# Studie 016 (CTN016-FCE20124)

Studienbericht

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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

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# 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

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thyroid-stimulating hormone

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

Pharmacia

**Document 9550083** 

#### REBOXETINE - PROTOCOL 20124/016 SYNOPSIS

Name of Company: Pharmacia Spa Name of finished product:	Individual study table referring to part IV of the dessier  Ref.:	(For national authority use only)
Name of active ingredient(s): Reboxetine	Vel.: Page:	

Title of study: Multicentre, Multinational Double-Blind Study of the Activity and Tolerability of Reboxetime or Fluoxetime 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 B Alvarez, Dr J Massana, Prof GD Burrows, Dr R Gopta, Dr T George, Dr JC Ferrali, Dr R Montenegro, Dr HJ Schierie, Dr J Zehner, Prof M Hummel, Dr W Bellaire

Study centres: Psychiatrische 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, Australia; Hospital Clinico de Barcelona, Barcelona, Spain; Dept. of Psychiatry, University of Melbourne, Australia; Hospital; Philip Health Centre, Camberra, 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; Psychiatrische 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 (b.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 Sieep. 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 HCG.

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.

# Pharmacia

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Name of Company: Pharmacia Spa Name of finished product:	Individual study table referring to part IV of the dossier  Ref.:	(For national authority use only)
Name of active ingredient(s): Reboxetine	Vol.: Page:	

Test product: capsules containing RBX methanesulphonate tablets

Unit dese: 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 dese: 20 mg fluoxetine

Made 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 and-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) ( $\geq$ 20% w baseline), or such modifications associated with critical values ( $\geq$ 160 or  $\leq$ 100 mmHg for systolic BP;  $\geq$ 100 or  $\leq$ 70 mmHg for diastolic BP;  $\geq$ 100 or  $\leq$ 70 beats/min for HR). Orthostatic hypotension (decrease of systolic BP  $\geq$ 30 mmHg form lying to standardised. Clinically relevant changes of laboratory tests and abnormal BCG 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.

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#### 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 mmFig for diastolic blood pressure; ≥100 or ≤50 bests/min for heart rate) at each evaluation time were

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 w 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.

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 gauge and 20 (22,5%) in fluoretine gauge 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 fluoretine-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.L: -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 fluoretine-treated patients were classified as responders, while 67.1% and 66.7%, respectively, were seen to be in mission. The between treatment difference in the proportion of response was of 4.1% (95% C.I.: -9.1%  $\pm$ 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).

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#### 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 was 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: 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 reboxetinetreated patients with at least one assessment in addition to baseline, and to 4.1 at Day 56 in the 59 reboxetime 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  $(EI \ge 2)$  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 nowly 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% w 9.0%, respectively), constipation (21.5% vs 6.7%), hypotension and related symptoms (19.0% vs 7.9%), urinary heattancy/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 heaitancy, 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.

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#### 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 we 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 constituting 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 paraesthesis and, conversely, it was higher in fluoxetine patients for diarrhoes and agitation/anxiety/nervousness, but again not significantly so.

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#### 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 ws 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.

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#### 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.

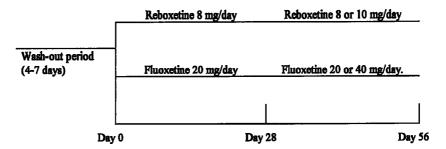
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Safety and tolerability were assessed by the reporting of any adverse events and measurements of vital signs (blood pressure and heart rate (supine and standing)), ECG and laboratory tests.

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

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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:

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- 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<sub>A</sub>), 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

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- 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.

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#### 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 w 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].

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#### 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.

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#### 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.

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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:

	<u>Item</u>	Score range	<u>Factor</u>
1.	Depressed mood	(0-4)	V
2.	Feelings of guilt	(0-4)	Ш
3.	Suicide	(0-4)	Ш
4.	Insomnia early	(0-2)	VI
5.	Insomnia middle	(0-2)	M
6.	Insomnia late	(0-2)	VI
<b>7</b> .	Work and activities	(0-4)	V
8.	Retardation	(0-4)	v
9.	Agitation	(0-4)	ш
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)	n
17.	Insight	(0-2)	I
18.	Diurnal variation	(0-2)	<b>IV</b>
19.	Depersonalisation and derealisation	(0-4)	ш
20.	Paranoid symptoms	(0-3)	m
21.	Obsessional symptoms	(0-2)	Ш

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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

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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

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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.

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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.

<sup>\*</sup> Code of Federal Regulation, Vol. 21, Part 312. Revised as of April 1 1987, page 75.

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

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# 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<sub>4</sub>. 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	×
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

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#### 3.7.2 PROCEDURES AT EACH VISIT

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

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

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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 perprotocol assessment, when the patient completed the study, or the last assessment before dropping out was taken as the end of treatment.

Pharmacia	Document 9550083
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.

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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.

42 (1185)

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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.

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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.
- 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

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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

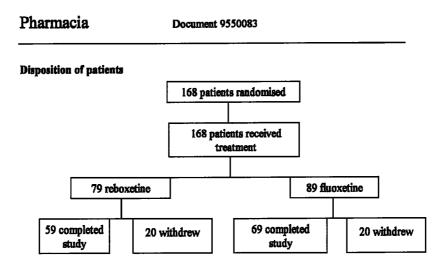
The original randomisation list is given in Appendix 12.1.7.

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.



#### 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 (5.6%) 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.

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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.

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#### **Summary of Demographic Data**

	Reboxetine (n=79)		Fluoz (n=	
	п	(%)	n	(%)
lex				
female	57	72.2	64	71.9
male	22	27.8	25	28.1
Total	79	100	89	100
lace				
Caucasian	78	98.7	89	100
Asian	1	1.3	-	-
Total	79	100	89	100
	Mean	SD	Mean	SD
lge (years)	44.0	12.6	43.6	11.8
leight (cm)	164.5	8.5	165.1	9.2
Veight (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 I 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

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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.

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#### 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 enisode.

# 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.

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#### 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

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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.L.: -9.1% + 17.2%) in favour of reboxetine.

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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 w 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%.

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#### 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,

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

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#### 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% ws 72.7%) and more frequently than males when on fluoxetine (75.0% ws 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% ws 9.0%), constipation (21.5% ws 6.7%), hypotension and related symptoms (19.0% ws 7.9%), urinary hesitancy/retention (12.7% ws 1.1%), paraesthesia (6.3% ws 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 ws 9.1% of male patients on reboxetine and 14.1% of female patients ws 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 ws 0% of male patients in both groups; paraesthesia was reported by 8.8% and 1.6% of female patients on reboxetine and fluoxetine, respectively ws 0% of male patients in both

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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 ws 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.

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#### 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.

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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),

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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] w 9.1% and 0% [male patients]), nausea (12.3% on reboxetine and 12.5% on fluoxetine [female patients] w 9.1% and 4.0% [male patients]), tremor (7.0%, 7.8% [female patients] w 0% in both treatment groups [male patients]) and paraesthesia (8.8%, 1.6% [female patients] w 0% in both treatments [male patients]). Urinary hesitancy was reported more by male patients than female patients (27.3%, ws 3.5%, respectively) in reboxetine-treated patients, while it was reported by 0% of male ws 1.6% of the female fluoxetine-treated

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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

		Rebox (n=7		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

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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:

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Treatment	Adverse event	Patient no.	Relationship to study drug
Reboxetine	G1 disorders		
	Nausca	37	Probable
	Vomiting	129	Possible
	Constipation	196, 503	Doubtful, Possible
	Dyspepsia	387	Missing
	Psychiatric disorders		
	Insomnia	104, 4	Possible, Probable
	Sommolence	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 ①	4, 196	Possible, Unknown
	Hepatitis infectious	196	None
	Urinary system disorders		
	Urinary retention	34	Probable
	Urinary hesitancy	503	Possible

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# Adverse Events Associated with Withdrawal (continued)

Treatment	Adverse event	Patient no.	Relationship to study drug
Fluoxetine	Gl 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 CI 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.

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#### 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 we 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%

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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

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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

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(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.

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#### 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 w baseline. In severe cases (55 reboxetine- and 66 fluoxetine-treated patients), the between treatment difference was of 5.3 points (95% C.I.:  $2.2 \pm 8.4$ ), 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.:  $-0.5 \pm 7.7$ ).

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

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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

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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.

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## 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.

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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TABLES

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PHARMACIA CHS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 1
NUMBER OF PATIENTS BY CENTRE, VISIT AND TREATHENT

Centre/Assigned treatment	eatment					Vis	Visit				
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
-	Fluoxetine	4	4	4	7	4	4	EÑ.	2	2	2
	Reboxetine	63	2	2	2	22	63	8	2	-	
2	Fluoxetine	8	40	8	7	7	7	7	9	9	
	Reboxetine	8	63	80	7	7	7	9	9	is)	
8	Fluoxetine	2	2	2	2	63	2	-	1	-	
	Reboxetine	2	2	2	2	2	2	٢			
4	Fluoxetine	S	S	5	ď	4	4	4	4	en	
	Reboxetine	4	7	4	m	3	æ	3	3	m	
5	Fluoxetine	1	-	-	-	1	-	1	-	-	
	Reboxetine	-	+-	1	+	-	-	1			
7'	Fluoxetine	ť	m		83	2	2	2	2	63	
7	Reboxetine	8	63	2	22	2	2	2	2	82	
11	Fluoxetine	1	7	7	7	7	7	9	9	9	
	Reboxetine	60	80	<b>40</b>	8	80	40	8	7	7	
12	Fluoxetine	rê	e	8	8	2	2	2	2	2	
	Reboxetine	2	2	2	2	2	22	2	2	61	
13	Fluoxetine	œ	80	so .	9	9	9	9	5	S	
	Reboxetine	o	6	6	€	7	7	9	vo	9	
14	Fluoxetine	10	10	10	10	10	6	6	6	8	
	Reboxetine	•	6	6	6	6	6	8	8	2	
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

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# 2 E 29 Day 49 72 66 138 Day 42 69 14.6 Bay 35 81 74 155 Day 28 NUMBER OF PATIENTS BY CENTRE, VISIT AND TREATMENT Visit 83 74 157 Day 21 REBOXETINE - PROTOCOL 20124/016 TABLE No.: 1 75 85 14 Pay 79 Day 168 Day 168 Screen Reboxetine Fluoxetine Reboxetine Fluoxetine Fluoxetine Fluoxetine Fluoxetine Reboxetine Centre/Assigned treatment

Day

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Total

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 2

		Treatment assigned	assigned			
	Fluoxetine	tine	Reboxetine	tine	Total	la
	No.	ж	ž.	×	No.	н
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	05	23.8

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

## PHARMACIA CNS 5500083

## REBOXETINE - PROTOCOL 20124/016 TABLE No.: 3

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

Assigned treat	tment / Reasons									Last	visi	t					
		To	tal	Da	у 7	Da	y 14	Da	y 21	Da	y 28	Da	y 35	Da	y 42	Da	y 49
		No	×	No	x	No	x	No	×	No	z	No	z	No	x	No	z
Fluoxetine	ADVERSE EVENT (*)	6	100		İ	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

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 4
PROTOCOL VIOLATION AT ADMISSION

	Fluo	Fluoxetine	Rebo	Reboxetine
	Ŋ.	%	Ņ.	%
Patients exposed	86	100.00	79	100.00
Age > 65 years			1	1.27
Pregnancy	1	1.12		1.27
Inyroid function tests abnormal*	6	10.11	5	6.33
Tryroid function tests missing	- 2	5.62	7	5.06
Evidence of Substance Use Disorder	I	1.12		
Associated endocrine disorder				
Not allowed concomitant medication during wash-out	<i>L</i>	78.7	L	8.86
Index episode < 4 weeks			7	2.53
Index episode > 8 months			7	2.53
Index episode duration; unknown			1	1.27
Clinical relevant associated pathology				

> 10% deviation from normal range limits

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 5 RANDONISATION: ASSIGNED TREATHENT vs RANDONISED TREATHENT

Assigned treatment	Randomized treatment	treatment	
	Fluoxetine	Reboxetine	Total
Fluoxetine	78	11	68
Reboxetine	12	69	79
Total	06	78	168

20124/016		
REBOXETINE - PROTOCOL	TABLE No.: 6	

COMPLIANCE TO SCHEDULE TIME AS PER PROTOCOL

		Screen	Day 0	Day	7 Day 14 Day 21	4		Day 28	Day 35	Day 42	Day 49	Day 56
Assessment time	No.	79	79		75	74	74	69	99	63	59	59
	Min	-62	•			£	20	27	*	41	48	53
	Max	-	73		6	91	31	31	45	45	9	99
	Median	7-	-		80	15	22	29	3.5	43	64	56
	95th percentile	-	-		6	15	24	30	37	44	52	09
Laboratory test	No.	78						68				57
	Kin	-59				_		15				51
	Kax	22						42				76
	Median	4-			_	-		29				56
	95th percentile	٢				<u> </u>		32				9
E.C.G.	No.	78				_		61				22
	Hin	-132				_		23				51
	Мах	<b>4</b>						42				76
	Median	4-				_		29				56
	95th percentile	2						36				65

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COMPLIANCE TO SCHEDULE TIME AS PER PROTOCOL PHARMACIA CNS R&D

		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Assessment time	No.	89	68	85	833	18	77	72	70	69	69
	Hin	-35	-	7	13	20	27	34	41	84	52
	Max	-	_	6	16	23	31	745	45	56	19
	Median	4-	_	8	15	22	29	36	45	64	95
	95th percentile	-	-	6	15	22	30	86	77	52	88
aboratory test	No.	689					73				89
	Hin	-35					22				50
	Мах	æ					45				84
	Median	4-					29				26
	95th percentile	1					35				65
E.C.G.	No.	87					70				67
	Min	-35					21				45
	Max	3					45				84
	Median	<b>5</b> -					29				56
	95th percentile	2					36				65

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 7

Class / Active principle		Fluoxetine Reboxetine	Reboxetine
BDZ long acting	FLUNITRAZEPAN	1	-
	NITRAZEPAM		-
	OXAZEPAN	1	
	LORAZEPAH	1	
	Tota1	e	2
Alcohol	ETHANOL	-	
	Total	1	
Neuroleptics	CHLORNEZANONE		-
	Total		_

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PHARMACIA CWS R&D

REBOXETINE - PROTOCOL 20124/016

Table No.: 8
OMITANT DRUGS NOT ALLOHED BY CLASS
NUMBER OF PATIENTS

Assigned treatment	Fluoretine Reboxetine	ব	<b>*</b>	m	
		At least one	Alcohol	BDZ long acting	Neuroleptics

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PHARMACIA CNS R&D
REBUXETINE - PROTOCOL 20124/016
Table No.: 9

DEMOGRAPHY BY ASSIGNED TREATMENT - ACE, WEIGHT, HEIGHT

Assigned treatment			Age			Weight			Height	
		Sex	_		Sex			Sex	×	
		Female	Hale	Total	Fenale	Male	Total	Female	Male	Total
Fluoxetine	No	64	25	89	49	25	89	63	25	88
	Kean	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
	Kin	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
	Hin	21.00	23.00	21.00	41.00	61.00	41.00	148.00	155.00	148.00
	Мах	78.00	61.00	78.00	140.00	113.00	140.00	179.00	186.00	186.00
<b>T</b> otal	No	121	47	168	121	47	168	120	64	167
	Неап	44.36	42.32	43.79	94.99	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
	Hin	19.00	18.00	18.00	41.00	44.10	41.00	147.00	155.00	147.00
	Мах	78.00	62.00	78.00	140.00	120.00	140.00	182.00	186.00	186.00

PHARMACIA CNS R&D TINE - PROTOCOL 20124/016 Table No.: 10

	DEMOGRAPHY BY ASSIGNED TREATHENT - RACE	Y ASSIGNE	D TREATHE	NT - RACE			
Assigned treatment / Sex	/ Sex		Race	o,			
	•	Caucasian	sian	Asian	an	Total	LE.
		No.	×	Ão.	×	No.	×
Fluoxetine	Fена1e	79	100.00			79	100.00
	Male	25	100.00			25	100.00
	Total	89	100.00			89	100.00
Reboxetine	Fenale	56	100.00			56	100.00
	Kale	22	95.65	-	4.35	23	100.00
	Total	78	98.73	•	1.27	79	100.00
Total	Female	120	100.00			120	100.00
	Hale	47	97.92	-	2.08	48	100.00
	Total	167	99.40	1	09.0	168	100.00

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 11

REBOXETINE - PROTOCOL 20124-016
TABLE No.: 11
DIACHOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATHENT
Sex

						Sex				
			Female			Male			Total	
		Fluoxetine	Fluoxetine Reboxetine	Total	Fluoxetine	Fluoxetine Reboxetine	Total	Fluoxetine	Fluoxetine Reboxetine	Total
DSM-III-R	296.2 No.	29	22	51	13	6	22	42	31	73
eraguos ro	296.3 No.	35	35	70	12	12	24	47	47	94
	other No.					-	+		1	-
Age of onset No.	No.	54	84	102	21	17	38	75	59	140
(30012)	Nean	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
	Kin	10	19	10	18	20	18	10	19	10
	Маж	79	9	65	99	99	95	49	99	65
	прквонп	10	6	19	*	S	6	14	7	28
Number of	No.	30	32	62	12	1	23	42	84	85
episades	Kean	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
	Nedian	2.00	2.00	2.00	3.50	2,00	3.00	2,00	2.00	2.60
	Nin	-	٦	1	1	-	1	1	•	1
	Kax	10	10	10	20	rů.	20	20	10	20

13.16 13.31 9550083

156

24

156

156

28

Min Max

8.00

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REBOXETINE - PROTOCOL 20124/016 TABLE No.: 11 PHARMACIA CNS R&D

Total Reboxetine Tota1 13.78 6.65 DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT 13.88 9.03 94.9 11.00 10.97 Total 11.59 7.60 12.00 7.00 Fluoxetine Reboxetine Kale 25 21.42 16.54 16.00 15.07 14.00 104 121 Tota1 22.25 18.61 20.00 14.61 20.85 53 104 Fluoxetine Reboxetine Female 20.61 14.49 16,00 13.45 52 49 6.72 STD Median Min f Duration or present episode (weeks)

15.22

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PRARNACIA CNS R&D

DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT REBOXETINE - PROTOCOL 20124/016 TABLE No.: 12

100.001 41.32 39.62 13.22 11.57 19.01 100.00 50.41 36.36 Total 4 23 50 48 121 ş 29.82 100.00 100.00 22.81 47.37 100.00 49.12 35.09 15.79 10.53 Reboxetine 17 13 27 22 82 28 Š 43.75 43.75 100.00 15.63 35.94 48.44 100.00 100.00 37.50 12.50 51.56 10.94 × Fluoxetine 9 8 8 49 33 24 28 ę Different from any prev. cond. Exacerbation of chronic cond. Subacute (>= 2 & < 12 weeks) Recurrence of similar prev. Insidious (>= 3 months) Definitely present Acute (< 2 weeks) Probably present First occurence Total Total Total Charact. of present episode Precipit. external stress Onset of present episode

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REBOXETINE - PROTOCOL 20124/016 TABLE No.: 12 PHARMACIA CNS R&D

DIAGNOSIS AND HISTORY OF MENTAL DISORDERS BY SEX AND ASSIGNED TREATMENT

Sex: Male

		Fluoxetine	tine	Reboxetine	tine	Total	a1	
i		Š	ж	S.	м	ž	ж	
haract, of present episode	Exacerbation of chronic cond.	4	16.00	w	13.64	7	14.89	
	Recurrence of similar prev.	6	36.00	10	45.45	19	40.43	
	Different from any prev. cond.	٦	4.00			-	2.13	
	First occurence	11	44.00	6	40.91	20	42.55	
	Total	25	100.00	22	100.00	47	100.00	
nset of present episode	Acute (< 2 weeks)	4	16.00	23	9.09	9	12.77	
	Subacute (>= 2 & < 12 weeks)	15	60.00	12	\$5.35	27	57.45	
	Insidious (>= 3 months)	9	24.00	80	36.36	74	29.79	
	Total	25	100.00	22	100.00	47	180.00	
recipit. 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	

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PHARMACIA CNS R&D

		Fluoxetine	tine	Reboxetine	tine	Total	al
		Š	N	£	×	No.	н
Charact. of present opisode	Exacerbation of chronic cond.	12	13.48	6	11.39	21	12.50
	Recurrence of similar prev.	37	41.57	07	50.63	77	45.83
	Different from any prev. cond.	٢	1.12	-	1.27	8	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

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 13

PREVIOU	S ANTIDEPRESS	TABLE NO.: 13 PREVIOUS ANTIDEPRESSIVE TREATMENT BY ACTIVE PRINCIPLE	BY ACTIVE PR	INCIPLE		
		Assigned treatment	reatment			
,	Fluoxetine	tine	Reboxetine	tine	Total	al
	Z	ж	£	ж	Q.	×
Screened patient	68	100.0	79	100.0	168	100.0
AMITRIPTYLINE	11	12.4	15	19.0	26	15.5
IMIPRAMINE	10	11.2	6	11.4	19	11.3
CLOMIPRAMINE	83	0.6	8	10.1	16	9.5
DOXEPIN	80	9.0	60	10.1	16	9.5
MOCLOBENIDE	€0	9.0	2	2.5	10	6.0
FLUOXETINE	4	4.5	9	7.6	10	6.0
TRANYLCYPROMINE	3	3.4	5	6.3	æ	4.8
DOSULEPIN	S	5.6	3	3.8	40	83.
HIANSERIN	S	5.6	2	2.5	7	4.2
TRIMIPRAMIME	7	2.2	en .	3.8	S	3.0
NORTRIPTYLINE			4	5.1	4	2.4
AMINEPTINE	2	2.2	1	1.3	e	8.
DPIPRAMOL	2	2.2	1	1.3	en en	8.1
MAPROTILINE	1	1.1	1	1.3	2	1.2
FLUVOXAMINE	2	2.2			2	1.2
ГІТНІОН	-	1.1	1	1.3	2	1.2
VENLAFAXINE			-	1.3	-	9.0
ANOXAPINE			1	1.3	1	9.0
DIBENZEPIN			1	1.3	ı	9.0

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# PHARMACIA CWS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 14

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

Princetine Reloacetine   Fluoretine   Fluoretine Reloacetine   Fluoretine Reloacetine   Fluoretine Reloacetine   Fluoretine   Fl	Previous diseases			Female	le le					Жаде						Total	,		
No   Pet.   No		Fluoxe	stine	Reboxe	tine	Tota	널	Fluoxe	atine	Reboxe	tine	Tota		Fluoxe	tine	Reboxe	tine	Tota	-
NOS 2 3.1			X on Pt.		£.		7 on	ł	z on Pt.		z on Pt.		z on Pt.		χon Pt.		% on Pt.		% on Pt.
MOS	Screened patients	99	100	57	100	121	100	25		22	100	47	100	89	100	79	100	168	100
NOS  NOS  NOS  NOS  NOS  NOS  NOS  NOS	OTHER GU NEOPLASM NOS	-	1.6	60	5.3	4	3,3				-			-	1:1	ю	3,8	4	2.4
NOS 2 3.1 2 3.5 4 3.3 NOS 2 3.1 1 1.8 3 2.5 2 8.0 2 4.3 4 4.5 1 1.3 2 2.2 2.2 2.2 2.2 2.2 2.2 2.2 2.2 2.2	APPENDICITIS NOS			w	5.3	3	2.5									es .	3.8	en	8.
NOS	UTERINE LEIDHYONA	2	3.1	12	3.5	4	3.3							67	2.2	8	2.5	4	2.4
MOS  HOS  HOS  HOS  HOS  HOS  HOS  HOS	OBESITY	2		-	1.8	8	2.5	23	8.0			23	4.3	4	4.5	-		5	3.0
1   1.6	VARICOSE VEIN OF LEG NOS			8	3.5	N	1.7									2	2.5	8	1.2
1   1   6   1   1   1   1   1   1   1	CHOLELITHIASIS NOS			7	3.5	8	1.7									2	2.5	2	1.2
1   1-6	CESAREAN DELIVERY NOS			73	3.5	N	1.7									2		2	1.2
1   1.6	PROSTATITIS NOS							61	8.0			21	4.3	2	2.2			61	1.2
1   1.6	HYPERTENSION NOS	-	1.6			-	8.0			2	9.1	23				61		9	1.8
1   1.6	TYPHOID FEVER	1	1.6			-	8.0							-	1.1			٦	9.0
1.6	PULMOWARY TB NEC	1	1.6			-	8.0							-				٦	9.0
1 1.6 1 1.8 2 1.7 1 1.3 1.1.1 1 1.3 1.1.1 1 1.3 1.1.1 1 1.3 1.1.1 1 1.3 1.1.1 1 1.3 1.1.1 1 1.3 1.1 1.3 1.1 1.3 1.1 1.3 1.1 1.3 1.1 1.3 1.1 1.3 1.1 1.3 1.1 1.3 1.3	SEPTICENIA NOS	1	1.6				8.0							-	1.1			-	9.0
1 1.6 1 0.8 1 1.1 1 1 1.1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	COLTER NOS	1	1.6	-	1.8	2	1.7							-	1.1	-		2	1.2
1 1.6 1 0.8 1 1.1 1 1.1 1 1.1 1 1.3 1 1.6 1 1 0.8 1 1 1.1 1 1.1 1 1.3 1 1.6 1 1 1.8 1 1 1.1 1 1.3 1 1.6 1 1 1.8 1 1 1 1	NIGRAINE	1	1.6			٦	8.0							7					9.0
1 1.6	RETINAL DETACH W DEFECT	•	1.6			۲	8.0							-				-	9.0
EC 1 1.6 1 0.8 1 1.1 1 1 1.1 1 1 1.1 1 1 1.1 1 1	DISSEMIN CHORIORETINITIS		1.6			-	0.8							-	l			-	9.0
1 1.6 1 1.8 2 1.7 1 1.1 1 1.1 1 1.3 1 1.6 1 1 0.8 1 1 1.6 1 1 0.8 1 1 1.6 1 1 0.8 1 1 1.1 1 1 1.1 1 1 1.1 1 1 1.1 1 1 1.1 1 1 1.1 1 1 1.1 1 1 1.1 1 1 1 1.1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	FLU W RESP MANIFEST NEC	1				-	9.0							-	7:			-	9.0
1 1.6 1 1.8 2 1.7 1 1.3 1 1.3 1 1.3 1 1.3 1 1.3 1 1.3 1 1.3 1 1.4 1 1.3 1 1.4 1.4	BRONCHITIS NDS	1	1.6			1	0.8							-	1.1			-	9.0
1 1.6	ASTHMA NOS	1		1	1.8	2								-					1.2
1 1.6	DIAPERAGNATIC HERNIA	_				1	8.0							-	1.1			ı	9.0
	CHRONIC LIVER DIS NEC	1				-								-				-	9.0

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 14

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

Previous diseases			Female	IJe					Kale						Total	4		
	Fluoxe	tine	Fluoxetine Reboxetine	tine	Total	_	Fluoxe	atine	Fluoxetine Reboxetine	tine	Total		Fluoxe	tine	Fluoretine Reboxetine	tine	Total	H
	No	z on Pt.	Š.	Z z	°Z.	7 g	S.	z on Pt.	No.	z on Pt.	£	Z on Pt.	2	χ on Pt.	ş	z an Pt.	2	х ая Рt.
CHRONIC PANCREATITIS	-	1.6			7	8.0							-	1.1			1	9.0
ENDONETRIOSIS NOS		1.6			-	9.0							-	-			-	9.0
EXCESSIVE MENSTRUATION	-	1.6	-	1.8	22	1.7							-	1.1	٦	1.3	81	1.2
ECTOPIC PREGNANCY NOS	-	1.6			-	8.0							-	-			-	9.0
SPONTANEOUS ABORTION	-	1.6			1	9.8							-	1.1			-	9.0
DERANGEMENT OF JOINT NOS	•	1.6			-	8.0							٣	1.1			7	9.0
THORAC/LUMB DISC DISPLAC	-	1.6	!		1	9.0							-	1.1			1	9.0
DISC DISPLACEMENT NOS	*	1.6	٦	1,8	2	1.7							-	1.1	-	1.3	23	1.2
RHEUMATISM NOS	-	1.6			•	8.0							٦	1.1			1	9'0
OSTEITIS DEFORMANS NOS	1	1.6			1	8.0							٦	1.1			1	9.0
CYSTIC KIDNEY DISEASE	-	1.6	٢	1.8	2	1.7							-	1.1	-	1.3	2	1.2
TACHYCARDIA NOS		1.6	-	1.8	2	1.7							٢	1.1	1	1.3	2	1.2
CARDIOVAS SYS SYMP NEC		1.6			-	9.0							-	1.1			-	9.0
FX SACRUM/COCCYX-CLOSED	٣	1.6			-	0.8							-	1.1			-	9.0
SUICIDE-PSYCHOTROPIC AGT	-	1.6			-	9.0							-	1.1			-	9.0
PULMONARY TB NOS			-	1.8	٦	9.8									-	1.3	-	9.0
PURE HYPERCHOLESTEROLEN			ŧ	1.8	٦	8.0			٦	4.5	-	2.1			2	2.5	2	1.2
MIXED HYPERLIPIDEMIA			1	1.8	-	8.0									-	1.3	-	9.0
HYPOPOTASSENTA			1	1.8	-	0.8	·								-	1.3	-	9.0
HYPERHETROPIA			٦	1.8	-	0.8										1.3	-	9.0
ASTIGNATISM			ı	1.8	ı	8.0									-	1.3	1	9.0
ALLERGIC RHINITIS NOS			1	1.8	1	0.8									1	1.3	-	9-0

PHARHACIA CMS 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	le					Male						Total	-		
	Fluox	etine	Fluoxetine Reboxetine	tine	Total		Fluoxe	stine	Fluoxetine Reboxetine	tine	Total		Fluoxe	tine	Fluoxetine Reboxetine	tine	Total	1
	No.	z on Pt.	£	% on Pt.	£	т, <sub>я</sub>	Š	z on Pt.	£	X on Pt.	°z	ж оп Р.	£	X on Pt.	. 5	ž on Pt.	£	z on Pt.
PNEUMONIA, ORGANISM NOS			1	1.8	٣	9.0									٢	1.3	-	9.0
BRONCHIECTASIS			-	1.8	-	0.8									-	7.3	-	9.0
PNEUMOTHORAX			-	1.8	-	0.8									-	1.3	-	9.0
ESOPHACITIS			٢	1.8	1	0.8									-	1.3	-	9.0
GASTRITIS/DUODENITIS NOS			٢	1.8	-	9.0									-	1.3	-	9.0
INGUINAL HERNIA NOS			-	1.8	-	9.0	-	0.4			-	2.1	-	1.1	-	1.3	61	1.2
HEPATITIS IN VIRAL DIS			٦	1.8	-	8.0									-	1.3	-	9.0
HYDRONEPHROSIS			۳-	1.8	1	8.0									٦	1.3	-	9.0
CYSTITIS NOS			1	1.8	-	8.0									-	1.3	-	9.0
SALPINGO-OOPHORITIS NOS			1	1.8	-	8.0									~	1.3	-	0.6
UTERINE PROLAPSE			1	1.8	-	8.0									٦	1.3	-	9.0
OVARIAN CYST NEC/NOS			-	1.8	-	8.0									-	1.3	-	9.0
NONINFL DIS OVA/ADNK NEC			٦	1.8	-	8.0									1	1.3	-	9.0
INCOMPETENCE OF CERVIX			-	1.8	-	8.0									1	1,3	-	9.0
OTHER PSORIASIS			1	1.8	-	8.0									-	1,3	-	9.0
OSTEOARTHROSIS NOS			1	1.8	4	8.0									1	1.3	-	9.0
TORTICOLLIS NOS			ı	1.8	٦	9.0									-	1.3	-	9.0
LUNBAGD			-	1.8	1	8.0									-	1.3	-	9.0
SCIATICA			-	٦. ۵.	٣	8.0					!				1	1.3	-	9.0
ENTHESOPATHY OF ANKLE			1	1.8	1	8.0									L	1.3	1	9.0
SCOLIOSIS			1	1.8	1	0.8									٦	1.3	-	9.0
OTHER ANOMALIES OF LUNG			1	1.8	-	8.0									1	1.3	+	9.0

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PHARMACIA CNS R&D

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

Previous diseases			Female	.Te					Male	91					Total	4		
	Fluox	etine	Fluoxetine Reboxetine	tine	Total		Fluoxe	tine	Fluoxetine Reboxetine	tine	Tota1	4	Fluoxe	Fluoxetine Reboxetine	Reboxe	tine	Total	4
	윤	z on Pt.	2	x on	٤	χ on Pt.	ş	% on Pt.	No	x on Pt.	Š	х оп Pt.	2	7 on Pt.	% %	χ on Pt.	Ş.	z on Pt.
CONGEN URETERAL OBSTRUCT			-	1.8	-	8.0									٦	1.3	1	9.0
ABN BLOOD CHEMISTRY NEC			1	1.8	-	8.0	-	4.0			-	2.1	-	1.1	7	1.3	13	1.2
CLAVICLE FRACTURE			-	1.8	-	8.0									٢	1.3	1	9.0
STERILIZATION			-	1.8	-	9.0									٣	1.3	1	9.0
BENIGN NEO UTERUS NOS							1	4.0			-	2.1	-	1.1			-	9.0
THYROTOXICOSIS NOS							-	0.4			-	2.1	-	-			1	9.0
RHEUM FEV M/O HRT INVOLV							-	4.0			-	2.1	-	-			-	9.0
OLD MYOCARDIAL INFARCT							٢	4.0			-	2.1	-	1:			-	9.0
STOMACH ULCER NOS							-	4.0	1	4.5	2	4.3	-	1.1	-	1,3	63	1.2
ALCOHOLIC GASTRITIS							-	4.0			-	2.1	-	1.1			٣	9.0
ALCOHOL LIVER DAMAGE NOS							٦	4.0			-	2.1	-	1.1			7	9.0
LIVER DISORDERS NEC							٦	4.0			-	2.1	-	1.1			-	9.0
ABN LIVER FUNCTION STUDY							-	4.0			-	2.1	-	1.1			٢	9.0
ADV EFF PHENOTHIAZ TRANQ							-	4.0			-	2.1	-	1:1			-	9.0
DUODENAL ULCER NOS									-	4.5	-	2.1			-	1.3	-	9.0
ARTHROPATHY NOS									-	4.5	-	2.1			-	1.3	1	9.0
CONCUSSION									~	4.5	-	2.1			-	1.3	٦	9.0

PHARMACIA CNS R&D REBONETINE - PROTOCOL 20124/016 TABLE No.: 15

HEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS OF SCREENED PATIENTS BY BODY SYSTEM, SEX AND ASSIGNED TREATHENT

Previous diseases (body			Fenale	4					Hale						Total	-		
system)	Fluoxe	stine	Fluoxetine Reboxetine	tine	Total		Fluoxetine Reboxetins	tine	Reboxe	tine	Total	-	Fluoxe	tine	Fluoxetine Reboxetine	tine	Total	1
	No.	z an Pt.	°Z	z on Pt.	2	% on Pt.	2	Pt.	£	ž ga Pt.	2	7 d	% S	z on Pt.	Š	z an Pt.	S.	z on Pt.
Screened Patients	79	100	57	100	121	9	52	100	22	100	47	100	89	100	79	100	168	100
KEOPLASM	3	4.7	10	8.8	60	9.9	-	4.0			-	2.1	4	4.5	r)	6.3	6	5.4
DIGESTIVE SYSTEM	8	4.7	6	15.8	12	6.6	m	12.0	-	4.5	4	8.5	9	6.7	2	12.7	16	9.5
ENDOCR., NUTRIT. AND HETAB. DISEASES	w	4.7	S)	80 80	60	9.9	ĸ	12.0	-	4.5	4	8.5	9	6.7	9	7.6	12	7.1
CIRCULATORY SYSTEM	-	1.6	73	3.5	m	2.5	77	8.0	63	1.6	4	8.5	æ	3.4	4	5.1	7	4.2
PREGNANCY, CHILDBIRTH AND PUERPERIUM	2	3.1	61	3.5	4	8.3							62	2.2	2	2.5	4	2.4
GENITOURINARY SYSTEM	2	3.1	7	12.3	6	7.4	82	8.0			8	4.3	4	4.5	7	8.9	11	6.5
INFECTIOUS AND PARASTITIC DISEASE	60	4.7	-	1.8	4	ы ы							m	3.4	-	1.3	4	2.4
NERVOUS SYSTEM AND SENSE ORGANS	23	3.1	-	1.8	en	2.5							2	2.2	-	1.3	w	1.8
RESPIRATORY SYSTEM	3	4.7	LO .	8.8	8	9.9							3	3.4	. 5	6.3	8	4.8
MUSCOLOSKELETAL SYS. AND CONNETIVE TISSUE	4	 6.	ru.	8.	6	7.4			-	4.5	1	2.7	4	4.5	40	7.6	10	6.0
CONGENITAL ANOMALIES	-	1.6	en	5.3	4	3.3							-	1.1	ŧ	3.8	4	2.4
SYMPTOMS, SIGNS AND ILL DEFINED CONDITIONS	2	3.1	23	3.5	4	3.3	01	8.0			22	4.3	4	4.5	63	2.5	9	3.6
INJURY AND POISONING		1.6	-	1.8	2	1.7			1	4.5	1	2.1	-	1.1	2	2.5	3	1.8
отнея	٦	1.6	-	6.	2	1.7	-	4.0			-	2.1	23	2.2		1.3	m	1.8
SKIN AND SUBCUTANEOUS TISSUE			٦	8.	-	8.0									-	£.	-	9.0

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

# PHARMACIA CNS955600083

## 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: Rebexetine

days of treatment				D-	(	mg/day	y )					
or carmone.		0		4		8	1	0	12	2	Tot	al
	No	z	No	7,	No	z	No	z	No	z	No	z
Day 0 1			12	15.2	67	84.8					79	100
2 3			1	1.3	77 76	98.7 98.7					78 77	100
4			1	1.3	76	98.7		·			77	100
5	ł		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 Dav 71					74	100 98.7			1	1.3	3 75	100
Day 71 2					75	100			· '	'3	75	101
3					75	100					75	100
4	1				75	100					75	100
5			2	2.7	73	97.3					75	100
6 7			1	1.3	74 71	98.7 98.6					75 72	100
8	1 :		٠.	1.7	٠ <u>′</u> i	100					1	100
Day 14 1					74	100					74	100
2			1	1,4	73	98.6					74	100
3 4			1	1.4	73 74	98.6 100					74 74	100
5					74	100					74	100
6					74	100				- 1	74	100
7			1	1.4	73	98.6			- 1		74	100
8					7	100					7	100
9 Day 21 1					74	100			i		74	100
Day 21 1 2			1	1.4	73	98.6				ļ	74	100
3			•		73	100					73	100
4					73	100					73	100
5	1		1	1.4	72	98.6					73 73	100
6 7			1	1.4	72 70	98.6					70	100
8	1		1	16.7	<b>5</b>	83.3		1		- 1	6	100
ğ			1	100	-			1		- 1	1	100
Day 28 1	1				57	82.6	12	17.4		i	69	100
2					56	82.4	12	17.6			68	100
3 4			1	1.5	55 56	80.9 82.4	12 12	17.6		- 1	68 68	100
5	1	1.5			54	80.6	12	17.9		ł	67	100
6	1 1	1.5			54	80.6	12	17.9		j	67	100
7	1	1,6	1,	1.6	49	77.8	12	19.0	- 1		63	100
8	1 1	33.3			2	66.7					3	100
Day 35 1	"	100	1	1.5	51	77.3	14	21.2			66	100
Day 35 1 2			•	1.3	52	78.8	14			]	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 7			1 3	1.5 4.7	52 49	78.8	13 12	19.7			66 64	100
á			3	4.7	2	100	12	10.5			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 5			1	1.6	50 50	79.4	12 12	19.0			63 63	100
6			•	3	51	81.0	12	19.0			63	100
7			2	3.2	48	77.4	12	19.4	ļ		62	100
8	1				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 59	100
3 4			1	1.7	50 50	84.7	8	15.3	- 1		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	1	,	3	100		1		1 1			3	100

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

## PHARMACIA CN9560083

## REBOXETINE - PROTOCOL 20124/016 TABLE No.: 16

EXPERIMENTAL TREATHENT: 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			D	ose (:	ng/dag	y)				
CLearment	,	0	2	0	4(	0	60	)	Tot	tal
	No	z	No	×	No	z	No	z	No	x
Day 0 1 2	11	12.4	78 88	87.6 100					89 88	104
3	1	1.1	87	98.9					88	10
4			87	100					87	10
5 6			86 86	100					86 86	10
7			86	100					86	10
	ا ا		6	100					6	10
Day 7 1 2	1 3	1.2	84 82	98.8 96.5			:		85 85	10
3	1	1.2	84	98.8					85	10
4 5	1	1.2	84 83	98.8 98.8					85 84	10
6	1	1.2	82	98.8					83	10
7	2	2.5	78	97.5					80	10
Day 14 1 2	2	2.4	83 81	100 97.6					83 83	10
3	1	1.2	81	98.8					82	10
4			82	100					82	10
5 6			82 82	100 100					82 82	10
7			82	100					82	10
8			3	100					3	101
Day 21 1 2			81 81	100					81 81	100
3			81	100				}	81	10
4	2	2.5	79	97.5					81	10
5 6	2	2.5 1.2	79 79	97.5 98.8					81 80	100
7	' I	1.4	79	100					79	10
8			5	100					_5	100
Day 28 1 2	1	1.3	65 67	84.4 87.0		13.0 10.4	1 1	1.3	77	100
3	i	1.3	64	85.3	9	12.0	i	1.3	75	10
4			65	86.7	9	12.0	1	1.3	75	100
5 6	1	1.3	63 64	84.0 85.3		13.3	1	1.3	75 75	100
7	1	1.4	60	83.3	11	15.3	1	۱۰۰۰	72	104
8	1	33.3	2	66.7					3	10
9 Day 35 1			- 1 60	100 83.3	12	16.7	-		72	10
2			61	84.7	11	15,3			72	10
3	ا		59	83.1	12	16.9			71 71	10
4 5	1	1.4	58 59	81.7 83.1	12	16.9			71	10
6			61	85.9	10	14.1			71	10
7	1	1.5	55	84.6	9	13.8			65	10
8 Day 42 1	1	1.4	2 58	100 82.9	11	15.7			2 70	10
2	i	1.4	58	82.9	11	15.7			70	10
3	1	1.4	58	82.9	11	15.7			70 70	10
4 5	1	1.4 1.4	58 58	82.9 82.9	11	15.7 15.7			70	10
6	1	1.4	58	82.9	11	15.7			70	10
7	1	1.4	58	84.1	10	14.5		j	69	10
8 Day 49 1	1	14.3 1.4	5 57	71.4 82.6	11	14.3 15.9		-	7 69	10
2	1	1.4	57	82.6	11	15.9		1	69	10
3	2	2.9	56	81.2	11	15.9			69	10
4 5	3 1	4.3 1.5	54 55	78.3 80.9	12 12	17.4 17.6			69 68	10
6	1	1.5	56	82.4	11	16.2			68	100
7 8	1	1.5	52	78.8 90.0	13	19.7 10.0		-	66 10	100
			9		1			- 1		

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PHARMACIA CNS RED

EXPERIMENTAL TREATHENT: NUMBER OF PATIENTS WHO SMITCHED FROM LOW TO HIGH DOSE BY ASSIGNED IREATHENT REBOXETINE - PROTOCOL 20124/016 TABLE No.: 16.1

		Total	a1	isiv	visit of first change in dose	change in d	lose
		No.	×	Day 0	Day 28	Day 35	Day 49
luoxetine	алнауз лон dose	7.5	84.27	75			
	at least one high dose	42	15.73		12	1	1
	Total	89	100.00	75	12	1	1
eboxetine	always low dose	79	81.01	99			
	at least one high dose	15	18,99		12	2	ı
	Total	79	100.00	79	12	2	1

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 17 EXPERIMENTAL TREATMENT: DISTRIBUTION OF PATIENTS ACCORDING TO CAPSULES TAKEN BY ASSIGNED TREATMENT

					Compliance	ance						
	< 80 X	×	- 08	80 - 89 x 90 - 95 x 98 - 98	- 06	95 Z	- 56	z 66	100	×	Total	ia1
	S.	ж	£	н	å	к	Ŷ.	×	S.	×	No	×
Fluoxetine	ю	3.4	-	1:1	9	3.4	29	29 32.6	53	53 59.6		89 100.0
Reboxetine	82	2.5	-	1.3	6	3.8	5	16.5	09	13 16.5 60 75.9	Ĭ	79 100.0
Total	5	3.0	23	1.2	9	3.6	42	25.0	113	42 25.0 113 67.3 168 100.0	168	100.0

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PHARMACIA CNS R&D

Concomitant drugs	Before treatment	eatment	During treatment	eatment	Tot	Total
	Fluoretine	Reboxetine	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine
	Ão.	No.	Μa.	No.	No.	No.
CHLORAL HYDRATE	æ	88	6	10	11	18
TEKAZEPAM	9	9	2	4	8	. 10
CLONETHIAZOLE	-	60	7	9	8	6
PARACETAMOL			10	S.	10	uń.
ACETYLSALICYLIC ACID	-	2	3	2	4	4
METOCLOPRANIDE			1	8	1	m
AHOXICILLIN	-		2	-	3	1
MAGALDRATE			1	83	ı	2
LACTULOSE		1		63		8
DOMPERIDONE		1	2		2	•
ESTRADIOL	-	1			1	1
DOXXCYCLINE			2		2	
CHLORPHENAMINE			-	1	ı	1
ESTROGENS CONJUGATED	-	-			ı	1
MEDROXYPROGESTERONE	-	1			L.	1
SENNA			-	1	L	1
FLUCLOXACILLIN				2		2
SODIUM PICOSULFATE			-	1	1	1
DICEOFENAC				2		2
FLUNITRAZEPAN	1				1	1
UREA			-	1	•	1
RANITIDINE		1	1		1	-

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PHARMACIA CHS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 18

Concomitant drugs	Before treatment	eatment	During treatment	eatment	Tot	Total
	Fluoxetine	Reboxetine	Fluoxetins	Reboxetine	Fluoxetine	Reboxetine
	No.	No.	М.	No.	No.	No.
ORCIPRENALINE		1				-
AMPICILLIN				1		-
PHENOXYNETHYLPENICILLIN			1		1	
ETHANOL			1		1	
ALLOPURINOL	-				1	
ASCORBIC ACID			1		1	
PETRIDINE				1		-
ERYTHROMYCIN				1		-
HYDROCHLOROTHIAZIDE				1		-
EUGYNON				-		1
HYDROCORTISONE			·		L	
PROPRANOLOL	-				•	
POTASSIUM		1				1
NITRAZEPAH				1		1
HYLANTA				1		1
OXAZEPAM	1				ı	
NORETHISTERONE	1				•	
GENTAMICIN				ı		1
CHLORMEZANONE				,		1
THIAMINE				1		1
CALCIUM GLUCONATE	1				L	
DOCUSATE			1		-	

(CONTINUED)

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	MEDICATION
	ANT DRUGS BY ACTIVE PRINCIPLE: NUMBER OF PATIENTS TAKING AT LEAST ONE CONCOMITANT MEDICATION By ASSIGNED TREATMENT AND INITIAL PERIOD OF ADMINISTRATION
	A CI
	ACTIVE PRINCIPLE: NUMBER OF PATIENTS TAKING AT LEAST ONE CO BY ASSIGNED TREATHENT AND INITIAL PERIOD OF ADMINISTRATION
910	S A
124/	NAXIN 000
REBOXETINE - PROTOCOL 20124/016 TABLE No.: 18	TIENTS 1
8 H	F PA
TAB!	O O
OXETIN	NUMBE MENT A
BEB	CIPLE:
	PRIN
	ASSI
	M AC
	S S
	DRUG
	ANT

Conconitant drugs	Before treatment	eatment	During treatment	eatment	Total	al
•	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine
	No.	No.	No.	No.	No.	No.
GASTROGEL				-		-
BACTRIM			-		-	
ETILEFRINE				-		-
IBUPROFEN				-		1
CEFALEXIN			1		-	
BECLOMETASONE		-				,
LORAZEPAM			•		-	
CALCIUM LACTATE	1				1	
KETOPROFEN		-				
PRAZOSIN				1		ı
NIFEDIPINE				-		-
ASPIRIN PLUS C			1		1	
NETOPROLOL			1		1	
PIPEMIDIC ACID				-		-
CERNILTON	-				1	
DIANE	1				1	
MOLSIDOMINE	ı				1	
MAGNESIUM OXIDE				1		ı
HARVELON			1		1	
ENALAPRIL				-		,
TERFENADINE				1		
EFFORTIL PLUS			-		-	

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PRARMACTA CHS R&D

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

					1		
oncomitant drugs	Before treatment	eatment	During treatment	eatment	Total	al	
	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine	
	No.	No.	No.	No.	No.	No.	
INSEED		-				1	
STEMIZOLE			1		1		
NALGILASA			-		-		
IPROFLOXACIN			-		1		
STROGEN NOS				1		1	
ISOPROLOL	1				1		
INCIGRIP			-		1		
INVASTATIN		1				1	
EBRUNYL				-		1	
OVASTATIN		1				1	

PHAKHACIA CHS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 19

						Visit	út				
		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	18	90	42	69	æ	69
	Kean	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
	Kin	22	16	6	69	61	1	0	0	0	0
	Nax	38	36	39	34	31	27	31	24	25	23
	Mean diff. vs day0 (x)			5.06	9.02	11.77	14.36	17.36	17.32	19.65	19,33
 Reboxetine	No	76	76	76	7.5	73	72	34	99	31	93
	Kean	28.53	28.62	23.97	18.93	15.78	13.69	12.82	10.06	10.06	7.29
	Nedian	27	27	54	20	15	13	12	10	80	S.
	STD	5.20	5,31	5.97	6.44	6,46	6.76	68.89	6.13	6.37	5.51
	Kin	22	22	11	4	67	67	0	0	٥	•
	Kax	64	49	43	34	37	28	27	28	25	25
	Mean diff. vs day0 (x)			49.4	9.73	13.01	15.15	16.29	18.45	19.39	21.51

oan (\*); mean of differ

PHARMACIA CNS RED REBOXETIME - PROTOCOL 20124/016 TABLE No.: 20

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

Factor: ANXIETY/SOMATIZATION

issigned treatment						Visit	it				
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
luoxetine	No	87	87	87	28	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	00.00	00.00	0.00	00.00	0.00	0.00	0.00
	Мах	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
deboxetine	No	76	76	76	75	73	72	*	99	31	59
	Nedian	1.33	1.33	1.17	0.83	0.83	0.67	0.67	0.50	0.50	0.33
	Kin	05.0	05.0	0.33	0.17	0.17	0.17	0.00	0.00	00.0	00.00
	Nax	2.33	2.33	2.00	2.33	2.33	1.63	1.67	1.33	1.50	1.33
	Median diff. vs day9 (*)			0.17	0.50	0.50	0.67	0.67	0.83	0.83	1.00

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PHARMACIA CHS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 20

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

signed treatment						Vis	Visit				
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
uoxetine	Z,	87	87	87	20	20	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
	Hin	0.17	0.17	00.00	00.00	00.00	00.00	0.00	0.00	00.00	0.00
	Hax	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	05.0	0.50	0.50	05.0	0.67
boxetine	No	92	76	76	75	73	72	34	99	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	00.00	0.00	0.00	00.00	0.00	00.0	00.00	00.00
	Маж	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

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 20

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

Assigned treatment						Visit	it				
		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	05.0	0.50
	Min	1.25	1.25	0.50	0.25	0.00	0.00	00.00	00.00	00.0	00.00
	Мах	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	Мо	76	76	76	75	73	72	34	99	31	65
	Median	2.00	2.13	1.75	1.50	1.25	1.00	0.75	0.75	05.0	0.50
	Min	1.00	1.00	1.00	0.25	00.00	00.0	00.00	00.00	00.00	00.0
	Мах	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

ian (\*): median of differences vs day0

PHARHACIA CHS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 20

									:		
Assigned treatment						Visit	it				
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	*8	18	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	00.0	0.00	0.00	0.00	0.00	00.00	0.00	0.00	00.0	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 (*)			00.00	0.33	0.33	0.67	0.67	0.67	0.67	1.00
Reboxetins	No	76	76	76	75	73	72	34	99	31	59
	Median	1.33	1.33	1.33	1.00	0.67	0.67	0.67	0.33	0.67	0.33
	Min	00.00	00.0	00.0	0.00	0.00	0.00	00.0	0.00	00.0	00.0
	Ках	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

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

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

Assigned treatment						Visit	iŧ				
		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	18	80	42	69	*	69
	Kedian	3	3	ю	2	61	-	-	٦	0	٢
	Min	1		0	0	0	0	0	0	0	0
	Мах	4	4	4	4	4	7	ħ	4	m	ĸ
Reboxetine	No	76	76	76	75	73	72	34	99	31	59
	Median	8	8	23	8	1	٢	٢	-	-	-
	Hîn	-		-	0	0	0	0	0	0	٥
	Мах	4	4	4	4	4	8	m	4	4	ю

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 21

SUNMARY STATISTICS ON SCORE

Item: GUILT											
Assigned treatment						Visit	it				
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day
Fluoxetine	No	87	87	87	84	81	80	42	69	34	
	Median	2	2		1	1	1	0	0	0	
	Hin	0		•	0	0	٥	0	0	0	
	Лах	en.	3	ю	8	en	62	-	2	2	
Reboxetine	No	76	76	76	7.5	73	72	34	99	31	
	Median	22	7	N	-	7	٦	0	0	0	
	Min	•	0	0	0	0	0	0	0	C	
	7	۰	•	٠	c		·	c	•	۴	

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PHARMACIA CNS RED REBGXETINE - PROTOCOL 20124/016 TABLE No.: 21 RAMILTON DEPRESSION RATING SCALE: SUMMARY STATISTICS ON SCORE OF EACH ITEN ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment						Visit	rit	!			
		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	745	69	*	69
	Median	-	-	-	a	0	0	0	6	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Hax	9	m	3	N	N	2	6	N	23	٢
Reboxetine	No	76	76	76	75	73	72	34	99	31	59
	Median	1	1	-	-	0	0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Мах	m	3	3	2	10	23	61	1	-	-

115

edian (\*): mean of differences vs day0

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 21 HAMILTON DEPRESSION RATING SCALE; SUMMARY STATISTICS ON SCORE OF EACH ITEN ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Itom: INSOMNIA EARLY

Fluoxetine   No   Rodian   Screen   Rodian   R	Assigned treatment						Visit	üt		. !		!
Fluoxetine         No         87         87         84         81         80         42         69         34           Madian         2         2         1         1         1         1         1         0 <th></th> <th></th> <th>Screen</th> <th>Day 0</th> <th>Day 7</th> <th>Day 14</th> <th>Day 21</th> <th>Day 28</th> <th>Day 35</th> <th>Day 42</th> <th></th> <th>Day 56</th>			Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42		Day 56
Modian         2         2         1         1         1         1         1         1         1         1         1         0 <td>Fluoxetine</td> <td>No</td> <td>87</td> <td>87</td> <td>87</td> <td></td> <td>18</td> <td>80</td> <td>42</td> <td>69</td> <td></td> <td>69</td>	Fluoxetine	No	87	87	87		18	80	42	69		69
Min         0		Median	N	2		1	1	1	-	0	0	0
Reboxetine         No         76		Min	0				0	0	0	0	0	•
Reboxetine         No         76         76         76         76         77         73         72         34         66         31           Modian         2         2         1         1         1         1         1         0         0         0           Min         0         0         0         0         0         0         0         0         0         0         0		Жаж	2	63					63	2		77
Min         2         2         1         1         1         1         1         1         0           Min         0 <td>Reboxetine</td> <td>No</td> <td>76</td> <td>76</td> <td></td> <td></td> <td></td> <td></td> <td>34</td> <td>99</td> <td></td> <td>59</td>	Reboxetine	No	76	76					34	99		59
Min         0		Median	es .	63	-	-	1	-	1	0		0
Мах 2 2 2 2 2 2 2 2 2 2		Hin	0				0		0	0		0
		Мах	7	63					8	И		2

PHARMACIA CNS RBD REBOXETINE - PROTOCOL 20124/016 TABLE No.: 21

Day 49 Day 56 45 Day Day 28 Day 35 HANILION DEPRESSION RATING SCALE: SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATHENT Visit Day 21 4 Day 7 Day Day No Median Min Median Max Item: INSONNIA MIDDLE Assigned treatment Fluoxetine Reboxetine

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No. - 24

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

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	*	81	80	42	69	34	69
	Median	-	-	1	-	-	0	0	0	0	0
	Nin	0	0	0	0	0	0	0	0	0	C
	Маж	2	2	64	61	7	2	2	73	7	2
Reboxetine	No	76	92	76	75	73	72	34	99	31	59
•	Median	01	2	-		1	0	-	0	0	0
	Min	0	0	0	0	0	0	o	0	0	0
	Kax	83	2	2	67	2	22	2	2	23	1

PHANMACIA CNS R&D
REBONETINE - PROTOCOL 20124/016
TABLE No.: 21

SUMMARY STATISTICS ON SCORE

Assigned treatment						Visit	#	į			
		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	90	42	69	*	69
	Kedian	æ	3	67	2	N	-	-	-	***	-
	Hin	-	[	0	8	•	0	0	0	0	0
	Иях	4	d.	4	4	4	4	4	4	4	4
Reboxetine	No	76	76	76	75	73	72	34	99	31	59
	Median	3	8	2	23	2	1	٣	-	٢	۳
	Hin	o	0	-	0	O	0	0	0	0	0
	Жах	*	7	*	4	7	æ	æ	8	4	71

Median (\*): mean of differences vs day0

PHARHACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 21

SUMMARY STATISTICS ON SCORE

Item: RETARDATION											
Assigned treatment						Visit	ţţ				
		Screen	Day 0	Day 7		Day 14 Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	\$8	81	80	42	69	34	69
	Kedian	٢	-	·	-	1	0	0	0	•	0
	Hin	0	0	0	0	0	0	0	0	0	0
	Kax	ĸ	8	£	2	64	01	77	.01	-	61
Rebaxetine	No	76	92	76	7.5	73	72	35	99	31	59
	Hedian	٢	-		-	0	0	0	0	0	0
	Kin	0	0	0	0	0	0	0	0	0	•
	Мах	8	3	2	2	2	63	23	2	-	2

PHARMACIA CNS RRD
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 21

SUNMARY STATISTICS ON SCORE

Item: AGITATION											
Assigned treatment						Visit	it				
		Screen	Day 0	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	0	0	0	0	0	0
	Kin	0	0	0	0	0	0	٥	0	0	0
	Max	8	e	ю	3	4	m	4	2	23	2
Reboxetine	No	76	9,6	76	75	73	72	34	99	31	59
	Median	1	1	۴	1	0	0	0	•	0	0
	Min	0	0	٥	0	0	0	0	0	0	0
	Max	6	6	3	23	3	3	2	23	63	2

dian (\*): mean of differences vs day

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 21

SUMMARY STATISTICS ON SCORE

ICEM: ANALEST PSICHIC											
Assigned treatment						Visit	it				
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	48	81	90	42	69	34	69
	Median	8	2	24	1	-	-	-	1	-	1
	Min	-	-	0	0	0	0	0	0	0	0
	Max	4	4	8	4	æ	8	4	4	3	3
Reboxetine	No	16	76	76	75	73	72	34	99	31	59
	Median	2	2	8	1	-	1	-	-	-	1
	Min	-	1	0	•	0	0	0	0	0	0
	Max	4	4	4	4	4	4	4	9	4	3

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 21

SUMMARY STATISTICS ON SCORE

Assigned treatment						Visit	it.				
		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	45	69	34	69
	Median	22	23	٦	-	1	-	-	1	0	0
	Hin	0	0	0	0	0	•	0	0	0	0
	Kax	4	4	m	3	ю	8	4	01	22	2
Reboxetine	No	76	76	9/	75	73	72	34	99	31	59
	Median	2		N	1	1	-	1	1	1	1
	Min	0	0	•	0	0	0	0	0	0	0
	Жах	60	æ	m	3	3	23	ю	Э	3	21

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PHARMACIA CNS RED TINE - PROTOCOL 20124/016 TABLE No.: 21

HAMILTON DEPRESSION RATING SCALE: SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED 1

KEBUXEIINE - PROTOCUL 2 TABLE No.: 21

Assigned treatment					1	Visit	iŧ				
		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	8	45	69	34	69
	Median	1		-	1		0	0	0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Max	61	2	23	2	7	22	-	-	-	-
Reboxetine	No	76	76	92	75	73	72	34	99	31	59
	Median	7		1	0	0	0	0	0	o	0
	Nin	0	0	0	0	0	0	0	0	0	0
	Hax	63		2 2	63	23	23	23	2	23	-

124

edian (\*): mean of differences vs

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 21

SUMMARY STATISTICS ON SCORE

Ltem: SUMATIC GENERAL											
Assigned treatment						Vi	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	7	-	-	-	-	1	0	-	0	0
	Min	0	0	0	•	0	0	0	0	0	0
	Мах	2	2	2	2	2	2	2	2	2	2
Reboxetine	No	9.2	7,6	76	75	73	72	34	99	31	59
	Median	2	2	-	-	-	-	1	1	٠	٥
	Min	0	0	0	0	0	0	0	0	0	0
	Мах	2	2	2	2	2	2	2	22	8	62

ian (\*); mean of differences vs day0

PHARMACIA CNS RRD REBOXETINE - PROTOCOL 20124/016 TABLE No.: 21

SUMMARY STATISTICS ON SCORE

Item: SOMATIC GENERAL											
Assigned treatment						Visit	it				
		Soreen	Day 0	Day 7	Day 7 Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 5
Fluoxetine	No	87	87	87	20	18	80	4.2	69	34	
	Median	1	1		-	1	1	0	٦	٥	
	Min	0	0	•	0	0	0	0	0	0	
	Маж	2	2	2	2	2	2	23	01	22	
Reboxetine	No	76	76	76	75	73	72	34	99	31	
	Nedian	2	2	-	1	1	٦	٦	1	1	
	Nin	0	0	0	0	0	o		0	0	
	Mark	2	2	2	2	2	2	2	2	2	

edian (\*): mean of differences vs o

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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

Assigned treatment						Visit	1:				*****
		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	18	80	42	69	34	69
	Kedian	-	-	1	~	1	-	-	1	0	0
	Hin	0	•	0	0	0	0	0	0	0	0
	Мах	61	2	2	2	77	61	2	2	8	И
Reboxetine	No	76	76	9/	75	73	72	34	99	31	59
	Median	63	101	1	1	<b>**</b>	-	-	٢	0	0
,	Min	0	0	0	0	0	0	0	0	0	0
	Hax	22	2	2	2	2	61	N	77	2	01

126

ian (\*); mean of differences vs day0

PRARMACIA CHS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 21

HAMILION DEPRESSION RATING SCALE: SUMMARY STATISTICS ON SCORE OF EACH ITCH ACCORDING TO TIME INTERVAL BY ASSIGNED TREATHENT

Assigned treatment						Visit	it					
		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	22	-	-	-	0	0	0	0	0	
	Min	0	0	0	0	0	0		0	0	0	
	Max	4	4	e	m	æ	m	e	2	C)	64	
Reboxetine	No	76	76	92	75	73	72	34	99	31	59	
	Median	2	2	-	-	-	-	٦	0	0	0	
	Nin	•	0	0	0	0	0	0	0	0	0	
	Max	4	4	3	60	E)	m	22	23	3	3	

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PHARMACIA CNS RED

SUMMARY STATISTICS ON SCORE

Item: LOSS OF WEIGHT

Assigned treatment						Visit	it				
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fluoxetine	No	87	87	87	\$8	81	80	42	69	34	69
	Median	0	0	0	0	0	0	0	0	o	0
	Hin	0	0	0	0	0	0	0	0	0	0
	Max	63	73	63	22	2	61	2		-	2
Reboxetine	No	76	76	76	7.5	73	72	34	99	31	59
	Hedian	-	-	0	°	0	0	0	0	0	0
	Hin	0	٥	0	0	•	G.	0	0	0	0
	Max	2	2	12	2	2	63	2	٢	-	23

128

Median (\*); mean of differences vs day0

PHARMACIA CNS R&D
REBDXEIINE - PROTOCOL 20124/016
TABLE No.: 21

SUMMARY STATISTICS ON SCORE

Assigned treatment						Visit	it				
		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	18	80	4.2	69	34	69
	Median	0	o	0	0	0	0	0	0	0	0
	Min	0	0	0	0	0	0	٥	0	0	0
-	Max	1		N	-	1	-	-	1	o	0
Reboxetine	N <sub>D</sub>	76	76	76	75	73	72	34	99	31	59
	Median	0	0	0	0	0	0	0	0	0	0
	n in	0	0	0	0	0	0	0	0	0	0
	Max	-	1	_	-	-	1	0	0	22	0

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PHARMACIA CNS R&D

SUMMARY STATISTICS ON SCORE

Assigned treatment						Vis	Visit				
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Pay 49	Day 56
Fluoxetine	No	87	87	87	84	81	80	42	69	34	69
	Nedian	•	-	٢	-	-	-	0	0	0	•
	Kin	0	0	0	0	0	0	0	0	0	0
	Мах	23	2	2	62	2	2	64	2	2	77
Reboxetine	No	92	76	76	75	73	72	34	99	31	59
	Nedian	1	-		-	-	υ	0	0	0	0
13	Min	0	0	0	•	0	0	0	0	0	0
	Max	2		2 2	2	2	2	87	2	2	

PHARMACIA CNS RRD REBOXETINE - PROTOCOL 20124/016 TABLE No.: 21

	NAMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT	E OF EACH	ITEM ACC	ORDING TO	DARLETUN DEPKESSLUN KATING SCALE: OF EACH ITEM ACCORDING TO TIME INTE	ERVAL BY A	SSIGNED 1	REATHENT			
Item: DEPERSONALIZATION											
Assigned treatment						Visit	i;				
		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	ä
Fluoxetine	No	87	87	87	78	81	80	42	69	34	
	Median	0	0		0	0	0	0	0	0	
	Min	0	0		0	0	0	0	0	0	
	Мах	9	6		3	8	8	77	62	22	
Reboxetine	Мо	76	76	9/	3 75	73	72	34	99	31	
	Median	0	0		0	0	0	0	0	0	
	Min	•	0		0 0	0	0	0	0	0	ĺ
	Kax		"		-	6		6		-	

dian (\*): mean of differences vs day0

PHARHACIA 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	it				
		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	٥	0	٥	0
	Hin	0	0	0	0	0	o	0	0	0	0
	Мах	2	2	2	63	٦	67	-	1	1	7
Reboxetine	No	76	9.6	76	75	73	72	34	99	31	89
	Median	0	0	0	0	0	0		0	0	0
	Min	0	0	0	0	0	0	0	0	0	0
	Маж	2	2	1	2	-	٢	-	٢	-	73

PHARMACIA CNS R&D
REBOXETINE - PROYOCOL 20124/016
TABLE No.: 21

TABLE No.: 21 HAMILTON DEPRESSION RATING SCALE: SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED T

Assigned treatment						Visit	1;				
,		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day S6
fluoxetine	No	87	87	87	84	81	80	45	69	34	69
	Median	0	0	0	0	0	0	0	0	0	0
	Min	O	0	0	0	0	0	0	0	0	0
	Max	23	4	2	2	M	63	6	8	8	2
Reboxetine	No	76	76	76	75	73	72	35	99	31	83
	Median	ı	-	1	1	1	0	0	0	0	0
	Hin	0	0	0	0	0	0	0	0	0	0
	Мах	62	2	22	2	2	2	01	2	77	8

PHARMACIA CNS RRD REBOXETIME - PROTOCOL 20124/016 TABLE No : 22

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

					Last	Last assessment	ŧ			
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	m	2	8	4	s	62		69	87
	Kean	31.33	30.00	25.50	19.50	16.20	12.00		7.77	10.62
	Median	28	30	26	24	4	12		7	60
	STD	99.9	00.0	7.78	9.04	11.52	11.31		5.25	8.66
	Min	27	30	20	9	Ŋ	4		0	0
	Нах	33	30	31	25	31	20		23	39
	Hean diff. vs day0 (*)	00.00	-2.00	2.00	5.00	14.00	17.00		19.33	16.76
Reboxetine	No	-	-	2	ĸ	٢	4	Э	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	S.	7
	STD			10.61	10.27		7.80	8.08	5.51	7.26
	Min	17	24	14	7	16	9	•	0	0
	Мах	17	42	29	24	16	24	25	25	53
	Mean diff. vs day0 (*)	8.00	-1.00	3.50	17.40	12.00	13.00	9.00	21.51	19.22

0.33 0.00

1.33

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REBOXETINE - PROTOCOL 20124/016 TABLE No.: 23 PHARMACIA CNS RED

FACTORIALISATION HAMILTON DEPRESSION RATING SCALE:

Tota1

Day 56

	SUBBARY STATISTICS ON SCORE OF EACH FACTOR AT LAST ASSESSMENT BY ASSIGNED TREATMENT	OF EACH F	ACTOR AT	LAST ASSE	SEMENT BY	ASSIGNED	TREATMEN	-	
actor: ANXIETY/SOMATIZATION	z								
Assigned treatment					Last	Last assessment	nt		i
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	1
Fluoxetine	No	e	2	2	4	S	0		1
	Median	1.33	1.42	1.25	1.08	1.00	0.42		l .
	Min	1.17	1.17	0.67	0.33	0.00	0.17		
	Мах	1.83	1.67	1.83	1,50	1.67	0.67		
	Median diff. vs day0 (*)	00.0	-0.17	0.17	0.00	0.83	0.58		I
Reboxetine	No	-	-	8	5		4	3	L
	Median	1.00	1.00	1.33	0.83	0.67	0.58	1.17	j
	Nin	1.00	1.00	1.00	0.17	0.67	0.17	05.0	L
	Мах	1.00	1.00	1.67	1.33	0.67	1.17	1.50	
	Median diff. vs day0 (*)	0.33	-0.17	-0.08	0.67	0.50	0.33	0.00	L

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 23

FACTORIALISATION MANILTON DEPRESSION RATING SCALE: SUNNARY STATISTICS ON SCORE OF EACH FACTOR AT LAST ASSESSMENT BY ASSIGNED TREAT

	1									
Assigned treatment					Last	Last assessment	nt			
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	6	2	2	4	ις.	2		69	87
	Median	1.33	1.08	0.58	0.42	0.17	0.33		0.17	0.17
	Hin	1.17	0.83	05.0	0.17	00.0	0.17		0.00	00.0
	Мах	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	00.0	0.33	0.67		0.67	0.50
Reboxetine	No	-	1	2	S	1	4	e	59	76
	Median	0.17	0.83	0.58	05.0	0.83	0.17	0.33	0.17	0.17
.,	Min	0.17	0.83	0.17	00'0	0.83	00.0	00.00	00.00	0.00
	Мах	0.17	0.83	1.00	0.67	0.83	0.67	1.00	1.50	1.50
	Mediam diff. vs day0 (*)	0.17	00.0	05.0	05.0	0.17	0.33	05.0	0.67	0.67

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 23

TABLE No.: 23
FACTORIALISATION HAMILTON DEPRESSION RATING SCALE:
SUMMARY STATISTICS ON SCORE OF EACH FACTOR AT LAST ASSESSMENT BY ASSIGNED TREATHENT

Factor: RETARDATION										
Assigned treatment					Last	Last assessment	nt			
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	ю	2	2	4	S	73		69	87
	Median	2.00	2.13	2.90	2.00	1.25	1.25		0.50	0.50
	Min	2.00	2.00	1.75	0,50	00.0	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 (*)	00.0	0.00	0.13	0.25	1.00	1.25		1.50	1.50
Reboxetine	No	-	-	2	Ŋ	1	4	8	59	76
	Median	1.50	1.75	1.25	1.50	1,25	1.00	1.25	0.50	0.50
	Hin	1.50	1.75	1.00	00.0	1.25	05.0	0.50	0.00	0.00
	Мах	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	00.0	1.75	1.50

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
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FACTORIALISATION HAMILTON DEPRESSION RATING SCALE: SUMMARY STATISTICS ON SCORE OF EACH FACTOR AT LAST ASSESSMENT BY ASSIGNED TREATHENT

Assigned treatment					Last	Last assessment	nt			
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	2	4	Z.	77		69	87
	Median	1.67	1.50	1.83	1.00	1.00	0.67		0.33	0.33
	Hin	1.00	1.33	1,67	00.00	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	73	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	1,60	1.67	0.67	00.0	00.00	0.33	0.33	00.00	00.0
	Мах	1.00	1.67	1.33	1.67	00.00	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

PHARHACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
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HAMILTON DEPRESSION RATING SCALE: SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Leall, Merkessen noon										
Assigned treatment					Last	Last assessment	ıt			
		Day 7	Day 14 Day 21		Day 28	Day 35	Day 42	Day 49	Day 49 Day 56	Total
Fluoxotine	No	æ	2	2	4	r)	67		69	87
	Hedian	33	m	4	m	-	2		-	-
	Kin	3	6	ю	1	0	0		0	0
	Ках	ধ	6	7	e	4	8		m	4
Reboxetine	No	,	-	23	S	-	4	3	59	76
	Kedian	20	8	N	2	2	-	. 2	٦	-
	Min	71	8	1	0	7	-	1	0	0
	Max	2	8	22	e	2	m	4	m	4

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 24

	TREATHENT	
	ASSIGNED	
	B	
	HAMILTON DEPRESSION RATING SCALE: ORE OF EACH ITEM AT LAST ASSESSMENT	
7	RATIN LAST	
9	AT	
TABLE No.: 24	RESSI	
2	EV DE	
	6. 9.	
	BCORE	
	š	
	HAMILTON DEPRESSION RATING SCALE: SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT	
	SUMMARY	

Assigned treatment					Last	Last assessment	it.			
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	ĸ	2	67	4	ĸ	22		69	87
	Hedian	61	2	N	-	0	-		0	0
	Nin	62	-	-	0	•	0		0	0
	Мах	9	2	2	0	1	-		63	m
Reboxetine	To.	1	1	2	S	-	4	et	59	76
	Hedian	0	co.		0	2	0	-	0	0
	Hin	0	ea	0	0	63	o	0	0	0
	Жах	۰	2	67	-	2	62	2	2	7

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 24 HAMILION DEPRESSION RATING SCALE: ARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESNENT BY ASSIGNED TREATMENT

rem: bolcine										
Assigned treatment					Last	Last assessment	nt			
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	6	2	2	4	æ	2		69	87
	Median	20	2	0	•	0	-		0	0
	Hin	N	-	0	0	O	0		0	0
	Мах	m	2	0	-	m	63		1	w
Reboxetine	No	-	-	23	S	-	4	æ	59	76
	Median	-	2	0	0	-	0	1	0	0
	Min	1	2	0	0	٦	0	0	0	0
	Max	-	2	0	2	٦	1	-	1	2

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/016
TARIE No.: 24

HAMILTON DEPRESSION RATING SCALE: SUNHARY STATISTICS ON SCORE OF EACH TIEM AT LAST ASSESSMENT BY ASSIGNED TREATM

Assigned treatment					Last	Last assessment	ıt				
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	[otal	
luoxetine	No	m	22	2	4		62		69	87	
	Median	7	63	2	N	-	-		0	0	
	Hin	0	63	2	0	-	-		0	0	
	Мах	23	63	61	2	N	-		63	2	
Reboxetine	No	-	-	C)	S	-	4	8	59	76	
	Median	0	-	1	2	0	+	63	0	0	
	Min	0	-	1	0	0	0	0	0	•	
	Max	0	-	۳	2	0	2	2	2	22	

Median (\*): mean of differe

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 24

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

Item: INSOMNIA MIDDLE										
Assigned treatment					Last	Last assessment	ııt			
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 35 Day 42 Day 49	Day 49	Day 56	Total
Fluoxetine	No	3	77	2	4	r)	2		69	87
	Nedian	2	2	2	•	1	-			0
	Min		1	2	•	0	0		0	0
	Nax	2	2	2	٦	2	-		2	8
Reboxetine	No		-	2	r.	1	7	3	59	76
	Median	•	2	1	-	0		٢	0	0
	Min		2	0	0	O	0	1	0	0
	Мах	L	N	2	23	0	2	1	7	2

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in (\*): mean of differences vs day0

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

Total Day 56 64 Day HAMILTON DEPRESSION RATING SCALE: SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATHENT Day 42 Last assessment Day 35 82 Day Day 21 Day 14 Day Median No Median Min Min Max Item: INSOMNIA LATE Assigned treatment

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PRARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 24

	HAMILTON DEPRESSION RATING SCALE: SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT	CLTON DER	HAMILTON DEPRESSION RATING SCALE: ORE OF EACH ITEM AT LAST ASSESSMEN	RATING SCA	ALE: SSMENT BY	ASSIGNED	TREATHENT			
Item: WORK AND ACTIVITIES										
Assigned treatment					Last	Last assessment	mt			
		Day 7	Day 14	Day 21	Day 28	Bay 35	Day 42	Day 49	Day 56	P
Fluoxetine	ON.	3	N	2	4	5	83		69	1
	Median	64	3	8	3	1	23		1	
	Min	63	27	2	0	0	-		0	1
	Max	3	e	4	E	en .	E		4	
Reboxetine	No	1	-	2	¥0	ęm	4	3	59	ł
	Median	1	2	3	2	2	82	2	-	
	Min	-	21	2	°	2	1	1	0	
	Max	-	23	3	3	2	60	4	2	

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PHARMACIA CNS R&D
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TABLE No : 24

Item: RETARDATION

Assigned treatment					Last	Last assessment	it.			
		Day 7	Day 7 Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No.	3	2	N	4	S	2		69	8.7
	Nedian	-	2	-	2	٢	-		0	0
	Nin	0	-	0	0	0	o		0	0
	Мах	2	2	-	23	2	-		2	2
Reboxetine	No	-	-	62	70	-	4	3	59	76
	Median	-	1	0	0	-	1	0	0	0
	Hin	1	1	0	0	-	0	0	0	0
	Мах	-	*	0	1	-	8	0	2	63

146

lian (\*): mean of differences vs days

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PHARMACIA CNS R&D
REBUXETINE - PROTOCOL 20124/016
TABLE No.: 24

	MANITON DEPRESSION RATING SCALE: SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT	ILTON DE OF EACH	BAMILTON DEPRESSION RATING SCALE: ORE OF EACH ITEN AT LAST ASSESSMEI	ATING SCA	LE: SMENT BY	ASSIGNED	TREATHENT			
tem: AGITATION										
Assigned treatment					Last	Last assessment	ut			
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	NO.	3	8	2	7	5	63		69	
	Median	-	В	1		٢	0		0	
	Kin	-	63	1	0	0	0		0	
	Max	8	9	1	N	m	0		71	
Reboxetine	No	-	1	2	£,	1	4	6	89	
	Median	•	1	2	۲.	23	-	0	0	
	Min	•	1	1	0	67	0	0	0	
	×	-	•	٠	,	•		-	6	

fedian (\*): mean of differences vs day0

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 24

PHARMACIA CNS RED

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

TOUR THUTTIN LOTONTO											
Assigned treatment					Last	Last assessment	at				
		Day 7	Day 7 Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total	
Fluoxetine	No	8	2	2	4	ιή	67		69	87	
	Median	m	3	2	•	-	-		1	1	
	Hin	2	2	-	-	0	-		0	0	
	Max	m	м	ю	23	4	-		8	4	
Reboxetine	ON	٢	-	2	S.	+	4	3	59	76	
	Median	-	2	2	-	1	-	2	-	,	
	Hin	-	62	-	0	1	0	2	0	0	
	Kax	-	62	62	72	٢	N	83	£	e	

edian (\*): mean of differences vs day0

PHARMACIA CKS RED REBOXETINE - PROTOCOL 20124/016 TABLE No : 24

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

Assigned treatment					Last	Last assessment	nt			
		Day 7	Day 7 Day 14 Day 21	Day 21	Day 28	Day 35	Day 42	Day 49	Day 42 Day 49 Day 56	Total
Fluoxatine	No	8	2	7	4	5	2		69	87
	Median	2	e	1	1	0	1		O	•
	Min	-	2	0	1	0	0		0	0
	Мах	2	8	2	23	4	2		8	4
Reboxetine	No	-	1	2	5	1	4	et .	59	76
	Median	-	1	2	1	1	1	1	1	٢
	Min	1	1	23	1	1	0	-	0	0
	Max	-	-	2	23	1	-	3	62	60

dian (\*): mean of differences vs day

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PHARMACIA CNS RBD REBOXETINE - PROTOCOL 20124/016 TABLE No.: 24

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

Treat Poliulic enginerality	700									
Assigned treatment					Last	Last assessment	ınt			
		Day 7	Day 7 Day 14 Day 21	Day 21	Day 28	Day 35	Day 42 Day 49	Day 49	Day 56	Total
Fluoxetine	No	m	2	2	7	Ŋ	2		69	87
	Median	8	1	1	-	0	0		0	
	Min	2	1	0	G	0	•		0	-
	Мах	2	-	1	1	1	0	:	1	63
Rebaxetine	No	1	-	2	r.	-	4	3	65	32
	Nedian	2	-	1	1	0	0	•	0	0
	Nin	23	-	1	0	0	0	0	0	0
	Nax	22	Ţ-	1	1	0	-	N	-	62

**15**0

ian (\*): mean of differences vs day0

PHARMACIA CMS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 24 HAMILTON DEPRESSION RATING SCALE: SUMMARY STATISTICS ON SCORE OF EACH ITEN AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: SOMATIC GENERAL										
Assigned treatment					Last	Last assessment	nt			
		Day 7	Day 14		Day 21 Day 28	Day 35	Day 42	Day 42 Day 49	Day 56	Total
Fluoxetine	No	3	2	2	#	S	N		69	87
	Median	2	-	63	1	0	-		0	-
	Hin	1	1	-	0	0	0		٥	0
	Max	2	-	2	67	77	1		2	63
Reboxetine	No	-	٣	2	S)	1	4	ю	59	76
	Median	2	2	1	-	1	1	2	0	1
	Min	2	2	-	0	•	0	0	0	0
	Мах	23	63	-	23	-	63	23	23	2

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 24

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

Item: GENITAL SYMPTOMS										
Assigned treatment					Last	Last assessment	nt			
		Day 7	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
	Nedian	1	2	-	-	0	٠		0	0
	Min	1	7	0	0	0	0		0	c
	Max	2	2	2	23	61	N		23	23
Reboxetine	No	1	1	2		1	4	69	59	76
	Median	2	-	-	۳	0	-	-	0	-
	Min	2	-	1	0	0	0	0	0	0
	Мах	2	-	1	2	0	2	2	23	2

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 T&BLE No.: 24

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

Assigned treatment					Last	Last assessment	ant			
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No.	ю	8	8	7	ut)	2		69	87
	Median	0	2	m	2	-	0		0	0
	Hin	0	0	63	0	0	0		0	
	Мах	1	8	m	ĸ	£	0		73	æ
Reboxetine	No	1	1	2	S	1	4	9	59	76
	Median	0	0	23	-	-	1	0	0	0
	Min	0	0	1	0	1	0	0	0	0
	Мах	0	0	3	81	1	23	-	8	e

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 24

Assigned treatment					Last	Last assessment	ant			
		Day 7	Day 7 Day 14	Day 21	Day 28	Day 35	Day 42	94 deq	Day 56	Total
Fluoxetine	No	m	2	61	4	T.	8		69	87
	Median	-	2	0	0	0	0		0	0
	Min	0	-	0	0	0	0		0	o
	Мах	63	22	0	0	2	0		2	N
Reboxetine	No	٦	-	7	c)	-	4	3	59	76
	Nedian	0	0	-	0	-	0	0	0	0
	Nin	0	0	0	0	7	0	0	0	0
	Маж	0	0	63	2	~	0	0	2	7

PHARMACIA CNS RRD REBOXETINE - PROIOCOL 20124/016 TABLE No.: 24

	TREATHENT
	ASSIGNED
	젊
HAMILTON DEPRESSION RATING SCALE:	S ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED T
RATI	LAST
š	¥
RESSI	ITEM
医医	EACH
5	冶
HAH	SCORE
	Š
	SUMMARY STATISTICS O
	SUMMARY

Item: INSIGET										
Assigned treatment				į	Last	Last assessment	nt			
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	ю	2	23	4	5	8		69	87
	Median	0	0	0	0	0	o		0	0
	Hin	o	0	0	0	0	0		0	•
	Нах	-	0	0	1	0	0		0	-
Reboxetine	No	-	•	2	S.	1	4	m	59	76
	Median	0	0	-	0	0	0	0		0
	Min	0	0	0	0	0	۰	0	-	0
	Kax	0	0	-	٢	•	0	0	-	-

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PHARMACIA CHS R&D
REBOXETINE - PROTOCOL 20124/016

	SNED TREATMENT
	ASSIC
	87
G SCALE:	ASSESSMENT
ILTON DEPRESSION RATING	LAST
ĕ	¥
RESSIG	ITER
N DEP	EACH
믑	Ä
HAM	SCORE
	õ
	SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TH
	SUMMARY

Item: DIURNAL VARIATION

Assigned treatment					Last	Last assessment	nt			
		Day 7	Day 7 Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	w	2	2	4	5	83		69	87
	Median	0	-	1	1	0	-		0	٥
	Hin	0	•	1	•	0	0		0	0
	Kax	2	-	1	61	-	-		2	2
Reboxetine	No	-	-	8	5	-	4	tf	59	76
	Median	-	-	-	-	F	0	0	0	0
	Min	٠	-	-	o	٦	0	0	•	0
	Kax	-	-		2	-	0	-	٢	2

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an (x): mean of differences vs day6

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PHARMACIA CNS RED

HANILTON DEPRESSION RATING SCALE: SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATHENT REBOXETINE - PROTOCOL 20124/016 TABLE No.: 24

Assigned treatment					Last	Last assessment	int			
		Day 7	Day 7 Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 49 Day 56	Total
Fluoxetine	No		3 2	8	4	ı,	2		69	87
	Median		-	0	-	0	-		0	
	Min		0	0	0	0	٥		0	•
	Max		3	0	-	0	-		•	e
Reboxetine	No		-	2	r.	٦	ħ	8	59	76
	Median		0	-	0	0	0	0	0	0
	Nin		0	0	0	0	0	0	0	0
	Мах		0	-	0	0	0	0	84	N

PHARNACIA CNS R&D REBOXETINE - PROTDCOL 20124/016 TABLE No.: 24

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

Assigned treatment					Last	Last assessment	ŧ				
		Day 7	Day 7 Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	Total	
Fluoxetine	No	8	63	2	4	r.	22		69	87	
	Median	a	-	0	0	G	-		0	O	
	Nin	0	0	0	0	•	0		0	0	
	Мах	-	-	0	0	0	0	,	-	1	
Reboxetine	No	1	٢	N	S	-	4	8	59	76	
	Median	0	0	0	0	0	0'	0	0	0	
	Nin	0	0	0	0	0	0	0	0	0	
	Мах	0	0	0	0	0	0	0	2	7	

edian (\*): mean of differences v

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 24

Total Day 56 Day 49 HANILTON DEPRESSION RATING SCALE: SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT Day 42 Last assessment Day 28 Day 35 Day 21 Day 14 Day Median Hin Kax Min Max Item: OBSESSIONAL/COMPULSIVE Assigned treatment

Median (\*): mean of differences vs day0

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

## PHARMACIA CN25450083

## 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 treat	ment	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
	952 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
TARIE No.: 24

EFFICACY: CLASSIFICATION OF PATIENTS ACCORDING TO PROTOCOL CRITERIA ON TOTAL SCORE OF HAMILTON DEPRESSION RATING SCALE At last assessment versus day o by assigned treatment

	Assigned treatment	reatment
	Fluoxetine	Reboxetine
Patients No.	87	76
Responders No.	49	59
Responders X	73.6	77.6
95x L.L.	63.0	9,99
95% U.L.	82.4	4.98
Remissions No.	85	51
Remissions X	66.7	67.1
95% L.L.	55.7	55.4
95z U.L.	76.4	77.5

BETHEEN TREATMENT DIFFERENCE AND 95% CONFIDENCE LIMITS

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

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PHARMACIA CNS R&D

CLINICAL GLOBAL IMPRESSION: SEVERITY OF ILLINESS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATHENT

Assigned treatment/Severity of	rity of illness									Visit	±,								
		Day	0	Day	7	Day 14	4	Day 2	21	Day 2	28	Day 35	35	Day 42	42	Day 49	64	Day	56
		£	×	ę	×	No	×	S.	н	- R	×	No.	м	No.	×	S.	ж	Ş.	×
Fluoxetine	NORMAL			-				61	2.5	00	10.0	æ	18.6	2	14.5	6	26.5	18	26.1
	BORDERLINE HENTALLY ILL			-	1.7	r)	6.0	12	14.8	16	20.0	7	16.3	23	33.3	11	32.4	27	39.1
	MICDLY ILL	-	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
	HODERATELY ILL	20	23.0	27	31.0	25	8.62	82	22.2	15	18.8	7	16.3	19	27.5	S	14.7	80	11.6
	MARKEDLY ILL	39	44.8	35	40.2	25	8.62	22	27.2	16	20.0	ιŋ	11.6	S.	7.2	2	5.9	ю	4.3
1	SEVERELY ILL	27	31.0	1	12.6	9	7.1	ις	6.2	27	2.5								
. 6 ;	EXTREMELY ILL			-	1.1							-	2.3						
2	Total	87	100.0	87	100.0	84.1	100.0	81	100.0	8	100.0	43	100.0	69	100.0	34	100,0	69	100.0
Reboxetine	NORMAL							-	4.6	4	5.6	N	5.7	7	10.6	64	6.3	13	22.0
	BORDERLINE NENTALLY ILL							9	8.2	15	20.8	6	25.7	24	36.4	15	46.9	28	47.5
	MILDLY ILL			'n	6.5	11	22.7	23	31.5	19	26.4	12	34.3	85	27.3	2	31.3	15	25.4
	NODERATELY ILL	22	28.6	32	41.6	₹.	45.3	27	37.0	22	30.6	9	17.1	13	19.7	-	3.1	٦	1.7
	MARKEDLY ILL	36	46.8	30	39.0	45	25.3	15	20.5	12	16.7	9	17.1	4	6.1	4	12.5	2	3.4
	SEVERELY ILL	17	22.1	6	11.7	r.	6.7	-	4.1										
	EXTRENELY ILL	8	2.6	-	1.3														
	Total	77	77 100.0	77	77 100.0	75	75 100.0	73	73 100.0	72	72 100.0	35	35 100.0	99	66 100.D	32	32 100.0	59	59 100.0

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 28

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

Assigned treatment/Severity of illness	erity of illness										Last Visit	sit							
		Total	la la	Day	7	Day 14	14	Day	2.1	Day	28	Day 35	35	Day 42	745	Day 49	49	Day	26
		£	×	o <sub>N</sub>	м	No	×	o N	×	No.	×	ON.	×	ě	×	No	×	ž	×
Fluoxetine	NORMAL	50	23.0									82	33.3					18	26.1
	BORDERLINE MENTALLY ILL	53	33.3							-	33.3			-	50.0			27	39.1
	MILDLY ILL	4	16.1									٦	16.7					13	18.8
	MODERATELY ILL	9	11.5					-	50.0					-	50.0			8	11.6
	MARKEDLY ILL	12	13.8	N	66.7	N	2 100.0	-	50.0	8	66.7	83	33.3					6	4.3
16	EXTREMELY ILL	61	2.3	-	33.3							-	16.7						
3	Total	87	87 100.0	ю	3 100.0	N	2 100.0	23	2 100.0	ю	3 100.0	9	6 100.0	N	2 100.D			69	100.0
Reboxetine	NORMAL	4	18.2							٢	25.0							13	22.0
	BORDERLINE MENTALLY ILL	33	40.3											2	66.7	-	25.0	28	47.5
	MILDLY ILL	18	23.4					-	50.0	1	25.0	-	50.0					15	25.4
	MODERATELY ILL	80	10.4	8	100.0	-	1 100.0	-	50.0	61	50.0			-	33.3			1	1.7
	MARKEDLY ILL	9	7.8									-	50.0			e	75.0	2	3.4
	Total	77	77 100.0	8	2 100.0	-	1 100.0	61	2 100.0	4	4 100.0	77	2 100.0	m	3 100,0		4 100.0		59 100.0
											1								

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	ift severity										Last visit	risit				i			
		Total	-F	Day 7	7	Day 14	75	Day 21	21	Day 28	28	Day 35	35	Day 42	42	Day 49	64	Day 56	26
		o <sub>N</sub>	×	No.	×	č.	×	S.	×	80	×	S.	×	£	и	ç	×	2	×
Fluoxetine	DECREASED	78	89.7	8	66.7			-	50.0	1	33.3	5	83.3	61	2 100.0			67	97.1
	NO CHANGE	9	6.9			61	2 100.0			67	66.7							63	2.9
	INCREASED	m	9.E	-	33.3			-	50.0			7	1 16.7						
	Total	87	87 100.0	m	3 100.0	61	2 100.0	N	2 100.0	3	3 100.0		6 100.0	23	2 100.0			69	69 100.0
Reboxetine	DECREASED	62	87.0					-	50.0	m	3 75.0	٦	50.0	7	66.7	73	50.0	58	98.3
	NO CHANGE	6	11.7	73	2 100.0	-	1 100.0	-	50.0	-	25.0	-	50.0	-	33,3	23	50.0		
	INCREASED	-	1.3															-	1.7
	Total	77	77 100.0	2	2 100.0	1	1 100.0	N	2 100.0		4 100.0		2 100.0		3 100.0		4 100.0	59	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	Assigned treatment/Global improvement								Visit	بد							
		Day	7	Day	14	Day	2.1	Day 2	28	Day 35	٠ <u>.                                    </u>	Day 42	27	Day	64	Рау	26
		ş	×	£	*	£	×	2	×	2	×	- R	×	No	и	ş	×
Fluoxetine	VERY MUCH INPROVED	۳	1.1	22	4.2	60	6.6	16	20.0	12	27.9	22	31.9	4	41.2	35	50.7
	MUCH IMPROVED	12	13.8	24	28.6	59	35.8	35	43.8	16	37.2	¥	49.3	4	41.2	27	39.1
	MINIMALLY IMPROVED	26	29.9	33	39.3	2	38.3	g	28.7	12	27.9	12	17.4	'n	14.7	c,	7.2
	NO CHANGE	43	49.4	19	22.6	6	11.1	r.	6.3			-	4.			23	2.9
	MINIMALLY WORSE	4	4.6	9	7.1	4	4.9			-	2.3			-	2.9		
	NUCH WORSE	٢	1.1					-	1.2	-	2.3						
	VERY MUCH NORSE									-	2.3						
	Total	87	100.0	\$	100.0	2	100.0	80	100.0	43	100.0	69	100.0	\$	100.0	69	100.0
Reboxetine	VERY MUCH IMPROVED					4	5.5	4	19.4	7	20.0	22	33.3	v	18.8	30	50.8
	MUCH IMPROVED	7	9.1	24	32.0	33	45.2	27	37.5	6	25.7	31	47.0	19	59.4	24	40.7
	MINIMALLY IMPROVED	28	36.4	35	46.7	56	35.6	23	31.9	4	40.0	6	13.6	77	6.3	3	5.1
	NO CHANGE	37	48.1	4	18.7	9	8.2	9	8. E.	83	5.7	82	3.0	4	12.5		
	MINIMALLY WORSE	S	6.5	2	2.7	4	5.5	77	2.8	2	5.7	2	3.0	-	3.1	67	3.4
	MUCH WORSE									-	2.9						
	Total	77	77 100.0	75	75 100.0	E.	73 100.0	72	72 100.0	35	35 100.0	99	0.001 99	32	32 100.0	59	59 100.0
		1		1	1			1			-	1	_	-			_

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 31

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

Total																	
	ta1	Day	7	Day 14	14	Day 21	2.1	Day	28	Day	ક્ષ	Day 42	45	Day 49	64	Day	56
S.	н	S.	×	No.	×	Š	н	20	н	£	к	S.	ж	S.	*	Š	×
37	42.5									2	33.3					35	50.7
29	33.3									-	16.7	-	50.0			27	39.1
7	8.0					-	50.0	-	33.3							5	7.2
7	8.0	-	33.3	-	50.0			8	66.7			-	50.0			63	2.9
4	4.6	-	33.3	-	50.0	-	50.0			-	16.7						
2	2.3	-	33.3							-	16.7						
1	1.1									-	16.7						
87	100.0	9	100.0	64	100.0	67	100.0	3	100.0	9	100.0	82	100.0			69	0.001 69
32								-	25.0			-	33.3			8	50.8
28	I					-	50.0	-	25.0			-	33.3	-	25.0	24	40.7
7	9.1	1	50.0							81	100.0			-	25.0	m	5.1
S		1	50.0	-	100.0			-	25.0					2			
S						-	50.0	-	25.0			1	33.3			81	3.4
77	100.0	N	100.0	-	100.0	2	100.0	4	100.0	2	100.0	w	100.0		100.0	59	59 100.0
	83 32 32 32 32 32 32 32 32 32 32 32 32 32	5 2 6 5	1.1 1.1 1.0 1.0 1.0 1.0 1.0 1.0 1.0 1.0	1.1 1.1 1.0 1.0 1.0 1.0 1.0 1.0 1.0 1.0	1.1 10.0 41.6 36.4 9.1 1 50.0 6.5 1 50.0 100.0 2 100.0	1.1 1.1 1.0 1.0 1.0 1.0 1.0 1.0 1.0 1.0	1.1 100.0 3 100.0 2 100.0 41.6 36.4 9.1 1 50.0 6.5 1 50.0 1 100.0	1.1 100.0 3 100.0 2 100.0 2 41.6 36.4 9.1 1 50.0 1 100.0 6.5 1 50.0 1 100.0 1	1.1 100.0 41.6 36.4 9.1 1 50.0 6.5 1 50.0 1 100.0 1 100.0 1 100.0 1 100.0 1 100.0	1.1 100.0 41.6 36.4 9.1 1 50.0 6.5 1 50.0 1 100.0 1 50.0 1 100.0 1 50.0 1 100.0 1 50.0 1 100.0 1 50.0 1 4.6 6.5 1 100.0 1 100.0	1.1       10.0       41.6       3 100.0       2 100.0       3 100.0       3 100.0       3 100.0       3 100.0       3 100.0       3 100.0       41.6       3 100.0       41.6       50.0       41.6       6.5       1 50.0       2 100.0       4 100.0	1.1 100.0 41.6 41.6 36.4 9.1 1 50.0 1 50.0 1 25.0 1 25.0 2 1 25.0 2 1 25.0 2 1 25.0 2 1 25.0	1.1         1.1 <td>  1.1</td> <td>1.1         1.1         1.6.7         1.0.0         1.0.0         1.0.0         1.0.0         2.100.0         2.100.0         2.100.0         2.100.0         2.100.0         2.100.0         2.100.0         2.100.0         3.3.3         1.33.3</td> <td>  1.1</td> <td>1.1         1.16.7         1.16.7           100.0         3.100.0         3.100.0         6.100.0         2.100.0           44.6         1.26.0         1.26.0         1.33.3         1.25.0           9.1         1.50.0         1.26.0         1.33.3         1.25.0           6.5         1.50.0         1.100.0         1.25.0         1.25.0           1.00.0         2.100.0         3.100.0         4.100.0         2.100.0</td>	1.1	1.1         1.1         1.6.7         1.0.0         1.0.0         1.0.0         1.0.0         2.100.0         2.100.0         2.100.0         2.100.0         2.100.0         2.100.0         2.100.0         2.100.0         3.3.3         1.33.3	1.1	1.1         1.16.7         1.16.7           100.0         3.100.0         3.100.0         6.100.0         2.100.0           44.6         1.26.0         1.26.0         1.33.3         1.25.0           9.1         1.50.0         1.26.0         1.33.3         1.25.0           6.5         1.50.0         1.100.0         1.25.0         1.25.0           1.00.0         2.100.0         3.100.0         4.100.0         2.100.0

PHARMACIA CMS R&D LINE - PROTOCOL 20124/016 TABLE No.: 32

CLINICAL GLOBAL IMPRESSION: EFFICACY INDEX
CREDING TO THE INTERNAL BY ASSIGNED PREATMENT

Assigned treatment	treatment /	Day	7	Day	14	Day	21	Day	28	Day	35	Day	42	Day	64	Day	56
		ě	×	₽	×	2	ж	£	к	ş	ж	£	×	£	×	£	*
Fluoxetine	< 1	20	23.0	15	17.9	6	11.1	8	3.8	2	4.7	71	2.9	-	2.9	63	2.9
	-	\$	39.1	22	26.2	17	21.0	2	12.5	9	4,0	7	6.2	-	2.9	-	1.4
	1.33 - 1.5	7	8.0	∞ .	9.5	ω.	9.6	4 .	17.5	-C	11.6	Ξ	15.9	e	8.8	·s	7.2
	2	17	19.5	22	26.2	21	25.9	24	30.0	41	32.6	22	31.9	12	35.3	16	23.2
	e	7	0.8	15	17.9	21	25.9	2	22.5	2	23.3	19	27.5	•0	23.5	15	21.7
	4	67	2.3	62	2.4	S	6.2	7	13.8	•	0.41	13	18.8	6	9 26.5	30	43.5
	Total	87	100	84	100	18	100	8	100	43	100	69	9	34	92	69	100
Reboxetine	د ۱	53	37.7	6	12.0	7	9.6	7	9.7	2	14.3	4	6.1	4	12.5	-	1.7
	-	24	31.2	25	33.3	19	26.0	13	18.1	7	20.0	9	9.1	6	9.4	m	5.
	1.33 - 1.5	c	6.5	16	21.3	14	19.2	10	13.9	en.	9.6	13	19.7	7	21.9	9	16.9
	2	16	20.8	44	18.7	55	17.8	44	19.4	7	20.0	Ξ	16.7	60	4.6	11	18.6
	89	m	3.9	11	14.7	18	24.7	75	19.4	80	22.9	٤	16.7	2	15.6	5	8.5
	ď					61	2.7	*	19.4	S	14.3	2	31.8	10	31.3	29	49.2
	Total	77	100	75	100	73	100	72	100	35	100	99	100	32	100	59	9

[CACY INDEX (\*): computed from the vector activity by the vector side effects

Assigned treatment	tment /		-	1						2	Last Assessment	333706	4						
EIIICACY INGOX (*)	( ) X	total	ığ.	Day	2	Day	4	Day	21	Day 28	28	Day	35	Day	42	Day	64	Day	56
		No	×	Š.	×	Ş.	3€	Š.	×	Νo	×	o X	×	£	м	£	м	ů.	н
Fluoxetins	< 1	10	11.49	2	2 66.67	-	50.00	-	1 50.00	-	33.33	2	33.33	-	50.00			2	2.90
	•	7	8.05	-	1 33.33	-	50.00	٢	1 50.00	-	1 33.33	61	33.33					-	1.45
	1,33 - 1.5	7	8.05							<b>**</b>	1 33.33	-	1 16.67					S	7.25
	2	17	17 19.54												20.00			19	23.19
	m	15	15 17.24															15	21.74
	4	31	31 35.63					-				۳	1 16.67					30	43.48
	Total	87	0.001 78	m	3 100.D	2	100.0	61	100.0	en en	100.0	9	6 100.0	23	2 100.0			69	100.0
Reboxetine		<b>«C</b>	8 10,39	U1	2 100.0					73	50.00			-	1 33.33	22	50,00	-	1.69
	1	80	8 10.39			-	1 100.0	-	1 50.00			-	1 50.00	-	1 33.33	٦	1 25.00	6	5.08
	1.33 - 1.5	12	15.58					-	1 50.00							٦	25.00	9	16.95
	2	4	18.18							-	25.00	-	50.00	٦	1 33.33			11	18.64
	8	S	6.49															5	8.47
	4	8	38.96							-	25.00							29	49.15
	Total	77	77 100.0	2	2 100.0	-	1 100.0	N	2 100.0	4	4 100.0	2	2 100.0	3	3 100.0		4 100.0	59	100.0

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 34

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

Assigned treatment						Visit				
		Day 0	0 Day 7	7 Day 14	14 Day 21	Day 28	28 Day 35	35 Day 42 Day	Day 49	49 Day 56
Fluoxetine	No	87	87	94	81	80	42	69	34	69
	Mean	16.2	13.6	11.3	9.4	7.7	9.9	5.9	5.2	4.3
	Median	16.0	13.5	12.0	9.0	7.5	9.0	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
	Маж	22.0	23.0	22.0	20.0	20.0	20.0	16.0	16.0	16.0
	Mean diff, vs day0 (*)		2.63	48.4	6.78	8.50	9.85	10.18	10.96	11.68
Reboxetine	No.	76	76	7.5	73	72	34	99	31	59
	Nean	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	6.9	5.0	3.0
	STD	3.3	4.2	3.8	3.8	4.5	4.4	3.9	4.5	3.3
	Kin	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

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PHARMACIA CNS R&D

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

Assigned treatment						Visit				
		Вау 0	0 Day 7	7 Day 14 Day 21 Day 28 Day 35 Day	Day 21	Day 28	Day 35	Day 42	42 Day 49 Day	Day 56
Fluoxetine	No.	87	87	\$	81	80	45	69	¥	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
	Мах	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	2.0
Reboxetine	No	76	76	7.5	73	72	*	99	31	59
	Median	2.0	2.0	1.5	1.0	1.0	1.0	1.0	0.0	0.0
	Kin	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Мах	3.0	3.0	3.0	3.0	3.0	3.0	2.0	2.0	2.0

PHARMACIA CMS R&D REBOXETINE - PROTOCOL 20124/016 TABLE NO.: 35

												Γ
Assigned treatment						Visit						
		Day 0	0 Day 7	7 Day 14 Day 21 Day 28 Day 35 Day	Day 21	Day 28	Day 3	5 Day	45	42 Day 49 Day	Day	26
Fluoxetine	No.	87	87	84	81	8	4.2	N .	69	34		69
	Median	2.0	2.0	1.5	1.0	1.0	1.0		1.0	1.0		1.0
	Hin	0.0	0.0	0.0	0.0	0.0	0.0		0.0	0.0		0.0
	Мах	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		99	31	ļ	59
	Median	2.0	2.0	1.0	1.0	1.0	1.0		1.0	1.0		1.0
	Nin	0.0	0.0	0.0	0.0	0.0	0.0		0.0	0.0		0.0
	Наж	3.0	3.0	3.0	3.0	3.0	2.0		2.5	2.0		2.0

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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

Assigned treatment						Visit				
		Day 0	0 Day 7	7 Day 14	Day 21	14 Day 21 Day 28 Day	Day 35	35 Day 42 Day 49 Day	Day 49	Day 56
Fluoxetine	No	87	87	98	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
	Kin	1.0	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	99	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
	Мах	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

dillocative recently											
Assigned treatment						Visit					
		Day 0	0 Day 7	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	
Fluoxetine	No	87	87	84	81	80	42	69	34	69	_
	Nedian	1.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	
<b>1</b> 10	Kin	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	1
Reboxetine	No	9.6	76	75	73	72	素	99	31	59	_
	Median	1.0	1.0	1.0	0.5	0.0	0.0	0.0	0.0	0.0	
	Nin	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
	Kax	3.0	2.5	2.5	2.0	2.0	1.5	2.5	2.0	1.5	1.4

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 35

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

Assigned treatment						Visit					
		Day 0	0 Day 7	7 Day 14 Day 21 Day	Day 21	Day 28	Day 35	28 Day 35 Day 42 Day 49 Day 56	Day 4	9 Day	26
Fluoxetine	No.	87	87	*	18	80	45	69		34	69
	Median	2.0	2.0	1.0	1.0	1.0	1.0	1.0	0.8	<b>c</b> 0	1.0
	Min	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0	0.0
	Мах	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	99		31	29
	Kedian	2.0	1.5	1.0	1.0	1.0	1.0	1.0	1,0		0.0
	Kin	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0	0.0
	Каж	3.0	3.0	3.0	3.0	2.0	2.0	2.0	2.0	0	1.0

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 35 MONTCOMERY ASBERG DEPRESSION RATING SCALE SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Itom: INABILITY TO FEEL										
Assigned treatment						Visit				
		Day 0	0 Day 7	7 Day 14 Day 21 Day	Day 21	Day 28	Day 35	Day 42	28 Day 35 Day 42 Day 49 Day 56	Day 56
Fluoxetine	No	87	87	25	81	8	42	69	\$	69
	Median	1.5	1.0	1.0	1.0	1.0	1.0	1.0	0.0	0.0
	Kin	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Ках	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Reboxetine	No	76	76	7.5	73	72	34	99	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
	Мах	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: PESSIMISTIC THOUGHTS

Assigned treatment						Visit				
		Day 0	0 Day 7	Day 14	Day 21	Day 28	Day 35	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day	Day 49	Day 56
Fluoxetine	No	87	87	48	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
	Маж	2.0	2.0	2.0	2.5	2.0	2.0	2.0	2.0	1.5
Reboxetine	No	9/	76	75	73	72	34	99	31	59
	Hedian	2.0	1.5	1.0	1.0	1.0	1.0	1.0	1.0	0.0
	Kin	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Nax	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

Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 MONTGOMERY ASBERG DEPRESSION RATING SCALE SUMMARY STATISTICS ON SCORE OF EACH ITEM ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT 1.0 0.0 3.0 1.0 Visit 73 0.0 4 1.0 3.0 0.0 2.0 .5 0.0 3.0 1.3 3.0 2.0 Nedian Median Item: CONCENTRATIONS DIFFICULTIES Nin Kax Min Assigned treatment Fluoxetine Reboxetine

PHARMACIA CNS R&D
REBDXETINE - PROTOCOL 20124/016
TABLE No.: 35

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

Assigned treatment						Visit				
		Day 0	0 Day 7	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56	Day 21	Day 28	Day 35	Day 42	Day 49	Day 5
Fluoxetine	No	87	87	84	81	80	42	69	34	69
	Nedian	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
	Nax	3.0	3.0	3.0	3.0	3.0	3.0	2.0	2.0	2.0
Reboxetine	Na	76	76	75	73	72	34	99	31	59
	Kedian	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

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

Assigned treatment						Visit				
		Day 0	0 Day 7	7 Day 14 Day 21	Day 21	Day	28 Day 35	Day	42 Day 49 Day	Day 56
Fluoxetine	No	87	87	98	81	80	42	69	*	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	*	99	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
	Мах	3.0	3.0	3.0	2.0	2.0	2.0	2.0	2.0	2.0

PHARMACIA CNS R&D

REBUXETINE - PROTDCOL 20124/016

TABLE No.: 36

HONTCOHERY ASBERG DEPRESSION RAIING SCALE
SUMMARY STATISTICS ON 10TAL SCORE A1 LAST ASSESSMENT BY ASSIGNED TREATMENT

Assigned treatment					Last	Last assessment	ent			
		Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Total	Total
Fluoxetine	No	m	N	Ø	4	S	63		69	87
	Kean	18.7	14.8	15.3	13.5	9.9	10.5		4.3	6.2
	Kedian	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
	Hin	16.5	14.0	13.0	4.0	1.0	5.0		0.0	0.0
	Нах	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	-	-	2	3	٢	4	6	59	76
	Kean	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
	CTS			3.5	7.8		4.9	5.5	3.3	4.9
	Hin	13.0	14.0	9.0	3.0	13.0	6.0	8.0	0.0	0.0
	Йах	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	3.80	13.10	11.33

an (\*): mean of differences vs o

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PHARHACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 37

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

Assigned treatment					Last	Last assessment	ent				
	<u> </u>	Day 7	Day 14	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Total	Day 28	Day 35	Day 42	Day 49	Day 56	Total	
Fluoxetine	No	6	2	2	4	S	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	
	Мах	3.0	2.0	2.0	3.0	2.0	2.0		2.0	3.0	
Reboxetine	No	-	-	2	5	-	4	Э	59	9,2	
	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	
	Мак	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

Assigned treatment					Last	Last assessment	ent					
	•	Day 7	Day 14	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Total	Day 28	Day 35	Day 42	Day 45	Day	86	[otal	
Fluoxetine	No.	ю	63	23	4	'n	2			69	87	
	Kedian	2.0	2.0	2.0	2.0	1.0	1.8		L	1.0	1.0	
	Min	2.0	2.0	2.0	1.0	0.0	1.0		_	0.0	0.0	
	Мах	2.5	2.0	2.0	2.0	2.0	2.5			2.0	2.5	
Reboxetine	No.	-	1	2	22	-	4	-\$t	m	59	76	
	Median	1.5	2.0	2.0	2.0	2.0	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

TABLE No.: 37
NONTCOMERY ASBERG DEPRESSION RATING SCALE
SUMMARY STATISTICS ON SCORE OF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

ssigned treatment					Last	Last assessment	ent			
		Day 7	Day 14	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Total	Day 28	Day 35	Day 42	Day 49	Day 56	Total
luoxetine	No	m	2	23	4	5	2	;	69	87
	Median	2.0	1.3	1.5	1.5	1.0	0.8		0.0	0.0
	Kin	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
eboxetine	Мо	٢	-	N	ĸ	-	4	8	59	76
	Nedian	1.5	1.5	0.5	1.0	2.0	1.0	2.0	0.0	0.5
	Kin	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

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

TABLE No.: 37

HOWTCOMERY ASSERG DEPRESSION RATING SCALE
SUMMARY STATISTICS DN SCORE DF EACH ITEM AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Item: SUICIDAL THOUGHTS

ssigned treatment					Last	Last assessment	ent				
		Day 7	Day 14	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Total	Day 28	Day 35	Day 42	Day 49	Day 56	Total	
luoxetine	No	3	2	2	4	c,	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	
	Мах	2.5	1.5	3.0	1.0	2.0	1.5		1.5	3.0	
eboxetine	No	-	-	8	S	٢	4	3	59	9.2	
	Kedian	1.5	2.5	0.0	1.0	1.0	0.0	1.0	0.0	0'0	
	Kin	1.5	2.5	0.0	0.0	1.0	0.0	1:0	0.0	0'0	
	Kax	1.5	2.5	0.0	2.0	1.0	2.0	2.0	1.5	2.5	

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 37

Assigned treatment					Last	Last assessment	ment			
		Day 7	Day 14	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Total	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	2	81	4	5	2		69	87
	Kedian	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	-	-	67	5	-	4	8	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
	Жах	1.5	1.0	2.0	2.0	1.0	1.0	2.0	1.0	2.0

PHARHACIA CNS RBD REBOXEITIKE - PROFOCOL 20124/016 TABLE No.: 37

Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Total 69 1.0 1.0 HONTGOHERY ASBERG DEPRESSION RATING SCALE SUHMARY STATISTICS ON SCORE OF EACH ITEM AI LAST ASSESSHENT BY ASSIGNED TREATHENT 0.0 .3 0.0 Last assessment 1.5 2.0 1.5 1.5 1.0 0.1 Median Дах Min Item: INABILITY TO FEEL Assigned treatment

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

PHARMACIA CNS R&D

Item: PESSIMISTIC THOUGHTS

Assigned treatment					Last	Last assessment	ent			
		Day 7	Day 14	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Total	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	3	62	2	4	5	73		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
	Ках	2.0	1.0	2.5	2.0	2.0	2.0		1.5	2.5
Reboxetine	No	_		2	S.	-	ব	3	59	76
	Nedian	1.5	1.0	1.5	1.0	2.0	1.0	2.0	0.0	0.5
	Kin	1.5	1.0	1.0	0.0	2.0	0.0	1.0	0.0	0.0
	Kax	1.5	1.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0

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PHARMACIA CNS R&D BOXEIINE - PROIOCOL 20124/016 TABLE No.: 37

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 37

Assigned treatment					Last	Last assessment	ent				
		Day 7	Day 14	Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Total	Day 28	Day 35	Day 42	Day 49	Day 56	Total	
Fluoxetine	No	3	2	7	4	5	23		69	87	
	Median	1.5	1.3	1.5	1.5	1.0	1.5		0.0	0.5	
	Hin	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	-	-	2	2	-	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	
	Мах	1.0	0.5	2.0	2.0	1.0	2.0	2.0	2.0	2.0	

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 37

Assigned treatment		L			Last	Last assessment	ent			
1				-	;			1		
		Day 7	Day 14	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Total	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	m	2	2	4	5	62		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	-	62	5	-	4	8	59	76
	Median	1.0	1.0	1.0	1.0	0.0	1.5	1.0	0.0	0.5
	nin	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	Last assessment	ent			
		Day 7	Day 14	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Total	Day 28	Day 35	Day 42	Day 49	Day 56	Total
Fluoxetine	No	e	61	23	4	c,	63		69	87
	Median	1.5	1.3	0.5	0.5	0.0	0.5		0.0	0.0
	Hin	0.0	1.0	0.0	0.0	0.0	0.0		0.0	0.0
	Xex	2.5	1.5	1.0	1.0	1.0	1.0		1.0	2.5
Reboxetine	No	1	-	2	5	1	4	9	59	26
	Median	1.0	1.0	1.0	1.0	1.0	0.0	1.0	0.0	0.0
	Hin	1.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0
	Мах	1.0	1.0	1.0	2.0	4.0	1.0	2.0	2.0	2.0

PHARMACIA CNS R&D

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

		•	Assigned treatment	reatment		
	ii.	Fluoxetine		26	Reboxetine	
	Female	Male	Total	Female	Male	Total
Pt exposed	<del>1</del> 99	25	89	57	22	79
Pt with adverse events	84	12	09	37	16	53
pesodxe uo x	75.00	48.00	67.41	64.91	72.72	67.08
95x L.L.	62.60	27.80	56.66	51.13	49.78	55.60
95z U.L.	86.98	68.69	76.98	77.09	89.27	77.25
No. of adverse events	156	54	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 CMS 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 TREATHENT

			•	Assigned treatment	reatment			
		Fluoxetine		,		Reboxetine	tine	
Tot	Total	18 - 30   31 - 45	31 - 45	> 45	Total	18 - 30	31 - 45	> 45
of exposed	68	13	37	39	79	14	29	36
Pt with adverse events	9	6	26	25	53	6	21	23
9 pasadxa uo ;	67.41	69.23	70.27	64.10	67.08	64.28	72.41	63.88
35% L.L.	56.66	38.57	53.02	47.18	55.60	35.14	52.76	46.22
95x U.L. 7	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 DSW III CLASSIFICATION AND ASSIGNED TREATMENT

			Assig	Assigned treatment	ment		
	ш,	Fluoxetine			Reboxetine	tine	
	Total	296.2	296.3	Total	295.7	296.2	296.3
Pt exposed	89	42	47	79	-	3.1	47
Pt with adverse events	09	28	32	53	0	18	35
% on exposed	67.41	99.99	68.08	67.08	00.00	58.06	74.46
95% L.L.	56.66	50.45	52.88	55.60	00.0	39.08	59.65
95% U.L.	76.98	80.43	16.08	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 E EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING TA

Adverse events/Assigned treatment	igned treatment			Female					Kale					Total		
		No of Pt.	z on exp.	X on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	X on Pt with AE	No of	Ratio (*)	No of Pt.	Z on exp.	Z 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	09	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
BEADACHE	Fluoxetine	19	29.7	39.5	27	1.42	-	4.0	8.3	-	1.00	20	22.5	33.3	28	1.40
	Reboxetine	12	21.1	32.4	16	1.33	S	22.7	31.2	5	1.00	11	21.5	32.0	2.1	1.23
HOUTH DRY	Fluoxetine	9	9.4	12.5	9	1.00	63	8.0	16.6	2	1.00	8	9.0	13.3	€0	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	9	9.4	12.5	7	1.16						<b>"</b>	6.7	10.0	7	1.16
	Reboxetine	12	21.1	32.4	13	1.08	ς,	22.7	31.2	2	1.00	12	21.5	32.0	81	1,05
DIZZINESS	Fluoxetine	9	9.4	12.5	80	1.33						٩	6.7	10.0	8	1.33
	Reboxetine	6	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	6	14.1	18.7	11	1.22						•	10.1	15.0	-	1.22
	Reboxetine	8	14.0	21.6	6	1.12	23	9.1	12.5	2	1.00	12	12.7	18.8	F	1.10
NAUSEA	Fluoxetine	8	12.5	16.6	14	1.75	1	4.0	8.3	-	1.00	6	10.1	15.0	15	1.66
	Reboxetine	7	12.3	18.9	6	1.28	2	9.1	12.5	2	1.00	6	11.4	16.9	٢	1.22
SWEATING INCREASED Fluoxetine	Fluoxetine	9	9.4	12.5	8	1.33	1	4.0	8.3	-	1.00	7	7.9	11.6	6	1.28
	Reboxetine	4	7.0	10.8	5	1.25	60	13.6	18.7	3	1.00	7	8.9	13.2	8	1.14
TREMOR	Fluoxetine	r.	7.8	10.4	ις.	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	Fluoxetine	-	1.6	2.0	-	1.00						٦	1.1	1.6	-	1.00
	Reboxetine	61	3,5	5.4	2	1.00	9	27.3	37.5	8	1.33	€0	10.1	15.0	10	1.25

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

TABLE No.: 41

EVENTS: NUMBER OF ANDERE EVENTS AND PATTENTS BIG COMPLAINED OF THEN DURING T

Adverse events/Assigned treatment	igned treatment			Female					Male					Total		
		No of Pt.	x on exp.	Z on Pt with AE	No of	Ratio (*)	No of Pt.	Z on exp.	Z on Pt With AE	No of AE	Ratio (*)	No of Pt.	z on	Z on Pt with AE	No of AE	Ratio (*)
AGITATION	Fluoxetine	5	7.8	10.4	ιŋ	1.00	61	8.0	16.6	23	1.00		7 7.9	11.6	7	1.00
	Reboxetine						-	4.5	6.2	٦	1.00		1.3	1.8	-	1.00
FATIGUE	Fluoxetine	8	4.7	6.2	6	1.00	-	4.0	8.3	٢	1.00		4 4.5	6.6	4	1.00
	Reboxetine	27	3.5	5.4	2	1.00	22	9.1	12.5	2	1.00		4 5.1	7.5	7	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	٩	1.00
	Reboxetine	٦	1.8	2.7	-	1.00						,	1.3	1.8	-	1.00
VISION ABNORMAL	Fluoxetine	9	4.7	6.2	6	1.00	-	4.0	8.3		1.00		4.5	9.9	4	1.00
	Reboxetine	-	1.8	2.7	-	1.00	2	9.1	12.5		1.00		3 3.8	5.6	9	1.00
INFLUENZA-LIKE	Fluoxetine	*	6.3	8.3	S	1.25							4.5	9.9	r,	1,25
	Reboxetine	8	5.3	8.1	3	1.00						.,	3.8	5.6	8	9.5
PARAESTHESIA	Fluoxetine		1.6	2.0	1	1.00						Ĺ	1.1	1.6	-	1.00
	Reboxetine	5	8.8	13.5	5	1.00							5 6.3	9.4	5	1.00
PRURITUS	Fluoxetine	_	1.6	2.0	-	1.00	-	4.0	8.3	-	1.00		2 2.2	3.3	2	1.00
	Reboxetine	2	3.5	5.4	2	1.00	-	4.5	6.2	-	1.00		3 3.8	5.6	6	1.90
VOMITING	Fluoxetine	~	3.1	4.1	2	1.00						<u> </u>	2 2.2	3.3	2	1.00
	Reboxetine	3	5.3	8.1	3	1.00							3 3.8	5.6	9	1.00
SOMNOLENCE	Fluoxetine	~	3.1	4.1	2	1.00	ı	0'5	8.3		1 1.00		3 3.4	5.0	3	1.00
	Reboxetine	2	3.5	5.4	7	1.00							2 2.5	3.7	2	1.00
DYSPEPSIA	Fluoxetine	4	6.3	8.3	5	1.25							4 4.5	9-9	S	1.25
	Reboxetine	-	1.8	2.7	١.	1.00							1 1.3	1.8	1	1.00
UPPER RESP TRACT	Fluoxetine	67	3 4.7	6.2	3	1.00							3 3.4	5.0	3	1.00
	Reboxetine	Na .	3.5	5,4	2	1,00							2 2.5	3.7	2	1.00

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

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 41 WENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURI

PHARMACIA CNS R&D

Adverse events/Assigned treatment	igned treatment			Female					Kale					Total		
		No of Pt.	z on exp.	X on Pt No with AE A	No of AE	Ratio (*)	No of Pt.	z on exp.	X on Pt with AE	No of	Ratio (*)	No of Pt.	x on exp.	% on Pt with AE	No of AE	Ratio (x)
NERVOUSNESS	Fluoxetine	m	4.7	6.2	63	1.00						8	3.4	5.0	æ	1.00
	Reboxetine	-	1.8	2.7	-	1.00						٦	1.3	1.8	1	1.00
RHINITIS	Fluoxetine	-	1.6	2.0	-	1.00	2	8.0	16.6	2	1.00	n	3.4	5.0	9	1.00
	Reboxetine	٢	1.8	2.7	1	1.00						-	1.3	1.8	1	1.00
BACK PAIN	Reboxetine	6	5.3	8.1	3	1.00						8	3.8	5.6	3	1.00
APPETITE INCREASED Fluoxetine	Fluoxetine	w	4.7	6.2	4	1.33						8	3.4	5.0	4	1.33
ABDOMINAL PAIN	Reboxetine	e	5.3	8.1	4	1.33						3	3.8	5.6	4	1.33
HYPERCHOLESTEROLA- Fluoxetine	Fluoxetine	-	1.6	2.0	-	1.00	1	4.0	8.3	-	1.00	63	2.2	3.3	2	1.00
	Reboxetine	-	1.8	2.7	-	1.00						-	1.3	1.8	1	1.00
PHARYNGITIS	Fluoxetine	8	3.1	4.1	2	1.8						61	2.2	3.3	27	1.00
	Reboxetine	-	1.8	2.7	-	1.00						1	1.3	1.8	-	1.00
URINARY TRACT	Fluoxetine	62	3.1	4.1	es.	1.0						2	2.2	3.3	2	1.00
INTECTION	Reboxetine	-	1.8	2.7	٦	1.00						-	1.3	1.8	-	1.00
FEVER	Fluoxetine	-	1.6	2.0	2	2.00						-	1.1	1.6	23	2.00
	Reboxetine	-	1.8	2.7	1	1.00	٦	4.5	6.2	-	1.00	77	2.5	3.7	2	1.00
HOT FLUSHES	Fluoxetine	-	1.6	2.0	-	1.00						-	1.1	1.6	-	1.00
	Reboxetine	67	3.5	5.4	2	1.00						2	2,5	3.7	23	1.00
RASH	Rebaxetine	67	3.5	5.4	ú	1.00						2	2.5	3.7	61	1.00
HYALGIA	Fluoxetine	-	1.6	2.0	-	1.00						1	1.1	1.6	-	1.00
	Reboxetine	-	1.8	2.7	-	1.00						•	1.3	1.8	-	1.00
HYPERTONIA	Fluoxetine	~	1.6	2.0	٦	1.00	-	4.0	8.3	-	1.00	2	2.2	3.3	23	1.00
VERTIGO	Reboxetine	٦	1.8	2.7	ſ	1.00	-	4.5	6.2	2	2.00	61	2.5	3.7	ю	1.50

CONTINUED

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

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PHARMACIA CNS R&D

dverse events/Assigned treatment	igned treatment			Female					Male					Total		
		No of Pt.	x on exp.	% on Pt with AE	No of	Ratio (*)	No of	z on exp.	Z on Pt with AE	No of AE	Ratio (*)	No of Pt.	x on exp.	% on Pt with AE	No of AE	Ratio (*)
RINARY RETENTION	Reboxetine	1	1.8	2.7	-	1.00	-	4.5	6.2	-	1.00	62	2.5	3.7	2	1.00
IYPERTENSION	Fluoxetine						-	4.0	8.3	1	1.00	-	1.1	1.6	٦	1.00
	Reboxetine	-	1.8	2.7	-	1.00						٢	1.3	1.8	-	1.00
YPDTENSION	Fluoxetine	-	1.6	2.0	٦	1.00						-	1.1	1.6	-	1.00
	Reboxetine	-	1.8	2.7	-	1.00						-	1.3	1.8	-	1.00
ALPITATION	Reboxetine	64	3.5	5.4	2	1.00						2	2.5	3.7	23	1.00
CONJUNCTIVITIS	Fluoxetine						-	4.0	8.3	٦	1,00	-	1.1	1.6	-	1.00
	Reboxetine	-	1.8	2.7	1	1.00						-	1.3	1.8	-	1.00
TINNITOS	Reboxetine	-	1.8	2.7	-	1.00	-	4.5	6.2	1	1.00	2	2.5	3.7	23	1.00
NKIETY	Fluoxetine	-	1.6	2.0	-	1.00						1	1.1	1.6	-	1.00
	Reboxetine	٦	1.8	2.7	-	1.00						1	1.3	1.8	-	1.00
SUICIDE ATTEMPT	Fluoxetine	-	1.6	2.0	-	1.00						1	1.1	1.6	-	1.00
	Reboxetine	-	1.8	2.7	-	1.00						-	1.3	1.8	-	1.00
SASTRITIS	Fluoxetine						-	4.0	8.3	-	1.00		1.1	1.6	-	1.00
	Reboxetine	-	1.8	2.7	-	1.00						-	1.3	1.8	1	1.00
HEPATIC ENZYNES INCREASED	Reboxetine	. 2	3.5	5.4	61	1.00						77	2.5	3.7	2	1.00
COUGHING	Fluoxetine	-	1.6	2.0	٦	1.00						-	1.1	1.6	ı	1.00
	Reboxetine	-	1.8	2.7	-	1.00						1	1.3	1.8	1	1.00
RESPIRATORY DISORDER	Reboxetine	23	3,5	5.4	N	1.00						73	2.5	3.7	N.	1.00
YSTITIS	Fluoxetine	٦	1.6	2.0	1	1.00						1	1.1	1.6	1	1.00
	Reboxetine	-	1.8	2.7	-	1.00						٦	1.3	1.8	1	1.00

PHARHACIA CKS R&D

REBOXETINE - PROTOCOL 20124/016

IABLE No.: 41

EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING T

		_		Female					Hale					Total		
		No of Pt.	z on exp.	X on Pt with AE	No of AE	Ratio (*)	Ratio No of (*) Pt.	x on exp.	Z on Pt No of	No of	Ratio (*)	No of Pt.	z an exp.	X on Pt with AE	No of AE	Ratio (*)
ALLERGIC REACTION	Fluoxetine	-	1.6	2.0	-	1.00						_	1.1	1.6	1	1.00
	Reboxetine	-	1.8	2.7	-	1.00						-	1.3	1.8	1	1.00
ABSCESS	Reboxetine						2	9.1	12.5	22	1.00	2	2.5	3.7	2	1.00
RASH MACULO- PAPULAR	Fluoxetine	-	1.6	2.0	-	1.00						-	1.1	1.6	-	1.00
TENDINITIS	Reboxetine						-	4.5	6.2	٢	1.00	-	1.3	1.8	-	1.00
HYPERKINESIA	Fluoxetine	-	1.6	2.0	-	1.00						•	1.1	1.6	-	1.00
MIGRAINE	Reboxetine	_	1.8	2.7	-	1.00						-	1.3	1.8	-	1.00
ANDREXIA	Reboxetine	_	1.8	2.7	-	1.00						-	1.3	1.8	-	1.00
FLUSBING	Reboxetine	-	1.8	2.7	67	2.00						-	1.3	1.8	63	2.00
HYPOTENSION POSTURAL	Reboxetine	1	1.8	2.7	-	1.00						-	1.3	1.8	-	1.00
TACHYCARDIA	Reboxetine	-	1.8	2.7	1	1.00						-	1.3	1.8	-	1.00
XEROPHTHALMIA	Reboxetine	-	1.8	2.7	-	1,00						-	1.3	1.8	-	1.00
TASTE PERVERSION	Reboxetine	٢	1.8	2.7	1	1.00						-	1.3	1.8	-	1.00
EUPHORIA	Reboxetine	_	1.8	2.7	2	2.00						_	1.3	1.8	2	2.00
LIBIDO DECREASED	Reboxetino						-	4.5	6.2		1.00	-	1.3	1.8	-	1.00
PARONIRIA	Fluoxetine	-	1.6	2.0	۴	1.00						-	1.1	1.6	-	1.00
FLATULENCE	Fluoxetine						-	4.0	ε0 Ε.		1.00	-	1.1	1.6	-	1.00
HEPATITIS INFECTIOUS	Reboxetine	1	1.8	2.7	1	1,00							1 1.3	1.8	-	1.00
HYPERURICAENIA	Fluoxetine	_	1.6	2.0	1	1.00						-	1.1	1.6	-	1.00
ALOPECIA	Reboxetine						-	4.5	6.2		1,00	-	1.3	1.8	1	1.00

CONTINUED

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

PHARMACIA CNS RRD

REBOXETINE - PROYOCOL 20124/016

TABLE No.: 41

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS HIG COMPLAINED OF THEM DURING THERAPY

BY ASSIGNED TREATMENT AND SEX

												7				1
Adverse events/Assigned treatment	igned treatment			Fenale					Kale					Total		
		No of X on Pt. exp.		% on Pt with AE	No of AE	Ratio (*)	No of X on Pt. exp.		% on Pt with AE	No of AE	Ratio (*)	Ratio No of (*) Pt.	z on exp.	Z on Pt No of with AE AE	No of AE	Ratio (*)
DEDEMA GENERALISED Fluoxatina	Fluoxetine	-	1.6	2.0	-	1.00						1	1.1	1.6	1	1.00
CIRCULATORY	Reboxetine						-	2.4	6.2	ı	1.00	ı	1.3	1.8	-	1.00
OEDEKA LEGS	Reboxetine	٦	1.8	2.7	-	1.00						ı	1.3	1.8	1	1.00
EPISTAXIS	Reboxetine	-	1.8	2.7	-	1.00						1	1.3	1.8	1	1.00
SINUSITIS	Fluoxetine						-	4.0	8.3	-	1.00	1	1.1	1.6	1	1.00
BRONCHITIS	Fluoxetine	-	1.6	2.0	-	1.00						ı	1.1	1.6	1	1.00
ANAEMIA	Reboxetine	-	1.8	2.7	-	1.00						-	1.3	1.8	1	1.00
RENAL PAIN	Fluoxetine	-	1.6	2.0	1	1.00						-	1.1	1.6	1	1.00
INPOTENCE	Fluoxetine						1	4.0	8.3	-	1.00	-	1.1	1.6	1	1.00
SPERMATORRHOEA	Reboxetine						٦	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	-	1.3	1.8	٦	1.00
BREAST FIBROADENOSIS	Reboxetine	-	1.8	2.7	-	1.00						-	1.3	1.8	-	1.00
ASTHENIA	Fluoxetine	-	1.6	2.0	-	1.00						-	1.1	1.6	-	1.00
CHEST PAIN PRECORDIAL	Fluoxetine	-	1.6	2.0	-	1.00						-	1.1	1.6	-	1.00
MALAISE	Fluoxetine						ı	4.0	8.3	•	1.00	•	1.1	1.6	-	1.00
HYPERPYREXIA	Reboxetine	_	1.8	2.7	-	1.00						-	1.3	1.8	•	1.00
INFECTION VIRAL	Fluoxetine		1.6	2.0	_	1.00					٠	1	1.1	1.6	-	1.00
OTITIS MEDIA	Fluoxetine	1	1.6	2.0	7	1.00						1	1.1	1.6	-	1.0

PHARMACIA CNS RED

SS	Female
DISORDE	
SYSTEM	ment
NERVOUS	d treatm
Body system: AUTONOMIC NERVOUS SYSTEM DISORDERS	dverse events/Assigned treatment
system:	rse eve
Body :	Adve

Adverse events/Assigned treatment	igned treatment			Female					Male					Total		
		No of Pt	Z on exp.	No of Z on Z on Pt No of Ratio No of Z on Z on Pt No of Ratio No of Z on Z on Pt No of Ratio Pt exp. with AE AE (x) Pt exp. with AE AE (x)	No of AE	Ratio (*)	No of Pt	Z on exp.	z on Pt with AE	No of	Ratio (*)	No of Pt	Z on exp.	% on Pt with AE	No of AE	Ratio (*)
MOUTH DRY	Fluoxetine	9	9.4	6 9.4 12.5	9	1.00	2	8.0	6 1.00 2 8.0 16.6 2 1.00 8 9.0 13.3	2	1.00	80	9.0	13.3		8 1.00
	Reboxetine	20	35.1	20 35.1 54.0 20 1.00 _7 31.8 43.7	20	1.00	-7	31.8	43.7		1.00	27	34.2	7 1.00 27 34.2 50.9		27 1.00
SWEATING INCREASED Fluoxetine	Fluoxetine	9	4.6	6 9.4 12.5	1	1.33	1	4.0	8 1.33 1 4.0 8.3	1	1.00	7	7.9	1 1.00 7 7.9 11.6		9 1.28
	Reboxetine	4	7.0	4 7.0 10.8 5 1.25 3 13.6 18.7	ď	1.25	60	13.6	18.7	İ	1.00	3 1.00 7 8.9	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 RED

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

Adverse events/Assigned treatment	igned treatment			Female					Hale		-			Total		
		No of 2 on Pt exp.	1	X on Pt with AE	Pt No of AE AE	Ratio (*)	Ratio No of Z on (*) Pt exp.		X on Pt with AE	No of AE	Ratio (*)	Ratio No of 2 on (*) Pt exp.	i	% on Pt	Pt No of AE	Ratio (*)
ASTHENIA / FATIGUE Fluoxetine	Fluoxetine	4	6.3	8.3	4	1.00	-	4.0	8.3	١	1.00	S	5.6	8.3	15)	1.00
	Reboxetine	61	3.5	5.4	23	1.00	8	9.1	12.5	2	1.00	4	5.1	7.5	4	1.00
INFLUENZA-LIKE	Fluoxetine	4	6.3	89	r)	1.25						4	4.5	6.6	r.	1.25
STAFTORS	Reboxetine	m	5.3	1.8	е	1.00						e	3.8	5.6	3	1.00
FEVER	Fluoxetine	-	1.6	2.0	62	2.00						-	1.1	1.6	2	2.00
	Reboxetine	-	, es.	2.7	٦	1.00	٦	4.5	6.2	-	1.00	23	2.5	3.7	2	1.00
ALLERGIC REACTION	Fluoxetine	-	1.6	2.0	-	1,00						-	1.1	1.6	_	1.00
	Reboxetine	-	1.8	2.7	1	1.00						٦	1.3	1.8	•	1.00
HYPERPYREXIA	Reboxetine	-	1.8	2.7	-	1.00						-	1.3	1.8	-	1.00
MALAISE	Fluoxetine						-	4.0	8.3	-	1.00	1	1.1	1.6	1	1.00

PHARMACIA CNS R&D

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

Body system: CARDIO	Body system: CARDIOVASCULAR DISORDERS, GENERAL	GENERAL	_											s.		
Adverse events/Assigned treatment	signed treatment			Female					Male					Total		
		No of 2 on Pt exp.		z on Pt No of with AE AE	No of AE	Ratio (*)	Ratio No of X on (*) Pt exp.	t .	X on Pt	No of AE	Ratio (*)	No of Pt	x on exp.	n x on Pt No of	No of AE	Ratio (x)
HYPOTENSION AND	Fluoxetine	7	10.9	14.5	6	1.28							7.9	11.6	ę.	1.28
	Reboxetine	7	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	Fluoxetine	_	1.6	2.0	1	1.00						-	1.1	1.6	-	1.00
	Reboxetine	6	5.3	8.1	4	1.33						8	3.8	5.6	4	1.33
AEDEMA	Fluoxetine	-	1.6	2.0	1	1.00						-	1.1	1.6	-	1.00
	Reboxetine	٢	1.8	2.7	-	1.00						٦	1.3	1.8	-	1.00
HYPERTENSION	Fluoxetine						-	4,0	8.3	1	1.00	-	1.1	1.6	-	1.00
	Reboxetine	-	1.8	2.7	1	1.00						-	1.3	1.8	-	1.00
PALPITATION	Reboxetine	8	3.5	5.4	2	1.00						81	2.5	3.7	2	1.00
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	Fluoxetine	-	1.6	2.0	-	1.00						-	1.1	1.6	-	1.00
CIRCULATORY FAILURE	Reboxetine						-	4.5	6.2	-	1,00	-	1.3	1.8	1	1.00
TACHYCARDIA	Reboxetine	-	1.8	2.7	-	1.00						-	1.3	1.8	1	1.00

PHARMACIA CNS R&D

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 Advers

Adverse events/Assigned treatment	rigned treatment			Female					Kale					Total		
		No of Z on Pt exp.		% on Pt with AE	No of	Ratio (*)	Ratio No of Z on (*) Pt exp.	1	z on Pt No of with AE AE		Ratio (*)	Ratio No of % on (*) Pt exp.		X on Pt No of with AE AE		Ratio (*)
HEADACHE /	Fluoxetine	19	29.7	39.5	27	1.42	-	4.0	8.3	-	1.00	20	22.5	33.3	28	1.40
	Reboxetine	12	21.1	32.4	17	1.41	S	22.7	31.2	3	1.00	17	21.5	32.0	22	1.29
TREMOR	Fluoxetine	75	7.8	10.4	5	1.00						5	5.6	8.3	ιŋ	1.00
	Reboxetine	4	7.0	10.8	4	1.00						4	5.1	7.5	4	1.00
PARAESTHESIA	Fluoxetine	-	1.6	2.0	-	1.00						-	1.1	1.6	-	1.00
	Reboxetine	'n	83.	13.5	5	1.00						ιŋ	6.3	4.6	r,	1.00
HYPERTONIA	Fluoxetine	-	1,6	2.0	-	1.00	-	4.0	8.3	-	1,00	81	2.2	3.3	N N	1.00
VERTIGO	Reboxetine	-	1.8	2.7	-	1.00	-	4.5	6.2	2	2.00	83	2.5	3.7	60	1.50
HYPERKINESIA	Fluoxetine	٦	1.6	2.0	-	1.00						-	1.1	1.6	1	1.00

PHARMACIA CNS RRD

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

Body system: GASTRO	Body system: GASTRO-INTESTINAL SYSTEM DISORDERS	SORDER	va													
Adverse events/Assigned treatment	igned treatment			Fema1e					Male					Total		
		No of X on Pt exp.	1	X on Pt No of with AE AE	No of AE	Ratio No of % on (*) Pt exp.	No of		X on Pt No of		Ratio (*)	Ratio No of Z on (x) Pt exp.		X on Pt No of with AE AE		Ratio (*)
NAUSEA AND RELATED Fluoxetine	Fluoxetine	13	20.3	27.0	21	1.61	63	8.0	16.6	2	1.00	15	16.9	25.0	23	1.53
STUL LOWS	Reboxetine	11	19.3	29.7	14	1.27	83	9.1	12.5	22	1.00	13	16.5	24.5	16	1.23
CONSTIPATION	Fluoxetine	9	9.4	12.5	4	1.16						9	6.7	10.0	7	1.16
	Reboxetine	12	21.1	32.4	13	1.08	Ŋ	22.7	31.2	r)	1.00	17	21.5	32.0	18	1.05
DIARRHOEA	Fluoxetine	4	6.3	8.3	4	1.00	7	8.0	16.6	2	1.00	9	6.7	10.0	9	1.00
	Reboxetine	1	1.8	2.7	-	1.00						-	1.3	1.8	-	1.00
ABDOMINAL PAIN	Reboxetine	e	5,3	8.1	4	1.33						6	3.8	5.6	4	1.33
APPETITE INCREASED Fluoxetine	Fluoxetine	æ	4.7	6.2	7	1.33						6	3.4	5.0	4	1.33
ANOREXIA	Reboxetine	١	1.8	2.7	-	1.00						-	1.3	1.8	1	1.00
FLATULENCE	Fluoxetine						٦	4.0	8.3	٦	1.00	1	1.1	1.6	ı	1.00

PHARMACTA CNS R&D

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	G AND VESTIBULAR DISC	RDERS														
Adverse events/Assigned treatment	igned treatment			Female					Male					Tota1		
		No of Pt	z on exp.	X on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	X on Pt With AE	No of AE	Ratio (*)	No of Pt	z on exp.	No of x on x on Pt No of Ratio No of x on x on Pt No of Ratio No of x on x on Pt No of Ratio Pt oxp. with AE AE (x) Pt oxp. with AE AE (x) Pt oxp. with AE AE (x)	No of AE	Ratio (*)
TINNITUS	Reboxetine	-	1.8	2.7	-	1.00		4.5	6.2	-	1.00	21	2.5	1 1.8 2.7 1 1.00 1 4.5 6.2 1 1.00 2 2.5 3.7 2 1.00	N	1.00

PHARMACIA CNS R&D

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

Body system: HEMATOLOGY DISORDERS Adverse events/Assigned treatment	LOGY DISORDERS			Female					Total		
		% of Pt	X on exp.	No of X on X on Pt No of Ratio No of X on Y on Pt No of Ratio Pt exp. with AE AE (*) Pt sxp. with AE AE (*)	No of AE	Ratio (*)	₹ Ft	X on axp.	X on Pt with AE	No of AE	Ç E
ANEHIA	Reboxetine	~	1.8	1 1.8 2.7 1 1.00 1 1.3 1.8 1 1.00	-	1.00	-	1.3	1.8	1	-

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 42

: EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS HHO COMPLAINED OF THEM DUI BY ASSIGNED TREATHENT, BODY SYSTEM AND SEX

Body system: LIVER !	Body system: LIVER AND BILLAR SYSTEM DISORDERS	SORDERS									
Adverse events/Assigned treatment	igned treatment			Female					Tota1		
		No of Pt	z on exp.	No of z on z on Pt No of Ratio No of z on z on Pt No of Ratio Pt exp. with AE AE (*) Pt exp. with AE AE (*)	No of AE	Ratio (*)	No of	Z on exp.	X on Pt With AE	No of AE	Ratio (*)
INCREASED LIVER ENZYMES	Reboxetine	N	3.5	5.4		1.00	. (1)	62 rč	2 1.00 2 2.5 3.7		2 1.00
HEPATITIS INFECTIOUS	Reboxetine	1	1.8	2.7		1.00	1 1.00 1 1.3	1.3	1.8		1.00

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

PHARMACIA CNS R&D

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

Body system: METABO	Body system: METABOLIC AND NUTRITIONAL DISORDERS	ISORDE	S													
Adverse events/Assigned treatment	igned treatment			Femals					Male					Total		
		No of Pt	x on exp.	X on Pt With AE	No of	Ratio (*)	No of Pt	x on exp.	% on Pt With AE	No of AE	Ratio (x)	No of Pt	z on exp.	No of x on x on Pt No of Ratio No of x on x on Pt No of Ratio No of x on x on Pt No of Ratio Pt exp. with AE AE (*) Pt exp. with AE AE (*) Pt exp. with AE AE (*)	No of	Ratio (*)
HYPERCHOLESTEROLA- Fluoxetine	Fluoxetine	1	1.6	1 1.6 2.0	1	1.00	-	4.0	8.3	-	1.00	N	2.2	1 1.00 1 4.0 8.3 1 1.00 2 2.2 3.3 2 1.00	67	1.00
viet of the control o	Reboxetine	1	1.8	1 1.8 2.7		1 1.00						-	1.3	1.3 1.8		1.00
HYPERURICAEMIA	Fluoxetine	1	1.6	1 1.6 2.0 1 1.00	1	1.00						۳	1.1	1 1.1 1.6	٠,	1.00

(\*) number

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 42

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

Body system: MUSCOLO-SKELETAL SYSTEM DISORDERS

Adverse events/Assigned treatment	igned treatment			Female					Kale				l.	Total		
		No of Pt	7 on exp.	% on Pt with AE	No of	Ratio (*)	No of Pt	z an exp.	X on Pt with AE	No of AE	Ratio (*)	No of Pt	z on exp.	No of z on z on Pt No of Ratio No of z on z on Pt No of Ratio No of z on z on Pt No of Ratio Pt oxp. with AE AE (*) Pt oxp. with AE AE (*)	No of AE	Ratio (*)
BACK PAIN	Reboxetine	60	5.3	3 5.3 8.1 3 1.00	60	1.00						3	3.8	3 3.8 5.6		3 1.00
HYALGIA	Fluoxetine	٦	1.6	1.6 2.0		1 1.00						1	1.1	1.1 1.6	1 1.00	1.00
	Reboxetine	·	8.1	1 1.8 2.7	1 1.00	1.00						1	1.3	1.3 1.8	ľ	9.1
TENDINITIS	Reboxetine						1	4.5	1 4.5 6.2		1.00	-	1.3	1 1.00 1 1.3 1.8		1 1.00

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

PHARMACTA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE NO.: 42

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS HEO COMPLAINED OF THEN DURING THERAPY BY ASSIGNED TREATHENT, BODY SYSTEM AND SEX

Body system: PSYCHIATRIC DISORDERS

Adverse events/Assigned treatment	igned treatment			Female					Male					Total		
		No of X on Pt exp.		% on Pt with AE	Pt No of AE AE	Ratio (*)	Ratio No of Z on (*) Pt exp.		X on Pt No of with AE AE	No of AE	Ratio (*)	Ratio No of Z (x) Pt ex	# d	% on Pt with AE	No of AE	Ratio (*)
INSOMNIA	Fluoxetine	6	14.1	18.7	11	1.22						Q.	10.1	15.0	11	1.22
	Reboxetine	60	14.0	21.6	6	1.12	2	9.1	12.5	2	1.00	10	12.7	18.8	11	1.10
AGITATION /	Fluoxetine	œ	12.5	16.6	6	1.12	61	8.0	16.6	2	1.00	92	11.2	16.6	11	1.10
NERVOUSNESS	Reboxetine	N	3.5	5.4	8	1.00	-	4.5	6.2	-	1.00	m	3.8	5.6	m	1.00
SOMNOLENCE	Fluoxetine	N	3.1	4.1	N	1.00	-	4.0	8.3	_	1.00	m	4.	5.0	m	1.00
	Reboxetine	N	3.5	5.4	8	1.00						8	2.5	3.7	61	1.00
SUICIDE ATTEMPT	Fluoxetine	-	1,6	2.0	-	1.00						-	1.1	1.6	-	1.00
	Reboxetine	-	1.8	2.7	-	1.00						-	1.3	1.8	-	1.00
EUPHORIA	Reboxetine	-	1.8	2.7	23	2.00						-	1.3	1.8	63	2.00
LIBIDO DECREASED	Reboxetine						-	4.5	6.2	-	1.00	-	1.3	1.8	-	1.00
PARONIRIA	Fluoxetine	-	1.6	2.0	1	1.00						_	7	1.6	٦	1.00

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

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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 TREATHENT, BODY SYSTEM AND SEX

y system: REPRODUCTIVE DISORDERS, FEMALE

		1									
se events/Assigned treatment	ned treatment			Fenale					Total		
		No of Pt	z on oxp.	No of Z on Z on Pt No of Ratio No of Z on Z on Pt No of Ratio Pt oxp. with AE AE (*) Pt exp. with AE AE (*)	No of AE	Ratio (*)	No of Pt	x on exp.	% on Pt with AE	No of AE	Ratio (*)
ADENOSIS	Reboxetine	-	1.8	1 1.8 2.7		1 1.00 1 1.3	-	1.3	1.8		1.00

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

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 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 DISORDER Adverse events/Assigned treatment EJACULATION Reboxetine DISORDER	Body system: REPRODUCTIVE DISORDERS, MALE Adverse events/Assigned treatment R EJACULATION Reboxetine DISORDER	No of Pt	ax on exp.		No of AE	Ratio (*)	No of Pt	7. on exp.	Ratio No of Z on Z on Pt   (*) Pt exp. with AE   11.00 1 1.3 1.8	Ro of AE	(*)
IMPOTENCE	Fluoxetine	_	4.0	1 4.0 8.3		1.00	1	1.1	1 1.00 1 1.1		9.
SPERMATORRHOEA	Reboxetine	-	1 4.5	6.2		1 1.00		1 1.3	4. eg		1.00

number of adverse events on patients who complained of adverse events

				REBOXI	REBOXETINE - PROTOCOL 20124/016 TABLE No.: 42	E - PROTOCOL ; TABLE No.: 42	OL 201	124/016							
	ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS HIG COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATHENT, BODY SYSTEM AND SEX	NUMBES	OF AE	DF ADVERSE EVENTS AND PATIENTS WHO COMPLAINE BY ASSIGNED TREATHENT, BODY SYSTEM AND SEX	VENTS AI TREATHI	ND PATI	DY SYS	HO COR	PLAINED ID SEX	OF THE	DURIN	IG THER	APY		
Body system: RESIST	Body system: RESISTANCE MECHANISM DISORDERS	ERS													
Adverse events/Assigned treatment	signed treatment			Female					Male					Total	1
		No of Pt	z on exp.	X on Pt with AE	No of AE	Ratio (*)	No of Pt	z on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	Z on exp.	No of X on X on Pt No of Retio No of X on X on Pt No of Retio No of X on X on Pt No of Retio No of X on Y on Pt No oxp. with AE AE (*) Pt oxp. with AE	ž
ABSCESS	Reboxetine						8	9.1	12.5		2 1.00	7	2.5	3.7	
INFECTION VIRAL	Fluoxetine	-	1.6	2.0		1.00						-	1.1	1.6	l
A POOL OFFICE			,			,						•	,		ı

PHARMACIA CNS RED

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

Body system: RESPIR	Body system: RESPIRATORY SYSTEM DISORDERS	æ														
Adverse events/Assigned treatment	igned treatment			Female					Male					Total		
		No of Z on Pt exp.	1	X on Pt No of with AE AE	No of AE	Ratio (*)	Ratio No of (*) Pt	z an exp.	x on Pt with AE	Pt No of		Ratio No of Z on (*) Pt exp.		X on Pt No of with AE AE		Ratio (*)
UPPER RESP TRACT	Fluoxetine	m	4.7	6.2	60	1.00						ю	3.4	5.0	8	1.00
	Reboxetine	77	3.5	5.4	8	1.00						63	2.5	3.7	72	1.00
RHINITIS	Fluoxetine	-	1.6	2.0	1	1.00	2	8.0	16.6	72	1.00	m	3.4	5.0	en	1.00
	Reboxetine	-	1.8	2.7	-	1.0						-	1.3	1.8	-	1.00
PHARYNGITIS	Fluoxetine	2	3,1	4.1	77	1.00						2	2.2	3.3	23	1.00
	Reboxetine	1	1.8	2.7	-	1.00						-	1.3	1.8	-	1.00
COUGHING	Fluoxetine	-	1.6	2.0	-	1.00						-	1.1	1.6	-	1.00
	Reboxetine	-	1.8	2.7	1	1.00						-	1.3	1.8	-	1.00
RESPIRATORY DISORDER	Reboxetine	81	3.5	5.4	2	1.00						61	2.5	3.7	63	1,00
BRONCHITIS	Fluoxetine	1	1.6	2.0	1	1.00						*	7.	1.6	-	1.00
EPISTAXIS	Reboxetine	٦	1.8	2.7	1	1.00						-	1.3	1.8	-	1.00
SINUSITIS	Fluoxetine						1	4.0	8.3	-	1.00	٦	1.1	1.6	1	1.00

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F ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATHENT, BODY SYSTEM AND SEX

Body system: SKIN A	Body system: SKIN AND APPENDAGES DISORDERS	SBS										•		i		
Adverse events/Assigned treatment	signed treatment			Female					Male					Tota1		
		No of	Z on exp.	X on Pt with AE	No of AE	Ratio (*)	M of Pt	X on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	Z on exp.	No of X on X on Pt No of Ratio No of X on X on Pt No of Ratio No of X on X on Pt No of Ratio Pt exp. with AE AE (*) Pt exp. with AE AE (*)	No of AE	Ratio (*)
PRURITUS	Fluoxetine		1.6	2.0	1	1 1.00	1	1 4.0	8.3		1.00	23	2 2.2	9.3	63	1.00
	Reboxetine	67	3.5	5.4		2 1.00	-	4.5	6.2	,	1.00		3.8	5.6	6	1.00
ERYTHEMA / RASH	Fluoxetine	1	1.6	2.0		1.00						-	1.1	1.6	-	1.00
	Reboxetine	2	3.5	5.4		2 1.00						61	2.5	3.7	73	1.00
ALOPECIA	Reboxetine						1	4.5	6.2		1.00	-	1.3	1.8		1.00

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No:: 42

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

Body system: SPECIA	Body system: SPECIAL SENSES OTHER, DISORDERS	DERS									
Adverse events/Assigned treatment	igned treatment			Fenale					Total		
		No of Pt	z on exp.	No of z on z on Pt No of Ratio No of z on z on Pt No of Ratio Pt exp. with AE AE (*) Pt exp. with AE AE (*)	No of AE	Ratio (*)	No of Pt	x on exp.	% on Pt with AE	No of AE	Ratio (*)
TASTE PERVERSION Reboxetine	Reboxetine	1	1.8	1 1.8 2.7	-	1.00	-	1.3	1 1.00 1 1.3 1.8	-	1.00
											4

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

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 42 RSE EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THERAPY BY ASSIGNED TREATHENT, BODY SYSTEM AND SEX

DISORDERS
SYSTEM
URINARY
system:
Body

Adverse events/Assigned treatment	igned treatment			Female					Male					Total		
-		No of Pt	x on x	No of Z on Z on Pt No of Ratio No of Z on Z on Pt No of Ratio No of Z on Z on Pt No of Pt oxp. with AE AE (*) Pt exp. with AE AE (*) Pt exp. with AE AE (*)	No of AE	Ratio (*)	F g	Z on exp.	X on Pt with AE	No of AE	Ratio (*)	No of Pt	Z on exp.	X on Pt with AE	No of AE	Ratio (*)
URINARY HESITANCY	Fluoxetine	-	1.6	2.0		1 1.00						-	1.1	1.6		1.00
WEITEN TON	Reboxetine	6	5. E.	8.1	м	1.00		7 31.8	43.7		9 1.28		10 12.7	18.8	12	1.20
URINARY TRACT	Fluoxetine	2	3.1	4.1	61	2 1.00						62	2.2	3.3	2	1.00
INFECTION	Reboxetine	-	4.	2.7	,	1.00						-	1.3	1.8	-	1.00
CYSTITIS	Fluoxetine	-	9	2.0		1.00					,	-	1.1	1.6		1.00
	Reboxetine	-	1.8	2.7		1 1.00						-	1.3	1.8		1.00
RENAL PAIN	Fluoxetine	-	1.6	2.0		1 1.00						-	1.1	1.6		1.9

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

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PHARMACIA CNS R&D

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

Body system: VISION DISORDERS

erse events/Ass	erse events/Assigned treatment			Female					Male					Total		
		No of Pt	z on exp.	X on Pt with AE	No of	Ratio (*)	No af	X on exp.	No of X on X on Pt No of Ratio No of X on X on Pt No of Ratio No of X on X on Pt No of Pt oxp. with AE AE (*) Pt oxp. with AE AE (*) Pt oxp. with AE AE (*)	No of AE	Ratio (x)	No of Pt	z on exp.	X on Pt with AE	No of AE	Ratio (*)
RRED VISION	Fluoxetine	3	3 4.7	6.2		1.00	٦	4.0	3 1.00 1 4.0 8.3		1 1.00 4 4.5	4	4.5	9.9	4	1.00
	Reboxetine	-	1.8	2.7		1 1.00		2 9.1	12.5		2 1.00 3 3.8	6	3.8	5.6	9	1.00
JUNCTIVITIS	Fluoxetine						-	4.0	8.3		1.00	-	1:1	1.6	-	1.00
	Reboxetine	-	1.8	2.7		1 1.00						-	1.3	1.8	-	1.00
OPHTHALMIA	Reboxetine	-	1.8	2.7		1 1.00						-	1.3	1.8	-	1.00

PHARMACIA CHS 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

Pt exposed Funcatine 64 100.0   7.0 m   2 m pt   No of   2 m   2 m pt   No of   2 m   2 m pt   No of   2 m   2 m pt   No of   2 m pt   No of   2 m pt   No of   2 m   2 m pt   No of   2 m   No of   2 m   2 m pt   No of    Body system/Assigned treatment	reatment			Female					Male					Total			
Proceditive   Colored			49	z on exp.	z on Pt with AE	ž	Ratio (*)	P. S.		% on Pt with AE	Ě	Ratio (*)	2 ₹	Z on		No of AE	Ratio (*)
Fluoretine   S7 100.0   156 3.25 12 100.0   24 2.00 60 67.4 1     Raboxetine   20 31.3 41.6 36 1.80 5 20.0 41.6 5 1.00 25 3.43 55 77.1 10.0     Raboxetine   20 31.3 41.6 36 1.80 5 20.0 41.6 5 1.00 25 28.1     Raboxetine   22 38.6 59.4 33 1.50 7 31.8 43.7 7 1.00 25 28.1     Raboxetine   16 28.1 43.2 27 1.86 6 27.3 37.5 7 1.16 22 27.8     Raboxetine   16 28.1 43.2 27 1.86 6 27.3 37.5 7 1.16 22 27.8     Raboxetine   16 28.1 37.5 2 1.19 9 40.9 56.2 1 1.11 39 38.0     Raboxetine   15 28.3 35.1 16 20.8 11.1 17.0 1 11.1 39 38.0     Raboxetine   15 28.3 35.1 16 20.8 11.1 17.0 1 11.1 12.4     Raboxetine   15 28.3 40.5 25.1 11.1 2.1 11.1 20 21.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1 11.1 20 21.1	Pt exposed	Fluoxetine	79	100.0				25	100.0				89	100.0	,		
Fluozetine		Reboxetine		100.0									79	100.0			
Reboxetine   27 64.9   100.0   166 4.46   16 72.7   100.0   55 3.43   59 67.1   1     Reboxetine   20 31.3   41.6   36 1.80   5 20.0   41.6   5 1.00   25 28.1     Reboxetine   22 38.6   59.4   33 1.52   2 8.0   16.6   2 1.00   25 28.1     Reboxetine   16 28.1   43.2   27 1.68   6 27.3   37.5   7 1.16   22 27.8     Reboxetine   16 28.1   43.2   27 1.68   6 27.3   37.5   7 1.16   22 27.8     Reboxetine   18 28.1   37.5   24 1.33   3 12.0   25.0   3 1.00   13 14.6     Reboxetine   19 12.6   35.1   16 1.23   3 12.0   25.0   3 1.00   13 14.6     Reboxetine   19 14.1   18.7   12 1.33   2 8.0   16.6   2 1.00   21 12.4     Reboxetine   7 12.3   18.9   8 1.14   3 12.0   25.0   3 1.00   10 11.2     Reboxetine   7 12.3   18.9   8 1.14   3 12.0   25.0   3 1.00   10 11.2     Reboxetine   7 12.3   18.9   8 1.14   3 12.0   25.0   3 1.00   10 11.2     Reboxetine   7 12.3   18.9   8 1.14   3 12.0   25.0   3 1.00   10 11.2     Reboxetine   7 12.3   18.9   8 1.14   3 12.0   25.0   3 1.00   10 11.2     Reboxetine   7 12.3   18.9   8 1.14   3 12.0   25.0   3 1.00   10 11.2     Reboxetine   7 12.3   18.9   8 1.14   3 12.0   25.0   3 1.00   10 11.2     Reboxetine   7 12.3   18.9   8 1.14   3 12.0   25.0   3 1.00   10 11.2     Reboxetine   7 12.3   18.9   8 1.14   3 12.0   25.0   3 1.00   10 11.2     Reboxetine   7 12.3   18.9   8 1.14   3 12.0   25.0   3 1.00   10 11.2     Reboxetine   7 12.3   18.9   8 1.14   3 12.0   25.0   3 1.00   10 11.2     Reboxetine   8 13.5   8 13.5   1.00   2 1.00   2 1.00   5 5.6     Reboxetine   8 13.5   8 1.00   2 1.00   2 1.00   5 5.6     Reboxetine   9 1.00   0 1.00	Pt with a.e.	Fluoxetine	48	1	100.0					ļ`	24	1			100.0	180	3.00
Princetime   20 31.3 41.6 36 1.80 5 20.0 41.6 5 1.00 25 28.1		Reboxetine	37	64.9	]					100.0	55			Ь.	100.0	221	4.16
Roboxetine   22 38.6 59.4 33 1.50   7 31.8 43.7   7 1.00 29 36.7	GASTRO-INTESTINAL	Fluoxetine	20	31.3					20.0	41.6				1	41.6	1.4	1.64
Reducetine   23 35.9   47.9   35 1.52   2 8.0   16.6   2 1.00   25 22.18		Reboxetine	22	38.6					31.8	43.7		1.00			54.7	40	1.37
Reboxetime   16 28.1   43.2   27 1.68   6 27.3   37.5   7 1.16   22 27.8	با	Fluoxetine	23	35.9			ł		8.0	16.6					41.6	37	1.48
Redoxetine   10 15.6   20.8   14 1.40   3 12.0   25.0   3 1.00   13 14.6     Redoxetine   13 26.8   56.7   25 1.19   9 40.9   56.2   10 1.11   30 38.0     Redoxetine   18 26.1   37.5   24 1.33   3 12.0   25.0   3 1.00   21 23.6     Redoxetine   19 22.8   35.1   16 1.23   3 13.6   18.7   4 1.33   16 20.3     Fluoxetine   10 15.6   20.8   12 1.20   1 4.0   8.3   1 1.00   11 12.4     Redoxetine   19 14.1   18.7   12 1.33   2 8.0   16.6   2 1.00   11 12.4     Redoxetine   7 12.3   18.9   8 1.14   3 12.0   25.0   3 1.00   10 17.2     Redoxetine   5 8.8   13.5   5 1.00   7 31.8   43.7   9 1.28   12 15.2     Redoxetine   5 8.8   13.5   5 1.00   2 8.0   16.6   2 1.00   10 17.2     Redoxetine   5 8.8   13.5   5 1.00   7 31.8   43.7   9 1.28   12 15.2     Redoxetine   5 8.8   13.5   8 1.00   2 8.0   16.6   2 1.00   5 5.6     Redoxetine   5 8.8   13.5   6.3   1.00   2 8.0   16.6   2 1.00   5 5.6     Redoxetine   5 8.8   13.5   8.1   10.0   2 8.0   10.6   5 6.3     Redoxetine   7 12.3   18.9   8 1.10   7 31.8   7 8.0     Redoxetine   8 8.8   13.5   8.1   10.0   2 8.0   10.6   5 6.3     Redoxetine   9 4.7   6.2   3 1.00   2 8.0   16.6   5 1.00   5 6.3     Redoxetine   9 4.7   6.2   3 1.00   2 8.0   16.6   5 1.00   5 6.3     Redoxetine   9 4.7   6.2   3 1.00   2 8.0   16.6   5 1.00   5 6.3     Redoxetine   9 4.7   6.2   3 1.00   2 8.0   16.6   5 1.00   5 6.3     Redoxetine   9 6.8   13.5   10.0   2 8.0   10.6   5 6.3     Redoxetine   9 6.8   13.5   10.0   2 8.0   10.6   5 8.0     Redoxetine   9 6.8   13.5   10.0   2 8.0   10.6   5 8.0     Redoxetine   9 6.8   13.5   10.0   2 8.0   10.0   5 6.3     Redoxetine   9 6.8   13.5   10.0   2 8.0   10.0   5 6.3     Redoxetine   9 6.8   13.5   10.0   2 8.0   10.0   5 6.3     Redoxetine   9 6.8   13.5   10.0   2 8.0   10.0   5 6.3     Redoxetine   9 6.8   13.5   13.0   13.0   13.0   13.0   13.0     Redoxetine   9 6.8   13.0   13.0   13.0   13.0   13.0   13.0     Redoxetine   9 6.8   13.0   13.0   13.0   13.0   13.0   13.0   13.0     Redoxetine   9 6.8   13.0   13.0   13.0   13.0   13		Reboxetine	16	28.1			1		27.3	37.5					41.5	34	1.54
No. No. No. No. No. No. No. No. No. No.	AUTONOMIC NERVOUS	Fluoxetine	10	15.6					12.0	25.0					21.6	17	1.30
RRS Fluoxetine         18 28.1         37.5         24 1.33         3 12.0         25.0         3 1.00         21 23.6           Reboxetine         13 22.8         35.1         16 1.23         3 13.6         18.7         4 1.33         16 20.3           Fluoxetine         10 15.6         20.8         12 1.20         1 4.0         8.3         1 1.00         11 12.4           Reboxetine         15 26.3         40.5         25 1.66         5 22.7         31.2         5 1.00         20 25.3           Fluoxetine         7 12.3         18.9         8 1.14         3 13.6         18.7         3 1.00         10 12.7           Reboxetine         7 12.3         18.9         1.14         3 12.0         25.0         3 1.00         10 12.7           Reboxetine         7 12.3         18.9         8 1.14         3 12.0         25.0         3 1.00         10 11.2           Reboxetine         7 12.3         18.9         8 1.14         3 12.0         25.0         3 1.00         10 11.2           Reboxetine         5 7.8         10.4         5 1.00         7 31.8         43.7         9 1.28         5 5.6           Fluoxetine         3 4.7         6.2         3 1.00         7 31.8		Reboxetine	21				1		40.9	56.2					56.6	35	1.16
Reboxetine         13         22.8         35.1         16         1.23         3         13.6         18.7         4         1.33         16         20.3           Fluoxetine         10         15.6         20.8         12         1.20         1         4.0         8.3         1         1.00         11         12.4           Fluoxetine         15         26.3         40.5         25         1.66         5         22.7         31.2         5         1.00         11         12.4           Reboxetine         7         12.3         18.9         8         1.14         3         12.0         25.0         3         1.00         10         12.7           Reboxetine         7         12.3         18.9         8         1.14         3         12.0         25.0         3         1.00         10         17.2           Reboxetine         7         12.3         18.9         8         1.14         3         12.0         25.0         3         1.00         11.2         11.2           Reboxetine         5         7.8         10.4         5         1.00         7         31.8         43.7         9         1.28	PSYCHIATRIC DISORDERS	Fluoxetine	81	ļ	İ				12.0	25.0		<u> </u>			35.0	27	1.28
Fluozetine         10         15.6         20.8         12         1.20         1         4.0         6.3         1         1.00         11         12.4           Reboxetine         15.6.3         40.5         25         1.66         5         22.7         31.2         5         1.00         20         25.3           Reboxetine         7         12.3         18.9         8         1.14         3         12.0         25.0         3         1.00         11         12.2           Reboxetine         7         12.3         18.9         8         1.14         3         12.0         25.0         3         1.00         10         17.2           Reboxetine         7         12.3         18.9         8         1.14         3         12.0         5         6.6         6         6         6         6         6         10         11.2         12.2		Reboxetine	13						13.6						30.1	20	1.25
Reboxetine         15         26.3         40.5         25         1.66         5         22.7         31.2         5         1.00         20         25.3           Fluoxetine         7         12.3         18.7         12         1.33         2         8.0         16.6         2         1.00         11         12.4           Reboxetine         7         12.3         18.9         8         1.14         3         12.0         25.0         3         1.00         10         11.2           Reboxetine         7         12.3         18.9         8         1.14         3         12.0         25.0         3         1.00         10         11.2           Reboxetine         7         12.3         18.9         8         1.14         3         12.0         25.0         3         1.00         10         11.2           Reboxetine         5         8.8         19.5         5         1.00         7         31.8         43.7         9         1.28         15.2           Reboxetine         3         4.7         6.2         3         1.00         2         9.1         12.3         10.0         5         6.3	CARDIOVASCULAR DISORDEDS GENERAL	Fluoxetine	2	15.6					4.0	8.3	-	1.00			18.3	13	1.18
Fluozetine         9 14.1         18.7         12 1.38         2         8.0         16.6         2         1.00         11 12.4           Reboxetine         7 12.3         18.9         8 1.14         3 12.0         25.0         3 1.00         10 12.7           Reboxetine         7 12.3         18.9         8 1.14         3 12.0         25.0         3 1.00         10 11.2           Pluoxetine         7 12.3         18.9         8 1.14         7 31.8         43.7         9 1.28         15.2           Pluoxetine         5 8.8         13.5         5 1.00         7 31.8         43.7         9 1.28         12 15.2           Reboxetine         3 4.7         6.2         3 1.00         2 8.0         16.6         2 1.00         5 5.6		Reboxetine	15							31.2					37.7	8	1.50
Reboxetine         7 12.3         18.9         8 1.14         3 13.6         18.7         3 1.00         10 12.7           Fluozetine         7 12.3         18.9         8 1.14         3 12.0         25.0         3 1.00         10 11.2           Reboxetine         7 12.3         18.9         8 1.14         7 31.8         7 8.9           Reboxetine         5 7.8         10.4         5 1.00         7 31.8         43.7         9 1.28         12.8           Fluoxetine         3 4.7         6.2         3 1.00         2 8.0         16.6         2 1.00         5 5.6           Reboxetine         3 5.3         8.1         3 1.00         2 9.1         12.5         2 1.00         5 6.3	BODY AS A WHOLE-	Fluoxetine	6	l					8.0	16.6		<u> </u>			18.3	#	1.27
Fluoxetine         7 10.9         14.5         8 1.14         3 12.0         25.0         3 1.00         10.12         11.2           Reboxetine         5 7.8         10.4         5 1.00         7 31.8         43.7         9 1.28         12.8           Fluoxetine         5 8.8         13.5         5 1.00         7 31.8         43.7         9 1.28         12.2           Fluoxetine         3 4.7         6.2         3 1.00         2 8.0         16.6         2 1.00         5 5.6           Reboxetine         3 5.3         8.1         3 1.00         2 9.1         12.5         2 1.00         5 6.3		Reboxetine	7	l			l		13.6			l			18.8	Ξ	1.10
Reboxetine         7 12.3         18.9         8 1.14         7 8.9         8 1.14         7 8.9           Machine         5 7.8         10.4         5 1.00         7 31.8         43.7         9 1.26         15.6           SORDERS         Fluoretine         3 4.7         6.2         3 1.00         2 8.0         16.6         2 1.00         5 5.6           Reboxetine         3 5.3         8.1         3 1.00         2 9.1         12.5         1.00         5 6.3	RESPIRATORY SYSTEM	Fluoxetine	7	i					L					L	16.6	£	1.10
SORDERS   Fluoretine   5 7.8 10.4 5 1.00   7 31.8 43.7 9 1.28 12 15.2   SORDERS   Fluoretine   5 8.8 13.5 5 1.00   7 31.8 43.7 9 1.28 12 15.2   SORDERS   Fluoretine   3 4.7 6.2 3 1.00   2 8.0 16.6 2 1.00   5 5.6   SORDERS		Reboxetine	7										_		13.2	60	1.14
SORDERS         Fluoretine         5         8.8         13.5         5         1.00         7         31.8         43.7         9         1.28         12         15.2           SORDERS         Fluoretine         3         4.7         6.2         3         1.00         2         8.0         16.6         2         1.00         5         5.6           Reboxetine         3         5.3         8.1         3         1.00         2         9.1         12.5         2         1.00         5         6.3	URINARY SYSTEM	Fluoxetine	Ŋ										r.		8.3	5	1.00
Fluoxetine 3 4.7 6.2 3 1.00 2 8.0 16.6 2 1.00 5 5.6 Reboxetine 3 5.3 8.1 3 1.00 2 9.1 12.5 2 1.00 5 6.3		Reboxetine	ιņ	!			ł								22.6	\$	1.16
3 5.3 8.1 3 1.00 2 9.1 12.5 2 1.00 5 6.3	VISION DISORDERS	Fluoxetine	6						8.0			i			8.3	5	1.00
		Reboxetine	3												9.4	5	1.00

CONTINUED

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

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

TABLE No.: 43

E EVENTS: NUMBER OF ADVERSE EVENTS AND PATIENTS WHO COMPLAINED OF THEM DURING THER

Body system/Assigned treatment	reatment			Female					Kale					Total		
		No of Pt	z on exp.	X on Pt No of with AE AE	No of	Ratio No of (*) Pt		x on x exp.	X on Pt No of with AE AE	No of AE	Ratio (*)	No of Pt		X on Pt No of with AE	No of	Ratio (*)
SKIN AND APPENDAGES	Fluoxetine	N	3.1	4.1	61	1.00	~	4.0	8.3	-	1.00	м	3.4	5.0	,e	1.8
a de la constante de la consta	Reboxetine	4	7.0	10.8	4	1.00	81	9.1	12.5	~	1.00	9	7.6	11.3	9	1.00
MUSCOLO-SKELETAL	Fluoxetine	-	1.6	2.0	-	1.00						-	1.1	1.6	-	1.00
CUPOUNCTO PETETS	Reboxetine	4	7.0	10.8	4	1.00	-	2.5	6.2	٦	1.00	ιŋ	6.3	4.6	5	1.00
METABOLIC AND	Fluoxetine	22	3.1	4.1	63	1.00	-	4.0	8.3	1	1.00	m	3.4	5.0	8	1.00
MULTITUDE DESCRIPTION	Reboxetine	-	1.8	2.7	-	1.00						-	1.3	1.8	-	1.00
RESISTANCE NECHANISM	Fluoxetine	23	3.1	4.1	63	1.00						2	2.2	3,3	2	1.00
	Reboxetine						62	9.1	12.5	2	1.00	2	2.5	3.7	2	1.00
REPRODUCTIVE DISCORDEDS MAIR	Fluoxetine						-	4.	8.3	_	1.00	1	1.1	1.6	1	1.00
PLESCRUCIOS) HOLE	Reboxetine						N	9.1	12.5	22	1.00	7	2.5	3.7	2	1.00
HEARING AND VESTIBULAR DISORDERS	Reboxetine		1.8	2.7	-	1.00	-	4.5	6.2	-	1.00	2	2.5	3.7	2	1.00
LIVER AND BILLIAR SYSTEM DISORDERS	Reboxetine	01	3.5	5.4	ю	1.50						83	2.5	3.7	3	1.50
HEMATOLOGY DISORDERS	Reboxetine	-	1.8	2.7	-	1.00						-	1.3	1.8	۳	1.00
REPRODUCTIVE DISORDERS, FEMALE	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1.8	-	1.00
SPECIAL SENSES OTHER, Reboxetine DISORDERS	Reboxetine	1	1.8	2.7	1	1.00						1	1.3	1,8	1	1.00

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

TABLE No.: 44

REBUNETINE - PROTOCOL 20124/016
TABLE No.: 44
ADVERSE EVENTS: OCCURENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATHENT

2											Days	Days of treatment	atment								
22:		Total	ם	0-7		8-14		15-21	-	22-28	_	29-35		36-42		43-49		50-56		> 56	
1		No AE	×	No AE	×	No AE Z	S.	AE	No No	AE	No X	AE.	몼	AE.	×	No AE	z No	AE	×	No AE	ж
Adverse events	Assigned treatment																				
HOUTH DRY	Fluozetine	80	100	9	75.0			61	25.0												
	Reboxetine	27	100	19	70.4	8	7.4	6	11.1					-	3.7	-	3.7	٦	3.7		
HEADACHE	Fluoxetine	28	100	80	28.6	8 21	28.6			E)	10.7	73	7.1	4	14.3	-	3.6	2	7.1		
	Reboxetine	21	100	7	33.3	3,	14.3	3.1	14.3	-	8.	4	19.0	-	4.8			2	9.5		
CONSTIPATION	Fluoxetine	7	100	83	28.6			2	28.6	-	14.3	2	28.6								
	Reboxetine	18	100	14	77.8	=	5.6	-	5.6	-	9.6						ļ	-	5.6		
INSOMNIA	Fluoxetine	11	100	N	18.2	8	27.3	2	18.2	-	9.1	-	9.1			2	18.2				İ
	Reboxetine	11	100	3	45.5	-	9.1	-	9.1	3	27.3			-	2.		_			-	
SHEATING INCREASED	Fluoxetine	6	100	4	44.4	60	33.3			-	11.1					1	11.1				
	Reboxetine	80	100	4	50,0	60	37.5	-	12.5	-		_									
DIZZINESS	Fluoxetine	8	100	en.	37.5	4 50	0.0	-	12.5												
	Reboxetine	18	100	7	38.9	8	16.7	2	11.1	-	5.6	21	2 11.1	-	5.6	2	11.1				
NAUSEA	Fluoxetine	15	100	9	0.04	4	26.7	2	13.3	-	6.7			-	6.7	-	6.7				
	Reboxetine	17	100	80	72.7			-	1.6			-	9.1	-	1.6	-					
TREMOR	Fluoxetine	s	300			1 2	20.0	2 4	40.0					-	20.0	1	20.02				
	Reboxetine	4	100	2	50.0	12	25.0	1	25.0												
MICTURITION DISORDER	Fluoxetine	-	100	-	90																
	Reboxetine	10	100	7	70.0	-	10.01			-	10.0			-	10.0						
INFLUENZA-LIKE	Fluoxetine	ro.	100			1 2	20.0			2 4	40.0	-	20.02			-	20.0				
	Reboxetine	8	100			2 6	66.7											-	33.3		
VISION ABNORMAL	Fluoxetine	4	100	**	25.0	2 20	0.0									-	25.0				
	Reboxetine	6	100	e	100								<u>-</u>								

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PHARHACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE NO.: 44 ADVERSE EVENTS: OCCURENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT

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Total   Color   Colo												ays of	Days of treatment	ent							
No AE	2		Tota	<u>-</u>	0-7		8-14		15-21	<u> </u>	22-28	61	29-35	36-42	-42	64-64	64	50-56	95	^	56
Fluozetine   Assigned treatment   100   5   100   10	22:		No AE	T			AE		AE		3	2	AE z	No AE	<b>R</b>	No AE	×	No AE	×	No AE	×
Reboxetine   1   100   5   100   1   100		ssigned treatment																			
Reboxetine		·luoxetine	-	100				100													
Fluozetine	<u>  104   </u>	Reboxetine	5	100	5	100					-		_								
Reboxetine		Juoxetine	4	100	8	50.0		-		-		_	1 25.0					1	25.0		
Fluozetine   2   100   1   50.0	102	Reboxetine	4	100	60	75.0		<u> </u>		0.0	_		_								
Reboxetine         3         100         1 38.3         1 33.3           Reboxetine         7         100         3 42.9         2 28.6         1           Reboxetine         3         100         1 33.3         1 33.3         1         1           Fluoxetine         2         100         1 50.0         1 100         1         1         1           Reboxetine         2         100         1 50.0         1 20.0         2         1		Tuoxetine.	63	100		0.02				_		_	1 50,0	<u> </u>							
Fluoxetine   7   100   3   42.9   238.6   1     Reboxetine   3   100   1   33.3   1   100     Reboxetine   2   100   1   50.0   1   100   1   100   1     Reboxetine   2   100   1   50.0   1   100   1   100   1   100   1   100   1   1	1 25	Reboxetine	ĸ	100	-	33.3				8.3				_		-	33.3				
Reboxetine         1         100         1         133.3         1           Reboxetine         2         100         1         50.0         1         1           Fluoxetine         2         100         1         50.0         1         1         1           Fluoxetine         5         100         2         40.0         1         20.0         2         1         1           Reboxetine         5         100         2         66.7         1		Juozetine	7	100	60	42.9	-		2 22	3.6		w	1 14.3	_							
Fluoxetime	i ee	Reboxetine	F	100				<u> </u>						ļ <u> </u>	1 100						
Reboxetime         2         100         1         50.0         1         100         1		luoxetine	en .	100	-	33.3					1 33	w.		-	1 33.3						
Flucatine	1 64	Reboxetine	23	100	-	50.0							1 50.0	_							
Feboxetine   2   100   1   50.0   2   40.0   3   40.0		luoxetine	-	100			L	100													
Flucatine   5 100   2 40.0   1 20.0   2   2   2   2   2   2   2   2   2	, us	Reboxetine	67	100		50.0						0.									
Reboxetine		Tuoxetine	S	100		40.0			1 20	9.0		0.									
Fluoxetine   3   100   2   66.7     100	114	Reboxetine	-	100	-	100			-	-											
Reboxetine		Tluoxetine	6	100			2 6	1.99	-		$\vdash$	-	1 33.3	·							
Flucoxetine   3   100   1   33.3   1   33.3   1   33.3       Reboxetine   4   100   2   50.0   1     Reboxetine   2   100   2   100   1     Flucoxetine   6   100   3   50.0   1	į iei	Reboxetine	٦	100						001											
Reboxetine         2         100         2         50.0         1           Reboxetine         4         100         2         50.0         1           Reboxetine         2         100         2         100         1           Fluoxetine         6         100         3         50.0         1		Fluoxetine	6	100	-	33.3	<u></u>	13.3	- 3	3.3		_									
INCREASED         Fluoxetine         4 100         2 50.0         1           Reboxetine         2 100         2 100         2 100         1           Fluoxetine         6 100         3 50.0         1         1		Reboxetine	77	100									1 50.0			-	1 50.0				
Reboxetine         2         100         2           Fluoxetine         6         100         3 50.0		Fluoxetine	4	100			61	0.0				0.				-	1 25.0				
Fluoxetine 6 100 3		Reboxetine	23	90				100						ļ							
		Fluoxetine	9	100	e)	50.0							2 33.3		1 16.7						
Reboxetine 1 100 1 100	LEG .	Reboxetine	1	100	1	100															

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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

											nays	15	mays or treatment								
22	•	Total		0-7		8-14	4	15-21	-	22-28	80	29-35		36-42		43-49		50-56		> 56	١
3		No AE	×	No AE	×	No AE	z n	No AE	×	No AE	×	No AE	Z No	Æ	×	No AE X		No AE	% No	38.	×
Adverse events	Assigned treatment														_						
CONJUNCTIVITIS	Fluoxetine	-	100	-	100																
	Reboxetine	-	100				_			-	100		ļ				-				
TASTE PERVERSION	Reboxetine	1	100	-	100						-									_	
HYPERTONIA	Fluoxetine	2	100	-	50.0	**	50.0				-										
HYPERTENSION	Fluoxetine	-	100	-	100		T				T	$\vdash$		$\dagger$							
	Reboxetine	-	90						T	-	100			-	_	-	-				
VOMITING	Fluoxetine	22	100	1	50.0							1.	50.0		$\vdash$		<u> </u>		<u> </u>	<del>                                     </del>	
	Reboxetine	6)	10	64	66.7			-	33.3						<u> </u>	_					
RHINITIS	Fluoxetine	en .	100	-	33.3			-	33.3			-	33.3								ŀ
	Reboxetine	-	100															-	100		
ABDOMINAL PAIN	Reboxetine	4	100	-	25.0							2 5	50.0	-	25.0		<del> </del>				
GASTRITIS	Fluoxetine	-	100			-	100								<u> </u>	-			<del>                                     </del>		
	Reboxetine	٦	92							-	100										
BREAST FIBROADENOSIS	Reboxetine	٢	100			-	100											-			
PHARYNGITIS	Fluoxetine	82	100							-	20.0					1 50	20.0		-		
	Reboxetine	-	100					-	100					1							
URINARY RETENTION	Reboxetine	63	100	1	50.0									-	50.0						
PALPITATION	Rebaxetine	77	90	-	50.0		-	-	50.0				-								
FEVER	Fluoxetine	77	100					-	50.0				-			1 50	20.0				ľ
	Reboxetine	77	100	-	50.0	-	50.0						-				-				
BACK PAIN	Reboxetine	m	100			22	66.7	-	33.3			_									
CVCTTTC		'			ľ		I	ľ	l	ĺ	ľ	l	-	f				l	ŀ	İ	

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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

2										_	ays	# THE	Days of treatment	ų						
2		Total	Ę.	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	z No	AE	×	No AE 2	No No	AE Z	2	AE x	€	AE z
Adverse events	Assigned treatment				ļ						H									
CYSTITIS	Reboxetine	_	100					-	100		_									
HEPATIC ENZYNES INCREASED	Reboxetine	67	100							1.5	50.0					1.	50.0			
ALLERGIC REACTION	Fluoxetine	-	100								-	_		-	100				_	
	Reboxetine	-	100													-	100			
FLUSHING	Reboxetine	22	100	-	50.0			-								7	50.0			
RESPIRATORY DISORDER	Reboxetine	N3	100	٢	50.0							-	50.0							
EUPHORIA	Reboxetine	2	100	-	50.0	-	1 50.0													
URINARY TRACT	Fluoxetine	61	100			-	50.0			1.00	50.0									
	Reboxetino	_	100	٦	100															
EPISTAXIS	Reboxetine	-	100			-	100													
HYPERURICAENIA	Fluoxetine	_	100						<b></b>	-	100									
COUGHING	Fluoxetine	-	100													-	100			
	Reboxetine	_	100															,	100	
OTITIS MEDIA	Fluoxetine	_	100			-	100													
ANXIETY	Fluoxetine	_	100					٦	100											
	Reboxetine	_	100			-	100				_									
HYPERKINESIA	Fluoxetine	_	100									-	100							
CHEST PAIN PRECORDIAL	Fluoxetine	-	100									1	100							
RASH	Reboxetine	2	100	-	50.0							-	50.0				_			
HYALGIA	Fluoxetine	-	100			-	100													
	Reboxetine	-	100	٦	100					-						-				_

PHARMACIA CNS R&D

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

2											Days	Days of treatment	tment							
2		Total	- <u>-</u>	0-7		8-14	4	15-21	_	22-28		29-35	36-42	8	43-49		50-56	-	> 56	
ú		No AE	×	No AE	×	No AE	×	No AE	×	No AE	×	No AE Z	No AE	ĸ	No AE	No No	SE SE	Z No	AE	×
Adverse events	Assigned treatment																			
VERTIGO	Reboxetine	m	100	-	33.3			~	33.3			- 33	w.							
TINNITUS	Reboxetine	83	100	2	100															
HYPOTENSION POSTURAL	Reboxetine	-	100						_	-	9				-				<u> </u>	
IMPOTENCE	Fluoxetine	٦	100									-	100	<u> </u>			1		T	
OEDEKA LEGS	Reboxetine	٦	30									-	100				<u> </u>			
HYPOTENSION	Fluoxetine	-	100												-	100				
	Reboxetine	-	100														-	100		
TENDINITIS	Reboxetine	٦	100												-	100				
ANOREXIA	Reboxetine	-	100												-	100				
HYPERCHOLESTEROLAEMIA Fluoxetine	Fluoxetine	2	100								ļ						-	50.0	7	50.0
	Reboxetine	1	100														-	100		
INFECTION VIRAL	Fluoxetine	-	100	-	100													-		
XERDPHTHALMIA	Reboxetine	•	100	-	100															
LIBIDO DECREASED	Reboxetine	•	100	_	100															
SPERMATORRHOEA	Reboxetine	-	100	-	100															
ASTHENIA	Fluoxetine	1	100			-	100													
OEDEMA GENERALISED	Fluoxetine	-	100					1	100											
SUICIDE ATTEMPT	Fluoxetine	-	100							-	9									
	Reboxetine	-	100									-	100							
FLATULENCE	Fluoxetine	-	100							-	100									
RASH MACULO-PAPULAR	Fluoxetine	1	100								ļ	-	100				-			
PARONIRIA	Fluozetine	-	100												-	100			_	

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PHARMACIA CNS RED

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

										ដ	ys of	Days of treatment	ment							
		Total	l	0-7	$\vdash$	8-14		15-21	22	22-28	ži	29-35	36-42	745	43	65-65	-50	99-09	^	26
		No AE 2	× No	AE	×	No AE	× ×	AE X	No A	AE x	N .	AE z	No AE	א	No A	AE z	No AE	×	No AE	×
Adverse events	Assigned treatment																			
ANAEMIA	Reboxetine	-	100													1 100				
SINUSITIS	Fluoxetine	-	100		-							_						1 100		
HYPERPYREXIA	Reboxetine	-	100	-	100			_								_		_		
CIRCULATORY FAILURE	Reboxetine	-	100			-	100											_		
EJACULATION DISORDER	Reboxetine	-	100			-	100									_				
HIGRAINE	Reboxetine	-	100					1	100											
RENAL PAIN	Fluoxetine	-	100		-					1 100	00									
MALAISE	Fluoxetine	-	100	_						1 16	100							_		
ALOPECIA	Reboxetine	•	100							1 100	00	- 11-				_				
BRONCHITIS	Fluoxetine	-	100									1 100	0			_				
TACHYCARDIA	Reboxetine	-	100		-							1 100	0							
HEPATITIS INFECTIOUS	Reboxetine	-	100																_	9

PHARMACIA CNS R&D

	ADVERSE EVENTS: OCCURENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY SYSTEM	ENCE OF	ADVER	SE EVI	ENTS ,	ACCORDI	NG TO	TIME	OF O	SET B	ASS.	CNED TR	EATHE	NT ANI	800	SXS	LEM		
Body system: AUTONOMIC NERYOUS SYSTEM DISORDERS	NERVOUS SYSTEM DISORDE	SS																	
Adverse events/Assigned troatment	d treatment			:							Day	Days of treatment	atmen						
		Total	_	0-2		8-1	8-14	15-21	12	22-28	80	29-35		36-42		43-49	64	50-56	Q.
		No AE	×	No AE	×	No AE	N	No AE	к	No AE	×	NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE	×	o AE	N	do AE	×	No AE	٠٠.
MOUTH DRY	Fluoxetine	80	8 100		6 75.0			2	2 25.0										
_	Reboxetine	27	27 100		19 70.4		2 7.4		3 11.1				<u> </u>	-	3.7	-	1 3.7	-	1"
SHEATING INCREASED	Fluoxetine	6	9 100	4	4.44.4		3 33.3			-	11.1					-	11.1		
	Dotomoting	۰	707	ı	4		0	٦	4 6 4						l				

No AE

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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 tr	d treatment										Days	Days of treatment	aatme	ij							
		Total		0-7		8-14	4	15-21	_	22-28	_	29-35	_	36-42	2	43-49	6	20-56	ų	> 56	9
		No AE	× %	AE	×	No AE	×	No AE	×	No AE	*	No AE	×	No AE	×	No AE	×	No AE	*	No AE	×
INFLUENZA-LIKE	Fluoxetine	ις	100			<del>,,,</del>	1 20.0			23	2 40.0	-	1 20.0			-	20.0				
	Reboxetine	8	100			73	2 66.7		-									-	33.3		
ASTHENIA / FATIGUE	Fluoxetine	-52	100	2	2 40.0	-	20.0				ļ	-	20.0					-	20.0		
	Reboxetine	4	100	3 7	3 75.0			-	1 25.0												
FEVER	Fluoxetine	2	100						1 50.0							-	1 50.0				
	Reboxetine	63	100	1.5	1 50.0	-	1 50.0														
ALLERGIC REACTION	Fluoxetine	-	100		<del>                                     </del>			-						1	100						
	Reboxetine	-	100						<u> </u>							-	100				
HYPERPYREXIA	Reboxetine	-	100	-	100																
HALAISE	Fluoxetine	-	100							-	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: CARDIOVASCULAR DISORDERS, GENERAL

Adverse events/Assigned	l treatment										Days	Days of treatment	reatm	ent							
		Total		0-7		8-14	-	15-21	_	22-28	38	29-35	35	36	36-42	-643-	65-65	99-09	95	^	95
		No AE	*	No AE	×	No AE	×	No AE	*	No AE	×	No AE	×	No AE	×	No AE	×	No AE	×	No AE	*
HYPOTENSION AND	Fluoxetine	60	101	æ	33.3	4	4.44.4	-	1 11.1								11.1				
	Reboxetine	20	100	7	7 35.0	m	15.0	2	2 10.0	10	2 10.0	8	2 10.0		1 5.0		2 10.0		5.0		
FLUSHING / HOT	Fluoxetine	-	901			٦	90	-													
	Reboxetine	4	100	23	2 50.0					-	25.0						1 25.0				
HYPERTENSION	Fluoxetine	٦	100	-	100																
	Reboxetine	-	100			-				-	100										
PALPITATION	Reboxetine	0	100	-	1 50.0			+	1 50.0												
AEDEMA	Fluoxetine	-	100					-	100												
	Reboxetine	-	90									ı	100								
CARDIAC ISCHENIA AND RELATED SYMPTOMS	Fluoxetine	-	5									L	100								
CIRCULATORY FAILURE	Reboxetine	-	100			-	100														
TACHYCARDIA	Reboxetine	-	100									1	100								

ome adverse events are grouped in clus

PHARMACIA CNS RED

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

Body system: CENTRAL & PERIPHERAL NERVOUS SYSTEM DISC

Adverse events/Assigned	d treatment										Days	of t	Days of treatment	nt nt							
		Total	-	0-7		8-14		15-21	_	22-28	60	29-35	35	36-42	2	43-49	ď.	20-56	يو	> 56	90
		No AE	×	No AE	×	No AE	*	No AE	×	No AE 2		No AE	×	No AE	×	No AE	*	No AE	×	No AE	н
HEADACHE / MIGRANE	Fluozetine	28	100	α	8 28.6	80	8 28.6			m	10.7	77	7.1	4	4 14.3	-	3,6	63	7.1		
	Reboxetine	22	100	7	7 31.8	ю	3 13.6	4	4 18.2	-	4.5	4	4 18.2	٢	4.5			61	9.1		
TREMOR	Fluoxetine	Ω	100			-	1 20.0	C3	2 40.0					-	1 20.0		1 20.0				
	Reboxetine	4	5	87	2 50.0	-	1 25.0	٦	1 25.0												
PARAESTHESIA	Fluoxetine	٦	9			-	100														
	Reboxetine	ιŋ	5	r)	5																
HYPERTONIA	Fluoxetine	2	100	-	90.0	-	1 50.0														
HYPERKINESIA	Fluoxetine	-	100									-	<b>1</b>								
VERTIGO	Reboxetine	6	100	-	1 33.3			-	33.3			-	1 33.3								

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	d treatment										Days	Days of treatment	eatme	int							
		Total	r-t	0-7		8-14	2	15-21	-	22-28	ag ag	29-35	2	36-42	42	43-49	<u></u>	50-56	9	> 56	, <u>e</u>
		No AE	×	No AE	×	No AE	×	No AE	×	No AE	×	No AE	74	No AE	×	No AE	×	No AE	x	No AE	ж
CONSTIPATION	Fluoxetine	7	Ē	2	2 28.6			64	2 28.6	-	14.3	И	2 28.6								
	Reboxetine	18	100	14	14 77.8	-	5.6	-	5.6	-	5.6							-	5.6		
NAUSEA AND RELATED	Fluoxetine	23	9	6	9 39.1	S	21.7	60	3 13.0	E)	3 13.0	1	4.3		4.3	-	4.3				
2001	Reboxetine	15	100	10	10 66.7			61	13.3	-	6.7	-	6.3		6.7						
APPETITE INCREASED	Fluoxetine	4	100			2	50.0			-	25.0					-	1 25.0				
DIARRHOEA	Fluoxetine	9	100	M	3 50.0							61	2 33.3		1 16.7						
	Reboxetine	-	100	-	100																
ABDOMINAL PAIN	Reboxetine	4	100	-	25.0							61	2 50.0		1 25.0						
ANDREXIA	Reboxetine	-	100													-	100				
FLATULENCE	Fluoxetine	-	100							-	100										

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PHARHACIA CNS R&D TINE - PROTOCOL 20124/016

REBOXETINE - PROYOCOL 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	d treatment									ă	Days of treatment	treatm	ent						
		Total	<u></u>	6-7		8-14 15-21	-	15-21		22-28	29	-35	22-28 29-35 36-42	_	67-67		50-56		> 56
		No AE	×	o AE	×	fo AE	No.	AE:	ž	AE Z	N ON	Z E	No AE z No AE z No AE z No AE z No AE z No AE z No AE z No AE z No AE z No AE	×	AE 2	2	Y Z	Q.	AE X
TINNITUS	Reboxetine	73	100	2 100	100				_									_	

adverse events are grouped in cluster)

PHARMACIA CNS R&D

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

Body system: HEMATOLOGY DISORDERS	DISORDERS																				
Adverse events/Assigned treatment	d treatment										Days	Days of treatment	atnen	٠,							
		Total		0-7		1	₹	8-14 15-21 22-28 29-35	-	22-25	_	29-35	_	36-42		36-42 43-49 50-56		50-5		> 56	92
		No AE	×	No AE	×	No AE	×	NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X	×	lo AE	*	10 AE	ž	o AE	×	O AE	2	o AE	×	No AE	×
ANEHIA	Reboxetine	-	100										Н	П	-	-	100				

Adverse events/Assigned treatment	i treatment									Da	Days of treatment	eatne	ıt						
		Total	1	0-7		8-14	-	8-14 15-21	22-28	-28	29-35		36-42	43-49	64-	50-56	95	> 56	26
		No AE	×	io AE	×	NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE	S.	AE z	No A	×	No AE	×	No AE 3	No A	z E	No AE	×	No AE	×
INCREASED LIVER ENZYMES	Reboxetine	8	100							1 50.0	6				1 50.0				
HEPATITIS INFECTIOUS Rebo	Reboxetine	-	100				-	-		_				_				1	100

PHARMACIA CNS R&D

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 tre	i treatment		_								Days	Days of treatment	reatm	art							
		Total		2-0		8-14		15-21	-	22-28	80	29-	29-35	36-4;	-	36-42 43-49		50-56	<u>.</u>	^ 56	ų,
		NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE	ž	, AE	×	No AE	*	No AE	×	No AE	и	No AE	×	No AE	и	No AE	×	O AE	×	AE.	N
HYPERURICAENIA	Fluoxetine	-	100							-	100										
HYPERCHOLESTEROLAEMIA Fluoxetine	Fluoxetine	2	2 100															-	1 50.0	-	50.0
	Reboxetine	-	100															-	100		

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 45

TABLE No.: 45
ADVERSE EVENTS: OCCURENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATMENT AND BODY EYSTEM

Body system: MUSCOLO-SKELETAL SYSTEM DISORDERS

Adverse events/Assigned	d treatment										Day	Days of treatment	reat	ment								
		Total	_	0-7		å	4	8-14 15-21	7:	22-28	28	29-35	35	ñ	36-42		64-64	Ľ.	50-56		> 26	
		NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE	×	No AE	*	No AE	×	No AE	×	No AE	м	No AE	×	No.	/E x	No A	×	운	AE 2	2	¥E.	ж
BACK PAIN	Reboxetine	m	3 100			2	2 66.7	ļ.	1 33.3						_			_				
HYALGIA	Fluoxetine	٦	5			-	100											_	-	_		
	Reboxetine	-	90	-	100										_				<u></u>			
TENDINITIS	Reboxetine	-	90												-		1 100	0				

me adverse events are grouped in cluster)

PRARMACIA CNS R&D

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

RDERS	
c DISO	
PSYCHIATRI	
system:	
ğ	

Adverse events/Assigned treatment	d treatment										Days	Days of treatment	atner	ı,							
		Total		0-7		8-14	4 -	15-21		22-28		29-35		36-42	2	43-49	ď.	50-56	92	^	> 56
		No AE	×	No AE	×	No AE	×	No AE	×	No AE	×	No AE	×	No AE	*	No AE	×	No AE	×	No AE	× 101
INSOMNIA	Fluoxetine	1	100	73	2 18.2	8	27.3	2 1	18.2	-	9.1	-	4.6			67	18.2				
	Reboxetine	11	100	2	5 45.5	-	9.1	-	9.1	3	27.3			٦	9.1						
AGITATION / ANXIETY / Fluo	Fluoxetine	11	100	60	27.3	10	18.2	8	27.3	-	9.1	63	2 18.2								
	Reboxetine	ĸ	100			-	33.3	-	33.3			-		-	33.3						
SOMNOLENCE	Fluoxetine	8	100	-	33.3				-	-	33.3			-	33.3						
	Reboxetine	61	100	-	50.0		-		-			-	1 50.0								
EUPRORIA	Reboxetins	63	100	-	1 50.0	-	50.0						_								
LIBIDO DECREASED	Reboxetine	1	100	-	100																
SUICIDE ATTEMPT	Fluoxetine	-	100							-	100										
	Reboxetine	-	100									-	100								
PARONIRIA	Fluoxetine	1	100						-							1	100				

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 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 tr	1 treatment										Days	Days of treatment	затшен	يد						
		Tota1	_	0-7		8-1	4	8-14 15-21	-	22-28	eg.	29-35		36-42		43-49	<u>-</u> '	50-56		> 56
		No AE	×	io AE	N	No AE	×	No AE	к	No AE	×	NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X	×	o AE	×	AE Z	2	AE z	No AE	z a
BREAST FIBROADENOSIS	Reboxetine	-	90,			٦	100								$\vdash$				_	

ome adverse events are grouped in cluste

PHARMACIA CNS RED INE - PROTOCOL 20124/016 TABLE No.: 45

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

	STATES EVENTS. OCCURATE OF STATES RESIDENCE OF THE OF ORDER OF STATES OF STA	3		1	975				5	1	, G						i		
Body system: REPRODUCTIVE DISORDERS, MALE	JE DISORDERS, MALE																		
Adverse events/Assigned treatment	i treatment	ļ									Days	Days of treatment	eatme	먋					
		Total		0-7		<u> </u>	8-14	15-21	_	22-28	28	29-35	5	36-42	2	43-49		50-56	_
		No AE	*	lo AE	×	No AE	×	No AE	*	No AE	z	No AE	×	No AE	×	NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X	ж	No AE	×
IMPOTENCE	Fluoxetine	-	100									-	100						
SPERMATORRHOEA	Reboxetine	-	100	-	100														
EJACULATION DISORDER Reboxetine	Reboxetine	-	100			-	100												
		1	1						١				1						

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	d treatment										Days	Days of treatment	eatme	at							
		Total	_	0-7		8-1	4	8-14 15-21	-	22-28	89	29-35	ıç.	36-42	9	43-49	6	50-56	9	> 56	9
		NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE	*	to AE	×	No AE	*	No AE	*	No AE	×	No AE	×	No AE	ж	No AE	×	No AE	×	No AE	×
ABSCESS	Reboxetine	77	2 100			23	2 100														
OTITIS MEDIA	Fluoxetine	-	100			-	1 100														
INFECTION VIRAL	Fluoxetine	-	100	-	300																

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No:: 45

	BODY SYSTEM
	BODY
	AND
	TREATMENT
	ASSIGNED
	T BY
	NG TO TIME OF ONSET B
_	P
?	TIME OF
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ייים איים איים איי	CORDI
	EVENTS AC
	ADVERSE
	: OF
	OCCURENCE
	EVENTS:
	ADVERSE EVENTS

Body system: RESPIRATORY SYSTEM DISORDERS

Adverse events/Assigned treatment	1 treatment		-								Days	Days of treatment	eatme	ııt							
		Total		0-7		8-14	4	15-21	_	22-28	60	29-35	'n	36-42	27	43-49	61	50-56	56	^	> 56
		No AE	N	No AE	ж	No AE	м	No AE	×	No AE	ĸ	No AE	×	No AE	×	No AE	×	No AE	*	No AE	×
UPPER RESP TRACT	Fluoxetine	w	100	-	1 33.3	٢	1 33.3	-	33.3												
	Reboxetine	67	100									1	50.0			-	1 50.0				
RHINITIS	Fluoxetine	m	100	۳	33.3			-	1 33.3			1	1 33.3								
	Reboxetine	-	100																100		
PHARYNGITIS	Fluoxetine	67	100							-	1 50.0					1	1 50.0				
	Reboxetine	-	100					-	100												
RESPIRATORY DISORDER	Rebuxetine	77	100	-	1 50.0							-	1 50.0								
EPISTAXIS	Reboxetine	٦	100			-	100														
COUGHING	Fluoxetine	-	100													-	100				
	Roboxetine	-	100															٢	100		
SINUSITIS	Fluoxetine	-	100																100		
BRONCHITIS	Fluoxetine	-	100									-	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

dy system: SKIN AND APPENDAGES DISORDERS	APPENDAGES DISORDERS																			
dverse events/Assigned treatment	ed treatment									Days	Days of treatment	eatme	벑							
		Total	<u></u>	0-7		8-14 ·	8-14 · 15-21		22-28	8	29-35	S	36-42		43-49		50-56	5	> 56	l,
		No AE	*	Yo AE	×	NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE X NO AE	No AE	×	o AE	N	No AE	×	No AE	N.	lo AE	×	o AE	*	No AE	*
RURITUS	Fluoxetine	2	100	-	1 50.0						-	20.0		-						
	Reboxetine	8	3 100	-	33.3		-	33.3							13	33.3				
RYTHEMA / RASH	Fluoxetine	-	100								-	100					<u> </u>			
	Reboxetine	22	2 100	٦	50.0						-	1 50.0					ļ			
LOPECIA	Reboxetine	-	100						-	100				-						

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ome adverse events are grouped in cluster)

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TARLE 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	ed treatment									Day:	Days of treatment	eatmer	<u>+</u>						
		Total	L	0-7		8-14	8-14 15-21	-21	22-28	28	29-35		36-42 43-49 50-56	-	43-49		95-0		> 56
		No AE	z ×	o AE	×	NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE	No A	<b>84</b>	No AE	×	No AE	*	to AE	ź	, AE	Š	AE ;	2	AE X
TASTE PERVERSION	Reboxetine	-	100	-	100			ļ								_			

erse events are grouped in cluster)

PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 45

	Y SYSTEM	
	ND BOD	
	INT A	
	EVENTS ACCORDING TO TIME OF ONSET BY ASSIGNED TREATME	
	E	
	ASSIC	
	T BY	
	ONSE	
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	E G	
	ING 1	
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	NTS A	
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	SRSE EVENTS: OC	DERS
	E E	ISORI
	ADVER	TEN
		Y SYS
		RINAR
		] :wa
		syst
		Body s

Adverse events/Assigned treatment	ed treatment										Days	Days of treatment	tment							ļ
		Total	<u> </u>	0-7	_	κ'n	8-14	15-21	<u>.</u>	22-28	_	29-35	ĕ	36-42	64-64	64	50-56	9	^ S	26
!		No AE	×	No AE	×	No AE	м	No AE	м	No AE	×	No AE X	×	AE Z	No AE	×	No AE	×	No AE	*
URINARY HESITANCY /	Fluoxetine	-	ē	-	100								-	-						
	Reboxetine	12	100	80	66.7	-	8.3		T	-	8.3	-	_	2 16.7	_					
CYSTITIS	Fluoxetine	-	10						1				-	-			-	100		
	Reboxetine	-	100					-	100	1										
URINARY TRACT	Fluoxetine	2	5			-	50.0		T	F	50.0			<u> </u>						
	Reboxetine	-	ē	-	100				<u> </u>					<del> </del>						
RENAL PAIN	Fluoxetine	-	5							-	100			-						

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/016

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

Body system: VISION DISORDERS

Adverse events/Assigned treatment	d treatment										Days	Days of treatment	satmei	쓮							
		Total	<u> </u>	0-7		8	8-14	15-21	-	22-28	80	29-35		36-42	8	43-49	6	50-56		, 56	يوا
		No AE	×	o AE	м	No AE	×	No AE	×	Yo AE	×	NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z NO AE Z	*	TO AE	×	No AE	ж	No AE	×	No AE	*
BLURRED VISION	Fluoxetine	4	4 100	-	1 25.0	8	2 50.0									-	1 25.0				
	Reboxetine	8	3 100	6	3 100																
CONJUNCTIVITIES	Fluoxetine	-	100	-	100																
	Reboxetine	-	1 100							-	100										
XEROPHTHALMIA	Reboxetine	-	1 100	-	1 100				_												

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PHARMACIA CNS R&D

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

										Day	t of	Days of treatment	ant.						
24		Į.	Total	0-7	7	8-14	-	15-21		22-28	29-	29-35	36-42	- 2	43-49	-	50-56	^	26
6		No	Ж	AE No	м	No AE	м	No AE Z	S S	×	No AE	×	AE AE	24	Ne Ne	No Z AE	- N	No AE	*
Body system	Assigned treatment						-		_							_			
AUTONOMIC NERVOUS	Fluoxetine	17	100	9	10 58.8	<u>8</u>	3 17.6	2 7	11.8	1 5.9					-	5.9			
	Reboxetine	35	100	23	65.7	5.1	5 14.3	4	11.4				-	2.9	-	2.9	2	2.9	
GASTRO-INTESTINAL	Fluoxetine	7	10	7	34.1	7 1	7 17.1	5 12	12.2	6 14.6	3	12.2	8	4.9	2	6.4			
SISTER DISORDERS	Reboxetine	40	100	27	67.5	-	2.5	3	7.5	2 5.0	3	7.5	8	5.0	-	2.5	7	2.5	
CENTRAL & PERIPHERAL	Fluoxetine	37	100	6	24.3	11 2	29.7	C2	5.4	3 8.1	8	8.1	5.	13.5	64	5.4	2 5	4.6	
MENTOUS SISTER ULSO	Reboxetine	*	100	15	44.1	4	4 11.8	6 17	17.6	1 2.9	5	14.7	-	2.9			2 5	5.9	
PSYCHIATRIC DISORDERS	Fluoxetime	27	100	9	22.2	5	18.5	5 18	18.5	4 14.8	3	11.1	-	3.7	ю -	11.1			
	Reboxetine	20	100	80	0.04	3	15.0	2 10	10.0	3 15.0	2	10.0	2	10.0	-				
CARDIOVASCULAR DISORDERS CENERAL	Fluoxetine	13	100	4	30.8	e.	38.5	2 15	15.4		_	7.7		-	<del>-</del>	7.7			
DISONDENS, SENERGE	Reboxetine	30	100	10	33.3	4	13.3	3 10	10.0	4 13.3	*	13.3	-	3.3	3	10.0	1 3	3.3	
BODY AS A WHOLE-	Fluoxetine	4	100	61	14.3	2	14.3	-	7.1	3 21.4	22	14.3	-	7.1	2	14.3	1 7	7.1	
SERVERGE PESSONDERS	Reboxetine	=	100	5	45.5	3	27.3	-	9.1				-		-	9.1	- 6	9.1	
RESPIRATORY SYSTEM	Fluoxetine	11	100	62	18.2	-	9.1	2 18.	3.2	1 9.1	2	18.2			2	18.2	-	1.6	
	Reboxetine	80	100	-	12.5	-	1 12.5	1 12	12.5		23	25.0			1 12.	5.5	2 25.0	0	
URINARY SYSTEM	Fluoxetine	2	100	-	20.0	1	20.0			2 40.0	_						1 20.	0.	
	Reboxetine	14	100	6	64.3	-	7.1		7.1	1 7.1			2 1	14.3					
VISION DISORDERS	Fluoxetine	r.	100	2	40.0	2	40.0								1	20.0			
	Reboxetine	ď	100	4	0.08					1 20.0	_								
SKIN AND APPENDAGES	Fluoxetine	е	100	1	33.3	<del> </del>					2	66.7		-					
CHICAGO	Reboxetine	9	100	2	33.3			1 16.7	5.7	1 16.7		1 16.7		-	1 16.7	6.7	_		_

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 46
WERSE EVENTS: OCCURENCE OF ADVERSE EVENTS ACCORDING TO TIME OF ONSE

											Days of treatment	f tr	atmen	يد						
		Total	덛	0-7	_	8-14		15-21	-	22-28	80	29-35		36-42		65-65	- in	50-56	_	82
		A E	×	No AE	м	Ne AE	*	P H	*	N S	2	No Y	Z 4	No AE x		No AE Z	N P	×	AE AE	×
Body system	Assigned treatment							-												
RESISTANCE MECHANISM	Fluoxetine	87	100	÷	1 50.0	-	50.0						-111							
	Roboxetine	82	9			72	5			$\vdash$		_	_							
MUSCOLO-SKELETAL	Fluoxetine	-	100			-	100	-												
	Reboxetine	r.	100	-	20.0	2 4	40.0	-	20.0							1 20.0	0			
SPECIAL SENSES OTHER, DISORDERS	Reboxetine	٦	92	-	100															
REPRODUCTIVE DISORDERS, FEMALE	Reboxetine	-	100			-	100													
LIVER AND BILIAR SYSTEM DISORDERS	Reboxetine	60	100							-	33.3					1 33.3	m		,	1 33.3
METABOLIC AND	Fluoxetine	6	100		-					4	33.3				_			1 33.3	,	1 33.3
	Reboxetine	-	100															1 100		
REPRODUCTIVE DISORDERS MAIF	Fluoxetine	-	100									-	100							
	Reboxetine	71	100	-	50.0	-	50.0													
HEARING AND VESTIBULAR Reboxetine DISORDERS	Reboxetine	7	100	23	100															
HEMATOLOGY DISORDERS	Reboxetine	-	9		П	П			H	Н	H	$\vdash$	$\vdash$	_		1 100	9			

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PHARMACIA CNS R&D

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

Adverse events / severity	averity	Adverse events	Dose	Dose taken on onset date	date	Highest dose	Highest dose taken from 3 days before	ays before
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
All adverse events Mild	Mild	66	76	S		95	4	
	Moderate	86	*	4		76	4	
	Severe	17	17			11		
	Unknoнn	7	7			4		
	Total	221	212	6		213	8	
READACHE	Mild	7	9	7-		9	ı	
	Moderate	14	14			14		
	Total	21	20	-		20	1	
NAUSEA	Mild	2	N			N		
	Moderate	6	6			G.		
	Total	11	11			11		
INSOMNIA	Nild	*	4			7		
	Moderate	9	S	1		\$	1	
	Severe	-				1		
	Total	1	10	1		10	1	
SWEATING INCREASED Mild	Hild	r)	S.			S		
	Moderate	R	Ø			3		
	Total	8	8			60		
DIZZINESS	Hild	13	12	•		13	٠	
	Moderate	5	4	-		4	1	
	Total	18	16	2		17	1	

FHARMCLA CHS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 47

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ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE By Severity and Assigned treatment

ssigned treatment: Reboxetine	Reboxetine							
Adverse events / severity	everity	Adverse events	Dose	Dose taken on onset date	date	Highest dose	Highest dose taken from 3 days before	ays before
		Number	Сом dose (*)	High dose	Overdose	Гон фозе (ж)	High dose	Overdose
HOUTH DRY	Mild	17	16	1		16	-	
	Moderate	80	80		,	0		
	Severe	2	2			2		
	Tota1	27	26	-		26	-	
CONSTIPATION	Nild	7	7			4		
	Moderate	8	8			æ		
	Severe	8	3			ĸ		
	Total	18	18			18		
AGITATION	Moderate	1		-			-	
	Total	-		-			1	
DIARRIGEA	Hild	•				1		
	Total	-	1			1		
TREMOR	изта		2			2		
	Moderate		2			2		
	Total	4	*			4		
DYSPEPSIA	Unknown	-	1			1		
	Total	-	-			1		
INFIUENZA-LIKE	Moderate	æ	ĸ			6		
	Total	ET.	ĸ			8		
VISION ABNORMAL	Nild	2	2			2		
	Moderate	1				1		

(\*) all remainder patients BOXETINE - luw dosse <= 8 mg/day, high doss > 8 mg/day LOXETINE - luw dosse <= 20 mg/day, high dosse > 20 mg/day

PHARMACIA CNS R&D

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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

dverse events / severity	sverity	Adverse events	Dose	Dose taken on onset date	date	Highest dose	Highest dose taken from 3 days before	lays before
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
TISTON ABNORMAL	Total	n	m			m		
ATICUE	изла	-	**			-		
	Noderate	NI NI	7			Ø		
	Severe	7	-			-		
	Total	4	4			7		
VERVOUSNESS	Moderate	-	1			1		
	Total	٢	1			-		
SOHNOLENCE	Mild	-	1			ı		
	Hoderate	**	-			-		
	Total	2	Ø			N		
HINITIS	Moderate	-	-			1		
	Total	-	-			ı		
UPPER RESP TRACT	Moderate	-	-			1		
	Unknown	-	١			1		
	Total	2	2			2		
HYPERCHOLESTEROLA- Mild	Nild	1	F			1		
	Total	1	ı			1		
URINARY TRACT	Unknown	1	1			-		
	Total	1	1			1		
FEVER	Mild	1	1			1		
	Moderate	1	ı			1		

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D

ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE By Severity and Assigned treathent

essigned treatment: Keboxetine	керохеттве							
Adverse events / severity	everity	Adverse events	Dose	Dose taken on onset date	date	Highest dose	Highest dose taken from 3 days before	lays before
		Nunber	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
FEVER	Total	8	и			2		
PRURITUS	Mild	2	N			N		
	Moderate	-		-			1	
	Total	en .	2	7		8	•	
VONITING	Moderate	N	N			N		
	Savere	٢	1			•		
	Total	ĸ	3			8		
PHARYNGITIS	Moderate		7			1		
	Total	1	1			•		
MYALGIA	Moderate	•	1			1		
	Total	-	1			1		
COUGHING	Moderate	•	1			ı		
	Total	•	1			1		
CYSTITIS	Severe		1			1		
	Total	1	1			1		
HOT FLUSHES	Nild		1			1		
	Moderate	1	1			1		
	Total	81	82			2		
PARAESTHESIA	нін	8	E			8		
,	Moderate	1	·			1		
	Severe	-	L			1		

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PHARMACIA CNS RRD

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

Adverse events / severity PARAESTHESIA Total HYPERTENSION Moderate Total HYPOTENSION Severe	Adverse event Number	Low dose	Dose taken on onset date (*) High dose O	late	Highest dose	Highest dose taken from 3 days before	days before
d: 72	Munber	Low dose (*)	High dose				
4 2				Overdose	Low dose (*)	High dose	Overdose
×		5			Ŋ		
		1			-		
		-			-		
		-			1		
Total		-			7		
CONJUNCTIVITIS Moderate		-			7		
Total		1			-		
GASTRITIS Mild		-			-		
CC Total		1			1		
MICTURITION Mild		4			4		
Moderate		5			S		
Severe		1			1		
Total	<del>-</del>	10 10			10		
ANXIETY		1			1		
Total		1			1		
SUICIDE ATTEMPT Severe		1			1		
Total		1			1		
ALLERGIC REACTION Moderate		1			1		
Total		1			1		
ABDOMINAL PAIN Mild		1			1		
Moderate		2			N		

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PHARMACIA CNS R&D TINE - PROTOCOL 20124/016 ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE BY SEVERITY AND ASSIGNED TREATHENT

Assigned treatment: Reboxetine

'								
Adverse events / severity	sverity	Adverse events		Dose taken on onset date	date	Highest dase	Highest dose taken from 3 days before	lays before
		Number	Low dose (*)	High dose	Overdose	Гон дозв (ж)	High dose	Overdose
ABDOMINAL PAIN	Severe	-	1			-		
	Total	4	4			4		
BACK PAIN	Mild	2	2			N		
	Moderate	-	-			-		
	Total	3	9			m		
VERTIGO	Mild	8	3			m		
	Total	E	3			m		
HEPATIC ENZYMES	Severe	٢	1	1		-		
	Unknown	-	1			-		
	Total	N	2			N		
RASH	Nild	-	1			1		
	Severe	-	1					
	Total	N	M			8		
URINARY RETENTION	Mild	-					-	
	Severe	-	1			1		
	Total	N	ı	1		1	•	
FLUSHING	Nild	-	1					
	Noderate	ı	ı			1		
	Total	N	2			8		
PALPITATION	Nild	1	ı			1		
	Noderate	1	ı			1		

( Called Annual Control

(\*) all remainder patients

EDOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day, tinewrine - low dose <= 0 mg/day, kich dose > 8 mg/day,

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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 TREATHENT

signed treatment: Reboxetine

Adverse events / severity	sverity	Adverse events	Dose	Dose taken on onset date	date	Highest dose	Highest dose taken from 3 days before	lays before
		Number	Low dose (*)	High dose	Overdose	Low dose (x)	Righ dose	Overdose
PALPITATION	Total	8	8			N		
TINNITUS	Mild	N	N			22		
	Total	2	N			2		
EUPHORIA	Hild	-	-			1		
	Moderate	-				1		
	Total	8	4			2		
RESPIRATORY	Mild	1	1			1		
	Moderate	-	1			1		
	Total	N	2			2		
ABSCESS	Unknown	10	N			22		
	Total	61	2			2		
TACHYCARDIA	Nild		1			1		
	Total		•			1		
XEROPHTHALMIA	Mild	-	1			ı		
	Total	•	1			•		
TASTE PERVERSION	Hild	1	1			1		
	Total	1	I.			-		
ALOPECIA	Mild	1	1			1		
	Total	1	ı			1		
CIRCULATORY	Mild	1	ı			1		
	Total	1	ı			1		

(\*) all remainder patients BOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day UDXETINE - low dose <= 20 mg/day. high dose > 20 mg/day

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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 TREATHENT

Assigned treatment: Reboxetine

issigned treatment: Repoxeling	repoxetine							
Adverse events / severity	severity	Adverse events		Dose taken on onset date	date	Highest dose	Highest dose taken from 3 days before	lays before
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
OEDENA LEGS	Mild	1		-			-	
	Total	-		-			-	
ANAEHIA	Mild	•	-			-		
	Total	-	1			-		
SPERKATORRHOEA	Mild	***	1			7		
	Total	-	-					
HYPERPYREXIA	Mild	-	-			1		
	Total	۲	-					
TENDINITIS	Moderate	-	**			**		
	Total	-	1					
MICRAINE	Moderate	-	-			1		
	Total	1	-			1		
ANOREXIA	Moderate	1	1			1		
	Total	1	1			+		
HYPOTENSION	Moderate	1	1			1		
	Total	-	1			1		,
LIBIDO DECREASED	Moderate	-	1			1		
	Total	1				1		
HEPATITIS INFECTIONS	Hoderate	1	1			1		
	Total	ı	1			1		
EPISTAXIS	Noderate	-	1			1		
								١

TINITANIE

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

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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 TREATHENT

signed treatment: Reboxetine

,								
Adverse events / severity	severity	Adverse events		Dose taken on onset date	date	Highest dose	Highest dose taken from 3 days before	lays before
		Number	Low dose (*) High dose	High dose	Overdose	Overdose Low dose (*) High dose	High dose	Overdose
EPISTAXIS	Total	-	1			1		
EJACULATION	Moderate	1	-			ı		
	Total	-	1			ı		
BREAST	Unknown	-	-			٦		
	Total	-	-			1		

(\*) all remainder patients
(E - low doss <= 8 mg/day, high doss > 8 mg/day and NE - low doss <= 20 mg/day, high doss > 20 mg/day
NE - low doss <= 20 mg/day, high doss > 20 mg/day

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 47

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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	sverity	Adverse events	Dose	Dose taken on onset date	late	Highest dose	Highest dose taken from 3 days before	ays before
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
All adverse events Mild	Mild	79	76	m		77	N	
	Moderate	62	72	7		73	9	
	Severe	14	12	N		44		
	Unknoen	60	9	2		9	2	
	Total	180	166	14		170	DE	
BEADACHE	Hild	6	100			8		
	Noderate	17	15	7		16	1	
	Severe	8	2			2		
	Unknown	-		-			1	
	Total	28	25	m		26	N	
NAUSEA	Mild	12	12			12		
	Moderate	-				1		
	Severe	-	1			1		
	Unknown	-	-			ı		
-	Total	31	15			15		
INSOMNIA	Mild	4	4			7		
	Moderate	4	8	,		8	1	
	Severe	61	-	-		2		
	Unknown	1	•			l		
	Total	11	6	82		10	-	
SWEATING INCREASED WILD	Nild	E	3			8		

WPTWIED)

(\*) all remainder patients REBOXETINE - low dose <= 8 mg/day, high dose > 8 mg/day FLUGXETINE - 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 DNSET AND THREE DAYS BEFORE BY SEVERTY AND ASSLIGNED TREATHENT

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Assigned treatment: Fluoxetine

Assigned treatment: fludxetine	LINGXetIDe							
Adverse events / severity	sverity	Adverse events	Dose	Dose taken on onset date	date	Highest dose	Highest dose taken from 3 days before	lays before
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
SHEATING INCREASED Moderate	Moderate	9	9			9		
	Tota1	6	o.			6		
DIZZINESS	Nild	9	Y)			9		
	Moderate	-	•			1		
	Severe	-	-			1		
	Total	60	SS			8		
MOUTH DRY	Hild	4	7			4		
	Moderate	-				L		
	Total	8	€0			8		
CONSTIPATION	Mild	m	m			8		
	Noderate	4	m	1		3	7	
	Total	7	v	•		9	-	
AGITATION	Mild	10	N			N		
	Moderate	E	n			£		
	Severe	77	8			2		
	Total	7	4			7		
DIARRHOEA	Mild	7	ħ			4		
	Koderate	2	8			8		
	Total	9	9			9		
TREMOR	Mild	1	1			-		
	Moderate	3	3			es .		

