00
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.33	1.33	1.00	0.33	0.67	0.67	0.67
				7.Total score	5.75	5.92	5.92	7.42	4.58	2.50	1.08	1.58	1.42	1.50
	3	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	1.33	0.67	0.50	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	0.67	0.50	0.50	0.33	0.17	0.00	0.00			0.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	1.00	1.00			1.00
				5.RETARDATION	1.75	1.75	1.75	1.00	1.00	0.50	0.75			0.50
				6.SLEEP DISTURBANCE	1.33	1.33	1.67	0.67	1.00	0.67	1.00			0.67
				7.Total score	6.92	6.75	7.25	3.67	3.67	2.50	3.08			2.50
	4	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.50	1.33	1.33	1.17	0.67	0.67		
				2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.50	0.33	0.33	0.17	0.17		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00		
				5.RETARDATION	2.25	2.25	2.00	1.75	1.25	0.75	0.50	0.50		
				6.SLEEP DISTURBANCE	1.00	0.67	1.33	1.33	1.33	1.33	1.33	1.33		
				7.Total score	8.42	8.08	6.50	5.92	4.25	3.58	2.67	2.67		
	5	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	1.17	1.17	1.17				
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00				
				3.COGNITIVE DISTURBANCE	0.33	0.33	0.33	0.33	0.50	0.50				
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	1.00				
				5.RETARDATION	2.25	2.25	2.00	2.00	1.25	2.00				
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.33	1.00	1.67				
				7.Total score	6.58	6.58	6.33	5.83	4.92	6.33				
	6	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.33	1.50	1.50	1.50	1.50	1.50				
				2.WEIGHT	1.00	0.00	0.00	0.00	0.00	0.00				
				3.COGNITIVE DISTURBANCE	0.17	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				
				5.RETARDATION	2.50	2.50	2.25	2.25	2.25	2.25				
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00				
				7.Total score	8.00	7.33	7.08	7.08	7.08	7.08				

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
2	33	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	0.83	0.83	0.50	0.83	0.83	0.33	0.67	0.33	0.67	0.67
				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	1.00	1.00	0.00	0.83	0.50	0.50	0.50	0.50	0.50	0.50
				4.DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	3.25	3.25	0.50	2.50	2.00	1.50	2.00	1.75	1.75	1.75
				6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.67	2.00	1.67	1.67	1.67	1.67	1.67
				7.Total score	10.08	10.08	3.00	5.83	5.33	4.00	4.83	4.25	4.58	4.58
	34	Reboxetine	Male	1.ANXIETY/SOMATIZATION	0.50	0.50	0.50	0.33	0.33	0.17	0.50	0.17		
				2.WEIGHT	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.50	0.17	0.00	0.17	0.00	0.17		
				4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	0.00	0.00	0.00	0.00		
				5.RETARDATION	2.50	2.50	1.25	0.75	0.75	0.50	0.00	0.50		
				6.SLEEP DISTURBANCE	2.00	2.00	1.67	1.33	1.67	0.67	1.33	0.67		
				7.Total score	7.83	7.83	5.92	3.58	2.75	1.50	1.83	1.50		
	35	Reboxetine	Female	1.ANXIETY/SOMATIZATION	2.33	2.33	1.33	1.00	1.00	1.67	0.83	1.00	1.33	1.00
				2.WEIGHT	0.00	0.00	1.00	2.00	2.00	1.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.33	0.33	0.00	0.00	0.67	0.33	0.33	0.33	0.33	0.33
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	1.00	1.00	1.00	2.00	1.00
				5.RETARDATION	2.75	2.75	1.75	1.50	1.00	1.00	1.00	1.00	1.00	1.00
				6.SLEEP DISTURBANCE	0.00	0.00	0.67	0.33	0.33	0.67	1.33	0.67	0.67	0.67
				7.Total score	7.42	7.42	6.75	6.83	7.00	5.67	4.50	4.00	5.33	4.00
	36	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.17	1.00	0.50	0.50	0.50	0.00	0.00	0.00	0.00	0.00
				2.WEIGHT	0.00	0.00	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	0.33	0.17	0.17	0.17	0.00	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	1.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.00	1.25	1.25	1.00	0.75	0.00	0.00	0.00	0.00	0.00
				6.SLEEP DISTURBANCE	0.00	0.33	0.00	0.33	0.33	0.00	0.00	0.00	0.00	0.00
				7.Total score	6.17	4.92	5.92	6.00	3.75	1.00	0.00	0.00	0.00	0.00
	37	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.67	1.67								
				2.WEIGHT	3.00	3.00								
				3.COGNITIVE DISTURBANCE	1.50	1.17								
				4.DIURNAL VARIATION	0.00	0.00								
				5.RETARDATION	1.75	1.75								
				6.SLEEP DISTURBANCE	0.00	0.67								
				7.Total score	7.92	8.25								
	38	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.50	1.50	0.83	0.67	0.50	0.17	0.00			
				2.WEIGHT	1.00	1.00	1.00	2.00	2.00	0.00	2.00			
				3.COGNITIVE DISTURBANCE	1.50	1.50	0.67	0.50	0.50	0.17	0.00			
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00	0.00			
				5.RETARDATION	1.50	1.50	1.00	1.00	1.00	0.25	0.00			

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
2	38	Fluoxetine	Male	6.SLEEP DISTURBANCE	1.67	1.67	1.00	0.67	0.67	0.67	1.00			
				7.Total score	8.17	8.17	5.50	5.83	4.67	1.25	3.00			
	39	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.67	1.67								
				2.WEIGHT	2.00	2.00								
				3.COGNITIVE DISTURBANCE	1.33	1.33								
				4.DIURNAL VARIATION	1.00	1.00								
				5.RETARDATION	1.75	1.75								
				6.SLEEP DISTURBANCE	0.67	0.67								
				7.Total score	8.42	8.42								
	40	Reboxetine	Male	1.ANXIETY/SOMATIZATION	0.83	0.83	1.33	0.83	1.00					
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00					
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.83	0.33	0.17					
				4.DIURNAL VARIATION	1.00	1.00	1.00	2.00	1.00					
				5.RETARDATION	1.25	1.25	1.50	1.00	1.00					
				6.SLEEP DISTURBANCE	2.00	2.00	1.67	1.00	0.67					
				7.Total score	6.08	6.08	6.33	5.17	3.83					
	41	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.83	1.83	1.00	1.00	0.50	0.33	0.33	0.50	0.33	0.33
				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	0.17	0.17	0.17	0.00	0.00	0.00	0.00	0.17	0.17	0.17
				4.DIURNAL VARIATION	0.00	0.00	1.00	0.00	0.00	0.00	1.00	0.00	0.00	1.00
				5.RETARDATION	3.00	3.00	3.00	2.25	2.25	2.25	1.25	1.50	0.75	0.50
				6.SLEEP DISTURBANCE	2.00	2.00	1.00	2.00	1.33	1.00	0.00	0.00	0.33	0.00
				7.Total score	7.00	7.00	6.17	5.25	4.08	3.58	2.58	2.17	1.58	2.00
	42	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.17	0.50	0.67	0.67	0.67	0.50	0.33	0.50
				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	1.17	1.17	1.33	0.33	0.17	0.50	0.00	0.17	0.00	0.33
				4.DIURNAL VARIATION	1.00	1.00	1.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	2.75	2.75	1.75	0.75	1.00	0.75	0.50	1.00	0.75	0.75
				6.SLEEP DISTURBANCE	1.00	1.00	1.67	1.67	1.67	1.67	1.33	1.00	1.00	0.67
				7.Total score	9.42	9.42	6.92	5.25	4.50	4.58	3.50	3.67	3.08	3.25
	43	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.67	1.50	1.00	1.00	0.83	1.00	1.17	0.67	0.83
				2.WEIGHT	0.00	0.00	0.00	1.00	1.00	2.00	1.00	1.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.17	1.17	0.83	0.67	0.83	0.50	0.50	0.83	0.50	0.50
				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	2.75	2.75	2.00	1.75	1.00	1.00	1.25	1.25	1.25	1.00
				6.SLEEP DISTURBANCE	1.33	1.33	1.67	0.67	1.00	0.67	1.67	1.00	1.00	0.67
				7.Total score	7.92	7.92	6.00	5.08	4.83	5.00	5.42	5.25	3.42	3.00
	44	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.00	1.00	0.67	0.67	0.50	0.33	0.33	0.17		
				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	0.83	0.33	0.33	0.17	0.17	0.17		

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
2	44	Fluoxetine	Male	4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	1.00	0.00	0.00		
				5.RETARDATION	2.50	2.50	1.25	1.25	0.75	0.25	0.50	0.25		
				6.SLEEP DISTURBANCE	1.67	1.67	0.33	1.00	0.00	0.33	0.00	0.33		
				7.Total score	8.50	8.50	5.08	5.25	2.58	2.08	1.00	0.92		
	45	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.83	1.83	0.67	0.67	0.50	0.50	0.33	0.33	0.50	0.50
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.50	1.50	0.50	0.50	0.67	0.67	0.50	0.67	0.50	0.50
				4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.25	2.25	1.00	0.75	1.00	1.00	0.50	0.50	0.25	0.25
				6.SLEEP DISTURBANCE	0.67	0.67	0.00	0.00	0.00	0.00	0.33	0.33	0.00	0.00
				7.Total score	8.25	8.25	3.17	2.92	2.17	2.17	1.67	1.83	1.25	1.25
	47	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.67	1.33	0.83	0.17	0.83	0.33	0.33	0.33	0.17
				2.WEIGHT	2.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.50	0.33	0.00	0.17	0.00	0.00	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	2.00	1.00	1.00	1.00	0.00
				5.RETARDATION	1.75	2.25	1.00	0.75	0.25	0.25	0.00	0.00	0.00	0.00
				6.SLEEP DISTURBANCE	1.33	1.33	1.00	0.67	0.67	0.33	0.33	0.33	0.33	1.00
				7.Total score	9.08	9.58	6.33	3.42	2.08	3.42	1.67	1.67	1.67	1.17
	48	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.83	1.67	1.33	1.33	1.17	1.17	1.00	1.00	1.33
				2.WEIGHT	2.00	2.00	0.00	0.00	1.00	0.00	2.00	0.00	0.00	2.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.33	0.33	0.33	0.67	0.33	0.17	0.50	0.50
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.25	2.50	2.75	2.00	2.25	1.75	1.75	1.75	1.75	1.75
				6.SLEEP DISTURBANCE	1.33	1.67	1.33	1.00	1.33	1.00	1.33	1.33	1.33	1.00
				7.Total score	8.25	9.00	6.08	4.67	6.25	4.58	6.58	4.25	4.58	6.58
	80	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.17	1.17	0.33	0.33	0.17	0.17	0.17	0.00	0.00	0.00
				2.WEIGHT	0.00	0.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.67	1.67	0.83	0.50	0.83	0.33	0.33	0.33	0.33	0.17
				4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.25	2.25	1.00	0.75	0.50	0.25	0.25	0.25	0.25	0.25
				6.SLEEP DISTURBANCE	2.00	2.00	1.67	2.00	2.00	1.67	1.33	1.00	1.00	0.67
				7.Total score	9.08	9.08	6.83	5.58	4.50	2.42	2.08	1.58	1.58	1.08
3	65	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.17	0.67	0.83	0.67	0.50	0.33	0.33	0.50
				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	0.17	0.17	0.17	0.17	0.17	0.50	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	2.00	2.00	2.00	2.00	2.00	1.00
				5.RETARDATION	1.75	1.75	1.50	1.50	1.50	0.75	0.50	0.75	1.25	0.50
				6.SLEEP DISTURBANCE	1.00	1.00	1.33	1.00	1.00	1.00	0.67	0.67	0.67	1.00
				7.Total score	8.42	8.42	5.17	4.33	5.50	4.92	3.67	3.75	4.25	3.00
	66	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	1.33	1.17	0.67					

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
3	66	Fluoxetine	Female	2.WEIGHT	0.00	0.00	2.00	0.00	0.00					
				3.COGNITIVE DISTURBANCE	1.17	0.83	1.00	0.83	0.50					
				4.DIURNAL VARIATION	1.00	1.00	0.00	1.00	1.00					
				5.RETARDATION	2.25	2.25	1.75	1.75	1.75					
				6.SLEEP DISTURBANCE	0.67	1.00	2.00	2.00	1.67					
				7.Total score	6.25	6.25	8.08	6.75	5.58					
	67	Reboxetine	Female	1.ANXIETY/SOMATIZATION	2.33	2.33	1.67	1.00	0.83	0.17				
				2.WEIGHT	0.00	0.00	1.00	0.00	0.00	0.00				
				3.COGNITIVE DISTURBANCE	1.17	1.33	1.00	0.50	0.33	0.00				
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	0.00				
				5.RETARDATION	2.25	2.50	2.25	2.00	0.50	0.25				
				6.SLEEP DISTURBANCE	2.00	2.00	1.67	1.33	0.67	0.00				
				7.Total score	9.75	10.17	9.58	5.83	3.33	0.42				
	68	Reboxetine	Female	1.ANXIETY/SOMATIZATION	2.00	2.00	2.00	1.33	1.00	0.67				
				2.WEIGHT	2.00	2.00	2.00	1.00	0.00	2.00				
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.17	0.67	1.00	0.67				
				4.DIURNAL VARIATION	2.00	2.00	0.00	2.00	1.00	2.00				
				5.RETARDATION	2.75	2.75	2.00	1.25	1.25	1.50				
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	2.00	1.67	1.67				
				7.Total score	11.42	11.42	8.83	8.25	5.92	8.50				
4	97	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.67	0.83	2.33	0.33	0.33	0.33	0.33	0.33	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	0.17	0.33	0.33	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	1.00	1.00	1.50	1.75	0.75	0.00	0.00	0.00	0.00	0.00
				6.SLEEP DISTURBANCE	2.00	2.00	1.33	2.00	1.33	0.33	1.33	0.67	1.00	1.67
				7.Total score	8.50	8.00	4.00	6.08	2.42	0.67	1.67	1.00	1.33	1.67
	98	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.83	1.50	1.50	0.50	0.67	0.33	0.00	0.17	0.17	0.00
				2.WEIGHT	2.00	2.00	2.00	0.00	2.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	0.33	0.00	0.33	0.83	1.33	1.17	0.17	0.17	0.00
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.50	2.75	1.50	0.75	1.50	1.75	0.00	0.00	0.00	0.00
				6.SLEEP DISTURBANCE	0.33	0.33	1.33	1.67	1.67	1.00	0.00	0.33	0.67	0.00
				7.Total score	7.67	6.92	6.33	3.25	6.67	4.42	1.17	0.67	1.00	0.00
	99	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33							
				2.WEIGHT	1.00	1.00	0.00							
				3.COGNITIVE DISTURBANCE	1.33	1.33	1.33							
				4.DIURNAL VARIATION	0.00	0.00	0.00							
				5.RETARDATION	1.50	1.50	2.00							
				6.SLEEP DISTURBANCE	1.33	1.33	1.00							
				7.Total score	6.50	6.50	5.67							

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
4	100	Reboxetine	Male	1.ANXIETY/SOMATIZATION	2.17	1.83								
				2.WEIGHT	2.00	2.00								
				3.COGNITIVE DISTURBANCE	0.83	0.83								
				4.DIURNAL VARIATION	0.00	0.00								
				5.RETARDATION	2.25	2.50								
				6.SLEEP DISTURBANCE	2.00	2.00								
				7.Total score	9.25	9.17								
	101	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.83	1.33	0.50	1.83	1.67	1.00	0.50	1.00
				2.WEIGHT	2.00	2.00	0.00	0.00	0.00	2.00	1.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.17	0.17	0.00	0.67	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	0.00	0.00	0.00	1.00	0.00	0.00	0.00	1.00	2.00	0.00
				5.RETARDATION	1.75	1.75	1.75	1.25	0.25	1.50	1.00	0.25	0.25	1.00
				6.SLEEP DISTURBANCE	1.33	1.33	2.00	1.33	1.33	0.67	1.67	1.00	0.00	0.67
				7.Total score	7.08	7.08	5.75	5.08	2.08	6.67	5.33	3.25	2.75	2.67
	102	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	0.50	0.00	0.83	0.50	1.33	0.83	0.83	0.83
				2.WEIGHT	0.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.17	1.17	0.00	0.33	0.00	0.00	0.00	0.33	0.67	0.00
				4.DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	1.00	2.00	1.00	1.00	1.00
				5.RETARDATION	1.50	1.50	1.00	0.25	1.75	0.00	1.75	0.75	1.50	0.75
				6.SLEEP DISTURBANCE	1.33	1.33	0.67	0.00	0.00	0.33	0.67	0.33	0.00	0.33
				7.Total score	6.33	8.33	2.17	0.58	2.58	1.83	5.75	3.25	4.00	2.92
	103	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	2.17	2.17	1.83	2.00	1.33	0.83	1.00			
				2.WEIGHT	0.00	0.00	0.00	2.00	0.00	0.00	0.00			
				3.COGNITIVE DISTURBANCE	0.83	0.83	1.33	0.83	0.33	0.33	0.83			
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00			
				5.RETARDATION	2.75	2.75	2.50	2.50	1.50	2.00	2.00			
				6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.67	1.67	2.00	2.00			
				7.Total score	7.75	7.75	7.67	9.00	4.83	5.17	5.83			
	104	Reboxetine	Female	1.ANXIETY/SOMATIZATION	0.83	0.83	1.00	0.50	0.50	0.67	0.50	0.50		
				2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.17	0.17	0.33	0.17	0.00	0.00	0.00	0.00		
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				5.RETARDATION	2.75	2.75	2.50	2.50	2.00	2.00	1.50	1.50		
				6.SLEEP DISTURBANCE	1.00	1.00	0.67	0.00	0.00	0.33	0.33	0.33		
				7.Total score	6.75	6.75	4.50	3.17	2.50	3.00	2.33	2.33		
	105	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.33	1.33	0.83	0.50	0.67	0.50	0.50	0.50	0.33	0.50
				2.WEIGHT	0.00	0.00	1.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.33	0.33	0.67	0.33	0.67	0.33	0.33	0.33	0.33	0.33
				4.DIURNAL VARIATION	2.00	2.00	0.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00
				5.RETARDATION	2.50	2.50	2.50	2.50	2.50	2.25	2.50	2.25	1.75	2.00

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
4	105	Fluoxetine	Male	6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.00	1.67	1.33	1.00	0.67	0.67	1.33
				7.Total score	7.83	7.83	6.67	4.33	6.50	4.42	5.33	3.75	3.08	4.17
5	129	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.67	1.50	1.50	1.50	1.33				
				2.WEIGHT	2.00	2.00	2.00	2.00	0.00	0.00				
				3.COGNITIVE DISTURBANCE	0.83	1.00	0.50	0.50	0.33	0.50				
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00				
				5.RETARDATION	2.25	2.25	2.00	2.00	2.00	1.75				
				6.SLEEP DISTURBANCE	2.00	2.00	1.00	1.00	0.33	1.67				
				7.Total score	9.75	9.92	8.00	8.00	5.17	6.25				
	130	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.50	1.00	0.83	0.67	0.67	0.83	0.67	0.67	0.50
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	1.17	0.67	0.67	0.50	0.50	0.83	0.50	0.33	0.33
				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	2.75	2.75	2.00	2.25	1.75	2.00	2.25	2.00	1.25	1.00
				6.SLEEP DISTURBANCE	0.00	0.00	0.00	0.67	0.00	0.00	0.00	0.00	0.00	0.00
				7.Total score	6.08	6.42	3.67	4.42	2.92	3.17	3.92	3.17	2.25	1.83
7	193	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.00	0.83	0.83	0.67	0.67	0.67	0.50	0.50
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.50	0.33	0.17	0.67	0.50	0.33	0.50	0.50
				4.DIURNAL VARIATION	0.00	0.00	2.00	2.00	2.00	2.00	1.00	1.00	0.00	0.00
				5.RETARDATION	2.00	2.00	1.75	1.75	1.50	2.00	2.00	1.50	1.50	1.75
				6.SLEEP DISTURBANCE	1.00	1.00	1.33	1.00	0.67	0.33	0.33	0.67	0.33	0.33
				7.Total score	6.00	6.00	6.58	5.92	5.17	5.67	4.50	4.17	2.83	3.08
	194	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.17	1.17	0.83	0.33	0.83	0.50	0.67	0.00
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.17	0.17	0.00	0.00	0.00	0.17	0.17	0.17	0.00	0.17
				4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	2.00	2.00	0.00	0.00	0.00	0.00
				5.RETARDATION	1.75	1.75	1.50	1.75	1.50	0.75	1.00	0.50	0.00	0.00
				6.SLEEP DISTURBANCE	0.67	0.67	1.00	0.67	0.00	1.00	0.67	0.33	0.33	0.00
				7.Total score	7.08	7.08	4.67	4.58	4.33	4.25	2.67	1.50	1.00	0.17
	195	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	0.83	0.83	0.83	0.33	0.17	0.83	0.67	0.67	0.33	0.33
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	2.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.33	0.33	0.33	0.00	0.00	0.33	0.33	0.33	0.17	0.00
				4.DIURNAL VARIATION	1.00	1.00	0.00	1.00	0.00	1.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.75	2.75	2.50	2.25	2.00	2.50	2.00	2.25	0.50	0.50
				6.SLEEP DISTURBANCE	1.00	1.00	0.33	1.00	0.67	0.67	0.33	0.67	0.67	1.00
				7.Total score	5.92	5.92	4.00	4.58	2.83	5.33	5.33	3.92	1.67	1.83
	196	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.50	1.50	1.33	1.33	1.33	1.50	1.33	1.50	
				2.WEIGHT	0.00	0.00	1.00	1.00	0.00	0.00	0.00	1.00	0.00	
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.83	0.67	0.67	0.33	0.17	0.33	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
7	196	Reboxetine	Female	4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	1.00	1.00	1.00	0.00	0.00	
				5.RETARDATION	2.50	2.25	2.00	2.00	2.00	2.00	2.00	2.25	2.50	
				6.SLEEP DISTURBANCE	1.33	1.67	2.00	2.00	2.00	2.00	1.33	1.00	1.33	
				7.Total score	6.17	6.08	7.17	7.17	7.00	7.00	6.17	5.75	5.67	
	197	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.33	1.33								
				2.WEIGHT	2.00	0.00								
				3.COGNITIVE DISTURBANCE	1.00	0.83								
				4.DIURNAL VARIATION	0.00	0.00								
				5.RETARDATION	2.00	2.00								
				6.SLEEP DISTURBANCE	1.00	0.67								
				7.Total score	7.33	4.83								
11	321	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.50	1.33	1.33	1.17	0.17	0.00	0.33
				2.WEIGHT	0.00	0.00	0.00	1.00	1.00	1.00	1.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	1.17	1.17	1.00	0.50	0.17	0.00	0.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	2.50	2.50	2.25	2.00	1.25	1.25	0.75	0.50	0.00	0.75
				6.SLEEP DISTURBANCE	2.00	1.67	1.67	1.00	1.00	1.00	0.33	0.33	0.33	0.33
				7.Total score	8.83	8.50	8.25	7.67	6.75	6.58	4.75	2.17	1.33	2.42
	322	Reboxetine	Female	1.ANXIETY/SOMATIZATION	2.00	2.00	1.50	1.50	2.17	1.50	1.50	1.17	1.17	1.17
				2.WEIGHT	2.00	2.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.33	1.50	1.33	1.17	1.50	0.83	1.00	1.00	0.83	1.00
				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	2.75	2.75	2.50	2.25	2.25	2.00	1.00	1.25	1.00	1.25
				6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.33	2.00	1.67	1.00	1.00	1.00	1.00
				7.Total score	10.08	10.25	9.33	7.25	7.92	6.00	4.50	4.42	4.00	4.42
	323	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.67	1.17	0.33	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	1.17	1.17	0.67	0.33	0.00	0.00				0.00
				4.DIURNAL VARIATION	1.00	1.00	0.00	0.00	0.00	0.00				0.00
				5.RETARDATION	1.50	2.00	0.75	0.25	0.00	0.00				0.00
				6.SLEEP DISTURBANCE	2.00	2.00	0.67	0.67	0.00	0.00				0.00
				7.Total score	8.17	8.83	4.25	1.58	0.33	0.33				0.33
	324	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.83	1.83	1.67	2.17	2.33	1.67	0.83	0.00	1.33	1.00
				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	1.17	1.00	1.00	1.33	0.67	0.33	1.00	0.33
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	2.00	1.00	1.00	2.00	1.00
				5.RETARDATION	1.75	1.75	1.50	2.00	1.25	1.25	0.75	0.50	0.50	0.75
				6.SLEEP DISTURBANCE	2.00	2.00	1.33	2.00	1.00	1.00	1.00	0.33	0.67	0.00
				7.Total score	7.75	7.75	6.67	8.17	6.58	7.25	4.25	2.17	5.50	3.08
	325	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.67	1.50	1.50	0.67	1.00	0.50	0.67	0.83	0.50

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
11	325	Reboxetine	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	0.83	1.00	0.50	0.50	1.00	0.50	0.33	0.33	0.17	0.67
				4.DIURNAL VARIATION	1.00	1.00	0.00	0.00	-1.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.00	2.00	2.25	2.00	1.50	0.75	1.00	0.75	0.25	0.25
				6.SLEEP DISTURBANCE	1.67	2.00	1.67	1.00	1.33	1.00	0.00	0.33	0.33	0.33
				7.Total score	7.17	7.67	5.92	5.00	5.50	3.25	1.83	2.08	1.58	1.75
	326	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.67	1.33	0.83	0.50	0.33	0.00	0.00	0.00	0.00
				2.WEIGHT	0.00	0.00	0.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.17	1.33	0.83	0.67	0.33	0.33	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	1.00	1.00	1.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	1.50	1.50	1.00	0.75	0.25	0.00	0.00	0.00	0.00	0.00
				6.SLEEP DISTURBANCE	2.00	2.00	1.33	0.67	0.00	0.00	0.00	0.00	0.00	0.00
				7.Total score	7.17	7.50	5.50	5.92	3.08	0.67	0.00	0.00	0.00	0.00
	327	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.00	0.50	0.50	0.33				
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00				
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.83	1.17	0.50	0.17				
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00				
				5.RETARDATION	1.75	2.00	1.25	1.25	1.00	0.50				
				6.SLEEP DISTURBANCE	1.00	1.00	0.67	0.00	0.00	0.00				
				7.Total score	6.25	6.50	4.75	3.92	3.00	2.00				
	328	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.67	0.83	1.00	1.00	0.83	0.67	0.17	0.17	0.17
				2.WEIGHT	0.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.50	0.83	1.00	0.33	0.67	0.33	0.17	0.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	0.00	1.00	0.00	0.00	0.00
				5.RETARDATION	1.75	1.75	1.50	1.75	2.00	1.00	0.50	0.00	0.00	0.00
				6.SLEEP DISTURBANCE	1.67	1.67	0.33	1.00	0.33	0.33	0.33	0.67	0.33	0.33
				7.Total score	8.08	8.08	5.17	6.58	7.33	2.50	3.17	1.17	0.67	0.50
	329	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	1.33	0.83	1.17	0.33	1.17	0.17	0.83	0.67
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	1.00	1.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.33	1.33	0.83	0.83	0.83	0.00	0.83	0.00	0.50	0.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00	1.00	0.00	1.00
				5.RETARDATION	1.75	1.75	1.50	0.75	0.50	0.00	1.00	0.25	0.00	0.00
				6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.67	1.00	0.00	1.33	0.00	0.00	0.00
				7.Total score	8.25	8.25	7.67	6.08	5.50	3.33	7.33	1.42	1.33	1.67
	330	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.00	1.00	1.50	1.00	1.33	1.33	1.00	1.17	1.17	
				2.WEIGHT	0.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00	
				3.COGNITIVE DISTURBANCE	1.83	1.83	0.50	1.17	0.50	0.83	0.83	1.00	1.00	
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
				5.RETARDATION	1.25	1.25	1.75	1.25	1.50	1.50	1.50	1.25	1.25	
				6.SLEEP DISTURBANCE	1.67	1.67	2.00	1.00	0.67	0.67	0.67	0.33	0.33	
				7.Total score	5.75	5.75	5.75	5.42	4.00	4.33	4.00	3.75	3.75	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
11	331	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.17	0.83	0.33	0.17	0.00	0.00	0.00	0.00
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	1.17	0.50	0.50	0.33	0.00	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.25	2.25	2.00	0.75	0.50	0.00	0.25	0.25	0.00	0.00
				6.SLEEP DISTURBANCE	2.00	2.00	0.67	0.33	0.00	0.00	0.00	0.00	0.00	0.33
				7.Total score	8.75	8.92	6.33	3.42	2.17	1.17	0.25	0.25	0.00	0.33
	332	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	0.83	0.50	0.33	0.00	0.17	0.50	0.00	0.00
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.33	0.33	0.17	0.00	0.17	0.00	0.00
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	2.25	2.25	2.00	0.75	1.00	0.75	0.50	0.00	0.50	0.00
				6.SLEEP DISTURBANCE	1.33	1.33	1.67	0.67	0.67	0.67	1.00	0.67	0.33	0.33
				7.Total score	6.58	6.58	6.00	3.25	3.33	2.58	2.67	3.33	1.83	1.33
	333	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.50	1.17	0.67	1.00	1.17	0.83	0.33	0.83	0.33
				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	1.17	1.00	0.33	0.83	0.50	0.33	0.33	0.33
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	1.00	2.00	1.00	1.00	1.00
				5.RETARDATION	1.75	1.75	1.75	1.50	1.00	0.75	0.50	0.25	0.00	0.00
				6.SLEEP DISTURBANCE	1.33	1.33	2.00	1.33	0.67	0.33	0.00	0.00	0.00	0.00
				7.Total score	7.25	7.42	8.08	5.50	4.00	4.08	3.83	1.92	2.17	1.67
	334	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.67	1.50	0.67	0.83	1.33	0.50	0.67	1.00	0.67
				2.WEIGHT	0.00	0.00	0.00	0.00	1.00	0.00	1.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.50	0.50	0.67	0.50	0.67	0.50	0.50	0.50
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	0.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	1.75	1.75	2.00	1.00	0.75	1.00	0.50	0.25	0.50	0.25
				6.SLEEP DISTURBANCE	2.00	2.00	0.67	0.00	1.00	0.67	0.00	0.33	0.00	0.33
				7.Total score	8.25	8.25	6.67	4.17	4.25	4.50	3.67	2.75	3.00	2.75
	335	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.17	1.17	1.00	0.83	1.00	0.67			
				2.WEIGHT	1.00	1.00	1.00	1.00	0.00	1.00	1.00			
				3.COGNITIVE DISTURBANCE	1.17	1.00	0.83	1.00	0.33	0.83	0.83			
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00			
				5.RETARDATION	1.75	2.25	1.75	1.25	1.50	1.25	1.25			
				6.SLEEP DISTURBANCE	1.67	1.33	1.00	0.33	0.00	0.67	0.00			
				7.Total score	8.08	7.75	6.75	5.58	3.67	5.75	4.75			
12	393	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	0.83	0.83	0.50	0.67	0.67	1.00	0.33	0.33
				2.WEIGHT	0.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00	1.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.17	1.33	1.17	1.00	1.00	1.00	0.83
				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	2.50	2.50	2.00	1.75	1.75	1.50	1.50	2.00	0.75	1.50

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
12	393	Fluoxetine	Female	6.SLEEP DISTURBANCE	1.33	1.33	1.67	1.33	1.00	1.00	0.67	1.33	1.33	1.00
				7.Total score	6.33	6.33	5.50	5.08	5.58	4.33	3.83	5.33	3.42	4.67
	394	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.00	1.00	0.83	0.50	0.50	0.83	1.00	1.00	0.50	0.50
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.33	1.00	1.00	1.33	1.50	1.33	1.17	1.50
				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	2.25	2.25	2.25	1.75	1.25	1.75	2.00	2.25	1.50	2.25
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.33	1.33	1.33	1.33	1.67	1.00	1.33
				7.Total score	6.58	6.58	5.75	4.58	4.08	5.25	5.83	6.25	4.17	5.58
	395	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.50	1.50	1.00	0.50	0.33	0.67	0.83	0.67	0.50	0.33
				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	0.67	0.67	0.83	0.33	0.17	0.17	0.33	0.50	0.67	0.50
				4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	0.00	0.00	1.00	1.00	1.00	1.00
				5.RETARDATION	1.75	1.75	1.50	1.00	0.75	1.25	0.75	1.00	1.00	0.50
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	0.67	0.33	0.00	0.33	0.67	0.00	0.67
				7.Total score	6.92	6.92	5.33	3.50	1.58	2.08	3.25	3.83	3.17	3.00
	396	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	0.83	0.83	1.17	1.17						
				2.WEIGHT	0.00	0.00	0.00	1.00						
				3.COGNITIVE DISTURBANCE	1.50	1.50	1.33	1.33						
				4.DIURNAL VARIATION	1.00	1.00	1.00	0.00						
				5.RETARDATION	2.25	2.25	2.00	2.25						
				6.SLEEP DISTURBANCE	1.33	1.33	1.67	1.67						
				7.Total score	6.92	6.92	7.17	7.42						
	497	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.17	1.17	1.00	0.83	0.67	1.00	0.83	0.67
				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	2.00	2.00	1.17	1.33	1.33	1.17	0.83	1.00	1.50	1.17
				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	2.00	2.25	2.25	2.25	2.00	1.75	2.00	2.00
				6.SLEEP DISTURBANCE	1.33	1.33	0.33	1.00	1.33	0.67	1.00	0.33	1.00	1.33
				7.Total score	6.67	6.67	4.67	5.75	5.92	4.92	4.50	4.08	5.33	5.17
13	385	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.17	0.83	0.67		0.50		0.33
				2.WEIGHT	0.00	0.00	1.00	0.00	0.00	0.00		0.00		0.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.67	0.50	0.33	0.00		0.17		0.17
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00		0.00		0.00
				5.RETARDATION	2.25	2.25	2.00	1.50	1.00	1.00		1.00		0.25
				6.SLEEP DISTURBANCE	0.67	0.67	0.67	0.67	0.33	0.33		0.67		0.33
				7.Total score	5.25	5.25	5.67	3.83	2.50	2.00		2.33		1.08
	386	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.50	1.33	1.83							
				2.WEIGHT	2.00	2.00	2.00							
				3.COGNITIVE DISTURBANCE	1.17	1.17	1.67							

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
13	386	Fluoxetine	Male	4.DIURNAL VARIATION	1.00	1.00	2.00							
				5.RETARDATION	2.25	2.25	2.00							
				6.SLEEP DISTURBANCE	2.00	2.00	2.00							
				7.Total score	9.92	9.75	11.50							
	387	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.00	1.17	1.00	0.83				
				2.WEIGHT	2.00	1.00	1.00	0.00	0.00	0.00				
				3.COGNITIVE DISTURBANCE	1.00	0.83	0.67	0.33	0.50	0.17				
				4.DIURNAL VARIATION	1.00	1.00	2.00	1.00	0.00	0.00				
				5.RETARDATION	2.00	2.00	1.25	0.75	0.75	0.00				
				6.SLEEP DISTURBANCE	2.00	1.67	1.67	1.33	0.67	0.67				
				7.Total score	9.50	8.00	7.58	4.58	2.92	1.67				
	388	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.00	1.00	1.33	0.83	0.50	0.83		0.67		0.50
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00		0.00		0.00
				3.COGNITIVE DISTURBANCE	0.83	0.83	1.33	0.67	0.33	0.67		0.67		0.50
				4.DIURNAL VARIATION	2.00	2.00	1.00	0.00	1.00	0.00		0.00		0.00
				5.RETARDATION	1.50	1.50	1.75	1.25	1.00	1.25		1.00		0.75
				6.SLEEP DISTURBANCE	1.67	1.67	2.00	1.00	1.00	1.00		1.00		0.67
				7.Total score	7.00	7.00	7.42	3.75	3.83	3.75		3.33		2.42
	389	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.17							
				2.WEIGHT	2.00	2.00	1.00							
				3.COGNITIVE DISTURBANCE	1.67	1.67	1.17							
				4.DIURNAL VARIATION	0.00	0.00	0.00							
				5.RETARDATION	2.00	2.00	2.00							
				6.SLEEP DISTURBANCE	2.00	2.00	1.67							
				7.Total score	9.00	9.00	7.00							
	390	Reboxetine	Male	1.ANXIETY/SOMATIZATION	0.83	0.83	1.00	0.67	0.67	0.50		0.67		0.33
				2.WEIGHT	1.00	1.00	1.00	0.00	1.00	2.00		0.00		0.00
				3.COGNITIVE DISTURBANCE	1.17	1.17	0.83	0.33	0.50	0.33		0.33		0.00
				4.DIURNAL VARIATION	0.00	0.00	1.00	1.00	2.00	1.00		0.00		0.00
				5.RETARDATION	2.25	2.25	1.75	1.50	1.25	1.00		1.25		0.25
				6.SLEEP DISTURBANCE	1.00	1.00	1.33	1.00	2.00	2.00		1.33		0.67
				7.Total score	6.25	6.25	6.92	4.50	7.42	6.83		3.58		1.25
	391	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.00	0.50	0.00	0.17	0.17	0.17			
				2.WEIGHT	1.00	1.00	0.00	0.00	2.00	0.00	0.00			
				3.COGNITIVE DISTURBANCE	0.67	0.50	0.00	0.17	0.00	0.00	0.17			
				4.DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.00	0.00	0.00			
				5.RETARDATION	2.00	2.00	1.25	1.00	0.50	0.50	0.25			
				6.SLEEP DISTURBANCE	1.67	1.00	1.00	1.00	1.33	1.00	1.00			
				7.Total score	7.67	6.50	3.75	2.17	4.00	1.67	1.58			
	392	Reboxetine	Female	1.ANXIETY/SOMATIZATION	0.83	0.83	1.00	1.00						

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
13	392	Reboxetine	Female	2.WEIGHT	2.00	2.00	0.00	0.00						
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.67	0.83						
				4.DIURNAL VARIATION	0.00	1.00	1.00	1.00						
				5.RETARDATION	2.25	2.25	1.75	1.75						
				6.SLEEP DISTURBANCE	1.33	0.33	2.00	1.67						
				7.Total score	7.25	7.25	6.42	6.25						
	501	Reboxetine	Male	1.ANXIETY/SOMATIZATION	0.83	0.83	1.00	0.50	0.83	0.50	0.50		0.17	
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00		0.00	
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.33	0.33	0.33	0.33	0.00		0.33	
				4.DIURNAL VARIATION	1.00	1.00	2.00	1.00	0.00	1.00	1.00		0.00	
				5.RETARDATION	2.25	2.25	2.00	1.25	1.75	1.00	1.00		0.75	
				6.SLEEP DISTURBANCE	2.00	1.67	1.67	1.00	1.33	0.67	0.67		0.67	
				7.Total score	7.58	7.25	7.00	4.08	4.25	3.50	3.17		1.92	
	502	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	0.83	0.83	1.00	0.83	0.50		0.00	
				2.WEIGHT	0.00	0.00	1.00	0.00	0.00	0.00	0.00		2.00	
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.33	0.67	0.67	0.33	0.33		0.00	
				4.DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.00	1.00	1.00		0.00	
				5.RETARDATION	1.75	1.75	1.25	1.75	1.00	1.75	0.75		0.75	
				6.SLEEP DISTURBANCE	1.33	1.33	0.67	1.00	1.00	1.00	1.00		0.67	
				7.Total score	5.92	5.92	5.08	4.25	3.67	4.92	3.58		3.42	
	503	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.00							
				2.WEIGHT	1.00	1.00	0.00							
				3.COGNITIVE DISTURBANCE	0.33	0.33	0.17							
				4.DIURNAL VARIATION	1.00	1.00	1.00							
				5.RETARDATION	2.25	2.25	1.50							
				6.SLEEP DISTURBANCE	1.33	1.33	1.00							
				7.Total score	7.25	7.25	4.67							
	504	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	0.83	1.00		0.67	0.67		0.50	
				2.WEIGHT	0.00	0.00	1.00	0.00		0.00	1.00		0.00	
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.67	0.50		1.00	0.00		0.17	
				4.DIURNAL VARIATION	1.00	1.00	1.00	0.00		2.00	1.00		0.00	
				5.RETARDATION	1.50	1.50	1.75	0.75		0.75	0.75		0.75	
				6.SLEEP DISTURBANCE	1.67	1.67	1.00	0.67		1.00	1.00		1.00	
				7.Total score	6.17	6.17	6.25	2.92		5.42	4.42		2.42	
	505	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	0.83	1.17	0.67	1.17	0.33		0.17	
				2.WEIGHT	1.00	1.00	1.00	0.00	0.00	0.00	0.00		0.00	
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	0.50	0.50	0.67	0.50		0.33	
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00	1.00		0.00	
				5.RETARDATION	2.00	1.75	1.00	1.50	1.25	1.25	0.75		0.25	
				6.SLEEP DISTURBANCE	1.33	1.67	1.00	1.00	1.33	1.00	0.33		0.33	
				7.Total score	7.33	7.42	5.83	5.17	3.75	4.08	2.92		1.08	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
13	506	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.33	1.33	0.33	0.33	0.17	0.50	0.17	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	0.33	0.33	0.00	0.17	0.00	0.00		
				4.DIURNAL VARIATION	1.00	1.00	0.00	1.00	0.00	0.00	0.00	0.00		
				5.RETARDATION	1.75	1.75	1.00	0.75	0.50	0.50	0.00	0.00		
				6.SLEEP DISTURBANCE	1.00	1.33	0.33	0.33	1.00	0.00	0.00	0.00		
				7.Total score	6.08	6.42	2.00	2.75	1.67	1.17	0.17	0.00		
	507	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	1.17	0.50	0.33	0.67	0.17		
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	1.17	1.17	0.83	0.67	0.50	0.33	0.50	0.00		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00		
				5.RETARDATION	1.25	1.25	1.50	1.25	0.75	1.00	0.50	0.50		
				6.SLEEP DISTURBANCE	1.33	1.33	0.67	1.00	1.00	0.67	1.00	0.33		
				7.Total score	5.75	5.75	5.00	5.08	2.75	2.33	2.67	1.00		
	508	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	0.83	0.83	0.50	0.33	0.50	0.33		
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.50	0.50	0.33	0.17	0.00	0.17		
				4.DIURNAL VARIATION	1.00	1.00	2.00	1.00	1.00	0.00	0.00	0.00		
				5.RETARDATION	2.00	2.00	1.50	1.50	0.75	1.00	0.00	0.25		
				6.SLEEP DISTURBANCE	2.00	2.00	1.00	2.00	0.67	0.33	0.33	0.33		
				7.Total score	6.83	6.83	5.83	5.83	3.25	1.83	0.83	1.08		
	521	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.00	0.83	0.67	0.33		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	0.83	0.83	1.00	0.50		0.33	0.17	0.17		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00		0.00	0.00	0.00		
				5.RETARDATION	2.00	2.25	1.75	1.00		0.75	0.75	0.25		
				6.SLEEP DISTURBANCE	1.00	1.33	1.00	0.33		0.67	0.00	0.00		
				7.Total score	6.83	7.25	5.42	3.17		1.92	1.08	0.75		
14	397	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	0.83	0.83	0.50	0.50	0.17	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	0.50	0.50	0.17	0.17	0.17	0.17		
				4.DIURNAL VARIATION	1.00	1.00	0.00	1.00	0.00	0.00	0.00	0.00		
				5.RETARDATION	2.00	2.00	2.00	1.75	1.00	0.75	1.00	0.75		
				6.SLEEP DISTURBANCE	1.67	1.67	1.33	1.33	1.00	1.00	0.67	0.67		
				7.Total score	6.17	6.17	4.67	5.42	2.67	2.42	2.00	2.25		
	398	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	0.50	0.83	0.33	0.50	0.50		
				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	0.83	0.17	0.17	0.17	0.33	0.00		
				4.DIURNAL VARIATION	2.00	2.00	1.00	0.00	1.00	0.00	0.00	0.00		
				5.RETARDATION	1.75	1.75	1.50	1.25	1.00	0.75	0.75	1.00		

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
14	398	Reboxetine	Female	6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	1.00	1.00	0.00	0.33		
				7.Total score	8.08	8.08	5.67	2.92	4.00	2.25	1.58	1.83		
	399	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	0.83	1.00	0.83	0.67	0.67		
				2.WEIGHT	1.00	1.00	0.00	0.00	1.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.50	0.17	0.33	0.00	0.17		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00		
				5.RETARDATION	2.00	2.00	2.00	2.00	1.50	1.00	0.75	0.75		
				6.SLEEP DISTURBANCE	2.00	2.00	1.67	1.33	1.67	1.67	1.67	0.67		
				7.Total score	8.00	8.00	6.67	5.67	6.33	4.83	4.08	2.25		
	400	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	0.33	0.33	0.50	0.50	0.33		
				2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.67	0.33	0.50	0.33	0.33	0.17		
				4.DIURNAL VARIATION	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00		
				5.RETARDATION	1.50	1.50	1.25	0.50	0.50	0.75	0.25	0.00		
				6.SLEEP DISTURBANCE	1.67	1.67	0.67	0.33	0.33	0.33	0.33	0.33		
				7.Total score	7.17	7.17	4.58	1.50	1.67	1.92	1.42	0.83		
	401	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	0.67	0.83	0.67	0.50	0.67	0.33		
				2.WEIGHT	2.00	2.00	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	0.33	0.33	0.17		
				4.DIURNAL VARIATION	1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00		
				5.RETARDATION	2.00	2.00	1.50	1.50	1.00	0.75	0.75	0.50		
				6.SLEEP DISTURBANCE	1.33	1.33	0.00	0.67	0.33	0.33	0.33	0.33		
				7.Total score	8.33	8.33	3.67	3.17	2.00	1.92	2.08	1.33		
	402	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.17	0.83	0.83	1.00	0.33	0.17		
				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	0.67	0.33	0.50	0.50	0.17	0.33		
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	0.00	1.00	0.00	0.00		
				5.RETARDATION	1.75	1.75	1.75	1.00	1.50	1.50	0.75	0.50		
				6.SLEEP DISTURBANCE	1.33	1.33	1.00	0.67	1.00	0.67	0.67	0.33		
				7.Total score	8.58	8.58	6.58	3.83	3.83	4.67	1.92	1.33		
	403	Reboxetine	Female	1.ANXIETY/SOMATIZATION	0.67	0.67	0.83	0.50	1.17	0.50	0.50	0.17		
				2.WEIGHT	2.00	2.00	0.00	0.00	1.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.33	0.33	0.33	0.00	0.00	0.17		
				4.DIURNAL VARIATION	1.00	1.00	0.00	0.00	1.00	0.00	0.00	0.00		
				5.RETARDATION	2.00	2.00	1.00	1.25	1.50	0.75	0.75	0.25		
				6.SLEEP DISTURBANCE	1.33	1.33	0.67	0.67	0.67	0.67	0.67	0.67		
				7.Total score	7.83	7.83	2.83	2.75	5.67	1.92	1.92	1.25		
	404	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	0.67	0.67	0.17	0.83	0.83		
				2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.33	0.17	0.17	0.17	0.00		

812

9550083

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
14	404	Fluoxetine	Female	4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	0.00	0.00	0.00		
				5.RETARDATION	2.00	2.00	2.00	1.25	1.00	0.75	0.75	0.50		
				6.SLEEP DISTURBANCE	0.67	0.67	0.67	0.67	0.33	0.67	0.67	0.33		
				7.Total score	7.67	7.67	5.67	3.92	3.17	1.75	2.42	1.67		
	405	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	0.50	0.33	0.67	0.50	0.17	0.17		
				2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	1.17	1.17	0.50	0.33	0.17	0.17	0.17	0.00		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00		
				5.RETARDATION	1.25	1.25	1.00	0.25	0.25	0.00	0.00	0.25		
				6.SLEEP DISTURBANCE	1.00	1.00	0.33	0.33	0.33	0.33	0.33	0.00		
				7.Total score	7.58	7.58	3.33	2.25	1.42	1.00	0.67	0.42		
	406	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.67	1.50	1.83	1.83					
				2.WEIGHT	1.00	1.00	0.00	1.00	0.00					
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.83	0.83	0.67					
				4.DIURNAL VARIATION	1.00	1.00	2.00	1.00	1.00					
				5.RETARDATION	2.00	2.00	1.75	1.75	2.25					
				6.SLEEP DISTURBANCE	1.33	1.33	1.67	2.00	2.00					
				7.Total score	8.00	8.00	7.75	8.42	7.75					
	407	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.33	1.33	1.67	1.33	1.33	1.50	1.17			
				2.WEIGHT	1.00	1.00	2.00	2.00	2.00	1.00	0.00			
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.50	0.50	0.50	0.67	0.67			
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	1.00	0.00			
				5.RETARDATION	2.50	2.50	2.25	2.25	2.25	2.00	2.50			
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.33	1.00	1.00			
				7.Total score	7.17	7.17	8.08	7.75	7.42	7.17	5.33			
	408	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.17	0.83	0.83	0.83	0.33	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	0.50	0.33	0.33	0.17		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	0.00	0.00		
				5.RETARDATION	2.25	2.25	1.75	1.25	1.25	1.00	0.50	0.25		
				6.SLEEP DISTURBANCE	0.67	0.67	1.00	0.33	0.33	0.33	0.33	0.33		
				7.Total score	5.92	5.92	5.58	3.75	3.92	3.50	1.50	1.25		
	509	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.17	1.00	1.00	1.00	0.67			
				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	0.33	0.50			
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	1.00	1.00			
				5.RETARDATION	2.50	2.50	2.50	2.25	2.25	1.75	2.25			
				6.SLEEP DISTURBANCE	1.67	1.67	1.33	1.33	0.67	1.33	1.00			
				7.Total score	7.83	7.83	7.50	7.08	6.42	5.42	5.42			
	510	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.17	1.17	0.67	0.67	0.50		

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
14	510	Fluoxetine	Female	2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00			0.00
				3.COGNITIVE DISTURBANCE	0.67	0.50	0.67	0.33	0.00	0.33	0.00			0.33
				4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	1.00	0.00			1.00
				5.RETARDATION	2.25	2.25	1.75	1.50	1.25	1.25	0.75			0.50
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	0.33	0.33	0.33	0.33			0.00
				7.Total score	7.25	7.08	5.75	4.33	3.75	3.58	1.75			2.33
	511	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.17	0.50	0.83	0.83	0.83	0.50		
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.33	0.33	0.33	0.00	0.33	0.00		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	0.00	0.00	1.00		
				5.RETARDATION	2.25	2.25	2.00	1.00	2.00	1.75	0.75	0.50		
				6.SLEEP DISTURBANCE	1.67	1.67	1.33	0.33	1.00	1.00	1.33	1.00		
				7.Total score	6.75	6.75	5.83	3.17	5.17	3.58	3.25	3.00		
	512	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	0.67	1.00	0.67	1.17				
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00				
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.17	0.17	0.50				
				4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	0.00	1.00				
				5.RETARDATION	2.25	2.25	1.50	1.25	1.00	2.00				
				6.SLEEP DISTURBANCE	1.67	1.67	1.33	1.33	0.33	1.33				
				7.Total score	8.42	8.42	5.00	4.75	2.17	6.00				
	537	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	0.50	0.50	0.17	0.33	0.17			0.00
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00			0.00
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.17	0.33	0.17	0.00	0.00			0.00
				4.DIURNAL VARIATION	2.00	2.00	1.00	0.00	0.00	0.00	0.00			0.00
				5.RETARDATION	1.75	1.75	1.00	0.50	0.25	0.25	0.25			0.00
				6.SLEEP DISTURBANCE	1.67	1.67	0.67	0.33	0.67	0.33	0.33			0.00
				7.Total score	8.25	8.25	3.33	1.67	1.25	0.92	0.75			0.00
	538	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	1.00	0.67	0.33	0.50	0.33			0.33
				2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00			0.00
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.50	0.00	0.17	0.00	0.00			0.00
				4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	0.00	0.00	0.00			0.00
				5.RETARDATION	2.00	2.00	1.00	0.25	0.25	0.50	0.75			0.25
				6.SLEEP DISTURBANCE	1.33	1.33	0.00	0.33	0.33	0.00	0.00			0.33
				7.Total score	9.17	9.17	3.50	2.25	1.08	1.00	1.08			0.92
	539	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	2.00	2.00	2.17	1.83	1.83	1.50	1.17			1.17
				2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00			0.00
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.67	0.67	0.50	0.50			0.50
				4.DIURNAL VARIATION	0.00	0.00	1.00	1.00	1.00	1.00	1.00			1.00
				5.RETARDATION	2.25	2.25	2.25	1.50	2.00	1.50	0.75			0.75
				6.SLEEP DISTURBANCE	1.67	1.67	1.33	1.00	1.33	1.00	1.33			1.33
				7.Total score	8.75	8.75	7.58	6.00	6.83	5.50	4.75			4.75

814

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
15	409	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.17	1.17	1.17	1.17	1.17	1.17	1.00	0.50		
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00	0.83	0.50		
				4.DIURNAL VARIATION	2.00	1.00	2.00	2.00	2.00	2.00	2.00	1.00		
				5.RETARDATION	2.25	2.25	2.25	2.25	2.25	1.75	1.50	0.75		
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00		
				7.Total score	7.42	6.42	7.42	7.42	6.42	5.92	5.33	2.75		
	410	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.50	1.50	1.33	1.17	0.83	0.67		
				2.WEIGHT	2.00	2.00	2.00	2.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.50	0.33	0.33	0.33	0.33		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	0.00	0.00		
				5.RETARDATION	1.25	1.25	1.25	1.25	1.25	1.25	0.75	0.50		
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.00	1.00	0.67	0.33		
				7.Total score	7.92	7.92	7.92	7.92	4.92	4.75	2.58	1.83		
	411	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	2.00	1.00	0.67	0.67	0.50	0.33		
				2.WEIGHT	2.00	2.00	2.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	1.33	1.33	1.33	0.50	0.33	0.17	0.17	0.00		
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	1.00	0.00	0.00		
				5.RETARDATION	1.75	1.75	2.50	0.75	0.75	0.50	0.50	0.25		
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	0.67	0.33	0.33	0.00	0.00		
				7.Total score	9.92	9.92	11.17	4.92	3.08	2.67	1.17	0.58		
	412	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	0.83	0.67	0.33	0.33	0.33		
				2.WEIGHT	2.00	2.00	2.00	2.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.50	0.50	0.17	0.17	0.17		
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	1.00	0.00	0.00		
				5.RETARDATION	1.25	1.25	1.25	1.00	0.75	0.50	0.50	0.50		
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	0.67	0.67	0.00	0.00		
				7.Total score	8.42	8.42	8.42	7.33	4.58	2.67	1.00	1.00		
	413	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	1.17	0.67	0.50	0.50	0.33	0.17		
				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	0.67	0.50	0.33	0.17	0.00		
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	1.00	0.00	0.00		
				5.RETARDATION	2.00	2.00	2.00	1.50	1.25	0.75	0.50	0.00		
				6.SLEEP DISTURBANCE	1.33	1.33	0.67	0.33	0.00	0.00	0.00	0.00		
				7.Total score	7.67	7.67	7.00	5.17	3.25	2.58	1.00	0.17		
	414	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	0.83	0.83	0.83	0.83	0.83	0.67	0.67	0.67		
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	1.00	0.83	0.83	1.00		
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00		
				5.RETARDATION	1.50	1.50	1.50	1.50	1.25	1.25	1.25	1.50		

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
15	414	Fluoxetine	Male	6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.67	1.00	1.00	1.67
				7.Total score	7.00	7.00	7.00	7.00	6.75	5.75	5.75	6.83
	415	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.17	0.83	0.50	0.50	0.17
				2.WEIGHT	2.00	2.00	2.00	2.00	2.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	0.83	0.33	0.17	0.00	0.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	1.00	0.00	0.00
				5.RETARDATION	2.50	2.50	2.50	2.50	1.75	1.00	0.50	0.50
				6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.00	0.67	0.00	0.00	0.00
				7.Total score	11.17	11.17	11.17	9.50	7.58	2.67	1.00	0.67
	416	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.33	1.33	1.00	0.67	0.67
				2.WEIGHT	2.00	2.00	2.00	2.00	2.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.50	0.50	0.50	0.33	0.17
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	2.00	1.00	0.00
				5.RETARDATION	1.75	1.75	1.75	1.75	1.75	1.25	1.00	0.75
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.33	0.67	0.33	0.33
				7.Total score	8.25	8.25	8.25	8.25	7.92	5.42	3.33	1.92
	417	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.17	0.83	0.33	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	0.83	0.83	0.83	0.67	0.17	0.17	0.17	0.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	0.00	0.00	0.00	0.00
				5.RETARDATION	1.25	1.25	1.25	0.75	0.50	0.25	0.25	0.25
				6.SLEEP DISTURBANCE	2.00	2.00	1.00	0.67	0.33	0.00	0.00	0.00
				7.Total score	7.58	7.58	6.25	3.92	1.33	0.75	0.58	0.42
	418	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.83	1.83	1.83	1.67	1.17	1.00	0.83	0.33
				2.WEIGHT	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	0.67	0.50	0.17	0.17	0.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	1.00	1.00	0.00
				5.RETARDATION	2.50	2.50	2.50	2.25	1.50	1.50	0.75	0.50
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	0.67	0.33	0.00	0.00	0.00
				7.Total score	10.00	10.00	10.00	8.25	5.50	3.67	2.75	0.83
	419	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	0.83	0.83	0.83	0.83	0.83	0.83	0.67	0.67
				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	0.83	0.83	0.67	0.67	0.50
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	0.00	0.00
				5.RETARDATION	2.00	2.00	2.00	2.00	2.00	1.50	1.25	0.75
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.67	1.00	0.67	0.33
				7.Total score	6.33	6.33	6.33	6.33	6.33	5.00	3.25	2.25
	420	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.17	0.83	0.83	0.67	0.50
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	0.83	0.33	0.33	0.33

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
15	420	Fluoxetine	Male	4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00		
				5.RETARDATION	1.75	1.75	1.75	1.50	1.50	1.25	1.00	0.75		
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.00	0.33	0.33	0.00	0.00		
				7.Total score	6.75	6.75	6.75	5.67	4.50	3.75	3.00	1.58		
	421	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.67	1.67	1.33	0.83	0.33	0.17		
				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	1.33	1.33	0.83	0.50	0.17	0.17		
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	2.00	1.00	0.00		
				5.RETARDATION	1.50	1.50	1.50	1.75	1.25	1.25	0.50	0.00		
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.67	1.00	1.00	0.33	0.33		
				7.Total score	7.50	7.50	7.83	8.42	6.42	5.58	2.33	0.67		
	422	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.33	1.00	0.67	0.50	0.33		
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.67	0.33	0.17	0.17	0.00		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	0.00	0.00		
				5.RETARDATION	2.00	2.00	2.00	2.00	1.75	1.25	0.50	0.50		
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.33	0.67	0.67	0.00	0.00		
				7.Total score	6.67	6.67	6.67	6.33	4.75	3.75	1.17	0.83		
	423	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.33	1.33	1.33	0.67	0.67		
				2.WEIGHT	2.00	2.00	2.00	2.00	2.00	2.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	1.00	1.00	0.67	0.17	0.17		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00		
				5.RETARDATION	1.25	1.25	1.25	1.25	1.25	1.25	0.75	0.75		
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	0.67	0.33	0.00		
				7.Total score	7.58	7.58	7.58	7.58	7.58	6.92	2.92	2.58		
	424	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.67	1.67	1.67	1.17	0.67	0.50	0.33	0.00		
				2.WEIGHT	2.00	2.00	2.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.83	0.67	0.33	0.17	0.17	0.17		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00		
				5.RETARDATION	1.25	1.25	1.25	1.25	1.00	1.00	0.75	0.75		
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	0.67	0.00	0.00	0.00		
				7.Total score	8.25	8.25	8.08	5.08	3.67	2.67	2.25	0.92		
	425	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.50	1.50	0.83	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	0.83	0.83	0.83	0.83	0.50	0.17	0.00	0.00		
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	0.00	0.00	0.00		
				5.RETARDATION	2.00	2.00	2.00	1.75	1.00	0.50	0.00	0.00		
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	0.67	0.33	0.00	0.00		
				7.Total score	7.67	7.67	7.67	7.08	4.00	1.33	0.17	0.17		
	426	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.83	1.83	1.83	1.33	1.33	1.33	1.00	1.00		

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
15	426	Fluoxetine	Male	2.WEIGHT	2.00	2.00	2.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	1.17	1.17	1.17	1.00	0.83	0.67	0.17	0.17		
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	1.00	1.00	1.00		
				5.RETARDATION	2.00	2.00	2.00	1.75	1.75	0.75	0.50	0.50		
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	1.00	0.67	0.67	0.33		
				7.Total score	10.33	10.33	10.33	7.08	6.92	4.42	3.33	3.00		
	427	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.50	1.33	1.33	1.33	1.00	0.50		
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.33	0.50	0.50	0.50	0.50	0.17	0.00	0.00		
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	1.00	1.00	0.00		
				5.RETARDATION	2.00	2.00	2.00	1.75	1.75	1.25	1.00	1.00		
				6.SLEEP DISTURBANCE	1.33	1.00	1.00	0.67	0.67	0.33	0.33	0.00		
				7.Total score	7.17	7.00	7.00	6.25	6.25	4.08	3.33	1.50		
	428	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.33	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	0.83	0.83	0.83	0.83	0.50	0.33	0.33	0.33		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00		
				5.RETARDATION	1.25	1.25	1.25	1.25	1.25	0.75	0.75	0.50		
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	0.67	0.67	0.33	0.33		
				7.Total score	5.42	5.42	5.42	5.42	4.42	3.75	3.42	3.17		
	449	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.33	1.33	1.17	1.17	0.50		
				2.WEIGHT	1.00	1.00	1.00	1.00	1.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.83	0.83	0.83	0.83	0.33		
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				5.RETARDATION	1.50	1.50	1.75	1.75	1.75	1.75	1.75	0.50		
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00	0.33	0.00		
				7.Total score	5.67	5.67	5.92	5.92	5.92	4.75	4.08	1.33		
	450	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.33	1.33	1.17	1.17	1.17		
				2.WEIGHT	2.00	2.00	2.00	1.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.50	0.50	0.33	0.33	0.33	0.33		
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00		
				5.RETARDATION	2.75	2.75	2.75	2.50	2.25	2.00	1.25	1.25		
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.33	0.67	0.33	0.00	0.00		
				7.Total score	8.92	8.92	8.92	7.67	5.58	4.83	3.75	3.75		
	451	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	1.17	1.33	1.00	0.83	0.67	0.50		
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.67	0.67	0.33	0.33	0.33		
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00		
				5.RETARDATION	1.75	1.75	1.75	1.75	1.25	0.75	0.50	0.50		
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	0.67	0.33	0.67	0.33		
				7.Total score	6.58	6.58	6.58	6.75	4.58	3.25	3.17	2.67		

818

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
15	452	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.17	0.67	0.83		0.67		0.17
				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	0.83	0.50	0.17		0.00		0.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	1.00		2.00		0.00
				5.RETARDATION	1.50	1.50	1.50	1.50	1.00	0.75		0.50		0.25
				6.SLEEP DISTURBANCE	0.33	0.33	0.33	0.33	0.00	0.00		0.00		0.00
				7.Total score	6.00	6.00	6.00	4.83	3.17	2.75		3.17		0.42
	454	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.50	1.50	1.50	1.50	1.50	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	0.83	0.83	0.83	0.83	0.83	0.67		0.50		0.17
				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	1.25	1.25	1.25		1.25		1.00
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	0.33	0.33		0.33		0.33
				7.Total score	5.58	5.58	5.58	5.58	4.92	4.25		4.08		3.50
16	429	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.00	0.50	0.17	0.17	0.17	0.17	0.17	0.17
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.83	1.83	0.83	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.25	2.25	1.25	0.75	0.50	0.50	0.25	0.75	0.75	0.50
				6.SLEEP DISTURBANCE	1.33	1.33	0.33	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				7.Total score	6.92	6.92	3.42	1.25	0.67	0.67	0.42	0.92	0.92	0.67
	430	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.33	1.33	0.67	0.67	0.33	0.33	0.67	0.67	0.17	0.17
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.17	1.17	0.33	0.33	0.33	0.33	0.33	0.33	0.00	0.00
				4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.50	2.50	1.00	0.75	0.75	0.75	1.00	1.00	0.50	0.50
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	0.67	0.67	0.67	0.67	0.67
				7.Total score	8.00	8.00	4.00	3.75	2.42	2.08	2.67	2.67	1.33	1.33
	431	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	0.83	0.67	0.67	0.33	0.50	0.50	0.33	0.50
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.83	1.83	0.83	0.67	0.83	0.50	0.50	0.67	0.50	0.50
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.50	2.50	1.00	1.00	0.75	0.50	0.75	0.75	0.75	0.75
				6.SLEEP DISTURBANCE	1.33	1.33	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				7.Total score	7.00	7.00	2.67	2.33	2.25	1.33	1.75	1.92	1.58	1.75
	432	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	0.83	0.17	0.00	0.00	0.00	0.00	0.00	0.00
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.50	1.50	0.33	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	3.25	3.25	1.50	0.75	0.50	0.50	0.75	0.75	0.75	0.75

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
16	432	Fluoxetine	Female	6.SLEEP DISTURBANCE	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				7.Total score	6.92	6.92	3.67	1.92	0.50	0.50	0.75	0.75	0.75	0.75
	433	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	0.67	0.17	0.17	0.17	0.17	0.17	0.17	0.17
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.50	1.50	0.50	0.00	0.00	0.17	0.17	0.17	0.33	0.33
				4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.50	2.50	1.00	0.25	0.00	0.00	0.00	0.00	0.00	0.25
				6.SLEEP DISTURBANCE	0.33	0.33	0.67	0.33	0.33	0.33	0.33	0.33	0.33	0.33
				7.Total score	7.83	7.83	3.83	1.75	0.50	0.67	0.67	0.67	0.83	1.08
	434	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	0.83	0.17	0.33	0.17	0.17	0.17	0.17	0.17
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.83	1.83	0.83	0.17	0.50	0.17	0.17	0.17	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	0.00
				5.RETARDATION	2.75	2.75	1.75	0.50	0.50	0.50	0.50	0.50	0.50	0.50
				6.SLEEP DISTURBANCE	1.33	1.33	0.67	0.67	1.00	0.67	0.67	0.67	0.67	0.67
				7.Total score	7.25	7.25	4.08	1.50	2.33	1.50	1.50	1.50	1.67	1.67
	435	Reboxetine	Female	1.ANXIETY/SOMATIZATION	2.17	2.17	1.33	0.83	0.17	0.17	0.17	0.17	0.00	0.00
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.83	1.83	1.00	0.67	0.33	0.17	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	2.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.75	2.75	1.75	1.25	0.50	0.50	0.50	0.50	0.50	0.50
				6.SLEEP DISTURBANCE	2.00	2.00	2.00	0.67	0.67	0.67	0.67	0.67	0.67	0.67
				7.Total score	11.75	11.75	7.08	3.42	1.67	1.50	1.33	1.33	1.17	1.17
	436	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.00	0.67	0.67	0.67	0.50	0.33	1.50	0.67
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	0.00
				3.COGNITIVE DISTURBANCE	2.00	2.00	1.33	0.83	0.83	0.67	0.50	0.17	0.83	0.67
				4.DIURNAL VARIATION	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.25	2.25	2.00	1.25	1.25	1.25	1.00	0.75	1.50	1.25
				6.SLEEP DISTURBANCE	0.67	0.67	0.67	0.33	0.33	0.33	0.33	0.33	1.00	0.67
				7.Total score	7.42	7.42	6.00	3.08	3.08	2.92	2.33	1.58	5.83	3.25
	437	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	0.33	0.17	0.17	0.17	0.17	0.17	0.17	0.17
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	2.17	2.17	1.67	0.83	0.83	0.83	0.83	0.33	0.17	0.17
				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	1.00	0.50	0.50	0.50	0.50	0.50	0.50	0.50
				6.SLEEP DISTURBANCE	1.33	1.33	1.00	0.67	0.67	0.67	0.67	0.67	0.67	0.67
				7.Total score	9.00	9.00	4.00	2.17	2.17	2.17	2.17	1.67	1.50	1.50
	438	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.67	1.67	0.83	0.83	0.83	0.83	1.00			
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00			
				3.COGNITIVE DISTURBANCE	1.83	1.83	0.67	0.50	0.17	0.17	0.17			

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
16	438	Fluoxetine	Female	4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00			
				5.RETARDATION	2.25	2.25	1.00	1.00	1.00	1.00	1.25			
				6.SLEEP DISTURBANCE	1.67	1.67	0.67	0.67	0.67	0.67	0.67			
				7.Total score	8.42	8.42	3.17	3.00	2.67	2.67	3.08			
	439	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.00	0.33	0.33	0.33	0.17	0.17	0.17	0.33
				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	1.83	1.83	1.33	0.33	0.33	0.17	0.17	0.17	0.17	0.33
				4.DIURNAL VARIATION	2.00	2.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.75	2.75	1.75	1.00	1.00	0.50	0.25	0.50	0.50	0.50
				6.SLEEP DISTURBANCE	1.00	1.00	0.67	0.33	0.33	0.00	0.00	0.00	0.00	0.00
				7.Total score	9.08	9.08	5.75	3.00	3.00	1.00	0.58	0.83	0.83	1.17
	440	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	0.67	0.50	0.50	0.33	0.33	0.33	0.33	0.33
				2.WEIGHT	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.67	1.67	0.83	0.17	0.17	0.17	0.17	0.17	0.17	0.17
				4.DIURNAL VARIATION	2.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.25	2.25	1.50	0.50	0.50	0.25	0.25	0.25	0.25	0.00
				6.SLEEP DISTURBANCE	1.33	1.33	0.67	0.33	0.33	0.00	0.00	0.00	0.00	0.00
				7.Total score	9.58	9.58	4.67	1.50	1.50	0.75	0.75	0.75	0.75	0.50
	441	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.00	0.33	0.33	0.17		0.17		0.17
				2.WEIGHT	2.00	2.00	1.00	0.00	0.00	0.00		0.00		0.00
				3.COGNITIVE DISTURBANCE	1.33	1.33	0.83	0.50	0.50	0.17		0.17		0.17
				4.DIURNAL VARIATION	2.00	2.00	1.00	0.00	0.00	0.00		0.00		0.00
				5.RETARDATION	2.25	2.25	1.75	1.25	1.25	0.75		0.50		0.50
				6.SLEEP DISTURBANCE	1.33	1.33	0.67	0.00	0.00	0.00		0.00		0.00
				7.Total score	10.42	10.42	6.25	2.08	2.08	1.08		0.83		0.83
	442	Reboxetine	Female	1.ANXIETY/SOMATIZATION	2.00	2.00	1.83	1.50	0.67	0.50		0.83		0.83
				2.WEIGHT	2.00	2.00	1.00	0.00	0.00	0.00		0.00		0.00
				3.COGNITIVE DISTURBANCE	2.33	2.33	2.00	1.33	1.00	1.00		1.00		1.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	1.00		1.00		1.00
				5.RETARDATION	3.25	3.25	2.75	2.00	1.50	1.25		1.25		1.00
				6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.33	1.00	1.00		1.00		1.00
				7.Total score	13.58	13.58	11.58	8.17	5.17	4.75		5.08		4.83
	443	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	0.83	0.83	0.83	0.17	0.17	0.17		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	1.00	1.00	0.83	0.33	0.17	0.17		0.17		0.17
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	0.00		0.00		0.00
				5.RETARDATION	1.50	1.50	1.50	1.00	0.75	0.75		0.50		0.75
				6.SLEEP DISTURBANCE	1.00	1.00	0.67	0.67	0.33	0.33		0.33		0.33
				7.Total score	6.33	6.33	5.83	3.17	2.42	1.42		1.17		1.42
	444	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	1.00	0.83	0.67	0.67		0.67		0.67

PHARMACIA CMS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
16	444	Reboxetine	Female	2.WEIGHT	2.00	2.00	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	1.00	1.00	0.00	0.00		
				5.RETARDATION	2.00	2.00	1.50	1.50	1.00	1.00	0.00	0.00		
				6.SLEEP DISTURBANCE	1.00	1.00	0.67	0.67	0.33	0.00	0.00	0.00		
				7.Total score	8.83	8.83	5.83	5.67	3.33	3.00	0.67	0.67		
	445	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.17	1.17	1.00	0.17	0.17	0.50	0.33	0.33		
				2.WEIGHT	2.00	2.00	2.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.50	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		
				5.RETARDATION	1.75	1.75	1.75	1.00	1.00	1.00	1.00	1.00		
				6.SLEEP DISTURBANCE	1.00	1.00	0.67	0.33	0.00	0.00	0.00	0.00		
				7.Total score	7.58	7.58	6.92	2.67	1.33	1.67	1.50	1.50		
	446	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	0.83	0.67	0.50	0.50	0.50		
				2.WEIGHT	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.83	0.67	0.67	0.67	0.17	0.17	0.17	0.17		
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	0.00	0.00	0.00		
				5.RETARDATION	1.75	1.75	1.75	1.25	1.25	1.00	1.00	1.00		
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	0.67	0.33	0.33	0.00	0.00		
				7.Total score	7.58	7.42	7.42	5.42	3.42	2.00	1.67	1.67		
	447	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.17	1.17	1.00	0.83	0.50	0.50	0.67	0.50		
				2.WEIGHT	2.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00		
				3.COGNITIVE DISTURBANCE	0.50	0.50	0.33	0.33	0.17	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	1.75	1.75	1.50	1.50	0.75	0.75	1.00	0.75		
				6.SLEEP DISTURBANCE	0.67	0.67	0.67	0.67	0.33	0.33	0.33	0.33		
				7.Total score	8.08	8.08	5.50	5.33	2.75	2.75	3.17	2.75		
	448	Reboxetine	Female	1.ANXIETY/SOMATIZATION	0.83	0.83	0.83	0.33	0.17	0.17	0.17	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	1.00	0.83	0.83	0.83	0.83	0.17		
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00		
				5.RETARDATION	1.75	1.75	1.50	1.25	1.25	1.25	1.25	1.25		
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	0.67	0.33	0.33	0.33		
				7.Total score	6.75	6.75	6.33	5.42	3.92	3.58	3.58	2.75		
	455	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.00	1.00	0.67	0.67	0.67		
				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	1.00	0.83	0.83	0.50	0.50	0.33		
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	2.00	1.00	1.00	1.00		
				5.RETARDATION	2.75	2.75	2.75	2.00	1.75	1.00	1.25	1.00		
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	1.00	0.67	0.67	0.33		
				7.Total score	8.58	8.58	8.42	6.83	6.58	3.83	4.08	3.33		

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
16	456	Reboxetine	Male	1.ANXIETY/SOMATIZATION	2.00	2.00	1.33	1.00	0.67	0.67		0.67		0.67
				2.WEIGHT	2.00	2.00	2.00	1.00	0.00	0.00		0.00		0.00
				3.COGNITIVE DISTURBANCE	1.33	1.33	1.00	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		1.00		1.00
				5.RETARDATION	2.50	2.50	2.00	1.50	1.25	1.25		1.25		1.25
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	0.33	0.33	0.33		0.33		0.33
				7.Total score	11.17	11.17	9.67	6.33	3.58	3.58		3.58		3.58
	457	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.50	1.50	1.50	0.83	0.83	0.83	0.00	0.00		0.00
				2.WEIGHT	1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00		0.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	1.00	0.50	0.50	0.50	0.17	0.17		0.17
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	1.00	0.00	0.00		0.00
				5.RETARDATION	2.00	2.00	2.00	1.50	1.50	1.50	1.00	1.00		1.00
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	0.67	0.33	0.33	0.00	0.00		0.00
				7.Total score	8.83	8.83	8.83	4.50	4.17	4.17	1.17	1.17		1.17
	458	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	2.00	2.00	2.00	1.17	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	0.83	0.83	0.50	0.33	0.33	0.33		0.33		0.33
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	1.00		1.00		1.00
				5.RETARDATION	2.75	2.75	2.75	2.00	2.00	2.00		2.00		2.00
				6.SLEEP DISTURBANCE	0.00	0.00	0.00	0.00	0.00	0.00		0.00		0.00
				7.Total score	7.58	7.58	7.25	4.50	4.33	4.33		4.33		4.33
	459	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.50	1.50	1.00	0.33	0.33	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	0.33	0.33	0.33	0.33	0.33	0.33		0.00		0.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	1.00	1.00		0.00		0.00
				5.RETARDATION	2.00	2.00	2.00	1.25	1.25	0.75		0.00		0.00
				6.SLEEP DISTURBANCE	1.33	1.33	0.33	0.33	0.33	0.33		0.00		0.00
				7.Total score	7.17	7.17	5.67	3.25	3.25	2.75		0.00		0.00
	460	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.67	1.67	1.17	1.17	0.50	0.50		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	1.17	1.00	0.17	0.17		0.17		0.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	2.00	1.00	1.00		0.00		0.00
				5.RETARDATION	2.75	2.75	2.50	2.25	1.25	1.25		0.50		0.50
				6.SLEEP DISTURBANCE	0.67	0.67	0.67	0.67	0.33	0.33		0.00		0.00
				7.Total score	8.58	8.58	7.50	7.08	3.25	3.25		0.67		0.50
18	25	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.00	1.00	1.00	1.00	1.00	1.00	0.67	0.67
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.50	0.33	0.33	0.33	0.33	0.17	0.17
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	1.50	1.50	1.50	1.25	0.75	0.75	0.75	0.75	0.00	0.00

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
18	25	Fluoxetine	Female	6.SLEEP DISTURBANCE	1.67	1.67	1.00	0.67	0.67	0.67	0.67	0.67	0.33	0.33
				7.Total score	6.17	6.17	5.17	4.42	3.75	3.75	3.75	3.75	2.17	2.17
	26	Reboxetine	Female	1.ANXIETY/SOMATIZATION	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.67	0.50	0.17
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.67	0.67	0.50	0.50	0.17	0.17	0.17
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	0.00
				5.RETARDATION	1.75	1.75	1.75	1.50	1.00	0.75	0.75	0.50	0.00	0.00
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.00	0.67	0.67	0.67	0.67	0.67
				7.Total score	5.92	5.92	5.92	5.50	4.33	3.58	3.58	3.00	1.33	1.00
	27	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	1.17	1.17	1.17	1.17	1.17	0.67	0.50	0.33
				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	0.67	0.33	0.17	0.17	0.17	0.00	0.00
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.00	2.00	1.75	1.25	1.25	1.00	1.00	0.25	0.00	0.00
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.33	1.00	0.67	0.67	0.67	0.33	0.33
				7.Total score	5.33	5.33	5.08	4.42	3.75	3.00	3.00	1.75	0.83	0.67
	28	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	1.00	1.00	1.00				
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00				
				3.COGNITIVE DISTURBANCE	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				
				5.RETARDATION	2.00	2.00	2.00	2.00	2.00	2.00				
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00				
				7.Total score	5.83	5.83	5.83	5.83	5.83	5.83				
	29	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.17	1.17	1.17	1.17	1.17	0.50	0.50	0.50	0.50	0.33
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.67	0.67	0.33	0.33	0.33	0.33	0.33
				4.DIURNAL VARIATION	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.25	2.25	2.25	1.75	1.75	1.00	0.25	0.75	0.25	0.00
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.00	1.00	0.00	1.00	0.33	0.33
				7.Total score	5.08	5.08	5.08	4.58	4.58	2.83	1.08	2.58	1.42	1.00
	30	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	0.83	0.83	0.83	0.83	0.83	0.83	0.83	0.83	0.50	0.50
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.83	0.83	0.50	0.50	0.50	0.50	0.50	0.50
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	0.00
				5.RETARDATION	2.00	2.00	2.00	1.50	1.00	1.00	1.00	1.00	0.50	0.50
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.00	1.00	1.00	1.00	1.00	1.00
				7.Total score	6.50	6.50	6.33	5.83	4.33	4.33	4.33	4.33	2.50	2.50
	31	Reboxetine	Female	1.ANXIETY/SOMATIZATION	0.83	1.00	1.00	1.00	1.00	1.00	1.00	0.50	0.50	0.50
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00	1.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.67	0.67	0.67	0.67	0.67	0.50	0.50	0.50

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
18	31	Reboxetine	Female	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	2.00	2.00	1.50	1.50	1.50	1.50	1.50	1.00	1.00	1.00
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.33	1.33	1.33	1.33	0.67	0.67	0.67
				7.Total score	6.17	6.33	5.50	5.50	5.50	5.50	5.50	3.67	4.67	4.67
	32	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.33	1.00	1.00	1.00	0.67	0.33	0.33
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.83	0.67	0.67	0.67	0.33	0.00	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00	0.00
				5.RETARDATION	2.00	1.75	1.75	1.75	1.50	1.00	0.75	0.75	0.25	0.25
				6.SLEEP DISTURBANCE	2.00	2.00	2.00	2.00	1.33	1.00	0.67	0.00	0.00	0.00
				7.Total score	7.17	6.75	6.75	6.75	5.17	4.00	3.42	2.42	0.58	0.58
	49	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	0.67	0.33	0.33	0.33	0.17	0.17	0.17	0.17
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.50	0.17	0.17	0.17	0.17	0.17	0.00	0.00
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	2.25	2.25	1.50	0.75	0.75	0.75	0.25	0.25	0.25	0.25
				6.SLEEP DISTURBANCE	1.33	1.33	0.67	0.67	0.67	0.67	0.67	0.67	0.33	0.33
				7.Total score	6.58	6.58	4.33	2.92	2.92	2.92	2.25	2.25	1.75	1.75
	50	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33								
				2.WEIGHT	0.00	0.00								
				3.COGNITIVE DISTURBANCE	0.83	0.83								
				4.DIURNAL VARIATION	0.00	0.00								
				5.RETARDATION	2.25	2.25								
				6.SLEEP DISTURBANCE	1.33	1.33								
				7.Total score	5.75	5.75								
	51	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	0.83	0.83	0.83	0.83	0.83	0.83	0.67
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	1.00	1.00	0.67	0.50	0.50	0.50	0.33	0.33	0.33	0.00
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	1.75	1.75	1.50	1.00	1.00	1.00	1.25	1.25	1.25	0.50
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	1.00	1.00	1.00	1.00	1.00	0.33
				7.Total score	6.08	6.08	5.50	4.33	4.33	4.33	4.42	4.42	4.42	2.50
	52	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.17
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.67	0.67	0.33	0.33	0.33	0.33	0.33	0.33
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	0.00
				5.RETARDATION	2.75	2.75	2.75	2.25	1.25	1.25	1.25	1.25	1.25	0.75
				6.SLEEP DISTURBANCE	1.33	1.33	1.33	1.00	0.67	0.67	0.67	0.67	0.67	0.67
				7.Total score	6.75	6.75	6.75	5.92	4.25	4.25	4.25	4.25	4.25	1.92
	53	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.33	1.33	1.33	1.00	1.00	0.33	0.33	0.33	0.33	0.33

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
18	53	Fluoxetine	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	0.67	0.83	0.83	0.83	0.83	0.50	0.50	0.50	0.50	0.33
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00
				5.RETARDATION	2.00	2.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00	0.50
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	1.67	1.67	1.00	1.00	1.00	1.00	0.33
				7.Total score	6.67	6.83	6.83	6.50	6.50	2.83	2.83	2.83	2.83	1.50
	54	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.17	1.17	1.17	0.67	0.50	0.50	0.50	0.33	0.33	0.33
				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	0.33	0.33	0.33	0.33	0.17	0.17	0.17
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				5.RETARDATION	2.00	2.00	2.00	1.25	0.75	0.75	0.75	0.25	0.25	0.25
				6.SLEEP DISTURBANCE	1.67	1.67	1.67	0.67	0.67	0.67	0.67	0.33	0.33	0.33
				7.Total score	6.67	6.67	6.67	3.92	3.25	3.25	3.25	2.08	2.08	2.08
20	21	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	2.00	2.00	0.83	1.00	0.33	0.67	0.17	0.17	0.00	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	1.33	1.33	0.50	0.50	0.00	0.17	0.00	0.00	0.00	0.00
				4.DIURNAL VARIATION	2.00	2.00	2.00	1.00	0.00	0.00	1.00	0.00	1.00	0.00
				5.RETARDATION	2.00	2.00	1.00	0.75	0.75	0.25	0.00	0.50	0.50	0.50
				6.SLEEP DISTURBANCE	0.67	0.67	1.67	1.67	1.00	0.67	1.00	0.67	0.67	0.67
				7.Total score	10.00	10.00	6.00	4.92	2.08	1.75	2.17	1.33	2.17	1.17
	22	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	0.83	0.83	1.17	1.00	1.00	1.33	1.67			
				2.WEIGHT	0.00	0.00	0.00	0.00	2.00	0.00	0.00			
				3.COGNITIVE DISTURBANCE	1.33	1.33	1.50	1.00	0.83	0.67	1.17			
				4.DIURNAL VARIATION	1.00	2.00	2.00	0.00	2.00	2.00	1.00			
				5.RETARDATION	2.25	2.25	2.75	1.75	2.00	2.25	1.75			
				6.SLEEP DISTURBANCE	1.00	1.00	1.33	1.33	0.67	1.33	2.00			
				7.Total score	6.42	7.42	8.75	5.08	8.50	7.58	7.58			
21	9	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	1.17	0.67	0.67	0.50	0.33	0.33	0.33	0.50
				2.WEIGHT	0.00	0.00	0.00	0.00	0.00	2.00	0.00	0.00	0.00	1.00
				3.COGNITIVE DISTURBANCE	0.83	0.83	0.83	0.50	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	0.00
				5.RETARDATION	2.50	2.50	2.50	2.25	2.25	2.00	0.75	0.50	0.25	0.25
				6.SLEEP DISTURBANCE	1.33	1.33	0.67	0.33	0.33	1.67	0.67	0.67	0.67	0.00
				7.Total score	5.83	5.83	5.17	3.75	3.42	6.33	1.92	1.67	1.42	1.92
22	113	Fluoxetine	Male	1.ANXIETY/SOMATIZATION	1.67	1.67	1.50	1.67						
				2.WEIGHT	2.00	0.00	0.00	2.00						
				3.COGNITIVE DISTURBANCE	0.67	0.83	0.83	0.83						
				4.DIURNAL VARIATION	1.00	1.00	1.00	1.00						
				5.RETARDATION	2.00	2.00	2.00	2.00						
				6.SLEEP DISTURBANCE	1.67	1.33	1.33	1.33						
				7.Total score	9.00	6.83	6.67	8.83						

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 Day	49 Day	56
22	115	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1.67	1.67	1.33	1.33	1.67					
				2.WEIGHT	1.00	1.00	1.00	0.00	2.00					
				3.COGNITIVE DISTURBANCE	1.17	1.17	1.17	1.00	1.00					
				4.DIURNAL VARIATION	0.00	0.00	0.00	1.00	1.00					
				5.RETARDATION	1.50	1.50	1.50	1.50	1.50					
				6.SLEEP DISTURBANCE	1.00	1.00	1.00	1.00	1.33					
				7.Total score	6.33	6.33	6.00	5.83	8.50					

827

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
1	1	Fluoxetine	Male	1	01.REPORTED SADNESS	1	1	0	0	0	0	0	1	0
					02.INNER TENSION	1	1	0	0	0	0	0	2	0
					03.APPARENT SADNESS	1	1	1	1	0	0	0	1	0
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0	0	0
					05.INERTIA	2	1	1	1	1	0	0	1	0
					06.INABILITY TO FEEL	1	1	1	0	1	0	0	1	0
					07.PESSIMISTIC THOUGHTS	2	1	1	1	0	0	0	1	0
					08.CONCENTRATIONS DIFFICULTIES	1	1	0	1	1	0	0	1	0
					09.REDUCED SLEEP	1	1	1	1	0	0	0	0	0
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	11	9	5	5	3	0	0	8	0
	2	Reboxetine	Male	1	01.REPORTED SADNESS	3	2	2	1	0	0	0	0	0
					02.INNER TENSION	2	1	2	1	1	0	0	0	0
					03.APPARENT SADNESS	2	1	2	1	1	0	0	0	0
					04.SUICIDAL THOUGHTS	1	0	1	0	0	0	0	0	0
					05.INERTIA	2	0	2	1	0	0	0	0	0
					06.INABILITY TO FEEL	2	1	1	1	1	0	0	0	0
					07.PESSIMISTIC THOUGHTS	0	1	2	1	0	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	2	1	2	2	1	1	1	1	1
					09.REDUCED SLEEP	2	3	3	2	2	0	1	1	1
					10.REDUCED APPETITE	0	0	1	0	0	0	0	0	0
					11.Total score	16	10	18	10	6	2	3	3	3
	3	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	1	0	0	1			0
					02.INNER TENSION	1	1	0	0	0	0			0
					03.APPARENT SADNESS	1	1	1	1	0	1			0
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0			0
					05.INERTIA	1	1	0	1	1	0			0
					06.INABILITY TO FEEL	2	2	1	0	1	0			0
					07.PESSIMISTIC THOUGHTS	2	2	1	1	1	1			1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	0	0			0
					09.REDUCED SLEEP	2	2	1	1	1	1			1
					10.REDUCED APPETITE	1	1	1	0	0	0			0
					11.Total score	14	14	7	5	4	4			2
	4	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	1	0	0		
					02.INNER TENSION	2	2	2	1	1	1	1		
					03.APPARENT SADNESS	2	2	2	2	1	1	1		
					04.SUICIDAL THOUGHTS	1	1	1	1	1	0	0		
					05.INERTIA	2	2	2	1	1	1	1		
					06.INABILITY TO FEEL	2	2	2	1	1	0	0		
					07.PESSIMISTIC THOUGHTS	2	2	2	1	1	1	1		
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	1		
					09.REDUCED SLEEP	1	2	2	2	2	2	2		
					10.REDUCED APPETITE	1	1	1	1	1	0	0		
					11.Total score	17	18	18	13	11	7	7		

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
1	5	Fluoxetine	Female	1	01.REPORTED SADNESS	3	2	2	2	2				
					02.INNER TENSION	2	1	2	2	2				
					03.APPARENT SADNESS	2	1	2	2	2				
					04.SUICIDAL THOUGHTS	1	1	0	0	0				
					05.INERTIA	2	2	2	2	2				
					06.INABILITY TO FEEL	2	2	2	2	2				
					07.PESSIMISTIC THOUGHTS	2	2	1	1	1				
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1				
					09.REDUCED SLEEP	2	2	2	2	2				
					10.REDUCED APPETITE	0	0	1	1	1				
					11.Total score	18	15	16	16	15				
	6	Fluoxetine	Male	1	01.REPORTED SADNESS	2	2	2	2	2				
					02.INNER TENSION	2	2	2	2	2				
					03.APPARENT SADNESS	3	3	3	3	3				
					04.SUICIDAL THOUGHTS	1	1	1	1	1				
					05.INERTIA	3	3	3	3	3				
					06.INABILITY TO FEEL	2	2	2	2	2				
					07.PESSIMISTIC THOUGHTS	2	2	2	2	2				
					08.CONCENTRATIONS DIFFICULTIES	3	3	3	3	3				
					09.REDUCED SLEEP	2	2	2	2	2				
					10.REDUCED APPETITE	0	0	0	0	0				
					11.Total score	20	20	20	20	20				
2	33	Fluoxetine	Female	1	01.REPORTED SADNESS	3	0	2	1	1	2	1	1	1
					02.INNER TENSION	1	0	2	2	1	2	2	1	1
					03.APPARENT SADNESS	2	0	2	1	1	2	1	1	1
					04.SUICIDAL THOUGHTS	1	0	1	1	1	1	1	1	1
					05.INERTIA	2	0	1	1	0	1	1	1	1
					06.INABILITY TO FEEL	3	0	2	3	3	2	1	1	3
					07.PESSIMISTIC THOUGHTS	1	0	1	2	0	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	0	0	0	0	0	0
					09.REDUCED SLEEP	3	3	2	2	2	3	2	2	2
					10.REDUCED APPETITE	2	1	1	1	1	1	1	1	1
					11.Total score	20	5	15	14	10	15	11	10	12
	34	Reboxetine	Male	1	01.REPORTED SADNESS	2	1	1	0	0	0	0		
					02.INNER TENSION	1	1	1	1	1	1	1		
					03.APPARENT SADNESS	2	1	1	0	0	0	0		
					04.SUICIDAL THOUGHTS	2	1	0	0	0	0	0		
					05.INERTIA	1	1	1	0	0	1	0		
					06.INABILITY TO FEEL	2	1	1	0	0	0	1		
					07.PESSIMISTIC THOUGHTS	1	1	0	1	1	0	1		
					08.CONCENTRATIONS DIFFICULTIES	1	0	0	1	1	2	1		
					09.REDUCED SLEEP	3	3	2	2	2	2	2		
					10.REDUCED APPETITE	0	0	0	0	0	0	0		

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
2	34	Reboxetine	Male	1	11.Total score	15	10	7	5	5	6	6		
	35	Reboxetine	Female	1	01.REPORTED SADNESS	3	0	0	1	3	1	1	1	1
					02.INNER TENSION	3	2	1	1	1	1	2	1	1
					03.APPARENT SADNESS	1	1	1	1	1	2	1	1	1
					04.SUICIDAL THOUGHTS	0	0	0	1	0	0	0	0	0
					05.INERTIA	3	2	1	1	2	1	2	1	1
					06.INABILITY TO FEEL	2	1	1	1	1	2	1	1	1
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	2	1	0	0	2	0	0	0	0
					09.REDUCED SLEEP	0	1	0	0	1	2	2	1	1
					10.REDUCED APPETITE	1	1	1	2	1	1	0	0	0
					11.Total score	16	10	6	9	13	11	10	7	7
	36	Fluoxetine	Male	1	01.REPORTED SADNESS	1	1	1	1	0	0	0	0	0
					02.INNER TENSION	1	1	0	0	0	0	0	0	0
					03.APPARENT SADNESS	1	1	1	1	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	1	0	1	0	0	0	0	0
					05.INERTIA	2	2	2	1	0	0	0	0	0
					06.INABILITY TO FEEL	1	1	1	1	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	2	1	0	1	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	0	0	0	0	0	0
					09.REDUCED SLEEP	1	0	1	0	0	0	0	0	0
					10.REDUCED APPETITE	2	2	1	2	0	0	0	0	0
					11.Total score	14	11	8	8	0	0	0	0	0
	37	Reboxetine	Male	1	01.REPORTED SADNESS	3								
					02.INNER TENSION	1								
					03.APPARENT SADNESS	1								
					04.SUICIDAL THOUGHTS	2								
					05.INERTIA	2								
					06.INABILITY TO FEEL	2								
					07.PESSIMISTIC THOUGHTS	2								
					08.CONCENTRATIONS DIFFICULTIES	1								
					09.REDUCED SLEEP	1								
					10.REDUCED APPETITE	1								
					11.Total score	16								
	38	Fluoxetine	Male	1	01.REPORTED SADNESS	3	1	1	1	0	0			
					02.INNER TENSION	2	1	1	1	1	0			
					03.APPARENT SADNESS	1	1	1	0	0	0			
					04.SUICIDAL THOUGHTS	1	1	1	1	0	0			
					05.INERTIA	2	1	1	1	0	0			
					06.INABILITY TO FEEL	1	1	1	1	0	0			
					07.PESSIMISTIC THOUGHTS	1	1	1	1	0	0			
					08.CONCENTRATIONS DIFFICULTIES	1	1	2	1	0	0			
					09.REDUCED SLEEP	3	2	2	2	0	1			

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
2	38	Fluoxetine	Male	1	10.REDUCED APPETITE	0	1	1	1	0	0			
					11.Total score	15	11	12	10	1	1			
	39	Fluoxetine	Male	1	01.REPORTED SADNESS	1								
					02.INNER TENSION	2								
					03.APPARENT SADNESS	1								
					04.SUICIDAL THOUGHTS	0								
					05.INERTIA	1								
					06.INABILITY TO FEEL	2								
					07.PESSIMISTIC THOUGHTS	2								
					08.CONCENTRATIONS DIFFICULTIES	2								
					09.REDUCED SLEEP	1								
					10.REDUCED APPETITE	2								
					11.Total score	14								
	40	Reboxetine	Male	1	01.REPORTED SADNESS	2	2	1	0					
					02.INNER TENSION	1	2	1	2					
					03.APPARENT SADNESS	0	1	0	0					
					04.SUICIDAL THOUGHTS	1	1	1	0					
					05.INERTIA	1	1	1	1					
					06.INABILITY TO FEEL	2	1	1	1					
					07.PESSIMISTIC THOUGHTS	1	1	0	1					
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2					
					09.REDUCED SLEEP	2	2	2	1					
					10.REDUCED APPETITE	0	0	1	1					
					11.Total score	12	13	10	9					
	41	Fluoxetine	Male	1	01.REPORTED SADNESS	1	1	1	1	1	0	1	0	0
					02.INNER TENSION	0	0	0	0	0	0	0	1	1
					03.APPARENT SADNESS	3	1	1	1	1	1	1	0	0
					04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0	0
					05.INERTIA	2	2	2	1	0	0	0	0	1
					06.INABILITY TO FEEL	1	1	1	1	1	1	1	0	0
					07.PESSIMISTIC THOUGHTS	0	1	0	0	0	1	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	3	3	2	2	2	1	1	1	0
					09.REDUCED SLEEP	2	2	2	2	1	0	0	1	0
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	12	11	9	8	6	4	4	3	2
	42	Reboxetine	Female	1	01.REPORTED SADNESS	2	1	0	0	0	0	1	0	0
					02.INNER TENSION	2	1	1	2	1	1	1	1	1
					03.APPARENT SADNESS	2	1	0	1	0	0	1	1	1
					04.SUICIDAL THOUGHTS	2	1	0	0	0	0	0	0	0
					05.INERTIA	2	2	1	1	1	1	0	1	1
					06.INABILITY TO FEEL	2	1	0	0	1	0	1	1	1
					07.PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1	1	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	2	2	2

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
2	42	Reboxetine	Female	1	09.REDUCED SLEEP	2	2	2	1	1	1	1	1	1
					10.REDUCED APPETITE	1	1	1	1	1	0	0	0	0
					11.Total score	19	14	7	8	7	5	8	8	7
	43	Reboxetine	Female	1	01.REPORTED SADNESS	2	1	1	0	1	1	1	0	1
					02.INNER TENSION	2	1	1	1	1	1	1	1	1
					03.APPARENT SADNESS	2	1	1	0	0	1	0	0	0
					04.SUICIDAL THOUGHTS	1	1	1	1	1	1	1	1	1
					05.INERTIA	2	2	1	1	1	1	1	1	1
					06.INABILITY TO FEEL	2	2	2	2	1	2	0	2	0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	0	0	1	0	0
					08.CONCENTRATIONS DIFFICULTIES	1	2	1	2	2	1	0	1	1
					09.REDUCED SLEEP	2	1	1	2	2	2	1	2	1
					10.REDUCED APPETITE	1	1	1	1	0	0	1	0	0
					11.Total score	16	13	11	11	9	10	7	8	6
	44	Fluoxetine	Male	1	01.REPORTED SADNESS	2	1	0	0	0	0	0		
					02.INNER TENSION	3	1	1	1	1	1	1		
					03.APPARENT SADNESS	2	1	0	0	0	0	0		
					04.SUICIDAL THOUGHTS	3	1	0	0	0	0	0		
					05.INERTIA	2	2	1	1	1	1	1		
					06.INABILITY TO FEEL	3	1	1	0	1	0	0		
					07.PESSIMISTIC THOUGHTS	2	1	1	0	0	0	1		
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	1		
					09.REDUCED SLEEP	2	1	1	1	1	0	1		
					10.REDUCED APPETITE	0	1	1	0	0	0	0		
					11.Total score	21	11	7	4	5	3	5		
	45	Reboxetine	Female	2	01.REPORTED SADNESS	2	1	0	0	0	0	0	0	0
					02.INNER TENSION	1	0	1	1	1	0	1	1	1
					03.APPARENT SADNESS	2	0	1	0	0	0	0	0	0
					04.SUICIDAL THOUGHTS	2	1	0	1	1	0	0	0	0
					05.INERTIA	2	1	1	0	0	0	0	1	1
					06.INABILITY TO FEEL	2	1	1	0	0	1	1	0	0
					07.PESSIMISTIC THOUGHTS	2	1	1	1	1	1	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	1	1	1
					09.REDUCED SLEEP	1	0	0	0	0	0	1	0	0
					10.REDUCED APPETITE	1	0	0	0	0	0	0	0	0
					11.Total score	17	6	6	4	4	3	4	3	3
	47	Fluoxetine	Female	1	01.REPORTED SADNESS	2	1	0	0	0	0	0	0	0
					02.INNER TENSION	2	1	1	1	1	1	0	1	1
					03.APPARENT SADNESS	2	1	0	0	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0	0
					05.INERTIA	1	0	1	0	0	0	0	0	0
					06.INABILITY TO FEEL	1	0	0	0	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	1	0	0	0	0	0	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
2	47	Fluoxetine	Female	1	08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	1	1	1	1
					09.REDUCED SLEEP	2	2	1	1	1	1	1	0	1
					10.REDUCED APPETITE	2	1	0	0	0	0	0	0	0
					11.Total score	16	8	4	3	3	3	2	2	3
	48	Reboxetine	Female	1	01.REPORTED SADNESS	2	3	2	3	2	2	2	2	2
					02.INNER TENSION	2	2	2	2	2	2	2	2	2
					03.APPARENT SADNESS	2	2	2	2	2	1	1	2	2
					04.SUICIDAL THOUGHTS	1	1	1	1	1	1	1	1	1
					05.INERTIA	1	2	2	1	1	2	1	1	1
					06.INABILITY TO FEEL	2	3	1	1	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	2	1	1	2	1	1	1	2	2
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	0	0	0	0	0	0
					09.REDUCED SLEEP	3	3	2	2	2	2	2	2	2
					10.REDUCED APPETITE	2	2	2	2	1	2	2	2	2
					11.Total score	19	21	16	16	13	14	13	15	15
	80	Fluoxetine	Male	1	01.REPORTED SADNESS	2	1	1	0	0	0	0	0	0
					02.INNER TENSION	1	1	1	0	0	0	0	0	0
					03.APPARENT SADNESS	2	1	1	0	0	0	0	0	0
					04.SUICIDAL THOUGHTS	2	1	0	0	0	0	0	0	0
					05.INERTIA	2	1	1	1	0	1	1	1	1
					06.INABILITY TO FEEL	2	1	1	1	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	2	1	1	1	1	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	1	2	1	1	1	1	0	0	1
					09.REDUCED SLEEP	3	2	2	2	2	2	1	1	0
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	17	11	9	6	5	5	3	3	3
3	65	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	1	2	1	1	1	1	1
					02.INNER TENSION	2	2	2	2	2	2	2	2	2
					03.APPARENT SADNESS	2	2	2	2	1	1	1	1	1
					04.SUICIDAL THOUGHTS	1	1	1	1	0	0	0	0	0
					05.INERTIA	2	2	1	1	0	0	1	1	1
					06.INABILITY TO FEEL	2	1	1	1	1	1	1	1	0
					07.PESSIMISTIC THOUGHTS	2	1	1	1	1	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	1	1	1	0
					09.REDUCED SLEEP	2	2	1	2	2	1	1	1	1
					10.REDUCED APPETITE	1	1	1	0	0	0	0	0	0
					11.Total score	18	16	13	14	10	8	9	9	7
	66	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	2	2					
					02.INNER TENSION	2	2	2	2					
					03.APPARENT SADNESS	2	2	2	1					
					04.SUICIDAL THOUGHTS	1	1	1	0					
					05.INERTIA	2	1	1	1					
					06.INABILITY TO FEEL	1	1	1	1					

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
3	66	Fluoxetine	Female	1	07.PESSIMISTIC THOUGHTS	2	2	2	2					
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2					
					09.REDUCED SLEEP	2	2	2	2					
					10.REDUCED APPETITE	0	1	1	0					
					11.Total score	16	16	16	13					
	67	Reboxetine	Female	1	01.REPORTED SADNESS	3	2	1	0	0				
					02.INNER TENSION	2	1	1	1	0				
					03.APPARENT SADNESS	3	2	1	0	0				
					04.SUICIDAL THOUGHTS	2	1	1	1	0				
					05.INERTIA	2	1	0	0	0				
					06.INABILITY TO FEEL	2	2	2	2	1				
					07.PESSIMISTIC THOUGHTS	2	2	1	0	0				
					08.CONCENTRATIONS DIFFICULTIES	3	2	2	1	1				
					09.REDUCED SLEEP	2	3	1	2	1				
					10.REDUCED APPETITE	2	2	0	0	0				
					11.Total score	23	18	10	7	3				
	68	Reboxetine	Female	1	01.REPORTED SADNESS	3	2	1	1	1				
					02.INNER TENSION	2	2	2	2	2				
					03.APPARENT SADNESS	1	2	2	1	1				
					04.SUICIDAL THOUGHTS	1	1	1	0	0				
					05.INERTIA	2	1	1	1	1				
					06.INABILITY TO FEEL	2	2	1	2	1				
					07.PESSIMISTIC THOUGHTS	2	2	2	2	1				
					08.CONCENTRATIONS DIFFICULTIES	3	3	1	2	2				
					09.REDUCED SLEEP	2	2	2	2	2				
					10.REDUCED APPETITE	2	2	2	2	2				
					11.Total score	20	19	15	15	13				
4	97	Reboxetine	Female	1	01.REPORTED SADNESS	0	0	0	0	0	0	0	0	0
					02.INNER TENSION	0	0	0	0	0	0	0	0	0
					03.APPARENT SADNESS	2	0	3	0	0	0	0	0	0
					04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0	0
					05.INERTIA	2	1	1	0	0	0	0	0	0
					06.INABILITY TO FEEL	2	1	1	1	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	1	0	0	1	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	0	0	0	0	0
					09.REDUCED SLEEP	3	3	3	1	1	1	1	1	1
					10.REDUCED APPETITE	2	2	3	0	0	0	0	0	0
					11.Total score	14	9	13	4	1	1	1	1	1
	98	Fluoxetine	Female	1	01.REPORTED SADNESS	2	1	1	0	2	0	0	0	0
					02.INNER TENSION	1	1	0	0	0	0	0	0	0
					03.APPARENT SADNESS	3	1	1	1	3	0	0	0	0
					04.SUICIDAL THOUGHTS	1	1	1	0	2	1	0	0	0
					05.INERTIA	2	1	1	1	0	0	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
4	98	Fluoxetine	Female	1	06.INABILITY TO FEEL	2	1	1	0	2	0	0	0	0
					07.PESSIMISTIC THOUGHTS	0	0	1	0	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	1	0	0	0	0	0	0	0	0
					09.REDUCED SLEEP	1	2	2	2	0	0	1	1	0
					10.REDUCED APPETITE	2	2	2	1	0	0	0	1	0
					11.Total score	15	10	10	5	9	1	1	2	0
	99	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2							
					02.INNER TENSION	2	2							
					03.APPARENT SADNESS	3	3							
					04.SUICIDAL THOUGHTS	2	2							
					05.INERTIA	2	2							
					06.INABILITY TO FEEL	2	2							
					07.PESSIMISTIC THOUGHTS	2	2							
					08.CONCENTRATIONS DIFFICULTIES	0	0							
					09.REDUCED SLEEP	2	2							
					10.REDUCED APPETITE	1	0							
					11.Total score	18	17							
	100	Reboxetine	Male	1	01.REPORTED SADNESS	3								
					02.INNER TENSION	2								
					03.APPARENT SADNESS	1								
					04.SUICIDAL THOUGHTS	1								
					05.INERTIA	2								
					06.INABILITY TO FEEL	3								
					07.PESSIMISTIC THOUGHTS	3								
					08.CONCENTRATIONS DIFFICULTIES	2								
					09.REDUCED SLEEP	1								
					10.REDUCED APPETITE	1								
					11.Total score	19								
	101	Reboxetine	Female	1	01.REPORTED SADNESS	1	2	1	0	1	3	0	0	0
					02.INNER TENSION	3	1	2	1	2	1	1	0	0
					03.APPARENT SADNESS	2	1	0	0	1	2	0	0	1
					04.SUICIDAL THOUGHTS	0	0	1	0	1	0	0	0	0
					05.INERTIA	2	1	1	0	0	0	0	1	1
					06.INABILITY TO FEEL	3	2	1	0	2	2	2	1	0
					07.PESSIMISTIC THOUGHTS	1	2	1	1	1	0	0	1	2
					08.CONCENTRATIONS DIFFICULTIES	3	2	2	0	2	1	1	0	1
					09.REDUCED SLEEP	1	3	2	1	1	2	2	1	1
					10.REDUCED APPETITE	1	2	1	0	1	1	1	2	1
					11.Total score	17	16	12	3	12	12	7	6	7
	102	Fluoxetine	Female	1	01.REPORTED SADNESS	1	0	0	2	0	1	1	1	0
					02.INNER TENSION	1	0	0	1	0	2	1	2	1
					03.APPARENT SADNESS	1	0	0	2	0	1	1	1	1
					04.SUICIDAL THOUGHTS	2	0	0	0	0	1	0	1	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
4	102	Fluoxetine	Female	1	05.INERTIA	3	1	1	1	0	2	1	1	1
					06.INABILITY TO FEEL	1	0	0	1	0	1	1	1	0
					07.PESSIMISTIC THOUGHTS	2	0	0	1	0	0	1	2	1
					08.CONCENTRATIONS DIFFICULTIES	1	2	0	2	0	2	0	1	1
					09.REDUCED SLEEP	2	1	0	0	0	2	1	1	1
					10.REDUCED APPETITE	0	0	0	0	0	0	0	1	1
					11.Total score	14	4	1	10	0	12	7	12	7
	103	Fluoxetine	Female	1	01.REPORTED SADNESS	3	3	3	2	2	2			
					02.INNER TENSION	2	2	2	2	2	2			
					03.APPARENT SADNESS	3	3	3	3	3	3			
					04.SUICIDAL THOUGHTS	2	2	2	1	2	2			
					05.INERTIA	3	3	3	1	0	2			
					06.INABILITY TO FEEL	3	3	2	2	1	3			
					07.PESSIMISTIC THOUGHTS	0	0	0	0	1	2			
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2			
					09.REDUCED SLEEP	2	3	2	2	2	2			
					10.REDUCED APPETITE	0	2	3	2	1	0			
					11.Total score	20	23	22	17	16	20			
	104	Reboxetine	Female	1	01.REPORTED SADNESS	3	3	3	1	1	1	1		
					02.INNER TENSION	1	1	1	0	1	0	0		
					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	2	1	1	1		
					06.INABILITY TO FEEL	2	2	2	2	1	1	2		
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	0		
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	2	2	2	2		
					09.REDUCED SLEEP	2	1	0	0	0	1	0		
					10.REDUCED APPETITE	0	0	0	0	0	0	0		
					11.Total score	16	15	13	9	8	8	7		
	105	Fluoxetine	Male	1	01.REPORTED SADNESS	3	3	3	3	3	3	3	3	2
					02.INNER TENSION	1	0	1	1	1	1	0	1	1
					03.APPARENT SADNESS	2	2	2	3	2	3	2	2	2
					04.SUICIDAL THOUGHTS	1	1	1	1	1	1	1	1	1
					05.INERTIA	2	2	2	2	2	2	2	2	2
					06.INABILITY TO FEEL	2	3	3	3	3	3	3	3	3
					07.PESSIMISTIC THOUGHTS	2	2	2	1	1	2	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	2	2	2	2
					09.REDUCED SLEEP	2	2	2	2	2	1	2	1	2
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	17	17	18	18	16	18	16	16	16
5	129	Reboxetine	Female	1	01.REPORTED SADNESS	3	1	1	1	2				
					02.INNER TENSION	2	1	1	1	2				
					03.APPARENT SADNESS	2	1	1	1	1				

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
5	129	Reboxetine	Female	1	04.SUICIDAL THOUGHTS	2	1	1	0	2				
					05.INERTIA	1	2	2	2	2				
					06.INABILITY TO FEEL	1	1	1	1	2				
					07.PESSIMISTIC THOUGHTS	0	0	0	0	2				
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	2				
					09.REDUCED SLEEP	2	1	1	1	3				
					10.REDUCED APPETITE	2	2	2	2	2				
					11.Total score	17	11	11	10	20				
	130	Fluoxetine	Female	1	01.REPORTED SADNESS	2	1	1	1	0	1	0	0	0
					02.INNER TENSION	2	1	1	1	1	1	1	1	0
					03.APPARENT SADNESS	2	1	1	1	1	1	1	0	0
					04.SUICIDAL THOUGHTS	1	1	1	0	1	1	1	0	0
					05.INERTIA	2	1	1	1	1	2	1	1	1
					06.INABILITY TO FEEL	1	1	1	1	1	1	1	0	0
					07.PESSIMISTIC THOUGHTS	2	1	1	1	1	2	1	0	1
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	1	1	0
					09.REDUCED SLEEP	1	0	1	0	0	0	0	0	0
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	15	8	9	7	7	10	7	3	2
7	193	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	2	2	2	2	2
					02.INNER TENSION	1	1	1	1	2	2	1	1	1
					03.APPARENT SADNESS	1	1	1	1	1	1	1	2	1
					04.SUICIDAL THOUGHTS	2	2	1	1	1	1	1	0	1
					05.INERTIA	2	1	1	1	1	1	1	1	1
					06.INABILITY TO FEEL	1	1	1	1	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	1	2	2	1	1	1	2	1	2
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	1	1	0
					09.REDUCED SLEEP	2	2	1	1	1	1	1	0	0
					10.REDUCED APPETITE	2	1	1	0	1	1	1	0	0
					11.Total score	16	15	13	11	12	12	12	9	9
	194	Fluoxetine	Female	1	01.REPORTED SADNESS	2	1	1	0	1	0	0	0	0
					02.INNER TENSION	1	1	1	1	1	1	1	1	0
					03.APPARENT SADNESS	1	1	1	1	1	0	0	0	0
					04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0	0
					05.INERTIA	2	1	1	1	1	1	1	0	0
					06.INABILITY TO FEEL	1	1	1	1	1	1	1	1	0
					07.PESSIMISTIC THOUGHTS	0	0	0	0	1	2	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	0	1	1	1	0
					09.REDUCED SLEEP	1	2	1	0	2	1	1	0	0
					10.REDUCED APPETITE	1	2	2	1	1	1	0	1	0
					11.Total score	10	10	9	6	9	8	5	4	0
	195	Fluoxetine	Male	1	01.REPORTED SADNESS	2	2	2	2	2	2	2	0	0
					02.INNER TENSION	2	1	1	1	1	1	1	1	1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
7	195	Fluoxetine	Male	1	03.APPARENT SADNESS	2	2	2	2	1	1	1	0	0
					04.SUICIDAL THOUGHTS	1	0	0	0	0	0	1	0	0
					05.INERTIA	2	2	2	1	1	1	1	1	0
					06.INABILITY TO FEEL	2	2	2	2	2	2	1	1	0
					07.PESSIMISTIC THOUGHTS	1	1	0	0	1	1	2	1	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	2	2	1	1	1
					09.REDUCED SLEEP	3	1	2	1	2	2	1	1	1
					10.REDUCED APPETITE	2	1	1	1	1	1	1	1	1
					11.Total score	19	14	13	11	13	13	12	7	4
	196	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	2	2	2	2	
					02.INNER TENSION	2	2	1	1	1	2	1	2	
					03.APPARENT SADNESS	1	2	2	2	1	2	1	2	
					04.SUICIDAL THOUGHTS	2	1	1	1	2	1	0	1	
					05.INERTIA	1	2	2	2	2	2	2	2	
					06.INABILITY TO FEEL	2	2	2	2	2	2	2	2	
					07.PESSIMISTIC THOUGHTS	2	2	1	2	2	1	2	2	
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	2	1	1	2	
					09.REDUCED SLEEP	3	3	2	2	3	2	2	2	
					10.REDUCED APPETITE	2	1	2	2	1	1	1	2	
					11.Total score	19	19	16	17	18	16	14	19	
	197	Fluoxetine	Male	1	01.REPORTED SADNESS	2								
					02.INNER TENSION	2								
					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	18								
11	321	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	2	1	1	0	1
					02.INNER TENSION	2	2	1	2	2	2	1	0	1
					03.APPARENT SADNESS	2	2	2	1	2	1	0	0	0
					04.SUICIDAL THOUGHTS	2	2	1	0	0	0	0	0	0
					05.INERTIA	2	3	3	1	0	1	1	0	0
					06.INABILITY TO FEEL	2	2	2	1	1	1	0	0	0
					07.PESSIMISTIC THOUGHTS	2	2	2	1	1	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	1	2	2	1	1	1	0	0	0
					09.REDUCED SLEEP	3	2	2	1	1	1	1	1	1
					10.REDUCED APPETITE	2	3	3	3	1	1	1	1	1
					11.Total score	20	22	20	13	11	9	5	2	4
	322	Reboxetine	Female	1	01.REPORTED SADNESS	3	2	2	2	2	1	1	1	1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
11	322	Reboxetine	Female	1	02.INNER TENSION	3	3	2	3	3	2	2	1	1
					03.APPARENT SADNESS	3	3	2	2	2	1	1	1	1
					04.SUICIDAL THOUGHTS	2	2	1	0	0	0	0	0	0
					05.INERTIA	2	3	2	3	2	1	2	2	1
					06.INABILITY TO FEEL	3	3	2	2	2	2	2	2	2
					07.PESSIMISTIC THOUGHTS	2	2	2	2	2	1	1	2	1
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	1	2	2	2
					09.REDUCED SLEEP	3	3	2	3	2	2	2	2	2
					10.REDUCED APPETITE	3	3	2	2	2	1	2	1	1
					11.Total score	26	26	19	21	19	12	15	14	12
	323	Fluoxetine	Female	1	01.REPORTED SADNESS	2	1	0	0	0				0
					02.INNER TENSION	2	1	1	0	0				0
					03.APPARENT SADNESS	2	2	0	0	0				0
					04.SUICIDAL THOUGHTS	2	0	0	0	0				0
					05.INERTIA	2	2	1	0	0				0
					06.INABILITY TO FEEL	2	1	0	0	0				0
					07.PESSIMISTIC THOUGHTS	1	2	1	0	0				0
					08.CONCENTRATIONS DIFFICULTIES	2	1	0	0	0				0
					09.REDUCED SLEEP	3	1	1	0	0				0
					10.REDUCED APPETITE	2	1	0	0	0				0
					11.Total score	20	12	4	0	0				0
	324	Reboxetine	Female	1	01.REPORTED SADNESS	3	3	2	2	2	2	2	1	1
					02.INNER TENSION	2	2	3	2	3	2	0	2	1
					03.APPARENT SADNESS	2	3	2	2	2	2	1	1	1
					04.SUICIDAL THOUGHTS	1	1	1	1	1	0	0	0	0
					05.INERTIA	1	1	1	1	1	1	0	1	0
					06.INABILITY TO FEEL	2	2	1	1	2	2	1	1	1
					07.PESSIMISTIC THOUGHTS	2	2	2	1	2	2	1	1	2
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	2	1	1	1	1
					09.REDUCED SLEEP	3	2	2	1	2	1	1	1	0
					10.REDUCED APPETITE	2	2	1	1	1	0	0	1	0
					11.Total score	20	20	17	13	18	13	7	10	7
	325	Reboxetine	Female	1	01.REPORTED SADNESS	3	2	2	1	1	1	1	0	0
					02.INNER TENSION	1	0	1	0	1	1	0	0	1
					03.APPARENT SADNESS	2	2	2	1	2	1	1	1	1
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0	0	0
					05.INERTIA	2	3	2	2	1	1	1	1	1
					06.INABILITY TO FEEL	2	2	2	1	1	0	0	0	0
					07.PESSIMISTIC THOUGHTS	2	2	2	2	1	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1	0	0
					09.REDUCED SLEEP	2	3	2	2	1	0	1	1	0
					10.REDUCED APPETITE	0	0	1	1	0	0	0	0	0
					11.Total score	16	16	15	11	9	6	6	4	4

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
11	326	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	1	0	0	0	0	0	0
					02.INNER TENSION	3	2	1	1	1	0	0	0	0
					03.APPARENT SADNESS	2	2	1	0	0	0	0	0	0
					04.SUICIDAL THOUGHTS	2	0	0	0	0	0	0	0	0
					05.INERTIA	2	2	1	1	0	0	0	0	0
					06.INABILITY TO FEEL	2	1	1	0	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	2	1	1	1	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	0	0	0	0	0
					09.REDUCED SLEEP	3	2	1	0	0	0	0	0	0
					10.REDUCED APPETITE	0	1	1	1	0	0	0	0	0
					11.Total score	20	15	10	5	1	0	0	0	0
	327	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	2	1	1				
					02.INNER TENSION	2	1	1	1	1				
					03.APPARENT SADNESS	1	2	1	1	0				
					04.SUICIDAL THOUGHTS	1	0	0	0	0				
					05.INERTIA	2	2	1	2	0				
					06.INABILITY TO FEEL	2	2	1	1	0				
					07.PESSIMISTIC THOUGHTS	1	2	1	1	0				
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1				
					09.REDUCED SLEEP	2	1	0	0	0				
					10.REDUCED APPETITE	0	0	0	1	1				
					11.Total score	15	14	9	10	4				
	328	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	1	1	0	0	0
					02.INNER TENSION	2	1	2	1	1	2	0	0	0
					03.APPARENT SADNESS	2	2	2	2	2	1	0	0	0
					04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0	0
					05.INERTIA	2	2	2	2	0	0	0	0	0
					06.INABILITY TO FEEL	1	2	2	1	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	1	1	2	1	1	1	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	1	2	2	1	1	0	0	0	0
					09.REDUCED SLEEP	2	1	2	2	0	1	1	1	1
					10.REDUCED APPETITE	1	0	1	1	0	0	0	0	0
					11.Total score	15	13	17	13	6	6	1	1	1
	329	Reboxetine	Female	1	01.REPORTED SADNESS	3	2	1	2	0	2	1	0	0
					02.INNER TENSION	2	1	1	1	0	1	0	2	1
					03.APPARENT SADNESS	2	2	1	2	0	2	1	0	1
					04.SUICIDAL THOUGHTS	1	1	1	1	0	1	0	0	0
					05.INERTIA	2	1	0	0	0	1	0	0	0
					06.INABILITY TO FEEL	2	2	1	1	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	1	2	1	1	0	1	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	0	1	0
					09.REDUCED SLEEP	2	2	2	2	0	2	0	0	0
					10.REDUCED APPETITE	1	0	0	0	1	2	0	1	0
					11.Total score	17	14	9	11	2	13	2	4	2

