Studie 009

(CTN009-FCE20124)

Studienbericht

Pharmacia Document 9550321

Reboxetine	CLINICAL STUDY	10 January 1996
	009	

Phase II Controlled Study of the Activity and Tolerability of Reboxetine in Comparison with Placebo in Patients Hospitalized for Major Depressive Disorders

(Phase II)

Final report of study
CTN009-FCE20124

Authors
Dubini A, Di Nicolò P

Pharmacia Document 9550321

STUDY CO-ORDINATION, MANAGEMENT AND REPORTING

Study Director

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

signature date

Medical Research Associate

Paola Di Nicolò Biol.D.
Pharmacia, CNS R&D
Milan, Italy

signature date

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LIST OF ABBREVIATIONS AND TERMS

b.i.d	twice daily
BUN	blood urea nitrogen
CGI	clinical global impression
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
REM	rapid eye movement
SD	standard deviation
SGOT	serum glutamic-oxaloacetic transaminase
SGPT	serum glutamic-pyruvic transaminase
T3	triiodothyronine
T4	thyroxine

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SYNOPSIS

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

Title of the study	Phase II controlled study of the activity and tolerability of reboxetine in comparison with placebo in patients hospitalized for Major Depressive Disorder (Protocol ADE 009, internal report 9550321)
Investigators:	S Levine, R Deo, E Stonehill, M Cozzolino, H Mathew, SK Chakravarti, Sharma, PK Mukherjee
Study centers:	No. 7 centers involved in England: - Oldham & District General Hospital, Oldham - Central Middlesex Hospital, London - Roundwood Day Hospital, Willesden London - Staincliffe General Hospital, Dewsbury - St. Luke's Hospital, Huddersfield - Hartwood Hospital, Shotts - Monklands Dist. Gen. Hospital, Airdrie
Publication (reference): none	
Study period: Nov. 87 - June 89	**Clinical Phase:** II
Objectives:	To evaluate the antidepressant activity and the tolerability of reboxetine in comparison with placebo in Major Depressive Episode.
Methodology:	A multicenter double blind, parallel group design where in each center subjects were randomly allocated to experimental treatment in number of 10. The patients received 1 capsule b.i.d (4 mg) from Day 1 to Day 3, 3 capsules daily (6 mg) from Day 4 to Day 7 and 2 capsules b.i.d (8 mg) from Day 8 do Day 28.
Number of subjects (planned and actual, total and for each treatment):	80 patients to be recruited, 50 patients (33 females and 17 males) entered the study: 26 were treated with reboxetine while 24 with placebo.
Diagnosis and criteria for inclusion:	Patients aged from 21 to 65 with DSM-III diagnosis of Major Depression Episode with presence of illness for at least one month and the Hamilton Depressions rating scale total score ≥18. For each patient the correspondence with ICD-9 diagnostic classification has been also reported. Informed consent has been provided from all the patients.

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SYNOPSIS (continued)

Name of Company: Pharmacia Spa **Name of finished product:** **Name of active ingredient(s):** Reboxetine	**Individual study table referring to part IV of the dossier** **Vol.:** **Page:**	**(For national authority use only)**
Duration of treatment: 28 days		
Test product: Capsules containing reboxetine methanesulphonate **dose:** 2 mg (free base) **mode of administration:** by oral route **batch no.:** SF 898		
Reference therapy: placebo capsules **dose:** - **mode of administration:** by oral route **batch no.:** SF 897		
Criteria for evaluation: **efficacy criteria:** 17-items Hamilton Depression Rating scale (HAMD), Clinical Global Impression (CGI), Montgomery-Asberg Depression Rating Scale and Levine-Pilowsky Depression Questionnaire. The study end point was defined as a decrease of at least 50% of HAMD total score. **safety criteria:** Vital signs (lying and standing heart rate, body weight and body temperature) laboratory tests, ECG and adverse events were monitored.		
Statistical methods: Confidence interval of the between treatment difference in response rate at Day 28 and last assessment and cumulative risk of emergence of adverse events according to Kaplan-Meier method and log-rank test.		

SYNOPSIS (continued)

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

Results:

efficacy: In view of the inconclusiveness of the study the analysis of the efficacy assessments has been limited to the HAMD and CGI rating scale.

At admission the mean HAMD total score was 25.33 (SD 3.55) in the reboxetine group and 25.27 (SD 4.94) in the placebo group. The end point of the study, a 50% decreased of HAMD total score after 28 days of treatment, was reached by 12 patients (46.1% of the exposed) in the reboxetine group and by 7 patients (29.2%) in placebo group. At the last assessment the corresponding figures were respectively 14 (53.8%) and 9 (37.5%) in reboxetine and in placebo group. As far as the Clinical Global Impression is concerned, at admission, most of the patients in both group has been judge as "moderately ill" (50% in reboxetine group and 66.7% in placebo group) or "markedly ill" (25% and 38.5% in placebo group and reboxetine group respectively). At last assessment, 8.7% of the patients on placebo and 7.7% of patients on reboxetine were considered "normal". Only 13% of the patients on placebo were judged to be "borderline mentally ill" compared to 42.3% on reboxetine. At last assessment the cases much and very much improved were 34.8% on placebo and 53.9% on reboxetine while the efficacy index scores were more frequently of 1 or lower in patients treated with placebo (47.8%) than in patients treated with reboxetine (30.8%). In the latter group the maximum efficacy index of 4 was scored in 23.1% of patients, compared to 13.0% of the cases on placebo.

safety: Fifteen patients of placebo group (62.5%) and 18 in reboxetine (69.23%) complained of 39 and 42 adverse events (AEs), respectively. The most frequently reported AEs (under reboxetine and placebo respectively) were headache (33.3 and 26.6%), constipation (27.7 and 33.3%), dry mouth (33.3 and 26.6%), nausea (16.6 and 20%). The analysis of the cumulative risk of developing the first adverse event during the treatment showed no differences between the two groups. The maximal severity of AEs more frequently reported was moderate on both reboxetine (66.7%) and placebo (64.3%). No significant modifications of note were apparent in both groups on results of laboratory tests. Vital signs and ECG assessment did not indicate differences of any relevance between the two treatment groups.

Conclusions: Both frequency of response (at least 50% decrease of HAMD total score) and CGI-Severity of Illness and Global Improvement distribution of scores suggest antidepressant activity of reboxetine in comparison with placebo when administered for 4 weeks to hospitalized patients at fixed-changing doses, with maximum doses of 8 mg/day. The extent of the difference *vs* placebo, as estimated in this sample of 50 patients, is compatible with the study being conclusive (i.e. allowing rejection of the null hypothesis) in the foreseen total sample of 40 patients per treatment arm.

1. INTRODUCTION

Reboxetine (FCE 20124 or (2RS, αRS)-2- [α- (2-ethoxy-phenoxy) benzyl] morpholine) is a new norepinephrine re-uptake inhibitor, highly potent in the pharmacological tests predictive of antidepressant activity in patients, such as reserpine antagonism and REM sleep latency increase [1]. In a model in rodents (prevention of clonidine-induced hypothermia) where tricyclic antidepressants were effective only after multiple doses, a single oral administration of reboxetine prevented clonidine-induced effect: on this basis the compound was hypothesized to exert antidepressant efficacy of faster onset compared to classical antidepressant agents in patients [1].

Pharmacodynamic studies in healthy volunteers have been carried out using single doses from 0.2 to 5 mg. The administration of 5 mg was associated with orthostatic hypotension accompanied by tachycardia. Single doses of 1 and 3 mg reboxetine were compared to 75 mg of imipramine and placebo in a quantitative EEG and psychometric study. Reboxetine induced dose-related modifications of EEG power bands and of performance in psychometric tests suggestive of stimulating properties, while following imipramine changes consistent with the known sedative activity of the compound were apparent [2, 3].

Pharmacokinetics studies carried out administering 2 mg of ^{14}C- FCE 20124 to 3 healthy volunteers showed that the compound is mainly eliminated by renal excretion, with a plasma half life of 13.2h [4]. Steady-state levels are expected to be reached in three days upon repeated administration.

A dose range finding multicenter 4-week study in 98 patient suffering from major depressive episodes was carried out with fixed-changing doses, and maximum doses of 4 to 12 mg daily [5]. At the highest dosage hypotension accompanied by dizziness and tachycardia newly appeared in 5 of the 12 patients exposed. Daily doses of 8 and 10 mg were associated with maximal therapeutic benefit and minimal side-effects.

The present study was carried out to evaluate the efficacy and tolerability of reboxetine in controlled conditions in comparison with placebo.

2. STUDY OBJECTIVES

To evaluate the antidepressant activity and the tolerability of reboxetine in comparison with placebo in Major Depressive Disorders.

3. INVESTIGATIONAL PLAN

3.1 Study Design and Plan - Description and Rationale

3.1.1 OVERVIEW AND JUSTIFICATION

The study was performed according to a multicenter double-blind, parallel group design in 4 centers, expected to recruit 20 patients each in a period of 12 months. After an initial drug-free wash-out period of 7-14 days, patients hospitalized due to a Major Depressive episode (first episode or recurrence) were randomly allocated to treatment with either reboxetine or placebo at increasing dosages from 4 mg/day (Day 1-3), to 6 mg/day (Day 4-7), and to 8 mg/day up to Day 28. The response rate (i.e. the frequency of patients showing $\geq$ 50% decrease of HAMD total score) at Day 28 was defined as the study end-point. The total population of 40 patients per treatment arm was expected to provide the test of the null hypothesis with a power of 0.8 in presence of a difference in response rate of at least 30%, assuming a placebo response rate of 40% and a 0.05 one-sided α level.

In view of the very slow recruitment rate (eventually corresponding to 50 patients included in 18 months) the number of centers was extended to 7, and the protocol was amended to extend inclusion capacity to day-hospital patients. These actions, however, did not improve satisfactorily recruitment rate and an interim analysis of the results obtained in the accrued sample of 50 patients was decided.

The results of the analysis showed a between treatment difference in response rate lower than 30%, corresponding to 21% at Day 28. However, the calculated 90% confidence interval (-1/43%) is compatible with the study being conclusive (i.e. allowing rejection of the null hypothesis) if completed in the initially foreseen sample size.

3.1.2 PROTOCOL AMENDMENTS

As previously mentioned, a protocol amendment was implemented, to extend recruitment capacity to day-hospital patients.

3.2 Ethics

3.2.1 PATIENT INFORMATION

All patients were informed about the nature of the study and protocol requirement and gave their consent to participation by signing the consent form.

3.3 Study population

3.3.1 INCLUSION CRITERIA

The patients admitted to the study were to be 21 to 65 years old and to fulfil the DSM-III diagnostic criteria for Major Depression Disorders [6], with presence of symptoms for at least one month, and with an HAMD total score $\geq$18. The correspondence with ICD-9 diagnostic classification was also reported for each patient.

3.3.2 EXCLUSION CRITERIA

For safety reasons, patients with pathologies known to interfere with the absorption, distribution, metabolism and excretion of drugs as gastrointestinal, liver, or kidney diseases were excluded. Important hematopoietic or cardiovascular illness as well as current evidence of urinary retention, thyroid disease, glaucoma and abnormal findings in the physical examination, laboratory tests or ECG, were also not compatible with inclusion in the study.

Patients with an history of brain seizure or brain trauma, hypersensitivity to psychotropic drugs, with evidence of substance use disorders, and patients who, during the four weeks prior to inclusion, were treated with any drug with well-defined potential for toxicity to a major organ, or displayed signs of any important clinical illnesses were also excluded.

Finally, pregnant or breast feeding women, or patients who participated in clinical trials with an investigational drugs within the six months preceeding the study were not admitted.

3.3.3 WITHDRAWAL CRITERIA

The patients could discontinue the study in case of deterioration of the clinical status reported as worsening of CGI-Global Improvement on Day 7 or Day 10. On Day 14, an unchanged or worsened CGI-Global Improvement could also be considered as a reason for discontinuation.

Patients who dropped out because unwilling to continue, for administrative reasons or for intercurrent medical illness without having completed at least 14 days of drug administration were to be replaced while patients discontinued for inefficacy or intolerable adverse reactions were not. At the moment of discontinuation, for any reason, a complete battery of all clinical tests assessment was performed.

3.4 Treatments

3.4.1 TREATMENTS TO BE COMPARED

Reboxetine and placebo were administered orally in identical capsules, containing 2 mg of reboxetine plus excipients or excipients only.

3.4.2 IDENTITY OF TEST TREATMENTS

Reboxetine (batch no. SF 898) and excipients (placebo batch no. SF 897) were both manufactured by Farmitalia Carlo Erba.

3.4.3 DOSE SELECTION AND TIMING

Patients received 1 capsule b.i.d., at 10 a.m. and 8 p.m., from Day 1 to Day 3. If well tolerated the dosage was increased to 2 capsules in the morning and 1 in the evening from Day 4 to Day 7 and 2 capsules b.i.d. from Day 8 to Day 28. The study required hospitalization for at least 14 days to assure adequate monitoring of tolerability of the experimental treatment. After Day 14, the patient could be discharged in case of improvement or if necessary at the discretion of the investigator. These patients continued the treatment as "out-patients" receiving the needed capsules up to the following visit foreseen at Day 21 and at Day 28.

Day-hospital patients, admitted following the protocol amendement, started treatment on Monday, and on Friday received the exact number of capsules needed for the treatment on the following Saturday and Sunday.

3.4.4 METHOD OF ASSIGNING PATIENTS TO TREATMENT GROUPS

A randomization list of progressive numbers randomly assigned to one of the two treatments, balanced in blocks of 4 treatments, was prepared and the study medication was labeled accordingly. Patients were allocated to the progressive treatment numbers on the basis of their temporal entry into the study. Investigators were given individual sealed envelopes, containing the information of the treatment actually administered to each patient, to be opened in case of emergency necessitating treatment identification.

3.4.5 TREATMENT SUPPLY AND BLINDING

For each patient one bottle containing 105 capsules (maximum needed +3) of either reboxetine or placebo was provided; the bottles were labeled with the progressive number of the patient according to the treatment code.

3.5 Treatment Procedures

3.5.1 PRE-TREATMENT WASH-OUT

Before starting the experimental treatment a drug-free wash out period of 7 days (14 days in case of MAOI administration) was required.

3.5.2 TREATMENT CONDITIONS

The study required hospitalization (including day-hospital following the amendment) for the initial two weeks of treatment to assure adequate monitoring of tolerability of the experimental treatment. After Day 14, patients could be discharged in case of improvement or if necessary at the discretion of the investigator, to continue treatment as out-patients.

3.5.3 CONCOMITANT THERAPY

No concomitant medications were allowed to be administered during the study, except for temazepan at bed-time as sleep inducer.

3.6 Efficacy and Safety Variables

3.6.1 EFFICACY

The efficacy evaluations included the 17-item Hamilton Depression Rating Scale (HAMD) [7] and the Clinical Global Impression (CGI) [8] assessed on Day 0, 4, 7, 10, 14, 21 and 28, the Montgomery-Asberg [9] Depression Rating Scale, evaluated on Day 0, 7, 14, 21 and 28, and the Levine-Pilowsky [10] Depression Questionnaire administered to the patients on Day 0, 14 and 28.

The end-point of the study was defined as the frequency of decrease of at least 50% of the total score of the Hamilton Depression Rating Scale (17 items HAMD).

3.6.2 SAFETY

Safety assessments were carried out throughout the 28 days of treatment, always before the morning dose.

3.6.2.1 Adverse Events

During the trial all the adverse reactions (AEs) solicited from patients using the AEs check list (Newly Observed Signs and Symptoms), or spontaneously complained by the patients, or observed by the investigator, were recorded along with time of onset, duration, severity, outcome and drug-relationship. The information concerning any serious AE were promptly reported to the Study Monitor in the UK.

3.6.2.2 Clinical and Laboratory Tests

Vital signs assessment included the measurement of blood pressure and heart rates (both taken in lying position after 5 minutes rest and 2 minutes after standing-up) and body temperature on Day 0, 4, 7, 14, 21 and 28 and of body weight on Day 0, 14 and 28.

Standard 12-leads ECG was recorded at pre-treatment and at the end of treatment (unless cardiac complaints required additional investigations during the study).

Haematology and blood chemistry tests and urinalysis were performed at admission and on Day 7, 14 and 28. In case of abnormal findings the cause had to be investigated and the tests repeated. According to the inclusion/exclusion criteria, the thyroid function was also tested at screening assaying the blood concentration of T_3 and T_4.

At Day 28, before the morning dose, 5 ml of blood were to be collected in heparinized tubes for the determination of reboxetine plasma levels at steady-state.

3.7 GCP Compliance

This study has been performed according to the Tokyo revision of Helsinki declaration and has been approved by the Southampton and South-west Hampshire Health Authority Committee.

The study was carried out before the formal adoption af GCP guidelines by European Regulatory Authorities and in the absence of Company standard operating procedures.

3.8 Statistical Analysis

3.8.1 DETERMINATION OF SAMPLE SIZE

The calculated sample size of 40 patients per group provides the test of the null hypothesis of no difference in response rate (defined as the frequency of patients showing a decrease ≥50 % of the Hamilton Depression Scale total score at Day 28) between the two treatments with a power of 0.8, i.e. 80% probability of rejecting it in presence of a between treatments difference in response rate of at least 30%, assuming a 40% response rate under placebo and 0.05 one-sided alpha level.

3.8.2 STATISTICAL ANALYSIS

3.8.2.1 Efficacy Analyses

Statistical tests appropriate for parametric and non parametric data were to be carried out, including non-parametric test of the between treatment difference in response rate (see above).

3.8.2.2 Safety

Descriptive statistics was to be provided. Laboratory tests results were to be classified as normal or abnormal by comparison with the normal ranges provided by the performing Laboratory, and frequencies of abnormal results after treatment were to be analysed, if appropriate.

3.8.2.3 Changes in the Conduct of the Study or Planned Analysis

As mentioned above, following the very slow recruitment rate, the study was discontinued. The analysis has therefore been limited to the study end-point, in order to check if the between treatment difference in response rate was compatible with the hypotheses made for the calculation of the sample size. In view of the small size of the sample, the 90% confidence interval of the between treatment difference in response rate at Day 28 and at the last assessment was calculated.

In view of the above, in the present report the documentation and analysis of efficacy assessments has been limited to the HAMD and CGI scales, while the analysis has been focused on safety assessments. As to the latter, an additional analysis of the cumulative risk of emergence of adverse events according to the Kaplan-Meier method and log-rank test [11] has been provided.

3.9 Data Management

R&D Biostatistics Dpt. of Farmitalia Carlo Erba was responsible for data processing and analysis.

CRF data were entered into an IBM 3090 computer through data entry masks generated by SAS FSP release 6.06 and 6.07.

ECG tracings were classified and subsequently grouped according to the codes reported in Appendix 12.1.7. Previous and concomitant diseases were coded according to ICD9 dictionary [12]; concomitant drugs according to the Drug Reference List [13]; adverse events according to the WHO-ART dictionary [14].

4. STUDY PATIENTS

4.1 Disposition of Patients

Fifty patients entered the study from November 1987 to June 1989 in the 7 centers involved. Recruitment by centre is shown in Table 1. Twenty-six patients received reboxetine and 24 placebo.

A total of 37 patients (20 of the reboxetine group and 17 of the placebo group) completed the 28-day treatment period as foreseen by the protocol, while 6 and 7 patients, respectively, discontinued the study (Table 2). As shown in Table 3, 3 patients from the placebo group discontinued because of adverse events (patient no. 23 because of extrasystoles and agitation, patient no. 51 because of fatigue, paraesthesia and intermenstrual bleeding, patient no. 65 because of macular rash); 3 patients were withdrawn because of inefficacy, while 1 patient refused to continue with the treatment. In the reboxetine group 1 patient dropped out for an adverse event (patient no. 8 paresthesias and cyanosis), 3 patients for inefficacy, 1 patient for administrative reason and 1 patient for treatment refusal.

4.2 Demographic Data

The reboxetine group included 17 female and 9 male patients while the placebo group included 16 female and 8 male patients. Patient's age ranged from 24 to 64 years (mean 45.81, SD 11.30) in the reboxetine group and from 24 to 65 years (mean 47.04, SD 13.48) in the placebo group.

The two groups were also similar as for weight (mean/SD 69.21/11.50 kg in the reboxetine group and 65.88/18.21 kg in the placebo group) and height (mean/SD 166.63/6.57 cm in the reboxetine and 164.26/9.58 cm in the placebo group (Table 4).

4.2.1 DIAGNOSIS AND HISTORY OF THE DEPRESSIVE DISORDER

Nineteen of the placebo-treated as well as of the reboxetine-treated patients had a diagnosis Major Depressive Disorder, recurrent (DSM-III 296.3), while 5 patients in the placebo group and 7 in the reboxetine group were at their first episode (DSM-III 296.2) (Table 5). At the time of admission the severity of illness according to HAMD total score and CGI-Severity of Illness were similar in the groups (see Tables 12, 14).

The duration of the index episode was somewhat higher in the reboxetine (mean/SD 32.19/83.99 weeks) than in the placebo group (mean/SD 19.63/21.08 weeks) (Table 7).

The current episode was considered as an "exacerbation of a chronic condition" in 4 patients of the placebo group and 5 of the reboxetine group; a "recurrence of a similar previous condition" for 14 patient and 13 patient of the reboxetine and placebo group, respectively; and as "different from any previous episodes" only for 2 subjects treated with placebo. In both groups for most patients (53.8 *vs* 58.3%, reboxetine *vs* placebo) there were no precipitating external factors contributing to the onset of the current episode (Table 6).

As for the history of the mental disorder, the number of previous episodes was ranging from 1 to 20 in the placebo group and from 1 to 12 in the reboxetine group (median 4 in both cases) (Table 8). The last episode had a relatively lower duration in the reboxetine (mean/SD 12.15/10.89 weeks) than in the placebo group (mean/SD 24.68/33.12 weeks) (Table 7).

4.2.2 MEDICAL HISTORY

The medical history of the two groups of patients, grouped by body system, is shown in Table 9. In the placebo and reboxetine groups a total of 10 and 5 disorders, respectively, were reported. Disorders of the digestive system were the most frequent (3 and 2 cases in the reboxetine and placebo groups). No major differences between the two groups are apparent.

4.2.3 PREVIOUS ANTIDEPRESSANT TREATMENTS

The frequency of previous antidepressant therapies administered to the patients is described by active principle in Table 10. As expected, the most frequently prescribed drugs were tricyclic antidepressant.

5. STUDY MEDICATION

All the patients, except for two under placebo, have been reportedly treated according to protocol, i.e. with 4 mg/day in the first 3 days, 6 mg/day from Day 4 to Day 7, and with 8 mg/day from Day 8 to Day 28 (see Listing no. 15.1). Two patients on placebo (no. 27, 75) had the daily dose decreased from 8 to 4 mg because of adverse events.

6. CONCOMITANT MEDICATIONS

All the medications reportedly administered during the study period are summarized by active principle in Table 11. In both groups the most frequently administered drug was temazepam, as symptomatic treatment for insomnia. The other drugs have been mainly administrated because of adverse reactions.

7. EFFICACY RESULTS

In view of the inconclusiveness of the study the documentation and analysis of efficacy assessments has been limited to the HAMD and CGI rating scales.

7.1 Hamilton Depression Rating Scale

Summary statistics of HAMD total scores at each visit in the two groups are shown in Table 12, while summary statistics of HAMD total scores at the last assessment are presented in Table 13. At admission to the study no difference between the two groups is apparent: in patients allocated to reboxetine the mean HAMD total score was 25.33 (SD 3.55) while in patients allocated to placebo it was 25.27 (SD 4.94). The mean values to the total scores were only marginally lower in the reboxetine group compared to the placebo group on Days 21-28 (14.33-12.56, SD 6.62-8.3 *vs* 16.63-15.12, SD 6.16-8.28 respectively) as well as at last assessment (14.38, SD 8.9 *vs* 15.1, SD 8.5).

The "intent to treat" analysis of the frequency of patients reaching the study end-point, i.e. a decrease of at least 50% of HAMD total score after 28 days of treatment (fully evaluated cases) as well as at last assessment with respect to patients admitted is given below.

Absolute and percent frequency of patients with at least 50% decrease of HAMD total score among patients admitted

Assigned treatment	Day 28		last assessment	
placebo	7/24	29.2%	9/24	37.5%
reboxetine	12/26	46.1%	14/26	53.8%

Results of the calculation of the 90% confidence intervals of the between treatment differences are given below.

Day 28			last assessment		
between treatment difference	lower limit	upper limit	between treatment difference	lower limit	upper limit
16.9%	-5%	39%	16.3%	-6.5%	40

In the sub-sample of patients completing the study and fully evaluated, the between treatment difference in response rate is somewhat higher than observed in the "intent to treat" analysis, as shown below.

Absolute and percent frequency of patients with at least 50% decrease of HAMD total score among patients completing the treatment period and fully evaluated

Assigned treatment	Day 28	
placebo	7/17	41.2%
reboxetine	12/18	66.7%

7.2 Clinical Global Impression

7.2.1 SEVERITY OF ILLNESS

At entry into the study, most of the patients in both groups have been judged as "moderately ill" (50% in the reboxetine group and 66.7% in the placebo group), or "markedly ill" (38.5% and 25% in the reboxetine and placebo groups, respectively). Only 8.3% of the cases in the placebo group and 11.5% of the cases in the reboxetine group were judged to be "mildly ill" (Table 14).

At last assessment, 8.7% of patients on placebo and 7.7% of patients on reboxetine were considered "normal". However, only 13% on the patients on placebo were judged to be "borderline mentally ill", compared to 42.3% of patients on reboxetine, while frequency of "mildly ill" cases was similar in the two groups (26.1% on placebo and 26.9% on reboxetine), "moderately ill" patients were 39.1% in the placebo group and only 7.7% in the reboxetine group. Most severely ill cases were similarly represented in the reboxetine and placebo groups (Table 15).

Considering the shift of the severity of illness *vs* Day 0, 10 patients (43.5%) treated with placebo showed a decrease of severity, 12 (52.2%) patients were unchanged and 1 patient (4.3%) became worse. In the reboxetine group the severity was judged to be decreased in 19 patients (73.1%), unchanged in 5 (19.2%) and worsened in 2 patients (7.7%). (Table 16)

7.2.2 GLOBAL IMPROVEMENT

The frequency distribution of global improvement scores *vs* baseline at each assessment interval in the observed cases is shown in Table 17, while the corresponding results at last assessment are given in the Table 18. Among patients treated for 28 days, 6 patients on placebo (33.3%) and 12 patients on reboxetine (60%) were considered much to very much improved, 5 patients on placebo and 4 on reboxetine were minimally improved, 4 cases on placebo and 2 on reboxetine were judged to be unchanged, while 3 cases on placebo and 2 cases on reboxetine were considered to be worsened. At last assessment again the most relevant between treatment difference is related to much to very much improved cases, corresponding to 34.8% of the placebo-treated and to 53.9% of the reboxetine-treated.

7.2.3 EFFICACY INDEX

The distribution of the Efficacy Index scores at the different time intervals is shown in Table 19, while results at last assessment are given in Table 20.

At last assessment the Efficacy Index was more frequently of 1 or lower (no net benefit from treatment) in patients treated with placebo (47.8%) than in patients taking reboxetine (30.8%). In the latter group the maximum efficacy index of 4 (maximum efficacy, no side-effects) was scored in 23.1% of the patients, compared to 13.0% of the cases on placebo.

7.2.4 EFFICACY CONCLUSIONS

Both frequency of response (at least 50% decrease of HAMD total score) and CGI-Severity of Illness and -Global Improvement distribution of scores suggest antidepressant activity of reboxetine in comparison with placebo when administered for 4 weeks to hospitalized patients at fixed-changing doses, with maximum doses of 8 mg/day. The 90% confidence interval of the between treatment differences of study end-point is compatible with the study be conclusive (i.e. allowing rejection of the null hypothesis) in the foreseen total sample of 40 patients per treatment arm.

8. SAFETY RESULTS

8.1 Safety Population and Extent of Exposure

All treated patients have been included in the safety evaluation.

8.2 Adverse Events

8.2.1 ANALYSIS OF ADVERSE EVENTS

8.2.1.1 Absolute and Per Cent Frequency

As shown in Table 21, 15 patients of the placebo group (62.5%) and 18 in the reboxetine group (69.23%) complained of 39 and 42 adverse events (AEs), respectively.

The most frequently reported AEs, under reboxetine and placebo respectively, were headache (33.3 and 26.6%), constipation (27.7 and 33.3%), dry mouth (33.3 and 26.6%), nausea (16.6 and 20%), and agitation (20% only under placebo) (Table 22). Newly reported AEs are grouped by body system in Table 23. No differences between the two treatment groups are apparent.

8.2.1.2 Cumulative Risk of Emergence of Adverse Events

The analysis of the cumulative risk of developing the first AE during treatment is shown in Figure 1. No significant difference between the two groups is apparent.

8.2.1.3 Maximal Severity

The maximal severity of AEs is reported by event in Table 24 and by body system in Table 25. Events were more frequently moderate on both reboxetine (66.7%) and placebo (64.3%), severe to very severe events being reported in two patients on both reboxetine (reported events increased sweating, constipation and rash) and placebo (reported events headache, constipation, nausea and vomiting).

8.2.1.4 Duration

The duration of AEs is described in Table 26. Among most frequent events the median duration was similar under both treatments, except for dry mouth, constipation, vomiting and sweating increased, longer lasting on placebo.

8.2.1.5 Symptomatic Treatment

As shown in Table 27 the adverse events which occurred on placebo required symptomatic treatment more often than those which occurred on reboxetine (28.2% *vs* 9.5% of the events).

8.2.1.6 Relationship Between Adverse Events and Study Medication

The relationship between AEs and study medication is illustrated in Table 28. Most of the newly emerged events on reboxetine (61.9%) and on placebo (48.7%) were judged by the investigators of "possible/doubtful" relationship with the experimental treatment. Two cases were judged certainly related: an episode of dry mouth under reboxetine and a case of constipation under placebo. Events were judged probably related more frequently on placebo (30.8%) than on reboxetine (11.9%).

8.2.1.7 Modification of Study Medication

Modification of study medication, as a consequence of newly observed symptoms, is described in Table 29. Six adverse events (15.4%) under placebo (agitation and extrasystoles in patient no. 23, paresthesia, fatigue and intermenstrual bleeding in patient no. 51, and rash in patient no. 65) and 2 (4.8%) under reboxetine (paresthesia and cyanosis in patient no. 8) were associated with discontinuation of the study drug. In the vast majority of the cases in both treatment groups the treatment regimen was not modified following the events. However 51.3% of the adverse events occurred under placebo and 45.2% of those occurred under reboxetine disappeared, while in 25.6 % of the cases on placebo and in 50% of the cases on reboxetine the newly observed symptoms were still present at the end of the observation period.

8.2.2 SERIOUS ADVERSE EVENTS

No serious events were reported during the study.

8.3 Laboratory Tests

8.3.1 SUMMARY STATISTICS OF LABORATORY VALUES

Summary statistics of results of laboratory tests are given by treatment group and assessment interval in Table 30. No significant modifications of note were apparent in either treatment group.

8.3.2 URINALYSIS

Frequencies of normal and abnormal findings of urinalysis tests at the different assessment intervals and at last assessment are given in Table 31 and 32, respectively. No increased frequency of abnormal findings during treatment in either group was noticed.

8.3.3 ABNORMAL LABORATORY VALUES

Frequencies of patients shifted from laboratory tests results below, within, or above the normal range at baseline to values below, within, or above the normal range at the different assessment intervals are given by treatment group and assessment interval in Table 33. No significant modifications were apparent in either treatment group.

8.3.4 ABNORMAL LABORATORY VALUES OF CLINICAL RELEVANCE

Laboratory abnormalities have been defined as clinically relevant according to standardized criteria. Individual abnormal findings are given, together with the standardized criteria, in Table 34. Clinically relevant abnormal findings were observed only occasionally during the treatment period. Possibly worth noting two cases of lymphocytopenia, one under reboxetine (patient no. 76, from 1.8 thousands/ml at screen to 0.9 after 4 weeks of treatment) and the second under placebo (patient no. 75, from 1.4 thousands/ml at screen to 0.7 after 4 weeks of treatment) and one case of transient thrombocytopenia under placebo (patient no. 27, from 247 thousands/ml at screen to 93 thousand/ml after one week, back to normal at the following assessment).

8.4 Vital Signs

8.4.1 BLOOD PRESSURE AND HEART RATE

Summary statistic of lying and standing systolic and diastolic blood pressure and heart rate are shown by assessment interval and treatment group in Table 35. No important modifications with respect to baseline in either group are apparent.

Frequencies of change of systolic and diastolic blood pressure and of heart rate in lying and standing position of clinical relevance *vs* baseline (at least 20% decrease or increase) are reported in Table 36. Such modifications have been reported only occasionally throughout the study period in both treatment groups.

Frequency of patients with orthostatic hypotension (decrease of systolic blood pressure of at least 30 mmHg from lying to standing) is shown in Table 37. The event was observed in very few cases in both groups.

8.4.2 BODY WEIGHT

Summary statistics of body weight values are given by assessment interval and treatment group in Table 38. No tendency toward modification and no differences between the two groups were apparent.

8.4.3 BODY TEMPERATURE

Summary statistics of body temperature values are given by assessment interval and treatment group in Table 39. No tendency toward modification and no differences between the two groups were apparent.

8.5 Electrocardiogram

As shown in Table 40 only 6 patients in the placebo group and 9 patients in the reboxetine group could be evaluated, having the ECG recorded at screen and at least once during treatment. Modifications of ECG tracings in each treatment group are described in Table 41. Newly emerged abnormal findings were observed in 3 patients per treatment group. In the reboxetine group, ECG signs of repolarization disturbances (patient no. 73), left anterior hemiblock and myocardial ischemia (patient no. 82) and left ventricular hypertrophy (patient no. 89) were reported, while in the placebo group left axial deviation (patient no. 55) and repolarization disturbances (patients no. 65 and 74) were apparent.

8.6 Safety Conclusions

Results of safety assessments, including adverse events, vital signs, laboratory tests and, in a proportion of patients, ECG recording did not indicate differences of any relevance between the two treatment groups.

9. DISCUSSION

This multicenter double-blind, parallel group study was carried out to evaluate the antidepressant activity and the tolerability of reboxetine in comparison with placebo in patients affected by Major Depressive Disorder and with a HAMD total score of $\geq$ 18. The patients were treated for 28 days with 2 mg capsules of reboxetine in increasing dosage, from 4 mg/day (Day 1 to Day 3) to 6 mg/day (Day 4 to Day 7) and 8 mg/day (Day 8 to Day 28). The study end-point was a decrease of at least 50% of the HAMD total score. Fifty patients entered the study, 26 received reboxetine and 24 placebo. Among these patients, 17 under placebo and 20 under reboxetine completed the study.

Three placebo-treated and 1 reboxetine treated patients discontinued the study because of adverse reactions, 3 per treatment group because of inefficacy. In addition 1 placebo-treated patient refused to continue receiving the experimental treatment, while 1 reboxetine-treated patient witheld his consent and a second one discontinued for administrative reasons.

According to an "intent to treat" analysis, the frequency of patients reaching the study end-point, i.e. a decrease of at least 50% of HAMD total score after 28 days of treatment (fully evaluated cases), was of 12 out of 26 in the reboxetine group (46.1%) and 7 out of 24 in the placebo group (29.2%). Therefore the between treatment difference in response rate at Day 28 (17%, study end-point) was lower than 30%, the hypothesis made in the calculation of the sample size. However, the calculated 90% confidence interval (-5÷39%) is compatible with the study be conclusive (i.e. allowing rejection of the null hypothesis) if completed in the initially foreseen sample of 80 patients.

Considering the sub-sample of patients completing the study and fully evaluated, the between treatment difference in response rate is somewhat higher than the one observed in the "intent to treat" analysis: in fact in this case the percent frequency of response is of 66.7% on reboxetine, compared to 41.2% on placebo.

The most important differences between reboxetine and placebo were apparent from the CGI-Severity of Illness scores at last assessment in comparison with baseline: in 73.1% of the reboxetine-treated cases *vs* 43.5% of the placebo-treated cases the severity was judged to be decreased, while in 19.2% *vs* 52.2%, respectively, it was considered unchanged and in 7.7% *vs* 4.3% worse.

Reboxetine did not show any effect of clinical relevance on laboratory tests, vital signs, and, in the small sample of evaluable cases, ECG.

The occurrence of newly observed symptoms during the study period did not differ between the two treatment groups.

10. CONCLUSION

Both frequency of response (at least 50% decrease of HAMD total score) and CGI-Severity of Illness and -Global Improvement distribution of scores suggest antidepressant activity of reboxetine in comparison with placebo when administered for 4 weeks to hospitalized patients at fixed-changing doses, with maximum doses of 8 mg/day. The extent of the difference *vs* placebo, as estimated in this sample of 50 patients, is compatible with the study be conclusive (i.e. allowing rejection of the null hypothesis) in the foreseen total sample of 40 patients per treatment arm.

11. REFERENCES

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TABLES AND FIGURES

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 1

NUMBER OF PATIENTS BY CENTRE, VISIT AND TREATMENT

Centre/Assigned treatment		Visit							
		Screen	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28
1	Placebo	7	7	7	7	7	7	7	6
	Reboxetine	6	8	8	8	8	8	6	6
2	Placebo	2	2	2	2	1	1	1	1
	Reboxetine	3	3	3	3	3	3	3	3
3	Placebo	2	2	2	2	2	2	1	1
	Reboxetine	1	1	1	1	1	1	1	
4	Placebo	9	9	8	7	7	6	6	6
	Reboxetine	7	7	7	7	7	7	5	5
5	Placebo	3	3	3	3	3	3	3	3
	Reboxetine	4	4	4	4	4	4	4	4
6	Placebo	1	1	1	1	1	1	1	1
	Reboxetine	2	2	2	2	2	2	2	2
7	Reboxetine	1	1	1	1	1	1		
Total	Placebo	24	24	23	22	21	20	19	18
	Reboxetine	26	26	26	26	26	26	21	20
	Total	50	50	49	48	47	46	40	38

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 2

PATIENT DISPOSITION

	Treatment assigned				Total	
	Placebo		Reboxetine			
	No.	%	No.	%	No.	%
Screened	24	100.00	26	100.00	50	100.00
Exposed	24	100.00	26	100.00	50	100.00
Completed	17	70.83	20	76.92	37	74.00
Dropped	7	29.17	6	23.08	13	26.00

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 3

END OF STUDY: REASONS FOR DISCONTINUATION BY ASSIGNED TREATMENT

Reasons	Placebo		Reboxetine	
	No	%	No	%
PATIENT REFUSAL	1	14.29	1	16.67
INEFFECTIVENESS	3	42.86	3	50.00
ADVERSE EXPERIENCE	3	42.86	1	16.67
ADMINISTRATIVE			1	16.67
Total	7	100.00	6	100.00

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REBOXETINE - PROTOCOL ADE09
Table No.: 4

DEMOGRAPHIC DATA

Assigned treatment		Age			Weight			Height		
		Female	Male	Total	Female	Male	Total	Female	Male	Total
Placebo	No	16	8	24	16	7	23	14	5	19
	Unknown	0	0	0	0	1	1	2	3	5
	Mean	44.06	53.00	47.04	64.61	68.80	65.88	161.43	172.20	164.26
	STD	13.57	11.89	13.48	21.15	9.10	18.21	6.38	13.20	9.58
	Median	42.50	58.50	46.50	61.20	71.00	66.00	160.50	170.00	162.00
	Min	24.00	33.00	24.00	36.70	52.00	36.70	153.00	156.00	153.00
	Max	65.00	64.00	65.00	119.00	78.00	119.00	172.00	190.00	190.00
Reboxetine	No	17	9	26	15	8	23	13	6	19
	Unknown	0	0	0	2	1	3	4	3	7
	Mean	48.06	41.56	45.81	67.57	72.30	69.21	165.85	168.33	166.63
	STD	10.37	12.36	11.30	11.46	11.65	11.50	5.70	8.50	6.57
	Median	50.00	41.00	44.00	67.00	70.75	68.00	167.00	169.00	168.00
	Min	31.00	24.00	24.00	50.00	56.90	50.00	155.00	155.00	155.00
	Max	63.00	64.00	64.00	95.00	96.00	96.00	175.00	178.00	178.00

weight and height at screening visit

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TABLE No.: 5

DIAGNOSIS OF MENTAL DISORDERS

		Placebo	Reboxetine	Total
DSM-III-R diagnosis	296.2 No.	5	7	12
	296.3 No.	19	19	38
Age of onset (years)	No.	22	23	45
	Mean	34.36	36.13	35.27
	STD	15.70	14.63	15.02
	Median	34.00	35.00	34.00
	Min	8.00	3.00	3.00
	Max	60	64	64
	unknown	2	3	5

DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode

REBOXETINE - PROTOCOL ADE09
TABLE No.: 6

DIAGNOSIS - PRESENT EPISODE

		Placebo		Reboxetine		Total	
		No	%	No	%	No	%
Charact. of present episode	Exacerbation of chronic cond.	4	16.67	5	19.23	9	18.00
	Recurence of similar prev. cond.	13	54.17	14	53.85	27	54.00
	Different from any prev. cond.	2	8.33			2	4.00
	First occurence	5	20.83	7	26.92	12	24.00
	Total	24	100.00	26	100.00	50	100.00
Precipit. external stress	Absent	14	58.33	14	53.85	28	56.00
	Probably present	8	33.33	11	42.31	19	38.00
	Definitely present	2	8.33	1	3.85	3	6.00
	Total	24	100.00	26	100.00	50	100.00

REBOXETINE - PROTOCOL ADE09
TABLE No.: 7

HISTORY OF MENTAL DISORDERS

		Placebo	Reboxetine	Total
Duration of last episode (weeks)	No.	19	20	39
	Mean	24.68	12.15	18.26
	STD	33.12	10.89	24.88
	Median	12.00	8.00	8.00
	Min	7.00	4.00	4.00
	Max	128	48	128
	unknown	5	6	11
Duration of present episode (weeks)	No.	24	26	50
	Mean	19.63	32.19	26.16
	STD	21.08	83.99	62.03
	Median	12.00	8.00	10.50
	Min	4.00	1.43	1.43
	Max	104	416	416
	unknown			

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REBOXETINE - PROTOCOL ADE09
TABLE No.: 8

HISTORY OF MENTAL DISORDERS
Number of previous episodes in patients whose diagnosis is DSM-III = 296.3

	Placebo	Reboxetine	Total
No.	19	19	38
Unknown	0	0	0
Mean	4.79	3.89	4.34
STD	4.53	3.18	3.89
Median	4.00	4.00	4.00
Min	1.00	1.00	1.00
Max	20	12	20

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REBOXETINE - PROTOCOL ADE09
Table No.: 9

MEDICAL HISTORY BY BODY SYSTEM

Body system	Assigned treatment	
	Placebo	Reboxetine
INFECTIOUS AND PARASTITIC DISEASE	1	
NERVOUS SYSTEM AND SENSE ORGANS	1	2
CIRCULATORY SYSTEM		1
RESPIRATORY SYSTEM	1	
DIGESTIVE SYSTEM	3	2
GENITOURINARY SYSTEM	2	
SKIN AND SUBCUTANEOUS TISSUE	1	
MUSCOLOSKELETAL SYS.AND CONNETIVE TISSUE	1	
Total	10	5

REBOXETINE - PROTOCOL ADE09
TABLE No. : 10

PREVIOUS ANTIDEPRESSIVE TREATMENTS

Last treatment	Placebo	Reboxetine	Total
AMITRIPTYLINE	1	3	4
LITHIUM	2	4	6
PHENELZINE	2		2
IMIPRAMINE	5		5
TRANYLCYPROMINE	1		1
FLUPENTIXOL		1	1
CLOMIPRAMINE	1	2	3
DOXEPIN	1	1	2
DOSULEPIN	2	8	10
MIANSERIN	1	1	2
TRAZODONE	1		1
LOFEPRAMINE	1	2	3
FLUVOXAMINE	1		1
FLUOXETINE	1		1

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 11

CONCOMITANT DRUGS BY ACTIVE PRINCIPLE: NUMBER OF CONCOMITANT MEDICATIONS BY ASSIGNED TREATMENT AND INITIAL PERIOD OF ADMINISTRATION

Concomitant drugs	Before treatment		During treatment		Total	
	Placebo	Reboxetine	Placebo	Reboxetine	Placebo	Reboxetine
	No.	No.	No.	No.	No.	No.
TEMAZEPAM	11	12	3	4	14	16
LACTULOSE	1		1	1	2	1
CHLORPROMAZINE	1		1		2	
PARACETAMOL			2		2	
CHLORDIAZEPOXIDE				1		1
ISPAGHULA		1				1
IBUPROFEN		1				1
GLYCEROL			1		1	
LORAZEPAM		1				1
ATENOLOL		1				1
TRIAZOLAM	1				1	
RANITIDINE		1				1
SALBUTAMOL		1				1

REBOXETINE - PROTOCOL ADE09
TABLE No.: 12

HAMILTON DEPRESSION RATING SCALE : SUMMARY STATISTICS OVER TIME

Assigned treatment		VISIT					
		SCREEN	DAY0	DAY7	DAY14	DAY21	DAY28
PLACEBO	Evaluated	24	24	22	20	19	17
	Missing	0	0	0	0	0	1
	Mean	26.33	25.33	20.82	18.20	16.63	15.12
	SD	2.93	3.55	6.74	6.89	6.16	8.28
	Median	26.00	25.50	23.00	19.50	15.00	15.00
	Min	20	19	7	0	8	2
	Max	31	31	30	30	30	31
REBOXETINE	Evaluated	26	26	25	26	21	18
	Missing	0	0	1	0	0	2
	Mean	26.54	25.27	21.60	18.50	14.33	12.56
	SD	4.71	4.94	7.13	6.03	6.62	8.30
	Median	26.50	25.00	21.00	20.00	15.00	11.50
	Min	18	18	4	7	3	1
	Max	33	34	33	32	28	31

REBOXETINE - PROTOCOL ADE09
TABLE No.: 13

HAMILTON DEPRESSION RATING SCALE - SUMMARY STATISTICS AT LAST ASSESSMENT

Assigned treatment		DAY0	DAY7	DAY14	DAY21	DAY28	TOTAL
PLACEBO	N	2	2	1	1	17	23
	Mean	25.00	11.50	0.00	17.00	15.12	15.09
	SD	2.83	6.36			8.28	8.52
	Median	25.00	11.50	0.00	17.00	15.00	16.00
	Min	23	7	0	17	2	0
	Max	27	16	0	17	31	31
REBOXETINE	N			5	1	18	24
	Mean			19.20	23.00	12.56	14.38
	SD			10.18		8.30	8.94
	Median			18.00	23.00	11.50	13.00
	Min			9	23	1	1
	Max			32	23	31	32

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REBOXETINE - PROTOCOL 20124/ADE009

TABLE No.: 14

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

Assigned treatment/Severity of illness		Visit													
		Day 0		Day 4		Day 7		Day 10		Day 14		Day 21		Day 28	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%
Placebo	NORMAL							1	4.8	1	5.0			1	5.6
	BORDERLINE MENTALLY ILL			1	4.3	2	9.1	1	4.8	2	10.0	5	26.3	3	16.7
	MILDLY ILL	2	8.3	2	8.7	7	31.8	5	23.8	7	35.0	5	26.3	4	22.2
	MODERATELY ILL	16	66.7	13	56.5	8	36.4	12	57.1	6	30.0	6	31.6	7	38.9
	MARKEDLY ILL	6	25.0	7	30.4	5	22.7	2	9.5	4	20.0	3	15.8	3	16.7
	Total	24	100.0	23	100.0	22	100.0	21	100.0	20	100.0	19	100.0	18	100.0
Reboxetine	NORMAL							1	3.8			1	4.8	2	10.0
	BORDERLINE MENTALLY ILL			1	3.8	2	7.7	2	7.7	6	23.1	3	14.3	9	45.0
	MILDLY ILL	3	11.5	4	15.4	7	26.9	8	30.8	5	19.2	9	42.9	6	30.0
	MODERATELY ILL	13	50.0	13	50.0	10	38.5	11	42.3	12	46.2	6	28.6	1	5.0
	MARKEDLY ILL	10	38.5	7	26.9	6	23.1	3	11.5	3	11.5	2	9.5	1	5.0
	SEVERELY ILL			1	3.8	1	3.8	1	3.8					1	5.0
	Total	26	100.0	26	100.0	26	100.0	26	100.0	26	100.0	21	100.0	20	100.0

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 15

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

Assigned treatment/Severity of illness		Total		Last Visit											
				Day 4		Day 7		Day 10		Day 14		Day 21		Day 28	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%
Placebo	NORMAL	2	8.7							1	100.0			1	5.6
	BORDERLINE MENTALLY ILL	3	13.0											3	16.7
	MILDLY ILL	6	26.1			1	100.0	1	100.0					4	22.2
	MODERATELY ILL	9	39.1	1	100.0							1	100.0	7	38.9
	MARKEDLY ILL	3	13.0											3	16.7
	Total	23	100.0	1	100.0	1	100.0	1	100.0	1	100.0	1	100.0	18	100.0
Reboxetine	NORMAL	2	7.7											2	10.0
	BORDERLINE MENTALLY ILL	11	42.3							2	40.0			9	45.0
	MILDLY ILL	7	26.9							1	20.0			6	30.0
	MODERATELY ILL	2	7.7							1	20.0			1	5.0
	MARKEDLY ILL	3	11.5							1	20.0	1	100.0	1	5.0
	SEVERELY ILL	1	3.8											1	5.0
	Total	26	100.0							5	100.0	1	100.0	20	100.0

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 16

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

Assigned treatment/Shift severity		Total		Last visit											
				Day 4		Day 7		Day 10		Day 14		Day 21		Day 28	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%
Placebo	DECREASED	10	43.5			1	100.0			1	100.0			8	44.4
	NO CHANGE	12	52.2	1	100.0			1	100.0			1	100.0	9	50.0
	INCREASED	1	4.3											1	5.6
	Total	23	100.0	1	100.0	1	100.0	1	100.0	1	100.0	1	100.0	18	100.0
Reboxetine	DECREASED	19	73.1							3	60.0			16	80.0
	NO CHANGE	5	19.2							1	20.0	1	100.0	3	15.0
	INCREASED	2	7.7							1	20.0			1	5.0
	Total	26	100.0							5	100.0	1	100.0	20	100.0

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 17

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

Assigned treatment	Global improvement	Visit													
		Day 4		Day 7		Day 10		Day 14		Day 21		Day 28			
		No	%	No	%	No	%	No	%	No	%	No	%		
Placebo	VERY MUCH IMPROVED									1	5.3	2	11.1		
	MUCH IMPROVED			3	13.6	3	14.3	7	35.0	5	26.3	4	22.2		
	MINIMALLY IMPROVED	5	21.7	8	36.4	9	42.9	6	30.0	6	31.6	5	27.8		
	NO CHANGE	17	73.9	9	40.9	8	38.1	5	25.0	5	26.3	4	22.2		
	MINIMALLY WORSE					1	4.8	2	10.0			1	5.6		
	MUCH WORSE			1	4.5					2	10.5	2	11.1		
	unknown	1	4.3	1	4.5										
	Total	23	100.0	22	100.0	21	100.0	20	100.0	19	100.0	18	100.0		
Reboxetine	VERY MUCH IMPROVED									3	14.3	4	20.0		
	MUCH IMPROVED			3	11.5	5	19.2	8	30.8	9	42.9	8	40.0		
	MINIMALLY IMPROVED	8	30.8	12	46.2	12	46.2	12	46.2	3	14.3	4	20.0		
	NO CHANGE	17	65.4	8	30.8	8	30.8	2	7.7	4	19.0	2	10.0		
	MINIMALLY WORSE	1	3.8	3	11.5			3	11.5	2	9.5	2	10.0		
	MUCH WORSE					1	3.8	1	3.8						
	Total	26	100.0	26	100.0	26	100.0	26	100.0	21	100.0	20	100.0		

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 18

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

Assigned treatment/Global improvement		Total		Last visit											
				Day 4		Day 7		Day 10		Day 14		Day 21		Day 28	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%
Placebo	VERY MUCH IMPROVED	2	8.7											2	11.1
	MUCH IMPROVED	6	26.1			1	100.0			1	100.0			4	22.2
	MINIMALLY IMPROVED	6	26.1					1	100.0					5	27.8
	NO CHANGE	6	26.1	1	100.0							1	100.0	4	22.2
	MINIMALLY WORSE	1	4.3											1	5.6
	MUCH WORSE	2	8.7											2	11.1
	Total	23	100.0	1	100.0	1	100.0	1	100.0	1	100.0	1	100.0	18	100.0
Reboxetine	VERY MUCH IMPROVED	4	15.4											4	20.0
	MUCH IMPROVED	10	38.5							2	40.0			8	40.0
	MINIMALLY IMPROVED	5	19.2							1	20.0			4	20.0
	NO CHANGE	2	7.7											2	10.0
	MINIMALLY WORSE	4	15.4							1	20.0	1	100.0	2	10.0
	MUCH WORSE	1	3.8							1	20.0				
	Total	26	100.0							5	100.0	1	100.0	20	100.0

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 19

CLINICAL GLOBAL IMPRESSION - EFFICACY INDEX: ABSOLUTE AND PERCENT FREQUENCY OF PATIENTS WITH EFFICACY INDEX LOWER THAN, EQUAL TO AND HIGHER THAN 1 ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment / Efficacy index (*)		Day 4		Day 7		Day 10		Day 14		Day 21		Day 28	
		No	%	No	%	No	%	No	%	No	%	No	%
Placebo	< 1	3	13.0	4	18.2	3	14.3	1	5.0	1	5.3	2	11.1
	1	15	65.2	8	36.4	8	38.1	8	40.0	10	52.6	6	33.3
	1.33 - 1.5			2	9.1	2	9.5	2	10.0	1	5.3		
	2	4	17.4	5	22.7	4	19.0	3	15.0	1	5.3	4	22.2
	3	1	4.3	3	13.6	3	14.3	4	20.0	3	15.8	4	22.2
	4					1	4.8	2	10.0	3	15.8	2	11.1
	Total	23	100	22	100	21	100	20	100	19	100	18	100
Reboxetine	< 1	4	15.4	2	7.7	2	7.7	3	11.5				
	1	14	53.8	11	42.3	9	34.6	4	15.4	6	28.6	5	25.0
	1.33 - 1.5							2	7.7	1	4.8	1	5.0
	2	8	30.8	10	38.5	11	42.3	11	42.3	3	14.3	4	20.0
	3			2	7.7	3	11.5	3	11.5	6	28.6	5	25.0
	4			1	3.8	1	3.8	3	11.5	5	23.8	5	25.0
	Total	26	100	26	100	26	100	26	100	21	100	20	100

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

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 20

CLINICAL GLOBAL IMPRESSION - EFFICACY INDEX: ABSOLUTE AND PERCENT FREQUENCY OF PATIENTS WITH EFFICACY INDEX LOWER THAN, EQUAL TO AND HIGHER THAN 1 AT LAST ASSESSMENT BY ASSIGNED TREATMENT

Assigned treatment / Efficacy index (*)		total		Last Assessment											
				Day 4		Day 7		Day 10		Day 14		Day 21		Day 28	
		No	%	No	%	No	%	No	%	No	%	No	%	No	%
Placebo	< 1	2	8.70											2	11.11
	1	9	39.13	1	100.0			1	100.0			1	100.0	6	33.33
	1.33 - 1.5	1	4.35			1	100.0								
	2	4	17.39											4	22.22
	3	4	17.39											4	22.22
	4	3	13.04							1	100.0			2	11.11
	Total	23	100.0	1	100.0	1	100.0	1	100.0	1	100.0	1	100.0	18	100.0
Reboxetine	< 1	1	3.85							1	20.00				
	1	7	26.92							1	20.00	1	100.0	5	25.00
	1.33 - 1.5	2	7.69							1	20.00			1	5.00
	2	5	19.23							1	20.00			4	20.00
	3	5	19.23											5	25.00
	4	6	23.08							1	20.00			5	25.00
	Total	26	100.0							5	100.0	1	100.0	20	100.0

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

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 21

ADVERSE EVENTS: NUMBER OF PATIENTS WHO COMPLAINED OF AT LEAST ONE ADVERSE EVENT DURING THERAPY BY SEX AND ASSIGNED TREATMENT

	Assigned treatment					
	Placebo			Reboxetine		
	Female	Male	Total	Female	Male	Total
Pt exposed	16	8	24	17	9	26
Pt with adverse events	10	5	15	13	5	18
% on exposed	62.50	62.50	62.50	76.47	55.55	69.23
95% L.L.	35.43	24.49	40.59	50.10	21.20	48.21
95% U.L.	84.80	91.48	81.20	93.19	86.30	85.67
No. of adverse events	29	10	39	33	9	42
Ratio A.E. on Pt with A.E.	2.90	2.00	2.60	2.53	1.80	2.33

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 22

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

Adverse events/Assigned treatment		Female					Male					Total				
		No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)
Pt exposed	Placebo	16	100.0				8	100.0				24	100.0			
	Reboxetine	17	100.0				9	100.0				26	100.0			
Pt with a.e.	Placebo	10	62.5	100.0	29	2.90	5	62.5	100.0	10	2.00	15	62.5	100.0	39	2.60
	Reboxetine	13	76.5	100.0	33	2.53	5	55.6	100.0	9	1.80	18	69.2	100.0	42	2.33
HEADACHE	Placebo	3	18.8	30.0	3	1.00	1	12.5	20.0	1	1.00	4	16.7	26.6	4	1.00
	Reboxetine	5	29.4	38.4	5	1.00	1	11.1	20.0	1	1.00	6	23.1	33.3	6	1.00
CONSTIPATION	Placebo	3	18.8	30.0	3	1.00	2	25.0	40.0	2	1.00	5	20.8	33.3	5	1.00
	Reboxetine	3	17.6	23.0	3	1.00	2	22.2	40.0	2	1.00	5	19.2	27.7	5	1.00
MOUTH DRY	Placebo	2	12.5	20.0	2	1.00	2	25.0	40.0	2	1.00	4	16.7	26.6	4	1.00
	Reboxetine	4	23.5	30.7	4	1.00	2	22.2	40.0	2	1.00	6	23.1	33.3	6	1.00
NAUSEA	Placebo	2	12.5	20.0	2	1.00	1	12.5	20.0	1	1.00	3	12.5	20.0	3	1.00
	Reboxetine	2	11.8	15.3	2	1.00	1	11.1	20.0	2	2.00	3	11.5	16.6	4	1.33
DIZZINESS	Placebo	2	12.5	20.0	2	1.00	1	12.5	20.0	1	1.00	3	12.5	20.0	3	1.00
	Reboxetine	2	11.8	15.3	2	1.00						2	7.7	11.1	2	1.00
VOMITING	Placebo	1	6.3	10.0	1	1.00	1	12.5	20.0	1	1.00	2	8.3	13.3	2	1.00
	Reboxetine	2	11.8	15.3	2	1.00						2	7.7	11.1	2	1.00
PARAESTHESIA	Placebo	1	6.3	10.0	1	1.00						1	4.2	6.6	1	1.00
	Reboxetine	2	11.8	15.3	2	1.00						2	7.7	11.1	2	1.00
SWEATING INCREASED	Placebo	2	12.5	20.0	2	1.00						2	8.3	13.3	2	1.00
	Reboxetine	1	5.9	7.6	1	1.00						1	3.8	5.5	1	1.00
AGITATION	Placebo	2	12.5	20.0	2	1.00	1	12.5	20.0	1	1.00	3	12.5	20.0	3	1.00
RASH	Reboxetine	2	11.8	15.3	3	1.50						2	7.7	11.1	3	1.50

(CONTINUED)

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

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 22

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

Adverse events/Assigned treatment		Female					Male					Total				
		No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)
URINARY RETENTION	Placebo	1	6.3	10.0	1	1.00						1	4.2	6.6	1	1.00
	Reboxetine	1	5.9	7.6	1	1.00						1	3.8	5.5	1	1.00
ANOREXIA	Placebo	1	6.3	10.0	1	1.00						1	4.2	6.6	1	1.00
	Reboxetine	1	5.9	7.6	1	1.00						1	3.8	5.5	1	1.00
SOMNOLENCE	Placebo	1	6.3	10.0	1	1.00						1	4.2	6.6	1	1.00
	Reboxetine						1	11.1	20.0	1	1.00	1	3.8	5.5	1	1.00
MICTURITION DISORDER	Placebo	1	6.3	10.0	1	1.00						1	4.2	6.6	1	1.00
	Reboxetine						1	11.1	20.0	1	1.00	1	3.8	5.5	1	1.00
RASH ERYTHEMATOUS	Placebo						1	12.5	20.0	1	1.00	1	4.2	6.6	1	1.00
BULLOUS ERUPTION	Reboxetine	1	5.9	7.6	1	1.00						1	3.8	5.5	1	1.00
TREMOR	Placebo	1	6.3	10.0	1	1.00						1	4.2	6.6	1	1.00
DIARRHOEA	Reboxetine	1	5.9	7.6	1	1.00						1	3.8	5.5	1	1.00
VISION ABNORMAL	Reboxetine	1	5.9	7.6	1	1.00						1	3.8	5.5	1	1.00
CONFUSION	Placebo	1	6.3	10.0	1	1.00						1	4.2	6.6	1	1.00
INSOMNIA	Reboxetine	1	5.9	7.6	1	1.00						1	3.8	5.5	1	1.00
CYANOSIS	Reboxetine	1	5.9	7.6	1	1.00						1	3.8	5.5	1	1.00
EXTRASYSTOLES	Placebo	1	6.3	10.0	1	1.00						1	4.2	6.6	1	1.00
DYSPNOEA	Reboxetine	1	5.9	7.6	1	1.00						1	3.8	5.5	1	1.00
MICTURITION FREQUENCY	Placebo	1	6.3	10.0	1	1.00						1	4.2	6.6	1	1.00
INTERMENSTRUAL BLEEDING	Placebo	1	6.3	10.0	1	1.00						1	4.2	6.6	1	1.00
UTERINE SPASM	Placebo	1	6.3	10.0	1	1.00						1	4.2	6.6	1	1.00

(CONTINUED)

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

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 22

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

Adverse events/Assigned treatment		Female					Male					Total				
		No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt.	% on exp.	% on Pt with AE	No of AE	Ratio (*)
FATIGUE	Placebo	1	6.3	10.0	1	1.00						1	4.2	6.6	1	1.00
HOT FLUSHES	Reboxetine	1	5.9	7.6	1	1.00						1	3.8	5.5	1	1.00

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

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 23

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

Body system/Assigned treatment		Female					Male					Total				
		No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
Pt exposed	Placebo	16	100.0				8	100.0				24	100.0			
	Reboxetine	17	100.0				9	100.0				26	100.0			
Pt with a.e.	Placebo	10	62.5	100.0	29	2.90	5	62.5	100.0	10	2.00	15	62.5	100.0	39	2.60
	Reboxetine	13	76.5	100.0	33	2.53	5	55.6	100.0	9	1.80	18	69.2	100.0	42	2.33
GASTRO-INTESTINAL SYSTEM DISORDERS	Placebo	4	25.0	40.0	7	1.75	2	25.0	40.0	4	2.00	6	25.0	40.0	11	1.83
	Reboxetine	7	41.2	53.8	9	1.28	3	33.3	60.0	4	1.33	10	38.5	55.5	13	1.30
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO	Placebo	6	37.5	60.0	6	1.00	1	12.5	20.0	1	1.00	7	29.2	46.6	7	1.00
	Reboxetine	7	41.2	53.8	7	1.00	1	11.1	20.0	1	1.00	8	30.8	44.4	8	1.00
AUTONOMIC NERVOUS SYSTEM DISORDERS	Placebo	3	18.8	30.0	4	1.33	2	25.0	40.0	2	1.00	5	20.8	33.3	6	1.20
	Reboxetine	4	23.5	30.7	5	1.25	2	22.2	40.0	2	1.00	6	23.1	33.3	7	1.16
CARDIOVASCULAR DISORDERS, GENERAL	Placebo	3	18.8	30.0	3	1.00	1	12.5	20.0	1	1.00	4	16.7	26.6	4	1.00
	Reboxetine	4	23.5	30.7	4	1.00						4	15.4	22.2	4	1.00
PSYCHIATRIC DISORDERS	Placebo	3	18.8	30.0	3	1.00	1	12.5	20.0	1	1.00	4	16.7	26.6	4	1.00
	Reboxetine	1	5.9	7.6	1	1.00	1	11.1	20.0	1	1.00	2	7.7	11.1	2	1.00
SKIN AND APPENDAGES DISORDERS	Placebo						1	12.5	20.0	1	1.00	1	4.2	6.6	1	1.00
	Reboxetine	3	17.6	23.0	4	1.33						3	11.5	16.6	4	1.33
URINARY SYSTEM DISORDERS	Placebo	2	12.5	20.0	3	1.50						2	8.3	13.3	3	1.50
	Reboxetine	1	5.9	7.6	1	1.00	1	11.1	20.0	1	1.00	2	7.7	11.1	2	1.00
BODY AS A WHOLE-GENERAL DISORDERS	Placebo	1	6.3	10.0	1	1.00						1	4.2	6.6	1	1.00
REPRODUCTIVE DISORDERS, FEMALE	Placebo	1	6.3	10.0	2	2.00						1	4.2	6.6	2	2.00

(CONTINUED)

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

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 23

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

Body system/Assigned treatment		Female					Male					Total				
		No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)	No of Pt	% on exp.	% on Pt with AE	No of AE	Ratio (*)
RESPIRATORY SYSTEM DISORDERS	Reboxetine	1	5.9	7.6	1	1.00						1	3.8	5.5	1	1.00
VISION DISORDERS	Reboxetine	1	5.9	7.6	1	1.00						1	3.8	5.5	1	1.00

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

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 24

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

Adverse events / Severity		Assigned treatment																			
		Placebo								Reboxetine											
		Female			Male			Total			Female			Male			Total				
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
All adverse events	Mild	2	20.0	20.0	1	25.0	20.0	3	21.4	20.0	3	23.1	23.1	1	20.0	20.0	4	22.2	22.2
	Moderate	7	70.0	70.0	2	50.0	40.0	9	64.3	60.0	8	61.5	61.5	4	80.0	80.0	12	66.7	66.7
	Very severe	1	10.0	10.0				1	7.1	6.7									
	Severe				1	25.0	20.0	1	7.1	6.7	2	15.4	15.4				2	11.1	11.1
	Total	10	100	100	4	100	80.0	14	100	93.3	13	100	100	5	100	100	18	100	100
HEADACHE	Mild	1	33.3	10.0				1	25.0	6.7	2	40.0	15.4				2	33.3	11.1
	Moderate	2	66.7	20.0				2	50.0	13.3	3	60.0	23.1	1	100	20.0	4	66.7	22.2
	Severe				1	100	20.0	1	25.0	6.7									
	Total	3	100	30.0	1	100	20.0	4	100	26.7	5	100	38.5	1	100	20.0	6	100	33.3
CONSTIPATION	Mild	1	33.3	10.0				1	20.0	6.7	1	33.3	7.7				1	20.0	5.6
	Moderate	1	33.3	10.0	1	50.0	20.0	2	40.0	13.3	1	33.3	7.7	2	100	40.0	3	60.0	16.7
	Very severe	1	33.3	10.0				1	20.0	6.7									
	Severe				1	50.0	20.0	1	20.0	6.7	1	33.3	7.7				1	20.0	5.6
	Total	3	100	30.0	2	100	40.0	5	100	33.3	3	100	23.1	2	100	40.0	5	100	27.8
MOUTH DRY	Mild	1	50.0	10.0	1	50.0	20.0	2	50.0	13.3	1	25.0	7.7	2	100	40.0	3	50.0	16.7
	Moderate	1	50.0	10.0	1	50.0	20.0	2	50.0	13.3	3	75.0	23.1				3	50.0	16.7
	Total	2	100	20.0	2	100	40.0	4	100	26.7	4	100	30.8	2	100	40.0	6	100	33.3
NAUSEA	Mild	1	50.0	10.0				1	33.3	6.7									
	Moderate				1	100	20.0	1	33.3	6.7	2	100	15.4	1	100	20.0	3	100	16.7
	Very severe	1	50.0	10.0				1	33.3	6.7									

(CONTINUED)

(*) % on all patients with adverse events

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 24

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

Adverse events / Severity		Assigned treatment																	
		Placebo									Reboxetine								
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
NAUSEA	Total	2	100	20.0	1	100	20.0	3	100	20.0	2	100	15.4	1	100	20.0	3	100	16.7
DIZZINESS	Mild	2	100	20.0	1	100	20.0	3	100	20.0	1	50.0	7.7				1	50.0	5.6
	Moderate										1	50.0	7.7				1	50.0	5.6
	Total	2	100	20.0	1	100	20.0	3	100	20.0	2	100	15.4				2	100	11.1
VOMITING	Mild										2	100	15.4				2	100	11.1
	Moderate				1	100	20.0	1	50.0	6.7									
	Very severe	1	100	10.0				1	50.0	6.7									
	Total	1	100	10.0	1	100	20.0	2	100	13.3	2	100	15.4				2	100	11.1
PARAESTHE-SIA	Mild	1	100	10.0				1	100	6.7	1	50.0	7.7				1	50.0	5.6
	Missing										1	50.0	7.7				1	50.0	5.6
	Total	1	100	10.0				1	100	6.7	2	100	15.4				2	100	11.1
SWEATING INCREASED	Mild	1	50.0	10.0				1	50.0	6.7									
	Moderate	1	50.0	10.0				1	50.0	6.7									
	Severe										1	100	7.7				1	100	5.6
	Total	2	100	20.0				2	100	13.3	1	100	7.7				1	100	5.6
AGITATION	Mild	1	50.0	10.0				1	33.3	6.7									
	Moderate	1	50.0	10.0	1	100	20.0	2	66.7	13.3									
	Total	2	100	20.0	1	100	20.0	3	100	20.0									
RASH	Moderate										1	50.0	7.7				1	50.0	5.6
	Severe										1	50.0	7.7				1	50.0	5.6

(CONTINUED)

(*) % on all patients with adverse events

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 24

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

Adverse events / Severity		Assigned treatment																			
		Placebo								Reboxetine											
		Female			Male			Total			Female			Male			Total				
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
RASH	Total										2	100	15.4				2	100	11.1
URINARY RETENTION	Mild	1	100	10.0				1	100	6.7							1	100	5.6
	Moderate										1	100	7.7				1	100	5.6
	Total	1	100	10.0				1	100	6.7	1	100	7.7				1	100	5.6
ANOREXIA	Mild										1	100	7.7				1	100	5.6
	Moderate	1	100	10.0				1	100	6.7									
	Total	1	100	10.0				1	100	6.7	1	100	7.7				1	100	5.6
SOMNOLENCE	Mild	1	100	10.0				1	100	6.7				1	100	20.0	1	100	5.6
	Total	1	100	10.0				1	100	6.7				1	100	20.0	1	100	5.6
MICTURITION DISORDER	Moderate	1	100	10.0				1	100	6.7				1	100	20.0	1	100	5.6
	Total	1	100	10.0				1	100	6.7				1	100	20.0	1	100	5.6
RASH ERYTHEMATOUS	Missing				1	100	20.0	1	100	6.7									
	Total				1	100	20.0	1	100	6.7									
BULLOUS ERUPTION	Mild										1	100	7.7				1	100	5.6
	Total										1	100	7.7				1	100	5.6
TREMOR	Moderate	1	100	10.0				1	100	6.7									
	Total	1	100	10.0				1	100	6.7									
DIARRHOEA	Moderate										1	100	7.7				1	100	5.6
	Total										1	100	7.7				1	100	5.6
VISION ABNORMAL	Mild										1	100	7.7				1	100	5.6

(CONTINUED)

(*) % on all patients with adverse events

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 24

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

Adverse events / Severity		Assigned treatment																	
		Placebo								Reboxetine									
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
VISION ABNORMAL	Total										1	100	7.7				1	100	5.6
CONFUSION	Moderate	1	100	10.0				1	100	6.7									
	Total	1	100	10.0				1	100	6.7									
INSOMNIA	Moderate										1	100	7.7				1	100	5.6
	Total										1	100	7.7				1	100	5.6
CYANOSIS	Missing										1	100	7.7				1	100	5.6
	Total										1	100	7.7				1	100	5.6
EXTRASYST-OLES	Moderate	1	100	10.0				1	100	6.7									
	Total	1	100	10.0				1	100	6.7									
DYSPNOEA	Moderate										1	100	7.7				1	100	5.6
	Total										1	100	7.7				1	100	5.6
MICTURITI-ON FREQUENCY	Moderate	1	100	10.0				1	100	6.7									
	Total	1	100	10.0				1	100	6.7									
INTERMENS-TRUAL BLEEDING	Moderate	1	100	10.0				1	100	6.7									
	Total	1	100	10.0				1	100	6.7									
UTERINE SPASM	Missing	1	100	10.0				1	100	6.7									
	Total	1	100	10.0				1	100	6.7									
FATIGUE	Mild	1	100	10.0				1	100	6.7									
	Total	1	100	10.0				1	100	6.7									

(CONTINUED)

(*) % on all patients with adverse events

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 24

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

Adverse events / Severity		Assigned treatment																	
		Placebo								Reboxetine									
		Female			Male			Total		Female			Male			Total			
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
HOT FLUSHES	Mild										1	100	7.7				1	100	5.6
	Total										1	100	7.7				1	100	5.6

(*) % on all patients with adverse events

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 25

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

Body system / Severity		Assigned treatment																	
		Placebo								Reboxetine									
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
All adverse events	Mild	2	20.0	20.0	1	25.0	20.0	3	21.4	20.0	3	23.1	23.1	1	20.0	20.0	4	22.2	22.2
	Moderate	7	70.0	70.0	2	50.0	40.0	9	64.3	60.0	8	61.5	61.5	4	80.0	80.0	12	66.7	66.7
	Very severe	1	10.0	10.0				1	7.1	6.7									
	Severe				1	25.0	20.0	1	7.1	6.7	2	15.4	15.4				2	11.1	11.1
	Total	10	100	100	4	100	80.0	14	100	93.3	13	100	100	5	100	100	18	100	100
GASTRO-INTESTINAL SYSTEM DISORDERS	Mild	2	50.0	20.0				2	33.3	13.3	2	28.6	15.4				2	20.0	11.1
	Moderate	1	25.0	10.0	1	50.0	20.0	2	33.3	13.3	4	57.1	30.8	3	100	60.0	7	70.0	38.9
	Very severe	1	25.0	10.0				1	16.7	6.7									
	Severe				1	50.0	20.0	1	16.7	6.7	1	14.3	7.7				1	10.0	5.6
	Total	4	100	40.0	2	100	40.0	6	100	40.0	7	100	53.8	3	100	60.0	10	100	55.6
CENTRAL & PERIPHERAL NERVOUS SYSTEM DISO	Mild	2	33.3	20.0				2	28.6	13.3	3	42.9	23.1				3	37.5	16.7
	Moderate	4	66.7	40.0				4	57.1	26.7	3	42.9	23.1	1	100	20.0	4	50.0	22.2
	Severe				1	100	20.0	1	14.3	6.7									
	Missing										1	14.3	7.7				1	12.5	5.6
	Total	6	100	60.0	1	100	20.0	7	100	46.7	7	100	53.8	1	100	20.0	8	100	44.4
AUTONOMIC NERVOUS SYSTEM DISORDERS	Mild	1	33.3	10.0	1	50.0	20.0	2	40.0	13.3	1	25.0	7.7	2	100	40.0	3	50.0	16.7
	Moderate	2	66.7	20.0	1	50.0	20.0	3	60.0	20.0	2	50.0	15.4				2	33.3	11.1
	Severe										1	25.0	7.7				1	16.7	5.6
	Total	3	100	30.0	2	100	40.0	5	100	33.3	4	100	30.8	2	100	40.0	6	100	33.3

(CONTINUED)