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

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität

und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

Overdose

High dose

se taken from 3 days before

PHARMACIA CNS R&D

DAYS BEFORE

ADVERSE El Assigned treatment: Fluoxetine	ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE FLUOXETING	BER OF ADVERSE	EVENTS ACCORDIN BY SEVERITY AND	G TO DOSE TAKEN ASSIGNED TREAT	THE DAY OF OWS HENT	ET AND THREE D
Adversa events / se	severity	Adverse events	Dose	Dose taken on onset date	date	Highest dos
		Number	Low dose (*)	High dose	Overdose	Low dose (*)
TREMOR	Severe	-	-			
	Total	'n	5			•
DYSPEPSIA	Nild	-	1			
	Moderate	4	4			,
	Total	S	S			37
INFLUENZA-LIKE	Mild	2	2			7
SEOT JUZZ	Koderate	en .	2	•		7
	Total	ĸ	ħ	1		7
APPETITE INCREASED MILE	Mild	2	23			
	Moderate	N	Ø			
	Total	4	7			,
VISION ABNORMAL	Hild	4	E	l .		_
	Total	7	ĸ	·		,
FATIGUE	Mild	-	1			
	Moderate	2	2			
	Severe	-		1		
	Total	7	e	1		
NERVOUSNESS	Nild	1	1	,		
	Moderate	2	1	1		
	Total	e	2	1		
SOMNOLENCE	Mild	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

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PHARMACIA CNS RRD

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

Adverse events / severity	werity	Adverse events	Dose	Dose taken on onset date	date	Highest dose	Highest dose taken from 3 days before	lays before
		Number	Low dose (*)	High dose	Overdose	Low dose (*)	High dose	Overdose
SOMNOLENCE	Noderate	-	1			1		
	Total	e	8			8		
RHINITIS	Nild	N	2			2		
	Moderate	-	-			1		
	Total	8	m			8		
UPPER RESP TRACT	Hild	-	-			1		
	Unknown	77	N			2		
	Total	m	3			3		
HYPERCHOLESTEROLA- Mild	Mild	1		ı			1	
	Severe		-			1		
	Total	2	1	1		1	1	
URINARY TRACT	PITM	1	1			1		
	Unknown	1	1			1		
	Total	N	2	•		2		
FEVER	ртін	1	ı			1		
	Moderate	1	1			1		
	Total	2	<b>Z</b> -			2		
PRURITUS	Moderate	2	2			2		
	Total	2	2			2		
HYPERTONIA	Moderate	2	NI NI			23		
	Total	2	23			6N		

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PBARMACIA 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 SEVENITY AND ASSIGNED TREATMENT

Assigned treatment: Fluoxetine

Adverse events / severity	everity	Adverse events		Dose taken on onset date	date	Highest dose	Highest dose taken from 3 days before	lays before
		Number	Low dose (*)	High dosa	Overdose	Гон dose (*)	High dose	Overdose
VOMITING	Moderate	8	2			77		
	Total	Ø	61			22		
PHARYNGITIS	Moderate	N	8			2		
	Total	2	2			77		
MYALGIA	Міла	-	١			٢		
	Total	7	٢			٢		
FLATULENCE	Mild	7	٦			٢		
	Total	7	1			7		
HYPERURICAEMIA	Mild	1	-			-		
	Total	-	-			1		
OEDEMA GENERALISED MILD	иіла	-	-			-		
	Total	-	-			-		
COUCHING	ИІЛ	-	1			-		
	Total	1	-			-		
CYSTITIS	Hild	,		1			7.0	
	Total	1		1	-		**	
RENAL PAIN	Nild	-	1			-		
	Total	-	-			-		
ASTHENIA	PIţĸ	1	1			-		
	Tota1	1	-			-		
NOT FLUSHES	Nild	1	1			1		

CONTINUED

(\*) all remaindor patients EBOXETINE - 104 doss <= 8 mg/day, high doss > 8 mg/day LIOXETINE - 104 doss <= 20 mg/day, high doss > 20 mg/day Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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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 TREATHENT

Assigned treatment: Fluoxetine

Adverse events / severity	everity	Adverse events	Dose	Dose taken on onset date	date	Highest dose	Highest dose taken from 3 days before	lays before
		Number	(*) esop Ao'j	High dose	Overdose	Low dose (*)	High dose	Overdose
HOT FLUSHES	Total	٢	-			ı		
INFECTION VIRAL	Mild	1	-			-		
	Total	1	-			-		
HYPERKINESIA	Moderate	-	-			-		
	Total	1	-			1		
PARAESTHESIA	Moderate	-	-		:	٢		
	Total	1	1			•		
HYPERTENSION	Noderate		-					
	Total	•	-			-		
HYPOTENSION	Moderate	•	-		:		•	
	Total	-	-				1	
CONJUNCTIVITIES	Moderate		1			-		
	Total	•	1			-		-
PARONIRIA	Noderate	1	ı			1		
	Total	1	1			1		
GASTRITIS	Moderate	ι	ı			1		
,	Total	1	L			1		
BRONCHITIS	Moderate	1	ı			1		
	Total	1	1			1		
MICTURITION	Moderate	1	1			1		
	Total	1	-			7		

CONTIN

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

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PHARMACIA CNS RRD :INE - PROTOCOL 20124/016 TABLE No.: 47 ADVERSE EVENTS: NUMBER OF ADVENSE EVENTS ACCORDING TO DOSE TAKEN THE DAY OF ONSET AND THREE DAYS BEFORE BY SEVERITY AND ASSIGNED TREATMENT

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 47

1								
Adverse events / severity	everity	Adverse events		Dose taken on onset date	date	Highest dose	Highest dose taken from 3 days before	days before
		Number	Low dose (*)	High dose	Overdose	Гон dose (*)	High dose	Overdose
IMPOTENCE	Moderate	-	-			-		
	Total	1	1			1		
CHEST PAIN	Moderate	1		-		-		
TWECOWN TOTAL	Total	1		1		٢		
MALAISE	Moderate	-	-			7		
	Total		-			7		
OTITIS MEDIA	Moderate	-	-			1		
<b>1)</b> (1)	Total	-	-			1		
C. RASH MACULO-	Severe	-	1			1		
	Total	-	1			1		
ANXIETY	Severe	-	1			-		
	Total	-	1			-		
SUICIDE ATTEMPT	Severe	-				-		
	Total	-	•			1		
SINUSITIS	Unknown	-	•			1		
	Total	-	1			1		
ALLERGIC REACTION Unknown	Unknown			-			L	
	Total	1		1			1	

(\*) all remainder patients REBOXETINE - low dose <5 mg/day, high dose > 8 mg/day bligh dose > 8 mg/day FIJUXETINE - low dose <= 20 mg/day thinh dose > 20 mg/day

PRARMACIA CNS RED

Assigned treat	Assigned treatment /			Sex	×					Age					DSM III	III	
á	4	Total	-	Fem	Female	ž	Male	18 - 30	8	31 - 45	45	> 45	5	296.2	2	296.3	ĸ,
		Mo. Pt	×	No. Pt	*	No. Pt	K	No. Pt	×	No. Pt	×	No. Pt	×	No. Pt	×	No. Pt	x
Fluoxetine	Missing	83	3.3		2.1	Ì	8.3			2	7.7			2	7.1		
	Kild	2	16.7	<b>"</b>	8 16.7		2 16.7	-	11.1	4	15.4	5	20.0	9	21.4	ţ,	12.5
	Koderate	36	60.0	29	60.4		7 58.3	3 7	77.8	15	57.7	14	56.0	15	53.6	21	9:59
	Severe	12	20.0	10	1 20.8		2 16.7	-	11.1	5	19.2	9	24.0	ιŋ	17.9	7	6'12
	Total	9	100.0	34	48 100.0		12 100.0		9 100.0		26 100.0	25	25 100.0	28	28 100.0	32	100.0
Reboxetine	Mild	10	18.9		6 16.2		4 25.0	-	11.1	7	19.0	5	21.7	c)	27.8	5	14.3
	Moderate	30	9.99	20	54.1		10 62.5	2	77.8	12	57.1	1	47.8	6	50.0	21	0.09
	Severe	13	24.5	11	1 29.7		2 12.5	-	11.1	S.	23.8	7	4.06	4	22.2	6	25.7
	Total	83	53 100.0	3	37 100.0		16 100.0		9 100.0		27 100.0	23	100.0		18 100.0	35	35 100.0

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 49

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

Adverse events / Severity	ents /								Assigned treatment	ned t	reatm	ent							
					Į.	Fluoxetine	g							Reb	Reboxetine				
		ŭ	Female			Male		F	Total		14	Fenale			Kale		_	Total	
		Pt.	ж	8 ×	Pt.	ж	8 ×		*	£×	£ ₹.	×	€ *	£ ₹.	ж	£×	Pt.	×	(¥)
All	Mild	00	17.0	16.7	22	18.2	16.7	2	17.2	16.7	v	16.2	16.2	4	25.0	25.0	10	18.9	18.9
events	Moderate	29	61.7	4.09	7	63.6	58.3	36	62.1	0.09	20	54.1	54.1	2	62.5	62.5	30	56.6	56.6
	Severe	10	21.3	20.8	81	18.2	16.7	12	20.7	20.0	Ξ	29.7	29.7	73	12.5	12.5	13	24.5	24.5
	Total	64	100	97.9	11	100	91.7	58	100	96.7	37	100	100	16	100	100	23	100	100
HEADACHE	Hild	ю	15.8	6.3				6	15.0	5.0	60	25.0	8.1	2	40.0	12.5	5	29.4	9.4
	Moderate	14	73.7	29.2	٦	9	8.3	15	75.0	25.0	6	75.0	24.3	3	0.09	18.8	12	70.6	22.6
	Severe	71	10.5	4.2				71	10.0	3.3									
	Total	6	5	39.6	-	100	8.3	20	100	33.3	12	100	32.4	S)	100	31.3	12	100	32,1
HOUTH DRY	РІІМ	2	83.3	10.4	63	<b>90</b>	16.7	7	87.5	11.7	13	65.0	35.1	4	57.1	25.0	11	63.0	32.1
	Moderate	ı	16.7	2.1				-	12.5	1.7	5	25.0	13.5	3	42.9	18.8	80	9.62	15.1
	Severe										2	10.0	5.4				64	<b>5</b> -6	3.8
	Total	9	100	12.5	61	100	16.7	8	100	13.3	20	100	54.1	4	100	43.8	27	100	50.9
CONSTIPAT-	Mild	3	50.0	6.3				33	50.0	5.0	9	50.0	16.2				9	35.3	11.3
	Moderate	3	50.0	6.3				6	50.0	5.0	6	25.0	8.1	S	100	31.3	8	47.1	15.1
	Severe										e,	25.0	8.1				3	17.6	5.7
	Total	9	100	12.5				9	100	10.0	12	100	32.4	r3	100	31.3	11	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	-	16.7	1.2				-	16.7	1.7									
	Total	9	100	12.5				9	100	10.0	6	100	100 24.3	4	100	25.0	13	100	24.5

Commentation

(\*) X 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 SEVENITY LEVEL, SEX AND ASSIGNED TREATHENT

Adverse events Severity	ents /							4	Assigned treatment	8d tr	eatm	it i							
•					E	Fluoxetine	2			$\vdash$				Reb	Reboxetine	2			
		-	Female		_	Male		ů	rota1	-	ř.	Female			Hale		H	Total	
		No. Pt.	м	€ ×	₽. ¥.	×	( ×	Pt.	*	€ ×	5 t.	ж	8 ×	5 4.	н	€ ×	₩. Pt.	ж	£ ×
INSOMNIA	Mild	3	33.3	6.3			<u> </u>	8	33.3	5.0	77	25.0	4.	-	50.0	6.3	m	30.0	5.7
	Moderate	6	33.3	6.3				3	33.3	5.0	2	62.5	13.5	-	50.0	6.3	9	0.09	11.3
	Severe	2	22.2	4.2				23	22.2	3.3	Ť	12.5	2.7				-	10.0	1.9
	Missing	-	11.1	2.1				-	11.1	1.7									
	Total	6	100	18.8				6	1001	15.0	80	9	21.6	10	100	12.5	9	100	18.9
NAUSEA	Mild	9	75.0	12.5				9	66.7 1	10.0				-	50.0	6.3	-	11.1	1.9
	Noderate	-	12.5	2.1				-	11.1	1.7	_	90	18.9	-	50.0	6.3	80	88.9	15.1
	Severe	1	12.5	2.1				-	11.1	1.7									
	Missing				-	5	8.3	-	11.1	1.7	-								
	Total	8	100	16.7	-	100	8.3	6	1001	15.0	7	9	18.9	63	100	12.5	6	100	17.0
SWEATING	Nild	3	50.0	6.3				6	42.9	5.0	63	50.0	5.4	63	66.7	12.5	4	57.1	7.5
	Moderate	£	50.0	6.3	-	ê ê	8.3	4*	57.1	6.7	62	50.0	5.4	-	33.3	6.3	6	42.9	5.7
	Total	9	100	12.5	-	100	8.3	7	1001	11.7	4	ê	10.8	60	100	18.8	-	100	13.2
TREMOR	Mild	1	20.0	2.1				-	20.0	1.7	63	50.0	5.4				61	50.0	3.8
	Moderate	3	60.0	6.3				9	0.09	5.0	8	20.0	4.6				63	50.0	8.8
	Severe	1	20.0	2.1				-	20.0	1.7									
	Total	5	100	10.4				2	100	8.3	*	100	10.8				4	100	7.5
MICTURITI- Mild ON	Mild										-	50.0	2.7	62	33.3	12.5	m	37.5	5.7
DISORDER	Moderate	1	100	2.1				-	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)

PHARMACIA CNS RED
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 /	ants /								Assigned treatment	ed tr	reatm	art							
					Fla	Fluoxetine	9							Seb Per	Reboxetine	2			
			Female			Male		E .	Tota1		ų,	Female			Male		-	Tota1	
		7 S.	и	(£	. t.	м	£ ×	No.	×	£×	₽	*	£ ×	М. Р.	×	£ ×	Pt.	×	£×
MICTURITI- Total ON DISORDER	Total	-	100	2.1				-	9	1.7	2	100	5.4	vo	100	37.5	60	100	15.1
AGITATION	Hild	7	40.0	4.2				2	28.6	3.3	ļ								
	Moderate	2	40.0	4.2	-	50.0	8.3	60	42.9	5.0				-	100	6.3	-	8	1.9
	Severe	-	20.0	2.1	-	50.0	8.3	77	28.6	3.3									
	Total	S	5	4.0₽	23	100	16.7	7	1001	11.7				-	100	6.3	-	100	1.9
FATIGUE	ртън	-	33.3	2.1				-	25.0	1.7				-	50.0	6.3	-	25.0	6:
	Moderate	77	66.7	4.2		-		2	50.0	3.3	7	100	5.4				22	50.0	3.8
	Severe				-	100	80	-	25.0	1.7				-	50.0	6.3	-	25.0	1.9
	[otal	3	90	6.3	-	100	8.3	4	100	6.7	67	100	5.4	22	100	12.5	4	100	7.5
DIARRHOEA	Mild	2	50.0	4.2	2	100	16.7	3	66.7	6.7	-	100	2.7				-	100	1.9
	Moderate	2	50.0	4.2				67	33.3	ω ω									
	Total	4	100	8.3	2	100	16.7	9	100	10.0	-	100	2.7				-	100	1.9
VISION	Hild	3	100	6.3	Ł	100	8.3	4	100	6.7	-	100	2.7	-	50.0	6.3	81	66.7	ω α
	Moderate									<u> </u>				٦	50.0	6.3	-	33.3	1.9
	Total	3	106	6.3	-	100	8.3	4	100	6.7	-	100	2.7	77	100	12.5	6	100	5.7
INFLUENZA- Mild	Hild	2	50.0	4.2		-		61	50.0	3.3									
SYMPTOMS	Moderate	2	50.0	4.2				71	50.0	3.3	m	ê	2.7				m	100	5.7
	Total	4	100	8.3				4	5	6.7	6	100	8.1				en .	100	5.7
PARAESTHE- SIA	Hild										ю	0.09	8.1				e,	60.09	5.7

CONTINUED

(\*) % on all patients with adverse events

PHARMACIA CMS R&D

KEBOXETINE - PROTOCOL, 20124/016

TABLE No.: 49

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

Adverse events /	ants /							•	Assigned treatment	ed to	reatm	ent							
					Flu	Fluoxetine	_ <u>_</u>							Reh	Reboxetine	118			
		Ľ.	Female			Male		Ē	Total		-	Female			Male			Tota1	
		₩. ₽t.	N	(¥)	₩. ₽t.	×	8 ×		×	£×		×	€×	₹.	н	€ №	7 % 7.	Ж	£ ×
PARAESTHE- Moderate SIA	Moderate	-	ē,	2.1			<del>                                     </del>	+	100	1.7	-	20.0	2.7				-	20.0	4.9
	Severe										-	20.0	2.7				٦	20.0	1.9
	Total	-	ş	2.1				-	100	1.7	3	100	13.5				5	100	9.6
PRURITUS	PITH										~	100	5.4				2	66.7	8. 80
	Moderate	1	100	2.1	-	9	e0 m	07	9	8.3				-	00	6.3	-	33.3	1.9
	Total	1	100	2.1	-	5	e0 E0	63	100	8.9	~	5	5.4	-	100	6.3	m	100	5.7
VOMITING	Moderate	0	100	4.2				64	100	3.3	62	66.7	5.4				22	66.7	3.8
	Severe										-	33.3	2.7					33.3	£.
	Total	7	100	4.2				72	100	3.3	ю	90	8.1				m	100	5.7
SOHNOLENCE Mild	Hild	1	50.0	2.1	1	100	8.3	62	66.7	3.3	۳-	50.0	2.7				-	50.0	1.9
	Moderate	1	50.0	2.1				-	33.3	1.7	-	50.0	2.7				-	56.0	1.9
	Total	7	100	4.2	-	2	8.3	ю	100	5.0	67.	100	5.4				63	100	3.8
DYSPEPSIA	Hild	1	25.0	2.1				-	25.0	1.7									
	Moderate	3	75.0	6.3				ю	75.0	5.0									
	Missing										-	100	2.7				-	100	1,9
	Total	4	100	8.3				4	100	6.3	1	100	2.7				1	100	1.9
UPPER RESP	Nild	1	33.3	2.1				-	33.3	1.7									
INFECTION	Moderate										1	50.0	2.7				_	50.0	1.9
	Missing	2	66.7	4.2				61	66.7	3.3	1	50.0	2.7				1	50,0	1.9
	Total	8	100	6.3				3	100	5.0	2	100	5.4				2	100	3.8

CHESTANGE

PHARMACIA CNS RBD REBOXETINE - PROTOCOL 20124/016 TABLE No.: 49

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

Adverse events	nts /							•	Assigned treatment	ed tr	eatme	int							
A 1000					Fluc	Fluoxetine	9			_				Reb	Reboxetine	2			
		-	Fenale		~	Kale		Ţ	Total		표	Fenale			Male		F	Total	
		76. Pt.	м	€ ×	Pt.	×	(¥) ×	No. Pt.	×	£ ×	Pt.	N	£ ×	7. T.	ж	¥ ×	. #:	м	£ ×
NERVOUSNE-	Mild	-	33.3	2.1				-	33.3	1.7	-								
}	Moderate	63	66.7	4.2				2	66.7	3.3	-	ē	2.7				-	100	1.9
	Total	6	100	6.3				m	100	5.0	-	ē	2.7				-	90	1.9
RHINITIS	Mild				74	001	16.7	2	66.7	3.3									
	Moderate	-	100	2.1				13	33.3	1.7	-	100	2.7				-	100	1.9
	Total	-	100	2.1	81	901	16.7	60	5	5.0	-	8	2.7				-	100	1.9
BACK PAIN	Mild						<u> </u>		_	<u> </u>	7	66.7	5.4				N	66.7	e.
	Koderate										-	33.3	2.7				-	33.3	1.9
	Tota1					-		_			m	9	8.1				60	9	5.7
APPETITE TNCPFASFN	Mild	-	33.3	2.1				-	33.3	1.7									
	Moderate	2	66.7	4.2				2	66.7	3.3									
	Total	3	100	6.3				6	9	5.0									
ABDOMINAL	PTIM										-	33.3	2.7				1	33.3	1.9
	Moderate										-	33.3	2.7				۳	33.3	1,9
	Severe										-	33.3	2.7				1	33.3	1.9
	Total										6	ş	8.1				m	100	5.7
HYPERCHOL -	Mild				-	9	80 .33	-	20.0	1.7	-	ş	2.7				1	100	1.9
MIA	Severe	1	100	2.1				F	50.0	1.7									
	[otal	1	100	2.1	٦	9	8.3	63	100	3,3	-	9	2.7				-	100	1.9
PHARYNGIT- Moderate IS	Hoderate	- 73	100	4.2				61	5	3,3	-	5	2.7				-	100	1.9

Tallet Land

(\*) % on all patients with adverse events

PHARMACIA CNS R&D

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

Adverse events	ants /								Assig	Assigned treatment	reatm	ent							
•					E	Fluoxetine	ine							Seb de	Reboxetine	92		•	
		_	Female			Male			Tota1		-	Female			Male		-	Total	
		P.	×	€ ×	₽ ¥.	*	€ *	7 S.	м	€ ≈	Pt.	*	€ ×	₽₽. ₽£.	м	€ ×	· # #	*	£ ×
PHARYNGIT- Total	Total	2	100	4.2				67	100	3.3	-	92	2.7				-	100	1.9
URINARY	Mild	-	50.0	2.1				-	20.0	1.7									
INFECTION	Hissing	-	50.0	2.1				-	50.0	1.7	-	100	2.7				-	100	1.9
	Total	2	100	4.2				2	100	3,3	-	100	2.7				-	100	1.9
FEVER	Mild													-	100	6.3	-	50.0	1.9
	Moderate	-	100	2.1				-	100	1.7	-	90	2.7				1	50.0	1.9
	Total	-	100	2.1				-	100	1.7	-	90	2.7	-	9	6.3	2	100	3.8
HOT	Mild	_	100	2.1				*	100	1.7	-	50.0	2.7				7	50.0	1.9
	Moderate										-	50.0	2.7				-	50.0	1.9
	Total	1	100	2.1				1	100	1.7	2	100	5.4				2	100	3.8
RASH	ніла										-	50.0	2.7				-	50.0	1.9
	Severe										-	50.0	2.7				-	50.0	1.9
	Total										2	ē	5.4				82	100	3.8
MYALGIA	Nild	1	100	2.1				٦	100	1.7									
	Moderate										-	5	2.7				•	100	1.9
	Total	_	100	2.1				٢	100	1.7	-	Ę	2.7				٦	100	6.1
HYPERTONIA Moderate	Moderate	-	100	2.1		100	8.3	N	90	3.3									
	Total	٢	100	2.1		100	8.3	2	100	3.3									
VERTIGO	Mild										-	100	2.7	1	5	6.3	67	100	9.8
	Total										٦	100	2.7	1	100	6.3	83	100	3.8

(\*) % on all patients with adverse events

PHARMACIA CHS 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 /	ants /							-	Assigned treatment	ned t	reatm	ent							
,					Flu	Fluoxetine	92							Sek	Reboxetine	9			
		ŭ.	Female			Hale		F	Total			Female			Male			Total	
		No.	*	8 ×	7¢.	ж	£ ×	₽. Y.	к	£ ×	₽.	×	£ ×	₽. ₽.	×	€ ×	No. Pt.	Ж	(¥) ×
URINARY	Mild		T		1						-	90	2.7				1	50.0	1.9
	Severe													-	100	6.3	-	50.0	1.9
	Tota1										-	100	2.7	-	100	6.3	61	100	3.8
HYPERTENS-	Koderate				-	100	8,3	-	5	1.7	-	Ş	2.7				-	300	1.9
	Total				-	100	8.3	-	100	1.7	-	100	2.7				-	100	1.9
HYPOTENSI- Moderate	Moderate	-	100	2.1				-	92	1.7							_		
i	Severe										-	100	2.7				-	100	1.9
	Total	-	100	2.1				-	100	1.7	-	100	2.7				_	100	1.9
PALPITATI- Mild	Hild										-	50.0	2.7				-	50.0	6.1
i	Moderate										-	50.0	2.7				-	50.0	6.
	Total										2	100	4.6				2	100	8.8
CONJUNCTI- Moderate	Moderate				-	100	8.3	-	9	1.7	-	100	2.7					100	6.
	Total				-	100	8.3	-	100	1.7	-	100	2.7				_	100	1.9
TINNITUS	Mild										-	90	2.7	-	100	6.3	~1	100	ω 80
	Total										-	90	2.7	-	100	6.3	23	100	3.8
ANXIETY	МІЛА										-	100	2.7				-	100	1.9
	Severe	٦	100	2.1				-	9	1.7									
	[otal	ı	100	2.1				-	100	1.7	**	100	2.7				-	100	1.9
SUICIDE	Severe	1	100	2.1				-	100	1.7	-	100	2.7				-	100	1.9
	Total	-	100	2.1				1	100	1.7	-	100	2.7				1	100	1.9
								1	1								-		

(\*) % on all patients with adverse events

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 49

NUMBER OF PATIENTS HED COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATHENT

Adverse events / Severity	ants /							€	Assigned treatment	led ti	reatm	it a							
					Fluc	Fluoxetine	<u>.</u>							Reb	Reboxetine	2			
		"	Female	-	_	Hale		£	Total		E.	Female		_	Male		H	Total	-
		%. Pt.	м	£ ×	£ ₹.	×	(¥) ×		×	£ ×	. <del>.</del> .	*	£ ×	7. Y.	×	£ ×	76.	ĸ	£ ×
GASTRITIS	Hild					$\dagger$	1	<del>                                     </del>			-	100	2.7	T			-	100	1.9
	Moderate				-	퉏	8.3	-	<u>8</u>	1.7									
j	Total				=	100	6.3	F	10	1.7	-	5	2.7				-	100	1.9
HEPATIC	Severe										-	50.0	2.7				-	20.0	1.9
INCREASED	Unknown										-	50.0	2.7				-	50.0	1.9
	Total										2	100	5.4				2	300	3.8
эктнэлоэ	Mild	-	100	2.1				-	100	1.7									
	Moderate										-	100	2.7				-	100	1.9
	Total	٢	100	2.1			_	-	90	1.7	-	100	2.7				-	160	1.9
RESPIRATO- RY	Mild										-	50.0	2.7				-	50.0	1.9
DISORDER	Moderate										-	50.0	2.7				1	50.0	1.9
	Total										63	100	5.4				83	100	3.8
CYSTITIS	Hild	1	100	2.1				-	100	1.7									
	Severe										-	100	2.7				-	100	1.9
	Total	-	100	2.1				**	5	1.7	-	100	2.7				1	100	1.9
ALLERGIC REACTION	Moderate .										-	100	2.7				-	90	6.
	Missing	1	100	2.1				-	100	1.7									
	Total	ı	100	2.1				-	100	1.7	+	100	2.7				1	100	1.9
ABSCESS	Missing													67	100	12.5	2	100	ε. εο
	Total													22	100	100 12.5	2	100	9. 80.

(\*) % on all patients with adverse events

PHARMACIA CNS R&D

NUMBER OF PATIENTS HRO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATHENT

Adverse events /	ents /								Assig	Assigned treatment	reatm	ar t							
Severity					Flu	Fluoxetine	2							Rep	Reboxetine	9			
			Female			Kale		-	Total		£4,	Female			Male		#	Total	
		78. Pt.	м	£ ×	£ £.	ж	8 **	. ₹ 	×	£ ×	£ ₹.	м	€.×	£ ₹.	м	£×	유 날	×	£ ×
RASH MACULO-	Severe	-	100	2.1				-	100	1.7									
PAPULAR	Total	-	90	2.1				-	100	1.7									
TENDINITIS Moderate	Moderate									_				-	180	6,3	-	100	1.9
	Total					.,								-	100	6.3	-	9	1.9
HYPERKINE-	Moderate	٦	100	2.1				-	100	1.7									
	Total	٦	100	2.1				-	100	1.7									
MICRAINE	Moderate										-	100	2.7				-	100	1.9
	Total										-	95	2.7				-	100	1.9
ANDREXIA	Moderate										-	199	2.7				٦	9	1.9
	Total										-	100	2.7				1	100	1.9
FLUSHING	Moderate										-	100	2.7				ı	100	1.9
	Total				`							90	2.7				1	100	1.9
HYPOTENSI- Moderate	Moderate										-	100	2.7				l	100	1.9
POSTURAL	Total										-	100	2.7				ı	100	1.9
TACHYCARD- IA	Hild										-	100	2.7				1	100	1.9
	Total										-	100	2.7				-	100	1.9
XEROPHTHA-	Nild											100	2.7				1	100	1.9
	Total										-	100	2.7				ı	100	1.9
TASTE	Nild										-	100	2.7				١	100	1.9
	<b>Total</b>										1	100	2.7				1	100	1.9

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 49

NUBBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATHENT

									1		amount notification								
					Flu	Fluoxetine	2							Reb	Reboxetine	91			
		C.	Female			Male		ě	[otal		SL.	Female			Male		_	Total	
		P. S.	ж	€ ×	76.	×	£ ×	₽. <del>7.</del>	×	£×	7	×	£ ×		*	8×	₩. Pt.	м	8 *
EUPHORIA Mode	Moderate									<del> </del>	-	2	2.7				-	100	1.9
Total	12								-		-	5	2.7				-	100	1.9
LIBIDO Mode	Moderate													-	100	6.3	-	100	1.9
Total	12													٦	100	6.3	_	100	1.9
PARONIRIA Mode	Moderate	-	100	2.1				-	100	1.7									
Total	12	-	100	2.1				-	100	1.7									
FLATULENCE Mild	_				-	100	8.3	-	100	1.7									
Total	12				*	100	8.3	-	100	1.7									
HEPATITIS Node	Noderate										-	Ē	2.7				-	100	1.9
Total	વ										-	2	2.7				-	5	1.9
HYPERURIC- Mild	-	-	100	2.1				-	100	1.7									
Total	교	-	100	2.1				-	100	1.7									
ALOPECIA Mild	-15													-	100	6.3	-	100	1.9
Total	댸													-	100	6.3	٢	100	1.9
GENERALIS-	70	L	100	2.1				٦	100	1.7									
ED Total	11	ı	100	2.1				-	100	1.7									
CIRCULATO- Mild RY FATLURE	ъ													_	ş	6.3	-	티	1.9
Total	a1													•	100	6.3	-	160	1.9
OEDENA Mild	75										-	100	2.7					100	1.9
Total	al										1	100	2.7				1	100	1.9

(\*) % on all patients with adverse events

PBARMACIA 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 TREATHENT

Adverse events /	ants /								Assigned treatment	led ti	reatm	a t							
ever ty					12	Fluoxetine	2							Reb	Reboxetine	2			
		<u>"</u>	Female			Male		Ţ	Total	-	ŭ	Fenale			Hale		۲	Total	
		. ± 	*	* ×	₽. ₹.	*	£ ×	ž <del>1.</del>	Ж	8 %	÷ ₹.	×	€ ×	No.	×	£ 14	7 %.	×	* *
EPISTAXIS	Moderate								-		-	160	2.7				-	5	1.9
	Total										-	100	2.7				-	90	1.9
SINUSITIS	Missing				-	9	8.3	-	9	1.7									
	Total				-	10	8.3	-	9	1.7									
BRONCHITIS Moderate	Moderate	-	100	2.1				-		1.7									
	Total	٦	100	2.1				-	100	1.7									
ANAERIA	Mild										-	100	2.7				-	9	1.9
	Total										-	9	2.7				-	100	1.9
RENAL PAIN Mild	Hild	-	100	2.1				-	100	1.7									
	Total	1	100	2.1				-	100	1.7									
IMPOTENCE	Moderate				-	100	8.3	-	50	1.7									
	Total				-	100	8.3	-	9	1.7									
SPERMATOR- RHOEA	Mild													-	100	6.3	-	9	1.9
	Total													٠	100	6.3	-	100	1.9
EJACULATI- Moderate	Moderate													٦	100	6.3	-	100	1.9
DISORDER	Total													-	100	6.3	-	92	1.9
BREAST FTREGAMEN-	Kissing										-	100	2.7				-	100	1.9
OSIS	Total										-	100	2.7				-	100	1.9
ASTHENIA	Mild	-	100	2.1				-	9	1.7									
	Total	-	Ę	2.1				-	100	1.7									
										1	1								

WETWIED

(\*) % on all patients with adverse events

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PHARHACIA CRS 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 /	ents /								Assigned treatment	ned t	reatm	ent							
ì					Flu	Fluoxetine	ne							% Seb	Reboxetine	9 2			
			Female			Male		۴	Tota1		"	Female	Γ		Male		_	Total	
		76. Pt.	ж	€ ×	도 및 도 및	ж	£ ×	ño. Pt.	×	€ ×	76.	×	€ ×	₩. ₽£.	×	£ ×	No. Pt.	×	£ ×
CHEST PAIN Moderate	Moderate	-	100	2.1				-	100	1.7									
	Total	-	100	2.1				-	100	1.7									
MALAISE	Moderate				-	100	8.3	۳-	100	1.7									
	Total				1	100	8.3	-	100	1.7									
HYPERPYRE- Mild	Hild										-	9	2.7				٦	100	1.9
	Total										-	100	2.7				-	100	1.9
INFECTION	Hild	-	100	2.1				-	100	1.7									
7007	Total	~	100	2.1				-	2	1.7									
OTITIS	Moderate	1	100	2.1				-	9	1.7									
	Total	1	100	2.1				-	90	1.7									

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 50 PHARMACIA CNS R&D

NUMBER OF PATIENTS HIG COMPLAINED OF ADVERSE EVENTS, GROUPED BY BODY SYSTEM, BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATMENT

A11 Mild																			ĺ
					Flu	Fluoxetine	ē							Rebe	Reboxetine	9			
	L	<u>د</u>	Female	_		Kale		Ē	Total		LE.	Female		_	Kale		Ē	Total	
		. <del>.</del> .	×	* *	Æ.	×	£ ×	£ .	*	(*) N d	₩.	×	£ ×	7. 7.	ж	¥ %	£ %	ж	€ ×
adresses.		00	17.0	16.7	67	18.2	16.7	2	17.2	16.7	9	16.2 1	16.2	4	25.0 2	25.0	2	18.9	18.9
	Noderate	29	61.7	4.09	2	63.6	58.3	36	62.1	60.09	20	54.1	54.1	2	62.5	62.5	8	56,6	56.6
Severe	2	2	21.3	20.8	N	18.2	16.7	12	20.7	20.02	12	29.7	29.7	7	12.5	12.5	13	24.5	24.5
Total	н	47	100	97.9	7	5	91.7	82	9	96.7	37	100	100	92	9	9	53	100	100
GASTRO- Mild		6	45.0	18.8	m	0.09	25.0	12	48.0	20.0	7	31.8	18.9	÷	14.3	6.3	80	27.6	15.1
	Moderate	2	50.0	20.8	-	20.0	8.3	=	44.0	18.3	10	45.5	27.0	9	85.7	37.5	9	55.2	30.2
Severe	To	-	5,0	2.1				-	0.4	1.7	S	22.7	13.5				Ŋ	17.2	9.4
Hissing	gui				-	20.0	8.3	-	0.4	1.7	-								
Total	-	20	100	41.7	ď	90	41.7	25	90,	41.7	22	100	59.5	7	100	43.8	59	9	54.7
CENTRAL & Mild		22	8.7	4.2				22	8.0	3.3	N.	31.3	13.5	m	50.0	18.8	æ	36.4	15.1
	Moderate	5	78.3	37.5	0	100	16.7	20	80.0	33.3	9	62.5	27.0	w	50.0	18.8	13	59.1	24.5
DISO Severe	1.6	(1)	13.0	6.3				m	12.0	5.0	-	6.3	2.7				1	4.5	1.9
Total	-	23	100	6.74	N	5	16.7	25	8	41.7	16	90	43.2	9	100	37.5	22	100	41.5
AUTONOMIC Mild		9	60.0	12.5	77	66.7	16.7	60	61.5	13.3	5	6.19	35.1	9	66.7	37.5	19	63.3	35.8
v.	Moderate	4	40.0	8.3	1	33.3	8.3	5	38.5	8.3	9	28.6	16.2	60	33.3	18.8	6	30.0	17.0
Severe	are										73	9.5	5.4				67	6.7	3.8
Total	П	9	100	20.8	М	5	25.0	t.	9	21.7	21	8	56.8	6	100	56.3	30	100	56.6
PSYCHIATR- Mild		r,	27.8	40.4	-	33.3	8.3	9	28.6	0.0	4	30.8	10.B	-	33.3	6.3	w	31.3	9.4
SORDERS	Moderate	7	38.9	14.6	-	33.3	8.3	80	38.1	13.3	7	53.8	18.9	N	66.7	12.5	6	56.3	17.0
Severe	ire	5	27.8	10.4	-	33.3	8.3	9	38.6	10.0	8	15.4	5.4	-			7	12.5	3.8

(CONTINUED)

PHARMACIA CNS R&D

NUMBER OF PATIENTS WHO COMPLAINED OF ADVERSE EVENTS, GROUPED BY BODY SYSTEM, BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATHENT

Body system	Body system / Severity								Assigned treatment	ad tr	eatme	ŧ							
					Flu	Fluoxetine	92							Reb	Reboxetine	9			
			Female			Hale		ř	Tota1		Fe	Female		-	Male		F	Tota1	
		₽	ж	£ ×	₩. Pt.	N	8 %		*	(*) N M	₹. 5. Ť.	- ×	£×	Pt.	ж	£ ×	. T.	×	% ×
PSYCHIATR-	Missing	-	5.6	2.1				-	8.	1.7									
DISORDERS	Total	18	100	37.5	ю	100	25.0	21	100	35.0	13	100	35.1		100	18.8	16	Ş	30.2
CARDIOVAS-	Mild	9	60.09	12.5				9	54.5	10.0	5	33.3	13.5	S	100	31.3	2	50.0	18.9
DISORDERS, Moderate	Moderate	3	30.0	6.3	-	100	8.3	4	36.4	6.7	6	60.0	24.3				0	45.0	17.0
Tarana a	Severe	1	10.0	2.1				-	9.1	1.7	~	6.7	2.7				-	5.0	1.9
	Total	10	100	20.8	-	100	8.3	7	100	18.3	15	100	40.5	Ŋ	100	31.3	20	100	37.7
BODY AS A	Mild	3	33.3	6.3				6	27.3	5.0	Ť	14.3	2.7	77	66.7	12.5	m	30,0	5.7
GENERAL	Koderate	5	55.6	10.4	-	50.0	8.3	9	54.5	10.0	9	85.7	16.2				٠	0.09	11.3
птопилсио	Severe				1	50.0	8.3	-	1.6	1.7				-	33.3	6.3	-	10.0	1.9
	Missing	٦	11.1	2.1				-	9.1	1.7									
	Total	6	100	18.8	2	100	16.7	7	100	18.3	7	100	18.9	e	100	18.8	2	100	18.9
RESPIRATO-	Nild	-	14.3	2.1	2	66.7	16.7	m	30.0	5.0	-	14.3	2.7				-	14.3	1.9
DISORDERS	Moderate	*	57.1	8.3				4	40.0	6.7	'n	71.4	13.5				S	71.4	9.4
	Missing	8	28.6	4.2	-	33.3	8.3	6	30.0	5.0	-	14.3	2.7				-	14.3	1.9
	Total	7	100	14.6	m	9	25.0	9	9	16.7		100	18.9				7	100	13.2
URINARY	Hild	6	0.09	6.3				6	0.09	5.0	67	60.0	4.	2	28.6	12.5	4	33.3	7.5
DISORDERS	Moderate	-	20.0	2.1				-	20.0	1.7				4	57.1	25.0	4	33.3	7.5
	Severe										٥.	40.0	5.4	-	14.3	6.3	3	25.0	5.7
	Missing	٦	20.0	2.1				-	20.0	1.7	-	20.0	2.7				-	8.3	1.9
	Total	r.	100	10.4				S	90	8.3	S	5	13.5	7	100	43.8	12	100	22.6

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 50 PHARMACIA CNS R&D

NUMBER OF PATIENTS HAD COMPLAINED OF ADVERSE EVENTS, GROUPED BY BODY SYSTEM, BY MAXIMAL SEVERITY LEVEL, SEX AND ASSIGNED TREATHENT

Body system	Body system / Severity								Assigned treatment	led to	reatm	ant							
					Flu	Fluoxetine	96							Reb	Reboxetine	an en			
			Female		_	Kale		Ĕ	Total		<u> </u>	Fenale			Xale		۲	Tota1	
		7. Y.	н	£×	No.	×	× ×	r	×	£ ×	F Š	ж	£×	5 t	и	£ ×		N	8 ×
VISION	Nild	60	100	6.3	-	20.0	8.3	4	80.0	6.7	64	66.7	5.4	-	50.0	6.3	6	0.09	5.7
	Moderate				٢	50.0	8.3	-	20.0	1.7	-	33.3	2.7	-	90.05	6.3	81	40.0	3.8
	Total	E	100	6.3	17	100	16.7	10	90	8.3	6	5	8.1	22	9	12.5	ī,	5	4.
SKIN AND	Hild										6	75.0	8.1	-	50.0	6.3	4	66.7	7.5
DISORDERS	Moderate	-	50.0	2.1	-	9	8,3	2	66.7	3.3				-	50.0	6.3	-	16.7	1.9
	Severe	-	50.0	2.1				-	33.3	1.7	-	25.0	2.7				-	16.7	1.9
	Total	63	100	4.2	-	300	8.3	m	100	5.0	4	5	10.8	64	90	12.5	9	100	11.3
MUSCOLO-	Kild		100	2.1				-	100	1.7	64	50.0	5.4				20	40.0	3.8
SYSTEM	Moderate										0	50.0	4.6	-	100	6.3	6	0.09	5.7
	Total	-	100	2.1				-	100	1.7	4	5	10.8	-	100	6.3	S	100	9.4
METABOLIC	Mild	-	50.0	2.1	-	ē	8.3	2	66.7	8.	-	윤	2.7				-	100	1.9
NUTRITION-	Severe	1	50.0	2.1				-	33.3	1.7									
DISORDERS	Total	2	100	4.2	-	100	8.3	e	100	5.0	-	100	2.7				-	100	1.9
RESISTANCE MECHANTSM	Mild	1	50.0	2.1				-	50.0	1.7									
DISORDERS	Moderate	1	50.0	2.1				-	50.0	1.7									
	Missing													62	100	12.5	2	5	3.8
	Total	23	100	2.4				2	400	3.3				2	100	12.5	2	100	3,8
REPRODUCT-	Hild													-	50.0	6.3	-	50.0	1.9
DISORDERS,	Moderate				ı	100	8.3	1	100	1.7				1	20.0	6.3	-	50.0	1.9
	Total				-	100	8.3	-	100	1.7				7	100	12.5	23	100	3,8

PHARMACIA CNS RED 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 TREATHENT

Body system	Body system / Severity								Assig	ned t	Assigned treatment	ent							
					Flu	Fluoxetine	2							Reb	Reboxetine	92			
	-	-	Female			Male		F	Total		14	Female			Male		F=	Total	
	1	No.	м	(¥)	76.	×	<b>*</b> ×	7. Y.	м	£ ×	£ ₹.	×	8×	7. Pt.	Ж	£ ×	5 T.	ж	¥ ¥
HEARING	Mild										-	100	2.7	-	100	6.3	2	100	3.8
VESTIBULAR Total	Total										1	100	2.7	-	100	6.3	77	100	3.8
LIVER AND	Severe										-	50.0	2.7				-	50.0	1.9
SYSTEM	Unknown										-	50.0	2.7				-	50.0	1.9
ULBURUERS	Total										22	9	5.4				2	100	3.8
MEMATOLOGY Mild	Kild										-	=	2.7				ı	100	1.9
	Total										-	10	2.7				1	180	1.9
REPRODUCT-	Missing										1	100	2.7				1	100	1.9
DISORDERS, Total FEMALE	Total										ı	100	2.7				1	100	1.9
SPECIAL	Hild										1	100	2.7				1	100	1.9
OTHER, DISORDERS	Total										-	100	2.7				_	100	1.9

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 51

ADVERSE EVENTS: DURATION OF EPISODES (\*) BY ASSIGNED TREATHENT

Adverse events/Assigned treatment		9	Durat	ion of ep	Duration of episodes (days)	ays)
		Episodes	Min	205	206	Мах
All adverse events	Fluoxetine	180	-	6	32	56
	Reboxetine	221	-	12	44	59
неарасне	Fluoxetine	28	1	9	24	36
	Reboxetine	21	1	6	19	32
MOUTH DRY	Fluoxetine	eG.	εα.	21	56	56
	Reboxetine	27	m	28	56	59
DIZZINESS	Fluoxetine	60	1	4	32	32
	Reboxetine	18	1	8	20	59
NAUSEA	Fluoxetine	15	-	7	15	12
	Reboxetine	11	-	6	17	25
CONSTIPATION	Fluoxetine	7	4	13	31	31
	Reboxetine	81	-	17	57	59
INSOMNIA	Fluoxetine	=	8	14	41	64
	Reboxetine	12	,	29	55	56
SWEATING INCREASED	Fluoxetine	e.	G.	21	53	53
	Reboxetine	¢0	rt.	13	20	20
MICTURITION DISORDER	Fluoxetine	٢	15	15	15	15
	Reboxetine	10	N	7	59	35
TREMOR	Fluoxetine	S	-	13	94,	46
	Reboxetine	4	4	12	45	42
AGITATION	Fluoxetine	7	·	12	21	21
	Reboxetine	-	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

ADVERSE EVENTS: DURATION OF EPISODES (\*) BY ASSIGNED TREATHENT

PHARMACIA CNS R&D

Adverse events/Assigned treatment		4	Durat	ion of ep	Duration of episodes (days)	ays)
		Fpisodes	Min	202	206	Max
FATIGUE	Fluoxetine	4	9	6	22	22
	Reboxetine	7	7	13	28	28
INFLUENZA-LIKE SYMPTOMS	Fluoxetine	ς,	1	17	37	37
	Reboxetine	æ	S	14	18	18
DIARRHOEA	Fluoxetine	9	N	4	æ	80
	Reboxetine	ξ		7	7	7
VISIDN ABNORMAL	Fluoxetine	4	e	12	23	23
	Reboxetine	m	S.	28	94	040
PARAESTHESIA	Fluoxetine	-	35	35	35	35
	Reboxetine	c)	r.	8	44	44
DYSPEPSIA	Fluoxetine	r,	1	4	60	0
	Reboxetine	•	25	25	25	25
PRURITUS	Fluoxetine	8	10	23	35	35
	Reboxetine	3	12	19	42	42
VDMITING	Fluoxetine	8	8	3	3	3
	Reboxetine	3	-	6	18	18
SOMNOLENCE	Fluoxetine	æ	60	8	31	31
	Reboxetine	2	7	11	27	27
UPPER RESP TRACT INFECTION	Fluoxetine	en en	1	9	27	27
	Reboxetine	8	S	9	4	4
APPETITE INCREASED	Fluoxetine	4	7	6	20	20
NERVOUSNESS	Fluoxetine	8	80	61	27	27

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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(\*) 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

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

PHARMACIA CNS RBD REBOXETINE - PROTOCOL 20124/016 TABLE No.: 51 ADVERSE EVENTS: DURATION OF EPISODES (\*) BY ASSIGNED TREATMENT

Adverse events/Assigned treatment			Durat	Duration of episodes (days)	p) saposi	ays)
		No of Episodes	Kin	20%	206	Max
NERVOUSNESS	Reboxetine	-	21	21	21	21
ABDOMINAL PAIN	Reboxetine	4	-	m	32	32
RHINITIS	Fluoxatine	m	7	80	4	10
	Reboxetine	-	S	r)	10	ιŋ
FEVER	Fluoxetine	62	9	10	13	13
	Reboxetine	2	2	4	9	vo
BACK PAIN	Reboxetine	e	4	12	14	41
VERTIGO	Reboxetine	e	٦	٦	r.	S
HYPERCHOLESTEROLAENIA	Fluoxetine	63	-	1	-	-
	Reboxetine	-	9	9	9	Ŷ
PHARYNGITIS	Fluoxetine	23	10	:	Ŧ	F
	Reboxetine	-	13	13	13	13
URINARY TRACT INFECTION	Fluoxetine	2	-	4	9	9
	Reboxetine	1	15	15	15	15
HOT FLUSHES	Fluoxetine	٣	6	6	6	6
	Reboxetine	23	23	38	53	53
RASH	Reboxetine	2	3	7	11	11
MYALGIA	Fluoxetine	1	10	10	10	10
	Reboxetine	-	23	8	2	2
HYPERTONIA	Fluoxetine	8	1	22	42	42
URINARY RETENTION	Reboxetine	2	3	21	39	39
FLUSHING	Reboxetine	2	14	16	17	17

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 51

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	REBOXETINE - PROTOCOL 20124/016 TABLE No.: 51	016				
ADVERSE E	ADVERSE EVENTS: DURATION OF EPISODES (*) BY ASSIGNED TREATHENT	ASSIGNED 1	FREATHENT			
Adverse events/Assigned treatment		,	Durat	ion of ap	Duration of episodes (days)	ays)
		No of Episodes	Min	202	206	Max
HYPERTENSION	Fluoxetine	-	21	21	21	
	Reboxetine	-	28	28	28	
HYPOTENSION	Fluoxetine	-	2	2	2	
	Reboxetine	-	100	8	60	
PALPITATION	Reboxetine	2	m	20	36	
CONJUNCTIVITIS	Fluoxetino	-	43	43	43	
	Reboxetine	-	0	6	6	
TINNITUS	Reboxetine	N	7	8	8	
ANXIETY	Fluoxetine	1	16	16	16	
	Reboxetine	-	-	1	1	
EUPHORIA	Reboxetine	63	8	12	SI	
SUICIDE ATTEMPT	Fluoxetine	1	1	-	1	
	Reboxetine	-	1	-	1	
GASTRITIS	Fluoxetine	1	22	22	22	
	Reboxetine	۳	27	27	27	
HEPATIC ENZYMES INCREASED	Reboxetine	2	22	25	27	
COUGHING	Fluoxetine	٦	1	1	11	
	Reboxetine	1	LC)	S	S)	
RESPIRATORY DISORDER	Reboxetine	23	10	19	27	
CYSTITIS	Fluoxetine	-	un	S	\$	
	Reboxetine	r	39	39	39	
ALLERGIC REACTION	Fluoxetine	-	22	22	22	

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(\*) 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

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 51 ADVERSE EVENTS: DURATION OF EPISODES (\*) BY ASSIGNED TREATMENT

Adverse events/Assigned treatment		9	Durat	Duration of episodes (days)	isodes (c	lays)
		Episodes	Kin	502	206	Max
ALLERGIC REACTION	Reboxetine	7	15	15	15	51
ABSCESS	Reboxetine	22	6	28	94	94
RASH HACULO-PAPULAR	Fluoxetine	~	ĸ	5	S	S.
TENDINITIS	Reboxetine	-	14	4	14	#
HYPERKINESIA	Fluoxetine	٦	28	28	28	28
MIGRAINE	Reboxetine	1	N	2	2	2
ANOREXIA	Rebaxetine	-	11	11	н	11
HYPOTENSION POSTURAL	Rebuxetine	-	15	15	15	15
TACHYCARDIA	Reboxetine	*	8	3	ĸ	£
ХЕКОРИТНАГИТА	Reboxetine	1	8	82	æ	8
TASTE PERVERSION	Reboxetine	1	56	56	99	95
LIBIDO DECREASED	Reboxetine	-	8	8	8	8
PARONIRIA	Flüoxetine	٦	8	8	8	€0
FLATULENCE	Fluoxetine	٦	6	6	6	6
HEPATITIS INFECTIOUS	Reboxetine	1	1	1	. 1	1
HYPERURICAEMIA	Fluoxetine	1	29	62	29	59
ALDPECIA	Reboxetine	1	3	£	3	3
OEDEMA GENERALISED	Fluoxetine		83	8	₩	60
CIRCULATORY FAILURE	Rebaxetine	1	1	1	-	1
OEDENA LEGS	Reboxetine	ı	16	91	16	16
EPISTAXIS	Reboxetine	1	26	97	26	26
SINUSILIS	Fluoxetine	1	4	4	4	4

CONTINUED

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 51

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

dverse events/Assigned treatment		9	Durat	ion of ep	Duration of episodes (days)	ays)
		No or Episodes	Min	202	206	ЖаЖ
SRONCHITIS	Fluoxetine	٦	9	9	9	9
INAEMIA	Reboxetine	1	40	80	80	80
RENAL PAIN	Fluoxetine	•	2	2	63	2
CMPOTENCE	Fluoxetine	-	13	13	13	13
SPERMATORRHOEA	Reboxetino	-	6	6	6	6
SJACULATION DISORDER	Reboxeting	1	6	8	e	m
SREAST FIBROADENOSIS	Reboxetine	٦	94	46	94	9†7
ASTHENIA	Fluoxetine	٢	æ	8	60	83
CHEST PAIN PRECORDIAL	Fluoxetine	1	22	22	22	22
HALAISE	Fluoxetine	-	-	٦	-	-
HYPERPYREXIA	Reboxetine	1	7	4	7	2
INFECTION VIRAL	Fluoxetine	1	9	9	9	9
OTITIS HEDIA	Fluoxetine	1	22	22	22	22

PHARMACIA CHS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 52
ADVERSE EVENTS: NUMBER OF ADVERSE EVENTS BY SYMPTOMATIC TREATHENT AND ASSIGNED TREATMENT

Adverse events					Ass	igned t	Assigned treatment	42				
			Fluoxetine	tine					Reboxetine	tine		
		Symp	tomatic	Symptomatic treatment	ent			Symi	Symptomatic treatment	treat	ent	
	YES	ra Ca	문	_	Total	Te.	YES	w	윤		Tot	Total
	No.	×	Жо.	×	No.	×	Š.	×	. ok	×	%.	ж
No. of pt. with A.E.	32	53.3	28	46.7	9	100.0	30	56.6	23	43.4	53	100.0
No. of adverse events	\$5	30.0	126	70.0	180	100.0	649	22.2	172	77.8	221	100.0
HEADACHE	12	42.9	16	57.1	28	100.0	S	23.8	16	76.2	21	100.0
HOUTH DRY			80	100.0	80	100.0	7	7.4	25	92.6	27	100.0
DIZZINESS			80	100.0	80	100.0	-	5.6	17	94.4	18	100.0
NAUSEA	61	13.3	13	86.7	15	100.0	3	27.3	80	72.7	11	100.0
CONSTIPATION	4	57.1	60	42.9	7	100.0	67	11.1	16	88.9	18	100.0
INSOMNIA	∞	72.7	10	27.3	11	100.0	80	72.7	6	27.3	11	100.0
SMEATING INCREASED			6	100.0	9.	100.0			æ	100.0	8	100.0
MICTURITION DISORDER			٢	100.0	1	100.0			9	100.0	10	100.0
TREMOR			S	100.0	5	100.0	-	25.0	m	75.0	4	100.0
AGITATION	4	57.1	3	42.9	7	100.0			-	100.0	1	100.0
FATIGUE			4	100.0	4	100.0			4	100.0	4	100.0
INFLUENZA-LIKE SYMPTOMS	8	60.09	2	40.0	5	100.0	73	66.7	-	33.3	9	100.0
DIARRHOEA	-	16.7	5	83.3	9	100.0			1	100.0	1	100.0
VISION ABNORMAL			7	100.0	4	100.0			3	100.0	8	100.0
PARAESTHESIA			-	100.0	1	100.0	-	20.0	4	80.0	5	100.0
DYSPEPSIA			5	100.0	S	100.0	-	100.0			-	100.0
PRURITUS	2	100.0			2	100.0	٢	33.3	2	66.7	e	100.0
VOMITING	2	100.0			2	100.0	2	66.7	1	33.3	E	100.0
SOMNOLENCE			E	100.0	E	100.0			2	100.0	2	100.0

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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					Ass	Assigned treatment	reatmen	بد ا				
			Fluoxetine	tine					Reboxetine	tine		
		Symp	tomatic	Symptomatic treatment	ent			Symp	tomatic	Symptomatic treatment	ent	
	23	YES	S.	_	Tot	Total	YES	54	ON		Total	al
	No.	×	No.	×	No.	×	۳ō.	×	No.	×	No.	×
UPPER RESP TRACT INFECTION	2	66.7	٢	33.3	Э	100.0	2	100.0			62	100.0
APPETITE INCREASED			4	100.0	4	100.0						
NERVOUSNESS			6	103.0	3	100.0			7	100.0	-	100,0
ABDOMINAL PAIN							1	25.0	e	75.0	4	100.0
RHINITIS			ю	100.0	3	100.0	1	100.0			-	100.0
FEVER	1	50.0	-	50.0	2	100.0	1	50.0	1	50.0	2	100.0
BACK PAIN							2	66.7	-	33.3	3	100.0
VERTIGO									3	100.0	3	100.0
HYPERCHOLESTEROLAEMIA			2	100.0	2	100.0			-	100.0	1	100.0
PHARYNGITIS	. 7	100.0			2	100.0			1	100.0	1	100.0
URINARY TRACT INFECTION	1	50.0	-	50.0	81	100.0	•	100.0			1	100.0
HOT FLUSBES			-	100.0	1	100.0			2	100.0	2	100.0
RASH							-	50.0	-	50.0	2	100.0
HYALGIA			1	100.0	-	100.0			-	100.0	1	100.0
HYPERTONIA			2	100.0	2	100.0						
URINARY RETENTION									2	100.0	7	100.0
FLUSHING									2	100.0	2	100.0
HYPERTENSION	7	100.0			L .	100.0	1	100.0			ı	100.0
HYPOTENSION	1	100.0			1	100.0			1	100.0	1	100.0
PALPITATION									2	100.0	2	100.0
CONJUNCTIVILIS	1	100.0			1	100.0			-	100.0	-	100.0

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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					ASS	Assigned treatment	reatmer	#				
			Fluoxetine	tine					Reboxetine	tine		
		Sym	tomatic	Symptomatic treatment	ent			Symp	Symptomatic treatment	treatu	ent	
	23	YES	Q.		Tot	Total	33	YES	운		Total	al
	No.	×	γο.	×	₩.	×	No.	×	No.	×	No.	×
TINNITUS									2	100.0	23	100.0
ANXIETY	-	100.0			-	100.0			-	100.0	-	100.0
EUPHORIA									2	100.0	2	100.0
SUICIDE ATTEMPT			1	100.0	1	100.0	1	100.0			-	100.0
GASTRITIS	-	100.0			-	100.0	1	100.0			-	100.0
HEPATIC ENZYMES INCREASED							1	50.0	1	50.0	2	180.0
COUGHING	٦	100.0			-	100,0	-	100.0			-	100.0
RESPIRATORY DISORDER									2	100.0	2	100.0
CYSTITIS			-	100.0	-	100.0		100.0				100.0
ALLERGIC REACTION			-	100.0	•	100.0	ı	100.0			1	100.0
ABSCESS							2	100.0			63	100.0
RASH MACULO-PAPULAR			-	100.0	1	100.0						
HYPERKINESIA			-	100.0	ı	100.0						
NIGRAINE									1	100,0	١	100.0
ANOREXIA									1	100.0	۲	100.0
HYPOTENSION POSTURAL							٦	100.0			1	100.0
TACHYCARDIA									1	100.0	-	100.0
XEROPHTHALMIA									-	100.0	1	160.0
TASTE PERVERSION									-	100.0	1	100.0
PARONIRIA			1	100.0	1	100.0						
HEPATITIS INFECTIOUS									1	100.0	1	100.0

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

TABLE No.: 52

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

Calledo octobre					Ass	Assigned treatment	reatmer	#2				
			Fluoxetine	stine					Reboxetine	tine		
		Symi	tomatic	Symptomatic treatment	ent			Sym	Symptomatic treatment	treat	nent	
	5	SE S	ON		To.	Total	17.	YES	8		Tot	Total
	У	×	No.	×	No.	×	No.	×	No.	×	No.	×
HYPERURICAEMIA			1	100.0	-	100.0						
OEDEMA GENERALISED	-	100.0			1	100.0						
OEDEMA LEGS									1	100.0	1	100.0
EPISTAXIS									1	100.0	1	100.0
BRONCHITIS	-	100.0			1	100.0						
ANAENIA									-	100.0	1	100.0
RENAL PAIN			-	100.0	1	100.0						
BREAST FIBROADENOSIS									1	100.0	-	100.0
ASTHENIA			-	100.0	-	100.0						
CHEST PAIN PRECORDIAL			٢	100.0	1	100.0						
HYPERPYREXIA									1	100.0	-	100.0
INFECTION VIRAL	_	100.0			7	100.0						
OTITIS MEDIA	_	100.0			-	100.0						
TENDINITIS							٢	100.0			-	100.0
LIBIDO DECREASED									-	100.0	-	100.0
FLATULENCE			-	100.0	1	100.0						
ALOPECIA									-	100.0	1	100.0
CIRCULATORY FAILURE									-	100.0	-	100.0
SINUSITIS			-	100.0	٢	100.0						
IMPOTENCE			1	100.0	ı	100.0						
SPERMATORRHOEA									1	100.0	1	100.0

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 52

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

Adverse events					ASS	igned t	Assigned treatment	Ŧ				
			Fluoxetine	tine					Reboxetine	tine		
		Sym	Symptomatic treatment	treatm	Rent			Sym	ptomati	Symptomatic treatment	lent	
	ы	YES	S		Total	a.l	7.7	YES	Q.		Total	183 183
	<u>چ</u>	×	No.	×	No.	×	No.	×	No.	×	No.	×
EJACULATION DISORDER										1 100.0	٢	100.0
HALAISE			1	100.0	-	100.0						

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PHARMACIA CNS R&D REBOXETINE - PROTDCOL 20124/016 TABLE No.: 53

## REBOXETINE - PROTOCOL 20124/016 TABLE No.: 53 ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	tment	L					Study drug	drug					
		No change	ange	Dose reduced	duced	Temporarily interrupted	arily upted	Definitively withdrawn	ively	Liss	Missing	Total	a1
		No.	×	No.	×	No.	×	No.	×	No.	×	No.	×
All adverse events	Fluoxetine	155	86.1	150	2.8	3	1.7	6	5.0	60	4.4	180	100.0
	Reboxetine	185	83.7	4	1.8	-	0.5	25	11.3	9	2.7	221	100.0
HEADACHE / MIGRANE	Fluoxetine	26	92.9	1	3.6					1	3.6	28	100.0
	Reboxetine	19	86.4	٢	4.5			2	9.1			22	100.0
NAUSEA AND RELATED SYMPTOMS	Fluoxetine	20	87.D					2	8.7	-	4.3	23	100.0
	Reboxetine	13	81.3					2	12.5	-	6.3	16	100.0
MOUTH DRY	Fluoxetine	8	100.0									83	100.0
	Reboxetine	25	92.6					2	7.4			27	100.0
HYPOTENSION AND RELATED	Fluoxetine	60	88.9	1	11.1							6	100.0
מיוחן בשוק	Reboxetine	11	85.0					33	15.0			20	100,0
CONSTIPATION	Fluoxetine	9	85.7	-	14.3							7	100.0
	Reboxetine	16	88.9					2	11.1			81	100.0
INSOHNIA	Fluoxetine	8	72.7	2	18.2					-	9.1	11	100.0
	Reboxetine	80	72.7	1	9.1			2	18.2			11	100.0
SWEATING INCREASED	Fluoxetine	6	100.0									6	100.0
	Reboxetine	8	100.0									8	100.0
AGITATION / ANXIETY /	Fluoxetine	89	72.7					e	27.3			1	100.0
	Reboxetine	2	66.7	-	33.3							3	100.0
URINARY HESITANCY /	Fluoxetine	-	100.0									-	100.0
	Reboxetine	2	83.3					2	16.7			12	100.0
ASTHENIA / FATIGUE	Fluoxetine	5	100.0									5	100.0

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 53

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

dverse events/Assigned treatment	Lment						Study drug	drug					
		No ch	No change	Dose reduced	peonpe	Tempo	Temporarily interrupted	Defini	Definitively withdrawn	Kis	Missing	Total	la la
		No.	×	No.	ж	No.	×	No.	×	No.	×	Ã.	×
ASTHENIA / FATIGUE	Reboxetine	60	75.0						25.0			4	100.0
TREMOR	Fluoxetine	S.	100.0									r)	100.0
	Reboxetine	4	100.0									4	100.0
INFLUENZA-LIKE SYMPTOMS	Fluoxetine	4	80.0			-	20.0					G	100.0
	Reboxetine	e	100.0									3	100.0
JIARRHOEA	Fluoxetine	w	83.3						16.7			9	100.0
	Reboxetine								1 100.0			-	100.0
BLURRED VISION	Fluoxetine	4	100.0									4	100.0
	Reboxetine	М	100.0									3	100.0
PARAESTHESIA	Fluoxetine	-	100.0									1	100.0
	Reboxetine	4	80.0					\ <u></u>	1 20.0			5	100.0
FLUSHING / HOT FLASHING	Fluoxetine	-	100.0									-	100.0
	Reboxetine	4	100.0									4	100.0
SOMNOLENCE	Fluoxetine	m	100.0					ļ				6	100.0
	Reboxetine	٢	50.0					,-	1 50.0			2	100.0
UPPER RESP TRACT INFECTION	Fluoxetine	١	33.3							2	66.7	8	100.0
	Reboxetine	-	50.0							1	50.0	22	100.0
PRURITUS	Fluoxetine	62	100.0									2	100.0
	Reboxetine	71	66.7	_	33.3							60	100.0
FEVER	Fluoxetine	22	100.0									2	100.0
	Reboxetine	1	50.0						1 50.0			21	100.0

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PHARMACIA CNS R&D

	DVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT
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: 53	DRUG
E - PROTOCOL TABLE No.: 53	STUDY
EABI	õ
EBOXETINE - PROTOCOL 20124/04 TABLE No.: 53	ACTION
2	BY
	EVENTS
	ADVERSE

Adverse events/Assigned treatment	tment						Study drug	drug					
		S Ct	No change	Dose reduced	duced	Tempor	Temporarily interrupted	Definitively withdrawn	tively	Mis	Kissing	Ĭõ	[otal
		No.	ĸ		×	No.	×	. o.	×	No.	×	No.	*
ABDOMINAL PAIN	Reboxetine	m	75.0			-	25.0					4	100.0
APPETITE INCREASED	Fluoxetine	4	100.0									4	100.0
RHINITIS	Fluoxetine	æ	100.0									3	100.0
	Reboxetine	-	100.0									٦	100.0
VERTIGO	Reboxetine	6	100.0									m	100.0
HYPERCHOLESTEROLAEMIA	Fluoxetine	23	100.0									23	100.0
	Reboxetine	1	100.0									٦	100.0
BACK PAIN	Reboxetine	33	100.0									e	100.0
PHARYNGITIS	Fluoxetine	-	50.0			-	50.0					27	100.0
	Reboxetine	•	100.0									•	100.0
ERYTHEMA / RASH	Fluoxetine							-	100.0			-	100.0
	Reboxetine	-	50.0					-	50.0			2	100.0
URINARY TRACT INFECTION	Fluoxetine	-	50.0								50.0	, 2	100.0
	Reboxetine									-	100.0	١	100.0
ALLERGIC REACTION	Fluoxetine									1	100.0	-	100.0
	Reboxetine	-	100.0									-	100.0
AEDEMA	Fluoxetine	-	100.0									۴	100.0
	Reboxetine	1	100.0									-	100.0
HYPERTENSION	Fluoxetine	1	100.0									-	100.0
	Reboxetine	-	100.0									-	100.0
PALPITATION	Reboxetine	23	100.0									2	100.0

PHARMACIA CNS RED

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment	tment		:				Study drug	drug					
		No change	apue	Dose reduced	peanpe	Temporarily interrupted		Definitively withdrawn	ively	Missing	ing	Total	al
		No.	×	S	×	No.	×	No.	×	No.	×	No.	и
HYPERTONIA	Fluoxetine	2	100.0									2	100.0
TINNITUS	Reboxetine	2	100.0									2	100.0
INCREASED LIVER ENZYMES	Reboxetine	1	50.0					-	50.0			2	100.0
HYALGIA	Fluoxetine	-	100.0									1	100.0
	Reboxetine	-	100.0									١	100.0
EUPHORIA	Rebaxetine	2	100.0									2	100.0
COUGHING	Fluoxetine	-	100.0									1	100.0
	Reboxetine	-	100,0									1	100.0
RESPIRATORY DISORDER	Reboxetine	23	100,0									2	100.0
CYSTITIS	Fluoxetine	٦	100.0									1	100.0
	Reboxetine	٢	100.0									ı	100.0
CONJUNCTIVITIS	Fluoxetine	٢	100.0									1	100.0
	Reboxetine	٢	100.0									٦	100.0
SUICIDE ATTEMPT	Fluoxetine							-	100.0			1	100.0
	Reboxetine							-	100.0			٦	100.0
ABSCESS	Reboxetine									2	100.0	2	100.0
HYPERPYREXIA	Reboxetine	-	100.0									-	100.0
CARDIAC ISCHEMIA AND RELATED Fluoxetine SYMPTOMS	Fluoxetine	1	100.0									-	100.0
CIRCULATORY FAILURE	Reboxetine	1	100.0									1	100.0
TACHYCARDIA	Reboxetine	-	100.0									-	100.0
HYPERKINESIA	Fluoxetine	-	100.0									٢	100.0

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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	eatment						Study drug	drug					
		No ch	No change	Dose reduced	peanpe	Tempor	Temporarily interrupted	Definitively withdrawn	tively	Miss	Missing	<u> </u>	Total
		No.	×	No.	×	₩.	×	No.	z	No.	×	No.	×
FLATULENCE	Fluoxetine	-	100.0									1	100.0
ANENTA	Reboxetine	٦	100.0									1	100.0
HYPERURICAEMIA	Fluoxetine	-	100.0									-	100.0
LIBIDO DECREASED	Reboxetine	٦	100.0									-	100,0
PARONIRIA	Fluoxetine	٦	100.0									-	100.0
BREAST FIBROADENOSIS	Rebuxetine	-	100.0									-	100.0
EJACULATION DISORDER	Reboxetine	-	100.0									-	100.0
INPOTENCE	Fluoxetine	1	100.0									-	100.0
SPERMATORRHOEA	Reboxetine	-	100.0									-	100.0
INFECTION VIRAL	Fluoxetine	-	100.0									-	100.0
OTITIS MEDIA	Fluoxetine	-	100.0									-	100,0
EPISTAXIS	Reboxetine	1	100.0									-	100.0
ALOPECIA	Reboxetine	4	100.0									-	100.0
TASTE PERVERSION	Reboxetine		100.0									1	100.0
RENAL PAIN	Fluoxetine	-	100.0			:						1	100.0
XEROPHTHALMIA	Reboxetine	-	100.0									-	100.0
MALAISE	Fluoxetine					-	100.0					-	100.0
ANOREXIA	Reboxetine							-	100.0			-	100.0
TENDINITIS	Reboxetine							-	100.0				100.0
BRONCHITIS	Fluoxetine							-	100.0			٦	100.0
HEPATITIS INFECTIOUS	Reboxetine									-	100.0		100.0

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 53	ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATHENT	Assigned treatment Study drug	No change Dose reduced interrupted withdrawn Missing Total	No. 2 No. 2 No. 2 No. 2 No. 3	Fluoretine 1 100.0 1 10
		Adverse events/Assigned treatment			SINUSITIS

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PHARMACIA CNS RÆD TINE - PROTOCOL 20124/016 TABLE No.: 54

SE EVENTS: DISAPPEARED AFTER ACTION ON STUDY DRUG AND REAPPEARED ON RESUMING IREATHENT BY ASSIGNED TREATHENT

Adverse events/Assigned treatment	treatment			Kodi	Modified study drug	tudy d	rug					Гепрог	arily	Temporarily interrupted	npted.		
					Disappeared	eared							Riappeared	ared			
		윤		37	83	Not applicable	t able	Total	al	2		2	82	Not applicable	rt able	Į.	Tota1
		₹0.	н	Ñ.	×	No.	×	2	×	- R	×	Ň.	к	Жо.	×	No.	×
All adverse events	Reboxetine	18	0.09	2	33.3	N	6.7	æ	30 100.0	-	1 100.0					-	100.0
	Fluoxetine	7	41.2	6	52.9	٦	5.9	17	17 100.0	61	66.7			-	33.3	m	100.0
INSONNIA	Reboxetine	63	66.7	٢	33.3			w	3 100.0								
	Fluoxetine	-	50.0	۳	50.0			12	2 100.0								
HYPOTENSION AND RELATED Reboxetine	Reboxetine	64	66.7			-	33.3	m	100.0								
	Fluoxetine			-	100.0			-	100.0								
HEADACHE / MIGRAINE	Reboxetine	2	66.7	•	33.3			e	100.0								
	Fluoxetine			-	100.0			-	1 100.0								
NAUSEA AND RELATED SYMPTOMS	Reboxetine			61	100.0			23	2 100.D								
	Fluoxetine	-	50.0	-	50.0			2	2 100.D								
AGITATION / ANXIETY /	Reboxetine			٦	100.0			-	1 100.0								
	Fluoxetine	e	3 100.0					3	3 100.0								
CONSTIPATION	Reboxetine	2	2 100.0					2	2 100.0								
	Fluoxetine			-	1 100.0			-	1 100.0								
HOUTH DRY	Reboxetine	-	50.0	-	50.0			2	2 100.0								
DIARRHOEA	Reboxetine	1	100.0					-	100.0								
	Fluoxetine			1	100.0			-	100.0								
SUICIDE ATTEMPT	Reboxetine					1	1 100.0	-	100.0								
	Fluoxetine	1	1 100.0					~	160.0								
ERYTHENA / RASH	Reboxetine	-	1 100.0					٦	1 100.0								

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(some adverse events are group

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 54

ERSE EVENTS: DISAPPEARED AFTER ACTION ON STUDY DRUG AND REAPPEARED ON RESUMING TREATHENT BY ASSIGNED TREATHENT

Adverse events/Assigned treatment	treatment			Modi	Modified study drug	dy dan	En.a					Temporarily interrupted	arily	inter	npted		
					Disappeared	ared							Riappeared	ared			
		욨	_	YES		Not applicable	t able	Total	a1	2		KES	<b>1</b> 02	Not applicable	Not icable	101	Total
		€	ж		н	S	×	₩.	×	No.	×	₩.	ж	No.	ж	No.	×
ERYTHENA / RASH	Fluoxetine	-	1 100.0					-	1 100.0	<u> </u>							
URINARY HESITANCY / RETENTION	Reboxetine	-	50.0	-7	50.0			10	2 100.0	1							
ASTHENIA / FATIGUE	Reboxetine	-	1 100.0					-	100.0								
FEVER	Reboxetine			-	1 100.0			-	1 300.0								
INFLUENZA-LIKE SYNPTOMS Fluoxetine	Fluoxetine			-	1 100.0			<b>F</b> =	100.0	-	1 100,0					٦	100.0
NALAISE	Fluoxetine					-	1 100.0	-	100.0					1	1 100.0	-	1 100.0
PARAESTHESIA	Reboxetine	-	1 100.0					-	100.0								
ABDOMINAL PAIN	Reboxetine			-	1 100.0			-	100.0	٦	100.0					-	100.0
ANOREXIA	Reboxetine			٢	1 100.0			-	100 .0								
INCREASED LIVER ENZYMES Reboxotine	Reboxetine	-	1 100.0					-	100.0								
TENDINITIS	Reboxetine	-	1 100.0					-	1 100.0								
SOHNOLENCE	Reboxetine		1 100.0					-	1 100.0								
BRONCHITIS	Fluoxetine			-	1 100.0			-	100.0								
PHARYNGITIS	Fluoxetine			-	1 100.0			1	1 100.0	-	1 100.0					-	1 100.0
PRURITUS	Reboxetine	-	1 100.0					-	1 100.0								

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PHARMACIA CNS R&D

Adverse events/Assigned treatment	signed treatment					Modifi	Modified study drug	ty dru	bp						Uncha	nged	study	Unchanged study drug	or Missing	ssing			
		Reco	vered	Recovered with Recovered sequelae	rered th	Still present		Death	Ä	Kissing	Total		Recover	Recovered with Recovered sequelae	Recovered with seguelae	rs id	Still present	Death	#	Missing	- P	Total	
		Š.	×	8	×	. ok	χ No.	*	Ã.	×	Ã.	×	No.	Z No.	×	ě	ĸ	80.	м	Νο.	No.	-	×
All adverse	Fluoxetine	10	58.8			7 4	41.2	-	_		42	100	105 64	4.49	1 0.6	ž	4 20.9			23 1	14.1	163	103
2000	Reboxetine	-	11 36.7			19 65	63.3				8	9	105 5	55.0	1 0.5	2	1 26.7			34	17.8	191	100
HEADACHE /	Fluoxetine		1 100								1	19	21 7	77.8	1 3.7		2 7.4			8	11.1	27	100
	Reboxetine	N	66.7			- 3	33.3				3	10	14 73	73.7		٠,	3 15.8			2	10.5	19	100
NAUSEA AND	Fluoxetine		50.0			1.5	50.0				2	2	16 74	76.2		<u> </u>	2 9.5			3	14.3	23	100
ACLELICO STOFFICOS	Reboxetine		1 50.0			1.5	50.0				2	9	11 72	78.6		Ľ	7.1			22	14.3	#	100
MOUTH DRY	Fluoxetine												22	25.0			3 37.5			3 37	7.5	60	10
	Reboxetine	Ĺ	50.0			1 5	50.0				2	100	80	32.0	_	۳	12 48.0			5 20	0.0	25	100
HYPOTENSION AND	Fluoxetine		1 100					_	-		7	100	7	87.5	_					1	12.5	80	100
	Reboxetine					m	100	_	_		3	100	<b>60</b>	47.1	1 5.9		3 17.6			5.	29.4	12	9
CONSTIPATION	Fluoxetine		100					_			1	100	5 83.	8.3						-	16.7	ų,	9
	Reboxetine					14	100		_	_	2	100	9 5	56.3			6 37.5			-	6.3	9	100
INSOMNIA	Fluoxetine		0.08			5	20.0				2	100	4	44.4		_	4.44.4			-	11.1	6	100
	Reboxetine	Ľ	33.3			2	66.7		_	_	69	100	23	25.0		Ĺ	4 50.0			2	25.0	8	100
SWEATING	Fluoxetine	-					-	L					3 33.	3.3	_		5 55.6			-	11.1	σ,	100
	Reboxetine												6 7	75.0			1 12.5			-	12.5	80	100
AGITATION /	Fluoxetine					ю	100	-			m ,	9	4	50.0			4 50.0					83	100
NERVOUSNESS	Reboxetine		1 100					_	<u> </u>		-	9	-	20.0						1.5	50.0	2	100
URINARY HESITANCY Fluoxetine	Fluoxetine								_					_			100					-	100
	Reboxetine	Ľ	1 50.0			1.5	50.0		_	<u> </u>	2	100	8 8	80.0	_		1 10.0			-	10.0	2	100
							-		$\left\{ \right.$											1	1		1

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 55	ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY

	ndverse events/assigned treatment					Modif	Modified study drug	udy d	trug						dD.	chang	Unchanged study drug or Missing	y drug	OF M	issing			
,		Reac	Recovered		Recovered with sequelae	Still present	11 ent	Death		Missing		Total	Rec	Recovered	Recovered with sequelae	g g	Still present		Death	Missing	ing	Total	-10
		Ã.	×	No.	м	No.	×	No.	×	No. x	No.	×	Š	*	No.	N	No. z	Š.	×	В	м	No.	×
ASTHENIA /	Fluoxetine	ļ												4 80.0			1 20.0	0				S	100
	Reboxetine					-	100					100		3 100								w	100
TREHOR	Fluoxetine									-				4 80.0			1 20.0	0				c)	100
	Reboxetine										_			3 75.0			1 25.0	0				4	100
INFLUENZA-LIKE	Fluoxetine	_	1 100									100		3 75.0		_				-	25.0	4	100
orn t auto	Reboxetine	_															2 66.7	7		-	33.3	6	100
DIARRHOEA	Fluoxetine	ļ <u>.</u>	100					-			_	1 100		5 100								ı,	100
	Reboxetine	_				٦	100				-	100	_					_					
BLURRED VISION	Fluoxetine								-				_	3 75.0			1 25.0	0				4	100
	Reboxetine							<u> </u>				_		1 33.3			2 66.7	7				60	100
PARAESTHESIA	Fluoretine								<u> </u>	_				1 100		-						-	100
	Reboxetine					-	100	<del> </del>		ļ		100	Ļ	3 75.0						٢	25.0	4	100
FLUSHING / HOT	Fluoxetine										<u> </u>			1 100								-	100
	Reboxetine											-		3 75.0			1 25.0	0				4*	100
SOMNOLENCE	Fluoxetine		_						-		ļ			2 66.7						-	33.3	m	100
	Reboxetine					-	100				-	1 100					-	100				-	100
UPPER RESP TRACT	Fluoxetine													2 66.7						-	33.3	m	9
	Reboxetine										_		_	1 50.0						~	50.0	~2	2
PRURITUS	Fluoxetine								<b> </b>				_	2 100			_	<u> </u>				23	100
	Reboxetine					-	100			<u> </u>		1 100	-				1 50.0	-		-	50.0	61	100

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 55
ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY

Adverse events/Assigned treatment	signed treatment					Modifi	Modified study drug	dy dr.	67						Unche	pegui	Unchanged study	drug	10	or Missing		
		Reco	Recovered	Recovered with sequelae	rered th	Still present	nt nt	Death		Missing	ě	Total	Recovered Recovered Recovered Sequelae	Red Ser	Recovered with sequelae		Still present	å	Death	Missing	<u></u>	Tota1
		%	×	No.	×	No.	X No.	N	₩.	*	₩.	×	No.	X No.	×	Š.	×	No.	×	No. x	8	
FEVER	Fluoxetine						_						-	50.0						1.50	50.0	2 100
	Reboxetine	-	100					<u></u>			_	100	-	100								1 100
ABDOMINAL PAIN	Reboxetine	-	100				<u> </u>			_	-	100	m	100		_						3 100
APPETITE INCREASED	Fluoxetine												8	75.0		<u> </u>	1 25.0					100
RHINITIS	Fluoxetine												2	66.7	_					1 33.	E	3 100
	Reboxetine														<u> </u>		1 100					1 100
VERTIGO	Reboxetine							<del> </del>					m	100								3 100
HYPERCHOLESTEROL- Fluoxetine	Fluoxetine															ļ	2 100					2 100
	Reboxetine							-	-	_	_						1 100					100
BACK PAIN	Reboxetine							_	_				м	100								3 100
PHARYNGITIS	Fluoxetine	-	100					_			_	100					100					100
	Reboxetine		L														100					100
ERYTHENA / RASH	Fluoxetine					-	100		<u> </u>		-	100										
	Reboxetine					-	100				-	100									100	1 100
URINARY TRACT	Fluoxetine						-						1.	50.0						1.5	50.0	2 100
WOT TO THE	Reboxetine													_						-	100	1 100
ALLERGIC REACTION Fluoxetine	Fluoxetine																			-	100	100
	Reboxetine																1 100					1 100
AEDEMA	Fluoxetine												-	100								1 100
	Reboxetine																			-	100	1 100

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 55

Adverse events/Assigned treatment	signed treatment					Hodif	Modified study drug	udy di	rug							nchan	ged :	Unchanged study drug or Missing	grag	or Hi	ssing			
		Reco	Recovered		Recovered with sequelae	Still present	nt —	Death		Missing		Tota1	Re	Recovered sequelae	Recovered with sequelae	ered h lae	St.	Still present	Death	#	Kissing	- E	Total	1
		Ñ.	×	¥a.	×	. ok	×	No.	ž ×	No. ×	₩.	×	S.	ĸ	8	ж	₽.	×	No.	×	No.	×	No.	×
HYPERTENSION	Fluoxetine								-				ļ	1 100								ļ	-	100
	Reboxetine																				-	100	-	ê ê
PALPITATION	Reboxetine								-	-			ļ	1 50.0			-	50.0			_		N	ē
HYPERTONIA	Fluoxetine	_									_			1 50.0			1	50.0					N	₽
TINNITUS	Reboxetine	_						-	<del> </del>		_			2 100									12	阜
INCREASED LIVER ENZYMES	Reboxetine	_	100									100					-	100					-	100
MYALGIA	Fluoxetine								ļ			ļ	_	1 100									-	100
	Reboxetine											_		1 100									-	100
EUPHORIA	Reboxetine												_	1 50.0							1 5	50.0	67	100
SUICIDE ATTEMPT	Fluoxetine					-	100	-	$\vdash$		_	100	6											
	Reboxetine	-	100					-	_		-	100												
ABSCESS	Reboxetine													-							77	100	N	둳
COUGHING	Fluoxetine							-	$\vdash$		-	_	_	-			-	100					-	퉏
	Reboxetine																-	100					-	100
RESPIRATORY DISORDER	Reboxetine																-	50.0			- 15	50.0	N	100
CYSTITIS	Fluoxetino							-									-	100				-	-	5
,	Reboxetine												<u> </u>				-	100					-	100
CONJUNCTIVITIS	Fluoxetine																-	100					-	5
	Reboxetine													1 100	_								-	5

(CONTINUED)

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PHAKMALIA UND KRU REBOXETINE - PROTOCOL 20124/016 TABLE No.: 55 ADVERSE EVENTS: OUTCOME OF EVENTS AT THE END OF THE THERAPY
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Adverse events/Assigned	signed treatment				É	lifie	stud	Modified study drug	_						Unct	anged	stud	Unchanged study drug		or Kissing	69		
		Recov	Recovered :	Recovered with sequelae	-	Still present		Death	Kis	Kissing	Total		Recovered		Recovered with sequelae		Still present		Death	H.	Missing	<u></u>	Total
		₩o.	×	No.	No.		8	×	No.	×	0	×	9	ž	No. x	Š.	*	%.	×	₩.	*	. ≥	×
HYPERPYREXIA	Reboxetine				_	_	<u> </u>						-	100								_	100
MALAISE	Fluoxetine	-	100								-	100		<u></u>									
CARDIAC ISCHENIA AND RELATED SYMPTOMS	Fluoxetine																				1 100		100
CIRCULATORY FAILURE	Reboxetine												-	100			ļ		<u> </u>			_	10
TACHYCARDIA	Reboxetine				-								-	100									100
HYPERKINESIA	Fluoxetine			_	ļ	_	-						-				100	-				_	100
ANOREXIA	Reboxetine					-	100				-	100											
FLATULENCE	Fluoxetine												-	100								-	100
ANEMIA	Reboxetine					-		_	L							_				Ĺ	100	-	100
HEPATITIS INFECTIOUS	Reboxetine																100						2
HYPERURICAENIA	Fluoxetine				ļ .									-			1 100						100
TENDINITIS	Reboxetine					1	100				-	100											
LIBIDO DECREASED	Reboxetine					_	-						-	100								-	100
PARONIRIA	Fluoxetine				-								-	100		_						-	100
BREAST FIBROADENOSIS	Reboxetine																-	100				-	100
EJACULATION DISORDER	Reboxetine												-	5								_	100
IMPOTENCE	Fluoxetine												1	160								-	100

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PHARMACIA CNS R&D

ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT REBOXETINE - PROTOCOL 20124/016 TABLE No.: 56

			2-2		ľ		-			L	1	-			-				!	:					4	l.
					eio.	8-14		15-21	Σ.		22-28		61	29-35		ĕ	36-42		43-49	4,0		50-56	26			^
		Pt.	F &	8	7. % 8. %	Z on exp. (*)	P. P.	% on exp.	3	£ ₹.	Z on exp.	8	No Pt.	X on exp. (3	(*)	No X Pt. ex	X on exp. (*)	5 T	X on exp.	€ 6	2 ±	x on .		2 %	Z on exp.	3
events t	Assigned treatment		ļ <u> </u>													-						_			ļ	-
Pt exposed F	Fluoxetine	68	1001	1.62	85	100 2.00	90 83	100	1.69	82	100	1.57	78	1001	1.70	73_	100	1.56 7	71 10	100 1.71	71 69	100	0 1.59	13	100	1.33
j es	Reboxetine	79	100	2.45	75	100 2.	50 74	100	1 2.30	74	300	2.22	72	100 2.	27	99	100 2.	2.26	63	100 2.2	.21 59	100	N	.00	100	1.88
HOUTH DRY F	Fluoxetine	9	6.7	1.00	vo	7.1 1.00		7 8.4	1.00	r.	6.1	1.00	m	3.8	1.00	2	2.7 1.	1.00	2 2	2.8 1.00	┖	2 2.9	9 1.00	<u> </u>	2 15.4	4 1.00
<u> </u> #	Reboxetine	19 2	24.1	1.00	21 28.	8.0 1.00	00 20	27.0	1.00	17	23.0	1.00	16 2	22.27	1.00	13 19	19.7 1.	1.00	12 19.0	0 1.00	13	3 22.0	0 1.00	1_	9 60.0	1.00
HEADACHE F	Fluoxetine	ω.	9.0	1.00	15 17	7.6 1.00	<u> </u>	9 10.8	1.00	~	8.5	1.00	4	5.11	1.00	7	9.6 1.	1.00	4	4.2 1.00		2 2.9	9 1.00		1 7.7	7 1.00
<u>64</u>	Reboxetine	7	6.9	1.00	7	9.3 1.00	<u></u>	8 10.8	3 1.00	4	5,4	1.09	10	8.3 1	1.00	5	7.6 1.	1.00	3.4	4.8 1.00		4 6.8	1,00		2 13.	3 1.00
CONSTIPATION	Fluoxetine	N	2.2	1.00	27	2.4 1.00		3.6	6 1.00	6	3.7	1.00	4	5.11	1.00	4	5.5 1.	1.00	3.4	4.2 1.00		1.4	4 1.00	9		
œ	Reboxetine	4.	17.71	1.00	141	18.7 1.00	11	14.9	1.00	80	10.8	1.12	2	9.7	1.00	7 10	9	1.00	7 11.1	1.00		9	.2 1.00		3 20.	00.1
INSOMNIA	Fluoxetine	N	2.2	1.00	ru 	5.9 1.00	<u> </u>	6 7.2	1.00	9	7.3	1.00	7	9.0	1.00	5	80	1.00	5 7.	7.0 1.00		4 5.8	8 1.00		7.	7 1,00
<u>α</u>	Reboxetine	ιŋ	6.3	1.00	9	8.0 1.00		6 8.1	1.00	6	12.2	1.00	8	11.11	1.00	8 12.	Ξ.	1.00	7 11.1	1.00	L.,	6 10.	1.00		2 13.	3 1.00
SWEATING	Fluoxetine	4	8.4	1.00	7	8.2 1.00	<u> </u>	6 7.2	1.00	ĸ	6.1	1.00	4	5.11	1.00	4	5.5 1.	1.00	5 7.	7.0 1.1	8	5 7.2	2 1.00		4 30.	8 1.00
J	Reboxetine	4	5.1	1.00	9	8.0 1.00		6 8.1	1.00	N	2.7	1.00	-	1.41	1.00	H			-		_	ļ	_			ļ. <u>.</u>
DIZZINESS	Fluoxetine	6	3.4	1.00	ري د.	5.9 1.00		2 2.4	1.00	N	2.4	1.00	-	1.3 1.	8.	-	1.41.	1.00	<u>+</u>	1.4 1.00	8		_			
<u>  64</u>	Reboxetine	2	8.9	1.00	8 10		1.00	7 9.5	5 1.00	4	5.4	1.00	ru.	6.9	1.00	9	9.1	1.00	5. 7.	7.9 1.00		4 6.8	8 1.00		9	7 1.00
NAUSEA	Fluoxetine	6	6.7	1.00	40	7.1 1.33		5 6.0	0 1.00	N	2.4	1.00	-	1.3 1	1.00	24	2.7 1.	1.8	2	2.8 1.1	90		.4 1.00	<u></u>		
DE .	Reboxetine	60	10.1	1.00	ro -	6.7 1.00		4.5.4	4 1.00	81	2.7	1.0	7	2.8 1	1.00	-	1.5	1.00						<u> </u>		
TREMOR	Fluoxetine				-	1.2 1.00		3 3.4	6 1.00	m	3.7	1.00	61	2.6 1	1.00	6	4.1	1.00	5.	9	00.	2 2.9	ή.	8	1 7.7	7 1.00
i ex	Reboxetine	N	2.5	1.00	61	2.7 1.00		2 2	7 1.00	-	1.4	1.00	~	1.4	1.00	-	1.5 1.	1,00	-	1.6 1.1	8.	-	1.7 1.6	00	6	.7 1.00
MICTURITION F	Fluoxetine	-	1.1	1.00	-	1.2 1.	1.00	1 1.2	1.00				-							-						
	Reboxetine	7	8.9	1.00	ı,	6.7 1.00	_	2	2.7 1.00	~	2.7	1.00	-	1.4	1.00	6	3.0 1	1.00	2	1.00		1 1.7	7 1.00		1 6.7	7 1.00

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

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PHARMACIA CNS R&D

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

													Days	돢	of treatment	int											
			0-7		_	8-14		12	15-21	-	-22-	22-28	$\vdash$	29-35	ñ		36-42	61		64-64			50-56		"	28	
		Pt.	χ on exp.	€	54	% on exp. (	8	No %	% on (*)	7 K	x on carp.	¥ .	₽ ¥.	x on exp.	€	2 %	z on exp.	€	P. S.	z on exp.	*	7. 3.	z on exp.	8	No.	x on exp.	*
Adverse events	Assigned treatment												-		ļ												
INFLUENZA-	Fluoxetine	T			-	1.2	1.00	-	1.2	1.00	ь Э	3.7 1.00		4.5.	5.1 1.00		4.	1.00	6	4.2	1.00	_	4.	1.00			
LLKE SIMPIUMS	Reboxetine				67	2.7	1.00	2	2.7 1.	1.00	2 2	2.7 1.00		1.4	1.00							-	1.7	1.00	-	6.7	1.00
VISION	Fluoxetine	-	1.1	1.00	en en	3.5	1.00	2	2.4 1.	1.00	-	1.2 1.00	8	_					-	4.1	1.00	-	1.4	1.00	-	7.7	1.00
annowing a	Reboxetine	6	3.8	1.00	6	4.0	1.00	22	2.7 1.	1.00	23	2.7 1.00		2 2.8	1.00	1	1.5	1.00									
PARAESTHESIA	Fluoxetine				-	1.2	1.00	-	1.2.1	1.00	<del></del>	1.2 1.00		1.3	3 1.00	1	1.4	1.00	-	1.4	1.08	ļ					
	Reboxetine	ı,	6.3	1.00	4	5.3	1.00	62	2.7 1.	1.00	-	1.4	1.00	1 1.4	1.00	-	1.5	1.00	-	1.6	1.00	-	1.7	1.00			
FATIGUE	Fluoxetine	23	2.2	1.00	63	2.4	1.00	-	1.2 1.	1.00	-	1.2 1.	1.00	1 1.3	3 1.00	1	1.4	1.00				-	1.4	1.00			
	Reboxetine	В	3.8	1.00	m	4.01	1.00	63	2.7 1.	8	-	1.4 1.00		1 1.4	1.00	-	1.5	1.00	~	1.6	1.00						
PRURITUS	Fluoxetine	1	-	1.00	-	1.2.1	1.00	-	1.2.1	1.00	-	1.2	1.00	2 2.6	1.00			1.4 1.00									
	Reboxetine	1	1.3	1.00	-	1.3	1.00	67	2.7 1.	1.00	-	1.4 1.00		1.4	4 1.00	-		1.5 1.00	73	3.2	3.2 1.00	62	3.4	1.00	61	13.3	1.00
AGITATION	Fluoxetine	3	3.4	1.00	64	2.4	1.00	4	4.8	1.00	3	3.7 1.	1.00	2.6	00.1	-		1.4 1.00	٦	1.4	1.4 1.00	-	1.4	1,00			
	Reboxetine								-						_	-	1.5	1.00	-	1.6	1.00	-	1.7	1.00			
SOMNOLENCE	Fluoxetime	-	1.1	1.00	-	1.2.1	1.00				-	1.2 1.	1.00	1 1.3	3 1.00	2	2.7	1.0	61	2.8	1.00	-	1.4	1.00			
	Reboxetine	-	1.3	1.00	-	1.3	1.00	-		-		-		1 1.4	4 1.00	1	1.5	1.00	-	1.6	1.00	-	1.7	1.00			
HOT FLUSHES	Fluoxetine				-	1.2.1	1.00	-	1.2	1.00			-														
	Reboxetine	-	£.	1.00	۳	1.3	1.00	-	1.41	1.00	2	2.7 1.	1.00	2 2.8	1.00	2	3.0	1.00	23	3.2	1.00	-	1.7	1.00			
DYSPEPSIA	Fluoxetine	2	2.2	1.00	-	1.2	1.00	-	1.2	1.00	ю.	3.71	1.00	1.3	3 1.00												
	Reboxetine	-	1.3	1.00	-	1.3	1.00	-	1.4 1	1.00	-	1.4 1.	1.00	1 1.4	4 1.00	-											
NERVOUSNESS	Fluoxetine				2	2.4	1.00	2	2.4	1.00				1 1.3	3 1.00	1	1.4	1.00	-	4.6	1.00	-	1.4	1.00	-	7.7	9.
	Reboxetine						<u> </u>	-	1.4.1	1.00	-	1.4 1,	1.00	1 1.4	4 1.00	-	1.5	1.00					-				

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

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

	TREATMENT
	ASSIGNED
	BY
	INTERVAL
	TIME
	2
TABLE No.: 56	ACCORDING
TABLE	EVENTS
	ADVERSE
	Ð
	RSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT
	EVENTS:
	RSE

<b>a</b> .				ŀ						L			-								-			-			1
۵. « «			0-7		æ	8-14	_	15	15-21		22-28	28		29-35	S.		36-42		ď	43-49		. 20	50-56		^	9	
RESP		Pt.	Z on exp.	€	Pt.	x on x exp.	ž á. *	No Z on Pt. exp.	£ 3	5 t.	a v o x	8	8 £	z on exp.	8	P P	z on exp.	(¥)	Pt.	Z on Z exp. ()	* % #	No Z Pt. ex	2 on exp. (*)		No Z Pt.	z on exp. (3	8
RESP	Assigned treatment									-												_					
_	Fluoxetine	-	1.1	1.00	-	1.2	1.00	7	2.4 1.00		2	2.4 1.00		1.3	= = = = = = = = = = = = = = = = = = = =	-	4:1	1.00									
INFECTION Rebox	Reboxetine							-					٣	1.4	1.00	-	1.5	1.00	-	1.6 1	1.00	_					
APPETITE Fluos INCREASED	Fluoxetine				N	2.4	1.00	22	2.4 1.00		1 1.2	2 1.00	-	1.3	1.00	-	1.4	1.00	N	2.8	1.00	-	1.4	1.00			
ABSCESS Rebox	Reboxetina				2	2.7 1.	1.00	72	2.7 1.00		1.4	4 1.00	-	1.4	1.00	-	1.5	1.00	-	1.6 1	1.00	-	1.7 1.	1.00	-	6.7 1	1.00
DIARRHOEA Fluos	Fluoxetine	м	3.4	1.00	-	1.2 1	9.1				-	_	23	2.6	1.00	-	1.4	1.00									1
Rebo:	Reboxetine	-	1.3	9.6	-	1.3	1.00					L															
CONJUNCTIVIT- Fluoxetine	xetine	-	-	1.00	-	1.2 1.	1.00	-	1.2 1.00		-	1.2 1.00	1	1.3	1.00	۳	1.4	1.00	-	1.4	1.00			<u> </u>			
Rebo:	Reboxetine										1.	1.4 1.00	1 0	1.4	1.00							_					
TASTE Rebox	Reboxetine	-	1.3	9.1	-	1.3	1.00	-	1.4 1.00			1.4 1.00	-	1.4	1.00	-	1.5	1.06	-	1.61	1.00	-	1.7 1.	1.00	-	6.7 1	1.00
RYPERTONIA Fluos	Fluoxetine	-	1.1	1.00	67	2.4	1.00	-	1.2 1.00		1.	1.2 1.00	1 0	1.3	1.00	-	1.4	1.4 1.00	-	1.41	1.00						
HYPERTENSION Fluo	Fluoxetine	-	1,1	1.00	-	1.2	1.00	-	1.2 1.00		-	1.2 1.00	0										-				
Rebu:	Reboxetine					-					1.	1.4 1.00	-		1.4 1.00	-	1.5	1.00	-	1.6 1	1.00			_			
VOMITING Fluox	Fluoxetine	-	1.1	1.00	-		-				_	_	-	1.3	1.00					ļ							
Rebo	Reboxetine	73	2.5	1.00	-	1.3	1.00	-	1.4 1.00		-	1.4 1.00	-		1.4 1.00				-								
RHINITIS Fluor	Fluoxetine	-	1.	1.00	-	1.2 1	1.00	-	1.2 1.00		-	1.2 1.00	0	1.3	1.00	۳	1.4	1.00	-	$\vdash$				-			
Rebo	Reboxetine							-		-	-	_								-		-	1.71	1.00	-	6.7 1	1.00
ABDOMINAL Rebox	Reboxetine	-	1.3	1.00	-	1.3	1.00	-	1.4 1.00		-	1.4 1.00	6	4.	1.00	-	1.5	1.00									
GASTRITIS Fluor	Fluoxetine				-	1.2	1.00	-	1.2 1.00		-	1.2 1.00	1	1.3	1.00											-	

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 56
ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

												0	ays (	Days of treatment	atmer	#											_
			2-0		<b>"</b>	8-14		15	15-21		22-28	80		29-35		Ĺ	36-42	_	4	43-49		ξ.	50-56		۸	26	
		F 5.	2 on exp.	*	Pt.	x on exp. (*	(*) No	2 on 2	P. (*)	윤밥	x on exp.	8	₽ <del>1</del>	% on exp.	8	2 ±	z on	2	P. t.	% on exp. (	¥ &	Pt.	z on exp. (*)	E E	× 8		*
Adverse events	Assigned treatment																										
GASTRITIS	Reboxetine	1								_		1.4 1.00	-	1.4	1.00	-	1,5	1.00	-	1.61	1.00						
BREAST FIBROADENOSIS	Reboxetine				-	1.3 1.	1.00	-	1.4 1.00	7		1.4 1.00	-	1.4	1.00	-	1.5	1.00	-	1.6	1.00	-	1.7 1.00	8	- 6	6.7 1.	1.00
PHARYNGITIS	Fluoxetine						$\vdash$		_	٦	1.2	1,00	٢	1.3	1.00				-	1.4 1.00	8.	-	1.4 1.00	00	1 7	7.7 1.00	00
	Reboxetine				l			-	1.4 1.00	7	1.4	1.00	_	1.4	1.00												
URINARY RETENTION	Reboxetine	-	1.3	1.00	-	1.3	1.00	-	1.4 1.00		1.4	1.00	-	4.	1.00	63	3.0	1.00									
PALPITATION	Reboxetine	-	1.3	1.00		-	-	-	1.4 1.00		1.4	1.00	1	1.4	1.00	-	1.5	1.00	-	1.6	1.00	-	1.7 1.	1.00			
FEVER	Fluaxetine						-	-	1.2 1.00		1 1.2	1.00							-	1.4	1.00	-	1,4 1.	00.			
	Reboxetine	-	1.3	1.00	-	1.3	1.00	-	1.4 1.00	0		_															
BACK PAIN	Reboxetine				77	2.7	1.00	8	4.1 1.00		2 2.7	1.00	_								_						
CYSTITIS	Fluoxetine					-																-	1.4 1.00	8			
	Reboxetine							-	1.4 1.00		1.4	1.00	1	1.4	1.00	-	1.5	1.00	-	1.6	1.00	-	1.7 1.	1.00			
WEPATIC ENZYMES INCREASED	Reboxetine										1.4	1.00		1.4	1.00	-	£.5	1.5 1.00	2	3.2	1.00		1.7 1.00	00.		6.7 1	1,00
ALLERGIC	Fluoxetine						-									-	4.4	1.00	1	1.4 1.00	1.00	-	1.4 1	1.00	- 7	7.7	1.00
No. 100 Per	Reboxetine					-		_	_	_									-	1.6	1.00	1	1.7 1	1.00	1 6	6.7 1	1.00
FLUSHING	Reboxetine	-	1.3	1.00	-	1.3	1.00	-	1.4 1.00	<u> </u>									-	1.6	1.00	1	1.7 1	1.00	1	6.7 1.00	00.
RESPIRATORY DISORDER	Reboxetine	-	1.3	1.00	-	1.3 1.00	8.						-	4.1	1.00		1.5	1.00		1.6 1.00	1.00	1	1.7 1.00	00.			
EUPHORIA	Reboxetine	-	1.3	1.00	-	1.3 2.00	00.	-	1.4 1.00		1.4	1,00	_											-	-		

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PHARMACIA CNS R&D INE - PROTOCOL 20124/016 TARLE NO.: 54

		DEPATENCE OF ANY PARTICULE OF ANY PARTICULAR AND THE TATEOUAL BY ASSIGNED TREATMENT
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		TATEDVAL 5
		THE
		Ę
KEDUADILINE - FRUIDCUL 20124/010	TABLE No.: 56	APPROPRIATING
	TABLE	STNEAM
KEDUALI		ADVEDSE
		٤
		PEFVALENCE
		FUFNTS
		ANVERSE

310

													Days	Days of treatment	eatme	'nt											
			0-7		~	8-14		=	15-21		22-28	28		29-35	တ္		36-42	63		43-49			50-56		^	> 56	
		7 t.	Z on exp.	*	₩ Pt.	z on exp. (	£ &	No Pt.	2 on exp. (*)		2 c	No Z on Pt. exp. (*)	Pt.	x on	7 on exp. (*)	유표	Z on exp.	X on exp. (*)	2 t	% on exp.	*	문감	x on exp. (	€	No Z on Pt. exp.	E G	€
Adverse	Assigned treatment								-																		
URINARY TRACT Fluoxetine	Fluoxetine				-	1.2 1.00	00.				<del>-</del>	1.2 1.90	_														
107107	Reboxetine	-	1.3	1.00	-	1.3	1.00	-	1.4 1.00	00	_	_			L												
EPISTAXIS	Reboxetine				-	1.3 1.00	90.	-	1.4 1.	1.00	-	1.4 1.00	-	4.1	1.00	-	1.5	1.00									
HYPERURICAEM- Fluoxetine IA	Fluoxetine							-			-	1.2 1.00	-	1.3	1.00	-	1.4	1.00	-	1.4	1.4 1.00	-	1.4 1.00	1.00			
COUCHING	Fluoxetine					-		-								<u> </u>			-		1.4 1.00	-	1.4 1.00	1.00	-	7.7	1.00
	Reboxetine									-							<u> </u>					-	1.7	1.00	-	6.7	1.00
OTITIS MEDIA	Fluoxetine				-	1.2	1.00	-	1.2 1.00	8	-	1.2 1.00		1.3	1.00	_											
ANXIETY	Fluoxetine							-	1.2 1.00	8	+	1.2 1.00		1 1.3	1.00	_											
	Reboxetine				-	1.3 1.00	00.1				_	_					<u> </u>	_									
HYPERKINESIA	Fluoxetine								-	-		_	ļ	1.3	1.00	-	1.4	1.00	7	1.4	1.00	-	4.1	1.00			
CHEST PAIN PRECORDIAL	Fluoxetine						-							1.3	1.3 1.00	•	1.4	1.00	7	1,4	1.00	-	4	1.00	-		
RASH	Reboxetine	-	1.3	1.00	-	1.3	1.00						,	1.4	1.00	_											
MYALGIA	Fluoxetine				-	1.2	1.00	-	1.2 1.00	8					_												
	Reboxetine	-	1.3	1.00			-		-		_																
VERTIGO	Reboxetine	-	1.3	1.00				-	1.4 1.00	00			Ľ	1.4	1.4 1.00	_											
TINNITUS	Reboxetine	77	2.5	1.00	-	1.3	1.00			-	<u> </u>		_														
HYPOTENSION POSTURAL	Reboxetine											1.4 1.00		1.4	1.4 1.00	-	1.5	1.00									
IMPOTENCE	Fluoxetine							<u> </u>					Ľ	1.3	1.3 1.00	7	1	1.4 1.00	7		1.4 1.00						

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

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 56

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

													Days	Days of treatment	eatme	int		}									
			0-7			8-14		=	15-21		22	22-28	_	29-35	က္ခ	_	36-42		4	64-64		SS.	50-56	-	^	28	Γ
		윤光	% on exp.	(*)	P.	z on exp. (*)		ند و	No % on Pt. exp. (*)	l	No Z on Pt. exp.		1	No X on Pt. exp.	€	€ ¥.	X on exp. (*)	7	No X Pt. G	Z on exp. (	¥ 2.	No X Pt. ey	x on exp.	8	No Z Pt. ex	Z on Exp.	8
Adverse A	Assigned treatment							<del> </del>		†	-	-	-	_					$\top$	+	+-	+	-	+	-	+-	
OEDENA LEGS R	Reboxetine													1 1.4	1.00		1.5 1.00	1.00	_	1.6 1.00	8.						
HYPOTENSION	Fluoxetine						-	-	-	-	-	-	$\vdash$	_					+	1.4	1.00	+	+	+-	╀	+-	
PK_	Reboxetine						$\vdash$	-	<u> </u>	<del> </del>	-	_	$\vdash$	_					$\vdash$	$\vdash$	+	-	1.71	1.00	-	6.7	1.00
TENDINITIS	Reboxetine							-	_	$\vdash$	$\vdash$	-	-	L	L			Γ	-	1.6 1.00	8	-	1.7 1.00	8	-	6.7 1.00	8
ANOREXIA	Reboxetine							$\vdash$	-	$\vdash$	-	-	-	_					-	1.6	1.00	-	1.7	1.00	10	6.7	1.00
HYPERCHOLEST- Fluoxetine	Luoxetine							+-	-	$\vdash$	$\vdash$	-	-			L		$\top$	+	+	$\dagger$	+	1.4.1	1.00	1	7.7	1.00
	Reboxetina							-	$\vdash$	$\vdash$	+	-	$\vdash$						+	+	+	-	1.71	1.00	+-	+	T
INFECTION F	Fluoxetine	-		1.1 1.00	-	1.2 1.00	1.00		-	+-	-	_	-	_					+-	+	+	+-	-	+	+-	+	T
XEROPHTRALMIA Reboxetine	Posetine	-	1.3	1.00	~	1.3	1.00	+	$\vdash$	+	-	-	+-	_	$\perp$				+-	+-	$\dagger$	-	+	+-	+	+-	T
LIBIDO R DECREASED	Reboxetine	-	1.3	1.00	-	1.3	1.00	-	-	+	-	_	<u> </u>	_					+-	1	-	1-	+-	+	-	+	
SPERMATORRHO- Reboxetine EA	leboxetine	-	1.3	1.00	-	1.3	1.00		-	+-		-	ــــ						+	+-	+	+-	+	+	-	+-	
ASTHENIA	Fluoxetine				-	1.2	1.00	-	1.2 1.	1.00	-	-	+-	-				T	+-	+	$\dagger$	+	+-	+	-	+-	T
OEDEMA GENERALISED	Fluoxetine							+	1.2 1.00	8		1.2 1.00	-	<u> </u>					-	+	+	-	+-	+-	-	+	
SUICIDE F	Fluoxetine						+-	+	_	$\vdash$	<del> -</del>	1.2 1.00	-	_				T	+	+	+	+-	+	+	+	+	T
	Reboxetine							_			_	-	-	1	1.4 1.00				+	+	-	-	+	+	-	╁	
FLATULENCE F	Fluoxetine							-	-	+-	-	1.2 1.00	-	1.3	1.00				+	+	$\top$	+	+	+	+	+-	T
RASH MACULO- F. PAPULAR	Fluoxetine							-	-				_	1.3	1.3 1.00	-	1.4 1.00	1.00	+	-	-	-	-	+		+	

(CONTINUED)

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

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 56 ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

PHARMACIA CNS R&D

No. 2 co.													ä	to syr	Days of treatment	tmen	ננ											
No z on   Pt. exp. (*)   Pt. exp.				0-2		έò	14	_	15-2	2.		22-28			9-35		F.03	16-42	_	4	3-49	-	3	95-0		"	26	
Princetime   Pri			P.F.	x on	Г—	₹. e. x	# # # #		X OK	3		z on exp.	€	5 T	ron (	1	P. S.	xp.	$\overline{}$	<u>و بر</u>	Ω di	¥	4.0 4.0	n dx	£	£ #.	No X on Pt. exp. (*)	€
Placetine	Adverse	Assigned treatment			-			-																				
Reboxetine	PARONIRIA	Fluoxetine								_										<del>.</del>	1.4	8		4.	8.1			
Proceetime	ANAEMIA	Reboxetine			<u> </u>	$\vdash$	-	$\vdash$	ļ								T		+		1.6	8.	Ĺ	1.7	8.			
Reboxetine	SINUSITIS	Fluoxetine			<del> </del>	-		1	_		$\perp$						$\vdash$		<del>                                     </del>	$\vdash$				1.4	8.	-	7.7	7.7 1.00
Reboxetine         1 1.3 1.00           Reboxetine         1 1.3 1.00           Fluoretine         1 1.4 1.00           Fluoretine         1 1.2 1.00           Reboxetine         1 1.4 1.00           Fluoretine         1 1.4 1.00           Reboxetine         1 1.4 1.00           Reboxetine         1 1.4 1.00		Reboxetine	1	1.3	00.1		_	_	_										_	$\vdash$					-			
Reboxetine	CIRCULATORY FAILURE	Reboxetine				1	1.3	8	ļ																			
Roboxetine	EJACULATION DISORDER	Reboxetine					1.3	2																				
Fluczetine	MIGRAINE	Reboxetine			<del>                                     </del>	-		-	1-	1.01	_						$\vdash$											
Fluoretine	RENAL PAIN	Fluoxetine									-	<u> </u>	1.00				<b> </b>			-								
Reboxetine	MALAISE	Fluoxetine		-		-					-		1.00				-	-		-								
Fluoxetine Reboxetine Reboxetine	ALOPECIA	Reboxetine				-		_			-		1.00				_		-									
Reboxetine	BRONCHITIS	Fluoxetine				_			_	L				-	1.3	1.00	_											
	TACHYCARDIA	Reboxetine								_				-	4	1.00	_											
	HEPATITIS INFECTIOUS	Reboxetine																								-	6.7 1.00	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: 4	Body system: AUTONDMIC NERVOUS SYSTEM DISORDERS	IS SY	STER	DISOR	ERS																	
Adverse events/Assigned treatment	s/Assigned												å	lys o	Days of treatment	atmen	44					
			0-7			8-14			15-21			22-28	_		29-35			36-42			43-49	
		8 T	No x on No x o	*	2 £	z on exp.	€	21	% on exp.	€	2 %	% on exp.	€	2 #	x on axp.	€	오건	Z on exp.	€	2 %	x on exp.	
HOUTH DRY	Fluoxetine	9	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	9	7.1	1.00	7	8.4	1.00	5	6.1	1.00	m	3.8	1.00	2	2.7	1.00	24	2.8	
	Reboxetine	19	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	21	28.0	1.00	20	27.0	1.00	17	23.0	1.00	2	22.2	1.00	£	19.7	1.08	72	19.0	
SWEATING	Flucxetine	4	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	7	8.2	1.00	9	7.2	1.00	SO.	6.1	1.00	4	5.1	1.00	4	5.5	1.00	5	7.0	
									Ī				Ī	1	1							

> 56

1.00 13 22.0 1.00

2 2.7 1.00

6 8.1 1.00

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

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 57 PHARMACIA CNS R&D

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	S/ASSIgned												n n	Days of treatment		T I I I												
31101135073			0-7			8-14			15-21	_	"	22-28		29-	29-35	_	ĕ	36-42		54	43-49		ភ	99-09		^	26	
		E #	% on exp.	£	윤武	Z on exp.	€	윤밥	% on exp.	8	2 ±	xp. (	× (*	No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         No	# .	žĀ.	о т В 26	E di	Z Å	0 to	ت ق 5	<b>z</b> û	4 G	д . Д	X G	د م 8 ×	ية 8	ភ
INFLUENZA-	Fluoxetine				-	1 1.2 1.00	1.00		1,2	1 1.2 1.00		3 3.7 1.00		4.	5.1 1.00	l	6	3 4.1 1.90	96.	60	3 4.2 1.00	8	-	1 1.4 1.00	8.			
Tive State	Reboxetine				2		2.7 1.00	<u> </u>	2 2.7 1.00	1.00	22	2.7 1.00	i	1 1.4 1.00	4	8	-	-		-		-	-	1.7 1.00	00.	-	6.7 1.00	8.
ASTHENIA /	Fluoxetine	77	ľ	2.2 1.00	ю		3.5 1.00	77		2.4 1.00	-	1.2 1.00	Į.	-	1.3 1.00	8		1.4 1.00	8		_	H	-	1.4 1.00	8.			
100111111	Reboxetine	60	ł	3.8 1.00	m		4.0 1.00	01		2.7 1.00	-	1.4 1.00	00.1	-	1.4 1.00	l	-	1.5 1.00	8.	-	1.6 1.00	00.				_		
FEVER	Fluoxetine						<u> </u>	-	1.2	1 1.2 1.00	-	1.2 1.00	0.1	<u> </u>	-					-	1.4 1.00		-	1 1.4 1.00	8			
	Reboxetine	-	1.3	1.3 1.00	ŀ	1 1.3 1.00	1.00		1 1.4 1.00	1.00				_		-	-	-		_							-	
ALLERGIC	Fluoxetine										Γ				_		-	1 1.4 1.00 1 1.4 1.00	8	-	1.4		-	1 1.4 1.00	L	1 7.7 1.00	1.7.1	00.
	Reboxetine										-						_			-	1 1.6 1.00	00.	-	1 1.7 1.00		1 6.7 1.00	5.7 1	8.
HYPERPYREXIA Reboxetine	Reboxetine	-	1 1.3 1.00	1.0	_												_											
MALAISE	Fluoxetine					L					-	1 1.2 1.00	00'1		_													
						_			_	_	-	-		_	-	-	_	_		_	_	_	_				1	1

8

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 57

SYSTEM
ED BODY
TREATHENT A
ASSIGNED
8
INTERVAL BY AS
TIME
ENTS ACCORDING TO
ADVERSE EV
A
PREVALENCE
EVENTS:
ADVERSE

Body system: CARDIOVASCULAR DISORDERS, GENERAL

Adverse events/Assigned	s/Assigned												Day	Days of treatment	trea	tment											
treatment			9-7			8-14			15-21	-	N	22-28		25	29-35	-	36	36-42		43	43-49		59	50-56		, 5	56
		2 t	Z on exp.	8	윤법	% on exp.	8	2 %	z on exp.	€ × E	Pt R	Z on exp. (	(¥)	No %	% on exp. (*)		No X Pt ex	% on (*)	2 K	N 60	x on exp. (*)	No Pt		x on exp. (*)	₽ ₽	и <u>в</u>	р. (*)
HYPOTENSION	Fluoxetine	6	3.4	1.00	c)	5.9	1.00	23	2.4 1.00	1.00	64	2.4	1.00	-	1.3 1.00	8	-	1.4 1.00	90	2	2.8 1.00	90					
SYMPTOMS	Reboxetine	7	8.9	8.9 1.00	60	10.7 1.00	1.00	2	9.5	1.00	r)	6.8	1.00	9	8.3 1.00	8.	7 10	10.6 1.00	00	5 7	7.9 1.00	8	5. 8.	2	1.00	2 13.	13.3 1.00
	Fluoxetine				-	1.2	1.2 1.00	-	1.2 1.00	0.0									_								
HOI FLASBING	Reboxetine	71	2.5	1.00	62	2.7	1.00	N	2.7 1.00	1.00	61	2.7 1.00	00.1	23	2.8	1.00	63	3.0 1.00	8	34	4.8 1.00	00	2 3	3.4 1.00	8	1 6,	6.7 1.00
HYPERTENSION Fluoxetine	Fluoxetine	-	1.1	1.00	-	1.2	1.00	-	1.2 1.00	1.00	-	1.2 1.00	1.00														-
	Reboxetine										-	1.4 1.00	9.0	-	1.4 1.00	9.	-	1.5 1.00	00.	-	1.6 1.00	8					$\dashv$
PALPITATION	Reboxetine	-	1.3	1.3 1.00				-	4.1	1.00	-	1.4	1.00	-	1.4	1.00	-	1.5 1.00	90.	1	1.6 1.00	00	7	1.7 1.00	8	_	-
AEDEMA	Fluoxetine							-	1.2	1.00	-	1.2	1.00	-			_	_	-	-							
	Reboxetine													-	1.4.1	1.00	1	1.5 1	1.00	-	1.6 1.00	8	-				
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	Fluozetine														1.3 1	1,00	-	1.4 1.00	00.		1.4 1.00	00,		1.4 1.00	80		
CIRCULATORY FAILURE	Reboxetine				-		1.3 1.00					-															
TACHYCARDIA	Reboxetine													-	1.4 1.00	e.				$\dashv$							

(\*) number of adverse events on number of patient who complained of 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	s/Assigned												Day	Jo s.	Days of treatment	tment												
			0-7			8-14		,"	15-21		12	22-28		25	29-35	-	36	36-42		43	43-49	-	ភ	50-56		^	> 56	
		8 t	% on exp. (*)	*	유감	No Z on Pt exp. (*)	8	2 #	No X on Pt exp. (*)	2	No X Pt es	No % on Pt exp. (*)	~ ~	No x Pt ey	No z on No Pt exp. (*) Pt	Σ Δ.	7 % 8 %	% on No exp. (*) Pt	Σ	No Pt &x	Z on exp. (*)	Ω Σ α	P P S	No X on Pt exp. (*)	ş	P. 8	E .	£
HEADACHE /	Fluoxetine	80		9.0 1.00		15 17.6 1.00	1.00	6	9 10.8 1.00	00.1	7	8.5 1.00	8.	47	5.1 1.00	00.	7	7 9.6 1.00	8	4	3 4.2 1.00	8	24	2.9 1.00	8	-	1 7.7 1.00	1.00
	Reboxetine	7	6.8	8.9 1.00	7	7 9.3 1.00	1.00	6	9 12.2 1.00	1.00	4	5.4 1.00	9.	9	8.3 1.00	8.	15	7.6 1.00	9.	3	4.8 1.00	8	4	6.8 1.90	.00	27	2 13.3 1.00	1.00
TREMOR	Fluoxetine				-	1.2 1.00	1.00	ю	3.6 1.00	1.00	m E	3.7 1.00	8.	2	2.6 1.00	8	εn	4.1 1.00	8	4 5	4 5.6 1.00	8	24	2.9 1.00	8.	-	7.7 1.00	1.00
	Reboxetine	7	l	2.5 1.00	2		2.7 1.00	2	2.7 1.00	1.00	-	1 1.4 1.00	8	-	1 1.4 1.00	8.	,-	1 1.5 1.00	8	-	1 1.6 1.00	I	-	1 1.7 1.00	8.	-	6.7 1.00	1.00
PARAESTHESIA	Fluoxetine				-	1.2	1.2 1.00	-	1 1.2 1.00	1.00	-	1 1.2 1.00	8	-	1 1.3 1.00	8.	-	1 1.4 1.00	8	-	1 1.4 1.00	8		<del> </del>				
	Reboxetine	c,		6.3 1.00	4	5.3	5.3 1.00	73	2.7 1.00	1.00	-	1 1.4 1.00	90.	-	1 1.4 1.00	8.	-	1 1.5 1.00	8.	<u>اح</u>	1 1.6 1.00	8	-	1.7 1.00	8.	<del> </del>		
HYPERTONIA	Flucxetine	-	1.1	1.1 1.00	61		2.4 1.00	-	1 1.2 1.00	1.00	-	1 1.2 1.00	00.	-	1 1.3 1.00	8	-	1 1.4 1.00	8	-	1 1.4 1.00	8				-		
HYPERKINESIA	Fluoxetine												$\vdash$	-	1.3 1.00	8	<u>-</u>	1 1.4 1.00	1	-	1 1.4 1.00	8	-	1.4 1.00	8.	_		
VERTIGO	Reboxetine	٦	1.3	1.3 1.00				-	1 1.4 1.00	1.00	<u> </u>			-	1 1.4 1.00	8	$\vdash$				$\vdash$	$\vdash$	-					

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

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 57

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

Body system: GASTRO-INTESTINAL SYSTEM DISORDERS

treatment	s, essigned												nay.	5	Jays of treatment	ment												_
		<u> </u>	0-2			8-14			15-21		22	22-28	-	25	29-35		36	36-42	_	43-49	6,5	_	50-56	99		> 56		
		S T	X on exp. (*)		r y	z on exp.	z on No exp. (*) Pt	P. P.	Z on exp. (*)		84 84	7 on exp. (*)	žā.	Pt ex	Z on exp. (*)	2 £	z z on exp.	Z on exp. (*)	2 %	2 on exp.	z on exp. (x)	2 t	z on exp.	z on exp. (*)	2 ₺	% on exp.	€	
CONSTIPATION Fluoxetin	Fluoxetine	2		2.2 1.00	7	1	2.4 1.00	m	3.6 1.00	1.00	60	3.7 1.00	8.	4 5	5.1 1.00	8	4	5.5 1.00		3 4.2 1.00	1.0		-	1 1.4 1.00	_			
	Reboxetine	4	14 17.7 1.00	1.00	J	18.7	14 18.7 1.00	F	11 14.9 1.00	1.00	8 16	8 10.8 1.12	.12	7	9.7 1.60	8	7 10	7 10.6 1.00		7 11.1 1.00	1.0		10.	6 10.2 1.00		3 20.0	1.00	
NAUSEA AND	Flüoxetine	6	10.1 1.00	1.00	60	9.4	9.4 1.25	~	8.4 1.00	1.8	9	7.3 1.00	00.	4	5.1 1.00	8	2	2.7 1.00		2 2.1	2.8 1.00		1.4	1.4 1.00				
SYMPTOMS	Reboxetine	2	12.7	12.7 1.10	Ψ		8.0 1.16	9	8.1 1.00	1.0	5	6.8 1.00	8.	2	6.9	8	2 3	3.0 1.00	2	-	1.6 1.00							
APPETITE INCREASED	Fluoxetine				77	2.4	2.4 1.00	77	2.4 1.00	1.00	<u> </u>	1.2 1.00	6.	-	1 1.3 1.00	8.	-	1 1.4 1.00		23	2.8 1.00		=	1 1.4 1.00	_			
DIARRHOEA	Fluoxetine	m	<u> </u>	3.4 1.00		1.2	1 1.2 1.00						<del> -</del>	27	2.6 1.00	8	-	1 1.4 1.00	9	_								
	Reboxetine	-		1.3 1.00		1.3	1.3 1.00						-															
ABDOHINAL PAIN	Reboxetine	-	1 1.3 1.00	1.00		1.3	1 1.3 1.00	1	1 1.4 1.00	1.00	<u>,</u>	1.4 1.00	8.	85 45	4.2 1.00	8	-	1.5 1.00	8									
ANOREXIA	Reboxetine													-	-	-				1 1.6 1.00	6 1.0			1 1.7 1.00	0	9 1	6.7 1.00	
FLATULENCE	Fluoxetine										-	1 1.2 1.00		-	1 1.3 1.00	8												

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

PHARHACIA 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	s/Assigned												Days	Days of treatment	eatm	int											
			0-7		"	8-14		7	15-21		22.	22-28		29-35	رو ا		36-42			43-49		35	95-05		۸	> 56	
		2 t	z on exp.	- <del>-</del>	2 #	axp. (	× a	6 %	No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         x on         No         x on         No         x on         No         x on         No         x on         No         x on         No         x on         No         x on         No         x on         No         x on         No         x on         No         x on         No         x on         No         x on         No         x on         No         x on         No         x on         No         x on         No         x on         No         X on         No         x on         No         x on         No         X on         No         X on         No         x on         No         X on         No         X on         No         X on         No         X on         No         X on         No	2 %	8 × ×	(x)	윤값	x on exp.	8	용값	X on exp.	€	2 t	No x on No x on Pt exp. (*)	÷ ÷	5 t	No Z on ) Pt exp. (*	<u>₹</u> <u>4.</u>	No Z on Pt exp.	on p. (*	
TINNITUS	Reboxetine	63	2.5 1.00 1 1.3 1.00	1.00	-	1.3	00.	_			-		ļ <u>.</u>														

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

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TANIE No.: 57 ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

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PHARMACIA CNS R&D

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

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 57

Body system: LIVER AND BILIAR SYSTEM DISORDERS

Adverse events/Assigned treatment	s/Assigned											Á	ays	Days of treatment	atmen	بـ											[
			6-7		**	8-14		15-21	2.1		22-28	φ		29-35			36-42		4	43-49		ភ	50-56		^	> 56	
		2 t	No z on No z o	£	2 t	xp.	S T	dxe :	¥ :	2 #	X on	€	多式	Z on exp.	E	2 #	z on	€	2 2	xp.	2	2 #	E dx	€	5 t	8 è	¥
INCREASED Reboxeting	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	1.00	-	1.4	1.00	-	1.5	1.00	10	3.2	8.	-	1.7	1.80	-	6.7	8.
HEPATITIS INFECTIOUS	Reboxetine								<u> </u>										-						-	1 6.7 1.00	8.

 $(\star)$  number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 57

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

DISORDERS
NUTRITIONAL
AND AND
METABOLIC
system:
ğ

Adverse events/Assigned treatment	:/Assigned												Days	Days of treatment	reatm	ent											
			0-7		-	8-14		=	15-21	_	22	22-28		29-35	35		36-42	N		43-49		<u> </u>	50-56		^	> 56	
		유물	z on exp.	*	2 %	No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         z on         No         x on         No	× 4	6 %	n d	<u>¥</u> €	2 C	* .	22	exp	8	2 t	x on exp.	*	유법	axp.	8	2 # 2	E d	¥	40	E è	¥
HYPERURICAEM- Fluoxeti IA	Fluoxetine					-		-			-	2.	8	1.	3 1.0	-	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	1,00	-	4.1	8.6	-	4.4	8.			
HYPERCHOLEST- Fluoxetine	Fluoxetine				$\top$	<del> </del>	†	-	-	+-	┼	-	+-	-		ļ						-	1 1.4 1.00 1 7.7 1.00	8	-	7.7	8.
	Reboxetine				$\vdash$		-			-		-		-								-	1.7 1.00	8.			

 $(\star)$  number of adverse events on number of patient who complained of adverse events (some adverse events are grouped in cluster)

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 57

PHARMACIA CNS R&D

TABLE NO.: 5/ ADVERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

Adverse events/Assigned	s/Assigned	_										2	Days of treatment	tres	tmen	دد									Ì
treatment			0-7	H	œ	8-14	-	15-21	2.1	_	22-28	80		29-35		8	36-42	 43	69-69	-	50-56	92		> 56	
		24	% on exp.	8	2 2	No 2 on No 2 o	2 2	× 8 X 0	€	84	Z on exp.	8	2 2	.dx	<u>\$</u>	2 t	xp.	 E X	# .	8#	exp exp	¥	8 X	z oz exp	€
BACK PAIN	Reboxetine				N	2 2.7 1.00 3 4.1 1.00 2 2.7 1.00	00	3 4.	1 1.00	2	2.7	1.00						-	$\dashv$	$\dashv$	_	_		_	
MYALGIA	Fluoxetine				-	1 1.2 1.00 1 1.2 1.00	00	-	2 1.06									 	+		-	_	4	_	
	Reboxetine	-	1 1.3 1.00	1.00		_		_		<u> </u>								$\dashv$		$\dashv$			_	_	_
TENDINITIS Reboxetine	Reboxetine			-	-		-											 -	, ,	00	1 1.6 1.00 1 1.7 1.00 1 6.7 1.00	7 1.0			:

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

## PHARMACIA CNS RBD REBOXELINE - PROTOCOL 20124/016 TABLE No.: 57

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

Adverse events/Assigned	:s/Assigned												Day	's of	Days of treatment	tment								
			0-7			8-14			15-21		"	22-28		2	29-35	-	36	36-42		43	43-49	$\vdash$	富	50-56
		2 X	% on exp. (*)		2 £	X on No exp. (*) Pt	8	2 2	% on % exp. (*)	€	5 t	No Z on Pt exp. (*)	¥.	P. K	2 on No 2 on exp. (*)	2 4	6 %	5 6	2 %	z z on	z on exp. (*)	2 %		% on exp. (*)
INSOMNIA	Fluoxetine	2	1	2.2 1.00	S	5.9 1.00	1.00	9	7.2 1.00	1.00	9	7.3 1.00	8.	7	7 9.0 1.00	8	5	6.8 1.00	8	5 7	7.0 1.00		5	5.8 1.00
	Reboxetina	5	1	6.3 1.00	9	8.0 1.00	1.00	9	8.1 1.00	1.00	9	9 12.2 1.00	8.	8	8 11.1 1.00	8	8	8 12.1 1.00	8	7	7 11.1 1.00	١	9	6 10.2 1.00
AGITATION /	Fluoxetine	e	1	3.4 1.00	4	4.7 1.00	9.1	7	8.4 1.00	1.00	4	4.9 1.00	8.	m	3.8 1.33	.33	2	2.7 1.00	8	2	2.8 1.00		2	2.9 1.00
NERVOUSNESS	Reboxetine				-	1.3 1.00	9.1	-	1.4 1.00	3.00	-	1.4 1.00	8.	-	1.4 1.00	8	67	3.0 1.00	8	-	1.6 1.00		-	1.7 1.00
SOMNOLENCE	Fluoxetine	-	1 1.1 1.00	1.00	-	1.2 1.00	8.		T		-	1.2 1.00	8.	-	1.3 1.00	8	2	2.7 1.00	8	2 2	2.8 1.00		-	1.4 1.00
	Reboxetine	_	1.3	1.3 1.00	-	1.3 1.00	8.				-	<del>                                     </del>		-	1.4 1.00	8	-	1.5 1.00	8	-	1.6 1.00		-	1.7 1.00
EUPHORIA	Reboxetine	-	1.3	1.3 1.00	-	1.3 2.80	2.80	-	1.4 1.00	1.00	-	1.4 1.00	00.				-	<del> </del>	╁	┼		-	-	
LIBIDO DECREASED	Reboxetine	-	1 1.3 1.00	1.00	-	1 1.3 1.00	9.6	<del>                                     </del>	<u> </u>		-								1	-		<u> </u>	-	
SUICIDE	Fluoxetine	<u> </u>					1	$\dagger$			-	1.2 1.00	8.	+	-		-		1-	+	+	+-	<del> </del>	-
	Reboxetine							-	T	·	1			-	1.4 1.00	8	-	<u> </u>	+	┼-	-	-	╀	-
PARONIRIA	Fluoxetine												<u> </u>		-		$\vdash$	ļ	+	-	1 1.4 1.00	1	-	1 1.4 1.00

7.7 1.00

× on exp.

13.3 1.00

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

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 57 PHARMACIA CNS R&D

THE INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM

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2
ACCORDING
EVENTS
ADVERSE
g
PREVALENCE
EVENTS:
ADVERSE

Body system: REPRODUCTIVE DISORDERS, FEMALE

Adverse events/Assigned	peu											Da	ys of	Days of treatment	ment										
1 10 10 10			0-7		8-14	-14	_	15-21	_		22-28		125	29-35		36-42	45		43-49	_	Š	50-56		> 56	92
		P S	xp. g	ž g	2 + 2	No z on No z o	2 t	Z on exp.	*	2 %	z on exp.	*	No Z	# d	N A	Z GX9	*	무감	% on exp.	8	F & B %	E di	ŽĀ.	6 ×	
BREAST Reboxetine FIBROADENOSIS	tine				-	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	9	4.1	1.00	-	1.4	1.00	-	1.4	8	-	1.0	-	1.6	1.00	-	1.7.1	8.	1 6	.7

(\*) 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

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

MALE
DISORDERS,
REPRODUCTIVE
system:
3ody

Adverse events/Assigned	s/Assigned												Days	Days of treatment	eatne	at											
			0-2		ω	8-14		=	15-21		22	22-28		29-35	T.		36-42			65-65			50-56			> 56	
		2 %	No z on No z o	€	2 t	y dxx	2	5 th	E 6	z A.	6 ×	W d	P B	z on exp.	€	2 t	Z on exp.	3	2 Z	z on exp.	€	P.	% on exp.	*	是式	x on exp.	€
IMPOTENCE	Fluoxetine							-				-	<u> </u>	1 1.3 1.00 1 1.4 1.00 1 1.4 1.00	1.0	-	1.4	1.00	-	1.4	1.00						
SPERMATORRHO- Reboxetine EA	Reboxetine	-	1.3	1.00	-	1.3 1.00 1 1.3 1.00	00.1				-																
EJACULATION Reboxetine DISORDER	Reboxetine				-	1 1.3 1.00	8.																				

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

PHARMACIA CNS R&D

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

NISM DISORDERS		
Body system: RESISTANCE MECHANISM DISORDERS	Adverse events/Assigned treatment	

verse events/Assigned	/Assigned												Da	ys of	Days of treatment	atnen	4.											
on timelia t			0-7			8-14			15-21		"	22-28		"	29-35		•	36-42		4	43-49		50	50-56		> 56	92	
		8 T	% on exp.	£	윤권	No z on No z o	<b>£</b>	2 %	% on exp.	Ξ	2 #	z on	8	2 %	X on	£	2 %	z on	8	2 2	₩ dx	* 4	6 ×	E 4	z ā. ∵	6 X	E 6.	2
SCESS	Reboxetine				2	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	1.00	27	2.7	1.00	<b>-</b>	4.4	1.0	-	4.1	9.1	-	1.5	1.00	-	1.6	8	-	.7	8	1 6	.7	8
ITIS MEDIA Fluoxetine	Fluoxetine				-	1 1.2 1.00 1 1.2 1.00 1 1.2 1.00 1 1.3 1.00	1.00	-	1.2	1.00	-	1.2	1.0	-	1.3	1.00	T		_	<del> </del>	$\vdash$			_				
FECTION	Fluoxetine	_		- S	_	1 1.1 1.00 1 1.2 1.00	1.00								<b></b>						-							

(\*) number

## PHARMACIA CNS RRD REBOXETINE - PROTOCOL, 20124/016 TABLE No.: 57

BODY SYSTEM
BODY
AND
TREATMENT
ASSIGNED
BY
INTERVAL BY
TIME
0 TO
ACCORDING
EVENTS
ADVERSE
P.
PREVALENCE
E EVENTS:
ADVERSE

Body system: RESPIRATORY SYSTEM DISORDERS

Adverse events/Assigned	s/Assigned												Day	Days of treatment	treat	tment												
rearment			0-7			8-14			15-21			22-28		29	29-35		36	36-42	_	£3	43-49		25	50-56		۸	56	
		2 t	X on exp.	€	& ₹.	z on exp.	*	2 £	z on exp.	8	2 %	z on exp. (	E	No X on Pt exp. (*)	E 6	5 T R	ر د و و ۲	% on exp. (*)	2 L		% on exp. (*)	2 £		x on ()	(*) Pt	o % on t exp.		£
UPPER RESP	Fluoxetine	-	1.1	1.1 1.00	-		1.2 1.00	83	2.4	1.8	7	2.4 1.00	00.1	-	1.3 1.00	8	-	1.4 1.00	8	<u> </u>			-			-	-	
INFECTION	Reboxetine											-		-	1.4 1.00	8	-	1.5 1.00	8	-	1.6 1.00	8		-		ļ	-	
RHINITIS	Fluoxetine	-	1.	1.1 1.00	-	1	1.2 1.00	-	1.2 1.00	1.00	-	1.2 1.00	1.00	-	1.3 1.00	8	-	1.4 1.00	8	_		_	<u> </u>					Γ
	Reboxetine														<del> </del>		-		_		_		-	1.7 1.00	8.	9	6.7 1	1.00
PHARYNGITIS	Fluoxetine										-	1.2 1.00	00.1	-	1.3 1.00	9.				-	1.4 1.00	8	-	1.4 1.00	8.	1	7.7 1.00	8
	Reboxetine							-	1.4 1.00	1.00	-	1.4 1.00	1.00	-	1.4 1.00	8.					-			ļ	-			
RESPIRATORY DISORDER	Reboxetine	-	1.3	1.3 1.00	-	1.3 1.00	1.00							-	1.4 1.00	8.	-	1.5 1.00	8	-	1.6	8	-	1.7 1.00	8.			
EPISTAXIS	Reboxetine				-	1 1.3 1.00	1.00	-	1.4 1.00	1.00	-	1.4 1.00	1.00	-	1.4 1.00	00.	-	1.5 1.00	8				_					
COUGHING	Fluoxetine													-	_					-	1 1.4 1.00	8	-	1.4 1.00	8	-	7.7 1.00	8
	Reboxetine													<del> </del>		-				-			-	1.7 1.00	8	9	6.7 1.00	9.
SINUSITIS	Fluoxetine												ļ		-	,		<u> </u>		_	-	-	-	1.4 1.00	8	1 7	7.7 1.00	00.
BRONCHITIS	Fluoxetine											-		-	1.3 1.00	8.												

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

REBOXETINE - PROTOCOL 20124/016 PHARMACIA CNS R&D

IGNED TREATMENT AND BODY SYSTEM

	ASST
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	INTERVAL
. 21	THE
ě	٤
TABLE No.:	ACCORDITAG
	STARAGE
	ANVEDSE
	Ä
	NUEBSE EVENTS: DDEVALENCE DE ANYEDSE EVENTS ACCORDITUG TO TIME INTERVAL RY ASSI
	FVENTS
	ASGAN

Body system: SKIN AND APPENDAGES DISORDERS

Adverse events/Assigned												en .	ys or	116	Linen	د											
		0-7			8-14		Ĺ	15-21		121	2-28		2	9-35		,,,	36-42			43-49		5	0-56		^	56	
	E £	% on exp.	Ξ	오出	% on exp.	*	Pt Pt	x on	8	, to	n o	¥	Pt 8	8 .d	8	2 %	wo z	£	2 t	an 2	(x)	Pt e	e dx	€	E #	on xp.	(*)
Fluoxetine	-	1.1	1.00	-	1.2	1.00	-	1.2	9.	-	1.2	00.1	24	2.6	9.1	-	1.4	1.00									
Reboxetine	٢	1.3	1.00	-	1.3	1.00	7	2.7	1.00	-	1.4	8.	-	1.4	0.00	-	1.5	1.00	62	3.2	9.1	61	3.4	1.00	7	3.3	1.00
Fluoxetine							<u> </u>			_	$\vdash$		-	1.3	9.	-	1.4	1.00									
Reboxetine	-	1.3	1.00	-	1.3	1.00							-	1.4	1.00												
Reboxetine										-	4.6	9.															
	Fluoxetine Reboxetine Fluoxetine Reboxetine Reboxetine																										No   x   on   x   on   x   on

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

idverse events/Assigned											Day	Days of treatment	treat	ment											
ł		4-0		8-14	4		15-21			22-28		29-35	-32		36-42	1.5		43-49			50-56		^	> 56	
	2 %	No z on No z o	žā.	t ext	€:	2 %	% on exp.	€	2 2	z on	8	9 %	<u>ٿ</u> چ 5	2 2	e X	€	22	z on exp.	£	문값	ao y	*	8 t	E d	<b>~</b>
RASTE Reboxetine PERVERSION	-	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 1.5 1.00 1 1.6 1.00 1 1.7 1.00 1 6.7 1.00	8.	-	3.0	-	1.4	1.00	-	4.	8.	<del>  `</del>	4.	00	-	1.0		1.6	1.00	-	1.7	1.00	-	6.7	8

 $(\star)$  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

sten: URIMARY SYSTEM DISORDERS

Adverse events/Assigned	s/Assigned												Das	Days of treatment	trea	tment												
regriment			0-7			8-14		_	15-21	_	Ĺ	22-28	-	Ñ	29-35		60	36-42			67-64		L.	50-56		^	> 56	
		2 %	2 on exp.	€	2 %	z on exp.	3	2 %	% on exp.	No z on No z o	2 %	z on exp.	8	2 t	£ 4	F	5 ¥	E dx	8	F L	u d xx	8	Pt 2	con	£	P 2 2	wo.	•
URINARY	Fluoxetine	-	1.7	1.0	_	1.2	1.0	_	1.2	1 1.1 1.00 1 1.2 1.00 1 1.2 1.00				$\vdash$			-			$\vdash$	_							
RETENTION	Reboxetine	40	10.1	8 10.1 1.00		6 8.0 1.00	1.00	m	4.1	3 4.1 1.00	æ	4.1	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	7	2.8	00.	4	6.1	1.00	C2	3.2	1.00	-	1.7	1.00	-	6.7	1.00
CYSTITIS	Fluoxetine	_		_	<u> </u>								T	$\vdash$	-	T	<del> </del>						-	1 1.4 1.00	1.00			
	Reboxetine			$oxed{oxed}$	_			_	1.4	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	_	4.1	1.00	-	1.4	8.	7-	1.5	1.00	-	9.	1.00	-	1.7	1.00			
URINARY TRACT Fluoretin	Fluoxetine				_	1 1.2 1.00	1.0					1 1.2 1.00	1.00	-			$\vdash$						<del> </del>					
TULECITON	Reboxetine	-	1.3	1.00	_	1.3	1.00	_	1.4	1 1.3 1.00 1 1.3 1.00 1 1.4 1.00				$\vdash$			$\vdash$											
RENAL PAIN	Fluoxetine						_		L		-	1 1.2 1.00	1.00															

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

## PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 57

LENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND BODY SYSTEM	
ITS: PREV	
ADVERSE EVENTS	system: VISION DISORDERS
	Bods

Adverse events/Assigned	s/Assigned												Days	Days of treatment	reatm	aut											
			0-2		"	8-14		<b>"</b>	15-21		22.	22-28	ļ	29-35	۳.		36-42	ŭ	_	43-49	6		50-56	9		> 56	
1		2 t	No % on Pt exp. (	8	2 #	un 3	8	, te	₩ dx	ž Ł	E X	# ÷	유법	axp.	€	윤값	X on exp.	8	유없	No z on No z o	8	2 X	% on exp.	8	7 %	X on exp.	£
BLURRED	Fluoxetine	٣	1 1.1 1.00 3 3,5 1.00 2 2.4 1.00 1 1.2 1.00	1.00	m	3.5	8.	22	2.4 1	80.	-	2.	8		_	<u> </u>		L	Ĺ	1 1.4 1.00 1 1.4 1.00 1 7.7 1.00	1.00	-	1.4	1.00	-	7.7	1.00
MOTOTA	Reboxetine	m	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	1.00	60	4.0	1.00	27	2.7	.00	2	1.	00	2 2.4	1.0	6	1.5	1.00	_								
CONJUNCTIVIT- Fluoxetine	Fluoxetine	-	1.1	1.00	-	1.2	1.00	-	1.2 1	00.	1	2.	00	1.	3 1.0	-	1.4	1.00		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	1.00						
2	Reboxetine						<u> </u>	<u> </u>			-	4.	90	1 1.4 1.00 1 1.4 1.00	4.1.0			_						<u> </u>			
XEROPHTHALMIA Reboxetine	Reboxetine	_	1 1.3 1.00 1 1.3 1.00	1.00	-	1.3	1.00		H	-	-	-	-		<u> </u>	<u> </u>			_								

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PHARMACIA CNS R&D

													Days	of treatment	eatm	ant											
			0-7		w	8-14		**	15-21	-	22	22-28	_	29-35	5		36-42	61		43-49	6		50-56	<b>.</b>		> 56	
		2 Z	x on	Ξ	8 t	Z on Z	¥ &	No Pt ex	% on (*)	2 %	8 X	₩ d	25	axb exp	8	22	dxo Z	€	22	dxe	€	a t	x on	*	2 %	z on	£
Body system Pt exposed	Assigned treatment Fluoxetine	8	ş	1.62	88	100	2	83	-	69.	26	100 1 57	7.2	7	2	, r	100	1 56	3	907	7	69	9	1 50	Ę.	Ę	7
	Reboxetine	8		2.42	75				Ni Ni									2.26	1		2.21		100				1.88
AUTONORIC	Fluoxetine	6	10.1	1.11	£	12.9	1.18	13	m.	1.18	10 12.2	.2 1.00	00	9.0	1.00	9	8.2	1.00	7	9.6	1.00	7	10.1	1.00	v	46.2	1.00
SYSTEM	Reboxetine	27	26.6	1.09	243	32.01	1.12	23 31	31.1 1.13		18 24	24.3 1.05	05 16		22.2 1.06	6 13	19.7	19.7 1.00	12	19.0	19.0 1.00	13	22.0	22.0 1.00	0	0.09	1.00
GASTRO- INTESTINAL	Fluoxetine	12	13.5	1,16	9	10.6	1.66	11 13.	3	1.09 1	10 12.	.2 1.10	10 10	12.8	1.20	7	9.6	1.14	9	8.5	1.16	m	4.3	1.00			
SYSTEM	Reboxetine	24	30.4	1.12	212	28.0 1	1.09	17 23	23.0 1.	1.05	14 18.9	.9 1.07	97 13	18.1	1.15	6	13.6	<u>+</u>	8	12.7	1 12	10	10.2	1.16	3	20.0	1.33
CENTRAL & PERIPHERAL	Fluoxotine	6	10.1	1.00	17 2	20.0	1.11	12 14.	r)	1.16 1	11 13.	.4 1.09	8 60	10.3	1.12	2 10	13.7	1.30	7	9.9	1.42	5	7.2	1.00	67	15.4	1.00
NERVOUS SYSTEM DISO	Reboxetine	12	15.2	1.25	13	17.3	1.00	41	18.9 1.	1.00	80	8.1 1.00	6 00	12.5	1.00	0 7	10.6	1.00		7.9	1.00	9	10.2	1.00	ю	20.0	1.00
PSYCHIATRIC DISORDERS	Fluoxetine	9	6.7	1.00	6	10.61	1.11	13 15	15.7 1.	1.00	12 14	14.6 1.00	10	12.8	1.20	6	12	.3 1.00	6	12.7	1.11	7	10.1	1.14	64	15.4	1.00
	Reboxetine	80	10.1	1.00	10	13.3	1.10	8 10	10.8 1.	1.00 1	11 14.9	.9 1.00	00 10	13.9	1.10	0 10	15.2	1,10	8		12.7 1.12	7	11.9	1.14	61	13.3	1.00
CARDIOVASCUL- Fluoxetine AR DISORDERS,	Fluoxetine	4	4.5	1.00	7	B.2 1	1.00	5	6.0 1.	1.00	4	4.9 1.00	00	2.6	1.00	0 2		2.7 1.00	9	4.2	1.00	-	4.4	1.00			
GENERAL	Reboxetine	10	12.7	1.00		14.7	1.00	10 13	13.5 1.	1.00	9 12.	12.2 1.00	10	13.9	1.20	0 10	15.2	1.20	8 (	12.7	1.37	7	11.9	1.14	m	20.0	1.00
BODY AS A WHOLE-GENERAL	Fluoxetine	2	2.2	1.00	4	4.7	1.00	4	4.8 1.	1.00	6 7.	7.3 1.00	4 00	5.1	1.25	4	5.5	1.25	32	7.0	1.00	4	5.8	1.00	-	7.7	1.00
DISORDERS	Reboxetine	S.	6.3	1.00	2	6.7 1	1.20	4	5.4 1.	1.25	4	4.1 1.00	00 2	2.8	1.00	-	1.5	1.00	2	3.2	1.00	2	3.4	1.00	2	13.3	1.00
RESPIRATORY SYSTEM	Fluoxetine	2	2.2	1.00	2	2.4 1	1.00	8	3.6 1.	1.00	4	4.9 1.00		4 5.1	1.00	0 2		2.7 1.00	7	1.4	2.00	72	2.9	1.50	77	15.4	1.50
DISORDERS	Reboxetine	1	1.3	1.00	83	2.7 1	1.00	2	2.7 1.	1.00	62	2.7 1.00		4 5.6	1.00	6	4.5	1.00	2	3.2	1.00	2	3.4	1.50	-	6.3	2.00
URINARY	Fluoxetine	-	1.1	1.00	2	2.41	1.00	-	1.2 1.	1.00	2	2.4 1.00	00									٢	1.4	1.00			
DISORDERS	Reboxetine	6	11.4 1.00	1.00	7	9.3	1.00	ru A	6.8 1.	1.00	4 5	5.4 1.00		3 4.2	4.2 1.00	5		7.6 1.00	3		4.8 1.00	N	3.4	1.00	-	6.7	6.7 1.00

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

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PHARMACIA CNS R&D

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													Days	Days of treatment	reat	ent											
			0-7			8-14		[	15-21	-	22	22-28	-	29-	29-35	-	36-42	12	_	43-49	6		50-56	,,		> 56	
		P. F.	dxe uo %	æ	2 ±	dxa exp	£	Pt ×	y on gran	žá. ¥	Pt 8x	x ou gas	*)	t exp	€	무없	dxe	3	22	dxo x	8	2 %	dxe exb	€	% <b>₹</b>	dxa uo z	(*)
Body system VISION DISORDERS	Assigned treatment Fluoxetine	71	2.2	1.00	4	4.7	1.00	m	3.6 1.00	8.	22	2.4 1.00	8		1.3 1.00			1.4	0	2.8	1.00	-	1.4	1.00	-	7.7	7.7 1.00
	Reboxetine	4	5.1	1,00	4	5.3	1.00	8	2.7	1.00	₩ 4	4.1	1.00	ε. 4.	4.2 1.00		1.5	1.00	_								
SKIN AND APPENDAGES	Fluoxetine	-	1.1	1,00	-	1.2	1.00	-	1.2	1.00	-	1.2 1.	1.00	3.	3.8 1.00		2 2.7	1.00			_						
DISORDERS	Reboxetine	N	2.5	1.00	77	2.7	1.00	8	2.7	1.00	2	2.7 1.	1.00	2	2.8 1.00		1 1.5	1.00	2	3.2	1.00	23	3.4	1.00	23	13.3	1.00
RESISTANCE	Fluoxetine	-	1.1	1.1 1.00	22	2.4	1.00	-	1.21	1.00	-	1.2 1.	1.00	-	1.3 1.00	2											
DISORDERS	Reboxetine				N	2.7	1.00	7	2.7	1.00	-	1.4 1.	1.00	-	1.4 1.00		1.5	1,00	-	1.6	1.00	-	1.7	1.00	-	6.7	1.00
MUSCOLO- SKELETAL	Fluoxetine				-	1.2	1.00	-	1.2.1	1.00			<u>                                     </u>		<u> </u>				<u> </u>	_	<u></u>						
SYSTEM DISORDERS	Reboxetine	-	1.3	1,00	~	2.7	1.00	m	4.1	1.00	62	2.7 1.	1.00						-	1.6	1.00	-	1.7	1.00	-	6.7	1.00
SPECIAL SENSES OTHER, DISORDERS	Reboxetine	٦	1.3	1.00	-	1.3	1.00	-	1.4.1	1.00	-	4.1	1.00	+	1.4 1.00	2	1 1.5	1.00		1.6	1.00	-	1.7	1.00	-	6.7	1.00
REPRODUCTIVE DISORDERS, FEMALE	Reboxetine				-	1.3	1.00	-	1.4 1.00	8	-	1.4 1.00	8		1.4 1.00		1 1.5	1.00		1.6	1.00	-	1.7	1.00	-	6.7	1.00
LIVER AND BILIAR SYSTEM DISORDERS	Reboxetine										-	1.4 1.00	8		1.4 1.00			1.5 1.00	8	ευ 21	1.00	-	1.7	1.00	2	13.3	13.3 1.00
METABOLIC AND Fluoxetine	Fluoxetine										-	1.2 1.	1.00	<del>-</del>	1.3 1.00		1 1.4	1.00	-	1.4	1.00	N	2.9	1.00	-	7.7	1.00
DISORDERS	Reboxetine															_						-	1.7	1.00			
REPRODUCTIVE DISORDERS.	Fluoxetine								<u></u>					-	1.3 1.00		1 1.4	1.00	-	1.4	1.0						
MALE	Reboxetine	-	1.3	1.3 1.00	7	2.7	1.00									<u> </u>		<u> </u>	ļ								

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 58

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 58 ERSE EVENTS: PREVALENCE OF ADVERSE EVENTS ACCORDING TO TIME INTERV

													Days	Days of treatment	reatm	ent										
			0-7			8-14		-	15-21		22-	22-28		29-35	જ	_	36-42	2		43-49			50-56		> 56	26
		2 £	dxa	8	P #	Ro         x         an         No         x         no	~	2 t	5 8 gr	žά	ext.	# ±	2 %	o x	*	22	dxe exp	€	2 2	dxe	8	2 t	E &	₹	4 o	(¥
Body system Assigned treatment	ned								-	-		-	-	-	_	-							-			_
						•		_							_			_								_
VESTIBULAR Rebox DISORDERS	Reboxetine	61	2.5	1.00	-	2 2.5 1.00 1 1.3 1.00	8.		<del>, ,</del>														····			
HENATOLOGY Reboxetine DISORDERS	etine							-				-							-	1 1.6 1.00 1 1.7 1.00	1.00	-	1.7	8.		

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

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PHANHACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 59 ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL TREATHENT AND ASSIGNED TREATHENT

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Adverse events/Assigned treatment	tment							œ.	Relationship	ship	ı						
		Definite	ite	Probable	ble	Possible	ble ble	Doubtful	<u> </u>	None		<b>Unknown</b>	umo	Missing	ing	Total	F.
!		No.	×	No.	×	No.	×	No.	×	Ão.	*	S	×	No,	×	₩.	*
Total adverse events	Reboxetine	-	0.5	63	28.5	79	35.7	35	15.8	5	8.6	19	8.6	S	2.3	221	221 100.0
	Fluoxetine	r.	2.8	64	27.2	35	31.1	31	17.2	18	10.0	4	7.8	7	3.9	180	180 100.0
HEADACHE / MIGRANE	Rebuxetine	-	4.5	4	18.2	9	27.3	7	31.8	-	-	4	18.2			22	100.0
	Fluoxetine			9	21.4	9	35.7	9	35.7			-	3.6	-	3.6	28	100,0
NAUSEA AND RELATED SYMPTOMS	Reboxetine			r.	31.3	7	43.8	6	18.8					-	6.3	16	16 100.0
	Fluoxetine			13	56.5	S	21.7	121	8.7	-		63	8.7	-	4.3	23	23 100.0
HOUTH DRY	Reboxetine			6	33.3	15	55.6	~	3.7	-		-	3.7	-	3.7	27	100.0
	Fluoxetine	-	12.5	-	12.5	S	62.5	-	12.5							80	100
HYPOTENSION AND RELATED SYMPTOMS	Reboxetine			60	40.0	60	40.0	8	15.0		-	٦	5.0			20	20 100.0
	Fluoxetine			2	22.2	9	66.7	-	1:1		-		T			6	9 100.0
CONSTIPATION	Reboxetine			9	33.3	7	38.9	4	22.2	-	5.6					18	18 106.0
	Fluoxetine			5	71.4	-	14.3	-	14.3								100.0
INSOMNIA	Reboxetine			4	36.4	ю	27.3	-	9.1	2	18.2	٦	9.1			=	100.0
	Fluoxetine	1	9.1	4	36.4	4	36.4	-	9.1				Γ	-	9.1	£	11 100.0
SWEATING INCREASED	Reboxetine			52	62.5	61	25.0	-	12.5							80	100.0
	Fluoxetine			2	22.2	9	66.7	-	11.1	-						6	100.0
AGITATION / ANXIETY /	Reboxetine			67	66.7			-	33.3	-						60	100.0
	Fluoxetine	٦	9.1	1	9.1	7	63.6	12	18.2	-					Г	1	11 100.0
URINARY HESITANCY / RETENTION	Reboxetine			5	41.7	3	41.7	-	8.3			-	8.3			12	12 100.0
	Fluoxetine			-	100.0											-	1 100.0
TREMOR	Reboxetine			-	25.0	27	50.0	-	25.0							4	4 100.0
	Fluoxetine			6	60.09	-	20.0			-		-	20.0	Γ		20	5 100.0

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( GAULT NOED)

(some adverse exempts are almost in allocton)

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PHARMACIA CNS R&D

ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL TREATMENT AND ASSIGNED TREATMENT

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Adverse events/Assigned treatment	atment							1~	Relationship	ship							
		Defi	Definite	Probable	able	Possible	ble ble	Doubtful	ful	None		Unknown	u <sub>M</sub>	Missing	gu	Total	יו
		€	×	No.	×	No.	н	No.	×	No.	×	No.	×	€	×	Νο.	*
ASTHENIA / FATIGUE	Reboxetine					4	100.0			$\vdash$	r	T		-	1	4	4 100.0
	Fluoxetine		L			2	40.0	2	40.0	-	20.0	$\dagger$	$\dagger$	$\dagger$	$\dagger$	Š	5 100.0
INFLUENZA-LIKE SYMPTONS	Reboxetine							T	-	12	66.7	-	33.3	$\vdash$	$\dagger$	m	3 100.0
	Fluoxetine		L					61	40.0	m	60.0	$\uparrow$	T	$\vdash$	$\dagger$	150	5 100.0
DIARRHOEA	Reboxetine								+	-	100.0	-		_	+	Ť	100.0
	Fluoxetine			-	16.7	10	33.3	2	33.3	$\vdash$		-	16.7	-	$\dagger$	9	100.0
BLURRED VISION	Reboxetine			2	66.7	-	33.3		-	$\top$			T	-	$\dagger$	8	100.0
	Fluoxetine			-	25.0	2	50.0		_	$\vdash$	-	-	25.0	$\dagger$	$\dagger$	4	4 100.0
PARAESTHESIA	Reboxetine				20.0			e	60.09	$\vdash$	$\dagger$	-	20.0		$\dagger$	5	5 100.0
	Fluoxetine					٦	1 100.0				$\dagger$				$\dagger$	-	1 100.0
FLUSHING / HOT FLASHING	Reboxetine			-	25.0	ы	75.0			+	†	1		$\dagger$	+	4	100.0
	Fluoxetine			-	100.0	1	$\top$		$\dagger$	+	$\dagger$	T	1	+	$\dagger$	-	100.0
SOMNOLENCE	Reboxetine					N	100.0			+	$\dagger$	$\dagger$		-	$\dagger$	2	100.0
	Fluoxetine			m	100 · D	T		1	+	+	$\dagger$	$\dagger$		$\dagger$	+	60	100.0
PRURITUS	Reboxetine			-	33.3	-	33.3	-	33.3	-	$\dagger$	-	$\dagger$	+	$\dagger$	8	100.0
	Fluoxetine					27	100.0	T	$\vdash$	╁┈	$\mid$			$\dagger$	T	2	100.0
UPPER RESP TRACT INFECTION	Reboxetine								+	2	2 100.0	T	T		$\dagger$	12	2 100.0
	Fluoretine								-	-	33.3	-	33.3	-	33.3	6	3 100.0
APPETITE INCREASED	Fluoxetine			63	50.0		-	$\top$	+	+	$\perp$	7	50.0	+	+	4	4 100.0
FEVER	Reboxetine					-	50.0		+	+	}-	-	50.0	+	1	2	100.0
	Fluoxetine					$\vdash$	_	<del>                                     </del>		+	-	2	2 100.0	$\dagger$	+	2	2 100.0
ABDOMINAL PAIN	Reboxetine					-	25.0	2	50.0		-	-	1 25.0	+	+	3	4 100.0

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רתמאמת בא ניאט איני	REBOXETIME - PROIDCOL 20124/016 TABLE No.: 59	ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL IREATHENT AND ASSIGNED TREATHENT

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Adverse events/Assigned treatment	tment							_	Relationship	onship	_						
		Definite	ite	Probable	able	Possible	<b>b</b> 1e	Doubtful	fu]	ž	None	n Unit	Unknown	R.	Missing	To	Tota1
		No.	×	No.	×	Жо.	м	₩.	*	ş	×	No.	×	No.	×	No.	×
RHINITIS	Reboxetine										1 100.0					1	1 100.0
	Fluoxetine									(1)	3 100.0					M	3 100.0
VERTIGO	Reboxetine			-	33.3					63	66.7					e	3 100.0
BACK PAIN	Reboxetine			_	33.3					-	33.3	-	33.3			en	100.0
ERYTHEMA / RASH	Reboxetine					2	100.0				_					N	2 100.0
	Fluoxetine			-	100.0											-	1 100.0
HYPERCHOLESTEROLAEHIA	Reboxetine											_	1 100.0			-	1 100.0
	Fluoxetine					-	50.0						1 50.0			2	2 100.0
PHARYNGITIS	Reboxetine												1 100.0			-	100.0
	Fluoxetine									,,,	2 100.0					2	2 100.0
URINARY TRACT INFECTION	Reboxetine														1 100.D	-	1 100.0
	Fluozetine										1 50.0			-	50.0		2 100.0
HYPERTONIA	Fluoxetine	-	50.0							Ĺ	50.0					2	2 100.0
AEDEMA	Reboxetine											,	1 100.0				1 100.0
	Fluoxetine				1 100.0											1	100.0
TINNITUS	Reboxetine			N	2 100.0											2	2 100.0
EUPHORIA	Reboxetine			N	2 100.0											2	2 100.0
PALPITATION	Reboxetine					-	50.0	-	50.0							2	2 100.0
INCREASED LIVER ENZYMES	Reboxetine					-	50.0						1 50.0	_		2	2 100.0
RESPIRATORY DISORDER	Reboxetine					٦	50.0	-	50.0				,			2	2 100.0
NYALGIA	Reboxetine							•	1 100.0								1 100.0
	Fluoxetine							-	1 100.0								1 100.0

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 59

REBOXETINE - PROTOCOC 20124/016
TABLE No.: 59
ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL TREATMENT AND ASSIGNED TREATMENT

338

Adverse events/Assigned treatment	tment							ž	Relationship	hip						
		Definite	ite	Probable	b1e	Possible	b1e	Doubtful	13	None	_	Unknown		Missing	Ţ	Total
		Š.	ж	₩.	ж	Š.	ж	. Š	×	No.	×	No. z	No.	×	Š	*
SUICIDE ATTEMPT	Reboxetine											1 100.0	0		_	100.0
	Fluoxetine							-	100.0						-	100.0
CONJUNCTIVITIS	Reboxetine									1 100.0	0.0				-	100.0
	Fluoxetine							-	100.0							100.0
ALLERGIC REACTION	Reboxetine									1 100.0	0.0	_			-	100.0
	Fluoxetine												<u> </u>	1 100.0	٦	100.0
COUGHING	Reboxetine									1 106.0	0.0					1 109.0
	Fluoxetine									1 100.0	0.0				_	1 100.0
CYSTITIS	Reboxetine									1 180.0	0.0					1 100.0
	Fluoxetine									1 100.0	0.0					1 100.0
HYPERTENSION	Reboxetine											1 100.0	0.			1 100.0
	Fluoxetine											1 100.0	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
INPOTENCE	Fluoxetine			1	1 100.0						-				_	1 100.0
TASTE PERVERSION	Reboxetine			-	1 100.0											100.0
XEROPHTHALMIA	Reboxetine			-	1 100.0										_	1 100.0
TACHYCARDIA	Reboxetine					-	100.0								-	1 100.0
ANDREXIA	Reboxetine					٢	1 100.0				-				-	1 100.0
ANEMIA	Reboxetine					-	1 100.0									1 100.0
LIBIDO DECREASED	Reboxetine					-	1 100.0									1 100.0

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some adverse events are grouped in cluster)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 59

ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL TREATMENT AND ASSIGNED TREATMENT

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									Relationship	<b>5</b> .						_
		Definite	ite	Probable	ole	Possible	_	Doubtful		None	Unkn	Опкночи	Missing	en g	Total	Π.
		No.	×	₩.	*	No.	*	No. z	8	N		×	Š.	×	No.	ж
EJACULATION DISORDER	Reboxetine				-	-	1 100.0								1 100.0	0.0
BRONCHITIS	Fluoxetine					-	1 100.0	<u> </u>							1 100.0	0.0
EPISTAXIS	Reboxetine					-	1 100.0	-							1 100.0	0.0
HYPERPYREXIA	Reboxetine						-	1 100.0	e.	<u></u>					1 100.0	0.0
CARDIAC ISCHEMIA AND RELATED SYMPTOMS	Fluoxetine							1 100.0	-						110	1 100.0
HYPERKINESIA	Fluoxetine						ļ	1 100.0	9.						1 100.0	0.0
PARONIRIA	Fluoxetine							1 100.0	•						1 10	1 100.0
SPERMATORRHOEA	Reboxetine							1 100.0	•						1 100.0	0.0
ALOPECIA	Reboxetine							1 100.0	-						1 100.0	0.0
MALAISE	Fluoxetine									1 100.0					1 10	1 100.0
HEPATITIS INFECTIOUS	Reboxetine									1 100.0					1	1 100.0
RYPERURICAENIA	Fluoxetine									1 100.0					1	1 100.0
TENDINITIS	Reboxetine									1 100.0					1	1 100.0
BREAST FIBROADENOSIS	Reboxetine									1 100.0					10	1 100.0
INFECTION VIRAL	Fluoxetine									1 100.0					1 100.0	0.0
OTITIS MEDIA	Fluoxetine									1 100.0					7	1 100.0
RENAL PAIN	Fluoxetine										_	1 100.0			7	100.0
SINUSITIS	Fluozetine												-	1 100.0	1 100.0	0.0

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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COMPTENSE

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

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PHARMACIA CNS RED REBUKETINE - PROTOCOL 20124/016 TABLE No.: 60 ADVERSE EVENTS(\*) PRESENT AT LAST DAY OF TREATMENT AND THEIR RELATIONSHIP TO STUDY MEDICATION (OMLY PATIENTS HAO KITHDREN FROM THE STUDY FOR ADVERSE EVENTS)

341

Total Missing Unknown None Relationship Probable Definite Possible Doubtful Ass. treatment Fluoxetine Reboxetine Reboxetine Reboxetine Fluoxetine Fluoxetine Fluoxetine Reboxetine Fluoxetine Fluoxetine Reboxetine Reboxetine Reboxetine Reboxetine Reboxetine Reboxetine Reboxetine Reboxetine UPPER RESP TRACT
INFECTION SUICIDE ATTEMPT Days of Treatment Adverse events RASH MACULO-PAPULAR CONSTIPATION CONSTIPATION MICTURITION DISORDER MICTURITION DISORDER HEPATITIS INFECTIOUS SOMNOLENCE MOUTH DRY VOMITING DIARRHOEA ACITATION DIZZINESS DIZZINESS DYSPEPSIA NAUSEA FATIGUE RASH 64 8 12 - 396 (Female) 16 - 438 (Female) 11 - 335 (Female) 13 - 503 (Female) 13 - 387 (Female) 13 - 391 (Female) Centre - Patient 7 - 196 (Female)

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(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
TARIE No. : 60

	ADVERSE EV	ENTS(*) PRESENT AT (ONLY PATIENTS	ADVERSE EVENTS(*) PRESENT AT LAST DAY OF TREATHENT AND THEIR RELATIONSHIP TO STUDY HEDICATION (ONLY PATIENTS NHO NITHDREN FROM THE STUDY FOR ADVERSE EVENTS)	IT AND THE THE STUDY	IR RELATI FOR ADVER	ONSHIP TO SE EVENTS	STUDY HE	DICATION			
					1	Re	Relationship	۰			
				Probable	Definite	Possible	Doubtful	None	Unknown	Probable Definite Possible Doubtful None Unknown Missing Total	Tota]
Centre - Patient	Days of Treatment	Centre - Patient Days of Treatment Adverse events Ass. treatment	Ass. treatment					! !			
16 - 438 (Female) 30	30	BRONCHITIS	Fluoxetine			~					
20 - 22 (Female) 35	35	INSONNIA	Fluoxetine	ţ.							

nly adverse events complained on the last day of treatment and still present or resulting in withdrawal

PHARMACIA CNS R&D REBOXETINE - PROJOCOL 20124/016 TABLE No.: 61

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

1.41 10.67 18.00 14.10 0.00 0.4016 6.08 30.29 62.60 42.00 9.22 0.4657 29-56 Days of treatment 4.92 3.20 5.88 32.00 0.7094 0.4687 1-28 3.58 8.21 13.91 9.28 19.50 13.69 6.36 27.25 64.28 98.0 1.61 Assigned treatment Screen 14.15 1.50 11.36 6.03 34.75 41.50 4.96 98.0 18.30 14.10 00'0 0.3622 60.20 0.3516 29-56 Days of treatment 10.93 13.90 4.89 0.75 1.43 18.50 -0.04 0.8059 43.00 42.00 0.00 0.6915 1-28 14.22 1.42 43.01 0.77 3.81 11.20 Screen Median diff. Median diff. Evaluated Evaluated P value P value Median Kean Kean STD Kin Kax STO RBC

(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 BLOND CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

aboratory test			⋖	Assigned treatment	reatment		
		ů.	Fluoxetine		<b>α</b>	Reboxetine	
		Days	Days of treatment	ent	Days	Days of treatment	ent
		Screen	1-28	29-56	Screen	1-28	29-56
380	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
LATELETS	Evaluated	81	77	67	70	99	57
	Mean	285.06	280.33	287.21	284.50	300.00	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
	Маж	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

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 61 LABORATORY TEST: HAEMATOLOCY AND BLOOD CHEMISTRY STATISTICAL AMALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATHENT

Laboratory test			•	Assigned treatment	reatment		
		e.	Fluoxetine			Reboxetine	
		Days	of treatment	ent	Days	of treatment	ent
		Screen	1-28	29-56	Screen	1-28	29-56
WBC	Evaluated	81	78	67	70	89	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
	Hin	3.96	3.53	3.57	4.27	4.21	4.59
	Мах	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
MBC: N	Evaluated	80	77	99	69	99	56
	Kean	63.27	62.77	63.45	63.12	63.03	63.30
	crs	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
	Ках	72.33	72.50	71.00	71.67	75.00	71.00
	Kedian	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	99	62	53
	Kean	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	00.0	-1.00	-1.00	-1.00
	Kax	5.00	4.33	5.00	5.67	7.00	3.40

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\* VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED T

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 61

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

Laboratory test			€	Assigned t	treatment		
		E.	Fluoxetine		æ	Reboxetine	
		Days	of treatment	ent	Days	of treatment	ent
		Screen	1-28	29-56	Screen	1-28	29-56
WBC: E	Kedian	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
HBC: B	Evaluated	76	73	62	99	62	53
	Nean	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	00.00	00.0	00.0	00.0	00.0	0.00
	Kax	0.83	0.75	1.20	9.75	1.28	0.75
	Median	00.0	00.0	0.00	00.00	00.00	00.00
	Median diff.		00.0	0.00		00.00	00.00
	P value		0.5602	0.2352		0.0682	0.2036
WBC: I	Evaluated	81	78	99	70	99	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
	Kin	14.00	11.00	14.00	17.00	12.00	19.67
	Kax	42.00	39.67	38.00	44.00	45.67	00'64
	Kedian	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	2528.0
WBC: M	Evaluated	77	74	79	89	49	52
	Mean	4.68	4.83	4.77	4.56	4.40	4.39

(CONTINUED)

THE WATER PROBABILITY EDOM THE WITCHWON RANK SICNED

PHARMACIA CHS R&D

REBOXETINE - PROTOCOL 20124/016

TABLE No.: 61

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

Laboratory test			•	Assigned treatment	reatment		
		L	Fluoxetine			Reboxetine	
		Days	Days of treatment	ent	Days	Days of treatment	ent
		Screen	1-28	29-56	Screen	1-28	29-56
MBC: M	STD	1.23	1.29	1.29	1.54	1.46	1.27
	Hin	1.00	1.40	1.00	-1.00	-1.00	1.00
	Z a x	7.90	8.00	8.75	7.67	7.67	7.67
	Kedian	4.60	4.98	4.60	4.60	4.59	4.60
	Median diff.		0,40	0.00		00.00	00.00
	P value		0.2516	0.3913		0.3388	0,5538

JE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

16.14

15.40

15.00

14.60

36.60

0,4408

-0.40 0.3138 23

Median diff.

Median

Max

10.28

13.14

11.62

3.09

Жеап

grs

Evaluated

BGK

P value

3.31

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

LABDRATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT -0.03 0.83 0.3301 26.74 29-56 Days of treatment 0.2562 1-28 0.83 28.23 -0.19 6.70 Assigned treatment Screen 0,58 0.00 0.1165 1.30 0.83 39 26.90 29-56 Days of treatment Fluoxetine 0.5017 1-28 45.0 25.89 5.96 1.48 0.86 82 0.57 1.38 0.84 Screen 7.20 Median diff. Evaluated Evaluated P value ats CREATININE UREA

(CONTINUED)

P VALUE: PROBABILITY FROM THE HILCOXON RANK SIGNED TEST

15.85

PHARMACIA CNS R&D

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

Laboratory test			•	Assigned treatment	reatment		
		<b>L</b>	Fluoxetine		24	Reboxetine	
	,	Days	Days of treatment	ent	Days of	of treatment	Hent
		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	49	99	49	56
	Kean	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 MILCOXON RANK SIGNED TEST

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

E
FREATMENT
NED 1
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BY
INTERVAL
INT
TO TIME INTERVAL BY
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D BLOOD CHEMISTRY STATISTICAL
D BLOOD CHENISTRY
D BLOOD C
3
HAEMATOLOGY A
HAEM!
ATORY TEST:
LABORATORY
_

			41	Assigned t	treatment		
		Ľ.	Fluoxetine		~	Reboxetine	
		Days	of treatment	ent	Days	of treatment	ent
		Screen	1-28	29-56	Screen	1-28	29-56
TOT. PROTEINS	Evaluated	79	74	64	69	99	57
	Nean	7.24	7.27	7.22	7.22	7.27	7.24
	STD	0.62	0.62	0.45	0.57	0.49	84.0
	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.		00.0	-0.10		00.00	00.00
	P value		0.9638	0.5722		0.6136	0.5699
ALBUMINE	Evaluated	76	71	63	49	61	56
	Kean	4.27	4.25	4.17	4.14	4.14	4.11
	STO	0.50	0.59	67.0	0.52	0.58	0.47
	Nin	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
	Nedian	4.30	4.29	4.19	4.10	4.13	4.01
	Median diff.		00.00	-0.03		90.0	00.0
	P value		6686'0	0.3776		0.5280	0.7012
TOT BILIRUBIN	Evaluated	78	74	63	89	99	99
	Nean	0.63	0.66	09.0	0.64	99.0	0.63
	STD	0.19	0.17	0.15	0.22	0.21	0.15
	Nin	0.20	0.20	0.28	0.20	0.20	0.26
	Маж	1.20	1.09	0.84	1.53	1.60	1.09

CONTINUE

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		Ine
RDING TO TIME INT	Assigned treatment	Reboxetine
AL ANALYSIS ACCOR	Assigned	Fluoxetine
HISTRY STATISTICA		ii.
X AND BLOOD CHE	test	
ST: HAENATOLOGY	Laboratory test	
LABORATORY TES		

Laboratory test			41	Assigned treatment	reatment		
		Ľ.	Fluoxetine		æ	Reboxetine	
		Days	Days of treatment	ent	Days	Days of treatment	ent
		Screen	1-28	29-56	Screen	1-28	29-56
TOT BILIRUBIN	Kedian	0.63	0.68	0.62	0.64	99.0	0.61
	Median diff.		00.0	0.00		00.0	-0.00
	P value		0.0220	0.5508		0.7329	0.2626
DIR BILIRUBIN	Evaluated	0+)	37	37	35	88	35
	Hean	0.12	0.12	0.11	0.11	0.11	0.11
	STD	0.04	0.04	90.0	0.04	0.04	0.04
	Kin	0.04	90.0	0.03	00.00	0.03	0.00
	Маж	0.20	0.25	0.20	0.20	0.20	0.17
	Kedian	0.12	0.12	01.0	0.12	01.0	0.12
	Median diff.		00.00	0.00		00.00	00.00
	P value		0.8241	0.1008		0.8856	0.9583

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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 TREATHENT

Laboratory test			41	Assigned t	treatment		
		L	Fluoxetine		œ	Reboxetine	
		Days	of treatment	ent	Days of	of treatment	ent
		Screen	1-28	29-56	Screen	1-28	29-56
SGOT	Evaluated	83	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
	Маж	53.75	42.00	45.00	90.09	153.75	538,00
	Median	20.00	21.67	21.67	20.29	20.29	21.67
	Median diff.		00.0	-1.14		0.57	00'0
	P value		0.7589	0.5040		0.7838	0.3371
SGPT	Evaluated	7.1	67	57	63	62	20
	Kean	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
	Kin	5.00	1.67	1.67	3.21	2.50	5.00
	Kax	103.53	51.43	38.82	65.71	219.29	1067.50
	Nedian	18.89	19.29	21.18	19.58	17.92	19.89
	Median diff.		00.00	00.00		-0.26	00.0
	P value		0.7513	0.5118		0.8599	0.5821
GAMMA GT	Evaluated	82	78	99	7.1	69	58
	Kean	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
	Nin	8.00	8,00	9.83	8.00	9.45	55'6
	Kax	173.00	120.61	166.17	81.89	122.67	318.86

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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 TREATHENT

Laboratory test			<b>~</b>	Assigned t	treatment		
		<u>.</u>	Fluoxetine		24	Reboxetine	
		Days	of treatment	ent	Days	of treatment	ent
		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		00.0	-0.59
	P value		0.0013	0.000		0.7737	0.7566
CDH	Evaluated	78	72	99	<del>1</del> 99	62	55
	Кеад	310.90	317.90	309.57	300.76	307.01	317.84
	sto	62.76	92.67	72.10	76.39	70.95	74.68
	Nin	192.50	203.70	183.75	128.10	159.25	166.95
	Мах	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	89	49	57
	Hean	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	49.44	44.69	41.86
	Мах	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

Processing   Pro	Laboratory test			∢	Assigned treatment	reatment		
ALPHA Evaluated Screen 1-28 29-56 Service Screen 1-28 29-56 Service Screen 1-28 29-56 Service Street 1-28 29-56 Service Street 1-28 29-56 Service Street 1-28 29-56 Service Street 1-28 29-56 Service Street 1-28 29-56 Service 1-29 29 29 29 29 29 29 29 29 29 29 29 29 2			4	luoxetine		~	Reboxetine	
ALPHA Evaluated 56 49 45 Screen 1-28 29-56 Screen Lo. 22 29-56 Screen Lo. 22 29-56 Screen Lo. 22 29-56 Screen Lo. 23 29-56 Screen Lo. 24 29 45 Screen Lo. 25 29-56 Screen Lo. 25 29-59 Scr			Days		ent	Days	of treatment	ent
Name			Screen	1-28	29-56	Screen	1-28	29-56
Noan   0.21   0.22   0.21   0.22   0.21	GLOBULINS ALPHA	Evaluated	56	64	45	44	43	39
Nin		Kean	0.21	0.22	0.21	0.22	0.22	0.22
Min		STD	0.05	90.0	90.0	0.07	0.05	0.06
Max   0.33   0.35   0.39   Modian   Modian   0.20   0.20   0.20   0.20   Modian   Modian   0.20   0.4154   0.106   0.00		Min	0.07	01.0	01.0	01.0	01.0	0.15
Median diff.   0.20   0.21   0.20   0.20		Мах	0.33	0.35	0.39	0.39	0.33	0.41
Notion diff.   0.00		Median	0.20	0.21	0.20	0.21	0.21	0.20
P. value   0.4154 0.1760				00.0	00.00		00.0	00.00
Noan   Noan		P value		0.4154	0.1760		0.5891	0.6994
Mean         0.65         0.88         0.86           STD         0.12         0.14         0.11           Min         0.59         0.62         0.59           Max         1.09         1.26         1.13           Median         0.85         0.85         0.87           Median diff.         0.01         0.00         0.00           P value         0.2266         0.0807         0.85           Man         0.94         0.94         4.5           Min         0.75         0.54         0.76           Max         1.16         1.33         1.40	GLOBULINS ALPHA		99	64	45	44	43	39
Min         0.12         0.14         0.11           Min         0.59         0.62         0.59           Max         1.09         1.26         1.13           Median         0.85         0.85         0.87           Median diff.         0.01         0.01         0.00           P value         0.2266         0.0807         45           Evaluated         56         49         45           Mean         0.94         0.95         0.95           Min         0.75         0.54         0.70           Min         0.75         0.54         0.70           Max         1.16         1.33         1.40	ı	Kean	0.85	0.88	0.86	0.82	0.85	0.82
Hin         0.59         0.62         0.59           Max         1.09         1.26         1.13           Hedian         0.85         0.85         0.87           Pedian diff.         0.01         0.00         0.00           P value         0.2266         0.0807         45           Hean         0.94         0.94         0.95           Man         0.75         0.74         0.70           Min         0.75         0.54         0.70           Max         1.16         1.33         1.40		STD	0.12	91.0	0.11	0.17	0.15	91.0
Max         1.09         1.26         1.13           Median         0.85         0.85         0.87           Median diff.         0.01         0.00         0.00           P value         0.2266         0.0807         45           Evaluated         56         49         45           Mean         0.94         0.94         0.95           STD         0.13         0.11           Min         0.75         0.54         0.70           Max         1.16         1.33         1.40		Min	0.59	0.62	0.59	0.23	0.28	0.20
Median         0.85         0.87           Median diff.         0.01         0.00           P value         0.2266         0.0807           Evaluated         56         49         45           Mean         0.94         0.95         0.95           STD         0.10         0.13         0.11           Min         0.75         0.54         0.70           Max         1.16         1.33         1.40		Kax	1.09	1.26	1.13	1.16	1.23	1.15
Median diff.     0.01     0.00       P value     0.2266     0.0807       Evaluated     56     49     45       Mean     0.94     0.95     0.95       STD     0.10     0.13     0.11       Min     0.75     0.54     0.70       Max     1.16     1.33     1.40		Median	0.85	0.85	0.87	£8'0	0.85	18.0
P value         0.2266         0.0807           Evaluated         56         49         45           Mean         0.94         0.94         0.95           STD         0.10         0.13         0.11           Min         0.75         0.54         0.70           Max         1.16         1.33         1.40				0.01	00.00		0.03	00.0
Evaluated         56         49         45           Mean         0.94         0.94         0.95           STD         0.10         0.13         0.11           Min         0.75         0.54         0.70           Max         1.16         1.33         1.40				0.2266	0.0807		0.3532	0.8294
0.10 0.13 0.11 0.75 0.54 0.70 1.16 1.33 1.40	GLOBULINS BETA	Evaluated	99	64	54	<del>5</del> 5	43	68
0.10 0.13 0.11 0.75 0.54 0.70 1.16 1.33 1.40		Hean	0.94	0.94	0.95	0.93	0.94	0.92
0.75 0.54 0.70 1.16 1.33 1.40		srb	01.0	0.13	0.11	11.0	01'0	01.0
1.16 1.33 1.40		Hin	0.75	0.54	0.70	99'0	67.0	89.0
		Нак	1.16	1.33	1.40	1.21	1.20	1.22

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P VALUE: PROBABILITY FROM THE WILCOMON RANK SIGNED TEST

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PHARMACIA CKS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 61

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

Laboratory test			₹	Assigned treatment	reatment		
		4	Fluoxetine		œ	Reboxetine	
		Days of	of treatment	ent	Days	Days of treatment	heat
		Screen	1-28	29-56	Screen	1-28	29-56
GLOBULINS BETA	Median	16.0	06.0	0.95	0.91	0.95	06.0
	Median diff.		00.00	0.01		00.0	00.00
	P value		0.5179	0.4268		0.6283	0.7667
GLOBULINS GAMMA	Evaluated	99	64	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
	Kin	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
	Modian	1.22	1.36	1.36	1.27	1.28	1.40
	Median diff.		00.0	0.00		0.02	0.02
	P value		0.6728	0.4872		0.4283	0.1199

LUE: 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	reatment		
		ŭ.	Fluoxetine		œ.	Reboxetine	
		Days	of treatment	ent	Days	of treatment	ent
		Screen	1-28	29-56	Screen	1-28	29-56
TOT. CHOLEST.	Evaluated	22	73	65	89	99	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
	Kin	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.		00.0	00.00		-10.15	-6.09
	P value		0.5897	0.8428		0.0550	0.2648
TRIGLYCERIDES	Evaluated	76	72	65	68	99	35
	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
	Мах	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.		00.00	-7.62		4.38	4.69
	P value		0.5557	0.0847		6.4725	0.3072
CLUCOSE	Evaluated	78	73	64	69	<del>7</del> 9	95
	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	94.75	57.40
	Max	128.33	195.13	129.57	237.67	299.53	271.05

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P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 61

KEBURLINE - PROTUCCU. 20124/016 TABLE No.: 61 LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATHENT

Laboratory test			₹	Assigned treatment	reatment		
		<b>34</b>	Fluoxetine		<b>A</b>	Reboxetine	
		Days	Days of treatment	ent	Days	Days of treatment	went
	•	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	0.8941 0.5331		0.4987	0.8015

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 61

LABORATORY TEST: HAEHATOLOGY AND BLOOD CHENISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATHENT

Laboratory test			₹	Assigned treatment	reatment		
		E.	Fluoxetine		2	Reboxetine	
	1	Days	of treatment	ent	Days	of treatment	ent
		Screen	1-28	29-56	Screen	1-28	29-56
NA+	Evaluated	80	76	99	7.1	89	59
	Rean	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
	Маж	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		00.0	00.00
	P value		0.6895	0.8364		0.7148	0.6274
급-	Evaluated	70	67	54	61	09	53
	Hean	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
	Nin	96.11	91.60	92.46	95.54	98.00	96.15
	Nax	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.		00.00	08.0		-0.73	08*0-
	P value		0.6993	0.2651		0.0143	0.0265
‡	Evaluated	77	74	63	70	99	65
	Mean	4.29	4.43	4.37	4.28	4.42	4.33
	STD	0.42	0.56	64.0	0.41	64.0	0.47
	Min	3.18	3.27	3.50	3.14	2.86	2.27
	Мах	5.26	7.66	90.9	5.42	5.26	5.21

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

PHARMACIA CNS RRD REBOXETINE - PROTOCOL 20124/016 TABLE No.: 61

	TREAT
	ASSIGNED
	BY
	INTERVAL
	묊
	P
4/016	ACCORDING T
rocol 2012 ).: 61	ANALYSIS
REBOXETINE - PROTOCOL 20124/016 TABLE No.: 61	STATISTICAL
REBO	CHEMISTRY
	BLOOD
	AND
	Y TEST: HAEMATOLOGY AND BLOOD CHEMISTRY STATISTICAL ANALYSIS ACCORDING TO TIME INTERVAL BY ASSIGNED TREAT
	Y TEST:

Laboratory test			A	Assigned t	treatment		
		Ľ.	Fluoxetine		2	Reboxetine	
	·	Days	of treatment	ent	Days	of treatment	ent
		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	92	99	69	65	57
	Kean	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	44.44	4.35	47.4
	Hax	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
٠	Median diff.		0.00	0.00		0.00	0.00
	P value		0.8360	0.1610		0.4600	0.5318
b0d	Evaluated	72	67	29	63	59	53
	Меап	1.33	1.31	1.35	1.27	1.30	1.30
	STD	92.0	0.15	0.34	0.13	0.14	0.15
	Min	1.04	1.03	0.87	1.00	0.94	0.85
	Маж	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.		00.0	00.0		0.04	00.0
	P value		0.6857	0.8484		0.0299	0.4849

VALUE: PROBABILITY FROM THE WILCOMON

PHARMACIA CNS RBD ... REBOXETINE - PROTOCOL 20124/016 TABLE No.: 62 URINALYSIS: NUMBER AND PERCENTAGE OF PATIENTS ACCORDING TO TIME INTERVAL, BY ASSIGNED TREATMENT AND SEX

signed treatment: Reboxetine

Urinalysis									Day	s of t	Days of treatment	ant						:	
				Sere	Screening					1-28 days	days					29-56	29-56 days		
		Fer	Female	_	Hale	1	Total	Fe	Female	e.	Male	Total	al	Fen	Female	E.	Kale	Total	12
		No.	×	Š	~	Ñ.	*	₹.	×	No.	x	No.	×	No.	×	No.	×	Мо.	×
SPECIFIC GRAVITY Normal	Normal	32	100.0	11	100.0		43 100.0	32	100.0	1	100.0	643	100.0	28	9.96	6	90.0	37	94.9
	Not done			<u>_</u>										-	3.4	-	10.0	22	5.1
	Total	32	100.0	11	100.0		43 100.0	32	100.0	7	100.0	643	100.0	53	100.0	2	100.0	39	100.0
ALBUNIN	Absent	\$	100.0	15	88	8	59 96.7	24 45	95.5	16	94.1	85	95.1		91.9	13	86.7	4.7	90.4
	Present				2 11.8		2 3.3	-	2.3	٢	5.9	N	e.	71	5.4	-	6.7	m	5.8
	Not done				L	ļ		-	2.3			-	1.6	-	2.7	~	6.7	61	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	22	100.0
SUGAR	Absent	43	7.76	17	0.001		60 98.4	45	95.5	17	100.0	83	96.7	8	94.6	14	93.3	64	94.2
	Present	-	2.3				1.6	9	2.3			-	1.6	-	2.7			-	1.9
	Not done							-	2.3		L.	-	1.6	٦	2.7	٦	6.7	63	3.8
	Total	44	100.0	17	7 106.0		61 100.0	44	100.0	17	100.0	61	100.0	37	100.0	15	100.0	52	100.0
RBC	Absent	37	24. 4	F	1 73.3	<b>[</b>	48 81.4	4 36	81.8	12	80.0	84	81.4	33	89.2	8	61.5	41	82.0
	Present	7	15.9		4 26.7		11 18.6	9	13.6	2	13.3	σ,	13.6	6	8.1	2	15.4	Ŋ	10.0
	Not done							23	4.5	-	6.7	m	5.1	-	2.7	m	23.1	4	8.0
	Total	44	100.0	5	100.0		59 100.0	4	100.0	15	100.0	59	100.0	37	100.0	13	100.0	20	100 . 0
ИВС	Absent	31	70.5		7 50.0	ļ	38 65.	5 29	62.9	8	57.1	37	63.8	24	64.9	æ	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	(f)	5.2	1	2.7	2	16.7	3	6.1
	Total	44	44 100.0		14 100.0		58 100.0		0.001 44		14 100.0		58 100.0	37	37 100.0		12 100.0	49	49 100.0

PRARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/016

IABLE No.: 62

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

Urinalysis									Days	of t	Days of treatment	nt							
				Screening	ping					1-28 days	days					29-5	29-56 days		
		Feir	Female	윤	Kale	Total	Total	Fem	Female	먶	Nale	Total	al	Fell	Female	=	Male	2	Tota1
		No.	×		н	2	×	.6	н	S	к	No.	×		ж		×	ŝ	×
SPECIFIC GRAVITY Normal	Normal	33	100.0	7	100.0	44	100.0	30	93.8	₽	100.0	9	95.2	30	96.8	11	100.0	4-1	97.6
	Not done							61	6.3			61	4.8	1	3.2			٢	2,4
	Total	33	100.0	1	11 100.0	44	44 100.0	32	100.0	9	10 100.0	45	100,0	31	31 100.0	L	11 100.0	245	100.0
ALBUMIN	Absent	45	90.0	16	100.0	19	92.4	43	87.8	15	100.0	58	90'6	39	86.7	‡	100.0	83	8.68
	Present	ιń	10.01			w	7.6	63	4.1			63	3.1	3	6.7			60	5.1
	Not done					,		4	8.2			4	6.3	3	6.7			3	5.1
	Total	20	100.0	16	100.0	99	100,0	64	100.0	15	100.0	49	100.0	45	100.0	41	100.0	59	100.0
SUGAR	Absent	20	100.0	16	100.0	99	100.0	45	91.8	15	100.0	9	93.8	42	93.3	14	100.0	56	94.9
	Not done							4	8.2			4	6.3	3	6.7			e,	5.1
	Total	20	100.0	16	100.0	99	100.0	49	100.0	15	100.0	99	100.0	45	100.0	14	100.0	59	100.0
RBC	Absent	77	88.0	16	94.1	99	89.6	39	79.6	5	93.8	54	83.1	34	73.9	12	85.7	94	76.7
	Present	9	12.0	-	5.9	7	10.4	4	8.2	-	6.3	LO.	7.7	6	19.6	2	14.3	11	18.3
	Not done							9	12.2			10	9.2	6	6.5			3	5.0
	Total	20	100.0	11	100.0	69	100.0	49	100.0	16	100.0	65	100.0	94	100.0	14	100.0	9	100.0
MBC	Absent	32	66.7	13	76.5	45	69.2	27	57.4	4	87.5	1.4	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	e	21.4	22	36.8
	Not done							4	8.5			4	6.3	4	9.3			4	7.0
	Total	84	48 100.0	17	17 100.0	65	65 100.0		47 100.0	16	16 100.0		63 100.0	İ	43 100.0		14 100.0		57 100.0

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 63 URINALYSIS: NUMBER AND PERCENTAGE OF PATIENTS AT LAST ASSESSMENT, BY ASSIGNED TREATMENT AND SEX

PHARMACIA CNS R&D

Urinalysis												5	Last assessment	essme	nt				
				Total	댙		•			1-28 days	days					29-56	29-56 days		
		Fem	Female	₩.	Male	Tol	Total	Fear	Fenale	<b>1</b>	Hale	Total	1.6	Fer	Female	Ma	Male	Tota1	12
		%.	н	ě	ж	₩.	ĸ	ě	ж	₽.	н	.8	ж	Νο.	×	No.	×	. ∘%	×
SPECIFIC GRAVITY Normal	Normal	31	6.96	9	6.06	41	95.3	m	100.0	-	100.0	4	100.0	28	96.6	6	90.0	37	94.9
	Not done	-	3.1	٦	9.1	2	4.7							-	3.4	-	10.0	67	5,1
	Total	32	32 100.0	7	100.0	43	100.0	60	100.0	7	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	62	100.0	6	100.0	34	91.9	13	86.7	4.7	90.4
	Present	67	4.5	-	5.9	3	4.9							23	5.4	-	6.7	rr)	5.8
	Not done	-	2.3	-	5.9	2	3,3							-	2.7	-	6.7	87	3.8
	Total	55	100.0	17	100.0	19	100.0	_	300.0	2	100.0	6	100.0	37	100.0	15	100.0	22	100.0
SUGAR	Absent	745	95.5	16	94.1	83	95.1	7	7 100.0	N	2 100.0	e,	100.0	35	94.6	14	93.3	49	94.2
	Present	-	2.3			-	1.6							1	2.7			-	1.9
	Not done	-	2.3	٢	6.0	61	3.3							٦	2.7	-	6.7	73	3.8
	Total	44	100.0	12	100.0	6	100.0	2	100.0	67	100.0	6	100.0	37	100.0	15	100.0	25	100.0
RBC	Absent	39	88.6	ę	66.7	64	83.1	9	85.7	67	100.0	8	88.9	33	89.2	8	61.5	41	82.0
	Present	4	9.1	7	13.3	9	10.2	-	14.3			-	11.1	6	8.1	N	15.4	20	10.0
	Not done	1	2.3	6	20.0	4	8.9							-	2.7	3	23.1	4	8.0
	Total	44	100 · D	15	100.0	59	100.0	7	100,0	61	2 100.0	6	100.0	37	100.0	13	100.0	50	100.0
MBC	Absent	28	63.6	5	35.7	33	56.9	4	57.1	7	100.0	9	66.7	24	64.9	3	25.0	27	55.1
	Present	15	34.1	7	50.0	22	37.9	е.	42.9			3	33.3	12	32.4	4	58.3	19	38.8
	Not done	1	2.3	2	14.3	3	5.2							1	2.7	2	16.7	8	6.1
	Total	44	0.001 44	14	100.0	58	100.0	7	7 100.0		2 100.0	6	100.0	37	100.0	12	100.0	64	100.0

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 63

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

Urinalysis												La	Last assessment	essme	ıt				
		,		Total	al				-	1-28 days	lays					29-56	29-56 days		
		Fem	Female	<b>1</b>	Male	Total	T <sub>z</sub>	Female	16	Male	9	Total	11	Fem	Female	<b>3C</b>	Hale	Total	급
		No.	×		×	P	×	No.	×	М.	×	No.	×	No.	×	No.	и	No.	ĸ
SPECIFIC GRAVITY Normal	Normal	32	97.0	Ξ	100.0	43	7.76	2	100.0			Ñ	100.0	8	96.8	F	100.0	141	97.6
	Not done	-	3.0			-	2.3							-	3.2			~	2.4
	Total	83	100.0	-	100.0	44	100.0	2	100,0			2	100.0	31	100.0	11	100.0	42	100.0
ALBUMIN	Absent	\$	88.0	16	100.0	09	6.06	5	100.0	N	100.0	7	7 100.0	39	86.7		14 100.0	53	89.8
	Present	е	0.9			60	4.5							в	6.7			m	5.1
	Not done	6	0.9			ю	4,5	_						ю	6.7			m	5.7
	Total	20	100.0	16	100.0	99	100.0	5	5 100.0	8	100.0		7 100.0	45	45 100.0	4	100.0	59	100.0
SUGAR	Absent	47	0.4.0	16	100.0	63	95.5	5	5 100.0	N	2 100.0	7	7 100.0	42	93.3	7	100.0	8	94.9
	Not done	æ	6.0			EF.	2.							e	6.7			m	5,1
	Total	20	100.0	16	100.0	99	100.0	5	5 100.0	73	2 100.0	7	7 100.0	45	45 100.0	4	100.0	59	100.0
RBC	Absent	38	76.0	15	88.2	S	79.1	4	100.0	6	3 100.0	7	7 100.0	34	73.9	12	85.7	949	76.7
	Present	6	18.0	73	11.8	1	16.4							6	19.6	63	14.3	1	18.3
	Not done	9	6.0			60	4.5							æ	6.5			60	5.0
	Total	20	100.0	17	100.0	. 69	100.0	4	4 100.0	60	3 100.0	7	100.0	94	100.0	14	100.0	09	100.0
ивс	Absent	23	6.74	14	82.4	37	56.9	81	40.0	60	100.0	-5	62.5	21	48.8	11	9'8'	38	56.1
	Present	21	43.8	6	17.6	24	96,98	60	0.09			8	37.5	18	41.9	в	21.4	12	36.8
	Not done	4	8.3			4	6.2							4	9.3			4	7.0
	Total	84	48 100.0	17	100.0	9	0.001 69	ro -	0.001 8	m	100.0	*	8 100.0	43	43 100.0		14 100.0	22	100.0

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/016

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

ssigned treatment: Reboxetine

Uninglusis test at baseline	t hasalina				Dave of treatment	reatment			
					and and				
			1-28	1-28 days			29-56 days	days	
		Absent	Present	Absent Present Not done	Total	Absent	Present	Not done	Total
ALBUNIN	Absent	22	1	-	59	46	23	23	50
	Present	1	1		23	-	1		8
	Total	58	2	-	19	44	E	81	52
SUGAR	Absent	59		F	9	64		2	51
	Present		1		-		-		1
	Total	59	ı	٦	61	647	ı	83	52
RBC	Absent	43	9	Ø	849	37	22	N	41
	Present	5	5	٢	11	4	8	23	6
	Total	48	8	8	59	41	5	7	50
NBC	Absent	32	4	N	38	24	5	1	30
	Present	S	ħL	-	20	3	14	2	¢ 19
	Total	37	18	8	58	27	19	æ	64

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 64

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

issigned treatment: Fluoxetine

Urinalysis test at baseline	t baseline				Days of treatment	reatment	i	i.		Г
			1-28	1-28 days			29-56 days	days		Τ
		Absent	Present	Not done	Total	Absent	Absent Present	Not done	Total	
ALBUHIN	Absent	55		7	59	51	1		en	55
	Present	33	2		r.	2	2			4
	Total	58	2	4	79	53	3		6	53
SUGAR	Absent	09		4	49	56			6	29
	Total	09		4	49	56			ю -	59
	Absent	52	1	κ	58	45	ις		6	53
	Present	2	4	-	7	-	9			7
	Total	54	5	9	99	94	11		en	60
	Absent	38	4	æ	45	3.1	m		4	38
	Present	8	14	-	18	•	18			19
	Total	41	18	4	63	32	21		4	57

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 65

URINALYSIS: SHIFT TABLE - NUMBER OF PATTENTS MITH ABSENT OR PRESENT URINALYSIS VALUE AT LAST ABSESSMENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

Urinalysis test at baseline	at baseline							Last	Last assessment	nt		
			Total	al	1,	-	1-28 days			29-56 days	days	
		Absent	Present	Present Not done	[ota]	Absent	Present	Total	Absent	Present	Not done	Total
ALBUMIN	Absent	55	61	7	65	6		G.	94	2	62	20
	Present	F	1		72				1	1		N
	Total	56	8	2	61	6		6	47	3	23	52
SUGAR	Absent	58		7	9	6		6	64)		67	51
	Present		-		-					1		-
	Total	58	-	2	61	60		6	49	1	2	52
RBC	Absent	£†	6	2	87	9	1	7	37	2	2	41
	Present	9	E	2	11	2		2	7	3	2	6
	<b>T</b> otal	64	9	Ŧ	59	80	٦	6	14	5	4	50
WBC	Absent	29	8	1	38	r)	9	80	<b>5</b> 2	5	ı	30
	Present	4	14	23	20	•		٦	£	τι	2	19
	Total	33	22	3	58	9	6	6	27	19	æ	64

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 65

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

Urinalysis test at baseline	at baseline							Last	Last assessment	iit		
			Total	la:	•		1-28 days			29-56	29-56 days	
		Absent	Present	Absent Present Not done	Total	Absent	Absent Present	Total	Absent	Present	Absent Present Not done Total	Total
ALBUMIN	Absent	57	1	m	61	9		9	51	-	ю	55
	Present	E	2		S	1		-	2	8		4
	Total	60	8	er.	99	7		7	53	m	m	59
SUGAR	Absent	63		m	99	7		7	56		ĸ	59
	Total	63		ĸ	99	7		7	56		ю	59
RBC	Absent	52	S	m	09	7		7	45	5	В	53
	Present	-	9		7				1	9		7
	Total	53	11	3	67	7		7	9+	11	e	09
WBC	Absent	36	5	7	45	5	2	7	31	3	4	38
	Present	ı	19		20		-	-	1	18		19
	Total	48	54	4	65	5	8	8	32	21	7	57

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 66 URINALYRIS: SHIFT TABLE - NUMBER OF PATIENTS WITH ABNORMAL OR NORMAL URINALYRIS VALUE AT EACH EVALUATION TIME AS COMPARED TO PRE-TREATHENT EVALUATION, BY ASSIGNED TREATHENT (SPECIFIC GRAVITY)

 Left of the standard of the

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 66

TABLE NO.: 66
SHIFT TABLE - NUMBER OF PATIENTS WITH ABNORMAL OR NORMAL URINALVSIS VALUE AT EACH EV
AS COMPARED TO PRE-TREATHENT EVALUATION, BY ASSIGNED TREATHENT (SPECIFIC GRAVITY)

Assigned treatment: Fluoxetine	:: Fluoxetine						
Urinalysis test at baseline	t baseline			Days of t	Days of treatment		
			1-28 days		· ·	29-56 days	
		Normal	Not done	[otal	Normal	Normal Not done Total Normal Not done Total	Total
SPECIFIC GRAVITY Normal	Normal	04	73	45	41	-	42
	Total	40	2	45	14	1	42

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 67

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

Assigned treatment: Reboxetine

cinalysis test at baseline	t baseline					Last	Last assessment	ant	
			Total	•	1-28 days	days		29-56 days	
		Normal	Not done	Total	Normal	Total	Normal	Normal Not done Total Normal Total Normal Not done Total	Total
PECIFIC GRAVITY Normal	Normal	41	2	643	4	4	37	2	39
<u>, • · · </u>	Total	41	2	43	4	4	37	2	39

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

### PHARMACTA CHE RED

## PERCEPTINE - PROTOCOL 20124/016

ETHALTEES: SKIFT TABLE - NVMMER OF PAYLESTS KITH ARMORDAL OR HORNAL UNITRALTEES VALUE AT LAST ASSESSMENT

larianal topotopot: Plusuetina

Urinnlysis tost at baseline					Last	-	oat.	
		Total		1-28	days		29-56 days	,
	Normal	Not dome	Total	Rosmal	Total	Normal	Not done	Total
SPECIFIC CRAVITY Normal	48	1	44	2	2	41	1	4
Total	48	1	44		,	44	•	4

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 68

Laboratory test	test							ASSI	Assigned treatment	reatm	ent						
					Fluoxetine	tine							Reboxetine	stine			
				Day	Days of treatment	reatm	ent					Pay	Days of treatment	treatm	ent		
			+	1-28			29-56	256			+	1-28			29-56	8	
		Low	Nor.	High	High P val Low		Nor.	Bigh	Nor. Bigh P val Low		Nor.	High	High P val Low		Nor.	High P	P val
#	LOW		8				m			N	-			٣	2		
	NORMAL	2	7.1	77		r)	57	7		е	S,	-		٦	64		
	ніся			-	0.368			-	0.287		-	2	2 0.607		7	-	1 0.717
HT	HO7	٦	87				7			6	4			77	r.		
	NORMAL		99	81		4	20	4		2	22	-			3	4	
	HIGH		N	ιŋ	0.368		4	m	0.717	-	6	9	0.435		4	67	0,082
RBC	КОЛ	4	4			8	e			63	4			-	4		
	NORMAL	m,	48	62		m	37	m		67	40	4		٦		٢	
	ндн		71		15 0.931		m	15	1.000		٦	15	15 0.291		-	15	15 0.407
PLATELETS	LOW										2				-		
	NORMAL	-	70	٦			62				58	4			20	m	
	HICH		61		3 0.513		m	2	2 0.250		2	2	2 0.264		61	-	1 0.549

P val : probability from

PHARMACIA CNS R&D

5 1 45 5 2 44 7 3 35 7	3 2 1	1.000 1.000 1.000 1.000		83 1 2 2 2 1 2 2 2 1 2 1 2 2 1	0 0 0 0 4	0 00 00			2 50 50 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	N N N V F	1.000	1 8 1	1 4 6 - 6 4 4	0 0 2		1.000				8 20 7 1 72 8	
0.253 1 7 4 0.607 2 2 2 2 2 0.479 3 0.223 2 0.479 61 1 2 1.000 61 1 000 1	0.253 1 7 4, 0.607 2 44 0.253 1 7 4, 0.607 2 2 1 2 50 0.479 3 0.223 2 2 50 1.000 1 1.000 3 60	45	4 4 0.390	0.390			2 W		42	9 -	890			4	3	896		4 4		3 50	3 50
2 0.253 1 7 4 0.607 1 2 2 2 2 2 2 2 2 3 0.479 3 0.223 61 1	2 0.253 1 7 4 0.607 1 0.479 3 0.223	2 5	0.500	0000			m	m		ď	8	-	- 6		m	200	-	-			4
2 0.253 1 7 4 0.607 2 2 2 2 2 2 2 2 1 1 2 2 2 2 1 0.479 3 0.223	2 0.253 1 7 4 0.607 2 44 2 0.253 1 7 4 0.607 2 1 1 54 1 2 2 1 1 0.479 3 0.223 2	0.500	0.500						09		000			٥٠		000		-		<del></del>	
2 0.253 1 7 4 0.607 2 2 1 2 2 1 2 50 1	2 0.253 1 7 4,0.607 2 44 7 7 4 0.607 2 2 1 1 1 45 5 1 1 2 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1						2.	e	22		223	<u>-</u>	_			479	ė	61		_	-
2 0.253 1 7 4 0.607 2 7	2 0.253 1 49 60.607 2 44 7 2 2 2 2 2 1 1 1	43		2				٦	50	62		-		rs.			1			Ш	Ш
2 0.253 1 7 4 0.607 2 7	2 0.253 1 7 4 0.607 2 7 0.211				2	_		•	-	N	-	_				_			œ .		_
	5 1 45 5 2 44 7 3	3		7				1	•	٩		_			2	Г					7
2 1		-	61	-	- m			2 2	44	N N 0	209				1 1 2	253	2 2 6	B 0 F			
2 0.368	2 0.368 4 2 0.407 2 2 0.513 1 2	1	-	53	- 6	2 3		2 2 2	2 44 7	0 0 0	407				2	368	2 2 0.	9 8 9 7		W. F	(f) (f)
2     1     56     1     3     59     1     53     1       2     0.368     4     2     0.407     2     2     0.513     1     2       3     2     1     1     1     1     1     2	2         1         56         1         3         59         1         53         1           2         0.368         4         2         0.407         2         2         0.513         1         2	'			- 6	2 0			2 2 44 2 2 2	m N N C	407				2	368	2 2 2 2 2 0.0		4 9 8 9 7	6 6 7	6 6 7
2     1     3     59     1     55     1       0.368     4     2     0.407     2     2     2     0.513     1     2       3     2     1     2     1     2     1     2	2     1       1     56       1     3       56     1       3     59       1     2       2     2       2     2       2     2       2     2       3     3       4     2       5     3       1     2       2     3       3     4       4     5       5     6       6     7       6     7       7     6       8     7       9     7       9     7       9     7       1     2       1     2       1     2       1     2       2     3       3     4       4     5       5     6       6     7       6     7       7     6       8     7       9     7       9     7       1     1       1     1       1     1       1     1       1     1       1     1       1	۵.			- 6	2 0			2 2 44 444 444 444 444 444 444 444 444	w 0 0	407				2 2	368	2 2 2 2 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		- 4 9 6 0 7		6 6 7
P val Low Nor. High P val Low Nor. High P val Low Nor. High Low Low Low Low Low Low Low Low Low Low	Nor.   High   P val   Low   Nor.   High   P val   Low   Nor.   High   High   Nor.   High   Nor.   High   Nor.   High   Nor.   High   High   Nor.   High   Nor.   High   Nor.   High   Nor.   High   High   Nor.   High	-		H.	- 6	- 0 <u></u>	0.51 0.21	High   1   1   2   2   2   2   2   2   3   3   3   3	Nor. 1 1 2 2 2 2 2 44 44 44 44 44 44 44 44 44 44	40 01 01 (	407 607	대	ET TO TO TO TO TO TO TO TO TO TO TO TO TO	Nor.	LOH 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	368 368 253	편 2 2 2 2 2 C C C C C C C C C C C C C C		. t 4 9 6 0 1		
Nor.   High   P val   Low   Nor.   High   P val   Low   Nor.   High   P val   Low   Nor.   High   P val   Low   Nor.   High	Nor.   High   P val   Low   Nor.   High   P val   Low   Nor.   High   P val   Low   Nor.   High   P val   Low   Nor.   High   P val   Low   Nor.   High   P val   Low   Nor.   High   P val   Low   Nor.   High   P val   Low   Nor.   High   P val   Low   Nor.   High   P val   High   P val   Nor.   High   P val   High   P val   High   P val   High   P val   High   P val   High   P val   High		٠	29-5		2 3 5	P va 0.21	1 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Nor. 1 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	40 01 01 0	407 607	다	H19	Nor.	Гон 1 1 2	368 368 253	다 2 2 2 2 C C C C C C C C C C C C C C C		1-28 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
Nor.   High   P.val   Low   P.val   Low   P.val   Low	Nor.   High   P val   Low   Nor.   High   P val   Low   Nor.   High   P val   Low   High   P val   Low   High   P val   Low   High   P val   Low   High   High   P val   Low   High   High   High   Nor.   High   High   Nor.		l <sub>o</sub>	29-5	- m	1 Lo	P va of	Day 28 11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Nor. 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2		ral I	편 는 23 20 4 다 O O	H H 19	29 29 Nor.	Геаты 1 1 1 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	of ti	ays 2 2 2 2 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		1-28 11 1 4 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Nor. Hi	Nor. B1. 1 1 1 28 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
Reboxetine   Repoxetine	Second   S			29-5		tres 11 Lou	P va of 0.51	Day 128 High 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		Leval I	□         □	H1g	Nor. 26	Feath Low 1	of tu	E 8 0 0	[편] [편] [2] 2   2   2	Day 1 - 28	1-28 Nor. Bi	Nor. Bi

P val : probability from Maxwell's test

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 68

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TABLE 3 COMPARI
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LABORATORY HEST: HAEMATORY AND BLOOD CHEMISTRY - SHIFT ? PATIENTS WITH VALUES BELOW, MITHIN OR ABOVE THE NORMAL RANGE ACCORDING TO TIME INTERVAL AS
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PATIE
30

Laboratory test	test							Assi	Assigned treatment	reatm	ent				:		
					Fluoxetine	tine							Reboxetine	tine			
				Day	Days of treatment	reatm	ent					Day	Days of treatment	reatn	ent		
			+	1-28			29-56	56			+	1-28			29-56	26	
		Low	Nor.	High	Nor. High P val Low		Nor.	High	Nor. High P val Low		Nor.	High	Nor. High P val Low	_	Nor. High P val	High	P val
CREATININE	LOW									-	-				23		
	NORMAL		77				65	-			63	-			52	72	
	HIGH			-	1 1.000			-	1 1.000		-	2	0.607		-	7	2 0.311
UREA	LOW		-													_	
	NORMAL		33				59	ro		-	29	٦			31		
	HICH		ø	-	1 0.030		7		0.344		9	7	2 0.102		7	-	1 0.016
BUN	LOH									-	63			2	-		
	NORMAL		98				22	-		67	19			-	14		
	HIGH				1.000				1.000				1.000				1.000
URIC ACID	LOW	-				-	-			2	٦			-	1		
	NORMAL		75	8			57				35	-		2	46	7	
	HICH		4	61	2 1.000		62	ю	3 0.223		-	m	3 0.607		9	1	1 0.766

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 68

LABORATORY TEST: HAEMATOLOGY AND BLOOD CHEMISTRY - SHIFT TABLE
NUMBER OF PATIENTS HITH VALUES BELOM, MITHIN OR ABOVE THE NORMAL RANGE ACCORDING TO TIME INTERVAL AS COMPARED TO PRE-TREATHENT, BY ASSIGNED TREATHENT-

Laboratory test	test							Assi	Assigned treatment	reatm	ent						
					Fluoxetine	tine							Reboxetine	tine			
				Day	Days of treatment	reatm	ent					Day	Days of treatment	treats	hent		
			+	1-28			29-56	26			+	1-28			29-56	56	
		Low	Nor.	High	High P val Low	1	Nor. 1	High	Nor. High P val Low		Nor.	High	High P val Low		Nor.	High P val	P val
TOT.	LOH	κ	n			М	-				m	-			8		
	NORMAL	60	59	4		7	99	-			19			61	52		
	HIGH		8		0.717		-	Ī	9,8.0		-		0.102			-	1 1.000
ALBUMINE	LOW	_	ю			-	7			7	m				9		
	NORMAL	4	54	æ		m	48	61		4	45	71		-	44	-	
	HICH		ю	60	0,931		*	m	3 0.648		6	12	0.842		4		0.068
TOT	ТОК																
	NORMAL		72	-			29				63	N			55		
	HICK		-		1.000		-		1.000		-		1.000			-	1 1.000
DIR	тон																
	NORMAL		98	-			37				33				35		
	HICH				1.000				1.000				1.000				1.000

val : probability from Maxwell's test

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 68

Laboratory test	test				i			Assi	Assigned treatment	reatm	ent						
					Fluoxetine	tine							Reboxetine	stine			
				Day	Days of treatment	reatm	ent			1		Day	Days of treatment	treat	ont		
			ļ	1-28			29-56	26			+	1-28			29-56	20	
		Low	Nor.	Kigh P	P val Low		Nor.	Kigh	P val	val Low	Nor.	High	P val	val Low	Nor.	High	P val
SCOT	гон		-								61				-		
	NORMAL		99	4			56	ю			5.1	7			48	63	
	нтсн		9	٦	0.497		5	-	0.727		r)	87	0.311		e	23	0.549
SGPT	LOW										N				-		
	NORMAL	-	\$5	m		٢	47	7		-	48	9			40	4	
	HIGH		7	N	0.273		2	77	0.319		m	61	0.513		æ	67	0.565
GAMKA GT	LOK																
	NORMAL		ş	-			46	-			57				45	61	
	нісн		12	1	0.003		13	9	0.002		ı,	^	0.063		S	9	0.453
LDH	LOW	-					-				5			-	ĸ		
	NORMAL	٦	62	4		ю	55	N		60	64	N			43	æ	
	HICH		3	٢	0.565		2	-	0.607		8	-	0.779		7	-	1 0.074
ALK.	гон	3				N				m	4			2	4		
	NORMAL	-	99	1		2	54				64	-		_	40	4	
	HIGH		2		4 0.513		-	4	4 0.223		m	4	4 0.082		4	64	2 0.407

P val : probability from Maxwell's test

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 68

LABORATORY TEST: HAEHATOLOGY AND BLOOD CHEMISTRY - SHIFT TABLE
NUMBER OF PATIENTS HITH VALUES BELOM, HITHIN OR ABOVE THE NORHAL RANGE ACCORDING TO TIME INTERVAL AS COMPARED TO PRE-TREATMENT, BY ASSIGNED TREATMENT

Laboratory test	test							Assi	Assigned treatment	reatm	ent						
					Fluoxetine	stine						_	Reboxetine	tine			
				Day	Days of treatment	treat	ent					Day	Days of treatment	reatm	ent		
			<u>-</u>	1-28			29-56	98			+	1-28			29-56	8	
		Low	Nor.		High P val Low	Low	Nor.	High	High P val Low		Nor.	High	Nor. High P val Low		Nor. High P val	High	P val
GLOBULINS	LOW		-				-										
	NORMAL		949	٦			42	-			39				36	-	
	HIGH		-		0.607			-	1 0.368		2	~	0.500		1	٢	1 1.000
GLOBULINS	LOH		۲			1				-	٦	-		٢	-		
4 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	NORMAL		04	4			39	77			35	63		-	31	-	
	HIGH		61	72	0.435		N	-	1.000		63	61	0.607		4		0.407
GLOBULINS	101										-				-		
4	NORMAL	•	\$	-			41				37	10		-	34		
	HIGH		-	N	2 0.607		N	22	0.500		24	-	0.607		22	-	1 0.368
GLOBULINS	LOW	4				æ				4				n			
	NORKAI.	•	30	23		٦	52	т			22	9			22	m	
	нісн		5		7 0.319		ĸ	æ	8 0.472		ю	60	8 0.508		-	10	10 0.625

al : probability from Maxwell's test

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 68

Laboratory test	test							Assi	Assigned treatment	reatu	ent						
					Fluoxetine	etine							Reboxetine	tine			
				Day	s of	Days of treatment	ent					ğ	Days of treatment	treatm	ent		
			+	1-28			29-56	56			+	1-28			29-56	26	
		Low	Nor.	High	High P val Low	Low	Nor.	High	High P val Low	LOW	Nor.	Righ	Righ P val Low	Low	Nor.	High	High P val
TOT.	LOK	77				-					-			-			
- receipt	NORMAL		36	9			æ	60		-	40	9		۳	33	e	
	HIGH		12		17 0.238		3	18	18 0.581	-	7	9	10 0.765		9	12	12 0.368
TRICLYCERI- LOW	1107	82	2				N			E)	6			-	m		
9	NORMAL	-	54	4		1	50	e			64	r,			43	4	
	HIGH		7	2	2 0.562		9	60	3 0.513	ı	60	23	2 0.598		1	w	3 0.091
GLUCOSE	LOW	٢	8			22	٦			1	7				27	-	
	NORMAL	4	58	60		3	54	~		60	\$5	21		2	44	*	
	нэгн		8	2	2 0.717		-	-	1 0.513		_	-	1 0.766		-	-	1 0.261

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 68

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

Laboratory test	test							Assi	Assigned treatment	reatm	ent						
					Fluoxetine	tine							Reboxetine	tine			
				Day	Days of treatment	reat	ent					Day	Days of treatment	reatm	ent		
			<del>-</del>	1-28			29-56	56			+	1-28			29-56	26	
		Low	Nor.	High	P val	Ę	Nor.	High P	val	Low	Nor.	High P	val	LOH	Nor. High	High	P val
NA+	LOW		r,			۳	4				62				61		
	NORMAL	5	65			ιŋ	54	8		ю	63	-			杏	71	
	HIGH		1		0.607				0.348		-		0.905		-		0.311
-To	LOW	2	23			-	-				e				m		
	NORMAL	-	54	4		4	41	ĸ			48			-	40	-	
	HIGH		m	-	0.788		7		0.214		7	7	0.007		9	71	0,102
X+	LOM		*				2				-				-		
	NORMAL	-	65	8			57	m			6	60		٦	55	-	
	HIGH		-		0.247		-		0.223	-			0.565		1		1.000
Ca++	KOT	3	4			6	4			-	-				2		
	NORMAL	4	55	8		e	45	4		4	51	2		2	94	-	
	нтен		4	e	0.931		۳	9	0.379		4	62	0.291		m	m	0.607
P04	жот																
	NORMAL		28	4		2	51	4		-	54	23		3	Sħ	1	
	HICH		8		1.000		61	3	3 0.264		67		0.607		3	-	1 0.135

P val : probability from Maxwell's test

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 69

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

aboratory test / Assigned treatment	gned treatment				Days of treatment	reatment		
		•	Screen	uo.	1-28	8	29-56	Se
			No	ж	ê	и	No.	×
£	Fluoxetine	Eval.	181	100.0	78	100.0	19	100.0
		имор	٦	1.2	1	1.3		
	Reboxetine	Eval.	70	100.0	68	100.0	57	100.0
		имор	-	1.4				
RBC	Reboxetine	Eval.	70	100.0	68	100.0	57	100.0
		фонп			-	1.5		
PLATELETS	Fluoxetine	Eval.	81	100,0	77	100.0	63	100.0
		доки			-	1.3		
		ďn	1	1.2	٢	1.3	1	1.5
	Reboxetine	Eval.	70	100.0	89	100.0	57	100.0
		инор	1	1.4				
		ďn			1	1.5	1	1.8
RBC	Fluoxetine	Eval.	8.1	100.0	78	100.0	19	100.0
		dn	,	1.2				
	Reboxetine	Eval.	70	100.0	68	100.0	57	160.0
		dn	2	2.9				
MBC: N	Reboxetine	Eval.	69	100.0	6.5	100.0	56	100.0
		пчор			~	1.5		
NBC: E	Fluoxetine	Eval.	16	100.0	73	100.0	62	100.0
		dn	3	3.9	-	1.4	•	1.6
	Reboxetine	Eval.	99	100.0	62	100.0	53	100.0
		dn	4	6.1	4	6.5		
HBC: B	Fluoxetine	Eval.	76	100.0	73	100.0	62	0.001

VATTANCE

PEARHACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 69 LABORATORY TEST: NUMBER AND PERCENTAGE OF PATIENTS HITH LABORATORY ABNORNALITIES OF CLINICAL RELEYANCE

HBC: B Reboxetine Reboxetine REC: L Fluoxetine REC: M Fluoxetine URIC ACID Fluoxetine SGOT Reboxetine SGPT Fluoxetine Reboxetine			,					
ACID			Norteen Norteen	ue	1-28	80	29-56	56
H ACID			S.	×	£	×	Š	ж
ACI D		đn					•	1.6
ACTD		Eval.	99	100.0	62	100.0	SS	100.0
ACID		dn			23	3.2		
ACID		Eval.	18	100.0	78	100.0	99	100.0
ACID		фонп	-	1.2	2	2.6		
ACID D	5	Eval.	70	100.0	99	100.0	57	100.0
ACID		дони	-	1.4	2	3.0	1	1.8
ACID		dn	-	1.4	2	3.0	٢	1.8
ACED	· o	Eval,	77	100.0	74	100.0	79	100.0
ACID		dn					-	1.6
		Eval.	78	100.0	74	100.0	49	100.0
		dn	-	1.3				
	0	Eval.	69	100.0	49	100.0	56	100.0
		dn	-	1.4	1	1.5	. 63	3.6
Reboxetin	Ð	Eval.	7.1	100.0	67	100.0	57	100.0
Reboxetin		đn	22	2.8				
		Eval.	63	100.0	62	100.0	50	100.0
		đn	٦	1.6	1	1.6	2	4.0
GAMMA GT Fluoxetime		Eval.	82	100.0	78	100.0	99	100.0
		ďn	4	4.9	-	1.3	1	1.5
Reboxetine	ø	Eval.	71	100.0	69	100.0	58	100.0
		ďn			1	1.4	4	6.9
LDH Fluoxetine	ф	Eval.	78	100.0	72	100.0	99	160.0

( name to the contract of the

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 69

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

Laboratory test / Assigned treatment	igned treatment				Days of treatment	reatment		
			Screen	200	1-28	9	29-56	56
			No	×	S.	и	Š	н
ron.	Fluoxetine	ďn			٢	1.4		
ALK. PHOSPH.	Fluoxetine	Eval.	80	100.0	76	100.0	63	100.0
		ďn	1	1.2	1	1.3	-	1.6
GLOBULINS ALPHA 1	Fluoxetine	Eval.	99	100.0	49	100.0	45	100.0
		down	1	1.8				
		ăn					-	2.2
	Reboxetine	Eval.	44	100.0	£ <del>,</del>	100.0	39	100.0
		đn	1	2.3			1	2.6
GLOBULINS ALPHA 2	Reboxetine	Eval.	\$45	100.0	43	100.0	39	100.0
		ф	1	2.3				
GLOBULINS GANMA	Fluoxetine	Eval.	99	100.0	67	100.0	45	100.0
		имор	3	5.4	2	4.1	2	4.4
	Reboxetine	Eval.	\$	100.0	643	100.0	39	100.0
		down	1	2.3	1	2.3		
		dn			1	2.3		
TOT. CHOLEST.	Fluoxetine	Eval.	77	100.0	73	100.0	99	100.0
		đn	m	3.9	2	2.7	3	9.4
	Reboxetine	Eval.	89	100.0	99	100.0	56	100.0
		đn	r.	7.4	2	3.0	S	8.9
TRIGLYCERIDES	Fluoxetine	Eval.	76	100.0	72	100.0	65	100.0
		dn	ıc.	9.9	٦	1.4	в	4.6
	Reboxetine	Eval.	89	100.0	99	100.0	5.5	100.D
		ďn	3	4.4	ĸ	4.5	-	1.8

( CELLINIER)

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 69

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

Laboratory test / Assigned treatment	gned treatment				Days of treatment	reatment		
			Screen	en	1-28	89	29-56	95
		,	S.	×	No.	×	o <sub>N</sub>	ĸ
GLUCOSE	Fluoxetine	Eval.	78	100.0	£	100.0	49	100.0
		имор					-	1.6
		ĝ.			1	1.4		
	Reboxetine	Eval.	29	100.0	79	100.0	55	100.0
		ďn	-	1.5	٦	1.6	1	1.8
NA+	Fluoxetine	Eval.	8	100.0	76	100.0	99	100.0
		фонт			٢	1.3		
X+	Fluoxetine	Eval.	7.2	100.0	74	100.0	63	100.0
		dn			٢	1.4	•	1.6
	Reboxetine	Eval.	70	100.0	99	100.0	59	100.0
		амор						1.7
Ca++	Fluoxetine	Eval.	80	100.0	9/	100.0	99	100.0
		down			-	1.3		
P04	Fluoxetine	Eval.	72	100.0	67	100.0	29	100.0
		down					-	1.6
		dn	-	1.4	2	3.0	-	1.6
	Reboxetine	Eval.	63	100.0	59	100.0	53	100.0
		ďn			-	1.7		

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

REBOXETINE - PROTOCOL 20124/016 TABLE No.: 70 PHARMACIA CNS R&D

Vital signs						LYTNG								ū	CTANDING				
1														1	autonu.				
					time	time interval	al							time	time interval	먑			
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56	рау о	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49 Day	lay 56
S.B.P.	Evaluated	7.7	77	75	73	77	37	99	33	57	77	76	75	73	7.1	37	99	31	57
	Kean	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
3 8	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
} <i>l</i> s	Kin	80.0	70.0	0.08	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	22	7.1	37	99	33	57	77	76	75	73	71	37	99	31	57
	Kean	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	8.64
	STD	13.2	14.0	11.7	11.6	12.4	13.8	10.9	6.6	11.4	12.4	12.6	12.0	11.1	11.9	12.7	12.2	11.9	12.3
	Nedian	80.0	80.0	0.08	80.0	80.0	80.0	80.0	80.0	86.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0
	Nin	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
	Нах	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	2	70	37	65	31	95	73	72	7	89	69	36	49	31	54
	Hean	77.0	78.9	78.9	79.3	79.0	80.2	79.8	81.5	79.9	83.8	7.48	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	4.8	7.8	9.6	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	0.09	0.09	62.0	65.0	0.09	62.0	68.0	63.0	63.0	65.0	65.0	64.0	65.0	62.0	0.99	71.0	65.0
	Маж	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

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PHARMACIA CNS R&D

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

Fluoxeti	
treatment:	
Assigned	

Vital signs						LYING								S	STANDING				
					time	time interval	'a1							time	time interval	al			
		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	98	98	82	080	77	643	63	36	89	86	98	82	81	78	\$	89	37	69
	Kean	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
3	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
8	Kin	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
ś	Kax	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	98	86	82	80	22	43	29	36	89	98	98	82	18	78	545	89	37	69
	Kean	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	9.8	9.2	8.9	12.5	10.8	11.5	8.5	4.6	10.5	9.6	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	0.09	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
	Мах	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	984	77	77	9,6	40	62	33	29	48	82	76	77	75	0,	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	90.08	81.7	78.9	77.8	77.7
	STO	9.5	9,0	4.6	8.3	9.0	8.0	8.5	6.3	8.8	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	6.09	0.09	56.0	52.0	59.0	60.0	56.0	63.0	52.0	0.99	60.09	0.09	56.0	63.0	64.0	0.09	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

OD PRESSURE AND HEART RATE; SUMMARY STATISTICS ON CHANGES FROM BASELINE OBSERVED DURING TREATME ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Vit	Vital signs					LYING	, AG							STANDING	ING			
						Time interval	terval							Time interval	terval			
	ı		Day 7	Day	14 Day 21	Day 28	Day 35	Day 42	Day 49 Day	8	Day 7	Bay	14 Day 21	Day	28 Day 35	35 Day 42	Day 49	Day 56
S.B.P.	نِه	Evaluated	77	75	73	7.1	37	99	3,	57	76	75	73	71	37	99	3	. 53
		Kean	0.1	9.0-	1.9	1.6	-4.1	0.7	-1.5	-0.7	-3.6	-4.3	0.0	-1.7	-2.5	4.1-	-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		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
		Hin	-25.0	-30.0	0.04-	-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
86		Мах	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.	<u>ب</u>	Evaluated	77	7.5	73	77	37	99	31	57	76	7.5	73	71	37	99	31	57
		Kean	9.0	8.0	1.9	2.5	4.0	2.2	1.3	1.7	P.	-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	6.6	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
Hea	Heart Rate	Evaluated	74	73	22	7.0	37	65	31	26	72	7.1	89	69	36	159	31	25
		Mean	2.1	1.9	4.2	1.7	2.2	2.4	2.7	2.8	1.0	4.4	0.1	1.9	2.3	4.1	2.6	2.4
		STO	9.5	8.3	6.8	8.8	10.7	9.6	10.6	10.7	11.3	8.3	2.2	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
		Kin	-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
		Kax	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	% 0.4%	28.0	44.0

-40.0

-50.0

12.4

30.0

22.0

68

1.3 8.0 0.0

## 9550083

-20.0

-30.0

0.0

25.0

20.0

62

14.0 -36.0

20.0 -31.0

20.0

10.4

PHARMACIA CNS R&D

BLOOD PRESSURE AND BEART RATE: SUMMARY STATISTICS ON CHANGES FROM BASELINE OBSERVED DURING TREATMENT ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Day 28 Day 35 Day 42 Day 49 Day 56 -14.0 -30.0 -35.0 25.0 25.0 -28.0 44.0 44 10.2 12.1 -3.0 13.3 Time interval -30.0 -30.0 30.0 -36.0 16.0 0.1 8.3 8.7 0.0 11.6 12.0 -50.0 Day 21 30.0 -20.0 0.0 -0.1 8.5 0.0 30.0 1. -40.0 50.0 -30.0 -40.0 36.0 Day 7 Day 14 13.2 -0.5 8.3 0.0 25.0 10.3 -2.0 82 25.0 7.9 0.0 18.0 -20.0 -20.0 9.1 0.0 9.4 0.0 25.0 82 16.0 -44.0 -45.0 25.0 -20.0 30.0 11.5 0.0 8.4 0.0 10.4 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 -45.0 25.0 -20.0 -28.0 16.1 -2.5 -2.5 20.0 9.4 9.3 12.0 -20.0 -45.0 50.0 -0.3 0.0 8.0 -33.0 14.0 0.0 63 -36.0 18.0 -40.0 32.0 -40.0 20.0 10.4 0.0 0.0 10.7 Time interval -40.0 30.0 -25.0 -36.0 12.5 -0.5 20.0 8.8 0.0 8.0 0.0 28.0 -25.0 10.1 -2.0 -36.0 20.0 30.0 -40.0 0.3 8 0.0 9.7 -3.7 40.0 -25.0 -40.0 -2.0 .. 0.0 -50.0 82 8.3 30.0 11.0 -2.0 0.0 86 Assigned treatment: Fluoxetine Evaluated Evaluated Median Median Median Kean STD E STD Nin Max Vital signs Heart Rate

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PHARMACIA CNS R&D

BLOOD PRESBURE AND HEART RATE: NUMBER AND PERCENTAGE OF PATIENTS MITH DECREASE OR INCREASE VS BASELINE OF CLINICAL RELEVANCE ACCORDING TO THE INTERVAL BY ASSIGNED TREATMENT

Vital signs						LYING	ÄĞ							STANDING	ING			
					25	time intervals	ervals						+	time intervals	ervals			
•			Day 7	7 Day 14	Day 21 Day	Day 28 Day	35	Day 42	Day 49	Day 56 1	Day 7	Day 14	Day 21 Day		28 Day 35	Day 42	42 Day 49	Day 56
S.B.P.	Evaluated	No	77	7.5	73	7.7	37	99	31	57	9,6	75	73	77	37	99	31	57
	Decrease (1)	No	62	-	64	8	m	-	-	-	-	m	64	4	4	2	-	
		×	2.6	1.3	2.7	2.8	1.8	1.5	3.2	8.	1.3	4.0	2.7	5.6	10.8	3.0	3.2	
	Increase (2)	No		2	22	-	-	-	<b>†</b>	-	٦		60	-	-	2	٢	8
		×		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	2	77	7.5	73	7.1	37	99	93	57	76	75	73	7.7	37	99	31	57
	Decrease (1)	P.										71			-	-		
38		×										2.7			2.7	1.5		
<b>3</b> 8	Increase (2)	(2) No	2	69	ď	9	-	4	-	c)	62	r.	4	7	m	5	3	8
		×	2.6	4.0	8.8	8.5	2.7	6.1	3.2	8.8	2.6	6.7	9.6	9.6	2.0	7.6	9.7	5.3
Both	Evaluated	No	77	75	73	77	37	99		57	76	75	73	71	37	99	31	57
	Decrease (1)	(1) No									er)	-		-		2	7	
		×									3.9	1.3		1.4		3.0	3.2	
	Increase (2)	No	22	2	63	-	-	77	-	-	-		64	-	-	64		-
		×	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	07	20	37	65	31	99	72	71	89	69	36	2	31	54
	Decrease (1)	No.		2		-			-		m	-	-	e	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.	9	9	r)	6	7	r)	4	7	ю	6	e	7	4	4	S)	9
		7	8.1	8.2	7 1	7	40 0		400	2					,	-	,	,

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PHARMACIA CNS R&D

PERCENTAGE OF PATIENTS WITH DECREASE OR INCREASE VS BASELINE OF CLINICAL RELEVANCE CORDING TO THE INTERVAL BY ASSIGNED TREATHENT

Fluoxetine	
treatment:	
Assigned	

/ital signs						LYING	NG							STANDING	DING			
					+	time intervals	ervals						-	ine in	time intervals			i i
			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 S6
.B.P.	Evaluated	No	86	82	80	77	43	67	36	89	86	82	81	78	44	68	37	69
	Decrease (1)	) No		63	-	4	6	e	æ	2		4	60		2	-	2	
		н		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	٢	63	-	7	-	2	-	-	-	-	6	*	٦	9		
		и	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	98	83	88	77	43	29	36	89	98	82	2	78	44	89	37	69
	Decrease (1)	) No	٢	77	m	22	4	63			2	CN	-	-	2		Ľ	-
3		м	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
<b>8</b> 9	Increase (2)	) No	4		4	S	æ	N	2	10)	6		-	2		١	-	_
		×	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	98	82	88	77	43	29	36	99	86	82	81	78	\$	99	37	69
	Decrease (1)	) No		-	-				1				-				<u> </u>	
		×		1.2	1.2				2.8				1.2				2.7	1.4
	Increase (2)	No.		m	-	-						-	-	-				
		×		3.7	1.2	1.3						1.2	1.2	1.3	2.3			1.4
Heart rate	Evaluated	S.	84	77	77	76	640	62	33	19	82	9/	7.7	75	64	62	35	29 67
	Decrease (1)	) No	S.	4	7	. 7	8	61	4	7	S	4	N.	E	m	22		цŋ
		ж	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	3 7.5
	Increase (2) No	) No	2	4	-		2	-		61	٢	N.		-	61			-
		×	2.4	5.2	1.3		5.0	1.6		3.0	1.2	2.6		1.3	5.0	1.6	2.9	

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

### PHARMACIA CN95780083

### REBOXETINE - PROTOCOL 20124/016 TABLE No.: 73

BLOOD PRESSURE AND HEART RATE: ABSOLUTE NUMBER OF PATIENTS SHOWING CLINICALLY RELEVANT CHANGES, COMPARED TO BASELINE, ONCE, THICE OR HORE TIMES DURING THE THERAPY

Assigned tres	tment / Vital sign	15		LYING			STANDING	
			1 time	2 times	3 times or more	1 time	2 times	3 times
Fluoxetine	S.B.P. (1)	Decrease	4			5		
		Increase	1			2		
	D.B.P. (2)	Decrease	6	1	1	2	2	
		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	
		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	

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<sup>(1)</sup> 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 diastolic value <= 50 boats/min
increase => 20 % vs baseline value and heart rate value <= 50 boats/min

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 74

E STUDY	
2	
DURING	
8	
BEFORE AND DURING	
£	L
NUMBER AND PERCENTAGE OF PATIENTS WITH ORTHOSTATIC HYPOTENSION (*) BEFORE AND DURING THE STUDY	ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT
E	SSI
DSI.	BY.
E T	Ä
WITH 0	INTER
STA	IKE
YTIE	2
<u>ت</u>	DING TO TIME I
띥	ACCORDING
PERCENTA	ACC
AMO	
NUMBER	
BLOOD PRESSURE: N	
BLOOD	

Assigned treatment / Vital signs	/ Vital signs				Accordi	According to time interval	ine in	terval				Γ
		Screen	Day	0 Day 7	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56	Day 21	Day 28	Day 35	Day 42	Day 49	Day 5	9
Fluoxetine	Eval.	88	98	86	82	80	77	42	69	36		89
	No.	-	1				-	-				Γ
	×	1.2	1.2				1.3	2.4				Γ
	Kean	30.0	30.0				40.0	30.0				т—
	Max.	30.0	30.0				40.0	30.0				
Reboxetine	Eval.	7.5	77	76	75	73	71	37	99	31		23
	No.	-	23	φ.	4	-	5		8	-		Π-
	×	1.3	2.6	7.9	5.3	1.4	7.0		4.5	3.2		Т
	Nean	30.0	30.0	34.2	33.8	30.0	38.0		30.0	30.0		
	Nax.	30.0	30.0	40.0	45.0	30.0	0.09		30.0	30.0		T -

(\*) orthostatic hypotension = decrease of systolic blood pressure in standing position => 30 mm hg as compared to lying position  $\,$ 

PHARMACIA CNS RÆD

REBONETINE - PROTOCOL 20124/016

TABLE No.: 75

BODY WEIGHT: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED IREATHENT AND SEX

Sex					Tim	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	45
	Hean	4.79	6.99	67.1	67.3	67.5	66.3	67.7	2.99	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	4.49	64.3	64.8	63.6	65.0
	Kin	41.0	41.1	41.5	42.8	42.9	43.7	43.8	0.44.0	44.0
	Мах	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	4	15
	Nean	76.9	76.8	7.97	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	74.8	73.5	72.5	75.0	74.5	78.5	74.5	78.3	74.5
	Kin	61.0	61.0	0.09	61.0	61.0	66.5	62.0	66.0	62.0
	Kax	113.0	113.0	113.0	113.0	112.0	113.0	113.0	113.0	115.0
Total	Evaluated	76	76	73	73	7.1	37	65	31	25
	Mean	6.69	69.5	8.69	6.69	6.69	68.9	70.3	4.69	6.07
	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	4.79	66.1	69.0
	Min	41.0	41.1	41.5	42.8	42.9	43.7	43.8	44.0	44.0
	Мах	140.0	140.0	140.0	140.0	140.0	140.0	140.0	140.0	146.0

PHARMACIA CNS R&D

BODY HEIGHT: SUMMARY STATISTICS ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT AND SEX

Sex					Tin	Time interval	1			
		Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
Fenale	Evaluated	99	75	09	09	57	36	49	30	51
	Kean	65.7	65.7	65.6	66.4	9.99	67.4	1.99	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	9.49	62.5
	Min	43.0	42.0	42.0	41.5	41.0	43.2	42.0	42.6	41.8
	Мах	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	6	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	60.09	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	98	98	82	18	77	45	67	37	69
	Hean	6.89	68.7	68.7	69.1	0.69	6.69	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	64.49	64.5	65.2	65.2	67.1	67.0	68.0	67.3
ŀ	Min	43.0	42.0	42.0	41.5	41.0	43.2	42.0	42.6	41.8
	Мах	120.0	118.0	117.0	118.0	119.0	119.0	119.0	120.0	119.0

PHARMACIA CMS R&D
REBOXETINE - PROTOCOL 20124/016
TABLE No.: 76

IGST: NUMBER AND PERCENTAGE OF PATIENTS WITH VALUES LONER OR HIGHER (\*) THAN PRE-TREATHENT AT EATH CULTUATION TIME BY ASSETTION POSESPHENT AND SEY

signed treatment: Reboxetine

Sex									Time interval	terval							
		Дау	7	Day 14	72	Day 21	21	Day	28	Day 3	35	Day	42	Day 49	49	Day	56
		Š	×	S.	×	ę.	×	S.	*	2	N	2	м	2	×	ž	м
Fenale	Lower					٣	1.9	-	1.9	-	3.3	N	4.3	m	12.5	4	9.5
	Same	\$5	4.96	5.	96.2	52	96.3	64	92.5	27	90.0	41	87.2	16	66.7	34	81.0
	Higher	63	3.6	8	89.	-	1.9	m	5.7	7	6.7	4	8.5	ιŋ	20.8	4	9.5
-	Total	26	100.0	53	100.0	\$5	100.0	S.	100.0	30	100.0	47	100.0	24	100.0	45	100.0
Male	Lower	1	5.0	-	5.0	2	10.5	2	11.1	-	14.3	2	11.1	۳	14.3	77	13.3
	Same	18	90.0	12	85.0	4	73.7	13	72.2	r)	71.4	13	72.2		71.4	12	80.0
	Higher	-	5.0	N	10.0	en	15.8	60	16.7	-	14.3	m	16.7	-	14.3	-	6.7
	Total	20	100.0	20	100.0	19	100.0	22	100.0	7	100.0	81	100.0	7	100.0	15	100.0
Total	Lower	-	1.3	-	4.4	m	4.1	E)	4.2	82	5.4	4	6.2	4	12.9	•	10.5
	Same	72	94.7	89	93.2	99	\$.06	62	87.3	32	86.5	55	83.1	21	67.7	94	80.7
	Righer	3	3.9	4	5.5	4	5.5	9	<b>80</b>	m	6.1	7	10.8	9	19.4	ıń	8.8
	Total	9/	100.0	73	100.0	73	100.0	7.1	100.0	37	100.0	65	100.0	31	100.0	57	100.0

(\*) LOMER: decrease > 2.5 Kg

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016

: NUMBER AND PERCENTAGE OF PATIENTS WITH VALUES LOWER OR BIGHER (\*) THAN PRE-TREATHENT AT EACH EVALUATION TIME, BY ASSIGNED TREATHENT AND SEX

ssigned treatment: Fluoxetine

Sex									Time interval	terval							
		Day	7	Day	14	Day	2.1	Day	28	Day 3	35	Day /	42	Day 4	67	Day	56
		£	ж	N <sub>o</sub>	м	Š	м	٤	м	£	×	ę.	×	£	×	£	*
Female	Lower	-	1.6	e)	5.0	2	3.3	6/3	3.5	-	2.8	ю	6.1	-	3.3	ro	9.8
	Ѕаше	62	6.96	99	93.3	55	91.7	48	84.2	8	83.3	9	81.6	2¢	9.08	39	76.5
	Righer	-	1.6	-	1.7	m	5.0	7	12.3	ιŋ	13.9	9	12.2	c)	16.7	-	13.7
	Total	79	100.0	09	100.0	09	100.0	57	100.0	36	100.0	649	100.0	30	100.0	5	106.0
Male	Same	21	95.5	19	86.4	20	95.2	17	85.0	9	66.7	16	88.9	S	71.4	16	88.9
	Higher	-	4.5	60	13.6	-	4.8	m	15.0	m	33.3	Ø	11.1	63	28.6	62	11.1
	Total	22	100.0	23	100.0	21	100.0	20	100.0	6	100.0	18	100.0	7	100.0	85	100.0
Tota1	Lower	-	1.2	en	3.7	2	2.5	71	2.6	-	2.2	6	4.5	-	2.7	υ	7.2
	Same	83	96.5	75	91.5	75	92.6	65	84.4	36	0.08	35	83.6	29	78.4	55	79.7
	Higher	22	2.3	4	6.4	4	4.9	2	13.0	60	17.8	80	11.9	7	18.9	0,	13.0
	Total	8	100.0	82	100.0	81	100.0	77	100.0	45	100.0	62	100.0	37	100.0	69	100.0

(\*) LOWER: decrease > 2.5 kg. HIGHER: increase > 2.5 kg.