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
11	330	Reboxetine	Male	1	01.REPORTED SADNESS	2	3	2	2	1	2	2	2	
					02.INNER TENSION	2	1	1	1	1	2	1	1	
					03.APPARENT SADNESS	2	2	2	2	2	1	2	2	
					04.SUICIDAL THOUGHTS	1	0	0	1	1	1	1	1	
					05.INERTIA	1	2	2	2	1	2	1	1	
					06.INABILITY TO FEEL	2	2	1	1	1	1	1	1	
					07.PESSIMISTIC THOUGHTS	2	2	1	1	2	2	2	2	
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1	1	
					09.REDUCED SLEEP	2	3	1	1	2	1	1	1	
					10.REDUCED APPETITE	0	2	1	1	1	1	1	1	
					11.Total score	15	18	12	13	13	14	13	13	
	331	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	1	1	0	0	0	0	0
					02.INNER TENSION	2	1	2	1	0	0	0	0	0
					03.APPARENT SADNESS	1	2	1	1	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0	0
					05.INERTIA	2	2	1	1	0	1	1	0	0
					06.INABILITY TO FEEL	2	1	1	0	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	1	2	1	0	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	0	0	0	0
					09.REDUCED SLEEP	2	1	1	0	0	0	0	0	1
					10.REDUCED APPETITE	1	1	1	0	1	0	0	0	0
					11.Total score	16	13	10	5	2	1	1	0	1
	332	Fluoxetine	Female	1	01.REPORTED SADNESS	3	2	1	1	0	0	0	0	0
					02.INNER TENSION	2	1	0	0	0	0	1	0	0
					03.APPARENT SADNESS	2	3	1	1	1	1	1	1	0
					04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0	0
					05.INERTIA	3	3	2	2	1	0	1	0	0
					06.INABILITY TO FEEL	2	2	1	1	1	1	1	0	0
					07.PESSIMISTIC THOUGHTS	2	2	1	1	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	0	1	1	0
					09.REDUCED SLEEP	2	3	1	1	1	1	1	1	1
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	18	18	8	8	5	3	6	3	1
	333	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	1	1	1	1	1
					02.INNER TENSION	1	1	2	1	1	0	1	1	1
					03.APPARENT SADNESS	2	2	1	0	1	1	1	0	0
					04.SUICIDAL THOUGHTS	1	1	1	0	0	0	0	0	0
					05.INERTIA	2	3	3	1	0	1	0	0	0
					06.INABILITY TO FEEL	2	3	2	1	1	1	0	0	0
					07.PESSIMISTIC THOUGHTS	2	2	1	1	1	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	1	1	2	0	1	1	0	0	0
					09.REDUCED SLEEP	2	2	2	2	0	0	1	1	0
					10.REDUCED APPETITE	1	1	0	0	0	0	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
11	333	Reboxetine	Female	1	11.Total score	16	18	16	8	6	6	5	4	3
	334	Fluoxetine	Female	1	01.REPORTED SADNESS	3	2	1	1	1	1	1	1	1
					02.INNER TENSION	3	3	2	2	2	2	2	2	2
					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	2	2	1	1	2	2	1	1	1
					06.INABILITY TO FEEL	1	2	2	1	2	1	1	1	1
					07.PESSIMISTIC THOUGHTS	2	2	1	2	1	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	0	1	0	0
					09.REDUCED SLEEP	2	2	0	0	1	0	0	0	0
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	18	17	9	9	11	8	8	7	7
	335	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	1	2	2			
					02.INNER TENSION	2	2	2	1	2	2			
					03.APPARENT SADNESS	2	2	1	1	1	2			
					04.SUICIDAL THOUGHTS	1	0	1	0	0	1			
					05.INERTIA	2	2	1	1	1	1			
					06.INABILITY TO FEEL	2	1	1	0	1	1			
					07.PESSIMISTIC THOUGHTS	2	2	1	1	2	2			
					08.CONCENTRATIONS DIFFICULTIES	1	2	1	1	2	1			
					09.REDUCED SLEEP	2	2	1	0	0	0			
					10.REDUCED APPETITE	1	2	1	1	1	1			
					11.Total score	17	17	12	7	12	13			
12	393	Fluoxetine	Female	2	01.REPORTED SADNESS	4	4	4	4	2	3	3	1	2
					02.INNER TENSION	4	3	3	3	2	3	3	1	2
					03.APPARENT SADNESS	2	1	2	1	1	1	1	2	2
					04.SUICIDAL THOUGHTS	3	3	2	2	2	2	2	2	2
					05.INERTIA	1	2	2	2	1	0	1	1	1
					06.INABILITY TO FEEL	3	2	4	4	4	3	2	2	2
					07.PESSIMISTIC THOUGHTS	4	3	2	4	2	2	2	2	2
					08.CONCENTRATIONS DIFFICULTIES	3	2	3	3	3	2	2	2	2
					09.REDUCED SLEEP	4	2	3	3	2	1	2	1	1
					10.REDUCED APPETITE	2	1	1	1	1	1	1	1	1
					11.Total score	30	23	26	27	20	18	19	15	17
	394	Reboxetine	Male	2	01.REPORTED SADNESS	4	4	4	2	4	4	4	3	4
					02.INNER TENSION	3	4	3	1	3	3	3	3	3
					03.APPARENT SADNESS	3	3	2	2	3	3	2	2	2
					04.SUICIDAL THOUGHTS	3	4	3	2	3	3	3	2	3
					05.INERTIA	3	3	0	0	1	1	2	0	1
					06.INABILITY TO FEEL	3	3	3	3	3	3	2	3	3
					07.PESSIMISTIC THOUGHTS	4	3	3	2	3	2	2	2	3
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	3	3	3	3	2
					09.REDUCED SLEEP	2	3	2	2	2	2	2	1	2

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
12	394	Reboxetine	Male	2	10.REDUCED APPETITE	3	2	2	1	1	1	1	1	1
					11.Total score	30	31	24	17	26	25	24	20	24
	395	Reboxetine	Male	2	01.REPORTED SADNESS	3	3	2	1	2	2	2	1	1
					02.INNER TENSION	2	2	1	1	1	2	1	1	1
					03.APPARENT SADNESS	2	2	2	2	2	2	2	2	2
					04.SUICIDAL THOUGHTS	2	1	1	1	0	0	0	0	2
					05.INERTIA	2	2	2	0	1	2	0	1	1
					06.INABILITY TO FEEL	3	2	2	1	2	1	2	1	1
					07.PESSIMISTIC THOUGHTS	2	2	2	1	2	2	2	2	2
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	2	2	2	2	1
					09.REDUCED SLEEP	2	1	1	0	1	1	1	1	1
					10.REDUCED APPETITE	1	1	1	0	1	1	1	1	1
					11.Total score	21	18	16	8	14	15	13	12	13
	396	Fluoxetine	Female	2	01.REPORTED SADNESS	4	4	4						
					02.INNER TENSION	3	3	4						
					03.APPARENT SADNESS	3	3	3						
					04.SUICIDAL THOUGHTS	3	3	3						
					05.INERTIA	2	2	3						
					06.INABILITY TO FEEL	3	3	3						
					07.PESSIMISTIC THOUGHTS	2	2	2						
					08.CONCENTRATIONS DIFFICULTIES	2	3	3						
					09.REDUCED SLEEP	3	2	3						
					10.REDUCED APPETITE	3	2	3						
					11.Total score	28	27	31						
	497	Fluoxetine	Female	2	01.REPORTED SADNESS	3	3	4	3	3	2	3	3	3
					02.INNER TENSION	3	3	4	3	3	2	2	3	3
					03.APPARENT SADNESS	2	3	3	2	3	2	2	3	3
					04.SUICIDAL THOUGHTS	3	0	2	3	2	2	2	2	2
					05.INERTIA	0	0	0	1	0	0	1	0	0
					06.INABILITY TO FEEL	2	2	3	3	3	2	2	2	2
					07.PESSIMISTIC THOUGHTS	3	2	4	3	3	3	1	3	3
					08.CONCENTRATIONS DIFFICULTIES	2	3	3	3	3	2	2	2	3
					09.REDUCED SLEEP	2	2	2	2	2	2	1	2	2
					10.REDUCED APPETITE	2	1	2	1	2	1	1	2	2
					11.Total score	22	19	27	24	24	18	17	22	23
13	385	Fluoxetine	Female	2	01.REPORTED SADNESS	4	5	5	3	1		1		1
					02.INNER TENSION	4	4	4	2	1		1		0
					03.APPARENT SADNESS	4	4	4	3	1		2		2
					04.SUICIDAL THOUGHTS	4	2	2	0	0		1		0
					05.INERTIA	2	3	4	3	0		0		0
					06.INABILITY TO FEEL	4	3	4	4	2		0		0
					07.PESSIMISTIC THOUGHTS	4	3	4	2	3		0		1
					08.CONCENTRATIONS DIFFICULTIES	3	4	4	0	0		0		1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
13	385	Fluoxetine	Female	2	09.REDUCED SLEEP	2	3	2	0	0		0		0
					10.REDUCED APPETITE	3	4	4	0	0		0		0
					11.Total score	34	35	37	17	8		5		5
	386	Fluoxetine	Male	2	01.REPORTED SADNESS	4	6							
					02.INNER TENSION	4	5							
					03.APPARENT SADNESS	4	4							
					04.SUICIDAL THOUGHTS	5	5							
					05.INERTIA	3	4							
					06.INABILITY TO FEEL	4	4							
					07.PESSIMISTIC THOUGHTS	4	4							
					08.CONCENTRATIONS DIFFICULTIES	3	4							
					09.REDUCED SLEEP	3	4							
					10.REDUCED APPETITE	3	5							
					11.Total score	37	45							
	387	Reboxetine	Female	2	01.REPORTED SADNESS	4	4	3	2	1				
					02.INNER TENSION	5	3	2	2	1				
					03.APPARENT SADNESS	3	3	2	1	1				
					04.SUICIDAL THOUGHTS	4	4	3	2	2				
					05.INERTIA	3	2	2	2	0				
					06.INABILITY TO FEEL	4	3	2	2	1				
					07.PESSIMISTIC THOUGHTS	4	3	2	1	1				
					08.CONCENTRATIONS DIFFICULTIES	3	2	2	1	0				
					09.REDUCED SLEEP	3	2	2	1	0				
					10.REDUCED APPETITE	2	1	1	0	0				
					11.Total score	35	27	21	14	7				
	388	Reboxetine	Male	2	01.REPORTED SADNESS	4	5	3	2	3		3		2
					02.INNER TENSION	4	4	3	3	3		3		2
					03.APPARENT SADNESS	4	4	4	3	3		2		3
					04.SUICIDAL THOUGHTS	4	4	2	3	3		3		2
					05.INERTIA	4	3	2	0	1		2		0
					06.INABILITY TO FEEL	4	4	3	3	3		2		3
					07.PESSIMISTIC THOUGHTS	3	4	2	2	2		2		0
					08.CONCENTRATIONS DIFFICULTIES	4	4	3	2	2		2		2
					09.REDUCED SLEEP	2	4	2	2	1		1		2
					10.REDUCED APPETITE	4	4	1	1	1		0		1
					11.Total score	37	40	25	21	22		20		17
	389	Fluoxetine	Female	2	01.REPORTED SADNESS	5	4							
					02.INNER TENSION	4	4							
					03.APPARENT SADNESS	3	3							
					04.SUICIDAL THOUGHTS	5	3							
					05.INERTIA	4	4							
					06.INABILITY TO FEEL	4	3							
					07.PESSIMISTIC THOUGHTS	3	3							

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
13	389	Fluoxetine	Female	2	08.CONCENTRATIONS DIFFICULTIES	3	3							
					09.REDUCED SLEEP	4	3							
					10.REDUCED APPETITE	5	3							
					11.Total score	40	33							
	390	Reboxetine	Male	2	01.REPORTED SADNESS	4	4	2	4	2		2		0
					02.INNER TENSION	4	4	2	4	3		2		0
					03.APPARENT SADNESS	4	2	2	3	2		2		2
					04.SUICIDAL THOUGHTS	5	4	4	3	2		3		0
					05.INERTIA	4	4	3	3	2		2		0
					06.INABILITY TO FEEL	4	4	2	3	3		2		2
					07.PESSIMISTIC THOUGHTS	4	3	2	2	2		2		1
					08.CONCENTRATIONS DIFFICULTIES	4	3	2	2	3		1		0
					09.REDUCED SLEEP	4	3	2	2	2		0		0
					10.REDUCED APPETITE	4	2	0	1	1		0		0
					11.Total score	41	33	21	27	22		16		5
	391	Fluoxetine	Female	2	01.REPORTED SADNESS	4	2	1	0	0	0			
					02.INNER TENSION	4	3	2	0	0	0			
					03.APPARENT SADNESS	3	3	1	2	0	1			
					04.SUICIDAL THOUGHTS	4	2	1	3	2	1			
					05.INERTIA	3	0	0	0	0	0			
					06.INABILITY TO FEEL	3	3	2	0	0	1			
					07.PESSIMISTIC THOUGHTS	3	2	1	0	2	0			
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	0	0	0			
					09.REDUCED SLEEP	2	1	0	0	0	0			
					10.REDUCED APPETITE	2	0	0	0	0	0			
					11.Total score	30	18	10	5	4	3			
	392	Reboxetine	Female	2	01.REPORTED SADNESS	5	4	4						
					02.INNER TENSION	3	4	4						
					03.APPARENT SADNESS	3	3	3						
					04.SUICIDAL THOUGHTS	5	5	5						
					05.INERTIA	3	3	2						
					06.INABILITY TO FEEL	3	3	3						
					07.PESSIMISTIC THOUGHTS	3	3	2						
					08.CONCENTRATIONS DIFFICULTIES	3	2	1						
					09.REDUCED SLEEP	2	2	2						
					10.REDUCED APPETITE	2	2	2						
					11.Total score	32	31	28						
	501	Reboxetine	Male	2	01.REPORTED SADNESS	4	3	3	3	2		2		2
					02.INNER TENSION	4	3	3	3	1		2		2
					03.APPARENT SADNESS	3	3	3	3	2		2		2
					04.SUICIDAL THOUGHTS	4	4	2	3	3		2		2
					05.INERTIA	3	1	1	2	0		0		0
					06.INABILITY TO FEEL	3	3	2	3	2		2		2

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
13	501	Reboxetine	Male	2	07.PESSIMISTIC THOUGHTS	4	3	2	2	2		1		2
					08.CONCENTRATIONS DIFFICULTIES	4	3	3	3	2		1		1
					09.REDUCED SLEEP	2	1	2	0	0		0		0
					10.REDUCED APPETITE	1	1	1	0	0		0		0
					11.Total score	32	25	22	22	14		12		13
	502	Fluoxetine	Female	2	01.REPORTED SADNESS	5	4	4	2	4		3		1
					02.INNER TENSION	4	3	4	3	4		3		1
					03.APPARENT SADNESS	4	3	3	3	3		2		0
					04.SUICIDAL THOUGHTS	4	3	3	4	3		3		2
					05.INERTIA	4	3	2	2	2		2		2
					06.INABILITY TO FEEL	3	3	3	3	2		0		0
					07.PESSIMISTIC THOUGHTS	3	2	2	3	2		2		0
					08.CONCENTRATIONS DIFFICULTIES	3	2	2	2	2		0		0
					09.REDUCED SLEEP	3	2	2	2	3		1		0
					10.REDUCED APPETITE	4	2	2	2	2		1		0
					11.Total score	37	27	27	26	27		17		6
	503	Reboxetine	Female	2	01.REPORTED SADNESS	5	3							
					02.INNER TENSION	5	3							
					03.APPARENT SADNESS	3	3							
					04.SUICIDAL THOUGHTS	4	3							
					05.INERTIA	3	3							
					06.INABILITY TO FEEL	3	2							
					07.PESSIMISTIC THOUGHTS	3	3							
					08.CONCENTRATIONS DIFFICULTIES	4	2							
					09.REDUCED SLEEP	2	2							
					10.REDUCED APPETITE	2	2							
					11.Total score	34	26							
	504	Fluoxetine	Female	2	01.REPORTED SADNESS	4	3	4		1		2		1
					02.INNER TENSION	4	4	3		3		2		1
					03.APPARENT SADNESS	3	3	3		3		2		1
					04.SUICIDAL THOUGHTS	4	2	3		3		3		2
					05.INERTIA	3	2	2		0		2		0
					06.INABILITY TO FEEL	3	3	3		4		1		1
					07.PESSIMISTIC THOUGHTS	2	2	3		4		1		1
					08.CONCENTRATIONS DIFFICULTIES	4	3	4		2		1		1
					09.REDUCED SLEEP	2	2	2		2		1		1
					10.REDUCED APPETITE	2	1	1		0		1		0
					11.Total score	31	25	28		22		16		9
	505	Reboxetine	Female	2	01.REPORTED SADNESS	5	4	3	3	4		3		2
					02.INNER TENSION	4	4	3	3	3		3		1
					03.APPARENT SADNESS	3	3	2	3	3		3		1
					04.SUICIDAL THOUGHTS	4	3	4	3	2		1		1
					05.INERTIA	0	0	2	0	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
13	505	Reboxetine	Female	2	06.INABILITY TO FEEL	4	3	2	2	3		2		1
					07.PESSIMISTIC THOUGHTS	4	3	2	2	3		2		0
					08.CONCENTRATIONS DIFFICULTIES	3	3	2	3	2		3		0
					09.REDUCED SLEEP	3	2	2	1	2		1		0
					10.REDUCED APPETITE	3	2	1	1	0		1		0
					11.Total score	33	27	23	21	22		19		6
	506	Fluoxetine	Male	2	01.REPORTED SADNESS	4	4	2	1	2		0		0
					02.INNER TENSION	4	3	2	1	1		0		0
					03.APPARENT SADNESS	3	3	1	1	2		1		0
					04.SUICIDAL THOUGHTS	3	2	1	3	0		0		0
					05.INERTIA	2	0	0	0	0		0		0
					06.INABILITY TO FEEL	3	2	2	1	1		1		0
					07.PESSIMISTIC THOUGHTS	3	3	1	0	0		0		0
					08.CONCENTRATIONS DIFFICULTIES	3	2	0	0	0		0		0
					09.REDUCED SLEEP	2	0	0	0	0		0		0
					10.REDUCED APPETITE	1	0	0	0	0		0		0
					11.Total score	28	19	9	7	6		2		0
	507	Fluoxetine	Female	2	01.REPORTED SADNESS	4	4	3	4	3		2		1
					02.INNER TENSION	4	4	3	3	3		2		1
					03.APPARENT SADNESS	4	4	3	3	2		1		0
					04.SUICIDAL THOUGHTS	4	3	4	3	2		3		0
					05.INERTIA	2	2	2	2	0		2		0
					06.INABILITY TO FEEL	2	3	3	3	2		2		0
					07.PESSIMISTIC THOUGHTS	2	3	3	3	2		1		0
					08.CONCENTRATIONS DIFFICULTIES	3	3	3	2	1		1		0
					09.REDUCED SLEEP	2	1	1	2	2		0		0
					10.REDUCED APPETITE	2	1	1	0	0		0		0
					11.Total score	29	28	26	25	17		14		2
	508	Reboxetine	Female	2	01.REPORTED SADNESS	4	3	4	2	1		0		1
					02.INNER TENSION	4	3	4	2	1		0		1
					03.APPARENT SADNESS	4	3	3	2	2		2		1
					04.SUICIDAL THOUGHTS	6	2	5	2	1		0		1
					05.INERTIA	3	2	3	0	0		1		0
					06.INABILITY TO FEEL	3	2	3	1	1		0		0
					07.PESSIMISTIC THOUGHTS	3	2	2	1	0		0		1
					08.CONCENTRATIONS DIFFICULTIES	3	2	3	1	1		0		0
					09.REDUCED SLEEP	3	2	2	1	0		2		0
					10.REDUCED APPETITE	2	2	3	0	0		0		0
					11.Total score	35	23	32	12	7		5		5
	521	Reboxetine	Male	2	01.REPORTED SADNESS	5	4	3		2		1		1
					02.INNER TENSION	5	4	4		2		1		1
					03.APPARENT SADNESS	3	3	3		2		1		1
					04.SUICIDAL THOUGHTS	4	4	3		2		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
13	521	Reboxetine	Male	2	05.INERTIA	3	2	2		0		0		0
					06.INABILITY TO FEEL	3	3	3		2		1		1
					07.PESSIMISTIC THOUGHTS	3	3	3		2		1		0
					08.CONCENTRATIONS DIFFICULTIES	3	2	2		2		0		0
					09.REDUCED SLEEP	3	3	2		1		1		0
					10.REDUCED APPETITE	3	2	2		1		0		0
					11.Total score	35	30	27		16		6		4
14	397	Fluoxetine	Female	2	01.REPORTED SADNESS	4	3	3	1	1		1		2
					02.INNER TENSION	4	4	3	1	2		2		1
					03.APPARENT SADNESS	3	3	3	2	2		2		1
					04.SUICIDAL THOUGHTS	4	4	4	3	4		3		2
					05.INERTIA	2	2	0	2	0		0		0
					06.INABILITY TO FEEL	3	3	3	0	1		2		0
					07.PESSIMISTIC THOUGHTS	4	4	3	1	1		1		2
					08.CONCENTRATIONS DIFFICULTIES	4	4	4	2	1		2		1
					09.REDUCED SLEEP	2	2	3	2	1		1		2
					10.REDUCED APPETITE	2	2	1	1	0		0		0
					11.Total score	32	31	27	15	13		14		11
8	398	Reboxetine	Female	2	01.REPORTED SADNESS	4	3	2	2	1		2		2
4					02.INNER TENSION	4	4	2	2	1		1		2
8					03.APPARENT SADNESS	3	3	2	2	2		2		1
					04.SUICIDAL THOUGHTS	4	4	3	3	3		1		1
					05.INERTIA	3	3	1	1	0		0		1
					06.INABILITY TO FEEL	4	3	3	2	2		1		0
					07.PESSIMISTIC THOUGHTS	4	4	2	2	1		2		1
					08.CONCENTRATIONS DIFFICULTIES	4	4	3	2	1		1		1
					09.REDUCED SLEEP	3	3	2	2	2		2		0
					10.REDUCED APPETITE	2	2	1	1	0		1		0
					11.Total score	35	33	21	19	13		13		9
	399	Reboxetine	Female	2	01.REPORTED SADNESS	4	3	3	3	2		2		2
					02.INNER TENSION	4	4	3	3	3		2		2
					03.APPARENT SADNESS	3	3	3	3	3		3		2
					04.SUICIDAL THOUGHTS	5	5	4	4	4		5		2
					05.INERTIA	2	2	1	2	2		0		1
					06.INABILITY TO FEEL	3	3	3	2	3		2		1
					07.PESSIMISTIC THOUGHTS	4	4	3	2	2		2		2
					08.CONCENTRATIONS DIFFICULTIES	4	4	3	2	2		2		1
					09.REDUCED SLEEP	2	2	2	2	1		1		1
					10.REDUCED APPETITE	2	2	1	1	0		1		0
					11.Total score	33	32	26	24	22		20		14
	400	Fluoxetine	Male	2	01.REPORTED SADNESS	4	3	1	1	2		1		1
					02.INNER TENSION	5	3	2	2	2		1		0
					03.APPARENT SADNESS	3	3	2	2	1		2		2

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
14	400	Fluoxetine	Male	2	04.SUICIDAL THOUGHTS	4	2	1	1	2		0		0
					05.INERTIA	4	3	0	2	1		0		0
					06.INABILITY TO FEEL	3	2	2	2	2		2		1
					07.PESSIMISTIC THOUGHTS	4	3	2	2	1		1		0
					08.CONCENTRATIONS DIFFICULTIES	4	3	1	1	2		0		0
					09.REDUCED SLEEP	3	3	2	2	1		1		0
					10.REDUCED APPETITE	2	1	0	1	0		0		0
					11.Total score	36	26	13	16	14		8		4
	401	Fluoxetine	Female	2	01.REPORTED SADNESS	4	3	3	2	2		1		1
					02.INNER TENSION	4	3	3	1	2		1		1
					03.APPARENT SADNESS	3	2	2	2	2		2		2
					04.SUICIDAL THOUGHTS	4	1	1	1	1		2		1
					05.INERTIA	3	3	2	1	0		2		0
					06.INABILITY TO FEEL	2	2	2	1	2		1		2
					07.PESSIMISTIC THOUGHTS	4	3	2	0	0		1		1
					08.CONCENTRATIONS DIFFICULTIES	4	3	3	1	2		2		1
					09.REDUCED SLEEP	2	2	2	1	0		1		0
					10.REDUCED APPETITE	2	1	1	0	0		0		0
					11.Total score	32	23	21	10	11		13		9
	402	Reboxetine	Female	2	01.REPORTED SADNESS	4	4	2	3	2		1		0
					02.INNER TENSION	5	4	2	2	2		2		0
					03.APPARENT SADNESS	3	3	2	2	2		2		2
					04.SUICIDAL THOUGHTS	4	3	2	2	2		2		1
					05.INERTIA	3	2	0	1	0		0		0
					06.INABILITY TO FEEL	3	3	1	2	3		1		2
					07.PESSIMISTIC THOUGHTS	4	4	2	2	2		2		1
					08.CONCENTRATIONS DIFFICULTIES	4	3	3	3	2		1		0
					09.REDUCED SLEEP	2	2	2	2	0		0		1
					10.REDUCED APPETITE	2	1	1	1	1		0		0
					11.Total score	34	29	17	20	16		11		7
	403	Reboxetine	Female	2	01.REPORTED SADNESS	4	2	2	2	1		1		0
					02.INNER TENSION	4	2	2	3	1		1		0
					03.APPARENT SADNESS	3	2	2	2	2		1		2
					04.SUICIDAL THOUGHTS	4	1	2	2	3		2		2
					05.INERTIA	3	2	1	2	1		2		0
					06.INABILITY TO FEEL	3	2	2	2	1		0		0
					07.PESSIMISTIC THOUGHTS	4	3	2	2	2		1		0
					08.CONCENTRATIONS DIFFICULTIES	4	3	2	2	1		1		1
					09.REDUCED SLEEP	2	2	1	2	0		0		1
					10.REDUCED APPETITE	2	1	1	1	0		0		0
					11.Total score	33	20	17	20	12		9		6
	404	Fluoxetine	Female	2	01.REPORTED SADNESS	4	4	3	2	1		1		0
					02.INNER TENSION	5	5	4	2	1		1		1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
14	404	Fluoxetine	Female	2	03.APPARENT SADNESS	3	3	3	2	2		2		0
					04.SUICIDAL THOUGHTS	3	3	2	1	1		2		2
					05.INERTIA	3	3	2	0	0		2		0
					06.INABILITY TO FEEL	3	3	2	1	2		1		2
					07.PESSIMISTIC THOUGHTS	4	4	2	1	2		2		1
					08.CONCENTRATIONS DIFFICULTIES	4	4	2	1	1		1		0
					09.REDUCED SLEEP	3	3	2	0	1		0		1
					10.REDUCED APPETITE	1	1	1	0	0		0		0
					11.Total score	33	33	23	10	11		12		7
	405	Fluoxetine	Female	2	01.REPORTED SADNESS	4	2	1	0	0		0		0
					02.INNER TENSION	4	2	1	0	0		0		0
					03.APPARENT SADNESS	3	2	2	2	2		2		1
					04.SUICIDAL THOUGHTS	3	2	1	1	1		0		0
					05.INERTIA	3	1	0	2	2		0		0
					06.INABILITY TO FEEL	3	1	1	2	0		0		0
					07.PESSIMISTIC THOUGHTS	4	0	1	1	1		0		1
					08.CONCENTRATIONS DIFFICULTIES	4	1	0	0	1		1		0
					09.REDUCED SLEEP	2	1	1	1	1		0		0
					10.REDUCED APPETITE	2	1	0	0	0		0		0
					11.Total score	32	13	8	9	8		3		2
	406	Fluoxetine	Female	2	01.REPORTED SADNESS	4	3	4	4					
					02.INNER TENSION	4	4	4	4					
					03.APPARENT SADNESS	4	4	4	4					
					04.SUICIDAL THOUGHTS	5	5	6	6					
					05.INERTIA	3	3	3	3					
					06.INABILITY TO FEEL	2	3	4	3					
					07.PESSIMISTIC THOUGHTS	4	4	4	5					
					08.CONCENTRATIONS DIFFICULTIES	3	2	2	2					
					09.REDUCED SLEEP	2	2	3	2					
					10.REDUCED APPETITE	2	1	1	2					
					11.Total score	33	31	35	35					
	407	Reboxetine	Male	2	01.REPORTED SADNESS	4	4	4	4	4		4		
					02.INNER TENSION	5	5	4	4	3		5		
					03.APPARENT SADNESS	3	4	4	4	4		3		
					04.SUICIDAL THOUGHTS	4	4	4	4	4		4		
					05.INERTIA	3	3	3	2	2		2		
					06.INABILITY TO FEEL	4	4	3	3	3		3		
					07.PESSIMISTIC THOUGHTS	3	3	3	3	3		4		
					08.CONCENTRATIONS DIFFICULTIES	4	4	4	4	3		4		
					09.REDUCED SLEEP	2	3	3	3	3		2		
					10.REDUCED APPETITE	1	1	1	1	1		2		
					11.Total score	33	35	33	32	30		33		
	408	Reboxetine	Female	2	01.REPORTED SADNESS	4	3	2	2	2		1		0

PHARMACIA

REBOXETINE - PROT
Listing No.: 13.6

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
14	408	Reboxetine	Female	2	02.INNER TENSION	5	3	2	2	2		1		1
					03.APPARENT SADNESS	3	3	3	3	2		1		1
					04.SUICIDAL THOUGHTS	1	3	2	2	2		1		0
					05.INERTIA	0	1	0	1	1		0		0
					06.INABILITY TO FEEL	3	2	2	2	1		1		1
					07.PESSIMISTIC THOUGHTS	3	2	2	2	2		1		0
					08.CONCENTRATIONS DIFFICULTIES	4	3	3	3	2		0		0
					09.REDUCED SLEEP	3	2	2	2	1		1		1
					10.REDUCED APPETITE	2	1	0	1	0		0		0
					11.Total score	28	23	18	20	15		7		4
	509	Fluoxetine	Female	2	01.REPORTED SADNESS	5	5	4	4	4		4		
					02.INNER TENSION	5	5	5	5	4		5		
					03.APPARENT SADNESS	3	3	3	3	3		3		
					04.SUICIDAL THOUGHTS	5	5	5	2	4		3		
					05.INERTIA	3	3	0	1	2		2		
					06.INABILITY TO FEEL	3	3	3	3	2		3		
					07.PESSIMISTIC THOUGHTS	3	4	4	4	3		4		
					08.CONCENTRATIONS DIFFICULTIES	4	4	3	3	3		4		
					09.REDUCED SLEEP	2	2	2	2	2		2		
					10.REDUCED APPETITE	2	2	2	2	2		2		
					11.Total score	35	36	31	29	29		32		
	510	Fluoxetine	Female	2	01.REPORTED SADNESS	3	3	3	2	3		2		1
					02.INNER TENSION	4	4	3	3	3		2		1
					03.APPARENT SADNESS	3	3	3	3	2		2		2
					04.SUICIDAL THOUGHTS	4	2	2	2	2		1		0
					05.INERTIA	2	2	1	0	0		0		0
					06.INABILITY TO FEEL	4	3	2	1	2		0		0
					07.PESSIMISTIC THOUGHTS	3	3	3	2	3		3		1
					08.CONCENTRATIONS DIFFICULTIES	4	4	3	2	2		2		0
					09.REDUCED SLEEP	2	2	2	2	2		1		1
					10.REDUCED APPETITE	2	1	0	0	0		0		0
					11.Total score	31	27	22	17	19		13		6
	511	Reboxetine	Female	2	01.REPORTED SADNESS	4	3	2	4	3		2	2	
					02.INNER TENSION	4	3	2	5	3		2	2	
					03.APPARENT SADNESS	3	3	3	3	3		3	3	
					04.SUICIDAL THOUGHTS	4	3	2	3	3		4	4	
					05.INERTIA	2	2	0	2	2		0	0	
					06.INABILITY TO FEEL	3	3	2	2	2		2	2	
					07.PESSIMISTIC THOUGHTS	4	4	2	3	3		2	2	
					08.CONCENTRATIONS DIFFICULTIES	3	3	2	3	2		2	0	
					09.REDUCED SLEEP	2	2	2	2	2		2	1	
					10.REDUCED APPETITE	1	1	0	1	1		0	0	
					11.Total score	30	27	17	28	24		19	16	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
14	512	Reboxetine	Female	2	01.REPORTED SADNESS	4	3	4	2	4				
					02.INNER TENSION	5	3	3	2	5				
					03.APPARENT SADNESS	3	2	3	2	3				
					04.SUICIDAL THOUGHTS	4	4	4	1	4				
					05.INERTIA	3	2	3	2	3				
					06.INABILITY TO FEEL	4	3	2	2	3				
					07.PESSIMISTIC THOUGHTS	4	4	4	2	4				
					08.CONCENTRATIONS DIFFICULTIES	4	4	3	1	4				
					09.REDUCED SLEEP	3	2	2	1	2				
					10.REDUCED APPETITE	2	1	0	0	2				
					11.Total score	36	28	28	15	34				
	537	Reboxetine	Female	2	01.REPORTED SADNESS	5	2	0	0	0		0		0
					02.INNER TENSION	5	2	0	0	0		0		0
					03.APPARENT SADNESS	3	2	2	2	2		2		0
					04.SUICIDAL THOUGHTS	4	2	2	2	1		0		0
					05.INERTIA	3	2	0	0	0		0		0
					06.INABILITY TO FEEL	3	2	2	0	0		0		0
					07.PESSIMISTIC THOUGHTS	4	2	1	1	0		1		0
					08.CONCENTRATIONS DIFFICULTIES	4	1	0	0	0		0		0
					09.REDUCED SLEEP	3	2	1	0	0		0		0
					10.REDUCED APPETITE	2	0	0	0	0		0		0
					11.Total score	36	17	8	5	3		3		0
	538	Fluoxetine	Female	2	01.REPORTED SADNESS	4	2	1	0	0		0		0
					02.INNER TENSION	5	3	1	0	0		1		0
					03.APPARENT SADNESS	3	2	2	2	2		2		2
					04.SUICIDAL THOUGHTS	5	0	2	0	0		0		0
					05.INERTIA	3	0	0	0	0		0		0
					06.INABILITY TO FEEL	3	3	2	2	2		2		2
					07.PESSIMISTIC THOUGHTS	4	3	0	2	1		1		1
					08.CONCENTRATIONS DIFFICULTIES	4	3	2	0	1		0		0
					09.REDUCED SLEEP	2	2	2	0	1		0		0
					10.REDUCED APPETITE	2	1	0	0	0		0		0
					11.Total score	35	19	12	6	7		6		5
	539	Fluoxetine	Female	2	01.REPORTED SADNESS	4	4	3	4	3		2		2
					02.INNER TENSION	5	4	4	4	3		2		2
					03.APPARENT SADNESS	4	4	4	4	4		3		3
					04.SUICIDAL THOUGHTS	5	4	3	4	4		3		3
					05.INERTIA	4	4	3	3	3		1		1
					06.INABILITY TO FEEL	3	3	3	2	3		2		3
					07.PESSIMISTIC THOUGHTS	4	4	3	4	3		2		2
					08.CONCENTRATIONS DIFFICULTIES	3	4	4	3	3		2		2
					09.REDUCED SLEEP	2	2	2	2	2		2		2
					10.REDUCED APPETITE	2	2	1	1	1		0		0
					11.Total score	36	35	30	31	29		19		20

852

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
15	409	Reboxetine	Male	1	01.REPORTED SADNESS	2	2	2	2	2		1		1
					02.INNER TENSION	2	2	2	2	2		2		1
					03.APPARENT SADNESS	2	2	2	2	1		1		0
					04.SUICIDAL THOUGHTS	2	2	2	2	2		1		0
					05.INERTIA	2	2	2	2	2		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	1	1	1	1	1		1		0
					09.REDUCED SLEEP	2	2	2	0	0		0		0
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	17	17	17	15	14		12		5
	410	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	2		1		1
					02.INNER TENSION	2	2	2	2	2		1		1
					03.APPARENT SADNESS	1	1	1	1	1		1		0
					04.SUICIDAL THOUGHTS	1	1	1	1	1		1		1
					05.INERTIA	2	2	2	2	2		2		1
					06.INABILITY TO FEEL	1	1	1	1	1		1		0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1		1		1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1		0		0
					09.REDUCED SLEEP	2	2	2	1	1		1		1
					10.REDUCED APPETITE	2	2	2	0	0		0		0
					11.Total score	15	15	15	12	12		9		6
	411	Reboxetine	Female	1	01.REPORTED SADNESS	3	3	1	1	0		0		0
					02.INNER TENSION	2	3	1	1	1		1		1
					03.APPARENT SADNESS	3	3	1	0	0		0		0
					04.SUICIDAL THOUGHTS	2	2	1	0	0		0		0
					05.INERTIA	2	3	1	1	1		1		0
					06.INABILITY TO FEEL	2	2	1	1	1		0		0
					07.PESSIMISTIC THOUGHTS	2	2	1	1	1		1		0
					08.CONCENTRATIONS DIFFICULTIES	2	3	2	1	1		0		0
					09.REDUCED SLEEP	2	2	2	1	0		0		0
					10.REDUCED APPETITE	2	2	0	0	0		0		0
					11.Total score	22	25	11	7	5		3		1
	412	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	1	1	1		1		1
					02.INNER TENSION	2	2	2	1	1		1		1
					03.APPARENT SADNESS	1	1	1	1	1		0		0
					04.SUICIDAL THOUGHTS	1	1	1	1	0		0		0
					05.INERTIA	1	1	1	1	1		1		1
					06.INABILITY TO FEEL	1	1	1	1	0		0		0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1		0		0
					08.CONCENTRATIONS DIFFICULTIES	0	0	0	0	0		0		0
					09.REDUCED SLEEP	2	2	1	1	0		0		0
					10.REDUCED APPETITE	1	1	0	0	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
15	412	Fluoxetine	Female	1	11.Total score	12	12	9	8	5		3		3
	413	Reboxetine	Female	1	01.REPORTED SADNESS	3	3	2	1	1		1		0
					02.INNER TENSION	2	2	1	1	1		1		1
					03.APPARENT SADNESS	2	2	1	1	0		0		0
					04.SUICIDAL THOUGHTS	2	2	2	2	1		0		0
					05.INERTIA	2	2	2	1	1		1		0
					06.INABILITY TO FEEL	2	2	1	1	0		0		0
					07.PESSIMISTIC THOUGHTS	2	2	1	1	1		0		0
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1		0		0
					09.REDUCED SLEEP	2	1	1	0	0		0		0
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	18	17	12	9	6		3		1
	414	Fluoxetine	Male	1	01.REPORTED SADNESS	2	2	2	2	2		2		2
					02.INNER TENSION	2	2	2	2	1		1		1
					03.APPARENT SADNESS	1	1	1	0	0		0		1
					04.SUICIDAL THOUGHTS	1	1	1	1	1		1		1
					05.INERTIA	2	2	2	2	1		1		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	1	1	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	13	13	13	12	10		10		12
	415	Reboxetine	Female	1	01.REPORTED SADNESS	3	3	3	2	1		0		0
					02.INNER TENSION	2	2	1	1	1		1		1
					03.APPARENT SADNESS	3	3	2	2	1		0		0
					04.SUICIDAL THOUGHTS	2	2	2	1	0		0		0
					05.INERTIA	3	3	3	2	2		1		1
					06.INABILITY TO FEEL	2	2	2	2	0		1		0
					07.PESSIMISTIC THOUGHTS	2	2	2	2	1		0		0
					08.CONCENTRATIONS DIFFICULTIES	1	1	0	0	0		0		0
					09.REDUCED SLEEP	2	2	2	1	0		0		0
					10.REDUCED APPETITE	2	2	2	0	0		0		0
					11.Total score	22	22	19	13	6		3		2
	416	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	1		1		1
					02.INNER TENSION	2	2	2	2	1		1		1
					03.APPARENT SADNESS	1	1	1	1	1		1		0
					04.SUICIDAL THOUGHTS	1	1	1	1	1		0		0
					05.INERTIA	2	2	2	2	2		1		1
					06.INABILITY TO FEEL	1	1	1	1	1		0		0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1		1		0
					08.CONCENTRATIONS DIFFICULTIES	0	0	0	0	0		0		0
					09.REDUCED SLEEP	2	2	2	2	1		1		1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
15	416	Fluoxetine	Female	1	10.REDUCED APPETITE	1	1	1	1	0		0		0
					11.Total score	13	13	13	13	9		6		4
	417	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	1	0	0		0		0
					02.INNER TENSION	2	1	1	0	1		1		1
					03.APPARENT SADNESS	1	1	1	0	0		0		0
					04.SUICIDAL THOUGHTS	1	1	1	0	0		0		0
					05.INERTIA	2	2	1	1	1		1		0
					06.INABILITY TO FEEL	1	1	0	0	0		0		0
					07.PESSIMISTIC THOUGHTS	1	1	1	0	0		0		0
					08.CONCENTRATIONS DIFFICULTIES	1	1	0	0	0		0		0
					09.REDUCED SLEEP	2	1	1	1	0		0		0
					10.REDUCED APPETITE	1	0	0	0	0		0		0
					11.Total score	14	11	7	2	2		2		1
	418	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	1	1		0		0
					02.INNER TENSION	3	3	2	1	1		1		1
					03.APPARENT SADNESS	3	3	2	2	1		0		0
					04.SUICIDAL THOUGHTS	1	1	1	1	0		0		0
					05.INERTIA	3	3	2	1	1		1		1
					06.INABILITY TO FEEL	2	2	1	1	1		1		0
					07.PESSIMISTIC THOUGHTS	2	2	2	1	1		1		0
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1		1		0
					09.REDUCED SLEEP	3	3	1	1	0		0		0
					10.REDUCED APPETITE	1	1	1	0	0		0		0
					11.Total score	22	22	15	10	7		5		2
	419	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	1		1		1
					02.INNER TENSION	2	2	2	2	2		1		1
					03.APPARENT SADNESS	1	1	1	1	1		0		0
					04.SUICIDAL THOUGHTS	1	1	1	1	1		1		0
					05.INERTIA	1	1	1	1	1		1		1
					06.INABILITY TO FEEL	1	1	1	1	0		0		0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1		1		1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1		0		0
					09.REDUCED SLEEP	2	2	2	2	2		1		1
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	12	12	12	12	10		6		5
	420	Fluoxetine	Male	1	01.REPORTED SADNESS	2	2	1	1	1		1		1
					02.INNER TENSION	1	1	1	1	1		1		1
					03.APPARENT SADNESS	1	1	1	1	1		1		1
					04.SUICIDAL THOUGHTS	1	1	1	1	0		0		0
					05.INERTIA	2	2	2	2	2		2		1
					06.INABILITY TO FEEL	1	1	1	1	0		0		0
					07.PESSIMISTIC THOUGHTS	2	2	1	1	1		1		1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1		1		0

PHARMACIA CMS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.8

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
15	420	Fluoxetine	Male	1	09.REDUCED SLEEP	2	2	1	1	1		0		0
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	13	13	10	10	8		7		5
	421	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	3	2	1		1		0
					02.INNER TENSION	2	2	2	1	1		0		0
					03.APPARENT SADNESS	2	2	3	2	1		0		0
					04.SUICIDAL THOUGHTS	1	1	1	1	1		0		0
					05.INERTIA	2	2	3	2	2		1		0
					06.INABILITY TO FEEL	1	1	1	1	1		1		0
					07.PESSIMISTIC THOUGHTS	2	2	2	2	1		1		1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1		0		0
					09.REDUCED SLEEP	2	2	3	2	1		1		0
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	15	15	19	14	10		5		1
	422	Fluoxetine	Male	1	01.REPORTED SADNESS	2	2	2	2	1		1		1
					02.INNER TENSION	2	2	2	1	1		1		1
					03.APPARENT SADNESS	2	2	2	1	1		0		0
					04.SUICIDAL THOUGHTS	1	1	1	1	0		0		0
					05.INERTIA	2	2	2	2	1		1		1
					06.INABILITY TO FEEL	1	1	1	1	1		0		0
					07.PESSIMISTIC THOUGHTS	2	2	2	1	1		1		0
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1		0		0
					09.REDUCED SLEEP	2	2	2	1	1		0		0
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	15	15	15	11	8		4		3
	423	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	2		1		1
					02.INNER TENSION	2	2	2	2	2		1		1
					03.APPARENT SADNESS	2	2	2	2	1		0		0
					04.SUICIDAL THOUGHTS	1	1	1	1	1		0		0
					05.INERTIA	1	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		1		1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1		1		1
					09.REDUCED SLEEP	2	2	2	2	1		0		0
					10.REDUCED APPETITE	1	1	1	1	1		0		0
					11.Total score	15	15	15	15	13		6		6
	424	Reboxetine	Male	1	01.REPORTED SADNESS	2	2	2	1	1		1		1
					02.INNER TENSION	2	2	1	1	1		1		0
					03.APPARENT SADNESS	2	2	1	1	0		0		0
					04.SUICIDAL THOUGHTS	1	1	1	0	0		0		0
					05.INERTIA	1	1	1	1	1		1		1
					06.INABILITY TO FEEL	1	1	0	0	0		0		0
					07.PESSIMISTIC THOUGHTS	2	2	2	1	1		1		1

856

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
15	424	Reboxetine	Male	1	08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1		1		0
					09.REDUCED SLEEP	2	2	2	1	0		0		0
					10.REDUCED APPETITE	1	1	0	0	0		0		0
					11.Total score	15	15	11	7	5		5		3
	425	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	1	1		0		0
					02.INNER TENSION	2	2	2	1	1		1		1
					03.APPARENT SADNESS	2	2	2	1	0		0		0
					04.SUICIDAL THOUGHTS	2	2	2	1	0		0		0
					05.INERTIA	3	3	2	1	1		0		0
					06.INABILITY TO FEEL	1	1	1	1	0		0		0
					07.PESSIMISTIC THOUGHTS	2	2	2	1	1		0		0
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	0		0		0
					09.REDUCED SLEEP	2	2	2	1	0		0		0
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	17	17	16	9	4		1		1
	426	Fluoxetine	Male	1	01.REPORTED SADNESS	3	3	2	2	1		1		1
					02.INNER TENSION	2	2	2	2	2		1		1
					03.APPARENT SADNESS	2	2	1	1	1		1		1
					04.SUICIDAL THOUGHTS	2	2	1	1	1		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		0		0
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1		1		1
					09.REDUCED SLEEP	2	2	2	2	2		1		1
					10.REDUCED APPETITE	2	2	0	0	0		0		0
					11.Total score	21	21	16	16	11		7		7
	427	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	1		1		1
					02.INNER TENSION	2	2	1	1	1		1		1
					03.APPARENT SADNESS	2	2	0	0	0		0		0
					04.SUICIDAL THOUGHTS	1	1	1	1	0		0		0
					05.INERTIA	1	1	1	1	1		1		1
					06.INABILITY TO FEEL	1	1	1	1	1		1		0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1		0		0
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1		1		1
					09.REDUCED SLEEP	2	2	2	2	1		1		0
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	13	13	10	10	7		6		4
	428	Fluoxetine	Male	1	01.REPORTED SADNESS	2	2	2	2	1		1		1
					02.INNER TENSION	2	2	2	1	1		1		1
					03.APPARENT SADNESS	1	1	1	1	0		0		0
					04.SUICIDAL THOUGHTS	1	1	1	1	0		0		0
					05.INERTIA	1	1	1	1	1		1		1
					06.INABILITY TO FEEL	1	1	1	1	1		1		1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
15	428	Fluoxetine	Male	1	07.PESSIMISTIC THOUGHTS	1	1	1	1	1		1		1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	0		0		0
					09.REDUCED SLEEP	2	2	2	2	2		1		1
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	12	12	12	11	7		6		6
	449	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	2		2		1
					02.INNER TENSION	2	2	2	2	2		2		1
					03.APPARENT SADNESS	1	1	1	1	1		1		0
					04.SUICIDAL THOUGHTS	1	1	1	1	1		1		0
					05.INERTIA	2	2	2	2	2		2		1
					06.INABILITY TO FEEL	1	1	1	1	1		1		0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1		1		1
					08.CONCENTRATIONS DIFFICULTIES	0	0	0	0	0		0		0
					09.REDUCED SLEEP	2	2	2	2	2		1		0
					10.REDUCED APPETITE	1	1	1	1	0		0		0
					11.Total score	13	13	13	13	12		11		4
	450	Fluoxetine	Male	1	01.REPORTED SADNESS	3	3	3	2	2		1		1
					02.INNER TENSION	1	1	1	1	1		1		1
					03.APPARENT SADNESS	2	2	2	1	1		1		1
					04.SUICIDAL THOUGHTS	0	0	0	0	0		0		0
					05.INERTIA	3	3	3	3	2		2		2
					06.INABILITY TO FEEL	2	2	1	1	1		1		1
					07.PESSIMISTIC THOUGHTS	2	2	2	1	1		1		1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1		1		1
					09.REDUCED SLEEP	2	2	2	1	1		0		0
					10.REDUCED APPETITE	1	1	1	1	0		0		0
					11.Total score	17	17	16	12	10		8		8
	451	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	1		1		1
					02.INNER TENSION	2	2	2	2	2		2		1
					03.APPARENT SADNESS	1	1	1	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	1	1	1	0	0		0		0
					07.PESSIMISTIC THOUGHTS	2	2	2	2	1		1		1
					08.CONCENTRATIONS DIFFICULTIES	0	0	0	0	0		0		0
					09.REDUCED SLEEP	2	2	2	1	1		1		1
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	13	13	13	9	7		7		6
	452	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	1	1		1		0
					02.INNER TENSION	2	2	1	1	1		1		0
					03.APPARENT SADNESS	1	1	1	0	1		0		0
					04.SUICIDAL THOUGHTS	1	1	1	1	0		0		0
					05.INERTIA	2	2	2	2	2		1		1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
15	452	Reboxetine	Female	1	06.INABILITY TO FEEL	1	1	1	1	0		0		0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1		0		0
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	0		0		0
					09.REDUCED SLEEP	1	1	1	0	0		0		0
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	12	12	11	8	6		3		1
	454	Fluoxetine	Male	1	01.REPORTED SADNESS	2	2	2	2	2		2		1
					02.INNER TENSION	2	2	2	2	1		1		1
					03.APPARENT SADNESS	1	1	1	1	1		1		1
					04.SUICIDAL THOUGHTS	1	1	1	1	1		1		0
					05.INERTIA	1	1	1	1	1		1		1
					06.INABILITY TO FEEL	1	1	1	1	1		0		0
					07.PESSIMISTIC THOUGHTS	2	2	2	2	2		1		1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1		0		0
					09.REDUCED SLEEP	2	2	2	1	1		1		1
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	13	13	13	12	11		8		6
16	429	Fluoxetine	Female	1	01.REPORTED SADNESS	3	1	1	1	0	0	0	0	0
					02.INNER TENSION	2	1	1	0	0	1	1	1	1
					03.APPARENT SADNESS	3	1	0	0	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0	0
					05.INERTIA	2	1	0	0	0	0	1	1	1
					06.INABILITY TO FEEL	2	1	0	0	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	2	1	1	0	1	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	3	1	1	1	1	1	1	1	1
					09.REDUCED SLEEP	2	1	0	0	0	0	0	0	0
					10.REDUCED APPETITE	0	1	0	0	0	0	0	0	0
					11.Total score	20	9	4	2	2	2	3	3	3
	430	Reboxetine	Male	1	01.REPORTED SADNESS	3	1	0	0	0	1	1	0	0
					02.INNER TENSION	2	1	1	1	1	1	1	0	0
					03.APPARENT SADNESS	2	1	1	1	1	1	1	0	0
					04.SUICIDAL THOUGHTS	0	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	1	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	2	1	1	1	1	1	1	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1	1	1	1
					09.REDUCED SLEEP	2	2	2	2	1	1	1	1	1
					10.REDUCED APPETITE	1	0	0	0	0	0	0	0	0
					11.Total score	18	9	8	8	7	8	8	4	4
	431	Reboxetine	Female	1	01.REPORTED SADNESS	3	1	1	1	0	1	1	1	1
					02.INNER TENSION	3	2	2	2	1	2	2	2	2
					03.APPARENT SADNESS	2	1	1	1	0	1	1	1	1
					04.SUICIDAL THOUGHTS	1	1	1	0	0	0	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
16	431	Reboxetine	Female	1	05.INERTIA	2	1	1	0	0	1	1	1	1
					06.INABILITY TO FEEL	2	1	1	1	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	0	1	1	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	0	0	0	0	0
					09.REDUCED SLEEP	1	1	0	0	0	0	0	0	0
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	17	10	9	7	1	6	6	5	5
	432	Fluoxetine	Female	1	01.REPORTED SADNESS	3	1	0	0	0	0	0	0	0
					02.INNER TENSION	2	1	1	0	0	0	0	0	0
					03.APPARENT SADNESS	3	1	1	0	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0	0	0
					05.INERTIA	3	1	1	1	0	1	1	1	1
					06.INABILITY TO FEEL	2	0	1	0	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	2	1	0	0	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	3	2	1	1	1	1	1	1	1
					09.REDUCED SLEEP	0	0	0	0	0	0	0	0	0
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	19	8	5	2	1	2	2	2	2
	433	Reboxetine	Female	1	01.REPORTED SADNESS	2	1	0	0	0	0	0	0	0
					02.INNER TENSION	3	2	2	1	1	1	1	1	1
					03.APPARENT SADNESS	2	1	0	0	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0	0
					05.INERTIA	2	1	0	0	0	0	0	0	0
					06.INABILITY TO FEEL	2	1	0	0	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	2	1	0	0	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	0	0	1	1
					09.REDUCED SLEEP	1	1	1	1	1	1	1	1	1
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	17	9	4	3	3	2	2	3	3
	434	Fluoxetine	Female	1	01.REPORTED SADNESS	3	2	0	0	0	0	0	0	0
					02.INNER TENSION	3	1	1	1	1	1	1	1	1
					03.APPARENT SADNESS	3	1	0	0	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0	0
					05.INERTIA	2	1	0	0	0	0	0	0	0
					06.INABILITY TO FEEL	3	1	0	0	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	2	1	0	1	0	0	0	1	1
					08.CONCENTRATIONS DIFFICULTIES	3	2	1	1	1	1	1	1	1
					09.REDUCED SLEEP	2	1	1	2	1	1	1	1	1
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	22	10	3	5	3	3	3	4	4
	435	Reboxetine	Female	1	01.REPORTED SADNESS	3	2	1	1	0	0	0	0	0
					02.INNER TENSION	3	2	1	1	1	1	1	0	0
					03.APPARENT SADNESS	3	2	1	1	0	0	0	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
16	435	Reboxetine	Female	1	04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0	0	0
					05.INERTIA	2	2	2	1	1	1	1	1	1
					06.INABILITY TO FEEL	3	2	1	0	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	2	1	1	0	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	3	1	1	0	0	0	0	0	0
					09.REDUCED SLEEP	3	3	1	1	1	1	1	1	1
					10.REDUCED APPETITE	2	1	0	0	0	0	0	0	0
					11.Total score	25	17	9	5	3	3	3	2	2
	436	Fluoxetine	Female	1	01.REPORTED SADNESS	3	2	1	1	1	1	0	1	1
					02.INNER TENSION	3	2	1	1	1	1	1	2	1
					03.APPARENT SADNESS	3	2	1	1	1	1	0	2	1
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0	0	0
					05.INERTIA	2	1	1	1	1	1	0	1	1
					06.INABILITY TO FEEL	2	1	1	1	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	2	1	1	0	0	0	0	1	0
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	0	0	1	1
					09.REDUCED SLEEP	1	1	1	1	1	1	1	2	2
					10.REDUCED APPETITE	2	1	1	1	1	1	1	2	1
					11.Total score	21	13	9	8	8	7	4	13	9
	437	Reboxetine	Female	1	01.REPORTED SADNESS	3	2	1	1	1	1	1	0	0
					02.INNER TENSION	2	1	1	1	1	1	1	1	1
					03.APPARENT SADNESS	2	1	1	1	1	1	1	0	0
					04.SUICIDAL THOUGHTS	2	1	1	1	1	1	0	0	0
					05.INERTIA	2	2	1	1	1	1	1	1	1
					06.INABILITY TO FEEL	2	1	1	1	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	2	1	0	0	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	3	2	1	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	21	12	8	8	8	8	7	5	5
	438	Fluoxetine	Female	1	01.REPORTED SADNESS	2	1	1	1	1	1			
					02.INNER TENSION	2	1	1	1	1	1			
					03.APPARENT SADNESS	2	1	1	1	1	1			
					04.SUICIDAL THOUGHTS	1	1	1	0	0	0			
					05.INERTIA	2	1	1	1	1	1			
					06.INABILITY TO FEEL	2	1	1	1	1	1			
					07.PESSIMISTIC THOUGHTS	2	1	1	0	0	0			
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1	1			
					09.REDUCED SLEEP	2	1	1	1	1	2			
					10.REDUCED APPETITE	1	1	1	1	1	1			
					11.Total score	18	10	10	8	8	9			
	439	Fluoxetine	Female	1	01.REPORTED SADNESS	3	2	1	1	0	0	0	0	0
					02.INNER TENSION	2	1	1	1	1	0	0	0	1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
16	439	Fluoxetine	Female	1	03.APPARENT SADNESS	3	2	1	1	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0	0	0
					05.INERTIA	2	2	1	1	0	0	0	0	0
					06.INABILITY TO FEEL	1	1	1	1	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	2	1	0	0	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	3	1	1	1	1	1	1	1	1
					09.REDUCED SLEEP	2	1	1	1	0	0	0	0	0
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	19	12	7	7	2	1	1	1	2
	440	Reboxetine	Female	1	01.REPORTED SADNESS	3	1	0	0	0	0	0	0	0
					02.INNER TENSION	2	1	1	1	1	1	1	1	1
					03.APPARENT SADNESS	2	1	1	1	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0	0
					05.INERTIA	2	1	1	1	1	1	1	1	0
					06.INABILITY TO FEEL	2	1	1	1	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	2	1	0	0	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	0	0	0	0	0
					09.REDUCED SLEEP	2	1	1	1	1	1	1	1	0
					10.REDUCED APPETITE	1	0	0	0	0	0	0	0	0
					11.Total score	19	8	6	6	3	3	3	3	1
	441	Fluoxetine	Female	1	01.REPORTED SADNESS	2	1	1	1	0		0		0
					02.INNER TENSION	2	1	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	0	0	1		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	2	1	1	1	1		1		1
					09.REDUCED SLEEP	2	1	0	0	0		0		0
					10.REDUCED APPETITE	2	2	0	0	0		0		0
					11.Total score	18	12	4	4	3		2		2
	442	Reboxetine	Female	1	01.REPORTED SADNESS	3	3	2	1	1		2		2
					02.INNER TENSION	3	3	2	1	1		1		1
					03.APPARENT SADNESS	3	3	2	1	1		1		1
					04.SUICIDAL THOUGHTS	2	2	2	1	1		1		1
					05.INERTIA	3	3	2	2	1		1		1
					06.INABILITY TO FEEL	3	2	2	1	1		1		1
					07.PESSIMISTIC THOUGHTS	3	3	2	1	1		1		1
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1		1		1
					09.REDUCED SLEEP	3	3	2	2	2		2		2
					10.REDUCED APPETITE	2	2	2	1	1		1		1
					11.Total score	27	26	19	12	11		12		12
	443	Fluoxetine	Male	1	01.REPORTED SADNESS	2	2	1	1	1		1		1

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
16	443	Fluoxetine	Male	1	02.INNER TENSION	2	2	1	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	1	1	1		1		1
					06.INABILITY TO FEEL	2	1	1	1	1		0		0
					07.PESSIMISTIC THOUGHTS	1	1	1	0	0		0		0
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1		1		1
					09.REDUCED SLEEP	2	1	1	1	0		0		0
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	15	13	8	7	5		4		4
	444	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	1	1		0		0
					02.INNER TENSION	2	1	1	1	1		1		1
					03.APPARENT SADNESS	2	2	2	1	1		0		0
					04.SUICIDAL THOUGHTS	1	1	1	0	0		0		0
					05.INERTIA	2	1	1	1	1		0		0
					06.INABILITY TO FEEL	2	1	1	1	1		0		0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1		0		0
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1		0		0
					09.REDUCED SLEEP	2	1	1	1	0		0		0
					10.REDUCED APPETITE	2	1	1	1	1		0		0
					11.Total score	18	12	12	9	8		1		1
	445	Reboxetine	Male	1	01.REPORTED SADNESS	2	2	1	0	0		0		0
					02.INNER TENSION	1	1	0	0	0		0		0
					03.APPARENT SADNESS	2	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	2	2	1	1	1		1		1
					07.PESSIMISTIC THOUGHTS	1	0	0	0	0		0		0
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1		1		1
					09.REDUCED SLEEP	2	1	1	0	0		0		0
					10.REDUCED APPETITE	2	1	0	0	1		1		1
					11.Total score	16	13	6	4	5		5		5
	446	Fluoxetine	Female	1	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	1	0	0		0		0
					04.SUICIDAL THOUGHTS	1	1	1	0	0		0		0
					05.INERTIA	2	2	1	1	1		1		1
					06.INABILITY TO FEEL	2	2	1	1	1		1		1
					07.PESSIMISTIC THOUGHTS	1	1	1	1	0		0		0
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1		1		1
					09.REDUCED SLEEP	2	2	2	1	1		0		0
					10.REDUCED APPETITE	1	1	1	0	0		0		0
					11.Total score	17	17	13	8	6		5		5

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
16	447	Fluoxetine	Male	1	01.REPORTED SADNESS	2	2	2	1	1		1		1
					02.INNER TENSION	2	1	1	1	1		1		1
					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	1	1		1		1
					06.INABILITY TO FEEL	2	2	1	0	0		1		0
					07.PESSIMISTIC THOUGHTS	1	1	1	0	0				0
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1		1		1
					09.REDUCED SLEEP	2	2	2	1	1		1		1
					10.REDUCED APPETITE	2	1	1	0	0		1		0
					11.Total score	18	14	13	6	5		7		5
	448	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	1	1		1		0
					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	1	1	1		1		1
					06.INABILITY TO FEEL	2	1	1	1	1		1		1
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1		1		0
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1		1		1
					09.REDUCED SLEEP	2	2	2	1	1		1		1
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	15	13	11	8	8		8		6
	455	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	1		1		1
					02.INNER TENSION	2	2	1	1	1		1		1
					03.APPARENT SADNESS	2	2	1	1	1		1		1
					04.SUICIDAL THOUGHTS	1	0	0	0	0		0		0
					05.INERTIA	2	2	2	1	1		1		1
					06.INABILITY TO FEEL	2	2	1	1	1		1		1
					07.PESSIMISTIC THOUGHTS	2	2	2	2	1		1		1
					08.CONCENTRATIONS DIFFICULTIES	3	3	2	2	1		1		1
					09.REDUCED SLEEP	3	3	3	3	2		2		2
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	19	18	14	13	9		9		9
	456	Reboxetine	Male	1	01.REPORTED SADNESS	3	2	1	1	1		1		1
					02.INNER TENSION	2	2	1	1	1		1		1
					03.APPARENT SADNESS	3	2	1	0	0		0		0
					04.SUICIDAL THOUGHTS	1	1	0	0	0		0		0
					05.INERTIA	2	2	2	1	1		1		1
					06.INABILITY TO FEEL	2	2	1	1	1		1		1
					07.PESSIMISTIC THOUGHTS	2	1	0	0	0		0		0
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	1		1		1
					09.REDUCED SLEEP	2	2	1	1	1		1		1
					10.REDUCED APPETITE	2	2	1	0	0		0		0
					11.Total score	21	18	10	6	6		6		6

498

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
16	457	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	1	1	1	1	1		1
					02.INNER TENSION	3	3	2	2	2	0	0		0
					03.APPARENT SADNESS	2	2	1	1	1	0	0		0
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0		0
					05.INERTIA	2	2	1	1	1	1	1		1
					06.INABILITY TO FEEL	2	2	1	1	1	0	0		0
					07.PESSIMISTIC THOUGHTS	2	2	1	1	1	0	0		0
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1		1
					09.REDUCED SLEEP	2	2	1	1	1	0	0		0
					10.REDUCED APPETITE	2	2	1	1	1	0	0		0
					11.Total score	19	19	10	10	10	3	3		3
	458	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	2		2		2
					02.INNER TENSION	2	2	1	1	1		1		1
					03.APPARENT SADNESS	2	2	2	2	2		2		2
					04.SUICIDAL THOUGHTS	1	0	0	0	0		0		0
					05.INERTIA	2	2	2	2	2		2		2
					06.INABILITY TO FEEL	2	2	1	1	1		1		1
					07.PESSIMISTIC THOUGHTS	2	2	1	1	1		1		1
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2		2		2
					09.REDUCED SLEEP	0	0	0	0	0		0		0
					10.REDUCED APPETITE	1	1	0	0	0		0		0
					11.Total score	16	15	11	11	11		11		11
	459	Reboxetine	Male	1	01.REPORTED SADNESS	2	2	1	1	1		0		0
					02.INNER TENSION	2	1	1	1	1		0		0
					03.APPARENT SADNESS	2	2	1	1	1		0		0
					04.SUICIDAL THOUGHTS	0	0	0	0	0		0		0
					05.INERTIA	2	2	1	1	0		0		0
					06.INABILITY TO FEEL	1	1	1	1	1		0		0
					07.PESSIMISTIC THOUGHTS	2	2	0	0	0		0		0
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	1	1		0		0
					09.REDUCED SLEEP	2	1	1	1	1		0		0
					10.REDUCED APPETITE	0	0	0	0	0		0		0
					11.Total score	15	12	7	7	6		0		0
	460	Reboxetine	Male	1	01.REPORTED SADNESS	3	2	2	1	1		0		0
					02.INNER TENSION	2	2	2	1	1		0		0
					03.APPARENT SADNESS	3	2	1	0	0		0		0
					04.SUICIDAL THOUGHTS	1	1	2	0	0		0		0
					05.INERTIA	2	2	2	1	1		0		0
					06.INABILITY TO FEEL	2	1	1	0	0		0		0
					07.PESSIMISTIC THOUGHTS	2	2	1	0	0		0		0
					08.CONCENTRATIONS DIFFICULTIES	3	2	2	1	1		0		0
					09.REDUCED SLEEP	2	2	1	1	1		0		0
					10.REDUCED APPETITE	0	0	0	0	0		0		0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
16	460	Reboxetine	Male	1	11.Total score	20	16	14	5	5		0		0
18	25	Fluoxetine	Female	1	01.REPORTED SADNESS	2	1	1	1	1	1	1	0	0
					02.INNER TENSION	0	0	0	0	0	0	0	0	0
					03.APPARENT SADNESS	2	2	1	1	1	1	1	0	0
					04.SUICIDAL THOUGHTS	1	1	0	0	0	0	0	0	0
					05.INERTIA	2	2	2	1	1	1	1	0	0
					06.INABILITY TO FEEL	2	1	1	0	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	0	0
					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	0	0	0	0	0	0	0	0	0
					11.Total score	13	11	9	6	6	6	6	2	2
	26	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	1	1	1	1	0	0	0
					02.INNER TENSION	1	1	1	0	0	0	0	0	0
					03.APPARENT SADNESS	2	2	1	1	0	0	0	0	0
					04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0	0
					05.INERTIA	1	1	1	1	1	1	0	0	0
					06.INABILITY TO FEEL	2	2	2	1	0	0	0	0	0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2	2	1	1	1
					09.REDUCED SLEEP	1	1	1	1	1	1	1	1	1
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	12	12	10	8	6	6	3	2	2
	27	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	1	1	1	0	0	0
					02.INNER TENSION	2	2	1	1	0	0	0	0	0
					03.APPARENT SADNESS	2	2	2	1	1	1	0	0	0
					04.SUICIDAL THOUGHTS	0	0	0	0	1	1	0	0	0
					05.INERTIA	1	1	1	1	0	0	0	0	0
					06.INABILITY TO FEEL	2	2	2	1	1	1	0	0	0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	0	0
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1	0	0
					09.REDUCED SLEEP	1	1	1	1	1	1	1	1	1
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	12	12	11	8	7	7	3	1	1
	28	Fluoxetine	Female	1	01.REPORTED SADNESS	3	3	3	3	3				
					02.INNER TENSION	2	2	2	2	2				
					03.APPARENT SADNESS	1	1	1	1	1				
					04.SUICIDAL THOUGHTS	0	0	0	0	0				
					05.INERTIA	1	1	1	1	1				
					06.INABILITY TO FEEL	2	2	2	2	2				
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1				
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	2				
					09.REDUCED SLEEP	3	3	3	3	3				

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
18	28	Fluoxetine	Female	1	10.REDUCED APPETITE	0	0	0	0	0				
					11.Total score	15	15	15	15	15				
	29	Reboxetine	Male	1	01.REPORTED SADNESS	3	2	2	2	1	1	1	0	0
					02.INNER TENSION	2	2	1	1	0	0	0	0	0
					03.APPARENT SADNESS	3	2	2	2	1	0	0	0	0
					04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0	0
					05.INERTIA	2	2	2	2	1	0	0	0	0
					06.INABILITY TO FEEL	2	2	2	2	1	1	1	0	0
					07.PESSIMISTIC THOUGHTS	2	2	2	2	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	2	1	1	1	1	1
					09.REDUCED SLEEP	2	2	2	2	1	1	1	1	1
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	18	16	15	15	6	4	4	2	2
	30	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	1	1	1	1	1	0	0
					02.INNER TENSION	2	2	2	1	1	1	1	0	0
					03.APPARENT SADNESS	2	2	1	0	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	1	1	0	0	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	0	0
					07.PESSIMISTIC THOUGHTS	1	1	1	1	1	1	1	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	2	1	1	1	1	1	1
					09.REDUCED SLEEP	1	1	1	0	0	0	0	0	0
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	15	15	13	6	6	6	6	2	2
	31	Reboxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	2	2	1	1	1
					02.INNER TENSION	1	0	0	0	0	0	0	0	0
					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	2	2	2	2	2	2	1	1	1
					06.INABILITY TO FEEL	2	1	1	1	1	1	1	0	0
					07.PESSIMISTIC THOUGHTS	2	2	2	2	2	2	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1	1	1
					09.REDUCED SLEEP	2	2	2	2	2	2	1	1	1
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	14	11	11	11	11	11	7	6	6
	32	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	2	1	0	1	1	0	0
					02.INNER TENSION	2	2	2	1	0	0	0	0	0
					03.APPARENT SADNESS	2	2	2	1	1	0	0	1	1
					04.SUICIDAL THOUGHTS	1	1	1	0	0	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	0	0
					07.PESSIMISTIC THOUGHTS	2	2	2	1	1	2	2	1	1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1	0	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
18	32	Fluoxetine	Female	1	09.REDUCED SLEEP	1	1	1	1	1	1	1	0	0
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	15	15	15	8	6	7	7	3	3
	49	Reboxetine	Female	1	01.REPORTED SADNESS	3	2	1	1	1	0	0	0	0
					02.INNER TENSION	3	1	1	1	1	1	1	0	0
					03.APPARENT SADNESS	2	2	1	1	1	0	0	0	0
					04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0	0
					05.INERTIA	2	1	1	1	1	1	1	0	0
					06.INABILITY TO FEEL	2	2	1	1	1	0	0	0	0
					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	2	2	1	1	1	1	1	1	1
					10.REDUCED APPETITE	1	1	1	1	1	1	1	1	1
					11.Total score	19	15	9	9	9	6	6	4	4
	50	Reboxetine	Female	1	01.REPORTED SADNESS	3								
					02.INNER TENSION	2								
					03.APPARENT SADNESS	3								
					04.SUICIDAL THOUGHTS	1								
					05.INERTIA	2								
					06.INABILITY TO FEEL	2								
					07.PESSIMISTIC THOUGHTS	2								
					08.CONCENTRATIONS DIFFICULTIES	1								
					09.REDUCED SLEEP	1								
					10.REDUCED APPETITE	1								
					11.Total score	18								
	51	Fluoxetine	Female	1	01.REPORTED SADNESS	3	2	1	1	1	1	1	1	0
					02.INNER TENSION	2	1	1	1	1	2	2	2	1
					03.APPARENT SADNESS	2	2	1	1	1	1	1	1	0
					04.SUICIDAL THOUGHTS	1	1	1	1	1	1	1	1	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	2	2	1	1	1	1	1	1	1
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1	1	0
					09.REDUCED SLEEP	1	1	1	1	1	1	1	1	0
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	16	14	9	9	9	10	10	10	3
	52	Fluoxetine	Female	1	01.REPORTED SADNESS	3	3	2	1	1	1	1	1	0
					02.INNER TENSION	2	2	2	1	1	1	1	1	0
					03.APPARENT SADNESS	2	2	1	1	1	1	1	1	0
					04.SUICIDAL THOUGHTS	1	1	1	0	0	0	0	0	0
					05.INERTIA	2	2	1	1	1	1	1	1	1
					06.INABILITY TO FEEL	3	3	2	2	2	2	2	2	1
					07.PESSIMISTIC THOUGHTS	2	2	2	1	1	1	1	1	0

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
18	52	Fluoxetine	Female	1	08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1	1	1
					09.REDUCED SLEEP	1	1	1	1	1	1	1	1	0
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	17	17	13	9	9	9	9	9	3
	53	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	2	2	1	1	1	1	1
					02.INNER TENSION	2	2	2	2	1	1	0	0	0
					03.APPARENT SADNESS	3	3	3	3	1	1	0	0	0
					04.SUICIDAL THOUGHTS	0	0	0	0	0	0	0	0	0
					05.INERTIA	2	2	2	2	1	1	0	0	0
					06.INABILITY TO FEEL	2	2	2	2	2	2	1	1	1
					07.PESSIMISTIC THOUGHTS	2	2	2	2	1	1	1	1	0
					08.CONCENTRATIONS DIFFICULTIES	1	1	1	1	1	1	1	1	0
					09.REDUCED SLEEP	2	2	2	2	2	2	2	2	1
					10.REDUCED APPETITE	0	0	0	0	0	0	0	0	0
					11.Total score	16	16	16	16	10	10	6	6	3
	54	Fluoxetine	Male	1	01.REPORTED SADNESS	2	2	1	1	1	1	0	0	0
					02.INNER TENSION	2	2	1	0	0	0	0	0	0
					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	1	0	0	0	0	0	0	0
					06.INABILITY TO FEEL	1	1	1	0	0	0	0	0	0
					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	1	1	1	1	1	1	1
					10.REDUCED APPETITE	1	1	1	0	0	0	0	0	0
					11.Total score	14	14	8	5	5	5	4	4	4
20	21	Fluoxetine	Female	1	01.REPORTED SADNESS	2	0	0	0	0	0	1	0	0
					02.INNER TENSION	2	1	1	1	1	0	0	0	0
					03.APPARENT SADNESS	1	1	0	0	0	0	0	0	0
					04.SUICIDAL THOUGHTS	1	0	0	0	0	0	0	0	0
					05.INERTIA	1	0	0	0	1	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
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	0	1	0	0	0	0
					09.REDUCED SLEEP	3	2	2	1	1	1	1	2	1
					10.REDUCED APPETITE	2	0	0	0	0	0	0	0	0
					11.Total score	16	7	5	3	5	2	3	3	2
	22	Fluoxetine	Female	1	01.REPORTED SADNESS	1	1	1	2	2	2			
					02.INNER TENSION	3	3	2	2	2	2			
					03.APPARENT SADNESS	3	3	2	3	2	3			
					04.SUICIDAL THOUGHTS	2	2	2	2	2	2			
					05.INERTIA	2	2	2	2	2	2			
					06.INABILITY TO FEEL	1	1	2	2	0	1			

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
20	22	Fluoxetine	Female	1	07.PESSIMISTIC THOUGHTS	2	2	1	2	2	2			
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	2	0	1			
					09.REDUCED SLEEP	2	2	2	2	2	3			
					10.REDUCED APPETITE	0	0	0	0	0	0			
					11.Total score	18	18	15	19	14	18			
21	9	Fluoxetine	Female	1	01.REPORTED SADNESS	2	2	2	1	1	1	1	1	1
					02.INNER TENSION	2	2	2	2	2	2	2	2	1
					03.APPARENT SADNESS	2	2	1	1	1	0	0	0	0
					04.SUICIDAL THOUGHTS	1	1	1	1	0	0	0	0	0
					05.INERTIA	2	2	2	2	2	1	1	1	1
					06.INABILITY TO FEEL	2	2	1	1	1	1	1	1	1
					07.PESSIMISTIC THOUGHTS	1	1	1	1	0	0	0	0	0
					08.CONCENTRATIONS DIFFICULTIES	2	2	1	1	1	0	0	0	0
					09.REDUCED SLEEP	1	1	1	1	2	0	0	0	0
					10.REDUCED APPETITE	1	1	0	0	1	0	0	0	0
					11.Total score	16	16	12	11	11	5	5	5	4
22	113	Fluoxetine	Male	1	01.REPORTED SADNESS	2	2	2						
					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	2	2						
					07.PESSIMISTIC THOUGHTS	1	1	1						
					08.CONCENTRATIONS DIFFICULTIES	1	1	1						
					09.REDUCED SLEEP	2	2	2						
					10.REDUCED APPETITE	1	1	1						
					11.Total score	13	14	14						
	115	Reboxetine	Male	1	01.REPORTED SADNESS	1	1	1	1					
					02.INNER TENSION	2	2	2	2					
					03.APPARENT SADNESS	1	1	1	1					
					04.SUICIDAL THOUGHTS	0	0	0	0					
					05.INERTIA	2	2	2	2					
					06.INABILITY TO FEEL	2	2	2	2					
					07.PESSIMISTIC THOUGHTS	1	2	2	2					
					08.CONCENTRATIONS DIFFICULTIES	2	1	1	2					
					09.REDUCED SLEEP	1	1	1	1					
					10.REDUCED APPETITE	1	1	1	1					
					11.Total score	13	13	13	14					

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
1	1	Fluoxetine	Male	Severity of illness	4.00	4.00	3.00	2.00	2.00	1.00	1.00	1.00	1.00
				Global improvement		3.00	2.00	2.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		6.00	2.00	2.00	2.00	2.00	2.00	2.00	1.00
				Efficacy index (*)		1.50	2.00	2.00	2.00	2.00	2.00	2.00	4.00
	2	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	4.00	3.00	2.00	3.00	3.00	3.00
				Global improvement		3.00	5.00	3.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	13.00	9.00	5.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		2.00	1.00	2.00	3.00	4.00	4.00	4.00	4.00
	3	Fluoxetine	Female	Severity of illness	4.00	4.00	3.00	3.00	3.00	3.00			2.00
				Global improvement		4.00	2.00	2.00	2.00	2.00			2.00
				Efficacy index		13.00	5.00	5.00	5.00	5.00			1.00
				Efficacy index (*)		1.00	3.00	3.00	3.00	3.00			4.00
	4	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	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	10.00	6.00	2.00		
				Efficacy index (*)		0.50	0.50	1.00	1.00	1.50	2.00		
	5	Fluoxetine	Female	Severity of illness	6.00	5.00	5.00	5.00	5.00	5.00			
				Global improvement		3.00	5.00	5.00	6.00	6.00			
				Efficacy index		9.00	13.00	14.00	14.00	14.00			
				Efficacy index (*)		2.00	1.00	0.50	0.50	0.50			
	6	Fluoxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00				
				Global improvement		4.00	4.00	4.00	4.00				
				Efficacy index		13.00	14.00	14.00	15.00				
				Efficacy index (*)		1.00	0.50	0.50	0.33				
2	33	Fluoxetine	Female	Severity of illness	6.00	2.00	4.00	4.00	4.00	5.00	4.00	4.00	4.00
				Global improvement		1.00	3.00	3.00	2.00	3.00	2.00	2.00	2.00
				Efficacy index		1.00	10.00	10.00	6.00	10.00	6.00	6.00	6.00
				Efficacy index (*)		4.00	1.00	1.00	1.50	1.00	1.50	1.50	1.50
	34	Reboxetine	Male	Severity of illness	5.00	4.00	3.00	2.00	2.00	2.00	2.00		
				Global improvement		2.00	2.00	2.00	2.00	1.00	2.00		
				Efficacy index		6.00	6.00	2.00	2.00	2.00	4.00		
				Efficacy index (*)		1.50	1.50	2.00	2.00	2.00	1.00		

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
2	35	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	4.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	3.00	3.00	3.00	3.00	3.00	4.00	5.00
				Efficacy index		9.00	9.00	9.00	9.00	9.00	9.00	13.00	13.00
				Efficacy index (*)		2.00	2.00	2.00	2.00	2.00	2.00	1.00	1.00
	36	Fluoxetine	Male	Severity of illness	4.00	4.00	3.00	4.00	1.00	1.00	1.00	1.00	1.00
				Global improvement		3.00	2.00	3.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		10.00	6.00	10.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		1.00	1.50	1.00	2.00	2.00	2.00	2.00	2.00
	37	Reboxetine	Male	Severity of illness	4.00	4.00							
				Global improvement		4.00							
				Efficacy index		16.00							
				Efficacy index (*)		0.25							
	38	Fluoxetine	Male	Severity of illness	5.00	4.00	4.00	4.00	2.00	1.00			
				Global improvement		3.00	3.00	3.00	1.00	1.00			
				Efficacy index		5.00	5.00	5.00	1.00	1.00			
				Efficacy index (*)		3.00	3.00	3.00	4.00	4.00			
	39	Fluoxetine	Male	Severity of illness	4.00								
				Global improvement									
				Efficacy index									
				Efficacy index (*)									
	40	Reboxetine	Male	Severity of illness	4.00	5.00	4.00	3.00					
				Global improvement		5.00	2.00	2.00					
				Efficacy index		14.00	6.00	6.00					
				Efficacy index (*)		0.50	1.50	1.50					
	41	Fluoxetine	Male	Severity of illness	6.00	6.00	5.00	4.00	3.00	4.00	4.00	3.00	2.00
				Global improvement		3.00	3.00	2.00	2.00	3.00	3.00	2.00	2.00
				Efficacy index		9.00	9.00	5.00	5.00	9.00	9.00	5.00	1.00
				Efficacy index (*)		2.00	2.00	3.00	3.00	2.00	2.00	3.00	4.00
	42	Reboxetine	Female	Severity of illness	6.00	5.00	3.00	3.00	3.00	2.00	3.00	3.00	3.00
				Global improvement		3.00	2.00	1.00	2.00	1.00	2.00	2.00	2.00
				Efficacy index		10.00	6.00	2.00	6.00	2.00	6.00	6.00	6.00
				Efficacy index (*)		1.00	1.50	2.00	1.50	2.00	1.50	1.50	1.50

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
2	43	Reboxetine	Female	Severity of illness	6.00	4.00	4.00	4.00	3.00	3.00	4.00	3.00	3.00
				Global improvement		3.00	3.00	3.00	2.00	3.00	3.00	2.00	2.00
				Efficacy index		10.00	10.00	10.00	6.00	10.00	10.00	6.00	6.00
				Efficacy index (*)		1.00	1.00	1.00	1.50	1.00	1.00	1.50	1.50
	44	Fluoxetine	Male	Severity of illness	5.00	4.00	3.00	3.00	2.00	2.00	2.00		
				Global improvement		3.00	2.00	2.00	1.00	1.00	2.00		
				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		
	45	Reboxetine	Female	Severity of illness	5.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	2.00
				Global improvement		2.00	2.00	2.00	2.00	2.00	2.00	2.00	1.00
				Efficacy index		5.00	5.00	5.00	5.00	5.00	5.00	5.00	1.00
				Efficacy index (*)		3.00	3.00	3.00	3.00	3.00	3.00	3.00	4.00
	47	Fluoxetine	Female	Severity of illness	5.00	3.00	3.00	2.00	2.00	2.00	1.00	2.00	2.00
				Global improvement		2.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		6.00	6.00	2.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		1.50	1.50	2.00	2.00	2.00	2.00	2.00	2.00
	48	Reboxetine	Female	Severity of illness	6.00	6.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		4.00	3.00	4.00	3.00	3.00	3.00	3.00	3.00
				Efficacy index		14.00	10.00	14.00	10.00	10.00	10.00	10.00	10.00
				Efficacy index (*)		0.50	1.00	0.50	1.00	1.00	1.00	1.00	1.00
	80	Fluoxetine	Male	Severity of illness	5.00	3.00	3.00	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	1.00	1.00
				Efficacy index		5.00	5.00	5.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		3.00	3.00	3.00	4.00	4.00	4.00	4.00	4.00
3	65	Fluoxetine	Female	Severity of illness	6.00	6.00	5.00	5.00	4.00	4.00	4.00	4.00	3.00
				Global improvement		4.00	3.00	3.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		13.00	9.00	9.00	9.00	5.00	6.00	6.00	5.00
				Efficacy index (*)		1.00	2.00	2.00	2.00	3.00	1.50	1.50	3.00
	66	Fluoxetine	Female	Severity of illness	6.00	6.00	5.00	4.00					
				Global improvement		5.00	4.00	3.00					
				Efficacy index		14.00	14.00	10.00					
				Efficacy index (*)		0.50	0.50	1.00					

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
3	67	Reboxetine	Female	Severity of illness	6.00	5.00	4.00	4.00	3.00				
				Global improvement		3.00	3.00	2.00	2.00				
				Efficacy index		9.00	9.00	5.00	1.00				
				Efficacy index (*)		2.00	2.00	3.00	4.00				
	68	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00			
				Global improvement		4.00	3.00	3.00	3.00	3.00			
				Efficacy index		14.00	10.00	10.00	9.00	9.00			
				Efficacy index (*)		0.50	1.00	1.00	2.00	2.00			
4	97	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	3.00	2.00	1.00	1.00	1.00	1.00
				Global improvement		3.00	3.00	2.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		9.00	6.00	6.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		2.00	1.50	1.50	4.00	4.00	4.00	4.00	4.00
	98	Fluoxetine	Female	Severity of illness	5.00	4.00	4.00	4.00	5.00	3.00	1.00	1.00	1.00
				Global improvement		3.00	3.00	3.00	4.00	2.00	1.00	1.00	1.00
				Efficacy index		11.00	6.00	10.00	13.00	5.00	1.00	2.00	1.00
				Efficacy index (*)		0.67	1.50	1.00	1.00	3.00	4.00	2.00	4.00
	99	Fluoxetine	Female	Severity of illness	6.00	5.00							
				Global improvement		5.00							
				Efficacy index		16.00							
				Efficacy index (*)		0.25							
	100	Reboxetine	Male	Severity of illness	5.00								
				Global improvement									
				Efficacy index									
				Efficacy index (*)									
	101	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	2.00	4.00	4.00	3.00	2.00	2.00
				Global improvement		3.00	3.00	2.00	5.00	6.00	2.00	2.00	2.00
				Efficacy index		6.00	6.00	2.00	14.00	14.00	6.00	6.00	7.00
				Efficacy index (*)		1.50	1.50	2.00	0.50	0.50	1.50	1.50	1.00
	102	Fluoxetine	Female	Severity of illness	4.00	4.00	3.00	5.00	2.00	5.00	4.00	5.00	3.00
				Global improvement		2.00	2.00	3.00	2.00	3.00	3.00	3.00	3.00
				Efficacy index		5.00	1.00	5.00	6.00	10.00	11.00	9.00	9.00
				Efficacy index (*)		3.00	4.00	3.00	1.50	1.00	0.67	2.00	2.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
4	103	Fluoxetine	Female	Severity of illness	6.00	6.00	5.00	5.00	5.00	5.00			
				Global improvement		3.00	3.00	3.00	3.00	5.00			
				Efficacy index		9.00	11.00	9.00	9.00	13.00			
				Efficacy index (*)		2.00	0.67	2.00	2.00	1.00			
	104	Reboxetine	Female	Severity of illness	6.00	5.00	5.00	5.00	5.00	4.00	4.00	5.00	
				Global improvement		3.00	3.00	3.00	3.00	2.00	2.00	3.00	
				Efficacy index		10.00	10.00	10.00	10.00	6.00	6.00	10.00	
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.50	1.50	1.00	
	105	Fluoxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		5.00	3.00	5.00	3.00	3.00	3.00	3.00	3.00
				Efficacy index		13.00	9.00	13.00	9.00	9.00	9.00	9.00	9.00
				Efficacy index (*)		1.00	2.00	1.00	2.00	2.00	2.00	2.00	2.00
5	129	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	4.00	4.00				
				Global improvement		3.00	3.00	3.00	4.00				
				Efficacy index		10.00	10.00	10.00	15.00				
				Efficacy index (*)		1.00	1.00	1.00	0.33				
	130	Fluoxetine	Female	Severity of illness	5.00	4.00	4.00	3.00	3.00	4.00	3.00	3.00	2.00
				Global improvement		2.00	3.00	2.00	2.00	2.00	2.00	2.00	1.00
				Efficacy index		5.00	9.00	6.00	6.00	6.00	6.00	6.00	2.00
				Efficacy index (*)		3.00	2.00	1.50	1.50	1.50	1.50	1.50	2.00
7	193	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00	3.00	3.00
				Global improvement		4.00	3.00	3.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		14.00	10.00	10.00	10.00	10.00	10.00	6.00	6.00
				Efficacy index (*)		0.50	1.00	1.00	1.00	1.00	1.00	1.50	1.50
	194	Fluoxetine	Female	Severity of illness	3.00	3.00	3.00	3.00	3.00	3.00	2.00	2.00	1.00
				Global improvement		3.00	3.00	2.00	2.00	2.00	2.00	2.00	1.00
				Efficacy index		10.00	10.00	6.00	6.00	6.00	6.00	2.00	2.00
				Efficacy index (*)		1.00	1.00	1.50	1.50	1.50	1.50	2.00	2.00
	195	Fluoxetine	Male	Severity of illness	5.00	5.00	4.00	4.00	4.00	4.00	4.00	3.00	2.00
				Global improvement		3.00	3.00	2.00	3.00	3.00	3.00	2.00	1.00
				Efficacy index		9.00	10.00	5.00	9.00	10.00	9.00	5.00	1.00
				Efficacy index (*)		2.00	1.00	3.00	2.00	1.00	2.00	3.00	4.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much inproved, 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
7	196	Reboxetine	Female	Severity of illness	5.00	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		14.00	14.00	14.00	14.00	14.00	14.00	14.00	
				Efficacy index (*)		0.50	0.50	0.50	0.50	0.50	0.50	0.50	
	197	Fluoxetine	Male	Severity of illness	4.00								
				Global improvement									
				Efficacy index									
				Efficacy index (*)									
11	321	Fluoxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	4.00	3.00	2.00	2.00	2.00
				Global improvement		4.00	4.00	3.00	3.00	3.00	2.00	1.00	1.00
				Efficacy index		13.00	15.00	10.00	10.00	6.00	6.00	1.00	1.00
				Efficacy index (*)		1.00	0.33	1.00	1.00	1.50	1.50	4.00	4.00
	322	Reboxetine	Female	Severity of illness	7.00	6.00	5.00	4.00	3.00	3.00	4.00	3.00	3.00
				Global improvement		4.00	3.00	3.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		14.00	10.00	9.00	9.00	9.00	9.00	5.00	5.00
				Efficacy index (*)		0.50	1.00	2.00	2.00	2.00	2.00	3.00	3.00
	323	Fluoxetine	Female	Severity of illness	5.00	4.00	2.00	1.00	1.00				1.00
				Global improvement		2.00	2.00	1.00	1.00				1.00
				Efficacy index		6.00	2.00	2.00	2.00				2.00
				Efficacy index (*)		1.50	2.00	2.00	2.00				2.00
	324	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	4.00	2.00	3.00	3.00
				Global improvement		4.00	4.00	5.00	4.00	3.00	2.00	5.00	3.00
				Efficacy index		14.00	14.00	15.00	14.00	10.00	6.00	14.00	6.00
				Efficacy index (*)		0.50	0.50	0.33	0.50	1.00	1.50	0.50	1.50
	325	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	4.00	3.00	3.00	2.00	2.00
				Global improvement		4.00	4.00	3.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		14.00	14.00	10.00	9.00	5.00	5.00	1.00	1.00
				Efficacy index (*)		0.50	0.50	1.00	2.00	3.00	3.00	4.00	4.00
	326	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	2.00	1.00	1.00	1.00	1.00	1.00
				Global improvement		3.00	2.00	2.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		10.00	6.00	6.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		1.00	1.50	1.50	2.00	2.00	2.00	2.00	2.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
11	327	Fluoxetine	Female	Severity of illness	4.00	3.00	3.00	2.00	2.00				
				Global improvement		3.00	4.00	3.00	3.00				
				Efficacy index		10.00	14.00	6.00	6.00				
				Efficacy index (*)		1.00	0.50	1.50	1.50				
	328	Fluoxetine	Female	Severity of illness	4.00	4.00	5.00	5.00	3.00	3.00	2.00	1.00	1.00
				Global improvement		4.00	5.00	4.00	3.00	2.00	1.00	1.00	1.00
				Efficacy index		13.00	13.00	13.00	5.00	6.00	2.00	2.00	2.00
				Efficacy index (*)		1.00	1.00	1.00	3.00	1.50	2.00	2.00	2.00
	329	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	1.00	4.00	2.00	2.00	1.00
				Global improvement		4.00	3.00	5.00	1.00	5.00	2.00	2.00	1.00
				Efficacy index		14.00	10.00	14.00	2.00	14.00	2.00	2.00	2.00
				Efficacy index (*)		0.50	1.00	0.50	2.00	0.50	2.00	2.00	2.00
	330	Reboxetine	Male	Severity of illness	5.00	5.00	4.00	4.00	5.00	5.00	5.00	5.00	
				Global improvement		4.00	3.00	5.00	4.00	4.00	4.00	4.00	
				Efficacy index		14.00	10.00	14.00	14.00	14.00	14.00	14.00	
				Efficacy index (*)		0.50	1.00	0.50	0.50	0.50	0.50	0.50	
	331	Fluoxetine	Female	Severity of illness	5.00	5.00	3.00	3.00	1.00	1.00	1.00	1.00	1.00
				Global improvement		4.00	3.00	3.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		13.00	9.00	10.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		1.00	2.00	1.00	2.00	2.00	2.00	2.00	2.00
	332	Fluoxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	3.00	2.00	2.00	1.00	1.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	2.00	1.00	1.00
				Efficacy index		14.00	10.00	10.00	6.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		0.50	1.00	1.00	1.50	2.00	2.00	2.00	2.00
	333	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	4.00	3.00	3.00	2.00	2.00
				Global improvement		5.00	3.00	3.00	3.00	3.00	2.00	2.00	1.00
				Efficacy index		14.00	10.00	10.00	10.00	10.00	6.00	6.00	2.00
				Efficacy index (*)		0.50	1.00	1.00	1.00	1.00	1.50	1.50	2.00
	334	Fluoxetine	Female	Severity of illness	6.00	5.00	4.00	4.00	4.00	3.00	3.00	3.00	3.00
				Global improvement		4.00	3.00	3.00	3.00	3.00	2.00	3.00	3.00
				Efficacy index		13.00	9.00	9.00	9.00	9.00	5.00	5.00	5.00
				Efficacy index (*)		1.00	2.00	2.00	2.00	2.00	3.00	3.00	3.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
11	335	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	4.00	3.00			
				Global improvement		4.00	3.00	3.00	3.00	3.00			
				Efficacy index		13.00	9.00	9.00	9.00	10.00			
				Efficacy index (*)		1.00	2.00	2.00	2.00	1.00			
12	393	Fluoxetine	Female	Severity of illness	5.00	5.00	5.00	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	2.00	3.00
				Efficacy index		14.00	10.00	9.00	10.00	9.00	9.00	5.00	9.00
				Efficacy index (*)		0.50	1.00	2.00	1.00	2.00	2.00	3.00	2.00
	394	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	4.00	5.00	5.00	4.00	4.00	5.00
				Global improvement		4.00	4.00	3.00	4.00	5.00	5.00	4.00	5.00
				Efficacy index		14.00	14.00	10.00	14.00	14.00	14.00	14.00	14.00
				Efficacy index (*)		0.50	0.50	1.00	0.50	0.50	0.50	0.50	0.50
	395	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	3.00	3.00	4.00	3.00	3.00	3.00
				Global improvement		4.00	3.00	2.00	3.00	3.00	3.00	2.00	3.00
				Efficacy index		14.00	10.00	6.00	10.00	10.00	10.00	6.00	6.00
				Efficacy index (*)		0.50	1.00	1.50	1.00	1.00	1.00	1.50	1.50
	396	Fluoxetine	Female	Severity of illness	5.00	4.00	5.00						
				Global improvement		4.00	5.00						
				Efficacy index		14.00	14.00						
				Efficacy index (*)		0.50	0.50						
	497	Fluoxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	5.00	4.00	4.00	3.00	3.00	5.00	4.00
				Efficacy index		14.00	14.00	14.00	14.00	10.00	10.00	14.00	14.00
				Efficacy index (*)		0.50	0.50	0.50	0.50	1.00	1.00	0.50	0.50
13	385	Fluoxetine	Female	Severity of illness	4.00	4.00	4.00	3.00	2.00		3.00		1.00
				Global improvement		4.00	3.00	3.00	2.00		2.00		1.00
				Efficacy index		13.00	10.00	10.00	2.00		6.00		1.00
				Efficacy index (*)		1.00	1.00	1.00	2.00		1.50		4.00
	386	Fluoxetine	Male	Severity of illness	6.00	7.00							
				Global improvement		6.00							
				Efficacy index		13.00							
				Efficacy index (*)		1.00							

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CMS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
13	387	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	3.00	1.00				
				Global improvement		3.00	3.00	2.00	1.00				
				Efficacy index		10.00	10.00	6.00	2.00				
				Efficacy index (*)		1.00	1.00	1.50	2.00				
	388	Reboxetine	Male	Severity of illness	4.00	6.00	4.00	4.00	4.00		4.00		3.00
				Global improvement		4.00	3.00	2.00	3.00		2.00		2.00
				Efficacy index		14.00	6.00	6.00	10.00		6.00		6.00
				Efficacy index (*)		0.50	1.50	1.50	1.00		1.50		1.50
	389	Fluoxetine	Female	Severity of illness	6.00	5.00							
				Global improvement		4.00							
				Efficacy index		15.00							
				Efficacy index (*)		0.33							
	390	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	4.00	3.00		4.00		2.00
				Global improvement		4.00	3.00	4.00	3.00		2.00		1.00
				Efficacy index		13.00	10.00	14.00	9.00		6.00		2.00
				Efficacy index (*)		1.00	1.00	0.50	2.00		1.50		2.00
	391	Fluoxetine	Female	Severity of illness	4.00	3.00	3.00	2.00	1.00	1.00			
				Global improvement		2.00	2.00	2.00	2.00	1.00			
				Efficacy index		6.00	6.00	2.00	2.00	3.00			
				Efficacy index (*)		1.50	1.50	2.00	2.00	1.33			
	392	Reboxetine	Female	Severity of illness	4.00	4.00	4.00						
				Global improvement		4.00	4.00						
				Efficacy index		13.00	13.00						
				Efficacy index (*)		1.00	1.00						
	501	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00		3.00		3.00
				Global improvement		4.00	3.00	3.00	3.00		2.00		2.00
				Efficacy index		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
	502	Fluoxetine	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00		4.00		1.00
				Global improvement		3.00	3.00	3.00	3.00		2.00		1.00
				Efficacy index		9.00	9.00	9.00	9.00		5.00		1.00
				Efficacy index (*)		2.00	2.00	2.00	2.00		3.00		4.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
13	503	Reboxetine	Female	Severity of illness	4.00	4.00							
				Global improvement		3.00							
				Efficacy index		12.00							
				Efficacy index (*)		0.50							
	504	Fluoxetine	Female	Severity of illness	4.00	4.00	4.00		2.00		4.00		3.00
				Global improvement		2.00	3.00		2.00		3.00		2.00
				Efficacy index		5.00	9.00		6.00		10.00		6.00
				Efficacy index (*)		3.00	2.00		1.50		1.00		1.50
	505	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	4.00	4.00		3.00		3.00
				Global improvement		4.00	4.00	3.00	3.00		2.00		2.00
				Efficacy index		14.00	14.00	10.00	10.00		6.00		2.00
				Efficacy index (*)		0.50	0.50	1.00	1.00		1.50		2.00
	506	Fluoxetine	Male	Severity of illness	4.00	3.00	3.00	3.00	1.00		1.00		1.00
				Global improvement		2.00	2.00	2.00	2.00		1.00		1.00
				Efficacy index		1.00	5.00	1.00	1.00		1.00		1.00
				Efficacy index (*)		4.00	3.00	4.00	4.00		4.00		4.00
	507	Fluoxetine	Female	Severity of illness	4.00	4.00	4.00	3.00	3.00		3.00		1.00
				Global improvement		4.00	3.00	2.00	2.00		2.00		1.00
				Efficacy index		14.00	9.00	6.00	6.00		6.00		1.00
				Efficacy index (*)		0.50	2.00	1.50	1.50		1.50		4.00
	508	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	3.00	3.00		1.00		1.00
				Global improvement		3.00	4.00	2.00	2.00		2.00		2.00
				Efficacy index		10.00	14.00	6.00	6.00		2.00		2.00
				Efficacy index (*)		1.00	0.50	1.50	1.50		2.00		2.00
	521	Reboxetine	Male	Severity of illness	4.00	4.00	4.00		2.00		2.00		1.00
				Global improvement		4.00	3.00		2.00		2.00		1.00
				Efficacy index		14.00	6.00		6.00		2.00		2.00
				Efficacy index (*)		0.50	1.50		1.50		2.00		2.00
14	397	Fluoxetine	Female	Severity of illness	4.00	4.00	4.00	3.00	2.00		2.00		2.00
				Global improvement		4.00	3.00	2.00	2.00		1.00		1.00
				Efficacy index		14.00	10.00	6.00	5.00		2.00		1.00
				Efficacy index (*)		0.50	1.00	1.50	3.00		2.00		4.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
14	398	Reboxetine	Female	Severity of illness	4.00	4.00	3.00	3.00	2.00		2.00		1.00
				Global improvement		4.00	2.00	2.00	1.00		2.00		1.00
				Efficacy index		14.00	6.00	6.00	6.00		6.00		2.00
				Efficacy index (*)		0.50	1.50	1.50	1.50		1.50		2.00
	399	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00		3.00		2.00
				Global improvement		4.00	3.00	3.00	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
	400	Fluoxetine	Male	Severity of illness	4.00	4.00	2.00	2.00	2.00		2.00		1.00
				Global improvement		3.00	2.00	2.00	1.00		1.00		1.00
				Efficacy index		10.00	6.00	5.00	2.00		2.00		2.00
				Efficacy index (*)		1.00	1.50	3.00	2.00		2.00		2.00
	401	Fluoxetine	Female	Severity of illness	4.00	3.00	3.00	2.00	2.00		2.00		2.00
				Global improvement		3.00	3.00	1.00	1.00		1.00		1.00
				Efficacy index		9.00	9.00	1.00	1.00		1.00		1.00
				Efficacy index (*)		2.00	2.00	4.00	4.00		4.00		4.00
	402	Reboxetine	Female	Severity of illness	4.00	4.00	3.00	3.00	3.00		2.00		1.00
				Global improvement		3.00	2.00	3.00	2.00		1.00		1.00
				Efficacy index		10.00	6.00	10.00	6.00		1.00		1.00
				Efficacy index (*)		1.00	1.50	1.00	1.50		4.00		4.00
	403	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	3.00	1.00		1.00		1.00
				Efficacy index		6.00	6.00	10.00	2.00		2.00		2.00
				Efficacy index (*)		1.50	1.50	1.00	2.00		2.00		2.00
	404	Fluoxetine	Female	Severity of illness	4.00	4.00	3.00	2.00	2.00		2.00		2.00
				Global improvement		4.00	2.00	2.00	1.00		2.00		1.00
				Efficacy index		14.00	6.00	6.00	2.00		2.00		2.00
				Efficacy index (*)		0.50	1.50	1.50	2.00		2.00		2.00
	405	Fluoxetine	Female	Severity of illness	4.00	3.00	2.00	2.00	1.00		1.00		1.00
				Global improvement		2.00	1.00	1.00	1.00		1.00		1.00
				Efficacy index		6.00	1.00	2.00	1.00		2.00		1.00
				Efficacy index (*)		1.50	4.00	2.00	4.00		2.00		4.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
14	406	Fluoxetine	Female	Severity of illness	4.00	4.00	4.00	5.00					
				Global improvement		4.00	4.00	5.00					
				Efficacy index		14.00	14.00	14.00					
				Efficacy index (*)		0.50	0.50	0.50					
	407	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00		4.00		
				Global improvement		4.00	4.00	4.00	3.00		5.00		
				Efficacy index		14.00	14.00	14.00	10.00		14.00		
				Efficacy index (*)		0.50	0.50	0.50	1.00		0.50		
	408	Reboxetine	Female	Severity of illness	4.00	4.00	3.00	3.00	3.00		2.00		2.00
				Global improvement		3.00	2.00	2.00	2.00		1.00		1.00
				Efficacy index		10.00	6.00	6.00	6.00		2.00		2.00
				Efficacy index (*)		1.00	1.50	1.50	1.50		2.00		2.00
	509	Fluoxetine	Female	Severity of illness	6.00	4.00	4.00	4.00	4.00		4.00		
				Global improvement		4.00	3.00	4.00	3.00		4.00		
				Efficacy index		14.00	10.00	14.00	10.00		14.00		
				Efficacy index (*)		0.50	1.00	0.50	1.00		0.50		
	510	Fluoxetine	Female	Severity of illness	4.00	4.00	4.00	3.00	3.00		2.00		2.00
				Global improvement		4.00	3.00	3.00	2.00		2.00		2.00
				Efficacy index		13.00	10.00	6.00	6.00		6.00		6.00
				Efficacy index (*)		1.00	1.00	1.50	1.50		1.50		1.50
	511	Reboxetine	Female	Severity of illness	4.00	4.00	3.00	4.00	4.00		4.00	2.00	
				Global improvement		4.00	2.00	3.00	3.00		3.00	2.00	
				Efficacy index		14.00	6.00	10.00	10.00		10.00	6.00	
				Efficacy index (*)		0.50	1.50	1.00	1.00		1.00	1.50	
	512	Reboxetine	Female	Severity of illness	4.00	3.00	3.00	3.00	4.00				
				Global improvement		3.00	3.00	2.00	5.00				
				Efficacy index		10.00	10.00	6.00	15.00				
				Efficacy index (*)		1.00	1.00	1.50	0.33				
	537	Reboxetine	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		1.00
				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		4.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
14	538	Fluoxetine	Female	Severity of illness	4.00	4.00	2.00	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	1.00	1.00		2.00		2.00
				Efficacy index (*)		1.50	1.50	4.00	4.00		2.00		2.00
	539	Fluoxetine	Female	Severity of illness	5.00	5.00	4.00	5.00	4.00		3.00		3.00
				Global improvement		4.00	3.00	3.00	3.00		2.00		2.00
				Efficacy index		14.00	10.00	10.00	10.00		6.00		6.00
				Efficacy index (*)		0.50	1.00	1.00	1.00		1.50		1.50
15	409	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		2.00		1.00
				Efficacy index		14.00	14.00	10.00	9.00		5.00		1.00
				Efficacy index (*)		0.50	0.50	1.00	2.00		3.00		4.00
	410	Fluoxetine	Female	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		2.00		1.00
				Efficacy index		14.00	14.00	10.00	10.00		5.00		1.00
				Efficacy index (*)		0.50	0.50	1.00	1.00		3.00		4.00
	411	Reboxetine	Female	Severity of illness	6.00	6.00	5.00	4.00	3.00		2.00		2.00
				Global improvement		5.00	2.00	2.00	1.00		1.00		1.00
				Efficacy index		14.00	6.00	6.00	1.00		1.00		1.00
				Efficacy index (*)		0.50	1.50	1.50	4.00		4.00		4.00
	412	Fluoxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	3.00		2.00		2.00
				Global improvement		4.00	2.00	2.00	1.00		1.00		1.00
				Efficacy index		14.00	5.00	5.00	1.00		1.00		1.00
				Efficacy index (*)		0.50	3.00	3.00	4.00		4.00		4.00
	413	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00		2.00		2.00
				Global improvement		4.00	2.00	2.00	1.00		1.00		1.00
				Efficacy index		13.00	5.00	5.00	1.00		1.00		1.00
				Efficacy index (*)		1.00	3.00	3.00	4.00		4.00		4.00
	414	Fluoxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00		5.00		5.00
				Global improvement		4.00	4.00	4.00	3.00		3.00		4.00
				Efficacy index		13.00	13.00	13.00	9.00		9.00		15.00
				Efficacy index (*)		1.00	1.00	1.00	2.00		2.00		0.33

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
15	415	Reboxetine	Female	Severity of illness	6.00	6.00	6.00	5.00	4.00		2.00		2.00
				Global improvement		4.00	3.00	2.00	1.00		1.00		1.00
				Efficacy index		14.00	10.00	5.00	1.00		1.00		1.00
				Efficacy index (*)		0.50	1.00	3.00	4.00		4.00		4.00
	416	Fluoxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	4.00		4.00		3.00
				Global improvement		4.00	4.00	4.00	2.00		2.00		1.00
				Efficacy index		14.00	14.00	14.00	6.00		5.00		1.00
				Efficacy index (*)		0.50	0.50	0.50	1.50		3.00		4.00
	417	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	2.00	2.00		2.00		2.00
				Global improvement		3.00	2.00	1.00	1.00		1.00		1.00
				Efficacy index		9.00	5.00	1.00	1.00		1.00		1.00
				Efficacy index (*)		2.00	3.00	4.00	4.00		4.00		4.00
	418	Reboxetine	Female	Severity of illness	6.00	6.00	6.00	5.00	4.00		3.00		2.00
				Global improvement		4.00	3.00	2.00	2.00		1.00		1.00
				Efficacy index		13.00	9.00	5.00	5.00		1.00		1.00
				Efficacy index (*)		1.00	2.00	3.00	3.00		4.00		4.00
	419	Fluoxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00		4.00		3.00
				Global improvement		4.00	4.00	4.00	3.00		2.00		2.00
				Efficacy index		14.00	14.00	14.00	10.00		6.00		5.00
				Efficacy index (*)		0.50	0.50	0.50	1.00		1.50		3.00
	420	Fluoxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00		4.00		2.00
				Global improvement		4.00	3.00	2.00	2.00		2.00		1.00
				Efficacy index		13.00	9.00	5.00	5.00		5.00		1.00
				Efficacy index (*)		1.00	2.00	3.00	3.00		3.00		4.00
	421	Reboxetine	Female	Severity of illness	6.00	6.00	6.00	6.00	5.00		2.00		2.00
				Global improvement		5.00	5.00	3.00	2.00		1.00		1.00
				Efficacy index		13.00	13.00	9.00	5.00		1.00		1.00
				Efficacy index (*)		1.00	1.00	2.00	3.00		4.00		4.00
	422	Fluoxetine	Male	Severity of illness	6.00	6.00	6.00	6.00	5.00		2.00		2.00
				Global improvement		4.00	4.00	3.00	2.00		1.00		1.00
				Efficacy index		13.00	13.00	9.00	5.00		1.00		1.00
				Efficacy index (*)		1.00	1.00	2.00	3.00		4.00		4.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
15	423	Fluoxetine	Female	Severity of illness	6.00	6.00	6.00	6.00	6.00		4.00		4.00
				Global improvement		4.00	4.00	4.00	4.00		2.00		2.00
				Efficacy index		14.00	14.00	14.00	13.00		5.00		5.00
				Efficacy index (*)		0.50	0.50	0.50	1.00		3.00		3.00
	424	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	4.00	4.00		3.00		2.00
				Global improvement		4.00	3.00	2.00	2.00		1.00		1.00
				Efficacy index		14.00	10.00	5.00	5.00		1.00		1.00
				Efficacy index (*)		0.50	1.00	3.00	3.00		4.00		4.00
	425	Reboxetine	Female	Severity of illness	6.00	6.00	6.00	5.00	2.00		2.00		2.00
				Global improvement		4.00	4.00	2.00	1.00		1.00		1.00
				Efficacy index		13.00	13.00	5.00	1.00		1.00		1.00
				Efficacy index (*)		1.00	1.00	3.00	4.00		4.00		4.00
	426	Fluoxetine	Male	Severity of illness	6.00	6.00	6.00	6.00	6.00		5.00		4.00
				Global improvement		4.00	3.00	3.00	2.00		2.00		2.00
				Efficacy index		13.00	9.00	9.00	5.00		5.00		5.00
				Efficacy index (*)		1.00	2.00	2.00	3.00		3.00		3.00
	427	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00		4.00		2.00
				Global improvement		4.00	3.00	3.00	2.00		2.00		1.00
				Efficacy index		13.00	9.00	9.00	5.00		5.00		1.00
				Efficacy index (*)		1.00	2.00	2.00	3.00		3.00		4.00
	428	Fluoxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	4.00		4.00		4.00
				Global improvement		4.00	4.00	3.00	2.00		2.00		2.00
				Efficacy index		13.00	13.00	9.00	5.00		5.00		5.00
				Efficacy index (*)		1.00	1.00	2.00	3.00		3.00		3.00
	449	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00		5.00		2.00
				Global improvement		4.00	4.00	4.00	4.00		3.00		1.00
				Efficacy index		13.00	13.00	13.00	13.00		9.00		1.00
				Efficacy index (*)		1.00	1.00	1.00	1.00		2.00		4.00
	450	Fluoxetine	Male	Severity of illness	6.00	6.00	6.00	6.00	5.00		5.00		5.00
				Global improvement		4.00	4.00	3.00	2.00		2.00		2.00
				Efficacy index		14.00	14.00	10.00	6.00		5.00		5.00
				Efficacy index (*)		0.50	0.50	1.00	1.50		3.00		3.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
15	451	Fluoxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	4.00		4.00		3.00
				Global improvement		4.00	4.00	3.00	2.00		2.00		2.00
				Efficacy index		13.00	14.00	10.00	6.00		5.00		5.00
				Efficacy index (*)		1.00	0.50	1.00	1.50		3.00		3.00
	452	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00		2.00		2.00
				Global improvement		4.00	4.00	2.00	1.00		1.00		1.00
				Efficacy index		14.00	13.00	5.00	1.00		1.00		1.00
				Efficacy index (*)		0.50	1.00	3.00	4.00		4.00		4.00
	454	Fluoxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	5.00		5.00		4.00
				Global improvement		4.00	4.00	3.00	3.00		2.00		2.00
				Efficacy index		13.00	13.00	9.00	9.00		5.00		5.00
				Efficacy index (*)		1.00	1.00	2.00	2.00		3.00		3.00
16	429	Fluoxetine	Female	Severity of illness	6.00	3.00	2.00	2.00	2.00	1.00	2.00	2.00	2.00
				Global improvement		2.00	2.00	1.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		5.00	5.00	1.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		3.00	3.00	4.00	4.00	4.00	4.00	4.00	4.00
	430	Reboxetine	Male	Severity of illness	5.00	4.00	3.00	3.00	3.00	3.00	3.00	2.00	2.00
				Global improvement		2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		6.00	6.00	6.00	6.00	6.00	6.00	2.00	2.00
				Efficacy index (*)		1.50	1.50	1.50	1.50	1.50	1.50	2.00	2.00
	431	Reboxetine	Female	Severity of illness	5.00	3.00	3.00	2.00	2.00	2.00	2.00	2.00	2.00
				Global improvement		2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		5.00	5.00	5.00	1.00	5.00	5.00	5.00	5.00
				Efficacy index (*)		3.00	3.00	3.00	4.00	3.00	3.00	3.00	3.00
	432	Fluoxetine	Female	Severity of illness	6.00	3.00	3.00	1.00	1.00	1.00	1.00	1.00	1.00
				Global improvement		3.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		9.00	5.00	1.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		2.00	3.00	4.00	4.00	4.00	4.00	4.00	4.00
	433	Reboxetine	Female	Severity of illness	5.00	4.00	3.00	2.00	2.00	2.00	2.00	2.00	2.00
				Global improvement		3.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		9.00	5.00	1.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		2.00	3.00	4.00	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=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
16	434	Fluoxetine	Female	Severity of illness	6.00	4.00	3.00	3.00	3.00	2.00	2.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	5.00	6.00	6.00	2.00	2.00	2.00	2.00
				Efficacy index (*)		2.00	3.00	1.50	1.50	2.00	2.00	2.00	2.00
	435	Reboxetine	Female	Severity of illness	6.00	5.00	4.00	3.00	2.00	2.00	2.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index		9.00	5.00	5.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		2.00	3.00	3.00	4.00	4.00	4.00	4.00	4.00
	436	Fluoxetine	Female	Severity of illness	6.00	5.00	3.00	3.00	3.00	3.00	2.00	4.00	3.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00	3.00	2.00
				Efficacy index		9.00	5.00	5.00	5.00	5.00	5.00	10.00	7.00
				Efficacy index (*)		2.00	3.00	3.00	3.00	3.00	3.00	1.00	1.00
	437	Reboxetine	Female	Severity of illness	6.00	4.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Efficacy index (*)		2.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00
	438	Fluoxetine	Female	Severity of illness	5.00	3.00	3.00	4.00	4.00	3.00			
				Global improvement		2.00	2.00	2.00	2.00	2.00			
				Efficacy index		5.00	5.00	5.00	5.00	7.00			
				Efficacy index (*)		3.00	3.00	3.00	3.00	1.00			
	439	Fluoxetine	Female	Severity of illness	6.00	5.00	4.00	4.00	2.00	1.00	1.00	1.00	1.00
				Global improvement		3.00	2.00	2.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		9.00	5.00	5.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		2.00	3.00	3.00	4.00	4.00	4.00	4.00	4.00
	440	Reboxetine	Female	Severity of illness	6.00	4.00	3.00	3.00	2.00	2.00	2.00	2.00	1.00
				Global improvement		2.00	2.00	2.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index		5.00	5.00	5.00	1.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		3.00	3.00	3.00	4.00	4.00	4.00	4.00	4.00
	441	Fluoxetine	Female	Severity of illness	5.00	4.00	3.00	3.00	2.00		2.00		2.00
				Global improvement		3.00	2.00	2.00	2.00		1.00		1.00
				Efficacy index		9.00	5.00	5.00	1.00		1.00		1.00
				Efficacy index (*)		2.00	3.00	3.00	4.00		4.00		4.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
16	442	Reboxetine	Female	Severity of illness	7.00	7.00	6.00	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	6.00	5.00		5.00		6.00
				Efficacy index (*)		1.00	2.00	1.50	3.00		3.00		1.50
	443	Fluoxetine	Male	Severity of illness	5.00	5.00	4.00	3.00	3.00		2.00		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		5.00
				Efficacy index (*)		1.00	2.00	3.00	3.00		3.00		3.00
	444	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	3.00	3.00		1.00		1.00
				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
	445	Reboxetine	Male	Severity of illness	5.00	5.00	4.00	4.00	2.00		2.00		2.00
				Global improvement		3.00	2.00	2.00	2.00		2.00		2.00
				Efficacy index		9.00	5.00	5.00	1.00		1.00		1.00
				Efficacy index (*)		2.00	3.00	3.00	4.00		4.00		4.00
	446	Fluoxetine	Female	Severity of illness	5.00	5.00	4.00	3.00	3.00		2.00		2.00
				Global improvement		4.00	3.00	2.00	2.00		1.00		2.00
				Efficacy index		13.00	9.00	5.00	5.00		1.00		1.00
				Efficacy index (*)		1.00	2.00	3.00	3.00		4.00		4.00
	447	Fluoxetine	Male	Severity of illness	5.00	4.00	4.00	3.00	3.00		3.00		3.00
				Global improvement		3.00	3.00	2.00	2.00		2.00		2.00
				Efficacy index		9.00	9.00	5.00	5.00		5.00		5.00
				Efficacy index (*)		2.00	2.00	3.00	3.00		3.00		3.00
	448	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	4.00		4.00		3.00
				Global improvement		4.00	3.00	3.00	3.00		3.00		2.00
				Efficacy index		13.00	9.00	9.00	9.00		9.00		5.00
				Efficacy index (*)		1.00	2.00	2.00	2.00		2.00		3.00
	455	Fluoxetine	Female	Severity of illness	6.00	6.00	5.00	5.00	3.00		3.00		3.00
				Global improvement		4.00	3.00	3.00	2.00		2.00		2.00
				Efficacy index		13.00	10.00	10.00	6.00		6.00		6.00
				Efficacy index (*)		1.00	1.00	1.00	1.50		1.50		1.50

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
16	456	Reboxetine	Male	Severity of illness	6.00	6.00	4.00	3.00	3.00		3.00		3.00
				Global improvement		3.00	2.00	2.00	2.00		2.00		2.00
				Efficacy index		9.00	6.00	6.00	6.00		6.00		6.00
				Efficacy index (*)		2.00	1.50	1.50	1.50		1.50		1.50
	457	Fluoxetine	Female	Severity of illness	6.00	6.00	4.00	4.00	4.00	2.00	2.00		2.00
				Global improvement		4.00	2.00	2.00	2.00	1.00	1.00		1.00
				Efficacy index		13.00	2.00	2.00	2.00	2.00	2.00		1.00
				Efficacy index (*)		1.00	2.00	2.00	2.00	2.00	2.00		4.00
	458	Fluoxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	4.00		4.00		4.00
				Global improvement		4.00	3.00	3.00	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
	459	Reboxetine	Male	Severity of illness	5.00	4.00	3.00	3.00	3.00		1.00		1.00
				Global improvement		3.00	2.00	2.00	2.00		1.00		1.00
				Efficacy index		9.00	5.00	5.00	5.00		1.00		1.00
				Efficacy index (*)		2.00	3.00	3.00	3.00		4.00		4.00
	460	Reboxetine	Male	Severity of illness	6.00	5.00	5.00	3.00	2.00		1.00		1.00
				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
18	25	Fluoxetine	Female	Severity of illness	5.00	5.00	4.00	3.00	3.00	3.00	3.00	2.00	2.00
				Global improvement		3.00	3.00	3.00	3.00	3.00	3.00	1.00	1.00
				Efficacy index		9.00	5.00	5.00	5.00	5.00	5.00	1.00	1.00
				Efficacy index (*)		2.00	3.00	3.00	3.00	3.00	3.00	4.00	4.00
	26	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	3.00	2.00	2.00	2.00	2.00	2.00
				Global improvement		4.00	3.00	3.00	3.00	3.00	2.00	2.00	2.00
				Efficacy index		13.00	9.00	5.00	6.00	5.00	5.00	1.00	1.00
				Efficacy index (*)		1.00	2.00	3.00	1.50	3.00	3.00	4.00	4.00
	27	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	3.00	2.00	2.00	2.00	2.00	2.00
				Global improvement		4.00	3.00	3.00	3.00	3.00	2.00	2.00	2.00
				Efficacy index		13.00	9.00	9.00	5.00	5.00	1.00	1.00	1.00
				Efficacy index (*)		1.00	2.00	2.00	3.00	3.00	4.00	4.00	4.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
18	28	Fluoxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00				
				Global improvement		4.00	4.00	4.00	4.00				
				Efficacy index		13.00	13.00	13.00	13.00				
				Efficacy index (*)		1.00	1.00	1.00	1.00				
	29	Reboxetine	Male	Severity of illness	6.00	5.00	5.00	5.00	3.00	3.00	2.00	2.00	2.00
				Global improvement		3.00	3.00	4.00	2.00	3.00	2.00	2.00	2.00
				Efficacy index		9.00	9.00	13.00	5.00	5.00	5.00	1.00	1.00
				Efficacy index (*)		2.00	2.00	1.00	3.00	3.00	3.00	4.00	4.00
	30	Fluoxetine	Female	Severity of illness	5.00	5.00	5.00	2.00	5.00	4.00	4.00	2.00	2.00
				Global improvement		4.00	4.00	2.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		13.00	13.00	5.00	9.00	9.00	9.00	5.00	5.00
				Efficacy index (*)		1.00	1.00	3.00	2.00	2.00	2.00	3.00	3.00
	31	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	3.00	2.00	2.00
				Global improvement		3.00	3.00	3.00	3.00	3.00	2.00	2.00	2.00
				Efficacy index		9.00	9.00	9.00	9.00	9.00	5.00	5.00	5.00
				Efficacy index (*)		2.00	2.00	2.00	2.00	2.00	3.00	3.00	3.00
	32	Fluoxetine	Female	Severity of illness	6.00	6.00	6.00	5.00	5.00	3.00	3.00	2.00	2.00
				Global improvement		5.00	5.00	2.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		13.00	13.00	5.00	5.00	5.00	5.00	1.00	1.00
				Efficacy index (*)		1.00	1.00	3.00	3.00	3.00	3.00	4.00	4.00
	49	Reboxetine	Female	Severity of illness	6.00	5.00	3.00	3.00	3.00	3.00	3.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00	1.00	2.00
				Efficacy index		9.00	5.00	5.00	5.00	5.00	5.00	1.00	1.00
				Efficacy index (*)		2.00	3.00	3.00	3.00	3.00	3.00	4.00	4.00
	50	Reboxetine	Female	Severity of illness	6.00								
				Global improvement									
				Efficacy index									
				Efficacy index (*)									
	51	Fluoxetine	Female	Severity of illness	6.00	4.00	3.00	3.00	3.00	3.00	3.00	3.00	2.00
				Global improvement		3.00	3.00	3.00	3.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	9.00	9.00	9.00	5.00	5.00	5.00	5.00
				Efficacy index (*)		2.00	2.00	2.00	2.00	3.00	3.00	3.00	3.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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	Day 49	Day 56
18	52	Fluoxetine	Female	Severity of illness	6.00	5.00	5.00	3.00	3.00	3.00	3.00	3.00	2.00
				Global improvement		4.00	4.00	3.00	3.00	3.00	3.00	3.00	2.00
				Efficacy index		13.00	13.00	9.00	9.00	9.00	9.00	9.00	1.00
				Efficacy index (*)		1.00	1.00	2.00	2.00	2.00	2.00	2.00	4.00
	53	Fluoxetine	Female	Severity of illness	6.00	3.00	3.00	3.00	3.00	3.00	2.00	2.00	2.00
				Global improvement		3.00	3.00	3.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	9.00	9.00	5.00	5.00	5.00	5.00	5.00
				Efficacy index (*)		2.00	2.00	2.00	3.00	3.00	3.00	3.00	3.00
	54	Fluoxetine	Male	Severity of illness	5.00	5.00	3.00	3.00	3.00	3.00	2.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	5.00	5.00	5.00	5.00	1.00	1.00	1.00
				Efficacy index (*)		2.00	3.00	3.00	3.00	3.00	4.00	4.00	4.00
20	21	Fluoxetine	Female	Severity of illness	5.00	4.00	3.00	2.00	2.00	2.00	2.00	1.00	1.00
				Global improvement		3.00	2.00	1.00	2.00	2.00	1.00	1.00	1.00
				Efficacy index		6.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00
				Efficacy index (*)		1.50	2.00	2.00	2.00	4.00	4.00	4.00	4.00
	22	Fluoxetine	Female	Severity of illness	6.00	5.00	6.00	6.00	3.00	7.00			
				Global improvement		4.00	5.00	5.00	3.00	7.00			
				Efficacy index		13.00	15.00	15.00	10.00	16.00			
				Efficacy index (*)		1.00	0.33	0.33	1.00	0.25			
21	9	Fluoxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	3.00	3.00	3.00	3.00	3.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Efficacy index (*)		2.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00
22	113	Fluoxetine	Male	Severity of illness	5.00	5.00	5.00						
				Global improvement		4.00	4.00						
				Efficacy index		13.00	13.00						
				Efficacy index (*)		1.00	1.00						
	115	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	4.00					
				Global improvement		4.00	4.00	5.00					
				Efficacy index		13.00	13.00	13.00					
				Efficacy index (*)		1.00	1.00	1.00					