(*) % on all patients with adverse events

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 25

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

Body system / Severity		Assigned treatment																		
		Placebo									Reboxetine									
		Female			Male			Total			Female			Male			Total		
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
CARDIOVASCULAR DISORDERS, GENERAL	Mild	2	66.7	20.0	1	100	20.0	3	75.0	20.0	2	50.0	15.4				2	50.0	11.1
	Moderate	1	33.3	10.0				1	25.0	6.7	1	25.0	7.7				1	25.0	5.6
	Missing										1	25.0	7.7				1	25.0	5.6
	Total	3	100	30.0	1	100	20.0	4	100	26.7	4	100	30.8				4	100	22.2
PSYCHIATRIC DISORDERS	Mild	2	66.7	20.0				2	50.0	13.3				1	100	20.0	1	50.0	5.6
	Moderate	1	33.3	10.0	1	100	20.0	2	50.0	13.3	1	100	7.7				1	50.0	5.6
	Total	3	100	30.0	1	100	20.0	4	100	26.7	1	100	7.7	1	100	20.0	2	100	11.1
SKIN AND APPENDAGES DISORDERS	Mild										1	33.3	7.7				1	33.3	5.6
	Moderate										1	33.3	7.7				1	33.3	5.6
	Severe										1	33.3	7.7				1	33.3	5.6
	Missing				1	100	20.0	1	100	6.7									
	Total				1	100	20.0	1	100	6.7	3	100	23.1				3	100	16.7
URINARY SYSTEM DISORDERS	Moderate	2	100	20.0				2	100	13.3	1	100	7.7	1	100	20.0	2	100	11.1
	Total	2	100	20.0				2	100	13.3	1	100	7.7	1	100	20.0	2	100	11.1
BODY AS A WHOLE-GENERAL DISORDERS	Mild	1	100	10.0				1	100	6.7									
	Total	1	100	10.0				1	100	6.7									
REPRODUCTIVE DISORDERS, FEMALE	Moderate	1	100	10.0				1	100	6.7									
	Total	1	100	10.0				1	100	6.7									

(CONTINUED)

(*) % on all patients with adverse events

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 25

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

Body system / Severity		Assigned treatment															
		Placebo								Reboxetine							
		Female			Male			Total		Female			Male			Total	
		No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %	No. Pt.	%	(*) %
RESPIRATORY SYSTEM DISORDERS	Moderate										1	100	7.7				1	100	5.6
	Total										1	100	7.7				1	100	5.6
VISION DISORDERS	Mild										1	100	7.7				1	100	5.6
	Total										1	100	7.7				1	100	5.6

(*) % on all patients with adverse events

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 26

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

Adverse events/Assigned treatment		No of Episodes	Duration of episodes (days)			
			Min	50%	90%	Max
All adverse events	Placebo	39	1	6	20	26
	Reboxetine	42	1	5	12	30
HEADACHE	Placebo	4	2	6	9	9
	Reboxetine	6	3	8	11	11
CONSTIPATION	Placebo	5	1	7	13	13
	Reboxetine	5	3	4	20	20
MOUTH DRY	Placebo	4	10	20	26	26
	Reboxetine	6	1	6	29	29
NAUSEA	Placebo	3	3	6	20	20
	Reboxetine	4	1	3	8	8
DIZZINESS	Placebo	3	3	6	16	16
	Reboxetine	2	4	6	7	7
VOMITING	Placebo	2	6	14	21	21
	Reboxetine	2	3	3	3	3
RASH	Reboxetine	3	2	4	6	6
PARAESTHESIA	Placebo	1	5	5	5	5
	Reboxetine	2	1	4	7	7
SWEATING INCREASED	Placebo	2	3	9	15	15
	Reboxetine	1	1	1	1	1
AGITATION	Placebo	3	2	3	12	12
URINARY RETENTION	Placebo	1	3	3	3	3
	Reboxetine	1	1	1	1	1

(CONTINUED)

(*) adverse event present before start treatment: onset date = start treatment date of first report visit with changed severity
adverse event still present at end of study: end date = visit date of last report visit

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 26

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

Adverse events/Assigned treatment		No of Episodes	Duration of episodes (days)			
			Min	50%	90%	Max
ANOREXIA	Placebo	1	5	5	5	5
	Reboxetine	1	7	7	7	7
SOMNOLENCE	Placebo	1	3	3	3	3
	Reboxetine	1	5	5	5	5
MICTURITION DISORDER	Placebo	1	3	3	3	3
	Reboxetine	1	3	3	3	3
RASH ERYTHEMATOUS	Placebo	1	3	3	3	3
BULLOUS ERUPTION	Reboxetine	1	19	19	19	19
TREMOR	Placebo	1	1	1	1	1
DIARRHOEA	Reboxetine	1	4	4	4	4
VISION ABNORMAL	Reboxetine	1	8	8	8	8
CONFUSION	Placebo	1	12	12	12	12
INSOMNIA	Reboxetine	1	30	30	30	30
CYANOSIS	Reboxetine	1	1	1	1	1
EXTRASYSTOLES	Placebo	1	2	2	2	2
DYSPNOEA	Reboxetine	1	8	8	8	8
MICTURITION FREQUENCY	Placebo	1	11	11	11	11
INTERMENSTRUAL BLEEDING	Placebo	1	8	8	8	8
UTERINE SPASM	Placebo	1	8	8	8	8
FATIGUE	Placebo	1	3	3	3	3
HOT FLUSHES	Reboxetine	1	12	12	12	12

(*) 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

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 27

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

Adverse events	Assigned treatment											
	Placebo						Reboxetine					
	Symptomatic treatment						Symptomatic treatment					
	YES		NO		Total		YES		NO		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
No. of pt. with A.E.	7	46.7	8	53.3	15	100.0	4	22.2	14	77.8	18	100.0
No. of adverse events	11	28.2	28	71.8	39	100.0	4	9.5	38	90.5	42	100.0
HEADACHE	2	50.0	2	50.0	4	100.0	2	33.3	4	66.7	6	100.0
CONSTIPATION	3	60.0	2	40.0	5	100.0	1	20.0	4	80.0	5	100.0
MOUTH DRY			4	100.0	4	100.0			6	100.0	6	100.0
NAUSEA	1	33.3	2	66.7	3	100.0			4	100.0	4	100.0
DIZZINESS			3	100.0	3	100.0			2	100.0	2	100.0
VOMITING	1	50.0	1	50.0	2	100.0			2	100.0	2	100.0
RASH									3	100.0	3	100.0
PARAESTHESIA			1	100.0	1	100.0			2	100.0	2	100.0
SWEATING INCREASED			2	100.0	2	100.0			1	100.0	1	100.0
AGITATION	1	33.3	2	66.7	3	100.0						
URINARY RETENTION			1	100.0	1	100.0			1	100.0	1	100.0
ANOREXIA			1	100.0	1	100.0			1	100.0	1	100.0
SOMNOLENCE			1	100.0	1	100.0			1	100.0	1	100.0
MICTURITION DISORDER	1	100.0			1	100.0			1	100.0	1	100.0
BULLOUS ERUPTION									1	100.0	1	100.0
TREMOR			1	100.0	1	100.0						
DIARRHOEA									1	100.0	1	100.0
VISION ABNORMAL									1	100.0	1	100.0
CONFUSION	1	100.0			1	100.0						

(CONTINUED)

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 27

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

Adverse events	Assigned treatment													
	Placebo						Reboxetine							
	Symptomatic treatment						Symptomatic treatment							
	YES		NO		Total		YES		NO		Total			
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%		
INSOMNIA							1	100.0			1	100.0		
CYANOSIS									1	100.0	1	100.0		
EXTRASYSTOLES			1	100.0	1	100.0								
DYSPNOEA									1	100.0	1	100.0		
MICTURITION FREQUENCY			1	100.0	1	100.0								
INTERMENSTRUAL BLEEDING	1	100.0			1	100.0								
UTERINE SPASM			1	100.0	1	100.0								
FATIGUE			1	100.0	1	100.0								
HOT FLUSHES									1	100.0	1	100.0		
RASH ERYTHEMATOUS			1	100.0	1	100.0								

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 28

ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL TREATMENT AND ASSIGNED TREATMENT

Adverse events/Assigned treatment		Relationship											
		Certain		Probable		Possible/ Doubtful		Unknown		Missing		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Total adverse events	Reboxetine	1	2.4	5	11.9	26	61.9	8	19.0	2	4.8	42	100.0
	Placebo	1	2.6	12	30.8	19	48.7	5	12.8	2	5.1	39	100.0
MOUTH DRY	Reboxetine	1	16.7	1	16.7	3	50.0	1	16.7			6	100.0
	Placebo			2	50.0	2	50.0					4	100.0
CONSTIPATION	Reboxetine					3	60.0	2	40.0			5	100.0
	Placebo	1	20.0	2	40.0	1	20.0	1	20.0			5	100.0
HEADACHE	Reboxetine			1	16.7	4	66.7	1	16.7			6	100.0
	Placebo					3	75.0	1	25.0			4	100.0
NAUSEA	Reboxetine			1	25.0	3	75.0					4	100.0
	Placebo			2	66.7	1	33.3					3	100.0
DIZZINESS	Reboxetine					2	100.0					2	100.0
	Placebo			1	33.3	2	66.7					3	100.0
VOMITING	Reboxetine					2	100.0					2	100.0
	Placebo			1	50.0	1	50.0					2	100.0
SWEATING INCREASED	Reboxetine					1	100.0					1	100.0
	Placebo			1	50.0	1	50.0					2	100.0
PARAESTHESIA	Reboxetine					1	50.0			1	50.0	2	100.0
	Placebo					1	100.0					1	100.0
AGITATION	Placebo					2	66.7	1	33.3			3	100.0
RASH	Reboxetine					2	66.7	1	33.3			3	100.0
ANOREXIA	Reboxetine							1	100.0			1	100.0
	Placebo			1	100.0							1	100.0

(CONTINUED)

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 28

ADVERSE EVENTS BY RELATIONSHIP TO THE EXPERIMENTAL TREATMENT AND ASSIGNED TREATMENT

Adverse events/Assigned treatment		Relationship													
		Certain		Probable		Possible/ Doubtful		Unknown		Missing		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
URINARY RETENTION	Reboxetine					1	100.0					1	100.0
	Placebo			1	100.0							1	100.0
SOMNOLENCE	Reboxetine					1	100.0					1	100.0
	Placebo					1	100.0					1	100.0
MICTURITION DISORDER	Reboxetine					1	100.0					1	100.0
	Placebo							1	100.0			1	100.0
FATIGUE	Placebo			1	100.0							1	100.0
INSOMNIA	Reboxetine			1	100.0							1	100.0
DYSPNOEA	Reboxetine			1	100.0							1	100.0
EXTRASYSTOLES	Placebo					1	100.0					1	100.0
CONFUSION	Placebo					1	100.0					1	100.0
DIARRHOEA	Reboxetine					1	100.0					1	100.0
INTERMENSTRUAL BLEEDING	Placebo					1	100.0					1	100.0
MICTURITION FREQUENCY	Placebo					1	100.0					1	100.0
VISION ABNORMAL	Reboxetine					1	100.0					1	100.0
HOT FLUSHES	Reboxetine							1	100.0			1	100.0
TREMOR	Placebo							1	100.0			1	100.0
BULLOUS ERUPTION	Reboxetine							1	100.0			1	100.0
CYANOSIS	Reboxetine									1	100.0	1	100.0
UTERINE SPASM	Placebo									1	100.0	1	100.0
RASH ERYTHEMATOUS	Placebo									1	100.0	1	100.0

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 29

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

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Adverse events/Assigned treatment		Study drug													
		Disappeared, trial drug continued		Persisted, trial drug continued		Disappeared, after reduct. of dose		Persisted, after reduct. of dose		Not tolerated, trial drug discont.		Missing		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
All adverse events	Placebo	20	51.3	10	25.6			2	5.1	6	15.4	1	2.6	39	100.0
	Reboxetine	19	45.2	21	50.0					2	4.8			42	100.0
MOUTH DRY	Placebo	1	25.0	3	75.0									4	100.0
	Reboxetine	2	33.3	4	66.7									6	100.0
HEADACHE	Placebo	3	75.0	1	25.0									4	100.0
	Reboxetine	3	50.0	3	50.0									6	100.0
CONSTIPATION	Placebo	4	80.0	1	20.0									5	100.0
	Reboxetine	3	60.0	2	40.0									5	100.0
NAUSEA	Placebo	3	100.0											3	100.0
	Reboxetine	1	25.0	3	75.0									4	100.0
DIZZINESS	Placebo	1	33.3	2	66.7									3	100.0
	Reboxetine	2	100.0											2	100.0
VOMITING	Placebo	2	100.0											2	100.0
	Reboxetine	2	100.0											2	100.0
SWEATING INCREASED	Placebo	1	50.0	1	50.0									2	100.0
	Reboxetine			1	100.0									1	100.0
AGITATION	Placebo	1	33.3					1	33.3	1	33.3			3	100.0
RASH	Reboxetine	1	33.3	2	66.7									3	100.0
PARAESTHESIA	Placebo									1	100.0			1	100.0
	Reboxetine			1	50.0					1	50.0			2	100.0
ANOREXIA	Placebo			1	100.0									1	100.0

(CONTINUED)

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 29

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment		Study drug													
		Disappeared, trial drug continued		Persisted, trial drug continued		Disappeared, after reduct. of dose		Persisted, after reduct. of dose		Not tolerated, trial drug discont.		Missing		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
ANOREXIA	Reboxetine	1	100.0											1	100.0
SOMNOLENCE	Placebo	1	100.0											1	100.0
	Reboxetine			1	100.0									1	100.0
URINARY RETENTION	Placebo	1	100.0											1	100.0
	Reboxetine	1	100.0											1	100.0
MICTURITION DISORDER	Placebo	1	100.0											1	100.0
	Reboxetine	1	100.0											1	100.0
HOT FLUSHES	Reboxetine	1	100.0											1	100.0
TREMOR	Placebo	1	100.0											1	100.0
DIARRHOEA	Reboxetine	1	100.0											1	100.0
INSOMNIA	Reboxetine			1	100.0									1	100.0
DYSPNOEA	Reboxetine			1	100.0									1	100.0
BULLOUS ERUPTION	Reboxetine			1	100.0									1	100.0
MICTURITION FREQUENCY	Placebo			1	100.0									1	100.0
VISION ABNORMAL	Reboxetine			1	100.0									1	100.0
CONFUSION	Placebo							1	100.0					1	100.0
FATIGUE	Placebo									1	100.0			1	100.0
CYANOSIS	Reboxetine									1	100.0			1	100.0
EXTRASYSTOLES	Placebo									1	100.0			1	100.0
INTERMENSTRUAL BLEEDING	Placebo									1	100.0			1	100.0
RASH ERYTHEMATOUS	Placebo									1	100.0			1	100.0

(CONTINUED)

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 29

ADVERSE EVENTS BY ACTION ON STUDY DRUG AND ASSIGNED TREATMENT

Adverse events/Assigned treatment		Study drug															
		Disappeared, trial drug continued		Persisted, trial drug continued		Disappeared, after reduct. of dose		Persisted, after reduct. of dose		Not tolerated, trial drug discont.		Missing		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
UTERINE SPASM	Placebo											1	100.0	1	100.0

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
HB	Evaluated	22	21	17	19	26	24	25	19
	Mean	14.19	14.11	14.12	14.00	14.73	14.76	14.64	14.38
	SD	1.12	1.25	1.45	1.37	1.29	1.17	1.16	1.29
	Min	11.45	10.55	10.36	10.64	12.45	12.91	12.27	12.27
	Max	16.62	16.78	16.94	16.22	17.18	17.02	16.70	16.91
	Median	14.16	14.18	14.00	13.90	14.77	14.62	14.64	14.18
	Median diff.		0.00	0.00	-0.27		0.04	-0.16	0.08
	P value		0.7306	0.7434	0.1627		0.6746	0.3162	0.4472
HT	Evaluated	19	18	15	17	15	13	14	10
	Mean	41.08	42.01	41.44	41.43	45.09	45.57	44.68	43.69
	SD	4.62	3.84	4.25	4.46	4.15	3.76	4.51	4.17
	Min	33.00	34.06	35.34	32.26	38.00	40.23	38.70	38.00
	Max	49.57	50.17	50.60	48.37	53.00	51.29	54.29	49.57
	Median	41.00	42.05	40.70	41.00	44.00	44.80	44.53	42.84
	Median diff.		0.91	0.40	0.00		0.86	-1.05	-0.99
	P value		0.0737	1.0000	0.9501		1.0000	0.7729	0.2500
RBC	Evaluated	22	21	17	19	26	24	25	19
	Mean	4.58	4.62	4.63	4.62	4.76	4.84	4.79	4.66
	SD	0.38	0.36	0.39	0.38	0.34	0.43	0.43	0.35
	Min	3.95	3.95	4.11	4.11	4.13	4.29	4.21	4.09
	Max	5.54	5.63	5.53	5.46	5.35	6.07	6.12	5.45

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
RBC	Median	4.49	4.59	4.49	4.49	4.66	4.69	4.69	4.61
	Median diff.		0.08	-0.01	-0.04		0.03	-0.03	-0.02
	P value		0.4473	0.7032	0.8990		0.3116	0.7606	0.5678
PLATELETS	Evaluated	22	21	17	19	26	24	25	19
	Mean	293.95	286.74	301.41	290.76	284.48	281.37	277.76	293.08
	SD	81.23	89.85	62.02	58.55	69.92	66.12	59.19	58.75
	Min	189.00	93.00	208.00	215.50	191.00	199.00	203.00	210.50
	Max	525.00	508.00	414.00	432.00	449.00	471.00	487.00	404.00
	Median	265.25	275.00	313.00	280.00	271.75	260.25	256.00	294.00
	Median diff.		-6.00	5.50	1.00		8.75	-2.50	-1.50
	P value		0.5674	0.5555	0.6436		0.1437	0.5850	0.9135

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
WBC	Evaluated	22	21	17	19	26	24	25	19
	Mean	8.22	7.61	7.39	7.77	8.07	7.91	7.78	7.30
	SD	1.96	1.64	1.34	1.28	2.37	2.27	1.92	2.13
	Min	4.31	4.44	4.77	4.95	5.04	4.59	4.69	4.22
	Max	10.60	10.44	9.48	9.70	13.88	13.41	14.06	11.73
	Median	8.06	7.63	7.19	7.95	7.24	7.34	7.66	6.92
	Median diff.		-0.56	-0.74	-1.02		0.01	-0.03	-0.19
	P value		0.1471	0.0110	0.1447		0.9063	0.6077	0.2101
WBC: N	Evaluated	14	13	9	11	17	16	16	11
	Mean	63.20	62.29	61.69	62.03	63.39	62.54	61.89	59.64
	SD	3.69	2.79	3.03	3.08	3.41	3.40	3.01	2.54
	Min	58.46	57.04	58.36	57.28	57.60	56.40	56.60	56.00
	Max	71.57	67.13	68.14	68.43	68.00	67.57	67.00	63.00
	Median	62.48	61.80	61.00	62.78	64.67	62.12	61.53	58.90
	Median diff.		-1.14	-2.29	-2.00		-0.69	-0.68	-1.64
	P value		0.2402	0.0078	0.1016		0.1102	0.1198	0.0137
WBC: E	Evaluated	20	18	15	17	24	23	23	18
	Mean	2.28	2.61	2.40	2.61	2.59	2.96	2.69	2.55
	SD	0.88	0.65	0.76	0.97	0.84	1.10	0.76	0.56
	Min	0.60	1.60	1.00	1.28	1.00	1.80	0.96	1.80
	Max	3.80	4.30	3.45	5.25	4.45	6.20	4.28	3.95

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
WBC: E	Median	2.38	2.60	2.30	2.60	2.60	2.60	2.88	2.60
	Median diff.		0.20	0.35	0.15		0.32	0.05	0.04
	P value		0.2808	0.4539	0.2958		0.0601	0.3513	0.7096
WBC: B	Evaluated	12	11	5	8	12	11	8	8
	Mean	0.58	0.66	0.38	0.48	0.65	0.72	0.73	0.86
	SD	0.75	0.73	0.71	0.70	0.71	0.69	0.73	0.73
	Min	-0.19	-0.09	-0.09	-0.19	-0.19	-0.09	-0.09	-0.09
	Max	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
	Median	0.41	0.60	-0.09	0.26	0.60	0.60	0.75	1.09
	Median diff.		0.00	0.00	0.00		0.00	0.05	0.00
	P value		0.1250	1.0000	1.0000		0.6250	0.5625	0.7500
WBC: L	Evaluated	20	18	15	17	25	24	24	18
	Mean	25.30	26.36	25.70	26.08	25.64	26.34	26.26	25.98
	SD	4.70	3.51	3.31	4.79	3.14	3.32	2.33	3.34
	Min	18.60	18.96	21.80	19.15	20.50	21.40	22.20	20.76
	Max	39.00	31.40	32.20	38.10	32.20	32.00	31.40	31.76
	Median	24.75	27.24	25.30	24.40	25.00	25.45	25.84	25.00
	Median diff.		1.50	2.40	0.44		0.45	0.74	0.75
	P value		0.0259	0.0049	0.4586		0.1781	0.2189	0.1594
WBC: M	Evaluated	11	11	6	8	17	16	16	12
	Mean	5.74	6.02	8.39	7.45	7.01	6.89	7.01	5.99

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
WBC: M	SD	2.49	2.37	3.03	3.86	4.91	4.44	5.55	3.86
	Min	2.07	2.67	4.00	3.47	2.07	2.07	2.07	1.93
	Max	11.00	11.00	11.00	15.00	19.00	19.00	23.00	15.00
	Median	6.33	6.33	9.00	6.67	6.33	6.33	6.33	6.33
	Median diff.		0.00	0.00	0.00		0.00	0.00	0.00
	P value		0.7500	0.5000	0.2500		0.5469	1.0000	0.6875

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
CREATININE	Evaluated	21	17	17	18	24	21	22	18
	Mean	0.76	0.71	0.77	0.77	0.76	0.76	0.75	0.77
	SD	0.22	0.21	0.15	0.15	0.17	0.19	0.17	0.17
	Min	0.40	0.43	0.51	0.56	0.54	0.44	0.46	0.52
	Max	1.15	1.16	1.02	1.05	1.08	1.17	1.15	1.08
	Median	0.70	0.71	0.75	0.72	0.70	0.70	0.73	0.79
	Median diff.		-0.05	-0.03	-0.05		0.00	0.00	0.00
	P value		0.2582	0.6441	0.3463		0.6778	0.8934	0.4918
BUN	Evaluated	21	19	17	18	21	19	21	15
	Mean	10.70	11.77	11.38	12.27	12.72	13.24	12.34	11.85
	SD	3.50	4.26	4.71	3.09	3.17	4.06	3.30	3.51
	Min	6.11	6.76	6.51	7.59	7.00	7.00	7.00	4.92
	Max	20.08	26.32	24.24	18.30	19.47	24.84	18.73	18.89
	Median	9.97	10.86	10.67	12.38	12.87	13.11	11.76	13.11
	Median diff.		1.71	0.00	0.73		0.00	-0.49	-0.24
	P value		0.0189	1.0000	0.2633		0.5398	0.1812	0.3373
URIC ACID	Evaluated	18	15	16	15	23	20	22	16
	Mean	4.42	4.46	4.50	4.80	4.17	4.21	4.28	4.05
	SD	2.11	1.97	2.05	2.42	1.80	1.93	1.93	2.11
	Min	2.19	2.44	2.46	2.41	2.37	2.27	2.33	2.10
	Max	10.53	9.74	9.54	10.72	8.63	9.21	9.17	10.23

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
URIC ACID	Median	4.09	3.55	3.80	3.84	3.66	3.62	3.48	3.41
	Median diff.		0.07	0.02	0.19		-0.05	-0.10	-0.10
	P value		0.9780	0.6788	0.4263		0.9217	0.8754	0.5619

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
TOT. PROTEINS	Evaluated	22	21	20	19	26	23	24	19
	Mean	7.46	7.32	7.31	7.26	7.43	7.30	7.48	7.48
	SD	0.51	0.47	0.50	0.49	0.42	0.32	0.32	0.37
	Min	6.50	6.40	6.40	6.40	6.31	6.69	6.88	6.88
	Max	8.49	8.02	8.30	8.11	8.21	7.83	8.21	8.11
	Median	7.40	7.35	7.26	7.35	7.40	7.26	7.45	7.54
	Median diff.		-0.19	0.00	-0.09		-0.09	0.05	0.00
	P value		0.2341	0.2673	0.2524		0.1010	0.6866	0.9854
ALBUMINE	Evaluated	22	21	20	19	26	23	25	19
	Mean	4.54	4.56	4.59	4.64	4.66	4.63	4.74	4.70
	SD	0.53	0.47	0.41	0.44	0.53	0.50	0.43	0.47
	Min	3.31	3.77	3.97	3.88	3.50	3.64	4.06	4.06
	Max	5.55	5.41	5.68	5.55	6.09	5.55	5.68	5.95
	Median	4.45	4.59	4.49	4.72	4.61	4.81	4.81	4.63
	Median diff.		0.00	0.00	0.00		-0.09	0.00	0.00
	P value		0.7898	0.8996	0.9900		0.6569	0.5312	0.2882
TOT BILIRUBIN	Evaluated	22	20	20	19	26	23	25	19
	Mean	0.52	0.47	0.53	0.49	0.45	0.43	0.40	0.46
	SD	0.18	0.24	0.23	0.20	0.16	0.12	0.11	0.14
	Min	0.25	0.21	0.17	0.16	0.20	0.24	0.19	0.20
	Max	0.95	1.16	1.09	0.95	0.89	0.70	0.62	0.72

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
TOT BILIRUBIN	Median	0.53	0.39	0.48	0.48	0.45	0.36	0.39	0.44
	Median diff.		-0.08	0.00	0.01		0.00	-0.06	-0.01
	P value		0.0720	0.6150	0.9411		0.1111	0.0195	0.7908

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
SGOT	Evaluated	19	16	15	16	22	19	21	16
	Mean	19.65	18.14	18.81	21.38	21.09	20.55	21.02	21.93
	SD	5.77	6.08	6.03	7.10	7.53	7.53	7.47	6.95
	Min	6.36	6.36	8.18	5.45	9.09	9.09	10.91	8.18
	Max	30.00	27.04	27.04	30.74	43.64	42.59	43.33	39.63
	Median	21.11	19.63	17.41	21.11	20.74	20.37	20.37	21.85
	Median diff.		-1.11	-0.74	2.22		-0.74	0.91	0.00
	P value		0.2072	0.7728	0.2125		0.3342	0.9764	0.9799
SGPT	Evaluated	20	17	16	17	22	19	21	16
	Mean	16.89	17.99	18.14	20.04	19.37	20.10	21.30	16.81
	SD	6.41	7.38	6.09	8.27	11.45	14.18	14.54	7.53
	Min	7.59	5.00	9.31	9.31	6.72	8.45	5.86	7.59
	Max	32.78	36.90	35.56	40.19	55.93	69.81	75.37	30.93
	Median	15.27	16.21	17.52	17.96	17.04	16.21	17.93	14.91
	Median diff.		0.93	1.72	1.85		0.86	0.86	-1.72
	P value		0.8552	0.9006	0.0335		0.8234	0.4175	0.8316
GAMMA GT	Evaluated	22	20	19	19	26	23	24	19
	Mean	24.70	23.07	21.27	20.56	20.10	21.14	19.55	19.12
	SD	14.06	10.98	9.83	10.11	9.77	9.34	9.00	7.59
	Min	12.43	8.98	10.95	11.94	7.26	10.74	7.26	10.95
	Max	54.77	43.02	43.89	50.00	46.51	42.15	43.89	36.04

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
GAMMA GT	Median	17.52	18.72	17.20	17.85	17.35	18.34	17.85	17.35
	Median diff.		-0.25	-0.49	0.00		0.00	-0.25	-0.49
	P value		0.0807	0.1136	0.3287		0.8139	0.6672	0.8078
ALK. PHOSPH.	Evaluated	22	21	18	19	25	22	24	18
	Mean	124.77	122.17	117.30	126.05	116.27	119.37	109.92	120.03
	SD	68.52	56.27	47.24	50.06	53.01	58.41	54.80	53.48
	Min	31.31	30.49	55.09	60.62	32.29	37.82	32.29	41.96
	Max	329.71	242.35	233.04	241.19	207.41	241.19	256.33	242.35
	Median	113.65	108.29	109.08	115.40	115.40	121.55	113.83	128.21
	Median diff.		0.00	-6.58	3.49		-1.16	-3.49	-1.75
	P value		0.9781	0.5437	0.5089		0.6995	0.1752	0.4948

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
GLOBULINS ALPHA 1	Evaluated	12	11	10	8	13	8	11	9
	Mean	0.18	0.17	0.15	0.17	0.16	0.18	0.16	0.15
	SD	0.07	0.04	0.06	0.06	0.02	0.04	0.03	0.03
	Min	0.10	0.11	0.03	0.10	0.11	0.13	0.10	0.11
	Max	0.30	0.22	0.24	0.27	0.20	0.27	0.20	0.19
	Median	0.16	0.18	0.16	0.15	0.16	0.18	0.16	0.15
	Median diff.		0.00	0.00	0.00		0.02	-0.01	0.01
	P value		0.9219	0.8867	0.8750		0.0313	0.6777	0.7109
GLOBULINS ALPHA 2	Evaluated	12	11	10	8	13	8	11	9
	Mean	0.78	0.79	0.74	0.73	0.75	0.77	0.80	0.76
	SD	0.11	0.08	0.08	0.06	0.07	0.07	0.07	0.06
	Min	0.55	0.66	0.55	0.61	0.65	0.67	0.70	0.68
	Max	1.00	0.98	0.86	0.83	0.88	0.91	0.98	0.88
	Median	0.77	0.76	0.73	0.73	0.74	0.75	0.80	0.76
	Median diff.		-0.02	0.01	-0.04		-0.01	0.03	0.02
	P value		0.9219	0.7695	0.4844		0.4688	0.0186	0.3828
GLOBULINS BETA	Evaluated	12	11	10	8	13	9	11	9
	Mean	0.86	0.87	0.85	0.84	0.80	0.81	0.79	0.82
	SD	0.14	0.12	0.07	0.08	0.06	0.05	0.07	0.04
	Min	0.70	0.70	0.77	0.75	0.63	0.73	0.65	0.76
	Max	1.17	1.06	0.97	0.97	0.87	0.87	0.89	0.87

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
GLOBULINS BETA	Median	0.82	0.91	0.84	0.81	0.80	0.79	0.81	0.82
	Median diff.		0.00	0.00	-0.01		0.00	0.02	0.01
	P value		0.8203	0.9414	0.9375		0.8125	0.7646	0.7344
GLOBULINS GAMMA	Evaluated	12	10	10	8	13	8	10	9
	Mean	1.19	1.11	1.07	1.03	1.10	1.11	1.16	1.11
	SD	0.24	0.14	0.19	0.14	0.17	0.22	0.16	0.17
	Min	0.90	0.90	0.85	0.76	0.77	0.94	0.92	0.85
	Max	1.60	1.34	1.46	1.19	1.42	1.57	1.37	1.41
	Median	1.16	1.08	1.06	1.02	1.07	1.04	1.14	1.11
	Median diff.		-0.07	-0.02	-0.08		-0.05	-0.01	-0.01
	P value		0.1641	0.3438	0.3125		0.9375	0.5566	0.7344

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
TOT. CHOLEST.	Evaluated	22	20	20	19	26	23	25	18
	Mean	287.52	283.65	283.76	289.64	287.35	292.13	287.27	293.60
	SD	44.34	35.53	37.88	33.54	46.18	47.02	49.79	56.61
	Min	215.80	225.47	179.45	247.12	225.43	231.72	214.19	240.93
	Max	383.27	349.05	343.43	365.90	410.86	450.19	416.48	444.57
	Median	291.20	273.06	281.62	276.00	279.60	272.12	275.73	279.17
	Median diff.		0.97	2.81	0.39		0.00	0.00	-1.88
	P value		0.6481	0.4837	0.6397		0.6112	0.5547	0.8891
TRIGLYCERIDES	Evaluated	22	20	20	19	25	22	24	18
	Mean	183.82	227.66	207.96	207.11	187.63	238.78	226.69	171.50
	SD	224.69	311.86	259.55	274.77	157.52	193.29	214.59	206.52
	Min	24.78	20.72	40.03	38.00	7.50	7.50	-10.80	-3.68
	Max	1028.17	1357.17	1197.37	1230.27	544.07	677.23	804.13	877.77
	Median	111.20	116.05	115.27	126.45	127.47	161.02	144.24	85.28
	Median diff.		10.88	13.73	20.33		9.78	1.16	-13.72
	P value		0.2943	0.0797	0.0874		0.0511	0.2083	0.4109
GLUCOSE	Evaluated	18	16	14	16	22	17	20	16
	Mean	80.95	77.91	80.12	78.01	79.13	79.66	80.90	78.82
	SD	6.63	4.77	5.22	4.52	9.48	7.92	7.44	3.91
	Min	71.62	65.15	72.15	69.46	66.23	70.54	74.85	68.92
	Max	96.92	85.62	92.62	87.23	116.85	102.31	106.08	87.77

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment								
		Placebo				Reboxetine				
		Days of treatment				Days of treatment				
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
GLUCOSE	Median	79.96	78.35	79.15	78.35	77.27	77.00	79.15	79.15
	Median diff.		-1.62	-0.81	-3.23		0.54	2.15	1.62
	P value		0.2310	0.8784	0.0632		0.8307	0.0312	0.4558

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
NA+	Evaluated	22	21	19	19	26	23	25	19
	Mean	140.70	140.29	140.42	140.39	140.20	140.02	140.19	139.94
	SD	2.27	2.56	2.77	1.59	1.49	2.14	2.13	1.62
	Min	136.67	136.67	133.33	136.67	137.33	134.00	132.67	136.00
	Max	145.09	146.91	146.00	143.27	143.27	145.09	143.27	143.27
	Median	140.27	139.33	140.67	140.00	140.27	140.00	140.55	140.00
	Median diff.		-0.67	0.00	-0.67		-0.67	0.00	0.00
	P value		0.2716	0.6492	0.4798		0.1717	0.9058	0.9597
K+	Evaluated	21	17	16	17	25	20	21	18
	Mean	4.31	4.27	4.53	4.39	4.45	4.56	4.47	4.55
	SD	0.47	0.67	0.51	0.42	0.45	0.41	0.40	0.38
	Min	3.61	3.29	3.61	3.50	3.61	3.82	3.71	3.82
	Max	5.42	5.42	5.21	4.89	5.53	5.53	5.31	5.21
	Median	4.25	4.25	4.67	4.35	4.46	4.57	4.46	4.57
	Median diff.		0.00	0.00	0.11		0.11	0.00	0.16
	P value		0.7928	0.2236	0.9350		0.0729	0.3583	0.1221
Ca++	Evaluated	18	15	15	16	26	22	25	19
	Mean	5.08	5.11	5.11	5.11	5.09	5.02	5.14	5.13
	SD	0.25	0.32	0.26	0.25	0.31	0.30	0.29	0.33
	Min	4.54	4.70	4.63	4.76	4.35	4.00	4.50	4.68
	Max	5.60	5.80	5.68	5.48	5.68	5.38	5.83	5.80

(CONTINUED)

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 30

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

Laboratory test		Assigned treatment							
		Placebo				Reboxetine			
		Days of treatment				Days of treatment			
		Screen	1-7	8-14	15-28	Screen	1-7	8-14	15-28
Ca++	Median	5.03	5.00	5.06	5.12	5.13	5.09	5.14	5.18
	Median diff.		0.05	0.04	0.03		-0.09	-0.02	0.06
	P value		0.3330	0.6093	0.9701		0.2464	0.5690	0.3682
PO4--	Evaluated	14	11	10	11	24	21	22	18
	Mean	1.28	1.19	1.13	1.19	1.22	1.19	1.24	1.26
	SD	0.24	0.13	0.14	0.14	0.14	0.13	0.13	0.12
	Min	0.89	0.99	0.93	1.01	0.99	0.95	1.01	1.02
	Max	1.86	1.44	1.36	1.49	1.51	1.44	1.45	1.49
	Median	1.26	1.17	1.10	1.19	1.21	1.21	1.25	1.24
	Median diff.		-0.03	-0.09	-0.05		-0.01	0.04	0.01
	P value		0.4258	0.0742	0.3311		0.5294	0.6485	0.4257

P VALUE: PROBABILITY FROM THE WILCOXON RANK SIGNED TEST

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 31

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

Assigned treatment: Placebo

Urinalysis		Days of treatment																							
		0 - Screening						1-7 days						8-14 days						15-28 days					
		Female		Male		Total		Female		Male		Total		Female		Male		Total		Female		Male		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
SPECIFIC GRAVITY	NORMAL	5	100	5	100	10	100	5	100	5	100	10	100	4	100	3	60.0	7	77.8	3	75.0	3	75.0	6	75.0
	NOT DONE															2	40.0	2	22.2	1	25.0	1	25.0	2	25.0
	Total	5	100	5	100	10	100	5	100	5	100	10	100	4	100	5	100	9	100	4	100	4	100	8	100
ALBUMIN	ABSENT	12	85.7	6	85.7	18	85.7	12	92.3	6	85.7	18	90.0	8	72.7	5	71.4	13	72.2	9	81.8	4	66.7	13	76.5
	NOT DONE																			1	9.1			1	5.9
	PRESENT	2	14.3	1	14.3	3	14.3	1	7.7	1	14.3	2	10.0	3	27.3	2	28.6	5	27.8	1	9.1	2	33.3	3	17.6
	Total	14	100	7	100	21	100	13	100	7	100	20	100	11	100	7	100	18	100	11	100	6	100	17	100
SUGAR	ABSENT	14	100	6	85.7	20	95.2	13	100	7	100	20	100	11	100	6	85.7	17	94.4	11	100	6	100	17	100
	PRESENT			1	14.3	1	4.8									1	14.3	1	5.6						
	Total	14	100	7	100	21	100	13	100	7	100	20	100	11	100	7	100	18	100	11	100	6	100	17	100
WBC	ABSENT	13	92.9	7	100	20	95.2	12	92.3	6	85.7	18	90.0	9	81.8	5	71.4	14	77.8	11	100	6	100	17	100
	NOT DONE															1	14.3	1	5.6						
	PRESENT	1	7.1			1	4.8	1	7.7	1	14.3	2	10.0	2	18.2	1	14.3	3	16.7						
	Total	14	100	7	100	21	100	13	100	7	100	20	100	11	100	7	100	18	100	11	100	6	100	17	100
RBC	ABSENT	7	77.8	3	75.0	10	76.9	7	77.8	4	100	11	84.6	6	85.7	3	75.0	9	81.8	4	66.7	4	100	8	80.0
	NOT DONE																			2	33.3			2	20.0
	PRESENT	2	22.2	1	25.0	3	23.1	2	22.2			2	15.4	1	14.3	1	25.0	2	18.2						
	Total	9	100	4	100	13	100	9	100	4	100	13	100	7	100	4	100	11	100	6	100	4	100	10	100

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 31

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

Assigned treatment: Reboxetine

Urinalysis		Days of treatment																					
		0 - Screening						1-7 days						8-14 days						15-28 days			
		Female		Male		Total		Female		Male		Total		Female		Male		Total		Female		Male		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
SPECIFIC GRAVITY	NORMAL	10	100	5	100	15	100	8	88.9	4	80.0	12	85.7	8	88.9	5	100	13	92.9	7	100	4	100	11	100
	NOT DONE							1	11.1	1	20.0	2	14.3	1	11.1			1	7.1						
	Total	10	100	5	100	15	100	9	100	5	100	14	100	9	100	5	100	14	100	7	100	4	100	11	100
ALBUMIN	ABSENT	13	81.3	8	88.9	21	84.0	11	84.6	7	87.5	18	85.7	12	85.7	7	87.5	19	86.4	11	91.7	5	83.3	16	88.9
	PRESENT	3	18.8	1	11.1	4	16.0	2	15.4	1	12.5	3	14.3	2	14.3	1	12.5	3	13.6	1	8.3	1	16.7	2	11.1
	Total	16	100	9	100	25	100	13	100	8	100	21	100	14	100	8	100	22	100	12	100	6	100	18	100
SUGAR	ABSENT	16	100	9	100	25	100	13	100	8	100	21	100	14	100	7	87.5	21	95.5	12	100	5	83.3	17	94.4
	PRESENT															1	12.5	1	4.5			1	16.7	1	5.6
	Total	16	100	9	100	25	100	13	100	8	100	21	100	14	100	8	100	22	100	12	100	6	100	18	100
WBC	ABSENT	14	87.5	9	100	23	92.0	11	84.6	8	100	19	90.5	12	85.7	8	100	20	90.9	10	83.3	6	100	16	88.9
	PRESENT	2	12.5			2	8.0	2	15.4			2	9.5	2	14.3			2	9.1	2	16.7			2	11.1
	Total	16	100	9	100	25	100	13	100	8	100	21	100	14	100	8	100	22	100	12	100	6	100	18	100
RBC	ABSENT	12	100	7	100	19	100	10	100	6	85.7	16	94.1	10	90.9	6	100	16	94.1	7	87.5	4	100	11	91.7
	PRESENT									1	14.3	1	5.9	1	9.1			1	5.9	1	12.5			1	8.3
	Total	12	100	7	100	19	100	10	100	7	100	17	100	11	100	6	100	17	100	8	100	4	100	12	100

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 32

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

Assigned treatment: Placebo

Urinalysis		Total						Last assessment															
								1-7 days				8-14 days						15-28 days					
		Female		Male		Total		Female		Total		Female		Male		Total		Female		Male		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
SPECIFIC GRAVITY	NORMAL	4	80.0	3	60.0	7	70.0	1	100	1	100							3	75.0	3	75.0	6	75.0
	NOT DONE	1	20.0	2	40.0	3	30.0							1	100	1	100	1	25.0	1	25.0	2	25.0
	Total	5	100	5	100	10	100	1	100	1	100			1	100	1	100	4	100	4	100	8	100
ALBUMIN	ABSENT	11	78.6	4	57.1	15	71.4	2	100	2	100							9	81.8	4	66.7	13	76.5
	NOT DONE	1	7.1			1	4.8											1	9.1			1	5.9
	PRESENT	2	14.3	3	42.9	5	23.8					1	100	1	100	2	100	1	9.1	2	33.3	3	17.6
	Total	14	100	7	100	21	100	2	100	2	100	1	100	1	100	2	100	11	100	6	100	17	100
SUGAR	ABSENT	14	100	6	85.7	20	95.2	2	100	2	100	1	100			1	50.0	11	100	6	100	17	100
	PRESENT			1	14.3	1	4.8							1	100	1	50.0						
	Total	14	100	7	100	21	100	2	100	2	100	1	100	1	100	2	100	11	100	6	100	17	100
WBC	ABSENT	14	100	6	85.7	20	95.2	2	100	2	100	1	100			1	50.0	11	100	6	100	17	100
	NOT DONE			1	14.3	1	4.8							1	100	1	50.0						
	Total	14	100	7	100	21	100	2	100	2	100	1	100	1	100	2	100	11	100	6	100	17	100
RBC	ABSENT	7	77.8	4	100	11	84.6	2	100	2	100	1	100			1	100	4	66.7	4	100	8	80.0
	NOT DONE	2	22.2			2	15.4											2	33.3			2	20.0
	Total	9	100	4	100	13	100	2	100	2	100	1	100			1	100	6	100	4	100	10	100

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 32

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

Assigned treatment: Reboxetine

Urinalysis		Total						Last assessment																	
								1-7 days						8-14 days						15-28 days					
		Female		Male		Total		Female		Male		Total		Female		Male		Total		Female		Male		Total	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
SPECIFIC GRAVITY	NORMAL	10	100	5	100	15	100	1	100			1	100	2	100	1	100	3	100	7	100	4	100	11	100
	Total	10	100	5	100	15	100	1	100			1	100	2	100	1	100	3	100	7	100	4	100	11	100
ALBUMIN	ABSENT	14	87.5	8	88.9	22	88.0	1	100	1	100	2	100	2	66.7	2	100	4	80.0	11	91.7	5	83.3	16	88.9
	PRESENT	2	12.5	1	11.1	3	12.0							1	33.3			1	20.0	1	8.3	1	16.7	2	11.1
	Total	16	100	9	100	25	100	1	100	1	100	2	100	3	100	2	100	5	100	12	100	6	100	18	100
SUGAR	ABSENT	16	100	8	88.9	24	96.0	1	100	1	100	2	100	3	100	2	100	5	100	12	100	5	83.3	17	94.4
	PRESENT			1	11.1	1	4.0															1	16.7	1	5.6
	Total	16	100	9	100	25	100	1	100	1	100	2	100	3	100	2	100	5	100	12	100	6	100	18	100
WBC	ABSENT	14	87.5	9	100	23	92.0	1	100	1	100	2	100	3	100	2	100	5	100	10	83.3	6	100	16	88.9
	PRESENT	2	12.5			2	8.0													2	16.7			2	11.1
	Total	16	100	9	100	25	100	1	100	1	100	2	100	3	100	2	100	5	100	12	100	6	100	18	100
RBC	ABSENT	10	83.3	7	100	17	89.5	1	100	1	100	2	100	2	66.7	2	100	4	80.0	7	87.5	4	100	11	91.7
	PRESENT	2	16.7			2	10.5							1	33.3			1	20.0	1	12.5			1	8.3
	Total	12	100	7	100	19	100	1	100	1	100	2	100	3	100	2	100	5	100	8	100	4	100	12	100

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 33

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

Laboratory test		Assigned treatment																							
		Placebo												Reboxetine											
		Days of treatment												Days of treatment											
		1-7				8-14				15-28				1-7				8-14				15-28			
		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
HB	LOW	1				1				1															
	NORMAL		20				16			1	17				23				24				17	1	
	HIGH				1.000				1.000				1.000		1		1.000		1		1.000		1		1.000
HT	LOW	1	1			1	1			1	1														
	NORMAL		15	1			13			1	14			1	10	1		1	11	1			9		
	HIGH				0.368				1.000				1.000		1		0.607		1		0.607		1		1.000
RBC	LOW	1																							
	NORMAL		20				17				19				23	1			24	1			19		
	HIGH				1.000				1.000				1.000				1.000				1.000				1.000
PLATELETS	LOW																								
	NORMAL	1	16	1			15				16				22				22				16		
	HIGH		2	1	0.513		1	1	1.000		2	1	0.500			2	1.000		2	1	0.500		2	1	0.500

P val : probability from Maxwell's test

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 33

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

Laboratory test		Assigned treatment																							
		Placebo												Reboxetine											
		Days of treatment												Days of treatment											
		1-7				8-14				15-28				1-7				8-14				15-28			
		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
WBC	LOW		1				1				1														
	NORMAL	1	19				16				18				20	1			22			1	15	1	
	HIGH				1.000				1.000				1.000		1	2	1.000		2	1	0.500		2		0.513
WBC: N	LOW																								
	NORMAL		10				6				8			1	12	1		1	13			2	8		
	HIGH		2	1	0.500		2	1	0.500		2	1	0.500		1	1	0.607		2		0.223		1		0.223
WBC: E	LOW		1				2				2														
	NORMAL		12	1			8	3			9	3			15	2		1	15	1			13		
	HIGH		2	2	0.513		1	1	0.223		2	1	0.333		2	4	1.000		1	5	0.607		3	2	0.250
WBC: B	LOW	3	2			3				3	1			3				2				2			
	NORMAL		1								1				3	1			1	1			2		
	HIGH			5	0.500		1	1	1.000		1	2	0.368			4	1.000		1	3	1.000			4	1.000
WBC: L	LOW	3	5			4	4			5	3			2	2			1	3			2	2		
	NORMAL		10				7			1	6	1		1	19			1	19			2	12		
	HIGH				0.063				0.125		1		0.607				1.000				0.625				1.000
WBC: M	LOW	1									1			3	1			4	1			4	1		
	NORMAL		9				3	2			5	1		1	6			1	4	1			4		
	HIGH			1	1.000			1	0.500			1	0.368		1	4	0.607		2	3	0.846		1	2	0.368

P val : probability from Maxwell's test

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 33

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

Laboratory test		Assigned treatment																							
		Placebo												Reboxetine											
		Days of treatment												Days of treatment											
		1-7				8-14				15-28				1-7				8-14				15-28			
		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
CREATININE	LOW	1					1				1							1							
	NORMAL	2	14				16				17			1	20				21				18		
	HIGH				0.500				1.000				1.000				1.000				1.000				1.000
BUN	LOW	1	1				1																		
	NORMAL		16			1	13	1			17				17	1			19	1		1	13	1	
	HIGH			1	1.000			1	0.607			1	1.000		1		1.000		1		1.000				0.368
URIC ACID	LOW	1	1			1				1				4	1			3	2			3	1		
	NORMAL	1	9	1		1	11	1		1	10	1			12	1			14	1		1	10		
	HIGH		1	1	1.000		1	1	0.607		1	1	0.607		1	1	0.607		1	1	0.368			1	1.000

P val : probability from Maxwell's test

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 33

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

Laboratory test		Assigned treatment																						
		Placebo												Reboxetine										
		Days of treatment												Days of treatment										
		1-7				8-14				15-28				1-7				8-14				15-28			
		Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val
TOT. PROTEINS	LOW														1										
	NORMAL		19				18				17				22				24				19		
	HIGH		2		0.500		2		0.500		2		0.500				1.000				1.000				1.000
ALBUMINE	LOW		1																						
	NORMAL		15				15				14				17				19				15		
	HIGH		1	4	0.368		2	3	0.500		3	2	0.250		2	4	0.500		2	4	0.500		2	2	0.500
TOT BILIRUBIN	LOW																		1				1		
	NORMAL		19	1		1	18	1		1	18				23			1	23				18		
	HIGH				1.000				0.368				1.000				1.000				1.000				1.000

P val : probability from Maxwell's test

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 33

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

Laboratory test		Assigned treatment																							
		Placebo												Reboxetine											
		Days of treatment												Days of treatment											
		1-7				8-14				15-28				1-7				8-14				15-28			
		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
SGOT	LOW	1					1			1									1						
	NORMAL	1	14			1	13			1	13	1		1	16	1			18	1		1	13	1	
	HIGH				1.000				1.000				0.368		1		0.607		1		0.607		1		0.607
SGPT	LOW																								
	NORMAL		15	1			15				15	1			16				17	1			14		
	HIGH			1	1.000			1	1.000			1	1.000		1	2	1.000		1	2	1.000		1	1	1.000
GAMMA GT	LOW														1			1	1				1		
	NORMAL		17				17				17				22				22				18		
	HIGH		2	1	0.500		2		0.500		2		0.500				1.000				1.000				1.000
ALK. PHOSPH.	LOW	2				1				1				5				6				4			
	NORMAL		14				13				13	1		1	10			1	12				9		
	HIGH			5	1.000			4	1.000			4	1.000		1	5	0.368		2	3	0.223		2	3	0.500

P val : probability from Maxwell's test

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 33

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

Laboratory test		Assigned treatment																							
		Placebo												Reboxetine											
		Days of treatment												Days of treatment											
		1-7				8-14				15-28				1-7				8-14				15-28			
		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
GLOBULINS ALPHA 1	LOW																								
	NORMAL		11			1	9				8				8				11				9		
	HIGH				1.000				1.000				1.000				1.000				1.000				1.000
GLOBULINS ALPHA 2	LOW		1				1				1														
	NORMAL		10			1	8				7				8				11				9		
	HIGH				1.000				1.000				1.000				1.000				1.000				1.000
GLOBULINS BETA	LOW														1				1						
	NORMAL		10				9				7				8			1	9				9		
	HIGH		1		1.000		1		1.000		1		1.000				1.000				1.000				1.000
GLOBULINS GAMMA	LOW														1				1						
	NORMAL		10				10			1	7				7				9				9		
	HIGH				1.000				1.000				1.000				1.000				1.000				1.000

P val : probability from Maxwell's test

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 33

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

Laboratory test		Assigned treatment																							
		Placebo												Reboxetine											
		Days of treatment												Days of treatment											
		1-7				8-14				15-28				1-7				8-14				15-28			
		Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val	Low	Nor.	High	P val
TOT. CHOLEST.	LOW																								
	NORMAL		7	1			4	2			5	1			4	2			7	1			5		
	HIGH		2	10	1.000		2	12	1.000		3	10	0.625		3	14	1.000		3	14	0.625		3	10	0.250
TRIGLYCERI-DES	LOW	1	1				2				2			1				1				1			
	NORMAL		13	2			13	2			13	1			10	4			13	3		1	10	2	
	HIGH		1	2	0.513		1	2	0.311		1	2	0.368		1	6	0.375		1	6	0.625		2	2	0.607
GLUCOSE	LOW																		1						
	NORMAL	1	15				14			1	15				16				17	1		1	14		
	HIGH				1.000				1.000				1.000		1		1.000		1		0.607		1		0.368

P val : probability from Maxwell's test

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 33

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

Laboratory test		Assigned treatment																							
		Placebo												Reboxetine											
		Days of treatment												Days of treatment											
		1-7				8-14				15-28				1-7				8-14				15-28			
		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
NA+	LOW																								
	NORMAL		20	1		1	18				19			1	22			1	24				19		
	HIGH				1.000				1.000				1.000				1.000				1.000				1.000
K+	LOW																								
	NORMAL	1	14	1			15				16				18				19				16	1	
	HIGH			1	0.368			1	1.000		1		1.000		1	1	1.000		1	1	1.000		1		1.000
Ca++	LOW														1				1				1		
	NORMAL		13	1			14				15			1	19				21	2			15	2	
	HIGH			1	1.000			1	1.000		1		1.000		1		0.607			1	0.223			1	0.223
PO4--	LOW	1				1					1				1				1				1		
	NORMAL		9			1	7				8			1	18				20				16		
	HIGH		1		1.000		1		0.368		2		0.223		1		0.607		1		0.368		1		0.368

P val : probability from Maxwell's test

PHARMACIA CNS R&D 9550321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 1 PATIENT: 3 (SEX: Female)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	17.0	3.7		15.3			16.4			15.3		
RBC	-15 (3.8-5.8)	5.3			4.8			5.1			4.8		
WBC	+-30.0 (4-11)	14.1	28.2		13.6	23.6		14.3	30.0		10.5		
WBC: L	+-30.0 (20-45)	26.8			27.0			28.9			18.6	-7.0	
WBC: E	30 (1-6)	2.2			3.0			0.9	-10.0		3.9		
PLATELETS	+-30.0 (150-400)	449.0	12.3		471.0	17.7		487.0	21.7		377.0		
NA+	+-10.0 (135-150)	142.0			141.0			142.0			140.0		
K+	+-15.0 (3.5-5)	4.3			4.2			4.0			4.2		
Ca++	+-15.0 (2.1-2.6)	2.1			2.3			2.2			2.2		
PO4--	+-15.0 (0.8-1.5)	0.9			0.9			1.2			1.1		
SGOT	100 (2-29)	12.0			13.0			15.0			14.0		
SGPT	100 (5-34)	10.0			12.0			14.0			14.0		
GAMMA GT	100 (0-65)	23.0			31.0			30.0			33.0		
ALK. PHOSPH.	100 (30-115)	112.0			111.0			109.0			98.0		
GLUCOSE	+-30.0 (3.5-10)	6.0			4.0			6.7			5.4		
BUN	50 (2.5-7)	3.6			4.6			3.8			3.1		
CREATININE	50 (59-120)	72.0			72.0			73.0			73.0		
URIC ACID	30 (200-500)	241.0			202.9			203.5			199.2	-0.4	
TOT BILIRUBIN	100 (3-20)	8.0			6.0			6.0			3.0		
TOT. PROTEINS	+-30.0 (60-80)	66.0			70.0			68.0			65.0		
ALBUMINE	+-30.0 (34-50)	47.0			48.0			48.0			46.0		
TOT. CHOLEST.	30 (0-6)	6.2	3.6		5.8			6.1	1.6		6.7	10.9	
TRIGLYCERIDES	30 (0.8-2)	1.8			3.3	64.1	(*)	3.6	80.7	(*)	2.8	40.3	(*)

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CORP 3580321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 1 PATIENT: 1 (SEX: Male)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	15.0			14.5			15.2			15.5		
RBC	-15 (4-6.5)	5.2			4.5			4.6			4.7		
WBC	+-30.0 (3.9-12)	11.4			7.8			6.7			7.3		
WBC: L	+-30.0 (20-45)	19.1	-4.5		24.2			26.5			23.5		
WBC: E	30 (1-6)	3.9			3.7			4.1			5.0		
PLATELETS	+-30.0 (100-600)	226.0			242.0			236.0			238.0		
NA+	+-10.0 (134-145)	144.0			142.0			140.0			140.0		
K+	+-15.0 (3.5-5)	4.0			4.4			4.0			4.2		
SGPT	100 (2-29)	16.0			19.0			16.0			18.0		
GAMMA GT	100 (0-65)	13.0			17.0			13.0			15.0		
ALK. PHOSPH.	100 (30-260)	149.0			118.0			124.0			117.0		
GLUCOSE	+-30.0 (3.5-10)	4.3			6.4			5.4			5.7		
BUN	50 (3-6.7)	3.3			4.3			4.3			5.0		
CREATININE	50 (76-120)	76.0			97.0			81.0			96.0		
URIC ACID	30 (180-340)	260.1			258.1			264.1			328.3		
TOT BILIRUBIN	100 (2-17)	10.0			13.0			17.0			14.0		
TOT. PROTEINS	+-30.0 (60-80)	75.0			70.0			74.0			71.0		
ALBUMINE	+-30.0 (35-46)	50.0	8.7		48.0	4.3		51.0	10.9		50.0	8.7	
TOT. CHOLEST.	30 (3.1-5.2)	7.1	36.7	(*)	5.8	12.2		5.8	12.2		5.9	14.1	
TRIGLYCERIDES	30 (0.5-2)	3.3	64.5	(*)	1.3			1.3			1.3		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA 95503021

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 1 PATIENT: 10 (SEX: Male)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	14.6			14.0			14.8			14.0		
HT	-15 (0.4-0.54)	0.4			0.4			0.4			0.5		
RBC	-15 (4-6.5)	5.0			4.7			5.1			5.7		
WBC	+-30.0 (3.9-12)	10.9			10.2			8.5			8.8		
WBC: L	+-30.0 (20-45)	10.7	-46.5	(*)	9.9	-50.5	(*)	17.2	-14.0		19.0	-5.0	
WBC: E	30 (1-6)	7.0	16.7		2.7			2.8			3.0		
PLATELETS	+-30.0 (100-600)	329.0			317.0			340.0			326.0		
NA+	+-10.0 (134-145)	143.0			141.0			141.0			140.0		
K+	+-15.0 (3.5-5)	4.9			5.0			4.8			4.8		
Ca++	+-15.0 (2.2-2.6)	2.4			2.6			2.5			2.5		
PO4--	+-15.0 (0.8-1.5)	1.0			1.0			1.1			1.1		
SGOT	100 (15-37)	17.0			18.0			20.0			26.0		
SGPT	100 (2-29)	19.0			20.0			22.0			40.0	37.9	
GAMMA GT	100 (0-65)	30.0			32.0			34.0			34.0		
ALK. PHOSPH.	100 (30-260)	100.0			80.0			86.0			88.0		
GLUCOSE	+-30.0 (3.5-10)	5.2			5.1			5.2			5.1		
BUN	50 (3-6.7)	7.4	10.4		9.5	41.8		8.8	31.3		6.8	1.5	
CREATININE	50 (76-120)	107.0			117.0			106.0			104.0		
URIC ACID	30 (180-340)	240.0			248.0			240.0			240.0		
TOT BILIRUBIN	100 (2-17)	4.0			5.0			6.0			8.0		
TOT. PROTEINS	+-30.0 (60-80)	71.0			65.0			66.0			70.0		
ALBUMINE	+-30.0 (35-46)	45.0			43.0			42.0			44.0		
TOT. CHOLEST.	30 (3.1-5.2)	6.2	19.2		6.3	21.2		6.3	21.2		6.4	22.3	
TRIGLYCERIDES	30 (0.5-2)	1.9			2.0			1.9			1.9		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CORP 00550321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 1 PATIENT: 12 (SEX: Male)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment								
		Screen			1-7			8-14		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	16.6			16.0			15.8		
RBC	-15 (4-6.5)	5.4			6.8	4.6		6.9	6.2	
WBC	+-30.0 (3.9-12)	6.8			5.5			5.8		
WBC: L	+-30.0 (20-45)	24.0			26.6			28.8		
WBC: E	30 (1-6)	5.9			12.6	110.0	(*)	9.2	53.3	(*)
PLATELETS	+-30.0 (100-600)	291.0			310.0			306.0		
NA+	+-10.0 (134-145)	141.0			139.0			140.0		
K+	+-15.0 (3.5-5)	4.2			4.3			4.4		
Ca++	+-15.0 (2.2-2.6)	2.6			2.3			2.4		
PO4--	+-15.0 (0.8-1.5)	1.0			1.4			1.4		
SGOT	100 (15-37)	22.0			16.0			18.0		
SGPT	100 (2-29)	29.0			12.0			16.0		
GAMMA GT	100 (0-65)	24.0			5.0			8.0		
ALK. PHOSPH.	100 (30-260)	133.0			89.0			88.0		
GLUCOSE	+-30.0 (3.5-10)	4.9			5.8			5.2		
BUN	50 (3-6.7)	3.0			9.0	34.3		6.0		
CREATININE	50 (76-120)	106.0			118.0			116.0		
URIC ACID	30 (180-340)	240.2			295.8			280.2		
TOT BILIRUBIN	100 (2-17)	4.0			2.8			6.0		
TOT. PROTEINS	+-30.0 (60-80)	76.0			69.0					
ALBUMINE	+-30.0 (35-46)	54.0	17.4		49.0	6.5		51.0	10.9	
TOT. CHOLEST.	30 (3.1-5.2)	4.4			4.4			4.5		
TRIGLYCERIDES	30 (0.5-2)	3.2	58.8	(*)	3.2	60.6	(*)	3.1	56.1	(*)

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA 9550321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 1 PATIENT: 4 (SEX: Male)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	15.6			15.7			15.4			15.7		
RBC	-15 (4-6.5)	5.1			5.0			5.1			5.1		
WBC	+-30.0 (3.9-12)	7.5			7.1			7.5			7.0		
WBC: L	+-30.0 (20-45)	30.6			35.9			30.6			36.2		
WBC: E	30 (1-6)	7.6	26.7		14.0	133.3	(*)	7.6	26.7		5.0		
PLATELETS	+-30.0 (100-600)	240.0			249.0			240.0			236.0		
NA+	+-10.0 (134-145)	138.0			144.0			139.0			140.0		
K+	+-15.0 (3.5-5)	4.0			4.6			4.5			4.6		
Ca++	+-15.0 (2.2-2.6)	2.3			2.0	-9.1		2.2			2.3		
PO4--	+-15.0 (0.8-1.5)	0.9			0.9			1.1			0.9		
SGOT	100 (15-37)	17.0			20.0			18.0			34.0		
SGPT	100 (2-29)	34.0	17.2		36.0	24.1		30.0	3.4		30.0	3.4	
GAMMA GT	100 (0-65)	29.0			31.0			27.0			30.0		
ALK. PHOSPH.	100 (30-260)	137.0			132.0			122.0			125.0		
GLUCOSE	+-30.0 (3.5-10)	12.2	22.0		4.6			5.9			4.6		
BUN	50 (3-6.7)	4.5			3.9			3.9			2.3	-23.3	
CREATININE	50 (76-120)	82.0			96.0			85.0			82.0		
URIC ACID	30 (180-340)	186.8			204.1			187.8			201.1		
TOT BILIRUBIN	100 (2-17)	14.0			10.0			8.0			11.0		
TOT. PROTEINS	+-30.0 (60-80)	70.0			66.0			66.0			67.0		
ALBUMINE	+-30.0 (35-46)	48.0	4.3		48.0	4.3		47.0	2.2		50.0	8.7	
TOT. CHOLEST.	30 (3.1-5.2)	5.4	3.1		6.4	23.0		5.3	1.2		6.4	23.0	
TRIGLYCERIDES	30 (0.5-2)	1.9			1.9			1.9			1.9		

(1): % deviation from limits of normal range - (2): clinical relevance

9550321
PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 1 PATIENT: 9 (SEX: Male)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	14.7			14.7			14.6			14.9		
HT	-15 (0.4-0.54)	0.3	-22.5	(*)	0.3	-20.2	(*)	0.3	-16.5	(*)	0.3	-25.5	(*)
RBC	-15 (4-6.5)	4.8			4.8			4.9			4.9		
WBC	+-30.0 (3.9-12)	7.6			7.6			6.7			6.8		
PLATELETS	+-30.0 (100-600)	357.0			414.0			445.0			359.0		
NA+	+-10.0 (134-145)	142.0			146.0	0.7		145.0			141.0		
K+	+-15.0 (3.5-5)	4.4			4.0			4.0			4.1		
Ca++	+-15.0 (2.2-2.6)	2.4			2.4			2.3			2.3		
PO4--	+-15.0 (0.8-1.5)	1.1			0.9			0.9			1.0		
SGOT	100 (15-37)	21.0			13.0	-13.3		13.0	-13.3		12.0	-20.0	
SGPT	100 (2-29)	23.0			16.0			14.0			16.0		
GAMMA GT	100 (0-65)	15.0			16.0			14.0			15.0		
ALK. PHOSPH.	100 (30-260)	85.0			110.0			142.0			163.0		
GLUCOSE	+-30.0 (3.5-10)	7.8			5.2			5.2			5.5		
BUN	50 (3-6.7)	5.0			4.3			4.9			5.8		
CREATININE	50 (76-120)	111.0			103.0			103.0			99.0		
URIC ACID	30 (180-340)	201.0			171.0	-5.0		203.0					
TOT BILIRUBIN	100 (2-17)	10.0			20.0	17.6		12.0			12.0		
TOT. PROTEINS	+-30.0 (60-80)	72.0			77.0			74.0			74.0		
ALBUMINE	+-30.0 (35-46)	47.0	2.2		47.0	2.2		47.0	2.2		45.0		
TOT. CHOLEST.	30 (3.1-5.2)	4.9			5.0			5.3	1.9		5.1		
TRIGLYCERIDES	30 (0.5-2)	1.0			0.9			1.1			1.3		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA 95500321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 2 PATIENT: 21 (SEX: Female)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	12.5			13.6			13.2			12.7		
RBC	-15 (3.8-5.8)	4.0			4.5			4.2			4.0		
WBC	+-30.0 (4-11)	5.0			10.9			6.1			3.7	-7.5	
WBC: N	+-30.0 (2.5-7.5)	2.8			7.3			3.7			2.0	-20.0	
WBC: L	+-30.0 (1.5-3.5)	2.0			3.3			2.1			1.5		
WBC: E	30 (0.04-0.44)	0.2			0.3			0.2			0.2		
WBC: M	30 (0.2-0.8)	0.7			0.7			0.7			0.7		
WBC: B	30 (0-0.1)	0.2	100.0	(*)	0.2	100.0	(*)	0.2	100.0	(*)	0.2	100.0	(*)
PLATELETS	+-30.0 (150-400)	191.0			199.0			203.0			220.0		
NA+	+-10.0 (135-150)	140.0			138.0			137.0			141.0		
K+	+-15.0 (3.5-5)	3.7			4.0			4.0			4.1		
Ca++	+-15.0 (2.1-2.6)	2.3			2.4			2.5			2.3		
PO4--	+-15.0 (0.8-1.5)	1.1			1.2			1.3			1.1		
SGOT	100 (2-29)	23.0			13.0			14.0			21.0		
SGPT	100 (5-34)	14.0			19.0			20.0			17.0		
GAMMA GT	100 (0-65)	8.0			7.0			7.0			7.0		
ALK. PHOSPH.	100 (30-115)	125.0	8.7		122.0	6.1		97.0			106.0		
GLUCOSE	+-30.0 (3.5-10)	4.6						5.5			5.0		
BUN	50 (2.5-7)	6.2			4.8			6.4			3.8		
CREATININE	50 (59-120)	73.0			79.0			114.0			88.0		
URIC ACID	30 (200-500)	180.0	-10.0		177.0	-11.5		214.0			156.0	-22.0	
TOT BILIRUBIN	100 (3-20)	9.0			6.0			7.0			8.0		
TOT. PROTEINS	+-30.0 (60-80)	69.0			68.0			73.0			69.0		
ALBUMINE	+-30.0 (34-50)	41.0			40.0			43.0			40.0		
TOT. CHOLEST.	30 (0-6)	5.9			4.9			5.1			4.7		
TRIGLYCERIDES	30 (0.8-2)	1.7			2.4	20.0		2.1	5.0		1.2		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CORP 0321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 2 PATIENT: 22 (SEX: Female)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	13.4			13.1			13.8			13.9		
RBC	-15 (3.8-5.8)	4.4			4.2			4.5			4.6		
WBC	+-30.0 (4-11)	8.8			7.0			6.9			7.7		
WBC: N	+-30.0 (2.5-7.5)	6.6			4.9			4.7			5.6		
WBC: L	+-30.0 (1.5-3.5)	1.9			1.8			1.9			1.7		
WBC: E	30 (0.04-0.44)	0.3			0.3			0.3			0.3		
WBC: M	30 (0.2-0.8)	0.7			0.7			0.7			0.7		
WBC: B	30 (0-0.1)	0.2	100.0	(*)	0.2	100.0	(*)	0.2	100.0	(*)	0.2	100.0	(*)
PLATELETS	+-30.0 (150-400)	358.0			320.0			352.0			374.0		
NA+	+-10.0 (135-150)	141.0			140.0			131.0	-3.0		143.0		
K+	+-15.0 (3.5-5)	3.6			3.6			4.7			3.8		
Ca++	+-15.0 (2.1-2.6)	2.4			2.5			2.4			2.4		
PO4--	+-15.0 (0.8-1.5)	1.5			1.4			1.3			1.1		
SGOT	100 (2-29)	17.0			11.0			12.0			14.0		
SGPT	100 (5-34)	13.0			16.0			15.0			16.0		
GAMMA GT	100 (0-65)	10.0			10.0			10.0			11.0		
ALK. PHOSPH.	100 (30-115)	165.0	43.5		177.0	53.9		182.0	58.3		189.0	64.3	
GLUCOSE	+-30.0 (3.5-10)	5.4			5.1			5.3			5.3		
BUN	50 (2.5-7)	5.1			5.2			8.5	21.4		6.2		
CREATININE	50 (59-120)	63.0			69.0			89.0			65.0		
URIC ACID	30 (200-500)	205.0			247.0			275.0			256.0		
TOT BILIRUBIN	100 (3-20)	11.0			10.0			10.0			10.0		
TOT. PROTEINS	+-30.0 (60-80)	75.0			72.0			76.0			78.0		
ALBUMINE	+-30.0 (34-50)	43.0			42.0			42.0			44.0		
TOT. CHOLEST.	30 (0-6)	7.4	23.3		7.5	25.0		7.3	21.7		8.0	33.3	(*)
TRIGLYCERIDES	30 (0.8-2)	0.9			1.7			1.5			1.1		
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	1.9			2.5			1.8					
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	6.6			6.2			7.5					
GLOBULINS BETA	+-30.0 (6-12)	9.7			9.3			10.1					
GLOBULINS GAMMA	+-30.0 (6-16)	13.8			12.8			14.3					

(1): % deviation from limits of normal range - (2): clinical relevance

9550321
PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 2 PATIENT: 23 (SEX: Female)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment					
		Screen			1-7		
		value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	14.5			15.0		
RBC	-15 (3.8-5.8)	4.5			4.9		
WBC	+-30.0 (4-11)	6.2			9.3		
WBC: N	+-30.0 (2.5-7.5)	4.1			6.8		
WBC: L	+-30.0 (1.5-3.5)	1.8			2.0		
WBC: E	30 (0.04-0.44)	0.3			0.5	13.6	
WBC: M	30 (0.2-0.8)	0.7			0.7		
WBC: B	30 (0-0.1)	0.2	100.0	(*)	0.2	100.0	(*)
PLATELETS	+-30.0 (150-400)	233.0			303.0		
NA+	+-10.0 (135-150)	139.0			138.0		
K+	+-15.0 (3.5-5)	3.6			3.5		
Ca++	+-15.0 (2.1-2.6)	2.1			2.3		
PO4--	+-15.0 (0.8-1.5)	1.3			1.2		
SGOT	100 (2-29)	21.0			18.0		
SGPT	100 (5-34)	15.0			17.0		
GAMMA GT	100 (0-65)	81.0	24.6		42.0		
ALK. PHOSPH.	100 (30-115)	265.0	130.4	(*)	169.0	47.0	
BUN	50 (2.5-7)	3.4			4.1		
CREATININE	50 (59-120)	64.0			59.0		
URIC ACID	30 (200-500)	164.0	-18.0		263.0		
TOT BILIRUBIN	100 (3-20)	12.0			10.0		
TOT. PROTEINS	+-30.0 (60-80)	79.0			68.0		
ALBUMINE	+-30.0 (34-50)	32.0	-5.9		39.0		
TOT. CHOLEST.	30 (0-6)	3.3			5.9		
TRIGLYCERIDES	30 (0.8-2)	1.2			3.1	55.0	(*)
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	2.6			2.5		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	7.5			6.3		
GLOBULINS BETA	+-30.0 (6-12)	7.9			10.0		
GLOBULINS GAMMA	+-30.0 (6-16)	12.1			9.2		

(1): % deviation from limits of normal range - (2): clinical relevance

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 2 PATIENT: 24 (SEX: Female)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	14.4			14.8			14.9			15.2		
RBC	-15 (3.8-5.8)	4.8			4.9			5.0			5.0		
WBC	+-30.0 (4-11)	10.5			8.5			9.0			7.7		
WBC: N	+-30.0 (2.5-7.5)	8.0	6.7		5.8			4.8			5.5		
WBC: L	+-30.0 (1.5-3.5)	1.9			2.0			2.8			1.9		
WBC: E	30 (0.04-0.44)	0.6	36.4	(*)	0.6	36.4	(*)	0.5	2.3		0.2		
WBC: M	30 (0.2-0.8)	0.7			0.7			1.0	23.8		0.7		
WBC: B	30 (0-0.1)	0.2	100.0	(*)	0.2	100.0	(*)	0.0			0.2	100.0	(*)
PLATELETS	+-30.0 (150-400)	416.0	4.0		432.0	8.0		346.0			404.0	1.0	
NA+	+-10.0 (135-150)	142.0			142.0			144.0			142.0		
K+	+-15.0 (3.5-5)	3.8			4.5			4.2			4.5		
Ca++	+-15.0 (2.1-2.6)	2.2			2.4			2.4			2.3		
PO4--	+-15.0 (0.8-1.5)	1.1			1.2			1.1			1.1		
SGOT	100 (2-29)	25.0			46.0	58.6		47.0	62.1		42.0	44.8	
SGPT	100 (5-34)	31.0			33.0			36.0	5.9		29.0		
GAMMA GT	100 (0-65)	22.0			21.0			22.0			22.0		
ALK. PHOSPH.	100 (30-115)	133.0	15.7		144.0	25.2		130.0	13.0		135.0	17.4	
GLUCOSE	+-30.0 (3.5-10)	5.1			5.0			5.1			5.6		
BUN	50 (2.5-7)	4.9			5.2			5.2			5.0		
CREATININE	50 (59-120)	67.0			67.0			73.0			67.0		
URIC ACID	30 (200-500)	195.0	-2.5		171.0	-14.5		176.0	-12.0		169.0	-15.5	
TOT BILIRUBIN	100 (3-20)	9.0			8.0			12.0			9.0		
TOT. PROTEINS	+-30.0 (60-80)	74.0			75.0			79.0			77.0		
ALBUMINE	+-30.0 (34-50)	43.0			42.0			42.0			43.0		
TOT. CHOLEST.	30 (0-6)	8.1	35.0	(*)	7.9	31.7	(*)	7.6	26.7		7.3	21.7	
TRIGLYCERIDES	30 (0.8-2)	1.2			0.8			1.0			1.0		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CNS R&D 9990321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 2 PATIENT: 25 (SEX: Female)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	15.1			14.1			13.8			14.8		
RBC	-15 (3.8-5.8)	4.6			4.3			4.2			4.7		
WBC	+-30.0 (4-11)	6.8			4.1			4.2			4.1		
WBC: N	+-30.0 (2.5-7.5)	4.7			2.2	-12.0		2.3	-8.0		2.1	-16.0	
WBC: L	+-30.0 (1.5-3.5)	1.7			1.6			1.7			1.8		
WBC: E	30 (0.04-0.44)	0.4			0.3			0.2			0.3		
WBC: M	30 (0.2-0.8)	0.7			0.7			0.7			0.7		
WBC: B	30 (0-0.1)	0.2	100.0	(*)	0.2	100.0	(*)	0.2	100.0	(*)	0.2	100.0	(*)
PLATELETS	+-30.0 (150-400)	354.0			221.0			255.0			335.0		
NA+	+-10.0 (135-150)	140.0			141.0			141.0			141.0		
K+	+-15.0 (3.5-5)	4.4			4.1			4.4			4.3		
Ca++	+-15.0 (2.1-2.6)	2.5			2.5			2.5			2.5		
PO4--	+-15.0 (0.8-1.5)	1.2			1.2			1.2			1.2		
SGOT	100 (2-29)	15.0			14.0			18.0			16.0		
SGPT	100 (5-34)	20.0			14.0			16.0			17.0		
GAMMA GT	100 (0-65)	56.0			33.0			31.0			24.0		
ALK. PHOSPH.	100 (30-115)	158.0	37.4		137.0	19.1		139.0	20.9		141.0	22.6	
GLUCOSE	+-30.0 (3.5-10)	5.9			4.8			5.4			5.7		
BUN	50 (2.5-7)	4.5			5.0			4.0			5.1		
CREATININE	50 (59-120)	63.0			67.0			68.0			65.0		
TOT BILIRUBIN	100 (3-20)	10.0			10.0			10.0			14.0		
TOT. PROTEINS	+-30.0 (60-80)	70.0			68.0			70.0			72.0		
ALBUMINE	+-30.0 (34-50)	43.0			41.0			40.0			48.0		
TOT. CHOLEST.	30 (0-6)	6.7	11.7		6.2	3.3		6.4	6.7		6.5	8.3	
TRIGLYCERIDES	30 (0.8-2)	1.0			1.1			1.0			0.8		
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	2.1									2.6		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	5.5									6.1		
GLOBULINS BETA	+-30.0 (6-12)	7.5									8.3		
GLOBULINS GAMMA	+-30.0 (6-16)	8.7									9.8		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CNS R&D 9550321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

ABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 3 PATIENT: 26 (SEX: Female)

ssigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	14.6			15.3			15.5			13.7		
RBC	-15 (3.8-5.8)	4.7			4.9			4.9			4.4		
WBC	+-30.0 (4-11)	7.8			7.0			6.1			5.4		
WBC: N	+-30.0 (2.5-7.5)	6.5			4.7			3.6			3.1		
WBC: L	+-30.0 (1.5-3.5)	1.0	-33.3	(*)	1.8			2.0			1.9		
WBC: E	30 (0.04-0.44)	0.3			0.6	36.4	(*)	0.4			0.4		
WBC: M	30 (0.2-0.8)	0.7			0.7			0.7			0.7		
WBC: B	30 (0-0.1)	0.2	100.0	(*)	0.2	100.0	(*)	0.2	100.0	(*)	0.2	100.0	(*)
PLATELETS	+-30.0 (150-400)	295.0			237.0			273.0			343.0		
NA+	+-10.0 (135-150)	138.0			140.0			142.0			142.0		
K+	+-15.0 (3.5-5)	3.6			3.8			3.7			3.8		
Ca++	+-15.0 (2.1-2.6)	2.3			2.4			2.3			2.4		
PO4--	+-15.0 (0.8-1.5)	1.1			1.0			0.9			1.1		
SGOT	100 (2-29)	12.0			9.0			9.0			10.0		
SGPT	100 (5-34)	7.0			12.0			12.0			11.0		
GAMMA GT	100 (0-65)	11.0			19.0			19.0			17.0		
ALK. PHOSPH.	100 (30-115)	160.0	39.1		189.0	64.3		202.0	75.7		190.0	65.2	
GLUCOSE	+-30.0 (3.5-10)	4.7			5.6			4.4			5.1		
CREATININE	50 (59-120)	74.0			71.0			65.0			70.0		
URIC ACID	30 (180-500)	175.0	-2.8										
	30 (2.5-8)				3.8			3.4			3.5		
TOT BILIRUBIN	100 (3-20)	11.0			10.0			9.0			6.0		
TOT. PROTEINS	+-30.0 (60-80)	70.0			74.0			74.0			73.0		
ALBUMINE	+-30.0 (34-50)	34.0			40.0			40.0			41.0		
TOT. CHOLEST.	30 (0-6)	5.0			5.5			5.0			4.9		
TRIGLYCERIDES	30 (0.8-2)	1.4			1.0			1.1			1.1		

(1): % deviation from limits of normal range - (2): clinical relevance

9550321

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 3 PATIENT: 27 (SEX: Female)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			15-28			8-14		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	15.5			14.2			14.0					
HT	-15 (36-60)	43.0											
	-15 (0.37-0.47)				0.4			0.4					
RBC	-15 (3.8-5.8)	4.8			4.5			4.4					
WBC	+-30.0 (4-11)	10.4			4.3			9.1					
WBC: N	+-30.0 (2.5-7.5)	5.5			4.7			5.4					
WBC: L	+-30.0 (1.5-3.5)	4.7	34.3	(*)				3.2					
WBC: E	30 (0.04-0.44)	0.2			0.3			0.6	36.4	(*)			
WBC: M	30 (0.2-0.8)	0.7			0.7			0.7					
WBC: B	30 (0-0.1)	0.2	100.0	(*)	0.2	100.0	(*)	0.2	100.0	(*)			
PLATELETS	+-30.0 (150-400)	247.0			93.0	-38.0	(*)	300.0					
NA+	+-10.0 (135-150)	140.0			139.0			139.0			142.0		
K+	+-15.0 (3.5-5)	3.9			3.3	-5.7		4.2			4.4		
Ca++	+-15.0 (2.1-2.6)	2.4			2.3			2.3			2.4		
PO4--	+-15.0 (0.8-1.5)	0.9			1.1			0.9			1.0		
SGOT	100 (2-29)	20.0			21.0			27.0			21.0		
SGPT	100 (5-34)	23.0			16.0			23.0			19.0		
GAMMA GT	100 (0-65)	57.0			60.0			34.0			44.0		
ALK. PHOSPH.	100 (30-115)	121.0	5.2		127.0	10.4		118.0	2.6		130.0	13.0	
GLUCOSE	+-30.0 (3.5-10)	4.9			4.8			4.5			6.2		
BUN	50 (2.5-7)	4.4			3.2			2.8			3.2		
CREATININE	50 (59-120)	68.0			52.0	-11.9		76.0			60.0		
URIC ACID	30 (200-500)	222.0						243.0			229.0		
TOT BILIRUBIN	100 (3-20)	14.0			7.0			10.0			9.0		
TOT. PROTEINS	+-30.0 (60-80)	70.0			68.0			66.0			70.0		
ALBUMINE	+-30.0 (34-50)	38.0			39.0			41.0			41.0		
TOT. CHOLEST.	30 (0-6)	7.2	20.0		6.1	1.7		6.1	1.7		6.3	5.0	
TRIGLYCERIDES	30 (0.8-2)	1.3			0.8			0.8			1.5		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CNS R&D 9950321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 3 PATIENT: 28 (SEX: Male)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment								
		Screen			1-7			8-14		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	13.8			15.2					
HT	-15 (36-60)	41.3								
	-15 (0.4-0.54)				0.4					
RBC	-15 (4-6.5)	4.4			4.9					
WBC	+-30.0 (3.9-12)	7.3			9.2					
WBC: N	+-30.0 (2-7.5)	5.2			5.9					
WBC: L	+-30.0 (1.5-4)	1.5			2.6					
WBC: E	30 (0.04-0.44)	0.6	36.4	(*)	0.7	59.1	(*)			
WBC: M	30 (0.2-0.8)	0.7			0.7					
WBC: B	30 (0-0.1)	0.2	100.0	(*)	0.2	100.0	(*)			
PLATELETS	+-30.0 (100-600)	255.0			177.0					
NA+	+-10.0 (134-145)	141.0			142.0			141.0		
K+	+-15.0 (3.5-5)	3.8			3.6			3.8		
Ca++	+-15.0 (2.2-2.6)	2.4			2.4			2.3		
PO4--	+-15.0 (0.8-1.5)	1.2			1.0			0.9		
SGOT	100 (15-37)	19.0			16.0			16.0		
SGPT	100 (2-29)	18.0			10.0			16.0		
GAMMA GT	100 (5-52)	31.0			27.0			30.0		
ALK. PHOSPH.	100 (95-260)	147.0			162.0			192.0		
GLUCOSE	+-30.0 (3.5-10)	5.0			4.2			4.6		
BUN	50 (3-6.7)	2.7	-10.0		3.6			3.3		
CREATININE	50 (76-120)	80.0			71.0	-6.6		79.0		
TOT BILIRUBIN	100 (2-17)	11.0			8.0			9.0		
TOT. PROTEINS	+-30.0 (60-80)	72.0			68.0			72.0		
ALBUMINE	+-30.0 (35-46)	41.0			37.0			42.0		
TOT. CHOLEST.	30 (3.1-5.2)	5.7	9.6		6.2	19.2		5.8	11.5	
TRIGLYCERIDES	30 (0.5-2)	1.6			1.9			1.6		
GLOBULINS ALPHA 1	+-30.0 (3-6)	6.0			3.2			2.0	-32.7	(*)
GLOBULINS ALPHA 2	+-30.0 (7-13)	13.0			8.8			6.3	-9.7	
GLOBULINS BETA	+-30.0 (7-14)	14.0			13.3			8.5		
GLOBULINS GAMMA	+-30.0 (10-20)	20.0			12.0			10.6		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CNS R&D 9950321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 4 PATIENT: 52 (SEX: Female)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	11.4	-5.0		10.4	-13.3		10.2	-15.0		10.5	-12.5	
HT	-15 (0.37-0.47)	0.3	-8.1		0.4			0.4			0.4		
RBC	-15 (3.8-5.8)	4.5			4.2			4.1			4.1		
WBC	+-30.0 (4-11)	10.3			7.2			8.5			9.6		
WBC: N	+-30.0 (40-75)	91.0	21.3		56.0			79.0	5.3		80.0	6.7	
WBC: L	+-30.0 (20-45)	9.0	-55.0	(*)	39.0			17.0	-15.0		16.0	-20.0	
WBC: E	30 (1-6)	0.0	-100.0		3.0			1.0			3.0		
WBC: M	30 (0-1)	0.0			0.0			2.0	100.0	(*)	1.0		
WBC: B	30 (2-10)	0.0	-100.0		2.0			1.0	-50.0		0.0	-100.0	
PLATELETS	+-30.0 (150-400)	525.0	31.3	(*)	508.0	27.0		414.0	3.5		432.0	8.0	
NA+	+-10.0 (135-150)	140.0			139.0			139.0			136.0		
K+	+-15.0 (3.5-5)	4.1			3.6			3.6			3.5		
Ca++	+-15.0 (2.1-2.6)	2.5									2.2		
PO4--	+-15.0 (0.8-1.5)	1.6	4.0								1.1		
SGOT	100 (2-29)	29.0			25.0			21.0			18.0		
SGPT	100 (5-34)	20.0			20.0			18.0			13.0		
GAMMA GT	100 (0-65)	16.0			19.0			17.0			15.0		
ALK. PHOSPH.	100 (4-13)	9.8			8.2			8.0			8.0		
GLUCOSE	+-30.0 (3.5-10)	4.9			5.0			6.9			6.1		
BUN	50 (2.5-7)	4.3			5.2			4.7			4.7		
CREATININE	50 (59-120)	79.0			62.0			72.0			70.0		
TOT BILIRUBIN	100 (3-20)	7.0			4.0			5.0			5.0		
TOT. PROTEINS	+-30.0 (60-80)	82.0	2.5		71.0			69.0			65.0		
ALBUMINE	+-30.0 (34-50)	44.0			40.0			39.0			38.0		
TOT. CHOLEST.	30 (0-6)	7.1	18.3					7.4	23.3		7.0	16.7	
TRIGLYCERIDES	30 (0.8-2)	1.1						1.5			1.4		
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	4.0			3.0			3.0			2.0		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	9.0			7.0			8.0			6.0		
GLOBULINS BETA	+-30.0 (6-12)	13.0	8.3		10.0			10.0			10.0		
GLOBULINS GAMMA	+-30.0 (6-16)	13.0			11.0			9.0			9.0		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CNS-RED

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 4 PATIENT: 53 (SEX: Male)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment								
		Screen			1-7			8-14		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	17.6			17.3			17.0		
HT	-15 (0.4-0.54)	0.5			0.5			0.5		
RBC	-15 (4-6.5)	5.5			5.8			5.3		
WBC	+-30.0 (3.9-12)	14.6	21.7		9.1			9.5		
WBC: N	+-30.0 (40-75)	78.0	4.0		77.0	2.7		75.0		
WBC: L	+-30.0 (20-45)	20.0			16.0	-20.0		18.0	-10.0	
WBC: E	30 (1-6)	1.0			5.0			6.0		
WBC: M	30 (0-1)	1.0			1.0			1.0		
WBC: B	30 (2-10)	0.0	-100.0		1.0	-50.0		1.0	-50.0	
PLATELETS	+-30.0 (100-600)	347.0			352.0			312.0		
NA+	+-10.0 (134-145)	138.0			137.0			138.0		
K+	+-15.0 (3.5-5)	4.7			4.7			4.7		
Ca++	+-15.0 (2.2-2.6)	2.6			2.5			2.5		
PO4--	+-15.0 (0.8-1.5)	1.2			1.1			1.0		
SGOT	100 (15-37)	36.0			36.0			37.0		
SGPT	100 (2-29)	57.0	96.6		72.0	148.3	(*)	78.0	169.0	(*)
GAMMA GT	100 (5-52)	34.0			41.0			45.0		
ALK. PHOSPH.	100 (4-13)	6.3								
	100 (95-260)				81.0	-14.7		80.0	-15.8	
GLUCOSE	+-30.0 (3.5-10)	6.1			9.5			10.2	2.0	
BUN	50 (3-6.7)	4.1			3.3			3.0		
CREATININE	50 (76-120)	96.0			108.0			91.0		
URIC ACID	30 (180-340)	338.0			348.0	2.4		328.0		
TOT BILIRUBIN	100 (2-17)	9.0			11.3			9.1		
TOT. PROTEINS	+-30.0 (60-80)	67.0			70.0			69.0		
ALBUMINE	+-30.0 (35-46)	43.0			46.0			45.0		
TOT. CHOLEST.	30 (3.1-5.2)	5.5	5.8		5.9	13.5		5.8	11.5	
TRIGLYCERIDES	30 (0.5-2)	3.3	67.0	(*)	2.7	35.0	(*)	2.1	7.0	

(1): % deviation from limits of normal range - (2): clinical relevance

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 4 PATIENT: 54 (SEX: Female)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	13.5			13.6			13.8			13.8		
HT	-15 (0.37-0.47)	0.4			0.4			0.4			0.4		
RBC	-15 (3.8-5.8)	4.3			4.4			4.3			4.7		
WBC	+-30.0 (4-11)	7.6			7.6			6.9			5.3		
WBC: N	+-30.0 (40-75)	79.0	5.3		72.0			67.0			64.0		
WBC: L	+-30.0 (20-45)	16.0	-20.0		21.0			24.0			26.0		
WBC: E	30 (1-6)	4.0			5.0			7.0	16.7		7.0	16.7	
WBC: M	30 (0-1)	1.0			1.0			2.0	100.0	(*)	3.0	200.0	(*)
PLATELETS	+-30.0 (150-400)	309.0			358.0			337.0			311.0		
NA+	+-10.0 (135-150)	140.0			138.0			140.0			144.0		
K+	+-15.0 (3.5-5)	4.6			4.7			5.0			4.7		
Ca++	+-15.0 (2.1-2.6)	2.4			2.3			2.4			2.4		
PO4--	+-15.0 (0.8-1.5)	0.7	-18.7	(*)	0.8	-2.5		0.7	-12.5		0.8		
SGOT	100 (2-29)	14.0			17.0			19.0			25.0		
SGPT	100 (5-34)	17.0			19.0			22.0			26.0		
GAMMA GT	100 (0-65)	17.0			14.0			38.0			22.0		
ALK. PHOSPH.	100 (30-115)	87.0			91.0			77.0			100.0		
GLUCOSE	+-30.0 (3.5-10)	5.6			4.9			5.1			4.2		
BUN	50 (2.5-7)	4.5			4.4			3.2			4.9		
CREATININE	50 (59-120)	63.0			64.0			83.0			80.0		
URIC ACID	30 (200-500)	251.0			282.0			242.0			355.0		
TOT BILIRUBIN	100 (3-20)	4.8			3.2			5.1			5.8		
TOT. PROTEINS	+-30.0 (60-80)	70.0			71.0			74.0			72.0		
ALBUMINE	+-30.0 (34-50)	40.0			41.0			43.0			42.0		
TOT. CHOLEST.	30 (0-6)	5.5			6.4	6.7		6.1	1.7		5.8		
TRIGLYCERIDES	30 (0.8-2)	1.6			1.4			1.3			1.0		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CNS R&D 9550321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 4 PATIENT: 55 (SEX: Male)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	15.6			15.6			15.8			15.6		
HT	-15 (0.4-0.54)	0.5			0.5			0.5			0.5		
RBC	-15 (4-6.5)	4.8			5.0			5.3			4.9		
WBC	+-30.0 (3.9-12)	6.4			7.7			5.8			7.5		
WBC: N	+-30.0 (40-75)	57.0			57.0			50.0			56.0		
WBC: L	+-30.0 (20-45)	35.0			35.0			42.0			36.0		
WBC: E	30 (1-6)	6.0			6.0			7.0	16.7		6.0		
WBC: M	30 (0-1)	1.0			1.0			1.0			1.0		
WBC: B	30 (2-10)	1.0	-50.0		1.0	-50.0					1.0	-50.0	
PLATELETS	+-30.0 (100-600)	287.0			306.0			285.0			317.0		
NA+	+-10.0 (134-145)	136.0			141.0			143.0			142.0		
K+	+-15.0 (3.5-5)	5.3	6.0		5.3	6.0		5.1	2.0		4.8		
Ca++	+-15.0 (2.2-2.6)	2.3			2.3			2.4			2.5		
PO4--	+-15.0 (0.8-1.5)	2.0	33.3	(*)	1.1			1.3			1.3		
SGOT	100 (15-37)	31.0			21.0			19.0			35.0		
SGPT	100 (2-29)	26.0			14.0			16.0			27.0		
GAMMA GT	100 (5-52)	10.0			8.0			16.0			18.0		
ALK. PHOSPH.	100 (95-260)	111.0			105.0			96.0			95.0		
GLUCOSE	+-30.0 (3.5-10)	4.1			4.7			3.9			5.0		
BUN	50 (3-6.7)	4.1									5.6		
CREATININE	50 (76-120)	103.0			95.0			92.0			96.0		
URIC ACID	30 (180-340)	317.0			361.0	6.2		355.0	4.4		389.0	14.4	
TOT BILIRUBIN	100 (2-17)	5.5			2.7			4.8			5.6		
TOT. PROTEINS	+-30.0 (60-80)	67.0			64.0			67.0			66.0		
ALBUMINE	+-30.0 (35-46)	42.0			42.0			44.0			44.0		
TOT. CHOLEST.	30 (3.1-5.2)	5.9	13.5		6.2	19.2		6.4	23.1		6.2	19.2	
TRIGLYCERIDES	30 (0.5-2)	3.2	60.5	(*)	5.1	153.0	(*)	3.8	87.5	(*)	3.5	74.0	(*)

(1): % deviation from limits of normal range - (2): clinical relevance

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 4 PATIENT: 56 (SEX: Female)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	13.0			13.0			12.3			12.3		
RBC	-15 (3.8-5.8)	4.6			4.6			4.3			4.3		
WBC	+-30.0 (4-11)	5.5			5.5			6.8			5.7		
WBC: N	+-30.0 (40-75)	49.0			49.0			60.0			52.0		
WBC: L	+-30.0 (20-45)	41.0			41.0			34.0			40.0		
WBC: E	30 (1-6)	6.0			6.0			4.0			5.0		
WBC: M	30 (0-1)	4.0	300.0	(*)	4.0	300.0	(*)	1.0			2.0	100.0	(*)
WBC: B	30 (2-10)	0.0	-100.0								1.0	-50.0	
PLATELETS	+-30.0 (150-400)	363.0			363.0			314.0			299.0		
NA+	+-10.0 (135-150)	140.0			140.0			143.0			140.0		
K+	+-15.0 (3.5-5)	5.4	8.0		5.4	8.0		5.2	4.0		4.9		
Ca++	+-15.0 (2.1-2.6)	2.5			2.5			2.5			2.5		
PO4--	+-15.0 (0.8-1.5)	1.3			1.3			1.4			1.2		
SGOT	100 (2-29)	15.0			17.0			11.0			9.0		
SGPT	100 (5-34)	17.0			15.0			18.0			11.0		
GAMMA GT	100 (0-65)	9.0			9.0			7.0			6.0		
ALK. PHOSPH.	100 (30-115)	99.0			99.0			85.0			93.0		
GLUCOSE	+-30.0 (3.5-10)	5.0			5.0			5.4			5.7		
BUN	50 (2.5-7)	5.2			5.2			4.4			5.1		
CREATININE	50 (59-120)	65.0			65.0			62.0			61.0		
URIC ACID	30 (200-500)	258.0			258.0			244.0			255.0		
TOT BILIRUBIN	100 (3-20)	6.2			6.2			6.0			7.0		
TOT. PROTEINS	+-30.0 (60-80)	74.0			74.0			71.0			72.0		
ALBUMINE	+-30.0 (34-50)	48.0			48.0			46.0			46.0		
TOT. CHOLEST.	30 (0-6)	6.1	1.7		6.1	1.7		4.9			5.2		
TRIGLYCERIDES	30 (0.8-2)	0.5	-37.5		0.5	-37.5		0.3	-60.0		0.4	-51.3	

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CNS 9580321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 4 PATIENT: 58 (SEX: Male)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment								
		Screen			1-7			8-14		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	13.3			13.3			13.1		
HT	-15 (0.4-0.54)	0.4			0.4	-2.3		0.4	-3.8	
RBC	-15 (4-6.5)	4.5			4.4			4.4		
WBC	+-30.0 (3.9-12)	8.7			10.6			8.6		
WBC: N	+-30.0 (40-75)	70.0			71.0			69.0		
WBC: L	+-30.0 (20-45)	24.0			24.0			25.0		
WBC: M	30 (0-1)	2.0	100.0	(*)	1.0			1.0		
PLATELETS	+-30.0 (100-600)	301.0			300.0			296.0		
NA+	+-10.0 (134-145)	139.0						138.0		
K+	+-15.0 (3.5-5)	4.4						3.8		
Ca++	+-15.0 (2.2-2.6)	2.4						2.4		
PO4--	+-15.0 (0.8-1.5)	1.2						1.3		
SGOT	100 (15-37)	14.0	-6.7					16.0		
SGPT	100 (2-29)	15.0						12.0		
GAMMA GT	100 (5-52)	3.0	-40.0					3.0	-40.0	
ALK. PHOSPH.	100 (95-260)	60.0	-36.8					52.0	-45.3	
GLUCOSE	+-30.0 (3.5-10)	4.7						5.2		
BUN	50 (3-6.7)	4.0						4.1		
CREATININE	50 (76-120)	72.0	-5.3					66.0	-13.2	
URIC ACID	30 (180-340)	245.0						215.0		
TOT BILIRUBIN	100 (2-17)	6.8						3.8		
TOT. PROTEINS	+-30.0 (60-80)	72.0						72.0		
ALBUMINE	+-30.0 (35-46)	45.0						44.0		
TOT. CHOLEST.	30 (3.1-5.2)	4.3						4.1		
TRIGLYCERIDES	30 (0.5-2)	0.7						1.2		
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	2.3						2.8		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	5.0						5.5		
GLOBULINS BETA	+-30.0 (6-12)	7.1						8.4		
GLOBULINS GAMMA	+-30.0 (6-16)	12.5						11.5		

(1): % deviation from limits of normal range - (2): clinical relevance

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 4 PATIENT: 60 (SEX: Female)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	12.8			12.3			12.2			11.4	-5.0	
HT	-15 (0.37-0.47)	0.4			0.4			0.4			0.3	-10.0	
RBC	-15 (3.8-5.8)	4.2			4.3			4.3			4.0		
WBC	+-30.0 (4-11)	4.7			4.8			4.3			5.5		
WBC: N	+-30.0 (40-75)	56.0			52.0			48.0			58.0		
WBC: L	+-30.0 (20-45)	36.0			41.0			43.0			31.0		
WBC: E	30 (1-6)	6.0			5.0			5.0			7.0	16.7	
WBC: M	30 (0-1)	2.0	100.0	(*)	2.0	100.0	(*)	2.0	100.0	(*)	2.0	100.0	(*)
WBC: B	30 (2-10)	0.0	-100.0		1.0	-50.0		1.0	-50.0		2.0		
PLATELETS	+-30.0 (150-400)	291.0			422.0	5.5		389.0			381.0		
NA+	+-10.0 (135-150)	142.0			142.0			143.0			141.0		
K+	+-15.0 (3.5-5)	4.4			5.3	6.0		5.0			4.8		
SGOT	100 (2-29)	24.0			16.0			23.0			24.0		
SGPT	100 (5-34)	8.0			5.0			10.0			10.0		
GAMMA GT	100 (0-65)	11.0			9.0			10.0			8.0		
ALK. PHOSPH.	100 (4-13)	5.4											
	100 (30-115)				60.0			66.0			70.0		
GLUCOSE	+-30.0 (3.5-10)	3.8			5.2			4.9			4.4		
BUN	50 (2.5-7)	3.0			3.8			4.0			4.1		
CREATININE	50 (59-120)	71.0			80.0			77.0			65.0		
TOT BILIRUBIN	100 (3-20)	11.0			10.4			12.3			4.3		
TOT. PROTEINS	+-30.0 (60-80)	82.0	2.5		76.0			77.0			72.0		
ALBUMINE	+-30.0 (34-50)	54.0	8.0		52.0	4.0		51.0	2.0		49.0		
TOT. CHOLEST.	30 (0-6)	4.5			4.3			4.8			5.0		
TRIGLYCERIDES	30 (0.8-2)	0.7	-16.2		0.6	-21.2		0.8			0.9		
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	2.0			1.8			2.1			2.0		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	5.0			4.6			5.2			3.8		
GLOBULINS BETA	+-30.0 (6-12)	7.0			6.1			7.1			6.7		
GLOBULINS GAMMA	+-30.0 (6-16)	14.0			11.5			11.6			10.5		

(1): % deviation from limits of normal range - (2): clinical relevance

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 4 PATIENT: 61 (SEX: Female)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	13.9			14.3			13.9			13.6		
HT	-15 (0.37-0.47)	0.4			0.4			0.4			0.4		
RBC	-15 (3.8-5.8)	4.5			4.8			4.6			4.5		
WBC	+-30.0 (4-11)	9.9			8.0			8.5			7.7		
WBC: N	+-30.0 (40-75)	62.0			50.0			54.0			46.0		
WBC: L	+-30.0 (20-45)	27.0			40.0			33.0			43.0		
WBC: E	30 (1-6)	5.0			6.0			7.0	16.7		5.0		
WBC: B	30 (2-10)	1.0	-50.0		1.0	-50.0		1.0	-50.0		1.0	-50.0	
PLATELETS	+-30.0 (150-400)	418.0	4.5		367.0			361.0			342.0		
NA+	+-10.0 (135-150)	140.0			139.0			139.0			140.0		
K+	+-15.0 (3.5-5)	4.9						4.8			4.2		
Ca++	+-15.0 (2.1-2.6)	2.5			2.5			2.5			2.5		
SGOT	100 (2-29)	20.0						25.0			30.0	3.4	
SGPT	100 (5-34)	16.0						25.0			20.0		
GAMMA GT	100 (0-65)	95.0	46.2		68.0	4.6		44.0			52.0		
ALK. PHOSPH.	100 (30-115)	195.0	69.6		190.0	65.2		150.0	30.4		169.0	47.0	
BUN	50 (2.5-7)	3.7			4.3			3.3			3.3		
CREATININE	50 (59-120)	107.0						97.0			98.0		
URIC ACID	30 (200-500)	379.0			403.0			458.0			439.0		
TOT BILIRUBIN	100 (3-20)	10.8			5.6			8.2			4.1		
TOT. PROTEINS	+-30.0 (60-80)	67.0			69.0			67.0			66.0		
ALBUMINE	+-30.0 (34-50)	43.0			47.0			45.0			45.0		
TOT. CHOLEST.	30 (0-6)	7.9	31.7	(*)	8.3	38.3	(*)	8.2	36.7	(*)	7.9	31.7	(*)
TRIGLYCERIDES	30 (0.8-2)	1.5			3.2	60.0	(*)	3.2	61.5	(*)	3.8	92.0	(*)
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	1.7			2.3			1.7			1.7		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	7.4			7.9			5.8			5.1		
GLOBULINS BETA	+-30.0 (6-12)	7.6			9.2			9.0			9.9		
GLOBULINS GAMMA	+-30.0 (6-16)	7.3			9.0			8.2			7.8		

(1): % deviation from limits of normal range - (2): clinical relevance

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 4 PATIENT: 63 (SEX: Female)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment								
		Screen			1-7			8-14		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	15.3			15.5			15.4		
HT	-15 (0.37-0.47)	0.4			0.5			0.5		
RBC	-15 (3.8-5.8)	4.9			5.3			5.0		
WBC	+-30.0 (4-11)	4.9			5.6			4.3		
WBC: N	+-30.0 (40-75)	57.0			53.0			48.0		
WBC: L	+-30.0 (20-45)	35.0			38.0			41.0		
WBC: E	30 (1-6)	5.0			6.0			6.0		
WBC: M	30 (0-1)	2.0	100.0	(*)	2.0	100.0	(*)	5.0	400.0	(*)
WBC: B	30 (2-10)	1.0	-50.0		1.0	-50.0				
PLATELETS	+-30.0 (150-400)	215.0			240.0			215.0		
NA+	+-10.0 (135-150)	142.0			141.0			138.0		
K+	+-15.0 (3.5-5)	5.1	2.0		4.4			5.0		
Ca++	+-15.0 (2.1-2.6)	2.5			2.5			2.5		
SGOT	100 (2-29)	14.0			27.0			24.0		
SGPT	100 (5-34)	18.0			21.0			33.0		
GAMMA GT	100 (0-65)	18.0			7.8					
ALK. PHOSPH.	100 (30-115)	66.0			69.0			68.0		
GLUCOSE	+-30.0 (3.5-10)	4.6			4.7			4.6		
BUN	50 (2.5-7)	7.6	8.6		6.8			6.1		
CREATININE	50 (59-120)	104.0			84.0			82.0		
URIC ACID	30 (200-500)	324.0			313.0			265.0		
TOT BILIRUBIN	100 (3-20)	8.6			8.7			5.5		
TOT. PROTEINS	+-30.0 (60-80)	68.0			68.0			71.0		
ALBUMINE	+-30.0 (34-50)	49.0			49.0			50.0		
TOT. CHOLEST.	30 (0-6)	7.3	21.7		7.3	21.7		6.9	15.0	
TRIGLYCERIDES	30 (0.8-2)	1.0			1.5			0.9		
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	1.6			1.9			2.0		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	5.9			4.8			7.5		
GLOBULINS BETA	+-30.0 (6-12)	5.0	-16.7		8.5			8.1		
GLOBULINS GAMMA	+-30.0 (6-16)	5.6	-6.7		7.8			7.5		

(1): % deviation from limits of normal range - (2): clinical relevance

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 4 PATIENT: 64 (SEX: Male)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	15.2			15.4			15.3			15.6		
HT	-15 (0.4-0.54)	0.5			0.5			0.5			0.5		
RBC	-15 (4-6.5)	5.3			5.1			5.1			5.4		
WBC	+-30.0 (3.9-12)	7.1			8.4			8.0			6.9		
WBC: N	+-30.0 (40-75)	75.0			71.0			68.0					
WBC: L	+-30.0 (20-45)	17.0	-15.0		21.0			22.0			19.0	-5.0	
WBC: E	30 (1-6)	5.0			5.0			6.0			6.0		
WBC: M	30 (0-1)	3.0	200.0	(*)	2.0	100.0	(*)	3.0	200.0	(*)	3.0	200.0	(*)
WBC: B	30 (2-10)	0.0	-100.0		1.0	-50.0		1.0	-50.0		1.0	-50.0	
PLATELETS	+-30.0 (100-600)	273.0			235.0			258.0			270.0		
NA+	+-10.0 (134-145)	139.0			140.0			139.0			142.0		
K+	+-15.0 (3.5-5)	4.1			4.2			4.5			4.4		
Ca++	+-15.0 (2.2-2.6)	2.4			2.3			2.4			2.5		
PO4--	+-15.0 (0.8-1.5)	1.3			1.2			1.2			1.4		
SGOT	100 (15-37)	15.0			14.0	-6.7		27.0			13.0	-13.3	
SGPT	100 (2-29)	15.0			15.0			24.0			16.0		
GAMMA GT	100 (5-52)	3.0	-40.0		7.0			10.0			8.0		
ALK. PHOSPH.	100 (95-260)	59.0	-37.9		62.0	-34.7		68.0	-28.4		69.0	-27.4	
GLUCOSE	+-30.0 (3.5-10)	3.8			4.7			4.7			4.8		
BUN	50 (3-6.7)	4.3			4.3			4.6			3.6		
CREATININE	50 (76-120)	80.0			64.0	-15.8		77.0			97.0		
URIC ACID	30 (180-340)	281.0			231.0			277.0			260.0		
TOT BILIRUBIN	100 (2-17)	5.6			7.9			3.4			8.9		
TOT. PROTEINS	+-30.0 (60-80)	67.0			65.0			65.0			69.0		
ALBUMINE	+-30.0 (35-46)	44.0			42.0			43.0			46.0		
TOT. CHOLEST.	30 (3.1-5.2)	6.4	23.1		5.8	11.5		6.0	15.4		6.1	17.3	
TRIGLYCERIDES	30 (0.5-2)	1.9			2.4	20.5		2.7	34.5	(*)	2.3	17.0	
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	2.2			2.3			2.5			2.6		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	7.1			6.1			7.0			6.8		
GLOBULINS BETA	+-30.0 (6-12)	7.6			7.2			8.1			7.7		
GLOBULINS GAMMA	+-30.0 (6-16)	10.6			9.2			10.7			10.5		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CNS 9550321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 4 PATIENT: 67 (SEX: Male)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	16.3			17.4			16.2			16.4		
HT	-15 (0.4-0.54)	0.5			0.5			0.5			0.5		
RBC	-15 (4-6.5)	5.4			5.8			5.3			5.7		
WBC	+-30.0 (3.9-12)	6.5			6.5			6.4			6.7		
WBC: N	+-30.0 (40-75)	51.0			54.0			52.0			54.0		
WBC: L	+-30.0 (20-45)	43.0			39.0			39.0			40.0		
WBC: E	30 (1-6)	4.0			5.0			6.0			5.0		
WBC: M	30 (0-1)	2.0	100.0	(*)	2.0	100.0	(*)	2.0	100.0	(*)	1.0		
PLATELETS	+-30.0 (100-600)	233.0			272.0			259.0			294.0		
NA+	+-10.0 (134-145)	137.0			141.0			142.0			139.0		
K+	+-15.0 (3.5-5)	4.6			4.5			4.4			4.7		
Ca++	+-15.0 (2.2-2.6)	2.5						2.6			2.7	4.6	
PO4--	+-15.0 (0.8-1.5)	0.9			1.0			1.0			1.3		
SGOT	100 (15-37)	52.0	40.5		29.0			34.0			36.0		
SGPT	100 (2-29)	31.0	6.9		26.0			24.0			29.0		
GAMMA GT	100 (5-52)	26.0			33.0			26.0			36.0		
ALK. PHOSPH.	100 (95-260)	52.0	-45.3		60.0	-36.8		55.0	-42.1		66.0	-30.5	
GLUCOSE	+-30.0 (3.5-10)	4.9			4.6			4.7			5.2		
BUN	50 (3-6.7)	5.7			4.9			6.0			7.0	4.5	
CREATININE	50 (76-120)	88.0			100.0			96.0			103.0		
URIC ACID	30 (180-340)	402.0	18.2		427.0	25.6		425.0	25.0		471.0	38.5	(*)
TOT BILIRUBIN	100 (2-17)	4.3			5.0			3.1			9.7		
TOT. PROTEINS	+-30.0 (60-80)	69.0			73.0			71.0			78.0		
ALBUMINE	+-30.0 (35-46)	47.0	2.2		50.0	8.7		50.0	8.7		53.0	15.2	
TOT. CHOLEST.	30 (3.1-5.2)	7.3	40.4	(*)	8.3	59.6	(*)	7.4	42.3	(*)	7.4	42.3	(*)
TRIGLYCERIDES	30 (0.5-2)	3.7	83.0	(*)	4.5	125.5	(*)	4.2	108.0	(*)	2.3	14.0	
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	1.9						1.5			2.0		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	4.5						6.5			5.0		
GLOBULINS BETA	+-30.0 (6-12)	8.5			6.4			5.2	-13.3		8.6		
GLOBULINS GAMMA	+-30.0 (6-16)	8.7									9.4		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 5 PATIENT: 72 (SEX: Female)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment								
		Screen			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	14.8			14.0			14.5		
HT	-15 (0.37-0.47)	0.5			0.4			0.5		
RBC	-15 (3.8-5.8)	4.8			4.7			4.6		
WBC	+-30.0 (4-11)	6.7			5.3			4.5		
WBC: N	+-30.0 (2.5-7.5)	4.1			3.2			2.6		
WBC: L	+-30.0 (1.5-3.5)	2.2			2.0			1.4	-7.3	
WBC: E	30 (0.04-0.44)	0.3			0.1			0.4		
PLATELETS	+-30.0 (150-400)	266.0			275.0			260.0		
NA+	+-10.0 (135-150)	142.0			142.0			141.0		
K+	+-15.0 (3.5-5)	4.2			4.4					
Ca++	+-15.0 (2.1-2.6)	2.4			2.4			2.3		
PO4--	+-15.0 (0.8-1.5)	1.3			0.8	-2.5				
SGOT	100 (2-29)	18.0			21.0			14.0		
SGPT	100 (5-34)	9.0			14.0			10.0		
GAMMA GT	100 (0-65)	12.0			6.0			10.0		
ALK. PHOSPH.	100 (30-115)	58.0			52.0			61.0		
GLUCOSE	+-30.0 (3.5-10)	5.3						3.4	-2.9	
BUN	50 (2.5-7)	7.0			4.6			4.7		
CREATININE	50 (59-120)	104.0			83.0			103.0		
URIC ACID	30 (200-500)	256.0			215.0			225.0		
TOT BILIRUBIN	100 (3-20)	6.5			6.3			8.2		
TOT. PROTEINS	+-30.0 (60-80)	69.0			65.0			66.0		
ALBUMINE	+-30.0 (34-50)	45.0			43.0			45.0		
TOT. CHOLEST.	30 (0-6)	11.0	83.3	(*)	8.8	46.7	(*)	9.0	50.0	(*)
TRIGLYCERIDES	30 (0.8-2)	1.7			2.1	5.5		1.8		
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	1.5			1.6			1.5		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	5.9			6.1			6.1		
GLOBULINS BETA	+-30.0 (6-12)	8.5			7.9			8.1		
GLOBULINS GAMMA	+-30.0 (6-16)	8.1			8.1			8.4		

(1): % deviation from limits of normal range - (2): clinical relevance

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 5 PATIENT: 73 (SEX: Male)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment								
		Screen			1-7			8-14		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	16.9			17.4			17.0		
HT	-15 (0.4-0.54)	0.5			0.5			0.6	2.8	
RBC	-15 (4-6.5)	5.5			5.7			5.7		
WBC	+-30.0 (3.9-12)	10.4			8.8			9.6		
WBC: N	+-30.0 (2-7.5)	6.2			4.8			6.4		
WBC: L	+-30.0 (1.5-4)	3.2			3.5			2.6		
WBC: E	30 (0.04-0.44)	0.7	65.9	(*)	0.4			0.4		
WBC: M	30 (0.2-0.8)	0.2			0.1	-55.0		0.1	-50.0	
PLATELETS	+-30.0 (100-600)	288.0			386.0			397.0		
NA+	+-10.0 (134-145)	142.0			141.0			141.0		
K+	+-15.0 (3.5-5)	4.8			5.0					
Ca++	+-15.0 (2.2-2.6)	2.6			2.5			2.6	0.4	
PO4--	+-15.0 (0.8-1.5)	1.1			1.0			1.2		
SGOT	100 (15-37)	30.0			17.0			18.0		
SGPT	100 (2-29)	17.0			11.0			21.0		
GAMMA GT	100 (5-52)	31.0			20.0			26.0		
ALK. PHOSPH.	100 (95-260)	80.0	-15.8		82.0	-13.7		88.0	-7.4	
GLUCOSE	+-30.0 (3.5-10)	2.8	-20.0					4.9		
BUN	50 (3-6.7)	6.1			4.6			5.7		
CREATININE	50 (76-120)	107.0			87.0			107.0		
URIC ACID	30 (180-340)	360.0	5.9		279.0			337.0		
TOT BILIRUBIN	100 (2-17)	8.7			8.7			5.0		
TOT. PROTEINS	+-30.0 (60-80)	72.0			71.0			71.0		
ALBUMINE	+-30.0 (35-46)	48.0	4.3		47.0	2.2		46.0		
TOT. CHOLEST.	30 (3.1-5.2)	6.8	30.8	(*)	6.1	17.3		6.8	30.8	(*)
TRIGLYCERIDES	30 (0.5-2)	3.1	55.5	(*)	3.4	68.5	(*)	5.3	166.0	(*)
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	2.4			2.8			2.3		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	7.2			6.2			7.7		
GLOBULINS BETA	+-30.0 (6-12)	8.6			8.6			7.0		
GLOBULINS GAMMA	+-30.0 (6-16)	10.4			9.9			9.9		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 5 PATIENT: 74 (SEX: Male)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	16.9			17.1			17.3			16.4		
HT	-15 (0.4-0.54)	0.5			0.5			0.5			0.5		
RBC	-15 (4-6.5)	5.9			6.0			5.8			5.7		
WBC	+-30.0 (3.9-12)	11.5			11.3			8.8			9.1		
WBC: N	+-30.0 (2-7.5)	7.6	1.2		7.6	0.9		4.8			5.2		
WBC: L	+-30.0 (1.5-4)	2.9			2.9			3.0			3.2		
WBC: E	30 (0.04-0.44)	0.5	4.5		0.5	2.3		0.5	20.5		0.4		
WBC: M	30 (0.2-0.8)	0.5			0.2			0.4			0.3		
WBC: B	30 (0-0.1)	0.1	20.0		0.1	10.0		0.1			0.1		
PLATELETS	+-30.0 (100-600)	226.0			284.0			280.0			231.0		
NA+	+-10.0 (134-145)	140.0			139.0			135.0			139.0		
K+	+-15.0 (3.5-5)	4.6			4.8			4.5			4.3		
Ca++	+-15.0 (2.2-2.6)	2.5			2.5			2.5			2.6		
PO4--	+-15.0 (0.8-1.5)	1.0			1.3			1.0			1.5		
SGOT	100 (15-37)	20.0			28.0			23.0			31.0		
SGPT	100 (2-29)	32.0	10.3		32.0	10.3		35.0	20.7		35.0	20.7	
GAMMA GT	100 (5-52)	54.0	3.8		43.0			45.0			52.0		
ALK. PHOSPH.	100 (95-260)	107.0			101.0			98.0			127.0		
GLUCOSE	+-30.0 (3.5-10)	6.3			4.8			5.3			5.1		
BUN	50 (3-6.7)	3.2			3.8			3.5			3.2		
CREATININE	50 (76-120)	105.0			89.0			96.0			93.0		
URIC ACID	30 (180-340)	484.0	42.4	(*)	450.0	32.4	(*)	441.0	29.7		492.0	44.7	(*)
TOT BILIRUBIN	100 (2-17)	8.2			3.8			10.1			5.5		
TOT. PROTEINS	+-30.0 (60-80)	73.0			73.0			69.0			75.0		
ALBUMINE	+-30.0 (35-46)	47.0	2.2		49.0	6.5		46.0			50.0	8.7	
TOT. CHOLEST.	30 (3.1-5.2)	6.5	25.0		6.5	25.0		5.9	13.5		6.8	30.8	(*)
TRIGLYCERIDES	30 (0.5-2)	6.8	237.5	(*)	8.9	342.5	(*)	7.8	291.5	(*)	8.0	302.0	(*)
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	2.5			2.8			2.3			2.5		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	2.7	-25.0		6.9			6.0			6.8		
GLOBULINS BETA	+-30.0 (6-12)	7.4			7.9			7.1			7.4		
GLOBULINS GAMMA	+-30.0 (6-16)	12.1			11.3			10.8			10.6		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CRS20321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 5 PATIENT: 75 (SEX: Female)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	14.3			14.4			14.2			13.0		
HT	-15 (0.37-0.47)	0.5			0.5	0.4		0.4			0.4		
RBC	-15 (3.8-5.8)	4.8			4.9			4.6			4.5		
WBC	+-30.0 (4-11)	5.0			3.9	-1.5		6.3			6.6		
WBC: N	+-30.0 (2.5-7.5)	3.2			2.5			4.2			5.6		
WBC: L	+-30.0 (1.5-3.5)	1.4	-6.0		1.2	-18.7		1.8			0.7	-51.3	(*)
WBC: E	30 (0.04-0.44)	0.4			0.2			0.3			0.3		
WBC: B	30 (0-0.1)	0.1									0.1		
PLATELETS	+-30.0 (150-400)	189.0			176.0			208.0			229.0		
NA+	+-10.0 (135-150)	148.0			145.0			142.0			139.0		
Ca++	+-15.0 (2.1-2.6)	2.7	1.9		2.8	5.8		2.7	3.5		2.6		
GAMMA GT	100 (0-65)	10.0			2.0			6.8			11.0		
ALK. PHOSPH.	100 (30-115)	84.0			91.0			89.0			151.0	31.3	
BUN	50 (2.5-7)	2.9			2.9			2.3	-8.0		6.4		
URIC ACID	30 (200-500)	239.0			273.0			251.0			282.0		
TOT BILIRUBIN	100 (3-20)	9.1			7.4			6.7			11.1		
TOT. PROTEINS	+-30.0 (60-80)	69.0			70.0			65.0			62.0		
ALBUMINE	+-30.0 (34-50)	47.0			48.0			46.0			40.0		
TOT. CHOLEST.	30 (0-6)	7.2	20.0		7.0	16.7		6.4	6.7		5.6		
TRIGLYCERIDES	30 (0.8-2)	1.1			1.1			1.2			1.2		
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	2.5			2.7			2.8			3.6		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	7.2			6.4			5.7			5.8		
GLOBULINS BETA	+-30.0 (6-12)	8.6			8.6			8.5			7.1		
GLOBULINS GAMMA	+-30.0 (6-16)	7.2			7.3			6.8			5.5	-8.3	

(1): % deviation from limits of normal range - (2): clinical relevance

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

ABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 5 PATIENT: 76 (SEX: Male)

ssigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	14.3			14.5			15.0			13.4		
HT	-15 (0.4-0.54)	0.4			0.4			0.5			0.4		
RBC	-15 (4-6.5)	4.3			4.7			4.6			4.1		
WBC	+-30.0 (3.9-12)	6.1			6.3			6.1			3.9		
WBC: N	+-30.0 (2-7.5)	3.6			3.6			3.4			2.7		
WBC: L	+-30.0 (1.5-4)	1.8			2.0			2.1			0.9	-37.3	(*)
WBC: E	30 (0.04-0.44)	0.5	22.7		0.5	13.6		0.6	25.0		0.2		
WBC: M	30 (0.2-0.8)	0.1	-70.0		0.1	-70.0		0.1	-70.0		0.0	-80.0	
WBC: B	30 (0-0.1)	0.1			0.1								
PLATELETS	+-30.0 (100-600)	226.0			331.0			296.0			221.0		
NA+	+-10.0 (134-145)	141.0			140.0			142.0			141.0		
K+	+-15.0 (3.5-5)	4.6			4.7			4.6			4.6		
Ca++	+-15.0 (2.2-2.6)	2.7	2.7		2.5			2.7	5.0		2.6	0.8	
PO4--	+-15.0 (0.8-1.5)	1.5	0.7		1.3			1.1			1.2		
GAMMA GT	100 (5-52)	48.0			43.0			43.0			32.0		
ALK. PHOSPH.	100 (95-260)	74.0	-22.1		72.0	-24.2		70.0	-26.3		75.0	-21.1	
BUN	50 (3-6.7)	3.2			3.4			3.1			3.9		
CREATININE	50 (76-120)	99.0			97.0			88.0			96.0		
URIC ACID	30 (180-340)	241.0			294.0			343.0	0.9		320.0		
TOT BILIRUBIN	100 (2-17)	6.8			4.6			5.6			5.8		
TOT. PROTEINS	+-30.0 (60-80)	76.0			74.0			77.0			72.0		
ALBUMINE	+-30.0 (35-46)	47.0	2.2		46.0			49.0	6.5		46.0		
TOT. CHOLEST.	30 (3.1-5.2)	5.6	7.7		5.6	7.7		6.5	25.0		6.2	19.2	
TRIGLYCERIDES	30 (0.5-2)	2.1	6.0		3.1	57.0	(*)	2.5	22.5		1.7		
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	2.7			3.6			2.5			2.0		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	8.5			9.0			7.9			6.8		
GLOBULINS BETA	+-30.0 (6-12)	7.9			8.1			8.8			6.9		
GLOBULINS GAMMA	+-30.0 (6-16)	11.4			15.6			12.9			10.3		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CRS0321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 6 PATIENT: 82 (SEX: Male)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			8-14			15-28		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (13-18)	16.1			13.6			15.3			16.2		
HT	-15 (0.4-0.54)	0.5			0.4			0.4			0.5		
RBC	-15 (4-6.5)	5.3			4.3			4.9			5.1		
WBC	+-30.0 (3.9-12)	6.6			7.5			9.0			9.0		
WBC: N	+-30.0 (2-7.5)	6.8			4.9			5.7			5.2		
WBC: L	+-30.0 (1.5-4)	2.0			2.1			2.6			2.9		
WBC: E	30 (0.04-0.44)	0.5	4.5		0.3			0.5	2.3		0.6	43.2	(*)
WBC: M	30 (0.2-0.8)	0.2	-25.0		0.2			0.3			0.4		
WBC: B	30 (0-0.1)	0.1			0.1			0.1			0.1		
PLATELETS	+-30.0 (100-600)	280.0			287.0			306.0			300.0		
NA+	+-10.0 (134-145)	140.0			139.0			140.0			139.0		
K+	+-15.0 (3.5-5)	4.8									5.1	2.0	
Ca++	+-15.0 (2.2-2.6)	2.1	-2.7		2.3			2.4			2.5		
PO4--	+-15.0 (0.8-1.5)	0.8	-2.5		0.9			0.8			1.1		
GAMMA GT	100 (5-52)	5.0			19.0			19.0			29.0		
ALK. PHOSPH.	100 (95-260)	78.0	-17.9		70.0	-26.3		73.0	-23.2		78.0	-17.9	
GLUCOSE	+-30.0 (3.5-10)	4.0			3.6						3.3	-5.7	
URIC ACID	30 (180-340)	285.0			271.0			251.0			267.0		
TOT BILIRUBIN	100 (2-17)	6.2			4.8			5.5			5.6		
TOT. PROTEINS	+-30.0 (60-80)	75.0			65.0			71.0			75.0		
ALBUMINE	+-30.0 (35-46)	43.0			36.0			40.0			42.0		
TOT. CHOLEST.	30 (3.1-5.2)	7.6	46.2	(*)	6.8	30.8	(*)	7.7	48.1	(*)	8.2	57.7	(*)
TRIGLYCERIDES	30 (0.5-2)	2.2	8.5		3.4	68.0	(*)	3.9	96.5	(*)	5.8	189.5	(*)
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	2.3			2.6			1.7			2.6		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	7.4			7.2			10.1			8.5		
GLOBULINS BETA	+-30.0 (6-12)	8.6			7.3			6.1			8.3		
GLOBULINS GAMMA	+-30.0 (6-16)	13.7			12.1			13.1			13.6		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CNS R&D 95500321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 6 PATIENT: 83 (SEX: Female)

Assigned treatment: Placebo

Laboratory test/% deviation max (range)		Days of treatment											
		Screen			1-7			15-28			8-14		
		value	(1)	(2)	value	(1)	(2)	value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	13.1			14.3			15.8					
HT	-15 (0.37-0.47)	0.4			0.4			0.5					
RBC	-15 (3.8-5.8)	4.1			4.5			4.9					
WBC	+-30.0 (4-11)	6.2			7.6			8.9					
WBC: N	+-30.0 (2.5-7.5)	3.5			4.3			3.2					
WBC: L	+-30.0 (1.5-3.5)	2.1			2.7			4.5	29.1				
WBC: E	30 (0.04-0.44)	0.5	13.6		0.4			0.9	102.3	(*)			
WBC: M	30 (0.2-0.8)	0.1	-70.0		0.2	-25.0		0.3					
WBC: B	30 (0-0.1)	0.1			0.1								
PLATELETS	+-30.0 (150-400)	403.0	0.8		238.0			238.0					
NA+	+-10.0 (135-150)	144.0			145.0			142.0			144.0		
K+	+-15.0 (3.5-5)	4.1						4.0					
Ca++	+-15.0 (2.1-2.6)	2.3			2.4			2.6			2.5		
GAMMA GT	100 (0-65)	9.0			9.0			9.0			9.0		
ALK. PHOSPH.	100 (30-115)	82.0			85.0			86.0			76.0		
CREATININE	50 (59-120)	71.0						80.0			112.0		
URIC ACID	30 (200-500)	223.0			209.0			183.0	-8.5		191.0	-4.5	
TOT BILIRUBIN	100 (3-20)	4.8			6.5			8.9			8.4		
TOT. PROTEINS	+-30.0 (60-80)	62.0			66.0			76.0			64.0		
ALBUMINE	+-30.0 (34-50)	38.0			41.0			50.0			41.0		
TOT. CHOLEST.	30 (0-6)	4.5			5.0			6.2	3.3		5.0		
TRIGLYCERIDES	30 (0.8-2)	1.4			1.1			1.6			1.2		
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	3.0			2.9			3.4			3.3		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	6.4			7.8			7.5			6.8		
GLOBULINS BETA	+-30.0 (6-12)	6.1			6.4			7.4			7.6		
GLOBULINS GAMMA	+-30.0 (6-16)	8.4			9.9			10.9			9.4		

(1): % deviation from limits of normal range - (2): clinical relevance

PHARMACIA CNS [illegible] 9580321

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 34

LABORATORY TEST: LISTING OF PATIENTS WITH LABORATORY ABNORMALITIES OF CLINICAL RELEVANCE ACCORDING TO SELECTED CRITERIA
CENTRE: 7 PATIENT: 89 (SEX: Female)

Assigned treatment: Reboxetine

Laboratory test/% deviation max (range)		Days of treatment					
		Screen			1-7		
		value	(1)	(2)	value	(1)	(2)
HB	-15 (12-16.4)	15.2			16.0		
HT	-15 (0.37-0.47)	0.5			0.5	5.1	
RBC	-15 (3.8-5.8)	4.9			5.3		
WBC	+-30.0 (4-11)	10.1			12.0	9.5	
WBC: N	+-30.0 (2.5-7.5)	6.9			7.7	2.8	
WBC: L	+-30.0 (1.5-3.5)	2.1			3.0		
WBC: E	30 (0.04-0.44)	0.5	13.6		0.6	36.4	(*)
WBC: M	30 (0.2-0.8)	0.5			0.7		
WBC: B	30 (0-0.1)	0.1			0.1	20.0	
PLATELETS	+-30.0 (150-400)	249.0			277.0		
NA+	+-10.0 (135-150)	144.0			141.0		
Ca++	+-15.0 (2.1-2.6)	2.4			2.4		
GAMMA GT	100 (0-65)	51.0			60.0		
ALK. PHOSPH.	100 (30-115)	146.0	27.0		164.0	42.6	
URIC ACID	30 (200-500)	247.0			242.0		
TOT BILIRUBIN	100 (3-20)	5.5			6.0		
TOT. PROTEINS	+-30.0 (60-80)	59.0	-1.7		63.0		
ALBUMINE	+-30.0 (34-50)	36.0			38.0		
TOT. CHOLEST.	30 (0-6)	5.1			6.1	1.7	
TRIGLYCERIDES	30 (0.8-2)	1.9			3.5	72.5	(*)
GLOBULINS ALPHA 1	+-30.0 (1.5-4)	2.3			2.7		
GLOBULINS ALPHA 2	+-30.0 (3.6-10.5)	5.6			6.1		
GLOBULINS BETA	+-30.0 (6-12)	6.8			7.9		
GLOBULINS GAMMA	+-30.0 (6-16)	8.3			8.3		

(1): % deviation from limits of normal range - (2): clinical relevance

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 35

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

Assigned treatment: Placebo

Vital signs		LYING								STANDING							
		time interval								time interval							
		Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28		Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28	
S.B.P.	Evaluated	23	22	20	3	18	19	19		23	22	20	3	18	19	19	
	Mean	132.8	132.9	132.2	145.3	130.6	132.4	131.6		123.3	127.5	127.7	140.7	125.4	124.9	125.5	
	SD	21.9	20.9	19.4	43.2	19.6	21.6	21.9		21.8	23.4	14.4	26.9	19.5	21.7	21.3	
	Median	130.0	133.0	133.0	150.0	130.0	130.0	130.0		120.0	120.0	128.0	152.0	122.0	120.0	120.0	
	Min	100.0	100.0	100.0	100.0	100.0	100.0	95.0		92.0	90.0	100.0	110.0	96.0	90.0	90.0	
	Max	184.0	182.0	186.0	186.0	164.0	184.0	190.0		164.0	175.0	150.0	160.0	170.0	180.0	180.0	
D.B.P.	Evaluated	23	22	20	3	18	19	19		23	22	20	3	18	19	19	
	Mean	79.6	81.0	79.9	82.0	82.3	82.3	80.7		80.7	83.7	80.6	82.7	81.8	81.5	80.1	
	SD	9.8	10.3	10.2	13.1	9.9	9.9	10.2		9.7	11.6	9.9	14.2	9.2	11.9	13.4	
	Median	80.0	81.0	80.0	80.0	82.5	80.0	80.0		80.0	83.5	80.0	80.0	80.0	80.0	80.0	
	Min	60.0	55.0	55.0	70.0	65.0	60.0	60.0		60.0	65.0	65.0	70.0	65.0	60.0	60.0	
	Max	100.0	94.0	100.0	96.0	100.0	100.0	100.0		100.0	110.0	100.0	98.0	100.0	110.0	110.0	
Heart Rate	Evaluated	23	22	20	3	18	19	19		23	22	20	3	18	19	19	
	Mean	83.5	87.7	83.5	89.3	83.3	84.2	84.3		88.6	87.5	90.0	95.3	89.8	87.6	89.6	
	SD	9.7	10.7	26.2	8.3	9.6	10.5	11.1		10.1	16.0	11.9	7.0	11.5	10.3	12.6	
	Median	86.0	88.0	84.5	92.0	80.0	84.0	84.0		88.0	90.0	90.0	96.0	88.0	88.0	90.0	
	Min	64.0	66.0	12.0	80.0	68.0	66.0	66.0		70.0	37.0	68.0	88.0	72.0	66.0	66.0	
	Max	100.0	105.0	150.0	96.0	102.0	100.0	112.0		116.0	112.0	125.0	102.0	111.0	108.0	120.0	

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 35

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

Assigned treatment: Reboxetine

Vital signs		LYING							STANDING						
		time interval							time interval						
		Day 0	Day 4	Day 7	Day 14	Day 21	Day 28		Day 0	Day 4	Day 7	Day 14	Day 21	Day 28	
S.B.P.	Evaluated	26	26	24	25	20	18		26	26	24	25	20	18	
	Mean	131.5	128.0	129.8	125.6	129.1	129.8		124.6	121.2	120.3	118.2	121.6	121.1	
	SD	17.7	13.7	14.8	16.7	14.1	15.0		18.0	14.3	17.2	15.9	16.2	14.5	
	Median	128.0	126.5	130.0	124.0	124.5	126.0		124.5	120.0	120.0	120.0	120.0	120.0	
	Min	110.0	110.0	110.0	100.0	105.0	110.0		100.0	96.0	90.0	92.0	90.0	100.0	
	Max	175.0	167.0	172.0	166.0	170.0	170.0		180.0	152.0	160.0	160.0	156.0	156.0	
D.B.P.	Evaluated	26	26	24	25	20	18		26	26	24	25	20	18	
	Mean	82.3	81.1	82.0	82.3	85.4	86.1		83.6	82.4	82.5	82.3	84.9	85.8	
	SD	7.3	6.7	11.3	8.9	5.3	8.2		9.5	8.3	8.6	8.6	6.9	8.4	
	Median	82.0	80.0	84.5	82.0	87.0	86.5		85.0	80.0	84.5	80.0	85.0	89.0	
	Min	68.0	66.0	40.0	60.0	72.0	70.0		68.0	68.0	60.0	60.0	70.0	68.0	
	Max	100.0	90.0	95.0	100.0	90.0	100.0		100.0	100.0	96.0	100.0	95.0	100.0	
Heart Rate	Evaluated	26	26	24	25	20	18		26	26	24	25	20	18	
	Mean	83.2	83.7	82.0	83.1	84.9	85.3		87.4	88.9	86.5	89.1	91.8	90.7	
	SD	11.8	10.0	9.8	11.2	9.0	11.2		13.6	10.4	9.5	11.9	10.9	11.1	
	Median	84.0	86.0	82.0	86.0	87.0	85.0		84.5	90.0	86.0	88.0	91.0	89.0	
	Min	64.0	68.0	64.0	62.0	72.0	68.0		68.0	73.0	70.0	70.0	76.0	78.0	
	Max	116.0	100.0	110.0	104.0	100.0	110.0		131.0	112.0	107.0	120.0	116.0	120.0	

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 36

BLOOD PRESSURE AND HEART RATE: NUMBER AND PERCENT OF PATIENTS WITH DECREASE OR INCREASE VS BASELINE OF CLINICAL RELEVANCE ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Placebo

Vital signs			LYING							STANDING						
			time intervals							time intervals						
			Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28
S.B.P.	Evaluated	No	23	22	20	3	18	19	19	23	22	20	3	18	19	19
	Decrease (1)	No			2		3	2	1							1
		%			10.0		16.7	10.5	5.3							5.3
	Increase (2)	No			1		1	1	2			2			1	1
		%			5.0		5.6	5.3	10.5			10.0			5.3	5.3
D.B.P.	Evaluated	No	23	22	20	3	18	19	19	23	22	20	3	18	19	19
	Decrease (1)	No			1			1	1				1	1		
		%			5.0			5.3	5.3				33.3	5.6		
	Increase (2)	No		2	1		1	2			1	1		1	1	1
		%		9.1	5.0		5.6	10.5			4.5	5.0		5.6	5.3	5.3
Both	Evaluated	No	23	22	20	3	18	19	19	23	22	20	3	18	19	19
	Decrease (1)	No														
		%														
	Increase (2)	No		1			2	1			1			1		
		%		4.5			11.1	5.3			4.5			5.6		
Heart rate	Evaluated	No	23	22	20	3	18	19	19	23	22	20	3	18	19	19
	Decrease (1)	No			1			2	1		1			1	2	3
		%			5.0			10.5	5.3		4.5			5.6	10.5	15.8
	Increase (2)	No		1	2		1	1	2		2	2		2	2	3
		%		4.5	10.0		5.6	5.3	10.5		9.1	10.0		11.1	10.5	15.8

(1) decrease => 20 % of baseline value
(2) increase => 20 % of baseline value

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 36

BLOOD PRESSURE AND HEART RATE: NUMBER AND PERCENT OF PATIENTS WITH DECREASE OR INCREASE VS BASELINE OF CLINICAL RELEVANCE ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment: Reboxetine

Vital signs			LYING						STANDING					
			time intervals						time intervals					
			Day 0	Day 4	Day 7	Day 14	Day 21	Day 28	Day 0	Day 4	Day 7	Day 14	Day 21	Day 28
S.B.P.	Evaluated	No	26	26	24	25	20	18	26	26	24	25	20	18
	Decrease (1)	No			1					1		2		1
		%			4.2					3.8		8.0		5.6
	Increase (2)	No		1	2					1				
		%		3.8	8.3					3.8				
D.B.P.	Evaluated	No	26	26	24	25	20	18	26	26	24	25	20	18
	Decrease (1)	No		1	1	1								
		%		3.8	4.2	4.0								
	Increase (2)	No				1	2					1	2	1
		%				4.0	10.0					4.0	10.0	5.6
Both	Evaluated	No	26	26	24	25	20	18	26	26	24	25	20	18
	Decrease (1)	No										1		
		%										4.0		
	Increase (2)	No												
		%												
Heart rate	Evaluated	No	26	26	24	25	20	18	26	26	24	25	20	18
	Decrease (1)	No		1	2	1	1	1			1	1		1
		%		3.8	8.3	4.0	5.0	5.6			4.2	4.0		5.6
	Increase (2)	No		2	1	2		3		3	1	3	3	2
		%		7.7	4.2	8.0		16.7		11.5	4.2	12.0	15.0	11.1

(1) decrease => 20 % of baseline value
(2) increase => 20 % of baseline value

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 37

BLOOD PRESSURE: NUMBER AND PERCENT OF PATIENTS WITH ORTHOSTATIC HYPOTENSION (*) BEFORE AND DURING THE STUDY ACCORDING TO TIME INTERVAL BY ASSIGNED TREATMENT

Assigned treatment / Vital signs		According to time interval							
		Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28
Placebo	Eval.	23	22	20	3	18	19	19
	No.	3	2	1	1		1	2
	%	13.0	9.1	5.0	33.3		5.3	10.5
	Mean	37.7	33.0	37.0	34.0		34.0	38.0
	Max.	45.0	36.0	37.0	34.0		34.0	40.0
Reboxetine	Eval.	26	26	24		25	20	18
	No.			1		1	2	1
	%			4.2		4.0	10.0	5.6
	Mean			40.0		30.0	30.0	30.0
	Max.			40.0		30.0	30.0	30.0

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

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 38

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

Assigned treatment: Placebo

Sex		Time interval						
		Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28
Female	Evaluated	13	1		2	11	1	13
	Mean	65.5	70.0		59.0	64.1	72.0	66.6
	SD	20.5			2.8	23.3		20.4
	Median	65.4	70.0		59.0	60.9	72.0	62.0
	Min	36.8	70.0		57.0	36.3	72.0	44.6
	Max	119.0	70.0		60.9	120.0	72.0	123.0
Male	Evaluated	6		1		6		5
	Mean	68.6		77.5		69.1		67.0
	SD	10.0				9.6		9.9
	Median	72.1		77.5		72.5		72.0
	Min	52.0		77.5		53.0		53.8
	Max	78.0		77.5		79.0		76.0
Total	Evaluated	19	1	1	2	17	1	18
	Mean	66.5	70.0	77.5	59.0	65.8	72.0	66.7
	SD	17.6			2.8	19.3		17.8
	Median	68.8	70.0	77.5	59.0	70.0	72.0	66.9
	Min	36.8	70.0	77.5	57.0	36.3	72.0	44.6
	Max	119.0	70.0	77.5	60.9	120.0	72.0	123.0

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 38

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

Assigned treatment: Reboxetine

Sex		Time interval				
		Day 0	Day 7	Day 14	Day 28
Female	Evaluated	14	1	14	10
	Mean	69.0	68.0	69.1	67.9
	SD	10.7		10.5	10.6
	Median	68.0	68.0	68.3	67.0
	Min	51.1	68.0	51.5	50.8
	Max	95.0	68.0	95.0	90.0
Male	Evaluated	8		8	5
	Mean	72.7		72.1	70.0
	SD	11.1		10.5	4.7
	Median	70.8		70.5	72.0
	Min	56.8		58.5	64.0
	Max	95.0		95.0	75.0
Total	Evaluated	22	1	22	15
	Mean	70.3	68.0	70.1	68.6
	SD	10.8		10.3	8.9
	Median	70.3	68.0	68.8	67.0
	Min	51.1	68.0	51.5	50.8
	Max	95.0	68.0	95.0	90.0

REBOXETINE - PROTOCOL ADE09
TABLE No.: 39

VITAL SIGN: BODY TEMPERATURE

Assigned treatment		VISIT							
		SCREEN	DAY0	DAY4	DAY7	DAY14	DAY21	DAY28
PLACEBO	No	24	24	22	20	18	19	19
	Missing	0	0	0	0	0	0	0
	Mean	36.70	36.76	36.76	36.87	36.71	36.67	36.91
	SD	0.51	0.50	0.31	0.50	0.45	0.46	0.29
	Median	36.85	36.95	37.00	36.90	36.65	36.60	37.00
	Min	35.00	35.10	36.00	36.00	35.80	35.60	36.50
	Max	37.50	37.50	37.00	38.00	37.50	37.50	37.50
REBOXETINE	No	26	26	26	24	24	19	18
	Missing	0	0	0	0	1	1	0
	Mean	36.82	36.87	36.89	36.83	36.82	36.81	36.76
	SD	0.39	0.37	0.40	0.51	0.35	0.39	0.36
	Median	36.85	36.95	37.00	36.90	36.80	36.60	36.65
	Min	36.00	36.20	36.00	35.40	36.20	36.30	36.20
	Max	37.50	37.50	37.50	37.80	37.50	37.50	37.50

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 40

E.C.G.: NUMBER OF PATIENTS EVALUATED BY ASSIGNED TREATMENT AND SEX

Assigned treatment / Sex		Screened	Exposed	Evaluated	Only screening data	Without E.C.G. data
Placebo	Female	16	16	3	12	1
	Male	8	8	3	5	
	Total	24	24	6	17	1
Reboxetine	Female	17	17	5	12	
	Male	9	9	4	5	
	Total	26	26	9	17	

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 41

E.C.G.: LISTING OF PATIENTS WITH ABNORMAL E.C.G. AT BASELINE CHANGED TO NORMAL AFTER TREATMENT OR VICEVERSA

Centre	Patient	Treatment	Sex	Days of treatment	E.C.G. value	Abnormality type	Abnormality group
5	73	Reboxetine	Male	0 - Screening 15-28 days	Normal Abnormal	REPOLARIZATION DISTURBANCES OTHER	Ischemic signs Other disorders
6	82	Reboxetine	Male	0 - Screening 15-28 days	Normal Abnormal	MYOCARDIAL ISCHEMIA LEFT ANTERIOR HEMIBLOCK	Ischemic signs Conduction disorders
7	89	Reboxetine	Female	0 - Screening 15-28 days	Normal Abnormal	LEFT VENTRICULAR HYPERTROPHY	Other disorders

PHARMACIA CNS R&D

REBOXETINE - PROTOCOL 20124/ADE009
TABLE No.: 41

E.C.G.: LISTING OF PATIENTS WITH ABNORMAL E.C.G. AT BASELINE CHANGED TO NORMAL AFTER TREATMENT OR VICEVERSA

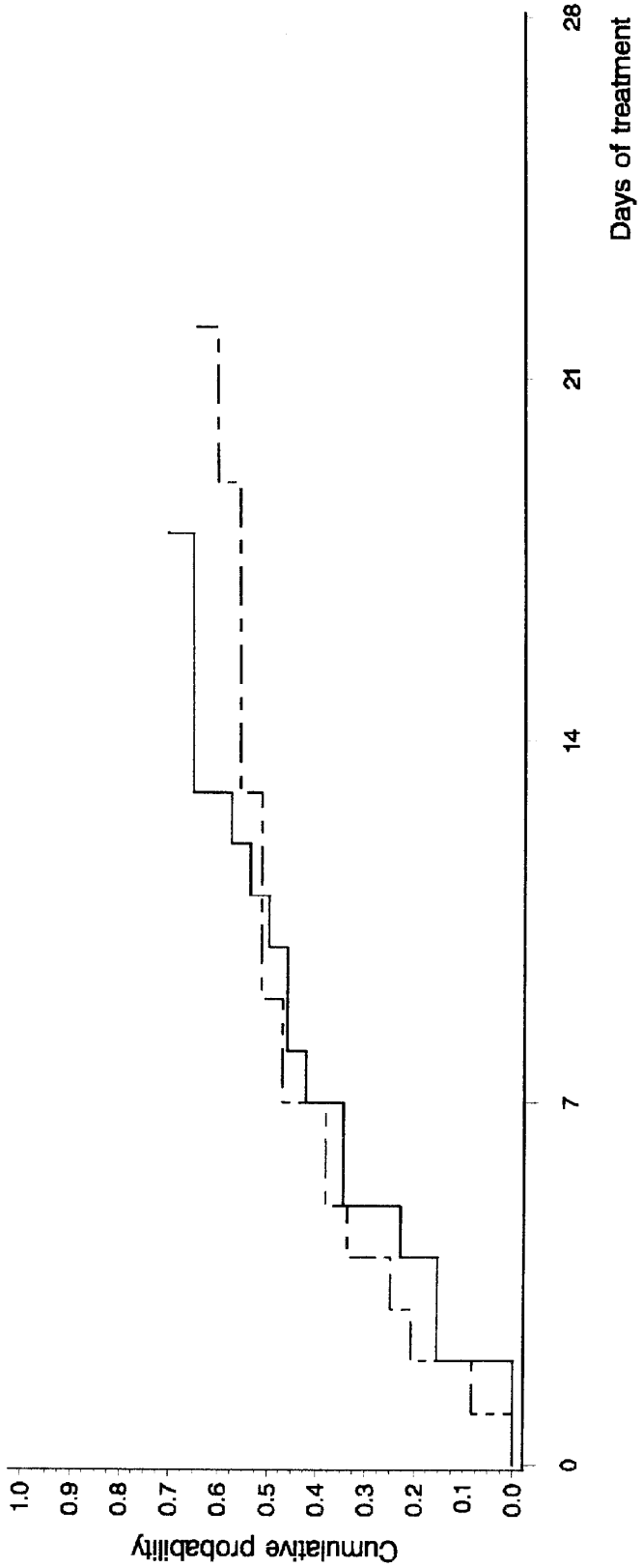
Centre	Patient	Treatment	Sex	Days of treatment	E.C.G. value	Abnormality type	Abnormality group
4	55	Placebo	Male	0 - Screening 1-14 days	Normal Abnormal	LEFT AXIAL DEVIATION	Conduction disorders
	65	Placebo	Male	0 - Screening 15-28 days	Normal Abnormal	RIPOLARIZATION DISTURBANCES	Ischemic signs
5	74	Placebo	Male	0 - Screening 15-28 days	Normal Abnormal	RIPOLARIZATION DISTURBANCES	Ischemic signs

PHARMACIA CNS R&D

REBOXETINE – PROTOCOL 20124/ADE009

CUMULATIVE RISK OF DEVELOPING THE FIRST ADVERSE EVENT DURING TREATMENT

Figure No.: 1



Log – Rank Test RBX vs PLC: (1 df) = 0.0319 P = 0.8582

12. APPENDICES

Pharmacia Document 9550321

12.1 Study Information

Pharmacia Document 9550321

12.1.1 PROTOCOL AND PROTOCOL AMENDMENTS

GRUPPO MONTEDISON
FARMITALIA CARLO ERBA

COMPOUND: REBOXETINE (FCE 20124)

PROTOCOL: ADE 009

TITLE: PHASE II CONTROLLED STUDY OF THE ACTIVITY AND TOLERABILITY OF REBOXETINE IN COMPARISON WITH PLACEBO IN PATIENTS HOSPITALIZED FOR MAJOR DEPRESSIVE DISORDERS

DATE: MARCH 1987

PHASE II CONTROLLED STUDY OF THE ACTIVITY AND TOLERABILITY OF REBOXETINE IN COMPARISON WITH PLACEBO IN PATIENTS HOSPITALIZED FOR MAJOR DEPRESSIVE DISORDERS.