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REBOXETINE - PROTOCOL 20124/016 TABLE No.: 77 PHARMACIA CNS R&D

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	eatment/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.	85	51	84	20	20	16	78	7.1	49
	Normal	No.	52	45	4.5	16	19	14	68	49	59
		м	99.68	88.24	93.75	80.00	95.00	87.50	87.18	90.14	92.19
	Abnornal	No.	9	9	8	4	-	2	10	4	ιŋ
		×	10.34	11.76	6.25	20.00	5.00	12.50	12.82	9.86	7.81
Reboxetine	Eval.	No.	51	47	14	17	14	15	89	19	56
	Normal	No.	42	04	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.	6	7	7	2	8	2	11	10	6
		×	17.65	14.89	17.07	11.76	21.43	13.33	16.18	16.39	16.07

PHARMACIA CNS R&D

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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 tre	issigned treatment/E.C.G. at	3. at		Time interval	terval	
01110000		1	1-28 days	days	29-56 days	days
			Abnormal	Normal	Abnormal	Normal
Pluoxetine	Abnormal	No.	3	9	2	9
		×	33.3	66.7	25.0	75.0
	Normal	No.	7	58	3	53
		×	6.5	93.5	5.4	94.6
	Tota1	No.	7	49	5	59
		×	6.6	90.1	7.8	92.2
Reboxetine	Abnorma1	No.	4	9	5	4
		×	49.0	0.09	55.6	4.44
	Normal	No.	9	45	4	843
		×	11.8	88.2	8.5	91.5
	Total	No.	10	51	6	47
			16.4	83.6	16.1	83.9

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TABLE No.: 79

	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	ſ
	LAST	
	E	1
	LE - NUMBER OF PATIENTS MITH NORMAL OR ABNORMAL E.C.G. VALUE AT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT	
	3.5	I
	5. K	١
	SSIG	
	A A	
	Na Sa	
:	OR A	
	ORMAL EVALU	
9	E E	1
i		1
	TS REA	1
	E T	ŀ
	PAT PR	1
	70 T0	1
	8 8	1
	E E	1
	78	1
	SLE AS	
	TA	
	SHIFT	

Assigned tre	Assigned treatment/E.C.G. at		Last assessment	essment			
0		Abnormal	mal	Normal	al	Total	11
		No.	×	No.	х	No.	×
Fluoxetine	Abnormal	63	20.0	80	80.0	10	100.0
	Normal	4	5.9	49	94.1	89	100.0
	Total	9	7.7	72	92.3	78	100.0
Reboxetine	Abnormal	S	45.5	v	54.5	11	100.0
	Normal	9	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 TREATHENT

E.C.G. abnormality type			Fluoxetine	tine					Reboxetine	stine		
	Screening	ning	1-28	days	1-28 days 29-56 days	days	Screening	ning	1-28	1-28 days	29-56 days	days
	Š	×	ê	×	No	×	S.	к	o <sub>N</sub>	×	Š	м
Evaluated Pt	78	78 100.0	7.1	71 100.0	499	64 100.0	68	68 100.0	61	61 100.0	56	100.0
ATRIAL ECTOPIC BEATS - OCCASIONAL									-	1.6		
CONDUCTION DISORDER							2	2.9	۳	1.6	-	6.
LEFT ANTERIOR HEMIBLOCK			٦	1.4	1	1.6						
LEFT VENTRICULAR HYPERTROPHY	٦	1.3										
MYOCARDIAL ISCHENIA	-	1.3					-	1.5				
NON SPECIFIC ST-T WAVE CHANGES	-	1.3					-	1.5				
PREVIOUS MYOCARDIAL INFARCTION	-	1.3	-	1.4	1	1.6	-	1.5	-	1.6	-	1.8
RIGHT BUNDLE BRANCH BLOCK	-	1.3					-	1,5	-	1.6	-	1.8
RIGHT INCOMPLETE BUNDLE BRANCH BLOCK	-	1.3	23	2.8	-	1.6	-	1.5				
RIPOLARIZATION DISTURBANCES									-	1.6		
SINUS BRADYCARDIA ( < 60)	4	5.1	8	4.2	8	3.1	2	2.9				
SINUS TACHYCARDIA ( > 100)	-	1.3					1	1.5	9	9.6	9	10.7
VENTRICULAR ECTOPIC BEATS - OCCASIONAL	-	1.3					1	1.5				

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 TARIE Mo.: 81 E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS WITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSHENT AS COMPARED TO PRE-TREATMENT EVALUATION, BY ASSIGNED TREATMENT

			and tou	Sections of the sections			
		Absent	甘	Present	ent	Total	al
	<b>J</b>	£	Ŕ	£	×	No	z
E.C.G. Abnormality	Baseline						
ATRIAL ECTOPIC BEATS -	Absent	29	98.5	-	1,5	89	100.0
מרכעפרמושה	Present						
	Total	69	98.5	1	1.5	89	100.0
CONDUCTION DISORDER	Baseline						
	Absent	99	100.0			99	100.0
	Present		50.0	-	50.0	23	100.0
	Total	67	98.5	-	1.5	68	100.0
LEFT ANTERIOR HEMIBLOCK Baseline	Baseline						
	Absent	89	100.0			68	100.0
	Total	89	100.0			99	100.0
LEFT VENTRICULAR	Baseline						
	Absent	88	100.0			63	100.0
	Total	89	100.0			68	100.0
NYOCARDIAL ISCHEMIA	Baseline						
	Absent	67	100.0			67	100.0
	Present	-	100.0			-	100.0
	Total	89	100.0			89	100.0
NON SPECIFIC ST-T MAVE	Baseline						
	Absent	69	100.0			69	100.0
	Present	٦	180.0			-	100.0
	Total	89	100.0			99	100.0

NTTNIED

PHARMACIA CNS RRD
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 ass	assessment			
	<del>1</del>	Absent	nt	Present	ent	Total	al
		2	×	S.	×	N <sub>o</sub>	×
E.C.G. Abnormality	Baseline						
PREVIOUS MYOCARDIAL	Absent	19	100.0			67	100.0
	Present			-	100.0	-	100.0
	Total	29	98.5	-	1.5	89	100.0
RIGHT BUNDLE BRANCH	Baseline						
	Absent	67	100.0			67	100.0
	Present			-	100.0	-	100.0
	Total	67	98.5	-	1.5	89	100.0
RIGHT INCOMPLETE BUNDLE	Baseline						
	Absent	63	100.0			29	100.0
	Present	-	100.0			-	100.0
	Total	89	100.0			89	100.0
RIPOLARIZATION DISTURBANCES	Baseline						
	Absent	67	98.5	-	1.5	89	100.0
	Present						
	Total	29	98.5	-	1.5	89	100.0
SINUS BRADYCARDIA ( <	Baseline						
	Absent	99	100.0			99	100.0
	Present	2	100.0			2	100.0
	Total	89	100.0			89	100.0
SINUS TACHYCARDIA ( >	Baseline						
	Absent	19	91.0	9	9.0	67	100.0

COSTATIVE

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-TREATHENT EVALUATION, BY ASSIGNED TREATMENT

	O Company						
			ast ass	Last assessment			
		Absent	ant	Present	ent	Total	al
		2	×	No	н	No.	*
E.C.G. Abnormality	Baseline						
SINUS TACHYCARDIA ( >	Present			-	100.0	-	100.0
	Total	61	89.7	7	10.3	68	100.0
VENTRICULAR ECTOPIC	Baseline						
מרכיים הרבים	Absent	69	100.0			69	100.0
	Present	-	100.0			-	100.0
	Total	89	100.0			89	100.0

PHARMACIA CNS RED
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

					ľ		
			Last ass	assessment			
		Absent	at	Present	ent	Total	a1
		No	н	S.	×	ě	×
.C.G. Abnormality	Baseline						
TRIAL ECTOPIC BEATS -	Absent	78	100.0			78	100.0
TOWN TOWN	Total	78	100,0			78	100.0
ONDUCTION DISORDER	Baseline						
	Absent	78	100.0			82	100.0
	Total	78	100.0			78	100.0
EFT ANTERIOR HEMIBLOCK	Baseline						
	Absent	77	98.7	-	1.3	78	100.0
	Present						
	Total	77	98.7	-	1.3	78	100.0
EFT VENTRICULAR	Baseline						
THE POWER OF THE	Absent	7.7	100.0			7.7	100.0
•	Present	٦	100.0			-	100.0
	Total	78	100.0			7.8	100.0
IYOCARDIAL ISCHEMIA	Baseline						
	Absent	7.	100.0			77	100.0
	Present	-	100.0			-	100.0
	Tota1	78	100.0			78	100.0
NON SPECIFIC ST-T MAVE	Baseline						
	Absent	77	100.0			77	100.0
	Present	-	100.0			-	100.0
	Total	78	100.0			78	100.0

(MOTANIEM)

PHARMACIA CNS RRD
REBOXETINE - PROTOCOL 20124/016
TARLE No.: 81

E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS HITH ABSENT OR PRESENT E.C.G. ABNORMALITIES AT LAST ASSESSMENT AS COMPARED TO PRE-TREATHENT EVALUATION, BY ASSIGNED TREATHENT

Assigned treatment: Fluoxetine

	_	ast ass	essment			
	Abse	ıt	Pres	ent	Tot	1
	No	×	Š	×	Š.	×
Baseline						
Absent	77	100.0	•		77	100.0
Present			٦	100.0	-	100.0
Total	77	7.86	1	1.3	78	100.0
Baseline						
Absent	77	100.0			77	100.0
Present	-	100.0			-	100.0
Total	78	100.0			78	100.0
RIGHT INCOMPLETE BUNDLE Baseline						
Absent	2,6	98.7	-	1.3	11	100.0
Present	-	100.0			¢	100.0
Total	77	98.7	1	1.3	78	100.0
Baseline						
Absent	7.8	100.8			78	100.0
Total	78	100.0			78	100.0
Baseline						
Absent	72	97.3	2	2.7	74	100.0
Present	3	75.0	1	25.0	4	100.0
Total	75	2.96	3	3.8	78	100.0
Baseline						
Absent	77	100.0			77	100.0
Present	1	100,0			1	100.0
		No   Baseline	Last   Absent   Absent	Last assess   Absent	Last assessment	Last assessment

CHAMILERY

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 TABLE No.: 81

REBOXETINE - PROTOCOL 20124/016
TABLE NO.: 581
E.C.G.: SHIFT TABLE - NUMBER OF PATIENTS HITH ABSENT OR PRESENT E.C.G. ABNORBALITIES AT LAST ASSESSMENT
AS COMPARED TO PRE-TREATHENT EXALUATION, BY ASSIGNED TREATHENT

		1	ast ass	Last assessment			
		Absent	int	Pres	Present	Total	al
		No	×	No	×	Š	×
E.C.G. Abnormality	Total						
SINUS TACHYCARDIA ( > 100)		78	78 100.0			. 78	100.0
VENTRICULAR ECTOPIC	Baseline						
100000000000000000000000000000000000000	Absent	77	77 100.6			77	100,0
	Present	١	1 100.0			-	100.0
	Total	78	100.0			87.	100.0

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PHARMACIA CNS RRD REBOXETINE - PROTOCOL 20124/016 TABLE No.: 82

DBSERVED DURING THE STUDY	
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MBER AND PERCENTAGE OF E.C.G. ABNORHALITIES, BY ARNDRALITY GROUP, O BY ASSIGNED TREATMENT	
ITY	
RMAL	
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Group of abnormalities			Fluoxetine	tine					Reboxetine	stine		
	Scree	aing	1-28	Screening 1-28 days 29-56 days	29-56	days		paine	1-28	days	Screening 1-28 days 29-56 days	days
	Š.	*	No.	*	£	×	No	м	S.	×	2	×
Evaluated Pt.	78	78 100.0	l	71 100.0		64 100.0		68 100.0		61 100.0		56 100.8
Rhythm disarders	5	6.4	60	4.2	61	3.1	ħ	5.9	7	11.5	Ì	6 10.7
Conduction disorders	2	2.6	e	4.2	61	3.1	ħ	5.9	22	3.3	2	3.6
Ischemic signs	101	2.6					2	2.9	-	1.6		
Other disorders	23	2.6	-	1.4		1 1.6		1.5	-	1.6	-	, .

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
TANIE No : 33

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 / Raseline	ormality /					Las	rt ass	Last assessment		:			
				Fluoxetine	ine					Reboxetine	tine		
		Absent	±	Present	ant	Total	-	Absent	ıţ	Present	ent	Total	7
		£	×	No	×	No	ж	N <sub>o</sub>	N	No	×	Ñ	×
Rhythm	Absent	7.1	71 97.3	2	2.7	73	100	57	1.68	7	10.9	<del>1</del> 99	100
	Present	4	80.0	-	20.0	5	100	ĸ	75.0	-	25.0	4	5
	Total	75	96.2	m	3.8	78	100	09	88.2	8	11.8	89	10
Conduction Absent	Absent	74	97.4	2	2.6	76	100	<del>1</del> 99	100			<del>1</del> 99	100
e Ton Toeth	Present	2	100			22	100	2	50.0	22	50.0	4	92
	Total	92	97.4	73	2.6	78	100	99	97.1	2	2.9	68	100
Ischemic	Absent	9/	100			2/2	100	99	98.5	1	1.5	99	100
1	Present	2	100			61	100	2	100			2	100
	Total	78	100			78	100	49	98.5	1	1.5	89	100
Other	Absent	76	100			9/	100	29	100			29	9
	Present	-	50.0	-	1 50.0	62	100			-	100	-	ē
	Total	77	77 98.7	-	1.3	78	100	63	67 98.5	1	1.5	89	100

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**FIGURES** 

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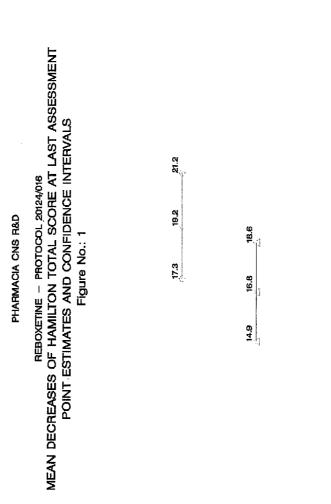
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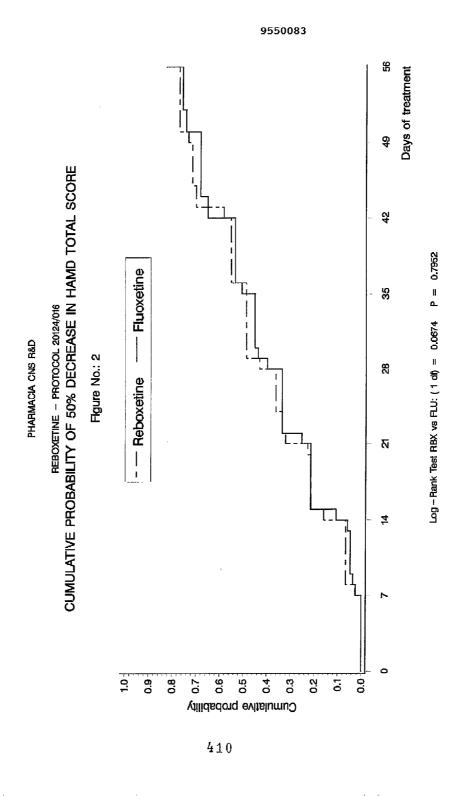
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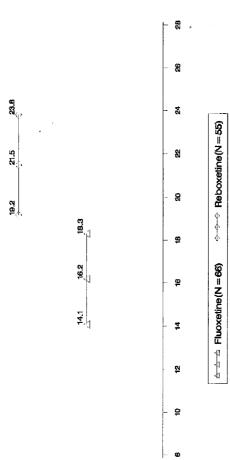
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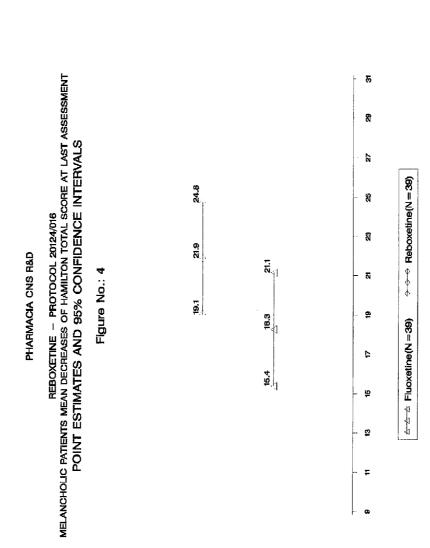


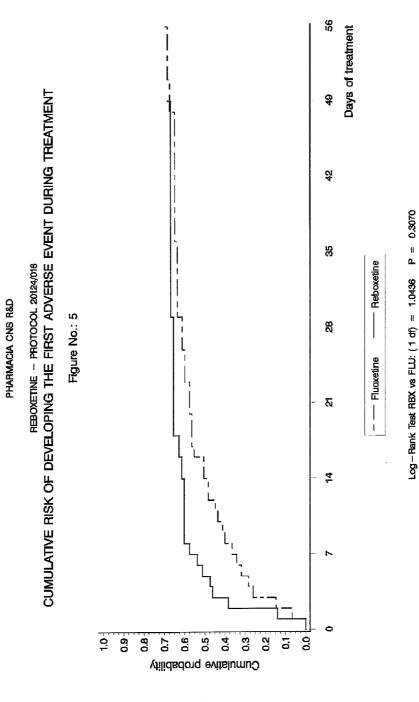




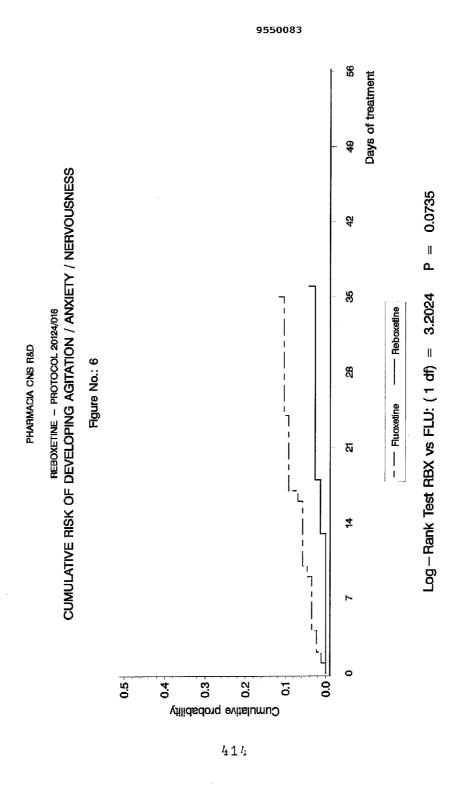
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SEVERE PATIENTS JUDGED BY CGI SEVERITY AT BASELINE
MEAN DECREASES OF HAMILTON TOTAL SCORE AT LAST ASSESSMENT
POINT ESTIMATES AND 95% CONFIDENCE INTERVALS
FIGURE NO.: 3

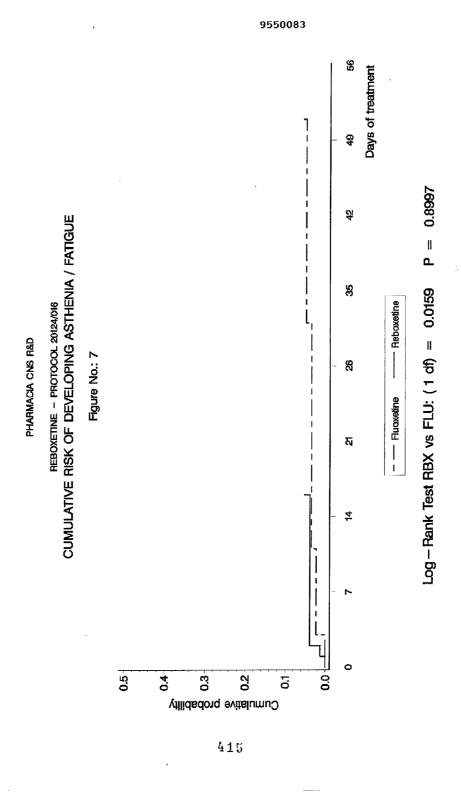


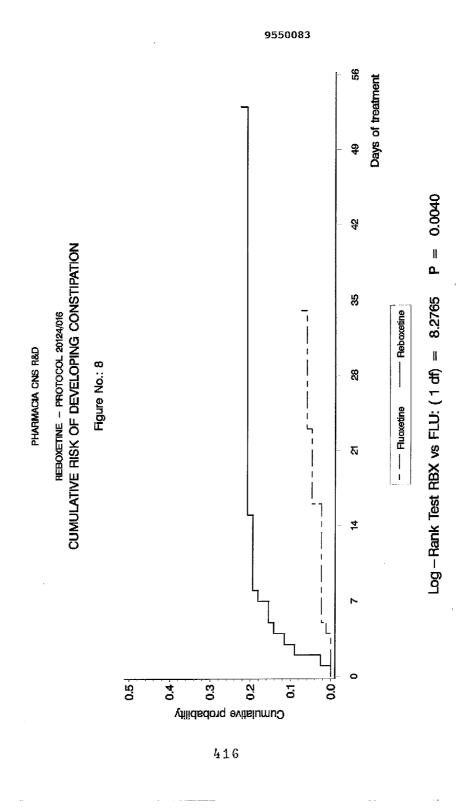


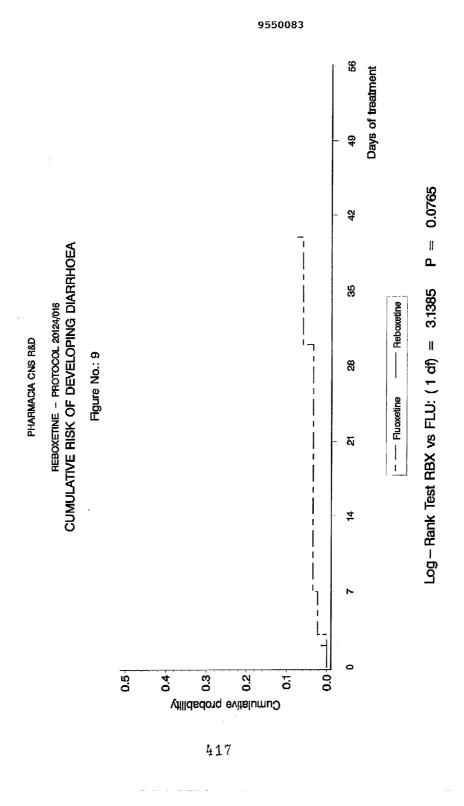


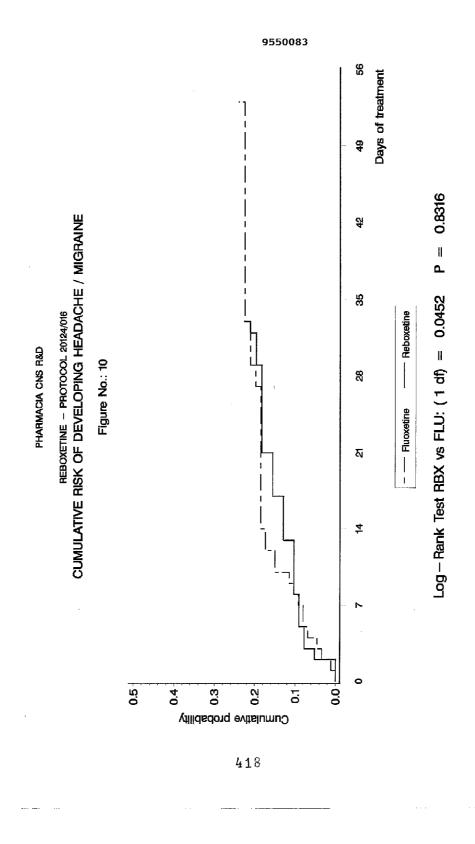
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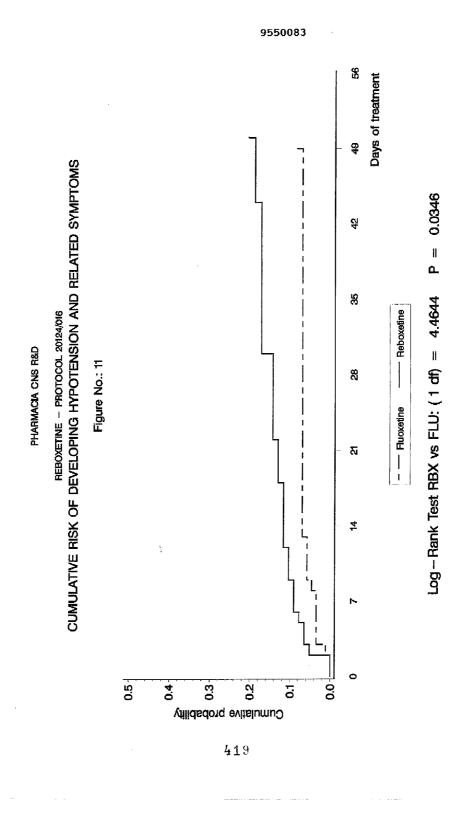


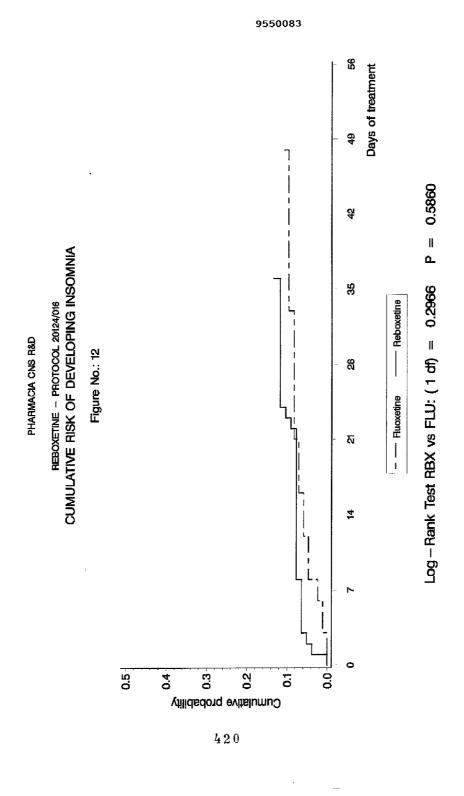


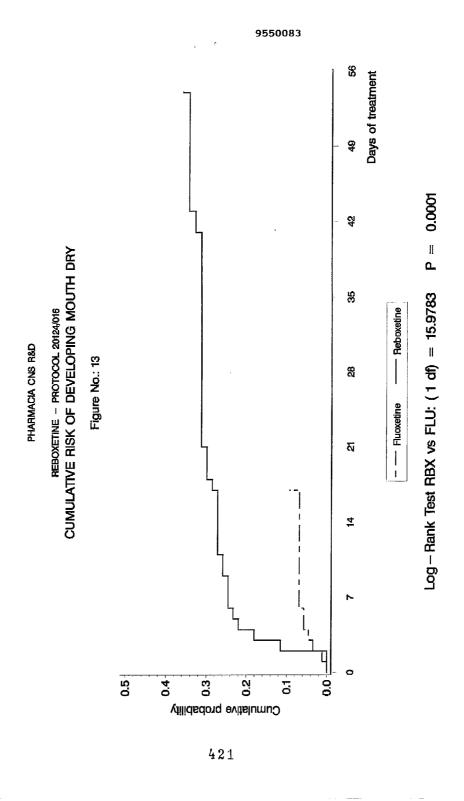


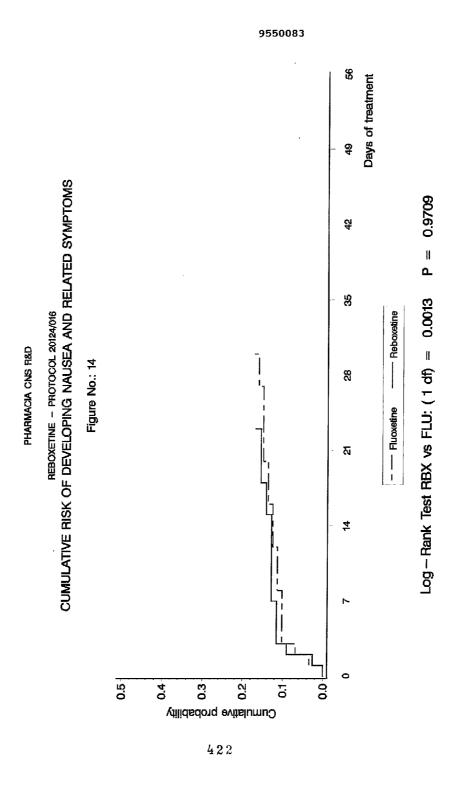


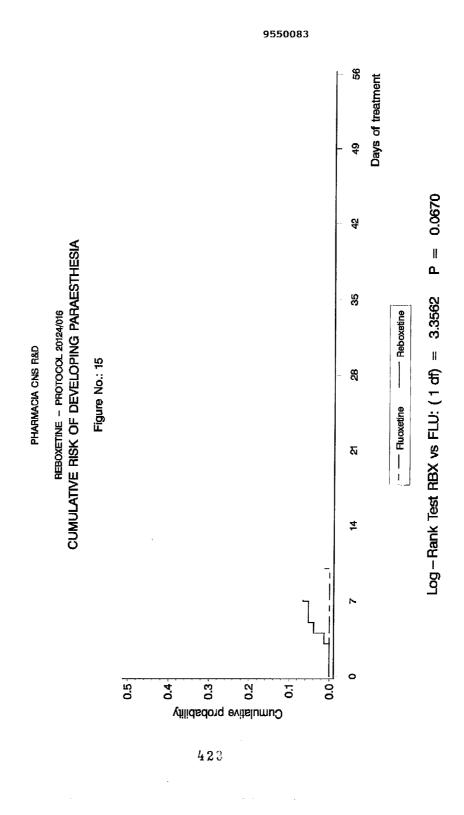


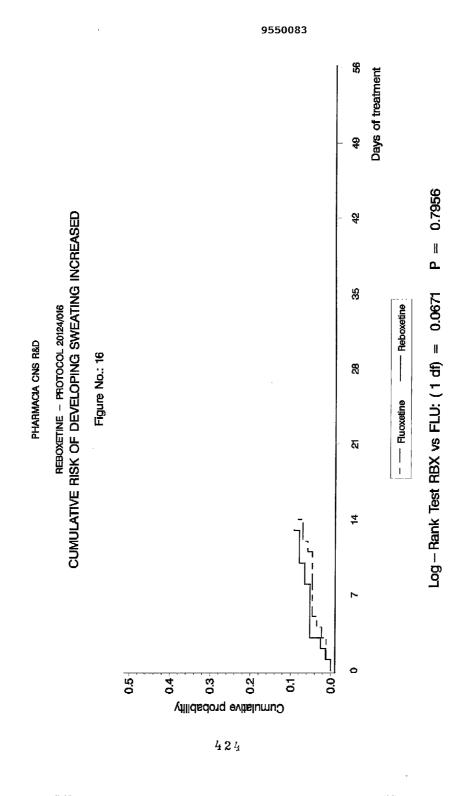


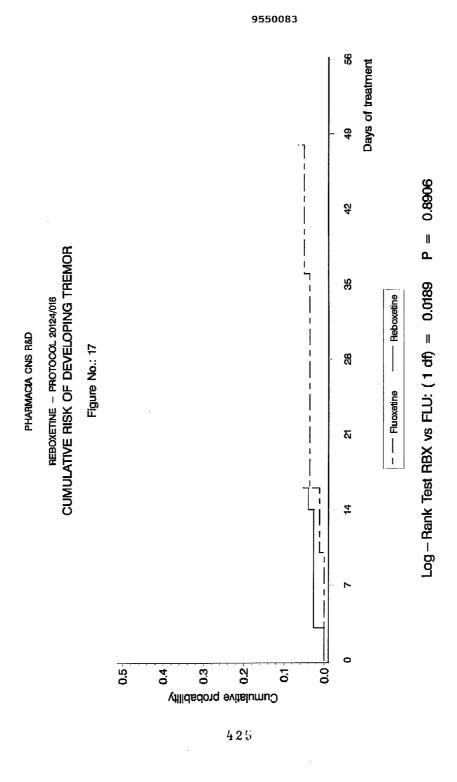


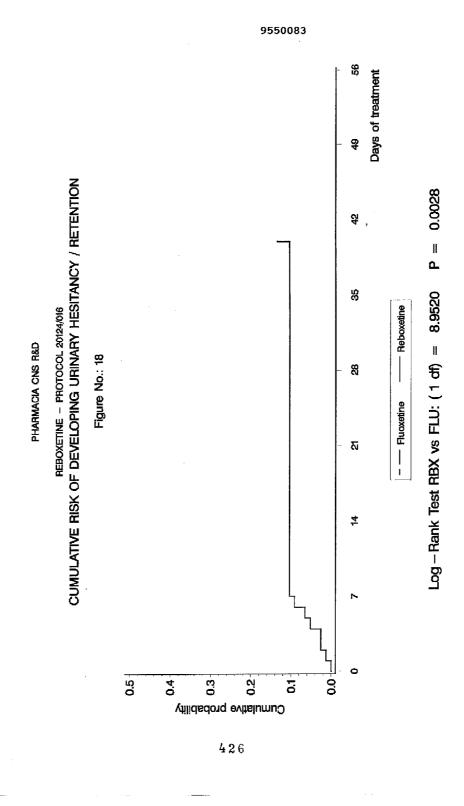


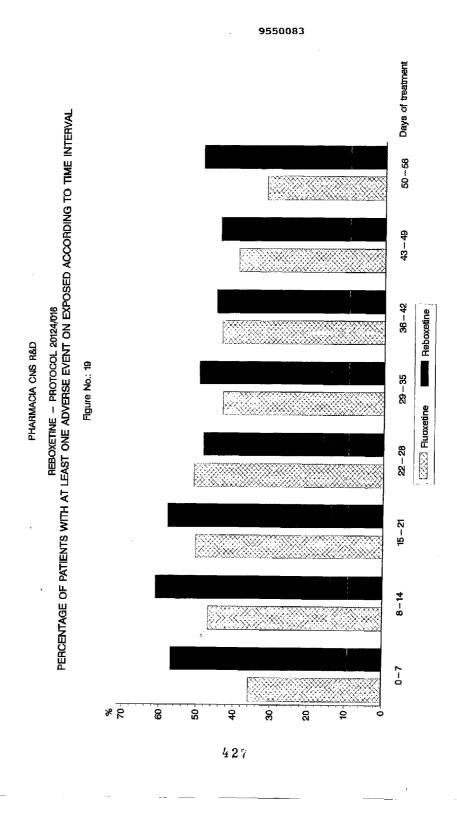












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- 12. APPENDICES
- 12.1 Study Information

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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).

	20124/016	Date: January	24, 19	•
4	430			
Biostatisticians _	land made Speedin			
Line Medical Head			<del></del>	
Product Leader	Mh Jame			
Study Monitor			_	
Investigator			_	
Signatures:				

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FARMITALIA CARLO ERBA EBRAMONT GRUOP CNS LINE

## 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 administrated. 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 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	1	^
Product Leader	in (loh )	Jam
Line Medical Head	Dhieno	Rhi
	20124/016 Australia	Date; December 19, 1991

9			

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 UMA
Line Medical Head Aduque Ruhiui
200 1000

20124/016 Amendment 3

Date: February 28, 1992

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.

S	Lg	na	ıt	u	r	е	S	:
---	----	----	----	---	---	---	---	---

Investigator	
Study Monitor	
Product Leader	club Arono
Line Medical Head	Higgs Dylini

20124/016 Amendment 4

Date: February 28, 1992

FARMITALIA CARLO ERBA

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ERBAMONT GROUP CNS LINE

> 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

This protocol contains strictly confidential information which is not to be communicated or published unless previously authorized by Farmitalia Carlo Erba R&D.

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20124/016 Date: September 24, 1990

# 9550083

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#### FARMITALIA CARLO ERBA ERBAMONT GROUP

CNS LINE

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#### 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-[ $\alpha$ -(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  $\alpha$ 2 noradrenergic receptors, one of the biochemical correlates of chronic antidepressant treatment, after single oral dose: therefore it may be expected to exert antidepressant effectiveness of faster onset with respect to available antidepressants in patients (1).

In phase I studies (2, 3) single doses of 0.5 - 5 mg of compound, were administered orally to healthy volunteers. After 5 mg orthostatic hypotension, accompanied by tachycardia and by subjective symptomatology consistent with the disturbed circulatory regulation was observed.

In these studies single doses of 1 & 3 mg of the compound showed dose-dependent CNS effects with EEG modifications (decreased power of theta and fast-beta waves in the fronto-central derivative), performance improvement (peg-board test) and growth hormone increase, the latter reportedly sensitive to hypothalamic noradrenergic stimulation by norepinephrine reuptake inhibitors.

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The comparison with the positive control, imipramine 75 mg, associated 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 -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 c-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  $\alpha\text{-adrenoceptor}$  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  $\alpha\text{-adrenoceptor}$  blockade. No evidence of noradrenaline-uptake blockade could be observed, since noradrenaline failed to evoke measurable pupillary response.

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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.

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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 REX 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  $\underline{\mathbf{vs}}$  non-tricyclic antidepressants, and particularly  $\underline{\mathbf{vs}}$  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

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This phase III study will be carried out according to a double blind parallel group design, controlled  $\underline{vs}$  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

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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  $4\ \mbox{weeks}$  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.

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#### 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 -reboxetine dose 2 (last 4 weeks)	1 cps 4 mg as above	1 cps 4 mg 1 cps 6 mg
-fluoxetine -fluoxetine dose 2 (last 4 weeks)	1 cps 20 mg as above	1 cps placebo 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

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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).

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#### 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.

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#### 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.

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# 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

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- 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  $\alpha_1$ ,  $\alpha_2$ ,  $\alpha_3$ , 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

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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 Pegulatory Authority in accordance with 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 copthe pathological report should be sent to the subsidiary monitor.

#### EVALUATION SCHEDULE 13.0

Is reported in table 1.

#### STATISTICAL CONSIDERATIONS 14.0

#### 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 difference between baseline and the 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.

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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 length 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.

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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

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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.

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#### 19.0 ADMINISTRATIVE ASPECTS

#### 19.1 Insurance policy

Farmitalia Carlo Erba Company declares to have a group insurance cover (policy NO. 4W8102 - Italia Assicurazioni) 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.

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#### 20.0 STUDY REPORT

#### 20.1 Clinical Study Final Report

The final Medical Study Report will be written by the Product Leader and will be submitted to the Investigator for approval and signature.

#### 20.2 Use and publication of study results

The Investigators, whilst free to use the data resulting from this study, are asked to discuss any paper with Farmitalia Carlo Erba prior to publication; to this purpose copy of manuscript/abstract 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

- Reboxetine Investigator Brochure, FICE, CNS Line, June 1988
- /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.
- /603i Herrmann W.M. (AFB Berlin)
   Reboxetine Quantitative pharmaco EEG and pharmacopsychological study.
   January, 1985.
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   Disposition and fate of <sup>14</sup>C-reboxetine administered orally to healthy volunteers.
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PARMITALIA CARLO ERBA

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ERBAMONT GROUP CNS LINE

- 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

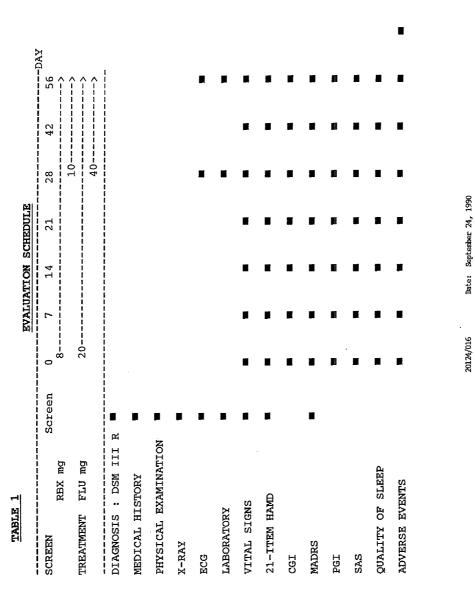
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Investigator
Study Monitor
Product Leader
Line Medical Head Hanous Duni
Biostatisticians licano Speni

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#### 9550083



FARMITALIA CARLO ERBA ERBAMONT GROUP 9550083

#### 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

# 9550083

#### 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.	tt	Dr. Ziegler Academic Teaching Hospital Saar	20
4.	u	Dr. Pflug Dept. of Psychiatry University of Frankfurt	20
5.	Spain	Dr. J. Lopez Ibor (Coordinate Hospital Ramon y Cajal Ctra. Colmenar Km. 9 28034 Madrid	or) 20
6.	#	Dr. Jose Luis Ayuso Hospital Universitario San Carlos c/ Dr. Martin Lago s/n 28040 Madrid	20
7.	11	Dr. Enrique Alvarez Hosp. de la Santa Creu y San San Antonio M. Claret, 167 08025 Barcelona	20 Pau
8.	n	Dra. Carmen Leal Hosp. Clinico Universitario Avda. Blasco Ibanez, 17 46010 Valencia	20

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PARMITALIA CARLO ERBA

# 9550083

9.	Spain	Dr. Miguel Gutierrez Hosp. Santiago Apostol Av. Olaguibel s/n 01004 Victoria	20
.0.	11	Dr. J. Giner Ubago/Dr. Camacho Hosp. Clinico Universitario Avda. Dr. Fedriani, s/n 41009 Sevilla	20
.1.	u	Prof. Ballus/Dr. J. Massana/ Dra. Aurora Otero/Dr. Gatell Hosp. Clinico de Barcelona Casanova, 143 08036 Barcelona	20
.2.	Australia	Prof. G.D. Burrows Department of Psychiatry University of Melbourne Austin Hospital Heidelberg, Vic 3084 phone: 4505111	4
13.	11	Dr. Ramesh Gupta Phillip Health Centre Woden, Canberra	10
L4.	11	Dr. Tom George Prince Charles Hospital Brisbane	10
L <b>5.</b>	Argentina	Dr. J. C. Ferrali Moldes 2166 8° D Buenos Aires phone: (+541)7860533	30
L6.	บ	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.	H	Dr H.J. Schierle Puiseaux Platz 2 6054 Rodgau 3	8
19.	*1	Dr Seichter Spiegelgassa 1 W-7407 Rottenburg	8

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FARMITALIA CARLO ERBA ERBAMONI GROUP CNS LINE	9550083		
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	

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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"

- 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.
  - 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
- 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
- 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)
- 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

#### 9550083

Encl. 3 cont's

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

#### Confidentiality

Participation in the study will be kept confidential to the extent permitted by law.

Problems and questions

#### 9550083

Cont'd Encl.3

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
THYESCHYACOL STYNACUTE date
Wittness Signature date
3

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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

Protocol No. 2 0 1 2 4 0 1 . FARMITALIA CARLO ERBA Erbamont Group Compound REBOXETINE Visit/cycle Centre No. Patient No. Investigator's name Date L Monitor's name Enclosure 5 PRE-STUDY CHECKLIST IN THE PATIENT: NO ARE THE FOLLOWING CONDITIONS PRESENT? YES  $\square$  $\sqcup$ - 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? Ш - 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 : 466

Investigator's signature \_\_\_\_

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität

und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

FARMITALIA CARLO ERBA Erbamont Group	Compound REBOXET	TINE	Protoco	No. 2 0 1	2
Centre No.	Patient No.	Initials		Visit/cycle L	L
	(CONT')	C	ont'd l	EncL.5	
				YES	
<ul> <li>Participation in a clinical trial w preceding the study?</li> </ul>	rith an investigational compound i	n the 4 weeks		Ш	
- Evidence of substance use dis	order within past 6 months or cur	rently?			
- Chronic respiratory insufficient	/?			$\sqcup$	
- History of drug hypersensitivity	?			$\sqcup$	
- Any history of seizures or brain	injury?				
- Any other important clinical illn	ess in the 4 weeks preceding the	study?			
- ECT in the previous 6 months?				$\sqcup$	
if the answer to any of the above no proceed further.	questions is NO the patient is un	suitable for entry	r into the s	tudy and sh	ouk
If the answer to any of the above no proceed further.		suitable for entry	into the s	tudy and sh	ouk
no proceed further.					-
conclusion		nat the available i	nformation		-
no proceed further.		nat the available i	nformation		-
conclusion		nat the available i	nformation		-
conclusion		nat the available i	nformation		-
conclusion		nat the available i	nformation		-
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conclusion		nat the available i	nformation		-

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FARMITALIA CARLO ERBA Erbamont Group	Co	mpound REB	OXETINE	Protocol No. 2 0	1 2 4 0
Centre No.	Patient No.		Initials	Visit/cycle	
				Date	D M
		LABORATO	DRY TESTS	Cont'd Encl.5	;
Tests	Value	Clinically Significant abnormality*	Tests	Value*	Clini Signi abnorn
BLOOD TESTS	1	į	BUN		L
HGB			Creatinine		· L
MCT			Uric acid		L
RBC		Ш	Total bilirubin		: [
WBC	,		Direct bilirubin		
Neutrophils		LJ	Total protein		i L
Lymphocytes			Blood albumin		· [
Eosinophils		Ш	Cholesterol		L
Monocytes			Triglycerides		L
Basophils		Ш	Globulins:	α1	L
Platelets		Ш		α 2	L
Na <sup>+</sup>		Ц		β	L
K⁺				γ	<u> </u>
CL.			rT <sub>3</sub>	<u> </u>	<u> </u>
Ça <sup>++</sup>			Т <sub>3</sub>		: L
PO <sub>4</sub>			T <sub>4</sub>		
SGOT			URINALYSIS		
SGPT		<u> </u>	Specific gravity		L
γ-GT		<u> </u>	Albumin		
			Sugar		
		; LJ	RBC	4	Į. Į
BLOOD SUGAR			1,50		

Investigator's signature \_\_\_\_

FARMITALIA CARLO ERBA Erbamont Group Protocol No. 2 0 1 2 4 0 1 Compound REBOXETINE Visit/cycle Centre No. Patient No. Initials \_\_\_\_\_ Cont'd EncL. 5 **ADMISSION EXAMINATION** CHEST X-RAY taken on normal \_\_\_\_ abnormal \_ If abnormal, detail \_\_\_ **VITAL SIGNS**  Body temperature (°C) - Respiratory rate (breaths/min) ± 5 min lying arterial blood press - 5 min lying heart rate (beats/mi - 2 min standing arterial blood pr - 2 min standing heart rate (beat MEDICAL HISTORY Important previous diseases \_\_\_

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität

und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

sure (mmHg) systo	olic LLL	diastolic L	
in)			
ressure (mmHg) systo	olic LLL	diastolic	
ts/min)			
	· · · · · · · · · · · · · · · · · · ·		
	<del></del>		
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Investigator's sig	nature		

Protocol No. 2 0 1 2 4 0 1 5 FARMITALIA CARLO ERBA Erbamont Group Compound REBOXETINE Visit/cycle Centre No. Initials Patient No. Cont'd Encl.5 **DIAGNOSIS** - DSM III-AXIS I ..... HISTORY OF THE MENTAL DISORDER: Unknown if known: years 📖 - Age of onset of disease Ш - Number of previous episodes weeks \_\_\_\_ months \_\_\_\_ years \_\_\_\_ - Approximate duration of last episode PRESENT EPISODE - Approximate duration at the time of admission to the study days \_\_\_\_ weeks \_\_\_ months \_\_\_ years \_\_\_ THE PRESENT EPISODE IS BEST CHARACTERIZED AS: 1 - Exacerbation of chronic condition 2 - Recurrence of similar previous conditions 3 - Significantly different from any previous conditions 4 - First occurrence, no previous psychiatric diagnosis ONSET OF PRESENT EPISODE WAS: - Acute (<2 weeks)

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität

und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

- Subacute (≥ 2 weeks)

- Insidious (≥ 3 months)

- Absent

- Probably present

- Definitely present

PRECIPITATING EXTERNAL STRESS WAS:

3

1

2

3

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Investigator's signature	 

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FARMITALIA CARLO ERBA Erbamont Group	Compound REI	BOXETINE	Protocol No. 2 0 1 2 4 0
Centre No.	Patient No.	Initials	Visit/cycle
	·		Date D. M
	HAMD: HAMILTON DEPI	RESSION RATING S	nt'd Encl.5
1. Depressed mood (Sadn	ness, hopeless, helpless, wo		
0 Absent	1 These feeling sta	ites indicated only on qu	estioning
2 These feeling states:	spontaneously, reported verba	lly	
3 Communicates feeling	g states non-verbally - i.e., thre	ough facial expression, p	osture, voice, and tendency to w
4 Patient reports VIRTU communication	JALLY ONLY these feeling sta	ates in his spontaneous	verbal and non-verbal
2. Feelings of guilt			
.0' Absent	·	els he has let people dov	vπ
2 Ideas of guilt or rumin	nation over past errors or sinfu	ıl deeds	
3! Present illness is a pu	unishment. Delusions of guilt		
Hears accusatory or o	denunciatory voices and/or ex	periences threatening vi	sual hallucinations
3. Suicide			
O Absent	Feels life is not w	orth living	
2 Wishes he were dead	or any throughts of possible	death to self	
3 Suicide ideas or gestu	ure		
Attempts at suicide (a	any serious attempt rates 4)		
4. Insomnia early			
O No difficulty falling asi	leep 🗓 Complains of occa	asional difficulty falling as	leep - i.e., more than 1/2 hour
2 Complains of nightly of	difficulty falling asleep		
5. Insomnia middle			
0 No difficulty	Patient complains	of being restless and di	sturbed during the night
2 Waking during the nig	ht - any getting out of bed rat	es 2 (except for purpose	es of voiding)
6. Insomnia late	,		
O No difficulty	11 Waking in early hi	ours of the morning but	goes back to slepp
2 Unable to fall asleep a	again if he gets out of bed		
7. Work and activities			
O: No difficulty			
1. Thoughts and feelings	s of incapacity, fatigue or weal	kness related to activitie	s; work or hobbies
	ivity; hobbies or work - either tion <i>(feels he has to push self</i>		ent. or indirect in listlessness,
Decrease in actual time not spend at least three	ne spent in activities or decrea see hours a day in activities (he	ase in productivity. In ho ospital job or hobbies) e	spital, rate 3 if patient does cclusive of ward chores
	ause of present illness. In hos ient fails to perform ward chor		gages in no activities except
	4.7.1 Investigator's sign	nature	

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FARMITALIA CARLO ERBA Erbamont Group	Compound REB	OXETINE	Protocol No. 2   0   1   2   4   0
Centre No.	Patient No.	Initials	Visit/cycle
			Date D M
0 Detendation (0/a			t'd Encl. 5
_	•	ireo abiiny to concen	trate; decreased motor activit
Normal speech and thou	_		
Slight retardation at inter			
2 Obvious retardation at in	terview		
3 Interview difficult			
4. Complete stupor			
9. Agitation			
Oi None	1 Fidgetine	ess [2]	Playing with hands, hair, etc.
Moving about, can't sit s	till 4 Hand wri	inging, nail biting, hair-p	oulling, biting of lips
10. Anxiety psychic			
O No difficulty	1 Subjectiv	e tension and irritability	1
2 Worrying about mirror m.	atters 3 Appreher	nsive attitude apparent	in face or speech
4 Fears expressed without			, ,
Sweating  O: Absent	1 Mild		ion, sighing); Urinary frequency:  Moderate
3 Severe	4 Incapacit	ating	
12. Somatic symptoms gastroi	ntestinal		
0 None	•		
Loss of appetite but eating	ng without staff encourageme	ent. Heavy feeelings in	abdomen
2 Difficulty eating without s medication for G.I. symp		uires laxatives or medic	cation for bowels or
13. Somatic symptoms genera	I		• .
0 None			
Heaviness in limbs, back	or head. Backaches, heada	ache, muscle aches. Lo	ss of energy and fatigability
2 Any clear-cut symptoms	rates 2		
14. Genital symptoms (Such as	: Loss of libido: Menstrual o	disturbances)	
O Absent	Mild	<u>. 2  </u>	Severe
15. Hypochondriasis		-	
0 Not present	1 Self-abso	orption (bodily)	
2 Preoccupation with health	h [3] Frequent	complaints, requests f	or help. etc.
4 Hypocondriacal delusions	3		
	472		
	***		

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FARMITALIA CARLO ERBA Erbamont Group	Compound REE	OXETINE F	Protocol No. 2 0 1 2 4 0
Centre No.	Patient No.	Initials	Visit/cycle
			Date
<u> </u>			. D M
6. Loss of weight Rate either	A or B	Cont'd En	c1.5
A. When Rating By History			
0 No weight loss			
	associated with present ill	ness	
2 Definite (according to	patient) weight loss		
3 Not assessed			
B. On Weakly Ratings By V		tual Weight Changes Are I	Measured:
Less than 1 lb. weigl Greater than 1 lb. we			
Greater than 1 lb. we			
3 Not assessed	agnt loss in week		
		<del>, -,</del>	,
7. Insight			
Acknowledges being dep		ad alimoto avanumi vinu	
2 Denies being ill at all	allinbutes cause to bad loo	od, climate, overwork, virus	s, need for rest, etc.
3. Diurnal variation			
A. Note Whether Symptoms			
O No variation	1 Worse in A.M		Worse in P.M.
When Present, Mark The     None	Severity Of The Variation.  11 Mild		on: Severe .
	LL MING		Severe .
Depersonalization and dere			
		•	eas)
O Absent	1 Mild	12	
Absent  3 Severe		12	eas)
3 Severe Paranoid symptoms	1 Mild	12	eas)
3 Severe Paranoid symptoms None	1 Mild	12	eas)
3 Severe Paranoid symptoms O None Suspicious	1 Mild	12	eas)
. Paranoid symptoms  Oi None  Suspicious  Ideas of reference	1 Mild Incapacitatin	12	eas)
3 Severe  Paranoid symptoms  O None  Suspicious	1 Mild Incapacitatin	12	eas)
Paranoid symptoms  O None  Suspicious  I deas of reference  Delusions of reference ar  Obsessional and compulsiv	1 Mild Incapacitation	<u> 2</u>	eas) Moderate
Paranoid symptoms  O None  Suspicious  I deas of reference  Delusions of reference ar	1 Mild Incapacitation	<u> 2</u>	eas)
Paranoid symptoms  O None  Suspicious  I deas of reference  Delusions of reference ar  Obsessional and compulsiv	1 Mild Incapacitation	<u> 2</u>	eas) Moderate
Paranoid symptoms  O None O None O Suspicious O Ideas of reference O Delusions of reference ar	1 Mild Incapacitation	<u> 2</u>	eas) Moderate
Paranoid symptoms  O None  Suspicious  I deas of reference  Delusions of reference ar  Obsessional and compulsiv	1 Mild Incapacitation of persecution we symptoms	<u> 2</u>	eas) Moderate  Severe
Paranoid symptoms  O None  Suspicious  I deas of reference  Delusions of reference ar  Obsessional and compulsiv	1 Mild Incapacitation	<u> 2</u>	eas) Moderate  Severe
Paranoid symptoms  O None  Suspicious  I deas of reference  Delusions of reference ar  Obsessional and compulsiv	1 Mild Incapacitation of persecution we symptoms	<u> 2</u>	eas) Moderate  Severe

amont Group		Comp				
tre No.	F	Patient No.		Initials 🔝		Visit/cycle
				•		Date D M
				Co	nt'd En	21.5
VIOUS TREATME	NTS					
NAME*	EF	FICACY (Very Fair, Good, Ve	poor, Poor, ry good)		SIDE EF	FECTS (if any)
	VP	P F	G VG			
	VP.	P F	G VG			
	VP	PF	G VG			
	VP	PF	G VG			
	VP	PF	G VG			
t treatment taken; n	ame*				Last day of	treatment D M
COMITANT DRUG	6 (during the	e drug free, w	ash-out period	d)		
	S (during the	e drug free, w	ash-out period	i)	Reason	n for the administration
free, Wash-Out Pe  COMITANT DRUGS  NAME	3 (during the Daily Dose	e drug free, w Started o (date)	ash-out period	d) ntinued on date)	Reasor	n for the administration
COMITANT DRUG	3 (during the Daily Dose	e drug free, w Started o (date)	ash-out period	d) ntinued on date)	Reason	n for the administration
COMITANT DRUG	3 (during the Daily Dose	e drug free, w Started o (date)	ash-out period	d) ntinued on date)	Reason	n for the administration
COMITANT DRUG	3 (during the Daily Dose	e drug free, w Started o (date)	ash-out period	d) ntinued on date)	Reasor	n for the administration
NAME	Daily Dose (mg)	e drug free, w Started o (date) D M	ash-out period n Disco	d) ntinued on date) M Y	Reason	n for the administration
NAME	Daily Dose (mg)	e drug free, w Started o (date) D M	ash-out period n Disco	d) ntinued on date) M Y	Reason	n for the administration
NAME*	Daily Dose (mg)	e drug free, w Started o (date) D M	ash-out period n Disco	d) ntinued on date) M Y	Reason	n for the administration
NAME*	Daily Dose (mg)	e drug free, w Started o (date) D M	ash-out period n Disco	d) ntinued on date) M Y	Reason	n for the administration
NAME*	Daily Dose (mg)	e drug free, w Started o (date) D M	ash-out period n Disco	d) ntinued on date) M Y	Reason	n for the administration
COMITANT DRUG	Daily Dose (mg)	e drug free, w Started o (date) D M	ash-out period n Disco	d) ntinued on date) M Y	Reason	n for the administration

RMITALIA CARLO ERBA amont Group	Compound REB	OXETINE	Protocol No. 2 0 1 2 4 0
ntre No.	Patient No.	Initials	Visit/cycle
			Date D M
			1.5.1.6
		Cont	d Encl.5
		E C G	
HEART RATE			
Abnormal if abnormal check on     Sinus bradycardia     Sinus tachycardia	e or more boxes as appropriat (<60)	te:	  
<ul> <li>Atrial estopic be</li> </ul>	ats Occasional Frequent (>6/mm) Couplets Supraventricular Tachyca		 
◆ Ventricular ectop	ic beats: - Occasional Frequent (>6/mm) Polymorphic Couplets		U
♦ A-V Block 1 nd deg	- Ventricular Tachycardia		
<ul> <li>Left ventricular!</li> <li>Right ventricular</li> <li>Myocardial ischem</li> </ul>	e hypertrophy hypertrophy		U
<ul> <li>Acute Myocardial</li> <li>Right bundle brand</li> <li>Left bundle brand</li> </ul>	al infarction		
<ul> <li>Left posterior her</li> <li>Bifascicular Bloc</li> <li>Trifascicular Bloc</li> </ul>	iblock niblock k (specify) ck (specify)		<u>U</u>
• Other			

FARMITALIA CARLO ERBA Erbamont Group	Compound REBOX	Protocol No. 2 0 1 2 4 0 1 6	
Centre No.	Patient No.	Initials	Visit/cycle
	CONT' E	CG	Cont'd Encl. 5
Please, add here the ORIGINAL	_ TRACING AND MEDICAL RE	PORT	

476

nvestigator's signature \_\_\_\_\_\_

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FARMITALIA CARLO ERBA Erbamont Group	Compound REB	OXETINE	Protocol No.  2  0  1  2  4  0  1  6
Centre No.	Patient No.	Initials	Visit/cycle
		<b>.</b>	Date D M Y
	HAMD: HAMILTON DEPR	ESSION RATING SC	Enclosure 6
1. Depressed mood (Sadne	ess, hopeless, helpless, wort	!hiess)	
0 Absent	These feeling state	es indicated only on que	estioning
	pontaneously reported verbally		
			osture, voice, and tendency to wee
Patient reports VIRTU communication	ALLY ONLY these feeling state	es in his spontaneous v	verbal and non-verbal
2. Feelings of guilt			
O Absent	Self reproach, feels	•	n
· ·	ation over past errors or sinful	deeds	
	nishment. Delusions of guilt		
Hears accusatory or d	enunciatory voices and/or expe	eriences threatening vis	sual hallucinations
3. Suicide			
0 Absent	1 Feels life is not wor	rth living	
	or any throughts of possible de	eath to self	
Suicide ideas or gestu	re		
4 Attempts at suicide (ar	ny serious attempt rates 4)		
4. Insomnia early			
No difficulty falling asle	ep 🗓 Complains of occas	ional difficulty falling as	leep - i.e., more than ½ hour
2 Complains of nightly di	fficulty falling asleep		_
5. Insomnia middle			
No difficulty	Patient complains of	of being restless and di-	sturbed during the night
2 Waking during the nigh	nt - any getting out of bed rates		
6. Insomnia late			``
O No difficulty	1 Waking in early hou	ars of the morning but o	noes back to slepp
Unable to fall asleep a			—
7. Work and activities			
O No difficulty	l .		
	of incapacity, fatigue or weakn	ness related to activities	s: work or hobbies
-	ity; hobbies or work - either di		
indecision and vacillation	on (feels he has to push self to	o work or activities)	
not spend at least three	e spent in activities or decreas e hours a day in activities <i>(hos</i>	spital job or hobbies) ex	clusive of ward chores
	use of present illness. In hospit nt fails to perform ward chores		ages in no activities except
	J. W. 19		

		083	
ARMITALIA CARLO ERBA Erbamont Group	Compound REBO	OXETINE	Protocol No. 201240
Centre No.	Patient No.	Initials	Visit/cycle
			Date
8 Batardatian (Claumans of th			it'd EncL.6
<ol> <li>Retardation (Slowness of the One of the State o</li></ol>		rea ability to concent	rate; decreased motor activit
Slight retardation at interv			
Obvious retardation at interv			
3 Interview difficult	erview		
Complete stupor			
3. Agitation			
O None	1 Fidgetines	ss 2	Playing with hands, hair, etc.
Moving about, can't sit stil	Hand wrin	nging, nail biting, hair-p	
). Anxiety psychic			
O No difficulty	1 Subjective	tension and irritability	
2 Worrying about mirror mat		sive attitude apparent in	1 face or speech
Fears expressed without of		The state of the s	- Auto of aposon
O Absent Severe	Mild Incapacita		Moderate
		- 3	
. Somatic symptoms gastroint	lestinal		
Loss of appetite but eating			
Difficulty eating without sta medication for G.I. sympton	iff urging. Hequests or requi ms	ires laxatives or medica	ition for bowels or
. Somatic symptoms general			
O None			•
Heaviness in limbs, back o	r head. Backaches, headac	the, muscle aches, Los	s of energy and fatigability
2 Any clear-cut symptoms ra			,0,
Genital symptoms (Such as:	Loss of libido; Menstrual dis	sturbances)	
0 Absent	⊥ Mild	2	Severe
Hypochondriasis			
	Self-absorp	ption (bodily)	
Not present		· · · · · · · · · · · · · · · · · · ·	
Not present Preoccupation with health	3 Frequent o	complaints, requests for	help, etc.

_	entation der Stellungn hkeit im Gesundheits		richt A05-20C	C. Institut für Qualität
	FARMITALIA CARLO ERBA Erbamont Group	Compound REBOX	ETINE	Protocol No. 2 0 1 2 4 0 1 K
	Centre No.	Patient No.	Initials	Visit/cycle
				Date D M Y
		,	Initials	Visit/cycle

		Patient No. Ini		Date
				р м
			Cont'd	Encl.6
	oss of weight Rate either A	or B		
A.	When Rating By History:			
	O No weight loss			
		ssociated with present illness		
	Definite (according to page 13) Not assessed	patient) weight loss		
ъ.		rd Psychiatrist, When Actual Weig	int Changes Are Me	asured:
	Less than 1 lb. weight			
	Greater than 1 lb. weig			
	2 Greater than 2 lb. weig	ITI IOSS IN WEEK		
	Not assessed			
	sight			
	Acknowledges being depre			
		ttributes cause to bad food, clima	te, overwork, virus,	need for rest, etc.
2	Denies being ill at all			
. Die	urnal variation	•		
A.	Note Whether Symptoms A	re Worse in Morning Or Evening.	If NO Diurnal Varia	tion, Mark "none":
	O No variation	Worse in A.M.		Vorse in P.M.
В.	When Present, Mark The S	everity Of The Variation, Mark "N	one" If NO Variation	:
	0 None	1 Mild	2 s	evere
. De	personalization and dereal	ization (Such as: Feelings of unr	eality, Nihilistic idea	s)
0	Absent	1 Mild	2 N	loderate
[3]	Severe	4 Incapacitating		
Pas	ranoid symptoms			-
	None			•
	Suspicious			
	Ideas of reference			
	Delusions of reference and	persecution		
Ob	sessional and compulsive	symotoms		<del></del>
	Absent	1 Mild	[2] S	evere
_				· ·
				Total score
		479		
		•		

Erbamont Group	Compound REBOXETIN	<b>8</b> 3	Protocol No. [2]0]1]2]4]0]1]6]
Centre No.	Patient No	als LLL	Visit/cycle
			Date D W Y
	CLINICAL GLOBAL IMPRES	SION (CGI)	ENCLOSURE Nº 7
A. SEVERITY OF ILLNESS			
Considering your clinical exp	rience with this particular population	n, how mental	lly ill is the patient at this time?
Į	Normal, not at all ill		
£	Borderline mentally ill		
Į.	Mildly ill		
Į.	Moderately III		
į	Markedly iff		
Į	Severily III		
,	Among the most extremely ill p	atients	
	e total improvement whether or not, i admission to the study, how much		ent, it is due entirely to drug treatment) ed?
[	Very much improved		
Į	Much improved		
L	Minimally improved		
Į	No change		_
	Minimally worse		•
L	Much worse		
L	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 inter- fere 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	δ	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			-
480				

ARMITALIA CARLO ERBA	Compound REB	OXETINE	Protocol No. 2 0 1 2 4 0 1 6
Centre No.	Patient No.	Initials 🔠	Visivcycle L LL, LLL
			Date D M Y
		٠	ENCLOSURE N⊄ 8
MADRS: I	MONTGOMERY ASBER	G DEPRESSION R	ATING SCALE
Reported sadness     Representing subjectively depressed mood, low spiriting a factor of the second se	its, despondency, and the fe	elina of beina beyon	flected in appearance or not, Includes d help and without hope. fluenced by events.
			s of sadness, but brighter moments
occur 1; Pervasive feelings			
circumstances 2; Continuo	us experience of misery or e	extreme despondency	<u>[3]</u>
<ul><li>and anguish.</li><li>Rate according to intensity</li><li>Distinguish from sadness,</li></ul>	, frequency, duration and the worrying and muscular tens	e extent of reassuranion.	•
			defined discomfort 1: Continuous
feelings of inner tension, or in		patient can only maste	er with some difficulty (2);
Unrelenting dread or anguish	. overwhelming panic 3.		<u></u>
	and posture, rate by depth a ited but brightens up occasi	and inability to brighte	nsient low spirits) reflected in in up. ad and unhappy all of the time 2;
Extreme and continuous gloor	m and despondency 3.		<u> </u>
<ul> <li>Sulcidal thoughts</li> <li>Representing the feeling the and preparations for suicide</li> <li>Suicidal attempts should no</li> </ul>	e. ot in themselves influence th	e rating.	
Enjoys life or takes it as it con			
Suicidal thoughts are common intention [2]; Explicit plans for			
. Inertia  - Representing a difficulty ge  - Distinguish from indecision	and fatiguability.		
No difficulty in getting started.	No sluggishness of Diffic	ulties in starting new	activities 1: Difficulties in starting
very simple routine activities,	which are carried out only w	rith effort [2]; Comple	ete inertia, unable to start any
activity without help [3]			
Inability to feel     Representing the subjective pleasure. The ability to read Distinguish from inertia.	experience of reduced inte that adequate emotion to	rest in the surroundir circumstances or per	ngs, or activities that normally give ople is produced.
Normal interest in the surroun			
ability to feel anger 11; loss of			
The experience of being emoti	ionally paralyzed, inability to	feel anger or grief,	and a complete or even painful
failure to feel for close relative			L
	Investigator's signate	ure481	

FARMITALIA CARLO ERBA Erbamont Group	Compound REB	OXETINE	Protocol No. 2 0 1 2 4 0 1 6
Centre No.	Patient No.	Initials	Visit/cycle
			Date L
		•	CONT.ENCLOSURE Nº ,8
7. Pessimistic thoughts  - Representing thoughts of	guilt, inferiority, self-reproac	h, sinfulness, remorse a	nd win.
No pessimistic thoughts			
accusations, or definite but	still rational ideas of guilt or s	sin. Increasingly pessimi	stic about the future 2;
Delusions of ruin, remorse a	und unredeemable sin. Absur	rd self-accusations 3.	<u>_</u>
Concentration difficulties     Representing difficulties in     Rate according to intensit     Distinguish from failing me	ly, frequency, and degree of i emory and disrupted thought	incapacity recorded.	•
No difficulties in concentration			
concentrating and sustaining concentration [3]	thoughts which interfere wit	th reading or conversation	on [2]; Incapacitating lack of
Reduced sleep     Representing a subjective sleep.	experience of reduced dura	tion or depth of sleep co	empared to the subject's own fitful
	fficulty dropping off to sleep	or slightly reduced, light	or fitful sleep 11; sleep reduced
or broken by at least 2 hours			Ш
Reduced appetite     Representing the feeling of Normal or increased appetite			ed is tastless. Need to force
oneself to eat 2; Must be f			Ц
			Total score
			•
		•	
	4	82	
	•		
		•	
	Investigator's	s signature	

FAI	ARMITALIA CARLO ERBA	Compound REBOXE		Protocol No. 2 0 1 2 4 0 1 6
	entre No. Patient	No.	Initials 📖	Visit/cycle DAY
inve	vestigator's name	Monitor's nam	e	Date D M V
	SASS: SOCIAL A  fe would like you to answer a set of simple asse circle one answer for each question	ple questions, expressi	LF-EVALUAT	
1.	I. Are you professionally active? YES If "yes":  A. Are you interested in your profess 3 - very 2 - moderately 1 - a			
	If "no":  B. Are you interested in your home a 3 - very 2 - moderately 1 - a	activities?		
2.	Do you exercise these activities with:  3 - much pleasure 2 - quite a pleasure		ure 0 - no pleasi	ure at all
3.	. Are you interested in hobbies/leisures 3 - very 2 - moderately 1 - a little			
4.	. The quality of your spare time is: 3 - very good 2 - good 1 - mode	rate 0 - unsatisfacto	ry	
5.	. How frequently do you seek contacts 3 - very frequently 2 - frequently		our family (spouse	, children, parents, etc.)?
6.	. How is the quality of the social relatio 3 - very good 2 - good 1 - fair			
7.	Outside your family, do you establish 3 - many person 2 - quite a few pe			ne
8.	Do you try to develop social relations  3 - very actively 2 - actively 1 - v	hip with others: with moderate activity	0 - not actively a	t all
9.	How do you estimate - in general - th 3 - very good 2 - good 1 - fair		you have with the o	other people?
10.	Do the relationships with the others a 3 - very valuable 2 - valuable 1		no valuable at all	
		83 Investigator's signatur	e	

FAI	RMITALIA CARLO ERBA amont Group	Compound REBOXET	INE	Protocol No. 2 0 1 2 4 0 1 6
Çei	ntre No.	Patient No.	Initials	Visit/cycle DAY
inve	estigator's name	Monitor's name		Date D M Y
				Cont'd Encl. 9
11.	How often do the persons from 3 - very often 2 - often	om your social circle seek the co 1 - rarely 0 - never	ntact with you?	
12.	·	iles, good manner, politeness, et time 1 - rarely 0 - never	c.?	
13.	To what extend do you partic 3 - fully 2 - moderately	cipate in the social life activities ( 1 - slightly 0 - not at all	such as club, chu	rch, etc.)?
14.		rmations in order to better under ely 1 - not much 0 - not at a		ations, subjects, etc.?
15.		c, technical or cultural informatio ely 1 - a little 0 - not at all	ns?	
16.	Do you have difficulties in exp 0 - always 1 - often 2 - s	pressing to people around you you go sometimes 3 - never	our personal opin	ions?
17.	Do you feel rejected, expelled 0 - always 1 - often 2 - s	•		
18.	Do you consider your physica 3 - very 2 - moderately 1	al outlook to be important? I - not very much 0 - not at all	ı	
19.	Do you have difficulties in ma 0 - always 1 - often 2 - s	naging your resources and incorsometimes 3 - never	nes?	
20.	Do you feel you could (or you 3 · very 2 · moderately 1	can) arrange your environment  - a little 0 - not at all	according to you	wishes and needs?
That	s all. Thank you for answering	the questions.		
For o	official use: Total score:			
		484		
		Investigator's signature .		

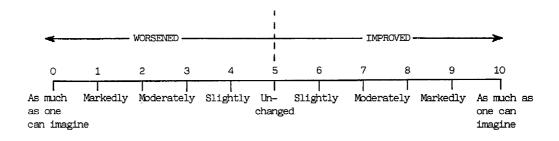
9550083

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  $\frac{1}{h} \frac{1}{m}$  Time of waking up  $\frac{1}{h} \frac{1}{m}$ Regarding your last 1-2 nights, do you consider that: A. After having turn off the light you have fallen asleep: Immediately After about 15-30 minutes After one hour or more 4 Not at all B. Have you been dreaming during the night? Not at all A little bit Moderately 4 All the night C. How many times have you been awakeing during the night? 1 No times 2 1 - 2 times 3 1 - 2 times 1 - 2 times for a short period of time1 - 2 times for a long period of time 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: Very good Good Fair Poor

ARMITALIA CARLO ERBA bamont Group	Compound REBC	EXETINE Prote	ocol No. 201124011
entre No.	Patient No.	Initials	Visit/cycle
			Date D M Y
,	NEWLY ADVERSE EV	ENTS: CHECK-LIST	Enclosure 12
1. AUTONOMIC		4. NEUROLOGIO	CAL
- Dry mouth		- Rigidity	
- Nasal congestion		- Tremor	
- Blurred vision		- Akathisia	
- Constipation		- Dystonia	
- Urinary hesitancy	•	- Paresthesias	
- Urinary retention		- Seizures	,
- Increased salivati	on	Myoclonus	
- Sweating			
- Vomiting		5. OTHER	
- Diarrhoea		- Skin-rash	
- Sexual disturbanc	œs	- Urticaria	
•		- Decreased app	etite
2. BEHAVIORAL T	OXICITY	- Headache	
- Confusional react	ion		
- Excitement/agitati	ion		
- increased motor a	activity		
- Decreased motor	activity		
- Insomnia			
- Drowsiness			
- Lassitude			
3. CARDIOVASCU	LAR		
- Hypotension	<del></del>		
- Dizziness			
- Circulatory collaps	¢ <b>a</b>	•	
- Tachycardia	<del></del>		
- Hypertension	,		
- Lisherrangian		487	

Farmitalia Carlo Erba Ertamont Group 9550083

ENGLOSURE 13

Constrate Medital Coordination

#### ADVERSE DRUG REACTION - A CRITICAL REVIEW

#### CAUSE-EFFECT RELATIONSHIP

F.E.KARCH, L.LASAGNA (JAMA Dec. 22, 1975-Vol.234)

1. DEPINITE (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 criteris above.

#### 5. UNKNOWN

Relationship for which no evaluation can be made.

#### 6.NOT RELATED

A reaction for which sufficient information exists to indicate that the aetiology is unrelated to the study drug.

#### 9550083

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 physicial and mental condition of the patient." The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment and the weifare 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 no relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

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Cont'd encl. 14

#### I. BASIC PRINCIPLES

- 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.
- 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.
   Biomedical research involving human subjects should be conducted only by scientifically.
- 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.
- 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.
- 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.
- 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.
- 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 compiled with.

#### 9550083

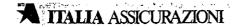
Contid encl. 14

#### MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE (Clinical research)

- 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.
- The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.
- 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.
- The refusal of the patient of participate in a study must never interfere with the physician-patient relationship.
- If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I, 2).
- 6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

#### III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Nonclinical blomedical research)

- 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.
- The subjects should be volunteers either healthy persons or patients for whom the experimental design is not related to the patient's illness.
- 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.
- in research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject.



9550083

bnclosure 15

Milano 11/81/90/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, scadenta 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

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

italia assicurazioni spa sede legale 18121 Genova via Fleschi 9 capitale sociale L. 30.000.000.000 trib. Genova 101 cciaa 30488 and processor autorizzata all'esercizio delle assicurazioni (art. 85 r.d.i. 986/29-4-23) c.f. 00432690105 processor all'acceptante della assicurazioni (art. 85 r.d.i. 986/29-4-23) c.f. 00432690105 processor all'acceptante della assicurazioni (art. 85 r.d.i. 986/29-4-23) c.f. 00432690105

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#### 9550083



Enclosure 15 Contid

prove cliniche, monche 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' imerenti 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 stassa. 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 tasto in lingua italiana. the one in Italian language will prevail for the purpose of interpretation.

In fede

ITAL A Assistanting S.p.A.

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MINTALIA CARLO MENA RAMONT GROUP S LIME	9550083		sure 16
	DRUG ACCOUNTABILITY		
mpound: REBOXETI	NE Protocol	N°: 20124/016	
4	nter, multinational double-blind study of the vs. Fluoxetine in patients suffering from Maj		
ntre N°/City	Investigat	or:	
	d m y to patient N° to patient N°:  received: 16 + 8 (dose 2)	Receipt	И•
Pat Pat. Date	Weekly treatment given	N° of remaining	N° of remaining
Init. Start		cartons per pat.	
	1 2 3 4 5 6 7 8 Dose 2 : 5 6 7 8	(dose 2)	+ L (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)
	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)	+
	1 2 3 4 5 6 7 8 Dome 2 : 5 6 7 8		(dose 2)
	1 2 3 4 5 6 7 8 Dome 2 : 5 6 7 8	+ (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)
	to be returned:	s signature:	494
• The present together wi	form, duly filled out, should be kept as r th his/her copy of CRFs.	ecord by the inves	stigator,
- A photocopy	of the present form should be given to the	monitor of Farmit	ALLE CETTO ETDE,

#### 9550083

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

The <u>start-up visit</u> 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;

#### 9550083

#### Prot. Nº 20124/016 Cont. Attachment A

- an IRB approved blank copy of the consent form;
- the list of the laboratory normal values or ranges of the lab. tests.

These documents will be sent to FICE-Milan. On the occasion of this visit the monitor will also check that the CRFs and the drug supply have been delivered to the Clinical Investigator and the accompanying letter, signed by the Clinical Investigator, will be collected. In addition the Monitor will identify the staff members who will be involved in the study conduct and the monitoring visits schedule will be agreed.

Following the start-up visit the form A (enclosed) will be filled in. Copy of it will be sent to FICE Milan.

 $\underline{\text{The first monitoring visit}}$  will be done immediately after the recruitment of the first two, three patients.

The periodic monitoring visits are carried out in order to:

- verify protocol adherence: patient eligibility (page 1
   of the CRF), times of assessments, completeness of
   data, pill count;
- 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

#### 9550083

#### Prot. Nº 20124/016

Cont. Attachment A

must immediately (within two working days) inform the Product Leader in Milan;

- 5 evaluate patient recruitment rate and treatment discontinuations:
- 6 verify study medication storage and accountability and collect bottles of completed treatments;
- 7 ensure continued acceptability of the facilities and of the staff.

CRFs will be completed in black ink and corrections, if needed, made only by the Clinical Investigator with a single line throughout; the corrections will be initialled by Clinical Investigator and dated. Each page of each completed CRF will be signed by Clinical Investigator.

After review for accuracy and completeness, the original and first copy of each page of the CRF will be removed (leaving the second copy with the Investigator). The first copy will be sent to Milan by Special Delivery Service for review and data processing while the original will be retained by the Monitor in the subsidiary until completion of the whole treatment period of the individual patient.

After each monitoring visit the periodic site visit report and the patients progress report form (form B and C enclosed) will be filled in. Copy of them will be sent to FICE Milan.

The study termination visit will be performed upon Investigator's completion of all CRFs of treated patients. During this visit:

- 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.

#### 9550083

Prot. Nº 20124/016

Cont. Attachment A

#### Study coordination

In order to obtain uniformity and standardization in the carrying out of the study a Steering Committee is established. All questions arising during the conduct of the study will be submitted to the Committee for advice and action taking.

In particular the Committee will take care of:

- queries about patients acceptability
- possible need of protocol amendments possible need of premature termination of the study
- acceptability of particular cases of protocol violations
- evaluation of clinically relevant adverse events and their scientific and ethical consequences in terms of issues raised or study discontinuation.

Members of the Committee will be 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 child. Monitors study Monitors.

#### 9550083

Pharmacia

Document 9550083

12.1.2 CRF SAMPLE

A complete CRF is filed in the Study Master File.

#### 9550083

## Pharmacia

Document 9550083

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

### 9550083

Pharma	acia Document 9550083
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 (Coinvestigators) 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

## 9550083

Pharmacia	a Document 9550083
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 <sup>0</sup> D Buenos Aires, Argentina
Centre 16:	Dr R. Montenegro (Principal investigator) Juncal 2425 8 <sup>0</sup> 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

Investigators signatures and Curricula vitae are filed in the Study Master File.

Homburg/Saar, Germany

### 9550083

Pharmacia

Document 9550083

12.1.5. CERTIFICATES OF ANALYSIS

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Pharmacıa Farmitalia Carlo Erba

9550083

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

Expiry date

: October, 1991 : 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 Abumelli

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

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9550083

CENTRO RICERCHE VIA GIOVANNI XXIII, 23 20014 NERVIANO

TELEFONO (0331) 587250 TELEGRAMMI FARMITAL A CAPLO EPBA 1-EP //ANO CASELLA POSTALE 2 TELES 310679 MONTED PER FARMITAL 4 "ERVIANO FARMITALIA CARLO ERBA

December 9th, 1992 DATA

#### CERTIFICATE OF ANALYSIS

#### REBOXETINE 6 mg capsules

Batch SF 1132

Manufacturing date

Expiry date

: September, 1990

: 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) : red-brown,

: positive

Identification

: mg 302.97

Average weight

: within the limits, according to Ph. Eur. 2nd Ed., Section V.5.2.2

Assav

: mg 5.993 of Reboxetine/capsule

Related substances

: 0.74%

Disintegration

: 6 minutes

Microbial contamination

Uniformity of content

: 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 Muuell

505

GRUPPO ERBAMONT

FARMITALIA CARLO ERBA

TELEFONO (02) 6995,1 (CENTRALINO) TELEGRAMMI ERBACAR MILANO CASELLA POSTALE 10519 C.C. POSTALE 619205 TELEX 330314 ERBA-1-

May 7th, 1992

VS. RIF

NS RIF

TEL DIRETTO CERTIFICATE OF ANALYSIS

REBOXETINE 6 mg capsules

Batch SF 1291

Manufacturing date

Expiry date

: March, 1992

: 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

S.R.L. PEDE LEGALL IN MILATO CAPITALE L. 528 782 127 000 IV. TRIBUNALE DI MILANO IFS N. 235246 VOL 6366 FASC, 16 C.C.I.A. N. 117/077 COD. FISC, E FART, IVA N. 07608290155

GRUPPO ERBAMONT

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VIA CARLO IMBONATI, 2 20159 MILANO 🌠 FARMITALIA CARLO ERBA

TELEFONO (02) 6995.1 (CENTRALINO TELEGRAMMI ERBACAR-MILANO CASELLA POSTALE 10519 C.C. POSTALE 619205

October 22, 1990

VS RIE

DATA

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 redbrown, 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</pre>

E. Coli and Salmonella : absent

Approved by

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: Virginio Busnelli Wousell

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S.R.L. - SEDE LEGALE IN MILANO CAPITALE L. 533.742.617.000 I.V. TRIBLITALE DI MILANO R.S. N. 238246 VOL. 6386 - FASC. 46 - C.C.J.A.A. N. 117107: COD. FISC. E PART. IVA N. 07608290156 GRUPPO ERBAMONT

9550083

VIA CARLO IMBONATI, 24 20159 MILANO

1

FARMITALIA CARLO ERBA

May 25th, 1992

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 Abusuelli

508

GRUPPO ERBAMONT

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VIA CARLO IMBONATI, 24

TELEFONO (02) 6895 1 (CENTRALINO TELEGRAMMI ERBACAR MILANO CASELLA POSTALE 10519 C.C. POSTALE 619205 🌠 FARMITALIA CARLO ERBA

DATA November 18th, 1992

VS. RIF

NS RIE

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</pre>

Approved by

: Virginio Busnelli

509

S.R.L. - REDE LEGALE IN MILANO CARITALE L. 528 702 127 000 1V FRIBUNALE DI MILANO H.S. N. 238246 VOL. 6366 - FASC. 46 - C.C.I.A.A. N. 117107 CCD, FISC. E. PART. IVA. N. 07808290158 GRUPPO ERBAMONT

. . . . . . .

VIA CARLO IMPIONATI. 24 20159 MILLERO FRAMITALIA CRALD ERSA

TELEFONO (102) 6995, I IGENTRALINO TELEGRAMMI ERRACAR MILANO CASELLA POSTALE (19519 C.C. POSTALE (1920) TELEX 192014 688A-1-

December 11th, 1991

VS. FIF.

NŞ. RIF

TEL CIRETTO

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

Appreciad his

: Virginio Busnelli

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GRUPPO ERBAMONT

# 9550083

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 No:

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 <u>vs</u> CRFs	Pharmacia - Milan	0217.11.1995	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: 7 - 30 H. 1996

### 9550083

Pharmacia

Document 9550083

12.1.7 RANDOMISATION LIST

REBOXETINE 016
Randomization 19550083

	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	reboxeti <b>ne</b>	
	27	1	27	reboxetine	
	28	1	28	fluoxetine	
	29	1	29	reboxetine	
	30	1	30	fluoxetine	
	31	1	31	reboxetine	
	32	1	32	fluoxetine	

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
33	2	1	fluoxetine
34	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	2	reboxetine
35	2	3	reboxetine
36	2	4	fluoxetine
37	2	5	reboxetine
38	2	6 7	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 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 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	29	fluoxetine
62	2	30	reboxetina
63	2	31	reboxetine
64	2	32	fluoxetine

514

Centers 19,20,21 and 22,23,24 are enlargement of centers 12,13,14 Centers 25,26 are enlargement of centers 15,16

REBCKETINE - 016
Rendomization 9550083

Nr Patient in the Study	Center	Mr Patient in the Center	Treatment	
65	3	1	fluoxetine	
66	3	1 2 3	fluoxetine	
67	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 3 '	28	fluoxetine	
93		29	fluoxetine	
94	3	30	fluoxetine	
95	3	31	reboxetine	
96	3	32	reboxetine	

 Center=4	

Nr Patient	Center	Nr Patient	Treatment
in the Study		in the Center	
In the Study		211 (110 0211(01	
97	4	1	reboxetine
°8	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

515

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

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. S	8	reboxetine
137	5	9	fluoxetine
138	5	10	reboxetine
139	5	11	reboxetine
140	555555555555555555555555555555555555555	12	fluoxetina
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		30	fluoxetine
159	5 5	31	fluoxetine
160	5	32	reboxetine

**	Center=6	***************************************

Nr Patient	Center	Nr Patient	Treatment
in the Study		in the Center	
161	6	1	fluoxetine
162	6	2	reboxetine
163	6	3	fluoxetine
164	6	4	reboxetine
165	6	5	fluoxetine
166	6	5	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
18Ì	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

516

Centers 19,20,21 and 22,23,24 are enlargement of centers 12,13,14 Centers 25,26 are enlargement of centers 15,16

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REBOXETINE - 016 Randomization9550083

Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
193	7	1	reboxetine
194	7 '	1 2 3	fluoxetine
195	7	3	fluoxetine
196	7	4	reboxetine
197	7	5 6	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 7	15	fluoxetine
208	7	16	reboxetire
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	reboxetina
253	8	29	fluoxetine
254	8	30	reboxetine
255	8	31 .	fluoxetine
256	8	32	reboxetine

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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
Randomization9550083

 	(	:enter=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	

			.,,	
Nr in	Patient 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	٠ 9	reboxetin <del>e</del>
	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	7.0	3.0	rehoveting

518

Centers 19,20,21 and 22,23,24 are enlargement of centers 12,13,14 Centers 25,26 are enlargement of centers 15,16

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REBOXETINE - 016
9550083
Randomization List

	C	enter=11	
Nr Pa in th	tient Center e Study	Nr Patient in the Center	Treatment
3	21 11	1	fluoxetine
	22 11	2	reboxetine
	23 11	3	fluoxetine
	24 11	4	reboxetine
	25 11	5	reboxetine
	26 11	6	reboxetine
	27 11	7	fluoxetine
	28 11	8	fluoxetine
	29 11	9	reboxetine
	30 11	10	reboxetine
	31 11	ii	fluoxetine
	32 11	12	fluoxetine
	33 11	13	reboxetine
	34 11	14	fluoxetine
	35 11	15	reboxetine
	36 11	16	fluoxetine
	37 11	17	reboxetine
	38 11	18	fluoxetine
	39 11	19	fluoxetine
	40 11	20	reboxetine
3	41 11	21	fluoxetine
	42 11	22	reboxetine
	43 11	23	reboxetine
	44 11	24	fluoxetine
· 3	45 11	25	reboxetine
3	46 11	26	fluoxetine
3	47 11	27	fluoxetine
3	48 11 '	28	reboxetine
3	49 11	29	fluoxetine
	50 11	30	reboxetine
	51 11	31	reboxetine
3	52 11	32	fluoxetine
	_		
	Ce	enter=12	
Nr Pa in th	tient Center e Study	Nr Patient in the Center	Treatment
*	53 12	,	fluoxetine
	53 12 54 12	1 2	fluoxetine
	54 12 55 12	<u>د</u> خ	reboyetine

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

519

Centers 19,20,21 and 22,23,24 are enlargement of centers 12,13,14 Centers 25,26 are enlargement of centers 15,16

		REBOXETI	NE - 016		
•		Pandoi	mization955008	3	
		C	anter=13	<del></del>	
	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	
	389 390	13 13	5 6	fluoxetine 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	
		Ce	enter=14		-
1	Nr Patient in the Study	Center	Nr Patient in the Center	Treatment	
	397	14 .	,	fluoxetine	
	398	14 .	1 2	reboxetine	
	399	14	3	reboxetine	
	400	14	4	fluoxetine	
	401	14	5	fluoxetine	
	402	14	6	reboxetine	
	403	14	7	reboxetine	
	404 405	14 14	8 9	fluoxetine fluoxetine	
	406	14	10	fluoxetine	
	407	14	11	reboxetine	
	408	14	12	reboxetine	
				• •	-
	Nr Patient in the Study	Center	Nr Patient in the Center	Treatment	
	409	15	1	reboxetine	
	410 411	15 15	2 3	fluoxetine reboxetine	
	412	15	4	fluoxetine	
	413	15	5	reboxetine	
	414	15	6	fluoxetine	
	415	15	7	reboxetine	
	416 417	15 15	8 9	fluoxetine reboxetine	
	418	15	10	reboxetine	
	419	15	ii	fluoxetine	
	420	15	12 .	fluoxetine	
	421	15	13	reboxetine	
	422	15	14	fluoxetine fluoxetine	
	423 424	15 15	15 16	reboxetine	
	425	15	17	reboxetine	
	426	15	18	fluoxetine	
	427	15	19	reboxetine	
	428	15	20	fluoxetine	
		'Ce	nte <del>r</del> =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	
	432 433	16 16	4 5	fluoxetine reboxetine	
	434	16	6	fluoxetine	
	435	16	7	reboxetine	
	436	16	8	fluoxetine	
<b>52</b> 0	437	16	9	reboxetine	
<del></del>	438	16	10	fluoxetine	
	439	16 '	11	fluoxetine	
Cen			are enlargement o Largement of cente	of centers 12,13,14 ers 15,16	

REBOXETINE - 016
Pandomization List

 	¢e	enter=16	
Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
440	37	10	u at accadina
440 441	16 16	12 13	reboxetine 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
 	Ce	enter=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 8	fluoxetine reboxetine
456 457	17 17	9	fluoxetine
458	17	1ó	fluoxetine
459	17	îi	reboxetine
460	17	12	reboxetine
461	17	. 13	fluoxetine
462	17	14	reboxetine
463	17	15	fluoxetine
464	17	16	reboxetine
465	,17	17 18	reboxetine fluoxetine
466 467	17 17	19	reboxetine
468	17	20	fluoxetine
 	Ce	enter=18	
Nr Patient in the Study	Center	Nr Patient in the Center	Treatment
469	18	1	reboxetine
470	18	2	fluoxetine
471	18	5	reboxetine
472	18	4	fluoxetine
473	18	5 6	fluoxetine
474 475	18 18	7	reboxetine 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 17	fluoxetine
485 486	18 18	18	reboxetine reboxetine
486 487	18	19	fluoxetine
488	18	20	fluoxetine

	*		NE 016		
•		Rando	800AGG <sub>notion</sub>	3	
		с	enter=19		
	Nr Patient	Center	Nr Patient	Treatment	
	in the Study		in the Center		
	489	19	1	reboxetine	
	490	19	ž	fluoxetine	
	491	19	3	reboxetine	
	492	19	4	fluoxetine	
	493	19	5	fluoxetine	
	494 495	19 19	6 7	reboxetine	
	496	19	8	reboxetine fluoxetine	•
	• • •		•	1100/1011110	
		_			
		C	enter=20		
	Nr Patient	Center	Nr Patient	Treatment	
	in the Study		in the Center		
	407				
	497 498	20 20	1 2	fluoxetine 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	
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		Ca	enter=21		
	Nr Patient	Center	Nr Patient	Treatment	
	in the Study		in the Center		
	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	
		Ce	enter=22		
	Nr Patient	Center	Nr Patient	Treatment	
	in the Study	Center	in the Center	irea (mec) (	
	513	22	1	fluoxetine	
	514	22	2	reboxetine	
	51 <b>5</b>	22	3	fluoxetine	
	516 517	22 22	4 5	reboxetine fluoxetine	
	518	22	6	reboxetine	
	519	22	7	reboxetine	
	520	22	8	fluoxetine	
		Ce	nter=23		
			i .		
	Nr Patient	Center	Nr Patient in the Center	Treatment	
	in the Study		in the center		
	521	23	1	reboxetine	
	522	23	2 3	fluoxetine	
	523	23	3	reboxetine	
	524	23	' 4	fluoxetine	
	525 524	23	5 4	reboxetine	
	526 527	23 23	6 7	fluoxetine reboxetine	
	528	23	8	fluoxetine	
	529	23	. 9	reboxetine	
	530	23	10	fluoxetine	
	531	23	11	reboxetine	
	532	23	12	fluoxetine	
522	533	23	13	fluoxetine	
9 A G	534	23	14	reboxetine	
	535	23	15	reboxetine	
	536	23	16	fluoxetine	
Ceni	ters 19,20.21 and	22,23.24	are enlargement	of centers 12,13,1	4
<b>V</b>			largement of cent		-
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REBOXETINE - 016
Randomization 9550083

	Nr Patient	Center	Nr Patient	Treatment	
	in the Study	0011101	in the Center		
			_		
	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	
	552 Nr Patient	24	16 nter=25 Nr Patient		
	552 Nr Patient in the Study	24 Ce Center	16 nter=25	reboxetine	
	552  Nr Patient in the Study  553	24 Ce Center 25	16 nter=25 Nr Patient in the Center 1	reboxetine  Treatment  fluoxetine	
	552 Nr Patient in the Study	24 Ce Center	16  Nr Patient in the Center  2	reboxetine	
	552  Nr Patient in the Study  553	24 Ce Center 25 25 25	16  Nr Patient in the Center  1 2 3	reboxetine  Treatment  fluoxetine	
	Nr Patient in the Study 553 554	24 Ce Center 25 25	16  nter=25  Nr Patient in the Center  1 2 3 4	Treatment fluoxetine fluoxetine fluoxetine	
	552 Nr Patient in the Study 553 554 555	24 Ce Center 25 25 25	16  Nr Patient in the Center  1 2 3 4 5	Treatment  fluoxetine fluoxetine reboxetine	
	552  Nr Patient in the Study  553 554 555 556	24 Ce Center 25 25 25 25	16  Nr Patient in the Center  1 2 3 4 5	Treatment  fluoxetine fluoxetine reboxetine reboxetine	
	552  Nr Patient in the Study 553 554 555 556 557	24 Ce Center 25 25 25 25 25 25	16  nter=25  Nr Patient in the Center  1 2 3 4	Treatment  fluoxetine fluoxetine reboxetine reboxetine reboxetine	
	552  Nr Patient in the Study  553 554 555 556 557 558	24 Ce Center 25 25 25 25 25 25 25	16  Nr Patient in the Center  2 3 4 5 6	Treatment  fluoxetine fluoxetine reboxetine reboxetine reboxetine fluoxetine	
·	552  Nr Patient in the Study  553 554 555 556 557 558 559	24 Ce Center 25 25 25 25 25 25 25 25	16  Nr Patient in the Center  1 2 3 4 5 6 7	Treatment  fluoxetine fluoxetine reboxetine reboxetine reboxetine fluoxetine fluoxetine fluoxetine	
	552  Nr Patient in the Study  553 554 555 556 557 558 559 560	24 Ce Center 25 25 25 25 25 25 25 25 25	16  Nr Patient in the Center  1 2 3 4 5 6 7	Treatment  fluoxetine fluoxetine reboxetine reboxetine fluoxetine fluoxetine fluoxetine fluoxetine	
	552  Nr Patient in the Study  553 554 555 556 557 558 559 560 561	24 Ce Center 25 25 25 25 25 25 25 25 25	16  Nr Patient in the Center  2 3 4 5 6 7 8 9	Treatment  fluoxetine fluoxetine reboxetine reboxetine reboxetine fluoxetine fluoxetine fluoxetine reboxetine reboxetine	

	Ce	inter=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

### 9550083

Pharmacia

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12.1.8 LABORATORY REFERENCE VALUES AND CRITERIA USED TO JUDGE LABORATORY ABNORMALITIES AS CLINICALLY RELEVANT

### PHARMACIA CNS550083

#### REBOXETINE - PROTOCOL 20124/016 APPENDIX No.: 12.1.8 LABORATORY REFERENCE VALUES

			Range va	1ues	
		Femal	9	Male	
		Min	Ман	Min	Max
Laboratory test	Units				
HB	g/dl	12.00	16.00	13.50	17.5
HT	ž	36.00	46.00	41.00	53.0
RBC	10-6/mm-3	4.00	5.20	4.50	5.9
PLATELETS	10-3/mm-3	150.00	400.00	150.00	400.0
ESR/SEDIMENT. RATE 1st h	min	0.00	10.00	0.00	10.0
ESR/SEDIMENT. RATE 2nd h	mm	0.00	20.00	0.00	20.0
HBC	10-3/mm-3	4.50	11.00	4.50	11.0
WBC: N	X	57.00	67.00	57.00	67.0
MBC: E	ä	1.00	3.00	1.00	3.0
HBC: B	ž	0.00	0.75	0.00	0.7
	ž	23.00	33.00	23.00	33.0
MBC: L MBC: M	â	3.00	7.00	3.00	7.0
	mg/dl	0.50	1.10	0.60	1.2
CREATININE	mg/di ml/min	88.00	128.00	97.00	137.0
CREATININE CLEARANCE		15.00	35.00	15.00	35.0
UREA	mg/dl	7.00	18.00	7.00	18.0
BUN	mg/dl	2.60	6.00	3.50	7.2
URIC ACID	mg/dl	6.40	8.30	6.40	8.3
TOT. PROTEINS	g/dl		5.00	3.50	5.0
ALBUMINE	g/dl	3,50		0.20	1.0
TOT BILIRUBIN	mg/dl	0.20	1.00	0.00	0.2
DIR BILIRUBIN	mg/dl	0.00	0.20		
SGOT	U/1	10.00	30.00	10.00	30.0
SGPT	U/1	5.00	30.00	5.00	30.0
GANNA GT	U/1	8.00	40.00	9.00	50.0
LDH	0/1	210.00	420.00	210.00	420.0
ALK. PHOSPH.	U/1	56.00	155.00	62.00	176.0
GLOBULINS ALPHA 1	g/d1	0.10	0.30	0.10	0.3
GLOBULINS ALPHA 2	g/dl	0.60	1.00	0.60	1.0
GLOBULINS BETA	g/dl	0.70	1.10	0.70	1.1
GLOBULINS GAMMA	g/dl	0.80	1.60	0.80	1.6
SEDIMENT.	mm/h	0.00	20.00	0.00	15.0
TOT. CHOLEST.	mg/dl	152.00	268.00	158.00	276.0
HDL	mg/dl	35.00	65.00	29.00	60.0
TRIGLYCERIDES	mg/dl	38.00	160.00	49.00	284.0
GLUCOSE	mg/d1	70.00	105.00	70.00	105.0
	mEq/1	136.00	146.00	136.00	146.0
NA+	mEq/1	98.00	106.00	98.00	106.0
CL-	mEq/1	3.50	5.10	3.50	5.1
K+		4.50	5.50	4.50	5.5
Ca++	mEq/I	1.00	1.50	1.00	1.5
P04~-	mEq/1		12.00	5.00	12.0
T4	ug/d1	5.00		2.00	10.0
TSH	mU/1	2.00	10.00	4.00	10.0

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1.8

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REBUXEIINE - PROIDCOL ZU124/016 APPENDIX No.: 12.1.8	10COL 20124/016 .: 12.1.8
CRITERIA USED TO JUDGE LABORATORY AB	ABNORMALITIES AS CLINICALLY RELEVANT
Laboratory test	Percent variation above or below normal range (*)
88	- 15
16	
DI APPLEME	
Laichelb	200
2.000	
1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 . July 1 .	200
2	
HDC: I	DS +
ADC: D	DR 1
CKEATININE	- PG +
UREA	- 20
NO.	- A
TOT. PROTEINS	
ACBUMINE	-+ 30
TOT BILIRUBIN	+ 100
DIR BILIRUBIN	+ 100
2001	+ 100
ZdbL	+ 100
GANNA CT	+ 400
	+ 100
	+ 100
ALPHA	-+ 30 •
	-+ 30
	+ 30
CLOBULINS CAMMA	-+ 30
TOT. CHOLEST.	+ 30
HOL	- 20
TRICLYCERIDES	
GLUCOSE	
NA+	
- <del>1</del>	
**	
Ca++	
	+ 13
13	
+1.	D. + +
ESD/SENTWONT DATE	
	מסוד נאפון

(\*) MINUS INDICATES BELOW THE LOWER LIMIT OF NORMAL RANGE, AND PLUS ABOVE THE UPPER LIMIT OF NORMAL RANGE

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12.1.9 ADVERSE EVENTS GROUPED IN CLUSTERS

# 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 of
GENERAL DISORDERS	ASTHENIA / FATIGUE	ASTHENIA	Fluoxetine	1	
		FATIGUE	Fluoxetine	4	
		FATIGUE	Reboxetine	4	
ISORDERS, GENERAL	AEDEMA	OEDEMA GENERALISED	Fluoxetime	1	
		OEDEMA LEGS	Reboxetine	1	
	CARDIAC ISCHEMIA AND RELATED SYMPTOMS	CHEST PAIN PRECORDIAL	Fluoxetine	1	
	FLUSHING / HOT FLASHING	FLUSHING	Reboxetine	2	
		HOT FLUSKES	Fluoxetine	1	
		HOT FLUSHES	Reboxetine	2	
	HYPOTENSION AND RELATED SYMPTOMS	DIZZINESS	Fluoxetine	8	
	HILDIGHOLON AND ADDRESS DIM TOND	DIZZINESS	Reboxetine	18	
		HYPOTENSION	Fluoxetine	1	
		HYPOTENSION	Reboxetine	i	
		HYPOTENSION POSTURAL	Reboxetine	i	
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	i	
		GASTRITIS	Reboxetine	i	
		NAUSEA	Fluoxetine	15	
		NAUSEA	Reboxetine	11	
DERS	ANEMIA	ANAEHIA	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	i	
		NERVOUSNESS	Fluoxetine	3	
		NERVOUSNESS	Reboxetine	1	
IGES DISORDERS	ERYTHEMA / RASH	rash	Reboxetine	2	
		RASH MACULO-PAPULAR	Fluoxetine	1	

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	PHARMACIA CNS R&D	RAD	
	REBOXETINE - PROTOCOL 20124/016 Appendix No.: 12.1.9	20124/016 .1.9	
	ADVERSE EVENTS GROUPED IN CLUSTERS	IN CLUSTERS	
Body System	Cluster	Adverse event	Treatment
URINARY SYSTEM DISORDERS	URINARY HESITANCY / RETENTION	URINARY RETENTION HICTURITION DISORDER HICTURITION DISORDER	Reboxetine Fluoxetine Reboxetine
VISION DISORDERS	BLURRED VISION	VISION ABNORMAL VISION ABNORMAL	Fluoxetine

No of AE with AE

# 9550083

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12.1.10 ECG CODES

#### PHARMACIA CNS RED REBOXETINE - PROTOCO 20124/016

APPENDIX No.: 12.1.10

ECG CODES

## 0 Normal

```
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
          ● Ventricular ectopic beats:
51 - Occasional
52 - Frequent (>6/mm)
53 - Polymorphic
54 - Couplets
55 - Ventricular Tachycardia
50
60

    Atrial fibrillation/flutter

105

    Vagotonia

108
           • Atrial-ventricular dissociation
2 Conduction disorders
          • A-V Block
71 -
72 -
73 -
70
                               Complete
85
           · Right bundle branch block
           · Left bundle branch block
86
87
             Left anterior hemiblock
           · Left posterior hemiblock
88
              Bifascicular Block (specify)
90
           • Trifascicular Block (specify)
             Conduction disorders
103

    Left axial deviation

106
           · Right incomplete bundle branch block
3 Ischemic signs
102
           • Ripolarization disturbances
107

    Non specific ST-T changes

    Myocardial ischemia

82
           · Acute Myocardial Infarction
84
4 Other
80
           · Left ventricular hypertrophy
81
              Right ventricular hypertrophy
83
           · Previous Myocardial infarction
93
              (specify)
```

• Right axial deviation

531

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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 : 195 -> % LOWER LIMIT u95 -> % UPPER LIMIT
   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:
    else 15-2; end; end; u95 = z * 100; if k > 100 then put '**1** convergence was not attained in 100 ' iterations ' k= z= pct= ls= li= ;
     ls=pct/100; * limite superiore;
li=0; * limite inferiore;
    do k =1 to 100;
  z=((ls - li) / 2) + li;
  a =1 - probbnml((1 - z), pop_,(_pop_ - _nr__));
  if .97501 > a > .97499 then leave;
  else
      else if a > .97501 then li = z; else ls=z;
   end; 195 = z * 100; 195 = z * 100 then put '**1** 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: LABO03
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 indice k
                                                             &var cod_trt
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 = .;
 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;
indlee = (lab_bas-1) * 3 + (lab_now);
output stat;
                         * proc univariate * ;
proc sort data = stat;
by &var cod_trt lab_par day;
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;
                                                                                        534
```

```
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;
                                     sum=k;
     data maxw(keep = &var cod_trt lab_par day p_maxw num_ord);
    set maxw;
      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(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;
                                 else do;
if a32 > 0 or a23 > 0 then do;
if a32 = a23 then p_maxw = 1;
                                                                                                                22 = a23 then p_man = ,
else do;
denx2=a32+a23;
numx2=min(a32,a23);
p_maxw = 2. * probbnm1(0.5,denx2,numx2);
                                    | Numxx=min(a32,a23); | P_maxw = 2. * probbnm1(0.5,denx2,numx2); | end; | end; | if a32 > 0 .....; | else if a21 > 0 or a12 > 0 then do; | if a21 = a12 then p_maxw = 1; | else do; | denx2=a21+a12; | numx2=min(a21,a12); | p_maxw = 2. * probbnm1(0.5,denx2,numx2); | end; | if a21 > 0 .....; | else if a31 > 0 or a13 > 0 then do; | if a31 = a13 then p_maxw = 1; | else do; | denx2=a31+a13; | numx2=min(a31,a13); | p_maxw = 2. * probbnm1(0.5,denx2,numx2); | end; | end; | if a31 > 0 .....; | else p_maxw = 1; | * tutti gli elementi no su diag.; | end; * if denx2 <= 0 .....; | else p_maxw = 1; | * tutti gli elementi no su diag.; | end; * if denx2 <= 0 .....; | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | end; * if last day. | en
                                      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;
                                                                                                                                                                                                                                                                 535
```

```
9550083
                          PHARMACIA CNS R&D
                      APPENDIX NO. : 12.1.11
       PGM NAME: tay50var
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;
 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 qminval= 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;
    proc sort data = graf;
  by level;
RUN;
                                                                               537
goptions reset=global gunit=pct /*rotate=landscape */
```