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severely ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
1	1	Fluoxetine	15/11/91	09/01/92	FLATULENCE	09/12/91	Detail	28			1	2	1	1		2	3	3	3		
							Detail	35	17/12/91		1	2	2	1		2	3	3	1		
							Summary		17/12/91	35	1	2	1	1		2	3	3	1		YES
					HYPERTONIA	22/11/91	Detail	7	22/11/91		2	2	1	1		3	3	3	1		
							Summary		22/11/91	7	2	2	1	1		3	3	3	1		YES
					IMPOTENCE	17/12/91	Detail	35			2	2	2	1		3	3	3	3		
							Detail	42			1	2	2	1		3	3	3	3		
							Detail	49	29/12/91		1	2	2	1		3	3	3	1		
							Summary		29/12/91	49	2	2	2	1		3	3	3	1		YES
					MOUTH DRY	18/11/91	Detail	7			1	2	1	1		3	3	3	3		
							Detail	35	16/12/91		1	2	2	1		3	3	3	1		
							Summary		16/12/91	35	1	2	1	1		3	3	3	1		YES
					RHINITIS	01/12/91	Detail	21			1	1	5	1		3	3	3	3		
							Detail	28	18/12/91		1	1	6	1		3	3	3	1		
							Summary		18/12/91	28	1	1	6	1		3	3	3	1		YES
	2	Reboxetine	26/06/92	20/08/92	INSOMNIA		Detail	0			2										
						24/06/92(@)	Summary		21/08/92(*)	8	2										NO
					TENDINITIS	08/08/92	Detail	49			2	1	6	1	YES	3	1	1	3		
							Detail	56			2	2	6	3	YES	3	1	1	3	Y	
							Summary		21/08/92(*)	56	2	1	6	3	YES	3	1	1	3	Y	YES
					VERTIGO	13/07/92	Detail	21	13/07/92		1	1	6	1		2	3	3	1		
							Summary		13/07/92	21	1	1	6	1		2	3	3	1		YES
						24/07/92	Detail	28	24/07/92		1	1	6	1		3	3	3	1		
							Summary		24/07/92	28	1	1	6	1		3	3	3	1		YES
	3	Fluoxetine	01/07/92	25/08/92	INSOMNIA		Detail	0			2										

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Sawa rity	Hist ory	Rel ship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(C)
1	3	Fluoxetine	01/07/92	25/08/92	INSOMNIA	23/08/92(@)	Summary		25/08/92(*)	8	2										NO
	4	Reboxetine	14/08/92	24/09/92	HEPATIC ENZYMES INCREASED	25/09/92	Detail	42			0	2	3	3		3	1	3	3	Y	
							Detail	99	21/10/92										1		
							Summary		21/10/92	99	0	2	3	3		3	1	3	1		YES
					INSOMNIA		Detail	0			2										
						11/08/92(@)	Summary		25/09/92(*)	0	2										NO
						14/08/92	Detail	7			2	2	2	1	YES	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			2	2	3	3	YES	3	1	3	3	Y	
							Summary		25/09/92(*)	42	2	2	2	3	YES	3	1	3	3	Y	YES
	5	Fluoxetine	13/10/92	11/11/92	ANXIETY	29/10/92	Detail	21			2	1	3	1	YES	3	3	3	3		
							Detail	35			3	1	4	1	YES	1	3	3	3	Y	
							Summary		13/11/92(*)	35	3	1	3	1	YES	1	3	3	3	Y	YES
					INSOMNIA		Detail	0			2										
						06/10/92(@)	Summary		13/11/92(*)	0	2										NO
	6	Fluoxetine	14/01/93	11/02/93	GASTRITIS	21/01/93	Detail	14			1	2	4	1	YES	3	3	3	3		
							Detail	28			2	3	4	3	YES	3	1	3	3	Y	
							Summary		11/02/93(*)	28	2	2	4	3	YES	3	1	3	3	Y	YES
2	33	Fluoxetine	04/05/91	28/06/91	HEADACHE	15/05/91	Detail	14	16/05/91		2	1	4	1		3	3	3	1		
							Summary		16/05/91	14	2	1	4	1		3	3	3	1		YES
					SWEATING INCREASED	17/05/91	Detail	21			1	2	4	1		3	3	3	3		
							Detail	28			1	2	4	1		3	3	3	3		
							Detail	35			1	2	4	1		3	3	3	3		
							Detail	42			1	2	4	1		3	3	3	3		
							Detail	49			1	2	4	1		3	3	3	3		
							Detail	56	25/06/91		1	2	4	1		3	3	3	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=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Dispp./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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
2	33	Fluoxetine	04/05/91	26/06/91	SWEATING INCREASED	17/05/91	Summary		23/06/91	56	1	2	4	1	3	3	3	3	1		YES
	34	Reboxetine	03/05/91	12/06/91	ALOPECIA	28/05/91	Detail	28	30/05/91		1	2	4	1	3	3	3	3	1		
							Summary		30/05/91	28	1	2	4	1	3	3	3	3	1		YES
					HEADACHE	15/05/91	Detail	14	16/05/91		2	1	4	1	3	3	3	3	1		
							Summary		16/05/91	14	2	1	4	1	3	3	3	3	1		YES
					MOUTH DRY	13/05/91	Detail	14			1	2	2	1	3	3	3	3	3		
							Detail	21			1	2	2	1	3	3	3	3	3		
							Detail	28			1								3		
							Detail	35			2	2	2	1	3	3	3	3	3		
							Detail	42	13/06/91		1	2	2	3	2	2	3	1			
							Summary		13/06/91	42	2	2	2	3	2	2	3	1		YES
					TINNITUS	03/05/91	Detail	7	09/05/91		1	2	2	1	3	3	3	1			
							Summary		09/05/91	7	1	2	2	1	3	3	3	1		YES
					URINARY RETENTION	06/05/91	Detail	7			2	2	2	1	3	3	3	3			
							Detail	14			1	2	2	1	3	3	3	3			
							Detail	21			1	2	2	1	3	3	3	3			
							Detail	28			1	2	2	1	3	3	3	3			
							Detail	35			2	2	2	1	3	3	3	3			
							Detail	42	13/06/91		3	2	2	3	2	2	3	1			
							Summary		13/06/91	42	3	2	2	3	2	2	3	1		YES
	36	Fluoxetine	02/05/91	26/06/91	SWEATING INCREASED	06/05/91	Detail	7			2	2	3	1	3	3	3	3			
							Detail	14			2	1	4	1	3	3	3	3			
							Detail	21			2	1	4	1	3	3	3	3			
							Detail	28			2	1	4	1	3	3	3	3			
							Detail	35			1	1	3	1	3	3	3	3			
							Detail	42			1	1	3	1	2	3	3	3			
							Detail	49			1	1	3	1	2	3	3	3			
							Detail	56			1	1	3	1	2	3	3	3	Y		
							Summary		27/06/91(*)	56	2	1	3	1	2	3	3	3	Y		YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 28124/816
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(c)
2	37	Reboxetine	07/10/91	10/10/91	FEVER	08/10/91	Detail	7	09/10/91		1	2	3	3		3	2	1	1		
							Summary		09/10/91	7	1	2	3	3		3	2	1	1		YES
					HEADACHE	08/10/91	Detail	7			2	3	2	3	YES	3	1		3	Y	
							Summary		10/10/91(*)	7	2	3	2	3	YES	3	1		3	Y	YES
					NAUSEA	08/10/91	Detail	7	10/10/91		2	3	2	3		3	2	2	1		
							Summary		10/10/91	7	2	3	2	3		3	2	2	1		YES
	38	Fluoxetine	20/06/91	25/07/91	INSOMNIA		Detail	0			2										
						17/06/91(2)	Summary		25/07/91(*)	0	2										NO
					MALAISE	15/07/91	Detail	28	15/07/91		2	2	6	4		3	3	3	1		
							Summary		15/07/91	28	2	2	6	4		3	3	3	1		YES
	39	Fluoxetine	19/06/91	22/06/91	AGITATION	22/06/91	Detail	7			3	3	3	3	YES	3	1	3	3	Y	
							Summary		22/06/91(*)	7	3	3	3	3	YES	3	1	3	3	Y	YES
					NAUSEA	21/06/91	Detail	7							YES					Y	
							Summary		22/06/91(*)	7					YES					Y	YES
	40	Reboxetine	06/06/91	04/07/91	CIRCULATORY FAILURE	19/06/91	Detail	14	19/06/91		1	2	2	1		2	3	3	1		
							Summary		19/06/91	14	1	2	2	1		2	3	3	1		YES
					MOUTH DRY	07/06/91	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14			2	2	2	1		2	3	3	3		
							Detail	21			2	2	2	1		2	3	3	3	Y	
							Summary		04/07/91(*)	21	2	2	2	1		2	3	3	3	Y	YES
					NAUSEA	23/06/91	Detail	21			1	2	3	1		2	3	3	3	Y	

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, -- History: 1=present before, 2=not observe bef., 3=unknown
Study drug: 1=no change, 2=dose reduced, 3=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
(2) onset date missing: first report visit date used

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
2	40	Reboxetine	06/06/91	04/07/91	NAUSEA	25/06/91	Summary		04/07/91(*)	21	1	2	3	1		2	3	3	3	Y	YES
					SWEATING INCREASED	15/06/91	Detail	14			1	2	2	1		2	3	3	3		
							Detail	21			2		2	1		2	3	3	3	Y	
							Summary		04/07/91(*)	21	2	2	2	1		2	3	3	3	Y	YES
					VISION ABNORMAL	07/06/91	Detail	7			2	1	3	1		3	3	3	3		
							Detail	21			2	1	3	1		2	3	3	3	Y	
							Summary		04/07/91(*)	21	2	1	3	1		2	3	3	3	Y	YES
	41	Fluoxetine	13/02/92	08/04/92	BACK PAIN		Detail	0			3										
						10/02/92(@)	Summary		09/04/92(*)	0	3										NO
					SOMNOLENCE		Detail	0			2										
						10/02/92(@)	Summary		09/04/92(*)	0	2										NO
	42	Reboxetine	05/03/92	29/04/92	ALLERGIC REACTION	16/04/92	Detail	42			2	1	6	1	YES	3	3	3	3	Y	
							Summary		30/04/92(*)	42	2	1	6	1	YES	3	3	3	3	Y	YES
					CONJUNCTIVITIS	31/03/92	Detail	28			2	2	6	1		3	3	3	3		
							Detail	35	08/04/92		1	2	6	1		3	3	3	1		
							Summary		08/04/92	35	2	2	6	1		3	3	3	1		YES
					HEADACHE	07/03/92	Detail	7			2	2	2	1		3	3	3	3		
							Detail	14			2	2	2	1	YES	3	3	3	3		
							Detail	21	25/03/92		1	2	2	1	YES	5	3	3	1		
							Summary		25/03/92	21	2	2	2	1	YES	5	3	3	1		YES
						25/04/92	Detail	56			2	2	3	1		5	5	5	5	Y	
							Summary		30/04/92(*)	56	2	2	3	1		5	5	5	5	Y	YES
					HYPOTENSION POSTURAL	26/03/92	Detail	28			2	1	3	1	YES	5	3	3	3	Y	
							Detail	35			1	1	3	1	YES	3	3	3	3		
							Summary		09/04/92(*)	35	2	1	3	1	YES	3	3	3	3		YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/816
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
2	42	Reboxetine	05/03/92	29/04/92	INSOMNIA	06/03/92	Detail	7			2	1	3	1	YES	2	3	3	3		
							Detail	21			1	1	3	1	YES	3	3	3	3		
							Detail	28			2	1	3	1		3	3	3	3		
							Detail	35			1	1	3	1		3	3	3	3	Y	
							Summary		30/04/92(*)	35	2	1	3	1	YES	2	3	3	3	Y	YES
					NAUSEA	07/03/92	Detail	7			2	1	3	1		3	3	3	3		
							Detail	14			1	1	3	1		3	3	3	3		
							Detail	21			1	1	3	1		3	3	3	3		
							Detail	28	31/03/92		1	1	3	1		3	3	3	1		
							Summary		31/03/92	28	2	1	3	1		3	3	3	1		YES
					TASTE PERVERSION	06/03/92	Detail	7			1	2	2	1		3	3	3	3	Y	
							Summary		30/04/92(*)	7	1	2	2	1		3	3	3	3	Y	YES
					TINNITUS	07/03/92	Detail	7			1	1	2	1		3	3	3	3		
							Detail	14	14/03/92		1	1	2	1		3	3	3	1		
							Summary		14/03/92	14	1	1	2	1		3	3	3	1		YES
	45	Reboxetine	19/11/91	13/01/92	GASTRITIS	11/12/91	Detail	28			1	1	4	1	YES	3	3	3	3		
							Detail	35									3	3			
							Detail	42													
							Detail	49	06/01/92		1	1	4	1	YES	3	3	3	1		
							Summary		06/01/92	49	1	1	4	1	YES	3	3	3	1		YES
					HEADACHE	13/11/91	Detail	0			3										
							Detail	7			2	1	4	1	YES	3	3	3	3		
							Detail	14			2	1	4	1	YES	3	3	3	3		
							Detail	21			2	1	4	1	YES	3	3	3	3		
							Detail	28			2	1	4	1	YES	3	3	3	3		
							Detail	35			1	1	4	1	YES	3	3	3	3		
							Detail	42			1	1	4	1	YES	3	3	3	3		
							Detail	49			1	1	4	1	YES	3	3	3	3		
							Detail	56			1	1	4	1	YES	3	3	3	3	Y	

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, -- History: 1=present before, 2=not observe bef., 3=unknown
Study drug: 1=no change, 2=dose reduced, 3=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	Hist ory	Rel ship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(C)
2	43	Reboxetine	19/11/91	13/01/92	HEADACHE	13/11/91	Summary		14/01/92(*)	56	3	1	4	1	YES	3	3	3	3	Y	NO
					MALAISE	16/11/91	Detail	0			2										
							Detail	7			1	1	4	1	YES	3	3	3	3		
							Detail	14			1	1	4	1	YES	3	3	3	3		
							Detail	21	10/12/91		1	1	4	1	YES	3	3	3	1		
							Summary		10/12/91	21	2	1	4	1	YES	3	3	3	1		NO
					PAIN	13/11/91	Detail	0			3										
							Detail	7			3	1	6	1	YES	3	3	3	3		
							Detail	14			3	1	6	1	YES	3	3	3	3		
							Detail	21			3	1	6	1	YES	3	3	3	3		
							Detail	28			3	1	6	1	YES	3	3	3	3		
							Detail	35			2	1	6	1	YES	3	3	3	3		
							Detail	42			2	1	6	1	YES	3	3	3	3		
							Detail	49			2	1	6	1	YES	3	3	3	3		
							Detail	56			2	1	6	1	YES	3	3	3	3	Y	
							Summary		14/01/92(*)	56	3	1	6	1	YES	3	3	3	3	Y	NO
					PRURITUS	04/12/91	Detail	21			1	1	3	1	YES	3	3	3	3		
							Detail	28			1	1	3	1	YES	3	3	3	3		
							Detail	35			1	1	3	1	YES	3	3	3	3		
							Detail	42			1	1	3	1	YES	3	3	3	3		
							Detail	49			1	1	3	1	YES	3	3	3	3		
							Detail	56			1	1	3	1	YES	3	3	3	3	Y	
							Summary		14/01/92(*)	56	1	1	3	1	YES	3	3	3	3	Y	YES
					UPPER RESP TRACT INFECTID	22/12/91	Detail	35			2	1	6	1	YES	3	3	3	3		
							Detail	42	26/12/91		2	1	6	1	YES	3	3	3	1		
							Summary		26/12/91	42	2	1	6	1	YES	3	3	3	1		YES
	44	Fluoxetine	13/12/91	30/01/92	CONJUNCTIVITIS		Detail	0			1										
							Detail	7			2	1	4	1		3	3	3	3		
							Detail	42			1	1	4	1	YES	2	3	3	3		
						12/12/91(@)	Summary		24/01/92(*)	42	2	1	4	1	YES	2	3	3	3		YES

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=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 : [illegible]

PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospital	Disapp.	Reapp.	Outcome	Still present (C)	
2	44	Fluoxetine	13/12/91	30/01/92	HEADACHE		Detail	0			2										
							Detail	7			2	1	4	1			3	3	3	3	
							Detail	21			1	1	4	1			3	3	3	3	
							Detail	42			1	1	4	1	YES	2	3	3	3		
						12/12/91(@)	Summary		24/01/92(*)	42	2	1	4	1	YES	2	3	3	3		NO
					HYPERTENSION	19/12/91	Detail	7			2	2	5	1	YES	3	3	3	3		
							Detail	28	08/01/92											1		
							Summary		08/01/92	28	2	2	5	1	YES	3	3	3	1		YES
					PRURITUS	13/12/91	Detail	7			2	1	3	1		3	3	3	3		
							Detail	14			1	1	4	1	YES	3	3	3	3		
							Detail	35	16/01/92		1	1	4	1	YES	2	3	3	1		
							Summary		16/01/92	35	2	1	3	1	YES	2	3	3	1		YES
	47	Fluoxetine	25/03/92	19/05/92	DIZZINESS	26/03/92	Detail	7			1	1	6	1		3	3	3	3		
							Detail	14	05/04/92		1	1	6	1		3	3	3	1		
							Summary		05/04/92	14	1	1	6	1		3	3	3	1		YES
					INFECTION VIRAL	27/03/92	Detail	7	01/04/92		1	1	6	1	YES	3	3	3	1		
							Summary		01/04/92	7	1	1	6	1	YES	3	3	3	1		YES
					PARAESTHESIA	03/04/92	Detail	14			2	2	3	1		3	3	3	3		
							Detail	21			1	2	3	1		3	3	3	3		
							Detail	35			1	2	3	1		3	3	3	3		
							Detail	49	07/05/92		1	2	3	1		3	3	3	1		
							Summary		07/05/92	49	2	2	3	1		3	3	3	1		YES
					SWEATING INCREASED	28/03/92	Detail	7			2	2	2	1		3	3	3	3		
							Detail	14	05/04/92		1	2	2	1		3	3	3	1		
							Summary		05/04/92	14	2	2	2	1		3	3	3	1		YES
						09/05/92	Detail	49			2	2	3	1		3	3	3	3	Y	
							Summary		20/05/92(*)	49	2	2	3	1		3	3	3	3	Y	YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Seve rity	Hist ory	Rel ship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(c)
2	47	Fluoxetine	25/03/92	19/05/92	TREMOR	03/04/92	Detail	14			2	1	3	1		3	3	3	3		
							Detail	21			1	1	3	1		3	3	3	3		
							Detail	56	18/05/92		1	1	3	1		3	3	3	1		
							Summary		18/05/92	56	2	1	3	1		3	3	3	1		YES
					URINARY TRACT INFECTION	02/04/92	Detail	14	07/04/92		1		6	1	YES	3	3	3	1		
							Summary		07/04/92	14	1		6	1	YES	3	3	3	1		YES
					VOMITING	25/03/92	Detail	7	26/03/92		2	1	3	1	YES	3	3	3	1		
							Summary		26/03/92	7	2	1	3	1	YES	3	3	3	1		YES
	48	Reboxetine	19/05/92	13/07/92	CONSTIPATION	22/05/92	Detail	7	22/05/92		1	1	6	1	YES	3	3	3	1		
							Summary		22/05/92	7	1	1	6	1	YES	3	3	3	1		YES
					HEADACHE	20/05/92	Detail	7	20/05/92		2	1	2	1	YES	3	3	3	1		
							Summary		20/05/92	7	2	1	2	1	YES	3	3	3	1		YES
					MOUTH DRY	27/05/92	Detail	14			2	1	3	1	YES	3	3	3	3		
							Detail	21			2	1	3	1	YES	3	3	3	3		
							Detail	28			2	1	3	1	YES	3	3	3	3		
							Detail	35			2	1	3	1	YES	3	3	3	3		
							Detail	42			2	1	3	1	YES	3	3	3	3		
							Detail	49			2	1	3	1	YES	3	3	3	3		
							Detail	56			2	1	3	1	YES	3	3	3	3	Y	
							Summary		14/07/92(*)	56	2	1	3	1	YES	3	3	3	3	Y	YES
					PARAESTHESIA	21/05/92	Detail	7	25/05/92		1	1	5	1	YES	3	3	3	1		
							Summary		25/05/92	7	1	1	5	1	YES	3	3	3	1		YES
					TREMOR	03/06/92	Detail	21			1	1	3	1	YES	3	3	3	3		
							Detail	28			2	1	3	1	YES	3	3	3	3		
							Detail	35			2	1	3	1	YES	3	3	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=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=na, 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(C)
2	48	Reboxetine	19/05/92	15/07/92	TREMOR	03/06/92	Detail	42			2	1	3	1	YES	3	3	3	3		
							Detail	49			2	1	3	1	YES	3	3	3	3		
							Detail	56			2	1	3	1	YES	3	3	3	3	Y	
							Summary		14/07/92(*)	56	2	1	3	1	YES	3	3	3	3	Y	YES
					VOMITING	19/05/92	Detail	7	19/05/92		2	1	2	1	YES	3	3	3	1		
							Summary		19/05/92	7	2	1	2	1	YES	3	3	3	1		YES
3	65	Fluoxetine	16/10/91	10/12/91	INSOMNIA		Detail	0			3										
						10/10/91(@)	Summary		10/12/91(*)	0	3										NO
					TREMOR	20/11/91	Detail	42			3	1	2	1		1	3	3	3		
							Detail	49	02/12/91		1	1	2	1		1	3	3	1		
							Summary		02/12/91	49	3	1	2	1		1	3	3	1		YES
	66	Fluoxetine	16/10/91	12/11/91	INSOMNIA		Detail	0			3										
						10/10/91(@)	Summary		12/11/91(*)	0	3										NO
					MOUTH DRY	16/10/91	Detail	7			1	2	3	1		3	3	3	3		
							Detail	21			2	2	3	1		3	3	3	3		
							Summary		05/11/91(*)	21	2	2	3	1		3	3	3	3		YES
					SUICIDE ATTEMPT	12/11/91	Detail	28			3	2	4	3		1	1	3	3	Y	
							Summary		12/11/91(*)	28	3	2	4	3		1	1	3	3	Y	YES
					SWEATING INCREASED	16/10/91	Detail	7			1	2	3	1		3	3	3	3		
							Detail	21			1	2	3	1		3	3	3	3		
							Summary		05/11/91(*)	21	1	2	3	1		3	3	3	3		YES
	67	Reboxetine	18/11/92	15/12/92	INSOMNIA		Detail	0			3										
						15/11/92(@)	Summary		16/12/92(*)	0	3										NO

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospital	Disapp.	Reapp.	Outcome	Still present	(C)
3	68	Reboxetine	30/11/92	28/12/92	INSOMNIA		Detail	0			3										
						25/11/92(D)	Summary		28/12/92(*)	0	3										ND
					NAUSEA	01/12/92	Detail	7			2	2	2	1	YES	3	3	3	3		
							Detail	14			1	2	2	1	YES	3	3	3	3		
							Detail	21	17/12/92		1	2	2	1	YES	3	3	3	1		
							Summary		17/12/92	21	2	2	2	1	YES	3	3	3	1		YES
4	97	Reboxetine	22/04/91	16/06/91	TREMOR	05/05/91	Detail	14			1	1	4	1		3	3	3	3		
							Detail	21	10/05/91		1	1	4	1		2	3	3	1		
							Summary		10/05/91	21	1	1	4	1		2	3	3	1		YES
	98	Fluoxetine	30/05/91	24/07/91	DIZZINESS	29/05/91	Detail	7			2	3	2	1		1	3	3	3		
							Detail	14	08/06/91		2	2	3	1		3	3	3	1		
							Summary		08/06/91	14	2	2	2	1		1	3	3	1		NO
					SWEATING INCREASED	29/05/91	Detail	21	29/05/91		1	2	3	1		3	3	3	1		
							Summary		29/05/91	21	1	2	3	1		3	3	3	1		NO
					TREMOR	29/05/91	Detail	7			2	2	2	1		3	3	3	3		
							Detail	14	08/06/91		1	3	4	1		3	3	3	1		
							Summary		08/06/91	14	2	2	2	1		3	3	3	1		NO
						16/07/91	Detail	49	16/07/91		2	2	5	1		3	3	3	1		
							Summary		16/07/91	49	2	2	5	1		3	3	3	1		YES
	99	Fluoxetine	15/10/91	25/10/91	DIZZINESS	22/10/91	Detail	7	22/10/91		3	3	3	1		3	3	3	1		
							Summary		22/10/91	7	3	3	3	1		3	3	3	1		YES
					HEADACHE	21/10/91	Detail	7	21/10/91		3	1	3	1		3	3	3	1		
							Summary		21/10/91	7	3	1	3	1		3	3	3	1		YES
	101	Reboxetine	02/07/92	26/08/92	ANOREXIA	17/08/92	Detail	49			2	1	3	1		3	3	3	3		
							Detail	56			2	1	4	3		3	2	3	3	Y	

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, -- History: 1=present before, 2=not observe bef., 3=unknown
Study drug: 1=no change, 2=dose reduced, 3=def. withdrawn, 4=temp. inter.
Hospital: 1=required, 2=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with sqe., 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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
4	101	Reboxetine	02/07/92	26/08/92	ANOREXIA	17/08/92	Summary		27/08/92(*)	56	2	1	3	3		3	2	3	3	Y	YES
					ARTHRITIS		Detail	0			2										
						01/07/92(Q)	Summary		27/08/92(*)	0	2										ND
					CONSTIPATION	02/07/92	Detail	7			3	1	2	1	YES	3	3	3	3		
							Detail	21			2	1	3	1	YES	3	3	3	3		
							Detail	28			2	1	2	1	YES	3	3	3	3		
							Detail	42			2	1	3	1	YES	3	3	3	3		
							Detail	56			2	1	3	3	YES	3	1	3	3	Y	
							Summary		27/08/92(*)	56	3	1	2	3	YES	3	1	3	3	Y	YES
					HEADACHE	14/07/92	Detail	14	16/07/92		1	1	3	1		3	3	3	1		
							Summary		16/07/92	14	1	1	3	1		3	3	3	1		YES
						31/07/92	Detail	35			1	1	4	1	YES	3	3	3	3		
							Detail	42			1	1	3	1	YES	3	3	3	3		
							Detail	49			2	1	3	1	YES	3	3	3	3		
							Detail	56	26/08/92		2	1	3	3	YES	3	2	3	1		
							Summary		26/08/92	56	2	1	3	3	YES	3	2	3	1		YES
					HYPOTENSION	28/08/92	Detail	56			3	1	3	3		2	1	3	3	Y	
							Summary		27/08/92(*)	56	3	1	3	3		2	1	3	3	Y	YES
					MOUTH DRY		Detail	0			3										
							Detail	7			1	1	4	1		3	3	3	3		
							Detail	14	14/07/92		1	1	3	1		3	3	3	1		
						01/07/92(Q)	Summary		14/07/92	14	3	1	3	1		3	3	3	1		ND
	102	Fluoxetine	10/07/92	05/09/92	CONSTIPATION	01/08/92	Detail	28			2	1	2	1	YES	3	3	3	3		
							Detail	35			2	1	3	1		3	3	3	3		
							Detail	42	21/08/92		2	1	3	2		3	2	3	1		
							Summary		21/08/92	42	2	1	2	2	YES	3	2	3	1		YES
					HEADACHE	11/08/92	Detail	35			2	2	3	1		3	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
4	102	Fluoxetine	10/07/92	05/09/92	HEADACHE	11/08/92	Detail	42	19/08/92		1	1	2	2		3	2	3	1		
							Summary		19/08/92	42	2	1	2	2		3	2	3	1		YES
					INSOMNIA	11/08/92	Detail	35			3	2	1	1		3	3	3	3		
							Detail	42	19/08/92		3	3	1	2	YES	3	2	3	1		
							Summary		19/08/92	42	3	2	1	2	YES	3	2	3	1		YES
					SOMNOLENCE		Detail	0			2										
						09/07/92(@)	Summary		04/09/92(*)	0	2										NO
	103	Fluoxetine	15/07/92	18/08/92	HEADACHE	21/07/92	Detail	14	23/07/92		3	2	3	1	YES	3	3	3	1		
							Summary		23/07/92	14	3	2	3	1	YES	3	3	3	1		YES
					INSOMNIA		Detail	0			2										
						12/07/92(@)	Summary		24/08/92(*)	0	2										NO
	104	Reboxetine	16/08/92	05/10/92	INSOMNIA	08/09/92	Detail	28			2	1	3	1	YES	3	3	3	3		
							Detail	49						3			1	3	3	Y	
							Summary		06/10/92(*)	49	2	1	3	3	YES	3	1	3	3	Y	YES
					PARAESTHESIA	24/08/92	Detail	7			2	2	4	1		3	3	3	3		
							Detail	28			3	2	4	1		3	3	3	3		
							Detail	35			2	2	4	1		3	3	3	3		
							Detail	49						3			1	3	3	Y	
							Summary		06/10/92(*)	49	3	2	4	3		3	1	3	3	Y	YES
	105	Fluoxetine	21/08/92	15/10/92	INSOMNIA	17/08/92	Detail	0			3										
							Summary		16/10/92(*)	0	3										NO
5	129	Reboxetine	29/11/91	29/12/91	CONSTIPATION		Detail	0			2										
						21/11/91(@)	Summary		30/12/91(*)	0	2										NO

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/816
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospital	Disapp.	Reapp.	Outcome	Still present	(C)
5	129	Reboxetine	29/11/91	29/12/91	HEADACHE	01/12/91	Detail	7	05/12/91		2	1	5	1	2	3	3	1			
							Summary		05/12/91	7	2	1	5	1	2	3	3	1			YES
						21/12/91	Detail	28	25/12/91		2	1	5	1	2	3	3	1			
							Summary		23/12/91	28	2	1	5	1	2	3	3	1			YES
					MOUTH DRY	29/09/91	Detail	0			2										
							Detail	28			3	1		1	2					Y	
							Summary		30/12/91(*)	28	3	1		1	2					Y	YES
					HYALGIA	05/12/91	Detail	7	06/12/91		2	3	4	1	2	3	3	1			
							Summary		06/12/91	7	2	3	4	1	2	3	3	1			YES
					NAUSEA	14/11/91	Detail	0			1										
							Summary		30/12/91(*)	0	1										NO
					TREMOR	01/12/91	Detail	7			1	2	2	1	2	3	3	3			
							Detail	21	17/12/91		1	2	4	1	2	3	3	1			
							Summary		17/12/91	21	1	2	2	1	2	3	3	1			YES
					VOMITING	13/12/91	Detail	21			3	1	4	1	2	3	3	3			
							Detail	35			3	2	3	3	1	2	3	3		Y	
							Summary		30/12/91(*)	35	3	1	3	3	1	2	3	3		Y	YES
	130	Fluoxetine	28/02/92	23/04/92	CONSTIPATION	01/04/92	Detail	35			1	2	4	1	2	3	3	3			
							Detail	42	04/04/92		1	2	4	1	2	3	3	1			
							Summary		04/04/92	42	1	2	4	1	2	3	3	1			YES
					NAUSEA	24/02/92	Detail	0			1										
							Summary		24/04/92(*)	0	1										NO
					TREMOR	14/03/92	Detail	21			2	2	2	1	2	3	3	3			
							Detail	42			1	2	2	1	2	3	3	3		Y	
							Summary		24/04/92(*)	42	2	2	2	1	2	3	3	3		Y	YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 28126/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
7	193	Reboxetine	06/12/91	31/01/92	CONSTIPATION		Detail	0			2										
							Detail	14			2	1	4	1	YES	3	3	3	3		
							Detail	28			1	1	4	1	YES	3	3	3	3		
							Detail	42			1		4	1	YES				3		
							Detail	56			1				YES					Y	
						30/11/91(D)	Summary		31/01/92(*)	56	2	1	4	1	YES	3	3	3		Y	NO
					DIZZINESS	07/12/91	Detail	7			1	3	4	1		3	3	3	3		
							Detail	14	16/12/91												
							Summary		16/12/91	14	1	3	4	1		3	3	3			YES
					INSOMNIA		Detail	0			2										
						30/11/91(D)	Summary		31/01/92(*)	0	2										NO
					MOUTH DRY	28/01/92	Detail	56	30/01/92		1	2	5	1		2	3	3	1		
							Summary		30/01/92	56	1	2	5	1		2	3	3	1		YES
					NAUSEA	08/12/91	Detail	7			2	3	2	1		3	3	3	3		
							Detail	21	29/12/91												
							Summary		29/12/91	21	2	3	2	1		3	3	3			YES
					PARAESTHESIA	09/12/91	Detail	7			1	2	4	1		3	3	3	3		
							Detail	14	15/12/91												
							Summary		15/12/91	14	1	2	4	1		3	3	3			YES
					URINARY RETENTION	14/01/92	Detail	42	16/01/92		1	2	5	1		3	3	3	1		
							Summary		16/01/92	42	1	2	5	1		3	3	3	1		YES
	194	Fluoxetine	10/01/92	05/03/92	FEVER	28/01/92	Detail	21			1	2	5	1		2	3	3	3		
							Detail	28	02/02/92		1	2	5	1		2	3	3	1		
							Summary		02/02/92	28	1	2	5	1		2	3	3	1		YES
						22/02/92	Detail	49			2	2	5	1	YES	2	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	Hist ory	Rel ship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(¢)
7	196	Fluoxetine	10/01/92	05/03/92	FEVER	22/02/92	Detail	56	05/03/92												
							Summary		05/03/92	56	2	2	5	1	YES	2	3	3			YES
					HEADACHE		Detail	0			3											
						01/01/92(@)	Summary		05/03/92(*)	0	3										NO
						19/01/92	Detail	14	21/01/92		2	1	4	1	YES	2			1		
							Summary		21/01/92	14	2	1	4	1	YES	2			1		YES
						15/02/92	Detail	42			1	1	5	1		2			3		
							Detail	49	23/02/92												
							Summary		23/02/92	49	1	1	5	1		2					YES
					HYPERKINESIA	07/02/92	Detail	28			2	2	4	1		2			3		
							Detail	35			1	2									
							Detail	42			1	2	4	1		2	3	3	3	Y	
							Summary		05/03/92(*)	42	2	2	4	1		2	3	3	3	Y	YES
					MOUTH DRY	26/01/92	Detail	21			1	3	3	1		2			3		
							Detail	28	06/02/92												
							Summary		06/02/92	28	1	3	3	1		2					YES
					NAUSEA	10/01/92	Detail	7	14/01/92		1	2	2	1		2			1		
							Summary		14/01/92	7	1	2	2	1		2			1		YES
						20/01/92	Detail	14	21/01/92		1	2	2	1		2			1		
							Summary		21/01/92	14	1	2	2	1		2			1		YES
						23/02/92	Detail	49			1	2	5	1	YES	2			3		
							Detail	56	29/02/92		1										
							Summary		29/02/92	56	1	2	5	1	YES	2					YES
					NERVOUSNESS	18/01/92	Detail	14			1	2	3	1		2			3		
							Detail	21	25/01/92		1	2	3	1		3	3	3	1		
							Summary		25/01/92	21	1	2	3	1		2	3	3	1		YES
					SOMNOLENCE	11/01/92	Detail	7			1	2	2	1		2			3		
							Detail	14	18/01/92												
							Summary		18/01/92	14	1	2	2	1		2					YES

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=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
symptomatic treatment: 0=no, 1=yes
(¢) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(@) onset date missing: first report visit date used

PHARMA

REBOXETINE - I
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Rel ship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(C)
7	194	Fluoxetine	10/01/92	05/03/92	UPPER RESP TRACT INFECTIO	28/01/92	Detail	21			1	2	5	1	2	1	3	3			
							Detail	28	02/02/92		1	2	6	1	2			1			
							Summary		02/02/92	28	1	2	5	1	2	1	3	1			YES
	195	Fluoxetine	14/02/92	09/04/92	DIARRHOEA	14/03/92	Detail	35	18/03/92		1	2	5	1	2	3	3	1			
							Summary		18/03/92	35	1	2	5	1	2	3	3	1			YES
					HEADACHE		Detail	0			1										
						18/02/92(@)	Summary		10/04/92(*)	0	1										ND
					RHINITIS	16/02/92	Detail	7			1	2	6	1	2	3	3	3			
							Detail	14	23/02/92												
							Summary		23/02/92	14	1	2	6	1	2	3	3				YES
					VISION ABNORMAL	22/02/92	Detail	14	24/02/92		1	2	5	1	2	3	3	1			
							Summary		24/02/92	14	1	2	5	1	2	3	3	1			YES
	196	Reboxetine	29/05/92	16/07/92	CONSTIPATION	30/05/92	Detail	7			1	1	4	1	3	3	3	3	Y		
							Summary		16/07/92(*)	7	1	1	4	1	3	3	3	3	Y		YES
					DIZZINESS	11/07/92	Detail	49			2	2	5	3	2	3	3	3	Y		
							Summary		16/07/92(*)	49	2	2	5	3	2	3	3	3	Y		YES
					HEADACHE		Detail	0			1										
							Detail	21	16/06/92		1	1	6	1	2	3	3	1			
						21/05/92(@)	Summary		16/06/92	21	1	1	6	1	2	3	3	1			NO
						29/06/92	Detail	35			1	1	5	1	2	3	3	3			
							Detail	42			1	1	6	1	3	3	3	3			
							Detail	49	14/07/92												
							Summary		14/07/92	49	1	1	5	1	2	3	3				YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 28124/916
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	Histology	Relationship	Study drug	Symptomatic treatment	Disapp.	Reapp.	Outcome	Still present	(C)
7	196	Reboxetine	29/05/92	16/07/92	HEPATIC ENZYMES INCREASED	28/06/92	Detail	28			2	2	5	1		2	3	3	3	
							Detail	49			3	2	5	1	YES	2	3	3	3	Y	
							Summary		16/07/92(*)	49	3	2	5	1	YES	2	3	3	3	Y	YES
					HEPATITIS INFECTIOUS	27/06/92	Detail	99			2	2	6			2	1	3	3	Y	
							Summary		27/06/92(*)	99	2	2	6			2	1	3	3	Y	YES
					HYPERTENSION		Detail	8			1										
							Detail	28			2	3	5	1	YES		3	5	3		
							Detail	49	16/07/92						YES						
						21/05/92(D)	Summary		16/07/92	49	2	3	5	1	YES		3	5			YES
					MOUTH DRY	01/06/92	Detail	7			1	2	4	1		2	3	5	3		
							Detail	14	08/06/92												
							Summary		08/06/92	14	1	2	4	1		2	3	5			YES
					OEDEMA LEGS	29/06/92	Detail	35			1	3	5	1		3	3	3	3		
							Detail	49	14/07/92												
							Summary		14/07/92	49	1	3	5	1		3	3	3			YES
	197	Fluoxetine	11/11/92	11/11/92	ANOREXIA		Detail	8			2										
						05/11/92(D)	Summary		11/11/92(*)	8	2										NO
					HEADACHE		Detail	8			2										
						05/11/92(D)	Summary		11/11/92(*)	8	2										NO
					HYPERTHYROIDISM	30/10/92	Detail	8			1										
							Summary		11/11/92(*)	8	1										NO
					HYPOTENSION	10/11/92	Detail	8			1										
							Summary		11/11/92(*)	8	1										NO

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. interr.
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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 28124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Seve rity	Hist ory	Rel ship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present (C)
7	197	Fluoxetine	11/11/92	11/11/92	INSOMNIA		Detail	0			2									
						05/11/92(D)	Summary		11/11/92(*)	0	2									ND
11	321	Fluoxetine	14/11/91	09/01/92	ANOREXIA		Detail	0			3									
						23/10/91(D)	Summary		10/01/92(*)	0	3									ND
					ASTHENIA		Detail	0			3									
						23/10/91(D)	Summary		10/01/92(*)	0	3									ND
					CONSTIPATION		Detail	0			2									
							Detail	35	16/12/91			1	6						1	
						23/10/91(D)	Summary		16/12/91	35	2	1	6						1	ND
					DIZZINESS	26/11/91	Detail	14			1	2	3	1		3	3	3	3	
							Detail	42	27/12/91											
							Summary		27/12/91	42	1	2	3	1		3	3	3		YES
					HEADACHE	25/11/91	Detail	14			2	3	3	1	YES	2	3	3	3	
							Detail	42	21/12/91											
							Summary		21/12/91	42	2	3	3	1	YES	2	3	3		YES
					VISION ABNORMAL	25/11/91	Detail	14			1	2	3	1		3	3	3	3	
							Detail	21	03/12/91				3	1			1	3	1	
							Summary		03/12/91	21	1	2	3	1		3	1	3	1	YES
	322	Reboxetine	14/11/91	09/01/92	ANOREXIA		Detail	0			2									
						27/10/91(D)	Summary		10/01/92(*)	0	2									ND
					CONSTIPATION		Detail	0			3									
						27/10/91(D)	Summary		10/01/92(*)	0	3									ND
					DIZZINESS	18/11/91	Detail	7			2	2	4	1		3	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Seve rity	Hist ory	Rel ship	Stud drug	Symp tres	Hosp	Dis app.	Re app.	Out come	Still present	(c)
11	522	Reboxetine	14/11/91	09/01/92	DIZZINESS	18/11/91	Detail	14	29/11/91												
							Summary		29/11/91	14	2	2	4	1		3	3	3			YES
					HEADACHE	18/11/91	Detail	7			2	1	4	1	YES	3	3	3	3		
							Detail	14	29/11/91				4				3	3	1		
							Summary		29/11/91	14	2	1	4	1	YES	3	3	3	1		YES
					INSOMNIA		Detail	0			3										
						27/10/91(B)	Summary		10/01/92(*)	0	3										NO
	525	Fluoxetine	19/11/91	13/01/92	ANXIETY		Detail	0			3										
							Detail	14	02/12/91		2	1	6	1		3	3	3	1		
						29/10/91(B)	Summary		02/12/91	14	3	1	6	1		3	3	3	1		NO
					ARTHRALGIA		Detail	0			3										
						29/10/91(B)	Summary		14/01/92(*)	0	3										NO
					HEADACHE	28/11/91	Detail	7	26/11/91		2	2	3	1		3	3	3	1		
							Summary		26/11/91	7	2	2	3	1		3	3	3	1		YES
					INSOMNIA		Detail	0			3										
							Detail	21	09/12/91		2	1	6				3	3	1		
						29/10/91(B)	Summary		09/12/91	21	3	1	6				3	3	1		NO
					MOUTH DRY	28/11/91	Detail	7			1	2	3	1		3	3	3	3		
							Detail	56			1	2	3	1		3	3	3	3	V	
							Summary		14/01/92(*)	56	1	2	3	1		3	3	3	3	V	YES
	524	Reboxetine	24/01/92	19/03/92	CONSTIPATION	11/01/92	Detail	7			3	1	3	1		3	3	3	3		
							Detail	42	04/03/92		1	1	3	1		3	3	3	1		
							Summary		04/03/92	42	3	1	3	1		3	3	3	1		NO

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=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
(B) onset date missing: first report visit date used

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(c)
11	324	Reboxetine	24/01/92	19/03/92	DIZZINESS	01/02/92	Detail	14			2	2	3	1	YES	3	3	3	3		
							Detail	21	13/02/92												
							Summary		13/02/92	21	2	2	3	1	YES	3	3	3			YES
					HEADACHE	13/02/92	Detail	21			2	3	4	1		3	3	3	3		
							Detail	35	26/02/92		1										
							Detail	42	01/03/92		1	1	1	1		3	3	3	1		
							Summary		01/03/92	42	2	1	1	1		3	3	3	1		YES
					INFLUENZA-LIKE SYMPTOMS	05/02/92	Detail	14			2	1	6	1		2	3	3	3		
							Detail	21													
							Detail	28	19/02/92												
							Summary		19/02/92	28	2	1	6	1		2	3	3			YES
					INSOMNIA		Detail	0			3										
						02/01/92(@)	Summary		20/03/92(*)	0	3										NO
					MOUTH DRY	06/03/92	Detail	49			2	2	3	1		3	3	3	3	Y	
							Summary		20/03/92(*)	49	2	2	3	1		3	3	3	3	Y	YES
					NERVOUSNESS	10/02/92	Detail	21			2	1	4	1		3	3	3	3		
							Detail	42	01/03/92												
							Summary		01/03/92	42	2	1	4	1		3	3	3			YES
					PARAESTHESIA	28/01/92	Detail	7			2	1	4	1		3	3	3	3		
							Detail	14	04/02/92		1	1	4	1		3	3	3	1		
							Summary		04/02/92	14	2	1	4	1		3	3	3	1		YES
					TORTICOLLIS	03/01/92	Detail	0			2										
							Detail	7	29/01/92				6				3	3	1		
							Summary		29/01/92	7	2		6				3	3	1		NO
	325	Reboxetine	12/02/92	07/04/92	HEADACHE	19/02/92	Detail	14			1	1	4	1		3	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 28124/816
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	Hist ory	Rel ship	Stud drug	Symp tom	Hosp	Dis app.	Re app.	Out come	Still present	(C)
11	825	Reboxetine	12/02/92	07/04/92	HEADACHE	19/02/92	Detail	21	01/03/92												
							Summary		01/03/92	21	1	1	4	1		3	3	3			YES
					HYPERPYREXIA	18/02/92	Detail	14	24/02/92		1	2	4	1		3	3	3	1		
							Summary		24/02/92	14	1	2	4	1		3	3	3	1		YES
					INSOMNIA		Detail	0			2										
							Detail	7			3	1	4	1	YES	3	3	3	3		
							Detail	28	04/03/92												
						09/01/92(S)	Summary		04/03/92	28	3	1	4	1	YES	3	3	3			YES
					MOUTH DRY	18/02/92	Detail	7			1	2	3	1		3	3	3	3		
							Detail	14	29/02/92												
							Summary		29/02/92	14	1	2	3	1		3	3	3			YES
					RASH	14/02/92	Detail	7			1	2	3	1		3	3	3	3		
							Detail	14	24/02/92												
							Summary		24/02/92	14	1	2	3	1		3	3	3			YES
	826	Reboxetine	12/02/92	07/04/92	ANXIETY		Detail	0			2										
							Detail	42	19/03/92												
						27/01/92(S)	Summary		19/03/92	42	2										NO
					CONSTIPATION	19/02/92	Detail	14			1	2	3	1		3	3	3	3	Y	
							Summary		07/04/92(=)	14	1	2	3	1		3	3	3	3	Y	YES
					CYSTITIS	29/02/92	Detail	21			3	1	4	1	YES	2	3	3	3	Y	
							Summary		07/04/92(=)	21	3	1	4	1	YES	2	3	3	3	Y	YES
					DIZZINESS	11/02/92	Detail	7	15/02/92		2	2	3	1		3	3	3	1		
							Summary		15/02/92	7	2	2	3	1		3	3	3	1		NO

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=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
symptomatic treatment: 0=no, 1=yes
(C) adverse event used for statistical analysis
(=) adverse event still present: end date = visit date
(S) onset date missing: first report visit date used
(P) [illegible]

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	Hist ory	Rel ship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(C)
11	326	Reboxetine	12/02/92	07/04/92	HYPERCHOLESTEROLAEMIA	02/04/92	Detail	56			1	2	5	1		2	3	3	3	Y	
							Summary		07/04/92(*)	56	1	2	5	1		2	3	3	3	Y	YES
					HYPERGLYCAEMIA		Detail	0			2											
						27/01/92(@)	Summary		07/04/92(*)	0	2										NO
					INSOMNIA		Detail	0			3											
							Detail	35	18/03/92												
						27/01/92(@)	Summary		18/03/92	35	3										NO
					MOUTH DRY	15/02/92	Detail	7			1	2	3	1		3	3	3	3	Y	
							Summary		07/04/92(*)	7	1	2	3	1		3	3	3	3	Y	YES
					NAUSEA	11/02/92	Detail	7	16/02/92		2	2	3	1		3	3	3	1		
							Summary		16/02/92	7	2	2	3	1		3	3	3	1		NO
					RESPIRATORY DISORDER	12/03/92	Detail	35			2	2	4	1		3	3	3	3	Y	
							Summary		07/04/92(*)	35	2	2	4	1		3	3	3	3	Y	YES
					SOMNOLENCE	12/03/92	Detail	35			1	2	3	1		3	3	3	3	Y	
							Summary		07/04/92(*)	35	1	2	3	1		3	3	3	3	Y	YES
	327	Fluoxetine	14/02/92	12/03/92	DYSPEPSIA	15/02/92	Detail	7			1	2	4	1		3	3	3	3		
							Detail	14	19/02/92												
							Summary		19/02/92	14	1	2	4	1		3	3	3			NO
						04/03/92	Detail	21			2	2	4	1		2	3	3	3		
							Detail	28			2	2		1		3				Y	
							Summary		12/03/92(*)	28	2	2	4	1		2	3	3		Y	YES
	328	Fluoxetine	19/02/92	14/04/92	CHEST PAIN PRECORDIAL	20/03/92	Detail	35			2	1	4	1		3	3	3	3		
							Detail	42													
							Detail	56	10/04/92												
							Summary		10/04/92	56	2	1	4	1		3	3	3			YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 28124/016
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	Hist ory	Rel ship	Stud drug	Symp tres	Hosp	Dis app.	Re app.	Out come	Still present	[c]
11	328	Fluoxetine	19/02/92	14/04/92	CYSTITIS	18/04/92	Detail	56			1	1	5	1		2	5	5	5	Y	
							Summary		14/04/92(=)	56	1	1	5	1		2	5	5	5	Y	YES
					INFLUENZA-LIKE SYMPTOMS	29/02/92	Detail	42			1	1	5	1		2	5	5	5			
							Detail	49	05/04/92												
							Summary		05/04/92	49	1	1	5	1		2	5	5			YES
	329	Reboxetine	31/03/92	27/05/92	ABDOMINAL PAIN	28/04/92	Detail	35	04/05/92		3	2	5	4		2	2	1	1		
							Summary		04/05/92	35	3	2	5	4		2	2	1	1		YES
					BACK PAIN		Detail	0			1										
							Detail	21	18/04/92												
						24/02/92(S)	Summary		18/04/92	21	1										NO
					CONSTIPATION	31/03/92	Detail	7			2	1	5	1		5	5	5	5	Y	
							Summary		28/05/92(=)	7	2	1	5	1		5	5	5	5	Y	YES
					HEADACHE		Detail	0			1										
							Detail	14	18/04/92												
						24/02/92(S)	Summary		18/04/92	14	1										NO
					MOUTH DRY		Detail	0			1										
						24/02/92(S)	Summary		28/05/92(=)	0	1										NO
						18/05/92	Detail	42			1	2	5	1		5	5	5	5	Y	
							Summary		28/05/92(=)	42	1	2	5	1		5	5	5	5	Y	YES
					PRURITUS	31/03/92	Detail	7			1	1	4	1		5	5	5	5		
							Detail	21	18/04/92												
							Summary		18/04/92	21	1	1	4	1		5	5	5			YES
					RESPIRATORY DISORDER	01/04/92	Detail	7			1	2	5	1		5	5	5	5		

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=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
symptomatic treatment: 0=no, 1=yes
[c] adverse event used for statistical analysis
[=] adverse event still present: end date = visit date
[S] onset date missing: first report visit date used

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 28124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Treatment Drug	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	Hist ory	Rel ship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(c)
11	329	Reboxetine	31/03/92	27/05/92	RESPIRATORY DISORDER	01/04/92	Detail	14	10/04/92												
							Summary		10/04/92	14	1	2	3	1		3	3	3			YES
	330	Reboxetine	21/04/92	08/06/92	CONSTIPATION	25/04/92	Detail	7			2	1	4	1		3	3	3	3	Y	
							Summary		09/06/92(*)	7	2	1	4	1		3	3	3	3	Y	YES
					DIZZINESS	26/05/92	Detail	35			1	2	3	1		3	3	3	3	Y	
							Summary		09/06/92(*)	35	1	2	3	1		3	3	3	3	Y	YES
					INSOMNIA		Detail	0			3										
							Detail	21			1		6	1		3	3	3	3		
						30/03/92(@)	Summary		12/05/92(*)	21	3		6	1		3	3	3	3		NO
					MICTURITION DISORDER	26/04/92	Detail	7			2	2	2	1		3	3	3	3		
							Detail	14	03/05/92												
							Summary		03/05/92	14	2	2	2	1		3	3	3			YES
					MOUTH DRY	25/04/92	Detail	7			2	2	3	1		3	3	3	3	Y	
							Summary		09/06/92(*)	7	2	2	3	1		3	3	3	3	Y	YES
					NERVOUSNESS		Detail	0			3										
						30/03/92(@)	Summary		09/06/92(*)	0	3										NO
					SPERMATORRHOEA	26/04/92	Detail	7			1	2	4	1		3	3	3	3		
							Detail	14	04/05/92												
							Summary		04/05/92	14	1	2	4	1		3	3	3			YES
	331	Fluoxetine	26/05/92	28/07/92	ANXIETY		Detail	0			2										
							Detail	14	05/06/92												
						06/05/92(@)	Summary		05/06/92	14	2										NO
					CONSTIPATION	18/05/92	Detail	21			1	2	3	1		3	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset data	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
11	331	Fluoxetine	26/05/92	20/07/92	CONSTIPATION	10/06/92	Detail	49	10/07/92												
							Summary		10/07/92	49	1	2	3	1		3	3	3			YES
					INSOMNIA		Detail	0			3											
							Detail	21	10/06/92												
						06/05/92(@)	Summary		10/06/92	21	3										NO
					MOUTH DRY	11/06/92	Detail	21			1	2	3	1		3	3	3	3		
							Detail	56												Y	
							Summary		21/07/92(*)	56	1	2	3	1		3	3	3		Y	YES
					RENAL PAIN	19/06/92	Detail	28	20/06/92		1	2	5	1		2	3	3	1		
							Summary		20/06/92	28	1	2	5	1		2	3	3	1		YES
	332	Fluoxetine	28/07/92	24/09/92	INSOMNIA		Detail	0			3										
							Detail	7			3	1	6	1	YES	3	3	3	3		
							Detail	28			2	1	5	1	YES	2	3	3	3		
							Detail	56			1	1	6	1	YES	3	3	3	3	Y	
						15/07/92(@)	Summary		25/09/92(*)	56	3	1	5	1	YES	2	3	3	3	Y	NO
					MOUTH DRY	02/08/92	Detail	7			1	2	3	1		3	3	3	3		
							Detail	21	14/08/92												
							Summary		14/08/92	21	1	2	3	1		3	3	3			YES
					SWEATING INCREASED	08/08/92	Detail	14			2	2	3	1		3	3	3	3		
							Detail	28	28/08/92												
							Summary		28/08/92	28	2	2	3	1		3	3	3			YES
	333	Reboxetine	15/09/92	09/11/92	ASTHENIA		Detail	0			3										
							Detail	14	25/09/92												
						13/07/92(@)	Summary		25/09/92	14	3										NO
					CONSTIPATION	18/09/92	Detail	7			3	2	3	1		3	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
11	333	Reboxetine	15/09/92	09/11/92	CONSTIPATION	18/09/92	Detail	14	25/09/92												
							Summary		25/09/92	14	3	2	3	1		3	3	3			YES
					INSOMNIA		Detail	0			3											
							Detail	28			2				YES						
							Detail	42			2	1			YES						
							Detail	49	30/10/92												
						13/07/92(D)	Summary		30/10/92	49	3	1			YES						NO
					MOUTH DRY	16/09/92	Detail	7			2	2	3	1		3	3	3	3	Y	
							Summary		10/11/92(*)	7	2	2	3	1		3	3	3	3	Y	YES
					SWEATING INCREASED	17/09/92	Detail	7			2	2	3	1		3	3	3	3		
							Detail	21	04/10/92												
							Summary		04/10/92	21	2	2	3	1		3	3	3			YES
	334	Fluoxetine	22/09/92	16/11/92	ANXIETY		Detail	0			2										
							Detail	7													
						31/08/92(D)	Summary		29/09/92(*)	7	2										NO
					ARTHRALGIA		Detail	0			3										
							Detail	7													
							Detail	56												Y	
						31/08/92(D)	Summary		17/11/92(*)	56	3									Y	NO
					HEADACHE		Detail	0			2										
							Detail	14	03/10/92												
						31/08/92(D)	Summary		03/10/92	14	2										NO
					MOUTH DRY		Detail	0			3										
							Detail	56												Y	
						31/08/92(D)	Summary		17/11/92(*)	56	3									Y	NO

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic trea	Hosp	Disapp.	Reapp.	Outcome	Still present	(¢)
11	334	Fluoxetine	22/09/92	16/11/92	OTITIS MEDIA	05/10/92	Detail	14			2	1	6	1	YES	2	3	3	3		
							Detail	35	26/10/92												
							Summary		26/10/92	35	2	1	6	1	YES	2	3	3			YES
					PARAESTHESIA		Detail	0			2										
							Detail	56												Y	
						31/08/92(@)	Summary		17/11/92(*)	56	2									Y	NO
	335	Reboxetine	13/10/92	16/11/92	ASTHENIA		Detail	0			3										
							Detail	35												Y	
						28/09/92(@)	Summary		17/11/92(*)	35	3									Y	NO
					CONSTIPATION		Detail	0			1										
							Detail	35												Y	
						28/09/92(@)	Summary		17/11/92(*)	35	1									Y	NO
					DIZZINESS	30/10/92	Detail	28			1	1	4	1		3	3	3	3		
							Detail	35												Y	
							Summary		17/11/92(*)	35	1	1	4	1		3	3	3		Y	YES
					HEADACHE		Detail	0			2										
							Detail	21	30/10/92												
						28/09/92(@)	Summary		30/10/92	21	2										NO
					INSOMNIA		Detail	0			2										
						28/09/92(@)	Summary		17/11/92(*)	0	2										NO
						05/11/92	Detail	28			2	1	6	1		2	3	3	3		
							Detail	35	16/11/92												
							Summary		16/11/92	35	2	1	6	1		2	3	3			YES
					MOUTH DRY		Detail	0			2										
							Detail	35												Y	
						28/09/92(@)	Summary		17/11/92(*)	35	2									Y	NO

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=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
symptomatic treatment: 0=no, 1=yes
(¢) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(@) onset date missing: first report visit date used

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
11	335	Reboxetine	13/10/92	16/11/92	SUICIDE ATTEMPT	16/11/92	Detail	35	16/11/92		3	2	5	3	YES	2	3	3	1		
							Summary		16/11/92	35	3	2	5	3	YES	2	3	3	1		YES
12	393	Fluoxetine	25/06/92	18/08/92	HEADACHE	25/06/92	Detail	7			2	1	4	1		2	3	3	3		
							Detail	14	10/07/92		2	1	5	1		2	3	3	2		
							Summary		10/07/92	14	2	1	4	1		2	3	3	2		YES
						17/07/92	Detail	28	21/07/92		2	1	3	1		2	3	3	1		
							Summary		21/07/92	28	2	1	3	1		2	3	3	1		YES
	394	Reboxetine	06/07/92	31/08/92	AGITATION	10/08/92	Detail	42			2	1	3	1		2	3	3	3		
							Detail	49			2	1	3	1		2	3	3	3		
							Detail	56	28/08/92		2	1	2	2		2	2	3	1		
							Summary		28/08/92	56	2	1	2	2		2	2	3	1		YES
					ANOREXIA	20/06/92	Detail	0			2										
							Summary		31/08/92(*)	0	2										NO
					CONSTIPATION	27/05/92	Detail	28			2	3	3	1		2	3	3	3		
							Detail	35			2	2	3	1		2	3	3	3		
							Detail	49			2	2	3	1		3	3	3	3	Y	
							Summary		31/08/92(*)	49	2	2	3	1		2	3	3	3	Y	YES
					INSOMNIA	10/08/92	Detail	56	28/08/92		2	1	2	2	YES	2	2	3	1		
							Summary		28/08/92	56	2	1	2	2	YES	2	2	3	1		YES
					MICTURITION DISORDER	06/07/92	Detail	7			1	2	3	1		2	3	3	3		
							Detail	14			2	2	3	1		2	3	3	3		
							Detail	21	27/07/92		1	2	3	1		2	3	3	1		
							Summary		27/07/92	21	2	2	3	1		2	3	3	1		YES
					PRURITUS	20/08/92	Detail	42			2	2	2	1		2	3	3	3		
							Detail	49			2	2	2	1		3	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 28124/816
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(¢)
12	394	Reboxetine	06/07/92	31/08/92	PRURITUS	20/08/92	Detail	56			2	2	2	2		2	1	3	3	Y	
							Summary		31/08/92(*)	56	2	2	2	2		2	1	3	3	Y	YES
					SWEATING INCREASED	06/07/92	Detail	7			1	1	3	1		2	3	3	3		
							Detail	21	23/07/92		1	1	3	1		2	3	3	1		
							Summary		23/07/92	21	1	1	3	1		2	3	3	1		YES
	395	Reboxetine	24/07/92	16/09/92	HEADACHE	13/08/92	Detail	28			1	1	3	1		2	3	3	3		
							Detail	35	25/08/92		1		3	1		2	3	3	1		
							Summary		25/08/92	35	1	1	3	1		2	3	3	1		YES
					MICTURITION DISORDER	30/07/92	Detail	14			2	2	2	1		2	3	3	3		
							Detail	21	10/08/92		2		3	1		2	3	3	1		
							Summary		10/08/92	21	2	2	2	1		2	3	3	1		YES
					NAUSEA		Detail	0			2										
							Detail	7			2	1	4	1		2	3	3	3		
							Detail	21			1	1	4	1		2	3	3	3		
							Detail	35			2	1	4	1		2	3	3	3		
							Detail	56			2	1	4	1		2	3	3	3	Y	
						22/07/92(@)	Summary		17/09/92(*)	56	2	1	4	1		2	3	3	3	Y	NO
	396	Fluoxetine	04/08/92	17/08/92	AGITATION		Detail	7			2	1	3	1	YES	2	3	3	3	Y	
							Detail	14			2	1	4	1	YES	2	3	3	3	Y	
						04/08/92(@)	Summary		18/08/92(*)	14	2	1	3	1	YES	2	3	3	3	Y	YES
					MICTURITION DISORDER	04/08/92	Detail	7			2	2	2	1		2	3	3	3		
							Detail	14			2	2	2	1		2	3	3	3	Y	
							Summary		18/08/92(*)	14	2	2	2	1		2	3	3	3	Y	YES
					NAUSEA	04/08/92	Detail	7			2	1	3	1		2	3	3	3		
							Detail	14			3	1	2	1		2	3	3	3	Y	
							Summary		18/08/92(*)	14	3	1	2	1		2	3	3	3	Y	YES

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=not req., 3=not appl. -- Outcome: 1=recovered, 2=rec. with seq., 3=still present, 4=death
Disapp./Reapp.: 1=no, 2=yes, 3=not appl. -- Relationship: 1=definite, 2=probable, 3=possible, 4=doubtful, 5=unknown, 6=none
symptomatic treatment: 0=no, 1=yes
(¢) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(@) onset date missing: first report visit date used

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 28124/016
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
12	497	Fluoxetine	24/02/93	21/04/93	AGITATION	19/03/93	Detail	28			2	1	3	1		2	3	3	3		
							Detail	35	30/03/93		2	1	3	1		3	3	3	1		
							Summary		30/03/93	35	2	1	3	1		2	3	3	1		YES
					DIARRHOEA	02/03/93	Detail	7	03/03/93		2	2	4	1		2	3	3	1		
							Summary		03/03/93	7	2	2	4	1		2	3	3	1		YES
					HEADACHE	22/03/93	Detail	28	23/03/93		2	1	4	1	YES	2	3	3	1		
							Summary		23/03/93	28	2	1	4	1	YES	2	3	3	1		YES
						07/04/93	Detail	42	07/04/93		2	1	3	1		3	3	3	1		
							Summary		07/04/93	42	2	1	3	1		3	3	3	1		YES
					INFLUENZA-LIKE SYMPTOMS	18/03/93	Detail	42	03/04/93		2	3	4	1	YES	3	3	3	1		
							Summary		03/04/93	42	2	3	4	1	YES	3	3	3	1		YES
						07/04/93	Detail	42	07/04/93		2	2	4	1		3	3	3	1		
							Summary		07/04/93	42	2	2	4	1		3	3	3	1		YES
					NERVOUSNESS	27/03/93	Detail	35			1	2	3	1		2	3	3	3		
							Detail	42			1	2	3	1		2	3	3	3		
							Detail	49			2	2	3	1		2	3	3	3		
							Detail	56			2	2	3	1		2	3	3	3	Y	
							Summary		22/04/93(*)	56	2	2	3	1		2	3	3	3	Y	YES
					SWEATING INCREASED	26/02/93	Detail	7			1	2	3	1		2	3	3	3		
							Detail	14			2	2	3	1		2	3	3	3		
							Detail	21	14/03/93		2	2	3	1		2	3	3	1		
							Summary		14/03/93	21	2	2	3	1		2	3	3	1		YES
						28/03/93	Detail	28			2	2	3	1		2	3	3	3		
							Detail	35			2	2	3	1		2	3	3	3		
							Detail	42			2	2	3	1		2	3	3	3		
							Detail	49			2	2	3	1		2	3	3	3		
							Detail	56			2		3	1		2	3	3	3	Y	
							Summary		22/04/93(*)	56	2	2	3	1		2	3	3	3	Y	YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
13	385	Fluoxetine	14/03/92	08/05/92	DYSPEPSIA	09/04/92	Detail	28			1	2	3	1		3	3	3	3		
							Detail	42	12/04/92		1	2	4	1		3	3	3	1		
							Summary		12/04/92	42	1	2	3	1		3	3	3	1		YES
					MYALGIA	23/03/92	Detail	14			1	2	4	1		3	3	3	3		
							Detail	21	01/04/92		1	2	4	1		2	3	3	1		
							Summary		01/04/92	21	1	2	4	1		2	3	3	1		YES
	387	Reboxetine	18/04/92	18/05/92	CONSTIPATION	20/04/92	Detail	7			2	2	4	1		3	3	3	3		
							Detail	21	04/05/92		2	2	4	1		3	3	3	1		
							Summary		04/05/92	21	2	2	4	1		3	3	3	1		YES
					DYSPEPSIA	24/04/92	Detail	28							YES					Y	
							Summary		18/05/92(*)	28					YES					Y	YES
					RASH	16/05/92	Detail	28			3	2	3	3	YES	2	1	1	3	Y	
							Summary		18/05/92(*)	28	3	2	3	3	YES	2	1	1	3	Y	YES
	388	Reboxetine	16/03/92	11/05/92	ABSCESS	24/03/92	Detail	14	01/04/92						YES						
							Summary		01/04/92	14					YES						YES
					DIZZINESS	15/03/92	Detail	7			2	2	3	1		3	3	3	3		
							Detail	56	05/05/92		2	2	3	1		3	3	3	1		
							Summary		05/05/92	56	2	2	3	1		3	3	3	1		NO
					SWEATING INCREASED	23/03/92	Detail	14			1	2	4	1		3	3	3	3		
							Detail	21	03/04/92		1	2	4	1		3	3	3	1		
							Summary		03/04/92	21	1	2	4	1		3	3	3	1		YES
	389	Fluoxetine	21/07/92	23/07/92	DIZZINESS	20/07/92	Detail	7			2	2	3	1		3	3	3	3	Y	
							Summary		23/07/92(*)	7	2	2	3	1		3	3	3	3	Y	NO

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 28124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
13	398	Reboxetine	28/05/92	22/07/92	ABSCESS	09/06/92	Detail	21								YES				Y	
							Summary		24/07/92(*)	21						YES				Y	YES
					CONSTIPATION	03/06/92	Detail	14			2	1	4	1		3	3	3	3		
							Detail	21	16/06/92		2	1	4	1		2	3	3	1		
							Summary		16/06/92	21	2	1	4	1		2	3	3	1		YES
	391	Fluoxetine	11/06/92	15/07/92	CONSTIPATION	15/06/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14			1	2	2	1		3	3	3	3		
							Detail	21	27/06/92		1	2	2	1		3	3	3	1		
							Summary		27/06/92	21	1	2	2	1		3	3	3	1		YES
					RASH MACULO-PAPULAR	12/07/92	Detail	35			3	2	2	3		2	1	3	3	Y	
							Summary		16/07/92(*)	35	3	2	2	3		2	1	3	3	Y	YES
					UPPER RESP TRACT INFECTIO	20/06/92	Detail	14							YES					Y	
							Summary		16/07/92(*)	14					YES					Y	YES
	501	Reboxetine	02/11/92	30/12/92	CONSTIPATION	03/11/92	Detail	7			2	2	3	1		2	3	3	3		
							Detail	14	14/11/92		2	2	3	1		3	3	3	1		
							Summary		14/11/92	14	2	2	3	1		2	3	3	1		YES
					DIZZINESS	03/11/92	Detail	7			1	2	3	1		3	3	3	3		
							Detail	56			1									Y	
							Summary		31/12/92(*)	56	1	2	3	1		3	3	3		Y	YES
					FATIGUE	17/11/92	Detail	21			1	2	3	1		3	3	3	3		
							Detail	28			1	2	3	1		3	3	3	3		
							Detail	42	14/12/92		1	2	4	1		3	3	3	1		
							Summary		14/12/92	42	1	2	3	1		3	3	3	1		YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relship	Study drug	Symp treat	Hosp	Dis app.	Re app.	Out come	Still present	(C)
13	501	Reboxetine	02/11/92	30/12/92	HEADACHE	30/11/92	Detail	28			1	2	4	1		3	3	3	3	Y	
							Summary		31/12/92(*)	28	1	2	4	1		3	3	3	3	Y	YES
					MOUTH DRY	03/11/92	Detail	7			1	2	3	1		3	3	3	3		
							Detail	56												Y	
							Summary		31/12/92(*)	56	1	2	3	1		3	3	3		Y	YES
	502	Fluoxetine	03/11/92	24/12/92	UPPER RESP TRACT INFECTIO	09/11/92	Detail	7	09/11/92				6		YES					1	
							Summary		09/11/92	7			6		YES					1	YES
	505	Reboxetine	12/11/92	18/11/92	CONSTIPATION	13/11/92	Detail	7			3	1	3	3		2	1	1	3	Y	
							Summary		19/11/92(*)	7	3	1	3	3		2	1	1	3	Y	YES
					DIZZINESS	13/11/92	Detail	7			2	2	3	3		2	1	3	3	Y	
							Summary		19/11/92(*)	7	2	2	3	3		2	1	3	3	Y	YES
					FATIGUE	13/11/92	Detail	7			2	2	3	3		2	1	3	3	Y	
							Summary		19/11/92(*)	7	2	2	3	3		2	1	3	3	Y	YES
					MICTURITION DISORDER	13/11/92	Detail	7			3	2	3	3		2	1	3	3	Y	
							Summary		19/11/92(*)	7	3	2	3	3		2	1	3	3	Y	YES
					MOUTH DRY	13/11/92	Detail	7			3	2	3	3		2	1	1	3	Y	
							Summary		19/11/92(*)	7	3	2	3	3		2	1	1	3	Y	YES
					SOMNOLENCE	13/11/92	Detail	7			2	2	3	3		2	1	3	3	Y	
							Summary		19/11/92(*)	7	2	2	3	3		2	1	3	3	Y	YES
	504	Fluoxetine	26/11/92	29/01/93	DIARRHOEA	04/01/93	Detail	42	06/01/93		1	2	4	1		2	3	3	1		
							Summary		06/01/93	42	1	2	4	1		2	3	3	1		YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start data	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
13	504	Fluoxetine	26/11/92	20/01/93	HEADACHE	24/12/92	Detail	28			1	1	2	1	YES	3	3	3	3		
							Detail	42	25/12/92		1	2	2	1	YES	3	3	3	1		
							Summary		25/12/92	42	1	1	2	1	YES	3	3	3	1		YES
	505	Reboxetine	31/08/92	22/10/92	ABDOMINAL PAIN	31/08/92	Detail	7			1	3	3	1	YES	3	3	3	3		
							Detail	42	01/10/92		1	3	3	1		3	3	3	1		
							Summary		01/10/92	42	1	3	3	1	YES	3	3	3	1		YES
					EPISTAXIS	10/09/92	Detail	28			2	1	3	1		3	3	3	3		
							Detail	42	05/10/92		2	1	3	1		3	3	3	1		
							Summary		05/10/92	42	2	1	3	1		3	3	3	1		YES
					MOUTH DRY	05/09/92	Detail	14			1	2	3	1	YES	2	3	3	3		
							Detail	56												Y	
							Summary		22/10/92(*)	56	1	2	3	1	YES	2	3	3		Y	YES
	506	Fluoxetine	27/10/92	23/12/92	SINUSITIS	21/12/92	Detail	56												Y	
							Summary		24/12/92(*)	56										Y	YES
	507	Fluoxetine	11/09/92	06/11/92	ALLERGIC REACTION	16/10/92	Detail	42				1								Y	
							Summary		06/11/92(*)	42		1								Y	YES
					HEADACHE	18/09/92	Detail	14			2	2	4	1		3	3	3	3		
							Detail	21	21/09/92		2	2	3	1		3	3	3	1		
							Summary		21/09/92	21	2	2	3	1		3	3	3	1		YES
						20/10/92	Detail	42	20/10/92						YES						
							Summary		20/10/92	42					YES						YES
					VISION ABNORMAL	13/09/92	Detail	7			1	2	4	1		3	3	3	3		
							Detail	21			1	2	4	1		3	3	3	3		
							Detail	28	05/10/92		1	2	3	1		3	3	3	1		
							Summary		05/10/92	28	1	2	3	1		3	3	3	1		YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present (*)	(c)
13	508	Reboxetine	02/11/92	29/12/92	HOT FLUSHES	04/11/92	Detail	7			1	2	3	1		3	3	3	3		
							Detail	56	26/12/92		1	3	3	1		3	3	3	1		
							Summary		26/12/92	56	1	2	3	1		3	3	3	1		YES
					MOUTH DRY	03/11/92	Detail	7			1	2	3	1		2	3	3	3		
							Detail	21			1	2	3	1		2	3	3	3		
							Detail	28	27/11/92		1	2	3	1		3	3	3	1		
							Summary		27/11/92	28	1	2	3	1		2	3	3	1		YES
					UPPER RESP TRACT INFECTID	14/12/92	Detail	56	20/12/92				6		YES						
							Summary		20/12/92	56			6		YES						YES
	521	Reboxetine	30/11/92	26/01/93	DIZZINESS	02/12/92	Detail	7			1	2	3	1		3	3	3	3		
							Detail	14													
							Detail	42			1	2		1					3		
							Detail	56	28/01/93		1	2	3	1		3	3	3	2		
							Summary		28/01/93	56	1	2	3	1		3	3	3	2		YES
					MOUTH DRY	02/12/92	Detail	7			1	1	3	1		2	3	3	3		
							Detail	14													
							Detail	42	31/12/92		1	2	3	1		3	3	3	1		
							Summary		31/12/92	42	1	1	3	1		2	3	3	1		YES
14	397	Fluoxetine	14/04/92	09/06/92	CONSTIPATION	17/04/92	Detail	7			2	2	2	1	YES	3	3	3	3		
							Detail	14	24/04/92		2	2	2	1		3	3	3	1		
							Summary		24/04/92	14	2	2	2	1	YES	3	3	3	1		YES
					HEADACHE	10/04/92	Detail	0			1										
							Detail	7	16/04/92		1	1	4	1		3	3	3	1		
							Summary		16/04/92	7	1	1	4	1		3	3	3	1		ND
						17/04/92	Detail	7			2	1	4	1		3	3	3	3		
							Detail	14			1	1	4	1	YES	3	3	3	3		
							Detail	21	29/04/92		1	1	4	1		3	3	3	1		
							Summary		29/04/92	21	2	1	4	1	YES	3	3	3	1		YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Seve rity	Hist ory	Rel ship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(C)
14	397	Fluoxetine	14/04/92	09/06/92	HOT FLUSHES	22/04/92	Detail	14			1	2	2	1		3	3	3	3		
							Detail	21	30/04/92		1	2	2	1		3	3	3	1		
							Summary		30/04/92	21	1	2	2	1		3	3	3	1		YES
					NAUSEA	15/04/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14	22/04/92		1	2	2	1		3	3	3	1		
							Summary		22/04/92	14	1	2	2	1		3	3	3	1		YES
						23/04/92	Detail	14			1	2	2	1		3	3	3	3		
							Detail	21	30/04/92		1	2	2	1		3	3	3	1		
							Summary		30/04/92	21	1	2	2	1		3	3	3	1		YES
					NERVOUSNESS	23/04/92	Detail	14			2	2	2	1		3	3	3	3		
							Detail	21	30/04/92		2	2	2	1		3	3	3	1		
							Summary		30/04/92	21	2	2	2	1		3	3	3	1		YES
					PRURITUS	13/05/92	Detail	35			2	2	3	1	YES	3	3	3	3		
							Detail	42	22/05/92		2	2	3	1	YES	3	3	3	1		
							Summary		22/05/92	42	2	2	3	1	YES	3	3	3	1		YES
	398	Reboxetine	15/04/92	10/06/92	ABDOMINAL PAIN	15/05/92	Detail	35	15/05/92		2	2	4	1		3	3	3	1		
							Summary		15/05/92	35	2	2	4	1		3	3	3	1		YES
						24/05/92	Detail	42	24/05/92		2	2	4	1		3	3	3	1		
							Summary		24/05/92	42	2	2	4	1		3	3	3	1		YES
					COUGHING	06/06/92	Detail	56			2	2	6	1	YES	3	3	3	3	Y	
							Summary		10/06/92(*)	56	2	2	6	1	YES	3	3	3	3	Y	YES
					EUPHORIA	16/04/92	Detail	7			2	2	2	1		3	3	3	3		
							Detail	14	23/04/92		2	2	2	1		3	3	3			
							Summary		23/04/92	14	2	2	2	1		3	3	3			YES
						23/04/92	Detail	14			1	2	2	1		3	3	3	3		
							Detail	28	07/05/92		1	2	2	1		3	3	3	1		
							Summary		07/05/92	28	1	2	2	1		3	3	3	1		YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	Hist ory	Rel ship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(c)
14	398	Reboxetine	15/04/92	10/06/92	HOT FLUSHES	08/05/92	Detail	42			2	2	5	1		3	3	3	3		
							Detail	49	30/05/92		2	2	3	1		3	3	3	1		
							Summary		30/05/92	49	2	2	3	1		3	3	3	1		YES
					INFLUENZA-LIKE SYMPTOMS	06/06/92	Detail	56			2	2	6	1	YES	3	3	3	3	Y	
							Summary		10/06/92(*)	56	2	2	6	1	YES	3	3	3	3	Y	YES
					MOUTH DRY	16/04/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14			1	2	2	1		3	3	3	3		
							Detail	21			1	2	2	1		3	3	3	3		
							Detail	42			1	2	2	1		3	3	3	3		
							Detail	56			1	2	2	1		3	3	3	3	Y	
							Summary		10/06/92(*)	56	1	2	2	1		3	3	3	3	Y	YES
					NAUSEA	15/04/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14	24/04/92		1	2	2	1		3	3	3	1		
							Summary		24/04/92	14	1	2	2	1		3	3	3	1		YES
						15/05/92	Detail	35	15/05/92		2	2	4	1		3	3	3	1		
							Summary		15/05/92	35	2	2	4	1		3	3	3	1		YES
						24/05/92	Detail	42	24/05/92		2	2	4	1		3	3	3	1		
							Summary		24/05/92	42	2	2	4	1		3	3	3	1		YES
					PALPITATION	16/04/92	Detail	7	18/04/92		1	2	4	1		3	3	3	1		
							Summary		18/04/92	7	1	2	4	1		3	3	3	1		YES
					RHINITIS	06/06/92	Detail	56			2	2	6	1	YES	3	3	3	3	Y	
							Summary		10/06/92(*)	56	2	2	6	1	YES	3	3	3	3	Y	YES
					SWEATING INCREASED	16/04/92	Detail	7	20/04/92		2	2	2	1		3	3	3	1		
							Summary		20/04/92	7	2	2	2	1		3	3	3	1		YES
	399	Reboxetine	21/04/92	15/06/92	DIZZINESS	02/05/92	Detail	14			1	2	2	1		3	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospital	Disapp.	Reapp.	Outcome	Still present	(C)
14	399	Reboxetine	21/04/92	16/06/92	DIZZINESS	02/05/92	Detail	21	10/05/92		1	2	2	1	3	3	3	3	1		
							Summary		10/05/92	21	1	2	2	1	3	3	3	3	1		YES
						17/05/92	Detail	28	17/05/92		2	2	2	1	3	3	3	3	1		
							Summary		17/05/92	28	2	2	2	1	3	3	3	3	1		YES
						31/05/92	Detail	42	31/05/92		1	2	2	1	3	3	3	3	1		
							Summary		31/05/92	42	1	2	2	1	3	3	3	3	1		YES
					HEADACHE	30/05/92	Detail	42	31/05/92		2	1	5	1	3	3	3	3	1		
							Summary		31/05/92	42	2	1	5	1	3	3	3	3	1		YES
					MIGRAINE	07/05/92	Detail	21	08/05/92		2	1	4	2	3	1	3	3	1		
							Summary		08/05/92	21	2	1	4	2	3	1	3	3	1		YES
					MOUTH DRY	22/04/92	Detail	7			2	2	2	1	3	3	3	3	3		
							Detail	14			2	2	2	1	3	3	3	3	3		
							Detail	21			2	2	2	1	3	3	3	3	3		
							Detail	28			2	2	2	1	3	3	3	3	3		
							Detail	42			2	2	2	1	2	3	3	3	3		
							Detail	56			2	2	2	1	3	3	3	3	3	Y	
							Summary		16/06/92(*)	56	2	2	2	1	2	3	3	3	3	Y	YES
	400	Fluoxetine	15/05/92	11/07/92	DIARRHOEA	17/05/92	Detail	7	28/05/92		1	2	3	1	3	3	3	3	1		
							Summary		28/05/92	7	1	2	3	1	3	3	3	3	1		YES
					MOUTH DRY	17/05/92	Detail	7			1	2	2	1	3	3	3	3	3		
							Detail	14	24/05/92		1	2	2	1	3	3	3	3	1		
							Summary		24/05/92	14	1	2	2	1	3	3	3	3	1		YES
					SOMNOLENCE	07/06/92	Detail	28			1	2	2	1	3	3	3	3	3		
							Detail	42			1	2	2	1	3	3	3	3	3		
							Detail	49			1	2	2	1	3	3	3	3	3		
							Detail	56	07/07/92		1	2	2	1	3	3	3	3	1		
							Summary		07/07/92	56	1	2	2	1	3	3	3	3	1		YES

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=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
(2) onset date missing: first report visit date used
(3) onset date [illegible]

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospital	Disapp.	Reapp.	Outcome	Still present	(C)
14	402	Reboxetine	27/05/92	22/07/92	BACK PAIN	15/06/92	Detail	21			1	1	5	1	YES	3	3	3	3		
							Detail	28	18/06/92		1	1	5	1		3	3	3	1		
							Summary		18/06/92	28	1	1	5	1	YES	3	3	3	1		YES
					CONSTIPATION	02/06/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	28	20/06/92		1		2	1		3	3	3	1		
							Summary		20/06/92	28	1	2	2	1		3	3	3	1		YES
					DIZZINESS	01/06/92	Detail	7	02/06/92		1	2	2	1		3	3	3	1		
							Summary		02/06/92	7	1	2	2	1		3	3	3	1		YES
						06/06/92	Detail	14	09/06/92		1	2	2	1		3	3	3	1		
							Summary		09/06/92	14	1	2	2	1		3	3	3	1		YES
						11/06/92	Detail	21	14/06/92		1	2	2	1		3	3	3	1		
							Summary		14/06/92	21	1	2	2	1		3	3	3	1		YES
					HEADACHE	28/06/92	Detail	35	28/06/92		2	2	4	1		3	3	3	1		
							Summary		28/06/92	35	2	2	4	1		3	3	3	1		YES
					INSOMNIA	14/05/92	Detail	42			1	1	6	1		3	3	3	3		
							Detail	56			1	1	6	1		3	3	3	3	Y	
							Summary		22/07/92(*)	56	1	1	6	1		3	3	3	3	Y	ND
					MOUTH DRY	12/06/92	Detail	21			1	2	2	1		3	3	3	3		
							Detail	35	26/06/92		1	2	2	1		3	3	3	1		
							Summary		26/06/92	35	1	2	2	1		3	3	3	1		YES
	403	Reboxetine	29/05/92	24/07/92	BREAST FIBROADENOSIS	09/06/92	Detail	14				3	6	1		3	3	3	3		
							Detail	56				3	6	1		3	3	3	3	Y	
							Summary		24/07/92(*)	56		3	6	1		3	3	3	3	Y	YES
					CONSTIPATION	30/05/92	Detail	7			2	2	2	1		3	3	3	3		
							Detail	28	19/06/92		2	2	2	1		3	3	3	1		
							Summary		19/06/92	28	2	2	2	1		3	3	3	1		YES
						21/06/92	Detail	28			1	2	2	1		3	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Treatment Drug	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(C)
14	403	Reboxetine	29/05/92	24/07/92	CONSTIPATION	21/06/92	Detail	49	12/07/92		1	2	2	1		5	5	5	1		
							Summary		12/07/92	49	1	2	2	1		5	5	5	1		YES
					FLUSHING	30/05/92	Detail	7			2	2	2	1		5	5	5	5		
							Detail	21	15/06/92		2	2	2	1		5	5	5	1		
							Summary		15/06/92	21	2	2	2	1		5	5	5	1		YES
						11/07/92	Detail	49			1	2	3	1		5	5	5	5		
							Detail	56			1	2	3	1		5	5	5	5	Y	
							Summary		24/07/92(*)	56	1	2	3	1		5	5	5	5	Y	YES
					INSOMNIA	28/06/92	Detail	28			1	2	5	1	YES	5	5	5	5		
							Detail	56			1	2	5	1	YES	5	5	5	5	Y	
							Summary		24/07/92(*)	56	1	2	5	1	YES	5	5	5	5	Y	YES
					MOUTH DRY	15/06/92	Detail	21			1	2	2	1		5	5	5	5		
							Detail	56			1	2	2	1		5	5	5	5	Y	
							Summary		24/07/92(*)	56	1	2	2	1		5	5	5	5	Y	YES
	404	Fluoxetine	16/06/92	11/08/92	APPETITE INCREASED	24/06/92	Detail	14			1	2	2	1		5	5	5	5		
							Detail	21	02/07/92		1	2	2	1		5	5	5	1		
							Summary		02/07/92	21	1	2	2	1		5	5	5	1		YES
					FATIGUE	17/07/92	Detail	42	24/07/92		1	2	6	1		5	5	5	1		
							Summary		24/07/92	42	1	2	6	1		5	5	5	1		YES
					HEADACHE	07/08/92	Detail	56			2	2	4	1	YES	5	5	5	5	Y	
							Summary		11/08/92(*)	56	2	2	4	1	YES	5	5	5	5	Y	YES
					INFLUENZA-LIKE SYMPTOMS	17/07/92	Detail	42			1	2	6	1	YES	5	5	5	5		
							Detail	49	04/08/92		1	2	6	1		5	5	5	1		
							Summary		04/08/92	49	1	2	6	1	YES	5	5	5	1		YES
					INSOMNIA	18/06/92	Detail	7			1	1	3	1		5	5	5	5		

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospital	Disapp.	Reapp.	Outcome	Still present	(C)
14	404	Fluoxetine	16/06/92	11/08/92	INSOMNIA	18/06/92	Detail	21	01/07/92		1	1	3	1	3	3	3	3	1		
							Summary		01/07/92	21	1	1	3	1	3	3	3	3	1		YES
						29/07/92	Detail	49			1	2	3	1	3	3	3	3	3		
							Detail	56			1	2	2	1	3	3	3	3	3	Y	
							Summary		11/08/92(*)	56	1	2	2	1	3	3	3	3	3	Y	YES
					NAUSEA	17/06/92	Detail	7			1	2	2	1	3	3	3	3	3		
							Detail	14	24/06/92		1	2	2	1	3	3	3	3	1		
							Summary		24/06/92	14	1	2	2	1	3	3	3	3	1		YES
						29/06/92	Detail	14	29/06/92		1	2	2	1	3	3	3	3	1		
							Summary		29/06/92	14	1	2	2	1	3	3	3	3	1		YES
					PARONIRIA	28/07/92	Detail	56	04/08/92		2	2	4	1	3	3	3	3	1		
							Summary		04/08/92	56	2	2	4	1	3	3	3	3	1		YES
					RHINITIS	17/07/92	Detail	42	23/07/92		2	2	6	1	3	3	3	3	1		
							Summary		23/07/92	42	2	2	6	1	3	3	3	3	1		YES
					TREMOR	01/07/92	Detail	21			1	2	2	1	3	3	3	3	3		
							Detail	28	09/07/92		1	2	2	1	3	3	3	3	1		
							Summary		09/07/92	28	1	2	2	1	3	3	3	3	1		YES
	405	Fluoxetine	22/06/92	18/08/92	DYSPEPSIA	23/06/92	Detail	7	25/06/92		2	2	2	1	3	3	3	3	1		
							Summary		25/06/92	7	2	2	2	1	3	3	3	3	1		YES
						13/07/92	Detail	21	13/07/92		2	2	3	1	3	3	3	3	1		
							Summary		13/07/92	21	2	2	3	1	3	3	3	3	1		YES
					NAUSEA	07/07/92	Detail	21	10/07/92		1	2	3	1	3	3	3	3	1		
							Summary		10/07/92	21	1	2	3	1	3	3	3	3	1		YES
						31/07/92	Detail	42	02/08/92		1	2	5	1	3	3	3	3	1		
							Summary		02/08/92	42	1	2	5	1	3	3	3	3	1		YES
	406	Fluoxetine	30/06/92	21/07/92	AGITATION	01/07/92	Detail	7			1	1	4	1	3	3	3	3	3		
							Detail	14			1	1	4	1	3	3	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Treatment Drug	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(c)
14	406	Fluoxetine	30/06/92	21/07/92	AGITATION	01/07/92	Detail	21			1	1	4	1		3	3	3	3	Y	
							Summary		21/07/92(*)	21	1	1	4	1		3	3	3	3	Y	YES
					DIARRHOEA	02/07/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14	09/07/92		1	2	2	1		3	3	3	1		
							Summary		09/07/92	14	1	2	2	1		3	3	3	1		YES
					MOUTH DRY	01/07/92	Detail	7			1	1	4	1		3	3	3	3		
							Detail	14			1	1	4	1		3	3	3	3		
							Detail	21			1	1	4	1		3	3	3	3	Y	
							Summary		21/07/92(*)	21	1	1	4	1		3	3	3	3	Y	YES
					NAUSEA	02/07/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14	10/07/92		1	2	2	1		3	3	3	1		
							Summary		10/07/92	14	1	2	2	1		3	3	3	1		YES
					URINARY TRACT INFECTION	21/07/92	Detail	21												Y	
							Summary		21/07/92(*)	21										Y	YES
	407	Reboxetine	14/07/92	24/08/92	HEADACHE	20/06/92	Detail	0			2										
							Summary		24/08/92(*)	0	2										NO
					MOUTH DRY	16/07/92	Detail	7			1	1	2	1		3	3	3	3		
							Detail	42			1	1	2	1		3	3	3	3	Y	
							Summary		24/08/92(*)	42	1	1	2	1		3	3	3	3	Y	YES
					VISION ABNORMAL	16/07/92	Detail	7			1	1	2	1		3	3	3	3		
							Detail	42			1	1	2	1		3	3	3	3	Y	
							Summary		24/08/92(*)	42	1	1	2	1		3	3	3	3	Y	YES
	408	Reboxetine	04/08/92	30/09/92	BACK PAIN	13/08/92	Detail	14			1	2	2	1		3	3	3	3		
							Detail	21	24/08/92		1	2	2	1		3	3	3	1		
							Summary		24/08/92	21	1	2	2	1		3	3	3	1		YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report-visit	Severity	Hist ory	Rel ship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(C)
14	408	Reboxetine	04/08/92	30/09/92	HEADACHE	20/08/92	Detail	21			1	1	4	1		3	3	3	3		
							Detail	28	28/08/92		1	1	4	1		3	3	3	1		
							Summary		28/08/92	28	1	1	4	1		3	3	3	1		YES
					INSOMNIA	06/08/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14	12/08/92		1	2	2	1		3	3	3	1		
							Summary		12/08/92	14	1	2	2	1		3	3	3	1		YES
						19/08/92	Detail	21			1	2	2	1		3	3	3	3		
							Detail	28			1	2	2	1		3	3	3	3		
							Detail	42	08/09/92		1	2	2	1		3	3	3	1		
							Summary		08/09/92	42	1	2	2	1		3	3	3	1		YES
					MOUTH DRY	08/08/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	56			1	2	2	1		3	3	3	3	Y	
							Summary		30/09/92(*)	56	1	2	2	1		3	3	3	3	Y	YES
					SWEATING INCREASED	16/08/92	Detail	14			1	2	2	1		3	3	3	3		
							Detail	21	24/08/92		1	2	2	1		3	3	3	1		
							Summary		24/08/92	21	1	2	2	1		3	3	3	1		YES
					TREMOR	06/08/92	Detail	7	09/08/92		2	2	3	1		3	3	3	1		
							Summary		09/08/92	7	2	2	3	1		3	3	3	1		YES
					VISION ABNORMAL	08/08/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14	12/08/92		1	2	2	1		3	3	3	1		
							Summary		12/08/92	14	1	2	2	1		3	3	3	1		YES
	509	Fluoxetine	29/09/92	10/11/92	APPETITE INCREASED	09/10/92	Detail	14			2	2	2	1		3	3	3	3		
							Detail	14			2	2	5	1		3	3	3	3		
							Detail	21	16/10/92		2	2	2	1		3	3	3	1		
							Detail	21	16/10/92		2	2	5	1		3	3	3	1		
							Summary		16/10/92	21	2	2	2	1		3	3	3	1		YES
						22/10/92	Detail	28			1	2	5	1		3	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
14	509	Fluoxetine	29/09/92	10/11/92	APPETITE INCREASED	22/10/92	Detail	35			1	2	5	1		3	3	3	3		
							Detail	42			1	2	5	1		3	3	3	3	Y	
							Summary		10/11/92(*)	42	1	2	5	1		3	3	3	3	Y	YES
					FATIGUE	01/10/92	Detail	7			2	2	4	1		3	3	3	3		
							Detail	14	10/10/92		2	2	4	1		3	3	3	1		
							Summary		10/10/92	14	2	2	4	1		3	3	3	1		YES
					HEADACHE	08/10/92	Detail	14			1	1	4	1		3	3	3	3		
							Detail	21	14/10/92		1	1	4	1		3	3	3	1		
							Summary		14/10/92	21	1	1	4	1		3	3	3	1		YES
						04/11/92	Detail	42			1	2	2	1		3	3	3	3	Y	
							Summary		10/11/92(*)	42	1	2	2	1		3	3	3	3	Y	YES
					HYPERTONIA	30/09/92	Detail	7			2	1	6	1		3	3	3	3		
							Detail	14			2	1	6	1		3	3	3	3		
							Detail	21			2	1	6	1		3	3	3	3		
							Detail	28			2	1	6	1		3	3	3	3		
							Detail	42			2	1	6	1		3	3	3	3	Y	
							Summary		10/11/92(*)	42	2	1	6	1		3	3	3	3	Y	YES
					NAUSEA	10/10/92	Detail	14			1	2	2	1		3	3	3	3		
							Detail	21	14/10/92		2	2	2	1		3	3	3	1		
							Summary		14/10/92	21	2	2	2	1		3	3	3	1		YES
						21/10/92	Detail	28			1	2	2	1		3	3	3	3		
							Detail	35			1	2	2	1		3	3	3	3		
							Detail	42			1	2	2	1		3	3	3	3	Y	
							Summary		10/11/92(*)	42	1	2	2	1		3	3	3	3	Y	YES
	518	Fluoxetine	30/09/92	26/11/92	ASTHENIA	10/10/92	Detail	21	17/10/92		1	1	4	1		3	3	3	1		
							Summary		17/10/92	21	1	1	4	1		3	3	3	1		YES
					COUGHING	16/11/92	Detail	56			1	1	6	1	YES	3	3	3	3	Y	
							Summary		26/11/92(*)	56	1	1	6	1	YES	3	3	3	3	Y	YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
14	510	Fluoxetine	30/09/92	26/11/92	HEADACHE	09/10/92	Detail	21	16/10/92		1	1	4	1		3	3	3	1		
							Summary		16/10/92	21	1	1	4	1		3	3	3	1		YES
						25/10/92	Detail	28	26/10/92		2	1	4	1	YES	3	3	3	1		
							Summary		26/10/92	28	2	1	4	1	YES	3	3	3	1		YES
						06/11/92	Detail	42	09/11/92		1	2	4	1		3	3	3	1		
							Summary		09/11/92	42	1	2	4	1		3	3	3	1		YES
						20/11/92	Detail	56	24/11/92		1	2	2	1		3	3	3	1		
							Summary		24/11/92	56	1	2	2	1		3	3	3	1		YES
					NAUSEA	15/10/92	Detail	21			1	2	2	1		3	3	3	3		
							Detail	28	23/10/92		1	2	2	1		3	3	3	1		
							Summary		23/10/92	28	1	2	2	1		3	3	3	1		YES
					PHARYNGITIS	16/11/92	Detail	56			2	2	6	1	YES	3	3	3	3	Y	
							Summary		26/11/92(*)	56	2	2	6	1	YES	3	3	3	3	Y	YES
	511	Reboxetine	23/10/92	10/12/92	CONSTIPATION	06/11/92	Detail	21			1	2	2	1		3	3	3	3		
							Detail	28			1	2	2	1		3	3	3	3		
							Detail	35			1	2	2	1		3	3	3	3		
							Detail	42			1	2	2	1		3	3	3	3		
							Detail	49			1	2	2	1		3	3	3	3	Y	
							Summary		11/12/92(*)	49	1	2	2	1		3	3	3	3	Y	YES
					DIZZINESS	21/11/92	Detail	35			1	2	2	1		3	3	3	3		
							Detail	42	02/12/92		1	2	2	1		3	3	3	1		
							Summary		02/12/92	42	1	2	2	1		3	3	3	1		YES
						06/12/92	Detail	49			1	2	2	1		3	3	3	3	Y	
							Summary		11/12/92(*)	49	1	2	2	1		3	3	3	3	Y	YES
					MICTURITION DISORDER	01/12/92	Detail	42			1	2	2	1		3	3	3	3		
							Detail	49	06/12/92		1	2	2	1		3	3	3	1		
							Summary		06/12/92	49	1	2	2	1		3	3	3	1		YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
14	511	Reboxetine	23/10/92	10/12/92	NAUSEA	24/10/92	Detail	7			2	1	3	1	YES	3	3	3	3		
							Detail	14	01/11/92		2	1	3	1		3	3	3	1		
							Summary		01/11/92	14	2	1	3	1	YES	3	3	3	1		YES
					PALPITATION	06/11/92	Detail	21			2	2	3	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			2	2	3	1		3	3	3	3		
							Detail	49			2	2	3	1		3	3	3	3	Y	
							Summary		11/12/92(*)	49	2	2	3	1		3	3	3	3	Y	YES
					SWEATING INCREASED	25/10/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14	30/10/92		1	2	2	1		3	3	3	1		
							Summary		30/10/92	14	1	2	2	1		3	3	3	1		YES
						06/11/92	Detail	21			1	2	2	1		3	3	3	3		
							Detail	28	18/11/92		1	2	2	1		3	3	3	1		
							Summary		18/11/92	28	1	2	2	1		3	3	3	1		YES
					VOMITING	24/10/92	Detail	7			2	1	3	1	YES	3	3	3	3		
							Detail	14	01/11/92		2	1	3	1		3	3	3	1		
							Summary		01/11/92	14	2	1	3	1	YES	3	3	3	1		YES
	512	Reboxetine	03/11/92	02/12/92	BACK PAIN	15/11/92	Detail	14			2	2	5	1	YES	3	3	3	3		
							Detail	21			2	2	5	1	YES	3	3	3	3		
							Detail	28	28/11/92		2	2	5	1	YES	3	3	3	1		
							Summary		28/11/92	28	2	2	5	1	YES	3	3	3	1		YES
					FEVER	15/11/92	Detail	14			2	2	5	1	YES	1	3	3	3		
							Detail	21	20/11/92		1	2	5	1	YES	3	3	3	1		
							Summary		20/11/92	21	2	2	5	1	YES	1	3	3	1		YES
					HEADACHE	04/11/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14	13/11/92		1	2	2	1		3	3	3	1		
							Summary		13/11/92	14	1	2	2	1		3	3	3	1		YES
						22/12/92	Detail	28			2	2	3	1		3	3	3	3	Y	

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, -- History: 1=present before, 2=not observe bef., 3=unknown
Study drug: 1=no change, 2=dose reduced, 3=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Treatment Drug	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
14	512	Reboxetine	05/11/92	02/12/92	HEADACHE	22/12/92	Summary		02/12/92(*)	28	2	2	3	1		3	3	3	3	Y	YES
					INFLUENZA-LIKE SYMPTOMS	15/11/92	Detail	14			2	2	5	1	YES	3	3	3	3		
							Detail	21			2	2	5	1	YES	3	3	3	3		
							Detail	28			2	2	5	1	YES	3	3	3	3	Y	
							Summary		02/12/92(*)	28	2	2	5	1	YES	3	3	3	3	Y	YES
					MOUTH DRY	05/11/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14	11/11/92		1	2	2	1		3	3	3	1		
							Summary		11/11/92	14	1	2	2	1		3	3	3	1		YES
					PHARYNGITIS	28/11/92	Detail	21			1	2	5	1		3	3	3	3		
							Detail	28			2	2	5	1		3	3	3	3	Y	
							Summary		02/12/92(*)	28	2	2	5	1		3	3	3	3	Y	YES
					KEROPHTHALMIA	04/11/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14	11/11/92		1	2	2	1		3	3	3	1		
							Summary		11/11/92	14	1	2	2	1		3	3	3	1		YES
	537	Reboxetine	03/11/92	29/12/92	ANXIETY	15/11/92	Detail	14	15/11/92		1	2	2	1		3	3	3	1		
							Summary		15/11/92	14	1	2	2	1		3	3	3	1		YES
					CONSTIPATION	05/11/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14			1	2	2	1		3	3	3	3		
							Detail	21	18/11/92		1	2	2	1		3	3	3	1		
							Summary		18/11/92	21	1	2	2	1		3	3	3	1		YES
					PARAESTHESIA	06/11/92	Detail	7			1	2	2	1		3	3	3	3		
							Detail	14			1	2	2	1		3	3	3	3		
							Detail	21	18/11/92		1	2	2	1		3	3	3	1		
							Summary		18/11/92	21	1	2	2	1		3	3	3	1		YES
					URINARY TRACT INFECTION	04/11/92	Detail	21	18/11/92						YES	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 29124/016
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Stud drug	Symp treat	Hosp	Dis app.	Re app.	Out come	Still present	(C)
14	537	Reboxetine	03/11/92	29/12/92	URINARY TRACT INFECTION	04/11/92	Summary		18/11/92	21					YES	3					YES
					VERTIGO	04/11/92	Detail	7	05/11/92		1	2	2	1		3	3	3	1		
							Summary		05/11/92	7	1	2	2	1		3	3	3	1		YES
	538	Fluoxetine	12/02/93	09/04/93	APPETITE INCREASED	28/03/93	Detail	49			2	2	5	1		3	3	3	3		
							Detail	56	03/04/93		2	2	5	1		3	3	3	1		
							Summary		03/04/93	56	2	2	5	1		3	3	3	1		YES
					BACK PAIN	03/04/92	Detail	56			2	1	6	1	YES	3	3	3	3	Y	
							Summary		09/04/93(*)	56	2	1	6	1	YES	3	3	3	3	Y	NO
					HEADACHE	13/02/93	Detail	7			2	2	2	1	YES	3	3	3	3		
							Detail	14	21/02/93		2	2	2	1		3	3	3	1		
							Summary		21/02/93	14	2	2	2	1	YES	3	3	3	1		YES
					SOMNOLENCE	21/03/93	Detail	42			2	2	2	1		3	3	3	3		
							Detail	49	28/03/93		2	2	2	1		3	3	3	1		
							Summary		28/03/93	49	2	2	2	1		3	3	3	1		YES
	539	Fluoxetine	10/03/93	05/05/93	CONSTIPATION	25/03/93	Detail	21			2	2	2	1	YES	3	3	3	3		
							Detail	28	05/04/93		2	2	2	1		3	3	3	1		
							Summary		05/04/93	28	2	2	2	1	YES	3	3	3	1		YES
						12/04/93	Detail	42			2	2	2	1	YES	3	3	3	3		
							Detail	56	02/05/93		2	2	2	1	YES	3	3	3	1		
							Summary		02/05/93	56	2	2	2	1	YES	3	3	3	1		YES
					DIZZINESS	18/03/93	Detail	14	21/03/93		1	1	2	1		3	3	3	1		
							Summary		21/03/93	14	1	1	2	1		3	3	3	1		YES
					DYSPEPSIA	12/03/93	Detail	7			2	2	2	1		3	3	3	3		
							Detail	14	18/03/93		2	2	2	1		3	3	3	1		
							Summary		18/03/93	14	2	2	2	1		3	3	3	1		YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 28124/016
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
14	559	Fluoxetine	10/03/93	05/05/93	HEADACHE		Detail	0			1										
							Detail	7	13/03/93		1	1	6	1		3	3	3	1		
						09/03/93(@)	Summary		13/03/93	7	1	1	6	1		3	3	3	1		NO
					INSOMNIA	30/03/93	Detail	35	10/04/93						YES						
							Summary		10/04/93	35					YES						YES
					NAUSEA		Detail	0			2										
							Detail	7	13/03/93		1	1	6	1		3	3	3	1		
						09/03/93(@)	Summary		13/03/93	7	2	1	6	1		3	3	3	1		NO
					SWEATING INCREASED	20/03/93	Detail	14			1	2	2	1		3	3	3	3		
							Detail	56			1	2	2	1		3	3	3	3	Y	
							Summary		05/05/93(*)	56	1	2	2	1		3	3	3	3	Y	YES
					VISION ABNORMAL	22/04/93	Detail	56			1	2	2	1		3	3	3	3	Y	
							Summary		05/05/93(*)	56	1	2	2	1		3	3	3	3	Y	YES
15	409	Reboxetine	08/04/92	02/06/92	CONSTIPATION	09/04/92	Detail	7			2	2	3	1		2	3	3	3		
							Detail	14	17/04/92		1	2	3	1		2	3	3	1		
							Summary		17/04/92	14	2	2	3	1		2	3	3	1		YES
					DIZZINESS	09/04/92	Detail	7	13/04/92		1	2	3	1		2	3	3	1		
							Summary		13/04/92	7	1	2	3	1		2	3	3	1		YES
					FATIGUE	09/04/92	Detail	7			3	1	3	1		2	3	3	3		
							Detail	14			2		3	1		2			3		
							Detail	21	22/04/92		1	1	3	1		2	3	3	1		
							Summary		22/04/92	21	3	1	3	1		2	3	3	1		YES
					HEADACHE	09/04/92	Detail	7			2	1	3	1		2	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Disapp.	Reapp.	Outcome	Still present	(C)
15	409	Reboxetine	08/04/92	02/05/92	HEADACHE	09/04/92	Detail	14			1	1	3	1	2	3	3	3		
							Detail	21	22/04/92		1		3	1	2	3	3	1		
							Summary		22/04/92	21	2	1	3	1	2	3	3	1		YES
					MICTURITION DISORDER	11/04/92	Detail	7	13/04/92		1	2	3	1	2	3	3	1		
							Summary		13/04/92	7	1	2	3	1	2	3	3	1		YES
					MOUTH DRY	09/04/92	Detail	7			1	2	3	1	2	3	3	3		
							Detail	14			1	2	3	1	2	3	3	3		
							Detail	21	25/04/92		1	2	3	1	2	3	3	1		
							Summary		25/04/92	21	1	2	3	1	2	3	3	1		YES
	410	Fluoxetine	17/04/92	11/06/92	DIZZINESS	19/04/92	Detail	7	22/04/92		2	2	3	1	2	3	3	1		
							Summary		22/04/92	7	2	2	3	1	2	3	3	1		YES
						25/04/92	Detail	14	28/04/92		1	2	3	1	2	3	3	1		
							Summary		28/04/92	14	1	2	3	1	2	3	3	1		YES
						01/05/92	Detail	21			1	2	3	1	2	3	3	3		
							Detail	28	12/05/92		1	2	3	1	2	3	3	1		
							Summary		12/05/92	28	1	2	3	1	2	3	3	1		YES
					HYPERURICAEMIA	14/05/92	Detail	28			1	2	6	1	3	3	3	3	Y	
							Summary		11/06/92(*)	28	1	2	6	1	3	3	3	3	Y	YES
	411	Reboxetine	22/04/92	16/05/92	FATIGUE	22/04/92	Detail	7			2	2	3	1	2	3	3	3		
							Detail	14	02/05/92		1	2	3	1	2	3	3	1		
							Summary		02/05/92	14	2	2	3	1	2	3	3	1		YES
					MOUTH DRY	24/04/92	Detail	7			2	2	3	1	2	3	3	3		
							Detail	14			1	2	3	1	2	3	3	3		
							Detail	21			1	2	3	1	2	3	3	3		
							Detail	21	10/05/92		1	2	3	1	2	3	3	1		
							Summary		10/05/92	21	2	2	3	1	2	3	3	1		YES
	412	Fluoxetine	25/04/92	17/06/92	DIZZINESS	25/04/92	Detail	7	28/04/92		1	2	3	1	2	3	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 28124/816
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(C)
15	412	Fluoxetine	23/04/92	17/06/92	DIZZINESS	25/04/92	Summary		28/04/92	7	1	2	3	1		2	3	3	1		YES
	414	Fluoxetine	02/06/92	27/07/92	FATIGUE	22/07/92	Detail	56			3	2	3	1		3	3	3	3	Y	
							Summary		27/07/92(*)	56	3	2	3	1		3	3	3	3	Y	YES
					HYPERCHOLESTEROLAEMIA	27/07/92	Detail	56			1	2	3	1		3	3	3	3	Y	
							Summary		27/07/92(*)	56	1	2	3	1		3	3	3	3	Y	YES
	415	Reboxetine	12/06/92	06/08/92	MOUTH DRY	15/06/92	Detail	7			1	2	3	1		2	3	3	3		
							Detail	14	20/06/92		1	2	3	1		2	3	3	1		
							Summary		20/06/92	14	1	2	3	1		2	3	3	1		YES
					NAUSEA	13/06/92	Detail	7	17/06/92		2	2	3	1		2	3	3	1		
							Summary		17/06/92	7	2	2	3	1		2	3	3	1		YES
	416	Fluoxetine	23/06/92	17/08/92	FATIGUE	25/06/92	Detail	7			2	2	3	1		2	3	3	3		
							Detail	14			1	2	3	1		2	3	3	3		
							Detail	21			1		3	1		3	3	3	3		
							Detail	28	16/07/92		1	2	3	1		3	3	3	1		
							Summary		16/07/92	28	2	2	3	1		2	3	3	1		YES
	418	Reboxetine	17/07/92	10/09/92	ANAEMIA	03/09/92	Detail	56			1	2	3	1		3	3	3		Y	
							Summary		10/09/92(*)	56	1	2	3	1		3	3	3		Y	YES
	419	Fluoxetine	16/07/92	09/09/92	HEADACHE	19/07/92	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		
							Detail	28			1	2	3	1		2	3	3	3		
							Detail	42	23/08/92		1	2	3	1		3	3	3	1		
							Summary		23/08/92	42	1	2	3	1		2	3	3	1		YES
	423	Fluoxetine	21/08/92	15/10/92	HEADACHE	25/08/92	Detail	14			2	2	3	1		3	3	3	3		
							Detail	21	06/09/92		2	2	3	1		3	3	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 28124/015
Listing No.: 17.8

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalization	Disapp.	Reapp.	Outcome	Still present	(C)
15	423	Fluoxetine	21/08/92	15/10/92	HEADACHE	25/08/92	Summary		06/09/92	21	2	2	3	1		3	3	3	1		YES
	424	Reboxetine	21/08/92	15/10/92	LIBIDO DECREASED	25/08/92	Detail	7			2	2	3	1		3	3	3	3		
							Detail	14	01/09/92		2	2	3	1		3	3	3	1		
							Summary		01/09/92	14	2	2	3	1		3	3	3	1		YES
					MICTURITION DISORDER	25/08/92	Detail	7	26/08/92		2	2	3	1		3	3	3	1		
							Summary		26/08/92	7	2	2	3	1		3	3	3	1		YES
						29/08/92	Detail	14	30/08/92		2	2	3	1		3	3	3	1		
							Summary		30/08/92	14	2	2	3	1		3	3	3	1		YES
	450	Fluoxetine	18/12/92	03/02/93	HEADACHE	12/12/92	Detail	7			2	2	3	1	YES	3	3	3	3		
							Detail	14			2	2	2	1	YES	3	3	3	3		
							Detail	21			2	2	3	1	YES	3	3	3	3		
							Detail	28	04/01/93		2	2	3	1	YES	3	3	3	1		
							Summary		04/01/93	28	2	2	2	1	YES	3	3	3	1		YES
	451	Fluoxetine	18/12/92	11/02/93	AGITATION	03/01/93	Detail	21			1	1	4	1		3	3	3	3		
							Detail	28	10/01/93		1	1	4	1		3	3	3	1		
							Summary		10/01/93	28	1	1	4	1		3	3	3	1		YES
					HEADACHE	31/12/92	Detail	14			2	2	3	1	YES	3	3	3	3		
							Detail	21			2	2	3	1	YES	3	3	3	3		
							Detail	28	12/01/93		1	2	3	1	YES	3	3	3	1		
							Summary		12/01/93	28	2	2	3	1	YES	3	3	3	1		YES
	452	Reboxetine	23/12/92	16/02/93	NAUSEA	24/12/92	Detail	7	28/12/92		2	2	3	1	YES	3	3	3	1		
							Summary		28/12/92	7	2	2	3	1	YES	3	3	3	1		YES
16	430	Reboxetine	30/03/92	25/05/92	EJACULATION DISORDER	10/04/92	Detail	14	12/04/92		2	2	3	1		3	3	3	1		
							Summary		12/04/92	14	2	2	3	1		3	3	3	1		YES
					MICTURITION DISORDER	04/04/92	Detail	7	05/04/92		1	2	4	1		3	3	3	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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospital	Disapp.	Reapp.	Outcome	Still present	(¢)
16	430	Reboxetine	30/03/92	25/05/92	MICTURITION DISORDER	04/04/92	Summary		05/04/92	7	1	2	4	1		3	3	3	1		YES
						21/04/92	Detail	28			1	2	3	1		3	3	3	3		
							Detail	35			1	2	2	1		3	3	3	3		
							Detail	42			1	2	2	1		3	3	3	3		
							Detail	49			1	2	2	1		3	3	3	3		
							Detail	56			1	2	3	1		2	3	3	3	Y	
							Summary		25/05/92(*)	56	1	2	2	1		2	3	3	3	Y	YES
	434	Fluoxetine	07/04/92	01/06/92	INSOMNIA	22/04/92	Detail	21			2	1	3	1	YES	2	1	3	3		
							Detail	28			1	1	3	1	YES	3	3	3	3		
							Detail	49			1	1	3	1	YES	3	3	3	3		
							Detail	56			1	1	3	1	YES	2	3		3	Y	
							Summary		01/06/92(*)	56	2	1	3	1	YES	2	3	3	3	Y	YES
	436	Fluoxetine	24/04/92	18/06/92	HYPOTENSION	11/05/92	Detail	49			2	2	2	2	YES	2	1	3	3		
							Detail	56	12/06/92		1	2	3	2	YES	3	2	3	1		
							Summary		12/06/92	56	2	2	2	2	YES	2	2	3	1		YES
					INSOMNIA	10/05/92	Detail	49			2	1	2	2		2	1	3	3		
							Detail	56			2	1	2	2		2	1	3	3	Y	
							Summary		18/06/92(*)	56	2	1	2	2		2	1	3	3	Y	YES
	438	Fluoxetine	20/05/92	18/06/92	BRONCHITIS	17/06/92	Detail	35	22/06/92		2	1	3	3	YES	2	2	3	1		
							Summary		22/06/92	35	2	1	3	3	YES	2	2	3	1		YES
					DIARRHOEA	18/06/92	Detail	35	20/06/92		2	2	3	3	YES	2	2	3	1		
							Summary		20/06/92	35	2	2	3	3	YES	2	2	3	1		YES
					VOMITING	18/06/92	Detail	35	20/06/92		2	2	3	3	YES	2	2	3	1		
							Summary		20/06/92	35	2	2	3	3	YES	2	2	3	1		YES
	442	Reboxetine	22/07/92	14/09/92	INSOMNIA	22/07/92	Detail	14			2	1	4	1	YES	2	3	3	3	Y	
							Summary		14/09/92(*)	14	2	1	4	1	YES	2	3	3	3	Y	YES

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, -- History: 1=preseat bafora, 2=nat observe bef., 3=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
(¢) adverse event used for statistical analysis
(*) adverse event still present: end date = visit date
(@) onset date missing: first report visit date used

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Stud drug	Symp trea	Hosp	Dis app.	Re app.	Out come	Still present	(C)
16	455	Fluoxetine	19/09/92	15/11/92	INSOMNIA	26/09/92	Detail	14			1	1	3	1	YES	2	3	3	3	Y	
							Summary		15/11/92(*)	14	1	1	3	1	YES	2	3	3	3	Y	YES
	456	Reboxetine	16/12/92	09/02/93	INSOMNIA	23/12/92	Detail	14			1	2	3	1	YES	2	3	3	3		
							Detail	56			1	2	3	1	YES	2	3	3	3	Y	
							Summary		09/02/93(*)	56	1	2	3	1	YES	2	3	3	3	Y	YES
	457	Fluoxetine	16/12/92	09/02/93	INSOMNIA	23/12/92	Detail	14			1	1	4	1	YES	2	3	3	3		
							Detail	49	28/01/93		1	1	6	1	YES	2	3	3	1		
							Summary		28/01/93	49	1	1	4	1	YES	2	3	3	1		YES
18	26	Reboxetine	06/10/92	30/11/92	TACHYCARDIA	03/11/92	Detail	28	05/11/92		1	3	3	1		2	3	3	1		
							Summary		05/11/92	28	1	3	3	1		2	3	3	1		YES
	50	Reboxetine	17/11/92	18/11/92	DIARRHOEA	18/11/92	Detail	7			1	3	6	3		1	1	1	3	Y	
							Summary		24/11/92(*)	7	1	3	6	3		1	1	1	3	Y	YES
					HYPERLIPAEMIA		Detail	0			1										
							Detail	0			1										
						09/11/92(@)	Summary		24/11/92(*)	0	1										NO
20	21	Fluoxetine	06/11/92	30/12/92	AGITATION	10/12/92	Detail	35			3	1	1	3	YES	2	1	3	3	Y	
							Summary		30/12/92(*)	35	3	1	1	3	YES	2	1	3	3	Y	YES
					HYPERCHOLESTEROLAEMIA	06/01/95	Detail	56			3	3	5	1		2	3	3	3	Y	
							Summary		30/12/92(*)	56	3	3	5	1		2	3	3	3	Y	YES
					INSOMNIA	11/11/92	Detail	7	13/11/92		2	1	2	1	YES	2	3	3	1		
							Summary		13/11/92	7	2	1	2	1	YES	2	3	3	1		YES
						27/11/92	Detail	28	04/12/92		2	2	3	1	YES	2	3	1	1		
							Summary		04/12/92	28	2	2	3	1	YES	2	3	1	1		YES

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=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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last report visit	Severity	History	Relationship	Study drug	Symptomatic treatment	Hospitalisation	Disapp.	Reapp.	Outcome	Still present	(C)
20	21	Fluoxetine	06/11/92	30/12/92	OEDEMA GENERALISED	20/11/92	Detail	14			1	2	2	1	YES	2	3	3	3		
							Detail	21	27/11/92										1		
							Summary		27/11/92	21	1	2	2	1	YES	2	3	3	1		YES
	22	Fluoxetine	12/11/92	16/12/92	INSOMNIA	23/11/92	Detail	14			3	1	2	1	YES	2	3	3	3	Y	
							Summary		17/12/92(*)	14	3	1	2	1	YES	2	3	3	3	Y	YES
21	9	Fluoxetine	19/10/92	13/12/92	INFLUENZA-LIKE SYMPTOMS	10/11/92	Detail	28			2	2	6	4	YES	2	1	3	3		
							Detail	35	19/11/92		2	2	6	4	YES	2	2	1	1		
							Summary		19/11/92	35	2	2	6	4	YES	2	2	1	1		YES
					PHARYNGITIS	10/11/92	Detail	28			2	2	6	4	YES	2	1	3	3		
							Detail	35	19/11/92		2	2	6	4	YES	2	2	1	1		
							Summary		19/11/92	35	2	2	6	4	YES	2	2	1	1		YES
22	113	Fluoxetine	03/12/92	18/12/92	AGITATION	18/12/92	Detail	21			2	3	3	3	YES	2	1	3	3	Y	
							Summary		21/12/92(*)	21	2	3	3	3	YES	2	1	3	3	Y	YES

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=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