INTRODUCTION

Reboxetine (PCE 20124 or RS, RS 2-[α-(2-ethoxy-phenoxy) benzyl]morpholine methanesulphonate) is a chemically new compound highly potent in pharmacological and biochemical tests predictive of antidepressant effectiveness: reserpine antagonism, norepinephrine reuptake inhibition, REM sleep latency increase. In addition reboxetine has been found to be able to prevent clonidine effects in rodents after single oral administration, in contrast with what observed following tricyclic monoamine uptake inhibitors, which were found to be active only upon repeated dosees: these results indicate that reboxetine is highly potent in decreasing the sensitivity of α_2-noradrenergic receptors after single oral dose; would desensitization of α_2-noradrenergic receptors correlate with antidepressant effects, reboxetine should exert antidepressant effectiveness of faster onset with respect to available antidepressants in patients (Investigator's Brochure: 2).

Phase I studies in healthy volunteers (3,4), orally administered single doses of 0.5 - 5 mg of the compound, indicate good tolerability of doses ≤5 mg; the latter dose was in fact associated to orthostatic hypotension, accompanied by tachycardia and by subjective symptomatology consistent with the disturbed circulatory regulation.

In these studies single doses of 1 and 3 mg of the compound showed dose-dependent CNS effects with EEG modifications (decrease of power of theta and fast-β waves in the fronto-central derivative), performance improvement (peg-board test) and growth hormone increase, the latter reportedly sensitive to hypothalamic noradrenergic stimulation by norepinephrine reuptake inhibitors. The comparison with the positive control, imipramine 75 mg, associated to similar EEG modifications in the fronto-central derivative, to modifications indicative of sedative activity in the occipito-temporal derivative and to deterioration of the Pauli performance test (in the absence of growth hormone modifications) indicate that reboxetine does not possess the marked sedative activity of imipramine, but rather psychostimulating properties. After all active

treatments standing heart rate increase and salivation decrease were 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 ^{14}C-FCE 20124 to 3 healthy volunteers (5). Most of the radioactivity circulating in plasma (73% in terms of AUC) was accounted for by unchanged reboxetine; its plasma half-life was estimated as 13.2 h, slightly lower than that of total radioactivity. The overall results obtained suggest for the compound linear pharmacokinetics in the dose range tested. Upon repeated administration steady-state levels are expected to be reached within 3 days.

An open, dose-range finding multicenter study is being carried out in patients hospitalized for Major Depressive Disorders. A total of 82 patients participated in the study. Reboxetine was administered for 4 weeks according to 5 different fixed changing dose schedules, with maximum daily doses of 4 mg (28 pts), 6 mg (24 pts), 8 mg (12 pts), 10 mg (6 pts) and 12 mg (12 pts). At the latter dose hypotension accompanied by dizziness and tachycardia was apparent in five patients; as a consequence the daily dose was decreased to 10 mg/day; on this dosage all 5 patients completed the study. On the average in the 12 mg dose group a maximum drop of standing systolic-diastolic blood pressure of 30-20 mm Hg and increase of 14 beats/min of standing heart rate was observed on day 15-16 of treatment. When administered up to 10 mg/day the compound was well tolerated: no patient dropped from the study due to adverse events; the side-effects reported were mainly mild and transient; no clinically relevant average modifications of vital signs were apparent; laboratory tests didn't show individual modifications of clinical significance; no EEG modifications were observed with the exception of slight prolongation of PR interval in one patient receiving 4 mg/day. Improvement of psychopathology indicative of antidepressant activity of the compound was present at all dose levels. Frequency of relevant modifications as well as average decrease of the rating scales at the end of treatment were dose-related up to the 10 mg dosage.

The study provides therefore information on the tolerability of repeated doses and indications about the possibly active doses of reboxetine; the effectiveness and therapeutic usefulness of the compound need now to be tested in double blind conditions in comparison with placebo.

AIM OF THE STUDY

The purpose of this study is to evaluate the antidepressant activity and the tolerability of reboxetine in comparison with placebo in Major Depressive Disorders.

CLINICAL INVESTIGATORS AND CENTERS

1) Prof. D. Eccleston, Dept. of Psychological Medicine, Royal Victoria Infirmary, Newcastle Upon Tyne

2) Dr. Guy Edwards, Dept. of Psychiatry, Royal South Hants Hospital, Southampton

3) Dr. Sidney Levine, Oldham & District General Hospital, Oldham

4) Dr. T. Stonehill, Central Middlesex Hospital, London

The curricula-vitae of the investigators will be summarized in enclosure 1.

STUDY POPULATION

The study population will consist of 80 in-patients or day-hospital patients from four centers, each center contributing 20 patients within a period of 12 months.

Inclusion criteria

The patients admitted to the study will meet the following criteria:

1. Males or females from 21 through 65 years.

2. DSM-III diagnosis of Major Depression (296.2-296.3, Enclosure 2) with presence of illness for at least one month. The correspondence with ICD-9 diagnostic classification will also be reported for each patient.

3. Informed consent obtained in written form.

4. Total score of Hamilton-Depression Rating Scale ≥18.

Exclusion criteria

1. Pregnancy (by laboratory testing) or breast feeding.

2. Past history of hypersensitivity to psychotropic drugs.

3. Participation in a clinical trial with an investigational drug within the six months preceding the study.

4. Evidence of Substance Use Disorders with abuse and dependence within past 5 years or currently.

5. Treatment within previous four weeks with any drug known to have a well-defined potential for toxicity to a major organ (e.g., chloramphenicol).

6. History or presence of gastrointestinal, liver, or kidney disease, or other conditions known to interfere with the absorption, distribution, metabolism and excretion of drugs.

7. History of seizures or brain trauma; current evidence of clinically important hematoporetic or cardiovascular disease; current evidence of urinary retention, thyroid disease, or glaucome.

8. Symptoms of any other important clinical illness in the four weeks preceding the study.

9. Clinically relevant abnormal findings in the physical examination, laboratory tests and ECG at admission visit.

EXPERIMENTAL DESIGN

The study will be carried out according to a multicenter double-blind, parallel group design. In each of the 4 centers 20 patients will be randomly allocated to treatment with either reboxetine (10 patients) or placebo (10 patients).

The total sample size of 40 patients per group is expected to provide to the test of the null hypothesis of no difference in treatment response (defined as 50% decrease of the Hamilton Depression Rating Scale at the end of treatment) between active compound and placebo a power of 0.8, i.e. a 80% probability of rejecting it in presence of a between treatments difference in response rate of 30%, assuming a 40% response rate under placebo and a 0.05 one-sided alpha level.

STUDY MEDICATION

Study medication will be supplied in indistinguishable capsules containing either reboxetine 2 mg with excipients or excipients only (analytical certificates, enclosure 3).

One bottle containing 105 capsules (maximum needed + 3 capsules) of one of the treatments will be prepared for each patient and labelled with the progressive number of the patient according to the treatment code. Sealed individual codes will be provided for each patient.

At the conclusion of the study all unused medication will be returned to Farmitalia Carlo Erba.

STUDY PROCEDURE

Pre-treatment period

For all but those patients treated with a MAOI antidepressant, the study will begin with a 7 days, drug-free washout period (from Day -6 to Day 0). For patients treated with a MAOI the pre-treatment drug-free washout period will need to be 14 days. Screening for inclusion and exclusion criteria will take place prior to admission. However only those patients who fulfill inclusion/exclusion criteria on Day 0, will commence with active treatment on Day 1.

Experimental treatment

Patients will receive 1 capsule b.i.d. from Day 1 to Day 3. Depending upon tolerability of each dose level this dosage will be increased to 2 capsules in the morning and 1 in the evening from Day 4 to Day 7 and to 2 capsules b.i.d. from Day 8 to Day 28.

The treatments will be administered in the morning (10 a.m.) and in the evening (8 p.m.); in case of modification of clinical relevance of tolerability parameters with dosage increase, the dose will be decreased to the previously well tolerated level.

The patients should remain hospitalized for the whole study period. At the discretion of the Investigator, after day 14, patients could be discharged in case of improvement of symptomatology of such magnitude as to require it. In this event the patient will be asked to attend the following

visits according to the protocol and provided at discharge and at the subsequent visit with the number of capsules needed for the treatment up to the following visit.

CONCOMITANT MEDICATION

No concomitant medication should be used by patients for the duration of the study, with the exception of a sleep inducer (Temazepam) at bed-time. If any concomitant medication is taken, the details must be entered on the appropriate forms.

DROPOUTS

In case of deterioration of the clinical picture (worsening of global improvement item of CGI) at assessments on day 7 or 10 or of lack on improvement (unchange or worsening of global improvement item of CGI) on day 14, the patient will be identified as treatment failure and discontinued from study treatment.

Patients can obviously discontinue the study at any time for any reason. All patients who discontinue the study due to (a) refusal or withdrawal of consent, (b) administrative reasons, or (c) intercurrent medical illness without completing at least 14 days of drug administration will be replaced. To this purpose request for the material needed will be immediately addressed to Study Monitor in U.K.; the material will be provided with the label carrying the number of the patient and the "bis" indication. Patients discontinued for inefficacy or intolerable adverse reactions will not be replaced.

If the study medication is discontinued for any reason, a complete final battery of all assessments will be done immediately prior to or after discontinuation.

ASSESSMENTS

Tolerability

1. Newly Observed Signs and Symptoms (Enclosure 4).
On Days 0,7,14,21,28. In addition it will also be completed at times when adverse reaction(s) occur. Any serious or alarming adverse reaction, whether or not related to the experimental treatment, must be reported immediately to the Study Monitor in U.K.

2. Vital Signs.
They include oral body temperature, supine and standing radial pulse rates, supine and standing systolic and diastolic blood pressure. Supine recordings will be made after the patient has been recumbent for 15 minutes. Standing recordings will be made 2 minutes after the patient had been erect. All recordings will be made before the morning dose on Day 0, 4, 7, 14, 21 and 28.

3. Weight.
On Days 0, 14, and 28 prior to breakfast.

4. ECG.
The standard 12-lead ECG will be done at pretreatment and repeated at the end of treatment. In case of any cardiological concern during treatment, ECG will be performed.

5. Laboratory tests.
Hematology, blood chemistry and urinalysis will be done at admission and on days 7, 14 and 28. Samples for laboratory tests will be taken before the morning dose, after an overnight fast. Tests with clinically significant abnormal results must be repeated. Persistent abnormal values must be checked until the cause is determined, they return to baseline, or no further change is anticipated. The same for ECG results.

6. T_3 and T_4 assays at pretreatment.

Efficacy

All psychiatric evaluations and ratings (both observer and self-ratings) should be made, as much as possible, in the morning and in the same setting on the days they are scheduled to occur. The same rater should carry out all clinical evaluations for a given patient.

On days 0, 4, 7, 10, 14, 21, 28:

1. Clinical Global Impression (CGI, Enclosure 5)

On days 0, 7, 14, 21, 28:

2. Hamilton Depression Rating Scale (17 items HAMD, Enclosure 6).

3. Montgomery-Asberg Depression Rating Scale (MADRS, Enclosure 7).

On days 0,14,28:

4. Levine-Pilowsky Depression Questionnaire (Enclosure 8).

Pharmacokinetics

In each patient a 5 ml blood sample will be collected before the morning dose on Day 28. The sample will be put in heparinized tubes, centrifuged and the plasma separated and stored at -20°C up to the assay.

Follow-up

A follow-up visit will be carried out in all patients 4 weeks after completion of the study to collect information on the clinical conditions of the patient and on the interval events.

CASE REPORT FORMS

All data, including patient identification, present diagnosis and history, treatment specifications and information on study termination and follow-up in each patient will be recorded on specially designed forms, supplied by Farmitalia Carlo Erba. Forms on each completed patient will be sent to Study Monitor without delay with copy of each form retained by Investigator.

DOCUMENTATION AND ANALYSIS

Data documentation and analyses will be carried out at Farmitalia Carlo Erba, R & D, Biometrics Dept.

Documentation and analyses appropriate to non-parametric and parametric data will be provided for each assessment instrument (frequency of treatment failures included). In addition the results of laboratory tests will be classified as normal or abnormal by comparison with the normal ranges of the performing laboratory and the frequencies of abnormal results after treatment documented and analyzed, if appropriate.

STUDY MONITORING

Monitoring will be carried out by A. Dubini (Farmitalia Carlo Erba, CNS Line, Via Imbonati 24, 20159 Milan - Phone: 39.2.6990.2749. Home address: Via Abbadesse 44, Milan - Phone: 39.2.6089039) and by J. Powell (Farmitalia Carlo Erba U.K.).

Serious Events and Emergencies

The Investigators will inform the trial monitor at Farmitalia Carlo Erba U.K.:

Mrs Jackie Powell
Farmitalia Carlo Erba Ltd
Italia House
33, Grosvenor Road
St Albans
AL1 3AW
Tel. Office hours: 0727 40041
Outside office hours: 01 936 9067

Notification

The Company, in accordance with statutory obligations, will inform the CSM of adverse events. In the case of adverse reactions severe enough to warrant discontinuation of treatment, the subject's treatment will be de-coded and the CSM informed.

INVESTIGATORS MEETINGS

There will be 2 investigators meetings, one prior to commencement of the clinical study and one with all results in hand.

PUBLICATIONS

Final results of collaborative study will be published in single publication. Any proposed publication by the investigator will need to be discussed with the Monitors prior to publication.

ETHICAL ASPECTS

The study will be carried out according to the Tokyo revision of the Helsinki declaration (Enclosure 9) and after approval of the protocol by the local Ethical Committees. Other than modifications required for patient safety, no protocol changes will be made once the study has started without the specific written agreement between the investigator, the Ethical Committee and the study Monitor.

Monitor Signature:.....

Principal Investigator's Signature:.....

Date:.....

REFERENCES

1) SIEVER L. J., UHDE T. W.
New studies and perspectives on the noradrenergic receptor system in depression : effects of the α -adrenergic agonist clonidine.
Biological Psychiatry, 19:211-236 (1984).

2) DUBINI G., RIVA F.
FCE 20124 - Basic Interaction (Summary of preclinical studies up to June 1985).
(Farmitalia Carlo Erba Investigator's Brochure).

3) HERRMANN W. M. et al.
Safety and tolerance of FCE 20124 in healthy male volunteers. A single rising dose tolerance study.
Internal report N° 502 June 1984).

4) HERRMANN W. M.
FCE 20124 - Quantitative pharmaco EEG and pharmaco-psychological study.
Internal report N° 503 (January 1985).

5) Disposition and fate of ^{14}C-FCE 20124 administered orally to healthy volunteers.
Internal report N° 504 (March 1985).

6) Open, dose-range finding study of the activity and tolerability of oxaflozane in Major Depressive Disorders.
(Report in preparation).

AD/Lc

March 1987

9550321

ENCLOSURE 1

STATEMENT OF INVESTIGATOR

NAME OF INVESTIGATOR

INSTITUTION

HOME ADDRESS (and phone)

NAME OF THE DRUG UNDER INVESTIGATION AND PROTOCOL NUMBER

STATEMENT OF EDUCATION AND EXPERIENCE

COLLEGES, UNIVERSITIES, AND MEDICAL OR OTHER PROFESSIONAL SCHOOLS ATTENDED, WITH DATES OF ATTENDANCE, DEGREES, AND DATES DEGREES WERE AWARDED.

POSTGRADUATE MEDICAL OR OTHER PROFESSIONAL TRAINING (INDICATE DATES, NAMES OF INSTITUTIONS, AND NATURE OF TRAINING)

TEACHING OR RESEARCH EXPERIENCE (INDICATE DATES, INSTITUTIONS, AND BRIEF DESCRIPTION OF EXPERIENCE)

EXPERIENCE IN MEDICAL PRACTICE OR OTHER PROFESSIONAL EXPERIENCE (INDICATE DATES, INSTITUTIONAL APPLICATIONS, NATURE OF PRACTICE, OR OTHER PROFESSIONAL EXPERIENCE)

9550321

4.

REPRESENTATIVE LIST OF PERTINENT MEDICAL OR OTHER SCIENTIFIC PUBLICATION (INDICATE TITLES OF ARTICLES, NAMES OF PUBLICATIONS AND VOLUME, PAGE NUMBER, AND DATE)

DATE _____ SIGNATURE _____

(b) Any of the following catatonic symptoms: stupor, mutism, negativism, posturing.

2– Without Psychotic Features. Meets the criteria for manic episode, but no psychotic features are present.

0– Unspecified.

Major Depressive Episode

The essential feature is either a dysphoric mood, usually depression, or loss of interest or pleasure in all or almost all usual activities and pastimes. This disturbance is prominent, relatively persistent, and associated with other symptoms of the depressive syndrome. These symptoms include appetite disturbance, change in weight, sleep disturbance, psychomotor agitation or retardation, decreased energy, feelings of worthlessness or guilt, difficulty concentrating or thinking, and thoughts of death or suicide or suicidal attempts.

An individual with a depressive syndrome will usually describe his or her mood as depressed, sad, hopeless, discouraged, down in the dumps, or in terms of some other colloquial variant. Sometimes, however, the mood disturbance may not be expressed as a synonym for depressive mood but rather as a complaint of "not caring anymore," or as a painful inability to experience pleasure. In a child with a depressive syndrome there may not be complaints of any dysphoric mood, but its existence may be inferred from a persistently sad facial expression.

Loss of interest or pleasure is probably always present in a major depressive episode to some degree, but the individual may not complain of this or even be aware of the loss, although family members may notice it. Withdrawal from friends and family and neglect of avocations that were previously a source of pleasure are common.

Appetite is frequently disturbed, usually with loss of appetite, but occasionally with increased appetite. When loss of appetite is severe, there may be significant weight loss or, in the case of children, failure to make expected weight gains. When appetite is markedly increased there may be significant weight gain.

Sleep is commonly disturbed, more frequently with insomnia present, but sometimes with hypersomnia. The insomnia may involve difficulty falling asleep (initial insomnia), waking up during sleep and then returning to sleep only with difficulty (middle insomnia), or early morning awakening (terminal insomnia).

Psychomotor agitation takes the form of inability to sit still, pacing, handwringing, pulling or rubbing of hair, skin, clothing, or other objects, outbursts of complaining or shouting, or pressure of speech. Psychomotor retardation may take the form of slowed speech, increased pauses before answering, low or monotonous speech, slowed body movements, a markedly decreased amount of speech (poverty of speech), or muteness. (In children there may be hypoactivity rather than psychomotor retardation.) A decrease in energy level is almost

invariably present, and is experienced as sustained fatigue even in the absence of physical exertion. The smallest task may seem difficult or impossible to accomplish.

The sense of worthlessness varies from feelings of inadequacy to completely unrealistic negative evaluations of one's worth. The individual may reproach himself or herself for minor failings that are exaggerated and search the environment for cues confirming the negative self-evaluation. Guilt may be expressed as an excessive reaction to either current or past failings or as exaggerated responsibility for some untoward or tragic event. The sense of worthlessness or guilt may be of delusional proportions.

Difficulty in concentrating, slowed thinking, and indecisiveness are frequent. The individual may complain of memory difficulty and appear easily distracted.

Thoughts of death or suicide are common. There may be fear of dying, the belief that the individual or others would be better off dead, wishes to die, or suicidal plans or attempts.

Associated features. Common associated features include depressed appearance, tearfulness, feelings of anxiety, irritability, fear, brooding, excessive concern with physical health, panic attacks, and phobias.

When delusions or hallucinations are present, their content is usually clearly consistent with the predominant mood (mood-congruent). A common delusion is that one is being persecuted because of sinfulness or some inadequacy. There may be nihilistic delusions of world or personal destruction, somatic delusions of cancer or other serious illness, or delusions of poverty. Hallucinations, when present, are usually transient and not elaborate, and may involve voices that berate the individual for his or her shortcomings or sins.

Less commonly the content of the hallucinations or delusions has no apparent relationship to the mood disturbance (mood-incongruent). This is particularly the case with persecutory delusions, in which the individual may be at a loss to explain why he or she should be the object of persecution. The usefulness of the distinction between mood-congruent and mood-incongruent psychotic features is controversial.

Age-specific associated features. Although the essential features of a major depressive episode are similar in infants, children, adolescents, and adults, there are differences in the associated features.

In prepubertal children separation anxiety may develop and cause the child to cling, to refuse to go to school, and to fear that he or she or the parents will die. A previous history of separation anxiety may result in more intense anxiety symptoms with the onset of a major depressive episode.

In adolescent boys negativistic or frankly antisocial behavior may appear. Feelings of wanting to leave home or of not being understood and approved of, restlessness, grouchiness, and aggression are common. Sulkiness, a reluctance to cooperate in family ventures, and withdrawal from social activities, with retreat to one's room, are frequent. School difficulties are likely. There may be

inattention to personal appearance and increased emotionality, with particular sensitivity to rejection in love relationships. Substance Abuse may develop.

In elderly adults there may be symptoms suggesting Dementia, such as disorientation, memory loss, and distractibility. Loss of interest or pleasure in the individual's usual activities may appear as apathy; difficulty in concentration as inattentiveness. These symptoms make the differential diagnosis of "pseudodementia" (due to depression) from true Dementia (an Organic Mental Disorder) particularly difficult (p. 111).

Differential diagnosis of major depressive episode. An **Organic Affective Syndrome with depression** may be due to substances such as reserpine, to infectious diseases such as influenza, or to hypothyroidism. Only by excluding organic etiology can one make the diagnosis of a major depressive episode. For further discussion, see p. 117.

Primary Degenerative Dementia or **Multi-infarct Dementia**, because of the presence of disorientation, apathy, and complaints of difficulty concentrating or of memory loss, may be difficult to distinguish from a major depressive episode occurring in the elderly. If the features suggesting a major depressive episode are at least as prominent as those suggesting Dementia, it is best to diagnose a major depressive episode and assume that the features suggesting Dementia represent a pseudo-dementia that is a manifestation of the major depressive episode. In such cases the successful treatment of the major depressive episode often results in the disappearance of the symptoms suggesting Dementia. If the features suggesting Dementia are more prominent than the depressive features, the diagnosis should be the appropriate form of Dementia, but the presence of depressive features should be noted.

If a **psychological reaction to the functional impairment associated with a physical illness** that does not involve the central nervous system causes a depression that meets the full criteria for a major depressive episode, the Major Depression should be recorded on Axis I, the physical disorder on Axis III, and the severity of the psychosocial stressor on Axis IV. Examples would include the psychological reaction to the amputation of a leg or to the development of a life-threatening or incapacitating illness.

In **Schizophrenia** there is usually considerable depressive symptomatology. If an episode of depression follows an episode of Schizophrenia and is superimposed upon the residual phase of Schizophrenia, the additional diagnosis of either Atypical Depression or Adjustment Disorder with Depressed Mood may be made, but not Major Depression. An individual with a major depressive episode may have psychotic symptoms; however, the diagnosis of Schizophrenia is made in the presence of a full depressive syndrome only if the affective symptoms follow the psychotic symptoms or are brief relative to the duration of the psychotic symptoms. An individual with Schizophrenia, Catatonic Type, may appear to be withdrawn and depressed, and it may be difficult to distinguish this condition from Major Depression with psychomotor retardation. In such instances it may be necessary to rely on features that on a statistical basis are associated differentially with the two disorders. For example, the diagnosis of a major depressive episode is more likely if there is a family history

of Affective Disorder, good premorbid adjustment, and a previous episode of affective disturbance from which there was complete recovery.

The diagnosis of **Schizoaffective Disorder** can be made whenever the clinician is unable to make a differential diagnosis between a major depressive episode and Schizophrenia. Although no criteria for Schizoaffective Disorder are provided in this manual, several examples of clinical situations in which this diagnosis might be appropriate are given on p. 202.

In **Dysthymic** and **Cyclothymic Disorders** there are features of the depressive syndrome, but they are not of sufficient severity and duration to meet the criteria for a major depressive episode. However, in some instances, a major depressive episode is superimposed on one of these disorders. In such cases both diagnoses should be recorded, since it is likely that after recovering from the major depressive episode, either a Dysthymic or a Cyclothymic Disorder will persist.

Chronic mental disorders, such as **Obsessive Compulsive Disorder** or **Alcohol Dependence**, when associated with depressive symptoms, may suggest a Major Depression. The additional diagnosis of Major Depression should be made only if the full depressive syndrome is present and persistent. In such instances both the chronic mental disorder and the superimposed Major Depression should be recorded.

In **Separation Anxiety Disorder**, depressive symptoms are common, but if the full depressive syndrome is not present, only Separation Anxiety Disorder should be diagnosed. On the other hand, children with Separation Anxiety Disorder may develop a superimposed major depressive episode, in which case both diagnoses should be made.

Uncomplicated Bereavement is distinguished from a major depressive episode and is not considered a mental disorder even when associated with the full depressive syndrome (see p. 333). However, if bereavement is unduly severe or prolonged, the diagnosis may be changed to Major Depression.

Diagnostic criteria for major depressive episode

A. Dysphoric mood or loss of interest or pleasure in all or almost all usual activities and pastimes. The dysphoric mood is characterized by symptoms such as the following: depressed, sad, blue, hopeless, low, down in the dumps, irritable. The mood disturbance must be prominent and relatively persistent, but not necessarily the most dominant symptom, and does not include momentary shifts from one dysphoric mood to another dysphoric mood, e.g., anxiety to depression to anger, such as are seen in states of acute psychotic turmoil. (For children under six, dysphoric mood may have to be inferred from a persistently sad facial expression.)

B. At least four of the following symptoms have each been present nearly every day for a period of at least two weeks (in children under six, at least three of the first four).

(1) poor appetite or significant weight loss (when not dieting) or increased appetite or significant weight gain (in children under six, consider failure to make expected weight gains)
(2) insomnia or hypersomnia
(3) psychomotor agitation or retardation (but not merely subjective feelings of restlessness or being slowed down) (in children under six, hypoactivity)
(4) loss of interest or pleasure in usual activities, or decrease in sexual drive not limited to a period when delusional or hallucinating (in children under six, signs of apathy)
(5) loss of energy; fatigue
(6) feelings of worthlessness, self-reproach, or excessive or inappropriate guilt (either may be delusional)
(7) complaints or evidence of diminished ability to think or concentrate, such as slowed thinking, or indecisiveness not associated with marked loosening of associations or incoherence
(8) recurrent thoughts of death, suicidal ideation, wishes to be dead, or suicide attempt

C. Neither of the following dominate the clinical picture when an affective syndrome (i.e., criteria A and B above) is not present, that is, before it developed or after it has remitted:

(1) preoccupation with a mood-incongruent delusion or hallucination (see definition below)
(2) bizarre behavior

D. Not superimposed on either Schizophrenia, Schizophreniform Disorder, or a Paranoid Disorder.

E. Not due to any Organic Mental Disorder or Uncomplicated Bereavement.

Fifth-digit code numbers and criteria for subclassification of major depressive episode
(When psychotic features and Melancholia are present the coding system requires that the clinician record the single most clinically significant characteristic.)

6– In Remission. This fifth-digit category should be used when in the past the individual met the full criteria for a major depressive episode but now is essentially free of depressive symptoms or has some signs of the disorder but does not meet the full criteria.

4– With Psychotic Features. This fifth-digit category should be used when there apparently is gross impairment in reality testing, as when there are delusions or hallucinations, or depressive stupor (the individual

is mute and unresponsive). When possible, specify whether the psychotic features are mood-congruent or mood-incongruent. (The non-ICD-9-CM fifth-digit 7 may be used instead to indicate that the psychotic features are mood-incongruent; otherwise, mood-congruence may be assumed.)

Mood-congruent Psychotic Features. Delusions or hallucinations whose content is entirely consistent with the themes of either personal inadequacy, guilt, disease, death, nihilism, or deserved punishment; depressive stupor (the individual is mute and unresponsive).

Mood-incongruent Psychotic Features. Delusions or hallucinations whose content does not involve themes of either personal inadequacy, guilt, disease, death, nihilism, or deserved punishment. Included here are such symptoms as persecutory delusions, thought insertion, thought broadcasting, and delusions of control, whose content has no apparent relationship to any of the themes noted above.

3– With Melancholia.

A. Loss of pleasure in all or almost all activities.

B. Lack of reactivity to usually pleasurable stimuli (doesn't feel much better, even temporarily, when something good happens).

C. At least three of the following:

(a) distinct quality of depressed mood, i.e., the depressed mood is perceived as distinctly different from the kind of feeling experienced following the death of a loved one

(b) the depression is regularly worse in the morning

(c) early morning awakening (at least two hours before usual time of awakening)

(d) marked psychomotor retardation or agitation

(e) significant anorexia or weight loss

(f) excessive or inappropriate guilt

2– Without Melancholia

0– Unspecified

OTHER FEATURES OF BOTH MANIC AND MAJOR DEPRESSIVE EPISODES

Age at onset. The first manic episode of Bipolar Disorder typically occurs before age 30. Major Depression may begin at any age, including infancy, and the age at onset is fairly evenly distributed throughout adult life.

Course. Manic episodes typically begin suddenly, with a rapid escalation of symptoms over a few days. The episodes usually last from a few days to months and are briefer and end more abruptly than major depressive episodes.

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enclosure 4

PAGE NO. [ ]

NEWLY OBSERVED SIGNS AND SYMPTOMS CHECK-LIST

1. AUTONOMIC

- -DRY MOUTH
- -NASAL CONGESTION
- -BLURRED VISION
- -CONSTIPATION
- -URINARY HESITANCY
- -URINARY RETENTION
- -INCREASED SALIVATION
- -SWEATING
- -NAUSEA
- -VOMITING
- -DIARRHOEA
- -SEXUAL DISTURBANCES

2. BEHAVIORAL TOXICITY

- -CONFUSIONAL REACTION
- -EXCITEMENT/AGITATION
- -INCREASED MOTOR ACTIVITY
- -DECREASED MOTOR ACTIVITY
- -INSOMNIA
- -DROWSINESS
- -LASSITUDE

3. CARDIOVASCULAR

- -HYPOTENSION
- -DIZZINESS
- -CIRCULATORY COLLAPSE
- -TACHYCARDIA
- -HYPERTENSION

4. NEUROLOGICAL

- -RIGIDITY
- -TREMOR
- -AKATHISIA
- -DYSTONIA
- -PARESTHESIAS
- -SEIZURES

5. OTHER

- -SKIN-RASH
- -URTICARIA
- -DECREASED APPETITE
- -HEADACHE
- -WEIGHT GAIN
- -WEIGHT LOSS

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ALL NEWLY OBSERVED SIGNS AND SYMPTOMS

PROGRESSIVE NO.	1	2	3
SIGN OR SYMPTOM			
REPORTED	☐ SPONTANEOUSLY ☐ UPON ENQUIRY	☐ SPONTANEOUSLY ☐ UPON ENQUIRY	☐ SPONTANEOUSLY ☐ UPON ENQUIRY
PRESENT BEFORE START OF STUDY	☐ YES ☐ NO ☐ UNKNOWN	☐ YES ☐ NO ☐ UNKNOWN	☐ YES ☐ NO ☐ UNKNOWN
DATE OF ONSET	MONTH DAY YEAR	MONTH DAY YEAR	MONTH DAY YEAR
DURATION (DURING TREATMENT)	DAYS HOURS MIN	DAYS HOURS MIN	DAYS HOURS MIN
SEVERITY -MILD	☐	☐	☐
-MODERATE	☐	☐	☐
-SEVERE	☐	☐	☐
-VERY SEVERE	☐	☐	☐
RELATIONSHIP TO TRIAL MEDICATION -NONE	☐	☐	☐
-POSSIBLE, DOUBTFUL	☐	☐	☐
-PROBABLE	☐	☐	☐
-CERTAIN	☐	☐	☐
DID SIGN OR SYMPTOM REQUIRE TREATMENT?	☐ YES ☐ NO	☐ YES ☐ NO	☐ YES ☐ NO
IF YES SPECIFY: DRUG(S)			
DAILY DOSE AND ROUTE OF ADMINISTRATION			
DURATION OF TREAT. (DAYS)			
COURSE -DISAPPEARED, TRIAL DRUG CONTINUED	☐	☐	☐
-PERSISTED, TRIAL DRUG CONTINUED	☐	☐	☐
-DISAPPEARED, AFTER REDUCT. OF DOSE	☐	☐	☐
-PERSISTED, AFTER REDUCT. OF DOSE	☐	☐	☐
-NOT TOLERATED, TRIAL DRUG DISCONTINUED: -TEMPORARILY	☐	☐	☐
-DEFINITIVELY	☐	☐	☐
FOLLOW-UP: DURATION AFTER DISCONTINUATION OF TRIAL DRUG	___ DAYS	___ DAYS	___ DAYS
PATIENT OUTCOME -FULLY RECOVERED			
-RECOVERED WITH SEQUELAE			

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ASSESSMENT DAY [0 | 3 | 7 | 14 | 21 | 26] DATE [ ] DAY [ ] MONTH [ ] YEAR

CLINICAL GLOBAL IMPRESSION (CGI)

A. SEVERITY OF ILLNESS

CONSIDERING YOUR TOTAL CLINICAL EXPERIENCE WITH THIS PARTICULAR POPULATION, HOW MENTALLY ILL IS THE PATIENT AT THIS TIME?

[1] NORMAL, NOT AT ALL ILL
[2] BORDERLINE MENTALLY ILL
[3] MILDLY ILL
[4] MODERATELY ILL
[5] MARKEDLY ILL
[6] SEVERELY ILL
[7] AMONG THE MOST EXTREMELY ILL PATIENTS

B. GLOBAL IMPROVEMENT (RATE TOTAL IMPROVEMENT WHETHER OR NOT, IN YOUR JUDGEMENT, IT IS DUE ENTIRELY TO DRUG TREATMENT)

COMPARED TO HIS CONDITION AT ADMISSION TO THE STUDY, HOW MUCH HAS HE CHANGED?

[1] VERY MUCH IMPROVED
[2] MUCH IMPROVED
[3] MINIMALLY IMPROVED
[4] NO CHANGE
[5] MINIMALLY WORSE
[6] MUCH WORSE
[7] VERY MUCH WORSE

C. EFFICACY INDEX (RATE THIS ITEM ON THE BASIS OF DRUG EFFECT ONLY)

	TOLERABILITY: SIDE EFFECTS			
ACTIVITY	NONE	DO NOT SIGNIFICANTLY INTERFERE WITH PATIENT'S FUNCTIONING	SIGNIFICANTLY INTERFERE WITH PATIENT'S FUNCTIONING	OUTWEIGH THERAPEUTIC EFFECT
MARKED - VAST IMPROVEMENT, COMPLETE OR NEARLY COMPLETE REMISSION OF ALL SYMPTOMS	1	2	3	4
MODERATE - DECIDED IMPROVEMENT, PARTIAL REMISSION OF SYMPTOMS	5	6	7	8
MINIMAL - SLIGHT IMPROVEMENT WHICH DOES NOT ALTER STATUS OF CARE OF PATIENT	9	10	11	12
UNCHANGED OR WORSE	13	14	15	16

Enclosure C

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HAMD: HAMILTON DEPRESSION RATING SCALE

ITEMS	SCORE
1. DEPRESSED MOOD (SADNESS, HOPELESS, HELPLESS, WORTHLESS) 0 = ABSENT 1 = THESE FEELING STATES INDICATED ONLY ON QUESTIONING 2 = THESE FEELING STATES SPONTANEOUSLY REPORTED VERBALLY 3 = COMMUNICATES FEELING STATES NON-VERBALLY - I.E., THROUGH FACIAL EXPRESSION, POSTURE, VOICE, AND TENDENCY TO WEEP 4 = PATIENT REPORTS VIRTUALLY ONLY THESE FEELING STATES IN HIS SPONTANEOUS VERBAL AND NON-VERBAL COMMUNICATION	
2. FEELINGS OF GUILT 0 = ABSENT 1 = SELF REPROACH, FEELS HE HAS LET PEOPLE DOWN 2 = IDEAS OF GUILT OR RUMINATION OVER PAST ERRORS OR SINFUL DEEDS 3 = PRESENT ILLNESS IS A PUNISHMENT, DELUSION OF GUILT 4 = HEARS ACCUSATORY OR DENUNCIATORY VOICES AND/OR EXPERIENCES THREATENING VISUAL HALLUCINATIONS	
3. SUICIDE 0 = ABSENT 1 = FEELS LIFE IS NOT WORTH LIVING 2 = WISHES HE WERE DEAD OR ANY THOUGHTS OF POSSIBLE DEATH TO SELF 3 = SUICIDE IDEAS OR GESTURE 4 = ATTEMPTS AT SUICIDE (ANY SERIOUS ATTEMPT RATES 4)	
4. INSOMNIA EARLY 0 = NO DIFFICULTY FALLING ASLEEP 1 = COMPLAINS OF OCCASIONAL DIFFICULTY FALLING ASLEEP - I.E., MORE THAN ½ HOUR 2 = COMPLAINS OF NIGHTLY DIFFICULTY FALLING ASLEEP	
5. INSOMNIA MIDDLE 0 = NO DIFFICULTY 1 = PATIENT COMPLAINS OF BEING RESTLESS AND DISTURBED DURING THE NIGHT 2 = WAKING DURING THE NIGHT - ANY GETTING OUT OF BED RATES 2 (EXCEPT FOR PURPOSES OF VOIDING)	
6. INSOMNIA LATE 0 = NO DIFFICULTY 1 = WAKING IN EARLY HOURS OF THE MORNING BUT GOES BACK TO SLEEP 2 = UNABLE TO FALL ASLEEP AGAIN IF HE GETS OUT OF BED	
7. WORK AND ACTIVITIES 0 = NO DIFFICULTY 1 = THOUGHTS AND FEELINGS OF INCAPACITY, FATIGUE OR WEAKNESS RELATED TO ACTIVITIES; WORK OR HOBBIES 2 = LOSS OF INTEREST IN ACTIVITY; HOBBIES OR WORK - EITHER DIRECTLY REPORTED BY PATIENT, OR INDIRECT IN LISTLESSNESS, INDECISION AND VACILLATION (FEELS HE HAS TO PUSH SELF TO WORK OR ACTIVITIES) 3 = DECREASE IN ACTUAL TIME SPENT IN ACTIVITIES OR DECREASE IN PRODUCTIVITY. IN HOSPITAL, RATE 3 IF PATIENT DOES NOT SPEND AT LEAST THREE HOURS A DAY IN ACTIVITIES (HOSPITAL JOB OR HOBBIES) EXCLUSIVE OF WARD CHORES 4 = STOPPED WORKING BECAUSE OF PRESENT ILLNESS. IN HOSPITAL, RATE 4 IF PATIENT ENGAGES IN NO ACTIVITIES EXCEPT WARD CHORES, OR IF PATIENT FAILS TO PERFORM WARD CHORES UNASSISTED	
8. RETARDATION (SLOWNESS OF THOUGHT AND SPEECH, IMPAIRED ABILITY TO CONCENTRATE; DECREASED MOTOR ACTIVITY) 0 = NORMAL SPEECH AND THOUGHT 1 = SLIGHT RETARDATION AT INTERVIEW 2 = OBVIOUS RETARDATION AT INTERVIEW 3 = INTERVIEW DIFFICULT 4 = COMPLETE STUPOR	
9. AGITATION 0 = NONE 1 = FIDGETINESS 2 = PLAYING WITH HANDS, HAIR, ETC. 3 = MOVING ABOUT, CAN'T SIT STILL 4 = HAND WRINGING, NAIL BITING, HAIR-PULLING, BITING OF LIPS	
10. ANXIETY PSYCHIC 0 = NO DIFFICULTY 1 = SUBJECTIVE TENSION AND IRRITABILITY 2 = WORRYING ABOUT MINOR MATTERS 3 = APPREHENSIVE ATTITUDE APPARENT IN FACE OR SPEECH 4 = FEARS EXPRESSED WITHOUT QUESTIONING	
11. ANXIETY SOMATIC 0 = ABSENT 1 = MILD 2 = MODERATE 3 = SEVERE 4 = INCAPACITATING PHYSIOLOGICAL CONCOMITANTS OF ANXIETY, SUCH AS: -GASTRO-INTESTINAL: DRY MOUTH, WIND, INDIGESTION, DIARRHEA, CRAMPS, BELCHING -CARDIO-VASCULAR: PALPITATIONS, HEADACHES -RESPIRATORY: HYPERVENTILATION, SIGHING -URINARY FREQUENCY -SWEATING	

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I T E M S	SCORE
12. SOMATIC SYMPTOMS GASTROINTESTINAL 0 = NONE 1 = LOSS OF APPETITE BUT EATING WITHOUT STAFF ENCOURAGEMENT. HEAVY FEELINGS IN ABDOMEN 2 = DIFFICULTY EATING WITHOUT STAFF URGING. REQUESTS OR REQUIRES LAXATIVES OR MEDICATION FOR BOWELS OR MEDICATION FOR G.I. SYMPTOMS.	
13. SOMATIC SYMPTOMS GENERAL 0 = NONE 1 = HEAVINESS IN LIMBS, BACK OR HEAD. BACKACHES, HEADACHE, MUSCLE ACHES. LOSS OF ENERGY AND FATIGABILITY. 2 = ANY CLEAR-CUT SYMPTOM RATES 2	
14. GENITAL SYMPTOMS 0 = ABSENT 1 = MILD (SYMPTOMS SUCH AS: LOSS OF LIBIDO, MENSTRUAL DISTURBANCES) 2 = SEVERE	
15. HYPOCHONDRIASIS 0 = NOT PRESENT 1 = SELF-ABSORPTION (BODILY) 2 = PREOCCUPATION WITH HEALTH 3 = FREQUENT COMPLAINTS, REQUESTS FOR HELP, ETC. 4 = HYPOCHONDRIACAL DELUSIONS	
16. LOSS OF WEIGHT (RATE EITHER A OR B) A. WHEN RATING BY HISTORY 0 = NO WEIGHT LOSS 1 = PROBABLE WEIGHT LOSS ASSOCIATED WITH PRESENT ILLNESS 2 = DEFINITE (ACCORDING TO PATIENT) WEIGHT LOSS 3 = NOT ASSESSED B. ON WEEKLY RATINGS BY WARD PSYCHIATRISTS, WHEN ACTUAL WEIGHT CHANGES ARE MEASURED 0 = LESS THAN 1 LB. WEIGHT LOSS IN WEEK 1 = GREATER THAN 1 LB. WEIGHT LOSS IN WEEK 2 = GREATER THAN 2 LB. WEIGHT LOSS IN WEEK 3 = NOT ASSESSED	
17. INSIGHT 0 = ACKNOWLEDGES BEING DEPRESSED AND ILL 1 = ACKNOWLEDGES ILLNESS BUT ATTRIBUTES CAUSE TO BAD FOOD, CLIMATE, OVERWORK, VIRUS, NEED FOR REST, ETC. 2 = DENIES BEING ILL AT ALL	

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MADRS: MONTGOMERY ASBERG DEPRESSION RATING SCALE

I T E M S	SCORE
1. REPORTED SADNESS REPRESENTING SUBJECTIVELY EXPERIENCED MOOD, REGARDLESS OF WHETHER IT IS REFLECTED IN APPEARANCE OR NOT. INCLUDES DEPRESSED MOOD, LOW SPIRITS, DESPONDENCY, AND THE FEELING OF BEING BEYOND HELP AND WITHOUT HOPE. RATE ACCORDING TO INTENSITY, DURATION AND THE EXTENT TO WHICH THE MOOD IS INFLUENCED BY EVENTS. ELATED MOOD IS SCORED ZERO ON THIS ITEM. 0 = OCCASIONAL SADNESS MAY OCCUR IN THE CIRCUMSTANCES 1 = PREDOMINANT FEELINGS OF SADNESS, BUT BRIGHTER MOMENTS OCCUR 2 = PERVASIVE FEELINGS OF SADNESS OR GLOOMINESS. THE MOOD IS HARDLY INFLUENCED BY EXTERNAL CIRCUMSTANCES 3 = CONTINUOUS EXPERIENCE OF MISERY OR EXTREME DESPONDENCY	
2. INNER TENSION REPRESENTING FEELINGS OF ILL-DEFINED DISCOMFORT, EDGINESS, INNER TURMOIL, MENTAL TENSION MOUNTING TO PANIC, DREAD AND ANGUISH. RATE ACCORDING TO INTENSITY, FREQUENCY, DURATION AND THE EXTENT OF REASSURANCE CALLED FOR. DISTINGUISH FROM SADNESS, WORRYING AND MUSCULAR TENSION. 0 = PLACID. ONLY FLEETING INNER TENSION 1 = OCCASIONAL FEELINGS OF EDGINESS AND ILL-DEFINED DISCOMFORT 2 = CONTINUOUS FEELINGS OF INNER TENSION, OR INTERMITTENT PANIC WHICH THE PATIENT CAN ONLY MASTER WITH SOME DIFFICULTY 3 = UNRELENTING DREAD OR ANGUISH. OVERWHELMING PANIC	
3. APPARENT SADNESS REPRESENTING DESPONDENCY, GLOOM AND DESPAIR (MORE THAN JUST ORDINARY TRANSIENT LOW SPIRITS) REFLECTED IN SPEECH, FACIAL EXPRESSION, AND POSTURE. RATE BY DEPTH AND INABILITY TO BRIGHTEN UP. 0 = NO SADNESS 1 = LOOKS DISPIRITED BUT BRIGHTENS UP OCCASIONALLY 2 = APPEARS SAD AND UNHAPPY ALL OF THE TIME 3 = EXTREME AND CONTINUOUS GLOOM AND DESPONDENCY	
4. SUICIDAL THOUGHTS REPRESENTING THE FEELING THAT LIFE IS NOT WORTH LIVING, THAT A NATURAL DEATH WOULD BE WELCOME, SUICIDAL THOUGHTS, AND PREPARATIONS FOR SUICIDE. SUICIDAL ATTEMPTS SHOULD NOT IN THEMSELVES INFLUENCE THE RATING. 0 = ENJOYS LIFE OR TAKES IT AS IT COMES 1 = WEARY OF LIFE. ONLY FLEETING SUICIDAL THOUGHTS 2 = MUCH BETTER OFF DEAD. SUICIDAL THOUGHTS ARE COMMON, AND SUICIDE IS CONSIDERED AS A POSSIBLE SOLUTION, BUT WITHOUT SPECIFIC PLANS OR INTENTION 3 = EXPLICIT PLANS FOR SUICIDE WHEN THERE IS AN OPPORTUNITY. ACTIVE PREPARATION FOR SUICIDE	
5. INERTIA REPRESENTING A DIFFICULTY GETTING STARTED OR SLOWNESS INITIATING AND PERFORMING EVERYDAY ACTIVITIES. DISTINGUISH FROM INDECISION AND FATIGUABILITY. 0 = NO DIFFICULTY IN GETTING STARTED. NO SLUGGISHNESS 1 = DIFFICULTIES IN STARTING NEW ACTIVITIES 2 = DIFFICULTIES IN STARTING VERY SIMPLE ROUTINE ACTIVITIES, WHICH ARE CARRIED OUT ONLY WITH EFFORT 3 = COMPLETE INERTIA. UNABLE TO START ANY ACTIVITY WITHOUT HELP	
6. INABILITY TO FEEL REPRESENTING THE SUBJECTIVE EXPERIENCE OF REDUCED INTEREST IN THE SURROUNDINGS, OR ACTIVITIES THAT NORMALLY GIVE PLEASURE. THE ABILITY TO REACT WITH ADEQUATE EMOTION TO CIRCUMSTANCES OR PEOPLE IS REDUCED. DISTINGUISH FROM INERTIA. 0 = NORMAL INTEREST IN THE SURROUNDINGS AND IN OTHER PEOPLE 1 = REDUCED ABILITY TO ENJOY USUAL INTERESTS. REDUCED ABILITY TO FEEL ANGER 2 = LOSS OF INTEREST IN THE SURROUNDINGS. LOSS OF FEELINGS FOR FRIENDS AND ACQUAINTANCES 3 = THE EXPERIENCE OF BEING EMOTIONALLY PARALYZED, INABILITY TO FEEL ANGER OR GRIEF, AND A COMPLETE OR EVEN PAINFUL FAILURE TO FEEL FOR CLOSE RELATIVES AND FRIENDS	

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I T E M S	SCORE
7. PESSIMISTIC THOUGHTS REPRESENTING THOUGHTS OF GUILT, INFERIORITY, SELF-REPROACH, SINFULNESS, REMORSE AND RUIN. 0 = NO PESSIMISTIC THOUGHTS 1 = FLUCTUATING IDEAS OF FAILURE, SELF-REPROACH OR SELF-DEPRECIATION 2 = PERSISTENT SELF-ACCUSATIONS, OR DEFINITE BUT STILL RATIONAL IDEAS OF GUILT OR SIN. INCREASINGLY PESSIMISTIC ABOUT THE FUTURE 3 = DELUSIONS OF RUIN, REMORSE AND UNREDEEMABLE SIN. ABSURD SELF-ACCUSATIONS	
8. CONCENTRATION DIFFICULTIES REPRESENTING DIFFICULTIES IN COLLECTING ONE'S THOUGHTS MOUNTING TO INCAPACITATING LACK OF CONCENTRATION. RATE ACCORDING TO INTENSITY, FREQUENCY, AND DEGREE OF INCAPACITY PRODUCED. DISTINGUISH FROM FAILING MEMORY AND DISRUPTED THOUGHTS. 0 = NO DIFFICULTIES IN CONCENTRATING 1 = OCCASIONAL DIFFICULTIES IN COLLECTING ONE'S THOUGHTS 2 = DIFFICULTIES IN CONCENTRATING AND SUSTAINING THOUGHT WHICH INTERFERE WITH READING OR CONVERSATION 3 = INCAPACITATING LACK OF CONCENTRATION	
9. REDUCED SLEEP REPRESENTING A SUBJECTIVE EXPERIENCE OF REDUCED DURATION OR DEPTH OF SLEEP COMPARED TO THE SUBJECT'S OWN FITFUL SLEEP. 0 = SLEEP AS USUAL 1 = SLIGHT DIFFICULTY DROPPING OFF TO SLEEP OR SLIGHTLY REDUCED, LIGHT OR FITFUL SLEEP 2 = SLEEP REDUCED OR BROKEN BY AT LEAST 2 HOURS 3 = LESS THAN TWO OR THREE HOURS SLEEP	
10. REDUCED APPETITE REPRESENTING THE FEELING OF A LOSS OF APPETITE COMPARED WITH WHEN WELL 0 = NORMAL OR INCREASED APPETITE 1 = SLIGHTLY REDUCED APPETITE 2 = NO APPETITE. FOOD IS TASTLESS. NEED TO FORCE ONESELF TO EAT 3 = MUST BE FORCED TO EAT. FOOD REFUSAL	

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Enclosure 8

DO NOT WRITE IN THIS SPACE

PROJECT NO
INVESTIGATOR NO
PATIENT NO

INVESTIGATOR'S NAME

DO NOT WRITE IN THIS SPACE FOR USE IN COMPILING DATA

PATIENT'S INITIALS (FIRST, MID, LAST) PATIENT NO

VISIT NO 1

L.P.D. QUESTIONNAIRE

NAME (In full) ..... DATE .....
(Mr. Mrs. Miss)

AGE ..... RELIGION ..... OCCUPATION .....

MARRIED: SINGLE: WIDOWED: DIVORCED: SEPARATED:
(Please tick where appropriate)

How long have you been ill? .....

INSTRUCTIONS: Please answer these questions as quickly as possible.
Put a circle round your answer.

1. Are you more irritable towards other people ..... Yes No
2. Have you lost interest in watching television ..... Yes No
3. Do you have difficulty in falling asleep without tablets ..... Yes No
4. Do you feel depressed all day long ..... Yes No
5. Do you feel slowed up in your thinking ..... Yes No
6. Have you any serious money worries ..... Yes No
7. Have you had any recent family worries ..... Yes No
8. Have you lost someone you love in the past year ..... Yes No
9. Do you feel you are a bad person ..... Yes No
10. Have you moved house in the past year ..... Yes No
11. Do you avoid company ..... Yes No
12. Is it more difficult to concentrate on your work ..... Yes No
13. Have you any housing worries ..... Yes No
14. Do you wish you were able to cry ..... Yes No
15. Do you have a restless and disturbed sleep without tablets ..... Yes No
16. Do you feel most depressed in the evenings ..... Yes No
17. Are there times when you do not feel depressed ..... Yes No
18. Do you have less interest in reading newspapers ..... Yes No
19. Do you think you will get better ..... Yes No
20. Do you feel that people are sometimes talking about you ..... Yes No
21. Is it easy to fall asleep without tablets ..... Yes No
22. Is your appetite normal ..... Yes No
23. Have you less interest in sex ..... Yes No
24. Do you feel you are a burden to others ..... Yes No
25. Is life worth living ..... Yes No

Please turn over

9550321

DO NOT WRITE IN THIS SPACE

PROJECT NO ______

INVESTIGATOR NO ______

PATIENT NO ______

INVESTIGATOR'S NAME

DO NOT WRITE IN THIS SPACE (FOR USE IN COMPILING DATA)

PATIENT'S INITIALS FIRST | MID | LAST | PATIENT NO

VISIT NO. 1

PAGE 11 OF 12

L.P.D. QUESTIONNAIRE

26. Do you cry a lot .... Yes No
27. Are you unable to cry .... Yes No
28. Have you become constipated .... Yes No
29. Do you feel happier in the mornings .... Yes No
30. Do you suffer from a dry mouth .... Yes No
31. Have you less feeling for those close to you .... Yes No
32. Do you feel you are letting other people down .... Yes No
33. Have you lost your appetite .... Yes No
34. Have you had trouble at work in the past year .... Yes No
35. Do you wish you were dead .... Yes No
36. Do you waken much earlier than your usual time without tablets .... Yes No
37. Are you as good a person as most of your friends .... Yes No
38. Do you feel less depressed when you are with company .... Yes No
39. Do you think your illness is a punishment that you deserve .... Yes No
40. Do you have less interest in things you usually enjoy .... Yes No
41. Can you sleep normally without tablets .... Yes No
42. Do you waken at your usual time without tablets .... Yes No
43. Do you think there is something seriously wrong with your body .... Yes No
44. Is your depression the same all day long .... Yes No
45. Do you find difficulty in relaxing .... Yes No
46. Do you feel life is not worth living .... Yes No
47. Have you lost weight .... Yes No
48. Do you feel most depressed in the mornings .... Yes No
49. Have you overheard people talking about you .... Yes No
50. Do you feel this illness has been brought upon you by yourself .... Yes No
51. Do you feel slowed up in doing things .... Yes No
52. Does the future look hopeful .... Yes No
53. Do you feel happier in the evenings .... Yes No
54. Have you thought recently about ending your life .... Yes No
55. Do you feel time passing more slowly .... Yes No
56. Are you doing your work as well as you used to .... Yes No
57. Can you easily be cheered up .... Yes No

SCORE ....

PLEASE NOTE: THIS FORM MUST BE REPRODUCED — TYPE OR PRINT LEGIBLY WITH BLACK BALL POINT PEN

9550321

Enclosure 9

DECLARATION OF HELSINKI

RECOMMENDATIONS GUIDING MEDICAL DOCTORS IN BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

ADOPTED BY THE 18TH WORLD MEDICAL ASSEMBLY, HELSINKI, FINLAND, 1964, AND AS REVISED BY THE 29TH WORLD MEDICAL ASSEMBLY, TOKYO, JAPAN, 1975.

Med. J. Aust., 1976, 1: 206–207.

INTRODUCTION

It is the mission of the medical doctor to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the doctor with the words, "The health of my patient will be my first consideration", and the International Code of Medical Ethics declares that, "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest".

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 *a fortiori* to biomedical research.

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

In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, The World Medical Association has prepared the following recommendations as a guide to every doctor 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. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. BASIC PRINCIPLES

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

7. Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Doctors should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the doctor is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the research project the doctor 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 doctor who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE (CLINICAL RESEARCH)

1. In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, reestablishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient—including those of a control group, if any—should be assured of the best proven diagnostic and therapeutic method.

4. The refusal of the patient to participate in a study must never interfere with the doctor-patient relationship.

5. If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (1, 2).

6. The doctor can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (NON-CLINICAL BIOMEDICAL RESEARCH)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers—either healthy persons or patients for whom the experimental design is not related to the patient's illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

9550321

GRUPPO MONTEDISON
FARMITALIA CARLO ERBA
C N S Line

COMPOUND: REBOXETINE (FCE 20124)

PROTOCOL: A D E 0 0 9 - AMENDMENT

TITLE: PHASE II CONTROLLED STUDY OF THE ACTIVITY AND TOLERABILITY OF REBOXETINE IN COMPARISON WITH PLACEBO IN PATIENTS HOSPITALIZED FOR MAJOR DEPRESSIVE DISORDERS

DATE: JULY 1988

RATIONALE

The study protocol requires patient hospitalization for a minimum of 14 days in order to assure adequate monitoring of tolerability of the experimental treatment, particularly during the initial scaling-up week and the following week.

Several months of experience in the implementation of the protocol indicate that patient recruitment is not compatible with study completion in a reasonable time frame, the requirement for hospitalization being the major cause.

On the other hand, during these months phase II studies which are being carried out in Europe, Canada and Latin-America in patients suffering from Major Depressive Disorders and Panic Disorders have provided further evidence on the tolerability of reboxetine (in addition to the information gained in the dose range-finding study carried out in a total of 98 patients summarized in the protocol introduction).

In the running studies the compound is administered under double-blind conditions (vs desipramine and/or placebo) at maximum doses of 8 mg/day for 4-8 weeks.

A total of about 115 patients have so far participated in the ongoing studies, 45 of them having received reboxetine. No major adverse reactions were encountered, in no case treatment being discontinued because of intolerance.

ACTION

Patient source is extended to Day Hospital. Daily attendance is required. Treatment will be administered just after patient arrival to the Day Hospital in the morning and before departure in the evening. On Fridays patients will be provided with the exact number of capsules needed for the treatment on the following Saturday and Sunday. Treatment will be started on Monday in order to assure during the scaling up phase the monitoring of tolerability of each dose level with Day Hospital attendance for at least two consecutive days.

12.1.2 CRF SAMPLE

A complete CRF is filed in the Study Master File.

12.1.3 ETHICS 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 are filed in the Study Master File.

Pharmacia Document 9550321

12.1.4 CLINICAL INVESTIGATORS LIST

Centre 1:
Dr S Levine / Dr R Deo
Oldham & District General Hospital,
Rochdale Road,
Oldham, Lancashire, UK

Centre 2:
Dr E Stonehill
Central Middlesex Hospital,
Acton Lane - Royal Park,
London, UK

Centre 3:
Dr E Stonehill / Dr M Cozzolino
Roundwood Day Hospital,
Harlesden Road,
Willesden-London, UK

Centre 4:
Dr H Mathew
Staincliffe General Hospital,
Healds Road,
Dewsbury, Yorkshire, UK

Centre 5:
Dr S K Chakravarti
St Luke's Hospital,
St Luke's House,
Blackmoorfoot Road,
Huddersfield, UK

Centre 6:
Dr Sharma / Dr P K Mukherjee
Hartwood Hospital,
Shotts,
Lanarkshire, UK

Centre 7:
Dr P K Mukherjee
Monklands Dist. Gen. Hospital,
Airdrie, UK

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12.1.5 CERTIFICATES OF ANALYSIS

FARMITALIA CARLO ERBA

20159 MILANO - ITALIA
TELEFONO (02) 6115 1 (10
TELEGRAMMI ERBACAR -
CASELLA POSTALE 10519
C.C. POSTALE 617205
TELEX 330314 ERBAMI

ANALYSIS CERTIFICATE

FCE 20124 hard-gelatin capsules .
Capsules mg : 2 Batch : 898 .

MANUFACTURING DATE	: JUNE, 1987 .
EXPIRATION DATE	: JUNE, 1989 (stored at room temperature)
APPEARANCE	: opaque-white, hard gelatin capsule, self locking, size No.4, containing a white granular powder.
IDENTIFICATION	: positive (HPLC method) .
AVERAGE WEIGHT	: mg 91.22 .
UNIFORMITY OF WEIGHT	: within the limits, according to European Pharm. 1980, Section V.5.2 .
CONTENT UNIFORMITY	: complies, according to USP XXI page 1277 .
ASSAY	: mg 2.018 of FCE 20124/capsule.
DISINTEGRATION TIME	: 3 minutes .
ANALYZED BY	: Silvio Gambini . Silvio Gambini
APPROVED BY	: Virginio Busnelli : Busnelli Virginio
DATE	: JUNE 22, 1987 .

MOD 8133

FARMITALIA CARLO ERBA

9550321

ANALYSIS CERTIFICATE

PLACEBO for FCE 20124 capsules .
Batch SF : 897 .

MANUFACTURING DATE : MAY. 1987 .

APPEARANCE : opaque-white, hard gelatin capsule, self locking, size No.4, containing an off white powder .

IDENTIFICATION : absence of FCE 20124 (HPLC method) .

AVERAGE WEIGHT : mg 98.35 .

WEIGHT VARIATION : according to Europ. Pharm. Section V.5.2 .

DISINTEGRATION TIME : 2 minutes and 40 seconds .

ANALYZED BY : Silvio Gambini . Silvio Gambini

APPROVED BY : Virginio Busnelli. Busnelli Virginio

DATE : JUNE 22, 1987 .

MOD 5133

S.p.A. SEDE LEGALE IN MILANO - CAPITALE L. 70.866.677.100 I.V. - TRIBUNALE DI MILANO ...

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12.1.6 RANDOMIZATION LIST

R E B O X E T I N E 9550321 RANDOMIZATION CODE

PROTOCOL ADE 009

PATIENT N°	TREATMENT	PATIENT N°	TREATMENT
1	PL	26	RE
2	PL	27	PL
3	RE	28	PL
4	RE	29	RE
5	PL	30	PL
6	RE	31	RE
7	PL	32	PL
8	RE	33	RE
9	PL	34	RE
10	PL	35	PL
11	RE	36	PL
12	RE	37	RE
13	RE	38	RE
14	PL	39	PL
15	PL	40	PL
16	RE	41	PL
17	PL	42	RE
18	PL	43	RE
19	RE	44	PL
20	RE	45	PL
21	RE	46	PL
22	PL	47	RE
23	PL	48	RE
24	RE	49	RE
25	RE	50	RE

RE = REBOXETINE 2 mg - Batch N° SF 808

PL = PLACEBO Batch N° 807

R E B O X E T I N E - 9550321 RANDOMIZATION CODE

PROTOCOL ADE 009

PATIENT N°	TREATMENT	PATIENT N°	TREATMENT
51	PL	76	RE
52	PL	77	RE
53	RE	78	PL
54	PL	79	PL
55	PL	80	RE
56	RE	81	RE
57	PL	82	RE
58	RE	83	PL
59	RE	84	PL
60	PL	85	RE
61	PL	86	PL
62	PL	87	PL
63	RE	88	RE
64	RE	89	RE
65	PL	90	PL
66	RE	91	RE
67	RE	92	PL
68	PL	93	RE
69	RE	94	PL
70	PL	95	PL
71	RE	96	RE
72	PL	97	RE
73	RE	98	PL
74	PL	99	RE
75	PL	100	PL

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12.1.7 ECG CODES

REBOXETINE - PROTOCOL 20124/ADE009

APPENDIX No.: 12.1.7

ECG CODES

0 Normal

1 Rhythm disorders

10 Sinus bradycardia (<60)

20 Sinus tachycardia (>100)

30 Sick Sinus Syndrome

40 • Atrial ectopic beats:
- 41 - Occasional
- 42 - Frequent (>6/mm)
- 43 - Couplets
- 44 - Supraventricular Tachycardia

50 • Ventricular ectopic beats:
- 51 - Occasional
- 52 - Frequent (>6/mm)
- 53 - Polymorphic
- 54 - Couplets
- 55 - Ventricular Tachycardia

60 • Atrial fibrillation/flutter

105 • Vagotonia

108 • Atrial-ventricular dissociation

2 Conduction disorders

70 • A-V Block
- 71 - 1st degree
- 72 - 2nd degree - Mobitz 1
- 73 - - Mobitz 2
- Complete

85 • Right bundle branch block

86 • Left bundle branch block

87 • Left anterior hemiblock

88 • Left posterior hemiblock

89 • Bifascicular Block (specify)

90 • Trifascicular Block (specify)

91 • Conduction disorders

103 • Left axial deviation

106 • Right incomplete bundle branch block

3 Ischemic signs

102 • Ripolarization disturbances

107 • Non specific ST-T changes

82 • Myocardial ischemia

84 • Acute Myocardial infarction

4 Other

80 • Left ventricular hypertrophy

81 • Right ventricular hypertrophy

83 • Previous Myocardial infarction

93 • Other (specify)_____

104 • Right axial deviation

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12.1.8 STATISTICAL ANALYSIS

REBOXETINE - PROTOCOL 20124/ADE009
APPENDIX No.: 12.1.8

CUMULATIVE RISK OF DEVELOPING THE FIRST ADVERSE EVENT DURING TREATMENT

The LIFETEST Procedure

Summary of the Number of Censored and Uncensored Values

COD_TRT	Total	Failed	Censored	%Censored
PLC	24	15	9	37.5000
RBX	26	18	8	30.7692
Total	50	33	17	34.0000

Testing Homogeneity of Survival Curves over Strata
Time Variable DAY

Rank Statistics

COD_TRT	Log-Rank	Wilcoxon
PLC	-0.49189	15.000
RBX	0.49189	-15.000

Covariance Matrix for the Log-Rank Statistics

COD_TRT	PLC	RBX
PLC	7.57910	-7.57910
RBX	-7.57910	7.57910

Covariance Matrix for the Wilcoxon Statistics

COD_TRT	PLC	RBX
PLC	9751.62	-9751.62
RBX	-9751.62	9751.62

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.0319	1	0.8582
Wilcoxon	0.0231	1	0.8793
-2Log(LR)	0.2731	1	0.6013

12.2 Patient Information

Pharmacia Document 9550321

12.2.1 INDIVIDUAL DATA LISTINGS

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Sex	Age (years)	Weight (kg)	Height (cm)	DSM-III-R (*)	Date of hospitalization
1	1	Placebo	FA	Male	61			296.3	12/11/87
	3	Reboxetine	HH	Female	53			296.3	12/11/87
	4	Reboxetine	PG	Male	44			296.2	04/11/87
	5	Placebo	LS	Female	65	65.4	158.0	296.3	03/02/88
	6	Reboxetine	JW	Female	52			296.2	20/04/88
	7	Placebo	AI	Male	61	73.1	165.0	296.3	24/05/88
	8	Reboxetine	MP	Female	45	60.0	162.0	296.3	12/07/88
	9	Placebo	NP	Male	64	61.5	170.0	296.3	04/10/88
	10	Placebo	SH	Male	63	52.0	156.0	296.2	04/10/88
	11	Reboxetine	KM	Female	61	60.4	162.0	296.3	15/11/88
	12	Reboxetine	PO	Male	24	70.5	170.0	296.3	17/11/88
	13	Reboxetine	JF	Female	54	60.0	170.0	296.2	04/01/89
	14	Placebo	LE	Female	39	44.0	158.0	296.3	11/01/89
	15	Placebo	RB	Female	50	57.0	160.0	296.3	23/03/89
	16	Reboxetine	NL	Female	56	51.0	155.0	296.3	21/04/89
2	21	Reboxetine	KG	Female	44	76.5	169.0	296.3	29/01/88
	22	Placebo	KC	Female	60	57.0	155.0	296.2	25/04/88
	23	Placebo	MK	Female	34	96.0	169.0	296.2	15/12/88
	24	Reboxetine	MC	Female	50	76.0	169.0	296.3	24/01/89
	25	Reboxetine	IG	Female	60	68.0	167.0	296.3	09/02/89
3	26	Reboxetine	AM	Female	38	71.0	172.0	296.3	14/12/88
	27	Placebo	SW	Female	34	73.0	164.0	296.3	12/12/88
	28	Placebo	MM	Male	33	78.0	190.0	296.3	04/12/88
4	51	Placebo	RM	Female	30	50.8	172.0	296.3	08/04/88
	52	Placebo	J	Female	46	68.8	172.0	296.3	27/06/88
	53	Reboxetine	WS	Male	51	56.9	168.0	296.3	15/08/88
	54	Placebo	J	Female	37	119.0	166.0	296.3	14/11/88
	55	Placebo	JF	Male	47	76.0		296.3	20/05/88
	56	Reboxetine	JE	Female	31	63.5	175.0	296.3	05/01/89
	57	Placebo	MB	Female	36	66.0		296.3	10/03/89
	58	Reboxetine	RS	Male	24	96.0		296.2	16/03/89
	60	Placebo	M	Female	24	36.7	155.0	296.3	07/03/89
	61	Placebo	CK	Female	46	80.0		296.3	02/05/89
	62	Placebo	C	Female	27	41.0	155.0	296.3	04/05/89
	63	Reboxetine	PM	Female	43	80.0		296.3	09/05/89
	64	Reboxetine	DS	Male	41	68.0		296.3	07/12/88
	65	Placebo	PT	Male	56	70.0		296.2	18/05/89
	66	Reboxetine	PF	Female	33	95.0		296.3	23/05/89
	67	Reboxetine	BB	Male	44	80.0	155.0	296.3	09/05/89

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode
296.5=Major Depressive Disorder, Bipolar
300.4=Dysthymia

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 1.0

PATIENT IDENTIFICATION

Centre	Patient	Treatment	Initials	Sex	Age (years)	Weight (kg)	Height (cm)	DSM-III-R (*)	Date of hospitalization
5	71	Reboxetine	AC	Female	32	50.0	158.0	296.3	05/05/89
	72	Placebo	CC	Female	50	73.0	153.0	296.3	05/05/89
	73	Reboxetine	JH	Male	41	72.0	178.0	296.3	16/05/89
	74	Placebo	FK	Male	39	71.0	180.0	296.2	17/05/89
	75	Placebo	MS	Female	64	57.0	162.0	296.3	18/05/89
	76	Reboxetine	BM	Male	41	71.0	176.0	296.3	15/05/89
	77	Reboxetine	MB	Female	63	67.0	167.0	296.2	26/05/89
6	81	Reboxetine	RS	Female	44	69.0	162.0	296.2	08/02/89
	82	Reboxetine	GH	Male	64	64.0	163.0	296.2	27/02/89
	83	Placebo	MH	Female	63	49.0	161.0	296.3	03/12/86
7	89	Reboxetine	CM	Female	58	66.1	168.0	296.3	06/03/89

(*) DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode
296.5=Major Depressive Disorder, Bipolar
300.4=Dysthymia

REBOXETINE - PROTOCOL ADE09
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

Centre	Patient No.	Initials	DSM III Axis 1	Men. Dis. Unknown	Onset Age (years)	Number of Prev. Epis.	Last Episode Duration	Present Episode Duration at Admission	Present Episode Characterization	Present Episode Precip. External Stress
1	1	FA	296.3		21	4	2months	7weeks	rec. prev. cond.	absent
	3	HH	296.3		33	3	6months	3weeks	exac. chron. cond.	absent
	4	PG	296.2	YES				4weeks	first occ.	absent
	5	LS	296.3		45	4	3months	6weeks	rec. prev. cond.	absent
	6	JW	296.2	YES				3months	first occ.	absent
	7	AI	296.3		28	4	4months	5weeks	rec. prev. cond.	absent
	8	MP	296.3		41	1	2months	3months	rec. prev. cond.	absent
	9	NP	296.3		59	3	4months	3months	rec. prev. cond.	prob. pres.
	10	SH	296.2	YES				3months	first occ.	absent
	11	KM	296.3		60	1	2months	6weeks	rec. prev. cond.	prob. pres.
	12	PO	296.3		23	1	2months	3weeks	rec. prev. cond.	absent
	13	JF	296.2	YES	54			2months	first occ.	absent
	14	LE	296.3		38	1	2months	4weeks	rec. prev. cond.	prob. pres.
	15	RB	296.3		18	3	5months	4months	rec. prev. cond.	absent
	16	NL	296.3		37	4	4months	8months	rec. prev. cond.	prob. pres.
2	21	KG	296.3		41	1	12weeks	2months	rec. prev. cond.	defin. pres.
	22	KC	296.2		60			6months	first occ.	prob. pres.
	23	MK	296.2		34	0		3months	first occ.	defin. pres.
	24	MC	296.3		42	4	8months	8weeks	rec. prev. cond.	absent
	25	IG	296.3		60	5	3months	2months	rec. prev. cond.	prob. pres.
3	26	AM	296.3		17	10	6weeks	4weeks	rec. prev. cond.	absent
	27	SW	296.3		8	5	3months	6months	exac. chron. cond.	absent
	28	MM	296.3		14	10	8months	5months	exac. chron. cond.	absent
4	51	RM	296.3		20	6	4months/6weeks	5weeks	rec. prev. cond.	prob. pres.
	52	J	296.3		35	6	3months	3months	rec. prev. cond.	absent
	53	WS	296.3		33	5	5weeks	6weeks/3days	exac. chron. cond.	prob. pres.
	54	J	296.3		27	20	2months	3months	rec. prev. cond.	absent
	55	JF	296.3		40	1	2years	8months	rec. prev. cond.	prob. pres.
	56	JE	296.3		26	6	1months/1weeks	6weeks	exac. chron. cond.	absent
	57	MB	296.3	YES	34	1	6months	3months	diff. from prev. cond.	defin. pres.
	58	RS	296.2	YES	23	0		8months	first occ.	prob. pres.
	60	M	296.3		21	3	2months	8months	rec. prev. cond.	prob. pres.
	61	CK	296.3		21	10	2years/6months	5months	exac. chron. cond.	absent
	62	C	296.3		25	1	2months	2years	diff. from prev. cond.	absent
	63	PM	296.3		42	4	1months	1months	rec. prev. cond.	prob. pres.
	64	DS	296.3	YES	30	6	1months	12months	exac. chron. cond.	prob. pres.
	65	PT	296.2	YES	55			1years	first occ.	prob. pres.

DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode

REBOXETINE - PROTOCOL ADE09
Listing No.: 2.0

HISTORY OF MENTAL DISORDER AND PRESENT EPISODE

Centre	Patient No.	Initials	DSM III Axis 1	Men. Dis. Unknown	Onset Age (years)	Number of Prev. Epis.	Last Episode Duration	Present Episode Duration at Admission	Present Episode Characterization	Present Episode Precip. External Stress
4	66	PF	296.3	YES	28	12	12months	3years	rec. prev. cond.	prob. pres.
	67	BB	296.3		43	1	2months	8years	exac. chron. cond.	absent
5	71	AC	296.3		28	1	2months	6weeks	rec. prev. cond.	absent
	72	CC	296.3		40	3	4months	8weeks	rec. prev. cond.	absent
	73	JH	296.3		24	1	3months	6months	rec. prev. cond.	prob. pres.
	74	FK	296.2	YES				3months	first occ.	prob. pres.
	75	MS	296.3		54	2	8weeks	8weeks	rec. prev. cond.	absent
	76	BM	296.3		35	2	2months	8weeks	rec. prev. cond.	prob. pres.
	77	MB	296.2					9weeks	first occ.	absent
6	81	RS	296.2	YES	44		2months	8weeks	first occ.	absent
	82	GH	296.2	YES	64			4weeks	first occ.	prob. pres.
	83	MH	296.3		59	4	7weeks	5months	exac. chron. cond.	absent
7	89	CM	296.3		3	6	7weeks	10days	rec. prev. cond.	absent

DIAGNOSIS: 296.2=Major Depressive Disorder, First Episode
296.3=Major Depressive Disorder, Multiple Episode

REBOXETINE - PROTOCOL ADE09
Listing No.: 3.0

MEDICAL HISTORY

Centre	Patient	Previous diseases
1	9	DUODENAL ULCER NOS
2	22	MENIERE DISEASE
3	26	CHOLELITHIASIS NOS
	27	BRONCHITIS NOS
4	54	CHOLELITHIASIS NOS APPENDICITIS NOS IRREGULAR MENSTRUATION
	57	CYSTITIS NOS
	61	PULMONARY TB NOS RHEUMATOID ARTHRITIS OTHER PSORIASIS
	63	HERED PROG MUSC DYSTRPHY
7	89	DUODENAL ULCER NOS MASTOIDITIS NOS HYPERTENSION NOS FX ANKLE NOS-CLOSED

REBOXETINE - PROTOCOL ADE09
Listing No.: 4.0

PREVIOUS ANTIDEPRESSANT TREATMENTS

Centre	Patient	Initials	Treatment	Efficacy	Side Effects	Last Treatment Taken	Last Day of Treatment
1	1	FA	GAMANIL	FAIR		NARDIL	
1	3	HH	AMITRIPTYLINE	FAIR	YES	FLUANXOL	14OCT87
1	5	LS	MIANSERIN AMITRIPTYLINE LITHIUM	GOOD GOOD GOOD		LITHIUM	02FEB88
1	6	JW	PROTHIADEN GAMANIL	POOR POOR		GAMANIL	16APR88
1	7	AI	FLUVOXAMINE PROTHIADEN AMITRIPTYLINE MIANSERIN	VERY POOR POOR FAIR POOR		FLUVOXAMINE	21MAY88
1	8	MP	AMITRIPTYLINE	FAIR	YES	AMITRIPTYLINE	
1	9	NP	IMIPRAMINE AMITRIPTYLINE	GOOD GOOD		IMIPRAMINE	
1	11	KM	DOTHIEPIN	GOOD		DOTHIEPIN	
1	12	PO	PROTHIADEN	VERY GOOD		PROTHIADEN	
1	14	LE	PROTHIADEN	FAIR		PROTHIADEN	
1	15	RB	DOXEPIN PROTHIADEN	POOR VERY POOR		DOXEPIN	21MAR89
1	16	NL	AMITRIPTYLINE CLOMIPRAMINE MIANSERIN	POOR POOR FAIR		AMITRIPTYLINE	18APR89
2	22	KC	TRAZODONE	POOR	YES	TRAZODONE	25APR88
2	23	MK	TRANYLCYPROMINE	POOR		TRANYLCYPROMINE	15DEC88
2	24	MC	AMITRIPTYLINE	FAIR	YES	AMITRIPTYLINE	07FEB89

REBOXETINE - PROTOCOL ADE09
Listing No.: 4.0

PREVIOUS ANTIDEPRESSANT TREATMENTS

Centre	Patient	Initials	Treatment	Efficacy	Side Effects	Last Treatment Taken	Last Day of Treatment
2	25	IG	CLOMIPRAMINE	GOOD		CLOMIPRAMINE	13FEB89
3	26	AM	DOTHIEPIN LITHIUM CARBONATE	GOOD GOOD		LITHIUM CARBONATE	14DEC88
3	27	SH	AMITRIPTYLINE	POOR		AMITRIPTYLINE	11NOV88
4	51	RM	NORVAL SURMONTIL LUDIOMIL ANAFRANIL	VERY POOR VERY POOR GOOD POOR POOR	YES YES	NORVAL	19MAR88
4	52	J	PROTHIADEN SURMONTIL LITHIUM	FAIR FAIR GOOD	YES YES YES	IMIPRAMINE	26JUN88
4	53	WS	PARSTELIN AMITRIPTYLINE LITHIUM CARBONATE	POOR POOR POOR		LITHIUM CARBONATE	17AUG88
4	54	J	CLOMIPRAMINE GAMANIL	POOR POOR		GAMANIL	07AUG87
4	55	JF	MIANSERIN GAMANIL	POOR FAIR		IMIPRAMINE	12DEC88
4	56	JE	OPTIMAX CLOMIPRAMINE PRIADEL	POOR FAIR FAIR	YES YES	CLOMIPRAMINE	09JAN89
4	57	MB	PROTHIADEN PRIADEL			PROTHIADEN	03MAR89
4	58	RS	PROTHIADEN	VERY POOR		PROTHIADEN	
4	60	M	IMIPRAMINE	VERY POOR			05MAR89
4	61	CK	ANAFRANIL HOPANAL	POOR POOR		LITHIUM	01MAY89

REBOXETINE - PROTOCOL ADE09
Listing No.: 4.0

PREVIOUS ANTIDEPRESSANT TREATMENTS

Centre	Patient	Initials	Treatment	Efficacy	Side Effects	Last Treatment Taken	Last Day of Treatment
4	61	CK	LITHIUM	POOR	YES		
4	62	C	IMIPRAMINE	POOR		IMIPRAMINE	
4	63	PM	MIANSERIN	POOR		MIANSERIN	
4	64	DS	LITHIUM CARBONATE	POOR	YES	LITHIUM CARBONATE	
4	65	PT	NARDIL	POOR	YES	NARDIL	21APR89
4	66	PF	PROTHIADEN	POOR	YES	PROTHIADEN	03MAY89
4	67	BB	PARSTELIN PRIADEL	POOR POOR		PRIADEL	09MAY89
5	71	AC	PROTHIADEN	POOR	YES	PROTHIADEN	20APR89
5	72	CC	CLOMIPRAMINE	FAIR	YES	CLOMIPRAMINE	24APR89
5	73	JH	PROTHIADEN	POOR	YES	PROTHIADEN	10MAY89
5	75	MS	IMIPRAMINE	FAIR	YES	IMIPRAMINE	10MAY89
5	76	BM	PROTHIADEN	POOR	YES	PROTHIADEN	01APR89
6	81	RS	DOXEPIN	POOR		DOXEPIN	20MAR89
6	82	GH	DOTHIEPIN	POOR		DOTHIEPIN	19MAR89
6	83	MH	NOMIFENSINE	POOR POOR		FLUOXETINE	04MAY89
7	89	CM	GAMANIL	FAIR		GAMANIL	14JAN89

REBOXETINE - PROTOCOL ADE09
Listing No.: 5.0

CONCOMITANT DRUGS

Centre	Patient	Treatment Started on	Concomitant Drugs	Starting Date	Discontinuation Date	Reason for administration	Days of Administration	Interval Conc.Drug-Treat.
1	1	14NOV87	TEMAZEPAM	12NOV87		INSOMNIA	30	-2
1	3	14NOV87	TEMAZEPAM	12NOV87		INSOMNIA	30	-2
1	4	09DEC87	TEMAZEPAM	08DEC87		INSOMNIA	29	-1
1	8	15JUL88	TEMAZEPAM	13JUL88	30JUL88	INSOMNIA	18	-2
1	9	06OCT88	TEMAZEPAM	05OCT88	02NOV88	INSOMNIA	29	-1
1	10	07OCT88	TEMAZEPAM	06OCT88			30	-1
1	12	18NOV88	TEMAZEPAM	18NOV88	30NOV88		13	0
1	13	07JAN89	TEMAZEPAM	04JAN89		INSOMNIA	33	-3
			LORAZEPAM	06JAN89		INSOMNIA	31	-1
			LORAZEPAM	27JAN89		INSOMNIA	10	20
1	14	12JAN89	TEMAZEPAM	11JAN89		INSOMNIA	31	-1
1	16	24APR89	CHLORDIAZEPOXIDE	25APR89	22MAY89	ANXIETY	28	1
2	21	20FEB88	TEMAZEPAM	27FEB88			27	7
2	22	10MAY88	TEMAZEPAM	27MAY88			12	17
2	23	29DEC88	TEMAZEPAM	18DEC88		INSOMNIA	20	-11
2	24	15FEB89	TEMAZEPAM	21FEB89		INSOMNIA	22	6
2	25	21FEB89	TEMAZEPAM	22FEB89			28	1
3	27	28DEC88	TEMAZEPAM	30DEC88		INSOMNIA	27	2
			CHLORPROMAZINE	03JAN89	28JAN89	VOMITING,AGITATION,	26	6
			GLYCERIN	30DEC88	30DEC88	CONSTIPATION	1	2
3	28	28DEC88	PARACETAMOL	30DEC88		HEADACHE	14	2
			LACTULOSE	03JAN89			10	6
4	51	22APR88	TEMAZEPAM	08APR88		INSOMNIA	25	-14
			PARACETAMOL	02MAY88		ABDOMINAL PAIN	1	10
4	52	08JUL88	LACTULOSE	30JUN88	04AUG88	CONSTIPATION	36	-8
			TEMAZEPAM	27JUN88	28JUN88	INSOMNIA	2	-11
			TRIAZOLAM	29JUN88	04AUG88	INMOMNIA	37	-9
4	53	30SEP88	FYBOGEL	15SEP88		CONSTIPATION	36	-15
			TEMAZEPAM	22SEP88		INSOMNIA	29	-8

REBOXETINE - PROTOCOL ADE09
Listing No.: 5.0

CONCOMITANT DRUGS

Centre	Patient	Treatment Started on	Concomitant Drugs	Starting Date	Discontinuation Date	Reason for administration	Days of Administration	Interval Conc.Drug-Treat.
4	54	29NOV88	TEMAZEPAM					
4	55	23JAN89	TEMAZEPAM	10JAN89	08MAR89	INSOMNIA	58	-13
4	61	09MAY89	TEMAZEPAM					
4	64	23MAY89	TEMAZEPAM					
4	66	30MAY89	TEMAZEPAM					
4	67	30MAY89	TEMAZEPAM			INSOMNIA		
5	71	15MAY89	TEMAZEPAM	06MAY89	12JUN89	INSOMNIA	38	-9
5	72	11MAY89	TEMAZEPAM	10MAY89	08JUN89	INSOMNIA	30	-1
5	73	23MAY89	TEMAZEPAM	16MAY89	21JUN89	INSOMNIA	37	-7
5	74	23MAY89	TEMAZEPAM	20MAY89	21JUN89	INSOMNIA	33	-3
5	75	23MAY89	TEMAZEPAM	23MAY89		INSOMNIA	30	0
			CHLORPROMAZINE	19MAY89		AGITATION	34	-4
5	76	23MAY89	TEMAZEPAM	16MAY89	21JUN89	INSOMNIA	37	-7
5	77	01JUN89	VENTOLINE INHALATOR			BREATHING PROBLEMS		
6	82	24MAR89	LACTULOSE	05APR89		CONSTIPATION	20	12
7	89	12MAR89	ATENOLOL	01JAN84		HYPERTENSION	1919	-1897
			RANITIDINE	01JAN84		DUODENAL ULCER	1919	-1897
			IBUPROFEN	09MAR89		ARTHRITIS (L) ANKLE	25	-3
			TEMAZEPAM	06MAR89		SLEEP PROBLEMS	28	-6

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 6.0

EXPERIMENTAL TREATMENT

Centre	Patient	Treatment	From date	To date	Treat. days	Daily dose (mg)	Daily Caps.
1	1	Placebo	14/11/87	16/11/87	3	0	2
			17/11/87	20/11/87	4	0	3
			21/11/87	11/12/87	21	0	4
					28		
	3	Reboxetine	14/11/87	16/11/87	3	4	2
			17/11/87	20/11/87	4	6	3
			21/11/87	11/12/87	21	8	4
					28		
	4	Reboxetine	09/12/87	10/12/87	2	4	2
			11/12/87	15/12/87	5	6	3
			16/12/87	05/01/88	21	8	4
					28		
	5	Placebo	11/02/88	13/02/88	3	0	2
			14/02/88	17/02/88	4	0	3
			18/02/88	09/03/88	21	0	4
					28		
	6	Reboxetine	23/04/88	25/04/88	3	4	2
			26/04/88	29/04/88	4	6	3
			30/04/88	20/05/88	21	8	4
					28		
	7	Placebo	28/05/88	29/05/88	2	0	2
			30/05/88	03/06/88	5	0	3
			04/06/88	24/06/88	21	0	4
					28		
	8	Reboxetine	15/07/88	17/07/88	3	4	2
			18/07/88	21/07/88	4	6	3
			22/07/88	12/08/88	22	8	4
					29		
	9	Placebo	06/10/88	08/10/88	3	0	2
			09/10/88	12/10/88	4	0	3
			13/10/88	02/11/88	21	0	4
					28		
	10	Placebo	07/10/88	09/10/88	3	0	2

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EXPERIMENTAL TREATMENT

Centre	Patient	Treatment	From date	To date	Treat. days	Daily dose (mg)	Daily Caps.
1	10	Placebo	10/10/88	13/10/88	4	0	3
			14/10/88	04/11/88	22	0	4
					29		
	11	Reboxetine	15/11/88	17/11/88	3	4	2
			18/11/88	20/11/88	3	6	3
			21/11/88	12/12/88	22	8	4
					28		
	12	Reboxetine	18/11/88	20/11/88	3	4	2
			21/11/88	24/11/88	4	6	3
			25/11/88	30/11/88	6	8	4
					13		
	13	Reboxetine	07/01/89	09/01/89	3	4	2
			10/01/89	13/01/89	4	6	3
			14/01/89	05/02/89	23	8	4
					30		
	14	Placebo	12/01/89	15/01/89	4	0	2
			16/01/89	18/01/89	3	0	3
			19/01/89	10/02/89	23	0	4
					30		
	15	Placebo	28/03/89	30/03/89	3	0	2
			31/03/89	03/04/89	4	0	3
			04/04/89	17/04/89	14	0	4
					21		
	16	Reboxetine	24/04/89	26/04/89	3	4	2
			27/04/89	30/04/89	4	6	3
			01/05/89	22/05/89	22	8	4
					29		
2	21	Reboxetine	20/02/88	22/02/88	3	4	2
			23/02/88	27/02/88	5	6	3
			28/02/88	24/03/88	26	8	4
					34		
	22	Placebo	10/05/88	12/05/88	3	0	2
			13/05/88	16/05/88	4	0	3

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EXPERIMENTAL TREATMENT

Centre	Patient	Treatment	From date	To date	Treat. days	Daily dose (mg)	Daily Caps.
2	22	Placebo	17/05/88	07/06/88	22	0	4
					29		
	23	Placebo	29/12/88	31/12/88	3	0	2
			01/01/89	03/01/89	3	0	3
			04/01/89	06/01/89	3	0	4
					9		
	24	Reboxetine	15/02/89	17/02/89	3	4	2
			18/02/89	21/02/89	4	6	3
			22/02/89	14/03/89	21	8	4
					28		
	25	Reboxetine	21/02/89	23/02/89	3	4	2
			24/02/89	27/02/89	4	6	3
			28/02/89	21/03/89	22	8	4
					29		
3	26	Reboxetine	29/12/88	31/12/88	3	4	2
			01/01/89	04/01/89	4	6	3
			05/01/89	17/01/89	13	8	4
					20		
	27	Placebo	28/12/88	30/12/88	3	0	2
			31/12/88	02/01/89	3	0	3
			03/01/89	09/01/89	7	0	2
			10/01/89	25/01/89	16	0	4
					29		
	28	Placebo	28/12/88	30/12/88	3	0	2
			31/12/88	03/01/89	4	0	3
			04/01/89	12/01/89	9	0	4
					16		
4	51	Placebo	22/04/88	24/04/88	3	0	2
			25/04/88	28/04/88	4	0	3
			29/04/88	02/05/88	4	0	4
					11		
	52	Placebo	08/07/88	10/07/88	3	0	2
			11/07/88	14/07/88	4	0	3

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EXPERIMENTAL TREATMENT

Centre	Patient	Treatment	From date	To date	Treat. days	Daily dose (mg)	Daily Caps.
4	52	Placebo	15/07/88	04/08/88	21	0	4
					28		
	53	Reboxetine	30/09/88	02/10/88	3	4	2
			03/10/88	06/10/88	4	6	3
			07/10/88	20/10/88	14	8	4
					21		
	54	Placebo	29/11/88	01/12/88	3	0	2
			02/12/88	04/12/88	3	0	3
			05/12/88	26/12/88	22	0	4
					28		
	55	Placebo	23/01/89	26/01/89	4	0	2
			27/01/89	29/01/89	3	0	3
			30/01/89	20/02/89	22	0	4
					29		
	56	Reboxetine	24/01/89	26/01/89	3	4	2
			27/01/89	30/01/89	4	6	3
			31/01/89	22/02/89	23	8	4
					30		
	57	Placebo	15/03/89	16/03/89	2	0	2
			17/03/89	20/03/89	4	0	3
			21/03/89	10/04/89	21	0	4
					27		
	58	Reboxetine	21/03/89	23/03/89	3	4	2
			24/03/89	27/03/89	4	6	3
			28/03/89	03/04/89	7	8	4
					14		
	60	Placebo	14/03/89	17/03/89	4	0	2
			18/03/89	20/03/89	3	0	3
			21/03/89	10/04/89	21	0	4
					28		
	61	Placebo	09/05/89	11/05/89	3	0	2
			12/05/89	14/05/89	3	0	3
			15/05/89	05/06/89	22	0	4

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EXPERIMENTAL TREATMENT

Centre	Patient	Treatment	From date	To date	Treat. days	Daily dose (mg)	Daily Caps.
					28		
4	62	Placebo	09/05/89	11/05/89	3	0	2
					3		
	63	Reboxetine	16/05/89	18/05/89	3	4	2
			19/05/89	21/05/89	3	6	3
			22/05/89	11/06/89	21	8	4
					27		
	64	Reboxetine	23/05/89	26/05/89	4	4	2
			27/05/89	30/05/89	4	6	3
			31/05/89	19/06/89	20	8	4
					28		
	65	Placebo	23/05/89	25/05/89	3	0	2
			26/05/89	28/05/89	3	0	3
					6		
	66	Reboxetine	30/05/89	01/06/89	3	4	2
			02/06/89	05/06/89	4	6	3
			06/06/89	26/06/89	21	8	4
					28		
	67	Reboxetine	30/05/89	01/06/89	3	4	2
			02/06/89	04/06/89	3	6	3
			05/06/89	28/06/89	24	8	4
					30		
5	71	Reboxetine	15/05/89	17/05/89	3	4	2
			18/05/89	21/05/89	4	6	3
			22/05/89	12/06/89	22	8	4
					29		
	72	Placebo	11/05/89	14/05/89	4	0	2
			15/05/89	17/05/89	3	0	3
			18/05/89	08/06/89	22	0	4
					29		
	73	Reboxetine	23/05/89	25/05/89	3	4	2

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EXPERIMENTAL TREATMENT

Centre	Patient	Treatment	From date	To date	Treat. days	Daily dose (mg)	Daily Caps.
5	73	Reboxetine	26/05/89	30/05/89	5	6	3
			31/05/89	21/06/89	22	8	4
					30		
	74	Placebo	23/05/89	25/05/89	3	0	2
			26/05/89	31/05/89	6	0	3
			01/06/89	21/06/89	21	0	4
					30		
	75	Placebo	23/05/89	25/05/89	3	0	2
			26/05/89	31/05/89	6	0	3
			01/06/89	18/06/89	18	0	4
			19/06/89	21/06/89	3	0	2
					30		
	76	Reboxetine	23/05/89	25/05/89	3	4	2
			26/05/89	31/05/89	6	6	3
			01/06/89	21/06/89	21	8	4
					30		
	77	Reboxetine	01/06/89	03/06/89	3	4	2
			04/06/89	09/06/89	6	6	3
			10/06/89	29/06/89	20	8	4
					29		
6	81	Reboxetine	24/03/89	30/03/89	7	4	2
			31/03/89	02/04/89	3	6	3
			03/04/89	24/04/89	22	8	4
					32		
	82	Reboxetine	24/03/89	30/03/89	7	4	2
			31/03/89	02/04/89	3	6	3
			03/04/89	24/04/89	22	8	4
					32		
	83	Placebo	15/05/89	18/05/89	4	0	2
			19/05/89	21/05/89	3	0	3
			22/05/89	12/06/89	22	0	4
					29		
7	89	Reboxetine	12/03/89	15/03/89	4	4	2

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EXPERIMENTAL TREATMENT

Centre	Patient	Treatment	From date	To date	Treat. days	Daily dose (mg)	Daily Caps.
7	89	Reboxetine	16/03/89	19/03/89	4	6	3
			20/03/89	02/04/89	14	8	4
					22		

REBOXETINE - PROTOCOL ADE09
Listing No.: 7.0

REASONS FOR DISCONTINUATION OF TREATMENT

Centre	Patient	Reason for Discontinuation	Specify Reason
1	8	ADVERSE EXPERIENCE	PARESTHESIAS CYANOSIS
	12	INEFFECTIVENESS,DETERIORATION	
	15	INEFFECTIVENESS,NO CHANGE	
2	23	ADVERSE EXPERIENCE	EXTRASYSTOLES
3	26	INEFFECTIVENESS,DETERIORATION	
	28	PATIENT REFUSAL	
4	51	ADVERSE EXPERIENCE	BLEED.P.V,LASSITUDE,ABD.PAIN.
	53	PATIENT REFUSAL	FEELING AWFUL
	58	INEFFECTIVENESS,NO CHANGE	
	62	INEFFECTIVENESS,DETERIORATION	
	65	ADVERSE EXPERIENCE	MACULAR RASH ON NECK
5	75	INEFFECTIVENESS,DETERIORATION	
7	89	ADMINISTRATIVE	

REBOXETINE - PROTOCOL ADE09
Listing No.: 8.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Visit	Date Performed HAMD	It.1	It.2	It.3	It.4	It.6	It.6	It.7	It.8	It.9	It.10	It.11	It.12	It.13	It.14	It.15	It.16	It.17	Total Score
1	1	SCREEN	13NOV87	3	1	1	1	0	2	4	2	1	2	1	1	1	2	1	2	0	25
		DAY0	13NOV87	3	1	1	1	0	2	4	2	1	2	1	1	1	2	1	2	0	25
		DAY7	20NOV87	2	1	1	0	0	1	4	2	1	2	1	0	1	2	1	1	1	21
		DAY14	27NOV87	3	1	1	0	0	1	4	2	2	2	1	2	2	2	2	2	1	28
		DAY21	04DEC87	4	1	2	0	0	1	4	2	2	2	1	2	1	2	2	1	1	28
		DAY28	11DEC87	4	2	3	0	0	1	4	3	2	2	1	2	0	2	2	2	1	31
1	3	SCREEN	12NOV87	3	2	2	1	2	2	2	1	3	2	2	1	1	1	0	1	1	27
		DAY0	13NOV87	3	2	2	2	2	1	2	0	3	3	2	0	2	2	2	2	0	30
		DAY7	20NOV87	2	2	1	2	2	1	2	0	2	3	2	0	2	2	2	0	0	25
		DAY14	27NOV87	2	1	1	1	1	1	2	0	2	2	2	0	1	2	1	0	0	19
		DAY21	04DEC87	1	1	0	0	1	0	1	0	1	1	0	0	1	2	1	1	0	11
		DAY28	11DEC87	1	1	0	0	1	0	0	0	1	1	0	0	0	1	0	0	0	6
1	4	SCREEN	08DEC87	2	2	3	1	1	2	3	2	1	3	1	1	2	1	0	1	0	26
		DAY0	08DEC87	2	2	3	1	1	2	3	2	1	3	1	1	2	1	0	1	0	26
		DAY7	15DEC87	2	2	2	0	0	2	4	2	0	3	1	2	2	1	1		0	
		DAY14	22DEC87	1	1	0	0	0	1	3	1	0	2	1	1	1	1	0	0	0	13
		DAY21	29DEC87	1	0	0	0	0	0	1	0	0	1	0	1	0	0	0	0	0	4
		DAY28	05JAN88	2	1	1	0	0	2	2	1	1	2	0	0	1	1	1		0	
1	5	SCREEN	03FEB88	4	3	3	1	2	2	3	2	0	2	1	2	1	0	0	0	0	26
		DAY0	10FEB88	4	3	1	1	2	2	2	2	0	2	1	1	2	0	0	0	0	23
		DAY7	12FEB88	4	2	1	0	1	2	3	2	0	2	1	1	1	0	0	2	0	22
		DAY14	24FEB88	3	2	2	0	1	2	3	2	0	2	1	2	1	0	0	1	0	22
		DAY21	02MAR88	3	2	1	0	0	1	3	2	0	2	1	2	1	0	0	2	0	20
		DAY28	09MAR88	3	2	1	0	1	1	3	2	0	2	1	1	0	0	0	0	0	17
1	6	SCREEN	20APR88	3	3	2	1	1	2	3	2	3	2	2	1	1	2	2	2	0	32
		DAY0	22APR88	3	3	2	1	1	1	3	2	2	2	2	1	1	2	1	2	0	29
		DAY7	29APR88	2	2	2	1	0	0	3	2	1	2	2	1	1	2	1	0	0	22
		DAY14	06MAY88	2	2	2	0	0	1	2	2	1	2	2	1	1	2	1	0	0	21
		DAY21	13MAY88	1	1	0	0	0	1	1	1	1	1	1	0	0	1	1	0	0	10
		DAY28	20MAY88	0	0	0	0	0	1	0	1	1	0	0	0	0	1	0	1	0	5
1	7	SCREEN	25MAY88	4	1	2	2	2	2	4	1	2	2	1	1	1	1	0	1	0	27
		DAY0	27MAY88	4	1	3	2	2	2	4	2	3	3	1	1	1	1	0	1	0	31
		DAY7	03JUN88	2	1	1	1	2	2	2	1	0	2	0	0	1	1	0	0	0	16
		DAY14	10JUN88	1	1	0	0	1	1	1	0	0	2	0	0	0	1	0	0	0	8
		DAY21	17JUN88	1	1	0	1	1	1	1	0	0	2	1	0	1	1	0	0	0	11
		DAY28	24JUN88	2	1	0	2	1	1	2	1	0	1	1	0	2	1	0	0	0	15

HAMD: It.1=Depressed (0-4) It.2=Guilt (0-4) It.3=Suicide(0-4) It.4=Insomnia Early (0-2)
It.5=Insomnia Middle (0-2) It.6=Insomnia Late (0-2) It.7=Work/Activities (0-4) It.8=Retardation (0-4)
It.9=Agitation (0-4) It.10=Anxiety Psychic (0-4) It.11=Anxiety Somatic (0-4) It.12=Gastroin. Symp. (0-2)
It.13=General Symp. (0-2) It.14=Genital Symp. (0-2) It.15=Hypocondriasis (0-4) It.16=Loss Weight A or B (0-3)
It.17=Insight (0-2)

REBOXETINE - PROTOCOL ADE09
Listing No.: 8.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Visit	Date Performed HAMD	It.1	It.2	It.3	It.4	It.6	It.6	It.7	It.8	It.9	It.10	It.11	It.12	It.13	It.14	It.15	It.16	It.17	Total Score
1	8	SCREEN	13JUL88	3	2	2	2	1	2	2	2	3	2	1	1	2	2	1	2	0	30
		DAY0	14JUL88	3	2	2	2	1	2	2	2	2	2	1	1	2	2	1	2	0	29
		DAY7	22JUL88	2	1	1	1	2	2	1	1	1	1	1	1	2	2	1	0	0	20
		DAY14	28JUL88	2	1	0	1	1	0	0	0	1	1	1	0	0	1	1	0	0	10
1	9	SCREEN	04OCT88	3	1	1	2	1	2	3	1	2	3	1	1	1	1	0	2	0	25
		DAY0	05OCT88	3	1	1	2	1	2	3	1	2	3	1	1	1	1	0	2	0	25
		DAY7	12OCT88	3	1	1	2	2	1	3	2	2	3	1	1	0	1	1	1	0	25
		DAY14	19OCT88	1	1	0	2	0	1	3	1	2	3	1	0	0	0	0	0	0	15
		DAY21	26OCT88	1	1	0	1	0	1	3	1	2	3	1	1	0	0	0	0	0	15
		DAY28	02NOV88	1	1	0	1	0	1	2	1	2	3	1	0	0	0	0	0	0	13
1	10	SCREEN	04OCT88	3	1	1	1	1	2	3	2	2	2	1	1	2	2	0	2	0	26
		DAY0	06OCT88	3	1	1	1	1	2	3	2	2	2	1	1	2	2	0	2	0	26
		DAY7	13OCT88	2	1	1	0	0	1	2	1	2	2	1	1	2	2	2	1	0	21
		DAY14	21OCT88	2	1	0	0	0	0	2	1	2	1	2	1	2	2	2	0	0	18
		DAY21	28OCT88	1	0	0	0	0	0	1	0	1	1	1	1	1	1	1	0	0	9
		DAY28	04NOV88	0	0	0	0	0	0	1	0	0	1	0	0	1	0	0	0	0	3
1	11	SCREEN	15NOV88	2	3	2	0	1	1	3	1	2	3	1	1	1	1	0	0	0	22
		DAY0	15NOV88	2	3	2	0	1	1	3	1	2	3	1	1	1	1	0	0	0	22
		DAY7	22NOV88	1	3	1	0	1	1	2	1	1	3	1	1	1	1	0	0	0	18
		DAY14	29NOV88	1	2	0	0	1	0	1	1	1	2	0	0	1	1	0	0	0	11
		DAY21	05DEC88	0	1	0	0	0	0	0	0	1	1	0	0	1	1	0	0	0	5
		DAY28	12DEC88	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	2
1	12	SCREEN	17NOV88	3	1	1	2	1	2	3	2	0	2	0	1	1	1	0	2	0	22
		DAY0	18NOV88	3	1	1	2	1	2	3	2	0	2	0	1	1	1	0	2	0	22
		DAY7	25NOV88	3	2	2	2	0	2	3	2	1	2	1	1	1	1	1	2	1	27
		DAY14	30NOV88	3	2	3	1	1	2	3	2	1	2	2	2	2	2	1	2	1	32
1	13	SCREEN	04JAN89	2	2	2	1	2	2	2	2	1	2	2	1	2	1	2	2	0	28
		DAY0	06JAN89	2	2	2	1	2	2	2	1	2	2	1	2	1	2	2	2	0	28
		DAY7	13JAN89	2	1	2	1	2	2	2	1	1	2	2	1	2	1	2	0	0	24
		DAY14	20JAN89	2	0	1	1	2	2	2	1	1	2	1	1	2	1	2	0	0	21
		DAY21	27JAN89	1	0	0	1	2	2	1	0	1	1	1	1	1	1	1	0	0	14
		DAY28	03FEB89	1	0	0	0	1	2	0	0	1	2	1	0	0	1	1	0	0	10
1	14	SCREEN	11JAN89	3	0	1	1	1	1	2	2	3	2	2	2	2	2	1	2	0	27
		DAY0	11JAN89	3	0	1	1	1	1	2	2	3	2	2	2	2	2	1	2	0	27
		DAY7	18JAN89	3	0	1	0	0	1	2	2	2	2	2	1	2	2	1	1	2	24

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HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Visit	Date Performed HAMD	It.1	It.2	It.3	It.4	It.6	It.6	It.7	It.8	It.9	It.10	It.11	It.12	It.13	It.14	It.15	It.16	It.17	Total Score
1	14	DAY14	25JAN89	2	0	0	0	0	0	1	1	1	2	2	1	1	2	1	0	0	14
		DAY21	01FEB89	1	0	0	0	0	0	1	0	0	1	1	1	0	2	0	0	0	8
		DAY28	10FEB89	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	2
1	15	SCREEN	23FEB89	3	2	2	0	2	1	4	2	0	3	1	1	1	1	0	2	0	25
		DAY0	27MAR89	3	2	2	0	2	1	4	2	0	3	1	1	1	1	0	2	0	25
		DAY7	03APR89	3	1	1	0	1	1	3	2	3	4	3	1	1	1	1	0	0	26
		DAY14	10APR89	2	1	1	1	1	1	3	1	0	3	2	1	1	0	1	0	0	19
		DAY21	17APR89	2	2	1	0	2	2	3	1	0	1	1	0	1	1	0	0	0	17
1	16	SCREEN	21APR89	3	2	1	2	1	0	4	1	1	3	2	1	1	1	1	0	0	24
		DAY0	24APR89	3	2	1	2	1	1	4	1	0	3	1	1	1	1	0	0	0	22
		DAY7	02MAY89	0	0	0	1	0	0	2	0	0	0	0	1	0	0	0	0	0	4
		DAY14	08MAY89	2	2	0	2	1	2	2	0	0	3	2	1	2	0	2	0	0	21
		DAY21	15MAY89	1	1	0	2	2	2	2	0	1	1	2	1	1	0	1	0	0	17
		DAY28	22MAY89	2	1	0	2	1	2	2	0	1	2	1	1	1	0	1	0	0	17
2	21	SCREEN	15FEB88	2	2	1	1	1	2	2	0	0	2	1	1	1	1	0	1	0	18
		DAY0	19FEB88	2	2	1	1	1	2	2	0	0	2	1	1	1	1	1	1	0	19
		DAY7	29FEB88	2	2	1	0	2	2	2	0	0	2	1	1	1	1	1	0	0	18
		DAY14	07MAR88	2	2	1	1	2	2	2	0	1	2	1	1	1	1	1	1	0	21
		DAY21	16MAR88	1	1	0	1	2	1	0	0	0	0	1	1	0	1	1	0	0	10
		DAY28	23MAR88	0	1	0	1	1	0	0	0	0	0	1	1	0	1	1	0	0	7
2	22	SCREEN	29APR88	3	1	0	2	1	2	2	1	1	3	2	1	1	0	3	2	0	25
		DAY0	09MAY88	3	1	0	2	1	2	3	2	2	3	2	1	1	0	2	2	0	27
		DAY7	16MAY88	3	1	0	2	1	1	3	1	2	3	2	1	1	0	2	1	0	24
		DAY14	23MAY88	3	1	0	2	2	2	2	1	1	2	2	1	1	0	2	1	0	23
		DAY21	31MAY88	3	1	0	0	1	2	2	1	1	2	2	1	1	0	2	0	0	19
		DAY28	07JUN88	3	1	0	0	0	2	3	1	1	2	2	1	0	2	0	0	0	18
2	23	SCREEN	16DEC88	2	1	1	2	1	2	4	0	1	2	1	1	1	1	0	1	0	21
		DAY0	28DEC88	3	1	1	2	2	2	4	1	1	1	1	1	1	1	0	0	0	22
		DAY7	05JAN89	1	1	0	1	2	2	3	1	1	1	1	1	0	1	0	0	0	16
2	24	SCREEN	07FEB89	2	1	1	2	1	2	3	2	0	2	2	1	1	2	2	1	0	25
		DAY0	14FEB89	2	0	0	2	1	2	3	1	0	2	2	1	1	2	2	1	0	22
		DAY7	21FEB89	2	0	0	1	1	2	3	1	0	2	1	1	1	2	2	1	0	20
		DAY14	01MAR89	2	1	0	2	1	2	3	2	0	2	1	1	1	2	2	1	0	23
		DAY21	08MAR89	2	1	0	2	2	2	3	1	0	1	1	1	1	2	1	0	0	20
		DAY28	15MAR89	3	1	1	2	2	2	3	2	2	3	1	1	1	1	1	0	0	26

HAMD: It.1=Depressed (0-4) It.2=Guilt (0-4) It.3=Suicide(0-4) It.4=Insomnia Early (0-2)
It.5=Insomnia Middle (0-2) It.6=Insomnia Late (0-2) It.7=Work/Activities (0-4) It.8=Retardation (0-4)
It.9=Agitation (0-4) It.10=Anxiety Psychic (0-4) It.11=Anxiety Somatic (0-4) It.12=Gastroin. Symp. (0-2)
It.13=General Symp. (0-2) It.14=Genital Symp. (0-2) It.15=Hypocondriasis (0-4) It.16=Loss Weight A or B (0-3)
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REBOXETINE - PROTOCOL ADE09
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HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Visit	Date Performed HAMD	It.1	It.2	It.3	It.4	It.6	It.6	It.7	It.8	It.9	It.10	It.11	It.12	It.13	It.14	It.15	It.16	It.17	Total Score
2	25	SCREEN	13FEB89	3	1	1	2	2	2	4	1	2	3	1	1	2	2	2	1	0	30
		DAY0	20FEB89	3	1	2	2	2	2	3	0	2	3	2	1	1	2	0	1	0	27
		DAY7	28FEB89	3	1	1	2	2	2	3	1	2	3	2	1	1	2	1	1	0	28
		DAY14	07MAR89	3	1	1	2	2	2	2	1	1	1	1	1	1	2	1	0	0	22
		DAY21	14MAR89	3	2	1	2	2	2	2	2	2	2	1	1	1	2	2	1	0	28
		DAY28	21MAR89	3	2	1	2	2	2	3	2	2	3	2	1	1	2	2	1	0	31
3	26	SCREEN	14DEC88	2	1	0	2	2	0	2	1	1	2	2	1	1	1	1	1	0	20
		DAY0	29DEC88	2	1	0	2	2	0	2	1	1	2	2	1	1	1	1	1	0	20
		DAY7	04JAN89	3	1	0	2	1	0	2	2	0	2	1	1	2	2	0	1	0	20
		DAY14	11JAN89	3	1	0	2	1	0	2	2	0	2	1	1	2	2	0	1	0	20
		DAY21	18JAN89	3	2	0	1	0	2	3	2	1	3	1	1	1	2	0	1	0	23
3	27	SCREEN	13DEC88	2	2	3	2	0	1	3	1	1	2	2	1	1	2	0	0	0	23
		DAY0	28DEC88	2	2	3	2	0	0	3	1	1	2	2	1	1	2	0	0	0	22
		DAY7	03JAN89	3	3	2	2	2	2	3	1	3	2	2	1	1	2	1	0	0	30
		DAY14	10JAN89	2	1	2	2	1	0	2	1	1	2	2	1	1	2	0	0	0	20
		DAY21	18JAN89	1	2	1	2	0	1	1	1	0	2	2	1	1	2	1	2	0	20
		DAY28	26JAN89	2	2	2	2	2	2	2	1	0	2	1	0	1	2	0		0	
3	28	SCREEN	12DEC88	2	3	3	2	2	1	3	0	2	2	1	1	1	1	0	1	0	25
		DAY0	28DEC88	2	3	3	2	2	1	3	0	2	2	1	1	1	1	0	1	0	25
		DAY7	03JAN89	0	0	0	0	2	1	0	0	1	1	1	0	1	0	0	0	0	7
		DAY14	10JAN89	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	51	SCREEN	15APR88	1	1	0	2	2	2	2	1	1	1	2	2	1	1	0	2	1	22
		DAY0	22APR88	1	2	0	1	1	2	2	1	1	1	1	0	1	1	2	2	1	20
		DAY7	29APR88	1	0	0	0	0	1	1	0	1	1	0	0	0	1	0	1	0	7
4	52	SCREEN	01JUL88	4	0	3	2	2	2	3	1	2	1	3	1	1	1	0	0	0	26
		DAY0	07JUL88	3	0	0	0	2	0	4	1	0	1	1	2	1	1	0	2	1	19
		DAY7	14JUL88	1	0	0	2	1	1	3	1	0	1	1	1	1	1	0	0	0	14
		DAY14	21JUL88	1	0	0	1	2	1	2	1	0	2	1	1	1	1	0	0	0	14
		DAY21	28JUL88	1	0	0	1	2	1	0	0	0	2	1	1	1	1	0	0	0	11
		DAY28	04AUG88	4	0	0	2	0	0	2	1	0	3	2	2	1	1	0	0	0	18
4	53	SCREEN	27SEP88	3	1	0	2	1	2	4	1	3	2	2	2	1	2	3	1	1	31
		DAY0	29SEP88	3	1	0	2	1	2	4	1	3	2	2	2	1	2	3	1	1	31
		DAY7	06OCT88	3	0	1	2	2	2	3	3	1	3	3	1	2	2	4	1	0	33
		DAY14	13OCT88	3	1	0	1	1	2	3	1	1	3	2	1	1	2	4	1	0	27

HAMD: It.1=Depressed (0-4) It.2=Guilt (0-4) It.3=Suicide(0-4) It.4=Insomnia Early (0-2)
It.5=Insomnia Middle (0-2) It.6=Insomnia Late (0-2) It.7=Work/Activities (0-4) It.8=Retardation (0-4)
It.9=Agitation (0-4) It.10=Anxiety Psychic (0-4) It.11=Anxiety Somatic (0-4) It.12=Gastroin. Symp. (0-2)
It.13=General Symp. (0-2) It.14=Genital Symp. (0-2) It.15=Hypocondriasis (0-4) It.16=Loss Weight A or B (0-3)
It.17=Insight (0-2)

REBOXETINE - PROTOCOL ADE09
Listing No.: 8.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Visit	Date Performed HAMD	It.1	It.2	It.3	It.4	It.6	It.6	It.7	It.8	It.9	It.10	It.11	It.12	It.13	It.14	It.15	It.16	It.17	Total Score
4	54	SCREEN	26NOV88	4	2	3	1	1	2	3	1	2	3	2	0	1	2	2	0	0	29
		DAY0	28NOV88	2	3	2	1	1	1	3	2	2	3	2	2	3	1	3	0	0	31
		DAY7	05DEC88	1	2	1	1	1	1	2	2	2	2	2	1	2	2	2	0	1	25
		DAY14	12DEC88	1	2	0	1	1	1	2	2	1	2	2	1	1	1	2	0	1	21
		DAY21	19DEC88	2	3	1	1	1	1	2	2	1	2	2	1	1	0	2	0	0	22
		DAY28	28DEC88	1	2	1	1	1	1	2	2	1	2	2	0	2	1	1	0	0	20
4	55	SCREEN	20JAN89	3	3	2	1	1	1	3	1	2	2	1	0	1	2	1	1	1	26
		DAY0	24JAN89	3	3	2	1	1	1	3	1	2	2	1	0	1	2	1	1	1	26
		DAY7	30JAN89	3	2	2	1	1	1	3	1	1	2	1	0	1	1	1	1	1	23
		DAY14	06FEB89	2	0	1	1	1	0	2	1	2	1	2	1	0	0	1	1	0	16
		DAY21	13FEB89	2	0	0	1	1	0	2	1	2	1	2	1	0	1	0	1	0	15
		DAY28	20FEB89	1	1	0	1	1	1	2	1	0	1	1	0	0	0	1	0	1	12
4	56	SCREEN	20JAN89	2	2	3	1	2	0	4	2	3	3	4	2	1	2	0	2	0	33
		DAY0	23JAN89	2	2	2	0	2	0	4	2	3	2	2	2	2	2	0	2	0	29
		DAY7	30JAN89	3	0	0	0	2	1	3	1	1	3	3	2	2	2	0	1	0	24
		DAY14	06FEB89	3	0	0	1	1	0	4	1	2	1	2	1	1	2	0	0	0	19
		DAY21	13FEB89	3	0	1	1	1	1	4	1	1	1	1	1	2	2	0	0	0	20
		DAY28	20FEB89	2	0	0	1	1	0	4	0	2	1	1	1	1	2	0	0	0	16
4	57	SCREEN	10MAR89	4	3	2	2	2	2	3	2	2	1	1	1	1	0	0	1	1	28
		DAY0	14MAR89	3	3	2	2	2	2	2	2	2	1	1	1	1	0	0	1	1	26
		DAY7	20MAR89	1	2	1	1	1	1	2	1	1	1	1	1	1	0	0	0	1	16
		DAY14	28MAR89	3	1	0	2	1	2	3	1	1	1	2	2	2	0	1	0	0	22
		DAY21	05APR89	2	1	0	2	2	2	1	1	0	1	1	0	1	1	0	0	0	15
		DAY28	10APR89	1	0	0	1	2	1	1	0	1	1	0	1	0	0	0	0	0	9
4	58	SCREEN	16MAR89	3	0	0	0	0	0	4	3	2	2	2	1	2	2	2	0	0	23
		DAY0	20MAR89	3	0	0	0	0	0	3	1	2	1	1	2	2	1	3	0	0	19
		DAY7	28MAR89	3	1	0	0	0	0	2	1	1	1	2	1	1	1	0	0	0	14
		DAY14	03APR89	2	1	0	0	0	0	3	2	2	1	2	1	1	1	2	0	0	18
4	60	SCREEN	07MAR89	3	2	0	2	2	2	3	2	2	2	2	0	1	1	2	2	0	28
		DAY0	13MAR89	3	2	0	2	2	1	2	1	1	1	0	0	1	1	2	2	0	21
		DAY7	20MAR89	1	1	0	0	0	0	1	1	0	0	1	1	0	1	1	2	0	10
		DAY14	28MAR89	1	0	0	0	0	0	4	1	1	1	1	0	0	2	0	0	0	11
		DAY21	03APR89	2	1	0	0	0	0	1	0	0	2	1	0	1	2	1	0	0	11
		DAY28	10APR89	2	0	0	0	0	0	1	0	0	1	0	0	1	1	0	0	0	6
4	61	SCREEN	02MAY89	3	3	1	2	1	1	3	0	2	2	2	1	1	1	3	0	1	27

HAMD: It.1=Depressed (0-4) It.2=Guilt (0-4) It.3=Suicide(0-4) It.4=Insomnia Early (0-2)
It.5=Insomnia Middle (0-2) It.6=Insomnia Late (0-2) It.7=Work/Activities (0-4) It.8=Retardation (0-4)
It.9=Agitation (0-4) It.10=Anxiety Psychic (0-4) It.11=Anxiety Somatic (0-4) It.12=Gastroin. Symp. (0-2)
It.13=General Symp. (0-2) It.14=Genital Symp. (0-2) It.15=Hypocondriasis (0-4) It.16=Loss Weight A or B (0-3)
It.17=Insight (0-2)

REBOXETINE - PROTOCOL ADE09
Listing No.: 8.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Visit	Date Performed HAMD	It.1	It.2	It.3	It.4	It.6	It.6	It.7	It.8	It.9	It.10	It.11	It.12	It.13	It.14	It.15	It.16	It.17	Total Score
4	61	DAY0	09MAY89	3	2	2	0	1	2	3	0	2	3	3	1	1	1	3	0	1	28
		DAY7	15MAY89	3	1	1	1	1	1	3	2	1	2	2	1	1	1	3	0	1	25
		DAY14	22MAY89	3	2	1	1	2	1	3	1	2	1	1	1	2	1	2	0	1	25
		DAY21	01JUN89	3	0	1	0	2	1	3	1	2	2	1	1	1	1	1	0	0	20
		DAY28	05JUN89	3	0	2	0	1	1	2	1	2	1	2	1	1	0	2	0	0	19
4	62	SCREEN	04MAY89	3	3	0	2	1	2	2	2	2	2	2	1	2	2	2	1	1	30
		DAY0	09MAY89	3	3	0	2	2	1	3	2	2	1	1	2	1	1	1	1	1	27
4	63	SCREEN	09MAY89	3	2	0	1	1	2	3	2	1	2	3	2	2	0	2	2	2	30
		DAY0	16MAY89	3	2	0	1	1	2	2	2	2	1	1	1	1	1	2	1	0	23
		DAY7	22MAY89	3	1	0	0	1	0	2	2	1	1	1	1	2	0	1	0	0	16
		DAY14	01JUN89	2	1	0	1	1	1	2	1	1	2	2	1	1	0	1	0	0	17
		DAY21	05JUN89	3	0	0	1	1	1	2	2	1	2	1	1	1	0	1	0	0	17
		DAY28	12JUN89	1	0	0	0	1	1	1	0	1	1	1	1	0	0	1	0	0	9
4	64	SCREEN	16MAY89	3	2	0	1	1	1	3	2	1	1	1	1	1	1	2	1	1	23
		DAY0	23MAY89	3	1	0	1	1	1	2	2	1	1	1	1	1	1	2	0	1	20
		DAY7	31MAY89	2	1	1	1	2	2	3	1	1	2	2	1	1	1	1	0	0	22
		DAY14	05JUN89	2	1	1	1	1	1	2	1	1	2	1	1	1	0	1	0	0	17
		DAY21	12JUN89	2	1	0	1	1	1	2	1	0	1	1	1	1	1	1	0	0	15
		DAY28	19JUN89	2	1	1	1	1	1	1	2	1	1	1	1	1	0	1	0	0	16
4	65	SCREEN	18MAY89	3	2	0	2	2	1	4	2	2	3	2	1	2	2	2	0	0	30
		DAY0	23MAY89	3	2	0	2	1	1	2	2	2	2	1	1	1	1	2	0	0	23
4	66	SCREEN	23MAY89	3	1	0	2	1	2	4	2	1	1	2	1	1	0	0	0	1	22
		DAY0	31MAY89	3	1	0	2	2	2	3	1	1	1	1	1	0	0	0	0	1	19
		DAY7	05JUN89	2	2	0	1	1	1	2	2	2	1	1	1	1	0	1	0	0	18
		DAY14	12JUN89	2	1	0	0	1	1	2	1	2	1	1	1	1	0	1	0	0	15
		DAY21	19JUN89	2	1	0	0	1	0	2	1	1	1	1	1	0	0	0	0	0	11
		DAY28	26JUN89	1	0	0	0	0	0	1	0	1	1	2	1	0	0		1	0	
4	67	SCREEN	25MAY89	3	1	0	0	2	1	3	3	2	2	2	2	2	2	1	0	0	26
		DAY0	31MAY89	2	2	0	1	1	1	2	1	2	2	1	0	1	1	1	0	0	18
		DAY7	05JUN89	2	1	0	1	1	1	2	0	3	1	3	2	1	1	2	0	0	21
		DAY14	12JUN89	2	1	0	1	1	1	2	1	3	1	2	1	1	0	2	1	0	20
		DAY21	19JUN89	2	1	0	1	1	1	2	1	3	1	1	1	1	0	2	1	0	19
		DAY28	26JUN89	2	1	0	1	1	1	3	1	3	2	2	1	1	0	1	1	0	21
5	71	SCREEN	10MAY89	3	3	2	1	1	1	3	3	3	3	3	1	1	1	2	1	0	32

HAMD: It.1=Depressed (0-4) It.2=Guilt (0-4) It.3=Suicide(0-4) It.4=Insomnia Early (0-2)
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It.13=General Symp. (0-2) It.14=Genital Symp. (0-2) It.15=Hypocondriasis (0-4) It.16=Loss Weight A or B (0-3)
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REBOXETINE - PROTOCOL ADE09
Listing No.: 8.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Visit	Date Performed HAMD	It.1	It.2	It.3	It.4	It.6	It.6	It.7	It.8	It.9	It.10	It.11	It.12	It.13	It.14	It.15	It.16	It.17	Total Score
5	71	DAY0	15MAY89	3	3	2	1	1	1	3	3	3	3	3	3	1	1	2	1	0	34
		DAY7	22MAY89	3	3	2	1	1	1	3	3	3	3	3	1	1	1	2	1	0	32
		DAY14	29MAY89	3	2	1	1	1	1	2	3	2	2	2	2	1	1	2	0	0	26
		DAY21	05JUN89	2	2	1	1	1	1	2	2	2	2	2	1	1	1	1	0	0	22
		DAY28	12JUN89	2	2	1	1	1	1	2	2	1	2	1	1	1	1	1	0	0	20
5	72	SCREEN	10MAY89	3	2	2	1	1	1	3	3	3	3	3	1	1	1	2	0	0	30
		DAY0	11MAY89	3	2	2	1	1	1	3	3	3	3	3	1	1	1	1	0	0	29
		DAY7	18MAY89	3	2	1	1	1	1	3	3	3	3	2	1	1	1	2	0	0	28
		DAY14	25MAY89	3	1	1	1	1	1	1	2	2	2	2	1	1	1	1	0	0	21
		DAY21	01JUN89	2	0	0	1	0	0	2	2	1	1	1	1	1	1	1	0	0	14
		DAY28	08JUN89	2	0	0	1	0	0	2	1	1	1	1	1	1	1	0	0	0	12
5	73	SCREEN	22MAY89	3	3	3	1	1	1	3	3	3	3	3	1	1	1	2	1	0	33
		DAY0	23MAY89	3	3	3	1	1	1	3	3	3	3	3	1	1	1	2	1	0	33
		DAY7	31MAY89	3	3	2	1	1	1	3	3	3	3	3	3	1	1	2	0	0	33
		DAY14	07JUN89	2	2	1	1	0	0	2	2	2	2	2	1	1	1	2	0	0	21
		DAY21	14JUN89	2	0	0	1	0	0	2	2	1	2	1	1	0	0	0	0	0	12
		DAY28	21JUN89	2	0	0	1	0	0	1	1	1	2	1	0	0	0	0	0	0	9
5	74	SCREEN	22MAY89	3	1	1	1	1	1	3	3	3	3	3	1	1	1	3	1	0	30
		DAY0	23MAY89	3	1	1	1	1	1	3	3	3	3	3	1	1	1	2	1	0	29
		DAY7	31MAY89	3	1	1	1	1	1	2	2	3	3	3	1	1	1	2	0	0	26
		DAY14	07JUN89	2	0	0	1	0	0	2	2	1	2	2	0	1	1	2	0	0	16
		DAY21	14JUN89	2	1	0	1	0	0	2	1	0	1	1	1	0	0	0	0	0	10
		DAY28	21JUN89	2	0	0	1	0	0	2	1	1	1	1	0	0	0	0	0	0	9
5	75	SCREEN	22MAY89	3	3	2	1	1	1	3	3	3	3	3	1	1	0	2	1	0	31
		DAY0	23MAY89	3	2	2	1	1	1	3	3	3	3	3	1	1	1	2	1	0	31
		DAY7	31MAY89	3	2	2	1	1	1	3	3	3	3	3	1	1	0	2	0	0	29
		DAY14	07JUN89	3	2	2	1	1	1	3	3	3	3	3	1	1	0	2	1	0	30
		DAY21	14JUN89	3	2	2	1	1	1	3	3	3	3	3	1	1	0	2	1	0	30
		DAY28	21JUN89	3	2	2	1	1	1	3	3	3	3	3	1	1	0	2	1	0	30
5	76	SCREEN	22MAY89	3	3	3	1	1	1	3	3	3	3	3	1	1	1	2	1	0	33
		DAY0	23MAY89	3	3	2	1	1	1	3	3	3	3	3	1	1	1	2	1	0	32
		DAY7	31MAY89	3	2	2	1	1	1	3	3	3	3	3	1	1	1	2	0	0	30
		DAY14	07JUN89	3	1	1	1	1	1	2	2	2	2	2	1	1	1	2	0	0	23
		DAY21	14JUN89	2	1	0	1	1	1	2	2	1	2	1	1	1	1	1	0	0	18
		DAY28	21JUN89	2	1	1	1	0	0	2	1	1	1	1	0	1	1	0	0	0	13

HAMD: It.1=Depressed (0-4) It.2=Guilt (0-4) It.3=Suicide(0-4) It.4=Insomnia Early (0-2)
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It.13=General Symp. (0-2) It.14=Genital Symp. (0-2) It.15=Hypocondriasis (0-4) It.16=Loss Weight A or B (0-3)
It.17=Insight (0-2)

REBOXETINE - PROTOCOL ADE09
Listing No.: 8.0

HAMILTON DEPRESSION RATING SCALE

Centre	Patient	Visit	Date Performed HAMD	It.1	It.2	It.3	It.4	It.6	It.6	It.7	It.8	It.9	It.10	It.11	It.12	It.13	It.14	It.15	It.16	It.17	Total Score
5	77	SCREEN	31MAY89	3	2	2	1	1	1	3	3	3	3	3	1	1	0	3	1	0	31
		DAY0	01JUN89	3	2	2	1	1	1	3	3	3	3	3	1	1	1	3	0	0	31
		DAY7	08JUN89	3	2	1	1	1	1	3	3	3	3	3	1	1	1	2	0	0	29
		DAY14	15JUN89	3	1	1	1	0	0	2	2	2	2	2	1	1	0	2	0	0	20
		DAY21	22JUN89	2	0	0	0	0	0	2	2	2	2	2	1	1	0	1	0	0	15
		DAY28	29JUN89	2	0	0	0	0	0	1	2	1	2	2	1	1	0	1	0	0	13
6	81	SCREEN	20MAR89	3	2	2	0	1	2	2	0	1	1	2	2	0	0	1	0	0	19
		DAY0	27MAR89	4	2	2	1	2	2	2	0	1	1	2	2	0	0	1	0	0	22
		DAY7	03APR89	2	1	0	0	1	2	2	0	0	1	1	0	0	0	1	0	0	11
		DAY14	10APR89	1	1	0	0	2	2	0	0	0	1	0	0	0	0	0	0	0	7
		DAY21	14APR89	0	0	0	0	1	1	0	0	0	0	0	1	0	0	0	0	0	3
		DAY28	24APR89	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1
6	82	SCREEN	22MAR89	3	2	3	0	1	2	4	2	0	2	0	0	1	1	0	1	0	22
		DAY0	27MAR89	3	2	3	0	2	2	4	3	0	2	0	0	1	1	0	1	0	24
		DAY7	03APR89	2	2	1	0	0	1	3	2	0	2	0	0	1	1	0	0	0	15
		DAY14	10APR89	1	1	0	0	1	1	2	0	1	1	0	0	0	0	0	0	0	8
		DAY21	17APR89	1	1	0	0	0	1	1	0	0	1	1	0	1	0	0	0	0	7
		DAY28	24APR89	1	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	4
6	83	SCREEN	05MAY89	3	0	1	0	0	1	3	0	2	2	2	2	1	0	3	0	0	20
		DAY0	15MAY89	3	0	1	0	0	1	3	0	3	2	2	1	1	0	3	0	0	20
		DAY7	22MAY89	3	0	0	0	1	2	3	0	3	2	2	1	1	0	3	1	1	23
		DAY14	29MAY89	2	0	0	0	1	2	3	0	3	1	2	2	1	0	3	0	1	21
		DAY21	05JUN89	3	0	0	0	1	2	3	0	3	2	0	2	1	0	3	0	1	21
		DAY28	12JUN89	3	0	0	0	1	2	3	0	3	2	2	2	1	0	3	1	0	23
7	89	SCREEN	06MAR89	3	2	2	2	1	0	4	3	2	3	2	1	1	0	0	2	0	28
		DAY0	12MAR89	3	2	2	2	2	1	4	3	2	3	1	0	1	0	0	0	0	26
		DAY7	19MAR89	2	2	0	1	1	0	3	2	1	2	2	0	0	0	0	0	0	16
		DAY14	26MAR89	1	0	0	2	2	2	0	0	0	2	0	0	0	0	0	0	0	9

HAMD: It.1=Depressed (0-4) It.2=Guilt (0-4) It.3=Suicide(0-4) It.4=Insomnia Early (0-2)
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It.13=General Symp. (0-2) It.14=Genital Symp. (0-2) It.15=Hypocondriasis (0-4) It.16=Loss Weight A or B (0-3)
It.17=Insight (0-2)

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 9.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28
1	1	Placebo	Male	Severity of illness	4.00	4.00	4.00	4.00	5.00	5.00	5.00
				Global improvement		4.00	3.00	4.00	5.00	6.00	6.00
				Efficacy index		13.00	9.00	13.00	13.00	13.00	13.00
				Efficacy index (*)		1.00	2.00	1.00	1.00	1.00	1.00
	3	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	3.00	3.00	2.00
				Global improvement		3.00	3.00	3.00	2.00	2.00	1.00
				Efficacy index		9.00	9.00	9.00	5.00	1.00	1.00
				Efficacy index (*)		2.00	2.00	2.00	3.00	4.00	4.00
	4	Reboxetine	Male	Severity of illness	3.00	3.00	3.00	3.00	2.00	2.00	3.00
				Global improvement		4.00	4.00	3.00	2.00	1.00	3.00
				Efficacy index		13.00	13.00	9.00	5.00	1.00	9.00
				Efficacy index (*)		1.00	1.00	2.00	3.00	4.00	2.00
	5	Placebo	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		3.00	4.00	4.00	4.00	4.00	4.00
				Efficacy index		10.00	14.00	14.00	13.00	13.00	9.00
				Efficacy index (*)		1.00	0.50	0.50	1.00	1.00	2.00
	6	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	3.00	2.00
				Global improvement		3.00	3.00	4.00	3.00	2.00	1.00
				Efficacy index		9.00	9.00	13.00	9.00	5.00	1.00
				Efficacy index (*)		2.00	2.00	1.00	2.00	3.00	4.00
	7	Placebo	Male	Severity of illness	4.00	4.00	3.00	3.00	3.00	3.00	4.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	3.00
				Efficacy index		9.00	5.00	5.00	1.00	5.00	9.00
				Efficacy index (*)		2.00	3.00	3.00	4.00	3.00	2.00
	8	Reboxetine	Female	Severity of illness	4.00	4.00	3.00	3.00	2.00		
				Global improvement		4.00	3.00	2.00	2.00		
				Efficacy index		13.00	9.00	5.00	1.00		
				Efficacy index (*)		1.00	2.00	3.00	4.00		
	9	Placebo	Male	Severity of illness	4.00	4.00	4.00	4.00	3.00	3.00	4.00
				Global improvement			4.00	4.00	3.00	3.00	3.00
				Efficacy index		13.00	14.00	14.00	9.00	6.00	10.00
				Efficacy index (*)		1.00	0.50	0.50	2.00	1.50	1.00

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 9.0

CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28
1	10	Placebo	Male	Severity of illness	4.00	4.00	3.00	3.00	3.00	2.00	2.00
				Global improvement		4.00		2.00	2.00	1.00	1.00
				Efficacy index		9.00	5.00	5.00	5.00	1.00	1.00
				Efficacy index (*)		2.00	3.00	3.00	3.00	4.00	4.00
	11	Reboxetine	Female	Severity of illness	4.00	4.00	3.00	3.00	2.00	2.00	1.00
				Global improvement		4.00	3.00	3.00	2.00	1.00	1.00
				Efficacy index		13.00	9.00	9.00	5.00	1.00	1.00
				Efficacy index (*)		1.00	2.00	2.00	3.00	4.00	4.00
	12	Reboxetine	Male	Severity of illness	3.00	3.00	4.00	4.00	5.00		
				Global improvement		4.00	5.00	6.00	6.00		
				Efficacy index		13.00	13.00	13.00	13.00		
				Efficacy index (*)		1.00	1.00	1.00	1.00		
	13	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	4.00	3.00	2.00
				Global improvement		4.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		13.00	9.00	9.00	9.00	5.00	5.00
				Efficacy index (*)		1.00	2.00	2.00	2.00	3.00	3.00
	14	Placebo	Female	Severity of illness	4.00	5.00	4.00	4.00	3.00	2.00	1.00
				Global improvement		4.00	3.00	3.00	2.00	2.00	1.00
				Efficacy index		13.00	9.00	9.00	5.00	1.00	1.00
				Efficacy index (*)		1.00	2.00	2.00	3.00	4.00	4.00
	15	Placebo	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	
				Global improvement		3.00	3.00	3.00	2.00	4.00	
				Efficacy index		9.00	9.00	10.00	6.00	13.00	
				Efficacy index (*)		2.00	2.00	1.00	1.50	1.00	
	16	Reboxetine	Female	Severity of illness	4.00	4.00	2.00	1.00	4.00	4.00	3.00
				Global improvement		3.00	2.00	2.00	3.00	3.00	3.00
				Efficacy index		9.00	1.00	1.00	9.00	9.00	10.00
				Efficacy index (*)		2.00	4.00	4.00	2.00	2.00	1.00
2	21	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	3.00	2.00
				Global improvement		4.00	4.00	4.00	4.00	2.00	2.00
				Efficacy index		14.00	14.00	14.00	14.00	6.00	6.00
				Efficacy index (*)		0.50	0.50	0.50	0.50	1.50	1.50

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GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28
2	22	Placebo	Female	Severity of illness	5.00	5.00	5.00	4.00	5.00	4.00	4.00
				Global improvement		4.00	4.00	3.00	4.00	3.00	3.00
				Efficacy index		13.00	13.00	13.00	13.00	13.00	13.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	1.00
	23	Placebo	Female	Severity of illness	4.00	4.00	3.00				
				Global improvement		3.00	2.00				
				Efficacy index		9.00	6.00				
				Efficacy index (*)		2.00	1.50				
	24	Reboxetine	Female	Severity of illness	5.00	4.00	4.00	4.00	4.00	4.00	5.00
				Global improvement		4.00	3.00	3.00	3.00	4.00	4.00
				Efficacy index		13.00	9.00	9.00	9.00	13.00	13.00
				Efficacy index (*)		1.00	2.00	2.00	2.00	1.00	1.00
	25	Reboxetine	Female	Severity of illness	5.00	6.00	6.00	6.00	5.00	5.00	6.00
				Global improvement		4.00	3.00	3.00	2.00	4.00	5.00
				Efficacy index		13.00	9.00	9.00	6.00	13.00	13.00
				Efficacy index (*)		1.00	2.00	2.00	1.50	1.00	1.00
3	26	Reboxetine	Female	Severity of illness	5.00	4.00	5.00	4.00	5.00	5.00	
				Global improvement		3.00	4.00	4.00	5.00	5.00	
				Efficacy index		9.00	13.00	13.00	13.00	13.00	
				Efficacy index (*)		2.00	1.00	1.00	1.00	1.00	
	27	Placebo	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		4.00	6.00	4.00	4.00	4.00	4.00
				Efficacy index		14.00	14.00	15.00	14.00	14.00	14.00
				Efficacy index (*)		0.50	0.50	0.33	0.50	0.50	0.50
	28	Placebo	Male	Severity of illness	4.00	4.00	2.00	1.00	1.00		
				Global improvement		4.00	2.00	2.00	2.00		
				Efficacy index		14.00	2.00	1.00	1.00		
				Efficacy index (*)		0.50	2.00	4.00	4.00		
4	51	Placebo	Female	Severity of illness	3.00	3.00	3.00	3.00			
				Global improvement		4.00	3.00	3.00			
				Efficacy index		10.00	14.00	10.00			
				Efficacy index (*)		1.00	0.50	1.00			

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GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28
4	52	Placebo	Female	Severity of illness	4.00	3.00	3.00	3.00	2.00	2.00	4.00
				Global improvement		4.00	3.00	3.00	2.00	3.00	3.00
				Efficacy index		13.00	10.00	6.00	6.00	10.00	10.00
				Efficacy index (*)		1.00	1.00	1.50	1.50	1.00	1.00
	53	Reboxetine	Male	Severity of illness	4.00	4.00	5.00	4.00	4.00		
				Global improvement		4.00	5.00	2.00	5.00		
				Efficacy index		13.00	13.00	14.00	14.00		
				Efficacy index (*)		1.00	1.00	0.50	0.50		
	54	Placebo	Female	Severity of illness	4.00	4.00	3.00	4.00	4.00	4.00	3.00
				Global improvement		4.00	3.00	4.00	3.00	3.00	4.00
				Efficacy index		12.00	3.00	3.00	10.00	10.00	9.00
				Efficacy index (*)		0.50	1.33	1.33	1.00	1.00	2.00
	55	Placebo	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00	3.00	2.00
				Global improvement		4.00	4.00	5.00	3.00	3.00	3.00
				Efficacy index		13.00	13.00	13.00	10.00	10.00	9.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	2.00
	56	Reboxetine	Female	Severity of illness	4.00	3.00	3.00	3.00	3.00	4.00	2.00
				Global improvement		4.00	3.00	3.00	3.00	4.00	3.00
				Efficacy index		14.00	10.00	9.00	9.00	9.00	10.00
				Efficacy index (*)		0.50	1.00	2.00	2.00	2.00	1.00
	57	Placebo	Female	Severity of illness	5.00	5.00	3.00	3.00	3.00	2.00	2.00
				Global improvement		4.00	3.00	3.00	4.00	3.00	2.00
				Efficacy index		13.00	9.00	9.00	13.00	9.00	5.00
				Efficacy index (*)		1.00	2.00	2.00	1.00	2.00	3.00
	58	Reboxetine	Male	Severity of illness	3.00	2.00	2.00	2.00	2.00		
				Global improvement		3.00	3.00	4.00	3.00		
				Efficacy index		9.00	9.00	9.00	9.00		
				Efficacy index (*)		2.00	2.00	2.00	2.00		
	60	Placebo	Female	Severity of illness	3.00	2.00	2.00	2.00	2.00	2.00	3.00
				Global improvement		3.00	3.00	3.00	3.00	2.00	2.00
				Efficacy index		5.00	5.00	5.00	5.00	1.00	5.00
				Efficacy index (*)		3.00	3.00	3.00	3.00	4.00	3.00

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GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28
4	61	Placebo	Female	Severity of illness	4.00	4.00	4.00	4.00	3.00	4.00	4.00
				Global improvement		4.00	4.00	4.00	4.00	4.00	5.00
				Efficacy index		13.00	13.00	13.00	13.00	13.00	13.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	1.00
	62	Placebo	Female	Severity of illness	4.00						
				Global improvement							
				Efficacy index							
				Efficacy index (*)							
	63	Reboxetine	Female	Severity of illness	4.00	3.00	3.00	3.00	4.00	4.00	3.00
				Global improvement		3.00	3.00	3.00	5.00	5.00	3.00
				Efficacy index		9.00	9.00	9.00	14.00	13.00	9.00
				Efficacy index (*)		2.00	2.00	2.00	0.50	1.00	2.00
	64	Reboxetine	Male	Severity of illness	4.00	4.00	3.00	3.00	3.00	3.00	3.00
				Global improvement		4.00	3.00	3.00	3.00	3.00	5.00
				Efficacy index		14.00	10.00	10.00	9.00	9.00	9.00
				Efficacy index (*)		0.50	1.00	1.00	2.00	2.00	2.00
	65	Placebo	Male	Severity of illness	4.00	4.00					
				Global improvement		4.00					
				Efficacy index		13.00					
				Efficacy index (*)		1.00					
	66	Reboxetine	Female	Severity of illness	4.00	4.00	4.00	3.00	3.00	4.00	2.00
				Global improvement		4.00	4.00	3.00	3.00	3.00	2.00
				Efficacy index		14.00	14.00	10.00	10.00	10.00	2.00
				Efficacy index (*)		0.50	0.50	1.00	1.00	1.00	2.00
	67	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		5.00	5.00	4.00	4.00	4.00	4.00
				Efficacy index		13.00	13.00	13.00	13.00	13.00	13.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	1.00
5	71	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	5.00	4.00	3.00	3.00
				Global improvement		4.00	4.00	4.00	3.00	2.00	2.00
				Efficacy index		13.00	13.00	13.00	9.00	5.00	5.00
				Efficacy index (*)		1.00	1.00	1.00	2.00	3.00	3.00

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GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28
5	72	Placebo	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00	3.00	3.00
				Global improvement		4.00	4.00	3.00	3.00	2.00	2.00
				Efficacy index		13.00	13.00	9.00	9.00	5.00	5.00
				Efficacy index (*)		1.00	1.00	2.00	2.00	3.00	3.00
	73	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	4.00	3.00	2.00
				Global improvement		4.00	4.00	4.00	3.00	2.00	2.00
				Efficacy index		13.00	13.00	13.00	9.00	5.00	5.00
				Efficacy index (*)		1.00	1.00	1.00	2.00	3.00	3.00
	74	Placebo	Male	Severity of illness	5.00	5.00	5.00	4.00	3.00	3.00	3.00
				Global improvement		4.00	4.00	3.00	2.00	2.00	2.00
				Efficacy index		13.00	13.00	9.00	5.00	5.00	5.00
				Efficacy index (*)		1.00	1.00	2.00	3.00	3.00	3.00
	75	Placebo	Female	Severity of illness	5.00	5.00	5.00	5.00	5.00	5.00	5.00
				Global improvement		4.00	4.00	4.00	5.00	6.00	6.00
				Efficacy index		13.00	13.00	13.00	13.00	13.00	15.00
				Efficacy index (*)		1.00	1.00	1.00	1.00	1.00	0.33
	76	Reboxetine	Male	Severity of illness	5.00	5.00	5.00	5.00	4.00	3.00	3.00
				Global improvement		4.00	4.00	4.00	3.00	2.00	2.00
				Efficacy index		13.00	13.00	13.00	9.00	5.00	5.00
				Efficacy index (*)		1.00	1.00	1.00	2.00	3.00	3.00
	77	Reboxetine	Female	Severity of illness	5.00	5.00	5.00	4.00	4.00	3.00	2.00
				Global improvement		4.00	4.00	3.00	3.00	2.00	2.00
				Efficacy index		13.00	13.00	9.00	9.00	5.00	5.00
				Efficacy index (*)		1.00	1.00	2.00	2.00	3.00	3.00
6	81	Reboxetine	Female	Severity of illness	4.00	4.00	3.00	3.00	2.00	1.00	1.00
				Global improvement		3.00	2.00	3.00	2.00	1.00	1.00
				Efficacy index		9.00	5.00	9.00	1.00	1.00	1.00
				Efficacy index (*)		2.00	3.00	2.00	4.00	4.00	4.00
	82	Reboxetine	Male	Severity of illness	4.00	4.00	4.00	2.00	2.00	2.00	2.00
				Global improvement		3.00	2.00	2.00	2.00	2.00	2.00
				Efficacy index		9.00	5.00	5.00	1.00	1.00	1.00
				Efficacy index (*)		2.00	3.00	3.00	4.00	4.00	4.00

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GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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CLINICAL GLOBAL IMPRESSION

Centre	Patient	Treatment	Sex	C.G.I.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28
6	83	Placebo	Female	Severity of illness	4.00	4.00	4.00	4.00	4.00	4.00	4.00
				Global improvement		4.00	4.00	4.00	3.00	4.00	4.00
				Efficacy index		13.00	13.00	13.00	9.00	13.00	13.00
				Efficacy index (*)		1.00	1.00	1.00	2.00	1.00	1.00
7	89	Reboxetine	Female	Severity of illness	5.00	5.00	4.00	4.00	3.00		
				Global improvement		4.00	3.00	2.00	2.00		
				Efficacy index		13.00	9.00	5.00	6.00		
				Efficacy index (*)		1.00	2.00	3.00	1.50		

SEVERITY OF ILLNESS: 1=normal, 2=borderline mentally ill, 3=mildly ill, 4=moderately ill, 5=markedly ill, 6=severily ill, 7=extremely ill
GLOBAL IMPROVEMENT: 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse
EFFICACY INDEX (*): computed from the vector activity by the vector side effects

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ADVERSE EVENTS

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last visit	Severity	History	Relship	Course	Symptrea	Outcome	(¢)
1	1	Placebo	14/11/87	11/12/87	CONSTIPATION	18/11/87	Detail	7			2	2	2	1	YES		
							Detail	10			1	2	3	0	NO	1	
							Summary		23/11/87(*)	10	2	2	2	0	YES	1	YES
					MOUTH DRY	16/11/87	Detail	4			1	2	3	1	NO		
							Detail	7			2	2	3	1	NO		
							Detail	10			2	2	3	1	NO		
							Detail	14			2	2	3	1	NO		
							Detail	21			1	2	3	1	NO		
							Detail	28			1	2	3	1	NO		
							Summary		11/12/87(*)	28	2	2	3	1			YES
	3	Reboxetine	14/11/87	11/12/87	HEADACHE	15/11/87	Detail	4			2	2	3	1	YES		
							Detail	7			2	2	3	1	YES		
							Detail	10			1	2	3	0	NO	1	
							Summary		23/11/87(*)	10	2	2	3	0	YES	1	YES
					HOT FLUSHES	16/11/87	Detail	4			1	2	4	1	NO		
							Detail	7			1	2	4	1	NO		
							Detail	10			1	2	4	1	NO		
							Detail	14			1	2	4	0	NO	1	
							Summary		27/11/87(*)	14	1	2	4	0		1	YES
	4	Reboxetine	09/12/87	05/01/88	CONSTIPATION	12/12/87	Detail	7			2	2	3	1	NO		
							Summary		15/12/87(*)	7	2	2	3	1			YES
	5	Placebo	11/02/88	09/03/88	CONSTIPATION	11/02/88	Detail	4			1	2	3	0	NO	1	
							Detail	7			1	2	3	0	NO	1	
							Summary		17/02/88(*)	7	1	2	3	0		1	YES
					MOUTH DRY	09/02/88	Detail	0			1				NO		
							Detail	7			1	1	3	1	NO		
							Detail	10			1	1	4	0	NO		
						09/02/88(@)	Summary		20/02/88(*)	10	1	1	3	0			NO

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=very severe -- History: 1=present before, 2=not observe bef., 3=unknown
Course: 0=disapp., 1=persisted, 2=disapp. dose reduction, 3=persisted dose reduction, 4=not tolerated
Outcome: 1=fully recovered, 2=rec. with sequelae -- Relationship: 1=certain, 2=probable, 3=possible/doubtful, 4=unknown
symptomatic treatment: 0=no, 1=yes
(¢) adverse event used for statistical analysis
(*) end date = last report visit date used
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ADVERSE EVENTS

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last visit	Severity	History	Relship	Course	Symp treat	Outcome	(¢)
1	6	Reboxetine	23/04/88	20/05/88	DIZZINESS	27/04/88	Detail	7			2	2	3	0	NO	1	
							Detail	10			1	2	3	0	NO	1	
							Summary		03/05/88(*)	10	2	2	3	0		1	YES
					HEADACHE	27/04/88	Detail	7			2	2	3	0	NO	1	
							Detail	10			1	2	3	0	NO	1	
							Summary		03/05/88(*)	10	2	2	3	0		1	YES
					MOUTH DRY	30/04/88	Detail	10			1		3	1	NO		
							Detail	14			1	2	3	0	NO	1	
						30/04/88(&)	Summary		06/05/88(*)	14	1	2	3	0		1	YES
	7	Placebo	28/05/88	24/06/88	MOUTH DRY	26/05/88	Detail	0			1				NO		
						26/05/88(@)	Summary		27/07/88(*)	0	1						NO
					VOMITING	26/05/88	Detail	0			2				NO		
						26/05/88(@)	Summary		27/07/88(*)	0	2						NO
	8	Reboxetine	15/07/88	12/08/88	CYANOSIS	28/07/88	Detail	14						4			
							Summary		28/07/88(*)	14				4			YES
					PARAESTHESIA	28/07/88	Detail	14						4			
							Summary		28/07/88(*)	14				4			YES
					RASH	25/07/88	Detail	10			2	2	3	1	NO		
							Detail	14			2	2	3	1	NO		
							Summary		28/07/88(*)	14	2	2	3	1			YES
	9	Placebo	06/10/88	02/11/88	MOUTH DRY	10/10/88	Detail	7			1	2	2		NO		
							Detail	10			1	2	3	1	NO		
							Detail	14			1	2	3	1	NO		