```
rotate=portrait device=gddmfam4 gddmtoken=fine240 gddmnickname=p3820 vsize= hsize= 7 in hpos= vpos= vorigin=1.25 in horigin=2.25 in ftext=swiss htitle=3 htext=2 display;
  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
                    rame value=(f=swiss h=2.0) position=(bottom center outside);
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 ml-ml0 sti-st10 i 0;
format trt1-trt10 $8. trt_con $30.;
retain trt1-trt10;
array tmean (10) ml-ml0;
array tstd (10) st1-st10;
array tstd (10) trt1-trt10;
i = i + 1;
file print;
  i = i + 1;
file print;
if i > 10 then
   put 'MORE THAN 10 TREATMENTS '
        ' delle array ' i= trt1= trt2= trt3= trt4= trt5= trt6=
        trt7= trt8= trt9= trt10=;
  else do;
    ttrt(i) = cod_trt;
    tmean(i) = lsmean;
    tstd(i) = stderr;
                                                                                                         538
  tstd(1) = stdell,
end;
if fine=1 then do;
da = 0;
DO K = 1 TO I - 1; *
                                                                              MAX NUMBER OF TREATMENTS
```

## 9550083

Pharmacia

Document 9550083

12.1.12 SELECTION OF STATISTICAL ANALYSIS OUTPUTS

#### 9550083

#### 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 PHARMACEVIICAL MILANO - CNS REBUXETINE - PROTOCOL 20124/016 APPENDIX No.: 12.1.12

ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON AT BASELINE

Joneral Linear Models Procedure Class Level Information Number of observations in data set = 163

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FEBREALTH FILMAGALEUTILAL MILANO - CNS REBUXETINE - PROTOCOL 20124/016 APPENDIX No.: 12.1.12	ALYSTS OF VADIANCE ON TOTAL SCHOOL MANIFOLM AT DASSITION

depondent variable: nano	OUND : D				
Source	占	Sum of Squares	Mean Square	F Value	Pr v F
Kode1	-	62.28241736	62,28241736	2.79	0.0966
Error	191	3590,41696915	22,30072652		
Corrected Total	162	3652,69938650			
	R-Square	C. V.	Root MSE		HAMO Bean
	0.017051	16.89149	4,72236450		27.95705521
Source	10	Type I SS	Kean Square	F Value	Pr > F
COD_TRI	-	62.28241736	62.28241736	2.79	9960.0
Source	Ą	Type III SS	Mean Square	F Value	Pr > F
COD_TRT	-	62.28241736	62.28241736	2.79	0.0966

PHARMACIA CNS RRD
REBOXETINE - PROTOCOL 20124/016
APPENDIX NO.:12.1.12
HAMILYON DEPRESSION RATIVE SCALE
STRUTTYE STATISTICS ON LAST ASSESSENEY

TOTAL SCORE HAMILTON	)RE	BASELINE	LAST ASSESS.	DECREASE
TREATNE- NT				
Fluoxet-	×	87	87	87
)	HEAN	27.38	10.62	16.76
	S.D.	4.15	8.66	8.89
Reboxet-	z	9.6	76	16
991	MEAN	28.62	9.39	19.22
	S.D.	5.31	7.26	8.50

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PHARMACIA PHARMACEUTICAL MILAND - CNS

REBOXETINE - PROTOCOL 20124/016 APPENDIX No.: 12.1.12

· ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT HITH RESPECT TO BASELINE VALUE

Number of observations in data set = 163

N

PHARNACIA PHARMACEUTICAL MILANO - CNS
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REBOXETINE - PROTOCOL 20124/016 APPENDIX No.: 12.1.12 AMALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT WITH RESPECT TO BASELINE VALUE.

Pependent Variable: DIFFN	B: DIFFN				
ource	Ä	Sum of Squares	Mean Square	F Value	P. v. F.
lodel	τ-	246.49122900	246.49122900	3.25	0.0734
kror	161	12217.12840290	75.88278511		
corrected Total	162	12463.61963190			
	R-Square	c.v.	Roat MSE		DIFFN Mean
	0.019777	48.64354	8.71107256		17.90797546
ource	占	Type I SS	Mean Square	F Value	Pr > F
OD_TRT	-	246.49122900	246.49122900	3.25	0.0734
source	占	Type III SS	Nean Square	F Value	Pr > F
OD TRT	-	246.49122900	246.49122900	3.25	0.0734

PHARMACEUTICAL MILANO - CMS

REBOXETINE - PROTOCOL 20124/016

APPENDIX NO.: 12.1.12

AMALVEIS DF VARIANCE ON TOTAL SCORE HAMILION DECREASE AT LAST ASSESSMENT MITH RESPECT TO BASELINE VALUE

General Linear Models Procedure

Least Squares Means

COD\_TRT

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016

APPENDIX NO.: 12.1.12

RAMILTOW DEFRESSION RATING SCALE
DESCRIPTIVE STATISTICS ON LAST ASSESSMENT
VERE PATIENTS AUDGED BY CGI SEVERITY AT ARSELINE

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TOTAL SCORE HAMILTON	E HAMILTON		BASELINE	LAST ASSESS.	DECREASE
SEVERE	TREATHENT				
NO	Fluoxetine	z	2.1	27	21
		MEAN	24.71	6.24	18.48
		s.b.	3.08	6.56	5.90
	Reboxetine	Z	21	21	21
		MEAN	25.43	12.24	13.19
		S.D.	1.63	8.29	8.31
YES	Fluoxetine	Z	99	99	99
		MEAN	28.23	12.02	16.21
		s.D.	4.10	8.82	9.63
	Reboxetine	N	55	55	25
		MEAN	29.84	8.31	21.53
		S.D.	5.71	6.58	7.42

PHARHACIA PHARNACEUTICAL MILANO - CNS

APPENDIX No.: 12.1.12

SEVERE PATIENTS JUDGED BY CGI SEVERITY AT BASELINE IS OF VARIANCE DM TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENT MITH RESPECT TO BASELINE VALUE

meral Linear Models Procedure Class Level Information

lass Level Information

NA Levels Values

Due to missing values, only 121 observations can be used in this analysis.

PHARMACIA PHARMACEUTICAL MILANO - CNS

SOXETINE - 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

Dependent Variable: Ultrn	B: ULFFA					
Source	10 10	Sum of Squares	Kean Square	F Value	Pr > F	
Model	-	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 Heam	
	0.086041	46.69231	8.69788895		18,62809917	
Source	¥	Type I SS	Rean Square	F Value	Pr > 7	
COD_TRT	-	847.52506887	847.52506887	11.20	0.0011	
Source	DF	Type III SS	Mean Square	F Value		
COD TRT	-	847.52506887	847.52506887	11.20	0.0011	

PHARHACIA PHARHACEUTICAL MILANO - CNS

FINE - PROTOCOL 20124/016

SEVERE PATIENTS JUDGED BY CGI SEVERITY AT BASELINE OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSHENT WITH RESPECT TO BASELINE Y

Least Squares Heens
COD\_TRT DIFFN
LSMEAN
FLU 16.2121212
RBX 21.5272727

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ACIA CNS R&D
PROTOCOL 20124/016

N NO:: 12.1.12
ESSION RATING SCALE
TITGS ON LAST ASSESSMENT

TOTAL SCI	TOTAL SCORE BAMILTON	NO	BASELINE	LAST ASSESS.	DECREASE
MELANCH- OLIC	TREATHE- NT				
OX.	Fluoxet-	z	38	38	38
		MEAN	26.21	11.32	14.89
		S.D.	4,48	8.74	8.26
	Reboxet-	z	29	29	29
		NEAN	26.79	10.66	16.14
		S.D.	3.43	8.33	8.28
YES	Fluoxet-	z	39	39	39
	0	MEAN	28.74	10.46	18.28
		S.D.	3.87	8.71	9.46
	Reboxet-	z	39	39	39
		HEAN	30.67	8.74	21.92
		S.D.	6.11	6.85	8.50

PHARMACIA PHARMACEUTICAL MILANO - CNS

MELANCHIC PATIENTS
ANALYSIS OF VARIANCE ON TOTAL SCORE HANILION DECREASE AT LAST ASSESSMENTN WITH RESPECT TO BASELINE VALUE

FLU RBX COD\_TRI Class

Number of observations in data set = 80

NOTE: Due to missing values, only 78 observations can be used in this amalysis.

PHARMACIA PHARMACEUTICAL MILANO - CNS

XETINE - PROTOCOL 20124/016 APPENDIX No.: 12.1.12 ANALYSIS OF VARIANCE ON TOTAL SCORE HAMILTON DECREASE AT LAST ASSESSMENTN NITH RESPECT TO BASELINE VALUE

General Linear Models Procedure

Dependent Variable: DIFFN	B: DIFFN				
Source	40	Sum of Squares	Mean Square	F Value	P. v. F.
Model.	~	258.51282051	258.51282051	3.20	0.0777
Error	76	6144.6666667	80.85087719		
Corrected Total	77	6403.17948718			
	R-Square	C.V.	Root MSE		DIFFN Mean
	0.040373	44,72918	8.99171158		20.10256410
Source	쓤	Type I SS	Mean Square	F Value	Pr > F
COD_TRT	-	258.51282051	258.51282051	3.20	0.0777
Source	ĐĘ.	Type III SS	Mean Square	F Value	ያ › ፕ
COD_TRT	-	258.51282051	258.51282051	3.20	0.0777

PHARMACIA PHARMACEUTICAL MILANO - CNS

DIFFN COD\_TRT

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#### 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
REBDXETINE - PROTOCOL 20124/016
APPENDIX No.: 12.1,12

EFFICACY; KAPLAN / MEIER ANALYSIS - TIME TO ONSET OF RESPONSE (50 % HAMILTON DECREASE)
The ITEFFER Proceedings

The LIFFIEST Procedure Summary of the Number of Censored and Uncensored Values	Censored 2Censored	26.4368 22.3684	24,5399
rocedure ed and Unce	Censored	23	40
The LIFETEST Procedure mber of Censored and U	Failed	55 GE	123
The the Number	Total	87 76	163
Summary of	COD_TRI	FLU	Total

Testing Homogeneity of Survival Curves over Strata Time Variable DAY

٠	Wilcoxon	-227.00 227.00	
Rank Statistics	Log-Rank	-1.3551	
	COD_TRET	FLU	

nk Statistics	RBX	-27.2588 27.2588	on Statistics
for the Log-Ra	FLU	27.2588 -27.2588	for the Wilco
Covariance Matrix for the Log-Rank Statistics	COD_TRT	FLU	Covariance Matrix for the Wilcoxon Statistics

COD\_TRT

-299728 299728	Strata	Pr > Chi-Square	0.7952 0.6784 0.7349
80 80	over		
299728 -299728	Test of Equality over Strata	Chi-Square	0.0674 0.1719 0.1147
FLU RBX	Test	Test	Log-Rank Hilcoxon -2Log(LR)

PHARMACIA CNS R&D

CUMULATIVE RISK OF DEVELOPING THE FIRST ADVERSE EVENT DURING TREATHENT REBOXETINE - PROTOCOL 20124/016 APPENDIX No.: 12.1.12

The LIFETEST Procedure the Number of Censored and Uncensored Values	Censored XCensored	32,5843 32,9114	32.7381
rocedure ed and Unce	Censored	29 26	55
The LIFETEST Procedure Imber of Censored and Ur	Failed (	60 53	113
The Number	Total	89 79	168
Summary of	COD_TRI	FLU RBX	Total

		٠		
	Wilcoxon	-1289.0 1289.0	Rank Statistics	i
Rank Statistics	Log-Rank	-5.1212 5.1212	x for the Log-	:
æ	COD_TRT	FLU RBX	Covariance Matrix for the Log-Rank Statistics	EGB GOO

RBX	-25, 1296 25, 1296	n Statistics	RBX	-359527 359527
FLU	25.1296 -25.1296	for the Wilcoxon	FLU	359527 -359527
COD_TRT	FLU	Covariance Matrix f	COD_TRT	FLU RBX

Pr > Chi-Square	0.3070 0.0316 0.3451
P	
Chi-Square	1.0436 4.6214 0.8914
Test	Log-Rank Wilcoxon -2Log(LR)
	Chi-Square DF

CUMULATIVE RISK OF DEVELOPING AGITATION / ANXIETY / NERVOUSNESS

The LIFETEST Procedure Summary of the Number of Consored and Uncensored Values	Consored 2Censored	88.7640 96.2025	92.2619
rocedure ed and Unce	Censored	79	155
The LIFETEST Procedure umber of Censored and U	Failed	₽ m	13
The the Number	Total	89 79	168
Summary of	COD_TRT	FLU RBX	Total

Testing Homogeneity of Survival Curves ovor Strata Time Variable DAY

			tics			tics
3	Wilcoxon	514.00 -514.00	g-Rank Statis	RBX	-3.24045 3.24045	Wilcoxon Statistics
num pearsons	Log-Rank	3.2214	r the Lo	FLU	3.24045 -3.24045	r the Ni
· vernu	COD_TRT Le	FILU RBX	Covariance Matrix for the Log-Rank Statistics	COD_TRT	FLU	Covariance Matrix for the

Strata	Pr > Chi-Square	0.0735	0.0624	0.0643
over	OF	-	-	-
of Equality	Chi-Square	3.2024	3.4722	3.4226
Test	Test	Log-Rank	Kilcoxon	-2Log(LR)
	Test of Equality over Strata	Test of Equality over S Chi-Square DF	t of Equality over Strat P Chi-Square DF Chi-	t of Equality over Strat  Chi-Square DF Chi- 3.2024 1 3.4722 1

CUMULATIVE RISK OF DEVELOPING ASTHENIA / FATIGUE

The LIFETEST Procedure Summary of the Number of Censored and Uncensored Values	XCensored	94.3820 94.9367	94.6429
rocedure ed and Unce	Censored	84 75	159
The LIFETEST Procedure wher of Censored and U	Failed	w ≄	6
The the Number	Total	89	168
Summary of	COD_TRT	FLU	Total

Testing Homogeneity of Survival Curves over Strata Time Variable DAY

	Wilcoxon	-4.0000 4.0000	the Log-Rank Statistics	RBX	-2,23278
RAIIR DISCLES	Log-Rank	0,18839 -0,18839	t for the Log-h	FLU	2,23278
New York	COD_TRT	FLU RBX	Covariance Matrix for	COD_TRT	FLU

RBX	-53566.5 53566.5	Strata	Pr > Chi-Square	0.8997	0.8676
5	ល្ស	over	늄		-
FLU	53566.5 -53566.5	Test of Equality over Strata	Chi-Square	0.0159	0.0278
COD_TRT	FLU RBX	Test	Test	Log-Rank Wilcoxon	-2Log(LR)

und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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CUBULATIVE RISK OF DEVELOPING CONSTIPATION

83 62 145

	Wilcowon	-1085.0 1085.0
Rank Statistics	Log-Rank	-6.8156 6.8156
	COD_TRT	FLU

ank Statistics	RBX	-5.61253 5.61253	xon Statistics
for the Lag-R	FLU	5.61253	k for the Wilco
Covariance Matrix for the Log-Rank Statistics	COD_TRT	FLU RBX	Covariance Matrix for the Wilcoxon Statistics

COD\_TRT FLU

Pr > Chi-Square	0.0040 0.0025 0.0029
占	
 Chi-Square	8.2765 9.1411 8.8755
Test	Log-Rank Hilcoxon -2Log(LR)

PHARMACIA CNS RED	REBOXETINE - PROTOCOL 20124/016 APPENDIX No.: 12.1,12	CUNULATIVE RISK OF DEVELOPING DIARRHOEA
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The LIFETEST Procedure Summary of the Number of Censored and Unconsored Values	XCensored	93.2584 98.7342	95.8333
rocedure ed and Unce	Censored	83 78	161
The LIFETEST Procedure mber of Censored and Un	Failed	9 -	7
The the Number	Total	89 79	168
Summary of	COD_TRT	FLU	Total

sting Homogeneity of Survival Curves over Strata Time Variable DAY

Kank Statistics  COD_IRT Log-Rank Wilcoxon FLU 2.3363 348.00 RBX -2.3363 -348.00  Covariance Matrix for the Log-Rank Statistics COO_TRY FLU RBX	Milcoxon 348.00 -348.00 Rank Statistics PRW
rd ×	nk Statistics Log-Rank 2.3363 -2.3363 for the Log-

or the Log-i FLU 1.73909 -1.73909 or the Milco FLU 41632.4	41632.4
4 for 1	-41632.4
Covariance Matrix for the Log-Rank Statistics COD_TRT FLU REX FLU 1.73909 -1.73909 RBX -1.73909 1.73909 Covariance Matrix for the Milcoxon Statistics COD_TRT FLU 44632.4 -44632.4	KBX

Strata	Pr > Chi-Square	0.0765 0.0881 0.0573
over	된	
Test of Equality over Strata	Chi-Square	3.1385 2.9089 3.6144
Test	Test	Log-Rank Wilcoxon -2Log(LR)

FARRIBULE CRO KED	REBOXETINE - PROTOCOL 20124/016 APPENDIX No.: 12.1.12	CUNULATIVE RISK OF DEVELOPING HEADACHE / MIGRANE	Company Danced

The LIFETEST Procedure Number of Censored and Uncensored Values	XCensored	77.5281 78.4810	77.9762
rocedure ed and Unce	Censored	69 62	131
The LIFETEST Procedure Imber of Censored and Un	Failed	20	37
The the Number	Total	89 79	168
Summary of	COD_TRT	FLU	Total

Strata	
over St	
Curves	¥Χ
Survival	ariable D
	.≍ ø
Homogeneity o	Tim
esting	

1	Hilcoxon	93,000 -93,000	-Rank Statistics	RBX	-9.12765 9.12765	
	Log-Rank	0.64242	for the Log	FLU	9.12765	
	COB_TRT	FLU RBX	Covariance Matrix for the Log-Rank Statistics	COD_TRT	FLU RBX	

xon Statistic	RBX	-188081 188081	Strata	Pr > Chi-Square	0.8316
Wilco	FLU	181	over	DF	
rix for the	Ĭ.	188081 - 188081	Test of Equality over Strata	Chi-Square	0.0452
Covariance Matrix for the Wilcoxon Statistic	COD_TRI	FLU RBX	Test	Test	Log-Rank Wilcoxon

CUMULATIVE RISK OF DEVELOPING HYPOTENSION AND RELATED SYMPT	The LIFETEST Procedure Summary of the Number of Censored and Unconsored Values	Censored 2Censored	92.1348 81.0127	86.9048
HYPOTENSION	rocedure ed and Unce	Censored	87 64 97	146
DEVELOPING	The LIFETEST Procedure imber of Censored and Us	Failed	7 51	22
VE RISK OF	The f the Numbe	Total	89 79	168
COMULATI	Summary o	COD_TRI	FLU RBX	Total

ing Homogeneity of Survival Curves over Strata Time Variable DAY

	Wilcoxon	-712.00 712.00	tatistics	RBX	-5.41364 5.41364
ics			og-Rank S	_	
Rank Statistics	Log-Rank	-4.9161 4.9161	ix for the l	FLU	5.41364
	COD_TRT	FLU RBX	Covariance Matrix for the Log-Rank Statistics	COD_TRT	FLU

5.41364	xon Statistics	RBX	-120071 120071	Strata	Pr > Chi-Square	0.0346
-5.41364	Covariance Matrix for the Wilcoxon Statistics	FLU	120071 -120071	Test of Equality over Strata	Chi-Square DF	4.4644 1
RBX	Covariance Mat	COD_TRT	FLU RBX	Test	Test	Log-Rank Wilcoxon

PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 APPENDIX No.: 12.1.12	CUMULATIVE RISK OF DEVELOPING INSORNIA
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S			
The LIFERST Procedure Summary of the Number of Censored and Uncensored Values	XCensored	89.8876 87.3418	88.6905
rocedure ed and Unce	Censored	80 89	149
The LIFETEST Procedure imber of Censored and U	Failed	e. 6	19
The Numbe	Total	89	168
Summary of	COD_TRT	FLU	Total

	Wilcoxon	-213.00 213.00	:
Rank Statistics	Log-Rank	1,1811	:
-	COD_TRT	FLU	

CONTRACTOR THE TAX THE PASS MAIN PLACES.	COD_TRT FLU RBX	FLU 4.70280 -4.70280 RBX -4.70280 4.70280	Covariance Matrix for the Milcoxon Statistics	COD_TRT FLU RBX	FLU 105541 -105541 RBX -105541 105541	Tact of Donality ones Steats
	COD	FLU RBX	Covariance	Coo	FLU	•

0.5860 0.5121 0.5933
0.2966 0,4299 0.2853
Log-Rank Wilcoxon -2Log(LR)

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 APPENDIX No.: 12.1.12	
-------------------------------------------------------------------------------	--

CUMULATIVE RISK OF DEVELOPING MOUTH DRY

8			
nsored Valu	Censored XCensored	91.0112 65.8228 79.1667	
The LIFETEST Procedure Sunmary of the Number of Censored and Uncensored Values	Censored	81 52 133	
LIFETEST P of Censor	Failed	8 27 35	
The the Number	Iotal	89 79 168	
Summary of	COD_TRT	FLU RBX Total	

iting Homogeneity of Survival Curves over Strata Time Variable DAY

	Wilcoxon	-1661.0 1661.0	Denl. Other Continue
Rank Statistics	Log-Rank	-11.555 11.555	Particular Matheway for the Township Charleston
	COD_TRT	FLURBX	

Covariance Matrix for the Log-Rank Statistics	T FLU RBX	8.35602 -8.35602 -8.35602 8.35602	Covariance Matrix for the Wilcoxon Statistics	700
Covariance Ma	COD_TRT	FLURBX	Covariance M	TOT GOT

FLU

Pr > Chi-Square	0.0001
Ŗ	
Chi-Square	15.9783 15.1203 18.7290
Test	Log-Rank Hilcoxon -2Log(LR)

9550083

		SYMP.
	,016	PELATE
5	124.	OKY C
CNSKE	OCOL 2	NAUSEA
PHAKMACLA UNS KKD	REBOXETINE - PROTOCOL 20124/016 APPENDIX No.: 12.1.12	THE PERSON OF DEVELOPING NAMES AND RELATED SYMPT
	D XE	Ę
	REB	ASTO
		UMULATIVE

The LIFETEST Procedure Summary of the Number of Censored and Uncensored Values	XCensored	83.1461 83.5443	83,3333
rocedure ad and Unce	Censored	74	140
The LIFETEST Procedure mber of Censored and U	Failed	£1 £1	28
The the Number	Total	89 79	168
Surmary of	COD_TRT	FLU	Total

5		
1000 000		Wilcoxon
restring nonegonetry of buttards through bridges (voi strates)	Rank Statistics	Log-Rank
		COD_TRT
ST ASS		

Wilcoxon	-7.0000 7.0000	Rank Statistics	RBX	-6.82025 6.82025	Wilcoxon Statistics	RBX
Log-Rank	0.09527	for the Log-	FLU	6.82025 -6.82025	the	FLU
COD_TRT	FLU	Covariance Matrix for the Log-Rank Statistics	COD_TRT	FLU RBX	Covariance Matrix for	COD_TRT

-158582 158582	Strata	Pr > Chi-Square	0.9709	0.9860	0.9574
N N	OVOL	DF	-	-	-
158582 -158582	Test of Equality over Strata	Chi-Square	0.0013	0.0003	0.0029
FLU	Test	Test	Log-Rank	Wilcoxon	-2Log(LR)

PHARMACIA CNS RED 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\_IRT Total Failed Censored XCensored

PLU

sting Homogeneity of Survival Curves over Strata Time Variable DAY

Rank Statistics COD\_IRI Log-Rank Milcoxon

FLU -2.2344 -364.00

FLU -2.2344 -364.00

COVARIANCE MATXIX for the Log-Rank Statistics

COD\_TRT FLU REX

FLU 1.48756 -1,48756

RBX -1.48756 1.48756

Covariance Matrix for the Wilcoxon Statistics

FLU 38338.4 -38338.4 RBX -38338.4 RBX -38338.4 38338.4 Test of Equality over Strata

Test Chi-Square DF Chi-Square Log-Rank 3.3562 1 0.0670 Wilcoxn 3.4560 1 0.0670 -21.09(LR) 3.6177 1 0.0572

CUMULATIVE RISK OF DEVELOPING SWEATING INCREASED

The LIFFIEST Procedure the Number of Censored and Uncensored Values	XCensored	92.1348 91.1392	91.6667
rocedure ed and Unce	Censored	82 72	421
The LIFETEST Procedure mber of Censored and V	Failed		4
The the Number	Total	89	168
Summary of	COD_TRT	FLU RBX	Tota1

ting Homogeneity of Survival Curves over Strata Time Variable DAY

	Wilcoxon	-85.000 85.000	the Log-Rank Statistics	RBX	-3.47097 3.47097	Covariance Matrix for the Wilcoxon Statistics
Rank Statistics	Log-Rank	-0.48254 0.48254	rix for the Log-	FLU	3,47097	rix for the Wild
	COD_TRT	FLURBX	Covariance Matrix for	COD_TRI	FLURBS	Covariance Mat

KBX	-85336.6 85336.6	Strata	Pr > Chi-Square	0.7956 0.7711 0.8216
,	vo vo	over	PF	
LLO	85336.6 -85336.6	Test of Equality over Strata	Chi-Square	0.0671
COD_IRE	FLU	Test	Test	Log-Rank Milcoxon -2Log(LR)

PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 APPENDIX No.: 12.1.12
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CUNULATIVE RISK OF DEVELOPING TRENOR

The LIFFTEST Procedure Summary of the Number of Censored and Uncensored Values	XCensored	94.3820 94.9367	94.6429
rocedure ed and Unce	Censored	84 75	159
The LIFETEST Procedure unber of Censored and Us	Failed	លេង	6
The The	Total	89 79	168
Summary of	COD_TRI	FLU	Total

Testing Homogeneity of Survival Curves over Strata Time Variable DAY

	Wilcoxon	-3.0000 3.0000	Covariance Matrix for the Log-Bank Statistics
Rank Statistics	Log-Rank	0.20534 -0.20534	ix for the Log-
	COD_TRT	FLU RBX	Covariance Matr

RBX	-2.22732 2.22732	oxon Statistics	RBX	-51339.6 51339.6
FLU	2,22732	ix for the Wilc	FLU	51339.6 -51339.6
COD_TRT	FLU RBX	Covariance Matrix for the Milcoxon Statistics	COD_TRT	FLU RBX

Pr > Chi-Square	0.8906 0.9894 0.8743
70	~~~
Chi-Square	0.0189 0.0002 0.0250
Test	Log-Rank Wilcoxon -2Log(LR)

Test of Equality over Strata

PHARMACIA CNS R&D REBOXETIME - PROTOCOL 20124/016 APPENDIX No.: 12.1.12 CUMULATIVE RISK OF DEVELOPING URINARY BESITANCY / RETENTION
The LIFFIEST Procedure
Of the Number of Company and Headenson University

The LIFETEST Procedure Summary of the Number of Censored and Uncensored Values	XCensored	98.8764 87.3418	93.4524
rocedure ed and Unce	Censored	88.99	157
The LIFETEST Procedure Imber of Censored and U	Failed	<b>.</b> 6	7
The the Number	Total	88 87	168
Summary of	COD_TRT	FLU	Total

Testing Homogeneity of Survival Curves over Strata Time Variable DAY

	Hilcoxon	-751,00 751.00	Rank Statistics
Rank Statistics	Log-Rank	-4.9337 4.9337	x for the Log-
ě.	COD_TRT	FLU	Covariance Matrix for the Log-Rank Statistics

Rank Statistics	RBX	-2.71913 2.71913	Station Station
c for the Log-R	FLU	2.71913 -2.71913	v for the Wiles
Covariance Matrix for the Log-Rank Statistics	COD_TRT	FLU RBX	Coussisses Matrix for the Wilcowes Statiotics

COD\_TRT FLU RBX

strata	Pr > Chi-Square	0.0028 0.0034 0.0012
over	품	
of Equality over Strata	Chi-Square	8.9520 8.5732 10.5227
Test of	Test	Log-Rank Wilcoxon -2Log(LR)

## 9550083

Pharmacia

Document 9550083

12.2 Patient Information

#### 9550083

Pharmacia

Document 9550083

# 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.

#### 9550083

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.

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

# 9550083

Pharmacia

Document 9550083

# CLINICAL REPORT

ADE ID	DD 0184
PROTOCOL Nº	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

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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Pharmacia

Document 9550083

12.2.2. INDIVIDUAL DATA LISTINGS

PBARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 Listing No.: 1.0	
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DSK-III-	ssian 296.2 ssian 296.3 ssian 296.3 ssian 296.3 ssian 296.3		Caucasian 296.3 Caucasian 296.3 Caucasian 296.3 Caucasian 296.3 Caucasian 296.3 Caucasian 296.2 Caucasian 296.2	Caucasian 296.2 Caucasian 296.3 Caucasian 296.2 Caucasian 296.3	Caveasian 296.2 Caveasian 296.3 Caveasian 296.7 Caveasian 296.3 Caveasian 296.3 Caveasian 296.3 Caveasian 296.2	Caucasian 296.3 Caucasian 296.2
Race	Caucasian Caucasian Caucasian Caucasian Caucasian	Caucasian Caucasian Caucasian Caucasian Caucasian Caucasian				
Height (cm)	184.0 168.0 164.0 160.0 174.0		163.0 163.0 158.0 171.0 168.0 169.0 178.0	166.0 166.0 160.0 163.0	156.0 160.0 153.0 175.0 175.0 158.0 157.0 163.0 176.0	162.0
Weight (kg)	72.0 85.0 74.2 73.0 89.5		72.0 64.0 72.0 73.0 73.0 78.5 52.3 78.5	64.5 65.8 72.1 57.0	61.5 80.5 7.6 8.6 8.6 8.6 1.2 1.2 1.2 1.2 1.2 1.3 1.3 1.3 1.3 1.3 1.3 1.3 1.3 1.3 1.3	64.0 1 47.0 First Priesd
Age (years)	21 51 61 65		4 6 6 4 9 4 4 5 8 8 4 4 5 8 4 4 5 8 4 4 5 8 4 4 4 5 8 4 4 4 5 8 4 4 4 5 8 4 4 4 4	63 27 29	23 24 23 24 25 25 25 25 25 25 25 25 25 25 25 25 25	
Sex	Male Male Female Female Female		Male Female Female Nale Female Female Female	Female Female Female Female	Female Female Male Female Female Female Female	Female Female
Patient status In-out Hospital patient date	08/11/91 16/06/92 22/06/92 07/08/92 05/10/92	02/05/91 29/04/91 05/04/91 25/04/91 18/06/91	02/06/91 10/02/92 02/03/92 10/12/91 09/09/92 24/03/92 08/01/93	01/10/91 11/10/91 28/10/92 26/11/92	17/04/91 23/05/91 10/10/91 07/05/92 07/07/92 06/07/92 12/08/92	in Table
Patient In-out patient		aaaaaa		aaaa		TUO TUO
Initials	S A 5 E B S	S S S S S S S S S S S S S S S S S S S	AH B K & & & & K & K & K & K & K & K & K &	NG US MFS C2		JMS OUT Female 5 INU OUT Female 3 (X) NIACHORIS: 294 2-Median Demonstran Discontinu
Treatment	Fluoxetine Reboxetine Fluoxetine Fluoxetine Fluoxetine	Fluoxetine Reboxetine Reboxetine Fluoxetine Reboxetine Reboxetine Fluoxetine	Fluoretine Reboxetine Reboxetine Reboxetine Fluoretine Fluoretine Fluoretine Fluoretine	Fluoxetine Fluoxetine Reboxetine Reboxetine	Reboxetine Fluoxetine Fluoxetine Reboxetine Reboxetine Fluoxetine Fluoxetine Fluoxetine	Reboxetine Fluoxetine
Patient	- ሪክ ቀ ሪ ሪ	3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	8 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	65 67 68	97 98 99 100 101 102 103	130
Centre	-	N		ო	4	ι <b>ດ</b>

PHARMACIA CNS RED

	DSH-III-R (*)	296.3	296.2 296.2	296.3	296.2	296.2	296.3	296.2	296.3	296.2	296.3	296.3	296.2	296.3	206.2	1	296.3	296.3	296.3	296.3	296.3	296.3	296.3	296.3	296.3	296.2	2,96.2	296.2		236.2	296.3	296.2	
	Race	Caucasian	Caucasian Caucasian Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Camerana	Cawcastan	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian		Caucasian	Caucasian	Caucasian	
	Height (cm)	157.0	158.0 181.0	156.0	167.0 157.0	154.0	152.0	148.0	159.0	151.0	165.0	160.0	166.0	165.0	25.0	2.78	160.0	155.0	169.0	157.0	155.0	163.0	165.0	161.0	170.0	165.0	174.0	158.0		1/3.0	165.0	175.0	ode pisode
	Meight (kg)	41.0	88.0 85.0	‡ 13	79.0	79.0	48.0	86.5	65.0	9 8	82.0	55.0	55.5	 	200	9	44.0	77.0	67.5	47.0	0.89	71.0	70.7	76.2	68.7	59.3	84.0	26.0		. 2	57.0	29.0	rst Epis Itiple E Polar
z	Age (years)	25	3 4 5	8	356	3	# c	25	* 1	8 4	<u>.</u>	38	25	9 9	ř	3	19	45	45	33	2 <b>7</b>	43	62	78	ŝ	22	g (	25 e	3 6	£ £	48	, 유	order, Fi order, Mu order, Bi
TIFICATIO	Sex (	Female	Female Male Female	Male	Female Female	Female	Female	Female	Female	Female	Hale	Female	Female	Female	Consto		Female	Male	Male	Female	Female	Fenale	Male	Female	Kale	Female	Hale F	Female	, compare	naie Female	Female	Female	ssive Dis ssive Dis ssive Dis
PATIENT IDENTIFICATION	Patient status_ In-out Hospital	01/12/91		27/10/92																			22/04/92	14/04/92	15/03/92	18/07/92		10/08/02	20,000				296.2=Hajor Depressive Disorder, First Episode 296.3=Hajor Depressive Disorder, Multiple Episode 296.5=Hajor Depressive Disorder, Bipolar 300.4=Dysthymla
¥.	_Patient In-out patient	Ā	1 1 1 E	E H	P P	100	100	9 5	9 g	į	OUT	our	TUO!		100	Ē	TOO	TOO	100	TOO	6	TUO	N	H	ž i	NT.	100	106			TNO	er.	3: 296.2=18 296.3=19 300.4=10
	Initials	ENG.	JAN MBV	ΓĀ	RPB	봀	ESS	178	SHC	5	AJG.	DTH	MSG	CMF	2 5		NB NB	ZB	TH.	2 H	Ħ	HH	2	ဌ	Ħ	2	9 1	S	2 1	# 5	: 8	뉥	(*) DIAGNOSIS: 296.2-Major Depressive Disorder, First Episode 296.3-Major Depressive Disorder, Multiple Episs 296.5-Major Depressive Disorder, Bipolar 300.4-Dysthymia
	Treatment	Reboxetine	Fluoxetine Fluoxetine Reboxetine	Fluoxetine	Fluoxetine Reboxetine	Fluoxetine	Keboxetine	Reboxetine	Fluoxetine	Pehovetine	Reboxetine	Fluoxetine	Fluoxetine	Reboxetine	Deboueting		Fluoxetine	Reboxetins	Reboxetine	Fluoxetine	Fluoxetine	Fluoxetine	Fluoxetine	Reboxetine	Repoxetine	Fluoxetine	Reboxetine	Fluoxetine	Walker Tille	Fluoretine	Reboxetine	Fluoxetine	٤
	Patient	193	194 195 196	197	321	323	324	326	327	926	33	331	332	333	100	2	393	394	395	396	483	385	386	387	388	389	396	39.1	300	5 5	503	504	
	Centre	7			7												12					5											

PHARMACIA CNS R&D

Patient status				REBOXE	REBOXETINE - PROTOCOL 20124/016 Listing No.: 1.0	Procot. 21	0124/016				
Patient status   Latinals patient atatus   Latinals patient atatus   Latinals patient data   Cyanzo   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg   Ckg				æ	ATIENT IDER	NTIFICAT:	NOI				
1.8	Trea	taent	Initials	ند	status Rospital date	Sex	Age (years)	Weight (kg)	Height (cm)	Race	I-HSQ (X)
Lik	1			į			3	8	6 6 7	1	200
March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   March   Marc	Men o	xerrue	¥:	3 !		remare	7 8			Caucastan	0 0
Formal	9 :	xetine	3 1	100		na le	7	9.7.0	20.00	Caucasian	2,00
The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The color   The		retine	<u> </u>	1 2		remaile	2 5	0.70	0.62	Caucastan	200
LK	Rebo	retine	IPK	100		Male	, S	72.0	166.0	Caucasian	296
LM											
JP         OUT         Feneral of Male         41 44.0 158.0 Caucasian         Caucasian           RH         OUT         Fanalo de Male         31 79.0 160.0 Caucasian         Caucasian           JT         IM         26/05/92 Female de Male         49 90.0 170.0 Caucasian         Caucasian           AA         OUT         Female de Male         49 77.0 179.0 Caucasian         Caucasian           AA         OUT         Female de Male         40 57.0 170.0 Caucasian         Caucasian           DA         OUT         Female de Male         40 57.0 179.0 Caucasian         Caucasian           VJ         OUT         Female de Male         37 75.0 176.0 Caucasian         Caucasian           VJ         OUT         Female de Male         40 55.5 5.0 Caucasian         Caucasian           VJ         OUT         1770/92 Female de Male         40 55.5 5.0 Caucasian         Caucasian           VJ         OUT         1770/92 Female de Male         40 55.5 5.0 Caucasian         Caucasian           CG         OUT         1770/92 Female de Male         40 65.0 Caucasian         40 65.0 Caucasian           CG         OUT         1770/92 Female de Male         40 65.0 Caucasian         40 65.0 Caucasian           M         OUT         Female de Male	Fluo	xetine	Ę	TUO		Female	83	58.0	151.0	Caucasian	296
Ji	Rebo	xetine	음	OUT		Fenale	41	44.0	158.0	Caucasian	296
Riff   OUT	Rebo	xetine	8	OUT		Female	43	55.0	173.0	Caucasian	296
E.C. OUT	Fluo	xetine	퓚	TUO		Male	31	79.0	160.0	Caucasian	296
JT         IN         21/05/92         Female         48         99.0         179.0         Caucasian           CA         IN         26/05/92         Female         43         99.0         179.0         Caucasian           DA         OUT         Female         61         57.0         151.0         Caucasian           DA         OUT         Female         60         60.0         153.0         Caucasian           LO         OUT         Female         57         165.0         Caucasian           LO         DUT         Female         22         106.0         176.0         Caucasian           LO         DUT         Female         29         102.0         176.0         Caucasian           LO         DUT         Female         29         102.0         176.0         Caucasian           LB         LN         17/10/92         Female         40         40.0         176.0         Caucasian           LB         LN         17/10/92         Female         40         40.0         160.0         Caucasian           LB         LN         17/10/92         Female         40         40.0         160.0         Caucasian	Fluo	xetine	ដ	OUT		Female	40	51.5	171.0	Caucasian	296
CA         IN         26/05/92         Female         4/3         71.0         179.0         Caucasian           JR         00T         Female         61         57.0         157.0         Caucasian           VJ         00T         Female         60.0         65.0         Caucasian           VJ         00T         Female         57.0         165.0         Caucasian           LO         00T         Female         37         75.0         165.0         Caucasian           KL         1N         17/10/92         Female         22         106.0         156.0         Caucasian           LD         1N         17/10/92         Female         40         55.5         155.0         Caucasian           LD         1N         17/10/92         Female         40         55.5         155.0         Caucasian           LD         1N         27/10/92         Female         40         43.0         150.0         Caucasian           CD         1N         27/10/92         Female         40         43.0         150.0         Caucasian           CD         1N         27/10/92         Female         40         43.0         150.0         <	Rebo	xetine	r,	H	21/05/92	Female	48	99.0	173.0	Caucasian	296
AAA         OUT         Female         61         57.0         187.0         Caucasian           DA         OUT         Female         40         57.0         183.0         Caucasian           LO         OUT         Female         50         60.0         165.0         Caucasian           LO         DOT         Female         37         75.0         165.0         Caucasian           KI         DOT         Female         22         106.0         165.0         Caucasian           KI         DOT         Female         22         106.0         165.0         Caucasian           LB         LIN         177.09-92         Female         40         76.0         160.0         Caucasian           CG         OUT         Female         40         70.0         160.0         Caucasian           LB         LIN         27.10-92         Female         40         70.0         160.0         Caucasian           CG         OUT         Female         57         66.0         155.0         Caucasian           LB         OUT         Female         57         78.0         150.0         Caucasian           LB         OUT	Rebo	xetine	₹.	Ľ	26/02/92	Female	43	71.0	179.0	Caucasian	296
JR         OUT         Female         40         51.0         165.0         Caucasian           VJ         OUT         Male         37         75.0         165.0         Caucasian           LO         DUT         Male         37         75.0         165.0         Caucasian           KL         DUT         Theralo         29         102.0         176.0         Caucasian           GN         DUT         Femalo         29         102.0         176.0         Caucasian           LB         LN         0.0T         Femalo         29         102.0         176.0         Caucasian           CG         CO         CG         20         102.0         176.0         Caucasian           LB         LN         0.0T         Femalo         30         57.5         175.0         Caucasian           CG         CG         CG         100.0         Caucasian         40         40         40         40         60.0         Caucasian           CG         CG         CG         CG         Caucasian         40         40         40         60.0         Caucasian           LB         CG         CG         CG         CG </td <td>Flao</td> <td>xetine</td> <td>V.</td> <td>ino i</td> <td></td> <td>Female</td> <td>5</td> <td>57.0</td> <td>151.0</td> <td>Caucasian</td> <td>296</td>	Flao	xetine	V.	ino i		Female	5	57.0	151.0	Caucasian	296
DA	F120	xetine	<b>#</b>	Loo		Female	04	51.0	163.0	Caucasian	296
V.   OUT   Fenale   37   75.0   Caucasian   Fenale   27   75.0   Caucasian   Caucasian   Fenale   28   75.0   Caucasian   Fenale   29   102.0   75.0   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian	Fluo	xetine	<b>e</b> :	100		Female	B !	0.09	165.0	Caucastan	296
Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia   Harmonia	Rebo	Xetine	r.	Loc		Male	37	75.0	165.0	Caucasian	296
Canada	Keb	xetine	3 ;	TOT	47,00,000	Female	7 6	106.0	156.0	Caucasian	2 0
TO   OUT   Female   28 64.0   160.0   Caucasian   LB   IN   27/10/22   Female   34   56.0   165.0   Caucasian   CG   OUT   27/10/22   Female   40   70.0   165.0   Caucasian   CG   OUT   29/03/93   Female   40   70.0   165.0   Caucasian   Caucasian   CG   OUT   Female   51   60.0   150.0   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Caucasian   Ca	Flan	metine	ł &	FIIO	76 16 16 16 16	Female	604	55.5	155.0	Caucasian	29.
LB	Reb	oxetine	10	TUO		Female	28	64.0	160.0	Caucasian	296
DR         IN         27/10/92 Femalo         34         56.0 165.0         Caucasian           CG         OUT         29/08/93 Female         40         70.0 160.0         Caucasian           JL         OUT         29/08/93 Female         56         78.0 160.0         Caucasian           BB         OUT         Female         56         78.0 160.0         Caucasian           RL         OUT         Female         57         60.0 167.0         Caucasian           RL         OUT         Female         51         60.0 162.0         Caucasian           RL         OUT         Female         51         60.0 162.0         Caucasian           RR         OUT         Female         51         60.0 162.0         Caucasian           RR         OUT         Female         54         52.0 166.0         Caucasian           RR         OUT         Female         54         62.0 166.0         Caucasian           RR         OUT         Female         54         62.0 166.0         Caucasian           RG         OUT         Female         54         62.0 166.0         Caucasian           RG         OUT         Female         56         161.	Reb	oxetine	2	NI	01/11/92	Fenale	32	57.5	175.0	Caucasian	296
CG         OUT         Female         40         70.0         160.0         Caucasian           JH         OUT         29/03/93         Female         40         43.0         156.0         Caucasian           BB         OUT         Female         56         78.0         160.0         Caucasian           RL         OUT         Female         51         60.0         167.0         Caucasian           RF         OUT         Female         51         52.0         160.0         Caucasian           RF         OUT         Female         51         59.0         160.0         Caucasian           RF         OUT         Female         51         59.0         160.0         Caucasian           RF         OUT         Female         51         59.0         160.0         Caucasian           RF         OUT         Female         54         55.0         160.0         Caucasian           RF         OUT         Female         54         62.0         164.0         Caucasian           RG         OUT         Female         56         70.0         164.0         Caucasian           RG         OUT         Female	Reb	oxetine	æ	NI	27/10/92	Fenale	34	56.0	165.0	Caucasian	5
JR         OUT         29/03/93         Female         40         43.0         153.0         Caucasian           JL         OUT         Female         51         60.0         167.0         Caucasian           BA         OUT         Female         51         60.0         167.0         Caucasian           RF         OUT         Female         51         60.0         167.0         Caucasian           RF         OUT         Female         51         52.0         152.0         Caucasian           RF         OUT         Female         43         58.0         166.0         Caucasian           RB         OUT         Female         54         62.0         160.0         Caucasian           RB         OUT         Female         54         62.0         166.0         Caucasian           RF         OUT         Female         54         62.0         166.0         Caucasian           RG         OUT         Female         54         62.0         166.0         Caucasian           RG         OUT         Female         56         72.0         166.0         Caucasian           RG         OUT         Female	Flu	oxetine	9	OUT		Female	40	70.0	160.0	Caucasian	29
J.L.         OUT         Hale         56         78.0         180.0         Caucastan           EB         OUT         Female         51         60.0         167.0         Caucastan           RL         OUT         Female         51         50.0         157.0         Caucastan           RF         OUT         Female         51         52.0         152.0         Caucastan           RF         OUT         Female         51         93.0         165.0         Caucastan           RB         OUT         Female         43         56.0         176.0         Caucastan           RP         OUT         Female         54         56.0         150.0         Caucastan           RF         OUT         Female         54         62.0         164.0         Caucastan           RG         OUT         Female         54         62.0         164.0         Caucastan           AGG         OUT         Female         56         70         175.0         Caucastan           RCB         OUT         Female         61         75.0         164.0         Caucastan           RCB         OUT         Female         41         6	F	oxetine	<b>F</b>	TUO	29/03/93	Female	40	43.0	153.0	Caucasian	29
EB         OUT         Femala         51         60.0         167.0         Caucastan           RL         OUT         Femala         61.0         167.0         Caucastan           RF         OUT         Femala         51         52.0         162.0         Caucastan           RF         OUT         Femala         51         59.0         160.0         Caucastan           RB         OUT         Femala         43         56.0         Caucastan           RB         OUT         Femala         43         56.0         Caucastan           RP         OUT         Femala         54         62.0         164.0         Caucastan           RP         OUT         Femala         54         62.0         164.0         Caucastan           RP         OUT         Femala         54         62.0         164.0         Caucastan           AGG         OUT         Femala         56         70         164.0         Caucastan           RCB         OUT         Femala         61         72.0         175.0         Caucastan           RCB         OUT         Femala         41         61.0         163.0         Caucastan <td>Rep</td> <td>oxetine</td> <td>Ħ</td> <td>TUO</td> <td></td> <td>Male</td> <td>26</td> <td>78.0</td> <td>180.0</td> <td>Caucasian</td> <td>29</td>	Rep	oxetine	Ħ	TUO		Male	26	78.0	180.0	Caucasian	29
RA         OUT         Female         61         52.0         122.0         Caucasian           RL         OUT         Female         51         59.0         165.0         Caucasian           RF         OUT         Female         51         59.0         165.0         Caucasian           RM         OUT         Female         42         61.0         150.0         Caucasian           RF         OUT         Female         42         61.0         150.0         Caucasian           RF         OUT         Female         54         62.0         165.0         Caucasian           CG         OUT         Female         56         59.0         165.0         Caucasian           AGG         OUT         Female         61         72.0         165.0         Caucasian           CG         OUT         Female         61         72.0         165.0         Caucasian           RCR         OUT         Female         61         72.0         175.0         Caucasian           FG         OUT         Female         41         61.0         163.0         Caucasian           FG         OUT         Female         41	Flu	oxetine	8	TUO		Female	51	60.0	167.0	Caucasian	296
RL         OUT         Femala         51         59.0         166.0         Caucasian           HB         OUT         Femalo         51         59.0         166.0         Caucasian           HB         OUT         Femalo         53         83.0         176.0         Caucasian           TR         OUT         Femalo         43         58.0         150.0         Caucasian           NF         OUT         Femalo         54         62.0         164.0         Caucasian           CG         OUT         Femalo         54         62.0         164.0         Caucasian           CG         OUT         Femalo         56         59.0         161.0         Caucasian           AGG         OUT         Femalo         47         67.0         156.0         Caucasian           RCR         OUT         Femalo         41         61.0         156.0         Caucasian           RCR         OUT         Femalo         47         61.0         156.0         Caucasian           RCR         OUT         Femalo         47         61.0         156.0         Caucasian           RC         OUT         Femalo         58 <t< td=""><td>Reb</td><td>oxetine</td><td>ΒA</td><td>TOO</td><td></td><td>Female</td><td>29</td><td>52.0</td><td>152.0</td><td>Caucasian</td><td>5</td></t<>	Reb	oxetine	ΒA	TOO		Female	29	52.0	152.0	Caucasian	5
RF         OUT         Fenale         51         93.0         165.0         Caucasian           BB         OUT         Fenale         43         58.0         176.0         Caucasian           RR         OUT         Fenale         43         56.0         150.0         Caucasian           NF         OUT         Fenale         54         62.0         164.0         Caucasian           NF         OUT         Fenale         54         65.0         164.0         Caucasian           CG         OUT         Fenale         54         55.0         165.0         Caucasian           AGG         OUT         Fenale         61         72.0         175.0         Caucasian           RCB         OUT         Fenale         61         72.0         175.0         Caucasian           RCB         OUT         Fenale         41         61.0         163.0         Caucasian           FG         OUT         Fenale         27         58.0         175.0         Caucasian           ARP         OUT         Fenale         27         58.0         77.0         Caucasian           ABP         OUT         Fenale         56 <t< td=""><td>Flu</td><td>oxetine</td><td>RL</td><td>TOO</td><td></td><td>Female</td><td>2</td><td>59.0</td><td>160.0</td><td>Caucasian</td><td>5</td></t<>	Flu	oxetine	RL	TOO		Female	2	59.0	160.0	Caucasian	5
HB         OUT         Male         38         63.0         178.0         Caucasian           TR         OUT         Fenale         42         56.0         150.0         Caucasian           NF         OUT         Fenale         42         61.0         156.0         Caucasian           NF         OUT         Fenale         34         52.0         166.0         Caucasian           CG         OUT         Fenale         56         59.0         166.0         Caucasian           CB         OUT         Fenale         61         72.0         176.0         Caucasian           CB         OUT         Fenale         61         72.0         176.0         Caucasian           FG         OUT         Fenale         41         61.0         156.0         Caucasian           FG         OUT         Fenale         41         61.0         156.0         Caucasian           FG         OUT         Fenale         41         61.0         156.0         Caucasian           FG         OUT         Fenale         27         176.0         Caucasian           ARP         OUT         Fenale         56         77.0         176	Reb	oxetine	r.	TOO		Female	5	93.0	165.0	Caucasian	53
BH         OUT         Fenale         43         58.0         150.0         Caucasian           FR         OUT         Fenale         42         61.0         150.0         Caucasian           FF         OUT         Fenale         54         62.0         164.0         Caucasian           FF         OUT         Fenale         54         62.0         164.0         Caucasian           AGG         OUT         Fenale         56.0         161.0         Caucasian           AGG         OUT         Fenale         61         72.0         165.0         Caucasian           RCR         OUT         Fenale         41         61.0         155.0         Caucasian           FG         OUT         Fenale         27         58.0         176.0         Caucasian           FG         OUT         Fenale         27         58.0         176.0         Caucasian           ARP         OUT         Fenale         56         72.0         157.0         Caucasian           ABO         OUT         Fenale         56         72.0         157.0         Caucasian	FIL	oxetine	Ħ	TOO		Male	88	83.0	178.0	Caucasian	5
TR         OUT         Fenale         42         61.0         158.0         Caucasian           NF         OUT         Fenale         34         62.0         164.0         Caucasian           CG         OUT         Fenale         34         62.0         164.0         Caucasian           AG         OUT         Fenale         56         59.0         161.0         Caucasian           CB         OUT         Fenale         62         87.0         163.0         Caucasian           FG         OUT         Fenale         41         61.0         158.0         Caucasian           FG         OUT         Fenale         47         61.0         163.0         Caucasian           FG         OUT         Fenale         27         58.0         170.0         Caucasian           ARP         OUT         Fenale         56         71.0         176.0         Caucasian           ABO         OUT         Fenale         56         72.0         157.0         Caucasian	Reb	oxetine	æ	TOO		Female	43	58.0	150.0	Caucasian	29
NF         OUT         Fenale         54         62.0         166.0         Caucasian           CG         OUT         Fenale         34         52.0         165.0         Caucasian           AGG         OUT         Fenale         56         59.0         167.0         Caucasian           CB         OUT         Fenale         61         72.0         175.0         Caucasian           RCR         OUT         Fenale         41         61.0         168.0         Caucasian           FG         OUT         Fenale         27         88.0         178.0         Caucasian           ARP         OUT         Fenale         58.0         176.0         Caucasian           ABO         OUT         Fenale         56         71.0         176.0         Caucasian	FI	oxetine	£	TOO		Fenale	42	61.0	158.0	Caucasian	5
MP         OUIT         Female         34         52.0         165.0         Caucasian           CG         OUT         Female         56         59.0         165.0         Caucasian           AGG         OUT         Male         61         72.0         175.0         Caucasian           CR         OUT         Female         41         61.0         163.0         Caucasian           FG         OUT         Female         27         58.0         175.0         Caucasian           ARP         OUT         Female         32         71.0         175.0         Caucasian           ABO         OUT         Female         56         72.0         175.0         Caucasian	Rep	oxetine	¥	DO		Fenale	¥	62.0	164.0	Caucasian	53
CG         OUT         Female         56         59.0         161.0         Caucasian           AGG         OUT         Malo         61         72.0         175.0         Caucasian           CB         OUT         Male         41         61.0         163.0         Caucasian           FG         OUT         Female         47         61.0         163.0         Caucasian           ARP         OUT         Female         32         71.0         176.0         Caucasian           ABO         OUT         Female         56         72.0         157.0         Caucasian	Ret	oxetine	Œ.	OUT		Female	Ř	52.0	165.0	Caucasian	29
AGG OUT Male 61 72.0 178.0 Caucasian CBC OUT Male 61 72.0 178.0 Caucasian RCR OUT Female 62 87.0 186.0 Caucasian FG OUT Female 27 58.0 178.0 Caucasian ARP OUT Male 58 71.0 176.0 Caucasian ARP OUT Female 58 72.0 176.0 Caucasian ABO OUT Female 58 72.0 157.0 Caucasian	Ē	aoxetine	2	TIO		Female	26	59.0	161.0	Caucasian	53
CB 0UT Female 62 87.0 156.0 Caucasian RCR 0UT Male 41 61.0 163.0 Caucasian FG 0UT Female 27 58.0 179.0 Caucasian ARP 0UT Malo 32 71.0 176.0 Caucasian ABO 0UT Female 58 72.0 157.0 Caucasian	Ē	oxetine	AGG	THO		Male	6	72.0	175.0	Caucasian	23
RCR         OUT         Male         41         61.0         163.0         Caucasian           FG         OUT         Fonale         27         58.0         173.0         Caucasian           ARP         OUT         Malo         32         71.0         176.0         Caucasian           ABO         OUT         Fonale         56         72.0         157.0         Caucasian	Ba	oxetine	8	TUO		Female	62	87.0	158.0	Caucasian	59
FG         OUT         Female         27         58.0         178.0         Caucasian           ARP         OUT         Malab         32         73.0         176.0         Caucasian           ABO         OUT         Fomale         58         72.0         157.0         Caucasian	Ĭ	oxetine	RCR	TUO		Male	41	61.0	163.0	Caucasian	52
ARP 00T Malo 32 71.0 176.0 Caucasian ABO 00T Femalo 58 72.0 157.0 Caucasian	Ē	oxetine	2	TOO		Female	27	58.0	173.0	Caucasian	22
ABO 00T Female 58 72.0 157.0 Caucasian	8	oxetine	ARP	100		Male	33	71.0	176.0	Caucasian	Ñ
	æ	boxetine	AB0	190		Female	58	72.0	157.0	Caucasian	29

PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 1.0

				2	PATIENT IDENTIFICATION	TIFICATI	No.				
				_Patient In-out	Patient status In-out Hospital		φ	Weight	Height		DSM-III-R
Centre	Centre Patient	Treatment	Initials	patient	date	Sex	(years)	(kg)	(cm)	Race	( <b>x</b> )
15	426	Fluoxetine	QV	TIDO		Male of	Ę	9	179.0	Course	6 706
	427	Reboxetine	RE	TUO		Female	43	84.0	167.0	Caucasian	2.062
	428	Fluoxetine	잼	TUO		Male	38	69.0	167.0	Caucasian	296.2
	6449	Reboxetine	8	TUO		Female	8	70.0	161.0	Caucasian	296.3
	450	Fluoxetine	<b>a</b>	TUO		Kale	33	91.0	183.0	Caucasian	296.2
	451	Fluoxetine	d i	TIO		Female	49	68.0	167.0	Caucasian	296.3
	20.	Keboxetine	AHS	our		Female	8	65.0	168.0	Caucasian	296.2
	t St	Fluoxetine	ĕ	TOO		Male	ę.	67.0	173.0	Caucasian	296.3
16	429	Fluoxetine	LBA	TIIO		Female	87	S	155.0		6 306
	430	Reboxetine	JRE			Male	2	27.0	166.0	Caucastan	200.0
	431	Reboxetine	EM	TOO		Female	85	80.0	171	Caucastan	296.3
	432	Fluoxetine	IHC	TUO		Female	49	73.0	160.0	Caucasian	296.3
	433	Reboxetine	ĎŨŨ	TUO		Female	39	62.0	155.0	Caucasian	296.3
	434	Fluoxetine	MG	OUT		Female	48	63.0	158.0	Caucasian	296.3
	435	Reboxetine	55	TUO		Female	48	67.0	165.0	Caucasian	296.2
	924	Fluoxetine	HCH.	OUT		Female	40	51.0	163.0	Caucasian	296.3
	Ŷ.	Kepoxetine	AVE.	Ino		Female	22	54.5	163.0	Caucasian	296.2
	97	Fluoxetine	2 1	TIP		Female	49	62.0	151.0	Caucasian	296.2
	450	Patroxectne	4 6	TOO C		Female	51	105.0	169.0	Caucasian	296.2
	7	Kepoxetine	ž	Tio		Female	141	65.0	168.0	Caucasian	296.3
	442	Dehovetine	2 2	100		Female	22.5	59.0	165.0	Caucasian	296.2
	£43	Fluoxetine	2	TIO		remate No lo	y s	22.0	160.0	Caucastan	296.3
	444	Repoxetine	MBV	Ę		Fomelo	2 6	0.00	7.4.0	Concostan	7.067
	445	Reboxetine	2	TOO		Kale	4 4	9,5	153.0	Caucasian	2.96.2
	446	Fluoxetine	BK	TUO		Female	E	1	165.0	Cancastan	2.062
	<b>‡</b>	Fluoxetine	CAD	TUO		Male	36	73.0	179.0	Caucasian	2.96.2
	448	Reboxetine	AR	TUO		Female	42	59.0	157.0	Caucasian	296.2
	455	Fluoxetine	SSV	our		Female	40	58.0	150.0	Caucasian	296.2
	456	Reboxetine	E	OUT		Kale	49	71.0	173.0	Caucasian	296.2
	457	Fluoxetine	e :	מנד		Female	25	74.0	176.0	Caucasian	296.3
	900	Fluoxetine	¥.	TIO		Female	55	62.0	163.0	Caucasian	296.2
	, to	Keboxetine	ב ב	THO		Male	46	90.0	185.0	Caucasian	296.2
	<b>19</b>	Kenoxetine	ŝ	OUT		Kale	61	70.0	160.0	Caucasian	296.2
62	25	Fluoretine	Ą	Ė		Comolo	8	Š	9		
	76	Dohowat	1 2				5 :	) :	20.	Caucastan	5.067
	2.0	Debovetine	<b>5</b> 2			remaile	e e	0.69	169.0	Caucasian	2.96.2
	1 6	remarking Line	<b>5</b> !			Female	32	140.0	174.0	Caucasian	2.962
	9 6	Pohosotino	4 5	100		Female	47	62.0	161.0	Caucasian	296.3
	, 6	Cluster	E 5	5		nale G	<b>*</b>	113.0	181.0	Caucasian	2.962
	3 6	Patrontine	3 3			Female	5.	62.0	158.0	Caucasian	296.3
	5	Rebuse	£	ž		Female	ភ	58.0	154.0	Caucasian	2.96.2

DSM-III-R (*)	296.2 296.2 296.3 296.3 296.3 296.2	296.3 296.2	296.3	296.3
Race	Caucasian Caucasian Caucasian Caucasian Caucasian	Čaucasian Čaucasian	Caucasian	Caucasian Caucasian
Height (cm)	168.0 164.0 160.0 170.0 170.0 150.0	165.0 163.0	182.0	184.0 186.0
Weight (kg)	62.0 82.0 70.0 92.0 105.0 90.0	64.0 62.0	79.0	94.0 73.0
Age (years)	36 63 36 47 47 56	52	27	43 26
Sex	Fenale Fenale Fenale Fenale Fenale	Female Female	Fenale	Male Male
Patient status_ In-out Bospital patient date				
_Pationt In-out patient	710 710 710 710 710 710	T00 T00	TUO	TUO
Initials	6P TW TW 1G 1G 1G 1G 1G 1G 1G 1G 1G 1G 1G 1G 1G	25 岩	89	SS SS
Centre Patient Treatment	Fluoxetine Reboxetine Reboxetine Fluoxetine Fluoxetine Fluoxetine	Fluoxetine Fluoxetine	Fluoxetine	Fluoxetine Reboxetine
Patient	32 49 50 51 52 54	22 22	<b>o</b> r	113
Ceptre	<b>6</b>	20	12	22

(\*) DIAGNOSIS: 296.2-Major Depressive Disorder, First Episode 296.3-Major Depressive Disorder, Multiple Episode 296.5-Major Depressive Disorder, Sipolar ann 4-hvethumia

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PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 2.0

HISTORY OF HENTAL DISORDER AND PRESENT EPISODE

Comparison   Grant   Comparison of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of			HISCOL	v of menta.	1 disorder		- roser	- phiende	
Machone   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Court   Co			Age of	No.	Duration of	Duration at the time			
1	Patient	- 1	onset	episodes	last episode	of admission	Best characterized	Onset was	External stress
2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	•		3	•				3	
1	- ,		7 (	•			First occurence	Insidious (>= 3 months)	Delinitely present
Similar prov. cond.   Institution C = 2 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C = 3 months   Similar prov. cond.   Institution C	4 (		2	-			First occurence	Insidious (>= 3 months)	Absent
1	'n.		2.7	<b>20</b>			Similar prev. cond.	Insidious (>= 3 months)	Absent
5	4		46	-			Similar prev. cond.	Insidious (>= 3 months)	Absent
6	ı,		\$	4			Similar prev. cond.	Insidious (>= 3 months)	Absent
1	9		\$	•		4 months	First occurence	Subacute (>= 2 weeks)	Probably present
25   5   6 weeks   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2 months   2									
2	33		25	'n		2 months	Similar brev. gond.	Acute (< 2 upeks)	Absen+
Second Condition   Similar prov.   Condition   Similar prov.   Condition   Similar prov.   Condition   Similar prov.   Condition   Similar prov.   Condition   Similar prov.   Condition   Similar prov.   Condition   Similar prov.   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   Condition   C	34		8	•		1	011111111111111111111111111111111111111	Traiting (>= 0 matter)	AFTER
Second Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Control Contr			3 8	- 6	month of	t municus	brev.	Tustalous (>- 2 months)	
2.2	3 3		70	י י	l year	3 months	prev.	Insidious (>= 3 months)	
23	36		22	ឧ		4 weeks	Chronic condition	Subacute (>= 2 weeks)	Absent
25   25   25   25   25   25   25   25	37		23	8		5 months		Insidious (>= 3 months)	
35   36   36   36   37   39   39   39   39   39   39   39	38		25	5		6 months	prev.	Acute (< 2 weeks)	
40   56   2   2   2   2   2   2   2   2   2	33		g	60				Acute (< 2 weeks)	
41	40		35	84		1 month	Similar prev. cond.	Acute (< 2 weeks)	Probably present
42         46         1 B works         4 months         Similar prov. cond.         Insidious (>= 3 works)           43         40         3 1 month         4 works         4 months         Chronic condition         Subscute (>= 2 woeks)           45         27         26         4 1 month         4 weeks         Chronic condition         Subscute (>= 2 woeks)           45         20         3 woeks         2 woeks         2 works         Chronic condition         Subscute (>= 2 woeks)           46         20         3 woeks         4 works         Chronic condition         Subscute (>= 2 woeks)           65         65         1 woeks         4 months         First occurence         Insidious (>= 3 woeks)           66         16         1 year         6 months         First occurence         Insidious (>= 2 woeks)           67         68         1 woeks         4 woeks         First occurence         Insidious (>= 2 woeks)           99         7 wo         4 wo         4 wo         5 wo         4 wo         5 wo           101         4 wo         4 wo         5 wo         5 wo         4 wo         5 wo           101         4 wo         1 wo         5 wo         1 wo         2 wo         2 wo </td <td>41</td> <td></td> <td>56</td> <td>m</td> <td></td> <td>2 months</td> <td>Chronic condition</td> <td>Subscute (&gt;= 2 weeks)</td> <td>Absent</td>	41		56	m		2 months	Chronic condition	Subscute (>= 2 weeks)	Absent
43         40         3 I month         1 month         Chronic condition         Subsecte (>= 2 weeks)           45         CR         26         4 Imouth         1 weeks         Chronic condition         Subsecte (>= 2 weeks)           45         CR         26         4 month         7 weeks         Chronic condition         Subsecte (>= 2 weeks)           46         CR         38         3 weeks         2 months         Similar prev. cond.         Subsecte (>= 2 weeks)           65         65         6         1 jear         6 months         First occurence         Insidious (>= 3 weeks)           65         66         1 jear         6 months         First occurence         Insidious (>= 3 weeks)           67         56         0         4 months         First occurence         Insidious (>= 3 weeks)           67         56         0         4 months         First occurence         Insidious (>= 3 weeks)           97         Yes         66         1 jeeks         4 weeks         First occurence         Insidious (>= 3 weeks)           99         Yes         60         1 months         4 weeks         First occurence         Insidious (>= 3 weeks)           101         Weeks         1 months         3 months <td>42</td> <td></td> <td>46</td> <td>-</td> <td></td> <td></td> <td>Similar prev. cond.</td> <td>Insidious (&gt;= 3 months)</td> <td>Definitely present</td>	42		46	-			Similar prev. cond.	Insidious (>= 3 months)	Definitely present
44         CT         26         4 1 morth         4 weeks         Chronic condition         Subscute (>= 2 weeks)           47         CD         38         2 weeks         2 months         Chronic condition         Subscute (>= 2 weeks)           47         CD         38         weeks         2 months         First occurence         Insidious (>= 2 weeks)           65         6         0         weeks         4 months         First occurence         Insidious (>= 2 weeks)           65         16         1 months         First occurence         Insidious (>= 3 weeks)           66         24         months         First occurence         Insidious (>= 3 weeks)           67         A weeks         First occurence         Insidious (>= 3 weeks)           7         Nooths         First occurence         Subscute (>= 2 weeks)           99         Yes         62         4 weeks         Similar prev. cond.         Insidious (>= 3 weeks)           99         Yes         60         1 months         First occurence         Subscute (>= 2 weeks)           101         Yes         1 months         Final prev. cond.         Insidious (>= 3 weeks)           102         Yes         1 months         1 months         Similar prev.	43		4	e	1 month	1 month	Chronic condition	Subacute (>= 2 weeks)	Probably present
45         CV         32         1 years         7 weeks         Chronic condition         Subscute (>= 2 weeks)           46         CV         38         3 weeks         2 nonths         Similar prev. cond.         Subscute (>= 2 weeks)           65         65         0         4 weeks         4 weeks         First occurence         Insidious (>= 3 weeks)           65         62         1         1 year         6 nonths         Similar prev. cond.         Insidious (>= 3 weeks)           65         1         1 year         6 nonths         First occurence         Insidious (>= 3 menths)           66         1         1 year         6 nonths         First occurence         Insidious (>= 3 menths)           97         Yes         62         1         4 weeks         First occurence         Insidious (>= 3 menths)           99         Yes         46         1         3 weeks         First occurence         Subscute (>= 2 weeks)           101         40         40         40         40         40         40         40           99         Yes         46         1         3 weeks         5 insilar prev. cond.         Insidious (>= 3 menths)           101         Yes         1         3 men	44		56	4			Chronic condition	Subscute (>= 2 weeks)	Absent
47         OC         38         3 weeks         2 months         Similar prev. cond.         Subscute (>= 2 weeks)           66         65         6         1 pear         4 months         First occurence         Insidious (>= 3 months)           65         66         1 pear         6 months         Similar prev. cond.         Insidious (>= 3 months)           66         16         1 pear         6 months         First occurence         Insidious (>= 3 months)           67         56         0         1 pear         6 months         First occurence         Insidious (>= 3 months)           68         16         1 pear         6 months         First occurence         Insidious (>= 3 months)           99         Yes         62         1 pears         4 weeks         First occurence         Insidious (>= 3 months)           99         Yes         62         1 pears         4 weeks         Similar prev. cond.         Accurence         1 pears (>= 2 weeks)           100         Yes         1 pears         6 months         Similar prev. cond.         Insidious (>= 3 months)           104         Yes         5         1 pears         6 months         Similar prev. cond.         Insidious (>= 3 months)           105         Yes<	45	5	32	. 62			Chronic condition	Subscurte (SE 2 weeks)	Probably present
48         C.5         65         0         contents         First occurence         Insidious (>= 3 months)           65         62         0         1         1 year         4 months         First occurence         Insidious (>= 3 months)           66         16         1         1 year         6 months         First occurence         Insidious (>= 3 months)           66         21         2         5 months         First occurence         Insidious (>= 3 months)           97         Yeas         62         7 months         First occurence         Insidious (>= 3 months)           99         Yeas         62         7 months         First occurence         Insidious (>= 2 months)           99         Yeas         62         4 weeks         Similar prev. cond.         Insidious (>= 2 weeks)           100         Yeas         1         2         7 months         3 months         5 months           101         Yeas         4         1         3 months         5 months         1 months           102         Yea         1         2         4 weeks         5 months         1 months           103         Yea         1         2         4 weeks         5 months         1 months	4.7	8	8	1 (*		o months	Cinilin prof. cond	Cubacuta (No. 2 species)	through process
Similar prev. cond.   Similar prev. cond.   Similar prev. cond.   Similar prev. cond.   Similar prev. cond.   Similar prev. cond.   Institious (>= 3 months)	4,	3	65	. =		4 months	First promisers	Traidions (No 2 months)	Dofinitely magnest
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PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

	External stress	Probably present	Absent		Probably present	Probably present	Definitely present	Absent	Probably present	Probably present	Probably present	Definitely present	Absent	Definitely present	Probably present	Probably present	Absent	Appent Posts the second	Absent	Absent	Absent	Absent	Absent		Prohable and and	Probably present	Definitely present	Definitely present	Probably present	Definitely present	Probably present	Probably present	Probably present	Definitely present	Definitely present	Probabile proposet	Present	Definitely present	Probably present	Probably present		Absent	Absent	
Present episode	Onset was	Subacute (>= 2 weeks)	Subacute (>= 2 weeks)		Insidious (>= 3 months)	Insidious (>= 3 months)	Insidious (>= 3 months)	Acute (< 2 weeks)	Insidious (>= 3 months)	Insidious (>= 3 months)	Insidious (>= 3 months)	Insidious (>= 3 months)	Subacute (>= 2 weeks)	Subacute (>= 2 weeks)	Subacute (>= 2 weeks)	Insidious (>= 3 months)	Subacute (>= 2 weeks)	Traiding (>= 3 months)	Subacute (>= 2 gooks)	Subacute (>= 2 weeks)	Subacute (>= 2 weeks)	Insidious (>= 3 months)	Insidious (>= 3 months)		Subscrite (>= 2 usebs)	Insidious (>= 3 months)	Subacute (>= 2 weeks)	Subacute (>= 2 weeks)	Insidious (>= 3 months)	Insidious (>= 3 months)	Insidious (>= 3 months)	Subacute (>= 2 weeks)	Insidious (>= 3 months)	Subacute (>= 2 weeks)	Toeidings (>= 2 weeks)	Treiding (># 2 months)	Codements (All 2 molts)	Subacute (>= 2 weeks)	Insidious (>= 3 months)	Subacute (>= 2 weeks)		Acute (< 2 weeks)	Acute (< 2 weeks)	
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Bistory of mental disorder	Duration of last episode	3 months						2 months			9 months		:	1 month	3 months	- T	1 Year		6 months			2 months	3 months		6 months	9 months	6 months	10 weeks				+ Weeks						12 weeks			;	3 months	8 months	
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PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 2.0

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First occurence characterized HISTORY OF NENTAL DISORDER AND PRESENT EPISODE Similar Similar Similar Similar Weeks Duration at the time of admission History of mental disorder le of No Duration of mset episodes last episode 2 4 months 85 25 88 Unknown 585 Centre Patient 400 401 402 403 404 404 407 407 408 510 511 533 533 533 533 429 430 432 433 13 9

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PHARMACIA PHARMACEUTICAL MILANO - CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 2.0 HISTORY OF HENTAL DISORDER AND PRESENT EPISODE

			History	History of mastal disconden	di essados		, !!		
Centre	Centre Patient	Unknown	Age of onset	No Ppisodes	Duration of last episode	Duration at the time of admission	Best characterized	Onset was	External stress
16	767		2	"	t months	4400	Cinit and and	Territaine ()= 3 contline	Description of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the
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	447	Yes				1 month	First occurence	Subacute (>= 2 weeks)	Absent
	448	Yes				5 months	First occurence	Insidious (>= 3 months)	Absent
	455	Yes				6 months		Insidious (>= 3 months)	Absent
	456	Yes						Insidious (>= 3 months)	Absent
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		:	57	•		6 weeks	First occurence	Subacute (>= 2 weeks)	Probably present
	20		22	4	8 nonths	7 weeks	Chromic condition		
	51		36	•		5 veeks	First occurence	Subacute (>= 2 weeks)	Absent
	22		#	-	9 months	5 weeks	Similar prev. cond.		Probably present
	23		4	•		8 неекз	First occurence	Subacute (>= 2 yeeks)	Absent
	54		26	•			First occurence		Absent
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	22		3			onthic a	Change and think	Tanishing (>= 2 months)	About propert
	ł		:				mora comparation		
21	<b>6</b> 1		17	4	6 months	3 months	Chronic condition	Insidious (>= 3 months)	Probably present
23	113		56	e	2 months	5 weeks	Chronic condition	Subacute (>= 2 weeks)	Absent
	115		92	0		6 weeks	First occurence	Subacute (>= 2 weeks)	Absent

# PHARMACIA CMS R&D

# Listing No.: 3.0 DAGNOSTIC CRITERIA FOR THE MAJOR DEPRESSIVE EPISODE REBOXETINE - PROTOCOL 20124/016

At least five of the following symptoms have been present during the same two-week period and represent a change from provious functioning: at least one of the symptoms is either 1) depressed mode or 2) loss of interest or pleasure.

1) depressed mond most of day, nearly every day, as indicated by subjective account or observation by others

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

significant waight loss or weight gain when not dieting (e.g. more than 5% of body weight in a month), or decrease or increase in apportite nearly every day

4) insumnia or hypersomnia nearly every day

5) psychomotor agitation or retardation meanly every day (observable by others, not merely subjective feelings of restlessmoss or boing slowed down)

6) fatigue or loss of energy nearly every day

feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) mearly 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

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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

as two or C. At no time during the disturbance have there been delusions or hallucinations for as long weeks in the absence of prominent mood symptoms (i.e., before the mood symptoms developed after they have remitted) Not superimposed on Schizophrenia, Schizophreniform, Disorder, Delusional Disorder, or Psychotic Disorder NOS.

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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PHARMACIA CNS RED

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## 637   Female 62   256.2   X   X   X   X   X   X   X   X   X		436	Female	40	296.3	: ×	<b>×</b>	: ×	: ×	: ×	: ×	:	; ×		×	×		×	×
Female   64   286.2   X   X   X   X   X   X   X   X   X		437	Female	22	296.2	*	>	<b>&gt;</b>	×	×	: ×	×	: ><			×		×	×
439         Fomale         51         296.2         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         <		438	Female	49	296.2	×	×	>	:	×	*	×	×			×		×	×
### Female 41 296.3 X X X X X X X X X X X X X X X X X X X		439	Female	5	296.2	×	×	×	×	×	×	<b>×</b>	: ×			×		×	×
### Female 55 266.2 X X X X X X X X X X X X X X X X X X X		440	Female	4	296.3	<b>×</b>	×	×	<b>&gt;</b>	×	<b>×</b>	. ×	; ×	: ><	×	>		<b>3</b> 0	×
##2 Penals 55 266.3 X X X X X X X X X X X X X X X X X X X		441	Female	52	296.2		×	<b>×</b>	×	×	<b>×</b>	ź	. ×	: >0		×		×	×
##Is 23 266.2 X X X X X X X X X X X X X X X X X X X		442	Female	55	296.3	×	×	×	×	×	×	×	×	-		×		×	×
444 Female 42 296.2 X X X X X X X X X X X X X X X X X X X		443	Male	23	296.2	×	×	×		×	×	×		×	×	×		×	×
445		444	Female	27	296.2	×	×	×	×	×	×	×	×	×	×	×		×	×
446 Female 31 296.2 X X X X X X X X X X X X X X X X X X X		445	Kale	45	296.2	×	×	×	×	×	×	×	×	×	×	×		×	×
447         Male         30         296.2         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X <th< td=""><td></td><td>446</td><td>Fenale</td><td>æ</td><td>296.2</td><td>×</td><td>×</td><td>×</td><td>×</td><td>×</td><td>×</td><td>×</td><td>×</td><td>×</td><td>×</td><td>×</td><td></td><td>×</td><td>×</td></th<>		446	Fenale	æ	296.2	×	×	×	×	×	×	×	×	×	×	×		×	×
446 Female 40 296.2 X X X X X X X X X X X X X X X X X X X		447	Male	3	296.2	×	×	×	×	×	<b>&gt;</b> <	×		×	×	×		×	×
465 Female 40 296.2 × × × × × × × × × × × × × × × × × × ×		448	Fenale	45	296.2	×	×	×		×	×	×	×	×	×	×		×	×
456 Male 52 296.2 X X X X X X X X X X X X X X X X X X X		455	Female	40	296.2	×	×	×		×	×	×	×			×		×	×
4657 Female 55 296.3 X X X X X X X X X X X X X X X X X X X		456	Male	64	296.2	×	×	×	×	×	×	×	×			*		×	×
458 Nation		457	Female	22	296.3	×	×	×	×	×	×	×	×			~		×	×
469 Male 46 296.2 X X X X X X X X X X X X X X X X X X X		458	Female	22	296.2	×	×	×		×	×	×	×	×	×	×		×	×
### 61 Penale 59 296.3 X X X X X X X X X X X X X X X X X X X		459	Male	46	296.2	×	×	×		×	×	×		<b>×</b>	×	*		×	×
25 Female 59 296.3 X X X X X X X X X X X X X X X X X X X		094	Male	19	296.2	×	×	×		20	×	×	×	×	×	×		×	×
26 Female 33 256.2 X X X X X X X X X X X X X X X X X X X	_			5	0	2	:	:		:		:	:		2	•	-	•	;
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49 Female 57 236.2 X X X X X X X X X X X X X X X X X X X		. 6	Fomale	9 6	2000	٠,	٠,	¢ >		< >	¢	٠,	٠,	٠,	• >			•	< >
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51 Female 36 296.2 X X X X X X X X X X X X X X X X X X X		<b>.</b>	Found	5 5	2.062	< >	• >	<b>c</b> >		٠,	¢	٠,	٠,					<>	• >
52 Female 47 296.3 X X X X X X X X X X X X X X X X X X X		3 2	Fran 1	3 6	200	< >	( )	6 2		د >	,	د >	٠,					د >	4 5
53 Female 41 296.2 X X X X X X X X X X X X X X X X X X X		: 6	E CHECK	3 5	200	<>	( >	د >	>	< >	٠,	• >	٠,					: >	• >
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22 Female 41 296.2 X X X X X X X X X X X X X X X X X X X		17	Female	25	296.3	×	×	×		×	×	×				~		×	×
9 Female 27 296.3 X X X X X X X X X X X X X X 113 Male 43 296.3 X X X X X X X X X X X X X X X X X X X		22	Female	4	296.2	×	×	×	×	×	×	×	×			_		×	×
9 Female 27 296.3 X X X X X X X X X X X X X X 113 Male 43 296.3 X X X X X X X X X X X X X X X X X X X																			
113 Male 43 296.3 X X X X X X X X X X X X X X X X X X X	_	Φ	Female	27	296.3	×	×	×		×	×		×	×	×	_		×	×
113 Halle 43 296.3 X X X X X X X X X X X X X X X X X X X		;	:													·			
	N	113	Kale	43		×	× :	×:	×		×	×		×	×	•		~	×

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 4.0 MEDICAL HISTORY AND ADHISSION EXAMINATION FINDINGS

Centre	Patient	Sex	Age	Medical history	Admission examination
-	æ	Female	42	SEPTICEMIA MOS GOITER NOS	
	4	Fenale	5	PURE HYPERCHOLESTEROLEM CHOLELITHIASIS NOS	
м	34	Male	88	DUODENAL ULCER NOS STONACH ULCER NOS	HYPERTENSION NOS
	જ	Fenale	49	TORTICOLLIS NOS	
	66	Kale	£3	STOMACH ULCER NOS PROSTATITIS NOS	
	4	Hale	88	INGUINAL HERNIA NOS	
	£2	Female	20	UTERINE PROLAPSE GASTRITIS/DUODENITIS NOS	
	4.5	Fencale	37	SALPINGO-OOPHORITIS NOS UTERINE LEIOMYOMA	NIXED HYPERLIPIDENIA
	43	Female	9		TACHYCARDIA NOS
	80	Hale	\$	OLD MYOCARDIAL INFARCT	OBESITY ABN BLOOD CHEMISTRY NEC
м	8	Female	8	PULMONARY TB NEC	
	<i>L</i> 9	Fenale	56	APPENDICITIS NOS STERILIZATION VARICOSE VEIN OF LEG NOS UTERINE LEIONYOMA	
	89	Female	29	CLAVICLE FRACTURE	
*	76	Fenale	9	HYDRONEPHROSIS	HYDRONEPHROSIS

PHARMACIA CMS R&D
REBOXETINE - PROTOCOL 20124/016
Listing No.: 4.0
MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Medical history

Age

Centre Patient

SUICIDE-PSYCHOTROPIC ACT			CARDIOVAS SYS SYMP NEC			THYRDTOXICOSIS NOS			CYSTITIS NOS ABN BLOOD CHEMISTRY NEC	TACHYCARDIA NOS		
CTHER GU NEOPLASK NOS CHRONIC PANCREATITIS	CONCUSSION	CESAREAN DELIVERY NOS HONINFL DIS OVA-ADIX NEC HEPATITIS IN VIRAL DIS OVARIAN CYST NEC'NOS	ECTOPIC PREGNANCY NOS	CYSTIC KIDNEY DISEASE FX SACRUM/COCCYX-CLOSED SPONTANEOUS ABORTION	INGUINAL BERNIA NOS PHECHONIA, ORGANISM NOS ASTICHATISM HYPERHETROPIA	RENICH NED UTERUS NOS	TYPHOID FEVER	SCOLIOSIS			UTERINE LEIOMYONA	DISSEMIN CHORIORETINITIS
46	23	45	99	55	25	43	62	3,	22	44	38	49
Fenale	Male	Female	Female	Female	Гета 1 е	Male	Female	Fenale	Female	Female	Female	Female
66	100	101	102	103	193	197	323	324	326	329	331	334
J.							7					

PHARMACIA CNS R&D

HEDICAL BISTORY AND ADMISSION EXAMINATION FINDINGS REBOXETINE - PROTOCOL 20124/016 Listing No.: 4.0

Medical history

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	ABN LIVER FUNCTION STUDY ADV EFF PHENOTHIAZ TRANQ			ı							BRONCHITIS NOS		
OTHER ANOMALIES OF LUNG		ESOPHAGITIS	ARTHROPATHY NOS	OTHER GU NEOPLASM NOS ALLERGIC RHINITIS NOS	OTHER GU NEOPLASM NOS ASTRMA NOS	HYPERTENSION NOS	OSTEITIS DEFORMANS NOS	BRONCHIECTASIS	PULMONARY TB NOS PREUBOTHORAX EXCESSIVE MENSTRUATION OTHER PSORIASIS OSTEOARTHROSIS NOS	UTERINE LEIDNYONA		AŠTHMA NOS	CHOLELITHIASIS NOS
8	25	78	50	88	<b>8</b> <sup>4</sup>	20	63	4	43	19	40	20	22
Fenale	Kale	Female	Male	Female	Female	Kale	Female	Female	Female	Female	Female	Female	Female
335	386	387	388	392	503	521	397	398	399	404	405	706	408
<b>5</b>	£1						#						

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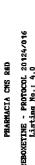
PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 4.0

MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS

Age Medical history

Centre Patient

							OBESITY				CERONIC LIVER DIS NEC OBESITY	LIVER DISORDERS NEC
MIGRAINE Derangement of Joint Nos	CYSTIC KIDNEY DISEASE	DISC DISPLACEMENT NOS THORAC/LUMB DISC DISPLAC	ENDOMETRIOSIS NOS	PURE HYPERCHOLESTEROLES	HYPERTENSION NOS	GOITER NOS		VARICOSE VEIN OF LEG NOS OTHER GU NEOPLASH NOS DISC DISPLACEMENT NOS APPENDICITIS NOS	ENTHESOPATHY OF ANKLE LUMBAGD SCIATICA APPENDICTIS NOS	RHEVMATISM NOS OBESITY	EXCESSIVE NEWSTRUATION CHRONIC LIVER DIS NEC OBESITY	ALCOHOLIC GASTRITIS
94	28	9	<b>\$</b>	5	2	88	35	52	8	44	4	56
Fenale	Female	Female	Female	Male	Female	Female	Female	Female	Fenale	Female	Female	Male
510	511	538	539	430	438	992	27	64	20	22	53	54
41				91		18						



FINDINGS	Admission examination		
MEDICAL HISTORY AND ADMISSION EXAMINATION FINDINGS			
ADMISSION	history		
STORY AND	Age Medical history	S6 OBESITY	
ICAL HIS	Age	95	
¥	Sex	Ha1e	
	Centre Patient Sex	**	
	Centre	85	;

PRARMACIA CHS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 5.0

												IELD			
Pulmonary FunctionAbsormality												ABN FINDINGS-LUNG FIELD			
_Chest X-Ray - Value	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Not done	Abnorma1	Normal	Normal	Normal
Cher	19/11/91	26/06/92	25/06/92	12/08/92	06/10/92	11/01/93	07/05/91	08/05/91	16/04/91	26/04/91		28/06/91	19/06/91	02/91	Screen 14/02/92
Assessment	Screen	Screen	Screen	Screen	Screen	Seroon	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen
Se x	Male	Kale	Female	Female	Female	Male	Female	Male	Female	Male	Male	Kale	Kale	Kale	Male
Patient	-	81	m	<b>4</b>	w	v	ន	34	35	96	37	38	39	40	41
Centre	-						N								

Screen

e	0124/016		- Pulmonary Function Abnormality			11 PLEURISY W/O EFFUS OR TB	11 VIRAL PHEUKOHIA		1 PULMONARY IN NEC											
CNS R&	TOCOL 2	X-RAY	Chest X-Ray Value	Normal	Normal	Abnormal	Abnormal	Norna.1	Abnormal	Normal	Normal	Normal	Normal	Normal	Normal	Norma1	Normal	Normal	Normal	Norma1
PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 5.0	CREST X-RAY	Ches	12/12/91	14/09/92	27/03/92	27/04/92	11/92	02/10/91	22/10/91	30/10/92	27/11/92	18/04/91	29/05/91	14/10/91	07/05/92	02/07/92	08/07/92	07/07/92	17/08/92
	REBOXI		Assessment	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen
			Sex	Male	Female	Female	Female	Kale	Female	Female	Female	Female	Female	Female	Fenale	Male	Female	Female	Female	Female
			Patient	#	45	47	48	80	<b>5</b> 9	99	67	89	97	86	66	100	101	102	103	104
			Centre	71					m			4	4							

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 Listing No.: 5.0

Pulmonary Function Abnormality																	
Chest X-Ray - Value	Nornal	Not done	Normal	Not done	Not done	Normal	Normal	Mormal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	;
Che	26/08/92		23/02/92			14/02/92	22/05/92	16/11/92	25/10/91	08/09/91	30/10/91	10/12/91	16/01/92	12/91	15/01/92	21/12/91	
Assessment	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Scroon	Screen	Screen	•
Sex	Male	Female	Female	Female	Female	Male	Female	Male	Female	Female	Female	Fenale	Female	Fenale	Fenale	Fenale	,
Patient	105	129	130	193	194	195	196	197	321	322	323	324	325	326	327	328	;
Centre	4	S		7					=								

Female

Screen 15/08/92 Abnormal OTHER ANDMALIES OF LUNG Chest X-Ray - Pulmonary Function Value Abnormality REBOXETINE - PROTOCOL 20124/016 Listing No.: 5.0 PHARMACIA CNS R&D Not done Normal Screen 20/04/92 Normal 20/01/92 Normal Screen 07/08/92 Normal Screen 14/06/92 Normal CHEST X-RAY 23/04/92 20/01/92 07/06/92 Assessment Date Screen Screen Screen Female Centre Patient Sex 331 332 335 497 385 387 330 334

Ę

28/05/92 Normal

Screen

Male

PHARMACIA CMS RED
REBOXETINE - PROTOCOL 20124/016
Listing No.: 5.0

Chest X-Ray - Pulmonary Function Value Abnormality														PULHONARY TB NOS			
ay - Pulmo Abaor	н	н	н	-	1	Ħ	п	one	ч	4	면	ᅽ	멸		ց	7	
st X-Re Value	Normal	Mormal	Normal	Normal	Normal	Normal	Normal	Not done	Normal	Normal	Normal	Normal	Normal	Absormal	Norma1	Normal	
Date	05/06/92	12/08/92	30/10/92	04/11/92	12/11/92	25/11/92	15/04/92		11/09/92	30/10/92	01/12/93	30/01/92	15/04/92	13/04/92	14/05/92	02/12/91	
Assessment	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	
Neg	Female	Female	Hale	Female	Fenale	Female	Female	Kale	Fenale	Female	Male	Female	Female	Female	Male	Female	
Patient	391	392	501	502	503	504	505	506	507	508	521	397	398	399	400	401	
entre	6											五					

Screen 25/05/92 Normal

PHARMACIA CHS RED REBOXETINE - PROTOCOL 20124/016 Listing No.: 5.0

											Ħ						
- Pulmonary FunctionAbnormality						,					FX RIB/STERN/LARYN/TRACH						
Chest X-Ray - 1 Value	Mornal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Abnormal	Normal	Normal	Normal	Normal	Normal	Learney
Ches	29/05/92	16/06/92	19/06/92	30/06/92	17/06/91	04/08/92	28/09/92	30/09/92	22/10/92	02/11/92	29/10/92	12/02/93	10/03/93	01/04/92	28/03/92	15/04/92	15/04/92
Assessment	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen
Xe	Female	Female	Female	Female	Male	Female	Female	Female	Female	Female	Female	Female	Fenale	Male	Female	Female	Female
Patient	403	404	405	406	407	408	509	510	511	512	537	538	539	604	410	114	412
Centre	4													51			

Chest X-Ray - Pulmonary Function Value Abnormality REBOXETINE - PROTOCOL 20124/016 Listing No.: 5.0 PHARMACIA CNS RED Normal Normal Normal Screen 16/08/92 Normal 20/10/92 Normal 17/06/92 Normal Normal Screen 19/11/92 Normal 20/04/92 Normal Screen 20/05/92 Normal Normal 12/08/92 12/07/92 Screen 13/08/92 05/12/92 17/07/92 Screen Fenale Fenale Centre Patient **‡** 417 418 420 413 414 415 5

Chest X-Ray - Pulmonary Function Value Abnormality REBOXETINE - PROTOCOL 20124/016 Listing No.: 5.0 PHARMACIA CNS R&D Normal Screen 15/05/92 Normal Screen 15/05/92 Normal Screen 27/11/92 Normal Screen 25/11/92 Normal Screen 09/03/92 Normal Normal CHEST X-RAY Screen 12/12/92 Normal Screen 13/07/92 26/03/92 Screen 08/04/92 Screen 30/03/92 09/04/92 20/04/92 30/06/92 04/01/93 Screen Female Female Female Female Female Centre Patient 440 1 433 435 436 429 432 452 9

PHARMACIA CHS RED REBOXETINE - PROTOCOL 20124/016 Listing No.: 5.0

			nction											TOMS NEC				
	9		Pulmonary Function Abnormality											GENERAL SYMPTONS NEC				
	124/01		- Pulr															
CNS R&D	TOCOL 20	X-RAY	Chest X-Ray	Normal	Normal	Normal	Normal	Normal	Norma1	Normal	Normal	Normal	Normal	Abnormal	Normal	Not done	Normail	Normal
PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 5.0	CHEST X-RAY	Ches	29/09/92	30/09/92	13/10/92	05/10/92	10/11/92	10/11/92	10/11/91	10/11/92	29/12/92	05/01/93	30/10/92	13/11/92			
	REBOXE		Assessment	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen	Screen
			Sex	Hale	Female	Female	Female	Female	Female	Female	Female	Female	Kale	Fenale	Female	Female	Male	Male
			Patient	59	30	25	32	64	20	51	52	53	54	27	22	<b>6</b> 0	113	115
			Centre	81										20		21	22	

PRARMACIA CKS R&D REBUKETINE - PROTUCOL 20124/016 Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATHENT

				Previous antidepressant treatment	depressant t	reatment			
er tre	Patient	Š	Age	Name	Efficacy	Side	Last	Last day	
			}						
	m	Fonale	<b>4</b> 7	LUDIONIL ANITRIPIVLINE HYDROCHLORIDE AURORIX	Poor Poor Very poor		XX	24/06/92	
	4	Female	2	TOLVIN	Poor		*	06/08/92	
	ហ	Female	99	AMAFRANIL	Poor		*	06/10/92	
	vo	Male	\$	FEVARIN	Poor		XX	01/01/93	
	83	Fenale	52	FLUOXETINE	Very poor		**	03/91	
	శ్	Male	88	SAROTEN	Very poor		×	30/04/91	
	35	Female	49	APONAL ANITRIPTYLINE BYDROCHLORIDE	Poor Poor	>1	*	11/04/91	
	98	Kale	<b>£</b>	SAROTEN	Poor	×	XX	26/04/91	
	37	Male	28	ANAFRANIL Insidon Antriptyline Antriptyline	Very poor Very poor Very poor Good			30/09/91	
	33	Kale	£3.	STANGYI. APONAL	Fair Very poor	×	*	11/06/91	
	6.0	Male	54	APONAL	Poor	×	*	04/06/91	
	4	Kale	58	EQUILIBRIN AURORIX	Poor Poor		*	09/02/92	
	42	Fenale	S	SAROTEN - SLON RELEASE	Very poor	*	*	03/03/92	
	£4.	Female	42	SAROTEN	Poor		***	12/11/91	

PHARMACIA CNS R&D BOXETINE - PROTOCOL 20124/016 Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

					Previous	Previous antidepressant treatment	t trea	trent			
antre	Patient	Sex	Age	Матю	i	Efficacy	a G	Side	Last taken	Last day of treat.	
	44	Kale	3	SAROTEN		Poor			×	09/12/91	
	. St	Female	37	SAROTEN		Very poor	Ħ	×	K K	26/08/92	
	4.7	Female	6	INSIBON		Very poor	i di		XX	22/03/92	
	48	Female	9	SARDTEN RETARD		Fair		*	X X X	15/05/92	
	8	Male	#	SAROTEN TOLVIN		Poor		<b>&gt;</b> 1	×	11/92	
	65	Female	63	TOFRANIL MITE APONAL		Very po	poor		**	11/10/91	
	99	Female	27	SAROTEN ANAFRANIL TOFRANIL TOLVIN		Fair Poor Poor					
	<i>2</i> 9	Female	×	APONAL		Very poor	10		×××	13/11/92	
	89	Female	53	ANITRIPTYLINE		Fair			X	25/11/92	
_	97	Female	62	SAROTEN RETARD		Very poor	100	*	××××	16/04/91	
	66	Female	46	DOXEPIN					×××	09/10/91	
	102	Female	65	AURORIX Anafranīl		Good			#	29/06/92	
	103	Female	85	FEVARIN FLUOXETINE		Poor Fair		×	Ħ	08/07/92	
	105	Kale	3	APONAL		Very poor	DOL		*	14/08/92	
ın	129	Fonale		TRYPIIZOL		Very good	Poo	×	**	05/91	

		,		Last day of treat.	25/11/91	28/10/92	15/01/91	27/06/92	15/07/92	15/07/92		25/01/92		14/04/92	02/03/92	25/05/92	03/06/92	25/08/92
				Last	*	XXX	ž	XXX	XXX	×××		**			ä	*	**	**
			treatment	Side	DI DI	×	34	×	ы		* *	×						
NS RED	PROTOCOL, 20124/016 ig No.: 6.0	SIVE TREATHENT	Previous antidepressant tr	Efficacy	Fair Good	Poor	Very good	Fair	Fair	Poor Good Poor Fair	Fair Fair Poor	Fair	Good	Fair Good	Good	Poor	Poor	Poor
PHARMACIA CNS RED	REBOXETINE - PROTOCOL 20 Listing No.: 6.0	PREVIOUS ANTIDEPRESSIVE TREATHENT	Pre	Name	ANAFRANIC TRYPTIZOL	ANAFRANIL	CLOKIPRAKINE	AURORIX	AHITRIPTYLINE	MOCLOBEHIDE PARNATE ANAFRANIL LITHIUM	PROTHIADEN PROZAC AURORIX	DOXEPIN	MIANSERIN	PROTHIADEN TRIMIPRAMINE	PROTHIADEN	DOXEPIN	PROTHIADEN	NORTRIPTYLINE LITHIUM
				Age	25	43	*	5	45	39	43	47	62	87.	8	28	35	4
				Sex	Fenale	Male	Female	Kale	Kale	Female	Female	Fenale	Male	Female	Nale	Male	Fenale	Female
				Patient	193	197	324	394	395	396	497	385	386	387	388	390	391	505
				Centre	2		£	12				<u>£</u>						

PHARMACIA CNS RED REBOXETINE - PROIOCOL 20124/016 Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATHENT

				Previous antidepressant treatment	idepressant	treatment	1	
انت	Patient	Sex	Ago	Мате	Efficacy	effects	taken	of treat.
ភ	505	Female	2	INIPRANINE FLUOXETINE	Poor Good			
ភ	506	Kale	88	ANAFRANII.	Fair	ы	XX	22/10/92
20	507	Female	64	PROTHIADEN	Fair		ä	09/09/92
23	521	Hale	20	PROZAC SURMONTIL	Fair	<b>&gt;</b> >	**	14/10/92
398	₩.	Female	14	DOTHIEPIN	Very good	×	***	29/08/91
405	ស្ន	Female	9	DOTHIEPIN		эı	жжж	12/06/92
407	2	Kale	37	VENLAFAXINE				
503	ō.	Femalo	53	DOTHIEPIN	Poor	<b>&gt;</b> +	XXX	20/00/02
510		Fenale	8	DOXEPIN	Fair	*	×	8
5	511	Female	28	DOXEPIN	Fair	*	×	02/09/92
539	ø,	Female	9	DOXEPIN	Poor	э		
3	409	Male	28	DEROLOX Parnate Nortriptyline	Fair Good Very good		**	20/03/92
2	410	Female	5	TOFRANIL	Fair		**	08/04/92
7	411	Female	2	ANAFRANIL Tranylcyprohine	Very good Fair		××	31/12/88
<b>Ξ</b>	413	Fenale	53	FLUOXETINE Topranil Survector	Good Very good Good		*	30/06/91

PHARMACIA CMS R&D ETINE - PROVOCOL 20124/016 Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

].	Last day of treat.	10/05/92	20/11/88	31/07/89	30/10/89	15/07/92	31/08/90	30/06/90	31/03/87	01/09/92	30/04/92	18/11/92
ļ	٠							XXX	***	×	**	×××
1	Last	X	×	***	X	X	*	Ŗ	¥	R	¥	*
treatment	Side		75	ਚ	70		ਯੂ	P.	B	good	good	
sant	acy		Very good	Very good	good		pood I	l good	Very good	y good d good	8 2	4 T
Previous antidepressant treatment.	Efficacy	Fair Good Good Poor	Very	Very	Good Very Good	Poor Good	Very Good Good Fair	Very	Ver	Fair Very Very Good	Very Good	Fair Good
Previous												
	Кале	FLUOXETINE TOFRANIL PARNATE LERIYON	NORTRIPTYLINE	ANAFRANIL	SURVECTOR Tofranil Parnate	AURORIX Tofranil Parnate	TRYPTANOL TOFRANIL NORTRIPTYLINE FLUOXETINE	FLUOXETINE	TOFRANIL	FLUOXETINË TOFRANIL TRYPTANOL PARNATE	ANAFRANIL PARNATE	AURORIX ARAFRANIL
	Age	643	54	\$	56	19	62	4	32	80 80	4.7	33
	Sex	Fonale	Female	Female	Fenale	Kale	Female	Male	Kale	Female	Female	Female
	Patient	415	417	418	419	420	421	422	454	425	427	<del>#</del>
	Centre	15										

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PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATMENT

				Previous antidepressant treatment	epressant t	reatment		
440	Dationt	200	Ş	N. C. C. C. C. C. C. C. C. C. C. C. C. C.	,	Side	Last	Last day
-	Justan	Y Ser	afiu	Nestio	EIIICACY	BII OCES	raken	10 11 10
ıo	450	Male	æ	TOFRANIL	Fair	*	**	30/11/92
	451	Female	\$	SURVECTOR ANAFRANIL	Fair Good	≱H	×××	07/12/92
	454	Kale	51	TOFRANIL	Good		XXX	30/01/90
v	429	Fenale	48	TRYPTANOL	Good	×	×	20/04/91
	431	Fenale	58	TOFRANIL	Bood	ы	**	05/10/86
	432	Fenale	49	TOFRANIL	poog	>+	**	19/05/89
	433	Female	39	TOFRANIL	Good	<b>54</b>	X	05/11/88
	434	Female	83	LERIVON TOFRANIL	Good Fair	<b>&gt;+</b> >+	**	19/03/92
	436	Female	40	LERIVON	Very poor	<b>&gt;</b> 4	X	25/07/91
	044	Female	4	SURMONTIL	Very good	*	XXX	05/04/88
	445	Female	55	ANAFRANIL Tofranil Anitriptyline	Poor Poor	<b>34 34</b>	×	05/03/92
œ	<b>5</b> 6	Female	33	APONAL	Poor		X X	23/09/92
	29	Male	24	NOVERIL - SLOW RELEASE	Poor		×	28/09/92
	8	Fenale	5	EQUILIBRIN	Poor		XX	30/09/92
	31	Female	52	NAUQUAN	Poor		22	12/10/92
	32	Female	36	INSIDON	Poor		ä	30/09/92

9550083

PHARMACIA CNS R&D XETINE - PROTOCOL 20124/016 Listing No.: 6.0

PREVIOUS ANTIDEPRESSIVE TREATHENT

					Previous antideoressant treatment	treatment		
entre	Patient	Sex	age age	Name	Efficacy	Side	Last	Last day of treat.
22	64	Female	57	SINGUAN	Poor		**	10/11/92
	50	Female	63	MAPROTILINE	Poor		**	09/11/92
	53	Female	%	EQUILIBRIN	Poor		×××	07/11/92
	22	Female	43	TOFRANIL	Poor		×	10/11/92
	\$	Male	26	AURORIX	Poor		XX	31/12/92
2	21	Female	52	STANGYL	Fair		×	10/10/92
	22	Female	2	EQUILIBRIN	Very poor	#	X	05/11/92
25	σ,	Female	27	NOCLOBENIDE CLOMIPRAMINE	Poor Poor		***	08/10/92
23	113	Male	£\$	AMITRIPTYLINE DOXEPIN	Fair Fair	>4	××××	15/11/92

REBOXETINE - PROTOCOL 20124/016 Listing No.: 6.1 DURATION OF DXUG-FREE MASH-OUT-PERIOD

PHARMACIA CHS R&D

Centre	Patient	Last day or previous treatment	From (*) To (a)	out period To (a)	Days	Start date	reatment to Randomized
_	-			14/11/91		15/11/91	Fluoxetine
	84			25/06/92		26/06/92	Reboxetine
	m	24/06/92	25/06/92	30/06/92		01/07/92	Fluoxetine
	4	06/08/92	07/08/92	13/08/92		14/08/92	Reboxetine
	ហ	06/10/92	07/10/92	12/10/92	10	13/10/92	Fluoxetine
	vo	01/01/93	06/01/93	13/01/93	œ	14/01/93	Fluoxetine
N	83	03/91	02/03/91	63/05/91	49	04/05/91	Fluoxetine
	**	30/04/91	01/05/91	02/05/91	ю	03/05/91	Reboxetine
	35	11/04/91	12/04/91	15/04/91	vo	16/04/91	Reboxetine
	36	26/04/91	27/04/91	01/05/91	κŋ	02/05/91	Fluoxetine
	37	30/09/91	01/10/91	16/10/91		07/10/91	Reboxetine
	38			19/06/91		20/06/91	Fluoxetine
	39	11/06/91	12/06/91	18/06/91	83	16/90/61	Fluoxetine
	40	04/06/91	05/06/91	05/06/91	82	16/90/90	Reboxetine
	14	09/02/92	10/02/92	12/02/92	ю	13/02/92	Fluoxetine
	45	03/03/92	04/03/92	04/03/92	84	05/03/92	Reboxetine

(\*) if missing date = last day of previous treatment + 1 day (3) same as start treatment date - 1 day

REBOXETINE - PROTOCOL 20124/016 Listing No.: 6.1

PHARMACIA CNS RED

LISTING No.: 6.1 DUBATION OF DRUG-FREE MASH-OUT-PERIOD		
LASTING NO.: DURATION OF DRUG-FREE	6.1	WASH-OUT-PERIOD
L. DURATION OF	sting No.:	DRUG-FREE
DURATION	3	늄
		DURATION

		1984 4981 05	į	Paris to the state of		ř	ļ.
Centre	Patient	previous treatment	From (*)	To (9)	Days	Start date	ite Randomized
84	43	12/11/91	13/11/91	18/11/91	v	19/11/91	Reboxetine
	‡	09/12/91	10/12/91	12/12/91	m	13/12/91	Fluoxetine
	45	26/08/92	27/08/92	26/60/60	5	10/09/92	Reboxetine
	47	22/03/92	23/03/92	24/03/92	M	25/03/92	Fluoxetino
	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
m	8	11/10/91	12/10/91	15/10/91	4	16/10/91	Fluoxetine
	99		12/10/91	15/10/91	4	16/10/91	Fluoxetine
	29	13/11/92	14/11/92	17/11/92	4	18/11/92	Reboxetine
	89	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	坊	22/04/91	Reboxetine
	88		24/05/91	29/05/91	10	30/05/91	Fluoxetine
	66	16/01/60	11/10/91	14/10/91	4	15/10/91	Fluoxetine
	400			07/05/92		08/05/92	Reboxetine
	401			01/07/92		02/07/92	Reboxetine
	102	29/06/92	30/06/92	09/07/92	5	10/07/92	Fluoxetine

(\*) if missing date = last day of previous treatment + 1 day (3) same as start treatment date - 1 day

		PHARMACIA CNS RED	RED			
	REBOXETINE List	CINE - PROTOCOL 20124/016 Listing No.: 6.1	20124/016 .1			
	DURATION	DURATION OF DRUG-FREE WASH-OUT-PERIOD	SH-OUT-PERIOD			
Patient	Last day of previous treatment		out period To (2)	Days	Start date	Treatment te Randomi
103	08/07/92	09/07/92	12/07/92	4	13/07/92	Fluoxe
104		10/08/92	17/08/92	60	18/08/92	Reboxe
105	14/08/92	15/08/92	20/08/92		21/08/92	Fluore
129	05/91	02/05/91	28/11/91	212	29/11/91	Reboxe
130			27/02/92		28/02/92	Fluoxe
193	25/11/91	30/11/91	05/12/91	9	06/12/91	Reboxe
194			09/01/92		10/01/92	Fluoxe
195			13/02/92		14/02/92	Fluoxe
196			28/05/92		29/02/92	Reboxe
197	28/10/92	29/10/92	10/11/92	13	11/11/92	Fluoxe
321			13/11/91		14/11/91	Fluoxe
322			13/11/91		14/11/91	Reboxe
323			18/11/91		19/11/91	Fluoxe
324	15/01/91	16/10/91	23/01/92	373	24/01/92	Reboxe
325		ı	11/02/92		12/02/92	Reboxe
326			11/02/92		12/02/92	Reboxe

(\*) if missing date = last day of previous treatment + 1 day (a) same as start treatment date - 1 day

REBOXETINE - PROTOCOL 20124/016 Listing No.: 6.1 DURATION OF DRUG-PREE MASH-OUT-PERIOD

PHARMACIA CNS RED

Centre	Patient	Last day of previous treatment	Hash out period   From (*) To (3)	out period To (3)	Days	Treat Start date	Treatment ite 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			25/02/92		26/02/92	Fluoxetine
	332			27/07/92		28/07/92	Fluoxetime
	333			14/09/92		15/09/92	Reboxetine
	334			21/09/92		22/09/92	Fluoxetine
	335			12/10/92		13/10/92	Reboxetine
52	393			24/06/92		25/06/92	Fluoxetine
	394	27/06/92	28/06/92	05/07/92	g,	06/01/92	Reboxatine
	395	15/07/92	16/07/92	23/07/92	60	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	£	24/02/93	Fluoxetine
13	385	25/01/92	26/01/92	13/03/92	49	14/03/92	Fluoxetine

(\*) if missing date = last day of previous treatment + 1 day (9) same as start treatment date - 1 day

24/04/92

83

23/04/92

386

PHARMACIA CNS RRD TINE - PROTOCOL 20124/016 Listing No.: 6.1

		DURATION (	DURATION OF DRUG-FREE WASH-OUT-PERIOD	SH-OUT-PERIOD			
Centre	Patient	Last day of provious treatment	From (*)	out period To (a)	Days	Start date	Treatment ite Randomized
	387	14/04/92	15/04/92	17/04/92	es	18/04/92	Reboxetine
	388	02/03/92	26/20/20	15/03/92	4	16/03/92	Reboxetins
	389		,	20/07/92		21/07/92	Fluoxetine
	390	25/05/92	26/02/92	27/05/92	m	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	М	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	w	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	81	11/09/92	Fluoxetime
	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
45	397		12/03/92	13/04/92	8	14/04/92	Fluoxetine

(\*) if missing date = last day of previous treatment + 1 day (3) same as start treatment date - 1 day

PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/016

		Treatment Start date Randomized	15/04/92 Reboxetime	21/04/92 Reboxetine	15/05/92 Fluoxetine	22/05/92 Fluoxetine	27/05/92 Reboxetine	29/05/92 Reboxetine	16/06/92 Fluoxetine	22/06/92 Fluoxetine	30/06/92 Fluoxetine	14/07/92 Reboxetine	04/08/92 Reboxetine	29/09/92 Fluoxetine	30/09/92 Fluoxetine	23/10/92 Reboxetine	03/11/92 Reboxetine	
		Days	229			129	i			<b>1</b>		133		<b>5</b> 0	2464	20		
	4-OUT-PERIOD	Mash out period () To (a)	14/04/92	20/04/92	14/05/92	21/05/92	26/02/92	28/05/92	15/06/92	21/06/92	29/06/92	13/07/92	03/08/92	28/09/92	29/09/92	22/10/92	02/11/92	
Listing No.: 6.1	DURATION OF DRUG-FREE WASH-OUT-PERIOD	From (x)	30/08/91			14/01/92				13/06/92		03/03/92		21/09/92	02/01/86	03/09/92		
Li	DURATION OF	Last day of previous treatment	29/08/91							12/06/92				20/09/92	98	02/09/92		
		Patient	398	399	400	401	402	403	404	405	904	407	408	509	510	511	512	

(\*) if missing date = last day of previous treatment + 1 day (9) same as start treatment date - 1 day

PHARMACIA CNS RED

-OUT-PERIOD
JG-FREE WASH-C
ATION OF DRU
DOUR

		East, day of	daek.	out period		Treat	Treatment
Centre	Patient	previous treatment	From (*)	(*) To (a)	Days	Start date	Randomized
\$	538			11/02/93		12/02/93	Fluoxetine
	539		23/02/93	09/03/93	51	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	æ	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	686	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	01/02/90	18/08/92	780	19/08/92	Fluoxetine

(\*) if missing date = last day of previous treatment + 1 day (0) same as start treatment date - 1 day

			PHARMACIA CNS R&D	R&D			
		REBOXET	REBOXETINE - PROTOCOL 20124/016 Listing No.: 6.1	20124/016			
		DURATION O	DURATION OF DRUG-FREE WASH-OUT-PERIOD	SH-OUT-PERIOD			
Centre	Patient	Last day of previous treatment	Hash From (*)	Hash out period From (*) To (3)	Days	Start date	Treatment te 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
	654	18/11/92	19/11/92	07/12/92	6	08/12/92	Rebaxetine
	450	30/11/92	01/12/92	09/12/92	O.	10/12/92	Fluoxetine
	451	07/12/92	08/12/92	17/12/92	<b>1</b>	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
5	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

		DOKATION	DUKATION OF DRUG-FREE MASH-DOT-FERIOD	3H-00T-PERIOD			1
Contre	Patient	previous treatment	From (*) To (a)	out period To (9)	Days	Start date	rearment te Randomized
<b>3</b> 5	434	19/03/92	20/03/92	06/04/92	8	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
	044	05/04/88	06/04/88	30/06/92	1547	01/07/92	Reboxetine
	441			21/07/92		22/01/92	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 (a) same as start treatment date - 1 day  $\,$ £

PHARMACIA CMS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 6.1

		DURATION O	DURATION OF DRUG-FREE WASH-OUT-PERIOD	SH-OUT-PERTOD			
Centre	Patient	Last day of previous treatment	From (*) To (2)	out period To (3)	Days	Start date	Treatment te Randomize
16	456			15/12/92		16/12/92	Reboxetin
	457			15/12/92		16/12/92	Fluoxetin
	458			15/12/92		16/12/92	Fluoxetin
	459			21/12/92		22/12/92	Reboxetin
	460			21/12/92		22/12/92	Reboxetin
18	25		23/09/92	05/10/92	13	06/10/92	Fluozetin
	56	23/09/92	24/09/92	05/10/92	£1	06/10/92	Reboxetin
	27			05/10/92		06/10/92	Reboxetin
	28		23/09/92	05/10/92	इ	06/10/92	Fluoxetin
	29	28/03/92	29/09/92	05/10/92	2	06/10/92	Reboxetin
	96 8	30/03/35	01/10/92	26/10/92		07/10/92	Fluoxetir
	31	12/10/92	13/10/92	19/10/92	7	20/10/92	Reboxetir
	32	30/09/92	01/10/92	06/10/92	vo	07/10/92	Fluoxetir

(\*) if missing date = last day of previous treatment + 1 day (0) same as start treatment date - 1 day

Reboxetine Reboxetine

16/11/92

17/11/92

			PRARMACIA CNS RED	RED			
		REBOXET	REBOXETINE - PROTOCOL 20124/016 Listing No.: 6.1	20124/016 .1			
		DURATION 0	DURATION OF DRUG-FREE MASH-OUT-PERIOD	SK-OUT-PERIOD			
Centre	Patient	Last day of previous treatment	Krom (*)	Wash out period   	Days	Start date	Treatment ite Random
18	22	10/11/92	11/11/92	16/11/92		17/11/92	Fluoxe
	83			14/01/93		15/01/93	Fluoxe
	<b>35</b>	31/12/92	05/01/93	11/01/93	7	12/01/93	Fluoxe
20	21	10/10/92	11/10/92	05/11/92	27	06/11/92	Fluoxe
	22	05/11/92	06/11/92	11/11/92	vo	12/11/92	Fluoxe
21	σ	08/10/92	09/10/92	18/10/92	2	19/10/92	Fluoxe
22	113	15/11/92	24/11/92	02/12/92	0	03/12/92	Fluoxe
	115			28/12/02		60/41/66	Dohove

(\*) if missing date = last day of previous treatment + 1 day
(@) same as start treatment date - 1 day

#### PHARMACIA CNSD SESSO 083

REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

			Pat	iont		
	1	2	3	4	5	6
	Male	Male	Fem.	Fem.	Fem,	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?					T	
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	XES	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 CNSSSO083

REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

Centre: 2

		****					Patien	t					
	33	34	35	36	37	38	39	40	41	42	43	44	45
	Fom.	Male	Fem.	Male	Male	Male	Male	Male	Male	Fom.	Fem.	Male	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?			1 -	1						<del>                                     </del>	<u> </u>	<del>                                     </del>	1
Aged between 18 and 65 years inclusive	YES	XES	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 ?											T	-	1
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 CN95990083

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

		Patien	t
	47	48	80
	Fom.	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 pravious antidepres. treat	YES	YES	YES
High risk of suicide	YES	YES	YES

## PHARMACIA CNG 550083

REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

		Pat	ient	
	65	66	67	68
	Fam.	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

#### PHARNACIA CNSSPSID083

REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

					Patier	t			
	97	98	99	100	101	102	103	104	105
	Fem.	Fem.	Fem.	Male	Fem.	Fem.	Fem.	Fem.	Halo
ARE THE FOLLOWING CONDITIONS PRESENT ?									<u> </u>
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 27HAMD	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.	МО	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	AER	YES	YES
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES

#### PHARMACIA CN9980083

REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

### INCLUSION / EXCLUSION CRITERIA

	Pat	ient
	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	YEŞ	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 550083

REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

			Patier	it	
	193	194	195	196	197
	Fem.	Fem.	Male	Fem.	Male
ARE THE FOLLOWING CONDITIONS PRESENT ?				İ	
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 21HAND	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	МО
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	МО
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 scizures 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
Rosistence to previous antidepres. treat	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES

#### PHARMACIA CNS98980083

REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

Centre: 11

							Patien	t					
	321	322	323	324	325	326	327	328	329	330	331	332	33
	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.	Male	Fem.	Fem.	Fem
ARE THE FOLLOWING CONDITIONS PRESENT ?		*									1	†^-	
Aged between 18 and 65 years inclusive	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YE
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 ?											İ	Ť	
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	МО	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
distory 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
ligh risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

(CONTINUED)

# PHARMACIA CNS9 550083

REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

	Pat	ient
	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 scizures 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 CNS95890083

REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

	Г		Patien	t	
	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	XES	YES
Any other important clinical illness	YES	YES	YES	YES	YES
ECT in the previous 6 months	YES	YES	YES	YES	YES
Resistence to provious antidepres. treat	YES	YES	YES	YES	YES
High risk of suicide	YES	YES	YES	YES	YES

#### PHARMACIA CNS 550083

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

Centre: 13

							Pation	t					
	385	386	387	388	389	390	391	392	501	502	503	504	505
	Fem.	Male	Fem.	Male	Fem.	Male	Fem.	Fem.	Male	Fem.	Fem.	Fom.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?										1			
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	XES	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	XES	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	Sak	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)

## РНАКМАСІА СМ**ЭДБЕТО** 083

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

		Pat	ient	
	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
Mith 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 CN9980083

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

Centre: 14

							Pation	t					
	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	ÄES	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 pravious 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)

## РНАКМАСІА СМ**ЭЗБО**083

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

	Ι		Pat	ient		
	510	511	512	537	538	539
					ļ	
	Fem.	Fem.	Fem.	Fem.	Fem.	Fem.
ARE THE FOLLOWING CONDITIONS PRESENT ?					ļ	
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 glaucema	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
Ristory 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 CNS9590083

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

Centre: 15

							Patier	t			·		
	409	410	411	412	413	414	415	416	417	418	419	420	42
	Male	Fem.	Fem.	Fem.	Fem.	Male	Fem.	Fem.	Fem.	Fem.	Fem.	Male	Fem
ARE THE FOLLOWING CONDITIONS PRESENT ?							T"		İ	<del></del>	İ	÷	İ
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 ?							<del> </del>					İ	<u> </u>
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 CNB 950083

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

### INCLUSION / EXCLUSION CRITERIA

						Pat	ient					
	422	423	424	425	426	427	428	449	450	451	452	454
	Male	Fem.	Male	Fom.	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	YE
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	YE
Chronic respiratory insufficienty	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	XE:
History of drug hypersensitivity	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YE
Any history of seizures of brain injury	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YE
Any other important clinical illness	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	XE
ECT in the previous 6 months	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YE
Resistence to previous antidepres. treat	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YE
High risk of suicide	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YE

## PHARMACIA CNS 19800083

REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

Centre: 16

							Patier	t			avram.5**		
	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 ?								Cold Consumer			·····	Ť	1
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 ?												l	ĺ
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 selzures 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 550083

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

							Patien	t					
	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 ?		1	1		1		<u> </u>	ļ <u> —</u>	1	_	†	<del> </del>	†
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 ?													T
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	YEŞ	YES	YES	YES
Refusal of contraceptive use during	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Clinically significant hematopoletic	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	XES

#### PHARMACIA CNESSEDO083

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

Centre: 18

							Patien	t					
	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	Sak	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	XE:

(CONTINUED)

# PHARMACIA CNS 5890083

REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

## INCLUSION / EXCLUSION CRITERIA

	Pati-
	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 CNS95550083

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

## INCLUSION / EXCLUSION CRITERIA

	Pa	tient
	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 CN9590083

REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

	Pati-
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	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
<del></del>	

## PHARMACIA CNS SEPO 083

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 7.0

#### INCLUSION / EXCLUSION CRITERIA

	Pat	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	
Hith 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	

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PHARMACTA	BOXETINE - PROTOC Listing No.:
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Centre	Centre Patient	у Вех	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
-	64	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
					NUSKEL TRANCOPAL	12/08/92	Day 49	20/08/92(*)	Day 56
					VOLTAREN	13/08/92	Day 49	20/08/92(*)	Day 56
	eń.	Female	Fluoxetine	YES	CHLORAL HYDRATE	03/07/92	Day 7	09/08/92	Day 42
6	4	Female	Reboxetine	ON	CHLORAL HYDRATE	18/08/92	Day 7	25/09/92	Day 42
48					SIMVASTATIN	12/08/92(\$)	Screen	24/09/92(*)	Day 42
	ις	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
	v	Male	Fluoxetime	NO	CHLORAL HYDRATE	09/01/93	Screen	14/01/93	Screen
					PASPERTIN	04/02/93	Day 28	11/02/93	Day 26
					RIOPAN	21/01/93	Day 14	26/01/93	Day 14
					ZANTIC	26/01/93	Day 14	04/02/93	Day 21
N	33	Female	Fluoxetine	YES	CHLORALDURAT	02/05/91 13/06/91	Screen Day 42	10/05/91 28/06/91(*)	Day 7 Day 56

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PHARMACIA CNS 1	REBOXETINE - PROTOCOL Listing No.: 8

Centre	Centre Patient	Sow	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
81	ä	Kale	Reboxetine	М	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	QX	CERNILTON	01/91	Day 7	22/06/91(*)	Day 7
6					DISTRANEURIN	22/06/91	Day 7	22/06/91(*)	Day 7
49					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	16/90/40	Screen	06/06/91	Screen
	745	Female	Reboxetime	YES	ASPIRINE	12/03/92	Day 14	25/03/92	Day 21
					CHLORAL BYDRATE	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

start date missing = screening date
 end date missing = last dose taken date

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PHARMACIA CNS RED

					CONCUSTIONI DRUGS				
Centre	Centre Patient Sex	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
81	74	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
	£3	Female	Reboxetine	YES	ASPIRIN 'BAYER'	14/11/91	Screen	24/11/91	Day 7
					ATARAX	08/01/91	Day S6	12/01/91	Day 56
					BASODEXAN	04/12/91	Day 35	08/01/92	Day S6
					CHLORALDURAT	13/11/91	Screen	13/01/92(*)	Day 56
65					IBUPROFEN	28/11/91	Day 14	13/01/92(*)	Day 56
0					MOTILIUM	15/11/91	Screen	06/12/91	Day 21
					RIOPAN	11/12/91	Day 28	06/01/92	Day 49
	44	Male	Fluoxetine	ę	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	26/60/60	Day 7	25/09/92	Day 21
					NEDROXYPROGESTERONE ACETA	68	Screen	04/11/92(*)	Day S6
					PROGYNOVA	89	Screen	04/11/92(*)	Day 56

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					PHARMACIA CNS RED			
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					CONCONITANT DRUGS			,
Centre	Centre Patient	Xex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date rep
N	4.7	Female	Fluoxetine	YES	CHLORAL HYDRATE	24/03/92	Screen	08/04/92
					COTRINSTADA	02/04/92	Day 14	07/04/92
					INDOBLOC	24/03/92(\$)	Screen	26/03/92
					NOTILIUM	27/03/92	Day 7	07/04/92
					VITAHIN C	27/03/92	Day 7	01/04/92
	<b>48</b>	Fenale	Reboxetine	YES	BETABION	21/05/92	Day 7	25/05/92
					CHLORALDURAT	24/04/92	Screen	18/05/92
6					DISTRANEURIN	19/05/92	Day 7	13/07/92(*)
<b>š</b> 1					LAXOBERAL	22/05/92	Day 7	22/05/92
					TAVOR	24/04/92	Screen	17/05/92
	80	Kale	Fluoxetine	KES	ALLOPURINOL	93	Screen	11/03/93(*)
					ASPIRIN 'BAYER'	89	Screen	11/03/93(*)
					CONCOR	89	Screen	11/03/93(*)
					CORVATON	68	Screen	11/03/93(*)
en	65	Female	Fluoxetine	YES	CHLORALDURAT	11/10/91	Screen Day 49	27/11/91 10/12/91
	99	Fела1e	Fluoxetine	Q.	CHLORAL HYDRATE	11/10/91 23/10/91	Screen Day 14	15/10/91 12/11/91

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			First report visit	Day 7	Screen	Screen	Day 7	Screen	Screen	Day 14	Screen	Screen	Day 42	Day 7 Day 49	Day 14	Day 7	Day 7	Day 56	
	124/016	_	Start date	17/10/91	13/11/92	26/11/92	04/12/92	17/04/91	18/04/91	03/05/91	20/04/91	17/04/91	29/05/91	28/05/91	11/10/91	01/07/92	06/07/92	13/08/92	
PEARMACIA CNS RED	REBOXETINE - PROTOCOL 20124/016 Listing No.: 8.0	CONCOMITANT DRUGS	Concomitant drug	MARVELON	CHLORAL HYDRATE	CHLORAL HYDRATE	RIOPAN	CHLORALDURAT	DISTRANEURIN	EUGALAC	KALINOR	LINSEED	SENNA LEAF	CHLORALDURAT	CHLORAL HYDRATE	CHLORAL HYDRATE	EUGALAC	VOLTAREN	
			Complete as protocol	Q.	NO NO	QX		YES						YES	OK OK	YES			
			Treatment	Fluoxetine	Reboxetine	Reboxetine		Reboxetine						Fluoxetine	Fluozetine	Reboxetine			
			xeg	Female	Female	Female		Female						Female	Fema1e	Female			
			Centre Patient	99	67	89		97						88	66	101			
			Centre	en				ব			6 9	52							

start date missing = screening date

# Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

# PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 Listing No.: 8.0

Sex	Treatment	Complete as protocol	Concemitant drug	Start date	Pirst report vizit	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	מ
Female	Fluoxetine	но	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	B 0
			DISTRANEURINE	20/07/92	Day 14	17/08/92	
Female	Reboxetine	но	CHLORAL HYDRATE	08/09/92	Day 28	05/10/92(*)	t
Nale .	Fluoxetine	YES	CHLORAL HYDRATE	18/08/92	Screen	15/10/92(*)	τ
Female	Reboxetine	NO	DISTRANEURINE	22/11/91	Day 7	29/12/91(*)	τ
			VALIUN	19/11/91	Day 14	22/11/91	t
Female	Reboxetine	YES	DISTRANEURINE	04/12/91	Screen	31/01/92	ī
			LACTULOSE	04/12/91	Day 7	31/01/92(*)	
			MAGNESIA	19/12/91	Day 14	25/12/91	1
Fenale	Fluozetine	YES	ANALGILASA	21/01/92	Day 14	23/01/92	1
			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	}
			VINCIGRIP	22/01/92	Day 49	26/02/92	1

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8	PHARMACIA CNS	REBOXETINE - PROTOCOL Listing No.: 8

					CONCULTANT DAGGE				
Centre	Centre Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
7	195	Hale	Fluoxetine	YES	DISTRANEURINE	11/02/92	Screen	24/03/92	Day 42
	196	Fenale	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	Q	DISTRANEURINE	08/11/92	Screen	10/11/92	Day 7
=	321	Fenale	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
6					PARACETAMOL	18/11/91	Day 7	27/11/91	Day 14
54	324	Female	Reboxetine	YES	DENUBIL	07/02/92	Day 14	14/02/92	Day 21
	325	Female	Reboxetine	YES	DISTRANBURINE	18/02/92	Day 7	10/03/92	Day 28
	326	Fenale	Reboxetine	KES	PIPEMIDIC ACID	29/02/92	Day 21	07/04/92(*)	Day 56
	332	Female	Fluoxetine	KES KES	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	Nale	Reboxetine	YES	ROHYPNOL	90 13/07/92	Screen Day 14	04/07/92 31/08/92(*)	Screen Day 56
					TEMAZEPAN	06/07/92	Day 7	13/07/92	Day 7

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					REBOXETINE - PROTOCOL 20124/016 Listing No.: 8.0	4/016			
Centre	Centre Patient	×	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
12	396	Fenale	Fluoxetine	QX .	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	06	Screen	08/05/92(*)	Day 56
	386	Male	Fluoxetine	QN Q	TENAZEPAH	23/04/92	Screen	30/04/92(*)	Day 7
	387	Female	Reboxetine	ę	FLUCLOXACILLIN	16/05/92	Day 28	21/05/92	Day 28
65					HYLANTA	24/04/92	Day 7	06/05/92	Day 21
<b>5</b> 5					NDCTEC	07/05/92	Day 21	17/05/92	Day 28
					RANITIDINE	14/04/92	Screen	18/05/92(*)	Day 28
					TEMAZEPAN	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
					HOGADON	17/03/92	Day 7	18/03/92	Day 7
					ORUDIS - SLOW RELEASE	15/03/92	Screen	11/05/92(*)	Day 56
					TEHAZEPAN	14/03/92	Screen	26/03/92	Day 14

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Centre	Centre Patient Sex	Sex	Treatment	Complete as protocol	Conconitant drug	Start date r	First report visit	End date	Last report visit
13	389	Female	Fluoxetine	NO	TEHAZEPAH	20/01/92	Screen	23/07/92(*)	Day 7
	390	Kale	Reboxetine	YES	ERYTHROMYCIN	09/06/92	Day 14	18/06/92	Day 21
					HAXOLON	15/06/92	Day 21	15/06/92	Day 21
					PETHIDINE	15/06/92	Day 21	15/06/92	Day 21
					TEMAZEPAN	03/06/92	Day 7	22/07/92(*)	Day 56
6	391	Female	Fluoxetine	Q.	PANADOL	24/06/92	Day 14	24/06/92	Day 14
56					SQUIBB-HC	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	<b>Female</b>	Reboxetine	NO	NOCTEC	20/08/92	Day 7	27/08/92(*)	Day 14
					ТЕНАZЕРАН	16/08/92	Screen	20/08/92	Day 7
	202	Female	Fluoxetine	YES	PARACETAMOL	09/11/92	Day 7	09/11/92	Day 7
	503	Fenale	Reboxetine	Q	ALUPENT	28	Screen	18/11/92(*)	Day 7
					BECONASE	88	Screen	18/11/92(*)	Day 7
					ESTROGEN NOS	12/11/92(\$)	Screen	18/11/92(*)	Day 7

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STINE - PROTOCOL 20124/016 Listing No.: 8.0

CONCOMITANT DRUGS

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Centre	Centre Patient	Sex	Treatment	Complete as protocol	Conconitant drug	Start date r	First report visit	End date	Last report visit
ध	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	Hale	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
					TEHAZEPAN	10/09/92	Screen	06/11/92(*)	Day S6
657	508	Female	Reboretine	YES	PANADOL	14/12/92	Day 56	20/12/92	Day 56
7	521	Kale	Reboxetime	YES	MINIPRESS	30/11/92(\$)	Screen	26/01/93(*)	Day 56
					RENITEC	30/11/92(\$)	Screen	26/01/93(*)	Day 56
4	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
					PARACETAHOL	22/04/92	Day 14	27/04/92	Day 14
					SENOKOT	18/04/92	Day 7	20/04/92	Day 7
					TEMAZEPAN	16/10/89	Screen	09/06/92(*)	Day 56
	398	Female	Reboxetine	YES	CHLORPHENIRAMINE	07/06/92	Day 56	10/06/92(*)	Day 56

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					CONCOMITANT DRUGS				
Centre	Centre Patient	Sex	Treatment	Complete as protocol	Conconitant drug	Start date	First report visit	End date	Last report visit
4	398	Fenale	Reboxetine	YES	PARACETAHOI.	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	Rebaxetine	YES	PARACETANOL	16/06/92	Day 21	20/06/92	Day 28
					Tenazepan	21/05/92	Screen	02/01/92	Day 42
	403	Female	Reboxetine	YES	Tenazepan	14/04/92	Screen	24/07/92(*)	Day 56
	404	Female	Fluoretine	YES	CHLORPHENIRAMINE MALEATE	17/07/92	Day 35	20/07/92	Day 35
658					PARACETANOL.	17/07/92 28/07/92 08/08/92	Day 35 Day 42 Day 56	20/07/92 28/07/92 11/08/92(*)	Bay 35 Day 42 Day 56
	405	Female	Fluoxetine	YES	AMOXICILLIN	17/06/92	Screen	23/06/92	Day 7
	904	Female	Fluoxetine	ON	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	Q.	TEMAZEPAM	13/07/92	Screen	24/98/92(*)	Day 42
	509	Female	Fluoxetine	OX	TEMAZEPAN	17/09/92	Screen	10/11/92(*)	Day 42
	510	Female	Fluoxetine	YES	DOXYCYCLINE	17/11/92	Day 49	22/11/92	Day 56
					PARACETANOL	25/10/92	Day 28	25/10/92	Day 28
	511	Fenale	Reboxetine	ON	HETOCLOPRANIDE	26/10/92	Day 7	26/10/92	Day 7
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					REBOXETINE - PROTOCOL 20124/016 Listing No.: 8.0	24/016		; ;	
					CONCOMITANT DRUGS				
Contre	Contre Patient	Sex	Treatment	Complete as protocol	Concomitant drug	Start date	First report visit	End date	Last report visit
4	511	Female	Reboxetine	ON	TEMAZEPAN	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
					PARACETAHOL	16/11/92	Day 14	16/11/92	Day 14
					TEHAZEPAH	17/11/92	Day 21	02/12/92(*)	Day 28
6	537	Female	Reboxetine	YES	ANOXICILLIN	04/11/92	. Day 7	18/11/92	Day 21
59					MICROGYNON	07/11/92	Day 7	22/12/92	Day 56
	538	Female	Fluozetine	YES	PARACETANOL	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	16	Screen	05/05/93(*)	Day 56
					TEMAZEPAH	30/03/93	Day 21	10 / 04 / 93	Day 35
15	450	Hale	Fluoxetine	YES	ASPIRIN 'BAYER"	12/12/92	Day 7	04/01/93	Day 28
	451	Female	Fluozetine	YES	ASPIRIN 'BAYER'	31/12/92	Day 14	14/01/93	Day 28
	452	Female	Reboxetine	YES	NETOCL OPRAMIDE	24/12/92	Day 7	29/12/92	Day 7
91	430	Male	Reboxetine	YES	LOVASTATIN	88	Screen	25/05/92(*)	Day 56
	484	Fenale	Fluoxetine	YES	CHLORAL HYDRATE	27/04/92	Day 21	01/06/92(*)	Day 56
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		REBOXETINE - PROTOCOL 20124/016 Listing No.: 8.0	4/016			
		CONCONITANT DRUGS				
Treatment	Complete as protocol	Conconitant drug	Start date repo	First report visit	End date	Last report visit
Reboxetine	YES	CHLORAL HYDRATE	21/04/92	Day 14	08/06/92(*)	Day 56
Fluoxetine	YES	EFFORTIL PLUS	11/06/92	Day 49	12/06/92	Day 49
Fluoxetine	, ON	AMOXICILLIN	17/06/92	Day 35	23/06/92	Day 35
		ASPIRINA C	17/06/92	Day 35	20/06/92	Day 35
Reboxetine	YES	CHLORAL HYDRATE	29/01/92	Day 14	14/09/92(*)	Day 56
Fluoxetine	YES	CHLORAL BYDRATE	26/09/92	Day 14	13/11/92(*)	Day 56
Reboxetine	YES	CHLORAL BYDRATE	23/12/92	Day 14	09/02/93(*)	Day 56
Fluoxetine	YES	CHLORAL HYDRATE	23/12/92	Day 14	28/01/93	Day 49
Fluoxetine	YES	DISTRANEURINE	11/11/92 27/11/92	Day 7 Day 28	13/11/92 29/11/92	Day 7 Day 28
Fluoxetine	Q	CHLORAL HYDRATE	26/11/92	Day 14	16/12/92(*)	Day 35
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
Fluoxetine	NO	TAVOR	18/12/92	Day 21	18/12/92(*)	Day 21

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			<b>~</b>	REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0	INE - PROTOCOL 2 Listing No.: 9.0	L 20124/ 9.0	016			
		EXPERINE	NTAL TREJ	EXPERIMENTAL TREATMENT: DAILY DOSE AND CUNULATIVE COMPLIANCE	Y DOSE	AND CURE	LATIVE COMP	LIANCE		
reatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	z Compl. day	X Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)
luoxetine	15/11/91	09/01/92	56	20	22	160.0	100.0		20	0
			56							
eboxetine	26/06/92	20/08/92	*	æ	۵	100.0	100.0		4	4
			58							
luoxetine	01/07/92 25/08/92	24/08/92 25/08/92	35	20 20	20 20	100.0 100.0	100.0	8	20 20	•
			85							
eboxetine	14/08/92 11/09/92	10/09/92 24/09/92	28 14	<b>м</b> 5	<b>8</b> 5	100.0 100.0	100.0		44	46
			45							
luoxetine	13/10/92 10/11/92 11/11/92	09/11/92 10/11/92 11/11/92	28	70 70 70 70	2 4 8	100.0 100.0 100.0	100.0 100.0 100.0	99	20 S 20 S	200
			30							
luoxetine	14/01/93 11/02/93	10/02/93 11/02/93	2 <b>8</b>	20 20	20	100.0 100.0	100.0	9	20 20	•
			29							
'luoxetine	04/05/91	18/05/91	£1 *	50	20	100.0	100.0	ļ	20	0.0
	20/05/91	31/05/91	- 21 - 28	9 0 <del>9</del>	- 6 G	100.0	96.4 96.4	F	20 20	200
			26							

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03/05/91 12/06/91

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16/04/91 10/06/91

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<sup>(\*) 1-</sup>forgot to take, 2-lost medication, 3-advorse event, 4-change by patient, 5-change by physician, 6-drop out, 7-averdose, 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,

<sup>)</sup> felow 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 = 10 m = morning.

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EXPERIMENTAL TREATHENT: DAILY DOSE AND CUMULATIVE COMPLIANCE REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

Centre	Patient	Centre Patient Treatment	From date	To date	Treat. days	Dose prescribed (mg)	Daily dose (mg)	z Compl. day	z Compl. cumulat.	Reason (*)	Morning dose (ng)	Evening dose (ng)	Overdose (ac)	1
					73									
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N	36	Fluoxetine	02/05/91	26/06/91	26	20	20	100.0	100.0		20	•		
					26									
	27	Dohovotino	07/10/91	19/11/01	-	α	4	100	100	£		4		
•	ì		08/10/91	08/10/91		0 02	r 40	100.0	100.0	ŧ	•	- 4		
			16/01/60	16/01/60	-	•	4	100.0	100.0	38		4		
			10/10/91	10/10/91	-	<b>«</b> 0	4	100.0	100.0	99	4			
					4									
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	88	Fluoretine	20/06/91	20/06/91	-	20	-	100.0	100.0	<b>"</b> 6		0		
	}		21/06/91	14/02/91	24	20 2	20.	100.0	100.0	į	20			
			15/07/91	15/07/91	; -	200	2	0.0	2.96	<u>.</u>	ì			
			16/07/91		• •	2	, 2	100	47.1	į	20			
6 (			25/07/91		-	20	20	100.0	97.2	96	20			
6					}									
2					36									
	39	Fluoxetine	19/06/91	21/06/91	m	20	20	100.0	100.0		20	•		
			22/06/91		-	20	20	100.0	100.0	99	20			
					r									
	04	Reboxetine	06/06/91	06/06/91 04/07/91	29	œ	43	100.0	100.0		4	4		
					29									
	77	Fluoretine	13/02/42	13/02/92 08/04/92	ž	20		100	100.0		20	•		
	:				3	ì	2				ì	,		
				•	36									
	45	Reboxetine	05/03/92	29/04/92	56	<b>6</b> 0	<b>40</b>	100.0	100.0		4	4		
					26									
	£3	Reboxetine	19/11/91	19/11/91 13/01/92	56	<b>40</b>	<b>6</b> 0	100.0	100.0		4	4		
					35									

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<sup>(</sup>**\***\*)

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## PONETINE - PROTOCOL 20124/016

### EXPERIMENTAL TREATMENT: BAILY DOSE AND CONVLATIVE COMPLIANCE

restaut	From date	To date		lose prescribed (ng)	Daily doze (ng)	Z Compl. day	Y Compl. complet.	Rosson (2)	Horning dose (ng)	Breaking dose (mg)	Overdose (us)
luquetine	13/12/91	30/01/92	*	20	20	100.0	100.0		20	0	
obczetáne	18/09/92	<b>04/11/92</b>	56			108.5	100.0		4	•	
lumetine	28/03/92	19/08/92	56	20	20	100.0	100.0		20	0	
obcastipe		15/04/92 13/07/92	56 28 28	8 10	8 10	100.0 100.0	108.0 108.0		:	4	
locastine	15/01/93	11/08/93	56 54	20	20	100.0	100.0		20	0	
luczytine	16/10/91	10/12/91	56 56	20	20	180.0	100.0		20	0	
lecentime		11/11/91	56 27 1		20 20	100.0 100.0	100.0 100.0	30	20 20	•	
mbesetime		18/12/92	28			100.0	100.0		4		
mbozotino	30/11/92	28/12/92	26			100.0	100.0		4	4	
mbomstine	22/04/91	16/86/91	29		8	100.0	100.8		4	4	
'lucrotine	20/05/91	24/07/91	56		28	100.0	100,0		20	0	

<sup>(2) 1=</sup>forgot to take, 2=lost medication, 3=adverse event, 4=change by partient, 5=change by physicism, 6=drop out, 7=everdose, 9=start/end treatment in merning or evening 10=start/end treatment and treatment of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of the start of

<sup>(</sup>ax) I where does, 2 which does, 2 where the does a wheels high does, bedeaths her does. Chigh doily does in one administration. I where it is one administration or a wheels, a way on the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the contract of the

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PRARMACIA CNS RED

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUNULATIVE COMPLIANCE REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

To date

From date

Centre Patient Treatment

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		15/10/91 25/10/91	08/05/92	02/01/92	10/07/92 11/06/92 19/06/92	13/07/92 18/08/92	18/08/92 05/10/92	21/08/92 15/10/92	29/11/91 29/12/91	28/02/92 23/04/92
	,	Flyoxetine	Reboxetine	Reboxetine	Fluoxetine	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine	Fluoxetine
		66	100	101	102	103	104	105	129	130
1										

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<sup>(</sup>**\***\*)

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PHARMACIA CNS R&D

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0 To date From Centre Patient Treatment

11/01/92         36         8         100.0           11/01/92         31/01/92         21         10         100.0           11/01/92         31/01/92         21         10         10         10           11/02/92         11/02/92         32         20         20         100.0         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10	<b>4 4</b>		20	Ę.	20	at.	20	1e 20	20 0		30	9 6	07	<b>E</b>	1e 20			20 20		4	4		6e 20		20 0		4
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PHARMACIA CNS R&D

	Overdose (**)					(H - 8)
	Evening dose (ng)		0		4	∢.
	Morning dose (mg)		20		4	<b>6</b> 0 ·
LIANCE	Reason (*)					
ATIVE CORP.	z Compl. cumulat.		100.0		100.0	100.0
IND CURU	Daily X dose Compl. C (mg) day cu		20 100.0		100.0	100,0
Y DOSE A	Daily dose (mg)		20		00	2
EXPERIMENTAL TREATHENT: DAILY DOSE AND CUMULATIVE COMPLIANCE	Dose prescribed (mg)		20		œ	eo e
(TAL TRE	Treat.	57	98	56	7	~ ;
EXPERIMEN	To date		13/01/92		30/01/92	31/01/92
	From date		19/11/91 13/01/92		24/01/92	31/01/92
	Treat. Centre Patient Treatment From date To date days		Fluoxetine		Reboxetine	
	Patient		323		324	
	Centre		=			

		(H - 9)					
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	20	4044	444	4	20	20 20 20	4 4
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	100.0	100.0 100.0 100.0	100.0 100.0 100.0	100.0	100.0 92.9 96.4	100.0 88.9 96.4 98.2	100.0 100.0 100.0
	160.0	100.0 100.0 100.0 100.0	100.0 100.0 100.0	100.0	100.0 0.0 100.0	100.0 0.0 100.0 100.0	100.0 100.0 100.0
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	13/01/92	30/01/92 31/01/92 12/03/92 19/03/92	10/03/92 31/03/92 07/04/92	07/04/92	26/02/92 27/02/92 12/03/92	26/02/92 27/02/92 17/03/92 14/04/92	01/05/92 06/05/92 27/05/92
	19/11/91 13/01/92	24/01/92 31/01/92 01/02/92 13/03/92	12/02/92 11/03/92 01/04/92	12/02/92	14/02/92 27/02/92 28/02/92	19/02/92 27/02/92 28/02/92 18/03/92	31/03/92 02/05/92 07/05/92
	Fluoxetine	Reboxetine	Reboxetine	Reboxetine	Fluoxetine	Fluoxetine	Reboxetine
	323	324	325	326	327	328	329
	£		6	66			

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<sup>(\*\*</sup> 

PHARMACIA CNS R&D FINE - PROTOCOL 20124/016 Listing No.: 9.0 EXPERINENTAL TREATMENT: DAILY DOSE AND CONULATIVE COMPLIANCE

Overdose (**)	,	(B - 8)						
Evening dose (ng)	40	0000	o <b>o</b>	40	20 0	4 0	2000	<b>ታ</b> የ ተ
Moraing dose (mg)	44	20 20 20 20 20	20 20	44	20 20	<b>4</b> 20	20 20	विवव
Reason (*)		æ	£.				Ę	
z Compl. cumulat.	100.0	100.0 100.0 100.0 100.0	100.0 97.2 98.3	100.0	100.0	100.0 100.0	100.0 99.0 99.1	100.0 100.0 100.0
x Compl. day	100.0	100.0 100.0 100.0 100.0	100.0 100.0	100.0	100.0 100.0	100.0	100.0 50.0 100.0	100.0 160.0 100.0
Daily dose (mg)	æ 5	00040	20 20	a 5	40 40	<b>8</b> 20	40 40 40	a 5 a
Dose prescribed (ng)	8 01	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	20 20 20 20	8 <b>6</b> 1	07 70 70	S 8	4 <b>4 4</b>	<b>က</b> ဦး
Treat.	28 21 24	24 24 24 24 24 24 24 24 24 24 24 24 24 2	23 23 59	28 28 28	28 28	35 27	222	28 7
To date	18/05/92 08/06/92	18/06/92 19/06/92 22/06/92 23/06/92 20/07/92	31/08/92 01/09/92 24/09/92	12/10/92 09/11/92	16/11/92	16/11/92	12/08/92 13/08/92 18/08/92	02/08/92 24/08/92 31/08/92
From date	21/04/92 19/05/92	26/05/92 19/06/92 20/06/92 23/06/92 24/06/92	28/07/92 01/09/92 02/09/92	15/09/92	22/09/92	13/10/92	22/07/92 13/08/92 14/08/92	06/07/92 03/08/92 25/08/92
Centre Patient Treatment	Reboxetine	Fluoxotins	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine Fluoxetine		Reboxetine
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Centre	£			667		12		

 <sup>(\*) 1=</sup>forgot to take, 2=lost medication, 3=advarse 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,

<sup>|=</sup>low dows, 2=high dows, 3=low dows + high dows, A=double high dows, B=double low dows, |=high daily dows in one administration, D=low daily dows in one administration | memoring | memoring | e evening |

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0 PHARMACIA CNS R&D

Morning dose (mg) EXPERIMENTAL TREATHENT: DAILY DOSE AND CUMULATIVE COMPLIANCE To date Centre Patient Treatment

From date

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	24/07/92 20/08/92	04/08/92 11/08/92	24/02/93 24/03/93	14/03/92 25/04/92	24/04/92 30/04/92	18/04/92 18/05/92	16/03/92 20/03/92 21/03/92 22/03/92 11/05/92	21/07/92
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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

Listing No.: 9.0	EXPERINENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE	

To date

From date

Centre Patient Treatment

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<sup>(\*) 1=</sup>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

<sup>(\*\*) 1-</sup>low dose, 2-bigh dose, 3-low dose + high dose, A-double high dose, B-double low dose, E-bigh daily dose in one administration, D-low daily dose in one administration n = norming, e = evening

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15/11/92   15/11/92   1   8   4   50.0   97.2   10   4   10   10   10   10   10   10	15/11/92 07/12/92 08/12/92 13/12/92				;	4	4
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15/12/92   15/12/92   5 8 8   100.0   96.4   4   4   15/12/92   15/12/92   15   8   100.0   96.4   4   4   15/12/92   15/12/92   15   8   8   100.0   96.6   4   4   4   15/12/92   15/12/92   15   8   8   100.0   96.6   96.6   4   4   15/12/92   15   8   8   100.0   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6   96.6	13/12/92				ţ	•	•
14/12/92   14/12/92   1   8   4   50.0   95.3   10   4   4   15/12/92   14/12/92   15   8   8   100.0   96.6   4   4   4   5   10   10   10   10   10   10   10			•		•	4	- 4
15/12/92 29/12/92 15 8 8 100.0 96.6 4 4   15/12/92 29/12/92 29/12/92 15 8 8 100.0 100.0 4   15/12/92 26/10/93 58 8 100.0 100.0 4   15/12/92 26/10/93 58 8 8 100.0 100.0 5-change by physician, 6-drop out, 7-coverdose, 9-start/end treatment in morning or evening, 10-reason unknown	14/12/92				÷	. 4	•
Reboxetime 30/11/92 26/01/93 58 8 8 100.0 100.0 4  (*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change for pout, 7=cverdose, 9=start/end treatment in morning or evening, 10=reason unknown	29/12/92					•	4
Reboxetime 30/11/92 26/01/93 58 8 100.0 100.0 4  (*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change and patient, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, 10=reason unknown.	55	1.00					
Reboxetine 30/11/92 26/01/93 58 8 8 100.0 100.0 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							
	Reboxetine 30/11/92 26/01/93					4	*
		lication, 3=adv op out, 7=overd	Perse event lose, 9=sta	, 4=change by rt/end treat	/ patient, eat in morain	g or evening	
	10=reason unknown						

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.: 9.0

### EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

restment	From date	To date	Treat. days	Dose prescribed (ng)	Daily dose (mg)	Z Compl. day	Z Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
			58								
			20								
luoxetine	14/04/92	14/04/92	1	20	0	100.8	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	241	4	4	
	15/05/92	15/05/92	1	8	4	100.0	100.0	3e	4	•	
	16/05/92	09/06/92	25		ġ	100.0	100.0		4	4	
	10/06/92	10/06/92	1		4	100.0	100.0	9e	4		
			57								
eboxetine	21/04/92	21/04/92	1	8	4	100.0	100.0	9m		4	
GNOXOLING	22/04/92	06/05/92	15		8	100.0	100.0	210	4	4	
	07/05/92	07/05/92	1		4	100.0	100.0	3e	4	••	
	08/05/92	03/06/92	27		8	100.0	100.0		4	4	
	04/06/92	04/06/92	1		4	50.0	98.9	1e	4	•	
	05/06/92	15/06/92	11		8	100.0	99.1		4	4	
	16/06/92	16/06/92	1		4	100.0	99.1	9a	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	100.0	100.0		20	Ö	
	11/07/92	11/07/92	1	20	20	100.0	100.0	9 <b>e</b>	20		
			58	:							
			56	•							
luoxetine	22/05/92	22/05/92	1	20	0	100,0	100.0	9m		0	
	23/05/92	20/06/92	29		20	100.0	100.0		20	0	
	21/06/92	21/06/92	1		0	0.0	96.8	1m		0	
	22/06/92	16/07/92	25		20	100.0	98.2		20	6	
	17/07/92	17/07/92	1	20	20	100.0	98.2	9e	20		
			57	;							
Reboxetine	27/05/92	27/05/92	_1		4	100.0	100.0	9m		4	
	28/05/92	21/07/92	55	8	8	100.0	100.0		4	4	

 <sup>(\*) 1=</sup>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 ovening, 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 RRD REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

Marche   Patient   Troatcant   From date   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant   Troatcant	From date To date days Presett Bolton days Complete (as) (as) (as) (as) (as) (as) (as) (as)					EXPERIME	NTAL TRE	EMPERINENTAL TREATMENT: DAILY DOSE AND CONULATIVE COMPLIANCE	Y DOSE	AND COM	LATIVE COMP	LIANCE			
Reboxetine         22/07/92         22/07/92         1         8         4         100.0         100.0         9m         4           Reboxetine         29/05/92         28/07/92         1         8         4         100.0         100.0         9m         4           Fluoxetine         16/06/92         28/07/92         55         8         100.0         100.0         9m         4           Fluoxetine         16/06/92         14/06/92         15         20         100.0         100.0         9m         4           Fluoxetine         16/06/92         14/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92         16/06/92	Reboxetine 22/07/92 22/07/92 1 8 4 100.0 100.0 9n 4  Reboxetine 29/05/92 23/07/92 1 8 4 100.0 100.0 9n 4  24/07/92 23/07/92 1 8 4 100.0 100.0 9n 4  Fluoxetine 16/06/92 16/06/92 1 2 2 2 2 2 2 2 2 100.0 100.0 9n 20  11/06/92 10/08/92 1 2 2 2 2 2 2 2 2 2 100.0 100.0 9n 20  11/06/92 10/08/92 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Pa	tient	Treatment	From date	To date	Treat.	Dose prescribed (mg)	Daily dose (mg)	X Compi. day	x Compl. cumulat.	Reason (*)	Norning dose (ng)	Evening dose (mg)	Overdose (xx)
Redoxetime   23/05/92   29/05/92   1   8   4   100.0   100.0   9m   4   4   100.0   100.0   9m   4   4   100.0   100.0   9m   4   4   100.0   100.0   9m   4   4   100.0   100.0   9m   4   4   100.0   100.0   9m   4   4   100.0   100.0   9m   4   4   100.0   100.0   9m   4   4   100.0   100.0   9m   4   4   100.0   100.0   9m   4   4   100.0   100.0   9m   4   4   100.0   100.0   9m   4   4   100.0   100.0   9m   220   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06/92   22/06	Reboxetime   29/05/92   29/05/92   1   8   4   100.0   100.0   9m   4   4   4   4   4   4   4   4   4	405	81	Reboxetine	22/07/92	22/07/92	-	æ	4	100.0	100.0	96	4		
Fluoretine   29/05/92   23/05/92   55   8   4   100.0   100.0   9n   4   4   100.0   100.0   9n   4   4   100.0   100.0   9n   4   4   100.0   100.0   9n   4   4   100.0   100.0   9n   4   4   100.0   100.0   9n   4   4   100.0   100.0   9n   4   4   100.0   100.0   9n   20   20   20   20   20   20   20   2	Fluoxetine   23/05/92   23/05/92   1   8   4   100.0   100.0   9   4   4   100.0   100.0   9   4   4   100.0   100.0   9   4   4   100.0   100.0   100.0   9   4   4   100.0   100.0   100.0   9   4   4   100.0   100.0   100.0   9   4   4   100.0   100.0   100.0   9   4   4   100.0   100.0   100.0   9   4   4   100.0   100.0   9   4   4   100.0   100.0   9   4   4   100.0   100.0   9   4   4   100.0   100.0   9   4   4   100.0   100.0   9   4   4   100.0   100.0   9   4   4   100.0   100.0   9   4   4   100.0   100.0   9   4   4   100.0   100.0   9   4   4   100.0   100.0   9   4   4   100.0   100.0   9   4   4   100.0   100.0   9   4   4   100.0   100.0   9   4   4   4   100.0   100.0   9   4   4   4   4   4   4   4   4   4						57								
## 100.0 100.0 3m 4 100.0 100.0 3m 4 100.0 100.0 3m 4 100.0 100.0 3m 4 100.0 100.0 3m 4 100.0 100.0 3m 4 100.0 100.0 3m 4 100.0 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 100.0 3m 1	## 100.00	403	•	Reboxetine	29/05/92	29/05/92	-	40	4	100	9	d		•	
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08/08/92 1 8 4 50.0 90.0 2e 4 14/08/92 6 8 8 100.0 95.5 4 29/08/92 14 8 6 100.0 96.2 4 4 20/08/92 14 8 8 100.0 96.2 4 4 34/08/92 2 8 4 50.0 92.9 2e 4	08/08/92 08/08/92 1 8 4 50.0 90.0 2e 4 15/08/92 14/08/92 6 8 8 100.0 95.5 4 15/08/92 14/08/92 14/08/92 14/08/92 14/08/92 14/08/92 14/08/92 29/08/92 29/08/92 2 8 4 50.0 92.9 2e 4 1=forgot to take, 2=lost medication, 3=adverse event, 4=rhound by matint				05/08/92	07/08/92	m	•	e oc	10.0	9 6	E		4	
14/08/92 6 8 8 100.0 95.5 6 4 115/08/92 14 8 6 100.0 96.2 6 4 50.0 91.7 2e 4 50.0 91.7 2e 4 50.0 92.9 2e 4 50.0 92.9 2e 4	15/08/92 14/08/92 6 8 8 100.0 95.5 4 4 15/08/92 15/08/92 14 8 4 50.0 91.7 2e 4 4 50.0 91.7 2e 4 4 50.0 91.7 2e 4 4 50.0 91.7 2e 4 4 50.0 92.9 2e 4 1=forgot to take, 2=lost medication, 3=adverse event, 4=chance by matini				08/08/92	08/08/92	-	- α	<b>.</b>	20.05	9.6	ć	<b>.</b>	4	
15/08/92 14 8 4 50.0 91.7 2e 4 20.08/92 14 8 8 100.0 96.2 4 4 31/08/92 2 8 4 50.0 92.9 2e 4	16/08/92 15/08/92 1 8 4 50.0 91.7 2e 4 16/08/92 29/08/92 14 8 100.0 96.2 4 30.0 96.2 4 17.08/92 2 8 4 50.0 96.2 6 4 17.08/92 11.08 100.0 96.2 8 4 17.08/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/100/92 11.08/				09/08/92	14/08/92	9	æ	•	100.0	9. 7.	97	# 4	•	
29/08/92 14 8 8 100.0 96.2 4 31/08/92 2 8 4 50.0 92.9 2e 4	16/08/92 29/08/92 14 8 8 100.0 96.2 4 4 50.0 92.9 2e 4 1=forgot to take, 2=lost medication, 3=adverse event, 4=channe h. madia.t				15/08/92	15/08/92	-	80	4	20.0	21.7	ć	* <	4	
31/08/92 2 8 4 50.0 92.9 2e 4	30/88/92 31/08/92 2 8 4 50.0 92.9 2e 4 1=50rgot to take, 2=lost medication, 3=adverse event, 4=channe h. madiant				16/08/92	29/08/92	‡	œ	· cc	100.0	96.3	9	r d	٠	
					30/08/92	31/08/92	63	ω	4	50.0	92.9	2e	r 4	r	

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

PHARMACIA CNS R&D

				EXPERINE	NTAL TRE	EXPERIMENTAL TREATHENT: DAILY DOSE AND CUNULATIVE COMPLIANCE	'Y DOSE	AND CUMB	LATIVE COMP	LIANCE			
Centre	Patient	Centre Patient Treatment	From date	To date	Treat.	Dose prescribed (mg)	Daily dose (mg)	% Compl. day	z Compl. cumulat.	Reason (*)	Morning dose (mg)	Evening dose (mg)	Overdose (**)
						•	,				•	•	
4	408	Reboxetine	01/09/92	18/09/92	8	œ	40	100,0	95.7		4	4	
			19/09/92	19/09/92	-	∞	4	50.0	94.7	20	4		
			20/09/92	29/09/92	2	æ	€0	100.0	95.6		4	4	
			30/09/92	30/09/92	-	œ	4	100,0	95.7	96	4		
					58								
	903		00,000	00,000	•	;	•	;	;	•		,	
	202	rTMOXBLING	26/69/62	26/60/62	- ,	25	- ;	100.0	100.0	£	;	0 (	
			26/60/08	36/60/08	-	2	20	0.00	100.0		20	-	
			01/10/92	01/10/92	- ;	50	20	100.0	100.0		29	0	(e - e)
			02/10/92	09/11/92	33	20	20	100.0	100.0		20	0	
			10/11/92	10/11/92	-	20	20	100.0	100.0	9	20		
					43								
	510	Fluoretine	30/09/92	30/09/42	٠	ç	•	907	007	å		c	
	1		01/10/92	16/40/92	- 7	9 6	- ç		0.00	Ē	ę		
			17/10/92	17/10/92	•	3 6	9 0	9 9	0.001	ţ	0		
			18/10/92	25/11/92	. 0	3 5	, 5			•	90		
6			26/11/00	25/44/00	; •	3 6	9 6	900	4.6	ć	9 6	•	
7			76 /11 /07	76 /1 1 /07	-	0.2	2	100.0	50.3	96	20		
3					88								
	474	Doboughting	99740700	207.007.00	•	,	٠	•		,		•	
	;		26/10/22	09/10/20	- ;	0 0	+ 0	9	0.00	Ę	4	+ <	
			10/12/42	10/19/09	ì	0 0	0 <	900	0.00	,	r <	•	
					•	3	r	9.90	9.00	<b>D</b>	r		
					64								
	512	Reboxetine	03/11/92	03/11/92	-	40	4	100.0	100.0	8		4	
			04/11/92	01/12/92	28	60	<b>4</b> 0	100.0	100.0		4	*	
			02/12/92	02/12/92	-	<b>6</b> 0	₫	100.0	100.0	\$	4		
					8								
					ñ								
	537	Reboxetine	03/11/92	03/11/92	-	40	4	100.0	100.0	<b>E6</b>		4	
			04/11/92	28/12/92	53	<b>40</b>	40	100.0	100.0		4	4	
			29/12/92	29/12/92	-	<b>«</b> 0	4	100.0	100.0	96	4		
					57								
	538	Fluoxetine	12/02/93	12/02/93	τ-1	20	•	100.0	100.0				
			13/02/93	19/02/93		20	20	100.0	100.0		<b>79</b>	-	

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PHARMACIA CNS R&D
REBGXETINE - PROTOCOL 20124/016
Listing No.: 9.0

	COMPLIANCE
	CUMULATIVE
	DAILY DOSE AND
Burre	DAILY I
1	TREATHENT:
	EXPERIMENTAL

					1	Dose	Daily	×	N		Morning	Evening		
antro.	Dation+	Tanton Dationt Treatment	Canal Arts	4-4-4	Linear.	prescribed	dose	Comp1.	Comp.	Keason	dose	dose	Overdose	
01110	THOTAL	irea unen c	rrom date	to date	aays	(Bur)	(BE)	day	cumilat.		(Bill)	(Bill)	(**)	1
≇	538	Fluoxetine	20/02/93	20/02/93	-	20	•	0	6.	Ē		-		
			21/02/93		•	20	20	100.0	93.3	ł	20	•		
			27/02/93	27/02/93	-	20	0	0.0	87.5	Ę		•		
			28/02/93	_	36	20	20	100.0	96.2		20	0		
			05/04/93	_	_	20		0.0	46	1m 1e	1	•		
			06/04/93	08/04/93	m	20	20	100.0	9.4.6		20	•		
			09/04/93	09/04/93	-	20	20	100.0	94.7	96	20			
					57									
	539	Fluoxetine	10/03/93	10/03/93	~	20	0	100.0	100.0	9 E		0		
			11/03/93	06/04/93	27	20	20	100.0	100.0		20	0		
			07/04/93	04/05/93	28	9	ş	100.0	100.0		20	20		
			05/05/93	05/05/93	-	9	20	100.0	100.0	96	20			
					23									
15	604	Reboxetine	08/04/92		28	¢	œ	100	100		4	4		
			06/05/92	02/06/92	28	. 5	2	100.0	100.0		- 4	- 42		
			!			1	:		) ) )		•	,		
					56									
	410	Fluoxetine	17/04/92	17/04/92 11/06/92	26	20	20	100.0	100,0		20	0		
6					56									
7														
l <u>s</u>	411	Reboxetine	22/04/92	22/04/92 16/06/92	26	89	60	100.0	100.0		4	4		
					38									
	412	Fluoxetine	23/04/92	23/04/92 17/06/92	28	20	20	100.0	100.0		20	0		
					8									
	413	Reboxetine	30/04/92	24/06/92	26	<b>40</b>	ø	100.0	100.0		₫	4		
					56									
	446	1	007.707.00		•	į	;				;	•		
	<u>r</u>	LIGASETING	21/07/92	27/07/92	4	0 7 0 7	9 5		100.0		2 2	- ç		
					.	!	2		•		1	}		
					56									

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE

forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening,

£

(\*\*) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low d C=high daily dose in one administration, D=low daily dose in one administration m = morning, e = evening

29

100.0

100

20

20

451

56 26 26 56 56 26

16/02/93

452

100.0

100.0

20

20

03/02/93

450

676

20

100.0

100.0

15/03/93

454

20

100.0

100.0

29

26/03/92 20/05/92

Fluoxetine

459

16

ĕ

100 .0 100 .0

100.0 100.0

30/03/92 25/05/92

30/03/92 31/03/92

Reboxetine

430

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PHARMACIA CNS R&D

16

Overdose (xx)									
Evening dose (mg)		•		4		•		4	•
Morning dose (ng)		20		4		20		4	4
Reason (x)									
% Compl. cumulat.		100.0		100.0		100.0		100.0	100.0
ž Compl. day		100,0		100.0		100.0		100.0	100.0
i e c		20		60		20		80	10
Dose Dai t. prescribed dos s (ng) (ng		20		α)		20		æ	2
Treat.	28	56	58	55	56	26	56	28	28
To date		22/12/92		27/01/93		27/01/93		04/01/93	01/02/93
From date To date		28/10/92		03/12/92		03/12/92		08/12/92	05/01/93
Centre Patient Treatment		Fluoxetine		Reboxetine		Fluoxetine		Reboxetine	
Patient		426		427		428		644	
Centre		15							

take, 2=lost medication, 3=adverse event, 4=change by patient,
physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening). £

(xx

4

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016

	Evening dose Overc (mg) (%x
	Morning Edose (mg)
LIANCE	Reason (*)
LATIVE COM	Compl.
AND CUNO	Daily x dose Compl. (mg) day
Y DOSE	Daily dose (mg)
KPERINENTAL TREATHENT: DAILY DOSE AND CUNULATIVE COMPLIANCE	Dose prescribed (ng)
NTAL TRE	Treat.
EXPERINE	To date
	From date
	Treatment
	볉

																	,								
		4		•		4		0		4		-		20	20	20	8	20	20			4		•	
-		4		20		4		20		4		20	20	20		20	:	8 8	2 2			4		20	20
															_		_				•				_
													4		Ę		ŧ	é	š						8
		•		0.		•		۰.		•		-		ĸ,	6.	uj.	-	mo o	. 4.			٠.		0	0.
		100.0		100.0		100.0		100.0		100.0		100	96.7	97	95	96	95	26.0	4.96			100.0		100	100,0
		0.001		100.0		100.0		100.0		100.0		0.00	50.0	100.0	50.0	100.0	20.0	0.001	0.00			190.0		0.00	100.0
				20 1		« -		20 1		8		•							33			60			20
		•		20		60		20		40		20	40	40	40	40	9	5 4	6 4			<b>60</b>		20	20
İ	57	95	26	25	26	26	28	26	26	26	26	88	N	•	,	e	<del>-</del> 1		٠.	1.2	ŝ	26	36	29	<b>-</b>
	, s	S	-	ιŋ	, s	ιŋ	6	LC)	۳,	un	"	•									,	e,	47	**	
		5/92		25/05/92		27/05/92		01/06/92		08/06/92		21/05/92	23/05/92	29/05/92	30/05/92	32/06/92	3/06/92	10/06/92	18/06/92			24/06/92		92	18/06/92
		25/0								08/1		-			٠.	_	_	- •	•					17/1	18/
		31/03/92 25/05/92		31/03/92		02/04/92		07/04/92		14/04/92		24/04/92	22/05/92	/05/92	30/05/92	31/05/92	03/06/92	24/00/42	12/06/92			30/04/92		/05/92	18/06/92
				31		92						24	22	24	30	8	8	5 5	12						18
1		Reboxetine		Fluoxetine		Reboxetine		Fluoxetine		Reboxetine		Fluoxetine										Reboxetine		Fluoxetine	
		Rebox		Fluox		Rebox		Fluox		Rebox		Fluox										Rebox		Fluox	
		_		۸,		~			*													2		æ	
		431		432		433		434		435		436										437		438	
		9								6	77	,													

(\*) 1-forgot to take, 2-lost medication, 3-adverse event, 4-change by patient, 5-change by physician, 6-drop out, 7-everdose, 9-start/end treatment in morning or evening, 10-reason unknown

<sup>(\*\*) 1-</sup>low dose, 2-high dose, 3-low dose + high dose, A-double high dose, B-double low dose, 2-high daily dose in one administration.
D-low 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

	Overdose (*x)		
	Evening dose (ng)		0
	Morning l dose (ng)		20
LIANCE	Reason (*)		
ATIVE COMP	X Compl. cumulat.		100.0
AND CUMUI	Daily X 1 dose Compl. (mg) day		20 100.0 100.0
Y DOSE	Daily dose (mg)		20
XPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE	Dose prescribe (mg)		20
ITAL TRE	Treat.   days	=	3 %
EXPERIMEN	To date		14/07/92
	From date To date		20/05/92 14/07/92
	Patient Treatment		Fluoxetine
	Patient		439

					·				
		,							
	•	4	•	4.0	•	4	4	0	00000
	20	4	20	44	20	4	*	20	2 2 2
									t t
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0 66.7 96.2 92.6
	100.0	100.0	100.0	100.0	100.0	100.0	160.0	100.0	100.0 0.0 100.0 100.0
	20	α <b>o</b>	20	8 OL	20	<b>©</b>	œ	20	5 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
	20	<b>w</b>	20	ø 0	20	80	æ	20	2000 2000 2000 2000
30	56 56	8 8	8 8	27 28 25	85   85	56	56	36   36	23 - 23
·	14/07/92	25/08/92	14/09/92	17/08/92 14/09/92	18/10/92	19/10/92	12/11/92	18/09/92 12/11/92	19/09/92 20/09/92 13/10/92 14/10/92 12/11/92
	20/05/92 14/07/92	61/07/92	22/07/92	22/07/92 18/08/92	25/08/92	25/08/92	18/09/92	18/09/92	18/09/92 20/09/92 21/09/92 14/10/92
	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine	Reboxetine	Fluoxetine	Fluoxetine
	439	440	#	442	#3	555	445	955	447
	•				678				

<sup>£</sup> 

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EXPERIMENTAL TREATMENT: DAILY DOSE AND COMULATIVE COMPLIANCE

Centre	Patient	Centre Patient Treatment	From date	To date	Treat. days	Treat. prescribed dose days (mg) (mg)	dose (mg)	Compl. day	Compl. cumulat.	Reason (*)	dose (mg)	dose (mg)	5 C	Overdose (*xt)	
					56										
16	448	Reboxetine	19/09/92	03/10/92	15	60	œ	100.0	100.0		4	4			
			94/10/92	04/10/92	-	•	4	50.0	6.96	Ę		4			
			05/10/92	02/11/92	29	**	90	100.0	98,9		4	4			
			03/11/92	03/11/92	-	40	4	50.0	97.8	16	4				
			04/11/92	13/11/92	2	αĵ	<b>e</b> Q	100.0	98.2		4	4			
					56										
	455	Fluozetine	19/09/92 13/11/92	13/11/92	28	20	20	100.0	100.0		20	•			
					56										
	456	Reboxetine	16/12/92 09/02/93	09/02/93	98	80	•	100.0	100.0		4	4			
					26										
	457	Fluoxetine	16/12/92	16/12/92 09/02/93	26	20	20	100.0	100.0		20	0			
6					56										
7	458	Fluoxetine	16/12/92	16/12/92 09/02/93	56	20	20	100.0	100.0		20	0			
9					35										
					3										
	429	Reboxetine	22/12/92	22/12/92 15/02/93	26	æ	₩	100.0	100.0		4	4			
					56										
	09+	Reboxetine	22/12/92	22/12/92 15/02/93	56	80	89	100.0	100.0		4	4			
					38										
18	25	Fluoxetine	06/10/92	07/11/92	33	20	20	100.0	100.0		20	0			
			08/11/92	08/11/92	_	20	20	100.0	100.0		20	0	9	<b>6</b>	
			09/11/92	30/11/92		20	20	100.0	100.0		20	0			
					8										
	92	Reboxetine	06/10/92	06/10/92 30/11/92	26	už	<b>60</b>	100.0	100.0		4	4			

(\*\*)

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PARKHACIA CHS RED REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0 EXPERIMENTAL TREATMENT: DAILY DOSE AND CUMULATIVE COMPLIANCE	
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To date

From date

Centre Pationt Treatment

						,	,	•				,			
				•											
					26										
18	27	Reboxetine	06/10/92 30/11/92	30/11/92	26	<b>6</b> 0	60	100.0	100.0		4	4			
					26										
	28	Fluoxetime	06/10/92	02/11/92	28	20	20	100.0	100.0		20	•			
					28										
	53	Reboxetine	06/10/92	30/11/92	85	₩.	100	100.0	100.0		4	4			
					56										
	93	Fluoxetine	07/10/92	03/11/92	28	20	20	100.0	100.0		20	•			
			04/11/92	09/11/92	9	20	8	100.0	100.0		40	50	(3	E) (3	(e -
			10/11/92	10/11/92	~	20	6	100.0	100.0		20	20			
			11/11/92	23/11/92	13	<b>9</b> (	40	100.0	100.0		20	20			
			24/11/92	24/11/92	~ r	<b>9</b> 9	9	9.0	98.0	Jn Je		5			
,						2	2	2			ì	ì			
68					95										
0	33	Reboxetine	20/10/92	20/10/92 14/12/92	26	æ	10	100.0	100.0		4	4			
					28										
	32	Fluoxetine	07/10/92	29/11/92	ą.	20	20	100.0	100.0		50	•			
			30/11/92	30/11/92	-	20	0,4	100.0	100.0		9	•	G .	9	(0 '
					55										
	64	Reboxetine	17/11/92	17/11/92 11/01/93	36	€	60	100.0	100.0		4	4			
					56										
	20	Reboxetine	17/11/92	17/11/92	-	æ	œ	100.0	100.0		4	4			
			18/11/92	18/11/92	-	1 40	4	100.0	100.0	99	4	•1			
					03										
	51	Fluoxetine	17/11/92	17/11/92 11/01/93	56	20	20	100.0	100.0		20	0			
		<b>(*</b> )	1=forgot to 5=change by	=forgot to take, 2=lost medication, 3=adverse event, 4=change by pationt,  S=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in mo	st medica 6=drop o	tion, 3=ad	lverse e	vent, 4=c =start/er	hange by p	1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=cycrdose, 9=start/end treatment in morning or evening.	or eveni				
			10=reason unknown	Inknown	•					•		;			

2

EBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

Evening dose (mg) Norning dose (ng) EXPERIMENTAL TREATHENT: DAILY DOSE AND CUNULATIVE COMPLIANCE z Compl. day Daily dose (mg) Dose (mg) Treat. days To date Centre Patient Treatment

	0		•		0		•		0		0	,	0	•				0	0		•		-	ì	
	70		22		20		20		20		20	20	20	ć	9	20	20	20		20	20		5	202	
												<b>J</b> e	,	311 36	ť	ŝ	ę		Ē	ę				99	
	100.0		100.0		100.0		100.0		100.0		100.0	100.0	100.0	100.0	160.0	0.001	100.0	100.0	96.3	96.4	96.4		9	100.0	
	100.0		100.0		100,0		100.0		100.0		100.0	100.0	100.0	100.0	100.0	100.0	0.00	180.0	0.0	100.0	100.0			100.0	
	20		20		82		20		20		20	20	20		20	9 6	3 5	20	•	20	20		;	20 20	
	20		20		20		20		20		20	20	20	20	20	2 8	9 5	20	20	20	20		;	20 20 20	
56	26	<b>2</b> 6	56	26	26	36	55	55	38	ક્ષ	9	_	11	м	10	N 6	o <del>-</del>	. 6	8	-	-	56	!	5 -	
ı	11/01/93		11/03/93	ı	08/03/93	ı	30/12/92		16/12/92	•	24/10/92	25/10/92	11/11/92	13/11/92	15/11/92	17/11/92	26/11/62	09/12/92	11/12/92	12/12/92	13/12/92			17/12/92	
	17/11/92 11/01/93		15/01/93		12/01/93		06/11/92		12/11/92		19/10/92	25/10/92	26/10/92	12/11/92	14/11/92	16/11/92	26/11/81	25/11/20	10/12/92	12/12/92	13/12/92			03/12/92 18/12/92	
	Fluoxetine		Fluoxetine		Fluoretine		Fluoxetine		Fluoretine		Fluovetine													Fluoxetine	
	25		53		54		21		22		a													113	
	18						20		6	81	,	-												22	

(\*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 2=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening, a=movern medican.

<sup>(\*\*) 1=10#</sup> dose), 2=high dose, 3=10# dose + high dose, A=double high dose, B=double low dose), C=high daily dose in one administration, D=10# daily dose in one administration

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				ı			
			Overdose	(##)			
	ž		Morning Evening dose dose	(Bd)	4		
			Morning dose	(Bill)	4	4	
		LIANCE	Reason	€		99	
	91	ATIVE COMPI	Daily x x x d dose Compl.	cumulat.	100.0	100.0	
R&D	L 20124/0 9.0	AND CUMUL	z Compl.	day	100.0	100.0	
PHARMACIA CNS R&D	PROTOCO 9 No.:	N DOSE	Daily dose	(mg)	<b>eû</b>	•	
PHARMA	REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0	EXPERIMENTAL TREATMENT: DALLY DOSE AND CUMULATIVE COMPLIANCE	Dose I Treat. prescribed	(Bill)	φ	60	
	2	TAL TRE	Treat.	days	22	-	23
		EXPERIMEN		To date	19/01/93	20/01/93	
				From date	29/12/92	20/01/93	
				Patient Treatment	Reboxetine		
				Patient	115		
				.			

(\*) t=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=everdose, 9=start/end treatment in morning or even 10=reason unknown

10-reason unknown (\*\*) 1=low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dos C=high daily dose in one administration, D=low daily dose in one administration n = morning, e = evening

PHARMACIA CNS R&D

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Centre	Pationt	Centre Pationt Treatment	From date	To date	Treat.	Cps prescribed	Daily Cps	x / Compl. day	z Compl. cumulat.	Horning Cps	Evening Cps	Reason (*)	Overdose (**)	
-	-	Fluoxetine	15/11/91	15/11/91 09/01/92	26	N	61	100.0	100.0	-	-			
					56									
	81	Reboxetine	26/06/92	20/08/92	95	71	73	100.0	100.0	-	-			
					56									
	ĸ	Fluoxetine	01/07/92	24/08/92	55	83	81	100.0	100.0	-	-			
			25/08/92	25/08/92	-	82	-	100.0	100.0	-	•	96		
					56									
	4	Reboxetine	14/08/92	14/08/92 24/09/92	42	83	82	100.0	100.0	-	-			
			•		42									
6	ιŋ	Fluoxetine	13/10/92		29		8	100.0	100.0	-	-			
8			11/11/92	11/11/92		81	-	50.D	98.3	-		99		
3					30									
	9	Fluoxetine	14/01/93		28		81	100,0	100.0	-	-			
			11/02/93	11/02/93		N	-	50.0	98.3	-		99		
					29									
73	33	Fluoxetine	04/05/91		15	84	67	100.0	100.0	-	-			
			19/05/91	19/05/91	۲,	01 00	<del>-</del> (	50.0	96.9	•		E.		
			20,03/31		7		v	9.00		-	-			
					56			,						
	*	Reboxetine	03/05/91	03/05/91 12/06/91	41	83	Ø	100,0	100.0	-	-			
					4									
	35	Rebozetine		16/04/91 10/06/91	56	84	N	100.0	100.0	-	-			
					56									
	36	Fluoxetine		02/05/91 26/06/91	56	N	84	100.0	100.0	-	-			

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<sup>(\*\*)</sup> 

9	OXETINE - PROTOCOL 20124/016 Listing No.: 9.0
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PHARMACIA CNS P.ED	Listing No.: 9.0
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EXPERIMENTAL TREATHENT: DAILY AND CUNULATIVE COMPLIANCE

Overdose (xx)																											
Reason (*)		,	Ę	Ę				<b>m</b> 6		ŧ		96			9												
Evening Cps		•			-			-	-	-	-	•		-				-		-		-		-		-	
Horning Cps		•	<b>-</b>	-	-			٥	-		<b>,-</b>	-		-	~			-		-		-		-		-	
z Compl. cumulat.	:	;	300.0	9.00	87.5	5		100.0	100.0	98.1	98.6	98.6		100.0	87.5			100.0		100.0		100.0		100.0		100.0	
z Compl. day		;	100.0	9 6	50.0			100.0	100.0	50.0	100.0	100.0		100.0	50.0			100.0		100.0		100.0		100.0		100.0	
Daily Cps		•	٠,	4 -	-			-	~1	-	7	-		67	-			81		61		64		71		63	
Cps presuribed		,	N 6	4 6	1 63			81	63	63	63	81		73	61			67		Ø		64		N		81	
Treat.	56	•				4	•	-	24	-	6	-	36	m	-		4	29	29	26	98	99	56	56	56	64	64
To date			07/10/91	09/10/91	10/10/91			20/06/91	14/07/91	15/07/91	24/07/91	25/07/91		21/06/91	22/06/91			06/06/91 04/07/91		08/04/92		29/04/92		19/11/91 13/01/92		13/12/91 30/01/92	
From date			16/01/70	19/10/91	10/10/91			20/06/91	21/06/91	15/07/91	16/01/91	25/07/91		19/06/91	22/06/91			06/06/91		13/02/92		05/03/92		19/11/91		13/12/91	
Centre Patient Treatment		:	Keboxetine					Fluoxetine						Fluoxetine				Reboxetine		Fluoxetine		Reboxetine		Reboxetine		Fluoxetine	
Patient		į	ñ					88						39				40		41		4.2		43		44	
Centre			N											ı	6	8	t						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.

<sup>(\*\*) 1=</sup>low dose, 2=high dose, 3=low dose + high dose, A=double high dose, B=double low dose, C=high daily dose in one administration, D=low daily dose in one administration m = morning, e = evening

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PHARMACIA CNS R&D

EXPERIMENTAL TREATHENT: DAILY AND CUNULATIVE COMPLIANCE REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

Centre	Patient	Centre Pationt Treatment	From date	To date	Treat.	Cps prescribed	Daily Cps	x Cumpl. day	Z Compl. cumulat.	Morning Cps	Evening Cps	Reason (*)	Overdose (xx)	
N	45	Reboxetine	10/09/92 04/11/92	04/11/92	26	n	~	100.0	100.0	-	-			1
					58									
	4.7	Fluoxetine	25/03/92 19/05/92	19/05/92	56	81	81	100.0	100.0	<del>-</del>	-			
					56									
	48	Reboxetine	19/05/92	19/05/92 13/07/92	26	63	8	100.0	100.0	-	-			
					26									
	88	Fluoxetine	15/01/93	15/01/93 11/03/93	26	63	81	100.0	100.0	-	-			
					26									
κħ	92	Fluoxetine	16/10/91	16/10/91 10/12/91	35	63	~	100.0	100.0	-	-			
					56									
	99	Fluoxetine	16/10/91	11/11/91	27	N	61	100.0	100.0	•	-			
			12/11/91	12/11/91	· •	1 81	-	100.0	100,0	-	•	3e		
68					28									
3 5	67	Reboxetine	18/11/92	18/11/92 15/12/92	28	Ø	61	100.0	100.0	-	-			
					28		٠							
	89	Reboxetine	30/11/92	30/11/92 28/12/92	59	83	N	100.0	100.0	-	~			
					29									
4	97	Reboretine	22/04/91	22/04/91 16/06/91	26	63	84	100.0	100.0	-	-			
					8									
	86	Fluoxetine	30/05/91	30/05/91 24/07/91	35	м	81	100.0	100.0	-	-			
					56									
	66	Fluoxetine	15/10/91	24/10/91	5	84	63	100.0	100.0	~	-			
			25/10/91	25/10/91		83	-	20.0	95.5	-		99		
		(*)	1=forgot. +	o take. 2m	Joseph Wale	(*) 1=fordot to take. 2=lost medication. Stadymense event. 4=chande hy nationt	dynama	- tuene	i=chance h	u matient				

(xx)

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUNULATIVE COMPLIANCE

Overdose (xx)							•																		
Reason Or (*)		69							69			99											Ę	ng,	
Evening R Cps				-				-			-			-		-		-		-		-	-	g or eveni	low dose, on
Morning Eve Cps (		-		-		-		-	<del>-</del>		-	-		-		-		-		-		-		tient, in mornin	B=double ministrati
z Compl. Nos cumulat. (		50.0		100.0		100.0		100.0	98.6		0.00	0.66		100.0		100.0		100.0		100.0		100.0	98.5	iange by pa I treatment	high dose, in one ad
X Compl. C day cu		50.0		100.00		100.001		·	50.0			20.0		100.001		100.00		100.0		100.0		100.0		event, 4=cl 9=start/en	, A=double daily dose
Daily Cps		~		М		84		N	~		67	~		61		81		81		0		73	-	adverse erdose,	igh dose , D≈lew
Cps prescribed		N		N		М		8	72		64	2		61		81		8		64		77	64	=forgot to take, 2=lost medication, 3=advorse event, 4=change by patient, =change by physician, 6=drop out, 7=overdose, 9=start/ond treatment in morning or evening, nd=nesses numbers.	filter does, $2=high$ dose, $3=low$ dose + high dose, A-double high dose, $8=double$ low C-high daily dose in one administration $0=low$ daily dose in one administration $m=morning$ , $e=evening$
Treat. days	11	-		56	8	35	\%	36	-	37	84	-	64	26	95	33	3	26	26	57	57	32	-	lost med: n, 6=drop	ose, 3=1e one admi ning
To date		08/05/92		26/08/92		03/09/92		17/08/92	18/08/92		04/10/92	05/10/92		15/10/92		29/12/91		23/04/92		31/01/92		10/02/92	11/02/92	o take, 2= y physicia unknoun	1=low dose, 2=high dose, C=high daily dose in one m = morning, e = evening
From date		08/05/92 08/05/92		02/07/92 26/08/92		10/07/92		13/07/92	18/08/92		18/08/92	05/10/92		21/08/92		29/11/91 29/12/91		28/02/92		06/12/91		10/01/92	11/02/92	1=forgot to take, 5=change by physic 10=reason unknown	
Patient Treatment		Reboxetine		Reboxetine		Fluoxetine		Fluoxetine			Reboxetine			Fluoxetine		Reboxetine		Fluoxetine		Reboxetine		Fluoxetine		<b>(</b>	( KX
Patient		100		101		102		103			104			105		129		130		193		194			
Centre		4									6	8 (	ì			ĸ				7					

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4/016

REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

PRARMACIA CNS RED

EXPERINENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Cumulat. Ops Cops (*) Cumulat. Ops Cops (*) Cumulat. Ops Cops (*) Cumulat. Ops Cops (*) Cumulat. Ops Cops (*) Cumulat. Ops Cops (*) Cumulat. Ops Cops (*) Cumulat. Ops Cops Cops Cops Cops Cops Cops Cops Co							ć	2			1		-	
194   Fluoractine   12/02/92   16/02/92   5   2   100.0   98.7   1   1   1   1   1   1   1   1   1	Centre	Patient	Treatment	From date	To date	days	cps prescribed	Cps	day.	cumulat.	Cps	Cps	Keason (*)	(xx)
194   Fluozetine   17/02/29   16/02/29   5   2   2   100.0   99.7   1   1   1   1   1   1   1   1   1	,	į	;				,							
Horacetine 14/702/22 25/02/24 11 2 1 55.0 97.4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		ţ	Fluoxetine	12/02/92	16/02/92	n	N	N	100.0	98.7	-	-		
195   Fluozotine   14/02/92   22/02/92   11   2   2   100.0   99.0   1   1   1   1   1   1   1   1   1				17/02/92	17/02/92	_	63	-	50.0	97.4		_	£	
195 Fluozotine 14/02/22 25/02/22 5 2 100.0 97.3 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				18/02/92	28/02/92	7	64	61	100.0	98.0	<del>-</del>	τ-		
195   Fluoratine   14/12/29   02/04/29   5   2   100.0   97.3   1   1   1   1   1   1   1   1   1				29/02/92	29/02/92	•	2	-	50.0	97.1	-		9	
Fluozetine 14/72/92 02/04/92 49 2 2 100.0 100.0 1 1 1 1 1 1 1 1 1 1 1 1 1 1				01/03/92	05/03/92	ď	84	2	100.0	97.3	-	-		
195   Fluoxatine   14/02/92   02/04/92   49   2   2   100.0   100.0   1   1   1   1   1   1   1   1   1														
195   Fluoxetine   14/02/92   02/04/92   49   2   2   100.0   100.0   1   1   1   1   1   1   1   1   1						56								
195   Fluoxetine   14/10/22   02/04/92   49   2   2   400.0   100.0   1   1   1   1   1   1   1   1   1														
10   10   10   10   10   10   10   10		195	Fluoxetine	14/02/92	02/04/92	67	2	8	100.0	108.0	-	-		
25 26 No.04/92 04/04/92 1 2 2 100.0 99.0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				03/07/03	03/07/02	•		۱ ۳	9	9		-		
25   Seboxetine   19/11/91   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/11/92   19/1				26,707,10	76,767,76	- ,	4 4	- ,		22.0	•		=	
06/04/92 07/04/92 1 2 1 50.0 98.1 1 1 1 0 10 10 10 10 10 10 10 10 10 10				26/60/60	26/60/60	-	N	N	100.	9.6	-	-		
06/04/92 08/04/92 1 2 100.0 98.1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				05/04/92	05/04/92	~	7	-	50.0	1.86	-		<b>-</b>	
09.04/92 08.04/92 1 2 1 50.0 97.3 1 1 1 1 0 1				06/04/92	07/04/92	83	63	N	100.0	98.1	-	-		
95. 196 Roboxotino 29/06/92 16/07/92 49 2 2 100.0 100.0 1 1 1  197 Fluoxetine 14/11/91 09/01/92 57 2 100.0 100.0 1 1 1  321 Fluoxetine 14/11/91 09/01/92 57 2 100.0 100.0 1 1 1  322 Roboxetine 19/11/91 13/01/92 57 2 2 100.0 100.0 1 1 1  324 Roboxetine 24/01/92 30/01/92 7 2 2 100.0 100.0 1 1 1  325 Fluoxetine 19/11/91 13/01/92 48 2 2 100.0 100.0 1 1 1 1  326 Roboxetine 24/01/92 30/01/92 7 2 2 100.0 100.0 1 1 1 1  327 Roboxetine 19/11/91 13/01/92 55 2 2 100.0 100.0 1 1 1 1  328 Fluoxetine 24/01/92 30/01/92 7 2 2 100.0 100.0 1 1 1 1  329 Roboxetine 24/01/92 30/01/92 7 2 2 100.0 100.0 100.0 1 1 1 1 1 1 1 1 1 1 1				08/04/92	08/04/92	_	8	-	50.0	97.3	-		9	
321 Fluoxetine 19/11/91 13/01/92 57 2 100.0 100.0 1 1 1 322 Reboxetine 19/11/91 13/01/92 57 2 100.0 100.0 1 1 1 323 Fluoxetine 19/11/91 13/01/92 56 2 100.0 100.0 100.0 1 1 1 324 Reboxetine 24/01/92 30/01/92 7 2 2 100.0 100.0 100.0 1 1 1 325 Reboxetine 24/01/92 30/01/92 56 2 2 100.0 100.0 100.0 1 1 1 326 Reboxetine 24/01/92 30/01/92 48 2 2 100.0 100.0 100.0 1 1 1 327 Reboxetine 24/01/92 30/01/92 48 2 2 100.0 100.0 100.0 1 1 1 1 1 1 1 1 1 1 1				09/04/92	09/04/92	_	8	~	100.0	97.3	-	-		
196   Reboxetine   11/11/92   11/11/92   49   2   2   100.0   100.0   1   1   1   1   1   1   1   1   1														
196   Reboxatine   29/05/92   16/07/92   49   2   2   100.0   100.0   1   1   1   1   1   1   1   1   1	6					26								
197   Fluoxetine   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   1	8													
197   Fluoxetine   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/92   11/11/91   19/01/92   57   2   2   100.0   100.0   1   1   1   1   1   1   1   1   1	7	196	Reboxetine	29/05/92		64	61	8	100.0	100.0	-	-		
197   Fluoxetine   11/11/92   11/11/92   11/11/92   1   2   1   50.0   50.0   1   66     321   Fluoxetine   14/11/91   09/01/92   57   2   2   100.0   100.0   1   1     322   Reboxetine   14/11/91   13/01/92   57   2   2   100.0   100.0   1   1     323   Fluoxetine   19/11/91   13/01/92   56   2   2   100.0   100.0   1   1     324   Reboxetine   24/01/92   31/01/92   31/01/92   48   2   2   100.0   96.9   2   1   1     325   Reboxetine   19/11/91   13/01/92   56   2   2   100.0   100.0   1   1   1     326   Reboxetine   24/01/92   31/01/92   31/01/92   48   2   2   2   100.0   96.9   2   1   1     327   Reboxetine   24/01/92   31/01/92   48   2   2   2   100.0   96.9   2   1   1     328   Reboxetine   24/01/92   31/01/92   48   2   2   2   2   2   2   2   2   2														
197   Fluoxetine   11/11/92   11/11/92   11/11/92   1   2   1   50.0   50.0   1   66     321   Fluoxetine   14/11/91   09/01/92   57   2   100.0   100.0   1   1   1     322   Reboxetine   19/11/91   13/01/92   56   2   100.0   100.0   1   1   1     323   Fluoxetine   19/11/91   13/01/92   56   2   2   100.0   100.0   1   1   1     324   Reboxetine   24/01/92   30/01/92   31/01/92   48   2   2   100.0   95.9   2   1   1   1     325   Reboxetine   19/11/91   13/01/92   2   2   2   2   2   2   2   2   2						49								
321 Filozetine 14/11/91 09/01/92 57 2 2 100.0 100.0 1 1 1 1 322 Reboxetine 14/11/91 09/01/92 57 2 2 100.0 100.0 1 1 1 1 323 Filoxetine 19/11/91 13/01/92 56 2 2 100.0 100.0 1 1 1 1 55 324 Reboxetine 24/01/92 30/01/92 7 2 2 100.0 100.0 1 1 1 1 1 1 1 1 1 1 1 1 1 1		197	Fluoxetine	11/11/92	11/11/92	-	7	-	50.0	50.0	-		99	
321 Fluoxetine 14/11/91 09/01/92 57 2 100.0 100.0 1 1 1  322 Reboxetine 14/11/91 09/01/92 57 2 2 100.0 100.0 1 1 1  323 Fluoxetine 19/11/91 13/01/92 56 2 100.0 100.0 1 1 1  324 Reboxetine 24/01/92 30/01/92 7 2 100.0 100.0 1 1 1  324 Reboxetine 24/01/92 30/01/92 7 2 2 100.0 100.0 1 1 1  325 Reboxetine 24/01/92 30/01/92 48 2 2 100.0 100.0 1 1 1  326 Reboxetine 24/01/92 30/01/92 48 2 2 100.0 100.0 1 1 1 1 1 1 1 1 1 1 1 1 1 1														
321 Fluoxetine 14/11/91 09/01/92 57 2 100.0 100.0 1 1 1  322 Reboxetine 14/11/91 13/01/92 57 2 2 100.0 100.0 1 1 1  323 Fluoxetine 19/11/91 13/01/92 56 2 1 100.0 100.0 1 1 1  324 Reboxetine 24/01/92 30/01/92 7 2 100.0 100.0 1 1 1  324 Reboxetine 24/01/92 30/01/92 7 2 100.0 100.0 100.0 1 1 1  324 Reboxetine 24/01/92 31/01/92 48 2 100.0 99.6 1 1 1						-								
322 Reboxetine 14/11/91 09/01/92 57 2 2 100.0 100.0 1 1 1 323 Fluoxetine 19/11/91 13/01/92 56 2 2 100.0 100.0 1 1 1 1 56 32 4/01/92 30/01/92 7 2 2 100.0 100.0 1 1 1 1 324 Reboxetine 24/01/92 30/01/92 7 2 2 100.0 100.0 1 1 1 1 1 1 1 1 1 1 1 1 1 1	_	321	Fluoxetine	14/11/91	09/01/92	57		•	100.0	100.0	-	-		
Reboxetime 14/11/91 09/01/92 57 2 100.0 100.0 1 1 1  Flucxetime 19/11/91 13/01/92 56 2 2 100.0 100.0 1 1 1  Seboxetime 24/01/92 30/01/92 7 2 2 100.0 100.0 1 1 1  Reboxetime 24/01/92 30/01/92 7 2 2 100.0 100.0 1 1 1 1 1 (B 1/01/92 31/01/92 48 2 2 100.0 99.6 1 1 1 1 1 (B 1/01/92 19/01/92 48 2 2 100.0 99.6 1 1 1 1 1 1 (B 1/01/92 19/01/92 48 2 2 100.0 99.6 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1						i		•						
Reboxetine         14/11/91         09/01/92         57         2         2         100.0         100.0         1         1           Flucxetine         19/11/91         13/01/92         56         2         2         100.0         100.0         1         1           Reboxetine         24/01/92         30/01/92         7         2         2         100.0         100.0         1         1           Alonysetine         24/01/92         31/01/92         31/01/92         31/01/92         3         75.0         96.9         2         1         1           Alonysetine         31/01/92         31/01/92         31/01/92         31/01/92         3         75.0         96.9         2         1         1						57								
Fluometine 19/11/91 13/01/92 56 2 2 100.0 100.0 1 1 1 1		322	Reboxetine	14/11/91	09/01/92	52	~	*	100.0	100.0	-	-		
Fluometine 19/11/91 13/01/92 56 2 2 100.0 100.0 1 1 1						i	ı	•			•	,		
Fluoxetine 19/11/91 13/01/92 56 2 2 100.0 100.0 1 1 1						57								
Reboxetine 24/01/92 30/01/92 7 2 2 100.0 100.0 1 1 1 1 1 1 1 1 1 1 1 1 1 1		323	Fluoxetine	19/11/91	13/01/92	26	ca	N	100,0	100,0	-	-		
Seboxetine 24/01/92 30/01/92 7 2 2 100.0 100.0 1 1 1 (B 31/01/92 31/01/92 31/01/92 1 2 3 75.0 96.9 2 1 1 (B 01/02/92 19/03/92 48 2 2 100.0 99.6 1 1 1														
Reboxetine 24/01/92 30/01/92 7 2 2 100.0 100.0 1 1 1 (B 31/01/92 31/01/92 31/01/92 31/01/92 43 2 3 100.0 99.6 1 1 1						56								
31/01/92 31/01/92 1 2 3 75.0 96.9 2 1 (B		324	Reboxetine	24/01/92			6	6	100.0	100.0	-	•		
19/03/92 48 2 2 100.0 99.6 1 1		i		31/01/92		•		ı «	25.0	9 9	٠,			(R - B)
				01/02/92		. 44			100	9 6				

(\*) 1=forgot to take, 2=lost medication, 3=adverse event, 4=change by patient, 5=change by physician, 6=drop out, 7=everdose, 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,

ion acco, z-migu acco, z-rom acco - mign acco, z-accura ingle daily dose in one administration, D=low daily dose morning, e = evening

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATHENT: DAILY AND CUMULATIVE COMPLIANCE

Overdose (\*\*) Reason (\*) event, 4=change by patient, 9=start/end treatment in morning or evening, Evening Cps Morning Cps Compl. 100.0 100.0 555 x Compl. day 100.0 100.0 100.0 100.0 Cps prescribed 64 01/05/92 06/05/92 27/05/92 date 08/06/92 07/04/92 ္ 21/04/92 14/02/92 27/02/92 28/02/92 19/02/92 27/02/92 28/02/92 31/03/92 02/05/92 07/05/92 12/02/92 From date 8 Fluoxetine Reboxetine Reboxetine Treatment Centre Patient 332 330 331 327 328 329 325 326 688

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PRARMACIA CNS RED

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE REBOXETINE - PROTOCOL 20124/016 Listing No.: 9,0

Evening Reason Overdose (ps (x) (xx)	-				· •	· •		<b>.</b>	<b>- - -</b>			 E	£			Ę		<u> </u>	£		
Morning Eveni Cps Cps	-			-	-																
cumulat.	98.3			100.0																	
Compl. day	100.0		100,0			100.0	100.0	100.0	100.0	100.0	100.0 100.0 50.0	100.0 100.0 50.0 100.0	100.0 100.0 50.0 100.0	100.0 100.0 50.0 100.0	100.0 100.0 50.0 100.0						
Daily Cps	N	•	64			61	N	ol o	N N	0 0 0	0 0 0-0	0 0 050	0 0 0 0	0 0 070 0	0 0 0F0 N	0 0 070 0 0	0 0 070 0 0	0 0 070 0 0 0	0 0 070 0 0	, , , , , , , , , , , , , , , , , , ,	0 0 0 0 0 0 0 0
Cps prescribed	N	,	83			N	N	n n	n n	N N N	n n an	0 0 000	N N N N N N N N N N N N N N N N N N N	0 0 000 0	0 0 000 0	n n nnn n n					
Treat.	73	8	26		56	5, 56	56 56 56	35 35 85 35 85 35 85	56 56 35 35	35	35 8 8 8 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	2	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	35	56 56 56 56 56 56 56 56 56 56 56 56 56 5	56 56 35 35 35 35 35 35 35 35 35 35 35 35 35	56   56   56   56   56   56   56   56				
To date	24/09/92		09/11/92			16/11/92	16/11/92	16/11/92	16/11/92	16/11/92	16/11/92 16/11/92 12/08/92 13/08/92	16/11/92 16/11/92 12/08/92 18/08/92	16/11/92 16/11/92 12/08/92 18/08/92	16/11/92 16/11/92 12/08/92 18/08/92 31/08/92	16/11/92 16/11/92 12/08/92 13/08/92 31/08/92	16/11/92 16/11/92 12/08/92 18/08/92 31/08/92	16/11/92 16/11/92 12/08/92 13/08/92 18/08/92 16/09/92	16/11/92 16/11/92 13/08/92 18/08/92 16/09/92 10/08/92			
From date	02/09/92		15/09/92			22/09/92	22/09/92	22/09/92 16/11/92	22/09/92 13/10/92	22/09/92	22/09/92 13/10/92 25/06/92 14/08/92	22/09/92 13/10/92 25/06/92 14/08/92	22/09/92 13/10/92 25/06/92 13/08/92	22/09/92 16/11/92 13/10/92 16/11/92 25/06/92 12/08/92 13/08/92 13/08/92 06/07/92 31/08/92	22/09/92 13/10/92 25/06/92 13/08/92 14/08/92 06/07/92	22/09/92 16/11/92 13/10/92 16/11/92 25/06/92 12/08/92 13/08/92 13/08/92 14/08/92 18/08/92 06/07/92 16/09/92	22/09/92 13/10/92 25/06/92 14/08/92 06/07/92	22/09/92 13/10/92 25/06/92 14/08/92 06/07/92 24/07/92 11/08/92	22/09/92 13/10/92 25/06/92 13/08/92 14/08/92 24/07/92 24/07/92		
Centre Patient Treatment	Fluoxetine	1	Reboxetine			Fluoxetine	Fluoxetine	Fluoxetine Reboxetine	Fluoxetine Reboxetine	Fluoxetine Reboxetine Fluoxetine	Fluoxetine Reboxetine Fluoxetine	Fluoxetine Beboxetine Fluoxetine	Fluoxetine Reboxetine Fluoxetine	Fluoxatine Reboxetine Fluoxetine Reboxetine	Fluoxetine Reboxetine Fluoxetine Reboxetine	Fluoxatine Reboxatine Reboxatine Reboxatine	Fluoxetine Reboxetine Fluoxetine Reboxetine	Fluoxetine Reboxetine Reboxetine	Fluoxetine Reboxetine Reboxetine Reboxetine	Fluoxetine Reboxetine Reboxetine Reboxetine Fluoxetine	Fluoxetine Reboxetine Reboxetine Fluoxetine
Patient	332	6	333			334	334	334 335	334	334 393	334 393	33 337 393	33 337 393	334 393 394	334 394 394	33 334 4 33 338 338 338 338 338 338 338	334 395 395	334 395 396 396 396	334 393 396 396	334 393 395 497	334 395 396 497
Centre	<del>ت</del>									22	25	2	2	2 6	₽ 689	<b>2</b> 689	<b>2</b> 689	<b>2</b> 689	<b>2</b> 689	<b>≅</b> 689	<b>689</b>

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Overdose (xx)																												
Reason (*)			e e			69			10e	10m 10e	:	10m 10e						10m 10e				3m 6e			9			10e
Evening Cps		-			-			-		,	-			-			-	,	-		-			,			•	-
Morning Cps		-	-		-	-		-	-	,	-			-			-	•	-		-			-	-		•	
z Compl. cumulat.		100.0	92.9		100.0	98.4		100.0	90.0	75.0	97.3	92.6		100.0			100.0	97.7	28.2		100.0	98.6		100.0	96.4		907	95.8
z Compl. day		300.0	8.0		100.0	50.0		100.0	20.0	0.0	100.0	<u>.</u>		100.0			100.0	0.6	100.0		100.0	20.0		100.0	50.0		9	2.05 2.00 2.00
Daily Cps		N	~		N	-		61	<del>-</del>		~1			N			N	•	N		61			8	-		,	N 4-
Cps prescribed		61	N		71	8		63	co.	61	<b>~</b> 1	64		6			8	01 0	N		63	22		8	101		٢	N 60
Treat.	38	40	-	1	30	-	3.	4	_	Ψ;	ß.	-	57	m	1	n	42	- ;	13	28	35	_	38	13	-	≇	;	= "
To date		29/04/92	30/04/92		17/05/92	18/05/92		19/03/92	20/03/92	21/03/92	10/05/92	11/05/92		23/03/92			08/07/92	09/07/92	26/10/22			16/07/92			27/08/92			13/11/92
From date		24/04/92	30/04/92		18/04/92	18/05/92		16/03/92	20/03/92	21/03/92	22/03/92	11/05/92		21/07/92			28/05/92	09/07/92	26//0/01		11/06/92	16/07/92		14/08/92	27/08/92		00/14/00	13/11/92
Centre Patient Treatment		Fluoxetine			Reboxetine			Reboxetine						Fluoxetine			Reboxetine				Fluoxetine			Reboxetine			Determent	Keboxetine
Patient		386			387			388						389			390				391			392			703	-
Centre		13										6	9	0														

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PHARMACIA CNS RED

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Overdose (**)	į																																			
Reason (*)		100		10e		10e		10e				10e		10e			á	e v				;	-10e					10e		99				10e		
Evening Cps	-	•	-		-		-				-		-		-		,		-			-	•	-		•	-		-				-		-	
Morning Cps	-	-	-	-	-	-	-	-			-	_	-	-	-		•	<b>-</b> •	-		,	-		-		,	_	-	-	-			ς	ζ-	-	
Compl. cumulat.	97.5	95.2	97.1	95.7	96.3	95.2	96.5	4.9			100.0	96.2	87.8	95.8	98.1		,	9.00.0	0.001		:	100.0	98.6	1.66			100.0	98.8	99.0	98.1			100.0	93.8	99.1	
Compl.	100.0	20	100.0	20.0	100.0	50.0	100.0	50.0			100.0	50.0	100.0	50.0	100.0			9.6	9.00		;	100.0	50.0	100.0		;	100.0	20.0	100.0	50°0			100.0	50.0	100.0	
Daily Cps	81	-	81	-	~	-	64	-			8	-	8	-	7		•	- •	1			Ν.	- (	N		•	N	-	N	<b></b>			8	_	63	
Cps prescribed	8	N	61	83	83	64	N	83			63	87	27	N	87		•	46	4		,	N (	N (	N		,	71 -	7	73	61			8	~	17	
Treat.	60	•	13	-	9	-	15	8	8	ñ	12	-	2	-	28	22	•	- 4	•	7	;	ň '	- ;	7	56	:	-	- :	9	-		S,	7	<del>,-</del>	20	
To date	21/11/92	22/11/92	05/12/92	06/12/92	12/12/92	13/12/92	28/12/92	30/12/92			14/11/92	15/11/92	25/11/92	26/11/92	24/12/92		407.447.00	18/11/92			00.00	26/21/62	30/12/02	56/10/02		000	26/0L/0L	26/01/11	26/01/12	22/10/92			02/11/92	03/11/92	23/12/92	
From date	14/11/92	22/11/92	23/11/92	06/12/92	07/12/92	13/12/92	14/12/92	29/12/92			03/11/92	15/11/92	16/11/92	26/11/92	27/11/92		40747700	13/11/92	1		000	26/11/92	307.127.92	76.77 /15		20, 20,	31/08/92	26/01/11	72/10/92	22/10/92			27/10/92	03/11/92	04/11/92	
Centre Patient Treatment	Reboxetine										Fluoxetine						Doboughting	PORTOGOR				runaxerme					Kepoxetine						Fluoxetine			
Patient	501										502						503	}			ž	100				202	505						206			
Centre	13																6	9	1																	

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PHARMACIA CNS R&D KINE - PROTOCOL 20124/016 Listing No.: 9.0

REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

13 507 508	Fluoxetine Reboxetine	11/09/92 22/10/92 23/10/92		days	prescribed	d Cps	day	cumulat.	Morning Cps	Cps	( <b>x</b> )	(xx)
808	Reboxetine	23/10/92	21/10/92	14	01 0	2	100.0	100.0	-	-	400	
808	Reboxetine		06/11/92	- 51	v 101	62	100.0	98.5	-	-		
<b>208</b>	Reboxetine			22								
		02/11/92	07/11/92	۰	N	8	100.0	100.0	-	-		
		08/11/92	08/11/92	- (	61 6	<del>-</del> (	50.0	92.9	٠,	,	10e	
		15/11/92	15/11/92	- م	N 6	v =		7.06		-	100	
		16/11/92	07/12/92	22	1 64	. 62	100.0	97.2	-	-		
		08/12/92	08/12/92	-	83	-	50.0	95.9		-	Ē	
		09/12/92	13/12/92	n)	7	~	100	96.4	<b>-</b>	-	,	
		14/12/92	14/12/92	- i	<b>6</b> 7	ς,	8 5	95.3		,	<b>J</b> e	
69			!	588	Ī	1			•	•		
252	Reboxetine	30/11/92	26/01/93	58	N	ĸ	100.0	100.0	-	-		
				88								
14 397	Fluoxetine	14/04/92	14/04/92	-	8	-	100.0	100.0	•	-	<b>46</b>	
		15/04/92	_	. 55	1 01	. 61	100.0	100.0	÷	-		
		09/06/92	_	-	77	-	100.0	100.0	-	0	98	
				57								
866	Reboxetine	15/04/92	15/04/92	-	~	-	100	100.0	-	-	<b>6</b>	
:		16/04/92	14/05/92	53	181	. 62	100.0	100.0	-	-		,
		15/05/92	15/05/92	-	81	-	100.0	100.0	-		98	
		16/05/92	09/06/92	52	01 0	61 1	100.0	100.0		- 0	d	
		10/00/92	26/90/AL	-	N	-		100.0	-	>	R	
				57								
399	Reboxetine	21/04/92	21/04/92	-	8	-	100.0	100.0	•	_	£	
		22/04/92	26/20/90	15	N	23	100.0	100.0	-	-		
		07/05/92	07/05/92	-	cs.	-	100.0	100.0	-		8	
		08/05/92	26/90/60	27	<b>1</b> 1	61	100.0	100.0	<b></b>	-	•	
		04/06/92	04/06/92	- ;	N (	- 1	50.0	98.9		,	10	
		16/06/92	16/06/92	= -	N 10	N F	90.00	9.66		- 0	96	
	<b>X</b>	1=forgot t	=forgot to take. 2=lost medication. 3=adverse event. 4=change by batient.	lost med	lication.	3=adverse	event.	t=change br	patient.			
		5=change t	=change by physician, 6=drop out, 7=overdose, 9=start/end treatment in morning or evening,	n, 6=dro	op out, 7=	overdose,	9=start	end treats	ent in mo	rning or e	vening,	
	(XX)		Thereason whiteher a second does think does ledonkis him does Behankis lost does		t coop no	high does	Andrea	ole bink de	Berghan	and John do	9	

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EXPERIMENTAL TREATHENT: DAILY AND CUMULATIVE COMPLIANCE REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

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Overdose (**)																																		
Reason (*)			<b>E</b> 6		96		5		Ē	,	<b>0</b>		,	Ę		96			5	ţ	96			<b>#6</b>		96			#6		10e		96	
Evening Cps			γ-	~	0		τ.	-	<b></b> .	- (	-		•		_	•			-					-	-	•			-	-		-	0	
Morning Cps			0	~	<b>*</b>		<b>o</b> ·	-	•	- 1	-		•		-	-			-	· <del></del>	-			•	-	-			•	-	-	-	-	
Z Compl. cumulat.			100.0	100.0	100.0		100.0	100.0	98.4	1.66	99.1		,	100.0	100.0	100.0			1001	100.0	100.0			100.0	100.0	100.0			100.0	100.0	98.8	99.1	99.1	
Compl.			100.0	100.0	100.0		100.0	100.0	20.0	100.0	100.0			100.0	100.0	100.0			100	100.0	100.0			100.0	100.0	100.0			100.0	100,0	50.0	100.0	100.0	
Daily Cps			-	84	-		ς.	0	-	N •	-		,	- 1	N	-			•	۰ ۵	-			ς-	7	~			-	63	-	63	-	
Cps prescribed			м	7	7		61	63	64	NI (	N		,	NI I	7	63			•	1 72	8			72	82	<b>63</b>			8	83	7	83	73	
Treat.		57	-	26	-	58	- ;	29	- ;	22	-	57	•	-:	ก	-	8	'n	-	. K	-	1	ì	-	55	-	1	ò	-	38	-	11	-	88
To date			15/05/92	10/07/92	11/07/92		22/05/92	20/06/92	21/06/92	16/07/92	267/07/1			26/50//2	26//0/12	22/01/92			29/02/92	23/07/92	24/07/92			16/06/92	10/08/92	11/08/92			22/06/92	30/07/92	31/07/92	17/08/92	18/08/92	
From date			15/05/92	16/05/92	11/07/92		22/05/92	23/05/92	21/06/92	22/06/92	26//0//1		40,000	26/60/12	26/02/92	22/07/92			29/05/92	30/65/92	24/07/92			16/06/92	17/06/92	11/08/92			22/06/92	23/06/92	31/07/92	01/08/92	18/08/92	
Centre Pationt Treatment			Fluoxetine				Fluoxetine							Keboxetine					Reboxetine					Fluoxetine					Fluoxetine					
Patient			400				401						700	704					403					404					405					
Centre			14												6	9	3																	

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					A MINISTER CITY AND						
			_	REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0	TINE - PROTOCOL 20 Listing No.: 9.0	OL 20124	7016				
	,	EXPE	RIMENTAL	EXPERIMENTAL TREATMENT: DAILY AND CUNULATIVE COMPLIANCE	DAILY A	ND CUMUL	ATIVE COMP	LIANCE			
Treatment	From date	To date	Treat.	z z Treat, Cps Baily Compl. Compl. Morning Treatment From date To date days prescribed Cps day cumulat. Cps	Daily Cps	z Compl. day	X Compl. cumulat.	Morning Cps	ng Evening Cps	Reason (*)	ò
Fluoxetine	30/06/92	30/06/92	-	2	-	100.0	100.0		-	16 16	
	01/07/92	01/07/92 20/07/92	20	84	83	100.0	100.0	-	~		
	24/107/42	24/07/92	•	2	-	50.0	47.7	,		99	

		30/06/92	-	04	-	100.0	100.0	•	-	8	
		-	20	1 61	• 81	100.0	100.0	· <del>-</del>	٠,-	Į	
	21/07/92	21/07/92	-	8	-	20.0	97.7	τ-		99	
			73								
407 Reboxetine	Ċ	23/08/92	4	83	81	100.0	100.0	-	-		
	24/08/92	24/08/92	-	81	-	50.0	98.8	-		99	
			42								
408 Reboxetine	ne 04/08/92	04/08/92	-	84	•	100.0	100.0	•	,	8	
	_	07/08/92	· m	ı N	. 64	100.0	100.0	~	~	ļ.	
	08/08/92	08/08/92	-	N	-	50.0	90.06	-		28	
	09/08/92	14/08/92	9	81	61	100.0	95.5	-	-		
	15/08/92	15/08/92	-	61	-	50.0	91.7	-		2 <del>a</del>	
	16/08/92	29/08/92	4	7	N	100.0	96.2	-	-		
	30/08/92	31/08/92	8	7	-	50.0	92.9	-		28	
	01/09/92	18/09/92	18	7	2	100.0	95.7	-	-		
	19/09/92	19/09/92	~	8	-	50.0	94.7	_		20	
	20/09/92	29/09/92	10	77	8	100.0	92.6	-	-		
	30/09/92	30/09/92	-	73	-	100.0	95.7	<b>,</b>	0	96	
			28								
509 Fluoxetine	ne 29/09/92	29/09/92	-	N	-	100.0	100.0	•	~	<b>F</b> 6	
		30/09/92	_	84	8	100.0	100.0	-	-		
	01/10/92	01/10/92	-	84	er!	50.0	83.3	-	64		(a - c)
	02/10/92		39	1 64		100	8.86		٠,		
	10/11/92		-	1 64	τ-	50.0	97.7	-		99	
			£43								
510 Fluoxetine	ae 30/09/92	30/09/92	-	8	-	100.0	100.0	0	-	- M	
		16/10/92	16	N	8	100.0	100.0	-	-		
	17/10/92	17/10/92	~	84	-	50.0	97.2		-	Ē	
	18/10/92		39	8	~~	100.0	99.1	-	-		
	26/11/92		-	8	-	100.0	99.1	-	0	96	
			88						,		
511 Reboxetine			-	8	-	100.0	100.0	•	-	₽.	
	24/10/92	09/12/92	43	61	81	100.0	100.0	-	-		

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PHARMACIA CNS R&D

EXPERIMENTAL TREATMENT: DAILY AND CUNULATIVE COMPLIANCE REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

Centre Patient Treatment From date To date		From date 10/12/92	1	To date 10/12/92	freat. days	Cps prescribed 2	Cps Cps	Compl. day	Compl. cumulat.	Norning Cps	Evening Cps	Reason (*)	Overdose (**)
64	64	64	64								,	(	
512 Reboxetine 03/11/92 03/11/92 1 06/11/92 01/12/92 28	03/11/92 03/11/92 04/11/92 01/12/92	03/11/92		28		~ ~	<del>-</del> 61	100.0	100.0	o ~	<b></b>	Ē	
02/12/92	02/12/92	02/12/92		-		64	-	50.0	98.3	-		69	
30	30	30	30	30									
03/11/92	03/11/92 03/11/92	03/11/92		-		62	-	100.0	100.0	•	-	<b>e</b> 6	
04/11/92 28/12/92 55 29/12/92 29/12/92 1	28/12/92 29/12/92	28/12/92 29/12/92				N N	N F	100.0	100.0		- 0	96	
25	57	25	57	57									
538 Fluoxetine 12/02/93 12/02/93 1	12/02/93	-	12/02/93 1	-		81	-	100.0	100.0		-	9m	
13/02/93	13/02/93	•	19/02/93 7	7		N	7	100.0	100.0	-	-	,	
•••	•••	•••	20/02/93 1	-		63	-	50.0	4.4		-	a.	
•	•	•	26/02/93 6	9		or ·	C1 ·	100.0	96.7	-		į	
27/02/93 27/02/93 1	27/02/93	27/02/93		۲,		0.0		20.0	93.8	-		Ē	
05/04/93	05/04/93	05/04/93		3 -		1 (	4	9	96.2	•		1n Je	
-	-	-	08/04/93 3	· M		N	61	100.0	4.96	-	-		
09/04/93 09/04/93 1	_	_	09/04/93 1	-		~	-	100.0	96.5	-	0	96	
57		57	57	57									
10/03/93	10/03/93 10/03/93	10/03/93	10/03/93	-		8	-	100.0	100.0	•	-	e6	
11/03/93 04/05/93 55	04/05/93	04/05/93	04/05/93	22		63	7	100.0	100.0	-	ς.	,	
				-		N	-	100.0	100.0	τ-	0	96	
		57	57	57									
409 Reboxetine 08/04/92 02/06/92 56	08/04/92 02/06/92			35		N	N	100.0	100.0	-	-		
56	56	99	99	26									
410 Fluoxetine 17/04/92 11/06/92 56	17/04/92 11/06/92			56		N	8	100.0	100.0	-	-		
56	56	99	95	28									
411 Reboxetine 22/04/92 16/06/92 56	22/04/92 16/06/92			26		8	61	100.0	100.0	-	-		
				•									

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PHARMACIA CNS R&D

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Reason (\*) EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0 Daily Cps Cps prescribed To date From date Centre Patient Treatment

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		-	~	<del>-</del>	-	-	-	<del>-</del>	-	<del>(-</del>	-
		-	-	•	-	-	-	-	<b>.</b>	<del>-</del>	•
		100.0	100.0	100.0	100.0	188.0	100.0	100.0	100.0	100.0	100.0
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
		60	64	62	м	64	81	81	N	8	N
		N	61	<b>N</b>	N	N	N	м	N	64	N
	56	8 8	56	56	55 5	8 8	8 8	8 8	5, 5,	5, 5,	95
		17/06/92	24/06/92	27/07/92	06/08/92	17/08/92	13/08/92	10/09/92	09/09/92	14/10/92	25/09/92
		23.04/92 17/06/92	30/04/92	02/06/92 27/07/92	12/06/92	23/06/92 17/08/92	19/06/92 13/08/92	17/07/92 10/09/92	16/07/92	20/08/92 14/10/92	01/08/92
		Fluoxetine	Reboxetine	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine	Reboxetine	Fluoxetine	Fluoxetine	Reboxetine
									419 F1		
		412	413	414	415	<b>696</b>	417	418	2	420	421
1											

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PHARMACIA CNS R&D

EXPERIMENTAL TREATMENT: DAILY AND CUNULATIVE COMPLIANCE REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

Evening Reason Overdose Cps (*)	-		F			_	-														
Morning E Cps	<b></b>		-		-			-	-			<del>-</del>	·								
z Compl. cumulat.	100.0		100.0		100.0			100.0	100.0	100.0	160.0	160.0	100.0 100.0	100.00	100.0 100.0 100.0	100.00	100.0 100.0 100.0 100.0	100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100.00 100	100.0 100.0 100.0 100.0 100.0	100.0 100.0 100.0 100.0 100.0	100.0 100.0 100.0 100.0 100.0
Z Compl. day	100.0		0.001		100.0			100.0	100.0	100.0	100.0	100.0	100.0	100.001	100.0	100.0 100.0 100.0 100.0	100.0 100.0 100.0 100.0	100.0 100.0 100.0 100.0 100.0	100.0 100.0 100.0 100.0	100.0 100.0 100.0 100.0 100.0 100.0	100.0 100.0 100.0 100.0
Dail)	N		61		84			N	N	N N	N N	0 0 N	0 0 0	0 0 0 0	0 0 N N	0 0 0 0 0	a a a a a	0 0 0 N N N	0 0 0 0 0 0	0 0 0 0 0 0	
Cps prescribed	. 64		N		81			74													,
Treat.	56	56	55	26	28		56	56	56 56		56 56 56	56 56 56 56 56 56 56 56 56 56 56 56 56 5	56 58 88 88 88								
To date	13/10/92		15/10/92		15/10/92			26/11/92	26/11/92	26/11/92	26/11/92	26/11/92 22/12/92 27/01/93	26/11/92 22/12/92 27/01/93	02/10/92 26/11/92 28/10/92 22/12/92 03/12/92 27/01/93	26/11/92 22/12/92 27/01/93	02/10/92 26/11/92 28/10/92 22/12/92 03/12/92 27/01/93 03/12/92 27/01/93	26/11/92 22/12/92 27/01/93 27/01/93	02/10/92 26/11/92 28/10/92 22/12/92 03/12/92 27/01/93 03/12/92 27/01/93 10/12/92 03/02/93	26/11/92 22/12/92 27/01/93 27/01/93 01/02/93	02/10/92 26/11/92 28/10/92 22/12/92 03/12/92 27/01/93 03/12/92 27/01/93 10/12/92 03/02/93 18/12/92 11/02/93	26/11/92 22/12/92 27/01/93 27/01/93 03/02/93
From date	19/08/92 13/10/92		21/08/92 15/10/92		21/08/92 15/10/92			02/10/92 26/11/92	02/10/92	02/10/92 26/11/92	02/10/92 28/10/92	02/10/92 26/11/92 28/10/92 22/12/92 03/12/92 27/01/93	02/10/92 28/10/92 03/12/92	02/10/92 28/10/92 03/12/92	02/10/92 28/10/92 03/12/92	02/10/92 28/10/92 03/12/92 03/12/92	02/10/92 28/10/92 03/12/92 03/12/92	02/10/92 28/10/92 03/12/92 08/12/92	02/10/92 28/10/92 03/12/92 03/12/92	02/10/92 28/10/92 03/12/92 08/12/92 10/12/92	02/10/92 28/10/92 03/12/92 08/12/92 10/12/92
Contro Patient Treatment	Fluoxetine		Fluoxetine		Reboxetine			Reboxetine	Reboxetine	Reboxetine Fluoxetine	Reboxetine Fluoxetine	Reboxetine Fluoxetine Reboxetine	Reboxetine Fluoxotine Reboxetine	Reboxetine Fluoxotine Reboxetine Fluoxetine	Reboxetine Fluoxetine Reboxetine Fluoxetine	Reboxetine Fluoxotine Reboxetine Fluoxetine	Reboxetine Fluoxetine Reboxetine Fluoxetine	Reboxetine Fluoxotine Reboxetine Fluoxetine Reboxetine	Reboxetine Fluoxotine Reboxetine Fluoxetine Reboxetine	Reboxetine Reboxetine Fluoxetine Reboxetine Fluoxetine	Reboxetine Reboxetine Fluoxetine Reboxetine Fluoxetine
Pationt	422		423		424			425	425	42 <b>5</b> 42 <b>6</b>	425	425 426 427	42 <b>5</b> 42 <b>6</b> 427	42 <b>5</b> 42 <b>6</b> 427 428	425 426 427 427	425 426 427 449	425 426 427 449	42 <b>5</b> 42 <b>6</b> 428 449	425 427 427 449 450	425 426 427 449 450 451	425 426 427 449 450 451
Centre	15											6.5	697	697	697	697	697	697	697	697	697

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

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	100.0		100.0		100.0	9.0		100.0		100.0		100.0		100.0		100.0		100.0	96.7	97.2	95.9	96.3	95.1	95.8	
	100.0		100.0		100.0	9.00		100.0		100.0		100.0		100.0		100.0		100.0	50.0	100.0	50.0	100	50.0	100.0	
	77		81			N		8		61		N		61		61		8	-	N	Ψ-	N	-	8	•
	83		N		010	N		и		N		И	•	84		N		64	61	61	81	81	N	N	•
38	35	56	95	95	۲:	8	57	, 99	56	56	99	26	56	99	26	26	56	28	61	•	-	en	-	7	•
	15/03/93		20/05/92		30/03/92	25/02/52		25/05/92		25/05/92		27/05/92		01/06/92		08/06/92		21/05/92	23/05/92	29/05/92	30/05/92	02/06/92	03/06/92	10/06/92	
	19/01/93 15/03/93		26/03/92		30/03/92	31/03/92		31/03/92		31/03/92		02/04/92		07/04/92 01/06/92		14/04/92		24/04/92	22/05/92	24/05/92	30/05/92	31/05/92	03/06/92	04/06/92	
	Fluoxetine		Fluoxetine		Reboxetine			Reboxetine		Fluoxetine		Reboxetine		Fluoxetine		Reboxetine		Fluoxetine							
	454		429		430			431		432		433		434		435		436							
	15		91							(	59	8													

9550083

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

==low dose, 2=high dose, 3=low dose + high dose, A=d ==high dally dose in one administration, D=low dail = morning, e = evoning

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Fluoxetine   From date   To d   Fluoxetine   11/06/92   11/06   Reboxetine   30/04/92   24/06   Fluoxetine   20/05/92   17/06   Fluoxetine   20/05/92   14/07   Reboxetine   01/07/92   25/08	ETHENTAL.  Treat. days  1 7 7 7 6 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	TREATHENT: DAILY AND C Cps Daily Comp Proscribed Cps da 2 1 100 2 2 100 2 2 100 2 2 100 2 2 100 2 2 2 100 2 2 2 100	ATILY AND Chaily of Chaily of Chaily of Chaily of Chaily of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail of Chail	Compl. day 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0	TIVE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE COMPINE C	LIANCE Borning Cps 1	Evening Cps	Reason (*)	Overdose (xx)
Patient Treatment F 436 Fluoxetine 437 Reboxetine 439 Fluoxetine 440 Reboxetine	17 days. 29 29 29 29 29 29 29 29 29 29 29 29 29	1	i	Compl. day 1100.0 1100.0 1100.0 1100.0 1100.0	Z Compl. cumulat. 1. 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100	Morning Cps	Evening Ches	Reason (*) 3e 3e	Overdese (xx)
436 Fluoxetine 437 Reboxetine 438 Fluoxetine 439 Fluoxetine		00 0 00 0 0		100.0 100.0 100.0 100.0 100.0	95.9 96.4 100.0 100.0 100.0				
437 Reboxetine 436 Fluoxetine 439 Fluoxetine		0 00 0 0		100.0 100.0 100.0	100.0 100.0 100.0 100.0			e e	
437 Reboxetine 438 Fluoxetine 439 Fluoxetine		a aa a a		100.0	100.0 100.0 100.0 100.0			<b>8</b> 17	
438 Fluometine 439 Fluometine		00 N N		100.0 100.0 100.0	180.0 180.0 190.0	ee e c		e e	
436 Fluoxetine 439 Fluoxetine		N N N		100.0 100.0 100.0	100.0 100.0 100.0	<del>.</del>		e.	
439 Fluoxetine 440 Reboxetine		n n		100.0	100.0	÷~ .	-		
439 Fluoxetine		0 0		100.0	100.0	e	-		
440 Reboxetine 01/07/92		0		100.0	100.0	•			
440 Reboxetine 01/07/92		8		100.0	100.0	-			
							-		
69	56								
C 441 Fluoxetine 22/07/92 14/09/92	2 55	N	13	100.0	100.0	-	-		
	55								
442 Reboxetine 22/07/92 14/09/92	2 55	84	81	100.0	100.0	-	-		
	55								
443 Fluoxetine 25/08/92 18/10/92	2 55	63	N	100.0	100.0	-	-		t
	25								
444 Reboxetine 25/08/92 19/10/92	2 56	N	83	100.0	100.0	-	-		
	38								
445 Rebaxatine 18/09/92 12/11/92	2 56	8	81	100.0	100.0	~	-		
	56								
446 Fluoxetine 18/09/92 12/11/92	2 56	Ø	8	100.0	100.0	-	-		
(*) 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 [12] 4=1	2=lost medici ilan, 6=drop	ation, 3=adout, 7=over	verse e dese, 9	event, 4:	=change by end treatm	patient,	orning or ev	oning,	
C-high daily dose in one administration, D-Low daily dose in one administration	in one admin	istration,	D=10K	daily d	ose in one	adminis	tration	ì	

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PHARMACIA CNS RED

REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0

EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE

Overdose (**)			
Reason (*)			į
Evening Cps		~	۳
Morning Cps		-	
X Compl. cumulat.		100.0	000
z Compl. day		100.0	6
Daily		61	•
Cps prescribe		N	•
Treat.	26	7	•
To date		19/09/92	20/00/02
From date To date		18/09/92	20/00/02
Treatment		Fluoxetine	
Patient		447	

		Ę		Æ					Ę		ę.														
	-	<del>-</del>	-	-	-			-	-	-		<del>-</del>		-		-		-		-		-		-	
	-		<del>-</del>		-			-		-	-	-		-		-		-		-		-		-	
	100.0	83.3	28.1	96.3	98.2			100.0	6.96	98.9	97.8	98.2		100.0		100.0		100.0		100.0		100.0		100.0	
	100.0	50.0	100.0	0.	100.0			100.0	50.0	100.0	50.0	100.0		100.0		109.0		100.0		100.0		100.0		100.0	
	И	-	61	-	63			N	-	61	-	61		23		63		83		NI		71		81	
	81	8	61	63	87			61	63	ca	N	61		61		81		N		N		М		83	
38	81	-	ជ	-	29	2	ñ	15	-	59	~	2	98	95	\%	56	56	56	56	56	26	26	26	26	1
	19/09/92	20/09/92	13/10/92	14/10/92	12/11/92			03/10/92	04/10/92	02/11/92	03/11/92	13/11/92		13/11/92		09/02/93		09/02/93		09/02/93		15/02/93		15/02/93	
	18/09/92	20/09/92	21/09/92	14/10/92	15/10/92			19/09/92	04/10/92	05/10/92	03/11/92	04/11/92	•	19/09/92		16/12/92		16/12/92		16/12/92 09/02/93		22/12/92 15/02/93		22/12/92 15/02/93	
	Fluoxetine							Reboxetine						Fluoxetine		Reboxetine		Fluoxetine		Fluoxetine		Reboxetine		Reboxetine	
	447							448						455		456		457		458		459		460	
	16													7	0 0										

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0 PHARMACIA CNS R&D

5

(a) Overdose (xx) 3 <u>e</u> Reason (\*) Ē Evening Cps Morning Cps EXPERIMENTAL TREATMENT: DAILY AND CUNULATIVE COMPLIANCE 100.0 100.0 100.0 100.0 98.2 100.0 100.0 98.5 99.1 100.0 100,0 Z Compl. day 100.0 100.0 100.0 100.0 100.0 5 8 E Daily Cps 4 Cps prescribed 26 freat. 28 28 26 28 29/11/92 17/11/92 11/01/93 14/12/92 30/11/92 02/11/92 To date 30/11/92 06/10/92 20/10/92 06/10/92 From date Fluoxetine Reboxetine Fluoxetine Reboxetine Fluoxetine Patient Treatment 64 25 92 27 28 29 ٤ 8 18

1-forgot to take, 2-lost medication, 3-adverse event, 4-change by patient,
Jechange by physician, 6-drop out, 7-everdose, 9-start/end treatment in morning or evening,
10-reason unknown
11-low dose, 2-high dose, 3-low dose + high dose, A-double high dose, B-double low dose,
11-low dose, 2-high dose in one administration,
12-low dose, 13-per none administration
12-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per dose, 13-per **\***\* 3

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PHARMACIA CNS R&D

						REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0	PROTOCI ng No.:	9.0	919					
				EXPE	RINENTAL	EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE	DAILY AI	ND CUMBE	ATIVE COMP	LIANCE				
Centre	Patient	Centre Patient Treatment	From date	To date	Treat.	Cps prescribed	Daily Cps	z / Compl. day	z Compl. cumulat.	Norming Cps	Evening Cps	Reason (*)	Overdose (**)	
<b>2</b>	20	Reboxetine	17/11/92	17/11/92		2.2	7 +	100.0 50.0	100.0 75.0		-	99		
	25	Fluoxetine	17/11/92	17/11/92 11/01/93	2 2 2	N	63	100,0	100.0	-	~			
	52	Fluoxetine	17/11/92	17/11/92 11/01/93	56	N	64	100.0	100.0	-	₩			
*	83	Fluozetine	15/01/93	15/01/93 11/03/93	56	69	77	100.0	100.0	<b>-</b>	-			
702	\$5	Fluoxetine	12/01/93	12/01/93 08/03/93	56	0	N	100.0	100.0	-	-			
20	21	Fluoxetine	06/11/92	06/11/92 30/12/92	8 8	74	N	100.0	100.0	-	-			
	22	Fluoxetine	12/11/92	16/12/92	35	N	81	100.0	100.0	-	-			
21	6	Fluoxetine	19/10/92 25/10/92 26/10/92	24/10/92 25/10/92 11/11/92	9 - 5	01 01 00	0 T 0	50.0	100.0 92.9 97.9		<del>-</del> -	<del>-</del>		
			12/11/92			10101	. 61 4	100.0	98.1	-		3n 3e		
		I	16/11/92 18/11/92 26/11/92 27/11/92		_	N 61 61	- 01 - 01	100.0 50.0 100.0	98.7 97.4 98.1		·	- <del>-</del>		
			10/12/92 12/12/92 13/12/92	11/12/92 12/12/92 13/12/92	W	0 0 0	<del>-</del> - 0	50.0 50.0 100.0	96.3 95.5			Ęę		

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<sup>(</sup>xx)

PHARMACIA CNS R&D

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COL 20124/016	EXPERIMENTAL TREATMENT: DAILY AND CUMULATIVE COMPLIANCE	X X I Compl. Morning Evening Reason Overdose s day cumulat. Cps (x) (xx)		100.0 100.0 1 1 68 50.0 96.9 1 68		100.0 100.0 1 1 6e 6e	
REBOXETINE - PROTOCOL 20124/016 Listing No.: 9.0	REATHENT: DAILY	Cps Daily prescribed Cps		22		00	
<b>33</b>	EXPERIMENTAL T	freat. days	56	17/12/92 15 18/12/92 1	16	19/01/93 22 20/01/93 1	
		From date To date		03/12/92 17 18/12/92 18		29/12/92 19 20/01/93 20	
		Centre Patient Treatment		Fluoxetine		Reboxetine	
		Patient		113		115	
		Centre		22			

(xx) 8

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OTEN	20124/0' 0.0	TOCAME
HARMACLA FIRKNACEVILCAE BILANU " CNS	REBOXETINE - PROTOCOL 20124/016 Listing No.: 10.0	ASSTENED BANDOWITED TOFATHENT
משמשבדע	REBOXET	ACCTONES

		Ē	Gioon			Postantania	7		Error
Centre	Sequen. black	Treatment	Start treat, date	Patient	Patient	Treatment	Sequen.	block	Ξ
	•	:				:			
-		Fluoxetine	15/11/91	-	-	Fluoxetine		-	
	-	Reboxetine	26/06/92	84	Ø	Reboxetine		_	
	-	Fluoxetine	01/07/92	m	m	Fluoretine		-	
	-	Reboxetine	14/08/92	4	4	Reboxetine		-	
	64	Fluoxetine	13/10/92	ĸ	s	Fluoxetine		7	
	N	Fluoxetine	14/01/93	9	•	Fluoretine		63	
2	-	Reboxetine	16/04/91	35	83	Fluoxetine		_	*
	-	Fluoxetine	02/05/91	36	*	Reboxetine		_	×
	-	Reboxetine	03/05/91	34	35	Reboxetine		-	
	_	Fluoxetine	04/05/91	33	36	Fluoxetine		-	
	61	Reboxetine	16/90/90	40	37	Reboxetine		N	
	63	Fluoxetine	19/06/91	39	38	Fluoxetine		N	
	61	Fluoxetine	20/06/91	86	39	Fluoxetine		и	
	67	Reboxetine	19/11/0	37	40	Reboxetine		01	
	m	Reboxetine	19/11/91	43	14	Fluoxetine		8	*
	ო	Fluoxetine	13/12/91	#	45	Reboxetine		8	×
	m	Fluoxetine	13/02/92	41	43	Reboxetine		8	×
	m	Reboxetine	05/03/92	42	44	Fluoretine		60	×
	4	Fluoretine	25/03/92	47	45	Repoxetine		4	×
	4	Repoxetine	19/05/92	87	77	Fluoretine		. 4	*
	4	Reboxetine	10/09/92	5.4	4.7	Fluoxetine		. 4	*
	S	Fluoretine	15/01/93	8	48	Reboxetine		4	*
					!				
	,	:	;	!	;	;			
m	-	Fluoxetine	16/10/91	65	9	Fluoxetine		_	
	-	Fluoxetine	16/10/91	99	99	Fluoxetine		-	
	-	Repoxetine	18/11/92	63	67	Reboxetine		_	
	-	Reboxetine	30/11/92	99	89	Reboxetine		-	
	,	1	***************************************	Ş	ş			,	
•		PARTICIPATION	6 (40 (77		ì	Kepoxetine		_	
	-	Fluoxetine	30/05/91	96	86	Fluoxetine		_	
	-	Fluoxetine	15/10/91	66	66	Fluoxetine		-	
	-	Repoxetine	08/05/92	100	100	Repoxetine		_	
	8	Reboxetine	02/07/92	101	101	Reboxetine		8	
	7	Fluoxetine	10/07/92	102	102	Fluoxetine		8	
	7	Fluoxetine	13/07/92	103	103	Fluoxetine		8	
	84	Reboxetine	18/08/92	104	104	Repoxetine		8	
	"	Fluoretine	21/08/02	105	105	Tluevotine		, ÇT	
	ì			}	3			,	
ď	•	Dehovetine	19/11/60	120	120	Dahassatina			
ו	- •	Fluoretine	16 (11 ) (57	67.7	67.0	Kepoxecine		- ,	
	-	PUTTERONT	76 /70 /07	130	<u>2</u>	FINOXECIDE		-	

PHARMACIA PRARMACEUTICAL MILANO - CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 10.0

			ë					3	Erro
Centre	Sequen, block	block	Treatment	Start treat. date	Patient	Patient	Treatment	Sequen. black	¥
7		-	Reboxetine	06/12/91	193	193	Reboxetine	•	
			Fluoretine	10/01/92	194	196	Fluoretine		
		. ,-	Fluoxetine	14/02/92	195	195	Fluoxetine		
		_	Reboxetine	29/05/92	196	196	Reboxetine	-	
		81	Fluoxetine	11/11/92	197	197	Fluoxetine	N	
£		_	Fluoxetine	14/11/91	321	321	Fluoxetine	-	
		<b>-</b>	Reboxetine	14/11/91	322	322	Reboxetine	-	
		_	Fluoxetine	19/11/91	323	323	Fluoxetine	-	
		_	Reboxetine	24/01/92	324	324	Reboxetine	-	
		~	Reboxetine	12/02/92	325	325	Reboxetine	63	
		~1	Reboxetine	12/02/92	326	326	Reboxetine	<b>63</b>	
		~	Fluoxetine	14/02/92	327	327	Fluoxetine	64	
		<b>83</b>	Fluoxetine	19/02/92	328	328	Fluoxetine	<b>N</b>	
		m ·	Reboxetine	31/03/92	329	329	Reboxetine	m	
		m	Reboxetine	21/04/92	330	330	Reboxetine	m	
		m	Fluoxetine	26/02/92	331	331	Fluoxetine	m ·	
		m ·	Fluoxetine	28/01/92	332	332	Fluoxetine	m ·	
		<b>.</b>	Reboxetine	15/09/92	333	333	Reboxetine	4	
		<b>.</b>	Fluoxetine	22/09/92	334	334	Fluoxetine	4	
		4	Reboxetine	13/10/92	335	338	Reboxetine	4	
12		-	Fluoxetine	25/06/92	393	393	Fluoxetine	-	
		-	Reboxetine	06/07/92	394	394	Reboxetine	-	
		-	Reboxetine	24/07/92	395	395	Reboxetine	-	
		-	Fluoxetine	04/08/92	396	396	Fluoxetine	-	
		7	Fluoxetine	24/02/93	497	497	Fluoxetine	87	
13		-	Fluoxetine	14/03/92	385	385	Fluozetine	-	
		-	Reboxetine	16/03/92	388	386	Fluoxetine	-	×
		-	Reboxetine	18/04/92	387	387	Reboxetine	-	
		-	Fluoxetine	24/04/92	386	388	Reboxetine	-	×
		03	Reboxetine	28/05/92	390	389	Fluoxetine	Ø	×
		o,	Fluoxetine	11/06/92	391	390	Reboxetine	61	×
		~1	Fluoxetine	21/07/92	389	391	Fluoxetine	61	
		67	Reboxetine	14/08/92	392	392	Reboxetine	01	
		m.	Reboxetine	31/08/92	505	202	Reboxetine	m	
		en i	Fluoxetine	11/09/92	507	206	Fluoxetine	en i	
		m (	Fluoxetine	27/10/92	206	202	Fluoxetine	m	
		7	Keboxetine	26/11/20	202	200	Keboxetine	'n	

(\*) Assigned treatment different from randomized

PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 10.0

reatment Start treat.	Sequen. block Treatment Star
eboxetine	Reboxetine
luoxetine	Fluoxetine
eboxetine 30/11/92	Reboxetine
luoxetine	Fluoxetine
eboxetine	Reboxetine
eboxetine	Reboxetine
luoxetine	Fluoxetine
luoxetine	Fluoxetine
eboxetine	Reboxetine
eboxetine	Reboxetine
luoxetine	Fluoxetine
luoxetine	Fluoxetine
luoretine	Fluoretine
oboxetine	Reboxetine
oboxetine	Reboxetine
luoxetine	Fluoxetine
luoxetine	Fluoxetine
eboxetine	Reboxetine
eboxetine	Reboxetine
eboxetine	Reboxetine
luoxetine	Fluoxetine
luoxetine	Fluoxetine
eboxetine	Reboxetine
Juoxetine	Fluoxetine
eboxetine	Reboxetine
luoxetine	Fluoxetine
eboxetine	Reboxetine
luoxetine	Fluoxetine
aboxetine	Reboxetine
eboxetine	Reboxetine
'luoxetine	Fluoxetine
luoxetine	Fluoxetine
eboxetine	Reboxetine
Seboxetine	Reboxetine
Tuorestine.	Fluoretine
1.0404.100	Clunestino
Database T	Flucksting
010101010	Debototino
CONCRETING	POPONETING
ומאסיים	Kepoxerrae

PHARMACIA PHARMACEUTICAL MILANO - CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 10.0

ASSIGNED vs RANDOMIZED TREATMENT

Start treat, date   Patient   Treat				Given			Randomized	Per		Erro
Fluoretine	ontre	Sequen, block	Treatment	Start treat. date	Patient	Patient	Treatment	Sequen.	black	€
Fluoretine   28/10/92   4/26   Fluoretine   5								3		
5         Reboxetine         09-12/92         428         428         Fluoretine         6           6         Fluoretine         08-12/92         449         428         Fluoretine         6           6         Fluoretine         18-12/92         449         469         149         469         6           6         Fluoretine         18-12/92         451         451         451         140         6           7         Fluoretine         18-12/92         454         459         Fluoretine         6           7         Fluoretine         19/01/93         454         454         Fluoretine         6           8         Fluoretine         20/03/92         454         454         Fluoretine         7           1         Reboxetine         31/03/92         430         430         Reboxetine         7           2         Reboxetine         20/03/92         432         432         Fluoretine         7           3         Fluoretine         31/03/92         443         Abboxetine         7           4         Fluoretine         10/04/92         443         Fluoretine         6           5         Fluoretine <td< td=""><td>'n</td><td>κŋ</td><td>Fluoxetine</td><td>28/10/92</td><td>426</td><td>426</td><td>Fluoxetine</td><td></td><td>LC.</td><td></td></td<>	'n	κŋ	Fluoxetine	28/10/92	426	426	Fluoxetine		LC.	
Fluozetine   03-72-92   449   420   Fluozetine   6		κŋ	Reboxetine	03/12/92	427	427	Reboxetine		ď	
Reboxetine   10/12/92		ĸŋ	Fluoxetine	03/12/92	428	428	Fluoretine		י ני	
Fluoratine   10/12/92   455   510coetine   6		v	Reboxetine	08/12/92	644	677	Pehoretine		, ,	
Fluoretine   18-12/92   457   Fluoretine   6		vo	Fluoxetine	10/12/92	450	027	Flinwoting			
Fluoxetina   23/12/22   452   452   Reboxetina   19/01/23   452   452   Reboxetina   19/01/23   452   452   Fluoxetina   19/01/23   453   454   Fluoxetina   19/01/22   451   454   Fluoxetina   19/01/22   451   451   Reboxetina   19/01/22   451   451   Reboxetina   19/01/22   452   452   Fluoxetina   19/01/22   452   452   Fluoxetina   19/01/22   452   452   Fluoxetina   19/01/22   452   452   Fluoxetina   19/01/22   452   452   Fluoxetina   19/01/22   452   452   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454   454   Fluoxetina   19/01/22   454		9	Fluoxetine	18/12/92	451	124	Flumetine			
Thurstine   19/01/3   454 454 Fluctine   19   19   19   19   19   19   19   1		40	Reboxetine	23/12/92	45.52	77	Dohovotino		, v	
Fluozotine   26/13/92   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429   429		7	Fluoxetine	19/01/93	454	454	Fluoxetine			
Fluozetine										
Reboxetine	9	~	Fluoxetine	26/03/92	429	429	Fluorotino		,	
Reboxetine		-	Reboxetine	30/03/92	727	067	Dohowotino		- ,	
Plucatine		-	Reboxetine	31/03/92	431	431	Deboretine			
2         Reboxetine         07/04/92         433         433         Reboxetine         2           2         Fluozetine         14/04/92         434         434         Fluozetine         2           3         Fluozetine         14/04/92         435         436         Fluozetine         2           3         Fluozetine         20/04/92         437         Reboxetine         2           4         Fluozetine         20/05/92         436         436         Fluozetine         2           4         Fluozetine         20/05/92         436         440         Reboxetine         3           4         Fluozetine         20/05/92         443         441         Reboxetine         4           4         Fluoxetine         22/07/92         444         444         Reboxetine         4           5         Reboxetine         18/09/92         444         444         Reboxetine         5           5         Fluoxetine         19/09/92         444         444         Reboxetine         5           6         Fluoxetine         19/09/92         446         446         Reboxetine         5           6         Fluoxetine         19/09/		-	Fluoxetine	31/03/92	432	432	Fluoretine			
2         Fluoractine         47/14/22         434         Fluoractine         2           2         Fluoractine         47/14/22         435         435         Fluoractine         2           3         Fluoractine         24/16/22         435         437         Fluoractine         3           3         Fluoractine         30/16/22         439         437         Fluoractine         3           4         Fluoractine         22/10/22         439         Fluoractine         3           4         Fluoractine         22/10/22         449         440         Fluoractine         4           4         Fluoractine         22/10/22         443         444         Fluoractine         4           4         Fluoractine         22/10/22         444         444         Fluoractine         4           5         Fluoractine         18/10/22         444         444         Raboxactine         4           5         Fluoractine         18/10/22         444         444         Raboxactine         5           6         Fluoractine         18/10/22         445         444         Raboxactine         6           5         Fluoractine         16/1		67	Reboxetine	02/04/92	433	433	Reboxetine		• •	
2         Reboxetine         14/144/92         435         435         Reboxetine         2           3         Flucatine         30/14/92         435         436         Flucatine         2           3         Flucatine         30/14/92         436         436         Flucatine         3           4         Flucatine         20/15/92         439         438         Flucatine         3           4         Flucatine         20/15/92         449         440         Reboxetine         3           4         Reboxetine         22/07/92         443         443         Reboxetine         4           4         Flucatine         18/109/92         444         444         Reboxetine         4           5         Flucatine         18/109/92         444         444         Flucatine         5           5         Flucatine         18/109/92         444         444         Flucatine         5           6         Flucatine         19/109/92         444         444         Flucatine         5           5         Flucatine         19/109/92         446         446         Flucatine         5           6         Flucatine		63	Fluoxetine	07/04/92	434	434	Fluoretine		1 6	
2   Fluoretine   20/19/22   436 Fluoretine   2   5   5   5   5   5   5   5   5   5		61	Reboxetine	14/04/92	435	435	Reboxetine		1 60	
3         Reboxetine         30.014,92         437         437         Reboxetine         3           3         Flucatine         20.015,92         439         438         Flucatine         3           4         Flucatine         20.015,92         449         440         Reboxetine         3           4         Flucatine         20.07,92         449         440         Flucatine         4           4         Flucatine         22.07,92         443         442         Flucatine         4           4         Reboxetine         25.08,92         443         444         Flucatine         4           5         Flucatine         18.09,92         444         444         Flucatine         4           5         Flucatine         18.09,92         444         444         Flucatine         4           5         Flucatine         18.09,92         444         444         Flucatine         5           6         Flucatine         19.09,92         444         444         Flucatine         5           5         Flucatine         19.09,92         445         446         Flucatine         5           6         Flucatine         1		87	Fluoxetine	24/04/92	436	964	Fluoxetine		1 10	