947

9550083

PHARMACIA PHARMACEUTICAL RESEARCH - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 1 Patient: 2 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date							
			Screen		Day 14		Day 28		Day 56	
			25/06/92		10/07/92		24/07/92		21/08/92	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)	value	(◊)
HB	14-18 (G/DL)	10/11/91	14.40		15.10		15.10		15.60	
HT	42-52 (%)	10/11/91	42.00		44.00		44.00		46.00	
RBC	4.3-5.9 (10-6/MM3)	10/11/91	4.81		5.06		5.09		5.27	
WBC	4000-8000 (/MM3)	10/11/91	5280.00		6300.00		5900.00		6600.00	
WBC: N	50-70 (%)	10/11/91	67.00		57.00		61.00		69.00	
WBC: L	25-40 (%)	10/11/91	25.00		40.00		31.00		27.00	
WBC: E	2-4 (%)	10/11/91	3.00		3.00					
WBC: M	2-8 (%)	10/11/91	5.00		0.00	<			4.00	
WBC: B	0-1 (%)	10/11/91	0.00		0.00					
PLATELETS	150000-400000 (/MM3)	10/11/91	266000		253000		250000		272000	
NA+	135-150 (MEQ/L)	10/11/91	141.00		142.00		140.00		141.00	
K+	3.6-5.2 (MEQ/L)	10/11/91	4.30		4.30		4.20		4.30	
CL-	94-111 (MEQ/L)	10/11/91	107.00		104.00		103.00		104.00	
Ca++	4.4-5.5 (MEQ/L)	10/11/91	4.50		4.60		4.50			
PO4--	2.5-5 (MG/DL)	10/11/91			2.30	<	2.60			
SGOT	5-18 (U/L)	10/11/91	15.00		15.00		15.00			
SGPT	5-22 (U/L)	10/11/91	19.00		19.00		31.00	>		
GAMMA GT	6-28 (U/L)	10/11/91	45.00	>	29.00	>	51.00	>		
ALK. PHOSPH.	80-170 (U/L)	10/11/91					160.00		169.00	
GLUCOSE	70-110 (MG/100ML)	10/11/91							91.00	
CREATININE	0.7-1.2 (MG/DL)	10/11/91	0.90		0.90		0.90		1.00	
URIC ACID	3.4-7 (MG/100ML)	10/11/91	4.90		5.50				4.80	
TOT BILIRUBIN	0-1 (MG/100ML)	10/11/91	0.90		0.90		0.90		0.90	
DIR BILIRUBIN	0-0.24 (MG/DL)	10/11/91			0.00					
TOT. PROTEINS	6.5-7.9 (G/DL)	10/11/91					7.00		7.60	
ALBUMINE	51.8-65.4 (%)	10/11/91					64.10		65.70	>
TOT. CHOLEST.	130-220 (MG/100ML)	10/11/91	249.00	>					300.00	>>
TRIGLYCERIDES	74-172 (MG/100ML)	10/11/91	231.00	>>					280.00	>>
GLOBULINS ALPHA 1	2.2-5.6 (%)	10/11/91					2.10	<	2.60	
GLOBULINS ALPHA 2	5-10.2 (%)	10/11/91					9.10		7.40	
GLOBULINS BETA	8.8-15.6 (%)	10/11/91					10.60		10.90	
GLOBULINS GAMMA	11.9-23.3 (%)	10/11/91					14.60		13.40	
TSH	0.1-4 (UU/ML)	10/11/91	0.67							
T4	5-12.5 (UG/DL)	10/11/91	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 nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL RESEARCH - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 1 Patient: 4 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date							
			Screen		Day 14		Day 28		Day 42	
			12/08/92		28/08/92		11/09/92		25/09/92	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)	value	(◊)
HB	12-16 (G/DL)	10/11/91	13.70		14.30		14.50		14.10	
HT	37-47 (%)	10/11/91	41.00		44.00		44.00		41.00	
RBC	3.9-5.3 (10-6/MM3)	10/11/91	4.62		4.84		4.88		4.93	
WBC	4000-8000 (/MM3)	10/11/91	5300.00		5000.00		5900.00		4300.00	
WBC: N	50-70 (%)	10/11/91	73.00	>	77.00	>	77.00	>	75.00	>
WBC: L	25-40 (%)	10/11/91	22.00	<	20.00	<	19.00	<	20.00	<
PLATELETS	150000-400000 (/MM3)	10/11/91	238000		235000		224000		254000	
NA+	135-150 (MEQ/L)	10/11/91	139.00		141.00		142.00		141.00	
K+	3.6-5.2 (MEQ/L)	10/11/91	4.60		4.40		4.20		4.50	
CL-	94-111 (MEQ/L)	10/11/91	105.00		101.00		100.00		101.00	
Ca++	4.4-5.5 (MEQ/L)	10/11/91	4.40		4.80		4.70		4.60	
SGOT	5-15 (U/L)	10/11/91	10.00		12.00		17.00	>	269.00	>>
SGPT	5-17 (U/L)	10/11/91	10.00		14.00		20.00	>	515.00	>>
GAMMA GT	4-18 (U/L)	10/11/91	28.00	>	25.00	>	20.00	>	140.00	>>
LDH	120-240 (U/L)	10/11/91							240.00	
ALK. PHOSPH.	80-170 (U/L)	10/11/91	162.00				144.00		270.00	>
GLUCOSE	70-110 (MG/100ML)	10/11/91	92.00				69.00	<	83.00	
BUN	10-50 (MG/DL)	10/11/91	19.00							
CREATININE	0.5-1 (MG/DL)	10/11/91	0.80				0.80		0.70	
URIC ACID	2.4-5.7 (MG/100ML)	10/11/91	4.20				4.90		4.90	
TOT BILIRUBIN	0-1 (MG/100ML)	10/11/91	0.90				0.90			
TOT. PROTEINS	6.5-7.9 (G/DL)	10/11/91	6.50		6.70					
ALBUMINE	51.8-65.4 (%)	10/11/91	60.80							
TOT. CHOLEST.	130-220 (MG/100ML)	10/11/91	377.00	>>			346.00	>>	346.00	>>
TRIGLYCERIDES	74-172 (MG/100ML)	10/11/91	99.00				128.00			
GLOBULINS ALPHA 1	2.2-5.6 (%)	10/11/91	3.10		3.00					
GLOBULINS ALPHA 2	5-10.2 (%)	10/11/91	10.00		8.20					
GLOBULINS BETA	8.8-15.6 (%)	10/11/91	14.70		14.40					
GLOBULINS GAMMA	11.9-23.3 (%)	10/11/91	11.50	<	11.00	<				
TSH	0.1-4 (UU/ML)	10/11/91	0.11							
T4	5-12.5 (UG/DL)	10/11/91	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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centro: 2 Patient: 34 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date			
			Screen		Day 28	
			02/05/91		03/06/91	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)
HB	14-18 (G/DL)	01/03/91	14.40		14.90	
HT	0.38-0.57 (L/L)	01/03/91	0.42		0.42	
RBC	4.4-6 (10¬12/L)	01/03/91	4.38	<	4.44	
WBC	4.3-10 (10¬9/L)	01/03/91	4.10	<	5.40	
WBC: N	50-70 (%)	01/03/91	47.00	<	47.00	<
WBC: L	25-40 (%)	01/03/91	47.00	>	48.00	>
WBC: E	2-4 (%)	01/03/91	2.00		2.00	
WBC: M	2-6 (%)	01/03/91	4.00		3.00	
WBC: B	0-1 (%)	01/03/91	0.00		0.00	
PLATELETS	140-440 (10¬9/L)	01/03/91	94.00	<<	230.00	
NA+	135-145 (MMOL/L)	01/03/91	141.00		140.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.80		4.70	
CL-	98-108 (MMOL/L)	01/03/91	99.00		102.00	
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.30		2.30	
PO4--	0.81-1.61 (MMOL/L)	01/03/91	1.08		1.17	
SGOT	3-18 (U/L)	01/03/91	19.00	>	8.00	
SGPT	5-22 (U/L)	01/03/91	18.00		7.00	
GAMMA GT	6-28 (U/L)	01/03/91	40.00	>	18.00	
LDH	120-240 (U/L)	01/03/91	177.00		114.00	<
ALK. PHOSPH.	60-170 (U/L)	01/03/91	112.00		83.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	69.00	<	64.00	<
BUN	17-56 (MG/DL)	01/03/91	23.00		36.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.90		0.90	
URIC ACID	3.4-7 (MG/DL)	01/03/91			6.90	
TOT. PROTEINS	65-85 (G/L)	01/03/91	60.90	<	72.70	
ALBUMINE	36-58 (G/L)	01/03/91	38.90		48.20	
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	171.00		180.00	
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	107.00	<	69.00	<
GLOBULINS ALPHA 1	1.3-4.3 (G/L)	01/03/91	2.40		2.40	
GLOBULINS ALPHA 2	3.9-8.5 (G/L)	01/03/91	5.80		6.80	
GLOBULINS BETA	5.2-11.9 (G/L)	01/03/91	7.70		9.10	
GLOBULINS GAMMA	5.9-16.2 (G/L)	01/03/91	6.10		7.20	
TSH	0.3-3.5 (MU/L)	01/03/91	0.30			
T4	9-21 (NG/L)	01/03/91	14.00			

(¢) << 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
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL-MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 35 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			16/04/91		16/05/91		10/06/91	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/04/91	15.40		15.50		15.10	
HT	0.37-0.46 (L/L)	01/04/91	0.44		0.45		0.45	
RBC	4.2-5.5 (10¬12/L)	01/04/91	5.05		5.21		5.07	
WBC	4.3-10 (10¬9/L)	01/04/91	14.50	>>	9.90		10.40	>
WBC: N	50-70 (%)	01/04/91	67.00		60.00		61.00	
WBC: L	25-40 (%)	01/04/91	33.00		36.00		38.00	
WBC: E	2-4 (%)	01/04/91	0.00	<	2.00		0.00	<
WBC: M	2-6 (%)	01/04/91	0.00	<	1.00	<	0.00	<
WBC: B	0-1 (%)	01/04/91	0.00		1.00		0.00	
PLATELETS	140-440 (10¬9/L)	01/04/91	361.00		292.00		327.00	
NA+	135-145 (MMOL/L)	01/04/91	138.00		137.00		139.00	
K+	3.5-5 (MMOL/L)	01/04/91	4.20		4.10		4.20	
CL-	98-108 (MMOL/L)	01/05/91			100.00		102.00	
Ca++	2.3-2.75 (MMOL/L)	01/04/91	2.30		2.40		2.40	
PO4--	0.81-1.61 (MMOL/L)	01/04/91	1.06		0.99		0.98	
SGOT	3-15 (U/L)	01/04/91	9.00		13.00		12.00	
SGPT	5-17 (U/L)	01/04/91	12.00		18.00	>	17.00	
GAMMA GT	4-18 (U/L)	01/04/91	25.00	>	26.00	>	24.00	>
LDH	120-240 (U/L)	01/04/91	175.00		210.00		288.00	>
ALK. PHOSPH.	60-170 (U/L)	01/04/91	149.00		160.00		177.00	>
GLUCOSE	70-110 (MG/DL)	01/04/91	96.00		108.00		117.00	>
BUN	17-56 (MG/DL)	01/04/91	22.00		29.00		23.00	
CREATININE	0.4-1.2 (MG/DL)	01/04/91	0.80		0.50		0.50	
URIC ACID	2.4-5.7 (MG/DL)	01/04/91	6.60	>	6.00	>	5.60	
TOT BILIRUBIN	0-1 (MG/DL)	01/04/91	0.50		0.40		0.40	
TOT. PROTEINS	65-85 (G/L)	01/04/91	79.90		79.90		78.50	
ALBUMINE	56-68 (%)	01/04/91	59.20					
	36-58 (G/L)	01/05/91			42.90		48.20	
TOT. CHOLEST.	130-200 (MG/DL)	01/04/91	200.00		218.00	>	201.00	>
TRIGLYCERIDES	130-200 (MG/DL)	01/04/91	167.00		146.00		198.00	
GLOBULINS ALPHA 1	2-5 (%)	01/04/91	4.10					
	1.3-4.3 (G/L)	01/05/91			3.60		3.00	
GLOBULINS ALPHA 2	6-10 (%)	01/04/91	9.20					
	3.9-8.5 (G/L)	01/05/91			10.30	>	7.20	
GLOBULINS BETA	8-14 (%)	01/04/91	13.60					
	5.2-11.9 (G/L)	01/05/91			12.20	>	10.40	
GLOBULINS GAMMA	9-19 (%)	01/04/91	13.70					
	5.9-16.2 (G/L)	01/05/91			10.90		9.70	
TSH	0.3-3.5 (MU/L)	01/04/91	0.10	<<				
T4	9-21 (NG/L)	01/04/91	19.00					

(¢) << 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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centro: 2 Patient: 37 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date	
			Screen	
			01/10/91	
			value	(¢)
Laboratory test	Range value	Range date		
HB	14-18 (G/DL)	01/03/91	14.90	
HT	0.38-0.57 (L/L)	01/03/91	0.43	
RBC	4.4-6 (10¬12/L)	01/03/91	5.05	
WBC	4.3-10 (10¬9/L)	01/03/91	7.00	
WBC: N	50-70 (%)	01/03/91	50.00	
WBC: L	25-40 (%)	01/03/91	48.00	>
WBC: E	2-4 (%)	01/03/91	1.00	<
WBC: M	2-6 (%)	01/03/91	1.00	<
WBC: B	0-1 (%)	01/03/91	0.00	
PLATELETS	140-440 (10¬9/L)	01/03/91	203.00	
NA+	135-145 (MMOL/L)	01/03/91	141.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.20	
CL-	98-108 (MMOL/L)	01/03/91	97.00	<
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.40	
PO4--	0.81-1.61 (MMOL/L)	01/03/91	1.11	
SGOT	3-18 (U/L)	01/03/91	14.00	
SGPT	5-22 (U/L)	01/03/91	17.00	
GAMMA GT	6-28 (U/L)	01/03/91	22.00	
LDH	120-240 (U/L)	01/03/91	139.00	
ALK. PHOSPH.	60-170 (U/L)	01/03/91	115.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	67.00	<
BUN	17-56 (MG/DL)	01/03/91	55.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.90	
URIC ACID	3.4-7 (MG/DL)	01/03/91	7.30	>
TOT BILIRUBIN	0-1 (MG/DL)	01/03/91	0.30	
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	274.00	>>
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	241.00	>
TSH	0.3-3.5 (MU/L)	01/03/91	1.20	
T4	9-21 (NG/L)	01/03/91	12.20	

(¢) << 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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 40 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date	
			Screen	
			04/06/91	
			value	(¢)
Laboratory test	Range value	Range date		
HB	14-18 (G/DL)	01/03/91	15.90	
HT	0.38-0.57 (L/L)	01/03/91	0.45	
RBC	4.4-6 (10¬12/L)	01/03/91	4.80	
WBC	4.3-10 (10¬9/L)	01/03/91	14.50	>>
WBC: N	50-70 (%)	01/03/91	59.00	
WBC: L	25-40 (%)	01/03/91	38.00	
WBC: E	2-4 (%)	01/03/91	1.00	<
WBC: M	2-6 (%)	01/03/91	2.00	
WBC: B	0-1 (%)	01/03/91	0.00	
PLATELETS	140-440 (10¬9/L)	01/03/91	266.00	
NA+	135-145 (MMOL/L)	01/03/91	141.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.50	
CL-	98-108 (MMOL/L)	01/03/91	98.00	
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.50	
PO4--	0.81-1.61 (MMOL/L)	01/03/91	1.29	
SGOT	3-18 (U/L)	01/03/91	14.00	
SGPT	5-22 (U/L)	01/03/91	13.00	
GAMMA GT	6-28 (U/L)	01/03/91	21.00	
LDH	120-240 (U/L)	01/03/91	149.00	
ALK. PHOSPH.	60-170 (U/L)	01/03/91	126.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	85.00	
BUN	17-56 (MG/DL)	01/03/91	23.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.80	
URIC ACID	3.4-7 (MG/DL)	01/03/91	4.60	
TOT. PROTEINS	65-85 (G/L)	01/03/91	81.10	
ALBUMINE	36-58 (G/L)	01/03/91	51.20	
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	296.00	>>
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	113.00	<
GLOBULINS ALPHA 1	1.3-4.3 (G/L)	01/03/91	1.80	
GLOBULINS ALPHA 2	3.9-8.5 (G/L)	01/03/91	5.20	
GLOBULINS BETA	5.2-11.9 (G/L)	01/03/91	8.70	
GLOBULINS GAMMA	5.9-16.2 (G/L)	01/03/91	14.20	
TSH	0.3-3.5 (MU/L)	01/03/91	1.30	
T4	9-21 (NG/L)	01/03/91	16.40	

(¢) << 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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 42 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			04/03/92		02/04/92		30/04/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	01/03/91	14.50		14.70		15.70	
HT	0.37-0.46 (L/L)	01/03/91	0.44		0.45		0.48	>
RBC	4.2-5.5 (10¬12/L)	01/03/91	4.84		4.94		5.26	
WBC	4.3-10 (10¬9/L)	01/03/91	5.00		6.30		6.60	
WBC: N	50-70 (%)	01/03/91	55.00				46.00	<
WBC: L	25-40 (%)	01/03/91	40.00				50.00	>
WBC: E	2-4 (%)	01/03/91	3.00				1.00	<
WBC: M	2-6 (%)	01/03/91	2.00				2.00	
WBC: B	0-1 (%)	01/03/91	0.00				1.00	
PLATELETS	140-440 (10¬9/L)	01/03/91	238.00		299.00		343.00	
NA+	135-145 (MMOL/L)	01/03/91	142.00		140.00		138.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.80		4.90		4.00	
CL-	98-108 (MMOL/L)	01/03/91			98.00		92.00	<
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.60		2.60		2.50	
PO4--	0.81-1.61 (MMOL/L)	01/03/91	0.90		0.86			
SGOT	3-15 (U/L)	01/03/91	10.00		8.00		14.00	
SGPT	5-17 (U/L)	01/03/91	10.00		7.00		13.00	
GAMMA GT	4-18 (U/L)	01/03/91	9.00		9.00		12.00	
LDH	120-240 (U/L)	01/03/91	187.00		169.00		168.00	
ALK. PHOSPH.	60-170 (U/L)	01/03/91	67.00		80.00		106.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	89.00		85.00			
BUN	17-56 (MG/DL)	01/03/91	19.00		28.00		36.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.70		0.60		0.60	
URIC ACID	2.4-5.7 (MG/DL)	01/03/91	4.60		3.60		3.70	
TOT. PROTEINS	65-85 (G/L)	01/03/91	68.60		77.60		75.60	
ALBUMINE	36-58 (G/L)	01/03/91	44.70		51.00		49.30	
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	248.00	>	234.00	>	301.00	>>
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	68.00	<	87.00	<	108.00	<
GLOBULINS ALPHA 1	1.3-4.3 (G/L)	01/03/91	2.20		2.70		2.30	
GLOBULINS ALPHA 2	3.9-8.5 (G/L)	01/03/91	5.00		6.40		5.70	
GLOBULINS BETA	5.2-11.9 (G/L)	01/03/91	7.60		7.90		8.40	
GLOBULINS GAMMA	5.9-16.2 (G/L)	01/03/91	9.10		9.60		9.90	
TSH	0.3-3.5 (MU/L)	01/03/91	1.00					
T4	9-21 (NG/L)	01/03/91	13.50					

(¢) << 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

PHARMACIA PHARMACEUTICAL MILANO - CNS
9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 43 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date							
			Screen		Day 14		Day 28		Day 56	
			19/11/91		03/12/91		17/12/91		14/01/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	01/03/91	12.00		12.20		12.00		12.20	
HT	0.37-0.46 (L/L)	01/03/91	0.34	<	0.35	<	0.33	<	0.35	<
RBC	4.2-5.5 (10-12/L)	01/03/91	3.93	<	4.09	<	3.84	<	3.93	<
WBC	4.3-10 (10-9/L)	01/03/91	9.70		10.80	>	8.10		11.90	>
WBC: N	50-70 (%)	01/03/91	66.00		71.00	>	65.00		74.00	>
WBC: L	25-40 (%)	01/03/91	32.00		22.00	<	34.00		23.00	<
WBC: E	2-4 (%)	01/03/91	2.00		4.00		1.00	<	0.00	<
WBC: M	2-6 (%)	01/03/91	0.00	<	3.00		0.00	<	3.00	
WBC: B	0-1 (%)	01/03/91	0.00		0.00		0.00		0.00	
PLATELETS	140-440 (10-9/L)	01/03/91	294.00		371.00		281.00		271.00	
NA+	135-145 (MMOL/L)	01/03/91	138.00						138.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.70						4.00	
CL-	98-108 (MMOL/L)	01/03/91	98.00							
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.30						2.30	
PO4--	0.81-1.61 (MMOL/L)	01/03/91	0.91						0.77	<
SGOT	3-15 (U/L)	01/03/91	11.00				18.00	>	17.00	>
SGPT	5-17 (U/L)	01/03/91	15.00				22.00	>	25.00	>
GAMMA GT	4-18 (U/L)	01/03/91	25.00	>	17.00		19.00	>	59.00	>>
LDH	120-240 (U/L)	01/03/91	157.00				136.00		276.00	>
ALK. PHOSPH.	60-170 (U/L)	01/03/91	219.00	>	182.00	>	169.00		151.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	62.00	<					116.00	>
BUN	17-56 (MG/DL)	01/03/91	14.00	<			13.00	<	19.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.50				0.50		0.50	
URIC ACID	2.4-5.7 (MG/DL)	01/03/91	5.20				5.40		4.80	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/91	0.20				0.30		0.30	
TOT. PROTEINS	65-85 (G/L)	01/03/91	75.00				67.90		72.90	
ALBUMINE	56-68 (%)	01/03/91	63.30				45.50	<	62.40	
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	238.00	>	229.00	>	227.00	>	228.00	>
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	378.00	>>	239.00	>	203.00	>	239.00	>
GLOBULINS ALPHA 1	2-5 (%)	01/03/91	2.20				3.90		3.30	
GLOBULINS ALPHA 2	6-10 (%)	01/03/91	7.70				8.40		7.70	
GLOBULINS BETA	8-14 (%)	01/03/91	12.50				14.50	>	12.10	
GLOBULINS GAMMA	9-19 (%)	01/03/91	14.30				27.70	>>	14.50	
TSH	0.3-3.5 (MU/L)	01/03/91	1.50				0.90			
T4	9-21 (NG/L)	01/03/91	15.10				11.00			

(¢) << 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 PHARMACEUTICAL - MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 45 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			10/09/92		08/10/92	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	01/03/91	14.50		14.40	
HT	0.37-0.46 (L/L)	01/03/91	0.43		0.42	
RBC	4.2-5.5 (10¬12/L)	01/03/91	4.76		4.59	
WBC	4.3-10 (10¬9/L)	01/03/91	10.40	>	11.90	>
NBC: N	50-70 (%)	01/03/91	66.00		29.00	<<
NBC: L	25-40 (%)	01/03/91	31.00		59.00	>>
NBC: E	2-4 (%)	01/03/91	1.00	<	8.00	>>
NBC: M	2-6 (%)	01/03/91	1.00	<	3.00	
NBC: B	0-1 (%)	01/03/91	1.00		1.00	
PLATELETS	140-440 (10¬9/L)	01/03/91	427.00		265.00	
NA+	135-145 (MMOL/L)	01/03/91	142.00		131.00	<
K+	3.5-5 (MMOL/L)	01/03/91	4.60			
CL-	98-108 (MMOL/L)	01/03/91	108.00		101.00	
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.30		2.40	
PO4--	0.81-1.61 (MMOL/L)	01/03/91	0.96		1.00	
SGOT	3-15 (U/L)	01/03/91	6.00		9.00	
SGPT	5-17 (U/L)	01/03/91	5.00		6.00	
GAMMA GT	4-18 (U/L)	01/03/91	6.00		7.00	
LDH	120-240 (U/L)	01/03/91	120.00		225.00	
ALK. PHOSPH.	60-170 (U/L)	01/03/91	160.00		148.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	110.00		117.00	>
BUN	17-56 (MG/DL)	01/03/91	16.00	<	21.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.80		0.70	
URIC ACID	2.4-5.7 (MG/DL)	01/03/91	4.50		4.30	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/91	0.20		0.60	
TOT. PROTEINS	65-85 (G/L)	01/03/91			78.80	
ALBUMINE	56-68 (%)	01/03/91			65.30	
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	343.00	>>	124.00	<
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	276.00	>>	26.00	<
GLOBULINS ALPHA 1	2-5 (%)	01/03/91			3.00	
GLOBULINS ALPHA 2	6-10 (%)	01/03/91			8.50	
GLOBULINS BETA	8-14 (%)	01/03/91			10.00	
GLOBULINS GAMMA	9-19 (%)	01/03/91			13.20	
TSH	0.3-3.5 (MU/L)	01/03/91	0.80			
T4	9-21 (NG/L)	01/03/91	11.90			

(¢) << 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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 48 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			18/05/92		16/06/92		14/07/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	01/03/91	13.90		13.80		13.00	
HT	0.37-0.46 (L/L)	01/03/91	0.42		0.38		0.38	
RBC	4.2-5.5 (10¬12/L)	01/03/91	4.88		4.49		4.48	
WBC	4.3-10 (10¬9/L)	01/03/91	10.80	>	7.60		9.20	
WBC: N	50-70 (%)	01/03/91	67.00		86.00	>	78.00	>
WBC: L	25-40 (%)	01/03/91	30.00		12.00	<<	20.00	<
WBC: E	2-4 (%)	01/03/91	0.00	<	0.00	<	0.00	<
WBC: M	2-6 (%)	01/03/91	3.00		2.00		2.00	
WBC: B	0-1 (%)	01/03/91	0.00		0.00		0.00	
PLATELETS	140-440 (10¬9/L)	01/03/91	552.00	>	495.00	>	436.00	
NA+	135-145 (MMOL/L)	01/03/91	136.00		137.00		136.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.60		4.90		4.20	
CL-	98-108 (MMOL/L)	01/03/91	98.00		104.00		109.00	>
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.80	>	2.70		2.60	
PO4--	0.81-1.61 (MMOL/L)	01/03/91	1.21		0.89		0.79	<
SGOT	3-15 (U/L)	01/03/91	10.00		5.00		7.00	
SGPT	5-17 (U/L)	01/03/91	15.00		9.00		9.00	
GAMMA GT	4-18 (U/L)	01/03/91	11.00		12.00		11.00	
LDH	120-240 (U/L)	01/03/91	149.00		110.00	<	124.00	
ALK. PHOSPH.	60-170 (U/L)	01/03/91	147.00		137.00		125.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	95.00					
BUN	17-56 (MG/DL)	01/03/91	24.00		17.00		19.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.50		0.60		0.60	
URIC ACID	2.4-5.7 (MG/DL)	01/03/91			2.40		2.80	
TOT. PROTEINS	65-85 (G/L)	01/03/91	76.10		71.00		63.90	<
ALBUMINE	36-58 (G/L)	01/03/91	48.90		46.80		42.90	
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	320.00	>>	270.00	>>	264.00	>>
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	78.00	<	131.00		160.00	
GLOBULINS ALPHA 1	1.3-4.3 (G/L)	01/03/91	2.30		2.30		2.00	
GLOBULINS ALPHA 2	3.9-8.5 (G/L)	01/03/91	5.20		5.40		4.60	
GLOBULINS BETA	5.2-11.9 (G/L)	01/03/91	8.60		7.50		6.50	
GLOBULINS GAMMA	5.9-16.2 (G/L)	01/03/91	11.10		9.00		7.90	
TSH	0.3-3.5 (MU/L)	01/03/91	0.30					
T4	9-21 (NG/L)	01/03/91	11.00					

(¢) << 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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 3 Patient: 67 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			14/11/92		16/12/92	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	18/09/91	12.50		13.20	
HT	37-46 (%)	18/09/91	37.50		39.60	
RBC	4.4-6 (10¬12/L)	18/09/91	4.26	<	4.50	
WBC	4.3-10 (10¬9/L)	18/09/91	5.60		4.10	<
WBC: N	45-80 (%)	18/09/91	32.00	<	43.00	<
WBC: L	20-40 (%)	18/09/91	62.00	>>	54.00	>>
WBC: E	1-4 (%)	18/09/91	3.00		2.00	
WBC: M	2-8 (%)	18/09/91	3.00		1.00	<
WBC: B	0-1 (%)	18/09/91	0.00		0.00	
PLATELETS	140-440 (10¬9/L)	18/09/91	223.00		205.00	
NA+	132-146 (MMOL/L)	18/09/91	142.00		140.00	
K+	3.6-5 (MMOL/L)	18/09/91	4.60		4.40	
Ca++	2.2-2.7 (MMOL/L)	18/09/91	2.30		2.30	
SGOT	5-15 (U/L)	18/09/91	8.00		7.00	
SGPT	5-19 (U/L)	18/09/91	13.00		8.00	
GAMMA GT	4-18 (U/L)	18/09/91	10.00		5.00	
LDH	120-240 (U/L)	18/09/91	178.00		155.00	
ALK. PHOSPH.	40-190 (U/L)	18/09/91			106.00	
GLUCOSE	70-100 (MG/DL)	18/09/91	93.00		93.00	
CREATININE	0.5-0.9 (MG/DL)	18/09/91	0.90		0.70	
URIC ACID	2.4-5.7 (MG/DL)	18/09/91	2.80		3.20	
TOT BILIRUBIN	0-1 (MG/DL)	18/09/91	0.20		0.30	
TOT. PROTEINS	66-87 (G/L)	18/09/91	68.00		67.00	
ALBUMINE	58-70 (%)	18/09/91	62.20			
TOT. CHOLEST.	130-220 (MG/DL)	18/09/91	220.00		285.00	>
TRIGLYCERIDES	30-150 (MG/DL)	18/09/91	72.00		106.00	
GLOBULINS ALPHA 1	1.5-4 (%)	18/09/91	2.10			
GLOBULINS ALPHA 2	5-10 (%)	18/09/91	8.80			
GLOBULINS BETA	8-13 (%)	18/09/91	11.50			
GLOBULINS GAMMA	10-19 (%)	18/09/91	15.40			
TSH	0.1-3.5 (UU/ML)	18/09/91	3.30		4.10	>>
T4	5-12.5 (UG/100ML)	18/09/91	7.10		9.00	

(¢) << 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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 3 Patient: 68 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			26/11/92		28/12/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)
HB	12-16 (G/DL)	18/09/91	13.40		15.00	
HT	37-46 (%)	18/09/91	40.20		43.00	
RBC	4.4-6 (10¬12/L)	18/09/91	4.55		4.82	
WBC	4.3-10 (10¬9/L)	18/09/91	5.80		7.10	
WBC: N	45-80 (%)	18/09/91	66.00		51.00	
WBC: L	20-40 (%)	18/09/91	27.00		47.00	>
WBC: E	1-4 (%)	18/09/91	0.00	<	0.00	<
WBC: M	2-8 (%)	18/09/91	7.00		2.00	
WBC: B	0-1 (%)	18/09/91	0.00		0.00	
PLATELETS	140-440 (10¬9/L)	18/09/91	229.00		269.00	
NA+	132-146 (MMOL/L)	18/09/91	143.00		142.00	
K+	3.6-5 (MMOL/L)	18/09/91	4.30		4.40	
Ca++	2.2-2.7 (MMOL/L)	18/09/91	2.40		2.40	
SGOT	5-15 (U/L)	18/09/91	9.00		10.00	
SGPT	5-19 (U/L)	18/09/91	7.00		6.00	
GAMMA GT	4-18 (U/L)	18/09/91	6.00		8.00	
LDH	120-240 (U/L)	18/09/91	181.00		186.00	
ALK. PHOSPH.	40-190 (U/L)	18/09/91	104.00		115.00	
GLUCOSE	70-100 (MG/DL)	18/09/91	87.00		71.00	
CREATININE	0.5-0.9 (MG/DL)	18/09/91	0.80		0.90	
URIC ACID	2.4-5.7 (MG/DL)	18/09/91	2.80		4.50	
TOT BILIRUBIN	0-1 (MG/DL)	18/09/91	0.50		0.60	
TOT. PROTEINS	66-87 (G/L)	18/09/91	65.00	<	73.00	
ALBUMINE	58-70 (%)	18/09/91			68.40	
TOT. CHOLEST.	130-220 (MG/DL)	18/09/91	203.00		209.00	
TRIGLYCERIDES	30-150 (MG/DL)	18/09/91	64.00		70.00	
GLOBULINS ALPHA 1	1.5-4 (%)	18/09/91	2.60		2.50	
GLOBULINS ALPHA 2	5-10 (%)	18/09/91	6.70		6.50	
GLOBULINS BETA	8-13 (%)	18/09/91	10.60		9.80	
GLOBULINS GAMMA	10-19 (%)	18/09/91	12.50		12.80	
TSH	0.1-3.5 (UU/ML)	18/09/91	2.30			
T4	5-12.5 (UG/100ML)	18/09/91	7.70			

(¢) << 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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 4 Patient: 97 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			19/04/91		19/05/91		16/06/91	
			value	(◊)	value	(◊)	value	(◊)
Laboratory test	Range value	Range date						
HB	12-18 (G/DL)	15/04/91	12.20		12.30		13.00	
HT	37-54 (%)	15/04/91	36.60	<	37.50		39.40	
RBC	4.2-6.3 (10¬12/L)	15/04/91	4.01	<	4.08	<	4.29	
WBC	4.3-10 (10¬9/L)	15/04/91	4.90		5.80		5.00	
WBC: N	42.2-75.2 (%)	15/04/91	66.90		67.00		55.60	
WBC: L	1.2-3.4 (10¬9/L)	15/04/91	1.40		1.60		2.00	
WBC: M	0.11-0.59 (10¬9/L)	15/04/91	0.30		0.30		0.20	
PLATELETS	140-440 (10¬9/L)	15/04/91	426.00		395.00		408.00	
NA+	137-147 (MMOL/L)	15/04/91	141.00		145.00		142.00	
K+	3.5-5.3 (MMOL/L)	15/04/91	3.10	<	4.90		4.30	
CL-	98-111 (MMOL/L)	15/04/91	111.00		102.00		105.00	
Ca++	2.1-2.7 (MMOL/L)	15/04/91	2.35		2.58		2.58	
PO4--	2.3-4.2 (MMOL/L)	15/04/91	2.80		3.40		3.00	
SGOT	5-18 (U/L)	15/04/91	9.00		11.00		14.00	
SGPT	5-23 (U/L)	15/04/91	5.00		5.00		13.00	
GAMMA GT	6-28 (U/L)	15/04/91	8.00		7.00		7.00	
LDH	100-200 (U/L)	15/04/91	174.00		261.00	>	210.00	>
ALK. PHOSPH.	68-195 (U/L)	15/04/91	106.00		102.00		111.00	
GLUCOSE	70-117 (MG/DL)	15/04/91	91.00		99.00		72.00	
BUN	4-52 (MG/DL)	15/04/91	17.00		21.00		28.00	
CREATININE	0.3-1.39 (MG/DL)	15/04/91	1.00		0.70		1.10	
URIC ACID	2.9-7.4 (MG/DL)	15/04/91	4.20		5.20		4.60	
TOT BILIRUBIN	0.3-1.54 (MG/DL)	15/04/91	0.30		0.50		0.40	
DIR BILIRUBIN	0-0.3 (MG/DL)	15/04/91			0.06		0.03	
TOT. PROTEINS	6.6-8.3 (G/DL)	15/04/91	6.80		7.50		7.80	
ALBUMINE	3.7-5.4 (G/DL)	15/04/91	4.10		4.60		4.80	
TOT. CHOLEST.	150-260 (MG/DL)	15/04/91	271.00	>	310.00	>	354.00	>>
TRIGLYCERIDES	30-170 (MG/DL)	15/04/91	92.00		130.00		135.00	
GLOBULINS ALPHA 1	1-4 (%)	15/04/91	5.40	>>	4.30	>	5.60	>>
GLOBULINS ALPHA 2	6-11 (%)	15/04/91	9.40		9.90		8.40	
GLOBULINS BETA	10-15 (%)	15/04/91	14.50		11.00		11.60	
GLOBULINS GAMMA	12-22 (%)	15/04/91	13.70		22.10	>	20.30	
TSH	0.1-3.5 (UU/ML)	15/04/91	0.30					
T4	4.5-12.5 (UG/DL)	15/04/91	8.00					

(◊) << 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 PHARMACEUTICAL MILANO - CNS

9550085

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 4 Patient: 100 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date	
			Screen	
			08/05/92	
			value	(¢)
Laboratory test	Range value	Range date		
HB	12-18 (G/DL)	15/05/91	16.20	
HT	37-54 (%)	15/05/91	48.00	
RBC	4.2-6.3 (10¬12/L)	15/05/91	5.37	
WBC	4.3-10 (10¬9/L)	15/05/91	5.50	
WBC: N	42.2-75.2 (%)	15/05/91	73.90	
WBC: L	1.2-3.4 (10¬9/L)	15/05/91	1.20	
WBC: M	0.11-0.59 (10¬9/L)	15/05/91	0.20	
PLATELETS	140-440 (10¬9/L)	15/05/91	280.00	
NA+	137-147 (MMOL/L)	15/05/91	145.00	
K+	3.5-5.3 (MMOL/L)	15/05/91	4.40	
CL-	98-111 (MMOL/L)	15/05/91	104.00	
Ca++	2.1-2.7 (MMOL/L)	15/05/91	2.50	
PO4--	2.3-4.2 (MMOL/L)	15/05/91	2.70	
SGOT	5-18 (U/L)	15/05/91	8.00	
SGPT	5-23 (U/L)	15/05/91	14.00	
GAMMA GT	6-28 (U/L)	15/05/91	9.00	
LDH	100-200 (U/L)	15/05/91	159.00	
ALK. PHOSPH.	68-195 (U/L)	15/05/91	116.00	
GLUCOSE	70-117 (MG/DL)	15/05/91	111.00	
BUN	4-52 (MG/DL)	15/05/91	32.00	
CREATININE	0.3-1.39 (MG/DL)	15/05/91	1.10	
URIC ACID	2.9-7.4 (MG/DL)	15/05/91	6.10	
TOT BILIRUBIN	0.3-1.54 (MG/DL)	15/05/91	0.90	
DIR BILIRUBIN	0-0.3 (MG/DL)	15/05/91	0.20	
TOT. PROTEINS	6.6-8.3 (G/DL)	15/05/91	7.50	
ALBUMINE	3.7-5.4 (G/DL)	15/05/91	5.10	
TOT. CHOLEST.	150-260 (MG/DL)	15/05/91	161.00	
TRIGLYCERIDES	30-170 (MG/DL)	15/05/91	67.00	
TSH	0.1-3.5 (UU/ML)	15/05/91	1.40	
T4	4.5-12.5 (UG/DL)	15/05/91	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 PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 4 Patient: 101 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			02/07/92		30/07/92		27/08/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-18 (G/DL)	01/07/92	13.00		13.20		13.70	
HT	37-54 (%)	01/07/92	38.20		39.10		39.80	
RBC	4.2-6.3 (10¬12/L)	01/07/92	4.40		4.43		4.54	
WBC	4.3-10 (10¬9/L)	01/07/92	5.80		6.20		6.70	
WBC: N	42.2-75.2 (%)	29/07/92					67.80	
WBC: L	1.2-3.4 (10¬9/L)	01/07/92	1.90		1.70		1.90	
WBC: E	0-0.7 (10¬9/L)	29/07/92			0.00		0.00	
WBC: M	0.11-0.59 (10¬9/L)	29/07/92			0.30		0.30	
WBC: B	0-0.2 (10¬9/L)	29/07/92			0.00		0.00	
PLATELETS	140-440 (10¬9/L)	01/07/92	159.00		214.00		172.00	
NA+	137-147 (MMOL/L)	01/07/92	148.00	>	142.00		146.00	
K+	3.5-5.3 (MMOL/L)	01/07/92	3.90		3.70		3.70	
CL-	98-111 (MMOL/L)	01/07/92	111.00		105.00		106.00	
Ca++	2.1-2.7 (MMOL/L)	01/07/92	2.40		2.40		2.40	
PO4--	2.3-4.2 (MMOL/L)	01/07/92	3.50		2.90		3.10	
SGOT	5-18 (U/L)	01/07/92	4.00	<	6.00		7.00	
SGPT	5-23 (U/L)	01/07/92	5.00		6.00		13.00	
GAMMA GT	6-28 (U/L)	01/07/92	8.00		9.00		13.00	
LDH	100-200 (U/L)	01/07/92	100.00		105.00		124.00	
ALK. PHOSPH.	68-195 (U/L)	01/07/92	64.00	<	90.00		83.00	
GLUCOSE	70-117 (MG/DL)	01/07/92	84.00		63.00	<	81.00	
BUN	4-52 (MG/DL)	01/07/92	48.00		36.00		38.00	
CREATININE	0.3-1.39 (MG/DL)	01/07/92	0.70		0.70		0.80	
URIC ACID	2.9-7.4 (MG/DL)	01/07/92	4.20		4.20		3.80	
TOT BILIRUBIN	0.3-1.54 (MG/DL)	01/07/92	0.70		0.90		0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/07/92	0.20				0.10	
TOT. PROTEINS	6.6-8.3 (G/DL)	01/07/92	6.60		7.20		7.10	
ALBUMINE	3.7-5.4 (G/DL)	01/07/92	4.10		4.70		4.80	
TOT. CHOLEST.	150-260 (MG/DL)	01/07/92	177.00		261.00	>	216.00	
TRIGLYCERIDES	30-170 (MG/DL)	01/07/92	82.00		99.00		126.00	
GLOBULINS ALPHA 1	0.12-0.28 (G/DL)	01/07/92	0.20					
	1-4 (%)	29/07/92			3.60		3.50	
GLOBULINS ALPHA 2	0.45-0.82 (G/DL)	01/07/92	0.50					
	6-11 (%)	29/07/92			8.60		7.60	
GLOBULINS BETA	0.74-1.1 (G/DL)	01/07/92	0.70	<				
	10-15 (%)	29/07/92			11.70		11.10	
GLOBULINS GAMMA	0.88-1.6 (G/DL)	01/07/92	1.10					
	12-22 (%)	29/07/92			19.00		20.40	
TSH	0.1-3.5 (UU/ML)	01/07/92	0.50					
T4	4.5-12.5 (UG/DL)	01/07/92	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 PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 4 Patient: 104 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			17/08/92		15/09/92	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	12-18 (G/DL)	15/05/91	14.00		14.10	
HT	37-54 (%)	15/05/91	40.60		41.50	
RBC	4.2-6.3 (10¬12/L)	15/05/91	4.38		4.48	
WBC	4.3-10 (10¬9/L)	15/05/91	10.00		11.40	>
WBC: N	42.2-75.2 (%)	15/05/91	56.70		60.00	
WBC: L	1.2-3.4 (10¬9/L)	15/05/91	3.80	>	4.30	>
WBC: E	0-0.7 (10¬9/L)	14/09/92			0.00	
WBC: M	0.11-0.59 (10¬9/L)	15/05/91	0.50		0.30	
WBC: B	0-0.2 (10¬9/L)	14/09/92			0.00	
PLATELETS	140-440 (10¬9/L)	15/05/91	336.00		319.00	
NA+	137-147 (MMOL/L)	15/05/91	144.00		145.00	
K+	3.5-5.3 (MMOL/L)	15/05/91	4.10		4.00	
CL-	98-111 (MMOL/L)	15/05/91	112.00	>	104.00	
Ca++	2.1-2.7 (MMOL/L)	15/05/91	2.30		2.50	
PO4--	2.3-4.2 (MMOL/L)	15/05/91	3.70		3.40	
SGOT	5-18 (U/L)	15/05/91	6.00		7.00	
SGPT	5-23 (U/L)	15/05/91	4.00	<	6.00	
GAMMA GT	6-28 (U/L)	15/05/91	6.00		7.00	
LDH	100-200 (U/L)	15/05/91	127.00		152.00	
ALK. PHOSPH.	68-195 (U/L)	15/05/91	116.00		128.00	
GLUCOSE	70-117 (MG/DL)	15/05/91	85.00		96.00	
BUN	4-52 (MG/DL)	15/05/91	22.00		23.00	
CREATININE	0.3-1.39 (MG/DL)	15/05/91	0.70		0.70	
URIC ACID	2.9-7.4 (MG/DL)	15/05/91	4.80		4.30	
TOT BILIRUBIN	0.3-1.54 (MG/DL)	15/05/91	0.40		0.30	
DIR BILIRUBIN	0-0.3 (MG/DL)	15/05/91	0.10			
TOT. PROTEINS	6.6-8.3 (G/DL)	15/05/91	7.20		7.40	
ALBUMINE	3.7-5.4 (G/DL)	15/05/91	4.20		4.40	
TOT. CHOLEST.	150-260 (MG/DL)	15/05/91	223.00		271.00	>
TRIGLYCERIDES	30-170 (MG/DL)	15/05/91	162.00		192.00	>
GLOBULINS ALPHA 1	0.12-0.28 (G/DL)	15/05/91	0.30	>	0.30	>
GLOBULINS ALPHA 2	0.45-0.82 (G/DL)	15/05/91	0.70		0.70	
GLOBULINS BETA	0.74-1.1 (G/DL)	15/05/91	1.00		1.00	
GLOBULINS GAMMA	0.88-1.6 (G/DL)	15/05/91	1.20		1.30	
TSH	0.1-3.5 (UU/ML)	15/05/91	1.00			
T4	4.5-12.5 (UG/DL)	15/05/91	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 nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 5 Patient: 129 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			25/11/91		26/12/91	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)
HB	12.5-18 (G/DL)	09/09/91	14.80		14.30	
HT	37-47 (%)	09/09/91	42.10		40.70	
RBC	4.5-5.5 (10¬6/UL)	09/09/91	4.85		4.68	
WBC	4-10.8 (10¬3/UL)	09/09/91	6.30		7.40	
WBC: N	40-74 (%)	09/09/91	45.10		62.50	
WBC: L	19-48 (%)	09/09/91	48.30	>	30.90	
WBC: E	0-4 (%)	09/09/91	0.80		1.10	
WBC: M	3.4-9 (%)	09/09/91	5.30		5.00	
WBC: B	0-1.5 (%)	09/09/91	0.50		0.60	
PLATELETS	150-400 (10¬3/UL)	09/09/91	304.00		314.00	
NA+	135-148 (MEQ/L)	09/09/91	140.00		144.00	
K+	3.5-5.3 (MEQ/L)	09/09/91	4.20		4.40	
Ca++	8.1-10.4 (MG/DL)	09/09/91	10.30		10.20	
PO4--	2.5-5 (MG/DL)	09/09/91	3.70		4.20	
SGOT	4-40 (U/L)	09/09/91	18.00		20.00	
SGPT	4-40 (U/L)	09/09/91	15.00		25.00	
GAMMA GT	7-50 (U/L)	09/09/91	15.00		16.00	
LDH	230-460 (U/L)	09/09/91	324.00		328.00	
ALK. PHOSPH.	98-280 (U/L)	09/09/91	298.00	>	309.00	>
GLUCOSE	60-110 (MG/DL)	09/09/91	109.00		121.00	>
BUN	4-22 (MG/DL)	09/09/91	18.20		17.80	
CREATININE	0.3-1.2 (MG/DL)	09/09/91	1.00		0.90	
URIC ACID	2,4-7 (MG/DL)	09/09/91	4,20		3.80	
TOT BILIRUBIN	0.3-1.2 (MG/DL)	09/09/91	0.50		0.40	
TOT. PROTEINS	6-8 (G/DL)	09/09/91	7.60		7.60	
TOT. CHOLEST.	140-260 (MG/DL)	09/09/91	251.00		271.00	>
TRIGLYCERIDES	30-150 (MG/DL)	09/09/91	84.00		107.00	
TSH	0.4-4.5 (UU/ML)	09/09/91	1.18			
T4	0.8-2 (NG/100ML)	09/09/91	1.45			

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9550089

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 7 Patient: 193 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			03/12/91		02/01/92		30/01/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/12/91	11.50	<	13.80		13.90	
HT	37-47 (%)	01/12/91	35.60	<	41.00		40.00	
RBC	4.2-5.4 (10¬6/UL)	01/12/91	3.78	<	4.37		4.24	
WBC	4.3-10 (10¬3/UL)	01/12/91	6.49		6.40		6.80	
WBC: N	1.8-8 (10¬3/UL)	01/12/91	4.72		3.28		3.46	
WBC: L	1-5 (10¬3/UL)	01/12/91	1.04		2.40		2.65	
WBC: E	0-0.5 (10¬3/UL)	01/12/91	0.06		0.14		0.14	
WBC: M	0.1-0.8 (10¬3/UL)	01/12/91	0.51		0.39		0.46	
WBC: B	0-0.1 (10¬3/UL)	01/12/91	0.05		0.17	>>	0.07	
PLATELETS	150-350 (10¬3/UL)	01/12/91	203.00		284.00		299.00	
NA+	140-148 (MMOL/L)	01/12/91	139.00	<	147.00		146.00	
K+	3.9-5.1 (MMOL/L)	01/12/91	4.33		4.50		4.52	
CL-	96-109 (MMOL/L)	01/12/91	111.00	>	112.00	>	109.00	
Ca++	2.14-2.54 (MMOL/L)	01/12/91	2.26		2.49		2.38	
PO4--	0.85-1.33 (MMOL/L)	01/12/91	0.99		1.20		1.26	
SGOT	9-25 (U/L)	01/12/91	11.00		14.00		11.00	
SGPT	8-36 (U/L)	01/12/91	6.00	<	12.00		8.00	
GAMMA GT	7-43 (U/L)	01/12/91	11.00		17.00		15.00	
LDH	230-460 (U/L)	01/12/91	243.00		334.00		231.00	
ALK. PHOSPH.	81-263 (U/L)	01/12/91	113.00		162.00		145.00	
GLUCOSE	4.1-5.9 (MMOL/L)	01/12/91	4.10		4.70		4.40	
BUN	3.8-8.6 (MMOL/L)	01/12/91	4.20		3.50	<	2.60	<
CREATININE	55-94 (UMOL/L)	01/12/91	76.00		71.00		77.00	
URIC ACID	147-372 (UMOL/L)	01/12/91	163.00		203.00		194.00	
TOT BILIRUBIN	0-17 (UMOL/L)	01/12/91	4.00		4.00		8.00	
DIR BILIRUBIN	0-6 (UMOL/L)	01/12/91	2.00		2.00		3.00	
TOT. PROTEINS	64-76 (G/L)	01/12/91	63.40	<	79.80	>	68.90	
ALBUMINE	40-48 (G/L)	01/12/91	43.90		53.00	>	47.10	
TOT. CHOLEST.	4.3-7.6 (MMOL/L)	01/12/91	2.82	<	4.47		3.45	<
TRIGLYCERIDES	0.34-1.9 (MMOL/L)	01/12/91	1.08		0.41		0.49	
TSH	0.3-4 (MUI/L)	01/12/91	0.89					
T4	9-24 (PMOL/L)	01/12/91	8.76	<				

(¢) << 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 PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 7 Patient: 196 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 42	
			22/05/92		25/06/92		14/07/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/12/91	13.40		12.80			
HT	37-47 (%)	01/12/91	40.00		39.00			
RBC	4.2-5.4 (10¬6/UL)	01/12/91	4.61		4.34			
WBC	4.3-10 (10¬3/UL)	01/12/91	7.10		5.80			
WBC: N	1.8-8 (10¬3/UL)	01/12/91	3.37		3.07			
WBC: L	1-5 (10¬3/UL)	01/12/91	3.15		2.01			
WBC: E	0-0.5 (10¬3/UL)	01/12/91	0.13		0.19			
WBC: M	0.1-0.8 (10¬3/UL)	01/12/91	0.40		0.48			
WBC: B	0-0.1 (10¬3/UL)	01/12/91	0.02		0.03			
PLATELETS	150-350 (10¬3/UL)	01/12/91	286.00		288.00			
NA+	140-148 (MMOL/L)	01/12/91	142.00		146.00		141.00	
K+	3.9-5.1 (MMOL/L)	01/12/91	4.32		4.26		2.98	<<
CL-	96-109 (MMOL/L)	01/12/91	105.00		104.00		93.00	<
Ca++	2.14-2.54 (MMOL/L)	01/12/91	2.60	>	2.26		2.33	
PO4--	0.85-1.33 (MMOL/L)	01/12/91	1.40	>	1.08		1.27	
SGOT	9-25 (U/L)	01/12/91	49.00	>	124.00	>>	162.00	>>
SGPT	8-36 (U/L)	01/12/91	76.00	>>	248.00	>>	277.00	>>
GAMMA GT	7-43 (U/L)	01/12/91	50.00	>	136.00	>>	175.00	>>
LDH	230-460 (U/L)	01/12/91	326.00		441.00		433.00	
ALK. PHOSPH.	81-263 (U/L)	01/12/91	231.00		325.00	>	482.00	>
GLUCOSE	4.1-5.9 (MMOL/L)	01/12/91	4.70		5.20		6.90	>
BUN	3.8-8.6 (MMOL/L)	01/12/91	6.30		2.10	<	4.20	
CREATININE	55-94 (UMOL/L)	01/12/91	93.00		91.00		117.00	>
URIC ACID	147-372 (UMOL/L)	01/12/91	235.00		268.00		445.00	>
TOT BILIRUBIN	0-17 (UMOL/L)	01/12/91	4.00		10.00		10.00	
DIR BILIRUBIN	0-6 (UMOL/L)	01/12/91	2.00		6.00		4.00	
TOT. PROTEINS	64-76 (G/L)	01/12/91	79.70	>	73.90		83.50	>
ALBUMINE	40-48 (G/L)	01/12/91	47.70		48.50	>	51.00	>
TOT. CHOLEST.	4.3-7.6 (MMOL/L)	01/12/91	9.03	>	5.73		6.70	
TRIGLYCERIDES	0.34-1.9 (MMOL/L)	01/12/91	1.84		1.90		1.90	
TSH	0.3-4 (MUI/L)	01/12/91	4.26	>				
T4	9-24 (PMOL/L)	01/12/91	16.20					

(¢) << 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 CUS-R&D 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 322 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 56	
			06/11/91		03/01/92	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	115-145 (G/L)	01/10/91	130.00		136.00	
HT	0.42-0.5 (L/L)	01/10/91	0.39	<	0.39	<
RBC	4.2-5.2 (10~12/L)	01/10/91	4.41		4.50	
WBC	4.5-10 (10~9/L)	01/10/91	5.70		5.51	
WBC: N	40-70 (%)	01/10/91	64.10		47.30	
WBC: L	20-45 (%)	01/10/91	24.10		37.90	
WBC: E	1-5 (%)	01/10/91	1.40		2.70	
WBC: M	2-10 (%)	01/10/91	7.80		9.00	
WBC: B	0-1 (%)	01/10/91	0.50		0.90	
PLATELETS	150-350 (10~9/L)	01/10/91	178.00		255.00	
NA+	135-145 (MEQ/L)	01/10/91	142.00		139.00	
K+	3.5-4.5 (MEQ/L)	01/10/91	3.50		3.70	
CL-	95-106 (MEQ/L)	01/10/91				
Ca++	8.5-10.5 (MG/DL)	01/10/91	9.70		9.80	
PO4--	2.3-4.3 (MG/DL)	01/10/91	4.40	>	3.80	
SGOT	10-40 (UI/L)	01/10/91	20.00		21.00	
SGPT	10-40 (UI/L)	01/10/91	11.00		20.00	
GAMMA GT	5-40 (UI/L)	01/10/91	12.00		11.00	
LDH	250-450 (UI/L)	01/10/91	244.00	<	209.00	<
ALK. PHOSPH.	123-345 (UI/L)	01/10/91	126.00		116.00	<
GLUCOSE	64-107 (MG/DL)	01/10/91	92.00		88.00	
BUN	10-25 (MG/DL)	01/10/91	7.00	<	8.00	<
UREA	()	01/10/91				
CREATININE	0.5-1.3 (MG/DL)	01/10/91	0.70		0.60	
URIC ACID	1.9-7.4 (MG/DL)	01/10/91	2.70		3.20	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/10/91	1.10	>	1.10	>
DIR BILIRUBIN	()	01/10/91				
TOT. PROTEINS	60-80 (G/L)	01/10/91	72.00		67.00	
ALBUMINE	57-69 (%)	01/10/91	67.40		67.00	
TOT. CHOLEST.	148-247 (MG/DL)	01/10/91	153.00		144.00	<
TRIGLYCERIDES	50-150 (MG/DL)	01/10/91	57.00		64.00	
GLOBULINS ALPHA 1	2.1-3.5 (%)	01/10/91	2.40		3.10	
GLOBULINS ALPHA 2	6-10 (%)	01/10/91	6.40		6.10	
GLOBULINS BETA	6.5-11.5 (%)	01/10/91	7.80		8.00	
GLOBULINS GAMMA	15-22 (%)	01/10/91	16.00		15.80	
TSH	0.5-5 (UU/ML)	01/10/91				
T4	4.5-12.5 (UG/100ML)	01/10/91				

(¢) << 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

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 324 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			21/01/92		19/02/92		08/04/92	
			value	(◊)	value	(◊)	value	(◊)
Laboratory test	Range value	Range date						
HB	115-145 (G/L)	20/01/92	146.00	>	131.00			
	120-170 (G/L)	01/04/92					127.00	
HT	0.42-0.5 (L/L)	20/01/92	0.46		0.39	<		
	0.36-0.51 (L/L)	01/04/92					0.39	
RBC	4.2-5.2 (10¬12/L)	20/01/92	4.87		4.41			
	3.9-5.5 (10¬12/L)	01/04/92					4.35	
WBC	4.5-10 (10¬9/L)	20/01/92	7.90		8.33			
	4-11 (10¬9/L)	01/04/92					8.11	
WBC: N	40-70 (%)	20/01/92	77.50	>	77.40	>		
	45-75 (%)	01/04/92					81.70	>
WBC: L	20-45 (%)	20/01/92	10.20	<<	15.30	<		
	17-55 (%)	01/04/92					11.00	<<
WBC: E	1-5 (%)	20/01/92	1.30		0.80	<		
	0-5 (%)	01/04/92					0.40	
WBC: M	2-10 (%)	20/01/92	8.30		4.90		5.80	
WBC: B	0-1 (%)	20/01/92	0.60		0.50			
	0-2 (%)	01/04/92					0.30	
PLATELETS	150-350 (10¬9/L)	20/01/92	205.00		175.00			
	150-400 (10¬9/L)	01/04/92					247.00	
NA+	135-145 (MEQ/L)	20/01/92	144.00		140.00		137.00	
K+	3.5-4.5 (MEQ/L)	20/01/92	4.20		3.70		3.80	
CL-	95-106 (MEQ/L)	20/01/92	98.00		99.00		97.00	
Ca++	8.5-10.5 (MG/DL)	20/01/92	10.50		9.90		9.20	
PO4--	2.3-4.3 (MG/DL)	20/01/92	3.60		3.10		3.10	
SGOT	10-40 (UI/L)	20/01/92	21.00		15.00		31.00	
SGPT	10-40 (UI/L)	20/01/92	14.00		11.00		47.00	>
GAMMA GT	5-40 (UI/L)	20/01/92	28.00		23.00		80.00	>>
LDH	250-450 (UI/L)	20/01/92	242.00	<	271.00		337.00	
ALK. PHOSPH.	123-345 (UI/L)	20/01/92	189.00		151.00		272.00	
GLUCOSE	64-107 (MG/DL)	20/01/92	89.00		85.00		76.00	
BUN	10-25 (MG/DL)	20/01/92	18.00		23.00		17.00	
CREATININE	0.5-1.3 (MG/DL)	20/01/92	0.70		0.70		0.60	
URIC ACID	1.9-7.4 (MG/DL)	20/01/92	2.10		2.40		1.30	<
TOT BILIRUBIN	0.1-1 (MG/DL)	20/01/92	0.60		0.70		0.60	
TOT. PROTEINS	60-80 (G/L)	20/01/92	76.00		74.00		71.00	
ALBUMINE	57-69 (%)	20/01/92	69.40	>	69.90	>	60.30	
TOT. CHOLEST.	148-247 (MG/DL)	20/01/92	263.00	>	226.00		196.00	
TRIGLYCERIDES	50-150 (MG/DL)	20/01/92	108.00		70.00		66.00	
GLOBULINS ALPHA 1	2.1-3.5 (%)	20/01/92	2.70		2.40		3.70	>
GLOBULINS ALPHA 2	6-10 (%)	20/01/92	7.80		8.30		11.50	>
GLOBULINS BETA	6.5-11.5 (%)	20/01/92	10.10		9.50		11.50	
GLOBULINS GAMMA	15-22 (%)	20/01/92	9.80	<<	9.90	<<	13.00	<
TSH	0.5-5 (UU/ML)	20/01/92	1.00					
T4	4.5-12.5 (UG/100ML)	20/01/92	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

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 325 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			14/01/92		04/03/92		07/04/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	115-145 (G/L)	01/01/92	120.00		133.00			
	120-170 (G/L)	05/04/92					128.00	
HT	0.42-0.5 (L/L)	01/01/92	0.35	<<	0.40	<		
	0.36-0.51 (L/L)	05/04/92					0.37	
RBC	4.2-5.2 (10¬12/L)	01/01/92	4.19	<	4.57			
	3.9-5.5 (10¬12/L)	05/04/92					4.56	
WBC	4.5-10 (10¬9/L)	01/01/92	6.51		6.44			
	4-11 (10¬9/L)	05/04/92					5.28	
WBC: N	40-70 (%)	01/01/92	51.30		51.80			
	45-75 (%)	05/04/92					47.50	
WBC: L	20-45 (%)	01/01/92	34.80		33.50			
	17-55 (%)	05/04/92					38.20	
WBC: E	1-5 (%)	01/01/92	5.40	>	6.80	>>		
	0-5 (%)	05/04/92					4.70	
WBC: M	2-10 (%)	01/01/92	4.80		4.50		6.20	
WBC: B	0-1 (%)	01/01/92	0.70		0.70			
	0-2 (%)	05/04/92					1.00	
PLATELETS	150-350 (10¬9/L)	01/01/92	339.00		382.00	>		
	150-400 (10¬9/L)	05/04/92					372.00	
NA+	135-145 (MEQ/L)	01/01/92	142.00		146.00	>	141.00	
K+	3.5-4.5 (MEQ/L)	01/01/92	3.80		4.30		3.70	
CL-	95-106 (MEQ/L)	01/01/92			103.00		98.00	
Ca++	8.5-10.5 (MG/DL)	01/01/92	10.00		10.10		9.40	
PO4--	2.3-4.3 (MG/DL)	01/01/92	4.00		3.90		4.20	
SGOT	10-40 (UI/L)	01/01/92	16.00		20.00		15.00	
SGPT	10-40 (UI/L)	01/01/92	18.00		24.00		15.00	
GAMMA GT	5-40 (UI/L)	01/01/92	19.00		13.00		13.00	
LDH	250-450 (UI/L)	01/01/92	265.00		319.00		276.00	
ALK. PHOSPH.	123-345 (UI/L)	01/01/92	116.00	<	128.00		92.00	<
GLUCOSE	64-107 (MG/DL)	01/01/92	86.00		89.00		86.00	
BUN	10-25 (MG/DL)	01/01/92	9.00	<	13.00		8.00	<
CREATININE	0.5-1.3 (MG/DL)	01/01/92	0.70		0.80		0.70	
URIC ACID	1.9-7.4 (MG/DL)	01/01/92	4.60		5.10		4.10	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/01/92	0.40		0.30		0.40	
TOT. PROTEINS	60-80 (G/L)	01/01/92	71.00		74.00		73.00	
ALBUMINE	57-69 (%)	01/01/92	64.80		65.60		65.50	
TOT. CHOLEST.	148-247 (MG/DL)	01/01/92	231.00		240.00		222.00	
TRIGLYCERIDES	50-150 (MG/DL)	01/01/92	176.00	>	151.00	>	156.00	>
GLOBULINS ALPHA 1	2.1-3.5 (%)	01/01/92	3.90	>	2.70		3.40	
GLOBULINS ALPHA 2	6-10 (%)	01/01/92	7.30		6.60		6.80	
GLOBULINS BETA	6.5-11.5 (%)	01/01/92	11.80	>	11.30		11.20	
GLOBULINS GAMMA	15-22 (%)	01/01/92	12.20	<	13.80	<	13.10	<
TSH	0.5-5 (UU/ML)	01/01/92	9.50	>>				
T4	4.5-12.5 (UG/100ML)	01/01/92	11.40					

(¢) << 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 PHARMACEUTICAL MILANO - CNS

9990085

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 326 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			29/01/92		20/03/92		07/04/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	115-145 (G/L)	25/01/92	136.00					
	120-170 (G/L)	15/03/92			152.00		148.00	
HT	0.42-0.5 (L/L)	25/01/92	0.41	<				
	0.36-0.51 (L/L)	15/03/92			0.46		0.45	
RBC	4.2-5.2 (10¬12/L)	25/01/92	4.48					
	3.9-5.5 (10¬12/L)	15/03/92			5.03		5.07	
WBC	4.5-10 (10¬9/L)	25/01/92	6.99					
	4-11 (10¬9/L)	15/03/92			6.89		6.47	
WBC: N	40-70 (%)	25/01/92	51.70					
	45-75 (%)	15/03/92			44.80	<	43.30	<
WBC: L	20-45 (%)	25/01/92	34.30					
	17-55 (%)	15/03/92			42.90		40.50	
WBC: E	1-5 (%)	25/01/92	1.40					
	0-5 (%)	15/03/92			0.90		0.70	
WBC: M	2-10 (%)	25/01/92	9.90		8.30		2.62	
WBC: B	0-1 (%)	25/01/92	0.50					
	0-2 (%)	15/03/92			0.50		0.08	
PLATELETS	150-350 (10¬9/L)	25/01/92	272.00					
	150-400 (10¬9/L)	15/03/92			326.00		300.00	
NA+	135-145 (MEQ/L)	25/01/92	141.00		136.00		140.00	
K+	3.5-4.5 (MEQ/L)	25/01/92	4.00		4.20		4.30	
CL-	95-106 (MEQ/L)	25/01/92	98.00		97.00		97.00	
Ca++	8.5-10.5 (MG/DL)	25/01/92	9.00		9.70		9.50	
PO4--	2.3-4.3 (MG/DL)	25/01/92	3.10		3.20		3.20	
SGOT	10-40 (UI/L)	25/01/92	15.00		14.00		13.00	
SGPT	10-40 (UI/L)	25/01/92	28.00		24.00		20.00	
GAMMA GT	5-40 (UI/L)	25/01/92	22.00		16.00		19.00	
LDH	250-450 (UI/L)	25/01/92	355.00		319.00		343.00	
ALK. PHOSPH.	123-345 (UI/L)	25/01/92	190.00		234.00		245.00	
GLUCOSE	64-107 (MG/DL)	25/01/92	270.00	>>	346.00	>>	311.00	>>
BUN	10-25 (MG/DL)	25/01/92	19.00		18.00		15.00	
CREATININE	0.5-1.3 (MG/DL)	25/01/92	0.80		1.00		1.00	
URIC ACID	1.9-7.4 (MG/DL)	25/01/92	2.00		2.10		2.70	
TOT BILIRUBIN	0.1-1 (MG/DL)	25/01/92	0.80		0.90		0.70	
TOT. PROTEINS	60-80 (G/L)	25/01/92	67.00		70.00		70.00	
ALBUMINE	57-69 (%)	25/01/92	64.00		66.20		61.10	
TOT. CHOLEST.	148-247 (MG/DL)	25/01/92	214.00		245.00		272.00	>
TRIGLYCERIDES	50-150 (MG/DL)	25/01/92	110.00		125.00		172.00	>
GLOBULINS ALPHA 1	2.1-3.5 (%)	25/01/92	2.70		2.20		2.60	
GLOBULINS ALPHA 2	6-10 (%)	25/01/92	8.70		7.60		9.70	
GLOBULINS BETA	6.5-11.5 (%)	25/01/92	12.90	>	12.70	>	13.00	>
GLOBULINS GAMMA	15-22 (%)	25/01/92	11.70	<	11.30	<	13.10	<
TSH	0.5-5 (UU/ML)	25/01/92	2.10					
T4	4.5-12.5 (UG/100ML)	25/01/92	6.30					

(¢) << 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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 329 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			16/03/92		11/05/92		25/05/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	120-170 (G/L)	15/03/92	131.00		135.00		130.00	
HT	0,36-0.51 (L/L)	15/03/92	0.39		0.38		0.39	
RBC	3.9-5.5 (10¬12/L)	15/03/92	4.44		4.39		4.44	
WBC	4-11 (10¬9/L)	15/03/92	5.17		7.65		5.79	
WBC: N	45-75 (%)	15/03/92	72.50		73.30		64.50	
WBC: L	17-55 (%)	15/03/92	19.50		18.20		25.40	
WBC: E	0-5 (%)	15/03/92	0.90		1.20		1.20	
WBC: M	2-10 (%)	15/03/92	5.20		5.20		6.70	
WBC: B	0-2 (%)	15/03/92	0.20		0.40		0.50	
PLATELETS	150-400 (10¬9/L)	15/03/92	169.00		228.00		178.00	
NA+	135-145 (MEQ/L)	15/03/92	140.00		142.00		138.00	
K+	3.5-4.5 (MEQ/L)	15/03/92	4.00		4.40		4.20	
CL-	95-106 (MEQ/L)	15/03/92	101.00		101.00			
Ca++	8.5-10.5 (MG/DL)	15/03/92	8.40	<	8.70		8.90	
PO4--	2.3-4.3 (MG/DL)	15/03/92	2.30		2.60		2.80	
SGOT	10-40 (UI/L)	15/03/92	20.00		17.00		17.00	
SGPT	10-40 (UI/L)	15/03/92	21.00		26.00		18.00	
GAMMA GT	5-40 (UI/L)	15/03/92	9.00		12.00		9.00	
LDH	250-450 (UI/L)	15/03/92	243.00	<	250.00		283.00	
ALK. PHOSPH.	123-345 (UI/L)	15/03/92	103.00	<	107.00	<	131.00	
GLUCOSE	64-107 (MG/DL)	15/03/92	92.00		107.00		113.00	>
BUN	10-25 (MG/DL)	15/03/92	11.00		15.00		19.00	
CREATININE	0,5-1.3 (MG/DL)	15/03/92	0.40	<	0.80		0.80	
URIC ACID	1.9-7.4 (MG/DL)	15/03/92	3.20		3.60		3.10	
TOT BILIRUBIN	0.1-1 (MG/DL)	15/03/92	0.40		0.50		0.40	
TOT. PROTEINS	60-80 (G/L)	15/03/92	62.00		65.00		66.00	
ALBUMINE	57-69 (%)	15/03/92			64.40			
	27-58 (G/L)	20/05/92					39.00	
TOT. CHOLEST.	148-247 (MG/DL)	15/03/92	178.00		165.00		173.00	
TRIGLYCERIDES	50-150 (MG/DL)	15/03/92	48.00	<	56.00		51.00	
GLOBULINS ALPHA 1	2.1-3.5 (%)	15/03/92			4.00	>	3.10	
GLOBULINS ALPHA 2	6-10 (%)	15/03/92			8.40		7.00	
GLOBULINS BETA	6.5-11.5 (%)	15/03/92			9.30		9.20	
GLOBULINS GAMMA	15-22 (%)	15/03/92			13.90	<	14.40	<
TSH	0.5-5 (UU/ML)	15/03/92	1.50					
T4	4.5-12.5 (UG/DL)	15/03/92	10.30					

(¢) << 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
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS

9990083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 330 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date			
			Screen		Day 28	
			03/04/92		27/05/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)
HB	120-170 (G/L)	01/04/92	141.00		132.00	
HT	0.36-0.51 (L/L)	01/04/92	0.41		0.41	
RBC	3.9-5.5 (10¬12/L)	01/04/92	4.91		4.67	
WBC	4-11 (10¬9/L)	01/04/92	5.42		5.90	
WBC: N	45-75 (%)	01/04/92	64.30		59.10	
WBC: L	17-55 (%)	01/04/92	22.60		25.80	
WBC: E	0-5 (%)	01/04/92	3.40		5.10	>
WBC: M	2-10 (%)	01/04/92	6.60		6.90	
WBC: B	0-2 (%)	01/04/92	1.00		1.50	
PLATELETS	150-400 (10¬9/L)	01/04/92	191.00		165.00	
NA+	135-145 (MEQ/L)	01/04/92	140.00		138.00	
K+	3.5-4.5 (MEQ/L)	01/04/92	3.90		4.30	
CL-	95-106 (MEQ/L)	01/04/92	98.00		99.00	
Ca++	8.5-10.5 (MG/DL)	01/04/92	8.80		8.80	
PO4--	2.3-4.3 (MG/DL)	01/04/92	3.60		3.30	
SGOT	10-40 (UI/L)	01/04/92	23.00		19.00	
SGPT	10-40 (UI/L)	01/04/92	19.00		17.00	
GAMMA GT	5-40 (UI/L)	01/04/92	17.00		12.00	
LDH	250-450 (UI/L)	01/04/92	317.00		285.00	
ALK. PHOSPH.	123-345 (UI/L)	01/04/92	157.00		157.00	
GLUCOSE	64-107 (MG/DL)	01/04/92	93.00		102.00	
BUN	10-25 (MG/DL)	01/04/92	17.00		18.00	
CREATININE	0.5-1.3 (MG/DL)	01/04/92	1.10		0.90	
URIC ACID	1.9-7.4 (MG/DL)	01/04/92	6.80		5.30	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/04/92	1.60	>	0.60	
TOT. PROTEINS	60-80 (G/L)	01/04/92	67.00		67.00	
ALBUMINE	57-69 (%)	01/04/92	71.50	>		
	27-58 (G/L)	25/05/92			40.00	
TOT. CHOLEST.	148-247 (MG/DL)	01/04/92	196.00		158.00	
TRIGLYCERIDES	50-150 (MG/DL)	01/04/92	56.00		99.00	
GLOBULINS ALPHA 1	2.1-3.5 (%)	01/04/92	2.30			
GLOBULINS ALPHA 2	6-10 (%)	01/04/92	6.20			
GLOBULINS BETA	6.5-11.5 (%)	01/04/92	10.10			
GLOBULINS GAMMA	15-22 (%)	01/04/92	9.90	<<		
TSH	0.5-5 (UU/ML)	01/04/92	2.00			
T4	4.5-12.5 (UG/DL)	01/04/92	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 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 333 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			17/07/92		13/10/92	
			value	(◊)	value	(◊)
Laboratory test	Range value	Range date				
HB	120-170 (G/L)	13/03/92			129.00	
HT	0.36-0.51 (L/L)	13/03/92			0.40	
RBC	3.9-5.5 (10¬12/L)	13/03/92			4.84	
WBC	4-11 (10¬9/L)	13/03/92			7.68	
WBC: N	45-75 (%)	13/03/92			64.50	
WBC: L	17-55 (%)	13/03/92			26.30	
WBC: E	0-5 (%)	13/03/92			0.80	
WBC: M	2-10 (%)	13/03/92			5.50	
WBC: B	0-2 (%)	13/03/92			1.00	
PLATELETS	150-400 (10¬9/L)	13/03/92			188.00	
NA+	135-145 (MEQ/L)	13/03/92	144.00		141.00	
K+	3.5-4.5 (MEQ/L)	13/03/92	4.00		4.00	
CL-	95-106 (MEQ/L)	13/03/92			101.00	
Ca++	8.5-10.5 (MG/DL)	13/03/92	9.30		9.40	
PO4--	2.3-4.3 (MG/DL)	13/03/92	3.00		3.30	
SGOT	10-40 (UI/L)	13/03/92	9.00	<	16.00	
SGPT	10-40 (UI/L)	13/03/92	16.00		14.00	
GAMMA GT	5-40 (UI/L)	13/03/92	14.00		21.00	
LDH	250-450 (UI/L)	13/03/92			251.00	
ALK. PHOSPH.	123-345 (UI/L)	13/03/92	91.00	<	101.00	<
GLUCOSE	64-107 (MG/DL)	13/03/92	99.00		96.00	
BUN	10-25 (MG/DL)	13/03/92	16.00		16.00	
UREA	()	13/03/92				
CREATININE	0.5-1.3 (MG/DL)	13/03/92	0.90		0.70	
URIC ACID	1.9-7.4 (MG/DL)	13/03/92	4.90		4.50	
TOT BILIRUBIN	0.1-1 (MG/DL)	13/03/92	0.50		0.30	
DIR BILIRUBIN	()	13/03/92				
TOT. PROTEINS	60-80 (G/L)	13/03/92	74.00		74.00	
ALBUMINE	27-58 (G/L)	13/03/92	45.00		45.00	
TOT. CHOLEST.	148-247 (MG/DL)	13/03/92	174.00		179.00	
TRIGLYCERIDES	50-150 (MG/DL)	13/03/92	120.00		89.00	
GLOBULINS ALPHA 1	2.1-3.5 (%)	13/03/92	3.20			
GLOBULINS ALPHA 2	6-10 (%)	13/03/92	7.80			
GLOBULINS BETA	6.5-11.5 (%)	13/03/92	10.60			
GLOBULINS GAMMA	15-22 (%)	13/03/92	15.10			
TSH	0.5-5 (UU/ML)	13/03/92	0.80			
T4	4.5-12.5 (UG/DL)	13/03/92	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

PHARMACIA PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 335 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			02/10/92		10/11/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)
HB	120-170 (G/L)	13/03/92	128.00		126.00	
HT	0.36-0.51 (L/L)	13/03/92	0.39		0.37	
RBC	3.9-5.5 (10¬12/L)	13/03/92	4.45		4.36	
MBC	4-11 (10¬9/L)	13/03/92	5.21		3.69	<
WBC: N	45-75 (%)	13/03/92	58.20		55.10	
WBC: L	17-55 (%)	13/03/92	29.90		33.60	
WBC: E	0-5 (%)	13/03/92	1.40		1.80	
WBC: M	2-10 (%)	13/03/92	5.80		6.50	
WBC: B	0-2 (%)	13/03/92	1.00		0.60	
PLATELETS	150-400 (10¬9/L)	13/03/92	321.00		253.00	
NA+	135-145 (MEQ/L)	13/03/92	138.00		136.00	
K+	3.5-4.5 (MEQ/L)	13/03/92	4.00		3.50	
CL-	95-106 (MEQ/L)	13/03/92	99.00		105.00	
Ca++	8.5-10.5 (MG/DL)	13/03/92	9.60		9.40	
PO4--	2.3-4.3 (MG/DL)	13/03/92	3.30		2.90	
SGOT	10-40 (UI/L)	13/03/92	17.00		12.00	
SGPT	10-40 (UI/L)	13/03/92	20.00		7.00	<
GAMMA GT	5-40 (UI/L)	13/03/92	17.00		10.00	
LDH	250-450 (UI/L)	13/03/92			248.00	<
ALK. PHOSPH.	123-345 (UI/L)	13/03/92	141.00		125.00	
GLUCOSE	64-107 (MG/DL)	13/03/92	77.00		72.00	
BUN	10-25 (MG/DL)	13/03/92	15.00		11.00	
CREATININE	0.5-1.3 (MG/DL)	13/03/92	0.60		0.50	
URIC ACID	1.9-7.4 (MG/DL)	13/03/92	3.50		2.40	
TOT BILIRUBIN	0.1-1 (MG/DL)	13/03/92	0.30		0.30	
TOT. PROTEINS	60-80 (G/L)	13/03/92	76.00		71.00	
ALBUMINE	27-58 (G/L)	13/03/92	47.00		43.00	
TOT. CHOLEST.	148-247 (MG/DL)	13/03/92	165.00		142.00	<
TRIGLYCERIDES	50-150 (MG/DL)	13/03/92	43.00	<	38.00	<
GLOBULINS ALPHA 1	2.1-3.5 (%)	13/03/92	3.90	>	3.50	
GLOBULINS ALPHA 2	6-10 (%)	13/03/92	8.60		7.20	
GLOBULINS BETA	6.5-11.5 (%)	13/03/92	10.00		8.90	
GLOBULINS GAMMA	15-22 (%)	13/03/92	15.00		16.10	
TSH	0.5-5 (UU/ML)	13/03/92	0.50			
T4	4.5-12.5 (UG/DL)	13/03/92	11.30			

(¢) << 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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 12 Patient: 394 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			07/07/92		03/08/92		27/08/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	13-18 (G/DL)	01/06/92	15.00		15.20		15.10	
HT	40-54 (%)	01/06/92	42.40		42.50		43.40	
RBC	4.5-6.5 (10¬12/L)	01/06/92	4.83		4.88		4.95	
WBC	4-11 (10¬9/L)	01/06/92	5.80		6.50		7.10	
WBC: N	2-8 (10¬9/L)	01/06/92	3.40		3.60		4.00	
WBC: L	1-4 (10¬9/L)	01/06/92	1.90		2.50		2.20	
WBC: E	0-0.6 (10¬9/L)	01/06/92	0.10		0.20		0.40	
WBC: M	0-1 (10¬9/L)	01/06/92	0.30		0.20		0.40	
WBC: B	0-0.2 (10¬9/L)	01/06/92	0.10		0.10		0.10	
PLATELETS	150-450 (10¬9/L)	01/06/92	230.00		263.00		250.00	
NA+	136-146 (MMOL/L)	01/06/92	141.00		140.00		140.00	
K+	3.5-5 (MMOL/L)	01/06/92	4.50		4.40		4.50	
CL-	95-110 (MMOL/L)	01/06/92	102.00		102.00		102.00	
Ca++	2.15-2.65 (MMOL/L)	01/06/92	2.45		2.42		2.42	
PO4--	0.8-1.4 (MMOL/L)	01/06/92	1.10		1.20		1.10	
SGPT	0-40 (U/L)	01/06/92	25.00		34.00		32.00	
GAMMA GT	0-45 (U/L)	01/06/92	17.00		18.00		18.00	
LDH	250-520 (U/L)	01/06/92	217.00	<	261.00		320.00	
ALK. PHOSPH.	30-120 (U/L)	01/06/92	69.00		70.00		74.00	
GLUCOSE	4-5.5 (MMOL/L)	01/06/92	5.40		4.70		4.80	
UREA	2.3-7.6 (MMOL/L)	01/06/92	5.10		5.80		6.30	
CREATININE	0.05-0.11 (MMOL/L)	01/06/92	0.12	>	0.13	>	0.13	>
URIC ACID	0.18-0.48 (MMOL/L)	01/06/92	0.34		0.45		0.41	
TOT BILIRUBIN	0-20 (UMOL/L)	01/06/92	12.00		11.00		10.00	
TOT. PROTEINS	60-80 (G/L)	01/06/92	80.00		77.00		79.00	
ALBUMINE	35-50 (G/L)	01/06/92	46.00		43.00		45.00	
TOT. CHOLEST.	3-5.5 (MMOL/L)	01/06/92	4.50		4.60		4.80	
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/06/92	1.90		1.80		1.50	
TSH	0.5-4 (MIU/L)	01/06/92	1.10					
T4	10-19 (PMOL/L)	01/06/92	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
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS
9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 12 Patient: 395 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			24/07/92		20/08/92		17/09/92	
			value	(◊)	value	(◊)	value	(◊)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/06/92	15.10		14.00		13.80	
HT	40-54 (%)	01/06/92	45.60		42.10		40.20	
RBC	4.5-6.5 (10¬12/L)	01/06/92	5.23		4.88		4.66	
WBC	4-11 (10¬9/L)	01/06/92	8.30		6.80		8.00	
WBC: N	2-8 (10¬9/L)	01/06/92	6.20		4.50		5.20	
WBC: L	1-4 (10¬9/L)	01/06/92	1.40		1.80		1.90	
WBC: E	0-0.6 (10¬9/L)	01/06/92	0.20		0.00		0.20	
WBC: M	0-1 (10¬9/L)	01/06/92	0.30		0.50		0.50	
WBC: B	0-0.2 (10¬9/L)	01/06/92	0.00		0.00		0.00	
PLATELETS	150-450 (10¬9/L)	01/06/92	355.00		329.00		328.00	
NA+	136-146 (MMOL/L)	01/06/92	141.00		139.00		142.00	
K+	3.5-5 (MMOL/L)	01/06/92	4.30		4.10		3.90	
CL-	95-110 (MMOL/L)	01/06/92	101.00		102.00		102.00	
Ca++	2.15-2.65 (MMOL/L)	01/06/92	2.36				2.28	
PO4--	0.8-1.4 (MMOL/L)	01/06/92	1.20				1.10	
SGPT	0-40 (U/L)	01/06/92	26.00		29.00		24.00	
GAMMA GT	0-45 (U/L)	01/06/92	25.00		18.00		19.00	
LDH	250-520 (U/L)	01/06/92			228.00	<	237.00	<
ALK. PHOSPH.	30-120 (U/L)	01/06/92	76.00		65.00		72.00	
GLUCOSE	4-5.5 (MMOL/L)	01/06/92	4.60		4.30		4.00	
UREA	2.3-7.6 (MMOL/L)	01/06/92	7.20		5.20		5.20	
CREATININE	0.05-0.11 (MMOL/L)	01/06/92	0.09		0.09		0.10	
URIC ACID	0.18-0.48 (MMOL/L)	01/06/92	0.24		0.29		0.26	
TOT BILIRUBIN	0-20 (UMOL/L)	01/06/92	12.00		19.00		10.00	
TOT. PROTEINS	60-80 (G/L)	01/06/92	75.00		65.00		65.00	
ALBUMINE	35-50 (G/L)	01/06/92	43.00		40.00		39.00	
TOT. CHOLEST.	3-5.5 (MMOL/L)	01/06/92	5.00		3.80		3.50	
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/06/92	1.00		0.70		0.90	
TSH	0.5-4 (MIU/L)	01/06/92	1.00					
T4	10-19 (PMOL/L)	01/06/92	14.90					

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max r
< out of range (value lower than min range) > out of range (value higher than max r
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS
9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 387 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			15/04/92		01/06/92	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)
HB	12-16 (G/DL)	01/03/92	14.20		12.90	
HT	37-47 (%)	01/03/92	42.00		39.00	
RBC	3.8-5.8 (10-12/L)	01/03/92	4.47		4.12	
WBC	4-11 (10-9/L)	01/03/92	7.20		6.30	
WBC: N	2-7.5 (10-9/L)	01/03/92	4.50		3.50	
WBC: L	1.3-3.6 (10-9/L)	01/03/92	2.10		1.70	
WBC: E	0-0.7 (10-9/L)	01/03/92	0.10		0.50	
WBC: M	0.2-0.8 (10-9/L)	01/03/92	0.40		0.60	
WBC: B	0-0.2 (10-9/L)	01/03/92	0.10		0.00	
PLATELETS	150-400 (10-9/L)	01/03/92	204.00		240.00	
NA+	137-145 (MMOL/L)	01/03/92	141.00		139.00	
K+	3.5-5 (MMOL/L)	01/03/92	3.90		5.10	>
CL-	100-111 (MMOL/L)	01/03/92			105.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92			2.15	
PO4--	0.7-1.4 (MMOL/L)	01/03/92			1.12	
SGOT	5-35 (U/L)	01/03/92	26.00		59.00	>
SGPT	7-56 (U/L)	01/03/92	16.00		24.00	
GAMMA GT	8-78 (U/L)	01/03/92	24.00		19.00	
LDH	300-540 (U/L)	01/03/92			630.00	>
ALK. PHOSPH.	19-95 (U/L)	01/03/92	50.00		48.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92			5.10	
UREA	2.5-7.5 (MMOL/L)	01/03/92			6.00	
CREATININE	60-110 (UMOL/L)	01/03/92	106.00		92.00	
URIC ACID	180-440 (UMOL/L)	01/03/92			269.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	11.00		12.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	76.00		69.00	
ALBUMINE	35-50 (G/L)	01/03/92	44.00		41.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92			5.43	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92			1.38	
TSH	0.2-3.2 (MU/L)	01/03/92	0.50			
T4	11-24 (PMOL/L)	01/03/92	13.30			

977

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 388 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			15/03/92		30/03/92		11/05/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/03/92					12.70	<
HT	41-53 (%)	01/03/92					37.00	<
RBC	4.5-6.5 (10¬12/L)	01/03/92					3.89	<
WBC	4-11 (10¬9/L)	01/03/92					5.40	
WBC: N	2-7.5 (10¬9/L)	01/03/92					2.80	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92					1.80	
WBC: E	0-0.7 (10¬9/L)	01/03/92					0.20	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92					0.50	
WBC: B	0-0.2 (10¬9/L)	01/03/92					0.10	
PLATELETS	150-400 (10¬9/L)	01/03/92					231.00	
NA+	137-145 (MMOL/L)	01/03/92	141.00		141.00		140.00	
K+	3.5-5 (MMOL/L)	01/03/92	4.10		4.20		5.00	
CL-	100-111 (MMOL/L)	01/03/92	101.00		102.00		106.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.33		2.26		2.29	
PO4--	0.7-1.4 (MMOL/L)	01/03/92	0.96		1.02		1.11	
SGOT	5-35 (U/L)	01/03/92	80.00	>>	31.00		34.00	
SGPT	7-56 (U/L)	01/03/92	55.00		48.00		49.00	
GAMMA GT	8-78 (U/L)	01/03/92	50.00		35.00		22.00	
LDH	300-540 (U/L)	01/03/92	714.00	>	515.00		614.00	>
ALK. PHOSPH.	19-95 (U/L)	01/03/92	58.00		57.00		44.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92			5.10		5.30	
BUN	()	01/03/92						
UREA	2.5-7.5 (MMOL/L)	01/03/92	5.10		6.40		6.20	
CREATININE	60-110 (UMOL/L)	01/03/92	92.00		108.00		86.00	
URIC ACID	180-440 (UMOL/L)	01/03/92	447.00	>	388.00		295.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	18.00		8.00		10.00	
DIR BILIRUBIN	0-19 (UMOL/L)	01/03/92						
TOT. PROTEINS	62-81 (G/L)	01/03/92	78.00		70.00		70.00	
ALBUMINE	35-50 (G/L)	01/03/92	46.00		42.00		44.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	7.68	>>	6.38	>	7.10	>
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	1.44		2.77	>>	1.59	
GLOBULINS ALPHA 1	()	01/03/92						
GLOBULINS ALPHA 2	()	01/03/92						
GLOBULINS BETA	()	01/03/92						
GLOBULINS GAMMA	()	01/03/92						
TSH	0.2-3.2 (MU/L)	01/03/92	0.80		0.50		1.40	
T4	11-24 (PMOL/L)	01/03/92	14.00		23.60		11.90	

(¢) << 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 PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 390 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			25/05/92		25/06/92		24/07/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	14-18 (G/DL)	01/03/92	14.30		13.80	<	13.90	<
HT	41-53 (%)	01/03/92	40.00	<	40.00	<	41.00	
RBC	4.5-6.5 (10¬12/L)	01/03/92	4.56		4.46	<	4.54	
WBC	4-11 (10¬9/L)	01/03/92	5.90		6.40		5.30	
WBC: N	2-7.5 (10¬9/L)	01/03/92	3.20		3.70		3.30	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	1.80		1.70		1.30	
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.20		0.20		0.00	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.70		0.70		0.00	<
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.00		0.10		0.00	
PLATELETS	150-400 (10¬9/L)	01/03/92	245.00		251.00		240.00	
NA+	137-145 (MMOL/L)	01/03/92	141.00		142.00		141.00	
K+	3.5-5 (MMOL/L)	01/03/92	4.20		4.80		4.50	
CL-	100-111 (MMOL/L)	01/03/92	102.00		104.00		102.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92			2.32		2.28	
PO4--	0.7-1.4 (MMOL/L)	01/03/92			1.27		1.07	
SGOT	5-35 (U/L)	01/03/92	31.00		61.00	>	31.00	
SGPT	7-56 (U/L)	01/03/92	37.00		36.00		28.00	
GAMMA GT	8-78 (U/L)	01/03/92	31.00		25.00		23.00	
LDH	300-540 (U/L)	01/03/92			599.00	>	376.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92	69.00				74.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	4.10		5.00		5.40	
UREA	2.5-7.5 (MMOL/L)	01/03/92	4.70		4.40		5.80	
CREATININE	60-110 (UMOL/L)	01/03/92	127.00	>	118.00	>	116.00	>
URIC ACID	180-440 (UMOL/L)	01/03/92			452.00	>	429.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	20.00		14.00		13.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	78.00		76.00		73.00	
ALBUMINE	35-50 (G/L)	01/03/92	44.00		49.00		46.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92			5.16		4.94	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92			1.11		0.90	
TSH	0.2-3.2 (MU/L)	01/03/92	1.90		2.10		2.40	
T4	11-24 (PMOL/L)	01/03/92	14.30		13.50		14.60	

(¢) << 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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 392 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 14	
			13/08/92		28/08/92	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	01/03/92	15.20		14.40	
HT	37-47 (%)	01/03/92	44.00		40.00	
RBC	3.8-5.8 (10¬12/L)	01/03/92	5.22		4.89	
WBC	4-11 (10¬9/L)	01/03/92	7.10		6.70	
WBC: N	2-7.5 (10¬9/L)	01/03/92	3.55		3.60	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	2.91		2.20	
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.21		0.20	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.36		0.40	
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.07		0.30	>>
PLATELETS	150-400 (10¬9/L)	01/03/92	308.00		368.00	
NA+	137-145 (MMOL/L)	01/03/92	138.00		139.00	
K+	3.5-5 (MMOL/L)	01/03/92	4.00		3.90	
CL-	100-111 (MMOL/L)	01/03/92	103.00		103.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.34		2.33	
PO4--	0.7-1.4 (MMOL/L)	01/03/92	1.05		1.32	
SGOT	5-35 (U/L)	01/03/92	54.00	>	30.00	
SGPT	7-56 (U/L)	01/03/92	45.00		12.00	
GAMMA GT	8-78 (U/L)	01/03/92	29.00		24.00	
LDH	300-540 (U/L)	01/03/92	362.00		492.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92	75.00		70.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	4.50		4.70	
UREA	2.5-7.5 (MMOL/L)	01/03/92			5.00	
CREATININE	60-110 (UMOL/L)	01/03/92	81.00		81.00	
URIC ACID	180-440 (UMOL/L)	01/03/92	244.00		311.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	12.00		13.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	74.00		73.00	
ALBUMINE	35-50 (G/L)	01/03/92	44.00		43.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	5.50		5.00	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	2.23	>	0.79	
TSH	0.2-3.2 (MU/L)	01/03/92	0.70		0.60	
T4	11-24 (PMOL/L)	01/03/92	15.60		19.70	

(¢) << 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 PHARMACEUTICAL RESEARCH - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 501 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			29/10/92		30/11/92		30/12/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	14-18 (G/DL)	01/03/92	16.50		16.50		16.90	
HT	41-53 (%)	01/03/92	49.00		49.00		49.00	
RBC	4.5-6.5 (10¬12/L)	01/03/92	5.70		5.66		5.72	
WBC	4-11 (10¬9/L)	01/03/92	7.80		10.30		9.40	
WBC: N	2-7.5 (10¬9/L)	01/03/92	3.50		5.00		5.00	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	3.40		4.10	>	3.20	
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.30		0.30		0.30	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.50		0.90	>	0.80	
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.10		0.00		0.10	
PLATELETS	150-400 (10¬9/L)	01/03/92	432.00	>	428.00	>	447.00	>
NA+	137-145 (MMOL/L)	01/03/92	138.00		138.00		140.00	
K+	3.5-5 (MMOL/L)	01/03/92	4.40		4.60		4.50	
CL-	100-111 (MMOL/L)	01/03/92	99.00	<	100.00		104.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.37		2.32		2.39	
PO4--	0.7-1.4 (MMOL/L)	01/03/92	1.10		1.08		1.46	>
SGOT	5-35 (U/L)	01/03/92	46.00	>	39.00	>	39.00	>
SGPT	7-56 (U/L)	01/03/92	49.00		41.00		35.00	
GAMMA GT	8-78 (U/L)	01/03/92	79.00	>	63.00		60.00	
LDH	300-540 (U/L)	01/03/92	513.00		424.00		525.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92	79.00		70.00		71.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	4.40		4.50		4.60	
UREA	2.5-7.5 (MMOL/L)	01/03/92	5.30		5.10		6.90	
CREATININE	60-110 (UMOL/L)	01/03/92	89.00		86.00		68.00	
URIC ACID	180-440 (UMOL/L)	01/03/92	284.00		279.00		306.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	15.00		13.00		9.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	80.00		80.00		78.00	
ALBUMINE	35-50 (G/L)	01/03/92	49.00		48.00		42.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	5.54	>	5.36		5.71	>
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	1.30		2.51	>>	1.39	
TSH	0.2-3.2 (MU/L)	01/03/92	1.10				1.20	
T4	11-24 (PMOL/L)	01/03/92	15.40				16.90	

(¢) << 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 PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 503 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 7	
			12/11/92		19/11/92	
			value	(◊)	value	(◊)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	01/03/92	13.00		12.60	
HT	37-47 (%)	01/03/92	38.00		37.00	
RBC	3.8-5.8 (10¬12/L)	01/03/92	4.25		4.16	
WBC	4-11 (10¬9/L)	01/03/92	7.70		7.50	
WBC: N	2-7.5 (10¬9/L)	01/03/92	3.70		3.40	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	3.10		3.00	
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.20		0.20	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.60		0.70	
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.10		0.20	
PLATELETS	150-400 (10¬9/L)	01/03/92	309.00		301.00	
NA+	137-145 (MMOL/L)	01/03/92	137.00		136.00	<
K+	3.5-5 (MMOL/L)	01/03/92	4.60		4.50	
CL-	100-111 (MMOL/L)	01/03/92	101.00		100.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.29		2.20	
PO4--	0.7-1.4 (MMOL/L)	01/03/92	1.22		1.30	
SGOT	5-35 (U/L)	01/03/92	28.00		23.00	
SGPT	7-56 (U/L)	01/03/92	30.00		25.00	
GAMMA GT	8-78 (U/L)	01/03/92	15.00		14.00	
LDH	300-540 (U/L)	01/03/92	351.00		309.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92	48.00		41.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	4.80		5.50	
UREA	2.5-7.5 (MMOL/L)	01/03/92	5.40		5.30	
CREATININE	60-110 (UMOL/L)	01/03/92	68.00		73.00	
URIC ACID	180-440 (UMOL/L)	01/03/92	144.00	<	151.00	<
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	17.00		12.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	69.00		62.00	
ALBUMINE	35-50 (G/L)	01/03/92	43.00		38.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	4.79		4.09	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	0.94		0.89	
TSH	0.2-3.2 (MU/L)	01/03/92	1.20		1.30	
T4	11-24 (PMOL/L)	01/03/92	14.50		18.30	

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max r-
< out of range (value lower than min range) > out of range (value higher than max ra
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS 9550883

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 505 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			31/08/92		28/09/92		22/10/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/03/92	14.20		14.10		14.20	
HT	37-47 (%)	01/03/92	41.00		42.00		41.00	
RBC	3.8-5.8 (10¬12/L)	01/03/92	4.47		4.45		4.36	
WBC	4-11 (10¬9/L)	01/03/92	8.10		7.70		6.20	
WBC: N	2-7.5 (10¬9/L)	01/03/92	5.10		4.90		3.50	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	1.80		2.00		1.80	
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.30		0.20		0.30	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.90	>	0.40		0.60	
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.00		0.20		0.00	
PLATELETS	150-400 (10¬9/L)	01/03/92	229.00		273.00		252.00	
NA+	137-145 (MMOL/L)	01/03/92	139.00		139.00		139.00	
K+	3.5-5 (MMOL/L)	01/03/92	4.90		4.60		5.10	>
CL-	100-111 (MMOL/L)	01/03/92	103.00		102.00		104.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.27		2.38		2.28	
PO4--	0.7-1.4 (MMOL/L)	01/03/92	0.90		1.19		0.95	
SGOT	5-35 (U/L)	01/03/92	21.00		31.00		23.00	
SGPT	7-56 (U/L)	01/03/92	13.00		10.00		22.00	
GAMMA GT	8-78 (U/L)	01/03/92	19.00		19.00		12.00	
LDH	300-540 (U/L)	01/03/92	477.00		464.00		456.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92	73.00		74.00		66.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	4.10		4.40		3.10	<
UREA	2.5-7.5 (MMOL/L)	01/03/92	3.70		6.10		5.40	
CREATININE	60-110 (UMOL/L)	01/03/92	79.00		111.00	>	90.00	
URIC ACID	180-440 (UMOL/L)	01/03/92	99.00	<	140.00	<	155.00	<
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	6.00		7.00		10.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	69.00		72.00		70.00	
ALBUMINE	35-50 (G/L)	01/03/92	40.00		42.00		42.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	4.93		5.10		4.70	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	0.76		1.33		0.76	
TSH	0.2-3.2 (MU/L)	01/03/92	0.90		0.90		0.90	
T4	11-24 (PMOL/L)	01/03/92	12.50		12.30		13.50	

(¢) << 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

PHARMACIA PHARMACEUTICAL AB/MD - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 508 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			29/10/92		30/11/92		31/12/92	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	12-16 (G/DL)	01/03/92	12.70		13.70		13.20	
HT	37-47 (%)	01/03/92	38.00		42.00		40.00	
RBC	3.8-5.8 (10¬12/L)	01/03/92	4.41		4.77		4.62	
WBC	4-11 (10¬9/L)	01/03/92	5.60		4.70		4.80	
WBC: N	2-7.5 (10¬9/L)	01/03/92	3.30		2.40		2.40	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	1.70		1.60		1.70	
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.10		0.10		0.10	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.50		0.60		0.50	
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.00		0.00		0.10	
PLATELETS	150-400 (10¬9/L)	01/03/92	255.00		244.00		302.00	
NA+	137-145 (MMOL/L)	01/03/92	144.00		139.00		139.00	
K+	3.5-5 (MMOL/L)	01/03/92	3.80		5.10	>	4.90	
CL-	100-111 (MMOL/L)	01/03/92	107.00		104.00		104.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.22		2.24		2.19	
PO4--	0.7-1.4 (MMOL/L)	01/03/92	1.36		1.34		1.15	
SGOT	5-35 (U/L)	01/03/92	14.00		39.00	>	23.00	
SGPT	7-56 (U/L)	01/03/92	32.00		14.00		13.00	
GAMMA GT	8-78 (U/L)	01/03/92	10.00		12.00		12.00	
LDH	300-540 (U/L)	01/03/92	548.00	>	545.00	>	496.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92	67.00		77.00		71.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	5.40		4.70		4.20	
UREA	2.5-7.5 (MMOL/L)	01/03/92	4.70		4.70		4.40	
CREATININE	60-110 (UMOL/L)	01/03/92	72.00		74.00		63.00	
URIC ACID	180-440 (UMOL/L)	01/03/92	206.00		226.00		212.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	6.00		8.00		8.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	70.00		74.00		73.00	
ALBUMINE	35-50 (G/L)	01/03/92	41.00		42.00		39.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	4.53		4.64		4.79	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	0.83		0.86		0.57	
TSH	0.2-3.2 (MU/L)	01/03/92	0.40		0.70		0.70	
T4	11-24 (PMOL/L)	01/03/92	15.60		14.80		14.80	

(◊) << 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 PHARMACEUTICALS 9550093 - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 521 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			30/11/92		30/12/92		27/01/93	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/03/92	15.10		14.70		14.50	
HT	41-53 (%)	01/03/92	44.00		42.00		43.00	
RBC	4.5-6.5 (10¬12/L)	01/03/92	4.91		4.81		4.70	
WBC	4-11 (10¬9/L)	01/03/92	5.00		5.20		4.10	
WBC: N	2-7.5 (10¬9/L)	01/03/92	2.90		2.70		1.90	<
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	1.50		1.60		1.30	
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.00		0.20		0.20	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.55		0.60		0.60	
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.05		0.10		0.10	
PLATELETS	150-400 (10¬9/L)	01/03/92	233.00		211.00		216.00	
NA+	137-145 (MMOL/L)	01/03/92			137.00		139.00	
K+	3.5-5 (MMOL/L)	01/03/92			4.30		6.30	>>
CL-	100-111 (MMOL/L)	01/03/92			100.00		98.00	<
Ca++	2.1-2.5 (MMOL/L)	01/03/92			2.28		2.32	
PO4--	0.7-1.4 (MMOL/L)	01/03/92			1.00		1.20	
SGOT	5-35 (U/L)	01/03/92			37.00	>	36.00	>
SGPT	7-56 (U/L)	01/03/92			37.00		66.00	>
GAMMA GT	8-78 (U/L)	01/03/92			71.00		77.00	
LDH	300-540 (U/L)	01/03/92			428.00		477.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92			65.00		66.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92			7.40	>	5.80	
UREA	2.5-7.5 (MMOL/L)	01/03/92			2.40	<	2.70	
CREATININE	60-110 (UMOL/L)	01/03/92			117.00	>	84.00	
URIC ACID	180-440 (UMOL/L)	01/03/92			343.00		337.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92			11.00		13.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92			74.00		73.00	
ALBUMINE	35-50 (G/L)	01/03/92			44.00		46.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92			5.61	>	5.65	>
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92			2.08	>	2.38	>>
TSH	0.2-3.2 (MU/L)	01/03/92			0.70		0.70	
T4	11-24 (PMOL/L)	01/03/92			14.30		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 done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 398 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			15/04/92		13/05/92		10/06/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/02/92	14.90		13.30		14.30	
HT	0.35-0.47 (L/L)	01/02/92	0.45		0.43		0.42	
RBC	3.9-5.6 (10¬12/L)	01/02/92	5.04		4.81		4.76	
WBC	3.5-12 (10¬9/L)	01/02/92	11.00		7.60		9.50	
WBC: N	2.5-8 (10¬9/L)	01/02/92	8.60	>			7.00	
WBC: L	1.2-4 (10¬9/L)	01/02/92	1.40				1.40	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.40				0.60	>
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.60				0.50	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.00				0.00	
PLATELETS	150-400 (10¬9/L)	01/02/92	219.00		253.00		213.00	
NA+	135-145 (MMOL/L)	01/02/92	139.00		139.00		140.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	3.70		4.10		4.20	
CL-	95-105 (MMOL/L)	01/02/92	100.00		104.00		101.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.25		2.30		2.39	
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.20		1.21		1.12	
SGOT	0-35 (U/L)	01/02/92	18.00		20.00		18.00	
GAMMA GT	5-23 (U/L)	01/02/92	24.00	>	17.00		17.00	
LDH	70-170 (U/L)	01/02/92	144.00		113.00		109.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	68.00		64.00		62.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	4.40		4.90		5.30	
UREA	2.5-7.5 (MMOL/L)	01/02/92	3.80		4.10		3.40	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.06		0.07		0.06	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.21		0.20		0.15	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	7.00		7.00		6.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	2.00		3.00		3.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	70.00		68.00		73.00	
ALBUMINE	36-49 (G/L)	01/02/92	47.00		45.00		48.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	3.90		4.20		4.10	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.50		1.50		1.50	
TSH	0.5-6.5 (MIU/L)	01/02/92	1.79					
T4	86-148 (NMOL/L)	01/02/92	52.00	<<				

(¢) << 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 PHARMACEUTICALS [illegible] - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 399 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			13/04/92		19/05/92		16/06/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/02/92	13.70		13.40		13.80	
HT	0.35-0.47 (L/L)	01/02/92	0.40		0.40		0.41	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.55		4.52		4.70	
WBC	3.5-12 (10¬9/L)	01/02/92	6.90		6.30		7.00	
WBC: N	2.5-8 (10¬9/L)	01/02/92	4.50		4.00		5.00	
WBC: L	1.2-4 (10¬9/L)	01/02/92	1.90		2.00		1.70	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.00		0.00		0.00	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.40		0.30		0.40	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.00		0.00		0.00	
PLATELETS	150-400 (10¬9/L)	01/02/92	218.00		226.00		244.00	
NA+	135-145 (MMOL/L)	01/02/92	139.00		139.00		135.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	3.90		4.30		3.80	
CL-	95-105 (MMOL/L)	01/02/92	103.00		103.00		99.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.22	<	2.23	<	2.27	
PO4--	0.6-1.3 (MMOL/L)	01/02/92	0.81		1.03		1.15	
SGOT	0-35 (U/L)	01/02/92	16.00		18.00		19.00	
GAMMA GT	5-23 (U/L)	01/02/92	16.00		16.00		16.00	
LDH	70-170 (U/L)	01/02/92	168.00		146.00		167.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	49.00		53.00		46.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	5.50		5.10		5.70	
UREA	2.5-7.5 (MMOL/L)	01/02/92	2.60		2.20	<	2.80	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.08		0.07		0.09	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.31		0.26		0.28	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	8.00		8.00		8.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	3.00		2.00		4.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	72.00		68.00		72.00	
ALBUMINE	36-49 (G/L)	01/02/92	45.00		44.00		46.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	5.90		5.40		5.90	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.60		1.30		1.40	
TSH	0.5-6.5 (MIU/L)	01/02/92	0.79					
T4	86-148 (NMOL/L)	01/02/92	56.00	<<				

(¢) << 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 PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 402 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			22/05/92		24/06/92		22/07/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/02/92	14.00		12.70		12.80	
HT	0.35-0.47 (L/L)	01/02/92	0.42		0.38		0.38	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.71		4.31		4.34	
WBC	3.5-12 (10¬9/L)	01/02/92	9.30		11.10		8.40	
WBC: N	2.5-8 (10¬9/L)	01/02/92	6.90		7.20		5.20	
WBC: L	1.2-4 (10¬9/L)	01/02/92	2.00		3.00		2.60	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.00		0.00		0.00	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.40		0.90		0.50	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.00		0.00		0.00	
PLATELETS	150-400 (10¬9/L)	01/02/92	375.00		344.00		349.00	
NA+	135-145 (MMOL/L)	01/02/92	141.00		136.00		138.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	3.90		3.90		4.30	
CL-	95-105 (MMOL/L)	01/02/92	104.00		98.00		102.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.40		2.28		2.25	
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.18		1.34	>	1.22	
SGOT	0-35 (U/L)	01/02/92	17.00		18.00		18.00	
GAMMA GT	5-23 (U/L)	01/02/92	25.00	>	27.00	>	22.00	
LDH	70-170 (U/L)	01/02/92	152.00		140.00		151.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	95.00	>	108.00	>	108.00	>
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	5.50		6.10		4.80	
UREA	2.5-7.5 (MMOL/L)	01/02/92	4.80		6.60		4.30	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.08		0.07		0.06	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92			0.26		0.23	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	11.00		8.00		8.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	3.00		4.00		2.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	77.00		72.00		71.00	
ALBUMINE	36-49 (G/L)	01/02/92	50.00	>	47.00		42.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	7.90		8.00		7.60	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.70		2.50	>>	1.80	>
TSH	0.5-6.5 (MIU/L)	01/02/92	1.17					
T4	86-148 (NMOL/L)	01/02/92	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 nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 403 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			28/05/92		26/06/92		24/07/92	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	11.5-16.5 (G/DL)	01/02/92	13.30		12.60		12.70	
HT	0.35-0.47 (L/L)	01/02/92	0.40		0.37		0.38	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.55		4.27		4.34	
WBC	3.5-12 (10¬9/L)	01/02/92	7.20		8.20		7.30	
WBC: N	2.5-8 (10¬9/L)	01/02/92	5.50		5.90		5.00	
WBC: L	1.2-4 (10¬9/L)	01/02/92	1.60		2.10		2.20	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.00		0.00		0.00	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.10		0.20		0.10	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.00		0.00		0.00	
PLATELETS	150-400 (10¬9/L)	01/02/92	257.00		241.00		244.00	
NA+	135-145 (MMOL/L)	01/02/92	140.00		139.00		137.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	3.50		3.60		3.90	
CL-	95-105 (MMOL/L)	01/02/92	102.00		101.00		102.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.37		2.24	<	2.22	<
PO4--	0.6-1.3 (MMOL/L)	01/02/92	0.91		1.28		1.22	
SGOT	0-35 (U/L)	01/02/92	13.00		14.00		12.00	
GAMMA GT	5-23 (U/L)	01/02/92	20.00		19.00		22.00	
LDH	70-170 (U/L)	01/02/92	160.00		146.00		143.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	48.00		63.00		56.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	3.60		4.80		4.60	
UREA	2.5-7.5 (MMOL/L)	01/02/92	6.10		4.60		5.80	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.07		0.07		0.06	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.23		0.22		0.19	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	10.00		8.00		8.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	2.00		2.00		2.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	79.00		72.00		73.00	
ALBUMINE	36-49 (G/L)	01/02/92	50.00	>	46.00		43.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	5.50		4.70		4.90	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.10		1.30		1.20	
TSH	0.5-6.5 (MIU/L)	01/02/92	0.83					
T4	86-148 (NMOL/L)	01/02/92	108.00					

(◊) << 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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 407 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 42	
			13/07/92		10/08/92		25/08/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	13.5-17.5 (G/DL)	01/02/92	15.50		15.00		15.60	
HT	0.4-0.54 (L/L)	01/02/92	0.45		0.44		0.45	
RBC	4.5-6.5 (10¬12/L)	01/02/92	5.20		5.09		5.23	
WBC	3.5-10 (10¬9/L)	01/02/92	9.60		7.90		9.40	
WBC: N	1.5-6.5 (10¬9/L)	01/02/92	6.30		5.50		7.40	>
WBC: L	1.2-4 (10¬9/L)	01/02/92	3.00		2.00		1.70	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.10		0.20		0.00	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.20		0.30		0.30	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.00		0.00		0.00	
PLATELETS	150-400 (10¬9/L)	01/02/92	269.00		308.00		298.00	
NA+	135-145 (MMOL/L)	01/02/92	140.00		137.00		144.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	4.30				4.30	
CL-	95-105 (MMOL/L)	01/02/92	101.00		100.00		100.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.26		2.20	<	2.30	
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.18		1.15		0.88	
SGOT	0-35 (U/L)	01/02/92	20.00		16.00		19.00	
GAMMA GT	5-23 (U/L)	01/02/92	37.00	>	26.00	>	30.00	>
LDH	70-170 (U/L)	01/02/92	31.00	<	165.00		132.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	65.00		60.00		75.00	>
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	5.70		4.50		5.80	
UREA	2.5-7.5 (MMOL/L)	01/02/92	8.10	>	5.70		4.60	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.07		0.06		0.07	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.35		0.32		0.29	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	12.00		11.00		10.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	3.00		3.00		3.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	76.00		74.00		71.00	
ALBUMINE	36-49 (G/L)	01/02/92	45.00		43.00		40.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	4.80		4.00			
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	2.00	>	1.50			
TSH	0.5-6.5 (MIU/L)	01/02/92	1.71					
T4	86-148 (NMOL/L)	01/02/92	113.00					

(¢) << 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 PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 408 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 56	
			04/08/92		30/09/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)
HB	11.5-16.5 (G/DL)	01/02/92	12.40		13.20	
HT	0.35-0.47 (L/L)	01/02/92	0.37		0.42	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.58		4.92	
WBC	3.5-12 (10¬9/L)	01/02/92	11.00		7.99	
WBC: N	2.5-8 (10¬9/L)	01/02/92	7.20		5.19	
WBC: L	1.2-4 (10¬9/L)	01/02/92	3.20		1.98	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.10		0.12	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.60		0.36	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.00		0.05	
PLATELETS	150-400 (10¬9/L)	01/02/92	328.00		261.00	
NA+	135-145 (MMOL/L)	01/02/92	138.00		144.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	4.10		3.90	
CL-	95-105 (MMOL/L)	01/02/92	100.00		104.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.26		2.24	<
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.45	>	1.21	
SGOT	0-35 (U/L)	01/02/92	16.00		16.00	
GAMMA GT	5-23 (U/L)	01/02/92	24.00	>	41.00	>
LDH	70-170 (U/L)	01/02/92	161.00		161.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	46.00		42.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	4.70		6.00	
UREA	2.5-7.5 (MMOL/L)	01/02/92	5.00		5.30	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.06		0.06	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.32		0.37	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	5.00		7.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	2.00		2.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	74.00		77.00	
ALBUMINE	36-49 (G/L)	01/02/92	43.00		43.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92			5.70	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92			1.70	
TSH	0.5-6.5 (MIU/L)	01/02/92	1.04			
T4	86-148 (NMOL/L)	01/02/92	102.00			

(¢) << 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 PHARMACEUTICI S.p.A. MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 511 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 49	
			22/10/92		20/11/92		11/12/92	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	11.5-16.5 (G/DL)	01/02/92	13.50		13.70		13.10	
HT	0.35-0.47 (L/L)	01/02/92	0.40		0.39		0.38	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.60		4.60		4.37	
WBC	3.5-12 (10¬9/L)	01/02/92	6.39		8.15		6.67	
WBC: N	2.5-8 (10¬9/L)	01/02/92	4.05		5.04		3.93	
WBC: L	1.2-4 (10¬9/L)	01/02/92	1.78		2.65		2.25	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.07		0.04		0.06	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.24		0.39		0.39	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.05		0.03		0.04	
PLATELETS	150-400 (10¬9/L)	01/02/92	272.00		283.00		244.00	
NA+	135-145 (MMOL/L)	01/02/92	138.00		133.00	<	136.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	3.70		3.70		3.70	
CL-	95-105 (MMOL/L)	01/02/92	105.00		101.00		102.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.38		2.27		2.30	
PO4--	0.6-1.3 (MMOL/L)	01/02/92	0.90		1.12		1.25	
SGOT	0-35 (U/L)	01/02/92	17.00		9.00		10.00	
GAMMA GT	5-23 (U/L)	01/02/92	26.00	>	23.00		23.00	
LDH	70-170 (U/L)	01/02/92	174.00	>	146.00		127.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	78.00	>	59.00		60.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	4.80		4.60		4.50	
UREA	2.5-7.5 (MMOL/L)	01/02/92	5.70		4.70		5.80	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.07		0.10		0.06	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.21		0.21		0.17	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	7.00		11.00		8.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	2.00		2.00		3.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	71.00		68.00		69.00	
ALBUMINE	36-49 (G/L)	01/02/92	42.00		39.00		41.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	3.70		3.00		3.30	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.40		0.70		0.90	
TSH	0.5-6.5 (MIU/L)	01/02/92	1.35					
T4	86-148 (NMOL/L)	01/02/92	110.00					

(◊) << 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 PHARMACEUTICAL [illegible] - CNS

3556083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 512 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date	
			Screen	
			02/11/92	
			value	(¢)
Laboratory test	Range value	Range date		
HB	11.5-16.5 (G/DL)	01/02/92	13.20	
HT	0.35-0.47 (L/L)	01/02/92	0.40	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.40	
WBC	3.5-12 (10¬9/L)	01/02/92	7.04	
WBC: N	2.5-8 (10¬9/L)	01/02/92	3.63	
WBC: L	1.2-4 (10¬9/L)	01/02/92	2.64	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.18	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.51	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.08	
PLATELETS	150-400 (10¬9/L)	01/02/92	232.00	
NA+	135-145 (MMOL/L)	01/02/92	138.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	4.90	>
CL-	95-105 (MMOL/L)	01/02/92	102.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.28	
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.06	
SGOT	0-35 (U/L)	01/02/92	20.00	
GAMMA GT	5-23 (U/L)	01/02/92	25.00	>
LDH	70-170 (U/L)	01/02/92	166.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	68.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	3.70	
UREA	2.5-7.5 (MMOL/L)	01/02/92	5.80	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.06	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.23	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	14.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	4.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	68.00	
ALBUMINE	36-49 (G/L)	01/02/92	39.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	4.40	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.20	
TSH	0.5-6.5 (MIU/L)	01/02/92	1.32	
T4	86-148 (NMOL/L)	01/02/92	119.00	

(¢) << 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 PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 537 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			29/10/92		02/12/92		04/01/93	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	11.5-16.5 (G/DL)	01/02/92	13.40		12.50		13.90	
HT	0.35-0.47 (L/L)	01/02/92	0.41		0.39		0.43	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.61		4.39		4.86	
WBC	3.5-12 (10¬9/L)	01/02/92	6.13		5.58		6.69	
WBC: N	2.5-8 (10¬9/L)	01/02/92	3.58		3.06		3.73	
WBC: L	1.2-4 (10¬9/L)	01/02/92	1.95		2.10		2.32	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.17		0.08		0.05	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.39		0.00	<	0.51	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.03		0.03		0.07	
PLATELETS	150-400 (10¬9/L)	01/02/92	255.00		306.00		274.00	
NA+	135-145 (MMOL/L)	01/02/92	142.00		143.00		141.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	4.70	>	3.10	<	4.30	
CL-	95-105 (MMOL/L)	01/02/92	107.00	>	104.00		102.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.34		2.23	<	2.28	
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.48	>	1.20		1.34	>
SGOT	0-35 (U/L)	01/02/92	23.00		17.00		18.00	
GAMMA GT	5-23 (U/L)	01/02/92	21.00		23.00		20.00	
LDH	70-170 (U/L)	01/02/92	167.00		177.00	>	167.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	66.00		43.00		47.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	7.30	>	5.60		4.00	
UREA	2.5-7.5 (MMOL/L)	01/02/92	8.60	>	5.50		6.40	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.11		0.08		0.09	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.37		0.28		0.29	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	16.00		19.00	>	14.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	5.00		2.00		3.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	72.00		71.00		71.00	
ALBUMINE	36-49 (G/L)	01/02/92	43.00		43.00		43.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	7.00		7.80		7.90	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.50		1.70		1.50	
TSH	0.5-6.5 (MIU/L)	01/02/92	0.93					
T4	86-148 (NMOL/L)	01/02/92	84.00	<				

(¢) << 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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 409 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			24/03/92		05/05/92		02/06/92	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	13.5-15.5 (G/DL)	01/03/92	16.50	>	16.10	>	15.70	>
HT	40-45 (%)	01/03/92	49.70	>	50.20	>	48.00	>
RBC	4200000-4800000 (/MM3)	01/03/92	5790000	>	5910000	>	5700000	>
WBC	5000-9000 (/MM3)	01/03/92	12300.0	>>	11700.0	>	11100.0	>
WBC: N	50-65 (%)	01/03/92	63.00		63.00		66.00	>
WBC: L	30-40 (%)	01/03/92	31.00		31.00		31.00	
WBC: E	0-3 (%)	01/03/92	2.00		2.00		1.00	
WBC: M	0-5 (%)	01/03/92	4.00		4.00		2.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	210000		478000	>>	414000	>>
NA+	130-150 (MEQ/L)	01/03/92	144.00		145.00		145.00	
K+	3-5 (MEQ/L)	01/03/92	4.60		5.20	>	4.70	
CL-	95-105 (MEQ/L)	01/03/92	103.00		100.00		103.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	8.80		9.20		8.50	
PO4--	2.5-5 (MG/DL)	01/03/92	3.20		4.20		5.00	
SGOT	0-12 (MU/ML)	01/03/92	11.00		7.00		11.00	
SGPT	0-12 (MU/ML)	01/03/92	23.00	>	13.00	>	15.00	>
GAMMA GT	6-28 (UI/L)	01/03/92	18.00		15.00		19.00	
LDH	120-240 (UI/L)	01/03/92	165.00		165.00		165.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	77.00	>	68.00	>	67.00	>
GLUCOSE	70-110 (MG/DL)	01/03/92	95.00		107.00		93.00	
UREA	15-40 (MG/DL)	01/03/92	35.00		40.00		33.00	
CREATININE	0.5-1.4 (MG/DL)	01/03/92	0.90		1.17		1.02	
URIC ACID	3.4-7 (MG/DL)	01/03/92	2.89	<	4.91		4.66	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.55		0.60		0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.15		0.10		0.10	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	6.70		7.20		6.50	
ALBUMINE	3.8-5 (G/DL)	01/03/92	3.48	<	3.74	<	3.93	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	338.00	>>	275.00	>	275.00	>
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	146.00		149.00		155.00	>
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.27		0.21		0.17	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.87	>	0.92	>	0.65	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.87		0.99		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.21		1.28		0.95	
TSH	0-5 (UUI/ML)	01/03/92	0.60					
T4	4.5-13 (UG/DL)	01/03/92	10.00					

995

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (value lower than min range) > out of range (value higher than max range
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL-MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 411 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			21/04/92		19/05/92		16/06/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-15 (G/DL)	20/04/92	14.00		14.30		13.80	
HT	38-43 (%)	20/04/92	43.00		44.00	>	42.00	
RBC	4200000-4800000 (/MM3)	20/04/92	4800000		4900000	>	4520000	
WBC	4500-10000 (/MM3)	20/04/92	5100.00		6100.00		5400.00	
WBC: N	50-65 (%)	20/04/92	55.00		52.00		64.00	
WBC: L	30-40 (%)	20/04/92	38.00		44.00	>	28.00	<
WBC: E	0-3 (%)	20/04/92	2.00		2.00		1.00	
WBC: M	0-5 (%)	20/04/92	5.00		2.00			
	0-6 (%)	15/06/92					7.00	>
WBC: B	0-1 (%)	20/04/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	20/04/92	126000	<	290000		210000	
NA+	130-150 (MEQ/L)	20/04/92	141.00		141.00			
	136-146 (MEQ/L)	15/06/92					139.00	
K+	3-5 (MEQ/L)	20/04/92	4.00		3.90			
	3.5-5.4 (MEQ/L)	15/06/92					3.70	
CL-	95-105 (MEQ/L)	20/04/92	99.00		99.00			
	98-109 (MEQ/L)	15/06/92					101.00	
Ca++	8.1-10.4 (MG/DL)	20/04/92	8.40		8.60			
	9-11 (MG/DL)	15/06/92					9.80	
PO4--	2.5-4.5 (MG/DL)	20/04/92	2.91		3.10			
	3-4 (MG/DL)	15/06/92					2.70	<
SGOT	0-12 (U/L)	20/04/92	7.00		12.00			
	2-30 (U/L)	15/06/92					25.00	
SGPT	0-12 (U/L)	20/04/92	5.00		10.00			
	2-30 (U/L)	15/06/92					29.00	
GAMMA GT	4-18 (U/L)	20/04/92	13.00		16.00		16.00	
LDH	120-240 (U/L)	20/04/92	134.00		210.00			
	130-300 (U/L)	15/06/92					202.00	
ALK. PHOSPH.	20-48 (U/L)	20/04/92	23.00		36.00			
	45-170 (U/L)	15/06/92					101.00	
GLUCOSE	60-110 (G/DL)	20/04/92	96.00		70.00			
	70-110 (MG/DL)	15/06/92					95.00	
UREA	15-35 (MG/DL)	20/04/92	37.00	>	49.00	>		
	10-50 (MG/DL)	15/06/92					26.00	
CREATININE	8-14 (MG/DL)	20/04/92	1.07	<	1.38	<		
	0.1-1.5 (MG/DL)	15/06/92					0.70	
URIC ACID	1.5-5 (MG/DL)	20/04/92	3.40		2.90			
	2.5-6 (MG/DL)	15/06/92					4.20	
TOT BILIRUBIN	0.2-1 (MG/DL)	20/04/92	0.66		0.66		0.55	
DIR BILIRUBIN	0-0.2 (MG/DL)	20/04/92	0.15		0.18			
	0-0.15 (MG/DL)	15/06/92					0.00	
TOT. PROTEINS	6.2-8 (G/DL)	20/04/92	7.00		7.50		7.00	
ALBUMINE	3.8-5 (G/DL)	20/04/92	4.07		4.10		4.80	
TOT. CHOLEST.	50-250 (MG/DL)	20/04/92	258.00	>	261.00	>		
	150-250 (MG/DL)	15/06/92					240.00	
TRIGLYCERIDES	50-160 (MG/DL)	20/04/92	98.00		114.00			
	35-150 (MG/DL)	15/06/92					106.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	20/04/92	0.24		0.28		0.19	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	20/04/92	0.62		0.73		0.40	<
GLOBULINS BETA	0.6-1 (G/DL)	20/04/92	0.94		0.98		0.58	<
GLOBULINS GAMMA	0.8-1.4 (G/DL)	20/04/92	1.13		1.41	>	1.00	
TSH	0-5 (UUI/ML)	20/04/92	2.70					
T4	4.6-12.2 (UG/DL)	20/04/92	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