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Course: 0=disapp., 1=persisted, 2=disapp. dose reduction, 3=persisted dose reduction, 4=not tolerated
Outcome: 1=fully recovered, 2=rec. with sequelae -- Relationship: 1=certain, 2=probable, 3=possible/doubtful, 4=unknown
symptomatic treatment: 0=no, 1=yes
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ADVERSE EVENTS

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last visit	Severity	History	Relship	Course	Symp treat	Outcome	(¢)
1	9	Placebo	06/10/88	02/11/88	MOUTH DRY	10/10/88	Detail	28			1	2	3	1	NO		
							Summary		02/11/88(*)	28	1	2	2	1			YES
	11	Reboxetine	15/11/88	12/12/88	DIARRHOEA	02/12/88	Detail	21			2	2	3	0	NO	1	
							Summary		05/12/88(*)	21	2	2	3	0		1	YES
	15	Placebo	28/03/89	17/04/89	SWEATING INCREASED	03/04/89	Detail	10			2	2	2	1	NO		
							Detail	14			2	2	2	1	NO		
							Detail	21			1	2	3	1	NO		
							Summary		17/04/89(*)	21	2	2	2	1			YES
	16	Reboxetine	24/04/89	22/05/89	CONSTIPATION	06/05/89	Detail	14			1	2	4	1	NO		
							Detail	21			1		4	0	NO	1	
							Summary		15/05/89(*)	21	1	2	4	0		1	YES
					PARAESTHESIA	16/05/89	Detail	28			1	2	3	1	NO		
							Summary		22/05/89(*)	28	1	2	3	1			YES
					VISION ABNORMAL	15/05/89	Detail	28			1	2	3	1	NO		
							Summary		22/05/89(*)	28	1	2	3	1			YES
2	21	Reboxetine	20/02/88	24/03/88	INSOMNIA	23/02/88	Detail	4			2	2	3	1	NO		
							Detail	7			2	2	2	1	YES		
							Detail	10			2	2	2	1	YES		
							Detail	14			2	2	2	1	YES		
							Detail	21			2	2	2	1	YES		
							Detail	28			1	2	3	1	YES		
							Summary		23/03/88(*)	28	2	2	2	1	YES		YES
					MOUTH DRY	24/02/88	Detail	4			2	2	3	1	NO		
							Detail	7			2	2	3	1	NO		
							Detail	10			2	2	1	1	NO		
							Detail	14			2	2	1	1	NO		
							Detail	21			2	2	2	1	NO		

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Course: 0=disapp., 1=persisted, 2=disapp. dose reduction, 3=persisted dose reduction, 4=not tolerated
Outcome: 1=fully recovered, 2=rec. with sequelae -- Relationship: 1=certain, 2=probable, 3=possible/doubtful, 4=unknown
symptomatic treatment: 0=no, 1=yes
(¢) adverse event used for statistical analysis
(*) end date = last report visit date used
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ADVERSE EVENTS

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last visit	Severity	History	Relship	Course	Symp trea	Out come	(¢)
2	21	Reboxetine	20/02/88	24/03/88	MOUTH DRY	24/02/88	Detail	28			2	2	3	1	NO		
							Summary		23/03/88(*)	28	2	2	1	1			YES
	22	Placebo	10/05/88	07/06/88	MICTURITION FREQUENCY	21/05/88	Detail	14			2	2	3	1	NO		
							Detail	21			1	2	3	1	NO		
							Summary		31/05/88(*)	21	2	2	3	1			YES
					TREMOR	08/05/88	Detail	0			1				NO		
							Detail	4			2	1	4	0	NO	1	
						08/05/88(@)	Summary		13/05/88(*)	4	2	1	4	0		1	YES
	23	Placebo	29/12/88	06/01/89	AGITATION	04/01/89	Detail	7			1	2	3	4	NO	1	
							Summary		05/01/89(*)	7	1	2	3	4		1	YES
					EXTRASYSTOLES	04/01/89	Detail	7			2	2	3	4	NO	1	
							Summary		05/01/89(*)	7	2	2	3	4		1	YES
					SWEATING INCREASED	27/12/88	Detail	0			2				NO	1	
						27/12/88(@)	Summary		05/01/89(*)	0	2					1	NO
	25	Reboxetine	21/02/89	21/03/89	CONSTIPATION	19/02/89	Detail	0			2				YES		
							Detail	4			2	1	4	0	NO	1	
						19/02/89(@)	Summary		24/02/89(*)	4	2	1	4	0	YES	1	NO
					DIZZINESS	04/03/89	Detail	14			1	2	3	0	NO	1	
							Summary		07/03/89(*)	14	1	2	3	0		1	YES
					PARAESTHESIA	19/02/89	Detail	0			1				NO		
							Detail	4			1	1	4	0	NO	1	
						19/02/89(@)	Summary		24/02/89(*)	4	1	1	4	0		1	NO
3	26	Reboxetine	29/12/88	17/01/89	CONSTIPATION	28/12/88	Detail	0			1				NO	1	

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Outcome: 1=fully recovered, 2=rec. with sequelae -- Relationship: 1=certain, 2=probable, 3=possible/doubtful, 4=unknown
symptomatic treatment: 0=no, 1=yes
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ADVERSE EVENTS

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last visit	Severity	History	Relship	Course	Symp treat	Outcome	(¢)
3	26	Reboxetine	29/12/88	17/01/89	CONSTIPATION	28/12/88	Detail	4			1	1	4	1	NO		
							Detail	7			2	1	4	1	NO		
							Detail	10			1	1	4	0	NO	1	
						28/12/88(ə)	Summary		06/01/89(*)	10	2	1	4	0		1	YES
					HEADACHE	28/12/88	Detail	0			1				NO	1	
							Detail	4			1		4	1	NO		
							Detail	7			1	1	4	1	NO		
							Detail	10			1	1	4	0	NO	1	
						28/12/88(ə)	Summary		06/01/89(*)	10	1	1	4	0		1	NO
					MOUTH DRY	28/12/88	Detail	0			1				NO	1	
							Detail	4			1	1	4	1	NO		
							Detail	7			2	1	4	1	NO		
							Detail	10			1	1	4	0	NO	1	
						28/12/88(ə)	Summary		06/01/89(*)	10	2	1	4	0		1	YES
	27	Placebo	28/12/88	25/01/89	CONSTIPATION	29/12/88	Detail	4			4	2	2	1	YES		
							Detail	7			2	1	2	1	YES		
							Detail	10			1		3	3			
							Detail	14			1	1	3	0	NO		
						29/12/88(&)	Summary		10/01/89(*)	14	4	1	2	0	YES		YES
					DIZZINESS	11/01/89	Detail	21			1	2	3	1	NO		
							Detail	28			1	2	4	0	NO	1	
						11/01/89(&)	Summary		26/01/89(*)	28	1	2	3	0		1	YES
					HEADACHE	27/12/88	Detail	0			2				NO		
							Detail	10			1		3	3			
							Detail	14			1	1	3	2	NO		
						27/12/88(ə)	Summary		10/01/89(*)	14	2	1	3	2			NO
					INSOMNIA	27/12/88	Detail	0			4				NO		
							Detail	4			4	1	3	1	YES		
							Detail	7			4	1	2	1	NO		

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Course: 0=disapp., 1=persisted, 2=disapp. dose reduction, 3=persisted dose reduction, 4=not tolerated
Outcome: 1=fully recovered, 2=rec. with sequelae -- Relationship: 1=certain, 2=probable, 3=possible/doubtful, 4=unknown
symptomatic treatment: 0=no, 1=yes
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ADVERSE EVENTS

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last visit	Severity	History	Rel ship	Course	Symp trea	Out come	(¢)
3	27	Placebo	28/12/88	25/01/89	INSOMNIA	27/12/88	Detail	21			2	1	4	0	YES		
						27/12/88(@)	Summary		18/01/89(*)	21	4	1	2	0	YES		NO
					NAUSEA	27/12/88	Detail	0			1				NO		
							Detail	4			2	1	3	1	NO		
							Detail	7			4	1	2	1	NO		
							Detail	10			1	1	2	3	YES		
							Detail	21			1	1	3	0	YES		
						27/12/88(@)	Summary		18/01/89(*)	21	4	1	2	0	YES		YES
					VOMITING	29/12/88	Detail	4			2	1	3	1	NO		
							Detail	7			4	1	2	1	NO		
							Detail	10			1	1	2	3	YES		
							Detail	14			1	1	3	1	YES		
							Detail	21			1	1	3	0	YES		
						29/12/88(&)	Summary		18/01/89(*)	21	4	1	2	0	YES		YES
	28	Placebo	28/12/88	12/01/89	CONSTIPATION	01/01/89	Detail	7			3	2	3	1	YES		
							Detail	10			1	2	1	0	YES	1	
							Detail	14			1	2	3	0	NO	1	
							Summary		10/01/89(*)	14	3	2	1	0	YES	1	YES
					DIZZINESS	29/12/88	Detail	3			1	2	3	1	NO		
							Detail	7			1	2	3	1	NO	1	
							Summary		03/01/89(*)	7	1	2	3	1		1	YES
					HEADACHE	27/12/88	Detail	0			1				NO		
							Detail	3			3	1	3	1	YES		
							Detail	7			1	1	3	1	YES		
							Detail	10			1	1	4	0	NO	1	
						27/12/88(@)	Summary		06/01/89(*)	10	3	1	3	0	YES	1	YES
					NAUSEA	29/12/88	Detail	3			2	2	3	1	NO	1	
							Detail	7			1	2	3	0	NO	1	
							Summary		03/01/89(*)	7	2	2	3	0		1	YES

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Course: 0=disapp., 1=persisted, 2=disapp. dose reduction, 3=persisted dose reduction, 4=not tolerated
Outcome: 1=fully recovered, 2=rec. with sequelae -- Relationship: 1=certain, 2=probable, 3=possible/doubtful, 4=unknown
symptomatic treatment: 0=no, 1=yes
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ADVERSE EVENTS

Centre	Patient	Treatment Drug	Start date	End date	Adverse event	Onset date	Type record	Visit No	End date	Last visit	Severity	History	Relship	Course	Symp treat	Outcome	(¢)
3	28	Placebo	28/12/88	12/01/89	VOMITING	29/12/88	Detail	3			2	2	3	0	NO	1	
							Detail	7			1	2	3	0	NO	1	
							Summary		03/01/89(*)	7	2	2	3	0		1	YES
4	51	Placebo	22/04/88	02/05/88	ANOREXIA	25/04/88	Detail	7			2	2	2	1	NO		
							Summary		29/04/88(*)	7	2	2	2	1			YES
					CONSTIPATION	21/04/88	Detail	0			1				NO		
							Detail	4			2	1	4	1	NO		
						21/04/88(@)	Summary		26/04/88(*)	4	2	1	4	1			YES
					FATIGUE	30/04/88	Detail	10			1	1	2	4	NO		
							Summary		02/05/88(*)	10	1	1	2	4			YES
					INSOMNIA	21/04/88	Detail	0			2				NO		
							Detail	4			2	1	4	1	YES		
						21/04/88(@)	Summary		26/04/88(*)	4	2	1	4	1	YES		NO
					INTERMENSTRUAL BLEEDING	25/04/88	Detail	10			2	2	3	4	YES		
							Summary		02/05/88(*)	10	2	2	3	4	YES		YES
					PARAESTHESIA	25/04/88	Detail	7			1	2	3	4	NO		
							Summary		29/04/88(*)	7	1	2	3	4			YES
					SWEATING INCREASED	21/04/88	Detail	0			1				NO		
							Detail	4			1	3	3	1	NO	2	
						21/04/88(@)	Summary		26/04/88(*)	4	1	3	3	1		2	NO
					UTERINE SPASM	25/04/88	Detail	10									
							Summary		02/05/88(*)	10							YES

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Course: 0=disapp., 1=persisted, 2=disapp. dose reduction, 3=persisted dose reduction, 4=not tolerated
Outcome: 1=fully recovered, 2=rec. with sequelae -- Relationship: 1=certain, 2=probable, 3=possible/doubtful, 4=unknown
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ADVERSE EVENTS

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last visit	Severity	History	Relship	Course	Symp treat	Outcome	(¢)
4	52	Placebo	08/07/88	04/08/88	CONSTIPATION	06/07/88	Detail	0			2				NO		
						06/07/88(@)	Summary		04/08/88(*)	0	2					NO	
					FATIGUE	06/07/88	Detail	0			2				NO		
							Detail	4			1	1	3	1	NO		
							Detail	7			2	1	4	1	NO		
							Detail	10			2	2	3	1	NO		
							Detail	14			2	1	3	1	NO		
							Detail	21			1	1	3	1	NO		
							Detail	28			1	1	3	1	NO		
						06/07/88(@)	Summary		04/08/88(*)	28	2	1	3	1			NO
					INSOMNIA	06/07/88	Detail	0			2				NO		
							Detail	4			2	2	3	1	YES		
							Detail	7			2	2	2	1	YES		
						06/07/88(@)	Summary		14/07/88(*)	7	2	2	2	1	YES		NO
	53	Reboxetine	30/09/88	20/10/88	MOUTH DRY	06/10/88	Detail	7			1	2	2	1	NO		
							Summary		06/10/88(*)	7	1	2	2	1			YES
	54	Placebo	29/11/88	26/12/88	DIZZINESS	03/12/88	Detail	7			1	2	2	1	NO	1	
							Summary		05/12/88(*)	7	1	2	2	1		1	YES
					HEADACHE	07/12/88	Detail	10			2	2	3	0	NO	1	
							Summary		08/12/88(*)	10	2	2	3	0		1	YES
					MICTURITION DISORDER	06/12/88	Detail	10			2	3	4	0	YES	1	
							Summary		08/12/88(*)	10	2	3	4	0	YES	1	YES
					MOUTH DRY	29/11/88	Detail	4			1	2	3	1	NO		
							Detail	10			1	2	2	0	NO	1	
							Summary		08/12/88(*)	10	1	2	2	0		1	YES

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Course: 0=disapp., 1=persisted, 2=disapp. dose reduction, 3=persisted dose reduction, 4=not tolerated
Outcome: 1=fully recovered, 2=rec. with sequelae -- Relationship: 1=certain, 2=probable, 3=possible/doubtful, 4=unknown
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ADVERSE EVENTS

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last visit	Severity	History	Rel ship	Course	Symp trea	Outcome	(¢)
4	54	Placebo	29/11/88	26/12/88	NAUSEA	30/11/88	Detail	4			1	2	2	0	NO	1	
							Summary		02/12/88(*)	4	1	2	2	0		1	YES
					SOMNOLENCE	03/12/88	Detail	7			1	2	3	0	NO	1	
							Summary		05/12/88(*)	7	1	2	3	0		1	YES
					SWEATING INCREASED	30/11/88	Detail	4			1	2	3	0	NO	1	
							Summary		02/12/88(*)	4	1	2	3	0		1	YES
					URINARY RETENTION	03/12/88	Detail	7			1	2	2	0	NO	1	
							Summary		05/12/88(*)	7	1	2	2	0		1	YES
	55	Placebo	23/01/89	20/02/89	AGITATION	31/01/89	Detail	10			2	2	4	0	NO	1	
							Summary		02/02/89(*)	10	2	2	4	0		1	YES
	56	Reboxetine	24/01/89	22/02/89	HEADACHE	25/01/89	Detail	4			1	2	3	0	NO	1	
							Summary		27/01/89(*)	4	1	2	3	0		1	YES
					NAUSEA	25/01/89	Detail	4			2	2	3	1	NO	2	
							Summary		27/01/89(*)	4	2	2	3	1		2	YES
					RASH	29/01/89	Detail	7			3	2	3	0	NO	1	
							Summary		30/01/89(*)	7	3	2	3	0		1	YES
						01/02/89	Detail	10			1	2	4	1	NO		
							Detail	14			2	2	4	1	NO		
							Summary		06/02/89(*)	14	2	2	4	1			YES
					VOMITING	25/01/89	Detail	4			1	2	3	0	NO	1	
							Summary		27/01/89(*)	4	1	2	3	0		1	YES

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=very severe -- History: 1=present before, 2=not observe bef., 3=unknown
Course: 0=disapp., 1=persisted, 2=disapp. dose reduction, 3=persisted dose reduction, 4=not tolerated
Outcome: 1=fully recovered, 2=rec. with sequelae -- Relationship: 1=certain, 2=probable, 3=possible/doubtful, 4=unknown
symptomatic treatment: 0=no, 1=yes
(¢) adverse event used for statistical analysis
(*) end date = last report visit date used
(∂) onset date missing: day0 visit date minus 1 day used
(&) onset date missing: previous visit date of first report visit plus 1 day used

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 10.0

ADVERSE EVENTS

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last visit	Severity	History	Relship	Course	Symptrea	Outcome	(¢)
4	58	Reboxetine	21/03/89	03/04/89	NAUSEA	19/03/89	Detail	0			1				NO	1	
						19/03/89(@)	Summary		03/04/89(*)	0	1					1	NO
					RHINITIS	19/03/89	Detail	0			1				NO	1	
						19/03/89(@)	Summary		03/04/89(*)	0	1					1	NO
					SWEATING INCREASED	19/03/89	Detail	0			1				NO	1	
						19/03/89(@)	Summary		03/04/89(*)	0	1					1	NO
	61	Placebo	09/05/89	05/06/89	HEADACHE	02/06/89	Detail	28			2	2	3	1	YES		
							Summary		05/06/89(*)	28	2	2	3	1	YES		YES
					MOUTH DRY	21/05/89	Detail	21			2	2	3	1	NO	2	
							Detail	28			2	2	3	1	NO		
							Summary		05/06/89(*)	28	2	2	3	1			YES
	63	Reboxetine	16/05/89	11/06/89	HEADACHE	25/05/89	Detail	14			1	2	4	1	NO	1	
							Summary		01/06/89(*)	14	1	2	4	1		1	YES
					NAUSEA	25/05/89	Detail	14			2	2	3	1	NO	1	
							Summary		01/06/89(*)	14	2	2	3	1		1	YES
	64	Reboxetine	23/05/89	19/06/89	HEADACHE	24/05/89	Detail	4			2	2	2	1	NO	1	
							Summary		26/05/89(*)	4	2	2	2	1		1	YES
					MOUTH DRY	27/05/89	Detail	7			1	3	3	1	NO	1	
							Summary		31/05/89(*)	7	1	3	3	1		1	YES
					NAUSEA	24/05/89	Detail	4			1	2	2	0	NO	1	
							Summary		26/05/89(*)	4	1	2	2	0		1	YES
						01/06/89	Detail	10			2	2	3	1	NO	1	
							Summary		01/06/89(*)	10	2	2	3	1		1	YES

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=very severe -- History: 1=present before, 2=not observe bef., 3=unknown
Course: 0=disapp., 1=persisted, 2=disapp. dose reduction, 3=persisted dose reduction, 4=not tolerated
Outcome: 1=fully recovered, 2=rec. with sequelae -- Relationship: 1=certain, 2=probable, 3=possible/doubtful, 4=unknown
symptomatic treatment: 0=no, 1=yes
(¢) adverse event used for statistical analysis
(*) end date = last report visit date used
(@) onset date missing: day0 visit date minus 1 day used
(&) onset date missing: previous visit date of first report visit plus 1 day used

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 10.0

ADVERSE EVENTS

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last visit	Severity	History	Rel ship	Course	Symp trea	Out come	(¢)
4	64	Reboxetine	23/05/89	19/06/89	SOMNOLENCE	27/05/89	Detail	7			1	2	3	1	NO	1	
							Summary		31/05/89(*)	7	1	2	3	1		1	YES
	65	Placebo	23/05/89	28/05/89	RASH ERYTHEMATOUS	24/05/89	Detail	4						4			
							Summary		26/05/89(*)	4				4			YES
	66	Reboxetine	30/05/89	26/06/89	BULLOUS ERUPTION	08/06/89	Detail	28			1	2	4	1	NO		
							Summary		26/06/89(*)	28	1	2	4	1			YES
					CONSTIPATION	09/06/89	Detail	14			3	2	3	1	NO		
							Summary		12/06/89(*)	14	3	2	3	1			YES
					HEADACHE	09/06/89	Detail	14			2	2	3	1	YES		
							Detail	21			2	2	3	1	YES		
							Summary		19/06/89(*)	21	2	2	3	1	YES		YES
					MOUTH DRY	31/05/89	Detail	4			2	2	3	1	NO		
							Detail	7			2	2	3	1	NO		
							Detail	10			2	2	3	1	NO		
							Summary		08/06/89(*)	10	2	2	3	1			YES
					PALPITATION	29/05/89	Detail	0			2				NO	2	
						29/05/89(@)	Summary		26/06/89(*)	0	2					2	NO
					SWEATING INCREASED	29/05/89	Detail	0			2				NO	2	
							Detail	4			2	2	3	1	NO		
							Detail	7			2	2	3	1	NO		
							Detail	10			2	2	3	1	NO	2	
							Detail	14			2	2	3	1	NO		
							Detail	21			2	2	3	1	NO		
							Detail	28			3	2	3	1	NO		
						29/05/89(@)	Summary		26/06/89(*)	28	3	2	3	1			YES

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Course: 0=disapp., 1=persisted, 2=disapp. dose reduction, 3=persisted dose reduction, 4=not tolerated
Outcome: 1=fully recovered, 2=rec. with sequelae -- Relationship: 1=certain, 2=probable, 3=possible/doubtful, 4=unknown
symptomatic treatment: 0=no, 1=yes
(¢) adverse event used for statistical analysis
(*) end date = last report visit date used
(@) onset date missing: day0 visit date minus 1 day used
(&) onset date missing: previous visit date of first report visit plus 1 day used

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 10.0

ADVERSE EVENTS

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last visit	Severity	History	Rel ship	Course	Symp trea	Outcome	(¢)
4	66	Reboxetine	30/05/89	26/06/89	VOMITING	29/05/89	Detail	0			1				NO	1	
						29/05/89(@)	Summary		26/06/89(*)	0	1					1	NO
						31/05/89	Detail	4			1	2	3	0	NO	1	
							Summary		02/06/89(*)	4	1	2	3	0		1	YES
	67	Reboxetine	30/05/89	28/06/89	MICTURITION DISORDER	03/06/89	Detail	7			2	2	3	0	NO	1	
							Summary		05/06/89(*)	7	2	2	3	0		1	YES
5	72	Placebo	11/05/89	08/06/89	HEADACHE	01/06/89	Detail	21			1	2	4	0	NO	1	
							Detail	28			1	2	4	0	NO	1	
							Summary		09/06/89(*)	28	1	2	4	0		1	YES
	75	Placebo	23/05/89	21/06/89	AGITATION	10/06/89	Detail	21			2	2	3	1	NO		
							Detail	28			2	2	3	3	YES		
							Summary		21/06/89(*)	28	2	2	3	3	YES		YES
					CONFUSION	10/06/89	Detail	21			2	2	3	1	NO		
							Detail	28			2	2	3	3	YES		
							Summary		21/06/89(*)	28	2	2	3	3	YES		YES
6	81	Reboxetine	24/03/89	24/04/89	ANOREXIA	28/03/89	Detail	4			1	2	4	1	NO		
							Detail	7			1	2	4	0	NO	1	
							Summary		03/04/89(*)	7	1	2	4	0		1	YES
	82	Reboxetine	24/03/89	24/04/89	CONSTIPATION	05/04/89	Detail	10			2	2	4	0	YES		
							Detail	14			1	2	4	0	YES		
							Detail	21			1	2	3	1	YES		
							Detail	28			1	2	3	0	YES	1	
							Summary		24/04/89(*)	28	2	2	3	0	YES	1	YES
7	89	Reboxetine	12/03/89	02/04/89	DYSPNOEA	19/03/89	Detail	10			2	2	2	1	NO		
							Detail	14			2	2	3	1	NO		

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Course: 0=disapp., 1=persisted, 2=disapp. dose reduction, 3=persisted dose reduction, 4=not tolerated
Outcome: 1=fully recovered, 2=rec. with sequelae -- Relationship: 1=certain, 2=probable, 3=possible/doubtful, 4=unknown
symptomatic treatment: 0=no, 1=yes
(¢) adverse event used for statistical analysis
(*) end date = last report visit date used
(@) onset date missing: day0 visit date minus 1 day used
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REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 10.0

ADVERSE EVENTS

Centre	Patient	Drug	Treatment Start date	Treatment End date	Adverse event	Onset date	Type record	Visit No	End date	Last visit	Severity	History	Relship	Course	Symptrea	Outcome	(¢)
7	89	Reboxetine	12/03/89	02/04/89	DYSPNOEA	19/03/89	Summary		26/03/89(*)	14	2	2	2	1			YES
					FATIGUE	11/03/89	Detail	0			2				NO		
							Detail	4			2	1	4	1	NO	1	
						11/03/89(@)	Summary		16/03/89(*)	4	2	1	4	1		1	NO
					INSOMNIA	11/03/89	Detail	0			2				NO		
							Detail	4			2	1	4	0	NO	1	
						11/03/89(@)	Summary		16/03/89(*)	4	2	1	4	0		1	NO
					MOUTH DRY	11/03/89	Detail	0			1				NO		
							Detail	4			1	1	4	1	NO		
							Detail	7			1	1	4	0	NO	1	
						11/03/89(@)	Summary		19/03/89(*)	7	1	1	4	0		1	NO
					URINARY RETENTION	19/03/89	Detail	7			2	2	3	0	NO	1	
							Summary		19/03/89(*)	7	2	2	3	0		1	YES

Severity: 0=unknown, 1=mild, 2=moderate, 3=severe, 4=very severe -- History: 1=present before, 2=not observe bef., 3=unknown
Course: 0=disapp., 1=persisted, 2=disapp. dose reduction, 3=persisted dose reduction, 4=not tolerated
Outcome: 1=fully recovered, 2=rec. with sequelae -- Relationship: 1=certain, 2=probable, 3=possible/doubtful, 4=unknown
symptomatic treatment: 0=no, 1=yes
(¢) adverse event used for statistical analysis
(*) end date = last report visit date used
(@) onset date missing: day0 visit date minus 1 day used
(&) onset date missing: previous visit date of first report visit plus 1 day used

PHARMACIA CN 95 0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 1 Sex: Male

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			13/11/87		20/11/87		27/11/87		11/12/87	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	13-18 (G/DL)	01/11/87	15.00		14.50		15.20		15.50	
HT	0.4-0.54 (L/L)	01/11/87		nd	0.42		0.44		0.45	
RBC	4-6.5 (10**12/L)	01/11/87	5.18		4.47		4.59		4.73	
WBC	3.9-12 (10**9/L)	01/11/87	11.40		7.80		6.70		7.30	
WBC: N	40-75 (%)	01/11/87		nd		nd		nd		nd
WBC: L	20-45 (%)	01/11/87	19.10	<	24.20		26.50		23.50	
WBC: E	1-6 (%)	01/11/87	3.90		3.70		4.10		5.00	
WBC: M	0-1 (%)	01/11/87		nd		nd		nd		nd
WBC: B	2-10 (%)	01/11/87		nd		nd		nd		nd
PLATELETS	100-600 (10**9/L)	01/11/87	226.00		242.00		236.00		238.00	
NA+	134-145 (MMOL/L)	01/11/87	144.00		142.00		140.00		140.00	
K+	3.5-5 (MMOL/L)	01/11/87	4.00		4.40		4.00		4.20	
CL-	95-108 (MMOL/L)	01/11/87		nd	104.00		108.00		107.00	
Ca++	2.2-2.6 (MMOL/L)	01/11/87		nd	2.20		2.10	<	2.20	
PO4--	0.8-1.5 (MMOL/L)	01/11/87		nd	1.20		0.80		0.91	
SGOT	15-37 (IU/L)	01/11/87		nd	19.00		18.00		16.00	
SGPT	2-29 (IU/L)	01/11/87	16.00		19.00		16.00		18.00	
GAMMA GT	0-65 (IU/L)	01/11/87	13.00		17.00		13.00		15.00	
GRANOLOCYTES	()	01/11/87		nd		nd		nd		nd
ALK. PHOSPH.	30-260 (IU/L)	01/11/87	149.00		118.00		124.00		117.00	
GLUCOSE	3.5-10 (MMOL/L)	01/11/87	4.30		6.40		5.40		5.70	
BUN	3-6.7 (MMOL/L)	01/11/87	3.30		4.30		4.30		5.00	
CREATININE	76-120 (MMOL/L)	01/11/87	76.00		97.00		81.00		96.00	
PCV	()	01/11/87		nd		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	01/11/87	260.10		258.10		264.10		328.30	
TOT BILIRUBIN	2-17 (UMOL/L)	01/11/87	10.00		13.00		17.00		14.00	
DIR BILIRUBIN	()	01/11/87		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/11/87	75.00		70.00		74.00		71.00	
ALBUMINE	35-46 (G/L)	01/11/87	50.00	>	48.00	>	51.00	>	50.00	>
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	01/11/87	7.11	>>	5.83	>	5.84	>	5.93	>
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/11/87	3.29	>>	1.29		1.31		1.29	
GLOBULINS ALPHA 1	3-6 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS ALPHA 2	7-13 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS BETA	7-14 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS GAMMA	10-20 (G/L)	01/11/87		nd		nd		nd		nd
T3	92-121 (NMOL/L)	01/11/87		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/11/87		nd		nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 3 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			12/11/87		20/11/87		27/11/87		11/12/87	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	12-16.4 (G/DL)	01/11/87	17.00	>	15.30		16.40		15.30	
HT	0.37-0.47 (L/L)	01/11/87		nd	0.44		0.46		0.44	
RBC	3.8-5.8 (10**12/L)	01/11/87	5.28		4.78		5.06		4.83	
WBC	4-11 (10**9/L)	01/11/87	14.10	>	13.60	>	14.30	>	10.50	
WBC: N	40-75 (%)	01/11/87		nd		nd		nd		nd
WBC: L	20-45 (%)	01/11/87	26.80		27.00		28.90		18.60	<
WBC: E	1-6 (%)	01/11/87	2.20		3.00		0.90	<	3.90	
WBC: M	0-1 (%)	01/11/87		nd		nd		nd		nd
WBC: B	2-10 (%)	01/11/87		nd		nd		nd		nd
PLATELETS	150-400 (10**9/L)	01/11/87	449.00	>	471.00	>	487.00	>	377.00	
NA+	135-150 (MMOL/L)	01/11/87	142.00		141.00		142.00		140.00	
K+	3.5-5 (MMOL/L)	01/11/87	4.30		4.20		4.00		4.20	
CL-	95-108 (MMOL/L)	01/11/87		nd	103.00		111.00	>	107.00	
Ca++	2.1-2.6 (MMOL/L)	01/11/87	2.10		2.30		2.20		2.20	
PO4--	0.8-1.5 (MMOL/L)	01/11/87	0.90		0.90		1.20		1.10	
SGOT	2-29 (IU/L)	01/11/87	12.00		13.00		15.00		14.00	
SGPT	5-34 (IU/L)	01/11/87	10.00		12.00		14.00		14.00	
GAMMA GT	0-65 (IU/L)	01/11/87	23.00		31.00		30.00		33.00	
GRANOLOCYTES	()	01/11/87		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/11/87	112.00		111.00		109.00		98.00	
GLUCOSE	3.5-10 (MMOL/L)	01/11/87	6.00		4.00		6.70		5.40	
BUN	2.5-7 (MMOL/L)	01/11/87	3.60		4.60		3.80		3.10	
CREATININE	59-120 (MMOL/L)	01/11/87	72.00		72.00		73.00		73.00	
PCV	()	01/11/87		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/11/87	241.00		202.90		203.50		199.20	<
TOT BILIRUBIN	3-20 (UMOL/L)	01/11/87	8.00		6.00		6.00		3.00	
DIR BILIRUBIN	()	01/11/87		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/11/87	66.00		70.00		68.00		65.00	
ALBUMINE	34-50 (G/L)	01/11/87	47.00		48.00		48.00		46.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/11/87	6.22	>	5.80		6.10	>	6.66	>
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/11/87	1.80		3.28	>>	3.61	>>	2.81	>>
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS BETA	6-12 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS GAMMA	6-16 (G/L)	01/11/87		nd		nd		nd		nd
T3	92-121 (NMOL/L)	01/11/87		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/11/87	98.00			nd		nd		nd

(¢) << 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 C[illegible]0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 4 Sex: Male

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			08/12/87		15/12/87		22/12/87		05/01/88	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	13-18 (G/DL)	01/11/87	15.60		15.70		15.40		15.70	
HT	0.4-0.54 (L/L)	01/11/87		nd	0.45		0.46		0.46	
RBC	4-6.5 (10**12/L)	01/11/87	5.06		5.04		5.06		5.12	
WBC	3.9-12 (10**9/L)	01/11/87	7.50		7.10		7.50		7.00	
WBC: N	40-75 (%)	01/11/87		nd		nd		nd		nd
WBC: L	20-45 (%)	01/11/87	30.60		35.90		30.60		36.20	
WBC: E	1-6 (%)	01/11/87	7.60	>	14.00	>>	7.60	>	5.00	
WBC: M	0-1 (%)	01/11/87		nd		nd		nd		nd
WBC: B	2-10 (%)	01/11/87		nd		nd		nd		nd
PLATELETS	100-600 (10**9/L)	01/11/87	240.00		249.00		240.00		236.00	
NA+	134-145 (MMOL/L)	01/11/87	138.00		144.00		139.00		140.00	
K+	3.5-5 (MMOL/L)	01/11/87	4.00		4.60		4.50		4.60	
CL-	95-108 (MMOL/L)	01/11/87		nd	102.00		107.00		106.00	
Ca++	2.2-2.6 (MMOL/L)	01/11/87	2.29		2.00	<	2.20		2.28	
PO4--	0.8-1.5 (MMOL/L)	01/11/87	0.87		0.87		1.10		0.87	
SGOT	15-37 (IU/L)	01/11/87	17.00		20.00		18.00		34.00	
SGPT	2-29 (IU/L)	01/11/87	34.00	>	36.00	>	30.00	>	30.00	>
GAMMA GT	0-65 (IU/L)	01/11/87	29.00		31.00		27.00		30.00	
GRANOLOCYTES	()	01/11/87		nd		nd		nd		nd
ALK. PHOSPH.	30-260 (IU/L)	01/11/87	137.00		132.00		122.00		125.00	
GLUCOSE	3.5-10 (MMOL/L)	01/11/87	12.20	>	4.60		5.90		4.60	
BUN	3-6.7 (MMOL/L)	01/11/87	4.50		3.90		3.90		2.30	<
CREATININE	76-120 (MMOL/L)	01/11/87	82.00		96.00		85.00		82.00	
PCV	()	01/11/87		nd		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	01/11/87	186.80		204.10		187.80		201.10	
TOT BILIRUBIN	2-17 (UMOL/L)	01/11/87	14.00		10.00		8.00		11.00	
DIR BILIRUBIN	()	01/11/87		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/11/87	70.00		66.00		66.00		67.00	
ALBUMINE	35-46 (G/L)	01/11/87	48.00	>	48.00	>	47.00	>	50.00	>
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	01/11/87	5.36	>	6.40	>	5.26	>	6.40	>
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/11/87	1.87		1.93		1.88		1.93	
GLOBULINS ALPHA 1	3-6 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS ALPHA 2	7-13 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS BETA	7-14 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS GAMMA	10-20 (G/L)	01/11/87		nd		nd		nd		nd
T3	92-121 (NMOL/L)	01/11/87		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/11/87	108.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 00321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 5 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 10		Day 28	
			03/02/88		17/02/88		24/02/88		09/03/88	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	12-16.4 (G/DL)	02/02/88	14.40		14.80		14.50		14.40	
HT	36-60 (%)	02/02/88	41.50		44.00		42.50		43.20	
RBC	3.8-5.8 (10**12/L)	02/02/88	4.38		4.68		4.52		4.62	
WBC	4-11 (10**9/L)	02/02/88	7.60		8.10		6.80		7.80	
WBC: N	40-75 (%)	02/02/88		nd	62.00			nd		nd
WBC: L	20-45 (%)	02/02/88	19.90	<	32.00		27.70		19.50	<
WBC: E	1-6 (%)	02/02/88	2.20		6.00		4.20		1.70	
WBC: M	0-1 (%)	02/02/88		nd		nd		nd		nd
WBC: B	2-10 (%)	02/02/88		nd		nd		nd		nd
PLATELETS	150-400 (10**9/L)	02/02/88	343.00		325.00		327.00		298.00	
NA+	135-150 (MMOL/L)	02/02/88	139.00		141.00		143.00		141.00	
K+	3.5-5 (MMOL/L)	02/02/88	3.90		3.80		3.90		4.00	
CL-	95-108 (MMOL/L)	02/02/88		nd	100.00		103.00		97.00	
Ca++	2.1-2.6 (MMOL/L)	02/02/88	2.60		2.65	>	2.57		2.59	
PO4--	0.8-1.5 (MMOL/L)	02/02/88		nd	0.98		0.95		1.00	
SGOT	2-29 (IU/L)	02/02/88	22.00		23.00		21.00		24.00	
SGPT	5-34 (IU/L)	02/02/88	23.00		42.00	>	25.00		25.00	
GAMMA GT	0-65 (IU/L)	02/02/88	20.00		20.00		15.00		9.00	
GRANOLOCYTES	()	02/02/88		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	02/02/88	148.00	>	136.00	>	122.00	>	127.00	>
GLUCOSE	3.5-10 (MMOL/L)	02/02/88	6.00		5.70		4.80		5.60	
BUN	2.5-7 (MMOL/L)	02/02/88	5.20		6.80		4.40		4.50	
CREATININE	59-120 (MMOL/L)	02/02/88	87.00		89.00		84.00		82.00	
PCV	()	02/02/88		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	02/02/88	341.30			nd	314.00		253.40	
TOT BILIRUBIN	3-20 (UMOL/L)	02/02/88	15.00		7.00		14.00		12.00	
DIR BILIRUBIN	()	02/02/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	02/02/88	68.00		76.00		69.00		71.00	
ALBUMINE	34-50 (G/L)	02/02/88	46.00		49.00		44.00		47.00	
TOT. CHOLEST.	0-6 (MMOL/L)	02/02/88	7.50	>	6.74	>	1.42		6.46	>
TRIGLYCERIDES	0.8-2 (MMOL/L)	02/02/88	1.44		1.36		1.32		1.67	
GLOBULINS ALPHA 1	1.5-4 (G/L)	02/02/88		nd		nd		nd		nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	02/02/88		nd		nd		nd		nd
GLOBULINS BETA	6-12 (G/L)	02/02/88		nd		nd		nd		nd
GLOBULINS GAMMA	6-16 (G/L)	02/02/88		nd		nd		nd		nd
T3	92-121 (NMOL/L)	02/02/88		nd		nd		nd		nd
T4	58-160 (NMOL/L)	02/02/88	135.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CR[illegible]0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 6 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			20/04/88		29/04/88		06/05/88		20/05/88	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	01/11/87	13.60		13.60		13.90		14.00	
HT	0.37-0.47 (L/L)	01/11/87		nd	0.40		0.42		0.42	
RBC	3.8-5.8 (10**12/L)	01/11/87	4.55		4.65		4.67		4.80	
WBC	4-11 (10**9/L)	01/11/87	6.10		6.20		7.40		6.80	
WBC: N	40-75 (%)	01/11/87		nd		nd		nd		nd
WBC: L	20-45 (%)	01/11/87	22.60		23.10		24.20		23.20	
WBC: E	1-6 (%)	01/11/87	3.90		3.90		4.00		4.00	
WBC: M	0-1 (%)	01/11/87		nd		nd		nd		nd
WBC: B	2-10 (%)	01/11/87		nd		nd		nd		nd
PLATELETS	150-400 (10**9/L)	01/11/87	298.00		290.00		262.00		290.00	
NA+	135-150 (MMOL/L)	01/11/87	142.00		139.00		141.00		142.00	
K+	3.5-5 (MMOL/L)	01/11/87	4.80		4.50		4.10		4.20	
CL-	95-108 (MMOL/L)	01/11/87		nd	101.00		105.00		103.00	
Ca++	2.1-2.6 (MMOL/L)	01/11/87	2.46		2.39		2.33		2.32	
PO4--	0.8-1.5 (MMOL/L)	01/11/87	1.24		0.99		0.98		0.97	
SGOT	2-29 (IU/L)	01/11/87	29.00		18.00		18.00		20.00	
SGPT	5-34 (IU/L)	01/11/87	19.00		14.00		12.00		16.00	
GAMMA GT	0-65 (IU/L)	01/11/87	18.00		15.00		14.00		14.00	
GRANOLOCYTES	()	01/11/87		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/11/87	97.00		94.00		93.00		94.00	
GLUCOSE	3.5-10 (MMOL/L)	01/11/87	5.40		7.70		8.00		6.80	
BUN	2.5-7 (MMOL/L)	01/11/87	6.30		6.90		7.30	>	6.20	
CREATININE	59-120 (MMOL/L)	01/11/87	93.00		106.00		98.00		96.00	
PCV	()	01/11/87	0.40	()		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/11/87	284.10			nd		nd		nd
TOT BILIRUBIN	3-20 (UMOL/L)	01/11/87	10.00		6.00		5.00		6.20	
DIR BILIRUBIN	()	01/11/87		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/11/87	77.00		69.00		72.00		74.00	
ALBUMINE	34-50 (G/L)	01/11/87	52.00	>	48.00		49.00		48.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/11/87	7.49	>	7.47	>	7.46	>	7.40	>
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/11/87	1.60		1.61		1.62		1.64	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS BETA	6-12 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS GAMMA	6-16 (G/L)	01/11/87		nd		nd		nd		nd
T3	92-121 (NMOL/L)	01/11/87		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/11/87	100.00			nd		nd		nd

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** missing laboratory test value nd laboratory not done () missing range value

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 7 Sex: Male

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			25/05/88		03/06/88		10/06/88		24/07/88	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	13-18 (G/DL)	24/05/88	15.60		13.30		13.90		13.50	
HT	36-60 (%)	24/05/88	45.30		39.50		39.60		40.00	
RBC	4-6.5 (10**12/L)	24/05/88	4.70		4.10		4.22		4.18	
WBC	3.9-12 (10**9/L)	24/05/88	10.30		9.30		10.10		8.70	
WBC: N	40-75 (%)	24/05/88		nd		nd		nd		nd
WBC: L	20-45 (%)	24/05/88	16.30	<	21.80		17.80	<	23.20	
WBC: E	1-6 (%)	24/05/88	4.70		4.20		3.70		3.70	
WBC: M	0-1 (%)	24/05/88		nd		nd		nd		nd
WBC: B	2-10 (%)	24/05/88		nd		nd		nd		nd
PLATELETS	100-600 (10**9/L)	24/05/88	310.00		301.00		294.00		278.00	
NA+	134-145 (MMOL/L)	24/05/88	139.00		137.00		140.00		141.00	
K+	3.5-5 (MMOL/L)	24/05/88	4.50		4.30		4.80		4.60	
CL-	95-108 (MMOL/L)	24/05/88		nd	100.00		102.00		102.00	
Ca++	2.2-2.6 (MMOL/L)	24/05/88		nd		nd	2.32		2.30	
PO4--	0.8-1.5 (MMOL/L)	24/05/88		nd		nd	1.13		0.95	
SGOT	15-37 (IU/L)	24/05/88	11.00	<	11.00	<	18.00		10.00	<
SGPT	2-29 (IU/L)	24/05/88	13.00		13.00		15.00		18.00	
GAMMA GT	5-52 (IU/L)	24/05/88	44.00		44.00		38.00		35.00	
GRANOLOCYTES	()	24/05/88		nd		nd		nd		nd
ALK. PHOSPH.	95-260 (IU/L)	24/05/88	83.00	<	82.00	<	85.00	<	93.00	<
GLUCOSE	3.5-10 (MMOL/L)	24/05/88	5.50		6.40		7.70		4.20	
BUN	3-6.7 (MMOL/L)	24/05/88	4.00		4.00		3.50		3.80	
CREATININE	76-120 (MMOL/L)	24/05/88	116.00		102.00		99.00		109.00	
PCV	()	24/05/88		nd		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	24/05/88	349.70	>	238.20		334.10		324.00	
TOT BILIRUBIN	2-17 (UMOL/L)	24/05/88	7.00		7.00		10.00		10.00	
DIR BILIRUBIN	()	24/05/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	24/05/88	72.00		61.00		62.00		62.00	
ALBUMINE	35-46 (G/L)	24/05/88	48.00	>	44.00		44.00		44.00	
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	24/05/88	5.60	>	5.10		5.30	>	5.20	
TRIGLYCERIDES	0.5-2 (MMOL/L)	24/05/88	1.00		1.30		0.79		1.50	
GLOBULINS ALPHA 1	3-6 (G/L)	24/05/88		nd		nd		nd		nd
GLOBULINS ALPHA 2	7-13 (G/L)	24/05/88		nd		nd		nd		nd
GLOBULINS BETA	7-14 (G/L)	24/05/88		nd		nd		nd		nd
GLOBULINS GAMMA	10-20 (G/L)	24/05/88		nd		nd		nd		nd
T3	92-121 (NMOL/L)	24/05/88		nd		nd		nd		nd
T4	58-160 (NMOL/L)	24/05/88	105.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) > clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CM5 [illegible] 0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 8 Sex: Female

			Visit number / Laboratory date					
			Screen		Day 7		Day 14	
			13/07/88		22/07/88		29/07/88	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16.4 (G/DL)	01/11/87	14.00		14.20		14.20	
HT	0.37-0.47 (L/L)	01/11/87		nd	0.41		0.42	
RBC	3.8-5.8 (10**12/L)	01/11/87	4.90		5.20		5.60	
WBC	4-11 (10**9/L)	01/11/87	5.80		6.80		7.20	
WBC: N	40-75 (%)	01/11/87		nd		nd		nd
WBC: L	20-45 (%)	01/11/87	36.80		24.80		26.50	
WBC: E	1-6 (%)	01/11/87	3.20		5.20		5.50	
WBC: M	0-1 (%)	01/11/87		nd		nd		nd
WBC: B	2-10 (%)	01/11/87		nd		nd		nd
PLATELETS	150-400 (10**9/L)	01/11/87	298.00		320.00		346.00	
NA+	135-150 (MMOL/L)	01/11/87	140.00		140.00		141.00	
K+	3.5-5 (MMOL/L)	01/11/87	4.20		4.20		4.20	
CL-	95-108 (MMOL/L)	01/11/87		nd	98.00		96.00	
Ca++	2.1-2.6 (MMOL/L)	01/11/87	2.28		2.23		2.42	
PO4--	0.8-1.5 (MMOL/L)	01/11/87	0.90		0.88		0.98	
SGOT	2-29 (IU/L)	01/11/87	18.00		20.00		28.00	
SGPT	5-34 (IU/L)	01/11/87	20.00		30.00		32.00	
GAMMA GT	0-65 (IU/L)	01/11/87	22.00		24.00		26.00	
GRANOLOCYTES	()	01/11/87		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/11/87	101.00		100.00		98.00	
GLUCOSE	3.5-10 (MMOL/L)	01/11/87	4.50		4.80		4.60	
BUN	2.5-7 (MMOL/L)	01/11/87	5.80		5.60		4.80	
CREATININE	59-120 (MMOL/L)	01/11/87	78.00		78.00		76.00	
PCV	()	01/11/87	0.46	()		nd		nd
URIC ACID	200-500 (UMOL/L)	01/11/87	180.00	<	188.00	<	196.00	<
TOT BILIRUBIN	3-20 (UMOL/L)	01/11/87	6.00		6.00		7.00	
DIR BILIRUBIN	()	01/11/87		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/11/87	76.00		68.00		72.00	
ALBUMINE	34-50 (G/L)	01/11/87	42.00		46.00		48.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/11/87	5.58		6.21	>	6.13	>
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/11/87	1.68		1.38		1.39	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/11/87		nd		nd		nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/11/87		nd		nd		nd
GLOBULINS BETA	6-12 (G/L)	01/11/87		nd		nd		nd
GLOBULINS GAMMA	6-16 (G/L)	01/11/87		nd		nd		nd
T3	92-121 (NMOL/L)	01/11/87		nd		nd		nd
T4	58-160 (NMOL/L)	01/11/87	102.00			nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CN9550321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 9 Sex: Male

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			04/10/88		12/10/88		19/10/88		02/11/88	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	13-18 (G/DL)	01/11/87	14.70		14.70		14.60		14.90	
HT	0.4-0.54 (L/L)	01/11/87	0.31	<<	0.32	<<	0.33	<<	0.30	<<
RBC	4-6.5 (10**12/L)	01/11/87	4.80		4.81		4.86		4.91	
WBC	3.9-12 (10**9/L)	01/11/87	7.60		7.60		6.70		6.80	
WBC: N	40-75 (%)	01/11/87		nd		nd		nd		nd
WBC: L	20-45 (%)	01/11/87		nd	11.60	<<	17.20	<	17.60	<
WBC: E	1-6 (%)	01/11/87		nd	4.80		5.90		5.70	
WBC: M	0-1 (%)	01/11/87		nd		nd		nd		nd
WBC: B	2-10 (%)	01/11/87		nd		nd		nd		nd
PLATELETS	100-600 (10**9/L)	01/11/87	357.00		414.00		445.00		359.00	
NA+	134-145 (MMOL/L)	01/11/87	142.00		146.00	>	145.00		141.00	
K+	3.5-5 (MMOL/L)	01/11/87	4.40		4.00		4.00		4.10	
CL-	95-108 (MMOL/L)	01/11/87		nd		nd	107.00		110.00	>
Ca++	2.2-2.6 (MMOL/L)	01/11/87	2.39		2.37		2.25		2.32	
PO4--	0.8-1.5 (MMOL/L)	01/11/87	1.11		0.90		0.86		1.01	
SGOT	15-37 (IU/L)	01/11/87	21.00		13.00	<	13.00	<	12.00	<
SGPT	2-29 (IU/L)	01/11/87	23.00		16.00		14.00		16.00	
GAMMA GT	0-65 (IU/L)	01/11/87	15.00		16.00		14.00		15.00	
GRANOLOCYTES	()	01/11/87		nd		nd		nd		nd
ALK. PHOSPH.	30-260 (IU/L)	01/11/87	85.00		110.00		142.00		163.00	
GLUCOSE	3.5-10 (MMOL/L)	01/11/87	7.80		5.20		5.20		5.50	
BUN	3-6.7 (MMOL/L)	01/11/87	5.00		4.30		4.90		5.80	
CREATININE	76-120 (MMOL/L)	01/11/87	111.00		103.00		103.00		99.00	
PCV	()	01/11/87		nd		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	01/11/87	201.00		171.00	<	203.00			nd
TOT BILIRUBIN	2-17 (UMOL/L)	01/11/87	10.00		20.00	>	12.00		12.00	
DIR BILIRUBIN	()	01/11/87		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/11/87	72.00		77.00		74.00		74.00	
ALBUMINE	35-46 (G/L)	01/11/87	47.00	>	47.00	>	47.00	>	45.00	
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	01/11/87	4.90		5.00		5.30	>	5.15	
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/11/87	1.05		0.92		1.08		1.26	
GLOBULINS ALPHA 1	3-6 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS ALPHA 2	7-13 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS BETA	7-14 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS GAMMA	10-20 (G/L)	01/11/87		nd		nd		nd		nd
T3	92-121 (NMOL/L)	01/11/87		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/11/87	137.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CN[illegible]0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 10 Sex: Male

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			04/10/88		13/10/88		21/10/88		04/11/88	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	13-18 (G/DL)	01/11/87	14.60		14.00		14.80		14.00	
HT	0.4-0.54 (L/L)	01/11/87	0.44		0.42		0.43		0.46	
RBC	4-6.5 (10**12/L)	01/11/87	5.02		4.67		5.08		5.68	
WBC	3.9-12 (10**9/L)	01/11/87	10.90		10.20		8.50		8.80	
WBC: N	40-75 (%)	01/11/87		nd		nd		nd		nd
WBC: L	20-45 (%)	01/11/87	10.70	<<	9.90	<<	17.20	<	19.00	<
WBC: E	1-6 (%)	01/11/87	7.00	>	2.70		2.80		3.00	
WBC: M	0-1 (%)	01/11/87		nd		nd		nd		nd
WBC: B	2-10 (%)	01/11/87		nd		nd		nd		nd
PLATELETS	100-600 (10**9/L)	01/11/87	329.00		317.00		340.00		326.00	
NA+	134-145 (MMOL/L)	01/11/87	143.00		141.00		141.00		140.00	
K+	3.5-5 (MMOL/L)	01/11/87	4.90		5.00		4.80		4.80	
CL-	95-108 (MMOL/L)	01/11/87		nd	105.00		102.00		102.00	
Ca++	2.2-2.6 (MMOL/L)	01/11/87	2.39		2.58		2.48		2.46	
PO4--	0.8-1.5 (MMOL/L)	01/11/87	1.04		1.04		1.08		1.06	
SGOT	15-37 (IU/L)	01/11/87	17.00		18.00		20.00		26.00	
SGPT	2-29 (IU/L)	01/11/87	19.00		20.00		22.00		40.00	>
GAMMA GT	0-65 (IU/L)	01/11/87	30.00		32.00		34.00		34.00	
GRANOLOCYTES	()	01/11/87		nd		nd		nd		nd
ALK. PHOSPH.	30-260 (IU/L)	01/11/87	100.00		80.00		86.00		88.00	
GLUCOSE	3.5-10 (MMOL/L)	01/11/87	5.20		5.10		5.20		5.10	
BUN	3-6.7 (MMOL/L)	01/11/87	7.40	>	9.50	>	8.80	>	6.80	>
CREATININE	76-120 (MMOL/L)	01/11/87	107.00		117.00		106.00		104.00	
PCV	()	01/11/87		nd		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	01/11/87	240.00		248.00		240.00		240.00	
TOT BILIRUBIN	2-17 (UMOL/L)	01/11/87	4.00		5.00		6.00		8.00	
DIR BILIRUBIN	()	01/11/87		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/11/87	71.00		65.00		66.00		70.00	
ALBUMINE	35-46 (G/L)	01/11/87	45.00		43.00		42.00		44.00	
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	01/11/87	6.20	>	6.30	>	6.30	>	6.36	>
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/11/87	1.90		2.00		1.90		1.89	
GLOBULINS ALPHA 1	3-6 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS ALPHA 2	7-13 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS BETA	7-14 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS GAMMA	10-20 (G/L)	01/11/87		nd		nd		nd		nd
T3	92-121 (NMOL/L)	01/11/87		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/11/87	108.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 11 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			15/11/88		22/11/88		29/11/88		12/12/88	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	12-16.4 (G/DL)	01/11/87	13.40		13.60		13.30		12.90	
HT	0.37-0.47 (L/L)	01/11/87	0.41		0.47		0.40		0.39	
RBC	3.8-5.8 (10**12/L)	01/11/87	4.86		4.92		4.78		4.83	
WBC	4-11 (10**9/L)	01/11/87	5.80		6.20		7.60		6.30	
WBC: N	40-75 (%)	01/11/87		nd		nd		nd		nd
WBC: L	20-45 (%)	01/11/87	36.20		27.00		26.70		41.90	
WBC: E	1-6 (%)	01/11/87	5.80		5.00		5.70		5.80	
WBC: M	0-1 (%)	01/11/87		nd		nd		nd		nd
WBC: B	2-10 (%)	01/11/87		nd		nd		nd		nd
PLATELETS	150-400 (10**9/L)	01/11/87	314.00		302.00		304.00		343.00	
NA+	135-150 (MMOL/L)	01/11/87	139.00		139.00		140.00		139.00	
K+	3.5-5 (MMOL/L)	01/11/87	4.20		4.70		4.40		4.50	
CL-	95-108 (MMOL/L)	01/11/87		nd	108.00		106.00		107.00	
Ca++	2.1-2.6 (MMOL/L)	01/11/87	2.30		2.24		2.21		2.19	
PO4--	0.8-1.5 (MMOL/L)	01/11/87	0.90		0.80		0.81		0.83	
SGOT	2-29 (IU/L)	01/11/87	17.00		16.00		20.00		21.00	
SGPT	5-34 (IU/L)	01/11/87	14.00		18.00		22.00		27.00	
GAMMA GT	0-65 (IU/L)	01/11/87	14.00		20.00		12.00		11.00	
GRANOLOCYTES	()	01/11/87		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/11/87	101.00		106.00		108.00		104.00	
GLUCOSE	3.5-10 (MMOL/L)	01/11/87	4.50		4.60		4.50		4.80	
BUN	2.5-7 (MMOL/L)	01/11/87	5.80		5.60		5.60		5.10	
CREATININE	59-120 (MMOL/L)	01/11/87	73.00		76.00		78.00		70.00	
PCV	()	01/11/87		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/11/87	189.80	<	198.20	<	196.40	<	167.90	<
TOT BILIRUBIN	3-20 (UMOL/L)	01/11/87	9.00		9.00		8.00		9.00	
DIR BILIRUBIN	()	01/11/87		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/11/87	73.00		73.00		76.00		73.00	
ALBUMINE	34-50 (G/L)	01/11/87	45.00		48.00		49.00		45.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/11/87	5.28		5.31		5.34		5.80	
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/11/87	0.88		0.88		0.89		0.85	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS BETA	6-12 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS GAMMA	6-16 (G/L)	01/11/87		nd		nd		nd		nd
T3	92-121 (NMOL/L)	01/11/87		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/11/87	105.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CN 0550321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 12 Sex: Male

			Visit number / Laboratory date					
			Screen		Day 7		Day 14	
			17/11/88		25/11/88		30/11/88	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/11/87	16.60		16.00		15.80	
HT	0.4-0.54 (L/L)	01/11/87		nd	0.48		0.43	
RBC	4-6.5 (10**12/L)	01/11/87	5.36		6.80	>	6.90	>
WBC	3.9-12 (10**9/L)	01/11/87	6.80		5.48		5.80	
WBC: N	40-75 (%)	01/11/87		nd		nd		nd
WBC: L	20-45 (%)	01/11/87	24.00		26.60		28.80	
WBC: E	1-6 (%)	01/11/87	5.90		12.60	>>	9.20	>>
WBC: M	0-1 (%)	01/11/87		nd		nd		nd
WBC: B	2-10 (%)	01/11/87		nd		nd		nd
PLATELETS	100-600 (10**9/L)	01/11/87	291.00		310.00		306.00	
NA+	134-145 (MMOL/L)	01/11/87	141.00		139.00		140.00	
K+	3.5-5 (MMOL/L)	01/11/87	4.20		4.30		4.40	
CL-	95-108 (MMOL/L)	01/11/87		nd	100.00		96.00	
Ca++	2.2-2.6 (MMOL/L)	01/11/87	2.58		2.30		2.42	
PO4--	0.8-1.5 (MMOL/L)	01/11/87	1.05		1.42		1.42	
SGOT	15-37 (IU/L)	01/11/87	22.00		16.00		18.00	
SGPT	2-29 (IU/L)	01/11/87	29.00		12.00		16.00	
GAMMA GT	0-65 (IU/L)	01/11/87	24.00		5.00		8.00	
GRANOLOCYTES	()	01/11/87		nd		nd		nd
ALK. PHOSPH.	30-260 (IU/L)	01/11/87	133.00		89.00		88.00	
GLUCOSE	3.5-10 (MMOL/L)	01/11/87	4.90		5.80		5.20	
BUN	3-6.7 (MMOL/L)	01/11/87	3.00		9.00	>	6.00	
CREATININE	76-120 (MMOL/L)	01/11/87	106.00		118.00		116.00	
PCV	()	01/11/87		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	01/11/87	240.20		295.80		280.20	
TOT BILIRUBIN	2-17 (UMOL/L)	01/11/87	4.00		2.80		6.00	
DIR BILIRUBIN	()	01/11/87		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/11/87	76.00		69.00			nd
ALBUMINE	35-46 (G/L)	01/11/87	54.00	>	49.00	>	51.00	>
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	01/11/87	4.41		4.41		4.52	
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/11/87	3.18	>>	3.21	>>	3.12	>>
GLOBULINS ALPHA 1	3-6 (G/L)	01/11/87		nd		nd		nd
GLOBULINS ALPHA 2	7-13 (G/L)	01/11/87		nd		nd		nd
GLOBULINS BETA	7-14 (G/L)	01/11/87		nd		nd		nd
GLOBULINS GAMMA	10-20 (G/L)	01/11/87		nd		nd		nd
T3	92-121 (NMOL/L)	01/11/87		nd		nd		nd
T4	58-160 (NMOL/L)	01/11/87	114.00			nd		nd

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PHARMACIA CN 9550321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 13 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			04/01/89		13/01/89		20/01/89		03/02/89	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	01/11/87	14.90		14.10		14.20		14.40	
HT	0.37-0.47 (L/L)	01/11/87		nd	0.42		0.42		0.43	
RBC	3.8-5.8 (10**12/L)	01/11/87	4.72		4.54		4.50		4.57	
WBC	4-11 (10**9/L)	01/11/87	8.40		7.80		7.20		9.82	
WBC: N	40-75 (%)	01/11/87	68.70			nd		nd		nd
WBC: L	20-45 (%)	01/11/87	27.50		36.50		34.00		34.50	
WBC: E	1-6 (%)	01/11/87	3.80		5.60		5.80		5.00	
WBC: M	0-1 (%)	01/11/87		nd		nd		nd		nd
WBC: B	2-10 (%)	01/11/87		nd		nd		nd		nd
PLATELETS	150-400 (10**9/L)	01/11/87	315.00		328.00		310.00		340.00	
NA+	135-150 (MMOL/L)	01/11/87	143.00		144.00		143.00		140.00	
K+	3.5-5 (MMOL/L)	01/11/87	4.60		5.00		4.90		4.90	
CL-	95-108 (MMOL/L)	01/11/87		nd	107.00		106.00		102.00	
Ca++	2.1-2.6 (MMOL/L)	01/11/87	2.52		2.43		2.43		2.29	
PO4--	0.8-1.5 (MMOL/L)	01/11/87	1.34		1.27		1.24		1.28	
SGOT	2-29 (IU/L)	01/11/87	21.00		18.00		16.00		14.00	
SGPT	5-34 (IU/L)	01/11/87	31.00		20.00		20.00		25.00	
GAMMA GT	0-65 (IU/L)	01/11/87	20.00		18.00		20.00		19.00	
GRANOLOCYTES	()	01/11/87		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/11/87		nd	70.00		76.00		72.00	
GLUCOSE	3.5-10 (MMOL/L)	01/11/87		nd	5.60		5.20		5.40	
BUN	2.5-7 (MMOL/L)	01/11/87	3.70		2.50		3.20		3.30	
CREATININE	59-120 (MMOL/L)	01/11/87	113.00		84.00		82.00		95.00	
PCV	()	01/11/87		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/11/87	220.00		200.00		210.00		206.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/11/87	5.00		5.00		6.00		6.00	
DIR BILIRUBIN	()	01/11/87		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/11/87	71.00		71.00		72.00		74.00	
ALBUMINE	34-50 (G/L)	01/11/87	43.00		43.00		46.00		47.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/11/87	6.70	>	6.70	>	6.91	>		nd
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/11/87		nd	1.89		1.91			nd
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS BETA	6-12 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS GAMMA	6-16 (G/L)	01/11/87		nd		nd		nd		nd
T3	92-121 (NMOL/L)	01/11/87		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/11/87	108.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 14 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			11/01/89		18/01/89		25/01/89		10/02/89	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	01/11/87	14.90		14.60		13.80		14.00	
HT	0.37-0.47 (L/L)	01/11/87	0.42		0.43		0.41		0.42	
RBC	3.8-5.8 (10**12/L)	01/11/87	4.11		4.80		3.99		4.52	
WBC	4-11 (10**9/L)	01/11/87	10.40		9.80		9.30		8.66	
WBC: N	40-75 (%)	01/11/87		nd		nd		nd		nd
WBC: L	20-45 (%)	01/11/87	17.40	<	17.80	<	18.40	<	18.50	<
WBC: E	1-6 (%)	01/11/87	0.80	<		nd	4.50		4.50	
WBC: M	0-1 (%)	01/11/87		nd		nd		nd		nd
WBC: B	2-10 (%)	01/11/87		nd		nd		nd		nd
PLATELETS	150-400 (10**9/L)	01/11/87	358.00		350.00		254.00		280.00	
NA+	135-150 (MMOL/L)	01/11/87	136.00		138.00		139.00		140.00	
K+	3.5-5 (MMOL/L)	01/11/87	4.30		4.40		4.70		4.80	
CL-	95-108 (MMOL/L)	01/11/87		nd	106.00		108.00		108.00	
Ca++	2.1-2.6 (MMOL/L)	01/11/87	2.26		2.20		2.30		2.28	
PO4--	0.8-1.5 (MMOL/L)	01/11/87	0.95		0.95		0.86		0.88	
SGOT	2-29 (IU/L)	01/11/87	11.00		12.00		10.00		16.00	
SGPT	5-34 (IU/L)	01/11/87	16.00		18.00		12.00		18.00	
GAMMA GT	0-65 (IU/L)	01/11/87	18.00		20.00		17.00		20.00	
GRANOLOCYTES	()	01/11/87		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/11/87	66.00		68.00		64.00		64.00	
GLUCOSE	3.5-10 (MMOL/L)	01/11/87	5.70		5.20		4.80		4.90	
BUN	2.5-7 (MMOL/L)	01/11/87	3.10		4.20		3.20		3.30	
CREATININE	59-120 (MMOL/L)	01/11/87	49.00	<	56.00	<	63.00		68.00	
PCV	()	01/11/87		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/11/87	180.00	<	186.00	<	188.00	<	184.00	<
TOT BILIRUBIN	3-20 (UMOL/L)	01/11/87	4.00		5.10		9.00		8.00	
DIR BILIRUBIN	()	01/11/87		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/11/87	61.00		60.00		60.00		60.00	
ALBUMINE	34-50 (G/L)	01/11/87	42.00		42.00		42.00		48.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/11/87	4.90		4.80		4.90		4.92	
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/11/87	1.58		1.54		1.58		1.68	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS BETA	6-12 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS GAMMA	6-16 (G/L)	01/11/87		nd		nd		nd		nd
T3	92-121 (NMOL/L)	01/11/87		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/11/87	120.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CN8550321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 15 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			23/03/89		03/04/89		10/04/89		17/04/89	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	22/03/89	13.80		15.00		15.70		15.10	
HT	36-60 (%)	22/03/89	41.10							
	0.37-0.47 (L/L)	02/04/89			0.44		0.46		0.44	
RBC	3.8-5.8 (10**12/L)	22/03/89	4.60		4.83		5.06		4.80	
WBC	4-11 (10**9/L)	22/03/89	3.80	<	5.50		5.80		8.80	
WBC: N	40-75 (%)	22/03/89		nd		nd		nd		nd
WBC: L	20-45 (%)	22/03/89	30.80		30.20		25.80		28.00	
WBC: E	1-6 (%)	22/03/89	1.60		5.70		3.20		2.00	
WBC: M	0-1 (%)	22/03/89		nd		nd		nd		nd
WBC: B	2-10 (%)	22/03/89		nd		nd		nd		nd
PLATELETS	150-400 (10**9/L)	22/03/89	235.00		239.00		313.00		311.00	
NA+	135-150 (MMOL/L)	22/03/89	145.00		137.00			nd	140.00	
K+	3.5-5 (MMOL/L)	22/03/89	4.20		4.00			nd	4.30	
CL-	95-108 (MMOL/L)	22/03/89		nd	108.00			nd	108.00	
Ca++	2.1-2.6 (MMOL/L)	22/03/89	2.47		2.24			nd	2.49	
PO4--	0.8-1.5 (MMOL/L)	22/03/89	1.32		0.96			nd	1.09	
SGOT	2-29 (IU/L)	22/03/89	15.00		18.00			nd	14.00	
SGPT	5-34 (IU/L)	22/03/89	13.00		21.00			nd	19.00	
GAMMA GT	0-65 (IU/L)	22/03/89	22.00		21.00			nd	19.00	
GRANOLOCYTES	()	22/03/89		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	22/03/89	84.00		84.00			nd	82.00	
GLUCOSE	3.5-10 (MMOL/L)	22/03/89	8.50		4.20			nd	6.70	
BUN	2.5-7 (MMOL/L)	22/03/89	3.20		5.10			nd	5.00	
CREATININE	59-120 (MMOL/L)	22/03/89	102.00		88.00			nd	80.00	
PCV	()	22/03/89		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	22/03/89		nd	195.00	<	241.00		195.00	<
TOT BILIRUBIN	3-20 (UMOL/L)	22/03/89	19.00		19.00		22.00	>	19.00	
DIR BILIRUBIN	()	22/03/89		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	22/03/89	73.00		76.00		80.00		74.00	
ALBUMINE	34-50 (G/L)	22/03/89	46.00		47.00		49.00		45.00	
TOT. CHOLEST.	0-6 (MMOL/L)	22/03/89	6.60	>	5.90		5.90		5.90	
TRIGLYCERIDES	0.8-2 (MMOL/L)	22/03/89	0.70	<	0.90		1.10		0.90	
GLOBULINS ALPHA 1	1.5-4 (G/L)	22/03/89		nd		nd		nd		nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	22/03/89		nd		nd		nd		nd
GLOBULINS BETA	6-12 (G/L)	22/03/89		nd		nd		nd		nd
GLOBULINS GAMMA	6-16 (G/L)	22/03/89		nd		nd		nd		nd
T3	92-121 (NMOL/L)	22/03/89		nd		nd		nd		nd
T4	58-160 (NMOL/L)	22/03/89	112.00			nd		nd		nd

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REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 1 Patient: 16 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			21/04/89		02/05/89		08/05/89		22/05/89	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	12-16.4 (G/DL)	01/11/87	15.70		15.30		15.50		17.40	>
HT	0.37-0.47 (L/L)	01/11/87	0.46		0.44		0.45		0.47	
RBC	3.8-5.8 (10**12/L)	01/11/87	4.73		4.57		4.68		4.82	
WBC	4-11 (10**9/L)	01/11/87	11.80	>	11.90	>	10.20		10.20	
WBC: N	40-75 (%)	01/11/87		nd		nd		nd		nd
WBC: L	20-45 (%)	01/11/87	15.40	<	18.60	<	19.40	<	24.70	
WBC: E	1-6 (%)	01/11/87	2.00		3.90		2.80		5.50	
WBC: M	0-1 (%)	01/11/87		nd		nd		nd		nd
WBC: B	2-10 (%)	01/11/87		nd		nd		nd		nd
PLATELETS	150-400 (10**9/L)	01/11/87	309.00		320.00		285.00		332.00	
NA+	135-150 (MMOL/L)	01/11/87	137.00		132.00	<	130.00	<	135.00	
K+	3.5-5 (MMOL/L)	01/11/87	4.10		4.30		4.50		5.00	
CL-	95-108 (MMOL/L)	01/11/87		nd	102.00		99.00		94.00	<
Ca++	2.1-2.6 (MMOL/L)	01/11/87	2.57		2.40		2.42		2.67	>
PO4--	0.8-1.5 (MMOL/L)	01/11/87	0.90		1.14		1.16		1.13	
SGOT	2-29 (IU/L)	01/11/87	16.00		16.00		16.00		18.00	
SGPT	5-34 (IU/L)	01/11/87	12.00		9.00		8.00		10.00	
GAMMA GT	0-65 (IU/L)	01/11/87	18.00		20.00		20.00		20.00	
GRANOLOCYTES	()	01/11/87		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/11/87	118.00	>	111.00		112.00		111.00	
GLUCOSE	3.5-10 (MMOL/L)	01/11/87	4.80		4.20		5.30		4.60	
BUN	2.5-7 (MMOL/L)	01/11/87	5.50		5.80		3.30		3.90	
CREATININE	59-120 (MMOL/L)	01/11/87	98.00		76.00		86.00		95.00	
PCV	()	01/11/87		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/11/87		nd		nd		nd		nd
TOT BILIRUBIN	3-20 (UMOL/L)	01/11/87	5.00		8.00		6.00		8.00	
DIR BILIRUBIN	()	01/11/87		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/11/87	79.00		72.00		74.00		77.00	
ALBUMINE	34-50 (G/L)	01/11/87	50.00		48.00		48.00		50.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/11/87	6.50	>	5.30		5.30		5.40	
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/11/87	1.20		1.10		0.90		0.90	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS BETA	6-12 (G/L)	01/11/87		nd		nd		nd		nd
GLOBULINS GAMMA	6-16 (G/L)	01/11/87		nd		nd		nd		nd
T3	92-121 (NMOL/L)	01/11/87		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/11/87	99.00			nd		nd		nd

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** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 3580321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 2 Patient: 21 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			15/02/88		29/02/88		07/03/88		23/03/88	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	01/02/88	12.50		13.60		13.20		12.70	
HT	0.37-0.47 (L/L)	01/02/88		nd	0.37	<	0.39		0.37	
RBC	3.8-5.8 (10**12/L)	01/02/88	4.01		4.45		4.15		3.95	
WBC	4-11 (10**9/L)	01/02/88	5.00		10.90		6.10		3.70	<
WBC: N	2.5-7.5 (10**9/L)	01/02/88	2.80		7.30		3.70		2.00	<
WBC: L	1.5-3.5 (10**9/L)	01/02/88	2.00		3.30		2.10		1.50	
WBC: E	0.04-0.44 (10**9/L)	01/02/88	0.20		0.30		0.20		0.20	
WBC: M	0.2-0.8 (10**9/L)	01/02/88	0.70		0.70		0.70		0.70	
WBC: B	0-0.1 (10**9/L)	01/02/88	0.20	>>	0.20	>>	0.20	>>	0.20	>>
PLATELETS	150-400 (10**9/L)	01/02/88	191.00		199.00		203.00		220.00	
NA+	135-150 (MMOL/L)	01/02/88	140.00		138.00		137.00		141.00	
K+	3.5-5 (MMOL/L)	01/02/88	3.70		4.00		4.00		4.10	
CL-	95-108 (MMOL/L)	01/02/88		nd		nd		nd		nd
Ca++	2.1-2.6 (MMOL/L)	01/02/88	2.30		2.35		2.51		2.29	
PO4--	0.8-1.5 (MMOL/L)	01/02/88	1.06		1.19		1.30		1.08	
SGOT	2-29 (IU/L)	01/02/88	23.00		13.00		14.00		21.00	
SGPT	5-34 (IU/L)	01/02/88	14.00		19.00		20.00		17.00	
GAMMA GT	0-65 (IU/L)	01/02/88	8.00		7.00		7.00		7.00	
GRANOLOCYTES	()	01/02/88		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/02/88	125.00	>	122.00	>	97.00		106.00	
GLUCOSE	3.5-10 (MMOL/L)	01/02/88	4.60			nd	5.50		5.00	
BUN	2.5-7 (MMOL/L)	01/02/88	6.20		4.80		6.40		3.80	
CREATININE	59-120 (MMOL/L)	01/02/88	73.00		79.00		114.00		88.00	
PCV	()	01/02/88		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/02/88	180.00	<	177.00	<	214.00		156.00	<
TOT BILIRUBIN	3-20 (UMOL/L)	01/02/88	9.00		6.00		7.00		8.00	
DIR BILIRUBIN	()	01/02/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/02/88	69.00		68.00		73.00		69.00	
ALBUMINE	34-50 (G/L)	01/02/88	41.00		40.00		43.00		40.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/02/88	5.90		4.90		5.10		4.70	
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/02/88	1.70		2.40	>	2.10	>	1.20	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/02/88		nd	2.71			nd	0.57	<<
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/02/88		nd	4.95			nd	5.65	
GLOBULINS BETA	6-12 (G/L)	01/02/88		nd	7.10			nd	8.77	
GLOBULINS GAMMA	6-16 (G/L)	01/02/88		nd	12.58			nd	14.14	
T3	92-121 (NMOL/L)	01/02/88		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/02/88	109.00			nd		nd		nd