3   Fluoretine   20/05/92   438   438   Fluoretine   3		m	Reboxetine	30/04/92	437	437	Reboxetine		(1)	
Reboxetine   22/07/92   449   443   Fluozetine   3		m i	Fluoxetine	20/05/92	438	438	Fluoxetine		m	
4         Reboxetine         01/07/92         440         440         Relobatine         3           4         Reboxetine         22/07/92         442         442         Reloactine         4           4         Reboxetine         22/07/92         443         444         Reloactine         4           5         Reboxetine         18/08/92         444         444         Reboxetine         4           5         Reloactine         18/08/92         445         445         Reboxetine         4           5         Reloactine         18/08/92         445         Reboxetine         5           6         Fluoxetine         18/08/92         445         Reboxetine         5           6         Fluoxetine         19/08/92         445         Reboxetine         5           6         Fluoxetine         16/12/92         448         Reboxetine         5           6         Fluoxetine         16/12/92         455         Fluoxetine         5           7         Reboxetine         16/12/92         456         456         Reboxetine         7           7         Reboxetine         16/10/92         25         25         Fluoxetine		ro 1	Fluoxetine	20/05/92	439	439	Fluoxetine		3	
Fluozetine   22/07/92   444   441   Fluozetine   4		m,	Reboxetine	01/07/92	440	440	Reboxetine		69	
Heboxetine   25/08/92   442   442   Reboxetine   4		<b>.</b>	Fluoxetine	22/07/92	‡	441	Fluoxetine		4	
Trunvatine   25/08/72   443   443   Fluoratine   4		# <	Keboxetine	22/07/92	142	445	Reboxetine		*	
Reboxetine   25/08/72   444   444   Reboxetine   4   444   Reboxetine   4   444   Reboxetine   4   444   Reboxetine   4   444   Reboxetine   18/09/72   445   445   Reboxetine   5   Fluoxetine   18/09/72   446   446   Fluoxetine   5   447   447   Fluoxetine   5   447   447   Fluoxetine   5   447   447   Fluoxetine   6   Fluoxetine   6   7   447   447   7   Fluoxetine   6   7   455   455   7   Fluoxetine   6   7   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   457   45			ridoxetine	25/08/92	#3	443	Fluoxetine		4	
Secondaria		<b>.</b>	Reboxetine	25/08/92	‡	444	Reboxetine		4	
S		0 1	Keboxetine	18/09/92	445	445	Reboxetine		5	
S		ın, ı	Fluoxetine	18/09/92	446	446	Fluoxetine		5	
Suboxetine   19.099/22   448   448   Rebuxetine   5		η .	Fluoxetine	18/09/92	447	447	Fluoxetine		S	
6 Fluoxetine 1970972 455 455 Fluoxetine 6 Reboxetine 16712792 455 456 Reboxetine 6 7 Fluoxetine 16712792 456 456 Reboxetine 7 7 Fluoxetine 16712792 458 458 Fluoxetine 7 7 Reboxetine 16712792 459 459 Reboxetine 7 7 Reboxetine 06710792 25 25 Fluoxetine 7 1 Reboxetine 06710792 25 25 Fluoxetine 1 1 Reboxetine 06710792 25 26 Reboxetine 1 1 Reboxetine 06710792 27 Reboxetine 1 2 Reboxetine 06710792 28 28 Fluoxetine 1 2 Reboxetine 07710792 39 29 Reboxetine 2 2 Fluoxetine 07710792 31 Reboxetine 2 2 Fluoxetine 07710792 33 Reboxetine 2 2 Fluoxetine 07710792 33 Reboxetine 2		ימ	Repoxetine	19/09/92	448	448	Reboxetine		5	
Neboxetine   16/12/92   456   456   Reboxetine   6		•	Fluoxetine	19/09/92	455	455	Fluoxetine		9	
Tlucatine   16/12/92   457   457   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine   7   Flucatine		<b>.</b>	Reboxetine	16/12/92	456	456	Reboxetine		9	
7 Fluoxetine 16.712.92 458 Fluoxetine 7 7 Reboxetine 22.712.92 459 Reboxetine 7 7 Reboxetine 22.712.92 460 460 Reboxetine 7 1 Fluoxetine 06.710.92 25 25 Fluoxetine 1 1 Reboxetine 06.710.92 27 Reboxetine 1 1 Fluoxetine 06.710.92 28 28 Fluoxetine 1 2 Reboxetine 06.710.92 29 29 Reboxetine 1 2 Fluoxetine 06.710.92 39 39 29 Reboxetine 2 2 Fluoxetine 07.710.92 30 30 Fluoxetine 2 2 Fluoxetine 07.710.92 31 Reboxetine 2			Fluoxetine	16/12/92	457	457	Fluoxetine		7	
Neboxetine   22/12/92   459   Reboxetine   7			Fluoxetine	16/12/92	458	458	Fluoxetine		7	
Reboxetine   22/12/92   460   Reboxetine   7			Reboxetine	22/12/92	459	459	Reboxetine		2	
Fluoretine 06/10/92 25 25 Fluoretine 1   Reboxetine 06/10/92 26 26 Reboxetine 1   Reboxetine 06/10/92 27 27 Reboxetine 1   Fluoretine 06/10/92 28 28 Fluoretine 1   Fluoretine 06/10/92 29 29 Reboxetine 2   Fluoretine 07/10/92 39 31 Reboxetine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 2   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3   Fluoretine 3			Reboxetine	22/12/92	460	460	Reboxetine		7	
Reboxetine 06/10/92 25 25 Fluoxetine 1   Reboxetine 06/10/92 27 27 Reboxetine 1   Fluoxetine 06/10/92 28 28 Fluoxetine 1   Fluoxetine 06/10/92 29 29 Reboxetine 1   Fluoxetine 06/10/92 29 29 Reboxetine 2   Fluoxetine 07/10/92 31 Reboxetine 2   Fluoxetine 07/10/92 32 31 Reboxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 2   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluoxetine 3   Fluox	α	•			;	;				
Reboxetine		• •	HITTOURY !	76/01/00	S.	22	Fluoxetine		_	
Reboxetine 06/10/92 27 27 Reboxetine 1   Reboxetine 1   Reboxetine 06/10/92 28 28 Fluoxetine 1   Reboxetine 06/10/92 29 29 Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 2   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   Reboxetine 3   R		-	Keboxetine	06/10/92	56	56	Reboxetine		_	
Flucatine 06/10/92 28 28 Flucatine 1   Reboxetine 06/10/92 29 29 Reboxetine 2   Flucatine 2   Flucatine 07/10/92 30 31 Reboxetine 2   Flucatine 07/10/92 32 31 Reboxetine 2   Flucatine 07/10/92 32 31 Reboxetine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 2   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine 3   Flucatine		_	Reboxetine	06/10/92	27	23	Reboxetine		_	
Reboxetine         06/10/92         29         Reboxetine         2           Fluoretine         07/10/92         30         Fluoretine         2           Fluoretine         07/10/92         32         31         Reboxetine         2		- 1	Fluoxetine	06/10/92	2 <b>8</b>	23 25	Fluoxetine		_	
Fluoxotine 07/10/92 30 30 Fluoxotine 2 Fluoxotine 07/10/92 32 31 Reboxotine 2		NI f	Keboxetine	06/10/92	29	52	Reboxetine		N	
Fluoxetine 07/10/92 32 31 Reboxetine 2		N	Fluoxetine	07/10/92	8	8	Fluoxetine		8	
		~	Fluoxetine	07/10/92	32	31	Reboxetine		۱6	*

(\*) Assigned treatment different from randomized

PHARMACIA PHARMACEUTICAL MILANO - CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 10.0

ASSIGNED VS RANDOHIZED TREATHENT

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	bloc	63	m	60	m	m	4	4	÷	-	-	~	~
ped	Sequen. block												
Randomized	Patient Treatment	Fluoxetine	Reboxetine	Reboxetine	Fluoxetine	Fluoxetine	Fluoxetine	Fluoretine	Fluoxetine	Fluoxetine	Fluoxetine	Fluoxetine	Fluoxetine
		32	49	20	51	25	53	ģ	21	22	o	113	114
	Patient	31	649	20	51	52	\$5	53	21	22	o.	113	115
Given	Start treat. date Patient	20/10/92	17/11/92	17/11/92	17/11/92	17/11/92	12/01/93	15/01/93	06/11/92	12/11/92	19/10/92	03/12/92	29/12/92
Ġ.	Sequen. block Treatment	Reboxetine	Reboxetine	Reboxetine	Fluoxetine	Fluoxetine	Fluoxetine	Fluoxetine	Fluoxetine	Fluoxetine	Fluoxetine	Fluozetine	Reboxetine
	block	83	æ	60	er)	m	4	4	-	-	-	-	-
	Centre	18							20		21	22	

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(\*) Assigned treatment different from randomized

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				Drug compliance	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed
				Decision to discontinue				Physician Patient	Physician Patient	Physician Patient		Patient			Physician Patient	Patient	Patient	Patient		
!	PHARMACIA CNS RED	REBOXETINE - PROTOCOL 20124/016 LISTING No.: 11.0	REASONS FOR DISCONTINUATION OF THE TREATMENT	Reason				Adverse event	Deterioration	Adverse event Deterioration		Adverse event		·	Adverse event	Patient uncooperative	Patient uncooperative	Patient uncooperative		
	PHARMACI	EBOXETINE - PR LISTING	FOR DISCONTINU	Complete as protocol	KES	YES	YES	£	Q.	NO	YES	ON	YES	YES	ON.	ON.	ON	OH.	YES	YES
		<b>~</b>	REASONS	Date of last dose	09/01/92	20/08/92	25/08/92	24/09/92	11/11/92	11/02/93	28/06/91	12/06/91	10/06/91	26/06/91	10/10/91	25/07/91	22/06/91	04/07/91	08/04/92	29/04/92
			٠	Last visit	Day 56	Day 56	Day 56	Day 42	Day 35	Day 28	Day 56	Day 42	Day 56	Day 56	Day 7	Day 35	Day 7	Day 28	Day 56	Day 56
				Sex	Kale	Kale	Female	Fenale	Fenale	Male	Female	Male	Fenale	Male	Male	Kale	Male	<b>Ka</b> le	Hale	Fenale
				Patient	-	74	m	4	ю	9	æ	**	35	36	37	38	39	04	14	42
				entre																

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REBOXETINE - PROTOCOL 20124/016 LISTING No.: 11.0

PRARMACIA CNS RED

	Drug
	Decision to discontinue
REASONS FOR DISCONTINUATION OF THE TREATMENT	=
NUATION	Reaso
FOR DISCONTI	Date of Complete last dose as protocol Reason
REASONS	Date of last dose
	ast visit
	Last
	28 28
	Centre Patient Sex
	Centre

											,					
As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed
	Patient						Physician	Patient	Physician			Physician	Physician			Physician
	Lost to follow up						Adverse event	Patient uncooperative	Deterioration			Deterioration	Protocol violation			Deterioration
YES	£	YES	YES	YES	YES	YES	ON	Q,	Q	YES	YES	Q	ON	YES	YES	8
13/01/92	30/01/92	04/11/92	19/05/92	13/07/92	11/03/93	10/12/91	12/11/91	15/12/92	28/12/92	16/00/91	24/07/91	25/10/91	08/05/92	26/08/92	03/09/92	18/08/92
Day 56	Day 49	Day 56	Day 56	Day 56	Day 56	Day 56	Day 28	Day 28	Day 35	Day 56	Day 56	Day 14	Day 7	Day 56	Day 56	Day 42
Female	Nale	Female	Female	Fenale	Male	Female	Female	Female	Fema1e	Female	Female	Female	Male	Female	Female	Female
£	**	45	43	84	80	89	99	67	89	97	86	66	100	101	102	103
64						м				4						

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PHARMACIA CNS R&D

REASONS FOR DISCONTINUATION OF THE TREATHENT

Drug compliance	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed
Decision to discontinue	Patient		Physician					n Physician	Physician							Physician	
Reason	Adverse event		Adverse event					Intercurrent medical problem	Protecol violation		ş					Protocol violation	
Complete as protocol	Q.	YES	Q.	YES	YES	YES	YES	MO	ON	YES	YES	YES	YES	YES	YES	0N	XES
Date of last dose	05/10/92	15/10/92	29/12/91	23/04/92	31/01/92	05/03/92	09/04/92	16/07/92	11/11/92	09/01/92	09/01/92	13/01/92	19/03/92	07/04/92	07/04/92	12/03/92	14/04/92
Last visit	Day 49	Day 56	Day 35	Day 56	Day 56	Day 56	Day 56	Day 49	Day 7	Day 56	Day 56	Day 56	Day 56	Day 56	Day 56	Day 28	Day 56
Sex	Female	Male	Female	Female	Female	Female	Male	Female	Male	Female	Female	Female	Female	Female	Female	Female	Female
Cemtre Patient	<b>1</b> 04	105	129	130	193	194	195	196	197	321	322	323	324	325	326	327	328
Centre	4		κ)		7					ξ							

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PHÁRNACIA CNS RÆD STINE - PROTOCOL 20124/016 LISTING No.: 11.0

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	Drug compliance	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	Unknown	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed
		As p	As p	A Si	As p	As p	As p	As I	As	As	As	Unka	As 1	As	γs	As	As
	Decision to discontinue		Physician					Physician				Patient	Physician Patient		Physician	Physician	
REASONS FOR DISCONTINUATION OF THE TREATHENT	Reason		Deterioration			,		Adverse event				Adverse event Protocol violation			Deterioration	Adverse event	
FOR DISCONTINU	Complete as protocol	YES	S.	YES	YES	YES	YES	NO ON	TES	YES	YES	Q.	ŸES	YES	ÖK	ON ON	YES
REASONS	Date of last dose	27/05/92	08/06/92	20/07/92	24/09/92	09/11/92	16/11/92	16/11/92	18/08/92	31/08/92	16/09/92	17/08/92	21/04/93	08/05/92	30/04/92	18/05/92	11/05/92
	Last visit	Day 56	Day 49	Day 56	Day S6	Day 56	Day 56	Day 35	Day 56	Day 56	Day 56	Day 14	Day 56	Day 56	Day 7	Day 28	Day 56
	Sex	Female	Male	Female	Fenale	Female	Female	Female	Female	Male	Male	Female	Female	Fenale	Male	Female	Male
	Centre Patient	329	330	331	332	333	334	335	393	394	395	396	497	385	386	387	388
	Centro	1					71	2	12					<b>£</b> 1			

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PHARMACIA CNS RED REBUXETINE - PROTOCOL 20124/016 LISTING No.: 11.0 REASONS FOR DISCONTINUATION OF THE TREATMENT
Date of Complete
Sex Last visit last dose as protocol Reason disco

As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed
₹	₹			∢	<	<	•	•	•		•	~	•	•	•
Patient		Physician	Physician			Patient				Physician Patient					
Patient uncooperative		Adverse event	Deterioration			Adverse event				Improvement					
SS.	YES	8	8	YES	YES	ON	YES	YES	YES	YES	YES	YES	TES	YES	YES
23/07/92	22/01/92	15/07/92	27/08/92	30/12/92	24/12/92	18/11/92	20/01/93	22/10/92	23/12/92	06/11/92	29/12/92	26/01/93	26/90/60	10/06/92	16/06/92
Day 7	Day 56	Day 35	Day 14	Day 56	Day 56	Day 7	Day S6	Day 56	Day 56	Day 56	Day 56	Day 56	Day 56	Day 56	Day 56
Female	Male	Fenale	Fenale	Male	Female	Female	Fenale	Female	Male	<b>Fenale</b>	Female	Male	Female	Female	Female
389	390	391	392	501	502	503	504	505	206	507	508	521	397	398	399

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PHARMACIA CHS RED

		o Brug compliance	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As presoribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed
		Decision to discontinue							Physician	Patient		Patient		Physician	Patient				
REBUXETINE - PROTOCOL 20124/016 LISTING No.: 11.0	REASONS FOR DISCONTINUATION OF THE TREATMENT	Reason							Deterioration	Deterioration		Deterioration		Protocol violation	Patient uncooperative				
EBOXETINE - F LISTING	FOR DISCONTIN	Complete as protocol	YES	YES	YES	YES	KES	YES	8	NO	YES	ON	YES	õ	ON	YES	YES	YES	YES
24	REASONS	Date of last dose	11/07/92	17/07/92	22/01/92	24/07/92	11/08/92	18/08/92	21/07/92	24/08/92	30/09/92	10/11/92	26/11/92	10/12/92	02/12/92	29/12/92	09/04/93	05/05/93	02/06/92
		Last visit	Day 56	Day 56	Day 56	Day 56	Day 56	Day 56	Day 21	Day 42	Day 56	Day 42	Day 56	Day 49	Day 28	Day 56	Day 56	Day 56	Day 56
		Sex	Kale	Fenale	Female	Female	Female	Female	Female	Male	Female	Fenale	Fenale	Female	Female	Female	Female	Female	Male
		Centre Patient	400	401	402	403	404	405	406	407	408	509	510	511	512	537	538	539	604
		Centre	4							71	l <sub>±</sub>								15

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REASONS FOR DISCONTINUATION OF THE TREATMENT	Date of Complete Last visit last dose as protocol Reason discontinue Drug compliance	Day 56 11/06/92 YES As prescribed	Bay 56 16/06/92 YES As prescribed	a Day 56 17/06/92 YES As prescribed	a Day 56 24/06/92 YES As prescribed	Day 56 - 27/07/92 YES As prescribed	Day 56 06/08/92 VES As prescribed	e Day 56 17/08/92 YES As prescribed	e Day 56 13/08/92 YES As proscribed	e Day 56 10/09/92 YES As prescribed	e Day 56 09/09/92 YES As prescribed	Day 56 14/10/92 YES As prescribed	o Day 56 25/09/92 YES As prescribed	Day 56 13/10/92 YES As prescribed	e Day 56 15/10/92 YES As prescribed	Day 56 15/10/92 YES As prescribed	e Day 56 26/11/92 YES As prescribed	
REAS														·				
	ationt Sex	410 Female	411 Fomale	412 Female	413 Female	414 Male	415 Female	416 Female	417 Female	418 Female	419 Female	420 Male	421 Female	422 Male	423 Female	424 Kale	425 Female	
	Centre Patient	15 41	74	14	14	14	7	4	71		ù-	¥	¥	¥	¥	¥	ĕ	

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				REASONS	REBOXETINE - F LISTING FOR DISCONTIN	REBOXETINE - PROTOCOL 20124/016 LIBTING No.: 11.0 REASONS FOR DISCONTINUATION OF THE TREATMENT		
₽	Centre Patient	XeX	Last visit	Date of Last dose	Complete as protocol	Reason	Decision to discontinue	Drug compliance
8	439	Fenale	Day 56	14/07/92	YES			As prescribed
3	0 <b>*</b>	Female	Day 56	25/08/92	YES			As prescribed
3	441	Female	Day 56	14/09/92	YES			As prescribed
4	442	Female	Day 56	14/09/92	YES			As prescribed
3	6443	Male	Day 56	18/10/92	YES			As prescribed
4	444	Female	Day 56	19/10/92	YES			As prescribed
3	445	Nale	Day 56	12/11/92	YES			ds prescribed
3+	944	Fenale	Day S6	12/11/92	YES			As prescribed
3	447	Kale	Day 56	12/11/92	YES			As prescribed
3	448	Female	Day 56	13/11/92	YES			As prescribed
3	455	Female	Day 56	13/11/92	YES			As prescribed
3	456	Male	Day 56	09/02/93	YES			As prescribed
4	457	Female	Day 56	09/02/93	YES			As prescribed
3	458	Female	Day 56	09/02/93	YES			As prescribed
4	429	Male	Day 56	15/02/93	YES			As prescribed
4	095	Male	Day 56	15/02/93	YES			As prescribed
•		,						

YES

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 LISTING No.: 11.0

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REASONS FOR DISCONTINUATION OF THE IREATHENT

Date of Complete

Centre Patient Sex Last visit last dose as protocol Reason discontinue Drug co

As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	As prescribed	Confirmed irregularities	As prescribed	As prescribed	As prescribed	As prescribed	Suspected irregularities	As prescribed	As prescribed
4	A.	Patient A	¥	4	4	◀	₩	Patient C	₹	4	₹	4	va	Physician A Patient	•
		Patient uncooperative						Patient uncooperative						Adverse event	
YES	YES	Ö	YES	YES	YES	XES	YES	QN Q	YES	YES	YES	YES	YES	ON ON	YES
30/11/92	30/11/92	02/11/92	30/11/92	01/12/92	14/12/92	30/11/92	11/01/93	18/11/92	11/01/93	11/01/93	11/03/93	08/03/93	30/12/92	16/12/92	13/12/92
Day 56	Day 56	Day 28	Day 56	Day 56	Day 56	Day 56	Day 56	Day 7	Day 56	Day 56	Day 56	Day 56	Day 56	Day 35	Day 56
Female	Fenale	Female	Male	Female	Female	Female	Female	Female	Fenale	Fenale	Female	Male	Female	Female	Female
26	22	28	53	30	3	32	49	20	5	22	53	ž	21	22	6
€													20		21

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				•	REBOXETINE - { LISTING	REBOXETINE - PROTOCOL 20124/016 LISTING No.: 11.0		•	
				REASONS	FOR DISCONTIN	REASONS FOR DISCONTINUATION OF THE TREATHENT			
ntre	ntre Patient Sex	Sex	Last visit	Bate of last dose	Date of Complete Last visit last dose as protocol Reason	Reason	Decision to discontinue	Decision to discontinue Drug compliance	
	113	Male	Day 21	Day 21 18/12/92	NO	Protucol violation	Physician	As prescribed	ı
	115	Kale	Day 28	Day 28 20/01/93	9	Lost to follow un	Patient	As prescribed	

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PHARMACIA CNS RED

HANILTON DEPRESSION RATING SCALE

Hamilton depression rating scale

Centre Patient Treatment

Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56

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PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0	HAHILTON DEPRESSION RATING SCALE	x Hamilton depression rating scale	Female 09.AGITATION 10.ANXIETY PSYCHIC 11.ANXIETY PSYCHIC 12.SOHATIC GASTROLITESTINAL 13.SOHATIC GENERAL 14.GENTAL SYMPTOHS 15.SOHATIC GENERAL 16.LOSS OF WEIGHT 17.HSYCHY 19.DERESSOHALIZATION 20.PREANOID 21.OSSISIONAL/COMPULSIVE 22.10tal score	10 01.DEPRESSED MOOD 02.GUILT 03.SUICIDE 04.INSOMIA EARLY 05.INSOMIA ANDLE 06.INSOMIA ANTE 07.NORK AND ACTIVITIES 09.AGITATION 09.AGITATION 10.ANXIETY SOVCHIC 11.ANXIETY SOVCHIC 12.SUMATIC GASTRONVESTINAL 19.SUMATIC GASTRONVESTINAL 19.SUMATIC GASTRONVESTINAL 19.INSIGHT 10.INSIGHT 10.INSIGHT 10.INSIGHT 11.DEPAL VARIATION 20.PARANDID 21.OBSESSIONALZATION 20.PARANDID 22.TOTAL SCOPE	Fewale 01.DEPRESSED HOOD 02.GULT 03.SULTIDE 04.INSORNIA HIDDLE 05.INSORNIA HIDDLE 05.INSORNIA HIDDLE 05.INSORNIA HIDDLE 07.NORK AND ACTIVITIES 08.REFEMENTATION 09.ASTYATION 10.ANKIETY PSYCHAIC 11.ANKIETY SORATIC 12.SOMATIC GASTROLIMESTINAL
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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 RAMILTON DEPRESSION RATING SCALE

PHARMACIA CNS RED

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

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PHARMACIA CMS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

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PHARMACIA CNS R&D
EBOXETINE - PROTOCOL 20124/016
Listing No.: 12.0

REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 HAMILTON DEPRESSION RATING SCALE

Mamilton depression rating scale

Centre Patient Treatment

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PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

Listing No.: 12.0 HAMILTON DEPRESSION RATING SCALE

Centre Patient Treatment

Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56

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BOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

BAMILTON DEPRESSION RATING SCALE

Centre Patient Treatment

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 BAMILION DEPRESSION RATING SCALE

49 Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day Screen Day Hamilton depression rating scale 13. SOMATIC GENERAL
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08.RETARION
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11.ANIETY SORATIC
12.SOBATIC GENERAL
14.GENTAL SYMPTOMS
15.HYDCERONDRIASIS
16.LOSS OF RELORY Female Female Male Sex Fluoxetine Centre Patient Treatment 4 48 729

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HAMILION DEPRESSION RATING SCALE

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

Listing No.: 12.0 EAMILTON DEPRESSION RATING SCALE 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56

Screen Day

Hamilton depression rating scale

Centre Patient Treatment

01.DEPRESSED MOOD
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08.RETARDATION
09.AGITATION
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14.GENITAL SYRPTONS
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16.LOSS OF WEIGHT
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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

HAMILION DEPRESSION RATING SCALE

Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Mamilton depression rating scale

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HAMILTON DEPRESSION RATING SCALE

Centr	e Patient	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	y 21 Day 28	Day 35 De	ay 42 Day	49 Day	98
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42 Day 49 Day Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day HANILION DEPRESSION RATING SCALE Hamilton depression rating scale 09.AGITATION
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11.ANXIETY PSYCHIC
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PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

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PHARMACIA CNS RED

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PHARMACIA CNS R&D

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Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 HAMILTON DEPRESSION RATING SCALE Hamilton depression rating scale Sex Centre Patient Treatment

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PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0	HAMILTON DEPRESSION RATING SCALE	Centro Patient Treatment Sex Hamilton depression rating scale	324 Reboxotime Female 13.SOMATIC GEMERAL 14.GEMITAL SYMPTHAS 15.HWPOCHORIASIS 16.LOSS OF MEIGHT 17.INSIGHT 17.INSIGHT 19.DEPERSONALIZATION 20.PARANOID 21.OBSESSIONAL/COMPULSIVE 22.Total Score	325 Reboxetime Female 01.DEPRESSED MOOD  02.GUILT  04.INSONNIA ALDDE  05.INSONNIA MIDDLE  05.INSONNIA MIDDLE  06.INSONNIA MIDDLE  07.NOR AND ACTIVITIES  08.RETARDATION  09.AGITATION  10.ANIZETY PSYCHIC  11.ANIZETY SOURIC  12.SOURIC GARRALL  13.SOURIC GARRALL  14.GENIAL STRITON  15.REVEROUNDLASIS  16.LOSS OF RECHT  17.INSIGHT  19.INERAL VARIATION  21.ORSESSEIGHBALICATION  21.ORSESSEIGHBALICATION  21.ORSESSEIGHBALICATION  22.ORANIAL SOURINIAL  22.TOTAL SCOTE	326 Reboxotine Female 01.DEPRESSED HOOD 02.GUII 03.SUICIDE 04.SUIXIDE 04.INSONNIA REALY 05.INSONNIA LAFE 07.NORK AND ACTIVITIES 07.NORK AND ACTIVITIES 09.AETARDATION 19.AETARDATION 11.ANNIETY SOWHIC 12.SOMATIC GENRAL 14.GENIEL SYMPOSSINAL 14.GENIEL SYMPOSSINAL 15.HPDGSONDRIASIS 15.HPDGSONDRIASIS
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PHARMACIA CNS R&D

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HAMILTON DEPRESSION RATING SCALE

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BOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

PHARMACIA CNS R&D

Listing No.: 12.0	HAMILION DEPRESSION RATING SCALE
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HAMILTON DEPRESSION RATING SCALE

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PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0	HAMILTON DEPRESSION RATING SCALE	Hamilton depression rating scale	10.AWXIETY PEYCHIC 11.AWXIETY SUBAIC 12.SOMATIC GARROINESTINAL 13.SOMATIC GARRAIL 14.GENIZAL SYMPTOMS 15.HYPOCHONDALASIS 15.HYPOCHONDALASIS 15.HYPOCHONDALASIS 17.INSIGHT 17.INSIGHT 18.DIURNAL VARIATION 19.IMPRESSICNALIZATION 20.PARANOID 21.ORSESSICNALIZALION 22.TOTAI SCORE	01. DEPRESSED MOOD 02.GUILT 03.SUTCIDE 04.INSONNIA BARIX 05.INSONNIA AIDDLE 05.INSONNIA LATE 05.INSONNIA LATE 07. HORK AND ACTIVITIES 07. HORK AND ACTIVITIES 09. ACTIVITIES 09. ACTIVITIES 10. ANXIETY PSYCHIC 11. ANXIETY PSYCHIC 12. SUBATIC GENERAL 13. SONATIC GENERAL 14. GENITAL SYMPONS 15. HYPOCHONDALASIS 16.LOSS OF WEIGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPRESSIONALIZATION 20. PARANOID 21. OBSESSIONALIZATION 22. TOTAL SCOPE	01.DEPRESSED MODD 02.GUILT 03.SUICIDE 04.INSOMIA EARLY 06.INSOMIA LATE 07.MORK AND ACTIVITIES 07.MORK AND ACTIVITIES 10.ANXIETY PSYCHIC 11.ANXIETY SOMATIC 12.SOMATIC GASTRODATESTIVAL
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			Centre Patient Treatment	Reboxetine	Fluoxetine	Roboxetine
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HAMILTON DEPRESSION RATING SCALE

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Patient Treatment Sex Hamilton depression rating scale	394 Reboxetine Male 13.SOMATIC GENERAL 14.GENITAL SYRPTONS 15.HYPOCHONDRIASIS 16.LOSS OF NEIGHT 17.INSIGN 19.DEPENSOMALIZATION 20.PARANOID 21.OBSESSIONAL/COMPULSIVE 22.Total score	395 Reboxetine Male 01.DEPRESED MOD0 02.GUIT 03.SUITCIDE 04.INSOHMIA MIDDLE 06.INSOHMIA MIDDLE 06.INSOHMIA MIDDLE 07.WORK AND ACTIVITIES 09.AGITATION 09.AGITATION 11.ANTETY SOMATIC 11.ANTETY SOMATIC 12.SOMATIC GENERAL 13.SOMATIC GENERAL 14.GENIAL SYMPONS 15.INSOGN 16.LOSS OF WEIGHT 17.INSIGN 19.INSIGN 19.INSIGN 19.INSIGN 19.INSIGN 19.INSIGN 19.INSIGN 19.INSIGN 19.INSIGN 19.INSIGN 19.INSIGN 19.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.INSIGN 10.	996 Fluoxetine Female 01.DEPRESSED MODD 02.GUII 03.SUICIDE 04.INSONHIA HIDDLE 06.INSONHIA HIDDLE 06.INSONHIA HIDDLE 07.WORX AND ACTIVILES 07.WORX AND ACTIVILES 09.ACITATION 10.ANXIETY SOXATIC 11.ANXIETY SOXATIC 12.SOMATIC GENERAL 14.GENIAL SYMICHOMS 15.LOSS OF WEIGHT
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Here Patient Treatment Sex Hamilton depression  396 Fluometine Female 17.1NSIGHT  49.DEPERSONALIZATION  20.DEPERSONALIZATION  21.DEPERSONALIZATION  22.DEPERSONALIZATION  23.DEFERSONALIZATION  24.DEPERSONALIZATION  25.DEPERSONALIZATION  26.INSONALA ALTE  76.INSONALA ALTE  76.INSONALA ALTE  76.INSONALA ALTE  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT  77.INSIGHT	NS PRD	COL 20124/016 : 12.0	RATING SCALE	0 Day 7	288	# N N T N T N N N N N N	,000-000000000000000000000000000000000	w-vowwww-woooo
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				REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0	COL 20124/016 : 12.0		,				,	
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Centr	e Patient	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day 1	4 Day 2	:1 Day	28 Day 35 Da	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56	26
13	385	Fluoxetine	Female	21. OBSESSIONAL/COMPULSIVE 22. Total score	0 25	0 25	23 1	0.8	0 2	0.6	000	0 43
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PHARMACIA CNS RED	REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0	HAMILTON DEPRESSION RATING SCALE

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Sex	Male	Fenale	Male
ent	Reboxetine	Fluoxetine	Reboxetine
Centre Patient Treats	<b>9</b> 750	389	390
Centre	<b>£</b>		

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HANILTON DEPRESSION RATING SCALE

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			HAMILTON DEPRESSION RATING SCALE	N RATING SCALE					
Centre Patis	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day (	0 Day 7	Day 14 Da	7 21 Day 28	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56	9 Day 56
392	Rebexotine	Fomale	09. AGITATION 10. ANXIETY PSYCHIC 11. ANXIETY SOMATIC 12. SOMATIC GENERAL 13. SOMATIC GENERAL 14. GENTIAL SYMPTONS 15. LOSS OF HEIGHT 17. INSIGHT 19. DEPERSOMALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. TOTAL SCORE	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	2	£244440004004			
5 752	Reboxetine	Male	01. DEPRESSED MODD 02. GUILT 03. SUITUDE 04. LYSONHIA EARLY 05. INSONHIA LATDLE 06. INSONHIA LATDLE 07. HORK AND ACTIVITIES 08. RETARRATION 09. ACTIVITIES 10. ANTIETY POYCHIC 11. ANXIETY POYCHIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GASTROINTESTINAL 14. CRAITAL SYMPTONS 15. HYPOCHOMPLASIS 16. LOSS OF WEIGHT 17. INSIGHT 17. INSIGHT 18. DIPPRESSONALIZATION 19. DEPERSSONALIZATION 20. PARANDIA LIZATION 21. OSSESSIONAL/COMPULEIVE 22. TOTAL SCORE	8,	\$2000000000000000000000000000000000000	%			
502	Fluoxetino	Female	01. DEPRESSED HOOD 02. GUILT 03. SULCIDE 04. INSONIA EARLY 05. INSONIA LATE 07. NORK AND ACTIVITIES 08. REFARANTON 09. AGITATION 10. ANYLETY PSYCHIC 11. ANXLETY SOMATIC 12. SOMATIC GASTROLIVELY	W L W O W W O C W W L	#F#00000F000	**********	~~~~~~~~~~~	o-00-0-0,	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

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			REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0	OCOL 20124/016					
,			HAMILTON DEPRESSION RATING SCALE	W RATING SCALE					
Centre Pal	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day 0 Day		Day 21 Day 2	28 Day 35 Day	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day	56
13 562	2 Fluoxotine	Femalo	13.SOMATIC GENERAL 14.GENTIAL SYNFTONS 15.HYPOCHONDELASIS 16.LOSS GF NEIGHT 17.HUSIGHT 18.DIURNAL VARIATION 19.DEPERSONALIZATION 20.PARANOID 21.OBSESSIONAL/COMPULSIVE 22.10tal score	7 3 0 0 0 0 0 7 7 7 8 7 8 7 8 7 8 7 8 7 8 7	7700000009	40000000	88000000 <b>0</b>	7-000-0002	4000000000
<b>%</b> 753	3 Rebaxotine	Female	01.DEPRESSED NOOD 02.GUTTOR 03.SUICIDE 04.INSONTA EARLY 05.INSONTA LAID 06.INSONTA LAID 06.INSONTA LAID 06.AUTEN PARTAIN 09.AGITATION 10.ANTELY PRESIDE 11.SONATIC GARROITETES 12.SONATIC GENERAL 13.SONATIC GENERAL 14.GENITAL SYMPTOMS 15.HPOCHINDBLISSI 16.LOSS OF MEIGHT 17.INSTGHT 18.DIURNAL VARATION 19.DEPRESONALIZATION 20.PARANOID ASSESSIONAL/COMPULSIVE 21.OSSESSIONAL/COMPULSIVE 22.TOTAL SCOPE	25 0 0 0 1 0 1 0 2 2 2 2 2 2 2 2 2 2 2 2 2	00-0-01-01-000000000000000000000000000				
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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

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MEBOXELINE - PROTOCOL 20124/016 Listing No.: 12.0 RAMILTON DEPRESSION RATING SCALE

e Patien	Centre Fatient Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Day 2	7 Day 14 Day 21 Day 28 Day	35 Day 42 Day 49	) Day 56	
204	Fluoxetine	Fenale	17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANGID 21. OBSESSIONAL/COMPULSIVE 22. TOTAL SCORE	0 - 0 0 4	0 - 0 0 0 4	20007	000004	0000t#	0 - 0 0 0 %	000005	,
<b>754</b>	Reboxetine	Fenale	01.DEPRESSED MOOD 02.GUILT 03.SUICTOE 04.TNSONNIA RARLY 05.TNSONNIA LATE 06.TNSONNIA LATE 07.NORK AND ACTIVITIES 08.RETARADATION 09.AGITARIUN 10.ANXIETY ENYCHIC 11.ANXIETY ENYCHIC 11.ANXIETY ENYCHIC 13.SOMATIC GAREAL 14.GENITAL SYMPOMS 15.TNSIGHT 16.LDIURNAL VARIATION 19.DEPRESSONALIZATION 20.PARANOID 21.OBSESSIONAL/COMPULSIVE 22.TOTAL SCORE	m n n o o n n n m n n n n m m n o m o m	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	000000000000000000000000000000000000000	NULLL-0000000000000000000000000000000000	0	***************************************	#F0#0000#F0000000000000000000000000000	
20 6	Fluoxetine	Malo	01.DEPRESSED HOOD 02.GUILT 03.SUICEDE 04.INSORNIA EARLY 05.INSORNIA LATE 05.INSORNIA LATE 07.WORK AND ACTIVITIES 09.RETARIUN 09.AGITATIUN 09.AGITATIUN 10.AGNIETY PSYCHIC 11.SOMATIC GRIEBAL 12.SOMATIC GRIEBAL 14.GENITAL SYMPTOMS 15.ETPCOMOMDATSIS 16.LOSS OF REIGHT 17.INSTGHT 18.INURNAE VARIATION 19.DEPERSORALIZATION	N = = = = = N = N = N = N N N O O = = O	00-0000-00-00-0	Nooroororrooroooo			000000000000000000000000000000000000000	000000000000000000000000000000000000000	

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 BAMILTON DEPRESSION RATING SCALE

Centre	Patient	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Day 21	Day 28 Day 39	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day	ay 56
£ £	506	Fluoxetine	Kale	21.08SESSICMAL/COMPULSIVE 22.Total score	1 25	72	0.60	0 %	c v	0-	00
	755	Fluoxetine	Female	01. DEPRESSED MOOD 02. GUILT 03. SUICIDE 04. INSONIAL RARLY 06. INSONIAL ALIDE 07. MORE AND ACTIVITIESS 08. DETABORIAN ALIDE 07. MORE AND ACTIVITIESS 09. ACTIVITIESS 09. ACTIVITIES SOCIETY 10. ANXIETY SOURTIC 11. ANXIETY SOURTIC 12. SOURTIC GENERAL 14. AGMITTLE SYRPTOMS 15. INFOCHONDELASIS 16. LOSS OF WEIGHT 17. INSIGHT 17. INSIGHT 19. INSERSONALIZATION 20. PARANOLD 21. OBSESSIONAL/COMPULSIVE 22. TOTAL SCOURCE	w ar a a o a a a o o o o o w	8 9 1 1 1 1 0 0 0 0 1 1 1 1 0 0 0 0 1 1 1 1 0 8	W 0 4 4 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6		%0000000000000000000000000000		<b>~000,000,000,000</b>
	ଷ . ପ୍ରମ	Reboxetino	Foma 1 o	01.DEPRESSED MOOD 02.GULT 04.INSONITA EARLY 05.INSONITA HIDDLE 05.INSONITA HIDDLE 05.INSONITA HIDDLE 06.INSONITA LATE 07.NORK AND ACTIVITIES 06.RETARDATION 09.ACTIVITIES 10.ANTELY PSYGRIC 11.ANXIETY PSYGRIC 12.SONATIC GENERAL 14.GENTIAL SYRPTON 15.SUPACHONDELSEN 16.LOSS OF METERY 17.INSTGHT 18.DIURMAL VARIATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 19.DEPRESON	0 7 7 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	, 02-00000000000000000000000000000000000	W	4-44444	~000~0~~~~~0~~~00000000000000000000000	•••••••••••••••	W

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 PHARMACIA CNS RED

HAMILION DEPRESSION RATING SCALE

Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day Mamilton depression rating scale 01. DEPRESSED MOOD
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03. 5011CIDE
04. INSOMNIA EARLY
05. INSOMNIA HIDDLE
06. INSOMNIA MIDDLE
06. INSOMNIA MIDDLE
07. MORE AND ACTIVITIES
08. RETARDATION
09. AGITATION
10. ANXERY PSYCHIC
11. ANXERY PSYCHIC
11. ANXERY SURATIC
13. SOMATIC CASTROINTESTINAL
13. SOMATIC CASTROINTESTINAL
14. GENTAL SYMPTONS
15. BYPCOHONDALASIS
16. LOSS OF WEIGHT
17. INSIGHT
18. DIURACH VARIATION
19. DEPRESONALIZATION
19. DEPRESONALIZATION
22. OF PARMOID
22. COPPLIANTON
22. TORLI SOCVE 01. DEPRESSED MODD
02. SULTIDE
03. SULTIDE
04. INSOMNIA EARLY
05. INSOMNIA ALIDOLE
06. INSOMNIA ALIDOLE
07. INSOMNIA ALIDOLE
07. INSOMNIA ALIDOLE
07. MOSK AND ACTIVITIES
07. MOSK AND ACTIVITIES
07. MOSK AND ACTIVITIES
08. RETARDATION
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11. ANDIETY SOMNIC
12. SOMATIC GASTROINTESTIN
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13. SOMATIC GASTROINTESTIN
14. GENITAL SYMPTOMS
15. SOMATIC GASTROINTESTIN
16. LOSS OF MEIGHT
17. INSIGHT
17. INSIGHT
17. INSIGHT
18. DIVERAR YARATION
20. PARANOZI
21. OBSESSIONALICATION
22. TOTAL SCOPE 01.DEPRESSED HOOD 02.GULT 03.SUICIDE 04.INSOHNIA EARLY Female Female Sex Reboxetine Fluoxetine Centre Patient Treatment 521 397 398 756

PHARMACIA CNS RED

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Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 HAMILTON DEPRESSION RATING SCALE Hamilton depression rating scale Sex

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	05. INSORNIA HIDDLE 06. INSORNIA HIDDLE 07. HORA AND ACTIVITIES 08. RELABATION 09. ACTIVITIES 09. ACTIVITIES 10. AKTERY SOWHET 11. ANYERY SOWHET 12. SOMATIC GENERAL 13. SOMATIC GENERAL 14. GENERAL 14. GENERAL 15. SOMATIC GENERAL 16. LOSS OF WEIGHT 17. INSIGN 17. INSIGN 19. DEPERSONALIZATION 19. DEPERSONALIZATION 20. PARANOID 21. OSSESSIONAL/COMPULSIVE 22. TOTAL SCORE	01. DEPRESSED MOOD 02. GUILDE 03. SUICIDE 06. INSOMINA HIDDLE 06. INSOMINA HIDDLE 06. INSOMINA HIDDLE 06. AGITATION 10. ANKIETY RESCRITC 11. SOMATIC MASTROINTESTINAL 13. SOMATIC GASTROINTESTINAL 14. GENTRAL SYMPTOMS 15. SUMATIC GASTROINTESTINAL 14. GENTRAL SYMPTOMS 15. SUMATIC GASTROINTESTINAL 14. GENTRAL SYMPTOMS 15. NEFOCHONDELESTINAL 16. DIUDRAL VERLATION 19. DEPRESOMALIZATION 21. DOSSESSIONAL/COMPULSIVE 21. OPSESSIONAL/COMPULSIVE 22. Total score	91.DEPRESSED MODD 02.GUILT 03.SUICIDE 04.INSOMUTA EARLY 05.THROMATA MITDALE
1	Penale	Female	Kale
	Roboxetine	Roboxetine	Fluoxetine
	9 <b>8</b>	6. 6.	400

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HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Centre Patient Treatment	Sex	Namilton depression rating scale	Screen Day 0 D	Day 7 Day	y 14 Day	2	Day 28 Bay 35 Day 42 Day 49	) Day 56
<b>4</b>	004	Flauxatine	male 1	09. AGITATION 10. ARXIETY PSYCHIC 11. ARXIETY SOMATIC 12. SOMATIC GENERAL 13. SOMATIC GENERAL 14. GENERAL 14. GENERAL 15. STORTICAL SYPTONS 15. HYPOCHOMPLASIS 16. LOSS OF WEIGHT 17. INSIGHT 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. TOTAL SCORE	25 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	-007	0770000000077	070700000000000000000000000000000000000	0770000007	077000000074
758	# P C C	Fluoxetine	Female	01. DEPRESSED NOOD 02. GUILT 03. SUICIDE 04. INSDMIAL EARLY 05. INSDMIAL EARLY 05. INSDMIAL AIDLE 07. NORK AND ACTIVITIES 07. NORK AND ACTIVITIES 07. NORK AND ACTIVITIES 08. RETARABATION 09. ACTIVATION 09. ACTIVATION 10. ANATICTY SCHOOL 11. SOMATIC GASTEOLINEE 11. SOMATIC GASTEOLINEE 13. SOMATIC GASTEOLINEE 14. GENITAL SYMPTONS 15. MIPOCHNOMELASI 16. LORS OF WEIGHT 17. INSIGHT 17. INSIGHT 18. DUBMIAL VARIATION 19. DEPRESSOMALIZATION 19. DEPRESSOMALIZATION 20. PARANGID 21. OBSESSIOMAL/COMPULEIVE 22. TOTAL SCHOOL	W - L - M - L - W - W - W - L - W - C - C - C - C - C - C - C - C - C	0100000010110000010004	n	00000077007700700000		0,0000000000000000000000000000000000000
	4 0 2 2	Reboxetine	Female	01.DEPRESSED HOOD 02.GUILT 03.GUILT 05.SUICIDE 06.INSORNIA EARLY 05.INSORNIA LATE 07.NOK AND ACTIVITIES 08.RETARADATION 10.ARKETY PSEVEIC 11.ANXEETY PSEVEIC	8 0 0 0 0 8 0	************	N F O F O F O O N N	4-0	-00000	00070070070

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 HAMILION DEPRESSION RATING SCALE

PHARMACIA CNS R&D

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7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day Screen Day 0 Day Hamilton depression rating scale 01. DEPRESSED MO00
02. CUIT.
03. SUICIDE
04. INSONIA EARLY
05. INSONIA MIDDLE
06. INSONIA MIDDLE
06. INSONIA AIDDLE
09. MOTATATON
09. AOTATATON
09. AOTATATON
11. ANYENTY PSYCHIC
11. ANYENTY SORATIC
6ASTROINTESTINAL
12. SOMATIC GASTROINTESTINAL
14. GENITAL SYRPTON
15. ANYEOTONOMALASIS
16. LOSS OF WEIGHT
17. INSIGHT
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14.GENTAL SYMPTONS
15.HYPOCHONDELASIS
16.LOSS OF MELGHT
17.INSIGHT
18.DTURMAL VARIATION
19.DEPERSOMALIZATION
21.OBSESSIGNAL/COMPULSIVE
22.Total score 01. DEPRESSED MODD
02. GUILT
03. SUICIDE
04. INSOMIA EARLY
05. INSOMIA LATE
07. NORY AND ACTIVITIES
09. ACTIVITION
10. ANXIETY PSYCHIC
11. SOMATIC GASTROINTESTID
13. SOMATIC GASTROINTESTID
13. SOMATIC GENERAL Female Fenale Rebaxetine Centre Patient Treatment 402 759

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PHARNACIA CNS R&D KETINE - PROTOCOL 20124/016 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centr	Centre Patient Treat	Treatment	Sex	Hamilton depression rating scale	Screen Day	O Day	7 Day 1	14 Day 21 Day	Day 28 Day	28 Day 35 Day 42 Day 49	9 Day 56
<del>2</del>	404	Fluoxetine	Fenale	17. INSIGHT 18. DIORAGL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. TOTAL SCORE	25 25 25 25 25 25 25 25 25 25 25 25 25 2	0 1 2 2 2 2 2 5 5	22 23 7	0 1 0 0 1 7	000077	000075	0 0 0 0 0 0
	405	Fluoretine	Fenale		W 0 L 0 L 0 0 0 0 0	<b>60-0-000</b>	~~000~~		000700007	000070000	00000-00-
	760			11.ANATIC SATECTIVAL 12.SOMATIC GASTROITE 13.SOMATIC GENERAL 14.GENTLE SYMPONIS 15.LOSS PREGHT 16.LOSS PREGHT 17. INSIGN PREGHT 19. DEPERSONALIZATION 20. PARANOID 21. GRSESSIONAL/COMPULSIVE 22. TOTAL SCORE	- 44 0 0 0 0 0 - 1 - 0 - 1 1 1 1 1 1 1 1 1 1	- 44000000-10	-0-2000-0-2		~ 0 ~ 0 0 0 0 0 ~ W		
	909	Fluoxetine	Female	01.DEPRESED MOD 02.GULT 03.SULTDE 04.INSORILA MIDLE 05.INSORILA MIDLE 07.WORK AND ACTIVITIES 07.WORK AND ACTIVITIES 07.MORK AND ACTIVITIES 07.MORK AND ACTIVITIES 07.MORK AND ACTIVITIES 10.ANTICTY PSYCHIC 11.ANYICTY PSYCHIC 11.ANYICTY PSYCHIC 12.SOBATIC GASTROLIVESTIMAL 13.SOBATIC GASTROLIVESTIMAL 14.GENITAL SYMPTOMS 15.HVPOCHONDRIASIS 15.INSULT 17.INSULT 17.INSULT 18.DIURMAL VARIATION 19.DEPESSORMALTZAFINAL	w	8777778888887788878787878787878	N-0-10000000000000000000000000000000000	01-0000W000W0=00W0=000W00000000000000000			

PHARMACIA CNS RGD	REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0
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Contro Patient Treatment	발	Sex	HANILTON DEPRESSION RATING SCALE Hamilton depression reting scale Screen Day	RATING SCALE	į		46 Per	2	AC STATE	7 Par 46 Par 24 Par 28 Par 45 Par 60 Par 60 Par 56	3 1 1
Fluoxeti	92	Fenale	21.OBSESSIONAL/COMPULSIVE 22.Iotal score	30	F 8		3.2	3.2		Cr 600 71 600	
Reboxetine	ine	Hale	01.DEPRESSED MOD 02.GULLT 03.SULCIDE 04.INSORMIA EARLY 05.INSORMIA LIDDLE 06.INSORMIA LATE 07.WORK AND ACTIVITIES 09.AGTAALION	w - + 0 0 - w 0 0	m == 0 0 = m 0 =	w 01 + 01 + 01 w + 0	# 00 PP P 0 00 M P 0	8 07 T T N T 8 T C	w w L L L L M L C	m n + o n + m n e	
			10.ANXIETY PSYCHIC 11.ANXIETY SONATIC 12.SOMATIC GENERAL 13.SOMATIC GENERAL 14.GENTLAL SYMPTONS 15.HYPOCHONDELASIS 15.HYPOCHONDELASIS 16.LOSS OF WEIGHT 17.INSTOHT 18.DIURNAL VARIATION 20.PARANOID 21.OBSESSIONAL/COMPULSIVE 22.Total score	, , , , , , , , , , , , , , , , , , ,	84+000++2000	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	, , , , , , , , , , , , ,	000000000 <del>-</del> 40000	0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	, , , , , , , , , , , , , , , , , , ,	
Reboxeti	ine	Fenale	01.DEPRESSED MODD 02.GUILT 03.SUICIDE 04.INSONHIA EARLY 05.INSONHIA EARLY 05.INSONHIA MIDDLE 06.INSONHIA MIDDLE 07.NORK AND ACTIVITIES 08.RETARDATION 09.AGITATION 11.ANKIETY PSYCHIC 11.ANKIETY PSYCHIC 13.SUMATIC ARSTROTUTESTERALY	<b>4000000000000000000000000000000000000</b>		444-044	0 ~ 0 ~ 0 0 0 0 0 0 ° 0	N==00=N00N==		-+00+000+00	00000000000
			19. SOMATIC GENERAL 19. GENERAL 19. GENTLAL SYRPONS 15. LOSS OF REIGHT 17. INSIGHT 19. DEPESSOMALIZATION 20. PARANOID 21. ORDESSISSIONAL/COMPULSIVE 22. TOTAL SCORE	- 00 7 0 0 7 0 0 7 %	- 00 - 00 - 00 - 4	- 11 11 10 10 10 10 10 10 10 10 10 10 10	, , , , , , ,			-9-090090-1	0-000000-

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 HANILTON DEPRESSION RATING SCALE

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0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Screen Day Hamilton depression rating scale 01. DEPRESSED MOOD
02. GUILT
03. SULCIDE
04. INSONITA EARLY
05. INSONITA EARLY
05. INSONITA LATE
06. INSONITA LATE
06. INSONITA LATE
06. AGITATION
10. ANITETY PSYCHIC
11. ANYLETY PSYCHIC
11. ANYLETY PSYCHIC
12. SONATIC GASTROINTESTINAL
13. SONATIC GASTROINTESTINAL
14. GENTLAL SYMPTONS
15. REPOCHONDELASIS
16. LOSS OF MEIGHT
17. INSIGHT
18. DIDENERSONALIZATION
19. DEPRESSONALIZATION
19. DEPRESSONALIZATION
21. OBSESSIONAL/COMPULSIVE
22. TOTAL SCUR Female Sex Fluoxetine Centre Patient Treatment 509

01.DEPRESSED MOOD
02.GUILT
03.SUCCIDE
04.INSONNIA EARLY
05.INSONNIA EARLY
05.INSONNIA LATE
06.INSONNIA LATE
07.NOR AND ACTIVITIES
08.RETARDATION
09.AGITATION
10.AMIETY SOMATIC
11.AMIETY SOMATIC
12.SOMATIC GASTROITHESTINAL
13.SOMATIC GASTROITHESTINAL
13.SOMATIC GASTROITHESTINAL
14.CENITAL SYMPTOMS
15.INFOCHONDELASIS
16.LOSS OF MEIGHT
17.INSIGHT
18.DIURMAL VARIATION
19.DEPRESONALIZATION
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19.DEPRESONALIZATION Female Female Fluoxetine 510 511 762

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PHARMACIA CNS R&D

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HANTLYON DEPRESSION RATING SCALE

ale		Bam 05.	Hamilton depression rating scale 05.INSOMNIA MIDDLE	Screen Day 0 Day	ì	y 14 Day	21 Day	28 Day 36	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day	1 49 Day	<b>9</b>
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Centre Patient Treatment

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 PHARMACIA CNS RED

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17. INSIGN
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19. DEPENSOMALIZATION
20. PARAMOID
21. OBSESSIONAL/COMPULSIVE
22. Total score Male Sex Fluoxetine Centre Patient Ireatment

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01. DEPRESSED MODD
02. GUILT
03. SUTCIDE
04. INSOMITA EARLY
05. INSOMITA ALDELE
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Centre Patient Treatment

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		PHARMACIA CNS RED	S R&D										42
		REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0	OL 20124/016 12.0										
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HAMILTON DEPRESSION RATING SCALE

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Sex	Fenale	Fenale	Male
Sex	Fluoxetine Female	Roboxatine Female	Fluoxetine Male
	Fenale	Fenale	Male

PHARMACIA CNS RED

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

HANILTON DEPRESSION RATING SCALE

0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day Screen Day Hamilton depression rating scale

Female Sex Reboxetine Centre Patient Treatment

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01.DEPRESSED MODD
02.GUILT
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Fluoxetine

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04.INSONNIA EARLY
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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

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PHARMACIA CNS R&D

BANILTON DEPRESSION RATING SCALE

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HAMILTON DEPRESSION RATING SCALE REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

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Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day Hamilton depression rating scale Male Centre Patient Treatment

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DEPRESSED NOOD

Female

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PRARMACIA CNS RED

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 HAMILTON DEPRESSION RATING SCALE

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
Listing No.: 12 0

HAMILTON DEPRESSION RATING SCALE

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Centre Patient Treatment	Reboxetine	Fluoxetine	Rebuxetine
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PHARMACIA CNS R&D

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 HAMILTON DEPRESSION RATING SCALE

Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Hamilton depression rating scale

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day HANILTON DEPRESSION RATING SCALE

Hamilton depression rating scale

Sex

Centre Patient Treatment

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03. SULCIDE
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06. RETARDATION Female Female Male Fluoxetine 450 452 775 15

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PHARMACTA CHS PAGE	REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0	HAMILTON DEPRESSION RATING SCALE	Sex Hamilton depression rating scale	Reboxetine Fomale 09.AGITATION 10.AMXIETY PSYCHIC 11.AMXIETY SOMATIC 12.SOMATIC GASTROINTESTINAL 13.SOMATIC GENERAL 14.SENITAL SYRPONS 15.HYPOCHONDRIASIS 16.LOSS OF WEIGHT 17.INSIGHT 19.DIUNALL VARIATION 20.PARANDD 21.OBSESSIONAL/ZATION 22.Total score	Flucxetime Male 01.DEPRESSED MODD 02.GUILT 03.SUICIDE 04.INSOMNIA EARLY 05.INSOMNIA HIDDLE 06.INSOMNIA HIDDLE 06.INSOMNIA MIDLE 07.RORK AND ACITATION 09.ACITATION 09.ACITATION 10.ANXLETY PSYCHIC 11.SUMAIL SYCHIC 11.SUMAIL GENERAL 14.CENTIAL SYRPTOMS 16.LOSS OF WEIGHT 17.INSIGHT 17.INSIGHT 17.INSIGHT 18.DIURNAL VARIATION 19.DEPRESOMALIZATION 20.PARMOLD 21.OBSESSIONALIZATION 21.OBSESSIONALIZATION 22.1CORP.	Flucactime Female 01.DEPRESSED NOOD 02.GUILT 03.SUICIDE 04.INSOMIALA MIDOLE 06.INSOMIALA MIDOLE 06.INSOMIALA MIDOLE 07.NORA AND ACTIVITIES 07.NORA AND ACTIVITIES 07.NORA AND ACTIVITIES 07.NORA AND ACTIVITIES 07.NORA AND ACTIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORATIVITIES 07.NORA
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EBOXETINE - PROTOCOL 20124/016	Listing No.: 12.0

				REBOXETINE - PROFOCOL 20124/016 Listing No.: 12.0	COL 20124/016 : 12.0								
				BAMILTON DEPRESSION RATING SCALE	RATING SCALE								
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PRARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 HAMILTON DEPRESSION RATING SCALE

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/016
Listing No.: 12.0

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779	\$ m m ti	Fluozetina	Fenala	01.DEPRESSED HOOD 02.GUILT 03.SULUIDE 04.INSONIA BARLY 05.INSONIA HIDDLE 06.INSONIA HIDDLE 07.WORK AND ACTIVITIES 08.REPREDATION 10.ANATELY SOMATIC 11.ANATELY SOMATIC 12.SOMATIC GENERAL 14.GENTAL SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15.INSUMITA SYMPONS 15	\$ 10 10 10 10 10 10 10 10 10 10 10 10 10	\$ 0700700000000000000000000000000000000	0-0000-00000	7007700070007000		7007700070007000079	-000000-00-00000-0	v = 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		770070007000700077
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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 PHARMACIA CNS R&D

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HANILTON DEPRESSION RATING SCALE

Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Hamilton depression rating scale Centre Patient Treatment

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PHARMACIA CNS R&D

HAMILTON DEPRESSION RATING SCALE

Hamilton depression rating scale

Centre Patient Treatment

Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56

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<b>5</b>	781	

PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
Listing No.: 12.0

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 BAMILTON DEPRESSION RATING SCALE

Centri	Patient	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Day	1 Day 28	21 Day 28 Day 35 Day 42 Day	Day 49 Day 56	
9	44	Reboxetine	Female	13. SCHATIC GENERAL 14. CENITAL SYRPTONS 15. HYPOCHOMDRIASIS 16. LOSS OF NELGHT 17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARAMOID 21. ORSESSIONAL/COMPULSIVE 22. TOTAL SCORE	- 000000000000000000000000000000000000		- 0 W - 0 0 0 - 0 0	£000001-10E	200017777777777777777777777777777777777	666	,	~~~00~~~~~
100	\$ 783 ·	Fluoxotine	Kale	01.DEPRESSED NOOD 02.GULI 03.SULTOR 04.INSONIA HIDDLE 05.INSONIA HIDDLE 05.INSONIA HIDDLE 07.NORA AND ACTIVITIES 07.NORA AND ACTIVITIES 07.NORA AND ACTIVITIES 07.NORATIC RESEAL 14.GENITELY PRYCHIC 15.SONATIC GREGAL 14.GENITAL SYMPTONS 15.NUFOCHORDEASIS 16.LOSS OF WILLY 17.INSIGHT 18.DURRAL VARIATION 19.DEPRESONALIZATION 19.DEPRESONALIZATION 21.OBSESSIONAL/COMPULSIVE 22.Total score	00000000000000000000000000000000000000	000-00-0-0-0-0-0-0-0-0-0-0-0-0-0	W O O T T O W T W T T T T T T T T T T T		710000000000000000000000000000000000000			
	444	Reboxetine	Fomalo	01.DEPRESSED MODD 02.GULLT 03.GULCIDE 04.INSORINA EARLY 05.INSORINA LATE 07.WORK AND ACTIVITIES 08.RETARDATION 09.AGTIVITIES 09.AGTIVITIES 10.AKXIETY SORGHIC 11.AKXIETY SORGHIC 11.SORGHIC GASTROINTESTIVAL 14.GENTRAL SYRGHIC 14.GENTRAL SYRGHIC 14.GENTRAL SYRGHIC 15.SORGHIC GASTROINTESTIVAL 14.GENTRAL SYRGHIC 15.HPOCHONDS 15.HPOCHONDSTASTS	000 <b>0-</b> 0-0-0	07000-07-00-00-00-00-00-00-00-00-00-	<i>и</i>	<i>и</i>	-000+00+0++++000			0000000077700

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PHARMACIA CNS RED

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HANTLION DEPRESSION RATING SCALE

Centre	Patient	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day 1	14 Day 21 Day	Day 28 Day	28 Day 35 Day 42 Day 49 Day	9 Day 56
<b>3</b> 5	***	Reboxetine	Female	17. INSIGHT 18. DUDRAL VARIATION 19. DEFESSORALIZATION 20. PARANGID 21. ORSESSIONAL/COMPULSIVE 22. Total Score	971-01-9	007079	021010	021010	0 0	000004	000004
	§ 784	Reboxetine	Hale.	01. DEPRESSED HOOD 02.GUILT 04.INSONIA EARLY 04.INSONIA EARLY 05.INSONIA LAIE 05.INSONIA LAIE 07.NORK AND ACTIVITIES 08.REFARBATION 09.AGITATION 10.ANKIETY PRYCHIC 11.AKKIETY PRYCHIC 13.SONATIC GARTROLI 14.GANTAL SYMPTON 15.RYDOCHOUDALASIS 16.LOSS OF WEIGHT 17.INSIGHT 18.DUDWAL VARIATION 19.DEPESSONALIZATION	0-000000	0-000000	N0077000077770077	00001100001100000		-0000000000000	
	944	Fluoxetine	Femalo	20. PRAMOID 21.0BSESSIONAL/COMPULSIVE 22. Total score 01.DEPRESSED MODD 02.GUILDE 03.GUILDE 04.INSOWILA MIDDLE 05.INSOWILA ALIDDLE 06.INSOWILA ALIDDLE 06.AUTATION 09.AGITATION 09.AGITATION 10.ANXIETY PRYCHIC 11.SOMAIT GREERAL 13.SOMAIT GREERAL 14.SCHARL STREPHYDES 15.WFPOCHONDRIASIS 16.LOSS OF WEIGHT 17.INSIGHT 18.DURANL WARLINGN 19.DURANL WARLINGN 19.DURANL WARLINGN 19.DURANL WARLINGN 19.DURANL WARLINGN 19.DURANL WARLINGN 19.DURANL WARLINGN						00-6 -000000000	00-6

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 HANTLION DEPRESSION RATING SCALE

PHARMACIA CNS RED

Centre	Patient	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Day	7 Day 14 Day 21 Day	28 Day 35 Day 42 Day 49 Day	, 42 Day 49 D	ay 56
99	446	Fluoxetine	Female	21.OBSESSIONAL/COMPULSIVE 22.Total score	24.	<b>-</b> £	23.0	o &	- 2	0.6	0 50	0 83
	44,	Fluoxetine	Ma 16	01.DEPRESSED MODD 02.0111.T 03.SUTCIDE 04.INSONITA EARLY 05.INSONITA LATE 06.INSONITA LATE 06.INSONITA LATE 06.RETARDATION 10.ANYIETY PSYCHIC 11.ANXIETY SONATIC	Noroermeere	00-0m	00000	4000ttWttt			-00000	
785	WOF			12.50MATUT GASTGUMTESTIMAL 13.50MATUT GASTGUMTESTIMAL 14.GENITAL SYMPTOMS 15.MYPOGNONDEASIS 16.LOSS OF WEIGHT 17.INSIGHT 18.DIOTRAL VARIATION 20.PARANOID 21.0BSESSIONAL/COMPULSIVE 22.Total score		7 0 0 7 7 7 7 7 7 7 7 7 7 7 7 7 7	-0-40-400- <b>6</b>	-00-00-6	00000000000	000000000000000000000000000000000000000		000-00-00-0
	448	Reboxetine	Fomale	01.DEPRESSED MOOD 02.GUILLE 03.SUTCIDE 04.INSONITA EARLY 05.INSONITA LATE 06.INSONITA LATE 06.INSONITA LATE 17.INSTETY PSYCHIC 10.ANTETY PSYCHIC 11.SONATIC GASTONITESTRAL 12.SONATIC GASTONITESTRAL 13.SONATIC GASTONITESTRAL 14.GETITAL SYMPTONS 15.HPOCHONDRIAS 16.LOSS OF MEIGHT 17.INSTEH 19.DIURNAL WARTATON 19.DEPRESONALIZATION 20.PARANID 21.OSESSIONAL/COMPULSIVE 22.Total scope	 ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	0 - 0 0 - 10 - 10 - 10 - 10 - 1	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			1-00-1		F0070077000000000000000000000000000000

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NS Red	- PROTOCOL 20124/016	RATING SCALI	Screen Day	4 2 7 2 7 7 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9 9 9 9	4	0 0 <del>-</del> 0
PHABMACIA CNS RED	REBOXETINE - PROTOCOL 20. Listing No.: 12.0	HAMILION DEPRESSION RATING SCALE	Mamilton depression rating scale	01.DEPRESSED MOOD 02.GUILT 08.SUICED 04.INSOMNIA MIDDLE 06.INSOMNIA MIDDLE 06.INSOMNIA MIDDLE 07.MOR AND ACTIVITIES 08.BETARDATION 09.AGITATION 10.ANXELY PSYCHIC 11.ANXELY PSYCHIC 11.ANXELY PSYCHIC 13.SOMATIC GENERAL 14.GENITAL SYMPTOMS 15.MYDGONDALTASIS 16.LOSS OF MITGHT 19.DEPERSONALIZATION 19.DEPERSONALIZATION 20.PRARMOID 21.GBSESSIONALIZATION 20.TARANOID	01.DEPRESSED MODD 02.UTLT 03.SUICIDE 04.INSONIA MIDDE 06.INSONIA MIDDE 06.INSONIA MIDDE 06.INSONIA MIDDE 07.WORK AND ACTIVITIES 07.WORK AND ACTIVITIES 08.EETARDATION 09.AGITATION 10.AMXIETY PSYCHIC 11.AMXIETY SONATIC 12.SONATIC GASTROINESTINAL 14.GENTRAL SYMPTOMS 14.GENTRAL SYMPTOMS 15.LOSS OF WEIGHT 17.INSONATIC GENERAL 14.GENTRAL SYMPTOMS 16.LOSS OF WEIGHT 17.INSONATIC GENERAL 19.DEPRESONALIZATION 20.PARANOID 21.GOSSESIONAL/COMPULSIVE 22.TOTAL SCORE	01.DEPRESSED MODD 02.GULT 03.SUCCIDE 04.INSOMIA EARLY
			Sex	Fonale	Halo	Female
			Centre Patient Treatment	Fluoxetine	Reboxetine	Fluoxetine
			Patient	786	456	457
			Centre	9		

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PHARMACIA CNS RED

HANILTON DEPRESSION RATING SCALE

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7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56		
42 Da	007700007000000000000000000000000000000	200000000000000000000000000000000000000
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Screen Day		4
Hamilton depression rating scale	06.INSONMIA HIDDLE 06.INSONMIA LATE 07.NORA AND ACTIVITIES 08.RETARBATION 09.AGITATION 10.ANXIETY SOMATIC 11.SONATIC GASTROUTESTINAL 12.SONATIC GASTROUTESTINAL 13.SONATIC GASTROUTESTINAL 14.GENTIAL SYMPONE 15.HYPOGHONDENAS 15.HYPOGHONDENAS 16.LOSS OF MEIGHT 17.INSTGHT 18.DIURNAL VARIATION 19.DEPERSONALIZATION 20.PARANOID 21.ORESSIONALCOMPULSIVE 22.TOREL SCORE	01.DEPRESSED MOOD 02.GULT. 03.SULT. 04.INSONIA EARLY 05.INSONATA KIDDLE 06.INSONATA AIDLE 07.NORK AND ACTIVITIES 08.RETARDATION 10.AKITETY SONATIC 11.AKITETY SONATIC 11.AKITETY SONATIC 12.SONATIC GENERAL 14.CRITAL SYMPONS 15.HPOCRONDRIASIS 15.HPOCRONDRIASIS 15.INSTER 16.LOSS OF HEIGHT 17.INSTER 19.DEPRESSONALIZATION 20.PARANOID STRONDLISTUR 21.ORSESSIONALIZATION 20.PARANOID STRONDLISTUR 21.ORSESSIONALIZATION 21.ORSESSIONALIZATION 22.TOTAL SCORE
Sex Hamilton depression rating scale	Female 05.INSONTIA HIDDLE 66.INSONTIA LAIE 09.INSC AND ACTIVITIES 09.ETARDATION 09.ACITATION 10.ANTEST PSCHIC 11.SUMATIC PSCHIC 12.SUMATIC CREMENL 13.SUMATIC CREMENL 14.GENITAL STHPTON 17.INSTGHI 17.INSTGHI 18.DIURNAL VARIATION 19.DEPERSONALIZATION 20.PARANOLD 21.OSSESSIONAL/COMPULSIVE 22.Total score	Penale 01.DEPRESSED MODD 02.GUILT 03.SUICIDE 04.INSORNIA EARLY 05.INSORNIA EARLY 05.INSORNIA LATE 06.INSORNIA LATE 07.KORK AND ACTIVITIES 08.KETARDATION 07.ACTIVITON 10.AATIKTY SENCHIC 11.ACKIKTY SENCHIC 11.ACKIKTY SENCHIC 12.SOMATIC GENERAL 14.CENTITAL SUMPTONS 15.INSTORNIA SENCHIC 17.INSTORNIA SENCHIC 17.INSTORNIA SENCHICON 20.PARANOUD 21.OBSESSIONAL/COMPULSIVE 22.TORIA SCORE
Sex	Female	Peralis
Sex	Fluoretine Femalo	Fluoxetino Female
	Female	Peralis

Hale

PHARMACIA CNS R&D REBOXETINE - PROYOCOL 20124/016 Listing No.: 12.0

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0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day Screen Day HANILTON DEPRESSION RATING SCALE Manilton depression rating scale Sex Centre Patient Treatment

ATIC GASTROINTESTINAL ATIC GENERAL ITAL SYMPTOMS 01.DEPRESSED MOOD 02.GULT Female Male Kale Reboxetine 459 460 25 788

N KED	OL 20124/016	12.0
PHAKRACIA CRS KRU	REBOXETINE - PROTOCOL 20124/016	Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patien	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Day 2	1 Day 2	8 Day 35	21 Day 28 Day 35 Day 42 Day 49 Day	ny 49 Day	S6
<b>8</b>	80 80	Fluoxetine	Female	13.SOHATIC GENERAL 14.GENITAL SYRPTOHS 15.HYDCHONDRIASIS 16.LOSS OF NEIGHT 17.LNSIGHT 19.DEPERSOHALIZATION 20.FRANOID 21.OBSESSIONAL/COMPULSIVE 22.Total score	7000777003	**************************************	50-1-1-000	00-0005	00-0004	200777004	0010111004	9010011007	00+00++00
789	92	Reboxetine	Female	01. DEPRESSED HOOD 02. CUTLOR 03. SUICIDE 04. INSOMITA EARLY 105. INSOMITA HIDDLE 05. INSOMITA LATE 06. INSOMITA LATE 10. ANDIETY PSYCHIC 11. ANDIETY PSYCHIC 11. SODATIC GASTRINTESTINAL 13. SODATIC GASTRINTESTINAL 13. SODATIC GASTRINTESTINAL 14. GENITAL SYMPTOMS 15. HEPCHONORIALSIS 16. LOSS OF METCHT 17. INSUSISION 19. DEPERSONALIZATION 20. PARANDID 21. OBSESSIONAL/COMPULSIVE 22. TOTAL SCORE	x x 0 0 1 7 1 0 7 1 7 1 7 1 7 1 7 1 7 1 8 1 8 1 8 1 8 1	800-1001-0	2001100110110011008	20072272727772772277	<u>-</u>	13 000 11 12 11 12 11 11 11 11 11 11 11 11 11	0008004-0000-0000	000077007770000000000000000000000000000	00007700707000000000000
	23	Reboxetine	Female	01.DEPRESSED MODD 02.GULT 03.SULTO 04.INSONIA EARLY 05.INSONIA LAIDLE 06.INSONIA LAIDLE 07.WORK AND ACTIVITIES 08.REFERDATION 09.ASTRATION 10.ANXIETY SOMATIC 11.SOMATIC GENERAL 14.GENITAL SYRPIDMS 15.HYBOCHONDRAISS 16.HYBOCHONDRAISS 16.HYBOCHONDRAISS 16.HYBOCHONDRAISS 16.HYBOCHONDRAISS	w 01 - 10 - 10 - 10 - 10 - 10 - 10 - 10	m	00-00000				00007707070007	000000000000000000000000000000000000000	0000700000000

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PHARMACIA CNS R&D HEBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

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				HAMILTON DEPRESSION RATING SCALE	RATING SCALE										
Centre	Patient	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day	14 Da	7 Day 14 Day 21 Day 28	, 28 Day	Day 35 Day	42 Day	, 49 Day	y 56	
81	23	Reboxetine	Fema1e	17.INSIGHT 18.DIRAL VARIATION 19.DIREASONALIZATION 20.PARANOID 21.OSSESSIONAL/COMPULSIVE 22.Total score	200004	00-004	0 0 0 0 23	20 00 70 00	0 1 17	00 = 00 4	001004	00-00	000004	00000	
·	<b>8</b> 790	Fluoxetine	Female	01.DEPRESSED MODD 02.GUILT 03.SUICIDE 04.INSOMILA HIDDLE 06.INSOMILA HIDDLE 06.INSOMILA HIDDLE 07.NOR AND ACTIVITIES 08.RETARDATION 09.AGITATION 10.ANLETY PSYCUIC 11.ANLETY SYGATIC 11.SUBATIC GASTROINHESTINAL 13.SUBATIC GASTROINHESTINAL 14.GENITAL SYMPTOMS 15.REPORTONDRIASIE 16.LOSS OF WELGHT 18.JUBNAL VARIATION 19.DEPERSONALIZATION 21.ORSESSIONALIZATION 22.O.PRANOUD 22.ORSESSIONALIZATION 22.TOTAL SCOVE	w 00w	230011002111111111111111111111111111111	20011008111111111	% 00	8 00-1-100 11-1-1-100 18	230011002111111111111111111111111111111					
	<b>50</b>	Reboxetine	Mal o	01. DEPRESSED HOOD 02. GUILT 03. SUICIDE 04. INSORNIA EARLY 05. INSORNIA LATE 07. WORK AND ACTIVITIES 06. ENTRORNIA LATE 07. WORK AND ACTIVITIES 09. ASTIRATION 09. ASTIRATION 10. ANXIETY SOMATIC 12. SOBATIC GENERAL 14. STRITAL SYRPTOMS 15. SUPPRICE GENERAL 14. GENERAL 14. GENERAL 14. STRITAL SYRPTOMS 15. INSUGRI 17. INSUGRI 17. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19. INSUGRI 19.	# C O C C C C C C C C C C C C C C C C C	M - 0 W W W W W 0 0 0 -	m-0maaaa	0 - 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		-00	0+0000+00+00+00+000	-00777007700707000	000000000000000000000000000000000000000	000007007700700000	

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HAMILTON DEPRESSION RATING SCALE

Centre Patient Treatment	tient Tr	eatment	Sex	Hamilton depression rating scale	Screen Day	0 Day		y 14 Day	7 21 Da	/ 28 Day	38	3y 42 D	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day	ıy 56	
18 29		Reboxetine	Ма1е	21. OBSESSIONAL/COMPULSIVE 22. Total score	23	23	23	270	0.5	0 22	0.0	-2	0 2	9 55	
8		Fluoxetine	Fonale	01.DEPRESSED MODD 02.GULLT 02.GULLT 04.SUICIDE 06.INSOMINA MIDDLE 07.INSOMINA AND 05.INSOMINA AND 07.NORK AND ACTIVITIES 07.NORK AND ACTIVITIES 09.AGTRATION 10.ANXIETY PSYCHIC 11.ANXIETY SOMICE 12.SOMATIC GASTROLITIESSTIMA.	<b>887-888</b>	<i>mm</i>	88778887778	00000			~~0~~~~~				
791				13.SOMATIC GENERAL 14.CENTIAL SYMPOHS 15.HYPOCHONDSLASIS 17.INSIGNAT 17.INSIGNAT 19.DEPERSONALIZATION 20.PARANOID 21.OBSESSIGNAL/COMPULSIVE 22.TOTAL SCORE			**************************************	7 0 0 7 7 0 0 7 7 7							
٤		Reboxetino	Fonale	01. DEPRESSED MOOD 02. GUILT 03. SUICED 04. INSOMINA EARLY 05. INSOMINA HIDDLE 06. INSOMINA HIDDLE 07. HORK AND ACTIVITIES 09. RETRADATION 09. AGITALTON 11. ANXIETY PSYCHIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GREENAL 14. GENIAL SYRPTOMS 16. HYPOCHONDELASIS 16. LOSS OF WEIGHT	w w - 0 0 0 0 0 0 0	***************************************	000-0000-00-00	000000000000000000000000000000000000000	000000000000000000000000000000000000000	000707707770000	000000000000000000000000000000000000000				
				18. DIUBNAL WARLATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE	~~00;		00	00	00		~~00	00	-0		

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

HANTLTON DEPRESSION RATING SCALE

Hamilton depression rating scale

Sex

Centre Patient Treatment

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0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56 Screen Day REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0 HANTLION DEPRESSION RATING SCALE PHARMACIA CNS R&D Hamilton depression rating scale Female Sex Centre Patient Treatment 5

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HAMILTON DEPRESSION RATING SCALE

Centre	Centre Patient Treat	t Troatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day 14	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day	lay 28 Da	у 35 Лау	42 Day		56
82	22	Fluoxetine	Femalo	09. AGITATION 10. ANYLETY PSYCHIC 11. ANYLETY SOMATIC 12. SOMATIC GASTROINTESTINAL 13. SOMATIC GASTROINTESTINAL 14. GENTRAL SYMPTONS 15. HYPOCHOMORIASIS 16. LOSS OF WEIGHT 17. INSTANT 19. DEPENSIONAL STATION 19. DEPENSIONAL COMPULSIVE 20. PARANOID 21. OBSESSIONAL COMPULSIVE 22. Total score	2		26 23 23 23 24 24 24 24 24 24 24 24 24 24 24 24 24	0	0411110011002	0111110011002	01-1-1000-1006	077777007700 <u>7</u>	00000770007000
794	<b>8</b>	Fluoxetine	Fenale	01.DEPRESSED MOOD 02.GULT 03.SUICIDE 04.INSOMIA MIDBLE 05.INSOMIA MIDBLE 06.INSOMIA MIDBLE 07.MOOK AND ACTIVITIES 08.RETARDATON 10.ANYIETY SYCHIC 11.ANYIETY SYCHIC 11.ANYIETY SYCHIC 11.ANYIETY SYCHIC 12.SOMATIC GASTROATPESTINAL 13.SOMATIC GASTROATPESTINAL 14.GENTRAL SYMTONIESTINAL 15.LOBATIC GENERAL 15.LOBATIC GASTROATPESTINAL 16.LOSS OF WEIGHT 17.INSTANT ANTATION 19.DEPERSOMALIZATION 20.PARANOID 21.OBERSSIONALIZATION 21.OBERSSIONALIZATION 22.TOTAL SCOFE	8 00 00 00 00 00 00 00 00 00 00 00 00 00	27-0	2,0011000111100018	80000000000000000000000000000000000000	010000101100000000000000000000000000000	4-0-40-+41-00000000000000000000000000000	0-0-00-00-00-00-00-00-00-00-00-00-00-00	u-o-uouoooooooo	7-00-00-7-7-00-00-00-00-00-00-00-00-00-0
	ទ័	Fluoxetine	Male	01. DEPRESSED MOD 02. GULT 03. SULCIDE 04. INSOMIA MIDLE 05. INSOMIA MIDLE 05. INSOMIA MIDLE 07. MORE AND ACTIVITIES 08. RETARDATION 10. ANXIETY SYCHIC	# W.F. F. W. W. W. F. F. W. F.	800080-	8211322122					<b>-</b> 0000-000-0	

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HAMILTON DEPRESSION RATING SCALE

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Jentre Pat	ient	Centre Patient Treatment	Бел	Hamilton depression rating scale	Screen Bay	0 Day	7 Day	14 Day 21 Day		28 Day 35	Day 42 Day	49	Day 56	
54 54		Fluometine	Кале	13.SOMATIC GENERAL 14.GENITAL SYNFTONS 15.HYPOCHONDRIASIS 16.LOSS GF WELGIT 17.LNSIGHT 19.DEPRESIMALIZATION 20.PARMOTD 21.OBSESSIONAL/COMPULSIVE 22.Total score	. 26	7770077009	7	00004	***************************************		00000##00%	0000077009	000077000	
ក 795	_	Fluoxetine	Female	01. DEPRESSED NOOD 02. GUILT 03. SUITLIDE 04. LYRSOMELA EARLY 05. LYRSOMELA EARLY 06. LYRSOMELA LATE 07. NORE AND ACTIVITIES 08. RETARBATION 09. AGITATION 09. AGITATION 10. ANYERY PSYCHIC 11. ANYERY PSYCHIC 11. ANYERY PSYCHIC 11. SOMATIC GASTREALLY 11. SOMATIC GASTREALLY 12. SOMATIC GASTREALLY 13. SOMATIC GASTREALLY 14. GENTTAL SYMPTOMS 15. INFOCHOMBLASIS 16. LOSS OF MEIGHT 17. INSTERN WEIGHT 19. DIUDNAL VARIATION 19. DEPRESSIONAL/COMPULSIVE 22. TOTAL SCOPE	www.co-anannnnan-acc-&	www.cocococococococococococococococococo			**************************************	00010000000000000000000000000000000000	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	000 000 000 000 000 000 00	80977008008000004	
. 22	-	Fluoxetime	Female	01. DEPRESSED MODD 02. GUILT 03. SUTLIT 06. SINCOMIA EARLY 05. INSOMIA MIDDLE 06. INSOMIA ALDLE 07. WORK AND CATVITIES 08. RETARANTOM 10. ANXIETY PEYCHIC 11. MAXIETY PEYCHIC 12. SOMATIC GASTPOINTESTIMAL 13. SOMATIC GASTPOINTESTIMAL 14. GENTIAL SYMEPONS 15. HYPOCHOMERASIS	\$ 11 10 0 7 11 11 11 11 11 11 11 11 11 11 11 11 1	4000-000000000000000000000000000000000	\$ 0 W F F C W C C W F F F C C C C	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	w-4000ww-ww0000					

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.0

HAMILTON DEPRESSION RATING SCALE

Centr	e Patien	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	0 Day	7 Day 14	Day	21 Day 28 Day	y 35 Day	35 Day 42 Day 49 Day 56	9 Day 5	vo.
20	23	Fluoxetine	Female	17. INSIGHT 18. DIURNAL VARIATION 19. DEPERSONALIZATION 20. PARANOID 21. OBSESSIONAL/COMPULSIVE 22. TOTAL SCORE	0.0026	000007	2 0 0 0 0 0 0 0 0 3 3 3 3 3 3 3 3 3	22 1 0 0 0 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	3,000			ı
2	796	Fluoxetine	Femalo	01. DEPRESSED HOOD 02. GUILT 04. INSONIA EARLY 04. INSONIA HIDDIE 05. INSONIA HIDDIE 05. INSONIA HIDDIE 07. HORE AND ACTIVITIES 08. RETARANIO MACTIVITIES 09. ACITATION 10. ANNIETY PREVENTE 11. SONATIC GENERAL 14. GENTAL SYNPONIS 15. RYPOGNONIA, SINFONIS 15. RYPOGNONIA, SINFONIS 16. LOSS OF WEIGHT 17. INSURING 19. DEPRENONALIZATION 19. DEPERSONALIZATION 21. OBSESSIONALIZATION 21. OBSESSIONALIZATION 22. TOREL	, 000000000000000000000000000000000000	% % % % % % % % % % % % % % % % % % %	20000000000000000000000000000000000000	71000000000000000000000000000000000000	w	N-0-000-00-00-00-00		770707000000000000000000000000000000000	770000000000000000000000000000000000000
22	5.	Fluoxetine	Kale	01. DEPRESSED MOD 02. GULT 03. SULCIDE 04. INSORIA ERRLY 05. INSORIA HIDDLE 04. INSORIA HIDDLE 07. WORK AND ACTIVITIES 09. ACTIVITIES 09. ACTIVITIES 10. SURVICELY SORATIC 11. ANXIETY SORATIC 12. SORATIC GASTROLIVESTINAL 14. GENTRAL SYMPTONS 14. GENTRAL SYMPTONS 15. MYPOCHONDELASIS 16. LOSS OF HEIGHT 17. INSURAL VARIATION 19. DURRAL VARIATION 19. DURRAL VARIATION 19. DURRAL VARIATION 19. DURRAL VARIATION 19. DURRAL VARIATION 19. DURRAL VARIATION	<b>петатаптаппеттаαοго</b> ∙	8778778888877780000	W0W-W0WW00-0	#FFWFF##WOF0					

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PHARMACIA CNS R&D

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				BAMILTON DEPRESSION RATING SCALE	RATING SCAL	ш			
Centre	Patient	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Da	y 0 Day	7 Day	14 Day	Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56
22	113	Fluoxetine	Male	21. DESESSIONAL/COMPULSIVE 22. Total scoro	30	28	0 27	30	
	115	Reboxetine	Kale	01. DEPRESSED MOOD 02.GUILD 03.SUICEDE	<del>-</del> 01 -	n n ←	0 0 <del>c</del>	01 00	<i>11 10 0</i>
				04.INSONNIA ERLY 05.INSONNIA HIDDLE 06.INSONNIA HIDDLE 07.HORK AND ACTIVITIES	m	m	en		ଟେଷଟଡ଼ି
				US.KITAMONIUN 09.ACITATION 10.ANXIETY PSYCHIC 11.ANXIETY SOMATIC 12.SOMATIC GASTROINTESTINAL 13.SOMATIC GRENEATH	- 4444-	0000	0 0 - 0 0	000000	D (1) (1) (1) (2) (2) (3) (3) (4) (4) (4) (4) (4) (4) (4) (4) (4) (4
	797			15. HYPOCHONDRIASIS 16. LOSS OF REIGHT 17. INSIGHT 18. DIURNAL VARIATION 20. PREPRESONALIZATION 21. DESESSIONAL COMPULSIVE 22. Total score	27	. 6 - 1 0 - 0 - 7	25 1 0 4 0 1 1 3	. 6 2	29 - 1 - 1 - 2 - 3

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PHARMACIA CNS RED

PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 Listing No:: 12.1

Listing No.: 12.1
HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Hamilton depression rating scale

Centre Patient Treatment

Screen Day 1 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56

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0.67 0.00 0.00 1.75 4.58		1.33 0.00 0.33 2.00 1.00 0.67 5.33	000000000000000000000000000000000000000		
0.33 0.00 0.50 0.00 1.75 4.25	0.17 0.00 0.00 0.50 1.50	1.00 0.00 0.33 1.00 1.00 4.00	00.00		
0.67 0.00 0.00 0.00 1.67 4.83	0.50 0.00 0.00 0.00 1.33	0.83 0.00 1.00 1.00 4.50	0000000		2.00 0.00 0.00 0.00
0.33 0.00 0.50 0.00 1.50 4.00	0.17 0.00 0.17 0.50 0.67	1.67 1.00 0.33 1.00 1.00 5.67	00.00 1.00 1.00 1.00		0.17 0.00 0.17 0.00
0.83 0.50 0.50 2.00 5.33	0.33 0.00 0.00 0.75 1.67 2.75	1.00 2.00 0.67 2.00 1.00 7.00	0.50 0.00 2.00 0.75 0.33		0.50 2.00 0.50 1.00
0.83 0.00 0.03 0.00 2.50 5.83	0.33 0.00 1.00 1.33 3.58	2.00 2.00 2.00 1.50 6.83	0.50 2.00 2.00 1.00 6.00		0.67 2.00 0.50 1.00
0.50 0.00 0.00 0.50 3.00	0.56 1.00 1.00 1.55 1.67 5.92	1.33 1.00 0.00 2.00 1.75 6.75	0.50 2.00 0.17 2.00 1.25 5.92		0.83 1.00 1.00 1.00
9.83 2.90 1.90 3.25 10.98	0.50 0.00 0.83 2.00 2.50 2.00 7.83	2.33 0.00 0.33 2.75 7.42	1.00 0.33 2.00 1.25 4.92	1.67 3.00 1.17 0.00 1.75 0.67 8.25	1.50 1.00 1.50 1.50
0.83 2.00 1.00 1.00 3.25 70.00	0.50 0.83 2.00 2.50 7.83	2.33 0.00 0.33 2.00 2.75 7.42	1.17 0.00 1.00 2.00 2.00 0.00	1.67 3.00 1.50 0.00 1.75 7.92	1.50
1. ANXIETY/SONATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.AMXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTUBBANCE 4.DIUNNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1- 1.ANKIETY/SDMATIZATION 2.KEIGHT 3.COGNITIVE DISTUBBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.AMXIETY/SOMATIZATION 2.NEIGHT 3.COGNITYBE DISTUBBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SIEEP DISTURBANCE 7.Total score	1. ANXIETY/SOMATIZATION 2. WEIGHT 3. COGNITIVE DISTURBANCE 4. DIURNAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	1. ANXIETY/SORATIZATION 2. MEIGHT 3. COGNITIVE DISTURBANCE 4. DIURNAL VARIATION 5. RETARDATION
Female	Male	Female	Kale	Hale	<b>K</b> ale
Fluoxotine	Reboxetino	Reboxetins	Fluoxetine	Rebaxetine	Fluoxetine
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PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1 HANILION DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Centre Patient Treatment	Sex	Bamilton depression rating scale	Screen Day		0 Day 7 D	ay 14 De	1y 21 De	y 28 D	ay 35 De	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day	y 49 De	y 56
N	88	Fluoxetine	Male	6.SLEEP DISTURBANCE 7.Total score	1.67	1.67	1.00	5.83	4.67	1.25	3.00			
	39	Fluoxetino	Male	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIURBAL VARATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.67 2.00 1.33 1.00 1.75 8.42	1.67 2.00 1.33 1.00 1.75 8.42								
	0,	Reboxetine	Malo	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIUGHAL VAREATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	0.83 1.00 1.00 1.25 2.00 6.08	0.83 0.00 1.00 1.00 1.25 2.00 6.08	1.33 0.00 1.00 1.50 1.67 6.33	0.83 0.00 0.33 2.00 1.00 5.17	1.00 0.17 1.00 1.00 3.83					
800	2	Fluoxetine	Male	1.ANXIETY/SOHATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIVURAL VAREATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.83 0.00 0.17 0.00 3.00 7.00	1.83 0.00 0.17 0.00 3.00 7.00	1.00 0.17 1.00 3.00 1.00	1,00 0.00 0.00 0.00 2,25 5,25	0.50 0.00 0.00 0.00 2.25 1.33 4.08	0.33 0.00 0.00 0.00 1.00 3.58	0.33 0.00 1.00 1.25 2.58	0.50 0.17 0.00 1.50 2.17	0.33 0.00 0.00 0.75 0.33	0.33 0.00 0.17 1.00 0.50 2.00
	45	Reboxetine	Fenale	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIUMARI VARATION 5.RETAXDATION 6.SLEEP DISTURBANCE 7.Total score	1.50 2.00 1.17 1.00 2.75 9.42	1.50 2.00 1.17 1.00 2.75 1.00 9.42	1.17 0.00 1.33 1.00 1.75 1.67	0.50 0.00 0.33 2.00 1.67 5.25	0.67 0.00 0.17 1.00 1.67 4.50	0.67 0.00 0.50 1.90 1.67 4.58	0.67 0.00 1.00 1.33 3.50	0.50 0.00 0.17 1.00 1.00 3.67	0.33 0.00 1.00 1.00 1.00 3.08	0.50 0.00 1.00 1.00 0.67 3.25
	43	Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITYVE DISTURBANCE 4.DIURNAL VARIATION 5.RETANDATION 6.SLEEP DISTURBANCE 7.Total store	1.67 1.17 1.10 1.00 1.33 7.92	1.67 0.00 1.17 1.00 2.75 1.33	1.50 0.00 0.00 2.00 1.67	1.90 0.67 0.00 1.75 5.08	1.00 1.00 0.83 0.00 1.00 4.83	0.83 0.50 0.50 1.00 1.00 5.00	1.00 0.50 0.00 1.25 1.67 5.42	1.17 1.00 0.83 0.00 1.25 1.00 5.25	0.67 0.00 0.50 1.25 1.00	0.83 0.00 0.50 1.00 1.00 3.00
	#	Fluoxetine	Nale	1.ANXIETY/SOMATIZATION 2.NEIGHT 3.COGNITIVE DISTURBANCE	1.00 0.00 1.33	1.00 0.00 1.33	0.67 0.00 0.83	0.67	9.50 0.00 0.33	0.33	0.33 0.00 0.17	0.17		

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PHARMACIA CHS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 72.1 HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centr	e Patient	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	ay 0 Day	2	Day 14 Da	Day 21 Da	y 28 Da	y 35 De	Day 28 Day 35 Day 42 Day 49 Day	y 49 Da	y 56
N	\$	Fluoxetine	Male	4-DIURNAL VARIATION 5-RETARDATION 6-SLEEP DISTURBANCE 7-Total Scote	2.00 2.50 1.67 8.50	2.00 2.50 1.67 8.50	2.00 1.25 0.33 5.08	2.00 1.25 1.00 5.25	1.00 0.75 0.00 2.58	1.00 0.25 0.33 2.08	0.00	0.00 0.25 0.33 0.92		
	45	Reboxatine	Fenale	1.ARXIETY/SOMATIZATION 2.HEIGHT 3.COGNITYE DISTURBANCE 4.DIDRALL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.83 0.00 1.50 2.20 2.25 0.67	1.83 0.00 1.50 2.25 0.67 8.25	0.67 0.50 1.00 1.00 3.17	0.67 0.50 0.50 1.00 0.75 0.00	0.50 0.00 0.00 1.00 2.47	0.50 0.00 0.00 1.00 2.17	6.33 0.50 0.50 0.50 0.33	0.33 0.00 0.50 0.33 1.83	0.50 0.00 0.50 0.00 0.25 0.00	6.50 0.00 0.50 0.25 0.00
80	¢	Fluoxetine	Female	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITYE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	2.00 2.00 0.50 2.00 1.75 1.33 9.08	7.67 2.00 2.00 2.25 1.33 9.58	1.33 2.00 1.00 1.00 6.33	0.83 0.17 1.60 0.75 0.67 3.42	0.17 0.00 0.00 1.00 0.25 0.67 2.08	0.83 0.00 2.00 0.33 3.42	0.33 0.00 0.00 1.00 0.00 1.67	0.00 0.00 0.00 0.00 1.67	0.33 0.00 0.00 1.00 0.33	6.00 6.00 6.00 1.00 1.17
.L	<b>8</b> <b>5</b>	Reboxetine	Fonale	1.ANXIETY/SOMATIZATION 2.HEIGHT 3.COGNITUE DISTURBANCE 4.DIDENAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.67 2.00 1.00 2.25 1.33 8.25	1.83 2.00 1.00 0.00 2.50 9.00	1.67 0.00 0.33 0.00 2.75 6.08	1.33 0.00 0.00 2.00 1.00	1.33 0.00 0.00 2.25 1.33	1.17 0.00 0.05 0.00 1.75 4.58	1.17 2.00 0.03 0.00 1.75 1.33 6.58	1.00 0.00 0.00 1.75 4.25	1.00 0.00 0.50 0.00 1.33 4.58	1.33 2.00 0.50 0.00 1.75 6.58
	08	Fluoxetine	Male	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COMITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	2.25 2.25 2.20 2.25 2.25 2.25 9.08	1.17 0.00 2.00 2.25 9.08	0.33 0.83 1.00 1.67 6.83	0.33 1.00 0.50 1.00 0.75 5.58	0.17 0.83 1.00 0.50 2.00 4.50	0.17 0.00 0.33 0.00 0.25 2.42	0.17 0.00 0.33 0.25 1.33 2.08	0.00 0.33 0.25 1.00	0.00 0.00 0.33 0.00 1.00	0.00 0.00 0.17 0.00 0.25 0.67
en en	8	Fluoxotine	Female	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITYE DISTURBANCE 4.DIURAL VARRATION 5.RETARBATION 6.SLEEP DISTURBANCE 7.TOTAL SCOTE	1.50 2.00 0.17 2.00 1.75 1.00 8.42	7.50 0.17 2.00 1.75 1.00 8.42	1.17 0.00 0.17 1.00 1.33 5.17	0.67 0.00 0.17 1.00 1.50 4.33	0.83 0.00 0.17 1.50 5.50	0.67 0.00 0.50 0.50 0.75 4.92	0,50 0,00 2,00 0,50 3,67	0.33 0.00 2.00 0.75 3.75	0.33 0.00 2.00 1.25 4.25	9.50 9.50 1.90 3.90

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PHARMACIA CNS R&D	EBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1
Z	REBOXETIN

HANTLION DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Centre	Patient	Contro Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	ay 0 Day	- 1	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day	y 21 Da	y 28 Da	y 35 Da	y 42 Da	y 49 De	ıy 56
σ	99	Fluoxetine	Fenale	2.WEIGHT S.COGNITYE DISTURBANCE 4.DUTWARL VARIATION 5.ERTARDATION 6.SIEEP DISTURBANCE 7.Total score	0.00 1.17 1.00 2.25 0.67 6.25	0.00 0.83 1.00 2.25 1.00	2.00 1.00 1.75 1.75 8.08	0.00 0.83 1.00 1.75 2.00 6.75	0.00 0.50 1.00 1.67 5.58				0	
	69	Reboxetins	Female	1.ANXIETY/SOMATIZATION 2.REIGHT 9.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	2.33 0.00 1.17 2.00 2.25 2.00 9.75	2.33 0.00 1.33 2.00 2.50 10.17	7.67 1.00 2.00 2.25 1.67 9.58	1.00 0.00 1.00 2.00 5.83	0.83 0.00 1.00 0.50 0.67 3.33	0.00				
802	80 90	Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.NEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	2.00 2.00 1.00 2.00 2.75 1.67	2.00 2.00 1.00 2.00 2.75 1.67	2.00 2.00 1.17 0.00 2.00 1.67 8.83	1.33 2.00 2.00 2.00 2.00 8.25	1.00 1.00 1.00 1.25 5.92	0.67 2.00 2.00 1.50 1.67 8.50				
<b>4</b>	26	Reboxetine	Female	1.ANXIETY/SONATIZATION 2.NEIGHT 3.CGCANTITYE DISTURBANCE 4.DIUNNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	7.33 2.00 2.00 1.00 2.00 8.50	1.67 2.00 0.33 1.00 1.00 2.00 8.00	0.83 0.00 0.33 0.00 1.50 4.00	2.33 0.00 0.00 0.00 1.75 6.08	0.33 0.00 0.00 0.75 1.33 2.42	0.33 0.00 0.00 0.00 0.33	0.33 0.00 0.00 0.00 1.33	0.33 0.00 0.00 0.00 1.67	0.33 0.00 0.00 0.00 1.00	0.00 0.00 0.00 0.00 1.67
	886	Fluoxetine	Female	1.ANXIETY/SOMATIZATIOM 2.KEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.ERTARDATION 6.SLEEP DISTURBANCE 7.Total score	1.83 2.00 1.00 0.00 2.50 7.67	1.50 2.00 0.33 0.00 2.75 6.92	1.50 2.00 0.00 1.50 1.33 6.33	0.50 0.00 0.03 0.75 1.67 3.25	0.67 2.00 0.83 0.00 1.50 6.67	0.33 1.33 0.00 0.00 1.75 4.42	0.00 0.00 0.00 0.00 1.17	0.17 0.00 0.00 0.00 0.33	0.17 0.00 0.00 0.00 1.00	0000000
	<b>6</b> 6	Fluoxetine	Female	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIGHARAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.33 1.00 1.50 1.50 1.50 6.50	1.33 1.33 0.00 1.50 1.33 6.50	1.33 1.33 1.33 2.00 1.00 5.67							

PHARMACIA CNS RED	REBONETINE - PROTOCOL 20124/016 Listing No.: 12.1	HAMILION DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56	2.17 1.83 2.06 2.00 0.83 0.83 0.00 0.00 2.25 2.50 2.00 2.00	1.50         1.64         1.83         1.30         1.60         1.00         0.50         1.00         0.50         1.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00 <td< th=""><th>1.33         1.38         0.50         0.00         0.83         0.56         1.33         0.83         0.83         0.83           0.00         2.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         0.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.</th><th>2.17         2.17         1.83         2.00         1.33         0.48         1.00           0.00         0.00         0.00         2.00         0.00         0.00         0.00           0.83         0.83         1.33         0.83         0.83         0.83           0.00         0.00         0.00         0.00         0.00         0.00           2.75         2.75         2.50         2.50         1.50         2.00         2.00           2.00         2.00         1.67         1.67         2.00         2.00         2.00           7.75         7.75         7.67         9.00         4.83         5.17         5.63</th><th>0.83 0.83 1.00 0.50 0.50 0.67 0.50 0.50 0.50 0.00 0.00 0.00 0.00 0.17 0.17 0.30 0.70 0.00 0.00 0.00 0.00 0.00 0.0</th><th>1.33 1.33 0.83 0.50 0.67 0.50 0.56 0.50 0.50 0.33 0.50 0.00 0.00 0.00 1.00 0.00 1.00 0.00 1.00 0.00 0.00 0.00 0.00 0.00 0.00 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 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0.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.00         1.	2.17         2.17         1.83         2.00         1.33         0.48         1.00           0.00         0.00         0.00         2.00         0.00         0.00         0.00           0.83         0.83         1.33         0.83         0.83         0.83           0.00         0.00         0.00         0.00         0.00         0.00           2.75         2.75         2.50         2.50         1.50         2.00         2.00           2.00         2.00         1.67         1.67         2.00         2.00         2.00           7.75         7.75         7.67         9.00         4.83         5.17         5.63	0.83 0.83 1.00 0.50 0.50 0.67 0.50 0.50 0.50 0.00 0.00 0.00 0.00 0.17 0.17 0.30 0.70 0.00 0.00 0.00 0.00 0.00 0.0	1.33 1.33 0.83 0.50 0.67 0.50 0.56 0.50 0.50 0.33 0.50 0.00 0.00 0.00 1.00 0.00 1.00 0.00 1.00 0.00 0.00 0.00 0.00 0.00 0.00 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 0.33 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PHARM	REBOXETINE - Listi	HAMILTON DEPRESSION RATIN	Sex Hamilton depression rating scale	Male 1.ANKIETY/SOMATIZATION 2.NEIGHT 3.COGNITYE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.total score	Female 1.AMXIETY/SOMATIZATION 2.REIGHT 3.COGNITYED DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SIERP DISTURBANCE 7.Total soure	Female 1.ANXIETY/SOMATIZATION 2.KEIGHT 2.KEIGHT 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE: 7.Total score	Femalo 1.AMXIETY/SOMATIZATIOM 2.WEIGHT 2.WEIGHT 4.DUWNAL VARIATIOM 5.RETABDATION 6.SLEEP DISTURBANCE 7.Total score	Female 1.AKXIETY/SUMATIZATION 2.WEIGHT 2.WEIGHT 4.DIUWAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	Male 1.ANXIETY-SOMATIZATION 2.MEIGHT 2.GOGNITYE DISTURBANCE 4.DIDRAL VARIATION 5.RETARDATION
				Reboxetine	Reboxetine	Fluoxetine	Fluoxetine	Reboxetine	Fluoxetine
			Centre Patient Treatment	100	<u></u>	§ 803	103	104	105

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PRARHACIA CNS RED
REBOXETINE - PROTOCOL 20124/016

				HANILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	: FACTOR AN	D TOTAL	SCORE							
Centre	Patient	Centre Patient Treatment	Sex	Mamilton depression rating scale	Screen Day	ny o Day	y 7 Day	ty 14 Day	1y 21 D	21 Day 28 Day	8	Day 42 De	Day 49 Dt	Day 56
4	105	Fluoxetine	Male	6.SLEEP DISTURBANCE 7.Total score	1.67 7.83	1.67	1.67	1.00	1.67	1.33	1.00 5.33	0.67 3.75	3.08	1.33
κ)	129	Reboxetine	Fenale	1.ANXIETY/SCHATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIUGHAR VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.67 2.00 1.00 2.25 2.00 9.75	1,67 1,00 1,00 2,25 9,92	2,50 2,50 1,50 8,00 8,00	1,50 0,50 1,00 1,00 8,00	1.50 0.00 0.33 1.00 2.00 0.33 5.17	1.33 0.00 0.50 1.00 1.67 6.25				
804	130	Fluoxetine	Female	1.ANXIETY/SORATIZATION 2.HEIGHT 3.COGNITY/E DISTUBRANCE 4.DIURHAL VARIATION 5.RETARDALION 6.SLEEP DISTUBRANCE 7.Total score	1.33 1.00 1.00 2.75 6.08	1.50 0.00 1.17 1.00 2.75 0.00	1.00 0.00 0.67 2.00 0.00	0.83 0.00 0.67 2.25 4.42	0.67 0.00 0.00 1.75 0.00	0.67 0.50 0.00 2.00 0.00	0.83 0.00 2.25 3.92	0.67 0.00 0.50 0.00 2.00 3.17	0.67 0.00 0.33 0.00 1.25 0.00	0.50 0.33 0.00 1.00 1.83
	193	Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITYE DISTURBANCE 4.DIURAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1,33 1,00 0.67 0.00 2.00 1.00 6.00	1,33 1,00 0.67 0.00 1,00 6.00	1.00 0.00 0.50 2.00 1.75 1.33 6.58	0.63 0.00 0.33 2.00 1.75 1.00	0.83 0.00 0.17 2.00 1.50 0.67	0.67 0.00 0.67 2.00 2.00 0.33	0.67 0.00 0.50 0.33 4.50	0.67 0.00 0.33 1.00 0.67 4.17	0.50 0.00 0.50 0.50 0.33 2.83	0.50 0.00 0.00 1.75 0.33 3.08
	44	Fluoxotine	Female	1.ANXIETY/SOMATIZATION 2.HEIGHT 3.COGNITYE DISTURBANCE 4.DIDENAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.50 1.00 0.17 2.00 1.75 7.08	1.50 1.00 0.17 2.00 1.75 7.08	1.17 0.00 0.00 1.00 1.00 4.67	1.17 0.00 0.00 1.00 1.75 4.58	0.83 0.00 0.00 0.00 0.00 4.33	0.33 0.00 0.17 2.00 1.00 4.25	0.83 0.00 1.00 2.67	0.50 0.00 0.17 0.00 0.50 1.50	0.67 0.00 0.00 0.00 0.33	0.00 0.00 0.00 0.00 0.00
	195	Fluoxetine	МаЛе	1.ANYIETY/SOMATIZATION 2.HEIGHT 3.COGNITYE DISTURBANCE 4.DIURNAL VARIATION 5.EETANDATION 6.SLEEP DISTURBANCE 7.Total score	0.83 0.00 0.33 1.00 5.92	0.83 0.00 1.00 1.00 1.00	0.83 0.00 0.00 2.50 4.00	0.33 0.00 1.00 1.00 4.58	0.17 0.00 0.00 2.00 2.83	0.83 0.00 1.00 2.50 5.33	0.67 2.00 0.33 0.00 0.33 5.33	0.67 0.00 0.33 0.00 2.25 3.92	0.33 0.00 0.17 0.00 0.50 1.67	0.33 0.00 0.00 0.00 1.00 1.83
	196	Reboxetine	Fonale	1.ANXIETY/SONATIZATION 2.NEIGHT 3.COGNIIYE DISTURBANCE	1.67 0.00 0.67	1.50 0.00 0.67	1.58 1.00 0.67	1.33 1.00 0.83	1.33 0.00 0.67	1.33 0.00 0.67	1.50 0.00 0.33	1.33	1.50 0.00 0.33	

PHARMACIA CNS RRD

				Listing No.: 12.1	12.1									
				HANILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	FACTOR A	ATOT ON	L SCORE							
Centre	Patient	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	ay 0 Day		14 D	ay 21 Di	ıy 28 D≅	ay 35 De	ay 42 De	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56	8
4	196	Reboxetine	Fenale	4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total store	0.00 2.50 1.33 6.17	0.00 2.25 1.67 6.08	0.00 2.00 2.00 7.17	0.00 2.00 2.00 7.17	1.00 2.00 2.00 7.00	1.00 2.00 2.00 7.00	1.00 2.00 1.33 6.17	0.00 2.25 1.00 5.75	0.00 2.50 1.33 5.67	
	197	Fluoxetine	Male	1.ANXIETY/SCHATIZATION 2.HEIGHT 3.OCGNITHE DISTURBANCE 4.DIUBHAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total Score	7 1 2 0 0 0 0 1 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	1.33 0.00 0.83 0.00 2.00 4.83				•				
<b>5</b> 80	321	Fluoxetine	Female	1.ANXIETY/SOMATIZATION 2.HEIGHT 3.OGMITTYE DISTURBANCE 4.DIUGNAL VARLATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.67 0.00 2.50 2.50 8.83	1.67 0.00 0.67 2.00 1.67 8.50	1.67 0.00 0.67 2.00 1.67 8.25	1.50 1.00 1.17 1.00 2.00 7.67	1.33 1.00 1.17 1.00 1.25 1.00 6.75	1.33 1.00 1.00 1.00 1.25 6.58	1.17 1.00 0.50 1.00 0.75 0.33	0.17 0.00 0.17 1.00 0.50 0.33	0.00 0.00 1.00 0.33 1.33	0.33 0.00 1.00 0.75 0.33
5	322	Reboxetine	Fonale	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIUBNAL WARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	2.00 2.00 1.33 0.00 2.75 2.00	2.00 1.50 0.00 2.75 2.00 10.25	1.50 2.00 1.33 0.00 2.50 2.00 9.33	1.50 1.17 1.17 0.00 2.25 1.33 7.25	2.17 0.00 1.50 0.00 2.25 2.00 7.92	1,50 0.00 0.83 0.00 2.00 1.67 6.00	1.50 0.00 1.00 1.00 4.50	1.17 0.00 1.00 0.00 1.25 1.00	1.17 0.00 0.83 0.00 1.00 4.00	4.00 4.00 4.00 4.00 4.00
	323	Fluoxetine	Fonale	1.ANXIETY/SONATIZATION 2.MEIGHT 2.MEIGHT 3.OGGNITYED DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.TOTAL SCORE	7.50 7.17 7.18 2.00 8.17	1.67 1.00 1.17 1.00 2.00 8.83	1.17 1.00 0.67 0.00 0.75 4.25	0.33 0.00 0.33 0.00 0.25 1.58	0.33 0.00 0.00 0.00 0.00 0.33	0.33 0.00 0.00 0.00 0.00 0.33				0.00 0.00 0.00 0.00 0.00 0.33
	324	Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.OCONTIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.83 0.00 1.17 1.00 1.75 2.00 7.75	1.83 0.00 1.17 1.00 1.75 7.75	1.67 1.17 1.00 1.50 1.33 6.67	2.2.2.00 8.2.00 8.1.00	2.33 0.00 1.00 1.00 1.25 1.00 6.58	1.67 0.00 1.33 2.00 1.25 7.25	0.83 0.00 0.67 1.00 1.00 4.25	0.00 0.33 1.00 0.58 0.33	1.33 0.00 1.00 2.00 0.50 5.50	1.00 0.33 1.00 0.75 3.08
	325	Reboxetine	Fenale	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 RED

				Listing No.: 12.1	: 12.1									
				HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	E: FACTOR A	ND TOTA	L SCORE							
Centre	Patient	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen D	Day O Day		ay 14 De	ıy 21 De	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56	ıy 35 Da	1y 42 De	y 49 Da	ıy 56
<b>5</b>	325	Reboxetine	Fenale	2.WEIGHT S.COGNITYE DISTURBANCE 4.DIVHALI VARIATION S.EELARDATION 6.SIEEP DISTURBANCE 7.Total score	0.00 0.83 1.00 2.00 1.67	0.00 1.00 1.00 2.00 2.00 7.67	0.00 0.50 0.00 2.25 1.67 5.92	0.00 0.50 0.00 2.00 1.00	0.00 1.00 1.50 1.33 5.50	0.00 0.50 0.00 1.00 3.25	0.00 0.33 0.00 1.00 1.83	0.00 0.33 0.75 0.33 2.68	0.00 0.17 0.00 0.25 0.33	0.00 0.67 0.00 0.25 0.33
	326	Reboxetine	Fema19	1. ANXIETY/SOMATIZATION 2. KEIGHT 3. COGNITIVE DISTUBBANCE 4. DIURNAL VARIATION 5. RETAXDATION 6. SLEEP DISTURBANCE 7. Total score	1,50 0,00 1,17 1,00 1,50 7,17	1.67 1.33 1.00 1.50 2.00 7.50	1.33 0.00 0.83 1.00 1.33 5.50	0.83 1.00 0.67 2.00 0.75 5.92	0.58 0.33 1.00 1.00 0.00 3.08	0.33 0.00 0.00 0.00 0.00	00.00	00.00	00.00	0.000000
806	327	Fluoxetine	Female	1.ANXIETY/SOMATIZATION 2.NEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARBATION 6.SLEEP DISTURBANCE 7.Total score	1.50 0.00 1.00 1.75 1.05	1.50 1.00 1.00 1.00 6.50	1.00 0.00 1.00 1.25 0.67 4.75	0.50 1.17 1.00 1.25 0.00	0.50 0.50 1.00 0.00 3.00	0.33 0.00 1.00 0.50 2.00				
	32 <b>8</b>	Fluoxetine	Female	1.AKXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURALL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.67 0.00 1.00 2.00 1.75 1.67	1.67 0.00 1.00 2.00 1.75 1.67 8.08	0.83 0.00 0.50 2.00 1.50 0.33 5.17	1.00 0.00 0.83 2.00 1.75 6.58	1.00 1.00 1.00 2.00 0.33 7.33	0.83 0.00 0.33 1.90 2.50	0.67 0.00 1.00 0.50 0.33 3.17	0.17 0.00 0.33 0.00 0.67	0.17 0.00 0.17 0.00 0.33	0.17 0.00 0.00 0.00 0.00 0.33
	329	Reboxetine	Fenale	1. ANXIETY/SOMATIZATION 2. MELGHT 3. COGNITIVE DISTURBANCE 4. DIUGNITIVE DAIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	1.17 1.33 1.33 2.00 2.00 2.00 2.00	1.17 0.00 1.33 2.00 1.75 2.00 2.00 8.25	1.33 0.00 0.83 2.00 2.00 7.67	0.83 0.00 0.83 2.00 1.67 6.08	1.17 0.00 0.83 2.00 1.00 5.50	0.33 0.00 0.00 0.00 3.33	1.17 1.00 0.83 2.00 1.33 7.33	0.17 0.00 1.00 1.00 1.42	0.83 0.50 0.00 0.00 1.33	0.00
	330	Reboxetine	Male	1. ANXIETY/SOMATIZATION 2. MEIGHT 3. COGNITIVE DISTURBANCE 4. DIURNAL VARIATION 5. RETARRATION 6. SLEEP DISTURBANCE 7. Total score	1.00 0.00 1.83 1.25 1.67	1.00 0.00 1.83 1.25 1.67 5.75	1.50 0.00 0.50 1.75 2.00 5.75	1.00 1.00 1.17 1.25 1.00 5.42	1.33 0.00 0.50 0.00 1.50 4.00	1.33 0.00 0.83 0.00 1.50 4.33	1.00 0.00 0.83 0.00 1.50 4.00	1.17 0.00 1.00 0.00 1.25 0.33 3.75	1.17 0.00 1.00 0.00 1.25 0.33 3.75	

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PHARMACIA CNS R&D REBGXETINE - PROTOCOL 20124/016 Listing No.: 12.1 HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

0.33 0.83 0.00 1.50 0.00 0.33 1.00 0.00 1.67 0.67 0.90 1.90 6.25 0.33 2.75 0.00 0.00 1.00 1.00 0.33 1.33 26 49 Day Day 1.00 1.00 2.00 2.00 0.33 0.00 1.00 0.25 0.00 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 0.67 1.00 0.83 1.00 1.25 0.00 0.00 0.00 0.00 0.25 0.00 0.67 1.17 0.00 1.50 0.00 0.00 0.17 1.00 0.75 0.67 2.58 1.17 0.00 0.83 1.00 0.75 0.33 0.10 0.83 1.00 0.67 0.75 1.00 4.25 0.33 0.33 1.00 0.50 0.00 1.00 1.00 1.00 1.25 5.58 0.50 0.00 0.33 1.00 0.75 0.67 0.67 1.00 1.50 1.33 5.50 1.17 0.00 1.17 2.00 1.75 2.00 8.08 1.17 1.00 0.83 1.00 1.75 6.75 0.83 0.00 0.00 2.00 1.50 0.90 2.00 2.00 2.00 6.67 1.17 0.00 2.00 2.00 6.57 6.33 0.83 0.00 1.00 2.00 1.67 6.00 1.67 0.00 0.83 2.00 1.75 2.00 2.00 1.17 1.00 1.00 1.00 1.33 7.75 1.50 0.00 1.17 2.00 2.25 2.00 8.92 1.50 0.00 1.00 1.33 6.58 1.50 0.00 0.83 2.00 1.75 7.42 Day Screen 1.50 0.00 1.00 2.00 2.25 2.00 8.75 1.33 0.00 0.83 2.00 1.75 1.33 1.67 0.00 0.83 2.00 1.75 2.00 8.25 1.50 1.00 1.75 1.67 1.67 Hamilton depression rating scale 1.AWXIETY/SOMATIZATION
2.WEIGHT
3.COGNITIVE DISTURBANCE
4.DIURNAL VARIATION
5.RETARDATION 2. MEIGHT 3. COGNITIVE DISTURBANCE 4. DIUENAL VARIATION 6. SLEEP DISTURBANCE 7. Total score 1. ANXIETY/SOMATIZATION
2. MESSERT
3. COGNITIVE DISTUBBANCE
4. DIURMAI VARIATION
5. REFARBATION
6. SLEEP DISTURBANCE
7. I otal score . WEIGHT C. COGNITIVE DISTURBANCE . DIURNAL VARIATION . RETARDATION . SIEEP DISTURBANCE . Total score 3.COGNIIVE DISTURBANCE
4.DIURNAL VARIATION
5.ELEPADARION
6.SLEEP DISTURBANCE
7.Total score . WEIGHT
.. COCNITIVE DISTURBANCE
.. DIDRAAL VARIATION
.. RETARBATION
.. S.LEEP DISTURBANCE
.. Total score ANXIETY/SOMATIZATION 1.ANXIETY/SOMATIZATION 2.WEIGHT ANXIETY/SOMATIZATION 1.ANXIETY/SOMATIZATION Female Female Female Female Female Female Sex Fluoxetine Fluoxetine Reboxetine Fluoxetine Reboxetine Fluoxetine Centre Patient Treatment 335 393 334 331 332 333 807 2 Ţ

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				PHARMACIA CNS R&D	CNS R&D					;				-	<u>-</u>
				REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1	OCOL 20124/0 .: 12.1	16									
			,	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	LE: FACTOR A	NO TOTA	L SCORE								
Centr	e Patien	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen D	Day 0 Day	7	Day 14 Da	14 Day 21 Day 28	ıy 28 Day	8	Day 42 Day	ıy 49 Day	y 56	
52	393	Fluoxetine	Fenale	6.SLEEP DISTURBANCE 7.Total score	1.33	1.33	1.67 5.50	1,33	1.00	1.00	0.67 3,83	1,33 5,33	1.33	1.00	
	394	Reboxetine	На1е	1.ANXIETY/SDHATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURMAL, VARIATION 5.RETARDATION 6.SIEZP DISTURBANCE 7.Total score	1.00 1.00 1.00 0.00 2.25 1.33	1.00 1.00 1.00 2.25 1.33 6.58	0.83 1.33 1.33 2.25 5.75	0.50 0.00 0.00 1.75 4.58	0.50 0.00 0.00 0.00 1.25 4.08	0.83 1.33 0.00 1.75 5.25	7.00 1.50 0.00 1.33 5.83	1.00 6.00 1.33 6.00 2.25 1.67	0.50 0.00 1.17 0.00 1.50 4.17	0.50 0.00 1.50 2.25 1.33	
8	395	Reboxetine	Kale	1.ANXIETY/SOMATIZATION 2.NEIGHT 3.COGNITIYE DISTURBANCE 4.DUGNARAL VARLATION 6.SLEEP DISTURBANCE 7.Total score	1.50 0.00 0.67 2.00 1.75 6.92	1.50 0.00 0.67 2.00 1.75 1.00 6.92	1.00 0.00 0.83 1.00 1.50 5.33	0.50 0.00 0.33 1.00 1.00 0.67	0.33 0.00 0.00 0.75 0.33	0.67 0.00 0.17 0.00 2.08	0.83 0.00 0.33 0.75 0.33 3.25	0.67 0.00 0.50 1.00 0.67 3.83	0.50 0.00 1.00 0.00 3.17	0.33 0.00 1.00 0.50 0.67 3.00	
08	396	Fluoxetine	Female	1. ARXIETY/SONATIZATION 2. KEIGHT 3. COGNITIVE DISTURBANCE 4. DIVINAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	0.83 0.00 1.50 1.00 2.25 1.33	0.83 0.00 1.50 1.00 2.25 1.33	1.17 0.00 1.33 1.00 2.00 7.17	1.17 1.00 1.33 0.00 2.25 1.67							
	497	Fluoxetine	Fenale	1.ANXIETY/SOMATIZATION 2.KEIGHT 3.COGNITIVE DISTURBANCE 4.DIURAL, VARIATION 5.EETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.33 0.00 2.00 0.00 2.00 1.33	1.33 0.00 2.00 2.00 1.33	1.17 0.00 1.17 2.00 0.33 4.67	1.17 0.00 1.33 0.00 1.00 5.75	1.00 0.00 1.33 0.00 1.33 5.92	0.83 0.00 1.17 0.00 2.25 0.67	0.67 0.00 0.83 0.00 1.00 4.50	1.00 0.00 1.00 0.00 1.75 0.33 4.08	0.83 0.00 1.50 1.00 5.33	0.67 0.00 1.17 0.00 2.00 1.33	
5	385	Fluoxetine	Female	1. ANXIETY/SOMATIZATION 2. MELGHT 3. COGNITIVE DISTUBBANCE 4. DIURMAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	1.33 0.00 1.00 0.00 2.25 5.25	1.33 1.00 1.00 0.00 2.25 0.67 5.25	1.33 1.00 0.67 0.00 0.67 5.67	1.17 0.00 0.50 1.50 3.83	0.83 0.00 0.00 1.00 2.50	0.67 0.00 0.00 1.00 2.00		0.50 0.00 0.17 0.00 1.00 2.33		0.33 0.00 0.17 0.00 0.25 0.33	
	386	Fluoxetine	Male	1. ARXIETY/SOMATIZATION 2. MEIGHT 3. COGNITIVE DISTURBANCE	1.50 2.00 1.17	1.33 2.00 1.17	1.83 2.00 1.67								

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PRARMACIA CNS RED

Centre	Patien1	Centra Patient Treatment	Sex	HAMILION DEFESSION KATING SCALE: FACTOR AND TOTAL SCORE Hamilton depression rating scale Screen Day 0 Day 7 Da	LE: FACTOR AND Screen Day	IND TUTAL S lay 0 Day	L BOOKE ay 7 De	ıy 14 Da	y 21 Da	ly 28 De	JOKE 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day	42 Day 49	49 Day 56
13	386	Fluoxetine	Kale	4.DIUENAL VARIATION 5.RETARBATION 6.SIEEP DISTURBANCE 7.Total Score	1.00 2.25 2.00 2.00	1.00 2.25 2.00 9.75	2.00 2.00 11.50						
	387	Reboxetine	Fenale	1. ANXIETY/SOMATIZATIOM 2. MEIGHT 3. COGNITIVE DISTURBANCE 4. DIVINAL, VARIATIOM 5. RETAKDATIOM 6. SLEEP DISTURBANCE 7. Total score	1.50 2.00 1.00 2.00 2.00 9.50	1.50 1.00 1.00 1.00 2.00 1.67 8.00	1.00 1.00 0.67 2.00 1.25 7.58	1,17 0,00 0,33 1,00 1,33 4,58	1.00 0.00 0.50 6.00 0.75 2.92	0.83 0.00 0.17 0.00 0.00			
809	386	Reboxetine	Male	1.ANXIETY/SOMATIZATION 2.MEISHT 3.COGNITIVE DISTURBANCE 4.DIURAKI VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.00 0.00 0.83 2.00 1.50 7.00	1.00 0.83 2.00 1.50 7.00	1.33 1.33 1.00 1.00 7.42	0.83 0.00 0.00 1.25 1.00 3.75	0.50 0.00 0.33 1.00 3.83	0.63 0.00 0.00 1.25 3.75	0000770	0.67 0.00 0.00 1.00 1.00	0.50 0.00 0.00 0.00 0.75 0.67
	389	Fluoxetine	Female	1.ANXIETY/SOMATIZATION 2.NEIGHT 3.COGNITYWE DISTUBBANCE 4.DIGNAL VARIATION 5.RETAMANION 6.SLEEP DISTURBANCE 7.Total score	1.33 1.67 1.67 2.00 2.00 9.00	1.33 2.00 1.67 2.00 2.00 9.00	1.17 1.00 1.17 0.00 2.00 1.67 7.00			•			
	390	Reboxetine	Male	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTUBBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SIREP DISTURBANCE 7.Total score	0.83 1.00 1.17 0.00 2.25 1.25 6.25	0.83 1.00 1.17 0.00 2.25 1.00 6.25	1.00 1.00 0.83 1.00 1.75 1.33 6.92	0.67 0.33 1.00 1.50 1.00	1.00 0.50 0.50 1.25 7.42	0.50 2.00 1.33 1.00 1.00 6.83	0000	0.67 0.00 0.00 1.25 3.58	0.33 0.00 0.00 0.25 1.25
	1991	Fluoxetine	Female	1.ANXIETY/SOMATIZATION 2.NEIGHTY 3.COGNITYE DISTURBANCE 4.DTURNAL VARIATION 5.RETAEDATION 6.SLEEP DISTURBANCE 7.Total score	1.33 0.67 1.00 2.00 1.67 7.67	1.00 1.00 1.00 2.00 1.00 6.50	0.50 0.00 1.00 1.25 3.75	0.00 0.00 0.47 1.00 2.17	0.17 2.00 0.00 0.50 1.33 4.00	0.17 0.00 0.00 0.50 1.00	0.17 0.00 0.17 0.25 1.00		

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PHARMACIA CWS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1

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		49 Day 56		0.17 0.00 0.33 0.00 0.75 1.92	0.00 2.00 0.00 0.75 0.67		0.50 0.00 0.17 0.00 1.00 2.42	0.17 0.33 0.33 0.25 0.33 0.33
		5 Day 42 Day		0.50 0.00 1.00 1.00 3.17	0.50 0.00 0.33 1.00 1.00 3.58		0.67 1.00 1.00 1.00 4.42	0.33 0.00 0.50 1.00 0.75 2.92
		0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56		0.50 0.00 0.33 1.00 1.00 0.67	0.83 0.00 0.33 1.00 1.75 1.60		0.67 1.00 2.00 0.75 1.00 5.42	1.17 0.00 0.67 0.00 1.25 1.00
		ay 21		0.83 0.33 0.00 1.75 1.33 4.25	1.00 0.00 0.00 1.00 1.00 3.67			0.67 0.00 0.50 0.00 1.25 1.33
		y 14 D	0.00 0.83 1.00 1.75 1.67 6.25	0.50 0.90 0.33 1.00 4.08	0.83 0.00 0.67 1.75 4.25		1.00 0.00 0.50 0.00 0.75 2.92	1.17 0.00 0.50 1.00 1.50 1.00
	SCORE	y 7 Da	0.00 1.00 1.75 2.00 6.42	1.00 0.33 2.00 2.00 7.00	0.83 0.33 1.00 1.25 0.67 5.08	1.00 0.17 1.00 1.50 4.67	0.83 1.00 1.00 1.75 1.00 6.25	1.00 1.00 1.00 5.83
vo	D TOTAL		2.00 1.00 1.00 2.25 7.25	0.83 1.00 1.00 2.25 7.25	1.00 0.00 0.83 1.00 1.75 5.92	1,33 1,00 0,33 1,00 1,33 7,25	7.00 1.00 1.00 1.50 6.17	1.00 1.00 1.00 1.75 7.42
OL 20124/01 12.1	: FACTOR AN	Screen Day	2.00 0.83 0.00 2.25 7.25	0.83 1.00 0.50 1.00 2.25 2.00 7.58	7.00 0.00 0.83 1.08 1.35 5.92	1,33 1,00 1,00 2,25 1,33 7,25	1.00 0.00 1.00 1.50 1.67 6.17	1.00 1.00 1.00 2.00 7.33
REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	Hamilton depression rating scale	2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURAL VAREATION 5.RETARDATION 6.SIEEP DISTURBANCE 7.Total score	1.AKXIETY/SOMATIZATION 2.HEIGHT 3.COMITUTE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.ANXIETY/SDMATIZATION 2.MEIGHT	1.AKXIETY/SOMATIZATION 2.NEIGHT 3.NEIGHT 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.TOtal score	1. AKXIETY/SOHATIZATION 2. MELGHT 3. COGNITYED DISTURBANCE 4. DIURNAL VARLATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	1.ANXIETY/SDMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL YARIATION 5.RETABDIION 6.SLEEP DISTURBANCE 7.Total score
		Sex	Fenale	Male	Female	Formale	Fomale	Fomale
		Treatment	Reboxetine	Reboxetine	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine
		entre Patient Treatment	3 392	501	§ 810	503	504	505

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1 PHARMACIA CNS R&D

HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

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0.67 0.00 0.00 0.75 0.67 2.25 8.888.8 0.33 0.00 0.25 0.33 Day 49 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 0.67 0.50 0.50 0.50 1.00 2.67 0.50 0.00 0.33 0.75 0.17 0.00 0.00 0.00 0.00 0.00 0.50 0.00 0.00 0.33 0.83 0.50 0.00 0.17 0.00 1.00 0.17 0.00 0.33 0.00 0.75 0.67 0.50 0.00 0.00 0.50 0.00 0.33 0.00 0.33 0.00 1.00 2.33 0.33 0.17 0.00 1.00 1.83 0.17 0.00 0.00 0.50 1.00 1.67 0.83 0.50 1.90 5.00 5.00 5.00 5.00 5.00 0.33 0.50 1.00 1.00 0.33 0.33 0.33 1.00 0.75 0.33 2.75 0.33 0.33 0.33 0.33 0.33 0.33 0.83 0.00 0.50 2.00 2.00 4.67 1.00 1.00 1.50 5.00 5.00 0.83 0.00 2.00 1.50 1.00 5.83 0.67 1.00 1.00 1.00 1.00 1.00 1.00 0.00 1.17 1.25 1.33 5.75 1.17 0.00 1.00 1.00 2.00 2.00 6.83 1.00 0.50 1.00 2.00 1.67 6.17 Ä Hamilton depression rating scale 1.ANXIETY.SOMATIZATION
2.MEIGHT
3.COGNITIVE DISTURBANCE
4.DIURNAL VARIATION
5.RETARDATION
6.SLEEP DISTURBANCE
7.1043.SOOVE 2. MEIGHT
3. COCNITIVE DISTURBANCE
4. DIDINAL VARIATION
5. RETARDATION
7. STEEP DISTURBANCE
7. FORAL 1.ANXIETY/SOMATIZATION
2.MEIGHT
2.MEIGHT
4.DIURNAL VARIATION
5.METARABATION
6.SLEEP DISTURBANCE
7.Total score 1.ANXIETY.SOMATIZATION
2.MELGHT
2. REIGHT
4. DIURNAL VARIATION
5. REFARDATION
6. SLEEP DISTURBANCE
7. I otal score 1. ANXIETY/SOMATIZATION
2. MEGENT
3. COCKITIVE DISTURBANCE
4. DIUGNAL VARIATION
5. RETARBATION
6. SIEEP DISTURBANCE
7. ICALL SOCKE .MEIGHT .COGNITIVE DISTURBANCE .DIURNAL VARIATION .RETARDATION 1.ANXIETY/SOMATIZATION 1. ANXIETY/SONATIZATION Female Female Female Female Male Male Sex Fluoxetine Reboxetine Fluoxetine Reboxetine Reboxetine Centro Patient Treatment 398 508 521 397 507 506 811 4

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				REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1	XOL 20124/0	16							
				HAMILTON DEPRESSION RAIING SCALE: FACTOR AND TOTAL SCORE	: FACTOR A	IND TOTA	I SCORE						
Centre	Patient	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day		lay 7 D	ay 14 D	ay 21 Da	0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42	Day 42 Day 49 Day 56	Day 56	
\$	398	Reboretine	Fenale	6.SLEEP DISTURBANCE 7.Total score	1.33 8.08	1.33 8.08	1.33	1.00	1.00	1.00	0.00	0.33 1.83	
	399	Reboxetine	Female	1. ANXIETY/SOMATIZATION 2. REIGHT 3. COGNITIVE DISTURBANCE 4. DIUBNAL WARATION 5. REIARDATION 6. SLEEP DISTURBANCE 7. Total soore	1.33 1.00 1.00 2.00 2.00 8.00	1.33 1.00 1.00 2.00 2.00	1.33 0.00 0.67 1.00 2.00 1.67	0.83 0.00 0.50 1.00 1.33 5.67	1.00 1.00 0.17 1.00 1.50	0.83 0.00 0.33 1.00 1.67 4.83	0.67 0.00 0.00 1.00 0.75 1.67	0.67 0.10 0.17 0.00 0.75 2.25	
•	400	Fluoxetine	Male	1.ANXIETY/SOMATIZATION 2.NEIGH 3.NEIGHTYE DISTURBANCE 4.DIVENAL VARIATION 6.SIREP DISTURBANCE 7.Total score	1.00 2.00 1.00 1.50 1.50	1.00 2.00 1.00 0.00 1.50 1.67	1.00 0.00 0.67 1.00 1.25 4.58	0.33 0.00 0.33 0.50 0.51	0.33 0.00 0.50 0.50 0.50 1.53	0.50 0.00 0.33 0.75 1.92	0.50 0.00 0.03 0.03 0.33	0.33 0.00 0.00 0.00 0.33	
812	401	Fluoxetine	Female	1. ANXIETY/SOMATIZATION 2. WEIGHT 3. COGNITYE DISTURBANCE 4. DIUNNAL VARIATION 5. RETARDATION 6. SIERP DISTURBANCE 7. Total score	1.33 2.00 0.67 1.00 2.00 1.33 8.33	1,33 2,00 1,00 2,00 1,33 8,33	0.67 0.50 1.00 1.50 0.00 3.67	0.83 0.00 0.17 0.00 1.50 0.67 3.17	0.67 0.00 0.00 1.00 2.00	0.50 0.00 0.00 0.00 0.75 1.92	0.67 0.33 0.33 0.00 0.75 2.08	0.33 0.00 0.17 0.50 0.33 1.33	
	402	Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.HEIGHT 3.COCNITIVE DISTURBANCE 4.DIUTAMAL VARIATION 6.SIEER DISTURBANCE 7.Total score	1.50 1.00 2.00 1.75 1.33	1.50 1.00 2.00 1.75 1.33 8.58	1.17 0.00 0.67 2.00 1.00 6.58	0.83 0.33 1.00 1.00 3.83	0.83 0.00 0.50 1.50 1.00	1.00 0.50 1.00 1.50 0.67	0.33 0.00 0.17 0.00 0.75 1.92	0.17 0.00 0.00 0.00 0.50 0.33	
	403	Reboxetine	Female	1.ANXIETY/SOMATIZATIOM 2.REIGHT 3.COGNITIVE DISTURBANCE 4.DIURAL VARIATIOM 5.RETARDATIOM 6.SLEEP DISTURBANCE 7.Total score	0.67 2.00 0.83 1.00 2.00 2.00 1.33	0.67 2.00 0.83 1.00 1.33 7.83	0.83 0.00 0.33 0.00 1.00 2.83	0.50 0.00 0.33 0.00 1.25 2.75	1.17 1.00 1.00 1.00 1.50 5.67	0.50 0.00 0.00 0.75 0.67	0.50 0.00 0.00 0.00 0.75 1.92	0.17 0.00 0.17 0.00 0.25 0.67	
	404	Fluoxetine	Fenale	1.ANXIETY/SOHATIZATION 2.NEIGHT 3.COGNITIVE DISTURBANCE	1.33 2.00 0.67	1.33 2.00 0.67	1.33 0.00 0.67	0.67 0.00 0.33	0.67 0.00 0.17	0.17 0.00 0.17	0.83 0.00 0.17	0.83 0.00 0.00	

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PRARMACIA CNS RED

				Listing No.: 12.1	.: 12.1							
				HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	LE: FACTOR A	IND TOTA	L SCORE					
Centre	Patient	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	lay 0 Day		ay 14 De	ay 21 D	ay 28 Day 3	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day	19 Day 56
2	<b>†0</b> †	Fluoxetine	Female	4.DIURNAL VARIATION	1.00	1.00	1.00	1.00	1.00	0.00	0.00	0.00
				5.RETARDATION 6.SLEEP DISTURBANCE	2.00	2.00	2.00	1.25	9.00	0.75	0.75	0.50
				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.COCNITIVE DISTURBANCE	1.17	1.1	0,50	33	0.17	0.17	0.12	0.0
				4.bloknel Vaklalium 5.retardation	1.00	3.5	8 8	0.25	0.25	0.00	0.0	0.25
				6.SLEEP DISTURBANCE	1.00	1.00	0.33	0.33	0.33	0.33	0.33	0.00
				/.lotal score	7.58	7.58	8	2.25	1.42	3. B	6.67	24.0
	904	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	9.5	8.5	83	0.83	0.67			
				S.RETARDATION	2.00	2.0	1.75	1.75	2.25			
				6.SLEEP DISTURBANCE	1.33	1.33	1.67	2.00	2.00			
8:				7.Total score	8.00	8.00	7.75	8.42	7.75			
13												
3	404	Reboxetine	Male	1.ANXIETY/SOMATIZATION	1,33	1.33	1.67	1.33	1.33	1.50	1.17	
				2.WEIGHT	1.00	00.	2,00	2.00	2.00	9.5	0.0	
				3.COGNITIVE DISTURBANCE	0.67	0.67	0.20	9.20	95.0	0.67	0.67	
				5.RETARDATION	2.50	2,5	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	Fenale	1.ANXIETY/SOMATIZATION	1.33	1.33	1.12	0.83	83	0.83	0.33	0.50
				2.MELGHT	0.00	8.6	9.0	8.6	8.9	9.00	0.00	0.00
				4.DIURNAL VARIATION	1.00	1 00	9.0	3 6	. 6	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
	209	Fluoxetine	Female	1.ANXIETY/SOMATIZATION	1.00	9.6	1.17	1.00	9.6	9.6	0.67	
				2.COGNITIVE DISTURBANCE	0.00	20.0	3 5	9 6	9 6	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.SLEEF DISTURBANCE 7.Total score	7.83	7.83	7.50	7.08	6.42	5.42	5.42	
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PHARMACIA CNS RED	REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1	HAMILION DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	rating scale Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 42 Day 49 Day 56	ANCE 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.	TDN 1.33 1.33 1.17 0.50 0.83 0.83 0.83 0.50 0.50 0.00 0.00 0.00 0.00 0.00 0.0	HANCE 1.00 1.00 0.67 1.00 0.67 1.17 1.10 1.00 1.00 0.67 1.17 1.10 1.00 0.00 0.00 0.00 0.00 0.0	HANCE 1.33 1.33 0.50 0.50 0.17 0.33 0.17 0.00 0.00 0.00 0.00 0.00 0.00 0.00	TION 1.17 1.17 1.10 0.67 0.33 0.50 0.33 0.33 0.33 0.33 2.00 2.00 2.00 0.00 0	AMCE 2.00 2.00 2.17 1.83 1.83 1.50 1.17 1.17 1.17 1.17 2.00 2.00 2.00 0.00 0.00 0.00 0.00 0.0
	REBOXE	HANILTON DEPRESSION	Mamilton depression rating scale	2. MEIGHT 3. COGNITIVE DISTURBANCE 4. DIURNAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COOKITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total socre	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIDENAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1. ARXIETY/SOMATIZATION 2. MEIGHT 3. COGNITYE DISTURBANCE 4. DITERAL VARIATION 5. RETARDATION 6. SIEEP DISTURBANCE 7. Total score	1. ANYIETY/SOMATIZATION 2. MEIGHT 3. COGNITIVE DISTURBANCE 4. DINEAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	1. ANXIETY/SDMATIZATION 2. NEIGHT 3. COGNITIVE DISTURBANCE 4. DIURNAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score
			Sex	Fenale	Female	Female	Fenale	Female	Female
			t Treatment	Fluoxetine	Reboxetine	Reboxetine	Reboxetine	Fluoxetine	Fluoxetine
			Centre Patient Treatment	14 510	511	ቼ 814	537	538	53.9

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PHARMACIA CHS R&D REBUNETINE - PROTOCOL 20124/016 Listing No.: 12.1 HAMILION DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

0.67 0.00 1.00 1.50 0.33 0.33 0.17 0.00 0.50 1.00 0.00 0.50 0.50 1.00 0.75 2.75 8 49 Day g 0.33 0.00 0.17 0.00 0.50 0.33 0.00 0.17 0.00 0.00 1.00 0.67 0.08 0.83 2.00 1.25 0.50 0.00 0.17 0.00 0.00 0.00 42 1.00 2.00 1.50 5.00 5.00 5.00 0.83 0.00 0.33 0.75 0.67 2.58 Day 35 0 Day 7 Day 14 Day 21 Day 28 Day 0.00 0.00 2.00 1.25 0.33 0.17 1.00 0.50 0.67 2.67 0.67 0.00 0.17 1.00 0.50 0.33 2.67 0.50 0.33 1.00 0.75 0.00 2.58 1.17 0.00 1.00 2.00 1.75 0.00 1.17 0.00 1.00 2.25 0.00 6.42 0.83 0.00 1.00 2.00 1.50 0.67 0.00 2.00 1.50 0.33 5.47 1.00 0.00 0.50 2.00 0.75 0.67 1.17 1.00 2.00 2.25 1.00 1.17 1.17 2.00 2.00 2.00 7.00 0.83 0.00 1.00 2.00 1.50 2.00 2.00 1.33 2.50 1.33 22.00 2.00 2.00 0.50 1.00 1.57 7.92 1.00 1.50 1.50 1.50 1.67 1.50 2.00 1.33 1.75 1.33 Pay 1,00 2,00 0.83 1,25 1,33 8,42 1.17 1.00 1.00 1.00 1.00 7.42 1.50 2.00 2.00 2.00 1.75 1.33 7.17 0.00 2.00 2.00 7.67 Screen Hamilton depression rating scale 1.ANXIETY/SCHATIZATION
2.HEIGHT
3.COGNITIVE DISTURBANCE
4.DIURNAL VARIATION
5.RETARDATION 2. MEIGHT
3. COGNITYED DISTURBANCE
4. DIURNAL VARIATION
5. RETARDATION
6. SLEEP DISTURBANCE
7. Total score 2. WEIGHT 3. COGNITIVE DISTURBANCE 4. DIUMNAL VARIATION 5. RETARBATION 6. SILEP DISTURBANCE 7. Total score 3.COGNIIVE DISTURBANCE 4.DIURNAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 1. ANXIETY/SOMATIZATION
2. MEIGHT
2. ALCIGHT
4. LIUDNAL VARIATION
5. REFARANTION
6. SLEEP DISTURBANCE
7. Total score ACCOUNTIVE DISTURBANCE
DIURNAL VARIATION
S.ELEEP DISTURBANCE
7.Total score ANXIETY/SOMATIZATION WEIGHT 1.ANXIETY/SONATIZATION 2.WEIGHT ANXIETY/SOMATIZATION I.ANXIETY/SOMATIZATION Female Female Female Female Hale Male Sex Reboxetine Fluoxetine Fluoxetine Fluoxetine Reboxetine Reboxetine Centre Patient Treatment 413 414 410 411 412 409 815 35

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			Listing No.: 12.1	: 12.1	2						
entre Patie	Centre Patient Treatment	Sex	Mamilton depression rating scale Scroen Day 0 Day 7 D	E: FACTOR AND Screen Day	AND TOTAL S Day 0 Day	L SCORE ay 7 Da	y 14 Da	y 21 Da	.DRE 7 Day 14 Day 21 Day 28 Day 35	Day 42 Day 49	Day 56
15 414	Fluoxetine	Male	6.SLEEP DISTURBANCE 7.Iotal score	1.67	7.00	1.67	1.67	1.67	-	1.00	
415	Reboxetine	Fenale	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIURBAL VARIATION 5.RELARDATION 6.SLEEP DISTURBANCE 7.Total score	1.67 2.08 2.08 2.50 2.50 11.17	2.60 2.00 2.00 2.50 2.50	1.67 2.00 1.00 2.00 2.50	2.00 2.00 2.00 2.00 1.00	0.83 0.33 0.33 1.75 7.58	0.50 0.00 1.00 0.00 0.00	0.50 0.00 0.00 0.00 0.50 1.00	0.17 0.00 0.00 0.00 0.50 0.67
8 14 16	Fluoxetine	Fenale	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIUNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.33 2.00 0.50 1.00 1.75 1.67	1.33 2.00 6.50 1.00 1.75 1.67	1.33 2.00 6.50 1.00 1.75 8.25	1.33 2.00 0.50 1.00 1.75 1.67	1.33 2.00 0.50 1.00 1.75 7.92	1.00 0.50 2.00 11.25 0.67 5.42	0.67 0.00 0.00 1.00 1.00 6.33 3.33	0.67 0.00 0.17 0.75 0.33
\$ 316	Reboxetine	Female	1. ANXIETY/SOMATIZATION 2. MEIGHT 2. MEIGHT 4. DIURNAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	1.50 0.00 0.83 2.00 1.25 7.58	1.50 0.00 0.83 2.00 1.25 2.00 7.58	1.17 0.00 0.08 2.00 1.25 1.00	0.83 0.00 0.67 1.00 0.75 3.92	0.33 0.00 0.00 0.50 0.33	0.33 0.00 0.00 0.25 0.00	0.17 0.10 0.17 0.25 0.25 0.00	0.17 0.00 0.00 0.00 0.05 0.42
418	Reboxotine	Female	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTUBBANCE 4.DIURMAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.83 1.00 1.00 2.00 2.50 1.67	1.83 1.00 1.00 2.00 2.50 1.67	1.83 1.00 1.00 2.00 2.50 1.67	1.67 1.00 2.00 2.25 0.67 8.25	1,17 0,00 2,00 1,50 0,33	1.00 0.10 0.17 1.50 0.00	0.83 0.90 0.17 1.00 0.75	0.33 0.00 0.00 0.00 0.50 0.83
419	Fluoxetine	Female	1.ANXIETY/SOMATIZATION 2.MEIGHT 2.MEIGHT 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	0.83 0.00 1.00 2.00 1.67	0.83 0.00 1.00 1.67	0.83 0.08 0.83 1.00 1.67 6.33	0.83 0.00 1.00 1.67	0.83 1.00 2.00 1.67	0.83 0.00 0.67 1.50 1.00 5.00	0.67 0.00 0.67 0.00 1.25 0.67	0.67 0.00 0.50 0.00 0.75 2.25
420	Fluoxetine	Kale	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNIILVE DISTURBANCE	1.33 0.00 1.00	1.33 0.00 1.00	1.33 0.00 1.00	1.17	0.83 0.00 0.83	0.83 0.00 0.33	0.67 0.00 0.33	0.50 0.00 0.33

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PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1 HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

4.DIURNAL VARIATION 5.RETARRALION 6.SIEEP DISTURBANCE 6.SIEEP DISTURBANCE 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 1.ANXIETY/SOMATIZATION 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score 7.Total score	1.00 1.00 1.00 1.00 1.75 1.75 1.75 1.75 1.75 1.67 1.67 1.67 1.67 1.67 1.67 1.67 1.67	4. DIURNAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score 7. Total score 7. Total score 7. Total score 7. Total score 7. Total score 7. Total score 7. Total score 7. Total score 7. Total score 7. Total score 8. SEER DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. SCORITIVE DISTURBANCE 9. S
1.00 1.00 1.75 1.75 1.67 1.67 6.75 6.75 6.75 6.75 1.30 1.30 1.33 1.33 1.33 1.33 1.33 1.33 1.33 1.33 1.33 1.33 1.33 1.33 2.00 2.00	4. DIURNAL VARIATION 5. RETARDATION 6. SIEEP DISTURBANCE 7. Total score 1. ANXIETY/SOMATIZATION 6. SIEEP DISTURBANCE 7. Total score 1. ANXIETY/SOMATIZATION 6. SIEEP DISTURBANCE 7. Total score 1. ANXIETY/SOMATIZATION 7. SOM 6. SIEEP DISTURBANCE 1. ANXIETY/SOMATIZATION 6. SIEEP DISTURBANCE 7. Total score 7. Total score 6. SIEEP DISTURBANCE 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 1. ANXIETY/SOMATIZATION 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2. OU 2.	Hale   4.DIURNAL VARIATION   1.00   1.00   1.00     S.RETARDATION   1.75   1.75   1.75     J. Total score   1.67   1.67   1.67     J. Total score   1.60   1.50   1.50     J. GOMITIVE DISTURBANCE   1.77   1.77     J. GOMITIVE DISTURBANCE   1.70   1.70     J. GOMITIVE DISTURBANCE   1.70   1.70     J. GOMITIVE DISTURBANCE   1.50   1.50     J. SO   1.50   1.50     J. Total score   1.50   1.67     J. JURNAL VARIATION   1.67   1.67     J. JURNAL VARIATION   1.67   1.67     J. JURNAL VARIATION   1.67   1.67     J. JURNAL VARIATION   1.33   1.33     J. Total score   1.33   1.33   1.33     J. SHEEP DISTURBANCE   1.33   1.33     J. SHEIGHT   1.40   1.33   1.33   1.33     J. SHEIGHT   2. HEIGHT   2. 100   2.00     J. SO   2.00   2.00   2.00     J. SO   2.00   2.00   2.00     J. SO   2.00   2.00   2.00     J. SO   2.00   2.00   2.00     J. SO   2.00   2.00   2.00     J. SO   3.00   2.00   2.00     J. SO   3.00   3.00   3.00     J. SO   3.00   3.00   3.00     J. SO   3.00   3.00   3.00     J. SO   3.00   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00     J. SO   3.00
	4 DIURNAL VARIATION 5 RETARBATION 6 SIEEP DISTURBANCE 7 Total score 1 ANXIETY/SONATIZATION 2 MEIGHT 3 COGNITIVE DISTURBANCE 4 DIURNAL VARIATION 5 RETARBATION 6 SIEEP DISTURBANCE 7 TOTAL SCORE 1 ANXIETY/SONATIZATION 2 MEIGHT 6 SIEEP DISTURBANCE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SCORE 7 TOTAL SC	Male 4. DIUSNAL VARIATION 5. RETARBATION 6. SIEEP DISTURBANCE 7. Total score 2. WEIGHT DISTURBANCE 4. DIUBNAL VARIATION 5. RETARBATION 6. SIEEP DISTURBANCE 7. Total score 7. Total score 8. COGNITIVE DISTURBANCE 7. Total score 9. COGNITIVE DISTURBANCE 7. Total score 6. SIEEP DISTURBANCE 7. Total score 7. Total score 7. Total score 7. Total score 7. Total score 8. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. SETARBATION 9. S
4.DIUXNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score 4.DIURNAL VARIATION 2.WEIGHT 8.COMITIVE DISTURBANCE 4.DIURNAL VARIATION 6.SLEEP DISTURBANCE 7.Total score 7.Total score 7.Total score 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SCORE 7.TOTAL SC		Male Male Female
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				PHARMACIA CNS R&D	CNS R&D							21
				REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1	OCOL 20124/0	<b>3</b>						
				HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	LE: FACTOR AN	ND TOTAL	L SCORE					
Centre F	atient	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen Day	ay O Day		14 De	y 21 De	ny 28 Day 35 I	7 Day 14 Day 21 Day 28 Day 35 Dey 42 Day 49 Day	lay 56
<b>25</b>	426	Fluometine	Kale	2.WEIGHT 3.COGNITYE DISTURBANCE 4.DIUMAL VARIATION 5.ERLARDATION 6.SLEEP DISTURBANCE 7.Total score	2.00 1.17 2.00 2.00 1.33	2,00 1,17 2,00 2,00 1,33	2.00 2.00 2.00 2.00 1.33	0.00 1.00 2.00 1.75 7.08	0.00 0.83 2.00 1.75 6.92	0.00 0.67 1.00 0.75 4.42	0.00 0.17 1.00 0.50 0.67 3.33	0.00 0.17 1.00 0.50 0.33
Ť	427	Reboxetine	Female	1.ANXIETY/SOMATIZATIOM 2.NEIGHT 3.COGNITIVE DISTURBANCE 4.DIUMAL VARIATIOM 5.NETANDATIOM 6.SLEEP DISTURBANCE 7.Total score	1.50 0.00 0.33 2.00 2.00 7.17	1.50 0.00 0.50 2.00 2.00 7.00	1.50 0.00 0.50 2.00 1.00	1.33 0.00 0.50 2.00 1.75 6.25	1.33 0.00 2.00 1.75 0.67 6.25	1.33 0.00 0.17 1.25 6.33 4.08	1.00 0.00 1.00 1.00 0.33 3.33	0.50 0.00 0.00 1.00 1.50
818	<b>4</b> 2 <b>8</b>	Fluoxetine	Male	1.ANXIETY/SOMATIZATION 2.REIGHT 3.COGNITYE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.33 0.00 0.83 1.25 1.60	1.33 0.00 0.00 1.00 1.25 1.00 5.42	1.33 0.00 0.83 1.00 1.00 5.42	1.33 0.00 0.83 1.25 1.00 5.42	1.00 0.00 0.50 1.25 0.67 4.42	1.00 0.00 0.33 1.00 0.75 3.75	1.00 0.33 1.00 0.75 0.33 3.42	1,00 0.00 0.33 1,00 0.50 3.17
ਚ	6449	Reboxetine	Female	1. AKXIETY/SONATIZATION 2. KETGHT 3. CUGNITIVE DISTUBBANCE 4. DIURNAL VARIATION 5. RETAKBATION 6. SLEEP DISTURBANCE 7. Total spore	1.33 0.83 0.00 1.50 1.00 5.67	1.33 1.00 0.83 1.50 1.00 5.67	1.33 1.00 0.83 0.00 1.75 5.92	1.33 1.00 0.83 1.75 1.00	1,33 1,00 0,83 1,75 1,00 5,92	1.17 0.00 0.08 0.00 1.75 1.00 4.75	1.17 0.00 0.00 1.75 0.33 4.08	0.50 0.00 0.33 0.00 0.00
<b>ਚ</b>	450	Fluoxetine	Male	1. ANXIETY/SOMATIZATION 2. HEIGHT 3. CUGNITIVE DISTUBBANCE 4. DIURNAL VARIATION 5. RETAXDATION 6. SLEEP DISTUBBANCE 7. Total score	7.33 7.50 7.75 7.33 8.52 8.52	1.33 2.00 0.50 1.00 2.75 1.33	1.33 2.00 0.50 1.00 2.75 1.33 8.92	1.33 1.00 1.00 2.50 1.33	1,33 0,00 0,33 1,00 2,25 0,67 5,58	1.17 0.10 1.00 2.00 0.33 4.83	1.17 0.33 1.00 1.25 3.75	1,17 0,00 0,33 1,00 1,25 0,00
<i>ਚ</i> '	451	Fluoxetine	Female	1. ANXIETY/SONATIZATION 2. HEIGHT 3. COGNITYE DISTURBANCE 4. DIURNAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	1.17 0.00 0.67 2.00 1.75 6.58	1.17 0.00 0.67 2.00 1.75 6.58	1.17 0.00 0.67 2.00 1.75 1.00 6.58	1.33 0.00 0.67 2.00 1.75 6.75	1.00 0.67 0.67 1.25 0.67 4.58	0.83 0.00 1.00 0.75 3.25	0.67 0.33 1.00 0.50 0.50	0.50 0.00 0.33 1.00 0.55 2.67

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PRARMACIA CNS RRD REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1

				HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	LE: FACTOR AND TO	OTAL SCOR	ñ					
Centre	Centre Patient Treat	Treatment	Sex	Hamilton depression rating scale	Screen Day (	0 Day 7	7 Day 14 Day	2	Day 28 Day	35 Day 42 Day	2 Bay 49	Day 56
<del>2</del>	254	Reboxetine	Female	1. ANXIETY/SOMATIZATION 2. HEIGHT 3. COGNITIVE DISTURBANCE 4. DIUMALI VARIATION 6. SIERY DISTURBANCE 7. Total score	1.33 1.33 0.80 0.80 0.80 0.80 0.80 0.80 0.80 0	3 1,33 0 0,00 0 2,00 0 1,50 0 6,30 0 6,30	1.17 0.00 0.83 1.00 1.50 4.83	0.67 0.00 0.50 1.00 1.00 0.00	0.83 0.17 0.17 1.00 0.00 2.75	0.67 0.00 0.00 0.00 0.50 0.00 0.10	, o o o o o o	0.17 0.00 0.00 0.00 0.25 0.00
819	<b>4</b> 54	Fluoxetine	Kale	1. ANXIETY/SOMATIZATION 2. HEIGHT 3. COGNITATE DISTURBANCE 4. DIORNAL VARIATION 5. RETARDATION 6. SIERP DISTURBANCE 7. Total score	1.50 1.50 0.00 0.00 0.00 0.03 0.83 0.83 0.83 1.00 1.00 1.00 1.00 1.00 1.00 1.00 1.0	60 1.50 60 1.50 60 1.25 60 1.25 7.25 8 5.58	1.50 0.00 0.83 1.00 1.00 1.00	1.50 0.00 0.83 1.00 1.25 4.92	1.00 0.67 1.00 1.25 4.25	1.00 0.00 0.50 1.00 1.25 0.33	តិ ច ច ច ស ស <b>ស ស</b>	1.00 1.00 1.00 3.50
<del>2</del>	429	Fluoxetine	Female	1. ANXIETY/SOMATIZATION 2. KEIGHT 2. KEIGHT 4. DIGNITAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Tokal score	1.50 1.50 0.00 0.00 1.83 1.83 0.00 0.00 2.25 2.25 1.33 1.33 6.92 6.92	0 1.00 0 0.00 0 0.83 0 0.83 1.25 2 3.42	0.50 0.00 0.00 0.00 0.75 1.25	0.17 0.00 0.00 0.00 0.50 0.50	0.00 0.00 0.00 0.00 0.50 0.50	0.17 0.17 0.00 0.00 0.00 0.00 0.25 0.75 0.00 0.00	17 0.17 10 0.00 10 0.00 15 0.75 10 0.00	0.17 0.00 0.00 0.00 0.50 0.00
i,	430	Reboxetine	Кале	1.ANXIETY/SOMATIZATION 2.METGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARRATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.33 1.33 0.00 0.00 1.17 1.17 2.00 2.00 2.50 2.50 1.00 1.00 8.00 8.00	73 0.67 00.00 00.03 1.00 1.00 4.00	0.67 0.33 0.33 1.00 1.00	0.33 0.00 0.33 0.75 1.00 2.42	0.33 0.00 0.33 0.75 2.08	0.67 0.67 0.00 0.00 0.33 0.33 0.00 0.00 1.00 1.00 0.67 0.67 2.67 2.67	57 0.17 58 0.00 58 0.00 50 0.00 57 0.50 7.1.33	0.00
	431	Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITYE DISTUBBANCE 4.DIURALL VARIATION 5.RETARDATION 6.SLEEP DISTUBBANCE 7.Total score	1.33 1.33 1.33 1.33 1.33 1.33 1.33 1.33	33 0.83 10 0.00 13 0.83 10 0.00 13 0.00 2.67	0.67 0.00 1,00 0.00 2.33	0.67 0.00 0.00 0.00 0.75 2.25	0.50	0.50 0.50 0.00 0.00 0.50 0.67 0.00 0.00 0.75 0.75 0.00 0.00	50 0.33 30 0.00 57 0.50 30 0.00 75 0.75 92 1.58	0.50 0.00 0.00 0.00 0.00 1.75
	432	Fluoxetine	Female	1.ANXIETY/SOMATIZATION 2.METGHT 3.COCHITIYE DISTURBANCE 4.DIUGNAL VRIATION 5.RETARDATION	1.17 1.17 0.00 0.00 1.50 1.50 1.00 1.00 3.25 3.25	77 0.83 50 0.00 50 0.33 50 1.00 25 1.50	0.17 0.00 1.00 1.00	0.00	0.00	0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.75 0.75	00 0.00 00 0.00 00 0.00 00 0.00 75 0.75	0.00

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PHARMACIA CNS RED

				PRAKHACIA CNS RED	: RED										
				REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1	12.1	916								•	
				HANILION DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	FACTOR A	AND TOTA	L SCORE								
entre	Patient	entre Patient Treatment	Sex	Mamilton depression rating scale	Screen D	Day 6 Day		7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day	ay 21 De	ay 28 D	ay 35 D	lay 42 D	lay 49 E	lay 56	
w	432	Fluoxetine	Female	6.SLEEP DISTURBANCE 7.Total score	6.92	6.92	3.67	1.92	0.00	0.00	0.00	0.00	0.00	0.00	
	433	Reboxetine	Female	1.AKXIETY/SOMATIZATION 2.HEIGHT 3.CGANTIVE DISTURBANCE 4.DIUNEAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.50 1.50 2.50 7.83	7.50 2.50 2.50 7.83	0.67 0.00 0.50 1.00 1.00 3.83	0.17 0.00 1.00 1.00 1.75	0.17 0.00 0.00 0.00 0.33 0.50	0.17 0.17 0.00 0.00 0.33	0.17 0.00 0.17 0.00 0.00 0.33	0.17 0.10 0.10 0.00 0.33	0.17 0.33 0.00 0.00 0.33 0.83	0.17 0.00 0.33 0.25 0.33	
820	434	Fluoxetine	Femalo	1.ANXIETY/SOHATIZATION 2.MEIGHT 2.MEIGHT 4.DIOBNAL VARIATION 5.RETARRATION 6.SLEEP DISTURBANCE 7.Total score	1.33 0.00 1.83 0.00 2.75 7.25	1.33 0.00 1.83 0.00 2.75 1.33	0.83 0.00 0.83 0.00 1.75 4.08	0.17 0.00 0.17 0.00 0.50 1.50	0.33 0.00 0.50 0.50 1.00 2.33	0.17 0.00 0.17 0.00 0.50 1.50	9.17 0.00 0.17 0.00 0.50 0.67	0.17 0.00 0.17 0.50 0.50 1.50	0.17 0.00 0.33 0.00 0.50 0.67	0.17 0.00 0.33 0.00 0.50 1.67	
	435	Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.MEIGHT 2.MEIGHT 5.COGNITIVE DISTURBANCE 4.DIUNIAL VARIATION 5.REFARARATION 6.SLEEP DISTURBANCE 7.Total score	2.17 1.00 1.83 2.00 2.75 2.00 11.75	2.17 1.83 2.00 2.75 2.00	1.33 0.00 1.00 1.75 2.00 7.08	0.83 0.00 0.67 1.25 3.42	0.17 0.00 0.33 0.00 0.50 1.67	0.17 0.00 0.17 0.00 0.50 1.50	0.17 0.00 0.00 0.00 0.50 0.67	0.17 0.00 0.00 0.50 0.50	0.00 0.00 0.00 0.90 0.50 1.17	0.00 0.00 0.00 0.50 1.17	
	436	Fluoxetine	Female	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIUREMA VARIATION 5.REPREMATION 6.SLEEP DISTURBANCE 7.Total score	2,50 0,00 0,00 0,67 7,42	1.50 1.00 2.00 0.00 7.42	1,00 1,33 1,33 1,00 2,00 6,00	0.67 0.00 0.83 0.00 1.25 0.33 3.68	0.67 0.00 0.03 1.25 3.08	0.67 0.00 0.67 1.25 2.92	0.50 0.00 0.50 1.00 2.33	0.33 0.10 0.17 0.00 0.75 0.33	1.50 1.00 0.00 1.50 1.00 5.83	0.67 0.00 0.67 1.25 3.25	
	437	Reboxetine	Female	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIURMAL VARIATION 5.REFARDATION 6.SLEEP DISTURBANCE 7.Total scoro	1.58 1.06 1.00 1.33 9.00	1.50 1.00 1.00 2.00 1.33	0.33 1.67 1.00 1.00 4.00	0.17 0.83 0.00 0.50 0.67	0.17 0.00 0.83 0.00 0.50 0.67	0.17 0.00 0.83 0.00 0.50	0.17 0.83 0.00 0.00 0.50	0.17 0.00 0.33 0.00 0.50 0.67	0.17 0.00 0.17 0.00 0.50 0.67	6.17 6.00 0.17 0.00 0.50 0.50	
	438	Fluoxetine	Female	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE	1.67 1.00 1.83	1.67 1.00 1.83	0.83 0.00 0.67	0.83	0.83 0.00	0.83 0.00 0.17	1.00 0.00 0.17				

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				PRARMACIA CNS RED	S R&D									42
				REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1	OL 20124/0 12.1	5								
				HANILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	: FACTOR A	NO TOTA	L SCORE							
Centre	Patient	Centre Patient Treatment	Sex	Hamilton depression rating scale	Screen D	Day 0 Day		ay 14 De	y 21 Da	ty 28 Da	7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day	y 42 Da	y 49 Da	y 56
16	438	Fluoxetine	Female	4.DIURNAL VARIATION S.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	0.00 2.25 1.67 8.42	0.00 2.25 1.67 8.42	0.00 1.00 0.67 3.17	0.00 1.00 0.67 3.00	0.00 1.00 0.67 2.67	0.00 1.00 0.67 2.67	0.00 1.25 0.67 3.08			
	439	Fluoxetine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.50 0.00 1.83 2.00 2.75 1.00	1.50 1.83 2.75 1.00 9.08	1.00 0.00 1.33 1.00 1.75 0.67 5.75	0.33 0.00 1.00 1.00 3.00	0.33 0.33 1.00 3.00	0.33 0.00 0.17 0.50 1.00	0.17 0.00 0.17 0.00 0.00 0.00	0.17 0.00 0.17 0.00 0.50 0.83	0.17 0.00 0.17 0.50 0.83	0.33 0.00 0.00 0.50 1.17
821	440	Reboxetine	Female	1.ANXIETY/SCMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIURAL VARATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.33 1.00 1.67 2.20 2.25 1.33	1,33 1,00 1,67 2,25 1,33 9,58	0.67 0.00 1.00 1.50 0.67 4.67	0.50 0.00 0.17 0.50 0.33	0.50 0.17 0.00 0.50 1.50	0.33 0.00 0.17 0.00 0.25 0.75	0.33 0.00 0.17 0.00 0.25 0.00	0.33 0.00 0.17 0.00 0.00	0.33 0.00 0.17 0.00 0.25 0.75	0.33 0.00 0.00 0.00 0.00
	144	Fluoxetine	Female	1. ANXIETY/SOMATIZATION 2. MEIGHT 3. CDGNITIVE DISTURBANCE 4. DIURMAL VARAMION 5. RETARRATION 6. SLEEP DISTURBANCE 7. Total score	1.50 2.00 2.00 2.25 1.33 1.43	1,50 2,00 2,00 2,20 1,33 1,33	1.00 0.83 1.00 1.75 0.67 6.25	0.33 0.00 0.00 1.25 2.08	0.33 0.00 0.50 0.00 1.25 2.08	0.17 0.00 0.17 0.00 0.00 1.08		0.17 0.00 0.17 0.50 0.83		0.17 0.00 0.17 0.00 0.50
	442	Reboxetino	Female	1. ANXIETY/SOMATIZATION 2. WEIGHT 3. COGNITIVE DISTURBANCE 4. DIURBAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.	2.00 2.00 2.33 2.00 3.25 13.58	1.83 2.00 2.00 2.75 2.75 11.58	1.50 0.00 1.33 2.00 2.00 1.33 8.17	0.67 1.00 1.00 1.00 1.00 5.17	0.50 0.00 1.00 1.00 1.25 1.00		0.83 1.00 1.00 1.25 5.08		0.83 0.00 1.00 1.00 4.83
	#43	Fluoxetine	Male	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIURAH, VARIATION 5.REPREATION 6.SLEEP DISTURBANCE 7.Total score	0.83 1.00 2.00 1.50 1.50	0.83 0.00 1.00 2.00 1.50 1.00 6.33	0.83 0.00 0.83 2.00 1.50 0.67	0.17 0.33 1.00 1.00 0.67	0.17 0.00 0.17 1.00 0.75 2.42	0.17 0.00 0.17 0.00 0.75 1.42		0.17 0.00 0.17 0.00 0.50 1.17		0.17 0.00 0.17 0.00 0.75 1.42
	444	Reboxetine	Female	1.ANXIETY/SOMATIZATION	1.17	1.17	1.00	0.83	0.67	0.67		0.67		0.67

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			49 Day 56	0.00 0.00 0.00 0.00 0.00	0.33 0.00 0.17 0.00 1.00 1.50	0.50 0.90 0.17 0.00 1.00 0.00	0.50 0.00 1.17 1.00 0.75 2.75	0.00 0.00 0.17 1.00 1.25 0.33	0.67 0.00 0.33 1.00 1.00 3.33
			14 Day 21 Day 28 Day 35 Day 42 Day 49 Day	0.00 0.00 0.00 0.00 0.00	0.33 0.00 0.17 0.00 1.00 0.00	0.50 0.17 0.19 1.00 1.00	0.67 0.00 0.17 1.00 1.33 3.17	0.17 0.00 0.83 1.00 1.25 3.58	0.67 0.00 0.50 1.00 1.25 0.67
			Day 28 Day	0.00 0.33 1.00 1.00 3.00	0.50 0.17 0.17 1.00 1.67	0.50 0.00 0.17 1.00 1.00 2.00	0.50 0.00 0.17 1.00 0.75 2.75	0.17 0.00 0.83 1.25 1.25 3.58	0.67 0.00 0.50 1.00 1.00 3.83
			lay 21	0.00 1.00 1.00 1.33 3.33	0.17 0.00 0.17 0.00 1.00 1.33	0.67 0.00 1.00 1.25 0.33 3.42	0.50 0.00 0.17 1.00 0.75 0.33 2.75	0.17 0.00 0.83 1.08 1.25 0.67 3.92	1.00 0.00 0.83 2.90 1.75 1.00 6.58
			ay 14 [	0.00 0.67 2.00 1.50 0.67 5.67	0.17 0.00 0.17 1.00 0.33 2.67	0.83 1.00 1.00 1.25 0.67 5.42	0.83 0.00 0.33 2.00 1.50 0.67	0.33 0.00 0.83 2.00 1.25 1.00 5.42	7.00 0.00 0.00 2.00 7.00 1.00 6.83
		L SCORE	ay 7 Day	0.00 0.67 2.00 1.50 0.67 5.83	1.00 2.00 0.50 1.00 1.75 6.92	1.00 1.00 2.00 1.75 7.42	1,00 0,00 0,33 2,00 1,50 0,67 5,50	0.83 0.00 1.00 1.50 1.00 6.33	1.33 0.00 1.00 2.00 2.75 1.33 8.42
	92	ND TOTA	ay 0 Day	2.00 2.00 2.00 1.00 8.83	1.17 2.00 0.67 1.00 1.75	1.00 1.00 0.67 2.00 1.75 7.42	2.00 0.50 2.00 1.75 0.67 8.08	0.83 0.00 1.17 2.00 1.75 1.00 6.75	1.33 0.00 1.17 2.00 2.75 1.33 8.58
R&D	12.1	FACTOR A	Screen Day	2.00 0.67 2.00 2.00 1.00 8.83	1.17 2.00 0.67 1.00 1.75 7.58	1.00 1.00 0.83 2.00 1.75 7.58	1,17 2,00 0,50 2,00 1,75 0,67 8,08	0.83 0.00 1.17 2.00 1.75 1.00 6.75	1.33 0.00 1.17 2.00 2.75 1.33 8.58
PHARMACIA CMS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1	BANILTON DEPRESSION RAIING SCALE: FACTOR AND TOTAL SCORE	Hamilton depression rating scale	2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIUBANET VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.TOTAL SCORE	1.AMXIETY/SOMATIZATION 2.MEIGHT 2.MEIGHT 3.COGMITYE DISTURBANCE 4.DIUBNAL VARIATION 5.RETARDATION 6.SIEEP DISTURBANCE 7.Total Score	1.ANXIETY/SOMATIZATION 2.MEIGHT 2.MEIGHT PESTURBANCE 4.DIUGHAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1. ANXLETY/SOMATIZATION 2. MEIGHT 3. COGNITUR DISTURBANCE 4. DIGDNAL VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. TOTAL SCOTO	1. ARKIETY-SOMATIZATION 2. MEIGHT 3. COGNITYED DISTUBBANCE 4. DIUDNAL, VARIATION 5. RETARDATION 6. SLEEP DISTURBANCE 7. Total score	1.ANXIETY/SONATIZATION 2.NEIGHT 3.CGGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARDATION 6.SIEEP DISTURBANCE 7.Total score
			Sex	Female	Kale	Fenale	Male	Female	Female
			t Treatment	Reboxetine	Reboxetine	Fluoxetine	Fluoxetine	Reboxetine	Fluoxetine
			Centre Patient Treatment	444	445	§ 822	744	855	455

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PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/016

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Listing No.: 12.1 BAHILTOM DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE

Hamilton depression rating scale

Centre Patient Treatment

Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 49 Day 56

0.67 0.00 0.33 1.25 0.33 3.58	0.00 0.17 0.17 1.00 4.10	1.00 0.33 1.00 2.00 0.00	0.00 0.00 0.00 0.00 0.00 0.00	0.00	0.67 0.10 1.00 0.00
	•				0.67 0.00 0.17 1.00
0.67 0.33 1.00 1.25 0.33 3.58	0.00 0.00 1.00 1.00 1.00 1.00	1.00 0.00 1.00 2.00 6.33 4.33		0.00 0.17 0.00 0.00 0.00 0.00	1.00 0.00 0.33 1.00
	0.00 0.17 1.00 1.17		•		1.00 0.00 0.33 1.00
0.67 0.33 1.00 1.25 0.33 3.58	0.83 0.00 1.00 1.50 0.33 4.17	1.00 0.00 1.00 2.00 0.00 4.33	0.33 0.00 1.00 1.00 0.75 0.33 2.75	0.50 0.00 1.00 1.25 0.33 3.25	1.00 0.00 0.33 1.00
0.67 0.00 0.33 1.25 0.33 3.58	0.83 0.00 1.00 1.50 1.50 0.33 4.17	1.00 0.00 0.33 1.00 2.00 6.00 4.33	0.33 0.00 1.00 1.25 0.33 3.25	0.50 0.00 1.00 1.25 0.33 3.25	1.00 0.00 0.33 1.00
1.00 1.00 0.50 2.00 1.50 0.33	0.83 0.00 1.00 1.50 1.50 4.50	1.17 0.00 1.00 2.00 4.50	0.33 0.33 1.00 1.25 0.33 3.25	1.17 0.00 1.00 2.00 2.25 0.67 7.08	1.00 0.50 1.00 1.25
2.00 2.00 2.00 2.00 1.33	1.50 1.00 2.00 2.00 1.33 8.83	2.00 0.00 0.50 2.00 2.75 0.00	1.00 0.00 0.33 2.00 2.00 5.67	1.17 0.00 1.17 2.00 2.50 0.67 7.50	1.00 0.00 1.00 1.50
2.00 2.00 1.33 2.00 2.50 1.33	1.50 1.00 1.00 2.00 2.00 1.33 8.83	2.00 0.00 0.83 2.00 2.75 0.00	1.50 0.00 0.33 2.00 2.00 1.33	1.67 1.50 2.00 2.75 0.67 8.58	1.33 0.00 1.00 1.50
2.00 2.00 1.33 2.00 2.50 1.33 11.17	1.50 1.00 1.00 2.00 2.00 1.33 8.83	2.00 0.00 0.83 2.00 2.75 0.00 7.58	1.50 0.00 0.33 2.00 2.00 1.33	1.67 0.00 1.50 2.00 2.75 0.67 8.58	1.33 0.00 1.00 1.50
Male 1.ANXIETY/SOMATIZATION 2.HEIGHT 3.COGHITIVE DISTURBANCE 4.DIUMAL VARATION 5.RETARBATION 5.RETARBATION 6.SIEEP DISTURBANCE 7.Total score	Female 1.ANXIETY/SOMATIZATION 2.HEIGHT 3.COGNITIVE DISTURBANCE 4.DIURMAL VARIATION 5.RETANDATION 6.SLEEP DISTURBANCE 7.Total score	Female 1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETAKOATION 6.SLEEP DISTURBANCE 7.Total score	Male 1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL VARIATION 5.RETARCATION 6.SLEEP DISTURBANCE 7.Total score	Male 1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNATIVE DISTURBANCE 4.DIUGHALI VARIATION 5.REPARDATION 6.SIEEP DISTURBANCE 7.Total score	Female 1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIURNAL YARIATION 5.RETARDATION
Roboxetine	Fluoxetine	Fluoxetine	Reboxetine	Reboxetine	Fluoxetine
456	457	野 23	459	460	25
4	· 8	5 <b>2</b> 3			82

		PHARHACIA CNS RBD REBOXETINE - PROTOCOL 20124/016	CNS R&D DCOL 20124/01	22				:				27
		LASTING NO.: 12.1 HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	.: 12.1 Le: factor an	(D TOTAL	SCORE							
Sex Kamilton	amilton	Hamilton depression rating scale	Screen Day	ay 0 Day		7 Day 14 Day	21	Day 28 Day	, 35 Day	7 42 Day	42 Bay 49 Day	26
Female 6.SLEEP 7.Total	Total	6.SLEEP DISTURBANCE 7.Total score	1.67	1.67	1.00	4.42	3,75 3	3.75 3	3.75	3.75	2.17	0.33
Female 1.ANXIETY/SONI 2.HEIGHT 3.COGNITIVE DI 4.DIUGNAL VAR 5.RETARDATUR 6.SLEEP DISTU	ANXIETY HEICHT COCNITI .DIURNAL .RETARDA .SLEEP D	1. ANXIETY/SOMATIZATIOM 2. MEIGHT 2. MEIGHT 4. DIGENAL VARIATION 6. SLEEP DISTURBANCE 7. TOTAL	0.67 0.00 0.83 1.75 1.75 5.92	0.67 0.00 0.83 1.00 1.75 5.92	0.67 0.00 0.83 1.00 1.75 5.92	0.67 0.00 1.00 1.50 5.50	0.67 0 0.06 0 0.67 0 1.00 1	0.67 0.50 1.00 1.00 0.75 0.67 3.58	0.67 0.00 0.50 1.00 0.75 0.67	0.67 0.17 0.18 0.50 0.50 0.67	0.50 0.00 0.17 0.00 0.00	0.17 0.00 0.17 0.00 0.00 1.00
Female 1.ANXIETY/SOM 2.HEIGHT 3.COGNITIVE D 4.DIUWALL VAR 5.RETARDATION 6.SIERP DISTU	A.ANXIETY. S.HEIGHT G.COGNIII DIURNAL RETARDAS SLEEP DI Total se	1.ANXIETY/SOMATIZATION 2.HEIGHT 2.HEIGHT 4.DIUNAL VARIATION 5.RETRADATION 6.SLEEP DISTURBANCE 7.Total score	1,17 0.00 0.83 0.00 2.00 2.00 5.33	1.17 0.00 0.83 0.00 2.00 1.33 5.33	1.17 0.00 0.83 0.00 1.75 1.33 5.08	1.17 0.00 0.67 1.25 4.42	1.17 1 0.00 0.33 0 1.25 1 3.75 3	1.17 0.00 0.17 0.00 1.00 0.67 3.00	1.17 0.00 0.17 0.00 1.00 3.00	0.67 0.00 0.17 0.00 0.25 0.67	0.50 0.00 0.00 0.00 0.33 0.83	0.33 0.00 0.00 0.00 0.33 0.67
Female 1.ANXIETY/SOMATIZATIG 2.WELGHT 3.COGNITIVE DISTURBAT 4.DIURMAL VARIATION 5.REFARBATION 6.SLEEP DISTURBANCE 7.Total SOUR	1.ANXIETY/ S.WEIGHT B.COGNITIV B.DIURNAL F.RETARDAT S.EEEP DI	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.ACOGHITYE DISTURBANCE 4.DIURNAL VARIATION 6.SLEEP DISTURBANCE 7.Total score	1.00 0.00 0.83 1.00 2.00 1.00 5.83	1.00 0.00 0.83 1.00 1.00 5.83	1.00 0.00 0.83 1.00 1.00 5.83	1.00 0.00 0.83 1.00 1.00 5.83	1.00 0.83 0.83 1.00 1.00 5.83	1.00 0.00 0.83 1.00 1.00 5.83				
Male 1.ANXIETY/ 2.REIGHT 3.COGNITIV 4.DIURNAL 5.EETARDAN 6.SLEEP DI	1.ANXIETY/ 2.REIGHT 5.COGNITIV DIURNAL F.RETARDAL SLEEP DI	1.ANXIETY/SOHATIZATION 2.MEIGHT 3.COCHTIVE DISTURBANCE 4.DIURAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.17 0.00 0.67 0.00 2.25 1.00	1.17 0.00 0.67 0.00 2.25 1.00 5.08	1.17 0.00 0.67 0.00 1.00 5.08	1.17 0.00 0.67 0.00 1.75 4.58	1.17 0.00 0.67 0.00 1.75 4.58	0.50 0.33 0.33 1.00 2.83	0.50 0.00 0.33 0.00 0.25 1.08	0.50 0.00 0.33 0.00 1.00 2.58	9.50 0.00 0.00 0.25 0.33	0.33 0.00 0.00 0.00 1.00
Female 1.ANXIETY/SON 2.WIGHT 3.COGNITYE D 4.DIURNAL VAN 5.RETARBATION 6.SLEEP DISTU	1.ANXIETY 2.MEIGHT 3.COGNITI 1.DIORNAL 3.RETARDA 3.SLEEP D	1. ANXIETY/SOMATIZATION 2. WEIGHT 3. COGNITIVE DISTUBBANCE 4. DIUGNAL VARIATION 6. SLEEP DISTURBANCE 7. Total score	0.83 1.00 1.00 2.00 1.67	0.83 0.00 1.00 1.00 2.00 6.50	0.83 0.00 1.00 2.00 6.33	0.83 0.00 0.83 1.00 1.50 5.83	0.83 0.50 0.50 1.00 4.33	0.83 0.00 0.50 1.00 1.00 4.33	0.83 0.50 1.00 1.00 1.00 4.33	0.83 0.00 0.50 1.00 1.00 4.33	0.50 0.50 0.50 0.50 1.00 2.50	0.50 0.50 0.50 0.50 2.50
Fenale 1.ANXIETY/ 2.WEIGHT 3.COGNITIY	1. ANXIETY/ 2. WEIGHT 1. COGNITIV	1 ARXIETY/SOHATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE	0.83 0.00 1.00	1.00	1.00 0.00 0.67	1.00 0.00 0.67	1.00 0.00 0.67	1.00 0.00 0.67	1.00 0.00 6.67	0.50	0.50 1.00 0.50	0.50 1.00 0.50

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## PHARMACIA CNS RED

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		ı		HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	E: FACTOR AND	TOTAL	SCORE								
entre	Patient	entre Pationt Treatment	Sex	Hamilton depression rating scale	Screen Day		y 7 Da	y 14 Da	y 21 Da	y 28 D	ay 35 De	0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 56	1y 49 De	ıy 56	
<b>«</b>	31	Reboxetine	Female	4.DIURNAL VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	1.00 1 2.00 2 1.33 1	1,00 1,33 6.33	1.00 1.50 1.33 5.50	1.00 1.50 1.33 5.50	1.00 1.50 1.33 5.50	1.00 1.50 1.33 5.50	1.00 1.50 1.33 5.50	1.00 1.00 0.67 3.67	1.00 1.00 0.67 4.67	1.00 1.00 0.67 4.67	
	32	Fluoxetino	Female	1. ANXIETY/SONATIZATION 2. WELGHT 3. COGNITIVE DISTURBANCE 4. DUINMAL VARRATION 5. RETARBATION 6. SLEEP DISTURBANCE 7. Total score	1.33 1 0.00 0 0.83 0 1.00 1 2.00 1 7.17 6	1.33 0.00 0.67 1.00 1.75 2.00 6.75	1.33 0.00 0.67 1.00 1.75 6.75	1.33 0.00 0.67 1.00 1.75 6.75	1.00 0.00 0.33 1.50 1.50 5.17	1.00.1.1.4 0.00.00 0.00.00 0.00.00	1.00 0.00 0.00 1.00 0.75 0.67	0.67 0.00 1.00 0.75 2.42	0.33 0.00 0.00 0.25 0.00	0.33 0.00 0.00 0.25 0.00	
825	6,	Reboxetine	Fenale	1. ANXIETY/SOMATIZATION 2. WEIGHT 3. COGNITIVE DISTURBANCE 4. DIUMBAL VARZATION 5. RETARBATION 6. SLEEP DISTURBANCE 7. Total score	1.33 1 0.00 0 1.67 0 2.25 2 1.33 1	1,33 0,00 0,67 1,00 2,25 1,33 6,58	0.67 0.00 0.50 1.00 0.67 4.33	0.33 0.00 0.17 1.00 0.75 2.92	0.33 0.00 0.17 1.00 0.75 2.92	0.33 0.00 0.17 1.00 0.75 2.92	0.17 0.00 0.17 1.00 0.25 0.67	0.17 0.00 0.17 1.00 0.25 0.67	0.17 0.00 0.00 1.00 0.33 1.75	0.17 0.00 0.00 1.00 0.25 0.33	
	50	Reboxetins	Female	1. ANXIETY/SOMATIZATION 2. MELGHT 3. COGNITIVE DISTURBANCE 4. DIORMAL VARFATION 5. RETARRATION 6. SLEEP DISTURBANCE 7. Total score	1.33 1 0.00 0 0.03 0 2.25 2 1.33 1	1.33 0.00 0.83 0.00 2.25 1.33									
•	51	Fluoxetine	Female	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIURMAL VAREATION 5.RETARRATION 6.SLEEP DISTURBANCE 7.Total score	1.00 1.00 1.00 1.00 1.00 1.00 1.00 1.00	1.00 0.00 1.00 1.75 1.33	1.00 0.00 0.67 1.90 1.33 5.50	0.83 0.50 1.00 1.00 4.33	0.83 0.00 1.00 4.33	0.83 0.00 0.50 1.00 1.00 4.33	0.83 0.00 1.00 1.25 4.42	0.83 0.00 0.33 1.00 1.25 4.42	0.83 0.00 0.33 1.25 1.00 4.42	0.67 0.00 0.00 1.00 0.50 2.50	
	25.2	Fluoxetine	Female	1. ANXIETY/SOMATIZATION 2. MEIGHT 3. COGNITIVE DISTURBANCE 4. DIUMBAL VAREATION 5. RETARBATION 6. SLEEP DISTURBANCE 7. Total score	1.00 1 0.00 0.00 1.00 1.00 1.00 1.00 1.0	1.00 0.00 0.67 1.00 2.75 6.75	1.00 0.00 0.67 1.00 2.75 6.75	1.00 0.00 0.67 1.00 5.92	1.00 0.33 0.33 1.25 0.67	1.00 0.00 0.33 1.00 1.25 0.67	1.00 0.00 0.33 1.00 1.25 0.67 4.25	1.00 0.00 0.33 1.25 4.25	1.00 0.00 0.33 1.00 1.25 0.67	0.17 0.00 0.33 0.75 0.67	
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### PHARMACIA CMS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1

ient	Pationt Treatment 53 Fluoxetine	Sex Fenale	HAMILTON DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE   Hamilton depression rating scale   Screen Day 0 Day 7 D   2.HEIGHT   0.00 0.00 0.00 0.00 3.00GHINTUTE DISTURBANCE   0.67 0.83 0.83 4.DIURNAL VARIATION   1.00 1.00 1.00 6.SLEED DISTURBANCE   1.67 1.67 1.67 1.67 1.67 1.67 1.67 1.67	Screen Day 0.00 0 0.67 0 1.00 1 1.67 1	AY 0 1000 0.00 0.00 1.00 2.00 1.67	CAL SCORE Day 7 E 0.00 0.03 1.00 2.00 1.67	7 Day 14 Day 21 Day 28 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35 Day 35	0.00 0.83 1.00 2.00 1.67	0.00 0.50 0.00 1.00 1.00	0.00 0.50 0.00 1.00	Day 42 Day 49 Day 0.00 0.00 0.00 0.50 0.50 0.00 0.00 0.00	ay 49 D	% 56 0.00 0.33 0.50 0.33
	Fluoxetine	Male	7.Total score 1.ANXIETY/SONATIZATION 2.WEIGHT 2.WEIGHT 4.DIURAL VARIATION 6.SLEEP DISTURBANCE 7.Total score 7.Total score	6.67 1.17 0.00 0.83 1.06 2.00 1.67	6.83 1.17 1.00 2.00 1.67	6.83 0.00 0.00 1.00 2.00 2.00 6.67	6.50 0.67 0.08 1.00 1.25 0.67	6.50 0.50 0.00 1.00 0.75 0.75	2.83 0.50 0.33 1.00 0.67 3.25	2.83 0.50 0.00 0.33 1.00 0.75 0.67	2.83 0.00 1.00 0.25 2.08	2.83 0.33 0.25 0.33 2.06	1.50 0.00 0.17 0.25 0.33
	Fluoxetine	Female	1. AKXIETY/SOHATIZATION 2. NEIGHT 3. COGNITYUE DISTURBANCE 4. DIURAKL VARIATION 5. RETARDATION 6.SLEEP DISTURBANCE 7. Total SCOPE	2.00 2.00 1.33 2.00 2.00 10.00	2.00 2.00 2.00 2.00 2.00 10.67	0.83 0.00 0.50 2.00 1.00 1.67	1.00 0.00 1.00 1.67 4.92	0.33 0.00 0.00 0.75 1.00	0.67 0.00 0.17 0.00 0.25 0.67	0.17 0.00 1.00 0.00 1.00 1.00	0.17 0.00 0.00 0.50 0.67 1.33	0.00 0.00 1.00 0.50 0.67 2.17	0.00 0.00 0.00 0.00 0.50 0.67
	Fluoxotino	Fenale	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIURANA VARIATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	0.83 1.33 1.00 2.25 1.00	0.83 1.33 2.00 1.00 7.42	1.17 0.00 1.50 2.75 1.33 8.75	1.00 1.00 1.75 1.33 5.08	1.00 2.00 0.83 2.00 2.00 2.00 6.67	1.33 0.00 0.67 2.00 2.25 1.33 7.58	1.67 0.00 1.17 1.00 1.75 2.00 7.58			
	Fluoxetine	Female	1.ANXIETY/SOMATIZATION 2.WEIGHT 3.COGNITIVE DISTURBANCE 4.DIURANT VARAATION 5.RETARRATION 6.SLEEP DISTURBANCE 7.Total score	1.17 0.00 0.83 0.00 2.50 1.33 5.83	1.17 0.00 0.83 0.00 2.50 1.33 5.83	1.17 0.00 0.83 0.00 2.50 6.67	0.67 0.00 0.50 0.00 2.25 0.33 3.75	0.67 0.17 0.00 2.25 0.33 3.42	0.50 2.00 0.17 0.00 1.67 6.33	0.33 0.00 0.17 0.00 0.75 1.92	0.33 0.17 0.00 0.00 0.50 0.67	0.33 0.10 0.17 0.00 0.25 0.67	0.50 1.00 0.17 0.00 0.25 1.92
	Fluoxetine	Male	1.ANXIETY/SOMATIZATION 2.MEIGHT 3.COGNITIVE DISTURBANCE 4.DIUBMAT VARIATION 5.RETARBATION 6.SLEEP DISTURBANCE 7.Total score	1.67 2.00 1.00 2.00 1.67 1.67	1.67 0.00 0.83 1.00 2.00 1.33 6.83	1.50 0.00 0.83 1.00 2.00 1.33	1.67 2.00 1.00 2.00 1.33 8.83						

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CMS R&D	TOCOL, 20124/016 0.: 12.1	ALE: FACTOR AND TOTAL SCORE	Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 56	1.67 1.67 1.33 1.33 1.67 1.00 1.00 1.01 0.00 2.00 1.47 1.17 1.17 1.00 1.00 0.00 0.00 0.00 1.00 1.00 1.50 1.50 1.50 1.50 1.50 1.00 1.00 1.00 1.00 1.33 6.33 6.33 6.00 5.83 8.50	
PHARMACIA CMS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 12.1	HAMILION DEPRESSION RATING SCALE: FACTOR AND TOTAL SCORE	Hamilton depression rating scale	1.AWKIETY/SOMATIZATION 2.WILGHT 3.COGNITIVE DISTURBANCE 4.DIURMAL VAREATION 5.RETARDATION 6.SLEEP DISTURBANCE 7.Total score	
			Sex	Жало	
			Centre Patient Treatment	Roboxetine	
			re Patie	11s	827
			Cents	23	

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

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Montgomery Asberg Depression Rating Scale	01.REPORTED SADNESS 02.INDER TENSION 03.APRAENT SADNESS 04.SILCIDAL THOUGHTS 05.INDERLITY TO FEEL 07.PESSIMISTIC THOUGHTS 09.CONCENTRATIONS DIFFICULITES 19.REDUCED SIEEP 10.REDUCED SIEEP 11.TOTAL SCORE	01.REPORTED SADNESS 02.INNER TENSION 03.APARENT SALNESS 04.SUICIDAL THOUGHIS 04.SUICIDAL THOUGHIS 06.INMENIA 06.INMENIA 07.PESSIHISTIC THOUGHIS 09.EXDUCED APPETITE 11.TOTAL SEOF	01.REPORTED SADNESS 02.INHER TENSION 03.APPARENT SADNESS 04.SULCIDAL THOUGHTS 05.INERTIA 06.INABLITY TO FEL 07.PESSIMISTIC THOUGHTS 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	01.REPORTED SADMESS 02.INMER TENSION 03.APPARENT SADMESS 04.SUJCIDAL TROUGHTS 06.INABILITY TO FEEL 07.PESSIAISTIC TROUGHTS 09.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED SLEEP 11.Total score
	1 01.REPORTED SADNESS 02.INGER TENSION 03.APPRENT SADNESS 04.SUTCIDAL TROUGHTS 05.INGRITA 06.TABABLILY TO FEEL 07.PESSIMISHIC THOUGHTS 09.REDUCED RIEFP 10.REDUCED REPEITE 11.Total score	1 01.REPORTED SADMESS 02.IMMER TENSION 03.APREMT SADMESS 04.SUICIDAL THOUGHIS 05.IMBETIA 06.IMBETIA 06.CHABILITY TO FEEL 07.PESSIAISTIC THOUGHTS 09.EEDUCED SIEEP 10.EEDUCED APPETITE 11.TOTAL SCORE	1 01. REPORTED SADMESS 02. INMER TENSION 03. APPRENT SADMESS 04. SUICCIDAL THOUGHTS 05. INMERITA 06. INMERITA TO FEEL 07. PESSIMISTIC THOUGHTS 09. CHOCKTRAIN TONS DIFFICULTIES 09. REDUCED SIREP 10. REDUCED APPETITE 11. Total score	1 01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SULCIDAL TROUGHTS 05.INABLILTY TO FEEL 07.PESSIMISTIC TROUGHTS 09.CHOCKSTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APELITE 11.Total score
Scale Montgomery Asberg Depression type Rating Scale		-	F	-
		•		
Sex type	Hale 1	Male 1	Female 1	Female 1
Sex type	Hale 1	Male 1	ino Femalo 1	Female 1
Sex type	-	-	Female 1	-
Sex type	Hale 1	Male 1	ino Femalo 1	Female 1
Sex type	Hale 1	Reboxetine Male 1	ino Femalo 1	Female 1
Scale type	Hale 1	Reboxatine Male 1	Fluoxetine Female 1	Reboxetine Female 1

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PHARMACIA CNS RED REBUXETINE - PROTOCOL 20124/016 Listing No:: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

2 Fluoxetine Female 1 01 02 05 05 05 05 05 05 05 05 05 05 05 05 05	sex type kating Scale	Day 0 Di	Day 7 D	Day 14 De	Day 21 Da	Day 28 Da	Day 35 De	Day 42	Day 49	Day 56
S Fluoxetine Male 1 34 Reboxetine Male 1										
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C. 33 Fluoxetine Female 1 34 Reboxetine Male 1	-	N	61	**	~	64				
G & & & & & & & & & & & & & & & & & & &	02.INNER TENSION	61	101	101	18	N				
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G. S. Reboxetine Male 1	05.INERTIA	m	· m	· 07	- ო	- m				
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Reboxetine Male 1								:	!	!
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9 6	07.PESSIMISTIC THOUGHTS		-	•	<del>-</del>	-		-		
•	09.REDUCED SLEEP	r- (r	<b>•</b> "	۰ ،	٠,	<b>-</b>	64 6			
10.	10.REDUCED APPETITE		0	0		. 0	10	۰.		

PHARMACIA REBOXETINE - PRO Listing N
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Centr	e Patie	Centre Patient Treatment	Sex	type	nontgomeny asperg Depression Rating Scale	Day 0	Day	7 Day	14 Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
М	శ్	Reboxetine	Hale	+	11. Total score	5		e P	7 5	ស	9	vo		
	e S	Rebuxetine	Fenale	-	01. REPORTED SADMESS 02. INNER TENSION 03. APPERENT SADMESS 04. SULCIDAL THOUGHTS 05. INBELITY TO FEEL 07. PESSIHISTIC THOUGHTS 09. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	<b>బబ</b> -0801-00-5		021-021-11-12	0	w	40-44-04-5	- 22 - 0 24 - 0 20 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		00-0
839	* 830	Fluoxatine	м п 10	-	01. REPORTED SADNESS 02. INNER TENSION 03. APPRENT SADNESS 04. SUZCIDAL THOUGHTS 05. INERILAY 06. INBLILTY OF PEEL 07. PESSIMISTIC THOUGHTS 09. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED SLEEP 11. Total Score	***************************************			.0.000.00.000	000000000	accoccoco	0000000000	000000000	
	37	Reboxatine	Hale of	-	01. REPORTED SADNESS 02.INNER TENSION 03.APPERRIT SADNESS 04.SULCIDAL THOUGHTS 05.INBRILITY TO FEEL 07. PESSIAISTIC THOUGHTS 09. CONCENTRATIONS DIFFICULIES 09. REDUCED RAPETIE 10.TOKAL SHOPE	w								
	<b>80</b> 67	Fluoxetine	Male	-	01.REPORTED SADMESS 02.INNER TERSION 03.AFRERIT SADMESS 04.SULCIDAL THOUGHIS 05.INERTIA THOUGHIS 05.INERTIAT TO FEEL 07.FESSIALSTIC THOUGHIS 09.COUNCETRALIONS DIFFICULTIES	W 44		~~~~~~~		0-000000	\$\$000000			

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PHARMACIA CNS R&D SBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0 HONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre Patie	Centre Patient Treatment	Sex	Scale type	Hontgomery Asberg Depression Rating Scale	Day 0	Day	7	Day 14 Di	Day 21 Da	Day 28 Da	Day 35	Day 42	. Day 49	- 1	Day 56
38	Fluoxetine	Hale	-	10.REDUCED APPETITE 11.Total score	0 ST		- =	- 2	<b>-</b> 0	۰-	o -				
66	Fluoxetino	Kale	~	01.REPORTED SADMESS 02.INER TENSION 03.APPARETT SADMESS 04.SULTCIAL THOUGHTS 05.INERTIA TO FEEL 06.INBALLTY TO FEEL 07.PESSINESTIC THOUGHTS 09.CONCENTRATION DIFFICULIES 10.REDUCED APPETITE 11.REDUCED APPETITE											
\$ 831	Reboxetine	Жаде	7	01.REPORTED SADNESS 02.INER FERSION 03.APPARENT SADNESS 04.SULCIDAL THOUGHTS 05.INERITA 06.INERITA TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	01-01-01-00-0 <u>5</u>		00000 <u>0</u>	044 <b>-</b> 6	00000						
£	Fluoxetine	Hale	~	01.REPORTED SADNESS 02.INNER TERRIOR 03.APPRENT SADNESS 04.SULCIDAL THOUGHTS 05.INERIA 06.INBILITY TO FEEL 07.PESSINISTIC TROUGHTS 09.CONCENTRATIONS DIFFICULTIES 10.REDUCED SIERP 11.Total score			-0-08880 <b>-</b>		60606690000	F0F00700709	00-00004		707007070	0-000000	0-00-00000
ठ र	Reboxetine	Fenale	16	01. REPORTED SADMESS 02. LYNER TENSION 03. APPARENT SADMESS 04. SULCIDAL THOUGHTS 05. INBELITY TO FEEL 07. PESSINISTIC TROUGHTS 08. CONCENTRATIONS DIFFICULTIES		~~~~~~~		0-00-0	00707077	0.006.66	0-00-0			000	0++0++04

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HONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Centre Patient Treatment	Xe X	Scale type	Hontgomery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28 Da	Day 35 D	Day 42 De	Day 49 [	Day 56	
61	72	Reboxetine	Female	-	09.REDUCED SLEEP 10.REDUCED APPEITE 11.Total score	2 = 6	2 T 2	446	a		£04	~ o ¢0	£0 &	-07	
	83	Reboxetine	Fomale	<del>-</del>	01.REPORTED SADNESS 02.INNEW TENSION 03.APARENY SADNESS 04.SUICIDAL THOUGHTS 05.INEWILA 06.IMBALITY TO FEEL 06.IMBALITY TO FEEL 09.REDUCED SLEEP 10.REDUCED SLEEP 10.REDUCED APETITE 11.Total score	0 0 0 T 0 0 C T 0 C V	44440444E		0-00-00	000000		00	0-000-0	6404400440	
832	\$	Fluoxetime	<b>н</b> Э.	<del>.</del>	01.REPORTED SADNESS 02.INNER TERSION 03.APPARENT SADNESS 04.SUICTDAL THOUGHTS 05.INERTLY TO FEEL 06.INABLITY TO FEEL 09.PESSATISTIC THOUGHTS 09.CONCENTRATIONS DIFFICULIES 10.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	<b>ରଖରଖରଖର</b> ଖର ଓ ୦ ଫୁ	*****	000000000000000000000000000000000000000	0-00-0004	0.00640640	0-00+00-00M	0-00-0-7-09			
	<b>3</b>	Reboxetine	Fomale	N	01. REPORTED SADNESS 02. INNER TERSION 03. APP ARENT SADNESS 04. SULCIDAL THOUGHTS 05. INRALITY TO FEEL 06. INRALITY TO FEEL 09. RESCHISTIC THOUGHTS 09. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	0-000000 <del></del> 5		**************************************	0-0-00004	0-0-00004	0000-77000	<b>\$07707000</b>	0-00-00-00	0-00-00-00	
	47	Fluoxetine	Fenale	•	01. REPORTED SADNESS 02. INNER TERSION 03. APPARENT SADNESS 04. SULTIDAL TROUGHTS 05. INNERTIA 06. INARLITY OF PEEL	0004444			0-0000	0-0000	0-00000	000000	0-0000	0-0000	

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PEARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No:: 13.0 HONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Centre Patient Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day	7 Day	Day 14 Day 21	21 Day 28	Day	35 Day 42	42 Day 49	49 Day	56
83	47	Fluoxetine	Fenale	-	08.CONCENTRATIONS DIFFICULTIES 10.REDUCED APPETITE 11.Total score	4444		01 01 <b>44 80</b>	o4	~~ o m	6 0 0		<b></b> 02	1 0 2	
	89	Reboxetine	Female	-	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL TROUGHTS 05.INERTIA TO FEEL 06.INBALLIY TO FEEL 09.RESULEDS 10.RESULEDS SLEEP 10.REDUCED APPETITE 11.Yotal secre	aaa++aaa <b>a</b> a4 <b>€</b>		222223222	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	8000000°	0001001-E	2011-01-0004 2011-01-0004	881088 <u>6</u>	លលសក្កក <b>ព</b> ទ្ធបលស៊្	44444444444444444444444444444444444444
833	<b>Q</b>	Fluoxetine	м а 1 о	-	01.REPORTED SADNESS 02.INDER TERBITOR 03.APPARENT SADNESS 04.SUICTDAL THOUGHTS 05.INBRILITY TO FEEL 06.INBRILITY TO FEEL 09.RESUMED SIERP 10.REDUCED SIERP 10.REDUCED APPITIE 11.Total score	0-00000-00 <u>+</u>				0000	00000	0 0 0 7 7 0 7 0 0 0 0	000000-0	000077 <b>0070</b> M	. 0000##0#00#
m	65	Fluoxetine	Female	-	01. REPORTED SADRESS 02. INRER TENSION 03. APPARENT SADRESS 04. SULTCIAL THOUGHTS 05. INERTIAL TO FEEL 07. PESSILISTIC THOUGHTS 09. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED APPETITE 11. TOKAL SCORE	44444444444444444444444444444444444444		8885855885 <mark>6</mark>	-00401-E	44444444444444444444444444444444444444	£01-001-1000°	- 0 - 0 0 0 <b>0</b>	-0-0	-0-0	-44-0-0-0-07
	99	Fluoxotino	Female	-	01.REPORTED SADNESS 02.INER TERSION 03.APPARENT SADNESS 04.SUTCIDAL THOUGHTS 05.INERTA 06.INABILITY TO FEEL	200404		000	000	00C0CC					•

PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0
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Centre Patient Treatment	Treatment	Sex	Scale type	Montgonery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21	Day 28 Da	Day 35 Bay	Bay 42 Day	64	Day 56
99	Fluoxotine	Female	۲-	07.PESSIMISTIC THOUGHTS DB.CCNCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total store	44404	2002-2	2222	0000 <b>©</b>					
	Reboxetine	Female	~	01.REPORTED SADNESS 02.IMPR TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 06.IMPRILITY TO FEEL 07.PRESILISTICT THOUGHTS 09.RESILISTICT THOUGHTS 09.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE	<b>Რ</b> െഡ് പെ പെ പെ പെ പ് പെ പ് പ്	0 = 0 = = 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		0-0-000-00	90000-00				
<b>3</b> 8 3 4	Reboxetime	Female	-	01.REPORTED SADNESS 02.THURE TENSION 03.APPARENT SADNESS 04.SUICTDAL THOUGHTS 05.THURTIA 05.THURTIA TO FEEL 07.PESSIMISTIT THOUGHTS 08.COUNCENTRAITONS DIFFICULTIES 09.REDUICED SLEEP 10.REDUICED APPETITE		i	·	. +นะอะหมหมนั	- 44-0-4-44 M				
4	Reboxetine	Female	-	01.REPORTED SADNESS 02.INIER TENSION 03.APPARENT SADNESS 04.SUICIDL INOUGHTS 05.INERTIA TO FREI 07.FESSIMISTIC THOUGHTS 08.CONCENTRATION DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE	00000000000	000000000	000000000	0000077704	000000707	0000000707		000000000	000000000
86	Fluoxetine	Female	٣	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 06.SULCIDAL THOUGHTS	<b>85858</b>	***	*0~~	0.0404	N <b>O</b> M N O	00070		0000	0000

S	tre P	atient	Centre Patient Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 6	Day	7 Da	Day 14 Da	Day 21 Day	82	Day 35 Day	27	Day 49 De	Day 56	
*	ëñ.	86	Fluoxotino	Fomalo	-	06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRALIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPEITE 11.Total score	20 E E SE		-0000 <u>6</u>	0445	00001540	40000	00000	000404	0004	00000	
	835	66	Fluoxotine	Female	-	101.REPORTED SADMESS 02.INMER TENSION 03.APARENT SADMESS 04.SULCIDAL THOUGHTS 05.INMELTA 06.INMELLY TO FEEL 07.PESSIAUSTIC THOUGHTS 09.EGDUCED SILERP 10.REDUCED APPETITE 11.Total score	ии w и и и и и о и с е е		4000000000								
		90	Reboxetine	Hale	<b>~</b>	01.REPORTED SADWESS 02.INWER TENSION 03.APPRERT SADWESS 04.SUICCIDAL THOUGHTS 05.INARILIY TO FEEL 07.PESSIALSTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED AFPETITE 11.Reduced APPETITE	w <i>a</i> 400005										
	•	101	Reboxetine	Female	•	01. REPORTED SADNESS 02. INNER TENSION 03. APPRENT SADNESS 04. SUICIDAL THOUGHTS 06. INBELLIY TO FEEL 07. PESSINISTIC THOUGHTS 09. REDUCED SIEEP 10. REDUCED SIEEP 11. Total score	£820028££££		00-000000 <u>6</u>	-40400-2	0-0000-0-0		w-0000-0-5	0-00000-040	00007770700	0010102777	
	•	102	Fluoxetine	Female	-	01. REPORTED SADNESS 02. ITANER TENSION 03. APPARENT SADNUSSS 04. SHITCTIAN TRANICESS			0000	0000	0 - 0 c		- 0		# 22 F F	9	

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	Centre Patient Treatment	Sex	Scale	e Montgomery Asberg Depression e Rating Scale	Day 0	Day	7 Day 14	4 Day 21	Day 28 D	Day 35 Da	Day 42 D	Day 49 1	Day 56	
4	102	Fluoxetine	Fomale	}	1	W=0405		#00NF04		000000	24.04405			-0	
300	§ 836	Fluoxetine	Female	<del>-</del>	01.REPORTED SADNESS 02.INMER TENSION 03.APPRENT SADNESS 04.SUTCIDAL THOUGHTS 05.INMELITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE	<b></b>		<b>କ୍ରାକ୍ରାକ୍ଟ୍ର</b>	2,822,922,922,922,922,922,922,922,922,92	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~			•	
	104	Reboxetine	Female		1 01.REPORTED SADNESS 02.INVER IENSION 03.APPRENT SADNESS 04.SUICIDAL THOUGHTS 05.INVERIA 06.INVALILIY TO FEEL 07.PESSIMISTIC TROUGHTS 08.CONCENTRATION DIFFICULIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	w-4-444-4405		W-0-00-04-05	& - 0 - 0 0 - 0 0 & 0 0 0 0 0 0 0 0 0 0	0N00 <b>0</b>		700000000			
	105	Fluoxetine	Hale	•	1 01 REPORTED SADNESS 02.INNER TENSION 03.AFRRENT SADNESS 04.SUTCIDAL TROUGHTS 05.INABILITY TO FEEL 07.PESSALMISTIC TROUGHTS 08.CONCENTRATIONS DIFFICULTIES 10.REDUCED SIEEP 11.TOTAL SCORE	8-4-44444465 <u>+</u>	4000000000	wed-nwadae5	2 2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3	w-0-0w005	8 - 8 - 4 8 4 4 7 7 8 - 8 <del>2</del>	wo 01 = 01 w - 01 01 0 5	w-0-0w-0-0 <del>-</del>	0-0-09-00- <u>0</u>	
ις	129	Reboxetine	Female		1 01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS		<b>600</b>			0 0 F					

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0 PHARMACIA CNS R&D

HONTGOMERY ASBERG DEPRESSION RATING SCALE

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Day 49 Day 56 Day 42 Day 35 7 Day 14 Day 21 Day 28 Day 0 Day Montgomery Asberg Depression Rating Scale 04.SUICIDAL THOUGHTS 05.INERTIA Scale Female Female Female Female Sex Reboxetine Reboxetine Centre Patient Treatment 195 193 194 130 129 837

Male

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			Day 42	***	- 00	, 00-F-0	2444444			-
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C&D	3.0	N RA	Day		•	-	•	-	a	
PHARMACIA CNS RED	REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0		1		07. PESSILISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED AFFETTIE 11. THAI SCORE		05.IMERTIA 06.IMERILIY TO FEBL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFICULTIES 09.REDUCED APPETITE 10.REDUCED APPETITE 11.Total score	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.AUGUTICAL, THOUGHTS 05.INDRILLTY FOR FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATION DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED SLEEP 11.Total score	01.REPORTED SADNESS 02.INKER TENSION 03.APPARENT SADNESS 04.SUITIDAL THOUGHTS 05.INRETA 07.PESSIMISTIC THOUGHTS 08.CONCENTRATION DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	01.REPORTED SADNESS
		Scale	type	-		-		-	-	~
			Sex	Male		Female		Male	Female	Female
			Treatment	Fluoxetine		Reboxetine		Fluoxetino	Fluoxetine	Reboxetine
		:	Centre Patient Treatment			196	838	197	321	322
			ů ů						£	

PHARMACIA CNS RED
REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Contre	Patient	Contre Patient Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day	0 Day	7 Day	/ 14 Day	y 21 Day	/ 28 Day	S	Day 42 Day	64	Day 56
<b>£</b>	322	Reboxetine	Fenale	-	02.IMMER TENSION 03.APPARENT SADNESS 04.SUICTOAL THOUGHTS 05.IMMERIA 05.THABILITY TO FEEL 07.PESSIRISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SIEEP 10.REDUCED APPETITE	ă ă	<b>๛๛๛๛๛๛๛๛</b>		00-000000 <u>6</u>	# 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<b>20000000000</b>	00-0-0-0-0- <u>0</u>	0=000=000 <del>0</del>	0 <i>000000</i> -4	0-0-00-0
	<b>83</b> 9	Fluoxetine	Female	-	01.REPORTED SADNESS 02.IMBR TENSION 03.APPARENT SADNESS 04.SUICIDAL TROUGHTS 05.IMBRILA 06.IMBRILA 07.PESSIMISTIC TROUGHTS 09.CONCENTRATIONS DIFFICULTIES 09.REDUCED SIEEP 10.REDUCED REIEP 11.Total Score		200000-0000	404-44	0-00-0-0-04	0000000000	0000000000				
	324	Rebaxetine	Fenale	-	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SULTIDAL THOUGHTS 06.INBRILLTY 06.INBRILLTY 07.PESSENISTIC THOUGHTS 09.REDOCED SLEEP 10.REDOCED RAPELITE 11.Total score	8	000000000000000000000000000000000000000	80877000000	080000-5	00000000000000000000000000000000000000	0000000- <del>0</del>	4440-440 <u>\$</u>	N0-000		77700787007
	325	Reboxetine	Гета1 е	<b>-</b>	01.REPORTED SADMESS 02.INTER TENSION 03.APPARENT SADMESS 04.SINCTOBA. THOUGHTS 06.INERTIA. 06.INABILITY TO FEEL 07.RESSIMISTIC THOUGHTS 09.CONCENTRATIONS DIFFICULTIES 10.REDUCED SLEEP 10.REDUCED SLEEP 10.REDUCED APPETITE	•	W = 0 = 0 0 0 0 = 0 0 5	000-000-00 <sup>2</sup>	0-00000-0-£	-0-00-0-0-0-		0-000x	-0-0-00	00-0-0-0-04	00-0-000

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

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HONTGOMERY ASBERG DEPRESSION RATING SCALE

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	Sex	Female	Female	Fепа Le	Femalo	Male
	Treatment	Reboxetine	Fluoxetine	Reboxetine	Fluoxetine	Reboxetine
	Centre Patient Treatment	333	88 8	§ 842	393	35
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PHARMACIA CNS RED	REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0	MONTGOMERY ASBERG DEPRESSION RATING SCALE	Montgomery Asberg Depression Rating Scale	10.REDUCED APPETITE 11.Total score	01.EEPORTED SADMESS 02.INWER TENSION 03.APARAENT SADMESS 04.SUICIDAL THOUGHTS 05.INBILITY TO FEEL 07.PESSADMISTIC THOUGHTS 08.CONCENTRAITON DIFFICULTIES 09.REDUCED SIEEP 10.REDUCED APPETITE	01.REPORTED SADRESS 02.INNER TENSION 03.AFARENT SADRESS 04.SUICIDAL THOUGHTS 05.INSETIA 07.RESTIAL 07.PESSIMISTIC THOUGHTS 08.COUNCENTRAITIONS DIFFICULTIES	10.REDUCED APPETITE 11.Total score 01.REPORTED SADNESS 02.INHER TENSION 03.APARENT SADNESS 06.SICTICAL TAINCESTS 06.INABILITY TO FEEL 07.PESSIMISTIC TROUGHTS 08.CONCENTRATION DIFFICULTIES	10. REDUCED APPETITE 11. Total score 11. Total score 11. Total score 11. Total score 10. INPER TENSION 10. APPARENT SADNESS 10. SICCIDAL TROUGHTS 10. INBLITY 10. FESSINISTIC TROUGHTS 10. PESSINISTIC TROUGHTS 10. CONCENTRATIONS DIFFICULTIES
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			Centre Patient Treatment	Reboxetine	Reboxetine	Fluoxetine	Fluoxetine	Fluoxetine
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8 4 4	Reboxetine	Female	N ·	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SULTIDAL TROUGSTS 05.INEXTIA 06.INEXTIA 07.PESSALMISTIC TROUGHTS 09.CONCENTRATIONS DIFFICULIES 09.REDUCED APPETITE 11.Total score	<b>ታ</b> ለመ ፋ መ ፋ ፋ ፴ ፴ ወ ል		7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	8 0 0 8 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	000000					
888	Reboxetino	Male	N	01.REPORTED SADNESS 02.INNER TENSION 03.EPPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIAL THOUGHTS 05.INERTIAL TO FEEL 06.INBALLITY TO FEEL 06.INBALLITY TO SEEL 09.REDUCED SLEEP 10.REDUCED SLEEP 10.REDUCED APPLITE	কককক <b>ক</b> এবেএব		অবেবন অবেবন বব কু কু		8888-8822		0 - 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		00m00m000cc	
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PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0	KONTGOMERY ASBERG DEPRESSION RATING SCALE	Montgomery Asberg Depression Rating Scale	08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SIERP 10.REDUCED APPETITE 11.Total score	01.REPORTED SADNESS 02.LINER TENSION 03.AFPARENT SADNESS 04.SUTCIDAL THOUGHTS 05.INERTA 06.TARBILITY TO FEEL 07.PESSIMISTIC THOUGHTS 09.CONCENTRATIONS DIFICULTIES 09.REDUCED SLEEP 10.REDUCED SAPETITE 11.Total score	01.REPORTED SADNESS 02.INUR TENSION 03.APPARENT SADNESS 04.SULCIDAL THOUGHTS 06.INERTIA 06.INERTIA 07.PESSIMISTIC THOUGHTS 09.REDOCED SLEEP 10.REDOCED APPETITE 11.Fotal score	01.REPORTED SADNESS 02.INURR TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 06.INRRILA TO FEEL 07.PESSHIRSITC THOUGHTS 09.CONCENTRATIONS DIFFICULTIES 109.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	01.REPORTED SADNESS 02.INHER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INBRILATY TO FEEL
			Scale type	W	N	и	co.	N
			Sex	Female	Male	Female	Fenale	Male
			Centre Patient Treatment	Fluoxetine	Reboxetine	Fluoxotino	Reboxetine	Reboxetine
			Patient	389	330	397	392	501
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Centre	Patient	Centre Patient Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day	7 Day 14	14 Day 21	1 Day 28	Day 35	Day 42 Day 49	Day 56	
٤	501	Reboxetine	Male	8	07.PESSIMISTIC THOUGHTS 09.CCHCENTRATIONS DIFFICULTIES 09.REDUCED SIEEP 10.REDUCED APPEITE 11.Fotal score	447 <b>~</b>		25 - 1 - 3 - 3 - 3 - 3 - 3 - 3 - 3 - 3 - 3	2	2 3 0 0 0 0 22 44		1 0 0 2 1 0 0 0 2	27 0 0 E	
	502	Fluozotine	Fenale	N	01.REPORTED SADMESS 02.INBE TENSION 03.APBERT SADMESS 04.SUTCIDAL THOUGHTS 05.INBELLITY TO PEEL 07.PESSILISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	8444488884 <u>8</u>		4 พพพพพพ๗๗๗๗๗๖	2 2 2 2 3 3 3 4 4 5 5 7 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7	200000000000000000000000000000000000000			++0%%0000 <b>%</b>	
846	503	Reboxetine	Female	N	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL TROUGHTS 05.INRILITY TO FEEL 07.PESSIMISTIC THOUGHTS 09.REDOKED SIERP 10.REDOKED SIERP 11.TOTAL SCOTE	<b>កា</b> ហើយ <b>4 ស ស ស 4 4 4 4 4 4</b> 4 4 4 4 4 4 4 4 4 4		<b>ೲೲೲೲೲೲೲೲೲ</b> ೲ	ı					
	\$0 <b>.</b>	Fluoxetino	Fomale	N	01.REPORTED SADMESS 02.INRER TENSION 03.APPERENT SADMESS 04.SULCIDAL THOUGHTS 05.INRELITY TO FEEL 07.PESSIMISTIC THOUGHTS 09.CONCENTRATIONS DIFICULTIES 10.REDUCED APPETITE 11.Total score	<b>ቀ</b> ቀመቀመመለ <b>ቀ</b> የላቸ		ଅଟେ ଅପର ପ୍ରତାର କରା କରା କରା କରା କରା କରା କରା କରା କରା କ	4 W W W W W W 4 W - 50		- W W W O 4 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	000000000000000000000000000000000000000		
	505	Reboxetine	Female	81	D1.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SULCIDAL THOUGHTS 05.INREYLA	2,4 8,4 6	ಬರಣಕರ	44000	<b>ww</b> u4 <i>u</i>		48800	ოოთ ← ロ	<b>%</b> 0	

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

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NONTGONERY ASBERG DEPRESSION RATING SCALE

Centre	Patien	Centre Patient Treatment	Sex	type	Rating Scale	Day 0	Day 7	Day 14	Day 21 Day	y 28 Day 35	Day 42	Day 49	Day 56
ह	505	Reboxetine	Fema1e	N	06.IMABILITY TO FEEL 07.PESSIMISTIC THOUGHYS 08.CONCENTRATION DIFFICULTIES 19.REDUCED SLEEP 10.REDUCED APPETITE 11.TOTAL SCORE	448888	200000	00000 = 60	22862	8800000	228776		#0000 <b>%</b>
	206	Fluoxotine	Halo	И	01.KEPORTED SADMESS 02.INNER TENSION 03.APARENT SADMESS 04.SUICIDAL THOUGHTS 05.INERTIA TO FEEL 07.PESSIAISTIC THOUGHTS 09.REDUCED SLEEP 10.REDUCED SLEEP 11.TOTAL SCORE	<del></del> ଫଟ ଫ ପ ପ ପ ପ ପ ପ ପ ପ ପ ପ ପ ପ ପ ପ ପ ପ ପ	4 W W M D M W M D D &	N N F F O N F O O O O	W0000V	N T N O O T O O O O O	00-00-0000		000000000
847	507	Fluoxetine	Female	N	01.REPORTED SADNESS 02.INNER TENSION 03.APARENT SADNESS 04.SUICIDAL THOUGHTS 05.THERITA 05.THERITA 06.THERITA 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIOS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE	<b>୯୯୯ଟର ପର୍ଷ</b> ପ୍ରତ୍ତ	24400000cc		ୁ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ	www.woww.wot	00-00000 <del>2</del>		
	508	Reboxetine	Female	N	01.REPORTED SANNESS 02.INWER TENSION 03.APPARENT SADNESS 04.SULCIDA, THOUGHTS 05.INBELIA 05.INBELIA 07.PESSIMISTIC THOUGHTS 08.CONCENTRATION DIFFICULTIES 09.EEDUCED SLEEP 10.EEDUCED APPETITE	<del>ବ</del> ସ ସ କ ଉ ଘ ଘ ଘ ଘ ଘ ଘ ଘ ଘ ଘ ଘ ଘ ଘ ଘ ଘ ଘ ଘ ଘ ଘ	W 10 10 10 10 10 10 10 10 10 10 10 10 10	<del>ବ</del> କ ଲ କ ଲ କ ଲ କ ଲ କ ଲ କ ଲ କ ଲ କ ଲ କ ଲ କ	888898989 88889	LL41010400V	0000-00000		
	521	Reboxetine	Hale	N	01.REPORTED SADNESS 02.IVNRR TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS	លលលជ	<b>ক</b> কলক	ଉସଉପ		60 00 00 00	0		a

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

MONTCOMERY ASBERG DEPRESSION RATING SCALE

Centr	e Patient	Centre Patient Treatment	X S	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day	7 Day 1	14 Day 21	Day 28 Day 35	Day 42 Day 49	Day 56
ঠ	521	Reboxetine	Male	M	05.IMERTIA 06.IMABILITY TO FEEL 07.PESSIMISTIC TROUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SIERP 10.REDUCED APPETITE 11.Total score		<b>W</b>	0 m m 0 m 0 m 0 m 0 m 0 m 0 m 0 m 0 m 0	7 0 0 0 0 0 0	0 4 4 4 4 5	0770700	0-00004
\$	<b>6</b> 6	Fluoxetine	Гома 1 е	N	01.REPORTED SADMESS 02.INNER TENSION 03.APARENT SADMESS 04.SUICIDAL TADDUSTS 04.SUICIDAL TADDUSTS 06.THABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 09.ECDUCED SIEEP 10.REDUCED APPETITE 11.TOTAL SCOPE	<b>ସ</b> ସ୩ସର୩ସସରର କୁ		#4#4##################################	88840884577777	- 4 4 4 0	- 4 4 8 0 4 7 7 7 <del>2</del> <del>2</del>	<i>4</i> 40004400
	86 8 8	Rebuxetine	Female	N	01.REPORTED SADNESS 02.INNER TERSION 03.APPRENT SADNESS 04.SUTCIDAL THOUGHTS 05.IMENILTY TO FEEL 07.PESSIMISTIC THOUGHTS 08.COMPERTMALITY TO SEEP 09.REDUCED APPETITE 11.REDUCED APPETITE	<b>କ</b> ବଳବଳବକ ବଳ କଳ	-	ଜ୍ୟ ଜ୍ୟ ଜ୍ୟ ଜ୍ୟ ଜ୍ୟ ଜ୍ୟ ଜ୍ୟ ଜ୍ୟ ଜ୍ୟ ଜ୍ୟ	2228-8282-2 2228-2222-5		и-и-о-и-а- <u>б</u>	N N T T T O T T O O S
	396	Reboxetine	Female	N	01. REPORTED SADNESS 02. INNER TENSION 03. APPERIN SADNESS 04. SUTCIDAL TROUGHTS 05. INRETIA 06. INABILITY TO FFEL 07. PESSIMISTIC THOUGHTS 09. CREDUCED RIFFI SIFFE 10. REDUCED APPETITE 11. TOTAL SCORE	<u> </u>		ଷ୍ୟୱଦପଷ୍ୟ <del>ୟ</del> ଧ୍ୟ ପ୍ରଥି	8 8 8 8 7 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	00004000000000000000000000000000000000	. 2	~~~~~~~~
	400	Fluoxetine	Male	61	01, REPORTED SABNESS 02, INNER TENSION	4.0		ოო	£ 23	n n	4- 4-	-0

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

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NONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	Patient	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	19 Day 56	
4	000	Fluoxotine	Male	N	04.SUICIDAL THOUGHTS 05.INERTIA 06.INABILITY TO FEEL 07.PRESTHISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total store	<b>ቀ</b> ቀወቀቀመሪሪ	000000-6	-000-00 <u>E</u>	-444-44-5	N-N-N-04.	00770700	0070004	
8	401	Fluoxetine	Fomals	N	01.REPORTED SADMESS 02.INNER TENSION 03.APPARENT SADMESS 04.SUICIDAL THOUGHTS 05.INRETIA 06.INRETIA 07.PESSIMISTIC THOUGHTS 08.COUCHTNEATIONS DIFFICULTIES 09.REDUICED SLEEP 10.REDUICED APPETITE 11.Total score	<b>ተ</b> ቀመ <b>ቀ</b> መመቀቀበበ <b>0</b> 0	<b>₩₩₩₩₩₩₩₩₩₩₩₩₩</b>	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	0101110110	000 <del>0000</del> 5	4444-0 <b>8</b>		
49	402 4	Reboxetine	Female	N	01.REPORTED SADMESS 02.IMURA TENSION 03.APARENT SADMESS 04.SUTCIDAL THOUGHTS 05.IMURILA 06.TABBLITY TO FEEL 07.PESSIMISTIC TROUGHTS 08.CONCENTRATIONS DIFFICULTIES 10.REDUCED APPETITE 11.Total score	<b>ፋ</b> ለመ <b>ፋ</b> መመቀፋሪሪላች	44000040040	00000-080- <u>F</u>	80001000010	00000000000000000000000000000000000000	-4440-44-00 <b>-</b>	0000000000	
	403	Reboxetine	Female	N	01.REPORTED SADNESS 02.IMURE TENSION 03.APARENT SADNESS 04.SUICIDAL THOUGHTS 05.IMURLITY TO FEEL 06.IMURLITY TO FEEL 07.PESSIALISTIC THOUGHTS 08.CUNCENTRATIONS DIFFICULTIES 09.REDUCED SIERP 10.REDUCED SIERP 11.Total Score	<b></b> ଫଟଟଟଟଟଟ ପର କ୍	0 - 0 - 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	99991999 <del>1</del> -5	0 7 10 10 10 10 10 10 10 10 10 10 10 10 10			00000000000	
	<b>4</b> 0 <b>4</b>	Fluoxetine	Female	8	01.REPORTED SADNESS 02.TNNFP TENSTON	471	47 1	m 4	N C	₩,	€.	0	_

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

Centre	Patient	Centre Patient Treatment	Sex	Scale	Montgomery Asberg Depression Rating Scale	Day 0	Day	7 Day	<b>4</b>	Day 21 D	Day 28 Day 35	Day 42	Day 49 Day	8	
<b>\$</b>	<b>404</b>	Fluoxetine	Female	N	03.APPAEENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA TO FEEL 07.PESSHIGHT TO FEEL 07.PESSHIGHT THOUGHTS 08.CONCENTRATIONS DIFFICULIES 10.REDUCED SLEEP 11.Total Score	କ୍ଷର ବ୍ୟସ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ମ କ୍ଷ୍ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ୍ୟ କ୍ଷ		ឧឧឧឧឧឧ	8-1000000	2-0	01-0001-101			000010101	
85	405	Fluoxotine	Fomale	61	01.REPORTED SADNESS 02.IMPR TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.IMERILAT TO FEEL 06.IMABILITY TO FEEL 09.REDUCED SIERP 10.REDUCED SIERP 11.TOTAL SCOPE	<b>ታ</b> ቀመመመጥታታጣለ <u></u>		4444 <del></del>		00070070700	000770077700	000000000		00 <b>-000-</b> 000	
0	90	Fluoxetine	Fomale	N	01. REPORTED SADNESS 02. INRET ETRICION 03. APPARENT SADNESS 04. SUTCIDAL THOUGHTS 05. INRETIA. 05. INRAILITY TO FEEL 07. PESSIMISTIC THOUGHTS 09. REDUCED SLEEP 10. REDUCED APPETITE 11. IDIAL SCORO	<b>ች</b> ፋፋሲ መሪካ ላ ይ		W440004004 W4400004004	ተቀቀውጠቀቀለጠ F M	<b>44400000000000</b>					
	407	Reboxetine	Hale	N	01.REPORTED SADNESS 02.INNER TENSION 03.APPRENT SADNESS 04.SUICIDAL TROUGHTS 05.INSETIA 06.INABLILTY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENRALINESD DIFFICULITIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.ROTAL SCORE	<b></b> ተለወ4ወ4ወ4 <i>ጠ</i> 60		ታለታታለታለታለም 60 00	<b>ସସସସଲଲେସ</b> କ <b>୮</b> ଲ	<b>୯୯୯୯୯୯୯୯୯୯</b> ୯ ୯	ୁ ୩ ଏ ଏ ଏ ଏ ଶ ଶ ଶ ଶ ଶ ଶ ଶ ଶ ଶ ଶ ଶ ଶ ଶ ଶ ଶ	<b>ୁ ଅଟେ ଅଟି ଅଟି ଅଟି ଅଟି ଅଟି ଅଟି ଅଟି ଅଟି ଅଟି ଅଟି</b>			
	408	Reboxetine	Female	7	01.REPORTED SADNESS		4	ø	81	N	es	-			

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REBOXETINE - PROT Listing No.: 13.0

HONTGOHERY ASBERG DEPRESSION RATING SCALE

Day S6	* <b></b> 0000-			
Day 49 De				00 W 40 00 00 00 00 00 00 00 00 00 00 00 00
- 1		4 W W W W W 4 4 0 0 0 0	2012000010 <b>0</b>	00 <b>2000000</b>
Day 42			,	
Day 35				
Day 28	0001-001-05	44640000000000000000000000000000000000	6600000000 <del>0</del>	ののののとのののとしなる。
Day 21 D	0801-0080 <del>-</del> 0	ተመመለ⊏ መተመ <i>ዘ</i> መው ታ	00000-0000 <del>0</del>	4 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	ผนบอบบนบอ <mark>ธ</mark>	ችለሠለዐህ4ሠ <i>U U</i> L		40000000000
7 Day 14	23 - 20 - 20 - 20 - 20 - 20 - 20 - 20 -	សសមសមស្ <u>ង</u> ជ្រកស្ត	646000040 <u>-</u> 5	00000000000000000000000000000000000000
Day	N	to.		
Day 0	, , , , , , , , , , , , , , , ,	សសសសស <i>សសសសសសស</i> សសសសសស <i>ង៧ស</i> ស	0404040400E	<u> </u>
Montgomery Asberg Depression Rating Scale	02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL TEOUGETS 06.INFRITA 06.INFRITA TO FEEL 07.PESSIMISTIC TEOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SIERP 10.REDUCED APPETITE 11.Total score	01. REPORTED SADNESS 02. INHER TENSION 03. APPARENT SADNESS 04. SULCIDAL TROUGHTS 05. INERTIA 06. INABLITY TO FEEL 07. PESSTHISTIC THOUGHTS 09. CONFORMATIONS DIFFICULTIES 09. REDUCED ALEPP 10. REDUCED APPETITE 11. TOTAL SCORE	01. REPORTED SADMESS 02. INDER TRANSION 03. APPARENT SADMESS 04. SUICIDAL THOUGHTS 05. INDETITA 05. INDETITY TO PEEL 07. PESSICHISTIC THOUGHTS 09. CONCENTRATIONS DIFFICULTIES 09. REDUCED SLEEP 10. REDUCED SLEEP 11. TOTAL	01.REPORTED SANNESS 02.INNER TENSION 03.APRERT SANNESS 04.SULCIDAL THOUGHTS 05.INABILITY TO FEEL 07.PESSIRISTIC THOUGHTS 09.REDUCED SLEEP 10.REDUCED SLEEP 11.Intal score
Scale Montgowery Asberg Depression type Rating Scale	2 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL TEOUGETS 05.IMENIA 05.IMENIATY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SIERP 10.REDUCED APPETITE 11.Total score	N	N	N
Scale Sex type	N	N	N	N
Scale type	Female 2	Femalo 2	Female 2	Fonale 2

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

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HONTGOKERY ASBERG DEPRESSION RATING SCALE

Day 56		0000000000	000070000	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
Day 49				
Day 42		00000+0008	0 # 0 0 0 0 # 0 0 0 0	0 0 W W = 0 0 0 0 0 0 0 0
Day 35				
Day 28	458448444844	60N#000660M	0000000000	n n 4 4 m m m m ≈ 5 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
Day 21	444444444	000000000000000000000000000000000000000	00000000 <b>0</b>	4444M04M0-E
Day 14	4 4 4 4 4 4 4 4 A B B B B B B B B B B B	00000000000		ଲେଖ୍ୟ ଲେଖ୍ୟ ଲେଖ୍ୟ ଅଟେ ଅଟି । ଜିନ୍
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Day				
0	40040444008	សស	<b>ឯ</b> ឧបឧបឧបឧបឧបឧ	404040400000
Day				
Montgomery Asberg Depression Rating Scale	01.REPORTED SADNESS 02.IMURR TENSION 03.APARENT SADNESS 04.SUICIDAL THOUGHTS 05.IMERILA 06.IMERILA 07.PESSIMISTIC THOUGHTS 08.COMENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE	01.REPORTED SADNESS 02.INRER TENSION 03.APARENT SADNESS 04.SULCIDAL THOUGHTS 05.INRETLA 07.PESSIANISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE	01.REPORTED SADNESS 02.INNER IENSION 03.AFARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERTIA 06.INABLITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPEITTE	01.REPORTED SADNESS 02.IMREN TENSION 03.AFARENT SADNESS 04.SUTCIDAL THOUGHTS 06.IMRENTA 06.IMRENTA 07.DESSAMISTIC THOUGHTS 08.CHOCKENTRAINED DIFFICULTIES 109.REDUCED SLEEP 10.REDUCED APPETITE
	2 01.REPORTED SADNESS 02.INMER TENSION 03.APPRENT SADNESS 04.SUICIDAL HOUGHIS 05.INMERILLY TO FEEL 07.PESSINIENIC THOUGHIS 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 01.REPORTED SADNESS 02.INNER TENSION 03.APPRENT SADNESS 04.SULCIDAL THOUGHTS 05.INERTIA 06.INERTIA 07.PESSIAKESTIC THOUGHTS 08.CHOKCHYRALICUS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	2 01.REPORTED SADMESS 02.INMER TENSION 03.APPRENT SADMESS 04.SUTCIDAL THOUGHTS 05.INERTIA 06.INBLITY TO FEEL 07.PESSIANESTIC THOUGHTS 08.CHOKSTYRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.TOTAL SCORE	2 01.REPORTED SADNESS 02.INNER TENSION 03.APPERIT SADNESS 04.SUTCIDAL SADNESS 05.INERTIA 06.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 09.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score
- 1				
Sex type	Ø	N	N	и
Scale type	Female 2	Formale 2	Female	Fenale 2

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HONTCOMERY ASBERG DEPRESSION RATING SCALE

Day 49 Day Day 35 Pay Ā 2 Day \$ Day Bay 02.IMRE TENSION
03.APPARENT SADNESS
04.SUICIDAL THOUGHTS
06.IMBELIAY TO FEEL
07.PESSIMISTIC THOUGHTS
09.CONCENTRATION DIFFICULTIES
09.REDUCED SLEEP
11.TOTAL SCORE Montgomery Asberg Depression Rating Scale Scale Female Fluoxetine Female Female Male Sex Rebaxetine Centre Patient Treatment 411 410 409 853

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MONTCOMERY ASBERG DEPRESSION RATING SCALE REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

Centre	Patient	Centre Patient Treatment	žė,	Scale	Montgonery Asberg Depression Rating Scale	Day 0	Day 7	Day 14	Day 21 De	Day 28 Day 35	Day 42 Day	64	Day 56
15	412	Fluoxetine	Female	-	11.Total score	12	5	6	80	LO)	m		m
	413	Reboxetine	Female	-	01.REPORTED SADNESS 02.INRER TENSION 03.APPARENT SADNESS 05.INRETIA. THOUGHTS 05.INRETIA. 06.INRETIA. TO FEEL 06.INRETIA. 07.PESSIMISTIC TROUGHTS 09.REDUCED SLEEP 10.REDUCED SLEEP 11.Total score	& 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	w ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	ииио <u>й</u>		~~0~~0~~00			9-99000000
00.	\$ 854	Fluoxetine	Male	~	01.REPORTED SADNESS 02.INTER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 06.INERTIAL 06.TABAILLIY TO FEEL 07.PESSIMISTIC THOUGHTS 09.REDUCED SLEEP 10.REDUCED REPERF 11.Total SCORE	996-696-696	0000-	24440 <u>6</u>	000-04-400 <u>0</u>	0=0noō	4-000°		0000 <u>5</u>
	415	Reboxetime	Female	-	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INRRILAT TO FEEL 06.INBRILITY TO FEEL 07.PESSTHISTIC THOUGHTS 09.COHCENTRAINS DIFFICULIES 10.REDUCED SLEEP 10.REDUCED APPLITE	ฅณฅณฅณฅ๛ฅ๛ฉ	# 6 # 6 # 6 # 6 # 6 # 6 # 6 # 6 # 6 # 6	8-70889999	4-4-4440 <del>6</del>		0 - 0 0 - 7 - 0 0 0 0 0		0700700000
	416	Fluoxetime	Female	-	01.REPORTED SADNESS 02.INNER TERISION 03.APPARENT SADNESS 04.SUJCIDAL THOUGHTS 05.INERITA 06.INBLILTY TO FEEL 07.PESSINISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES	0000	W W L L W L L D (	00440440	00FF0FF0	00	~~~ <b>0</b> ~0~0		

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centr	Patient	Centre Patient Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day	0 Day	7 0	Day 14	Day 21	Day 28 Day 35	Day 42 Day 49	49 Day	26
15	416	Fluoxetine	Female	<del>-</del>	10.REDUCED APPETITE 11.Total score	13	- 8	13	<b>←</b> £1	<b>- £</b>	<b>.</b>	o <b>v</b>		04
	417	Reboxetine	Fonale	<del>-</del>	01.REPORTED SADNESS 02.INNER TENSION 03.APARENT SADNESS 04.SUICTIDAL THOUGHTS 05.INERTIA 07.PESSIATSTIC THOUGHTS 06.CONCENTRATION DIFFICULTIES 07.REDUCED SLEEP 10.REDUCED APPETITE		~~~~~~~~~~	00		00007000700	0-00-0000	0-00-000000		0-0000000
0 0 0	<b>§</b> 855	Reboxetine	Female	<b>.</b>	01.REPORTED SABMESS 02.INTER ITERSTON 02.APPARENT SADMESS 04.SULCIDAL THOUGHTS 05.INTERIAL 07.PESSIMISTITY TO FEL. 07.PESSIMISTITY TO FEL. 07.PESSIMISTITY TO FEL. 07.PESSIMISTITY TO FEL. 07.PESSIMISTITY TO FEL. 07.PESSIMISTITY SADVENTE 10.REDUCED PREPTITE 10.TOTAL SCORE		. വേയയ-യഗവശയ <u>-</u> ന		. 000 <b>6060666</b>	40	, <u></u>	) 0-0000N		- 0#00#00000
•	419	Fluoxetine	Female	-	01. REPORTED SADNESS 02. INTER TRISTON 03. APPARENT SADNESS 04. SULCIDAL THOUGHTS 05. INERTIA TO FEEL 07. RESIALISTIC THOUGHTS 09. REDUCED SLEEP 10. REDUCED APPETITE 11. TOTAL SCOTE	•	224	00uo h	44 <b></b> 400	0000 <sup>5</sup>	- w			
	420	Fluoxetine	Male	-	01.REPORTED SADNESS 02.INKER TREATSON 03.APPRENT SADNESS 04.SUTCIDAL TBOUGHTS 05.INERTIA 06.NABILITY TO FEEL		0 <del></del> 0 - 0	WW-W			<b>0</b> 00-	000-		

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centr	e Patient	Centre Patient Treatment	Sex	Scale type	Montgomery Asberg Depression Rating Scale	Day 0	Day	7 Di	Day 14 D:	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
15	420	Fluoxetine	Male	-	09.REDUCED SIZEP 10.REDUCED APPETITE 11.Total store	2 0 ET		200	£0£	-06	-08		007		
	421	Reboxetine	Female	-	01.REPORTED SADNESS 02.INNER TENSION 03.APARENT SADNESS 04.SULCIDAL, TROUGHTS 05.IMERILIY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REBOUCED SIREP 10.REBUICED APPETITE 11.Total Score	444-4-405		000-0-0-0 <del>0</del>	W 44 44 44 44 44 44 44 44 44 44 44 44 44	0-0-0-0-0-0 <del>-</del>					000000000
***	§ 856	Fluoxetine	Male	-	01.REPORTED SADNESS 02.INURE TENSION 03.APPARENT SADNESS 04.SINICIDAL THOUGHTS 05.INURENT. 06.INURENTED TO FEEL 07.PESSINICITO THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 11.REDUCED APPETITE	444444465		444-4-4-40 <del>1</del>	888484848 <mark>5</mark>	00000000000000000000000000000000000000			~~00~0~004		
	423	Fluoxetine	Female	~	01.REPORTED SADMESS 02.INNER TERSION 09.APPARENT SADMESS 06.SUICIDAL THOUGHTS 06.SIMERILA 06.IMERILA 07.PESSHURSIC THOUGHTS 09.CONCENTRATIONS DIFFICULTIES 10.REDUCED SLEEP 10.REDUCED APPETITE 11.Total SCORO	999		0000-0- <del>6</del>	000LLL0L0L <mark>0</mark>	000cee0e0e5	22		V C C C T T T C C C T T		~~007~~~00%
	424	Reboxetine	Male	<del>-</del>	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUCIDAL THOUGHTS 06.INERTIA 06.INERTIA 06.THERILITY TO PEEL	0000		000	0 E E E E O	F-F-0-F-0	*****		, 550000		-000-0

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PHARMACIA CNS R&D REBOXETINE - PROFOCOL 20124/016 Listing No.: 13.0

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SCALE
RATING
DEPRESSION
ASBERG
HONTCOMERY
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Centre	Patien	Centre Patient Treatment	Sex	type	Rontgomery Asberg Depression Rating Scale	Day 0	Day	7 Day	Day 14 Day	Day 21 Day	y 2B Day	35	Day 42	Day 49	Day 56	w
र	424	Reboxetine	Male	**	08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total sogre	2 T L S		+ 4 <b>-</b> ₹	- 20 <del>L</del>	++01	- 0 0 <b>s</b> s		-00%			
	425	Reboxetine	Female	-	01.REPORTED SADNESS 02.IMURE TENSION 03.APARENT SADNESS 04.SUICIDAL THOUGHTS 05.IMERTIA 06.THARILITY FO FEEL 07.PESSI MISTIC THOUGHTS 08.COUCENTRAINDS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPEITE	44444446	·	00000-01-005	00000000000 <b>5</b>				0700000007		070000007	0-0000000
857	456	Fluoxetine	Male	~	01.REPORTED SADNESS 02.INNER TENSION 03.AFARENT SADNESS 06.INERTIA 06.INERTIA TO FEEL 06.INERTIA TO FEEL 07.PESSI MISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 10.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	80000000000000000000000000000000000000		, , , , , , , , , , , , , , , , , , ,	00177000000 <b>2</b>	0017000000 <b>5</b>	+2+++++0° <del>+</del>		+000		**********	************
	427	Reboxetine	Female	-	D1.REPORTED SADNESS D2.INVER TENSION D3.APPARENT SADNESS D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTIA. D6.INENTI	000 <del>0000</del>	•	00000 <b>0</b>	00000000000000000000000000000000000000	WL0L1L1W05			~~00~~0~~0			rr00r00r004
	42 <b>8</b>	Fluoxetine	Male	-	01.REPORTED SADNESS 02.INKER TENSION 03.APPARENT SADNESS 04.SUTCIDAL THOUGHTS 05.INERIA	00		00 0 C C C	00 <del></del>	07			~~00~		F-60F-	55005

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PHARMACIA CNS RED

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MONTCOMERY ASBERG DEPRESSION RATING SCALE

Day 56	F0F0 <b>%</b>	++00+0+0004		0-0-0-0%	0000-
Day 49 I				•	
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Day 42					
Day 35					
28	70007	001-01-0100	0 = 40 0 ± ± ± ± 0 0	-4-0-0-0-0	+-0
21 Day		44404-E	408 <u>-</u> 5	00707000 <b>0</b>	
t Day 21		001101100F	8 - 4 0 8 - 4 - 4 - 5	иит-итиои <b>е</b> й	0+++0
Day 14	402		• • • • • • • • • • • • • • • • • • •	•	
Day 7	002	884-84-08-5	#140#441	0001-00 <b>0</b>	00440
-	% o %	4444444	w-40w44-4- <del>6</del>	444-4040 <u>£</u>	00770
Day					
Montgomery Asberg Depression Rating Scale	07.PESSIMISTIC TROUGHIS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPRIIE 11.Total score	01.REPORTED SADNESS 02.INNER TENSION 03.APPRARTY SADNESS 04.SULCIDAL THOUGHTS 05.INRETTA 07.PESSIAISTIC TROUGHTS 08.CONCENTRATIONS DIFFICULITIES 09.REDUCED SIEEP 10.REDUCED APPETITE 11.Total score	01 REPORTED SADMESS 02.INMER TENSION 03.APPARENT SADMESS 04.SUTCIDAL TROUGHTS 05.INMELLIY TO FEEL 07.PESSIMISILY TO FEEL 07.PESSIMISILY TO FEEL 09.REDUCED SIERP 10.REDUCED APPETITE 11.TOTAL SCORE	01 REPORTED SADMESS 02.INMER TENSION 03.APPARENT SADMESS 04.SUXCIDAL THOUGHTS 05.INABILITY TO FEEL 07.PESSIATISTIC THOUGHTS 09.REDUCED SIEEP 10.REDUCED APPETITE 11.Total score	01.REPORTED SADMESS 02.IMMER TENSION 03.APPERENT SADMESS 04.SUICIDAL THOUGHIS 05.IMERIIA
Scale Montgomery Asberg Depression type Rating Scale	1 07.PESSIMISTIC THOUGHIS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPRIITE 11.Total score	<b>-</b>	1 01 REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUTCIDAL TROUGHTS 05.INABILITY TO FEEL 07.PESSIMISILY TO FEEL 07.PESSIMISILY TO FEEL 09.EDUCED SIERP 10.REDUCED APPETITE 11.TOTAL SCORE	<del>-</del>	-
	Male 1 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score				
Scale Sex type	<b>-</b>	<b>-</b>	-	<del>-</del>	-
Scale type	Hale 1	Female 1	Halo 1	Female 1	e Female 1

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PHARMACIA CMS RED REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

Centre Patient Treatment

452

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Day 28 Day 35 Day 42 Day 49 Day 56 7 Pay Day 14 MONTGOMERY ASBERG DEPRESSION RATING SCALE 7 Day 0 Day Montgomery Asberg Depression Rating Scale Scale type Female Female Male Sex Reboxetine

Hale

430

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

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atient	Centre Patient Treatment	Sex	type	Rating Scale	Day 0	Day	7 Day 14	Day 21	Day 26 Day	y 35 Day	42	Day 49	Day 56
	Reboxetine	Fenale	<b>-</b>	05.INERTIA 06.IMABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRAITONS DIFFICULTIES 10.REDUCED SLEEP 10.REDUCED APPETITE 11.FOEal score	2212122	******	~~~~~°°	000	00000	~ a ~ a a a a	-0-000w	-000000	+00000W
	Fluoxetine	Female	-	01.REPORTED SADNESS 02.INNER TERBITOR 03.APPARRYT SADNESS 04.SUICTOAL THOUGHTS 05.IMERILA TO FEEL 06.TRABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 09.COMCENTRATICH TO OFFICULITES 09.REDUCED SLEEP 10.REDUCED APPETITE			777777777777777777777777777777777777777	0000-00-000	000000000		00007007000	0000-00-000	0000-00-000
	Reboxetine	Female	-	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SULCIDAL, THOUGHTS 05.INBERIA 07.PESSIMISTIC TROUGHTS 09.CONCENTRATIONS DIFFICULTIES 09.CONCENTRATIONS DIFFICULTIES 10.REDUCED SIERP 10.REDUCED APPETITE 11.TOTAL SCOTE	080-0000-05		£ 0 1 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 + 0 0 0 0 0 7 + 0 M	0000000	0 + 0 0 0 0 0 + 0 10	0-00000-04	0-000000	0-00000 <b>0</b>
	Fluoxetine	Female	~	01.REPORTED SADNESS 02.INNER TENSION 03.APARENT SADNESS 04.SUICIDAL THOUGHTS 05.INABILITY TO FEEL 07.PESSIMISTIC THOUGHTS 09.CONCENTRATION DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE		404-0 <del>-</del>	0.00000.00	000007000000000000000000000000000000000	0-0000000	0-0000000	0-0000000	to##7000070	0-000004
	Reboxetine	Female	-	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SANNESS	е е	0.00		~ ~ ~	0-0	o = 0	<b>0</b> ~ 0	000	00

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REBOXETINE - PROTOCOL 20124/016
Listing No.: 13.0

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		Day S6	0-000-00	00-0-0	0-00000		-
		49	0-000-00		0-0000		0
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		Day 42	<b>U</b>				
		ង	0-000-08	00		00-0-0	0
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	•	Day 2					
		Day 21	0#00070%			£00	-
		Day 14 D	0444400	***********			-
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9	SCAL	Day 7		4444	444-0 <u>-</u>		
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13.0	ION R	Day	,,				
REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0	MONTCONERY ASBERG DEPRESSION RATING SCALE	Montgomery Asberg Depression Rating Scale	04.SUICIDAL THOUGHTS 05.INERTIA 06.INBAILIY TO FEEL 09.PESSIMISTIC THOUGHTS 09.REDUCED SIEEF 10.REDUCED APPETITE 11.ICATAL SCORE	01 REPORTED SADNESS 02.INNER TENSION 03.APPRARY SADNESS 04.SUICTDAL THOUGHTS 05.TNERTLA TO FEEL 07.PESSIMISTIC THOUGHTS 09.REDUCED SIEEP 10.REBUCED SIEEP 11.Total, SECRE			01. REPORTED SADNESS
		Scale type	~	-	-	-	-
		Ziex X	Fenale	Fenale	Гела 1.е	Ferale	Female
		Treatment	Reboxetine	Fluoxetine	Reboxetine	Fluoxetine	Fluoxetine
		Centre Patient Treatment	16 435	98 6	1	438	439
		۱ د	•"				

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0 PHARMACIA CNS RED

MONTCOHERY ASBERG DEPRESSION RATING SCALE

Day 28 Day 35 Day 42 Day 49 Day 56 14 Day 21 Day 7 Day Montgomery Asberg Depression Rating Scale Scale type Female Female Fenale Sex Centre Patient Treatment 862 \$ 440 16

443

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

Day Day 42 Day 49 28 Day 35 Day 14 Day 21 7 Day NONTGONERY ASBERG DEPRESSION RATING SCALE Day Day Montgowery Asberg Depression Rating Scale Scale type Female Reboxetine Female Male Male Sex Fluoxetine Centre Patient Treatment 446 445 443 # 863

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PHARMACIA CNS RED REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

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NONTCOMERY ASBERG DEPRESSION RATING SCALE

Day Day 49 Day 42 Day 7 Day 14 Day 21 Day 28 Day 35 Scale Female Male Hale Sex Fluoxetine Centre Patient Treatment 448 447 864

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PEARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

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MONTGOMERY ASBERG DEPRESSION RATING SCALE

26 Day Day 49 42 Day 35 Day 28 Day 2 Pay # Pay V Day Montgomery Asberg Depression Rating Scale Scale Female Female Male Male Sex Fluoxetine Centre Patient Treatment 458 429 457 865

PHARMACIA CHS R&D

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

MONTGOMERY ASBERG DEPRESSION RATING SCALE

Centre	e Patient	Centre Patient Treatment	Sox	Scale type	Montgomery Asberg Depression   Rating Scale	Day 0	Day	7	Day 14 E	Day 21 D	Day 28	Day 35	Day 42	Day 49	Day	26
16	094	Reboxetine	Male	-	11.Total score	20		<b>5</b> 5	\$	w	'n		0			۰ ا
8	25	Fluoxatine	Female	-	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SULCIDAL TROUGHTS 05. INBRILTY TO FEEL 07. PEESAHISTY CHOUGHTS 08. CONCENTRATION DIFFICULIES 10. REDUCED SLEEP 10. REDUCED APPETITE 11. Total score	4004400EL00E			-0-0 <i>0</i>	-0-0-0 <b>v</b>		-0-0-00	404040446A	000000077700		000000
	× 866	Roboxetine	Female	-	01.REPORTED SADMESS 02.IMURE TENSION 03.APPARETE SADMESS 04.SULCIDAL INOUGHTS 05.IMBILITY TO FEEL 06.IMBILITY TO FEEL 09.REDUCED SIEEP 10.REDUCED SIEEP 11.Total score	0-00-0F0F0F		0-00-0-0-0 <u>0</u>		-0-00	<b>,</b> 000-0-4-0 <b>,</b>	-000-0-01-09	000000FFF0M		0000007700	0000007700
	2	Reboxetine	Female	<b>-</b>	01. REPORTED SADNESS 02. INNER TENSION 03. AFPARENT SADNESS 04. SUICIDAL TAUGHTS 05. INREILTY TO FEEL 07. PESSI MISTIC THOUGHTS 08. CONCENTRATIONS DIFFICULTIES 09. REDUCED SIEEP 10. REDUCED APPETITE 11. Total score	4440-4	2220-22	000000000000000000000000000000000000000	4-40-4	+++0++++0 <b>d</b>	-00			00000077700	00000000707	
	<b>8</b>	Fluoxetine	Fenale	•	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL TROUGHTS 05.INBELLIT 10 PEEL 06.YABILLIT TO PEEL 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES		80707070	80-0-0-0	80-0-0-0	W 4 6 6 9 6 9	40-0-0-0					

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

PHARMACIA CNS RED

MONTCOMERY ASBERG DEPRESSION RATING SCALE

3entr	e Patier	Centre Patient Treatment	Sex	Scale	Montgonery Asberg Depression Rating Scale	Day 0	Day	7 Day 14	14 Day	21 Day	28 Day	35 Day 42	42 Day	49 Day	y 56	
8	2 <b>3</b>	Fluoxetine	Female	1	10.REDUCED APPETITE 11.Total score	15		o <b>2</b> 1	15	0 St	15					
	23	Reboxetine	Male	<del>-</del>	01.REPORTED SADNESS 02.INER FENSION 03.AFPARENT SADNESS 04.SUTCIDAL THOUGHTS 05.INERTA 06.INABLITY TO FEEL 07.PESSIMISTIC THOUGHTS 09.REDUCED SAFETURE 10.REDUCED AFPETURE 11.Total score	80 80 80 80 80 80 80 80 80 80 80 80 80 8		4440044444 <del>5</del>	и-иоииииио <del>й</del>	4 <b>-</b> 40 0 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	-0-0009	-0000 <del>-</del> 004	-0000-0 <del>-</del> 04	0000007700	0000007700	
867	<b>0</b>	Fluoxetine	Female	<u>-</u>	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SULCIDAL THOUGHTS 05.INERTIA 06.INABLILY TO PEEL 07.PESSIMENT TO TREE 09.REDUCED SEEPER 10.REDUCED SAPETITE 11.Total score	44444444444444444444444444444444444444		0001-00-01-0 <del>1</del>	- 0 0 0 - 0 - 0 0	~~00~~ <del>~</del>		~~00~~~~00		0000+00+000	0000-00-000	
	e M	Reboxetine	Fenale	9	01.REPORTED SADNESS 02.IMURR TENSION 03.APPARENT SADNESS 04.SUICIDAL TROUGHTS 05.IMBRILA 06.IMBRILA 07.PESSILISTIC TROUGHTS 09.CONCENTRATIONS DIFFICULTIES 10.REDOCED SIERP 10.REDOCED APPEITE 11.Total score	2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 -		00-00-04005	000000000 <b>0</b>	,0000000000 <u>0</u>	00-00-0 <del>-</del> 00 <del>-</del>	00-00-01-00 <b>-</b>	-0-0-7-7-7	-0-0- <del>00</del>	-0-0-00%	
	32	Fluoxetine	Female	99 T	01.REPORTED SADNESS 02.THRIR TENSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.TREPTIA 06.INABILITY TO FEEL 09.ECONNEMICATIONS DIFFICULTSS	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	000+0005	~~~~	000 <del>-</del> 000 -		00-0	F000FF07		00-0-0-0	00-0-0-0	

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Centr	e Patient	Centre Pationt Treatment	Sex	Scale type	Montgonery Asberg Depression Rating Scale	Day 0	Day	7 Day	Day 14 Day	Day 21 Day 28	28 Day	35 Day 42	42 Day 49	49 Day	, 56
18	32	Fluoxetine	Fenale	-	09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	1 0 St		1 0 15	د د و	-08	£0.0	7 O 7	<b>407</b>	000	000
	64	Rebozetine	Fomale	•	01.REPORTED SADMESS 02.INNER TERSION 03.APPARENT SADMESS 06.SUICIDAL TROUGHTS 06.SUICIDAL TROUGHTS 06.TABALLITY TO FEEL 07.PESSIMISTIC TROUGHTS 09.CONCENTRATIONS DIFFICULTIES 10.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	₩₩₩₩₽₩₩₩ <b>₩</b>		и-ип-ииии <b>-</b> 5			**********	0-00-1	0-00-09	00000007774	000000
868	<b>9</b>	Roboxetine	Female	•	01.REPORTED SADNESS 02.INNER TENSION 03.APABENT SADNESS 04.SUJCIDAL TROUGHTS 05.INERTIA 06.INBALLIYTY FO FEEL 07.PESSATIGYTC TROUGHTS 09.CONCENTRATIONS DIFFICULTIES 09.REDUCED RAPETITE 11.Total score	8 0 8 € 0 9 9 L L L €									
	2	Fluoxetine	Female	-	01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SUICIDAL HOUGHTS 05.INRRITA 06.INBLITY TO FEEL 07.PESSIMISTIC TROUGHTS 09.CONCENTRATION DIFFICULIES 09.REDUCED SIEEP 10.REDUCED APPETITE 11.Total score	8 44 44 44 44 44 44 44 44 44 44 44 44 44	<b>6</b> 000-000	~~~~~~ <del>~</del>		~~~~ <del>~~~</del>	~~~~~~~~ <b>~</b>			- 0	0-0000-0-0
	22	Fluoxetine	Female	-	01. REPORTED SADNESS 02. INNER TENSION 03. APPARENT SADNESS 04. SUDICIDAL TROCERTS 05. INNERTA 06. INABLILITY TO FEEL	With	# # # # # # # # # # # # # # # # # # #	₩ 10 10 10 10 10 10 10 10 10 10 10 10 10	000	0-8		~~~o~~		0-0	0000==

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0

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NONTGOMERY ASBERG DEPRESSION RATING SCALE

Day 56	F-0-0%		00700077404	0000000000	
Day 49 I			00-00004	00000-0000	
Day 42 D		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	00-00004	4000000000	
Day 35 D		0-0000	-0-000-r-0 <b>v</b>	00000000000	ଷ ଷ ଅ ଷ ଷ ଷ ଫ
Day 28 D			-0-000+0N	0-00-0	000000
Day 21 D	<b>0</b>	44444444444444444444444444444444444444	-0-000-e-00	0-0000-0-00	0000000
Day 14 D		44 W O 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	00	0-000000	- 000000
Day 7 D	6	4440444444	000000- <del>-</del> 4	0440044400	<b>-</b> ოოთ∾-
0	4011	000000000000000000000000000000000000000	0000004	~~~~~~~~~ <b>%</b>	
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Day					
Nontgumery Asberg Depression Rating Scale Da	08.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	01.REPORTED SADNESS 02.INBR TENSION 02.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INBRIA 07.PESSITHSTIV TO FEEL 07.PESSITHSTIV TO HOUGHTS 08.CONCENTRATIONS DIFFICULIES 09.REDUCED SIEEP 10.REDUCED APPETITE	01.REPORTED SADMESS 02.INNER TENSION 03.APAREAT SADMESS 05.SINCELAL THOUGHTS 05.INSETLA 06.INSETLA 06.ENDUCKTRETTA 08.CONCENTRATION DIFFICULTIES 08.CONCENTRATIONS DIFFICULTIES 10.REDUCED APPETITE 11.Total scop	01.REPORTED SADMESS 02.INNER TENSION 03.APPARENT SADMESS 03.APPARENT SADMESS 05.INERIA 07.PESSIMISTIC THOUGHTS 07.PESSIMISTIC THOUGHTS 08.CONCENTRATIONS DIFFICULTIES 10.REDUCED APPETITE 11.Total score	01.REPORTED SADNESS 02.INNER TERSION 03.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INERIA 06.INABILITY TO FEEL
	1 06.CONCENTRATIONS DIFFICULTIES 09.REDUCED SLEEP 10.REDUCED APPETITE 11.Total score	1 01.REPORTED SADNESS 02.INRE TENSION 02.APPARENT SADNESS 04.SUICIDAL THOUGHTS 05.INRETIA 06.IMBRILLY TO FEEL 07.PESSITHSITY TO HERL 07.RESITHSITY TO HOUGHTS 08.CONCENTRATIONS DIFFICULIES 10.REDUCED APPETITE 11.Total score	1 01. REPORTED SADMESS 02. INNER TENSION 03. APPARENT SADMESS 05. SUICIDAL THOUGHIS 05. INSERIA 06. INSERIATY TO FEEL 07. PESSIBHISIT THOUGHIS 08. CONCENTRATIONS DIFFICULIES 10. REDUCED SIEEP 10. REDUCED APPETITE 11. Total scope	-	-
dontgowery Asberg Depression Rating Scale				Female 1 01.REPORTED SADNESS 02.INNER TENSION 03.APPARENT SADNESS 04.SINICIDA THOUGHTS 05.INERIA 06.INBALLINY TO PEEL 07.PESSIMISTIC THOUGHTS 09.REDUCED SIERP 10.REDUCED APPETITE 11.Total score	
Scale Montgowery Asberg Depression Sex type Rating Scale	<del>-</del>	<b>-</b>	-	-	-
Scale Rontgomery Asberg Depression type Rating Scale	Female 1	Femalo 1	Malo 1	Female 1	Female 1

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 13.0 MONTGOMERY ASBERG DEPRESSION RATING SCALE

Day 28 Day 35 Day 42 Day 49 Day 56 0 Day 7 Day 14 Day 21 Montgomery Asberg Depression Rating Scale Scale type Female Female Male Reboxetine Male Sex Centre Pationt Treatment 115 113 22 870 2 7

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				CLINIC	CLINICAL GLOBAL IMPRESSION	INPRESSI	*						
Centre	Patient	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
<b>-</b>	-	Fluoxetine	Kale	Severity of illness Global improvement Efficacy index Efficacy index	4.00	4.00 3.00 4.00	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	2.00 2.00 2.00 2.00	2.00 1.00 2.00 2.00	1.00 1.00 2.00 2.00	2.00 2.00 2.00	2.00	1.00 1.00 4.00
	N	Reboxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 3.00 2.00	5.00 5.00 13.00	4.00 3.00 2.00	3.00 3.00 3.00	2.00 1.00 4.00	3.00 2.00 1.00 4.00	3.00 2.00 1.00 4.00	3.00 1.00 4.00
	ø	Fluoxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 13.00 1.00	3.00 3.00 3.00	3.00 5.00 3.00	3.00 5.00 3.00	3.00 2.00 5.00			2.00 2.00 1.00 4.00
871	ব	Reboxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	5,00	5.00 5.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 3.00 10.00	4.00 3.00 10.00	3.00 2.00 6.00 1.50	2.00 1.00 2.60 2.00		
	κı	Fluoxetine Female	Female	Severity of illmess Global improvement Efficacy index Efficacy index (*)	6.00	5.00 3.00 9.00 2.00	5.00 5.00 13.00	5.00 5.00 14.00 6.50	5.00 6.00 14.00 0.50	5.00 6.00 14.00			
	vo	Fluoxetine	Kale	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 13.00	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 4.00 15.00 0.33				
N	33	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	2.00 1.00 1.00 4.00	4.00 3.00 10.00	4.00 3.00 10.00	4.00 2.00 6.00 1.50	5.00 3.00 10.00	4.00 2.00 6.00 1.50	4.00 2.00 6.00 1.50	4.00 4.00 1.50
	¥	Reboxetine	Kale	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	4.00 2.00 6.00 1.50	3.00 2.00 6.00	2.00 2.00 2.00 2.00	2.00 2.00 2.00 2.00	2.00 1.00 2.00 2.00	2.00 2.00 4.00		

RHA	REBOXETINE - PROTOCOL 20124/016 Listing No.: 16.0
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				CLINIC	AL GLOBAL	CLINICAL GLOBAL IMPRESSION	¥						
Sentre	Patient	entre Patient Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
N	×	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index	5,00	3.00 9.00 2.00	4.00 3.00 9.00 2.00	4.00 3.00 2.00	3,00 2,00 2,00	3.00 3.00 2.00	3.00 3.00 2.00	3.00 4.00 13.00	3.00 5.00 13.00
	36	Fluoxetine Male	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	3.00 10.00 1.00	3.00 2.00 6.00 1.50	4.00 3.00 10.00	1.00 1.00 2.00 2.00	1.00 1.00 2.00 2.00	1.00 2.00 2.00	1.00 2.00 2.00	1.00 1.00 2.00 2.00
	37	Reboxetine	Kale	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 4.00 16.00 0.25							
87	88	Fluoxetine	Hale	Severity of illness Global improvement Efficacy index Efficacy index	5.00	3.00 3.00 3.00 3.00	4.00 3.00 5.00	4.00 3.00 5.00	2.00 1,00 1.00 4.00	1.00 1.00 1.00			
2	89	Fluoxetine Male	Male	Severity of illness Global imprevement Efficacy index Efficacy index	4.00								
	6	Reboxetime	Kale	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	5.00 5.00 14.00 0.50	4.00 2.00 6.00 1.50	3.00 2.00 6.00 1.50					
	2	Fluoxetine Male	Hale	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	3.00 3.00 2.00	3.00 3.00 2.00	4.00 2.00 5.00 3.00	3.00 2.00 5.00	4.00 3.00 9.00 2.00	4.00 3.00 9.00 2.00	3.00 2.00 5.00 3.00	2.00 1.00 4.00
	4. 0.	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	3.00 10.00 1.00	3.00 2.00 6.00 1.50	3.00 1.00 2.00 2.00	3.00 2.00 6.00 1.50	2.00 1.00 2.00 2.00	3.00 2.00 6.00 1.50	3.00 2.00 6.00 1.50	3.00 2.00 6.00

Day 56

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				PI REBOXETII	PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 16.0	CNS R&D OCOL 2012	24/016						
				CTINIC	CLINICAL GLOBAL IMPRESSION	IMPRESSI	NO						
tre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	_
	8	Reboxetine Ferale	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	4.00 3.00 10.00	4.00 3.00 10.00	4.00 3.00 10.00	3.00 2.00 6.00	3.00 3.00 10.00	4.00 3.00 10.00	3.00 2.00 6.00 1.50	
	<b>#</b>	Fluoxetine Male	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	4.00 3.00 10.00	3.00 2.00 6.00 1.50	8 2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3	2.00 2.00 2.00	2.00 2.00 2.00	8888 8888 8888		
	45	Reboxetine Femals	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	3.00 3.00 3.00	3.00 2.00 5.00 3.00	3.00 3.00 3.00	3.00 2.00 3.90	3.00 2.00 5.00	3.00 2.00 5.00 3.00	3.00 2.00 5.00 3.00	
	4,4	Fluoxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	5,00	3.00 2.00 6.00	3.00 1.00 6.00	2.00 2.00 2.00	2.00 1.00 2.00 2.00	2.00 1.00 2.00 2.00	1.90 1.00 2.00 2.00	2.00 2.00 2.00	
	83	Reboxetine Ferale	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	6.00 4.00 14.00 0.50	5.00 3.00 10.00	5.00 4.00 14.00 0.50	3.00 10.00 1.00	5.00 3.00 10.00	5.00 3.00 10.00	5.00 3.00 10.00	
	08	Fluoxetine Male	Male	Severity of illness Global improvement Efficacy index Efficacy index	5.00	3.00 3.00 3.00	3.00 2.00 5.00 3.00	3.00 3.00 3.00	3.00 1.00 1.00	2.00 1.00 1.00 4.00	2.00 1.00 4.00	2.00 1.00 4.00	
	59	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index	6.00	6.00 4.00 13.00	3.00 3.00 9.00 2.00	5.00 3.00 9.00 2.00	3.00 3.00 2.00 2.00	4.00 2.00 3.00	2.00 6.00 7.50	4.00 2.00 6.00 1.50	
	99	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index	6.00	6.00 5.00 14.00 0.50	5.00 4.00 14.00 0.50	4.00 3.00 10.00					

SEVERITY OF ILLNESS: 4=normal, 2=borderline mentally ill, 3=middy ill, 4=moderately ill, 5=markedly ill, 6=severily ill, 7=extremely ill GLOBAL IMPROVEMENT: 4=very much improved, 2=much improved, 8=minimally morse, 6=much worse, 6=much worse, 7=very much iEFFICACY INDEX (\*): computed from the vector activity by the vector side effects

PHARMACIA CNS R&D

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				CLINIC	AL GLOBAL	CLINICAL GLOBAL INPRESSION	¥6.						
Sentre	Patient	Pationt Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
<b>m</b>	<b>19</b>	Reboxetins Female	Female	Severity of illness Global improvement Efficacy index Efficacy index	6.00	5.00 3.00 2.00	2.00 2.00 2.00	3.00 3.00 9.00	3.00 2.00 4.00				
	89	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 14.00 0.50	5.00 3.00 10.00	3.00 10.00 1.00	5.00 3.00 2.00	5.00 3.00 9.00 2.00			
at.	76	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	2,00 2,00 2,00	4.00 3.00 6.00	3.00 2.00 6.00 1.50	2.00 1.00 4.00	1.00 1.00 4.00	1.00 1.00 4.00	1.90 1.90 1.90 1.90	1.00 1.00 1.00 4.00
Q	86	Fluoxetine Female	Fenale	Severity of illness Global improvement Efficacy indox Efficacy index	5.00	4.00 3.00 11.00	4.00 3.00 6.00 1.50	4.00 3.00 10.00	5.00 4.00 13.00	3.00 2.00 5.00	1.00 1.00 1.00 4.00	1.00 2.00 2.00	1.00 1.00 4.00
74	66	Fluoxetino Femalo	Female	Severity of illness Global improvement Efficacy index Efficacy index	6.00	5.00 16.00 0.25							
	100	Reboxetine Male	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00								
	101	Reboxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	4.00 3.00 6.00 1.50	4.00 3.00 6.00 1.50	2.00 2.00 2.00 2.00	4.00 5.00 14.00 0.50	4.00 6.00 14.00 0.50	3.00 2.00 6.00 1.50	2.00 2.00 1.50	2.00 2.00 7.00
	102	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	2,00 2,00 3,00	3.00 2.00 4.00	3.00 3.00 3.00	2.00 2.00 6.00	5.00 3.00 10.00	4.00 3.00 11.00	5.00 3.00 2.00	3.00 3.00 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 RED

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				REBOXETI	REBOXETINE - PROTOCOL 20124/016 Listing No.: 16.0	OCOL 2012	24/016						
				CLINIC	CLINICAL GLOBAL INPRESSION	INPRESSI	TON						
Centre	Patient	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 Global improvement Efficacy index Efficacy index	6.00	6.00 3.00 9.00 2.00	5.00 3.00 11.00	5.00 3.00 9.00 2.00	2.00 2.00 2.00	5.00 5.00 13.00			
	104	Reboxetine Female		Severity of illness Elobal improvement Efficacy index Efficacy index	90.9	5.00 3.00 10.00	5.00 3.00 10.00	5.00 3.00 10.00	5.00 3.00 10.00	4.00 2.00 6.00	4.00 2.00 6.00	5.00 3.00 10.00	
	105	Fluoxetine	Мале	Severity of illness Global improvement Erficacy index Erficacy index	5.00	5.00 5.00 13.00	5.00 3.00 2.00	5.00 5.00 13.00	5.00 3.00 2.00	5.00 9.00 2.00	5.00 3.00 2.00	5.00 3.00 2.00	5.00 3.00 2.00
875	129	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	4.00 3.00 10.00	4.00 3.00 10.00	4.00 3.90 10.00	4.00 4.00 15.00 0.33				
	130	Fluoretino Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	4.00 2.00 5.00 3.00	4.00 3.00 9.00 2.00	3.00 2.00 6.00	3.00 2.00 6.00	4.00 2.00 6.00	3.00 2.00 6.00 1.50	3.00 2.00 6.00	2.00 2.00 2.00
2	193	Reboxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 4.00 14.00 0.50	4.00 3.00 10.00	4.00 3.00 10.00	4.00 3.00 10.00	4.00 3.00 10.00	4.00 3.00 10.00	3.00 2.00 6.00	3.00 2.00 6.00
	194	Fluoxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index	3.00	3.00 3.00 10.00	3.00 3.00 10.00	3.00 2.00 6.00 1.50	3.00 2.00 6.00 1.50	3.00 2.00 6.00 1.50	2.00 2.00 6.00	2.00 2.00 2.00	1.00 1.00 2.00
	195	Fluoxetine	Ма16	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	3.00 2.00 2.00	4.00 3.00 10.00	4.00 2.00 5.00 3.00	4.00 3.00 9.00 2.00	4.00 3.00 10.00	4.00 3.00 9.00 2.00	3.00 5.00 3.00	2.00 1.00 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, 8-minimally improved, 4-no change, 5-minimally worse, 6-much worse, 7-very much EFFICACY INDEX (\*): computed from the vector activity by the vector side effects

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PHARMACIA CNS R&D

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				REBOXETII L:	INE - PROTOCOL 201 Listing No.: 16.0	REBOXETINE - PROTOCOL 20124/016 Listing No.: 16.0	4/016						
				CLINIC	AL GLOBAI	CLINICAL GLOBAL IMPRESSION	¥6						
Centre	Patient	Treatment	Sex	c.c.1.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Pay
	196	Reboxetine	Fema.l.e	Severity of illness Global improvement Efficacy index Efficacy index	5.00	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	
	197	Fluoxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index	4.00								
<del>-</del>	32.1	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index	5.00	5.00 4.00 13.00	5.00 4.00 15.00 0.33	5.00 3.00 10.00	4.00 3.00 10.00	3.00 3.00 6.00	2.00 2.00 6.00	2.00 1.00 1.00 4.00	4444
87	322	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index	7.00	6.00 4.00 14.00 0.50	5.00 3.00 10.00	3.00 3.00 2.00	3.00 3.00 9.00 2.00	3.00 3.00 9.00 2.00	3.00 3.00 2.00	3,00 2,00 3,00	(1) (4 8) (1)
<sup>7</sup> 6	323	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	4.00 2.00 6.00 1.50	2.00	1.00 1.00 2.00 2.00	1.00 1.00 2.00 2.00				
	324	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 5.00 15.00 0.33	5.00 4.00 14.00 0.50	4.00 3.00 10.00 1.00	2.00 2.00 6.00	3.00 5.00 14.00 0.50	
	325	Reboxetine	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 3.00 10.00	4.00 3.00 2.00 2.00	3.00 2.00 5.00 3.00	3.00 2.00 3.00	2.00 1.00 4.00	
	326	Reboxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	4.00 3.00 10.00	4.00 2.00 6.00 1,50	2.00 2.00 6.00	1.00 1.00 2.00 2.00	1,00 1,00 2,00	1.00 2.00 2.00	1.00 2.00 2.00	

, 3=mindly ill, 4=moderately ill, 5=markedly ill, 6=severily ill, 7=extremely ill the farminimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse the vector side effects SEVERITY OF ILLNESS: 1-normal, 2-borderline mentally ill, GLOBAL IMPROVEMENT: 1-very much improved, 2-much improved, EFFICACY INDEX (\*): computed from the vector activity by t

1.00 1.00 2.00 2.00

PHARMACIA CNS RED

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			REBOXETI L	INE - PROTOCOL 20 <sup>-</sup> Listing No.: 16.0	REBOXETINE - PROTOCOL 20124/016 Listing No.: 16.0	4/016			•			
			CFINIC	AL GLOBAL	CLINICAL GLOBAL INPRESSION	¥o.						
 ontre Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	g
 327	Fluozetine Female	Formale	Soverity of illness Global improvement Efficacy index Efficacy index (*)	4.00	3.00 3.00 10.00	3.00 4.00 14.00 0.50	2.08 3.00 6.00	2.00 3.00 6.00				
328	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (x)	4.00	4.00 4.00 13.00	5.00 5.00 13.00	5.00 4.00 13.00	8.00 8.00 8.00	3.00 2.00 6.00	2.00 2.00 2.00	1.00 1.00 2.00 2.00	
329	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 14.00 0.50	3.00 10.00 1.00	4.00 5.00 14.00 0.50	1.00 1.00 2.00 2.00	4.00 74.00 0.50	2.00 2.00 2.00	2.00	
330	Reboxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	8.00	5.00 4.00 14.00 0.50	4.00 3.00 10.00	4.00 5.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 4.00 14.00	5.00 4.00 14.00 6.50	
331	Fluoxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 13.00	3.00 3.00 2.00	3.00 3.00 10.00	1.00 1.00 2.00 2.00	1.00 1.00 2.00 2.00	1.00 1.00 2.00 2.00	1.00 1.00 2.00 2.00	
332	Fluoxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 14.00 0.50	4.00 3.00 10.00	4.00 3.00 10.00	3.00 2.00 6.00 1.50	22.00	2.00 2.00 2.00 2.00	1.80 1.80 2.00 2.00	
333	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 74.00 0.50	4.80 3.00 10.00	4.00 3.00 10.00	4.00 3.00 10.00	3.00 3.00 10.00	3.00 2.00 6.00 1.50	2.00 2.00 6.00	
334	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	5.00 13.00 1.00	4.00 3.00 9.00 2.00	4.00 3.00 9.00 2.00	3.00 2.00 2.00	3.00 3.00 2.00	3.00 2.00 5.00 3.00	3.00 3.00 3.00	

SEVERITY OF ILLNESS: 4-mormal, 2-borderline mentally ill, 3-mildly ill, 4-moderately ill, 5-markedly ill, 6-mormally ill, 7-extremely ill GLOBAL INPROVEMENT: 4-very much improved, 2-much improved, 3-minimally improved, 4-mo 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 RED REBOXENINE - PROTOCOL 20124/016 Listing No.: 16.0	
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Contra	Pationt	Centre Patient Treatment	Sov				÷	į		36	9	9	95
			405			•	rey it	nay 2.	az Ama	2 Am	at year	cr feet	
£	335	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 13.00	2.60 9.00 9.00 9.00	3.00 9.00 2.00	2.00 9.00 2.00	3.00 3.00 10.00			
12	393	Fluoxotine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 0.50	3.00 10.00 1.00	3.00 9.00 2.00	4.00 3.00 10.00	3.00 2.00 2.00	3.00 3.00 2.00	4.00 2.00 5.00	4.00 3.00 2.00
	394	Reboxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 4.00 14.00 0.50	4.00 4.00 14.00	4.00 3.00 10.00	5.00 4.00 14.00	5.00 5.00 14.00	4.00 5.00 14.00	4.00 4.00 14.00	5.00 5.00 14.00