PHARMACIA PHARMACEUTICI S.p.A. MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 413 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			22/04/92		27/05/92		24/06/92	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	12-16 (G/DL)	20/04/92	12.40		10.80	<		
	12.5-15 (GR%)	20/06/92					13.20	
HT	37-47 (%)	20/04/92	39.30		33.50	<		
	38-43 (%)	20/06/92					40.00	
RBC	4200000-5200000 (/MM3)	20/04/92	4210000		3530000	<<		
	4000000-4500000 (/MM3)	20/06/92					4350000	
WBC	4800-10800 (/MM3)	20/04/92	5400.00		4800.00			
	5000-9000 (/MM3)	20/06/92					5100.00	
WBC: N	60-70 (%)	20/04/92	62.00		61.00			
	50-65 (%)	20/06/92					62.00	
WBC: L	20-35 (%)	20/04/92	34.00		35.00			
	30-40 (%)	20/06/92					34.00	
WBC: E	2-4 (%)	20/04/92	2.00		2.00			
	0-3 (%)	20/06/92					3.00	
WBC: M	4-6 (%)	20/04/92	2.00	<	2.00	<		
	0-5 (%)	20/06/92					1.00	
WBC: B	0-2 (%)	20/04/92	0.00		0.00			
	0-1 (%)	20/06/92					0.00	
PLATELETS	130000-400000 (/MM3)	20/04/92	223000		231000			
	150000-300000 (/MM3)	20/06/92					250000	
NA+	135-146 (MEQ/L)	20/04/92	135.00		139.00			
	130-150 (MEQ/L)	20/06/92					142.00	
K+	3.5-5 (MEQ/L)	20/04/92	3.60		5.00			
	3-5 (MEQ/L)	20/06/92					3.90	
CL-	96-106 (MEQ/L)	20/04/92	96.00		96.00			
	95-105 (MEQ/L)	20/06/92					99.00	
Ca++	8.5-10.5 (MG/DL)	20/04/92	10.50		8.50			
	8.1-10.4 (MG/DL)	20/06/92					8.80	
PO4--	2.5-4.5 (MG/DL)	20/04/92	3.70		3.70			
	2.5-5 (MG/DL)	20/06/92					4.60	
SGOT	5-30 (U/L)	20/04/92	25.00		10.00			
	0-12 (MU/ML)	20/06/92					12.00	
SGPT	0-12 (MU/ML)	20/06/92					10.00	
	5-40 (U/L)	20/04/92	15.00		21.00			
GAMMA GT	6-28 (U/L)	20/04/92	7.80		7.70			
	4-18 (UI/L)	20/06/92					9.00	
LDH	120-240 (U/L)	20/04/92	160.00		149.00			
	120-240 (UI/L)	20/06/92					140.00	
ALK. PHOSPH.	20-48 (U/L)	20/04/92	20.00		26.00			
	20-48 (MU/ML)	20/06/92					25.00	
GLUCOSE	60-115 (MG/DL)	20/04/92	79.00		79.00			
	70-110 (MU/DL)	20/06/92					85.00	
UREA	18-40 (MG/DL)	20/04/92	20.00		20.00			
	15-40 (MG/DL)	20/06/92					20.00	
CREATININE	0.5-1.6 (MG/DL)	20/04/92	0.70		0.80			
	0.5-1.4 (MG/DL)	20/06/92					0.90	
URIC ACID	2.4-5.7 (MG/DL)	20/04/92	2.90		3.00		3.60	
TOT BILIRUBIN	0.1-1 (MG/DL)	20/04/92	0.90		0.82			
	0-1 (MG/DL)	20/06/92					0.80	
DIR BILIRUBIN	0-0.25 (MG/DL)	20/04/92	0.15		0.20			
	0-0.3 (MG/DL)	20/06/92					0.20	
TOT. PROTEINS	6-8 (G/DL)	20/04/92	7.30		7.60			
	6.3-8 (G/DL)	20/06/92					7.40	
ALBUMINE	2.7-4.8 (G/DL)	20/04/92	4.20		4.30			
	3.8-5 (G/DL)	20/06/92					4.70	
TOT. CHOLEST.	150-250 (MG/DL)	20/04/92	209.00		179.00			
	160-240 (MG/DL)	20/06/92					180.00	
TRIGLYCERIDES	35-160 (MG/DL)	20/04/92	85.00		67.00			

(CONTINUED)

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (value lower than min range) > out of range (value higher than max range
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICALS - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 413 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			22/04/92		27/05/92		24/06/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
TRIGLYCERIDES	30-150 (MG/DL)	20/06/92					75.00	
GLOBULINS ALPHA 1	0.12-0.4 (G/DL)	20/04/92	0.25		0.30			
	0.1-0.3 (G/DL)	20/06/92					0.20	
GLOBULINS ALPHA 2	0.3-0.64 (G/DL)	20/04/92	0.70	>	0.75	>		
	0.45-0.75 (G/DL)	20/06/92					0.65	
GLOBULINS BETA	0.66-1.2 (G/DL)	20/04/92	0.95		1.00			
	0.6-1 (G/DL)	20/06/92					0.78	
GLOBULINS GAMMA	0.9-1.6 (G/DL)	20/04/92	1.20		1.25			
	0.8-1.3 (G/DL)	20/06/92					1.07	
TSH	0-6.5 (UU/ML)	20/04/92	1.30					
T4	4.5-11.5 (UG/DL)	20/04/92	6.30					

(¢) << 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

			04/06/92		09/07/92		06/08/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12.5-15 (G/DL)	01/03/92	13.10		13.30			
	12-16 (G/DL)	05/08/92					15.50	
HT	38-43 (%)	01/03/92	40.00		41.00			
	37-47 (%)	05/08/92					46.00	
RBC	4000000-4500000 (/MM3)	01/03/92	4400000		4500000			
	4200000-5200000 (/MM3)	05/08/92					5170000	
WBC	5000-9000 (/MM3)	01/03/92	5900.00		6100.00			
	4500-9000 (/MM3)	05/08/92					5300.00	
WBC: N	50-65 (%)	01/03/92	49.00	<	58.00		41.00	<
WBC: L	30-40 (%)	01/03/92	47.00	>	38.00		56.00	>>
WBC: E	0-3 (%)	01/03/92	1.00		2.00		1.00	
WBC: M	0-5 (%)	01/03/92	3.00		2.00		2.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	215000		230000			
	150000-400000 (/MM3)	05/08/92					296000	
NA+	130-150 (MEQ/L)	01/03/92	139.00		142.00		140.00	
K+	3-5 (MEQ/L)	01/03/92	3.70		4.30			
	3-6 (MEQ/L)	05/08/92					3.70	
CL-	95-105 (MEQ/L)	01/03/92	100.00		100.00		101.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	10.20		9.90		9.80	
PO4--	2.5-5 (MG/DL)	01/03/92	4.10		3.90		4.70	
SGOT	0-12 (MU/ML)	01/03/92	19.00	>	12.00			
	5-21 (U/L)	05/08/92					15.00	
SGPT	0-12 (MU/ML)	01/03/92	23.00	>	12.00			
	5-22 (U/L)	05/08/92					14.00	
GAMMA GT	4-18 (UI/L)	01/03/92	5.20		14.00			
	5-25 (U/L)	05/08/92					19.00	
LDH	120-240 (UI/L)	01/03/92	215.00		200.00			
	160-320 (U/L)	05/08/92					191.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	66.00	>	60.00	>		
	45-170 (U/L)	05/08/92					110.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	95.00					
	70-110 (MU/DL)	20/06/92			90.00			
	60-105 (MG/DL)	05/08/92					91.00	
UREA	15-40 (MG/DL)	01/03/92	52.00	>	40.00			
	10-45 (MG/DL)	05/08/92					12.00	
CREATININE	0.5-1.4 (MG/DL)	01/03/92	0.80		0.90			
	0.8-1.4 (MG/DL)	05/08/92					0.86	
URIC ACID	2.4-5.7 (MG/DL)	01/03/92	4.90		4.60		5.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.50		0.50			
	0.1-1 (MG/DL)	05/08/92					0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.10		0.10		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	6.00	<	6.50			
	6.5-8 (G/DL)	05/08/92					6.70	
ALBUMINE	3.8-5 (G/DL)	01/03/92	3.80		4.00		3.80	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	220.00		175.00			
	150-240 (MG/DL)	05/08/92					180.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	82.00		80.00		88.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.10		0.16		0.15	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.60		0.54		0.75	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.70		0.72		0.90	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	0.80		1.08		1.10	
TSH	0-5 (UUI/ML)	01/03/92	2.10					
T4	4.5-13 (UG/DL)	01/03/92	9.60					

PHARMACIA PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 417 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			11/06/92		16/07/92		13/08/92	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	12.5-15 (G/DL)	01/03/92	10.80	<	12.00	<	13.00	
HT	38-43 (%)	01/03/92	38.00		40.00		39.00	
RBC	4000000-4500000 (/MM3)	01/03/92	4180000		4250000		4300000	
WBC	5000-9000 (/MM3)	01/03/92	5100.00		5400.00		5800.00	
WBC: N	50-65 (%)	01/03/92	60.00		56.00		65.00	
WBC: L	30-40 (%)	01/03/92	32.00		40.00		30.00	
WBC: E	0-3 (%)	01/03/92	4.00	>>	1.00		2.00	
WBC: M	0-5 (%)	01/03/92	4.00		3.00		3.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	220000		250000		250000	
NA+	130-150 (MEQ/L)	01/03/92	139.00		142.00		137.00	
K+	3-5 (MEQ/L)	01/03/92	4.30		4.60		4.60	
CL-	95-105 (MEQ/L)	01/03/92	104.00		102.00		101.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	11.40	>	10.70	>	10.80	>
PO4--	2.5-5 (MG/DL)	01/03/92	4.20		4.00		4.00	
SGOT	0-12 (MU/ML)	01/03/92	7.00		14.00	>	6.00	
SGPT	0-12 (MU/ML)	01/03/92	9.00		10.00		8.00	
GAMMA GT	4-18 (UI/L)	01/03/92	14.00		11.00		16.00	
LDH	120-240 (UI/L)	01/03/92	205.00		190.00		200.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	30.00		38.00		35.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	76.00		82.00		85.00	
UREA	15-40 (MG/DL)	01/03/92	45.00	>	40.00		46.00	>
CREATININE	0.5-1.4 (MG/DL)	01/03/92	1.25		1.05		1.20	
URIC ACID	2.4-5.7 (MG/DL)	01/03/92	4.50		4.20		4.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.65		0.60		0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.15		0.13		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	6.70		7.00		7.02	
ALBUMINE	3.8-5 (G/DL)	01/03/92	3.80		3.70	<	3.90	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	232.00		225.00		225.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	110.00		103.00		120.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.25		0.28		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.55		0.65		0.60	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.80		0.88		0.85	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.30		1.25		1.27	
TSH	0-5 (UUI/ML)	01/03/92	2.50					
T4	4.5-13 (UG/DL)	01/03/92	8.10					

1000

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL RESEARCH - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 418 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			07/07/92		13/08/92		10/09/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-15 (G/DL)	01/07/92	11.30	<	11.70	<	11.00	<
HT	36-43 (%)	01/07/92	34.00	<	36.00		32.00	<
RBC	4200000-5200000 (/MM3)	01/07/92	4200000		4250000		4180000	<
WBC	4500-10000 (/MM3)	01/07/92	7100.00		7000.00		6500.00	
WBC: N	50-65 (%)	01/07/92	70.00	>	68.00	>	65.00	
WBC: L	30-40 (%)	01/07/92	24.00	<	28.00	<	30.00	
WBC: E	0-3 (%)	01/07/92	4.00	>>	1.00		1.00	
WBC: M	0-5 (%)	01/07/92	2.00		3.00		4.00	
WBC: B	0-1 (%)	01/07/92	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM3)	01/07/92	320000		310000		300000	
NA+	130-150 (MEQ/L)	01/07/92	142.00		140.00		139.00	
K+	3-5 (MEQ/L)	01/07/92	3.10		3.50		4.20	
CL-	95-105 (MEQ/L)	01/07/92	98.00		100.00		100.00	
Ca++	8.1-10.4 (MG/DL)	01/07/92	8.30		8.50		8.80	
PO4--	2.5-5 (MG/DL)	01/07/92	4.20		3.90		3.50	
SGOT	2-19 (U/L)	01/07/92	9.00		10.00		10.00	
SGPT	2-24 (U/L)	01/07/92	12.00		11.00		15.00	
GAMMA GT	6-28 (U/L)	01/07/92	14.00		15.00		12.00	
LDH	120-240 (U/L)	01/07/92	179.00		175.00		200.00	
ALK. PHOSPH.	45-170 (U/L)	01/07/92	171.00	>	165.00		160.00	
GLUCOSE	0.7-1.1 (G/L)	01/07/92	0.81		0.90		0.85	
UREA	0.15-0.4 (G/DL)	01/07/92	0.28		0.30		0.22	
CREATININE	0.8-1.4 (MG/DL)	01/07/92	1.00		0.90		0.85	
URIC ACID	2.4-5.7 (MG/DL)	01/07/92	4.60		4.40		5.00	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/07/92	0.34		0.30		0.35	
DIR BILIRUBIN	0-0.2 (MG/DL)	01/07/92	0.04		0.03		0.07	
TOT. PROTEINS	6-8 (G/DL)	01/07/92	7.10		7.50		7.20	
ALBUMINE	3.5-4.5 (G/DL)	01/07/92	4.52	>	4.60	>	4.50	
TOT. CHOLEST.	100-220 (MG/DL)	01/07/92	178.00		185.00		205.00	
TRIGLYCERIDES	50-160 (MG/DL)	01/07/92	45.00	<	60.00		70.00	
GLOBULINS ALPHA 1	0.2-0.48 (G/DL)	01/07/92	0.24		0.25		0.28	
GLOBULINS ALPHA 2	0.6-0.75 (G/DL)	01/07/92	0.46	<	0.48	<	0.45	<
GLOBULINS BETA	0.75-1 (G/DL)	01/07/92	0.78		0.77		0.85	
GLOBULINS GAMMA	0.9-1.3 (G/DL)	01/07/92	1.09		1.10		1.20	
TSH	0.1-6.5 (UU/ML)	01/07/92	0.48					
T4	4.6-12.2 (UG/DL)	01/07/92	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

PHARMACIA PHARMACEUTICA HOLDING - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 421 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			24/07/92		28/08/92		25/09/92	
			value	(◊)	value	(◊)	value	(◊)
Laboratory test	Range value	Range date						
HB	12.5-15 (G/DL)	01/03/92	14.40		13.80		13.40	
HT	38-43 (%)	01/03/92	44.00	>	41.00		43.00	
RBC	4000000-4500000 (/MM3)	01/03/92	4840000	>	4750000	>	4730000	>
WBC	5000-9000 (/MM3)	01/03/92	7000.00		7100.00		7100.00	
WBC: N	50-65 (%)	01/03/92	72.00	>	70.00	>	62.00	
WBC: L	30-40 (%)	01/03/92	28.00	<	26.00	<	35.00	
WBC: E	0-3 (%)	01/03/92	0.00		1.00		0.00	
WBC: M	0-5 (%)	01/03/92	0.00		3.00		3.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	270000		280000		265000	
NA+	130-150 (MEQ/L)	01/03/92	139.00		143.00		142.00	
K+	3-5 (MEQ/L)	01/03/92	4.80		4.60		4.50	
CL-	95-105 (MEQ/L)	01/03/92	109.00	>	104.00		105.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	11.40	>	10.80	>	10.80	>
PO4--	2.5-5 (MG/DL)	01/03/92	4.20		4.50		4.20	
SGOT	0-12 (MU/ML)	01/03/92	10.00		9.00		7.00	
SGPT	0-12 (MU/ML)	01/03/92	13.00	>	11.00		9.00	
GAMMA GT	4-18 (UI/L)	01/03/92	10.00		12.00		8.00	
LDH	120-240 (UI/L)	01/03/92	195.00		185.00		212.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	25.00		29.00		36.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	69.00	<	75.00		96.00	
UREA	15-40 (MG/DL)	01/03/92	43.00	>	38.00		40.00	
CREATININE	0.5-1.4 (MG/DL)	01/03/92	1.20		1.05		1.15	
URIC ACID	2.4-5.7 (MG/DL)	01/03/92	6.70	>	6.10	>	5.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.75		0.80		0.75	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.25		0.20		0.25	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	7.15		7.15		7.10	
ALBUMINE	3.8-5 (G/DL)	01/03/92	4.00		4.30		3.80	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	163.00		175.00		202.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	63.00		65.00		86.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.25		0.20		0.30	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.70		0.65		0.75	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.80		0.90		0.85	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.40	>	1.10		1.40	>
TSH	0-5 (UUI/ML)	01/03/92	0.80					
T4	4.5-13 (UG/DL)	01/03/92	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 PHARMACEUTICAL NOVARA - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 424 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			13/08/92		17/09/92		15/10/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	13.5-15.5 (G/DL)	01/03/92	15.80	>	16.00	>	14.50	
HT	40-45 (%)	01/03/92	47.00	>	45.00		45.00	
RBC	4200000-4800000 (/MM3)	01/03/92	5170000	>	5200000	>	4950000	>
WBC	5000-9000 (/MM3)	01/03/92	8100.00		7600.00		7700.00	
WBC: N	50-65 (%)	01/03/92	59.00		57.00		62.00	
WBC: L	30-40 (%)	01/03/92	35.00		37.00		34.00	
WBC: E	0-3 (%)	01/03/92	5.00	>>	4.00	>>	1.00	
WBC: M	0-5 (%)	01/03/92	1.00		2.00		3.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	245000		240000		230000	
NA+	130-150 (MEQ/L)	01/03/92	138.00		130.00		141.00	
K+	3-5 (MEQ/L)	01/03/92	4.60		4.80		4.80	
CL-	95-105 (MEQ/L)	01/03/92	108.00	>	100.00		100.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	10.60	>	9.80		10.90	>
PO4--	2.5-5 (MG/DL)	01/03/92	4.10		4.50		3.70	
SGOT	0-12 (MU/ML)	01/03/92	8.00		9.00		7.00	
SGPT	0-12 (MU/ML)	01/03/92	10.00		11.00		10.00	
GAMMA GT	6-28 (UI/L)	01/03/92	12.00		15.00		14.00	
LDH	120-240 (UI/L)	01/03/92	205.00		195.00		145.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	38.00		35.00		34.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	101.00		95.00		88.00	
UREA	15-40 (MG/DL)	01/03/92	36.00		30.00		29.00	
CREATININE	0.5-1.4 (MG/DL)	01/03/92	1.00		0.90		0.90	
URIC ACID	3.4-7 (MG/DL)	01/03/92	5.00		4.50		4.50	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.70		0.60		0.75	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.20		0.15		0.25	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	7.00		7.00		7.25	
ALBUMINE	3.8-5 (G/DL)	01/03/92	4.00		4.25		4.00	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	242.00	>	230.00		202.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	95.00		80.00		92.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.25		0.10		0.30	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.60		0.65		0.70	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.80		0.90		0.85	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.35	>	1.10		1.40	>
TSH	0-5 (UUI/ML)	01/03/92	0.80					
T4	4.5-13 (UG/DL)	01/03/92	12.70					

1003

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL RESEARCH - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 425 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			24/09/92		29/10/92		26/11/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-15 (G/DL)	20/09/92	13.87		14.00		13.72	
HT	38-43 (%)	20/09/92	42.00		42.50		43.00	
RBC	4200000-4800000 (/MM3)	20/09/92	4540000		4700000		4620000	
WBC	4500-10000 (/MM3)	20/09/92	5400.00		5200.00		4900.00	
WBC: N	50-65 (%)	20/09/92	64.00		67.00	>	53.00	
WBC: L	30-40 (%)	20/09/92	27.00	<	30.00		41.00	>
WBC: E	0-3 (%)	20/09/92	2.00		1.00		2.00	
WBC: M	0-6 (%)	20/09/92	7.00	>	2.00		4.00	
WBC: B	0-1 (%)	20/09/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	20/09/92	230000		240000		242000	
NA+	136-146 (MEQ/L)	20/09/92	143.00		140.00		140.00	
K+	3.5-5.4 (MEQ/L)	20/09/92	4.50		4.20		3.90	
CL-	98-109 (MEQ/L)	20/09/92	101.00		99.00		102.00	
Ca++	9-11 (MG/DL)	20/09/92	9.20		8.70	<	10.00	
PO4--	3-4 (MG/DL)	20/09/92	3.80		4.00		3.80	
SGOT	2-30 (U/L)	20/09/92	12.00		10.00		15.00	
SGPT	2-30 (U/L)	20/09/92	9.00		12.00		10.00	
GAMMA GT	4-18 (U/L)	20/09/92	11.00		15.00		20.00	>
LDH	130-300 (U/L)	20/09/92	200.00		230.00		266.00	
ALK. PHOSPH.	45-170 (U/L)	20/09/92	105.00		102.00		127.00	
GLUCOSE	70-110 (MG/DL)	20/09/92	89.00		92.00		95.00	
UREA	10-50 (MG/DL)	20/09/92	57.00	>	47.00		28.00	
CREATININE	0.1-1.5 (MG/DL)	20/09/92	1.40		1.10		1.00	
URIC ACID	2.5-6 (MG/DL)	20/09/92	5.60		4.70		4.20	
TOT BILIRUBIN	0.2-1 (MG/DL)	20/09/92	0.58		0.65		0.60	
DIR BILIRUBIN	0-0.15 (MG/DL)	20/09/92	0.00		0.10		0.00	
TOT. PROTEINS	6.2-8 (G/DL)	20/09/92	6.40		6.80		7.10	
ALBUMINE	3.8-5 (G/DL)	20/09/92	4.25		3.80		4.00	
TOT. CHOLEST.	150-250 (MG/DL)	20/09/92	247.00		230.00		273.00	>
TRIGLYCERIDES	35-150 (MG/DL)	20/09/92	104.00		99.00		105.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	20/09/92	0.16		0.25		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	20/09/92	0.18	<<	0.70		0.75	
GLOBULINS BETA	0.6-1 (G/DL)	20/09/92	0.63		0.95		1.00	
GLOBULINS GAMMA	0.8-1.4 (G/DL)	20/09/92	1.18		1.10		1.15	
TSH	0.6-6.5 (UU/ML)	20/09/92	2.00					
T4	4.5-12.5 (UG/DL)	20/09/92	8.50					

(¢) << 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 PHARMACEUTICAL RESEARCH - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 427 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			25/11/92		30/12/92		27/01/93	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12.5-15 (G/DL)	01/03/92	13.00		13.30		14.00	
HT	38-43 (%)	01/03/92	40.20		40.10		39.00	
RBC	4000000-4500000 (/MM3)	01/03/92	4200000		4600000	>	4500000	
WBC	5000-9000 (/MM3)	01/03/92	5900.00		5500.00		6300.00	
WBC: N	50-65 (%)	01/03/92	60.00		58.00		65.00	
WBC: L	30-40 (%)	01/03/92	35.00		38.00		30.00	
WBC: E	0-3 (%)	01/03/92	3.00		1.00		2.00	
WBC: M	0-5 (%)	01/03/92	2.00		3.00		3.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	319000	>	280000		280000	
NA+	130-150 (MEQ/L)	01/03/92	131.00		133.00		142.00	
K+	3-5 (MEQ/L)	01/03/92	4.60		4.40		4.70	
CL-	95-105 (MEQ/L)	01/03/92	105.00		102.00		104.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	8.70		8.60		9.20	
PO4--	2.5-5 (MG/DL)	01/03/92	3.60		3.80		4.10	
SGOT	0-12 (MU/ML)	01/03/92	12.00		11.00		10.00	
SGPT	0-12 (MU/ML)	01/03/92	11.00		13.00	>	19.00	>
GAMMA GT	4-18 (UI/L)	01/03/92	10.00		15.00		15.00	
LDH	120-240 (UI/L)	01/03/92	116.00	<	120.00		130.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	22.00		24.00		33.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	78.00		75.00		80.00	
UREA	15-40 (MG/DL)	01/03/92	20.00		23.00		31.00	
CREATININE	0.5-1.4 (MG/DL)	01/03/92	1.00		1.04		0.90	
URIC ACID	2.4-5.7 (MG/DL)	01/03/92	3.30		3.20		2.90	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.92		0.95		0.80	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.18		0.15		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	8.00		7.90		6.15	<
ALBUMINE	3.8-5 (G/DL)	01/03/92	4.65		4.80		4.00	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	227.00		220.00		205.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	68.00		72.00		85.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.30		0.25		0.15	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.75		0.70		0.45	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	1.00		0.90		0.70	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.30		1.20		0.85	
TSH	0-5 (UUI/ML)	01/03/92	1.99					
T4	4.5-13 (UG/DL)	01/03/92	5.40					

(¢) << 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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 449 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory data					
			Screen		Day 28		Day 56	
			01/12/92		04/01/93		01/02/93	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12.5-15 (G/DL)	01/03/92	13.50		12.90		14.40	
HT	38-43 (%)	01/03/92	42.00		41.60		43.60	>
RBC	4000000-4500000 (/MM3)	01/03/92	4700000	>	4590000	>	4820000	>
WBC	5000-9000 (/MM3)	01/03/92	6500.00		7200.00		7300.00	
WBC: N	50-65 (%)	01/03/92	68.00	>	63.00		61.00	
WBC: L	30-40 (%)	01/03/92	28.00	<	33.00		36.00	
WBC: E	0-3 (%)	01/03/92	2.00		1.00		1.00	
WBC: M	0-5 (%)	01/03/92	2.00		3.00		2.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	240000		215000		225000	
NA+	130-150 (MEQ/L)	01/03/92	133.00		141.00		141.00	
K+	3-5 (MEQ/L)	01/03/92	4.20		4.90		4.80	
CL-	95-105 (MEQ/L)	01/03/92	99.00		103.00		98.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	10.00		10.50	>	10.40	
PO4--	2.5-5 (MG/DL)	01/03/92	4.10		4.70		3.40	
SGOT	0-12 (MU/ML)	01/03/92	6.00		8.00		9.00	
SGPT	0-12 (MU/ML)	01/03/92	9.00		8.00		8.00	
GAMMA GT	4-18 (UI/L)	01/03/92	11.00		14.00		11.00	
LDH	120-240 (UI/L)	01/03/92	142.00		150.00		190.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	18.00	<	21.00		32.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	88.00		85.00		85.00	
UREA	15-40 (MG/DL)	01/03/92	28.00		24.00		31.00	
CREATININE	0.5-1.4 (MG/DL)	01/03/92	1.15		1.00		0.90	
URIC ACID	2.4-5.7 (MG/DL)	01/03/92	2.90		2.60		4.40	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.65		0.50		0.55	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.11		0.08		0.10	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	6.60		6.80		6.90	
ALBUMINE	3.8-5 (G/DL)	01/03/92	3.70	<	3.90		3.90	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	185.00		190.00		185.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	77.00		80.00		77.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.20		0.25		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.70		0.60		0.70	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.80		0.95		0.90	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.20		1.10		1.20	
TSH	0-5 (UUI/ML)	01/03/92	2.10					
T4	4.5-13 (UG/DL)	01/03/92	8.60					

1006

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL-MIDWEST - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 452 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			15/12/92		19/01/93		16/02/93	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	12.5-15 (G/DL)	01/03/92	12.80		13.00		14.00	
HT	38-43 (%)	01/03/92	41.00		41.20		43.00	
RBC	4000000-4500000 (/MM3)	01/03/92	4510000	>	4600000	>	4730000	>
WBC	5000-9000 (/MM3)	01/03/92	7100.00		7200.00		7100.00	
WBC: N	50-65 (%)	01/03/92	66.00	>	68.00	>	59.00	
WBC: L	30-40 (%)	01/03/92	32.00		30.00		37.00	
WBC: E	0-3 (%)	01/03/92	0.00		1.00		2.00	
WBC: M	0-5 (%)	01/03/92	2.00		1.00		2.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	220000		210000		210000	
NA+	130-150 (MEQ/L)	01/03/92	138.00		141.00		139.00	
K+	3-5 (MEQ/L)	01/03/92	4.30		4.70		4.20	
CL-	95-105 (MEQ/L)	01/03/92	106.00	>	101.00		105.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	10.80	>	10.40		9.80	
PO4--	2.5-5 (MG/DL)	01/03/92	3.70		4.30		3.70	
SGOT	0-12 (MU/ML)	01/03/92	7.00		5.00		7.00	
SGPT	0-12 (MU/ML)	01/03/92	8.00		9.00		9.00	
GAMMA GT	4-18 (UI/L)	01/03/92	8.00		10.00		8.00	
LDH	120-240 (UI/L)	01/03/92	195.00		190.00		207.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	22.00		25.00		24.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	85.00		90.00		79.00	
UREA	15-40 (MG/DL)	01/03/92	32.00		30.00		28.00	
CREATININE	0.5-1.4 (MG/DL)	01/03/92	0.90		0.85		0.75	
URIC ACID	2.4-5.7 (MG/DL)	01/03/92	2.50		2.40		4.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.65		0.55		0.65	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.15		0.10		0.15	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	6.70		6.80		7.20	
ALBUMINE	3.8-5 (G/DL)	01/03/92	3.60	<	3.70	<	3.95	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	212.00		205.00		222.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	86.00		90.00		95.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.30		0.25		0.25	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.65		0.70		0.75	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.75		0.85		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.40	>	1.30		1.45	>
TSH	0-5 (UUI/ML)	01/03/92	1.40					
T4	4.5-13 (UG/DL)	01/03/92	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

PHARMACIA PHARMACEUTICALS [illegible] - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 430 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			26/03/92		27/04/92		25/05/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	13.5-15.5 (GR%)	01/02/92	13.60		14.00		14.50	
HT	40-45 (%)	01/02/92	43.00		44.00		45.00	
RBC	4200000-4800000 (/MM3)	01/02/92	4900000	>	5000000	>	4950000	>
WBC	5000-9000 (/MM3)	01/02/92	6200.00		8000.00		7100.00	
WBC: N	50-65 (%)	01/02/92	56.00		65.00		62.00	
WBC: L	30-40 (%)	01/02/92	34.00		29.00	<	38.00	
WBC: E	0-3 (%)	01/02/92	7.00	>>	4.00	>>	0.00	
WBC: M	0-5 (%)	01/02/92	3.00		2.00		0.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	210000		230000		240000	
NA+	130-150 (MEQ/L)	01/02/92	135.00		140.00		141.00	
K+	3-5 (MEQ/L)	01/02/92	3.90		4.20		4.00	
CL-	95-105 (MEQ/L)	01/02/92	105.00		101.00		105.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.00		9.80		10.00	
PO4--	2.5-5 (MG/DL)	01/02/92	3.20		2.20	<	2.90	
SGOT	0-12 (MU/ML)	01/02/92	11.00		10.00		10.00	
SGPT	0-12 (MU/ML)	01/02/92	6.00		5.00		9.00	
GAMMA GT	6-28 (UI/L)	01/02/92	34.00	>	13.00		12.00	
LDH	120-240 (UI/L)	01/02/92	128.00		91.00	<	142.00	
ALK. PHOSPH.	68-210 (MU/ML)	01/02/92	202.00		143.00			
	20-48 (MU/ML)	20/05/92					22.00	
GLUCOSE	70-110 (MG/L)	01/02/92	68.00	<	85.00		91.00	
UREA	15-40 (MG/DL)	01/02/92	33.00		41.00	>	33.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.50	>	0.92		1.00	
URIC ACID	3.4-7 (MG/DL)	01/02/92	4.50		5.00		3.00	<
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.77		0.70		0.65	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.15		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.50				6.95	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.70	<			4.00	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	186.00		179.00		215.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	127.00		82.00		85.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.23		0.22		0.25	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.62		0.62		0.65	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.82		0.80		0.75	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.13		1.13		1.30	
TSH	0-5 (UUI/ML)	01/02/92	1.80					
T4	4.5-13 (UG/DL)	01/02/92	6.80					

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (value lower than min range) > out of range (value higher than max range
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICALS - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 431 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			26/03/92		27/04/92		25/05/92	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	12.5-15 (G/DL)	01/02/92	13.50		13.00		13.50	
HT	38-43 (%)	01/02/92	42.00		43.00		42.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4620000	>	4730000	>	4620000	>
WBC	5000-9000 (/MM3)	01/02/92	7000.00		6600.00		6900.00	
WBC: N	50-65 (%)	01/02/92	60.00		68.00	>	70.00	>
WBC: L	30-40 (%)	01/02/92	40.00		30.00		30.00	
WBC: E	0-3 (%)	01/02/92	0.00		2.00		0.00	
WBC: M	0-5 (%)	01/02/92	0.00		0.00		0.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	220000		235000		235000	
NA+	130-150 (MEQ/L)	01/02/92	143.00		138.00		142.00	
K+	3-5 (MEQ/L)	01/02/92	4.20		4.70		4.10	
CL-	95-105 (MEQ/L)	01/02/92	108.00	>	98.00		106.00	>
Ca++	8.1-10.4 (MG/DL)	01/02/92	9.20		10.90	>	9.80	
PO4--	2.5-5 (MG/DL)	01/02/92	3.10		4.80		3.00	
SGOT	0-12 (MU/ML)	01/02/92	8.00		8.00		6.00	
SGPT	0-12 (MU/ML)	01/02/92	5.00		10.00		8.00	
GAMMA GT	4-18 (UI/L)	01/02/92	12.00		14.00		9.00	
LDH	120-240 (UI/L)	01/02/92	125.00		225.00		139.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	28.00		46.00		23.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	100.00		102.00		100.00	
UREA	15-40 (MG/DL)	01/02/92	43.00	>	48.00	>	30.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.20		1.20		1.90	>
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	5.00		4.20		3.50	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.60		0.70		0.59	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.10		0.20		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.75		7.25		7.00	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.60	<	3.80		3.90	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	250.00	>	204.00		220.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	102.00		115.00		90.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.25		0.30		0.30	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.70		0.80	>	0.60	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.80		0.90		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40	>	1.45	>	1.40	>
TSH	0-5 (UUI/ML)	01/02/92	0.87					
T4	4.5-13 (UG/DL)	01/02/92	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

PHARMACIA PHARMACEUTICAL TRAINING - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 433 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			28/03/92		29/04/92		27/05/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12.5-15 (GRX)	25/03/92	13.30		12.80		12.50	
HT	38-43 (%)	25/03/92	40.00		42.00		41.00	
RBC	4000000-4500000 (/MM3)	25/03/92	4400000		4620000	>	4510000	>
WBC	5000-9000 (/MM3)	25/03/92	6300.00		6900.00		6900.00	
WBC: N	50-65 (%)	25/03/92	55.00		71.00	>	70.00	>
WBC: L	30-40 (%)	25/03/92	40.00		29.00	<	30.00	
WBC: E	0-3 (%)	25/03/92	3.00		0.00		0.00	
WBC: M	0-5 (%)	25/03/92	2.00		0.00		0.00	
WBC: B	0-1 (%)	25/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	25/03/92	200000		210000		230000	
NA+	130-150 (MEQ/L)	25/03/92	147.00		140.00		145.00	
K+	3-5 (MEQ/L)	25/03/92	4.40		3.50		3.90	
CL-	95-105 (MEQ/L)	25/03/92	105.00		104.00		100.00	
Ca++	8.1-10.4 (MG/DL)	25/03/92	10.00		10.00		9.20	
PO4--	2.5-5 (MG/DL)	25/03/92	4.10		3.00		2.90	
SGOT	0-12 (MU/ML)	25/03/92	7.00		6.00		7.00	
SGPT	0-12 (MU/ML)	25/03/92	8.00		8.00		7.00	
GAMMA GT	4-18 (UI/L)	25/03/92	8.00		12.00		14.00	
LDH	120-240 (UI/L)	25/03/92	164.00		155.00		166.00	
ALK. PHOSPH.	20-48 (MU/ML)	25/03/92	18.00	<				
GLUCOSE	70-110 (MG/L)	25/03/92	94.00		77.00		79.00	
UREA	15-40 (MG/DL)	25/03/92	23.00		31.00		33.00	
CREATININE	0.5-1.4 (MG/DL)	25/03/92	1.00		1.20		1.05	
URIC ACID	2.4-5.7 (MG/DL)	25/03/92	3.30		5.00		5.10	
TOT BILIRUBIN	0-1 (MG/DL)	25/03/92	0.70		0.60		0.55	
DIR BILIRUBIN	0-0.3 (MG/DL)	25/03/92	0.10		0.20		0.25	
TOT. PROTEINS	6.3-8 (G/DL)	25/03/92	6.80		7.25		7.15	
ALBUMINE	3.8-5 (G/DL)	25/03/92	4.02		4.00		3.90	
TOT. CHOLEST.	160-240 (MG/DL)	25/03/92	176.00		240.00		220.00	
TRIGLYCERIDES	0.3-1.7 (G/L)	25/03/92	0.40					
	30-150 (MG/DL)	25/04/92			105.00		100.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	25/03/92	0.21		0.25		0.30	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	25/03/92	0.66		0.75		0.70	
GLOBULINS BETA	0.6-1 (G/DL)	25/03/92	0.75		0.85		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	25/03/92	1.16		1.40	>	1.45	>
TSH	0-5 (UUI/ML)	25/03/92	1.10					
T4	4.5-13 (UG/DL)	25/03/92	5.50					

(¢) << 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

PHARMACIA PHARMACEUTICALS/UPJOHN - CNS 9550883

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 435 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			09/04/92		11/05/92		08/06/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12.5-15 (G/DL)	01/02/92	12.50		12.00	<	12.50	
HT	38-43 (%)	01/02/92	42.00		42.00		41.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4620000	>	4620000	>	4510000	>
WBC	5000-9000 (/MM3)	01/02/92	7500.00		6200.00		6000.00	
WBC: N	50-65 (%)	01/02/92	72.00	>	58.00		62.00	
WBC: L	30-40 (%)	01/02/92	28.00	<	38.00		38.00	
WBC: E	0-3 (%)	01/02/92	0.00		1.00		0.00	
WBC: M	0-5 (%)	01/02/92	0.00		3.00		0.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	230000		215000		230000	
NA+	130-150 (MEQ/L)	01/02/92	138.00		138.00		146.00	
K+	3-5 (MEQ/L)	01/02/92	3.60		4.40		4.00	
CL-	95-105 (MEQ/L)	01/02/92	110.00	>	110.00	>	106.00	>
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.40		9.20		9.00	
PO4--	2.5-5 (MG/DL)	01/02/92	3.40		4.30		4.00	
SGOT	0-12 (MU/ML)	01/02/92	7.00		15.00	>	6.00	
SGPT	0-12 (MU/ML)	01/02/92	10.00		13.00	>	5.00	
GAMMA GT	4-18 (UI/L)	01/02/92	8.00		14.00		12.00	
LDH	120-240 (UI/L)	01/02/92	165.00		155.00		150.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	40.00		34.00		30.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	79.00		70.00		78.00	
UREA	15-40 (MG/DL)	01/02/92	28.00		34.00		30.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.10		1.20		1.15	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	5.00		4.50		4.40	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.75		1.75	>	0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.25		0.15		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.85		6.60		6.75	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.80		3.60	<	3.70	<
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	264.00	>	232.00		220.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	90.00		85.00		78.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.20		0.25	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.70		0.65		0.60	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.75		0.80		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40	>	1.35	>	1.40	>
TSH	0-5 (UUI/ML)	01/02/92	1.80					
T4	4.5-13 (UG/DL)	01/02/92	5.60					

(¢) << 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 PHARMACEUTICALS MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 437 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			24/04/92		27/05/92		24/06/92	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	12.5-15 (G/DL)	01/02/92	13.50		13.80		13.00	
HT	38-43 (%)	01/02/92	41.00		41.00		40.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4500000		4510000	>	4400000	
WBC	5000-9000 (/MM3)	01/02/92	6200.00		7000.00		6100.00	
WBC: N	50-65 (%)	01/02/92	64.00		68.00	>	63.00	
WBC: L	30-40 (%)	01/02/92	32.00		30.00		37.00	
WBC: E	0-3 (%)	01/02/92	2.00		0.00		0.00	
WBC: M	0-5 (%)	01/02/92	2.00		0.00		0.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	210000		270000		270000	
NA+	130-150 (MEQ/L)	01/02/92	140.00		138.00		144.00	
K+	3-5 (MEQ/L)	01/02/92	3.90		4.10		4.00	
CL-	95-105 (MEQ/L)	01/02/92	110.00	>	105.00		98.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	9.30		9.10		10.20	
PO4--	2.5-5 (MG/DL)	01/02/92			3.80		3.90	
SGOT	0-12 (MU/ML)	01/02/92	16.00	>	7.00		9.00	
SGPT	0-12 (MU/ML)	01/02/92	18.00	>	8.00		11.00	
GAMMA GT	4-18 (UI/L)	01/02/92	15.00		13.00		11.00	
LDH	120-240 (UI/L)	01/02/92	195.00		144.00		125.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	22.00		33.00		29.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	93.00		77.00		79.00	
UREA	15-40 (MG/DL)	01/02/92	35.00		28.00		25.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	0.80		0.85		0.82	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	4.50		2.90		3.10	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.50		0.70		0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.30		0.20		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.30		6.80		6.70	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.70	<	3.90		3.80	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	181.00		185.00		177.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	193.00	>	91.00		92.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.22		0.20		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.83	>	0.55		0.55	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	1.01	>	0.75		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.44	>	1.40	>	1.35	>
TSH	0-5 (UUI/ML)	01/02/92	2.88					
T4	4.5-13 (UG/DL)	01/02/92	14.10	>				

1012

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (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 PHARMACEUTICALS S.p.A. - CNS

9590083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 440 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date	
			Day 56	
			25/08/92	
			value	(¢)
Laboratory test	Range value	Range date		
HB	12.5-15 (G/DL)	01/02/92	13.00	
HT	38-43 (%)	01/02/92	40.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4400000	
WBC	5000-9000 (/MM3)	01/02/92	7000.00	
WBC: N	50-65 (%)	01/02/92	71.00	>
WBC: L	30-40 (%)	01/02/92	29.00	<
WBC: E	0-3 (%)	01/02/92	0.00	
WBC: M	0-5 (%)	01/02/92	0.00	
WBC: B	0-1 (%)	01/02/92	0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	290000	
NA+	130-150 (MEQ/L)	01/02/92	139.00	
K+	3-5 (MEQ/L)	01/02/92	4.30	
CL-	95-105 (MEQ/L)	01/02/92	102.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	9.00	
PO4--	2.5-5 (MG/DL)	01/02/92	4.20	
SGOT	0-12 (MU/ML)	01/02/92	6.00	
SGPT	0-12 (MU/ML)	01/02/92	7.00	
GAMMA GT	4-18 (UI/L)	01/02/92	13.00	
LDH	120-240 (UI/L)	01/02/92	155.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	39.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	70.00	
UREA	15-40 (MG/DL)	01/02/92	31.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	0.95	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	3.90	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.65	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.65	<
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	240.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	90.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.65	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.85	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.30	

(¢) << 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 PHARMACEUTICI [illegible] - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 442 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			14/07/92		17/08/92		14/09/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12.5-15 (G/DL)	01/02/92	13.00		12.50		14.00	
HT	38-43 (%)	01/02/92	41.00		42.00		44.00	>
RBC	4000000-4500000 (/MM3)	01/02/92	4510000	>	4620000	>	4840000	>
WBC	5000-9000 (/MM3)	01/02/92	7000.00		6700.00		6500.00	
WBC: N	50-65 (%)	01/02/92	65.00		62.00		63.00	
WBC: L	30-40 (%)	01/02/92	32.00		38.00		32.00	
WBC: E	0-3 (%)	01/02/92	2.00		0.00		2.00	
WBC: M	0-5 (%)	01/02/92	1.00		0.00		3.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	210000		230000		270000	
NA+	130-150 (MEQ/L)	01/02/92	142.00		143.00		145.00	
K+	3-5 (MEQ/L)	01/02/92	4.00		4.00		4.80	
CL-	95-105 (MEQ/L)	01/02/92	101.00		98.00		100.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.00		9.80		9.00	
PO4--	2.5-5 (MG/DL)	01/02/92	4.10		3.80		4.50	
SGOT	0-12 (MU/ML)	01/02/92	6.00		7.00		7.00	
SGPT	0-12 (MU/ML)	01/02/92	8.00		7.00		8.00	
GAMMA GT	4-18 (UI/L)	01/02/92	12.00		10.00		10.00	
LDH	120-240 (UI/L)	01/02/92	144.00		138.00		145.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	22.00		28.00		30.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	97.00		77.00		90.00	
UREA	15-40 (MG/DL)	01/02/92	28.00		21.00		38.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.05		1.00		0.90	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	4.00		4.00		4.50	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.55		0.65		0.55	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.15		0.25		0.25	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.80		7.00		6.85	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.90		4.00		3.80	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	205.00		207.00		210.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	105.00		107.00		89.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.28		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.60		0.62		0.65	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.75		0.70		0.85	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.35	>	1.40	>	1.35	>
TSH	0-5 (UUI/ML)	01/02/92	1.02					
T4	4.5-13 (UG/DL)	01/02/92	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 PHARMACEUTICALS/UPJOHN - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 444 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			20/08/92		21/09/92		19/10/92	
			value	(◊)	value	(◊)	value	(◊)
Laboratory test	Range value	Range date						
HB	12.5-15 (G/DL)	01/02/92	13.00		13.20		13.00	
HT	38-43 (%)	01/02/92	42.00		43.00		41.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4620000	>	4730000	>	4510000	>
WBC	5000-9000 (/MM3)	01/02/92	7000.00		7100.00		6800.00	
WBC: N	50-65 (%)	01/02/92	62.00		61.00		61.00	
WBC: L	30-40 (%)	01/02/92	38.00		39.00		39.00	
WBC: E	0-3 (%)	01/02/92	0.00		0.00		0.00	
WBC: M	0-5 (%)	01/02/92	0.00		0.00		0.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	270000		265000		280000	
NA+	130-150 (MEQ/L)	01/02/92	144.00		139.00		140.00	
K+	3-5 (MEQ/L)	01/02/92	4.80		4.00		4.00	
CL-	95-105 (MEQ/L)	01/02/92	102.00		98.00		101.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	9.20		10.00		9.80	
PO4--	2.5-5 (MG/DL)	01/02/92	4.00		4.00		3.80	
SGOT	0-12 (MU/ML)	01/02/92	6.00		8.00		7.00	
SGPT	0-12 (MU/ML)	01/02/92	8.00		8.00		8.00	
GAMMA GT	4-18 (UI/L)	01/02/92	12.00		8.00		8.00	
LDH	120-240 (UI/L)	01/02/92	155.00		180.00		165.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	35.00		25.00		31.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	81.00		85.00		80.00	
UREA	15-40 (MG/DL)	01/02/92	30.00		31.00		28.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.20		1.09		1.06	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	3.00		3.90		3.10	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.55		0.50		0.50	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.20		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.70		6.60		6.90	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.80		3.70	<	3.90	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	213.00		220.00		220.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	92.00		101.00		80.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.15		0.20		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.55		0.60		0.60	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.80		0.75		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40	>	1.35	>	1.40	>
TSH	0-5 (UUI/ML)	01/02/92	1.20					
T4	4.5-13 (UG/DL)	01/02/92	8.00					

1015

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (value lower than min range) > out of range (value higher than max range
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS

9350085

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 445 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			12/09/92		15/10/92		12/11/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	13.5-15.5 (G/DL)	01/02/92	15.00		14.50		15.00	
HT	40-45 (%)	01/02/92	48.00	>	47.00	>	49.00	>
RBC	4200000-4800000 (/MM3)	01/02/92	5280000	>	5180000	>	5500000	>
WBC	5000-9000 (/MM3)	01/02/92	6800.00		7000.00		7100.00	
WBC: N	50-65 (%)	01/02/92	70.00	>	69.00	>	60.00	
WBC: L	30-40 (%)	01/02/92	30.00		29.00	<	38.00	
WBC: E	0-3 (%)	01/02/92	0.00		2.00		2.00	
WBC: M	0-5 (%)	01/02/92	0.00		1.00		0.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	270000		220000		290000	
NA+	130-150 (MEQ/L)	01/02/92	144.00		144.00		144.00	
K+	3-5 (MEQ/L)	01/02/92	3.50		4.80		4.50	
CL-	95-105 (MEQ/L)	01/02/92	98.00		100.00		102.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	9.00		10.00		10.20	
PO4--	2.5-5 (MG/DL)	01/02/92	4.50		3.90		4.50	
SGOT	0-12 (MU/ML)	01/02/92	6.00		6.00		7.00	
SGPT	0-12 (MU/ML)	01/02/92	8.00		8.00		9.00	
GAMMA GT	6-28 (UI/L)	01/02/92	12.00		12.00		10.00	
LDH	120-240 (UI/L)	01/02/92	144.00		166.00		145.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	32.00				33.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	75.00		92.00		101.00	
UREA	15-40 (MG/DL)	01/02/92	33.00		30.00		30.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	0.90		1.10		1.00	
URIC ACID	3.4-7 (MG/DL)	01/02/92	4.00		4.00		4.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.70		0.65		0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.15		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.25		7.35		7.20	
ALBUMINE	3.8-5 (G/DL)	01/02/92	4.00		4.25		4.20	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	230.00		245.00	>	235.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	100.00		105.00		105.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.20		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.80	>	0.65		0.60	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.95		0.85		0.75	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.30		1.40	>	1.45	>
TSH	0-5 (UUI/ML)	01/02/92	0.95					
T4	4.5-13 (UG/DL)	01/02/92	6.40					

1016

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (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 PHARMACEUTICAL - MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 448 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			14/09/92		16/10/92		13/11/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12.5-15 (G/DL)	01/02/92	13.00		14.00		13.80	
HT	38-43 (%)	01/02/92	41.00		43.00		41.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4510000	>	4730000	>	4510000	>
WBC	5000-9000 (/MM3)	01/02/92	7000.00		6900.00		6500.00	
WBC: N	50-65 (%)	01/02/92	62.00		70.00	>	68.00	>
WBC: L	30-40 (%)	01/02/92	36.00		28.00	<	30.00	
WBC: E	0-3 (%)	01/02/92	0.00		0.00		2.00	
WBC: M	0-5 (%)	01/02/92	2.00		2.00		0.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	270000		260000		255000	
NA+	130-150 (MEQ/L)	01/02/92	144.00		149.00		147.00	
K+	3-5 (MEQ/L)	01/02/92	4.00		4.80		4.70	
CL-	95-105 (MEQ/L)	01/02/92	98.00		101.00		100.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	9.50		8.90		9.00	
PO4--	2.5-5 (MG/DL)	01/02/92	4.00		4.10		4.20	
SGOT	0-12 (MU/ML)	01/02/92	7.00		8.00		7.00	
SGPT	0-12 (MU/ML)	01/02/92	8.00		9.00		7.00	
GAMMA GT	4-18 (UI/L)	01/02/92	7.00		9.00		9.00	
LDH	120-240 (UI/L)	01/02/92	144.00		155.00		160.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	32.00		39.00		38.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	90.00		101.00		98.00	
UREA	15-40 (MG/DL)	01/02/92	35.00		38.00		32.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.05		1.00		0.98	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	4.00		3.80		3.90	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.65		0.65		0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.20		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.95		6.95		7.20	
ALBUMINE	3.8-5 (G/DL)	01/02/92	4.00		3.90		4.05	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	195.00		205.00		210.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	98.00		105.00		110.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.25		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.60		0.65		0.70	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.75		0.80		0.85	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40	>	1.35	>	1.40	>
TSH	0-5 (UUI/ML)	01/02/92	0.90					
T4	4.5-13 (UG/DL)	01/02/92	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

PHARMACIA PHARMACEUTICAL - MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 456 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			09/12/92		12/01/93		09/02/93	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	13.5-15.5 (G/DL)	01/02/92	15.00		14.50		14.70	
HT	40-45 (%)	01/02/92	46.00	>	44.00		45.00	
RBC	4200000-4800000 (/MM3)	01/02/92	5060000	>	4840000	>	4950000	>
WBC	5000-9000 (/MM3)	01/02/92	6800.00		7900.00		7200.00	
WBC: N	50-65 (%)	01/02/92	63.00		62.00		60.00	
WBC: L	30-40 (%)	01/02/92	34.00		34.00		38.00	
WBC: E	0-3 (%)	01/02/92	2.00		3.00		0.00	
WBC: M	0-5 (%)	01/02/92	1.00		1.00		2.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	265000		230000		225000	
NA+	130-150 (MEQ/L)	01/02/92	139.00		141.00		139.00	
K+	3-5 (MEQ/L)	01/02/92	4.10		4.10		3.80	
CL-	95-105 (MEQ/L)	01/02/92	92.00	<	100.00		99.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.20		9.30		9.50	
PO4--	2.5-5 (MG/DL)	01/02/92	3.80		3.80		4.00	
SGOT	0-12 (MU/ML)	01/02/92	8.00		6.00		8.00	
SGPT	0-12 (MU/ML)	01/02/92	9.00		4.00		5.00	
GAMMA GT	6-28 (UI/L)	01/02/92	10.00		8.00		9.00	
LDH	120-240 (UI/L)	01/02/92	190.00		185.00		190.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	38.00		38.00		32.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	85.00		92.00		86.00	
UREA	15-40 (MG/DL)	01/02/92	24.00		36.00		35.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	0.85		1.10		0.98	
URIC ACID	3.4-7 (MG/DL)	01/02/92	6.20		5.40		5.20	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.65		0.85		0.80	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.15		0.15		0.10	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.10		6.92		7.10	
ALBUMINE	3.8-5 (G/DL)	01/02/92	4.00		3.90		4.00	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	232.00		201.00		194.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	92.00		94.00		78.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.30		0.25		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.65		0.65		0.70	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.85		0.77		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.30		1.35	>	1.40	>
TSH	0-5 (UUI/ML)	01/02/92	0.61					
T4	4.5-13 (UG/DL)	01/02/92	10.42					

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 459 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			17/12/92		18/01/93		15/02/93	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	13.5-15.5 (G/DL)	01/02/92	14.00		14.50		14.00	
HT	40-45 (%)	01/02/92	45.00		44.00		43.00	
RBC	4200000-4800000 (/MM3)	01/02/92	4950000	>	4840000	>	4730000	
WBC	5000-9000 (/MM3)	01/02/92	6700.00		7200.00		7400.00	
WBC: N	50-65 (%)	01/02/92	62.00		63.00		65.00	
WBC: L	30-40 (%)	01/02/92	38.00		37.00		32.00	
WBC: E	0-3 (%)	01/02/92	0.00		0.00		2.00	
WBC: M	0-5 (%)	01/02/92	0.00		0.00		1.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	270000		260000		265000	
NA+	130-150 (MEQ/L)	01/02/92	144.00		142.00		143.00	
K+	3-5 (MEQ/L)	01/02/92	3.80		3.90		3.80	
CL-	95-105 (MEQ/L)	01/02/92	105.00		103.00		102.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.00		10.20		10.10	
PO4--	2.5-5 (MG/DL)	01/02/92	3.50		3.90		4.10	
SGOT	0-12 (MU/ML)	01/02/92	6.00		8.00		9.00	
SGPT	0-12 (MU/ML)	01/02/92	7.00		5.00		6.00	
GAMMA GT	6-28 (UI/L)	01/02/92	12.00		11.00		10.00	
LDH	120-240 (UI/L)	01/02/92	144.00		158.00		191.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	30.00		34.00		33.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	98.00		100.00		94.00	
UREA	15-40 (MG/DL)	01/02/92	26.00		32.00		30.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	0.90		0.85		0.90	
URIC ACID	3.4-7 (MG/DL)	01/02/92	5.00		5.40		5.10	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.70		0.65		0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.15		0.10	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.10		7.18		7.15	
ALBUMINE	3.8-5 (G/DL)	01/02/92	4.00		4.10		4.05	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	205.00		215.00		205.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	100.00		105.00		115.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.20		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.65		0.68		0.70	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.85		0.85		0.85	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40	>	1.35	>	1.30	
TSH	0-5 (UUI/ML)	01/02/92	0.80					
T4	4.5-13 (UG/DL)	01/02/92	8.00					

1019

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 460 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			17/12/92		18/01/93		15/02/93	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	13.5-15.5 (G/DL)	01/02/92	15.00		15.10		14.80	
HT	40-45 (%)	01/02/92	47.00	>	46.00	>	45.00	
RBC	4200000-4800000 (/MM3)	01/02/92	5170000	>	5060000	>	4950000	>
WBC	5000-9000 (/MM3)	01/02/92	6800.00		7100.00		7500.00	
WBC: N	50-65 (%)	01/02/92	72.00	>	70.00	>	66.00	>
WBC: L	30-40 (%)	01/02/92	28.00	<	26.00	<	30.00	
WBC: E	0-3 (%)	01/02/92	0.00		0.00		3.00	
WBC: M	0-5 (%)	01/02/92	0.00		4.00		1.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	250000		245000		235000	
NA+	130-150 (MEQ/L)	01/02/92	145.00		144.00		140.00	
K+	3-5 (MEQ/L)	01/02/92	4.10		4.20		4.10	
CL-	95-105 (MEQ/L)	01/02/92	105.00		103.00		100.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.10		9.80		9.50	
PO4--	2.5-5 (MG/DL)	01/02/92	3.30		3.90		3.70	
SGOT	0-12 (MU/ML)	01/02/92	5.00		7.00		6.00	
SGPT	0-12 (MU/ML)	01/02/92	8.00		6.00		4.00	
GAMMA GT	6-28 (UI/L)	01/02/92	11.00		10.00		9.00	
LDH	120-240 (UI/L)	01/02/92	148.00		155.00		180.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	39.00		37.00		35.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	101.00		100.00		90.00	
UREA	15-40 (MG/DL)	01/02/92	31.00		36.00		35.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	0.95		0.85		0.90	
URIC ACID	3.4-7 (MG/DL)	01/02/92	5.10		5.20		5.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.65		0.60		0.50	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.10		0.10	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.10		7.09		7.10	
ALBUMINE	3.8-5 (G/DL)	01/02/92	4.10		4.05		4.00	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	220.00		230.00		215.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	115.00		143.00		101.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.15		0.15		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.70		0.72		0.70	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.80		0.82		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.35	>	1.35	>	1.40	>
TSH	0-5 (UUI/ML)	01/02/92	1.50					
T4	4.5-13 (UG/DL)	01/02/92	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

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 26 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			30/09/92		03/11/92		01/12/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/09/92	12.50		12.80		12.60	
HT	35-47 (%)	01/09/92	36.00		38.00		39.00	
RBC	3.8-5.2 (10-6/MM3)	01/09/92	4.30		4.40		4.40	
WBC	4000-10000 (/MM3)	01/09/92	6600.00		6800.00		6900.00	
WBC: N	50-70 (%)	01/09/92	53.00		52.00		56.00	
WBC: L	30-40 (%)	01/09/92	37.00		39.00		40.00	
WBC: E	0-4 (%)	01/09/92	1.00		1.00		1.00	
WBC: M	0-8 (%)	01/09/92	6.00		6.00		1.00	
WBC: B	0-2 (%)	01/09/92	1.00		1.00		1.00	
PLATELETS	200-300 (10-3/MM3)	01/09/92	295.00		304.00	>	315.00	>
NA+	135-144 (MMOL/L)	01/09/92	136.00		136.00		146.00	>
K+	3.6-5.6 (MMOL/L)	01/09/92	4.80		4.70		4.70	
CL-	95-108 (MMOL/L)	01/09/92	103.00		102.00		101.00	
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.46		2.44		2.52	
PO4--	0.81-1.45 (MMOL/L)	01/09/92	0.83		1.18		1.21	
SGOT	0-15 (U/L)	01/09/92	6.00		7.00		8.00	
SGPT	0-17 (U/L)	01/09/92	5.00		4.00		5.00	
GAMMA GT	4-18 (U/L)	01/09/92	5.00		6.00		6.00	
LDH	120-240 (U/L)	01/09/92	137.00		132.00		146.00	
ALK. PHOSPH.	60-200 (U/L)	01/09/92	74.00		72.00		74.00	
GLUCOSE	60-110 (MG/DL)	01/09/92	81.00		88.00		115.00	>
BUN	4-50 (MG/DL)	01/09/92	29.00		26.00		41.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	0.99		1.00		1.09	
URIC ACID	2.5-6 (MG/DL)	01/09/92	4.30		4.40		5.40	
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.35		0.33		0.32	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	7.50		7.30		7.30	
ALBUMINE	58.8-69.6 (%)	01/09/92	62.80		68.70		62.60	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	243.00	>	229.00	>	234.00	>
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	132.00		138.00		167.00	
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	3.60		2.80		3.30	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	7.70		6.50		8.30	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	11.30		9.80		10.60	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	14.60		12.20		15.10	
TSH	0.2-5 (UU/ML)	01/09/92	0.10	<<				

1021

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9590083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 27 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			30/09/92		03/11/92		01/12/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/09/92	13.80		13.60			
HT	35-47 (%)	01/09/92	39.00		41.00			
RBC	3.8-5.2 (10-6/MM3)	01/09/92	4.60		4.80			
WBC	4000-10000 (/MM3)	01/09/92	6300.00		5700.00			
WBC: N	50-70 (%)	01/09/92	51.00		51.00			
WBC: L	30-40 (%)	01/09/92	37.00		38.00			
WBC: E	0-4 (%)	01/09/92	3.00		3.00			
WBC: M	0-8 (%)	01/09/92	8.00		6.00			
WBC: B	0-2 (%)	01/09/92	1.00		1.00			
PLATELETS	200-300 (10-3/MM3)	01/09/92	313.00	>	281.00			
NA+	135-144 (MMOL/L)	01/09/92	135.00		138.00		140.00	
K+	3.6-5.6 (MMOL/L)	01/09/92	4.40		4.30		4.20	
CL-	95-108 (MMOL/L)	01/09/92	104.00		103.00		101.00	
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.48		2.47		2.44	
PO4--	0.81-1.45 (MMOL/L)	01/09/92	1.18		1.43		1.41	
SGOT	0-15 (U/L)	01/09/92	6.00		5.00		7.00	
SGPT	0-17 (U/L)	01/09/92	7.00		6.00		7.00	
GAMMA GT	4-18 (U/L)	01/09/92	10.00		11.00		9.00	
LDH	120-240 (U/L)	01/09/92	191.00		158.00		170.00	
ALK. PHOSPH.	60-200 (U/L)	01/09/92	95.00		117.00		121.00	
GLUCOSE	60-110 (MG/DL)	01/09/92	84.00		88.00		84.00	
BUN	4-50 (MG/DL)	01/09/92	32.00		30.00		22.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	0.98		0.97		0.93	
URIC ACID	2.5-6 (MG/DL)	01/09/92	7.60	>	6.80	>	6.40	>
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.51		0.48		0.46	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	7.10		7.00		6.90	
ALBUMINE	58.8-69.6 (%)	01/09/92	62.60		62.50		60.90	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	203.00		173.00		181.00	
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	155.00		149.00		137.00	
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	3.70		2.80		3.10	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	9.40		8.80		8.60	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	12.10		11.90		12.60	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	12.30		14.10		14.80	
TSH	0.2-5 (UU/ML)	01/09/92	1.50					

1022

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 29 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			30/09/92		03/11/92		01/12/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/09/92	15.80		15.10		16.50	>
HT	35-47 (%)	01/09/92	46.00		46.00		49.00	>
RBC	3.8-5.2 (10¬6/MM3)	01/09/92	5.40	>	5.20		5.40	>
WBC	4000-10000 (/MM3)	01/09/92	7100.00		7100.00		5400.00	
WBC: N	50-70 (%)	01/09/92	59.00		64.00		61.00	
WBC: L	30-40 (%)	01/09/92	32.00		25.00	<	28.00	<
WBC: E	0-4 (%)	01/09/92	2.00		4.00		3.00	
WBC: M	0-8 (%)	01/09/92	6.00		5.00		5.00	
WBC: B	0-2 (%)	01/09/92	1.00		1.00		1.00	
PLATELETS	200-300 (10¬3/MM3)	01/09/92	258.00		249.00		245.00	
NA+	135-144 (MMOL/L)	01/09/92	136.00		141.00		145.00	>
K+	3.6-5.6 (MMOL/L)	01/09/92	3.70		4.40		4.30	
CL-	95-108 (MMOL/L)	01/09/92	101.00		102.00		102.00	
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.37		2.47		2.63	>
PO4--	0.81-1.45 (MMOL/L)	01/09/92	1.10		1.73	>>	1.42	
SGOT	0-15 (U/L)	01/09/92	10.00		11.00		10.00	
SGPT	0-17 (U/L)	01/09/92	13.00		14.00		15.00	
GAMMA GT	4-18 (U/L)	01/09/92	12.00		14.00		11.00	
LDH	120-240 (U/L)	01/09/92	206.00		205.00		226.00	
ALK. PHOSPH.	60-200 (U/L)	01/09/92	108.00		124.00		125.00	
GLUCOSE	60-110 (MG/DL)	01/09/92	73.00		78.00		60.00	
BUN	4-50 (MG/DL)	01/09/92	31.00		37.00		23.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	0.93		0.94		0.94	
URIC ACID	2.5-6 (MG/DL)	01/09/92	5.90		7.10	>	6.20	>
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.33		0.57		0.49	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	6.50		6.80		7.00	
ALBUMINE	58.8-69.6 (%)	01/09/92	62.40		65.10		67.70	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	170.00		172.00		163.00	
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	36.00		48.00		88.00	
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	3.60		2.90		2.60	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	8.70		7.40		6.50	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	12.50		11.30		10.20	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	12.90		13.40		13.00	

1023

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (value lower than min range) > out of range (value higher than max range
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 31 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			13/10/92		17/11/92		15/12/92	
			value	(◊)	value	(◊)	value	(◊)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/09/92	13.20		29.00	>	14.20	
HT	35-47 (%)	01/09/92	40.00		44.00		42.00	
RBC	3.8-5.2 (10-6/MM3)	01/09/92	4.60		4.80		4.90	
WBC	4000-10000 (/MM3)	01/09/92	4200.00		5600.00		4600.00	
WBC: N	50-70 (%)	01/09/92	50.00		72.00	>	54.00	
WBC: L	30-40 (%)	01/09/92	41.00	>	19.00	<<	34.00	
WBC: E	0-4 (%)	01/09/92	3.00		1.00		3.00	
WBC: M	0-8 (%)	01/09/92	5.00		5.00		6.00	
WBC: B	0-2 (%)	01/09/92	1.00		2.00		1.00	
PLATELETS	200-300 (10-3/MM3)	01/09/92	244.00		283.00		319.00	>
NA+	135-144 (MMOL/L)	01/09/92	126.00	<	138.00		138.00	
K+	3.6-5.6 (MMOL/L)	01/09/92	3.90		4.00		4.10	
CL-	95-108 (MMOL/L)	01/09/92	91.00	<	99.00		100.00	
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.32		2.36		2.39	
PO4--	0.81-1.45 (MMOL/L)	01/09/92			1.18		1.00	
SGOT	0-15 (U/L)	01/09/92	8.00		6.00		8.00	
SGPT	0-17 (U/L)	01/09/92	7.00		6.00		6.00	
GAMMA GT	4-18 (U/L)	01/09/92	6.00		7.00		8.00	
LDH	120-240 (U/L)	01/09/92	145.00		129.00		159.00	
ALK. PHOSPH.	60-200 (U/L)	01/09/92	58.00	<	67.00		67.00	
GLUCOSE	60-110 (MG/DL)	01/09/92	68.00		73.00		71.00	
BUN	4-50 (MG/DL)	01/09/92	40.00		21.00		27.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	0.90		0.83		0.83	
URIC ACID	2.5-6 (MG/DL)	01/09/92	3.20		2.90		3.20	
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.51		0.29		0.62	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	6.60		7.10		6.70	
ALBUMINE	58.8-69.6 (%)	01/09/92	63.10		61.30		64.10	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	277.00	>	280.00	>	240.00	>
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	46.00		76.00		42.00	
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	3.00		3.30		2.80	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	9.00		10.30		8.60	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	11.30		11.20		10.60	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	13.60		13.90		13.90	
TSH	0.2-5 (UU/ML)	01/09/92	0.70					
T4	4-13 (UG/DL)	01/09/92	8.10					

1024

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 49 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			10/11/92		15/12/92		12/01/93	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/09/92	14.40		14.20		14.10	
HT	35-47 (%)	01/09/92	41.00		41.00		42.00	
RBC	3.8-5.2 (10¬6/MM3)	01/09/92	4.60		4.70		4.60	
WBC	4000-10000 (/MM3)	01/09/92	4300.00		3900.00	<	4600.00	
WBC: N	50-70 (%)	01/09/92	58.00		54.00		55.00	
WBC: L	30-40 (%)	01/09/92	32.00		36.00		36.00	
WBC: E	0-4 (%)	01/09/92	4.00		4.00		2.00	
WBC: M	0-8 (%)	01/09/92	5.00		4.00		3.00	
WBC: B	0-2 (%)	01/09/92	1.00		1.00		1.00	
PLATELETS	200-300 (10¬3/MM3)	01/09/92	282.00		310.00	>	292.00	
NA+	135-144 (MMOL/L)	01/09/92	140.00		141.00		136.00	
K+	3.6-5.6 (MMOL/L)	01/09/92	4.50		4.00		4.30	
CL-	95-108 (MMOL/L)	01/09/92	105.00		101.00		99.00	
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.30		2.34		2.34	
PO4--	0.81-1.45 (MMOL/L)	01/09/92	1.12		1.28		1.35	
SGOT	0-15 (U/L)	01/09/92	10.00		9.00		8.00	
SGPT	0-17 (U/L)	01/09/92	12.00		12.00		9.00	
GAMMA GT	4-18 (U/L)	01/09/92	7.00		8.00		6.00	
LDH	120-240 (U/L)	01/09/92	219.00		197.00		196.00	
ALK. PHOSPH.	60-200 (U/L)	01/09/92	38.00	<	44.00	<	40.00	<
GLUCOSE	60-110 (MG/DL)	01/09/92	77.00		58.00	<	42.00	<
BUN	4-50 (MG/DL)	01/09/92	24.00		26.00		20.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	1.01		0.94		0.89	
URIC ACID	2.5-6 (MG/DL)	01/09/92	5.50		5.60		4.90	
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.41		0.38		0.32	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	6.90		6.60		6.80	
ALBUMINE	58.8-69.6 (%)	01/09/92	61.40		62.30		62.10	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	224.00	>	204.00		227.00	>
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	162.00		190.00	>	190.00	>
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	3.00		3.10		3.50	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	7.70		8.20		8.80	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	12.40		11.80		12.60	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	15.40		14.70		13.10	
TSH	0.2-5 (UU/ML)	01/09/92	1.60					
T4	4-13 (UG/DL)	01/09/92	8.30					

1025

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

3950083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 50 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date	
			Screen	
			10/11/92	
			value	(¢)
Laboratory test	Range value	Range date		
HB	12-16 (G/DL)	01/09/92	13.70	
HT	35-47 (%)	01/09/92	41.00	
RBC	3.8-5.2 (10-6/MM3)	01/09/92	4.40	
WBC	4000-10000 (/MM3)	01/09/92	5800.00	
WBC: N	50-70 (%)	01/09/92	55.00	
WBC: L	30-40 (%)	01/09/92	27.00	<
WBC: E	0-4 (%)	01/09/92	4.00	
WBC: M	0-8 (%)	01/09/92	10.00	>
WBC: B	0-2 (%)	01/09/92	1.00	
PLATELETS	200-300 (10-3/MM3)	01/09/92	371.00	>
NA+	135-144 (MMOL/L)	01/09/92	136.00	
K+	3.6-5.6 (MMOL/L)	01/09/92	4.60	
CL-	95-108 (MMOL/L)	01/09/92	97.00	
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.52	
PO4--	0.81-1.45 (MMOL/L)	01/09/92	1.54	>
SGOT	0-15 (U/L)	01/09/92	8.00	
SGPT	0-17 (U/L)	01/09/92	9.00	
GAMMA GT	4-18 (U/L)	01/09/92	10.00	
LDH	120-240 (U/L)	01/09/92	228.00	
ALK. PHOSPH.	60-200 (U/L)	01/09/92	126.00	
GLUCOSE	60-110 (MG/DL)	01/09/92	80.00	
BUN	4-50 (MG/DL)	01/09/92	49.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	1.04	
URIC ACID	2.5-6 (MG/DL)	01/09/92	4.80	
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.06	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	7.20	
ALBUMINE	58.8-69.6 (%)	01/09/92	64.60	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	298.00	>>
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	526.00	>>
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	3.20	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	8.60	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	13.30	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	10.40	
TSH	0.2-5 (UU/ML)	01/09/92	0.40	
T4	4-13 (UG/DL)	01/09/92	7.00	

1026

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS 9550085

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 22 Patient: 115 Treatment: Reboxetine Sex: Male

			Visit number / Laboratory date	
			Screen	
			22/12/92	
			value	(◊)
Laboratory test	Range value	Range date		
HB	14-18 (G/DL)	01/11/92	16.20	
HT	0.38-0.52 (L/L)	01/11/92	0.51	
RBC	4.4-6 (10¬12/L)	01/11/92	5.27	
WBC	4.3-10 (10¬9/L)	01/11/92	7.35	
WBC: N	50-70 (%)	01/11/92	61.00	
WBC: L	25-45 (%)	01/11/92	31.00	
WBC: E	2-4 (%)	01/11/92	1.00	<
WBC: M	2-6 (%)	01/11/92	6.00	
WBC: B	0-1 (%)	01/11/92	1.00	
PLATELETS	140-440 (10¬9/L)	01/11/92	202.00	
NA+	135-145 (MMOL/L)	01/11/92	141.00	
K+	3.8-5 (MMOL/L)	01/11/92	4.10	
CL-	98-106 (MEQ/L)	01/11/92	95.00	<
Ca++	2.2-2.55 (MMOL/L)	01/11/92	2.47	
SGOT	5-18 (U/L)	01/11/92	10.00	
SGPT	5-22 (U/L)	01/11/92	11.00	
ALK. PHOSPH.	60-190 (U/L)	01/11/92	124.00	
GLUCOSE	50-100 (U/L)	01/11/92	24.00	<<
CREATININE	0.6-1.1 (MG/DL)	01/11/92	1.10	
URIC ACID	3.5-7 (MG/DL)	01/11/92	6.80	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/92	0.44	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/92	0.20	
TOT. PROTEINS	6.5-8 (G/DL)	01/11/92	7.20	
ALBUMINE	55.3-68.9 (%)	01/11/92	64.80	
TOT. CHOLEST.	50-220 (MG/DL)	01/11/92	227.00	>
TRIGLYCERIDES	60-150 (MG/DL)	01/11/92	134.00	
GLOBULINS ALPHA 1	1.6-5.8 (%)	01/11/92	3.60	
GLOBULINS ALPHA 2	5.9-11.1 (%)	01/11/92	8.30	
GLOBULINS BETA	7.9-13.9 (%)	01/11/92	9.10	
GLOBULINS GAMMA	11.4-18.2 (%)	01/11/92	14.20	
TSH	0.3-4 (NU/L)	01/11/92	1.50	
T4	5-13.4 (UG/DL)	01/11/92	6.40	

1027

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 1 Patient: 1 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			15/11/91		13/12/91		10/01/92	
			value	(◊)	value	(◊)	value	(◊)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/11/91	16.50		17.70		16.70	
HT	42-52 (%)	01/11/91	47.00		49.00		48.00	
RBC	4.3-5.9 (10-6/MM3)	01/11/91	5.22		5.49		5.33	
WBC	4000-8000 (/MM3)	01/11/91	4900.00		5600.00		9600.00	>
WBC: N	50-70 (%)	01/11/91	59.00		62.00		67.00	
WBC: L	25-40 (%)	01/11/91	31.00		29.00		29.00	
PLATELETS	150000-400000 (/MM3)	01/11/91	207000		254000		226000	
NA+	135-150 (MEQ/L)	01/11/91	139.00		141.00		133.00	<
K+	3.6-5.2 (MEQ/L)	01/11/91	4.20		4.90			
CL-	94-111 (MEQ/L)	01/11/91			109.00			
Ca++	4.4-5.5 (MEQ/L)	01/11/91	4.80		4.90		4.60	
PO4--	2.5-5 (MG/DL)	01/11/91			3.20			
SGOT	5-18 (U/L)	01/11/91	9.00		11.00		22.00	>
SGPT	5-22 (U/L)	01/11/91	10.00		9.00		17.00	
GAMMA GT	6-28 (U/L)	01/11/91	10.00		10.00		7.00	
LDH	120-240 (U/L)	01/11/91	121.00		150.00			
ALK. PHOSPH.	80-170 (U/L)	01/11/91	98.00		107.00			
GLUCOSE	70-110 (MG/100ML)	01/11/91	92.00		83.00		86.00	
BUN	10-50 (MG/DL)	01/11/91	12.00		12.00			
CREATININE	0.7-1.2 (MG/DL)	01/11/91	0.80		1.00		0.90	
URIC ACID	3.4-7 (MG/100ML)	01/11/91	4.50		4.40		4.00	
TOT BILIRUBIN	0-1 (MG/100ML)	01/11/91	1.00		1.00			
TOT. CHOLEST.	130-220 (MG/100ML)	01/11/91	240.00	>				
TRIGLYCERIDES	74-172 (MG/100ML)	01/11/91	118.00					
GLOBULINS ALPHA 1	2.2-5.6 (%)	01/11/91	2.60					
GLOBULINS ALPHA 2	5-10.2 (%)	01/11/91	6.50					
GLOBULINS BETA	8.8-15.6 (%)	01/11/91	11.30					
GLOBULINS GAMMA	11.9-23.3 (%)	01/11/91	12.30					
TSH	0.5-4.2 (UU/ML)	01/11/91	0.70					
T4	68-185 (MMOL/L)	01/11/91	161.40					

1028

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 1 Patient: 3 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory data							
			Screen		Day 14		Day 28		Day 56	
			29/06/92		18/07/92		30/07/92		25/08/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	10/11/91	15.40		14.30		15.30		14.50	
HT	37-47 (%)	10/11/91	46.00		43.00		46.00		43.00	
RBC	3.9-5.3 (10-6/MM3)	10/11/91	5.07		4.80		5.05		4.68	
WBC	4000-8000 (/MM3)	10/11/91	8200.00	>	9700.00	>	7200.00		9900.00	>
WBC: N	50-70 (%)	10/11/91	57.00		56.00		49.00	<	69.00	
WBC: L	25-40 (%)	10/11/91	36.00		38.00		42.00	>	26.00	
PLATELETS	150000-400000 (/MM3)	10/11/91	284000		258000		226000		250000	
NA+	135-150 (MEQ/L)	10/11/91	141.00		140.00		144.00		139.00	
K+	3.6-5.2 (MEQ/L)	10/11/91	3.80		4.20		4.70		4.30	
CL-	94-111 (MEQ/L)	10/11/91			107.00		105.00		110.00	
Ca++	4.4-5.5 (MEQ/L)	10/11/91	4.20	<	4.30	<	4.40		4.40	
PO4--	2.5-5 (MG/DL)	10/11/91			3.10		3.30		2.60	
SGOT	5-15 (U/L)	10/11/91	17.00	>	13.00		9.00		11.00	
SGPT	5-17 (U/L)	10/11/91	25.00	>	19.00	>	15.00		12.00	
GAMMA GT	4-18 (U/L)	10/11/91	52.00	>>	13.00		12.00		10.00	
LDH	120-240 (U/L)	10/11/91					134.00		147.00	
ALK. PHOSPH.	80-170 (U/L)	10/11/91			120.00		115.00		112.00	
GLUCOSE	70-110 (MG/100ML)	10/11/91			83.00		90.00		87.00	
BUN	10-50 (MG/DL)	10/11/91			11.00		16.00		10.00	
CREATININE	0.5-1 (MG/DL)	10/11/91	0.70		0.80		1.00		0.90	
URIC ACID	2.4-5.7 (MG/100ML)	10/11/91			4.70				5.40	
TOT BILIRUBIN	0-1 (MG/100ML)	10/11/91			1.00		1.00		1.00	
TOT. PROTEINS	6.5-7.9 (G/DL)	10/11/91			5.90	<			6.30	<
ALBUMINE	51.8-65.4 (%)	10/11/91			68.20	>			66.10	>
TOT. CHOLEST.	130-220 (MG/100ML)	10/11/91	352.00	>>	215.00		254.00	>	273.00	>
TRIGLYCERIDES	74-172 (MG/100ML)	10/11/91	249.00	>>	119.00		87.00		115.00	
GLOBULINS ALPHA 1	2.2-5.6 (%)	10/11/91			2.70				2.70	
GLOBULINS ALPHA 2	5-10.2 (%)	10/11/91			5.50				6.50	
GLOBULINS BETA	8.8-15.6 (%)	10/11/91			10.70				11.00	
GLOBULINS GAMMA	11.9-23.3 (%)	10/11/91			13.00				13.60	
TSH	0.1-4 (UU/ML)	10/11/91	1.07							
T4	5-12.5 (UG/DL)	10/11/91	9.30							

1029

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 1 Patient: 5 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 14		Day 28	
			07/10/92		27/10/92		10/11/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	10/11/91	14.90		14.30		13.50	
HT	37-47 (%)	10/11/91	44.00		43.00		41.00	
RBC	3.9-5.3 (10-6/MM3)	10/11/91	4.62		4.45		4.36	
WBC	4000-8000 (/MM3)	10/11/91	5200.00		3800.00	<	4300.00	
WBC: N	50-70 (%)	10/11/91	68.00		59.00		68.00	
WBC: L	25-40 (%)	10/11/91	26.00		36.00		24.00	<
PLATELETS	150000-400000 (/MM3)	10/11/91	225000		249000		237000	
NA+	135-150 (MEQ/L)	10/11/91	145.00		139.00		144.00	
K+	3.6-5.2 (MEQ/L)	10/11/91	4.60		4.50		4.20	
CL-	94-111 (MEQ/L)	10/11/91	104.00		109.00		105.00	
Ca++	4.4-5.5 (MEQ/L)	10/11/91	4.60		4.60		4.50	
PO4--	2.5-5 (MG/DL)	10/11/91	2.80					
SGOT	5-15 (U/L)	10/11/91	7.00		8.00		13.00	
SGPT	5-17 (U/L)	10/11/91	10.00		10.00		12.00	
GAMMA GT	4-18 (U/L)	10/11/91	21.00	>	19.00	>	19.00	>
LDH	120-240 (U/L)	10/11/91	150.00					
ALK. PHOSPH.	80-170 (U/L)	10/11/91	117.00				108.00	
GLUCOSE	70-110 (MG/100ML)	10/11/91	106.00				213.00	>>
CREATININE	0.5-1 (MG/DL)	10/11/91	0.70		0.80		1.00	
URIC ACID	2.4-5.7 (MG/100ML)	10/11/91	5.60				5.90	>
TOT BILIRUBIN	0-1 (MG/100ML)	10/11/91	1.00				1.00	
TOT. PROTEINS	6.5-7.9 (G/DL)	10/11/91	6.40	<			5.60	<
ALBUMINE	51.8-65.4 (%)	10/11/91	63.20				70.30	>
TOT. CHOLEST.	130-220 (MG/100ML)	10/11/91	255.00	>				
TRIGLYCERIDES	74-172 (MG/100ML)	10/11/91	123.00					
GLOBULINS ALPHA 1	2.2-5.6 (%)	10/11/91	3.20				2.40	
GLOBULINS ALPHA 2	5-10.2 (%)	10/11/91	10.30	>			8.90	
GLOBULINS BETA	8.8-15.6 (%)	10/11/91	14.20				12.60	
GLOBULINS GAMMA	11.9-23.3 (%)	10/11/91	9.10	<			5.80	<<
TSH	0.1-4 (UU/ML)	10/11/91	1.99					
T4	5-12.5 (UG/DL)	10/11/91	10.00					

1030

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICALS AND - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 1 Patient: 6 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 14		Day 28	
			11/01/93		28/01/93		11/02/93	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/01/93	16.10		16.90		16.40	
HT	42-52 (%)	01/01/93	47.00		48.00		48.00	
RBC	4.3-5.9 (10-6/MM3)	01/01/93	5.52		5.63		5.61	
WBC	4000-8000 (/MM3)	01/01/93	5500.00		7900.00		7800.00	
WBC: N'	50-70 (%)	01/01/93	60.00		72.00	>	72.00	>
WBC: L	25-40 (%)	01/01/93	33.00		22.00	<	20.00	<
PLATELETS	150000-400000 (/MM3)	01/01/93	182000		217000		210000	
NA+	135-150 (MEQ/L)	01/01/93	140.00		140.00		142.00	
K+	3.6-5.2 (MEQ/L)	01/01/93	3.50	<	4.80		4.40	
CL-	94-111 (MEQ/L)	01/01/93	107.00		105.00		108.00	
Ca++	4.4-5.5 (MEQ/L)	01/01/93	4.40		5.10		5.00	
PO4--	2.5-5 (MG/DL)	01/01/93			3.00		3.10	
SGOT	5-18 (U/L)	01/01/93	11.00		8.00		8.00	
SGPT	5-22 (U/L)	01/01/93	25.00	>	16.00		16.00	
GAMMA GT	6-28 (U/L)	01/01/93	19.00		14.00		12.00	
LDH	120-240 (U/L)	01/01/93	160.00		135.00		128.00	
ALK. PHOSPH.	80-170 (U/L)	01/01/93	153.00		145.00		145.00	
GLUCOSE	70-110 (MG/100ML)	01/01/93	114.00	>	103.00		100.00	
CREATININE	0.7-1.2 (MG/DL)	01/01/93	1.10		0.80		0.70	
URIC ACID	3.4-7 (MG/100ML)	01/01/93	5.90		5.60		5.20	
TOT BILIRUBIN	0-1 (MG/100ML)	01/01/93	0.90		0.90		0.90	
TOT. PROTEINS	6.5-7.9 (G/DL)	01/01/93			6.90		6.40	<
TOT. CHOLEST.	130-220 (MG/100ML)	01/01/93	222.00	>	242.00	>	248.00	>
TRIGLYCERIDES	74-172 (MG/100ML)	01/01/93	101.00		110.00		110.00	
GLOBULINS ALPHA 1	2.2-5.6 (%)	01/01/93			2.00	<		
GLOBULINS ALPHA 2	5-10.2 (%)	01/01/93			9.30			
GLOBULINS BETA	8.8-15.6 (%)	01/01/93			13.10			
GLOBULINS GAMMA	11.9-23.3 (%)	01/01/93			13.20			
TSH	0.5-4.2 (UU/ML)	01/01/93	1.21					
T4	68-185 (NMOL/L)	01/01/93	84.00					

1031

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL RELAND - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 33 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			03/05/91		04/06/91		29/06/91	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/03/91	13.20		13.20		13.80	
HT	0.37-0.46 (L/L)	01/03/91	0.38		0.40		0.40	
RBC	4.2-5.5 (10-12/L)	01/03/91	4.13	<	4.24		4.26	
WBC	4.3-10 (10-9/L)	01/03/91	4.70		6.90		7.70	
WBC: N	50-70 (%)	01/03/91	63.00		81.00	>	66.00	
WBC: L	25-40 (%)	01/03/91	37.00		15.00	<<	29.00	
WBC: E	2-4 (%)	01/03/91	0.00	<	0.00	<	1.00	<
WBC: M	2-6 (%)	01/03/91	0.00	<	4.00		4.00	
WBC: B	0-1 (%)	01/03/91	0.00		0.00		0.00	
PLATELETS	140-440 (10-9/L)	01/03/91	281.00		451.00	>	402.00	
NA+	135-145 (MMOL/L)	01/03/91	140.00		140.00		138.00	
K+	3.5-5 (MMOL/L)	01/03/91	3.80		4.90		4.40	
CL-	98-108 (MMOL/L)	01/03/91	102.00		102.00		98.00	
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.30		2.40		2.30	
PO4--	0.81-1.61 (MMOL/L)	01/03/91			0.81		1.27	
SGOT	3-15 (U/L)	01/03/91	9.00		7.00		7.00	
SGPT	5-17 (U/L)	01/03/91	7.00		5.00		5.00	
GAMMA GT	4-18 (U/L)	01/03/91	8.00		10.00		12.00	
LDH	120-240 (U/L)	01/03/91	152.00		132.00		145.00	
ALK. PHOSPH.	60-170 (U/L)	01/03/91	98.00		123.00		110.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	77.00		95.00		123.00	>
BUN	17-56 (MG/DL)	01/03/91	22.00		33.00		31.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.60		0.50		0.70	
URIC ACID	2.4-5.7 (MG/DL)	01/03/91	4.10		3.70		4.80	
TOT. PROTEINS	65-85 (G/L)	01/03/91	75.20		86.50	>	85.80	>
ALBUMINE	36-58 (G/L)	01/03/91	51.90		56.30		58.50	>
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	171.00		200.00		208.00	>
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	193.00		191.00		141.00	
GLOBULINS ALPHA 1	1.3-4.3 (G/L)	01/03/91	2.30		2.70		2.20	
GLOBULINS ALPHA 2	3.9-8.5 (G/L)	01/03/91	4.20		6.80		5.50	
GLOBULINS BETA	5.2-11.9 (G/L)	01/03/91	7.70		9.50		9.20	
GLOBULINS GAMMA	5.9-16.2 (G/L)	01/03/91	9.10		11.20		10.40	
TSH	0.3-3.5 (MU/L)	01/03/91	0.60					
T4	9-21 (NG/L)	01/03/91	16.00					

1032

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 C[illegible]0083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 36 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date							
			Screen		Day 14		Day 28		Day 56	
			26/04/91		16/05/91		07/06/91		27/06/91	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)	value	(◊)
HB	14-18 (G/DL)	01/03/91	14.40				14.20		13.90	<
HT	0.38-0.57 (L/L)	01/03/91	0.44				0.42		0.42	
RBC	4.4-6 (10¬12/L)	01/03/91	4.62				4.40		4.42	
WBC	4.3-10 (10¬9/L)	01/03/91	9.40				11.40	>	9.00	
WBC: N	50-70 (%)	01/03/91	70.00				71.00	>	62.00	
WBC: L	25-40 (%)	01/03/91	27.00				28.00		35.00	
WBC: E	2-4 (%)	01/03/91	1.00	<			0.00	<	1.00	<
WBC: M	2-6 (%)	01/03/91	2.00				1.00	<	2.00	
WBC: B	0-1 (%)	01/03/91	0.00				0.00		0.00	
PLATELETS	140-440 (10¬9/L)	01/03/91	263.00				264.00		263.00	
NA+	135-145 (MMOL/L)	01/03/91	139.00				141.00		141.00	
K+	3.5-5 (MMOL/L)	01/03/91	3.90				4.60		4.20	
CL-	98-108 (MMOL/L)	01/03/91	102.00				102.00		102.00	
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.40				2.50		2.60	
PO4--	0.81-1.61 (MMOL/L)	01/03/91	1.28				1.23		0.73	<
SGOT	3-18 (U/L)	01/03/91	32.00	>	10.00		9.00		8.00	
SGPT	5-22 (U/L)	01/03/91	72.00	>>	16.00		14.00		7.00	
GAMMA GT	6-28 (U/L)	01/03/91	94.00	>>	27.00		14.00		10.00	
LDH	120-240 (U/L)	01/03/91	197.00				158.00		164.00	
ALK. PHOSPH.	60-170 (U/L)	01/03/91	173.00	>	127.00		135.00		131.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	80.00				63.00	<	69.00	<
BUN	17-56 (MG/DL)	01/03/91	32.00				36.00		40.00	
UREA	()	01/03/91								
CREATININE	0.4-1.2 (MG/DL)	01/03/91	1.00				0.80		1.00	
URIC ACID	3.4-7 (MG/DL)	01/03/91	5.90				4.90		5.80	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/91	0.30				0.40		0.40	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/03/91								
TOT. PROTEINS	65-85 (G/L)	01/03/91	75.70				80.10		80.20	
ALBUMINE	56-68 (%)	01/03/91	59.90				59.80			
	36-58 (G/L)	25/06/91							50.50	
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	241.00	>	233.00	>	259.00	>	267.00	>>
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	160.00		88.00	<	101.00	<	75.00	<
GLOBULINS ALPHA 1	2-5 (%)	01/03/91	3.40				2.70			
	1.3-4.3 (G/L)	25/06/91							2.10	
GLOBULINS ALPHA 2	6-10 (%)	01/03/91	9.10				8.40			
	3.9-8.5 (G/L)	25/06/91							6.70	
GLOBULINS BETA	8-14 (%)	01/03/91	14.20	>			16.50	>		
	5.2-11.9 (G/L)	25/06/91							9.90	
GLOBULINS GAMMA	9-19 (%)	01/03/91	13.40				12.60			
	5.9-16.2 (G/L)	25/06/91							11.00	
TSH	0.3-3.5 (MU/L)	01/03/91	2.10							
T4	9-21 (NG/L)	01/03/91	11.40							

(◊) << 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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 38 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date			
			Screen		Day 28	
			18/06/91		18/07/91	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	14-18 (G/DL)	01/03/91	15.10		15.00	
HT	0.38-0.57 (L/L)	01/03/91	0.42		0.43	
RBC	4.4-6 (10¬12/L)	01/03/91	4.25	<	4.35	<
WBC	4.3-10 (10¬9/L)	01/03/91	8.30		7.50	
WBC: N	50-70 (%)	01/03/91	48.00	<	43.00	<
WBC: L	25-40 (%)	01/03/91	46.00	>	50.00	>
WBC: E	2-4 (%)	01/03/91	1.00	<	4.00	
WBC: M	2-6 (%)	01/03/91	5.00		1.00	<
WBC: B	0-1 (%)	01/03/91	0.00		1.00	
PLATELETS	140-440 (10¬9/L)	01/03/91	218.00		211.00	
NA+	135-145 (MMOL/L)	01/03/91	139.00		140.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.60		4.50	
CL-	98-108 (MMOL/L)	01/03/91	96.00	<	101.00	
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.30		2.40	
SGOT	3-18 (U/L)	01/03/91	12.00		11.00	
SGPT	5-22 (U/L)	01/03/91	9.00		9.00	
GAMMA GT	6-28 (U/L)	01/03/91	13.00		16.00	
LDH	120-240 (U/L)	01/03/91	156.00		160.00	
ALK. PHOSPH.	60-170 (U/L)	01/03/91	117.00		118.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	72.00		74.00	
BUN	17-56 (MG/DL)	01/03/91	31.00		31.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	1.00		0.80	
URIC ACID	3.4-7 (MG/DL)	01/03/91	6.00			
TOT BILIRUBIN	0-1 (MG/DL)	01/03/91	0.40		0.70	
TOT. PROTEINS	65-85 (G/L)	01/03/91	79.10		78.90	
ALBUMINE	36-58 (G/L)	01/03/91	51.00		53.90	
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	150.00			
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	88.00	<		
GLOBULINS ALPHA 1	1.3-4.3 (G/L)	01/03/91	2.50		2.20	
GLOBULINS ALPHA 2	3.9-8.5 (G/L)	01/03/91	8.40		6.50	
GLOBULINS BETA	5.2-11.9 (G/L)	01/03/91	9.00		8.50	
GLOBULINS GAMMA	5.9-16.2 (G/L)	01/03/91	8.20		7.80	
TSH	0.3-3.5 (MU/L)	01/03/91	0.50		0.60	
T4	9-21 (NG/L)	01/03/91	17.30		10.60	

(¢) << 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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 39 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date	
			Screen	
			19/06/91	
			value	(¢)
Laboratory test	Range value	Range date		
HB	14-18 (G/DL)	01/03/91	14.70	
HT	0.38-0.57 (L/L)	01/03/91	0.42	
RBC	4.4-6 (10¬12/L)	01/03/91	4.70	
WBC	4.3-10 (10¬9/L)	01/03/91	6.20	
WBC: N	50-70 (%)	01/03/91	60.00	
WBC: L	25-40 (%)	01/03/91	32.00	
WBC: E	2-4 (%)	01/03/91	2.00	
WBC: M	2-6 (%)	01/03/91	5.00	
WBC: B	0-1 (%)	01/03/91	1.00	
PLATELETS	140-440 (10¬9/L)	01/03/91	188.00	
NA+	135-145 (MMOL/L)	01/03/91	141.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.30	
CL-	98-108 (MMOL/L)	01/03/91	101.00	
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.40	
PO4--	0.81-1.61 (MMOL/L)	01/03/91	1.20	
SGOT	3-18 (U/L)	01/03/91	11.00	
SGPT	5-22 (U/L)	01/03/91	21.00	
GAMMA GT	6-28 (U/L)	01/03/91	20.00	
LDH	120-240 (U/L)	01/03/91	98.00	<
ALK. PHOSPH.	60-170 (U/L)	01/03/91	123.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	73.00	
BUN	17-56 (MG/DL)	01/03/91	34.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.80	
URIC ACID	3.4-7 (MG/DL)	01/03/91	6.10	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/91	0.90	
TOT. PROTEINS	65-85 (G/L)	01/03/91	79.30	
ALBUMINE	36-58 (G/L)	01/03/91	51.10	
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	238.00	>
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	120.00	<
GLOBULINS ALPHA 1	1.3-4.3 (G/L)	01/03/91	2.70	
GLOBULINS ALPHA 2	3.9-8.5 (G/L)	01/03/91	8.20	
GLOBULINS BETA	5.2-11.9 (G/L)	01/03/91	9.50	
GLOBULINS GAMMA	5.9-16.2 (G/L)	01/03/91	7.70	
TSH	0.3-3.5 (MU/L)	01/03/91	0.70	
T4	9-21 (NG/L)	01/03/91	14.30	

(¢) << 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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 41 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date							
			Screen		Day 14		Day 28		Day 56	
			11/02/92		27/02/92		12/03/92		09/04/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	14-18 (G/DL)	01/03/91	16.60		14.60		15.20		14.60	
HT	0.38-0.57 (L/L)	01/03/91	0.48		0.46		0.47		0.45	
RBC	4.4-6 (10¬12/L)	01/03/91	5.20		4.86		5.09		4.80	
WBC	4.3-10 (10¬9/L)	01/03/91	8.70		7.20		8.10		6.50	
WBC: N	50-70 (%)	01/03/91	47.00	<	76.00	>	53.00		66.00	
WBC: L	25-40 (%)	01/03/91	44.00	>	20.00	<	41.00	>	30.00	
WBC: E	2-4 (%)	01/03/91	4.00		0.00	<	2.00		4.00	
WBC: M	2-6 (%)	01/03/91	4.00		4.00		4.00		0.00	<
WBC: B	0-1 (%)	01/03/91	1.00		0.00		0.00		0.00	
PLATELETS	140-440 (10¬9/L)	01/03/91	263.00		227.00		280.00		307.00	
NA+	135-145 (MMOL/L)	01/03/91	140.00		139.00		141.00		140.00	
K+	3.5-5 (MMOL/L)	01/03/91	5.00		4.40		4.40		4.30	
CL-	98-108 (MMOL/L)	01/03/91	100.00		97.00	<	90.00	<	97.00	<
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.50		2.50		2.70		2.60	
PO4--	0.81-1.61 (MMOL/L)	01/03/91	1.08		1.30		1.13		1.11	
SGOT	3-18 (U/L)	01/03/91	13.00		11.00		13.00		14.00	
SGPT	5-22 (U/L)	01/03/91	24.00	>	20.00		21.00		28.00	>
GAMMA GT	6-28 (U/L)	01/03/91	40.00	>	22.00		21.00		29.00	>
LDH	120-240 (U/L)	01/03/91	181.00		138.00		146.00		140.00	
ALK. PHOSPH.	60-170 (U/L)	01/03/91	155.00		156.00		133.00		165.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	78.00		68.00	<				
BUN	17-56 (MG/DL)	01/03/91	54.00		38.00		36.00		40.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.90		0.80		0.80		0.90	
URIC ACID	3.4-7 (MG/DL)	01/03/91	5.10		5.00		4.90		5.70	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/91	0.40		0.40		0.50		0.30	
TOT. PROTEINS	65-85 (G/L)	01/03/91	79.70		69.20		74.40		71.70	
ALBUMINE	56-68 (%)	01/03/91	68.80	>	66.80				63.90	
	36-58 (G/L)	10/03/92					51.00			
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	289.00	>>	276.00	>>	275.00	>>	269.00	>>
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	183.00		209.00	>	222.00	>	248.00	>
GLOBULINS ALPHA 1	2-5 (%)	01/03/91	2.60		2.60				3.30	
	1.3-4.3 (G/L)	10/03/92					2.00			
GLOBULINS ALPHA 2	6-10 (%)	01/03/91	7.10		6.60				8.80	
	3.9-8.5 (G/L)	10/03/92					6.10			
GLOBULINS BETA	8-14 (%)	01/03/91	10.80		12.10				12.00	
	5.2-11.9 (G/L)	10/03/92					8.60			
GLOBULINS GAMMA	9-19 (%)	01/03/91	10.60		12.10				12.00	
	5.9-16.2 (G/L)	10/03/92					6.70			
TSH	0.3-3.5 (MU/L)	01/03/91	0.80							
T4	9-21 (NG/L)	01/03/91	13.00							

1036

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS 9550085

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 44 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date			
			Screen		Day 28	
			13/12/91		10/01/92	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	14-18 (G/DL)	01/03/91	14.60		14.80	
HT	0.38-0.57 (L/L)	01/03/91	0.40		0.43	
RBC	4.4-6 (10~12/L)	01/03/91	4.44		4.77	
WBC	4.3-10 (10~9/L)	01/03/91	8.90		6.10	
WBC: N	50-70 (%)	01/03/91	56.00		66.00	
WBC: L	25-40 (%)	01/03/91	39.00		27.00	
WBC: E	2-4 (%)	01/03/91	1.00	<	2.00	
WBC: M	2-6 (%)	01/03/91	4.00		5.00	
WBC: B	0-1 (%)	01/03/91	0.00		0.00	
PLATELETS	140-440 (10~9/L)	01/03/91	251.00		223.00	
NA+	135-145 (MMOL/L)	01/03/91	142.00		142.00	
K+	3.5-5 (MMOL/L)	01/03/91	3.60		4.20	
CL-	98-108 (MMOL/L)	01/03/91	102.00		102.00	
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.30		2.50	
PO4--	0.81-1.61 (MMOL/L)	01/03/91	1.41		0.87	
SGOT	3-18 (U/L)	01/03/91	8.00		8.00	
SGPT	5-22 (U/L)	01/03/91	8.00		10.00	
GAMMA GT	6-28 (U/L)	01/03/91	11.00		9.00	
LDH	120-240 (U/L)	01/03/91	110.00	<	119.00	<
ALK. PHOSPH.	60-170 (U/L)	01/03/91	61.00		43.00	<
GLUCOSE	70-110 (MG/DL)	01/03/91	78.00		57.00	<
BUN	17-56 (MG/DL)	01/03/91	34.00		27.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.90		0.90	
URIC ACID	3.4-7 (MG/DL)	01/03/91	5.80		5.80	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/91	0.40		0.50	
TOT. PROTEINS	65-85 (G/L)	01/03/91	62.10	<	65.80	
ALBUMINE	56-68 (%)	01/03/91	64.70		66.40	
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	195.00		218.00	>
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	28.00	<	56.00	<
GLOBULINS ALPHA 1	2-5 (%)	01/03/91	3.50		3.00	
GLOBULINS ALPHA 2	6-10 (%)	01/03/91	6.90		6.40	
GLOBULINS BETA	8-14 (%)	01/03/91	11.50		10.90	
GLOBULINS GAMMA	9-19 (%)	01/03/91	13.40		13.30	
TSH	0.3-3.5 (MU/L)	01/03/91	0.30			
T4	9-21 (NG/L)	01/03/91	21.10	>		

(¢) << 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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 47 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			25/03/92		22/04/92		20/05/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	01/03/91	14.10		14.40		14.30	
HT	0.37-0.46 (L/L)	01/03/91	0.43		0.43		0.43	
RBC	4.2-5.5 (10~12/L)	01/03/91	4.75		4.66		4.62	
WBC	4.3-10 (10~9/L)	01/03/91	7.50		9.90		7.60	
WBC: N	50-70 (%)	01/03/91	66.00		66.00		67.00	
WBC: L	25-40 (%)	01/03/91	29.00		29.00		28.00	
WBC: E	2-4 (%)	01/03/91	0.00	<	2.00		2.00	
WBC: M	2-6 (%)	01/03/91	4.00		2.00		3.00	
WBC: B	0-1 (%)	01/03/91	1.00		1.00		0.00	
PLATELETS	140-440 (10~9/L)	01/03/91	308.00		329.00		325.00	
NA+	135-145 (MMOL/L)	01/03/91	140.00		139.00		139.00	
K+	3.5-5 (MMOL/L)	01/03/91	3.80		4.10		4.30	
CL-	98-108 (MMOL/L)	01/03/91	99.00		98.00		97.00	<
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.20	<	2.40		2.40	
PO4--	0.81-1.61 (MMOL/L)	01/03/91	0.88				0.85	
SGOT	3-15 (U/L)	01/03/91	13.00		14.00		14.00	
SGPT	5-17 (U/L)	01/03/91	23.00	>	19.00	>	16.00	
GAMMA GT	4-18 (U/L)	01/03/91	17.00		14.00		13.00	
LDH	120-240 (U/L)	01/03/91	165.00		180.00		166.00	
ALK. PHOSPH.	60-170 (U/L)	01/03/91	87.00		99.00		103.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	109.00				92.00	
BUN	17-56 (MG/DL)	01/03/91	19.00		23.00		24.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	1.00		0.90		0.90	
URIC ACID	2.4-5.7 (MG/DL)	01/03/91	4.10		4.80			
TOT. PROTEINS	65-85 (G/L)	01/03/91	70.10		73.70		78.20	
ALBUMINE	36-58 (G/L)	01/03/91	43.20		43.70		47.90	
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	138.00		189.00		176.00	
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	121.00	<	185.00		142.00	
GLOBULINS ALPHA 1	1.3-4.3 (G/L)	01/03/91	1.70		1.90		2.00	
GLOBULINS ALPHA 2	3.9-8.5 (G/L)	01/03/91	4.80		5.20		5.70	
GLOBULINS BETA	5.2-11.9 (G/L)	01/03/91	7.40		8.40		8.10	
GLOBULINS GAMMA	5.9-16.2 (G/L)	01/03/91	13.00		14.50		14.50	
TSH	0.3-3.5 (MU/L)	01/03/91	0.60					
T4	9-21 (NG/L)	01/03/91	17.40					

1038

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 80 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date							
			Screen		Day 14		Day 28		Day 56	
			15/01/93		29/01/93		12/02/93		12/03/93	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	14-18 (G/DL)	01/03/91	17.50		16.50		16.80		16.00	
HT	38-57 (%)	01/03/91	50.60		49.20		49.30		47.90	
RBC	4.4-6 (10¬12/L)	01/03/91	5.41		5.25		5.25		5.01	
WBC	4.3-10 (10¬9/L)	01/03/91	8.00		10.40	>	8.70		8.80	
WBC: N	50-70 (%)	01/03/91	54.90				62.00			
WBC: L	25-40 (%)	01/03/91	33.70				34.00			
WBC: E	2-4 (%)	01/03/91	3.40				2.00			
WBC: M	2-6 (%)	01/03/91	6.90	>			2.00			
WBC: B	0-1 (%)	01/03/91	1.10	>			0.00			
PLATELETS	140-440 (10¬9/L)	01/03/91	162.00		194.00		171.00		186.00	
NA+	135-145 (MMOL/L)	01/03/91	134.00	<			136.00		141.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.90				4.90		5.40	>
CL-	98-108 (MMOL/L)	01/03/91	99.00				99.00		103.00	
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.30				2.30		2.30	
PO4--	0.81-1.61 (MMOL/L)	01/03/91	0.88				0.90		0.60	<<
SGOT	3-18 (U/L)	01/03/91	9.00		16.00		11.00		8.00	
SGPT	5-22 (U/L)	01/03/91	21.00		17.00		20.00		16.00	
GAMMA GT	6-28 (U/L)	01/03/91	30.00	>	20.00		21.00		23.00	
LDH	120-240 (U/L)	01/03/91	170.00						137.00	
ALK. PHOSPH.	60-170 (U/L)	01/03/91	158.00		175.00	>	161.00		144.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	99.00							
BUN	17-56 (MG/DL)	01/03/91	32.00				23.00		35.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.70				0.90		0.90	
URIC ACID	3.4-7 (MG/DL)	01/03/91	5.00							
TOT. PROTEINS	65-85 (G/L)	01/03/91	65.60						73.10	
ALBUMINE	56-68 (%)	01/03/91	66.70						65.00	
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	245.00	>						
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	282.00	>>						
GLOBULINS ALPHA 1	2-5 (%)	01/03/91	2.40						3.00	
GLOBULINS ALPHA 2	6-10 (%)	01/03/91	10.80	>					10.20	>
GLOBULINS BETA	8-14 (%)	01/03/91	10.90						13.40	
GLOBULINS GAMMA	9-19 (%)	01/03/91	9.20						8.20	<
TSH	0.3-3.5 (MU/L)	01/03/91	2.00						1.40	
T4	9-21 (NG/L)	01/03/91	13.30						10.50	

(¢) << 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
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL - MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 3 Patient: 65 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date									
			Screen		Day 14		Day 28		Day 42		Day 56	
			11/10/91		29/10/91		12/11/91		26/11/91		10/12/91	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	18/09/91	13.10		14.10		13.20		14.60		13.80	
HT	37-46 (%)	18/09/91	38.80		42.10		41.00		44.00		41.50	
RBC	4.4-6 (10¬12/L)	18/09/91	4.14	<	4.42		4.30	<	4.62		4.37	<
WBC	4.3-10 (10¬9/L)	18/09/91	5.70		7.20		7.50		12.74	>	9.60	
WBC: N	45-80 (%)	18/09/91	43.00	<			49.00				71.00	
WBC: L	20-40 (%)	18/09/91	48.00	>			49.00	>			26.00	
WBC: E	1-4 (%)	18/09/91	6.00	>>			0.00	<			1.00	
WBC: M	2-8 (%)	18/09/91	2.00				2.00				2.00	
WBC: B	0-1 (%)	18/09/91	1.00				0.00				0.00	
PLATELETS	140-440 (10¬9/L)	18/09/91	220.00		256.00		242.00		272.00		278.00	
NA+	132-146 (MMOL/L)	18/09/91	141.00		142.00		143.00		142.00		140.00	
K+	3.6-5 (MMOL/L)	18/09/91	4.00		4.30		4.50		4.10		3.70	
Ca++	2.2-2.7 (MMOL/L)	18/09/91	2.70		2.80	>	2.80	>	2.90	>	2.70	
SGOT	5-15 (U/L)	18/09/91	7.00		10.00		9.00		12.00		11.00	
SGPT	5-19 (U/L)	18/09/91	5.00		8.00		7.00		10.00		10.00	
GAMMA GT	4-18 (U/L)	18/09/91	4.00		4.00		5.00		6.00			
LDH	120-240 (U/L)	18/09/91	132.00								164.00	
ALK. PHOSPH.	40-190 (U/L)	18/09/91	148.00		148.00		123.00				124.00	
GLUCOSE	70-100 (MG/DL)	18/09/91	91.00		88.00		82.00		89.00		85.00	
CREATININE	0.5-0.9 (MG/DL)	18/09/91	0.70		0.70		0.90		0.80		0.70	
URIC ACID	2.4-5.7 (MG/DL)	18/09/91	4.00		3.90		4.30				3.90	
TOT BILIRUBIN	0-1 (MG/DL)	18/09/91	0.40		0.40		0.40		0.50		0.40	
TOT. PROTEINS	66-87 (G/L)	18/09/91	59.00	<	69.00		62.00	<	70.00		65.00	<
ALBUMINE	58-70 (%)	18/09/91	66.40				65.90				65.20	
TOT. CHOLEST.	130-220 (MG/DL)	18/09/91	212.00				234.00	>			252.00	>
TRIGLYCERIDES	30-150 (MG/DL)	18/09/91	89.00				141.00				103.00	
GLOBULINS ALPHA 1	1.5-4 (%)	18/09/91	2.70				2.80				3.30	
GLOBULINS ALPHA 2	5-10 (%)	18/09/91	6.50				6.70				6.60	
GLOBULINS BETA	8-13 (%)	18/09/91	10.40				10.30				10.40	
GLOBULINS GAMMA	10-19 (%)	18/09/91	14.00				14.30				14.50	
TSH	0.1-3.5 (UU/ML)	18/09/91	0.60				1.20				1.00	
T4	5-12.5 (UG/100ML)	18/09/91	7.20				7.30				7.80	

1040

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL - MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 3 Patient: 66 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			11/10/91		12/11/91	
			value	(◊)	value	(◊)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	10/10/91	12.80		13.20	
HT	37-46 (%)	10/10/91	38.30		42.40	
RBC	4.4-6 (10~12/L)	10/10/91	4.16	<	4.57	
WBC	4.3-10 (10~9/L)	10/10/91	10.80	>	10.10	>
WBC: N	45-80 (%)	10/10/91	45.00		60.00	
WBC: L	20-40 (%)	10/10/91	51.00	>	38.00	
WBC: E	1-4 (%)	10/10/91	2.00		0.00	<
WBC: M	2-8 (%)	10/10/91	2.00		2.00	
WBC: B	0-1 (%)	10/10/91	0.00		0.00	
PLATELETS	140-440 (10~9/L)	10/10/91	374.00		402.00	
NA+	132~146 (MMOL/L)	10/10/91	138.00		143.00	
K+	3.6-5 (MMOL/L)	10/10/91	4.30		3.40	<
Ca++	2.2-2.7 (MMOL/L)	10/10/91	2.50		2.30	
SGOT	5-15 (U/L)	10/10/91	10.00		16.00	>
SGPT	5-19 (U/L)	10/10/91	9.00		14.00	
GAMMA GT	4-18 (U/L)	10/10/91	10.00		9.00	
LDH	120-240 (U/L)	10/10/91	164.00		201.00	
ALK. PHOSPH.	40-190 (U/L)	10/10/91	153.00		77.00	
GLUCOSE	70-100 (MG/DL)	10/10/91	120.00	>	99.00	
CREATININE	0.5-0.9 (MG/DL)	10/10/91	0.80		0.60	
URIC ACID	2.4-5.7 (MG/DL)	10/10/91	4.50		3.50	
TOT BILIRUBIN	0-1 (MG/DL)	10/10/91	0.30		0.30	
TOT. PROTEINS	66-87 (G/L)	10/10/91	68.00			
	5.6-7.8 (G/DL)	10/11/91			5.40	<
ALBUMINE	58-70 (%)	10/10/91	62.50		64.50	
TOT. CHOLEST.	130-220 (MG/DL)	10/10/91	270.00	>	144.00	
TRIGLYCERIDES	30-150 (MG/DL)	10/10/91	92.00			
GLOBULINS ALPHA 1	1.5-4 (%)	10/10/91	3.70		3.20	
GLOBULINS ALPHA 2	5-10 (%)	10/10/91	7.90		7.00	
GLOBULINS BETA	8-13 (%)	10/10/91	12.20		11.40	
GLOBULINS GAMMA	10-19 (%)	10/10/91	13.70		13.90	
TSH	0.1-3.5 (UU/ML)	10/10/91	0.90		0.30	
T4	5-12.5 (UG/100ML)	10/10/91	16.40	>>	15.20	>>

1041

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL-MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 4 Patient: 98 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			27/05/91		26/06/91		24/07/91	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-18 (G/DL)	20/05/91	15.80		15.10		14.80	
HT	37-54 (%)	20/05/91	46.00		44.80		43.60	
RBC	4.2-6.3 (10¬12/L)	20/05/91	4.55		4.39		4.28	
WBC	4.3-10 (10¬9/L)	20/05/91	11.60	>	8.60		8.90	
WBC: N	42.2-75.2 (%)	20/05/91	79.30	>	73.40		75.60	>
WBC: L	1.2-3.4 (10¬9/L)	20/05/91	1.90		2.10		1.80	
WBC: M	0.11-0.59 (10¬9/L)	20/05/91	0.50		0.20		0.30	
PLATELETS	140-440 (10¬9/L)	20/05/91	327.00		288.00		286.00	
NA+	137-147 (MMOL/L)	20/05/91	146.00		141.00			
K+	3.5-5.3 (MMOL/L)	20/05/91	4.00		4.00			
CL-	98-111 (MMOL/L)	20/05/91	113.00	>	111.00			
Ca++	2.1-2.7 (MMOL/L)	20/05/91	2.53		2.45			
PO4--	2.3-4.2 (MMOL/L)	20/05/91	2.90		2.50			
SGOT	5-18 (U/L)	20/05/91	10.00		9.00			
SGPT	5-23 (U/L)	20/05/91	10.00		8.00			
GAMMA GT	6-28 (U/L)	20/05/91	13.00		12.00			
LDH	100-200 (U/L)	20/05/91	212.00	>	189.00			
ALK. PHOSPH.	68-195 (U/L)	20/05/91	113.00		95.00			
GLUCOSE	70-117 (MG/DL)	20/05/91	80.00		90.00			
BUN	4-52 (MG/DL)	20/05/91	13.00		17.00			
CREATININE	0.3-1.39 (MG/DL)	20/05/91	0.90		1.00			
URIC ACID	2.9-7.4 (MG/DL)	20/05/91	5.80		6.40			
TOT BILIRUBIN	0.3-1.54 (MG/DL)	20/05/91	1.30		0.50		1.10	
DIR BILIRUBIN	0-0.3 (MG/DL)	20/05/91	0.20				0.10	
TOT. PROTEINS	6.6-8.3 (G/DL)	20/05/91	7.70		7.10			
ALBUMINE	3.7-5.4 (G/DL)	20/05/91	4.80		4.60			
TOT. CHOLEST.	150-260 (MG/DL)	20/05/91	261.00	>	241.00			
TRIGLYCERIDES	30-170 (MG/DL)	20/05/91	90.00		112.00			
GLOBULINS ALPHA 1	1-4 (%)	20/05/91	4.20	>			5.40	>>
GLOBULINS ALPHA 2	6-11 (%)	20/05/91	9.90				8.30	
GLOBULINS BETA	10-15 (%)	20/05/91	14.50				13.00	
GLOBULINS GAMMA	12-22 (%)	20/05/91	12.50				12.80	
T4	4.5-12.5 (UG/DL)	20/05/91	7.70					

1042

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 4 Patient: 99 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date	
			Screen	
			14/10/91	
			value	(¢)
Laboratory test	Range value	Range date		
HB	12-18 (G/DL)	15/05/91	14.10	
HT	37-54 (%)	15/05/91	42.00	
RBC	4.2-6.3 (10¬12/L)	15/05/91	4.63	
WBC	4.3-10 (10¬9/L)	15/05/91	7.70	
WBC: N	42.2-75.2 (%)	15/05/91	62.10	
WBC: L	1.2-3.4 (10¬9/L)	15/05/91	2.60	
WBC: M	0.11-0.59 (10¬9/L)	15/05/91	0.40	
PLATELETS	140-440 (10¬9/L)	15/05/91	261.00	
NA+	137-147 (MMOL/L)	15/05/91	142.00	
K+	3.5-5.3 (MMOL/L)	15/05/91	4.50	
CL-	98-111 (MMOL/L)	15/05/91	104.00	
Ca++	2.1-2.7 (MMOL/L)	15/05/91	2.50	
PO4--	2.3-4.2 (MMOL/L)	15/05/91	3.20	
SGOT	5-18 (U/L)	15/05/91	9.00	
SGPT	5-23 (U/L)	15/05/91	10.00	
GAMMA GT	6-28 (U/L)	15/05/91	10.00	
LDH	100-200 (U/L)	15/05/91	149.00	
ALK. PHOSPH.	68-195 (U/L)	15/05/91	168.00	
GLUCOSE	70-117 (MG/DL)	15/05/91	148.00	>
BUN	4-52 (MG/DL)	15/05/91	32.00	
CREATININE	0.3-1.39 (MG/DL)	15/05/91	0.80	
URIC ACID	2.9-7.4 (MG/DL)	15/05/91	3.70	
TOT BILIRUBIN	0.3-1.54 (MG/DL)	15/05/91	1.00	
TOT. PROTEINS	6.6-8.3 (G/DL)	15/05/91	7.10	
ALBUMINE	3.7-5.4 (G/DL)	15/05/91	4.90	
TOT. CHOLEST.	150-260 (MG/DL)	15/05/91	214.00	
TRIGLYCERIDES	30-170 (MG/DL)	15/05/91	142.00	
GLOBULINS ALPHA 1	1-4 (%)	15/05/91	4.20	>
GLOBULINS ALPHA 2	6-11 (%)	15/05/91	8.80	
GLOBULINS BETA	10-15 (%)	15/05/91	12.80	
GLOBULINS GAMMA	12-22 (%)	15/05/91	13.00	
TSH	0.1-3.5 (UU/ML)	15/05/91	0.70	
T4	4.5-12.5 (UG/DL)	15/05/91	11.40	

1043

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 4 Patient: 102 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			10/07/92		07/08/92		04/09/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-18 (G/DL)	15/05/91	12.80		12.60		14.00	
HT	37-54 (%)	15/05/91	38.00		37.70		40.50	
RBC	4.2-6.3 (10¬12/L)	15/05/91	4.16	<	4.09	<	4.45	
WBC	4.3-10 (10¬9/L)	15/05/91	6.40		6.40		6.80	
WBC: N	42.2-75.2 (%)	15/05/91	61.50		64.80		69.60	
WBC: L	1.2-3.4 (10¬9/L)	15/05/91	2.30		2.00		1.80	
WBC: E	0-0.7 (10¬9/L)	15/05/91	0.00		0.00			
WBC: M	0.11-0.59 (10¬9/L)	15/05/91	0.20		0.30		0.80	>>
WBC: B	0-0.2 (10¬9/L)	15/05/91	0.00		0.00			
PLATELETS	140-440 (10¬9/L)	15/05/91	359.00		327.00		346.00	
NA+	137-147 (MMOL/L)	01/08/92			144.00		144.00	
K+	3.5-5.3 (MMOL/L)	01/08/92			3.80		3.70	
CL-	98-111 (MMOL/L)	01/09/92					105.00	
Ca++	2.1-2.7 (MMOL/L)	15/05/91	2.30		2.20		2.30	
PO4--	2.3-4.2 (MMOL/L)	15/05/91	3.00		2.80		2.80	
SGOT	5-18 (U/L)	15/05/91	10.00		11.00		9.00	
SGPT	5-23 (U/L)	15/05/91	12.00		11.00		10.00	
GAMMA GT	6-28 (U/L)	15/05/91	29.00	>	16.00		9.00	
LDH	100-200 (U/L)	15/05/91	199.00		172.00		179.00	
ALK. PHOSPH.	68-195 (U/L)	15/05/91	192.00		171.00		145.00	
GLUCOSE	70-117 (MG/DL)	15/05/91	104.00		99.00		150.00	>
BUN	4-52 (MG/DL)	15/05/91	36.00		29.00		36.00	
CREATININE	0.3-1.39 (MG/DL)	15/05/91	0.80		0.80		0.90	
URIC ACID	2.9-7.4 (MG/DL)	15/05/91	4.90		6.10		6.50	
TOT BILIRUBIN	0.3-1.54 (MG/DL)	15/05/91	0.60		0.90		0.50	
DIR BILIRUBIN	0-0.3 (MG/DL)	15/05/91	0.10		0.20		0.10	
TOT. PROTEINS	6.6-8.3 (G/DL)	15/05/91	4.90	<	7.20		7.50	
ALBUMINE	3.7-5.4 (G/DL)	15/05/91	4.40		4.30		4.60	
TOT. CHOLEST.	150-260 (MG/DL)	15/05/91	271.00	>	252.00		270.00	>
TRIGLYCERIDES	30-170 (MG/DL)	15/05/91	244.00	>>	154.00		233.00	>>
GLOBULINS ALPHA 1	0.12-0.28 (G/DL)	15/05/91	0.20					
	1-4 (%)	01/08/92			3.60			
GLOBULINS ALPHA 2	0.45-0.82 (G/DL)	15/05/91	0.80					
	6-11 (%)	01/08/92			10.90			
GLOBULINS BETA	0.74-1.1 (G/DL)	15/05/91	0.90					
	10-15 (%)	01/08/92			11.00			
GLOBULINS GAMMA	0.88-1.6 (G/DL)	15/05/91	1.10					
	12-22 (%)	01/08/92			16.90			
TSH	0.1-3.5 (UU/ML)	15/05/91	0.60					
T4	4.5-12.5 (UG/DL)	15/05/91	8.10					