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PHARMACIA CN 0550321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 2 Patient: 22 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			29/04/88		16/05/88		23/05/88		07/06/88	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	01/02/88	13.40		13.10		13.80		13.90	
HT	0.37-0.47 (L/L)	01/02/88		nd	0.38		0.41		0.41	
RBC	3.8-5.8 (10**12/L)	01/02/88	4.43		4.23		4.53		4.57	
WBC	4-11 (10**9/L)	01/02/88	8.80		7.00		6.90		7.70	
WBC: N	2.5-7.5 (10**9/L)	01/02/88	6.60		4.90		4.70		5.60	
WBC: L	1.5-3.5 (10**9/L)	01/02/88	1.90		1.80		1.90		1.70	
WBC: E	0.04-0.44 (10**9/L)	01/02/88	0.30		0.30		0.30		0.30	
WBC: M	0.2-0.8 (10**9/L)	01/02/88	0.70		0.70		0.70		0.70	
WBC: B	0-0.1 (10**9/L)	01/02/88	0.20	>>	0.20	>>	0.20	>>	0.20	>>
PLATELETS	150-400 (10**9/L)	01/02/88	358.00		320.00		352.00		374.00	
NA+	135-150 (MMOL/L)	01/02/88	141.00		140.00		131.00	<	143.00	
K+	3.5-5 (MMOL/L)	01/02/88	3.60		3.60		4.70		3.80	
CL-	95-108 (MMOL/L)	01/02/88		nd		nd		nd		nd
Ca++	2.1-2.6 (MMOL/L)	01/02/88	2.37		2.46		2.39		2.39	
PO4--	0.8-1.5 (MMOL/L)	01/02/88	1.46		1.42		1.31		1.14	
SGOT	2-29 (IU/L)	01/02/88	17.00		11.00		12.00		14.00	
SGPT	5-34 (IU/L)	01/02/88	13.00		16.00		15.00		16.00	
GAMMA GT	0-65 (IU/L)	01/02/88	10.00		10.00		10.00		11.00	
GRANOLOCYTES	()	01/02/88		nd		nd	.	nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/02/88	165.00	>	177.00	>	182.00	>	189.00	>
GLUCOSE	3.5-10 (MMOL/L)	01/02/88	5.40		5.10		5.30		5.30	
BUN	2.5-7 (MMOL/L)	01/02/88	5.10		5.20		8.50	>	6.20	
CREATININE	59-120 (MMOL/L)	01/02/88	63.00		69.00		89.00		65.00	
PCV	()	01/02/88		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/02/88	205.00		247.00		275.00		256.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/02/88	11.00		10.00		10.00		10.00	
DIR BILIRUBIN	()	01/02/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/02/88	75.00		72.00		76.00		78.00	
ALBUMINE	34-50 (G/L)	01/02/88	43.00		42.00		42.00		44.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/02/88	7.40	>	7.50	>	7.30	>	8.00	>>
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/02/88	0.90		1.70		1.50		1.10	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/02/88	1.90		2.52		1.80			nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/02/88	6.60		6.15		7.50			nd
GLOBULINS BETA	6-12 (G/L)	01/02/88	9.70		9.26		10.10			nd
GLOBULINS GAMMA	6-16 (G/L)	01/02/88	13.80		12.75		14.30			nd
T3	92-121 (NMOL/L)	01/02/88		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/02/88	123.00			nd		nd		nd

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PHARMACIA CNS 9550321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 2 Patient: 23 Sex: Female

			Visit number / Laboratory date			
			Screen		Day 7	
			16/12/88		05/01/89	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	12-16.4 (G/DL)	01/02/88	14.50		15.00	
HT	0.37-0.47 (L/L)	01/02/88		nd	0.44	
RBC	3.8-5.8 (10**12/L)	01/02/88	4.54		4.85	
WBC	4-11 (10**9/L)	01/02/88	6.20		9.30	
WBC: N	2.5-7.5 (10**9/L)	01/02/88	4.10		6.80	
WBC: L	1.5-3.5 (10**9/L)	01/02/88	1.80		2.00	
WBC: E	0.04-0.44 (10**9/L)	01/02/88	0.30		0.50	>
WBC: M	0.2-0.8 (10**9/L)	01/02/88	0.70		0.70	
WBC: B	0-0.1 (10**9/L)	01/02/88	0.20	>>	0.20	>>
PLATELETS	150-400 (10**9/L)	01/02/88	233.00		303.00	
NA+	135-150 (MMOL/L)	01/02/88	139.00		138.00	
K+	3.5-5 (MMOL/L)	01/02/88	3.60		3.50	
CL-	95-108 (MMOL/L)	01/02/88		nd		nd
Ca++	2.1-2.6 (MMOL/L)	01/02/88	2.12		2.30	
PO4--	0.8-1.5 (MMOL/L)	01/02/88	1.28		1.21	
SGOT	2-29 (IU/L)	01/02/88	21.00		18.00	
SGPT	5-34 (IU/L)	01/02/88	15.00		17.00	
GAMMA GT	0-65 (IU/L)	01/02/88	81.00	>	42.00	
GRANOLOCYTES	()	01/02/88		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/02/88	265.00	>>	169.00	>
GLUCOSE	3.5-10 (MMOL/L)	01/02/88	4.90			nd
BUN	2.5-7 (MMOL/L)	01/02/88	3.40		4.10	
CREATININE	59-120 (MMOL/L)	01/02/88	64.00		59.00	
PCV	()	01/02/88		nd		nd
URIC ACID	200-500 (UMOL/L)	01/02/88	164.00	<	263.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/02/88	12.00		10.00	
DIR BILIRUBIN	()	01/02/88		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/02/88	79.00		68.00	
ALBUMINE	34-50 (G/L)	01/02/88	32.00	<	39.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/02/88	3.30		5.90	
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/02/88	1.20		3.10	>>
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/02/88	2.64		2.52	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/02/88	7.46		6.33	
GLOBULINS BETA	6-12 (G/L)	01/02/88	7.93		10.04	
GLOBULINS GAMMA	6-16 (G/L)	01/02/88	12.11		9.16	
T3	92-121 (NMOL/L)	01/02/88		nd		nd
T4	58-160 (NMOL/L)	01/02/88	79.00			nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CN9 350321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 2 Patient: 24 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			07/02/89		21/02/89		01/03/89		15/03/89	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	01/02/88	14.40		14.80		14.90		15.20	
HT	0.37-0.47 (L/L)	01/02/88		nd	0.42		0.44		0.45	
RBC	3.8-5.8 (10**12/L)	01/02/88	4.82		4.85		4.95		5.04	
WBC	4-11 (10**9/L)	01/02/88	10.50		8.50		9.00		7.70	
WBC: N	2.5-7.5 (10**9/L)	01/02/88	8.00	>	5.80		4.77		5.50	
WBC: L	1.5-3.5 (10**9/L)	01/02/88	1.90		2.00		2.79		1.90	
WBC: E	0.04-0.44 (10**9/L)	01/02/88	0.60	>>	0.60	>>	0.45	>	0.20	
WBC: M	0.2-0.8 (10**9/L)	01/02/88	0.70		0.70		0.99	>	0.70	
WBC: B	0-0.1 (10**9/L)	01/02/88	0.20	>>	0.20	>>	0.00		0.20	>>
PLATELETS	150-400 (10**9/L)	01/02/88	416.00	>	432.00	>	346.00		404.00	>
NA+	135-150 (MMOL/L)	01/02/88	142.00		142.00		144.00		142.00	
K+	3.5-5 (MMOL/L)	01/02/88	3.80		4.50		4.20		4.50	
CL-	95-108 (MMOL/L)	01/02/88		nd		nd		nd		nd
Ca++	2.1-2.6 (MMOL/L)	01/02/88	2.24		2.42		2.38		2.34	
PO4--	0.8-1.5 (MMOL/L)	01/02/88	1.07		1.16		1.12		1.07	
SGOT	2-29 (IU/L)	01/02/88	25.00		46.00	>	47.00	>	42.00	>
SGPT	5-34 (IU/L)	01/02/88	31.00		33.00		36.00	>	29.00	
GAMMA GT	0-65 (IU/L)	01/02/88	22.00		21.00		22.00		22.00	
GRANOLOCYTES	()	01/02/88		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/02/88	133.00	>	144.00	>	130.00	>	135.00	>
GLUCOSE	3.5-10 (MMOL/L)	01/02/88	5.10		5.00		5.10		5.60	
BUN	2.5-7 (MMOL/L)	01/02/88	4.90		5.20		5.20		5.00	
CREATININE	59-120 (MMOL/L)	01/02/88	67.00		67.00		73.00		67.00	
PCV	()	01/02/88		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/02/88	195.00	<	171.00	<	176.00	<	169.00	<
TOT BILIRUBIN	3-20 (UMOL/L)	01/02/88	9.00		8.00		12.00		9.00	
DIR BILIRUBIN	()	01/02/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/02/88	74.00		75.00		79.00		77.00	
ALBUMINE	34-50 (G/L)	01/02/88	43.00		42.00		42.00		43.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/02/88	8.10	>>	7.90	>>	7.60	>	7.30	>
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/02/88	1.20		0.80		1.00		1.00	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/02/88	2.29			nd		nd		nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/02/88	6.18			nd		nd		nd
GLOBULINS BETA	6-12 (G/L)	01/02/88	7.86			nd		nd		nd
GLOBULINS GAMMA	6-16 (G/L)	01/02/88	12.27			nd		nd		nd
T3	92-121 (NMOL/L)	01/02/88		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/02/88	99.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CN 950321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 2 Patient: 25 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			13/02/89		28/02/89		03/03/89		21/03/89	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	01/02/88	15.10		14.10		13.80		14.80	
HT	0.37-0.47 (L/L)	01/02/88		nd	0.40		0.40		0.44	
RBC	3.8-5.8 (10**12/L)	01/02/88	4.57		4.29		4.24		4.65	
WBC	4-11 (10**9/L)	01/02/88	6.80		4.10		4.20		4.10	
WBC: N	2.5-7.5 (10**9/L)	01/02/88	4.70		2.20	<	2.30	<	2.10	<
WBC: L	1.5-3.5 (10**9/L)	01/02/88	1.70		1.60		1.70		1.80	
WBC: E	0.04-0.44 (10**9/L)	01/02/88	0.40		0.30		0.20		0.30	
WBC: M	0.2-0.8 (10**9/L)	01/02/88	0.70		0.70		0.70		0.70	
WBC: B	0-0.1 (10**9/L)	01/02/88	0.20	>>	0.20	>>	0.20	>>	0.20	>>
PLATELETS	150-400 (10**9/L)	01/02/88	354.00		221.00		255.00		335.00	
NA+	135-150 (MMOL/L)	01/02/88	140.00		141.00		141.00		141.00	
K+	3.5-5 (MMOL/L)	01/02/88	4.40		4.10		4.40		4.30	
CL-	95-108 (MMOL/L)	01/02/88		nd		nd		nd		nd
Ca++	2.1-2.6 (MMOL/L)	01/02/88	2.47		2.45		2.46		2.45	
PO4--	0.8-1.5 (MMOL/L)	01/02/88	1.23		1.16		1.24		1.18	
SGOT	2-29 (IU/L)	01/02/88	15.00		14.00		18.00		16.00	
SGPT	5-34 (IU/L)	01/02/88	20.00		14.00		16.00		17.00	
GAMMA GT	0-65 (IU/L)	01/02/88	56.00		33.00		31.00		24.00	
GRANOLOCYTES	()	01/02/88		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/02/88	158.00	>	137.00	>	139.00	>	141.00	>
GLUCOSE	3.5-10 (MMOL/L)	01/02/88	5.90		4.80		5.40		5.70	
BUN	2.5-7 (MMOL/L)	01/02/88	4.50		5.00		4.00		5.10	
CREATININE	59-120 (MMOL/L)	01/02/88	63.00		67.00		68.00		65.00	
PCV	()	01/02/88		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/02/88		nd	164.00	<	180.00	<	189.00	<
TOT BILIRUBIN	3-20 (UMOL/L)	01/02/88	10.00		10.00		10.00		14.00	
DIR BILIRUBIN	()	01/02/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/02/88	70.00		68.00		70.00		72.00	
ALBUMINE	34-50 (G/L)	01/02/88	43.00		41.00		40.00		48.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/02/88	6.70	>	6.20	>	6.40	>	6.50	>
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/02/88	1.00		1.10		1.00		0.80	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/02/88	2.10			nd		nd	2.55	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/02/88	5.53			nd		nd	6.07	
GLOBULINS BETA	6-12 (G/L)	01/02/88	7.45			nd		nd	8.26	
GLOBULINS GAMMA	6-16 (G/L)	01/02/88	8.71			nd		nd	9.84	
T3	92-121 (NMOL/L)	01/02/88		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/02/88		nd		nd		nd		nd

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PHARMACIA CNS R&D 9550321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 3 Patient: 26 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 21	
			28/12/88		04/01/89		11/01/89		18/01/89	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	12-16.4 (G/DL)	27/12/88	14.60		15.30		15.50		13.70	
HT	0.37-0.47 (L/L)	27/12/88		nd	0.46		0.45		0.41	
RBC	3.8-5.8 (10**12/L)	27/12/88	4.72		4.92		4.86		4.35	
WBC	4-11 (10**9/L)	27/12/88	7.80		7.00		6.10		5.40	
WBC: N	2.5-7.5 (10**9/L)	27/12/88	6.50		4.70		3.60		3.10	
WBC: L	1.5-3.5 (10**9/L)	27/12/88	1.00	<<	1.80		2.00		1.90	
WBC: E	0.04-0.44 (10**9/L)	27/12/88	0.30		0.60	>>	0.40		0.40	
WBC: M	0.2-0.8 (10**9/L)	27/12/88	0.70		0.70		0.70		0.70	
WBC: B	0-0.1 (10**9/L)	27/12/88	0.20	>>	0.20	>>	0.20	>>	0.20	>>
PLATELETS	150-400 (10**9/L)	27/12/88	295.00		237.00		273.00		343.00	
NA+	135-150 (MMOL/L)	27/12/88	138.00		140.00		142.00		142.00	
K+	3.5-5 (MMOL/L)	27/12/88	3.60		3.80		3.70		3.80	
CL-	95-108 (MMOL/L)	27/12/88		nd		nd		nd		nd
Ca++	2.1-2.6 (MMOL/L)	27/12/88	2.34		2.38		2.30		2.40	
PO4--	0.8-1.5 (MMOL/L)	27/12/88	1.11		0.99		0.86		1.13	
SGOT	2-29 (IU/L)	27/12/88	12.00		9.00		9.00		10.00	
SGPT	5-34 (IU/L)	27/12/88	7.00		12.00		12.00		11.00	
GAMMA GT	0-65 (IU/L)	27/12/88	11.00		19.00		19.00		17.00	
GRANOLOCYTES	()	27/12/88		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	27/12/88	160.00	>	189.00	>	202.00	>	190.00	>
GLUCOSE	3.5-10 (MMOL/L)	27/12/88	4.70		5.60		4.40		5.10	
BUN	2.5-7 (MMOL/L)	27/12/88	3.70			nd		nd		nd
CREATININE	59-120 (MMOL/L)	27/12/88	74.00		71.00		65.00		70.00	
PCV	()	27/12/88		nd		nd		nd		nd
URIC ACID	180-500 (UMOL/L)	27/12/88	175.00	<						
	2.5-8 (MG/DL)	03/01/89			3.80		3.40		3.50	
TOT BILIRUBIN	3-20 (UMOL/L)	27/12/88	11.00		10.00		9.00		6.00	
DIR BILIRUBIN	()	27/12/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	27/12/88	70.00		74.00		74.00		73.00	
ALBUMINE	34-50 (G/L)	27/12/88	34.00		40.00		40.00		41.00	
TOT. CHOLEST.	0-6 (MMOL/L)	27/12/88	5.00		5.50		5.00		4.90	
TRIGLYCERIDES	0.8-2 (MMOL/L)	27/12/88	1.40		1.00		1.10		1.10	
GLOBULINS ALPHA 1	1.5-4 (G/L)	27/12/88	4.00			nd		nd		nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	27/12/88	7.50			nd		nd		nd
GLOBULINS BETA	6-12 (G/L)	27/12/88	6.70			nd		nd		nd
GLOBULINS GAMMA	6-16 (G/L)	27/12/88	11.50			nd		nd		nd
T3	()	03/01/89				nd		nd		nd
	92-121 (NMOL/L)	27/12/88		nd						
T4	()	03/01/89				nd		nd		nd
	58-160 (NMOL/L)	27/12/88		nd						

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PHARMACIA CNS 96 0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 3 Patient: 27 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			14/12/88		03/01/89		10/01/89		26/01/89	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	13/12/88	15.50		14.20			nd	14.00	
HT	36-60 (%)	13/12/88	43.00							
	0.37-0.47 (L/L)	02/01/89			0.42			nd	0.41	
RBC	3.8-5.8 (10**12/L)	13/12/88	4.79		4.53			nd	4.41	
WBC	4-11 (10**9/L)	13/12/88	10.40		4.30			nd	9.10	
WBC: N	2.5-7.5 (10**9/L)	13/12/88	5.50		4.70			nd	5.40	
WBC: L	1.5-3.5 (10**9/L)	13/12/88	4.70	>>		nd		nd	3.20	
WBC: E	0.04-0.44 (10**9/L)	13/12/88	0.20		0.30			nd	0.60	>>
WBC: M	0.2-0.8 (10**9/L)	13/12/88	0.70		0.70			nd	0.70	
WBC: B	0-0.1 (10**9/L)	13/12/88	0.20	>>	0.20	>>		nd	0.20	>>
PLATELETS	150-400 (10**9/L)	13/12/88	247.00		93.00	<<		nd	300.00	
NA+	135-150 (MMOL/L)	13/12/88	140.00		139.00		142.00		139.00	
K+	3.5-5 (MMOL/L)	13/12/88	3.90		3.30	<	4.40		4.20	
CL-	95-108 (MMOL/L)	13/12/88		nd		nd		nd		nd
Ca++	2.1-2.6 (MMOL/L)	13/12/88	2.43		2.31		2.36		2.25	
PO4--	0.8-1.5 (MMOL/L)	13/12/88	0.89		1.11		1.00		0.87	
SGOT	2-29 (IU/L)	13/12/88	20.00		21.00		21.00		27.00	
SGPT	5-34 (IU/L)	13/12/88	23.00		16.00		19.00		23.00	
GAMMA GT	0-65 (IU/L)	13/12/88	57.00		60.00		44.00		34.00	
GRANOLOCYTES	()	13/12/88		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	13/12/88	121.00	>	127.00	>	130.00	>	118.00	>
GLUCOSE	3.5-10 (MMOL/L)	13/12/88	4.90		4.80		6.20		4.50	
BUN	2.5-7 (MMOL/L)	13/12/88	4.40		3.20		3.20		2.80	
CREATININE	59-120 (MMOL/L)	13/12/88	68.00		52.00	<	60.00		76.00	
PCV	()	13/12/88		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	13/12/88	222.00			nd	229.00		243.00	
TOT BILIRUBIN	3-20 (UMOL/L)	13/12/88	14.00		7.00		9.00		10.00	
DIR BILIRUBIN	()	13/12/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	13/12/88	70.00		68.00		70.00		66.00	
ALBUMINE	34-50 (G/L)	13/12/88	38.00		39.00		41.00		41.00	
TOT. CHOLEST.	0-6 (MMOL/L)	13/12/88	7.20	>	6.10	>	6.30	>	6.10	>
TRIGLYCERIDES	0.8-2 (MMOL/L)	13/12/88	1.30		0.80		1.50		0.80	
GLOBULINS ALPHA 1	1.5-4 (G/L)	13/12/88		nd	3.60		3.80		3.50	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	13/12/88		nd	9.70		10.50		10.40	
GLOBULINS BETA	6-12 (G/L)	13/12/88		nd	13.00	>	13.60	>	12.60	>
GLOBULINS GAMMA	6-16 (G/L)	13/12/88		nd	11.70		11.70		11.70	
T3	92-121 (NMOL/L)	13/12/88		nd		nd		nd		nd
T4	58-160 (NMOL/L)	13/12/88		nd		nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 5590321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 3 Patient: 28 Sex: Male

			Visit number / Laboratory date					
			Screen		Day 7		Day 14	
			12/12/88		03/01/89		10/01/89	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	11/12/88	13.80		15.20			nd
HT	36-60 (%)	11/12/88	41.30					
	0.4-0.54 (L/L)	02/01/89			0.45			nd
RBC	4-6.5 (10**12/L)	11/12/88	4.40		4.89			nd
WBC	3.9-12 (10**9/L)	11/12/88	7.30		9.20			nd
WBC: N	2-7.5 (10**9/L)	11/12/88	5.20		5.90			nd
WBC: L	1.5-4 (10**9/L)	11/12/88	1.50		2.60			nd
WBC: E	0.04-0.44 (10**9/L)	11/12/88	0.60	>>	0.70	>>		nd
WBC: M	0.2-0.8 (10**9/L)	11/12/88	0.70		0.70			nd
WBC: B	0-0.1 (10**9/L)	11/12/88	0.20	>>	0.20	>>		nd
PLATELETS	100-600 (10**9/L)	11/12/88	255.00		177.00			nd
NA+	134-145 (MMOL/L)	11/12/88	141.00		142.00		141.00	
K+	3.5-5 (MMOL/L)	11/12/88	3.80		3.60		3.80	
CL-	95-108 (MMOL/L)	11/12/88		nd		nd		nd
Ca++	2.2-2.6 (MMOL/L)	11/12/88	2.38		2.40		2.32	
PO4--	0.8-1.5 (MMOL/L)	11/12/88	1.21		0.97		0.89	
SGOT	15-37 (IU/L)	11/12/88	19.00		16.00		16.00	
SGPT	2-29 (IU/L)	11/12/88	18.00		10.00		16.00	
GAMMA GT	5-52 (IU/L)	11/12/88	31.00		27.00		30.00	
GRANOLOCYTES	()	11/12/88		nd		nd		nd
ALK. PHOSPH.	95-260 (IU/L)	11/12/88	147.00		162.00		192.00	
GLUCOSE	3.5-10 (MMOL/L)	11/12/88	5.00		4.20		4.60	
BUN	3-6.7 (MMOL/L)	11/12/88	2.70	<	3.60		3.30	
CREATININE	76-120 (MMOL/L)	11/12/88	80.00		71.00	<	79.00	
PCV	()	11/12/88		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	11/12/88		nd		nd	273.00	
TOT BILIRUBIN	2-17 (UMOL/L)	11/12/88	11.00		8.00		9.00	
DIR BILIRUBIN	()	11/12/88		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	11/12/88	72.00		68.00		72.00	
ALBUMINE	35-46 (G/L)	11/12/88	41.00		37.00		42.00	
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	11/12/88	5.70	>	6.20	>	5.80	>
TRIGLYCERIDES	0.5-2 (MMOL/L)	11/12/88	1.60		1.90		1.60	
GLOBULINS ALPHA 1	3-6 (G/L)	11/12/88	6.00		3.20		2.02	<<
GLOBULINS ALPHA 2	7-13 (G/L)	11/12/88	13.00		8.80		6.32	<
GLOBULINS BETA	7-14 (G/L)	11/12/88	14.00		13.30		8.54	
GLOBULINS GAMMA	10-20 (G/L)	11/12/88	20.00		12.00		10.60	
T3	92-121 (NMOL/L)	11/12/88		nd		nd		nd
T4	58-160 (NMOL/L)	11/12/88		nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 51 Sex: Female

			Visit number / Laboratory date			
			Screen		Day 7	
			15/04/88		29/04/88	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	12-16.4 (G/DL)	14/04/88	13.80		13.50	
HT	0.37-0.47 (L/L)	14/04/88	0.39		0.39	
RBC	3.8-5.8 (10**12/L)	14/04/88	3.71	<	3.71	<
WBC	4-11 (10**9/L)	14/04/88	9.60		6.50	
WBC: N	40-75 (%)	14/04/88	58.00		58.00	
WBC: L	20-45 (%)	14/04/88	41.00		33.00	
WBC: E	1-6 (%)	14/04/88	1.00		5.00	
WBC: M	0-1 (%)	14/04/88	0.00		1.00	
WBC: B	2-10 (%)	14/04/88	0.00	<	3.00	
PLATELETS	150-400 (10**9/L)	14/04/88	259.00		275.00	
NA+	135-150 (MMOL/L)	14/04/88	139.00		140.00	
K+	3.5-5 (MMOL/L)	14/04/88	3.90		4.20	
CL-	95-108 (MMOL/L)	14/04/88		nd	108.00	
Ca++	2.1-2.6 (MMOL/L)	14/04/88		nd	2.37	
PO4--	0.8-1.5 (MMOL/L)	14/04/88		nd	1.23	
SGOT	2-29 (IU/L)	14/04/88	17.00		14.00	
SGPT	5-34 (IU/L)	14/04/88	9.00		14.00	
GAMMA GT	0-65 (IU/L)	14/04/88	58.00		40.00	
GRANOLOCYTES	()	14/04/88		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	14/04/88	8.80	<	8.10	<
GLUCOSE	3.5-10 (MMOL/L)	14/04/88	4.40		2.60	<
BUN	2.5-7 (MMOL/L)	14/04/88	2.40	<	2.40	<
CREATININE	59-120 (MMOL/L)	14/04/88	70.00		71.00	
PCV	()	14/04/88		nd		nd
URIC ACID	0.09-0.36 (MMOL/L)	14/04/88	0.22		0.20	
TOT BILIRUBIN	3-20 (UMOL/L)	14/04/88	10.00		7.00	
DIR BILIRUBIN	0-3.4 (UMOL/L)	14/04/88		nd	5.00	>
TOT. PROTEINS	60-80 (G/L)	14/04/88	68.00		66.00	
ALBUMINE	34-50 (G/L)	14/04/88	44.00		43.00	
TOT. CHOLEST.	0-6 (MMOL/L)	14/04/88	3.80		3.80	
TRIGLYCERIDES	0.8-2 (MMOL/L)	14/04/88	1.81		1.05	
GLOBULINS ALPHA 1	1.5-4 (G/L)	14/04/88	2.00		2.00	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	14/04/88	6.00		6.00	
GLOBULINS BETA	6-12 (G/L)	14/04/88	6.00		6.00	
GLOBULINS GAMMA	6-16 (G/L)	14/04/88	9.00		9.00	
T3	4-7.4 (PMOL/L)	14/04/88	5.40			nd
T4	10-31 (PMOL/L)	14/04/88	13.00			nd

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** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CR[illegible]0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 52 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			01/07/88		14/07/88		21/07/88		04/08/88	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	12-16.4 (G/DL)	30/06/88	11.40	<	10.40	<	10.20	<	10.50	<
HT	0.37-0.47 (L/L)	30/06/88	0.34	<	0.43		0.38		0.43	
RBC	3.8-5.8 (10**12/L)	30/06/88	4.46		4.21		4.11		4.13	
WBC	4-11 (10**9/L)	30/06/88	10.30		7.20		8.50		9.60	
WBC: N	40-75 (%)	30/06/88	91.00	>	56.00		79.00	>	80.00	>
WBC: L	20-45 (%)	30/06/88	9.00	<<	39.00		17.00	<	16.00	<
WBC: E	1-6 (%)	30/06/88	0.00	<	3.00		1.00		3.00	
WBC: M	0-1 (%)	30/06/88	0.00		0.00		2.00	>>	1.00	
WBC: B	2-10 (%)	30/06/88	0.00	<	2.00		1.00	<	0.00	<
PLATELETS	150-400 (10**9/L)	30/06/88	525.00	>>	508.00	>	414.00	>	432.00	>
NA+	135-150 (MMOL/L)	30/06/88	140.00		139.00		139.00		136.00	
K+	3.5-5 (MMOL/L)	30/06/88	4.10		3.60		3.60		3.50	
CL-	95-108 (MMOL/L)	30/06/88		nd	103.00		105.00		104.00	
Ca++	2.1-2.6 (MMOL/L)	30/06/88	2.45			nd		nd	2.23	
PO4--	0.8-1.5 (MMOL/L)	30/06/88	1.56	>		nd		nd	1.08	
SGOT	2-29 (IU/L)	30/06/88	29.00		25.00		21.00		18.00	
SGPT	5-34 (IU/L)	30/06/88	20.00		20.00		18.00		13.00	
GAMMA GT	0-65 (IU/L)	30/06/88	16.00		19.00		17.00		15.00	
GRANOLOCYTES	()	30/06/88		nd		nd		nd		nd
ALK. PHOSPH.	4-13 (KAU/DL)	30/06/88	9.80		8.20		8.00		8.00	
GLUCOSE	3.5-10 (MMOL/L)	30/06/88	4.90		5.00		6.90		6.10	
BUN	2.5-7 (MMOL/L)	30/06/88	4.30		5.20		4.70		4.70	
CREATININE	59-120 (MMOL/L)	30/06/88	79.00		62.00		72.00		70.00	
PCV	()	30/06/88		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	30/06/88		nd		nd		nd		nd
TOT BILIRUBIN	3-20 (UMOL/L)	30/06/88	7.00		4.00		5.00		5.00	
DIR BILIRUBIN	0-3.4 (UMOL/L)	30/06/88		nd	2.00		2.00		1.00	
TOT. PROTEINS	60-80 (G/L)	30/06/88	82.00	>	71.00		69.00		65.00	
ALBUMINE	34-50 (G/L)	30/06/88	44.00		40.00		39.00		38.00	
TOT. CHOLEST.	0-6 (MMOL/L)	30/06/88	7.10	>		nd	7.40	>	7.00	>
TRIGLYCERIDES	0.8-2 (MMOL/L)	30/06/88	1.12			nd	1.54		1.38	
GLOBULINS ALPHA 1	1.5-4 (G/L)	30/06/88	4.00		3.00		3.00		2.00	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	30/06/88	9.00		7.00		8.00		6.00	
GLOBULINS BETA	6-12 (G/L)	30/06/88	13.00	>	10.00		10.00		10.00	
GLOBULINS GAMMA	6-16 (G/L)	30/06/88	13.00		11.00		9.00		9.00	
T3	4-7.4 (PMOL/L)	30/06/88	6.20			nd		nd		nd
T4	10-31 (PMOL/L)	30/06/88	16.40			nd		nd		nd

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PHARMACIA CMS 95 0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 53 Sex: Male

			Visit number / Laboratory date					
			Screen		Day 7		Day 14	
			27/09/88		06/10/88		13/10/88	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	26/09/88	17.60		17.30		17.00	
HT	0.4-0.54 (L/L)	26/09/88	0.52		0.51		0.50	
RBC	4-6.5 (10**12/L)	26/09/88	5.51		5.84		5.26	
WBC	3.9-12 (10**9/L)	26/09/88	14.60	>	9.10		9.50	
WBC: N	40-75 (%)	26/09/88	78.00	>	77.00	>	75.00	
WBC: L	20-45 (%)	26/09/88	20.00		16.00	<	18.00	<
WBC: E	1-6 (%)	26/09/88	1.00		5.00		6.00	
WBC: M	0-1 (%)	26/09/88	1.00		1.00		1.00	
WBC: B	2-10 (%)	26/09/88	0.00	<	1.00	<	1.00	<
PLATELETS	100-600 (10**9/L)	26/09/88	347.00		352.00		312.00	
NA+	134-145 (MMOL/L)	26/09/88	138.00		137.00		138.00	
K+	3.5-5 (MMOL/L)	26/09/88	4.70		4.70		4.70	
CL-	95-108 (MMOL/L)	26/09/88		nd	102.00		102.00	
Ca++	2.2-2.6 (MMOL/L)	26/09/88	2.56		2.50		2.52	
PO4--	0.8-1.5 (MMOL/L)	26/09/88	1.19		1.09		0.99	
SGOT	15-37 (IU/L)	26/09/88	36.00		36.00		37.00	
SGPT	2-29 (IU/L)	26/09/88	57.00	>	72.00	>>	78.00	>>
GAMMA GT	5-52 (IU/L)	26/09/88	34.00		41.00		45.00	
GRANOLOCYTES	()	26/09/88		nd		nd		nd
ALK. PHOSPH.	4-13 (KAU/DL)	26/09/88	6.30					
	95-260 (IU/L)	05/10/88			81.00	<	80.00	<
GLUCOSE	3.5-10 (MMOL/L)	26/09/88	6.10		9.50		10.20	>
BUN	3-6.7 (MMOL/L)	26/09/88	4.10		3.30		3.00	
CREATININE	76-120 (MMOL/L)	26/09/88	96.00		108.00		91.00	
PCV	()	26/09/88		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	26/09/88	338.00		348.00	>	328.00	
TOT BILIRUBIN	2-17 (UMOL/L)	26/09/88	9.00		11.30		9.10	
DIR BILIRUBIN	0-3.4 (UMOL/L)	26/09/88		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	26/09/88	67.00		70.00		69.00	
ALBUMINE	35-46 (G/L)	26/09/88	43.00		46.00		45.00	
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	26/09/88	5.50	>	5.90	>	5.80	>
TRIGLYCERIDES	0.5-2 (MMOL/L)	26/09/88	3.34	>>	2.70	>>	2.14	>
GLOBULINS ALPHA 1	1.5-4 (G/L)	26/09/88	2.00			nd		nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	26/09/88	5.00			nd		nd
GLOBULINS BETA	6-12 (G/L)	26/09/88	8.00			nd		nd
GLOBULINS GAMMA	6-16 (G/L)	26/09/88	9.00			nd		nd
T3	()	05/10/88				nd		nd
	4-7.4 (PMOL/L)	26/09/88	5.10					
T4	()	05/10/88				nd		nd
	10-31 (PMOL/L)	26/09/88	15.60					

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PHARMACIA CM[illegible]0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 54 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			25/11/88		05/12/88		12/12/88		23/12/88	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	12-16.4 (G/DL)	01/04/88	13.50		13.60		13.80		13.80	
HT	0.37-0.47 (L/L)	01/04/88	0.40		0.40		0.40		0.42	
RBC	3.8-5.8 (10**12/L)	01/04/88	4.30		4.38		4.27		4.69	
WBC	4-11 (10**9/L)	01/04/88	7.60		7.60		6.94		5.25	
WBC: N	40-75 (%)	01/04/88	79.00	>	72.00		67.00		64.00	
WBC: L	20-45 (%)	01/04/88	16.00	<	21.00		24.00		26.00	
WBC: E	1-6 (%)	01/04/88	4.00		5.00		7.00	>	7.00	>
WBC: M	0-1 (%)	01/04/88	1.00		1.00		2.00	>>	3.00	>>
WBC: B	2-10 (%)	01/04/88		nd	1.00	<		nd	0.00	<
PLATELETS	150-400 (10**9/L)	01/04/88	309.00		358.00		337.00		311.00	
NA+	135-150 (MMOL/L)	01/04/88	140.00		138.00		140.00		144.00	
K+	3.5-5 (MMOL/L)	01/04/88	4.60		4.70		5.00		4.70	
CL-	95-108 (MMOL/L)	01/04/88		nd	106.00		108.00		108.00	
Ca++	2.1-2.6 (MMOL/L)	01/04/88	2.35		2.34		2.38		2.39	
PO4--	0.8-1.5 (MMOL/L)	01/04/88	0.65	<<	0.78	<	0.70	<	0.81	
SGOT	2-29 (IU/L)	01/04/88	14.00		17.00		19.00		25.00	
SGPT	5-34 (IU/L)	01/04/88	17.00		19.00		22.00		26.00	
GAMMA GT	0-65 (IU/L)	01/04/88	17.00		14.00		38.00		22.00	
GRANOLOCYTES	()	01/04/88		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/04/88	87.00		91.00		77.00		100.00	
GLUCOSE	3.5-10 (MMOL/L)	01/04/88	5.60		4.90		5.10		4.20	
BUN	2.5-7 (MMOL/L)	01/04/88	4.50		4.40		3.20		4.90	
CREATININE	59-120 (MMOL/L)	01/04/88	63.00		64.00		83.00		80.00	
PCV	()	01/04/88		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/04/88	251.00		282.00		242.00		355.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/04/88	4.80		3.20		5.10		5.80	
DIR BILIRUBIN	0-3.4 (UMOL/L)	01/04/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/04/88	70.00		71.00		74.00		72.00	
ALBUMINE	34-50 (G/L)	01/04/88	40.00		41.00		43.00		42.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/04/88	5.50		6.40	>	6.10	>	5.80	
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/04/88	1.58		1.40		1.29		0.95	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/04/88		nd		nd		nd		nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/04/88		nd		nd		nd		nd
GLOBULINS BETA	6-12 (G/L)	01/04/88		nd		nd		nd		nd
GLOBULINS GAMMA	6-16 (G/L)	01/04/88		nd		nd		nd		nd
T3	92-121 (NMOL/L)	01/04/88		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/04/88		nd		nd		nd		nd

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PHARMACIA CNS R&D 9550321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 55 Sex: Male

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			20/01/89		30/01/89		06/02/89		20/02/89	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	13-18 (G/DL)	01/04/88	15.60		15.60		15.80		15.60	
HT	0.4-0.54 (L/L)	01/04/88	0.46		0.48		0.49		0.47	
RBC	4-6.5 (10**12/L)	01/04/88	4.79		5.01		5.26		4.89	
WBC	3.9-12 (10**9/L)	01/04/88	6.40		7.69		5.82		7.53	
WBC: N	40-75 (%)	01/04/88	57.00		57.00		50.00		56.00	
WBC: L	20-45 (%)	01/04/88	35.00		35.00		42.00		36.00	
WBC: E	1-6 (%)	01/04/88	6.00		6.00		7.00	>	6.00	
WBC: M	0-1 (%)	01/04/88	1.00		1.00		1.00		1.00	
WBC: B	2-10 (%)	01/04/88	1.00	<	1.00	<		nd	1.00	<
PLATELETS	100-600 (10**9/L)	01/04/88	287.00		306.00		285.00		317.00	
NA+	134-145 (MMOL/L)	01/04/88	136.00		141.00		143.00		142.00	
K+	3.5-5 (MMOL/L)	01/04/88	5.30	>	5.30	>	5.10	>	4.80	
CL-	95-108 (MMOL/L)	01/04/88		nd	107.00		109.00	>	107.00	
Ca++	2.2-2.6 (MMOL/L)	01/04/88	2.32		2.32		2.40		2.46	
PO4--	0.8-1.5 (MMOL/L)	01/04/88	2.00	>>	1.15		1.28		1.27	
SGOT	15-37 (IU/L)	01/04/88	31.00		21.00		19.00		35.00	
SGPT	2-29 (IU/L)	01/04/88	26.00		14.00		16.00		27.00	
GAMMA GT	5-52 (IU/L)	01/04/88	10.00		8.00		16.00		18.00	
GRANOLOCYTES	()	01/04/88		nd		nd		nd		nd
ALK. PHOSPH.	95-260 (IU/L)	01/04/88	111.00		105.00		96.00		95.00	
GLUCOSE	3.5-10 (MMOL/L)	01/04/88	4.10		4.70		3.90		5.00	
BUN	3-6.7 (MMOL/L)	01/04/88	4.10			nd		nd	5.60	
CREATININE	76-120 (MMOL/L)	01/04/88	103.00		95.00		92.00		96.00	
PCV	()	01/04/88		nd		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	01/04/88	317.00		361.00	>	355.00	>	389.00	>
TOT BILIRUBIN	2-17 (UMOL/L)	01/04/88	5.50		2.70		4.80		5.60	
DIR BILIRUBIN	0-3.4 (UMOL/L)	01/04/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/04/88	67.00		64.00		67.00		66.00	
ALBUMINE	35-46 (G/L)	01/04/88	42.00		42.00		44.00		44.00	
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	01/04/88	5.90	>	6.20	>	6.40	>	6.20	>
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/04/88	3.21	>>	5.06	>>	3.75	>>	3.48	>>
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/04/88		nd		nd	1.80		1.90	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/04/88		nd		nd	6.40		5.80	
GLOBULINS BETA	6-12 (G/L)	01/04/88		nd		nd	7.00		6.80	
GLOBULINS GAMMA	6-16 (G/L)	01/04/88		nd		nd	7.80		7.50	
T3	92-121 (NMOL/L)	01/04/88		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/04/88		nd		nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CN 00321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 56 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			22/01/89		30/01/89		06/02/89		20/02/89	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	01/04/88	13.00		13.00		12.30		12.30	
HT	0.37-0.47 (L/L)	01/04/88		nd	0.38		0.37		0.38	
RBC	3.8-5.8 (10**12/L)	01/04/88	4.59		4.59		4.28		4.32	
WBC	4-11 (10**9/L)	01/04/88	5.53		5.53		6.81		5.70	
WBC: N	40-75 (%)	01/04/88	49.00		49.00		60.00		52.00	
WBC: L	20-45 (%)	01/04/88	41.00		41.00		34.00		40.00	
WBC: E	1-6 (%)	01/04/88	6.00		6.00		4.00		5.00	
WBC: M	0-1 (%)	01/04/88	4.00	>>	4.00	>>	1.00		2.00	>>
WBC: B	2-10 (%)	01/04/88	0.00	<		nd		nd	1.00	<
PLATELETS	150-400 (10**9/L)	01/04/88	363.00		363.00		314.00		299.00	
NA+	135-150 (MMOL/L)	01/04/88	140.00		140.00		143.00		140.00	
K+	3.5-5 (MMOL/L)	01/04/88	5.40	>	5.40	>	5.20	>	4.90	
CL-	95-108 (MMOL/L)	01/04/88		nd	106.00		108.00		105.00	
Ca++	2.1-2.6 (MMOL/L)	01/04/88	2.47		2.47		2.46		2.45	
PO4--	0.8-1.5 (MMOL/L)	01/04/88	1.29		1.29		1.43		1.23	
SGOT	2-29 (IU/L)	01/04/88	15.00		17.00		11.00		9.00	
SGPT	5-34 (IU/L)	01/04/88	17.00		15.00		18.00		11.00	
GAMMA GT	0-65 (IU/L)	01/04/88	9.00		9.00		7.00		6.00	
GRANOLOCYTES	()	01/04/88		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/04/88	99.00		99.00		85.00		93.00	
GLUCOSE	3.5-10 (MMOL/L)	01/04/88	5.00		5.00		5.40		5.70	
BUN	2.5-7 (MMOL/L)	01/04/88	5.20		5.20		4.40		5.10	
CREATININE	59-120 (MMOL/L)	01/04/88	65.00		65.00		62.00		61.00	
PCV	()	01/04/88		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/04/88	258.00		258.00		244.00		255.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/04/88	6.20		6.20		6.00		7.00	
DIR BILIRUBIN	0-3.4 (UMOL/L)	01/04/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/04/88	74.00		74.00		71.00		72.00	
ALBUMINE	34-50 (G/L)	01/04/88	48.00		48.00		46.00		46.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/04/88	6.10	>	6.10	>	4.90		5.20	
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/04/88	0.50	<	0.50	<	0.32	<	0.39	<
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/04/88		nd		nd	2.10		2.20	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/04/88		nd		nd	5.30		5.90	
GLOBULINS BETA	6-12 (G/L)	01/04/88		nd		nd	7.50		7.70	
GLOBULINS GAMMA	6-16 (G/L)	01/04/88		nd		nd	10.10		10.20	
T3	92-121 (NMOL/L)	01/04/88		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/04/88		nd		nd		nd		nd

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PHARMACIA CNS R&D 9550321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 57 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			10/03/89		20/03/89		28/03/89		10/04/89	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	12-16.4 (G/DL)	01/04/88	13.90		14.00		13.70		13.40	
HT	0.37-0.47 (L/L)	01/04/88	0.46		0.43		0.43		0.41	
RBC	3.8-5.8 (10**12/L)	01/04/88	4.63		4.63		4.51		4.22	
WBC	4-11 (10**9/L)	01/04/88	8.06		5.70		8.19		7.30	
WBC: N	40-75 (%)	01/04/88		nd	57.00		61.00		41.00	
WBC: L	20-45 (%)	01/04/88		nd	34.00		30.00		48.00	>
WBC: E	1-6 (%)	01/04/88		nd	7.00	>	6.00		7.00	>
WBC: M	0-1 (%)	01/04/88		nd	1.00		3.00	>>	4.00	>>
WBC: B	2-10 (%)	01/04/88		nd	1.00	<	1.00	<		nd
PLATELETS	150-400 (10**9/L)	01/04/88	338.00		327.00		354.00		294.00	
NA+	135-150 (MMOL/L)	01/04/88	141.00		136.00		138.00		141.00	
K+	3.5-5 (MMOL/L)	01/04/88	4.30			nd		nd	4.60	
CL-	95-108 (MMOL/L)	01/04/88		nd	94.00	<	100.00		110.00	>
Ca++	2.1-2.6 (MMOL/L)	01/04/88	2.47			nd	2.37		2.31	
PO4--	0.8-1.5 (MMOL/L)	01/04/88	0.88			nd		nd	1.07	
SGOT	2-29 (IU/L)	01/04/88	10.00			nd		nd	14.00	
SGPT	5-34 (IU/L)	01/04/88	16.00			nd		nd	19.00	
GAMMA GT	0-65 (IU/L)	01/04/88	11.00			nd	10.00		11.00	
GRANOLOCYTES	()	01/04/88		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/04/88	77.00		87.00			nd	81.00	
GLUCOSE	3.5-10 (MMOL/L)	01/04/88	6.90			nd		nd	4.10	
BUN	2.5-7 (MMOL/L)	01/04/88	4.00		4.00		4.00		4.10	
CREATININE	59-120 (MMOL/L)	01/04/88	89.00			nd		nd	70.00	
PCV	()	01/04/88		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/04/88	429.00		284.00		297.00		309.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/04/88	8.60			nd	2.40	<	2.20	<
DIR BILIRUBIN	0-3.4 (UMOL/L)	01/04/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/04/88	68.00		76.00		71.00		66.00	
ALBUMINE	34-50 (G/L)	01/04/88	44.00		48.00		45.00		42.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/04/88	4.90		5.80		6.00		6.00	
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/04/88	1.29		1.58		1.93		1.23	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/04/88	2.00		2.30		2.40		2.20	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/04/88	5.70		10.20		5.80		5.50	
GLOBULINS BETA	6-12 (G/L)	01/04/88	7.40		9.50		8.40		7.90	
GLOBULINS GAMMA	6-16 (G/L)	01/04/88	8.90			nd	9.40		8.40	
T3	92-121 (NMOL/L)	01/04/88		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/04/88	97.00			nd		nd		nd

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PHARMACIA CNS 9880321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 58 Sex: Male

			Visit number / Laboratory date					
			Screen		Day 7		Day 14	
			16/03/89		28/03/89		03/04/89	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/04/88	13.30		13.30		13.10	
HT	0.4-0.54 (L/L)	01/04/88	0.42		0.39	<	0.39	<
RBC	4-6.5 (10**12/L)	01/04/88	4.53		4.42		4.42	
WBC	3.9-12 (10**9/L)	01/04/88	8.72		10.62		8.60	
WBC: N	40-75 (%)	01/04/88	70.00		71.00		69.00	
WBC: L	20-45 (%)	01/04/88	24.00		24.00		25.00	
WBC: E	1-6 (%)	01/04/88		nd	4.00		4.00	
WBC: M	0-1 (%)	01/04/88	2.00	>>	1.00		1.00	
WBC: B	2-10 (%)	01/04/88		nd		nd		nd
PLATELETS	100-600 (10**9/L)	01/04/88	301.00		300.00		296.00	
NA+	134-145 (MMOL/L)	01/04/88	139.00			nd	138.00	
K+	3.5-5 (MMOL/L)	01/04/88	4.40			nd	3.80	
CL-	95-108 (MMOL/L)	01/04/88		nd		nd	106.00	
Ca++	2.2-2.6 (MMOL/L)	01/04/88	2.44			nd	2.41	
PO4--	0.8-1.5 (MMOL/L)	01/04/88	1.16			nd	1.32	
SGOT	15-37 (IU/L)	01/04/88	14.00	<		nd	16.00	
SGPT	2-29 (IU/L)	01/04/88	15.00			nd	12.00	
GAMMA GT	5-52 (IU/L)	01/04/88	3.00	<		nd	3.00	<
GRANOLOCYTES	()	01/04/88		nd		nd		nd
ALK. PHOSPH.	95-260 (IU/L)	01/04/88	60.00	<		nd	52.00	<
GLUCOSE	3.5-10 (MMOL/L)	01/04/88	4.70			nd	5.20	
BUN	3-6.7 (MMOL/L)	01/04/88	4.00			nd	4.10	
CREATININE	76-120 (MMOL/L)	01/04/88	72.00	<		nd	66.00	<
PCV	()	01/04/88		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	01/04/88	245.00			nd	215.00	
TOT BILIRUBIN	2-17 (UMOL/L)	01/04/88	6.80			nd	3.80	
DIR BILIRUBIN	0-3.4 (UMOL/L)	01/04/88		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/04/88	72.00			nd	72.00	
ALBUMINE	35-46 (G/L)	01/04/88	45.00			nd	44.00	
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	01/04/88	4.30			nd	4.10	
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/04/88	0.67			nd	1.23	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/04/88	2.30			nd	2.80	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/04/88	5.00			nd	5.50	
GLOBULINS BETA	6-12 (G/L)	01/04/88	7.10			nd	8.40	
GLOBULINS GAMMA	6-16 (G/L)	01/04/88	12.50			nd	11.50	
T3	92-121 (NMOL/L)	01/04/88	116.00			nd		nd
T4	58-160 (NMOL/L)	01/04/88	83.00			nd		nd

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PHARMACIA CNS 0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 60 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			13/03/89		20/03/89		28/03/89		10/04/89	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	12/03/89	12.80		12.30		12.20		11.40	<
HT	0.37-0.47 (L/L)	12/03/89	0.37		0.38		0.37		0.33	<
RBC	3.8-5.8 (10**12/L)	12/03/89	4.18		4.32		4.27		3.99	
WBC	4-11 (10**9/L)	12/03/89	4.70		4.84		4.29		5.53	
WBC: N	40-75 (%)	12/03/89	56.00		52.00		48.00		58.00	
WBC: L	20-45 (%)	12/03/89	36.00		41.00		43.00		31.00	
WBC: E	1-6 (%)	12/03/89	6.00		5.00		5.00		7.00	>
WBC: M	0-1 (%)	12/03/89	2.00	>>	2.00	>>	2.00	>>	2.00	>>
WBC: B	2-10 (%)	12/03/89	0.00	<	1.00	<	1.00	<	2.00	
PLATELETS	150-400 (10**9/L)	12/03/89	291.00		422.00	>	389.00		381.00	
NA+	135-150 (MMOL/L)	12/03/89	142.00		142.00		143.00		141.00	
K+	3.5-5 (MMOL/L)	12/03/89	4.40		5.30	>	5.00		4.80	
CL-	95-108 (MMOL/L)	12/03/89		nd	108.00		106.00		106.00	
Ca++	2.1-2.6 (MMOL/L)	12/03/89		nd	2.39		2.68	>	2.57	
PO4--	0.8-1.5 (MMOL/L)	12/03/89		nd	1.31		1.28			nd
SGOT	2-29 (IU/L)	12/03/89	24.00		16.00		23.00		24.00	
SGPT	5-34 (IU/L)	12/03/89	8.00		5.00		10.00		10.00	
GAMMA GT	0-65 (IU/L)	12/03/89	11.00		9.00		10.00		8.00	
GRANOLOCYTES	()	12/03/89		nd		nd		nd		nd
ALK. PHOSPH.	4-13 (KAU/DL)	12/03/89	5.40							
	30-115 (IU/DL)	19/03/89			60.00		66.00		70.00	
GLUCOSE	3.5-10 (MMOL/L)	12/03/89	3.80		5.20		4.90		4.40	
BUN	2.5-7 (MMOL/L)	12/03/89	3.00		3.80		4.00		4.10	
CREATININE	59-120 (MMOL/L)	12/03/89	71.00		80.00		77.00		65.00	
PCV	()	12/03/89		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	12/03/89		nd	199.00	<	215.00		164.00	<
TOT BILIRUBIN	3-20 (UMOL/L)	12/03/89	11.00		10.40		12.30		4.30	
DIR BILIRUBIN	0-3.4 (UMOL/L)	12/03/89		nd		nd	7.00	>>		nd
TOT. PROTEINS	60-80 (G/L)	12/03/89	82.00	>	76.00		77.00		72.00	
ALBUMINE	34-50 (G/L)	12/03/89	54.00	>	52.00	>	51.00	>	49.00	
TOT. CHOLEST.	0-6 (MMOL/L)	12/03/89	4.50		4.30		4.80		5.00	
TRIGLYCERIDES	0.8-2 (MMOL/L)	12/03/89	0.67	<	0.63	<	0.82		0.90	
GLOBULINS ALPHA 1	1.5-4 (G/L)	12/03/89	2.00		1.80		2.10		2.00	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	12/03/89	5.00		4.60		5.20		3.80	
GLOBULINS BETA	6-12 (G/L)	12/03/89	7.00		6.10		7.10		6.70	
GLOBULINS GAMMA	6-16 (G/L)	12/03/89	14.00		11.50		11.60		10.50	
T3	()	19/03/89				nd		nd		nd
	4-7.4 (PMOL/L)	12/03/89	4.60							
T4	()	19/03/89				nd		nd		nd
	10-31 (PMOL/L)	12/03/89	15.50							

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PHARMACIA CLINICAL 9550321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 61 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			02/05/89		15/05/89		22/05/89		05/06/89	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	01/04/88	13.90		14.30		13.90		13.60	
HT	0.37-0.47 (L/L)	01/04/88	0.42		0.43		0.42		0.41	
RBC	3.8-5.8 (10**12/L)	01/04/88	4.53		4.78		4.59		4.46	
WBC	4-11 (10**9/L)	01/04/88	9.89		7.97		8.46		7.72	
WBC: N	40-75 (%)	01/04/88	62.00		50.00		54.00		46.00	
WBC: L	20-45 (%)	01/04/88	27.00		40.00		33.00		43.00	
WBC: E	1-6 (%)	01/04/88	5.00		6.00		7.00	>	5.00	
WBC: M	0-1 (%)	01/04/88		nd	1.00		5.00	>>	5.00	>>
WBC: B	2-10 (%)	01/04/88	1.00	<	1.00	<	1.00	<	1.00	<
PLATELETS	150-400 (10**9/L)	01/04/88	418.00	>	367.00		361.00		342.00	
NA+	135-150 (MMOL/L)	01/04/88	140.00		139.00		139.00		140.00	
K+	3.5-5 (MMOL/L)	01/04/88	4.90			nd	4.80		4.20	
CL-	95-108 (MMOL/L)	01/04/88		nd		nd	104.00		104.00	
Ca++	2.1-2.6 (MMOL/L)	01/04/88	2.47		2.53		2.51		2.48	
PO4--	0.8-1.5 (MMOL/L)	01/04/88		nd		nd	1.51	>	1.31	
SGOT	2-29 (IU/L)	01/04/88	20.00			nd	25.00		30.00	>
SGPT	5-34 (IU/L)	01/04/88	16.00			nd	25.00		20.00	
GAMMA GT	0-65 (IU/L)	01/04/88	95.00	>	68.00	>	44.00		52.00	
GRANOLOCYTES	()	01/04/88		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/04/88	195.00	>	190.00	>	150.00	>	169.00	>
GLUCOSE	3.5-10 (MMOL/L)	01/04/88		nd		nd	5.10		4.80	
BUN	2.5-7 (MMOL/L)	01/04/88	3.70		4.30		3.30		3.30	
CREATININE	59-120 (MMOL/L)	01/04/88	107.00			nd	97.00		98.00	
PCV	()	01/04/88		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/04/88	379.00		403.00		458.00		439.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/04/88	10.80		5.60		8.20		4.10	
DIR BILIRUBIN	0-3.4 (UMOL/L)	01/04/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/04/88	67.00		69.00		67.00		66.00	
ALBUMINE	34-50 (G/L)	01/04/88	43.00		47.00		45.00		45.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/04/88	7.90	>>	8.30	>>	8.20	>>	7.90	>>
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/04/88	1.46		3.20	>>	3.23	>>	3.84	>>
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/04/88	1.70		2.30		1.70		1.70	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/04/88	7.40		7.90		5.80		5.10	
GLOBULINS BETA	6-12 (G/L)	01/04/88	7.60		9.20		9.00		9.90	
GLOBULINS GAMMA	6-16 (G/L)	01/04/88	7.30		9.00		8.20		7.80	
T3	92-121 (NMOL/L)	01/04/88	115.00			nd		nd		nd
T4	58-160 (NMOL/L)	01/04/88	102.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA [redacted] 0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 62 Sex: Female

			Visit number / Laboratory date	
			Screen	
			04/05/89	
			value	(¢)
Laboratory test	Range value	Range date		
HB	12-16.4 (G/DL)	01/04/88	14.50	
HT	0.37-0.47 (L/L)	01/04/88	0.43	
RBC	3.8-5.8 (10**12/L)	01/04/88	4.66	
WBC	4-11 (10**9/L)	01/04/88	6.87	
WBC: N	40-75 (%)	01/04/88	79.00	>
WBC: L	20-45 (%)	01/04/88	16.00	<
WBC: E	1-6 (%)	01/04/88	4.00	
WBC: M	0-1 (%)	01/04/88	1.00	
WBC: B	2-10 (%)	01/04/88	1.00	<
PLATELETS	150-400 (10**9/L)	01/04/88	255.00	
NA+	135-150 (MMOL/L)	01/04/88	141.00	
K+	3.5-5 (MMOL/L)	01/04/88		nd
CL-	95-108 (MMOL/L)	01/04/88		nd
Ca++	2.1-2.6 (MMOL/L)	01/04/88	2.55	
PO4--	0.8-1.5 (MMOL/L)	01/04/88	0.98	
SGOT	2-29 (IU/L)	01/04/88	21.00	
SGPT	5-34 (IU/L)	01/04/88	38.00	>
GAMMA GT	0-65 (IU/L)	01/04/88	11.00	
GRANOLOCYTES	()	01/04/88		nd
ALK. PHOSPH.	30-115 (IU/L)	01/04/88	86.00	
GLUCOSE	3.5-10 (MMOL/L)	01/04/88	3.60	
BUN	2.5-7 (MMOL/L)	01/04/88	3.20	
CREATININE	59-120 (MMOL/L)	01/04/88	61.00	
PCV	()	01/04/88		nd
URIC ACID	200-500 (UMOL/L)	01/04/88	185.00	<
TOT BILIRUBIN	3-20 (UMOL/L)	01/04/88	3.60	
DIR BILIRUBIN	0-3.4 (UMOL/L)	01/04/88		nd
TOT. PROTEINS	60-80 (G/L)	01/04/88	81.00	>
ALBUMINE	34-50 (G/L)	01/04/88	49.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/04/88	5.00	
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/04/88	0.50	<
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/04/88	3.20	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/04/88	9.80	
GLOBULINS BETA	6-12 (G/L)	01/04/88	8.00	
GLOBULINS GAMMA	6-16 (G/L)	01/04/88	11.00	
T3	92-121 (NMOL/L)	01/04/88	122.00	>
T4	58-160 (NMOL/L)	01/04/88	152.00	

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA C[illegible]95[illegible]0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 63 Sex: Female

			Visit number / Laboratory date					
			Screen		Day 7		Day 14	
			09/05/89		22/05/89		01/06/89	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16.4 (G/DL)	01/04/88	15.30		15.50		15.40	
HT	0.37-0.47 (L/L)	01/04/88	0.44		0.46		0.47	
RBC	3.8-5.8 (10**12/L)	01/04/88	4.85		5.27		5.00	
WBC	4-11 (10**9/L)	01/04/88	4.88		5.61		4.29	
WBC: N	40-75 (%)	01/04/88	57.00		53.00		48.00	
WBC: L	20-45 (%)	01/04/88	35.00		38.00		41.00	
WBC: E	1-6 (%)	01/04/88	5.00		6.00		6.00	
WBC: M	0-1 (%)	01/04/88	2.00	>>	2.00	>>	5.00	>>
WBC: B	2-10 (%)	01/04/88	1.00	<	1.00	<		nd
PLATELETS	150-400 (10**9/L)	01/04/88	215.00		240.00		215.00	
NA+	135-150 (MMOL/L)	01/04/88	142.00		141.00		138.00	
K+	3.5-5 (MMOL/L)	01/04/88	5.10	>	4.40		5.00	
CL-	95-108 (MMOL/L)	01/04/88		nd	105.00		101.00	
Ca++	2.1-2.6 (MMOL/L)	01/04/88	2.49		2.54		2.45	
PO4--	0.8-1.5 (MMOL/L)	01/04/88		nd	0.94		1.31	
SGOT	2-29 (IU/L)	01/04/88	14.00		27.00		24.00	
SGPT	5-34 (IU/L)	01/04/88	18.00		21.00		33.00	
GAMMA GT	0-65 (IU/L)	01/04/88	18.00		7.80			nd
GRANOLOCYTES	()	01/04/88		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/04/88	66.00		69.00		68.00	
GLUCOSE	3.5-10 (MMOL/L)	01/04/88	4.60		4.70		4.60	
BUN	2.5-7 (MMOL/L)	01/04/88	7.60	>	6.80		6.10	
CREATININE	59-120 (MMOL/L)	01/04/88	104.00		84.00		82.00	
PCV	()	01/04/88		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/04/88	324.00		313.00		265.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/04/88	8.60		8.70		5.50	
DIR BILIRUBIN	0-3.4 (UMOL/L)	01/04/88		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/04/88	68.00		68.00		71.00	
ALBUMINE	34-50 (G/L)	01/04/88	49.00		49.00		50.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/04/88	7.30	>	7.30	>	6.90	>
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/04/88	1.05		1.50		0.90	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/04/88	1.60		1.90		2.00	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/04/88	5.90		4.80		7.50	
GLOBULINS BETA	6-12 (G/L)	01/04/88	5.00	<	8.50		8.10	
GLOBULINS GAMMA	6-16 (G/L)	01/04/88	5.60	<	7.80		7.50	
T3	92-121 (NMOL/L)	01/04/88	109.00			nd		nd
T4	58-160 (NMOL/L)	01/04/88	84.00			nd		nd

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** missing laboratory test value nd laboratory not done () missing range value

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 64 Sex: Male

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			16/05/89		31/05/89		05/06/89		19/06/89	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	13-18 (G/DL)	01/04/88	15.20		15.40		15.30		15.60	
HT	0.4-0.54 (L/L)	01/04/88	0.45		0.48		0.48		0.49	
RBC	4-6.5 (10**12/L)	01/04/88	5.25		5.10		5.09		5.40	
WBC	3.9-12 (10**9/L)	01/04/88	7.05		8.39		8.03		6.92	
WBC: N	40-75 (%)	01/04/88	75.00		71.00		68.00			nd
WBC: L	20-45 (%)	01/04/88	17.00	<	21.00		22.00		19.00	<
WBC: E	1-6 (%)	01/04/88	5.00		5.00		6.00		6.00	
WBC: M	0-1 (%)	01/04/88	3.00	>>	2.00	>>	3.00	>>	3.00	>>
WBC: B	2-10 (%)	01/04/88	0.00	<	1.00	<	1.00	<	1.00	<
PLATELETS	100-600 (10**9/L)	01/04/88	273.00		235.00		258.00		270.00	
NA+	134-145 (MMOL/L)	01/04/88	139.00		140.00		139.00		142.00	
K+	3.5-5 (MMOL/L)	01/04/88	4.10		4.20		4.50		4.40	
CL-	95-108 (MMOL/L)	01/04/88		nd	107.00		106.00		107.00	
Ca++	2.2-2.6 (MMOL/L)	01/04/88	2.38		2.34		2.38		2.53	
PO4--	0.8-1.5 (MMOL/L)	01/04/88	1.30		1.21		1.21		1.42	
SGOT	15-37 (IU/L)	01/04/88	15.00		14.00	<	27.00		13.00	<
SGPT	2-29 (IU/L)	01/04/88	15.00		15.00		24.00		16.00	
GAMMA GT	5-52 (IU/L)	01/04/88	3.00	<	7.00		10.00		8.00	
GRANOLOCYTES	()	01/04/88		nd		nd		nd		nd
ALK. PHOSPH.	95-260 (IU/L)	01/04/88	59.00	<	62.00	<	68.00	<	69.00	<
GLUCOSE	3.5-10 (MMOL/L)	01/04/88	3.80		4.70		4.70		4.80	
BUN	3-6.7 (MMOL/L)	01/04/88	4.30		4.30		4.60		3.60	
CREATININE	76-120 (MMOL/L)	01/04/88	80.00		64.00	<	77.00		97.00	
PCV	()	01/04/88		nd		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	01/04/88	281.00		231.00		277.00		260.00	
TOT BILIRUBIN	2-17 (UMOL/L)	01/04/88	5.60		7.90		3.40		8.90	
DIR BILIRUBIN	0-3.4 (UMOL/L)	01/04/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/04/88	67.00		65.00		65.00		69.00	
ALBUMINE	35-46 (G/L)	01/04/88	44.00		42.00		43.00		46.00	
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	01/04/88	6.40	>	5.80	>	6.00	>	6.10	>
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/04/88	1.93		2.41	>	2.69	>>	2.34	>
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/04/88	2.20		2.30		2.50		2.60	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/04/88	7.10		6.10		7.00		6.80	
GLOBULINS BETA	6-12 (G/L)	01/04/88	7.60		7.20		8.10		7.70	
GLOBULINS GAMMA	6-16 (G/L)	01/04/88	10.60		9.20		10.70		10.50	
T3	92-121 (NMOL/L)	01/04/88	112.00			nd		nd		nd
T4	58-160 (NMOL/L)	01/04/88	80.00			nd		nd		nd

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** missing laboratory test value nd laboratory not done () missing range value

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 65 Sex: Male

			Visit number / Laboratory date	
			Screen	
			15/05/89	
			value	(¢)
Laboratory test	Range value	Range date		
HB	13-18 (G/DL)	14/05/89	13.00	
HT	36-60 (%)	14/05/89	44.00	
RBC	4-6.5 (10**12/L)	14/05/89	4.68	
WBC	3.9-12 (10**9/L)	14/05/89	13.00	>
WBC: N	40-75 (%)	14/05/89	68.00	
WBC: L	20-45 (%)	14/05/89	28.00	
WBC: E	1-6 (%)	14/05/89	4.00	
WBC: M	0-1 (%)	14/05/89		nd
WBC: B	2-10 (%)	14/05/89		nd
PLATELETS	100-600 (10**9/L)	14/05/89	318.00	
NA+	134-145 (MMOL/L)	14/05/89	142.00	
K+	3.5-5 (MMOL/L)	14/05/89	4.50	
CL-	95-108 (MMOL/L)	14/05/89		nd
Ca++	2.2-2.6 (MMOL/L)	14/05/89	2.45	
PO4--	0.8-1.5 (MMOL/L)	14/05/89	1.15	
SGOT	15-37 (IU/L)	14/05/89	16.00	
SGPT	2-29 (IU/L)	14/05/89	8.00	
GAMMA GT	5-52 (IU/L)	14/05/89		nd
GRANOLOCYTES	()	14/05/89		nd
ALK. PHOSPH.	95-260 (IU/L)	14/05/89	165.00	
GLUCOSE	3.5-10 (MMOL/L)	14/05/89		nd
BUN	3-6.7 (MMOL/L)	14/05/89	4.40	
CREATININE	76-120 (MMOL/L)	14/05/89	87.00	
PCV	()	14/05/89		nd
URIC ACID	180-340 (UMOL/L)	14/05/89		nd
TOT BILIRUBIN	2-17 (UMOL/L)	14/05/89		nd
DIR BILIRUBIN	0-3.4 (UMOL/L)	14/05/89		nd
TOT. PROTEINS	60-80 (G/L)	14/05/89	67.00	
ALBUMINE	35-46 (G/L)	14/05/89	47.00	>
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	14/05/89		nd
TRIGLYCERIDES	0.5-2 (MMOL/L)	14/05/89		nd
GLOBULINS ALPHA 1	1.5-4 (G/L)	14/05/89		nd
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	14/05/89		nd
GLOBULINS BETA	6-12 (G/L)	14/05/89		nd
GLOBULINS GAMMA	6-16 (G/L)	14/05/89		nd
T3	92-121 (NMOL/L)	14/05/89		nd
T4	58-160 (NMOL/L)	14/05/89		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D 9550321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 66 Sex: Female

			Visit number / Laboratory date					
			Screen		Day 14		Day 28	
			23/05/89		12/06/89		26/06/89	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16.4 (G/DL)	01/04/88	13.80		13.50		14.00	
HT	0.37-0.47 (L/L)	01/04/88	0.43		0.41		0.42	
RBC	3.8-5.8 (10**12/L)	01/04/88	4.57		4.59		4.83	
WBC	4-11 (10**9/L)	01/04/88	9.70		9.32		11.79	>
WBC: N	40-75 (%)	01/04/88		nd	64.00		61.00	
WBC: L	20-45 (%)	01/04/88		nd	31.00		32.00	
WBC: E	1-6 (%)	01/04/88		nd		nd	5.00	
WBC: M	0-1 (%)	01/04/88		nd	2.00	>>	2.00	>>
WBC: B	2-10 (%)	01/04/88		nd	3.00			nd
PLATELETS	150-400 (10**9/L)	01/04/88	270.00		309.00		294.00	
NA+	135-150 (MMOL/L)	01/04/88	141.00		141.00		142.00	
K+	3.5-5 (MMOL/L)	01/04/88	4.60		4.50		4.70	
CL-	95-108 (MMOL/L)	01/04/88		nd	108.00		108.00	
Ca++	2.1-2.6 (MMOL/L)	01/04/88	2.41		2.42		2.44	
PO4--	0.8-1.5 (MMOL/L)	01/04/88	1.27		1.36		1.49	
SGOT	2-29 (IU/L)	01/04/88	7.00		10.00		12.00	
SGPT	5-34 (IU/L)	01/04/88	16.00		13.00		8.00	
GAMMA GT	0-65 (IU/L)	01/04/88	14.00		8.00		12.00	
GRANOLOCYTES	()	01/04/88		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/04/88	57.00		65.00		58.00	
GLUCOSE	3.5-10 (MMOL/L)	01/04/88	4.40		4.80		5.20	
BUN	2.5-7 (MMOL/L)	01/04/88	4.00			nd		nd
CREATININE	59-120 (MMOL/L)	01/04/88	80.00		89.00		116.00	
PCV	()	01/04/88		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/04/88	234.00		263.00		288.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/04/88	6.20		2.70	<	5.00	
DIR BILIRUBIN	0-3.4 (UMOL/L)	01/04/88		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/04/88	67.00		67.00		67.00	
ALBUMINE	34-50 (G/L)	01/04/88	44.00		44.00		44.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/04/88	4.70		4.90		5.00	
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/04/88	0.93		1.89		1.33	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/04/88	2.00		2.10		2.10	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/04/88	6.20		7.10		6.20	
GLOBULINS BETA	6-12 (G/L)	01/04/88	7.20		6.60		7.80	
GLOBULINS GAMMA	6-16 (G/L)	01/04/88	8.80		9.50		7.90	
T3	92-121 (NMOL/L)	01/04/88	112.00			nd		nd
T4	58-160 (NMOL/L)	01/04/88	94.00			nd		nd

(¢) << clinically relevant (value lower than min range) > clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 9590321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 4 Patient: 67 Sex: Male

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			25/05/89		05/06/89		12/06/89		26/06/89	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	13-18 (G/DL)	01/04/88	16.30		17.40		16.20		16.40	
HT	0.4-0.54 (L/L)	01/04/88	0.49		0.52		0.50		0.48	
RBC	4-6.5 (10**12/L)	01/04/88	5.43		5.76		5.31		5.70	
WBC	3.9-12 (10**9/L)	01/04/88	6.45		6.47		6.41		6.67	
WBC: N	40-75 (%)	01/04/88	51.00		54.00		52.00		54.00	
WBC: L	20-45 (%)	01/04/88	43.00		39.00		39.00		40.00	
WBC: E	1-6 (%)	01/04/88	4.00		5.00		6.00		5.00	
WBC: M	0-1 (%)	01/04/88	2.00	>>	2.00	>>	2.00	>>	1.00	
WBC: B	2-10 (%)	01/04/88		nd		nd	1.00	<		nd
PLATELETS	100-600 (10**9/L)	01/04/88	233.00		272.00		259.00		294.00	
NA+	134-145 (MMOL/L)	01/04/88	137.00		141.00		142.00		139.00	
K+	3.5-5 (MMOL/L)	01/04/88	4.60		4.50		4.40		4.70	
CL-	95-108 (MMOL/L)	01/04/88		nd	102.00		108.00		130.00	>>
Ca++	2.2-2.6 (MMOL/L)	01/04/88	2.51			nd	2.59		2.72	>
PO4--	0.8-1.5 (MMOL/L)	01/04/88	0.94		0.98		0.98		1.31	
SGOT	15-37 (IU/L)	01/04/88	52.00	>	29.00		34.00		36.00	
SGPT	2-29 (IU/L)	01/04/88	31.00	>	26.00		24.00		29.00	
GAMMA GT	5-52 (IU/L)	01/04/88	26.00		33.00		26.00		36.00	
GRANOLOCYTES	()	01/04/88		nd		nd		nd		nd
ALK. PHOSPH.	95-260 (IU/L)	01/04/88	52.00	<	60.00	<	55.00	<	66.00	<
GLUCOSE	3.5-10 (MMOL/L)	01/04/88	4.90		4.60		4.70		5.20	
BUN	3-6.7 (MMOL/L)	01/04/88	5.70		4.90		6.00		7.00	>
CREATININE	76-120 (MMOL/L)	01/04/88	88.00		100.00		96.00		103.00	
PCV	()	01/04/88		nd		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	01/04/88	402.00	>	427.00	>	425.00	>	471.00	>>
TOT BILIRUBIN	2-17 (UMOL/L)	01/04/88	4.30		5.00		3.10		9.70	
DIR BILIRUBIN	0-3.4 (UMOL/L)	01/04/88		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/04/88	69.00		73.00		71.00		78.00	
ALBUMINE	35-46 (G/L)	01/04/88	47.00	>	50.00	>	50.00	>	53.00	>
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	01/04/88	7.30	>>	8.30	>>	7.40	>>	7.40	>>
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/04/88	3.66	>>	4.51	>>	4.16	>>	2.28	>
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/04/88	1.90			nd	1.50		2.00	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/04/88	4.50			nd	6.50		5.00	
GLOBULINS BETA	6-12 (G/L)	01/04/88	8.50		6.40		5.20	<	8.60	
GLOBULINS GAMMA	6-16 (G/L)	01/04/88	8.70			nd		nd	9.40	
T3	92-121 (NMOL/L)	01/04/88		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/04/88	64.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 950321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 5 Patient: 71 Sex: Female

			Visit number / Laboratory date					
			Screen		Day 14		Day 28	
			10/05/89		29/05/89		12/06/89	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16.4 (G/DL)	01/05/89	12.50		14.20		13.10	
HT	0.37-0.47 (L/L)	01/05/89	0.39		0.42		0.39	
RBC	3.8-5.8 (10**12/L)	01/05/89	4.32		4.91		4.45	
WBC	4-11 (10**9/L)	01/05/89	9.31		7.80		6.05	
WBC: N	2.5-7.5 (10**9/L)	01/05/89	6.80		4.76		3.45	
WBC: L	1.5-3.5 (10**9/L)	01/05/89	1.86		2.34		2.00	
WBC: E	0.04-0.44 (10**9/L)	01/05/89	0.47	>	0.55	>	0.48	>
WBC: M	0.2-0.8 (10**9/L)	01/05/89	0.09	<	0.16	<	0.12	<
WBC: B	0-0.1 (10**9/L)	01/05/89	0.09			nd		nd
PLATELETS	150-400 (10**9/L)	01/05/89	430.00	>	319.00		342.00	
NA+	135-150 (MMOL/L)	01/05/89	139.00		139.00		139.00	
K+	3.5-5 (MMOL/L)	01/05/89	4.40		4.60		4.00	
CL-	95-108 (MMOL/L)	01/05/89		nd	104.00		103.00	
Ca++	2.1-2.6 (MMOL/L)	01/05/89	2.28		2.47		2.47	
PO4--	0.8-1.5 (MMOL/L)	01/05/89	1.41		1.15		1.37	
SGOT	2-29 (IU/L)	01/05/89	17.00		17.00		22.00	
SGPT	5-34 (IU/L)	01/05/89	7.00		6.00		11.00	
GAMMA GT	0-65 (IU/L)	01/05/89	8.00		9.00		6.00	
GRANOLOCYTES	()	01/05/89		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/05/89	81.00		67.00		66.00	
GLUCOSE	3.5-10 (MMOL/L)	01/05/89	4.90		5.40		5.20	
BUN	2.5-7 (MMOL/L)	01/05/89	4.10		3.70		5.50	
CREATININE	59-120 (MMOL/L)	01/05/89	80.00		84.00		88.00	
PCV	()	01/05/89		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/05/89	296.00		327.00		358.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/89	2.90	<	5.60		8.40	
DIR BILIRUBIN	()	01/05/89		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/05/89	65.00		71.00		68.00	
ALBUMINE	34-50 (G/L)	01/05/89	41.00		45.00		44.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/05/89	5.00		5.40		4.60	
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/05/89	1.48		1.03		0.60	<
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/05/89	2.70		2.30		2.00	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/05/89	4.90		5.30		5.30	
GLOBULINS BETA	6-12 (G/L)	01/05/89	7.00		7.80		6.90	
GLOBULINS GAMMA	6-16 (G/L)	01/05/89	9.40		12.60		11.80	
T3	92-121 (NMOL/L)	01/05/89	111.00			nd		nd
T4	58-160 (NMOL/L)	01/05/89	91.00			nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA [illegible] 9550321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 5 Patient: 72 Sex: Female