878	395	Reboxetine	МаЛе	Soverity of illness Global improvement Efficacy index Efficacy index	4.00	4.00 4.00 14.00 0.50	4.00 3.00 10.00	3.00 2.00 6.00	3.00 10.00 1.00	4.00 3.00 10.00	3.00 3.00 1.00	3.00 2.00 6.00	3.00 3.00 6.00
	396	Fluoxetine Female	Fomale	Severity of illness Global improvement Efficacy index Efficacy index (*)	5,00	4.00 14.00 0.50	5.00 5.00 14.00 0.50						
	497	Fluoxetine Femalo	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5,00 4,00 14,00 0,50	5.00 74.00 0.50	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	4.00 3.00 10.00	4.00 3.00 10.00	4.00 5.00 14.00 0.50	4.00 4.00 14.00 0.50
13	385	Fluoxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 4.00 13.00 1.00	4.00 3.00 10.00	3.00 3.00 10.00	2.00 2.00 2.00 2.00		3.00 2.00 6.00		1.00 1.00 4.00
	386	Fluoxetine	Male	Soverity of illness Global improvement Efficacy index Efficacy index (*)	6.00	7.00 6.00 13.00							

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 16.0

PHARMACIA CNS R&D

			CLINIC	AL GLOBAL	CLINICAL GLOBAL IMPRESSION	8						
Patient	Treatment	Sex	C.6.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
387	Reboxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	4.00 3.00 1.00	4.00 3.00 1.00	3.00 2.00 6.00 1.50	1.00 1.00 2.00 2.00				
388	Reboxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	6.00 4.00 14.00 0.50	4.00 3.00 6.00	4.00 2.00 6.00 1.50	4.00 3.00 10.00		4.08 2.00 6.90 1.50		3.00 2.00 6.00
389	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index	6.00	5.00 4.00 15.00							
390	Reboxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 4.00 13.00	4.00 3.00 10.00	4.00 4.00 14.00 0.50	3.00 3.00 9.00 2.00		4.00 2.90 1.50		2.00 2.00 2.00
391	Fluoxetine Female	Female	Severity of illness Clobal improvement Efficacy index Efficacy index	4.00	3.00 2.00 6.00	3.00 2.00 6.00	2.00 2.00 2.00 2.00	2.00 2.00 2.00	1.00 1.00 3.00 1.33			
392	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 4.00 13.00	4.00 4.00 13.00						
501	Reboxetine Male	Kale	Severity of illness Global improvement Efficacy index Efficacy index	4.00	4.00 4.00 14.00	4.00 3.00 10.00	4.00 3.00 10.00	4.00 3.00 10.00		3.00 2.00 6.00 1.50		3.00 2.00 4.50
. 205	Fluoxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	3.00 9.00 2.00	4.00 3.00 9.00 2.00	3.00 3.00 2.00 2.00	4.00 3.00 2.00 2.00		4.00 2.00 5.00 3.00		7.00 1.00 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, 4-mo change, 5-minimally worse, 6-much worse, 7-very much worse EFFICACY INDEX (\*): computed from the vector activity by the vector side effects

Day 56

PHARMACIA CHS RED	REBOXETINE - PROTOCOL 20124/016 Listing No.: 16.0	CLINICAL GLOBAL IMPRESSION	Sex C.G.I. Day 0 Day 7 Day 14 Day 21 Day 28 Day 35 Day 42 Day 49 Day 14 Day 21 Day 22 Day 35 Day 42 Day 49 Day	Female Severity of illness 4.00 4.00 Global improvement 3.00 Efficacy index (*) 0.50	Femals Severity of illness 4.00 4.00 4.00 5.00 5.00 4.00 5.00 5.00	Female Severity of illness 5.00 4.00 4.00 4.00 4.00 3.00 5.00 Efficacy index (*) 0.50 14.00 14.00 10.00 6.00 6.00 Efficacy index (*) 0.50 0.50 1.00 1.00 1.00 1.50	Male Severity of illness 4.00 3.00 3.00 1.00 1.00 1.00 Clobal improvement 2.00 2.00 2.00 2.00 1.00 Efficacy index (*) 4.00 5.00 1.00 1.00 1.00 1.00 Efficacy index (*) 4.00 3.00 4.00 4.00 4.00 4.00	Female Severity of illness 4.00 4.00 4.00 3.00 3.00 6.00 6.00 2.00 2.00 Efficacy index (*) 0.50 2.00 1.50 1.50 1.50 1.50	Femals Severity of illness 4.00 4.00 4.00 3.00 3.00 1.00 6.00 Efficacy index (*) 1.00 14.00 6.00 6.00 2.00 Efficacy index (*) 1.00 14.00 6.00 6.00 2.00 2.00	Male Global improvement 4.00 4.00 2.00 2.00 2.00 Efficacy index (*) 0.50 1.50 2.00 2.00	Female Severity of illness 4.00 4.00 4.00 3.00 2.00 2.00 Global improvement 4.00 3.00 2.00 2.00 1.00 Efficacy index 3.00 10.00 6.00 5.00 2.00
	REBO	10								7	
			Patient Treatment S	503 Reboxetine Female	504 Fluoxetine Femals	505 Reboxetine Female	506 Fluoxotine Male	507 Fluoxetine Female	508 Reboxetine Female	521 Reboxetime Male	397 Fluoxetine Female
			Centre Pa	13	ភ័	ភ	880	ហើ	ທີ	เก๋	4. E

SEVERITY OF ILLNESS: 1-mornal, 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 inproved, 3-minimally improved, 4-mo change, 5-minimally worse, 6-much worse, 7-very much worse EFFICACY INDEX (\*): computed from the vector activity by the vector side effects

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CLINICAL GLOBAL IMPRESSION

PHARMACIA CNS R&D

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	398	Reboxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 14.00 0.50	3.00 2.00 6.00 1.50	3.00 2.00 6.00 1.50	2.00 1.00 6.00 1.50		2.00 2.00 4.50		2.000
	399	Reboxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 4.00 14.00 0.50	4.00 10.00 1.00	4.00 3.00 10.00	4.80 3.80 10.00		3.00 2.00 6.00		2.00 2.00 6.00 1.50
	400	Fluoxetine	Ма1е	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 3.00 10.00	2.00 2.00 6.00	2.00 2.00 5.00 3.00	2.00 1.00 2.00 2.00		2.00 1.00 2.00		1.00 2.00 2.00
881	401	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	3.00 9.00 2.00	3.00 2.00 2.00	2.00 1.00 1.00 4.00	2.00 1.00 4.00		4 1.00		2.00 1.00 4.00
	7402	Roboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 3.00 10.00	3.00 2.00 6.00 1.50	3.00 3.00 10.00	3.00 2.00 6.00		2.00 1.00 4.00		1.00 1.00 4.00
	403	Reboxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index	4.00	3.00 2.00 6.00 1.50	3.00 2.00 6.00	3.00 10.00 1.00	2.00 2.00 2.00		2,00 1,00 2,00 2,00		1.00 2.00 2.00
	<b>40</b> 4	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 4.00 14.00 0.50	3.00 2.00 6.00 1.50	2.00 2.00 6.00 1.50	2.00 2.00 2.00		22.00		2.00 2.00 2.00
1	405	Fluoxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	3.00 2.00 6.00 1.50	2.00 1.00 1.00 4.00	2.00 1.00 2.00 2.00	1.00 1.00 4.00		1.00 1.00 2.00 2.00		1.00 1.00 4.00

Day 56

PHARMACTA CNS R&D

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2.00 2.00 6.00 1.50

904	Treatment Sex Fluoxetine Female	Sex Formale	C.G.I. Severity of illness Global improvement Estimacy index	CLINICAL GLOBAL IMPRESSION Day 0 Day 7 D eess 4.00 4.00 mt 14.00	Day 7 4.00 4.00 14.00	000 4 14 4.00 4.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00 14.00	5.00 5.00 14.00	Day 25	Day 35	Day 42	Day 49
408	Reboxetine Male Reboxetine Female	Male Female	Severity of illness Global improvement Efficacy index Efficacy index (*) Severity of illness Global improvement Global improvement	4.00	44.00 0.44.0 0.00 0.40 0.00	4.00 4.00 14.00 9.00 9.00	4.90 4.90 14.90 0.50 3.00	4.00 10.00 10.00 10.00 10.00		6.50 0.50 0.50 0.50 0.50	
510	Fluoxetine Female	Female Female	Efficacy index (*) Efficacy index (*) Severity of illaess Ciobal improvement Efficacy index (*) Efficacy index (*)	6.00	4.00 4.00 4.00 4.00 4.00	3.00 10.00 1.00 4.00	7.50 4.00 7.4.00 9.50	3.00 1.00 1.00 3.00		7.00 74.00 14.00 15.00 2.00	
511	Roboxetine Female	Female	Efficacy index (*) Efficacy index (*) Efficacy index (*) Efficacy index (*) Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 13.00 1.00 4.00 14.00	3.00 1.00 2.00 6.00 1.50	3.00 6.00 1.50 4.00 3.00 10.00	2.00 6.00 1.50 4.00 3.00 1.00		2.00 6.00 1.50 3.00 1.00	2.00 2.00 6.00
512 537	Reboxetine Female Reboxetine Female	Female Female	Severity of illness Global improvement Efficacy index (*) Efficacy index (*) Severity of illness Global improvement Efficacy index Efficacy index	4.00	3.00 10.00 1.00 3.00 6.00 1.50	3.00 10.00 1.00 2.00 2.00 2.00	6.23.00 1.50 1.50 1.50 1.00 1.00 1.00 1.00	7.00 7.00 7.00 7.00 7.00 7.00 7.00 7.00		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 INTROVEMENT: 1-very much improved, 2=much improved, 2=minimally incres, 5=minimally worse, 6=much worse, 7=very much worse EFFICACY INDEX (\*): computed from the vector activity by the vector side effects

6.1.0 8.0.1 8.0.0 8.0.0

PHARMACIA CNS RRD	REBOXEIINE - PROTOCOL 20124/016 Listing No.: 16.0	

				CLINIC	CLINICAL GLOBAL IMPRESSION	IMPRESSI	<b>X</b>						
Centre	Patient	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	538	Fluoxetine Femals	Fenale	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	8.5		9.6		9.6
				Efficacy index Pfficacy index (x)		6.60	8.5	8.5	20.4		2.00		2.00
				Tomas Company		:	:	3	}		i		:
	539	Fluoxetine Female	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		5.00
				Efficacy index		14.00	10.00	10.00	10.00		9.00		9.90
				Efficacy index (*)		0.50	1.00	1.00	1.00		1.50		1.50
5	409	Reboxetine	Kale	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	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
88				Efficacy index (*)		0.50	0.50	1.00	1.00		3.00		4.00
3	411	Rebuxetine Female	Female	Separity of illness	9	9	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
	12	Fluoxetine Female	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	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	3.60	3.00	<b>4</b> .8		4.00 0.4		4. B
	414	Fluoxetine Male	Kale	Severity of illness	5.00	5.00	5.00	5.00			5.00		5.00
				Global improvement		4.00	4.00	4.00			3.00		4.00
				Efficacy index		13.00	13.00	13.00	9.6		9.00		15.00
				Efficacy index (*)		1.00	1.00	٦.00			z.uu		C.33

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PHARMACIA CNS R&D

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				REBOXETIN	E - PROT sting No	REBOXETINE - PROTOCOL 20124/016 Listing No.: 16.0	4/016						
				CLINICA	T GLOBAL	CLINICAL GLOBAL IMPRESSION	¥6						
tre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day S6
	415	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	6.00 4.00 14.00 0.50	6.00 3.00 10.00	5.00 2.00 5.00 3.00	4.00 1.00 1.00 4.00		2.00 1.00 1.00 4.00		2.00 1.00 1.00 4.00
	416	Fluoxetine Female	Female	Soverity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	4.00 2.00 6.00 1.50		4.00 2.00 5.00 3.00		3.00 1.00 4.00
	417	Roboxetine Femalo	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 3.00 9.00 2.00	4.00 2.00 5.00 3.00	2.00 1.00 1.00 4.00	2.00 1.00 4.00		2.00 1.00 4.00		2.00 1.00 1.00 4.00
	418	Reboxetine Female	Female	Severity of illmess Global improvement Efficacy index Efficacy index (*)	6.00	6.00 4.00 13.00	6.00 3.00 2.00	5.00 2.00 5.00	4.00 2.00 5.00 3.00		3.00 1.00 4.00		2.00 1.00 4.00
	419	Fluoxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 4.00 14.00 0.50	5.00 3.00 10.00		4.00 2.00 6.00 1.50		3.00 3.00 3.00
	420	Fluoxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index	5.00	5.00 4.00 13.00	5.00 3.00 9.00 2.00	5.00 2.00 5.00 3.00	5.00 5.00 3.00		4.00 2.00 5.00		2.00 1.00 4.00
	421	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	6.00 5.00 13.00	6.00 5.00 13.00	6.00 3.00 9.00 2.00	5.00 3.00 3.00		2.00 1.00 1.00 4.00		2.00 1.00 4.00
	422	Fluoxetine	Kale	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	6.00 4.00 13.00	6.00 4.00 13.00	3.00 2.00 2.00	5.00 2.00 3.00		2.80 1.00 1.00 4.00	,	2.00 1.00 4.00

SEVERITY-OF ILLMESS: 4-normal, 2-borderline mentally ill, 3-middly ill, 4-moderately ill, 5-markedly ill, 6-severily ill, 7-extremely ill GLOBAL IMPROVEMENT: 1-very much improved, 2-much improved, 3-midimally improved, 4-mo change, 5-minimally worse, 6-much worse, 7-very much EFFICACY INDEX (\*): computed from the vector activity by the vector side effects

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 16.0

PHARMACIA CNS R&D

				CLINIC	AL GLOBAL	CLINICAL GLOBAL IMPRESSION	æ						
Centre	Patient	Patient Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
51	423	Fluoxetine	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	90.9	6.00 4.00 14.00 0.50	6.00 4.00 14.00 0.50	6.00 4.00 14.00 0.58	6.00 4.00 13.00		4.00 2.00 3.00		4.00 2.00 5.00
	424	Reboxetine	Мале	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 14.00 0.50	3.00 10.00	2.00 3.00 9.00	4.00 2.00 3.00		3.00 1.00 1.00 4.00		2.00 1.00 1.00 4.00
	425	Reboxetino Femalo	Fenale	Severity of illness Global improvement Efficacy index Efficacy index	9.00	6.00 4.00 13.00	6.00 13.00 1.00	8.00 3.00 3.00	2.00 1.00 4.00		2.00 1.00 1.00		2.00 1.00 1.00
885	426	Fluoxetine	Kale	Severity of illness Global improvement Efficacy index Efficacy index	6.00	6.00 4.00 13.00	6.00 3.00 2.00	6.00 3.00 2.00 2.00	6.00 2.00 5.00 3.00		5.00 5.00 3.00		4.00 2.00 5.00 3.00
	427	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index	5.00	5.00 4.00 13.00	5.00 9.00 2.00	5.00 3.00 2.00	5.00 5.00 3.00		4.00 2.00 5.00 3.00		7.00 7.00 4.00
	428	Fluozotine Male	Male	Severity of illness Global improvement Efficacy index Efficacy index	5,00	5.00 4.00 13.00	5.00 4.00 13.00	3.00 3.00 2.00	2.00 2.00 3.00		4.00 2.00 5.00 3.00		2.00 3.00 9.00
	644	Reboxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index	5.00	5.00 4.00 13.00	5.00 4.00 13.00	5.00 4.00 13.00	5.00 4.00 13.00		5.00 3.00 9.00 2.00		2.00 1.00 4.00
	450	Fluoxetine Male	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	6.00 4.00 14.00 0.50	6.00 4.00 14.00 0.50	6.00 3.00 10.00	5.00 2.00 6.00		5.00 5.00 3.00		5.00 3.00 3.00

SEVERITY OF ILLNESS: 4=normal, 2=borderline mentally ill, 3=middly ill, 4=moderately ill, 5=markedly ill, 6=severily ill, 7=extremely ill GLOBAL IMPROVEMENT: 4=very much improved, 2=minimally improved, 4=no change, 5=minimally worse, 6=nuch worse, 7=very much worse EFFICACY INDEX (\*): computed from the vertor activity by the vector side effects

				CEINIC	AL GLOBAL	CLINICAL GLOBAL IMPRESSION							
Centre	Patient	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
<del>2</del>	451	Fluoxetine	Fonale	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 13.00	5,00 4,00 14,00 0,50	5.00 3.00 1.00	4.20 2.00 1.50	•	4.00 2.00 3.00		3.00 3.00 3.00
	452	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index	5.00	5.00 4.00 14.00 0.50	5.00 4.00 13.00	4.00 2.00 3.00	4.00 1.00 1.00 4.00		2.00 1.00 4.00		2.00 1.00 4.00
	454	Fluoxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index	5.00	5.00 4.00 13.00	5.00 4.00 13.00	5.00 3.00 9.00 2.00	5.00 3.00 2.00		3.00 3.00		4.00 2.00 3.00
<b>5</b> 1	429	Fluoxetine	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	3.00 2.00 3.00	2.00 2.00 5.00 3.00	2.00 1.00 1.00 4.00	2.00 1.00 4.00	4.1.00 6.1.00 6.00	2.00 1.00 1.00	2.00 1.00 1.00	2.00 1.00 1.00 4.00
886	430	Reboxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	4.00 2.00 6.00 1.50	3.00 2.00 6.00 1.50	3.00 2.00 6.00 1.50	3.00 2.00 6.00 1.50	3.00 2.00 6.00	3.00 2.00 6.00 1.50	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	2.00
	431	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	3.00 2.00 5.00	3.00 2.00 5.00	2.00 5.00 3.00	2.00 1.00 4.00	2.00 2.00 5.00	3.00 3.00 3.00	2.00 2.00 5.00 3.00	2.00 2.00 3.00
	432	Fluoxetine Female	Fenale	Severity of illness Clobal improvement Efficacy index Efficacy index	6.00	3.00 3.00 9.00 2.00	3.00 2.00 5.00 3.00	1.00 1.00 4.00	1.00 1.00 1.00 4.00	1.00 1.00 4.00	1.00 1.00 1.00	1.00	1.00 1.00 4.00
	433	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	4.00 3.00 2.00 2.00	3.00 5.00 3.00	2.00 1.00 4.00	2.00 1.00 4.00	7.00 7.00 4.00	2.00 1.00 4.00	2.00 1.00 1.00 4.00	2.00 1.00 4.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=middly ill, 4=moderately ill, 5=markedly ill, 6=severily ill, 7=extremely ill GLOBAL IMPROVENENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much EFFICACY INDEX (\*): computed from the vector activity by the vector side effects

PHARMACIA CNS R&D

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				REBOXET1	REBOXETINE - PROTOCOL 20124/016 Listing No.: 16.0	OCOL 2012	4/016						
				CLINIC	CLINICAL GLOBAL IMPRESSION	IMPRESSI	¥6						
Centre	Centre Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	ا څ
91	434	Fluoxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	4.00 3.00 9.00 2.00	3.00 2.00 5.00 3.00	3.00 2.00 6.00 1.50	3.00 2.00 6.00	22.00	22.00	2.00	
	435	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6,00	5.00 2.00 2.00	4.00 2.00 3.00	3.00 5.00 3.00	2 7 7 7 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2.00 1.00 1.00	2.00 1.00 4.00	2.00 1.00 4.00	
	436	Fluoxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	5.00 3.00 2.00	3.00 3.00 3.00	3.00 2.00 5.00	3.00 2.00 5.00 3.00	3.00 2.00 5.00 3.00	2.00 2.00 5.00	4.00 3.00 10.00 1.00	
88	437	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	4.00 3.00 9.00 2.00	8 2 00 8 8 00 8 00 00 00 00 00 00 00 00 00	3.00 2.00 3.00	3.00 3.00	3.00 2.00 5.00 3.00	3.00 2.00 5.00 3.00	3.00 5.00 3.00	
7	438	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	3.00 2.00 5.00 3.00	3.00 2.00 5.00 3.00	2,00 5,00 3,00	4.00 2.00 5.00 3.00	3.00 2.00 7.00 1.00			
	439	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	9.00	5.00 3.00 9.00 2.00	4.00 2.00 5.00 3.00	4.00 2.00 5.00	2.00 1.00 1.00 4.00	1.00 1.00 4.00	1.00 1.00 4.00	1.00 1.00 4.00	
	440	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	4.00 2.00 5.00 3.00	3.00 2.00 3.00	3.00 2.00 5.00 3.00	1.00 1.00 4.00	2.00 1.00 4.00	2.00 1.00 1.00 4.00	2.00 1.00 1.00 4.00	
	441	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	4.00 3.00 9.00 2.00	3.00 2.00 5.00 3.00	3.00 2.00 5.00 3.00	2.00 2.00 1.00 4.00		2.00 1.00 1.00 4.00		109

SEVERITY OF ILLNESS: 1-normal, 2-borderline mentally ill, 3-middly ill, 4-moderately ill, 5-markedly ill, 6-severily ill, 7-extremely ill GLOBAL INPROVEMENT: 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

Day 56

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				E.	PHARMACIA CNS RED	CNS RED						
				REBOXETI	NE - PRO isting N	REBOXETINE - PROTOCOL 20124/016 Listing No.: 16.0	24.7016					
				CLINIC	AL GLOBAI	CLINICAL GLOBAL IMPRESSION	ED#					
ntre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49
	442	Reboxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	7.00	7.00 4.00 13.00	6.00 3.00 9.00 2.00	4.00 2.00 6.00 1.50	4.00 2.00 3.00		4.00 2.00 5.00	
	443	Fluoxetine Male	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 13.00	4.00 9.00 9.00	3.00 3.00 3.00	3.00 3.00 3.00		2.00 5.00 3.00	
	444	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	4.00 3.00 9.00 2.00	4.00 3.00 9.00 2.00	3.00 2.00 5.00 3.00	3.00 3.00 3.00		1.00 1.00 4.00	
	445	Reboxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 3.00 2.00 2.00	4.00 2.00 3.00	4.00 2.00 5.00 3.00	2.00 2.00 1.00 4.00		22.00 1.00 4.00	
	944	Fluoxetine	Fеля Зе	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5,00 4,00 13,00	2.00 2.00 2.00	3.00 2.00 5.00 3.00	3.00 2.00 5.00		2.00 1.00 4.00	
	447	Fluoxetine	Hale	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	3.00 3.00 2.00 2.00	3.00 3.00 2.00	3.00 2.00 5.00 3.00	3.00 3.00 3.00		3.00 2.00 5.00 3.00	
	448	Reboxetine Female	Fessale	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5,00 4,00 13,00 1,00	3.00 3.00 2.00 2.00	4.00 3.00 9.00 2.00	2.00 2.00 2.00		4.80 3.00 9.00 2.00	
	455	Fluoxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	6.00 4.00 13.00	5.00 3.00 10.00	5.00 3.00 10.00	3.00 2.00 6.00 1.50		3.00 2.00 6.00	

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 norse, 6-much worse, 7-very much EFFICACY INDEX (\*): computed from the vector activity by the vector side effects

REBOXETINE - PROTOCOL 20124/016 Listing No.: 16.0
REBOXETINE - PROTOCOL 20124/016 Listing No.: 16.0

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				CETUTE	CLINICAL SEVEN ARTACOSION	THERESO	5						
Centre	Patient	Centre Patient Treatment	Хех	C.G.I.	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42	Day 49	Day 56
16	456	Reboxetine	Kale	Severity of illness Global improvement Efficacy index	6.00	6.00 3.00 9.00	4.00 2.00 6.00	3.00 2.00 6.00	3.00 2.00 6.00		3.00		8.69.9
				Efficacy index (x)		2.00	1.50	1.50	1.50		1.50		 
	457	Fluoxetine Female	Female	Severity of illness	6.00	6.00	4.00	4.00	4.00	2.00	2.00		2.00
				Global improvement		8.4 8.8		2.00	2.00	8 8	2.00		8 8
				Efficacy index (*)		1.8	2.00	2.00	2.00	2.00	2.80		4.00
		•	,	:				8	9		4.00		4.00
	458	Fluoxetine Female	Female	Severity of illness	9.00	9.4	9.5	8 6	3.6		3.00		3.00
	6			Efficacy index		13.00	9.6	9.00	9.00		9.00		9.6
				Efficacy index (*)		1.00	2.00	2.00	2.00		Z.00		7.00
	9	4000	1	County of illness	80.5	4.00	3,00	3.00	3.00		1.00		1.00
8	¥0.	Kenoxettae	пате	Glabal improvement	;	3.00	2.00	2.00	2.00		1.00		1.99
8				Efficacy index		9.00	5.00	5.00	5.00		1.00		2.8
3				Efficacy index (*)		2.00	3.00	3.00	3.00		<b>4</b> .00		4.00
				;	;	;	,		. ?		5		1,00
	460	Reboxetine	Male	Severity of illness	9.00	5.00	9.6	9.5	8.6		0.0		9.
				Global improvement		9.0	9 6	9.5	5.00		1.00		1.00
				Efficacy index (*)		2.00	2.00	3.00	3.00		4.00		4.00
		•		:	•			ć	6	6	00.6	2.00	2.00
92	52	Fluoxetine	Female	Severity of illness	6	9.6	9 5	9	9.6	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
	,	Determined Const.	Comp 1	Security of illusion	5	8	4.00	3.00	2.00	2.00			2.00
	07	Reporetine	Louging	Global improvement	3	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	5.0			 8 .
				Efficacy index (*)		1.00	2.00	3.00	1.50	3. n			ř
	50	Dehovetine Female	Fonale	Severity of illness	5.00	5.00			2.00				2.00
	3	Venuescring	o Temp	Global improvement		4.00			3.00				2.0
-				Efficacy index (*)		13.00	2.00	9.60	3.80	3.00	4.00	4,00	. 4

SEVERITY OF ILLNESS: 4=normal, 2=borderline mentally ill, 3=middly ill, 4=moderately ill, 5=markedly ill, 6=severily ill, 7=axtremoly ill 6=severily ill, 7=axtremoly ill 6=Severily ill, 7=axtremoly ill 6=Severily ill, 7=axtremoly ill 6=Severily ill, 6=Severily ill, 7=axtremoly ill 6=Severily ill, 6=Severily ill, 7=axtremoly ill 6=Severily ill, 7=axtremoly ill 6=Severily ill, 6=Severily ill, 7=axtremoly ill 6=Severily ill, 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill, 6=Severily ill, 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=axtremoly ill 7=a

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PHARMACIA CNS RED REBOXEVINE - PROTOCOL 20124/016 Listing No.: 16.0

				CLINIC	AL GLOBAL	CLINICAL GLOBAL IMPRESSION	<b>5</b>						
Centre	Patient	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
<b>\$</b>	69 69	Fluoxetine	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 13.00 1.00	5.00 4.00 13.00	5.00 4.00 13.00	5.00 4.00 13.00				
	29	Reboxetine Hale	Male	Severity of illness Global improvement Efficacy index Efficacy index	6.00	3.00 2.00 2.00	5.00 9.00 2.00	5.00 4.00 13.00	3.00 5.00 3.00	3.00 3.00 3.00 3.00	2.00 2.00 3.00	2.00 2.00 1.00 4.00	4.00 4.00 4.00
	30	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index	5.00	5.00 4.00 13.00	5.00 4.00 13.00	2.00 3.00 3.00	3.00 3.00 2.00	4.00 3.00 2.00	4.00 3.00 2.00	2.00 2.00 5.00 3.00	3.00 3.00 3.00
890	31	Reboxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index	5.00	5.00 3.00 2.00 2.00	5.00 3.00 9.00 2.00	5.00 3.00 2.00	3.90 3.00 2.00	5.00 3.00 2.00	3.00 3.00 3.00	2.00 2.00 5.00 3.00	2.00 3.00 3.00
	32	Fluoxetine Female	<b>Ге</b> та Le	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	6.00 5.00 13.00	6.00 5.00 13.00	3.00 3.00 3.00	8.00 8.00 8.00 8.00	8 2 2 8 8 2 9 8 8 9 9 9 9	3.00 2.00 5.00	2.00 2.00 1.00 4.00	2.00 1.00 4.00
	ê. 6	Reboxetine Femalo	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	5.00 3.00 9.00 2.00	3.00 2.00 5.00 3.00	3.00 5.00 3.00	3.00 2.00 3.00	3.00 5.00 3.00	3.00 3.00 3.00	2.00 1.00 4.00	2.00 1.00 4.00
	20	Reboxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00								
	25	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	9.00 9.00 2.00	3.00 3.00 9.00 2.00	3.00 3.00 2.00	3.00 3.00 2.00	3.00 2.00 5.00 3.00	3.00 2.00 5.00 3.00	3.00 3.00 3.00	2.00 2.00 3.00

PHARMACIA CNS R&D

				-	Listing No.: 16.0	.: 16.0							
				CLINIC	CLINICAL GLOBAL IMPRESSION	IMPRESSI	NO						
Centre	Patient	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
81	25	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index	9.00	5.00 6.00	5.00 4.00	3.00	3.00	3.00	3.00	3.00	2.00
				Efficacy index (*)		1.00	1.00	2.00	2.80	2.00	2.00	2.00	<b>*</b> .00
	S	Fluoxetine Female	Fenale	Severity of illness Global improvement Efficacy index Efficacy index	6.00	3.00 3.00 2.00	3.00 9.00 2.00	3.00 3.00 2.00	3.00 2.00 5.00	3.00 2.00 5.00	2.00 5.00 3.00	2.00 5.00 3.00	2.00 2.00 5.00
8 9	*5	Fluoxetine Male	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 3.00 9.00 2.00	3.00 2.00 5.00	3.00 2.00 5.00 3.00	3.00 2.00 5.00	3.00 5.00 3.00	2.00 1.00 4.00	2.00 1.00 4.00	2.00 2.00 1.00 4.00
2	21	Fluoxotine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	4.00 3.00 6.00	3.00 2.00 2.00	2.00 2.00 2.00	2.00 2.00 2.00	2.00 2.00 1.00 4.00	2.00 1.00 4.00	1.00 1.00 4.00	1.00 1.00 4.00
	22	Fluoxetine Female	Female	Severity of illness Global improvement Efficacy index Efficacy index (*)	6.00	5.00 4.00 13.00	6.00 5.00 15.00	6.00 5.00 15.00	3.00 3.00 10.00	7.00 7.00 16.00			
22	٥	Fluoxetime Female	Fomale	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 9.00 2.00	4.00 5.00 3.00	4.00 2.00 5.00	3.00 5.00 3.00	3.00 5.00 3.00	3.00 2.00 5.00	3.00 3.00	3.00 5.00 3.00
22	113	Fluoxetine	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	5.00	5.00 4.00 13.00	5.00 4.00 13.00						
	115	Reboxetine Male	Male	Severity of illness Global improvement Efficacy index Efficacy index (*)	4.00	4.00 4.00 13.00	4.00 4.00 13.00	4.00 5.00 13.00					

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PHARMACIA CNS R&D

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	,	date Adverse event	09/01/92 FLATULENCE			HYPERTONIA			IMPOTENCE				MOUTH DRY				RHINITIS			MIA			TENDINITIS				3				MINIA
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REBOXETINE - PROTOCOL 20124/016 Listing No.: 17.0

ADVERSE EVENTS: DETAIL AND SUMMARY

			Treatment						Last									
			Start	End		Onset	Type V	Type Visit End	report Sava Hist Rel Stud Symp	va His	it Re	Stud S	d w	ä	Dis R	8	Re Out Still	
Centre	Centre Patient Drug	. Drug	date		date Adverse event	date	record	No date	wisit rity ory ship drug trea Hosp app. app. come present (c)	ty of	y shil	drug t	H H	de es	9	. CO	presen	9
-	m2	Fluoxetine	01/07/92	25/08/92 INSOMNIA	NSOWNIA	23/05/92(2) Summary	Summary	25/08/92(M)		N								2
	4	Rebaxetine	14/08/92	24/09/92 F	14/88/72 24/09/92 HEPATIC ENZYMES INCREASED 25/09/72	25/09/92	Detail Detail Summary	42 99 21/10/92 21/10/92	<b>5</b>		N N	m m		m m		и и	>	YES
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893	ю	Fluoxatina	13/18/92	13/18/92   11/11/92 AMKIETY	ANKIETV	29/10/92	Detail Detail Summary	21 36 13/11/92(*)	35	ими		W 4 W	YES YES	m	מו מו מו	m m m	> > a m a	YES
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N	<b>10</b>	Fluoxetina	16/50/50	28/06/91 HEADACHE	HEADACHE	15/88/61	Detail Summary	14 16/05/91 16/05/91	14	~ ~				ממ	m m	мм		YES
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Study drug: Iwn change, Zedom reduced, Sader, withdrawn, detemp. inter.

Disapp. Reapp.: Trendrind, Zenot reg., Sanot appl. — Dutcome: Interpreted, Zeroc. with meq., Sastill present, dedeath

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Experiment content of the State of Sanot appl.

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100	Fluoxetine	04/05/91	28/06/91	28/06/91 SMEATING INCREASED	12/05/91	Summary	16/90/22	ž.	-	N	4	_	MS	ю	м	-	>	YES
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REBOXETINE - PROTOCOL 20124/016 Listing No.: 17.0

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er m	Fluoxetine	19/00/61	22/06/91	22/06/91 AGITATION	22/08/91	Detail	7		m i	м ,	м 1	YES	· ·	m 1	<b>m</b> •	> >	,	
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ADVERSE EVENTS: DETAIL AND SUMMARY

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Severity: D'eunknom, l'emild, 2-moderate, 3-severe,
Studd fugge | Legislate | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed | Severed

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PHARMACIA CNS RED	WETINE - PROTOCOL 20124/016	Listing No.: 17.0

		ī	Treatment						Last										
			Start	End		Onset	Type V.	Type Visit End	report Seve Hist Rel Stud Symp	re Hist	Rel	Stud S	<u>.</u>	Dis	e.	Dut	Re Dut Still		
Centre Patient Drug	Patient	t Drug	date	date	date Adverse event	date	record	No date	wisit rity ory ship drug trea Hosp app. app. come present (¢)	y.	Sh1p	drug t	rea Ho	sp ap	. app.	COME	prese	2	- 1
N	42	Reboxetine	05/03/92	05/03/92 29/04/92 INSOMNIA	INSOMNIA	06/03/92	Detail	2		2	м	_	YES	cu.	m	ю			
							Detail	21		1 1	М	_	YES	м	en en	113			
							Detail	28		2	m	-		м	м	M			
							Detail	35			M	-		ю	10	м	*		
							Summary	30/04/92(*)	35	2	10	-	YES	N	ro ro	10	>	YES	s
					NAUSEA	07/03/92	Detail	2			м	-		m	in m	m			
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							Detail	21			М	н		m	n				
							Detail	28 31/03/92		-	M	-1		м	10	3			
							Summary	51/03/92	28	2	m	-		m	M3	-		YES	ø
					TASTE PERVERSION	06/03/92	Detail	,		~	61	-		м	m	m 	>		
0							Summary	30/04/92[#]	7	-	2			м	m	m	> m	YES	ø
g r																			
4					TIMMITUS	07/03/92	Detail	,		_	N	-		67	m	m	m		
							Detail	14 14/83/92		_	æ	-		м	m				
							Summary	14/03/92	14	_	N	-		м	w			YES	y)
-	Ю.	Reboxetine	19/11/91	13/01/92	19/11/91 13/01/92 GASTRITIS	11/12/91	Detail	28		_	•	-	YES	м	w	m	м		
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							Detail	42											
							Detail	49 06/01/92		_	•	-	YES	m	m				
							Summary	06/01/92	\$	_	•	-	YES	м	m	-	7	YES	so.
					HEADACHE	13/11/91	Detail	۰		м									
							Detail	2		2	4	-	YES	м	m		м		
							Detail	14		~	4	-	YES	m	 	 10			
							Detail	12		~	4	-	YES	ю	n				
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							Detail	45		_	4	-	YES	w	en en	m			
							Detail	44		_	4	-	YES	w	m		м		

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Saverity: Grankbown, leniid, Zemoderate, Sesvere,
Study dres; Len obnose, Zedose reduced, Sedef withdrawn, 4rtem. Inter.
Hospital: Irredulated, Zenot reduced, Sedef withdrawn; 4rtem. Inter.
Hospital: Irredulated, Zenot reput. Senot appl. — Outcome: Irreduced, Zeroc. with sed., Setill present, 4rdeath
DARSPOWERD: Irro, Zeyos, Senot appl. — Relationship: Irdefinite, Zeprobable, Seporable, 4rdouth, Grunnbown, Benome
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REBOXETINE - PROTOCOL 20124/016	Listing No.: 17.0	

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М	8	Reboxetine	16/11/61	19/11/91 13/01/92 HEADACHE	13/11/91	Summary	14/01/92(K)	ų	m	-	4	-	YES	m	æ	т	m	>	2
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						Detail	14		-	-	ų	_	VES	M	M	M	M		
						Detail	21 10/12/91		-		•	_	YES	102	m	m			
						Summary	19/12/91	23	61	1	æ	_	YES	m	80	m			ş
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				PAIN	13/11/91	Detail			Ma										
						Deta11	7		m	-	٠	_	YES	m	m	m	m		
						Detall	14		м	-	9	_	YES	M3	m	m	m		
						Detail	23		m	1	9	_	YES	М	m	m2	m		
						Detail	28		m	-	و	_	YES	M	m	m	m		
						Detail	ž		N	-	9	_	YES	м	m	м	m		
						Detail	42		"	-	9	_	YES	м	m	м	m		
						Detail	49		N	-	9	_	YES	n	м	м	м		
8						Detail	33		7	-	9	_	YES	M	м	m	M	>	
9						Summary	14/01/92[*]	56	м	-	9		YES	м	m	ĸī	m	>	ž
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						Detail	28		н	-	М	m	YES	n	m	m	м		
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						Detail	45		7	-	м	-	YES	M	m	m	m		
						Detail	43		1	-	M	_	YES	m	m	m	m		
						Detail	56		1	-	M	-	YES	M	m	м	m	>	
						Summary	14/01/92(*)	26	-	-	M	-	ÆS	м	m	м	ю	>	YES
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						Detail	42 26/12/91		8	-	•	-	YES	ю	ĸ	м	_		
						Summary	26/12/91	45	84	-	9	-	YES	м	ю			^	YES
	44	Fluoxetine	13/12/91	13/12/91 50/01/92 CONJUNCTIVITIS		Detail	•		-										
						Detail	2		8	-	¥			м	м	м	м		
						Detail	42		-	-	4		YES	N	М	ю	м		
					12/12/91(2)	Summary	24/81/92(#)	42	٠	-	4	-	VES	8	M	M	M	,	VES

			ADV	ADVERSE EVENTS: DETAIL AND SUMMARY	ETAIL AND	SUHHARY												
		Treatment					Last						i		į	į		
stieni	stient Drug	Start	End date Adverse event	Onset	Type V	Type Visit End	report Seve Hist Rei Stud Symp visit rity ory ship drug trea	10. H	ist i	isp dr.	es tre	T HOSE	app.	app.	COME	eport Save Hist Rel Stud Symp Dis Ka Dut Still wight rity ory ship drug trea Hosp app, app. come present (c)	(6)	
v.	Fluoxatine	13/12/91	30/01/92 HEADACHE		Detail	•		N										
					Detail	2		N	-	ď	-		in M					
					Detail	21		7	-	4	_		m	m				
					Detail	42		-	-	4	1 YE		2	MO .				
				12/12/91(3)	Summary	24/01/92(#)	45	7	-	4	, ,	VES .	ra N	ns ns	m		2	
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					Detail	35 16/01/92		~		4	5	YES						
					Summary	16/01/92	SS.	N	-	ю	5	YES	CI.	w ""	ra.	1	YES	
	Fluoxetine	25/03/92	25/03/92 19/05/92 DIZZINESS	26/03/92	Detail	7		-	-	v.	м		MI.		m	м		
					Detail	14 05/04/92		7	н	J	-				_	_		
					Summery	05/04/92	14	-	-	var	-		м	m	m m	_	× Sii	
			INFECTION VIRAL	27/03/92	Detail	7 01/04/92		-	-	•	-	YES				r4		
					Viewens	01/04/92	2	-	-	•	-	YES	m	m.	m	-	VES	
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			PARAESTHESIA	03/04/92	Detail	1.6		٠.		3 14			3 80			3 M		
					TERROR			• •		3 10								
					Detail	35		-	N 6	n 100								
					Summary	07/05/92	67	1 13	1 (1)	m					m	_	YES	
			SMEATING INCREASED	28/03/92	Detail	,		7	N	C4	-		м	ю	m	m		
					Detail	14 05/04/92		н	7	N	-		m		m			
					Summery	05/04/92	14	17	7	N			M	so.	m		KB2	
				09/05/92	Detail	63		N	7	ю	-		m	м	M			
					Summary	20/05/92(=)	. 49		14	ю	-		er3	m		> M	YES	

Severity: Brunknown, Jemild, Zemederste, Bessere,

Study drugs lane change, Zedes reduced, Bedef, Withdrawn, 4etemp. Inter.

Hospital, Teredurad, Serior Ten.

Dissay Respo.: Teneurad, Serior ten.

Dissay Respo.: Ten.

Symbologic Creatent; Orno, 1998

(C) doverse went ten.

(C) doverse went till present and date - Visit date

(S) onest date missing; First report Visit date used

		Treatment						Last										
		Start	End		Onset	Type V:	Type Visit End	report Seve Hist Rel Stud Symp	ve His	Rel	Stud	Symp	P	Dis	8 0	Out Still	117	
Centre Patient Drug	ent Drug	date	date	date Adverse event	date	record	No date	wisit rity ory ship drug trea Hosp app. app. come present (c)	Į.	ship.	Sn.10	tres Ho	sp ap	ď.		P P	sent (	<b>3</b>
2 47	Fluoxetine	25/03/92	19/05/92 TREHOR	TREMOR	03/04/92	Detail	14		es.	m	-		м	м	м	м		
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				VOMITING	25/03/92	Detail	7 26/03/92		N	10	-		м	м	м	_		
						Summary	26/03/92	~	N	'n	-	YES	м	м	м	_	_	YES
48	Reboxetins	19/05/92	13/07/92	19/05/92 13/07/92 CONSTIPATION	22/05/92	Detail	7 22/05/92		_	1 6	м	YES	м	ю	m	_		
•						Summary	22/05/92	7		1 6	-1	YES	м	m	ю	_		YES
•				HEADACHE	20/05/92	Detail	7 20/05/92		N	1 2			ю	м	m	_		
						Summary	20/05/92	7	N	2	п	YES	м	мэ '	m	-		YES
				MOUTH DRY	27/05/92	Detail	14		N	1 3	-		m	м	w	m		
						Deta11	21		7	. 3			m	m	m	m		
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				PARAESTHESIA	21/05/92	Detail	7 25/05/92		-	9	-	YES	м	м	M	-		
						Summary	25/05/92	1	_	1 5	-	YES	м	м	M	1	•	YES
				TREMOR	03/06/92	Detail	21		-		-	YES	М	м	м	м		
						Detail	28		~	3	-	VES	(1)	м	m	м		
	:					Detail	35		2		~	YES	1/3	м	м	10		

Severity; Psukhown, lemid, Gemedrate, Segevere,
Study drug: Irno change, Zedose reduced, Segevere,
Haspital: Lerequized, Zender sedeced, Seder, Withfram, Getamp, inter,
Haspital: Lerequized, Zender ser, Sende appl. — Outcome: Jercovered, Zenco with seq., Sestill present, dedeath
Bisapp. Reapp. Reapp.: Isna, Zeyes, Sende appl. — Raistinanip: ledefaite, Zeprobable, Seposible, Gedoubfful, Seuntnown, Genome
symptomatic treatment: Pero, Pleys
(C) adverse event ware for statistical analysis
(C) adverse event ware for statistical analysis
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ADVERSE EVENTS: DETAIL AND SUMMARY Listing No.: 17.0

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	Type	record	Detail	Detail	Detail	Supressiy	Detail	Summary	Detail	Summary	Detail	Detail	Summery		Detail	01	Deta11	Detail	Summary	Detail	Summary	Detail	Detail	Summary	Deta11	
	Onset	date	03/06/92				19705/92			10/10/91(0)	20/11/91					10/10/91(9)	16/10/31			12/11/91		16/10/91				13/11/92(9)
	_	date Adverse event	2 TREMOR				BHILLROA	*	16/10/91 10/12/91 INSOMNIA		TREMOR				16/10/91 12/11/91 INSOWIA		MOUTH DRY			SUICIDE ATTEMPT		SMEATING INCREASED			18/11/92 15/12/92 INSDMIA	
	End	datı	13/07/93						10/12/9						12/11/9										15/12/9	
Treatment	Start	date	19/05/92 13/07/92 TREMOR						16/10/91						16/10/91										18/11/92	
		of Drug	Reboxetine						Fluoxetine						Fluoxetine										Reboxetine	
		Centre Patlent Drug	85						65						99										29	
		Ē	N						m																	

Severity; Pauknown, lealid, 2-moderate, 3-movere.
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Study drug: I am olarge, Zedos raduced, Scafe, withdrawn, 4stemp. Inter.

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Disapp. Respo.: Stafe Sent appl. — Balationship: I scafe, Septemble, Septemble, Septemble, 6stemp. Sent sppl. — Ralationship: I scafe, 2sprobable, Septemble, 4stoubtful, Seunknown, 6stemp symptomatic treatment: Deno, 1-yes.

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Sewelly: Granktoon, lealid, Esmoderate, Steware.

Study drug: leng change, Zedost reduced, Sadef. withdrawn, datems. Inter.

Hospital: In-required, Proter rate, Strot appl. — Dutome: Interovered, Zete. with seq., Setill present, dedeath

Supplication, Zetes, Strot appl. — Relationship: Indefinite, Zeprobable, Sepossible, dedoubtful, Seunknown, Genome
Symptomatic treatment: Broo, 1-yes

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PHARMACIA CNS R&D

YES .

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PARTICINESS   07/12/91   Detail   14 16/12/91   14   17   17   18   18   18   18   18   18						Detail	56				YES				>	
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MALOSEA   Detail   Signol/92   St   1   2   5   1   2   3   5   1   5   5   1   5   5   5   5   5																
Summary   Sa/01/92   Sa   1   2   5   1   2   3   5   1   5   5   5   5   5   5   5   5				MOUTH DRY	28/01/92	Detail	56 30/01/92		7		-	N	m m	_		
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REBOXETINE - PROTOCOL 20124/015	Listing No.: 17.0

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in in	Reboxetine	15/09/92	15/09/92 09/11/92 CONSTIPATION	18/09/92	Detail	14 25/09/92											
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Severity: Pauknawn, lamid, Zawderate, Jasevere,
Study drus Inan chamse, Zalose reduced, Jader, withdrawn, Getamp, inter.
Study drus Inan chamse, Zalose reduced, Jader, withdrawn, Getamp, inter.
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Disapp. Resept. I Ind., Zayes, Janet appl. -- Relationship: Indefinite, Zaprobable, Japossible, 4-doubtful, 5-unknown, benome
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PHARMACIA CNS RED	REBOXETINE - PROTOCOL 20124/016 Listing No.: 17.0	ADVERSE EVENTS: DETAIL AND SUMMARY	,	record No date	Detail	Detail	Detail	Detail	Summary	Detail	Detail	Summary	Detail	Datail	Summary	5		Summary		Detail	Detail	Summary	Detail	Summary	Detail	Detail	Summary	Detail	Datail
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PHARM	Listi	VENTS		<u>.</u>	05/10/92			,	317 08/92(4)			28/89/92(3)			28/09/92(3)	7871078						26/09/92(9)		28/119/92(2)	05/11/92				
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Study drugs Inno change, 2-date reduced, 3-def. withdrawn, 4-temb. ister.

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335	Reboxetina	13/10/92	16/11/92 SUICIDE ATTEMPT	16/11/92	Detail	35 16/11/92		ю	N	м	YES	N	M	м	-		
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393	Fluoxetine	25/06/92	18/08/92 HEADACHE	25/06/92	Detail	2		~	_	~		N	м	м	м		
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394	Reboxetine	06/117/92	05/07/92 31/08/92 AGITATION	10/08/92	Detail	45		N	_	m		М	M	м	м		
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REBOXETINE - PROTOCOL 20124/016 Listing No.: 17.0	ADVERSE EVENTS: DETAIL AND SUMMARY		Onset	date	20/16/92		06/07/92				13/08/92			30/07/92							20,000, 200,000	(0)26/10/22			84/08/92(8)		04/08/92		
	द		End	date Adverse event	31/08/92 PRURITUS		SHEATING INCREASED				16/09/92 HEADACHE			HICTURITION DISORDER			NAUSEA						17/08/92 AGITATION				MICTURITION DISORDER		
		Trestment	Start	date	26/20/90						24/01/92												04/08/92						
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9				INFLUENZA-LIKE SYMPTOMS	18/03/93	Detail	42 03/04/93		~	w	-	YES	м	ы			
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				NERVDUSNESS	27/03/93	Detail	35		_	CA.	-		N	ma ma	m		
						Detail	42		-	21	-		O.	m	M		
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						Summary	22/04/93[*]	26	n.	ev.	-		N	103 104	EN EN	>	YES
				SWEATING INCREASED	26/05/93	Detail	7		-	64	-		N	N)	M		
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REBOXETIME - PROTOCOL 20124/016 Listing No.: 17.0

ADVERSE EVENTS; DETAIL AND SUMMARY

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PHARMACIA CNS R&D

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390	Reboxetine	28/05/92	22/07/92 ABSCESS	09/06/92	Detail	12					YES				
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391	Fluoxetine	11/06/92	15/07/92 CONSTEPATION	15/06/92	Detail	~ ;		٠,	N I	 N :		n i		0 1	
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			RASH MACULD-PAPULAR	12/07/92	Detail	35		м	N	N		N	_		
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105	Reboxetine	02/11/92	30/12/92 CONSTIPATION	03/11/92	Detail	7		73	N	3		N.	m	m	
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					Summary	14/12/92	45	-	ru.			m			

Severity: Deunknoun, Lemind, Zemaderate, Segware,
Study drug; Inco change, Zegoe reduced, Sedf, withdrawn, 4etom; inco.
Study drug; Inco change, Zegoe reduced, Sedf, withdrawn, 4etom; inco.
Biospital: Jereduized, Zegot reduced, Sedf, withdrawn, 4etom; inco.
Biospital: Jereduized, Zegot reduced, Sedf, withdrawn, 1erocovered, Zegot Seguized, Segotial present, 4edarth
Biospital: Jereduized, Zegot segot appl. — Dutcom: Jerecovered, Zegotials, Segosabla, Geosabla, Segotial present, 4edarth
Symptomic treatment; Jeroch
Symptomic treatment; Jeroch
Symptomic treatment; Jeroch
Symptomic treatment; Jeroch
Symptomic treatment
(10) advance event still present; end date = visit date
(20) advance event still present; end date = visit date
(20) advance the massing first report visit date event

E - PROTOCOL 20124/016	Listing No.: 17.0

		Treatment						Last										
		Start			Onset	Type V		report Seve Hist Rel Stud Symp	ve Hi	St Ze	1 Stud 5	Symp	ដ	Dis Ri	Re Out Still	Sti	=	
Centre Patient Drug	ant Drug	date		date Adverse event	date	recard	No date	wisit rity ory ship drug trea Hosp app. app. come present (c)	2	ry sh	drug (	trea Hos	999	dda .	COM	Pres	ent (c	۱ م
13 501	Reboxetine	02/11/92	30/12/92 HEADACHE	HEADACHE	30/11/92	Detail	28 31/12/92(*)	58		N N			מו ויא	m m	n n	> >	VES	10
			-	MOUTH DRV	03711792	Detail Detail Sunmary	7 56 31/12/92(#)	SG.		01 14			m m	и и	m m m	» >	¥	u)
502	Fluoxetine	03/11/92		24/12/92 UPFER RESP TRACT INFECTIO 09/11/92	09/11/92	Detail Summary	7 09/11/92 09/11/92	,			us va	ves ves					YES	co.
19 19	Reboxetine	12/11/92	16/11/92	12/11/92 18/11/92 CONSTITENTION	13/11/92	Detail Summary	7 19/11/92(H)	7	wa wa		мм		N N			* *	YES	u)
			_	DIZZINESS	13/11/92	Detall	7 19/11/92(#)	7	NN	0 0	мм		ии		en en	> >	YES	10
			-	FATIGUE	13/11/92	Detail	7 19/11/92(#)	7	N N	17 17	na na na na		N N		m m	> > n n	YES	100
			-	MICTURITION DISORDER	13/11/92	Detail Summary	7 19/11/92(R)	1	ю ю	N1 N1	NO NO	,	NN		m m	> > m m	ΥES	ø
			_	моитн вку	13/11/92	Detail Summary	7 19/11/92(#)	1	n m	N1 N1	en en		8 8			× ×	YES	ø
				SOMMOLENCE	13/11/92	Detail Summary	7 19/11/92(#)	7	N N	01 01	ma ma na ma		N N		m m	>>	YES	10
504	Fluoxetine	26/11/92	26/11/92 20/01/93 DIARRHOEA	DIARRHOEA	26/10/50	Detail	42 05/01/93	4		N N	44		~ ~	m m	m m		YES	w

Severity: D'auntown, l'amid, 2-moderate, 3-severe,
Study drugs l'ano change, 2-dose reduced, 3-severe,
Hospital: l'accudired, 2-dose reduced, 3-deff. dithdrawn, detemp. Anter.
Hospital: l'accudired, 2-dos a reduced, 3-deff. dithdrawn, detemp. Anter.
Hospital: l'accudired, 2-dos a reduced, 3-deff. dithdrawn l'arconared, 2-dec. with seq., 3-still present, dedeath
Simptomatic treatment: Geno, 2-yes, 3-der a ppl. — Outcome: l'accourad, 2-processible, Groundrawn, Genome
symptomatic treatment: Geno, 1-yes
symptomatic treatment: Geno, 1-yes
(C) adverse event still present: and des visit date
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PHARMACIA CNS R&D

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date Adverse event date re	date record	resord	3	No date		visit r	ity .	i j	44	4 4	Ë	dde ds	n ·		eport sees mist kee stud symp . Dis ke but Still Visit rity ory ship drug frem Hosp app. app. comm present (c)	1 2
	24/12/92 Detail	Detail		28			-	-	8	-	YES	m	81	м	м	
Detail 42 ZB/12/92 Summary 25/12/92	45	45	45	42 25/12/92 25/12/92		45		N =	N N		¥ES	מו מו	и и	n n		YES
31/88/92 22/10/92 AEDOMINAL PAIN 31/88/92 Detail 7	31/08/92 Detail	Detail		2			7	m	173	_	YES	м	M2	10	m	
Detail 42	Detail	Detail		42 01/10/92		:	н .	м	M I		1	м (	m	er i		
Summary 01/10/92				01/10/92		3	-	м	M	-	žį.	м	m	eo.	-	YES
EPISTAXIS 10/09/92 Detail 28	10/89/92 Detail	Detail		28 28			. 4	-	м	-		м	м	м	м	
5				42 05/10/92			74	1	м	-		м	ะก	м		
Summary 05/10/92				85/10/9	N	Çţ	64	-	M			м	м	m	-	YES
A LYPTH LOOMED AND TALLET		,		:				,			9				,	
26769760	US/83/92 Detail	Detail		20 1			-	4	n		3		n	n	,	
Summary 22/10/92[#]				22/10/9	32[×]	30	-	N	ю		YES	2	ю	ın.	>	YES
27/18/92 23/12/92 SIMUSITIS 21/12/92 Detail 56	23/12/92 SINUSITIS 21/12/92 Detail	Detail		zs.											>	
Vienary	Vienary			24/12	24/12/92(#)	Š									>	YES
11/09/92 66/11/92 ALLERGIC REACTION 16/10/92 Detail 42	86/11/92 ALLERGIC REACTION 16/10/92 Detail	Detail		59				-							>	
Summary 05/11/92(#)				06/11/	92(#)	45		-							>	YES
HEADACHE 18/09/92 Datail 14	18/09/92 Detail	Detail		14			8	N	4			m	ŧ0	m	m	
21	21	21	21	21 21/09	792		N	N	m	п		ю	ю	ю		
Summary	Summary	Summary			35	21	N	~	M2	-		м	M	m	-	Æ
45	Detail 42	Detail 42	42	42 20/10/	2 :	;					YES					!
Summary 20/10/92				20/10/	7	7					ŭ					ES.
VISION ABNORMAL 13/09/92 Detail 7	13/09/92 Detail	Detail		~ ;				OI 0	4			K H	м м	m n	m m	
				70 00			٠,	N C	a w	٠.		a #	a #	n #	n -	
				05/10	7.5	28	, н	י וע	m			m	, N3	. m		Š

Saverity: O=unknown, Immild, 2-moderate, 3-severe,
Study drugs Immo change, 2-dece reduced, 3-severe,
Study drugs Immo change, 2-dece reduced, 3-dece without change, 2-dece reduced, 3-dece with seq., 3-decill present, 4-death
Dispo. Respo., I and, 2-yes, 3-mot appl. -- Relationship: I=resourcered, 2-rec. with seq., 3-decill present, 4-death
Dispo. Respo., I and, 2-yes, 3-mot appl. -- Relationship: I=definite, 2-probable, 3-possible, 4-doubtful, 5-unknown, 4-none
Sometownith Immo, 1-yes
IV) adverse event used for setitation analysis
IV) adverse event will present and date = visit date
IV) none date missing fart repet visit date used
IV) none from the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of the property of

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PHARMACIA CNS RBD	REBOXETINE - PROTOCOL 20124/016	Listing No.: 17.0
PHARMACI	REBOXETINE - PR	Listing

	1	Treatment	i i	4.000	- Ann	Tobe West Food	Last	1 6 6	ţ	541	E S		Dis	e e	, a	Out Still	
tten	Patient Drug	date	date Adverse event	date	record	No date	visit	rity	01.9 \$1	th dr	t tre	Hosp.	9	9	8	visit rity ory ship drug trea Hosp app. app. come present (c)	<u> </u>
800	Reboxetine	02/11/92	02/11/92 29/12/92 HOT FLUSHES	04/11/92	Detail	,		1	64	M2		1/3	м	м	М		
					Detail	56 26/12/92		7	173	m	-	M	m	6/3	-		
					Summary	26/12/92	35	-	N	m	-	M	м	м	-		YES
			MOUTH DRY	03/11/62	Detail	^		~	N	ю	-	CI.					
					Detail	21		-	N	m		64		N			
					Deta11	28 27/11/92		-	N	м	-	6		M	н		
					Summary	27/11/92	<b>58</b>	-	N	m	-	61	m	ĸ			YES
			UPPER RESP TRACT INFECTIO 14/12/92	CTID 14/12/92	Detail	56 20/12/92				•9	YES	s					
					Summary	20/12/92	55			•	YES	co.					YES
521	Reboxetina	30/11/92	26/01/93 DIZZINESS	02/12/92	Deta11	2		-	84	m	_	м	m	м	м		
					Detail	14											
					Detail	45		~	N		_				м		
					Detail	56 20/01/93		-	N	m	-	м	m 	iva .			
					Summary	20/01/93	25	-	N	m	-	м	m 	m	F4		VES
			MOUTH DRY	02/12/92	Detail	7				m	-	N	ma 	m	N/3		
					Detail	14		-	r		-			*	-		
					Summary	31/12/92	42	-		m				· 102			YES
297	Fluoxetine	14/04/92	09/06/92 CONSTIPATION	17/04/92	Detail	7		64	7	8	1	YES	M2	KA KA	м		
					Detail	14 24/04/92		2	7	7	-	172	m		-		
					Summary	24/04/92	14	64	13	8	-	yes :	Ma Ma	**			YES
			HEADACHE	10/04/92	Detail	-		-									
					Detail	7 16/04/92			-	J	-				-		
					Summary	16/04/92	2		-	•	-						9
				17/04/92	Detail	7		N .		J.			m :		m (		
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					Detail	21 29/04/92		6	<u>.</u>	•		., ,	9 1				917
					Summary	29/04/92	. 51	M.	-		-				•		ž

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				app.	m	m m	**	м	M	M W	מו נ	M	M	1/2		M	m	es.	м	177	м	м	m	m	m*1	m	m m	1 H7
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			Last	report Save Hist Rel Stud Symp visit rity ory ship drug trea		2			7		21			23				2		Z,		42		55			14	
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				_		21 30/04/92 30/04/92		4792	22/04/92	14	30/04/92		21 30/04/92	30/04/92			42 22/05/92	22/05/92	35 15/05/92	15/05/92	42 24/05/92	24/05/92		16/06/92(#)		04792	23/04/92	28 07/05/92
	91	Fα		sit End No date		30/0	,	14 22/04/92	22/1	14	30/02		30/0	30/0			25/1	22/0	15/0	15/0	24/0	54/		10/0	2	14 23/04/92	23/1	9 0771
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25 RB	, 12.5 17.6	7. A		Type Visit End racord No date	Detail	Detail Summary	6 6 7	Deta11	Summary	Detail	Summary	Detail	Detail	Summary		Detail	etail	A Lewe	Detail	Summary	Detail	Summary	Detall	Summary	Detail	Detall	Summary	Detail
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PHARMACIA CNS RBD	REBOXETINE - PROTOCOL 20124/016 Listing No.: 17.0	ADVERSE EVENTS: DETAIL AND SUMMARY			785		Ş	!		785		792				7.92			26		7.85		745		1,42		60%	7.
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	RE	ADVER																										
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				End date Adverse event	14/04/92 09/06/92 HOT FLUSHES							NERVDUSNESS				TUS			15/84/92 10/06/92 ABDOMINAL PAIN				SK.		RIA			
				Adver	HOT F		, SPAIN					NERVO		•		PRURITUS			ABDOM				COUGHING		EUPHORIA			
				End	6/92														6/92									
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			Treatment	ដ	14704														15/84									
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					Fluoxetina														Reboxetine									
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FORWARDS CAS NO.	REBOXETINE - PROTOCOL 20124/016	Listing No.: 17.0

			Treatment					Last										
			Start	End	Onset	Type V		report Save Hist Rel Stud Symp	Save H	tst R	el Sti	od Symb		pis	2	Re Out Still	1111	
Cent	Centre Patient Drug	t Drug	date	date Adverse event	date	record	No date	visit	71ty	ary sh	ilp dri	visit rity ory ship drug trea Hosp app, app, come present (c)	Hosp	в .	рв. сс	nne pr	esent	9
14	398	Reboxetine	15/04/92	15/04/92 10/06/92 HOT FLUSHES	08/05/92	Detail	42		8	м	м	п	n	мз	ю	м		
						Detail	49 30/05/92		OI.	œ	<b>8</b> 73		М	м	ю	7		
						Summary	30/05/92	49	N	7	м		M	m	m	-		YES
				INFLUENZA-LIKE SYMPTOMS	06/08/92	Detail Summarr	56	ä	or c	<b>C4</b> C	ب ب	YES	ик	n n	ng pe	va no	<b>&gt;</b> >	VES
									4		,			•	,	,		1
				MOUTH DRY	16/04/92	Detail	~		-	2	C4	_	м	м	ю	m		
						Detail	14		-	8	2	_	M	м	m	m		
						Detail	23		м	24	2	_	M	m	m	m		
						Datail	5		г	N	64	_	m	m	ю	m		
						Detail	56		н	71	7	_	'n	m	m	m	>	
						Summary	10/06/92[*]	ß	-	N	7	_	m	m	m	m	>	YES
				NALISEA	15/04/92	Detail	7		7	13	22		63	ĸ	m	м		
						Detail	14 24/04/92		н	C)	c4	-	MI	м	м	н		
ç						Summary	24/04/92	14	7	N	nı.		М	М	m	H		YES
) ;					15/05/92	Detail	35 15/05/92		N	œ	·		М	м	м	-		
2 :						Summary	15/05/92	35	N	N	4		м	М	м	-		YES
9					24/05/92	Detail	42 24/05/92		C4	'n	¥	-	М	м	M	-		
						Summary	24/02/92	45	N	N	4	-	М	м	m	1		YES
				PALPITATION	16/04/92	Detail	7 18/04/92		•	7	æ		M	м	M	-		
						Summary	18/04/92	7		7	v.		м	м	м	-		YES
				RHINITIS	05/06/92	Detail	25		7	N	9	1 YES		***	10	,,	>	
						Summary	10/06/92(*)	25	œ	8	9	1 YES	eri 	м	м	м	>	VES
				SWEATING INCREASED	16/04/92	Detail	7 20/04/92		8	(4	7	_	M	m	M	-		
						Summary	20/04/92	7	N	N	8	-	m	м	м	-		ĘŞ
					:								•		,	,		
	399	Reboxetine	21/04/92	21/04/92 16/06/92 DIZZINESS	12/05/92	Detail	14		-	N	N	-	m	m	**	n		

PHARMACIA CNS R&D

ADVERSE EVENTS: DETAIL AND SUMMARY
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	F	Treat					4									
		Start	End	Onset	Type	Type Visit End	report Ser	# H15	t Rel	report Seve Hist Rel Stud Symp	٥	DIS	2	Re Dut Still	5	
e Patient Drug	it Drug	date	date Adverse event	date	record	No date	visit rii		y shift	visit rity ory ship drug trea Hosp app. app. come present (c)	de dso	ď.	00 .	e prese	int (c)	
G N		30,00			:				'			١,	١.			
;		36 460 413	101 007 32 7177118233	24.750.750	Summary	10/05/42	2	٠.	v 0		a K	o m	a m		S. F.	
				17/05/92	Date	28 17/05/92	i				м	1 1/7			1	
					Summary	17/05/92	28	N		-	м	100	m		YES	
				31/05/92	Detail	42 31/05/92			2	-	м	luz.	m2	1		
					Summary	31/05/92	3		2 2	-	м	(1)	m		YES	
			HEADACHE	30/05/92	Datail	42 31/05/92		cu.	1 5	-	м	m	m			
					Summary	31/05/92	25	N	. 5	-	m	m	m	-	YES	
			MIGRAINE	07/05/92	Detail	21 08/05/92		~		2	873	_	m			
					Summary	08/05/92	23	N	•	2	m	_	м	-	YES	
			MOUTH DRY	22/04/92	Detail	7		8	.,	-	м	m)	M)	*1		
					Detail	14		7	2	-	ы	m	m	м		
					Detail	21		17	2	-	м	м	м	м		
					Detail	28		ч	2	-	m	m	m	м		
			•		Detail	25		8	2	-	N	ma	m	м		
					Detail	56		2		-	m	m	s)			
					Skingary	16/06/92(*)	56	7	2	-	N	m	м	ж ^	YES	
400	Fluoxetine	15/05/92	15/05/92 11/07/92 DIARRHDEA	17/05/92	Detail	7 28/05/92			2	-	m	m	m	,		
					Summary	20/05/92	7	1	N	-	m	m	м	,	YES	
			MDUTH DRY	17/05/92	Detail	2		7	2	-	m	m	m	m		
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Huspitali irrestanced, Zenos restaced, Senos appl. — Outcome: Irrecovered, Zerec, with seef., Sertill present, Gegeth
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Estudy drugs land change, Zesse reduced, Seffe, Hithfram, detemp, inter.

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ADVERSE EVENTS: DETAIL AND SUMMARY

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				DIZZINESS	21/11/92	Detail	35		,	2 2	-		м	м	ю	м		
						Detail	42 02/12/92		_	N	-		м	m	м	-		
						Summary	02/12/92	5.5	H	2	<b>-</b>		ю	м	м	-		YES
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						Summary	11/12/92(*)	43	_	2	_		m	м	м	м	>	YES
				MICTURITION DISORDER	01/12/92	Detail	42		_	2	-		м	м	м	ю		
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						Summary	06/12/92	63	_	2 2	-		м	m	м	,		YES

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Severity: Drunknown, lamild, Zamoderate, Szevera,
Study drug: Lena change, Z-dose reduced, S-def. withdrawn, G-ttmp. inter.
Hopstrial irrequised, Zand req., Sand appl. — Ostcome: lareovered, Zarec, with sed., Zastill present, G-death
Dissp./Reapp.: Leng., 29ves, S-and appl. — Relationship: ladefinite, Zaprobable, S-possible, G-doubful, S-unknown, E-none
symptometic treatement D-no, 1-yes

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ADVERSE EVENTS: DETAIL AND SUMMARY

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						Summary	01/11/92	14	N	п	ю	1 YES	М	м	м	-		YES
				PALPITATION	06/11/92	Detail	23		N	84	м	_	m	m	m	m		
						Detail	58		ч	7	м	_	m	M	m	м		
						Detail	35		м	ņ	lv3	_	m	ю	m	m		
						Detail	42		N	71	м	_	m	ю	m	м		
						Detail	48		çų	7	m	-	м	м	м	m	>	
						Summary	11/12/92(*)	43	ÇI	8	m	_	м	m	м	M	>	YES
				SHEATING INCREASED	25/10/92	Detail	7		-	2	N		м	м	м	м		
						Datesi	14 30/10/92		1	8	N	п	м	м	м	-		
						Summary	30/10/92	2	-	61	61		m	M	м	-		YES
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3						Detail	28 18/11/92			N	N		M	m	ю	۲,		
8						Summery	18/11/92	2B	-	N	64		ю	m	N3	-		YES
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						Summery	01/11/92	14	2	-	m	1 YES	ю	ю	173	-		YES
		512 Reboxetine		03/11/92 02/12/92 BACK PAIN	15/11/92	Detail	14		œ	C4	ĸ	1 YES	1/3	м	м	10		
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						Detail	28 28/11/92		N	œ	ĸ	1 YES	n	м	M	-		
						Summary	28/11/92	58	œ	œ	ıs	1 YES	ю	M	м	-		ΥES
				FEVER	15/11/92	Detail	14		N	ø	ហ	I YES	-	м	м	м		
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						Summary	20/11/92	21	N	N	5	1 YES	-	м	м	-		ÆS
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						Summary	13/11/92	14	-	N	N	_	m	M	m	-		VES
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Type Visit End record No date	Summary	Detail Detail Detail Summary	Detail Detail Summary	Detail Detail Summary	Detail Detail Summary	Detail Summary	Detail Detail Detail Summary	Detail Detail Detail Summary
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End date Adverse event	03/11/92 02/12/92 HEADADHE	INFLUBIZA-LIXE SWIPTOMS 15/11/92	ажа нтисм	S111SMARHIJ	ХЕКОРИТНАЦИЈА	29/12/92 ANKIETV	CONSTIPATION	Paraesthesia
Treatment Start date	03/11/92					03/11/92		
5						Reboxetina		
	Reboxetine							
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Severity: Grunkmoun, Ismild, Zimoderate, Sissevere,
Study drus: Ismo change, Zidose reduced, Bidef. withdrawn, Gitemp Hossitail Ismoquifuel, Sever rete, Sands appl. — Outcome: Isree Dison, Coarm - Ism, Stude, Study and

adverse event used for statistical an adverse event still present; end date

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-	ADVERSE EVENTS; DETAIL AND SUMMARY
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14	537	Reboxetine	03/11/92	29/12/92 URIMARY TRACT INFECTION	04/11/92	Summary	18/11/92	23				ž	m sa					YES
		ı		VERTIGO	04/11/92	Detail Summary	7 08/11/92 08/11/92	۲		N N	NN		m m	мм	10 m			YES
	10 10 10	Fluoxetine	12/02/93	09/04/93 APPETITE INCREASED	28/03/93	Detail Detail Summary	49 56 03/04/93 03/04/93	<b>3</b>	N N N	иии			ммм	מא מא מא	לא מא מא	M = =		YES
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	529	Fluoxetine	10/03/93	05/05/93 CD45TIPATIQN	25/03/93	Detail Detail Summary Detail Detail	21 28 05/04/93 05/04/93 42 56 02/05/93 02/05/93	5, 28 28	***************************************	*********		1 YES 1 YES 1 YES 1 YES 1 YES		<b>ממממממ</b>	מא מא מא מא מא	w w		YES
				DIZZINESS	18/03/93	Detail Summary	14 21/03/93	7			N N		m m	ю ю	m m			¥E8
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Savarity: Geunkaben, Jemile, Zemoderate, Sesavare,
Study drug: Lea change, Zedose reducate, Sedef. withdrawn, 4ttom. Inter.
Hospitali Internate, 2 2 and teq., 3 and appl. — Detcom: Tercevared, 2 arec. with seq., Sestill present, 4 death
Bospitali Internate, 2 2 and teg., 3 and appl. — Relationship: Tedefinite, Zeprobable, Sepossible, 4 deabtful, Seunhown, 4 mone symptomatic treatment: Deno, 1 eyes

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-- History: 1-present before, 2-not observe bef., 3-unknown Severity; Beanknown, Lemiid, Zemoderate, Steavare,
Study drug: Leno change, Zedase reduced, Stade: withdrawn, detamp: inter.
Hospital: Intenduals Zends requised, Stade: withdrawn, detamp: inter.
Hospital: Intenduals Zends requised: Denome: Intenduals Zends with seq., Sextill present, dedath
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ADVERSE EVENTS: DETAIL AND SUMMARY

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Treatment	date	18/04/92							/50//									22/04/92								3/04/		drug:	1:1	./Kes matic	Verse	Set d
Trea		5							-									2								N		oeverlity: D=unknown, l=milo, Z=moderate, 3=severe, Study drug: l=no change, Z=dose reduced, 3=def. withdrawn, 4=temp. inter.	Hospital: l=required, 2=not req., 3=not appl.	Disapp./Keopp.: i=no, Z=yes, 3=not appi Keibtionship: i=definite, Z=probabie, 3=possible, 4=douottui, 5=unknown, b=none symptomatic treatment: 0=no, 1=yes	(c) adverse event used for statistical analysis	(a) adverse event Still Present: end date = visit date (b) onset date missing: first report visit date used
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	5	Reboxetine							Fluoxetine									Reboxetine								Fluoxetine						
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ADVERSE EVENTS: DETAIL AND SUMMARY

		Treatment					Last										
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Centre Patier	or Drug	date	date Adverse event	date	PECO1	No date	Visit 7	2	2	Ē	wisit rity ory ship drug trea Hosp app. app. come present (c)	4	8	5		1	c
15 412	Fluoxetine	23/84/92	17/06/92 DIZZINESS	25/04/92	Summary	28/04/92	۲		8	1/3		N.	10			YES	10
414	fluoxetine	02/06/92	27/07/92 FATEGUE	22/07/92	Detail	56 27/07/92(*)	ą,	mm	n n	10 ES		m m	n 10	m 10	> > n n	VES	9
			HVPERCHOLESTEROLAEMIA	27/07/92	Detail Summary	56 27/07/92(*)	ធំ		N N	M M		мм	m m	m m	> > n n	YES	ξŲ.
415	Reboxetine	12/06/92	86/08/92 <b>HD</b> UTH DRV	15/06/92	Detail Detail Summary	7 14 20/06/92 20/06/92	14		01 N1 N1				בא בא בא		м	VES	es.
			NAUSEA	13/06/92	Detail	7 17/06/92		n n	N N	m m	m m	N N	m m	10 10		YES	ι.
416	Fluoxetine	23/06/92	17/88/92 FATIGUE	25/06/92	Detail Detail Detail Detail	7 14 21 28 16/07/92 16/07/92	82	N N	N N N N N				m m m m		10 10 10	YES	92
418	Reboxetins	17/07/92	17/07/92 10/09/92 AMEHIA	03/09/92	Detail Summary	56 10/09/92(≅)	95		01 01	мм		m m	m m	m m	* *	ΥES	- 23
41.9	Fluoxetine	16/07/92	09/18/92 HEADACHE	19/07/92	Detail Detail Detail Detail Detail	7 14 21 28 42 23,08/92 23,08/92	42			***************************************		***********				VES	88
423	Fluoxetine	21/08/92	15/10/92 PEADACHE	25/08/92	Detail Detail	14 21 06/09/92		N N	и и	мм		m m	m m	ю и	<b>m</b> =		
	* # # # # # # # # # # # # # # # # # # #	Severity: Deun) Study drug; laq Hospital: lared Disapp./Keapp.; Symptometic tri [C) adverse evu [a) adverse evu [b) noset data	Known, landid, Campuderate, Sasew Outried, Poats reduced, Sedet United, Poats Fent appl. — R I lano, Poats, Sent appl. — R Mannerit Ban. 1998 Ant word for Statistical analysis and teldi presents and date = vd malesing: first expert visit date	withdrawn, 4=1  Outcome: L= ationship: 1=4 t date	Histo Lemp. inter- recovered, definite, 2:	Fre.	efore, 2= , 3=still ible, 4=d	Pres Pres cubté	oservi 11, 5:	bef.	. 3=unknow	-					

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FINANCIA LAS KAD EBOXETINE - PROTOCOL 20124/016 Listing No.: 17.0		_	
~	THEN THE THE YEAR	REBOXETINE - PRDTOCOL 20124/016	Listing No.: 17.8

			Treatment						Last									
			Start	End		Dusat	Type V.	Type Visit End	report Seve Hist Rel Stud Symp	HISt	Rel	tud Syn	ū	Dis	S.	Š	Re Dut Still	
ន	intre Pak	Centre Patient Drug	date		date Adverse event	date	record	No date	visit rity ory ship drag tree Hosp app. app. came present [c)	P.	sh Lp	rag tra	E Hos	4 P	ф.	CDMe	present	≘
15	423	3 Fluoxetine	21/08/92	15/10/92 HEADACHE	FADACHE	25/08/92	Summary	26/03/92	23	N	м	н	••	n	м			YES
	424	4 Reboxetine	21/08/92	15/10/92 L	21/08/92 15/10/92 LIBIDO DECREASED	25/08/92	Detail Detail Summary	7 14 01/09/92 01/09/92	2 2 2	8 8 8	m m m			m m m	n n n	м		YES
				*	MICTURITION DISCRDER	25/09/92	Detail Summary Detail Summary	7 26/08/92 26/08/92 14 30/08/92 30/08/92	r 4.	пппп	мммм		, , , , , , , , , , , , , , , , , , ,		мммм			YES YES
	450	Fluoxetine		18/12/92 05/02/93 HEADACHE	∉АВАС <del>) ≿</del>	12/12/92	Datail Detail Datail Datail	7 21 28 04/01/93 04/01/93	8	~ ~ ~ ~ ~ ~	M M M M M		YES YES YES		м m m m	10 10 10 11 11 11 10 10 10 11 11 11 11 1		YES
	451	Fluoxetine		16/12/92 11/02/93 AGITATION	ADITATION	03/11/93	Detail Detail Summary	21 28 10/01/93 10/01/93	288		444			מאנא מא	מממ	m		YES
				•	HEADACHE	31/12/92	Detail Detail Detail Summary	14 21 28 12/01/93 12/01/93	89	0000	വ വ വ വ	***	YES YES YES					YES
	452	2 Rebuxetine		23/12/92 16/02/93 NAUSEA	<b>4AUSEA</b>	24/12/92	Detail	7 28/12/92 28/12/92	~	N N	мм		YES	мм	мм			YES
16	430	0 Raboxatine		25/02/92 6	30/83/92 25/85/92 EJACULATION DISORDER	10/04/92	Detail Summary	14 12/04/92	4	0 01 0 01	M M			м м	n n			YES

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 17.0
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PHARMACIA CNS R&D

ADVERSE EVENTS: DETAIL AND SUMMARY

		9	Ę						YES					YES			YES			YES		YES		ÆS			× Es		≺ES
	1111	visit rity ory ship drug trea Hosp app. mpp. come present (¢)						>	>				>	>					>	>								>	>
	Re Dut Still	DE DE	-	м	м	6/3	m	m	m	m	m	m	м	м	М	-	-	м	M3	мз		-	-	-	-		-	M	ю
	2		м	м	м	M	m	м	ы	м	м	m		e7	м	м	м	m	60	m	m	ю	,	m	M	•	m	MZ	m
	Dis	<u>.</u>	(M)	m	м	ma	м	m	MZ	~	m	m	m	M)	-	N	N	-	-		N	N	N	N.	8		N	м	173
		dso	M	M	m	m	м	N	¢4	αi	m	m	OL	N	N	М	CH	N	N	N	CZ.	ru:	N	N	8		N	N	N
	ymp	Ra L								YES	YES	YES	YES	YES	<b>VES</b>	YES	YES				YES	ΥES	K.	YES	YES		¥ĒS	YES	YES
	Stud	dr ug	-	-	-	-	-	-	-	-	-	~	-	-	N	œ	8	N	М	И	m	м	'n	м	en.		m	7	-
	report Seve Hist Rel Stud Symp	sh 1p	4	м	64	24	cu.	M	N	m	ю	M	м	M	8	m	7	N	74	64	м	м	n	N2	MG.		m	rat.	4
	Hist	5	N	64	8	24	24	24	~	-	-	-	н	-	N	N	61	-	-	-	-	-	2	73	2		N	-	-
	Seve	rity	-		~	-	-	-	-	21	н	н	-	23	N	-	N	*	71	7	C4	74	7	2	2		1	N	N
Last	port	/1s1t	7						5					30			56			56		35		35			<b>9</b>		14
	•	No date	15/04/92	28	35	42	49	56	25/05/92(#)	-	28	49	26	01/06/92(*)	49	56 12/06/92	12/06/92	69	95	18/06/92(*)	35 22/06/92	22/06/92	55 20/06/92	20/06/92	35.20/06/92		20/06/92	14	14/09/92(*)
	ゼ	- 1												_			_					_							
	Type	record	Summery	Detail	Detail	Detail	Detail	Detail	Summary	Detail.	Detail	Detail	Detail	Summary	Detail	Detail	Summary	Detail	Detail	Summery	Detail	Summary	Detail	Summary	Detail		Summary	Detail	Summary
	Onset	date	04/04/92	21/04/92						22/04/92					11/05/92			10/05/92			17/06/92		18/06/92		18/106/42			22/01/92	
	End	date Adverse event	25/05/92 MICTURITION DISORDER							01/86/92 INSOMIA					18/86/92 HYPOTENSION			INSOHNIA			18/06/92 BRONCHITIS		DIARRHOEA		SWILLIAMON			22/07/92 14/09/92 INSOMNIA	
Treatment	Start	date	30/03/92							07/04/92					24/04/92						20/05/92							22/07/92	
		Centre Patient Drug	Reboxetine							Fluoxetine					Fluoxetine						Fluoxetine							Reboxetine	
		Patte	430							434					436						438							445	
		entre	15																										
		o	-																										

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Severity; Funktion, l'amid, 2-moderate, Secvere,

Study d'uns l'am change, 2-con reduced, 3-cevere,

Study d'uns l'am change, 2-con reduced, 3-cefe, mithdram, ettem, intre.

Massital: l'erequired, 2-net reduced, 3-net appl. — Option i Precovered, 2-res, vith set., 3-settil present, 4-death

Disapp./Raspp.: l'amo, 2-yes, 3-net appl. — Relationship: l'affainte, 2-probable, 3-possible, 4-doubtful, 5-unknown, 6-none
symptomistic treatment l'amo, 1-yes

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 17.0
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			Treatment						Last									
			Start	End		Onset	Type V	Type Visit End	report Seve Hist Rel Stud Symp	ive Hi	st Rej	Stud	Symp	Д	Dis	e G	Dut Still	1
Centr	Centre Patient Drug	t Drug	date		date Adverse event	date	record	No date	visit rity ory ship drug trea Hosp app, app, come present (c)	Ity a	y shift	grug	trea H	de dsof	р. ар	P. C.	in pres	inst C
16	455	Fluoxetine	19/09/92	19/09/92 13/11/92 INSDMNIA	INSDMNIA	26/09/92	Detail	91		-		-	YES	61	ю	10	'n	
							Summary	13/11/92(#)	14	-	_		YES	73	ю	м	'n	YES
	456	Reboxeting	16/12/92	09/02/93 INSDMILA	INSDANI A	23/12/92	Deta11	14		-	2	1	YES	8	м	era	m	
							Detail			-			ÆS	C.Z	M	m		
							Summery	09/02/93(*)	56	-	e.	 m	YES	rs.	M	m	m	, ¥ES
	Ę		***************************************				1	;			,	-	Ü	¢				
	ĝ	aut laxont.	76/71/91	16/12/92 U9/U2/93 INSUMILE	INSUMILE	26/21/62	Detail	+T		٠,			2 4	4 0	2 1		, ,	
							Decar	66/10/02 44		٠,		•	2 1 1	4 0	2 N	2 K	٠,-	>
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91	92	Reboxetine	06/10/92		30/11/92 TACHYCARDIA	03/11/92	Detail	28 05/11/92			n			N	N7	*1		
_							Summary	05/11/92	28	-	ю			N	м	M	_	VES
1. 1																		
	Š	Reboxetine	17/11/92	17/11/92 18/11/92 DIARRHOEA	DIARRHOEA	18/11/92	Detail	7		-	м	m		-	п	-	M	
							Summary	24/11/92(#)	7	-	м	m		-	п	1	m	, YES
					HYPERLIPAENIA		Detail	•		-								
							Detail	0		-								
						09/11/92(0)	Summary	24/11/92(#)	В	-								¥
20	21	Fluoxetine	06/11/92	06/11/92 30/12/92 AGITATION	AGITATION	10/12/92	Detail	35		10		1 3	YES	64	-	m	m	
							Summary	30/12/92(#)	35	M2	-		ΥES	2	-	м	m	, YES
					HYPERCHOLESTERDLAEMIA	26/10/90	Deteil	56		m	m			C4	r)	M	m	>
							Summary	30/12/92(#)	56	m	тэ			CI.	(r)	M.	m	νEs
						:	:				,		ţ		,			
					INSDMILA	24/11/11	Detail	7 13/11/32		ų.	٠,		2	u i	a i	n i	٠,	
							Summery	13/11/92		NI I	٠	- ·	YES.	N I	ומי	'n.	٠,	YES
						27/11/92	Detail	26 04/12/92		C4	N	m	VES	c.	m		_	

Swurity: G-unknown ]-ediid, 2-modertte, 3-severe,
Study drug: I-no change, 2-dose reduced, 3-def. withdrawn, ditemp. inter.
Hostelia Irrequied, 2-not toes, 3-not appl. —- Outcome i 3-ceowerds, 2-rec. with sad., 3-still present, d-death
Disaps, Reapp. i I-no, 2-yes, 3-not appl. —- Relationship: I-definite, 2-probable, 3-possible, 4-doubtful, 5-unknown, 6-none
Symptomatic fractment: D-no, I-yes

YES

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ADVERSE EVENTS: DETAIL AND SUMMARY

		ıT.	Treatment					Last										
Centr	Centre Patient Drug	T Drug	Start	End date Adverse event	Onset	Type Vi	Type Visit End ricord No date	report Seve Hist Rel Stud Symp Dis Re Out Still visit rity ory ship drug trea Hosp app. app. come present (C)	Hist ory	Re1 Ship	Stud	Symp	Hospa	Dis.	P .	96	Re Out Still Ipp. come present	3
			,															
52	21	Fluoxetine	06/11/92	30/12/92 DEDEMA GENERALISED	20/11/92	Detail Detail	14	_	~	N	-	¥ES	N	m	м	m =		
						Summery	27/11/92	12	~	N	-	ž.	N	m	m	-		YES
	22	Fluoxetine	12/11/92	12/11/92 16/12/92 INSOMMIA	23/11/92	Detail	14		, .	[N		YES	N	м	м	m	>	
						Summery	17/12/92(*)	4	m	1/1	-	YES	N	кз	м	m	>	Š
12	6	Fluoxetine	19/10/92	19/10/92 13/12/92 INFLUENZA-LIKE SYMPTOMS	10/11/92	Deteil	28		61	۰	4	Æ	DI	-	м	м		
						Summary	35 19/11/92 19/11/92	52	N N	99	4 4	YES	ии	or or				YES
				PHARYNGITIS	10/11/92	Detail	28		2	•	•	YES	~	-	м	ю		
						Detail	35 19/11/92		2	40	4	YES	N	'n	-	-		
						Summary	19/11/92	χΩ.	21	-0	4	YES	~	N	-	-		YES
25	113	Fluoxetine	03/12/92	03/12/92 18/12/92 ABITATION	18/12/92	Detail	12		81	m	m	YES	N	-	м	м	>	
						C. man	(1) (0) (1) (0)			N	ĸ	0 H >		-	M	M	>	N H N

#### PHARMACIA PHARMACEUTICS 5 5 5 6 603 - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 1 Patient: 2 Treatment: Reboxetine Sex: Male

				Vis	it number	- / 1	Laborato	ry d	ate	
			Scree	n.	Day 1	4	Day 2	8	Day 5	6
			25/06/	92	10/07/9	92	24/07/	92	21/08/	92
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
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	1
RBC	4.3-5.9 (10-6/MM3)	10/11/91	4.81		5.06		5.09		5.27	l
WBC	4000-8000 (/MM3)	10/11/91	5280.00		6300.00		5900.00		6600.00	l
WBC: N	50-70 (%)	10/11/91	67.00		57.00		61.00		69.00	l
WBC: L	25-40 (%)	10/11/91	25.00	1	40.00		31.00		27.00	1
WBC: E	2-4 (%)	10/11/91	3.00		3.00				1	l
WBC: M	2-8 (%)	10/11/91	5.00		0.00	<	l		4.00	l
WBC: B	0-1 (%)	10/11/91	0.00	]	0.00					1
PLATELETS	150000-400000	10/11/91	****							l
PLRIELEID	(/MM3)	10. 11. 21	266000	1	253000		250000		272000	l
•••	135-150 (MEQ/L)	10/11/91	141.00		142.00		140.00		141.00	l
NA+	3,6-5,2 (MEQ/L)	10/11/91	4.30		4.30		4.20		4.30	l
K+	94-111 (MEQ/L)	10/11/91	107.00	1	104.00	i	103.00		104.00	l
Cr-	4.4-5.5 (MEQ/L)	10/11/91	4.50	1	4.60		4.50		1	l
Ca++		10/11/91	1.50		2.30	اح	2,60			l
P04	2.5-5 (MG/DL)		15.00		15.00	_	15.00			l
SGOT	5-18 (U/L)	10/11/91	19.00	]	19.00		31.00		ļ	ı
SGPT	5-22 (U/L)	10/11/91	45.00		29.00		51.00			1
GAMMA GT	6-28 (U/L)	10/11/91	45.00	_	29.00		160.00		169.00	1
ALK, PHOSPH.	80-170 (U/L)	10/11/91					160.00		91.00	1
GLUCOSE	70-110 (MG/100ML)	10/11/91	0.90		0.90		0.90		1.00	
CREATININE	0.7-1.2 (MG/DL)	10/11/91			5.50		0.90	1	4.80	
URIC ACID	3.4-7 (MG/100ML)	10/11/91	4.90		0.90		0.90		0.90	
TOT BILIRUBIN	0-1 (MG/100ML)	10/11/91	0.90				0,90		0.50	
DIR BILIRUBIN	0-0.24 (MG/DL)	10/11/91			0.00		7.00	1	7.60	
TOT. PROTEINS	6.5-7.9 (G/DL)	10/11/91		ŀ		ļ	64.10		65.70	
ALBUMINE	51.8-65.4 (%)	10/11/91		١.			64.10	İ	300.00	
TOT. CHOLEST.	130-220 (MG/100ML)		249.00						280.00	
TRIGLYCERIDES	74-172 (MG/100ML)	10/11/91	231.00	>>	Į.	1		l.	2.60	
GLOBULINS ALPHA 1	2.2-5.6 (%)	10/11/91		1		l	2.10	١٠		1
GLOBULINS ALPHA 2	5-10.2 (2)	10/11/91			1	l	9,10	l	7.40	
GLOBULINS BETA	8.8-15.6 (%)	10/11/91			1	l	10.60		10.90	
GLOBULINS GAMMA	11.9-23.3 (%)	10/11/91				l	14.60	1	13.40	
TSH	0.1-4 (UU/ML)	10/11/91	0.67		l	l			1	1
T4	5-12.5 (UG/DL)	10/11/91	8.40	1	1	l	1	1	1	1

<sup>(</sup>c) << clinically relevant (value lower than min range) < out of range (value lower than min range) \*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max renge)
> out of range (value higher than max renge)
() missing range value

#### PHARMACIA PHARMACEUTICAS AT 6803 - CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 1 Patient: 4 Treatment: Reboxetine Sex: Female

				Vis	it numbe	c / 1	Laborato	ry d	ate	
			Scree	n	Day 1	4	Day 2	В	Day 4	2
-			12/08/	92	28/08/9	92	11/09/	92	25/09/	92
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB .	12-16 (G/DL)	10/11/91	13.70	ĺ	14.30		14.50		14,10	
HT	37-47 (%)	10/11/91	41.00		44.80		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	l	5000.00		5900.00		4300.00	1
WBC: N	50-70 (%)	10/11/91	73.00		77.80		77.00		75.00	
WBC: L	25-40 (%)	10/11/91	22.00	<	20.00	<	19.00	<	20.00	<
PLATELETS	150000-400000	10/11/91								1
	(/KN3)		238000		235000		224000		254000	1
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	1	4.20		4.50	1
CL-	94-111 (MEQ/L)	10/11/91	105.00		101.00		100.00		101.00	1
Ca++	4.4-5.5 (MEQ/L)	10/11/91	4.40		4.80		4.70		4.60	
SCOT	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			l	69.00	<	83.00	l
BUN	10-50 (MG/DL)	10/11/91	19.00							
CREATININE	0.5-1 (MG/DL)	10/11/91	0.80			i	0.80		0.70	
URIC ACID	2.4-5.7 (MG/100ML)		4.20				4,90		4.90	l
TOT BILIRUBIN	0-1 (MG/100ML)	10/11/91	0.90				0.90			ŀ
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)		377,00	>>			346.00	>>	346.00	>>
TRIGLYCERIDES	74-172 (MG/100ML)	10/11/91	99.00	ĺ		ĺ	128.00		1	l
GLOBULINS ALPHA 1	2.2-5.6 (%)	10/11/91	3.10	l	3.00	l		l	l	l
GLOBULINS ALPHA 2	5-10.2 (%)	10/11/91	10.00	ĺ	8.20	l			1	1
GLOBULING ALPHA 2	8.8-15.6 (2)	10/11/91	14.70	l	14.40			l	l	l
GLOBULING GAMMA	11.9-23.3 (%)	10/11/91	11.50	۱ د	11.00	ح			1	
	0.1-4 (UU/ML)	10/11/91	0.11		1,1100	ĺ			1	1
TSH	5-12.5 (UG/DL)	10/11/91	7,90	ĺ		l			1	l
T4	3-12.3 (UG/UL)	107 117 21	1 7130	I		i		l	l	l

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(¢) << clinically relevant (value lower than min range)
< out of range (value lower than min range)
\*\* missing laboratory test value nd laboratory not done

>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIGAL DIANG - CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 34 Treatment; Reboxetine Sex: Male

					imber / ory date	
			Scree	1	Day 2	β
			02/05/	71	03/06/	91
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
кв	14-18 (G/DL)	01/03/91	14.40		14.90	l
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	
MBC	4,3-10 (10-9/L)	01/03/91	4.10		5,40	1
MBC: N	50-70 (%)	01/03/91	47.00		47.00	
KBC: L	25-40 (%)	01/03/91	47.00	>	48.00	>
MBC: E	2-4 (%)	01/03/91	2.00		2.00	l
MBC: K	2-6 (%)	01/03/91	4.00		3.00	
MBC: 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	
P04	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	i
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	1
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	1
GLUCOSE	70-110 (MG/DL)	01/03/91	69.00	<	64.00	<
BUN	17-56 (MG/DL)	01/03/91	23.00		36.00	1
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	
SLOBULINS ALPHA 2	3.9-8.5 (G/L)	01/03/91	5.80		6.80	1
GLOBULINS BETA	5.2-11.9 (G/L)	01/03/91	7.70		9.10	1
GLOBULINS GAMMA	5.9-16.2 (G/L)	01/03/91	6.10		7.20	1
GLUBULINS GARRA TSH	0.3-3.5 (MU/L)	01/03/91	0.30			1
Ton T4	9-21 (NG/L)	01/03/91	14.00			
14	3-41 (NO/L/	31,00,71	1	1	l	i

950

(¢) << clinically relevant (value lower than min range)
< out of range (value lower than min range)
\*\* missing laboratory test value nd laboratory not done

>> clinically relevant (value higher than max range > out of range (value higher than max range () missing range value

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#### PHARMACIA PHARMACEUTIGAL 5410489 - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 35 Treatment: Reboxetine

			Visit	numl	ber / La	bora	tory dat	.e
			Scree	n	Day 2	В	Day 5	6
			16/04/	91	16/05/	91	10/06/	91
			value	(¢)	value	(¢)	value	(4)
Laboratory test	Range value	Range date						<u> </u>
HB	12-16 (G/DL)	01/04/91	15.40		15.50	1	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	
MBC	4,3-10 (10~9/L)	01/04/91	14.50	>>	9.90		10.40	>
WBC: N	50-70 (%)	01/04/91	67.00	j	60.00	1 1	61.00	1
WBC: L	25-40 (%)	01/04/91	33.00	li	36.00		38.00	1
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	<
MBC: B	0-1 (%)	01/04/91	0,00		1,00		0.00	ł
PLATELETS	140-440 (10-9/L)	01/04/91	361.00		292.00		327.00	i
NA+	135-145 (MNOL/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	l i	102.00	
Ca++	2.3-2.75 (MMOL/L)	01/04/91	2.30		2.40		2.40	
P04	0.81-1.61 (MMOL/L)		1.06		0.99	- 1	0.98	
SCOT	3-15 (U/L)	01/04/91	9.00		13.00	- 1	12.00	
SGPT	5-17 (U/L)	01/04/91	12.00		18.00	.	17.00	
GAMMA CT	4-18 (U/L)	01/04/91	25.00	. 1	26.00		24.00	١.
LDH	120-240 (U/L)	01/04/91	175.00	_	210.00	1	288.00	
ALK. PHOSPH.	60-170 (U/L)	01/04/91	149.00		160.00	- 1	177.00	
GLUCOSE	70-110 (MG/DL)	01/04/91				- 1	117.00	
			96.00	1	108.00	- 1		()
BUN	17-56 (MG/DL)	01/04/91	22.00		29.00	1	23.00	
CREATININE	0.4-1.2 (MG/DL)	01/04/91	0.80	. 1	0.50	1	0.50	
URIC ACID	2.4-5.7 (NG/DL)	01/04/91	6.60	۱ ۲	6.00	<b>&gt;</b>	5.60	
TOT BILIRUBIN	0-1 (MG/DL)	01/04/91	0.50	ı	0.40		0.40	
TOT. PROTEINS	65-85 (G/L)	01/04/91	79.90	- 1	79.90	- 1	78.50	
ALBUNINE	56-68 (%)	01/04/91	59.20					l
	36-58 (G/L)	01/05/91			42.90		48.20	
TOT. CHOLEST.	130-200 (MG/DL)	01/04/91	200.00	- [	218.00	۱ ۱	201.00	>
TRIGLYCERIDES	130-200 (MG/DL)	01/04/91	167.00		146.00	- 1	198.00	ŀ
GLOBULINS ALPHA 1	2-5 (%)	01/04/91	4.10			- 1	- 1	
	1.3-4.3 (G/L)	01/05/91			3.60	- 1	3.00	
GLOBULINS ALPHA 2	6-10 (%)	01/04/91	9.20	i				
	3.9-8.5 (G/L)	01/05/91		J	10.30	>	7.20	
GLOBULINS BETA	8-14 (%)	01/04/91	13.60	- 1				
	5,2-11,9 (G/L)	01/05/91		- 1	12.20	>	10.40	
GLOBULINS GAMMA	9-19 (%)	01/04/91	13.70	ĺ	ĺ	- [	1	
	5.9-16.2 (G/L)	01/05/91		1	10.90	l	9.70	
Hat	0.3-3.5 (MU/L)	01/04/91	0.10	<<				
T4	9-21 (NG/L)	01/04/91	19.00	,		- 1	ł	

<sup>&</sup>gt;> clinically relevant (value higher than max range)
> out of range (value higher than max range)
() missing range value

# PHARMACIA PHARMACEUTICAL NILANO - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centro: 2 Patient: 37 Treatment: Reboxetine Sex: Male

			Visi number Laborat data	ory
			Scree	n
			01/10/	91
			value	(¢)
Laboratory test	Range value	Range date	4. 00	
HB	14-18 (G/DL)	01/03/91	14.90	1
HT	0.38-0.57 (L/L)	01/03/91	0.43	
RBC	4.4-6 (10-12/L)	01/03/91	5.05 7.00	
MBC	4.3-10 (10-9/L)	01/03/91	50.00	
NBC: N	50-70 (%)	01/03/91	48.00	
WBC: L	25-40 (%)	01/03/91	1.00	
WBC: E	2-4 (%)	01/03/91	1.00	
NBC: M	2-6 (%)	01/03/91 01/03/91	0.00	
WBC: B	0-1 (%) 140-440 (10-9/L)	01/03/91	203.00	
PLATELETS		01/03/91	141.00	
NA+	135-145 (MMOL/L)	01/03/91	4.20	
K+	3.5-5 (MMOL/L)	01/03/91	97.00	
CL-	98-108 (MMOL/L) 2.3-2.75 (MMOL/L)		2.40	
Ca++	0.81-1.61 (MMOL/L)		1.11	
P04		01/03/91	14.00	
SCOT	3-18 (U/L) 5-22 (U/L)	01/03/91	17.00	1
SGPT	5-22 (U/L) 6-28 (U/L)	01/03/91	22.00	1
GAMMA GT	120-240 (U/L)	01/03/91	139.00	1
LDH	60-170 (U/L)	01/03/91	115.00	
ALK. PHOSPH.	70-110 (MG/DL)	01/03/91	67.00	
GLUCOSE	17-56 (MG/DL)	01/03/91	55.00	
BUN CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.90	
URIC ACID	3.4-7.2 (MG/DL)	01/03/91	7.30	
TOT BILIRUBIN	0-1 (NG/DL)	01/03/91	0.30	1
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	274.00	>>
TRIGLYCERIDES	130-200 (NG/DL)	01/03/91	241.00	
TRIGLICERIDES	0.3-3.5 (NU/L)	01/03/91	1.20	
15n T4	9-21 (NG/L)	01/03/91	12.20	

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>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTICS 55 TUBYS - CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centro: 2 Patient: 40 Treatment: Reboxetine Sex: Male

			Visi number Laborat date	/ ory
			Scree	n
			04/06/	91
			value	(0)
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	1
NBC	4,3-10 (10¬9/L)	01/03/91	14.50	
WBC: N	50-70 (%)	01/03/91	59.00	
MBC: L	25-40 (%)	01/03/91	38,00	
NBC: 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	
P04	0.81-1.61 (MMOL/L)		1.29	:
SCOT	3-18 (U/L)	01/03/91	14.00	
SGPT	5-22 (U/L)	01/03/91	13.00	
GANNA GT	6-28 (U/L)	01/03/91	21.00	
LDH	120-240 (U/L)	01/03/91	149.00	i
ALK. PHOSPH.	60-170 (U/L)	01/03/91	126.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	85.00	1
BUN	17-56 (NG/DL)	01/03/91	23.00	ļ
CREATININE	0.4-1.2 (NG/DL)	01/03/91	0.80	1
URIC ACID	3.4-7 (MG/DL)	01/03/91	4.60	1
TOT. PROTEINS	65-85 (G/L)	01/03/91	81.10	1
ALBUMINE	36-58 (G/L)	01/03/91	51.20	
TOT, CHOLEST.	130-200 (MG/DL)	01/03/91	296.00	
TRICLYCERIDES	130-200 (MG/DL)	01/03/91	113.00	<
GLOBULINS ALPHA 1		01/03/91	1.80	
GLOBULINS ALPHA 2		01/03/91	5.20	
GLOBULINS BETA	5.2-11.9 (G/L)	01/03/91	8.70	1
GLOBULINS GAMMA	5,9-16.2 (G/L)	01/03/91	14.20	1
TSH GARRA	0.3-3.5 (MU/L)	01/03/91	1.30	i
100 T4	9-21 (NG/L)	01/03/91	16.40	İ
17	> 21 (NO.1)	U VIII 7 1	1	ı

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>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICALS NO. - CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 42 Treatment: Reboxetine Sex: Female

			Visit	numb	er / Lai	borat	ory dat	e e
			Screen	n.	Day 2	В	Day 5	6
			04/03/	92	02/04/	92	30/04/	92
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
нв	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	i i	4.94	1 1	5.26	
MBC	4.3-10 (10-9/L)	01/03/91	5.00		6,30	1	6.60	
MBC: N	50-70 (%)	01/03/91	55.00			Ιí	46.00	
WBC: L	25-40 (%)	01/03/91	40.00	ıl		1	50,00	
NBC: E	2-4 (%)	01/03/91	3.00				1.00	
MBC: M	2-6 (X)	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	ll	299.00	l í	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	
P04	0.81-1.61 (MMOL/L)	01/03/91	0.90	1 1	0.86			
SCOT	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	i
LDH	120-240 (U/L)	01/03/91	187.00		169.00		168.00	i
ALK. PHOSPH.	60-170 (U/L)	01/03/91	67.00	l i	80.00	1 1	106.00	1
CLUCOSE	70-110 (MG/DL)	01/03/91	89.00		85.00			
BUN	17-56 (MG/DL)	01/03/91	19.00		28.00	li	36.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.70	l i	0.60	ll	0.60	
URIC ACID	2.4-5.7 (MG/DL)	01/03/91	4.60		3.60		3.70	1
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	<b> &gt;</b>	301.00	
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	68.00	<	87.00	<b> </b>	108.00	<
GLOBULINS ALPHA 1	1.3-4.3 (G/L)	01/03/91	2.20		2.70	) [	2.30	1
GLOBULINS ALPHA 2	3,9-8.5 (G/L)	01/03/91	5.00		6.40		5.70	1
GLOBULINS BETA	5.2-11.9 (G/L)	01/03/91	7.60		7.90		8.40	l
GLOBULINS GAMMA	5.9-16.2 (G/L)	01/03/91	9.10		9.60	l i	9.90	l
TSH	0.3-3.5 (MU/L)	01/03/91	1.00					l
T4	9-21 (NG/L)	01/03/91	13.50	1 1		ıl		1

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range)

\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range to missing range value)

## PHARMACIA PHARMACEUTICAL HILANG - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 43 Treatment: Reboxetine

				Visi	it numbe	c / 1	Laborato	ry da	ate	
			Scree	n	Day 1	4	Day 2	8	Day 5	6
			19/11/	91	03/12/	91	17/12/	91	14/01/	92
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
нв	12-16 (G/DL)	01/03/91	12.00		12.20	l i	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	
HBC	4.3-10 (10-9/L)	01/03/91	9.70		10.80		8.10		11.90	
MBC: 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	1	23.00	
WBC: E	2-4 (%)	01/03/91	2.00	i	4.00		1.00	<	0.00	
WBC: N	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	1
NA+	135-145 (MMOL/L)	01/03/91	138.00			1			138.00	Ι'
K+	3.5-5 (MMOL/L)	01/03/91	4.70						4.00	
CL-	98-108 (MMOL/L)	01/03/91	98.00			ļ		i I		i
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.30						2.30	
P04	0.81-1.61 (MMOL/L)	01/03/91	0.91			1			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	1 1	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	į.
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	1
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.50				0.50		0.50	1
URIC ACID	2.4-5.7 (MG/DL)	01/03/91	5.20				5.40	1	4.80	1
TOT BILIRUBIN	0-1 (MG/DL)	01/03/91	0.20				0.30		0.30	1
TOT. PROTEINS	65-85 (G/L)	01/03/91	75.00				67.90		72.90	ľ
ALBUMINE	56-68 (%)	01/03/91	63.30	1			45.50	<	62.40	ŀ
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	1
	6-10 (%)	01/03/91	7.70				8.40		7.70	
GLOBULINE ALPHA 2	6-10 (%) 8-14 (%)	01/03/91	12.50	]			14.50	>	12.10	
GLOBULINS BETA		01/03/91	14.30				27.70		14.50	
GLOBULINS GAMMA	9-19 (%) 0.3-3,5 (MU/L)	01/03/91	1.50				0.90	1		1
TSH		01/03/91	15.10	1 1			11,00			
T4	9-21 (NG/L)	01/03/71	15, 10			1 1				1

<sup>&</sup>gt;> clinically relevant (value higher than max range
> out of range (value higher than max range

## PHARMACIA PHARMACEUTISASSHIPANS - CNS REBOXETINE - PROTOCOL 20124/016

Listing No.: 18.0

		LA	BURATORY DA	ra -	
Centre: 2	Patient:	45	Treatment:	Reboxetine	Sex: Female

					umber / ory date	
			Scree	n	Day 2	8
			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	
HBC WBC: N	4.3-10 (10-9/L) 50-70 (2)	01/03/91 01/03/91	10.40 66.00		11.90 29.00	
MBC: N	25-40 (%)	01/03/91	31.00		29.00 59.00	
MBC: L WBC: E	25-40 (X) 2-4 (X)	01/03/91	1.00		8.00	
WBC: M	2-6 (%)	01/03/91	1.00		3.00	
WBC: B	0-1 (%)	01/03/91	1.00	ı`	1.00	1
PLATELETS	140-440 (10-9/L)	01/03/91	427.00		265.00	
NA+	135-145 (NMOL/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	ĺ
P04	0.81-1.61 (MNOL/L)	01/03/91	0.96		1.00	
SGOT	3-15 (U/L)	01/03/91	6.00	1 1	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	060.00		65.30	ایا
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	343.00 276.00			
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	276.00	>>	26.00	٠.
GLOBULINS ALPHA 1 GLOBULINS ALPHA 2	2-5 (%) 6-10 (%)	01/03/91 01/03/91			3.00 8.50	
GLOBULINS ALPHA 2	8-14 (%)	01/03/91			10.00	
GLOBULINS GAMMA	9-19 (%)	01/03/91			13.20	
ish	0.3-3.5 (MU/L)	01/03/91	0.80	1	13.20	
				Į		
T4	9-21 (NG/L)	01/03/91	11.90			_

<sup>(¢) &</sup>lt;< clinically relevant (value lower cut of range (value lower than min range)

\*\* missing laboratory test value nd laboratory not done

### PHARMACIA PHARMACEUTIGAS 511 HANG - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

# LABORATORY DATA Centro: 2 Patient: 48 Troatment: Reboxetine Sex: Female

			Visit	numl	er / La	borat	ory date	•
			Scree	n	Day 2	В	Day 5	6
			18/05/	92	16/06/	92	14/07/	92
			value	(4)	value	(4)	value	(¢)
Laboratory test	Range value	Range date						
нв	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	
MBC	4,3-10 (10-9/L)	01/03/91	10.80	>	7.60		9.20	
MBC: N	50-70 (%)	01/03/91	67.00	1 1	86.00	>	78.00	
MBC: L	25-40 (%)	01/03/91	30.00		12.00	<<	20.00	
MBC: E	2-4 (%)	01/03/91	0.00	<	0.00	<	0.00	<
NBC: N	2-6 (%)	01/03/91	3.00	1	2.00		2.00	
WBC: B	0-1 (%)	01/03/91	0.00		0.00		0.00	l
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	1 1	136.00	
K+	3.5-5 (MMOL/L)	01/03/91	4.60		4.90	li	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	l I	2.60	l
P04	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	1
SGPT	5-17 (U/L)	01/03/91	15.00		9.00		9.00	1
GANNA GT	4-18 (U/L)	01/03/91	11.00		12.00	ll	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	1 1	137.00	i I	125.00	
GLUCOSE	70-110 (MG/DL)	01/03/91	95.00	1 1				
BUN	17-56 (MG/DL)	01/03/91	24.00		17.00	l I	19.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.50		0.60	1	0.60	
URIC ACID	2.4-5.7 (MG/DL)	01/03/91	1		2.40		2.80	
TOT. PROTEINS	65-85 (G/L)	01/03/91	76.10		71.00		63.90	<
ALBUNINE	36-58 (G/L)	01/03/91	48.90		46.80	ΙI	42.90	
TOT. CHOLEST.	130-200 (MG/DL)	01/03/91	320.00	>>	270.00	<b>&gt;&gt;</b>	264.00	>>
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	78.00	<	131.00	i	160.00	l
GLOBULINS ALPHA 1	1.3-4.3 (G/L)	01/03/91	2.30		2.30		2.00	l
GLOBULINS ALPHA 2	3.9-8.5 (G/L)	01/03/91	5.20	l 1	5.40		4.60	1
GLOBULINS BETA	5,2-11.9 (G/L)	01/03/91	8.60		7.50		6.50	l
GLOBULINS GAMMA	5.9-16.2 (G/L)	01/03/91	11.10		9.00		7.90	1
TSH	0.3-3.5 (MU/L)	01/03/91	0.30	1				1
18H T4	9-21 (NG/L)	01/03/91	11.00					1
4.7	2 M 2 (NO-M)		1	1				

957

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAL HILLAND - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

# LABORATORY DATA Patient: 67 Treatment: Reboxetine Sex: Female

					mber / ory date	
			Screen	n	Day 2	8
			14/11/	92	16/12/9	92
			value	(¢)	value	(0)
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	l
RBC	4.4-6 (10-12/L)	18/09/91	4.26	<	4.50	
HBC	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	>>
MBC: E	1-4 (%)	18/09/91	3,00		2.00	
WBC: M	2-8 (%)	18/09/91	3.00		1.00	<
MBC: 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	İ
SGPT	5-19 (U/L)	18/09/91	13.00		8.00	Į.
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	l
ALK. PHOSPH.	40-190 (U/L)	18/09/91			106.00	ł
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	Ì
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	1
TOT. PROTEINS	66-87 (G/L)	18/09/91	68.00	]	67.00	1
ALBUMINE	58-70 (%)	18/09/91	62.20			
TOT. CHOLEST.	130-220 (MG/DL)	18/09/91	220.00		285.00	>
TRICLYCERIDES	30-150 (MG/DL)	18/09/91	72,00		106.00	1
GLOBULINS ALPHA 1	1.5-4 (%)	18/09/91	2.10			
GLOBULINS ALPHA 2	5-10 (%)	18/09/91	8.80			1
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	1

<sup>(</sup>c) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

## PHARMACIA PHARMACEUTICAS BY SN9 - CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 3 Patient: 68 Treatment: Reboxetine Sex: Female

					mber / ory date	
			Scree	р	Day 2	8
			26/11/	92	28/12/	92
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
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	1
MBC	4.3-10 (10¬9/L)	18/09/91	5.80		7.10	l
MBC: N	45-80 (%)	18/09/91	66.00		51.00	
MBC: L	20-40 (%)	18/09/91	27.00		47.00	
WBC: E	1-4 (%)	18/09/91	0.00	<	0.00	<
MBC: M	2-8 (%)	18/09/91	7.00		2.00	
KBC: 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	1 1	142.00	1
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	1 1	2.40	
SCOT	5-15 (U/L)	18/09/91	9.00		10.00	
SGPT	5-19 (U/L)	18/09/91	7.00	1 1	6.00	
GAMMA GT	4-18 (U/L)	18/09/91	6.00		8.00	1
LDH	120-240 (U/L)	18/09/91	181.00	1 1	186.00	
ALK. PHOSPH.	40-190 (U/L)	18/09/91	104.00	1 1	115.00	l
GLUCOSE	70-100 (MG/DL)	18/09/91	87.00	l i	71.00	
CREATININE	0.5-0.9 (MG/DL)	18/09/91	0.80		0.90	l
URIC ACID	2.4-5.7 (MG/DL)	18/09/91	2.80		4.50	i
TOT BILIRUBIN	0-1 (NG/DL)	18/09/91	0.50		0.60	[
TOT. PROTEINS	66-87 (G/L)	18/09/91	65.00	ایا	73.00	)
ALBUMINE	58-70 (%)	18/09/91	00.00		68.40	1
TOT. CHOLEST.	130-220 (MG/DL)	18/09/91	203.00		209.00	Ì
TOT. CHOLEST. TRIGLYCERIDES	30-150 (MG/DL)	18/09/91	64.00		70.00	
	1.5-4 (%)	18/09/91	2.60		2.50	
GLOBULINS ALPHA 1		18/09/91	6.70		6.50	1
GLOBULINS ALPHA 2	5-10 (%)	18/09/91	10.60		9.80	
GLOBULINS BETA	8-13 (%)	18/09/91	12.50		12.80	1
GLOBULINS GAMMA	10-19 (%)		2.30		12.60	
TSH	0.1-3.5 (UU/ML)	18/09/91	7.70	l i		1
T4	5-12.5 (UG/100ML)	18/09/91	7.70	i l		1

959

(¢) << clinically relevant (value lower than min range)
<pre>c out of range (value lower than min range)
than min range)
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than min range)

>> clinically relevant (value higher than max range to out of range (value higher than max range () missing range value

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# PHARMACIA PHARMACEUTICAL HILANO - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 4 Patient: 97 Treatment: Reboxetine Sex: Female

|                   |                    |            | Visit   | numi | er / Lai | borat | ory date | e   |
|-------------------|--------------------|------------|---------|------|----------|-------|----------|-----|
|                   |                    |            | Scree   | n    | Day 2    | В     | Day 5    | 6   |
|                   |                    |            | 19/04/9 | 91   | 19/05/   | 91    | 16/06/   | 91  |
|                   |                    |            | value   | (4)  | value    | (¢)   | value    | (¢) |
| Laboratory test   | Range value        | Range date |         |      |          |       |          |     |
| НВ                | 12-18 (G/DL)       | 15/04/91   | 12.20   | 1 1  | 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    | 1 1  | 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     | 1     | 2.00     | 1   |
| WBC: M            | 0.11-0.59 (10-9/L) | 15/04/91   | 0.30    |      | 0.30     | i l   | 0.20     |     |
| PLATELETS         | 140-440 (10-9/L)   | 15/04/91   | 426.00  |      | 395.00   | li    | 408.00   |     |
| NA+               | 137-147 (MMOL/L)   | 15/04/91   | 141.00  |      | 145.00   |       | 142.00   | 1   |
| 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     | 1   |
| P04               | 2.3-4.2 (MMOL/L)   | 15/04/91   | 2.80    | 1    | 3.40     | 1 1   | 3.00     | 1   |
| SCOT              | 5-18 (U/L)         | 15/04/91   | 9.00    |      | 11.00    | 1 1   | 14.00    | 1   |
| SCPT              | 5-23 (U/L)         | 15/04/91   | 5.00    |      | 5.00     | l i   | 13.00    |     |
| GANNA GT          | 6-28 (U/L)         | 15/04/91   | 8.00    |      | 7.00     | 1 1   | 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   | 1   |
| GLUCOSE           | 70-117 (NG/DL)     | 15/04/91   | 91.00   |      | 99.00    | 1 1   | 72.00    | l   |
| BUN               | 4-52 (MG/DL)       | 15/04/91   | 17.00   |      | 21.00    | ΙÌ    | 28.00    | l   |
| CREATININE        | 0.3-1.39 (MG/DL)   | 15/04/91   | 1.00    |      | 0,70     | 1 1   | 1.10     |     |
| URIC ACID         | 2.9-7.4 (MG/DL)    | 15/04/91   | 4.20    |      | 5.20     | l I   | 4.60     | İ   |
| TOT BILIRUBIN     | 0.3-1.54 (MG/DL)   | 15/04/91   | 0.30    |      | 0.50     |       | 0.40     | l   |
| DIR BILIRUBIN     | 0-0.3 (MG/DL)      | 15/04/91   |         |      | 0.06     |       | 0.03     | l   |
| TOT. PROTEINS     | 6.6-8.3 (G/DL)     | 15/04/91   | 6.80    |      | 7.50     | 1 1   | 7.80     | l   |
| ALBUMINE          | 3.7-5.4 (G/DL)     | 15/04/91   | 4.10    |      | 4.60     | l I   | 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 (2)           | 15/04/91   | 9.40    |      | 9.90     | j     | 8.40     |     |
| GLOBULINS BETA    | 10-15 (%)          | 15/04/91   | 14.50   |      | 11.00    |       | 11.60    | İ   |
| GLOBULINS GAMMA   | 12-22 (%)          | 15/04/91   | 13.70   |      | 22.10    | >     | 20.30    | İ   |
| TSH               | 0.1-3.5 (UU/ML)    | 15/04/91   | 0.30    |      |          |       |          | 1   |
| T4                | 4.5-12.5 (UG/DL)   | 15/04/91   | 8.00    | 1 1  |          | 1     |          | I   |

 $9\,6\,0$ 

>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

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# РНАКНАСІА РНАКНАСЕЦТВУБЬ ВНАМО - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 100 Treatment: Reboxetine Sex: Male

|                 |                    |            | Visi<br>number<br>Laborat<br>date | ory |
|-----------------|--------------------|------------|-----------------------------------|-----|
|                 |                    |            | Scree                             | n   |
|                 |                    |            | 08/05/                            | 92  |
|                 |                    |            | value                             | (6) |
| 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                              | i   |
| KBC             | 4.3-10 (10-9/L)    | 15/05/91   | 5.50                              |     |
| MBC: N          | 42.2-75.2 (%)      | 15/05/91   | 73.90                             |     |
| MBC: L          | 1.2-3.4 (10-9/L)   | 15/05/91   | 1.20                              | ĺ   |
| NBC: M          | 0.11~0.59 (10~9/L) |            | 0.20                              |     |
| PLATELETS       | 140-440 (10¬9/L)   | 15/05/91   | 280.00                            | i   |
| 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 (MNOL/L)    | 15/05/91   | 104.00                            |     |
| Ca++            | 2.1-2.7 (MMOL/L)   | 15/05/91   | 2.50                              |     |
| P04~~           | 2.3-4.2 (MMOL/L)   | 15/05/91   | 2.70                              |     |
| SGOT            | 5-18 (U/L)         | 15/05/91   | 8.00                              |     |
| SCPT            | 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 (NG/DL)    | 15/05/91   | 161.00                            |     |
| TRIGLYCERIDES   | 30-170 (MG/DL)     | 15/05/91   | 67.00                             |     |
| TSH             | 0.1-3.5 (UU/NL)    | 15/05/91   | 1.40                              | - 1 |
| T4              | 4.5-12.5 (UG/DL)   | 15/05/91   | 10.80                             | - 1 |

 $9\,6\,1$ 

(¢) << clinically relevant (value lower cout of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

>> clinically relevant (value higher than max range > out of range (value higher than max range () missing range value

## PHARMACIA PHARMACEUTICAL NILANG - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 4 Patient: 101 Treatment: Reboxetine

|                   |                    |            | Visit           | numk | or / La | borat | ory date | 9   |
|-------------------|--------------------|------------|-----------------|------|---------|-------|----------|-----|
|                   |                    |            | Scree           | n    | Day 2   | В     | Day S    | 6   |
|                   |                    |            | 02/07/          | 92   | 30/07/  | 92    | 27/08/9  | 92  |
|                   |                    |            | value           | (¢)  | value   | (¢)   | value    | (¢) |
| Laboratory test   | Range value        | Range date |                 |      |         |       |          |     |
| нв                | 12-18 (G/DL)       | 01/07/92   | 13.00           | 1 1  | 13.20   |       | 13.70    | ļ   |
| HT                | 37-54 (%)          | 01/07/92   | 38.20           |      | 39.10   |       | 39.80    | ļ   |
| RBC               | 4,2-6.3 (10-12/L)  | 01/07/92   | 4.40            |      | 4,43    |       | 4.54     |     |
| WRC               | 4.3-10 (10-9/L)    | 01/07/92   | 5.80            | 1 1  | 6.20    |       | 6.70     |     |
| MBC: 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     | l   |
| WBC: E            | 0-0.7 (10-9/L)     | 29/07/92   |                 | ı    | 0.00    |       | 0.00     | l   |
| WBC: M            | 0.11-0.59 (10-9/L) | 29/07/92   |                 |      | 0.30    |       | 0.30     | l   |
| MBC: B            | 0-0.2 (10-9/L)     | 29/07/92   |                 | l    | 0.00    |       | 0.00     | 1   |
| 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    | 1 1   | 3.70     |     |
| CL-               | 98-111 (MMOL/L)    | 01/07/92   | 111.00          |      | 105.00  |       | 106.00   |     |
| Ca++              | 2.1-2.7 (MNOL/L)   | 01/07/92   | 2.40            |      | 2.40    |       | 2.40     |     |
| P04               | 2.3-4.2 (MMOL/L)   | 01/07/92   | 3.50            | 1 1  | 2.90    |       | 3.10     |     |
| PO4<br>SGOT       | 5-18 (U/L)         | 01/07/92   | 4,00            | <    | 6.00    |       | 7.00     |     |
|                   | 5-23 (U/L)         | 01/07/92   | 5.00            | 1    | 6.00    |       | 13.00    | 1   |
| SCPT              | 5-23 (U/L)         | 01/07/92   | 8.00            |      | 9.00    |       | 13.00    | 1   |
| GAMMA GT          | 100-200 (U/L)      | 01/07/92   | 100.00          | 1 1  | 105.00  |       | 124.00   | 1   |
| LDH               | 68-195 (U/L)       | 01/07/92   | 64.00           | <    | 90.00   |       | 83.00    | 1   |
| ALK. PHOSPH.      | 70-117 (MG/DL)     | 01/07/92   | 84.00           |      | 63.00   | -     | 81.00    | ]   |
| GLUCOSE           |                    | 01/07/92   | 48.00           | 1    | 36.00   |       | 38.00    |     |
| BUN               | 4-52 (MG/DL)       |            | 0.70            | 1    | 0.70    |       | 0.80     | Ì   |
| CREATININE        | 0.3-1.39 (MG/DL)   | 01/07/92   | 4.20            |      | 4.20    |       | 3.80     | i   |
| URIC ACID         | 2.9-7.4 (MG/DL)    | 01/07/92   | 0.70            | i I  | 0.90    |       | 0.60     | l   |
| TOT BILIRUBIN     | 0.3-1.54 (MG/DL)   | 01/07/92   | 0.20            | ll   | 0.90    |       | 0.10     |     |
| DIR BILIRUBIN     | 0-0.3 (MG/DL)      | 01/07/92   | 6.60            |      | 7.20    |       | 7.10     |     |
| TOT. PROTEINS     | 6.6-8.3 (G/DL)     | 01/07/92   |                 |      | 4.70    |       | 4.80     |     |
| ALBUMINE          | 3.7-5.4 (G/DL)     | 01/07/92   | 4.10            |      | 261.00  | l. I  | 216.00   |     |
| TOT. CHOLEST.     | 150-260 (NG/DL)    | 01/07/92   | 177.00<br>82.00 | i    | 99.00   |       | 126.00   | l   |
| TRIGLYCERIDES     | 30-170 (MG/DL)     | 01/07/92   |                 |      | 99.00   |       | 126.00   | l   |
| GLOBULINS ALPHA 1 | 0.12-0.28 (G/DL)   | 01/07/92   | 0.20            | 1 1  |         |       | 3.50     | l   |
|                   | 1-4 (%)            | 29/07/92   |                 |      | 3.60    |       | 3.50     | l   |
| GLOBULINS ALPHA 2 | 0.45-0.82 (G/DL)   | 01/07/92   | 0.50            |      |         | 1     | 7.60     | i   |
|                   | 6-11 (%)           | 29/07/92   |                 | 1.   | 8.60    |       | /.00     | 1   |
| GLOBULINS BETA    | 0.74-1.1 (G/DL)    | 01/07/92   | 0.70            | ۲ ا  |         |       | 44 60    | 1   |
|                   | 10-15 (%)          | 29/07/92   |                 | 1    | 11.70   |       | 11.10    | 1   |
| GLOBULINS GAMMA   | 0.88-1.6 (G/DL)    | 01/07/92   | 1.10            |      |         |       |          | 1   |
|                   | 12-22 (%)          | 29/07/92   |                 |      | 19.00   | '     | 20.40    | l   |
| TSH               | 0.1-3.5 (UU/ML)    | 01/07/92   | 0.50            |      |         |       |          | 1   |
| T4                | 4.5-12.5 (UG/DL)   | 01/07/92   | 8.70            | !    |         | 1     |          | 1   |

<sup>(¢) &</sup>lt;< clinically relevant (value lower than min range)
< out of range (value lower than min range)
\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range > out of range (value higher than max range () missing range value

# PHARMACIA PHARMACEUTISAIS WHANS - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 4 Patient: 104 Treatment: Reboxetine Sex: Female

|                   |                    |            |                 |      | umber /<br>ory date |     |
|-------------------|--------------------|------------|-----------------|------|---------------------|-----|
|                   |                    |            | Scree           | n    | Day 2               | 8   |
|                   |                    | •          | 17/08/          | 92   | 15/09/              | 92  |
|                   |                    |            | value           | (¢)  | value               | (¢) |
| Laboratory test   | Range value        | Range date |                 |      |                     |     |
| HВ                | 12-18 (G/DL)       | 15/05/91   | 14.00           |      | 14.10               |     |
| HT                | 37-54 (%)          | 15/05/91   | 40.60           |      | 41.50               | 1   |
| RBC               | 4.2-6.3 (10-12/L)  | 15/05/91   | 4.38            |      | 4.48                |     |
| MBC               | 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                | >   |
| NBC: E            | 0-0.7 (10→9/L)     | 14/09/92   |                 |      | 0.00                | l   |
| NBC: M            | 0.11-0.59 (10-9/L) | 15/05/91   | 0.50            |      | 0.30                | ĺ   |
| WBC: B            | 0-0.2 (10-9/L)     | 14/09/92   |                 |      | 0.00                |     |
| PLATELETS         | 140-440 (10-9/L)   | 15/05/91   | 336.00          | 1    | 319.00              |     |
| NA+               | 137-147 (MMOL/L)   | 15/05/91   | 144.00          |      | 145.00              | Į . |
| K+                | 3.5-5.3 (MMOL/L)   | 15/05/91   | 4.10            |      | 4.00                |     |
| CL-               | 98-111 (MMOL/L)    | 15/05/91   | 112.00          | ادا  | 104.00              |     |
| Ca++              | 2.1-2.7 (MMOL/L)   | 15/05/91   | 2.30            | ·    | 2.50                | 1   |
| Ca++<br>P04       | 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            | ا را | 6.00                | 1   |
|                   | 6-28 (U/L)         | 15/05/91   | 6.00            | `    | 7.00                |     |
| GAMMA GT          | 100-200 (U/L)      | 15/05/91   | 127.00          | 1    | 152.00              | ĺ   |
| LDH               |                    |            |                 |      | 128.00              | l   |
| ALK, PHOSPH.      | 68-195 (V/L)       | 15/05/91   | 116.00<br>85.00 | 1    | 96.00               |     |
| GLUCOSE           | 70-117 (MG/DL)     | 15/05/91   |                 |      |                     |     |
| 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            | 1    |                     |     |
| TOT. PROTEINS     | 6.6-8.3 (G/DL)     | 15/05/91   | 7.20            |      | 7.40                |     |
| ALBUNINE          | 3.7-5.4 (G/DL)     | 15/05/91   | 4.20            |      | 4.40                | l   |
| 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            |      |                     | l   |
| T4                | 4.5-12.5 (UG/DL)   | 15/05/91   | 8.40            |      |                     | ı   |

<sup>(¢) &</sup>lt;< clinically rolevant (value lower cut of range (value lower than min range) than min range) than min range) than min range) and laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range)
> out of range (value higher than max range)
() missing range value

# PHARMACIA PHARMACEUTICAS HILAND - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 129 Treatment: Reboxetine

|                 |                   |            |        | Visit number /<br>Laboratory date |          |     |  |  |  |
|-----------------|-------------------|------------|--------|-----------------------------------|----------|-----|--|--|--|
|                 |                   |            | Scree  | a                                 | Day 2    | 8   |  |  |  |
|                 |                   |            | 25/11/ | 91                                | 26/12/91 |     |  |  |  |
|                 |                   |            | value  | (¢)                               | value    | (¢) |  |  |  |
| Laboratory test | Range value       | Range date |        |                                   |          |     |  |  |  |
| HB              | 12.5-18 (G/DL)    | 09/09/91   | 14.80  |                                   | 14.30    | 1   |  |  |  |
| HT              | 37-47 (%)         | 09/09/91   | 42.10  |                                   | 40.70    | 1   |  |  |  |
| RBC             | 4.5-5.5 (10¬6/UL) | 09/09/91   | 4.85   |                                   | 4.68     | 1   |  |  |  |
| MBC             | 4-10.8 (10-3/UL)  | 09/09/91   | 6.30   |                                   | 7.40     |     |  |  |  |
| WBC: N          | 40-74 (%)         | 09/09/91   | 45.10  |                                   | 62.50    |     |  |  |  |
| MBC: L          | 19-48 (%)         | 09/09/91   | 48.30  | >                                 | 30.90    |     |  |  |  |
| MBC: E          | 0-4 (%)           | 09/09/91   | 0.80   | 1                                 | 1.10     | ľ   |  |  |  |
| HBC: H          | 3.4-9 (%)         | 09/09/91   | 5.30   |                                   | 5.00     |     |  |  |  |
| MBC: 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   | - 1                               | 4.40     | 1   |  |  |  |
| Ca++            | 8,1-10.4 (MG/DL)  | 09/09/91   | 10.30  |                                   | 10.20    |     |  |  |  |
| P04             | 2.5-5 (MG/DL)     | 09/09/91   | 3.70   |                                   | 4.20     |     |  |  |  |
| SCOT            | 4-40 (U/L)        | 09/09/91   | 18.00  |                                   | 20.00    | i   |  |  |  |
| SGPT            | 4-40 (U/L)        | 09/09/91   | 15.00  |                                   | 25.00    |     |  |  |  |
| GAMMA GT        | 7-50 (U/L)        | 09/09/91   | 15.00  | - 1                               | 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  | ĺ                                 | 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   | - 1                               | 3.80     |     |  |  |  |
| TOT BILIRUBIN   | 0.3-1.2 (MG/DL)   | 09/09/91   | 0.50   | 1                                 | 0.40     |     |  |  |  |
| TOT. PROTEINS   | 6-8 (G/DL)        | 09/09/91   | 7.60   | - 1                               | 7.60     |     |  |  |  |
| TOT. CHOLEST.   | 140-260 (MG/DL)   | 09/09/91   | 251.00 | - 1                               | 271.00   | >   |  |  |  |
| TRIGLYCERIDES   | 30-150 (MG/DL)    | 09/09/91   | 84.00  | ı                                 | 107.00   |     |  |  |  |
| TSH             | 0.4-4.5 (UU/ML)   | 09/09/91   | 1.18   | - 1                               |          |     |  |  |  |
| T4              | 0.8-2 (NG/100ML)  | 09/09/91   | 1.45   | - 1                               | -        |     |  |  |  |

964

(t) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range cout of range (value higher than max range could missing range value)

## PHARMACIA PHARMACEUTEDS5000 - CNS

# REBOXETINE ~ PROTOCOL 20124/016 Listing No.: 18.0

# LABORATORY DATA Patient: 193 Treatment: Reboxetine Sex: Female

|                   | •                                  |             | Visit  | numb | er / Lai | borat | ory date | B  |
|-------------------|------------------------------------|-------------|--------|------|----------|-------|----------|----|
|                   |                                    |             | Screen | 1    | Day 2    | В     | Day 5    | 6  |
|                   |                                    |             | 03/12/ | 91   | 02/01/   | 92    | 30/01/9  | 92 |
|                   |                                    |             | value  | (¢)  | value    | (¢)   | value    | (¢ |
| Laboratory test   | Range value                        | Range date  |        |      |          |       | 40.00    |    |
| ЯВ                | 12-16 (G/DL)                       | 01/12/91    | 11.50  |      | 13.80    |       | 13.90    | l  |
| HT                | 37-47 (%)                          | 01/12/91    | 35.60  |      | 41.00    | 1 1   | 40.00    | i  |
| RBC               | 4.2-5.4 (10-6/UL)                  | 01/12/91    | 3.78   | <    | 4.37     | 1 1   | 4.24     | l  |
| HBC               | 4.3-10 (10-3/VL)                   | 01/12/91    | 6.49   |      | 6.40     |       | 6.80     | l  |
| HBC: N            | 1.8-8 (10-3/UL)                    | 01/12/91    | 4.72   |      | 3.28     |       | 3.46     | l  |
| MBC: L            | 1-5 (10-3/UL)                      | 01/12/91    | 1.04   |      | 2.40     | 1     | 2,65     | l  |
| WBC: E            | 0-0.5 (10-3/UL)                    | 01/12/91    | 0.06   |      | 0.14     | 1     | 0.14     | l  |
| MBC: M            | 0.1-0.8 (10-3/UL)                  | 01/12/91    | 0.51   |      | 0.39     |       | 0.46     | 1  |
| MBC: B            | 0-0.1 (10-3/UL)                    | 01/12/91    | 0.05   | 1    | 0.17     | >>    | 0.07     | 1  |
| 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   | 1  |
| Ca++              | 2.14-2.54 (MMOL/L)                 | 01/12/91    | 2.26   |      | 2.49     |       | 2.38     |    |
| P04               | 0.85-1.33 (MMOL/L)                 | 01/12/91    | 0.99   |      | 1.20     | 1     | 1.26     |    |
| SGOT              | 9-25 (U/L)                         | 01/12/91    | 11.00  | 1    | 14.00    | 1     | 11,00    |    |
| SGPT              | 8-36 (U/L)                         | 01/12/91    | 6,00   | <    | 12.00    |       | 8.00     | 1  |
| GAMMA GT          | 7-43 (U/L)                         | 01/12/91    | 11.00  |      | 17.00    | 1 1   | 15.00    | 1  |
| 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   | i  |
|                   | 4.1-5.9 (MMOL/L)                   | 01/12/91    | 4.10   |      | 4.70     |       | 4.40     | l  |
| GLUCOSE<br>BUN    | 3.8-8.6 (MMOL/L)                   | 01/12/91    | 4.20   |      | 3,50     | <     | 2.60     | <  |
| BUN<br>CREATININE | 55-94 (UMOL/L)                     | 01/12/91    | 76.00  |      | 71.00    |       | 77.00    | 1  |
| URIC ACID         | 147-372 (UMOL/L)                   | 01/12/91    | 163.00 |      | 203.00   |       | 194.00   | 1  |
| TOT BILIRUBIN     | 0-17 (UMOL/L)                      | 01/12/91    | 4.00   |      | 4.00     |       | 8.00     | ĺ  |
| DIR BILIRUBIN     | 0-6 (UMOL/L)                       | 01/12/91    | 2.00   |      | 2.00     | 1     | 3.00     |    |
|                   | 64-76 (G/L)                        | 01/12/91    | 63.40  | <    | 79.80    | >     | 68.90    |    |
| TOT. PROTEINS     | 40-48 (G/L)                        | 01/12/91    | 43.90  | 1    | 53.00    | >     | 47.10    |    |
| ALBUMINE          | 40-48 (G/L)<br>4.3-7.6 (MMOL/L)    | 01/12/91    | 2.82   | <    | 4.47     | 1     | 3.45     | <  |
| TOT. CHOLEST.     | 0.34-1.9 (MMOL/L)                  | 01/12/91    | 1.08   |      | 0.41     |       | 0,49     | 1  |
| TRIGLYCERIDES     | 0.34-1.9 (MNUL/L)<br>0.3-4 (MUI/L) | 01/12/91    | 0.89   |      |          | 1     |          | 1  |
| TSH               | 0.3-4 (NOL/L)<br>9-24 (PMOL/L)     | 01/12/91    | 8.76   |      |          |       |          | 1  |
| T4                | 3-24 (PROL/L)                      | V 1. 12. 21 | 1      | 1    |          | l     |          |    |

<sup>(¢) &</sup>lt;< clinically relevant (value lower than min range)
< out of range (value lower than min range)
than min range)
than min range)
than min range)
than min range)
than min range)

<sup>&</sup>gt;> clinically relevant (value higher than max rang out of range (value higher than max rang () missing range value

# PHARMACIA PHARMACEUTISASSHILANG - CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

# LABORATORY DATA Centre: 7 Patient: 196 Treatment: Reboxetine Sex: Female

|                      |                    |            | Visit    | numt  | er / Lai | borat  | ory dat | a                                            |
|----------------------|--------------------|------------|----------|-------|----------|--------|---------|----------------------------------------------|
|                      |                    |            | Scree    | Day 2 | В        | Day 42 |         |                                              |
|                      |                    |            | 22/05/92 |       | 25/06/   | 92     | 14/07/  | 92                                           |
|                      |                    |            | value    | (¢)   | value    | (¢)    | value   | (¢)                                          |
| Laboratory test      | Range value        | Range date |          |       |          |        |         |                                              |
| нв                   | 12-16 (G/DL)       | 01/12/91   | 13.40    |       | 12.80    |        |         | i i                                          |
| HT                   | 37-47 (%)          | 01/12/91   | 40.00    |       | 39.00    |        |         | i                                            |
| RBC                  | 4,2-5.4 (10-6/UL)  | 01/12/91   | 4.61     |       | 4.34     |        |         |                                              |
| MBC                  | 4.3-10 (10-3/UL)   | 01/12/91   | 7,10     |       | 5.80     |        |         | l                                            |
| WBC: N               | 1.8-8 (10-3/UL)    | 01/12/91   | 3.37     |       | 3.07     | l l    |         | l                                            |
| WBC: L               | 1-5 (10-3/UL)      | 01/12/91   | 3,15     |       | 2.01     | l 1    |         |                                              |
| MBC: E               | 0-0.5 (10-3/UL)    | 01/12/91   | 0.13     |       | 0.19     | l I    |         |                                              |
| NBC: M               | 0.1-0.8 (10-3/UL)  | 01/12/91   | 0.40     |       | 0.48     | l 1    |         |                                              |
| NBC: B               | 0-0.1 (10-3/UĹ)    | 01/12/91   | 0.02     |       | 0.03     | l 1    |         |                                              |
| PLATELETS            | 150-350 (10-3/UL)  | 01/12/91   | 286.00   |       | 288.00   |        |         |                                              |
| NA+                  | 140-148 (NMOL/L)   | 01/12/91   | 142.00   |       | 146.00   |        | 141.00  |                                              |
| K+                   | 3.9-5.1 (MMOL/L)   | 01/12/91   | 4,32     |       | 4.26     | 1      | 2.98    |                                              |
| CL-                  | 96-109 (MMOL/L)    | 01/12/91   | 105.00   |       | 104.00   | 1      | 93.00   |                                              |
| Ca++                 | 2.14-2.54 (MMOL/L) | 01/12/91   | 2.60     | >     | 2,26     | 1 1    | 2.33    |                                              |
| P04                  | 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  |                                              |
| GANNA 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   | 1 }    | 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    | l j    | 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    | 1 1    | 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    | l                                            |
| TRIGLYCERIDES        | 0.34-1.9 (MMQL/L)  | 01/12/91   | 1.84     |       | 1.90     | ] [    | 1.90    |                                              |
| TRIGLYCERIDES<br>TSH | 0.3-4 (MUI/L)      | 01/12/91   | 4.26     |       |          |        |         | 1                                            |
| 15n<br>T4            | 9-24 (PMOL/L)      | 01/12/91   | 16.20    |       |          |        |         | l                                            |
| 17                   | 3-24 (FNOL, M)     | O 10 12/71 | .5.20    |       |          |        |         | $ldsymbol{ldsymbol{ldsymbol{ldsymbol{eta}}}$ |

<sup>(¢) &</sup>lt;< clinically relevant (value lower than min range)
< out of range (value lower than min range)
than min range)
than min range)
at missing laboratory test value at laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA CMS5880083

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 322 Treatment: Reboxetine

|            | Labo    | rato | ry date |    |
|------------|---------|------|---------|----|
|            | Screen  | •    | Day 5   | 5  |
|            | 06/11/9 | 1    | 03/01/  | 92 |
|            | value   | (¢)  | value   | (¢ |
| Range date |         |      |         |    |
| 01/10/91   | 130.00  |      | 136.00  |    |
| 01/10/91   | 0.39    | <    | 0.39    | <  |
| 01/10/91   | 4.41    | l    | 4.50    |    |
| 01/10/91   | 5.70    |      | 5.51    |    |
| 01/10/91   | 64.10   |      | 47.30   |    |
| 01/10/91   | 24.10   | - 1  | 37.90   |    |
| 01/10/91   | 1.40    | 1    | 2.70    |    |
| 01/10/91   | 7.80    | - 1  | 9,00    |    |
| 01/10/91   | 0.50    | - 1  | 0.90    |    |
| 01/10/91   | 178.00  |      | 255.00  |    |
| 01/10/91   | 142,00  | 1    | 139.00  |    |
| 01/10/91   | 3.50    | - 1  | 3.70    |    |
| 01/10/91   |         | - 1  |         |    |
| 01/10/91   | 9,70    |      | 9.80    |    |
| 01/10/91   | 4.40    | >    | 3.80    | l  |
| 01/10/91   | 20.00   |      | 21.00   |    |
| 01/10/91   | 11.00   |      | 20.00   | l  |

Visit number /

|                    |                            |             | value  | (4) | value  | (¢) |
|--------------------|----------------------------|-------------|--------|-----|--------|-----|
| Laboratory test    | Range value                | Range date  |        |     |        |     |
| HB                 | 115-145 (Q/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   |     |
| MBC                | 4.5-10 (10-9/L)            | 01/10/91    | 5.70   |     | 5.51   |     |
| WBC: N             | 40-70 (%)                  | 01/10/91    | 64.10  |     | 47.30  |     |
| MBC: 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   |     |
| HBC: 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   |     |
| P04                | 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 (VI/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 (NG/DL)             | 01/10/91    | 92.00  |     | 88.00  |     |
|                    | 10-25 (MG/DL)              | 01/10/91    | 7.00   | <   | 8.00   | <   |
| BUN<br>Urea        | ()                         | 01/10/91    | ''''   |     |        |     |
| UKEA<br>CREATININE | 0.5-1.3 (MG/DL)            | 01/10/91    | 0.70   |     | 0.60   | İ   |
| URIC ACID          | 1.9-7.4 (MG/DL)            | 01/10/91    | 2.70   | 1   | 3.20   |     |
| TOT BILIRUBIN      | 0.1-1 (MG/DL)              | 01/10/91    | 1.10   | >   | 1.10   | >   |
| TOT BILIRUBIN      | ()                         | 01/10/91    |        |     |        | 1   |
|                    | 60-80 (G/L)                | 01/10/91    | 72.00  | l   | 67.00  | l   |
| TOT. PROTEINS      | 57-69 (%)                  | 01/10/91    | 67.40  | l   | 67.00  | l   |
| ALBUNINE           | 148-247 (MG/DL)            | 01/10/91    | 153.00 | l   | 144.00 | ۱ د |
| TOT, CHOLEST.      | 50-150 (MG/DL)             | 01/10/91    | 57.00  |     | 64.00  | 1   |
| TRIGLYCERIDES      | 2.1-3.5 (%)                | 01/10/91    | 2.40   | l   | 3.10   | -   |
| GLOBULINS ALPHA 1  |                            | 01/10/91    | 6.40   | ĺ   | 6.10   | 1   |
| GLOBULINS ALPHA 2  | 6-10 (%)<br>6.5-11.5 (%)   | 01/10/91    | 7.80   |     | 8.00   |     |
| GLOBULINS BETA     | 15-22 (%)                  | 01/10/91    | 16.00  | 1   | 15.80  | 1   |
| GLOBULINS GAMMA    | 75-22 (Z)<br>0.5-5 (UU/ML) | 01/10/91    | ,5.00  | 1   |        | 1   |
| TSH                |                            | 01/10/91    | 1      |     | i      |     |
| T4                 | 4.5-12.5<br>(UG/100ML)     | 0.15.105.21 |        |     |        |     |

<sup>(¢) &</sup>lt;< clinically relevant (value lower cut of range (value lower than min range) than min range) (\*\* missing laboratory test value cut of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range value higher than max range () missing range value

## PHARMACIA PHARMACEUT 5035 (1846) - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 324 Treatment: Reboxetine

|                   |                                        |                      | Visit         | numl     | er / Lai      | ocat     | ory dat       | e   |
|-------------------|----------------------------------------|----------------------|---------------|----------|---------------|----------|---------------|-----|
|                   |                                        |                      | Screen        | Screen   |               |          | Day 5         | 6   |
|                   |                                        |                      | 21/01/9       | 21/01/92 |               | 19/02/92 |               | 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        | ĺ   |
| HT                | 0.42-0.5 (L/L)                         | 20/01/92             | 0.46          |          | 0.39          | ۱۲ ا     |               |     |
| <b>DD</b> 4       | 0.36-0.51 (L/L)                        | 01/04/92             |               |          | 4.41          |          | 0.39          |     |
| RBC               | 4.2-5.2 (10-12/L)<br>3.9-5.5 (10-12/L) | 20/01/92<br>01/04/92 | 4.87          |          | 4.41          |          | 4.35          |     |
| MBC               | 4.5-10 (10-9/L)                        | 20/01/92             | 7.90          |          | 8.33          |          | 4.55          |     |
| MBC               | 4-11 (10-9/L)                          | 01/04/92             | 7.50          |          | 0.33          |          | 8.11          |     |
| MBC: N            | 40-70 (%)                              | 20/01/92             | 77.50         |          | 77.40         | , l      | 0             |     |
| NDC. II           | 45-75 (%)                              | 01/04/92             | ,,,,,,        | _        |               | ·        | 81.70         | -   |
| WBC: L            | 20-45 (%)                              | 20/01/92             | 10.20         | <<       | 15.30         | <        |               | ľ   |
| NDC. 1            | 17-55 (%)                              | 01/04/92             | 10125         |          |               | Ī.       | 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          | l        | 4.90          | ٠        | 5.80          | 1   |
| WBC: B            | 0-1 (%)                                | 20/01/92             | 0.60          |          | 0.50          |          |               | 1   |
|                   | 0-2 (%)                                | 01/04/92             | i i           |          | i             |          | 0.30          | l   |
| PLATELETS         | 150-350 (10¬9/L)                       | 20/01/92             | 205.00        | 1        | 175.00        |          |               |     |
|                   | 150-400 (10¬9/L)                       | 01/04/92             |               | 1        |               |          | 247.00        |     |
| NA+               | 135-145 (NEQ/L)                        | 20/01/92             | 144.00        |          | 140.00        |          | 137.00        | ļ   |
| K+                | 3.5-4.5 (MEQ/L)                        | 20/01/92             | 4.20          |          | 3.70          |          | 3.80          | i   |
| CL-               | 95-106 (NEQ/L)                         | 20/01/92             | 98.00         |          | 99.00         |          | 97.00         | İ   |
| Ca++              | 8,5-10.5 (MG/DL)                       | 20/01/92             | 10.50         |          | 9.90          | - 1      | 9.20          |     |
| P04               | 2.3-4.3 (MG/DL)                        | 20/01/92             | 3.60<br>21.00 |          | 3.10<br>15.00 |          | 3.10<br>31.00 |     |
| SGOT              | 10-40 (UI/L)<br>10-40 (UI/L)           | 20/01/92<br>20/01/92 | 14.00         |          | 11.00         | - 1      | 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        | 1   |
| ALK. PHOSPH.      | 123-345 (UI/L)                         | 20/01/92             | 189.00        | `        | 151.00        |          | 272.00        | i   |
| 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         | ı        | 17.00         |     |
| CREATININE        | 0.5-1.3 (MG/DL)                        | 20/01/92             | 0.70          | - 1      | 0.70          | - 1      | 0.60          |     |
| URIC ACID         | 1.9-7.4 (MG/DL)                        | 20/01/92             | 2.10          | - 1      | 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         | - 1      | 69.90         | >        | 60.30         |     |
| TOT. CHOLEST.     | 148-247 (MG/DL)                        | 20/01/92             | 263.00        | >        | 226.00        |          | 196.00        | 1   |
| TRIGLYCERIDES     | 50-150 (MG/DL)                         | 20/01/92             | 108.00        | - 1      | 70.00         | ı        | 66.00         |     |
| GLOBULINS ALPHA 1 | 2.1-3.5 (%)                            | 20/01/92             | 2.70          |          | 2.40          | l        | 3.70          |     |
| GLOBULINS ALPHA 2 | 6-10 (%)                               | 20/01/92             | 7.80          | - 1      | 8.30          | l        | 11.50         | >   |
| GLOBULINS BETA    | 6.5-11.5 (%)                           | 20/01/92             | 10.10         |          | 9.50          |          | 11.50         | -   |
| GLOBULINS GAMMA   | 15-22 (X)                              | 20/01/92             | 9.80          | <۲       | 9.90          | <<       | 13.00         | ١ ٠ |
| TSH<br>To         | 0.5-5 (UU/ML)                          | 20/01/92             | 1.00          |          |               |          |               | l   |
| T4                | 4.5-12.5                               | 20/01/92             | 40.00         |          |               |          |               | 1   |
|                   | (UG/100ML)                             |                      | 10.20         |          | - 1           | - [      |               | ı   |

<sup>(\$) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

# PHARMACIA PHARMACEUTECAS (1814) - CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 325 Treatment: Roboxetine Sex: Female

|                                         |                                  |            | Visit  | numk     | er / Lai | borat    | ory date | •  |
|-----------------------------------------|----------------------------------|------------|--------|----------|----------|----------|----------|----|
|                                         |                                  |            | Scree  | n        | Day 2    | В        | Day 56   |    |
|                                         |                                  |            | 14/01/ | 14/01/92 |          | 04/03/92 |          | 92 |
|                                         |                                  |            | value  | (¢)      | value    | (4)      | value    | (¢ |
| Laboratory test                         | Range value                      | Range date |        |          |          |          |          |    |
| HB                                      | 115-145 (G/L)                    | 01/01/92   | 120.00 |          | 133.00   | ΙÌ       |          |    |
|                                         | 120-170 (G/L)                    | 05/04/92   |        | i i      |          | l I      | 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   | 1      | 1 1      |          |          | 0.37     | 1  |
| RBC                                     | 4.2-5.2 (10-12/L)                | 01/01/92   | 4.19   | <        | 4.57     | l I      |          |    |
|                                         | 3.9-5.5 (10-12/L)                | 05/04/92   |        |          |          | i I      | 4.56     |    |
| KBC                                     | 4.5-10 (10-9/L)                  | 01/01/92   | 6.51   | 1 1      | 6.44     |          |          |    |
|                                         | 4-11 (10~9/L)                    | 05/04/92   |        | 1        |          |          | 5.28     |    |
| WBC: N                                  | 40-70 (%)                        | 01/01/92   | 51.30  |          | 51.80    |          |          |    |
|                                         | 45-75 (2)                        | 05/04/92   |        |          |          |          | 47.50    | ł  |
| HBC: L                                  | 20-45 (%)                        | 01/01/92   | 34.80  |          | 33.50    | l 1      |          |    |
|                                         | 17-55 (%)                        | 05/04/92   |        | 1 1      |          | 1 1      | 38.20    |    |
| MBC: E                                  | 1-5 (%)                          | 01/01/92   | 5.40   | >        | 6.80     | >>       |          |    |
| .,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | 0-5 (%)                          | 05/04/92   |        | 1 1      |          | l I      | 4.70     |    |
| WBC: M                                  | 2-10 (%)                         | 01/01/92   | 4.80   |          | 4.50     |          | 6.20     |    |
| NBC: B                                  | 0-1 (%)                          | 01/01/92   | 0.70   | 1 1      | 0.70     | I I      |          |    |
| ilde. D                                 | 0-2 (%)                          | 05/04/92   |        | 1        |          |          | 1.00     |    |
| PLATELETS                               | 150-350 (10-9/L)                 | 01/01/92   | 339.00 | 1 1      | 382.00   | - I      |          |    |
| FLATELLID                               | 150-400 (10-9/L)                 | 05/04/92   |        |          |          | 1        | 372.00   |    |
| NA+                                     | 135-145 (MEQ/L)                  | 01/01/92   | 142.00 | 1 1      | 146.00   | >        | 141.00   |    |
| K+                                      | 3.5-4.5 (MEQ/L)                  | 01/01/92   | 3.80   |          | 4.30     | 1 I      | 3.70     |    |
| CL-                                     | 95-106 (MEQ/L)                   | 01/01/92   |        | 1 1      | 103.00   | ł I      | 98.00    |    |
| Ca++                                    | 8.5-10.5 (NG/DL)                 | 01/01/92   | 10.00  |          | 10.10    | ł I      | 9.40     |    |
| P04                                     | 2.3-4.3 (MG/DL)                  | 01/01/92   | 4.00   | l i      | 3.90     | 1        | 4.20     |    |
| SGOT                                    | 10-40 (UI/L)                     | 01/01/92   | 16.00  | l i      | 20.00    | 1 I      | 15.00    |    |
| SGPT                                    | 10-40 (UI/L)                     | 01/01/92   | 18.00  | 1 1      | 24.00    |          | 15.00    |    |
|                                         | 5-40 (UI/L)                      | 01/01/92   | 19.00  |          | 13.00    |          | 13,00    |    |
| GANNA GT                                | 250-450 (UI/L)                   | 01/01/92   | 265.00 |          | 319.00   | [ ]      | 276.00   |    |
| LDH                                     | 123-345 (UI/L)                   | 01/01/92   | 116.00 | <        | 128.00   | f I      | 92.00    | ۱۷ |
| ALK. PHOSPH.                            | 123-345 (UI/L)<br>64-107 (MG/DL) | 01/01/92   | 86.00  | '        | 89.00    | l I      | 86.00    |    |
| GLUCOSE                                 | 10-25 (MG/DL)                    | 01/01/92   | 9.00   | <        | 13.00    |          | 8.00     | ۱, |
| BUN                                     |                                  | 01/01/92   | 0.70   | `        | 0.80     |          | 0.70     | 1  |
| CREATININE                              | 0.5-1.3 (MG/DL)                  |            | 4.60   |          | 5.10     | 1 1      | 4.10     |    |
| URIC ACID                               | 1.9-7.4 (MG/DL)                  | 01/01/92   | 0.40   |          | 0.30     |          | 0.40     |    |
| TOT BILIRUBIN                           | 0.1-1 (MG/DL)                    | 01/01/92   | 71.00  | 1 1      | 74.00    | 1 1      | 73.00    |    |
| TOT, PROTEINS                           | 60-80 (G/L)                      | 01/01/92   | 64.80  |          | 65.60    | li       | 65.50    |    |
| albumine                                | 57-69 (X)                        | 01/01/92   |        |          | 240.00   |          | 222.00   |    |
| TOT. CHOLEST.                           | 148-247 (MG/DL)                  | 01/01/92   | 231.00 |          |          | l. i     | 156.00   | I. |
| TRIGLYCERIDES                           | 50-150 (MG/DL)                   | 01/01/92   |        | >        | 151.00   |          | 3.40     |    |
| GLOBULINS ALPHA 1                       | 2.1-3.5 (%)                      | 01/01/92   | 3.90   |          | 2.70     |          | 6.80     | ı  |
| GLOBULINS ALPHA 2                       | 6-10 (%)                         | 01/01/92   | 7.30   |          | 6.60     |          |          |    |
| GLOBULINS BETA                          | 6.5-11.5 (%)                     | 01/01/92   | 11.80  | >        | 11.30    | 1.       | 11.20    | ١. |
| GLOBULINS GAMMA                         | 15-22 (%)                        | 01/01/92   | 12.20  | <        | 13.80    | <b> </b> | 13.10    | ۲  |
| TSH                                     | 0.5-5 (UU/ML)                    | 01/01/92   | 9.50   | >>       |          |          |          |    |
| T4                                      | 4.5-12.5                         | 01/01/92   |        |          |          |          |          | l  |
|                                         | (UG/100HL)                       |            | 11.40  | 1        |          | 1        |          | ı  |

<sup>(¢) &</sup>lt;< clinically relevant (value lower cut of range) (value lower than min range) than min range) (value lower missing laboratory test value cut of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTISMS OF CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 326 Treatment: Reboxetine

|                   |                   |            | Visit   | numi | oer / La | borat | ory dat  | 8   |
|-------------------|-------------------|------------|---------|------|----------|-------|----------|-----|
|                   |                   |            | Scree   | п    | Day 2    | В     | Day 5    | 6   |
|                   |                   |            | 29/01/9 | 92   | 20/03/   | 92    | 07/04/92 |     |
|                   |                   |            | value   | (4)  | 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    | <    |          |       |          | ł   |
|                   | 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    |      |          |       |          | l   |
|                   | 3.9-5.5 (10-12/L) | 15/03/92   |         | 1 1  | 5.03     |       | 5.07     |     |
| WBC               | 4.5-10 (10-9/L)   | 25/01/92   | 6.99    | ll   |          |       |          |     |
|                   | 4-11 (10-9/L)     | 15/03/92   |         |      | 6.89     |       | 6,47     | 1   |
| 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   | ll   |          |       |          |     |
| noc. D            | 17-55 (%)         | 15/03/92   |         | ll   | 42.90    |       | 40.50    |     |
| WBC: E            | 1-5 (%)           | 25/01/92   | 1.40    | ll   |          |       |          |     |
| MDC: E            | 0-5 (%)           | 15/03/92   | 1       |      | 0.90     | l 1   | 0.70     |     |
| WBC: M            | 2-10 (%)          | 25/01/92   | 9.90    |      | 8.30     |       | 2.62     |     |
|                   | 0-1 (%)           | 25/01/92   | 0.50    |      | 0.50     |       | 2.02     |     |
| MBC: B            | 0-1 (%)           | 15/03/92   | 0.50    | 1 1  | 0.50     |       | 0.08     |     |
| D                 |                   |            | 272.00  |      | 0.50     |       | 0.00     |     |
| PLATELETS         | 150-350 (10-9/L)  | 25/01/92   | 272.00  |      | 204 00   |       | 300.00   |     |
|                   | 150-400 (10-9/L)  | 15/03/92   |         | i I  | 326.00   |       |          |     |
| 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     | l   |
| P04               | 2.3-4.3 (MG/DL)   | 25/01/92   | 3.10    |      | 3.20     |       | 3.20     |     |
| SGOT              | 10-40 (VI/L)      | 25/01/92   | 15.00   |      | 14.00    | !     | 13.00    | ł   |
| SGPT              | 10-40 (UI/L)      | 25/01/92   | 28.00   | 1    | 24.00    | !     | 20.00    | l   |
| GANMA GT          | 5-40 (UI/L)       | 25/01/92   | 22.00   | li   | 16.00    |       | 19.00    |     |
| LDH               | 250-450 (UI/L)    | 25/01/92   | 355.00  |      | 319.00   |       | 343.00   | 1   |
| 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     | ĺ   |
| URIC ACID         | 1.9-7.4 (NG/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     | İ   |
| TOT. PROTEINS     | 60-80 (G/L)       | 25/01/92   | 67.00   |      | 70.00    |       | 70.00    | İ   |
| ALBUMINE          | 57-69 (%)         | 25/01/92   | 64.00   |      | 66.20    |       | 61,10    | 1   |
| TOT. CHOLEST.     | 148-247 (MG/DL)   | 25/01/92   | 214.00  |      | 245.00   | i I   | 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     | 1   |
| GLOBULINS ALPHA 2 | 6-10 (%)          | 25/01/92   | 8.70    |      | 7.60     |       | 9.70     | ł   |
| GLOBULING ALPHA 2 | 6.5-11.5 (%)      | 25/01/92   | 12.90   |      | 12.70    | ,     | 13.00    | ۱,  |
|                   | 15-22 (%)         | 25/01/92   | 11.70   |      | 11.30    |       | 13.10    |     |
| GLOBULINS GAMMA   | 0.5-5 (UU/ML)     | 25/01/92   | 2.10    | ı •  |          | l`    |          | ١-  |
| TSH               |                   | 25/01/92   | 2.10    |      |          |       |          | 1   |
| T4                | 4.5-12.5          | 43/01/34   | 6.30    |      |          |       |          |     |
| 1                 | (UG/100ML)        |            | 0.30    | 1 1  |          | 1 1   |          | 1   |

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUT 6045 (1516 NO - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 329 Treatment: Reboxetine Sex: Female

|                                  |                   |            | Visit    | numb | per / La | borat        | cory date | e   |  |
|----------------------------------|-------------------|------------|----------|------|----------|--------------|-----------|-----|--|
|                                  |                   |            | Scree    | n    | Day 2    | В            | Day 5     | 16  |  |
|                                  |                   |            | 16/03/92 |      | 11/05/   | 92           | 25/05/92  |     |  |
|                                  |                   |            | value    | (¢)  | value    | (¢)          | value     | (¢) |  |
| Laboratory test                  | Range value       | Range date |          |      |          |              |           |     |  |
| НВ                               | 120-170 (G/L)     | 15/03/92   | 131.00   |      | 135.00   |              | 130.00    | 1   |  |
| HT ·                             | 0,36-0.51 (L/L)   | 15/03/92   | 0.39     | 1 1  | 0.38     | j l          | 0.39      |     |  |
| RBC                              | 3.9-5.5 (10-12/L) | 15/03/92   | 4.44     |      | 4.39     |              | 4.44      |     |  |
| MBC                              | 4-11 (10-9/L)     | 15/03/92   | 5.17     |      | 7.65     | 1            | 5.79      | l   |  |
| NBC: N                           | 45-75 (%)         | 15/03/92   | 72.50    |      | 73.30    | 1            | 64.50     | 1   |  |
| NBC: L                           | 17-55 (%)         | 15/03/92   | 19.50    |      | 18.20    |              | 25.40     | İ   |  |
| HBC: E                           | 0-5 (%)           | 15/03/92   | 0.90     |      | 1.20     | 1            | 1.20      | l   |  |
| HBC: H                           | 2-10 (%)          | 15/03/92   | 5.20     |      | 5.20     |              | 6.70      | l   |  |
| MBC: B                           | 0-2 (%)           | 15/03/92   | 0.20     |      | 0.40     |              | 0.50      | l   |  |
| PLATELETS                        | 150-400 (10¬9/L)  | 15/03/92   | 169.00   |      | 228.00   |              | 178.00    | 1   |  |
| NA+                              | 135-145 (MEQ/L)   | 15/03/92   | 140.00   | 1    | 142.00   |              | 138.00    |     |  |
| K+                               | 3.5-4.5 (MEQ/L)   | 15/03/92   | 4.00     |      | 4.40     |              | 4.20      | 1   |  |
| CL-                              | 95-106 (MEQ/L)    | 15/03/92   | 101.00   |      | 101.00   |              |           | ĺ   |  |
| Ca++                             | 8.5-10.5 (MG/DL)  | 15/03/92   | 8.40     | <    | 8.70     |              | 8.90      | 1   |  |
| P04                              | 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    | li   | 17.00    |              | 17.00     | ļ.  |  |
| 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     | 1 1  | 12.00    |              | 9.00      | ŀ   |  |
| 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    | 1   |  |
| GLUCOSE                          | 64-107 (MG/DL)    | 15/03/92   | 92.00    |      | 107.00   | 1            | 113.00    |     |  |
| BUN                              | 10-25 (MG/DL)     | 15/03/92   | 11.00    |      | 15.00    |              | 19.00     | 1   |  |
| CREATININE                       | 0.5-1.3 (MG/DL)   | 15/03/92   | 0.40     | <    | 0.80     |              | 0.80      | 1   |  |
| 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      | 1   |  |
| TOT. PROTEINS                    | 60-80 (G/L)       | 15/03/92   | 62.00    |      | 65.00    |              | 66.00     | ł   |  |
| ALBUMINE                         | 57-69 (%)         | 15/03/92   | 1        |      | 64.40    | 1 1          |           |     |  |
| WEDOWINE                         | 27-58 (G/L)       | 20/05/92   |          |      |          | 1            | 39.00     | l   |  |
| TOT, CHOLEST.                    | 148-247 (MG/DL)   | 15/03/92   | 178.00   |      | 165.00   |              | 173.00    | l   |  |
| TOT, CHOLEST.<br>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     | <b> &gt;</b> | 3.10      |     |  |
| GLOBULINS ALPHA 2                | 6-10 (%)          | 15/03/92   |          |      | 8.40     |              | 7.00      | 1   |  |
| GLUBULINS ALPHA 2 GLOBULINS BETA | 6.5-11.5 (%)      | 15/03/92   |          | 1    | 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     |      |          |              |           | ŀ   |  |
| 18H<br>T4                        | 4.5-12.5 (UG/DL)  | 15/03/92   | 10.30    |      |          |              |           | 1   |  |
| 14                               | 4.3-14.3 (UG/UL/  | 10, 00, 12 | 1 10.50  | 1 1  |          | l l          |           | 1   |  |

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTJESSO - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centro: 11 Patient: 330 Treatment: Reboxetine Sex: Male

|                   |                   |            |         |          | umber /<br>ory date |     |
|-------------------|-------------------|------------|---------|----------|---------------------|-----|
|                   |                   |            | Screen  | 1        | Day 2               | В   |
|                   |                   |            | 03/04/9 | 92       | 27/05/              | 92  |
|                   |                   |            | value   | (¢)      | value               | (¢) |
| Laboratory test   | Range value       | Range date |         |          | 400.00              | ļ . |
| HB                | 120-170 (G/L)     | 01/04/92   | 141.00  | i        | 132.00              | l   |
| HT                | 0.36-0.51 (L/L)   | 01/04/92   | 0.41    |          | 0.41                | l   |
| 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                | 1   |
| HBC: N            | 45-75 (%)         | 01/04/92   | 64.30   |          | 59.10               | l   |
| NBC: L            | 17-55 (%)         | 01/04/92   | 22.60   |          | 25.80               | 1   |
| WBC: E            | 0-5 (%)           | 01/04/92   | 3.40    |          | 5.10                | >   |
| WBC: M            | 2-10 (%)          | 01/04/92   | 6.60    |          | 6.90                | 1   |
| WBC: B            | 0-2 (%)           | 01/04/92   | 1.00    |          | 1.50                |     |
| PLATELETS         | 150-400 (10-9/L)  | 01/04/92   | 191.00  |          | 165.00              | 1   |
| NA+               | 135-145 (MEQ/L)   | 01/04/92   | 140.00  |          | 138.00              | 1   |
| K+                | 3.5-4.5 (MEQ/L)   | 01/04/92   | 3.90    |          | 4.30                | 1   |
| CL-               | 95-106 (MEQ/L)    | 01/04/92   | 98.00   |          | 99.00               | 1   |
| Ca++              | 8.5-10.5 (MG/DL)  | 01/04/92   | 8.80    |          | 8.80                |     |
| P04               | 2.3-4.3 (MG/DL)   | 01/04/92   | 3.60    |          | 3,30                | 1   |
| SGOT              | 10-40 (UI/L)      | 01/04/92   | 23.00   |          | 19.00               |     |
| SGPT              | 10-40 (UI/L)      | 01/04/92   | 19.00   |          | 17.00               | 1   |
| GAMMA GT          | 5-40 (UI/L)       | 01/04/92   | 17.00   |          | 12.00               | 1   |
| LDH               | 250-450 (UI/L)    | 01/04/92   | 317.00  |          | 285.00              | 1   |
| ALK. PHOSPH.      | 123-345 (UI/L)    | 01/04/92   | 157.00  |          | 157.00              | 1   |
| GLUCOSE           | 64-107 (MG/DL)    | 01/04/92   | 93.00   |          | 102.00              | 1   |
| BUN               | 10-25 (MG/DL)     | 01/04/92   | 17.00   |          | 18.00               | 1   |
| CREATININE        | 0.5-1.3 (MG/DL)   | 01/04/92   | 1.10    |          | 0.90                | 1   |
| URIC ACID         | 1.9-7.4 (MG/DL)   | 01/04/92   | 6.80    |          | 5.30                | 1   |
| TOT BILIRUBIN     | 0.1-1 (MG/DL)     | 01/04/92   | 1.60    | >        | 0.60                | 1   |
| TOT BILINUBIN     | 60-80 (G/L)       | 01/04/92   | 67.00   | -        | 67.00               | 1   |
|                   | 57-69 (%)         | 01/04/92   | 71.50   | <b>.</b> | 2,.55               | 1   |
| ALBUMINE          | 27-58 (G/L)       | 25/05/92   | /1.30   | _        | 40.00               |     |
| mam GUAL FOR      | 148-247 (MG/DL)   | 01/04/92   | 196.00  |          | 158.00              |     |
| TOT. CHOLEST.     | 50-150 (MG/DL)    | 01/04/92   | 56.00   |          | 99.00               |     |
| TRIGLYCERIDES     |                   | 01/04/92   | 2.30    |          | ,,,,,,,             | 1   |
| GLOBULINS ALPHA 1 | 2.1-3.5 (%)       | 01/04/92   | 6.20    |          |                     | 1   |
| GLOBULINS ALPHA 2 | 6-10 (%)          | 01/04/92   | 10.10   |          |                     |     |
| GLOBULINS BETA    | 6.5-11.5 (%)      |            | 9.90    | ا ررا    |                     |     |
| GLOBULINS GAMMA   | 15-22 (%)         | 01/04/92   |         | **       |                     | i   |
| TSH               | 0.5-5 (UU/ML)     | 01/04/92   | 2.00    |          |                     | 1   |
| T4                | 4.5-12.5 (UG/DL)  | 01/04/92   | 8.60    |          |                     | 1   |

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA 9585 64983

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

Centre: 11 Patient: 333 Treatment: Reboxetine

|                   |                               |            |        |     | umber /<br>ory date |     |
|-------------------|-------------------------------|------------|--------|-----|---------------------|-----|
|                   |                               |            | Scree  | п   | Day 2               | 8   |
|                   |                               |            | 17/07/ | 92  | 13/10/              | 92  |
|                   |                               |            | value  | (¢) | value               | (¢) |
| Laboratory test   | Range value                   | Range date |        |     | 400.00              |     |
| HB                | 120-170 (G/L)                 | 13/03/92   | 1      |     | 129.00              |     |
| at                | 0.36-0.51 (L/L)               | 13/03/92   |        |     | 0.40                |     |
| RBC               | 3.9-5.5 (10-12/L)             | 13/03/92   | 1      |     | 4.84                |     |
| KBC               | 4-11 (10-9/L)                 | 13/03/92   | 1      |     | 7.68                |     |
| IBC: N            | 45-75 (%)                     | 13/03/92   |        |     | 64.50               |     |
| WBC: L            | 17-55 (%)                     | 13/03/92   |        | 1   | 26.30               |     |
| NBC: E            | 0-5 (%)                       | 13/03/92   |        |     | 0.80                |     |
| HBC: M            | 2-10 (%)                      | 13/03/92   |        | 1 1 | 5.50                | 1   |
| HBC: B            | 0-2 (%)                       | 13/03/92   | 1      |     | 1.00                | 1   |
| PLATELETS         | 150-400 (10 <del>-</del> 9/L) | 13/03/92   |        |     | 188.00              | 1   |
| NA+               | 135-145 (MEQ/L)               | 13/03/92   | 144.00 |     | 141.00              | l   |
| K+                | 3.5-4.5 (MEQ/L)               | 13/03/92   | 4.00   |     | 4.00                | 1   |
| CL-               | 95-106 (MEQ/L)                | 13/03/92   |        | }   | 101.00              | l   |
| Ca++              | 8.5-10.5 (MG/DL)              | 13/03/92   | 9.30   |     | 9.40                |     |
| P04               | 2.3-4.3 (MG/DL)               | 13/03/92   | 3.00   |     | 3,30                | i   |
| SGOT              | 10-40 (UI/L)                  | 13/03/92   | 9.00   | <   | 16.00               |     |
| SGPT              | 10-40 (UI/L)                  | 13/03/92   | 16.00  | 1   | 14.00               |     |
| GANNA GT          | 5-40 (UI/L)                   | 13/03/92   | 14.00  | i I | 21.00               | 1   |
| LDH               | 250-450 (UI/L)                | 13/03/92   |        |     | 251.00              | 1   |
| 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               | 1   |
| BUN               | 10-25 (MG/DL)                 | 13/03/92   | 16.00  |     | 16.00               |     |
| UREA              | Ö                             | 13/03/92   |        |     |                     |     |
| CREATININE        | 0.5-1.3 (MG/DL)               | 13/03/92   | 0.90   | l i | 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                | l   |
| OIR BILIRUBIN     | O                             | 13/03/92   |        |     |                     |     |
| TOT. PROTEINS     | 60-80 (G/L)                   | 13/03/92   | 74.00  |     | 74.00               | l   |
| ALBUMINE          | 27-58 (G/L)                   | 13/03/92   | 45.00  |     | 45.00               | 1   |
| 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 |                               | 13/03/92   | 3,20   |     |                     | 1   |
| GLOBULINS ALPHA 2 | 6-10 (%)                      | 13/03/92   | 7.80   |     |                     | i   |
| GLOBULING 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   |     |                     | 1   |
| T4                | 4.5-12.5 (UG/DL)              | 13/03/92   | 9.30   |     |                     | 1   |
| 14                | 7,3-12.3 (00/06/              | 10- 406    | 1 2100 | 1   |                     | ı   |

<sup>(\$) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

### PHARMACIA PHARMACEUTICAL OTTENS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA Patient: 335 Treatment: Reboxetine

| Sex: | Fomale |
|------|--------|

|                   |                   |            |         |     | umber /<br>ory date |     |
|-------------------|-------------------|------------|---------|-----|---------------------|-----|
|                   | *                 |            | Screen  | 1   | Day 28              | 3   |
|                   |                   |            | 02/10/9 | 92  | 10/11/9             | 92  |
|                   |                   |            | value   | (¢) | value               | (¢  |
| Laboratory test   | Range value       | Range date | 128.00  |     | 126.00              |     |
| нв                | 120-170 (G/L)     | 13/03/92   |         |     | 0.37                |     |
| HT                | 0.36-0.51 (L/L)   | 13/03/92   | 0.39    |     | 4.36                | l   |
| RBC               | 3.9-5.5 (10-12/L) | 13/03/92   | 4.45    |     | 3.69                | ۔ ا |
| HBC               | 4-11 (10-9/L)     | 13/03/92   | 5.21    |     | 55.10               | `   |
| MBC: N            | 45-75 (%)         | 13/03/92   | 58.20   |     |                     | l   |
| MBC: L            | 17-55 (%)         | 13/03/92   | 29.90   | ١ . | 33.60               | l   |
| MBC; E            | 0-5 (%)           | 13/03/92   | 1.40    |     | 1,80                | l   |
| NBC: M            | 2-10 (%)          | 13/03/92   | 5.80    |     | 6.50                | ı   |
| WBC: B            | 0-2 (X)           | 13/03/92   | 1.00    | l   | 0.60                | l   |
| PLATELETS         | 150-400 (10→9/L)  | 13/03/92   | 321.00  | ŀ   | 253.00              |     |
| NA+               | 135-145 (MEQ/L)   | 13/03/92   | 138.00  | l   | 136.00              |     |
| K+                | 3.5-4,5 (MEQ/L)   | 13/03/92   | 4,00    |     | 3.50                |     |
| CL-               | 95-106 (NEQ/L)    | 13/03/92   | 99.00   | 1   | 105.00              |     |
| Ca++              | 8.5-10.5 (MG/DL)  | 13/03/92   | 9.60    |     | 9.40                |     |
| P04               | 2.3-4.3 (MG/DL)   | 13/03/92   | 3.30    | ŀ   | 2.90                |     |
| SCOT              | 10-40 (UI/L)      | 13/03/92   | 17.00   | 1   | 12.00               | ١.  |
| SGPT              | 10-40 (UI/L)      | 13/03/92   | 20.00   | 1   | 7.00                | ١^  |
| 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  | 1   | 125.00              | 1   |
| GLUCOSE           | 64-107 (MG/DL)    | 13/03/92   | 77.00   |     | 72.00               |     |
| BUN               | 10-25 (MG/DL)     | 13/03/92   | 15.00   |     | 11.00               | l   |
| CREATININE        | 0.5-1.3 (MG/DL)   | 13/03/92   | 0.60    |     | 0.50                | l   |
| URIC ACID         | 1.9-7.4 (MG/DL)   | 13/03/92   | 3.50    | 1   | 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   | 1   | 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                |     |
| GLOBULING ALPHA 2 | 6-10 (%)          | 13/03/92   | 8.60    |     | 7.20                |     |
| GLOBULINS BETA    | 6.5-11.5 (%)      | 13/03/92   | 10.00   |     | 8.90                |     |
| GLOBULING GAMMA   | 15-22 (%)         | 13/03/92   | 15.00   | 1   | 16.10               | 1   |
| TSH CAME          | 0.5-5 (UU/ML)     | 13/03/92   | 0.50    |     | 1                   |     |
| Ton               | 4.5-12.5 (UG/DL)  | 13/03/92   | 11.30   | 1   | 1                   |     |

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max rang out of range (value higher than max rang () missing range value

### PHARMACIA PHARMACEUTJESSONS - CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 12 Patient: 394 Treatment: Reboxetine Sex: Male

|                 |                    |            | Visit  | nuni | er / Lai | borat | tory date |     |
|-----------------|--------------------|------------|--------|------|----------|-------|-----------|-----|
|                 |                    |            | Scree  | n    | Day 2    | В     | Day 5     | 6   |
|                 |                    |            | 07/07/ | 92   | 03/08/   | 92    | 27/08/    | 92  |
|                 |                    |            | value  | (¢)  | value    | (¢)   | value     | (¢) |
| Laboratory test | Range value        | Range date |        |      |          |       |           |     |
| 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      |     |
| HBC             | 4-11 (10~9/L)      | 01/06/92   | 5.80   |      | 6.50     |       | 7.10      |     |
| MBC: N          | 2-8 (10-9/L)       | 01/06/92   | 3.40   | 1    | 3.60     |       | 4.00      |     |
| NBC: L          | 1-4 (10-9/L)       | 01/06/92   | 1.90   |      | 2.50     |       | 2.20      |     |
| MBC: E          | 0-0.6 (10-9/L)     | 01/06/92   | 0.10   |      | 0.20     |       | 0.40      |     |
| HBC: M          | 0-1 (10-9/L)       | 01/06/92   | 0.30   |      | 0.20     |       | 0.40      | 1   |
| NBC: 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      |     |
| PQ4             | 0.8-1.4 (MMOL/L)   | 01/06/92   | 1.10   |      | 1.20     | 1 1   | 1.10      |     |
| SGPT            | 0-40 (U/L)         | 01/06/92   | 25.00  |      | 34.00    |       | 32.00     | l   |
| 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   | 1 1   | 320.00    |     |
| ALK. PHOSPH.    | 30-120 (U/L)       | 01/06/92   | 69.00  |      | 70.00    |       | 74.00     |     |
| GLUCOSE         | 4-5.5 (MHOL/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) |            | 0.34   | [ ]  | 0.45     |       | 0.41      | ļ   |
| TOT BILIRUBIN   | 0-20 (UMOL/L)      | 01/06/92   | 12.00  |      | 11.00    |       | 10.00     | 1   |
| 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     | 1   |
| 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      | 1   |
| TSH             | 0.5-4 (MIU/L)      | 01/06/92   | 1.10   |      |          |       |           |     |
| T4              | 10-19 (PMOL/L)     | 01/06/92   | 17.60  |      |          | I 1   |           |     |

<sup>&</sup>gt;> clinically relevant (value higher than max range > out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTJEALOWILANO - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

### LABORATORY DATA Patient: 395 Treatment: Reboxetine

|                 |                    |             | Visit  | numi | er / La | borat | ory dat  | 8   |
|-----------------|--------------------|-------------|--------|------|---------|-------|----------|-----|
|                 |                    |             | Scree  | n    | Day 2   | 8     | Day 5    | 6   |
|                 |                    |             | 24/07/ | 92   | 20/08/  | 92    | 17/09/92 |     |
|                 |                    |             | value  | (4)  | value   | (¢)   | value    | (4) |
| Laboratory test | Range value        | Range date  |        |      |         |       |          |     |
| HB              | 13-18 (G/DL)       | 01/06/92    | 15.10  | ł    | 14.00   | 1 1   | 13.80    |     |
| HT              | 40-54 (%)          | 01/06/92    | 45.60  | 1    | 42.10   | } {   | 40.20    |     |
| RBC             | 4.5~6.5 (10~12/L)  | 01/06/92    | 5.23   |      | 4.88    | } }   | 4.66     | ł   |
| MBC             | 4-11 (10-9/L)      | 01/06/92    | 8.30   | 1    | 6.80    | 1 1   | 8.00     | l   |
| HBC: N          | 2-8 (10-9/L)       | 01/06/92    | 6.20   | łi   | 4.50    | 1 }   | 5.20     | }   |
| WBC: L          | 1-4 (10→9/L)       | 01/06/92    | 1.40   |      | 1.80    |       | 1.90     | 1   |
| NBC: 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     | Į   |
| WBC: B          | 0-0.2 (10-9/L)     | 01/06/92    | 0.00   | 1 1  | 0.00    | {     | 0.00     | }   |
| PLATELETS       | 150-450 (10-9/L)   | 01/06/92    | 355.00 | 1 1  | 329.00  | 1 1   | 328.00   | l   |
| NA+             | 136-146 (MMOL/L)   | 01/06/92    | 141.00 | il   | 139.00  | 1 1   | 142.00   | 1   |
| K+              | 3.5-5 (MMOL/L)     | 01/06/92    | 4.30   | 1 {  | 4.10    | 1 1   | 3.90     | }   |
| CL-             | 95-110 (MMOL/L)    | 01/06/92    | 101.00 | 1 1  | 102.00  | 1 1   | 102.00   | ł   |
| Ca++            | 2.15-2.65 (MMOL/L) | 01/06/92    | 2,36   | İ    |         | ! !   | 2.28     | 1   |
| P04             | 0.8-1.4 (MMOL/L)   | 01/06/92    | 1.20   | i    |         | 1 1   | 1.10     | ł   |
| SGPT            | 0-40 (U/L)         | 01/06/92    | 26.00  |      | 29.00   | 1 1   | 24.00    | ŀ   |
| GAMMA GT        | 0-45 (U/L)         | 01/06/92    | 25.00  |      | 18.00   | 1     | 19.00    |     |
| LDH             | 250-520 (U/L)      | 01/06/92    | 1      |      | 228.00  | <     | 237.00   | <   |
| ALK. PHOSPH.    | 30-120 (U/L)       | 01/06/92    | 76.00  |      | 65.00   | l i   | 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    | 1     | 5.20     |     |
| CREATININE      | 0.05-0.11 (MMOL/L) |             | 0.09   |      | 0.09    | 1 1   | 0.10     | 1   |
| URIC ACID       | 0.18-0.48 (MMOL/L) |             | 0.24   |      | 0.29    | 1     | 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    | 1   |
| ALBUNINE        | 35-50 (G/L)        | 01/06/92    | 43.00  | ĺĺ   | 40.00   | l     | 39.00    | 1   |
| TOT. CHOLEST.   | 3-5.5 (MNOL/L)     | 01/06/92    | 5.00   | İ    | 3.80    |       | 3.50     | l   |
| TRIGLYCERIDES   | 0.5-2 (MMOL/L)     | 01/06/92    | 1.00   | i    | 0.70    |       | 0.90     | l   |
| ikirikicekines  | 0.5-4 (MIU/L)      | 01/06/92    | 1.00   |      | 0.70    |       | 0.30     | l   |
| TSH<br>T4       | 10-19 (PMOL/L)     | 01/06/92    | 14.90  |      |         |       |          |     |
| 14              | IO- IS (FUOLIL)    | A 11 AA1 38 | 14.50  | ' 1  | 1       | 1     |          |     |

<sup>&</sup>lt;< clinically relevant (value lower than min range)
< cut of range (value lower than min range)
\*\* missing laboratory test value nd laboratory not done</pre>

<sup>&</sup>gt;> clinically relevant (value higher than max r> out of range (value higher than max r() missing range value

### PHARMACIA PHARMACEUTICAL MILANG - CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 387 Treatment: Roboxetine Sex: Female

					mber / ry date	
			Screen		Day 28	В
			15/04/9	2	01/06/9	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
НВ	12-16 (G/DL)	01/03/92	14.20	Į	12.90	ł
HT	37-47 (2)	01/03/92	42.00		39.00	
RBC	3.8-5.8 (10-12/L)	01/03/92	4.47		4.12	}
MBC	4-11 (10-9/L)	01/03/92	7.20		6.30	1
MBC: N	2-7.5 (10-9/L)	01/03/92	4.50		3.50	
MBC: L	1,3-3.6 (10-9/L)	01/03/92	2.10		1.70	1
MBC: E	0-0.7 (10→9/L)	01/03/92	0.10	- 1	0.50	1
HBC: M	0.2-0.8 (10¬9/L)	01/03/92	0.40		0.60	
MBC: 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	- 1	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	1
Ca++	2.1-2.5 (MMOL/L)	01/03/92			2.15	
 P04	0.7-1.4 (MMOL/L)	01/03/92			1.12	ı
SGOT	5-35 (U/L)	01/03/92	26.00	- 1	59.00	>
SGPT	7-56 (U/L)	01/03/92	16.00	- 1	24.00	i
GAMMA GT	8-78 (U/L)	01/03/92	24.00	- 1	19.00	
LDH	300-540 (U/L)	01/03/92		- 1	630.00	>
ALK. PHOSPH.	19-95 (U/L)	01/03/92	50.00	- 1	48.00	ĺ
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	l i	- 1	5.10	İ
UREA	2.5-7.5 (MMOL/L)	01/03/92			6.00	
CREATININE	60-110 (UMOL/L)	01/03/92	106,00	i	92.00	
URIC ACID	180-440 (UMOL/L)	01/03/92			269.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	11.00	i	12.00	l
TOT. PROTEINS	62-81 (G/L)	01/03/92	76.00		69.00	1
ALBUMINE	35-50 (G/L)	01/03/92	44.00		41.00	l
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92			5.43	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92		- 1	1.38	1
TSH	0.2-3.2 (MU/L)	01/03/92	0.50	- 1		1
T4	11-24 (PHOL/L)	01/03/92	13.30	1		l

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(c) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

>> clinically relevant (value higher than max range > out of range (value higher than max range () missing range value

#### PHARMACIA CND 18900083

#### REBOXETINE - PROTOCOL 20124/016 Listing No.; 18.0

LABORATORY DATA
Centre: 13 Patient: 388 Treatment: Reboxetine Sex:

. :			Visit	num	ber / La	bora	tory dat	0
			Scree	n	Day 2	8	Day 5	6
			15/03/	92	30/03/	92	11/05/	92
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						1
HB	14-18 (G/DL)	01/03/92					12.70	<
HT	41-53 (%)	01/03/92		i		l i	37.00	<
RBC	4.5-6.5 (10-12/L)	01/03/92				1 1	3.89	<
MBC	4-11 (10-9/L)	01/03/92				ļ	5.40	
MBC: N	2-7.5 (10~9/L)	01/03/92	1	Į į	ļ	1 1	2.80	]
WBC: L	1.3-3.6 (10-9/L)	01/03/92	l				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				1 1	0.50	
WBC: B	0-0.2 (10-9/L)	01/03/92	1			1 [	0.10	{
PLATELETS	150-400 (10-9/L)	01/03/92		1 1		l l	231.00	1
NA+	137-145 (MNOL/L)	01/03/92	141.00	l I	141.00		140.00	1
K+	3.5-5 (MMOL/L)	01/03/92	4,10		4.20		5,00	l
CL-	100-111 (MMOL/L)	01/03/92	101.00	1 1	102.00	1 1	106.00	ı
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.33	ll	2.26	1 1	2.29	
P04	0.7-1.4 (MMOL/L)	01/03/92	0.96	ll	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	ll	48.00	li	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	1
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	1	1 1	5.10	! }	5.30	1
BUN	()	01/03/92			5115			
UREA	2.5-7.5 (MNOL/L)	01/03/92	5.10		6.40		6.20	1
CREATININE	60-110 (UMOL/L)	01/03/92	92.00		108.00		86.00	i
URIC ACID	180-440 (UMOL/L)	01/03/92	447.00	5	388.00		295.00	
TOT BILIRUBIN	3-22 (UNOL/L)	01/03/92	18.00	- 1	8.00		10.00	
DIR BILIRUBIN	0-19 (UNOL/L)	01/03/92	.5.00		2.00			i
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	اددا		>	7.10	<b>a</b>
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	1.44		2.77		1.59	_
GLOBULINS ALPHA 1	()	01/03/92	1		4.77		,	
GLOBULINS ALPHA 2	ö	01/03/92						
GLOBULINS BETA	ö	01/03/92	1		1			
GLOBULINS GAMMA	ö	01/03/92						
TSH	0.2-3.2 (MU/L)	01/03/92	0.80		0.50		1.40	
160 T4	11-24 (PMOL/L)	01/03/92	14.00	'	23.60	ı	11.90	
.7	11 27 (1100/2)	01/03/74	14.00	į į	25.60			

<sup>&</sup>gt;> clinically relevant (value higher than max range)
> cut of range (value higher than max range)

<sup>()</sup> missing range value

### PHARMACIA PHARMACEUTICA 550083 CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 390 Treatment: Roboxetine Sex: Hale

			Visit	numk	er / Lai	ograt	ory date	
			Screen	1	Day 28		Day 5	6
			25/05/9	92	25/06/9	92	24/07/	92
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date						_
HB .	14-18 (G/DL)	01/03/92	14.30		13.80		13.90	١ ٩
HT	41-53 (%)	01/03/92	40.00		40.00		41.00	1
RBC	4.5-6.5 (10~12/L)	01/03/92	4.56		4.46		4.54	
MBC	4-11 (10-9/L)	01/03/92	5.90		6.40		5.30	
NBC: 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	i I	1.30	1
NBC: 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	1	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	l
NA+	137-145 (MMOL/L)	01/03/92	141.00		142.00	i i	141.00	
K+	3.5-5 (MMOL/L)	01/03/92	4.20		4.80	i	4.50	ļ
CL-	100-111 (MMOL/L)	01/03/92	102.00		104.00		102.00	
 Ca++	2.1-2.5 (NMOL/L)	01/03/92			2.32	l i	2.28	
P04	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	
GANNA 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	1
UREA	2.5-7.5 (MMOL/L)	01/03/92	4.70		4.40		5.80	1
CREATININE	60-110 (UNOL/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	1
ALBUMINE	35-50 (G/L)	01/03/92	44.00		49.00		46.00	t
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	1
T4	11-24 (PMOL/L)	01/03/92	14,30		13.50		14.60	1

<sup>(¢) &</sup>lt;< clinically relevant (value lower than min range) < out of range (value lower than min range) 
\*\* missing laboratory test value nd laboratory not

<sup>&</sup>gt;> clinically relevant (value higher than max range value higher than max range () missing range value

### PHARMACIA PHARMACEUTICAS

## REBOXETINE - PROTOCOL 20124/016 Listing No.; 18.0

LABORATORY DATA
Centre: 13 Patient: 392 Treatment: Reboxetine Sex: Female

					mber / ory date	
			Screen	en Day		4
			13/08/9	2	28/08/	92
			value	(4)	value	(¢)
Laboratory test	Range value	Range date				
НВ	12-16 (G/DL)	01/03/92	15.20		14.40	
HT	37-47 (%)	01/03/92	44.00		40.00	İ
RBC	3.8-5.8 (10-12/L)	01/03/92	5.22		4.89	1
MBC	4-11 (10-9/L)	01/03/92	7.10		6.70	1
MBC: N	2-7.5 (10-9/L)	01/03/92	3.55	- 1	3.60	
MBC: L	1.3-3.6 (10-9/L)	01/03/92	2.91		2.20	
NBC: E	0-0.7 (10-9/L)	01/03/92	0.21	i	0.20	
MBC: M	0.2-0.8 (10-9/L)	01/03/92	0.36		0.40	
MBC: 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	1	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	
P04	0.7-1.4 (MNOL/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	į	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	1

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory text value od laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range) out of range (value higher than max range) missing range value

### PHARMACIA PHARMACEUTICAS #1003- CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 501 Treatment: Reboxetine Sex: Male

			Visit	numb	oer / La	borat	ory date	e
			Scree	n	Day 2	В	Day 5	6
			29/10/	92	30/11/	92	30/12/	92
			value	(¢)	value	(4)	value	(¢)
Laboratory test	Range value	Range date						
HB	14-18 (G/DL)	01/03/92	16.50		16.50	1	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	l i	5.72	
NBC	4-11 (10-9/L)	01/03/92	7.80	1	10.30		9.40	
HBC: N	2-7.5 (10-9/L)	01/03/92	3.50		5.00		5.00	
HBC: L	1.3-3.6 (10-9/L)	01/03/92	3.40		4.10	>	3.20	l
NBC: E	0-0.7 (10~9/L)	01/03/92	0.30		0.30		0.30	1
HBC: N	0.2-0.8 (10-9/L)	01/03/92	0.50		0.90	>	0.80	
MBC: B	0-0.2 (10-9/L)	01/03/92	0.10	1 !	0.00	1	0.10	
PLATELETS	150-400 (10-9/L)	01/03/92	432.00	>	428.00	>	447.00	>
NA+	137-145 (HMOL/L)	01/03/92	138.00		138.00		140.00	İ
K+	3.5-5 (MMOL/L)	01/03/92	4.40	1 1	4.60	1	4.50	1
CL-	100-111 (MMOL/L)	01/03/92	99.00	<	100.00		104.00	l
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.37		2.32		2.39	l
P04	0.7-1.4 (MMOL/L)	01/03/92	1.10		1.08	}	1.46	
SCOT	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	1 1	35.00	l
GANNA GT	8-78 (U/L)	01/03/92	79.00	>	63.00	1 1	60.00	1
LDH	300-540 (U/L)	01/03/92	513.00	1 1	424.00		525.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92	79.00		70.00		71.00	1
GLUCOSE	3.6-5.8 (MNOL/L)	01/03/92	4.40	1	4.50	1 1	4.60	!
UREA	2,5-7,5 (MMOL/L)	01/03/92	5.30		5.10		6.90	1
CREATININE	60-110 (UNOL/L)	01/03/92	89.00		86.00		68.00	
URIC ACID	180-440 (UMOL/L)	01/03/92	284.00	1 1	279.00	ł	306.00	1
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	15.00	1	13.00	1	9.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	80.00	1 1	80.00		78.00	
ALBUMINE	35-50 (G/L)	01/03/92	49.00		48.00	l	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	1	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	1

<sup>(¢) &</sup>lt;< clinically relevant (value lower cut of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTICAL HOOS- CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

### LABORATORY DATA Centre: 13 Patient: 503 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date					
			Screen	1	Day	7		
			12/11/9	92	19/11/	92		
			value	(4)	value	(4)		
Laboratory test	Range value	Range date						
НB	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			
HBC	4-11 (10-9/L)	01/03/92	7.70		7.50			
NBC: 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	- 1	3.00			
WBC: E	0-0.7 (10-9/L)	01/03/92	0.20	- 1	0.20			
MBC: M	0.2-0.8 (10-9/L)	01/03/92	0.60	- }	0.70	l		
WBC: B	0-0.2 (10-9/L)	01/03/92	0.10	ì	0.20	ł		
PLATELETS	150-400 (10-9/L)	01/03/92	309.00	- 1	301.00	l		
NA+	137-145 (MMOL/L)	01/03/92	137.00	Ì	136.00	<		
K+	3.5-5 (MMOL/L)	01/03/92	4.60	i	4.50	i		
CL-	100-111 (MMOL/L)	01/03/92	101.00		100.00	ĺ		
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.29		2.20	(		
P04-~	0.7-1.4 (MMOL/L)	01/03/92	1.22	J	1.30			
SGOT	5-35 (U/L)	01/03/92	28.00	j	23.00	}		
SGPT	7-56 (U/L)	01/03/92	30.00	- 1	25.00			
GAMMA CT	8-78 (U/L)	01/03/92	15.00	- 1	14.00			
LDH	300-540 (U/L)	01/03/92	351.00	- 1	309.00			
ALK. PHOSPH.	19-95 (U/L)	01/03/92	48.00	į	41.00			
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	4.80	- 1	5.50			
UREA	2.5-7.5 (MMOL/L)	01/03/92	5.40	- 1	5.30			
CREATININE	60-110 (UMOL/L)	01/03/92	68.00	- 1	73.00	1		
URIC ACID	180-440 (UMOL/L)	01/03/92	144.00	<	151.00	<		
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	17.00	1	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	1	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	Į	0.89			
TSH	0.2-3.2 (MU/L)	01/03/92	1.20		1.30			
150 T4	11-24 (PMOL/L)	01/03/92	14.50	- 1	18.30			

<sup>(¢) &</sup>lt;< clinically relevant (value lower than min range)
 < out of range (value lower than min range)
 \*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max r> out of range (value higher than max ra
() missing range value

### РНАВМАСІА РНАВМАСЕЦТІСФІБ МІНОМОЗ- CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 505 Treatment: Reboxetine Sex: Female

			Visit	numl	or / Lai	borat	ory dat	8
			Screen	72	Day 2	В	Day 5	6
			31/08/	92	28/09/	92	22/10/	92
			value	(¢)	value	(¢)	value	(0)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/03/92	14.20	1 1	14.10	]	14.20	
HT	37-47 (%)	01/03/92	41.00		42.00	1	41.00	l
RBC	3.8-5.8 (10-12/L)	01/03/92	4.47	1 1	4.45	i I	4.36	l
MBC	4-11 (10 <b>-9/L</b> )	01/03/92	8.10		7.70		6.20	
MBC: N	2-7.5 (10-9/L)	01/03/92	5.10	1 1	4.90	i I	3.50	l
MBC: L	1.3-3.6 (10-9/L)	01/03/92	1.80	1	2.00		1.80	l
WBC: E	0-0.7 (10~9/L)	01/03/92	0.30		0.20		0.30	l
NBC: N	0.2-0.8 (10¬9/L)	01/03/92	0.90	>	0.40	[ ]	0.60	l
NBC: B	0-0.2 (10~9/L)	01/03/92	0.00	1	0.20	1 1	0.00	l
PLATELETS	150-400 (10-9/L)	01/03/92	229.00		273.00		252.00	l
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	1 1	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	l
P04	0.7-1.4 (MMOL/L)	01/03/92	0.90	]	1.19		0.95	l
SGOT	5-35 (U/L)	01/03/92	21.00		31.00		23.00	i
SGPT	7-56 (U/L)	01/03/92	13.00		10.00		22.00	i
GAMMA GT	8-78 (U/L)	01/03/92	19.00		19.00		12.00	1
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	l
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 (UNOL/L)	01/03/92	99.00	-	140.00	<	155.00	<
	3-22 (UMOL/L)	01/03/92	6.00	`	7.00	_	10.00	
TOT BILIRUBIN TOT. PROTEINS	62-81 (G/L)	01/03/92	69.00		72.00		70.00	
	35-50 (G/L)	01/03/92	40.00		42.00		42.00	
ALBUMINE	3.5-5.5 (MMOL/L)	01/03/92	4.93		5.10		4,70	i
TOT. CHOLEST.		01/03/92	0.76		1.33		0.76	İ
TRIGLYCERIDES	0.4-1.75 (MMOL/L) 0.2-3.2 (MU/L)	01/03/92	0.90		0.90		0.90	
TSH		01/03/92	12.50		12.30		13.50	
T4	11-24 (PMOL/L)	0 1/ 03/ 72	12.50		12.30		.5.50	İ

<sup>(¢) &</sup>lt;< clinically relevant (value lower cut of range (value lower than min range) than min range)

\*\* missing laboratory tost value cut of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICO15 515 61893 - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 508 Treatment: Reboxetine Sex: Female

			Visit	numk	er / Lai	borat	tory date	•
			Scree	n	Day 2	В	Day 5	6
			29/10/	92	30/11/	92	31/12/9	92
		,	value	(4)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
KB	12-16 (G/DL)	01/03/92	12.70		13.70		13.20	
HT	37-47 (%)	01/03/92	38.00	1 1	42.00		40.00	
RBC	3.8-5.8 (10-12/L)	01/03/92	4.41		4.77	1 1	4.62	ĺ
KBC	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	l I	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	
NBC: N	0,2-0.8 (10-9/L)	01/03/92	0.50		0.60		0.50	l
WRC: 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	1
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	l
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.22		2.24		2.19	l
P04	0.7-1.4 (MMOL/L)	01/03/92	1.36		1.34		1.15	l
SCOT	5-35 (U/L)	01/03/92	14.00		39.00	>	23.00	l
SGPT	7-56 (U/L)	01/03/92	32.00		14.00		13.00	l
GAMMA GT	8-78 (U/L)	01/03/92	10.00		12.00		12.00	l
LDH	300-540 (U/L)	01/03/92	548.00	>	545.00	>	496.00	l
ALK. PHOSPH.	19-95 (U/L)	01/03/92	67.00		77.00		71.00	1
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	5.40		4.70		4.20	1
UREA	2.5-7.5 (MMOL/L)	01/03/92	4.70		4.70		4.40	1
CREATININE	60-110 (UMOL/L)	01/03/92	72.00		74,00	1 1	63.00	1
URIC ACID	180-440 (UMOL/L)	01/03/92	206.00		226.00		212.00	1
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	6,00		8.00		8.00	1
TOT. PROTEINS	62-81 (G/L)	01/03/92	70.00		74.00		73,00	1
ALBUMINE	35-50 (G/L)	01/03/92	41.00		42.00		39.00	ĺ
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	4.53		4.64		4.79	l
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	0.83		0.86		0.57	l
TSH	0.2-3.2 (NU/L)	01/03/92	0.40		0.70		0.70	1
T4	11-24 (PMOL/L)	01/03/92	15.60	i	14.80		14.80	1

<sup>(</sup>c) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICONS 573-67893- CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 521 Treatment: Reboxetine

			Visit	numb	er / Lai	orat	ory date	•
			Screen	1	Day 2	3	Day 5	6
			30/11/9	2	30/12/	92	27/01/	93
			value	(0)	value	(¢)	value	(¢
Laboratory test	Range value	Range date						
нв	14-18 (G/DL)	01/03/92	15.10	l	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	
HBC	4-11 (10-9/L)	01/03/92	5.00		5.20		4.10	
MBC: 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	
MBC: E	0-0.7 (10-9/L)	01/03/92	0.00		0.20		0.20	
MBC: M	0.2-0.8 (10-9/L)	01/03/92	0.55		0.60		0.60	
MBC: 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	l i	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	
P04	0.7-1.4 (MMOL/L)	01/03/92			1.00	l l	1.20	
SCOT	5-35 (U/L)	01/03/92			37,00	>	36.00	
SCPT	7-56 (U/L)	01/03/92			37.00		66.00	
GAMMA GT	8-78 (U/L)	01/03/92			71.00		77.00	i
LDH	300-540 (U/L)	01/03/92	i i		428.00		477.00	
ALK. PHOSPH.	19-95 (U/L)	01/03/92			65.00	1	66.00	į .
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	i		7.40	ا جا	5.80	Į
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	i
URIC ACID	180-440 (UMOL/L)	01/03/92			343.00		337.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92			11.00	1 1	13.00	1
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	>>
TRIGLYCERIDES	0.4-1.75 (MU/L)	01/03/92			0.70		0.70	
T4	11-24 (PMOL/L)	01/03/92			14.30	1 1	14.70	1

<sup>&</sup>lt;< clinically relevant (value lower than min range)</p>
< out of range (value lower than min range)</p>
\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 398 Treatment: Reboxetine

	· ·		Visit	numk	er / Lai	borat	ory date	9
			Scree	n '	Day 2	В	Day 5	6
			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	l
RBC	3.9-5.6 (10-12/L)	01/02/92	5.04		4.81		4.76	1
WBC	3.5-12 (10-9/L)	01/02/92	11.00		7.60	1	9.50	
WBC: N	2,5-8 (10-9/L)	01/02/92	8.60	>		II	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	>
MBC: M	0,1-1,1 (10-9/L)	01/02/92	0.60	ll		l	0.50	
WBC: B	0-0.1 (10-9/L)	01/02/92	0.00	ll			0.00	
PLATELETS	150~400 (10~9/L)	01/02/92	219.00	li	253.00	l t	213.00	
NA+	135-145 (MMOL/L)	01/02/92	139.00		139.00	l	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	
P04	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	
GANNA 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	l i	62.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	4.40		4.90		5.30	
UREA	2.5-7.5 (MNOL/L)	01/02/92	3.80	1	4.10	l i	3.40	
CREATININE	0.04-0.12 (MMOL/L)		0.06		0.07		0.06	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.21	i	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	l	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				,,	
13n T4	86-148 (NNOL/L)	01/02/92	52.00			1		

<sup>(¢) &</sup>lt;< clinically relevant (value lower than min range) < out of range (value lower than min range) \*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICONS STICKES - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 399 Treatment: Reboxetine Sex: Female

			11111	LI CHILL			ory date	•
			Scree	1	Day 2	В	Day 5	s
			13/04/	92	19/05/	92	16/06/9	92
			value	(4)	value	(¢)	value	(¢:
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/02/92	13.70		13.40		13.80	1
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	l I	4.70	
HBC	3.5-12 (10-9/L)	01/02/92	6.90		6.30	!	7.00	ı
HBC: N	2.5-8 (10¬9/L)	01/02/92	4.50		4.00		5.00	
HBC: L	1.2-4 (10¬9/L)	01/02/92	1.90		2.00	t I	1.70	
HBC: E	0-0.5 (10 <del>-9</del> /L)	01/02/92	0.00		0.00	1	0.00	
MBC: M	0.1-1.1 (10∽9/%)	01/02/92	0.40	1	0.30		0.40	
MBC: B	0-0.1 (10¬9/L)	01/02/92	0.00		0.00		0.00	
PLATELETS	150-400 (10 <b>-</b> 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 (HMOL/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	
P04	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	
KOJ	70-170 (U/L)	01/02/92	168.00	1	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)		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 (UNOL/L)	01/02/92	8.00		8.00		8.00	
DIR BILIRUBIN	0-5 (UNOL/L)	01/02/92	3.00		2.00	i I	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	l	1.40	Ì
iriglicerides	0.5-6.5 (MIU/L)	01/02/92	0.79					
15H F4	86-148 (NMOL/L)	01/02/92	56.00	~				

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTIONS # # 6493- CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Contro: 14 Patient: 402 Treatment: Reboxetine Sex: Female

			Visit	numb	er / Lai	borat	ory date	•
			Screen	n	Day 2	В	Day 5	6
			22/05/	92	24/06/	92	22/07/	92
			value	(4)	value	(¢)	value	(¢
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/02/92	14.00	l i	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	
HBC	3.5-12 (10-9/L)	01/02/92	9.30		11.10		8.40	
MBC: N	2.5-8 (10-9/L)	01/02/92	6.90		7.20		5.20	
MBC: L	1.2-4 (10-9/L)	01/02/92	2.00		3.00		2.60	
MBC: E	0-0.5 (10-9/L)	01/02/92	0.00		0.00		0.00	
HBC: M	0.1-1.1 (10~9/L)	01/02/92	0.40	! I	0.90		0.50	
HBC: 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	1 1	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	
P04	0.6-1.3 (MMOL/L)	01/02/92	1.18		1.34	>	1.22	
SCOT	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	1
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	1		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	1
ALBUMINE	36-49 (G/L)	01/02/92	50.00	>	47.00		42.00	i
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	7.90		8.00		7,60	l
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.70	[	2.50	<<	1.80	>
TSH	0.5-6.5 (NIU/L)	01/02/92	1.17					ı
T4	86-148 (NNOL/L)	01/02/92	116.00					l

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range cut of range (value higher than max range cut) missing range value

### PHARMACIA PHARMACEUTICAL BHOND3- CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 403 Treatment: Reboxetine

	- 40		Visit	numk	er / Lal	borat	ory date	0
			Scree	n	Day 2	В	Day 5	6
			28/05/	92	26/06/	92	24/07/9	92
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/02/92	13.30	1 1	12.60	1 1	12.70	1
HT	0.35-0.47 (L/L)	01/02/92	0.40		0.37	1 1	0.38	1
RBC	3.9-5.6 (10-12/L)	01/02/92	4.55		4.27	1	4.34	1
HBC	3.5-12 (10¬9/L)	01/02/92	7.20	1 1	8.20		7.30	1
MBC: N	2.5-8 (10-9/L)	01/02/92	5.50	1	5.90		5.00	1
NBC: L	1,2-4 (10¬9/L)	01/02/92	1.60		2.10		2,20	1
NBC: E	0-0.5 (10-9/L)	01/02/92	0.00	l 1	0.00		0.00	1
HBC: N	0.1-1.1 (10 <del>-9</del> /L)	01/02/92	0.10		0.20		0.10	1
HBC: B	0-0.1 (10~9/L)	01/02/92	0.00		0.00		0.00	1
PLATELETS	150-400 (10~9/L)	01/02/92	257.00	1 1	241.00	i 1	244.00	
NA+	135-145 (MMOL/L)	01/02/92	140.00		139.00		137.00	1
K+	3.5-4.5 (MMOL/L)	01/02/92	3.50		3.60	1 1	3.90	1
CL-	95-105 (MMOL/L)	01/02/92	102.00		101.00	i 1	102.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.37		2.24	<	2.22	<
P04	0.6-1.3 (MMOL/L)	01/02/92	0,91	1 1	1.28		1.22	ļ
SGOT	0-35 (U/L)	01/02/92	13.00		14.00	ll	12.00	1
GAMMA GT	5-23 (U/L)	01/02/92	20.00		19.00		22.00	١.
LDH	70-170 (U/L)	01/02/92	160.00	1 1	146.00	1 1	143.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	48.00	1 1	63.00	f l	56.00	ļ
GLUCOSE	3.3-6.7 (MNOL/L)	01/02/92	3.60	1 1	4.80	ł I	4.60	l
UREA	2.5-7.5 (HNOL/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	l
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.23		0.22	i I	0.19	1
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	10.00	1	8.00		8.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	2.00	1	2.00	i I	2.00	1
TOT. PROTEINS	68-83 (G/L)	01/02/92	79.00	1 1	72.00	l I	73.00	1
ALBUMINE	36-49 (G/L)	01/02/92	50.00	>	46,00		43.00	1
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	5.50	1 1	4.70		4.90	1
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.10		1.30	il	1.20	1
TSH	0.5-6.5 (MIU/L)	01/02/92	0.83					ı
T4	86-148 (NMOL/L)	01/02/92	108.00	1 1		i I		l

989

>> clinically relevant (value higher than max range > out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTICAS HTHONG3- CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 407 Treatment: Reboxetine Sex: Male

			Visit	numb	er / Lai	orat	tory dat	e
			Screen	1	Day 28	3	Day 4	2
			13/07/9	92	10/08/9	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	l
MBC	3.5-10 (10-9/L)	01/02/92 .	9.60		7.90		9.40	l
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	l
MBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.20		0.30		0.30	l
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	ł
NA+	135-145 (MMOL/L)	01/02/92	140.00		137.00		144.00	
K+	3.5-4.5 (MNOL/L)	01/02/92	4.30				4.30	1
CL-	95-105 (MMOL/L)	01/02/92	101.00		100.00		100.00	ł
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.26		2.20	<	2,30	
P04	0.6-1.3 (MMOL/L)	01/02/92	1.18		1.15		0.88	
SCOT	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 (MNOL/L)	01/02/92	8.10	>	5.70	1	4.60	
CREATININE	0.04-0.12 (MMOL/L)		0.07	_	0.06		0.07	İ
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	l
DIR BILIRUBIN	0-1/ (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	1
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			1
TOT, CHOLEST.	0.1-1.7 (MMOL/L)	01/02/92	2.00	<b> </b>	1.50			1
TRIGLYCERIDES TSH	0.1-1.7 (MMUL/L) 0.5-6.5 (MIU/L)	01/02/92	1.71	-	50			1
	86-148 (NMOL/L)	01/02/92	113.00					l
T4	00-140 (MMOD) D)	V 1. VA. PA						1

990

>> clinically relevant (value higher than max range to out of range (value higher than max range to missing range value)

### PHARMACIA PHARMACEUTICAS 55603- CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA Patient: 408 Treatment: Reboxetine Sex: Female

					imber / ory date	
			Screen	1	Day 5	6
			04/08/9	92	30/09/	92
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
нв	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	
NBC	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	
NBC: L	1.2-4 (10~9/L)	01/02/92	3.20		1.98	
NBC: E	0-0.5 (10~9/L)	01/02/92	0.10		0.12	
MBC: M	0.1-1.1 (10-9/L)	01/02/92	0.60		0.36	
NBC: 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	1
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.26		2.24	<
P04	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	
GANNA 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	1
GLUCOSE	3,3-6,7 (MMOL/L)	01/02/92	4,70		6.00	l
UREA	2.5-7.5 (MMOL/L)	01/02/92	5.00		5.30	1
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	l
TOT. PROTEINS	68-83 (G/L)	01/02/92	74.00		77.00	l
ALBUMINE	36-49 (G/L)	01/02/92	43.00		43.00	1
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92			5.70	l
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92			1.70	l
TSH	0.5-6.5 (MIU/L)	01/02/92	1.04			l
T4	86-148 (NMOL/L)	01/02/92	102.00			l

991

(0) << clinically relevant (value lower than min range)
< out of range (value lower than min range)
than min range)
than min range)
missing laboratory test value nd laboratory not done

>> clinically relevant (value higher than max range > out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTIGAS STATEMS - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 511 Treatment: Reboxetine Sex: Female

			Visit	numb	er / Lai	orai	ory date	8
			Screen	n	Day 2	3	Day 49	9
			22/10/9	92	20/11/9	92	11/12/9	92
			value	(¢)	value	(0)	value	(¢)
Laboratory test	Range value	Range date						
нв	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	1	0.39		0.38	
RBC	3.9-5.6 (10-12/L)	01/02/92	4.60		4.60		4.37	l
MBC	3.5-12 (10-9/L)	01/02/92	6.39		8.15		6.67	l
MBC: N	2.5-8 (10-9/L)	01/02/92	4.05		5.04		3.93	l
MBC: L	1.2-4 (10-9/L)	01/02/92	1.78		2.65		2.25	
MBC: E	0-0,5 (10-9/L)	01/02/92	0.07		0.04		0.06	
MBC: M	0.1-1.1 (10¬9/L)	01/02/92	0.24		0.39		0.39	
MBC: 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	1 1	102.00	
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.38		2.27		2.30	1
P04	0.6-1.3 (MMOL/L)	01/02/92	0.90		1.12		1.25	l
SCOT	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	ł
LDH	70-170 (U/L)	01/02/92	174.00	>	146.00		127.00	1
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	1
UREA	2.5-7.5 (MMOL/L)	01/02/92	5.70		4.70	li	5.80	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.07		0.10		0.06	ĺ
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.21		0.21	li	0.17	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	7.00		11.00	1 1	8.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	2.00		2.00		3.00	i
TOT. PROTEINS	68-83 (G/L)	01/02/92	71.00		68.00		69.00	1
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 (HNOL/L)	01/02/92	1.40		0.70		0.90	l
TSH	0.5-6.5 (MIU/L)	01/02/92	1.35					1
10a T4	86-148 (NMOL/L)	01/02/92	110.00	l l		1 1		l

<sup>(0) &</sup>lt;< clinically relevant (value lower than min range) < out of range (value lower than min range) \*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTICAS #14403 - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 512 Treatment: Reboxotine Sex: Female

			Visit number Laborate date	/
			Screen	n
			02/11/9	92
			value	(4)
Laboratory test	Range value	Range date		
нв	11.5-16.5 (G/DL)	01/02/92	13.20	l
HT	0.35-0.47 (L/L)	01/02/92	0.40	l
RBC	3.9-5.6 (10-12/L)	01/02/92	4.40	l
MBC	3.5-12 (10-9/L)	01/02/92	7.04	
WBC: N	2.5-8 (10-9/L)	01/02/92	3.63	
MBC: L	1.2-4 (10-9/L)	01/02/92	2.64	
NBC: E	0-0.5 (10¬9/ಒ)	01/02/92	0.18	
WBC: M	0.1-1.1 (10~9/L)	01/02/92	0.51	
NBC: B	0-0.1 (10-9/L)	01/02/92	0.08	i
PLATELETS	150-400 (10-9/L)	01/02/92	232.00	l
NA+	135-145 (MMQL/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	
P04	0.6-1.3 (MMOL/L)	01/02/92	1.06	
SCOT	0-35 (U/L)	01/02/92	20.00	1
GAMMA GT	5-23 (U/L)	01/02/92	25.00	>
LDH	70-170 (U/L)	01/02/92	166.00	1
ALK. PHOSPH.	18-70 (U/L)	01/02/92	68.00	ł
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	3.70	
UREA	2.5-7.5 (MMOL/L)	01/02/92	5.80	1
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.06	1
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.23	
TOT BILIRUBIN	0-17 (UNOL/L)	01/02/92	14.00	ł
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	4.00	1
TOT. PROTEINS	68-83 (G/L)	01/02/92	68.00	
ALBUNINE	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	l
T4	86-148 (NMOL/L)	01/02/92	119.00	l

993

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range) with missing laboratory test value of laboratory not done

>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTICAL HHOW3- CMS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA Centre: 14 Patient: 537 Treatment: Reboxetine Sex: Fema

			Visit	numi	er / La	borat	ory date	0
			Scree	n	Day 2	В	Day 5	6
			29/10/	92	02/12/	92	04/01/9	93
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date						
нв	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	i I	0.43	l
RBC	3.9-5.6 (10~12/L)	01/02/92	4.61		4.39	l	4.86	
MBC	3.5-12 (10-9/L)	01/02/92	6.13		5.58		6.69	
HBC: N	2.5-8 (10-9/L)	01/02/92	3.58		3.06		3.73	1
NBC: L	1.2-4 (10~9/L)	01/02/92	1.95		2.10	1 1	2.32	
NBC: E	0-0.5 (10→9/L)	01/02/92	0.17		0.08		0.05	
MBC: M	0.1-1.1 (10-9/L)	01/02/92	0.39		0.00	<	0.51	
MBC: 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	li	274.00	
NA+	135-145 (MMOL/L)	01/02/92	142.00		143.00	1 1	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	
P04	0.6-1.3 (MMOL/L)	01/02/92	1.48	>	1.20		1.34	>
SCOT	D-35 (U/L)	01/02/92	23.00		17.00		18.00	
GANNA 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	l i	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	1 1	3.00	ì
TOT. PROTEINS	68-83 (G/L)	01/02/92	72.00		71.00	1 1	71.00	
ALBUNINE	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	1
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					l
T4	86-148 (NMOL/L)	01/02/92	84.00	- 1				1

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTICAL MINOS - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA Patient: 409 Treatment: Reboxetine Sex: Male

			Visit	num	ber / La	bora	tory date	
			Scree	n.	Day 2	8	Day 5	6
			24/03/	92	05/05/	92	02/06/9	92
			value	(¢)	value	(4)	value	(¢
Laboratory test	Range value	Range date						
нв	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	01/03/92				l	1	l
	(/MM3)		5790000	>	5910000	>	5700000	>
NBC	5000-9000 (/MM3)	01/03/92	12300.0	>>	11700.0	>	11100.0	>
NBC: N	50-65 (%)	01/03/92	63.00		63.00		66.00	>
WBC: L	30-40 (%)	01/03/92	31.00		31.00	l	31.00	1
MBC: E	0-3 (%)	01/03/92	2.00		2.00		1.00	1
WBC: M	0-5 (%)	01/03/92	4.00		4.00		2.00	
WBC: B	0-1 (%)	01/03/92	0.00		0.00	1	0.00	
PLATELETS	150000-300000	01/03/92	1					
DAIDDELD	(/MM3)	• • • • • • • • • • • • • • • • • • • •	210000		478000	>>	414000	>>
NA+	130-150 (MEQ/L)	01/03/92	144.00	1	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	ľ	103.00	
Ca++	8.1-10.4 (MG/DL)	01/03/92	8.80		9.20		8.50	
Ca++ P04	2.5-5 (MG/DL)	01/03/92	3.20		4.20		5.00	
PU4 SGOT	0-12 (MU/ML)	01/03/92	11.00		7.00		11.00	
		01/03/92	23.00		13.00	l、	15.00	l.
SGPT	0-12 (MU/ML)		18.00	_	15.00	-	19.00	-
GANNA GT	6-28 (UI/L)	01/03/92	165.00		165.00		165.00	
LDH	120-240 (UI/L)	01/03/92	77.00		68.00		67.00	Ĺ
ALK. PHOSPH.	20-48 (MU/NL)	01/03/92		_	107.00		93.00	1-
GLUCOSE	70-110 (MG/DL)	01/03/92	95.00 35.00		40.00		33.00	1
UREA	15-40 (NG/DL)	01/03/92				1		i
CREATININE	0.5-1.4 (MG/DL)	01/03/92	0.90		1.17		1.02	1
URIC ACID	3.4-7 (MG/DL)	01/03/92	2.89	٠	4.91		0.70	l
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			l
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	6.70		7.20		6.50	l
ALBUMINE	3,8-5 (G/DL)	01/03/92	3,48		3.74		3.93	l.
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	l
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.87	>	0.92	>	0.65	İ
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.87		0.99		0.80	l
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.21		1.28		0.95	1
TSH	0-5 (UUI/ML)	01/03/92	0.60					1
T4	4.5-13 (UG/DL)	01/03/92	10.00		i	1	1	1

<sup>(6) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) to with the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the co

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTIGAL STEAMS - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Contro: 15 Patient: 411 Treatment: Reboxetine Sex: Female

			Visit	numi	ber / La	borat	tory date	•
			Screen	1	Day 2	В	Day 5	5
			21/04/9	2	19/05/	92	16/06/9	92
			value	(¢)	value	(¢)	value	(0
Laboratory test	Range value	Range date	44.00		14.30		13.80	
HB	12-15 (G/DL)	20/04/92	14.00		44.00		42.00	
HT	38-43 (%)	20/04/92	43.00		44.00	_	42.00	
RBC	4200000-4800000 (/MM3)	20/04/92	4800000		4900000	>	4520000	
MBC	4500-10000 (/MM3)	20/04/92	5100.00		6100.00		5400.00	ŀ
MBC: 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	<
NBC; E	0-3 (%)	20/04/92	2.00		2.00	1	1.00	
WBC: H	0-5 (%)	20/04/92	5.00		2.00			
	0-6 (%)	15/06/92				1	7.00	>
WBC: B	0-1 (%)	20/04/92	0.00		0.00		0.00	
PLATELETS	150000-300000	20/04/92			1	1		
<del></del>	(/MM3)		126000	<	290000		210000	
NA+	130-150 (MEQ/L)	20/04/92	141.00		141.00		į	
	136-146 (MEQ/L)	15/06/92			1		139.00	
K+	3-5 (MEQ/L)	20/04/92	4.00		3.90			
n.	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			
Carr	9-11 (MG/DL)	15/06/92					9.80	
P04	2.5-4.5 (MG/DL)	20/04/92	2.91		3.10	1 1		
Pu4	3-4 (MG/DL)	15/06/92	2.,,		1		2.70	<
SGOT	0-12 (U/L)	20/04/92	7.00		12.00			
2601	2-30 (U/L)	15/06/92	,				25.00	
SGPT	0-12 (U/L)	20/04/92	5.00		10.00			
SUP I	2-30 (U/L)	15/06/92	1 2.00	l			29.00	
CLUMA CE	4-18 (U/L)	20/04/92	13.00		16.00		16.00	
GAMMA GT	120-240 (U/L)	20/04/92	134.00		210.00		,,,,,,	
LDH	130-300 (U/L)	15/06/92	134.00		2.0.00		202.00	
01100011	20-48 (U/L)	20/04/92	23.00		36.00			
ALK. PHOSPH.		15/06/92	20.00				101.00	
	45-170 (U/L)		96.00		70.00	li		
GLUCOSE	60-110 (G/DL)	20/04/92 15/06/92	70.00		70.00		95.00	
	70-110 (MG/DL)		37.00		49.00	l	,,,,,,	
UREA	15-35 (MG/DL)	20/04/92	37.00	_	49.00		26.00	
	10-50 (MG/DL)	15/06/92	1.07	<	1.38	ا را	20.00	
CREATININE	8-14 (MG/DL)	20/04/92	1.07	`	1.30		0.70	
	0.1-1.5 (MG/DL)	15/06/92	3.40		2.90		0.75	
URIC ACID	1.5-5 (NG/DL)	20/04/92	3.40		2.90		4,20	
	2.5-6 (MG/DL)	15/06/92			0.66		0.55	
TOT BILIRUBIN	0.2-1 (MG/DL)	20/04/92	0.66		0.18	1	ψ.35	ļ
DIR BILIRUBIN	0-0.2 (MG/DL)	20/04/92	0.15	}	0.10	1	0.00	
	0-0.15 (MG/DL)	15/06/92			7.50		7.00	l
TOT, PROTEINS	6.2-8 (G/DL)	20/04/92	7.00	1	7.50		4.80	l
ALBUMINE	3.8-5 (G/DL)	20/04/92	4.07		4.10	L	4.80	
TOT, CHOLEST.	50-250 (MG/DL)	20/04/92	258.00	>	261.00	>		
	150-250 (NG/DL)	15/06/92				1	240.00	
TRIGLYCERIDES	50-160 (MG/DL)	20/04/92	98.00	1	114.00	1		
	35-150 (MG/DL)	15/06/92		1		1	106.00	l
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	20/04/92	0.24	l	0.28	I	0.19	١.
GLOBULINS ALPHA 2	0,45-0.75 (G/DL)	20/04/92	0.62	l	0.73	1	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	l
TSH	0-5 (UUI/ML)	20/04/92	2.70	1		1		
T4	4.6-12.2 (UG/DL)	20/04/92	7.50	1	I	I	!	ı

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range) (value lower missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTIONS STORMS - CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 413 Treatment: Rebuxetine Sex: Female

			Visit	numi	ber / Lai	borat	tory date	9
			Scree	n	Day 2	3	Day 5	6
			22/04/9	92	27/05/9	92	24/06/9	92
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date 20/04/92	12.40		10.80			
HB	12-16 (G/DL) 12.5-15 (GR%)	20/04/92	12.40	Ì	10.00	`	13.20	
HT	37-47 (%)	20/04/92	39.30		33.50	<		
***	38-43 (2)	20/06/92					40.00	ĺ
RBC	4200000-5200000 (/NM3)	20/04/92	4210000		3530000	<<		
	4000000-4500000	20/06/92					4350000	
	(/MM3)	20/04/92	5400.00		4800.00		4350000	
WBC	4800-10800 (/MM3) 5000-9000 (/MM3)	20/06/92	3400.00		7500.00		5100.00	
WBC: N	60-70 (%)	20/04/92	62.00		61.00			
NDC: II	50-65 (%)	20/06/92					62.00	
MBC: L	20-35 (%)	20/04/92	34.00	1	35.00			
	30-40 (%)	20/06/92			٠		34.00	
MBC: E	2-4 (%)	20/04/92	2.00		2.00			
	0-3 (%)	20/06/92		_		_	3.00	
MBC: M	4~6 (%)	20/04/92 20/06/92	2.00	`	2.00	-	1.00	
una. n	0-5 (%) 0-2 (%)	20/04/92	0.00		0.00		1155	i
MBC: B	0-2 (%)	20/06/92	0.00				0.00	
PLATELETS	130000-400000	20/04/92						
, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	(/MM3)		223000		231000	1		
	150000-300000	20/06/92					250000	
	(/MM3)		405.00		430 00		250000	
NA+	135-146 (MEQ/L)	20/04/92 20/06/92	135.00		139.00		142.00	
w.	130-150 (MEQ/L) 3.5-5 (MEQ/L)	20/04/92	3.60		5.00		142.00	
K+	3-5 (MEQ/L)	20/06/92	5,00				3,90	
CL-	96-106 (MEQ/L)	20/04/92	96.00		96.00			
<b></b>	95-105 (HEQ/L)	20/06/92	1				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	
P04	2.5-4.5 (MG/DL)	20/04/92	3.70		3.70		4.60	
	2.5-5 (MG/DL)	20/06/92	25.00	1	10.00		4.00	
SGOT	5-30 (U/L) 0-12 (MU/NL)	20/04/92 20/06/92	25.00	l	10.00		12.00	
SGPT	0-12 (MU/ML)	20/06/92			1		10.00	
agr I	5-40 (U/L)	20/04/92	15.00		21.00			
GAMMA GT	6-28 (U/L)	20/04/92	7.80	l	7.70			
	4-18 (UI/L)	20/06/92					9.00	1
LDH	120-240 (U/L)	20/04/92	160.00		149.00			1
	120-240 (UI/L)	20/06/92					140.00	
ALK. PHOSPH.	20-48 (U/L)	20/04/92	20.00		26,00		25.00	ŀ
	20-48 (MU/ML)	20/06/92	79.00		79.00		23.00	ĺ
GLUCOSE	60-115 (MG/DL) 70-110 (MU/DL)	20/04/92 20/06/92	',,00	l	//	1	85,00	l
UREA	18-40 (MG/DL)	20/04/92	20.00		20.00	1	1	1
Washing .	15-40 (MG/DL)	20/06/92	"	1	1	1	20.00	
CREATININE	0.5-1.6 (NG/DL)	20/04/92	0.70		0.80	1		
	0.5-1.4 (NG/DL)	20/06/92					0.90	l
URIC ACID	2.4-5.7 (NG/DL)	20/04/92	2.90	1	3.00	1	3.60	1
TOT BILIRUBIN	0.1-1 (MG/DL)	20/04/92	0.90	1	0.82		0.80	Ĺ
	0-1 (MG/DL)	20/06/92	0.15		0.20	1	0.80	l
DIR BILIRUBIN	0-0.25 (MG/DL)	20/04/92 20/06/92	0.15	1	0.20	1	0,20	
MAN DRATETHE	0-0.3 (MG/DL) 6-8 (G/DL)	20/06/92	7.30	1	7.60		*,50	1
TOT. PROTEINS	6-8 (G/DL) 6.3-8 (G/DL)	20/06/92	7.30	1		1	7.40	1
ALBUMINE	2,7-4.8 (G/DL)	20/04/92	4.20	1	4.30	1		1
	3,8-5 (G/DL)	20/06/92		1			4.70	1
TOT, CHOLEST.	150-250 (MG/DL)	20/04/92	209.00		179.00			1
	160-240 (MG/DL)	20/06/92					180.00	1
TRIGLYCERIDES	35-160 (MG/DL)	20/04/92	85.00	1	67.00	I	1	1

(CONTINUED)

<sup>(¢) &</sup>lt;< clinically relevant (value lower than min range)
< out of range (value lower than min range)
\*\* missing laboratory test value nd laboratory not done

<sup>997
&</sup>gt;> clinically relevant (value higher than max range
> out of range (value higher than max range
() missing range value

### PHARMACIA PHARMACEUTICAS 50000 - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 413 Treatment: Reboxetine

			Visit	numb	or / La	borat	ory dat	e
			Scree	n	Day 2	8	Day 5	6
			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	İ
GLOBULINS ALPHA 1	0.12-0.4 (G/DL)	20/04/92	0.25	1 1	0.30	1 1		
	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	İ	1 1		1	0.65	1
GLOBULINS BETA	0.66-1.2 (G/DL)	20/04/92	0.95	ìì	1.00	1 1		
	0.6-1 (G/DL)	20/06/92				1 1	0.78	İ
GLOBULINS GAMMA	0.9-1.6 (G/DL)	20/04/92	1.20		1.25	1		ĺ
	0.8-1.3 (G/DL)	20/06/92				1	1.07	ĺ
TSH	0-6.5 (UU/ML)	20/04/92	1.30					
T4	4.5-11.5 (UG/DL)	20/04/92	6.30			[ ]		ŀ

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>> clinically relevant (value higher than max range > out of range (value higher than max range () missing range value

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ratory test  " " " " " " " " " " " " " " " " " " "	33	Range date 01/03/92 05/08/92		3	value	3	value	3
ratury test  N  E. E.  R  RELETS  RELETS  A GT  A GT  A GT  A GT  BILIRUBIN  BILIRUBIN	22	Range date 01/03/92 05/08/92	-1	1		1		1
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B ELETS LETS LETS LETS LETS LETS LETS LETS	000	01/03/92	3.00		2.00		2.00	
LETS  ( GT  PROSPH.  SSE  ACID  ACID  ACID  ACID  ACID  ACID  ACID  ACID	000	01/03/92	0.00	_	0.0		0.0	
GT PROSPH. SE ACTD ILLIRUBIN	900	01/03/92			0000			
GT PBOSPH. SSE ACTD ILLIRUBIN	200		215000		230000	_		
GT PROSPH. NSE TININE ACID ACID ACID ACID ACID ACID ACID ACID		76.48n./cn	_	_			296000	
GT PROSPH. INTRE ACTD ILLIEUBIN	CD/C3	01/03/92	139.00	_	142.00	_	140.00	
I GT PBOSPH. SSE ACTD ILLIRUBIN		01/03/92	3.70		4.30	_		
GT PBOSPH. SSE INTRE ACID ACID ACID ACID ACID ACID ACID ACID	•	05/08/92					3.70	
I GT PROSPH. INTRE ACTD ILLIEUBIN	(T/A	01/03/92	100.00		100.00	_	101.00	
I GT PBOSPH. SSE TILIRUBIN LILIRUBIN	(C/DL)	01/03/92	10.20		9.90		8 6	
I GT PBOSPH. INTRE ACID ACID ACIDALIEUBIN	G:	01/03/92			200	_	?	
FBOSPH. SSE TRIENE ACTD ALTERUBER	3	04/05/92	2	`	3		15.00	
I GT PROSPH. ISE ININE ACID ILLIRUBIN	3	01/03/92	23.00	^	12.00	_		
, GT PBOSPH. INE ACID ILLEVBIN		05/08/92			:		14.00	
PBOSPH. ISE TININE ACID ALIENUBIN	_	01/03/92	5.20		14.00	_	9	
PBOSPH. ININE ACID ILLIRUBIN		05/08/92	245		200 00	_	3	
PBOSPH. SSE TININE ACTD ACTD ACTINITIENDETR	35	01/03/92	20.61	_	2010		191.00	
ISE INTRE ACID ALLIRUBIN	3	01/03/92	66.00	_	60.00	^		
OSE TININE ACID BILIRUBIN	3	05/08/92					110.00	
TININE ACID BILIRUBIN BILIRUBIN	(DE)	01/03/92	95.00		9			
TININE ACID BILIRUBIN BILIRUBIN	36	20/06/92			3		01.00	
TININE ACID BILIRUBIN BILIRUBIN	j.	03/00/32	52.00	_	40.00			
	i i	05/08/92					12.00	
	G/DL)	01/03/92	0.80		06.0		,	
	G/DE)	05/08/92	,	_	5		9 6	
	G/DT)	01/03/92		_	200		5	
0-0.3	). DI. )	05/08/92	;				0.70	
	12	01/03/92	0.10		0.10	_	0.20	
6.3-8	3	01/03/92	6.00	v	6.50			
6.5-8	3	05/08/92			-		6.70	
IINE	3	01/03/92	3.80		175.00		2.80	
TOT. CHOLEST. 160-240 (NG/UL)		01/03/92	220.00		2		180.00	
10/50) 047-061 (10/50) 047-061	6/UL)	03/08/32	82.00	_	80.00		88.00	
ALPHA 1	3	01/03/92	0,10	_	0.16		0.15	
ALPHA 2 0.45-0	(C/DL)	01/03/92	09.0		0.54		0.75	
BETA	ای	01/03/92	0.00		0.72		9.50	
BULINS GAMMA		01/03/03	00.0	_			:	
TSH 0-5 (001/01)	3 6	01/03/92	09.6					
	ì					٦		

### PHARMACIA PHARMACEUTICAS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

	LA	BOKATOKI DAT	8		
atro: 15	Patient: 417	Treatment:	Reboxetine	Sex:	Female

			Visit	numi	ber / Lai	bora	tory dat	
			Scree	3	Day 2	В	Day 5	6
			11/06/	92	16/07/	92	13/08/	92
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
нв	12.5-15 (G/DL)	01/03/92	10.80	<	12.00	<	13.00	i
HT	38-43 (%)	01/03/92	38.00		40.00		39.00	1
RBC	4000000-4500000	01/03/92				İ	1	
	(/MM3)		4180000		4250000	ļ	4300000	
NBC	5000-9000 (/MM3)	01/03/92	5100.00		5400.00		5800.00	l
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	1
WBC: E	0-3 (%)	01/03/92	4.00	>>	1.00		2.00	1
WBC: M	0-5 (%)	01/03/92	4.00		3.00		3.00	1
MBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	1
PLATELETS	150000-300000	01/03/92	i					
	(/MM3)		220000	١.	250000	1	250000	1
NA+	130-150 (NED/L)	01/03/92	139.00		142.00		137.00	1
K+	3-5 (MEQ/L)	01/03/92	4.30		4.60		4.60	
CL-	95-105 (NEQ/L)	01/03/92	104.00		102.00		101.00	1
Ca++	8.1-10.4 (MG/DL)	01/03/92	11.40	>	10.70	>	10.80	>
P04	2.5-5 (MG/DL)	01/03/92	4.20		4.00		4.00	
SGOT	0-12 (NU/ML)	01/03/92	7.00		14.00	>	6.00	
SGPT	0-12 (MU/ML)	01/03/92	9.00		10.00		8.00	
GANNA 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 (NU/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	<b>,</b>	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	1
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.55		0.65		0.60	ĺ
GLOBULING ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.80		0.88		0.85	
GLOBULINS BETA	0.8-1.3 (G/DL)	01/03/92	1.30		1,25		1.27	1
GLUBULING GARRA TSH	0.8-1.3 (G/DL) 0-5 (UUI/ML)	01/03/92	2.50		''	1		1
TSH T4	4.5-13 (UG/DL)	01/03/92	8.10		1			Į
**	7.0-10 (00/00/	J		1	1	1		l

<sup>&</sup>gt;> clinically relevant (value higher than max range 
> out of range (value higher than max range 
() missing range value

### PHARMACIA PHARMACEUTICA5 44683- CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 418 Treatment: Reboxetine Sex: Female

			Visit	num	per / Lai	bora	tory date	0
			Scree	n	Day 2	В	Day 5	6
			07/07/	92	13/08/	92	10/09/	92
			value	(¢)	value	(¢)	value	(4
Laboratory test	Range value	Range date						
нв	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	01/07/92						
	(/MM3)		4200000	i i	4250000		4180000	<
WRC	4500-10000 (/MM3)	01/07/92	7100.00		7000.00		6500.00	
NBC: N	50-65 (%)	01/07/92	70.00	>	68.00		65.00	
HBC: L	30-40 (%)	01/07/92	24.00	<	28.00	<	30.00	
HBC: E	0-3 (%)	01/07/92	4.00	>>	1.00		1.00	
MBC: M	0-5 (%)	01/07/92	2.00	1	3.00		4.00	
HBC: B	0-1 (%)	01/07/92	0.00		0.00		0.00	
PLATELETS	150000-400000	01/07/92		ļ			ļ	
	(/MM3)		320000		310000		300000	
NA+	130-150 (MEQ/L)	01/07/92	142.00	1	140.00		139.00	
K+	3-5 (MEQ/L)	01/07/92	3.10	ļ	3.50		4.20	
CL-	95-105 (MEQ/L)	01/07/92	98.00	l	100.00		100.00	
Ca++	8.1-10.4 (MG/DL)	01/07/92	8.30		8.50		8.80	
P04	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	Ì	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	
CLUCOSE	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	l	0.30		0.22	ĺ
CREATININE	0.8-1.4 (MG/DL)	01/07/92	1.00	ĺ	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	
ALBUNINE	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	ŀ	185.00		205.00	
TRIGLYCERIDES	50-160 (MG/DL)	01/07/92	45.00	<	60,00	ĺ	70.00	l
GLOBULINS ALPHA 1	0.2-0.48 (G/DL)	01/07/92	0.24	1	0.25	l	0.28	l
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	1	0.77		0.85	l
GLOBULING GAMMA	0.9-1.3 (G/DL)	01/07/92	1.09	1	1,10		1.20	1
TSH	0.1-6.5 (UU/NL)	01/07/92	0.48	1	'''			1
	V. 1 V. 2 (40/112)	A 1. AL. 48		ı		i	ı	

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range) (value lower wissing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range value higher than max range () missing range value

### PHARMACIA PHARMACEUTIGAS STORMES - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 421 Treatment: Reboxetine Sex: Female

			Visit	num	ber / La	bora	tory dat	6
			Scree	n	Day 2	8	Day 5	6
			24/07/	92	28/08/	92	25/09/	92
			value	(4)	value	(4)	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	l
RBC	4000000-4500000	01/03/92	i		1	ĺ	ĺ	i
	(/MM3)		4840000	>	4750000	>	4730000	>
WBC	5000-9000 (/MN3)	01/03/92	7000.00		7100.00		7100.00	-
WBC: N	50-65 (%)	01/03/92	72.00	>	70,00	>	62.00	1
WBC: L	30-40 (%)	01/03/92	28.00	<	26,00	<	35,00	1
MBC: E	0-3 (%)	01/03/92	0.00		1.00	1	0.00	l
WBC: M	0-5 (%)	01/03/92	0.00		3.00		3.00	
HBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000	01/03/92						
	(/MM3)		270000		280000		265000	
+AV	130-150 (MEQ/L)	01/03/92	139.00		143.00		142.00	
K+	3-5 (MEQ/L)	01/03/92	4.80	1	4.60		4.50	ł
CL-	95-105 (MEQ/L)	01/03/92	109.00	>	104.00		105.00	ĺ
Ca++	8.1-10.4 (MG/DL)	01/03/92	11.40	>	10.80	>	10.80	>
04	2.5-5 (MG/DL)	01/03/92	4.20		4.50		4.20	
SGOT	0-12 (MU/NL)	01/03/92	10.00		9.00		7.00	
GPT	0-12 (NU/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 (HU/ML)	01/03/92	25.00		29.00		36.00	
LUCOSE	70-110 (MG/DL)	01/03/92	69.00	۷ ا	75.00		96.00	
IREA	15-40 (MG/DL)	01/03/92	43.00	> [	38.00		40.00	
REATININE	0.5-1.4 (MG/DL)	01/03/92	1.20	- 1	1.05	- 1	1,15	
RIC ACID	2.4-5.7 (MG/DL)	01/03/92	6.70	>	6.10	ا د	5.00	
OT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.75	1	0.80	·	0.75	
OIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.25	- 1	0.20		0.25	
OT. PROTEINS	6.3-8 (G/DL)	01/03/92	7.15	- 1	7.15		7.10	
LBUMINE	3.8-5 (G/DL)	01/03/92	4.00		4.30		3.80	
OT. CHOLEST.	160-240 (MG/DL)	01/03/92	163.00		175.00		202.00	
RIGLYCERIDES	30-150 (MG/DL)	01/03/92	63.00		65.00		86.00	
CLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.25		0.20	- 1	0.30	
LOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.70		0.65	- 1	0.75	
LOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.80	İ	0.90	1	0.85	
LOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.40	ا د	1.10	ĺ	1.40	>
SH CANAL	0-5 (UUI/ML)	01/03/92	0.80	•		ŀ		-
14	4.5-13 (UG/DL)	01/03/92	12.10		1		ì	

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(¢) << clinically relevant (value lower cout of range (value lower than min range) to than min range) than min range) than min range) and laboratory not done

>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAS HEIGHOS - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 424 Treatment: Reboxetine Sex: Male

			Visit	numi	ber / Lai	bora	tory date	8
			Scree	n.	Day 2	8	Day 5	6
•			13/08/	92	17/09/	92	15/10/	92
			value	(¢)	value	(¢)	value	(4)
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	01/03/92	ı		1			
	(/MM3)		5170000	>	5200000	>	4950000	>
MBC	5000-9000 (/MM3)	01/03/92	8100.00		7600.00		7700.00	