1044

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 4 Patient: 103 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			13/07/92		10/08/92	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	12-18 (G/DL)	15/05/91	16.00		13.90	
HT	37-54 (%)	15/05/91	47.40		42.10	
RBC	4.2-6.3 (10¬12/L)	15/05/91	5.36		4.76	
WBC	4.3-10 (10¬9/L)	15/05/91	8.30		7.30	
WBC: N	42.2-75.2 (%)	02/08/92			64.10	
WBC: L	1.2-3.4 (10¬9/L)	15/05/91	2.50		2.00	
WBC: E	0-0.7 (10¬9/L)	15/05/91	0.00		0.00	
WBC: M	0.11-0.59 (10¬9/L)	15/05/91	0.00	<	0.60	>
WBC: B	0-0.2 (10¬9/L)	15/05/91	0.00		0.00	
PLATELETS	140-440 (10¬9/L)	15/05/91	294.00		318.00	
NA+	137-147 (MMOL/L)	02/08/92			143.00	
K+	3.5-5.3 (MMOL/L)	02/08/92			3.60	
CL-	98-111 (MMOL/L)	02/08/92			108.00	
Ca++	2.1-2.7 (MMOL/L)	15/05/91	2.50		2.30	
PO4--	2.3-4.2 (MMOL/L)	15/05/91	3.80		2.70	
SGOT	5-18 (U/L)	15/05/91	7.00		5.00	
SGPT	5-23 (U/L)	15/05/91	7.00		5.00	
GAMMA GT	6-28 (U/L)	15/05/91	8.00		6.00	
LDH	100-200 (U/L)	15/05/91	175.00		152.00	
ALK. PHOSPH.	68-195 (U/L)	15/05/91	156.00		116.00	
GLUCOSE	70-117 (MG/DL)	15/05/91	83.00		115.00	
BUN	4-52 (MG/DL)	15/05/91	33.00		26.00	
CREATININE	0.3-1.39 (MG/DL)	15/05/91	0.90		0.90	
URIC ACID	2.9-7.4 (MG/DL)	15/05/91	4.20		4.20	
TOT BILIRUBIN	0.3-1.54 (MG/DL)	15/05/91	0.60		0.30	
DIR BILIRUBIN	0-0.3 (MG/DL)	15/05/91	0.10		0.10	
TOT. PROTEINS	6.6-8.3 (G/DL)	15/05/91	7.50		6.50	<
ALBUMINE	3.7-5.4 (G/DL)	15/05/91	4.90		4.30	
TOT. CHOLEST.	150-260 (MG/DL)	15/05/91	293.00	>	255.00	
TRIGLYCERIDES	30-170 (MG/DL)	15/05/91	136.00		153.00	
GLOBULINS ALPHA 1	0.12-0.28 (G/DL)	15/05/91	0.30	>		
	1-4 (%)	02/08/92			3.90	
GLOBULINS ALPHA 2	0.45-0.82 (G/DL)	15/05/91	0.90	>		
	6-11 (%)	02/08/92			14.20	>
GLOBULINS BETA	0.74-1.1 (G/DL)	15/05/91	0.90			
	10-15 (%)	02/08/92			14.20	
GLOBULINS GAMMA	0.88-1.6 (G/DL)	15/05/91	0.60	<<		
	12-22 (%)	02/08/92			9.30	<
TSH	0.1-3.5 (UU/ML)	15/05/91	1.70			
T4	4.5-12.5 (UG/DL)	15/05/91	10.40			

1045

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 4 Patient: 105 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			20/08/92		18/09/92		16/10/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-18 (G/DL)	01/08/92	16.10		16.90		16.10	
HT	37-54 (%)	01/08/92	47.40		49.30		48.10	
RBC	4.2-6.3 (10¬12/L)	01/08/92	5.52		5.73		5.55	
WBC	4.3-10 (10¬9/L)	01/08/92	7.70		5.10		6.90	
WBC: N	42.2-75.2 (%)	01/08/92	78.10	>	74.20		76.00	>
WBC: L	1.2-3.4 (10¬9/L)	01/08/92	1.40		1.20		1.30	
WBC: E	0-0.7 (10¬9/L)	01/08/92	0.00		0.00		0.00	
WBC: M	0.11-0.59 (10¬9/L)	01/08/92	0.30		0.10	<	0.40	
WBC: B	0-0.2 (10¬9/L)	01/08/92	0.00		0.00		0.00	
PLATELETS	140-440 (10¬9/L)	01/08/92	165.00		185.00		222.00	
NA+	137-147 (MMOL/L)	01/08/92	145.00		146.00		142.00	
K+	3.5-5.3 (MMOL/L)	01/08/92	4.00		3.80		3.70	
CL-	98-111 (MMOL/L)	01/08/92	106.00		103.00			
Ca++	2.1-2.7 (MMOL/L)	01/08/92	2.30		2.30		2.40	
PO4--	2.3-4.2 (MMOL/L)	01/08/92	3.50		3.50		3.70	
SGOT	5-18 (U/L)	01/08/92	7.00		7.00		6.00	
SGPT	5-23 (U/L)	01/08/92	15.00		12.00		8.00	
GAMMA GT	6-28 (U/L)	01/08/92	11.00		11.00		9.00	
LDH	100-200 (U/L)	01/08/92	113.00		122.00		123.00	
ALK. PHOSPH.	68-195 (U/L)	01/08/92	94.00		98.00		104.00	
GLUCOSE	70-117 (MG/DL)	01/08/92	88.00		99.00		87.00	
BUN	4-52 (MG/DL)	01/08/92	22.00		34.00		22.00	
CREATININE	0.3-1.39 (MG/DL)	01/08/92	0.80		0.80		0.80	
URIC ACID	2.9-7.4 (MG/DL)	01/08/92	6.40		6.40		6.80	
TOT BILIRUBIN	0.3-1.54 (MG/DL)	01/08/92	0.30		0.50		0.50	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/08/92			0.10		0.10	
TOT. PROTEINS	6.6-8.3 (G/DL)	01/08/92	6.60		7.00		7.00	
ALBUMINE	3.7-5.4 (G/DL)	01/08/92	4.40		4.90		4.80	
TOT. CHOLEST.	150-260 (MG/DL)	01/08/92	200.00		195.00		187.00	
TRIGLYCERIDES	30-170 (MG/DL)	01/08/92	167.00		96.00		131.00	
GLOBULINS ALPHA 1	0.12-0.28 (G/DL)	01/08/92	0.20		0.20		0.20	
GLOBULINS ALPHA 2	0.45-0.82 (G/DL)	01/08/92	0.60		0.60		0.60	
GLOBULINS BETA	0.74-1.1 (G/DL)	01/08/92	0.80		0.60	<	0.80	
GLOBULINS GAMMA	0.88-1.6 (G/DL)	01/08/92	0.90		0.90		0.90	
TSH	0.1-3.5 (UU/ML)	01/08/92	0.50					
T4	4.5-12.5 (UG/DL)	01/08/92	8.30					

1046

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (value lower than min range) > out of range (value higher than max range
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 5 Patient: 130 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			24/02/92		20/03/92		24/04/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12.5-18 (G/DL)	09/09/91	13.70		13.10		13.40	
HT	37-47 (%)	09/09/91	39.00		38.40		39.60	
RBC	4.5-5.5 (10¬6/UL)	09/09/91	4.48	<	4.31	<	4.40	<
WBC	4-10.8 (10¬3/UL)	09/09/91	7.30		5.10		4.90	
WBC: N	40-74 (%)	09/09/91	55.80		44.90		45.60	
WBC: L	19-48 (%)	09/09/91	32.90		44.30		43.70	
WBC: E	0-4 (%)	09/09/91	3.50		2.50		2.30	
WBC: M	3.4-9 (%)	09/09/91	7.70		7.10		7.10	
WBC: B	0-1.5 (%)	09/09/91	0.10		1.20		1.30	
PLATELETS	150-400 (10¬3/UL)	09/09/91	199.00		164.00		191.00	
NA+	135-148 (MEQ/L)	09/09/91	139.00		141.00		142.00	
K+	3.5-5.3 (MEQ/L)	09/09/91	4.10		4.20		4.70	
Ca++	8.1-10.4 (MG/DL)	09/09/91	10.00		9.30		10.30	
PO4--	2.5-5 (MG/DL)	09/09/91	4.20		4.20		4.30	
SGOT	4-40 (U/L)	09/09/91	16.00		17.00		17.00	
SGPT	4-40 (U/L)	09/09/91	14.00		16.00		23.00	
GAMMA GT	7-50 (U/L)	09/09/91	12.00		11.00		11.00	
LDH	230-460 (U/L)	09/09/91	273.00		244.00		267.00	
ALK. PHOSPH.	98-280 (U/L)	09/09/91	121.00		110.00		125.00	
GLUCOSE	60-110 (MG/DL)	09/09/91	95.00		89.00		86.00	
BUN	4-22 (MG/DL)	09/09/91	21.70		16.50		23.80	>
CREATININE	0.3-1.2 (MG/DL)	09/09/91	1.20		1.00		1.10	
URIC ACID	2.4-7 (MG/DL)	09/09/91	6.00		5.30		5.20	
TOT BILIRUBIN	0.3-1.2 (MG/DL)	09/09/91	0.40		0.50		0.50	
TOT. PROTEINS	6-8 (G/DL)	09/09/91	6.90		6.70		7.00	
TOT. CHOLEST.	140-260 (MG/DL)	09/09/91	227.00		211.00		213.00	
TRIGLYCERIDES	30-150 (MG/DL)	09/09/91	71.00		50.00		66.00	
TSH	0.4-4.5 (UU/ML)	09/09/91	3.60					
T4	0.8-2 (NG/100ML)	09/09/91	1.10					

1047

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 7 Patient: 194 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			02/01/92		07/02/92		05/03/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	01/12/91	13.00		13.80		13.20	
HT	37-47 (%)	01/12/91	37.00		40.00		38.00	
RBC	4.2-5.4 (10¬6/UL)	01/12/91	4.02	<	4.30		4.12	<
WBC	4.3-10 (10¬3/UL)	01/12/91	7.70		7.80		5.70	
WBC: N	1.8-8 (10¬3/UL)	01/12/91	4.42		5.33		3.19	
WBC: L	1-5 (10¬3/UL)	01/12/91	2.82		2.05		2.12	
WBC: E	0-0.5 (10¬3/UL)	01/12/91	0.06		0.08		0.07	
WBC: M	0.1-0.8 (10¬3/UL)	01/12/91	0.33		0.24		0.26	
WBC: B	0-0.1 (10¬3/UL)	01/12/91	0.03		0.06		0.03	
PLATELETS	150-350 (10¬3/UL)	01/12/91	191.00		302.00		271.00	
NA+	140-148 (MMOL/L)	01/12/91	145.00		143.00		143.00	
K+	3.9-5.1 (MMOL/L)	01/12/91	3.82	<	4.88		4.41	
CL-	96-109 (MMOL/L)	01/12/91	113.00	>	104.00		103.00	
Ca++	2.14-2.54 (MMOL/L)	01/12/91	2.25		2.44		2.24	
PO4--	0.85-1.33 (MMOL/L)	01/12/91	1.39	>	1.28		0.93	
SGOT	9-25 (U/L)	01/12/91	44.00	>	23.00		24.00	
SGPT	8-36 (U/L)	01/12/91	74.00	>>	31.00		31.00	
GAMMA GT	7-43 (U/L)	01/12/91	30.00		30.00		26.00	
LDH	230-460 (U/L)	01/12/91	324.00		311.00		319.00	
ALK. PHOSPH.	81-263 (U/L)	01/12/91	95.00		103.00		92.00	
GLUCOSE	4.1-5.9 (MMOL/L)	01/12/91	3.80	<	4.00	<	4.00	<
BUN	3.8-8.6 (MMOL/L)	01/12/91	6.20		5.60		5.50	
CREATININE	55-94 (UMOL/L)	01/12/91	71.00		83.00		89.00	
URIC ACID	147-372 (UMOL/L)	01/12/91	246.00		208.00		220.00	
TOT BILIRUBIN	0-17 (UMOL/L)	01/12/91	4.00		6.00		9.00	
DIR BILIRUBIN	0-6 (UMOL/L)	01/12/91	2.00		4.00		3.00	
TOT. PROTEINS	64-76 (G/L)	01/12/91	69.80		80.10	>	72.50	
ALBUMINE	40-48 (G/L)	01/12/91	45.40		49.30	>	46.20	
TOT. CHOLEST.	4.3-7.6 (MMOL/L)	01/12/91	5.40		6.64		5.97	
TRIGLYCERIDES	0.34-1.9 (MMOL/L)	01/12/91	0.98		0.93		0.83	
TSH	0.3-4 (MUI/L)	01/12/91	2.50					
T4	9-24 (PMOL/L)	01/12/91	14.50					

(¢) << 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

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 7 Patient: 195 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			13/02/92		13/03/92		10/04/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	14-18 (G/DL)	01/12/91	15.50		15.80		14.60	
HT	42-52 (%)	01/12/91	46.00		47.00		41.00	<
RBC	4.5-6.3 (10¬6/UL)	01/12/91	5.18		5.18		4.79	
WBC	4.3-10 (10¬3/UL)	01/12/91	6.06		8.70		9.77	
WBC: N	1.8-8 (10¬3/UL)	01/12/91	2.92		4.36		5.77	
WBC: L	1-5 (10¬3/UL)	01/12/91	2.67		3.62		3.14	
WBC: E	0-0.5 (10¬3/UL)	01/12/91	0.07		0.19		0.06	
WBC: M	0.1-0.8 (10¬3/UL)	01/12/91	0.33		0.40		0.50	
WBC: B	0-0.1 (10¬3/UL)	01/12/91	0.03		0.10		0.16	>>
PLATELETS	150-350 (10¬3/UL)	01/12/91	208.00		233.00		184.00	
NA+	140-148 (MMOL/L)	01/12/91	146.00		144.00		144.00	
K+	3.9-5.1 (MMOL/L)	01/12/91	4.36		4.75		4.17	
CL-	96-109 (MMOL/L)	01/12/91	108.00		109.00		107.00	
Ca++	2.14-2.54 (MMOL/L)	01/12/91	2.27		2.41		2.35	
PO4--	0.85-1.33 (MMOL/L)	01/12/91	1.10		1.09		0.90	
SGOT	9-25 (U/L)	01/12/91	27.00	>	19.00		24.00	
SGPT	8-36 (U/L)	01/12/91	47.00	>	24.00		23.00	
GAMMA GT	7-43 (U/L)	01/12/91	53.00	>	36.00		42.00	
LDH	230-460 (U/L)	01/12/91	286.00		317.00		339.00	
ALK. PHOSPH.	81-263 (U/L)	01/12/91	229.00		215.00		196.00	
GLUCOSE	4.1-5.9 (MMOL/L)	01/12/91	4.70		4.60		4.20	
BUN	3.8-8.6 (MMOL/L)	01/12/91	5.30		6.90		5.60	
CREATININE	55-94 (UMOL/L)	01/12/91	106.00	>	112.00	>	100.00	>
URIC ACID	147-372 (UMOL/L)	01/12/91	429.00	>	378.00	>	391.00	>
TOT BILIRUBIN	0-17 (UMOL/L)	01/12/91	2.00		11.00		9.00	
DIR BILIRUBIN	0-6 (UMOL/L)	01/12/91	5.00		3.00		3.00	
TOT. PROTEINS	64-76 (G/L)	01/12/91	74.30		77.40	>	71.20	
ALBUMINE	40-48 (G/L)	01/12/91	47.00		49.00	>	48.80	>
TOT. CHOLEST.	4.3-7.6 (MMOL/L)	01/12/91	7.47		8.22	>	7.87	>
TRIGLYCERIDES	0.34-1.9 (MMOL/L)	01/12/91	2.56	>>	1.76		1.71	
TSH	0.3-4 (MUI/L)	01/12/91	1.40					
T4	9-24 (PMOL/L)	01/12/91	19.20					

1049

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 7 Patient: 197 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date	
			Screen	
			06/11/92	
			value	(¢)
Laboratory test	Range value	Range date		
HB	14-18 (G/DL)	01/12/91	10.90	<<
HT	42-52 (%)	01/12/91	32.00	<<
RBC	4.5-6.3 (10¬6/UL)	01/12/91	3.60	<<
WBC	4.3-10 (10¬3/UL)	01/12/91	7.60	
WBC: N	1.8-8 (10¬3/UL)	01/12/91	4.30	
WBC: L	1-5 (10¬3/UL)	01/12/91	2.66	
WBC: E	0-0.5 (10¬3/UL)	01/12/91	0.22	
WBC: M	0.1-0.8 (10¬3/UL)	01/12/91	0.38	
WBC: B	0-0.1 (10¬3/UL)	01/12/91	0.00	
PLATELETS	150-350 (10¬3/UL)	01/12/91	194.00	
NA+	140-148 (MMOL/L)	01/12/91	144.00	
K+	3.9-5.1 (MMOL/L)	01/12/91	4.24	
CL-	96-109 (MMOL/L)	01/12/91	108.00	
Ca++	2.14-2.54 (MMOL/L)	01/12/91	2.24	
PO4--	0.85-1.33 (MMOL/L)	01/12/91	1.36	>
SGOT	9-25 (U/L)	01/12/91	13.00	
SGPT	8-36 (U/L)	01/12/91	16.00	
GAMMA GT	7-43 (U/L)	01/12/91	11.00	
LDH	230-460 (U/L)	01/12/91	214.00	<
ALK. PHOSPH.	81-263 (U/L)	01/12/91	61.00	<
GLUCOSE	4.1-5.9 (MMOL/L)	01/12/91	4.50	
BUN	3.8-8.6 (MMOL/L)	01/12/91	5.10	
CREATININE	55-94 (UMOL/L)	01/12/91	77.00	
URIC ACID	147-372 (UMOL/L)	01/12/91	162.00	
TOT BILIRUBIN	0-17 (UMOL/L)	01/12/91	6.00	
DIR BILIRUBIN	0-6 (UMOL/L)	01/12/91	3.00	
TOT. PROTEINS	64-76 (G/L)	01/12/91	58.40	<
ALBUMINE	40-48 (G/L)	01/12/91	41.00	
TOT. CHOLEST.	4.3-7.6 (MMOL/L)	01/12/91	2.99	<
TRIGLYCERIDES	0.34-1.9 (MMOL/L)	01/12/91	0.71	
TSH	0.3-4 (MUI/L)	01/12/91	0.02	<<
T4	9-24 (PMOL/L)	01/12/91	16.60	

1050

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 321 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 56	
			05/11/91		09/01/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)
HB	115-145 (G/L)	01/10/91	138.00		134.00	
HT	0.42-0.5 (L/L)	01/10/91	0.44		0.41	<
RBC	4.2-5.2 (10¬12/L)	01/10/91	4.87		4.62	
WBC	4.5-10 (10¬9/L)	01/10/91	4.17	<	3.71	<
WBC: N	40-70 (%)	01/10/91	53.10		57.20	
WBC: L	20-45 (%)	01/10/91	33.70		30.00	
WBC: E	1-5 (%)	01/10/91	2.40		2.70	
WBC: M	2-10 (%)	01/10/91	6.60		7.30	
WBC: B	0-1 (%)	01/10/91	1.00		0.80	
PLATELETS	150-350 (10¬9/L)	01/10/91	224.00		220.00	
NA+	135-145 (MEQ/L)	01/10/91	142.00		144.00	
K+	3.5-4.5 (MEQ/L)	01/10/91	4.10		3.80	
CL-	95-106 (MEQ/L)	01/10/91			98.00	
Ca++	8.5-10.5 (MG/DL)	01/10/91	9.90		9.60	
PO4--	2.3-4.3 (MG/DL)	01/10/91	4.00		3.30	
SGOT	10-40 (UI/L)	01/10/91	28.00		18.00	
SGPT	10-40 (UI/L)	01/10/91	32.00		21.00	
GAMMA GT	5-40 (UI/L)	01/10/91	23.00		15.00	
LDH	250-450 (UI/L)	01/10/91	321.00		312.00	
ALK. PHOSPH.	123-345 (UI/L)	01/10/91	130.00		146.00	
GLUCOSE	64-107 (MG/DL)	01/10/91	105.00		100.00	
BUN	10-25 (MG/DL)	01/10/91	25.00		23.00	
CREATININE	0.5-1.3 (MG/DL)	01/10/91	1.00		0.80	
URIC ACID	1.9-7.4 (MG/DL)	01/10/91	4.50		4.50	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/10/91	0.40		0.40	
TOT. PROTEINS	60-80 (G/L)	01/10/91	70.00		63.00	
ALBUMINE	57-69 (%)	01/10/91	70.00	>	68.80	
TOT. CHOLEST.	148-247 (MG/DL)	01/10/91	304.00	>	289.00	>
TRIGLYCERIDES	50-150 (MG/DL)	01/10/91	117.00		83.00	
GLOBULINS ALPHA 1	2.1-3.5 (%)	01/10/91	2.40		3.10	
GLOBULINS ALPHA 2	6-10 (%)	01/10/91	8.00		7.40	
GLOBULINS BETA	6.5-11.5 (%)	01/10/91	10.50		10.50	
GLOBULINS GAMMA	15-22 (%)	01/10/91	9.10	<<	10.20	<<
TSH	0.5-5 (UU/ML)	01/10/91	1.40			
T4	4.5-12.5 (UG/100ML)	01/10/91	8.10			

1051

(¢) << 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 PHARMACEUTICAL MILANO - CNS

9550883

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 323 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			30/10/91		20/12/91		23/01/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	115-145 (G/L)	01/10/91	143.00		149.00	>	146.00	>
HT	0.42-0.5 (L/L)	01/10/91	0.45		0.45		0.44	
RBC	4.2-5.2 (10¬12/L)	01/10/91	5.26	>	5.25	>	5.27	>
WBC	4.5-10 (10¬9/L)	01/10/91	8.06		6.72		8.09	
WBC: N	40-70 (%)	01/10/91	66.00		62.10		66.70	
WBC: L	20-45 (%)	01/10/91	23.00		26.30		23.20	
WBC: E	1-5 (%)	01/10/91	1.70		2.00		1.50	
WBC: M	2-10 (%)	01/10/91	6.10		6.70		6.20	
WBC: B	0-1 (%)	01/10/91	1.00		0.80		0.60	
PLATELETS	150-350 (10¬9/L)	01/10/91	291.00		295.00		287.00	
NA+	135-145 (MEQ/L)	01/10/91	142.00		141.00		141.00	
K+	3.5-4.5 (MEQ/L)	01/10/91	4.10		6.10	>>	4.20	
CL-	95-106 (MEQ/L)	01/10/91					99.00	
Ca++	8.5-10.5 (MG/DL)	01/10/91	10.00		6.90	<<	9.80	
PO4--	2.3-4.3 (MG/DL)	01/10/91	3.80		3.70		3.70	
SGOT	10-40 (UI/L)	01/10/91	21.00		19.00		28.00	
SGPT	10-40 (UI/L)	01/10/91	26.00		22.00		31.00	
GAMMA GT	5-40 (UI/L)	01/10/91	34.00		23.00		30.00	
LDH	250-450 (UI/L)	01/10/91	373.00		382.00		374.00	
ALK. PHOSPH.	123-345 (UI/L)	01/10/91	213.00		161.00		191.00	
GLUCOSE	64-107 (MG/DL)	01/10/91	109.00	>	109.00	>	114.00	>
BUN	10-25 (MG/DL)	01/10/91	22.00		20.00		22.00	
CREATININE	0.5-1.3 (MG/DL)	01/10/91	0.70		0.80		0.70	
URIC ACID	1.9-7.4 (MG/DL)	01/10/91	4.00		4.50		4.10	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/10/91	0.60		0.70		0.70	
TOT. PROTEINS	60-80 (G/L)	01/10/91	76.00		72.00		68.00	
ALBUMINE	57-69 (%)	01/10/91			68.60		69.00	
TOT. CHOLEST.	148-247 (MG/DL)	01/10/91	279.00	>	274.00	>	242.00	
TRIGLYCERIDES	50-150 (MG/DL)	01/10/91	129.00		117.00		125.00	
GLOBULINS ALPHA 1	2.1-3.5 (%)	01/10/91			3.10		3.30	
GLOBULINS ALPHA 2	6-10 (%)	01/10/91			6.70		6.40	
GLOBULINS BETA	6.5-11.5 (%)	01/10/91			11.00		11.00	
GLOBULINS GAMMA	15-22 (%)	01/10/91			10.60	<	10.30	<<

1052

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 327 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			24/01/92		12/03/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)
HB	115-145 (G/L)	01/10/91	117.00		107.00	<
HT	0.42-0.5 (L/L)	01/10/91	0.35	<<	0.33	<<
RBC	4.2-5.2 (10-12/L)	01/10/91	4.33		4.15	<
WBC	4.5-10 (10-9/L)	01/10/91	4.43	<	3.77	<
WBC: N	40-70 (%)	01/10/91	63.20		69.70	
WBC: L	20-45 (%)	01/10/91	25.70		22.80	
WBC: E	1-5 (%)	01/10/91	0.90	<	0.30	<
WBC: M	2-10 (%)	01/10/91	7.00		4.00	
WBC: B	0-1 (%)	01/10/91	0.90		0.90	
PLATELETS	150-350 (10-9/L)	01/10/91	186.00		217.00	
NA+	135-145 (MEQ/L)	01/10/91	139.00		135.00	
K+	3.5-4.5 (MEQ/L)	01/10/91	4.00		3.70	
CL-	95-106 (MEQ/L)	01/10/91	99.00		98.00	
Ca++	8.5-10.5 (MG/DL)	01/10/91	9.60		9.10	
PO4--	2.3-4.3 (MG/DL)	01/10/91	3.50		3.20	
SGOT	10-40 (UI/L)	01/10/91	20.00		16.00	
SGPT	10-40 (UI/L)	01/10/91	24.00		16.00	
GAMMA GT	5-40 (UI/L)	01/10/91	10.00		11.00	
LDH	250-450 (UI/L)	01/10/91	286.00		299.00	
ALK. PHOSPH.	123-345 (UI/L)	01/10/91	95.00	<	99.00	<
GLUCOSE	64-107 (MG/DL)	01/10/91	89.00		79.00	
BUN	10-25 (MG/DL)	01/10/91	16.00		11.00	
CREATININE	0.5-1.3 (MG/DL)	01/10/91	0.70		0.70	
URIC ACID	1.9-7.4 (MG/DL)	01/10/91	3.10		3.20	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/10/91	0.50		1.10	>
TOT. PROTEINS	60-80 (G/L)	01/10/91	82.00	>	74.00	
ALBUMINE	57-69 (%)	01/10/91	66.20		64.30	
TOT. CHOLEST.	148-247 (MG/DL)	01/10/91	199.00		177.00	
TRIGLYCERIDES	50-150 (MG/DL)	01/10/91	33.00	<	39.00	<
GLOBULINS ALPHA 1	2.1-3.5 (%)	01/10/91	2.40		2.90	
GLOBULINS ALPHA 2	6-10 (%)	01/10/91	6.80		6.90	
GLOBULINS BETA	6.5-11.5 (%)	01/10/91	9.50		10.30	
GLOBULINS GAMMA	15-22 (%)	01/10/91	15.10		15.70	

1053

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9950883

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 328 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			07/02/92		24/03/92		21/04/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	115-145 (G/L)	01/10/91	126.00					
	120-170 (G/L)	13/03/92			130.00		127.00	
HT	0.42-0.5 (L/L)	01/10/91	0.38	<				
	0.36-0.51 (L/L)	13/03/92			0.40		0.38	
RBC	4.2-5.2 (10¬12/L)	01/10/91	4.05	<				
	3.9-5.5 (10¬12/L)	13/03/92			4.29		4.23	
WBC	4.5-10 (10¬9/L)	01/10/91	5.57					
	4-11 (10¬9/L)	13/03/92			4.64		4.49	
WBC: N	40-70 (%)	01/10/91	56.90					
	45-75 (%)	13/03/92			54.50		52.60	
WBC: L	20-45 (%)	01/10/91	30.70					
	17-55 (%)	13/03/92			32.90		34.30	
WBC: E	1-5 (%)	01/10/91	1.90					
	0-5 (%)	13/03/92			2.00		2.00	
WBC: M	2-10 (%)	01/10/91	6.20		7.60		6.50	
WBC: B	0-1 (%)	01/10/91	0.50					
	0-2 (%)	13/03/92			0.50		0.50	
PLATELETS	150-350 (10¬9/L)	01/10/91	199.00					
	150-400 (10¬9/L)	13/03/92			212.00		214.00	
NA+	135-145 (MEQ/L)	01/10/91	140.00		141.00		147.00	>
K+	3.5-4.5 (MEQ/L)	01/10/91	3.30	<	4.30		3.80	
CL-	95-106 (MEQ/L)	01/10/91	97.00				101.00	
Ca++	8.5-10.5 (MG/DL)	01/10/91	9.50		9.50		9.30	
PO4--	2.3-4.3 (MG/DL)	01/10/91	3.60		3.20		3.60	
SGOT	10-40 (UI/L)	01/10/91	22.00		13.00		15.00	
SGPT	10-40 (UI/L)	01/10/91	18.00		13.00		17.00	
GAMMA GT	5-40 (UI/L)	01/10/91	8.00		8.00		9.00	
LDH	250-450 (UI/L)	01/10/91	295.00		323.00		355.00	
ALK. PHOSPH.	123-345 (UI/L)	01/10/91	113.00	<	119.00	<	121.00	<
GLUCOSE	64-107 (MG/DL)	01/10/91	90.00		98.00		95.00	
BUN	10-25 (MG/DL)	01/10/91	19.00		17.00		17.00	
CREATININE	0.5-1.3 (MG/DL)	01/10/91	0.80		0.60		0.70	
URIC ACID	1.9-7.4 (MG/DL)	01/10/91	3.10		2.60		2.80	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/10/91	0.30		0.40		0.40	
TOT. PROTEINS	60-80 (G/L)	01/10/91	68.00		70.00		67.00	
ALBUMINE	57-69 (%)	01/10/91	69.40	>	70.40	>	71.60	>
TOT. CHOLEST.	148-247 (MG/DL)	01/10/91	281.00	>	250.00	>	249.00	>
TRIGLYCERIDES	50-150 (MG/DL)	01/10/91	86.00		74.00		108.00	
GLOBULINS ALPHA 1	2.1-3.5 (%)	01/10/91	3.00		2.80		2.80	
GLOBULINS ALPHA 2	6-10 (%)	01/10/91	5.90	<	6.20		5.90	<
GLOBULINS BETA	6.5-11.5 (%)	01/10/91	12.20	>	11.20		9.70	
GLOBULINS GAMMA	15-22 (%)	01/10/91	9.50	<<	9.40	<<	10.00	<<
TSH	0.5-5 (UU/ML)	01/10/91	3.40					
T4	4.5-12.5 (UG/100ML)	01/10/91	7.80					

1054

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9550085

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 331 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			08/05/92		29/06/92		06/08/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	120-170 (G/L)	01/05/92	124.00		121.00		122.00	
HT	0.36-0.51 (L/L)	01/05/92	0.37		0.37		0.37	
RBC	3.9-5.5 (10¬12/L)	01/05/92	3.97		3.79	<	3.89	<
WBC	4-11 (10¬9/L)	01/05/92	4.62		3.42	<	3.72	<
WBC: N	45-75 (%)	01/05/92	49.20		54.30		53.40	
WBC: L	17-55 (%)	01/05/92	38.20		33.40		35.50	
WBC: E	0-5 (%)	01/05/92	1.30		1.60		1.30	
WBC: M	2-10 (%)	01/05/92	7.00		8.10		6.50	
WBC: B	0-2 (%)	01/05/92	0.80		0.40		0.50	
PLATELETS	150-400 (10¬9/L)	01/05/92	216.00		194.00		169.00	
NA+	135-145 (MEQ/L)	01/05/92	141.00		133.00	<	141.00	
K+	3.5-4.5 (MEQ/L)	01/05/92	4.10		3.90		3.90	
CL-	95-106 (MEQ/L)	05/08/92					106.00	
Ca++	8.5-10.5 (MG/DL)	01/05/92	9.00		9.00		9.20	
PO4--	2.3-4.3 (MG/DL)	01/05/92	3.10		3.10		3.40	
SGOT	10-40 (UI/L)	01/05/92	25.00		10.00		26.00	
SGPT	10-40 (UI/L)	01/05/92	20.00		6.00	<	6.00	<
GAMMA GT	5-40 (UI/L)	01/05/92	9.00		10.00		10.00	
LDH	250-450 (UI/L)	01/05/92	262.00		244.00	<	254.00	
ALK. PHOSPH.	123-345 (UI/L)	01/05/92	67.00	<	60.00	<	56.00	<
GLUCOSE	64-107 (MG/DL)	01/05/92	80.00		87.00		81.00	
BUN	10-25 (MG/DL)	01/05/92	15.00		14.00		20.00	
CREATININE	0.5-1.3 (MG/DL)	01/05/92	0.90		1.00		0.80	
URIC ACID	1.9-7.4 (MG/DL)	01/05/92	2.90		3.40		2.90	
TOT BILIRUBIN	0.1-1 (MG/DL)	01/05/92	0.90		0.50		0.50	
TOT. PROTEINS	60-80 (G/L)	01/05/92	68.00		75.00		74.00	
ALBUMINE	57-69 (%)	01/05/92	69.40	>	68.90			
	27-58 (G/L)	05/08/92					48.00	
TOT. CHOLEST.	148-247 (MG/DL)	01/05/92	228.00		241.00		224.00	
TRIGLYCERIDES	50-150 (MG/DL)	01/05/92	94.00		96.00		75.00	
GLOBULINS ALPHA 1	2.1-3.5 (%)	01/05/92	2.40		2.30		2.10	
GLOBULINS ALPHA 2	6-10 (%)	01/05/92	6.50		7.00		7.20	
GLOBULINS BETA	6.5-11.5 (%)	01/05/92	7.10		7.90		8.50	
GLOBULINS GAMMA	15-22 (%)	01/05/92	14.10	<	13.90	<	14.00	<
TSH	0.5-5 (UU/ML)	01/05/92	2.60					
T4	4.5-12.5 (UG/DL)	01/05/92	6.40					

1055

(¢) << 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 PHARMACEUTICAL MILANO - CNS

9550085

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 332 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			17/07/92		10/09/92		15/09/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	120-170 (G/L)	13/03/92	133.00		129.00			
HT	0.36-0.51 (L/L)	13/03/92	0.42		0.39			
RBC	3.9-5.5 (10¬12/L)	13/03/92	4.44		4.18			
WBC	4-11 (10¬9/L)	13/03/92	4.90		5.16			
WBC: N	45-75 (%)	13/03/92	46.90		47.30			
WBC: L	17-55 (%)	13/03/92	40.80		41.20			
WBC: E	0-5 (%)	13/03/92	1.50		0.80			
WBC: M	2-10 (%)	13/03/92	8.90		5.90			
WBC: B	0-2 (%)	13/03/92	0.40		0.60			
PLATELETS	150-400 (10¬9/L)	13/03/92	224.00		253.00			
NA+	135-145 (MEQ/L)	13/03/92	139.00		138.00			
K+	3.5-4.5 (MEQ/L)	13/03/92	4.10		4.60	>		
CL-	95-106 (MEQ/L)	13/03/92	103.00		103.00			
Ca++	8.5-10.5 (MG/DL)	13/03/92	10.40		9.80			
PO4--	2.3-4.3 (MG/DL)	13/03/92	3.60		4.00			
SGOT	10-40 (UI/L)	13/03/92	22.00		23.00			
SGPT	10-40 (UI/L)	13/03/92	24.00		23.00			
GAMMA GT	5-40 (UI/L)	13/03/92	14.00		17.00			
LDH	250-450 (UI/L)	13/03/92			467.00	>		
ALK. PHOSPH.	123-345 (UI/L)	13/03/92	165.00		138.00			
GLUCOSE	64-107 (MG/DL)	13/03/92	86.00		78.00			
BUN	10-25 (MG/DL)	13/03/92	24.00		13.00			
CREATININE	0.5-1.3 (MG/DL)	13/03/92	1.10		0.80			
URIC ACID	1.9-7.4 (MG/DL)	13/03/92	4.20		2.60			
TOT BILIRUBIN	0.1-1 (MG/DL)	13/03/92	0.50		0.70			
TOT. PROTEINS	60-80 (G/L)	13/03/92	80.00		84.00	>		
ALBUMINE	27-58 (G/L)	13/03/92	50.00					
TOT. CHOLEST.	148-247 (MG/DL)	13/03/92	111.00	<	107.00	<		
TRIGLYCERIDES	50-150 (MG/DL)	13/03/92	45.00	<	53.00			
GLOBULINS ALPHA 1	2.1-3.5 (%)	13/03/92	3.00		2.70			
GLOBULINS ALPHA 2	6-10 (%)	13/03/92	8.00		9.50			
GLOBULINS BETA	6.5-11.5 (%)	13/03/92	9.00		8.30			
GLOBULINS GAMMA	15-22 (%)	13/03/92	15.10		14.40	<		
TSH	0.5-5 (UU/ML)	13/03/92					0.50	
T4	4.5-12.5 (UG/DL)	13/03/92					5.20	

1056

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9550883

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 334 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			10/09/92		21/10/92		14/12/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	120-170 (G/L)	13/03/92	128.00		134.00		139.00	
HT	0.36-0.51 (L/L)	13/03/92	0.38		0.40		0.44	
RBC	3.9-5.5 (10¬12/L)	13/03/92	4.50		4.84		5.00	
WBC	4-11 (10¬9/L)	13/03/92	4.03		5.64		5.80	
WBC: N	45-75 (%)	13/03/92	47.60		42.00	<	54.10	
WBC: L	17-55 (%)	13/03/92	38.90		43.50		33.20	
WBC: E	0-5 (%)	13/03/92	2.80		3.90		2.20	
WBC: M	2-10 (%)	13/03/92	4.50		6.30		6.70	
WBC: B	0-2 (%)	13/03/92	0.00		0.80		0.80	
PLATELETS	150-400 (10¬9/L)	13/03/92	213.00		232.00		234.00	
NA+	135-145 (MEQ/L)	13/03/92	139.00		142.00		139.00	
K+	3.5-4.5 (MEQ/L)	13/03/92	4.10		4.00		4.20	
CL-	95-106 (MEQ/L)	13/03/92	101.00		100.00			
Ca++	8.5-10.5 (MG/DL)	13/03/92	9.10		9.00		9.20	
PO4--	2.3-4.3 (MG/DL)	13/03/92	2.80		2.80		2.70	
SGOT	10-40 (UI/L)	13/03/92	14.00		13.00		16.00	
SGPT	10-40 (UI/L)	13/03/92	19.00		16.00		18.00	
GAMMA GT	5-40 (UI/L)	13/03/92	19.00		18.00		15.00	
LDH	250-450 (UI/L)	13/03/92	275.00		279.00		298.00	
ALK. PHOSPH.	123-345 (UI/L)	13/03/92	208.00		240.00		244.00	
GLUCOSE	64-107 (MG/DL)	13/03/92	94.00		83.00		89.00	
BUN	10-25 (MG/DL)	13/03/92	13.00		18.00		12.00	
CREATININE	0.5-1.3 (MG/DL)	13/03/92	0.70		0.90		0.60	
URIC ACID	1.9-7.4 (MG/DL)	13/03/92	4.20		3.30		2.60	
TOT BILIRUBIN	0.1-1 (MG/DL)	13/03/92	0.50		0.30		0.20	
TOT. PROTEINS	60-80 (G/L)	13/03/92	72.00		70.00		70.00	
ALBUMINE	27-58 (G/L)	13/03/92	37.00		40.00		42.00	
TOT. CHOLEST.	148-247 (MG/DL)	13/03/92	217.00		212.00		239.00	
TRIGLYCERIDES	50-150 (MG/DL)	13/03/92	113.00		96.00		91.00	
GLOBULINS ALPHA 1	2.1-3.5 (%)	13/03/92	2.90				2.60	
GLOBULINS ALPHA 2	6-10 (%)	13/03/92	7.60				7.60	
GLOBULINS BETA	6.5-11.5 (%)	13/03/92	11.80	>			12.30	>
GLOBULINS GAMMA	15-22 (%)	13/03/92	17.20				17.30	
TSH	0.5-5 (UU/ML)	13/03/92	1.30					
T4	4.5-12.5 (UG/DL)	13/03/92	7.30					

1057

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 12 Patient: 393 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			26/06/92		21/07/92		28/08/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	11.5-16.5 (G/DL)	01/06/92	12.90		15.90		13.80	
HT	37-47 (%)	01/06/92	36.40	<	45.30		39.70	
RBC	3.8-5.8 (10¬12/L)	01/06/92	4.33		5.25		4.65	
WBC	4-11 (10¬9/L)	01/06/92	5.60		6.30		7.10	
WBC: N	2-8 (10¬9/L)	01/06/92	3.60		3.70		5.30	
WBC: L	1-4 (10¬9/L)	01/06/92	1.70		1.70		1.30	
WBC: E	0-0.5 (10¬9/L)	01/06/92	0.10		0.20		0.10	
WBC: M	0-1 (10¬9/L)	01/06/92	0.20		0.60		0.40	
WBC: B	0-0.2 (10¬9/L)	01/06/92	0.00		0.10		0.10	
PLATELETS	150-450 (10¬9/L)	01/06/92	260.00				303.00	
NA+	136-146 (MMOL/L)	01/06/92	142.00		140.00		143.00	
K+	3.5-5 (MMOL/L)	01/06/92	4.00		4.10		4.50	
CL-	95-110 (MMOL/L)	01/06/92	103.00		102.00		105.00	
Ca++	2.15-2.65 (MMOL/L)	01/06/92	2.40		2.41		2.46	
PO4--	0.8-1.4 (MMOL/L)	01/06/92	1.20		1.20		1.30	
SGPT	0-40 (U/L)	01/06/92	36.00		36.00		37.00	
GAMMA GT	0-35 (U/L)	01/06/92	15.00		14.00		16.00	
LDH	250-520 (U/L)	01/06/92	352.00		357.00		338.00	
ALK. PHOSPH.	30-120 (U/L)	01/06/92	84.00		82.00		95.00	
GLUCOSE	4-5.5 (MMOL/L)	01/06/92	4.30		3.60	<	4.40	
UREA	2.3-7.6 (MMOL/L)	01/06/92	4.10		4.30		2.30	
CREATININE	0.05-0.11 (MMOL/L)	01/06/92	0.08		0.07		0.07	
URIC ACID	0.11-0.42 (MMOL/L)	01/06/92	0.25		0.19		0.31	
TOT BILIRUBIN	0-20 (UMOL/L)	01/06/92	25.00	>	20.00		15.00	
TOT. PROTEINS	60-80 (G/L)	01/06/92	77.00		77.00		74.00	
ALBUMINE	35-50 (G/L)	01/06/92	52.00	>	53.00	>	51.00	>
TOT. CHOLEST.	3-5.5 (MMOL/L)	01/06/92	5.70	>	5.20		4.80	
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/06/92	0.90		0.90		0.90	
TSH	0.5-4 (MIU/L)	01/06/92	2.20					
T4	10-19 (PMOL/L)	01/06/92	15.50					

1058

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 12 Patient: 396 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date	
			Screen	
			05/08/92	
			value	(¢)
Laboratory test	Range value	Range date		
HB	11.5-16.5 (G/DL)	01/06/92	13.90	
HT	37-47 (%)	01/06/92	41.60	
RBC	3.8-5.8 (10¬12/L)	01/06/92	4.35	
WBC	4-11 (10¬9/L)	01/06/92	6.10	
WBC: N	2-8 (10¬9/L)	01/06/92	4.10	
WBC: L	1-4 (10¬9/L)	01/06/92	1.50	
WBC: E	0-0.5 (10¬9/L)	01/06/92	0.20	
WBC: M	0-1 (10¬9/L)	01/06/92	0.20	
WBC: B	0-0.2 (10¬9/L)	01/06/92	0.10	
PLATELETS	150-450 (10¬9/L)	01/06/92	253.00	
NA+	136-146 (MMOL/L)	01/06/92	141.00	
K+	3.5-5 (MMOL/L)	01/06/92	4.50	
CL-	95-110 (MMOL/L)	01/06/92	106.00	
Ca++	2.15-2.65 (MMOL/L)	01/06/92	2.51	
PO4--	0.8-1.4 (MMOL/L)	01/06/92	1.30	
SGPT	0-40 (U/L)	01/06/92	22.00	
GAMMA GT	0-35 (U/L)	01/06/92	11.00	
LDH	250-520 (U/L)	01/06/92	323.00	
ALK. PHOSPH.	30-120 (U/L)	01/06/92	53.00	
GLUCOSE	4-5.5 (MMOL/L)	01/06/92	3.60	<
UREA	2.3-7.6 (MMOL/L)	01/06/92	3.10	
CREATININE	0.05-0.11 (MMOL/L)	01/06/92	0.08	
URIC ACID	0.11-0.42 (MMOL/L)	01/06/92	0.12	
TOT BILIRUBIN	0-20 (UMOL/L)	01/06/92	6.00	
TOT. PROTEINS	60-80 (G/L)	01/06/92	71.00	
ALBUMINE	35-50 (G/L)	01/06/92	43.00	
TOT. CHOLEST.	3-5.5 (MMOL/L)	01/06/92	5.10	
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/06/92	0.60	
TSH	0.5-4 (MIU/L)	01/06/92	0.80	
T4	10-19 (PMOL/L)	01/06/92	13.90	

1059

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 12 Patient: 497 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory data					
			Screen		Day 28		Day 56	
			26/02/93		26/03/93		26/04/93	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	11.5-16.5 (G/DL)	01/06/92	15.10		15.10		14.90	
HT	37-47 (%)	01/06/92	43.60		42.90		42.50	
RBC	3.8-5.8 (10¬12/L)	01/06/92	5.06		5.02		4.91	
WBC	4-11 (10¬9/L)	01/06/92	12.80	>	8.20		11.20	>
WBC: N	2-8 (10¬9/L)	01/06/92	8.20	>	4.80		7.30	
WBC: L	1-4 (10¬9/L)	01/06/92	3.80		2.80		3.40	
WBC: E	0-0.5 (10¬9/L)	01/06/92	0.30		0.20		0.10	
WBC: M	0-1 (10¬9/L)	01/06/92	0.50		0.40		0.40	
WBC: B	0-0.2 (10¬9/L)	01/06/92	0.00		0.10		0.00	
PLATELETS	150-450 (10¬9/L)	01/06/92	270.00		251.00		295.00	
NA+	136-146 (MMOL/L)	01/06/92	138.00		137.00		137.00	
K+	3.5-5 (MMOL/L)	01/06/92	4.50		4.50		4.20	
CL-	95-110 (MMOL/L)	01/06/92	100.00		101.00		103.00	
Ca++	2.15-2.65 (MMOL/L)	01/06/92	2.38		2.40		2.18	
PO4--	0.8-1.4 (MMOL/L)	01/06/92	1.30		1.30		1.30	
SGOT	0-40 (U/L)	01/06/92	27.00		25.00		24.00	
GAMMA GT	0-35 (U/L)	01/06/92	38.00	>	33.00		27.00	
LDH	250-520 (U/L)	01/06/92	286.00		263.00		250.00	
ALK. PHOSPH.	30-120 (U/L)	01/06/92	80.00		82.00		96.00	
GLUCOSE	4-5.5 (MMOL/L)	01/06/92	5.10		5.30		5.30	
UREA	2.3-7.6 (MMOL/L)	01/06/92	2.80		3.30		4.20	
CREATININE	0.05-0.11 (MMOL/L)	01/06/92	0.08		0.07		0.07	
URIC ACID	0.11-0.42 (MMOL/L)	01/06/92	0.33		0.29		0.27	
TOT BILIRUBIN	0-20 (UMOL/L)	01/06/92	10.00		10.00		7.00	
TOT. PROTEINS	60-80 (G/L)	01/06/92	72.00		73.00		66.00	
ALBUMINE	35-50 (G/L)	01/06/92	43.00		43.00		40.00	
TOT. CHOLEST.	3-5.5 (MMOL/L)	01/06/92	3.80		3.90		5.10	
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/06/92	2.80	>>	4.30	>>	13.50	>>
TSH	0.5-4 (MIU/L)	01/06/92	0.70					
T4	10-19 (PMOL/L)	01/06/92	12.80					

1060

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (value lower than min range) > out of range (value higher than max range
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 385 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 14		Day 56	
			13/03/92		30/03/92		08/05/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/03/92	13.80		14.40		14.10	
HT	37-47 (%)	01/03/92	41.00		42.00		41.00	
RBC	3.8-5.8 (10¬12/L)	01/03/92	4.63		4.80		4.64	
WBC	4-11 (10¬9/L)	01/03/92	9.00		7.40		7.70	
WBC: N	2-7.5 (10¬9/L)	01/03/92	4.90		3.80		4.30	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	3.20		2.70		2.50	
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.20		0.20		0.10	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.60		0.70		0.70	
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.10		0.00		0.10	
PLATELETS	150-400 (10¬9/L)	01/03/92	377.00		377.00		381.00	
NA+	137-145 (MMOL/L)	01/03/92	137.00		137.00		137.00	
K+	3.5-5 (MMOL/L)	01/03/92	4.00		4.30		4.30	
CL-	100-111 (MMOL/L)	01/03/92	100.00		103.00		102.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.46		2.39		2.41	
PO4--	0.7-1.4 (MMOL/L)	01/03/92	1.58	>	1.25		1.50	>
SGOT	5-35 (U/L)	01/03/92	21.00		25.00		26.00	
SGPT	7-56 (U/L)	01/03/92	25.00		25.00		18.00	
GAMMA GT	8-78 (U/L)	01/03/92	36.00		39.00		42.00	
LDH	300-540 (U/L)	01/03/92	331.00		366.00		356.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92	78.00		79.00		87.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	5.00		5.20		5.20	
UREA	2.5-7.5 (MMOL/L)	01/03/92			4.60		4.20	
CREATININE	60-110 (UMOL/L)	01/03/92	84.00		92.00		86.00	
URIC ACID	180-440 (UMOL/L)	01/03/92	236.00		275.00		286.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	7.00		10.00		9.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	73.00		77.00		71.00	
ALBUMINE	35-50 (G/L)	01/03/92	43.00		45.00		43.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	5.36		6.09	>	6.03	>
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	1.92	>	1.44		1.67	
TSH	0.2-3.2 (MU/L)	01/03/92	0.09	<<	0.10	<<		
T4	11-24 (PMOL/L)	01/03/92	25.00	>	28.30	>>		

1061

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9950083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 386 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date	
			Screen	
			23/04/92	
			value	(¢)
Laboratory test	Range value	Range date		
HB	14-18 (G/DL)	01/03/92	15.60	
HT	41-53 (%)	01/03/92	45.00	
RBC	4.5-6.5 (10¬12/L)	01/03/92	4.95	
WBC	4-11 (10¬9/L)	01/03/92	7.80	
WBC: N	2-7.5 (10¬9/L)	01/03/92	4.10	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	2.50	
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.40	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.70	
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.10	
PLATELETS	150-400 (10¬9/L)	01/03/92	393.00	
NA+	137-145 (MMOL/L)	01/03/92	141.00	
K+	3.5-5 (MMOL/L)	01/03/92	4.10	
CL-	100-111 (MMOL/L)	01/03/92	103.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.35	
PO4--	0.7-1.4 (MMOL/L)	01/03/92	1.07	
SGOT	5-35 (U/L)	01/03/92	23.00	
SGPT	7-56 (U/L)	01/03/92	23.00	
GAMMA GT	8-78 (U/L)	01/03/92	203.00	>>
LDH	300-540 (U/L)	01/03/92	480.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92	148.00	>
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	4.60	
UREA	2.5-7.5 (MMOL/L)	01/03/92	5.30	
CREATININE	60-110 (UMOL/L)	01/03/92	101.00	
URIC ACID	180-440 (UMOL/L)	01/03/92	293.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	12.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	70.00	
ALBUMINE	35-50 (G/L)	01/03/92	41.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	5.74	>
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	1.19	
TSH	0.2-3.2 (MU/L)	01/03/92	0.70	
T4	11-24 (PMOL/L)	01/03/92	14.20	

1062

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 389 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 7	
			20/07/92		24/07/92	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	01/03/92	15.60		14.90	
HT	37-47 (%)	01/03/92	46.00		44.00	
RBC	3.8-5.8 (10¬12/L)	01/03/92	5.01		4.86	
WBC	4-11 (10¬9/L)	01/03/92	8.40		5.90	
WBC: N	2-7.5 (10¬9/L)	01/03/92	3.95		3.00	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	3.44		2.20	
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.25		0.20	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.67		0.50	
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.08		0.00	
PLATELETS	150-400 (10¬9/L)	01/03/92	313.00		294.00	
NA+	137-145 (MMOL/L)	01/03/92	138.00		140.00	
K+	3.5-5 (MMOL/L)	01/03/92	3.40	<	4.00	
SGOT	5-35 (U/L)	01/03/92	13.00		35.00	
SGPT	7-56 (U/L)	01/03/92	38.00		11.00	
GAMMA GT	8-78 (U/L)	01/03/92	21.00		19.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92	72.00		54.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	3.40	<		
UREA	2.5-7.5 (MMOL/L)	01/03/92	2.40	<	3.30	
CREATININE	60-110 (UMOL/L)	01/03/92	85.00		85.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	16.00		14.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	74.00		72.00	
ALBUMINE	35-50 (G/L)	01/03/92	46.00		45.00	
TSH	0.2-3.2 (MU/L)	01/03/92	1.50			
T4	11-24 (PMOL/L)	01/03/92	22.50			

1063

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 391 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			04/06/92		10/07/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)
HB	12-16 (G/DL)	01/03/92	14.30		14.60	
HT	37-47 (%)	01/03/92	41.00		43.00	
RBC	3.8-5.8 (10¬12/L)	01/03/92	4.47		4.66	
WBC	4-11 (10¬9/L)	01/03/92	5.20		7.10	
WBC: N	2-7.5 (10¬9/L)	01/03/92	2.90		4.60	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	1.70		1.90	
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.20		0.10	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.30		0.30	
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.10		0.20	
PLATELETS	150-400 (10¬9/L)	01/03/92	269.00		320.00	
NA+	137-145 (MMOL/L)	01/03/92	141.00		139.00	
K+	3.5-5 (MMOL/L)	01/03/92	4.10		4.10	
CL-	100-111 (MMOL/L)	01/03/92	107.00		103.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.47		2.44	
PO4--	0.7-1.4 (MMOL/L)	01/03/92	1.19		1.04	
SGOT	5-35 (U/L)	01/03/92	2.00	<	19.00	
SGPT	7-56 (U/L)	01/03/92	17.00		12.00	
GAMMA GT	8-78 (U/L)	01/03/92	21.00		20.00	
LDH	300-540 (U/L)	01/03/92	391.00		482.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92	68.00		63.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	4.30		5.70	
UREA	2.5-7.5 (MMOL/L)	01/03/92	6.30		4.90	
CREATININE	60-110 (UMOL/L)	01/03/92	89.00		77.00	
URIC ACID	180-440 (UMOL/L)	01/03/92	360.00		276.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	10.00		15.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	74.00		76.00	
ALBUMINE	35-50 (G/L)	01/03/92	45.00		48.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	5.88	>	6.14	>
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	0.95		1.38	
TSH	0.2-3.2 (MU/L)	01/03/92	1.60		1.40	
T4	11-24 (PMOL/L)	01/03/92	17.10		16.20	

(¢) << 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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 502 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			03/11/92		30/11/92		24/12/92	
			value	(◊)	value	(◊)	value	(◊)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/03/92	13.40		12.90		13.50	
HT	37-47 (%)	01/03/92	39.00		39.00		41.00	
RBC	3.8-5.8 (10¬12/L)	01/03/92	4.62		4.63		4.77	
WBC	4-11 (10¬9/L)	01/03/92	8.80		6.60		5.60	
WBC: N	2-7.5 (10¬9/L)	01/03/92	5.90		4.40		3.02	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	2.10		1.60		2.24	
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.10		0.10		0.06	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.60		0.50		0.28	
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.10		0.00		0.00	
PLATELETS	150-400 (10¬9/L)	01/03/92	310.00		334.00		305.00	
NA+	137-145 (MMOL/L)	01/03/92	140.00		138.00		139.00	
K+	3.5-5 (MMOL/L)	01/03/92	4.20		4.80		5.90	>>
CL-	100-111 (MMOL/L)	01/03/92	104.00		100.00		102.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.37		2.24		2.25	
PO4--	0.7-1.4 (MMOL/L)	01/03/92	0.92		0.87		0.83	
SGOT	5-35 (U/L)	01/03/92	18.00		24.00		28.00	
SGPT	7-56 (U/L)	01/03/92	19.00		29.00		11.00	
GAMMA GT	8-78 (U/L)	01/03/92	15.00		18.00		12.00	
LDH	300-540 (U/L)	01/03/92	515.00		407.00		552.00	>
ALK. PHOSPH.	19-95 (U/L)	01/03/92	67.00		70.00		64.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	6.40	>	4.80		3.90	
UREA	2.5-7.5 (MMOL/L)	01/03/92	3.70		3.70		4.20	
CREATININE	60-110 (UMOL/L)	01/03/92	66.00		65.00		68.00	
URIC ACID	180-440 (UMOL/L)	01/03/92	326.00		337.00		306.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	7.00		9.00		9.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	74.00		75.00		78.00	
ALBUMINE	35-50 (G/L)	01/03/92	40.00		40.00		42.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	5.44		5.20		5.71	>
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	1.50		1.45		1.39	
TSH	0.2-3.2 (MU/L)	01/03/92	0.90		0.80		1.60	
T4	11-24 (PMOL/L)	01/03/92	17.00		16.90		18.70	

(◊) << 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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 504 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			25/11/92		24/12/92		20/01/93	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	01/03/92	13.20		13.90		13.10	
HT	37-47 (%)	01/03/92	39.00		41.00		38.00	
RBC	3.8-5.8 (10¬12/L)	01/03/92	4.34		4.55		4.29	
WBC	4-11 (10¬9/L)	01/03/92	7.40		6.60		6.70	
WBC: N	2-7.5 (10¬9/L)	01/03/92	4.90		4.70		4.70	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	1.50		1.20	<	1.20	<
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.20		0.20		0.30	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.70		0.50		0.50	
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.10		0.00		0.00	
PLATELETS	150-400 (10¬9/L)	01/03/92	236.00		249.00		232.00	
NA+	137-145 (MMOL/L)	01/03/92	139.00		134.00	<	141.00	
K+	3.5-5 (MMOL/L)	01/03/92	4.70		4.60		5.00	
CL-	100-111 (MMOL/L)	01/03/92	107.00		105.00		107.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.28		2.16		2.25	
PO4--	0.7-1.4 (MMOL/L)	01/03/92	1.15		0.88		1.03	
SGOT	5-35 (U/L)	01/03/92	44.00	>	31.00		31.00	
SGPT	7-56 (U/L)	01/03/92	20.00		16.00		12.00	
GAMMA GT	8-78 (U/L)	01/03/92	33.00		38.00		35.00	
LDH	300-540 (U/L)	01/03/92	356.00		343.00		281.00	<
ALK. PHOSPH.	19-95 (U/L)	01/03/92	47.00		41.00		43.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	4.30		3.90		3.70	
UREA	2.5-7.5 (MMOL/L)	01/03/92	4.10		4.80		3.80	
CREATININE	60-110 (UMOL/L)	01/03/92	86.00		88.00		85.00	
URIC ACID	180-440 (UMOL/L)	01/03/92	198.00		210.00		212.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	11.00		14.00		11.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	69.00		70.00		68.00	
ALBUMINE	35-50 (G/L)	01/03/92	43.00		40.00		38.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	2.95	<	3.03	<	3.11	<
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	0.99		1.15		0.97	
TSH	0.2-3.2 (MU/L)	01/03/92	1.80		2.00		1.50	
T4	11-24 (PMOL/L)	01/03/92	12.60		12.80		11.90	

(¢) << 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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 506 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			23/10/92		26/11/92		24/12/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/03/92	15.60		15.10		14.50	
HT	41-53 (%)	01/03/92	44.00		45.00		43.00	
RBC	4.5-6.5 (10¬12/L)	01/03/92	4.76		4.80		4.65	
WBC	4-11 (10¬9/L)	01/03/92	6.70		5.30		8.30	
WBC: N	2-7.5 (10¬9/L)	01/03/92	4.20		3.10		5.10	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	1.80		1.80		2.40	
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.10		0.00		0.10	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.60		0.40		0.60	
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.00		0.00		0.10	
PLATELETS	150-400 (10¬9/L)	01/03/92	305.00		328.00		325.00	
NA+	137-145 (MMOL/L)	01/03/92	138.00		138.00		136.00	<
K+	3.5-5 (MMOL/L)	01/03/92	4.80		4.50		4.50	
CL-	100-111 (MMOL/L)	01/03/92	99.00	<	98.00	<	106.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.42		2.34		2.20	
PO4--	0.7-1.4 (MMOL/L)	01/03/92	1.37		1.63	>>	1.34	
SGOT	5-35 (U/L)	01/03/92	30.00		53.00	>	26.00	
SGPT	7-56 (U/L)	01/03/92	11.00		18.00		12.00	
GAMMA GT	8-78 (U/L)	01/03/92	17.00		19.00		18.00	
LDH	300-540 (U/L)	01/03/92	495.00		534.00		403.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92	82.00		58.00		84.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	4.80		4.70		5.10	
UREA	2.5-7.5 (MMOL/L)	01/03/92	4.40		4.30		6.30	
CREATININE	60-110 (UMOL/L)	01/03/92	99.00		108.00		118.00	>
URIC ACID	180-440 (UMOL/L)	01/03/92	290.00		357.00		358.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	7.00		13.00		8.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	75.00		75.00		70.00	
ALBUMINE	35-50 (G/L)	01/03/92	46.00		46.00		41.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	5.23		5.31		4.92	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	0.89		0.60		0.64	
TSH	0.2-3.2 (MU/L)	01/03/92	1.00		0.90		1.60	
T4	11-24 (PMOL/L)	01/03/92	12.80		15.90		15.60	

(¢) << 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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 507 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			10/09/92		16/10/92		06/11/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	01/03/92	12.60		13.00		11.80	<
HT	37-47 (%)	01/03/92	38.00		39.00		36.00	<
RBC	3.8-5.8 (10¬12/L)	01/03/92	4.22		4.31		4.02	
WBC	4-11 (10¬9/L)	01/03/92	8.90		6.70		7.60	
WBC: N	2-7.5 (10¬9/L)	01/03/92	4.60		3.10		3.60	
WBC: L	1.3-3.6 (10¬9/L)	01/03/92	3.20		2.60		3.10	
WBC: E	0-0.7 (10¬9/L)	01/03/92	0.10		0.10		0.10	
WBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.90	>	0.90	>	0.80	
WBC: B	0-0.2 (10¬9/L)	01/03/92	0.10		0.00		0.00	
PLATELETS	150-400 (10¬9/L)	01/03/92	341.00		311.00		335.00	
NA+	137-145 (MMOL/L)	01/03/92	136.00	<	138.00		134.00	<
K+	3.5-5 (MMOL/L)	01/03/92	3.90		4.10		4.20	
CL-	100-111 (MMOL/L)	01/03/92	99.00	<	98.00	<	96.00	<
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.37		2.24		2.30	
PO4--	0.7-1.4 (MMOL/L)	01/03/92	1.21		1.25		1.22	
SGOT	5-35 (U/L)	01/03/92	32.00		34.00		32.00	
SGPT	7-56 (U/L)	01/03/92	24.00		21.00		15.00	
GAMMA GT	8-78 (U/L)	01/03/92	71.00		37.00		46.00	
LDH	300-540 (U/L)	01/03/92	464.00		520.00		447.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92	79.00		93.00		82.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	4.70		4.10		4.90	
UREA	2.5-7.5 (MMOL/L)	01/03/92	4.10		4.10		5.50	
CREATININE	60-110 (UMOL/L)	01/03/92	73.00		74.00		73.00	
URIC ACID	180-440 (UMOL/L)	01/03/92	302.00		345.00		312.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	10.00		9.00		9.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	77.00		77.00		77.00	
ALBUMINE	35-50 (G/L)	01/03/92	46.00		46.00		44.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	7.26	>>	6.99	>	6.46	>
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	1.14		1.98	>	1.09	
TSH	0.2-3.2 (MU/L)	01/03/92	2.00		1.50			
T4	11-24 (PMOL/L)	01/03/92	11.30		11.80			

(¢) << 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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 397 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			12/03/92		12/05/92		09/06/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/02/92	13.00		12.90		12.50	
HT	0.35-0.47 (L/L)	01/02/92	0.39		0.37		0.37	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.48		4.36		4.31	
WBC	3.5-12 (10¬9/L)	01/02/92	5.50		5.80		6.30	
WBC: N	2.5-8 (10¬9/L)	01/02/92	3.50		4.10		4.50	
WBC: L	1.2-4 (10¬9/L)	01/02/92	1.60		1.30		1.40	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.00		0.00		0.00	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.50		0.40		0.40	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.00		0.00		0.00	
PLATELETS	150-400 (10¬9/L)	01/02/92	375.00		313.00		386.00	
NA+	135-145 (MMOL/L)	01/02/92	134.00	<	136.00		139.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	3.80		4.00		3.70	
CL-	95-105 (MMOL/L)	01/02/92	101.00		102.00		102.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.34		2.21	<	2.29	
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.37	>	1.35	>	1.41	>
SGOT	0-35 (U/L)	01/02/92	21.00		21.00		19.00	
GAMMA GT	5-23 (U/L)	01/02/92	28.00	>	28.00	>	24.00	>
LDH	70-170 (U/L)	01/02/92	178.00	>	199.00	>	253.00	>
ALK. PHOSPH.	18-70 (U/L)	01/02/92	775.00	>>	684.00	>>	574.00	>>
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	4.90		5.70		5.90	
UREA	2.5-7.5 (MMOL/L)	01/02/92	4.90		4.50		6.20	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.08		0.08		0.09	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.21		0.19		0.20	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	9.00		9.00		11.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	3.00		1.00		2.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	67.00	<	65.00	<	66.00	<
ALBUMINE	36-49 (G/L)	01/02/92	45.00		46.00		47.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	6.60		6.80		7.20	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.70		2.10	>	1.30	

(¢) << 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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 400 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			14/05/92		12/06/92		14/07/92	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	13.5-17.5 (G/DL)	01/02/92	15.50		15.90		14.50	
HT	0.4-0.54 (L/L)	01/02/92	0.46		0.47		0.43	
RBC	4.5-6.5 (10¬12/L)	01/02/92	5.18		5.24		4.93	
WBC	3.5-10 (10¬9/L)	01/02/92	8.50		10.90	>	8.60	
WBC: N	1.5-6.5 (10¬9/L)	01/02/92	5.80		6.50		5.70	
WBC: L	1.2-4 (10¬9/L)	01/02/92	2.40		3.60		2.60	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.00		0.00		0.00	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.30		0.80		0.40	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.00		0.00		0.00	
PLATELETS	150-400 (10¬9/L)	01/02/92	302.00		331.00		320.00	
NA+	135-145 (MMOL/L)	01/02/92	139.00		140.00		137.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	4.10		4.90	>	4.10	
CL-	95-105 (MMOL/L)	01/02/92	101.00		102.00		104.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.32		2.45		2.24	<
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.06		1.33	>	1.16	
SGOT	0-35 (U/L)	01/02/92	22.00		23.00		18.00	
GAMMA GT	5-23 (U/L)	01/02/92	69.00	>>	54.00	>>	74.00	>>
LDH	70-170 (U/L)	01/02/92	170.00		175.00	>	170.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	86.00	>	88.00	>	81.00	>
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	5.70		5.20		5.30	
UREA	2.5-7.5 (MMOL/L)	01/02/92	3.50		3.70		4.10	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.06		0.07		0.06	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.27		0.31		0.30	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	10.00		10.00		8.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	3.00		3.00		4.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	74.00		78.00		72.00	
ALBUMINE	36-49 (G/L)	01/02/92	50.00	>	53.00	>	42.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	5.40		5.80		5.90	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.20		1.10		1.20	
TSH	0.5-6.5 (MIU/L)	01/02/92	0.58					
T4	86-148 (NMOL/L)	01/02/92	114.00					

(◊) << 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 PHARMACEUTICALS & BIOTECH - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 401 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			22/05/92		19/06/92		17/07/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	11.5-16.5 (G/DL)	01/02/92	14.20		14.60		14.70	
HT	0.35-0.47 (L/L)	01/02/92	0.42		0.43		0.43	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.72		4.87		4.85	
WBC	3.5-12 (10¬9/L)	01/02/92	10.90		10.80		9.50	
WBC: N	2.5-8 (10¬9/L)	01/02/92	7.20		6.80		6.00	
WBC: L	1.2-4 (10¬9/L)	01/02/92	2.10		3.10		2.70	
WBC: E	0-0.5 (10¬9/L)	01/02/92	1.00	>>	0.10		0.00	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.70		0.80		0.70	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.00		0.00		0.00	
PLATELETS	150-400 (10¬9/L)	01/02/92	419.00	>	311.00		301.00	
NA+	135-145 (MMOL/L)	01/02/92	136.00		137.00		137.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	4.20		4.30		4.20	
CL-	95-105 (MMOL/L)	01/02/92	100.00		103.00		104.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.19	<	2.24	<	2.16	<
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.35	>	1.45	>	1.34	>
SGOT	0-35 (U/L)	01/02/92	9.00		11.00		12.00	
GAMMA GT	5-23 (U/L)	01/02/92	21.00		19.00		19.00	
LDH	70-170 (U/L)	01/02/92	171.00	>	148.00		163.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	67.00		60.00		53.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	4.20		4.90		4.60	
UREA	2.5-7.5 (MMOL/L)	01/02/92	3.40		4.40		3.40	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.07		0.07		0.06	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.20		0.20		0.20	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	8.00		11.00		10.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	2.00		2.00		2.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	66.00	<	69.00		66.00	<
ALBUMINE	36-49 (G/L)	01/02/92	43.00		48.00		42.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	3.80		4.60		4.30	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.20		1.30		1.00	
TSH	0.5-6.5 (MIU/L)	01/02/92	0.84					
T4	86-148 (NMOL/L)	01/02/92	104.00					

(¢) << 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 PHARMACEUTICI S.p.A. - MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 404 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory data					
			Screen		Day 28		Day 56	
			16/06/92		14/07/92		11/08/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	11.5-16.5 (G/DL)	01/02/92	13.90		13.30		12.30	
HT	0.35-0.47 (L/L)	01/02/92	0.41		0.40		0.36	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.41		4.22		3.85	<
WBC	3.5-12 (10¬9/L)	01/02/92	7.20		6.80		5.40	
WBC: N	2.5-8 (10¬9/L)	01/02/92	5.40		4.70		4.10	
WBC: L	1.2-4 (10¬9/L)	01/02/92	1.50		1.60		1.20	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.00		0.00		0.00	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.30		0.40		0.10	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.00		0.00		0.00	
PLATELETS	150-400 (10¬9/L)	01/02/92	232.00		246.00		233.00	
NA+	135-145 (MMOL/L)	01/02/92	139.00		140.00		137.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	4.10		3.80		3.90	
CL-	95-105 (MMOL/L)	01/02/92	102.00		100.00		103.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.33		2.24	<	2.13	<
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.24		1.20		1.06	
SGOT	0-35 (U/L)	01/02/92	24.00		19.00		20.00	
GAMMA GT	5-23 (U/L)	01/02/92	28.00	>	24.00	>	29.00	>
LDH	70-170 (U/L)	01/02/92	147.00		162.00		149.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	48.00		49.00		44.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	5.50		6.80	>	5.10	
UREA	2.5-7.5 (MMOL/L)	01/02/92	6.40		7.10		6.70	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.08		0.09		0.07	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.21		0.22		0.19	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	8.00		10.00		9.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	3.00		2.00		3.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	75.00		69.00		67.00	<
ALBUMINE	36-49 (G/L)	01/02/92	47.00		41.00		39.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	5.60		5.00		4.80	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	2.00	>	1.60		1.50	
TSH	0.5-6.5 (MIU/L)	01/02/92	2.76					
T4	86-148 (NMOL/L)	01/02/92	105.00					

1072

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 405 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			19/06/92		20/07/92		17/08/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	11.5-16.5 (G/DL)	01/02/92	14.00		13.20		13.10	
HT	0.35-0.47 (L/L)	01/02/92	0.41		0.39		0.39	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.37		4.12		4.06	
WBC	3.5-12 (10¬9/L)	01/02/92	9.00		11.40		10.00	
WBC: N	2.5-8 (10¬9/L)	01/02/92	6.70		7.80		5.70	
WBC: L	1.2-4 (10¬9/L)	01/02/92	2.10		3.00		3.50	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.00		0.00		0.40	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.20		0.50		0.40	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.00		0.00		0.00	
PLATELETS	150-400 (10¬9/L)	01/02/92	273.00		269.00		287.00	
NA+	135-145 (MMOL/L)	01/02/92	141.00		139.00		139.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	3.60		3.70		3.60	
CL-	95-105 (MMOL/L)	01/02/92	102.00		100.00		105.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.19	<	2.07	<	2.14	<
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.10		0.93		0.90	
SGOT	0-35 (U/L)	01/02/92	14.00		13.00		12.00	
GAMMA GT	5-23 (U/L)	01/02/92	22.00		21.00		19.00	
LDH	70-170 (U/L)	01/02/92	135.00		148.00		144.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	61.00		69.00		49.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	5.10		4.80		4.90	
UREA	2.5-7.5 (MMOL/L)	01/02/92	3.10		3.60		3.10	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.08		0.06		0.07	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.16		0.20		0.17	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	7.00		6.00		5.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	1.00		3.00		1.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	72.00		69.00		67.00	<
ALBUMINE	36-49 (G/L)	01/02/92	49.00		43.00		41.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	4.10		4.20		3.90	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.10		0.90		1.00	
TSH	0.5-6.5 (MIU/L)	01/02/92	0.57					
T4	86-148 (NMOL/L)	01/02/92	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 nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 406 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 21	
			30/06/92		21/07/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)
HB	11.5-16.5 (G/DL)	01/02/92	13.50		15.40	
HT	0.35-0.47 (L/L)	01/02/92	0.39		0.45	
RBC	3.9-5.6 (10-12/L)	01/02/92	4.37		4.98	
WBC	3.5-12 (10-9/L)	01/02/92	8.30		10.20	
WBC: N	2.5-8 (10-9/L)	01/02/92	5.80		7.00	
WBC: L	1.2-4 (10-9/L)	01/02/92	2.30		2.40	
WBC: E	0-0.5 (10-9/L)	01/02/92	0.00		0.20	
WBC: M	0.1-1.1 (10-9/L)	01/02/92	0.20		0.50	
WBC: B	0-0.1 (10-9/L)	01/02/92	0.00		0.00	
PLATELETS	150-400 (10-9/L)	01/02/92	310.00		317.00	
NA+	135-145 (MMOL/L)	01/02/92	139.00		136.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	3.80		4.10	
CL-	95-105 (MMOL/L)	01/02/92	105.00		99.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.31		2.32	
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.02		1.16	
SGOT	0-35 (U/L)	01/02/92	11.00		12.00	
GAMMA GT	5-23 (U/L)	01/02/92	17.00		18.00	
LDH	70-170 (U/L)	01/02/92	121.00		115.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	41.00		52.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	5.80		5.70	
UREA	2.5-7.5 (MMOL/L)	01/02/92	3.10		3.00	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.08		0.07	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.22		0.24	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	10.00		12.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	2.00		2.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	68.00		71.00	
ALBUMINE	36-49 (G/L)	01/02/92	46.00		44.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	3.60		3.80	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	0.90		1.00	
TSH	0.5-6.5 (MIU/L)	01/02/92	0.45	<<		
T4	86-148 (NMOL/L)	01/02/92	116.00			

1074

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICI S.P.A. MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 509 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 42	
			21/09/92		29/10/92		11/11/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	11.5-16.5 (G/DL)	01/02/92	11.90		12.80		12.70	
HT	0.35-0.47 (L/L)	01/02/92	0.39		0.38		0.38	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.40		4.42		4.34	
WBC	3.5-12 (10¬9/L)	01/02/92	4.28		4.14		4.00	
WBC: N	2.5-8 (10¬9/L)	01/02/92	2.73		2.24	<	1.93	<
WBC: L	1.2-4 (10¬9/L)	01/02/92	1.22		1.50		1.59	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.09		0.10		0.17	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.19		0.27		0.29	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.05		0.03		0.03	
PLATELETS	150-400 (10¬9/L)	01/02/92	206.00		196.00		181.00	
NA+	135-145 (MMOL/L)	01/02/92	138.00		138.00		141.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	3.90		4.50		4.40	
CL-	95-105 (MMOL/L)	01/02/92	104.00		104.00		104.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.30		2.36		2.28	
PO4--	0.6-1.3 (MMOL/L)	01/02/92	0.97		1.16		1.18	
SGOT	0-35 (U/L)	01/02/92	21.00		17.00			
GAMMA GT	5-23 (U/L)	01/02/92	29.00	>	31.00	>		
LDH	70-170 (U/L)	01/02/92	151.00		133.00		129.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	69.00		65.00		60.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	5.60		5.10		5.80	
UREA	2.5-7.5 (MMOL/L)	01/02/92	3.50		3.80		3.40	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.08		0.09		0.08	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.25		0.23		0.20	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	13.00		12.00		10.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	4.00		3.00		4.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	82.00		80.00		79.00	
ALBUMINE	36-49 (G/L)	01/02/92	45.00		46.00		45.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	4.80		4.80		4.20	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	0.70		0.90		0.70	
TSH	0.5-6.5 (MIU/L)	01/02/92	1.21					
T4	86-148 (NMOL/L)	01/02/92	94.00					

(¢) << 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 PHARMACEUTICAL MILANO - CNS 9550085

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 510 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			30/09/92		29/10/92		26/11/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	11.5-16.5 (G/DL)	01/02/92	13.90		13.80		13.90	
HT	0.35-0.47 (L/L)	01/02/92	0.41		0.40		0.41	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.58		4.48		4.64	
WBC	3.5-12 (10¬9/L)	01/02/92	8.00		6.38		5.95	
WBC: N	2.5-8 (10¬9/L)	01/02/92	4.16		3.86		3.68	
WBC: L	1.2-4 (10¬9/L)	01/02/92	1.93		1.52		1.48	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.43		0.40		0.33	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.42		0.33		0.40	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.09		0.07		0.06	
PLATELETS	150-400 (10¬9/L)	01/02/92	260.00		255.00		265.00	
NA+	135-145 (MMOL/L)	01/02/92	139.00		136.00		140.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	4.00		3.60		4.10	
CL-	95-105 (MMOL/L)	01/02/92	104.00		107.00	>	106.00	>
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.15	<	2.27		2.23	<
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.00		0.83		0.97	
SGOT	0-35 (U/L)	01/02/92	16.00		15.00		16.00	
GAMMA GT	5-23 (U/L)	01/02/92	26.00	>	25.00	>	25.00	>
LDH	70-170 (U/L)	01/02/92	148.00		145.00		156.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	53.00		53.00		60.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	3.10	<	4.00		3.50	
UREA	2.5-7.5 (MMOL/L)	01/02/92	5.10		4.70		5.80	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.06		0.07		0.08	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.17		0.23		0.23	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	9.00		12.00		9.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	2.00		3.00		3.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	70.00		75.00		73.00	
ALBUMINE	36-49 (G/L)	01/02/92	40.00		43.00		42.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	4.40		5.00		4.70	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.20		0.80		0.60	
TSH	0.5-6.5 (MIU/L)	01/02/92	1.27					
T4	86-148 (NMOL/L)	01/02/92	81.00	<				

(¢) << 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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 538 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			12/02/93		12/03/93		07/04/93	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	11.5-16.5 (G/DL)	01/02/92	14.50		13.40		13.60	
HT	0.35-0.47 (L/L)	01/02/92	0.44		0.40		0.40	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.50		4.14		4.20	
WBC	3.5-12 (10¬9/L)	01/02/92	7.70		8.30		10.98	
WBC: N	2.5-8 (10¬9/L)	01/02/92	4.46		4.13		7.00	
WBC: L	1.2-4 (10¬9/L)	01/02/92	2.44		3.32		2.92	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.23		0.14		0.27	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.53		0.65		0.00	<
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.04		0.04		0.06	
PLATELETS	150-400 (10¬9/L)	01/02/92	227.00		204.00		224.00	
NA+	135-145 (MMOL/L)	01/02/92	137.00		136.00		138.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	4.30		3.70		4.00	
CL-	95-105 (MMOL/L)	01/02/92	101.00		101.00		104.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.13	<	2.23	<	2.27	
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.03		1.04		1.41	>
SGOT	0-35 (U/L)	01/02/92	11.00		18.00		17.00	
GAMMA GT	5-23 (U/L)	01/02/92	19.00		18.00		20.00	
LDH	70-170 (U/L)	01/02/92	151.00		183.00	>	195.00	>
ALK. PHOSPH.	18-70 (U/L)	01/02/92	39.00		39.00		40.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	4.90		4.30		5.60	
UREA	2.5-7.5 (MMOL/L)	01/02/92	7.10		5.50		8.00	>
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.07		0.06		0.05	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.26		0.20		0.20	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	10.00		11.00		11.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	3.00		2.00		2.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	68.00		65.00	<	69.00	
ALBUMINE	36-49 (G/L)	01/02/92	41.00		40.00		40.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	5.10		4.60		4.80	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	0.70		0.70		0.90	
TSH	0.5-6.5 (MIU/L)	01/02/92	1.20					
T4	86-148 (NMOL/L)	01/02/92	71.00	<<				

1077

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 539 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			10/03/93		08/04/93		06/05/93	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/02/92	13.00		13.20		13.10	
HT	0.35-0.47 (L/L)	01/02/92	0.39		0.40		0.41	
RBC	3.9-5.6 (10¬12/L)	01/02/92	4.18		4.25		4.28	
WBC	3.5-12 (10¬9/L)	01/02/92	6.20		5.12		6.10	
WBC: N	2.5-8 (10¬9/L)	01/02/92	3.30		3.45		3.42	
WBC: L	1.2-4 (10¬9/L)	01/02/92	2.47		1.37		2.23	
WBC: E	0-0.5 (10¬9/L)	01/02/92	0.03		0.01		0.06	
WBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.38		0.27		0.36	
WBC: B	0-0.1 (10¬9/L)	01/02/92	0.03		0.02		0.03	
PLATELETS	150-400 (10¬9/L)	01/02/92	223.00		193.00		222.00	
NA+	135-145 (MMOL/L)	01/02/92	138.00		137.00		138.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	4.20		3.80		4.00	
CL-	95-105 (MMOL/L)	01/02/92	101.00		101.00		105.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.26		2.26		2.35	
PO4--	0.6-1.3 (MMOL/L)	01/02/92	1.12		0.96		1.17	
SGOT	0-35 (U/L)	01/02/92	18.00		17.00		15.00	
GAMMA GT	5-23 (U/L)	01/02/92	19.00		18.00		17.00	
LDH	70-170 (U/L)	01/02/92	144.00		119.00		134.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	49.00		45.00		59.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	5.00		7.40	>	3.90	
UREA	2.5-7.5 (MMOL/L)	01/02/92	3.70		3.00		3.20	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.06		0.05		0.06	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.28		0.15		0.17	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	9.00		9.00		8.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	2.00		3.00		2.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	74.00		70.00		73.00	
ALBUMINE	36-49 (G/L)	01/02/92	43.00		42.00		44.00	
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	5.10		4.60		5.40	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.00		1.40		1.10	
TSH	0.5-6.5 (MIU/L)	01/02/92	1.10					
T4	86-148 (NMOL/L)	01/02/92	148.00					

(¢) << 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 PHARMACEUTICI S.P.A. MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 410 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			09/04/92		14/05/92		10/06/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-15 (G/DL)	05/04/92	12.90		13.10		13.60	
HT	38-43 (%)	05/04/92	39.00		41.00		41.00	
RBC	4200000-4800000 (/MM3)	05/04/92	4290000		4640000		4420000	
WBC	4500-10000 (/MM3)	05/04/92	7200.00		8300.00		5100.00	
WBC: N	50-65 (%)	05/04/92	65.00		49.00	<	62.00	
WBC: L	30-40 (%)	05/04/92	31.00		43.00	>	33.00	
WBC: E	0-3 (%)	05/04/92	3.00		5.00	>>	3.00	
WBC: M	0-5 (%)	05/04/92	1.00		3.00		2.00	
WBC: B	0-1 (%)	05/04/92	0.00		0.00		0.00	
PLATELETS	150000-450000 (/MM3)	05/04/92	240000		220000		290000	
NA+	135-148 (MEQ/L)	05/04/92	144.00		139.00		154.00	>
K+	3.5-5 (MEQ/L)	05/04/92	4.00		3.90		5.30	>
CL-	95-105 (MEQ/L)	05/04/92	100.00		101.00		105.00	
Ca++	8.1-10.4 (MG/DL)	05/04/92	8.90		10.10		8.40	
PO4--	2.5-4.5 (MG/DL)	05/04/92	4.00		3.30		4.50	
SGOT	0-40 (U/L)	05/04/92	18.00		20.00		21.00	
SGPT	0-40 (U/L)	05/04/92	12.00		22.00		20.00	
GAMMA GT	7-32 (U/L)	05/04/92	16.00		16.00		16.00	
LDH	100-240 (U/L)	05/04/92	134.00		180.00		110.00	
ALK. PHOSPH.	50-250 (U/L)	05/04/92	105.00		115.00		106.00	
GLUCOSE	65-110 (MG/DL)	05/04/92	88.00		83.00		80.00	
UREA	15-50 (MG/DL)	05/04/92	32.00		38.00		54.00	>
CREATININE	0.7-1.4 (MG/DL)	05/04/92	0.90		1.30		0.90	
URIC ACID	2.5-6.8 (MG/DL)	05/04/92	5.40		7.60	>	6.10	
TOT BILIRUBIN	0.2-1 (MG/DL)	05/04/92	0.60		0.70		0.70	
DIR BILIRUBIN	0-0.2 (MG/DL)	05/04/92	0.20		0.20		0.20	
TOT. PROTEINS	6.2-8 (G/DL)	05/04/92	7.40		7.10		7.20	
ALBUMINE	3-5 (G/DL)	05/04/92	4.30		4.10		4.10	
TOT. CHOLEST.	150-250 (MG/DL)	05/04/92	244.00		266.00	>	280.00	>
TRIGLYCERIDES	40-180 (MG/DL)	05/04/92	98.00		100.00		84.00	
GLOBULINS ALPHA 1	0.12-0.35 (G/DL)	05/04/92	0.23		0.22		0.20	
GLOBULINS ALPHA 2	0.35-0.65 (G/DL)	05/04/92	0.65		0.59		0.64	
GLOBULINS BETA	0.56-0.9 (G/DL)	05/04/92	0.78		0.64		0.71	
GLOBULINS GAMMA	1.1-1.7 (G/DL)	05/04/92	1.44		1.55		1.55	
TSH	0-6 (UU/ML)	05/04/92	0.50					
T4	4.5-13 (UG/DL)	05/04/92	9.50					

1079

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (value lower than min range) > out of range (value higher than max range
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICALS MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 412 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			10/04/92		20/05/92		17/06/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-15 (G/DL)	05/04/92	13.30		12.70		12.90	
HT	38-43 (%)	05/04/92	40.00		38.00		38.00	
RBC	4200000-4800000 (/MM3)	05/04/92	4400000		4180000	<	4200000	
WBC	4500-10000 (/MM3)	05/04/92	7600.00		7100.00		6800.00	
WBC: N	50-65 (%)	05/04/92	59.00		58.00		60.00	
WBC: L	30-40 (%)	05/04/92	36.00		38.00		36.00	
WBC: E	0-3 (%)	05/04/92	3.00		1.00		2.00	
WBC: M	0-6 (%)	05/04/92	2.00		3.00		2.00	
WBC: B	0-1 (%)	05/04/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	05/04/92	205000		205000		245000	
NA+	135-150 (MEQ/L)	05/04/92	141.00		141.00			
	137-145 (MEQ/L)	15/06/92					140.00	
K+	4-5 (MEQ/L)	05/04/92	4.40		4.60			
	3.5-5 (MEQ/L)	15/06/92					4.20	
CL-	95-108 (MEQ/L)	05/04/92	98.00		99.00			
	95-109 (MEQ/L)	15/06/92					102.00	
Ca++	8.5-10.5 (MG/DL)	05/04/92	9.10		8.90			
	8.1-10.4 (MG/DL)	15/06/92					9.80	
PO4--	2.5-4.5 (MG/DL)	05/04/92	4.20		4.10			
	2.5-5 (MG/DL)	15/06/92					4.50	
SGOT	4-20 (U/L)	05/04/92	5.00		7.00			
	7-22 (U/L)	15/06/92					8.00	
SGPT	2-18 (U/L)	05/04/92	3.00		3.00			
	7-26 (U/L)	15/06/92					10.00	
GAMMA GT	5-25 (U/L)	05/04/92	9.20		16.00			
	5-24 (U/L)	15/06/92					14.00	
LDH	60-150 (U/L)	05/04/92	120.00		110.00		120.00	
ALK. PHOSPH.	50-160 (U/L)	05/04/92	99.00		105.00			
	50-220 (U/L)	15/06/92					110.00	
GLUCOSE	70-110 (MG/DL)	05/04/92	83.00		75.00			
	60-100 (MG/DL)	15/06/92					85.00	
UREA	15-45 (MG/DL)	05/04/92	39.00		43.00			
	15-50 (MG/DL)	15/06/92					40.00	
CREATININE	5-14 (MG/L)	05/04/92	8.90		12.30			
	0.6-1.4 (MG/DL)	15/06/92					1.10	
URIC ACID	2-6 (MG/DL)	05/04/92	4.00		3.80		3.80	
TOT BILIRUBIN	0.1-1.1 (MG/DL)	05/04/92	0.70		0.70			
	0.1-1 (MG/DL)	15/06/92					0.60	
DIR BILIRUBIN	0-0.2 (MG/DL)	05/04/92	0.20		0.20			
	0-0.3 (MG/DL)	15/06/92					0.10	
TOT. PROTEINS	6-8 (G/DL)	05/04/92	7.70		7.30			
	6.5-8 (G/DL)	15/06/92					7.20	
ALBUMINE	3-5 (G/DL)	05/04/92	5.00		4.65			
	3.5-5.2 (G/DL)	15/06/92					4.30	
TOT. CHOLEST.	160-250 (MG/DL)	05/04/92	212.00		214.00			
	140-260 (MG/DL)	15/06/92					210.00	
TRIGLYCERIDES	10-160 (MG/DL)	05/04/92	118.00		112.00			
	50-160 (MG/DL)	15/06/92					120.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	05/04/92	0.10		0.10		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	05/04/92	0.60		0.60		0.70	
GLOBULINS BETA	0.6-1 (G/DL)	05/04/92	0.75		0.70		0.80	
GLOBULINS GAMMA	0.8-1.4 (G/DL)	05/04/92	1.25		1.25		1.20	
TSH	0.6-6.5 (UU/ML)	05/04/92	8.20	>>				
T4	5.5-14 (UG/DL)	05/04/92	4.00	<<				

1080

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICI MILANO - CNS 9550883

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 414 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			26/05/92		29/06/92		27/07/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	25/05/92	17.10	>	17.00	>	16.20	>
HT	40-48 (%)	25/05/92	52.00	>	51.00	>	49.00	>
RBC	4500000-5700000 (/MM3)	25/05/92	5720000	>	5600000		5530000	
WBC	4500-10000 (/MM3)	25/05/92	8500.00		8400.00		6900.00	
WBC: N	50-65 (%)	25/05/92	55.00		67.00	>	52.00	
WBC: L	30-40 (%)	25/05/92	42.00	>	31.00		43.00	>
WBC: E	0-3 (%)	25/05/92	1.00		1.00		2.00	
WBC: M	0-6 (%)	25/05/92	2.00		1.00		3.00	
WBC: B	0-1 (%)	25/05/92	0.00		0.00		0.00	
PLATELETS	150000-400000 (/MM3)	25/05/92	235000		160000		295000	
NA+	130-150 (MEQ/L)	25/05/92	143.00		145.00		142.00	
K+	3.6-5 (MEQ/L)	25/05/92	4.40		4.40		4.40	
CL-	85-105 (MEQ/L)	25/05/92	100.00		103.00		103.00	
Ca++	8.5-10.5 (MEQ/L)	25/05/92	10.60	>	10.10		9.80	
PO4--	2.5-4.5 (MG/DL)	25/05/92	3.10		3.60		3.90	
SGOT	0-44 (U/L)	25/05/92	19.00		13.00		28.00	
SGPT	0-44 (U/L)	25/05/92	10.00		19.00		33.00	
GAMMA GT	0-28 (U/L)	25/05/92	43.00	>	25.00		22.00	
LDH	0-240 (U/L)	25/05/92	256.00	>	172.00		206.00	
ALK. PHOSPH.	50-300 (U/L)	25/05/92	79.00		122.00		123.00	
GLUCOSE	0.6-1.1 (G/L)	25/05/92	0.81		0.90		0.79	
UREA	0.2-0.5 (G/L)	25/05/92	0.46		0.20		0.28	
CREATININE	0.8-1.5 (MG/DL)	25/05/92	1.23		1.20		1.19	
URIC ACID	2-7 (MG/DL)	25/05/92	5.00		5.20		6.60	
TOT BILIRUBIN	0-1.2 (MG/DL)	25/05/92	0.78		0.76		0.12	
DIR BILIRUBIN	0-0.2 (MG/DL)	25/05/92	0.05		0.25	>	0.05	
TOT. PROTEINS	6-8 (G/DL)	25/05/92	8.20	>	6.80		7.20	
ALBUMINE	3.8-5 (G/DL)	25/05/92	4.90		4.00		4.20	
TOT. CHOLEST.	140-250 (MG/DL)	25/05/92	251.00	>	228.00		313.00	>
TRIGLYCERIDES	50-172 (MG/DL)	25/05/92	195.00	>	150.00		117.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	25/05/92	0.30		0.20		0.25	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	25/05/92	0.70		0.55		0.75	
GLOBULINS BETA	0.6-1 (G/DL)	25/05/92	1.00		0.80		0.90	
GLOBULINS GAMMA	0.8-1.4 (G/DL)	25/05/92	1.30		1.25		1.10	
TSH	0.3-5 (UU/ML)	25/05/92	0.70					
T4	5-12 (UG/DL)	25/05/92	8.00					

(¢) << 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 PHARMACEUTICAL RELAND - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 416 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			19/06/92		20/07/92		17/08/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12.5-15 (G/DL)	01/03/92	13.20		13.00		14.00	
HT	38-43 (%)	01/03/92	42.00		40.00		41.00	
RBC	4000000-4500000 (/MM3)	01/03/92	4450000		4600000	>	4700000	>
WBC	5000-9000 (/MM3)	01/03/92	10900.0	>	7000.00		6700.00	
WBC: N	50-65 (%)	01/03/92	66.00	>	51.00		49.00	<
WBC: L	30-40 (%)	01/03/92	30.00		45.00	>	45.00	>
WBC: E	0-3 (%)	01/03/92	3.00		2.00		2.00	
WBC: M	0-5 (%)	01/03/92	1.00		2.00		4.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	315000	>	280000		250000	
NA+	130-150 (MEQ/L)	01/03/92	137.00		140.00		136.00	
K+	3-5 (MEQ/L)	01/03/92	4.00		4.30		4.60	
CL-	95-105 (MEQ/L)	01/03/92	98.00		102.00		105.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	9.20		9.60		9.50	
PO4--	2.5-5 (MG/DL)	01/03/92	4.50		4.10		3.80	
SGOT	0-12 (MU/ML)	01/03/92	14.00	>	17.00	>	21.00	>
SGPT	0-12 (MU/ML)	01/03/92	11.00		12.00		16.00	>
GAMMA GT	4-18 (UI/L)	01/03/92	14.20		12.30		10.00	
LDH	120-240 (UI/L)	01/03/92	129.00		135.00		150.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	35.00		50.00	>	47.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	86.00		90.00		96.00	
UREA	15-40 (MG/DL)	01/03/92	36.00		32.00		30.00	
CREATININE	0.5-1.4 (MG/DL)	01/03/92	1.30		1.20		0.90	
URIC ACID	2.4-5.7 (MG/DL)	01/03/92	5.10		4.80		4.30	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.32		0.40		0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.10		0.12		0.15	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	6.80		7.00		7.30	
ALBUMINE	3.8-5 (G/DL)	01/03/92	4.70		4.80		4.95	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	267.00	>	220.00		210.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	160.00	>	150.00		135.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.15		0.10		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.45		0.50		0.55	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.65		0.70		0.60	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	0.85		0.90		1.00	
TSH	0-5 (UUI/ML)	01/03/92	2.00					
T4	4.5-13 (UG/DL)	01/03/92	7.10					

1082

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 419 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			08/07/92		12/08/92		09/09/92	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	12.5-15 (G/DL)	01/03/92	13.30		13.80		12.10	<
HT	38-43 (%)	01/03/92	40.00		41.00		39.00	
RBC	4000000-4500000 (/MM3)	01/03/92	4400000		4500000		4290000	
WBC	5000-9000 (/MM3)	01/03/92	6500.00		7100.00		6800.00	
WBC: N	50-65 (%)	01/03/92	71.00	>	65.00		61.00	
WBC: L	30-40 (%)	01/03/92	29.00	<	32.00		35.00	
WBC: E	0-3 (%)	01/03/92	0.00		1.00		2.00	
WBC: M	0-5 (%)	01/03/92	0.00		2.00		2.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	255000		240000		220000	
NA+	130-150 (MEQ/L)	01/03/92	138.00		142.00		138.00	
K+	3-5 (MEQ/L)	01/03/92	4.50		4.10		4.40	
CL-	95-105 (MEQ/L)	01/03/92	100.00		102.00		106.00	>
Ca++	8.1-10.4 (MG/DL)	01/03/92	10.50	>	9.80		11.20	>
PO4--	2.5-5 (MG/DL)	01/03/92	4.00		4.40		4.20	
SGOT	0-12 (MU/ML)	01/03/92	6.00		8.00		8.00	
SGPT	0-12 (MU/ML)	01/03/92	8.00		7.00		10.00	
GAMMA GT	4-18 (UI/L)	01/03/92	16.00		14.00		14.00	
LDH	120-240 (UI/L)	01/03/92	190.00		175.00		178.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	40.00		43.00		40.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	91.00		98.00		96.00	
UREA	15-40 (MG/DL)	01/03/92	48.00	>	42.00	>	38.00	
CREATININE	0.5-1.4 (MG/DL)	01/03/92	1.30		1.05		1.15	
URIC ACID	2.4-5.7 (MG/DL)	01/03/92	5.00		5.30		4.30	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.70		0.80		0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.20		0.23		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	7.05		7.20		6.90	
ALBUMINE	3.8-5 (G/DL)	01/03/92	4.00		3.90		3.75	<
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	222.00		204.00		264.00	>
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	110.00		99.00		94.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.20		0.26		0.25	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.70		0.68		0.70	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.80		0.90		0.85	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.35	>	1.25		1.35	>
TSH	0-5 (UUI/ML)	01/03/92	1.30					
T4	4.5-13 (UG/DL)	01/03/92	9.60					

1083

(◊) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL RTI ANO CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 420 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			15/07/92		16/09/92		14/10/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	13.5-15.5 (G/DL)	01/03/92	14.00		13.50		14.00	
HT	40-45 (%)	01/03/92	43.00		40.00		44.00	
RBC	4200000-4800000 (/MM3)	01/03/92	4800000		4700000		4900000	>
WBC	5000-9000 (/MM3)	01/03/92	5100.00		5300.00		5900.00	
WBC: N	50-65 (%)	01/03/92	46.00	<	52.00		60.00	
WBC: L	30-40 (%)	01/03/92	49.00	>	41.00	>	30.00	
WBC: E	0-3 (%)	01/03/92	2.00		3.00		6.00	>>
WBC: M	0-5 (%)	01/03/92	3.00		4.00		4.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	230000		250000		230000	
NA+	130-150 (MEQ/L)	01/03/92	142.00		139.00		140.00	
K+	3-5 (MEQ/L)	01/03/92	4.80		4.50		3.20	
CL-	95-105 (MEQ/L)	01/03/92	99.00		101.00		103.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	8.90		8.50		9.40	
PO4--	2.5-5 (MG/DL)	01/03/92	4.10		4.30		3.90	
SGOT	0-12 (MU/ML)	01/03/92	12.00		10.00		9.00	
SGPT	0-12 (MU/ML)	01/03/92	10.00		12.00		8.00	
GAMMA GT	6-28 (UI/L)	01/03/92	22.00		20.00		12.00	
LDH	120-240 (UI/L)	01/03/92	180.00		185.00		196.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	35.00		35.00		44.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	85.00		90.00		81.00	
UREA	15-40 (MG/DL)	01/03/92	29.00		25.00		33.00	
CREATININE	0.5-1.4 (MG/DL)	01/03/92	0.94		0.89		0.94	
URIC ACID	3.4-7 (MG/DL)	01/03/92	5.20		4.80		4.80	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.71		0.70		0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.15		0.12		0.11	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	7.20		7.00		7.30	
ALBUMINE	3.8-5 (G/DL)	01/03/92	3.97		3.85		4.20	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	186.00		180.00		186.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	72.00		72.00		69.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.27		0.25		0.29	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.71		0.75		0.71	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.90		0.80		0.95	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.15		1.20		1.15	
TSH	0-5 (UUI/ML)	01/03/92	3.10					
T4	4.5-13 (UG/DL)	01/03/92	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 PHARMACEUTICAL RESEARCH - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 422 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			14/08/92		15/09/92		13/10/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	13.5-15.5 (G/DL)	01/03/92	14.60		14.50		14.60	
HT	40-45 (%)	01/03/92	48.00	>	47.00	>	48.00	>
RBC	4200000-4800000 (/MM3)	01/03/92	5280000	>	5230000	>	5250000	>
WBC	5000-9000 (/MM3)	01/03/92	6800.00		7100.00		7200.00	
WBC: N	50-65 (%)	01/03/92	63.00		60.00		62.00	
WBC: L	30-40 (%)	01/03/92	35.00		34.00		34.00	
WBC: E	0-3 (%)	01/03/92	0.00		2.00		1.00	
WBC: M	0-5 (%)	01/03/92	2.00		4.00		3.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	210000		220000		225000	
NA+	130-150 (MEQ/L)	01/03/92	141.00		145.00		139.00	
K+	3-5 (MEQ/L)	01/03/92	4.60		4.20		4.90	
CL-	95-105 (MEQ/L)	01/03/92	102.00		99.00		100.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	10.40		10.80	>	10.70	>
PO4--	2.5-5 (MG/DL)	01/03/92	3.90		3.50		3.50	
SGOT	0-12 (MU/ML)	01/03/92	6.00		7.00		5.00	
SGPT	0-12 (MU/ML)	01/03/92	8.00		7.00		9.00	
GAMMA GT	6-28 (UI/L)	01/03/92	10.00		12.00		35.00	>
LDH	120-240 (UI/L)	01/03/92	195.00		180.00		190.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	32.00		35.00		25.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	106.00		95.00		99.00	
UREA	15-40 (MG/DL)	01/03/92	45.00	>	40.00		38.00	
CREATININE	0.5-1.4 (MG/DL)	01/03/92	1.10		0.98		0.70	
URIC ACID	3.4-7 (MG/DL)	01/03/92	4.50		4.20		4.20	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.75		0.80		0.68	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.25		0.28		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	7.00		7.10		7.20	
ALBUMINE	3.8-5 (G/DL)	01/03/92	4.00		4.20		4.20	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	238.00		210.00		225.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	120.00		110.00		115.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.20		0.15		0.25	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.65		0.60		0.60	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.75		0.80		0.95	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.40	>	1.35	>	1.20	
TSH	0-5 (UUI/ML)	01/03/92	1.15					
T4	4.5-13 (UG/DL)	01/03/92	8.20					

1085

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 423 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			15/08/92		17/09/92		15/10/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12.5-15 (G/DL)	01/03/92	13.20		13.60		14.00	
HT	38-43 (%)	01/03/92	43.00		43.10	>	43.30	>
RBC	4000000-4500000 (/MM3)	01/03/92	4700000	>	4780000	>	4900000	>
WBC	5000-9000 (/MM3)	01/03/92	7000.00		6600.00		6800.00	
WBC: N	50-65 (%)	01/03/92	64.00		65.00		68.00	>
WBC: L	30-40 (%)	01/03/92	33.00		33.00		26.00	<
WBC: E	0-3 (%)	01/03/92	1.00		1.00		2.00	
WBC: M	0-5 (%)	01/03/92	2.00		1.00		4.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	240000		235000		230000	
NA+	130-150 (MEQ/L)	01/03/92	133.00		140.00		149.00	
K+	3-5 (MEQ/L)	01/03/92	3.80		4.40		3.00	
CL-	95-105 (MEQ/L)	01/03/92	101.00		98.00		96.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	10.50	>	11.00	>	11.10	>
PO4--	2.5-5 (MG/DL)	01/03/92	3.50		3.80		5.00	
SGOT	0-12 (MU/ML)	01/03/92	8.00		9.00		10.00	
SGPT	0-12 (MU/ML)	01/03/92	10.00		9.00		11.00	
GAMMA GT	4-18 (UI/L)	01/03/92	9.00		11.00		14.00	
LDH	120-240 (UI/L)	01/03/92	160.00		150.00		105.00	<
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	32.00		33.00		40.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	92.00		100.00		95.00	
UREA	15-40 (MG/DL)	01/03/92	28.00		21.00		28.00	
CREATININE	0.5-1.4 (MG/DL)	01/03/92	0.85		0.80		0.90	
URIC ACID	2.4-5.7 (MG/DL)	01/03/92	3.50		3.20		3.50	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.60		0.50		0.65	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.18		0.15		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	6.50		7.30		6.60	
ALBUMINE	3.8-5 (G/DL)	01/03/92	3.40	<	4.20		3.50	<
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	190.00		195.00		170.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	75.00		80.00		60.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.20		0.25		0.30	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.70		0.65		0.75	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.95		1.00		0.90	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.25		1.20		1.15	
TSH	0-5 (UUI/ML)	01/03/92	0.70					
T4	4.5-13 (UG/DL)	01/03/92	11.50					

(¢) << 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

PHARMACIA PHARMACEUTICI[illegible] - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 426 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			20/10/92		24/11/92		22/12/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	13.5-15.5 (G/DL)	15/10/92	14.80		14.50		14.60	
HT	40-45 (%)	15/10/92	47.00	>	46.00	>	44.00	
RBC	4200000-4800000 (/MM3)	15/10/92	5170000	>	5100000	>	5080000	>
WBC	5000-9000 (/MM3)	15/10/92	6900.00		7000.00		7000.00	
WBC: N	50-65 (%)	15/10/92	68.00	>	65.00		70.00	>
WBC: L	30-40 (%)	15/10/92	25.00	<	30.00		27.00	<
WBC: E	0-3 (%)	15/10/92	4.00	>>	1.00		1.00	
WBC: M	0-5 (%)	15/10/92	3.00		4.00		2.00	
WBC: B	0-1 (%)	15/10/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	15/10/92	190000		210000		205000	
NA+	130-150 (MEQ/L)	15/10/92	140.00		141.00		138.00	
K+	3-5 (MEQ/L)	15/10/92	4.50		4.20		4.20	
CL-	95-105 (MEQ/L)	15/10/92	95.00		101.00		100.00	
Ca++	8.1-10.4 (MG/DL)	15/10/92	8.10		7.50	<	7.80	<
PO4--	2.5-5 (MG/DL)	15/10/92	3.50		3.80		3.60	
SGOT	0-12 (MU/ML)	15/10/92	10.00		15.00	>	14.00	>
SGPT	0-12 (MU/ML)	15/10/92	9.00		12.00		11.00	
GAMMA GT	6-28 (UI/L)	15/10/92	28.00		21.00		25.00	
LDH	120-240 (UI/L)	15/10/92	183.00		160.00		177.00	
ALK. PHOSPH.	20-48 (MU/ML)	15/10/92	60.00	>	74.00	>	63.00	>
GLUCOSE	70-110 (MG/DL)	15/10/92	76.00		85.00		85.00	
UREA	15-40 (MG/DL)	15/10/92	35.00		33.00		37.00	
CREATININE	0.5-1.4 (MG/DL)	15/10/92	0.63		0.50		0.66	
URIC ACID	3.4-7 (MG/DL)	15/10/92	4.80		4.65		4.60	
TOT BILIRUBIN	0-1 (MG/DL)	15/10/92	0.50		0.65		0.55	
DIR BILIRUBIN	0-0.3 (MG/DL)	15/10/92	0.10		0.14		0.08	
TOT. PROTEINS	6.3-8 (G/DL)	15/10/92	7.30		7.20		7.50	
ALBUMINE	3.8-5 (G/DL)	15/10/92	4.08		3.90		4.00	
TOT. CHOLEST.	160-240 (MG/DL)	15/10/92	161.00		170.00		165.00	
TRIGLYCERIDES	30-150 (MG/DL)	15/10/92	107.00		95.00		103.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	15/10/92	0.07	<<	0.20		0.10	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	15/10/92	0.74		0.70		0.85	>
GLOBULINS BETA	0.6-1 (G/DL)	15/10/92	1.02	>	1.15	>	1.30	>
GLOBULINS GAMMA	0.8-1.3 (G/DL)	15/10/92	1.39	>	1.25		1.25	
TSH	0-5 (UUI/ML)	15/10/92	2.46					
T4	52-127 (NG/ML)	15/10/92	83.80					

(¢) << 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 PHARMACEUTICAL RESEARCH - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 428 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			25/11/92		30/12/92		27/01/93	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	13.5-15.5 (G/DL)	25/02/92	13.30	<	13.60		13.50	
HT	40-45 (%)	25/02/92	40.00		41.00		40.00	
RBC	4200000-4800000 (/MM3)	25/02/92	4400000		4500000		4450000	
WBC	5000-9000 (/MM3)	25/02/92	4900.00	<	5100.00		5000.00	
WBC: N	50-65 (%)	25/02/92	60.00		65.00		69.00	>
WBC: L	30-40 (%)	25/02/92	35.00		32.00		30.00	
WBC: E	0-3 (%)	25/02/92	2.00		1.00		0.00	
WBC: M	0-5 (%)	25/02/92	3.00		2.00		1.00	
WBC: B	0-1 (%)	25/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	25/02/92	245000		260000		250000	
NA+	130-150 (MEQ/L)	25/02/92	148.00		146.00		140.00	
K+	3-5 (MEQ/L)	25/02/92	5.20	>	4.90		4.40	
CL-	95-105 (MEQ/L)	25/02/92	100.00		102.00		98.00	
Ca++	8.1-10.4 (MG/DL)	25/02/92	8.00	<	8.50		10.00	
PO4--	2.5-5 (MG/DL)	25/02/92	3.60		3.80		4.40	
SGOT	0-12 (MU/ML)	25/02/92	9.00		10.00		12.00	
SGPT	0-12 (MU/ML)	25/02/92	13.00	>	15.00	>	14.00	>
GAMMA GT	6-28 (UI/L)	25/02/92	20.00		10.00		12.00	
LDH	120-240 (UI/L)	25/02/92	196.00		185.00		190.00	
ALK. PHOSPH.	45-170 (U/L)	25/02/92	103.00		98.00		110.00	
GLUCOSE	70-110 (MG/DL)	25/02/92	85.00		87.00		80.00	
UREA	15-40 (MG/DL)	25/02/92	37.00		38.00		28.00	
CREATININE	0.5-1.4 (MG/DL)	25/02/92	1.14		1.20		1.01	
URIC ACID	3.4-7 (MG/DL)	25/02/92	3.10	<	2.90	<	3.30	<
TOT BILIRUBIN	0-1 (MG/DL)	25/02/92	0.83		0.80		0.75	
DIR BILIRUBIN	0-0.3 (MG/DL)	25/02/92	0.17		0.12		0.10	
TOT. PROTEINS	6.3-8 (G/DL)	25/02/92	7.35		7.20		7.40	
ALBUMINE	3.8-5 (G/DL)	25/02/92	4.50		4.20		4.25	
TOT. CHOLEST.	160-240 (MG/DL)	25/02/92	175.00		180.00		170.00	
TRIGLYCERIDES	30-150 (MG/DL)	25/02/92	105.00		98.00		110.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	25/02/92	0.20		0.30		0.25	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	25/02/92	0.70		0.75		0.80	>
GLOBULINS BETA	0.6-1 (G/DL)	25/02/92	0.70		0.90		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	25/02/92	1.25		1.15		1.30	
TSH	0-5 (UUI/ML)	25/02/92	1.20					
T4	4.5-13 (UG/DL)	25/02/92	7.10					

(¢) << 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 PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 450 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			29/11/92		06/01/93		03/02/93	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	13.5-15.5 (G/DL)	01/03/92	15.20		15.90	>	15.20	
HT	40-45 (%)	01/03/92	47.00	>	47.40	>	44.50	
RBC	4200000-4800000 (/MM3)	01/03/92	5200000	>	5300000	>	5100000	>
WBC	5000-9000 (/MM3)	01/03/92	9600.00	>	9300.00	>	7500.00	
WBC: N	50-65 (%)	01/03/92	73.00	>	58.00		60.00	
WBC: L	30-40 (%)	01/03/92	21.00	<	35.00		38.00	
WBC: E	0-3 (%)	01/03/92	2.00		2.00		1.00	
WBC: M	0-5 (%)	01/03/92	4.00		5.00		1.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	280000		285000		230000	
NA+	130-150 (MEQ/L)	01/03/92	139.00		142.00		144.00	
K+	3-5 (MEQ/L)	01/03/92	4.40		4.70		4.90	
CL-	95-105 (MEQ/L)	01/03/92	101.00		103.00		101.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	9.40		9.50		11.00	>
PO4--	2.5-5 (MG/DL)	01/03/92	4.70		4.50		4.70	
SGOT	0-12 (MU/ML)	01/03/92	12.00		13.00	>	5.00	
SGPT	0-12 (MU/ML)	01/03/92	9.00		11.00		8.00	
GAMMA GT	6-28 (UI/L)	01/03/92	18.00		15.00		15.00	
LDH	120-240 (UI/L)	01/03/92	169.00		177.00		220.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	35.00		38.00		30.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	95.00		88.00		99.00	
UREA	15-40 (MG/DL)	01/03/92	38.00		35.00		22.00	
CREATININE	0.5-1.4 (MG/DL)	01/03/92	1.20		1.11		0.90	
URIC ACID	3.4-7 (MG/DL)	01/03/92	5.40		4.80		5.50	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.63		0.61		0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.28		0.23		0.10	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	7.60		7.40		7.20	
ALBUMINE	3.8-5 (G/DL)	01/03/92	4.00		4.30		4.10	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	166.00		170.00		195.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	147.00		130.00		60.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.20		0.25		0.15	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.70		0.75		0.75	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.80		0.90		0.95	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.10		1.20		1.25	
TSH	0-5 (UUI/ML)	01/03/92	2.90					
T4	4.5-13 (UG/DL)	01/03/92	9.10					

1089

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 451 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			07/12/92		14/01/93		11/02/93	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12.5-15 (G/DL)	01/03/92	14.50		13.70		15.00	
HT	38-43 (%)	01/03/92	45.00	>	44.20	>	47.00	>
RBC	4000000-4500000 (/MM3)	01/03/92	4950000	>	4700000	>	5210000	>
WBC	5000-9000 (/MM3)	01/03/92	6700.00		6900.00		6900.00	
WBC: N	50-65 (%)	01/03/92	68.00	>	67.00	>	63.00	
WBC: L	30-40 (%)	01/03/92	27.00	<	30.00		35.00	
WBC: E	0-3 (%)	01/03/92	2.00		1.00		0.00	
WBC: M	0-5 (%)	01/03/92	3.00		2.00		2.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	270000		260000		210000	
NA+	130-150 (MEQ/L)	01/03/92	139.00		140.00		143.00	
K+	3-5 (MEQ/L)	01/03/92	4.00		4.30		4.60	
CL-	95-105 (MEQ/L)	01/03/92	108.00	>	104.00		100.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	9.60		9.90		9.20	
PO4--	2.5-5 (MG/DL)	01/03/92	3.70		4.10		3.90	
SGOT	0-12 (MU/ML)	01/03/92	7.00		9.00		6.00	
SGPT	0-12 (MU/ML)	01/03/92	9.00		10.00		8.00	
GAMMA GT	4-18 (UI/L)	01/03/92	12.00		11.00		8.00	
LDH	120-240 (UI/L)	01/03/92	144.00		130.00		198.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	32.00		35.00		27.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	63.00	<	70.00		66.00	<
UREA	15-40 (MG/DL)	01/03/92	37.00		39.00		54.00	>
CREATININE	0.5-1.4 (MG/DL)	01/03/92	1.10		1.25		0.97	
URIC ACID	2.4-5.7 (MG/DL)	01/03/92	3.50		3.30		2.80	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.65		0.60		0.80	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.15		0.12		0.10	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	7.10		7.20		6.90	
ALBUMINE	3.8-5 (G/DL)	01/03/92	4.00		4.25		3.80	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	168.00		180.00		187.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	65.00		70.00		123.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.20		0.15		0.25	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.80	>	0.90	>	0.75	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.70		0.75		0.75	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.40	>	1.15		1.35	>
TSH	0-5 (UUI/ML)	01/03/92	0.50					
T4	4.5-13 (UG/DL)	01/03/92	7.00					

1090

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (value lower than min range) > out of range (value higher than max range
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 454 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			08/01/93		15/02/93		15/03/93	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	13.5-15.5 (G/DL)	01/03/92	14.60		15.30		15.90	>
HT	40-45 (%)	01/03/92	44.30		44.80		48.00	>
RBC	4200000-4800000 (/MM3)	01/03/92	5100000	>	5050000	>	5500000	>
WBC	5000-9000 (/MM3)	01/03/92	6800.00		7200.00		7600.00	
WBC: N	50-65 (%)	01/03/92	65.00		65.00		62.00	
WBC: L	30-40 (%)	01/03/92	32.00		31.00		34.00	
WBC: E	0-3 (%)	01/03/92	1.00		1.00		1.00	
WBC: M	0-5 (%)	01/03/92	2.00		3.00		3.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/03/92	260000		250000		260000	
NA+	130-150 (MEQ/L)	01/03/92	146.00		147.00		139.00	
K+	3-5 (MEQ/L)	01/03/92	4.90		4.80		4.80	
CL-	95-105 (MEQ/L)	01/03/92	101.00		103.00		102.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	10.90	>	10.50	>	11.10	>
PO4--	2.5-5 (MG/DL)	01/03/92	4.60		4.90		4.70	
SGOT	0-12 (MU/ML)	01/03/92	9.00		9.00		7.00	
SGPT	0-12 (MU/ML)	01/03/92	8.00		11.00		9.00	
GAMMA GT	6-28 (UI/L)	01/03/92	11.00		15.00		15.00	
LDH	120-240 (UI/L)	01/03/92	205.00		190.00		185.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	35.00		32.00		33.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	94.00		94.00		90.00	
UREA	15-40 (MG/DL)	01/03/92	31.00		33.00		32.00	
CREATININE	0.5-1.4 (MG/DL)	01/03/92	1.10		0.80		0.80	
URIC ACID	3.4-7 (MG/DL)	01/03/92	4.40		4.40		3.90	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.70		0.70		0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.20		0.15		0.05	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	7.10		7.10		7.00	
ALBUMINE	3.8-5 (G/DL)	01/03/92	4.10		3.90		4.10	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	195.00		202.00		170.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	88.00		110.00		85.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.30		0.30		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.75		0.70		0.70	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.80		0.90		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.15		1.30		1.20	
TSH	0-5 (UUI/ML)	01/03/92	2.90					
T4	4.5-13 (UG/DL)	01/03/92	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

PHARMACIA PHARMACEUTICAL RESEARCH - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 429 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			12/03/92		22/04/92		20/05/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12.5-15 (G/DL)	01/02/92	14.00		14.00		15.00	
HT	38-43 (%)	01/02/92	43.00		43.00		45.00	>
RBC	4000000-4500000 (/MM3)	01/02/92	4730000	>	4730000	>	4950000	>
WBC	5000-9000 (/MM3)	01/02/92	6200.00		8500.00		7900.00	
WBC: N	50-65 (%)	01/02/92	63.00		65.00		57.00	
WBC: L	30-40 (%)	01/02/92	34.00		32.00		38.00	
WBC: E	0-3 (%)	01/02/92	0.00		1.00		2.00	
WBC: M	0-5 (%)	01/02/92	3.00		2.00		3.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	210000		220000		210000	
NA+	130-150 (MEQ/L)	01/02/92	147.00		139.00		143.00	
K+	3-5 (MEQ/L)	01/02/92	4.80		4.00		4.40	
CL-	95-105 (MEQ/L)	01/02/92	105.00		110.00	>	109.00	>
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.40		9.80		10.20	
PO4--	2.5-5 (MG/DL)	01/02/92	4.40		4.30		4.50	
SGOT	0-12 (MU/ML)	01/02/92	10.00		7.00		8.00	
SGPT	0-12 (MU/ML)	01/02/92	4.00		9.00		10.00	
GAMMA GT	4-18 (UI/L)	01/02/92	28.00	>	14.00		12.00	
LDH	120-240 (UI/L)	01/02/92	184.00		170.00		220.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	24.00		36.00		32.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	100.00		99.00		86.00	
UREA	15-40 (MG/DL)	01/02/92	24.00		28.00		28.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.10		0.95		0.90	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	3.10		2.90		2.50	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.66		0.66		0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.26		0.26		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.90		6.70		6.70	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.90		3.50	<	3.70	<
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	205.00		290.00	>	246.00	>
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	105.00		109.00		96.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.30		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.70		0.80	>	0.70	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.80		0.80		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.30		1.30		1.30	
TSH	0-5 (UUI/ML)	01/02/92	2.40					
T4	4.5-13 (UG/DL)	01/02/92	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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 432 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			26/03/92		27/04/92		25/05/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12.5-15 (G/DL)	01/02/92	14.80		14.00		13.00	
HT	38-43 (%)	01/02/92	44.00	>	43.00		43.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4840000	>	4730000	>	4730000	>
WBC	5000-9000 (/MM3)	01/02/92	6800.00		6400.00		7000.00	
WBC: N	50-65 (%)	01/02/92	65.00		58.00		67.00	>
WBC: L	30-40 (%)	01/02/92	31.00		38.00		31.00	
WBC: E	0-3 (%)	01/02/92	2.00		2.00		2.00	
WBC: M	0-5 (%)	01/02/92	2.00		2.00		0.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	240000		205000		190000	
NA+	130-150 (MEQ/L)	01/02/92	137.00		138.00		144.00	
K+	3-5 (MEQ/L)	01/02/92	4.30		4.30		3.90	
CL-	95-105 (MEQ/L)	01/02/92	101.00		110.00	>	107.00	>
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.00		10.20		9.20	
PO4--	2.5-5 (MG/DL)	01/02/92	3.00				2.80	
SGOT	0-12 (MU/ML)	01/02/92	9.00		10.00		6.00	
SGPT	0-12 (MU/ML)	01/02/92	7.00		13.00	>	7.00	
GAMMA GT	4-18 (UI/L)	01/02/92	37.00	>>	10.00		10.00	
LDH	120-240 (UI/L)	01/02/92	200.00		185.00		144.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	24.00		34.00			
GLUCOSE	70-110 (MG/DL)	01/02/92	91.00		95.00		75.00	
UREA	15-40 (MG/DL)	01/02/92	47.00	>	36.00		30.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.10		1.10		1.00	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	6.80	>	5.70		5.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.65		0.75		0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.15		0.15		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.05		6.80		6.90	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.90		3.50	<	3.85	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	275.00	>	268.00	>	255.00	>
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	78.00		118.00		105.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.30		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.70		0.80	>	0.70	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.90		0.80		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.35	>	1.40	>	1.35	>
TSH	0-5 (UUI/ML)	01/02/92	17.00	>>				
T4	4.5-13 (UG/DL)	01/02/92	8.35					