WBC: N	50-65 (%)	01/03/92	59.00	ŀ	57.00		62.00	
WBC: L	30-40 (%)	01/03/92	35.00	l	37.00	l	34.00	l
WBC: E	0-3 (%)	01/03/92	5.00	>>	4.00	>>	1.00	
MBC: M	0-5 (%)	01/03/92	1.00		2.00	l	3.00	1
NBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000	01/03/92						}
	(/MM3)		245000		240000	ł	230000	i
NA+	130-150 (MEQ/L)	01/03/92	138.00		130.00		141.00	
K+	3-5 (MEQ/L)	01/03/92	4.60	i	4.80		4.80	l
CL-	95-105 (MEQ/L)	01/03/92	108.00		100.00	i	100.00	l
Ca++	8.1-10.4 (MG/DL)	01/03/92	10.60	>	9.80		10.90	>
P04	2.5-5 (MG/DL)	01/03/92	4.10		4.50		3,70	
SGOT	0-12 (NU/ML)	01/03/92	8.00		9.00		7.00	1
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	1
LDH	120-240 (UI/L)	01/03/92	205.00		195.00		145.00	
ALK. PHOSPH.	20-48 (NU/ML)	01/03/92	38.00		35.00		34.00	Į
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	ł
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	ł
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	242.00	>	230.00		202.00	i
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	1
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.60		0.65	İ	0.70	1
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.80		0.90		0.85	İ
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.35	>	1.10	l	1.40	>
TSH	D-5 (UUI/ML)	01/03/92	0.80					
T4	4.5-13 (UG/DL)	01/03/92	12.70	1	I	1	ı	i

<sup>&</sup>gt;> clinically relevant (value higher than max range to out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAS STATIONS - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Contre: 15 Patient: 425 Treatment: Roboxetine Sex: Famale

		•	Visit	num	ber / La	bora	tory dat	8
			Scree	n	Day 2	8	Day 5	6
			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	1	14.00	ĺ	13.72	ĺ
HT	38-43 (%)	20/09/92	42.00		42.50		43.00	
RBC	4200000-4800000	20/09/92						
	(/MM3)		4540000	1	4700000	ł	4620000	ł
MBC	4500-10000 (/MN3)	20/09/92	5400.00		5200.00	ł	4900.00	1
NBC: N	50-65 (%)	20/09/92	64.00		67.00	١,	53.00	1
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	[
MBC: M	0-6 (%)	20/09/92	7.00		2.00		4.00	
NBC: B	0-1 (%)	20/09/92	0.00		0.00	١.	0.00	ļ
PLATELETS	150000-300000	20/09/92	0.00		0.00		0.00	1
FLAXELLE	(/MM3)	20/03/32	230000		240000		242000	
NA+	136-146 (MEQ/L)	20/09/92	143.00		140.00		140.00	1
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			
CL- Ca++	9-11 (MG/DL)	20/09/92	9.20		8.70	_	102.00	
P04	3-4 (MG/DL)		3.80	ĺ		•		ľ
		20/09/92			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	
GANNA 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	1	102.00		127.00	
GLUCOSE	70-110 (MG/DL)	20/09/92	89.00	- 1	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	- 1	0.65		0.60	
DIR BILIRUBIN	0-0.15 (MG/DL)	20/09/92	0.00	- 1	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	- 1	99.00	- 1	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	- 1	0.75	
GLOBULINS BETA	0.6-1 (G/DL)	20/09/92	0.63	- 1	0.95	ł	1.00	
GLOBULINS GAMMA	0.8-1.4 (G/DL)	20/09/92	1.18	i	1.10	- 1	1.15	
TSH	0.6-6.5 (UU/ML)	20/09/92	2.00			-	l	
Г4	4.5-12.5 (UG/DL)	20/09/92	8.50	- 1	j	- 1	J	

<sup>(¢) &</sup>lt;< clinically relevant (value lower than min range)
< out of range (value lower than min range)
\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max rang > out of range (value higher than max rang

<sup>()</sup> missing range value

### PHARMACIA PHARMACEUTICAS BHOWS - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 427 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date						
			Scree	Screen 25/11/92		Day 28 30/12/92		Day 56 27/01/93	
			25/11/						
			value	(¢)	value	(¢)	value	(¢)	
Laboratory test	Range value	Range date							
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	1	39.00	1	
RBC	4000000-4500000	01/03/92					l .		
	(/MM3)		4200000		4600000	>	4500000		
MBC	5000-9000 (/MM3)	01/03/92	5900.00		5500.00	-	6300.00		
MBC: N	50-65 (%)	01/03/92	60.00		58.00	l	65.00		
MBC: L	30-40 (%)	01/03/92	35,00		38.00	l	30.00		
NBC: E	0-3 (%)	01/03/92	3.00		1.00	1	2.00	1	
MBC: M	0-5 (%)	01/03/92	2.00		3.00	ł	3.00		
MBC: B	0-1 (%)	01/03/92	0.00	1	0.00	1	0.00		
PLATELETS	150000-300000	01/03/92		1				l	
PLAIGUEID	(/MM3)		319000	>	280000	1	280000	l	
NA+	130-150 (MEQ/L)	01/03/92	131.00		133.00		142.00	l	
K+	3-5 (MEQ/L)	01/03/92	4.60		4.40	1	4.70	l	
CL-	95-105 (MEQ/L)	01/03/92	105.00		102.00		104.00	l	
Ca++	8.1-10.4 (MG/DL)	01/03/92	8.70		8.60		9.20	l	
P04	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	l	
SGPT	0-12 (MU/ML)	01/03/92	11.00		13.00	>	19.00	>	
GANNA GT	4-18 (UI/L)	01/03/92	10.00		15.00	ļ	15.00	l	
LDH	120-240 (UI/L)	01/03/92	116.00	۱<	120.00		130.00	l	
ALK, PHOSPH.	20-48 (MU/ML)	01/03/92	22.00		24.00		33.00	l	
GLUCOSE	70-110 (MG/DL)	01/03/92	78.00		75.00		80.00	l	
UREA	15-40 (MG/DL)	01/03/92	20.00	ĺ	23.00		31.00		
	0.5-1.4 (MG/DL)	01/03/92	1.00		1.04		0.90	l	
CREATININE URIC ACID	2,4-5.7 (MG/DL)	01/03/92	3.30	İ	3.20		2.90	l	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.92	l	0.95		0.80		
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.18		0.15	l	0.20	l	
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	8.00		7.90		6.15	ح	
ALBUMINE	3.8-5 (G/DL)	01/03/92	4.65	i	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	l	85.00	l	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.30	l	0.25		0.15		
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.75	l	0.70	l	0.45	l	
GLOBULINS ALPHA 2	0.6-1 (G/DL)	01/03/92	1.00	l	0.90		0.70	İ	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1,30		1.20	1	0.85		
	0.5-1.3 (G/DL) 0-5 (UUI/ML)	01/03/92	1.99	1				1	
TSH T	4.5-13 (UG/DL)	01/03/92	5.40			1		1	
T4	4.5*13 (UG/DL)	0 17 037 92	5.70	l	1	I	1	1	

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTIGAS 510 649 - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 449 Troatment: Reboxetine Sex: Female

· · · · · · · · · · · · · · · · · · ·		-	Visit number / Laboratory date						
			Screen 01/12/92		Day 28		Day 56 01/02/93		
		3							
			value	(¢)	value	(¢)	value	(¢)	
Laboratory test	Range value	Range date							
нв	12.5-15 (G/DL)	01/03/92	13.50		12.90	1	14.40	1	
HT	38-43 (%)	01/03/92	42.00		41.60		43.60	>	
RBC	4000000-4500000	01/03/92	į.						
	(EMM>)		4700000	>	4590000	>	4820000	>	
MBC	5000-9000 (/MM3)	01/03/92	6500.00		7200.00		7300.00		
MBC: N	50-65 (%)	01/03/92	68.00		63.00	Ι,	61.00	1	
HBC: L	30-40 (%)	01/03/92	28.00	<	33.00		36.00		
MBC: E	0-3 (%)	01/03/92	2.00		1.00		1.00		
MBC: M	0-5 (%)	01/03/92	2.00		3.00		2.00		
MBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00		
PLATELETS	150000~300000	01/03/92							
	(/MM3)		240000		215000		225000		
NA+	130-150 (MEQ/L)	01/03/92	133.00		141.00		141.00	ļ	
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	1	
P04	2.5-5 (MG/DL)	01/03/92	4.10		4.70	1 1	3.40	l	
SGOT	0-12 (NU/NL)	01/03/92	6.00		8.00		9.00	1	
SGPT	0-12 (NU/NL)	01/03/92	9.00		8.00		8.00		
GANKA 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	l	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	18.00	e	21.00		32.00		
GLUCOSE	70-110 (MG/DL)	01/03/92	88.00	`	85.00	1 1	85.00		
	15-40 (MG/DL)	01/03/92	28.00		24.00	i I	31.00		
UREA CREATININE	0.5-1.4 (MG/DL)	01/03/92	1.15		1.00		0.90		
	2.4-5.7 (MG/DL)	01/03/92	2.90		2.60		4.40		
URIC ACID		01/03/92	0.65		0.50		0.55		
TOT BILIRUBIN	0-1 (NG/DL)	01/03/92	0.03		0.08		0.10		
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	6.60		6.80		6.90		
TOT. PROTEINS	6,3-8 (G/DL)	01/03/92	3.70	<	3.90		3.90		
ALBUMINE	3.8-5 (G/DL)		185.00	`	190.00		185.00	!	
TOT, CHOLEST.	160-240 (HG/DL)	01/03/92 01/03/92	77.00		80.00		77.00	1	
TRICLYCERIDES	80-150 (MG/DL)		0.20		0.25		0.20	1	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.20		0.45		0.70	İ	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92					0.70	Į	
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.80		0,95			1	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.20		1.10		1.20	1	
Teh	0-5 (UUI/NL)	01/03/92	2.10		1			1	
T4	4.5-13 (UG/DL)	01/03/92	8.60		l	1 .		l	

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTIGAS STEEDERS - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Contro: 15 Patient: 452 Treatment: Reboxetine Sex: Female

			Visit number / Laboratory date						
			Screen 15/12/92		Day 28		Day 56 16/02/93		
			value	(4)	value	(¢)	value	(¢	
Laboratory test	Range value	Range date							
нв	12.5-15 (G/DL)	01/03/92	12.80		13.00	l	14.00	1	
HT	38-43 (%)	01/03/92	41.00		41.20	ŀ	43.00	1	
RBC	4000000-4500000	01/03/92				İ		l	
	(/MM3)		4510000	>	4600000	>	4730000	>	
MBC	5000-9000 (/MM3)	01/03/92	7100.00	1	7200.00	İ	7100.00	l	
MBC: N	50-65 (%)	01/03/92	66.00	>	68.00	>	59.00	l	
MBC: L	30-40 (2)	01/03/92	32.00		30.00		37.00	l	
MBC: E	0-3 (%)	01/03/92	0.00		1.00		2.00	l	
NBC: M	0-5 (%)	01/03/92	2.00		1.00		2.00	l	
MBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	l	
PLATELETS	150000-300000	01/03/92						i	
· DIII AMELIA	(/MM3)		220000		210000		210000	l	
NA+	130-150 (MEQ/L)	01/03/92	138.00		141.00		139.00	1	
K+	3-5 (MEQ/L)	01/03/92	4.30	ļ	4.70		4,20	İ	
CL-	95-105 (MEQ/L)	01/03/92	106.00	>	101.00		105.00	1	
Ca++	8.1-10.4 (MG/DL)	01/03/92	10.80	>	10.40		9.80	ł	
P04	2.5-5 (MG/DL)	01/03/92	3.70		4.30		3.70	1	
SGOT	0-12 (NU/NL)	01/03/92	7.00		5.00		7.00		
SGPT	0-12 (MU/NL)	01/03/92	8.00		9.00		9.00	l	
GANNA GT	4-18 (UI/L)	01/03/92	8.00		10.00		8.00	1	
LDH	120-240 (UI/L)	01/03/92	195.00		190.00		207.00	l	
ALK. PHOSPH.	20-48 (MU/NL)	01/03/92	22.00		25.00		24.00		
ALK. PRUSPR. GLUCOSE	70-110 (MG/DL)	01/03/92	85.00	l	90.00		79.00		
UREA	15-40 (MG/DL)	01/03/92	32,00		30.00		28.00		
CREATININE	0.5-1.4 (NG/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		
	3.8-5 (G/DL)	01/03/92	3.60		3.70	<	3.95		
ALBUMINE	160-240 (NG/DL)	01/03/92	212.00	_	205.00		222.00		
TOT. CHOLEST.		01/03/92	86.00		90.00		95.00		
TRIGLYCERIDES	30-150 (MG/DL) 0.1-0.3 (G/DL)	01/03/92	0.30		0.25		0.25		
GLOBULINS ALPHA 1		01/03/92	0.65		0.70		0.75		
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.75		0.85		0.80		
GLOBULINS BETA	0.6-1 (G/DL)		1.40	l_	1.30		1.45	-	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.40	1	1.30		'3	١-	
Teh	0-5 (UUI/NL)	01/03/92	9.30	1				l	
T4	4,5-13 (UG/DL)	01/03/92	9.30	ı		ı	I	I	

<sup>&</sup>gt;> clinically relevant (value higher than max range to missing range value)

#### PHARMACIA PHARMACEUTIGASSUTORIS - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Contro: 16 Patient: 430 Treatment: Reboxetine Sex: Male

			Visit	num	ber / La	bora	tory dat	e
			Scree	n	Day 2	8	Day 5	6
			26/03/	92	27/04/	92	25/05/	92
			value	(4)	value	(0)	value	(¢)
Laboratory test	Range value	Range date						
НВ	13.5-15.5 (GRX)	01/02/92	13.60	Į .	14.00		14.50	i
HT	40-45 (X)	01/02/92	43.00	ĺ	44.00	[	45.00	
RBC	4200000-4800000	01/02/92					1	
	( <mm3)< td=""><td></td><td>4900000</td><td>&gt;</td><td>5000000</td><td>&gt;</td><td>4950000</td><td>&gt;</td></mm3)<>		4900000	>	5000000	>	4950000	>
NBC	5000-9000 (/MM3)	01/02/92	6200.00		8000.00	1	7100.00	1
MBC: N	50-65 (%)	01/02/92	56.00		65.00		62.00	1
MBC: 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	
HBC: M	0-5 (%)	01/02/92	3.00		2.00		0.00	l
NBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000	01/02/92	1		0.00		0.00	
	(/MM3)	V (	210000		230000		240000	
NA+	130-150 (NEQ/L)	01/02/92	135.00		140.00	i J	141.00	ļ
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	
P04	2.5-5 (MG/DL)	01/02/92	3.20	- 1	2.20	_	2.90	
SGOT	0-12 (MU/ML)	01/02/92	11.00	- 1	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	۰ I	13.00		12.00	
LDH	120-240 (UI/L)	01/02/92	128.00	<b>1</b>	91.00	_	142.00	
ALK. PHOSPH.	68-210 (MU/ML)	01/02/92	202.00	ı	143.00	`	142.00	
ma. Inobin,	20-48 (NU/NL)	20/05/92	202.00	- 1	143.00	- 1	22.00	
GLUCOSE	70-110 (MG/L)	01/02/92	68.00	_	85.00	- 1	91.00	
JREA	15-40 (MG/DL)	01/02/92	33.00	٠ ا	41.00	- 1	33.00	
REATININE	0.5-1.4 (MG/DL)	01/02/92	1.50	、 l	0.92	1	1.00	
JRIC ACID	3.4-7 (MG/DL)	01/02/92	4.50	1	5.00		3.00	_
OT BILIRUBIN	0-1 (NG/DL)	01/02/92	0.77	- 1	0.70		0.65	`
OIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20	- 1	0.15		0.20	
OT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.50		0.15		6.95	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.70	.	- 1	Į	4.00	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	186.00	`	179.00	1	215.00	
RIGLYCERIDES	30-150 (MG/DL)	01/02/92	127.00	- 1	82.00	ł	85.00	
SLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.23	- 1	0.22		0.25	
SLOBULING ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.23	- 1	0.22	- 1	0.45	
SLOBULINS RETA	0.45-0.75 (G/DL)	01/02/92	0.82		0.62	- 1		
SLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.13	- 1	1.13	- 1	1.30	- 1
ish	0-5 (UUI/ML)	01/02/92	1.80	- 1	1.13		1.50	- 1
16n [4	4.5-13 (UG/DL)	01/02/92			ļ			l
1-4	4.5 15 (UG/UL)	0 17 02/32	6.80	- 1	- 1	1		- 1

1008

>> clinically relevant (value higher than max range 
> out of range (value higher than max range 
() missing range value

#### PHARMACIA PHARMACEUTIGAS 541648 - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 431 Treatment: Reboxetine

			Visit	numi	ber / Lai	bora	tory date	8
			Scree	1	Day 2	3	Day 5	6
			26/03/	92	27/04/	92	25/05/9	92
			value	(¢)	value	(0)	value	(¢
Laboratory test	Range value	Range date						
нв	12.5-15 (G/DL)	01/02/92	13.50		13.00		13.50	1
HT	38-43 (%)	01/02/92	42.00		43.00		42.00	l
RBC	4000000-4500000	01/02/92	l					l
	(/NH3)		4620000	>	4730000	>	4620000	>
MBC	5000-9000 (/MM3)	01/02/92	7000.00		6600.00		6900.00	١.
HBC: N	50-65 (%)	01/02/92	60.00		68.00	>	70.00	>
MBC: L	30-40 (%)	01/02/92	40.00		30.00		30.00	l
MBC: E	0-3 (%)	01/02/92	0.00		2.00		0.00	l
MBC: M	0-5 (%)	01/02/92	0.00	i	0.00		0.00	1
MBC: B	0-1 (%)	01/02/92	0.00		0.00	l	0.00	ł
PLATELETS	150000-300000	01/02/92				ļ		1
	(/MM3)		220000		235000	İ	235000	1
NA+	130-150 (MEQ/L)	01/02/92	143.00		138.00	l	142.00	
K+	3-5 (MEQ/L)	01/02/92	4.20		4.70		4.10	١.
CL-	95-105 (MEQ/L)	01/02/92	108.00	>	98.00	l	106.00	-
Ca++	8.1-10.4 (MG/DL)	01/02/92	9.20		10.90	2	9.80	1
P04	2.5-5 (MG/DL)	01/02/92	3.10		4.80	ļ	3.00	l
SGOT	0-12 (MU/ML)	01/02/92	8.00		8.00		6.00 8.00	i
SGPT	0-12 (MU/ML)	01/02/92	5.00		10,00	ŀ	9.00	
GAMMA GT	4-18 (UI/L)	01/02/92	12.00		14.00		139.00	ļ
LDH	120-240 (UI/L)	01/02/92	125.00		225.00	1	23.00	1
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	28.00		46.00	ŀ	100.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	100.00		102.00 48.00	L	30.00	1
UREA	15-40 (MG/DL)	01/02/92	43.00	>		2	1.90	١.
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.20		1.20	l	3.50	^
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	5.00		4.20	İ	0.59	}
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.60		0.70 0.20		0.39	1
DIR BILIRUBIN	0-0,3 (MG/DL)	01/02/92	0.10 6.75		7.25		7.00	1
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92		_	3.80		3.90	1
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.60 250.00	۲ >	204.00		220.00	1
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92		'	115.00		90.00	1
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	102.00		0.30	l	0.30	l
GLOBULING ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.25 0.70		0.80	l.	0.60	l
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92		1	0.80		0.80	l
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.80		1.45	l.	1.40	L
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40	*	1.45	_	1.40	1
TSH	0-5 (UUI/ML)	01/02/92	0.87		l	l	1	l
T4	4.5-13 (UG/DL)	01/02/92	8.50	I		1	1	1

1009

(c) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not

>> clinically relevant (value higher than max range value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIGASTONS - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 433 Treatment: Roboxetine Sex: Female

			Visit	num	ber / La	bora	tory dat	Э
			Screen	n	Day 2	8	Day 5	6
			28/03/	92	29/04/	92	27/05/	92
			value	(¢)	value	(4)	value	(¢)
Laboratory test	Range value	Range date						
HB	12.5-15 (GR%)	25/03/92	13.30		12.80		12.50	
HT	38-43 (%)	25/03/92	40.00		42.00		41.00	
RBC	4000000-4500000	25/03/92			ŀ		ŀ	
	(/MN3)		4400000		4620000	>	4510000	>
MBC	5000-9000 (/MM3)	25/03/92	6300.00		6900.00		6900.00	
MBC: N	50-65 (%)	25/03/92	55.00		71.00	>	70.00	>
MBC: L	30-40 (%)	25/03/92	40.00	ŀ	29,00	<	30.00	
NBC: E	0-3 (%)	25/03/92	3.00		0.00		0.00	l
MBC: 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	25/03/92						
FLATELLIB	(/MM3)	20, 00- 20	200000		210000	ŀ	230000	
NA+	130-150 (MEQ/L)	25/03/92	147.00		140.00	İ	145.00	
K+	3-5 (NEQ/L)	25/03/92	4.40		3.50		3.90	
CL-	95-105 (MEQ/L)	25/03/92	105.00		104.00	1	100.00	1
Ca++	8.1-10.4 (NG/DL)	25/03/92	10.00		10.00	l	9,20	l
P04	2.5-5 (MG/DL)	25/03/92	4.10		3.00	ì	2.90	i
SGOT	0-12 (MU/NL)	25/03/92	7.00		6.00		7.00	l
SGPT	0-12 (MU/NL)	25/03/92	8.00		8.00		7.00	l
GANNA GT	4-18 (UI/L)	25/03/92	8.00		12.00		14.00	l
LDH	120-240 (UI/L)	25/03/92	164.00		155.00		166.00	l
ALK. PHOSPH.	20-48 (MU/NL)	25/03/92	18.00	<	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
GLUCOSE	70-110 (NG/L)	25/03/92	94.00	-	77.00	l	79.00	
UREA	15-40 (MG/DL)	25/03/92	23.00		31.00		33.00	
CREATININE	0.5-1.4 (NG/DL)	25/03/92	1.00		1.20	ŀ	1.05	į
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	i	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	
	0.3-1.7 (G/L)	25/03/92	0.40		240.00			l
TRIGLYCERIDES	30-150 (NG/DL)	25/04/92	".70		105.00		100.00	
MI ARRITTME AT DEL 4	0.1-0.3 (G/DL)	25/03/92	0.21		0.25	i	0.30	1
GLOBULINS ALPHA 1	0.45-0.75 (G/DL)	25/03/92	0.66		0.75		0.70	1
GLOBULINS ALPHA 2		25/03/92	0.75		0.75		0.80	
GLOBULINS BETA	0.6-1 (G/DL)	25/03/92	1,16		1.40		1.45	,
GLOBULINS GANNA	0.8-1.3 (G/DL)		1.10		1.40	-	'+3	1
TSH	0-5 (UUI/ML)	25/03/92	5.50					
T4	4.5-13 (UG/DL)	25/03/92	3.50			1	l	1

<sup>(¢) &</sup>lt;< clinically relevant (value lower cout of range (value lower than min range) (\*\* missing laboratory test value could have a constant to the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of the country of

<sup>&</sup>gt;> clinically relevant (value higher than max range > out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIGASSIGNOS - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 435 Treatment: Reboxetine Sex: Female

			Visit	numl	ber / Lai	bora	tory dat	•
			Scree	n	Day 2	В	Day 5	6
			09/04/	92	11/05/	92	08/06/	92
			value	(4)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
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	İ	41.00	
RBC	4000000-4500000	01/02/92						
	(/MM3)		4620000	>	4620000	>	4510000	>
WBC	5000-9000 (/MM3)	01/02/92	7500.00	İ	6200.00		6000.00	
WBC: N	50-65 (%)	01/02/92	72.00	>	58.00	l	62.00	
WBC: L	30-40 (%)	01/02/92	28.00	<	38.00	l	38.00	
WBC: E	0-3 (2)	01/02/92	0.00		1.00	l	0.00	
MBC: M	0-5 (%)	01/02/92	0.00		3.00		0.00	
MBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000	01/02/92						
LATELLIS	(/MM3)		230000		215000		230000	
NA+	130-150 (MEQ/L)	01/02/92	138.00		138.00		146.00	1
K+	3-5 (MEQ/L)	01/02/92	3.60		4.40	1	4.00	1
CL-	95-105 (MEQ/L)	01/02/92	110.00	,	110.00	>	106.00	l_
Catt	8,1-10,4 (MG/DL)	01/02/92	10.40		9.20		9.00	
P04	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 (NU/NL)	01/02/92	10.00		13.00		5.00	
	4-18 (UI/L)	01/02/92	8.00		14.00	_	12.00	
GAMMA GT	120-240 (UI/L)	01/02/92	165.00		155.00		150.00	l
LDH	120-240 (017L) 20-48 (MU/NL)	01/02/92	40.00		34.00		30.00	İ
ALK. PHOSPH.	,	01/02/92	79.00		70.00		78.00	1
LUCOSE	70-110 (HG/DL)		28.00		34.00		30.00	1
JREA	15-40 (MG/DL)	01/02/92	1.10		1.20		1.15	1
REATININE	0.5-1.4 (MG/DL)	01/02/92	5.00		4,50		4.40	
JRIC ACID	2.4-5.7 (NG/DL)	01/02/92	0.75		1.75	.	0.70	
TOT BILIRUBIN	0-1 (NG/DL)	01/02/92	0.75		0.15	_	0.70	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	6.85		6.60		6.75	
POT. PROTEINS	6.3-8 (G/DL)	01/02/92	3.80		3.60	ایا	3.70	_
ALBUMINE	3.8-5 (G/DL)	01/02/92	264.00		232.00	`	220.00	`
OT. CHOLEST.	160-240 (NG/DL)	01/02/92		,			78.00	Ì
TRIGLYCERIDES	30-150 (NG/DL)	01/02/92	90.00		85.00 0.20		0.25	ŀ
COBULINS 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			0.65		0.60	1
CLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.75 1.40		1.35		1.40	
CLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40		1.35	1	1,40	_
rsh	O-5 (UUI/ML)	01/02/92						
Γ4	4.5-13 (UG/DL)	01/02/92	5.60					i

<sup>(¢) &</sup>lt;< clinically relevant (value lower cut of range (value lower wissing laboratory test value dispersion and laboratory not contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the contained to the

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTISAS 56689 - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA Patient: 437 Treatment: Reboxetine

			Visit	num	ber / La	bora	tory dat	0
			Screen	a	Day 2	8	Day 5	6
			24/04/9	92	27/05/	92	24/06/	92
			value	(4)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
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	01/02/92				1 1	10000	
	(/MH3)		4500000		4510000		4400000	
WBC	5000-9000 (/MM3)	01/02/92	6200.00		7000.00		6100.00	l
NBC: N	50-65 (%)	01/02/92	64.00		68.00		63.00	l
MBC: L	30-40 (X)	01/02/92	32.00		30.00		37,00	Ì
NBC: E	0-3 (%)	01/02/92	2.00		0.00		0.00	1
MBC: M	0-5 (%)	01/02/92	2.00	'	0.00		0.00	l
NBC: B	0-1 (%)	01/02/92	0.00		0.00			ĺ
PLATELETS			0.00		0,00	1	0.00	
PLATELETS	150000-300000	01/02/92						
	(/MM3)		210000	i	270000		270000	ĺ
NA+	130-150 (MEQ/L)	01/02/92	140.00		138.00		144.00	]
K+	3-5 (NEQ/L)	01/02/92	3.90	- 1	4.10		4.00	ĺ
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	- 1	9.10	- 1	10.20	
P04	2.5-5 (MG/DL)	01/02/92	i i	- 1	3.80	1	3,90	
SGOT	0-12 (MU/ML)	01/02/92	16.00	>	7.00	ĺ	9.00	
SGPT	0-12 (MU/ML)	01/02/92	18.00	>	8.00	1	11.00	
GAMMA GT	4-18 (UI/L)	01/02/92	15.00		13.00	i	11.00	
LDH	120-240 (UI/L)	01/02/92	195.00	ĺ	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	- 1	79.00	
UREA	15-40 (MG/DL)	01/02/92	35.00		28.00		25.00	
CREATININE	0.5-1.4 (NG/DL)	01/02/92	0.80	ì	0.85	i	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	- 1	0.70	- 1	0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.30	[	0.20	- 1	0.20	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.30	- 1	6.80	- 1	6.70	
ALBUMINE	3.8-5 (G/DL)	01/02/92		<	3.90	- 1	3.80	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	181.00	`	185.00		177.00	
TRIGLYCERIDES	30-150 (NG/DL)	01/02/92	193.00	.	91.00	ĺ	92,00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.22	<b>^</b>	0.20	}	0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.22	_	0.55	- [	0.20	
GLOBULINS RETA	0.45-0.75 (G/DL)	01/02/92				- 1		
GLOBULING GAMMA			1.01		0.75	_	0.80	_
	0.8-1.3 (G/DL)	01/02/92	1.44	<b>'</b> \	1.40	<b>'</b> \	1.35	,
rsh .	0-5 (UUI/ML)	01/02/92	2.88		J	- 1	Į	
T4	4.5-13 (UG/DL)	01/02/92	14.10	>			1	

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(¢) << clinically relevant (value lower than min range)
< out of range (value lower than min range)
\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range)
> out of range (value higher than max range)
() missing range value

#### PHARMACIA PHARMACEUTICA5550003- CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 440 Treatment: Reboxetine Sex: Female

Laboratory test Range value Range date  HB 12.5-15 (G/DL) 01/02/92  HT 38-43 (%) 01/02/92  HT 38-43 (%) 01/02/92  RBC 4000000-4500000 01/02/92  V/MM3) 4  HBC 5000-9000 (/MM3) 01/02/92  RBC: L 30-40 (%) 01/02/92  HBC: L 30-40 (%) 01/02/92  HBC: E 0-3 (%) 01/02/92  HBC: B 0-1 (%) 01/02/92  HBC: B 0-1 (%) 01/02/92  HBC: B 0-1 (%) 01/02/92  HBC: B 0-1 (%) 01/02/92  C/MM3)  NA+ 130-150 (MEQ/L) 01/02/92  C/MM3  NA+ 130-150 (MEQ/L) 01/02/92  CL- 95-105 (MEQ/L) 01/02/92  CL- 95-105 (MEQ/L) 01/02/92  SGOT 0-12 (MU/ML) 01/02/92  SGOT 0-12 (MU/ML) 01/02/92  GAMMA GT 4-18 (UI/L) 01/02/92  GAMMA GT 4-18 (UI/L) 01/02/92  ALK. PHOSPH. 20-48 (MU/ML) 01/02/92  ALK. PHOSPH. 20-48 (MU/ML) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  TOT BILIRUBIN 0-0.3 (MG/DL) 01/02/92  TOT PROTEINS 6.3-8 (G/DL) 01/02/92  ALBUMINE 10-240 (MG/DL) 01/02/92  ALBUMINE 10-240 (MG/DL) 01/02/92  GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92  GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92	Visit number Laborato date	/
Laboratory test Range value Range date  HB 12.5-15 (G/DL) 01/02/92  HT 38-43 (%) 01/02/92  HT 38-43 (%) 01/02/92  RBC 4000000-4500000 01/02/92  V/MM3) 4  HBC 5000-9000 (/MM3) 01/02/92  RBC: L 30-40 (%) 01/02/92  HBC: L 30-40 (%) 01/02/92  HBC: E 0-3 (%) 01/02/92  HBC: B 0-1 (%) 01/02/92  HBC: B 0-1 (%) 01/02/92  HBC: B 0-1 (%) 01/02/92  HBC: B 0-1 (%) 01/02/92  C/MM3)  NA+ 130-150 (MEQ/L) 01/02/92  C/MM3  NA+ 130-150 (MEQ/L) 01/02/92  CL- 95-105 (MEQ/L) 01/02/92  CL- 95-105 (MEQ/L) 01/02/92  SGOT 0-12 (MU/ML) 01/02/92  SGOT 0-12 (MU/ML) 01/02/92  GAMMA GT 4-18 (UI/L) 01/02/92  GAMMA GT 4-18 (UI/L) 01/02/92  ALK. PHOSPH. 20-48 (MU/ML) 01/02/92  ALK. PHOSPH. 20-48 (MU/ML) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  CREATININE 0.5-1.4 (MG/DL) 01/02/92  TOT BILIRUBIN 0-0.3 (MG/DL) 01/02/92  TOT PROTEINS 6.3-8 (G/DL) 01/02/92  ALBUMINE 10-240 (MG/DL) 01/02/92  ALBUMINE 10-240 (MG/DL) 01/02/92  GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92  GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92	Day 56	6
Laboratory test Range value Range date HB 12.5-15 (G/DL) 01/02/92 HT 38-43 (X) 01/02/92 RBC 4000000-4500000 01/02/92 78 RBC 4000000-4500000 01/02/92 78 RBC (/MH3) 01/02/92 78 RBC: 5000-9000 (/MH3) 01/02/92 78 RBC: N 50-65 (X) 01/02/92 79 RBC: L 30-40 (X) 01/02/92 RBC: E 0-3 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: CBC (/MH3) NA+ 130-150 (MEQ/L) 01/02/92 (/MH3) NA+ 130-150 (MEQ/L) 01/02/92 RBC: HBC: B 0-1 (X) 01/02/92 RBC: MBC: MBC: MBC: MBC: MBC: MBC: MBC: M	25/08/9	92
HB 12.5-15 (G/DL) 01/02/92 HT 38-43 (X) 01/02/92 HT 38-43 (X) 01/02/92 HRC 4000000-4500000 01/02/92 HBC: 4000000-4500000 01/02/92 HBC: 5000-9000 (/MM3) 01/02/92 HBC: N 50-65 (X) 01/02/92 HBC: L 30-40 (X) 01/02/92 HBC: E 0-3 (X) 01/02/92 HBC: B 0-1 (X) 01/02/92 HBC: B 0-1 (X) 01/02/92 HBC: B 0-1 (X) 01/02/92 HBC: B 0-1 (X) 01/02/92 HBC: B 0-1 (X) 01/02/92 C/MM3) NA+ 130-150 (MEQ/L) 01/02/92 C/MM3 NA+ 35 (MEQ/L) 01/02/92 CL- 95-105 (MEQ/L) 01/02/92 CL- 95-105 (MEQ/L) 01/02/92 SGDT 0-12 (HU/ML) 01/02/92 SGDT 0-12 (HU/ML) 01/02/92 SGPT 0-12 (HU/ML) 01/02/92 GAMMA GT 4-18 (UI/L) 01/02/92 GAMMA GT 4-18 (UI/L) 01/02/92 UREA 15-40 (MG/DL) 01/02/92 UREA 15-40 (MG/DL) 01/02/92 UREA 15-40 (MG/DL) 01/02/92 UREA 15-40 (MG/DL) 01/02/92 URIC ACID 0-1.4 (MG/DL) 01/02/92 URIC ACID 0-3 (MG/DL) 01/02/92 URIT OT BILIRUBIN 0-0.3 (MG/DL) 01/02/92 URIT OT SHILIRUBIN 0-0.3 (MG/DL) 01/02/92 URIT OT SHILIRUBIN 0-0.3 (MG/DL) 01/02/92 URIT OT CHOLEST 160-240 (MG/DL) 01/02/92 TOT SHILIRUBIN 0-0.3 (MG/DL) 01/02/92 TOT CHOLEST 160-240 (MG/DL) 01/02/92 TTOT CHOLEST 160-240 (MG/DL) 01/02/92 URIC ACID 0-1-03 (MG/DL) 01/02/92 URIC ACID 0-1-03 (MG/DL) 01/02/92 TTOT CHOLEST 160-240 (MG/DL) 01/02/92 URIC ACID 0-1-03 (MG/DL) 01/02/92 URIC ACID 0-1-03 (MG/DL) 01/02/92 URIC ACID 0-1-03 (MG/DL) 01/02/92 URIC ACID 0-1-03 (MG/DL) 01/02/92 URIC ACID 0-1-03 (MG/DL) 01/02/92 URIC ACID 0-1-03 (MG/DL) 01/02/92 URIC ACID 0-1-03 (MG/DL) 01/02/92 URIC ACID 0-1-03 (MG/DL) 01/02/92 URIC ACID 0-1-03 (MG/DL) 01/02/92 URIC ACID 0-1-03 (MG/DL) 01/02/92	value	(6
HT 38-43 (X) 01/02/92 RBC 400000-4500000 01/02/92 (/MH3) HBC 5000-9000 (/MH3) 01/02/92 RBC: N 50-65 (X) 01/02/92 RBC: L 30-40 (X) 01/02/92 RBC: L 30-40 (X) 01/02/92 RBC: E 0-3 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 CMHBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBC: B 0-1 (X) 01/02/92 RBCE: B 0-1 (X) 01/02/92 RBCE: B 0-1 (X) 01/02/92 RBCE: B 0-1 (X) 01/02/92 RBCE		
REC	13.00	
RBC	40.00	
MBC 5000-9000 (/MH3) 01/02/92 7 MBC: N 50-65 (X) 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92	<b> </b>	l
MBC: N 50-55 (X) 01/02/92 MBC: L 30-40 (X) 01/02/92 MBC: L 30-40 (X) 01/02/92 MBC: E 0-3 (X) 01/02/92 MBC: M 0-5 (X) 01/02/92 MBC: M 0-5 (X) 01/02/92 MBC: M 0-5 (X) 01/02/92 MBC: M 0-5 (X) 01/02/92 MBC: M 0-5 (X) 01/02/92 MBC: M 0-5 (X) 01/02/92 MBC: M 0-5 (X) 01/02/92 MBC: M 0-5 (X) 01/02/92 MBC: M 0-5 (MEQ/L) 01/02/92 MBC: M 0-10 (MEQ/L) 01/02/92 MBC: M 0-10 (MEQ/L) 01/02/92 MBC: M 0-10 (MEQ/L) 01/02/92 MBC: M 0-12 (MU/ML) 01/02/92 MBC: M 0-12 (MU/ML) 01/02/92 MBC: M 0-12 (MU/ML) 01/02/92 MBC: M 0-12 (MU/ML) 01/02/92 MBC: M 0-12 (MU/ML) 01/02/92 MBC: M 0-12 (MU/ML) 01/02/92 MBC: M 0-12 (MU/ML) 01/02/92 MBC: M 0-12 (MU/ML) 01/02/92 MBC: M 0-12 (MU/ML) 01/02/92 MBC: M 0-12 (MU/ML) 01/02/92 MBC: M 0-12 (MU/ML) 01/02/92 MBC: M 0-12 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: M 0-10 (MBC/DL) 01/02/92 MBC: MBC: M 0-10 (MBC/DL) 01/02/92 MBC: MBC: MBC: MBC: MBC: MBC: MBC: MBC:	4400000	
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(/MM3)  NA+	0.00	
(/MM3)  NA+ 130-150 (MEQ/L) 01/02/92  K+ 3-5 (MEQ/L) 01/02/92  CL- 95-105 (MEQ/L) 01/02/92  CL- 95-105 (MEQ/L) 01/02/92  CL- 95-105 (MEQ/L) 01/02/92  SGOT 0-12 (MU/ML) 01/02/92  SGOT 0-12 (MU/ML) 01/02/92  SGOT 0-12 (MU/ML) 01/02/92  GAMMA GT 4-18 (UI/L) 01/02/92  GAMMA GT 4-18 (UI/L) 01/02/92  GAMMA GT 4-18 (UI/L) 01/02/92  GAMMA GT 4-18 (UI/L) 01/02/92  GAMMA GT 4-18 (UI/L) 01/02/92  GAMMA GT 4-18 (UI/L) 01/02/92  GAMMA GT 4-18 (UI/L) 01/02/92  UNECA 15-0-10 (MG/DL) 01/02/92  UNECA 15-40 (MG/DL) 01/02/92  UNECA CID 2.4-5.7 (MS/DL) 01/02/92  UNETC ACID 0-1.4 (MG/DL) 01/02/92  UNETC ACID 0-1.4 (MG/DL) 01/02/92  UNETC ACID 0-3 (MG/DL) 01/02/92  TOT SILIRUBIN 0-0.3 (MG/DL) 01/02/92  TOT SHIRUBIN 0-0.3 (MG/DL) 01/02/92  TOT. PROTEINS 6.3-8 (G/DL) 01/02/92  ALBUNINE 3.8-5 (G/DL) 01/02/92  TOT. CHOLEST. 160-240 (MG/DL) 01/02/92  TOT. CHOLEST. 30-150 (MG/DL) 01/02/92  GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92  GLOBULINS ALPHA 2 0.4-5-0.75 (G/DL) 01/02/92		
X+   3-5 (MEQ/L)	290000	
N-	139.00	
CL- Ca++ B5-105 (MEQ/L) Ca++ B.1-10.4 (HG/DL) C1/02/92 P04 2.5-5 (MG/DL) C1/02/92 SGOT C-12 (HU/ML) C5PT C4-18 (UT/L) C1/02/92 C4-18 (UT/L) C1/02/92 C4-18 (UT/L) C1/02/92 C4-18 (UT/L) C1/02/92 C4-18 (UT/L) C1/02/92 C4-18 (UT/L) C1/02/92 C4-18 (UT/L) C1/02/92 C4-18 (UT/L) C1/02/92 C4-19 (UT/L) C1/02/92 C4-10 (UT/L) C1/02/92 C4-10 (UT/L) C1/02/92 C4-10 (UT/L) C1/02/92 C4-10 (UT/L) C1/02/92 C4-10 (UT/L) C1/02/92 C4-10 (UT/L) C1/02/92 C4-10 (UT/L) C1/02/92 C4-10 (UT/L) C1/02/92 C4-10 (UT/L) C1/02/92 C4-10 (UT/L) C1/02/92 C4-10 (UT/L) C1/02/92 C4-10 (UT/L) C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92 C1/02/92	4,30	
Ca++ 8.1-10.4 (MG/DL) 01/02/92 PD4 2.5-5 (MG/DL) 01/02/92 SGOT 0-12 (MU/ML) 01/02/92 SGOT 0-12 (MU/ML) 01/02/92 SGPT 0-12 (MU/ML) 01/02/92 GAMMA GT 4-18 (UL/L) 01/02/92 LDH 120-240 (UL/L) 01/02/92 GLUCOSE 70-110 (MG/DL) 01/02/92 UNEA 15-40 (MG/DL) 01/02/92 UNEA 15-40 (MG/DL) 01/02/92 UNEA 15-40 (MG/DL) 01/02/92 UNEC ACID 2.4-5.7 (MG/DL) 01/02/92 UNIC ACID 0-1 (MG/DL) 01/02/92 UNIC ACID 0-1 (MG/DL) 01/02/92 UNIC ACID 0-1 (MG/DL) 01/02/92 TOT BILIRUBIN 0-1 (MG/DL) 01/02/92 TOT BILIRUBIN 0-3.8 (G/DL) 01/02/92 TOT. PROTEINS 6.3-8 (G/DL) 01/02/92 ALBUMINE 3.8-5 (G/DL) 01/02/92 TOT. CHOLEST. 160-240 (MG/DL) 01/02/92 TOT. CHOLEST. 30-150 (MG/DL) 01/02/92 GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92 GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	102.00	
PO4 2.5-5 (MG/DL) 01/02/92 SGOT 0-12 (MU/ML) 01/02/92 SGOT 0-12 (MU/ML) 01/02/92 GAMMA GT 4-18 (UI/L) 01/02/92 LDH 120-240 (UI/L) 01/02/92 ALK. PHOSPH. 20-48 (MU/ML) 01/02/92 ALK. PHOSPH. 20-48 (MU/ML) 01/02/92 UNEA 15-40 (MG/DL) 01/02/92 UNEA 15-40 (MG/DL) 01/02/92 UNIC ACID 2.4-5.7 (MG/DL) 01/02/92 UNIC ACID 0-1.4 (MG/DL) 01/02/92 UNIC ACID 0-1.4 (MG/DL) 01/02/92 TOT BILIRUBIN 0-1 (MG/DL) 01/02/92 TOT BILIRUBIN 0-0.3 (MG/DL) 01/02/92 ALBUMINE 3.8-5 (G/DL) 01/02/92 ALBUMINE 3.8-5 (G/DL) 01/02/92 TOT. CHOLEST. 160-240 (MG/DL) 01/02/92 TOT. CHOLEST. 160-240 (MG/DL) 01/02/92 GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92 GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92 GLOBULINS ALPHA 2 0.48-0.75 (G/DL) 01/02/92	9.00	
SOOT	4.20	
SCET 0-12 (HU/ML) 01/02/92 GAMMA GT 4-18 (UI/L) 01/02/92 LDH 120-240 (UI/L) 01/02/92 ALK. PHOSPH. 20-48 (HU/ML) 01/02/92 GLUCOSE 70-110 (MG/DL) 01/02/92 UREA 15-40 (HG/DL) 01/02/92 UREA 15-40 (HG/DL) 01/02/92 URIC ACID 0.5-1.4 (MG/DL) 01/02/92 URIC ACID 0.5-1.4 (MG/DL) 01/02/92 URIC ACID 0-1 (MG/DL) 01/02/92 DIR BILIRUBIN 0-1 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-1 (MG/DL) 01/02/92 TOT. PROTEINS 6.3-8 (G/DL) 01/02/92 ALBUMINE 3.8-5 (G/DL) 01/02/92 TOT. CHOLEST. 160-240 (MG/DL) 01/02/92 TOT. CHOLEST. 30-150 (MG/DL) 01/02/92 GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92 GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	6.00	
GAMMA GT 4-1B (UI/L) 01/02/92 LDH 120-240 (UI/L) 01/02/92 ALK. PHOSPH. 20-48 (MU/ML) 01/02/92 GLUCOSE 70-110 (MG/DL) 01/02/92 UNEA 15-40 (MG/DL) 01/02/92 UNEA 15-40 (MG/DL) 01/02/92 UNETC ACID 2.4-5.7 (MG/DL) 01/02/92 UNIC ACID 2.4-5.7 (MG/DL) 01/02/92 UNIC ACID 01.6/DL) 01/02/92 TOT BILIRUBIN 0-1 (MG/DL) 01/02/92 TOT. PROTEINS 6.3-8 (G/DL) 01/02/92 ALBUMINE 3.8-5 (G/DL) 01/02/92 TOT. CHOLEST. 160-240 (MG/DL) 01/02/92 TTIGLYCERIDES 30-150 (MG/DL) 01/02/92 GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92 GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	7.00	
TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST.   TOT. CHOLEST	13.00	
ALK. PHOSPH. 20-46 (MU/HL) 01/02/92 GLUCOSE 70-110 (MG/DL) 01/02/92 UREA 15-40 (MG/DL) 01/02/92 URICA ACID 2.4-5.7 (MG/DL) 01/02/92 URICA ACID 2.4-5.7 (MG/DL) 01/02/92 URICA ACID 01-1 (MG/DL) 01/02/92 URICA ACID 01-1 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 6.3-8 (G/DL) 01/02/92 TOT. PROTEINS 6.3-8 (G/DL) 01/02/92 TOT. CHOLEST. 160-240 (MG/DL) 01/02/92 TOT. CHOLEST. 160-240 (MG/DL) 01/02/92 TRIGLYCERIDES 30-150 (MG/DL) 01/02/92 GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92 GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	155.00	
GLUCOSE 70-110 (MG/DL) 01/02/92 UREA 15-40 (MG/DL) 01/02/92 UREA 15-40 (MG/DL) 01/02/92 URIC ACID 2.4-5.7 (MG/DL) 01/02/92 URIC ACID 2.4-5.7 (MG/DL) 01/02/92 URIC ACID 0-1 (MG/DL) 01/02/92 URI BILIRUBIN 0-1 (MG/DL) 01/02/92 URI BILIRUBIN 0-0.3 (MG/DL) 01/02/92 TOT. PROTEINS 6.3-8 (G/DL) 01/02/92 ALBUMINE 3.8-5 (G/DL) 01/02/92 TOT. CHOLEST. 160-240 (MG/DL) 01/02/92 TRIGLYCERIDES 30-150 (MG/DL) 01/02/92 GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92 GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	39.00	
UREA 15-40 (HG/DL) 01/02/92  CREATININE 0.5-1.4 (NG/DL) 01/02/92  URIC ACID 0.5-1.4 (NG/DL) 01/02/92  URIC ACID 0.1-02/92  TOT BILIRUBIN 0-1 (NG/DL) 01/02/92  DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92  TOT. PROTEINS 6.3-8 (G/DL) 01/02/92  ALBUMINE 3.8-5 (G/DL) 01/02/92  TOT. CHOLEST. 160-240 (MG/DL) 01/02/92  TRIGLYCERIDES 30-150 (MG/DL) 01/02/92  GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92  GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	70.00	
CREATININE 0.5-1.4 (MG/DL) 01/02/92 URIC ACID 2.4-5.7 (MG/DL) 01/02/92 URIC ACID 0-1 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 0-1/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 0-1/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 0-1/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 0-1/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 0-1/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 0-1/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 0-1/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 0-1/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 0-1/02/92 DIR BILIRUB	31.00	
URIC ACID  URIC ACID  2.4-5.7 (MG/DL) 01/02/92  TOT BILIRUBIN 0-1 (MG/DL) 01/02/92  DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92  TOT. PROTEINS 6.3-8 (G/DL) 01/02/92  ALBUMINE 3.8-5 (G/DL) 01/02/92  TOT. CHOLEST. 160-240 (MG/DL) 01/02/92  TRIGLYCERIDES 30-150 (MG/DL) 01/02/92  GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92  GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	0.95	
TOT BILIRUBIN 0-1 (MG/DL) 01/02/92 DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 TOT. PROTEINS 6.3-8 (G/DL) 01/02/92 ALBUMINE 3.8-5 (G/DL) 01/02/92 TOT. CHOLEST. 160-240 (MG/DL) 01/02/92 TRIGLYCERIDES 30-150 (MG/DL) 01/02/92 GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92 GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	3.90	
DIR BILIRUBIN 0-0.3 (MG/DL) 01/02/92 TOT. PROTEINS 6.3-8 (G/DL) 01/02/92 ALBUMINE 3.8-5 (G/DL) 01/02/92 TOT. CHOLEST. 160-240 (MG/DL) 01/02/92 TRIGLYCERIDES 30-150 (MG/DL) 01/02/92 GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92 GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	0.60	
TOT. PROTEINS 6.3-8 (G/DL) 01/02/92 ALBUMINE 3.8-5 (G/DL) 01/02/92 TOT. CHOLEST. 160-240 (MG/DL) 01/02/92 TRIGLYCERIDES 30-150 (MG/DL) 01/02/92 GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92 GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	0.20	
ALBUMINE 3.8-5 (G/DL) 01/02/92 TOT. CHOLEST. 160-240 (M6/DL) 01/02/92 TRIGLYCERIDES 30-150 (MG/DL) 01/02/92 GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92 GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	6.65	l
TOT. CHOLEST. 160-240 (MG/DL) 01/02/92 TRIGLYCERIDES 30-150 (MG/DL) 01/02/92 GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92 GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	3.65	<
TRIGLYCERIDES 30-150 (MG/DL) 01/02/92 GLOBULINS ALPHA 1 0.1-0.3 (G/DL) 01/02/92 GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	240.00	1
GLOBULINS ALPHA 1 0.4-0.3 (G/DL) 01/02/92 GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	90.00	
GLOBULINS ALPHA 2 0.45-0.75 (G/DL) 01/02/92	0.20	
	0.65	l
	0.85	l
GLOBULINS BETA 0.6-1 (G/DL) 01/02/92 GLOBULINS GAMMA 0.8-1.3 (G/DL) 01/02/92	1.30	l

1013

>> clinically relevant (value higher than max range > out of range (value higher than max range () missing range value

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#### PHARMACIA PHARMACEUTIONS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 442 Treatment: Reboxetine Sex: Female

			Visit	num	ber / Lai	bora	tory date	0
			Scree	a	Day 2	8	Day 5	6
			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	ļ	14.00	
HT	38-43 (%)	01/02/92	41.00		42.00		44.00	>
RBC	4000000-4500000	01/02/92	i			1		ĺ
	(/MM3)		4510000	>	4620000	>	4840000	>
MBC	5000-9000 (/MM3)	01/02/92	7000.00	ĺ	6700.00		6500.00	
MBC: N	50-65 (%)	01/02/92	65.00	1	62.00		63.00	l
MBC: L	30-40 (%)	01/02/92	32.00	ŀ	38.00	l	32.00	l
NBC: E	0-3 (%)	01/02/92	2.00		0.00		2.00	
NBC: M	0-5 (%)	01/02/92	1.00		0.00		3.00	
MBC: N	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000	01/02/92	****					
PLAIELEIS	(/MM3)	01/02/32	210000		230000		270000	
	130-150 (MEQ/L)	01/02/92	142.00		143.00		145.00	
NA+	3-5 (MEQ/L)	01/02/92	4.00		4.00		4.80	
K+		01/02/92	101.00		98.00		100.00	
CL-	95-105 (MEQ/L)	01/02/92	10.00		9.80		9.00	l
Ca++	8.1-10.4 (MG/DL)	01/02/92	4.10		3.80		4.50	
P04	2.5-5 (MG/DL)	01/02/92	6.00		7.00		7.00	
SGOT	0-12 (MU/ML)		8.00		7.00		8.00	Į.
SGPT	0-12 (MU/ML)	01/02/92	12.00		10.00		10.00	
GANNA GT	4-18 (UI/L)	01/02/92					145.00	
LDH	120-240 (UI/L)	01/02/92	144.00		138.00 28.00		30.00	l
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	22.00		77.00		90.00	l
GLUCOSE	70-110 (MG/DL)	01/02/92	97.00					l
UREA	15-40 (MG/DL)	01/02/92	28.00		21.00		38.00	l
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 (KG/DL)	01/02/92	0.55		0.65		0.55	
OIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.15		0.25		0.25	
rot. 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	1
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	205.00		207.00		210.00	
TRIGLYCERIDES	30-150 (NG/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	1
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	l
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.35	>	1.40	>	1.35	>
TSH	0-5 (UUI/NL)	01/02/92	1.02					l
T4	4.5-13 (UG/DL)	01/02/92	6.40		l			ı

1014

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIGASSUTORS - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 444 Treatment: Reboxetine Sex: Female

			Visit	num	ber / La	bora	tory date	B
			Scree	1	Day 2	В	Day 5	6
			20/08/	92	21/09/	92	19/10/	92
			value	(4)	value	(¢)	value	(¢
Laboratory test	Range value	Range date		·				
НВ	12.5-15 (G/DL)	01/02/92	13.00	1	13.20		13.00	İ
HT	38-43 (%)	01/02/92	42.00		43.00		41.00	
RBC	4000000-4500000	01/02/92		[			1	ł
RDC	(/MM3)	• • • • • • • • • • • • • • • • • • • •	4620000	>	4730000	>	4510000	>
NBC	5000-9000 (/MM3)	01/02/92	7000.00		7100.00		6800.00	1
MBC: N	50-65 (%)	01/02/92	62.00		61.00	1	61.00	
MBC: L	30-40 (%)	01/02/92	38.00		39.00		39.00	1
NBC: E	0-3 (%)	01/02/92	0.00	1	0.00	l	0.00	
	0-5 (%)	01/02/92	0.00	l	0.00		0.00	i
NBC: M NBC: B	0-1 (%)	01/02/92	0.00		0.00	1	0.00	ı
MBC: B PLATELETS	150000-300000	01/02/92	7.55			İ		l
PLATELEIS	(/MM3)	01.02.72	270000		265000		280000	
	130-150 (NEO/L)	01/02/92	144.00		139.00		140.00	l
NA+	3-5 (MEQ/L)	01/02/92	4.80	İ	4.00		4.00	l
K+	95-105 (MEQ/L)	01/02/92	102.00	l	98.00		101.00	l
CL-		01/02/92	9.20		10.00		9.80	l
Ca++	8.1-10.4 (MG/DL)	01/02/92	4.00		4.00		3.80	
P04	2.5-5 (MG/DL)		6.00		8.00		7.00	1
SGOT	0-12 (MU/ML)	01/02/92	8.00		8.00	İ	8.00	1
SGPT	0-12 (MU/NL)	01/02/92	12.00	1	8.00	l	8.00	
gamma GT	4-18 (UI/L)	01/02/92				1	165.00	
LDH	120-240 (UI/L)	01/02/92	155.00		180.00			1
ALK, PHOSPH.	20-48 (MU/ML)	01/02/92	35.00	i	25.00	1	31.00 80.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	81.00		85.00			
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	1	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				l	
T4	4.5-13 (UG/DL)	01/02/92	8.00	l		l	l	ı

1015

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range) (value lower wissing laboratory test value of laboratory not done

>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### РНАВИАСІА РНАВИАСЕЦТВОЗБОНАВО - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 445 Treatment: Reboxetine Sex: Male

			Visit	num	ber / La	bora	tory det	8
			Screen	n	Day 2	B	Day 5	6
			12/09/	92	15/10/	92	12/11/	92
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
нв	13.5-15.5 (G/DL)	01/02/92	15.00		14.50	l	15.00	
HT	40-45 (%)	01/02/92	48.00	>	47.00	>	49.00	>
RBC	4200000-4800000	01/02/92				l		
	(/MM3)		5280000	>	5180000	>	5500000	>
MBC	5000-9000 (/MM3)	01/02/92	6800.00		7000.00		7100.00	
MBC: N	50~65 (X)	01/02/92	70.00	>	69.00	>	60.00	l
BC: L	30-40 (%)	01/02/92	30.00		29.00	۲ ا	38.00	
HBC: E	0-3 (X)	01/02/92	0.00		2.00		2.00	
IBC: M	0-5 (%)	01/02/92	0.00		1.00		0.00	
HBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
LATELETS	150000-300000	01/02/92						
	(/MM3)		270000		220000		290000	
iA+	130-150 (MEQ/L)	01/02/92	144.00		144.00		144.00	
<b>(</b> +	3-5 (NEQ/L)	01/02/92	3.50		4.80		4.50	
CL-	95-105 (MEQ/L)	01/02/92	98.00		100.00		102.00	
a++	8.1-10.4 (MG/DL)	01/02/92	9.00		10.00		10.20	
04	2.5-5 (MG/DL)	01/02/92	4.50		3.90		4.50	
GOT	0-12 (MU/ML)	01/02/92	6.00		6.00		7.00	
GPT	0-12 (MU/HL)	01/02/92	8.00		8.00		9.00	
ANNA GT	6-28 (UI/L)	01/02/92	12.00		12.00		10.00	
.DH	120-240 (UI/L)	01/02/92	144.00		166.00		145.00	
LK. PHOSPH.	20-48 (NU/ML)	01/02/92	32.00	- 1			33.00	
LUCOSE	70-110 (MG/DL)	01/02/92	75.00		92.00		101.00	
REA	15-40 (MG/DL)	01/02/92	33.00	į	30.00		30.00	
REATININE	0.5-1.4 (MG/DL)	01/02/92	0.90		1.10	- 1	1.00	
RIC ACID	3.4-7 (MG/DL)	01/02/92	4.00		4.00		4.00	
OT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.70		0,65		0.60	
IR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20		0.15		0.20	
OT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.25	- 1	7.35		7.20	
LBUMINE	3.8-5 (G/DL)	01/02/92	4.00	1	4.25		4.20	
OT. CHOLEST.	160-240 (MG/DL)	01/02/92	230.00	i	245.00	>	235,00	
RIGLYCERIDES	30-150 (MG/DL)	01/02/92	100.00		105.00		105.00	
LOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20	l	0.20	- 1	0.20	
LOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.80	>	0.65		0.60	
LOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.95	- 1	0.85		0.75	
LOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.30	j	1.40	>	1,45	>
SK	0-5 (UUI/ML)	01/02/92	0.95	- 1				
4	4.5-13 (UG/DL)	01/02/92	6.40	- 1		- 1		

1016

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range)
> out of range (value higher than max range)
() missing range value

#### PHARMACIA PHARMACEUTICAS NICHOS - CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Contro: 16 Patient: 448 Treatment: Reboxetine Sex: Female

			Visit	numi	ber / Lai	oora'	tory date	0
			Screen	1	Day 2	В	Day 5	6
			14/09/	92	16/10/	92	13/11/	92
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date						
НВ	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	01/02/92						
ILDU	(/MM3)		4510000	>	4730000	>	4510000	>
MBC	5000-9000 (/MM3)	01/02/92	7000.00		6900.00	l	6500.00	
NBC: N	50-65 (%)	01/02/92	62.00		70.00	>	68.00	>
MBC: L	30-40 (%)	01/02/92	36.00		28.00	<	30.00	l
MBC: E	0-3 (%)	01/02/92	0.00		0.00		2.00	
MBC: M	0-5 (%)	01/02/92	2.00		2.00	l	0.00	l
MBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	1
PLATELETS	150000-300000	01/02/92						1
LUMIETERS	(/MM3)	01,02,72	270000		260000	ŀ	255000	
	130-150 (MEQ/L)	01/02/92	144.00		149.00		147.00	
NA+	3-5 (MEQ/L)	01/02/92	4.00		4.80	l	4.70	1
K+		01/02/92	98.00		101.00		100.00	ļ į
CL-	95-105 (MEQ/L)		9.50		8.90		9.00	l
Ca++	8.1-10.4 (MG/DL)	01/02/92	4.00		4.10		4.20	l
P04	2.5-5 (MG/DL)	01/02/92	7.00		8.00		7.00	l
SGOT	0-12 (NU/NL)	01/02/92			9.00		7.00	l
SGPT	0-12 (MU/ML)	01/02/92	8.00				9.00	l
GAMMA GT	4-18 (UI/L)	01/02/92	7.00		9.00			l
LDH	120-240 (UI/L)	01/02/92	144.00		155.00		160.00	l
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	32.00		39.00		38.00	l
GLUCOSE	70-110 (MG/DL)	01/02/92	90.00		101.00		98.00	1
UREA	15-40 (MG/DL)	01/02/92	35.00		38.00		32.00	l
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.05		1.00		0.98	l
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	4.00		3,80		3.90	ı
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	l
TOT. PROTEINS	6,3-8 (G/DL)	01/02/92	6.95		6.95		7.20	l
ALBUMINE	3.8-5 (G/DL)	01/02/92	4.00		3.90		4.05	1
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	195.00		205.00		210.00	l
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	98.00		105.00	l	110.00	l
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.25		0.20	
GLOBULING ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.60		0.65	1	0.70	1
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.75		0.80	1	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	Ì		l	l	l
T4	4.5-13 (UG/DL)	01/02/92	7.50		l	ı	1	ı

<sup>(¢) &</sup>lt;< clinically relevant (value lower cout of range (value lower than min range) than min range) (value lower missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range to aut of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTIGALSHIPANG - CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 456 Treatment: Reboxetine Sex: Male

			Visit	num	ber / Lai	bora	tory date	0
			Scree	n	Day 2	8	Day 5	6
			09/12/	92	12/01/	93	09/02/	93
			value	(¢)	value	(4)	value	(¢
Laboratory test	Range value	Range date						
КВ	13.5-15.5 (G/DL)	01/02/92	15.00		14.50		14.70	l
HT	40-45 (%)	01/02/92	46.00	>	44.00		45.00	l
RBC	4200000-4800000	01/02/92		İ	I	1		l
NDC	(/MM3)		5060000	>	4840000	>	4950000	>
MBC	5000-9000 (/MM3)	01/02/92	6800.00	1	7900.00		7200.00	l
MBC: N	50-65 (%)	01/02/92	63.00	1	62.00	1	60.00	
MBC: L	30-40 (%)	01/02/92	34.00		34.00	1	38.00	
MBC: E	0-3 (%)	01/02/92	2.00		3.00	l	0.00	1
NBC: M	0-5 (%)	01/02/92	1.00		1.00	1	2.00	l
MBC: B	0-1 (%)	01/02/92	0.00		0.00	1	0.00	ı
PLATELETS	150000-300000	01/02/92				1		1
211122222	(/MM3)		265000		230000		225000	l
NA+	130-150 (MEQ/L)	01/02/92	139.00		141.00	1	139.00	
K+	3-5 (MEQ/L)	01/02/92	4.10		4.10	1	3.80	1
CL-	95-105 (MEQ/L)	01/02/92	92.00	<	100.00	1	99.00	1
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.20		9.30	1	9,50	]
P04	2.5-5 (MG/DL)	01/02/92	3.80		3.80		4.00	1
SGOT	0-12 (MU/ML)	01/02/92	8.00		6.00	1	8.00	
SGPT	0-12 (MU/NL)	01/02/92	9.00		4.00		5.00	1
GAMMA GT	6-28 (UI/L)	01/02/92	10.00		8.00	1	9.00	l
LDH	120-240 (UI/L)	01/02/92	190.00		185.00		190.00	1
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	38.00		38,00		32.00	1
GLUCOSE	70-110 (MG/DL)	01/02/92	85.00		92.00	1	86.00	
UREA	15-40 (MG/DL)	01/02/92	24.00		36.00	1	35.00	1
CREATININE	0.5-1.4 (MG/DL)	01/02/92	0.85		1.10		0.98	1
URIC ACID	3.4-7 (MG/DL)	01/02/92	6.20		5.40	ł	5.20	I
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.65		0.85	l	0.80	1
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.15		0.15		0.10	1
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	l
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	232.00		201.00	l l	194.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	92.00		94.00	ı	78.00	l
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.30		0.25		0.20	l
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.65		0.65	1	0.70	l
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.85		0.77		0.80	Į .
GLOBULING BETA 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					1
	4.5-13 (UG/DL)	01/02/92	10.42	1		1		1
T4	4.0.19 (00,00)	U VU. 7M		l	1	I	L	<u></u>

<sup>(</sup>c) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAS 5185648 - CMS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Cantre: 16 Patient: 459 Treatment: Reboxetine Sex: Hale

****			Visit	num	ber / Lai	bora.	tory dat	0
			Scree	n	Day 2	В	Day 5	6
			17/12/	92	18/01/9	93	15/02/9	93
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
НВ	13.5-15.5 (G/DL)	01/02/92	14.00	1	14.50	Į	14.00	
HT	40-45 (%)	01/02/92	45.00	l	44.00		43.00	
RBC	4200000-4800000	01/02/92						
	(/MM3)		4950000	>	4840000	>	4730000	
MBC	5000-9000 (/MM3)	01/02/92	6700.00	1	7200.00	1	7400.00	
WBC: N	50-65 (%)	01/02/92	62.00		63.00		65.00	l
WBC: L	30-40 (%)	01/02/92	38.00		37.00	1	32.00	l
WBC: E	0-3 (%)	01/02/92	0.00		0.00		2.00	
MBC: M	0-5 (%)	01/02/92	0.00		0.00		1.00	
NBC: B	0-1 (%)	01/02/92	0.00	1	0.00		0.00	ŀ
PLATELETS	150000-300000	01/02/92		l				
	(/MM3)		270000		260000		265000	
NA+	130-150 (MEQ/L)	01/02/92	144.00		142.00		143.00	
K+	3-5 (NEQ/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	}
P04	2.5-5 (MG/DL)	01/02/92	3.50		3.90		4.10	
SGOT	0-12 (MU/NL)	01/02/92	6.00		8.00		9.00	İ
	0-12 (MU/NL)	01/02/92	7.00		5.00	l	6.00	
SGPT	6-28 (UI/L)	01/02/92	12.00		11.00		10.00	1
GANNA GT		01/02/92	144.00		158.00		191.00	
LDH	120-240 (UI/L)	01/02/92	30.00		34.00		33.00	Ī
ALK. PHOSPH.	20-48 (MU/ML)		98.00		100.00		94.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	26.00		32.00		30.00	1
UREA	15-40 (MG/DL)	01/02/92	0.90		0.85		0.90	
CREATININE	0.5-1.4 (MG/DL)	01/02/92			5.40		5.10	
URIC ACID	3.4-7 (MG/DL)	01/02/92	5.00		0.65		0.70	
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 7.10		7.18		7.15	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	4.00		4 10		4.05	ł
ALBUMINE	3.8-5 (G/DL)	01/02/92						
TOT, CHOLEST.	160-240 (MG/DL)	01/02/92	205.00	ĺ	215.00	ĺ	205.00 115.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	100.00		105.00	l		l
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20	l	0.20	1	0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.65	1	0.68	1	0.70	ļ
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.85	ł	0.85	١.	0.85	l
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		l		l	l
T4	4.5-13 (UG/DL)	01/02/92	8.00	l	l	l	I	I

<sup>(¢) &</sup>lt;< clinically relevant (value lower than min range)
< out of range (value lower than min range)
\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTECHS HUMB - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 460 Treatment: Reboxetine Sex: Male

			Visit	numi	ber / Lai	bora	tory date	8
			Scree	n	Day 2	В	Day 5	6
			17/12/9	92	18/01/	93	15/02/	93
			value	(4)	value	(¢)	value	(¢:
Laboratory test	Range value	Range date						
iB	13.5-15.5 (G/DL)	01/02/92	15.00		15.10		14.80	1
HT .	40-45 (%)	01/02/92	47.00	>	46.00	>	45.00	l
RBC	4200000-4800000	01/02/92		l				1
ADC.	(/MM3)		5170000	>	5060000	>	4950000	>
KBC	5000-9000 (/MM3)	01/02/92	6800.00	1	7100.00		7500.00	
MBC: N	50-65 (%)	01/02/92	72.00	>	70.00	>	66.00	>
MBC: L	30-40 (%)	01/02/92		<	26.00	<	30.00	l
MBC: E	0-3 (%)	01/02/92	0.00		0.00	ĺ	3.00	l
NBC: E	0-5 (%)	01/02/92	0.00		4.00	l	1.00	l
MBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000	01/02/92	****	İ				
PLATELLIA	(/MM3)	01/02/32	250000		245000		235000	
NA+	130-150 (MEQ/L)	01/02/92	145.00		144.00		140.00	
NAT K+	3-5 (MEQ/L)	01/02/92	4.10		4.20		4.10	
K+ CG-	95-105 (MEQ/L)	01/02/92	105.00	i	103.00		100.00	
	8.1-10.4 (NG/DL)	01/02/92	10.10		9.80		9.50	
Ca++	2.5-5 (MG/DL)	01/02/92	3.30		3.90		3.70	
P04		01/02/92	5.00		7.00		6.00	
SGOT	0-12 (MU/ML)		8.00		6.00	l	4.00	
SGPT	0-12 (NU/NL)	01/02/92 01/02/92	11.00		10.00		9.00	l
GAMMA GT	6-28 (UI/L)		148.00		155.00		180.00	
LDH	120-240 (UI/L)	01/02/92	39.00		37.00	l	35.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	101.00		100.00	!	90.00	
GLUCOSE	70-110 (MG/DL)	01/02/92			36.00	ŀ	35.00	
JREA	15-40 (MG/DL)	01/02/92	31.00			{	0.90	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	0.95		0.85		5.00	1
URIC ACID	3.4-7 (MG/DL)	01/02/92	5.10		5.20			ĺ
COT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.65		0.60		0.50	1
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	1
ALBUMINE	3.8-5 (G/DL)	01/02/92	4.10		4.05		4.00	
POT. 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	1	0.20	1
CLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.70		0.72		0.70	
CLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.80		0.82	1	0.80	}
CLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.35	>	1.35	>	1.40	>
CSH	0-5 (UUI/ML)	01/02/92	1.50	'	1	ĺ		l
r4	4.5-13 (UG/DL)	01/02/92	8.10		l	ı	I	1

1020

>> clinically relevant (value higher than max range to missing range value)

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#### PHARMACIA PHARMACEUTIGAS 5 TO CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 26 Treatment; Reboxetine Sex: Female

			Visit	num	ber / La	bora	tory date	e
			Scree	1	Day 2	8	Day 5	6
			30/09/	92	03/11/	92	01/12/	92
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date			-			
НВ	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	
MBC	4000-10000 (/MM3)	01/09/92	6600.00		6800.00		6900.00	
MBC: N	50-70 (%)	01/09/92	53.00		52.00	1 3	56.00	
NBC: L	30-40 (%)	01/09/92	37.00	1	39.00		40.00	1
NBC: E	D-4 (Z)	01/09/92	1.00		1.00	1 :	1.00	
MBC: M	0-8 (2)	01/09/92	6.00		6.00	1	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	1	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	
P04	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	l i	8.00	
SGPT	0-17 (U/L)	01/09/92	5.00		4.00		5.00	
GANNA GT	4-18 (U/L)	01/09/92	5.00		6.00	1	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	l i	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	
ALBUNINE	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	ŀ	12.20		15.10	1
TSH	0.2-5 (UU/ML)	01/09/92	0.10	<<		1		1

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range) out of range (value higher than max range)

### PHARMACIA PHARMACEUTICAS ANG 1- CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 27 Treatment: Reboxetine Sox: Female

			Visit	num	ber / Lai	borat	ory date	•
			Screen	rı .	Day 2	В	Day 5	6
			30/09/	92	03/11/	92	01/12/	92
•			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
нв	12-16 (G/DL)	01/09/92	13.80		13.60	l I		i
HT	35-47 (%)	01/09/92	39.00		41.00	i I		
RBC	3.8-5.2 (10-6/NM3)	01/09/92	4.60		4.80			
KBC	4000-10000 (/MM3)	01/09/92	6300.00		5700.00			
WBC: N	50-70 (%)	01/09/92	51.00		51.00			İ
MBC: L	30-40 (%)	01/09/92	37.00	ļ	38.00			l
NBC: E	0-4 (%)	01/09/92	3.00		3.00			ĺ
NBC: M	0-8 (%)	01/09/92	8.00	ĺ	6.00			ĺ
MBC: B	0-2 (%)	01/09/92	1,00	1	1.00			l
PLATELETS	200-300 (10-3/MM3)	01/09/92	313.00	>	281.00	ΙÍ		l
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	l 1	4.20	l
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	
P04	0.81-1.45 (MMOL/L)	01/09/92	1.18		1,43	l f	1.41	
SGOT	0-15 (U/L)	01/09/92	6.00	ŀ	5.00	l	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	i
CREATININE	0.3-1.4 (MG/DL)	01/09/92	0.98		0.97	1 1	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	1	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 (HG/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 out of range (value lower than min range) than min range) \*\* missing laboratory test value of laboratory not done

>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAS HENOS - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Contro: 18 Patient: 29 Treatment: Roboxetine Sex: Male

			Visit	num	ber / La	bora	tory dat	0
			Scree	n	Day 2	В	Day 5	6
			30/09/	92	03/11/	92	01/12/	92
			value	(¢)	value	(¢)	value	(4)
Laboratory test	Range value	Range date						
нв	12-16 (G/DL)	01/09/92	15.80	l	15.10		16.50	
HT	35-47 (X)	01/09/92	46.00	ŀ	46.00		49.00	
RBC	3.8-5.2 (10-6/MM3)	01/09/92	5.40	>	5.20		5.40	>
MBC	4000-10000 (/MM3)	01/09/92	7100.00		7100.00	ŀ	5400.00	ļ
MBC: N	50-70 (%)	01/09/92	59.00		64.00		61.00	l
MBC: L	30-40 (%)	01/09/92	32.00	•	25.00	<	28.00	<
MBC: E	0-4 (%)	01/09/92	2.00		4.00		3.00	Į
WBC: K	0-8 (%)	01/09/92	6.00		5.00		5.00	1
NBC: B	0-2 (%)	01/09/92	1.00		1.00		1.00	1
PLATELETS	200-300 (10-3/MM3)	01/09/92	258.00		249.00	ł	245.00	1
NA+	135-144 (MMOL/L)	01/09/92	136.00		141.00	l	145.00	>
K+	3.6-5.6 (MMOL/L)	01/09/92	3.70		4.40	ĺ	4.30	l
CL-	95-108 (MMOL/L)	01/09/92	101.00		102.00	1	102.00	l
Cn++	2.1-2.6 (MMOL/L)	01/09/92	2.37		2.47	1	2.63	>
P04	0.81-1.45 (MMOL/L)		1,10	ĺ	1.73	>>	1.42	l
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	l
LDH	120-240 (U/L)	01/09/92	206.00	l	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	l
	0.3-1.4 (MG/DL)	01/09/92	0.93		0.94		0.94	l
CREATININE	2.5-6 (MG/DL)	01/09/92	5.90		7.10	>	6.20	
URIC ACID	0-1 (MG/DL)	01/09/92	0.33		0.57	-	0.49	1
TOT BILIRUBIN		01/09/92	6.50		6.80		7.00	l
TOT, PROTEINS	6-8 (G/DL)	01/09/92	62.40		65.10		67.70	
ALBUMINE	58.8-69.6 (X)		170.00		172.00		163.00	
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	36.00		48.00	1	88.00	
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	3.60		2.90		2.60	]
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	8.70		7.40		6.50	
GLOBULINS ALPHA 2	3.7-13.1 (X)	01/09/92	12.50		11.30	İ	10.20	1
GLOBULINS BETA	8.9-13.6 (%)	01/09/92			13.40	1	13.00	1
GLOBULINS GAMMA	8.4-18.3 (X)	01/09/92	12.90		13.40	i	15.00	1

1023

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

>> clinically relevant (value higher than max range value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAS HOUSE - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 31 Treatment: Reboxetine Sex: Female

			Visit	numi	ber / Lai	bora	tory dat	0
			Scree	n	Day 2	В	Day 5	6
			13/10/	92	17/11/	92	15/12/	92
			value	(¢)	value	(4)	value	(¢
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/09/92	13.20		29.00	>	14.20	
BT	35-47 (%)	01/09/92	40.00	1	44.00		42.00	1
RBC	3.8-5.2 (10-6/MM3)	01/09/92	4.60	1	4.80	1	4.90	
HBC	4000-10000 (/MM3)	01/09/92	4200.00		5600.00		4600.00	
MBC: N	50-70 (%)	01/09/92	50.00	1	72.00	>	54.00	
NBC: L	30-40 (%)	01/09/92	41.00	>	19.00	<<	34.00	l
WBC: E	0-4 (%)	01/09/92	3.00	i	1.00		3.00	
MBC: M	0-8 (%)	01/09/92	5.00		5.00		6.00	
KBC: B	0-2 (X)	01/09/92	1.00		2.00		1.00	
PLATELETS	200-300 (10-3/MN3)		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	
P04	0.81-1.45 (MMOL/L)				1.18		1.00	
SGOT	0-15 (U/L)	01/09/92	8.00		6.00	i :	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	ا دا	67.00		67.00	
GLUCOSE	60-110 (MG/DL)	01/09/92	68.00	1	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	1
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	l
TOT. PROTEINS	6-8 (G/DL)	01/09/92	6.60		7.10		6.70	l
ALBUNINE	58.8-69.6 (%)	01/09/92	63.10		61.30		64.10	l
TOT. CHOLEST.	150-220 (MG/DL)	01/09/92	277.00	,	280.00	,	240.00	-
TRIGLYCERIDES	30-170 (NG/DL)	01/09/92	46.00	-	76.00	-	42.00	
CLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	3.00		3.30		2.80	1
GLOBULING 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	1
GLOBULING BEIN	8,4~18.3 (%)	01/09/92	13.60		13.90		13.90	1
	0.2-5 (UU/ML)	01/09/92	0.70		,3,70		,3.30	
TSH T	4-13 (UG/DL)	01/09/92	8.10					
T4	4-13 (ARADE)	U 1/ U7/ 74	0.10	1			I	ı

<sup>(0) &</sup>lt;< clinically relevant (value lower cut of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAL MILANO3 - CNS REBOXETINE - PROTOCOL 2124/016 Listing No.: 18.0

LABORATORY DATA
Contro: 18 Patient: 49 Treatment: Reboxetine Sex: Female

			Visit	num	ber / Lai	DOFA	cory dat	e
			Screen	1	Day 2	В	Day 5	6
			10/11/9	2.	15/12/	92	12/01/	93
			value	(¢)	value	(6)	value	(¢)
Laboratory test	Range value	Range date						
нв	12-16 (G/DL)	01/09/92	14.40	1	14.20		14,10	
HT	35-47 (%)	01/09/92	41.00		41.00	ĺ	42,00	
RBC	3.8-5.2 (10-6/MM3)	01/09/92	4.60		4.70	İ	4.60	ł
MBC	4000-10000 (/MM3)	01/09/92	4300.00		3900.00	<	4600.00	1
MBC: N	50-70 (%)	01/09/92	58.00		54.00		55.00	
MBC: L	30-40 (%)	01/09/92	32.00		36.00		36.00	
MBC: E	0-4 (%)	01/09/92	4.00		4.00		2.00	
IBC: N	0-8 (%)	01/09/92	5.00		4.00	li	3.00	ł
IBC: B	0-2 (%)	01/09/92	1.00		1.00		1.00	1
LATELETS	200-300 (10-3/MM3)	01/09/92	282,00		310.00	>	292.00	
VA+	135-144 (MMOL/L)	01/09/92	140.00		141.00		136.00	
(n. (+	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	
204	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 (NG/DL)	01/09/92	77.00		58.00	<	42.00	<
BUN	4-50 (MG/DL)	01/09/92	24.00		26.00	į l	20.00	
PRATININE	0.3-1.4 (MG/DL)	01/09/92	1.01		0.94	i	0.89	
JRIC ACID	2.5-6 (NG/DL)	01/09/92	5.50		5.60		4.90	
OT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.41		0.38		0.32	
OT. PROTEINS	6-8 (G/DL)	01/09/92	6.90	ĺ	6.60	i i	6.80	
ALBUMINE	58.8-69.6 (%)	01/09/92	61.40		62.30		62.10	1
OT. CHOLEST.	150-220 (MG/DL)	01/09/92	224.00	>	204.00		227.00	>
RIGLYCERIDES	30-170 (MG/DL)	01/09/92	162.00		190.00	>	190.00	>
SLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	3.00		3.10	1	3.50	1
LOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	7.70		8.20		8.80	
GLOBULINS BETA	8.9-13.6 (2)	01/09/92	12.40		11.80		12.60	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	15.40		14.70	1	13.10	
TSH	0.2-5 (UU/ML)	01/09/92	1,60					i
rsn F4	4-13 (UG/DL)	01/09/92	8.30		1	l		l

1025

(¢) << clinically relevant (value lower cout of range (value lower than min range) (value lower missing laboratory test value nd laboratory not done

>> clinically relevant (value higher than max range
> out of range (value higher than max range
() missing range value

#### PHARMACIA PHARMACEUTIGH STORM - CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 50 Treatment: Reboxetine Sex: Female

			Visi number Laborat date	ory
			Scree	n
			10/11/	92
			value	(¢)
Laboratory test	Range value	Range date		
HB	12-16 (G/DL)	01/09/92	13.70	1
HT	35-47 (%)	01/09/92	41.00	1
RBC	3.8-5.2 (10-6/MM3)		4.40	1
MBC	4000-10000 (/MM3)		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	
MBC: B	0-2 (%)	01/09/92	1.00	
Platelets	200-300 (10-3/MM3)		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	
P04~-	0.81-1.45 (MMOL/L)		1.54	
EGOT	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	Į
LDH	120-240 (U/L)	01/09/92	228.00	
ALK, PHOSPH.	60-200 (U/L)	01/09/92	126.00	l
GLUCOSE	60-110 (MG/DL)	01/09/92	80.00	
BUN	4-50 (MG/DL)	01/09/92	49.00	1
CREATININE	0.3-1.4 (MG/DL)	01/09/92	1.04	1
URIC ACID	2.5-6 (MG/DL)	01/09/92	4.80	l
TOT BILIRUBIN	0-1 (NG/DL)	01/09/92	0.06	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	7.20	i
ALBUHINE	58.8-69.6 (2)	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		01/09/92	3.20	l
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	8.60	l
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	1

1026

>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIGALSHOWS - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 22 Patient: 115 Treatment: Reboxetine Sex: Male

	,		Visi number Laborat date	ory
			Scree	n
			22/12/	92
			value	(4)
Laboratory test	Range value	Range date		
HB.	14-18 (G/DL)	01/11/92	16.20	
НT	0.38-0.52 (L/L)	01/11/92	0.51	
RBC	4.4-6 (10-12/L)	01/11/92	5.27	
HBC	4.3-10 (10-9/L)	01/11/92 01/11/92	7.35 61.00	
MBC: N	50-70 (%)		,	
WBC: L	25-45 (%) 2-4 (%)	01/11/92 01/11/92	31.00	
WBC: E	2-4 (%)	01/11/92	6.00	
MBC: N	0-1 (%)	01/11/92	1.00	
MBC: B	140-440 (10-9/L)	01/11/92	202.00	
PLATELETS		01/11/92	141.00	
NA+	135-145 (MMOL/L) 3.8-5 (MMOL/L)	01/11/92	4.10	
K+	98-106 (MEQ/L)	01/11/92	95.00	
CL- Ca++	2,2-2,55 (MMOL/L)	01/11/92	2.47	
Ca++ SGOT	5-18 (U/L)	01/11/92	10.00	
SGPT	5-12 (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	
GLUCUSE 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	0-1 (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	
ALBUMINE TOT. CHOLEST.	50-220 (MG/DL)	01/11/92	227.00	
	60-150 (MG/DL)	01/11/92	134.00	
TRIGLYCERIDES GLOBULINS ALPHA 1		01/11/92	3.60	
GLOBULINS ALPHA 1 GLOBULINS ALPHA 2		01/11/92	8.30	
GLOBULINS ALPHA 2 GLOBULINS BETA	7.9-13.9 (%)	01/11/92	9.10	
GLOBULINS BETA GLOBULINS GAMMA	11.4-18.2 (%)	01/11/92	14.20	
GLOBULINS GAMMA TEH	11.4-18.2 (X) 0.3-4 (NU/L)	01/11/92	1.50	
	5-13.4 (UG/DL)	01/11/92	6.40	
T4	3-13.4 (UG/UL)	01/11/72	0.40	1

1027

(¢) << clinically relevant (value lower cut of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

>> clinically relevant (value higher than max range to out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIGAS - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
1 Treatment: Fluoxetine Sex: Male

		1 1222	tory dat	•			
		Scree	n	Day 2	В	Day 5	6
		15/11/	91	13/12/	91	10/01/	92
		value	(¢)	value	(¢)	value	(4)
Range value	Range date						
42-52 (X)	01/11/91				1		
50-70 (%)	01/11/91	59.00					
25-40 (%)	01/11/91	31.00		29.00		29.00	
150000-400000	01/11/91	1					
(/MM3)							
135-150 (MEQ/L)	01/11/91					133.00	<
3.6-5.2 (MEQ/L)	01/11/91	4.20					
94-111 (MEQ/L)	01/11/91						
4.4-5.5 (MEQ/L)	01/11/91	4.80				4.60	1
2.5-5 (MG/DL)	01/11/91						1
5-18 (U/L)	01/11/91						
5-22 (U/L)	01/11/91						
6-28 (U/L)	01/11/91	10.00		10.00		7.00	l
120-240 (U/L)	01/11/91	121.00		150.00			l
80-170 (U/L)	01/11/91	98.00		107.00			
70-110 (MG/100ML)	01/11/91	92.00		83.00		86.00	i
10-50 (MG/DL)	01/11/91	12.00		12.00			
	01/11/91	0.80		1.00		0.90	ļ
	01/11/91	4.50		4.40		4.00	1
	01/11/91	1,00		1.00			1
	01/11/91	240.00	>				ı
		118.00					1
		2.60					
		6.50					
		11.30					1
							1
_	14-18 (G/DL) 42-52 (X) 43-5.9 (10-6/MM3) 4000-8000 (/MM3) 50-70 (X) 55-40 (X) 150-00-400000 (/MM3) 135-150 (MEQ/L) 34-111 (MEQ/L) 4.4-5.5 (MEQ/L) 5-18 (U/L) 5-22 (U/L) 6-28 (U/L) 120-240 (U/L) 80-170 (U/L) 70-110 (MG/100ML) 0.7-1.2 (MG/DL) 3.4-7 (MG/100ML)	14-18 (C/DL) 01/11/91 42-52 (X) 01/11/91 43-5.9 (10-6/MH3) 01/11/91 4000-8000 (/MH3) 01/11/91 50-70 (X) 01/11/91 55-40 (X) 01/11/91 55-60 (X) 01/11/91 35-150 (HEQ/L) 01/11/91 94-111 (HEQ/L) 01/11/91 94-111 (HEQ/L) 01/11/91 94-111 (HEQ/L) 01/11/91 5-18 (U/L) 01/11/91 5-18 (U/L) 01/11/91 5-22 (U/L) 01/11/91 5-28 (U/L) 01/11/91 6-28 (U/L) 01/11/91 6-28 (U/L) 01/11/91 6-28 (U/L) 01/11/91 6-28 (U/L) 01/11/91 6-28 (U/L) 01/11/91 6-29 (U/L) 01/11/91 6-10 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (HG/100HL) 01/11/91 0.7-1.2 (XG/100HL) 01/11/91 0.7-1.2 (XG/100HL) 01/11/91 0.7-1.2 (XG/100HL) 01/11/91 0.7-1.2 (XG/100HL) 01/11/91 0.7-1.2 (XG/100HL) 01/11/91 0.7-1.2 (XG/100HL) 01/11/91 0.7-1.2 (XG/100HL) 01/11/91 0.7-1.2 (XG/100HL) 01/11/91 0.7-1.2 (XG/100HL) 01/11/91 0.7-1.2 (XG/100HL) 01/11/91	Range value Range date  14-18 (G/DL) 01/11/91 16.50  42-52 (X) 01/11/91 97.00  4.3-5.9 (10-6/MM3) 01/11/91 5.22  4.000-8000 (MM3) 01/11/91 59.00  50-70 (X) 01/11/91 31.00  150-70 (X) 01/11/91 31.00  155-40 (X) 01/11/91 31.00  155-45 (MEQ/L) 01/11/91 139.00  3.6-5.2 (MEQ/L) 01/11/91 4.20  94-111 (MEQ/L) 01/11/91 4.20  94-111 (MEQ/L) 01/11/91 9.00  5-18 (U/L) 01/11/91 9.00  5-22 (U/L) 01/11/91 10.00  6-28 (U/L) 01/11/91 10.00  6-28 (U/L) 01/11/91 10.00  6-28 (U/L) 01/11/91 12.00  80-170 (U/L) 01/11/91 92.00  10-50 (MG/DL) 01/11/91 92.00  10-50 (MG/DL) 01/11/91 92.00  10-50 (MG/DL) 01/11/91 12.00  3.4-7 (MG/100ML) 01/11/91 12.00  7-112 (MG/100ML) 01/11/91 12.00  74-172 (MG/100ML) 01/11/91 14.50  130-220 (MG/100ML) 01/11/91 1240.00  74-172 (MG/100ML) 01/11/91 18.00  74-172 (MG/100ML) 01/11/91 12.00  74-172 (MG/100ML) 01/11/91 12.00  74-172 (MG/100ML) 01/11/91 12.00  74-172 (MG/100ML) 01/11/91 12.00  74-172 (MG/100ML) 01/11/91 12.00  75-10.2 (X) 01/11/91 12.00  0.5-4.2 (U/ML) 01/11/91 118.00  0.5-4.2 (U/ML) 01/11/91 118.00  0.5-4.2 (U/ML) 01/11/91 11.30  0.5-4.2 (U/ML) 01/11/91 11.30  0.5-4.2 (U/ML) 01/11/91 11.30  0.5-4.2 (U/ML) 01/11/91 11.30	Range value 14-18 (G/DL) 01/11/91 16.50 42-52 (X) 01/11/91 47.00 4.3-5.9 (10-6/MH3) 01/11/91 5.22 4000-8000 (/HK3) 01/11/91 59.00 50-70 (X) 01/11/91 59.00 150-70 (X) 01/11/91 31.00 150-000-400000 01/11/91 31.00 155-150 (MEQ/L) 01/11/91 139.00 3.6-5.2 (MEQ/L) 01/11/91 4.20 94-111 (MEQ/L) 01/11/91 4.20 94-111 (MEQ/L) 01/11/91 9.00 1-5-15 (MEQ/L) 01/11/91 9.00 1-5-18 (U/L) 01/11/91 10.00 6-28 (U/L) 01/11/91 10.00 6-28 (U/L) 01/11/91 10.00 6-28 (U/L) 01/11/91 121.00 80-170 (U/L) 01/11/91 98.00 120-240 (U/L) 01/11/91 98.00 10-50 (MG/DL) 01/11/91 92.00 10-50 (MG/DL) 01/11/91 121.00 10-50 (MG/DL) 01/11/91 12.00 0.7-1.2 (MG/DL) 01/11/91 12.00 0.7-1.2 (MG/DL) 01/11/91 12.00 0.7-1.2 (MG/DL) 01/11/91 130 0-1 (MG/100ML) 01/11/91 1.00 130-220 (MG/100ML) 01/11/91 1.00 130-220 (MG/100ML) 01/11/91 1.00 130-220 (MG/100ML) 01/11/91 1.00 130-25.6 (X) 01/11/91 18.00 5-10.2 (X) 01/11/91 18.00 5-6-15.6 (X) 01/11/91 1.30 0.5-4.2 (UU/ML) 01/11/91 1.30 0.5-4.2 (UU/ML) 01/11/91 1.30 0.5-4.2 (UU/ML) 01/11/91 1.30 0.5-4.2 (UU/ML) 01/11/91 1.30 0.5-4.2 (UU/ML) 01/11/91 1.30	Range value Range date 14-18 (G/DL) 01/11/91 16.50 17.70 4.3-5.9 (10-6/MM3) 01/11/91 47.00 49.00 4.3-5.9 (10-6/MM3) 01/11/91 4900.00 5600.00 50-70 (X) 01/11/91 59.00 62.00 150-70 (X) 01/11/91 31.00 150-70 (X) 01/11/91 31.00 150-100-400000 01/11/91 207000 254000 1/MM3) 207000 254000 1/MM3) 207000 254000 1/MM3) 18-150 (MEQ/L) 01/11/91 4.20 4.90 94-111 (MEQ/L) 01/11/91 4.20 4.90 94-111 (MEQ/L) 01/11/91 9.00 14.1.00 1-15-18 (U/L) 01/11/91 9.00 11.00 5-22 (U/L) 01/11/91 10.00 9.00 5-22 (U/L) 01/11/91 10.00 9.00 5-28 (U/L) 01/11/91 10.00 10.00 5-28 (U/L) 01/11/91 10.00 10.00 5-28 (U/L) 01/11/91 10.00 10.00 5-28 (U/L) 01/11/91 10.00 10.00 5-28 (U/L) 01/11/91 10.00 10.00 5-28 (U/L) 01/11/91 12.00 10.00 10-50 (MG/100ML) 01/11/91 12.00 10.00 10-50 (MG/100ML) 01/11/91 12.00 17.00 10-50 (MG/100ML) 01/11/91 12.00 10.00 10-70-110 (MG/100ML) 01/11/91 12.00 10.00 10-74-172 (MG/100ML) 01/11/91 118.00 1-74-172 (MG/100ML) 01/11/91 118.00 1-5-10.2 (X) 01/11/91 22.60 5-10.2 (X) 01/11/91 11.30 11.90 15-10.5-4.2 (UU/ML) 01/11/91 11.30 10.5-4.2 (UU/ML) 01/11/91 11.30 10.5-4.2 (UU/ML) 01/11/91 11.30 10.5-4.2 (UU/ML) 01/11/91 12.30 0.5-4.2 (UU/ML) 01/11/91 0.50 0.5-4.2 (UU/ML) 01/11/91 0.50	Range value Range date 14-18 (G/DL) 01/11/91 16.50 17.70 42-52 (X) 01/11/91 47.00 49.00 4.3-5.9 (10-6/MN3) 01/11/91 5.22 5.49 4.000-8000 (YMN3) 01/11/91 59.00 62.00 50-70 (X) 01/11/91 31.00 29.00 150-70 (X) 01/11/91 31.00 29.00 150-70 (X) 01/11/91 31.00 29.00 150-150 (MEQ/L) 01/11/91 139.00 141.00 3.6-5.2 (MEQ/L) 01/11/91 4.20 4.90 94-111 (MEQ/L) 01/11/91 4.20 4.90 94-111 (MEQ/L) 01/11/91 9.00 11.00 4.4-5.5 (MEQ/L) 01/11/91 9.00 11.00 5-18 (U/L) 01/11/91 9.00 11.00 5-22 (U/L) 01/11/91 10.00 9.00 6-28 (U/L) 01/11/91 10.00 9.00 6-28 (U/L) 01/11/91 10.00 10.00 6-28 (U/L) 01/11/91 10.00 10.00 6-28 (U/L) 01/11/91 12.00 150.00 80-170 (U/L) 01/11/91 98.00 107.00 80-170 (U/L) 01/11/91 98.00 107.00 10-50 (MG/DL) 01/11/91 12.00 150.00 80-170 (MG/DAL) 01/11/91 12.00 12.00 0.7-1.2 (MG/DAL) 01/11/91 12.00 12.00 0.7-1.2 (MG/OBLL) 01/11/91 12.00 10.00 10-50 (MG/DL) 01/11/91 12.00 1.00 130-220 (MG/10ML) 01/11/91 18.00 2.2-5.6 (X) 01/11/91 18.00 2.2-5.6 (X) 01/11/91 18.00 2.2-5.6 (X) 01/11/91 18.00 0.5-4.2 (UU/ML) 01/11/91 11.30 0.5-4.2 (UU/ML) 01/11/91 11.30 0.5-4.2 (UU/ML) 01/11/91 12.30 0.5-4.2 (UU/ML) 01/11/91 11.30 0.5-4.2 (UU/ML) 01/11/91 0.70	Range value Range date 14-18 (G/DL) 01/11/91 16.50 17.70 48.00 4.3-5.9 (10-6/MM3) 01/11/91 5.22 5.49 5.33 4.000-8000 (/MM3) 01/11/91 4900.00 5600.00 9600.00 50-70 (X) 01/11/91 59.00 62.00 67.00 150-70 (X) 01/11/91 31.00 29.00 29.00 150-00 400000 01/11/91 31.00 29.00 29.00 170000 17000 01/11/91 139.00 141.00 133.00 3.6-5.2 (MEQ/L) 01/11/91 4.20 4.90 94-111 (MEQ/L) 01/11/91 4.80 4.90 94-111 (MEQ/L) 01/11/91 9.00 11.00 2.5-5 (MEQ/L) 01/11/91 10.00 4.90 5-18 (U/L) 01/11/91 10.00 9.00 17.00 5-22 (U/L) 01/11/91 10.00 9.00 17.00 6-28 (U/L) 01/11/91 10.00 9.00 17.00 6-28 (U/L) 01/11/91 10.00 9.00 17.00 6-28 (U/L) 01/11/91 12.00 150.00 80-170 (U/L) 01/11/91 98.00 107.00 10-50 (MG/100ML) 01/11/91 92.00 33.00 86.00 10-50 (MG/100ML) 01/11/91 12.00 150.00 80-170 (U/L) 01/11/91 12.00 10.00 10.5-4.2 (MG/100ML) 01/11/91 12.00 12.00 0.7-1.2 (MG/100ML) 01/11/91 12.00 13.00 0-1 (MG/100ML) 01/11/91 18.00 0-1 (MG/100ML) 01/11/91 18.00 0-1 (MG/100ML) 01/11/91 18.00 0-1 (MG/100ML) 01/11/91 18.00 0-5-4.2 (U/ML) 01/11/91 18.00 0-5-4.2 (U/ML) 01/11/91 18.00 0-5-4.2 (U/ML) 01/11/91 18.00 0-5-4.2 (U/ML) 01/11/91 18.00 0-5-4.2 (U/ML) 01/11/91 12.30 0.5-4.2 (U/ML) 01/11/91 12.30 0.5-4.2 (U/ML) 01/11/91 12.30 0.5-4.2 (U/ML) 01/11/91 0.570

<sup>(0) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIGAS 500 608 - CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 1 Patient: 3 Treatment: Fluoxetine Sex: Female

		·		Vis	it numbe	r /	Laborato	ry d	ate	
			Scree	n	Day 1	4	Day 2	8	Day 5	6
			29/06/	92	18/07/92		30/07/	92	25/08/	92
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
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	1	9900.00	
WBC: N	50-70 (2)	10/11/91	57.00	ļ	56.00	1	49.00		69,00	
WBC: L	25-40 (%)	10/11/91	36.00		38.00	Ì	42.00	>	26.00	
PLATELETS	150000-400000	10/11/91								ł
Latibolo	(/MM3)		284000		258000		226000		250000	1
NA+	135-150 (MEQ/L)	10/11/91	141.00		140.00		144.00		139.00	l
K+	3.6-5.2 (MEQ/L)	10/11/91	3.80		4.20		4.70		4.30	
CL-	94-111 (NEQ/L)	10/11/91			107.00		105.00		110.00	
Ca++	4.4-5.5 (MEQ/L)	10/11/91	4.20	۱<	4.30	<	4.40		4.40	
P04	2.5-5 (MG/DL)	10/11/91			3.10	ļ	3.30		2.60	
SGOT	5-15 (U/L)	10/11/91	17.00	>	13.00	1	9,00		11.00	
SGPT	5-17 (U/L)	10/11/91	25.00		19.00	>	15.00		12.00	l
GAMMA GT	4-18 (U/L)	10/11/91	52.00	>>	13.00		12.00		10.00	i
LDH	120-240 (U/L)	10/11/91			12777	1	134.00		147.00	
ALK. PHOSPH.	80-170 (U/L)	10/11/91			120.00	l	115.00		112.00	
GLUCOSE	70-110 (MG/100ML)	10/11/91			83.00		90.00		87.00	
BUN	10-50 (NG/DL)	10/11/91			11.00		16.00		10.00	
DUN CREATININE	0.5-1 (NG/DL)	10/11/91	0.70		0.80		1.00		0.90	
URIC ACID	2.4-5.7 (MG/100ML)		0.70		4.70	1	,,,,,		5.40	
TOT BILIRUBIN	0-1 (MG/100ML)	10/11/91			1,00	l	1.00		1.00	
TOT. PROTEINS	6.5-7.9 (G/DL)	10/11/91			5.90			ŀ	6.30	<
	51.8-65.4 (%)	10/11/91			68.20			ľ	66.10	
ALBUMINE TOT. CHOLEST.	130-220 (MG/100ML)		352.00	۱,,	215.00	1	254.00	>	273.00	
TRIGLYCERIDES	74-172 (NG/100NL)	10/11/91	249.00		119.00		87.00		115.00	
		10/11/91	245.00	1	2.70		5,.30		2.70	1
GLOBULINS ALPHA 1		10/11/91			5.50				6.50	
GLOBULINS ALPHA 2		10/11/91	1		10.70				11.00	
GLOBULINS BETA	8.8-15.6 (%)				13.00				13.60	
GLOBULINS GAMMA	11.9-23.3 (%)	10/11/91	1.07		13.00				13,00	
TSK	0.1-4 (UU/ML)	10/11/91	9.30							i
T4	5-12.5 (UG/DL)	10/11/91	9.30	ĺ		1		i		l

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range to out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIGAS 50008 - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 1 Patient: 5 Treatment: Fluoxetine Sex: Female

			Visit	nuni	ber / Lai	bora	tory date	0
			Scree	n	Day 1	4	Day 2	В
			07/10/	92	27/10/	92	10/11/	92
			value	(¢)	value	(4)	value	(¢)
Laboratory test	Range value	Range date						
НВ	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/NM3)	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	i
WBC: L	25-40 (%)	10/11/91	26.00		36.00		24.00	<
PLATELETS	150000-400000	10/11/91			ŀ		Į.	
	(/MM3)		225000		249000	l	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	l
CL-	94-111 (MEQ/L)	10/11/91	104.00		109.00	ŀ	105.00	ļ
Ca++	4.4-5.5 (MEQ/L)	10/11/91	4.60		4.60		4.50	1
P04	2.5-5 (MG/DL)	10/11/91	2.80		l :			i
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)		5.60		l :		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	<	1		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	>	1		1	
TRIGLYCERIDES	74-172 (MG/100ML)	10/11/91	123.00					
GLOBULINS ALPHA 1	2.2-5.6 (2)	10/11/91	3.20				2.40	
GLOBULINS ALPHA 2	5-10.2 (%)	10/11/91	10.30	>			8.90	l
GLOBULINS BETA	8.8-15.6 (%)	10/11/91	14.20				12.60	
	11.9-23.3 (%)	10/11/91	9.10	<	1		5.80	<<
TSH	0.1-4 (UU/NL)	10/11/91	1.99					
TA	5-12.5 (UG/DL)	10/11/91	10.00		1			1
	5 12.5 (35,05)		1					

#### PHARMACIA PHARMACEUTISH50060 - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 1 Patient: 6 Treatment: Fluoxetine

			Visit	num	ber / La	bora	tory dat	8
			Scree	n	Day 1	4	Day 2	8
			11/01/	93	28/01/	93	11/02/	93
,			value	(4)	value	(4)	value	(6)
Laboratory test	Range value	Range date						
нв	14-18 (G/DL)	01/01/93	16.10		16.90		16.40	
HT	42-52 (X)	01/01/93	47.00	}	48.00		48.00	1
RBC	4.3-5.9 (10-6/MM3)	01/01/93	5.52	ĺ	5.63		5.61	İ
ивс	4000-8000 (/NM3)	01/01/93	5500.00		7900.00		7800.00	
MBC: N'	50-70 (%)	01/01/93	60.00		72.00	>	72.00	>
MBC: L	25-40 (%)	01/01/93	33.00		22.00	<	20.00	<
PLATELETS	150000-400000	01/01/93					!	
	(/MM3)		182000	ł	217000		210000	ŀ
NA+	135-150 (MEQ/L)	01/01/93	140.00		140.00		142.00	Į.
K+	3.6-5.2 (MEQ/L)	01/01/93	3.50	<	4.80		4.40	ł
CL-	94-111 (MEQ/L)	01/01/93	107.00		105.00		108.00	1
Ca++	4.4-5.5 (MEQ/L)	01/01/93	4.40		5.10		5.00	
P04	2.5-5 (MG/DL)	01/01/93			3.00		3.10	ļ
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	
GANNA GT	6-28 (U/L)	01/01/93	19.00	_	14.00		12.00	
LDR	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	ļ
GLUCOSE	70-110 (NG/100NL)	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/100NL)	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	0.70		6.90		6.40	٧.
TOT. CHOLEST.	130-220 (MG/100ML)		222.00	. 1	242.00	. 1	248.00	
TRIGLYCERIDES	74-172 (MG/100ML)	01/01/93	101.00	1	110.00	1	110.00	_
GLOBULINS ALPHA 1		01/01/93	101.00	ļ	2.00	ا ر	110.00	
GLOBULING ALPHA 1	5-10.2 (%)	01/01/93		- 1	9.30	`		1
GLOBULING RETA	8.8-15.6 (%)	01/01/93	1 1		13.10			1
GLOBULINS BETA GLOBULINS GAMMA	11.9-23.3 (2)		1 1	- 1	13.10	- 1		
GLUBULINS GAMMA TSH		01/01/93	1,21	l	13.20	- 1		
	0.5-4.2 (UU/ML)	01/01/93						
T4	68-185 (MMOL/L)	01/01/93	84.00		- 1		1	

1031

(t) << clinically relevant (value lower out of range (value lower than min range)

\*\* missing laboratory test value nd laboratory no

#### PHARMACIA PHARMACEUTICAS #16803 - CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 33 Treatment: Fluoxetine Sex: Female

			Visit	numk	er / La	borat	ory dat	•
			Screen	n	Day 2	В	Day 5	6
			03/05/	91	04/06/	91	29/06/	91
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
нв	12-16 (G/DL)	01/03/91	13.20		13.20	1	13.80	
HT	0.37-0.46 (L/L)	01/03/91	0.38	1	0.40	i l	0.40	1
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	1 !	6.90	1 1	7.70	
WBC: N	50-70 (%)	01/03/91	63.00	1 1	81.00		66.00	1
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	١<
WBC: M	2-6 (%)	01/03/91	0.00	<	4.00		4.00	
WBC: B	0-1 (%)	01/03/91	0.00	1 1	0.00	1 1	0.00	
PLATELETS	140-440 (10-9/L)	01/03/91	281.00		451.00	>	402.00	
NA+	135-145 (MNOL/L)	01/03/91	140.00		140.00		138.00	1
K+	3.5-5 (MMOL/L)	01/03/91	3.80	1 1	4.90	1 1	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	i
P04	0.81-1.61 (MMOL/L)	01/03/91			0.81		1.27	1
SGOT	3-15 (U/L)	01/03/91	9.00	l i	7.00	1 1	7.00	
SGPT	5-17 (U/L)	01/03/91	7.00		5.00		5.00	
GÁNNA 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	1 1	145.00	
ALK. PHOSPH.	60-170 (U/L)	01/03/91	98.00		123.00		110.00	
GLUCOSE	70-110 (HG/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	i	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	1
TSH CAME	0.3-3.5 (MU/L)	01/03/91	0.60					1
T4	9-21 (NG/L)	01/03/91	16.00			1		1

1032

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

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#### PHARMACIA C98550083

### REBOXETINE - PROTOCOL 20124/016 Listing No.; 18.0

LABORATORY DATA
Centre: 2 Patient: 36 Treatment: Fluoxetine

				Vis	it numbe	r / 1	aborato	ry da	ate	
			Scree	n	Day 1	4	Day 2	8	Day 5	6
			26/04/	91	16/05/	91	07/06/	91	27/06/	91
			value	(4)	valus	(4)	value	(4)	value	(¢)
Laboratory test	Range value	Range date								
нв	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	i			0.42		0.42	
RBC	4.4-6 (10¬12/L)	01/03/91	4.62				4.40		4.42	
MBC	4.3-10 (10-9/L)	01/03/91	9.40				11.40		9.00	
MBC: N	50-70 (2)	01/03/91	70.00	i l		1 1	71.00	>	62.00	
WBC: L	25-40 (%)	01/03/91	27.00			1 1	28.00	1 1	35.00	
WBC: E	2-4 (%)	01/03/91	1.00	<		ΙÌ	0.00		1.00	
MBC: M	2-6 (%)	01/03/91	2.00			!!	1.00	<	2.00	
WBC: B	0-1 (%)	01/03/91	0.00			1 1	0.00		0.00	
PLATELETS	140-440 (10¬9/L)	01/03/91	263.00	lí		l i	264.00	!!	263.00	
NA+	135-145 (MMOL/L)	01/03/91	139.00	li			141.00		141.00	1
K+	3.5-5 (MMOL/L)	01/03/91	3.90	ll		1 1	4.60		4.20	ĺ
CL-	98-108 (MMOL/L)	01/03/91	102.00			li	102.00		102.00	
Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.40				2.50		2.60	1
P04	0.81-1.61 (MMOL/L)	01/03/91	1.28				1.23		0.73	<
SCOT	3-18 (U/L)	01/03/91	32.00		10.00		9.00	ĺĺ	8.00	1
SGPT	5-22 (U/L)	01/03/91	72.00	>>	16.00		14.00		7.00	1
GAMMA GT	6-28 (U/L)	01/03/91	94.00	<<	27,00	il	14.00		10.00	ĺ
LDH	120-240 (U/L)	01/03/91	197.00			1 1	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	- 1	40.00	
UREA	O	01/03/91				1		- 1		1
CREATININE	0.4-1.2 (MG/DL)	01/03/91	1.00			1	0.80		1.00	l
URIC ACID	3.4-7 (MG/DL)	01/03/91	5.90	1			4.90	1	5.80	l
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			ı					
TOT. PROTEINS	65-85 (G/L)	01/03/91	75.70			ĺĺ	80.10		80.20	ł
ALBUMINE	56-68 (%)	01/03/91	59.90				59.80			
	36-58 (G/L)	25/06/91						j	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			i	2.70			1
	1.3-4.3 (G/L)	25/06/91						- 1	2.10	
GLOBULINS ALPHA 2	6-10 (%)	01/03/91	9,10	1			8.40	- 1		1
	3.9-8.5 (G/L)	25/06/91	1	į			/-	- 1	6.70	l
GLOBULINS BETA	8-14 (%)	01/03/91	14.20	, I		- 1	16.50	-		ı
	5.2-11.9 (G/L)	25/06/91		l					9.90	
GLOBULINS GAMMA	9-19 (%)	01/03/91	13.40	J			12.60			Ì
	5.9-16.2 (G/L)	25/06/91	15,10			i i			11.00	
TSH	0.3-3.5 (MU/L)	01/03/91	2,10			l l				l
T4	9-21 (NG/L)	01/03/91	11.40					i		
				- 1				- 1		1

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) to the min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range)
> out of range (value higher than max range)
() missing range value

#### PHARMACIA PHARMACEUTIGAS 516 6489 - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Contre: 2 Patient: 38 Treatment: Fluoxetine Sex: Male

					umber / ory date	
:			Scree	n	Day 2	8
			18/06/	91	18/07/	91
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
НВ	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	۱<	4.35	۱<
MBC	4.3-10 (10-9/L)	01/03/91	8.30		7.50	ļ
MBC: 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	l i	1.00	<
MBC: B	0-1 (X)	01/03/91	0.00	i !	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	ļ
K+	3.5-5 (MMOL/L)	01/03/91	4.60	1	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	
SCOT	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	- 1	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	1	0.70	
TOT. PROTEINS	65-85 (G/L)	01/03/91	79.10	- 1	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	]	55.70	
TRIGLYCERIDES	130-200 (NG/DL)	01/03/91	88.00	ا ہ		
GLOBULINS ALPHA 1		01/03/91	2.50	`	2.20	
GLOBULINS ALPHA 2	3.9-8.5 (G/L)	01/03/91	8.40		6.50	
GLOBULING 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	Į.	0.60	- 1
T4	9-21 (NG/L)	01/03/91	17.30		10.60	
	, 21 (NO/L)	01/03/71	17.30		10.00	

<sup>&</sup>gt;> clinically relevant (value higher than max range)
> out of range (value higher than max range)
() missing range value

#### PHARMACIA PHARMACEUTIGALS WAS - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 39 Treatment: Fluoxotine Sex: Male

			Visi number Laborat date	ory
			Scree	n
			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	
MBC	4.3-10 (10-9/L)	01/03/91	6.20	
MBC: N	50-70 (%)	01/03/91	60.00	
NBC: 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	l
PLATELETS	140-440 (10-9/L)	01/03/91	188.00	
NA+	135-145 (MMOL/L)	01/03/91	141.00	l
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 (MHOL/L)	01/03/91	2.40	
P04	0.81-1.61 (MMOL/L)	01/03/91	1.20	l
	3-18 (U/L)	01/03/91	11.00	
SGPT	5-22 (U/L)	01/03/91	21.00	ŀ
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 (NG/DL)	01/03/91	34.00	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.80	ŀ
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 (NG/DL)	01/03/91	238.00	>
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	120.00	
GLOBULINS ALPHA 1		01/03/91	2.70	1
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	1
GLOBULINS GAMMA	5.9-16.2 (G/L)	01/03/91	7.70	1
GEDBULING CANAA	0.3-3.5 (MU/L)	01/03/91	0.70	1
15n T4	9-21 (NG/L)	01/03/91	14.30	1

1035

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIGAS SHOWN - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 41 Treatment: Fluoxetine Sex: Male

				Vis	it number	- / 1	aborato	ry da	ato	
			Scree	n	Day 1	4	Day 2	8	Day 5	6
			11/02/	92	27/02/	92	12/03/	92	09/04/	92
			value	(¢)	value	(4)	value	(¢)	value	(¢
Laboratory test	Range value	Range date								
HB	14-18 (G/DL)	01/03/91	16.60	1	14.60		15.20		14.60	
HT	0.3B-0.57 (L/L)	01/03/91	0.48	1 1	0.46		0.47		0.45	
RBC	4.4-6 (10-12/L)	01/03/91	5.20		4.86		5.09	1 1	4.80	
WBC	4.3-10 (10-9/L)	01/03/91	8.70		7.20		8.10	ļ l	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	<b> </b>	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	i I	0.00	
PLATELETS	140-440 (10-9/L)	01/03/91	263.00	1	227.00	l i	280.00		307.00	
NA+	135-145 (MMOL/L)	01/03/91	140.00		139.00	1	141.00	i I	140.00	
K+	3.5-5 (MMOL/L)	01/03/91	5.00	1	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	
P04	0.81-1.61 (MMOL/L)	01/03/91	1.08	1	1.30		1.13	i I	1.11	
SGOT	3-18 (U/L)	01/03/91	13.00		11,00		13.00	1 1	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	1 1	146.00	1 1	140.00	
ALK. PHOSPH.	60-170 (U/L)	01/03/91	155.00		156.00		133.00	1 1	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	ŀ	0.80		0.80	1 1	0.90	
URIC ACID	3.4-7 (MG/DL)	01/03/91	5,10		5.00		4.90	1 1	5.70	
TOT BILIRUBIN	0-1 (MG/DL)	01/03/91	0.40	i	0.40		0.50	1 1	0.30	
TOT. PROTEINS	65-85 (G/L)	01/03/91	79.70	l	69.20		74.40	1 1	71.70	1
ALBUMINE	56-68 (%)	01/03/91	68.80	>	66.80			1 1	63.90	Į
VEDOUTHE	36-58 (G/L)	10/03/92					51.00	1 1		
TOT, CHOLEST.	130-200 (NG/DL)	01/03/91	289.00	>>	276.00	>>	275.00	>>	269.00	>>
TRIGLYCERIDES	130-200 (NG/DL)	01/03/91	183.00	l	209.00	>	222.00	>	248.00	>
GLOBULINS ALPHA 1	2-5 (X)	01/03/91	2.60	į	2.60				3,30	
GLOBULING ALPHA 1	1.3-4.3 (G/L)	10/03/92					2.00	1 1		1
	6-10 (%)	01/03/91	7.10	1	6.60			1 1	8.80	1
GLOBULINS ALPHA 2	3.9-8.5 (G/L)	10/03/92	1 // 10	1			6.10			İ
OLODER THE DEST	8-14 (%)	01/03/91	10.80		12.10				12.00	1
GLOBULINS BETA	5.2-11.9 (G/L)	10/03/92	,,,,,				8.60			1
		01/03/91	10.60		12.10			'	12.00	1
GLOBULINS GAMMA	9-19 (%)	10/03/92		1	, 2, 10		6.70			1
	5.9-16.2 (G/L)	01/03/92	0.80			1				1
TSH	0.3-3.5 (MU/L)	01/03/91	13.00	l						1
T4	9-21 (NG/L)	01/09/97	13.00	1	l	1		1	l	1

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range) (value lower wissing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range)
> out of range (value higher than max range)
() missing range value

#### PHARMACIA PHARMACEUTIGAS 515 6489 - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

### LABORATORY DATA Centre: 2 Patient: 44 Treatment: Fluoxetine

					mber / ory date	
			Scree	n	Day 2	8
			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	
MBC	4.3-10 (10-9/L)	01/03/91	8.90		6.10	1
WBC: N	50-70 (%)	01/03/91	56.00		66.00	l
WBC: L	25-40 (2)	01/03/91	39.00	1	27.00	1
HBC: E	2-4 (%)	01/03/91	1.00	<	2.00	i
HBC: M	2-6 (%)	01/03/91	4.00		5.00	1
MBC: 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	l
K+	3.5-5 (MMOL/L)	01/03/91	3.60		4.20	1
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	1
P04	0.81-1.61 (MMOL/L)		1.41		0.87	l
SGOT	3-18 (U/L)	01/03/91	8.00		8.00	l
SGPT	5-22 (U/L)	01/03/91	8.00		10,00	l
GAMMA GT	6-28 (U/L)	01/03/91	11.00		9,00	l
LDH	120-240 (U/L)	01/03/91	110.00	<b> </b> <	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	1
CREATININE	0.4-1.2 (MG/DL)	01/03/91	0.90		0.90	l
URIC ACID	3.4-7 (MG/DL)	01/03/91	5.80		5.80	ł
TOT BILIRUBIN	0-1 (MG/DL)	01/03/91	0.40		0.50	1
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	ĺ
GLOBULINS ALPHA 2	6-10 (%)	01/03/91	6.90		6.40	
GLOBULINS BETA	8-14 (%)	01/03/91	11.50		10.90	l
GLOBULINS GAMMA	9-19 (%)	01/03/91	13.40		13.30	l
TSH	0.3-3.5 (MU/L)	01/03/91	0.30			l
T4	9-21 (NG/L)	01/03/91	21.10	ls I		ı

1037

(¢) << clinically relevant (value lower than min range) < out of range (value lower than min range) \*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAL 500 - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.; 18.0

LABORATORY DATA
Patient: 47 Treatment: Fluoxetine

			Visit	numb	er / La	borat	ory date	•
			Scree	n	Day 2	В	Day 5	6
			25/03/	92	22/04/	92	20/05/	92
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB _	12-16 (G/DL)	01/03/91	14.10	1 1	14.40		14.30	
HT	0.37-0.46 (L/L)	01/03/91	0.43	l i	0.43		0.43	
RBC	4,2-5,5 (10-12/L)	01/03/91	4.75		4.66		4.62	
HBC	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	ıl	67.00	l
MBC: L	25-40 (%)	01/03/91	29.00		29.00		28.00	l
NBC: E	2-4 (%)	01/03/91	0.00	<	2.00		2.00	l
MBC: M	2-6 (%)	01/03/91	4.00		2.00	lí	3.00	
NBC: B	0-1 (2)	01/03/91	1.00		1.00	1 1	0.00	
PLATELETS	140-440 (10-9/L)	01/03/91	308.00	1 1	329.00	li	325.00	
NA+	135-145 (MNOL/L)	01/03/91	140.00		139.00		139.00	
K+	3.5-5 (MMOL/L)	01/03/91	3.80		4.10	1 1	4.30	
CL-	98-108 (MMOL/L)	01/03/91	99.00		98.00		97.00	<
CD- Ca++	2.3-2.75 (MMOL/L)	01/03/91	2.20	<	2.40		2.40	
P04	0.81-1.61 (NMOL/L)		0.88	1		li	0.85	
SGOT	3-15 (U/L)	01/03/91	13.00		14.00		14.00	l
SGPT	5-17 (U/L)	01/03/91	23.00	-	19.00	ا دا	16.00	1
GANMA GT	4-18 (U/L)	01/03/91	17.00		14.00	l i	13.00	1
	120-240 (U/L)	01/03/91	165.00	i I	180.00		166.00	
LDH ALK. PHOSPH.	60-170 (U/L)	01/03/91	87.00		99.00	l I	103.00	
	70-110 (MG/DL)	01/03/91	109.00	!	32.00		92.00	1
GLUCOSE	17-56 (MG/DL)	01/03/91	19.00	i I	23.00	l I	24.00	
BUN	0.4-1.2 (MG/DL)	01/03/91	1.00	ll	0.90	l I	0.90	İ
CREATININE	2.4-5.7 (MG/DL)	01/03/91	4.10		4.80		0.70	
URIC ACID	65-85 (G/L)	01/03/91	70.10	Ιİ	73.70		78.20	l
TOT. PROTEINS	36-58 (G/L)	01/03/91	43.20		43.70		47.90	
ALBUMINE		01/03/91	138.00		189.00		176.00	
TOT. CHOLEST.	130-200 (NG/DL) 130-200 (NG/DL)	01/03/91	121.00		185.00		142.00	İ
TRIGLYCERIDES		01/03/91	1.70	`	1.90		2.00	ĺ
GLOBULINS ALPHA 1	1.3-4.3 (G/L) 3.9-8.5 (G/L)	01/03/91	4.80		5.20		5.70	
GLOBULINS ALPHA 2			7.40		8.40		8.10	
GLOBULINS BETA	5.2-11.9 (G/L)	01/03/91 01/03/91	13.00		14.50		14.50	
GLOBULINS GAMMA	5.9-16.2 (G/L)		0.60		14.30		17.00	1
TSK	0.3-3.5 (MU/L)	01/03/91	17.40					l
T4	9-21 (NG/L)	01/03/91	17.40			1		l

1038

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not

>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIGAS HULANG - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 2 Patient: 80 Treatment: Fluoxetine Sex: Male

				Vis:	it numbe	c / I	Laborato	ry da	ate	
			Scree	n	Day 1	4	Day 2	В	Day 5	6
			15/01/	93	29/01/	93	12/02/	93	12/03/	93
			value	(¢)	value	(¢)	value	(4)	value	(¢
Laboratory test	Range value	Range date								
НВ	14-18 (G/DL)	01/03/91	17.50	1	16.50		16.80	!	16.00	
HT	38-57 (%)	01/03/91	50.60	1	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	1	10.40	>	8.70		8.80	
MBC: N	50-70 (%)	01/03/91	54.90				62.00			
MBC: L	25-40 (X)	01/03/91	33.70	1			34.00			
MBC: E	2-4 (%)	01/03/91	3.40	1			2.00			
WBC: M	2-6 (%)	01/03/91	6.90	>			2.00			i
MBC: 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	1
NA+ K+	3.5-5 (MMOL/L)	01/03/91	4.90	1			4.90		5.40	>
K+	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	1			2.30		2.30	
P04	0.81-1.61 (MMOL/L)		0.88				0.90		0.60	<<
	3-18 (U/L)	01/03/91	9.00		16.00		11.00		8.00	l
SGOT	5-22 (U/L)	01/03/91	21.00		17.00		20.00		16.00	ŀ
	5-22 (U/L) 6-28 (U/L)	01/03/91	30.00		20.00		21.00		23.00	
GAMMA GT		01/03/91	170.00	-	20.00		2		137.00	
LDH	120-240 (U/L)	01/03/91	158.00		175.00	l ,	161.00		144.00	1
ALK. PHOSPH.	60-170 (U/L)		99.00		173.00	-	101100			
GLUCOSE	70-110 (MG/DL)	01/03/91	32.00				23.00		35.00	l
BUN	17-56 (MG/DL)	01/03/91	0.70				0.90		0.90	
CREATININE	0.4-1.2 (MG/DL)	01/03/91	5.00				0.50		0.,,0	ł
URIC ACID	3,4-7 (MG/DL)	01/03/91		į.					73.10	1
TOT. PROTEINS	65-85 (G/L)	01/03/91	65.60	l .					65.00	
ALBUMINE	56-6B (X)	01/03/91	66.70	l_					85.00	ŀ
TOT, CHOLEST.	130-200 (MG/DL)	01/03/91	245.00							
TRIGLYCERIDES	130-200 (MG/DL)	01/03/91	282.00	>>						1
GLOBULINS ALPHA 1	2-5 (%)	01/03/91	2.40						3.00	
GLOBULINS ALPHA 2	6-10 (%)	01/03/91	10.80	>					10.20	۱>
GLOBULINS BETA	8-14 (%)	01/03/91	10.90	1					13.40	١.
GLOBULINS GAMMA	9-19 (%)	01/03/91	9.20					-	8.20	
TSH	0.3-3.5 (MU/L)	01/03/91	2.00	l					1.40	
T4	9-21 (NG/L)	01/03/91	13.30	I		1			10.50	1

<sup>(</sup>c) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIGAL STORMS - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA Patient: 65 Treatment: Fluoxetine

					Visit	numb	er / La	bora	tory dat	0		
			Screen	ı	Day 1	4	Day 2	8	Day 4	2	Day 5	6
			11/10/	91	29/10/9	91	12/11/	91	26/11/	91	10/12/	91
			value	(¢)	value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						İ				
HB	12-16 (G/DL)	18/09/91	13.10	1	14.10		13.20		14.60		13.80	
HT	37-46 (%)	18/09/91	38.80		42.10		41.00		44.00	ļ	41.50	
RBC	4.4-6 (10~12/L)	18/09/91	4.14	<	4.42		4.30	<	4.62		4.37	
KBC	4.3-10 (10-9/L)	18/09/91	5.70		7.20	1	7.50		12.74	>	9.60	
MBC: N	45-80 (%)	18/09/91	43.00	<			49.00			İ	71.00	}
WBC: L	20-40 (%)	18/09/91	48.00	>			49.00	>			26.00	
MBC: E	1-4 (%)	18/09/91	6.00	>>			0.00	<			1.00	
MBC: M	2-8 (%)	18/09/91	2.00				2.00			1	2.00	Į.
MBC: B	0-1 (%)	18/09/91	1.00	- '			0.00				0.00	ł
PLATELETS	140-440 (10-9/L)	18/09/91	220.00		256.00		242.00	i I	272.00		278.00	1
NA+	132-146 (MMOL/L)	18/09/91	141.00		142.00		143,00		142.00		140.00	1
K+	3.6-5 (MMOL/L)	18/09/91	4.00		4.30		4.50	l	4.10		3.70	
Ca++	2.2-2.7 (MMOL/L)	18/09/91	2.70	- 1	2.80	c	2.80		2.90	>	2.70	
SGOT	5-15 (U/L)	18/09/91	7.00		10.00	- 1	9.00		12.00		11.00	
SGPT	5-19 (U/L)	18/09/91	5.00	į	8.00	- 1	7.00		10.00		10.00	l
GAMMA GT	4-18 (U/L)	18/09/91	4.00	- 1	4.00		5.00		6.00			
LDH	120-240 (U/L)	18/09/91	132.00	ŀ							164.00	1
ALK. PHOSPH.	40-190 (U/L)	18/09/91	148.00		148.00		123.00				124.00	1
GLUCOSE	70-100 (MG/DL)	18/09/91	91.00		88.00		82,00	l i	89.00		85.00	
CREATININE	0.5-0.9 (MG/DL)	18/09/91	0.70	- 1	0.70		0.90		0.80		0.70	1
URIC ACID	2.4-5.7 (MG/DL)	18/09/91	4.00	- 1	3.90		4.30				3.90	)
TOT BILIRUBIN	0-1 (MG/DL)	18/09/91	0.40	- 1	0.40	- 1	0.40		0.50		0.40	1
TOT. PROTEINS	66-87 (G/L)	18/09/91	59.00	<	69.00	- 1	62.00	۷ .	70.00		65,00	<
ALBUNINE	58-70 (%)	18/09/91	66.40	- 1		- 1	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	1
GLORULINS ALPHA 1	1.5-4 (%)	18/09/91	2.70			- 1	2.80				3.30	
GLOBULINS ALPHA 2	5-10 (%)	18/09/91	6.50			- 1	6.70				6.60	l
GLOBULINS BETA	8-13 (2)	18/09/91	10.40		i	i	10.30		i		10.40	1
GLOBULINS GAMMA	10-19 (%)	18/09/91	14,00				14.30				14.50	1
TSH	0.1-3.5 (UU/ML)	18/09/91	0.60				1.20		ļ		1.00	
T4	5-12.5 (UG/100ML)	18/09/91	7.20				7.30				7,80	I

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIGAS STATINGS - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 3 Patient: 66 Treatment: Fluoxotine Sex: Female

					imber / ory date	
			Scree	a	Day 2	8
			11/10/	91	12/11/	91
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date	12.80		13.20	
HB	12-16 (U/DL)	10/10/91			42.40	
HT	37-46 (%)	10/10/91	38.30 4.16		42.40	
RBC	4.4-6 (10-12/L)	10/10/91	10.80		10.10	
MBC	4.3-10 (10-9/L)	10/10/91			60.00	
MBC: N	45-80 (%)	10/10/91	45.00 51.00		38.00	
MBC: L	20-40 (%)	10/10/91	2.00		0.00	
MBC: E	1-4 (%)	10/10/91	2.00		2.00	
MBC: M	2-8 (X)	10/10/91 10/10/91	0.00		0.00	
MBC: B	0-1 (%) 140-440 (10-9/L)	10/10/91	374.00		402.00	
PLATELETS		10/10/91	138.00		143.00	Ì
NA+	132-146 (MMOL/L)	10/10/91	4.30		3.40	-
R+	3.6-5 (MMOL/L)	10/10/91	2.50		2.30	1
Ca++	2.2-2.7 (MMQL/L)	10/10/91	10.00		16.00	
SCOT	5-15 (U/L)	10/10/91	9.00		14.00	
SGPT	5-19 (U/L)		10.00		9.00	
GAMMA GT	4-18 (U/L)	10/10/91	164.00		201.00	
LDH	120-240 (U/L)	10/10/91	153.00		77.00	
ALK. PHOSPH.	40-190 (U/L)	10/10/91	120.00		99.00	
GLUCOSE	70-100 (MG/DL)	10/10/91	0.80		0.60	
CREATININE	0.5-0.9 (MG/DL)	10/10/91	4.50		3.50	
URIC ACID	2,4-5.7 (MG/DL)	10/10/91	0.30		0.30	
TOT BILIRUBIN	0-1 (MG/DL)	10/10/91	68.00		0.30	
TOT. PROTEINS	66-87 (G/L)	10/10/91	00.00		5.40	_
	5.6-7.8 (G/DL)	10/11/91	62.50		64.50	
ALBUMINE	58-70 (%)	10/10/91	270.00	.	144.00	
TOT. CHOLEST.	130-220 (MG/DL)	10/10/91	92.00		144.00	
TRIGLYCERIDES	30-150 (MG/DL)	10/10/91 10/10/91	3.70		3.20	
GLOBULINS ALPHA 1		10/10/91	7.90		7.00	
GLOBULINS ALPHA 2	5-10 (2)		12.20		11.40	
GLOBULINS BETA	8-13 (%)	10/10/91 10/10/91	13.70		13.90	
GLOBULINS GAMMA	10-19 (%)		0.90		0.30	
TSH	0.1-3.5 (UU/ML)	10/10/91	16.40	ا ۱۰۰	15.20	
T4	5-12.5 (UG/100ML)	10/10/91	10.40	''	15.20	

1041

(0) << clinically relevant (value lower out of range (value lower than min range) than min range) (value lower wissing laboratory text value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIGAL SHIPANG - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 4 Patient: 98 Treatment: Fluoxetine Sex: Female

			Visit	numk	er / La	borat	tory dat	0
			Scree	n	Day 2	В	Day 5	6
			27/05/	91	26/06/	91	24/07/	91
			value	(¢)	value	(0)	value	(4)
Laboratory test	Range value	Range date						ľ
НВ	12-18 (G/DL)	20/05/91	15.80	F 1	15.10	1 1	14.80	
HT	37-54 (%)	20/05/91	46.00		44.80	1 1	43.60	
RBC	4.2-6.3 (10-12/L)	20/05/91	4.55		4.39		4.28	}
MBC	4.3-10 (10-9/L)	20/05/91	11.60	>	8.60		8.90	1
MBC: N	42,2-75,2 (2)	20/05/91	79.30	>	73.40		75.60	>
MBC: L	1,2-3,4 (10-9/L)	20/05/91	1.90		2.10		1.80	
WBC: N	0.11-0.59 (10-9/L)	20/05/91	0.50	1 1	0.20		0.30	1
PLATELETS	140-440 (10-9/L)	20/05/91	327.00		288.00	1 I	286.00	l
NA+	137-147 (MMOL/L)	20/05/91	146.00		141.00	1		l
K+	3.5-5.3 (MMOL/L)	20/05/91	4.00	i I	4.00	1 1		l
CL-	98-111 (MMOL/L)	20/05/91	113.00	>	111.00	i I		l
Ca++	2.1-2.7 (MMOL/L)	20/05/91	2.53	ll	2.45	1		İ
P04	2.3-4.2 (MMOL/L)	20/05/91	2.90		2.50	1 1		l
SCOT	5-18 (U/L)	20/05/91	10.00		9.00	i I		ŀ
SGPT	5-23 (U/L)	20/05/91	10.00		8.00			ł
GAMMA GT	6-28 (U/L)	20/05/91	13.00		12.00			1
LDK	100-200 (U/L)	20/05/91	212.00	>	189.00			l
ALK. PHOSPH.	68-195 (U/L)	20/05/91	113.00		95.00	1		l
GLUCOSE	70-117 (MG/DL)	20/05/91	80.00		90.00			l
BUN	4-52 (MG/DL)	20/05/91	13.00		17.00			l
CREATININE	0.3-1.39 (MG/DL)	20/05/91	0.90		1.00			l l
URIC ACID	2.9-7.4 (NG/DL)	20/05/91	5.80		6.40			l
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	. 1			0.10	l
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			1
TRIGLYCERIDES	30-170 (MG/DL)	20/05/91	90.00		112.00			1
GLOBULINS ALPHA 1	1-4 (%)	20/05/91	4.20				5.40	>>
GLOBULINS ALPHA 2	6-11 (%)	20/05/91	9.90				8.30	1
GLOBULINS BETA	10-15 (%)	20/05/91	14.50			l l	13.00	
GLOBULING GAMMA	12-22 (%)	20/05/91	12.50			l l	12.80	
T4	4.5-12.5 (UG/DL)	20/05/91	7.70	ıi				ĺ
14	4.5-12.5 (UG/DL)	44, 49, 31	7.70					

1042

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range) (value lower missing laboratory test value of laboratory not done

>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIGAS 5868 - CNS

### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

### LABORATORY DATA Patient: 99 Treatment: Fluoxetine Sex: Female

			Visi number Laborat date	ory
			Scree	n
			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	
NBC: L	1.2-3.4 (10-9/L)	15/05/91	2.60	
WBC: M	0.11-0.59 (10-9/L)		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	
P04	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	ŀ
URIC ACID	2.9-7.4 (MG/DL)	15/05/91	3.70	ł
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	l
ALBUMINE	3.7-5.4 (G/DL)	15/05/91	4.90	
TOT. CHOLEST.	150-260 (MG/DL)	15/05/91	214.00	l
TRIGLYCERIDES	30-170 (MG/DL)	15/05/91	142.00	
GLOBULINS ALPHA 1		15/05/91	4.20	
GLOBULING ALPHA 2	6-11 (%)	15/05/91	8.80	
GLOBULINS BETA	10-15 (X)	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	I

1043

(t) << clinically relevant (value lower out of range (value lower than min range)

\*\* missing laboratory test value of laboratory not

>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTIGAS 5 NO 4 PG - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 102 Treatment: Fluoxetine

			Visit	numb	er / Lai	orat	ory date	•
			Scree	n	Day 2	3	Day 5	6
			10/07/	92	07/08/	2	04/09/	92
			value	(¢)	value	(4)	value	(¢)
Laboratory test	Range value	Range date						
KB	12-18 (G/DL)	15/05/91	12,80		12.60		14.00	1
HT	37-54 (X)	15/05/91	38.00		37.70		40.50	1
RBC	4.2-6.3 (10-12/L)	15/05/91	4.16	<	4.09	<	4.45	1
MBC	4.3-10 (10-9/L)	15/05/91	6.40	i I	6.40		6.80	1
WBC: N	42.2-75.2 (%)	15/05/91	61.50		64,80		69.60	1
WBC: L	1.2-3.4 (10-9/L)	15/05/91	2.30		2.00		1.80	t
WBC: E	0-0.7 (10-9/L)	15/05/91	0.00		0.00			1
MBC: 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	l i	0.00			t
PLATELETS	140-440 (10-9/L)	15/05/91	359.00		327.00	1	346.00	ł
NA+	137-147 (MMOL/L)	01/08/92	1		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	1				105.00	
Ca++	2.1-2.7 (MMOL/L)	15/05/91	2.30		2.20		2.30	
P04	2.3-4.2 (MMOL/L)	15/05/91	3.00	1 1	2.80		2.80	1
SGOT	5-18 (U/L)	15/05/91	10.00		11.00		9.00	
SGPT	5-23 (U/L)	15/05/91	12.00	1 1	11.00		10.00	1
GAMMA GT	6-28 (U/L)	15/05/91	29.00		16.00		9.00	
	100-200 (U/L)	15/05/91	199.00	l	172.00		179.00	i
LDH	68-195 (U/L)	15/05/91	192.00		171.00		145.00	
ALK. PHOSPH.	70-117 (MG/DL)	15/05/91	104.00	}	99.00	i 1	150.00	>
GLUCOSE	4-52 (MG/DL)	15/05/91	36.00		29.00		36.00	ľ
BUN		15/05/91	0.80		0.80	l	0.90	
CREATININE	0.3-1.39 (MG/DL)	15/05/91	4.90		6.10		6.50	
URIC ACID	2.9-7.4 (MG/DL)		0.60		0.90		0.50	
TOT BILIRUBIN	0.3-1.54 (MG/DL)	15/05/91			0.20		0.10	ŀ
DIR BILIRUBIN	0-0.3 (MG/DL)	15/05/91	0.10	_	7.20		7,50	
TOT. PROTEINS	6.6-8.3 (G/DL)	15/05/91	4.40	١ ١	4.30	l f	4.60	
ALBUMINE	3.7-5.4 (G/DL)	15/05/91	271.00	L	252.00		270.00	
TOT. CHOLEST.	150-260 (MG/DL)	15/05/91			154.00		233.00	
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					ł
	1-4 (%)	01/08/92			3.60			ł
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		44 00			1
	10-15 (%)	01/08/92	l		11.00			l
GLOBULINS GAMMA	0.88-1.6 (G/DL)	15/05/91	1.10					l
	12-22 (%)	01/08/92			16.90			1
TSH	0.1-3.5 (UU/ML)	15/05/91	0.60					1
T4	4.5-12.5 (UG/DL)	15/05/91	8.10	1	1	1 1		1

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTIGAS THE ANG - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 103 Treatment: Fluoxetine Sex: Female

					mber / ory date	
			Scree	1	Day 2	В
			13/07/	92	10/08/	92
			value	(¢)	value	(¢
Laboratory test	Range value	Range date				Г
HB	12-18 (G/DL)	15/05/91	16.00	l i	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	
MBC	4.3-10 (10-9/L)	15/05/91	8.30		7.30	
MBC: N	42.2-75.2 (%)	02/08/92			64.10	
NBC: L	1.2-3.4 (10-9/L)	15/05/91	2.50		2.00	
NBC: E	0-0.7 (10-9/L)	15/05/91	0.00		0.00	1
NBC: M	0.11-0.59 (10-9/L)	15/05/91	0.00	<	0.60	>
MBC: B	0-0.2 (10-9/L)	15/05/91	0.00		0.00	1
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	
P04	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	
	100-200 (U/L)	15/05/91	175.00	-	152.00	
LDH	68-195 (U/L)	15/05/91	156.00		116.00	
ALK. PHOSPH.	70-117 (NG/DL)	15/05/91	83.00		115.00	
GLUCOSE		15/05/91	33.00		26.00	
BUN	4-52 (MG/DL) 0.3-1.39 (MG/DL)	15/05/91	0.90		0.90	
CREATININE		15/05/91	4.20		4.20	
URIC ACID	2.9-7.4 (MG/DL)		0.60		0.30	
TOT BILIRUBIN	0.3-1.54 (MG/DL)	15/05/91	0.10		0.10	
DIR BILIRUBIN	0-0.3 (MG/DL)	15/05/91	7.50		6.50	۱,
TOT. PROTEINS	6.6-8.3 (G/DL)	15/05/91	4.90		4.30	`
ALBUMINE	3.7-5.4 (G/DL)	15/05/91 15/05/91	293.00	l. I	255.00	
TOT. CHOLEST.	150-260 (MG/DL)	,	136.00		153.00	
TRIGLYCERIDES	30-170 (MG/DL)	15/05/91	0.30		135.00	
GLOBULINS ALPHA 1	0.12-0.28 (G/DL)	15/05/91	0.30		3.90	
	1-4 (%)	02/08/92	0.90		3.90	1
GLOBULINS ALPHA 2	0.45-0.82 (G/DL)	15/05/91	0.90		14.20	l_
	6-11 (%)	02/08/92			14.20	^ا
GLOBULINS BETA	0.74-1.1 (G/DL)	15/05/91	0.90			l
	10-15 (%)	02/08/92		!	14.20	l
GLOBULINS GAMMA	0.88-1.6 (G/DL)	15/05/91	0.60	<<		١.
	12-22 (%)	02/08/92			9.30	<
TSH	0.1-3.5 (UU/ML)	15/05/91	1.70			1
T4	4.5-12.5 (UG/DL)	15/05/91	10.40	1		}

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTIGAS NILANG - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 4 Patient: 105 Treatment: Fluoxetine Sex: Hale

		_	Visit	numk	er / Lal	borat	ory date	9
			Scree	n	Day 2	8	Day 5	5
*			20/08/	92	18/09/	92	16/10/9	92
			value	(4)	value	(¢)	valu <del>o</del>	(¢
Laboratory test	Range value	Range date						
нв	12-18 (G/DL)	01/08/92	16.10	1 1	16.90	i	16.10	
НT	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	
KBC	4.3-10 (10¬9/L)	01/08/92	7.70		5.10		6.90	
MBC: N	42.2-75.2 (%)	01/08/92	78.10	>	74.20		76.00	>
MBC: L	1.2-3.4 (10-9/L)	01/08/92	1.40		1.20		1.30	
MBC: E	0-0.7 (10 <del>-9/</del> L)	01/08/92	0.00		0.00		0.00	1
WBC: N	0.11-0.59 (10-9/L)		0.30		0.10	<	0.40	
<b>ЯВС: В</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	i I		
Ca++	2.1-2.7 (MMOL/L)	01/08/92	2.30		2.30		2.40	
P04	2.3-4.2 (MMOL/L)	01/08/92	3.50		3.50		3.70	1
SCOT	5-18 (U/L)	01/08/92	7.00	1 1	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	ıl	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	ıl	6.40		6.80	
TOT BILIRUBIN	0.3-1.54 (MG/DL)	01/08/92	0.30		0.50	1 1	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					ĺ
T4	4.5-12.5 (UG/DL)	01/08/92	8.30	1 1				l

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range) (value lower than min range) than min range) than min range)

<sup>&</sup>gt;> clinically relevant (value higher than max range to out of range (value higher than max range to missing range value)

### PHARMACIA PHARMACEUTIGAL HILANG - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 5 Patient: 130 Treatment: Fluoxetine Sex: Female

			Visit	numk	or / La	borat	ory date	0
			Screen	n	Day 2	В	Day 5	6
			24/02/	92	20/03/	92	24/04/	92
			value	(4)	value	(¢)	value	(0)
Laboratory test	Range value	Range date						
нв	12.5-18 (G/DL)	09/09/91	13.70		13.10	1 1	13.40	
HT	37-47 (X)	09/09/91	39.00		38.40		39.60	l
RBC	4.5-5.5 (10~6/UL)	09/09/91	4.48	<	4.31	<	4.40	<
HBC	4-10.8 (10-3/UL)	09/09/91	7.30		5.10		4.90	l
NBC: N	40-74 (X)	09/09/91	55.80		44.90	1 1	45.60	
MBC: L	19-48 (%)	09/09/91	32.90		44.30	l i	43.70	l
NBC: E	0-4 (%)	09/09/91	3,50		2.50	1 1	2.30	ŀ
NBC: M	3.4-9 (%)	09/09/91	7.70		7.10	1 1	7.10	
MBC: B	0-1.5 (%)	09/09/91	0.10		1.20	1 1	1.30	
PLATELETS	150-400 (10-3/UL)	09/09/91	199.00		164.00	1 1	191.00	l
NA+	135-148 (MEQ/L)	09/09/91	139.00		141.00	1 1	142.00	
K+	3.5-5.3 (MEQ/L)	09/09/91	4.10		4.20	1 1	4.70	
Ca++	8.1-10.4 (MG/DL)	09/09/91	10.00		9.30	1 1	10.30	
P04	2.5-5 (MG/DL)	09/09/91	4.20		4.20	1 1	4.30	
SGOT	4-40 (U/L)	09/09/91	16.00		17.00	1 1	17.00	1
SGPT	4-40 (U/L)	09/09/91	14.00		16.00	i 1	23.00	ł
GAMMA GT	7-50 (U/L)	09/09/91	12.00	1 1	11.00	i I	11,00	[
LDH	230-460 (U/L)	09/09/91	273.00		244.00	Ιİ	267.00	1
ALK. PHOSPH.	98-280 (U/L)	09/09/91	121.00		110.00	1 1	125.00	ł
GLUCOSE	60-110 (MG/DL)	09/09/91	95.00	1	89.00	i I	86.00	ł
BUN	4-22 (NG/DL)	09/09/91	21.70		16.50		23.80	>
CREATININE	0.3-1.2 (MG/DL)	09/09/91	1.20		1.00	l 1	1.10	1
URIC ACID	2.4-7 (MG/DL)	09/09/91	6.00		5.30		5.20	1
TOT BILIRUBIN	0.3-1.2 (MG/DL)	09/09/91	0.40		0.50	I	0.50	1
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	1	211.00	I	213.00	1
TRIGLYCERIDES	30-150 (MG/DL)	09/09/91	71.00		50.00	l I	66.00	1
TSH	0.4-4.5 (UU/ML)	09/09/91	3.60	1 1				1
74	0.8-2 (NG/100ML)	09/09/91	1.10			l l		1

1047

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

### PHARMACIA PHARMACEUTICAL STATISTICS - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

# LABORATORY DATA Patient: 194 Treatment: Fluoxetine Sex: Female

			Visit	numi	er / La	borat	tory date	e
			Scree	n	Day 2	8	Day 5	6
			02/01/	92	07/02/	92	05/03/	92
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
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	۱<	4.30		4.12	
MBC	4.3-10 (10-3/UL)	01/12/91	7.70		7.80	1 1	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	1 1	2.12	
WBC: E	0-0.5 (10-3/UL)	01/12/91	0.06		0.08	l I	0.07	
WBC: M	0.1-0.8 (10-3/UL)	01/12/91	0.33		0.24		0.26	
NBC: 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	l i	2.24	
P04	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	li	24.00	
SGPT	8-36 (U/L)	01/12/91	74.00	>>	31.00		31.00	
GANNA GT	7-43 (U/L)	01/12/91	30.00	1	30.00		26.00	
LDH	230-460 (U/L)	01/12/91	324.00		311.00	1 1	319.00	
ALK. PHOSPH.	81-263 (U/L)	01/12/91	95.00	1 1	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	1 1	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	i I	6.00		9.00	
DIR BILIRUBIN	0-6 (UNOL/L)	01/12/91	2.00		4,00		3.00	l
TOT. PROTEINS	64-76 (G/L)	01/12/91	69.80		80.10	>	72.50	l
ALBUMINE	40-48 (G/L)	01/12/91	45.40		49.30	>	46,20	1
TOT. CHOLEST.	4.3-7.6 (MNOL/L)	01/12/91	5.40		6.64		5.97	1
TRIGLYCERIDES	0,34-1.9 (MMOL/L)	01/12/91	0.98		0.93		0.83	1
TSH	0.3-4 (MUI/L)	01/12/91	2.50			ı		l
T4	9-24 (PMOL/L)	01/12/91	14.50			i i		1

1048

#### PHARMACIA PHARMACEUTICALS NO - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 7 Patient: 195 Treatment: Fluoxetine Sex: Hale

			Visit	numb	er / Lai	borat	ory date	9
			Scree	n	Day 2	8	Day 5	6
			13/02/	92	13/03/	92	10/04/9	92
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date						
нв	14-18 (G/DL)	01/12/91	15.50	1	15.80	1 1	14.60	١.
HT	42-52 (%)	01/12/91	46.00		47.00	ł I	41.00	١<
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	1 1	5.77	
NBC: 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: N	0.1-0.8 (10-3/VL)	01/12/91	0.33		0.40		0.50	
MBC: B	0-0.1 (10-3/UL)	01/12/91	0.03		0.10		0.16	>>
PLATELETS	150-350 (10-3/VL)	01/12/91	208.00	1 1	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	ŀ
Ca++	2.14-2.54 (MMOL/L)	01/12/91	2.27		2.41	1 1	2.35	l
P04	0.85-1.33 (MMOL/L)	01/12/91	1.10	i I	1.09		0.90	
SGOT	9-25 (U/L)	01/12/91	27.00		19.00	Ιí	24.00	
SGPT	8-36 (U/L)	01/12/91	47.00		24.00	li	23.00	
GAMMA GT	7-43 (U/L)	01/12/91	53.00	>	36.00		42.00	1
LDH	230-460 (U/L)	01/12/91	286.00	i I	317.00	1 1	339.00	l
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	Ì
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	1 1	9.00	
DIR BILIRUBIN	0-6 (UMOL/L)	01/12/91	5.00		3.00	1 1	3.00	1
TOT. PROTEINS	64-76 (G/L)	01/12/91	74.30		77.40		71.20	1
ALBUMINE	40-4B (G/L)	01/12/91	47.00		49.00		48.80	
TOT. CHOLEST.	4.3-7.6 (MNOL/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	l
TSH	0.3-4 (MUI/L)	01/12/91	1.40	1				l
T4	9-24 (PMOL/L)	01/12/91	19.20	1		1		l

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range > out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTICALS NO - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 7 Patient: 197 Treatment: Fluoxetine Sex: Male

			Visi number Laborate date	•
			Scree	n
			06/11/9	92
			yalue	(¢)
Laboratory test	Range value	Range date	40.00	٠.
нв	14-18 (G/DL)	01/12/91	10.90	
HT	42-52 (%)	01/12/91	32.00	1
RBC	4.5-6.3 (10-6/UL)		3.60	
NBC	4.3-10 (10-3/UL)	01/12/91	7.60	
MBC: N	1.8-8 (10-3/UL)	01/12/91	4.30	1
WBC: L	1-5 (10-3/VL)	01/12/91	2.66	
NBC: E	0-0.5 (10-3/UL)	01/12/91	0.22	1
WBC: M	0.1-0.8 (10-3/UL)		0.38	
WBC: B	0-0.1 (10-3/UL)	01/12/91	0.00	
PLATELETS	150-350 (10-3/UL)		194.00	
NA+	140-148 (MMOL/L)	01/12/91	144.00	
K+	3.9-5.1 (MMOL/L)	01/12/91	4.24	1
CL-	96~109 (MMOL/L)	01/12/91	108.00	1
Ca++	2.14-2.54 (MMOL/L)		2.24	
P04	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	
RUN	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 (UNOL/L)	01/12/91	162.00	
TOT BILIRUBIN	0-17 (UMOL/L)	01/12/91	6.00	l
DIR BILIRUBIN	0-6 (UMOL/L)	01/12/91	3.00	l
TOT. PROTEINS	64-76 (G/L)	01/12/91	58.40	<
ALBUMINE	40-48 (G/L)	01/12/91	41.00	l
TOT. CHOLEST.	4.3-7.6 (MMOL/L)		2.99	<
	0.34-1.9 (MMOL/L)		0.71	
TRIGLYCERIDES	0.3-4 (MUI/L)	01/12/91	0.02	
TSH 	9-24 (PMOL/L)	01/12/91	16.60	
T4	9-24 (PMUL/L)	01/12/71	10.00	1

1050

<sup>&</sup>gt;> clinically relevant (value higher than max range)
> out of range (value higher than max range)
() missing range value

### PHARMACIA PHARMACEUTICAS STUDIOS - CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

# LABORATORY DATA Centre: 11 Patient: 321 Treatment: Fluoxetine Sex: Female

					imber / ory date	
			Screen	1	Day 5	6
			05/11/9	91	09/01/	92
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date	400.00		134.00	
HB	115-145 (G/L)	01/10/91	138.00		0.41	_
HT	0.42-0.5 (L/L)	01/10/91	0.44		4.62	
RBC	4.2-5.2 (10-12/L)	01/10/91	4.87		3.71	_
MBC	4.5-10 (10-9/L)	01/10/91	4.17	<b> </b>	57.20	١,
MBC: N	40-70 (%)	01/10/91	53.10			
MBC: L	20-45 (%)	01/10/91	33.70		30.00 2.70	
MBC: E	1-5 (%)	01/10/91	2.40		7.30	
MBC: M	2-10 (X)	01/10/91	6.60 1.00		0.80	1
MBC: B	0-1 (%)	01/10/91	224.00		220.00	
PLATELETS	150-350 (10-9/L)	01/10/91	142.00		144.00	
NA+	135-145 (MEQ/L)	01/10/91			3.80	
K+	3.5-4.5 (HEQ/L)	01/10/91	4.10		98.00	
CL-	95-106 (NEQ/L)	01/10/91	9.90		9.60	
Ca++	8.5-10.5 (MG/DL)	01/10/91	4.00		3.30	
P04	2.3-4.3 (MG/DL)	01/10/91	28.00		18.00	
SCOT	10-40 (UI/L)	01/10/91			21.00	
SGPT	10-40 (UI/L)	01/10/91	32.00			
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	1	63.00	ı
ALBUMINE	57-69 (%)	01/10/91	70.00	1	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	1	3.10	1
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 (X)	01/10/91	9.10	<<	10.20	<<
TSH	0.5-5 (UU/ML)	01/10/91	1.40	ĺ		1
T4	4.5-12.5	01/10/91	ŀ	1		
* '	(UG/100NL)		8.10	l		1

1051

(¢) << clinically relevant (value lower cut of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

() missing range value

<sup>&</sup>gt;> clinically relevant (value higher than max range) out of range (value higher than max range)

#### PHARMACIA PHARMACEUTISASSIGNIS - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centro: 11 Patient: 323 Treatment: Fluoxetine Sex: Female

			Visit	numb	er / Lai	borat	ory date	9
			Scree	n	Day 2	В	Day 5	6
			30/10/	91	20/12/	91	23/01/9	92
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date		П				
КB	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	>
MBC	4.5-10 (10-9/L)	01/10/91	8.06		6.72		8.09	1
MBC: N	40-70 (%)	01/10/91	66.00	1 1	62.10		66.70	1
WBC: L	20-45 (X)	01/10/91	23.00	1 1	26.30	l i	23.20	
MBC: E	1-5 (%)	01/10/91	1.70	1 1	2.00		1.50	
HBC: M	2-10 (X)	01/10/91	6.10		6.70		6.20	
MBC: B	0-1 (%)	01/10/91	1.00	i l	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	1 1	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	1	1 1			99.00	
Ca++	8.5-10.5 (MG/DL)	01/10/91	10.00		6.90	<<	9.80	
P04	2.3-4.3 (MG/DL)	01/10/91	3.80		3.70		3,70	
SCOT	10-40 (UI/L)	01/10/91	21.00		19.00		28.00	
SGPT	10-40 (UI/L)	01/10/91	26.00	l i	22.00	1 1	31.00	
GAMMA GT	5-40 (UI/L)	01/10/91	34.00		23,00		30.00	l
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	l i	161.00	f I	191.00	1
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	1
CREATININE	0.5-1.3 (MG/DL)	01/10/91	0.70	1 1	0.80	1	0.70	
URIC ACID	1.9-7.4 (MG/DL)	01/10/91	4.00	l	4.50		4.10	1
TOT BILIRUBIN	0.1-1 (MG/DL)	01/10/91	0.60	1 1	0.70	[	0.70	ı
TOT. PROTEINS	60-80 (G/L)	01/10/91	76.00		72.00	1	68.00	l
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	l
TRIGLYCERIDES	50-150 (MG/DL)	01/10/91	129.00		117.00		125.00	l
GLOBULINS ALPHA 1	2.1-3.5 (%)	01/10/91			3.10		3.30	l
GLOBULINS ALPHA 2	6-10 (%)	01/10/91			6.70		6.40	
GLOBULINS BETA	6.5-11.5 (%)	01/10/91		1	11.00	1	11.00	
GLOBULINS GAMMA	15-22 (%)	01/10/91	1	1	10.60	i	10.30	<<

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTEDAS NHANO - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 327 Treatment: Fluoxetine Sex: Female

					umber / ory date	
			Scree	n	Day 2	8
			24/01/	12/03/	92	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
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	<
NBC	4.5-10 (10-9/L)	01/10/91	4.43	<	3.77	<
MBC: N	40-70 (%)	01/10/91	63.20		69.70	1
MBC: L	20-45 (%)	01/10/91	25.70		22.80	
MBC: E	1-5 (%)	01/10/91	0.90	<	0.30	<
MBC: M	2-10 (%)	01/10/91	7.00	1	4.00	Ī
BC: B	0-1 (2)	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	J
il-	95-106 (MED/L)	01/10/91	99.00		98.00	
a++	8.5-10.5 (MG/DL)	01/10/91	9.60	1	9.10	l
204	2.3-4.3 (MG/DL)	01/10/91	3.50		3.20	
SGOT	10-40 (UI/L)	01/10/91	20.00	- 1	16.00	l
SGPT	10-40 (UI/L)	01/10/91	24.00	- 1	16.00	
GAMMA GT	5-40 (UI/L)	01/10/91	10.00	- 1	11.00	
DH	250-450 (UI/L)	01/10/91	286.00	- 1	299.00	
LK. PHOSPH.	123-345 (UT/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	
				- 1	0.70	
CREATININE	0.5-1.3 (MG/DL)	01/10/91	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	<b>&gt;</b>	74.00	
LBUMINE	57-69 (%)	01/10/91	66.20		64.30	
TOT. CHOLEST.	148-247 (MG/DL)	01/10/91	199.00	- 1	177.00	
RIGLYCERIDES	50-150 (MG/DL)	01/10/91	33.00	<	39.00	<
CLOBULINS ALPHA 1	2.1-3.5 (%)	01/10/91	2.40	-	2.90	
CLOBULINS ALPHA 2	6-10 (%)	01/10/91	6.80		6.90	
CLOBULINS BETA	6.5-11.5 (%)	01/10/91	9.50		10.30	
GLOBULINS GAMMA	15-22 (X)	01/10/91	15.10	- 1	15.70	

1053

(¢) << clinically relevant (value lower than min range)
< out of range (value lower than min range)
than min range)
than min range)
and laboratory not done

### PHARMACIA PHARMACEUTIGH HAM - CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centro: 11 Patient: 328 Treatment: Fluoxetine Sex: Female

			Visit	numb	er / La	borat	ory date	8
			Scree	Screen			Day 5	6
			07/02/9	92	24/03/	92	21/04/9	92
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date						
HB	115-145 (G/L)	01/10/91	126.00			ll		1
	120-170 (G/L)	13/03/92			130.00		127.00	1
HT	0,42-0.5 (L/L)	01/10/91	0.38	<		l i		1
	0.36-0.51 (L/L)	13/03/92	1		0.40	l I	0.38	1
RBC	4.2-5.2 (10-12/L)	01/10/91	4.05	<		1 1		1
	3.9-5.5 (10-12/L)	13/03/92			4.29	1 1	4.23	}
NBC	4.5-10 (10-9/L)	01/10/91	5.57			1 1		}
	4-11 (10-9/L)	13/03/92		l i	4.64	1 1	4.49	
MBC: N	40-70 (X)	01/10/91	56.90			1 1		
nbc. II	45-75 (%)	13/03/92			54.50	1 1	52.60	l
MBC: L	20-45 (X)	01/10/91	30.70					ĺ
NDC. D	17-55 (%)	13/03/92			32.90		34.30	l
WBC: E	1-5 (2)	01/10/91	1.90					İ
MDC: E	0-5 (2)	13/03/92			2.00		2.00	l
MBC: M	2-10 (%)	01/10/91	6.20		7.60		6.50	
MBC: R	0-1 (%)	01/10/91	0.50					
MDC: D	0-2 (%)	13/03/92		i i	0.50		0.50	
Dr Amer eme	150-350 (10-9/L)	01/10/91	199.00					
PLATELETS	150-330 (10-9/L)	13/03/92	177.00	1	212.00		214.00	
NA+	135-145 (MEQ/L)	01/10/91	140.00	1 1	141.00		147.00	>
NA* K+	3.5-4.5 (MEQ/L)	01/10/91	3.30	c	4.30	1 1	3.80	
K+ CL-	95-106 (MEQ/L)	01/10/91	97.00			1 1	101.00	
	8.5-10.5 (MG/DL)	01/10/91	9.50	i	9.50	1 1	9.30	
Ca++	2.3-4.3 (MG/DL)	01/10/91	3.60	i	3.20	1 1	3.60	
P04	2.3-4.3 (MG/DL)	01/10/91	22.00		13.00	1 1	15.00	
SGOT	10-40 (UI/L)	01/10/91	18.00		13.00	l	17.00	
SGPT		01/10/91	8.00		8.00		9.00	
gamma GT	5-40 (UI/L)	01/10/91	295.00		323.00		355.00	
LDH	250-450 (UI/L)	01/10/91	113.00	<sub>&lt;</sub>	119.00	ا ءا	121.00	<
ALK. PHOSPH.	123-345 (VI/L)	01/10/91	90.00		98.00	1	95.00	_
GLUCOSE	64-107 (NG/DL)	• • • • • •	19.00		17.00	1	17.00	
BUN	10-25 (MG/DL)	01/10/91 01/10/91	0.80		0.60	1	0.70	ł
CREATININE	0.5-1.3 (MG/DL)		3,10		2.60	1 1	2.80	1
URIC ACID	1.9-7.4 (MG/DL)	01/10/91	0.30		0.40	1 1	0.40	l
TOT BILIRUBIN	0.1-1 (MG/DL)	01/10/91	68.00	1	70.00	ì	67.00	1
TOT. PROTEINS	60-80 (G/L)	01/10/91	69.40	>	70.40	>	71.60	١.
ALBUMINE	57-69 (%)	01/10/91			250.00		249.00	
TOT. CHOLEST.	148-247 (MG/DL)	01/10/91	281.00	>	74.00		108.00	
TRIGLYCERIDES	50-150 (MG/DL)	01/10/91	86.00	1	2.80	1	2.80	1
GLOBULINS ALPHA 1	2.1-3.5 (%)	01/10/91	3.00				5.90	_
GLOBULINS ALPHA 2	6-10 (X)	01/10/91	5.90		6.20			1
GLOBULINS BETA	6.5-11.5 (%)	01/10/91	12.20		11.20	ا ا	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	1				1
T4	4.5-12.5	01/10/91	- 1	1	1			ı
	(UG/100ML)		7.80	1	ì	1		1

<sup>(¢) &</sup>lt;< clinically relevant (value lower cout of range (value lower than min range) than min range) (value lower than min range) than min range) than min range) than min range)

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range) missing range value

### PHARMACIA PHARMACEUTICAS OHIAND - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 331 Treatment: Fluoxetine

			Visit	numk	er / Lai	orat	ory date	•
			Scree	n	Day 2	В	Day 5	6
			08/05/	92	29/06/	92	06/08/	92
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
нв	120-170 (G/L)	01/05/92	124.00		121.00	II	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	
MBC	4-11 (10-9/L)	01/05/92	4.62		3.42	<	3.72	
MBC: N	45-75 (%)	01/05/92	49.20		54.30		53.40	
MBC: L	17-55 (%)	01/05/92	38.20		33.40		35.50	
MBC: E	0-5 (%)	01/05/92	1.30	i	1.60	i I	1.30	
MBC: M	2-10 (2)	01/05/92	7.00		8,10		6.50	1
MBC: B	0-2 (%)	01/05/92	0.80		0.40	i I	0.50	1
PLATELETS	150-400 (10-9/L)	01/05/92	216.00		194.00	i 1	169.00	
NA+	135-145 (NEQ/L)	01/05/92	141.00	1 1	133.00	<	141.00	
K+	3.5-4.5 (MEQ/L)	01/05/92	4.10		3.90		3.90	1
CL-	95-106 (MEQ/L)	05/08/92					106.00	1
Ca++	8.5-10.5 (MG/DL)	01/05/92	9.00		9.00		9.20	
P04	2.3-4.3 (MG/DL)	01/05/92	3,10		3.10		3.40	
SCOT	10-40 (UI/L)	01/05/92	25.00	1	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	1
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	l I	81.00	1
BUN	10-25 (MG/DL)	01/05/92	15.00		14.00		20.00	1
CREATININE	0.5-1.3 (MG/DL)	01/05/92	0.90	-	1.00	1 1	0.80	1
URIC ACID	1.9-7.4 (MG/DL)	01/05/92	2.90		3.40	1 1	2.90	1
TOT BILIRUBIN	0.1-1 (NG/DL)	01/05/92	0.90		0.50		0.50	
TOT. PROTEINS	60-80 (G/L)	01/05/92	68.00	l	75.00		74.00	1
ALBUMINE	57-69 (%)	01/05/92	69.40		68.90			
ALBUNINE	27-58 (G/L)	05/08/92		Ι΄			48.00	
	148-247 (MG/DL)	01/05/92	228.00	1	241.00		224.00	
TOT. CHOLEST.		01/05/92	94.00	1	96.00		75.00	
TRIGLYCERIDES	50-150 (MG/DL)	01/05/92	2.40		2.30		2.10	
GLOBULINS ALPHA 1	2.1-3.5 (%)		6.50		7.00		7.20	
GLOBULINS ALPHA 2	6-10 (%)	01/05/92	7.10	1	7.90		8.50	
GLOBULINS BETA	6.5-11.5 (%)	01/05/92	14.10	_	13.90	_	14.00	
GLOBULINS GAMMA	15-22 (%)	01/05/92		١`	13.70	1	17.00	1
TSH	0.5-5 (UU/ML)	01/05/92	2.60					1
T4	4.5-12.5 (UG/DL)	01/05/92	6.40	I	l	1 '		1

<sup>(¢) &</sup>lt;< clinically relevant (value lower than min range)
< out of range (value lower than min range)

\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max rang-> out of range (value higher than max rang-() missing range value

### PHARMACIA PHARMACEUTETAS HEAVY - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 332 Treatment: Fluoxetine Sex: Female

			Visit	numb	oer / La	borat	ory dat	e
			Screen	ra .	Day 2	В	Day 5	6
			17/07/	92	10/09/	92	15/09/	92
			value	(¢)	value	(4)	value	(¢)
Laboratory test	Range value	Range date				П		
нв	120-170 (G/L)	13/03/92	133.00		129.00			İ
HT	0.36-0.51 (L/L)	13/03/92	0.42		0.39			ł
RRC	3.9-5.5 (10-12/L)	13/03/92	4,44		4.18	1		
MBC	4-11 (10-9/L)	13/03/92	4.90		5.16			
NBC: N	45-75 (%)	13/03/92	46.90		47.30			l
NBC: L	17-55 (%)	13/03/92	40.80		41.20			l
WBC: E	0-5 (%)	13/03/92	1.50		0.80	l i		
WBC: N	2-10 (%)	13/03/92	8.90		5.90	l i		
MBC: 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	li		
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	1 1	9.80			
P04	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		1 1	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	l i		
URIC ACID	1.9-7.4 (MG/DL)	13/03/92	4,20	1 1	2.60			
TOT BILIRUBIN	0.1-1 (MG/DL)	13/03/92	0.50		0.70	ΙÍ		
TOT. PROTEINS	60-80 (G/L)	13/03/92	80.00		84.00			ŀ
ALBUMINE	27-58 (G/L)	13/03/92	50.00			1 1		ł
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			ĺ
GLOBULINS ALPHA 1	2.1-3.5 (%)	13/03/92	3.00	1 1	2.70	1		1
GLOBULING ALPHA 2	6-10 (%)	13/03/92	8.00		9.50			ł
GLOBULINS ALPHA 2	6.5-11.5 (%)	13/03/92	9.00		8.30	1		1
GLOBULING GAMMA	15-22 (%)	13/03/92	15.10		14.40			l
	0.5-5 (UU/ML)	13/03/92			- · · · •		0.50	1
TSH	4.5-12.5 (UG/DL)	13/03/92					5.20	1
T4	4.5-12.5 (VU/DL)	13, 03, 72		1				1

1056

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

### PHARMACIA PHARMACEUTEGAS OFFICE - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 11 Patient: 334 Treatment: Fluoxetine Sex: Female

			Visit	numb	er / La	borat	tory dat	8
			Screen	n.	Day 2	8	Day 5	6
			10/09/	92	21/10/	92	14/12/	92
			value	(4)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	120-170 (G/L)	13/03/92	128.00	1	134.00	l i	139.00	
HT	0.36-0.51 (L/L)	13/03/92	0.38	l i	0.40		0.44	ł
RBC	3.9-5.5 (10-12/L)	13/03/92	4.50		4.84		5.00	1
WBC	4-11 (10-9/L)	13/03/92	4.03		5.64	i I	5.80	
WBC: N	45-75 (%)	13/03/92	47.60		42.00	<	54.10	l
WBC: L	17-55 (%)	13/03/92	38.90		43.50		33.20	
MBC: E	0-5 (%)	13/03/92	2.80		3.90		2.20	l
WBC: M	2-10 (X)	13/03/92	4.50	- 1	6.30	ł	6.70	ŀ
WBC: B	0-2 (%)	13/03/92	0.00	- 1	0.80		0.80	
PLATELETS	150-400 (10~9/L)	13/03/92	213.00	- 1	232.00		234.00	
NA+	135-145 (MEQ/L)	13/03/92	139.00	- 1	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	J	100.00			ĺ
Ca++	8.5-10.5 (MG/DL)	13/03/92	9.10	- 1	9.00		9.20	
PO4	2.3-4.3 (MG/DL)	13/03/92	2.80	- 1	2.80		2.70	İ
SGOT	10-40 (UI/L)	13/03/92	14.00	i	13.00		16.00	
SGPT	10-40 (UI/L)	13/03/92	19.00	- 1	16.00		18.00	
GAMMA GT	5-40 (UI/L)	13/03/92	19.00	- 1	18.00	- 1	15.00	
LDH	250-450 (VI/L)	13/03/92	275.00		279.00		298.00	
ALK. PHOSPH.	123-345 (UI/L)	13/03/92	208.00	- 1	240.00		244.00	
LUCOSE	64-107 (MG/DL)	13/03/92	94.00	Į.	83.00	- 1	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	1	0.60	
URIC ACID	1.9-7.4 (MG/DL)	13/03/92	4.20		3.30	- 1	2.60	
OT BILIRUBIN	0.1-1 (MG/DL)	13/03/92	0.50		0.30	- 1	0.20	
OT. PROTEINS	60-80 (G/L)	13/03/92	72.00		70.00	- 1	70.00	
ALBUMINE	27-58 (G/L)	13/03/92	37.00	- 1	40.00	- 1	42.00	
OT. CHOLEST.	148-247 (MG/DL)	13/03/92	217.00	- 1	212.00	- 1	239.00	
RIGLYCERIDES	50-150 (MG/DL)	13/03/92	113.00	- 1	96.00		91.00	
LOBULINS ALPHA 1	2.1-3.5 (2)	13/03/92	2.90				2.60	
CLOBULINS ALPHA 2	6-10 (Z)	13/03/92	7.60		l		7.60	
SLOBULINS BETA	6.5-11.5 (%)	13/03/92	11.80	>		- 1	12.30	>
SLOBULINS GAMMA	15-22 (%)	13/03/92	17.20			- 1	17.30	
rsh	0.5-5 (UU/ML)	13/03/92	1,30	1		- 1		
C4	4.5-12.5 (UG/DL)	13/03/92	7.30			- 1		

1057

(¢) << clinically relevant (value lower out of range) (value lower than min range)

\*\* missing laboratory test value nd laboratory not done

- -

<sup>&</sup>gt;> clinically relevant (value higher than max range > out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTICAS NHAMO - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Contro: 12 Patient: 393 Treatment: Fluoxetine Sex: Female

			Visit	numb	er / Lai	borat	ory date	9
			Scree	n	Day 2	В	Day 5	6
			26/06/	92	21/07/92		28/08/9	92
			value	(4)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
KB.	11.5-16.5 (G/DL)	01/06/92	12.90	ll	15.90	1 1	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	ıl	6.30		7.10	l
WBC: N	2-8 (10-9/L)	01/06/92	3.60		3.70	ļ ļ	5.30	
KBC: L	1-4 (10-9/L)	01/06/92	1.70	ll	1.70	}	1.30	
MBC: E	0-0.5 (10-9/L)	01/06/92	0.10		0.20	1 I	0.10	
NBC: N	0-1 (10-9/L)	01/06/92	0.20	ll	0.60	ł I	0.40	l
MBC: B	0-0.2 (10-9/L)	01/06/92	0.00		0.10	i I	0.10	1
PLATELETS	150-450 (10-9/L)	01/06/92	260.00			i I	303.00	1
NA+	136-146 (MMOL/L)	01/06/92	142.00	ll	140.00	1 1	143.00	
K+	3.5-5 (MMOL/L)	01/06/92	4.00		4.10		4.50	1
CL-	95-110 (MMOL/L)	01/06/92	103.00	ll	102.00	1 1	105.00	1
Ca++	2.15-2.65 (MMOL/L)	01/06/92	2.40		2.41	1 1	2.46	1
P04	0.8-1.4 (MMOL/L)	01/06/92	1.20		1.20		1.30	1
SGPT	0-40 (U/L)	01/06/92	36.00		36.00		37.00	1
GAMMA GT	0-35 (U/L)	01/06/92	15.00	ll	14.00		16.00	1
LDH	250-520 (U/L)	01/06/92	352.00		357.00	1 1	338.00	1
ALK, PHOSPH.	30-120 (U/L)	01/06/92	84.00	ll	82.00	1 1	95.00	
GLUCOSE	4-5.5 (MMOL/L)	01/06/92	4.30		3,60	<	4.40	1
UREA	2.3-7.6 (MMOL/L)	01/06/92	4.10		4.30		2.30	i
CREATININE	0.05-0.11 (MMOL/L)	01/06/92	0.08	ll	0.07	1	0.07	1
URIC ACID	0.11-0.42 (MMOL/L)		0.25	ll	0.19		0.31	Į.
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	ll	77,00	1 1	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	1
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/06/92	0.90		0.90		0.90	l
TSH	0.5-4 (MIU/L)	01/06/92	2.20					
T4	10-19 (PMOL/L)	01/06/92	15.50	l l		1		1

1058

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

### PHARMACIA PHARMACEUTICAL NELANO - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 12 Patient: 396 Treatment: Fluoxetine Sex: Female

			Visi number Laborat date	ory
			Scree	n
			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	
MBC	4-11 (10 <del>-9/</del> L)	01/06/92	6.10	
MBC: N	2-8 (10-9/L)	01/06/92	4,10	
MBC: L	1-4 (10 <b>-</b> 9/Ľ)	01/06/92	1.50	
NBC: E	0-0.5 (10-9/L)	01/06/92	0.20	
HBC: M	0-1 (10-9/L)	01/06/92	0.20	
MBC: 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	
P04	0.8-1.4 (MMOL/L)	01/06/92	1.30	
SGPT	0-40 (U/L)	01/06/92	22,00	
GANMA 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 (MNOL/L)		0.12	
TOT BILIRUBIN	0-20 (UNOL/L)	01/06/92	6.00	
TOT. PROTEINS	60-80 (G/L)	01/06/92	71.00	l
ALBUMINE	35-50 (G/L)	01/06/92	43.00	l
TOT. CHOLEST.	3-5,5 (MMOL/L)	01/06/92	5.10	l
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/06/92	0.60	
TSH	0.5-4 (MIU/L)	01/06/92	0.80	l
T4	10-19 (PMOL/L)	01/06/92	13.90	1

1059

<< clinically relevant (value lower than min range)
< out of range (value lower than min range)
\*\* missing laboratory test value nd laboratory not done</pre>

# PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 12 Patient: 497 Treatment: Fluoxetine Sex: Female

			Visit	numk	er / Lai	borat	tory date	
			Scree	n	Day 2	В	Day 5	6
			26/02/	93	26/03/93		26/04/	93
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/06/92	15.10	ll	15.10	l i	14.90	
HT	37-47 (%)	01/06/92	43.60	ll	42.90	}	42.50	
RBC	3.8-5.8 (10-12/L)	01/06/92	5.06	ll	5.02	1 1	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	1	7.30	
WBC: L	1-4 (10-9/L)	01/06/92	3.80	ll	2.80		3,40	
WBC: E	0-0.5 (10~9/L)	01/06/92	0.30	ll	0.20		0.10	
WBC: M	0-1 (10 <b>-</b> 9/L)	01/06/92	0.50		0.40		0.40	
NBC: B	0-0.2 (10 <del>-9</del> /L)	01/06/92	0.00		0.10	li	0.00	
PLATELETS	150-450 (10¬9/L)	01/06/92	270.00		251.00	l i	295.00	
NA+	136-146 (MMOL/L)	01/06/92	138.00	1	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)		2.38		2.40		2.18	
P04	0.8-1.4 (MMOL/L)	01/06/92	1.30		1,30		1.30	
EGOT	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	li	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	li	0.27	
TOT BILIRUBIN	0-20 (UMOL/L)	01/06/92	10.00	1 1	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	ıl	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	l 1		ll		1

<sup>&</sup>gt;> clinically relevant (value higher than max range to out of range (value higher than max range to missing range value)

### PHARMACIA PHARMACEUTIGAL MINO - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 385 Treatment: Fluoxetine

tine Sex: Female

			Visit	numi	oer / La	bora	tory dat	e
			Scree	h	Day 1	4	Day 5	6
			13/03/	92	30/03/	92	08/05/	92
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date				$\vdash$		
HB	12-16 (G/DL)	01/03/92	13.80		14.40		14.10	
HT	37-47 (X)	01/03/92	41.00		42.00		41.00	1
RBC	3.8-5.8 (10-12/L)	01/03/92	4.63		4.80	li	4.64	-
MBC	4-11 (10-9/L)	01/03/92	9.00		7.40		7.70	
MBC: 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	1
KBC: E	0-0.7 (10~9/L)	01/03/92	0.20		0.20		0.10	1
KBC: M	0.2-0.8 (10-9/L)	01/03/92	0.60	!!	0.70		0.70	
MBC: B	0-0.2 (10-9/L)	01/03/92	0.10	1	0.00		0.10	
PLATELETS	150-400 (10-9/L)	01/03/92	377.00		377.00		381.00	l .
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	l
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.46		2.39		2.41	
P04	0.7-1.4 (MMOL/L)	01/03/92	1.58	>	1.25	1	1.50	>
SGOT	5-35 (U/L)	01/03/92	21.00	1	25.00		26.00	
SGPT	7-56 (U/L)	01/03/92	25.00	- 1	25.00		18.00	1
GAMMA GT	8-78 (U/L)	01/03/92	36.00	- 1	39.00		42.00	
LDH	300-540 (U/L)	01/03/92	331.00		366.00		356.00	ĺ
ALK, PHOSPH.	19-95 (U/L)	01/03/92	78.00		79.00		87.00	l
SLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	5.00	-	5.20	- 1	5.20	l
UREA	2.5-7.5 (MMOL/L)	01/03/92			4.60	1	4.20	
CREATININE	60-110 (UMOL/L)	01/03/92	84.00	1	92.00		86.00	
JRIC ACID	180-440 (UMOL/L)	01/03/92	236.00		275.00		286.00	
OT BILIRUBIN	3-22 (UMOL/L)	01/03/92	7.00		10.00		9.00	1
TOT. PROTEINS	62-81 (G/L)	01/03/92	73.00	ŀ	77.00		71.00	
ALBUNINE	35-50 (G/L)	01/03/92	43.00	ı	45.00		43.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	5.36	- 1	6.09	ا د	6.03	
RIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	1.92	,	1.44	٠	1.67	- 1
SH	0.2-3.2 (MU/L)	01/03/92	0.09			<<	/	
74	11-24 (PHOL/L)	01/03/92	25.00		28.30			l

1061

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

### PHARMACIA PHARMACEUTAGAS (1214) - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 386 Treatment: Fluoxetine Sex: Male

			Visit number / Laborator date	•
			Screen	
			23/04/92	2
			value (	(4)
Laboratory test	Range value	Range date	45.55	
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)		4.95	
MBC	4-11 (10-9/L)	01/03/92	7.80	
WBC: N	2-7.5 (10-9/L)	01/03/92	4.10 2.50	
WBC: L	1.3-3.6 (10-9/L)	01/03/92		
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	
MBC: B	0-0.2 (10-9/L)	01/03/92		
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	
P04	0.7-1.4 (MNOL/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 5.30	
UREA	2.5-7.5 (MMOL/L)	01/03/92	101.00	
CREATININE	60-110 (UMOL/L)	01/03/92	293.00	
URIC ACID	180-440 (UMOL/L)	01/03/92	12.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	70.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	41.00	
ALBUMINE	35-50 (G/L)	01/03/92	5.74 >	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	1.19	•
TRIGLYCERIDES	0.4-1.75 (NMOL/L)	01/03/92	0.70	
TSH	0.2-3.2 (MU/L)	01/03/92		
T4	11-24 (PMOL/L)	01/03/92	14.20	

1062

(c) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

### PHARMACIA PHARMACEUTICAL MILANO - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 389 Treatment: Fluoxetine Sex: Fomale

					mber / ry date	
			Scree	n	Day	7
			20/07/	92	24/07/	92
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
KB	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	
NBC	4-11 (10-9/L)	01/03/92	8.40		5.90	J
MBC: 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	
NBC: N	0.2-0.8 (10-9/L)	01/03/92	0.67		0.50	
MBC: 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 (MHOL/L)	01/03/92	138.00		140.00	
K+	3.5-5 (MMOL/L)	01/03/92	3.40	< 1	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	_ I	85.00	
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	16.00	1	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			

<sup>(0) &</sup>lt;< clinically relevant (value lower than min range) < out of range (value lower than min range) than min range) with missing laboratory test value and laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTGGA GAGANO - CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 391 Treatment: Fluoxetine Sex: Female

					mber / ory date	
			Screen	Day 2	8	
			04/06/9	92	10/07/	92
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
нв	12-16 (G/DL)	01/03/92	14.30		14.60	
HT	37-47 (X)	01/03/92	41.00		43.00	
RBC	3.8-5.8 (10-12/L)	01/03/92	4.47		4.66	
KBC	4-11 (10-9/L)	01/03/92	5.20		7.10	1
HBC: N	2-7.5 (10-9/L)	01/03/92	2.90		4.60	l
HBC: L	1.3-3.6 (10-9/L)	01/03/92	1.70		1.90	1
MBC: 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	
MBC: 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	1	320.00	
NA+	137-145 (MMOL/L)	01/03/92	141.00	l	139.00	
K+	3.5-5 (MMOL/L)	01/03/92	4.10	1	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	
P04	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	
GANNA GT	8-78 (U/L)	01/03/92	21.00	- 1	20.00	
LDH	300-540 (U/L)	01/03/92	391.00		482.00	1
ALK. PHOSPH.	19-95 (U/L)	01/03/92	68.00	- 1	63.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	4.30	j	5.70	1
UREA	2.5-7.5 (MMOL/L)	01/03/92	6.30		4.90	1
CREATININE	60-110 (UMOL/L)	01/03/92	89.00	1	77.00	i
URIC ACID	180-440 (UMOL/L)	01/03/92	360.00	1	276.00	1
TOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	10.00	l	15.00	l
TOT. PROTEINS	62-81 (G/L)	01/03/92	74.00	i	76.00	1
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 (MHOL/L)	01/03/92	0.95		1.38	
TSH	0.2-3.2 (MU/L)	01/03/92	1,60		1.40	l
T4	11-24 (PMOL/L)	01/03/92	17.10		16.20	ı

<sup>(\$) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range value higher than max range () missing range value

# PHARMACIA PHARMACEUTEGAS (NELANO - CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 502 Treatment: Fluoxetine Sex: Female

			Visit	numl	per / La	borat	tory dat	0
			Screen	n	Day 2	В	Day 5	6
			03/11/92		30/11/92		24/12/	92
			value	(¢)	value	(4)	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	1	39.00	1	41.00	
RBC	3.8-5.8 (10-12/L)	01/03/92	4.62	{	4.63		4.77	
RBC	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	1
KBC: E	0-0.7 (10¬9/L)	01/03/92	0.10		0.10		0.06	ł
HBC: K	0,2-0.8 (10-9/L)	01/03/92	0.60	i	0.50	l 1	0.28	l
MBC: B	0-0.2 (10¬9/L)	01/03/92	0.10		0.00		0.00	ļ
PLATELETS	150-400 (10¬9/L)	01/03/92	310.00	- 1	334.00		305.00	
NA+	137-145 (MMOL/L)	01/03/92	140.00	- 1	138.00		139.00	l
K+	3.5-5 (HMOL/L)	01/03/92	4.20		4.80		5.90	>>
CL-	100-111 (MMOL/L)	01/03/92	104.00	- 1	100.00	}	102.00	
Ca++	2.1-2.5 (MNOL/L)	01/03/92	2.37	ł	2.24		2.25	
P04	0.7-1.4 (MMOL/L)	01/03/92	0.92		0.87		0.83	
SCOT	5-35 (U/L)	01/03/92	18.00	- 1	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	J	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	- 1	68.00	1
URIC ACID	180-440 (UMOL/L)	01/03/92	326.00	1	337.00		306.00	
FOT BILIRUBIN	3-22 (UMOL/L)	01/03/92	7.00	į	9.00	- 1	9.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	74.00	i	75.00	1	78.00	
ALBUMINE	35-50 (G/L)	01/03/92	40.00	l	40.00	J	42.00	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	5.44		5.20		5.71	>
RIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	1.50	- 1	1.45	- 1	1.39	
rsh	0.2-3.2 (MU/L)	01/03/92	0.90		0.80		1.60	
Γ4	11-24 (PMOL/L)	01/03/92	17.00	- 1	16.90		18.70	

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(t) << clinically relevant (value lower than min range)
< out of range (value lower than min range)
\*\* missing laboratory test value nd laboratory not done

### PHARMACIA PHARMACEUTES 01189 - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 504 Treatment: Fluoxetine Sex: Female

			Visit	numi	er / La	borat	ory date	
			Scree	n	Day 2	В	Day 5	6
			25/11/92		24/12/92		20/01/	93
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/03/92	13.20		13.90		13.10	
HT	37-47 (X)	01/03/92	39.00		41.00	l	38.00	
RBC	3.8-5.8 (10-12/L)	01/03/92	4.34		4.55	1 1	4.29	
NBC	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	1 1	4.70	l i	4.70	
MBC: L	1.3-3.6 (10~9/L)	01/03/92	1.50	1 1	1.20	<b> </b>	1.20	
WBC: E	0-0.7 (10-9/L)	01/03/92	0.20		0.20	ΙÍ	0.30	
MBC: M	0.2-0.8 (10-9/L)	01/03/92	0.70	1	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	1	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	li	107.00	
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.28		2.16	1 1	2.25	
P04	0.7-1.4 (MMOL/L)	01/03/92	1.15		0.88	1 1	1.03	
SGOT	5-35 (U/L)	01/03/92	44.00	>	31.00	1 1	31.00	
SGPT	7-56 (U/L)	01/03/92	20.00	l	16.00	1 1	12.00	
GAMMA GT	8-78 (U/L)	01/03/92	33.00		38.00	1 1	35.00	
LDH	300-540 (U/L)	01/03/92	356.00	l	343.00		281.00	<
ALK. PHOSPH.	19-95 (U/L)	01/03/92	47.00	l	41.00		43.00	
GLUCOSE	3.6-5.8 (MMOL/L)	01/03/92	4.30	l	3.90		3.70	
	2.5-7.5 (MMOL/L)	01/03/92	4.10	l	4.80		3,80	
UREA	60-110 (UMOL/L)	01/03/92	86.00		88.00	]	85.00	
CREATININE	180-440 (UMOL/L)	01/03/92	198.00	l	210.00		212.00	
URIC ACID	3-22 (UMOL/L)	01/03/92	11.00	l	14.00		11.00	
TOT BILIRUBIN		01/03/92	69.00		70.00	1	68.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	43.00		40.00		38.00	
ALBUNINE	35-50 (G/L)	01/03/92	2.95	ا ہا	3.03	ا م	3.11	
TOT. CHOLEST.	3.5-5.5 (MMOL/L)	01/03/92	0.99		1.15	`	0.97	
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	1,80		2.00		1.50	
TSH	0.2-3.2 (MU/L)		12.60		12.80		11.90	
T4	11-24 (PMOL/L)	01/03/92	12.60	1	12.80	1	11.70	T

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### PHARMACIA PHARMACEUTICALS NILANG - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 13 Patient: 506 Treatment: Fluoxetine Sex: Male

			Visit	numl	or / La	borat	ory date	0
			Scree	n	Day 2	В	Day 5	6
			23/10/	92	26/11/	92	24/12/	92
			value	(¢)	value	(¢)	value	(4)
Laboratory test	Range value	Range date					44 50	
HB	14- <b>1</b> 8 (G/DL)	01/03/92	15.60		15.10		14.50	
HT	41-53 (%)	01/03/92	44.00		45.00	1 1	43.00	1
RBC	4.5-6.5 (10-12/L)	01/03/92	4.76		4.80		4.65	
MBC	4-11 (10¬9/L)	01/03/92	6.70		5.30	1 1	8.30	
MBC: N	2-7.5 (10~9/L)	01/03/92	4.20	1	3.10		5.10	1
HBC: L	1.3-3.6 (10-9/L)	01/03/92	1.80		1.80		2.40	
HBC: E	0-0.7 (10-9/L)	01/03/92	0.10		0.00		0.10	1
MBC: M	0,2-0.8 (10-9/L)	01/03/92	0.60		0.40		0,60	1
MBC: B	0-0.2 (10-9/L)	01/03/92	0.00		0.00	i I	0.10	l
PLATELETS	150-400 (10-9/L)	01/03/92	305.00		328.00		325.00	1
NA+	137-145 (HMOL/L)	01/03/92	138.00	1 !	138.00	1	136.00	
K+	3.5-5 (MMOL/L)	01/03/92	4.80		4.50	t l	4.50	ı
CL-	100-111 (MMOL/L)	01/03/92	99.00	<	98.00	<	106.00	1
Ca++	2.1-2.5 (MMOL/L)	01/03/92	2.42		2.34	1	2.20	i
P04	0.7-1.4 (MMOL/L)	01/03/92	1.37		1,63		1.34	l
SGOT	5-35 (U/L)	01/03/92	30.00	il	53.00	>	26.00	l
SGPT	7-56 (U/L)	01/03/92	11.00		18.00		12.00	l
GANNA GT	8-78 (U/L)	01/03/92	17.00		19.00		18.00	l
LDH	300-540 (U/L)	01/03/92	495.00		534.00	1	403.00	l
ALK. PHOSPH.	19-95 (U/L)	01/03/92	82.00	il	58.00		84.00	1
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	1	6.30	l
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	i
TOT BILIRUBIN	3-22 (UNOL/L)	01/03/92	7.00	1 1	13.00	1	8.00	
TOT. PROTEINS	62-81 (G/L)	01/03/92	75.00		75.00		70.00	1
ALBUMINE	35-50 (G/L)	01/03/92	46.00		46.00	1	41.00	1
TOT. CHOLEST.	3,5-5,5 (MMOL/L)	01/03/92	5.23		5.31	1 1	4.92	1
TRIGLYCERIDES	0.4-1.75 (MMOL/L)	01/03/92	0.89	(	0.60	1	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	1

1067

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

### PHARMACIA PHARMACEUTICAS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Contre: 13 Patient: 507 Treatment: Fluoxetine Sex: Female

		Visit	numi	er / La	borat	tory dat	0
		Scree	n	Day 2	8	Day 5	6
		10/09/	92	16/10/	92	06/11/	92
		value	(¢)	value	(¢)	value	(0)
Range value	Range date	"					
	01/03/92		1 1				
3.8-5.8 (10-12/L)	01/03/92				1 1		
4-11 (10¬9/L)	01/03/92				l t		
2-7.5 (10→9/L)	01/03/92	4.60		3.10		3.60	
1.3-3.6 (10-9/L)	01/03/92	3.20		2.60		3.10	
0-0.7 (10-9/L)	01/03/92	0.10		0.10	i I	0.10	
0.2-0.8 (10-9/L)	01/03/92	0.90	>	0.90	>	0.80	
0-0.2 (10-9/L)	01/03/92	0.10		0.00		0.00	
150-400 (10-9/L)	01/03/92	341.00		311.00	1 1	335.00	
137-145 (MMOL/L)	01/03/92	136.00	<	138.00	1 1	134.00	<
3.5-5 (MMOL/L)	01/03/92	3.90		4.10	l i	4.20	
100-111 (MMOL/L)	01/03/92	99.00	<	98.00	<	96.00	<
2.1-2.5 (MMOL/L)	01/03/92	2.37		2.24		2.30	
	01/03/92	1.21		1.25		1.22	
	01/03/92	32.00		34.00		32.00	
	01/03/92	24.00		21.00		15.00	
	01/03/92	71.00		37.00	li	46.00	ŀ
	01/03/92	464.00		520.00	1 1	447.00	
		79.00		93.00	1 1	82.00	l
		4.70	,	4.10	1 1	4.90	1
		4,10	1	4.10	ll	5.50	1
		73.00		74.00		73.00	1
		302.00		345.00	l I	312.00	
	01/03/92	10.00		9.00		9.00	l
				77.00	1 1	77.00	l
					[		
	12-16 (G/DL) 37-47 (Z) 3.8-5.8 (10-12/L) 4-11 (10-9/L) 2-7.5 (10-9/L) 1.3-3.6 (10-9/L) 0-0.7 (10-9/L) 0-0.2 (10-9/L) 150-400 (10-9/L) 137-145 (MMOL/L) 3.5-5 (MMOL/L)	12-16 (G/DL) 01/03/92 3,8-5.8 (10-12/L) 01/03/92 4-11 (10-9/L) 01/03/92 2-7.5 (10-9/L) 01/03/92 1.3-3.6 (10-9/L) 01/03/92 0.2-0.8 (10-9/L) 01/03/92 0.2-0.8 (10-9/L) 01/03/92 0-0.2 (10-9/L) 01/03/92 137-145 (MHDL/L) 01/03/92 137-145 (MHDL/L) 01/03/92 137-145 (MHDL/L) 01/03/92 137-145 (MHDL/L) 01/03/92 137-145 (MHDL/L) 01/03/92 2.1-2.5 (MHDL/L) 01/03/92 2.1-2.5 (MHDL/L) 01/03/92 2-3-5 (U/L) 01/03/92 3-58 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92 1-59 (U/L) 01/03/92	Range value Range date 12-16 (G/DL) 01/03/92 12.60 37-47 (Z) 01/03/92 38.00 3.8-5.8 (10-12/L) 01/03/92 4.22 4-11 (10-9/L) 01/03/92 3.90 0.13-3.6 (10-9/L) 01/03/92 3.20 0.10 0.2-0.8 (10-9/L) 01/03/92 0.10 0.2-0.8 (10-9/L) 01/03/92 0.10 0.2-0.8 (10-9/L) 01/03/92 0.10 0.3-0.5 (10-9/L) 01/03/92 0.10 0.150-400 (10-9/L) 01/03/92 0.10 0.150-400 (10-9/L) 01/03/92 0.10 0.170-4/L) 01/03/92 136.00 137-145 (MMOL/L) 01/03/92 136.00 137-145 (MMOL/L) 01/03/92 136.00 0.5-5 (MMOL/L) 01/03/92 136.00 0.5-5 (MMOL/L) 01/03/92 136.00 0.5-5 (U/L) 01/03/92 2.37 0.7-1.4 (MMOL/L) 01/03/92 2.37 0.7-1.4 (MMOL/L) 01/03/92 2.37 0.7-1.4 (MMOL/L) 01/03/92 1.21 0.7-56 (U/L) 01/03/92 1.21 0.300-540 (U/L) 01/03/92 71.00 19-95 (U/L) 01/03/92 464.00 01/03/92 4.70 0.5-7.5 (MMOL/L) 01/03/92 4.70 0.5-7.5 (MMOL/L) 01/03/92 79.00 180-440 (UMOL/L) 01/03/92 79.00 180-440 (UMOL/L) 01/03/92 79.00 180-440 (UMOL/L) 01/03/92 77.00 180-440 (UMOL/L) 01/03/92 77.00 180-440 (UMOL/L) 01/03/92 77.00 185-50 (G/L) 01/03/92 77.00 15-50.5 (MMOL/L) 01/03/92 77.00 15-50.5 (MMOL/L) 01/03/92 77.26 0.4-1.75 (MMOL/L) 01/03/92 77.26 0.4-1.75 (MMOL/L) 01/03/92 77.26 0.4-1.75 (MMOL/L) 01/03/92 77.26 0.4-1.75 (MMOL/L) 01/03/92 77.26 0.4-1.75 (MMOL/L) 01/03/92 77.26 0.4-1.75 (MMOL/L) 01/03/92 77.26 0.4-1.75 (MMOL/L) 01/03/92 77.26 0.4-1.75 (MMOL/L) 01/03/92 77.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92 7.26 0.4-1.75 (MMOL/L) 01/03/92	Range value	Range value	Range value	Range value Range date 12-16 (G/DL) 01/03/92 12.60 13.00 11.80 37-47 (Z) 01/03/92 38.00 39.00 36.00 3.8-5.8 (10-12/L) 01/03/92 4.22 4.31 4.02 4-11 (10-9/L) 01/03/92 4.60 3.10 3.60 1.3-3.6 (10-9/L) 01/03/92 3.20 2.60 3.10 0.2-7.5 (10-9/L) 01/03/92 3.20 2.60 3.10 0.2-0.8 (10-9/L) 01/03/92 0.10 0.10 0.10 0.2-0.8 (10-9/L) 01/03/92 0.90 > 0.90 > 0.80 0-0.2 (10-9/L) 01/03/92 341.00 311.00 335.00 137-145 (HMOL/L) 01/03/92 341.00 311.00 335.00 137-145 (HMOL/L) 01/03/92 3.90 < 98.00 < 96.00 100-111 (HMOL/L) 01/03/92 3.90 4.10 4.20 2.1-2.5 (HMOL/L) 01/03/92 3.90 4.10 4.20 0.7-1.4 (HMOL/L) 01/03/92 3.90 < 98.00 < 96.00 2.1-2.5 (HMOL/L) 01/03/92 1.21 1.25 1.22 5-35 (U/L) 01/03/92 32.00 34.00 32.00 8-78 (U/L) 01/03/92 32.00 34.00 32.00 8-78 (U/L) 01/03/92 71.00 37.00 46.00 19-95 (U/L) 01/03/92 77.00 37.00 46.00 19-95 (U/L) 01/03/92 79.00 93.00 40.00 19-95 (U/L) 01/03/92 79.00 93.00 46.00 180-440 (UMOL/L) 01/03/92 79.00 93.00 46.00 180-440 (UMOL/L) 01/03/92 79.00 93.00 46.00 180-440 (UMOL/L) 01/03/92 79.00 79.00 73.00 3.6-5.8 (HMOL/L) 01/03/92 79.00 79.00 79.00 3.6-5.8 (HMOL/L) 01/03/92 79.00 79.00 79.00 3.5-5 (UMOL/L) 01/03/92 79.00 79.00 79.00 3.5-5.5 (HMOL/L) 01/03/92 77.00 77.00 77.00 3.5-5.5 (HMOL/L) 01/03/92 77.00 77.00 77.00 3.5-5.5 (HMOL/L) 01/03/92 77.00 77.00 77.00 3.5-5.5 (HMOL/L) 01/03/92 77.26 >> 6.99 > 6.46 0.4-1.75 (HMOL/L) 01/03/92 77.26 >> 6.99 > 6.46 0.4-1.75 (HMOL/L) 01/03/92 7.26 >> 6.99 > 6.46 0.4-1.75 (HMOL/L) 01/03/92 7.26 >> 6.99 > 6.46 0.4-1.75 (HMOL/L) 01/03/92 7.26 >> 6.99 > 6.46 0.4-1.75 (HMOL/L) 01/03/92 7.26 >> 6.99 > 6.46 0.4-1.75 (HMOL/L) 01/03/92 7.26 >> 6.99 > 6.46 0.4-1.75 (HMOL/L) 01/03/92 7.26 >> 6.99 > 6.46 0.4-1.75 (HMOL/L) 01/03/92 7.26 >> 6.99 > 6.46 0.4-1.75 (HMOL/L) 01/03/92 7.26 >> 6.99 > 6.46 0.4-1.75 (HMOL/L) 01/03/92 7.26 >> 6.99 > 6.46 0.4-1.75 (HMOL/L) 01/03/92 7.26 >> 6.99 > 6.46 0.4-1.75 (HMOL/L) 01/03/92 7.26 >> 6.99 > 6.46 0.4-1.75 (HMOL/L) 01/03/92 7.26 >> 6.99 > 6.46

1068

(t) << clinically relevant (value lower than min range)
< out of range (value lower than min range)
than min range)
than min range)
than min range)
and laboratory not done

# PHARMACIA PHARMACEUTIGAS 5 - CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 397 Treatment: Fluoxetine Sex: Female

			Visit	numk	oer / Lai	borat	cory date	8
			Scree	1	Day 2	В	Day 5	6
			12/03/	92	12/05/	92	09/06/	92
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
НВ	11.5-16.5 (G/DL)	01/02/92	13.00	l i	. 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	
MBC	3.5-12 (10-9/L)	01/02/92	5.50		5,80		6.30	
MBC: N	2.5-8 (10-9/L)	01/02/92	3.50		4.10		4.50	1
NBC: L	1.2-4 (10-9/L)	01/02/92	1.60		1.30		1.40	
KBC: E	0-0.5 (10-9/L)	01/02/92	0.00		0.00		0.00	
NBC: M	0.1-1.1 (10-9/L)	01/02/92	0.50		0.40	Ιi	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	ΙÍ	139.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	3.80	l i	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	
P04	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)		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	<
	36-49 (G/L)	01/02/92	45.00		46.00		47.00	
ALBUMINE	3-8.5 (MMOL/L)	01/02/92	6.60		6.80		7.20	
TOT. CHOLEST. TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.70		2.10		1.30	

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### PHARMACIA PHARMACEUTIGAS 515 1489 - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 400 Treatment: Fluoxetine Sex: Male

Laboratory test KB KT RBC			Scree	n	Day 20			
HB HT						•	Day 5	5
HB HT			14/05/	92	12/06/9	92	14/07/	92
HB HT			value	(4)	value	(4)	value	(¢:
HT	Range value	Range date						
	13.5-17.5 (G/DL)	01/02/92	15.50	1 1	15.90		14.50	
RBC	0.4-0.54 (L/L)	01/02/92	0.46	1 1	0.47		0.43	
	4.5-6.5 (10-12/L)	01/02/92	5.18	1 1	5.24		4.93	
HBC	3.5-10 (10-9/L)	01/02/92	8.50	1 1	10.90	>	8.60	
MBC: N	1.5-6.5 (10¬9/L)	01/02/92	5.80	1	6.50	1 }	5.70	1
MBC: L	1,2-4 (10~9/L)	01/02/92	2.40		3.60		2.60	
HBC: E	0-0.5 (10-9/L)	01/02/92	0.00		0.00	{	0.00	
HBC: M	0.1-1.1 (10-9/L)	01/02/92	0.30		0.80	li	0.40	l
NBC: B	0-0.1 (10-9/L)	01/02/92	0.00		0.00	1 1	0.00	ļ
PLATELETS	150-400 (10-9/L)	01/02/92	302.00	1	331.00	ll	320.00	1
NA+	135-145 (MMOL/L)	01/02/92	139.00		140.00	ΙI	137.00	1
K+	3.5-4.5 (MMOL/L)	01/02/92	4.10		4.90	>	4.10	1
CL-	95-105 (MMOL/L)	01/02/92	101.00		102.00	1	104.00	1
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.32	1 1	2.45	ŀ	2.24	<
P04	0.6-1.3 (MMOL/L)	01/02/92	1.06	1 1	1.33	<	1.16	1
SGOT	0-35 (U/L)	01/02/92	22.00	1 1	23.00	1	18.00	ı
GANNA 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	ı
ALK. PHOSPH.	18-70 (U/L)	01/02/92	86.00	-	88.00	l>	81.00	>
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	5.70	i I	5.20	l I	5.30	ı
UREA	2.5-7.5 (MMOL/L)	01/02/92	3.50		3.70	l I	4.10	ı
CREATININE	0.04-0.12 (MMOL/L)		0.06		0.07	i I	0.06	ı
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.27	li	0.31		0.30	ı
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	10.00	ll	10.00	l I	8.00	ı
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	3.00		3.00		4.00	ı
TOT. PROTEINS	68-83 (G/L)	01/02/92	74.00	1 [	78.00		72.00	ı
ALBUMINE	36-49 (G/L)	01/02/92	50.00		53.00		42.00	ĺ
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	5.40		5.80	[ ]	5,90	ĺ
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.20		1.10		1,20	1
Len Luteracentres	0.5-6.5 (MIU/L)	01/02/92	0.58					ĺ
ron T4	86-148 (NMOL/L)	01/02/92	114.00		J			l

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range to out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTIO95970093- CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Contre: 14 Patient: 401 Treatment: Fluoxetine Sex: Female

			Visit	numi	er / La	borat	tory dat	0
			Scree	n	Day 2	В	Day 5	6
			22/05/	92	19/06/	92	17/07/	92
			value	(¢)	value	(¢)	value	(4)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/02/92	14.20		14.60	1 1	14.70	
HT	0.35-0.47 (L/L)	01/02/92	0.42		0.43	1 1	0.43	
RBC	3.9-5.6 (10-12/L)	01/02/92	4.72		4.87	li	4.85	
HBC	3.5-12 (10¬9/L)	01/02/92	10.90		10.80		9.50	
HBC: N	2.5-8 (10~9/L)	01/02/92	7.20		6.80		6.00	
HBC: L	1.2-4 (10-9/L)	01/02/92	2.10	l i	3.10		2.70	
NBC: E	0-0.5 (10~9/L)	01/02/92	1.00	>>	0.10		0.00	
MBC: M	0.1-1.1 (10-9/L)	01/02/92	0.70		0.80		0.70	
MRC: 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	1 1	4.20	
CL-	95-105 (HMOL/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	<
P04	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	1	19.00	
LDH CX	70-170 (U/L)	01/02/92	171.00	>	148.00	1 1	163.00	
ALK. PHOSPH.	18-70 (U/L)	01/02/92	67.00		60.00	1 ]	53.00	
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	4.20		4.90	1 }	4.60	
UREA	2.5-7.5 (MMOL/L)	01/02/92	3.40		4.40	1 1	3.40	
CREATININE	0.04-0.12 (MMOL/L)		0.07		0.07	1 1	0.06	ł
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.20		0.20	1 1	0.20	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	8.00		11.00	1 1	10.00	ŀ
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	1 1	66.00	<
ALBUNINE	36-49 (G/L)	01/02/92	43,00		48.00		42.00	l
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	3.80	lł	4.60	1 1	4.30	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.20		1.30	1 1	1.00	1
TSK	0.5-6.5 (MIU/L)	01/02/92	0.84					l
T4	86-148 (NMOL/L)	01/02/92	104.00			1		1

1071

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

### PHARMACIA PHARMACEUTICAS SANGROS - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 404 Treatment: Fluoxetine Sex: Female

			Visit	numi	er / La	borat	ory dat	8
			Scree	n.	Day 2	В	Day 5	6
			16/06/	92	14/07/	92	11/08/	92
			value	(¢)	value	(0)	value	(¢)
Laboratory test	Range value	Range date						
HB	11.5-16.5 (G/DL)	01/02/92	13.90		13.30	l i	12.30	
HT	0.35-0.47 (L/L)	01/02/92	0.41		0.40	1 1	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	1 1	4.10	
WBC: L	1.2-4 (10-9/L)	01/02/92	1.50		1.60		1.20	
MBC: E	0-0.5 (10-9/L)	01/02/92	0.00		0.00	i i	0.00	
MBC: M	0.1-1.1 (10-9/L)	01/02/92	0.30		0.40		0.10	
MBC: 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	1 1	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	<
P04	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	l	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	1 1	6.70	
CREATININE	0.04-0.12 (MMOL/L)	01/02/92	0.08	1	0.09	1 1	0.07	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.21		0.22	1 1	0.19	1
TOT BILIRUBIN	D-17 (UMOL/L)	01/02/92	8.00		10.00		9.00	
DIR BILIRUBIN	0-5 (UNOL/L)	01/02/92	3.00		2.00	li	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	l	39.00	1
TOT, CHOLEST.	3-8.5 (MMOL/L)	01/02/92	5.60		5.00		4.80	1
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	2.00		1.60		1.50	l
TSH	0.5-6.5 (MIU/L)	01/02/92	2.76			1 1		ĺ
158 T4	86-148 (NMOL/L)	01/02/92	105.00					
19	00-140 (MNOL/L)	01. 34. 34	100.00	1		1 1		I

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range cut of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTIGAS STATUS - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

# LABORATORY DATA Patient: 405 Treatment: Fluoxetine Sex: Female

			Visit	numi	er / La	borat	ory date	9
			Scree	n	Day 2	В	Day 5	6
			19/06/	92	20/07/	92	17/08/9	92
			value	(¢)	value	(¢)	value	(0
Laboratory test	Range value	Range date						
нв	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	1 1	4.06	
MBC	3.5-12 (10-9/L)	01/02/92	9.00		11.40	1 1	10.00	
HBC: N	2.5-8 (10¬9/L)	01/02/92	6.70		7.80		5.70	
MBC: L	1.2-4 (10-9/L)	01/02/92	2.10	i	3.00		3.50	
NBC: E	0-0.5 (10-9/L)	01/02/92	0.00		0.00	1	0.40	
MBC: M	Q,1-1.1 (10-9/L)	01/02/92	0.20		0.50	l f	0.40	
MBC: 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	1 1	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	<
P04	0.6-1.3 (MMOL/L)	01/02/92	1.10		0.93		0.90	
SCOT	0-35 (U/L)	01/02/92	14.00		13.00		12.00	
GAMMA GT	5-23 (U/L)	01/02/92	22.00	1	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	1 1	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	l i	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	D-17 (UMOL/L)	01/02/92	7.00		6.00		5.00	
DIR BILIRUBIN	0-5 (UNOL/L)	01/02/92	1.00		3.00	1 1	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 (NMOL/L)	01/02/92	4.10		4.20		3.90	1
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.10		0.90		1.00	l
TSH	0.5-6.5 (NIU/L)	01/02/92	0.57					1
1511 T4	86-148 (NMOL/L)	01/02/92	116.00			i i		l

1073

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range) (value lower wissing laboratory test value of laboratory not done

### PHARMACIA PHARMACEUTICAS 575689 - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

# LABORATORY DATA Contro: 14 Patient: 406 Treatment: Fluoxetine Sex: Female

		-			umber / ory date	
			Scree	n	Day 2	1
			30/06/	92	21/07/	92
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
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	
MBC	3.5-12 (10-9/L)	01/02/92	8.30		10,20	
MBC: N	2.5-8 (10-9/L)	01/02/92	5.80		7.00	Ì
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	ł
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	1
K+	3.5-4.5 (MMOL/L)	01/02/92	3.80		4.10	İ
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	ĺ
P04	0.6-1.3 (MMOL/L)	01/02/92	1.02	1 1	1.16	
SGOT	0-35 (U/L)	01/02/92	11.00		12.00	
GANNA GT	5-23 (U/L)	01/02/92	17.00		18.00	
LDH	70-170 (U/L)	01/02/92	121.00	l i	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)		0.08		0.07	
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.22		0.24	ĺ
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	10.00	1	12.00	
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	2.00		2.00	1
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	ĺ
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	3.60		3.80	ĺ
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	0.90		1.00	1
TSH	0.5-6.5 (MIU/L)	01/02/92	0.45	<		
15a T4	86-148 (NMOL/L)	01/02/92	116.00	1		l

1074

(t) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

### PHARMACIA PHARMACEUTICAS MANAGES - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 14 Patient: 509 Treatment: Fluoxetine Sex: Female

			Visit	numt	er / La	borat	tory date	8
			Scree	n	Day 2	В	Day 4	2
			21/09/	92	29/10/	92	11/11/	92
			value	(¢)	value	(¢)	value	(0)
Laboratory test	Range value	Range date						
нв	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	i I	4.42		4,34	
MBC	3.5-12 (10-9/L)	01/02/92	4.28		4.14		4.00	ł
HBC: N	2.5-8 (10-9/L)	01/02/92	2.73		2.24	<	1.93	
MBC: L	1.2-4 (10-9/L)	01/02/92	1.22		1.50		1.59	
KBC: E	0-0.5 (10~9/L)	01/02/92	0.09		0.10		0.17	1
MBC: M	0.1-1.1 (10-9/L)	01/02/92	0.19	1 1	0.27		0.29	
WBC: B	0-0.1 (10~9/L)	01/02/92	0.05	1	0.03		0.03	
PLATELETS	150-400 (10-9/L)	01/02/92	206.00	ll	196.00	li	181.00	
NA+	135-145 (MMOL/L)	01/02/92	138.00	1	138.00	lł	141.00	
K+	3.5-4.5 (MMOL/L)	01/02/92	3.90	1 1	4.50	i	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	
P04	0.6-1.3 (MMOL/L)	01/02/92	0.97		1.16		1.18	
SCOT	0-35 (U/L)	01/02/92	21.00	ıı	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 (HMOL/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	1 1	0.20	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	13.00		12.00		10.00	İ
DIR BILIRUBIN	0-5 (UMOL/L)	01/02/92	4.00	1	3.00		4.00	l
TOT, PROTEINS	68-83 (G/L)	01/02/92	82.00	l l	80.00		79.00	l
ALBUMINE	36-49 (G/L)	01/02/92	45.00		46.00		45.00	İ
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	4.80	1	4,80		4.20	l
TRIGLYCERIDES	0.1-1.7 (MNOL/L)	01/02/92	0.70		0.90		0.70	l
TSH	0.5-6.5 (MIU/L)	01/02/92	1.21		,,,,			İ
TSH T4	86-148 (NMOL/L)	01/02/92	94.00	1				l

1075

(¢) << clinically relevant (value lower than min range)
< out of range (value lower than min range)
than min range)
than min range)
than min range)
than min range)

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# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 510 Treatment: Fluoxotine Sex: Female

.,			Visit	numl	er / La	borat	ory dat	
			Scree	n	Day 2	В	Day 5	6
			30/09/	92	29/10/	92	26/11/	92
			value	(4)	value	(¢)	value	(4)
Laboratory test	Range value	Range date						
нв	11.5-16.5 (G/DL)	01/02/92	13.90		13.80	1 1	13.90	
HT	0.35-0.47 (L/L)	01/02/92	0.41		0,40	1 1	0.41	
RBC	3.9-5.6 (10-12/L)	01/02/92	4.58		4.48	1 1	4.64	
MBC	3.5-12 (10-9/L)	01/02/92	8.00		6.38	II	5.95	
WBC: N	2.5-8 (10-9/L)	01/02/92	4.16		3.86	1 1	3.68	
WBC: L	1,2-4 (10~9/L)	01/02/92	1.93		1.52	l i	1.48	
WBC: E	0-0.5 (10-9/L)	01/02/92	0.43		0.40	1 1	0.33	1
MBC: M	0.1-1.1 (10-9/L)	01/02/92	0.42		0.33	i i	0.40	1
MBC: B	0-0.1 (10-9/L)	01/02/92	0.09		0.07		0.06	1
PLATELETS	150-400 (10-9/L)	01/02/92	260.00		255.00		265.00	1
NA+	135-145 (MMOL/L)	01/02/92	139.00	1	136.00	i I	140.00	1
K+	3.5-4.5 (MMOL/L)	01/02/92	4.00		3.60	l I	4.10	ŀ
CL-	95-105 (MMDL/L)	01/02/92	104.00		107.00	>	106.00	<b> </b> >
Ca++	2.25-2.75 (MMOL/L)	01/02/92	2.15	<	2.27	i I	2.23	<
P04	0.6-1.3 (MMOL/L)	01/02/92	1.00		0.83	1 1	0.97	l
SGOT	0-35 (U/L)	01/02/92	16.00		15.00	l l	16.00	l
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	1	156.00	l
ALK. PHOSPH.	18-70 (U/L)	01/02/92	53.00		53.00	1	60.00	
GLUCOSE	3.3-6.7 (MHOL/L)	01/02/92	3.10	<	4.00	i I	3.50	l
UREA	2.5-7.5 (MMOL/L)	01/02/92	5.10		4.70	1	5,80	l
CREATININE	0.04-0.12 (MMOL/L)		0.06		0.07		0.08	1
URIC ACID	0.1-0.39 (MMOL/L)	01/02/92	0.17		0.23	1 1	0.23	
TOT BILIRUBIN	0-17 (UMOL/L)	01/02/92	9.00		12.00	i I	9.00	1
DIR BILIRUBIN	0-1/ (UNOL/L)	01/02/92	2.00		3.00	l l	3.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	70.00		75.00	ıl	73.00	l
ALBUMINE	36-49 (G/L)	01/02/92	40.00		43.00		42.00	1
TOT. CHOLEST.	3-8.5 (MMOL/L)	01/02/92	4.40	j l	5.00	i I	4.70	
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	1.20		0.80	Ιİ	0.60	
	0.5-6.5 (MIU/L)	01/02/92	1.27		2.00			1
TSH T4	86-148 (NMOL/L)	01/02/92	81.00	۱ د		1 1		1
14	00-140 (MNOL/L)	0 1. Op. 32	0	i		I		1

1076

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

### PHARMACIA PHARMACEUTICAS HHONO3- CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 538 Treatment: Fluoxetine Sex: Female

			Visit	numb	er / La	borat	ory dat	
			Scree	n	Day 2	В	Day 5	6
			12/02/	93	12/03/	93	07/04/	93
			value	(¢)	value	(¢)	value	(0)
Laboratory test	Range value	Range date						
НВ	11.5-16.5 (G/DL)	01/02/92	14.50		13.40	1 1	13.60	
HT	0.35-0.47 (L/L)	01/02/92	0.44		0.40	1	0.40	
RBC	3,9-5.6 (10-12/L)	01/02/92	4.50		4.14		4.20	
KBC	3.5-12 (10-9/L)	01/02/92	7.70	l I	8.30		10.98	
MBC: N	2.5-B (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	i I	2.92	
WBC: E	0-0.5 (10-9/L)	01/02/92	0.23	1 1	0.14		0.27	
MBC: N	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	1	3.70		4.00	1
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	1
P04	0.6-1.3 (MMOL/L)	01/02/92	1.03		1.04		1.41	>
SCOT	0-35 (U/L)	01/02/92	11.00	1 1	18.00		17,00	1
GAMMA GT	5-23 (U/L)	01/02/92	19.00	1 1	18,00	l	20.00	1
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	1
GLUCOSE	3.3-6.7 (MMOL/L)	01/02/92	4.90		4.30		5.60	1
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	l
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	1 1	2.00	
TOT. PROTEINS	68-83 (G/L)	01/02/92	68.00		65.00	c	69.00	1
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	1
TRIGLYCERIDES	0.1-1.7 (MMOL/L)	01/02/92	0.70	l l	0.70		0.90	l
TSH	0.5-6.5 (MIU/L)	01/02/92	1.20		,			
T4	86-148 (NMOL/L)	01/02/92	71.00	احدا		1 1		l

1077

### РНАЯМАСІА РНАЯМАСЕИТІСЯБ МИНОЗ- CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 539 Treatment: Fluoxetine Sex: Female

HB 11. RT 0.3 RBC 3.9 HBC 3.5 HBC: N 2.5 HBC: L 1.2 HBC: E 0-0 HBC: M 0.1 HBC: B 0-0 PLATELETS 150 NA+ 135 K+ 3.5 CL- 95- Ca++ 2.2 PO4 0.6 SGOT 0-3 GAMMA GT 5-2 LDH 70- ALK. PHOSPH. 18- GLUCOSE 3.3 URBC: M 3.5 CREATININE 0.0	ge value 5-16.5 (G/DL) 15-0.47 (L/L) 1-5.6 (10-12/L) 1-12 (10-9/L) 1-4 (10-9/L) 1-1.1 (10-9/L) 1-400 (10-9/L) 1-405 (MMOL/L) 1-4.5 (MMOL/L)	Rango date 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92	10/03/93 value (13.00 0.39 4.18 6.20 3.30 2.47 0.03 0.38 0.03 223.00 138.00	3 (0)	08/04/9 value  13.20 0.40 4.25 5.12 3.45 1.37 0.01 0.27 0.02 193.00		Day 50 06/05/9 value 13.10 0.41 4.28 6.10 3.42 2.23 0.06 0.36	93 (¢)
HB 11. RT 0.3 RBC 3.9 HBC 3.5 HBC: N 2.5 HBC: L 1.2 HBC: E 0-0 HBC: M 0.1 HBC: B 0-0 PLATELETS 150 NA+ 135 K+ 3.5 CL- 95- Ca++ 2.2 PO4 0.6 SGOT 0-3 GAMMA GT 5-2 LDH 70- ALK. PHOSPH. 18- GLUCOSE 3.3 URBC: M 3.5 CREATININE 0.0	5-16.5 (G/DL) iS-0.47 (L/L) i-5.6 (10-12/L) i-12 (10-9/L) i-8 (10-9/L) i-4 (10-9/L) i-5 (10-9/L) i-1 (10-9/L) i-1 (10-9/L) i-400 (10-9/L) i-400 (10-9/L)	01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92	value (13.00 0.39 4.18 6.20 3.30 2.47 0.03 0.38 0.03 223.00		value 13.20 0.40 4.25 5.12 3.45 1.37 0.01 0.27 0.02 193.00		value 13.10 0.41 4.28 6.10 3.42 2.23 0.06 0.36	(¢)
HB 11. RT 0.3 RBC 3.9 HBC 3.5 HBC: N 2.5 HBC: L 1.2 HBC: E 0-0 HBC: M 0.1 HBC: B 0-0 PLATELETS 150 NA+ 135 K+ 3.5 CL- 95- Ca++ 2.2 PO4 0.6 SGOT 0-3 GAMMA GT 5-2 LDH 70- ALK. PHOSPH. 18- GLUCOSE 3.3 URBC: M 3.5 CREATININE 0.0	5-16.5 (G/DL) iS-0.47 (L/L) i-5.6 (10-12/L) i-12 (10-9/L) i-8 (10-9/L) i-4 (10-9/L) i-5 (10-9/L) i-1 (10-9/L) i-1 (10-9/L) i-400 (10-9/L) i-400 (10-9/L)	01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92	13.00 0.39 4.18 6.20 3.30 2.47 0.03 0.38 0.03 223.00	( <del>¢</del> )	13.20 0.40 4.25 5.12 3.45 1.37 0.01 0.27 0.02 193.00	(¢)	13.10 0.41 4.28 6.10 3.42 2.23 0.06	
HB 11. RT 0.3 RBC 3.9 HBC 3.5 HBC: N 2.5 HBC: L 1.2 HBC: E 0-0 HBC: M 0.1 HBC: B 0-0 PLATELETS 150 NA+ 135 K+ 3.5 CL- 95- Ca++ 2.2 PO4 0.6 SGOT 0-3 GAMMA GT 5-2 LDH 70- ALK. PHOSPH. 18- GLUCOSE 3.3 URBC: M 3.5 CREATININE 0.0	5-16.5 (G/DL) iS-0.47 (L/L) i-5.6 (10-12/L) i-12 (10-9/L) i-8 (10-9/L) i-4 (10-9/L) i-5 (10-9/L) i-1 (10-9/L) i-1 (10-9/L) i-400 (10-9/L) i-400 (10-9/L)	01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92	0.39 4.18 6.20 3.30 2.47 0.03 0.38 0.03 223.00		0.40 4.25 5.12 3.45 1.37 0.01 0.27 0.02 193.00		0.41 4.28 6.10 3.42 2.23 0.06 0.36	
HT 0.3 RBC 3.9 RBC 3.5 HBC: N 2.5 HBC: L 1.2 HBC: E 0-0 HBC: N 0.1 HBC: B 0-0 PLATELETS 150 NA+ 135 K+ 3.5 CL- 95- Ca++ 2.2 PO4- 0.6 SGOT 0-3 GAMMA GT 5-2: LDB 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.5 CREATININE 0.0	IS-0.47 (L/L) 1-5.6 (10-12/L) 1-12 (10-9/L) 1-8 (10-9/L) 1-4 (10-9/L) 1-5 (10-9/L) 1-1.1 (10-9/L) 1-1.1 (10-9/L) 1-400 (10-9/L) 1-405 (10-9/L) 1-45 (MMOL/L)	01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92	0.39 4.18 6.20 3.30 2.47 0.03 0.38 0.03 223.00		0.40 4.25 5.12 3.45 1.37 0.01 0.27 0.02 193.00		0.41 4.28 6.10 3.42 2.23 0.06 0.36	
RBC 3.9 HBC: N 2.5 HBC: N 2.5 HBC: L 1.2 HBC: E 0-0 HBC: B 0-0 HBC: B 0-0 PLATELETS 150 NA+ 135 K+ 3.5 CL- 95- Ca++ 2.2 P04 0.6 SGGT 0-3 GAMMA GT 5-2 LDH 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA UREA 2.5 CREATININE 0.0	-5.6 (10-12/L) -12 (10-9/L) -8 (10-9/L) -4 (10-9/L) -5 (10-9/L) -1.1 (10-9/L) .1 (10-9/L) -400 (10-9/L) -400 (10-9/L)	01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92	4.18 6.20 3.30 2.47 0.03 0.38 0.03 223.00		4.25 5.12 3.45 1.37 0.01 0.27 0.02 193.00		4.28 6.10 3.42 2.23 0.06 0.36	
HBC: 3.5 HBC: N 2.5 HBC: N 1.2 HBC: L 1.2 HBC: E 0-0 HBC: B 0-0 PLATELETS 150 NA+ 135 K+ 3.5 CL- 95- Ca++ 2.2 PO4 0.6 SGOT 0-3 GAMMA GT 5-2 LDR 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.5 EREATININE 0.0	3-12 (10-9/L) 3-8 (10-9/L) 3-4 (10-9/L) 3-5 (10-9/L) 3-1.1 (10-9/L) 3-1.1 (10-9/L) 3-1.1 (10-9/L) 3-1.1 (10-9/L) 3-1.1 (10-9/L) 3-1.1 (10-10-10-10-10-10-10-10-10-10-10-10-10-1	01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92	6.20 3.30 2.47 0.03 0.38 0.03 223.00		5.12 3.45 1.37 0.01 0.27 0.02 193.00		6.10 3.42 2.23 0.06 0.36	
MBC: N 2.5 MBC: L 1.2 MBC: E 0-0 MBC: B 0-0 PLATELETS 150 NA+ 135 K+ 3.5 CL- 95- Ca++ 2.2 PO4 0.6 SGOT 0-3 GAMMA GT 5-2: LDB 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.5 EAPATININE 0.0	-8 (10-9/L) -4 (10-9/L) 1.5 (10-9/L) -1.1 (10-9/L) 1.1 (10-9/L) 1-400 (10-9/L) -145 (MMOL/L)	01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92	3.30 2.47 0.03 0.38 0.03 223.00		3.45 1.37 0.01 0.27 0.02 193.00		3.42 2.23 0.06 0.36	
MBC: L 1.2 MBC: E 0-0 MBC: B 0-0 PLATELETS 150 NA+ 135 K+ 3.5 CL- 95- Ca++ 2.2 PD4 0.6 SGOT 0-3 GAMMA GT 5-2 LDH 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UNEA 2.5 CREATININE 0.0	-4 (10~9/L) ,5 (10~9/L) -1.1 (10~9/L) .1 (10~9/L) -400 (10~9/L) -145 (MMOL/L)	01/02/92 01/02/92 01/02/92 01/02/92 01/02/92 01/02/92	2.47 0.03 0.38 0.03 223.00		1.37 0.01 0.27 0.02 193.00		2.23 0.06 0.36	
MBC: E 0-0 MBC: N 0.1 MBC: B 0-0 PLATELETS 150 NA+ 135 K+ 3.5 CL- 95- Ca++ 2.2 PO4- 0.6 SGOT 0-3 SGAMA GT 5-2: LDR 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.5 CREATININE 0.0	.5 (10-9/L) -1.1 (10-9/L) .1 (10-9/L) -400 (10-9/L) -145 (MMOL/L)	01/02/92 01/02/92 01/02/92 01/02/92 01/02/92	0.03 0.38 0.03 223.00		0.01 0.27 0.02 193.00		0.06 0.36	
MBC: M 0.1 MBC: B 0-0 MBC: B 150 MA+ 135 K+ 3.5 CL- 95- CA++ 2.2 PO4 0.6 SGOT 0-3 GAMMA GT 5-2 LALK. PHOSPH. 18- GLUCOSE 3.3 URFA 2.5 CREATININE 0.0	-1.1 (10~9/L) .1 (10~9/L) -400 (10~9/L) -145 (MMOL/L)	01/02/92 01/02/92 01/02/92 01/02/92	0.38 0.03 223.00		0.27 0.02 193.00		0.36	ļ
HBC: B 0-0 PLATELETS 150 NA+ 135 K+ 3.5 CL- 95- Ca++ 2.2 PO4- 0.6 SGOT 0-3 GAMMA GT 5-2 LDR 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.5 CREATININE 0.0	.1 (10-9/L) -400 (10-9/L) -145 (MMOL/L)	01/02/92 01/02/92 01/02/92	0.03 223.00		0.02 193.00			
PLATELETS 150 NA+ 135 K+ 3.5 CL- 95- Cm++ 2.2 PO4- 0.6 SGOT 0-3 GAMMA GT 5-2: LDB 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.5 EREATNINE 0.0	-400 (10~9/L) -145 (MMOL/L)	01/02/92 01/02/92	223.00		193.00		!	
NA+ 135 K+ 3.5 CL- 95- Ca++ 2.2 PO4 0.6 SGOT 0-3 GAMMA GT 5-2 LDH 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.5 CREATININE 0.0	-145 (MMQL/L)	01/02/92					0.03	
NA+ 135 K+ 3.5 CL- 95- CB++ 2.2 PO4- 0.6 SGOT 0-3 GAMMA GT 5-2: LDH 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.5 CREATININE 0.0			138 00	- 1		i	222.00	
K+ 3.5 CL- 95- CL- 95- CR++ 2.2 P04 0.6 SGOT 0-3 GAMMA GT 5-2 LDH 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.55 CREATININE 0.0					137.00	- 1	138.00	
CL- 95- Ca++ 2.2 Ca+- 0.6 SGOT 0-3 GAMMA GT 5-2: LDH 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.5 CREATININE 0.0		01/02/92	4,20	- 1	3.80	- 1	4.00	
P04 0.6 SGOT 0-3 GAMMA GT 5-2: LDH 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.5 CREATININE 0.0	105 (MMOL/L)	01/02/92	101.00	J	101.00	J	105.00	
P04 0.6 SGOT 0-3 GAMMA GT 5-2: LDH 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.5 CREATININE 0.0	5-2.75 (MMOL/L)	01/02/92	2.26		2,26	- 1	2.35	
SGOT 0-3 GAMMA GT 5-2 LDH 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.5 CREATININE 0.0	-1.3 (MMOL/L)	01/02/92	1.12		0.96	- 1	1.17	
GAMMA GT 5-2: LDH 70- ALK: PHOSPH: 18- GLUCOSE 3.3 UREA 2.5: CREATININE 0.0	5 (U/L)	01/02/92	18.00	ł	17.00	1	15.00	
LDH 70- ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.5 CREATININE 0.0	3 (U/L)	01/02/92	19.00		18.00	1	17.00	
ALK. PHOSPH. 18- GLUCOSE 3.3 UREA 2.5 CREATININE 0.0	170 (U/L)	01/02/92	144.00	- 1	119.00	1	134.00	
GLUCOSE 3.3 UREA 2.5 CREATININE 0.0	70 (U/L)	01/02/92	49.00		45.00		59.00	
UREA 2.5 CREATININE 0.0	-6.7 (MMOL/L)	01/02/92	5.00		7.40	<b>、</b>	3.90	
CREATININE 0.0	-7.5 (MMOL/L)	01/02/92	3.70		3.00	· [	3.20	
	4-0.12 (MMOL/L)		0.06		0.05	- 1	0.06	
URIC ACID 0.1	-0.39 (MMOL/L)	01/02/92	0.28		0.15	1	0.17	
	7 (UMOL/L)	01/02/92	9.00		9.00	- 1	8.00	
	(UMOL/L)	01/02/92	2.00		3.00		2.00	
	83 (G/L)	01/02/92	74.00		70.00		73.00	
	49 (G/L)	01/02/92	43.00		42.00	- 1	44.00	
	.5 (MMOL/L)	01/02/92	5.10		4.60	- 1	5.40	
	-1.7 (MMOL/L)	01/02/92	1.00	- 1	1.40	- }	1.10	
		01/02/92	1.10		1.40	- 1		
15n 0.5	-6.5 (MIU/L)	01/02/92	148,00	- 1				

1078

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value od laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTICAS 500 608 - CNS

# REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 410 Treatment: Fluoxetine

			Visit	num	ber / Lai	bora	tory dat	0
			Screen	n	Day 2	В	Day 5	6
			09/04/	92	14/05/	92	10/06/	92
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date				_		
нв	12-15 (G/DL)	05/04/92	12.90		13.10	1	13.60	ì
нт	38-43 (%)	05/04/92	39.00		41.00		41.00	
RBC	4200000-4800000	05/04/92	l :					
	(/MN3)		4290000		4640000	l	4420000	
NBC	4500-10000 (/MM3)	05/04/92	7200.00		8300.00	ĺ	5100.00	i
MBC: N	50-65 (%)	05/04/92	65.00		49,00	<	62,00	l
WBC: L	30-40 (%)	05/04/92	31.00		43.00	>	33.00	l
WBC: E	0-3 (2)	05/04/92	3.00		5.00	>>	3.00	
WBC: N	0~5 (%)	05/04/92	1.00		3.00		2.00	
MBC: B	0-1 (2)	05/04/92	0.00		0.00		0.00	
PLATELETS	150000-450000	05/04/92						
	(/MM3)		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 (NEQ/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	l
P04	2.5-4.5 (MG/DL)	05/04/92	4.00		3.30		4.50	
BGOT	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	
JREA	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	1	4.10		4.10	
TOT. CHOLEST.	150-250 (MG/DL)	05/04/92	244.00		266.00	>	280.00	>
TRIGLYCERIDES	40-180 (NG/DL)	05/04/92	98.00	- 1	100.00	-	84.00	
GLOBULINS ALPHA 1	0.12-0.35 (G/DL)	05/04/92	0.23		0.22		0.20	
GLOBULING ALPHA 2	0.35-0.65 (G/DL)	05/04/92	0.65	l	0.59		0.64	
SLOBULING RETA	0.56-0.9 (G/DL)	05/04/92	0.78	- 1	0.64		0.71	
SLOBULINS GAMMA	1.1-1.7 (G/DL)	05/04/92	1.44		1.55		1.55	
ISH	0-6 (UU/ML)	05/04/92	0.50		,,,,,,			
10fi 14	4.5-13 (UG/DL)	05/04/92	9.50	1				
1.44	4.5-15 (00/01)	03, 04, 72	7.30	- 1				

<sup>(¢) &</sup>lt;< clinically relevant (value lower than min range)
< out of range (value lower than min range)

\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range > out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIC95 910 6093 - CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 412 Treatment: Fluoxetine Sex: Fomale

			Visit	num	oer / Lal	bora	tory date	9
			Screen	1	Day 2	B	Day S	6
			10/04/9	92	20/05/	92	17/06/9	92
			value	(¢)	value	(\$)	value	(¢
Laboratory test	Range value	Range date	40.00		12.70		12.90	
HB	12-15 (G/DL)	05/04/92	13.30		38.00		38.00	ł
HT	38-43 (%)	05/04/92	40.00		36.00		36.00	
RBC	4200000-4800000 (/MN3)	05/04/92	4400000		4180000	ا حا	4200000	1
MBC	4500-10000 (/MM3)	05/04/92	7600.00		7100.00	-	6800.00	
MBC: N	50-65 (%)	05/04/92	59.00		58.00		60.00	İ
MBC: L	30-40 (%)	05/04/92	36.00		38.00		36,00	
MBC: E	0-3 (%)	05/04/92	3.00		1.00		2.00	
NBC: N	0-6 (%)	05/04/92	2.00		3.00		2.00	1
NBC: B	0-1 (%)	05/04/92	0.00		0.00		0.00	
PLATELETS	150000-300000	05/04/92	1					
	(/MM3)		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 (NEQ/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	
P04	2.5-4.5 (MG/DL)	05/04/92	4.20		4.10		4 50	
	2.5-5 (MG/DL)	15/06/92					4.50	
SGOT	4-20 (U/L)	05/04/92	5.00		7.00		8.00	
	7-22 (U/L)	15/06/92	0.00		3.00		6.00	
SGPT	2-18 (U/L)	05/04/92	3.00		3.00		10.00	
	7-26 (U/L)	15/06/92	9.20		16.00		10.50	
GAMMA GT	5-25 (U/L) 5-24 (U/L)	05/04/92 15/06/92	7.20		10.00		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			
ALK. FRUDER.	50-220 (U/L)	15/06/92	1				110.00	
GLUCOSE	70-110 (MG/DL)	05/04/92	83.00		75.00			
GEOCOPE	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	1
CREATININE	5-14 (MG/L)	05/04/92	8.90		12.30			
	0.6-1.4 (MG/DL)	15/06/92	i				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	1		1
	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	1	4.30	
	3.5-5.2 (G/DL)	15/06/92			044.00		4.30	
TOT. CHOLEST.	160-250 (NG/DL)	05/04/92	212.00		214.00	l	210.00	
	140-260 (MG/DL)	15/06/92	118.00		112.00	l		l
TRIGLYCERIDES	10-160 (MG/DL)	05/04/92 15/06/92	118.00		112.00	l	120.00	
# ADDIT THE	50-160 (MG/DL)	05/04/92	0.10		0.10	l	0.20	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL) 0.45-0.75 (G/DL)	05/04/92	0.60		0.60	l	0.70	l
GLOBULINS ALPHA 2 GLOBULINS BETA	0.45°0.75 (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	1.25		1.20	
TSH	0.6-6.5 (UU/ML)	05/04/92	8.20	>>		1		l
13h T4	5.5-14 (UG/DL)	05/04/92	4.00	<<	1	l	1	ı

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min range) than min range (min

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICO 5 5 HONO3 - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 414 Treatment: Fluoxetine

			Visit	num	ber / La	pora	tory dat	
			Scree	1	Day 2	В	Day 5	6
			26/05/	26/05/92 29/06/92		27/07/	92	
			value	(¢)	value	(¢)	value	(4)
Laboratory test	Range value	Range date						T
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	25/05/92						
	(/MM3)		5720000	>	5600000		5530000	
WBC	4500-10000 (/MM3)	25/05/92	8500.00		8400.00		6900.00	i
WBC: N	50-65 (%)	25/05/92	55.00		67.00	>	52.00	
HBC: L	30-40 (2)	25/05/92	42.00	>	31.00		43.00	
MBC: E	0-3 (%)	25/05/92	1.00		1.00		2.00	l
IBC: H	0-6 (%)	25/05/92	2.00		1.00		3.00	
(BC: B	0-1 (%)	25/05/92	0.00		0.00		0.00	1
PLATELETS	150000-400000	25/05/92						
	(/MM3)		235000		160000		295000	
iA+	130-150 (MEQ/L)	25/05/92	143.00		145.00		142.00	
(+	3.6-5 (MEQ/L)	25/05/92	4.40		4.40		4.40	
L-	85-105 (MEQ/L)	25/05/92	100.00		103.00		103.00	
2++	8.5-10.5 (MEQ/L)	25/05/92	10.60	>	10.10		9.80	
04	2.5-4.5 (MG/DL)	25/05/92	3.10		3,60		3.90	
GOT	0-44 (U/L)	25/05/92	19.00		13.00		28.00	
GPT	0-44 (U/L)	25/05/92	10.00		19.00		33,00	
AMMA GT	0-28 (U/L)	25/05/92	43.00	>	25.00		22.00	
.DH	0-240 (U/L)	25/05/92	256.00	>	172.00		206.00	
LK. PHOSPH.	50-300 (U/L)	25/05/92	79.00		122.00		123.00	
LUCOSE	0.6-1.1 (G/L)	25/05/92	0.81		0.90		0.79	
IREA	0.2-0.5 (G/L)	25/05/92	0.46		0.20		0.28	
REATININE	0.8-1.5 (MG/DL)	25/05/92	1.23		1.20		1.19	l
RIC ACID	2-7 (MG/DL)	25/05/92	5.00		5.20		6.60	l
OT BILIRUBIN	0-1.2 (MG/DL)	25/05/92	0.78		0.76		0.12	
IR BILIRUBIN	0-0.2 (MG/DL)	25/05/92	0.05		0,25	>	0.05	l
OT. PROTEINS	6-8 (G/DL)	25/05/92	8.20	>	6.80		7.20	l
LBUMINE	3.8-5 (G/DL)	25/05/92	4.90		4.00	. i	4.20	l
OT. CHOLEST.	140-250 (MG/DL)	25/05/92	251.00		228.00		313.00	>
RIGLYCERIDES	50-172 (MG/DL)	25/05/92	195.00	>	150.00		117.00	
LOBULINS ALPHA 1	0.1-0.3 (G/DL)	25/05/92	0.30		0.20		0.25	l
LOBULINS ALPHA 2	0.45-0.75 (G/DL)	25/05/92	0.70		0.55		0.75	l
LOBULINS BETA	0.6-1 (G/DL)	25/05/92	1.00		0.80		0.90	l
LOBULINS GAMMA	0.8-1.4 (G/DL)	25/05/92	1.30		1.25		1,10	Į
rsk	0.3-5 (UU/ML)	25/05/92	0.70					l
r4	5-12 (UG/DL)	25/05/92	8.00			1		ı

<sup>(</sup>c) << clinically relevant (value lower than min range)
< out of range (value lower than min range)
than min range)
than min range)
than min range)
than min range)

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIQ5点点设备。CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 416 Trentment: Fluoxetine Sex: Female

			Visit	numi	ber / La	bora'	tory date	0
			Scree	1	Day 2	В	Day 5	6
			19/06/	2	20/07/	92	17/08/	92
			value	(¢)	value	(4)	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	01/03/92						
	(/MM3)		4450000		4600000	>	4700000	>
MBC	5000-9000 (/MM3)	01/03/92	10900.0		7000.00	l	6700.00	١.
HBC: N	50-65 (%)	01/03/92	66.00	>	51.00	l	49.00	
MBC: L	30-40 (%)	01/03/92	30.00		45.00	>	45.00	>
HBC: E	0-3 (%)	01/03/92	3.00		2.00		2.00	
MBC: M	0-5 (%)	01/03/92	1.00		2.00		4.00	
MBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000	01/03/92						
	(/MM3)		315000	>	280000	ļ	250000	
NA+	130-150 (MEQ/L)	01/03/92	137.00		140.00	l	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	1
P04	2.5-5 (MG/DL)	01/03/92	4.50		4.10	l	3.80	1_
SGOT	0-12 (NU/ML)	01/03/92	14.00	>	17.00	>	21.00	
SGPT	0-12 (NU/ML)	01/03/92	11.00		12.00	l	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	l_	150.00	
ALK, PHOSPH.	20-48 (MU/ML)	01/03/92	35.00		50.00	>	47.00 96.00	
GLUCOSE	70-110 (MG/DL)	01/03/92	86.00		90.00			
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 4.80		4.30	
URIC ACID	2.4-5.7 (MG/DL)	01/03/92	5.10			ł		1
TOT BILIRUBIN	0-1 (MG/DL)	01/03/92	0.32		0.40	1	0.60	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.10		0.12		0.15	1
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	6,80		7.00	ŀ	7.30	1
ALBUMINE	3.8-5 (G/DL)	01/03/92	4.70		4.80		4.95 210.00	
TOT, CHOLEST.	160-240 (MG/DL)	01/03/92	267.00		220.00			
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	160.00	>	150.00	ĺ	135.00	l
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.15		0.10	ĺ	0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.45		0.50	ĺ		
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0,65		0.70	l	0.60	l
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	0.85		0.90	l	1.00	l
TSH	0-5 (UUI/ML)	01/03/92	2.00	1		ĺ		l
T4	4.5-13 (UG/DL)	01/03/92	7.10	l	1	ı	ł	1

1082

(¢) << clinically relevant (value lower than min range)
< out of range (value lower than min range)
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>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

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#### PHARMACIA PHARMACEUTICOS HELONO3- CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 419 Treatment: Fluoxetina Sex: Female

			Visit	numi	ber / La	bora	tory date	8
			Scree	n	Day 2	8	Day 5	6
			08/07/	92	12/08/	92	09/09/	92
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date						
HB	12.5-15 (G/DL)	01/03/92	13.30	Ì	13.80		12.10	<
HT	38-43 (%)	01/03/92	40.00		41.00		39.00	
RBC	4000000-4500000	01/03/92	į					
	(/MM3)		4400000		4500000		4290000	
MBC	5000-9000 (/MM3)	01/03/92	6500.00		7100.00		6800.00	
NBC: N	50-65 (%)	01/03/92	71.00	>	65.00		61.00	
WBC: L	30-40 (2)	01/03/92	29.00	<	32.00		35.00	
HBC: E	0-3 (%)	01/03/92	0.00	i	1.00		2.00	
MBC: N	0-5 (%)	01/03/92	0.00		2.00		2.00	
NBC: B	0-1 (%)	01/03/92	0.00	İ	0.00		0.00	
PLATELETS	150000-300000	01/03/92	1				l	
- MANUEL - M	(/MM3)		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	ŀ	102.00		106.00	>
Ca++	8.1-10.4 (MG/DL)	01/03/92	10.50	>	9.80		11.20	>
P04	2.5-5 (MG/DL)	01/03/92	4.00		4.40		4.20	
SGOT	0-12 (MU/ML)	01/03/92	6.00	1	8.00	:	8.00	
SGPT	0-12 (NU/NL)	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	ĺ
ALK, PHOSPH.	20-48 (MU/ML)	01/03/92	40.00		43.00		40.00	ĺ
GLUCOSE	70-110 (MG/DL)	01/03/92	91.00	l .	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	1
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 RILIRUBIN	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	1	0.26		0.25	
	0.45-0.75 (G/DL)	01/03/92	0.70		0.68	Ι '	0.70	l
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.80	l	0.90	l	0.85	l
GLOBULINS BETA		01/03/92	1.35		1.25	İ	1.35	
GLOBULINE GAMMA	0.8-1.3 (G/DL)	01/03/92	1.30	1	1.23	l	33	ľ
TSH T	0-5 (UUI/ML)	01/03/92	9.60			İ	1	
Γ4	4.5-13 (UG/DL)	01/03/74	7.00	1	l	l	l	ļ

<sup>(0) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 420 Treatment: Fluoxetine Sex: Male

			Visit	num	ber / La	bora	tory date	9
			Scree	n	Day 2	В	Day 5	6
			15/07/	92	16/09/	92	14/10/	92
			value	(¢)	value	(4)	value	(¢
Laboratory test	Range value	Range date						
НВ	13.5-15.5 (G/DL)	01/03/92	14.00	1	13.50		14.00	
HT	40-45 (%)	01/03/92	43.00	ł	40.00		44.00	
RBC	4200000-4800000	01/03/92	Į.	1	1			
	(/MM3)		4800000		4700000		4900000	>
MBC	5000-9000 (/MM3)	01/03/92	5100.00		5300.00		5900.00	
MBC: N	50-65 (%)	01/03/92	46.00	<	52.00		60.00	1
MBC: L	30-40 (%)	01/03/92	49.00	>	41.00	>	30.00	
MBC: E	0-3 (%)	01/03/92	2.00		3.00		6.00	>>
MBC: M	0-5 (%)	01/03/92	3.00		4.00		4.00	l
MBC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000	01/03/92	1					
PERILELIS	(/MM3)	• • • • • • • • • • • • • • • • • • • •	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	
P04-~	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	
	0-12 (NU/ML)	01/03/92	10.00		12.00		8.00	
SGPT GAMMA GT	6-28 (UI/L)	01/03/92	22.00		20.00		12.00	
• • • • • • • • • • • • • • • • • • • •	120-240 (UI/L)	01/03/92	180.00		185.00		196.00	
LDH ALK. PHOSPH.	20-48 (MU/HL)	01/03/92	35.00		35.00		44.00	
	70-110 (NG/DL)	01/03/92	85.00		90.00		81.00	
GLUCOSE 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	
···	0-1 (MG/DL)	01/03/92	0.71		0.70		0.60	
TOT BILIRUBIN DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.15		0.12		0.11	
	6.3-8 (G/DL)	01/03/92	7.20		7.00		7.30	
TOT, PROTEINS ALBUMINE	3.8-5 (G/DL)	01/03/92	3.97		3.85		4.20	
	160-240 (MG/DL)	01/03/92	186.00	l	180.00		186.00	l
TOT. CHOLEST. TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	72.00	l	72.00		69.00	l
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.27	1	0.25		0.29	l
	0.45-0.75 (G/DL)	01/03/92	0.71		0.75		0.71	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.90	1	0.80		0.95	l
GLOBULINS BETA		01/03/92	1.15	l	1.20		1.15	l
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	3.10		20			l
TSH T	0-5 (UUI/ML) 4.5-13 (UG/DL)	01/03/92	6.60		1		1	
T4	4.5-15 (06/06/	01/03/92	0.00	l	1	l	l	

1084

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<sup>(</sup>c) << clinically relevant (value lower than min range)
<- out of range (value lower than min range)
\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIO95316893- CMS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 422 Treatment: Fluoxetine Sex: Male

			Visit	num	ber / Lai	pora	tory date	9
			Screen	3	Day 2	В	Day 5	6
			14/08/	92	15/09/92		13/10/	92
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date		-				
нв	13.5-15.5 (G/DL)	01/03/92	14.60		14.50		14.60	1
HT	40-45 (%)	01/03/92	48.00	>	47.00	>	48.00	>
RBC	4200000-4800000	01/03/92	[				ł	t
RDC	(/MM3)		5280000	>	5230000	>	5250000	>
WBC	5000-9000 (/MM3)	01/03/92	6800.00		7100.00		7200.00	1
NBC: N	50-65 (%)	01/03/92	63.00	1	60.00		62.00	1
WRC: 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	l
PLATELETS	150000-300000	01/03/92			ŀ			
	(/MM3)		210000		220000		225000	l
NA+	130-150 (MEQ/L)	01/03/92	141.00		145.00		139.00	1
K+	3-5 (MEQ/L)	01/03/92	4.60		4.20		4.90	1
CL-	95-105 (MEQ/L)	01/03/92	102.00		99.00		100.00	1
Ca++	8.1-10.4 (MG/DL)	01/03/92	10.40		10.80	>	10.70	>
P04	2.5-5 (MG/DL)	01/03/92	3.90		3.50		3,50	
SGOT	0-12 (NU/ML)	01/03/92	6.00	l	7.00		5.00	l
SGPT	0-12 (MU/ML)	01/03/92	8.00		7.00		9.00	l
GANMA GT	6-28 (UI/L)	01/03/92	10.00	l	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	ľ	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	ŀ	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	1	4.20		4.20	
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	238.00	ł	210.00		225.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	120.00	[	110.00		115.00	l
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.20		0.15		0.25	l
GLOBULING 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	l	0.80		0.95	l
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.40	>	1.35	>	1.20	1
TSH	0-5 (UUI/ML)	01/03/92	1.15	l		l	1	
15n T4	4.5-13 (UG/DL)	01/03/92	8.20	l	I	ı	1	1

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range) (value lower than min range) than min range) than min range)

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICO 5 5 5 6 6 7 CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 423 Treatment: Fluoxetine Sex: Female

			Visit	numl	ber / Lai	bora	tory dat	8
			Scree	n	Day 2	В	Day 5	6
			15/08/	92	17/09/	92	15/10/	92
			value	(¢)	value	(4)	value	(¢)
Laboratory test	Range value	Range date						
HB	12.5-15 (G/DL)	01/03/92	13.20	1	13.60	1	14.00	
HT	38-43 (%)	01/03/92	43.00		43.10	>	43.30	>
RBC	4000000-4500000	01/03/92	l		İ			i
	(/MM3)		4700000	>	4780000	>	4900000	>
MBC	5000-9000 (/MM3)	01/03/92	7000.00		6600.00	1	6800.00	l
MBC: N	50-65 (%)	01/03/92	64.00		65.00		68.00	
MBC: L	30-40 (%)	01/03/92	33.00	l	33.00		26.00	
NBC: E	0-3 (%)	01/03/92	1.00		1.00		2.00	
NBC: H	0-5 (%)	01/03/92	2.00		1.00		4.00	ı
MRC: B	0-1 (%)	01/03/92	0.00		0.00		0.00	i
PLATELETS	150000-300000	01/03/92	l					l
	(/NM3)		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	l
CL-	95-105 (MEQ/L)	01/03/92	101.00		98.00		96.00	1
Ca++	8.1-10.4 (MG/DL)	01/03/92	10.50	>	11.00	>	11.10	>
P04	2.5-5 (MG/DL)	01/03/92	3.50		3.80	i	5.00	l
SGOT	0-12 (NU/NL)	01/03/92	8.00		9.00		10.00	l
SGPT	0-12 (NU/NL)	01/03/92	10.00		9.00		11.00	l
GANNA GT	4-18 (UI/L)	01/03/92	9.00		11.00		14.00	l
LDH	120-240 (UI/L)	01/03/92	160.00		150.00		105.00	<
ALK. PHOSPH.	20-48 (MU/NL)	01/03/92	32.00	i	33.00		40.00	l
GLUCOSE	70-110 (MG/DL)	01/03/92	92.00		100.00		95.00	l
UREA	15-40 (MG/DL)	01/03/92	28.00		21.00		28.00	l
OREATININE	0.5-1.4 (MG/DL)	01/03/92	0.85		0.80		0,90	i
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	l
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	0.18		0.15		0.20	l
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	6.50	ĺ	7.30		6.60	l
ALBUMINE	3.8-5 (G/DL)	01/03/92	3.40	۱ ح	4.20		3.50	<
TOT. CHOLEST.	160-240 (NG/DL)	01/03/92	190.00		195.00		170.00	l
TRIGLYCERIDES	30-150 (NG/DL)	01/03/92	75.00		80.00	1	60.00	l
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.20	1	0.25	ł	0.30	l
GLOBULINS ALPHA 2	0,45-0.75 (G/DL)	01/03/92	0.70		0.65		0.75	
GLOBULING REFIR 2	0.6-1 (G/DL)	01/03/92	0.95	1	1.00		0.90	ĺ
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.25	1	1.20		1.15	1
	0-5 (UUI/ML)	01/03/92	0.70	l				1
TSH T4	4.5-13 (UG/DL)	01/03/92	11.50	l	l		1	l
14	4.0715 (00/00)	J 1. USr 34		1	I	l		L

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(¢) << clinically relevant (value lower out of range (value lower than min range) than min range) (value lower wissing laboratory test value of laboratory not done

#### PHARMACIA PHARMACEUTICAS #50003 - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centro: 15 Patient: 426 Treatment: Fluoxetine Sex: Male

			Visit	num	ber / Lai	bora	tory date	9
			Screen	n	Day 2	В	Day 5	6
			20/10/	92	24/11/	92	22/12/	92
			value	(¢)	value	(4)	value	(¢
Laboratory test	Range value	Range date						
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	15/10/92		l				
	(/MM3)		5170000	>	5100000	>	5080000	>
WBC	5000-9000 (/MM3)	15/10/92	6900.00		7000.00		7000.00	
MBC: N'	50-65 (%)	15/10/92	68.00	>	65.00	l	70.00	>
WRC: L	30-40 (%)	15/10/92	25.00	<	30.00	l	27.00	<
NBC: 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	
MBC: B	0-1 (%)	15/10/92	0.00		0.00	Ι.	0.00	
PLATELETS	150000-300000	15/10/92	7,00		1			
PLAIGLGIS	(/MM3)	15, 10, 72	190000		210000	!	205000	
NA+	130-150 (MEQ/L)	15/10/92	140.00		141.00		138.00	
NAT K+	3-5 (MEQ/L)	15/10/92	4.50		4.20		4.20	1
CL-	95-105 (NEQ/L)	15/10/92	95.00		101.00		100.00	l
	8.1-10.4 (MG/DL)	15/10/92	8.10		7.50	_	7.80	۱,
Ca++ PO4	2.5-5 (MG/DL)	15/10/92	3.50		3.80	`	3.60	٦.
	0-12 (MU/ML)	15/10/92	10.00		15.00	l.	14.00	_
SGOT			9.00		12.00	-	11.00	-
SGPT	0-12 (MU/NL)	15/10/92 15/10/92	28.00		21.00		25.00	
GAMMA GT	6-28 (UI/L)		183.00		160.00		177.00	
LDH	120-240 (UI/L)	15/10/92		_	74.00		63.00	
ALK. PHOSPH.	20-48 (MU/ML)	15/10/92	60.00	,				_
GLUCOSE	70-110 (MG/DL)	15/10/92	76.00		85.00		85.00 37.00	
UREA	15-40 (MG/DL)	15/10/92	35.00		33.00		0.66	
CREATININE	0.5-1.4 (MG/DL)	15/10/92	0.63	١.	0.50			
URIC ACID	3.4-7 (MG/DL)	15/10/92	4.80		4.65		4.60	
FOT 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	
rot. 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	l
SLOBULINS 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/NL)	15/10/92	2.46					
Γ4	52-127 (NG/ML)	15/10/92	83.80					l

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAS BEGING - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Contro: 15 Patient: 428 Treatment: Fluoxetine Sex: Male

			Visit	numl	er / La	bora	tory date	•
			Scree	n	Day 2	В	Day 5	6
			25/11/	92	30/12/92		27/01/93	
			value	(¢)	value	(¢)	value	(4
Laboratory test	Range value	Range date						-
НВ	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	25/02/92						
RDC	(/MM3)		4400000		4500000		4450000	
MBC	5000-9000 (/MM3)	25/02/92	4900.00	<	5100.00		5000.00	
MBC: N	50-65 (%)	25/02/92	60.00	ŀ	65,00		69.00	>
MBC: L	30-40 (%)	25/02/92	35.00		32.00		30.00	
MBC: E	0-3 (%)	25/02/92	2.00		1.00		0.00	
NBC: M	0-5 (%)	25/02/92	3.00	ŀ	2.00		1.00	
NBC: B	0-1 (%)	25/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000	25/02/92						
LAIGUEID	(/MM3)		245000	l	260000		250000	
NA+	130-150 (MEQ/L)	25/02/92	148.00	Ì	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	
P04	2.5-5 (MG/DL)	25/02/92	3.60		3.80		4.40	
SGOT	0-12 (MU/ML)	25/02/92	9.00	ŀ	10.00		12.00	
SGPT	0-12 (NU/ML)	25/02/92	13.00	>	15.00	>	14.00	>
GAMMA GT	6-28 (UI/L)	25/02/92	20.00	ľ	10.00		12.00	
LDH .	120-240 (UI/L)	25/02/92	196.00	ļ	185.00		190.00	
ALK. PHOSPH.	45-170 (U/L)	25/02/92	103.00	l	98.00		110.00	
GLUCOSE	70-110 (MG/DL)	25/02/92	85.00	ļ	87.00		80.00	
UREA	15-40 (MG/DL)	25/02/92	37.00	ļ	38.00		28.00	
UKEA CREATININE	0.5-1.4 (MG/DL)	25/02/92	1.19	ŀ	1.20		1.01	İ
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	ļ	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	ľ	4.20		4.25	
	160-240 (MG/DL)	25/02/92	175.00		180.00		170.00	
TOT, CHOLEST. TRIGLYCERIDES	30-150 (MG/DL)	25/02/92	105.00	l	98.00		110.00	l
TRIGLYCERIDES GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	25/02/92	0.20		0.30		0.25	l
	0.45-0.75 (G/DL)	25/02/92	0.70	1	0.75		0.80	>
GLOBULINS ALPHA 2 GLOBULINS BETA	0.6-1 (G/DL)	25/02/92	0.70		0.90		0.80	l
	0.8-1.3 (G/DL)	25/02/92	1.25		1.15		1.30	l
GLOBULINS GAMMA		25/02/92	1.20			1	1	l
TSH	0-5 (UUI/ML)	25/02/92	7.10	1	i	1	l	l
T4	4.5-13 (UG/DL)	49/04/74	7.10	I	l	1	l	1

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range) \*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range cout of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTICAS # # 1003 - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 450 Treatment: Fluoxetine Sex: Male

			Visit	num	ber / La	bora	tory date	B
			Scree	n	Day 2	8	Day 5	6
			29/11/	92	06/01/	93	03/02/	93
			value	(¢)	value	(¢)	value	(4
Laboratory test	Range value	Range date						
нв -	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	l
RBC	4200000-4800000	01/03/92					1	
	(/MNS)		5200000	>	5300000	>	5100000	>
MBC	5000-9000 (/MM3)	01/03/92	9600.00	>	9300.00	>	7500.00	
MBC: N	50-65 (%)	01/03/92	73.00	>	58.00	ļ	60.00	
NBC: L	30-40 (%)	01/03/92	21.00	<	35.00		38.00	
NBC: E	Q-3 (X)	01/03/92	2.00		2.00		1.00	
WBC: M	0-5 (%)	01/03/92	4.00		5.00	İ	1.00	
MBC: B	0-1 (2)	01/03/92	0.00		0.00		0.00	
PLATELETS	150000-300000	01/03/92						
	(/MM3)		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	>
P04	2.5-5 (MG/DL)	01/03/92	4.70		4.50	Ι.	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	
GANMA 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	1	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	i I	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	
CLOBULINS 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					1

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAS 550003- CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 451 Treatment: Fluoxetine Sex: Female

			Visit	num	er / La	bora	tory dat	
			Scree	1	Day 2	В	Day 5	6
			07/12/	92	14/01/	93	11/02/	93
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
НВ	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	01/03/92						1
	(/MM3)		4950000	>	4700000	>	5210000	>
NBC	5000-9000 (/MM3)	01/03/92	6700.00		6900.00	l	6900.00	1
MBC: N	50-65 (%)	01/03/92	68.00	>	67.00	>	63.00	1
MBC: L	30-40 (%)	01/03/92	27.00	<	30.00	1	35.00	1
HBC: E	0-3 (%)	01/03/92	2.00		1.00	1	0.00	1
MBC: M	0-5 (%)	01/03/92	3.00		2.00		2.00	i
MBC: B	0-1 (2)	01/03/92	0.00		0.00		0.00	l
PLATELETS	150000-300000	01/03/92				l		1
FEATLUATE	(/MM3)		270000		260000	1	210000	1
NA+	130-150 (MEQ/L)	01/03/92	139.00		140.00	1	143.00	i
K+	3-5 (MEQ/L)	01/03/92	4.00		4.30	1	4.60	l
CL-	95-105 (MEQ/L)	01/03/92	108.00	>	104.00		100.00	l
Ca++	8.1-10.4 (MG/DL)	01/03/92	9.60		9.90		9.20	l
P04	2.5-5 (MG/DL)	01/03/92	3.70		4.10		3.90	l
BGOT	0-12 (NU/ML)	01/03/92	7.00		9.00		6.00	l
SGPT	0-12 (NU/NL)	01/03/92	9.00		10.00		8.00	l
GANNA GT	4-18 (UI/L)	01/03/92	12.00		11.00		8.00	l
	120-240 (UI/L)	01/03/92	144.00		130.00		198.00	l
LDH		01/03/92	32.00		35.00		27.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/03/92	63.00	<	70.00		66.00	ا ح
GLUCOSE	70-110 (MG/DL)	01/03/92	37.00	•	39.00		54.00	
UREA	15-40 (MG/DL)	01/03/92	1.10		1.25		0.97	ľ
CREATININE	0.5-1.4 (MG/DL)		3.50		3.30		2.80	
URIC ACID	2,4-5,7 (MG/DL)	01/03/92	0.65		0.60		0.80	l
TOT BILIRUBIN	0-1 (NG/DL)	01/03/92	0.15		0.12		0.10	l
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	7.10		7.20		6.90	i
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	4.00		4.25		3,80	l
ALBUMINE	3.8-5 (G/DL)	01/03/92	168.00		180.00		187.00	l
TOT. CHOLEST.	160-240 (NG/DL)	01/03/92			70.00		123.00	l
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92	65.00 0.20		0.15		0.25	l
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92		_	0.13		0.25	1
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/03/92	0.80	,		1	0.75	1
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.70		0.75	Ī	1.35	I.
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.40	,	1.15		1.35	١^
Teh	0-5 (UUI/ML)	01/03/92	0.50				1	1
T4	4.5-13 (UG/DL)	01/03/92	7.00	1		I	l	I

<sup>(¢) &</sup>lt;< clinically relevant (value lower cout of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIC95556083- CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 15 Patient: 454 Treatment: Fluoxetine Sex: Hale

			Visit	numi	ber / La	bora	tory date	8
			Scree	n .	Day 2	В	Day 5	6
			08/01/	93	15/02/	93	15/03/	93
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date						
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	01/03/92					l	ļ
	(/MM3)		5100000	>	5050000	>	5500000	>
MBC	5000-9000 (/MM3)	01/03/92	6800.00		7200.00	l	7600.00	i
MBC: N	50-65 (%)	01/03/92	65.00		65.00		62.00	l
MBC: L	30-40 (%)	01/03/92	32.00		31.00		34.00	l
MBC: E	0-3 (%)	01/03/92	1.00		1.00		1.00	
NBC: M	0-5 (%)	01/03/92	2.00		3.00		3.00	ı
MBC: B	0-1 (%)	01/03/92	0.00		0.00	ł	0.00	l
PLATELETS	150000-300000	01/03/92						l
- MILLIANIE	(/MM3)		260000		250000		260000	l
NA+	130-150 (MEQ/L)	01/03/92	146.00		147.00		139.00	l
K+	3-5 (MEQ/L)	01/03/92	4.90		4.80		4.80	l
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	>
P04	2.5-5 (MG/DL)	01/03/92	4.60		4.90		4.70	1
SGOT	0-12 (MU/ML)	01/03/92	9,00		9.00	İ	7,00	l
	0-12 (MU/ML)	01/03/92	8,00		11.00	j	9.00	1
SGPT	6-28 (UI/L)	01/03/92	11.00		15.00	1	15.00	1
GAMMA GT	120-240 (UI/L)	01/03/92	205.00		190.00		185.00	
LDH	20-48 (MU/ML)	01/03/92	35.00		32.00	İ	33.00	1
ALK. PHOSPH.	20-48 (MU/NL) 70-110 (MG/DL)	01/03/92	94.00		94.00		90.00	l
GLUCOSE		01/03/92	31.00		33.00		32.00	1
UREA	15-40 (HG/DL)	01/03/92	1.10		0.80		0,80	1
CREATININE	0.5-1.4 (MG/DL)		4.40		4.40		3.90	l
URIC ACID	3.4-7 (MG/DL)	01/03/92	0.70		0.70		0.60	l
TOT BILIRUBIN	0-1 (NG/DL)	01/03/92	0.20		0.70		0.05	l
DIR BILIRUBIN	0-0.3 (MG/DL)	01/03/92	7.10		7.10		7.00	ı
TOT. PROTEINS	6.3-8 (G/DL)	01/03/92	4.10		3.90		4.10	l
ALBUMINE	3.8-5 (G/DL)	01/03/92			202.00		170.00	l
TOT. CHOLEST.	160-240 (MG/DL)	01/03/92	195.00 88.00		110.00		85.00	l
TRIGLYCERIDES	30-150 (MG/DL)	01/03/92		ĺ	0.30		0.20	ı
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/03/92	0.30	l	0.70		0.70	
GLOBULINS ALPHA 2	0.45-0.75 (C/DL)	01/03/92	0.75			1		
GLOBULINS BETA	0.6-1 (G/DL)	01/03/92	0.80	l	0.90	1	0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/03/92	1.15		1.30	l	1.20	l
teh	0-5 (UUI/KL)	01/03/92	2.90	1				
T4	4.5-13 (UG/DL)	01/03/92	8.30	l	l	l	I	ŀ

1091

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range) missing range value

### PHARMACIA PHARMACEUTICAS 556483 CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 429 Treatment: Fluoxetine Sex: Female

			Visit	num	ber / Lai	ora.	tory date	0
			Scree	Day 2	В	Day 5	6	
			12/03/92		22/04/92		20/05/	92
			value	(¢)	value	(¢)	value	(4)
Laboratory test	Range value	Range date						
XB.	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	01/02/92						
ndc	(/MM3)		4730000	>	4730000	>	4950000	>
WBC	5000-9000 (/MM3)	01/02/92	6200.00		8500.00		7900.00	
MBC: N	50-65 (%)	01/02/92	63.00		65.00		57.00	
MBC: L	30-40 (2)	01/02/92	34.00		32.00		38.00	
WBC: E	0-3 (2)	01/02/92	0.00		1.00		2.00	
NBC: X	0-5 (%)	01/02/92	3.00		2,00		3.00	
WRC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	1
PLATELETS	150000-300000	01/02/92						1
PLAIELEID	(/MM3)	01/02/32	210000		220000		210000	1
NA+	130-150 (NEQ/L)	01/02/92	147.00		139.00		143.00	1
10+ K+	3-5 (MEQ/L)	01/02/92	4.80		4.00		4.40	1
K+ CL-	95-105 (MEQ/L)	01/02/92	105.00		110.00	>	109.00	<b> </b> >
	8.1-10.4 (MG/DL)	01/02/92	10.40		9.80	ľ	10.20	
Ca++	2.5-5 (MG/DL)	01/02/92	4.40		4.30		4.50	1
P04	0-12 (MU/ML)	01/02/92	10.00		7.00		8.00	1
SGOT	+	01/02/92	4.00		9.00		10.00	1
SGPT	0-12 (MU/ML)	01/02/92	28.00		14.00		12.00	1
GAMMA GT	4-18 (UI/L)	01/02/92	184.00	<u>ا ا</u>	170.00		220.00	
LDH	120-240 (UI/L)		24.00		36.00		32.00	
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92 01/02/92	100.00		99.00		86.00	İ
CLUCOSE	70-110 (MG/DL)	01/02/92	24.00		28.00	l	28.00	1
UREA	15-40 (MG/DL)	01/02/92	1.10		0.95		0.90	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	3.10		2.90		2.50	
URIC ACID	2.4-5.7 (MG/DL)		0.66		0.66		0.70	1
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.26		0.26	l	0.20	
DIR BILIRUBIN	0-0,3 (MG/DL)	01/02/92	6.90		6.70		6.70	1
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92				_	3.70	_
ALBUNINE	3.8-5 (G/DL)	01/02/92	3.90		3,50		246.00	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	205.00		290.00	^ ا		
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	105.00	1	109.00	l	96.00	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.30	L	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	ĺ	0.80	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.30	1	1.30	l	1,30	1
TSH	0-5 (UUI/ML)	01/02/92	2.40			l		1
T4	4.5-13 (UG/DL)	01/02/92	8.70	l	l	ı		1

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range) (value lower missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

### PHARMACIA PHARMACEUTICOS STORMS - CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 432 Treatment: Fluoxetine Sex: Female

		Visit number / Laboratory da					
		Scree	n	Day 2	В	Day 5	6
		26/03/	92	27/04/	92	25/05/	92
		value	(¢)	value	(¢)	value	(4)
Range value	Range date						
12.5-15 (G/DL)	01/02/92	14.80		14.00	i		
38-43 (%)	01/02/92	44.00	>	43.00	1	43.00	ļ
4000000-4500000	01/02/92	1		l	i		1
(/MM3)		4840000	>	4730000	>	4730000	>
5000-9000 (/MM3)	01/02/92	6800.00	l	6400.00		7000.00	1
50-65 (2)	01/02/92	65.00		58.00		67.00	>
	01/02/92	31.00		38.00		31.00	
	01/02/92	2.00		2.00		2.00	ĺ
	01/02/92			2.00	l	0.00	1
		0.00		0.00	ŀ	0.00	ļ.
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	01-02-72	240000		205000		190000	İ
	04/02/02						
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15-40 (MG/DL)			>		}		1
0.5-1.4 (MG/DL)					ĺ		
2,4-5.7 (MG/DL)			>				1
0-1 (MG/DL)	01/02/92						ļ
0-0.3 (MG/DL)	01/02/92				l		1
6,3-8 (G/DL)	01/02/92						
3.8-5 (G/DL)	01/02/92						
160-240 (MG/DL)	01/02/92		>		>		
30-150 (MG/DL)	01/02/92	78.00		118.00	l		1
0.1-0.3 (G/DL)	01/02/92	0,20	l	0.30			İ
0.45-0.75 (G/DL)	01/02/92	0.70			>		İ
0.6-1 (G/DL)	01/02/92	0.90		0.80	1	0.80	
	01/02/92	1.35	>	1.40	>	1.35	>
	01/02/92	17.00	>>	1			1
4.5-13 (UG/DL)	01/02/92	8.35	1	1	l	l	1
	12.5-15 (G/DL) 38-43 (X) 4000000-4500000 (/MM3) 5000-9000 (/MM3) 50-65 (X) 30-40 (X) 0-5 (X) 0-1 (X) 150000-300000 (/MM3) 130-150 (MEQ/L) 35-105 (MEQ/L) 95-105 (MEQ/L) 95-105 (MEQ/L) 0-12 (MU/ML) 0-12 (MU/ML) 0-12 (MU/ML) 0-12 (MU/ML) 0-14 (MG/DL) 155-40 (MG/DL) 155-40 (MG/DL) 0.5-1.4 (MG/DL) 0.5-1.4 (MG/DL) 0.5-1.4 (MG/DL) 0.5-1.4 (MG/DL) 0.5-1.4 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL) 0.10 (MG/DL)	12.5-15 (G/PL) 01/02/92 38-43 (X) 01/02/92 4000000-4500000 (/MM3) 01/02/92 5000-9000 (/MM3) 01/02/92 50-65 (X) 01/02/92 0-3 (X) 01/02/92 0-5 (X) 01/02/92 0-5 (X) 01/02/92 0-5 (X) 01/02/92 150000-300000 01/02/92 150000-300000 01/02/92 150000-300000 01/02/92 3-5 (MEQ/L) 01/02/92 3-5 (MEQ/L) 01/02/92 3-5 (MEQ/L) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-12 (MU/ML) 01/02/92 0-10 (MG/DL) 01/02/92 0-5-1,4 (MG/DL) 01/02/92 0-1 (MG/DL) 01/02/92 0-1 (MG/DL) 01/02/92 0-1 (MG/DL) 01/02/92 0-1 (MG/DL) 01/02/92 0-1-0,3 (G/DL) 01/02/92 0-1-0,3 (G/DL) 01/02/92 0.45-0.75 (G/DL) 01/02/92 0.45-0.75 (G/DL) 01/02/92 0.8-1.3 (G/DL) 01/02/92 0.8-1.3 (G/DL) 01/02/92 0.8-1.3 (G/DL) 01/02/92 0.5-5 (UUI/ML) 01/02/92	Range value Range date 12.5-15 (G/DL) 01/02/92 14.80 38-43 (2) 01/02/92 44.00 38-43 (2) 01/02/92 44.00 5000-30000 01/02/92 6800.00 5000-9000 (/MM3) 01/02/92 65.00 30.40 (2) 01/02/92 31.00 0-65 (2) 01/02/92 2.00 0-3 (2) 01/02/92 2.00 0-1 (2) 01/02/92 2.00 0-1 (2) 01/02/92 2.00 150000-300000 01/02/92 2.00 150000-300000 01/02/92 2.00 150000-300000 01/02/92 137.00 130-150 (MEQ/L) 01/02/92 137.00 3-5 (MEQ/L) 01/02/92 137.00 3-5 (MEQ/L) 01/02/92 10.00 3-5 (MEQ/L) 01/02/92 10.00 0-12 (MU/ML) 01/02/92 10.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-110 (MG/DL) 01/02/92 3.00 0-12 (MG/DL) 01/02/92 3.00 0-12 (MG/DL) 01/02/92 3.00 0-15-40 (MG/DL) 01/02/92 3.00 0-16 (MG/DL) 01/02/92 3.00 0-16 (MG/DL) 01/02/92 3.00 0-16 (MG/DL) 01/02/92 3.00 0-16 (MG/DL) 01/02/92 3.90 0-15 (MG/DL) 01/02/92 3.90 0-15 (MG/DL) 01/02/92 78.00 0-150 (MG/DL) 01/02/92 78.00 0-150 (MG/DL) 01/02/92 78.00 0-150 (MG/DL) 01/02/92 78.00 0-150 (MG/DL) 01/02/92 78.00 0-150 (MG/DL) 01/02/92 78.00 0-150 (MG/DL) 01/02/92 78.00 0-5 (UUI/ML) 01/02/92 1.355	Range value Range date 12.5-15 (G/DL) 01/02/92 14.80 38-43 (X) 01/02/92 44.00 > 40.00000-4500000 01/02/92 65.00 5000-9000 (/MM3) 01/02/92 65.00 5000-9000 (/MM3) 01/02/92 31.00 50-65 (X) 01/02/92 2.00 0-3 (X) 01/02/92 2.00 0-5 (X) 01/02/92 2.00 0-1 (X) 01/02/92 2.00 0-1 (X) 01/02/92 2.00 0-1 (X) 01/02/92 137.00 150000-300000 01/02/92 2.00 150000-300000 01/02/92 137.00 3-5 (MEQ/L) 01/02/92 137.00 3-5 (MEQ/L) 01/02/92 101.00 3-5 (MEQ/L) 01/02/92 101.00 2.5-5 (MG/DL) 01/02/92 101.00 2.5-5 (MG/DL) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 3.00 0-12 (MU/ML) 01/02/92 37.00 3-5 (MG/DL) 01/02/92 37.00 3-5 (MG/DL) 01/02/92 37.00 3-5 (MG/DL) 01/02/92 37.00 3-15 (MG/DL) 01/02/92 37.00 3-15 (MG/DL) 01/02/92 37.00 3-15-40 (MG/DL) 01/02/92 37.00 3-15-40 (MG/DL) 01/02/92 37.00 3-15-40 (MG/DL) 01/02/92 37.00 3-15-40 (MG/DL) 01/02/92 3.90 0-1 (MG/DL) 01/02/92 3.90 0-1 (MG/DL) 01/02/92 3.90 0-1 (MG/DL) 01/02/92 3.90 0-10 (MG/DL) 01/02/92 3.90 0-10 (MG/DL) 01/02/92 3.90 0-150 (MG/DL) 01/02/92 3.90 0-150 (MG/DL) 01/02/92 78.00 0-1-10 (MG/DL) 01/02/92 78.00 0-1-10 (MG/DL) 01/02/92 78.00 0-1-10 (MG/DL) 01/02/92 78.00 0-1-10 (MG/DL) 01/02/92 0.20 0.45-0.75 (G/DL) 01/02/92 0.20 0.45-0.75 (G/DL) 01/02/92 0.90 0.8-1.3 (G/DL) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 > 0-5 (UUI/ML) 01/02/92 1.35 >	Range value	Range value	Range value

1093

(¢) << clinically relevant (value lower cout of range (value lower than min range) than min range) (value lower than min range) than min range) (value lower than min range) (value lower than min range) (value lower than min range)

#### PHARMACIA PHARMACEUTICALS METANO3- CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Contro: 16 Patient: 434 Treatment: Fluoxetine Sex: Female

			Visit	numl	ber / Lai	bora	tory dat	
			Scree	n	Day 2	В	Day 5	6
			06/04/	92	04/05/	92	01/06/	92
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
нв	12.5-15 (G/DL)	01/02/92	12.90	l	14.00		14.00	
HT	38-43 (X)	01/02/92	42.00		44.00	>	43.00	l
RBC	4000000-4500000	01/02/92						Ì
	(/MM3)		4620000	>	4840000	>	4730000	
NBC	5000-9000 (/MM3)	01/02/92	8100.00		7000.00	ł	7100.00	i
MBC: N	50-65 (%)	01/02/92	55.00	l	62.00	1	68.00	>
MBC: L	30-40 (%)	01/02/92	41.00	>	38.00		30.00	
WBC: E	0-3 (2)	01/02/92	1.00	l	0.00		2.00	1
MBC: M	0-5 (2)	01/02/92	3.00	l	0.00		0.00	
NBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000	01/02/92	i				ļ	
PLATELLIS	(/MM3)	******	210000	l	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	
P04	2.5-5 (MG/DL)	01/02/92	3.20		3.50		3.60	
SCOT	0-12 (MU/ML)	01/02/92	8.00	ĺ	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/NL)	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	ľ	1.25		0.95	
URIC ACID	2.4-5.7 (MG/DL)	01/02/92	5.50		6.00	,	3.30	
		01/02/92	0.70		0.70	-	0.70	
TOT BILIRUBIN	0-1 (MG/DL) 0-0.3 (MG/DL)	01/02/92	0.10		0.20		0.20	l
DIR BILIRUBIN	+	01/02/92	7.15		7.20		6.95	
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	4.00		4.00		3.80	
ALBUMINE	3.8-5 (G/DL)		288.00		275.00	١. ا	245.00	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92			155.00		160.00	
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	240.00		0.30		0.25	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92			0.30	l	0.45	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.80	١,		l	0.85	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.85		0.85	İ	1.40	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.25	1	1.30	İ	1.40	_
TSH	0-5 (UUI/ML)	01/02/92	2.70			ĺ		l
T4	4.5-13 (UG/DL)	01/02/92	9.12	1		l	1	l

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range > out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAS OF CHOS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 436 Treatment: Fluoxetine Sex: Female

			Visi number Laborat date	ory
			Scree	n
			20/04/	92
			value	(¢)
Laboratory test	Range value	Range date		
HB	12.5-15 (GR%)	01/04/92	13.60	l
HT	38-43 (%)	01/04/92	42.00	!
RBC	4000000-4500000	01/04/92	1	1
	(/MM3)		4230000	l
MBC	5000-9000 (/MM3)	01/04/92	5400.00	l
MBC: N	50-65 (%)	01/04/92	63.00	
KBC: L	30-40 (%)	01/04/92	31.00	
WBC: E	0-3 (%)	01/04/92	3.00	!
MBC: M	0-5 (%)	01/04/92	3.00	
NBC: B	0-1 (%)	01/04/92	0.00	
NA+	130-150 (MEQ/L)	01/04/92	141.00	
K+	3-5 (MED/L)	01/04/92	3.90	
CL-	95-105 (MEQ/L)	01/04/92	102.00	1
Ca++	8.1-10.4 (MG/DL)	01/04/92	10.00	l
P04	2.5-5 (MG/DL)	01/04/92	3.80	
SGOT	0-12 (MU/NL)	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 (NG/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	1
URIC ACID	2.4-5.7 (MG/DL)	01/04/92	3.80	ł
TOT BILIRUBIN	0-1 (NG/DL)	01/04/92	0.36	ł
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	
TRIGLYCERIDES GLOBULINS ALPHA 1		01/04/92	0.18	
GLOBULING ALPHA 2		01/04/92	0.55	
GLOBULINS ALPHA 2 GLOBULINS BETA	0.45-0.75 (G/DL)	01/04/92	0.55	
GLOBULING BETA GLOBULING GAMMA	0.6-1 (G/DL) 0.8-1.3 (G/DL)	01/04/92	1.11	
			1.11	
TSH T	0-5 (UUI/ML)	01/04/92		
T4	50-115 (NG/ML)	01/04/92	68.20	1

1095

#### PHARMACIA PHARMACEUTIC955106193- CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 438 Treatment: Fluoxetine Sex: Female

					umber / ory date	
			Scree	3	Day 2	8
			15/05/9	92	16/06/	92
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
нв	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	01/02/92				
	(/MM3)		4840000	>	4730000	>
MBC	5000-9000 (/MM3)	01/02/92	7000.00		6500.00	ĺ
MBC: N	50-65 (%)	01/02/92	62.00		61.00	
MBC: L	30-40 (%)	01/02/92	36.00		39.00	
WBC: E	0-3 (%)	01/02/92	0.00		0.00	
MBC: M	0-5 (%)	01/02/92	2.00		0.00	
NBC: B	0-1 (%)	01/02/92	0.00		0.00	
PLATELETS	150000-300000	01/02/92				
	(/MM3)		245000		255000	
NA+	130-150 (MEQ/L)	01/02/92	138.00		137.00	i
K+	3-5 (MEQ/L)	01/02/92	4.20		4.00	1
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	
P04	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	1
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	l
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.80		6.60	j
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	l
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	1
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.70		0.75	1
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.85		0.80	ĺ
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40		1.30	ĺ
TSH	0-5 (UUI/ML)	01/02/92	10.50	>>		
T4	4.5-13 (UG/DL)	01/02/92	7.60		l .	ı

<sup>(¢) &</sup>lt;< clinically relevant (value lower than min range)
< out of range (value lower than min range)
than min range)
than min range)
than min range)
than min range)
than min range)

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

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## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 439 Treatment: Fluoxetine Sex: Female

			Visit	num	ber / Lai	bora	tory dat	0
			Screen	n	Day 2	В	Day 5	6
			15/05/	92	16/06/	92	14/07/	92
	•		value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
нв	12.5-15 (G/DL)	01/02/92	12.90	l	13.50		13.00	į
HT	38-43 (X)	01/02/92	41.00		42.00		40.00	
RBC	4000000-4500000	01/02/92					!	1
	(/MM3)		4510000	>	4620000	>	4400000	
MBC	5000-9000 (/MM3)	01/02/92	7100.00		6500.00		6900.00	
MBC: N	50-65 (%)	01/02/92	67.00	>	57.00		60.00	1
MBC: L	30-40 (%)	01/02/92	31.00		39.00		38.00	1
MBC: E	0-3 (2)	01/02/92	2.00		1.00		0.00	l
MBC: M	0-5 (%)	01/02/92	0.00		3.00		2.00	1
WBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000	01/02/92	1					1
	(/MN3)	*******	220000		240000		260000	
NA+	130-150 (MEQ/L)	01/02/92	139.00		140.00		138.00	1
K+	3-5 (MEQ/L)	01/02/92	3.50		4.10		3.90	l
CL-	95-105 (NEQ/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	
P04	2.5-5 (MG/DL)	01/02/92	3.50		4.00		3.00	
SCOT	0-12 (NU/NL)	01/02/92	7.00	1	7.00		8.00	
SCPT	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	1
LDH	120-240 (UI/L)	01/02/92	136.00		185.00		144.00	
ALK. PHOSPH.	20-48 (NU/ML)	01/02/92	30.00		28.00		33,00	
GLUCOSE	70-110 (MG/DL)	01/02/92	81.00		81.00		90.00	l
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	٠ ا	1.18		1.00	l
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	- 1	0.25	ļ
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.90		6.85	- 1	7.05	
ALBUMINE	3.8-5 (G/DL)	01/02/92	3.90		3.70	ا ء	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	1
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20		0.35	、 I	0.25	l
GLOBULING ALPHA 1	0.45-0.75 (G/DL)	01/02/92	0.65		0.65	_	0.60	
GLOBULINS ALPHA 2 GLOBULINS BETA		01/02/92	0.75	- 1	0.80	- 1	0.80	
	0.6-1 (G/DL)		1.40	. 1	1.35	、 l	1.40	
CLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40	1	1.35	1	1.40	-
TSH .	0-5 (UUI/ML)	01/02/92		l		- 1		
T4	4.5-13 (UG/DL)	01/02/92	7.90	]				

<sup>(¢) &</sup>lt;< clinically relevant (value lower cut of range (value lower than min range) than min range)

\*\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range cout of range (value higher than max range could missing range value)

#### PHARMACIA PHARMACEUTICO 5 MESONS - CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 441 Treatment: Fluoxetine Sex: Female

			Visit	numl	ber / Lai	bora	tory dat	8
			Scree	n	Day 2	8.	Day 5	6
			13/07/	92	17/08/	92	14/09/	92
			value	(¢)	value	(4)	value	(¢)
Laboratory test	Range value	Range date						
нв	12.5-15 (G/DL)	01/02/92	13.30	i	14.00		13.20	l
HT	38-43 (X)	01/02/92	40.00		42.00		43.00	1
RBC	4000000-4500000	01/02/92	'					ĺ
	(/MM3)		4400000		4620000	>	4730000	>
NBC	5000-9000 (/MM3)	01/02/92	7100.00		6700.00		6500.00	
MBC: N	50-65 (%)	01/02/92	70.00		62.00		60.00	1
MBC: L	30-40 (%)	01/02/92	28.00	<	35.00	l	34.00	1
MBC: E	0-3 (Z)	01/02/92	0.00		0.00		2.00	1
WBC: M	0-5 (%)	01/02/92	2.00		3.00		4.00	
MBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	1
PLATELETS	150000-300000	01/02/92	1					1
	(/MM3)		240000		265000		280000	1
NA+	130-150 (MEQ/L)	01/02/92	139.00		135.00	1	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	l	100.00		98.00	
Ca++	8,1-10.4 (MG/DL)	01/02/92	10.60	>	9.80	l	11.00	>
P04	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	ĺ	9.00	
SGPT	0-12 (MU/ML)	01/02/92	8.00		10.00	ļ	10.00	ł
GANNA 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	l	166.00	1
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	24.00		28.00	İ	33.00	1
GLUCOSE	70-110 (MG/DL)	01/02/92	82.00		91.00		82.00	l
IREA	15-40 (MG/DL)	01/02/92	43.00	>	30.00	Ì	30.00	
CREATININE	0.5-1.4 (MG/DL)	01/02/92	1.00		0.92		1.09	i
URIC ACID	2,4-5.7 (MG/DL)	01/02/92	4.00		5.20		3.90	1
ORIC ACID	0-1 (MG/DL)	01/02/92	0.60	i	0.70		0.65	1
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20	i	0.20		0.25	1
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.05	İ	6.95		6,90	i