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL RESEARCH - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 434 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			06/04/92		04/05/92		01/06/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12.5-15 (G/DL)	01/02/92	12.90		14.00		14.00	
HT	38-43 (%)	01/02/92	42.00		44.00	>	43.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4620000	>	4840000	>	4730000	>
WBC	5000-9000 (/MM3)	01/02/92	8100.00		7000.00		7100.00	
WBC: N	50-65 (%)	01/02/92	55.00		62.00		68.00	>
WBC: L	30-40 (%)	01/02/92	41.00	>	38.00		30.00	
WBC: E	0-3 (%)	01/02/92	1.00		0.00		2.00	
WBC: M	0-5 (%)	01/02/92	3.00		0.00		0.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	210000		220000		280000	
NA+	130-150 (MEQ/L)	01/02/92	137.00		144.00		139.00	
K+	3-5 (MEQ/L)	01/02/92	4.20		4.10		4.00	
CL-	95-105 (MEQ/L)	01/02/92	105.00		104.00		106.00	>
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.40		9.20		8.90	
PO4--	2.5-5 (MG/DL)	01/02/92	3.20		3.50		3.60	
SGOT	0-12 (MU/ML)	01/02/92	8.00		7.00		7.00	
SGPT	0-12 (MU/ML)	01/02/92	10.00		9.00		10.00	
GAMMA GT	4-18 (UI/L)	01/02/92	10.00		15.00		10.00	
LDH	120-240 (UI/L)	01/02/92	191.00		170.00		144.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	50.00	>				
GLUCOSE	70-110 (MG/DL)	01/02/92	102.00		81.00		77.00	
UREA	15-40 (MG/DL)	01/02/92	41.00	>	35.00		31.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.20		1.25		0.95	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	5.50		6.00	>	3.30	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.70		0.70		0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.10		0.20		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.15		7.20		6.95	
ALBUMINE	3.8-5 (G/DL)	01/02/92	4.00		4.00		3.80	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	288.00	>	275.00	>	245.00	>
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	240.00	>>	155.00	>	160.00	>
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.25		0.30		0.25	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.80	>	0.75		0.65	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.85		0.85		0.85	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.25		1.30		1.40	>
TSH	0-5 (UUI/ML)	01/02/92	2.70					
T4	4.5-13 (UG/DL)	01/02/92	9.12					

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL RESEARCH - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 436 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date	
			Screen	
			20/04/92	
			value	(¢)
Laboratory test	Range value	Range date		
HB	12.5-15 (GR%)	01/04/92	13.60	
HT	38-43 (%)	01/04/92	42.00	
RBC	4000000-4500000 (/MM3)	01/04/92	4230000	
WBC	5000-9000 (/MM3)	01/04/92	5400.00	
WBC: N	50-65 (%)	01/04/92	63.00	
WBC: L	30-40 (%)	01/04/92	31.00	
WBC: E	0-3 (%)	01/04/92	3.00	
WBC: M	0-5 (%)	01/04/92	3.00	
WBC: B	0-1 (%)	01/04/92	0.00	
NA+	130-150 (MEQ/L)	01/04/92	141.00	
K+	3-5 (MEQ/L)	01/04/92	3.90	
CL-	95-105 (MEQ/L)	01/04/92	102.00	
Ca++	8.1-10.4 (MG/DL)	01/04/92	10.00	
PO4--	2.5-5 (MG/DL)	01/04/92	3.80	
SGOT	0-12 (MU/ML)	01/04/92	5.00	
SGPT	0-12 (MU/ML)	01/04/92	4.00	
GAMMA GT	4-18 (UI/L)	01/04/92	10.00	
LDH	120-240 (UI/L)	01/04/92	180.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/04/92	30.00	
GLUCOSE	70-110 (MG/L)	01/04/92	79.00	
UREA	15-40 (MG/DL)	01/04/92	36.00	
CREATININE	0.5-1.4 (MG/DL)	01/04/92	1.30	
URIC ACID	2.4-5.7 (MG/DL)	01/04/92	3.80	
TOT BILIRUBIN	0-1 (MG/DL)	01/04/92	0.36	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/04/92	0.10	
TOT. PROTEINS	6.3-8 (G/DL)	01/04/92	6.82	
ALBUMINE	3.8-5 (G/DL)	01/04/92	4.20	
TOT. CHOLEST.	160-240 (MG/DL)	01/04/92	162.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/04/92	75.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/04/92	0.18	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/04/92	0.55	
GLOBULINS BETA	0.6-1 (G/DL)	01/04/92	0.75	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/04/92	1.11	
TSH	0-5 (UUI/ML)	01/04/92	1.11	
T4	50-115 (NG/ML)	01/04/92	68.20	

(¢) << 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 PHARMACEUTICA S.R.L. - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 438 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			15/05/92		16/06/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)
HB	12.5-15 (G/DL)	01/02/92	14.50		14.00	
HT	38-43 (%)	01/02/92	44.00	>	43.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4840000	>	4730000	>
WBC	5000-9000 (/MM3)	01/02/92	7000.00		6500.00	
WBC: N	50-65 (%)	01/02/92	62.00		61.00	
WBC: L	30-40 (%)	01/02/92	36.00		39.00	
WBC: E	0-3 (%)	01/02/92	0.00		0.00	
WBC: M	0-5 (%)	01/02/92	2.00		0.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	245000		255000	
NA+	130-150 (MEQ/L)	01/02/92	138.00		137.00	
K+	3-5 (MEQ/L)	01/02/92	4.20		4.00	
CL-	95-105 (MEQ/L)	01/02/92	98.00		100.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.80	>	10.00	
PO4--	2.5-5 (MG/DL)	01/02/92	3.80		4.00	
SGOT	0-12 (MU/ML)	01/02/92	13.00	>	7.00	
SGPT	0-12 (MU/ML)	01/02/92	15.00	>	8.00	
GAMMA GT	4-18 (UI/L)	01/02/92	24.00	>	22.00	>
LDH	120-240 (UI/L)	01/02/92	220.00		180.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	50.00	>	25.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	134.00	>	122.00	>
UREA	15-40 (MG/DL)	01/02/92	40.00		38.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.20		1.15	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	5.80	>	3.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.70		0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.80		6.60	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.60	<	3.50	<
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	248.00	>	230.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	115.00		105.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.25		0.25	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.70		0.75	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.85		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40	>	1.30	
TSH	0-5 (UUI/ML)	01/02/92	10.50	>>		
T4	4.5-13 (UG/DL)	01/02/92	7.60			

(¢) << 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
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 439 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			15/05/92		16/06/92		14/07/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12.5-15 (G/DL)	01/02/92	12.90		13.50		13.00	
HT	38-43 (%)	01/02/92	41.00		42.00		40.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4510000	>	4620000	>	4400000	
WBC	5000-9000 (/MM3)	01/02/92	7100.00		6500.00		6900.00	
WBC: N	50-65 (%)	01/02/92	67.00	>	57.00		60.00	
WBC: L	30-40 (%)	01/02/92	31.00		39.00		38.00	
WBC: E	0-3 (%)	01/02/92	2.00		1.00		0.00	
WBC: M	0-5 (%)	01/02/92	0.00		3.00		2.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	220000		240000		260000	
NA+	130-150 (MEQ/L)	01/02/92	139.00		140.00		138.00	
K+	3-5 (MEQ/L)	01/02/92	3.50		4.10		3.90	
CL-	95-105 (MEQ/L)	01/02/92	99.00		107.00	>	102.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.00		11.00	>	10.90	>
PO4--	2.5-5 (MG/DL)	01/02/92	3.50		4.00		3.00	
SGOT	0-12 (MU/ML)	01/02/92	7.00		7.00		8.00	
SGPT	0-12 (MU/ML)	01/02/92	6.00		8.00		7.00	
GAMMA GT	4-18 (UI/L)	01/02/92	15.00		14.00		14.00	
LDH	120-240 (UI/L)	01/02/92	136.00		185.00		144.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	30.00		28.00		33.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	81.00		81.00		90.00	
UREA	15-40 (MG/DL)	01/02/92	42.00	>	40.00		40.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.05		1.18		1.00	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	3.00		3.50		3.20	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.62		0.60		0.55	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.22		0.20		0.25	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.90		6.85		7.05	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.90		3.70	<	4.00	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	279.00	>	240.00		249.00	>
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	105.00		108.00		109.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.35	>	0.25	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.65		0.65		0.60	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.75		0.80		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40	>	1.35	>	1.40	>
TSH	0-5 (UUI/ML)	01/02/92	1.90					
T4	4.5-13 (UG/DL)	01/02/92	7.90					

1097

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (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 PHARMACEUTICAL RESEARCH - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 441 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			13/07/92		17/08/92		14/09/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12.5-15 (G/DL)	01/02/92	13.30		14.00		13.20	
HT	38-43 (%)	01/02/92	40.00		42.00		43.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4400000		4620000	>	4730000	>
WBC	5000-9000 (/MM3)	01/02/92	7100.00		6700.00		6500.00	
WBC: N	50-65 (%)	01/02/92	70.00	>	62.00		60.00	
WBC: L	30-40 (%)	01/02/92	28.00	<	35.00		34.00	
WBC: E	0-3 (%)	01/02/92	0.00		0.00		2.00	
WBC: M	0-5 (%)	01/02/92	2.00		3.00		4.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	240000		265000		280000	
NA+	130-150 (MEQ/L)	01/02/92	139.00		135.00		139.00	
K+	3-5 (MEQ/L)	01/02/92	4.30		4.00		3.80	
CL-	95-105 (MEQ/L)	01/02/92	99.00		100.00		98.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.60	>	9.80		11.00	>
PO4--	2.5-5 (MG/DL)	01/02/92	4.30		3.80		4.50	
SGOT	0-12 (MU/ML)	01/02/92	6.00		8.00		9.00	
SGPT	0-12 (MU/ML)	01/02/92	8.00		10.00		10.00	
GAMMA GT	4-18 (UI/L)	01/02/92	8.00		12.00		8.00	
LDH	120-240 (UI/L)	01/02/92	190.00		177.00		166.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	24.00		28.00		33.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	82.00		91.00		82.00	
UREA	15-40 (MG/DL)	01/02/92	43.00	>	30.00		30.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.00		0.92		1.09	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	4.00		5.20		3.90	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.60		0.70		0.65	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.20		0.25	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.05		6.95		6.90	
ALBUMINE	3.8-5 (G/DL)	01/02/92	4.00		4.05		3.80	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	216.00		205.00		205.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	85.00		90.00		105.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.25		0.20		0.25	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.60		0.55		0.65	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.80		0.80		0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40	>	1.35	>	1.40	>
TSH	0-5 (UUI/ML)	01/02/92	0.60					
T4	4.5-13 (UG/DL)	01/02/92	4.70					

(¢) << 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 PHARMACEUTICAL RESEARCH - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 443 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			20/08/92		21/09/92		19/10/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	13.5-15.5 (G/DL)	01/02/92	14.80		14.20		15.00	
HT	40-45 (%)	01/02/92	45.00		44.00		45.00	
RBC	4200000-4800000 (/MM3)	01/02/92	4950000	>	4980000	>	4950000	>
WBC	5000-9000 (/MM3)	01/02/92	6500.00		6800.00		7000.00	
WBC: N	50-65 (%)	01/02/92	61.00		59.00		71.00	>
WBC: L	30-40 (%)	01/02/92	39.00		37.00		29.00	<
WBC: E	0-3 (%)	01/02/92	0.00		2.00		0.00	
WBC: M	0-5 (%)	01/02/92	0.00		2.00		0.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	260000		255000		220000	
NA+	130-150 (MEQ/L)	01/02/92	141.00		138.00		144.00	
K+	3-5 (MEQ/L)	01/02/92	4.10		4.00		4.50	
CL-	95-105 (MEQ/L)	01/02/92	98.00		99.00		98.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	9.30		9.90		10.50	>
PO4--	2.5-5 (MG/DL)	01/02/92	3.90		4.00		4.00	
SGOT	0-12 (MU/ML)	01/02/92	6.00		8.00		7.00	
SGPT	0-12 (MU/ML)	01/02/92	6.00		6.00		8.00	
GAMMA GT	6-28 (UI/L)	01/02/92	12.00		14.00		8.00	
LDH	120-240 (UI/L)	01/02/92	144.00		180.00		155.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	35.00		38.00		38.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	79.00		89.00		81.00	
UREA	15-40 (MG/DL)	01/02/92	31.00		33.00		28.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.00		1.05		1.00	
URIC ACID	3.4-7 (MG/DL)	01/02/92	4.00		4.10		4.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.60		0.65		0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.25		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.00		7.25		7.35	
ALBUMINE	3.8-5 (G/DL)	01/02/92	4,00		4.20		4.30	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	202.00		212.00		220.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	100.00		108.00		110.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.20		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.65		0.65		0.70	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.80		0.80		0.85	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.35	>	1.40	>	1.30	
TSH	0-5 (UUI/ML)	01/02/92	0.90					
T4	4.5-13 (UG/DL)	01/02/92	5.60					

1099

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL [illegible] CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 446 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 56	
			12/09/92		12/11/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)
HB	12.5-15 (G/DL)	01/02/92	15.00		14.00	
HT	38-43 (%)	01/02/92	44.00	>	43.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4840000	>	4730000	>
WBC	5000-9000 (/MM3)	01/02/92	6500.00		7000.00	
WBC: N	50-65 (%)	01/02/92	65.00		61.00	
WBC: L	30-40 (%)	01/02/92	31.00		36.00	
WBC: E	0-3 (%)	01/02/92	2.00		1.00	
WBC: M	0-5 (%)	01/02/92	2.00		2.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	270000		260000	
NA+	130-150 (MEQ/L)	01/02/92	144.00		145.00	
K+	3-5 (MEQ/L)	01/02/92	4.00		3.90	
CL-	95-105 (MEQ/L)	01/02/92	101.00		100.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.90	>	10.50	>
PO4--	2.5-5 (MG/DL)	01/02/92	3.90		4.00	
SGOT	0-12 (MU/ML)	01/02/92	8.00		7.00	
SGPT	0-12 (MU/ML)	01/02/92	7.00		8.00	
GAMMA GT	4-18 (UI/L)	01/02/92	13.00		9.00	
LDH	120-240 (UI/L)	01/02/92	180.00		144.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	30.00		35.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	73.00		80.00	
UREA	15-40 (MG/DL)	01/02/92	33.00		30.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.00		1.05	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	3.50		4.10	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.70		0.65	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.25	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.05		6.80	
ALBUMINE	3.8-5 (G/DL)	01/02/92	4.00		3.80	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	222.00		225.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	110.00		108.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.60		0.60	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.80		0.85	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.45	>	1.35	>
TSH	0-5 (UUI/ML)	01/02/92	0.90			
T4	4.5-13 (UG/DL)	01/02/92	8.00			

1100

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 447 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date			
			Screen		Day 56	
			12/09/92		12/11/92	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	13.5-15.5 (G/DL)	01/02/92	15.00		15.00	
HT	40-45 (%)	01/02/92	45.00		47.00	>
RBC	4200000-4800000 (/MM3)	01/02/92	4950000	>	5170000	>
WBC	5000-9000 (/MM3)	01/02/92	6900.00		7000.00	
WBC: N	50-65 (%)	01/02/92	60.00		62.00	
WBC: L	30-40 (%)	01/02/92	40.00		34.00	
WBC: E	0-3 (%)	01/02/92	0.00		3.00	
WBC: M	0-5 (%)	01/02/92	0.00		1.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	210000		270000	
NA+	130-150 (MEQ/L)	01/02/92	139.00		135.00	
K+	3-5 (MEQ/L)	01/02/92	4.00		3.90	
CL-	95-105 (MEQ/L)	01/02/92	100.00		99.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	9.00		10.00	
PO4--	2.5-5 (MG/DL)	01/02/92	3.80		3.80	
SGOT	0-12 (MU/ML)	01/02/92	6.00		6.00	
SGPT	0-12 (MU/ML)	01/02/92	8.00		8.00	
GAMMA GT	6-28 (UI/L)	01/02/92	9.00		18.00	
LDH	120-240 (UI/L)	01/02/92	144.00		145.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	33.00		31.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	85.00		88.00	
UREA	15-40 (MG/DL)	01/02/92	30.00		31.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.05		1.09	
URIC ACID	3.4-7 (MG/DL)	01/02/92	3.90		3.50	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.65		0.65	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.15		7.40	
ALBUMINE	3.8-5 (G/DL)	01/02/92	4.20		4.20	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	235.00		225.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	88.00		100.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.60		0.70	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.85		0.85	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40	>	1.45	>
TSH	0-5 (UUI/ML)	01/02/92	1.20			
T4	4.5-13 (UG/DL)	01/02/92	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

PHARMACIA PHARMACEUTICAL RESEARCH - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 455 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			14/09/92		16/10/92		13/11/92	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	12.5-15 (G/DL)	01/02/92	13.00		13.10		14.80	
HT	38-43 (%)	01/02/92	42.00		43.00		41.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4620000	>	4730000	>	4510000	>
WBC	5000-9000 (/MM3)	01/02/92	6700.00		7100.00		6000.00	
WBC: N	50-65 (%)	01/02/92	68.00	>	67.00	>	71.00	>
WBC: L	30-40 (%)	01/02/92	30.00		30.00		29.00	<
WBC: E	0-3 (%)	01/02/92	2.00		2.00		0.00	
WBC: M	0-5 (%)	01/02/92	0.00		1.00		0.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	240000		290000		210000	
NA+	130-150 (MEQ/L)	01/02/92	142.00		140.00		138.00	
K+	3-5 (MEQ/L)	01/02/92	3.90		4.00		3.80	
CL-	95-105 (MEQ/L)	01/02/92	110.00	>	110.00	>		
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.50	>	11.00	>	10.60	>
PO4--	2.5-5 (MG/DL)	01/02/92	3.90		4.00		3.80	
SGOT	0-12 (MU/ML)	01/02/92	5.00		6.00		6.00	
SGPT	0-12 (MU/ML)	01/02/92	7.00		8.00		9.00	
GAMMA GT	4-18 (UI/L)	01/02/92	10.00		12.00		8.00	
LDH	120-240 (UI/L)	01/02/92	210.00		220.00		202.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	28.00		33.00		16.00	<
GLUCOSE	70-110 (MG/DL)	01/02/92	77.00		80.00		70.00	
UREA	15-40 (MG/DL)	01/02/92	25.00		22.00		21.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	0.95		0.99		0.80	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	5.10		3.90		5.00	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.80		0.60		0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.25		0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.20		7.15		7.00	
ALBUMINE	3.8-5 (G/DL)	01/02/92	4.10		4.00		4.00	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	195.00		205.00		192.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	105.00		98.00		120.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.25		0.25		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.60		0.70		0.65	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.90		0.85		0.85	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.35	>	1.35	>	1.30	

(◊) << 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 PHARMACEUTICAL MILANO - CNS 9590083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 457 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			09/12/92		12/01/93		09/02/93	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12.5-15 (G/DL)	01/02/92	12.90		12.30	<	12.50	
HT	38-43 (%)	01/02/92	42.00		38.00		39.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4620000	>	4180000		4290000	
WBC	5000-9000 (/MM3)	01/02/92	5200.00		7400.00		7000.00	
WBC: N	50-65 (%)	01/02/92	60.00		60.00		62.00	
WBC: L	30-40 (%)	01/02/92	38.00		35.00		34.00	
WBC: E	0-3 (%)	01/02/92	0.00		3.00		3.00	
WBC: M	0-5 (%)	01/02/92	2.00		2.00		1.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	210000		215000		220000	
NA+	130-150 (MEQ/L)	01/02/92	138.00		141.00		140.00	
K+	3-5 (MEQ/L)	01/02/92	4.20		4.20		3.80	
CL-	95-105 (MEQ/L)	01/02/92	101.00		99.00		99.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.40		10.30		10.00	
PO4--	2.5-5 (MG/DL)	01/02/92	3.70		4.10		4.10	
SGOT	0-12 (MU/ML)	01/02/92	6.00		7.00		9.00	
SGPT	0-12 (MU/ML)	01/02/92	8.00		8.00		6.00	
GAMMA GT	4-18 (UI/L)	01/02/92	8.00		10.00		9.00	
LDH	120-240 (UI/L)	01/02/92	220.00		192.00		193.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	24.00		30.00		30.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	76.00		92.00		90.00	
UREA	15-40 (MG/DL)	01/02/92	36.00		28.00		31.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.10		1.10		1.05	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	3.50		3.90		3.90	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.70		0.60		0.65	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.10		0.15	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.50		6.70		6.90	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.65	<	3.80		3.95	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	252.00	>	174.00		192.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	88.00		100.00		105.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.25		0.20		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.60		0.60		0.65	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.70		0.75		0.75	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.30		1.35	>	1.35	>
TSH	0-5 (UUI/ML)	01/02/92	1.34					
T4	4.5-13 (UG/DL)	01/02/92	8.87					

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 458 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			09/12/92		12/01/93		09/02/93	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	12.5-15 (G/DL)	01/02/92	12.00	<	13.50		14.00	
HT	38-43 (%)	01/02/92	42.00		41.00		43.00	
RBC	4000000-4500000 (/MM3)	01/02/92	4620000	>	4510000	>	4730000	>
WBC	5000-9000 (/MM3)	01/02/92	6200.00		7500.00		8100.00	
WBC: N	50-65 (%)	01/02/92	69.00	>	65.00		64.00	
WBC: L	30-40 (%)	01/02/92	28.00	<	31.00		31.00	
WBC: E	0-3 (%)	01/02/92	1.00		0.00		2.00	
WBC: M	0-5 (%)	01/02/92	2.00		4.00		3.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000 (/MM3)	01/02/92	210000		215000		230000	
NA+	130-150 (MEQ/L)	01/02/92	138.00		138.00		138.00	
K+	3-5 (MEQ/L)	01/02/92	4.20		3.90		3.90	
CL-	95-105 (MEQ/L)	01/02/92	100.00		101.00		99.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.00		9.80		10.00	
PO4--	2.5-5 (MG/DL)	01/02/92	3.90		4.10		4.20	
SGOT	0-12 (MU/ML)	01/02/92	6.00		7.00		7.00	
SGPT	0-12 (MU/ML)	01/02/92	8.00		8.00		5.00	
GAMMA GT	4-18 (UI/L)	01/02/92	12.00		9.00		10.00	
LDH	120-240 (UI/L)	01/02/92	190.00		201.00		196.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	36.00		26.00		31.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	105.00		95.00		99.00	
UREA	15-40 (MG/DL)	01/02/92	44.00	>	34.00		38.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.20		1.10		0.98	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	6.80	>	4.30		4.10	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.70		0.70		0.65	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.20		0.15	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.75		7.07		7.00	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.70	<	4.05		4.00	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	285.00	>	205.00		220.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	146.00		98.00		101.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.15		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.65		0.65		0.65	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.80		0.80		0.75	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40	>	1.42	>	1.40	>
TSH	0-5 (UUI/ML)	01/02/92	2.50					
T4	4.5-13 (UG/DL)	01/02/92	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
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 25 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			30/09/92		03/11/92		01/12/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	01/09/92	13.60		13.80		13.70	
HT	35-47 (%)	01/09/92	39.00		43.00		42.00	
RBC	3.8-5.2 (10¬6/MM3)	01/09/92	4.50		4.70		4.60	
WBC	4000-10000 (/MM3)	01/09/92	5400.00		5500.00		6900.00	
WBC: N	50-70 (%)	01/09/92	60.00		60.00		50.00	
WBC: L	30-40 (%)	01/09/92	34.00		32.00		42.00	>
WBC: E	0-4 (%)	01/09/92	1.00		1.00		1.00	
WBC: M	0-8 (%)	01/09/92	3.00		5.00		5.00	
WBC: B	0-2 (%)	01/09/92	1.00		1.00		1.00	
PLATELETS	200-300 (10¬3/MM3)	01/09/92	272.00		261.00		256.00	
NA+	135-144 (MMOL/L)	01/09/92	137.00		139.00		144.00	
K+	3.6-5.6 (MMOL/L)	01/09/92	5.10		4.90		5.20	
CL-	95-108 (MMOL/L)	01/09/92	103.00		101.00			
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.31		2.32		2.45	
PO4--	0.81-1.45 (MMOL/L)	01/09/92	1.07		1.37		1.55	>
SGOT	0-15 (U/L)	01/09/92	13.00		9.00		10.00	
SGPT	0-17 (U/L)	01/09/92	9.00		8.00		8.00	
GAMMA GT	4-18 (U/L)	01/09/92	10.00		10.00		9.00	
LDH	120-240 (U/L)	01/09/92	229.00		220.00		219.00	
ALK. PHOSPH.	60-200 (U/L)	01/09/92	107.00		105.00		116.00	
GLUCOSE	60-110 (MG/DL)	01/09/92	65.00		64.00		63.00	
BUN	4-50 (MG/DL)	01/09/92	30.00		27.00		32.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	0.99		0.99		1.04	
URIC ACID	2.5-6 (MG/DL)	01/09/92	6.10	>	6.10	>	6.10	>
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.50		0.47		0.37	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	6.80		6.70		6.70	
ALBUMINE	58.8-69.6 (%)	01/09/92	65.70		64.50		66.20	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	252.00	>	284.00	>	284.00	>
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	94.00		129.00		172.00	>
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	3.10		3.10		3.10	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	8.40		9.30		9.00	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	13.30		13.40		13.00	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	9.60		9.70		8.70	
TSH	0.2-5 (UU/ML)	01/09/92	0.70					

1105

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL RTI AND - CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 28 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			30/09/92		03/11/92	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	12-16 (G/DL)	01/09/92	14.70		13.90	
HT	35-47 (%)	01/09/92	41.00		41.00	
RBC	3.8-5.2 (10¬6/MM3)	01/09/92	4.80		4.70	
WBC	4000-10000 (/MM3)	01/09/92	5200.00		5200.00	
WBC: N	50-70 (%)	01/09/92	70.00		73.00	>
WBC: L	30-40 (%)	01/09/92	25.00	<	18.00	<<
WBC: E	0-4 (%)	01/09/92	2.00		1.00	
WBC: M	0-8 (%)	01/09/92	2.00		5.00	
WBC: B	0-2 (%)	01/09/92	1.00		1.00	
PLATELETS	200-300 (10¬3/MM3)	01/09/92	242.00		247.00	
NA+	135-144 (MMOL/L)	01/09/92	135.00		139.00	
K+	3.6-5.6 (MMOL/L)	01/09/92	4.70		3.70	
CL-	95-108 (MMOL/L)	01/09/92	100.00		102.00	
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.44		2.35	
PO4--	0.81-1.45 (MMOL/L)	01/09/92	0.87		0.85	
SGOT	0-15 (U/L)	01/09/92	7.00		9.00	
SGPT	0-17 (U/L)	01/09/92	6.00		10.00	
GAMMA GT	4-18 (U/L)	01/09/92	28.00	>	35.00	>
LDH	120-240 (U/L)	01/09/92	193.00		143.00	
ALK. PHOSPH.	60-200 (U/L)	01/09/92	96.00		101.00	
GLUCOSE	60-110 (MG/DL)	01/09/92	67.00		92.00	
BUN	4-50 (MG/DL)	01/09/92	40.00		30.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	1.00		1.10	
URIC ACID	2.5-6 (MG/DL)	01/09/92	6.00		5.40	
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.65		0.85	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	7.10		7.00	
ALBUMINE	58.8-69.6 (%)	01/09/92	63.60		69.20	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	240.00	>	258.00	>
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	117.00		154.00	
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	2.70		2.30	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	8.60		7.30	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	12.00		11.10	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	13.10		10.10	
TSH	0.2-5 (UU/ML)	01/09/92	0.80			

(¢) << 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 PHARMACEUTICAL MILANO 9550083 CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 30 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			30/09/92		04/11/92		01/12/92	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/09/92	14.70		13.40		11.40	<
HT	35-47 (%)	01/09/92	42.00		39.00		36.00	
RBC	3.8-5.2 (10¬6/MM3)	01/09/92	5.00		4.60		4.00	
WBC	4000-10000 (/MM3)	01/09/92	5600.00		5900.00		6800.00	
WBC: N	50-70 (%)	01/09/92	61.00		65.00		68.00	
WBC: L	30-40 (%)	01/09/92	30.00		24.00	<	21.00	<
WBC: E	0-4 (%)	01/09/92	2.00		2.00		2.00	
WBC: M	0-8 (%)	01/09/92	5.00		6.00		7.00	
WBC: B	0-2 (%)	01/09/92	1.00		1.00		1.00	
PLATELETS	200-300 (10¬3/MM3)	01/09/92	386.00	>	403.00	>>	437.00	>>
NA+	135-144 (MMOL/L)	01/09/92	134.00	<	138.00		143.00	
K+	3.6-5.6 (MMOL/L)	01/09/92	4.70		4.70		4.10	
CL-	95-108 (MMOL/L)	01/09/92	101.00		105.00		106.00	
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.37		2.24		2.44	
PO4--	0.81-1.45 (MMOL/L)	01/09/92	1.19		1.25		1.58	>
SGOT	0-15 (U/L)	01/09/92	12.00		7.00		9.00	
SGPT	0-17 (U/L)	01/09/92	15.00		9.00		12.00	
GAMMA GT	4-18 (U/L)	01/09/92	23.00	>	19.00	>	16.00	
LDH	120-240 (U/L)	01/09/92	178.00		169.00		173.00	
ALK. PHOSPH.	60-200 (U/L)	01/09/92	251.00	>	256.00	>	247.00	>
GLUCOSE	60-110 (MG/DL)	01/09/92	68.00		74.00		60.00	
BUN	4-50 (MG/DL)	01/09/92	37.00		31.00		37.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	1.06		1.02		0.99	
URIC ACID	2.5-6 (MG/DL)	01/09/92	5.40		5.30		4.40	
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.64		0.47		0.16	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	7.20		7.00		6.80	
ALBUMINE	58.8-69.6 (%)	01/09/92	60.80		64.80		65.40	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	213.00		200.00		209.00	
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	89.00		65.00		343.00	>>
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	3.50		3.10		3.00	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	8.50		8.40		7.40	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	12.40		11.30		11.40	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	14.80		12.40		12.80	
TSH	0.2-5 (UU/ML)	01/09/92	1.10					

(¢) << 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 PHARMACEUTICAL MILANO CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 32 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			05/10/92		04/11/92		01/12/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	01/09/92	15.00		12.40		14.40	
HT	35-47 (%)	01/09/92	44.00		40.00		42.00	
RBC	3.8-5.2 (10¬6/MM3)	01/09/92	4.70		4.40		4.50	
WBC	4000-10000 (/MM3)	01/09/92	7000.00		7200.00		6700.00	
WBC: N	50-70 (%)	01/09/92	64.00		63.00		67.00	
WBC: L	30-40 (%)	01/09/92	29.00	<	28.00	<	25.00	<
WBC: E	0-4 (%)	01/09/92	1.00		1.00		1.00	
WBC: M	0-8 (%)	01/09/92	4.00		6.00		5.00	
WBC: B	0-2 (%)	01/09/92	1.00		1.00		1.00	
PLATELETS	200-300 (10¬3/MM3)	01/09/92	286.00		132.00	<<	264.00	
NA+	135-144 (MMOL/L)	01/09/92	132.00	<	139.00		142.00	
K+	3.6-5.6 (MMOL/L)	01/09/92	3.80		4.00		3.70	
CL-	95-108 (MMOL/L)	01/09/92	98.00		103.00		102.00	
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.39		2.42		2.56	
PO4--	0.81-1.45 (MMOL/L)	01/09/92	3.60	>>	1.01		1.22	
SGOT	0-15 (U/L)	01/09/92	7.00		7.00		10.00	
SGPT	0-17 (U/L)	01/09/92	5.00		4.00		8.00	
GAMMA GT	4-18 (U/L)	01/09/92	19.00	>	9.00		9.00	
LDH	120-240 (U/L)	01/09/92	129.00		142.00		162.00	
ALK. PHOSPH.	60-200 (U/L)	01/09/92	69.00		67.00		84.00	
GLUCOSE	60-110 (MG/DL)	01/09/92	68.00		91.00		107.00	
BUN	4-50 (MG/DL)	01/09/92	26.00		25.00		22.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	0.95		0.92		0.98	
URIC ACID	2.5-6 (MG/DL)	01/09/92	4.00		3.00		3.60	
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.79		0.31		0.47	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	6.90		7.10		7.50	
ALBUMINE	58.8-69.6 (%)	01/09/92	64.20		67.60		64.00	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	223.00	>	232.00	>	241.00	>
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	103.00		59.00		91.00	
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	3.50		3.60		3.20	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	8.20		7.80		7.70	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	12.60		11.30		13.40	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	11.60		9.70		11.70	
TSH	0.2-5 (UU/ML)	01/09/92	1.30					
T4	4-13 (UG/DL)	01/09/92	8.20					

1108

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO CNS 3550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 51 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			10/11/92		15/12/92		12/01/93	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	01/09/92	12.40		12.50		11.70	<
HT	35-47 (%)	01/09/92	38.00		36.00		34.00	<
RBC	3.8-5.2 (10-6/MM3)	01/09/92	4.00		4.00		3.70	<
WBC	4000-10000 (/MM3)	01/09/92	10210.0	>	6100.00		6100.00	
WBC: N	50-70 (%)	01/09/92	65.00		64.00		57.00	
WBC: L	30-40 (%)	01/09/92	29.00	<	28.00	<	36.00	
WBC: E	0-4 (%)	01/09/92	1.00		1.00		1.00	
WBC: M	0-8 (%)	01/09/92	4.00		6.00		4.00	
WBC: B	0-2 (%)	01/09/92	0.00		0.00		0.00	
PLATELETS	200-300 (10-3/MM3)	01/09/92	338.00	>	311.00	>	263.00	
NA+	135-144 (MMOL/L)	01/09/92	135.00		136.00		130.00	<
K+	3.6-5.6 (MMOL/L)	01/09/92	4.30		3.80		3.70	
CL-	95-108 (MMOL/L)	01/09/92	99.00		101.00		95.00	
Ca++	2.1-2.6 (MMOL/L)	01/09/92			2.40		2.30	
PO4--	0.81-1.45 (MMOL/L)	01/09/92	1.29		1.01		1.10	
SGOT	0-15 (U/L)	01/09/92	7.00		6.00		5.00	
SGPT	0-17 (U/L)	01/09/92	8.00		8.00		8.00	
GAMMA GT	4-18 (U/L)	01/09/92	5.00		6.00		5.00	
LDH	120-240 (U/L)	01/09/92	169.00		122.00		109.00	<
ALK. PHOSPH.	60-200 (U/L)	01/09/92	62.00		65.00		54.00	<
GLUCOSE	60-110 (MG/DL)	01/09/92	85.00		92.00		105.00	
BUN	4-50 (MG/DL)	01/09/92	44.00		37.00		47.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	0.86		0.84		0.85	
URIC ACID	2.5-6 (MG/DL)	01/09/92	3.50		4.10		3.30	
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.10		0.43		0.18	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	7.60		7.10		7.00	
ALBUMINE	58.8-69.6 (%)	01/09/92	66.10		62.30		63.30	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	268.00	>	234.00	>	250.00	>
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	139.00		68.00		102.00	
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	3.40		3.30		3.90	>
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	8.60		9.40		9.10	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	9.50		11.00		10.30	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	12.40		14.10		13.40	
TSH	0.2-5 (UU/ML)	01/09/92	0.60					
T4	4-13 (UG/DL)	01/09/92	8.80					

(¢) << 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
xx missing laboratory test value nd laboratory not done () missing range value

PHARMACIA PHARMACEUTICAL RESEARCH CNS 3550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 52 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			10/11/92		15/12/92		12/01/93	
Laboratory test	Range value	Range date	value	(◊)	value	(◊)	value	(◊)
HB	12-16 (G/DL)	01/09/92	14.60		14.30		14.30	
HT	35-47 (%)	01/09/92	42.00		41.00		40.00	
RBC	3.8-5.2 (10-6/MM3)	01/09/92	4.50		4.30		4.40	
WBC	4000-10000 (/MM3)	01/09/92	3500.00	<	3100.00	<	3600.00	<
WBC: N	50-70 (%)	01/09/92	56.00		46.00	<	53.00	
WBC: L	30-40 (%)	01/09/92	35.00		43.00	>	35.00	
WBC: E	0-4 (%)	01/09/92	2.00		1.00		2.00	
WBC: M	0-8 (%)	01/09/92	6.00		6.00		7.00	
WBC: B	0-2 (%)	01/09/92	1.00		1.00		1.00	
PLATELETS	200-300 (10-3/MM3)	01/09/92	245.00		268.00		252.00	
NA+	135-144 (MMOL/L)	01/09/92	140.00		136.00		131.00	<
K+	3.6-5.6 (MMOL/L)	01/09/92	4.50		4.20		3.90	
CL-	95-108 (MMOL/L)	01/09/92	103.00		100.00		94.00	<
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.27		2.37		2.27	
PO4--	0.81-1.45 (MMOL/L)	01/09/92	1.30		1.15		1.09	
SGOT	0-15 (U/L)	01/09/92	8.00		7.00		7.00	
SGPT	0-17 (U/L)	01/09/92	9.00		11.00		11.00	
GAMMA GT	4-18 (U/L)	01/09/92	16.00		15.00		16.00	
LDH	120-240 (U/L)	01/09/92	164.00		150.00		150.00	
ALK. PHOSPH.	60-200 (U/L)	01/09/92	95.00		108.00		104.00	
GLUCOSE	60-110 (MG/DL)	01/09/92	80.00		81.00		86.00	
BUN	4-50 (MG/DL)	01/09/92	19.00		25.00		29.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	0.99		1.00		1.06	
URIC ACID	2.5-6 (MG/DL)	01/09/92	3.30		3.90		4.20	
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.50		0.40		0.38	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	7.00		6.60		7.00	
ALBUMINE	58.8-69.6 (%)	01/09/92	62.80		63.00		63.10	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	232.00	>	225.00	>	243.00	>
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	74.00		81.00		80.00	
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	2.60		3.00		2.50	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	8.90		9.10		9.40	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	12.70		12.70		12.00	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	12.90		12.10		12.90	
TSH	0.2-5 (UU/ML)	01/09/92	0.80					
T4	4-13 (UG/DL)	01/09/92	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 PHARMACEUTICAL MILANO - CNS

3550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centro: 18 Patient: 53 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			29/12/92		12/02/93		15/03/93	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	01/09/92	15.30		15.20		14.20	
HT	35-47 (%)	01/09/92	45.00		46.00		47.00	
RBC	3.8-5.2 (10-6/MM3)	01/09/92	5.10		5.10		4.90	
WBC	4000-10000 (/MM3)	01/09/92	6900.00		6400.00		6700.00	
WBC: N	50-70 (%)	01/09/92	56.00		64.00		62.00	
WBC: L	30-40 (%)	01/09/92	29.00	<	21.00	<	27.00	<
WBC: E	0-4 (%)	01/09/92	3.00		2.00		1.00	
WBC: M	0-8 (%)	01/09/92	9.00	>	10.00	>	8.00	
WBC: B	0-2 (%)	01/09/92	1.00		2.00		1.00	
PLATELETS	200-300 (10-3/MM3)	01/09/92	442.00	>>	313.00	>	337.00	>
NA+	135-144 (MMOL/L)	01/09/92	135.00		119.00	<<	129.00	<
K+	3.6-5.6 (MMOL/L)	01/09/92	4.10					
CL-	95-108 (MMOL/L)	01/09/92	100.00		96.00		86.00	<
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.27		2.35		2.33	
PO4--	0.81-1.45 (MMOL/L)	01/09/92	1.25		1.64	>	4.20	>>
SGOT	0-15 (U/L)	01/09/92	8.00		14.00		19.00	>
SGPT	0-17 (U/L)	01/09/92	14.00		21.00	>	19.00	>
GAMMA GT	4-18 (U/L)	01/09/92	25.00	>	22.00	>	26.00	>
LDH	120-240 (U/L)	01/09/92	168.00		502.00	>>		
ALK. PHOSPH.	60-200 (U/L)	01/09/92	107.00		94.00		97.00	
GLUCOSE	60-110 (MG/DL)	01/09/92	85.00		71.00		55.00	<
BUN	4-50 (MG/DL)	01/09/92	21.00		19.00		18.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	0.81		0.89		0.96	
URIC ACID	2.5-6 (MG/DL)	01/09/92	3.50		3.70		3.50	
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.19		0.33		0.47	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	6.90		6.90			
ALBUMINE	58.8-69.6 (%)	01/09/92	61.80		59.40		64.10	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	247.00	>	244.00	>	261.00	>
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	145.00		127.00		87.00	
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	3.00		3.30		3.00	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	9.80		10.50		8.10	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	13.30		13.30		11.90	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	12.00		13.50		13.00	
TSH	0.2-5 (UU/ML)	01/09/92	1.10					

1111

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL [illegible] CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 54 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date					
			Screen		Day 28		Day 56	
			05/01/93		09/02/93		09/03/93	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)
HB	12-16 (G/DL)	01/09/92	15.80		15.70		15.90	
HT	35-47 (%)	01/09/92	46.00		46.00		45.00	
RBC	3.8-5.2 (10¬6/MM3)	01/09/92	5.10		5.00		4.80	
WBC	4000-10000 (/MM3)	01/09/92	7100.00		7200.00		6800.00	
WBC: N	50-70 (%)	01/09/92	60.00		63.00		54.00	
WBC: L	30-40 (%)	01/09/92	31.00		26.00	<	35.00	
WBC: E	0-4 (%)	01/09/92	1.00		1.00		1.00	
WBC: M	0-8 (%)	01/09/92	6.00		7.00		7.00	
WBC: B	0-2 (%)	01/09/92	1.00		1.00		1.00	
PLATELETS	200-300 (10¬3/MM3)	01/09/92	239.00		229.00		255.00	
NA+	135-144 (MMOL/L)	01/09/92	141.00		134.00	<	139.00	
K+	3.6-5.6 (MMOL/L)	01/09/92	4.90		4.50		5.00	
CL-	95-108 (MMOL/L)	01/09/92	103.00		95.00		99.00	
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.30		2.35		2.29	
PO4--	0.81-1.45 (MMOL/L)	01/09/92	1.31		1.41		1.42	
SGOT	0-15 (U/L)	01/09/92	13.00		8.00		7.00	
SGPT	0-17 (U/L)	01/09/92	10.00		7.00		5.00	
GAMMA GT	4-18 (U/L)	01/09/92	33.00	>	18.00		16.00	
LDH	120-240 (U/L)	01/09/92	122.00		126.00		129.00	
ALK. PHOSPH.	60-200 (U/L)	01/09/92	163.00		173.00		162.00	
GLUCOSE	60-110 (MG/DL)	01/09/92	94.00		96.00		75.00	
BUN	4-50 (MG/DL)	01/09/92	39.00		34.00		48.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	1.30		1.30		1.26	
URIC ACID	2.5-6 (MG/DL)	01/09/92	8.30	>>	5.60		6.10	>
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.53		0.63		0.45	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	6.60		6.60		6.50	
ALBUMINE	58.8-69.6 (%)	01/09/92	65.20		64.10		63.60	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	246.00	>	211.00		229.00	>
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	88.00		76.00		88.00	
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	2.60		3.20		3.20	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	9.10		9.50		10.20	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	10.60		11.20		10.70	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	12.50		11.90		12.30	
TSH	0.2-5 (UU/ML)	01/09/92	0.90					

(¢) << 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 PHARMACEUTICAL MILANO - CNS 3550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 20 Patient: 21 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 56	
			30/10/92		06/01/93	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)
HB	13.5-18 (G/DL)	01/01/92	13.30	<	13.50	
HT	36-48 (%)	01/01/92	38.80			
RBC	4-5.5 (10-6/UL)	01/01/92			4.66	
WBC	5-9 (10-3/MM3)	01/01/92			5.10	
WBC: L	25-45 (%)	01/01/92	37.00			
WBC: E	0-4 (%)	01/01/92	1.00			
WBC: M	0-8 (%)	01/01/92	1.00			
WBC: B	0-2 (%)	01/01/92	0.00			
NA+	135-154 (MMOL/L)	01/01/92	140.00		143.00	
K+	3.6-5.4 (MMOL/L)	01/01/92	5.59	>		
CL-	97-108 (MMOL/L)	01/01/92			98.00	
Ca++	2.25-2.75 (MMOL/L)	01/01/92	2.34		2.46	
PO4--	0.8-1.53 (MMOL/L)	01/01/92			1.02	
SGOT	0-15 (U/L)	01/01/92	11.00		11.00	
SGPT	0-18 (U/L)	01/01/92	11.00		12.00	
GAMMA GT	4-18 (U/L)	01/01/92	19.00	>	10.00	
LDH	120-240 (U/L)	01/01/92	111.00	<	191.00	
ALK. PHOSPH.	70-175 (U/L)	01/01/92	105.00		117.00	
GLUCOSE	70-95 (MG/DL)	01/01/92	74.00		38.00	<<
BUN	10-50 (MG/DL)	01/01/92			51.00	>
CREATININE	0.5-1.5 (MG/DL)	01/01/92	0.99		1.14	
URIC ACID	2-7 (MG/DL)	01/01/92	1.82	<	3.64	
TOT BILIRUBIN	0-1 (MG/DL)	01/01/92	0.85		0.50	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/01/92			0.04	
TOT. PROTEINS	6.5-8 (G/DL)	01/01/92	7.63		7.39	
ALBUMINE	56-68 (%)	01/01/92	62.90		54.60	<
TOT. CHOLEST.	150-200 (MG/DL)	01/01/92	208.00	>	341.00	>>
TRIGLYCERIDES	75-180 (MG/DL)	01/01/92	72.00	<	96.00	
GLOBULINS ALPHA 1	2-5 (%)	01/01/92	3.10		2.90	
GLOBULINS ALPHA 2	6-10 (%)	01/01/92	6.90		7.80	
GLOBULINS BETA	8-14 (%)	01/01/92	10.80		11.20	
GLOBULINS GAMMA	9-19 (%)	01/01/92	16.20		23.50	>
TSH	0.2-4 (UU/ML)	01/01/92	1.35			
T4	0.8-2 (NG/DL)	01/01/92	8.06	>>		

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL RESEARCH CNS 9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 20 Patient: 22 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date			
			Screen		Day 28	
			10/11/92		14/12/92	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	13.5-18 (G/DL)	01/01/92	14.50		14.80	
HT	36-48 (%)	01/01/92	41.70		42.10	
RBC	4-5.5 (10~6/UL)	01/01/92	4.39		4.36	
WBC	5-9 (10~3/MM3)	01/01/92	16.50	>>	6.20	
WBC: N	50-75 (%)	01/01/92	82.10	>	52.60	
WBC: L	25-45 (%)	01/01/92	12.40	<<	38.50	
WBC: E	0-4 (%)	01/01/92	0.90		2.80	
WBC: M	0-8 (%)	01/01/92	3.60		5.40	
WBC: B	0-2 (%)	01/01/92	1.00		0.70	
PLATELETS	140-380 (10~3/UL)	01/01/92	334.00		249.00	
NA+	135-154 (MMOL/L)	01/01/92	155.00	>	143.00	
K+	3.6-5.4 (MMOL/L)	01/01/92	4.94			
CL-	97-108 (MMOL/L)	01/01/92	94.40	<	102.00	
Ca++	2.25-2.75 (MMOL/L)	01/01/92	2.65		2.52	
PO4--	0.8-1.53 (MMOL/L)	01/01/92	0.91		1.84	>>
SGOT	0-15 (U/L)	01/01/92	14.00		12.00	
SGPT	0-18 (U/L)	01/01/92	9.00		11.00	
GAMMA GT	4-18 (U/L)	01/01/92	27.00	>	22.00	>
LDH	120-240 (U/L)	01/01/92	148.00		273.00	>
ALK. PHOSPH.	70-175 (U/L)	01/01/92	118.00		85.00	
GLUCOSE	70-95 (MG/DL)	01/01/92	71.00			
BUN	10-50 (MG/DL)	01/01/92			37.00	
CREATININE	0.5-1.5 (MG/DL)	01/01/92	1.08		0.56	
URIC ACID	2-7 (MG/DL)	01/01/92	3.00		3.26	
TOT BILIRUBIN	0-1 (MG/DL)	01/01/92	0.92		0.68	
TOT. PROTEINS	6.5-8 (G/DL)	01/01/92	7.29		7.25	
ALBUMINE	56-68 (%)	01/01/92	62.00		47.50	<
TOT. CHOLEST.	150-200 (MG/DL)	01/01/92	212.00	>	272.00	>>
TRIGLYCERIDES	75-180 (MG/DL)	01/01/92	168.00		196.00	>
GLOBULINS ALPHA 1	2-5 (%)	01/01/92	3.40		4.00	
GLOBULINS ALPHA 2	6-10 (%)	01/01/92	9.10		11.60	>
GLOBULINS BETA	8-14 (%)	01/01/92	13.60		17.40	>
GLOBULINS GAMMA	9-19 (%)	01/01/92	11.90		19.70	>
TSH	0.2-4 (UU/ML)	01/01/92	0.80			
T4	0.8-2 (NG/DL)	01/01/92	1.07			

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICAL MILANO - CNS

9550083

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 21 Patient: 9 Treatment: Fluoxetine Sex: Female

			Visit number / Laboratory date							
			Screen		Day 14		Day 28		Day 56	
			16/10/92		02/11/92		16/11/92		14/12/92	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	120-160 (G/L)	31/12/91	142.00		138.00		145.00		142.00	
HT	0.37-0.47 (L/L)	31/12/91	0.42		0.41		0.43		0.41	
RBC	4-5.5 (10¬12/L)	31/12/91	4.49		4.36		4.59		4.42	
WBC	4.3-10 (10¬9/L)	31/12/91	4.70		5.40		7.30		5.56	
WBC: N	25-74 (%)	31/12/91	72.00		50.00		67.00		47.00	
WBC: L	20-44 (%)	31/12/91	25.00		48.00	>	33.00		49.00	>
WBC: E	1-5 (%)	31/12/91	0.00	<	0.00	<	0.00	<	1.00	
WBC: M	2-7 (%)	31/12/91	2.00		2.00		0.00	<	3.00	
WBC: B	0-1 (%)	31/12/91	1.00		0.00		0.00		0.00	
PLATELETS	150-440 (10¬9/L)	31/12/91	195.00		197.00		270.00		172.00	
NA+	135-144 (MMOL/L)	31/12/91	140.00		134.00	<	134.00	<	135.00	
K+	3.6-5.1 (MMOL/L)	31/12/91	4.40		3.50	<	4.50		4.50	
CL-	97-108 (MMOL/L)	31/12/91	108.00		107.00		101.00		103.00	
Ca++	2.2-2.6 (MMOL/L)	31/12/91	2.40		2.30		2.60		2.40	
PO4--	0.84-1.45 (MMOL/L)	31/12/91	1.14		0.82	<	1.11		1.31	
SGOT	5-15 (U/L)	31/12/91	10.00		10.00		12.00		7.00	
SGPT	5-19 (U/L)	31/12/91	13.00		6.00		31.00	>	6.00	
GAMMA GT	4-18 (U/L)	31/12/91	17.00		6.00		30.00	>	9.00	
LDH	120-240 (U/L)	31/12/91	198.00		140.00		135.00		164.00	
ALK. PHOSPH.	40-190 (U/L)	31/12/91	50.00		50.00		139.00		80.00	
GLUCOSE	70-180 (MG/DL)	31/12/91	78.00		76.00		77.00		73.00	
BUN	10-50 (MG/DL)	31/12/91	17.00		21.00		18.00		26.00	
CREATININE	0.5-1.2 (MG/DL)	31/12/91	0.80		0.80		0.70		0.80	
URIC ACID	2-6.3 (MG/DL)	31/12/91	3.20		2.90		2.60		4.20	
TOT BILIRUBIN	0.2-1 (MG/DL)	31/12/91	0.30		0.70		0.60		0.60	
TOT. PROTEINS	61-82 (G/L)	31/12/91	66.00		69.00		79.00		70.00	
ALBUMINE	35-55 (G/L)	31/12/91	56.70	>	61.30	>	51.20		58.00	>
TOT. CHOLEST.	130-250 (MG/DL)	31/12/91	184.00		187.00		218.00		212.00	
TRIGLYCERIDES	50-200 (MG/DL)	31/12/91	57.00		89.00		125.00		130.00	
GLOBULINS ALPHA 1	1.6-5.8 (%)	31/12/91	3.40		3.70		5.40		3.70	
GLOBULINS ALPHA 2	5.9-11.1 (%)	31/12/91	10.10		8.00		13.30	>	8.90	
GLOBULINS BETA	7.9-13.9 (%)	31/12/91	11.30		11.00		13.70		12.00	
GLOBULINS GAMMA	10-18.2 (%)	31/12/91	18.50	>	16.00		16.40		17.40	
TSH	0.1-3.5 (UU/ML)	31/12/91	1.05							
T4	0.8-2 (NG/DL)	31/12/91	0.81							

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range
< out of range (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 PHARMACEUTICALS MILANO - CNS

REBOXETINE - PROTOCOL 20124/016
Listing No.: 18.0

LABORATORY DATA
Centre: 22 Patient: 113 Treatment: Fluoxetine Sex: Male

			Visit number / Laboratory date	
			Screen	
			14/11/92	
			value	(¢)
Laboratory test	Range value	Range date		
HB	14-18 (G/DL)	01/11/92	15.30	
HT	0.38-0.52 (L/L)	01/11/92	0.48	
RBC	4.4-6 (10¬12/L)	01/11/92	4.83	
WBC	4.3-10 (10¬9/L)	01/11/92	4.54	
WBC: N	50-70 (%)	01/11/92	59.00	
WBC: L	25-45 (%)	01/11/92	34.00	
WBC: E	2-4 (%)	01/11/92	1.00	<
WBC: M	2-6 (%)	01/11/92	5.00	
WBC: B	0-1 (%)	01/11/92	1.00	
PLATELETS	140-440 (10¬9/L)	01/11/92	159.00	
NA+	135-145 (MMOL/L)	01/11/92	143.00	
K+	3.8-5 (MMOL/L)	01/11/92	3.20	<<
Ca++	2.2-2.55 (MMOL/L)	01/11/92	2.40	
SGOT	5-18 (U/L)	01/11/92	11.00	
SGPT	5-22 (U/L)	01/11/92	14.00	
GAMMA GT	6-28 (U/L)	01/11/92	23.00	
LDH	120-140 (U/L)	01/11/92	168.00	>
ALK. PHOSPH.	60-190 (U/L)	01/11/92	83.00	
GLUCOSE	50-100 (U/L)	01/11/92	67.00	
CREATININE	0.6-1.1 (MG/DL)	01/11/92	1.10	
URIC ACID	3.5-7 (MG/DL)	01/11/92	5.40	
TOT BILIRUBIN	0-1 (MG/DL)	01/11/92	0.70	
DIR BILIRUBIN	0-0.25 (MG/DL)	01/11/92	0.18	
TOT. PROTEINS	6.5-8 (G/DL)	01/11/92	6.70	
ALBUMINE	55.3-68.9 (%)	01/11/92	63.80	
TOT. CHOLEST.	50-220 (MG/DL)	01/11/92	231.00	>
TRIGLYCERIDES	60-150 (MG/DL)	01/11/92	145.00	
GLOBULINS ALPHA 1	1.6-5.8 (%)	01/11/92	2.90	
GLOBULINS ALPHA 2	5.9-11.1 (%)	01/11/92	7.10	
GLOBULINS BETA	7.9-13.9 (%)	01/11/92	11.20	
GLOBULINS GAMMA	11.4-18.2 (%)	01/11/92	15.00	
TSH	0.3-4 (NU/L)	01/11/92	1.40	
T4	5-13.4 (UG/DL)	01/11/92	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

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
1	1	Fluoxetine	Male	Only screening	15/11/91	09/01/92	56	Screen	15/11/91	1	Not done	Absent	Absent	Absent	Present
								Day 28	13/12/91	29	Not done	Not done	Not done	Not done	Not done
								Day 56	10/01/92	57	Not done	Not done	Not done	Not done	Not done
	2	Reboxetine	Male	Evaluated	26/06/92	20/08/92	56	Screen	25/06/92	0	Not done	Absent	Absent	Absent	Absent
								Day 14	10/07/92	15	Not done	Not done	Not done	Not done	Not done
								Day 28	24/07/92	29	Not done	Absent	Absent	Absent	Absent
								Day 56	21/08/92	57	Not done	Absent	Absent	Absent	Present
	3	Fluoxetine	Female	Evaluated	01/07/92	25/08/92	56	Screen	29/06/92	0	Missing	Absent	Absent	Absent	Absent
								Day 14	18/07/92	18	Not done	Not done	Not done	Not done	Not done
								Day 28	30/07/92	30	Not done	Absent	Absent	Absent	Absent
								Day 56	25/08/92	56	Not done	Not done	Not done	Not done	Not done
	4	Reboxetine	Female	Evaluated	14/08/92	24/09/92	42	Screen	12/08/92	0	Not done	Absent	Absent	Absent	Present
								Day 14	28/08/92	15	Not done	Not done	Not done	Not done	Not done
								Day 28	11/09/92	29	Not done	Absent	Absent	Absent	Present
								Day 42	25/09/92	43	Not done	Absent	Absent	Absent	Present
	5	Fluoxetine	Female	Only screening	13/10/92	11/11/92	30	Screen	07/10/92	0	Not done	Absent	Absent	Absent	Absent
								Day 14	27/10/92	15	Not done	Not done	Not done	Not done	Not done
								Day 28	10/11/92	29	Not done	Not done	Not done	Not done	Not done
	6	Fluoxetine	Male	Evaluated	14/01/93	11/02/93	29	Screen	11/01/93	0	Not done	Absent	Absent	Absent	Absent
								Day 14	28/01/93	15	Not done	Not done	Not done	Present	Not done
								Day 28	11/02/93	29	Not done	Not done	Not done	Absent	Absent
2	33	Fluoxetine	Female	Evaluated	04/05/91	28/06/91	56	Screen	03/05/91	0	Normal	Absent	Absent	Absent	Absent
								Day 28	04/06/91	32	Normal	Absent	Absent	Absent	Absent
								Day 56	29/06/91	57	Normal	Absent	Absent	Absent	Absent
	34	Reboxetine	Male	Evaluated	03/05/91	12/06/91	41	Screen	02/05/91	0	Normal	Absent	Absent	Absent	Absent
								Day 28	03/06/91	32	Normal	Absent	Absent	Absent	Absent
	35	Reboxetine	Female	Evaluated	16/04/91	10/06/91	56	Screen	16/04/91	1	Not done	Absent	Absent	Absent	Absent
								Day 28	16/05/91	31	Normal	Absent	Absent	Absent	Absent
								Day 56	10/06/91	56	Not done	Absent	Absent	Present	Present
	36	Fluoxetine	Male	Evaluated	02/05/91	26/06/91	56	Screen	26/04/91	0	Not done	Absent	Absent	Absent	Absent

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
2	36	Fluoxetine	Male	Evaluated	02/05/91	26/06/91	56	Day 14	16/05/91	15	Not done	Not done	Not done	Not done	Not done
								Day 28	07/06/91	37	Not done	Absent	Absent	Absent	Absent
								Day 56	27/06/91	57	Not done	Absent	Absent	Absent	Absent
	37	Reboxetine	Male	Without Urinal	07/10/91	10/10/91	4	Screen	01/10/91	0	Not done	Not done	Not done	Not done	Not done
	38	Fluoxetine	Male	Evaluated	20/06/91	25/07/91	36	Screen	18/06/91	0	Not done	Absent	Absent	Absent	Absent
								Day 28	18/07/91	29	Not done	Absent	Absent	Absent	Absent
	39	Fluoxetine	Male	Only screening	19/06/91	22/06/91	4	Screen	19/06/91	1	Not done	Absent	Absent	Absent	Absent
	40	Reboxetine	Male	Only screening	06/06/91	04/07/91	29	Screen	04/06/91	0	Normal	Absent	Absent	Absent	Absent
	41	Fluoxetine	Male	Without screen	13/02/92	08/04/92	56	Screen	11/02/92	0	Not done	Not done	Not done	Not done	Not done
								Day 14	27/02/92	15	Not done	Not done	Not done	Not done	Not done
								Day 28	12/03/92	29	Not done	Present	Present	Present	Present
								Day 56	09/04/92	57	Not done	Absent	Absent	Absent	Absent
	42	Reboxetine	Female	Evaluated	05/03/92	29/04/92	56	Screen	04/03/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	02/04/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	30/04/92	57	Normal	Absent	Absent	Absent	Absent
	43	Reboxetine	Female	Without screen	19/11/91	13/01/92	56	Screen	19/11/91	1	Not done	Not done	Not done	Not done	Not done
								Day 14	03/12/91	15	Not done	Not done	Not done	Not done	Not done
								Day 28	17/12/91	29	Not done	Absent	Absent	Absent	Absent
								Day 56	14/01/92	57	Not done	Absent	Absent	Absent	Absent
	44	Fluoxetine	Male	Evaluated	13/12/91	30/01/92	49	Screen	13/12/91	1	Not done	Absent	Absent	Absent	Absent
								Day 28	10/01/92	29	Not done	Absent	Absent	Absent	Absent
	45	Reboxetine	Female	Evaluated	10/09/92	04/11/92	56	Screen	10/09/92	1	Not done	Absent	Absent	Absent	Absent
								Day 28	08/10/92	29	Not done	Absent	Absent	Absent	Absent
	47	Fluoxetine	Female	Evaluated	25/03/92	19/05/92	56	Screen	25/03/92	1	Normal	Absent	Absent	Absent	Absent
								Day 28	22/04/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	20/05/92	57	Normal	Absent	Absent	Absent	Absent

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
2	48	Reboxetine	Female	Evaluated	19/05/92	13/07/92	56	Screen	18/05/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	16/06/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	14/07/92	57	Normal	Absent	Absent	Absent	Absent
	80	Fluoxetine	Male	Evaluated	15/01/93	11/03/93	56	Screen	15/01/93	1	Not done	Absent	Absent	Absent	Absent
								Day 14	29/01/93	15	Not done	Not done	Not done	Not done	Not done
								Day 28	12/02/93	29	Not done	Absent	Absent	Absent	Absent
								Day 56	12/03/93	57	Not done	Absent	Absent	Absent	Absent
3	65	Fluoxetine	Female	Without Urinal	16/10/91	10/12/91	56	Screen	11/10/91	0	Normal	Not done	Not done	Not done	Not done
								Day 14	29/10/91	14	Normal	Not done	Not done	Not done	Not done
								Day 28	12/11/91	28	Normal	Not done	Not done	Not done	Not done
								Day 56	10/12/91	56	Normal	Not done	Not done	Not done	Not done
	66	Fluoxetine	Female	Without Urinal	16/10/91	12/11/91	28	Screen	11/10/91	0	Normal	Not done	Not done	Not done	Not done
								Day 28	12/11/91	28	Not done	Not done	Not done	Not done	Not done
	67	Reboxetine	Female	Without Urinal	18/11/92	15/12/92	28	Screen	14/11/92	0	Normal	Not done	Not done	Not done	Not done
								Day 28	16/12/92	29	Normal	Not done	Not done	Not done	Not done
	68	Reboxetine	Female	Evaluated	30/11/92	28/12/92	29	Screen	26/11/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	28/12/92	29	Not done	Absent	Absent	Absent	Absent
4	97	Reboxetine	Female	Evaluated	22/04/91	16/06/91	56	Screen	19/04/91	0	Normal	Absent	Absent	Absent	Present
								Day 28	19/05/91	28	Normal	Absent	Absent	Absent	Absent
								Day 56	16/06/91	56	Not done	Not done	Not done	Not done	Not done
	98	Fluoxetine	Female	Evaluated	30/05/91	24/07/91	56	Screen	27/05/91	0	Normal	Absent	Absent	Absent	Absent
								Day 28	26/06/91	28	Not done	Not done	Not done	Not done	Not done
								Day 56	24/07/91	56	Normal	Absent	Absent	Absent	Absent
	99	Fluoxetine	Female	Only screening	15/10/91	25/10/91	11	Screen	14/10/91	0	Normal	Absent	Absent	Absent	Absent
								Day 14	25/10/91	11	Not done	Not done	Not done	Not done	Not done
	100	Reboxetine	Male	Without Urinal	08/05/92	08/05/92	1	Screen	08/05/92	1	Not done	Not done	Not done	Not done	Not done
	101	Reboxetine	Female	Without Urinal	02/07/92	26/08/92	56	Screen	02/07/92	1	Normal	Not done	Not done	Not done	Not done
								Day 28	30/07/92	29	Not done	Not done	Not done	Not done	Not done

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
4	101	Reboxetine	Female	Without Urinal	02/07/92	26/08/92	56	Day 56	27/08/92	57	Not done	Not done	Not done	Not done	Not done
	102	Fluoxetine	Female	Only screening	10/07/92	03/09/92	56	Screen	10/07/92	1	Normal	Absent	Absent	Absent	Present
								Day 28	07/08/92	29	Not done	Not done	Not done	Not done	Not done
								Day 56	04/09/92	57	Normal	Not done	Not done	Absent	Not done
	103	Fluoxetine	Female	Only screening	13/07/92	18/08/92	37	Screen	13/07/92	1	Normal	Absent	Absent	Absent	Absent
								Day 28	10/08/92	29	Not done	Not done	Not done	Not done	Not done
	104	Reboxetine	Female	Evaluated	18/08/92	05/10/92	49	Screen	17/08/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	15/09/92	29	Normal	Absent	Absent	Absent	Absent
	105	Fluoxetine	Male	Without Urinal	21/08/92	15/10/92	56	Screen	20/08/92	0	Normal	Not done	Not done	Not done	Not done
								Day 28	18/09/92	29	Normal	Not done	Not done	Not done	Not done
								Day 56	16/10/92	57	Normal	Not done	Not done	Not done	Not done
5	129	Reboxetine	Female	Evaluated	29/11/91	29/12/91	31	Screen	25/11/91	0	Normal	Not done	Not done	Present	Present
								Day 28	26/12/91	28	Normal	Absent	Absent	Absent	Absent
	130	Fluoxetine	Female	Only screening	28/02/92	23/04/92	56	Screen	24/02/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	20/03/92	22	Normal	Not done	Not done	Not done	Not done
								Day 56	24/04/92	57	Not done	Not done	Not done	Not done	Not done
7	193	Reboxetine	Female	Only screening	06/12/91	31/01/92	57	Screen	03/12/91	0	Normal	Absent	Absent	Absent	Absent
								Day 28	02/01/92	28	Normal	Not done	Not done	Not done	Not done
								Day 56	30/01/92	56	Normal	Not done	Not done	Not done	Not done
	194	Fluoxetine	Female	Without Urinal	10/01/92	05/03/92	56	Screen	02/01/92	0	Normal	Not done	Not done	Not done	Not done
								Day 28	07/02/92	29	Normal	Not done	Not done	Not done	Not done
								Day 56	05/03/92	56	Normal	Not done	Not done	Not done	Not done
	195	Fluoxetine	Male	Without screen	14/02/92	09/04/92	56	Screen	13/02/92	0	Not done	Not done	Not done	Not done	Not done
								Day 28	13/03/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	10/04/92	57	Not done	Not done	Not done	Not done	Not done
	196	Reboxetine	Female	Without Urinal	29/05/92	16/07/92	49	Screen	22/05/92	0	Not done	Not done	Not done	Not done	Not done
								Day 28	25/06/92	28	Normal	Not done	Not done	Not done	Not done
								Day 42	14/07/92	47	Not done	Not done	Not done	Not done	Not done

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
7	197	Fluoxetine	Male	Only screening	11/11/92	11/11/92	1	Screen	06/11/92	0	Normal	Absent	Absent	Absent	Absent
11	321	Fluoxetine	Female	Evaluated	14/11/91	09/01/92	57	Screen	05/11/91	0	Not done	Absent	Absent	Absent	Absent
								Day 28	13/12/91	30	Not done	Not done	Not done	Not done	Not done
								Day 56	09/01/92	57	Not done	Absent	Absent	Absent	Absent
	322	Reboxetine	Female	Evaluated	14/11/91	09/01/92	57	Screen	06/11/91	0	Not done	Absent	Absent	Absent	Absent
								Day 28	13/12/91	30	Not done	Not done	Not done	Not done	Not done
								Day 56	03/01/92	51	Not done	Absent	Absent	Absent	Absent
	323	Fluoxetine	Female	Evaluated	19/11/91	13/01/92	56	Screen	30/10/91	0	Not done	Absent	Absent	Absent	Absent
								Day 28	20/12/91	32	Not done	Absent	Absent	Absent	Absent
								Day 56	23/01/92	66	Not done	Absent	Absent	Absent	Absent
	324	Reboxetine	Female	Evaluated	24/01/92	19/03/92	56	Screen	21/01/92	0	Not done	Absent	Absent	Absent	Absent
								Day 28	19/02/92	27	Not done	Absent	Absent	Absent	Absent
								Day 56	08/04/92	76	Not done	Absent	Absent	Absent	Absent
	325	Reboxetine	Female	Evaluated	12/02/92	07/04/92	56	Screen	14/01/92	0	Not done	Absent	Absent	Absent	Present
								Day 28	04/03/92	22	Not done	Absent	Absent	Absent	Absent
								Day 56	07/04/92	56	Not done	Absent	Absent	Absent	Absent
	326	Reboxetine	Female	Evaluated	12/02/92	07/04/92	56	Screen	29/01/92	0	Not done	Absent	Present	Present	Absent
								Day 28	20/03/92	38	Not done	Present	Present	Absent	Absent
								Day 56	07/04/92	56	Not done	Present	Present	Absent	Present
	327	Fluoxetine	Female	Evaluated	14/02/92	12/03/92	28	Screen	24/01/92	0	Not done	Absent	Absent	Absent	Absent
								Day 28	12/03/92	28	Not done	Absent	Absent	Absent	Present
	328	Fluoxetine	Female	Evaluated	19/02/92	14/04/92	56	Screen	07/02/92	0	Not done	Absent	Absent	Absent	Present
								Day 28	24/03/92	35	Normal	Absent	Absent	Absent	Absent
								Day 56	21/04/92	63	Not done	Absent	Absent	Absent	Present
	329	Reboxetine	Female	Evaluated	31/03/92	27/05/92	58	Screen	16/03/92	0	Not done	Absent	Absent	Absent	Absent
								Day 28	11/05/92	42	Not done	Absent	Absent	Absent	Absent
								Day 56	25/05/92	56	Not done	Absent	Absent	Absent	Absent

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
11	330	Reboxetine	Male	Evaluated	21/04/92	08/06/92	49	Screen	03/04/92	0	Not done	Absent	Absent	Absent	Absent
								Day 28	27/05/92	37	Not done	Absent	Absent	Absent	Absent
	331	Fluoxetine	Female	Evaluated	26/05/92	20/07/92	56	Screen	08/05/92	0	Not done	Present	Absent	Absent	Absent
								Day 28	29/06/92	35	Not done	Absent	Absent	Absent	Absent
								Day 56	06/08/92	73	Not done	Absent	Absent	Absent	Absent
	332	Fluoxetine	Female	Evaluated	28/07/92	24/09/92	59	Screen	17/07/92	0	Not done	Absent	Absent	Absent	Absent
								Day 28	10/09/92	45	Not done	Absent	Absent	Absent	Absent
								Day 56	15/09/92	50	Not done	Not done	Not done	Not done	Not done
	333	Reboxetine	Female	Evaluated	15/09/92	09/11/92	56	Screen	17/07/92	0	Not done	Absent	Absent	Present	Absent
								Day 28	13/10/92	29	Not done	Absent	Absent	Absent	Present
	334	Fluoxetine	Female	Evaluated	22/09/92	16/11/92	56	Screen	10/09/92	0	Not done	Absent	Absent	Present	Absent
								Day 28	21/10/92	30	Not done	Absent	Absent	Absent	Present
								Day 56	14/12/92	84	Not done	Present	Absent	Absent	Present
	335	Reboxetine	Female	Evaluated	13/10/92	16/11/92	35	Screen	02/10/92	0	Not done	Absent	Absent	Absent	Absent
								Day 28	10/11/92	29	Not done	Absent	Absent	Absent	Present
12	393	Fluoxetine	Female	Evaluated	25/06/92	18/08/92	55	Screen	26/06/92	2	Normal	Present	Absent	Present	Present
								Day 28	21/07/92	27	Normal	Present	Absent	Absent	Absent
								Day 56	28/08/92	65	Normal	Present	Absent	Present	Present
	394	Reboxetine	Male	Without screen	06/07/92	31/08/92	57	Screen	07/07/92	2	Normal	Present	Absent	Not done	Not done
								Day 28	03/08/92	29	Normal	Absent	Absent	Not done	Not done
								Day 56	27/08/92	53	Normal	Absent	Absent	Present	Present
	395	Reboxetine	Male	Without screen	24/07/92	16/09/92	55	Screen	24/07/92	1	Normal	Absent	Absent	Not done	Not done
								Day 28	20/08/92	28	Normal	Absent	Absent	Present	Absent
								Day 56	17/09/92	56	Normal	Absent	Absent	Absent	Present
	396	Fluoxetine	Female	Only screening	04/08/92	17/08/92	14	Screen	05/08/92	2	Normal	Absent	Absent	Present	Present
	497	Fluoxetine	Female	Only screening	24/02/93	21/04/93	57	Screen	26/02/93	3	Not done	Absent	Absent	Absent	Absent

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
12	497	Fluoxetine	Female	Only screening	24/02/93	21/04/93	57	Day 28	26/03/93	31	Not done	Not done	Not done	Not done	Not done
								Day 56	26/04/93	62	Not done	Absent	Absent	Absent	Not done
13	385	Fluoxetine	Female	Evaluated	14/03/92	08/05/92	56	Screen	13/03/92	0	Not done	Absent	Absent	Present	Present
								Day 14	30/03/92	17	Not done	Not done	Not done	Not done	Not done
								Day 56	08/05/92	56	Not done	Absent	Absent	Present	Present
	386	Fluoxetine	Male	Only screening	24/04/92	30/04/92	7	Screen	23/04/92	0	Not done	Absent	Absent	Present	Present
	387	Reboxetine	Female	Without screen	18/04/92	18/05/92	31	Screen	15/04/92	0	Not done	Not done	Not done	Not done	Not done
								Day 28	01/06/92	45	Not done	Absent	Absent	Present	Present
	388	Reboxetine	Male	Without screen	16/03/92	11/05/92	57	Screen	15/03/92	0	Not done	Present	Absent	Present	Not done
								Day 28	30/03/92	15	Not done	Present	Absent	Present	Present
								Day 56	11/05/92	57	Not done	Present	Absent	Not done	Not done
	389	Fluoxetine	Female	Without Urinal	21/07/92	23/07/92	3	Screen	20/07/92	0	Not done	Absent	Absent	Not done	Not done
								Day 7	24/07/92	4	Not done	Not done	Not done	Not done	Not done
	390	Reboxetine	Male	Without screen	28/05/92	22/07/92	56	Screen	25/05/92	0	Not done	Absent	Absent	Not done	Not done
								Day 28	25/06/92	29	Not done	Absent	Absent	Not done	Not done
								Day 56	24/07/92	58	Not done	Absent	Absent	Absent	Absent
	391	Fluoxetine	Female	Without screen	11/06/92	15/07/92	35	Screen	04/06/92	0	Not done	Present	Absent	Not done	Not done
								Day 28	10/07/92	30	Not done	Absent	Absent	Present	Present
	392	Reboxetine	Female	Evaluated	14/08/92	27/08/92	14	Screen	13/08/92	0	Not done	Absent	Absent	Absent	Absent
								Day 14	28/08/92	15	Not done	Absent	Absent	Present	Present
	501	Reboxetine	Male	Evaluated	02/11/92	30/12/92	59	Screen	29/10/92	0	Not done	Not done	Not done	Present	Present
								Day 28	30/11/92	29	Not done	Absent	Absent	Absent	Absent
								Day 56	30/12/92	59	Not done	Absent	Present	Not done	Not done
	502	Fluoxetine	Female	Evaluated	03/11/92	24/12/92	52	Screen	03/11/92	1	Not done	Absent	Absent	Present	Present
								Day 28	30/11/92	28	Not done	Absent	Absent	Present	Present
								Day 56	24/12/92	52	Not done	Absent	Absent	Present	Present

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
13	503	Reboxetine	Female	Only screening	12/11/92	18/11/92	7	Screen	12/11/92	1	Not done	Absent	Absent	Present	Present
								Day 7	19/11/92	8	Not done	Absent	Absent	Not done	Not done
	504	Fluoxetine	Female	Evaluated	26/11/92	20/01/93	56	Screen	25/11/92	0	Not done	Present	Absent	Present	Present
								Day 28	24/12/92	29	Not done	Present	Absent	Present	Present
								Day 56	20/01/93	56	Not done	Present	Absent	Present	Present
	505	Reboxetine	Female	Evaluated	31/08/92	22/10/92	53	Screen	31/08/92	1	Not done	Absent	Absent	Present	Present
								Day 28	28/09/92	29	Not done	Absent	Absent	Present	Present
								Day 56	22/10/92	53	Not done	Present	Absent	Present	Present
	506	Fluoxetine	Male	Evaluated	27/10/92	23/12/92	58	Screen	23/10/92	0	Not done	Absent	Absent	Present	Present
								Day 28	26/11/92	31	Not done	Absent	Absent	Present	Present
								Day 56	24/12/92	59	Not done	Absent	Absent	Present	Present
1124	507	Fluoxetine	Female	Evaluated	11/09/92	06/11/92	57	Screen	10/09/92	0	Not done	Present	Absent	Present	Present
								Day 28	16/10/92	36	Not done	Absent	Absent	Present	Present
								Day 56	06/11/92	57	Not done	Absent	Absent	Present	Present
	508	Reboxetine	Female	Only screening	02/11/92	29/12/92	58	Screen	29/10/92	0	Not done	Absent	Absent	Absent	Absent
								Day 28	30/11/92	29	Not done	Not done	Not done	Not done	Not done
								Day 56	31/12/92	60	Not done	Not done	Not done	Not done	Not done
	521	Reboxetine	Male	Evaluated	30/11/92	26/01/93	58	Screen	30/11/92	1	Not done	Absent	Absent	Present	Present
								Day 28	30/12/92	31	Not done	Absent	Absent	Not done	Not done
								Day 56	27/01/93	59	Not done	Absent	Absent	Present	Present
14	397	Fluoxetine	Female	Evaluated	14/04/92	09/06/92	57	Screen	12/03/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	12/05/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	09/06/92	57	Normal	Absent	Absent	Absent	Absent
	398	Reboxetine	Female	Evaluated	15/04/92	10/06/92	57	Screen	15/04/92	1	Normal	Absent	Absent	Absent	Absent
								Day 28	13/05/92	29	Normal	Absent	Absent	Not done	Not done
								Day 56	10/06/92	57	Normal	Absent	Absent	Absent	Absent
	399	Reboxetine	Female	Evaluated	21/04/92	16/06/92	57	Screen	13/04/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	19/05/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	16/06/92	57	Normal	Absent	Absent	Absent	Absent

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
14	400	Fluoxetine	Male	Evaluated	15/05/92	11/07/92	58	Screen	14/05/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	12/06/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	14/07/92	61	Normal	Absent	Absent	Absent	Absent
	401	Fluoxetine	Female	Evaluated	22/05/92	17/07/92	57	Screen	22/05/92	1	Normal	Absent	Absent	Absent	Absent
								Day 28	19/06/92	29	Normal	Absent	Absent	Not done	Not done
								Day 56	17/07/92	57	Normal	Absent	Absent	Absent	Absent
	402	Reboxetine	Female	Evaluated	27/05/92	22/07/92	57	Screen	22/05/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	24/06/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	22/07/92	57	Normal	Absent	Absent	Absent	Absent
	403	Reboxetine	Female	Evaluated	29/05/92	24/07/92	57	Screen	28/05/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	26/06/92	29	Normal	Absent	Absent	Present	Absent
								Day 56	24/07/92	57	Normal	Absent	Absent	Absent	Present
	404	Fluoxetine	Female	Evaluated	16/06/92	11/08/92	57	Screen	16/06/92	1	Normal	Absent	Absent	Absent	Absent
								Day 28	14/07/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	11/08/92	57	Normal	Absent	Absent	Absent	Absent
	405	Fluoxetine	Female	Evaluated	22/06/92	18/08/92	58	Screen	19/06/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	20/07/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	17/08/92	57	Normal	Absent	Absent	Absent	Absent
	406	Fluoxetine	Female	Evaluated	30/06/92	21/07/92	22	Screen	30/06/92	1	Normal	Absent	Absent	Absent	Absent
								Day 21	21/07/92	22	Not done	Absent	Absent	Absent	Present
	407	Reboxetine	Male	Evaluated	14/07/92	24/08/92	42	Screen	13/07/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	10/08/92	28	Normal	Absent	Absent	Absent	Absent
								Day 42	25/08/92	43	Normal	Absent	Absent	Absent	Absent
	408	Reboxetine	Female	Without screen	04/08/92	30/09/92	58	Screen	04/08/92	1	Not done	Not done	Not done	Not done	Not done
								Day 28	01/09/92	29	Not done	Not done	Not done	Not done	Not done
								Day 56	30/09/92	58	Normal	Absent	Absent	Present	Present
	509	Fluoxetine	Female	Evaluated	29/09/92	10/11/92	43	Screen	21/09/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	29/10/92	31	Normal	Absent	Absent	Absent	Absent

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
14	509	Fluoxetine	Female	Evaluated	29/09/92	10/11/92	43	Day 42	11/11/92	44	Normal	Absent	Absent	Absent	Absent
	510	Fluoxetine	Female	Evaluated	30/09/92	26/11/92	58	Screen	30/09/92	1	Normal	Absent	Absent	Absent	Absent
								Day 28	29/10/92	30	Normal	Absent	Absent	Absent	Absent
								Day 56	26/11/92	58	Normal	Absent	Absent	Present	Absent
	511	Reboxetine	Female	Evaluated	23/10/92	10/12/92	49	Screen	22/10/92	0	Normal	Absent	Absent	Present	Present
								Day 28	20/11/92	29	Normal	Absent	Absent	Present	Absent
								Day 49	11/12/92	50	Normal	Absent	Absent	Absent	Absent
	512	Reboxetine	Female	Only screening	03/11/92	02/12/92	30	Screen	02/11/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	02/12/92	30	Not done	Not done	Not done	Not done	Not done
	537	Reboxetine	Female	Evaluated	03/11/92	29/12/92	57	Screen	29/10/92	0	Normal	Absent	Absent	Present	Present
								Day 28	02/12/92	30	Normal	Absent	Absent	Absent	Present
								Day 56	04/01/93	63	Normal	Absent	Absent	Absent	Absent
	538	Fluoxetine	Female	Evaluated	12/02/93	09/04/93	57	Screen	12/02/93	1	Normal	Absent	Absent	Absent	Absent
								Day 28	12/03/93	29	Normal	Absent	Absent	Absent	Absent
								Day 56	07/04/93	55	Normal	Absent	Absent	Present	Present
	539	Fluoxetine	Female	Evaluated	10/03/93	05/05/93	57	Screen	10/03/93	1	Normal	Absent	Absent	Absent	Absent
								Day 28	08/04/93	30	Normal	Absent	Absent	Absent	Absent
								Day 56	06/05/93	58	Normal	Absent	Absent	Present	Not done
15	409	Reboxetine	Male	Evaluated	08/04/92	02/06/92	56	Screen	24/03/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	05/05/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	02/06/92	56	Not done	Not done	Not done	Not done	Not done
	410	Fluoxetine	Female	Evaluated	17/04/92	11/06/92	56	Screen	09/04/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	14/05/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	10/06/92	55	Normal	Absent	Absent	Absent	Absent
	411	Reboxetine	Female	Evaluated	22/04/92	16/06/92	56	Screen	21/04/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	19/05/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	16/06/92	56	Normal	Absent	Absent	Absent	Absent
	412	Fluoxetine	Female	Evaluated	23/04/92	17/06/92	56	Screen	10/04/92	0	Normal	Absent	Absent	Absent	Absent

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
15	412	Fluoxetine	Female	Evaluated	23/04/92	17/06/92	56	Day 28	20/05/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	17/06/92	56	Normal	Absent	Absent	Absent	Absent
	413	Reboxetine	Female	Evaluated	30/04/92	24/06/92	56	Screen	22/04/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	27/05/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	24/06/92	56	Normal	Absent	Absent	Absent	Absent
	414	Fluoxetine	Male	Evaluated	02/06/92	27/07/92	56	Screen	26/05/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	29/06/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	27/07/92	56	Normal	Absent	Absent	Absent	Absent
	415	Reboxetine	Female	Evaluated	12/06/92	06/08/92	56	Screen	04/06/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	09/07/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	06/08/92	56	Normal	Absent	Absent	Absent	Absent
	416	Fluoxetine	Female	Evaluated	23/06/92	17/08/92	56	Screen	19/06/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	20/07/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	17/08/92	56	Normal	Absent	Absent	Absent	Absent
	417	Reboxetine	Female	Evaluated	19/06/92	13/08/92	56	Screen	11/06/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	16/07/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	13/08/92	56	Normal	Absent	Absent	Absent	Absent
	418	Reboxetine	Female	Evaluated	17/07/92	10/09/92	56	Screen	07/07/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	13/08/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	10/09/92	56	Normal	Absent	Absent	Absent	Absent
	419	Fluoxetine	Female	Evaluated	16/07/92	09/09/92	56	Screen	08/07/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	12/08/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	09/09/92	56	Normal	Absent	Absent	Absent	Absent
	420	Fluoxetine	Male	Evaluated	20/08/92	14/10/92	56	Screen	15/07/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	16/09/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	14/10/92	56	Normal	Absent	Absent	Absent	Absent
	421	Reboxetine	Female	Evaluated	01/08/92	25/09/92	56	Screen	24/07/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	28/08/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	25/09/92	56	Normal	Absent	Absent	Absent	Absent

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
15	422	Fluoxetine	Male	Evaluated	19/08/92	13/10/92	56	Screen	14/08/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	15/09/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	13/10/92	56	Normal	Absent	Absent	Absent	Absent
	423	Fluoxetine	Female	Evaluated	21/08/92	15/10/92	56	Screen	15/08/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	17/09/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	15/10/92	56	Normal	Absent	Absent	Absent	Absent
	424	Reboxetine	Male	Evaluated	21/08/92	15/10/92	56	Screen	13/08/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	17/09/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	15/10/92	56	Normal	Absent	Absent	Absent	Absent
	425	Reboxetine	Female	Evaluated	02/10/92	26/11/92	56	Screen	24/09/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	29/10/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	26/11/92	56	Normal	Absent	Absent	Absent	Absent
	426	Fluoxetine	Male	Evaluated	28/10/92	22/12/92	56	Screen	20/10/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	24/11/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	22/12/92	56	Normal	Absent	Absent	Absent	Absent
	427	Reboxetine	Female	Evaluated	03/12/92	27/01/93	56	Screen	25/11/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	30/12/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	27/01/93	56	Normal	Absent	Absent	Absent	Absent
	428	Fluoxetine	Male	Evaluated	03/12/92	27/01/93	56	Screen	25/11/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	30/12/92	28	Normal	Absent	Absent	Absent	Absent
								Day 56	27/01/93	56	Normal	Absent	Absent	Absent	Absent
	449	Reboxetine	Female	Evaluated	08/12/92	01/02/93	56	Screen	01/12/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	04/01/93	28	Normal	Absent	Absent	Absent	Absent
								Day 56	01/02/93	56	Normal	Absent	Absent	Absent	Absent
	450	Fluoxetine	Male	Evaluated	10/12/92	03/02/93	56	Screen	29/11/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	06/01/93	28	Normal	Absent	Absent	Absent	Absent
								Day 56	03/02/93	56	Normal	Absent	Absent	Absent	Absent
	451	Fluoxetine	Female	Evaluated	18/12/92	11/02/93	56	Screen	07/12/92	0	Normal	Absent	Absent	Absent	Absent

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albunin	Sugar	RBC	WBC
15	451	Fluoxetine	Female	Evaluated	18/12/92	11/02/93	56	Day 28	14/01/93	28	Normal	Absent	Absent	Absent	Absent
								Day 56	11/02/93	56	Normal	Absent	Absent	Absent	Missing
	452	Reboxetine	Female	Evaluated	23/12/92	16/02/93	56	Screen	15/12/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	19/01/93	28	Normal	Absent	Absent	Absent	Absent
								Day 56	16/02/93	56	Normal	Absent	Absent	Absent	Absent
	454	Fluoxetine	Male	Evaluated	19/01/93	15/03/93	56	Screen	08/01/93	0	Normal	Absent	Absent	Absent	Absent
								Day 28	15/02/93	28	Normal	Absent	Absent	Absent	Absent
								Day 56	15/03/93	56	Normal	Absent	Absent	Absent	Absent
16	429	Fluoxetine	Female	Evaluated	26/03/92	20/05/92	56	Screen	12/03/92	0	Not done	Absent	Absent	Absent	Present
								Day 28	22/04/92	28	Normal	Absent	Absent	Absent	Present
								Day 56	20/05/92	56	Normal	Absent	Absent	Absent	Present
	430	Reboxetine	Male	Evaluated	30/03/92	25/05/92	57	Screen	26/03/92	0	Not done	Absent	Absent	Present	Present
								Day 28	27/04/92	29	Normal	Absent	Absent	Present	Present
								Day 56	25/05/92	57	Normal	Absent	Absent	Absent	Present
	431	Reboxetine	Female	Evaluated	31/03/92	25/05/92	56	Screen	26/03/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	27/04/92	28	Normal	Absent	Absent	Absent	Present
								Day 56	25/05/92	56	Normal	Absent	Absent	Absent	Present
	432	Fluoxetine	Female	Evaluated	31/03/92	25/05/92	56	Screen	26/03/92	0	Not done	Absent	Absent	Absent	Present
								Day 28	27/04/92	28	Normal	Absent	Absent	Absent	Present
								Day 56	25/05/92	56	Normal	Absent	Absent	Absent	Present
	433	Reboxetine	Female	Evaluated	02/04/92	27/05/92	56	Screen	28/03/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	29/04/92	28	Normal	Absent	Absent	Absent	Present
								Day 56	27/05/92	56	Normal	Absent	Absent	Absent	Present
	434	Fluoxetine	Female	Evaluated	07/04/92	01/06/92	56	Screen	06/04/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	04/05/92	28	Normal	Absent	Absent	Absent	Present
								Day 56	01/06/92	56	Normal	Absent	Absent	Absent	Present
	435	Reboxetine	Female	Evaluated	14/04/92	08/06/92	56	Screen	09/04/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	11/05/92	28	Normal	Absent	Absent	Present	Present
								Day 56	08/06/92	56	Normal	Absent	Absent	Absent	Present

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
16	436	Fluoxetine	Female	Only screening	24/04/92	18/06/92	56	Screen	20/04/92	0	Normal	Absent	Absent	Absent	Present
	437	Reboxetine	Female	Evaluated	30/04/92	24/06/92	56	Screen	24/04/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	27/05/92	28	Normal	Absent	Absent	Absent	Present
								Day 56	24/06/92	56	Normal	Absent	Absent	Absent	Present
	438	Fluoxetine	Female	Evaluated	20/05/92	18/06/92	30	Screen	15/05/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	16/06/92	28	Normal	Absent	Absent	Absent	Present
	439	Fluoxetine	Female	Evaluated	20/05/92	14/07/92	56	Screen	15/05/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	16/06/92	28	Normal	Absent	Absent	Absent	Present
								Day 56	14/07/92	56	Normal	Absent	Absent	Absent	Present
	440	Reboxetine	Female	Without screen	01/07/92	25/08/92	56	Day 56	25/08/92	56	Normal	Absent	Absent	Absent	Present
	441	Fluoxetine	Female	Evaluated	22/07/92	14/09/92	55	Screen	13/07/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	17/08/92	27	Normal	Absent	Absent	Absent	Present
								Day 56	14/09/92	55	Normal	Absent	Absent	Absent	Present
	442	Reboxetine	Female	Evaluated	22/07/92	14/09/92	55	Screen	14/07/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	17/08/92	27	Normal	Absent	Absent	Absent	Present
								Day 56	14/09/92	55	Normal	Absent	Absent	Absent	Present
	443	Fluoxetine	Male	Evaluated	25/08/92	18/10/92	55	Screen	20/08/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	21/09/92	28	Normal	Absent	Absent	Absent	Present
								Day 56	19/10/92	56	Normal	Absent	Absent	Present	Present
	444	Reboxetine	Female	Evaluated	25/08/92	19/10/92	56	Screen	20/08/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	21/09/92	28	Normal	Absent	Absent	Absent	Present
								Day 56	19/10/92	56	Normal	Absent	Absent	Absent	Present
	445	Reboxetine	Male	Evaluated	18/09/92	12/11/92	56	Screen	12/09/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	15/10/92	28	Normal	Absent	Absent	Absent	Present
								Day 56	12/11/92	56	Normal	Absent	Absent	Present	Present
	446	Fluoxetine	Female	Evaluated	18/09/92	12/11/92	56	Screen	12/09/92	0	Normal	Absent	Absent	Absent	Present

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
16	446	Fluoxetine	Female	Evaluated	18/09/92	12/11/92	56	Day 56	12/11/92	56	Normal	Absent	Absent	Absent	Present
	447	Fluoxetine	Male	Evaluated	18/09/92	12/11/92	56	Screen	12/09/92	0	Normal	Absent	Absent	Absent	Present
								Day 56	12/11/92	56	Normal	Absent	Absent	Absent	Present
	448	Reboxetine	Female	Evaluated	19/09/92	13/11/92	56	Screen	14/09/92	0	Normal	Absent	Absent	Present	Present
								Day 28	16/10/92	28	Normal	Absent	Absent	Present	Present
								Day 56	13/11/92	56	Normal	Absent	Absent	Present	Present
	455	Fluoxetine	Female	Evaluated	19/09/92	13/11/92	56	Screen	14/09/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	16/10/92	28	Normal	Absent	Absent	Absent	Present
								Day 56	13/11/92	56	Normal	Absent	Absent	Absent	Present
	456	Reboxetine	Male	Evaluated	16/12/92	09/02/93	56	Screen	09/12/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	12/01/93	28	Normal	Absent	Absent	Absent	Present
								Day 56	09/02/93	56	Normal	Absent	Absent	Absent	Present
	457	Fluoxetine	Female	Evaluated	16/12/92	09/02/93	56	Screen	09/12/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	12/01/93	28	Normal	Absent	Absent	Absent	Present
								Day 56	09/02/93	56	Normal	Absent	Absent	Absent	Present
	458	Fluoxetine	Female	Evaluated	16/12/92	09/02/93	56	Screen	09/12/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	12/01/93	28	Normal	Absent	Absent	Absent	Present
								Day 56	09/02/93	56	Normal	Absent	Absent	Absent	Present
	459	Reboxetine	Male	Evaluated	22/12/92	15/02/93	56	Screen	17/12/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	18/01/93	28	Normal	Absent	Absent	Absent	Present
								Day 56	15/02/93	56	Normal	Absent	Absent	Absent	Present
	460	Reboxetine	Male	Evaluated	22/12/92	15/02/93	56	Screen	17/12/92	0	Normal	Absent	Absent	Absent	Present
								Day 28	18/01/93	28	Normal	Absent	Absent	Absent	Present
								Day 56	15/02/93	56	Normal	Absent	Absent	Absent	Present
18	25	Fluoxetine	Female	Evaluated	06/10/92	30/11/92	56	Screen	30/09/92	0	Not done	Absent	Absent	Absent	Absent
								Day 28	03/11/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	01/12/92	57	Normal	Absent	Absent	Absent	Absent
	26	Reboxetine	Female	Evaluated	06/10/92	30/11/92	56	Screen	30/09/92	0	Normal	Absent	Absent	Absent	Absent

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
18	26	Reboxetine	Female	Evaluated	06/10/92	30/11/92	56	Day 28	03/11/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	01/12/92	57	Normal	Absent	Absent	Absent	Absent
	27	Reboxetine	Female	Evaluated	06/10/92	30/11/92	56	Screen	30/09/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	03/11/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	01/12/92	57	Normal	Absent	Absent	Absent	Absent
	28	Fluoxetine	Female	Evaluated	06/10/92	02/11/92	28	Screen	30/09/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	03/11/92	29	Normal	Absent	Absent	Absent	Absent
	29	Reboxetine	Male	Evaluated	06/10/92	30/11/92	56	Screen	30/09/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	03/11/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	01/12/92	57	Normal	Absent	Absent	Absent	Absent
	30	Fluoxetine	Female	Evaluated	07/10/92	01/12/92	56	Screen	30/09/92	0	Normal	Absent	Absent	Absent	Absent
								Day 28	04/11/92	29	Normal	Absent	Absent	Absent	Absent
								Day 56	01/12/92	56	Normal	Absent	Absent	Absent	Absent
	31	Reboxetine	Female	Only screening	20/10/92	14/12/92	56	Screen	13/10/92	0	Not done	Absent	Absent	Absent	Absent
								Day 28	17/11/92	29	Not done	Not done	Not done	Not done	Not done
								Day 56	15/12/92	57	Not done	Not done	Not done	Not done	Not done
	32	Fluoxetine	Female	Without Urinal	07/10/92	30/11/92	55	Screen	05/10/92	0	Normal	Not done	Not done	Not done	Not done
								Day 28	04/11/92	29	Normal	Not done	Not done	Not done	Not done
								Day 56	01/12/92	56	Normal	Not done	Not done	Not done	Not done
	49	Reboxetine	Female	Evaluated	17/11/92	11/01/93	56	Screen	10/11/92	0	Not done	Absent	Absent	Absent	Absent
								Day 28	15/12/92	29	Not done	Absent	Absent	Absent	Absent
								Day 56	12/01/93	57	Not done	Absent	Absent	Absent	Absent
	50	Reboxetine	Female	Only screening	17/11/92	18/11/92	2	Screen	10/11/92	0	Not done	Absent	Absent	Absent	Absent
	51	Fluoxetine	Female	Evaluated	17/11/92	11/01/93	56	Screen	10/11/92	0	Not done	Absent	Absent	Absent	Absent
								Day 28	15/12/92	29	Not done	Absent	Absent	Absent	Absent
								Day 56	12/01/93	57	Not done	Absent	Absent	Absent	Absent
	52	Fluoxetine	Female	Evaluated	17/11/92	11/01/93	56	Screen	10/11/92	0	Not done	Absent	Absent	Absent	Absent
								Day 28	15/12/92	29	Not done	Absent	Absent	Absent	Absent

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

URINALYSIS

					Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
18	52	Fluoxetine	Female	Evaluated	17/11/92	11/01/93	56	Day 56	12/01/93	57	Not done	Absent	Absent	Absent	Absent
	53	Fluoxetine	Female	Evaluated	15/01/93	11/03/93	56	Screen	29/12/92	0	Not done	Absent	Absent	Absent	Absent
								Day 28	12/02/93	29	Not done	Absent	Absent	Absent	Absent
								Day 56	15/03/93	60	Not done	Not done	Not done	Not done	Not done
	54	Fluoxetine	Male	Evaluated	12/01/93	08/03/93	56	Screen	05/01/93	0	Not done	Absent	Absent	Absent	Absent
								Day 28	09/02/93	29	Not done	Absent	Absent	Absent	Absent
								Day 56	09/03/93	57	Not done	Absent	Absent	Absent	Absent
20	21	Fluoxetine	Female	Without Urinal	06/11/92	30/12/92	55	Screen	30/10/92	0	Not done	Absent	Absent	Present	Not done
								Day 28	04/12/92	29	Not done	Not done	Not done	Not done	Not done
								Day 56	06/01/93	62	Not done	Not done	Not done	Not done	Not done
	22	Fluoxetine	Female	Only screening	12/11/92	16/12/92	35	Screen	10/11/92	0	Normal	Absent	Absent	Present	Present
								Day 28	14/12/92	33	Not done	Not done	Not done	Not done	Not done
21	9	Fluoxetine	Female	Evaluated	19/10/92	13/12/92	56	Screen	16/10/92	0	Not done	Absent	Absent	Absent	Absent
								Day 14	02/11/92	15	Not done	Absent	Absent	Present	Present
								Day 28	16/11/92	29	Normal	Absent	Absent	Present	Present
								Day 56	14/12/92	57	Normal	Absent	Absent	Present	Present
22	113	Fluoxetine	Male	Only screening	03/12/92	18/12/92	16	Screen	14/11/92	0	Not done	Absent	Absent	Absent	Absent
	115	Reboxetine	Male	Only screening	29/12/92	20/01/93	23	Screen	22/12/92	0	Not done	Absent	Absent	Absent	Absent
								Day 28	27/01/93	30	Not done	Not done	Not done	Not done	Not done

(*) days of treatment

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

									BLOOD PRESSURE AND HEART RATE					
									lying			standing		
Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
1	1	Fluoxetine	Male	Screen	15/11/91	36.80	15		110	80	64	115	80	68
				Day 0	15/11/91	36.80		72.00	110	80	64	115	80	68
				Day 7	21/11/91	36.40		72.00	100	80	68	100	80	68
				Day 14	29/11/91	36.20		71.20	115	80	80	115	80	80
				Day 21	06/12/91	36.80		72.00				120	80	72
				Day 28	13/12/91	36.60		71.90				130	80	84
				Day 35	20/12/91	36.80		71.90				135	90	112
				Day 42	27/12/91	36.70		71.90				150	90	88
				Day 49	02/01/92	36.50		72.00				110	80	88
				Day 56	10/01/92	36.70		72.00				130	70	76
	2	Reboxetine	Male	Screen	25/06/92	36.60	12		120	70	80	115	70	84
				Day 0	26/06/92	36.60		84.00	120	70	80	115	70	84
				Day 7	03/07/92	36.30		83.20	120	80	68	110	80	75
				Day 14	10/07/92	36.40		83.00	115	70	80	105	75	96
				Day 21	17/07/92	36.90		83.10	110	70	76	120	80	84
				Day 28	24/07/92	36.80		84.30	130	80	88	180	90	112
				Day 35	31/07/92	36.50		83.30	120	70	76	130	70	76
				Day 42	07/08/92	36.40		83.50	105	70	86	120	80	84
				Day 49	14/08/92	36.50		84.00	110	70	88	125	76	88
				Day 56	21/08/92	36.60		83.50	140	65	90	125	70	104
	3	Fluoxetine	Female	Screen	24/06/92	36.80	11		110	70	76	115	70	76
				Day 0	01/07/92	37.50		74.20	100	60	120	110	60	80
				Day 7	08/07/92	36.80		73.80	120	80	88	120	80	88
				Day 14	15/07/92	36.90		75.00	125	75	84	125	75	84
				Day 21	22/07/92	36.90		75.00	100	70	84	115	75	76
				Day 28	29/07/92	36.80		75.50	100	70	84	100	70	80
				Day 35	05/08/92	36.90		75.00	100	60	84	100	65	88
				Day 56	25/08/92	36.80		74.50	120	80	76	120	80	76
	4	Reboxetine	Female	Screen	12/08/92	35.80			100	60	52	100	65	68
				Day 0	14/08/92	35.80		73.00	100	60	63	110	70	72
				Day 7	20/08/92	35.80		72.30	105	60	92	95	60	84
				Day 14	28/08/92	36.00		72.00	90	55	80	95	60	92
				Day 21	04/09/92	37.10		71.70	100	60	72	95	60	68
				Day 28	11/09/92	36.80		71.60	120	80	76	90	60	100
				Day 35	18/09/92	37.00		72.00	100	70	88	95	70	92
				Day 42	25/09/92				100	70	88	95	70	92
	5	Fluoxetine	Female	Screen	07/10/92	36.60	22		120	70	92	130	75	100
				Day 0	13/10/92	36.60		89.50	120	70	92	130	75	100
				Day 7	20/10/92	36.40		90.50	140	90	92	150	100	88
				Day 14	27/10/92			89.70	145	100	92	140	100	96
				Day 21	03/11/92	36.90		89.30	145	100	96	135	90	96

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
1	5	Fluoxetine	Female	Day 28	10/11/92			89.20	140	85	88	150	90	100
	6	Fluoxetine	Male	Screen	11/01/93	36.60	12		135	90	72	140	95	78
				Day 0	14/01/93	36.70		90.80	130	70	82	135	85	88
				Day 7	21/01/93	36.60		90.00	120	80	72	130	90	78
				Day 14	28/01/93	36.80		90.20	120	80	72	130	90	80
				Day 21	04/02/93	36.60		90.70	130	90	72	130	95	85
				Day 28	11/02/93	36.60		90.60	130	90	72	130	95	80
2	33	Fluoxetine	Female	Screen	03/05/91	36.20	17		140	90	84	110	70	92
				Day 0	04/05/91	36.20		62.80	140	80	84	110	70	92
				Day 7	11/05/91	36.30		64.00	120	95	80	125	95	88
				Day 14	18/05/91	36.40		64.50	120	85	72	130	95	92
				Day 21	25/05/91	36.50		65.20	150	95	88	140	100	100
				Day 28	01/06/91	36.00		65.20	110	70	68	140	100	76
				Day 35	08/06/91	36.00		65.80	115	80	84	135	95	88
				Day 42	15/06/91	36.30		64.70	150	95	88	130	60	96
				Day 49	22/06/91	36.50		65.20	120	80	72	125	90	84
				Day 56	29/06/91	36.30		65.00	140	90	72	140	95	84
	34	Reboxetine	Male	Screen	02/05/91	36.20	16		170	100	100	150	90	108
				Day 0	03/05/91	36.20		68.00	160	125	80	140	110	108
				Day 7	10/05/91	36.20		67.20	160	115	76	120	95	116
				Day 14	17/05/91	36.40		67.50	145	100	88	115	90	116
				Day 21	24/05/91	36.50		67.00	165	115	84	140	95	116
				Day 28	31/05/91	36.80		67.50	180	120	80	120	90	124
				Day 35	07/06/91	36.70		67.50	165	115	80	145	105	104
				Day 42	13/06/91	36.50		67.40	170	110	84	145	115	116
	35	Reboxetine	Female	Screen	16/04/91	36.70	16		150	80	80	120	70	90
				Day 0	16/04/91	36.70		65.00	150	80	80	120	70	90
				Day 7	24/04/91	36.80		62.00	140	80	80	120	80	90
				Day 14	30/04/91	36.80		63.20	135	80	76	125	75	84
				Day 21	07/05/91			63.00	110	80	72	120	85	80
				Day 28	16/05/91	37.00		62.30	120	80	90	130	90	100
				Day 35	22/05/91	37.00		62.90	120	80	90	130	95	105
				Day 42	29/05/91	37.50		62.00	120	90	80	110	80	80
				Day 49	06/06/91	37.00		62.00	120	80	90	130	95	110
				Day 56	10/06/91	36.70		62.30	120	90	100	135	100	110
	36	Fluoxetine	Male	Screen	26/04/91	36.50	23		120	85	68	135	90	76
				Day 0	02/05/91	36.80		77.50	115	85	68	135	90	100
				Day 7	09/05/91			76.00	125	95	108	120	90	76
				Day 14	16/05/91			74.50	120	85	108	100	80	84

1135

9550083

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
2	36	Fluoxetine	Male	Day 21	23/05/91			75.50	115	75	72	120	85	76
				Day 28	31/05/91	36.50		77.00	120	80	80	120	100	90
				Day 35	06/06/91	36.50		74.00	120	80		130	90	
				Day 42	13/06/91				125	80	76	130	90	80
				Day 49	20/06/91			74.50	130	80	72	130	90	80
				Day 56	27/06/91			74.50	110	70	72	110	75	80
	37	Reboxetine	Male	Screen	01/10/91	36.50	15		120	80	80	115	80	84
				Day 0	07/10/91	36.80		65.70	120	80	88	125	85	100
				Day 7	10/10/91				110	70	76	115	70	
	38	Fluoxetine	Male	Screen	18/06/91	36.80	18		135	80	80	135	80	82
				Day 0	20/06/91	36.80		62.50	135	80	76	135	80	84
				Day 7	27/06/91	36.80		62.00	130	85	72	135	90	80
				Day 14	04/07/91	36.80		61.00	140	90	88	130	80	76
				Day 21	11/07/91	36.80		60.00	135	80	74	135	80	74
				Day 28	18/07/91	36.80		59.30	125	75	68	135	80	76
				Day 35	25/07/91	36.80		58.20	110	70	68	140	80	64
	39	Fluoxetine	Male	Screen	19/06/91	36.70	17		135	90	60	120	90	88
				Day 0	19/06/91	36.70		68.50	135	90	60	120	90	88
	40	Reboxetine	Male	Screen	05/06/91	36.40	17		145	95	68	120	95	124
				Day 0	06/06/91	36.50		78.50	145	95	68	120	95	124
				Day 7	13/06/91	36.00		79.20	155	105	76	120	100	120
				Day 14	20/06/91	36.10		78.80	140	90	72	110	95	108
				Day 21	27/06/91	36.50		79.40	135	95	76	110	90	116
	41	Fluoxetine	Male	Screen	11/02/92	36.00	14		145	95	84	120	95	84
				Day 0	13/02/92	36.00		72.00	145	95	84	120	95	84
				Day 7	20/02/92	36.80		72.00	130	80	64	125	80	84
				Day 14	27/02/92	36.80		72.00	130	80	72	115	80	80
				Day 21	05/03/92	36.80		72.00	125	70	64	120	80	72
				Day 28	12/03/92	36.00		71.00	115	80	74	105	80	84
				Day 35	19/03/92			71.80	140	90	72	130	90	80
				Day 42	26/03/92			71.90	125	90	80	135	90	72
				Day 49	02/04/92			71.90	120	80	72	125	80	80
				Day 56	09/04/92			72.50	130	85	68	140	90	72
	42	Reboxetine	Female	Screen	04/03/92	36.40	16		110	75	60	90	50	80
				Day 0	05/03/92	36.80		65.50	120	90	52	90	70	80
				Day 7	12/03/92	36.40		66.00	120	85	60	85	70	80
				Day 14	19/03/92	36.20		66.50	110	80	64	100	80	96

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
2	42	Reboxetine	Female	Day 21	26/03/92	36.80		66.20	115	90	76	100	80	76
				Day 28	02/04/92	36.90		66.40	135	80	80	100	70	116
				Day 35	09/04/92	36.50		67.00	115	80	68	100	80	72
				Day 42	16/04/92	36.30		67.00	120	80	72	120	85	96
				Day 49	23/04/92	36.80		68.90	120	90	76	110	75	104
				Day 56	30/04/92	36.10		69.00	120	80	84	110	70	92
	43	Reboxetine	Female	Screen	19/11/91	37.50	26		125	80	88	140	80	92
				Day 0	19/11/91	37.50		72.10	125	80	88	140	80	92
				Day 7	26/11/91	37.30		72.30	120	85	72	115	75	92
				Day 14	03/12/91	37.30		70.90	110	90	80	105	85	92
				Day 21	10/12/91	37.40		72.10	130	85	92	115	80	96
				Day 28	17/12/91	37.40		70.90	120	80	84	110	80	92
				Day 35	24/12/91	37.60		71.00	120	85	76	110	75	88
				Day 42	31/12/91	37.40		70.30	135	85	80	105	75	88
				Day 49	07/01/92	37.10		71.10	135	90	84	125	80	100
				Day 56	14/01/92	37.20		70.90	130	80	76	120	85	88
	44	Fluoxetine	Male	Screen	13/12/91	37.00	20		140	95	96	150	95	100
				Day 0	13/12/91	37.00		71.70	140	95	96	150	95	100
				Day 7	20/12/91			71.70	130	95	64	140	105	80
				Day 14	27/12/91			71.30	105	75	56	120	85	60
				Day 21	03/01/92			71.40	125	75	60	100	75	68
				Day 28	10/01/92			71.00	115	90	76	130	100	96
				Day 35	17/01/92			70.60				120	98	72
				Day 42	24/01/92			70.60	100	85	80	120	90	100
	45	Reboxetine	Female	Screen	10/09/92	36.40	20		115	75	96	140	100	98
				Day - 0	10/09/92	36.40		63.50	115	75	96	140	100	98
				Day 7	17/09/92			63.90	105	70	84	110	70	96
				Day 14	24/09/92			64.90	105	75	88	115	80	92
				Day 21	01/10/92			64.50	110	75	84	120	80	88
				Day 28	08/10/92			63.90	110	70	88	115	85	92
				Day 35	15/10/92			64.10	105	75	80	100	80	96
				Day 42	22/10/92			63.90	120	80	80	125	80	92
				Day 49	29/10/92			63.70	115	75	80	120	80	84
	47	Fluoxetine	Female	Screen	24/03/92	37.70	17		125	90	60	120	90	72
				Day 0	25/03/92	37.70		80.50	130	90	84	120	90	100
				Day 7	01/04/92	36.40		79.40	145	100	60	120	90	72
				Day 14	08/04/92	36.60		79.90	140	90	60	140	90	68
				Day 21	15/04/92	36.60		79.60	150	100	56	135	95	68
				Day 28	22/04/92	36.60		81.00	135	90	60	135	90	64
				Day 35	29/04/92	36.60		80.00	140	95	80	120	80	84
				Day 42	06/05/92	36.40		81.30	180	100	60	165	100	80

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 lying S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
2	47	Fluoxetine	Female	Day 49	13/05/92	36.30		81.20	130	100	64	140	100	72
				Day 56	20/05/92	36.40		80.50	130	85	56	125	90	64
	48	Reboxetine	Female	Screen	18/05/92	36.20	16		125	95	96	110	100	112
				Day 0	19/05/92	36.20		52.30	125	95	96	110	100	112
				Day 7	26/05/92	36.30		53.00	150	110	88	160	110	104
				Day 14	02/06/92	36.70		52.50	165	100	94	120	90	112
				Day 21	09/06/92	36.50		51.60	155	95	84	135	95	100
				Day 28	16/06/92	36.40		51.90	150	95	92	135	100	100
				Day 35	23/06/92	36.80		50.90	135	100	92	140	100	100
				Day 42	30/06/92	36.10		53.20	155	100	88	125	85	92
				Day 49	07/07/92	36.90		53.00	120	85	96	115	90	104
				Day 56	14/07/92	36.40		49.50	170	110	92	160	110	100
	80	Fluoxetine	Male	Screen	15/01/93	36.80	20		160	90	84	150	95	84
				Day 0	15/01/93			120.00	160	90	76	160	95	80
				Day 7	22/01/93			118.00	140	95	72	140	95	80
				Day 14	29/01/93			117.00	110	80	84	120	90	76
				Day 21	05/02/93			118.00	120	85	68	120	90	76
				Day 28	12/02/93			119.00	130	90	64	150	90	76
				Day 35	19/02/93			119.00	120	75	76	125	80	80
				Day 42	26/02/93			119.00	115	80	76	125	85	84
				Day 49	05/03/93			120.00	115	80	72	120	85	72
				Day 56	12/03/93			119.00	115	80	76	120	75	80
3	65	Fluoxetine	Female	Screen	11/10/91	36.50	20		120	80	76	120	80	92
				Day 0	15/10/91	36.40		64.50	110	70	80	100	70	92
				Day 7	22/10/91	36.40		64.00	120	80	72	110	80	88
				Day 14	29/10/91	36.50		64.50	110	70	68	110	70	96
				Day 21	05/11/91	37.70		64.50	120	80	64	100	80	88
				Day 28	12/11/91	37.50		64.70	120	80	72	100	70	84
				Day 35	19/11/91	37.70		65.00	100	70	64	95	70	96
				Day 42	26/11/91	36.90		64.50	110	80	68	100	80	88
				Day 49	03/12/91	37.40		65.50	110	60	88	100	70	88
				Day 56	10/12/91	36.80		65.60	120	80	62	115	90	82
	66	Fluoxetine	Female	Screen	11/10/91	36.90	15		120	80	84	110	80	88
				Day 0	15/10/91	36.90		65.70	120	80	76	120	80	92
				Day 7	22/10/91	36.90		63.80	120	80	92	120	80	100
				Day 14	29/10/91	37.00		63.50	130	80	96	120	80	92
				Day 21	05/11/91	36.90		63.50	110	80	80	110	80	100
	67	Reboxetine	Female	Screen	14/11/92	36.20	19		120	85	64	120	95	72
				Day 0	18/11/92	36.20		73.30	120	80	68	120	70	76

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
3	67	Reboxetine	Female	Day 7	25/11/92	36.50		72.30	110	70	76	110	80	84
				Day 14	02/12/92	36.60		72.40	120	80	72	110	70	76
				Day 21	09/12/92	36.10		73.20	110	80	89	100	70	96
				Day 28	16/12/92	37.90		73.30	100	80	80	110	90	76
	68	Reboxetine	Female	Screen	26/11/92	36.80	24		130	80	80	110	80	96
				Day 0	30/11/92	36.80		57.00	130	80	84	110	90	96
				Day 7	07/12/92	37.10		55.00	135	75	88	120	80	96
				Day 14	14/12/92	37.30		54.40	120	75	60	100	75	88
				Day 21	21/12/92	37.20		54.90	135	75	68	120	75	88
				Day 28	28/12/92	36.80		53.80	130	85	80	110	90	96
4	97	Reboxetine	Female	Screen	19/04/91	36.40	17					110	80	120
				Day 0	21/04/91	36.40		60.00	130	75	76	130	80	80
				Day 7	28/04/91	36.70		60.40	110	70	75	100	60	80
				Day 14	05/05/91	36.60		62.10	100	60	75	80	60	80
				Day 21	12/05/91	36.90		61.70	100	60	75	95	70	80
				Day 28	19/05/91	36.40		62.10	100	60	88	95	70	95
				Day 35	26/05/91	37.40		62.50	90	60	75	95	70	84
				Day 42	02/06/91	36.00		61.40	114	70	80	120	80	96
				Day 49	09/06/91	36.50		62.20	110	75	80	140	90	96
				Day 56	16/06/91	36.50		63.00	100	70	85	110	75	124
	98	Fluoxetine	Female	Screen	23/05/91	37.60	17		140	105	104	130	100	100
				Day 0	29/05/91	37.60		80.50	140	105	104	130	100	100
				Day 7	05/06/91	37.20		79.80	140	90	88	140	90	96
				Day 14	12/06/91	36.60		79.80	140	80	108	125	90	116
				Day 21	19/06/91	36.00		77.00	125	80	72	135	80	84
				Day 28	26/06/91	36.90		77.90	130	80	120	120	80	116
				Day 35	03/07/91	37.90		77.80	125	80	96	120	90	108
				Day 42	10/07/91	36.90		75.50	130	100	105	140	90	90
				Day 49	17/07/91	36.70		72.70	130	90		130	90	84
				Day 56	24/07/91	37.60		73.60	125	85	75	110	85	85
	99	Fluoxetine	Female	Screen	11/10/91	36.80	16		130	80	78	110	85	84
				Day 0	15/10/91	36.80		53.90	130	80	78	110	85	84
				Day 7	22/10/91	37.60		54.40	135	80	76	110	90	84
	100	Reboxetine	Male	Screen	08/05/92	35.60			100	70	76	100	70	104
				Day 0	08/05/92	35.60		76.30	100	70	76	100	70	104
	101	Reboxetine	Female	Screen	02/07/92	36.40	20		90	60	68	95	70	68
				Day 0	02/07/92	35.90		54.00	90	60	68	95	70	68

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
4	101	Reboxetine	Female	Day 7	09/07/92	36.40		55.50	120	90	92	95	60	104
				Day 14	16/07/92	36.70		56.50	110	70	84	100	70	92
				Day 21	28/07/92	36.20		57.00	135	80	80	120	80	68
				Day 28	30/07/92	36.00		56.70	110	80	72	105	80	80
				Day 35	06/08/92	36.20		56.10	110	70	72	100	80	96
				Day 42	13/08/92	35.90		56.10	130	90	84	125	90	72
				Day 49	20/08/92	36.00		56.60						
				Day 56	27/08/92	36.00		56.20	110	80	76	95	70	84
	102	Fluoxetine	Female	Screen	10/07/92	35.00	13		160	60	80	140	80	96
				Day 0	10/07/92	35.70		66.00	160	60	80	140	80	96
				Day 7	17/07/92	35.30		68.30	140	80	88	135	60	84
				Day 14	24/07/92	36.00		68.00	150	70		190	80	76
				Day 21	31/07/92	35.80		68.40	130	70	76	120	70	84
				Day 28	07/08/92	35.70		68.30	160	80	64	120	80	68
				Day 35	14/08/92	35.70		67.10	140	80	72	120	70	84
				Day 42	21/08/92	35.40		67.50	140	90	64	140	85	68
				Day 49	28/08/92	36.20		67.10	120	80	76	120	70	92
				Day 56	04/09/92	36.00		67.30	160	60	76	140	60	84
	103	Fluoxetine	Female	Screen	13/07/92	36.90			100	80	84	110	80	88
				Day 0	13/07/92	35.90		58.00	100	80	84	110	80	88
				Day 7	20/07/92	35.70		57.00	110	70	80	90	70	84
				Day 14	27/07/92	35.90		57.00	120	70	80	105	80	124
				Day 21	03/08/92	35.80		57.00	120	90	80	140	90	100
				Day 28	10/08/92	35.70		57.20	130	80	72	150	70	104
				Day 35	17/08/92	36.00		58.20	120	80		110	90	
	104	Reboxetine	Female	Screen	17/08/92	36.60	20		110	75	88	85	60	120
				Day 0	18/08/92	36.80		51.20	105	70	90	90	60	114
				Day 7	25/08/92	36.70		51.30	110	60	116	80	60	120
				Day 14	01/09/92	35.50		52.00	100	60	84	90	60	108
				Day 21	08/09/92	35.50		52.00	110	60	100	100	70	104
				Day 28	15/09/92	35.60		52.80	115	80	100	100	75	120
				Day 35	22/09/92	35.50		53.00	105	80	112	100	80	132
				Day 42	29/09/92	35.50		54.10	100	80	92	105	85	108
	105	Fluoxetine	Male	Screen	20/08/92	36.40	26		120	80	88	110	70	75
				Day 0	20/08/92	36.40		79.00	120	80	88	110	70	92
				Day 7	28/08/92	36.80		78.40	105	60	92	105	60	108
				Day 14	04/09/92	36.40		78.00	120	65	72	100	65	100
				Day 21	11/09/92	36.60		77.30	110	70	72	120	80	80
				Day 28	18/09/92	36.40		77.50	110	70	68	105	80	96
				Day 35	25/09/92	36.40		78.00	120	80	72	115	70	84
				Day 42	02/10/92	36.40		78.00	130	75	72	105	80	80

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 lying S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
4	105	Fluoxetine	Male	Day 49	09/10/92	36.30		77.50	100	80	68	95	70	72
				Day 56	16/10/92	36.40		77.00	120	70	84	110	80	92
5	129	Reboxetine	Female	Screen	22/11/91	36.50	12		100	80	72	100	80	70
				Day 0	29/11/91	36.70		64.00	110	80	65	100	80	63
				Day 7	05/12/91	36.50		63.00	120	85	68	120	85	68
				Day 14	12/12/91	36.00		63.00	100	70	63	90	70	65
				Day 21	19/12/91	36.70		63.00	110	90	72	110	90	74
				Day 28	26/12/91	36.00		63.00	105	85	78	100	80	80
	130	Fluoxetine	Female	Screen	21/02/92	36.70	13		100	70	66	95	65	66
				Day 0	28/02/92	36.60		49.50	100	70	66	95	65	66
				Day 7	06/03/92	36.80		49.50	100	70	64	100	70	66
				Day 14	13/03/92	36.70		49.80	100	65	59	95	60	62
				Day 21	20/03/92	36.70		50.30	90	60		87	59	
				Day 28	27/03/92	36.80		50.30	90	60		85	55	
				Day 35	03/04/92	36.80		49.00	100	65		100	60	
				Day 42	10/04/92	36.80		49.70	95	60		90	60	
				Day 49	17/04/92	36.50		49.80	95	60		90	60	
				Day 56	24/04/92	36.80		50.10	100	65		95	60	
7	193	Reboxetine	Female	Screen	01/12/91	36.20	30		100	60	76	90	60	92
				Day 0	06/12/91	36.20		41.00	100	60	76	90	60	92
				Day 7	12/12/91	36.50		41.10	100	60	92	95	60	96
				Day 14	19/12/91	36.20		41.50	100	60	100	100	60	105
				Day 21	26/12/91	36.40		42.80	120	60	98	120	60	102
				Day 28	02/01/92	36.20		42.90	100	65	80	95	65	84
				Day 35	10/01/92	36.80		43.70	110	60	92	100	70	90
				Day 42	17/01/92	36.80		43.80	115	65	85	110	65	88
				Day 49	24/01/92	36.80		44.00	110	70	80	105	70	85
				Day 56	31/01/92	36.80		44.00	100	60	75	90	60	80
	194	Fluoxetine	Female	Screen	02/01/92	36.50	18		120	50	92	110	60	95
				Day 0	09/01/92	36.50		49.80	120	50	92	120	60	95
				Day 7	16/01/92	37.00		49.00	110	50	74	110	60	80
				Day 14	23/01/92	36.80		49.00	95	60	78	90	60	85
				Day 21	30/01/92	37.20		48.50	115	70	78	95	60	78
				Day 28	06/02/92	37.00		47.60	105	61	68	110	60	78
				Day 35	13/02/92	37.20		49.40	105	70	69			
				Day 42	20/02/92	37.00		49.80	110	60	59	115	80	65
				Day 49	27/02/92	37.20		50.00	100	60	64	95	70	64
				Day 56	05/03/92	36.80		49.40	120	80	65	100	60	68
	195	Fluoxetine	Male	Screen	11/02/92	35.20	20		120	84	80	120	70	85