ALBUMINE	3.8-5 (G/DL)	01/02/92	4.00		4.05		3.80	1
FOT. CHOLEST.	160-240 (MG/DL)	01/02/92	216.00	l	205.00	l	205.00	1
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	85.00	l	90.00		105.00	
SLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.25	l	0.20	l	0.25	ı
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.60		0.55		0.65	İ
GLOBULINS BETA	0.45-0.75 (0/DL)	01/02/92	0.80	1	0.80	1	0.80	
GLOBULINS BETA GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.40	>	1.35	>	1.40	
	0.8-1.3 (G/DL) 0-5 (UUI/NL)	01/02/92	0.60	ľ	1	ľ		1
TSH	4.5-13 (UG/DL)	01/02/92	4.70	i			1	1
T4	4.5-13 (UG/DL)	01/04/94	4.70		1	l	l	

1008

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

#### PHARMACIA PHARMACEUTICAS MTHOMO3- CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centro: 16 Patient: 443 Treatment: Fluoxetine Sex: Hale

4.0			Visit	numi	ber / La	bora	tory date	•
			Scree	n.	Day 2	8	Day S	6
			20/08/	92	21/09/	92	19/10/	92
			value	(¢)	value	(4)	value	(¢
Laboratory test	Range value	Range date						
нв	13.5-15.5 (G/DL)	01/02/92	14.80	l	14.20	l	15.00	
HT	40-45 (%)	01/02/92	45.00		44.00		45.00	
RBC	4200000-4800000	01/02/92		1	l		ŀ	
K	(/MM3)		4950000	>	4980000	>	4950000	>
HBC	5000-9000 (/MM3)	01/02/92	6500.00	İ	6800.00		7000.00	
MBC: N	50-65 (%)	01/02/92	61.00		59.00	l	71.00	>
MBC: L	30-40 (%)	01/02/92	39.00		37.00		29.00	<
MBC: E	0-3 (%)	01/02/92	0.00		2.00		0.00	
MBC: M	0-5 (%)	01/02/92	0.00		2.00		0.00	
MBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000	01/02/92	i					
	(/MM3)		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	l	10.50	>
P04	2.5-5 (MG/DL)	01/02/92	3.90		4.00	l	4.00	
SGOT	0-12 (MU/HL)	01/02/92	6.00		8.00	1	7.00	1
SGPT	0-12 (MU/ML)	01/02/92	6,00		6.00	1	8.00	
GAMMA GT	6-28 (UI/L)	01/02/92	12.00		14.00		8.00	1
	120-240 (UI/L)	01/02/92	144.00		180.00	ŀ	155.00	1
LDH	20-48 (MU/ML)	01/02/92	35.00		38.00	Ì	38.00	
ALK. PHOSPH.	70-110 (MG/DL)	01/02/92	79.00		89.00		81.00	
GLUCOSE		01/02/92	31.00		33.00		28.00	l
UREA	15-40 (MG/DL) 0.5-1.4 (MG/DL)	01/02/92	1.00		1.05		1.00	l
CREATININE		01/02/92	4.00		4.10		4.00	l
URIC ACID	3.4-7 (MG/DL)		0.60		0.65		0.70	l
TOT BILIRUBIN	0-1 (NG/DL)	01/02/92 01/02/92	0.20		0.25		0.20	l
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	7.00		7.25		7.35	l
TOT, PROTEINS	6.3-8 (G/DL)	01/02/92	4.00		4.20		4.30	l
ALBUMINE	3.8-5 (G/DL)		202.00		212.00		220.00	l
TOT. CHOLEST.	160-240 (NG/DL)	01/02/92	100.00		108.00	i	110.00	l
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	0.20		0.20	1	0.20	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.65		0.20	1	0.70	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.65	!	0.80		0.85	
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92			1.40	l_	1.30	
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.35	,	1.40	_	1.30	1
TSK	0-5 (UUI/ML)	01/02/92	0.90	. !		l		1
T4	4.5-13 (UG/DL)	01/02/92	5.60		l	l	1	l

<sup>(¢) &</sup>lt;< clinically relevant (value lower than min range)
< out of range (value lower than min range)
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<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTIC#5555693- CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 446 Treatment: Fluoxetine Sex: Female

					umber / ory date	
			Screen	a	Day 5	6
			12/09/9	92	12/11/	92
	•		value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	12.5-15 (G/DL)	01/02/92	15.00		14.00	1
HT	38-43 (2)	01/02/92	44.00	>	43.00	
RBC	4000000-4500000	01/02/92				1
	(/MH3)		4840000	>	4730000	>
NBC	5000-9000 (/MM3)	01/02/92	6500.00		7000.00	l
WBC: N	50-65 (%)	01/02/92	65.00		61.00	1
MBC: L	30-40 (%)	01/02/92	31.00		36.00	
NBC: E	0-3 (%)	01/02/92	2.00		1.00	
MBC: M	0-5 (%)	01/02/92	2.00		2.00	
NBC: B	0-1 (2)	01/02/92	0.00		0.00	
PLATELETS	150000-300000	01/02/92				ļ
· Marbbara	(/MM3)		270000		260000	1
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 (NEQ/L)	01/02/92	101.00		100.00	
Ca++	8.1-10.4 (MG/DL)	01/02/92	10.90	>	10.50	>
P04	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 (NU/NL)	01/02/92	7.00		8.00	
GAMMA GT	4-18 (UI/L)	01/02/92	13.00		9.00	i
LDH	120-240 (VI/L)	01/02/92	180.00		144.00	i
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	i	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	i
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	7.05		6.80	
	3.8-5 (G/DL)	01/02/92	4.00		3.80	1
ALBUMINE	160-240 (MG/DL)	01/02/92	222.00		225.00	
TOT. CHOLEST.	30-150 (MG/DL)	01/02/92	110.00		108.00	
TRIGLYCERIDES		01/02/92	0.20		0.20	
GLOBULINS ALPHA 1		01/02/92	0.60	1	0.60	1
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.80	l	0.85	
GLOBULINS BETA		01/02/92	1.45	l .	1.35	>
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	0.90	1	133	1
TSH	0-5 (UUI/ML)		8.00	1	1	
T4	4.5-13 (UG/DL)	01/02/92	0.00	1	l	ı

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) (value lower than min range) (value lower than min range) (than min range) (than min range) (than min range)

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICALS BY ANS 3- CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 447 Treatment: Fluoxetine Sex: Male

					umber / ory date	
			Scree	1	Day 5	6
			12/09/	92	12/11/	92
r			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
нв	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	01/02/92	1			
	(/MM3)		4950000	>	5170000	>
MBC	5000-9000 (/MM3)	01/02/92	6900.00		7000.00	ł
KBC: 'N	50-65 (%)	01/02/92	60.00		62.00	l
MBC: L	30-40 (%)	01/02/92	40.00		34.00	ĺ
WBC: E	D-3 (X)	01/02/92	0.00		3.00	
HBC: H	0-5 (%)	01/02/92	0.00		1,00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00	
PLATELETS	150000-300000	01/02/92	1		1	
	(/MM3)		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	
P04	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	1
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 (NG/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	1
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	1
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	235.00		225.00	1
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	1
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	-	''''	
ran T4	4.5-13 (UG/DL)	01/02/92	7.50			
14	4.3-13 (00/06/	01,02,32	1 7.55			i

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#### PHARMACIA PHARMACEUTICOS 550083 CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 455 Treatment; Fluoxetine Sex: Female

			Visit	num	ber / La	pora.	tory date	8
			Scree	n	Day 2	В	Day 5	6
			14/09/	92	16/10/	92	13/11/	92
			value	(¢)	value	(4)	value	(¢)
Laboratory test	Range value	Range date						
HB	12.5-15 (G/DL)	01/02/92	13.00		13.10	1	14.80	l
HT	38-43 (%)	01/02/92	42.00		43.00	1	41.00	l
RBC	4000000-4500000	01/02/92				_		L
	(/MM3)		4620000	>	4730000	>	4510000 6000.00	
MBC	5000-9000 (/MM3)	01/02/92	6700.00		7100.00	_	71.00	l.
HBC: N	50-65 (%)	01/02/92	68.00	>	67.00	^	29.00	
MBC: L	30-40 (%)	01/02/92	30.00		30.00		0.00	١٠
WBC: E	0-3 (%)	01/02/92	2.00		2.00 1.00		0.00	l
NBC: N	0-5 (%)	01/02/92	0.00	l			0.00	
MBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00	
PLATELETS	150000-300000	01/02/92	240000		290000		210000	
	(/MM3)		142.00		140.00		138.00	1
NA+	130-150 (MEQ/L)	01/02/92 01/02/92	3.90		4.00	ŀ	3.80	ı
K+	3-5 (MEQ/L)	01/02/92	110.00	>	110.00		3.00	
CL-	95-105 (MEQ/L) 8.1-10.4 (MG/DL)	01/02/92	10.50		11.00		10.60	
Ca++	2.5-5 (MG/DL)	01/02/92	3.90	-	4.00	-	3.80	_
P04	0-12 (MU/ML)	01/02/92	5.00		6.00		6.00	
SGOT	0-12 (MU/NL)	01/02/92	7.00		8.00		9.00	
SGPT	4-18 (UI/L)	01/02/92	10.00		12.00		8.00	
GANNA GT	120-240 (UI/L)	01/02/92	210.00	İ	220.00	i	202.00	
LDH ALK, PHOSPH.	20-48 (MU/ML)	01/02/92	28.00		33.00		16.00	
	70-110 (MG/DL)	01/02/92	77.00	İ	80.00		70.00	1
GLUCOSE UREA	15-40 (MG/DL)	01/02/92	25.00		22.00		21.00	1
CREATININE	0.5-1.4 (NG/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	1
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	l	4.00		4.00	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92	195.00	l	205.00		192.00	1
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	105.00		98.00		120.00	1
GLOBULINS ALPHA 1	0,1-0,3 (G/DL)	01/02/92	0.25	l	0.25		0.20	
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.60	l	0.70		0.65	1
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.90		0.85		0.85	1
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.35	١.	1.35		1.30	ı

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(6) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

#### PHARMACIA PHARMACEUTICAS #16003- CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Patient: 457 Treatment: Fluoxetine Sex: Female

			Visit	numl	ber / La	bora	tory date	9
			Scree	n	Day 2	В	Day 5	6
			09/12/	92	12/01/	93	09/02/9	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	l	39.00	
RBC	4000000-4500000	01/02/92				1		
	(/MM3)		4620000	>	4180000		4290000	
MBC	5000-9000 (/MM3)	01/02/92	5200.00		7400.00		7000.00	
MBC: N	50-65 (%)	01/02/92	60.00		60.00	]	62.00	
WBC: L	30-40 (2)	01/02/92	38.00		35.00		34.00	
WBC: E	0-3 (%)	01/02/92	0.00	l	3.00		3,00	
WBC: N	0-5 (%)	01/02/92	2.00	l	2.00		1.00	
WBC: B	0-1 (%)	01/02/92	0.00		0.00	ļ	0.00	1
PLATELETS	150000-300000	01/02/92				1		
FLATELLIS	(/MM3)	V 1. V2. V.	210000		215000		220000	1
NA+	130-150 (MEQ/L)	01/02/92	138.00		141.00	l	140.00	
K+	3-5 (MEQ/L)	01/02/92	4.20		4.20	1	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	1	10.00	i
P04	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	1	9.00	
	0-12 (MU/NL)	01/02/92	8.00	l	8.00	1	6.00	1
SGPT	4-18 (UI/L)	01/02/92	8.00		10.00	1	9.00	
GAMMA GT	120-240 (UI/L)	01/02/92	220.00	l	192.00		193.00	
LDH	20-48 (MU/NL)	01/02/92	24.00	ĺ	30.00	ļ	30.00	
ALK. PHOSPH.		01/02/92	76.00		92.00		90.00	
GLUCOSE	70-110 (MG/DL)	01/02/92	36.00		28.00	l	31.00	1
UREA	15-40 (MG/DL)		1.10		1.10	1	1.05	
CREATININE	0.5-1.4 (MG/DL)	01/02/92 01/02/92	3.50	İ	3.90	l	3.90	1
URIC ACID	2.4-5.7 (MG/DL)		0.70		0.60		0.65	
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.70		0.10		0.15	
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	6.50	ĺ	6.70	1	6.90	1
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	3.65	_ ا	3.80		3.95	
ALBUMINE	3.8-5 (G/DL)	01/02/92	252.00	1 -	174.00	1	192.00	
TOT. CHOLEST.	160-240 (MG/DL)	01/02/92			100.00	1	105.00	l
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	88.00		0.20		0.20	
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.25				0.20	i
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.60		0.60	1		l
GLOBULINS BETA	0,6-1 (G/DL)	01/02/92	0.70		0.75	l.	0.75	l.
GLOBULINS GAMMA	0.8-1.3 (G/DL)	01/02/92	1.30	١	1.35	>	1.35	١>
TSH	0-5 (UUI/ML)	01/02/92	1.34	ľ			l	l
T4	4.5-13 (UG/DL)	01/02/92	8.87	l	1	I	l	

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAS METANO3- CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 16 Patient: 458 Treatment: Fluoxetine Sex: Female

			Visit	num	ber / La	Laboratory date				
			Scree	n	Day 2	B	Day 5	6		
			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	12.00	<	13.50		14.00			
HT	38-43 (%)	01/02/92	42.00		41.00		43.00	Į.		
RBC	4000000-4500000	01/02/92			1					
	(/MM3)		4620000	>	4510000	>	4730000			
NBC	5000-9000 (/MM3)	01/02/92	6200.00		7500.00		8100.00			
HBC: N	50-65 (X)	01/02/92	69.00	>	65.00		64.00			
MBC: L	30-40 (%)	01/02/92	28.00	<	31.00		31.00			
MBC: E	0-3 (%)	01/02/92	1.00		0.00		2.00	1		
MBC: M	0-5 (%)	01/02/92	2.00		4.00	ĺ	3.00	1		
MBC: B	0-1 (%)	01/02/92	0.00		0.00		0.00			
PLATELETS	150000-300000	01/02/92								
LRICOLIO	(/MM3)		210000		215000		230000	ļ		
NA+	130-150 (MEQ/L)	01/02/92	138.00		138.00		138.00			
NA+	3-5 (MEQ/L)	01/02/92	4.20		3.90		3.90			
K+ CL-	95-105 (NEQ/L)	01/02/92	100.00		101.00	ľ	99.00			
	8.1-10.4 (MG/DL)	01/02/92	10.00		9.80	1	10.00	1		
Ca++	2.5-5 (MG/DL)	01/02/92	3.90		4.10		4.20			
P04	0-12 (NU/ML)	01/02/92	6.00		7.00	ļ	7.00	i		
SGOT	0-12 (MU/NL)	01/02/92	8.00		8.00	ł	5.00	i		
SGPT	0-12 (NU/NL) 4-18 (UI/L)	01/02/92	12.00		9.00		10.00	1		
GAMMA GT		01/02/92	190.00		201.00	I	196.00			
LDH	120-240 (UI/L)		36.00		26.00	ł	31.00			
ALK. PHOSPH.	20-48 (MU/ML)	01/02/92	105.00		95.00		99.00	1		
GLUCOSE	70-110 (MG/DL)	01/02/92	44.00		34.00	ļ	38.00	1		
UREA	15-40 (MG/DL)	01/02/92	1.20	_	1.10		0.98	1		
CREATININE	0,5-1.4 (MG/DL)	01/02/92	6.80	_	4.30		4.10	1		
URIC ACID	2,4-5.7 (MG/DL)	01/02/92		,	0.70		0.65	!		
TOT BILIRUBIN	0-1 (MG/DL)	01/02/92	0.70		0.20		0.15	1		
DIR BILIRUBIN	0-0.3 (MG/DL)	01/02/92	0.20	ļ	7.07	ĺ	7.00	1		
TOT. PROTEINS	6.3-8 (G/DL)	01/02/92	6.75							
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	٠.	220.00			
TRIGLYCERIDES	30-150 (MG/DL)	01/02/92	146.00	l	98.00		101.00	1		
GLOBULINS ALPHA 1	0.1-0.3 (G/DL)	01/02/92	0.20	l	0.15		0.20	1		
GLOBULINS ALPHA 2	0.45-0.75 (G/DL)	01/02/92	0.65	l	0.65		0.65			
GLOBULINS BETA	0.6-1 (G/DL)	01/02/92	0.80	l	0.80		0.75			
GLOBULING 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		1	1	ľ	1		
T4	4.5-13 (UG/DL)	01/02/92	6.90	l	1	i	1	1		

<sup>(</sup>c) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

# PHARMACIA PHARMACEUTICNS NO STANDARD CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 25 Treatment: Fluoxetine Sex: Female

			Visit	num	ber / La	bara	tory dat	e
			Scree	n	Day 2	В	Day 5	6
			30/09/	92	03/11/	92	01/12/	92
			value	(4)	value	(¢)	value	(¢
Laboratory test	Range value	Range date						
нв	12-16 (G/DL)	01/09/92	13.60		13.80	1	13.70	
HT	35-47 (%)	01/09/92	39.00	ļ	43.00		42.00	1
RBC	3.8-5.2 (10-6/MM3)	01/09/92	4.50	1	4.70		4.60	
MBC	4000-10000 (/MM3)	01/09/92	5400.00		5500.00		6900.00	
HBC: N	50-70 (%)	01/09/92	60.00		60.00		50.00	Į.
MBC: L	30-40 (%)	01/09/92	34.00		32.00		42.00	>
HBC: E	0-4 (%)	01/09/92	1.00		1.00		1.00	
HBC: M	0-8 (%)	01/09/92	3.00		5.00		5.00	
HBC: B	0-2 (X)	01/09/92	1.00		1.00		1.00	Į
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	i
K+	3.6-5.6 (MMOL/L)	01/09/92	5.10		4.90		5.20	1
CL-	95-108 (MMOL/L)	01/09/92	103.00		101.00			Į.
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2,31		2.32		2.45	
P04~~	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	l
BUN	4-50 (MG/DL)	01/09/92	30.00		27.00		32.00	ĺ
CREATININE	0.3-1.4 (MG/DL)	01/09/92	0.99		0.99		1.04	1
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	i	6.70		6.70	
ALBUMINE	58.8-69.6 (%)	01/09/92	65.70		64.50		66.20	
TOT. CHOLEST.	150-220 (NG/DL)	01/09/92	252.00	>	284.00	>	284.00	
FRIGLYCERIDES	30-170 (MG/DL)	01/09/92	94.00		129.00	ı	172.00	>
CLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	3.10		3.10	- 1	3.10	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	8.40		9.30	- 1	9.00	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	13.30		13,40	1	13.00	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	9,60	ŀ	9.70	- 1	8.70	
rsh .	0.2-5 (UU/ML)	01/09/92	0.70					

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range)

\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range > out of range (value higher than max range

#### PHARMACIA PHARMACEUTICAS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centro: 18 Patient: 28 Treatment: Fluoxetine

					umber / ory date	
			Scree	n	Day 2	8
V.			30/09/9	92	03/11/	92
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
нв	12-16 (G/DL)	01/09/92	14.70		13.90	
НT	35-47 (%)	01/09/92	41.00		41.00	
RBC	3,8-5.2 (10-6/MM3)	01/09/92	4.80		4.70	
NBC	4000-10000 (/MM3)	01/09/92	5200.00		5200.00	
HBC: N	50-70 (%)	01/09/92	70.00		73.00	
WBC: L	30-40 (%)	01/09/92	25.00	<	18.00	
NBC: E	0-4 (%)	01/09/92	2.00		1.00	1
MBC: M	0-8 (%)	01/09/92	2.00		5.00	
MBC: B	0-2 (X)	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	i
K+	3.6-5.6 (MMOL/L)	01/09/92	4.70		3.70	ĺ
CL-	95-108 (MNOL/L)	01/09/92	100.00		102.00	
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.44		2.35	
P04	0.81-1.45 (MMOL/L)		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	<b> </b>	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	
GLUCUSE BUN	4-50 (MG/DL)	01/09/92	40.00		30.00	
	0.3-1.4 (MG/DL)	01/09/92	1.00		1,10	
CREATININE	2.5-6 (MG/DL)	01/09/92	6.00		5.40	{
URIC ACID TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.65		0.85	
		01/09/92	7.10		7.00	
TOT. PROTEINS	6-8 (G/DL) 58.8-69.6 (%)	01/09/92	63.60		69.20	-
ALBUMINE	58.8-69.6 (X) 150-220 (MG/DL)	01/09/92	240.00	١.	258.00	-
TOT. CHOLEST.		01/09/92	117.00	ľ	154.00	
TRIGLYCERIDES	30-170 (NG/DL)	01/09/92	2.70		2.30	
GLOBULINS ALPHA 1		01/09/92	8.60		7.30	1
GLOBULINS ALPHA 2	3.7-13.1 (%)		12.00		11.10	-
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	13.10		10.10	1
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	0.80		13.10	
TSH	0.2-5 (UU/ML)	01/09/92	0.80		l	

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(0) << clinically relevant (value lower out of range (value lower than min range)

\*\* missing laboratory test value nd laboratory not done

#### PHARMACIA PHARMACEUTICAS 51564083 CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 30 Treatment: Fluoxetine

			Visit	num	ber / Lai	bora	tory date	В
			Scree	1	Day 2	В	Day 5	6
			30/09/	92	04/11/	92	01/12/1	92
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date						
нв	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)		5.00		4.60		4.00	
HBC	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	<
MBC: E	0-4 (2)	01/09/92	2.00		2.00		2.00	
HBC: M	0-8 (%)	01/09/92	5.00		6.00		7.00	l
WBC: B	0-2 (%)	01/09/92	1.00		1.00	ŀ	1.00	l
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	Į
K+	3.6-5.6 (MMOL/L)	01/09/92	4.70		4.70		4.10	l
CL-	95-108 (MMOL/L)	01/09/92	101.00		105.00		106.00	1
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.37		2.24		2.44	
P04	0.81-1.45 (MMOL/L)	01/09/92	1.19		1.25	1	1.58	>
SGOT	0-15 (U/L)	01/09/92	12.00		7.00	1	9.00	1
SGPT	0-17 (U/L)	01/09/92	15.00		9.00		12.00	ı
GAMMA GT	4-18 (U/L)	01/09/92	23.00	>	19.00	>	16.00	1
LDH	120-240 (U/L)	01/09/92	178.00		169.00		173.00	l
ALK. PHOSPH.	60-200 (U/L)	01/09/92	251.00	5	256.00	>	247.00	۱,
ALK. PHOSPH. GLUCOSE	60-110 (MG/DL)	01/09/92	68.00	-	74.00	ľ	60.00	
	4-50 (MG/DL)	01/09/92	37.00		31.00		37.00	l
BUN	0.3-1.4 (MG/DL)	01/09/92	1.06		1.02		0.99	l
CREATININE	2.5-6 (MG/DL)	01/09/92	5.40		5.30		4.40	l
URIC ACID	0-1 (MG/DL)	01/09/92	0.64		0.47		0.16	
TOT BILIRUBIN	6-8 (G/DL)	01/09/92	7.20		7.00		6.80	
TOT. PROTEINS	58.8-69.6 (%)	01/09/92	60.80		64.80		65.40	
ALBUMINE		01/09/92	213.00		200.00		209.00	
TOT, CHOLEST.	150-220 (NG/DL)		89.00	1	65.00		343.00	١.,
TRIGLYCERIDES	30-170 (NG/DL)	01/09/92	3.50	1	3.10	l	3.00	١
GLOBULINS ALPHA 1	1.8-3.8 (%)	01/09/92	8.50		8.40	1	7.40	l
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92		1			11.40	1
CLOBULINS BETA	8,9-13.6 (%)	01/09/92	12.40	l	11.30			1
GLOBULINS GAMMA	8.4~18.3 (2)	01/09/92	14.80	1	12.40		12.80	1
TSH	0.2-5 (UU/ML)	01/09/92	1.10	l	İ	ĺ	1	l

<sup>(¢) &</sup>lt;< clinically relevant (value lower than min range)
< out of range (value lower than min range)
\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAS 550083 CNS

#### REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 32 Treatment: Fluoxetine Sex: Female

			Visit	num	ber / La	bora	tory dat	8
			Scree	n	Day 2	В	Day 5	6
			05/10/	92	04/11/	92	01/12/	92
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
нв	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)		4.70		4.40		4.50	
MBC	4000~10000 (/MM3)	01/09/92	7000.00		7200.00		6700.00	
MBC: N	50-70 (%)	01/09/92	64.00		63.00		67.00	
WBC: L	30-40 (%)	01/09/92	29.00	<	28.00	۱<	25.00	
WBC: E	0-4 (%)	01/09/92	1.00		1.00		1.00	
MBC: M	0-8 (%)	01/09/92	4.00		6.00		5.00	
MBC: B	0-2 (%)	01/09/92	1.00		1.00		1.00	
PLATELETS	200-300 (10-3/MH3)	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	
P04	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	l
GLUCOSE	60-110 (MG/DL)	01/09/92	68.00	ļ	91.00		107.00	
BUN	4-50 (MG/DL)	01/09/92	26.00		25.00		22.00	İ
CREATININE	0.3-1.4 (MG/DL)	01/09/92	0.95		0.92		0.98	1
URIC ACID	2.5-6 (MG/DL)	01/09/92	4.00	ļ	3.00	1	3.60	i
TOT BILIRUBIN	0-1 (MG/DL)	01/09/92	0.79		0.31		0.47	l
TOT. PROTEINS	6-8 (G/DL)	01/09/92	6.90	l	7.10		7.50	l
ALBUNINE	58.8-69.6 (%)	01/09/92	64.20		67.60	1	64.00	1
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	1	59.00		91.00	
GLOBULINS ALPHA 1	1.8-3.8 (2)	01/09/92	3.50		3.60		3.20	1
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	l	11.30		13.40	1
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	l				1
T4	4-13 (UG/DL)	01/09/92	8.20	1	i	ı	ı	1

<sup>&</sup>gt;> clinically relevant (value higher than max range to out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICALSHEDAY83 CMS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 51 Treatment: Fluoxetina Sex: Female

			Visit	numi	per / Lai	bora	tory date	•
			Scree	n.	Day 2	В	Day 5	6
*			10/11/	92	15/12/	92	12/01/	93
			value	(¢)	value	(4)	value	(¢
Laboratory test	Range value	Range date						
нв	12-16 (G/DL)	01/09/92	12.40		12.50		11.70	
HT	35-47 (X)	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	<
MBC	4000-10000 (/MM3)	01/09/92	10210.0	>	6100.00		6100.00	l
MBC: N	50-70 (%)	01/09/92	65.00		64.00		57.00	
NBC: L	30-40 (%)	01/09/92	29.00	<	28.00	<	36.00	ĺ
NBC: E	0-4 (%)	01/09/92	1.00		1.00		1.00	
MBC: M	0-8 (%)	01/09/92	4.00		6.00	l	4.00	
MBC: B	0-2 (%)	01/09/92	0.00		0.00	l	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	1	3.80		3.70	
CL-	95-108 (MMOL/L)	01/09/92	99.00		101.00	1	95.00	
Ca++	2.1-2.6 (MMOL/L)	01/09/92	ļ	ĺ	2.40		2.30	
P04	0.81-1.45 (MMOL/L)	01/09/92	1.29		1.01	F	1.10	
SGOT	0-15 (U/L)	01/09/92	7.00		6.00	ł	5.00	1
SGPT	0-17 (U/L)	01/09/92	8.00		8.00	1	8.00	
GANNA GT	4-18 (U/L)	01/09/92	5.00		6.00	ŧ	5.00	
LDH	120-240 (U/L)	01/09/92	169.00	1	122.00		109.00	<
ALK. PHOSPH.	60-200 (U/L)	01/09/92	62.00		65.00	ł	54.00	<
GLUCOSE	60-110 (MG/DL)	01/09/92	85.00		92.00	ł	105.00	
BUN	4-50 (MG/DL)	01/09/92	44.00		37.00	ŀ	47.00	
CREATININE	0.3-1.4 (MG/DL)	01/09/92	0.86	1	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	l	0.18	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	7.60	!	7.10	1	7.00	
ALBUMINE	58.8-69.6 (%)	01/09/92	66.10		62.30	ļ	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	l	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	1
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	9.50	1	11.00	ŀ	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	1 '		l	1	1
T4 .	4-13 (UG/DL)	01/09/92	8.80	l		ı	{	1

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(¢) << clinically relevant (value lower out of range (value lower than min range) than min range) (value lower than min range) than min range) than min range)

#### PHARMACIA PHARMACEUTICAS 5156483 CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 52 Treatment: Fluoxetine Sex: Female

			Visit	numi	ber / Lai	bora	tory date	0
			Screen	1	Day 2	B	Day 5	6
			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	14.60		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	
NBC	4000-10000 (/MM3)	01/09/92	3500.00	<	3100.00	<	3600.00	<
MBC: N	50-70 (%)	01/09/92	56.00		46.00		53.00	
NBC: L	30-40 (%)	01/09/92	35.00	١.	43.00	> .	35.00	l
MBC: E	0-4 (%)	01/09/92	2.00		1.00		2.00	1
MBC: M	0-8 (%)	01/09/92	6.00		6.00	1	7.00	
NBC: B	0-2 (%)	01/09/92	1.00		1,00	l	1.00	
PLATELETS	200-300 (10-3/MM3)	01/09/92	245.00		268.00	ŀ	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	ľ	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	1	2.27	1
P04	0.81-1.45 (MMOL/L)		1.30		1.15		1.09	i
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	1
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	1
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	
	2.5-6 (MG/DL)	01/09/92	3.30		3.90		4.20	
URIC ACID	0-1 (MG/DL)	01/09/92	0.50		0.40		0.38	
TOT BILIRUBIN	0-1 (MG/DL) 6-8 (G/DL)	01/09/92	7.00		6.60		7.00	
TOT. PROTEINS		01/09/92	62.80		63.00	ĺ	63.10	
ALBUMINE	58.8-69.6 (%) 150-220 (MG/DL)	01/09/92	232.00		225.00		243.00	
TOT. CHOLEST.		01/09/92	74.00	_	81.00	ļ*.	80.00	
TRIGLYCERIDES	30-170 (MG/DL)	01/09/92	2.60		3.00		2.50	
GLOBULINS ALPHA 1	1.8-3.8 (%)		8.90		9.10		9.40	
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92			12.70		12.00	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	12.70				12.00	
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	12.90		12.10	İ	12.90	1
TSH	0.2-5 (UU/ML)	01/09/92	0.80			l .		1
T4	4-13 (UG/DL)	01/09/92	8.60			i		1

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 53 Treatment: Fluoxetine Sex: Female

			Visit	numi	ber / Lai	pora	tory date	
			Scree	n	Day 2	В	Day 5	6
			29/12/	92	12/02/	93	15/03/9	93
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date						
HB	12-16 (G/DL)	01/09/92	15.30	ŀ	15.20		14.20	
HT	35-47 (%)	01/09/92	45.00		46.00		47.00	
RBC	3.8-5.2 (10-6/MN3)	01/09/92	5.10	ŀ	5.10		4.90	
HBC	4000-10000 (/MM3)	01/09/92	6900.00		6400.00		6700.00	
MBC: N	50-70 (2)	01/09/92	56.00	ļ	64.00		62.00	
MBC: L	30-40 (%)	01/09/92	29.00	<	21.00	<	27.00	<
NBC: E	0-4 (%)	01/09/92	3.00	Į.	2.00		1.00	
NBC: M	0-8 (%)	01/09/92	9.00	>	10.00	>	8.00	
MBC: B	0-2 (%)	01/09/92	1.00	1	2.00		1.00	
PLATELETS	200-300 (10-3/MN3)	01/09/92	442.00	>>	313.00		337.00	
NA+	135-144 (MMOL/L)	01/09/92	135.00	1	119.00	<<	129.00	<
K+	3.6-5.6 (MMOL/L)	01/09/92	4.10				ł	
 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	l	2.35		2.33	
P04	0.81-1.45 (MMOL/L)	01/09/92	1.25	1	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	1	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	1	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	l	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	i	6.90			
ALBUMINE	58.8-69.6 (%)	01/09/92	61.80	İ	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	l	127.00	ĺ	87.00	
GLOBULINS ALPHA 1	1.8-3.8 (2)	01/09/92	3.00		3.30	l	3.00	1
GLOBULINS ALPHA 2	3.7-13.1 (%)	01/09/92	9.80	1	10.50	ĺ	8.10	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	13.30		13.30	l	11.90	1
GLOBULINS GAMMA	8.4-18.3 (%)	01/09/92	12.00		13.50	ĺ	13.00	
TSH	0.2-5 (UU/ML)	01/09/92	1.10	1	l	l	l	l

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(c) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

>> clinically relevant (value higher than max range value higher than max range value)

#### PHARMACIA PHARMACEUTICAS EN 683 CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 18 Patient: 54 Treatment: Fluoxetine Sex: Hele

		•	Visit	numi	ber / Lai	bora	tory date	0
			Scree	n	Day 2	В	Day 5	6
			05/01/	93	09/02/	93	09/03/9	93
			value	(¢)	value	(¢)	value	(¢
Laboratory test	Range value	Range date						
нв	12-16 (G/DL)	01/09/92	15.80	]	15.70		15.90	i
HT	35-47 (X)	01/09/92	46.00	i	46.00	İ	45.00	İ
RBC	3,8-5,2 (10-6/MN3)	01/09/92	5.10		5.00	l	4.80	l
MBC	4000-10000 (/MM3)	01/09/92	7100.00	1	7200.00		6800.00	l
MBC: N	50-70 (%)	01/09/92	60.00	1	63.00	1	54.00	İ
WBC: L	30-40 (%)	01/09/92	31.00	1	26.00	<	35.00	l
HBC: E	0-4 (%)	01/09/92	1.00		1.00		1.00	
MBC: M	0-8 (%)	01/09/92	6.00		7.00		7.00	
MBC: B	0-2 (%)	01/09/92	1.00		1.00		1.00	
PLATELETS	200-300 (10-3/MN3)	01/09/92	239.00		229.00		255.00	1
NA+	135-144 (MMOL/L)	01/09/92	141.00	ļ	134.00	<	139.00	
K+	3.6-5.6 (MMOL/L)	01/09/92	4,90		4.50	Ì	5.00	
CL-	95-108 (MMOL/L)	01/09/92	103.00	1	95.00		99.00	
Ca++	2.1-2.6 (MMOL/L)	01/09/92	2.30	1	2.35		2.29	
P04	0.81-1.45 (MMOL/L)	01/09/92	1.31	l	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	l	126.00		129.00	ı
ALK. PHOSPH.	60-200 (U/L)	01/09/92	163.00	l	173.00		162.00	l
GLUCOSE	60-110 (HG/DL)	01/09/92	94.00		96.00		75.00	
BUN	4-50 (MG/DL)	01/09/92	39.00	l	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	1	0.63		0.45	
TOT. PROTEINS	6-8 (G/DL)	01/09/92	6.60	l	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	
GLOBULING ALPHA 1	1.8-3.8 (%)	01/09/92	2.60	1	3.20		3.20	
GLOBULING ALPHA 2	3.7-13.1 (%)	01/09/92	9.10	1	9.50		10.20	
GLOBULINS BETA	8.9-13.6 (%)	01/09/92	10.60		11.20		10.70	
GLOBULING 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	l	l	1	l	l

1112

(c) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

#### PHARMACIA PHARMACEUTICAL STEAMS 3 CMS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 20 Patient: 21 Treatment: Fluoxetine Sex: Female

	-,				umber / ory date	
			Scree	n	Day 5	6
			30/10/	92	06/01/	93
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	13.5-18 (G/DL)	01/01/92	13.30	<	13.50	
HT	36-48 (2)	01/01/92	38.80			ł
RBC	4-5.5 (10~6/UL)	01/01/92			4.66	į
KBC	5-9 (10-3/MM3)	01/01/92	1		5.10	1
MBC: L	25-45 (%)	01/01/92	37.00			1
MBC: E	0-4 (%)	01/01/92	1.00			ı
MBC: M	0-8 (%)	01/01/92	1.00			l
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	>		
EL-	97-108 (MMOL/L)	01/01/92			98.00	
Ca++	2.25-2.75 (MMOL/L)	01/01/92	2.34		2.46	}
P04	0.8-1.53 (MMOL/L)	01/01/92			1.02	i
SGOT	0-15 (U/L)	01/01/92	11.00		11.00	
SCPT	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	1
ALK. PHOSPH.	70-175 (U/L)	01/01/92	105.00		117.00	
GLUCOSE	70-95 (NG/DL)	01/01/92	74.00		38.00	~
BUN	10-50 (NG/DL)	01/01/92	7.1.22		51.00	
CREATININE	0.5-1.5 (MG/DL)	01/01/92	0.99		1, 14	1
	2-7 (MG/DL)	01/01/92	1.82	ا ہا	3.64	
URIC ACID POT BILIRUBIN	0-1 (NG/DL)	01/01/92	0.85		0.50	
	0-0.25 (MG/DL)	01/01/92	0.02		0.04	
DIR BILIRUBIN	6.5-8 (G/DL)	01/01/92	7.63		7.39	
TOT. PROTEINS		01/01/92	62.90		54.60	_ ا
ALBUNINE	56-68 (%)	* * * * * * * * * * * * * * * * * * * *	208.00	\	341.00	
TOT. CHOLEST.	150-200 (MG/DL)	01/01/92	72.00		96.00	'"ا
TRIGLYCERIDES	75-180 (MG/DL)	01/01/92		`	2.90	ı
GLOBULINS ALPHA 1		01/01/92	3.10			l
GLOBULINS ALPHA 2	6-10 (%)	01/01/92	6.90		7.80	l
GLOBULINS BETA	8-14 (%)	01/01/92	10,80	ĺ	11.20	L
GLOBULINS GAMMA	9-19 (%)	01/01/92	16.20		23.50	>
rsh	0.2-4 (UU/ML)	01/01/92	1.35			l
r4	0.8-2 (NG/DL)	01/01/92	8.06	>>		ı

<sup>(¢) &</sup>lt;< clinically relevant (value lower out of range (value lower than min range) than min range) (\*\* missing laboratory test value of laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range to ut of range (value higher than max range () missing range value

#### PHARMACIA PHARMACEUTICAS 5150483 CNS

## REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Contre: 20 Patient: 22 Treatment: Fluoxotine Sex: Female

					ımber / ory date	
			Scree	n	Day 2	8
			10/11/9	92	14/12/	92
			value	(¢)	value	(4)
Laboratory test	Range value	Range date	14.50		14.80	
НВ	13.5-18 (G/DL)	01/01/92	41.70		42.10	
HT	36-48 (%)	01/01/92	41.70		42.10	
RBC	4-5.5 (10-6/UL)	01/01/92	16.50	l i	6.20	
MBC	5-9 (10-3/MM3)	01/01/92	16.50 82.10		52.60	l
WBC: N	50-75 (%)	01/01/92				l
WBC: L	25-45 (%)	01/01/92	12.40	``	38.50 2.80	ı
NBC: E	0-4 (%)	01/01/92	0.90		2,80 5,40	1
WBC: M	0-8 (%)	01/01/92	3.60			
MBC: B	0-2 (%)	01/01/92	1.00		0.70	1
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	1
K+	3.6-5.4 (MMOL/L)	01/01/92	4.94			ł
CL-	97-108 (MMOL/L)	01/01/92	94.40		102.00	1
Ca++	2.25-2.75 (MMOL/L)		2.65		2.52	
P04	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	
LDK	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			i
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	i I	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	
GLOBULING GAMMA	9-19 (2)	01/01/92	11.90		19.70	>
TSH	0.2-4 (UU/ML)	01/01/92	0.80			1
T4	0.8-2 (NG/DL)	01/01/92	1.07			1

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(¢) << clinically relevant (value lower than min range) 
< cut of range (value lower than min range) 
\*\* missing laboratory test value nd laboratory not done

### РНАВМАСІА РНАВМАСЕЦТІСЬТЬ МЕНЬ АНВЗ- CNS REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA 9 Treatment: Fluoxetine

				Vis	it numbe	r / I	Laborato	ry da	ate	
			Scree	n	Day 1	4	Day 2	8	Day 5	6
			16/10/	92	02/11/	92	16/11/	92	14/12/	92
			value	(4)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
нв	120-160 (G/L)	31/12/91	142.00		138.00	-	145.00		142.00	1
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	1 1	4.59		4.42	1
NBC	4.3-10 (10-9/L)	31/12/91	4.70	İ	5.40		7.30		5.56	
MBC: N	25-74 (%)	31/12/91	72.00	1 !	50.00	1	67.00	i I	47.00	1
MBC: L	20-44 (%)	31/12/91	25.00	1 i	48.00	>	33.00		49.00	>
WBC: E	1-5 (%)	31/12/91	0.00	<	0.00	<	0.00	<	1.00	
MBC: K	2-7 (X)	31/12/91	2.00	1 1	2.00	ll	0.00	<	3.00	1
NBC: B	0-1 (%)	31/12/91	1.00		0.00	i i	0.00		0.00	
PLATELETS	150~440 (10¬9/L)	31/12/91	195.00		197.00	l 1	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	i i	4.50	
CL-	97-108 (MMOL/L)	31/12/91	108.00		107.00	1 1	101.00	1 1	103.00	
Ca++	2.2-2.6 (MMOL/L)	31/12/91	2.40	1 1	2.30	1 1	2.60		2.40	
P04	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	1 1	6.00		31.00	<sub>&gt;</sub>	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	1	140.00		135.00	i - [	164,00	
ALK. PHOSPH.	40-190 (U/L)	31/12/91	50.00		50.00		139.00	l 1	80.00	
GLUCOSE	70-180 (MG/DL)	31/12/91	78,00	li	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	l	0.80	
URIC ACID	2-6.3 (NG/DL)	31/12/91	3.20	[ [	2.90	' I	2.60	1	4.20	ĺ
TOT BILIRUBIN	0.2-1 (MG/DL)	31/12/91	0.30	1	0.70	1	0.60	1	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	l´
TRIGLYCERIDES	50-200 (MG/DL)	31/12/91	57.00	1 /	89.00	1	125.00	- 1	130.00	1
GLOBULINS ALPHA 1	1.6~5.8 (%)	31/12/91	3.40		3.70	- 1	5.40		3.70	
GLOBULINS ALPHA 2	5.9~11.1 (%)	31/12/91	10.10	l i	8.00	1	13.30	.	8.90	
GLOBULINS BETA	7.9-13.9 (%)	31/12/91	11.30	1	11.00	1	13.70	_	12.00	
GLOBULINS GAMMA	10-18.2 (%)	31/12/91	18.50		16.00	- 1	16.40		17.40	ļ
TSH	0.1-3.5 (UU/ML)		1.05		10.00	- 1	10.40		17.40	l
15H T4	0.1~3.5 (UU/NL) 0.8~2 (NG/DL)	31/12/91								
14	U.D-Z (NG/DL)	31/12/91	0.81			- 1	i			1

1115

(¢) << clinically relevant (value lower than min range)
< out of range (value lower than min range)

\*\* missing laboratory test value nd laboratory not done

<sup>&</sup>gt;> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

#### PHARMACIA PHARMACEUTICO15 STEON93- CNS

REBOXETINE - PROTOCOL 20124/016 Listing No.: 18.0

LABORATORY DATA
Centre: 22 Patient: 113 Treatment: Fluoxetine Sex: Male

			Visit number Laborate date	/
			Screen	n
			14/11/9	92
			value	(¢)
Laboratory test	Range value	Range date	15.30	
HB	14-18 (G/DL)	01/11/92	0.48	
HT	0.38-0.52 (L/L)	01/11/92	4.83	
RBC	4.4-6 (10-12/L)	01/11/92	4.63	1
WBC	4.3-10 (10-9/L) 50-70 (%)	01/11/92	59.00	
WBC: N	25-45 (%)	01/11/92	34.00	
WBC: L	25-45 (%) 2-4 (%)	01/11/92	1.00	_
WBC: E	2-4 (%) 2-6 (%)	01/11/92	5.00	`
WBC: M	0-1 (%)	01/11/92	1.00	
HBC: B PLATELETS	140-440 (10-9/L)	01/11/92	159.00	
PLATELETS NA+	135-145 (MMOL/L)	01/11/92	143.00	
NAT 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	l
URIC ACID	3.5-7 (NG/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	1
TOT. PROTEINS	6.5-8 (G/DL)	01/11/92	6.70	1
ALBUNINE	55.3-68.9 (%)	01/11/92	63.80	1
TOT. CHOLEST.	50-220 (MG/DL)	01/11/92	231.00	>
TRIGLYCERIDES	60-150 (MG/DL)	01/11/92	145.00	
GLOBULINS ALPHA 1		01/11/92	2.90	1
GLOBULINS ALPHA 2	5.9-11.1 (%)	01/11/92	7.10	1
GLOBULINS BETA	7.9-13.9 (%)	01/11/92	11.20	1
GLOBULINS GAMMA	11.4-18.2 (X)	01/11/92	15.00	1
TSH	0.3-4 (NU/L)	01/11/92	1.40	]
T4	5-13.4 (UG/DL)	01/11/92	6.90	1

1116

(¢) << clinically relevant (value lower out of range (value lower than min range) than min range)

\*\* missing laboratory test value of laboratory not done

>> clinically relevant (value higher than max range out of range (value higher than max range () missing range value

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y.	KBC K	Absent P Not done N Not done N	Absent A Not done M Absent A	Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Ab	Absent R Not done P Absent E Absent R	Absent Not done I	Absent Present Absent	Absent Absent Absent	Absent	Absent Absent Present	Absent
	Sugar	Absent Not done Not done	bsent ot done bsent bsent	Absent Not done Absent Not done	Absent Not done Absent Absent	Absent Not done Not done	Absent Absent Absent Not done Not done Present Not done Not done Absent	Absent Absent Absent	Absent	Absent Absent Absent	Absent
Urinalveis test	Albumin	Not done Absent Not done Not done Not done Not done	Absent Not done Absent	Absent e Not done e Absent e Not done	e Absent e Not done e Absent e Absent	e Absent e Not done e Not done	e Absent e Not done e Not done	Absent Absent Absent	Absent	Absent Absent Absent	e Absent
, entire	S #	1 Not done 29 Not done 57 Not done	0 Not done Absent A 15 Not done Not done N 29 Not done Absent A 57 Not done Absent A	O Missing 18 Not done N 30 Not done 6 56 Not done 6	O Not done 15 Not done 6 29 Not done 6 43 Not done 6	O Not done Absent Absent 15 Not done Not done Not done 29 Not done Not done Not done	D Not done 15 Not done 29 Not done	0 Normal 32 Normal 57 Normal	O Normal 32 Normal	1 Not done Absent 31 Normal Absent 56 Not done Absent	O Not done Absent
	Date (x)	15/11/91 13/12/91 10/01/92	25/06/92 10/07/92 24/07/92 21/08/92	29/06/92 18/07/92 30/07/92 25/08/92	12/08/92 28/08/92 11/09/92 25/09/92	07/10/92 27/10/92 10/11/92	11701793 28/01/93 11/02/93	03/05/91 04/06/91 29/06/91	02/05/91	16/04/91 16/05/91 10/06/91	26/64/91
e.	Assessment	Screen Day 28 Day 56	Screen Day 14 Day 28 Day 56	Screen Day 14 Day 28 Day 56	Screen Day 14 Day 28	Screen Day 14 Day 28	Screen Day 14 Day 28	Screen Day 28 Day 56	Screen Day 28	Screen Day 28 Day 56	Screen
Listing No.: 19.0 URINALYSIS	Days	9	35	50	45	30	<b>5</b>	8	4	26	26
Listing No.: 19.0 URINALYSIS Treatment period	1 1	09/01/92	20/08/92	25/08/92	24/09/92	11/11/92	11/02/93	28/06/91	12/06/91	10/06/91	26/06/91
Treatee	Start date	15/11/91	26/06/92	01/07/92	14/08/92	13/10/92	14/01/93	04/05/91	03/05/91	16/04/91	02/05/91
	Patient type S	y screening	Evaluated	Evaluated	Evaluated	Only screening	Evaluated	Evaluated	Evaluated	Evaluated	Evaluated
	Sex	Male Omly	Hale	Female	Female	Female Onl	Kale	Female	Male	Female	Hale
	Treatment	Fluoxetine	Reboxetine	Fluoxotino Femalo	Reboxetine	Fluoxetine	Fluoxetine	Fluoxetine	Reboxetine	Reboxetine	Fluoxetine
	Patient	•	~	m	4	w	Vo	33	ŧ	38	36
	Centre				11	17		N			

(\*) days of treatment

REBOXETINE - PROTOCOL 20124/016 Listing No.: 19.0

PHARMACIA CNS RED

					Treatm	Treatment period					Urinaly	Urinalysis test			
antre	Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	(x)	Specific gravity	Albumin	Sugar	RBC	KBC
	36	Fluoxetine	Hale	Evaluated	02/05/91	26/06/91	95	Day 14 Day 28 Day 56	16/05/91 07/06/91 27/06/91	15 N 37 N 57 N	15 Not done Not don 37 Not done Absent 57 Not done Absent	Not done Absent Absent	Not done Absent Absent	Not done Absent Absent	Not done Absent Absent
	37	Reboxetine	Male	Without Urimal	07/10/91	10/10/91	4	Screen	01/10/91	0	ot done	Not done	Not done	8 Not done Not done Not done Not done	Not done
	38	Fluoxetine	Male	Evaluated	20/06/91	25/07/91	38	Screen Day 28	18/06/91 18/07/91		O Not done Absent 29 Not done Absent	Absent	Absent	Absent Absent	Absent Absent
	39	Fluoxetine	Male	Only screening	19/00/61	22/06/91	4	Screen	19/06/91	~	1 Not done Absent	Absent	Absent	Absent	Absent
	9	Reboxetine	Жале	Only screening	16/90/90	04/07/91	29	Screen	16/90/40	0	0 Normal	Absent	Absent	Absent	Absent
1118	2	Fluoxetine	Ма1е	Without screen	13/02/92	08/04/92	56	Screen Day 14 Day 28 Day 56	11/02/92 27/02/92 12/03/92 09/04/92	15 N 29 N 57 N	Not done Not done Not done Not done	done Not done done Not done done Present done Absent	Not done Not done Not done Not done Present Present Absent Absent	Not done Not done Present Absent	Not done Not done Present Absent
	<b>4</b> 2	Reboxetine	Female	Evaluated	05/03/92	29/04/92	95	Screen Day 28 Day 56	04/03/92 02/04/92 30/04/92	29 N 29 N 57 N	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	<b>ę</b>	Reboxetine	Female	Reboxetine Female Mithout screen	19/11/91	13/01/92	56	Screen Day 14 Day 28 Day 56	19/11/91 03/12/91 17/12/91 14/01/92	15 N 29 N 57 N	lot done lot done lot done	Not done Not done Absent Absent	Not done Not done Not done Not done Not done Not done Not done Absent Absent Absent Absent Absent Absent Absent	Not done Not done Absent Absent	Not done Not done Absent Absent
	\$	Fluoxetine	Male	Evaluated	13/12/91	30/01/92	64	Screen Day 28	13/12/91 10/01/92	29	Not done Absent Not done Absent	Absent Absent	Absent Absent	Absent Absent	Absent Absent
	45	Reboxetine	Female	Evaluated	10/09/92	04/11/92	35	Screen Day 28	10/09/92 08/10/92	29	Not done Not done	done Absent done Absent	Absent	Absent Absent	Absent Absent
	43	Fluoxetine	Fenale	Evaluated	25/03/92	19/05/92	8	Screen Day 28 Day 56	25/03/92 22/04/92 20/05/92	29 57	Normal Normal Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent

\*) days of treatmer

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 19.0

					Treatm	Treatment period_				Urinal	Urinalysis test_			
Patie	at	Contro Patient Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date (	Specific (*) gravity	Albumin	Sugar	RBC	MBC
48		Reboxetine	Forale	Evaluated	19/05/92	13/07/92	35	Screen Day 28 Day 56	18/05/92 16/06/92 14/07/92	0 Normal 29 Normal 57 Normal	Absent Absent Absent Absent	Absent / Absent / Absent /	Absent Absent Absent	Absent Absent Absent
8		Fluoxetine	Kale	Evaluated	15/01/93	11/03/93	8	Screen Day 14 Day 28 Day 56	15/01/93 29/01/93 12/02/93 12/03/93	1 Not done Absent 15 Not done Not done 29 Not done Absent 57 Not done Absent	9	Absent Mot done 1 Absent Absent	Absent Not done Absent Absent	Absent Not done Absent Absent
<b>5</b> 9		Fluoxetine	Fonale	Without Urinal	16/10/91	10/12/91	8	Screen Day 14 Day 28 Day 56	11/10/91 29/10/91 12/11/91 10/12/91	0 Normal 14 Normal 28 Normal 56 Normal	Not done Not done Not done Not done Not	lot done lot done lot done	Not done Not done Not done	Not done Not done Not done
99		Fluoxetine	Female	Hithout Urinal	16/10/91	12/11/91	28	Screen Day 28	11/10/91	O Normal Not done Not done Not 28 Not done Not done Not done Not	Not done Not done	Not done Not done	Not done Not done	Not done Not done
29		Reboxetine	Female	Mithout Urimal	18/11/92	15/12/92	<b>8</b> 2	Screen Day 28	14/11/92 16/12/92	0 Normal 29 Normal	Not done Not done	Not done Not done Not done Not done Not done Not done	Not done Not done	Not done Not done
89		Reboxetine	Fenale	Evaluated	30/11/92	28/12/92	23	Screen Day 28	26/11/92 28/12/92	0 Normal Absent 29 Not done Absent		Absent	Absent Absent	Absent Absent
97		Reboxetine	Female	Evaluated	22/04/91	16/06/91	35	Screen Day 28 Day 56	19/04/91 19/05/91 16/06/91	O Normal Absent Absent Absent 28 Normal Absent Absent 56 Not dome Not dome Not dome	Absent Absent Not done	Absent Absent Not done	Absent Absent Not done	Present Absent Not done
8		Fluoxetine	Female	Evaluated	30/05/91	24/07/91	26	Screen Day 28 Day 56	27/05/91 26/06/91 24/07/91	O Normal Absent Absent Absent 28 Net done Net done Net done 56 Normal Absent Absent Absent	Absent Not done Absent	Absent Not done Absent	Absent Not done Absent	Absent Not done Absent
66		Fluoxetine	Female	Only screening	15/10/91	25/10/91	7	Screen Day 14	14/10/91 25/10/91	0 Normal 11 Not done	Absent Not done	Absent Not done	Absent Not done	Absent Not dome
100		Reboxetine	Male	Without Urinal	08/05/92	08/05/92	-	Screen	08/05/92	1 Not done Not done Not done Not done	Not done	Not done	Not done	Not done
101		Reboxetine	Female	Rithout Urinal	02/07/92	26/08/92	55	Screen Day 28	02/07/92 30/07/92	1 Normal Not done Not done Not done 29 Not done Not done Not done	Not done Not done	Not done Not done	Not done Not done	Not done Not done

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PRARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listiag No.: 19.0

					Treatme	Treatment period				Urinal	Urinalysis test			
Centre	Centre Pationt Treatmen	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date ()	Specific (*) gravity	Albumin	Sugar	RBC	WBC
	101	Reboxetine	Female	Without Urinal	02/07/92	26/08/92	8	Day 56	27/08/92	57 Not done Not done Not done Not done	Not done	Not done		Not done
	102	Fluoxetine	Female	Only screening	10/07/92	03/09/92	35	Screen Day 28 Day 56	10/07/92 07/08/92 04/09/92	1 Normal 29 Not done 57 Normal	Absent Not done Not done	Absent Absent Absent Not done Not done Not done Not done	Absent Not done Absent	Present Not done Not done
	103	Fluoxetine	Fenale	Only screening	13/07/92	18/08/92	37	Screen Day 28	13/07/92	1 Normal Absent Absent Absent 29 Not done Not done Not done	Absent Not done	Absent Not done	Absent Not done	Absent Not done
1	104	Reboxetine	Female	Evaluated	18/08/92	05/10/92	64	Screen Day 28	17/08/92 15/09/92	0 Normal 29 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent
120	105	Fluoxetine	Kale	Without Urinal	21/08/92	15/10/92	56	Screen Day 28 Day 56	20/08/92 18/09/92 16/10/92	0 Normal 29 Normal 57 Normal	Not done Not done Not done	Not done Not done Not done Not done Not done Not done Not done	Not done Not done Not done	Not done Not done Not done
vn	129	Reboxetine	Fenale	Evaluated	29/11/91	29/12/91	93	Screen Day 28	25/11/91 26/12/91	0 Normal 28 Normal	Not done Absent	Not done Not done Present Absent Absent Absent	Present Absent	Present Absent
	130	Fluoxetine	Female	Only screening	28/02/92	23/04/92	35	Screen Day 28 Day 56	24/02/92 20/03/92 24/04/92	0 Normal 22 Normal 57 Not done	Absent Not done Not done	Absent Absent Absent Not done Not done Not done Not done	Absent Not done Not done	Present Not done Not done
	193	Reboxetine	Female	Only screening	06/12/91	31/01/92	52	Screen Day 28 Day 56	03/12/91 02/01/92 30/01/92	O Normal 28 Normal 56 Normal	Absent Not done Not done	Absent Not done	Absent Absent Not done Not done Not done Not done	Absent Not done Not done
	194	Fluoxetine	Female	Without Urinal	10/01/92	05/03/92	56	Screen Day 28 Day 56	02/01/92 07/02/92 05/03/92	0 Normal 29 Normal 56 Normal	Not done Not done Not done	Not done Not Not done Not Not done Not	Not done Not done Not done	Not done Not done Not done
	195	Fluoxetine	Male	Without screen	14/02/92	09/04/92	56	Screen Day 28 Day 56	13/02/92 13/03/92 10/04/92	O Not done Not done Not done Not done 29 Normal Absent Absent Absent 57 Not done Not done Not done	Not done Absent Not done	Not done Not done Absent Absent Not done Not done	Not done Absent Not done	Not done Absent Not done
	961	Reboxetine	Female	Without Urinal	29/05/92	16/07/92	49	Screen Day 28 Day 42	22.705.92 25.706.92 14.707.92	O Not done Not done Not done Not done 28 Normal Not done Not done 47 Not done Not done Not done Not done	Not done Not done	Not done Not done	Not done Not done Not done	Not done Not done Not done

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PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing No.: 19.0

					Treatme	Treatment period				Š	Urinalvais test	1		
į				:						ū	Specific			
Centre	Patient	Centre Patient Treatment	Nex	Patient type	Start date	End date	Days	Assessment	Date	(*) gravity	ity Albumin	n Sugar	SBC SBC	HBC
				r										
7	197	Fluoxetine	Male	Only screening	11/11/92	11/11/92	-	Screen	06/11/92	O Normal	al Absent	Absent	Absent	Absent
£	321	Fluoxetine	Female	Evaluated	14/11/91	09/01/92	53	Screen Day 28 Day 56	05/11/91 13/12/91 09/01/92	0 Not 30 Not 57 Not	Not done Absent Not done Not done Not done Absent	Absent me Not done : Absent	Absent e Not done Absent	Absent Not done Absent
	322	Reboxetine Female	Female	Evaluated	14/11/91	09/01/92	57	Screen Day 28 Day 56	06/11/91 13/12/91 03/01/92	0 Not 30 Not 51 Not	done Absent done Not done done Absent	. Absent one Not done : Absent	Absent e Not done Absent	Absent Not done Absent
1	323	Fluoxetine	Female	Evaluated	19/11/91	13/01/92	38	Screen Day 28 Day 56	30/10/91 20/12/91 23/01/92	0 Not 32 Not 66 Not	done Absent done Absent done Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
121	324	Reboxetine Fenale	Fenale	Evaluated	24/01/92	19/03/92	<b>3</b> 5	Screen Day 28 Day 56	21/01/92 19/02/92 08/04/92	0 Not 27 Not 76 Not	O Not done Absent 27 Not done Absent 76 Not done Absent	t Absent t Absent t Absent	Absent Absent Absent	Absent Absent Absent
	325	Reboxetine	Female	Evaluated	12/02/92	07/64/92	95	Screen Day 28 Day 56	14/01/92 04/03/92 07/04/92	0 Not 22 Not 56 Not	done Absent done Absent done Absent	Absent Absent Absent	Absent Absent Absent	Present Absent Absent
	326	Reboxetine	Female	Evaluated	12/02/92	07/04/92	35	Screen Day 28 Day 56	29/01/92 20/03/92 07/04/92	0 Not 38 Not 56 Not	done Absent done Present done Present	t Present nt Present nt Present	Present Absent Absent	Absent Absent Present
	327	Fluoxetine	Female	Evaluated	14/02/92	12/03/92	28	Screen Day 28	24/01/92 12/03/92	0 Not 28 Not	done Absent done Absent	t Absent t Absent	Absent	Absent Present
,	328	Fluoxetine	Female	Evaluated	19702792	14/04/92	35	Screen Day 28 Day 56	07/02/92 24/03/92 21/04/92	O Not done 35 Normal 63 Not done	Not done Absent Normal Absent Not done Absent	t Absent t Absent t Absent	Absent Absent Absent	Present Absent Present
	329	Reboxetine Female	Female	Evaluated	31/03/92	27/05/92	85	Screen Day 28 Day 56	16/03/92 11/05/92 25/05/92	0 Not 42 Not 56 Not	O Not done Absent 42 Not done Absent 56 Not done Absent	t Absent t Absent t Absent	Absent Absent Absent	Absent Absent Absent

() days of treatmen

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PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/016 Listing No.: 19.0

						OKTUBLISTS	qiqi							
					Ireatme	Treatment period	I			Urin	Urinalysis test		,,,,,	
Centre	Centre Patient	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date	specific (*) gravity	ıc 7 Albumin	Sugar	RBC	HBC
;	ļ													1
5	330	Reboxetine	Male	Evaluated	21/04/92	08/06/92	63	Screen Day 28	<b>03</b> /04/92 27/05/92	O Not done 37 Not done	done Absent done Absent	Absent Absent	Absent Absent	Absent Absent
	331	Fluoxetine	Female	Evaluated	26/02/92	20/07/92	92	Screen Day 28 Day 56	08/05/92 29/06/92 06/08/92	0 Not done 35 Not done 73 Not done	done Present done Absent done Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	332	Fluoxetine Female	Fenale	Evaluated	28/07/92	24/09/92	59	Screen Day 28 Day 56	17/07/92 10/09/92 15/09/92	0 Not do: 45 Not do: 50 Not do:	done Absent done Absent done Not done	Absent Absent Not done	Absent Absent Not done	Absent Absent Not done
11	333	Reboxetine	Fenale	Evaluated	15/09/92	09/11/92	38	Screen Day 28	17/07/92 13/10/92	0 Not done Absent 29 Not done Absent	ne Absent ne Absent	Absent Absent	Present Absent	Absent Present
2 2.	334	Fluoxotine Female	Fenale	Evaluated	22/09/92	16/11/92	95	Screen Day 28 Day 56	10/09/92 21/10/92 14/12/92	O Not done 30 Not done 84 Not done	done Absent done Absent done Present	Absent Absent Absent	Present Absent Absent	Absent Present Present
	335	Reboxetine	Fenale	Evaluated	13/10/92	16/11/92	જ્ઞ	Screen Day 28	02/10/92 10/11/92	0 Not done 29 Not done	ae Absent ae Absent	Absent Absent	Absent Absent	Absent Present
21	393	Fluoxetine Female	Fenale	Evaluated	25/06/92	18/08/92	55	Screen Day 28 Day 56	26/06/92 21/07/92 28/08/92	2 Normal 27 Normal 65 Normal	Present Present Present	Absent Absent Absent	Present Absent Present	Present Abseut Present
	394	Reboxetine	Male	Hithout screen	06/07/92	31/08/92	57	Screen Day 28 Day 56	07/07/92 03/08/92 27/08/92	2 Normal 29 Normal 53 Normal	Present Absent Absent	Absent Absent Absent	Not done Not done Present	Not done Not done Present
	395	Reboxetine	Kale	Mithout screen	24/01/92	16/09/92	55	Screen Day 28 Day 56	24/07/92 20/08/92 17/09/92	1 Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Not done Present Absent	Not done Absent Present
	396	Fluoxetine	Fenale	Only screening	04/08/92	17/08/92	#	Screen	05/08/92	2 Normal	Absent	Absent	Present	Present
	497	Fluoxetine	Female	Only screening	24/02/93	21/04/93	22	Screen	26/02/93	3 Not do	3 Not done Absent	Absent	Absent	Absent

REBOXETINE - PROTOCOL 20124/016 Listing No.: 19.0 PHARMACIA CNS R&D

					Treatme	Treatment period				_	rinaly	Urinalysis test			
Centre	Centre Patient Treatm	Treatment	Sex	Patient type	Start	End date	Days	Assessment	Date	(*) Spe	Specific	Albunin	Sugar	RBC	MBC
22	497	Fluoxetine	Female	Only screening	24/02/93	21/04/93	57	Day 28 Day 56	26/03/93	31 Not 62 Not	done	31 Not done Not done 62 Not done Absent	Not done Absent	Not done Not done Not done Absent Absent Absent	Not done Not done
13	385	Fluoxetine	Female	Evaluated	14/03/92	08/05/92	92	Screen Day 14 Day 56	13/03/92 30/03/92 08/05/92	0 No 17 No 56 No	done done	O Not dome Absent 17 Not dome Not dome 56 Not dome Absent	Absent Not done Absent	Absent Present Not done Not done Absent Present	Present Not done Present
	386	Fluoxetine	Male	Only screening	24/04/92	30/04/92	7	Screen	23/04/92	O Ko	t done	O Not done Absent	Absent	Present	Present
	387	Reboxetine	Female	Without screen	18/04/92	18/05/92	31	Screen Day 28	15/04/92 01/06/92	0 No.	t done	0 Not dome Not done 45 Not dome Absent	Not done Absent	Not done Present	Not done Present
11	388	Reboxetine	Male	Mithout screen	16/03/92	11/05/92	53	Screen Day 28 Day 56	15/03/92 30/03/92 11/05/92	0 No 15 No 57 No	t done t done t done	O Not done Present 15 Not done Present 57 Not done Present	Absent Absent Absent	Present Present Not done	Not done Present Not done
23	389	Fluoxetime	Female	Without Urinal	21/07/92	23/07/92	m	Screen Day 7	20/07/92 24/07/92	ON O	t done t done	O Not done Absent 4 Not done Not done	Absent Not done	Not done Not done	Not done Not done
	390	Reboxetine	Kale	Without screen	28/05/92	22/07/92	99	Screen Day 28 Day 56	25/05/92 25/06/92 24/07/92	0 Not 29 Not 58 Not	t done t done t done	0 Not dome Absent 29 Not dome Absent 58 Not dome Absent	Absent Absent Absent	Not done Not done Absent	Not done Not done Absent
	391	Fluoxetine	Female	Without screen	11/06/92	15/07/92	32	Screen Day 28	04/06/92 10/07/92	0 No 30 No 30 No	t done t done	. O Not done Present 30 Not done Absent	Absent Absent	Not done Present	Not done Present
	392	Reboxetine	Female	Evaluated	14/08/92	27/08/92	*	Screen Day 14	13/08/92 28/08/92	0 No 15 No	t done t done	O Not done Absent 15 Not done Absent	Absent Absent	Absent Present	Absent Present
	501	Reboxetine	Male	Evaluated	02/11/92	30/12/92	89	Screen Day 28 Day 56	29/10/92 30/11/92 30/12/92	0 Not c 29 Not c 59 Not c	t done t done	done Not done done Absent done Absent	U Not done Not done Not done Present !9 Not done Absent Absent Absent !9 Not done Absent Present Not dom	Present Absent Not done	Present Absent Not done
	502	Fluoxetine Female	Female	Evaluated	03/11/92	24/12/92	52	ŭää	03/11/92 30/11/92 24/12/92	28 No 52 No	t done t done	1 Not done Absent 28 Not done Absent 52 Not done Absent	Absent Absent Absent	Present Present Present	Present Present Present

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Present Present Present Present Present Present Absent Absent Absent Absent Not dome Not dome Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Urinalysis test\_ Specific gravity Albumin S Absent Not done Not done Absent Absent Absent Absent Absent Absent 1 Not done / done done done done done done done done done done done done done Normal Normal Normal S S S Not Not Not S S S \$ \$ \$ \$ Not Not S t t 230 25/11/92 24/12/92 20/01/93 31/08/92 28/09/92 22/10/92 23/10/92 26/11/92 24/12/92 10/09/92 16/10/92 06/11/92 Date Screen Day 28 Day 56 Screen Day 28 Day 56 Screen Day 28 Day 56 Screen Day 28 Day 56 Screen Day 28 Day 56 Screen Day 28 Day 56 Screen Day 28 Day 56 Screen Day 7 Screen Day 28 Day 56 Screen Day 28 Day 56 88 28 28 23 23 22 Days 26 23 23 Treatment period End date 23/12/92 06/11/92 29/12/92 26/01/93 09/06/92 10/06/92 16/06/92 18/11/92 20/01/93 22/10/92 Start date 02/11/92 30/11/92 21/04/92 27/10/92 11/09/92 14/04/92 15/04/92 12/11/92 26/11/92 31/08/92 Evaluated Patient type Evaluated Evaluated Evaluated Evaluated Reboxetine Female Only screening Evaluated Evaluated Evaluated Only screening Female Female Female Fenale Female Female Male Male Sex Reboxetine Fluoxetine Reboxetine Reboxetine Fluoxetine Fluoxetine Centre Patient 399 503 504 505 506 507 508 521 397 398 1124 13 4

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

					Treatm	Treatment period				Urinal	Urinalvsis test			
Centre	Centre Patient	Treatment	Sex	Patient type	Start	End date	Days	Assessment	Date (	Specific (*) gravity	Albumin	Sugar	BC	KBC
] ;	:	:												
<del>4</del>	004	Fluoxetine Male	Male	Evaluated	15/05/92	11/07/92	85	Screen Day 28 Day 56	14/05/92 12/06/92 14/07/92	0 Normal 29 Normal 61 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Absent Absent
	401	Fluoxetine Female	Female	Evaluated	22/05/92	17.07.92	57	Screen Day 28 Day 56	22/05/92 19/06/92 17/07/92	1 Normal 29 Normal 57 Normal	Absent Absent Absent	Absent Absent Absent	Absent Not done Absent	Absent Not done Absent
	402	Reboxetine	Fenale	Evaluated	27/05/92	22/07/92	57	Screen Day 28 Day 56	22/05/92 24/06/92 22/07/92	0 Normal 29 Normal 57 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
11	403	Reboxetine	Female	Evaluated	29/05/92	24/07/92	52	Screen Day 28 Day 56	28/05/92 26/06/92 24/07/92	0 Normal 29 Normal 57 Normal	Absent Absent Absent	Absent Absent Absent	Absent Present Absent	Absent Absent Present
25	404	Fluoxetine Female	Female	Evaluated	16/06/92	11/08/92	57	Screen Day 28 Day 56	16/06/92 14/07/92 11/08/92	1 Normal 29 Normal 57 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	405	Fluoxetine Female	Female	Evaluated	22/06/92	18/08/92	85	Screen Day 28 Day 56	19/06/92 20/07/92 17/08/92	0 Normal 29 Normal 57 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	406	Fluoxetine Female	Female	Evaluated	30/06/92	21/07/92	22	Screen Day 21	30/06/92 21/07/92	1 Normal 22 Not done	Absent	Absent Absent	Absent Absent	Absent Present
	407	Reboxetine	Hale	Evaluated	14/07/92	24/08/92	45	Screen Day 28 Day 42	13/07/92 10/08/92 25/08/92	0 Normal 28 Normal 43 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	408	Reboxetine	Female	Roboxetine Fenale Mithout screen	04/08/92	30/09/92	85	Screen Day 28 Day 56	04/08/92 01/09/92 30/09/92	1 Not done Not done 29 Not done Not done 58 Normal Absent	Not done Not done Absent	Not done Not done Absent	Not done Not done Not done Not done Absent Present	Not done Not done Present
	509	Fluoxetine Female	Female	<b>Evaluated</b>	29/09/92	10/11/92	43	Screen Day 28	21/09/92 29/10/92	0 Normal 31 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent

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Absent Absent Not done Absent Absent Present Absent Absent Absent Absent MBC Absent Not done Absent Absent Not done Absent Absent Present Present Present Absent Present Absent Absent Absent Absent Present Absent Absent Absent Absent Absent RBC Absent Not done Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Absent Normal Not done Normal Normal Not done Normal Normal Normal 0 Normal Normal Normal Normal Normal Normal Normal 44 Normal 28 2 28 55 28 83 29 0 90 930 29 2 30 30 Ξ 21/04/92 19/05/92 16/06/92 30/09/92 29/10/92 26/11/92 02/11/92 02/12/92 29/10/92 02/12/92 04/01/93 12/02/93 12/03/93 07/04/93 10/04/92 11/11/92 Date Assessment REBOXETINE - PROTOCOL 20124/016 Listing No.: 19.0 Screen Day 28 Day 56 Screen Day 28 Day 56 Screen Day 28 Day 56 Screen Day 28 Day 56 Screen Day 28 Day 56 Screen Day 28 Day 56 Screen Day 28 Day 49 Screen Day 28 Screen Day 28 Day 56 Screen Day 42 26 26 22 23 28 26 Days ę, 80 6 8 57 17/06/92 16/06/92 Start date End date 02/06/92 11/06/92 Treatment period 05/05/93 09/04/93 10/11/92 26/11/92 10/12/92 02/12/92 29/12/92 23/04/92 12/02/93 10/03/93 08/04/92 17/04/92 22/04/92 29/09/92 30/09/92 23/10/92 03/11/92 03/11/92 Evaluated **Evaluated** Evaluated Evaluated Patient type screening Evaluated Evaluated Evaluated Evaluated Evaluated Evaluated Only Female Female Female Female Female Female Female Female Male Sex Fluoxetine Fluoxetine Reboxetine Fluoxetine Fluoxetine Reboxetine Fluoxetine Reboxetine Treatment Patient 409 410 411 412 538 539 511 512 537 509 510 1126Centre

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					Treatme	Treatment period	-			Urina	Urinalysis test			
Centre	Centro Patient Trea	Treatment	Sex	Patient type	Start date	End date [	Days	Assessment	Date (	specific (*) gravity	Albumin	Sugar	RBC	WBC
\$	412	Fluoxetine	Female	Evaluated	23/04/92	17/06/92	8	Day 28 Day 56	20/05/92 17/06/92	28 Normal 56 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent
	413	Reboxetine	Female	Evaluated	30/04/92	24/06/92	56	Screen Day 28 Day 56	22/04/92 27/05/92 24/06/92	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	414	Fluoxetine	Hale	Evaluated	02/06/92	24/01/92	26	Screen Day 28 Day 56	26/05/92 29/06/92 27/07/92	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	415	Reboxetine	Female	Evaluated	12/06/92	06/08/92	%	Screen Day 28 Day 56	04/06/92 09/07/92 06/08/92	0 Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
1127	416	Fluoxetine	Female	Evaluated	23/06/92	17/08/92	35	Screen Day 28 Day 56	19/06/92 20/07/92 17/08/92	0 Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	417	Reboxetine	Female	Evaluated	19/06/92	13/08/92	56	Screen Day 28 Day 56	11/06/92 16/07/92 13/08/92	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	418	Reboxetine	Female	Evaluated	17/07/92	10/09/92	35	Screen Day 28 Day 56	07/07/92 13/08/92 10/09/92	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	419	Fluoxetine	Female	Evaluated	16/07/92	09/09/92	35	Screen Day 28 Day 56	08/07/92 12/08/92 09/09/92	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	420	Fluoxetine	Male	Evaluated	20/08/92	14/10/92	25	Screen Day 28 Day 56	15/07/92 16/09/92 14/10/92	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
,	421	Reboxetine	Female	Evaluated	01/08/92	25/09/92	55	Screen Day 28 Day 56	24/07/92 28/08/92 25/09/92	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 19.0

PHARMACIA CNS RED

		,	Treatme	Treatment period				Urina	Urinalysis test			
Sex Patient type	-		Start date	End date	Days	Assessment	Date	Specific (*) gravity	Albumin	Sugar	RBC	MBC
Male Evaluated		ated	19/08/92	13/10/92	56	Screen Day 28 Day 56	14/08/92 15/09/92 13/10/92	0 Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
Female Evaluated	14	rted	21/08/92	15/10/92	35	Screen Day 28 Day 56	15/08/92 17/09/92 15/10/92	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
Male Evaluated	<u>w</u>	ted	21/08/92	15/10/92	35	Screen Day 28 Day 56	13/08/92 17/09/92 15/10/92	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
Reboxetine Female Evaluated	<u>m</u>	te t	02/10/92	26/11/92	98	Screen Day 28 Day 56	24709792 29710792 26711792	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
Male Evaluated	草	b	28/10/92	22/12/92	56	Screen Day 28 Day 56	20/10/92 24/11/92 22/12/92	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
Female Evaluated	百	p g	03/12/92	27/01/93	56	Screen Day 28 Day 56	25/11/92 30/12/92 27/01/93	0 Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
Male Evaluated	真	<b>T</b> 5	03/12/92	27/01/93	Š.	Screen Day 28 Day 56	25/11/92 30/12/92 27/01/93	0 Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
Female Evaluated	ig .	<b>7</b>	08/12/92	01/02/93	ζ,	Screen Day 28 Day 56	01/12/92 04/01/93 01/02/93	0 Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
Male Evaluated	g	ted	10/12/92	03/02/93	95	Screen Day 28 Day 56	29/11/92 06/01/93 03/02/93	0 Mormal 28 Mormal 56 Mormal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
Fluoxetine Female Evaluated	3	ted	18/12/92	11/02/93	56	Screen	07/12/92	0 Normal	Absent	Absent	Absent	Absent

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PHARMACIA CNS R&D
REBOXETINE - PROTOCOL 20124/016
Listing No.: 19.0

					Trestm	Treatment neriod				Urina	Urinalvsis test			
	4100400	***************************************	3	+10.1-10	Start date	End date	556	Assessment	Bata	Specific (*) gravity	Albunia	Sugar	RBC	MBC
Centro	Lactone		T COMP	odia anorani	2000				İ		- 1	•		
Ŕ	451	Fluovetine Fenale	Female	Evaluated	18/12/92	11/02/93	95	Day 28	14/01/93	28 Normal	Absent	Absent	Absent	Absent
2	į				!			Day 56	11/02/93	S6 Normal	Absent	Absent	Absent	Missing
	46.9	Dohovatina	Fomelo	Evaluated	23/12/92	16/02/93	56	Screen	15/12/92	0 Normal	Absent	Absent	Absent	Absent
	į	None and a second					;	Day 28	19/01/93	28 Normal	Absent	Absent	Absent	Absent
*								Day 56	16/02/93	56 Normal	Absent	Absent	Absent	Absent
	į		į	To de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la constitución de la cons	40/04	45.03.00	ŭ	100	59/14/83	[ Mores	Absent	Absent	Absent	Absent
	ŧ,	FIUOXOLIUG	nare	PAGITACEA	56 /10 /61	200	3	Day 28	15/02/93	28 Normal	Absent	Absent	Absent	Absent
								Day 56	15/03/93	56 Normal	Absent	Absent	Absent	Absent
		;		,			1		00,000	4 - 3		44	Abresset	+ accord
9	429	Fluoxetine Female	Female	Evaluated	26/03/92	26/60/02	å	Date 28	72/03/92	28 Morma?	Absent	Absent	Absent	Present
								Day 56	20/02/92	56 Normal	Absent	Absent	Absent	Present
	430	Reboxetine	Male	Evaluated	30/03/92	25/05/92	57	Screen	26/03/92	0 Not done	0	Absent	Present	Present
1								Day 28	27/04/92	29 Normal	Absent	Absent	Present	Present
12								nay se	25/69/67	TPICION /C				
2 9	403	100	5	Feedund	24/03/02	25/05/92	ž	Srreen	26/8/192	0 Normal	Absent	Absent	Absent	Present
)	ş	Reduxeting		100 00100	1		3	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	Female	Evaluated	31/03/92	25/05/92	26	Screen	26/03/92	0 Not done	ø	Absent	Absent	Present
								Day 28 Day 56	25/04/92	28 Normal	Absent	Absent	Absent	Present
								ï						
	433	Reboxetine Female	Female	Evaluated	02/04/92	27/05/92	35	Screen	28/03/92	0 Normal	Absent	Absent	Absent	Present
	<u> </u>							Day 28	29/04/92	28 Normal	Absent	Absent	Absent	Present
								Day 56	26/50//2	De Normal	Absent	Absent	ADSBUC	Lesenic
	3	:			667.767.00	04,000,000	ä		06/04/02	Louis	Absont	Absont	Absent	Present
	#3#	FINOXetine		EVALUATEU					04/05/92	28 Normal		Absent	Absent	Present
					,			Day 56	01/06/92	56 Normal		Absent	Absent	Present
	435	Reboxetine Female	Female	Evaluated	14/04/92	08/06/92	26		09/04/92	0 Normal		Absent	Absent	Present
								Day 28	11/05/92	28 Normal	Absent	Absent	Present	Present
								Day So		100,100			,	

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PHARMACIA CMS RED REBOXETINE - PROTOCOL 20124/016 Listing No.: 19.0

					Treatme	Treatment period				Urinal	Urinalysis test				
Centre	Pationt	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date (	Specific (*) gravity	Albunin	Sugar	RBC	MBC	
16	436	Fluoxetine		Female Only screening	24/04/92	18/06/92	56	Screen	20/04/92	O Normal	Absent	Absent	Absent	Present	
	437	Reboxetine	Female	Evaluated	30/04/92	24/06/92	28	Screen Day 28 Day 56	24/04/92 27/05/92 24/06/92	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Present Present	
	438	Fluoxetine	Female	Evaluated	20/05/92	18/06/92	30	Screen Day 28	15/05/92 16/06/92	O Normal 28 Normal	Absent Absent	Absent Absent	Absent Absent	Present Present	
	439	Fluoxetine	Female	Evaluated	20/02/92	14/07/92	56	Screen Day 28 Day 56	15/05/92 16/06/92 14/07/92	D Normal 28 Mormal 56 Mormal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	
11	440	Reboxetine	Female	Mithout screen	01/07/92	25/08/92	99	Day 56	25/08/92	56 Normal	Absent	Absent	Absent	Present	
130	441	Fluoxetine	Female	Evaluated	22/07/92	14/09/92	ð.	Screen Day 28 Day 56	13/07/92 17/08/92 14/09/92	O Normal 27 Normal 55 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	
	2442	Reboxetine Female	Fomale	Evaluated	22/07/92	14/09/92	55	Screen Day 28 Day 56	14/07/92 17/08/92 14/09/92	O Normal 27 Normal 55 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	
	443	Fluoxetine	Male	Evaluated	25/08/92	18/10/92	SS	Screen Day 28 Day 56	20/08/92 21/09/92 19/10/92	0 Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Present	Present Present Present	
	444	Reboxetine Female	Female	Evaluated	25/08/92	19/10/92	58	Screen Day 28 Day 56	20/08/92 21/09/92 19/10/92	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	
	445	Reboxetine	Male	Evaluated	18/09/92	12/11/92	26	Screen Day 28 Day 56	12/09/92 15/10/92 12/11/92	D Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Present	Present Present Present	
	446	Fluoxetine Female	Female	Evaluated	18/09/92	12/11/92 56 Scree	35 j	Screen	12/09/92	O Normal	Absent	Absent	Absent	Present	
						1407	1	7 10 10 10 10 10 10 10 10 10 10 10 10 10							

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						Treatme	Treatment period				Urinal	Urinalysis test				
Centre		Patient Treatment	Sex	Patient type		Start date	End date	Days	Assassment	Date (	Specific (*) gravity	Albumin	Sugar	RBC	HBC	
91	446	Fluoxetine	Female	Evaluated	rted	18/09/92	12/11/92	8	Day S6	12/11/92	56 Normal	Absent	Absent	Absent	Present	
	447	Fluoxetine	Male	Evaluated	rted	18/09/92	12/11/92	35	Screen Day 56	12/09/92 12/11/92	O Normal 56 Normal	Absent	Absent Absent	Absent Absent	Present Present	
	448	Reboxetine	Female	Evaluated	ated	19/09/92	13/11/92	36	Screen Day 28 Day 56	14/09/92 16/10/92 13/11/92	0 Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Present Present Present	Present Present Present	
	455	Fluoxetine	Fenale	Evaluated	ated	19/09/92	13/11/92	56	Screen Day 28 Day 56	14/09/92 16/10/92 13/11/92	0 Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	
1	456	Reboxetine	Male	Evaluated	ated	16/12/92	09/02/93	56	Screen Day 28 Day 56	09/12/92 12/01/93 09/02/93	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	
131	457	Fluoxetine	Female	Evaluated	ated	16/12/92	09/02/93	8	Screen Day 28 Day 56	09/12/92 12/01/93 09/02/93	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	
	458	Fluoxetine	Female	Evaluated	ated	16/12/92	09/02/93	28	Screen Day 28 Day 56	09/12/92 12/01/93 09/02/93	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	
	459	Reboxetine	Male	Evaluated	ated	22/12/92	15/02/93	92	Screen Day 28 Day 56	17/12/92 18/01/93 15/02/93	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	
	,	Reboxetine	Nale	Evaluated	ated	22/12/92	15/02/93	56	Screen Day 28 Day 56	17/12/92 18/01/93 15/02/93	O Normal 28 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Present Present Present	
81	25	Fluoxetine	Female	Evaluated	lated	06/10/92	30/11/92	98	Screen Day 28 Day 56	30/09/92 03/11/92 01/12/92	O Not done 29 Normal 57 Normal	a Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	
	56	Reboxetine Female	Fenale	Evaluated	ated	06/10/92	30/11/92	35	Screen	30/09/92	O Normal	Absent	Absent	Absent	Absent	

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PHARMACIA CMS R&D BOXETINE - PROTOCOL 20124/016 Listing No.: 19.0

						URINALYSIS	ISIS							
					Treatme	Treatment period				Urinal	Urinalysis test			
Centro	Centro Patient Treatm	Treatment	Sex	Patient type	Start date	End date	Days	Assessment	Date (	Specific (*) gravity	Albumin	Sugar	RBC	KBC
81	26	Reboxetine	Female	Evaluated	06/10/92	30/11/92	35	Day 28 Day 56	03/11/92 01/12/92	29 Normal 57 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent
	7.2	Reboxetine	Female	Evaluated	06/10/92	30/11/92	56	Screen Day 28 Day 56	30/09/92 03/11/92 01/12/92	O Normal 29 Normal 57 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	2 <b>8</b>	Fluoxetine	Female	Evaluated	06/10/92	02/11/92	28	Screen Day 28	30/09/92 03/11/92	0 Normal 29 Normal	Absent Absent	Absent Absent	Absent Absent	Absent Absent
	29	Reboxetine	Hale	Evaluated	06/10/92	30/11/92	95	Screen Day 28 Day 56	30/09/92 03/11/92 01/12/92	0 Normal 29 Normal 57 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
113	30	Fluoxetine	Female	Evaluated	07/10/92	01/12/92	26	Screen Day 28 Day 56	30/09/92 04/11/92 01/12/92	0 Normal 29 Normal 56 Normal	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
2	33	Reboxetine	Female	Only screening	20/10/92	14/12/92	56	Screen Day 28 Day 56	13/10/92 17/11/92 15/12/92	0 Not dom 29 Not dom 57 Not dom	done Absent done Not done done Not done	Absent Abse Not done Not Not done Not	Absent Not done Not done	Absent Not done Not done
	82	Fluoxetine	Female	Without Vrinal	07/10/92	30/11/92	55	Screen Day 28 Day 56	05/10/92 04/11/92 01/12/92	O Normal 29 Normal 56 Normal	Not done Not done Not done	Not dome Not dome	Not done Not done Not done	Not done Not done Not done
	64	Reboretine	Female	Evaluated	17/11/92	11/01/93	28	Screen Day 28 Day 56	10/11/92 15/12/92 12/01/93	0 Not done 29 Not done 57 Not done	e Absent e Absent e Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	20	Reboxetine	Female	Only screening	17/11/92	18/11/92	8	Screen	10/11/92	0 Not done Absent	e Absent	Absent	Absent	Absent
	51	Fluoxetine	Female	Evaluated	17/11/92	11/01/93	56	Screen Day 28 Day 56	10/11/92 15/12/92 12/01/93	0 Not done 29 Not done 57 Not done	e Absent e Absent e Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
	22	Fluoxetine	rotino Female	Evaluated	17/11/92	11/01/93	98	Screen Day 28	10/11/92	O Not done Absent 29 Not done Absent	e Absent e Absent	Absent Absent	Absent Absent	Absent Absent

REBOXETINE - PROTOCOL 20124/016 Listing No.: 19.0 PHARMACIA CNS R&D

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				Treatment period	ant period_					_Urinaly.	Urinalysis test_			
e Patient	Patient Treatment	Sex	Patient type		End date	Days	Assessment	Date	(x)	Specific gravity Albumin	Albumin	Sugar	2880	#BC
52	Fluoxetine	Female	Evaluated	17/11/92	11/01/93	95	Day 56	12/01/93	57	57 Not done Absent		Absent	Absent	Absent
ន	Fluoxetins	Fenale	Evaluated	15/01/93	11/03/93	35	Screen Day 28 Day 56	29/12/92 12/02/93 15/03/93	29 1	fot done Not done Not done	0 Not done Absent 29 Not done Absent 60 Not done Not done	Absent Absent Not done	Absent Absent Absent Absent Not done Not done	Absent Absent Not done
ž	Fluoxetine	Ka19	Evaluated	12/01/93	08/03/93	35	Screen Day 28 Day 56	05/01/93 09/02/93 09/03/93	29	0 Not done Absent 29 Not done Absent 57 Not done Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent	Absent Absent Absent
23	Fluoxetine	Female	Fluoxetine Female Mithout Urimal	06/11/92	30/12/92	55	Screen Day 28 Day 56	30/10/92 04/12/92 06/01/93	629	Not done Not done Not done	Absent Not done Not done	Absent Not done Not done	O Not done Absent Absent Present 29 Not done Not done Not done 62 Not done Not done Not done	Not done Not done
22	Fluoxetine Fenale	Fenale	Only screening	12/11/92	16/12/92	35	Screen Day 28	10/11/92	33 0	Normal Not done	Absent Not done	Absent Not done	O Normal Absent Absent Present 33 Not done Not done Not done	Present Not done
<b>c</b> h	Fluoxetine	Female	Evaluated	19/10/92	13/12/92	35	Screen Day 14 Day 28 Day 56	16/10/92 02/11/92 16/11/92 14/12/92	0 15 29 57	O Not done A 15 Not done A 29 Normal A 57 Normal A	Absent Absent Absent Absent	Absent Absent Absent Absent	Absent Present Present Present	Absent Present Present Present
113	Fluoxetine	Male	Only screening	03/12/92	18/12/92	4	Screen	14/11/92	•	O Not done Absent	Absent	Absent	Absent	Absent
115	Reboxetine	Male	Only screening	29/12/92	20/01/93	23	Screen Day 28	22/12/92 27/01/93		Not done Not done	Absent Not done	Absent Not done	O Not done Absent Absent Absent 30 Not done Not done Not done Not done	Absent Not done

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			91	D.B.P. Heart Rate (mmHg) (beats/min)	89	89	89	72	*	112	8	76	8	\$ 1	5, S	8	112	9 48 9 48	£ 88	104	ì	€ 8	88	<b>3</b> %	2 82	88 76		3 68	38	25	5 8	95 95	5 5	8	9 %	•
			RATE	D.B.P. (mmHg)	8	8	8 8	3 2	8	2 2	8	2	70	2 8	35	8 8	8 1	2 %	76	70	i	2 8	80	35	2	8 8		5 5	9	8 9	8 8	6 6	75	100	<u>5</u> 8	•
			AND KEART	S.B.P. (mentig)	115	115	100	120	130	135	110	130	115	115	105	120	180	130	125	125	;	2 2	120	125	100	100 120		100	S	26 A	8 8	95 5	130	150	135	ĺ
			BLOOD PRESSURE AND HEART RATE,	Heart Rate (beats/min)	\$	\$	80 G	8					8	8	X 50	76	88	3,6	8 8	8	ì	120	88	# # 80 88	<b>*</b>	84 76	i	52	6 2	80	7.9	8 8 8 8	2 6	25:	9.5 9.6	
			BLOC 19ing.	D.B.P.	80	80	8 8	6					70	2 5	3 5	2 2	8	2 2	2 2	65	i	2 %	8	5 Z	2	9 8	:	8 6	9	8	8 8	22	2.5	6	6 5 5	:
				S.B.P. (madig)	110	110	100	2					120	120	115	12	130	120	5 5	140	;	2 2	120	125	9	190 120		5 5	105	8 5	120	5 6	120	140	145 145	
	24/016	DATES	Body	Weight (Kg)		72.00	72.00	72.00	71.90	71.90	72.00	72.00		84.00	83.00	83.10	84.30	83.30	84.00	83.50		74.20	73.80	75.00	75,50	75.00		73.00	72.30	72.00	71.60	72.00	69.50	90.50	89.70	
PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Respiratory	Rate (breaths/min)	15								12								7	=											22			
7H4	REBOXETINE Lia	VITAL SIGNS	Body	Temperature ( C)	36.80	36.80	36.40	36.80	36.60	36.70	36.50	36.70	36.60	36.60	36,40	36.90	36.80	86.98 94.98	36.50	36.60	9	37.50	36.80	36.90	36.80	36.90 36.80	;	35.80	35.80	37.10	36.80	37.00	36.60 36.60	36.40	36.90	
				Date	15/11/91	15/11/91	29/11/91	06/12/91	13/12/91	27/12/91	02/01/92	26/1.0/01	25/06/92	26/06/92	10/07/92	17/07/92	24/07/92	07/08/92	14/08/92	21/08/92	20770776	01/07/92	08/07/92	22/07/92	29/07/92	05/08/92 25/08/92		12/08/92	20/08/92	26/09/32	11/09/92	18/09/92 25/09/92	13/10/92	20/10/92	03/11/92	
				Visit	Screen	Day 0	Day 14	Day 21	Day 28	Day 42	Day 49	uay se	Screen	Day 7	Day 14	Day 21	Day 28	Day 42	Day 49	Day 56	9	Day 0	Day 7	Day 21	Day 28	Day 35 Day 56	ľ	Screen Day 0	Day 7	Day 14	Day 28	Day 35 Day 42	Screen Day 0	Day 7	Day 14 Day 21	
				Sex	Male								Kale								Toma							remate					Female			
				Treatment	Fluoxetine								Reboxetine								Fluoretine Tenele							Kenoretine remale					Fluoxetine Female			
				Centre Patient Treat	-								61								*	ì					4	r					ır,			
				Centre	-												1	1	. 3	4																

PHARMACIA CNS R&D REBOXETINE - PROTOCOL 20124/016 Listing Mo.: 20.0

\_BLOOD PRESSURE AND HEART RATE ying standing P. Heart Rate S.B.P. D.B.P. Heart Rate --- (heats/min) (mmHg) (mmHg) (beats/min) 2824 5 888888 **85 25 5** 150 130 130 130 130 130 110 1125 125 140 140 140 140 140 140 150 120 170 170 170 145 145 120 120 120 120 120 130 130 130 130 8882228888 8888 222222 7288888222 5 8 2 8 4 8 8 4 88 88 88 D.B.P. (mmHg) 222222222 100 115 115 120 115 115 150 140 140 170 120 120 120 120 120 125 125 125 S.B.P. (mmHg) 170 160 160 145 165 180 170 140 135 130 130 130 130 65.00 62.00 63.20 63.30 62.30 62.90 62.00 62.00 77.50 76.00 74.50 62.80 64.00 64.50 65.20 65.20 65.20 65.20 65.20 68.00 67.20 67.50 67.50 67.50 Body Weight (Kg) 89.20 VITAL SIGNS AND ASSESSMENT DATES Respiratory Rate (breaths/min) 9 33 17 Body Temperature ( C) 36.70 36.70 36.80 36.80 37.00 37.00 37.50 37.00 36.70 36.50 36.80 36.60 36.60 36.60 36.60 36.60 11/01/93 14/01/93 21/01/93 28/01/93 04/02/93 11/02/93 03.05.91 04.05.91 11.05.91 18.05.91 25.05.91 08.06.91 15.06.91 22.06.91 16/04/91 16/04/91 24/04/91 30/04/91 07/05/91 16/05/91 22/05/91 10/06/91 Date 10/11/92 88 Screen Day 0 Day 7 Day 14 Visit Screen Day Screen Day Day Day Day Day Day Day Day Day Scr. Day Day Day Day Day Day Scr Day Day Female Female Female Male Male Male Sex Reboxetine Reboxetine Fluoxetine Fluoxetine Fluoxetine Treatment Patient 36 츐 8 23 Centre 1135

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PHARMACIA CNS RAD
REBOXETINE - PROTOCOL 20124/016
Listing No.: 20.0

VITAL SIGNS AND ASSESSMENT DATES

						Body	Respiratory	Body		BLOC	BLOOD PRESSURE AND HEART RATE, inc	AND HEART	r RATE		
Contre	Patient	Contro Patient Treatment	Sex	Visit	Date	Temperature ( C)	Rate (breaths/min)	Weight (Kg)	S.B.P. (mmHg)	D.B.P. (mmHg)	D.B.P. Heart Rate (mmHg) (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	D.B.P. Hoart Rate (mmHg) (beats/min)	
84	38	Fluoxetine	Male	Day 21 Day 28	23/05/91	36.50		75.50	115	75	72	120	28 001	76 90	
				Day 35 Day 42	13/06/91	36.50		74.00	120	8 8	76	130 130	26 6	8	
				Day 49	20/06/91			74.50	6	2	72	130	8 8	80	
				ney 58	16/90/17			74.50	=	₹	72	<u> </u>	ę	2	
	37	Reboxetine Male	Male	Screen	01/10/91	36.50	15		120	80	80	115	88	\$	
				Day 0	07/10/91 10/10/91	36.80		65.70	120 110	8 2 8	88 76	125 115	8 8	100	
	æ	C. M. cuitomont	Š	ē.	70, 70, 87		;			8	8	į	;	•	
	3	PUTASSORT	Hall	Day D	20/06/91	36.80	2	62.50	5 5 5 5	8 8	2 2	135 25 25	2 6	7 7 8 80 8	
				Day 7	27/06/91	36.80		62.00	130	85	72	135	8	8	
				Day 14	04/07/91	36.80		61.00	140	8 1	<b>%</b> i	130	8	76	
1				Day 27	16//0/11	36.80		60.00	135	8 1	₹ (	135	8	* 1	
1				Day 35	25/07/91	36.80		58.30	2 5	£ 2	2 89 9 9	140	8 8	9,49	
3 (				ı											
ŝ	39	Fluoxetine	Male	Screen	19/06/91	36.70	17		135	96	9	120	8	88	
				Day 0	19/06/91	36.70		68.50	135	90	9	120	90	88	
	;														
	0	Reboxetine	Male		05/06/91	36.40	17		145	8 s	86 (	120	50.0	124	
				Day 7	13/06/91	36.00		79.20	55.	55	98 76	120	£ 5	120	
				Day 14	20/06/91	36.10		78.80	140	90	72	110	98	108	
				Day 21	27/06/91	36.50		79.40	135	95	76	110	8	116	
	41	Fluoxetine Male	Male	Screen	11/02/92	36.00	4		145	Ą	84	130	ą	84	
				Day 0	13/02/92	36.00	:	72.00	145	6.0	. 48	120	8	. 2	
				Day 7	20/02/92	36.80		72.00	136	8	9	125	8 8	8	
				Day 14	27/02/92	36.80		72.00	130	80	72	115	8	80	
				Day 21	05/03/92	36.80		72.00	125	70	<b>9</b>	120	80	72	
				Day 28	12/03/92	36.00		71.00	115	8 8	2.5	105	2 3	<b>7</b>	
				Day 42	26/03/6/			2.5	3 5	2 8	2 6	130	₹ 8	3 62	
				Day 49	02/04/92			71.90	120	8 8	22	35.	2 %	1 6	
				Day 56	09/04/92			72.50	130	85	8	140	8 8	72	
	45	Reboxetine	Femals	Scre	04/03/92	36.40	16		110	75	09	96	20	80	
				Day 0	12/03/92	36.80		65.50	120	8 8	225	8 8	2 5	8	
					19/03/92	36.20		66.50	120	8 8	9 99	8 5	2 8	96	

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			ğ	D.B.P. Heart Rate (mmHg) (beats/min)	2/6	116	72	96	92	8	8	26	92	96	× 82	88	100	88		100	100	3 5	8 %	8	72	100	86	8 7	\$ 6	2 8	65	96	92	ā	22	100	22	. 6	68	ŧ	4	8
			RATE	D.B.P. (mmHg)	8	2	8	<b>60</b> F	2 2	98	8	75	<b>8</b>	2 8	3.5	23	80	S		95	95	705 85	3 5	9	86	8	100	<u></u>	2 8	8 8	8	8	8	8	06	6	8 6	8	95	8	8 5	2
			AND HEART	S.B.P. (mmHg)		100	100	120	22	140	140	115	105	115	19	105	125	120		150	150	140	9	130	120	<b>1</b> 20	140	140	110	120	115	100	125	120	120	120	120	140	135	135	120	2
			BLOOD PRESSURE AND HEART RATE, ving	Heart Rate (beats/min)	76	80	89	72	8 %	80	88	72	8	26	26	80	84	9/		96	96 ;	4 4	8 6	76	;	2	96	8 8	\$ 8	8 8	88	80	98	8	9	8	9	9	26	99	80 (	9
			BLO	D.B.P. (mmBg)	96	8	2	2 8	2 8	8	8	35	8	8	8 8	8	90	80		95	95	35	1 1	2 6	1	60 50	75	75		5.5	2 2	75	8	7.	6	06	10.0	6	100	96	95	2
				S.B.P. (mnHg)	115	135	115	120	120	125	125	120	110	E 5	120	35	135	130		140	140	130	125	115	:	100	115	115	5 5 5	136	2 2	105	120	115	125	130	145	140	150	135	<del>1</del>	20.
	24/016	DATES	Body	Weight (Kg)	66.20	66.40	67.00	67.00	69.00		72.10	72.30	70.90	72.10	71.00	70.30	71.10	70.90			71.70	71.70	25.17	71.00	70.60	70.60		63.50	63.90	64.30	63.90	64.10	63.90	63.70		80.50	79.40	79.90	79.60	81.00	80.00	JE. F8
PHARMACIA CHS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Respiratory	Rate (breaths/min)						26	ì									20							20								11	•						
PRI	REBOXETINE Lis	VITAL SIGNS	Body	Temperature ( C)	36.80	36.90	36.50	36.30	36.10	37.50	37.50	37.30	37.30	37.40	37.60	37.40	37.10	37.20		37.00	37.00						36.40	36.40							37.70	37.70	36.40	36.60	36.60	36.60	36.60	30.40
				Date	26/03/92	02/04/92	09/04/92	16/04/92	30/04/92	19/11/91	19/11/91	26/11/91	03/12/91	10/12/91	24/12/91	31/12/91	07/01/92	14/01/92		13/12/91	13/12/91	20/12/91	03/01/92	10/01/92	17/01/92	24/01/92	10/09/92	10/09/92	26/60//1	01/10/92	08/10/92	15/10/92	22/10/92	29/10/62	24/03/92	25/03/92	01/04/92	08/04/92	15/04/92	22/04/92	29/04/92	26/00/90
				Visit					Day 56	Screen	Day 0	Day 7	Day 14	Day 21	Day 25	Day 42	Day 49	Day 56							Day 35		Screen	. Day .	Day 7	Day 21	Day 28	Day 35	Day 42	Day 49	Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 35	May 46
				Sex	Female					tine Female										Male							Female								Female							
				Centre Patient Treatment	Reboxetine					Reboxetine										Fluoxetine							Reboxetine Female								Fluoxetime							
1				Patient	42					43										#							45								4.7							
				Centre	М													-	1 1	. 3	7																					

						PR	PHARMACIA CNS R&D								ιΩ
						REBOXETIN Li	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	124/016							
						VITAL SIGN	VITAL SIGNS AND ASSESSMENT DATES	T DATES							
						Body	Respiratory	Body		BLO 1ying	BLOOD PRESSURE AND HEART RATE.	AND HEART	r RATE standing	19.	
Centre	Patient	Centre Patient Treatment	Sex	Visit	Date	Temperature ( C)	Rate (breaths/min)	Keight (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)	
N	4.	Fluoxetine	Fenale	Day 49 Day 56	13/05/92 20/05/92	36,30 36,40		81.20 80.50	130 130	100 85	56	140 125	100 90	72	
	48	Reboxetine	Fenale	Scre Day	18/05/92 19/05/92 26/05/92	36.20 36.20 36.30	16	52.30	125 125 150	95	96 69 9 98 89 9	110 140	100	112 112 404	
				Day 21 Day 28 Day 35 Day 42 Day 49	02/06/92 09/06/92 16/06/92 33/06/92 07/07/92	36.50 36.50 36.50 36.70 36.70		51.60 51.90 50.90 53.20 69.50	155 135 120 120 170 170	8 8 8 <u>6</u> 6 8 6 7	2 8 8 2 2 E 3 2 8 8 3 3 5 E 3	135 135 140 125 115	3. 26 1 1 2 2 2 5 C 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	700 100 100 700 700 700 700	
1138	8	Fluoxetine	Kale	Screen Day 0 Day 7 Day 14 Day 21 Day 21 Day 35 Day 45	15/01/93 15/01/93 22/01/93 05/02/93 12/02/93 19/02/93 26/02/93 05/03/93	36.80 36.80	20	128.00 118.00 117.00 118.00 119.00 119.00	160 140 110 120 130 115	888888888888888888888888888888888888888	84 7 7 6 8 4 7 7 8 8 7 7 6 8 8 7 7 8 7 7 8 7 7 8 7 7 7 8 7 7 7 8 7 7 7 8 7 7 7 8 7 7 8 7 7 8 7 7 8 7 8 7 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7	150 160 120 120 125 125 125	* * * * * * * * * * * * * * * * * * * *	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	
ø	ହୁ	Fluoxetine Femalo	Femalo	Day yell bay yell bay bay bay bay bay bay bay bay bay bay	12/03/93 11/10/91 15/10/91 22/10/91 05/11/91 19/11/91 03/12/91	. 36.50 36.40 36.40 37.70 37.70 37.70 36.90	50	64.50 64.50 64.50 64.50 65.70 65.00 65.00 65.60	120 120 120 120 120 120 120 120	880 200 200 880 880 880 880 880 880 880	68 2 7 8 8 7 7 8 8 8 9 7 7 8 8 8 8 8 8 8 8 8	120 120 110 110 100 95 100 100 115	25 20 20 20 20 20 20 20 20 20 20 20 20 20	2	
	99	Fluoxetine Female	Fenale	Screen Day 0 Day 7 Day 14 Day 21	11/10/91 15/10/91 22/10/91 29/10/91 05/11/91	36.90 36.90 36.90 37.00	5	65.70 63.80 63.50 63.50	120 120 120 130	8 2	84 76 92 96 96	110 120 120 120	80 80 80 80 80	88 92 100 92	
	29	Reboxetine	Female	Screen Day 0	14/11/92 18/11/92	36.20 36.20	. 61	73.30	120 120	88 80	79 99	120 120	95	72	

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						VITAL SIGN	VITAL SIGNS AND ASSESSMENT DATES	T DATES						
							•			BLO	BLOOD PRESSURE AND HEART RATE	AND HEART	r RATE	
	:		4	:		Body Temperature		Body	S.B.P.	D.B.P.	Heart Rate	S.B.P.	Standing D.B.P. H	ng Neart Rate
Centre	Patient	Centre Patient Treatment	Sex	Visit	Date	G .	(breaths/min)	(Kg)	- 1		(beats/min)	- 1	(mmHg)	(beats/min)
œ	62	Reboyetine	Series 6	Patr	25/11/92	36 50		20.20	6,1	Ę	ž	9	Č	γα
ı	ì				02/12/92	36.60		72.40	12.5	2 8	2.2	110	3 8	; <u>;</u>
				Day 21	09/12/92	36.10		73.20	19	8	68	100	2	96
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	e e	Rehovetine	elemol enitavo		26/41/02		ř		60	5	S	-	ā	8
	}				30/11/92		5	57.00	130	8 8	8	2	8 6	8 %
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				Day 14	14/12/92			54.40	120	75	9	100	75	88
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				oy Ken	40, 14, 34			99.60	3	2	â	2	₹	R
4	44	Rebovetine Female	Female		19/06/91	36.40	ţ					14	S	120
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				Day 14	_	36.60		62.10	100	9	75	80	9	80
				Day 21		36.90		61.70	100	9	75	95	2	80
1				Day 28		36.40		62.10	100	<b>9</b> (	<b>8</b> :	95	2 6	32
1				S S	26/05/91	37.40		62.50	8 ‡	9 5	3.5	35	2 8	84
3				Day 450		36.56		20.79	7	2 2	8 8	140	3 8	2 4
9				Day 56		36.50		63.00	5	2.2	8	12	75	124
	98	Fluoxetine Female	Female		23/05/91	37.60	17		140	105	104	130	100	
				Day 0		37.60		80.50	140	105	104	130	100	
				Day 7		37.20		79.80	140	8	88	140	6	96
				Day 14		36.60		79.80	140	90	108	125	<b>R</b> :	
				Day 21	E6/90/6L	38.00		77.00	125	2 6	27.	55	3 8	
				Day 20		26.90		8.7	130	2 6	021	021	3 8	
				Day 53		37.30		20.72	625	2 6	, ç	077	2 8	
				Day 49		36.70		72.70	5	8	2	13.5	2 2	
				Day 56		37.60		73.60	125	8	75	110	. <b>2</b>	
	56	Fluovetina	Female		14/10/91	36.80	ž		130	g	82	110	ď	86
	i i						2	53.90	3 2	8 8	28	19	8 8	. 45
				Day 7	22/10/91	37.60		54,40	135	8	76	110	8	8
	100	Reboxetine	Kale	Screen	08/05/92	35.60			100	52	76	100	70	104
	}			Day 0		35.60		76.30	5	2 2	92	100	2 2	104
	101	Reboxetine Female	Female	Screen	02/07/92	36.40	20		8	99	89	95	70	89
				Day 0				54.00	90	9	68	95	2	

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Column   Formal   Sex   Visit   Data   Temperature   Formal   Day   1   20.07/92   36.00   13   26.20   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   130   13	100 120 115 115	110 105 120 105	55 50 50 50 50 50 50 50 50 50 50 50 50 5	110	105	100			100	96	3	2	90	82	,	:	110	150	140	105	96	110	110	2	120	140	120	120	120	5	135	2 5	140	R		671	2 4	60.	120	190	95	S.B.P. (mmHg)	6	AND HEART				
Section   Female   Sex   Visit   Day 7   09/07/92   36.40   26.50   110   135   120   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   135   13	72 <b>68</b> 72 72 72	88 72 73 78 78 78	3 2 2 8	88	92	112	190	100	100	\$	<u>•</u>	31,	86	88				72	8	80	80	36	40	ę	76	64	72	9	36	3	8	8	Š	2	5	\$	7 6	7.5	8 8	<b>.</b>	65	Heart Rate (beats/min)		OD PRESSURE				
Coline   Formale   Extreme   Formale   Extreme   Formale   Extreme   Formale   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extreme   Extre	65 70 80 75	86 66 86 87 57 58 58 58 58 58 58 58 58 58 58 58 58 58	8 8 8	8	8	80	8 6	8 8	09	9	3	2 6	70	75	:	š	80	8	8	70	70	80	98	3	80	96	80	80	2 2	3 5	2 8	2 9	Ş	3	8	26	2 8	20 6	8	2	81	D.B.P. (mmHg)		BLO				
REBONETINE - PROTOCOL 20124   Ement   Sex   Visit   Date   Temperature   Protocol 20124   Ement   Sex   Visit   Date   Temperature   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate   Rate	120 110 120 130	120 120 110 110	120 120 120 120 120	120	100	105	5	1.	110	100	2	5 5	105	110		24	120	130	120	120	110	100	100	2	120	140	140	160	£	2	140	161	140	2	•	25	2 5	110	135	110	120			İ				
Contine   Sex   Visit   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date	78.00 77.30 77.50 78.00 78.00	79.06 78.40 78.00 77.30	79.86 78.40		£.35	53.00	32.50	52.20 82.80	52.00	52.00	51.30	24.14	51.20			20.40	58.20	57.20	57.00	57.00	57.00	58.00		97.30	67.10	67.50	67.10	68.30	68.60	9 6	89.09 89.09	90		26.20	9.5	2 :	2 5	56.70	57.00	56.50	55.50	Height (Kg)		-	3	-	2	
Tent   Sex   Visit   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date   Date				<b>36</b>										20																		ā	ţ									Rate (breaths/min)	Respiratory	4000	AND ASSESSAEM		ting No.: 20.0	
cotine Forale Day 7 Day 21 Day 22 Day 23 Day 35 Day 42 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 49 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day 40 Day	36.40 36.60 36.40 36.40	36.40 36.80 36.40 36.60	36.80 36.80 36.40	36.40	35,50	35.50	30.00	25.55	35.50	35.50	30.70	36.00	36.80	36.60	٠	20.00	36.00	35.70	35.80	35.90	35.70	35.90	36.90	36.00	36.20	35.40	35.70	35.70	35.50	35.30	35.70	35.00	25	30,00	36.00	35.75	36.20	36.00	36.20	36.70	36.40	Temperature ( C)	, and	1	TIME DIGUE		Liz	
cotine Female Day  Ectine Female Day  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine Female Screet  Exetine	04/09/92 11/09/92 18/09/92 25/09/92 02/10/92	20/08/92 28/08/92 04/09/92 11/09/92	26/08/92 28/08/92 04/09/92	20/08/92	29/09/92	22/09/92	76/60/01	15/00/02	08/09/92	01/09/92	76/90/07	25/08/22	18/08/92	17/08/92		76 (00 (1)	17/08/92	10/08/92	03/08/92	27/07/92	20/07/92	13/07/92	13/07/92	26/60/40	28/08/92	21/08/92	14/08/92	07/08/92	34/10/12	26/10/72	10/0//92	10/01/92	10/07/92	26/80//2	20/08/02	13/108/92	105/08/92	30/01/92	28/07/92	16/0/1/92	09/07/92	Date						
Treatment Sex Reboxotine Female Fluoxetine Female Reboxotine Female		Day 0 Day 7 Day 14 Day 21 Day 28														nay 33	Day 35	Day 28	Day 21	Day 14	Day 7	Day 0	Screen	Day 56	Day 49	Day 42	Day 35	Day 28	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	7	Day 0	Screen	School									Visit						
Treatment Reboxetine Fluoxetine Reboxetine														Female																		remale	Comala								Female	Sex						
		,	•	Fluoxetine										Reboxetine									Fluoxetine									rinoxetine	Flundating	•							Reboxetine	Treatment						
102 103 105 105				105										104								!	103									Z0L	10,								101	Centre Patient Irea						
1140																								0	Ĺ	l :	:														4	Centre						

<b>1</b>																																			
			9	Heart Rate (beats/min)	72	85	20	69	8	74 80	7	3 99	99	62					92	20.0	105	102	\$ 6	2 8	82	2	95	26.	9 60	82	78	4	3 45	89	82
			RATE	D.B.P. (mmHg)	22	8	88	8 4	2 (	88	ď	3 83	2	8 8	n s	3 2	9	2 6	9	6	2 6	9	9 8	2 59	2	3	09	8 9	3 3	9	9	S	2 8	9	70
			AND HEART	S.B.P. (mmHg)	95	110	100	9 5	8	19	ď	. 26	100	& :	S 6	2	8	2 8	90	8 6	£ 5	120	95	9 2	105	26	110	120	2 8	95	110	115	8	100	120
			BLOOD PRESSURE AND HEART RATE, ing	Heart Rate (beats/min)	89	\$	72	£ 8	8	72	¥	9	49	59					26	9,0	100	86	8	85 85	8	ą	85	26 1	78	78	<b>8</b>	r u	35	65	80
			BLOO	D.B.P. (mmHg)	8	2	8	8 4	2 8	S 8	Ş	2 2	20	£ (	8 6	8 8	9	65	99	6 6	2 6	9	£ 5	3 59	23	3	8	S 6	8 8	2	6	2 5	8 8	8	8
				S.B.P. (mnHg)	100	120	100	5 5	12	110	5	100	100	ē 8	2 5	5 2	95	2 0 O	100	9 9		120	9	115	110	906	120	120	95	115	105	5 5	2 2	120	120
	24/016	DATES	Body	Weight (Kg)	77.50	77.00		64.00	63.00	63.89 63.99		49.50	49.50	69.80	50.30	49.00	49.70	49.80 50.10	:	1.00	5 6	42.80	42.90	43.80	44.00	4+ · 00		49.80	49.00	48.50	47.60	49.40	20.00	49.40	
PHARMACIA CNS RED	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Respiratory	Rate (breaths/min)			12				Ş	2							30								81								20
PEA	REBOXETINE Lis	VITAL SIGNS	Body	Temperature ( C)	36.30	36.40	36.50	36.70	36.00	36.70 36.00	26	36.60	36.80	36.70	36.70	36.80	36.80	36.50	36.20	36.20	36.20	36.40	36.20	36.88	36.80	36.80	36,58	36.50	36.80	37.20	37.00	37.20	37.20	36.80	35.20
				Date	09/10/92	16/10/92	22/11/91	29/11/91	12/12/91	19/12/91 26/12/91	21/02/02	28/02/92	06/03/92	13/03/92	27/03/92	03/04/92	10/04/92	24/04/92	01/12/91	06/12/91	19/12/91	26/12/91	02/01/92	17/01/92	24/01/92	36/10/18	02/01/92	09/01/92	23/01/92	30/01/92	06/02/92	20,707,02	27/02/92	05/03/92	11/02/92
				Visit	Day 49	Day 56	Screen			Day 21 Day 28	200	Day 0						Day 49	2	o c	Day 14	Day 21	Day 28	Day 42	Day 49	nay 56	Scree	Day	Day 14	Day 21	Day 28	Day 55	Day 49	Day 56	Screen
				Sex	Male		Female				Formal o								Fenale								Female								Male
				Treatment	Fluometine		Reboxetine				Fluovetine								Reboxetine								Fluoxetine								Fluoxetine Male
				Centre Patient Treat	105		129				130	ì							193								194								195
				Centre	4		ιή									1 :	14	1	7																

ø.																																									
			B	Heart Rate (beats/min)	582	8	72	78	2	2 2	2		88	98	80		92	2	79	26		85	112	80	2 %	8 3	3 2	8	76	8 8	36	:	82	82	96	112	21.	120	116	100	120
			RATE	D.B.P. (mmflg)	8	8	8	8	2	8 8	8 8		8	8		2 5	2 5	105	119	8		9	22	8	2 4	8 8	2 &	80	8	8 F	8 8	;	70	2	45	ξ, (	9 4	5 53	45	45	65
			AND HEART	S.B.P. I	120	120	120	120	110	130	120		150	150	:	140	130	140	135	110		100	100	130	130	155	110	115	140	94C	25 140	!	100	100	70	28	2 5	2 8	2	20	28
	A ·		BLOOD PRESSURE AND HEART RATE	Heart Rate (beats/min)	æ	28	6	75	9 1	2.2	72 22		80	80	, <b>78</b>	2 8	20 8	2 8	26	26		80	96	76	9.6	0 9	26	76	72	9 2	S 8	}	¥	7.	88	88	112	6	115	96	112
			BLO 1ying	D.B.P. (mnHg)	7.0	2 2	80	8	2	8 8	8 8		110	110	105	130	185	10.5	110	8		99	20	2	2 6	0 5	8 8	8	85	8 :	8 8	}							8		
				S.B.P. (mmHg)	120	125	140	130	130	120	135		140	150	140	335	7 <del>4</del> 0	130	135	128		96	100	120	120	125	120	125	140	35	130	2	100	100	75	82	8.8	2 2	2	20	80
	34.016	DATES	Body	Weight (Kg)	00 88	87.20	86.80	87.80	85.60	84.00	87.80			85.30	84.30	83.40	83.40	50.50	81.20				44.10		79.00	23.00	78.10	76.20	75.30	75.40	75.40			44.80	44.80	44.80	45.10	26.44	44.90	45.00	44.70
PHARMACIA CNS RED	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Respiratory	Rate (breaths/min)																				19									23								
ANA	REBOXETINE Lis	VITAL SIGNS	Body	Tenperature (C)	25.00	36.50	36.50	36.50	36.40	36.80	36.80		36.50	36.50	36.80	36.50	36.70	37.20	37.20	36,50		36.50	36.50	37.00	37.00	36.80	37.10	37,50	36.80	37.00	36.70	3	36.00	37.70	36.50	36.50	36.60	35.00	36.00	36.00	36.50
				Date	46,702,709	21/02/92	28/02/92	06/03/92	20/03/92	27/03/92	10/04/92		22/05/92	28/05/92	04/06/92	11/06/92	18/06/92	25/06/92	26/19/50	16/07/92		06/11/92	10/11/92	24/10/91	14/11/91	22/11/91	05/12/91	13/12/91	20/12/91	27/12/91	10/01/92		28/10/91	14/11/91	22/11/91	29/11/91	05/12/91	15/15/91	27/12/91	03/01/92	10/01/92
				Visit		Day ~	Day 14	Day 21	Day 35	Day 42	Day 49	•	Screen	Day	Day 7	Day 14	Day 21	Day 28	Day 42	Day 49		Screen	Day 0	Screen	Day	Day 7	Day 14	Day 28	Day 35	Day 42	Day 49	ì	Screen	Day 0					Pay 42		Day S6
				Sex	1,1	0486							Female									Hale		Female									Female								
				Treatment	Cluster	FINDXCLLMG							Reboxetine Female									Fluoxetine		Fluoxetine									Reboxetine Female								
				Centre Patient	101	2							196	!								197		321									322								
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Second   17/12/27    36.00   19   19   19   19   19   19   19	Female   Sereen   31/11/27   36.00   Table   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secretary   Secreta	Sex   Visit   Date	SOVERTINE - DEPRESONS	240/961					
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Sec.   Visit   Date   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.   Co.	Sec.   Visit   Day   Complementary   Day   Complementary   Day   Complementary   Day   Complementary   Day   Complementary   Day   Complementary   Day   Complementary   Day   Complementary   Day   Complementary   Day   Complementary   Complementary   Day   Complementary   Complementary   Day   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Complementary   Compl	Sex Visit Bate    Female Screen 30/10/91	AL SIGNS AND ASSESSMENT	I DATES					
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Formula   Secretary   34/10/91   37.00   21   78.00   146   80   90   150   90   150   90   150   90   150   90   150   90   150   90   150   90   150   90   150   90   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150   150	Female Screen 39/10/91 37.00 21 78.00 145 90 90 150 90 150 90 150 90 90 90 90 90 90 90 90 90 90 90 90 90	Female Screen 30/10/91  Day 0 19/11/91  Day 1 26/11/91  Day 22 10/12/91  Day 23 17/12/91  Day 28 17/12/91  Day 28 17/12/91  Day 1 4/02/92  Day 4 07/02/92  Day 1 4/02/92  Day 4 07/02/92  Day 4 07/02/92  Day 4 07/02/92  Day 4 07/02/92  Day 4 07/02/92  Day 5 18/02/92  Day 6 13/02/92  Day 6 13/02/92  Day 6 13/02/92  Day 7 18/02/92  Day 6 17/02/92  Day 6 17/02/92  Day 7 18/02/92  Day 7 18/02/92  Day 9 11/02/92  Day 9 11/02/92  Day 9 31/03/92  Day 9 31/03/92  Day 9 14 25/02/92  Day 9 31/03/92  Day 9 14/02/92  Day 9 31/03/92  Day 9 14/03/92  Day 9 14/03/92  Day 9 14/03/92  Day 9 14/03/92  Day 9 14/03/92  Day 9 14/03/92  Day 9 14/03/92  Day 9 17/03/92  Day 9 17/03/92  Day 9 17/03/92  Day 9 17/03/92  Day 9 17/03/92  Day 9 17/03/92  Day 9 17/03/92  Day 9 17/03/92  Day 9 17/03/92  Day 9 17/03/92  Day 9 17/03/92					S.B.P. (madig)	(mallg)	Heart Kate (beats/min)
Powale   Screen   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   Colorado   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Formal Serven (1971/72) 36.70	Power Late         Evenue of Carbon Section         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Page 100         Pag	Female Screen 03/01/92  Female Screen 03/01/92  Day 28 17/12/91  Day 26 14/01/92  Day 14 07/02/92  Day 28 110.02/92  Day 28 210.02/92  Day 28 210.02/92  Day 49 13/03/92  Day 49 13/03/92  Day 14 25/02/92  Day 14 25/02/92  Day 14 25/02/92  Day 14 25/02/92  Day 14 25/02/92  Day 14 25/02/92  Day 14 25/02/92  Day 14 25/02/92  Day 14 25/02/92  Day 14 25/02/92  Day 19 31/03/92  Day 56 07/04/92  Day 56 07/04/92  Day 56 07/04/92  Day 56 07/04/92  Day 56 07/04/92  Day 56 07/04/92  Day 69 31/03/92  Day 69 31/03/92  Day 69 31/03/92  Day 69 31/03/92  Day 99 31/03/92  Day 99 31/03/92  Day 99 31/03/92  Day 99 31/03/92  Day 99 31/03/92		•			250	8 8	104
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Bay 42         2.0.0.2.92         46.10         110         76         70         112         78           Bay 42         2.0.0.2.92         36.00         46.10         115         80         80         112         78           Bay 42         16.0.0.3.92         36.00         46.10         115         80         80         105         75           Bay 42         16.0.0.3.92         36.00         46.10         115         80         80         105         75         80           Bay 1         15.0.0.2.92         37.00         66.30         95         60         78         90         55         70           Bay 1         25.02.92         37.00         66.30         95         60         88         80         55         115         70         70           Bay 4         25.02.92         37.00         66.30         95         60         88         80         55         115         70         105         80         105         80         105         80         105         80         105         80         105         105         80         105         105         105         105         105         105         105 <td>Screen 10/01/92 35.00 46.10 110 75 78 112 78 100 48.10 110 110 75 78 112 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 75 78 110 75 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 78 78 78 78 78 78 78 78 78 78 78</td> <td>Day 5.2 21/02/92 Day 49 13/02/92 Day 49 13/02/92 Day 6 14/02/92 Day 1 14/02/92 Day 1 14/02/92 Day 1 14/02/92 Day 2 14/02/92 Day 2 24/02/92 Day 49 31/02/92 Day 56 07/04/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 50 13/02/92 Day 50 13/02/92 Day 50 13/02/92 Day 60 13/02/92</td> <td>05.5</td> <td></td> <td></td> <td></td> <td>2 2</td> <td>9 5</td> <td>7 2</td>	Screen 10/01/92 35.00 46.10 110 75 78 112 78 100 48.10 110 110 75 78 112 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 110 75 78 110 75 78 110 75 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 110 78 78 78 78 78 78 78 78 78 78 78 78 78	Day 5.2 21/02/92 Day 49 13/02/92 Day 49 13/02/92 Day 6 14/02/92 Day 1 14/02/92 Day 1 14/02/92 Day 1 14/02/92 Day 2 14/02/92 Day 2 24/02/92 Day 49 31/02/92 Day 56 07/04/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 59 17/02/92 Day 50 13/02/92 Day 50 13/02/92 Day 50 13/02/92 Day 60 13/02/92	05.5				2 2	9 5	7 2
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The Female Screen 1707/92 37.00 15 65.90 95 60 78 95 50 100 85 50 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 85 100 100 100 100 100 100 100 100 100 10	The Female Screen 17,0292 37,00 65,90 95 60 78 95 70 100 85 50 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 100 85 10 100 85 10 100 85 10 100 85 10 100 85 10 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85 100 85	Day 7 14.02.92 Day 7 14.02.92 Day 14 25.02.92 Day 14 25.02.92 Day 26 10.3.03.92 Day 26 10.3.03.92 Day 49 31.03.92 Day 49 31.03.92 Day 49 31.03.92 Day 14 25.02.92 Day 14 25.02.92 Day 14 25.02.92 Day 14 25.02.92 Day 14 25.02.92 Day 15 24.03.92 Day 15 20.03.92 Day 15 20.03.92 Day 15 20.03.92 Day 15 20.03.92 Day 56 07.04.92 Day 56 07.04.92		•			116		ā
Day 1         16702/32         35.00         66.50         95         70         100         85         50         100         85         50         100         85         50         100         85         50         100         85         50         100         85         50         100         85         50         100         85         50         100         85         50         100         85         50         100         85         50         100         85         50         100         85         50         100         85         50         100         85         50         100         85         60         100         85         50         100         85         60         85         50         85         50         85         50         100         85         60         85         50         85         50         85         60         85         60         85         70         100         85         60         85         85         60         85         85         85         85         85         85         85         80         85         80         85         80         80         80         80	Day 1         1670272         37.00         66.50         95         70         100         85         90         100         85         90         100         95         60         100         85         95         70         100         95         60         100         85         95         70         100         95         60         100         85         95         70         100         95         60         100         85         95         70         100         95         60         100         85         95         70         100         95         60         100         85         95         70         100         95         60         100         95         60         100         95         60         100         95         60         100         95         60         100         95         60         100         95         60         100         95         60         100         95         60         100         95         60         100         95         60         100         95         60         100         95         60         100         95         60         100         95         60	Day 7 14702/92 Day 14 25.002/92 Day 26 10/03/92 Day 26 10/03/92 Day 26 10/03/92 Day 49 21/03/92 Day 56 07/04/92 Day 56 07/04/92 Day 14 25/02/92 Day 14 25/02/92 Day 14 25/02/92 Day 27 14/03/92 Day 28 10/03/92 Day 36 17/03/92 Day 56 07/04/92 Day 56 07/04/92 Day 56 07/04/92 Day 56 07/04/92 Day 56 07/04/92					6		22
Day 14         25/02/92         37,00         67,00         95         60         88         80         55           Day 21         25/02/92         37,00         67,00         95         60         85         82         57         11           Day 22         10/03/92         36,80         66,30         65,30         65         66         88         85         57         11           Day 42         24/03/92         36,00         66,30         65         95         60         68         85         60         88         65         11         85         60         88         60         88         60         88         60         88         60         88         60         88         60         88         60         88         60         88         60         88         60         88         60         88         60         88         60         89         88         60         89         88         60         89         88         60         80         80         60         80         80         60         80         80         60         80         80         60         80         80         80 <td< td=""><td>Day 14         25.02/92         37.00         67.00         95         60         88         80         55           Day 21         30.03/92         36.30         66.30         65.30         66.30         66.30         85         66.37         85         57         77           Day 22         30.03/92         36.30         66.30         95         66         85         85         66         85         57         71           Day 49         31.03/92         36.00         66.30         95         60         68         85         60         11           Day 49         31.03/92         36.00         66.20         80         66         86         85         60         60         11           Day 49         31.03/92         36.90         66.20         80         66         80         66         11         11         11         86         60         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11</td><td>Day 14, 25/02/92 Day 21, 02/02/92 Day 35, 10/03/92 Day 49, 21/03/92 Day 49, 31/03/92 Day 56, 07/04/92 Day 56, 07/04/92 Day 21, 03/02/92 Day 21, 03/03/92 Day 21, 03/03/92 Day 49, 31/03/92 Day 49, 31/03/92 Day 56, 07/04/92</td><td>50.5</td><td></td><td></td><td></td><td>85</td><td></td><td>112</td></td<>	Day 14         25.02/92         37.00         67.00         95         60         88         80         55           Day 21         30.03/92         36.30         66.30         65.30         66.30         66.30         85         66.37         85         57         77           Day 22         30.03/92         36.30         66.30         95         66         85         85         66         85         57         71           Day 49         31.03/92         36.00         66.30         95         60         68         85         60         11           Day 49         31.03/92         36.00         66.20         80         66         86         85         60         60         11           Day 49         31.03/92         36.90         66.20         80         66         80         66         11         11         11         86         60         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11	Day 14, 25/02/92 Day 21, 02/02/92 Day 35, 10/03/92 Day 49, 21/03/92 Day 49, 31/03/92 Day 56, 07/04/92 Day 56, 07/04/92 Day 21, 03/02/92 Day 21, 03/03/92 Day 21, 03/03/92 Day 49, 31/03/92 Day 49, 31/03/92 Day 56, 07/04/92	50.5				85		112
Day 21 103/03/92 36.80 66.40 95 60 85 82 57 100/03/92 36.80 66.40 95 66.40 95 60 85 82 57 100/03/92 36.70 66.30 66.30 85 55 82 85 65 10 100/03/92 36.60 66.30 95 66.30 85 55 82 85 65 10 100/03/92 36.60 66.30 100 65 55 85 82 85 65 10 100/03/92 37.00 66.30 100 65 95 92 85 65 11 100/03/92 36.90 66.20 80 60 80 80 80 80 80 80 80 100/03/92 36.90 86.50 130 75 92 130 70 11 100/03/92 36.90 85.10 110 70 95 1130 70 95 1130 70 110 110 110 110 110 110 110 110 110	Day 21 03/03/92         36.80         67.00         95         60         85         87         77           Day 22 1 03/03/92         36.80         66.40         95         60         95         85         85         85         95         60         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         65         10         95         95 </td <td>Day 21 03/03/92 Day 28 10/03/92 Day 49 28 17/03/92 Day 49 22/03/92 Day 46 07/04/92 Day 56 07/04/92 Day 14 25/02/92 Day 14 25/02/92 Day 14 25/02/92 Day 24 03/03/92 Day 35 17/03/92 Day 56 07/04/92 Seroen 23/01/92 Day 56 07/04/92 Day 56 07/04/92</td> <td>200</td> <td></td> <td></td> <td></td> <td>8</td> <td></td> <td>76</td>	Day 21 03/03/92 Day 28 10/03/92 Day 49 28 17/03/92 Day 49 22/03/92 Day 46 07/04/92 Day 56 07/04/92 Day 14 25/02/92 Day 14 25/02/92 Day 14 25/02/92 Day 24 03/03/92 Day 35 17/03/92 Day 56 07/04/92 Seroen 23/01/92 Day 56 07/04/92 Day 56 07/04/92	200				8		76
Day 28 10/03/92         10/03/92         36.80         66.40         90         60         92         85         65         10         65         10         65         30         65         65         60         68         65         60         68         65         60         68         65         60         68         65         60         68         65         60         68         65         60         68         65         60         68         65         60         68         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60 <t< td=""><td>Day 28 10/03/92 36.80         10/03/92 36.80         66.40         90 60         92 85         65 95         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         &lt;</td><td>Day 26 10/63/92 Day 42 17/03/92 Day 42 24/03/92 Day 5 07/04/92 Day 5 07/04/92 Day 1 18/02/92 Day 1 18/02/92 Day 2 1 10/03/92 Day 2 1 03/03/92 Day 2 1 03/03/92 Day 5 07/04/92 Day 5 07/04/92 Day 5 07/04/92 Day 5 07/04/92</td><td>90</td><td></td><td></td><td></td><td>82</td><td></td><td>75</td></t<>	Day 28 10/03/92 36.80         10/03/92 36.80         66.40         90 60         92 85         65 95         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         10 85         <	Day 26 10/63/92 Day 42 17/03/92 Day 42 24/03/92 Day 5 07/04/92 Day 5 07/04/92 Day 1 18/02/92 Day 1 18/02/92 Day 2 1 10/03/92 Day 2 1 03/03/92 Day 2 1 03/03/92 Day 5 07/04/92 Day 5 07/04/92 Day 5 07/04/92 Day 5 07/04/92	90				82		75
bay 35         17/03/92         36.710         66.30         65         55         65         65         66         60         68         60         68         60         68         60         68         60         68         60         68         60         68         60         68         60         68         60         68         60         68         60         68         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60 <td>bay 35         17/03/32         36.710         66.30         65         55         65         65         66         69         68         60         68         60         68         60         68         60         68         60         68         60         68         60         68         60         68         60         68         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60<td>Bay 35         17/03/92           Bay 42         24/03/92           Bay 49         34/03/92           Bay 56         07/04/92           Bay 60         07/04/92           Bay 10         14/02/92           Bay 11         25/02/92           Bay 21         14/02/92           Bay 21         10/03/92           Bay 23         17/03/92           Bay 49         31/03/92           Bay 49         31/03/92           Bay 49         31/03/92           Bay 56         07/04/92           Bay 56         07/04/92           Bay 67         03/01/92           Bay 68         03/04/92           Bay 91         31/03/92           Bay 69         03/04/92</td><td>98.90</td><td></td><td></td><td></td><td>85</td><td></td><td>100</td></td>	bay 35         17/03/32         36.710         66.30         65         55         65         65         66         69         68         60         68         60         68         60         68         60         68         60         68         60         68         60         68         60         68         60         68         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60 <td>Bay 35         17/03/92           Bay 42         24/03/92           Bay 49         34/03/92           Bay 56         07/04/92           Bay 60         07/04/92           Bay 10         14/02/92           Bay 11         25/02/92           Bay 21         14/02/92           Bay 21         10/03/92           Bay 23         17/03/92           Bay 49         31/03/92           Bay 49         31/03/92           Bay 49         31/03/92           Bay 56         07/04/92           Bay 56         07/04/92           Bay 67         03/01/92           Bay 68         03/04/92           Bay 91         31/03/92           Bay 69         03/04/92</td> <td>98.90</td> <td></td> <td></td> <td></td> <td>85</td> <td></td> <td>100</td>	Bay 35         17/03/92           Bay 42         24/03/92           Bay 49         34/03/92           Bay 56         07/04/92           Bay 60         07/04/92           Bay 10         14/02/92           Bay 11         25/02/92           Bay 21         14/02/92           Bay 21         10/03/92           Bay 23         17/03/92           Bay 49         31/03/92           Bay 49         31/03/92           Bay 49         31/03/92           Bay 56         07/04/92           Bay 56         07/04/92           Bay 67         03/01/92           Bay 68         03/04/92           Bay 91         31/03/92           Bay 69         03/04/92	98.90				85		100
Day 42         24/03/92         36.60         66.80         95         60         68         85         50         10           Day 42         24/03/92         36.60         66.20         80         66         80         66         10         66         10         66         10         66         10         66         10         10         66         10         10         66         10         10         66         10         10         66         10         10         66         10         10         66         11         10         10         66         11         10         10         66         11         10         10         66         11         10         10         66         11         10         10         66         11         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10	Day 42         24/03/92         36.60         66.80         95         60         68         B5         50           Day 42         24/03/92         36.60         66.20         80         66.20         80         60         10         66         10         66         10         66         10         66         10         66         10         66         10         66         10         66         10         66         10         66         10         66         10         66         10         66         10         10         66         10         10         66         10         66         10         66         10         66         10         66         10         10         66         10         10         66         10         10         66         10         10         66         10         10         66         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10	Day 42 24/03/92 Day 49 31/03/92 Day 56 07/04/92 Screen 28/01/92 Day 14 25/02/92 Day 14 25/02/92 Day 28 10/03/92 Day 35 17/03/92 Day 49 31/03/92 Day 56 07/04/92 Screen 23/01/92	7.30				88		*
Day 56         07/04/92         36.20         66.30         100         65.20         80         60         80         60         11           Day 56         07/04/92         36.90         21         66.20         80         60         80         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60         60	Day 56         31/03/92         37.00         66.20         80         66         92         90         60           Day 56         07/04/92         36.90         21         66.20         80         66         92         90         60         10           Bay 0         11/02/92         36.90         21         86.60         130         70         92         130         70         11           Day 0         11/02/92         36.90         24         120         70         92         130         66         11           Day 1         11/02/92         36.90         25.30         120         70         96         130         65         13           Day 21         36.02/92         36.60         85.30         110         60         88         80         65         11           Day 21         36.02/92         36.60         86.60         87.70         140         65         10         65         11           Day 42         36.03/92         36.60         83.70         130         70         100         100         70         10           Day 42         37.03/92         36.70         83.70         120 <t< td=""><td>Bay 49 31/03/92 Bay 56 07/04/92 Sereon 28/01/92 Bay 1 16/02/92 Bay 21 03/03/92 Bay 21 03/03/92 Bay 35 17/03/92 Bay 49 31/03/92 Bay 56 07/04/92 Bay 56 07/04/92 Bay 56 07/04/92</td><td>22.5</td><td></td><td></td><td></td><td>88</td><td></td><td>20</td></t<>	Bay 49 31/03/92 Bay 56 07/04/92 Sereon 28/01/92 Bay 1 16/02/92 Bay 21 03/03/92 Bay 21 03/03/92 Bay 35 17/03/92 Bay 49 31/03/92 Bay 56 07/04/92 Bay 56 07/04/92 Bay 56 07/04/92	22.5				88		20
Serreen 28/01/92 36.90 21 86.60 80 60 80 60 60 60 80 80 80 60 80 80 80 80 80 80 80 80 80 80 80 80 80	Bay 56         07/04/92         36.80         66.20         80         60         80         60         80         60         80         60         80         80         60         80         80         60         80         80         60         80         80         60         80         80         60         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80         80	Serees 28/01/92 Serees 28/01/92 Day 7 18/02/92 Day 14 03/02/92 Day 21 03/03/92 Day 35 10/03/92 Day 49 31/03/92 Day 56 07/04/92 Serees 23/01/92	2.00				96		100
Screen         28/01/92         36.90         21         66.60         130         70         92         130         70         91         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70 <td>Screen         28/01/92         36.90         21         66.60         130         70         92         130         70         130         70         130         70         130         70         130         70         130         70         130         70         130         70         130         70         130         70         130         70         130         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         140         60         85         60         140         140         60         85         60         140         140         60         85         60         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140</td> <td>Screen 28/01/92 Day 0 11/02/92 Day 1 16/02/92 Day 21 25/02/92 Day 23 10/03/92 Day 24 31/03/92 Day 49 31/03/92 Day 56 07/04/92 Screen 23/01/92 Day 60 13/02/92</td> <td>6.80</td> <td></td> <td></td> <td></td> <td>99</td> <td></td> <td>48</td>	Screen         28/01/92         36.90         21         66.60         130         70         92         130         70         130         70         130         70         130         70         130         70         130         70         130         70         130         70         130         70         130         70         130         70         130         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         140         60         85         60         140         140         60         85         60         140         140         60         85         60         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140	Screen 28/01/92 Day 0 11/02/92 Day 1 16/02/92 Day 21 25/02/92 Day 23 10/03/92 Day 24 31/03/92 Day 49 31/03/92 Day 56 07/04/92 Screen 23/01/92 Day 60 13/02/92	6.80				99		48
Day 2         11/02/92         36.90         86.60         130         75         92         130         65         130         45         130         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         140         150         60         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140	Day 1         17/02/92         36.90         86.60         130         75         92         130         65           Day 7         14/02/92         36.90         36.90         85.30         120         70         96         120         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         130         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         65         140         140         60         140         65         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140         140	Day 0 11/02/92 Day 1 16/02/92 Day 21 02/02/92 Day 28 10/03/92 Day 8 17/03/92 Day 69 31/03/92 Day 66 07/04/92 Screen 23/01/92					130		100
Bay 7         18/02/92         36.90         85.30         120         70         96         120         65           Bay 1         18/02/92         36.90         85.30         120         70         96         120         65           Bay 2         16.60         36.90         85.10         110         60         100         95         170         65         60         100         95         50         10         65         60         100         95         60         10         95         60         10         95         60         10         95         60         10         95         60         10         95         60         10         95         60         10         95         60         10         95         60         10         95         60         10         95         60         10         95         60         10         95         60         10         95         60         10         96         60         10         95         60         10         95         60         10         95         60         10         95         60         10         96         60         10         96	Bay 7         18/12/92         36.90         85.30         120         70         96         120         65           Bay 14         25/02/92         36.90         85.30         120         70         96         120         65           Bay 28         10/03/92         36.60         38.70         105         60         100         95         67         10           Bay 28         11/03/92         36.60         38.70         130         65         95         65         11           Bay 28         11/03/92         36.80         38.40         130         65         95         65         11           Bay 45         24/03/92         36.80         38.70         130         65         100         60         11         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10<	Day 7 18/02/92 Day 14 25/02/92 Day 24 03/03/92 Day 35 10/03/92 Day 49 31/03/92 Day 56 07/04/92 Day 56 07/04/92		. vy 38	-		130		100
Bay 14         25/02/92         35.90         85.10         110         60         88         80         55           Day 21         93/03/92         36.60         83.70         105         60         100         95         60         10           Day 35         17/03/92         36.70         84.60         95         70         10         96         10         95         60         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10         10	Lay 14         25/102/92         36.90         36.51         110         60         88         80         55           Day 28         103/02/92         36.60         38.70         105         66         95         60         11           Day 28         103/02/92         36.60         38.70         190         65         95         60         11           Day 28         17/03/92         36.70         84.60         95         70         96         100         60         11           Day 28         17/03/92         36.80         83.70         130         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         70         100         100         70         100         100	Day 14 25/02/92 Day 21 03/02/92 Day 28 10/03/92 Day 35 17/03/92 Day 49 31/03/92 Day 56 07/04/92 Bay 56 07/04/92 Day 60 13/02/92	200	85.30	-		120		67
Day 21         03/03/92         36.60         83.70         105         60         100         95         60         110           Day 22         10.03/92         36.70         84.90         130         65         95         65         11           Day 42         24.03/92         36.30         84.90         130         70         96         100         67         11           Day 42         24.03/92         36.30         83.70         130         70         96         100         60         60         100         70         100         70         10         60         100         70         11         80         70         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         11         12         11         12         12         12         12	Day 21         03/03/92         36.60         83.70         105         60         100         95         60         11           Day 22         10/03/92         36.70         84.90         130         66         100         95         60         11           Day 42         24/03/92         36.80         83.70         130         70         160         100         70         10           Day 42         24/03/92         36.80         83.70         130         70         100         100         70         10         10         70         10         10         70         10         10         70         10         10         70         10         10         70         10         10         70         10         70         10         70         10         70         10         70         10         70         10         70         10         70         10         70         70         10         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70	Day 21 03/03/92 Day 28 10/03/92 Day 36 17/03/92 Day 49 31/03/92 Day 56 07/04/92 Screen 23/01/92 Day 0 13/02/92		25 de			8		89
Day 28         10.703/92         35.70         84.50         130         65         95         65         11           Day 28         10.703/92         35.70         84.60         95         70         96         100         60         100         60         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100	Bay 28         10.033/92         36.70         84.90         130         65         95         65         11           Bay 48         17.03/92         35.70         84.60         95         70         96         100         60         100         70         100         70         100         70         100         70         100         70         100         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70         70<	Day 21 00 00 00 00 00 00 00 00 00 00 00 00 00	27.7	22 20			6		108
Lay 35 17 (1972) 23 (1973) 25 37.20 84.60 55 70 96 100 60 100 100 100 100 100 100 100 100	Institute of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of	Day 25 17.03.92 Day 35 17.03.92 Day 69 31.03.92 Day 56 07.04.92 Screen 23.01.92 Day 0 13.02.92	20.7				8		900
Lay 52 17-0372 2, 57.20  Lay 49 31/03/92 36.80  Lay 49 31/03/92 36.80  Lay 49 31/03/92 36.80  Lay 49 31/03/92 36.80  Lay 49 31/03/92 36.80  Lay 49 31/03/92 36.80  Lay 49 31/03/92 36.70  Lay 49 31/03/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20  Lay 14 27/02/92 37.20	Lay 52 17-03-72 35.20 83.70 130 70 100 70 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Bay 35 17.05.75.2 Bay 42 24.03.92 Bay 49 31.03.92 Bay 56 07.04.92 Screen 23.01.92 Bay 0 13.02.92	200	27.78			֭֭֓֞֝֞֜֝֝֓֓֓֟֝֟		8
Lay 42 24/03/92 36.60 83.70 130 70 100 100 100 100 100 100 100 100 100	Instruction         24.02/92         36.50         83.70         130         70         100         100         70           Day 56         0.704/92         36.70         82.70         120         80         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100         100<	Lay 42 24/03/92 Day 49 31/03/92 Day 56 07/04/92 Screen 23/01/92 Day 0 13/02/92	02.7	9.00			2 5		÷
49 31/03/92 36.60 83.20 120 80 100 110 30 15 15 17 17 12 12 10 10 10 110 30 10 10 10 10 10 10 10 10 10 10 10 10 10	Bay 54         31/03/92         36.60         83.20         120         80         100         110         80         125         90         70           Bay 56         07/04/92         36.70         21         82.70         120         80         88         125         90         70           Screen         23/04/92         36.70         21         65.00         80         65         78         90         70           Bay 0         13/02/92         37.00         64.80         110         70         78         90         70           Bay 14         27/02/92         37.20         64.90         65         60         72         90         60           Bay 21         05/03/92         37.20         64.90         65         60         72         90         60	Day 49 31/03/92 Day 56 07/04/92 Screen 23/01/92 Day 0 13/02/92	0.00	93.70					2 ;
Day 56         07/04/92         36,70         82.70         120         80         88         125         90           Screen         23/01/92         36,70         21         65,00         80         65         78         90         70           Day 7         20/02/92         37,00         64,80         110         70         78         90         70           Day 14         27/02/92         37,20         65,10         80         60         60	Bay 56         07/04/92         36.70         82.70         420         80         88         125         90           Screen         23/11/92         36.70         21         80         65         78         90         70           Bay 0         13/12/92         37.00         64.80         110         70         78         90         70           Bay 14         27/12/92         37.20         64.90         66         60         60           Bay 21         65/03/92         37.20         64.90         85         60         72         90         60	Day 56 07/04/92 Screen 23/01/92 Day 0 13/02/92	9.60	83.20			2 :		5
Screen         23.01/92         36.70         21         80         65         78         90         70           Day         0.13/02/92         37.00         64.80         110         70         78         90         70           Day         7.20/02/92         37.20         64.80         110         70         78         100         60           Day         14         27/02/92         37.20         65.10         80         60         60         60	Screen         23/101/92         36.70         21         65.00         80         65         76         90         70           Day         13/102/92         37.00         64.80         110         78         78         90         70           Day         14         27/12/92         37.20         65.10         80         60         72         90         60           Day         21         65/19         85         60         72         90         60	Screen 23/01/92 Day 0 13/02/92	6.70	82.70			125		g.
Screen 23/01/92 35,70 21 80 65 78 90 70 Day 0 13/02/92 37.00 65.00 80 65 78 90 70 Day 1 20/02/92 37.00 64.80 110 70 78 100 60 Day 14 27/02/92 37.20 65.10 80 60 60	Screen 23.01792 35.70 21 80 65 78 90 70 13.02.92 37.00 65.00 80 65 78 90 70 70 13.02.92 37.00 65.00 80 65 78 100 60 13.00 13.20 65.10 80 60 72 90 60 13.21 05.03.92 37.20 64.90 85 60 72 90 60	Screen 23/01/92 Day 0 13/02/92							i
Day 0 13.702.92 37.00 65.00 80 65 78 90 70 70 13.002.92 37.00 64.10 10 70 78 100 60 13.10 10 20 70 70 70 70 70 70 60 60 13.10 70 70 70 70 70 60 70 70 70 70 70 70 70 70 70 70 70 70 70	Day 0         13.702.92         37.00         65.00         80         65         78         90         70           Day 1         20.02.92         37.00         64.80         110         70         78         100         60           Day 14         27.02.92         37.20         65.10         80         60         72         90         60           Day 21         05.03.92         37.20         64.90         85         60         72         90         60	Day 0 13/02/92					96		78
7 20/02/92 37.00 64.80 110 70 78 100 60 14 27/02/92 37.20 65.10 80 60 70 60	7         20/02/92         37.00         64.80         110         70         78         100         60           14         27/02/92         37.20         65.10         80         60         70         60           21         05/03/92         37.20         64.90         85         60         72         90         60			65.00			96		8
14 27/02/92 37.20 65,10 80 60 70 60	14         27/02/92         37.20         65.10         80         60         70         60           21         05/03/92         37.20         64.90         85         60         72         90         60	7 20/02/92	2.00	64.80			100		80
	21 05/03/92 37.20 64.90 85 60 72 90 60	14 27/02/02	2 20	0F 39			20		
	00 00 00 00 00 00 00 00 00 00 00 00 00	30,70,77					. 6		9

	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0 VIVAL SIGMS AND ASSESSMENT DATES	D.O YENT DATES		BEO	BLOOD PRESSURE AND HEART RATE	AND HEART	RATE	
Body Testment Sox Visit Date (C)	Respiratory Eato (breaths/min)	y Body Weight n) (Kg)	S.B.P. (mattg)	D.B.P. H	Heart Rate (beats/min)	S.B.P. (mmHg)	standir D.B.P. (mnHg)	standing D.B.P. Heart Rate (mnHg) (beats/min)
	- 19		95	89	9/	806	99	80
Day 0 18/02/92		49.80	95	<b>9</b>	\$	8	8	2
7 25/02/92		49.60	8 8	8 9	22	90 6	8 4	9.6
21 10/03/92		48.90	2 2	3 6	2 <b>8</b>	2 8	8	8 6
28 17/03/92		49.10	82	8	76	80	20	8
35 24/03/92		49.10	28 £	8 8	3 8	110	2 20	8 8
Day 49 07/04/92 36.80 Day 56 14/04/92 37.10		49.00	120	5.28	7.9 80 80	120	282	72 80
25/02/92	96		8	04	72	8	20	26
Day 0 31/03/92		66.80	8	40	12	80	8	26
07/04/92		66.30	5	9	26	100	2	108
14/04/92		66.90	100	70	96	95	70	88
21/04/92	0.5	66.50	<b>5</b> 2	2 5	27.8	195 8	2 2	76 84
07/05/92		65.10	8	25	96	SS	9	100
14/05/92		64.80	92	8	92	8	8	98
Day 49 21/05/92 36.50 Day 56 28/05/92 36.30		63.50 64.70	R 8	8 8	2 <b>5</b>	8 8	S 65	g \$
330 Reboxetine Male Screen 31/03/92 36.7	0 21		120	70	89	120	20	89
21/04/92		82.00	120	2 8	8 4	120	2 5	9 6
26/40/92		79.10	91.	3	2 5	2 ;	2 6	7 (
Day 14 US/US/92 S6.6U		79.40	5 5	? 5	3 5	5 5	2 8	92
19/05/92		78.10	120	2	9	100	20	: 2
26/05/92		78.50	100	8	78	100	9	76
02/06/92	0	78.40	105	20	2	8	25	98
26/90/60	-	78.30	120	70	*	110	8	78
					,			
331 Fluoxetine Female Day 0 26/05/92 36.90		56.70	8 8	8 8	. 25	8 8	28 2	22
76/90/70 /1		00.00	2 5	9 5	4 6	2 u	8 6	6 1
21 16/06/92		55.00	9	2 5	3 %	2 6	8 6	2 &
28 23/06/92		26.00	300	9	8	6	202	2
35 30/05/00		25.30	2	3	3	2	4	2 %
42 07/07/92		55.70	8 8	3	4	8	2.04	8 %
49 14/07/92		55.70	88	45	89	6	20	70
56 21/07/92	9	55.70	58	55	89	8	20	70
332 Fluoxetine Female Screen 16/07/92 36.00	3		105	9	99	110	9	20

12								
			standing D.B.P. Heart Rate (nmHg) (beats/min)	67 72 72 67 70 70	88 88 88 88 88 88 88 88 88 88 88 88 88	88 89 97 97 97 98 88 88 88 88 88 88 88 88 88 88 88 88	74 120 82 120 120 74 100	96 100 88 96
	٠		standing B.B.P. He (mmHg) (1	66 66 66 66 66 66 66 66 66 66 66 66 66	5 5 6 6 6 6 5 5 5 5 5 5 5 5 5 5 5 5 5 5	23 23 23 23 23 24 25 25 25 25 25 25 25 25 25 25 25 25 25	20 04 04 08 08 08 08 08 08 08 08 08 08 08 08 08	60 60 80 80 75
	:		AND HEART S.B.P. (maHg)	106 107 108 110 85 85 85	88 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	110 110 100 100 82 82 90 100 100	80 70 70 70 90 80	28 28 20 20 20 20 20 20 20 20 20 20 20 20 20
			BLOOD PRESSURE AND HEART RATE ing. Beart Rate S.B.P. D.B.P. ) (beats/nin) (maHg) (maHg)	66 67 70 70 67 70 70	60 87 86 87 88 88 88 88 88 88	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	27.2 88.8 88.8 8.8 8.6 9.6 9.6	8 8 9 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8
			BLO 1ying D.B.P. (mmHg)	6 6 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8		, 666 666 666 666 666 666 666 666 666 6	6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	60 65 73 73 75 75
			S.B.P. (maßg)	501 011 088 888 888	88 6 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	120 120 100 110 105 105 100 1100	88 90 70 100 100 88 80 100 100	26 26 27 26 26 26 26
	24/016	DATES	Body Weight (Kg)	55.50 55.50 55.50 53.20 53.20 53.20	64.60 64.70 64.00 64.00 64.00 64.50 65.10 66.10	72.30 70.80 70.80 70.30 70.00 68.80 68.80 68.80	56.60 57.80 56.60 56.50 56.30 56.30	44.50 44.60 42.00 41.00
PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Respiratory Rate (breaths/min)		<del>6</del>	6	22	
PH	REBOXETINI Lis	VITAL SIGNS	Body Temperature ( C)	36.50 36.70 36.50 36.00 37.00 36.50 36.50	36.70 37.00 36.70 36.60 36.60 36.90 36.90 36.90	36.60 36.50 37.10 37.00 37.00 36.70 36.50 37.00	36.60 36.50 36.50 36.50 36.50 36.50	36.80 36.40 36.40 36.40 36.40
			Date	28/07/92 04/08/92 11/08/92 18/08/92 10/09/92 17/09/92	14,07,92 15,09,92 22,09,92 29,09,92 13,10,92 20,10,92 27,10,92 03,11,92	01/09/92 22/09/92 29/09/92 06/10/92 13/10/92 27/10/92 10/11/92	29/09/92 13/10/92 20/10/92 27/10/92 10/11/92	24/06/92 24/06/92 02/07/92 10/07/92 22/07/92
			Visit	Day 0 Day 7 Day 14 Day 21 Day 35 Day 42 Day 49	Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 42 Day 42	Screen Day 0 Day 17 Day 14 Day 28 Day 28 Day 42 Day 42 Day 42 Day 45 Day 56	Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 38	Screen Day 0 Day 7 Day 14 Day 21
			Sex	Fена 1e	Fema.le	Female	xetine Female	Female
			Treatment	Fluoxotino	Reboxetine Female	Fluoxetine	Reboxetine	Fluoxetine
			Centre Patient	332	333	334	335	393
			Centre	<b>±</b>	11	45		5

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PHARMACIA CNS RED

			•																																				
			Heart Rate (beats/min)	9	8	28.5	?	86	86	25	2 2	96	76	86	7 <b>8</b>	}	88	88	98	₹ 6	386	88	84	8 8 86		92	88	90	1	86	8	78	ž	98	8 8	ŧ	82	96	06
		RATE	D.B.P. (mmEg)	4	9	<b>3</b> 6	;	70	2	8 8	8 8	70	21	23	2 5	:	80	8	8	2 5	8	70	8 1	2 2		99	2	2 6	;	20	2	75	2 1	2 8	9 %	75	75	20	84
		AND HEART	S.B.P. (mnHg)	~	8	96 8	i	125	125	100	100	105	ē ;	105	105	!	110	110	110	103	100	110	105	105 95		88	8	3 K		90	66	105	100	100	501	115	100	100	116
		BLOOD PRESSURE AND HEART RATE	Heart Rate (beats/nin)	5	2	89 33	;	36	98	<b>:</b>	98	92	82	2 8	8		80	82	82	<b>.</b>	8	80	76	2 8		ž	82	8 8		\$	98	22	2 2	B 8	3 8	?	76	ŝ	92
		BLOC	D.B.P. (mnHg)	20	2	7.5		80	8	8 8	9 5	90	25	2 2	3 2		85	8	8 5	. 5	2	75	2 2	75		75	8			80	75	8	S 5	2 %	8 8	8	75	ę	26
			S.B.P. (ranHg)	6	95	900		130	<u>8</u>	25	£ 65	130	139	<u> </u>	6		120	120	110	115	13	125	110	120 115		100	<u></u>	8		100	100	110	110	2.5	2 5	125	105	2	118
24/016	DATES	Body	Weight (Kg)	43.20	42.50	42.60 41.80		:	8.2	89.68	83,50	81,50	81.20		81.30			67.50	66.50	66.50	66.50	66.50	99,99	65.80		!	47.00	45.40			68.00	68.70	200	2.5	68.30	65.40	68.00	00.00	
REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Respiratory	Rate (breaths/min)														16									20				16									
REBOXETINE Lis	VITAL SIGNS	Body	Temperature ( C)	36.20	36.40	36.20 36.40		36.80	36.80	36.40	36.40	36.40	36.40	36.60	36,40		36.60	36.40	36.40	36.40	36.60	36.20	36.40	36.40		36.40	36.60	36.40		36.60	36.40	36.60	36.40	36.60	36.40	36.80	36.40	2	36.20
			Date	29/01/92	05/08/92	12/08/92 19/08/92		26/0/90	13/07/92	20/07/92	27/07/92	03/08/92	17/08/92	25/08/92	31/08/92		23/07/92	29/07/92	26/08/05	13/08/92	20/08/92	27/08/92	10/09/92	17/09/92		04/08/92	11/08/92	18/08/92		24/02/93	24/02/93	10/03/93	18/03/93	24/03/93	31/03/93	07/04/93	15/04/93	?	13/03/92
			Visit			Day 49 Day 56		Screen	Day o	Day 14	Day 21	Day 28	Day 42	Day 49	Day 56		×		Day 14		Day 28					Screen	Day o	Day 14		*							Day 49		Screen
			Sex	Female				Male									Hale								i	Female				Female									Female
			Centre Patient Treatment	Fluoxetine				Reboxetine									Reboxetine						,	,	:	Fluoxetine				Fluoxetine	ı								Fluoxetine
			Patient	393				394									395								į	396				497									385
			Centre	12													1	11	4	6																			13

*																											
				Heart Rate (beats/min)	06	Ŗ	96	<b>.</b>	94			88 88	;	\$ \$	8	ì	88	82 72				98	786 80	8	<b>4</b> 8	:	2 6 43 2 6 43
			설	D.B.P. (mmHg)	* 5	2 8	9 5	88	98	8	2 2	2 2	i	£ \$	2 2	89	80 c	8 <u>5</u>	83	8 8	75	96	2 S	90	88	8	268
			AND HEAR!	S.B.P. (mmHg)	116	124	145	128	125 150	160	25 25 25 25 25 25 25 25 25 25 25 25 25 2	180 178	;	14	9 £	102	105	# #	122	120	120	125	130	135	122 130	ç	120
			BLOOD PRESSURE AND HEART RATE	Heart Rate (beats/min)	88	Ŕ	4 5	2 2	8	70		<b>58</b> 66	i	78	ă,	?	8 ;	8 <b>8</b>			96	48	8 &	88	922	8	2 6 3
			BLOG 1ving	D.B.P. (mnHg)	9,2	2 8	100 8	8 8 8	90	8 8	3 2	88 6	i	7.5	2 8	8 8	<b>60</b> 5	, §	48	R &	202	8	2 2	8	2 2	č	2 2 2
				S.B.P. (mmHg)	118	136	130	122	140 145	170	5 4	180	1	126 126	112	116	125	138	126	130	120	138	135 135	135	118	;	112 081
	24/016	DATES	Body	Keight (Kg)	71.00	69.00	69.00	69.50 75.00	70.70	75.80	75.20	75.00 75.50		68.70	74.00	75.00	76.50	76.00	:	59.30	98	83.00	83.50	80.00	74.50		56.00 59.00
PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Respiratory	Rate (breaths/min)																							
Ħ	REBOXETIN	VITAL SIGN	Body	Temperature ( C)	36.20	36.40	36.50	36.00	36.70 36.40	39.00		36.50 37.10	;	36.20 36.20	25 an	37.10	36.90	36.50			37.10	36.30	35.00	36.00	36.80 36.70		36.60 36.80
				Date	13/03/92	27/03/92	10/04/92	24/04/92	22/04/92 23/04/92	15/04/92	03/05/92	11/05/92		15/03/92	22/03/92	05/04/92	12/04/92	11/05/92	19/07/92	23/07/92	27/05/92	03/06/92	18/06/92	25/06/92	09/07/92 24/07/92	00,000	11/06/92 18/06/92
				Visit				Day 42 Day 56	Screen Day 0	Screen Day 0	Day 14	Day 21 Day 28	,	Screen Day 0	Day 7	Day 21	Day 28	Day 56		gá c	Screen Day 0	Day 7	Day 21	Day 28	Day 42 Day 56	ě	Day 0
				Sex	Female				Male	Female			,	пале					Female		Male					100	
				Patient Treatment	Fluoxetine				Fluoxetine	Reboxetine				Keboxetine hale					Fluoxetine Female		Reboxetine					S. Compt.	
				Patient	385				386	387			Ş	989					389		390					500	5

			ITE.	standing D. R. D. Heart Rate	- 1			88 90 90		100 BS		85			90 96						90 70				80 80 76			20 68			000 000		80 84		80 76		84 84	
			AND BEART RA	5	(mmHg) (mm	135	135	130	!	125	12 5	125	125	125	118	6 9	120	138	120	130	130	135	130	130	120 120	į	120	120	:	115	115	128	125	130	118	118	118	CC
			BLOOD PRESSURE AND BEART RATE	Heart Date	(beats/min)			76		8 5			88				*								22			906			* 5		3.2		72		72	
				1 1 1 1 1 1	(mmRig) (b	8	28	96	!	95	2 8	8	110	92	<b>£</b> 5	¥ 5	105	100	110						2 2			2.08					5				58.5	
				a a	(mmHg)	130	\$	136 144	•	140	120	120	140	130	136	145	150	138	140	130	130	135	30.5	130	120		130	130	1	120	126	128	120	130	118	138	138	<u>.</u>
	24/016	DATES		Body	(Kg)	59.00	57.00	57.50		ě	56.10			61.00	61.00	9.5	61.00	62.00	62.00		82.00	81.00	8 6	85.00	83.00			57.00	3		29.00	9.6	59.00	58,00	58.00		84.00	82.00
PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	,	Respiratory Pate	(breaths/min)					16																												
폾	REBOXETIN	VITAL SIGN		Body	(0)	36,50	37.00	36.70	!	37.00	97.76		37.10	36.80	37.10	37.10	37.10	36.90	37.00	36.00	36.90	36.80	36.80	36.80	36.80		37.00	37.10	ì		20	37.56	37.00	36.90	36.90		36.40	
					Date	25/06/92	02/07/92	10/07/92		12/08/92	21/08/92	27/08/92	30/10/92	02/11/92	09/11/92	24/1/92	30/11/92	14/12/92	31/12/92	03/11/92	03/11/92	11/11/92	23/11/92	30/11/92	14/12/92		12/11/92	12/11/92	<u> </u>	25/11/92	26/11/92	10/12/92	24/12/92	06/01/93	20/01/93	26/08/92	31/08/92	74760710
					Visit			Day 28			Day 2				Day 7										Day 42 Day 56		2	Day 7					Day 28			- 2	Day	
					Sex	Female				Female			Kale							Female							Female			Female						Fenale		
					Centre Patient Treatment	Fluoxetine				Reboxetine			Reboxetine							Fluoxetine							Reboxetine			Fluoxetine	,					Reboxetine Female		
					Patient	391				392			501							502							503			504						505		
					Centre	€	ł												11	4	8																	

v
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7																																			
			8	D.B.P. Heart Rate (mmHg) (beats/min)	8	\$	80		<b>\$</b> \$	28	\$	98	8	%	101	- F	8	98	96	90L	2	84	48	2 88		8 8		ž	* 6	9 %	102	8 8	}	82 22	100
			RATE	D.B.P. (mmBg)	8	98	98	8 8	85 75 75	8	8	75	8 8	80	8	2 8	2 8	90	8	100	2	80	88	2 6	100	9 2 3	8	100	5 5	3 5	98	8 8	<b>:</b>	82 82 82	8
			AND HEART	S.B.P. (renHg)	126	140	130	145 120	125	12	128	120	120	125	132	132	125	140	145	150	3	125	125	135	125	125	100	146	146	125	138	130	i	122	130
			BLOOD PRESSURE AND HEART RATE	Heart Rate (beats/min)	7.2	80	72	8	87.8	80	84	<b>3</b> 8 3	8	9/	96 3	9 2	9	88	8	100 86	3	80	8 8	8 9	1	8 2		*	\$ C	7 7	8	882	i	8 8	96
			BLOG	D.B.P. (mmHg)	95	8	56	8 <b>8</b>	8 8	8 8	8	70	8 8	75	88	2	2 2	8	6	5 5	2	85	88	2 5	88	9 2 4	8	100	<u></u>	2 8	115	8 8	?	8 8	8
				S.B.P. (mmHg)	142	145	145	145 130	140	2 2	130	138	120	125	142	142	. t	145	145	145	2	130	125	2 7	124	145	5	150	150	161 261	155	138	}	126	128
	24/016	DATES	Rody	Keight (Kg)	82.00	82.00	82.00	82.00 82.00	63	66.00	99	65.00	68.00	68.00	;	62.00	62.00	62.00	;	62,00	3		91.50	92.00	91.00	91.50	92.00			2 2	71.50	71.50		58.00	58.00
PHARMACIA CNS RED	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Respiratory	Rate (breaths/min)																														12	
PR	REBOXETIN Li	VITAL SIGN	Body	Temperature ( C)	37.00	37.10	36.40	36.70 36.60	32	36.50	36,90	37.10	37.20	37.00	36.80	36.80	36.80	37.10	;	37.20			37.20	37.00	37.10	37.00		37.00		37.10	37.10	37.00	2	36.70	
				Date	14/09/92	21/09/92	28/09/92	12/10/92 22/10/92	23/10/92	04/11/92	10/11/92	18/11/92	10/12/92	24/12/92	10/09/92	10/09/92	25/89/92	02/10/92	09/10/92	29/10/92		29/10/92	02/11/92	16/11/92	25/11/92	30/11/92	31/12/92	30/11/92	01/12/92	36/31/10	30/12/92	13/01/93		14/04/92	21/04/92
				Visit				Day 42 Day 56	Screen	a Signal	Day 14	Day 21	Day 42	Day 56	Screen	Day Der: 0	Day 14	Day 21	Day 28	Day 42	Š	×				Day 28		Screen	Day	Day 1	Day 28	Day 42	ì	8	Day 7
				Sex	Female				Male						Female							Female						Male						Female	
				Treatment	Reboxetine				Fluoxetine						Fluoxetine Female							Reboretine Female						Reboxetine						Fluoxetine	
				Centre Patient	505				206						203							508						521						397	
				Centre	£	l									1	l 1	4	9	l															<b>1</b>	

								2000						
						REBOXETIN	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	947076						
						VITAL SIGN	SIGNS AND ASSESSMENT	r DATES						
						Body	Respiratory	Body		BL00	BLOOD PRESSURE AND BEART RATE	AND BEAR	r RATEstanding	- Bu
Centre	Patient	Centre Patient Treatment	Sex	Visit	Date	Temperature ( C)	Rate (breaths/min)	Keight (Kg)	S.B.P. (mnHg)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
*	397	Fluoxetine	Fenale		28/04/92	36.60		59.00	126	2	48	126	74	**
					05/05/92	36.80		59.00	120	2	80	124	21	82
					12/05/92	36.80		59.00	120	2 %	9,6	120	2 %	9 8
				Day 56	09/06/92	36.70		58.50	120	\$	7.	122	*	2 2
	398	Reboxetine	Female	Screen	15/04/92	36.60	12		110	78	7.	112	78	87
	}			Day 0	15/04/92	36.60	!	44.00	110	78	7.	112	78	78
					22/04/92	36.60		44.00	120	88	ž	122	80	86
					29/04/92	36.80		44.50	112	8	82	110	8	\$ 8
					06/05/92	36.80		14.00	41.	80 g	2 2	172	2 2	3 6
				Day 20	26/09/20	36.80		66.50	112	8 8	28	110	26	82.8
				Day 56	10/06/92	36.90		47.00	106	Ž	98	104	92	8
	4	:				;	;		ç	ŧ	6	,	6	2
1	333	Keboxetine Female	Fenale	×	13/04/92	36.80	<b>J</b>	1	120	200	2 6	- 7	2 5	2 6
11				Day 0	21/04/92	36.80		56.90	106	2 20	8 8	102	3 %	8 0 22
5					05/05/92	36.70		54.00	114	78	*	112	8	98
0					12/05/92	36.70		53.00	120	8	82	116	80	<b>\$</b> ;
					19/05/92	36.70		53.50	‡	8 8	8 6	118	8 8	9.6
				Day 42	16/06/92	36.80		53.50	124	8 8	9 60	120	8 8	<b>8</b>
	400	Fluoxetine	Male	×	14/05/92	36.70	14	;	114	\$ 6	78	116	98	82
				Day	15/05/92	36.70		20.62	<b>\$</b> _;	ž	2 2	9 5	6	2 6
					22/05/92	36.90		77.50	114	9 6	5 %		3 2	ŧ 8
					05/06/92	36.80		77.50	110	8	28	108	82	78
					12/06/92	36.70		76.00	112	8	80	110	8	80
				Day 42	25/06/92	36.80		77.00	114	3,2	76	13	8 5	80 6
					76//0/41	36.90		8.	2	ŧ	₹	2	ţ	7/
	404	Fluoxetine	Female		22/05/92		. 51		110	80	82	112	80	88
					22/05/92			51.50	110	8	82	112	8	98
				Day 7	29/05/92			51.00	116	8	78	118	80	80
				Day 14	05/06/92			52.00	114	82	76	116	<b>2</b> :	2 :
					12/06/92			52.00	110	8	76	106	2 2	22 6
					19/06/92	8.98		23.62	104	2 %	9 8	102	2 6	2 %
				Day 56	17/07/92	36.90		52.00	2 2	8	26	108	8	1.2
								,						
	402	Reboxetine	Female		27/05/92		16		114	20	20	112		
	1		:	Day 0	27/05/92	36.80		99.00	114	20	20	112	72	70

81																																			•					
			6	Heart Rate (beats/min)	89	2	\$;	4. 80	82	8	8 8	98	<b>*</b>	9 %	8	96		78	9 G	48	80	74	70		80	8 8	<b>*</b>	82	72	9,2	ţ	. 83	82	80	06	2	Ş	280	<b>3</b> 8	
			RATE	D.B.P. (mmHg)	2	76	8	8 8	80	78	78	78	8 8	90	8	2		28	2 5	72	2	20	22		9/	9 %	2 2	7,4	2 2	2 %	?	78	78	8	ŧ i	å	8	2 8	8 % 8 %	
			AND HEART	S.B.P. (mmflg)	106	19	4 5	120	116	120	120	106	<b>*</b> :	112	12	104		102	70.	102	102	104	<u>5</u> 0		2	1 1	ě	102	102	2 6	;	114	114	134	132	2	60	132	130 116	
			) PRESSURE	sart Rate beats/min)	02	7	28 8	\$ \$	9/	78	78	86	N 6	2 6	76	96		8 2	0 %	82	138	<b>#</b> 1	70		2,6	e 8	82	80	72	2,9	•	80	80	80	8 6	2	9	28	08 80	
			BLOOM	D.B.P. (mmBg)	99	26	8.8	8 8	80	3/6	76	78	8 8	€ €	8	74		99	8 5	2	21	2 1	2 2		8 8	2 2	2	9/	9 6	9	3	. 38	78	80	8 8	5	6	8	8 8	
				S.B.P. (mmHg)	104	5	120	116	124	116	116	108	116	7 12	112	110		<b>Ž</b> Ž	= =	106	40,	106	108 108		17	120	104	102	96	2 25	:	114	114	134	130	•	020	130	120	
	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	DATES	Body	Reight (Kg)	99.00	100.00	100.00	98.00	98.00		71.00	70.50	B 5	70.00	70.00	69.00		52	58.00	58.00	57.00	57.00	57.00 57.00		3	51.50	52.00	52.00	52.00	54.0			60.00	59.50	2, 26			75.00	73.00	
PHARMACIA CNS R&D		SIGNS AND ASSESSMENT	Respiratory	Rate (breaths/min)						4								2						:	<b>‡</b>							16					ŕ	!		
PH	REBOXETINE Lis	VITAL SIGNS	Body	Temperature ( C)	36.80	36.80	36.80	36.80	36.90	36.70	36.70	36.80	36.00	36.90	36.90	37.00	;	36.90	36.80	36.80	36.80	26.00	36.90	;	36.80	36.80	36.90	36.80	36.80	36.80		36.80	36.80	36.90	37,00		36.90	36.90	36.80 36.90	
				Date	03/06/92	10/06/92	26/90/42	08/07/92	22/07/92	29/05/92	29/05/92	05/06/92	19/06/92	26/06/92	10/07/92	24/03/92	,	16/06/92	23/06/92	30/06/92	07/07/92	28/10/62	11/08/92		26/90/61	29/06/92	26/01/90	13/07/92	04/08/92	18/08/92		30/06/92	30/06/92	07/07/92	21/07/92	!	13/07/92	14/07/92	27/07/92	
				Visit			Day 21			Screen	Day 0	Day 7	Bay 21	Day 28	Day 42	Day 56					Day 21		Day 56	ç				Day 21							Day 21		Screen	Day	Day 14	
				Sex	Female					Female								rema														Female					Male			
				Treatment	Reboxetine					Reboxetine Femals							Classical Contract	e renxerine						Fluoretino Continua	DUTABONT .							Fluoxetine					Reboxetine Male			
				Centre Patient	402					403							404	5						507	2							905					407			
				Centre	4												-	11	. 5	1																				

6																																						
			0	Heart Rate (beats/min)		8	ž	*	**	*	***	28	82	88		<b>8</b> 8	2 4	8	8	8 %	2	82	82	80 6	32	78	78	;	22 52	82	80	98	28	: <b>3</b>	80	80	78	80
			녛	D.B.P. (nnHg)	96	98	\$	8	8	8	\$ \$	\$ 2	*	82		8 8	2 2	\$	若	<b>8</b> 2	3	7,4	<b>%</b> i	* 6	2 28	2 2	7.5	,	96 4	8 8	8	8 %	*	8	9	62	3 8	78
			AND REART	S.B.P. (mmHg)	130	124	128	130	130	124	130	126	122	124		124	124 134	4	132	120	3	108	90 3	196	9 9	92	<u>5</u> 5	;	2,50	7 2	138	136 124	126	126	102	102	10,	114
	· ·		BLOOD PRESSURE AND REART RATE.	Heart Rate (beats/min)	78	8	99	**	*	80	280	9 8	78	8		8 3	2 22	2 8	80	78	?	84	<b>5</b> 80	B 6	28	78	78	;	2 S	82	8	<b>%</b> %	8	<b>.</b>	80	80	7,8	80
			BL00 1ying	D.B.P. (mmHg)	6	* *	¥	98	8	98	4 6	2 2	8	82		80	8 8	8	*	8 8	<u>;</u>	74	₹ ;	9 8	2 28	<b>8</b> 0 i	\$ \$		5 5	8	92	8 8	8	8	9	9	2 89	78
				S.B.P. (mnHg)	128	124	130	126	126	130	126	122	126	126		130	130	<u>4</u>	136	124	2	108	108	110	86	6	108	;	144	15	142	4 t	130	130	106	106	108 108	114
	24/016	DATES	Body	Height (Kg)	72.00	7.00	71.50		106.00	106.00	107.00	106.00	107.00	107.00		;	102.00	105,00	105.00	104.90	2		55.50	55.90	55.00	55.50	56.00		**	65.00	59.00	63.69	62.00	61.00		57.50	55.00	56.00
PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Respiratory	Rate (breaths/min)				ž	!							4						16						:	9						4			
PHA	REBOXETINE Lis	VITAL SIGNS	Body	Temperature ( C)	37.00	37.00	37.00	36.90	36.90	37.00	36.90	37.00	37.00	37.00		37.00	37.00	37.00	37.00	37.00		37.00	37.00	37.00	37.00	37.00	36.70	;	36.90	37.00	36.90	37.00	36.80	36.80	36.90	36.90	37.40	36.60
				Date	04/08/92	10/08/92	24/08/92	04/08/92	04/08/92	11/08/92	18/08/92	01/09/92	15/09/92	30/09/92		29/09/92	29/09/92	13/10/92	20/10/92	28/10/92		30/09/92	30/09/92	16/10/92	22/10/92	29/10/92	26/11/92	;	22/10/92	29/10/92	05/11/92	13/11/92	04/12/92	11/12/92	03/11/92	03/11/92	17/11/92	24/11/92
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PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	SIGNS AND ASSESSMENT DATES	Respiratory	Rate (breaths/min)		91	<b>2</b> 5	<b>4</b>	4	<b>4</b>
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time Female Screen 1976/92 36.80	25	115         75         70           120         80         68           120         80         68           120         80         68           120         80         68           120         70         66           121         75         66           122         75         66           13         80         68	70 70 70 70 80 80	AND HEART RAITE S.B.P. D.B.P. Hourt Rato (nmHg) (nmHg) (beats/min) 110 70 95 110 70 95
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Freatment Sox Reboxetine Femal Reboxetine Femal	Day	Scre Day Day Day Day Day	Scra Day Day Day Day	Visi Day Day Day
Frestrent Reboxetine Reboxetine	e Fomal			
	Reboxetine Fluoxetine	Reboxetin	Fluoxetine	Treatment   Reboxetine
Centre Patient Treats 15 415 Rebox 416 Fluox 418 Rebox 419 Fluox			416	mtre Patient 5 415

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PHARMACIA CNS R&D FTWE - PROFINCE 20124/014

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KERUXELLINE - PROJUCUL 20124/016 Listing No.: 20.0 VITAL SIGNS AND ASSESSMENT DATES

						Body	Respiratory	Body		BLOC	BLOOD PRESSURE AND HEART RATE.	AND HEAR	r RATE	2
Centre	Centre Patient	Treatment	Sex	Visit	Date	Temperature ( C)	Rate (breaths/min)	Weight (Kg)	S.B.P. (mmHg)	D.B.P. (mmBg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
5	450	Fluoxetine	Hale		09/09/92	36.70		72.00	140	8	75	130	8	82
					16/09/92	36.80		72.00	140	8 1	2 1	130	8 8	92
				Day 56	14/10/92	36.60		72.00	140	2 2	25	15 15 15 15 15 15 15 15 15 15 15 15 15 1	8 8	8 2
	421	Pehovetine	Formale	Service	00/00/90	AT 35	į		977	8	ğ	7.5	8	ă
	į				31/07/92	36.70	2	87.00	1 2	8 8	78	145	8 8	8
				Day 7	07/08/92	36.70		87.00	140	8	76	150	6	82
					14/08/92	36.60		87.00	140	6	76	140	8	82
					21/08/92	36.60		87.00	140	8	75	140	90	8
					28/08/92	36.60		87.00	140	6	75	140	96	82
					04/09/92	36.60		87.00	140	6	29	140	90	76
				Day 42	11/09/92	36.60		87.06	140	8 8	2 5	92.5	8 8	9.28
					76 160 167	20.00		8.	2	2	7	2	2	Q
1		:				;	;				;		;	;
1	422	Fluoxetine	Male		14/08/92	36.60	4	;	130	8	21 C	120	8	8
5				Day C	18/08/92	36.60		61.00	130	8 8	22 6	130	80	8
6				Day 1	25/08/92	36.70		61.00	120	3 6	2 6	120	3 6	<b>9</b> 4
				Day 21	08/09/92	36.70		00.19	120	8 8	28	130	8 8	9 6
				Day 28	15/09/92	36.80		9	120	8 8	8	120	8	9 60
				Day 42	29/09/92	36.60		61.00	120	8	8	130	2	8
				Day 56	13/10/92	36.60		61.00	120	80	78	120	8	82
	423	Fluoxetine Female	Female		15/08/92	36.60	45		110	8	68	110	80	72
				Day 0	20/08/92	36.70		58.00	110	70	99	110	70	72
				Day 7	27/08/92	36.60		57.00	120	8	99	110	80	72
				Day 14	03/09/92	36.60		56.00	120	8	99	120	80	70
				Day 21	10/09/92	36.70		55.50	120	80	99	110	80	72
				Day 28	17/09/92	36.70		54.50	110	2	\$9	110	70	9 1
				Day 42	26/01/10	36.70		20.50	120	2 6	8 7	25	2 6	2 2
				ì	2	2			071	8	3	2	3	7/
	424	Reboxetine Male	Male	Screen	13/08/92	36.60	41		120	~	2	125	8	76
				Day D	20/08/92	36.60	:	71.00	120	8	2	125	80	76
					27/08/92	36,60		71.00	120	80	72	125	85	26
				Day 14	03/09/92	36.60		71.50	120	8	72	125	80	78
				Day 21	10/09/92	36.60		72.00	120	8	2	120	8	7.4
				Day 28	17/09/92	36.60		72.50	120	80	70	120	8	74
				Day 42	01/10/92	36.60		73.00	125	80	72	125	8	9,6
				Day 56	15/10/92	36.60		73.00	120	80	72	120	8	76
	425	Reboxetine	Female	Scre	24/09/92	36.70	15		130	8	72	140	80	78
				Day 0	01/10/92	36.70		72.00	130	8	72	140	8	78

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PHARMACIA CNS R&D	:IINE - PROTOCOL 20124/016 Listing No.: 20.0

REBUNETINE - PROTOCOL 20124/016 Listing No.: 20.0 VITAL SIGNS AND ASSESSMENT DATES

						Body	Respiratory	Body		lving	ing industrial		standing	ne
Centre	Centre Patient	Treatment	Sex	Visit	Date	Temperature ( C)	Rate (breaths/min)	Weight (Kg)	S.B.P. (mmfig)	D.B.P. (mmHg)	Heart Rate (beats/min)	S.B.P. (mmHg)	D.B.P. (mmHg)	Heart Rate (beats/min)
5	425	Reboxetine	Female		08/10/92	36.70		72.00	130	8	22	130	8	32
					15/10/92	36.60		72.00	5	8	2	130	8	78
					22/10/92	36.60		72.00	140	80	72	140	8	76
					29/10/92	36.70		72.00	140	80	72	140	80	75
				Day 42	12/11/92	36.70		72.00	140	8 8	2 5	5 5	88	76
					76/11/97	36.60		27.20	<b>3</b>	3	?	346	2	9
	767	61t	1	1	007 047 00	;	,		:		i	;	į	
	470	rtnoxetme		Per o	26/01/02	36.60	<u>*</u>	77	2 5	2 2	2.5	118	2 5	75
				7	76/11/20	36.70		5	2 5	2 8	2 5		2 5	
				Day 14	10/11/92	36.60		64.80	1 2	2 2	72	101	2 5	2 8
				Day 21	17/11/92	36.60		64.00	110	20	72	110	202	76
				Day 28	24/11/92	36.60		64.00	13	2 2	70	110	2 2	76
				Day 42	08/12/92	36,60	ŧ	64.00	110	70	70	110	70	74
				Day 56	22/12/92	36.60		64.00	110	20	70	5	70	74
1														
1	427	Reboxetine	xetine Female	Scre	25/11/92	36.60	13		130	8	72	120	96	26
į.				Day 0	02/12/92	36.60		84.00	130	96	72	120	96	76
7				Day 7	09/12/92	36.60		84.00	130	90	70	120	8	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	8 3	89 i	125	8 1	72
				0 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	30/ 12/ 32	00.00		10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to 10 to	25	2 2	2 ;	120	3	۹ ;
				Day 56	27/01/93	36.60		8 8 8 8	130	2 2	2 2	120	8 8	4 2
	428	Fluoxetine	Male	Screen	25/11/92	36.60	4		120	8	72	120	8	5
				Day 0	02/12/92	36.60	;	69,00	120	8	72	120	8	20
					09/12/92	36.60		69.00	120	80	7.	120	80	20
					16/12/92	36.60		69.00	120	80	20	115	80	76
					23/12/92	36.60		69.00	120	80	70	115	80	74
					30/12/92	36.60		69.00	120	80	20	120	80	72
				Day 42	13/01/93	36.60		69.00	120	8	89	115	80	72
					27/01/93	36.60		69.00	120	8	89	115	8	7.
	977	Determination			00,000	e e	;		į	į	;			
	ì	Direction of the second			07/12/92	36.70	<u>•</u>	90	077	2 8	8 9	22.		
				2	46.749.700			9.0	C71	2 8	8 8	071		
				Pay 76	21/12/42	36.86		69.50	621	2 5	2 8	120	2 5	9/2
					28/12/92			69.50	3,5	2 2	2.5	12		
					04/01/93	36,60		70.00	125	20.	9	120		
				Day 42	18/01/93	36,60		70.00	120	70	2	120		
					01/02/93	36,60		70.00	120	20	20	120		
	450	Fluoxetine Male	Male	Screen	29/11/92	36.60	13		110	20	80	110	70	82

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			r RATE standing	Heart Rate (beats/min)	ž	82	82	82	82 80 80 80 80	ž	2,2	92	7,7	2.5	74	72	ļ	78	75	76	80 8	2 2	82	ì	9 9	92	3,6	75	9,6	78	80	8	80	88	20 0	828	180	82 75	2
			RATE	D.B.P. (mmHg)	2	20	2 2	70	2 2	Š	8	6	8 8	8 8	8	80	;	8 8	8	8	2 5	2 2	80	;	2 2	8	8	8	80	8	80	80	89	8	2 8	8 8	8	8 8 8	š
			AND HEART	S.B.P. (maRg)	110	110	25	2 2	1 1	120	120	125	125	125	125	125	;	115	115	115	120	115	120	ţ	3 2	130	130	125	130	125	110	110	110	105	֚֚֚֓֞֞֜֜֝֞֜֜֝֟֝֟֝֟֝֓֓֟֟֜֟֜֟֜֟֜֟֜֜֟֜֜֟֓֓֓֓֓֓֓֜֜֜֜֜֓֓֡֓֜֜֜֡֡֡֡	115	120	120	2
			BLOOD PRESSURE AND HEART RATE	Heart Rate (beats/min)	8	78	78	87	2 %	2	2 2	2,	89 5	88	89	89	i	7,4	72	22	4.7	6 %	82	í	2 2	20	22	72	74	74	78	78	78	78	200	26	*	22	2
			BLOC 1ying	D.B.P.	20	22	2 5	2 2	22	ş	8	8	8 8	8 8	8	8	i	8 8	8	8	8 8	8 8	8	;	2 2	8	8 8	8 8	80	80	80	80	80	8	8 8	8 8	8	8 4	}
				S.B.P.	110	110	5 5	11:	1 2	130	13	130	) (5)	<u> </u>	130	130		120	120	120	120	120	125	;	<u> </u>	£	£ 5	3 5	130	130	110	110	110	2	116	120	125	120	2
	24/016	DATES	Body	Height (Kg)	91.00	91.00	91.60	91.0	91.00		68.00	68.00	68.00	68.00	68.00	68.00		65.00	65.00	65.00	65.00	65.00	65.00		67.00	67.00	62.69	67.90	67.00	67.00		62.00	62.00	62.00	8 5	62.00	62.50	62.00	2
PHARHACIA CNS RED	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Respiratory	Rate (breaths/min)						45	:						!	Ē						;	ŧ			•			17								
Par	REBOXETIN Li	VITAL SIGN	Body	Temperature ( C)	36.60	36.60	36.68	36.60	36.60 36.60	36.60	36.70	36.70	36.60	36.60	36.60	36.60	;	36.70	36.70	36.70	36.70	36.70	36.60	i	36.70	36.60	36,60	36.60	36.60	36.60	36.00	36.50	36.50	36.50	36.30	36.50	36.00	36.50	3
				Date	09/12/92	16/12/92	23/12/92	06/01/93	20/ <b>01/93</b> 03/02/93	07/12/92	17/12/92	24/12/92	31/12/92	14/01/93	28/01/93	11/02/93		15/12/92	29/12/92	05/01/93	12/01/93	02/02/93	16/02/93	00, 10,	18/01/93	25/01/93	01/02/93	15/02/93	01/03/93	15/03/93	12/03/92	25/03/92	01/04/92	08/04/92	15/104/92	29/04/92	26/50/90	13/05/92	1
				Visit					Day 42 Day 56	Screen		Day 7						Day 0		Day 14	Day 21		Day 56	c	Day 0	Day 7	Day 14	Day 28	Day 42	Day 56	Screen							Day 49	
				Sex	Male					Fenale								Female						,	9772						Female								
				Treatment	Fluoxetine					Fluoxetine							;	Keboxetine							LIGOXBLIDE						Fluoxetine Female								
				Centre Patient	450					451							:	452						101	ş						429								
				Centre	15											1	. 1	5	8												16								
				Centre	15											1	. 1	5	8												16								

26																																									
				Heart Rate (beats/min)	:	80 9	8	78	8	9 2	9 %	26	7.	;	8 6	8 6	86	8 6	86	88	8	8 5	1	80 e	8	8	86	80	¥.	ŧ,	7.2		80	80	80 6	2 2	* *	3 2	82	82	8
			RATE standing	D.B.P. 1 (mmHg)		60 6	8 8	8	8	8 8	2 2	8	S	;	8 8	3 8	8 5	8	90	8	2 2	ָה מַבְּ	3	80 6	8 6	8 8	8	92	82	2	3 %		8	80	8	8	e K	3 8	8	8	75
			AND HEART	S.B.P. (mnHg)		120	120	120	120	120	125	120	120	,	140	140	8 5	130	135	135	135	330	3	110	110	115	110	110	115	115	120		110	110	2;	21.	CL.	120	120	125	120
			BLOOD PRESSURE AND HEART RATE	Heart Rate (beats/min)		36	282	7.	78	92	9,4	72	20.		8	8 6	2 2	8 28	78	78	22 6	2 3	R	88	8 2	e e	3 2	80	27	<b>?</b> i	2 2		78	78	78	2 1	3 6	3 2	78	9/	42
			BLO	D.B.P. 1		<b>8</b> 8	8 %	8	82	<b>윤</b> 8	2 %	2 2	8		80	80	8 8	8	88	8	8 3	2 5	2	80	80	8 8	8 8	85	8	96	8 8		80	8	8	9	8 5	8	8	88	8
				S.B.P. (mmHg)		120	2 6	120	135	£ 5	130	3 5	125		140	140	140	2 2	145	140	145	4	2	120	120	120	120	125	125	125	125	ļ	120	120	125	120	125	125	120	120	120
24/016	2	DATES	Body	Weight (Kg)		2	3 5	71.00	71.00	71.00	2.58	71.00	71.50		;	80.00	8.8	80.00	80.00	80.50	80.00	80.50	9.1.0	;	73.00	73.00	73.00	73.00	73.50	73.50	74.00			62.00	62.00	62.50	62.00	62.50	62.00	62.00	61,00
PHARMACIA CNS R&D INE - PROTOCOL 201	Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Restrictory	Rate (breaths/min)		17									48									18									92	!							
PBA	Lis	VITAL SIGNS	Bode	Temperature (C)		36.00	36.50	36.00	36.00	36.50	36.00	36.00	36.00		36.00	36.50	36.50	36.50	36.50	36.50	36.50	36.50	36.30	36.50	36,50	36.30	36.50	36.00	36.00	36.00	38.00		36,50		36.50		36.50	36.50	36.50	36.50	36.50
				Date		26/03/92	30/03/92	13/04/92	20/04/92	27/04/92	04/05/92 44/06/02	18/05/92	25/05/92		26/03/92	30/03/92	13/04/92	20/04/92	27/04/92	04/05/92	11/05/92	18/05/92	26/60/62	26/03/92	30/03/92	13/04/03	20/04/92	27/04/92	04/05/92	11/05/92	18/05/92	: :	28/03/92	01/04/92	08/04/92	15/04/92	22/04/92	26/60/67	13/05/92	20/05/92	27/05/92
				Visit		Screen	Day o	Day 14	Day 21	Day 28	Day 35	Day 42	Day 56		Screen	O to C	Day 7	Day 21	Day 28	Day 35	Day 42	Day 49	uay se	Screen	Day 0	nay '	Day 21	Day 28	Day 35	Day 42	Day 49	•	Screen	Day 0	Day 7		Day 21				
				Sex		Male									Female									Female									Female								
				Treatment		Reboxetine									Reboxetine Fenale									Fluoxetine Female									Reboxetine								
				Centre Patient Treats		430									431									432									433								
				Centre		16												1	1	ទ	9																				

		RATE	Heart Rate (beats/min)		28											•			95										96			80 78						
		ND REART RATE	S.B.P. D.B.P. (makkg) (makkg)		120 80														135										70 50			120						
		BLOOD PRESSURE AND HEART RATE	B.P. Heart Rate mHg) (beats/min)	ì	92	72	2 8	78	78	26	78	!	æ	8 8	80	6	80 (	Q (8	8 8	78	80	35	95	8	Z 6	98	98	88	88	3	72	72	3,0	78	16	9,6	. %	76
		H. B.	D.B.P. (mmHg)	8	2 8	80	8 8	8	8	6	8 8 8	}							8 8										8 8			8 8						
			S.B.P. (mnHg)		1,04	140	140 140	145	140	145	140	:	140	15.3					140			120							8 5			120						
124/016	r DATES	9	Reight (Kg)		63.00	63.00	63.00	62.00	62.00	62.00	62.00				67.00	67.00	67.00	67.00	67.00	67.00	67.00		51.00	51.00	51.90	51.00	51.00	51.00	51.00	3		54.50	25.55	55.00	25.00	55.00	56.00	56.00
REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	SIGNS AND ASSESSMENT		Rate (breaths/min)	;	5								į	2								9									16							
REBOXETIN	VITAL BIGN	i pod	Temperature (C)	ć	36.50	36.50	36.50	36.50	36.50	36.50	36.50		36 00	36.00	36.50	36.50	36.50	36.50	36.50	36.50	36,50	36.50	36.50	36.50	36.50	36.50	36.50	36.50	36.00	9		36.50						
			Date	200	06/04/92	13/04/92	20/04/92	04/05/92	11/05/92	18/05/92	25/05/92		09/07/00	13/04/92	20/04/92	27/04/92	04/05/92	11/05/92	25/05/92	01/06/92	08/06/92	20/04/92	23/04/92	30/04/92	16/105/92	21/05/92	28/05/92	04/06/92	11/06/92		24/04/92	29/04/92	13/05/92	20/02/92	27/05/92	03/06/92	17/06/92	24/06/92
			Visit								Day 49		200	Day 0					Day 42			Screen	Day						Day 49		Screen	Day o	Day 14	Day 21	Day 28	Day 35	Day 42	Day S6
			Sex		remarie								Formula									Female									Female							
			Centre Patient Treatment	E	FIUOXOTIBO								Dohovotino									Fluoxetine Female									Reboxetine							
			Patient	ģ	ţ								435	2								436									437							
			Centre	,	2											1	1	6	0																			

28			"5	I				
		i	ng Heart Rate (beats/min)	5 8 8 4 8 4 8	2	77 77 78 78 78 88 78 78 78 78 78 78 78 7	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	6 8 8
			r RATE standing D.B.P. Her (mmHg) (be	100 100 100 100 100 100 100 100 100 100	25 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	***************************************	ස ස සි සි ස ස ස ස ස ස	90 80 80
			AND HEAR? S.B.P. (mmHg)	170 170 165 165 165	130 130 130 130 130 130 130	125 125 125 125 125 125 125 125 125	120 120 120 120 120 125 125 127 128 128	120
			BLOOD PRESSURE AND HEART RATE ing S.B.P. D.B.P. (heart Rate S.B.P. D.B.P. (heats/min) (mmHg) (mmHg)	9 9 9 9 8 % 8 8 8 8 8 8 8	22 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2		80 72 72 76 76 88 88 88 88 88 88 88	74
•			BLOC 1ying D.B.P. E	100 100 100 100 100 100 100 100 100 100		ରି କିନ୍ଦିର ପରି କିନ୍ଦିର ପରି କିନ୍ଦିର ପରି	S	88
			S.B.P. (mmHg)	178 170 170 170 175	140 140 135 135 140 140 140 140 140 140 140	130 130 130 130 130 130 130 130	130 125 130 130 130 130 130 130 130	140
	24/016	DATES	Body Weight (Kg)	62.00 62.00 62.00 62.00 62.00	105.00 105.00 105.00 104.00 104.00 104.00	65.00 65.00 65.00 65.00 65.00 65.00	59.00 59.00 60.00 62.00 62.00 62.00	52.00
PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Respiratory Rate (breaths/min)	<b>81</b>	4	5	2	
PH	REBOXETINI Li:	VITAL SIGN	Body Temperature ( C)	36.50 36.50 36.50 36.50 36.50	36.50 36.50 36.50 36.50 36.50 36.50 36.50		36.50 36.50 36.50 36.50 36.50 36.50 36.50 36.50	36.50 36.50
			Date	15/05/92 19/05/92 26/05/92 02/06/92 16/06/92 23/06/92	15/05/92 26/05/92 26/05/92 02/06/92 16/06/92 23/06/92 23/06/92 14/07/92	26/06/92 30/06/92 07/07/92 14/07/92 28/07/92 06/08/92 11/08/92 18/08/92	13/07/92 21/07/92 28/07/92 03/08/92 11/08/92 24/08/92 31/08/92 14/09/92	14/07/92 21/07/92
			Visit	Screen Day 0 Day 14 Day 21 Day 21 Day 22 Day 35	Screen Day 0 Day 14 Day 21 Day 28 Day 42 Day 42		Screen Day 0 Day 14 Day 14 Day 24 Day 28 Day 42 Day 42	Screen Day 0
			8 9 12	Fonale	Female	Forale	Femalo	Female
			Treatment	Fluoxetine	Fluoxetine Female	Reboxetine Female	Fluoxetine Female	Reboxetine Female
			Patient	438	439	640	144	442
			Centre	91	1161			

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29																																							
				Heart Rate (beats/min)	78	<b>3</b>	8 2	9.6	76	78	8	80	22	<b>*</b> 6	8 8	28	78		78	78	9,	9. i	ŧ	7,5	92	78	8 %	22	3,6	74	72	72	882	9 5	74	78	74	7;	ŧ
			RATE	D.B.P. (mnHg)	90	<b>2</b>	2 F	. E	8 8	8	8	75	80	2 5	2 8	8	8		70	2	21	26	2 8	5 5	2.2	8 8	2 5	2 2	06	8	90	96	8 8	8	8 8	8	88	8	2
			AND HEART	S.B.P. (mmBg)	120	120	120	130	3 55	135	115	115	115	110	2 5	115	120		110	110	110	110	9.5	- ;	12	130	5 5	130	135	130	135	135	120	120	5 5	115	115	120	120
			BLOOD PRESSURE AND HEART RATE.	Heart Rate (beats/min)	72	77	2,8	2 5	2 2	76	82	78	78	9 2	<b>*</b> :	7 7	7.		76	92	2 1	2.2	7.2	ŧ 2	74.	26	9 2	747	. 42	72	72	72	80	3 6	9 2	26	74	74	72
	,		BLO	D.B.P. 1 (mmHg)	8	96	8 8	2 6	2 2	8	80	80	8	8	8 8	8 8	88		20	70	20	2	2 2	2 5	2.2	6	6 8	2 6	8 6	6	90	90	2 3	200	2 %	8 8	80	8	8
				S.B.P. (mmHg)	140	140	를 등	140	£ 5	140	120	120	120	120	120	120	120		110	110	110	110	110	110	12	140	140	12.6	1 2	140	140	140	120	120	120	120	120	120	120
	24/016	DATES	, B	Keight (Kg)	80. \$	54.00	8 8	3 2	7. Y	54.50		73.00	73.00	73.00	3.8	3 E	3,00			48.00	48.00	48.00	48.00	48.00	<b>48</b> .00	:	84.00	94. T	85.58	85.00	85.00	85.00	i	54.00	3 3 \$ 3	3 35 35 35 35	55.00	55,00	22.00
PHARHACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Dagatica	Rate (breaths/min)						•	81								61							15							81						
PHA	REBOXETINE Liz	VITAL SIGNS	a de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la constante de la consta	Temperature ( C)	36.50	36.50	36.50	36.50	36.50	36.50	36.50	36,50	36.50	36.50	36,50	36.50	36.50		36.50	36.50	36.50	36.50	36.40	36.50	36.50	36.00	36.00	36.30	36.56	36,50	36,50	36.50	36.50	36.50	36.50	36.50	36,50	36.50	36.50
				Date	28/07/92	03/08/92	10/08/92	17/08/92	31/08/92	14/09/92	20/08/92	24/08/92	31/08/92	07/09/92	14/09/92	26/60/12	18/10/92		20/08/92	24/08/92	31/08/92	07/09/92	14/09/92	21/09/92	19/10/92	12/09/92	17/09/92	04/109/92	08/10/92	15/10/92	29/10/92	12/11/92	12/09/92	17/09/92	24/03/92	08/10/92	15/10/92	29/10/92	12/11/92
				Visit				20 6	Day 42	28	Screen						Day 56		Screen	Day 0	Day 7	Day 14	Day 21	Day 28	Day 56	Screen	Day 0	Day /	Day 21	Day 28	Day 42	Day 56						Day 42	
				Sex	Female						Kale								Female							Male							Female						
				Centre Patient Treatment	Reboxetine						Fluoxetine								Reboxetine							Reboxetine							Fluoxetine						
				Patient	445						443								444							442							446						
				Centre	5													1	1	6	2																		

8																																							
			Heart Rate		82	3.2	2	9/	<b>*</b> }	2,5	Ş	8	69	69	59	99	29	99		8	8 %	78	8	80 8	8	88	80	48	20.8	8 25	82	82	2	9	8 &	**	\$	84	
		RATE	녆 . ~	1	80	2 6	8 8	8	8	8 8	Š	2 2	70	2	2 2	2 2	2	65		2 2	2 2	2	75	2 2	2 2	2 2	80	2 8	8 8	8 8	8	80	8	é	3 8	8	88	8	
		AND HEART	S.B.P.		115	5 5	15	115	112	2 2	400	11 5	105	110	105	2 5	105	105		96	105	110	105	2 5	50	105 110	140	140	140	14	140	25	135	Ç	5 5 5 5	140	140	140	
		BLOOD PRESSURE AND HEART RATE	Heart Rate		75	5 2	<b>.</b> \$	74	<b>7</b> 8	\$ \$	ş	. <b>.</b>	65	65	69	3 %	65	g		76	8 8	26	82	7 A	5 62	87 76	80	78	2 2	80	78	78	76	á	78	80	80	90	
		18	1ying D.B.P. 1		8	8 8	8	80	8	8 8	Š	2 2	2	2	2 5	2 2	2	70		2 2	2 2	2	2	2 1	2 2	2 2	80	2 8	8 8	8 8	8	80	80	ā	8 8	8	8	80	
			S.B.P.	- 1	115	115	115	115	115	115	4	2 2	110	110	13	1 2	110	110		110	19	110	105	119	19	110	140	340	140	£ 5	140	140	135	,	5 4 <u>1</u>	140	140	140	
200,40	91074	DATES	Body Keight	Ì	;	3.8	73.50	74.00	74.00	74.00		59.00	59.00	29.00	29.00	59.00	58.00	29,00		9	58.00	58.00	58.00	58.00	58.00	58.00		71.00		71.00	71.00	71.00	71.00		74.00	74.00	74.00	76.00	
PHARMACIA CNS R&D	KEBUKEIINE - FROIGCOL 20124/U16 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Respiratory Rate (breathe/min)		19						ţ	2				,				18							17							ş	ē				
THA SAUGE	KEBUKEI 1ME	VITAL SIGNS	Body Temperature		36.50	36.50	36.50	36.50	36.50	36.50	26	36.50	36.50	36,50	36,50	36.50	36.50	36.50		36.50	36.50	36.50	36.50	36.50	36.50	36.50 36.50	36.50	36,50	36.36	36.50	36.50	36.50	36.50	3	36.50	36.50	36.50	36.50	
			4	- 1	12/09/92	17/09/92	01/10/92	08/10/92	15/10/92	12/11/92	47.700700	18/09/92	25/09/92	02/10/92	09/10/92	23/10/92	30/10/92	13/11/92		14/09/92	25/09/92	02/10/92	09/10/92	16/10/92	30/10/92	13/11/92	09/12/92	15/12/92	26/21/27	05/01/93	12/01/93	26/01/93	09/02/93	00,04,00	15/12/92	22/12/92	05/01/93	19/01/93	2
			, e				· 4	24	89 5	Day 56	10000	Day 0	Day 7	Day 14	Day 21	Day 35	Day 42	Day 56		Screen	Day 7	Day 14	Day 21	Day 28	Pay 42	Day 49 Day 56	×	Day 2	•		Day 28				<b>z</b>	Day 7	Day 21		
			b S		Male						Powerla	O TOWN								Female							Male												
			Treatment		Fluoxetine						Ochococking	Date -								Fluoxetine							Reboxetine								FIGOXBLING				
			Patient Treate		447						877	ř								455							456								ĝ				
			Contro		16											1	l 1	6	3																				

32								
			standing D.B.P. Heart Rate (mmHg) (beats/min)	80 780 780 884 884 885 885 885 885	76 78 78 79 79 78 77	76 78 80 78 78 78	78 78 78 78 78 78 75 82 82 82 82 82	80 80 75 74 74 73
			RATEstanding_ D.B.P. He (mmHg) (k	20 20 20 20 20 20 20 20 20 20 20 20 20 2	70 880 80 70 70 80 80 80 80 80 80 80 80 80 80 80 80 80	88 89 85 85 85	S S S S S S S S S S S	80 80 70 70 80 80 80 80 80 80 80 80 80 80 80 80 80
			AND HEART S.B.P. (mmHg)	135 135 150 150 140 135	110 130 135 125 125 135 146 140	120 160 140 165 150	150 145 145 145 145 130 130 140	120 120 120 120 115 115
			BLOOD PRESSURE AND HEART RATE.  Ting.  Heart Rate S.B.P. D.B.P.  (hearts/min) (mmHg) (mmHg)	80 80 755 755 80 86 86	76 76 76 75 75 74 74 73	78 78 76 76	78 78 75 75 75 76 76	78 78 72 72 71 70
	r		BLOC Tying D.B.P. F	222222	70 70 80 80 70 70 70 80 80 88	5 8 8 8 8 8 8 8 8	2 2 2 2 2 5 2 2 2 2 2 2 2 2 2 2 2 2 2 2	80 80 80 80 70 70 80
			S.B.P.	740 140 140 125 130 130	110 125 125 125 110 110 136 136 130	117 150 140 150 140	140 140 140 140 140 120 120 120	120 120 120 120 105 105
	24/016	DATES	Body Weight (Kg)	69.00 69.00 70.00 70.00 68.00 68.00 67.00	140.00 140.00 140.00 140.00 140.00 140.00 140.00	62.00 62.00 62.00 62.00	113.00 113.00 113.00 113.00 112.00 113.00 113.00	62.00 63.00 63.00 63.00 63.00 63.00
PHARMACIA CNS R&D	REBOXEIINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	Respiratory Rate (breaths/min)		\$	91	<b>5</b>	4
/Bd	REBOXETINE Lis	VITAL SIGNS	Body Temperature ( C)	36.70 36.70 36.20 36.20 36.20 36.40 36.40	36.60 36.20 36.20 36.20 36.30 36.40 36.40 36.40	36.20 36.20 36.20 36.20 36.40	36. 50 36. 30 36. 30 36. 30 36. 50 36. 40 36. 40 36. 50	36.30 36.30 36.30 36.30 36.30 36.30
			Date	13/10/92 20/10/92 27/10/92 10/11/92 17/11/92 24/11/92 01/12/92	30.09/92 06/10/92 13/10/92 20/10/92 03/11/92 10/11/92 24/11/92	30/09/92 06/10/92 13/10/92 20/10/92 27/10/92 03/11/92	30/09/92 13/10/92 13/10/92 20/11/92 10/11/92 10/11/92 24/11/92	30/09/92 07/10/92 14/10/92 21/10/92 04/11/92
			Visit	Day 7 Day 14 Day 21 Day 28 Day 38 Day 42 Day 42	Screen Day 0 Day 7 Day 14 Day 21 Day 28 Day 42 Day 42 Day 45	Screen Day 0 Day 7 Day 14 Day 21 Day 28	Screen Day 0 Day 14 Day 21 Day 28 Day 28 Day 42 Day 42 Day 45 Day 45	Screen Day 0 Day 7 Day 14 Day 21 Day 28
			M 60 70	Female	Fenale	Fenale	Male	Female
			Treatment	Reboxetine	Reboxetine	Fluoxetine	Roboxetine Male	Fluoxetine Female
			Centre Patient	26	,	<b>28</b>	58	30
			Centre	8	110	65		

		ı	La	I									ı																			
			Heart Rate (beats/min)	<b>27</b>	88 %	78	78	29	88 9	2 2	89	£ 8		27	*	*	9,2	2 2	72	72 81	ş	2,0	86	8 8	ŧ 5	88	88	98 76	82	92	96	
	•	RATE	D.B.P. (mmBg)	8	2 2	80	88	8	8 8	8 8	8	8 8		8 8	8	8	8 8	8 8	82	8 8	Ę	8 2	8	8 8	8 8	2	80	88	6	S.	06	
		AND HEAR!	S.B.P.	120	120	130	130	140	130	£ 5	125	3 3 2		120	125	130	125	<u> </u>	135	135 135	130	125	135	130	1 1	105	130	135 120	140	135	140	
,		BLOOD PRESSURE AND HEART RATE	Heart Rate (beats/min)	22	85 85	7.	<b>4</b> 4	72	48	8 9	82	96 76		<b>9</b> 2	27	72	2,20	72	69	73	89	72	82	8 3	76	06	98	80 72	78	82	98	
		Brc	D.B.P.	8	2 2	8	2 2	8	8 8	8 8	<b>8</b> 2	8 8		2 8	8 8	8	8 5	8	89	2 2	Ę	2 8	8	80 6	2 8	2	8	2 2	96	8	80	
			S.B.P.	12	2 2	120	120	130	120	120	130	130 25		110	129	125	120	125	130	9 9 9 9		120	130	120	135	5	125	<u> </u>	130	125	130	
24/016	DATES	į	Reight (Kg)	63.00	63.00		58.00	28.00	57.00	28.00	58.00	57.00 56.00		62.80	61.00	62.00	61.00	62.00	63.00	63.00		82.00	80.50	82.00	28.6	78.00	78.00	78.00		70.00		
FHAKBACIA CNS KRD REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES	O	Rate (breaths/min)											र्घ							ç	2							15		4	
PHA REBOXETINE Lis	VITAL SIGNS	e de	Temperature (C)	36.30	36.40 36.40	36.30	36.30	36.40	36.80	36.20	36,40	36.40 36.40		36.40	36.40	36.20	36.20	36.30	36.40	36.40 36.40	07 98	36,50	36.50	36.40	36.50	36,40	36.40	36.50	36.40	36.40	36.70	
			Date	17/11/92	02/11/92	13/10/92	20/10/92	03/11/92	10/11/92	24/11/92	01/12/92	08/12/92 15/12/92	;	05/10/92	14/10/92	21/10/92	28/10/92	10/11/92	17/11/92	24/11/92	10/11/92	17/11/92	24/11/92	01/12/92	15/12/92	22/12/92	29/12/92	12/01/93	10/11/92	26/11//1	10/11/92	
			Visit		Day 56	w.	Day 0	Day 14	Day 21	Day 35	Day 42	Day 49 Day 56	,	¥						Day 49 Day 56	Serren	Day 0						Day 49	8	nay n	Screen	
			Sex	Female		Female								Female							Famala								Female		Female	
			Centre Patient Treatment	Fluoxetine		Reboxetine Female							:	Fluoxetine Female							Reboxetine								Reboxetine		Fluoxetine Female	
			Patient	30		31							į	32							64								20		51	
			antre	18												1 1	16	6														

					<u> </u>	EBOXETIN	REBOXETINE - PROTOCOL 20129/016	124/016						
L. Caronia I.				EESOASILI [1]	Li	= **	Listing No.: 20.0	0 0 7.47						
VITAL SIG	VITAL SIG	VITAL SIG	VITAL SIG	VITAL SIG	VITAL SIG	ž	VITAL SIGNS AND ASSESSMENT DATES	T DATES						
Body	Body	Body	Body	Body	Body		Respiratory	Body		BLC 1ying	BLOOD PRESSURE AND HEART RATE	AND HEAR	T RATEstanding	1.5
Centre Patient Treatment Sex Visit Date (C)	Sex Visit Date	Sex Visit Date	Date		Temperature ( C)	_	Rate (breaths/min)	Weight (Kg)	S.B.P. (mnHg)	D.B.P. (mmHg)	).B.P. Heart Rate (mmHg) (beats/min)	S.B.P. (mmBg)	D.B.P. (mmHg)	Heart Rate (beats/min)
21 08/12/92	Female Day 21 08/12/92	Female Day 21 08/12/92	Day 21 08/12/92	08/12/92	36.70			94.00	130	96	70		95	42
Day 28 15/12/92	Day 28 15/12/92	Day 28 15/12/92	28 15/12/92	15/12/92	36.40			93.00	125	2 8	2.2	130	8 8	9.0
35 22/12/92	35 22/12/92	35 22/12/92	35 22/12/92	29/12/92	36.50			92.00	120	3 8	8 8	<u>8</u>	8 8	828
Day 49 05/01/93 36.40 Day 56 12/01/93 36.50	49 05/01/93 56 12/01/93	49 05/01/93 56 12/01/93	49 05/01/93 56 12/01/93	05/01/93	36.40 36.50			92.00	120 130	28	80 78	130 135	ଷ ଷ	# Z
	5mc Committee Comment	Comp. 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	44,44,00	10/11/00	9				967	G	ŗ	140	8	
Day 0 17/11/92	Day 0 17/11/92	Day 0 17/11/92	Day 0 17/11/92	17/11/92	36.30			104.00	130	8	. <b>8</b>	15	. 6	
7 24/11/92	7 24/11/92	7 24/11/92	7 24/11/92	24/11/92	36.40			105.00	130	8	80	140	8	
14 01/12/92	14 01/12/92	14 01/12/92	14 01/12/92	01/12/92	36.40			105.00	130	8	75	140	S	
21 08/12/92	21 08/12/92	21 08/12/92	21 08/12/92	08/12/92	36.70			105.00	135	8	20	145	8 8	
26/21/61 82	26/21/61 82	26/21/61 82	26/21/61 82	26/21/61	36.30			105.00	044	2 8	ŧ	10.0	2 4	
42 29/12/92	42 29/12/92	42 29/12/92	42 29/12/92	29/12/92	36.30			105.00	135	8 8	82	3 2	8 8	
Day 49 05/01/93 36.40	49 05/01/93	49 05/01/93	49 05/01/93	05/01/93	36.40			105.00	140	75	72	145	8	76
56 12/01/93	56 12/01/93	56 12/01/93	56 12/01/93	12/01/93	36.50			105.00	135	2	Z	740	88	
1														
53 Fluoxetine Female Screen 29/12/92	ine Female Screen 29/12/92	Female Screen 29/12/92	Screen 29/12/92	29/12/92	36.50			;	125	8	82.5	130		
Day 0 15/01/93	7 22,04,03	7 22,04,03	7 22,04,03	15/01/93	36.70			92.00	130	8 6	8 2	¥ 6		
Day 14 29/01/93	14 29/01/93	14 29/01/93	14 29/01/93	29/01/93	36.06			88.00	2 5	8 8	2 22	140		
21 05/02/93	21 05/02/93	21 05/02/93	21 05/02/93	05/02/93	36.60			90.00	120	8	7.	130		
28 12/02/93	28 12/02/93	28 12/02/93	28 12/02/93	12/02/93	36.70			89.00	130	80	29	140		
35 19/02/93	35 19/02/93	35 19/02/93	35 19/02/93	19/02/93	36.70			89.00	130	8	89	140		
42 26/02/93	42 26/02/93	42 26/02/93	42 26/02/93	26/02/93	36.70			88.00	120	70	20	125		
Day 49 05/03/93 36,40 Day 56 12/03/93 36,50	49 05/03/93 56 12/03/93	49 05/03/93 56 12/03/93	49 05/03/93 56 12/03/93	05/03/93 12/03/93	36.40 36.50			87.00	125 140	28	78	130 143	8 2	22 25
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26/10/21 0	26/10/21 0	26/10/21 0	26/10/21 0	12/0/23	00.00			00.00	0 2	2 8	2 6	2 6		
76 75/01/93	76 75/01/93	76 75/01/93	76 75/01/93	19/01/93	35.30			97.00		3 5	2 4	120		
77.70.70	77.70.70	77.70.70	77.70.70	20, 00, 00	9			22.00		2 6	ខ	i e		
20 00 00 00	20 00 00 00	20 00 00 00	20 00 00 00	05/00/00	9.00			9.70	2 4	8 6	3 5	100		
26 77 07 22	26 77 07 22	26 77 07 22	26 77 07 22	15,00,000	94.96			00.00	120	2 5	6 %	100		
42 22/02/03	42 22/02/03	42 22/02/03	42 22/02/03	23,00,02	36.50			20.70	22.	2.5	3 2	125		
20/20/20	20/20/20	20/20/20	20/20/20	60/60/60	95.96			2.0	9 6	2 6	3	2 5		
Day 56 09/03/93 36.50	56 69/13/93	56 69/13/93	56 69/13/93	66/60/60	36.50			84.00	110	2.2	6	120	2 8	89
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26/01/2	Day 0 06/11/92	Day 0 06/11/92	Day 0 06/11/92	26/01/2	37.00			66 00	5 5	8 8	0 %	125	8 8	22
13/11/92	13/11/92	13/11/92	13/11/92	13/11/92				65.00	135	8	;	130	_	
20/11/92	20/11/92	20/11/92	20/11/92	20/11/92				94.00	140	96	26	130		_
Day 21 27/11/92 37.10	27/11/92	27/11/92	27/11/92	27/11/92				75.50	120	85		120		

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			إ	Heart Rate (beats/min)	\$	8	8	98	92		i	72	96	8		49	68	89	78	79	92	8		;	ò	92	35	98	88	;	2 2	8 8	26	92
			RATE	D.B.P. (mmHg)	08 5	3 8	8	8	8	8	£ 1	23	5 1	0 8	8	8	80	80	96	90	8	8	<b>8</b> :	82	2	85	8	8	9	i	2 2	2 %	5 8	75
			IND REART	S.B.P. (mmHg)	120	5 5	120	120	130	110	120	120	120	9 6	R	125	115	120	135	140	135	125	130	130	130	130	140	130	120	;	120	2 5	3 4	140
			BLOOD PRESSURE AND HEART RATE	Beart Rate (beats/min)	72	8 8	26	8	98	72	8	\$	e :	8 6	77	89	99	89	89	70	89	92		ì	•	92	84	8	76	i	9.5	3,2	2 46	22
	1.		BLOC	D.B.P. (mnBg)	88	2 8	8	8	80	\$	8 3	80	8 8	òò	\$	80	80	80	2	75	2	8	90	6	2	96	85	85	65	1	72	8 5	2 2	8
				S.B.P. (mmHg)	130	125	130	130	120	120	£ 5	120	120		021	120	110	115	120	125	120	110	120	125	120	130	130	130	130	:	2 5	22.5	3 2	140
	24/016	DATES	e de de	Meight (Kg)	64.00	64.00	64.00	64.00		62.00	62.00	62.00	62.00	92.00	97.00		79,00	78.60	76.90	76.30	74.00	77.00	76.50	77.00	75.00		94.00	95.00	93.00		2	73.00	73.00	71.00
PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 20.0	VITAL SIGNS AND ASSESSMENT DATES		Respiratory Rate (breaths/min)												4										47				:	19			
Н	REBOXETIN Li	VITAL SIGN	170	Temperature ( C)	37.20	37.10	37.20	37.20	37.20	37.00	36.80	37.00	36.80	37.00	91 · /c	37.80	36.80	36.80	36.30	37.00	36.90	37.00	36.50	37.00	38.20	36.00	36.20	36.10	37.30	:	36.90	36.36	36.80	36,30
				Date	04/12/92	18/12/92	23/12/92	30/12/92	09/11/92	12/11/92	19/11/92	26/11/92	03/12/92	10/12/27	76 /71 //1	12/10/92	19/10/92	26/10/92	02/11/92	09/11/92	16/11/92	23/11/92	30/11/92	26/21/80	76/71/141	24/11/92	02/12/92	09/12/92	16/12/92	;	22/12/92	06/01/93	12/01/93	20/01/93
				Visit	Day 28		Day 49		ň				Day 21			Screen	Day 0				Day 28			Day 49		Screen	Day 0		Day 14		Screen	7	Bay 1	Day 21
				Sex	Female				Female							Fenale										Male					nale.			
				Treatment	Fluoxetine				Fluoretine Female							Fluoxetine Female										Fluoxetine				:	Keboxetzne			
				Centre Patient	21				22							0,										113				!	STL			
				Centre	20											12			1	1	6	8				22								

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PHARMACIA CNS RAD	REBUXETINE - PROTOCOL 20124/016 Listing No.: 21.0	ECC TRACINGS		End days of Date Value Abnormality	Screen -4 Screening 11/11/91	14 1-28 days 29/11/91		29-56 days 10/01/92	Screen -1 Screening 25/06/92 Normal	Day 26 28 1-28 days 24-07-92 Abbormal Sinus IACKICAKUIA ( > 100) Day 56 55 29-56 days 20/08/92 Normal	Screen -6 Screening 25/06/92	15 1-28 days	25/08/92		Canada	Day 14 1-28 days 28/08/92	28 1-28 days 11/09/92		Screen -6		Screen -3	14 1-28 days	20 1-20 days 11/02/75	Screen -2 Screening 02/05/91 Abnormal LEFT VENTRICULAR HYPERTROPHY	20 11.08 4000		2/06/91 Screen -1 Screening 02/05/91 Abmormal RIGHT INCOMPLETE BUNDLE BRANCH BLOCK Day 28 31 1-28 days 03/06/91 Normal	Screen -11 Screening 05/04/91 Day 28 30 1-28 days 16/05/91	51 29-56 days 06/06/91	
PEAR	REBOXETINE List	23		70	Screen	Day 14	Lay 28	Day 56	Screen	Day 26 Day 56	Screen	Day 14 Day 28	Day 56	•		Day 14	Day 28	Day 42	Screen	Day 28	Screen	Day 14	uay 20	Screen	Day 28	Day Se	Screen Day 28	Screen Day 28	Day 56	Common
			t period	- 1	09/01/92	-			20/08/92		25/08/92			'	00/00/90				11/11/92		11/02/93			28/06/91			12/06/91	10/06/91		19705/91 26/06/91
			_Treatment period_	Start date	15/11/91				26/06/92		01/07/92				14/08/02				Female 13/10/92		14/01/93			04/05/91			03/05/91	16/04/91		02/05/04
				Sex	Male				Hale		Female				Come 10						Male			Female			Male	Female		, C
				Patient Treatment	Fluoxetine				Reboxetine		Fluoxetine				Dehayatina				Fluoxetine		Fluoxetine			Fluoxetine			Reboxetine	Reboxetine		Fluoxetine
				Contre Patient	-				N		m				1 1	L 6	<b>3</b> 9	)	'n		49			2 33			₹ 9	38		38

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PHARMACIA CNS R&D	REBOXETINE - PROTOCOL 20124/014	Listing No.: 21.0

			_Treatment periodStartEnd	period		dava of		8	E.c.e.	
Centre Patient Treatment	ıt	Sex	date	date	Visit	treat.	Assessment	Date	Value	Abnormality
Fluoxetine	tine	Male	02/05/91	26/06/91	Day 28	88	1-28 days	16/90/90	Normal	
Reboxetine	tine	Male	07/10/91	10/10/91	Screen	សុ	Screening	02/10/91	Normal	
Fluoxetine	tine	Male	20/06/91	25/07/91	Screen Day 14	2 4	Screening 1-28 days	18/06/91 04/07/91	Abnormal Normal	RIGHT BUNDLE BRANCH BLOCK
Fluoxe	etine	Male	19/00/61	22/06/91	Screen	Ÿ	Screening	13/06/91	Normal	
Rebox	Reboxetine	Kale	06/06/91	04/07/91	Screen	7	Screening	05/06/91	Normal	
Fluos	Fluoxetine	Нале	13/02/92	08/04/92	Screen Day 28 Day 56	- 23 55	Screening 1-28 days 29-56 days	11/02/92 12/03/92 08/04/92	Normal Normal	
Rebo	Reboxetine	Female	05/03/92	29/04/92	Screen Day 28 Day 56	28 26	Screening 1-28 days 29-56 days	06/03/92 02/04/92 30/04/92	Normal Normal Normal	
Rebox	Reboxetine	Female	19/11/91	13/01/92	Screen Day 28 Day 56	1. 2.2.2. 5.6.	Screening 1-28 days 29-56 days	13/11/91 11/12/91 14/01/92	Normal Normal Normal	
Fluo	Fluoxetine	Kale	13/12/91	30/01/92	Day 28	27	1-28 days	09/01/92	Abnormal	SINUS BRADYCARDIA ( < 60)
Rebo	Reboxetine	Female	10/09/92	04/11/92	Screen Day 28	35	Screening 1-28 days	09/09/92 15/10/92	Normal Normal	
Pluo	Pluoxetine	Female	25/03/92	19/05/92	Screen Day 28 Day 56	-1 28 55	Screening 1-28 days 29-56 days	24/03/92 22/04/92 19/05/92	Abnormal Abnormal Abnormal	SINUS BRADYCARDIA ( < 60) SINUS BRADYCARDIA ( < 60) SINUS BRADYCARDIA ( < 60)
Reboxe	xetine	Female	19/05/92	13/07/92	Screen Day 28 Day 56	2.56 5.6	Screening 1-28 days 29-56 days	18/05/92 16/06/92 14/07/92	Abnormal Normal Normal	VENTRICULAR ECTOPIC BEATS - OCCASIONAL
Fluoxe	xetine	Kale	15/01/93 11/03/93	11/03/93	Screen Day 28	-7 20	Screening 1-28 days	08/01/93 04/02/93	Abnormal Abnormal	PREVIOUS MYGCARDIAL INPARCTION PREVIOUS MYGCARDIAL INFARCTION

PRARMACIA CNS R&D

							Listing No.: 21.0	Listing No.: 21.0			
							ECG TRACINGS	CINGS			
				Treatment	t period				Ä	E.C.G.	
Centre	Patient	Centre Patient Treatment	Sex	Start End date date	End	Visit	days of treat.	Assessment	Date	Value	Abnormality
N	80	Fluoxetins	Male	15/01/93	11/03/93	Day 56	56	29-56 days	12/03/93	Absormal	PREVIOUS MYOCARDIAL INFARCTION
æ	65	Fluoxetine	Female	16/10/91	10/12/91	Screen Day 28 Day 56	27 27 55	Screening 1-28 days 29-56 days	11/10/91 12/11/91 10/12/91	Normal Abnormal Abnormal	RIGHT INCOMPLETE BUNDLE BRANCH BLOCK RIGHT INCOMPLETE BUNDLE BRANCH BLOCK
	99	Fluoxetine	Female	16/10/91	12/11/91	Screen	សុ	Screening	11/10/91	Norma1	
	67	Reboxetine	Female	18/11/92	15/12/92	Screen Day 28	-4 28	Screening 1-28 days	14/11/92	Normal Normal	
	89	Reboxetine	Female	30/11/92	28/12/92	Screen Day 28	1 82 4 83	Screening 1-28 days	26/11/92 28/12/92	Normal Abnormal	ATRIAL ECTOPIC BEATS - OCCASIONAL
4	76	Reboxetine	Female	22/04/91	16/06/91	Screen Day 14 Day 28 Day 56	-3 15 29 56	Screening 1-28 days 1-28 days 29-56 days	19/04/91 07/05/91 21/05/91 17/06/91	Normal Normal Normal	
1171	86	Fluoxetine	Female	30/05/91	24/07/91	Screen Day 28 Day 56	28 28 55	Screening 1-28 days 29-56 days	27/05/91 27/06/91 24/07/91	Normal Normal Normal	
	66	Fluoxetine	Female	15/10/91	25/10/91	Screen	4	Screening	11/10/91	Normal	
	00,	Reboxetine	Hale	08/05/92	08/05/92	Screen	æ	Screening	11/05/92	Normal	
	101	Rebozetine	Female	02/07/92	26/08/92	Screen Day 28 Day 56	0 28 56	Screening 1-28 days 29-56 days	02/07/92 30/07/92 27/08/92	Normal Normal	
	102	Fluoxetine	Female	10/07/92	03/09/92	Screen Day 28 Day 56	31 33	Screening 1-28 days 29-56 days	10/07/92 10/08/92 07/09/92	Normal Normal Normal	
	103	Fluoxetine	Female	Female 13/07/92	18/08/92	Screen Day 28	2, 88 88	Screening 1-28 days	08/07/92 10/08/92	Normal Normal	

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						REBOXET	INE - PROTOCOL 20 Listing No.: 21.0	REBOXETINE - PROTOCOL 20124/016 Listing No.: 21.0			
							ECG TRACINGS	CINGS			
				Treatment	t period_	i			ы	E.C.G.	
Centre		Patient Treatment	Sex	Start End date date	End	Visit	days of treat.	Assessment	Date	Value	Abnormality
4	104	Reboxetine	Female	18/08/92	05/10/92	Screen Day 28	2 1 20 45	Screening 1-28 days	14/08/92	Normal Normal	
						,		,			
	105	Fluoxetine	Hale	21/08/92	15/10/92	Screen Day 28 Day 56	. 88 2 58 2	Screening 1-28 days 29-56 days	20/08/92 18/09/92 16/10/92	Normal Normal Normal	
						;	1				
v	129	Reboxetine	Fenale	29/11/91	29/12/91	Screen Day 28	-4 27	Screening 1-28 days	25/11/91	Normal Normal	
	130	Fluoxetine	Female	28/02/92	23/04/92	Screen	4,0	Screening	24/02/92	Normal	
						Day 56	3,95	29-56 days	24/04/92	Normal	
	193	Reboxetins	Female	06/12/91	31/01/92	Screen Day 56	o 88	Screening 29-56 days	06/12/91 30/01/92	Normal Abnormal	SINUS TACHYCARDIA ( > 100)
,	194	Fluoxetine	Female	10/01/92	05/03/92	Screen	eg i	Screening	02/01/92	Normal	
117						Day 28 Day 56	27 55	1-28 days 29-56 days	05/03/92	Normal Normal	
72	195	Fluoxetine	Male	14/02/92	09/04/92	Screen	ę,	Screening	11/02/92	Absormal	SINUS BRADYCARDIA ( < 60)
						Day 28 Day 56	28 67	1-28 days 29-56 days	13/03/92	Normal Normal	
	196	Reboxetine	Female	29/05/92	16/07/92	Screen Day 28	2.4	Screening 1-28 days	26/05/92 22/06/92	Normal Abnormal	SINUS TACHYCARDIA ( > 100) RIPOLARIZATION DISTURBANCES
	197	Fluoxetine	Hale	11/11/92	11/11/92	Screen	ė,	Screening	06/11/92	Normal	
£	321	Fluoxetine	Female	14/11/91	09/01/92	Screen Day 56	<b>€. 2</b>	Screening 29-56 days	05/11/91 17/01/92	Normal Normal	
	322	Reboxetine	Fenale	14/11/91	09/01/92	Screen Day 56	0 49	Screening 29-56 days	14/11/91	Abnormal	CONDUCTION DISORDER SINUS TACHYCARDIA ( > 100)
	323	Fluoxetine	Female	ine Female 19/11/91 13/01/92	13/01/92	Screen	-20	Screening	30/10/91 Normal	Normal	

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ECG TRACINGS

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	Abnormality			CONDUCTION DISORDER CONDUCTION DISORDER	MYOCARDIAL ISCHEMIA		NYOCARDIAL ISCHEMIA	SINUS TACHYCARDIA ( > 100) SINUS TACHYCARDIA ( > 100) SINUS TACHYCARDIA ( > 100)		NON SPECIFIC ST-T MAVE CHANGES	SINUS BRADYCARDIA ( < 60)		
6.0.6	Value	Normal	Normal Normal Normal	Abnormal Abnormal Abnormal	Abnormal Normal Normal	Normal	Abnormal Normal Normal	Abnormal Abnormal Abnormal	Normal Normal	Abnormal Normal Normal	Abnormal Normal	Normal Normal	Normal Normal
ci.	Date	14/01/92	23/01/92 04/03/92 08/04/92	14/01/92 17/03/92 21/04/92	10/02/92 19/03/92 02/04/92	03/02/92	21/02/92 03/04/92 03/04/92	16/03/92 11/05/92 01/06/92	16/04/92 09/06/92	25/05/92 30/06/92 06/08/92	17707792 15/09/92	17/07/92 13/10/92	10/09/92
	Assessment	29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-26 days 29-56 days	Screening	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 29-56 days	Screening 1-28 days 29-56 days	Screening 29-56 days	Screening 1-28 days	Screening 1-28 days
	days of treat.	56	-1 40 75	-29 34 69	38	+	7 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	-15 41 62	1, 4, 2, 6,	35 72	-11 49	-60 28	-12 29
	Visit	Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 49	Screen Day 28 Day 56	Screen Day 56	Screen Day 28	Screen Day 28
period	End	13/01/92	19/03/92	07/04/92	67/04/92	12/03/92	14/04/92	27/05/92	08/06/92	20/07/92	24/09/92	09/11/92	16/11/92
Treatment period	Start date	19/11/91	24/01/92	12/02/92	Female 12/02/92	14/02/92	19/02/92	31/03/92	21/04/92	26/02/92	28/07/92	15/09/92	Female 22/09/92
	Sex	Female	Female		Fenale	Female	Female	Female	Мале	Female	Female	Fenale	Female
	Treatment	Fluoxetine	Reboxetine	Reboxetine Female	Reboxetine	Fluoxetine	Fluoxetine	Reboxetine	Reboxetine Male	Fluoxetine	Fluoxetine Female	Reboxetine Female	Fluoxetine
	Centre Patient	323	324	325	326	327	328	329	330	331	332	333	334
	Centre	£					1173						

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PHARMACIA CNS R&D IINE - PROTOCOL 20124/016 Listing No.: 21.0

							ECG TRACINGS	CINGS	,	i	
Centre	Patient	Centre Patient Treatment	SS X	_Treatment period_ Start End date date	t period_ End date	Visit	days of treat.	Assessment	E. Date	E.C.G.	Abnormality
11	334	Fluoxetine	Fenale	22/09/92	16/11/92	Day 56	83	29-56 days	14/12/92	Normal	
	335	Reboxetine	Fonale	13/10/92	16/11/92	Screen	7	Screening	02/10/92	Normal	
25	393	Fluoxetine	Fenale	25/06/92	18/08/92	Screen Day 26 Day 56	26 64	Screening 1-28 days 29-56 days	26/06/92 21/07/92 28/08/92	Normal Normal	
	394	Reboxetine	Male	26/0/90	31/08/92	Screen Day 28 Day 56	28 52	Screening 1-28 days 29-56 days	07/07/92 03/08/92 27/08/92	Normal Normal Normal	
117	35 E 4 4 E	Reboxetine	МаЛе	24/01/92	16/09/92	Screen Day 28 Day 56	0 27 55	Screening 1-28 days 29-56 days	24/07/92 20/08/92 17/09/92	Normal Normal Normal	
4	396	Fluoxetine	Female	04/08/92	17/08/92	Screen	-	Screening	05/08/92	Normal	
	467	Fluozetine	Fenale	24/02/93	21/04/93	Screen Day 28 Day 56	30 61	Screening 1-28 days 29-56 days	26/02/93 26/03/93 26/04/93	Normal Normal Normal	
£	385	Fluoxetine	Female	14/03/92	68/05/92	Screen Day 56	- SS	Screening 29-56 days	13/03/92 08/05/92	Normal Normal	
	386	Fluoxetine	Male	24/04/92	30/04/92	Screen Day 7	7.9	Screening 1-28 days	23/04/92 30/04/92	Normal Normal	
	387	Reboxetine	Female	18/04/92	18/05/92	Screen Day 28	£-44	Screening 1-28 days	15/04/92 01/06/92	Abnormal Normal	NON SPECIFIC ST-T WAVE CHANGES
	388	Reboxetine	Male	16/03/92	11/05/92	Screen Day 56	.1	Screening 29-56 days	15/03/92	Normal Normal	
	389	Fluoxetine	Female	21/07/92	23/01/92	Screen Day 7	F 61	Screening 1-28 days	20/07/92 23/07/92	Normal Normal	
	390	Reboxetine Male	Male	28/05/92	22/01/92	Screen	7	Screening	27/05/92 Normal	Normal	

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PHARMACIA CNS R&D EBOXETINE - PROTOCOL 20124/014 Listing No.: 21.0

			_Treatment period_	period_		١		E.(	E.C.G.	
Treatment Sex	Sex		Start date	End	Visit	days of treat.	Assessment	Date	Value	Abnormality
Reboxetine Male	Kale		28/05/92	22/07/92	Day 28 Day 56	28 <b>60</b>	1-28 days 29-56 days	25/06/92	Normal Normal	
Fluoxetine Female 11/06/92	Femal	O.	11/06/92	15/07/92	Screen Day 28	35.55	Screening 1-28 days	16/07/92	Normal Normal	
Reboxetine Female	Femal	0	14/08/92	27/08/92	Screen Day 14	£ 4	Screening 1-28 days	11/08/92 28/08/92	Normal Normal	
Reboxetime Male			02/11/92	30/12/92	Screen Day 56	-3 59	Screening 29-56 days	30/10/92	Mormal Abnormal	SINUS TACHYCARDIA ( > 100)
Fluoxetine Femalo	Fema	9	03/11/92	24/12/92	Screen Day 28 Day 56	28 51	Screening 1-28 days 29-56 days	04/11/92 01/12/92 24/12/92	Normal Normal Normal	
Reboxetine Fem	Fem	ale	Female 12/11/92 18/11/92	18/11/92	Screen Day 7	0 8	Screening 1-28 days	12/11/92 30/11/92	Normal Normal	
Fluoxetine Fe		Fenale	26/11/92	20/01/93	Screen Day 56	-1-	Screening 29-56 days	25/11/92 25/01/93	Normal Normal	
Reboxetine Fe		Female	31/08/92	22/10/92	Screen Day 28 Day 56	52.2	Screening 1-28 days 29-56 days	26/08/92 29/09/92 22/10/92	Normal Normal Normal	
Fluoxetino Ma		Male	27/10/92	23/12/92	. Day 56	88	29-56 days	24/12/92	Normal	
Fluoxetine Fer		Female	11/09/92	06/11/92	2 Day 28 Day 42 Day 56	339	1-28 days 29-56 days 29-56 days	20/10/92 20/10/92 09/11/92	Normal Normal	
Reboxetine Fe		Female	B 02/11/92	29/12/92	2 Day 56	59	29-56 days	31/12/92	Normal	
Reboxetine Ma	E e	Hale	30/11/92	2 26/01/93	3 Screen Day 28	31	Screening 1-28 days	01/12/92 31/12/92	Normal Normal	
Fluoxetine Female 14/04/92 09/06/92	8 F	mal	e 14/04/9;	2 09/06/9;	2 Screen	-33	Screening	12/03/92	Normal	

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				Abnormality						SINUS BRADYCARDIA ( < 60)	SINUS TACHYCARDIA ( > 100) SINUS TACHYCARDIA ( > 100)				SINUS TACHYCARDIA ( > 100)
			E.C.G.	Value	Normal Normal	Normal Normal	Normal Normal Normal	Normal Normal Normal	Normal Normal Normal	Abnormal Normal Normal	Normal Abnormal Abnormal	Normal Normal Normal	Normal Normal	Normal Normal	Normal Abnormal Normal
			μ	Date	12/05/92 09/06/92	15/04/92 13/05/92 10/06/92	13/04/92 19/05/92 16/06/92	14/05/92 12/06/92 14/07/92	22/05/92 19/06/92 17/07/92	22/05/92 24/06/92 22/07/92	29/05/92 26/06/92 24/07/92	16/06/92 14/07/92 11/08/92	19/06/92 20/07/92	30/06/92 21/07/92	03/03/92 13/08/92 25/08/92
CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 21.0	INGS		Assessment	1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-26 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days	Screening 1-28 days	Screening 1-28 days 29-56 days
PHARMACIA CNS R&D	ETINE - PROTOCOL 20 Listing No.: 21.0	ECG TRACINGS		days of treat.	28 56	28 58 88	28 26 56	28 28 60	0 28 56	28 28 56	28 56	28 56	- 3 28	21	-133 30 42
	REBOXI		1	Visit	Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28	Screen Day 21	Screen Day 28 Day 42
			period_	End date	09/06/92	10/06/92	16/06/92	11/07/92	17/07/92	22/01/92	24/01/92	11/08/92	18/08/92	21/07/92	24/08/92
			_Treatment period_	Start date	14/04/92	15/04/92	21/04/92	15/05/92 11/07/92	Female 22/05/92	27/05/92	29/05/92	16/06/92	22/06/92	30/06/92	14/07/92
				Sex	Fenale	Fenale	Female	Male		Female	Female	Female	Female	Female	Male
				Treatment	Fluoxetine	Reboxetine	Reboxetine	Fluoxetine	Fluoxetine	Reboxetine	Reboxetine	Fluoxetine	Fluoxetine	Fluoxetine	Reboxetine
				Patient	397	398	399	400	401	402	403	404	405	406	407
				ntre					1176						

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				Abnormality			SINUS BRADYCARDIA ( < 60)				SINUS TACHYCARDIA ( > 100)		SINUS BRADYCARDIA ( < 60)		. SINUS BRADYCARDIA ( < 60)									
			E.C.G.	Value		HOLKAL	Mormal Abnormal	Normal	Normal	Normal	Abnormal Normal	Normal	Abnormal	Normal Normal	Abnormal	Normal Normal	Normal	Normal Normal	Normal	Normal	Normal	Normal	Normal	Normal Normal
	<b>5</b> 1		ä	Date	60/80/70	76,000,40	28/09/92 29/10/92	11/11/92	30/09/92	26/11/92	20/11/92	02/11/92	29/10/92	02/12/92 04/01/93	12/02/93	07/04/93	25/02/93	06/05/93 06/05/93	24/03/92	19/05/92	02/06/92	09/04/92	11/06/92	21/04/92 19/05/92
CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 21,0	CINGS		Assessment		эсгеентив	Screening 1-28 days	29-56 days	Screening		1-28 days 29-56 days	Screening	Screening		Screening		Screening		Screening			Screening		Screening 1-28 days
PHARMACIA CNS RED	XETINE - PROTOCOL 20 Listing No.: 21.0	ECG TRACINGS		days of treat.	c	•	30.7	43	- 5	32	28 49	7	r.	29	- 5	<b>9 3</b>	-13	29 57	-15	7.7	55	9 1	35	27
	REBO			Visit	3	oct den	Screen Day 28	Day 42	Screen Day 28	Day 56	Day 28 Day 49	Screen	Screen	Day 28 Day 56	Screen	Day 56	Screen	Day 28 Day 56	Screen	Day 42	Day 56	Screen	Day 56	Screen Day 28
			t period_	End	60/00/06	26 (60 (00	10/11/92		26/11/92		10/12/92	02/12/92	29/12/92		09/04/93		05/05/93		02/06/92			11/06/92		16/06/92
			Treatment period	Start	60780770	76 /90 /10	29/69/92		30/09/92		23/10/92	03/11/92	03/11/92		12/02/93		10/03/93		08/04/92			Fluoxetine Female 17/04/92		Reboxetine Female 22/04/92 16/06/92
				Sex	, c		Fenale		Female		Female	Fenale	Female		Female		Female		Male			Female		Female
				Centre Patient Treatment	d de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de la constant de l	PORTECTION	Fluoxetine		Fluoxetine		Reboxetine	Reboxetine	Reboxetine		Fluoxetine		Fluoxetine		Reboxetine			Fluoxetine		Reboxetine
				Patient	809	2	509		510		511	512	537		538		539		409			410		411
				Centre	2	Ľ					1	177							5				į	
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PHARMACIA CNS R&D

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REBOXETINE - PROTOCOL 20124/016 Listing No.: 21.0

ECG TRACINGS

	Abmormality											
E.C.6.	Date Value	Normal	Mormal Normal Normal	Normal Normal	Normal Normal	Normal Normal	Normal Normal Normal	Normal Normal	Normal Normal Normal	Normal Normal Normal	Normal Normal Normal	Normal Normal
ш	Date	16/06/92	10/04/92 20/05/92 17/06/92	22/04/92 27/05/92 24/06/92	26/05/92 29/06/92 27/07/92	04/06/92 09/07/92 06/08/92	19/06/92 20/07/92 17/08/92	11/06/92 16/07/92 13/08/92	07/07/92 13/08/92 10/09/92	08/07/92 12/08/92 09/09/92	15/07/92 16/09/92 14/10/92	24/07/92 28/08/92
	Assessment	29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-26 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days
	days of treat.	55	-13 27 55	-8 27 55	27 27 55	-8 27 55	-4 27 55	-8 27 55	-10 27 55	-8 27 55	-36 27 55	-8
	Visit	Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28
period	End date	16/06/92	17/06/92	24/06/92	27/07/92	06/08/92	17/08/92	13/08/92	10/09/92	09/09/92	14/10/92	25/09/92
Treatment period	Start	22/04/92	23/04/92	30/04/92	02/06/92	12/06/92	23/06/92	19/06/92	17/07/92	16/07/92	20/08/92	01/08/92
	Sex	Female	Female		Male	Female	Fenale	Fenale	Female	Fenale	Male	Female
	Centre Patient Treatment	Reboxetine	Fluoxetine Female	Reboxetine Female	Fluoxetine Male	Reboxetine Female 12/06/92 06/08/92	Fluoxetine Female	Roboxetine Female 19/06/92	Roboxotine Female 17/07/92	Fluoxetine Female 16/07/92	Fluoxetine	Roboxetine Female 01/08/92 25/09/92
	Patient	411	412	413	414	415	416	417	418	419	420	421
	Centre	ŧ.				1178						

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				Abnormality																													
			E.C.G.	Value	Normal	Normal	Normal	Mormal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	MOFFINAL	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Norma1	Normal	Normal	Normal	Normal	Normal	Normal	Normal
				Bate	25/09/92	14/08/92		15/08/92			13/08/92	17/09/92	15/10/92	24/09/92	29/10/92	26/11/92	20/10/92	24/11/92	22/12/92	25/11/92	30/12/92	27/01/93	25/11/92	30/12/92	27/01/93	01/12/92	04/01/93	01/02/93	29/11/92	06/01/93	03/02/93	07/12/42	14/01/93
NS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 21.0	ENGS		Assessment	29-56 days	Screening	29-56 days	en i noon-R	1-28 days	29-56 days	Screening	1-28 days	29-56 days	Screening	1-28 days	29-56 days	Screening	1-28 days	29-56 days	Screening	1-28 days	29-56 days	Sersoning	1-28 days	29-56 days	Screening	1-28 days	29-56 days	Screening	1-28 days	29-56 days	Sorgening	1-28 days
PHARMACIA CNS R&D	ETINE - PROTOCOL 20 Listing No.: 21.0	ECG TRACINGS		days of treat.	SS	សុទ្ធ			2,2			27	55		27			27		ec i	27	SS		27			27		-	27	SS	-	27
	REBOX			Visit	Day 56	Screen	Day 56	200	Day 28	Day 56	Screen	Day 28	Day 56	Screen	Day 28	Day 56	Screen	Day 28	Day 56	Screen	Day 28	Day 56	Services	Day 28	Day 56	Screen	Day 28	Day 56	Screen	Day 28	Day 56	Surgon	Day 28
			period_	End	25/09/92	13/10/92		15/10/92			15/10/92			26/11/92			22/12/92			27/01/93			59/10/24	200		01/02/93			03/02/93			11/02/03	
			Treatment period	Start	01/08/92	19/08/92		24/08/92			21/08/92			02/10/92			28/10/92			03/12/92	!		09/12/02	46 (4)		Female: 08/12/92			10/12/92			18/12/92	i i
				Sex	Female	Kale		Comple			Kale			Female			Male			Female			0	9160		Female			Male			Tomala	
				Treatment	Reboxetine	Fluoxetins		Clustotine	-		Reboxetine			Reboxetine			Fluoxetine			Reboxetine			Fluovotino	T TROVERTIES		Reboxetine			Fluoxetine			Elucanting Comple 48/12/62 41/02/63	
				Centre Patient	421	422		867	3		424			425			426	ì		427	ì		867	9 F		449			450			454	2
				Centre	5									1 1	L 7	9																	

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			Abnormality					PREVIOUS MYOCARDIAL INFARCTION PREVIOUS MYOCARDIAL INFARCTION PREVIOUS MYOCARDIAL INFARCTION		LEFT ANTERIOR HEMIBLOCK LEFT ANTERIOR HEMIBLOCK				
		e -	Value	Normal	Normal Normal Normal	Normal Normal Normal	Normal Normal	Abnormal Abnormal Abnormal	Normal Kormal Normal	Normal Abmormal Abmormal	Normal Normal	Normal Normal Normal	Normal Normal Normal	Normal Normal
		<u>.</u>	Date /	11/02/93	15/12/92   19/01/93   16/02/93	08/01/93 15/02/93 15/03/93	12/03/92 22/04/92 20/05/92	26/03/92 27/04/92 25/05/92	26/03/92 27/04/92 25/05/92	26/03/92 27/04/92 25/05/92	28/03/92 27/05/92	03/04/92 04/05/92 01/06/92	09/04/92 11/05/92 08/06/92	20/04/92 21/05/92 18/06/92
NS RED	REBOXETINE - PROTOCOL 20124/016 Listing No.: 21.0	NGS	Assessment	29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-26 days 29-56 days	Screening 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days
PHARMACIA CNS R&D	INE - PROTOCOL 20 Listing No.: 21.0	ECG TRACINGS	days of treat. /	55	27.27.55	-11 27 55	-14 27 55	-4 28 56	-5 27 55	-5 27 55	\$ \$ 1	-4 27 55	55. 55.	-4 27 55
	REBOXET		Visit	Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56
			period_ End date	11/02/93	16/02/93	15/03/93	20/05/92	25/05/92	25/05/92	25/05/92	27/05/92	01/06/92	08/06/92	18/06/92
			Treatment period Start End date date	18/12/92	23/12/92	19/01/93	26/03/92	30/03/92	31/03/92	31/03/92	02/04/92	07/04/92	14/04/92	24/04/92
			X S	Female	Female	Male	Female	Male	Female	Female	Female	Female	Female	Female
			Centre Patient Treatment	Fluoxetine	Reboxetine	Fluoxetine	Fluoxetine	Reboxetime	Reboxetine	Fluoxetine	Reboxetine	Fluoxetine	Reboxetime	Fluoxetine
			Patient	451	452	484	429	430	431	432	433	434	435	436
			Centre	15			36	1	180					

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				Date Value Abnormality
			E.C.G.	Value
	90		.a	Date
CNS RAD	REBOXETINE - PROTOCOL 20124/016 Listing No.: 21.0	CINGS		treat. Assessment
PHARMACIA CNS R&D	OXEIINE - PRO Listing N	ECG TRACINGS	go eriop	treat.
	2			Visit
			period	date
			Treatment period	date
				Sex
				Treatment

Centre Patient Treatment

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RICHT BUNDLE BRANCH BLOCK RICHT BUNDLE BRANCH BLOCK RICHT BUNDLE BRANCH BLOCK						,			
Abnormal Abnormal Abnormal	Normal Normal	Normal Normal Normal	Normal Normal Normal	Normal Normal	Normal Normal Normal	Normal Normal Normal	Normal Normal Normal	Normal Normal	Normal Normal
24/04/92 27/05/92 24/06/92	15/05/92 16/06/92	15/05/92 16/06/92 14/07/92	26/06/92 28/07/92 11/08/92 25/08/92	17/08/92 14/09/92	14/07/92 17/08/92 14/09/92	20/08/92 21/09/92 18/10/92	20/08/92 21/09/92 19/10/92	12/09/92 15/10/92 12/11/92	12/09/92 12/11/92
Screening 1-28 days 29-56 days	Screening 1-28 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days 29-56 days	1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 1-28 days 29-56 days	Screening 29-56 days
27 55	27	-5 27 55	-5 27 41 55	26 54	- 8 2.6 5.4	27 54	-5 27 55	-6 27 55	5.
Screen Day 28 Day 56	Screen Day 28	Screen Day 28 Day 56	Screen Day 28 Day 42 Day 56	Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 28 Day 56	Screen Day 56
24/06/92	18/06/92	14/07/92	25/08/92	14/09/92	14/09/92	18/10/92	19/10/92	12/11/92	12/11/92
30/04/92	Female 20/05/92 18/06/92	20/05/92	01/07/92	22/07/92 14/09/92	22/07/92 14/09/92	25/08/92 18/10/92	25/08/92	18/09/92	18/09/92
Fenale	Fomale	Female	Female		Female	Male	Female	Kale	Female
Reboxetine Female 30/04/92 24/06/92	Fluoretine	Fluoxotine Female 20/05/92 14/07/92	Reboxetine Female	Fluoxetine Female	Roboxetine Female	Fluoxetine	Reboxetine Femala 25/08/92 19/10/92	Reboxetine	Fluoxetine Female 18/09/92 12/11/92
437	438	439	4	441	442	443	***	448	944
16			118	31					

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							PHARMACIA CNS R&D	CNS R&D				4
						REBOXE	STINE - PROTOCOL 20 Listing No.: 21.0	REBOXETINE - PROTOCOL 20124/016 Listing No.: 21.0	9			
							ECG TRACINGS	CINGS				
				Treatment period	period_				B	E.C.G.		
Centre	Patient	Centre Patient Treatment	Sex	Start	End	Visit	days of treat.	Assessment	Date	Value	Abnormality	
16	447	Fluoxetine	Hale	18/09/92	12/11/92	Screen	9-		12/09/92	Normal		
						Day 28 Day 56	27		15/10/92			
						•	}					
	448	Reboxetine	Female	19/09/92	13/11/92	Screen	'n	Screening	14/09/92			
						Day 28 Day 56	27 55		16/10/92	Normal Normal		
				•								
	455	Fluoxetine		Female 19/09/92	13/11/92	Screen	Ϋ́		14/09/92			
						Day 28	27	1-28 days	16/10/92	Normal		
							3		76.41	TOWN		
	456	Reboxetine	Na1e	16/12/92	09/02/93	Screen	-2		09/12/92	Normal		
1.	1					Day 28	27	1-28 days	12/01/93	Normal		
ΤŞ	18					Day 56	55		09/02/93	Normal		
3 K				4		,	1		;	;		
,	45	FINOXOLING	remaile	26/21/91	09/02/93	Screen			09/12/92	Normal		
						Day 56	55	29-56 days	09/02/93	Normal		
	458	Fluoratine Comple	. Fomelo	16/19/09	00/00/00	S	٩		60,000			
	2				20, 120, 120	Day 28	27		12/01/93	Normal		
						Day 56	SS		09/02/93	Normal		
	459	Reboxetine	Kale	22/12/92	15/02/93	STREET	ų	Screening	17/12/92	Normal		
						Day 28	27		18/01/93	Normal		
						Day 56	S	29-56 days	15/02/93	Normal		
	094	Reboxetine	Male	22/12/92	15/02/93	Screen	5-	Screening	17/12/92	Normal		
55	25	Fluoxetine	Female	06/10/92	30/11/92	2000	1	Saringent	64/60/06	Normal		
						Day 28	28		03/11/92	Normal		
						Day 56	26		01/12/92	Normal		
	56	Reboxetine	Female	06/10/92	30/11/92	Screen	9		30/09/92	Normal		
						Day 28 Day 56	28		03/11/92		SINUS TACHYCARDIA ( > 100) SINUS TACHYCARDIA ( > 100)	
								•				
	27	Reboxetine	Female	06/10/92	30/11/92	Screen	9 6	Screening	30/09/92			
						Day 40	3		U3/ 11/76	NOFTH 1		

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Screen Day 28 Day 56

Fluoxetine Female 15/01/93 11/03/93

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Fluoxetine

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				Abnormality																					
				Abno									,												
			E.C.G.	Value	Normal	Normal Normal	Normal	Normal Normal	Normal	Normal Normal	Normal	Normal		Normal	Normal Normal	Normal	Normal	,	Normal	Normal	Normal	Normal	Normal	Normal	Normal
		,		Date	01/12/92	30/09/92 27/10/92	30/09/92	03/11/92	30/09/92	09/11/92	13/10/92	25/11/77		05/10/92	01/12/92	10/11/92	12/01/93		10/11/92	10/11/92	22/12/92	12/11/35	10/11/92	22/12/92	12/01/93
CNS R&D	REBOXETINE - PROTOCOL 20124/016 Listing No.: 21.0	INGS		Assossment	29-56 days	Screening 1-28 days	Screening	1-28 days 29-56 days	Screening	1-28 days 29-56 days	Screening	1-25 days	<u>;</u>	Screening	1-28 days 29-56 days	Screening	29-56 days 29-56 days		Screening	Screening	1-28 days	Zy-56 days	Screening	29-56 days	29-56 days
PHARMACIA CNS R&D	TINE - PROTOCOL 20 Listing No.: 21.0	ECG TRACINGS		days of treat.	98	212	99 5	28 28 29 29	-2	8 %	-7	28	1	N I	55		8 8	1	-2	-7	35	ร์		32	, S
	REBOXE			Visit	Day 56	Screen Day 28	Screen	Day 28 Day 56	Screen	Day 28 Day 56	Screen	Day 28	?	Screen	Day 28 Day 56	Screen	Day 35 Day 56	1	Screen	Screen	Day 28	Day 56	Screen	Day 35	Day 56
			period	End	30/11/92	02/11/92	30/11/92		01/12/92		14/12/92			30/11/92		11/01/93			18/11/92	11/01/93			11/01/93		
			Treatment period	Start	06/10/92 3	06/10/92	06/10/92		07/10/92		Female 20/10/92 14/12/92			Female 07/10/92		17/11/92			17/11/92	17/11/92			Female 17/11/92 11/01/93		
	ı			Sex	Female	Fenale	Male		Female		Female			Female		Female		1	Female	Female			Female		
						_	_		_		_			•		•				m			m		

Fluoxetine

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Fluoxetine

Centre Patient Treatment

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Reboxetine

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				Abnormality	SINUS BRADYCARDIA ( < 60)	SINUS BRADYCARDIA ( < 60) SINUS BRADYCARDIA ( < 60)					
			E.C.G.	Value	Mormal Mormal Abnormal	Normal Abnormal Abnormal	Normal Normal	Normal Normal Normal	Normal	Normal	
	<u>v</u>		ផ	Date	05/01/93 09/02/93 09/03/93	30/10/92 20/11/92 27/11/92	13/11/92	16/10/92 02/11/92 23/11/92 14/12/92	24/11/92 Normal	23/12/92 Normal	
CNS ReD	REBOXETINE - PROTOCOL 20124/016 Listing No.: 21.0	SINGS		Assessment	Screening 1-28 days 29-56 days	Screening 1-28 days 1-26 days	Screening 1-28 days	Screening 1-28 days 1-28 days 29-56 days	Screening	Screening	
PHARMACIA CNS R&D	ETINE - PROTOCOL 20 Listing No.: 21.0	ECG TRACINGS		days of treat.	-7 28 56	- 7 14 21	1 28	- 14 14 35 36	61	Ψ	
	REBOXE			Visit	Screen Day 28 Day 56	Screen Day 14 Day 21	Screen Day 28	Screen Day 14 Day 28 Day 56	Screen	Screen	
			period	End date	08/03/93	30/12/92	16/12/92	13/12/92	18/12/92	20/01/93	
			Treatment period	Start date	12/01/93 08/03/93	Fenale 06/11/92 30/12/92	Female 12/11/92	19/10/92	03/12/92 18/12/92 Screen	29/12/92 20/01/93 Screen	
				Sex	Male	Fenale	Female	Female	Male	Kale	
				Centre Pationt Ireatment	Fluoxetine	Fluoxetine	Fluoxetine	Fluoxetine	Fluoxetine	Reboxetine	
				Pationt	54	<b>1</b> 2	22	6	113	115	
				Centre	81	20		21	22		

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

#### 9550083

Pharmacia

Document 9550083

12.2.3 CRFs

Individual patient CRFs are filed in the Study Master File.