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 lying S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
7	195	Fluoxetine	Male	Day 0	14/02/92	35.20		88.00	120	70	80	120	80	85
				Day 7	21/02/92	36.50		87.20	125	90	78	120	80	80
				Day 14	28/02/92	36.50		86.80	140	80	69	120	80	72
				Day 21	06/03/92	36.50		87.80	130	90	75	120	80	78
				Day 35	20/03/92	36.40		85.60	130	70	76	110	70	76
				Day 42	27/03/92	36.80		84.00	120	90	70	110	80	70
				Day 49	03/04/92	36.80		86.30	130	60	75	120	80	78
				Day 56	10/04/92	36.80		87.80	135	90	72	120	80	
	196	Reboxetine	Female	Screen	22/05/92	36.50			140	110	80	150	90	98
				Day 0	28/05/92	36.50		85.30	140	110	80	150	90	98
				Day 7	04/06/92	36.80		84.30	140	105	78			80
				Day 14	11/06/92	36.50		83.40	135	110	76	140	110	
				Day 21	18/06/92	36.70		83.40	140	105	80	130	110	
				Day 28	25/06/92	37.20		83.40	150	120	68	130	110	70
				Day 35	02/07/92	36.80		82.20	140	105	72	140	105	
				Day 42	09/07/92	37.20		81.20	135	110	76	135	110	79
				Day 49	16/07/92	36.50			128	90	76	110	90	76
	197	Fluoxetine	Male	Screen	06/11/92	36.50			90	60	80	100	60	85
				Day 0	10/11/92	36.50		44.10	100	50	96	100	50	112
11	321	Fluoxetine	Female	Screen	24/10/91	37.00	19		120	70	76	130	80	80
				Day 0	14/11/91	37.00		79.00	120	70	76	130	80	80
				Day 7	22/11/91	36.80		79.00	125	75	78	135	85	86
				Day 14	29/11/91	37.10		77.30	150	70	68	155	70	64
				Day 21	05/12/91	37.00		78.10	120	80	76	110	80	70
				Day 28	13/12/91	37.50		76.20	125	80	76	115	80	80
				Day 35	20/12/91	36.80		75.30	140	85	72	140	90	76
				Day 42	27/12/91	37.00		75.40	135	80	76	140	85	80
				Day 49	03/01/92	36.70		75.40	130	80	75	135	85	80
				Day 56	10/01/92	36.90		74.60	140	80	80	140	80	76
	322	Reboxetine	Female	Screen	28/10/91	36.00	23		100	60	74	100	70	82
				Day 0	14/11/91	37.70		44.80	100	60	74	100	70	82
				Day 7	22/11/91	36.50		44.80	75	50	88	70	45	96
				Day 14	29/11/91	36.50		44.80	85	60	88	85	55	112
				Day 21	05/12/91	36.60		45.10	90	60	112	80	60	112
				Day 28	13/12/91	35.00		44.90	70	50	85	70	45	116
				Day 35	20/12/91	35.50		44.90	80	60	90	80	55	120
				Day 42	27/12/91	36.00		44.90	70	50	115	70	45	116
				Day 49	03/01/92	36.00		45.00	70	50	90	70	45	100
				Day 56	10/01/92	36.50		44.70	80	60	112	85	65	120

1142

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
11	323	Fluoxetine	Female	Screen	30/10/91	37.00	21		140	80	90	150	90	108
				Day 0	19/11/91	36.90		78.00	145	85	96	150	90	102
				Day 7	26/11/91	36.60		79.40	150	75	84	140	80	104
				Day 21	10/12/91	36.60		79.40	150	75		140	80	
				Day 28	17/12/91	36.70		79.50	140	80	84	140	85	104
				Day 56	14/01/92	36.80		77.30	140	85	84	140	80	82
	324	Reboxetine	Female	Screen	03/01/92	36.00	18		90	50	68	80	45	72
				Day 0	24/01/92	36.00		48.00	80	45	68	95	50	72
				Day 7	31/01/92	36.00		47.40	70	40	80	85	60	84
				Day 14	07/02/92	36.60		47.20	80	60	80	70	60	76
				Day 21	14/02/92	36.50		47.60	90	60	76	90	68	64
				Day 28	21/02/92	36.60		47.20	80	60	80	70	60	76
				Day 35	28/02/92	36.50		48.10	110	76	70	112	78	75
				Day 42	06/03/92	36.00		48.10	115	80	80	105	75	81
				Day 49	13/03/92	36.00		48.00	110	75	78	105	75	80
	325	Reboxetine	Female	Screen	10/01/92	37.00	19		100	60	82	115	70	80
				Day 0	11/02/92	37.00		65.90	95	60	78	90	55	72
				Day 7	18/02/92	36.80		66.50	95	70	100	85	50	112
				Day 14	25/02/92	37.00		67.00	95	60	88	80	55	76
				Day 21	03/03/92	36.80		67.00	95	60	85	82	57	75
				Day 28	10/03/92	36.80		66.40	90	60	92	85	65	100
				Day 35	17/03/92	36.70		66.30	85	55	82	85	60	84
				Day 42	24/03/92	36.60		66.80	95	60	68	85	50	70
				Day 49	31/03/92	37.00		66.30	100	65	92	90	60	100
				Day 56	07/04/92	36.80		66.20	80	60	80	80	60	84
	326	Reboxetine	Female	Screen	28/01/92	36.90	21		130	70	92	130	70	100
				Day 0	11/02/92	36.90		86.60	130	75	92	130	65	100
				Day 7	18/02/92	36.90		85.30	120	70	96	120	65	67
				Day 14	25/02/92	36.90		85.10	110	60	88	80	55	68
				Day 21	03/03/92	36.60		83.70	105	60	100	95	60	108
				Day 28	10/03/92	36.70		84.90	130	65	95	95	65	100
				Day 35	17/03/92	37.20		84.60	95	70	96	100	60	98
				Day 42	24/03/92	36.80		83.70	130	70	100	100	70	112
				Day 49	31/03/92	36.60		83.20	120	80	100	110	80	101
				Day 56	07/04/92	36.70		82.70	120	80	88	125	90	93
	327	Fluoxetine	Female	Screen	23/01/92	36.70	21		80	65	78	90	70	78
				Day 0	13/02/92	37.00		65.00	80	65	78	90	70	80
				Day 7	20/02/92	37.00		64.80	110	70	78	100	60	80
				Day 14	27/02/92	37.20		65.10	80	60		70	60	
				Day 21	05/03/92	37.20		64.90	85	60	72	90	60	69
				Day 28	12/03/92	37.20		64.50	110	85	80	95	70	84

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
11	328	Fluoxetine	Female	Screen	06/02/92	36.90	19		95	65	76	98	68	80
				Day 0	18/02/92	36.90		49.80	95	65	64	98	80	70
				Day 7	25/02/92	36.60		49.60	90	60	72	95	60	76
				Day 14	03/03/92	36.90		49.40	90	60	82	82	55	80
				Day 21	10/03/92	37.30		48.90	100	60	84	90	60	82
				Day 28	17/03/92	37.00		49.10	85	50	76	80	50	80
				Day 35	24/03/92	37.00		49.10	85	50	76	80	50	80
				Day 42	31/03/92	36.90		48.90	108	60	78	110	70	80
				Day 49	07/04/92	36.80		49.00	120	70	76	120	80	72
				Day 56	14/04/92	37.10		48.40	120	65	80	120	70	80
	329	Reboxetine	Female	Screen	25/02/92	36.90	19		80	40	72	80	50	76
				Day 0	31/03/92	36.90		66.80	80	40	72	80	50	76
				Day 7	07/04/92	36.80		66.30	100	60	92	100	70	108
				Day 14	14/04/92	36.80		66.90	100	70	96	95	70	88
				Day 21	21/04/92	36.50		66.50	110	70	72	105	70	76
				Day 28	28/04/92	36.90		66.70	95	60	80	90	50	84
				Day 35	07/05/92	36.60		65.10	85	50	96	85	60	100
				Day 42	14/05/92	36.50		64.80	85	50	92	80	50	86
				Day 49	21/05/92	36.50		63.50	90	60	90	80	60	85
				Day 56	28/05/92	36.30		64.70	80	50	100	80	50	104
	330	Reboxetine	Male	Screen	31/03/92	36.70	21		120	70	68	120	70	68
				Day 0	21/04/92	36.50		82.00	120	70	68	120	70	68
				Day 7	28/04/92	36.50		79.10	110	60	65	110	60	72
				Day 14	05/05/92	36.60		78.40	105	70	70	110	70	68
				Day 21	12/05/92	36.40		79.10	120	70	72	130	90	76
				Day 28	19/05/92	36.00		78.10	120	80	80	100	70	81
				Day 35	26/05/92	36.30		78.50	100	60	78	100	60	76
				Day 42	02/06/92	36.30		78.40	105	70	80	90	50	86
				Day 49	09/06/92	36.70		78.30	120	70	74	110	60	78
	331	Fluoxetine	Female	Day 0	26/05/92	36.90		56.70	90	60	75	80	50	72
				Day 7	02/06/92	36.30		56.60	90	50	72	80	50	76
				Day 14	09/06/92	36.70		55.90	120	70	80	95	50	75
				Day 21	16/06/92	36.50		55.00	90	60	68	80	50	80
				Day 28	23/06/92	36.70		56.00	100	60	68	90	70	70
				Day 35	30/06/92	37.00		55.70	80	40	64	80	40	68
				Day 42	07/07/92	37.00		55.70	80	40	64	80	40	68
				Day 49	14/07/92	37.00		55.70	85	45	68	90	50	70
				Day 56	21/07/92	36.50		55.70	85	55	68	90	50	70
	332	Fluoxetine	Female	Screen	16/07/92	36.00	18		105	60	66	110	65	70

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
11	332	Fluoxetine	Female	Day 0	28/07/92	36.50		55.50	105	60	66	106	60	67
				Day 7	04/08/92	36.70		55.50	106	60	67	107	60	68
				Day 14	11/08/92	36.50		55.50	110	65	70	108	65	72
				Day 21	18/08/92	36.00		55.50	110	65	70	110	65	72
				Day 35	03/09/92	37.00		53.20	80	50	67	80	50	67
				Day 42	10/09/92	36.50		53.20	85	50	70	85	50	70
				Day 49	17/09/92	36.50		53.20	85	50	70	85	50	70
				Day 56	25/09/92	36.50		53.20	85	50	70	85	50	70
	333	Reboxetine	Female	Screen	14/07/92	36.70	18		85	60	60	85	60	65
				Day 0	15/09/92	37.00		64.60	100	70	96	85	50	88
				Day 7	22/09/92	36.70		64.70	85	60	60	85	60	65
				Day 14	29/09/92	36.60		64.00	95	60	76	90	60	80
				Day 21	06/10/92	36.70		64.00	90	60	86	90	60	86
				Day 28	13/10/92	36.60		64.40	92	60	67	80	60	70
				Day 35	20/10/92	36.90		64.50	100	60	78	100	55	80
				Day 42	27/10/92	36.80		65.10	120	70	78	95	65	81
				Day 49	03/11/92	36.00		66.10	110	60	68	85	60	71
				Day 56	10/11/92	36.50		67.10	100	60	78	100	55	80
	334	Fluoxetine	Female	Screen	01/09/92	36.60	19		120	70	80	110	65	88
				Day 0	22/09/92			72.30	120	70	80	110	65	88
				Day 7	29/09/92	36.50		70.80	100	60	88	100	60	80
				Day 14	06/10/92	37.10		70.80	100	60	80	100	60	88
				Day 21	13/10/92	37.00		70.30	110	60	80	82	55	88
				Day 28	20/10/92	37.00		70.00	90	60	72	90	60	76
				Day 35	27/10/92	36.70		68.80	105	60	84	100	60	92
				Day 42	03/11/92	36.50		69.30	100	60	77	100	60	88
				Day 49	10/11/92	37.00		68.80	100	62	85	100	60	88
				Day 56	17/11/92	37.00		68.00	120	80	80	110	75	84
	335	Reboxetine	Female	Screen	29/09/92	36.60	22		88	60	72	80	55	74
				Day 0	13/10/92	36.60		56.60	90	50	88	70	40	120
				Day 7	20/10/92	36.50		57.80	70	40	80	70	40	82
				Day 14	27/10/92	36.50		56.60	90	50	88	70	40	120
				Day 21	03/11/92	36.50		56.50	100	60	85	90	50	95
				Day 28	10/11/92	36.50		56.30	88	60	72	80	55	74
				Day 35	17/11/92	36.50		56.50	100	60	96	110	65	100
12	393	Fluoxetine	Female	Screen	24/06/92	36.80			95	60	86	85	60	96
				Day 0	24/06/92	36.40		44.50	95	60	86	85	60	96
				Day 7	02/07/92	36.40		44.60	95	65	92	80	60	100
				Day 14	10/07/92	36.40		44.40	115	75	80	105	80	88
				Day 21	17/07/92	36.40		42.00	95	70	90	85	65	96
				Day 28	22/07/92	36.40		41.00	90	75	84	90	75	92

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
12	393	Fluoxetine	Female	Day 35	29/07/92	36.20		43.20	90	70	60	80	65	68
				Day 42	05/08/92	36.40		42.50	95	70	80	80	60	88
				Day 49	12/08/92	36.20		42.60	100	75	68	90	65	76
				Day 56	19/08/92	36.40		41.80	90	65	64	80	60	70
	394	Reboxetine	Male	Screen	06/07/92	36.80			130	80	86	125	70	98
				Day 0	06/07/92	36.80		77.00	130	80	86	125	70	98
				Day 7	13/07/92	36.60		79.00	105	80	84	100	80	92
				Day 14	20/07/92	36.40		80.60	130	80	90	105	80	98
				Day 21	27/07/92	36.40		83.50	130	95	86	100	80	94
				Day 28	03/08/92	36.40		81.50	130	80	92	105	70	96
				Day 35	10/08/92	36.40		81.20	110	75	82	100	70	94
				Day 42	17/08/92	36.80		81.50	130	80	90	105	75	98
				Day 49	25/08/92	36.60		81.50	130	80	84	100	75	92
				Day 56	31/08/92	36.40		81.30	130	75	80	105	70	88
	395	Reboxetine	Male	Screen	23/07/92	36.60	16		120	85	80	110	80	88
				Day 0	23/07/92	36.40		67.50	120	80	82	110	80	88
				Day 7	30/07/92	36.40		66.50	110	80	82	110	80	86
				Day 14	06/08/92	36.40		65.80	120	75	84	105	60	90
				Day 21	13/08/92	36.40		66.50	115	80	80	100	70	92
				Day 28	20/08/92	36.60		66.50	110	70	90	100	65	98
				Day 35	27/08/92	36.20		66.50	125	75	80	110	70	88
				Day 42	02/09/92	36.40		66.80	110	70	76	105	60	84
				Day 49	10/09/92	36.60		66.00	120	80	72	105	70	78
				Day 56	17/09/92	36.40		65.80	115	75	80	95	70	86
	396	Fluoxetine	Female	Screen	04/08/92	36.40	20		100	75	84	80	60	92
				Day 0	04/08/92	36.60		47.00	100	80	82	90	70	88
				Day 7	11/08/92	36.20		46.50	100	75	84	80	60	90
				Day 14	18/08/92	36.40		45.40	80	65	80	75	60	92
	497	Fluoxetine	Female	Screen	24/02/93	36.60	16		100	80	84	90	70	88
				Day 0	24/02/93	36.40		68.00	100	75	84	90	70	88
				Day 7	03/03/93	36.60		68.70	110	80	72	105	75	78
				Day 14	10/03/93	36.40		68.70	110	75	76	100	70	84
				Day 21	18/03/93	36.40		68.70	110	70	80	100	70	86
				Day 28	24/03/93	36.60		68.30	120	80	82	105	80	86
				Day 35	31/03/93	36.40		68.30	110	80	78	100	75	84
				Day 42	07/04/93	36.80		65.40	125	80		115	75	
				Day 49	15/04/93	36.40		68.00	105	75	76	100	75	82
				Day 56	22/04/93	36.40		68.00	110	75	86	100	70	96
13	385	Fluoxetine	Female	Screen	13/03/92	36.20			118	76	92	116	84	90

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
13	385	Fluoxetine	Female	Day 0	13/03/92	36.20		71.00	118	76	92	116	84	90
				Day 7	20/03/92			70.00	124	90	96	126	90	96
				Day 14	27/03/92	36.40		69.00	136	90		124	90	
				Day 21	03/04/92	36.50		69.00	130	100	94	145	100	96
				Day 28	10/04/92	36.40		69.00	122	82	100	130	100	100
				Day 42	24/04/92	36.00		69.50	122	80	84	122	80	
				Day 56	08/05/92	36.80		75.00	124	82	84	128	85	84
	386	Fluoxetine	Male	Screen	22/04/92	36.70			140	90	90	125	90	94
				Day 0	23/04/92	36.40		70.70	145	100		150	95	
	387	Reboxetine	Female	Screen	15/04/92				170	90	70			
				Day 0	19/04/92	39.00		75.80	140	80		160	90	
				Day 7	26/04/92			75.20	140	80		130	90	
				Day 14	03/05/92				140	80		135	80	
				Day 21	11/05/92	36.50		75.00	180	88	84	180	94	88
				Day 28	18/05/92	37.10		75.50	175	90	90	178	94	88
	388	Reboxetine	Male	Screen	15/03/92	36.20			126	75	78	114	75	84
				Day 0	15/03/92	36.20		68.70	126	75	78	114	84	84
				Day 7	22/03/92			74.00	112	70		92	70	
				Day 14	29/03/92	36.90		70.20	114	88	78	106	82	80
				Day 21	05/04/92	37.10		75.00	116	82		102	82	
				Day 28	12/04/92	36.90		76.50	125	85	80	105	85	88
				Day 42	26/04/92	37.10		76.00	118	76	86	105	85	92
				Day 56	11/05/92	36.50		76.00	138	100	78	140	106	82
	389	Fluoxetine	Female	Screen	19/07/92				126	84		122	82	
				Day 0	20/07/92			59.30	135	90		130	85	
				Day 7	23/07/92			59.30	130	80		110	90	
	390	Reboxetine	Male	Screen	27/05/92	37.10			120	70	90	120	75	
				Day 0	28/05/92			84.00	120	70	70	120	75	
				Day 7	03/06/92	36.30		83.00	138	90	84	125	95	86
				Day 14	10/06/92	36.00		83.50	135	94	96	122	92	106
				Day 21	18/06/92	37.20		81.00	135	90	84	130	85	80
				Day 28	25/06/92	36.00		80.00	135	90	88	135	90	80
				Day 42	09/07/92	36.80		78.00	118	88	82	122	90	84
				Day 56	24/07/92	36.70		74.50	135	88	92	130	90	96
	391	Fluoxetine	Female	Screen	04/06/92				112	84	90	120	90	90
				Day 0	11/06/92	36.60		56.00	112	84	90	120	90	90
				Day 7	18/06/92	36.80		59.00	130	90	64	145	90	64

1147

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

									BLOOD PRESSURE AND HEART RATE					
									lying			standing		
Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
13	391	Fluoxetine	Female	Day 14	25/06/92	36.50		59.00	130	90	64	135	90	60
				Day 21	02/07/92	37.00		57.00	140	85	64	135	90	64
				Day 28	10/07/92	36.70		57.50	136	90	76	130	88	82
				Day 35	16/07/92	36.40		57.50	144	92	86	145	90	90
	392	Reboxetine	Female	Screen	12/08/92	37.00	16		140	95	80	125	100	85
				Day 0	13/08/92	37.00		74.90	125	75	70	135	80	75
				Day 7	21/08/92			56.10	120	80	76	120	80	
				Day 14	27/08/92				120	85		125	85	
	501	Reboxetine	Male	Screen	30/10/92	37.10			140	110	88	125	110	94
				Day 0	02/11/92	36.80		61.00	130	92	88	125	90	90
				Day 7	09/11/92	37.10		61.00	136	90		118	90	96
				Day 14	16/11/92	37.10		60.00	138	94	84	120	90	92
				Day 21	23/11/92	37.20		61.00	145	100	84	140	100	84
				Day 28	30/11/92	37.10		61.00	150	105	84	120	98	90
				Day 42	14/12/92	36.90		62.00	138	100	96	138	100	98
				Day 56	31/12/92	37.00		62.00	140	110	88	120	110	92
	502	Fluoxetine	Female	Screen	03/11/92	36.00			130	90	70	130	90	72
				Day 0	03/11/92	36.90		82.00	130	90	70	130	90	70
				Day 7	11/11/92	36.80		81.00	135	85	72	135	85	
				Day 14	16/11/92			85.00	130	85	84	130	85	90
				Day 21	23/11/92	36.80		84.50	130	90	76	130	88	78
				Day 28	30/11/92	36.80		85.00	130	88	76	130	85	78
				Day 42	14/12/92	36.80		83.00	120	80	60	120	80	60
				Day 56	24/12/92	36.80		81.00	110	80	72	120	80	76
	503	Reboxetine	Female	Screen	12/11/92	37.00			130	80	64	120	80	68
				Day 0	12/11/92	37.10		57.00	130	80	64	120	80	68
				Day 7	19/11/92	37.10		57.00	125	70	70	90	70	70
	504	Fluoxetine	Female	Screen	25/11/92				120	80	74	115	80	80
				Day 0	26/11/92			59.00	126	80	74	115	80	80
				Day 7	04/12/92	36.80		59.00	118	88	60	118	88	60
				Day 14	10/12/92	37.10		59.00	128	78		128	80	
				Day 28	24/12/92	37.00		59.00	120	85	76	125	80	84
				Day 42	06/01/93	36.90		58.00	130	80		130	80	
				Day 56	20/01/93	36.90		58.00	118	80	72	118	80	76
	505	Reboxetine	Female	Screen	26/08/92	36.40			138	95	72	118	84	84
				Day 0	31/08/92	36.40		84.00	138	95	72	118	84	84
				Day 7	07/09/92	36.80		82.00	140	95	84	135	95	84

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
13	505	Reboxetine	Female	Day 14	14/09/92	37.00		82.00	142	95	77	126	90	88
				Day 21	21/09/92	37.10		82.00	145	95	80	140	95	84
				Day 28	28/09/92	36.40		82.00	145	95	72	130	95	80
				Day 42	12/10/92	36.70		82.00	145	90		145	90	
				Day 56	22/10/92	36.60		82.00	130	85	90	120	85	
	506	Fluoxetine	Male	Screen	23/10/92				140	85	78	125	85	84
				Day 0	27/10/92	37.00		67.00	140	85	84	125	85	96
				Day 7	04/11/92	36.50		66.00	130	90	82	120	85	96
				Day 14	10/11/92	36.90		66.00	130	90	84	128	85	84
				Day 21	18/11/92	37.10		65.00	118	70	84	120	75	86
				Day 28	26/11/92	37.20		65.00	128	85	66	122	85	76
				Day 42	10/12/92	37.20		68.00	120	80		120	80	
				Day 56	24/12/92	37.00		68.00	125	75	76	125	80	76
	507	Fluoxetine	Female	Screen	10/09/92	36.80			142	88	96	132	88	101
				Day 0	10/09/92	36.80		62.00	142	88	96	132	88	101
				Day 7	18/09/92	37.10		62.00	145	95	78	138	90	80
				Day 14	25/09/92	36.80		62.00	140	90		125	90	
				Day 21	02/10/92	37.10		62.00	145	90	88	140	90	86
				Day 28	09/10/92				145	90	92	145	90	90
				Day 42	23/10/92	37.20		62.00	145	105	100	140	100	100
				Day 56	06/11/92	36.90		62.00	150	100	86	150	100	90
	508	Reboxetine	Female	Screen	29/10/92				130	85	80	125	80	84
				Day 0	02/11/92	37.20		91.50	125	80	80	125	80	84
				Day 7	09/11/92	36.80		91.00	140	90	82	140	90	82
				Day 14	16/11/92	37.00		92.00	140	100	82	135	100	88
				Day 21	25/11/92	37.10		91.00	124	98		125	100	
				Day 28	30/11/92	37.00		91.50	145	100	78	125	100	80
				Day 42	14/12/92	37.20		91.50	122	85	80	118	85	80
				Day 56	31/12/92			92.00	110	80		100	80	
	521	Reboxetine	Male	Screen	30/11/92	37.00			150	100	84	146	100	84
				Day 0	01/12/92				150	100	84	146	100	84
				Day 7	07/12/92	37.10		71.00	160	110	84	140	90	96
				Day 14	14/12/92	37.10		72.00	135	90	84	125	90	86
				Day 28	30/12/92	37.10		71.50	155	105	94	138	95	102
				Day 42	13/01/93	37.00		71.50	138	95	82	130	90	86
				Day 56	27/01/93	37.10		71.00	135	90	84	130	90	86
14	397	Fluoxetine	Female	Screen	14/04/92	36.70	12		126	80	80	122	82	82
				Day 0	14/04/92	36.70		58.00	126	80	80	122	82	82
				Day 7	21/04/92	36.60		58.00	128	80	96	130	80	100

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
14	397	Fluoxetine	Female	Day 14	28/04/92	36.60		59.00	126	70	84	126	74	84
				Day 21	05/05/92	36.80		59.00	120	70	80	124	70	82
				Day 28	12/05/92	36.80		59.00	120	70	76	120	70	76
				Day 42	26/05/92	36.80		58.50	124	74	76	120	74	78
				Day 56	09/06/92	36.70		58.50	120	74	74	122	74	72
	398	Reboxetine	Female	Screen	15/04/92	36.60	12		110	78	74	112	78	78
				Day 0	15/04/92	36.60		44.00	110	78	74	112	78	78
				Day 7	22/04/92	36.60		44.00	120	80	84	122	80	86
				Day 14	29/04/92	36.80		44.50	112	80	82	110	80	84
				Day 21	06/05/92	36.80		44.00	114	78	80	112	78	80
				Day 28	13/05/92	36.80		44.50	110	80	76	114	80	78
				Day 42	27/05/92	36.80		46.50	112	80	78	110	76	82
				Day 56	10/06/92	36.90		47.00	106	74	86	104	76	88
	399	Reboxetine	Female	Screen	13/04/92	36.80	16		120	80	80	116	80	82
				Day 0	21/04/92	36.80		55.00	120	80	80	116	80	82
				Day 7	28/04/92	36.60		54.50	106	76	80	102	76	82
				Day 14	05/05/92	36.70		54.00	114	78	84	112	80	86
				Day 21	12/05/92	36.70		53.00	120	80	82	116	80	84
				Day 28	19/05/92	36.70		53.50	114	80	80	118	80	76
				Day 42	02/06/92	36.80		53.00	120	80	82	120	82	84
				Day 56	16/06/92	36.80		53.50	124	80	86	120	80	84
	400	Fluoxetine	Male	Screen	14/05/92	36.70	14		114	84	78	116	84	82
				Day 0	15/05/92	36.70		79.00	114	84	78	116	84	82
				Day 7	22/05/92	36.90		77.50	114	80	84	110	80	84
				Day 14	29/05/92	36.80		77.50	112	82	78	110	82	80
				Day 21	05/06/92	36.80		77.50	110	84	78	108	82	78
				Day 28	12/06/92	36.70		76.00	112	80	80	110	80	80
				Day 42	25/06/92	36.80		77.00	114	76	76	110	78	80
				Day 56	14/07/92	36.90		77.50	110	74	70	112	74	72
	401	Fluoxetine	Female	Screen	22/05/92	36.70	15		110	80	82	112	80	86
				Day 0	22/05/92	36.70		51.50	110	80	82	112	80	86
				Day 7	29/05/92	36.90		51.00	116	80	78	118	80	80
				Day 14	05/06/92	36.90		52.00	114	78	76	116	80	80
				Day 21	12/06/92	36.80		52.00	110	80	76	106	80	82
				Day 28	19/06/92	36.90		53.00	114	80	78	110	82	76
				Day 42	02/07/92	36.90		52.00	106	80	80	102	80	82
				Day 56	17/07/92	36.90		52.00	110	82	76	108	80	74
	402	Reboxetine	Female	Screen	27/05/92	36.90	16		114	70	70	112	70	70
				Day 0	27/05/92	36.80		99.00	114	70	70	112	70	70

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
14	402	Reboxetine	Female	Day 7	03/06/92	36.80		99.00	104	66	70	106	70	68
				Day 14	10/06/92	36.80		100.00	110	76	74	110	76	74
				Day 21	17/06/92	36.80		100.00	120	78	82	114	80	84
				Day 28	24/06/92	36.90		100.00	126	80	84	120	80	84
				Day 42	08/07/92	36.80		98.00	116	80	84	110	80	88
				Day 56	22/07/92	36.90		98.00	124	80	76	116	80	78
	403	Reboxetine	Female	Screen	29/05/92	36.70	14		116	76	78	120	78	80
				Day 0	29/05/92	36.70		71.00	116	76	78	120	78	80
				Day 7	05/06/92	36.80		70.50	108	78	86	106	78	86
				Day 14	11/06/92	36.80		71.00	116	80	82	114	80	84
				Day 21	19/06/92	36.80		70.00	112	78	80	112	80	76
				Day 28	26/06/92	36.90		70.00	116	80	86	112	76	84
				Day 42	10/07/92	36.90		70.00	112	80	76	110	80	80
				Day 56	24/07/92	37.00		69.00	110	74	96	104	70	96
	404	Fluoxetine	Female	Screen	16/06/92	36.90	14		104	66	78	102	70	78
				Day 0	16/06/92	36.90		57.00	104	66	78	102	70	78
				Day 7	23/06/92	36.80		58.00	110	70	76	100	70	78
				Day 14	30/06/92	36.80		58.00	106	70	82	102	72	84
				Day 21	07/07/92	36.80		57.00	104	70	78	102	70	80
				Day 28	14/07/92	36.80		57.00	106	70	74	104	70	74
				Day 42	28/07/92	36.90		57.00	108	70	76	104	70	76
				Day 56	11/08/92	36.90		57.00	104	70	70	100	70	70
	405	Fluoxetine	Female	Screen	19/06/92	36.80	14		114	80	76	110	76	80
				Day 0	22/06/92	36.80		51.00	114	80	76	110	76	80
				Day 7	29/06/92	36.80		51.50	120	76	80	114	76	84
				Day 14	06/07/92	36.90		52.00	104	70	82	104	70	84
				Day 21	13/07/92	36.80		52.00	102	76	80	102	74	82
				Day 28	20/07/92	36.80		52.00	100	68	72	102	70	72
				Day 42	04/08/92	36.80		54.00	102	76	76	102	76	76
				Day 56	18/08/92	36.80		54.00	94	66	74	94	70	74
	406	Fluoxetine	Female	Screen	30/06/92	36.80	16		114	78	80	114	78	82
				Day 0	30/06/92	36.80		60.00	114	78	80	114	78	82
				Day 7	07/07/92	36.90		59.50	134	80	80	134	80	80
				Day 14	14/07/92	36.90		57.50	130	80	88	132	84	90
				Day 21	21/07/92	37.00		57.50	124	84	90	120	84	90
	407	Reboxetine	Male	Screen	13/07/92	36.90	15		130	90	78	132	90	78
				Day 0	14/07/92	36.90		75.00	130	90	78	132	90	78
				Day 7	20/07/92	36.80		73.00	140	98	80	130	96	84
				Day 14	27/07/92	36.90		72.00	120	88	80	116	84	84

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
14	407	Reboxetine	Male	Day 21	04/08/92	37.00		72.00	128	90	78	130	90	80
				Day 28	10/08/92	37.00		71.00	124	84	78	124	86	80
				Day 42	24/08/92	37.00		71.50	130	94	80	128	94	84
	408	Reboxetine	Female	Screen	04/08/92	36.90	16		126	80	84	130	80	84
				Day 0	04/08/92	36.90		106.00	126	80	84	130	80	84
				Day 7	11/08/92	37.00		106.00	130	86	80	124	80	84
				Day 14	18/08/92	36.90		107.00	126	84	80	130	84	84
				Day 21	26/08/92	37.00		106.00	124	82	78	126	84	80
				Day 28	01/09/92	37.00		106.00	122	84	80	126	84	78
				Day 42	15/09/92	37.00		107.00	126	82	78	122	84	82
				Day 56	30/09/92	37.00		107.00	126	82	80	124	82	80
	509	Fluoxetine	Female	Screen	29/09/92	37.00	14		130	80	80	124	80	80
				Day 0	29/09/92	37.00		102.00	130	80	80	124	80	80
				Day 7	06/10/92	37.00		103.00	134	80	78	134	82	84
				Day 14	13/10/92	37.00		105.00	140	86	80	134	84	80
				Day 21	20/10/92	37.00		105.00	136	84	80	132	84	80
				Day 28	28/10/92	37.00		104.00	124	80	78	120	80	80
				Day 42	10/11/92	37.00		101.00	126	84	78	130	82	78
	510	Fluoxetine	Female	Screen	30/09/92	37.00	16		108	74	84	108	74	82
				Day 0	30/09/92	37.00		55.50	108	74	84	108	74	82
				Day 7	08/10/92	37.00		55.00	110	76	80	106	74	80
				Day 14	15/10/92	36.90		55.00	110	80	82	106	80	82
				Day 21	22/10/92	37.00		55.00	98	72	76	100	72	76
				Day 28	29/10/92	37.00		55.50	90	68	78	92	70	78
				Day 42	12/11/92	36.80		56.00	114	74	78	108	72	82
				Day 56	26/11/92	36.70		56.00	108	74	76	100	74	78
	511	Reboxetine	Female	Screen	22/10/92	36.90	16		144	100	78	140	96	82
				Day 0	23/10/92	36.90		64.00	144	100	78	140	96	82
				Day 7	29/10/92	37.00		65.00	140	90	82	142	90	82
				Day 14	05/11/92	36.90		59.00	142	92	80	138	90	80
				Day 21	13/11/92	37.00		63.00	140	90	86	136	90	86
				Day 28	20/11/92	37.00		62.00	130	90	92	124	86	98
				Day 42	04/12/92	36.80		62.00	130	84	80	126	84	82
				Day 49	11/12/92	36.80		61.00	130	80	84	126	80	84
	512	Reboxetine	Female	Screen	03/11/92	36.90	14		106	60	80	102	62	80
				Day 0	03/11/92	36.90		57.50	106	60	80	102	62	80
				Day 7	10/11/92	36.90		56.00	110	70	76	110	68	76
				Day 14	17/11/92	37.40		55.00	108	68	74	104	68	78
				Day 21	24/11/92	36.60		56.00	114	78	80	114	78	80

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
14	537	Reboxetine	Female	Screen	03/11/92	36.80	16		100	60	78	100	62	78
				Day 0	03/11/92	36.80		56.00	100	60	78	100	62	78
				Day 7	10/11/92	37.00		55.00	110	66	78	100	70	82
				Day 14	17/11/92	36.90		56.00	124	82	78	120	82	80
				Day 21	24/11/92	36.80		55.00	114	76	76	114	76	76
				Day 28	02/12/92	36.90		56.00	120	84	70	116	84	70
				Day 42	15/12/92	36.70		55.00	110	78	80	106	78	80
				Day 56	07/01/93	37.00		55.00	96	60	80	85	60	82
	538	Fluoxetine	Female	Screen	12/02/93	36.80	15		110	68	70	112	68	74
				Day 0	12/02/93	36.80		70.00	110	68	70	112	68	74
				Day 7	19/02/93	36.90		70.00	124	80	76	118	80	80
				Day 14	26/02/93	37.00		68.00	110	74	76	104	74	76
				Day 21	05/03/93	36.90		67.00	104	78	76	104	80	76
				Day 28	12/03/93	36.80		69.00	110	60	70	100	64	72
				Day 42	26/03/93	36.90		69.00	104	70	74	104	70	74
				Day 56	09/04/93	37.00		68.50	96	66	70	94	66	68
	539	Fluoxetine	Female	Screen	10/03/93	36.90	16		104	76	88	100	76	88
				Day 0	10/03/93	36.90		43.00	104	76	88	100	76	88
				Day 7	17/03/93	37.00		42.00	104	78	84	100	72	86
				Day 14	24/03/93	36.80		42.00	104	70	78	100	70	78
				Day 21	31/03/93	36.90		41.50	104	70	80	92	70	84
				Day 28	07/04/93	36.80		42.50	114	74	76	110	76	80
				Day 42	21/04/93	36.90		42.00	102	60	88	100	62	88
				Day 56	05/05/93	36.90		42.00	104	80	82	100	76	84
15	409	Reboxetine	Male	Screen	24/03/92	36.70	14		130	100	80	120	100	90
				Day 0	07/04/92	36.70		78.00	130	100	78	120	90	88
				Day 7	14/04/92	36.60		78.00	130	90	80	110	90	94
				Day 14	21/04/92	36.60		78.00	140	90	88	120	90	94
				Day 21	28/04/92	36.70		78.00	130	90	84	120	90	90
				Day 28	05/05/92	36.70		78.00	120	90	78	120	90	86
				Day 42	19/05/92	36.70		78.00	120	85	78	125	85	86
				Day 56	02/06/92	36.70		78.00	120	80	75	125	85	80
	410	Fluoxetine	Female	Screen	09/04/92	36.70	15		140	90	72	140	90	80
				Day 0	16/04/92	36.70		60.00	140	90	72	140	90	80
				Day 7	23/04/92	36.70		60.00	140	90	72	130	90	80
				Day 14	30/04/92	36.70		60.00	140	90	76	130	90	80
				Day 21	07/05/92	36.80		61.00	130	85	76	120	85	82
				Day 28	14/05/92	36.50		61.00	140	90	65	140	90	72
				Day 35	21/05/92	36.50		61.00	140	90	68	130	90	75

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

									BLOOD PRESSURE AND HEART RATE					
									lying			standing		
Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	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	410	Fluoxetine	Female	Day 42	28/05/92	36.50		61.00	140	90	65	140	90	70
				Day 56	11/06/92	36.50		61.00	130	90	75	140	90	84
	411	Reboxetine	Female	Screen	21/04/92	36.60	16		150	80	70	150	90	75
				Day 0	21/04/92	36.60		51.00	150	80	78	140	80	84
				Day 7	28/04/92	36.60		50.00	160	100	84	130	100	96
				Day 14	05/05/92	36.60		50.00	150	90	88	140	90	96
				Day 21	12/05/92	36.60		51.00	140	85	88	130	85	96
				Day 28	19/05/92	36.50		51.00	130	80	75	140	80	84
				Day 42	02/06/92	36.50		51.00	130	80	78	130	80	84
				Day 56	16/06/92	36.70		51.00	130	80	75	125	80	80
	412	Fluoxetine	Female	Screen	10/04/92	36.90	14		130	80	75	130	80	80
				Day 0	22/04/92	36.70		59.00	130	80	74	130	80	85
				Day 7	29/04/92	36.50		59.00	135	80	72	130	80	80
				Day 14	06/05/92	36.70		59.00	130	80	75	120	80	80
				Day 21	13/05/92	36.50		60.00	130	80	70	120	80	80
				Day 28	20/05/92	36.50		62.00	130	80	72	120	80	78
				Day 42	03/06/92	36.70		62.00	130	80	70	120	70	76
				Day 56	17/06/92	36.70		62.00	120	80	70	115	80	76
	413	Reboxetine	Female	Screen	22/04/92	36.50	14		120	80	84	110	80	92
				Day 0	29/04/92	36.50		93.00	120	80	84	110	80	92
				Day 7	06/05/92	36.50		93.00	120	80	84	110	80	88
				Day 14	13/05/92	36.60		93.00	130	80	78	120	80	86
				Day 21	20/05/92	36.60		93.00	120	80	72	120	80	76
				Day 28	27/05/92	36.60		93.00	120	80	70	120	80	76
				Day 42	10/06/92	36.70		93.00	120	80	68	115	80	74
				Day 56	24/06/92	36.70		93.00	125	80	72	115	80	78
	414	Fluoxetine	Male	Screen	26/05/92	36.50	14		120	80	75	125	80	80
				Day 0	01/06/92	36.70		83.00	120	80	75	125	80	80
				Day 7	08/06/92	36.70		83.00	120	80	72	130	80	80
				Day 14	15/06/92	36.80		83.00	120	80	72	120	80	78
				Day 21	22/06/92	36.70		83.00	120	80	75	120	80	80
				Day 28	29/06/92	36.70		83.00	125	80	78	120	80	84
				Day 42	13/07/92	36.70		83.00	130	80	75	125	80	84
				Day 56	27/07/92	36.50		83.00	130	80	72	120	80	78
	415	Reboxetine	Female	Screen	04/06/92	36.70	14		110	70	90	110	70	95
				Day 0	11/06/92	36.80		58.00	110	70	80	110	70	88
				Day 7	18/06/92	36.80		57.00	110	70	88	110	70	95
				Day 14	25/06/92	36.70		56.00	110	70	80	110	70	86
				Day 21	02/07/92	36.80		56.50	120	80	80	110	70	86

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
15	415	Reboxetine	Female	Day 28	09/07/92	36.80		57.50	120	80	90	110	70	95
				Day 42	23/07/92	36.70		57.50	120	80	90	110	70	95
				Day 56	06/08/92	36.70		57.50	120	80	90	110	70	95
	416	Fluoxetine	Female	Screen	19/06/92	36.80	15		120	80	75	110	70	84
				Day 0	22/06/92	36.80		61.00	120	80	75	110	70	84
				Day 7	29/06/92	36.80		61.00	120	70	80	110	70	88
				Day 14	06/07/92	36.80		61.00	120	70	75	110	70	84
				Day 21	13/07/92	36.80		62.00	120	70	75	110	70	80
				Day 28	20/07/92	36.60		62.00	130	80	85	120	80	90
				Day 42	03/08/92	36.60		62.00	130	80	80	120	80	85
				Day 56	17/08/92	36.60		62.00	120	80	82	110	70	88
	417	Reboxetine	Female	Screen	11/06/92	36.80	14		120	80	65	115	75	70
				Day 0	18/06/92	36.80		62.00	120	80	65	115	75	70
				Day 7	25/06/92	36.70		62.00	120	80	65	120	80	68
				Day 14	02/07/92	36.80		62.50	120	80	66	120	80	68
				Day 21	09/07/92	36.70		63.00	115	75	62	110	70	70
				Day 28	16/07/92	36.60		63.50	120	80	65	120	80	68
				Day 42	30/07/92	36.50		63.50	125	80	62	120	75	66
				Day 56	13/08/92	36.60		63.50	120	80	65	115	80	68
	418	Reboxetine	Female	Screen	07/07/92	36.60	14		110	70	76	100	70	82
				Day 0	16/07/92	36.60		52.00	110	70	76	100	70	82
				Day 7	23/07/92	36.60		52.00	110	70	75	100	70	80
				Day 14	30/07/92	36.60		52.00	120	70	75	110	70	80
				Day 21	06/08/92	36.70		53.00	120	70	72	110	70	82
				Day 28	13/08/92	36.70		54.00	120	80	75	110	80	82
				Day 42	27/08/92	36.70		54.00	120	70	75	110	70	82
				Day 56	10/09/92	36.60		54.00	120	80	75	120	80	80
	419	Fluoxetine	Female	Screen	08/07/92	36.60	14		140	80	64	130	80	68
				Day 0	15/07/92	36.60		59.00	140	80	64	130	80	68
				Day 7	22/07/92	36.70		59.00	140	80	60	130	80	66
				Day 14	29/07/92	36.70		59.00	130	80	62	125	80	68
				Day 21	05/08/92	36.60		59.00	140	80	62	130	80	68
				Day 28	12/08/92	36.80		59.00	140	80	64	130	80	70
				Day 49	02/09/92	36.80		59.00	140	80	63	130	80	68
				Day 56	09/09/92	36.70		59.00	140	80	66	130	80	70
	420	Fluoxetine	Male	Screen	15/07/92	36.70	13		140	90	75	130	90	82
				Day 0	19/08/92	36.70		72.00	140	90	75	130	90	82
				Day 7	26/08/92	36.70		72.00	140	90	78	140	90	86
				Day 14	02/09/92	36.70		72.00	140	90	74	130	90	80

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
15	420	Fluoxetine	Male	Day 21	09/09/92	36.70		72.00	140	90	75	130	90	82
				Day 28	16/09/92	36.80		72.00	140	90	70	130	90	76
				Day 42	30/09/92	36.60		72.00	140	90	70	130	90	76
				Day 56	14/10/92	36.60		72.00	140	90	72	140	90	76
	421	Reboxetine	Female	Screen	24/07/92	36.70	15		140	90	78	145	90	84
				Day 0	31/07/92	36.70		87.00	140	90	78	145	90	84
				Day 7	07/08/92	36.70		87.00	140	90	76	150	90	82
				Day 14	14/08/92	36.60		87.00	140	90	76	140	90	82
				Day 21	21/08/92	36.60		87.00	140	90	75	140	90	80
				Day 28	28/08/92	36.60		87.00	140	90	75	140	90	82
				Day 35	04/09/92	36.60		87.00	140	90	70	140	90	76
				Day 42	11/09/92	36.60		87.00	140	90	72	140	90	78
				Day 56	25/09/92	36.70		87.00	130	90	72	140	90	78
	422	Fluoxetine	Male	Screen	14/08/92	36.60	14		130	80	82	120	80	88
				Day 0	18/08/92	36.60		61.00	130	80	82	130	80	86
				Day 7	25/08/92	36.70		61.00	120	80	80	120	80	86
				Day 14	01/09/92	36.70		61.00	120	80	80	130	80	86
				Day 21	08/09/92	36.70		61.00	120	80	78	130	80	86
				Day 28	15/09/92	36.80		61.00	120	80	80	120	80	86
				Day 42	29/09/92	36.60		61.00	120	80	80	130	80	88
				Day 56	13/10/92	36.60		61.00	120	80	78	120	80	82
	423	Fluoxetine	Female	Screen	15/08/92	36.60	14		110	80	68	110	80	72
				Day 0	20/08/92	36.70		58.00	110	70	68	110	70	72
				Day 7	27/08/92	36.60		57.00	120	80	66	110	80	72
				Day 14	03/09/92	36.60		56.00	120	80	66	120	80	70
				Day 21	10/09/92	36.70		55.50	120	80	66	110	80	72
				Day 28	17/09/92	36.70		54.50	110	70	65	110	70	70
				Day 42	01/10/92	36.70		55.50	120	80	66	110	80	72
				Day 56	15/10/92	36.70		57.50	120	80	66	110	80	72
	424	Reboxetine	Male	Screen	13/08/92	36.60	14		120	80	70	125	80	76
				Day 0	20/08/92	36.60		71.00	120	80	70	125	80	76
				Day 7	27/08/92	36.60		71.00	120	80	72	125	85	76
				Day 14	03/09/92	36.60		71.50	120	80	72	125	80	78
				Day 21	10/09/92	36.60		72.00	120	80	70	120	80	74
				Day 28	17/09/92	36.60		72.50	120	80	70	120	80	74
				Day 42	01/10/92	36.60		73.00	125	80	72	125	80	76
				Day 56	15/10/92	36.60		73.00	120	80	72	120	80	76
	425	Reboxetine	Female	Screen	24/09/92	36.70	15		130	80	72	140	80	78
				Day 0	01/10/92	36.70		72.00	130	80	72	140	80	78

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
15	425	Reboxetine	Female	Day 7	08/10/92	36.70		72.00	130	80	72	130	80	76
				Day 14	15/10/92	36.60		72.00	130	80	74	130	80	78
				Day 21	22/10/92	36.60		72.00	140	80	72	140	80	76
				Day 28	29/10/92	36.70		72.00	140	80	72	140	80	75
				Day 42	12/11/92	36.70		72.00	140	80	72	140	80	76
				Day 56	26/11/92	36.60		72.00	140	80	70	140	80	76
	426	Fluoxetine	Male	Screen	20/10/92	36.60	14		110	70	70	110	70	75
				Day 0	27/10/92	36.70		64.00	110	70	70	110	70	76
				Day 7	03/11/92	36.70		64.00	110	70	70	110	70	76
				Day 14	10/11/92	36.60		64.00	110	70	72	110	70	78
				Day 21	17/11/92	36.60		64.00	110	70	72	110	70	76
				Day 28	24/11/92	36.60		64.00	110	70	70	110	70	76
				Day 42	08/12/92	36.60		64.00	110	70	70	110	70	74
				Day 56	22/12/92	36.60		64.00	110	70	70	110	70	74
	427	Reboxetine	Female	Screen	25/11/92	36.60	13		130	90	72	120	90	76
				Day 0	02/12/92	36.60		84.00	130	90	72	120	90	76
				Day 7	09/12/92	36.60		84.00	130	90	70	120	90	74
				Day 14	16/12/92	36.60		84.00	130	90	70	125	90	76
				Day 21	23/12/92	36.60		84.00	135	90	68	125	90	72
				Day 28	30/12/92	36.60		84.00	130	80	70	120	80	76
				Day 42	13/01/93	36.60		84.00	130	80	70	120	80	74
				Day 56	27/01/93	36.60		84.00	130	80	70	120	80	74
	428	Fluoxetine	Male	Screen	25/11/92	36.60	14		120	80	72	120	80	70
				Day 0	02/12/92	36.60		69.00	120	80	72	120	80	70
				Day 7	09/12/92	36.60		69.00	120	80	74	120	80	70
				Day 14	16/12/92	36.60		69.00	120	80	70	115	80	76
				Day 21	23/12/92	36.60		69.00	120	80	70	115	80	74
				Day 28	30/12/92	36.60		69.00	120	80	70	120	80	72
				Day 42	13/01/93	36.60		69.00	120	80	68	115	80	72
				Day 56	27/01/93	36.60		69.00	120	80	68	115	80	74
	449	Reboxetine	Female	Screen	01/12/92	36.70	14		125	70	68	120	70	74
				Day 0	07/12/92	36.60		70.00	125	70	68	120	70	74
				Day 7	14/12/92	36.60		69.50	125	70	70	120	70	76
				Day 14	21/12/92	36.60		69.50	130	70	70	120	70	76
				Day 21	28/12/92	36.60		69.50	125	70	70	120	70	74
				Day 28	04/01/93	36.60		70.00	125	70	68	120	70	72
				Day 42	18/01/93	36.60		70.00	120	70	70	120	70	76
				Day 56	01/02/93	36.60		70.00	120	70	70	120	70	76
	450	Fluoxetine	Male	Screen	29/11/92	36.60	13		110	70	80	110	70	82

1157

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
15	450	Fluoxetine	Male	Day 0	09/12/92	36.60		91.00	110	70	80	110	70	84
				Day 7	16/12/92	36.60		91.00	110	70	78	110	70	82
				Day 14	23/12/92	36.60		91.00	110	70	78	110	70	82
				Day 21	30/12/92	36.60		91.00	110	70	78	110	70	84
				Day 28	06/01/93	36.60		91.00	110	70	78	110	70	82
				Day 42	20/01/93	36.60		91.00	110	70	76	110	70	82
				Day 56	03/02/93	36.60		91.00	110	70	74	110	70	80
	451	Fluoxetine	Female	Screen	07/12/92	36.60	14		130	90	70	120	85	76
				Day 0	17/12/92	36.70		68.00	130	90	70	120	85	76
				Day 7	24/12/92	36.70		68.00	130	90	70	125	90	76
				Day 14	31/12/92	36.60		68.00	130	90	68	125	85	74
				Day 21	07/01/93	36.70		68.00	130	80	70	125	80	76
				Day 28	14/01/93	36.60		68.00	130	90	68	125	90	74
				Day 42	28/01/93	36.60		68.00	130	80	68	125	80	74
				Day 56	11/02/93	36.60		68.00	130	80	68	125	80	72
	452	Reboxetine	Female	Screen	15/12/92	36.70	13		120	80	74	115	80	78
				Day 0	22/12/92	36.70		65.00	120	80	74	115	80	78
				Day 7	29/12/92	36.70		65.00	120	80	72	115	80	75
				Day 14	05/01/93	36.70		65.00	120	80	72	115	80	76
				Day 21	12/01/93	36.70		65.00	120	80	74	120	80	78
				Day 28	19/01/93	36.70		65.00	120	80	76	115	80	80
				Day 42	02/02/93	36.70		65.00	120	80	75	115	70	80
				Day 56	16/02/93	36.60		65.00	125	80	82	120	80	88
	454	Fluoxetine	Male	Screen	08/01/93	36.70	14		130	80	72	130	80	76
				Day 0	18/01/93	36.70		67.00	130	80	72	130	80	76
				Day 7	25/01/93	36.60		67.00	130	80	70	130	80	76
				Day 14	01/02/93	36.60		67.00	130	80	72	130	80	76
				Day 21	08/02/93	36.60		67.00	130	80	72	130	80	76
				Day 28	15/02/93	36.60		67.00	130	80	72	125	80	75
				Day 42	01/03/93	36.60		67.00	130	80	74	130	80	76
				Day 56	15/03/93	36.60		67.00	130	80	74	125	80	78
16	429	Fluoxetine	Female	Screen	12/03/92	36.00	17		110	80	78	110	80	80
				Day 0	25/03/92	36.50		62.00	110	80	78	110	80	80
				Day 7	01/04/92	36.50		62.00	110	80	78	110	80	80
				Day 14	08/04/92	36.50		62.00	110	80	78	105	80	85
				Day 21	15/04/92	36.50		62.00	110	80	82	110	80	88
				Day 28	22/04/92	36.50		62.00	115	80	80	110	80	88
				Day 35	29/04/92	36.50		62.00	120	80	76	115	80	82
				Day 42	06/05/92	36.00		62.50	125	80	74	120	80	80
				Day 49	13/05/92	36.50		62.00	120	80	74	120	85	82
				Day 56	20/05/92	36.50		63.00	120	85	72	120	80	76

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
16	430	Reboxetine	Male	Screen	26/03/92	36.00	17		120	85	76	120	85	80
				Day 0	30/03/92	36.00		71.00	120	85	76	120	85	80
				Day 7	06/04/92	36.50		71.00	120	85	78	120	80	80
				Day 14	13/04/92	36.00		71.00	120	85	74	120	80	78
				Day 21	20/04/92	36.00		71.00	135	85	78	120	90	80
				Day 28	27/04/92	36.50		71.00	130	85	76	120	90	78
				Day 35	04/05/92	36.00		71.00	130	90	76	125	90	78
				Day 42	11/05/92	36.50		71.50	135	95	76	120	90	76
				Day 49	18/05/92	36.00		71.00	130	90	72	120	90	76
				Day 56	25/05/92	36.00		71.50	125	90	70	120	85	74
	431	Reboxetine	Female	Screen	26/03/92	36.00	18		140	80	80	140	90	88
				Day 0	30/03/92	36.50		80.00	140	80	80	140	90	88
				Day 7	06/04/92	36.50		80.00	140	80	80	135	85	90
				Day 14	13/04/92	36.50		80.00	140	80	80	130	90	86
				Day 21	20/04/92	36.50		80.00	140	80	82	130	85	90
				Day 28	27/04/92	36.50		80.00	145	85	78	135	90	86
				Day 35	04/05/92	36.50		80.50	140	80	78	135	90	88
				Day 42	11/05/92	36.50		80.00	145	90	82	135	90	88
				Day 49	18/05/92	36.50		80.50	145	90	78	140	95	80
				Day 56	25/05/92	36.50		81.00	140	100	96	130	100	100
	432	Fluoxetine	Female	Screen	26/03/92	36.50	18		120	80	80	110	85	85
				Day 0	30/03/92	36.50		73.00	120	80	80	110	85	85
				Day 7	06/04/92	36.50		73.00	120	80	76	115	80	80
				Day 14	13/04/92	36.50		73.00	120	80	80	115	80	84
				Day 21	20/04/92	36.50		73.00	120	80	84	110	85	84
				Day 28	27/04/92	36.00		73.00	125	85	80	110	85	80
				Day 35	04/05/92	36.00		73.50	125	85	72	115	85	74
				Day 42	11/05/92	36.00		73.50	125	90	70	115	90	74
				Day 49	18/05/92	36.00		74.00	125	90	72	120	80	74
				Day 56	25/05/92	36.00		74.00	120	90	70	120	85	72
	433	Reboxetine	Female	Screen	28/03/92	36.50	16		120	80	78	110	80	80
				Day 0	01/04/92	36.50		62.00	120	80	78	110	80	80
				Day 7	08/04/92	36.50		62.00	125	80	78	110	80	80
				Day 14	15/04/92	36.50		62.50	120	85	72	110	80	78
				Day 21	22/04/92	36.50		62.00	125	85	80	115	85	84
				Day 28	29/04/92	36.50		62.00	120	80	82	120	85	86
				Day 35	06/05/92	36.50		62.50	125	80	80	120	80	84
				Day 42	13/05/92	36.50		62.00	120	80	78	120	80	82
				Day 49	20/05/92	36.50		62.00	120	80	76	125	80	82
				Day 56	27/05/92	36.50		61.00	120	80	74	120	75	80

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
16	434	Fluoxetine	Female	Screen	01/04/92	36.50	19		140	80	76	120	80	80
				Day 0	06/04/92	36.50		63.00	140	80	76	120	80	80
				Day 7	13/04/92	36.50		63.00	140	80	72	130	90	80
				Day 14	20/04/92	36.50		63.00	140	80	70	120	90	74
				Day 21	27/04/92	36.50		62.00	140	80	80	130	80	82
				Day 28	04/05/92	36.50		62.00	145	85	78	135	80	82
				Day 35	11/05/92	36.50		62.00	140	85	78	130	80	80
				Day 42	18/05/92	36.50		62.00	145	90	76	135	85	80
				Day 49	25/05/92	36.50		62.00	140	85	78	130	80	80
				Day 56	01/06/92	36.50		62.00	140	85	76	135	80	80
	435	Reboxetine	Female	Screen	09/04/92	36.00	19		140	90	80	135	90	88
				Day 0	13/04/92	36.00			140	90	80	135	90	88
				Day 7	20/04/92	36.50		67.00	140	90	80	130	80	88
				Day 14	27/04/92	36.50		67.00	140	90	90	120	90	100
				Day 21	04/05/92	36.50		67.00	140	90	80	120	90	90
				Day 28	11/05/92	36.50		67.00	145	90	78	130	85	80
				Day 35	18/05/92	36.50		67.00	140	90	80	130	85	84
				Day 42	25/05/92	36.50		67.00	140	90	80	135	90	84
				Day 49	01/06/92	36.50		67.00	145	90	78	135	85	82
				Day 56	08/06/92	36.50		67.00	140	90	80	130	80	84
	436	Fluoxetine	Female	Screen	20/04/92	36.50	16		120	80	95	120	80	106
				Day 0	23/04/92	36.50		51.00	120	80	95	120	80	106
				Day 7	30/04/92	36.50		51.00	125	85	90	120	80	98
				Day 14	07/05/92	36.50		51.00	115	80	92	115	80	100
				Day 21	14/05/92	36.50		51.00	120	80	90	120	75	96
				Day 28	21/05/92	36.50		51.00	115	80	86	115	80	92
				Day 35	28/05/92	36.50		51.00	115	80	86	110	80	94
				Day 42	04/06/92	36.50		51.00	110	70	86	105	70	90
				Day 49	11/06/92	36.00		51.00	90	60	88	70	50	96
				Day 56	18/06/92	36.50		50.50	110	80	86	110	80	90
	437	Reboxetine	Female	Screen	24/04/92	36.50	16		120	80	72	120	80	78
				Day 0	29/04/92	36.50		54.50	120	80	72	120	80	78
				Day 7	06/05/92	36.50		55.00	120	80	72	115	80	76
				Day 14	13/05/92	36.50		55.00	120	80	70	120	80	74
				Day 21	20/05/92	36.50		55.00	120	80	78	110	75	84
				Day 28	27/05/92	36.50		55.00	115	80	76	110	75	86
				Day 35	03/06/92	36.50		55.00	115	80	76	110	80	84
				Day 42	10/06/92	36.50		55.50	115	80	74	110	80	80
				Day 49	17/06/92	36.50		56.00	110	80	76	105	75	80
				Day 56	24/06/92	36.50		56.00	115	80	76	110	80	78

1160

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
16	438	Fluoxetine	Female	Screen	15/05/92	36.50	18		170	100	96	170	105	100
				Day 0	19/05/92	36.50		62.00	170	100	92	170	105	96
				Day 7	26/05/92	36.50		62.00	170	100	90	170	105	96
				Day 14	02/06/92	36.50		62.00	170	100	90	165	100	94
				Day 21	09/06/92	36.50		62.00	175	100	85	170	100	92
				Day 28	16/06/92	36.50		62.00	170	100	88	165	100	94
				Day 35	23/06/92	36.50		61.00	160	100	86	160	100	92
	439	Fluoxetine	Female	Screen	15/05/92	36.50	17		140	80	64	130	85	76
				Day 0	19/05/92	36.50		105.00	140	80	66	130	85	76
				Day 7	26/05/92	36.00		105.00	140	80	65	130	80	76
				Day 14	02/06/92	36.50		105.00	135	80	66	130	70	72
				Day 21	09/06/92	36.50		104.00	135	85	66	125	70	70
				Day 28	16/06/92	36.50		104.00	140	85	64	130	80	70
				Day 35	23/06/92	36.50		104.00	140	80	70	130	80	74
				Day 42	30/06/92	36.50		104.00	135	80	72	125	80	76
				Day 49	07/07/92	36.50		104.00	135	80	72	130	80	74
				Day 56	14/07/92	36.50		103.00	140	85	72	135	80	76
	440	Reboxetine	Female	Screen	26/06/92	36.50	17		130	80	77	125	85	77
				Day 0	30/06/92	36.50		65.00	130	80	77	125	85	77
				Day 7	07/07/92	36.50		65.00	130	80	77	125	80	78
				Day 14	14/07/92	36.50		65.00	130	85	76	125	80	78
				Day 21	21/07/92	36.50		65.00	130	80	76	125	85	78
				Day 28	28/07/92	36.50		65.00	130	80	76	125	80	80
				Day 35	04/08/92	36.50		65.00	130	80	76	125	80	78
				Day 42	11/08/92	36.50		65.00	130	80	76	125	80	78
				Day 49	18/08/92	36.50		65.00	130	80	76	125	80	78
				Day 56	25/08/92	36.50		65.00	125	80	72	125	80	78
	441	Fluoxetine	Female	Screen	13/07/92	36.50	17		130	80	80	120	80	84
				Day 0	21/07/92	36.50		59.00	130	80	80	120	80	86
				Day 7	28/07/92	36.50		59.00	125	80	72	120	80	76
				Day 14	03/08/92	36.50		59.00	130	80	80	120	80	84
				Day 21	10/08/92	36.50		60.00	130	80	78	120	80	80
				Day 28	17/08/92	36.50		60.00	130	80	76	125	80	78
				Day 35	24/08/92	36.50		60.00	130	80	80	120	80	88
				Day 42	31/08/92	36.50		62.00	125	80	82	120	80	86
				Day 49	07/09/92	36.50		62.00	130	80	82	125	80	84
				Day 56	14/09/92	36.50		62.50	130	80	80	125	80	86
	442	Reboxetine	Female	Screen	14/07/92	36.50	17		140	90	74	120	90	90
				Day 0	21/07/92	36.50		52.00	140	90	74	120	80	80

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
16	442	Reboxetine	Female	Day 7	28/07/92	36.50		54.00	140	90	72	120	80	78
				Day 14	03/08/92	36.50		54.00	140	90	77	120	80	80
				Day 21	10/08/92	36.50		54.00	140	90	70	120	75	78
				Day 28	17/08/92	36.50		54.00	140	90	70	120	75	76
				Day 35	24/08/92	36.50		54.00	140	90	70	130	80	76
				Day 42	31/08/92	36.50		54.00	140	90	72	135	85	76
				Day 56	14/09/92	36.50		54.50	140	90	76	135	90	78
	443	Fluoxetine	Male	Screen	20/08/92	36.50	18		120	80	78	115	80	80
				Day 0	24/08/92	36.50		73.00	120	80	78	115	75	80
				Day 7	31/08/92	36.50		73.00	120	80	78	115	80	82
				Day 14	07/09/92	36.50		73.00	120	80	76	110	80	84
				Day 21	14/09/92	36.50		73.00	120	80	74	110	85	80
				Day 28	21/09/92	36.50		73.00	120	80	72	110	80	80
				Day 42	04/10/92	36.50		73.00	120	80	74	115	80	78
				Day 56	18/10/92	36.50		73.00	120	80	74	120	80	78
	444	Reboxetine	Female	Screen	20/08/92	36.50	19		110	70	76	110	70	78
				Day 0	24/08/92	36.50		48.00	110	70	76	110	70	78
				Day 7	31/08/92	36.50		48.00	110	70	72	110	70	76
				Day 14	07/09/92	36.50		48.00	110	70	72	110	70	76
				Day 21	14/09/92	36.40		48.00	110	70	72	110	70	74
				Day 28	21/09/92	36.50		48.00	110	70	74	110	70	74
				Day 42	05/10/92	36.50		48.00	110	70	76	110	70	76
				Day 56	19/10/92	36.50		48.00	110	70	74	110	70	76
	445	Reboxetine	Male	Screen	12/09/92	36.00	15		140	90	76	130	90	78
				Day 0	17/09/92	36.00		84.00	140	90	76	130	90	78
				Day 7	24/09/92	36.50		84.50	140	90	74	130	90	76
				Day 14	01/10/92	36.50		85.00	135	90	74	130	90	72
				Day 21	08/10/92	36.50		85.00	140	90	74	135	90	76
				Day 28	15/10/92	36.50		85.00	140	90	72	130	90	74
				Day 42	29/10/92	36.50		85.00	140	90	72	135	90	72
				Day 56	12/11/92	36.50		85.00	140	90	72	135	90	72
	446	Fluoxetine	Female	Screen	12/09/92	36.50	18		120	80	80	120	80	82
				Day 0	17/09/92	36.50		54.00	120	80	80	120	80	80
				Day 7	24/09/92	36.50		54.00	120	80	76	115	80	76
				Day 14	01/10/92	36.50		54.00	120	80	74	115	80	74
				Day 21	08/10/92	36.50		54.50	120	80	76	115	80	78
				Day 28	15/10/92	36.50		55.00	120	80	74	115	80	74
				Day 42	29/10/92	36.50		55.00	120	80	74	120	80	74
				Day 56	12/11/92	36.50		55.00	120	80	72	120	80	74

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
16	447	Fluoxetine	Male	Screen	12/09/92	36.50	19		115	80	75	115	80	78
				Day 0	17/09/92	36.50		73.00	115	80	75	115	80	75
				Day 7	24/09/92	36.50		73.00	115	80	74	115	80	74
				Day 14	01/10/92	36.50		73.50	115	80	74	115	80	74
				Day 21	08/10/92	36.50		74.00	115	80	74	115	80	76
				Day 28	15/10/92	36.50		74.00	115	80	74	115	80	74
				Day 42	29/10/92	36.50		74.00	115	80	74	110	80	76
				Day 56	12/11/92	36.50		74.00	115	80	74	110	80	74
	448	Reboxetine	Female	Screen	14/09/92	36.50	17		110	70	63	105	70	68
				Day 0	18/09/92	36.50		59.00	110	70	63	110	70	68
				Day 7	25/09/92	36.50		59.00	110	70	65	105	70	69
				Day 14	02/10/92	36.50		59.00	110	70	65	110	70	69
				Day 21	09/10/92	36.50		59.00	110	70	63	105	70	65
				Day 28	16/10/92	36.50		59.00	110	70	65	110	70	65
				Day 35	23/10/92	36.50		59.00	110	70	65	110	70	66
				Day 42	30/10/92	36.50		58.00	110	70	65	105	70	67
				Day 56	13/11/92	36.50		59.00	110	70	63	105	65	65
	455	Fluoxetine	Female	Screen	14/09/92	36.50	18		110	70	76	100	70	80
				Day 0	18/09/92	36.50		58.00	110	70	76	110	70	80
				Day 7	25/09/92	36.50		58.00	110	70	78	105	70	78
				Day 14	02/10/92	36.50		58.00	110	70	76	110	70	78
				Day 21	09/10/92	36.50		58.00	105	70	88	105	75	88
				Day 28	16/10/92	36.50		58.00	110	70	78	110	70	80
				Day 35	23/10/92	36.50		58.00	110	75	78	110	70	80
				Day 42	30/10/92	36.50		58.00	110	70	78	105	70	82
				Day 49	06/11/92	36.50		58.00	110	70	78	105	70	80
				Day 56	13/11/92	36.50		58.00	110	70	76	110	70	80
	456	Reboxetine	Male	Screen	09/12/92	36.50	17		140	80	80	140	80	80
				Day 0	15/12/92	36.50		71.00	140	80	78	140	80	84
				Day 7	22/12/92	36.50		71.00	140	80	78	140	80	82
				Day 14	29/12/92	36.50		71.00	140	80	78	140	80	82
				Day 21	05/01/93	36.50		71.00	140	80	80	140	80	84
				Day 28	12/01/93	36.50		71.00	140	80	78	140	80	82
				Day 42	26/01/93	36.50		71.00	140	80	78	140	80	82
				Day 56	09/02/93	36.50		71.00	135	80	76	135	80	80
	457	Fluoxetine	Female	Screen	09/12/92	36.50	18		130	80	84	135	80	88
				Day 0	15/12/92	36.50		74.00	140	80	78	135	80	84
				Day 7	22/12/92	36.50		74.00	140	80	80	140	80	84
				Day 21	05/01/93	36.50		74.00	140	80	80	140	80	84
				Day 28	12/01/93	36.50		74.00	140	80	80	140	80	84
				Day 35	19/01/93	36.50		74.00	140	80	80	140	80	84

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

									BLOOD PRESSURE AND HEART RATE					
									lying			standing		
Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
16	457	Fluoxetine	Female	Day 42	26/01/93	36.50		74.00	135	80	78	140	80	82
				Day 56	09/02/93	36.50		74.00	135	80	78	140	80	82
	458	Fluoxetine	Female	Screen	09/12/92	36.50	18		150	80	76	140	85	80
				Day 0	15/12/92	36.50		62.00	150	80	76	140	85	80
				Day 7	22/12/92	36.50		62.00	150	80	74	140	90	78
				Day 14	29/12/92	36.50		62.00	150	80	74	140	80	78
				Day 21	05/01/93	36.50		62.00	150	80	78	145	85	80
				Day 28	12/01/93	36.50		62.00	150	80	78	145	85	80
				Day 42	26/01/93	36.50		62.00	150	80	78	145	85	80
				Day 56	09/02/93	36.50		62.00	150	80	78	145	85	80
	459	Reboxetine	Male	Screen	17/12/92	36.50	16		130	80	80	130	80	82
				Day 0	21/12/92	36.50		90.00	120	80	84	125	80	84
				Day 7	28/12/92	36.50		90.00	130	80	78	125	80	78
				Day 14	04/01/93	36.50		90.00	120	80	80	125	80	80
				Day 21	11/01/93	36.50		90.00	125	80	82	120	80	84
				Day 28	18/01/93	36.50		90.00	120	80	78	120	80	80
				Day 42	01/02/93	36.50		90.00	125	80	74	120	80	78
				Day 56	15/02/93	36.50		90.00	120	80	76	115	80	80
	460	Reboxetine	Male	Screen	17/12/92	36.50	16		140	80	84	135	80	88
				Day 0	21/12/92	36.50		70.00	140	80	80	140	80	84
				Day 7	28/12/92	36.50		70.00	140	80	80	135	80	84
				Day 14	04/01/93	36.50		70.00	140	80	80	140	80	82
				Day 21	11/01/93	36.50		69.00	135	80	76	140	80	80
				Day 28	18/01/93	36.50		69.00	140	80	76	135	80	80
				Day 42	01/02/93	36.50		69.00	140	80	76	140	80	78
				Day 49	08/02/93	36.50		69.00	145	80	78	140	80	78
				Day 56	15/02/93	36.50		69.00	140	80	74	140	80	78
18	25	Fluoxetine	Female	Screen	30/09/92	36.60	15		150	80	66	155	80	68
				Day 0	06/10/92	36.40		90.00	170	90	76	170	90	76
				Day 7	13/10/92	36.40		89.00	140	80	76	150	80	76
				Day 14	20/10/92	36.40		89.00	140	80	74	150	80	76
				Day 21	27/10/92	36.30		89.00	135	70	76	145	80	78
				Day 28	03/11/92	36.40		87.00	130	80	59	140	90	63
				Day 35	10/11/92	36.40		87.00	135	85	63	150	90	66
				Day 42	17/11/92	36.40		88.00	130	80	63	140	90	66
				Day 49	24/11/92	36.40		89.50	135	85	72	140	90	76
				Day 56	01/12/92	36.50		88.50	130	80	52	135	90	56
	26	Reboxetine	Female	Screen	30/09/92	36.90	15		140	80	80	120	80	80
				Day 0	06/10/92	36.70		69.00	140	80	80	135	85	80

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
18	26	Reboxetine	Female	Day 7	13/10/92	36.70		69.00	140	80	80	135	85	80
				Day 14	20/10/92	36.70		69.00	140	80	80	135	85	80
				Day 21	27/10/92	36.30		70.00	140	80	75	150	90	78
				Day 28	03/11/92	36.20		70.00	140	80	84	150	90	89
				Day 35	10/11/92	36.30		68.00	125	80	80	140	80	84
				Day 42	17/11/92	36.40		68.00	125	85	86	135	90	89
				Day 49	24/11/92	36.40		68.50	130	90	78	135	90	82
				Day 56	01/12/92	36.30		67.00	130	90	78	135	90	80
	27	Reboxetine	Female	Screen	30/09/92	36.60	14		110	70	76	110	70	76
				Day 0	06/10/92	36.10		140.00	125	70	76	130	75	78
				Day 7	13/10/92	36.20		140.00	125	80	76	130	80	78
				Day 14	20/10/92	36.20		140.00	125	80	76	135	80	78
				Day 21	27/10/92	36.30		140.00	110	70	75	120	70	79
				Day 28	03/11/92	36.40		140.00	110	70	75	125	75	79
				Day 35	10/11/92	36.20		140.00	130	80	74	135	80	78
				Day 42	17/11/92	36.30		140.00	135	85	74	140	90	78
				Day 49	24/11/92	36.40		140.00	130	80	80	135	90	84
				Day 56	01/12/92	36.70		140.00	135	85	73	140	90	77
	28	Fluoxetine	Female	Screen	30/09/92	36.80	16		117	70	78	120	80	76
				Day 0	06/10/92	36.20		62.00	150	80	78	160	80	78
				Day 7	13/10/92	36.30		62.00	140	90	78	140	90	80
				Day 14	20/10/92	36.20		62.00	150	80	76	165	85	78
				Day 21	27/10/92	36.40		62.00	140	80	82	150	90	84
				Day 28	03/11/92	36.20		62.00	150	80	76	165	85	78
	29	Reboxetine	Male	Screen	30/09/92	36.50	16		140	80	72	150	80	78
				Day 0	06/10/92	36.30		113.00	140	80	78	145	80	80
				Day 7	13/10/92	36.50		113.00	140	80	75	140	80	78
				Day 14	20/10/92	36.50		113.00	140	80	75	145	80	78
				Day 21	27/10/92	36.30		113.00	140	80	75	145	80	78
				Day 28	03/11/92	36.40		112.00	140	90	65	145	90	68
				Day 35	10/11/92	36.40		113.00	110	80	71	120	80	75
				Day 42	17/11/92	36.50		113.00	120	80	76	130	80	82
				Day 49	24/11/92	36.50		113.00	120	80	76	130	80	82
				Day 56	01/12/92	36.40		115.00	130	80	78	140	90	82
	30	Fluoxetine	Female	Screen	30/09/92	36.30	14		120	80	78	120	80	80
				Day 0	07/10/92	36.30		62.00	120	80	78	120	80	80
				Day 7	14/10/92	36.30		63.00	120	80	72	120	80	75
				Day 14	21/10/92	36.30		63.00	120	80	72	120	80	75
				Day 21	28/10/92	36.20		63.00	105	70	71	115	70	74
				Day 28	04/11/92	36.30		63.00	105	70	70	115	70	73
				Day 35	11/11/92	36.30		63.00	110	80	72	120	80	75

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
18	30	Fluoxetine	Female	Day 42	17/11/92	36.30		63.00	110	80	72	120	80	75
				Day 49	25/11/92	36.40		63.00	110	70	70	120	80	76
				Day 56	02/12/92	36.40		65.00	110	80	85	120	80	88
	31	Reboxetine	Female	Screen	13/10/92	36.30			120	80	74	130	80	78
				Day 0	20/10/92	36.30		58.00	120	80	74	130	80	78
				Day 7	27/10/92	36.50		58.00	135	80	74	140	80	76
				Day 14	03/11/92	36.40		58.00	130	80	72	140	80	76
				Day 21	10/11/92	36.80		57.00	120	80	84	130	80	88
				Day 28	17/11/92	36.60		57.00	120	80	66	130	80	69
				Day 35	24/11/92	36.20		58.00	120	80	60	130	80	62
				Day 42	01/12/92	36.40		58.00	130	85	85	125	80	89
				Day 49	08/12/92	36.40		57.00	130	80	96	140	90	94
				Day 56	15/12/92	36.40		56.00	135	80	76	140	80	80
	32	Fluoxetine	Female	Screen	05/10/92	36.40	15		110	70	60	120	80	62
				Day 0	07/10/92	36.20		62.00	125	80	72	130	80	74
				Day 7	14/10/92	36.40		61.00	120	80	72	125	80	74
				Day 14	21/10/92	36.20		62.00	125	80	72	130	80	74
				Day 21	28/10/92	36.20		61.00	120	80	70	125	80	76
				Day 28	04/11/92	36.30		61.00	115	70	72	120	80	78
				Day 35	10/11/92	36.30		62.00	125	80	72	130	80	74
				Day 42	17/11/92	36.40		63.00	130	80	69	135	85	72
				Day 49	24/11/92	36.40		63.00	130	80	69	135	80	72
				Day 56	01/12/92	36.40		62.00	130	80	79	135	80	81
	49	Reboxetine	Female	Screen	10/11/92	36.40	10		110	70	68	120	70	72
				Day 0	17/11/92	36.50		82.00	120	80	72	125	80	76
				Day 7	24/11/92	36.50		80.50	130	80	82	135	90	86
				Day 14	01/12/92	36.40		82.00	120	80	80	130	80	83
				Day 21	08/12/92	36.50		80.00	125	80	91	140	85	94
				Day 28	15/12/92	36.50		78.00	135	70	76	140	80	80
				Day 35	22/12/92	36.40		78.00	100	70	90	105	70	88
				Day 42	29/12/92	36.40		78.00	125	80	86	130	80	88
				Day 49	05/01/93	36.50		78.00	130	75	80	135	80	86
				Day 56	12/01/93	36.50		78.50	110	70	72	120	80	76
	50	Reboxetine	Female	Screen	10/11/92	36.40	15		130	90	78	140	90	82
				Day 0	17/11/92	36.40		70.00	125	80	87	135	85	92
	51	Fluoxetine	Female	Screen	10/11/92	36.70	14		130	80	86	140	90	90
				Day 0	17/11/92	36.60		95.00	125	80	68	135	80	72
				Day 7	24/11/92	36.80		95.00	125	80	61	130	80	64
				Day 14	01/12/92	36.20		94.00	120	80	60	135	85	62

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
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 S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
18	51	Fluoxetine	Female	Day 21	08/12/92	36.70		94.00	130	90	70	140	95	74
				Day 28	15/12/92	36.40		93.00	125	70	74	130	80	76
				Day 35	22/12/92	36.50		94.00	120	80	86	125	80	88
				Day 42	29/12/92	36.20		92.00	120	80	80	130	80	82
				Day 49	05/01/93	36.40		92.00	120	70	80	130	80	84
				Day 56	12/01/93	36.50		92.00	130	80	78	135	80	82
	52	Fluoxetine	Female	Screen	10/11/92	36.60			130	80	73	140	90	78
				Day 0	17/11/92	36.30		104.00	130	80	85	140	90	88
				Day 7	24/11/92	36.40		105.00	130	80	80	140	90	84
				Day 14	01/12/92	36.40		105.00	130	80	75	140	85	78
				Day 21	08/12/92	36.70		105.00	135	85	70	145	90	74
				Day 28	15/12/92	36.30		105.00	145	90	74	150	90	76
				Day 35	22/12/92	36.40		105.00	150	90	90	155	90	94
				Day 42	29/12/92	36.30		105.00	135	80	82	140	80	84
				Day 49	05/01/93	36.40		105.00	140	75	72	145	80	76
				Day 56	12/01/93	36.50		105.00	135	80	71	140	85	74
	53	Fluoxetine	Female	Screen	29/12/92	36.50			125	80	78	130	80	80
				Day 0	15/01/93	36.70		92.00	130	80	78	140	80	80
				Day 7	22/01/93	36.60		89.00	120	80	75	130	80	78
				Day 14	29/01/93	36.60		88.00	130	80	73	140	90	76
				Day 21	05/02/93	36.60		90.00	120	80	71	130	80	74
				Day 28	12/02/93	36.70		89.00	130	80	67	140	90	70
				Day 35	19/02/93	36.70		89.00	130	80	68	140	90	73
				Day 42	26/02/93	36.70		88.00	120	70	70	125	70	72
				Day 49	05/03/93	36.40		87.00	125	70	73	130	75	70
				Day 56	12/03/93	36.50		87.00	140	90	78	143	82	72
	54	Fluoxetine	Male	Screen	05/01/93	36.50	15		120	75	70	125	80	72
				Day 0	12/01/93	36.30		90.00	125	75	70	135	80	74
				Day 7	19/01/93	36.50		87.00	110	80	72	120	80	76
				Day 14	26/01/93	36.50		87.00	110	70	66	120	80	68
				Day 21	02/02/93	36.50		87.00	125	80	52	130	90	56
				Day 28	09/02/93	36.40		86.00	120	70	67	125	70	70
				Day 35	16/02/93	36.50		87.00	120	70	68	125	80	70
				Day 42	23/02/93	36.50		86.00	120	70	56	125	70	60
				Day 49	02/03/93	36.60		87.00	120	70	64	110	60	58
				Day 56	09/03/93	36.50		84.00	110	70	60	120	70	68
20	21	Fluoxetine	Female	Screen	27/10/92	37.00			130	86	78	130	96	86
				Day 0	06/11/92	36.80		64.00	130	90	68	125	90	72
				Day 7	13/11/92	37.10		65.00	135	80		130	80	
				Day 14	20/11/92	37.20		64.00	140	90	76	130	90	
				Day 21	27/11/92	37.10		75.50	120	85		120	86	

1167

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

									BLOOD PRESSURE AND HEART RATE					
									lying			standing		
Centre	Patient	Treatment	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Height (Kg)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
20	21	Fluoxetine	Female	Day 28	04/12/92	37.20		64.00	130	85	72	120	80	
				Day 35	11/12/92	37.20		64.00	130	50	78	120	50	82
				Day 42	18/12/92	37.10		64.00	125	80	80	140	80	86
				Day 49	23/12/92	37.20		64.00	130	80	76	120	80	80
				Day 56	30/12/92	37.20		64.00	130	80	80	120	70	86
	22	Fluoxetine	Female	Screen	09/11/92	37.20			120	80	86	130	90	92
				Day 0	12/11/92	37.00		62.00	120	84	72	110	80	
				Day 7	19/11/92	36.80		62.00	130	90	80	120	85	
				Day 14	26/11/92	37.00		62.00	120	80	64	120	75	72
				Day 21	03/12/92	36.80		62.00	120	80	60	120	75	76
				Day 28	10/12/92	37.00		62.00	110	80	66	120	75	68
				Day 35	17/12/92	37.10		62.00	120	84	72	90	80	
21	9	Fluoxetine	Female	Screen	12/10/92	37.80	14		120	80	68	125	80	64
				Day 0	19/10/92	36.80		79.00	110	80	60	115	80	68
				Day 7	26/10/92	36.80		78.60	115	80	68	120	80	68
				Day 14	02/11/92	36.30		76.90	120	70	68	135	90	78
				Day 21	09/11/92	37.00		76.30	125	75	70	140	90	79
				Day 28	16/11/92	36.90		74.00	120	70	68	135	80	76
				Day 35	23/11/92	37.00		77.00	110	80	76	125	85	80
				Day 42	30/11/92	36.50		76.50	120	80		130	85	
				Day 49	08/12/92	37.00		77.00	125	85		130	85	
				Day 56	14/12/92	36.20		75.00	120	70	76	130	80	80
22	113	Fluoxetine	Male	Screen	24/11/92	36.00	17		130	90	92	130	85	92
				Day 0	02/12/92	36.20		94.00	130	85	84	140	90	92
				Day 7	09/12/92	36.10		95.00	130	85	80	130	80	84
				Day 14	16/12/92	37.30		93.00	130	65	76	120	60	88
	115	Reboxetine	Male	Screen	22/12/92	36.90	19		110	75	76	120	70	84
				Day 0	29/12/92	36.90		73.00	120	80	72	130	70	88
				Day 7	06/01/93	36.40		72.00	130	70	76	130	75	80
				Day 14	12/01/93	36.80		73.00	140	70	84	140	60	92
				Day 21	20/01/93	36.30		71.00	140	85	72	140	75	76

1168

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	days of treat.	Assessment	Date	Value	Abnormality
1	1	Fluoxetine	Male	15/11/91	09/01/92	Screen	-4	Screening	11/11/91	Normal	
						Day 14	14	1-28 days	29/11/91	Normal	
						Day 28	28	1-28 days	13/12/91	Normal	
						Day 42	42	29-56 days	27/12/91	Normal	
						Day 56	56	29-56 days	10/01/92	Normal	
	2	Reboxetine	Male	26/06/92	20/08/92	Screen	-1	Screening	25/06/92	Normal	-
						Day 28	28	1-28 days	24/07/92	Abnormal	SINUS TACHYCARDIA (> 100)
						Day 56	55	29-56 days	20/08/92	Normal	
	3	Fluoxetine	Female	01/07/92	25/08/92	Screen	-6	Screening	25/06/92	Normal	
						Day 14	15	1-28 days	16/07/92	Normal	
						Day 28	29	1-28 days	30/07/92	Normal	
						Day 56	55	29-56 days	25/08/92	Normal	
	4	Reboxetine	Female	14/08/92	24/09/92	Screen	-2	Screening	12/08/92	Normal	
						Day 14	14	1-28 days	28/08/92	Normal	
						Day 28	28	1-28 days	11/09/92	Normal	
						Day 42	42	29-56 days	25/09/92	Normal	
	5	Fluoxetine	Female	13/10/92	11/11/92	Screen	-6	Screening	07/10/92	Normal	
						Day 14	14	1-28 days	27/10/92	Normal	
						Day 28	28	1-28 days	10/11/92	Normal	
	6	Fluoxetine	Male	14/01/93	11/02/93	Screen	-3	Screening	11/01/93	Abnormal	SINUS TACHYCARDIA (> 100)
						Day 14	14	1-28 days	28/01/93	Normal	
						Day 28	28	1-28 days	11/02/93	Normal	
2	33	Fluoxetine	Female	04/05/91	28/06/91	Screen	-2	Screening	02/05/91	Abnormal	LEFT VENTRICULAR HYPERTROPHY RIGHT INCOMPLETE BUNDLE BRANCH BLOCK
						Day 28	30	1-28 days	03/06/91	Abnormal	RIGHT INCOMPLETE BUNDLE BRANCH BLOCK
						Day 56	56	29-56 days	29/06/91	Normal	
	34	Reboxetine	Male	03/05/91	12/06/91	Screen	-1	Screening	02/05/91	Abnormal	RIGHT INCOMPLETE BUNDLE BRANCH BLOCK
						Day 28	31	1-28 days	03/06/91	Normal	
	35	Reboxetine	Female	16/04/91	10/06/91	Screen	-11	Screening	05/04/91	Normal	
						Day 28	30	1-28 days	16/05/91	Normal	
						Day 56	51	29-56 days	06/06/91	Normal	
	36	Fluoxetine	Male	02/05/91	26/06/91	Screen	-6	Screening	26/04/91	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	days of treat.	Assessment	Date	Value	Abnormality
2	36	Fluoxetine	Male	02/05/91	26/06/91	Day 28	35	1-28 days	06/06/91	Normal	
	37	Reboxetine	Male	07/10/91	10/10/91	Screen	-5	Screening	02/10/91	Normal	
	38	Fluoxetine	Male	20/06/91	25/07/91	Screen	-2	Screening	18/06/91	Abnormal	RIGHT BUNDLE BRANCH BLOCK
						Day 14	14	1-28 days	04/07/91	Normal	
	39	Fluoxetine	Male	19/06/91	22/06/91	Screen	-6	Screening	13/06/91	Normal	
	40	Reboxetine	Male	06/06/91	04/07/91	Screen	-1	Screening	05/06/91	Normal	
	41	Fluoxetine	Male	13/02/92	08/04/92	Screen	-2	Screening	11/02/92	Normal	
						Day 28	28	1-28 days	12/03/92	Normal	
						Day 56	55	29-56 days	08/04/92	Normal	
	42	Reboxetine	Female	05/03/92	29/04/92	Screen	1	Screening	06/03/92	Normal	
						Day 28	28	1-28 days	02/04/92	Normal	
						Day 56	56	29-56 days	30/04/92	Normal	
	43	Reboxetine	Female	19/11/91	13/01/92	Screen	-6	Screening	13/11/91	Normal	
						Day 28	22	1-28 days	11/12/91	Normal	
						Day 56	56	29-56 days	14/01/92	Normal	
	44	Fluoxetine	Male	13/12/91	30/01/92	Day 28	27	1-28 days	09/01/92	Abnormal	SINUS BRADYCARDIA (< 60)
	45	Reboxetine	Female	10/09/92	04/11/92	Screen	-1	Screening	09/09/92	Normal	
						Day 28	35	1-28 days	15/10/92	Normal	
	47	Fluoxetine	Female	25/03/92	19/05/92	Screen	-1	Screening	24/03/92	Abnormal	SINUS BRADYCARDIA (< 60)
						Day 28	28	1-28 days	22/04/92	Abnormal	SINUS BRADYCARDIA (< 60)
						Day 56	55	29-56 days	19/05/92	Abnormal	SINUS BRADYCARDIA (< 60)
	48	Reboxetine	Female	19/05/92	13/07/92	Screen	-1	Screening	18/05/92	Abnormal	VENTRICULAR ECTOPIC BEATS - OCCASIONAL
						Day 28	28	1-28 days	16/06/92	Normal	
						Day 56	56	29-56 days	14/07/92	Normal	
	80	Fluoxetine	Male	15/01/93	11/03/93	Screen	-7	Screening	08/01/93	Abnormal	PREVIOUS MYOCARDIAL INFARCTION
						Day 28	20	1-28 days	04/02/93	Abnormal	PREVIOUS MYOCARDIAL INFARCTION

1170

9550083

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	days of treat.	Assessment	Date	Value	Abnormality
2	80	Fluoxetine	Male	15/01/93	11/03/93	Day 56	56	29-56 days	12/03/93	Abnormal	PREVIOUS MYOCARDIAL INFARCTION
3	65	Fluoxetine	Female	16/10/91	10/12/91	Screen	-5	Screening	11/10/91	Normal	
						Day 28	27	1-28 days	12/11/91	Abnormal	RIGHT INCOMPLETE BUNDLE BRANCH BLOCK
						Day 56	55	29-56 days	10/12/91	Abnormal	RIGHT INCOMPLETE BUNDLE BRANCH BLOCK
	66	Fluoxetine	Female	16/10/91	12/11/91	Screen	-5	Screening	11/10/91	Normal	
	67	Reboxetine	Female	18/11/92	15/12/92	Screen	-4	Screening	14/11/92	Normal	
						Day 28	28	1-28 days	16/12/92	Normal	
	68	Reboxetine	Female	30/11/92	28/12/92	Screen	-4	Screening	26/11/92	Normal	
						Day 28	28	1-28 days	28/12/92	Abnormal	ATRIAL ECTOPIC BEATS - OCCASIONAL
4	97	Reboxetine	Female	22/04/91	16/06/91	Screen	-3	Screening	19/04/91	Normal	
						Day 14	15	1-28 days	07/05/91	Normal	
						Day 28	29	1-28 days	21/05/91	Normal	
						Day 56	56	29-56 days	17/06/91	Normal	
	98	Fluoxetine	Female	30/05/91	24/07/91	Screen	-3	Screening	27/05/91	Normal	
						Day 28	28	1-28 days	27/06/91	Normal	
						Day 56	55	29-56 days	24/07/91	Normal	
	99	Fluoxetine	Female	15/10/91	25/10/91	Screen	-4	Screening	11/10/91	Normal	
	100	Reboxetine	Male	08/05/92	08/05/92	Screen	3	Screening	11/05/92	Normal	
	101	Reboxetine	Female	02/07/92	26/08/92	Screen	0	Screening	02/07/92	Normal	
						Day 28	28	1-28 days	30/07/92	Normal	
						Day 56	56	29-56 days	27/08/92	Normal	
	102	Fluoxetine	Female	10/07/92	03/09/92	Screen	0	Screening	10/07/92	Normal	
						Day 28	31	1-28 days	10/08/92	Normal	
						Day 56	59	29-56 days	07/09/92	Normal	
	103	Fluoxetine	Female	13/07/92	18/08/92	Screen	-5	Screening	08/07/92	Normal	
						Day 28	28	1-28 days	10/08/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	days of treat.	Assessment	Date	Value	Abnormality
4	104	Reboxetine	Female	18/08/92	05/10/92	Screen	-4	Screening	14/08/92	Normal	
						Day 28	28	1-28 days	15/09/92	Normal	
	105	Fluoxetine	Male	21/08/92	15/10/92	Screen	-1	Screening	20/08/92	Normal	
						Day 28	28	1-28 days	18/09/92	Normal	
						Day 56	56	29-56 days	16/10/92	Normal	
5	129	Reboxetine	Female	29/11/91	29/12/91	Screen	-4	Screening	25/11/91	Normal	
						Day 28	27	1-28 days	26/12/91	Normal	
	130	Fluoxetine	Female	28/02/92	23/04/92	Screen	-4	Screening	24/02/92	Normal	
						Day 28	28	1-28 days	27/03/92	Normal	
						Day 56	56	29-56 days	24/04/92	Normal	
7	193	Reboxetine	Female	06/12/91	31/01/92	Screen	0	Screening	06/12/91	Normal	
						Day 56	55	29-56 days	30/01/92	Abnormal	SINUS TACHYCARDIA (> 100)
	194	Fluoxetine	Female	10/01/92	05/03/92	Screen	-8	Screening	02/01/92	Normal	
						Day 28	27	1-28 days	06/02/92	Normal	
						Day 56	55	29-56 days	05/03/92	Normal	
	195	Fluoxetine	Male	14/02/92	09/04/92	Screen	-3	Screening	11/02/92	Abnormal	SINUS BRADYCARDIA (< 60) VENTRICULAR ECTOPIC BEATS - OCCASIONAL
						Day 28	28	1-28 days	13/03/92	Normal	
						Day 56	67	29-56 days	21/04/92	Normal	
	196	Reboxetine	Female	29/05/92	16/07/92	Screen	-3	Screening	26/05/92	Normal	
						Day 28	24	1-28 days	22/06/92	Abnormal	SINUS TACHYCARDIA (> 100) RIPOLARIZATION DISTURBANCES
	197	Fluoxetine	Male	11/11/92	11/11/92	Screen	-5	Screening	06/11/92	Normal	
11	321	Fluoxetine	Female	14/11/91	09/01/92	Screen	-9	Screening	05/11/91	Normal	
						Day 56	64	29-56 days	17/01/92	Normal	
	322	Reboxetine	Female	14/11/91	09/01/92	Screen	0	Screening	14/11/91	Abnormal	CONDUCTION DISORDER
						Day 56	64	29-56 days	17/01/92	Abnormal	SINUS TACHYCARDIA (> 100)
	323	Fluoxetine	Female	19/11/91	13/01/92	Screen	-20	Screening	30/10/91	Normal	

1172

9550083

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	days of treat.	Assessment	Date	Value	Abnormality
11	323	Fluoxetine	Female	19/11/91	13/01/92	Day 56	56	29-56 days	14/01/92	Normal	
	324	Reboxetine	Female	24/01/92	19/03/92	Screen	-1	Screening	23/01/92	Normal	
						Day 28	40	1-28 days	04/03/92	Normal	
						Day 56	75	29-56 days	08/04/92	Normal	
	325	Reboxetine	Female	12/02/92	07/04/92	Screen	-29	Screening	14/01/92	Abnormal	CONDUCTION DISORDER
						Day 28	34	1-28 days	17/03/92	Abnormal	CONDUCTION DISORDER
						Day 56	69	29-56 days	21/04/92	Abnormal	CONDUCTION DISORDER
	326	Reboxetine	Female	12/02/92	07/04/92	Screen	-2	Screening	10/02/92	Abnormal	MYOCARDIAL ISCHEMIA
						Day 28	36	1-28 days	19/03/92	Normal	
						Day 56	50	29-56 days	02/04/92	Normal	
	327	Fluoxetine	Female	14/02/92	12/03/92	Screen	-11	Screening	03/02/92	Normal	
	328	Fluoxetine	Female	19/02/92	14/04/92	Screen	2	Screening	21/02/92	Abnormal	MYOCARDIAL ISCHEMIA
						Day 28	44	1-28 days	03/04/92	Normal	
						Day 56	44	29-56 days	03/04/92	Normal	
	329	Reboxetine	Female	31/03/92	27/05/92	Screen	-15	Screening	16/03/92	Abnormal	SINUS TACHYCARDIA (> 100)
						Day 28	41	1-28 days	11/05/92	Abnormal	SINUS TACHYCARDIA (> 100)
						Day 56	62	29-56 days	01/06/92	Abnormal	SINUS TACHYCARDIA (> 100)
	330	Reboxetine	Male	21/04/92	08/06/92	Screen	-5	Screening	16/04/92	Normal	
						Day 49	49	29-56 days	09/06/92	Normal	
	331	Fluoxetine	Female	26/05/92	20/07/92	Screen	-1	Screening	25/05/92	Abnormal	NON SPECIFIC ST-T WAVE CHANGES
						Day 28	35	1-28 days	30/06/92	Normal	
						Day 56	72	29-56 days	06/08/92	Normal	
	332	Fluoxetine	Female	28/07/92	24/09/92	Screen	-11	Screening	17/07/92	Abnormal	SINUS BRADYCARDIA (< 60)
						Day 56	49	29-56 days	15/09/92	Normal	
	333	Reboxetine	Female	15/09/92	09/11/92	Screen	-60	Screening	17/07/92	Normal	
						Day 28	28	1-28 days	13/10/92	Normal	
	334	Fluoxetine	Female	22/09/92	16/11/92	Screen	-12	Screening	10/09/92	Normal	
						Day 28	29	1-28 days	21/10/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	Visit	days of treat.	Assessment	E.C.G. Date	E.C.G. Value	E.C.G. Abnormality
11	334	Fluoxetine	Female	22/09/92	16/11/92	Day 56	83	29-56 days	14/12/92	Normal	
	335	Reboxetine	Female	13/10/92	16/11/92	Screen	-11	Screening	02/10/92	Normal	
12	393	Fluoxetine	Female	25/06/92	18/08/92	Screen	1	Screening	26/06/92	Normal	
						Day 28	26	1-28 days	21/07/92	Normal	
						Day 56	64	29-56 days	28/08/92	Normal	
	394	Reboxetine	Male	06/07/92	31/08/92	Screen	1	Screening	07/07/92	Normal	
						Day 28	28	1-28 days	03/08/92	Normal	
						Day 56	52	29-56 days	27/08/92	Normal	
	395	Reboxetine	Male	24/07/92	16/09/92	Screen	0	Screening	24/07/92	Normal	
						Day 28	27	1-28 days	20/08/92	Normal	
						Day 56	55	29-56 days	17/09/92	Normal	
	396	Fluoxetine	Female	04/08/92	17/08/92	Screen	1	Screening	05/08/92	Normal	
	497	Fluoxetine	Female	24/02/93	21/04/93	Screen	2	Screening	26/02/93	Normal	
						Day 28	30	1-28 days	26/03/93	Normal	
						Day 56	61	29-56 days	26/04/93	Normal	
13	385	Fluoxetine	Female	14/03/92	08/05/92	Screen	-1	Screening	13/03/92	Normal	
						Day 56	55	29-56 days	08/05/92	Normal	
	386	Fluoxetine	Male	24/04/92	30/04/92	Screen	-1	Screening	23/04/92	Normal	
						Day 7	6	1-28 days	30/04/92	Normal	
	387	Reboxetine	Female	18/04/92	18/05/92	Screen	-3	Screening	15/04/92	Abnormal	NON SPECIFIC ST-T WAVE CHANGES
						Day 28	44	1-28 days	01/06/92	Normal	
	388	Reboxetine	Male	16/03/92	11/05/92	Screen	-1	Screening	15/03/92	Normal	
						Day 56	56	29-56 days	11/05/92	Normal	
	389	Fluoxetine	Female	21/07/92	23/07/92	Screen	-1	Screening	20/07/92	Normal	
						Day 7	2	1-28 days	23/07/92	Normal	
	390	Reboxetine	Male	28/05/92	22/07/92	Screen	-1	Screening	27/05/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	Visit	days of treat.	Assessment	E.C.G. Date	E.C.G. Value	E.C.G. Abnormality
13	390	Reboxetine	Male	28/05/92	22/07/92	Day 28	28	1-28 days	25/06/92	Normal	
						Day 56	60	29-56 days	27/07/92	Normal	
	391	Fluoxetine	Female	11/06/92	15/07/92	Screen	-5	Screening	06/06/92	Normal	
						Day 28	35	1-28 days	16/07/92	Normal	
	392	Reboxetine	Female	14/08/92	27/08/92	Screen	-3	Screening	11/08/92	Normal	
						Day 14	14	1-28 days	28/08/92	Normal	
	501	Reboxetine	Male	02/11/92	30/12/92	Screen	-3	Screening	30/10/92	Normal	
						Day 56	59	29-56 days	31/12/92	Abnormal	SINUS TACHYCARDIA (> 100)
	502	Fluoxetine	Female	03/11/92	24/12/92	Screen	1	Screening	04/11/92	Normal	
						Day 28	28	1-28 days	01/12/92	Normal	
						Day 56	51	29-56 days	24/12/92	Normal	
	503	Reboxetine	Female	12/11/92	18/11/92	Screen	0	Screening	12/11/92	Normal	
						Day 7	18	1-28 days	30/11/92	Normal	
	504	Fluoxetine	Female	26/11/92	20/01/93	Screen	-1	Screening	25/11/92	Normal	
						Day 56	60	29-56 days	25/01/93	Normal	
	505	Reboxetine	Female	31/08/92	22/10/92	Screen	-5	Screening	26/08/92	Normal	
						Day 28	29	1-28 days	29/09/92	Normal	
						Day 56	52	29-56 days	22/10/92	Normal	
	506	Fluoxetine	Male	27/10/92	23/12/92	Day 56	58	29-56 days	24/12/92	Normal	
	507	Fluoxetine	Female	11/09/92	06/11/92	Day 28	39	1-28 days	20/10/92	Normal	
						Day 42	39	29-56 days	20/10/92	Normal	
						Day 56	59	29-56 days	09/11/92	Normal	
	508	Reboxetine	Female	02/11/92	29/12/92	Day 56	59	29-56 days	31/12/92	Normal	
	521	Reboxetine	Male	30/11/92	26/01/93	Screen	1	Screening	01/12/92	Normal	
						Day 28	31	1-28 days	31/12/92	Normal	
14	397	Fluoxetine	Female	14/04/92	09/06/92	Screen	-33	Screening	12/03/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	days of treat.	Assessment	Date	Value	Abnormality
14	397	Fluoxetine	Female	14/04/92	09/06/92	Day 28	28	1-28 days	12/05/92	Normal	
						Day 56	56	29-56 days	09/06/92	Normal	
	398	Reboxetine	Female	15/04/92	10/06/92	Screen	0	Screening	15/04/92	Normal	
						Day 28	28	1-28 days	13/05/92	Normal	
						Day 56	56	29-56 days	10/06/92	Normal	
	399	Reboxetine	Female	21/04/92	16/06/92	Screen	-8	Screening	13/04/92	Normal	
						Day 28	28	1-28 days	19/05/92	Normal	
						Day 56	56	29-56 days	16/06/92	Normal	
	400	Fluoxetine	Male	15/05/92	11/07/92	Screen	-1	Screening	14/05/92	Normal	
						Day 28	28	1-28 days	12/06/92	Normal	
						Day 56	60	29-56 days	14/07/92	Normal	
	401	Fluoxetine	Female	22/05/92	17/07/92	Screen	0	Screening	22/05/92	Normal	
						Day 28	28	1-28 days	19/06/92	Normal	
						Day 56	56	29-56 days	17/07/92	Normal	
	402	Reboxetine	Female	27/05/92	22/07/92	Screen	-5	Screening	22/05/92	Abnormal	SINUS BRADYCARDIA (< 60)
						Day 28	28	1-28 days	24/06/92	Normal	
						Day 56	56	29-56 days	22/07/92	Normal	
	403	Reboxetine	Female	29/05/92	24/07/92	Screen	0	Screening	29/05/92	Normal	
						Day 28	28	1-28 days	26/06/92	Abnormal	SINUS TACHYCARDIA (> 100)
						Day 56	56	29-56 days	24/07/92	Abnormal	SINUS TACHYCARDIA (> 100)
	404	Fluoxetine	Female	16/06/92	11/08/92	Screen	0	Screening	16/06/92	Normal	
						Day 28	28	1-28 days	14/07/92	Normal	
						Day 56	56	29-56 days	11/08/92	Normal	
	405	Fluoxetine	Female	22/06/92	18/08/92	Screen	-3	Screening	19/06/92	Normal	
						Day 28	28	1-28 days	20/07/92	Normal	
	406	Fluoxetine	Female	30/06/92	21/07/92	Screen	0	Screening	30/06/92	Normal	
						Day 21	21	1-28 days	21/07/92	Normal	
	407	Reboxetine	Male	14/07/92	24/08/92	Screen	-133	Screening	03/03/92	Normal	
						Day 28	30	1-28 days	13/08/92	Abnormal	SINUS TACHYCARDIA (> 100)
						Day 42	42	29-56 days	25/08/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	Visit	days of treat.	Assessment	E.C.G. Date	E.C.G. Value	E.C.G. Abnormality
14	408	Reboxetine	Female	04/08/92	30/09/92	Screen	0	Screening	04/08/92	Normal	
	509	Fluoxetine	Female	29/09/92	10/11/92	Screen	-1	Screening	28/09/92	Normal	
						Day 28	30	1-28 days	29/10/92	Abnormal	SINUS BRADYCARDIA (< 60)
						Day 42	43	29-56 days	11/11/92	Normal	
	510	Fluoxetine	Female	30/09/92	26/11/92	Screen	0	Screening	30/09/92	Normal	
						Day 28	29	1-28 days	29/10/92	Normal	
						Day 56	57	29-56 days	26/11/92	Normal	
	511	Reboxetine	Female	23/10/92	10/12/92	Day 28	28	1-28 days	20/11/92	Abnormal	SINUS TACHYCARDIA (> 100)
						Day 49	49	29-56 days	11/12/92	Normal	
	512	Reboxetine	Female	03/11/92	02/12/92	Screen	-1	Screening	02/11/92	Normal	
	537	Reboxetine	Female	03/11/92	29/12/92	Screen	-5	Screening	29/10/92	Abnormal	SINUS BRADYCARDIA (< 60)
						Day 28	29	1-28 days	02/12/92	Normal	
						Day 56	62	29-56 days	04/01/93	Normal	
	538	Fluoxetine	Female	12/02/93	09/04/93	Screen	0	Screening	12/02/93	Abnormal	SINUS BRADYCARDIA (< 60)
						Day 28	28	1-28 days	12/03/93	Normal	
						Day 56	54	29-56 days	07/04/93	Normal	
	539	Fluoxetine	Female	10/03/93	05/05/93	Screen	-13	Screening	25/02/93	Normal	
						Day 28	29	1-28 days	08/04/93	Normal	
						Day 56	57	29-56 days	06/05/93	Normal	
15	409	Reboxetine	Male	08/04/92	02/06/92	Screen	-15	Screening	24/03/92	Normal	
						Day 28	27	1-28 days	05/05/92	Normal	
						Day 42	41	29-56 days	19/05/92	Normal	
						Day 56	55	29-56 days	02/06/92	Normal	
	410	Fluoxetine	Female	17/04/92	11/06/92	Screen	-8	Screening	09/04/92	Normal	
						Day 28	27	1-28 days	14/05/92	Normal	
						Day 56	55	29-56 days	11/06/92	Normal	
	411	Reboxetine	Female	22/04/92	16/06/92	Screen	-1	Screening	21/04/92	Normal	
						Day 28	27	1-28 days	19/05/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	days of treat.	Assessment	Date	Value	Abnormality
15	411	Reboxetine	Female	22/04/92	16/06/92	Day 56	55	29-56 days	16/06/92	Normal	
	412	Fluoxetine	Female	23/04/92	17/06/92	Screen	-13	Screening	10/04/92	Normal	
						Day 28	27	1-28 days	20/05/92	Normal	
						Day 56	55	29-56 days	17/06/92	Normal	
	413	Reboxetine	Female	30/04/92	24/06/92	Screen	-8	Screening	22/04/92	Normal	
						Day 28	27	1-28 days	27/05/92	Normal	
						Day 56	55	29-56 days	24/06/92	Normal	
	414	Fluoxetine	Male	02/06/92	27/07/92	Screen	-7	Screening	26/05/92	Normal	
						Day 28	27	1-28 days	29/06/92	Normal	
						Day 56	55	29-56 days	27/07/92	Normal	
	415	Reboxetine	Female	12/06/92	06/08/92	Screen	-8	Screening	04/06/92	Normal	
						Day 28	27	1-28 days	09/07/92	Normal	
						Day 56	55	29-56 days	06/08/92	Normal	
	416	Fluoxetine	Female	23/06/92	17/08/92	Screen	-4	Screening	19/06/92	Normal	
						Day 28	27	1-28 days	20/07/92	Normal	
						Day 56	55	29-56 days	17/08/92	Normal	
	417	Reboxetine	Female	19/06/92	13/08/92	Screen	-8	Screening	11/06/92	Normal	
						Day 28	27	1-28 days	16/07/92	Normal	
						Day 56	55	29-56 days	13/08/92	Normal	
	418	Reboxetine	Female	17/07/92	10/09/92	Screen	-10	Screening	07/07/92	Normal	
						Day 28	27	1-28 days	13/08/92	Normal	
						Day 56	55	29-56 days	10/09/92	Normal	
	419	Fluoxetine	Female	16/07/92	09/09/92	Screen	-8	Screening	08/07/92	Normal	
						Day 28	27	1-28 days	12/08/92	Normal	
						Day 56	55	29-56 days	09/09/92	Normal	
	420	Fluoxetine	Male	20/08/92	14/10/92	Screen	-36	Screening	15/07/92	Normal	
						Day 28	27	1-28 days	16/09/92	Normal	
						Day 56	55	29-56 days	14/10/92	Normal	
	421	Reboxetine	Female	01/08/92	25/09/92	Screen	-8	Screening	24/07/92	Normal	
						Day 28	27	1-28 days	28/08/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	days of treat.	Assessment	Date	Value	Abnormality
15	421	Reboxetine	Female	01/08/92	25/09/92	Day 56	55	29-56 days	25/09/92	Normal	
	422	Fluoxetine	Male	19/08/92	13/10/92	Screen	-5	Screening	14/08/92	Normal	
						Day 28	27	1-28 days	15/09/92	Normal	
						Day 56	55	29-56 days	13/10/92	Normal	
	423	Fluoxetine	Female	21/08/92	15/10/92	Screen	-6	Screening	15/08/92	Normal	
						Day 28	27	1-28 days	17/09/92	Normal	
						Day 56	55	29-56 days	15/10/92	Normal	
	424	Reboxetine	Male	21/08/92	15/10/92	Screen	-8	Screening	13/08/92	Normal	
						Day 28	27	1-28 days	17/09/92	Normal	
						Day 56	55	29-56 days	15/10/92	Normal	
	425	Reboxetine	Female	02/10/92	26/11/92	Screen	-8	Screening	24/09/92	Normal	
						Day 28	27	1-28 days	29/10/92	Normal	
						Day 56	55	29-56 days	26/11/92	Normal	
	426	Fluoxetine	Male	28/10/92	22/12/92	Screen	-8	Screening	20/10/92	Normal	
						Day 28	27	1-28 days	24/11/92	Normal	
						Day 56	55	29-56 days	22/12/92	Normal	
	427	Reboxetine	Female	03/12/92	27/01/93	Screen	-8	Screening	25/11/92	Normal	
						Day 28	27	1-28 days	30/12/92	Normal	
						Day 56	55	29-56 days	27/01/93	Normal	
	428	Fluoxetine	Male	03/12/92	27/01/93	Screen	-8	Screening	25/11/92	Normal	
						Day 28	27	1-28 days	30/12/92	Normal	
						Day 56	55	29-56 days	27/01/93	Normal	
	449	Reboxetine	Female	08/12/92	01/02/93	Screen	-7	Screening	01/12/92	Normal	
						Day 28	27	1-28 days	04/01/93	Normal	
						Day 56	55	29-56 days	01/02/93	Normal	
	450	Fluoxetine	Male	10/12/92	03/02/93	Screen	-11	Screening	29/11/92	Normal	
						Day 28	27	1-28 days	06/01/93	Normal	
						Day 56	55	29-56 days	03/02/93	Normal	
	451	Fluoxetine	Female	18/12/92	11/02/93	Screen	-11	Screening	07/12/92	Normal	
						Day 28	27	1-28 days	14/01/93	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	Visit	days of treat.	Assessment	E.C.G. Date	E.C.G. Value	E.C.G. Abnormality
15	451	Fluoxetine	Female	18/12/92	11/02/93	Day 56	55	29-56 days	11/02/93	Normal	
	452	Reboxetine	Female	23/12/92	16/02/93	Screen	-8	Screening	15/12/92	Normal	
						Day 28	27	1-28 days	19/01/93	Normal	
						Day 56	55	29-56 days	16/02/93	Normal	
	454	Fluoxetine	Male	19/01/93	15/03/93	Screen	-11	Screening	08/01/93	Normal	
						Day 28	27	1-28 days	15/02/93	Normal	
						Day 56	55	29-56 days	15/03/93	Normal	
16	429	Fluoxetine	Female	26/03/92	20/05/92	Screen	-14	Screening	12/03/92	Normal	
						Day 28	27	1-28 days	22/04/92	Normal	
						Day 56	55	29-56 days	20/05/92	Normal	
	430	Reboxetine	Male	30/03/92	25/05/92	Screen	-4	Screening	26/03/92	Abnormal	PREVIOUS MYOCARDIAL INFARCTION
						Day 28	28	1-28 days	27/04/92	Abnormal	PREVIOUS MYOCARDIAL INFARCTION
						Day 56	56	29-56 days	25/05/92	Abnormal	PREVIOUS MYOCARDIAL INFARCTION
	431	Reboxetine	Female	31/03/92	25/05/92	Screen	-5	Screening	26/03/92	Normal	
						Day 28	27	1-28 days	27/04/92	Normal	
						Day 56	55	29-56 days	25/05/92	Normal	
	432	Fluoxetine	Female	31/03/92	25/05/92	Screen	-5	Screening	26/03/92	Normal	
						Day 28	27	1-28 days	27/04/92	Abnormal	LEFT ANTERIOR HEMIBLOCK
						Day 56	55	29-56 days	25/05/92	Abnormal	LEFT ANTERIOR HEMIBLOCK
	433	Reboxetine	Female	02/04/92	27/05/92	Screen	-5	Screening	28/03/92	Normal	
						Day 56	55	29-56 days	27/05/92	Normal	
	434	Fluoxetine	Female	07/04/92	01/06/92	Screen	-4	Screening	03/04/92	Normal	
						Day 28	27	1-28 days	04/05/92	Normal	
						Day 56	55	29-56 days	01/06/92	Normal	
	435	Reboxetine	Female	14/04/92	08/06/92	Screen	-5	Screening	09/04/92	Normal	
						Day 28	27	1-28 days	11/05/92	Normal	
						Day 56	55	29-56 days	08/06/92	Normal	
	436	Fluoxetine	Female	24/04/92	18/06/92	Screen	-4	Screening	20/04/92	Normal	
						Day 28	27	1-28 days	21/05/92	Normal	
						Day 56	55	29-56 days	18/06/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	days of treat.	Assessment	Date	Value	Abnormality
16	437	Reboxetine	Female	30/04/92	24/06/92	Screen	-6	Screening	24/04/92	Abnormal	RIGHT BUNDLE BRANCH BLOCK
						Day 28	27	1-28 days	27/05/92	Abnormal	RIGHT BUNDLE BRANCH BLOCK
						Day 56	55	29-56 days	24/06/92	Abnormal	RIGHT BUNDLE BRANCH BLOCK
	438	Fluoxetine	Female	20/05/92	18/06/92	Screen	-5	Screening	15/05/92	Normal	
						Day 28	27	1-28 days	16/06/92	Normal	
	439	Fluoxetine	Female	20/05/92	14/07/92	Screen	-5	Screening	15/05/92	Normal	
						Day 28	27	1-28 days	16/06/92	Normal	
						Day 56	55	29-56 days	14/07/92	Normal	
	440	Reboxetine	Female	01/07/92	25/08/92	Screen	-5	Screening	26/06/92	Normal	
						Day 28	27	1-28 days	28/07/92	Normal	
						Day 42	41	29-56 days	11/08/92	Normal	
						Day 56	55	29-56 days	25/08/92	Normal	
	441	Fluoxetine	Female	22/07/92	14/09/92	Day 28	26	1-28 days	17/08/92	Normal	
						Day 56	54	29-56 days	14/09/92	Normal	
	442	Reboxetine	Female	22/07/92	14/09/92	Screen	-8	Screening	14/07/92	Normal	
						Day 28	26	1-28 days	17/08/92	Normal	
						Day 56	54	29-56 days	14/09/92	Normal	
	443	Fluoxetine	Male	25/08/92	18/10/92	Screen	-5	Screening	20/08/92	Normal	
						Day 28	27	1-28 days	21/09/92	Normal	
						Day 56	54	29-56 days	18/10/92	Normal	
	444	Reboxetine	Female	25/08/92	19/10/92	Screen	-5	Screening	20/08/92	Normal	
						Day 28	27	1-28 days	21/09/92	Normal	
						Day 56	55	29-56 days	19/10/92	Normal	
	445	Reboxetine	Male	18/09/92	12/11/92	Screen	-6	Screening	12/09/92	Normal	
						Day 28	27	1-28 days	15/10/92	Normal	
						Day 56	55	29-56 days	12/11/92	Normal	
	446	Fluoxetine	Female	18/09/92	12/11/92	Screen	-6	Screening	12/09/92	Normal	
						Day 56	55	29-56 days	12/11/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	Visit	E.C.G. days of treat.	E.C.G. Assessment	E.C.G. Date	E.C.G. Value	E.C.G. Abnormality
16	447	Fluoxetine	Male	18/09/92	12/11/92	Screen	-6	Screening	12/09/92	Normal	
						Day 28	27	1-28 days	15/10/92	Normal	
						Day 56	55	29-56 days	12/11/92	Normal	
	448	Reboxetine	Female	19/09/92	13/11/92	Screen	-5	Screening	14/09/92	Normal	
						Day 28	27	1-28 days	16/10/92	Normal	
						Day 56	55	29-56 days	13/11/92	Normal	
	455	Fluoxetine	Female	19/09/92	13/11/92	Screen	-5	Screening	14/09/92	Normal	
						Day 28	27	1-28 days	16/10/92	Normal	
						Day 56	55	29-56 days	13/11/92	Normal	
	456	Reboxetine	Male	16/12/92	09/02/93	Screen	-7	Screening	09/12/92	Normal	
						Day 28	27	1-28 days	12/01/93	Normal	
						Day 56	55	29-56 days	09/02/93	Normal	
	457	Fluoxetine	Female	16/12/92	09/02/93	Screen	-7	Screening	09/12/92	Normal	
						Day 28	27	1-28 days	12/01/93	Normal	
						Day 56	55	29-56 days	09/02/93	Normal	
	458	Fluoxetine	Female	16/12/92	09/02/93	Screen	-7	Screening	09/12/92	Normal	
						Day 28	27	1-28 days	12/01/93	Normal	
						Day 56	55	29-56 days	09/02/93	Normal	
	459	Reboxetine	Male	22/12/92	15/02/93	Screen	-5	Screening	17/12/92	Normal	
						Day 28	27	1-28 days	18/01/93	Normal	
						Day 56	55	29-56 days	15/02/93	Normal	
	460	Reboxetine	Male	22/12/92	15/02/93	Screen	-5	Screening	17/12/92	Normal	
18	25	Fluoxetine	Female	06/10/92	30/11/92	Screen	-6	Screening	30/09/92	Normal	
						Day 28	28	1-28 days	03/11/92	Normal	
						Day 56	56	29-56 days	01/12/92	Normal	
	26	Reboxetine	Female	06/10/92	30/11/92	Screen	-6	Screening	30/09/92	Normal	
						Day 28	28	1-28 days	03/11/92	Abnormal	SINUS TACHYCARDIA (> 100)
						Day 56	56	29-56 days	01/12/92	Abnormal	SINUS TACHYCARDIA (> 100)
	27	Reboxetine	Female	06/10/92	30/11/92	Screen	-6	Screening	30/09/92	Normal	
						Day 28	28	1-28 days	03/11/92	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	days of treat.	Assessment	Date	Value	Abnormality
18	27	Reboxetine	Female	06/10/92	30/11/92	Day 56	56	29-56 days	01/12/92	Normal	
	28	Fluoxetine	Female	06/10/92	02/11/92	Screen	-6	Screening	30/09/92	Normal	
						Day 28	21	1-28 days	27/10/92	Normal	
	29	Reboxetine	Male	06/10/92	30/11/92	Screen	-6	Screening	30/09/92	Normal	
						Day 28	28	1-28 days	03/11/92	Normal	
						Day 56	56	29-56 days	01/12/92	Normal	
	30	Fluoxetine	Female	07/10/92	01/12/92	Screen	-7	Screening	30/09/92	Normal	
						Day 28	33	1-28 days	09/11/92	Normal	
						Day 56	56	29-56 days	02/12/92	Normal	
	31	Reboxetine	Female	20/10/92	14/12/92	Screen	-7	Screening	13/10/92	Normal	
						Day 28	28	1-28 days	17/11/92	Normal	
						Day 56	63	29-56 days	22/12/92	Normal	
	32	Fluoxetine	Female	07/10/92	30/11/92	Screen	-2	Screening	05/10/92	Normal	
						Day 28	27	1-28 days	03/11/92	Normal	
						Day 56	55	29-56 days	01/12/92	Normal	
	49	Reboxetine	Female	17/11/92	11/01/93	Screen	-7	Screening	10/11/92	Normal	
						Day 35	35	29-56 days	22/12/92	Normal	
						Day 56	56	29-56 days	12/01/93	Normal	
	50	Reboxetine	Female	17/11/92	18/11/92	Screen	-7	Screening	10/11/92	Normal	
	51	Fluoxetine	Female	17/11/92	11/01/93	Screen	-7	Screening	10/11/92	Normal	
						Day 28	35	1-28 days	22/12/92	Normal	
						Day 56	56	29-56 days	12/01/93	Normal	
	52	Fluoxetine	Female	17/11/92	11/01/93	Screen	-7	Screening	10/11/92	Normal	
						Day 35	35	29-56 days	22/12/92	Normal	
						Day 56	56	29-56 days	12/01/93	Normal	
	53	Fluoxetine	Female	15/01/93	11/03/93	Screen	-17	Screening	29/12/92	Normal	
						Day 28	28	1-28 days	12/02/93	Normal	
						Day 56	56	29-56 days	12/03/93	Normal	

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016
Listing No.: 21.0

ECG TRACINGS

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	days of treat.	Assessment	Date	Value	Abnormality
18	54	Fluoxetine	Male	12/01/93	08/03/93	Screen	-7	Screening	05/01/93	Normal	
						Day 28	28	1-28 days	09/02/93	Normal	
						Day 56	56	29-56 days	09/03/93	Abnormal	SINUS BRADYCARDIA (< 60)
20	21	Fluoxetine	Female	06/11/92	30/12/92	Screen	-7	Screening	30/10/92	Normal	
						Day 14	14	1-28 days	20/11/92	Abnormal	SINUS BRADYCARDIA (< 60)
						Day 21	21	1-28 days	27/11/92	Abnormal	SINUS BRADYCARDIA (< 60)
	22	Fluoxetine	Female	12/11/92	16/12/92	Screen	1	Screening	13/11/92	Normal	
						Day 28	28	1-28 days	10/12/92	Normal	
21	9	Fluoxetine	Female	19/10/92	13/12/92	Screen	-3	Screening	16/10/92	Normal	
						Day 14	14	1-28 days	02/11/92	Normal	
						Day 28	35	1-28 days	23/11/92	Normal	
						Day 56	56	29-56 days	14/12/92	Normal	
22	113	Fluoxetine	Male	03/12/92	18/12/92	Screen	-9	Screening	24/11/92	Normal	
	115	Reboxetine	Male	29/12/92	20/01/93	Screen	-6	Screening	23/12/92	Normal	

1184

9550083

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

12.2.3 CRFs

Individual patient CRFs are filed in the Study Master File.