			Visit number / Laboratory date					
			Screen		Day 14		Day 28	
			10/05/89		29/05/89		09/06/89	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	12-16.4 (G/DL)	01/05/89	14.80		14.00		14.50	
HT	0.37-0.47 (L/L)	01/05/89	0.46		0.42		0.45	
RBC	3.8-5.8 (10**12/L)	01/05/89	4.78		4.68		4.60	
WBC	4-11 (10**9/L)	01/05/89	6.68		5.30		4.48	
WBC: N	2.5-7.5 (10**9/L)	01/05/89	4.14		3.18		2.64	
WBC: L	1.5-3.5 (10**9/L)	01/05/89	2.20		1.96		1.39	<
WBC: E	0.04-0.44 (10**9/L)	01/05/89	0.33		0.12		0.36	
WBC: M	0.2-0.8 (10**9/L)	01/05/89		nd	0.05	<	0.09	<
WBC: B	0-0.1 (10**9/L)	01/05/89		nd		nd		nd
PLATELETS	150-400 (10**9/L)	01/05/89	266.00		275.00		260.00	
NA+	135-150 (MMOL/L)	01/05/89	142.00		142.00		141.00	
K+	3.5-5 (MMOL/L)	01/05/89	4.20		4.40			nd
CL-	95-108 (MMOL/L)	01/05/89		nd	105.00		105.00	
Ca++	2.1-2.6 (MMOL/L)	01/05/89	2.36		2.38		2.33	
PO4--	0.8-1.5 (MMOL/L)	01/05/89	1.33		0.78	<		nd
SGOT	2-29 (IU/L)	01/05/89	18.00		21.00		14.00	
SGPT	5-34 (IU/L)	01/05/89	9.00		14.00		10.00	
GAMMA GT	0-65 (IU/L)	01/05/89	12.00		6.00		10.00	
GRANOLOCYTES	()	01/05/89		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/05/89	58.00		52.00		61.00	
GLUCOSE	3.5-10 (MMOL/L)	01/05/89	5.30			nd	3.40	<
BUN	2.5-7 (MMOL/L)	01/05/89	7.00		4.60		4.70	
CREATININE	59-120 (MMOL/L)	01/05/89	104.00		83.00		103.00	
PCV	()	01/05/89		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/05/89	256.00		215.00		225.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/89	6.50		6.30		8.20	
DIR BILIRUBIN	()	01/05/89		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/05/89	69.00		65.00		66.00	
ALBUMINE	34-50 (G/L)	01/05/89	45.00		43.00		45.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/05/89	11.00	>>	8.80	>>	9.00	>>
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/05/89	1.72		2.11	>	1.77	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/05/89	1.50		1.60		1.50	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/05/89	5.90		6.10		6.10	
GLOBULINS BETA	6-12 (G/L)	01/05/89	8.50		7.90		8.10	
GLOBULINS GAMMA	6-16 (G/L)	01/05/89	8.10		8.10		8.40	
T3	92-121 (NMOL/L)	01/05/89	110.00			nd		nd
T4	58-160 (NMOL/L)	01/05/89	92.00			nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA C[illegible]0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 5 Patient: 73 Sex: Male

			Visit number / Laboratory date					
			Screen		Day 7		Day 14	
			23/05/89		31/05/89		07/06/89	
			value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date						
HB	13-18 (G/DL)	01/05/89	16.90		17.40		17.00	
HT	0.4-0.54 (L/L)	01/05/89	0.50		0.51		0.56	>
RBC	4-6.5 (10**12/L)	01/05/89	5.47		5.70		5.69	
WBC	3.9-12 (10**9/L)	01/05/89	10.36		8.80		9.60	
WBC: N	2-7.5 (10**9/L)	01/05/89	6.22		4.75		6.43	
WBC: L	1.5-4 (10**9/L)	01/05/89	3.21		3.52		2.59	
WBC: E	0.04-0.44 (10**9/L)	01/05/89	0.73	>>	0.35		0.38	
WBC: M	0.2-0.8 (10**9/L)	01/05/89	0.21		0.09	<	0.10	<
WBC: B	0-0.1 (10**9/L)	01/05/89		nd	0.09		0.10	
PLATELETS	100-600 (10**9/L)	01/05/89	288.00		386.00		397.00	
NA+	134-145 (MMOL/L)	01/05/89	142.00		141.00		141.00	
K+	3.5-5 (MMOL/L)	01/05/89	4.80		5.00			nd
CL-	95-108 (MMOL/L)	01/05/89		nd	101.00		104.00	
Ca++	2.2-2.6 (MMOL/L)	01/05/89	2.57		2.54		2.61	>
PO4--	0.8-1.5 (MMOL/L)	01/05/89	1.11		1.01		1.20	
SGOT	15-37 (IU/L)	01/05/89	30.00		17.00		18.00	
SGPT	2-29 (IU/L)	01/05/89	17.00		11.00		21.00	
GAMMA GT	5-52 (IU/L)	01/05/89	31.00		20.00		26.00	
GRANOLOCYTES	()	01/05/89		nd		nd		nd
ALK. PHOSPH.	95-260 (IU/L)	01/05/89	80.00	<	82.00	<	88.00	<
GLUCOSE	3.5-10 (MMOL/L)	01/05/89	2.80	<		nd	4.90	
BUN	3-6.7 (MMOL/L)	01/05/89	6.10		4.60		5.70	
CREATININE	76-120 (MMOL/L)	01/05/89	107.00		87.00		107.00	
PCV	()	01/05/89		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	01/05/89	360.00	>	279.00		337.00	
TOT BILIRUBIN	2-17 (UMOL/L)	01/05/89	8.70		8.70		5.00	
DIR BILIRUBIN	()	01/05/89		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/05/89	72.00		71.00		71.00	
ALBUMINE	35-46 (G/L)	01/05/89	48.00	>	47.00	>	46.00	
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	01/05/89	6.80	>>	6.10	>	6.80	>>
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/05/89	3.11	>>	3.37	>>	5.32	>>
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/05/89	2.40		2.80		2.30	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/05/89	7.20		6.20		7.70	
GLOBULINS BETA	6-12 (G/L)	01/05/89	8.60		8.60		7.00	
GLOBULINS GAMMA	6-16 (G/L)	01/05/89	10.40		9.90		9.90	
T3	92-121 (NMOL/L)	01/05/89	115.00			nd		nd
T4	58-160 (NMOL/L)	01/05/89	122.00			nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA 95[illegible]321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 5 Patient: 74 Sex: Male

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			23/05/89		31/05/89		07/06/89		21/06/89	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	13-18 (G/DL)	01/05/89	16.90		17.10		17.30		16.40	
HT	0.4-0.54 (L/L)	01/05/89	0.50		0.51		0.51		0.49	
RBC	4-6.5 (10**12/L)	01/05/89	5.86		6.01		5.84		5.71	
WBC	3.9-12 (10**9/L)	01/05/89	11.50		11.30		8.77		9.08	
WBC: N	2-7.5 (10**9/L)	01/05/89	7.59	>	7.57	>	4.82		5.18	
WBC: L	1.5-4 (10**9/L)	01/05/89	2.88		2.94		2.98		3.18	
WBC: E	0.04-0.44 (10**9/L)	01/05/89	0.46	>	0.45	>	0.53	>	0.36	
WBC: M	0.2-0.8 (10**9/L)	01/05/89	0.46		0.23		0.35		0.27	
WBC: B	0-0.1 (10**9/L)	01/05/89	0.12	>	0.11	>	0.09		0.09	
PLATELETS	100-600 (10**9/L)	01/05/89	226.00		284.00		280.00		231.00	
NA+	134-145 (MMOL/L)	01/05/89	140.00		139.00		135.00		139.00	
K+	3.5-5 (MMOL/L)	01/05/89	4.60		4.80		4.50		4.30	
CL-	95-108 (MMOL/L)	01/05/89		nd	103.00		99.00		107.00	
Ca++	2.2-2.6 (MMOL/L)	01/05/89	2.49		2.47		2.48		2.55	
PO4--	0.8-1.5 (MMOL/L)	01/05/89	1.01		1.29		1.01		1.49	
SGOT	15-37 (IU/L)	01/05/89	20.00		28.00		23.00		31.00	
SGPT	2-29 (IU/L)	01/05/89	32.00	>	32.00	>	35.00	>	35.00	>
GAMMA GT	5-52 (IU/L)	01/05/89	54.00	>	43.00		45.00		52.00	
GRANOLOCYTES	()	01/05/89		nd		nd		nd		nd
ALK. PHOSPH.	95-260 (IU/L)	01/05/89	107.00		101.00		98.00		127.00	
GLUCOSE	3.5-10 (MMOL/L)	01/05/89	6.30		4.80		5.30		5.10	
BUN	3-6.7 (MMOL/L)	01/05/89	3.20		3.80		3.50		3.20	
CREATININE	76-120 (MMOL/L)	01/05/89	105.00		89.00		96.00		93.00	
PCV	()	01/05/89		nd		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	01/05/89	484.00	>>	450.00	>>	441.00	>	492.00	>>
TOT BILIRUBIN	2-17 (UMOL/L)	01/05/89	8.20		3.80		10.10		5.50	
DIR BILIRUBIN	()	01/05/89		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/05/89	73.00		73.00		69.00		75.00	
ALBUMINE	35-46 (G/L)	01/05/89	47.00	>	49.00	>	46.00		50.00	>
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	01/05/89	6.50	>	6.50	>	5.90	>	6.80	>>
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/05/89	6.75	>>	8.85	>>	7.83	>>	8.04	>>
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/05/89	2.50		2.80		2.30		2.50	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/05/89	2.70	<	6.90		6.00		6.80	
GLOBULINS BETA	6-12 (G/L)	01/05/89	7.40		7.90		7.10		7.40	
GLOBULINS GAMMA	6-16 (G/L)	01/05/89	12.10		11.30		10.80		10.60	
T3	92-121 (NMOL/L)	01/05/89	116.00			nd		nd		nd
T4	58-160 (NMOL/L)	01/05/89	111.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CM95-0321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 5 Patient: 75 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			23/05/89		31/05/89		07/06/89		21/06/89	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	01/05/89	14.30		14.40		14.20		13.00	
HT	0.37-0.47 (L/L)	01/05/89	0.47		0.47	>	0.43		0.41	
RBC	3.8-5.8 (10**12/L)	01/05/89	4.76		4.93		4.62		4.51	
WBC	4-11 (10**9/L)	01/05/89	5.04		3.94	<	6.33		6.62	
WBC: N	2.5-7.5 (10**9/L)	01/05/89	3.23		2.52		4.18		5.56	
WBC: L	1.5-3.5 (10**9/L)	01/05/89	1.41	<	1.22	<	1.77		0.73	<<
WBC: E	0.04-0.44 (10**9/L)	01/05/89	0.35		0.16		0.32		0.26	
WBC: M	0.2-0.8 (10**9/L)	01/05/89		nd	0.04	<	0.06	<		nd
WBC: B	0-0.1 (10**9/L)	01/05/89	0.05			nd		nd	0.07	
PLATELETS	150-400 (10**9/L)	01/05/89	189.00		176.00		208.00		229.00	
NA+	135-150 (MMOL/L)	01/05/89	148.00		145.00		142.00		139.00	
K+	3.5-5 (MMOL/L)	01/05/89		nd		nd	4.30		3.70	
CL-	95-108 (MMOL/L)	01/05/89		nd	103.00		106.00		103.00	
Ca++	2.1-2.6 (MMOL/L)	01/05/89	2.65	>	2.75	>	2.69	>	2.56	
PO4--	0.8-1.5 (MMOL/L)	01/05/89		nd		nd	0.98		0.76	<
SGOT	2-29 (IU/L)	01/05/89		nd		nd	25.00		83.00	>>
SGPT	5-34 (IU/L)	01/05/89		nd		nd	14.00		55.00	>
GAMMA GT	0-65 (IU/L)	01/05/89	10.00		2.00		6.80		11.00	
GRANOLOCYTES	()	01/05/89		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/05/89	84.00		91.00		89.00		151.00	>
GLUCOSE	3.5-10 (MMOL/L)	01/05/89		nd		nd	7.40		7.40	
BUN	2.5-7 (MMOL/L)	01/05/89	2.90		2.90		2.30	<	6.40	
CREATININE	59-120 (MMOL/L)	01/05/89		nd		nd	87.00		84.00	
PCV	()	01/05/89		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/05/89	239.00		273.00		251.00		282.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/89	9.10		7.40		6.70		11.10	
DIR BILIRUBIN	()	01/05/89		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/05/89	69.00		70.00		65.00		62.00	
ALBUMINE	34-50 (G/L)	01/05/89	47.00		48.00		46.00		40.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/05/89	7.20	>	7.00	>	6.40	>	5.60	
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/05/89	1.08		1.14		1.20		1.21	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/05/89	2.50		2.70		2.80		3.60	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/05/89	7.20		6.40		5.70		5.80	
GLOBULINS BETA	6-12 (G/L)	01/05/89	8.60		8.60		8.50		7.10	
GLOBULINS GAMMA	6-16 (G/L)	01/05/89	7.20		7.30		6.80		5.50	<
T3	92-121 (NMOL/L)	01/05/89	105.00			nd		nd		nd
T4	58-160 (NMOL/L)	01/05/89	83.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CM5 [illegible] 9550321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 5 Patient: 76 Sex: Male

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			22/05/89		31/05/89		07/06/89		21/06/89	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	13-18 (G/DL)	01/05/89	14.30		14.50		15.00		13.40	
HT	0.4-0.54 (L/L)	01/05/89	0.42		0.44		0.47		0.43	
RBC	4-6.5 (10**12/L)	01/05/89	4.32		4.66		4.58		4.12	
WBC	3.9-12 (10**9/L)	01/05/89	6.05		6.30		6.09		3.90	
WBC: N	2-7.5 (10**9/L)	01/05/89	3.63		3.59		3.35		2.73	
WBC: L	1.5-4 (10**9/L)	01/05/89	1.75		2.02		2.13		0.94	<<
WBC: E	0.04-0.44 (10**9/L)	01/05/89	0.54	>	0.50	>	0.55	>	0.20	
WBC: M	0.2-0.8 (10**9/L)	01/05/89	0.06	<	0.06	<	0.06	<	0.04	<
WBC: B	0-0.1 (10**9/L)	01/05/89	0.06		0.06			nd		nd
PLATELETS	100-600 (10**9/L)	01/05/89	226.00		331.00		296.00		221.00	
NA+	134-145 (MMOL/L)	01/05/89	141.00		140.00		142.00		141.00	
K+	3.5-5 (MMOL/L)	01/05/89	4.60		4.70		4.60		4.60	
CL-	95-108 (MMOL/L)	01/05/89		nd	106.00		102.00		105.00	
Ca++	2.2-2.6 (MMOL/L)	01/05/89	2.67	>	2.52		2.73	>	2.62	>
PO4--	0.8-1.5 (MMOL/L)	01/05/89	1.51	>	1.34		1.09		1.22	
SGOT	15-37 (IU/L)	01/05/89		nd	25.00		26.00		22.00	
SGPT	2-29 (IU/L)	01/05/89		nd	30.00	>	40.00	>	21.00	
GAMMA GT	5-52 (IU/L)	01/05/89	48.00		43.00		43.00		32.00	
GRANOLOCYTES	()	01/05/89		nd		nd		nd		nd
ALK. PHOSPH.	95-260 (IU/L)	01/05/89	74.00	<	72.00	<	70.00	<	75.00	<
GLUCOSE	3.5-10 (MMOL/L)	01/05/89		nd	3.60		3.60		4.20	
BUN	3-6.7 (MMOL/L)	01/05/89	3.20		3.40		3.10		3.90	
CREATININE	76-120 (MMOL/L)	01/05/89	99.00		97.00		88.00		96.00	
PCV	()	01/05/89		nd		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	01/05/89	241.00		294.00		343.00	>	320.00	
TOT BILIRUBIN	2-17 (UMOL/L)	01/05/89	6.80		4.60		5.60		5.80	
DIR BILIRUBIN	()	01/05/89		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/05/89	76.00		74.00		77.00		72.00	
ALBUMINE	35-46 (G/L)	01/05/89	47.00	>	46.00		49.00	>	46.00	
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	01/05/89	5.60	>	5.60	>	6.50	>	6.20	>
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/05/89	2.12	>	3.14	>>	2.45	>	1.73	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/05/89	2.70		3.60		2.50		2.00	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/05/89	8.50		9.00		7.90		6.80	
GLOBULINS BETA	6-12 (G/L)	01/05/89	7.90		8.10		8.80		6.90	
GLOBULINS GAMMA	6-16 (G/L)	01/05/89	11.40		15.60		12.90		10.30	
T3	92-121 (NMOL/L)	01/05/89	101.00			nd		nd		nd
T4	58-160 (NMOL/L)	01/05/89	109.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS R&D 9990321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 5 Patient: 77 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			31/05/89		06/06/89		14/06/89		26/06/89	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	01/05/89	15.00		14.70		14.80		14.60	
HT	0.37-0.47 (L/L)	01/05/89	0.48	>	0.45		0.44		0.43	
RBC	3.8-5.8 (10**12/L)	01/05/89	5.00		4.81		4.78		4.90	
WBC	4-11 (10**9/L)	01/05/89	8.16		7.43		8.68		7.95	
WBC: N	2.5-7.5 (10**9/L)	01/05/89	5.96		5.42		6.51		5.41	
WBC: L	1.5-3.5 (10**9/L)	01/05/89	1.88		1.56		1.82		2.15	
WBC: E	0.04-0.44 (10**9/L)	01/05/89	0.24		0.22		0.26		0.24	
WBC: M	0.2-0.8 (10**9/L)	01/05/89	0.08	<	0.15	<	0.09	<	0.16	<
WBC: B	0-0.1 (10**9/L)	01/05/89		nd	0.07			nd		nd
PLATELETS	150-400 (10**9/L)	01/05/89	213.00		241.00		250.00		247.00	
NA+	135-150 (MMOL/L)	01/05/89	139.00		137.00		143.00		138.00	
K+	3.5-5 (MMOL/L)	01/05/89	4.10		4.80			nd		nd
CL-	95-108 (MMOL/L)	01/05/89		nd	101.00		92.00	<	104.00	
Ca++	2.1-2.6 (MMOL/L)	01/05/89	2.43		2.48		2.66	>	2.56	
PO4--	0.8-1.5 (MMOL/L)	01/05/89	1.09		1.17			nd		nd
SGOT	2-29 (IU/L)	01/05/89	19.00		18.00			nd	18.00	
SGPT	5-34 (IU/L)	01/05/89	8.00		9.00			nd	14.00	
GAMMA GT	0-65 (IU/L)	01/05/89	12.00		10.00		10.00		16.00	
GRANOLOCYTES	()	01/05/89		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/05/89	70.00		74.00		99.00		91.00	
GLUCOSE	3.5-10 (MMOL/L)	01/05/89	6.50		6.80			nd	5.20	
BUN	2.5-7 (MMOL/L)	01/05/89	5.20		5.40		5.50		5.30	
CREATININE	59-120 (MMOL/L)	01/05/89	118.00		118.00			nd	118.00	
PCV	()	01/05/89		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/05/89	318.00		309.00		291.00		328.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/05/89	17.60		13.00		11.80		12.70	
DIR BILIRUBIN	()	01/05/89		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/05/89	68.00		67.00		74.00		68.00	
ALBUMINE	34-50 (G/L)	01/05/89	46.00		45.00		49.00		46.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/05/89	6.20	>	6.20	>	6.80	>	6.80	>
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/05/89	1.22		1.36		1.80		1.19	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/05/89	2.40		2.40		2.40		1.60	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/05/89	6.50		7.20		6.90		6.40	
GLOBULINS BETA	6-12 (G/L)	01/05/89	7.40		7.40		7.70		7.40	
GLOBULINS GAMMA	6-16 (G/L)	01/05/89	8.50		7.80		8.00		6.60	
T3	92-121 (NMOL/L)	01/05/89	113.00			nd		nd		nd
T4	58-160 (NMOL/L)	01/05/89	120.00			nd		nd		nd

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REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 6 Patient: 81 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			20/03/89		03/04/89		10/04/89		24/04/89	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	12-16.4 (G/DL)	01/03/89	15.20		14.20		14.40		14.30	
HT	0.37-0.47 (L/L)	01/03/89	0.45		0.42		0.42		0.43	
RBC	3.8-5.8 (10**12/L)	01/03/89	5.26		4.97		4.65		4.66	
WBC	4-11 (10**9/L)	01/03/89	4.58		4.49		5.60		5.17	
WBC: N	2.5-7.5 (10**9/L)	01/03/89	2.98		2.83		3.53		3.21	
WBC: L	1.5-3.5 (10**9/L)	01/03/89	1.19	<	1.26	<	1.68		1.45	<
WBC: E	0.04-0.44 (10**9/L)	01/03/89	0.23		0.27		0.22		0.41	
WBC: M	0.2-0.8 (10**9/L)	01/03/89	0.14	<	0.09	<	0.06	<	0.10	<
WBC: B	0-0.1 (10**9/L)	01/03/89	0.09		0.04		0.11	>	0.05	
PLATELETS	150-400 (10**9/L)	01/03/89	278.00		251.00		231.00		242.00	
NA+	135-150 (MMOL/L)	01/03/89	144.00		142.00		140.00		139.00	
K+	3.5-5 (MMOL/L)	01/03/89	4.20			nd		nd	4.30	
CL-	95-108 (MMOL/L)	01/03/89		nd	105.00		99.00		107.00	
Ca++	2.1-2.6 (MMOL/L)	01/03/89	2.42		2.30		2.35		2.24	
PO4--	0.8-1.5 (MMOL/L)	01/03/89	1.04		0.73	<		nd	1.13	
SGOT	2-29 (IU/L)	01/03/89	29.00			nd		nd		nd
SGPT	5-34 (IU/L)	01/03/89	18.00			nd		nd		nd
GAMMA GT	0-65 (IU/L)	01/03/89	25.00		21.00		22.00		23.00	
GRANOLOCYTES	()	01/03/89		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/03/89	88.00		72.00		85.00		81.00	
GLUCOSE	3.5-10 (MMOL/L)	01/03/89		nd	5.00			nd	4.90	
BUN	2.5-7 (MMOL/L)	01/03/89		nd		nd		nd		nd
CREATININE	59-120 (MMOL/L)	01/03/89	77.00		75.00			nd	77.00	
PCV	()	01/03/89		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/03/89	232.00		213.00		216.00		212.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/03/89	8.20		6.50		8.60		7.90	
DIR BILIRUBIN	()	01/03/89		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/03/89	71.00		66.00		68.00		67.00	
ALBUMINE	34-50 (G/L)	01/03/89	45.00		42.00		43.00		41.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/03/89	7.60	>	6.00		5.80		5.40	
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/03/89	2.02	>	1.62		1.47		1.86	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/03/89	2.10		2.00		2.00		2.10	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/03/89	6.10		6.10		6.80		6.60	
GLOBULINS BETA	6-12 (G/L)	01/03/89	8.20		7.20		7.00		8.50	
GLOBULINS GAMMA	6-16 (G/L)	01/03/89	9.60		8.70		9.20		8.80	
T3	92-121 (NMOL/L)	01/03/89		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/03/89	88.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 9550321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 6 Patient: 82 Sex: Male

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			20/03/89		03/04/89		10/04/89		24/04/89	
Laboratory test	Range value	Range date	value	(¢)	value	(¢)	value	(¢)	value	(¢)
HB	13-18 (G/DL)	01/03/89	16.10		13.60		15.30		16.20	
HT	0.4-0.54 (L/L)	01/03/89	0.54		0.40		0.45		0.50	
RBC	4-6.5 (10**12/L)	01/03/89	5.31		4.29		4.88		5.09	
WBC	3.9-12 (10**9/L)	01/03/89	6.56		7.50		8.98		9.04	
WBC: N	2-7.5 (10**9/L)	01/03/89	6.75		4.88		5.66		5.15	
WBC: L	1.5-4 (10**9/L)	01/03/89	2.00		2.10		2.60		2.89	
WBC: E	0.04-0.44 (10**9/L)	01/03/89	0.46	>	0.30		0.45	>	0.63	>>
WBC: M	0.2-0.8 (10**9/L)	01/03/89	0.15	<	0.23		0.27		0.36	
WBC: B	0-0.1 (10**9/L)	01/03/89	0.07		0.08		0.09		0.09	
PLATELETS	100-600 (10**9/L)	01/03/89	280.00		287.00		306.00		300.00	
NA+	134-145 (MMOL/L)	01/03/89	140.00		139.00		140.00		139.00	
K+	3.5-5 (MMOL/L)	01/03/89	4.80			nd		nd	5.10	>
CL-	95-108 (MMOL/L)	01/03/89		nd	104.00		103.00		101.00	
Ca++	2.2-2.6 (MMOL/L)	01/03/89	2.14	<	2.32		2.44		2.48	
PO4--	0.8-1.5 (MMOL/L)	01/03/89	0.78	<	0.89		0.84		1.14	
SGOT	15-37 (IU/L)	01/03/89	24.00			nd		nd		nd
SGPT	2-29 (IU/L)	01/03/89	15.00			nd		nd		nd
GAMMA GT	5-52 (IU/L)	01/03/89	5.00		19.00		19.00		29.00	
GRANOLOCYTES	()	01/03/89		nd		nd		nd		nd
ALK. PHOSPH.	95-260 (IU/L)	01/03/89	78.00	<	70.00	<	73.00	<	78.00	<
GLUCOSE	3.5-10 (MMOL/L)	01/03/89	4.00		3.60			nd	3.30	<
BUN	3-6.7 (MMOL/L)	01/03/89		nd		nd		nd		nd
CREATININE	76-120 (MMOL/L)	01/03/89		nd	80.00		86.00		81.00	
PCV	()	01/03/89		nd		nd		nd		nd
URIC ACID	180-340 (UMOL/L)	01/03/89	285.00		271.00		251.00		267.00	
TOT BILIRUBIN	2-17 (UMOL/L)	01/03/89	6.20		4.80		5.50		5.60	
DIR BILIRUBIN	()	01/03/89		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/03/89	75.00		65.00		71.00		75.00	
ALBUMINE	35-46 (G/L)	01/03/89	43.00		36.00		40.00		42.00	
TOT. CHOLEST.	3.1-5.2 (MMOL/L)	01/03/89	7.60	>>	6.80	>>	7.70	>>	8.20	>>
TRIGLYCERIDES	0.5-2 (MMOL/L)	01/03/89	2.17	>	3.36	>>	3.93	>>	5.79	>>
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/03/89	2.30		2.60		1.70		2.60	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/03/89	7.40		7.20		10.10		8.50	
GLOBULINS BETA	6-12 (G/L)	01/03/89	8.60		7.30		6.10		8.30	
GLOBULINS GAMMA	6-16 (G/L)	01/03/89	13.70		12.10		13.10		13.60	
T3	92-121 (NMOL/L)	01/03/89		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/03/89	98.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
< out of range (value lower than min range) > out of range (value higher than max range)
** missing laboratory test value nd laboratory not done () missing range value

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 6 Patient: 83 Sex: Female

			Visit number / Laboratory date							
			Screen		Day 7		Day 14		Day 28	
			05/05/89		22/05/89		29/05/89		12/06/89	
			value	(¢)	value	(¢)	value	(¢)	value	(¢)
Laboratory test	Range value	Range date								
HB	12-16.4 (G/DL)	01/03/89	13.10		14.30			nd	15.80	
HT	0.37-0.47 (L/L)	01/03/89	0.40		0.44			nd	0.47	
RBC	3.8-5.8 (10**12/L)	01/03/89	4.06		4.49			nd	4.94	
WBC	4-11 (10**9/L)	01/03/89	6.20		7.62			nd	8.86	
WBC: N	2.5-7.5 (10**9/L)	01/03/89	3.53		4.34			nd	3.19	
WBC: L	1.5-3.5 (10**9/L)	01/03/89	2.05		2.67			nd	4.52	>
WBC: E	0.04-0.44 (10**9/L)	01/03/89	0.50	>	0.38			nd	0.89	>>
WBC: M	0.2-0.8 (10**9/L)	01/03/89	0.06	<	0.15	<		nd	0.27	
WBC: B	0-0.1 (10**9/L)	01/03/89	0.06		0.08			nd		nd
PLATELETS	150-400 (10**9/L)	01/03/89	403.00	>	238.00			nd	238.00	
NA+	135-150 (MMOL/L)	01/03/89	144.00		145.00		144.00		142.00	
K+	3.5-5 (MMOL/L)	01/03/89	4.10			nd		nd	4.00	
CL-	95-108 (MMOL/L)	01/03/89		nd	103.00		103.00		99.00	
Ca++	2.1-2.6 (MMOL/L)	01/03/89	2.30		2.38		2.46		2.58	
PO4--	0.8-1.5 (MMOL/L)	01/03/89	1.43			nd		nd		nd
SGOT	2-29 (IU/L)	01/03/89	28.00			nd		nd		nd
SGPT	5-34 (IU/L)	01/03/89	13.00			nd		nd		nd
GAMMA GT	0-65 (IU/L)	01/03/89	9.00		9.00		9.00		9.00	
GRANOLOCYTES	()	01/03/89		nd		nd		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/03/89	82.00		85.00		76.00		86.00	
GLUCOSE	3.5-10 (MMOL/L)	01/03/89		nd		nd		nd		nd
BUN	2.5-7 (MMOL/L)	01/03/89		nd		nd		nd		nd
CREATININE	59-120 (MMOL/L)	01/03/89	71.00			nd	112.00		80.00	
PCV	()	01/03/89		nd		nd		nd		nd
URIC ACID	200-500 (UMOL/L)	01/03/89	223.00		209.00		191.00	<	183.00	<
TOT BILIRUBIN	3-20 (UMOL/L)	01/03/89	4.80		6.50		8.40		8.90	
DIR BILIRUBIN	()	01/03/89		nd		nd		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/03/89	62.00		66.00		64.00		76.00	
ALBUMINE	34-50 (G/L)	01/03/89	38.00		41.00		41.00		50.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/03/89	4.50		5.00		5.00		6.20	>
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/03/89	1.37		1.09		1.21		1.64	
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/03/89	3.00		2.90		3.30		3.40	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/03/89	6.40		7.80		6.80		7.50	
GLOBULINS BETA	6-12 (G/L)	01/03/89	6.10		6.40		7.60		7.40	
GLOBULINS GAMMA	6-16 (G/L)	01/03/89	8.40		9.90		9.40		10.90	
T3	92-121 (NMOL/L)	01/03/89		nd		nd		nd		nd
T4	58-160 (NMOL/L)	01/03/89	100.00			nd		nd		nd

(¢) << clinically relevant (value lower than min range) >> clinically relevant (value higher than max range)
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** missing laboratory test value nd laboratory not done () missing range value

PHARMACIA CNS 9950321

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 11.0

LABORATORY DATA
Centre: 7 Patient: 89 Sex: Female

			Visit number / Laboratory date			
			Screen		Day 7	
			06/03/89		19/03/89	
			value	(¢)	value	(¢)
Laboratory test	Range value	Range date				
HB	12-16.4 (G/DL)	01/03/89	15.20		16.00	
HT	0.37-0.47 (L/L)	01/03/89	0.45		0.49	>
RBC	3.8-5.8 (10**12/L)	01/03/89	4.89		5.34	
WBC	4-11 (10**9/L)	01/03/89	10.05		12.04	>
WBC: N	2.5-7.5 (10**9/L)	01/03/89	6.93		7.71	>
WBC: L	1.5-3.5 (10**9/L)	01/03/89	2.11		3.01	
WBC: E	0.04-0.44 (10**9/L)	01/03/89	0.50	>	0.60	>>
WBC: M	0.2-0.8 (10**9/L)	01/03/89	0.50		0.72	
WBC: B	0-0.1 (10**9/L)	01/03/89	0.10		0.12	>
PLATELETS	150-400 (10**9/L)	01/03/89	249.00		277.00	
NA+	135-150 (MMOL/L)	01/03/89	144.00		141.00	
K+	3.5-5 (MMOL/L)	01/03/89		nd		nd
CL-	95-108 (MMOL/L)	01/03/89		nd	96.00	
Ca++	2.1-2.6 (MMOL/L)	01/03/89	2.38		2.42	
PO4--	0.8-1.5 (MMOL/L)	01/03/89		nd		nd
SGOT	2-29 (IU/L)	01/03/89		nd		nd
SGPT	5-34 (IU/L)	01/03/89		nd		nd
GAMMA GT	0-65 (IU/L)	01/03/89	51.00		60.00	
GRANOLOCYTES	()	01/03/89		nd		nd
ALK. PHOSPH.	30-115 (IU/L)	01/03/89	146.00	>	164.00	>
GLUCOSE	3.5-10 (MMOL/L)	01/03/89		nd		nd
BUN	2.5-7 (MMOL/L)	01/03/89		nd		nd
CREATININE	59-120 (MMOL/L)	01/03/89		nd	105.00	
PCV	()	01/03/89		nd		nd
URIC ACID	200-500 (UMOL/L)	01/03/89	247.00		242.00	
TOT BILIRUBIN	3-20 (UMOL/L)	01/03/89	5.50		6.00	
DIR BILIRUBIN	()	01/03/89		nd		nd
TOT. PROTEINS	60-80 (G/L)	01/03/89	59.00	<	63.00	
ALBUMINE	34-50 (G/L)	01/03/89	36.00		38.00	
TOT. CHOLEST.	0-6 (MMOL/L)	01/03/89	5.10		6.10	>
TRIGLYCERIDES	0.8-2 (MMOL/L)	01/03/89	1.92		3.45	>>
GLOBULINS ALPHA 1	1.5-4 (G/L)	01/03/89	2.30		2.70	
GLOBULINS ALPHA 2	3.6-10.5 (G/L)	01/03/89	5.60		6.10	
GLOBULINS BETA	6-12 (G/L)	01/03/89	6.80		7.90	
GLOBULINS GAMMA	6-16 (G/L)	01/03/89	8.30		8.30	
T3	92-121 (NMOL/L)	01/03/89		nd		nd
T4	58-160 (NMOL/L)	01/03/89	106.00			nd

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REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 12.0

URINALYSIS

Centre	Patient	Treatment	Sex	Treatment period: Start date	Treatment period: End date	Days	Urinalysis test: Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
1	1	Placebo	Male	14/11/87	11/12/87	28	Screen	13/11/87	0	NORMAL	PRESENT	ABSENT	ABSENT	ABSENT
							Day 7	20/11/87	7	NORMAL	PRESENT	ABSENT	PRESENT	ABSENT
							Day 14	27/11/87	14	NORMAL	PRESENT	ABSENT	PRESENT	ABSENT
							Day 28	11/12/87	28	NORMAL	PRESENT	ABSENT	ABSENT	ABSENT
	3	Reboxetine	Female	14/11/87	11/12/87	28	Screen	12/11/87	0	NORMAL	ABSENT	ABSENT	PRESENT	ABSENT
							Day 7	20/11/87	7	NORMAL	ABSENT	ABSENT	PRESENT	ABSENT
							Day 14	27/11/87	14	NORMAL	ABSENT	ABSENT	PRESENT	ABSENT
							Day 28	11/12/87	28	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	4	Reboxetine	Male	09/12/87	05/01/88	28	Screen	08/12/87	0	NORMAL	PRESENT	ABSENT	ABSENT	ABSENT
							Day 7	15/12/87	7	NORMAL	PRESENT	ABSENT	ABSENT	ABSENT
							Day 14	22/12/87	14	NORMAL	PRESENT	PRESENT	ABSENT	ABSENT
							Day 28	05/01/88	28	NORMAL	PRESENT	PRESENT	ABSENT	ABSENT
	5	Placebo	Female	11/02/88	09/03/88	28	Screen	03/02/88	0	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	17/02/88	7	NORMAL	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 10	24/02/88	14	NORMAL	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 28	09/03/88	28	NORMAL	ABSENT	ABSENT	ABSENT	NOT DONE
	6	Reboxetine	Female	23/04/88	20/05/88	28	Screen	20/04/88	0	NORMAL	PRESENT	ABSENT	ABSENT	ABSENT
							Day 7	29/04/88	7	NORMAL	PRESENT	ABSENT	ABSENT	ABSENT
							Day 14	06/05/88	14	NORMAL	PRESENT	ABSENT	ABSENT	ABSENT
							Day 28	20/05/88	28	NORMAL	PRESENT	ABSENT	ABSENT	ABSENT
	7	Placebo	Male	28/05/88	24/06/88	28	Screen	25/05/88	0	NORMAL	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 7	03/06/88	7	NORMAL	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 14	10/06/88	14	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 28	24/07/88	58	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
	8	Reboxetine	Female	15/07/88	12/08/88	29	Screen	13/07/88	0	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	22/07/88	8	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	29/07/88	15	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	9	Placebo	Male	06/10/88	02/11/88	28	Screen	04/10/88	0	NORMAL	ABSENT	PRESENT	ABSENT	ABSENT
							Day 7	12/10/88	7	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	19/10/88	14	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	02/11/88	28	NORMAL	PRESENT	ABSENT	ABSENT	ABSENT
	10	Placebo	Male	07/10/88	04/11/88	29	Screen	04/10/88	0	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT

(*) days of treatment

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 12.0

URINALYSIS

				Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
1	10	Placebo	Male	07/10/88	04/11/88	29	Day 7	13/10/88	7	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	21/10/88	15	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	04/11/88	29	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	11	Reboxetine	Female	15/11/88	12/12/88	28	Screen	15/11/88	1	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	22/11/88	8	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	29/11/88	15	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	12/12/88	28	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	12	Reboxetine	Male	18/11/88	30/11/88	13	Screen	17/11/88	0	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	25/11/88	8	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	30/11/88	13	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	13	Reboxetine	Female	07/01/89	05/02/89	30	Screen	04/01/89	0	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	13/01/89	7	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	20/01/89	14	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	03/02/89	28	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	14	Placebo	Female	12/01/89	10/02/89	30	Screen	11/01/89	0	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	18/01/89	7	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	25/01/89	14	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	10/02/89	30	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	15	Placebo	Female	28/03/89	17/04/89	21	Screen	23/03/89	0	NORMAL	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 7	03/04/89	7	NORMAL	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 14	10/04/89	14	NORMAL	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 28	17/04/89	21	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	16	Reboxetine	Female	24/04/89	22/05/89	29	Screen	21/04/89	0	NORMAL	ABSENT	ABSENT	PRESENT	NOT DONE
							Day 7	02/05/89	9	NORMAL	ABSENT	ABSENT	PRESENT	ABSENT
							Day 14	08/05/89	15	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	22/05/89	29	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
2	21	Reboxetine	Female	20/02/88	24/03/88	34	Screen	15/02/88	0	NORMAL	PRESENT	ABSENT	ABSENT	ABSENT
							Day 7	29/02/88	10	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	07/03/88	17	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	23/03/88	33	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	22	Placebo	Female	10/05/88	07/06/88	29	Screen	29/04/88	0	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	16/05/88	7	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT

(*) days of treatment

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 12.0

URINALYSIS

				Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
2	22	Placebo	Female	10/05/88	07/06/88	29	Day 14	23/05/88	14	NORMAL	ABSENT	ABSENT	PRESENT	ABSENT
							Day 28	07/06/88	29	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	23	Placebo	Female	29/12/88	06/01/89	9	Screen	16/12/88	0	NOT DONE	ABSENT	ABSENT	ABSENT	PRESENT
							Day 7	05/01/89	8	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
	24	Reboxetine	Female	15/02/89	14/03/89	28	Screen	07/02/89	0	NOT DONE	PRESENT	ABSENT	ABSENT	ABSENT
							Day 7	21/02/89	7	NOT DONE	PRESENT	ABSENT	ABSENT	ABSENT
							Day 14	01/03/89	15	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	15/03/89	29	NOT DONE	ABSENT	ABSENT	PRESENT	ABSENT
	25	Reboxetine	Female	21/02/89	21/03/89	29	Screen	13/02/89	0	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	28/02/89	8	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	03/03/89	11	NOT DONE	PRESENT	ABSENT	ABSENT	PRESENT
							Day 28	21/03/89	29	NOT DONE	missing	missing	missing	missing
3	26	Reboxetine	Female	29/12/88	17/01/89	20	Screen	28/12/88	0	NORMAL	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 7	04/01/89	7	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 14	11/01/89	14	NOT DONE	ABSENT	ABSENT	PRESENT	NOT DONE
							Day 21	18/01/89	21	NOT DONE	ABSENT	ABSENT	PRESENT	NOT DONE
	27	Placebo	Female	28/12/88	25/01/89	29	Screen	14/12/88	0	NORMAL	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 7	03/01/89	7	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 14	10/01/89	14	NOT DONE	PRESENT	ABSENT	ABSENT	NOT DONE
							Day 28	26/01/89	30	NOT DONE	PRESENT	ABSENT	ABSENT	NOT DONE
	28	Placebo	Male	28/12/88	12/01/89	16	Screen	12/12/88	0	NORMAL	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 7	03/01/89	7	NORMAL	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 14	10/01/89	14	NOT DONE	PRESENT	PRESENT	NOT DONE	NOT DONE
4	51	Placebo	Female	22/04/88	02/05/88	11	Screen	15/04/88	0	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	29/04/88	8	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	52	Placebo	Female	08/07/88	04/08/88	28	Screen	01/07/88	0	NORMAL	PRESENT	ABSENT	ABSENT	PRESENT
							Day 7	14/07/88	7	NOT DONE	ABSENT	ABSENT	PRESENT	PRESENT
							Day 14	21/07/88	14	NOT DONE	ABSENT	ABSENT	PRESENT	PRESENT
							Day 28	04/08/88	28	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
	53	Reboxetine	Male	30/09/88	20/10/88	21	Screen	27/09/88	0	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT

(*) days of treatment

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 12.0

URINALYSIS

				Treatment period			Urinalysis test							
Centre	Patient	Treatment	Sex	Start date	End date	Days	Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
4	53	Reboxetine	Male	30/09/88	20/10/88	21	Day 7	06/10/88	7	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	13/10/88	14	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
	54	Placebo	Female	29/11/88	26/12/88	28	Screen	25/11/88	0	NOT DONE	PRESENT	ABSENT	PRESENT	ABSENT
							Day 7	05/12/88	7	NOT DONE	PRESENT	ABSENT	ABSENT	ABSENT
							Day 14	12/12/88	14	NOT DONE	PRESENT	ABSENT	ABSENT	ABSENT
							Day 28	23/12/88	25	NOT DONE	NOT DONE	ABSENT	ABSENT	NOT DONE
	55	Placebo	Male	23/01/89	20/02/89	29	Screen	20/01/89	0	NOT DONE	ABSENT	ABSENT	ABSENT	PRESENT
							Day 7	30/01/89	8	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	06/02/89	15	NORMAL	ABSENT	ABSENT	ABSENT	PRESENT
							Day 28	20/02/89	29	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	56	Reboxetine	Female	24/01/89	22/02/89	30	Screen	22/01/89	0	NOT DONE	missing	missing	missing	missing
							Day 7	30/01/89	7	NORMAL	ABSENT	ABSENT	ABSENT	PRESENT
							Day 14	06/02/89	14	NOT DONE	ABSENT	ABSENT	NOT DONE	NOT DONE
							Day 28	20/02/89	28	NORMAL	NOT DONE	NOT DONE	NOT DONE	NOT DONE
	57	Placebo	Female	15/03/89	10/04/89	27	Screen	10/03/89	0	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	20/03/89	6	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	28/03/89	14	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	10/04/89	27	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
	58	Reboxetine	Male	21/03/89	03/04/89	14	Screen	16/03/89	0	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	28/03/89	8	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	03/04/89	14	NOT DONE	missing	missing	missing	missing
	60	Placebo	Female	14/03/89	10/04/89	28	Screen	13/03/89	0	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	20/03/89	7	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	28/03/89	15	NORMAL	PRESENT	ABSENT	ABSENT	ABSENT
							Day 28	10/04/89	28	NOT DONE	missing	missing	missing	missing
	61	Placebo	Female	09/05/89	05/06/89	28	Screen	02/05/89	0	NOT DONE	missing	missing	missing	missing
							Day 7	15/05/89	7	NOT DONE	missing	missing	missing	missing
							Day 14	22/05/89	14	NOT DONE	missing	missing	missing	missing
							Day 28	05/06/89	28	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	62	Placebo	Female	09/05/89	11/05/89	3	Screen	04/05/89	0	NOT DONE	missing	missing	missing	missing

(*) days of treatment

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URINALYSIS

Centre	Patient	Treatment	Sex	Treatment period: Start date	Treatment period: End date	Treatment period: Days	Urinalysis test: Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
4	63	Reboxetine	Female	16/05/89	11/06/89	27	Screen	09/05/89	0	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	22/05/89	7	NOT DONE	missing	missing	missing	missing
							Day 14	01/06/89	17	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	64	Reboxetine	Male	23/05/89	19/06/89	28	Screen	16/05/89	0	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	31/05/89	9	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	05/06/89	14	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	19/06/89	28	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	65	Placebo	Male	23/05/89	28/05/89	6	Screen	15/05/89	0	NOT DONE	missing	missing	missing	missing
	66	Reboxetine	Female	30/05/89	26/06/89	28	Screen	23/05/89	0	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	12/06/89	14	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	26/06/89	28	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	67	Reboxetine	Male	30/05/89	28/06/89	30	Screen	25/05/89	0	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	05/06/89	7	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	12/06/89	14	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	26/06/89	28	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
5	71	Reboxetine	Female	15/05/89	12/06/89	29	Screen	10/05/89	0	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 14	29/05/89	15	NOT DONE	missing	missing	missing	missing
							Day 28	12/06/89	29	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
	72	Placebo	Female	11/05/89	08/06/89	29	Screen	10/05/89	0	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 14	29/05/89	19	NOT DONE	missing	missing	missing	missing
							Day 28	09/06/89	30	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
	73	Reboxetine	Male	23/05/89	21/06/89	30	Screen	23/05/89	1	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 7	31/05/89	9	NOT DONE	missing	missing	missing	missing
							Day 14	07/06/89	16	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 28	21/06/89	30	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
	74	Placebo	Male	23/05/89	21/06/89	30	Screen	23/05/89	1	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 7	31/05/89	9	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 14	07/06/89	16	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 28	21/06/89	30	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
	75	Placebo	Female	23/05/89	21/06/89	30	Screen	23/05/89	1	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE

(*) days of treatment

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URINALYSIS

Centre	Patient	Treatment	Sex	Treatment period: Start date	End date	Days	Urinalysis test: Assessment	Date	(*)	Specific gravity	Albumin	Sugar	RBC	WBC
5	75	Placebo	Female	23/05/89	21/06/89	30	Day 7	31/05/89	9	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 14	07/06/89	16	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 28	21/06/89	30	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
	76	Reboxetine	Male	23/05/89	21/06/89	30	Screen	22/05/89	0	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 7	31/05/89	9	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 14	07/06/89	16	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 28	21/06/89	30	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
	77	Reboxetine	Female	01/06/89	29/06/89	29	Screen	31/05/89	0	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 7	06/06/89	6	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 14	14/06/89	14	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
							Day 28	26/06/89	26	NOT DONE	ABSENT	ABSENT	ABSENT	NOT DONE
6	81	Reboxetine	Female	24/03/89	24/04/89	32	Screen	20/03/89	0	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	03/04/89	11	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 14	10/04/89	18	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	24/04/89	32	NOT DONE	ABSENT	ABSENT	ABSENT	PRESENT
	82	Reboxetine	Male	24/03/89	24/04/89	32	Screen	20/03/89	0	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	03/04/89	11	NORMAL	ABSENT	ABSENT	ABSENT	PRESENT
							Day 14	10/04/89	18	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	24/04/89	32	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
	83	Placebo	Female	15/05/89	12/06/89	29	Screen	05/05/89	0	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	22/05/89	8	NOT DONE	ABSENT	ABSENT	ABSENT	PRESENT
							Day 14	29/05/89	15	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
							Day 28	12/06/89	29	NOT DONE	ABSENT	ABSENT	ABSENT	ABSENT
7	89	Reboxetine	Female	12/03/89	02/04/89	22	Screen	06/03/89	0	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT
							Day 7	19/03/89	8	NORMAL	ABSENT	ABSENT	ABSENT	ABSENT

(*) days of treatment

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VITAL SIGNS

Centre	Patient	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE lying S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
1	1	Male	Screen	12/11/87	36.50	36		110	70	88	100	60	80
			Day 0	12/11/87	36.80			110	70	86	100	60	80
			Day 4	17/11/87	36.80			150	90	92	120	70	90
			Day 7	20/11/87	36.60			140	80	84	130	70	100
			Day 14	27/11/87	36.50			150	90	90	124	80	96
			Day 21	04/12/87	36.50			140	80	100	120	70	88
			Day 28	11/12/87	36.80			130	80	80	90	60	96
	3	Female	Screen	12/11/87	36.70	32		160	90	90	150	100	94
			Day 0	13/11/87	36.50			150	100	90	140	80	96
			Day 4	17/11/87	36.00			130	70	88	120	70	84
			Day 7	20/11/87	36.00			130	90	88	116	80	92
			Day 14	27/11/87	36.50			130	90	92	100	80	88
			Day 21	04/12/87	36.50			140	90	94	130	80	104
			Day 28	11/12/87	36.40			140	100	90	120	90	88
	4	Male	Screen	08/12/87	36.60	21		120	70	100	110	70	90
			Day 0	08/12/87	36.60			120	70	116	100	70	120
			Day 4	11/12/87	36.80			120	70	84	130	80	102
			Day 7	15/12/87	36.40			110	70	80	100	70	70
			Day 14	22/12/87	36.50			112	60	100	110	80	120
			Day 21	29/12/87	36.50			140	90	90	120	90	102
			Day 28	05/01/88	36.50			110	70	80	106	68	78
	5	Female	Screen	03/02/88	36.80	24	65.40	160	95	100	156	90	94
			Day 0	10/02/88	36.50		65.40	160	100	90	164	90	92
			Day 4	14/02/88	36.40			160	90	100	144	90	102
			Day 7	17/02/88	36.50			140	70	90	150	80	94
			Day 10	24/02/88	36.50		60.90	150	80	96	160	70	102
			Day 14	24/02/88	36.50		60.90	150	80	96	160	70	102
			Day 21	02/03/88	36.50			128	70	92	134	80	80
			Day 28	09/03/88	36.50		59.90	140	80	94	146	80	94
	6	Female	Screen	20/04/88	37.00	22		120	90	92	100	70	84
			Day 0	22/04/88	37.00			120	88	90	100	70	86
			Day 4	26/04/88	36.60			120	80	100	112	70	84
			Day 7	29/04/88	37.00			130	80	110	90	60	96
			Day 14	06/05/88	37.00			110	70	100	100	70	110
			Day 21	13/05/88	36.60			130	80	100	100	70	110
			Day 28	20/05/88	36.50			140	100	110	110	90	100
	7	Male	Screen	25/05/88	36.50	16	73.10	130	70	70	120	70	74
			Day 0	27/05/88	36.50		73.20	160	80	74	150	80	80
			Day 4	30/05/88	36.00			140	70	76	160	70	70

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VITAL SIGNS

Centre	Patient	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE lying S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
1	7	Male	Day 7	03/06/88	36.20			130	80	68	126	80	68
			Day 14	10/06/88	36.50		74.00	120	80	78	130	80	72
			Day 21	17/06/88	36.00			150	80	82	140	70	84
			Day 28	24/07/88	36.50		74.00	130	70	66	140	70	74
	8	Female	Screen	13/07/88	36.80	17	60.00	130	90	86	120	86	84
			Day 0	14/07/88	36.80		60.00	128	88	84	120	86	80
			Day 4	18/07/88	37.00			120	88	80	120	86	84
			Day 7	22/07/88	37.00			120	90	86	116	84	90
			Day 14	29/07/88	36.80		60.50	124	86	90	120	84	86
	9	Male	Screen	04/10/88	37.00	20	61.50	120	80	90	130	70	90
			Day 0	05/10/88	37.00		61.50	140	70	90	140	80	90
			Day 4	09/10/88	37.00			150	90	90	145	85	90
			Day 7	12/10/88	37.00			120	80	90	130	70	90
			Day 14	19/10/88	37.00		62.50	140	65	80	130	65	80
			Day 21	26/10/88	37.00			120	60	70	135	70	80
			Day 28	02/11/88	37.00		59.00	130	80	85	110	70	85
	10	Male	Screen	04/10/88	37.00	18	52.00	150	80	84	146	84	86
			Day 0	06/10/88	37.00		52.00	140	80	84	136	84	84
			Day 4	10/10/88	36.50			150	90	82	146	80	84
			Day 7	13/10/88	37.50			140	90	82	130	86	80
			Day 14	21/10/88	37.00		53.00	130	86	80	120	84	82
			Day 21	28/10/88	36.60			140	80	86	136	84	82
			Day 28	04/11/88	36.80		53.80	130	90	86	120	86	82
	11	Female	Screen	15/11/88	36.00	16	60.40	110	80	84	106	80	88
			Day 0	15/11/88	36.50		60.50	110	80	84	106	82	86
			Day 4	18/11/88	36.80			116	84	86	110	80	84
			Day 7	22/11/88	37.00			120	80	86	110	82	88
			Day 14	29/11/88	36.50		61.20	124	82	104	116	80	106
			Day 21	05/12/88	37.00			118	88	98	110	80	100
			Day 28	12/12/88	36.70		61.30	120	88	98	116	88	100
	12	Male	Screen	17/11/88	36.90	21	70.50	120	80	80	120	84	82
			Day 0	18/11/88	37.00		70.50	128	88	86	120	80	84
			Day 4	22/11/88	36.80			130	90	86	126	84	80
			Day 7	25/11/88	36.90			120	86	84	120	80	82
			Day 14	30/11/88	36.80		69.00	126	86	86	120	84	84
	13	Female	Screen	04/01/89	36.80	22	60.00	130	90	88	120	88	84
			Day 0	06/01/89	37.00		60.00	136	88	84	130	90	82

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VITAL SIGNS

Centre	Patient	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE lying S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
1	13	Female	Day 4	10/01/89	37.00			128	88	90	120	86	96
			Day 7	13/01/89	36.80			120	80	88	120	86	84
			Day 14	20/01/89	36.80		61.00	126	84	90	120	80	88
			Day 21	27/01/89	36.60			130	90	88	126	84	84
			Day 28	03/02/89	36.60		61.50	130	90	90	120	86	84
	14	Female	Screen	11/01/89	36.50	20	44.00	130	90	88	120	88	84
			Day 0	11/01/89	36.80		44.00	130	88	86	120	84	86
			Day 4	16/01/89	37.00			130	80	86	120	82	84
			Day 7	18/01/89	36.70			120	80	86	120	76	84
			Day 14	25/01/89	36.80		44.20	130	90	76	120	84	80
			Day 21	01/02/89	36.80			126	86	84	120	84	82
			Day 28	10/02/89	37.00		44.60	120	80	84	116	82	86
	15	Female	Screen	23/03/89	37.00	16	57.00	164	90	88	160	90	90
			Day 0	27/03/89	36.80		57.00	158	90	90	160	88	92
			Day 4	31/03/89	36.20			150	90	105	135	95	112
			Day 7	03/04/89	36.00			160	100	120	145	90	125
			Day 14	10/04/89	36.00		47.70	164	100	86	170	96	111
			Day 21	17/04/89	36.60			168	100	66	180	110	66
			Day 28	17/04/89	36.60		48.10	168	100	66	180	110	66
	16	Female	Screen	21/04/89	36.50	18	51.00	150	80	90	130	80	92
			Day 0	24/04/89	36.80		51.10	158	80	92	150	90	94
			Day 4	28/04/89	36.00			130	90	92	110	80	94
			Day 7	02/05/89	36.80			120	80	94	130	80	96
			Day 14	08/05/89	36.50		51.50	160	100	82	160	100	92
			Day 21	15/05/89	36.50			140	90	90	148	90	92
			Day 28	22/05/89	36.50		50.80	150	80	96	150	80	90
2	21	Female	Screen	15/02/88	36.70	16	76.50	150	80	82	145	85	86
			Day 0	19/02/88	36.50		76.00	140	85	80	130	80	84
			Day 4	25/02/88	36.80			130	75	86	110	75	90
			Day 7	29/02/88	36.50			150	40	84	125	85	92
			Day 14	07/03/88	36.80		74.00	120	80	86	105	75	92
			Day 21	16/03/88	37.00			115	85	78	105	80	78
			Day 28	23/03/88	36.50		75.00	120	80	82	100	80	86
	22	Female	Screen	29/04/88	36.70	25	57.00	160	85	62	110	75	68
			Day 0	09/05/88	36.50		57.00	150	80	70	105	75	78
			Day 4	13/05/88	36.70			140	90	72	175	100	78
			Day 7	16/05/88	36.50			110	90	12	105	85	80
			Day 14	23/05/88	36.80		56.00	110	85	80	105	80	82
			Day 21	31/05/88	36.70			115	90	72	105	80	84

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VITAL SIGNS

Centre	Patient	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE lying S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
2	22	Female	Day 28	07/06/88	36.50		56.00	120	90	76	110	80	82
	23	Female	Screen	16/12/88	36.60	14	96.00	150	90	74	140	90	80
			Day 0	28/12/88	36.50		96.00	155	85	80	140	90	82
			Day 4	03/01/89	36.50			140	80	74	140	90	76
			Day 7	05/01/89	36.70			140	75	72	140	85	78
	24	Female	Screen	07/02/89	36.80	16	76.00	140	80	84	130	90	88
			Day 0	14/02/89	36.30		76.00	130	85	80	125	85	82
			Day 4	17/02/89	36.60			140	80	76	140	85	74
			Day 7	21/02/89	36.40			140	85	76	130	85	76
			Day 14	01/03/89	36.60		77.00	130	80	78	120	80	80
			Day 21	08/03/89	36.30			125	90	76	115	85	76
			Day 28	15/03/89	36.70		75.00	120	90	74	110	90	78
	25	Female	Screen	13/02/89	36.30	16	68.00	130	75	78	120	80	84
			Day 0	20/02/89	36.40		69.00	140	80	86	130	90	82
			Day 4	24/02/89	36.40			120	85	90	110	80	90
			Day 7	28/02/89	36.70			120	90	82	110	90	86
			Day 14	07/03/89	36.50		68.50	120	85	86	110	80	90
			Day 21	14/03/89	36.40			130	90	82	120	85	82
			Day 28	21/03/89	36.50		67.00	120	90	78	120	95	82
3	26	Female	Screen	14/12/88	36.40	20	71.00	110	70	75	105	70	74
			Day 0	29/12/88	36.20		71.00	110	70	75	105	70	74
			Day 4	01/01/89	36.40			110	80	70	100	80	90
			Day 7	04/01/89	37.80		68.00	110	70	72	100	75	88
			Day 14	11/01/89			68.00	100	70	88	110	80	80
			Day 21	18/01/89	36.50			120	90	88	105	90	90
	27	Female	Screen	13/12/88	36.20	24	73.00	110	70	88	110	75	88
			Day 0	28/12/88	36.00		73.00	110	70	86	110	75	88
			Day 4	30/12/88	37.00			100	70	88	110	90	80
			Day 7	03/01/89	38.00			110	70	90	115	65	94
			Day 10	10/01/89	36.40			100	70	80	110	80	88
			Day 14	10/01/89	36.40		73.00	100	70	80	110	80	88
			Day 21	18/01/89	36.00			105	80	92	100	60	84
			Day 28	26/01/89	36.80		72.00	95	75	92	110	65	84
	28	Male	Screen	12/12/88	36.90	20	78.00	120	80	72	120	80	80
			Day 0	28/12/88	36.90		78.00	120	80	72	120	80	80
			Day 4	30/12/88	37.00			120	75	80	120	80	76
			Day 7	03/01/89	36.80		77.50	120	80	68	120	70	84

REBOXETINE - PROTOCOL 20124/ADE009
Listing No.: 13.0

VITAL SIGNS

Centre	Patient	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE lying S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
3	28	Male	Day 14	10/01/89	36.50		75.00	100	70	74	120	75	80
4	51	Female	Screen	15/04/88	36.00	20	50.80	116	80	80	100	70	70
			Day 0	22/04/88	37.50		55.60	110	70	90	100	70	100
			Day 4	26/04/88	36.50			120	70	84	110	65	86
	52	Female	Screen	01/07/88	36.50	17	68.80	130	80	74	110	80	72
			Day 0	07/07/88	36.50		68.80	110	80	73	110	80	78
			Day 4	11/07/88	36.50			110	90	96	100	90	102
			Day 7	14/07/88	36.70			130	80	85	120	85	92
			Day 14	21/07/88	37.50		71.60	140	90	88	130	90	94
			Day 21	28/07/88	36.50			110	80	78	100	80	72
			Day 28	04/08/88	37.50		71.80	138	90	86	130	86	96
	53	Male	Screen	27/09/88	36.80	13	56.90	180	95	90	180	95	90
			Day 0	29/09/88	36.80		56.80	175	85	90	180	85	93
			Day 4	03/10/88	37.00			150	85	90	150	85	95
			Day 7	06/10/88	36.90			145	85	90	150	85	95
			Day 14	13/10/88	36.90		58.50	150	90	85	140	90	94
	54	Female	Screen	25/11/88	37.00	27	119.00	140	80	92	150	90	96
			Day 0	28/11/88	37.00		119.00	140	80	90	150	90	96
			Day 4	02/12/88	37.00			150	90	96	170	110	108
			Day 7	05/12/88	37.00			140	90	88	150	100	88
			Day 14	12/12/88	37.00		120.00	152	100	100	148	100	108
			Day 21	19/12/88	37.00			152	100	100	148	100	108
			Day 28	23/12/88	37.00		123.00	140	80	84	140	90	96
	55	Male	Screen	19/01/89	37.00	26	76.00	130	70	100	120	70	116
			Day 0	24/01/89	37.00		76.00	130	70	100	120	70	116
			Day 4	27/01/89	37.00			132	70	100	120	70	100
			Day 7	30/01/89	37.00			136	72	150	123	70	100
			Day 14	06/02/89	37.00		79.00	130	80	80	110	80	88
			Day 21	13/02/89	37.00			130	80	80	118	80	88
			Day 28	20/02/89	37.00		76.00	130	80	80	120	80	88
	56	Female	Screen	20/01/89	36.90	17	63.50	122	82	90	110	80	92
			Day 0	23/01/89	36.90		63.50	124	84	90	110	80	92
			Day 4	27/01/89	37.00			110	80	96	96	78	98
			Day 7	30/01/89	36.80			110	84	82	90	82	86
			Day 14	06/02/89	36.40		63.50	112	90	86	92	82	92
			Day 21	13/02/89	37.00			120	80	78	90	80	92
			Day 28	20/02/89	37.00		62.00	122	84	78	110	78	90

REBOXETINE - PROTOCOL 20124/ADE009
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VITAL SIGNS

Centre	Patient	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE lying S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
4	57	Female	Screen	10/03/89	37.00	26	66.00	115	80	110	112	70	116
			Day 0	14/03/89	37.00		69.00	100	60	88	95	70	90
			Day 4	17/03/89	37.00		70.00	110	55	104	100	75	98
			Day 7	20/03/89	37.00			110	55	104	100	75	98
			Day 14	28/03/89	36.50		70.00	130	86	102	110	90	100
			Day 21	05/04/89	37.20		72.00	130	78	98	120	78	100
			Day 28	10/04/89	37.00		72.00	130	72	96	120	78	100
	58	Male	Screen	16/03/89	37.00	20	96.00	120	78	84	115	78	88
			Day 0	20/03/89	37.50		95.00	110	76	78	100	70	74
			Day 4	28/03/89	37.40			140	80	78	120	80	74
			Day 7	28/03/89	37.40			140	80	78	120	80	74
			Day 14	03/04/89	37.00		95.00	130	90	64	110	90	70
	60	Female	Screen	07/03/89	37.00	17	36.70	130	76	82	90	70	98
			Day 0	13/03/89	37.00		36.80	126	84	80	92	74	98
			Day 4	17/03/89	37.00			110	70	88	90	70	90
			Day 7	20/03/89	37.00			100	68	78	110	90	90
			Day 14	28/03/89	36.50		36.30	100	76	92	96	80	88
			Day 21	03/04/89	36.50			100	70	88	90	70	90
			Day 28	10/04/89	37.00		62.00	98	68	70	95	60	70
	61	Female	Screen	02/05/89	36.00	26	80.00	120	80	70	110	70	70
			Day 0	09/05/89	36.20		82.00	124	76	72	112	72	70
			Day 4	12/05/89	37.00			130	78	76	120	76	76
			Day 7	15/05/89	37.50			136	78	78	126	78	78
			Day 14	22/05/89	37.00		80.00	140	78	78	130	76	72
			Day 21	01/06/89	36.50			110	80	72	105	80	100
			Day 28	05/06/89	37.00		81.00	110	60	92	110	62	100
	62	Female	Screen	04/05/89	36.80	18	41.00	120	78	80	115	80	88
			Day 0	09/05/89	37.00		41.00	122	72	82	116	82	88
	63	Female	Screen	09/05/89	37.00	26	80.00	130	70	102	110	70	100
			Day 0	16/05/89	37.00		80.00	128	80	100	120	100	100
			Day 4	19/05/89	37.00			130	80	100	124	100	98
			Day 7	22/05/89	37.00			130	86	96	126	96	100
			Day 14	01/06/89	36.50		80.00	120	80	88	120	85	92
			Day 21	05/06/89				120	80	84	120	85	92
	64	Male	Screen	16/05/89	37.00	22	68.00	120	80	72	110	76	80

REBOXETINE - PROTOCOL 20124/ADE009
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VITAL SIGNS

Centre	Patient	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE lying S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
4	64	Male	Day 0	23/05/89	37.00		70.00	120	76	72	116	78	80
			Day 4	26/05/89	37.00			120	80	72	110	78	80
			Day 7	31/05/89	36.50			120	80	76	110	85	80
			Day 14	05/06/89	37.00		70.00	122	80	80	115	82	88
			Day 21	12/06/89	37.00			124	80	86	118	82	88
			Day 28	19/06/89	37.00		64.00	126	82	86	120	82	88
	65	Male	Screen	18/05/89	37.00	24	70.00	100	80	100	92	65	95
			Day 0	23/05/89	37.00		70.00	100	82	100	98	75	88
			Day 4	26/05/89	37.00			100	82	96	100	78	37
	66	Female	Screen	23/05/89	37.00	20	95.00	120	75	72	115	65	100
			Day 0	31/05/89	37.00		95.00	120	74	72	115	72	76
			Day 4	02/06/89	37.00			118	70	88	120	70	100
			Day 7	05/06/89	37.00			120	72	72	115	65	100
			Day 14	12/06/89	37.00		95.00	122	72	72	120	70	100
			Day 21	19/06/89	37.00			124	72	72	120	70	100
			Day 28	26/06/89	37.00		90.00	120	72	72	120	70	100
	67	Male	Screen	25/05/89	37.00	20	80.00	135	92	77	130	85	96
			Day 0	31/05/89	37.00		80.00	135	90	77	128	96	85
			Day 4	02/06/89	37.00			140	90	96	122	98	112
			Day 7	05/06/89	37.00			140	90	77	142	90	84
			Day 14	12/06/89	37.50		75.00	140	96	96	122	98	100
			Day 21	19/06/89	37.50			145	90	92	145	88	88
			Day 28	26/06/89	37.00		75.00	130	90	94	120	90	104
5	71	Female	Screen	10/05/89	37.20	18	50.00	110	65	74	115	67	87
			Day 0	15/05/89	37.00		50.00	112	68	74	118	68	86
			Day 4	18/05/89	37.10			113	66	72	118	68	84
	72	Female	Screen	10/05/89	37.10	20	73.00	131	90	90	125	95	95
			Day 0	11/05/89	37.10		73.00	132	92	90	125	96	94
			Day 4	15/05/89	37.00			134	89	86	125	92	90
			Day 21	01/06/89	37.10			134	84	84	124	89	90
			Day 28	09/06/89	37.10		73.00	132	88	84	125	92	90
	73	Male	Screen	22/05/89	37.50	20	72.00	123	80	71	126	90	92
			Day 0	23/05/89	37.50		72.00	128	80	72	124	90	88
			Day 4	25/05/89	37.50			125	82	72	120	91	90
			Day 14	07/06/89	37.50		72.00	125	82	74	127	90	92
			Day 21	14/06/89	37.50			124	78	74	128	92	90
			Day 28	21/06/89	37.50		73.00	126	80	96	124	82	90

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VITAL SIGNS

Centre	Patient	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE lying S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
5	74	Male	Screen	22/05/89	37.50	19	71.00	147	86	74	132	96	88
			Day 0	23/05/89	37.50		71.00	146	84	74	130	92	94
			Day 7	31/05/89	37.50			146	85	76	130	88	92
			Day 14	07/06/89	37.50		71.00	150	86	72	140	92	98
			Day 21	14/06/89	37.50			148	85	72	138	86	90
			Day 28	21/06/89	37.50		72.00	150	84	76	138	86	90
	75	Female	Screen	22/05/89	37.10	20	57.00	180	95	90	148	100	104
			Day 0	23/05/89	37.00		57.00	184	94	92	150	100	102
			Day 4	25/05/89	37.00			182	94	92	146	98	100
			Day 7	31/05/89	37.00			186	94	92	149	98	100
			Day 10	07/06/89	37.10		57.00	186	96	92	152	98	96
			Day 21	14/06/89	37.10			184	96	92	150	98	94
			Day 28	21/06/89	37.10		56.00	190	96	92	154	100	104
	76	Male	Screen	22/05/89	37.50	18	71.00	139	84	65	133	92	78
			Day 0	23/05/89	37.50		71.00	138	86	68	134	91	77
			Day 4	25/05/89	37.50			140	86	68	132	90	76
			Day 7	31/05/89	37.50			142	86	70	134	90	80
			Day 14	07/06/89	37.50		71.00	142	86	70	134	90	78
			Day 21	14/06/89	37.50			142	86	72	135	90	79
			Day 28	21/06/89	37.50		72.00	142	84	68	132	92	78
	77	Female	Screen	31/05/89	37.50	20	67.00	170	89	68	156	90	78
			Day 0	01/06/89	37.50		67.00	168	89	70	154	90	78
			Day 4	04/06/89	37.50			167	89	70	152	94	78
			Day 7	06/06/89	37.50			172	92	72	160	96	76
			Day 14	14/06/89	37.00		67.00	166	88	70	152	90	76
			Day 21	22/06/89	37.00			170	88	72	156	92	80
			Day 28	26/06/89	37.00		67.00	170	90	70	156	93	80
6	81	Female	Screen	20/03/89	37.00	15	69.00	125	85	84	135	100	96
			Day 0	27/03/89	37.10		71.00	115	90	104	125	100	131
			Day 4	31/03/89	37.10			110	80	88	105	85	106
			Day 7	03/04/89	37.10			130	95	78	110	85	107
			Day 14	10/04/89	36.80		71.00	100	80	72	105	80	76
			Day 21	17/04/89	36.40			105	85	96	115	90	116
			Day 28	24/04/89	36.50		69.00	110	85	90	110	90	120
	82	Male	Screen	20/03/89	36.00	19	64.00	125	90	84	120	90	84
			Day 0	27/03/89	36.40		66.00	120	80	86	130	90	94
			Day 4	31/03/89	36.60			125	80	90	130	90	96

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VITAL SIGNS

Centre	Patient	Sex	Visit	Date	Body Temperature (C)	Respiratory Rate (breaths/min)	Body Weight (Kg)	BLOOD PRESSURE AND HEART RATE lying S.B.P. (mmHg)	lying D.B.P. (mmHg)	lying Heart Rate (beats/min)	standing S.B.P. (mmHg)	standing D.B.P. (mmHg)	standing Heart Rate (beats/min)
6	82	Male	Day 7	03/04/89	35.40			145	95	84	135	90	82
			Day 14	10/04/89	36.20		66.00	100	70	76	100	60	84
			Day 21	17/04/89	36.60			120	85	88	125	95	92
			Day 28	24/04/89	36.20		66.00	140	95	84	135	100	96
	83	Female	Screen	05/05/89	35.00	9	49.00	145	90	84	140	90	90
			Day 0	15/05/89	35.10		49.00	120	65	64	110	80	80
			Day 4	18/05/89	36.60			115	80	66	110	85	96
			Day 7	22/05/89	36.20			130	80	56	135	70	84
			Day 14	29/05/89	35.80		45.00	115	70	68	105	70	96
			Day 21	05/06/89	35.60			125	85	92	110	80	102
			Day 28	12/06/89	36.60		47.00	120	70	112	130	85	120
7	89	Female	Screen	06/03/89	36.50	14	66.10	140	80	100	140	90	76
			Day 0	12/03/89	36.80		66.10	155	80	64	130	90	68
			Day 4	16/03/89	37.20			145	80	68	145	80	73
			Day 7	19/03/89	36.50			130	82	64	128	80	73
			Day 14	26/03/89	37.00		68.50	130	80	62	126	78	70

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ECG

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	E.C.G. Value	E.C.G. Abnormality
1	1	Placebo	Male	14/11/87	11/12/87	Screen	Normal	
	3	Reboxetine	Female	14/11/87	11/12/87	Screen	Normal	
	4	Reboxetine	Male	09/12/87	05/01/88	Screen	Normal	
	5	Placebo	Female	11/02/88	09/03/88	Screen	Normal	
	6	Reboxetine	Female	23/04/88	20/05/88	Screen	Normal	
	7	Placebo	Male	28/05/88	24/06/88	Screen	Normal	
	8	Reboxetine	Female	15/07/88	12/08/88	Screen	Normal	
	9	Placebo	Male	06/10/88	02/11/88	Screen	Normal	
	10	Placebo	Male	07/10/88	04/11/88	Screen	Normal	
	11	Reboxetine	Female	15/11/88	12/12/88	Screen	Normal	
	12	Reboxetine	Male	18/11/88	30/11/88	Screen	Normal	
	13	Reboxetine	Female	07/01/89	05/02/89	Screen	Normal	
	14	Placebo	Female	12/01/89	10/02/89	Screen	Normal	
	15	Placebo	Female	28/03/89	17/04/89			
	16	Reboxetine	Female	24/04/89	22/05/89	Screen	Normal	
2	21	Reboxetine	Female	20/02/88	24/03/88	Screen	Normal	
	22	Placebo	Female	10/05/88	07/06/88	Screen	Normal	

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ECG

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	E.C.G. Value	E.C.G. Abnormality
2	23	Placebo	Female	29/12/88	06/01/89	Screen	Normal	
	24	Reboxetine	Female	15/02/89	14/03/89	Screen	Normal	
	25	Reboxetine	Female	21/02/89	21/03/89	Screen	Normal	
3	26	Reboxetine	Female	29/12/88	17/01/89	Screen	Normal	
	27	Placebo	Female	28/12/88	25/01/89	Screen	Normal	
	28	Placebo	Male	28/12/88	12/01/89	Screen	Normal	
4	51	Placebo	Female	22/04/88	02/05/88	Screen	Normal	
	52	Placebo	Female	08/07/88	04/08/88	Screen	Normal	
	53	Reboxetine	Male	30/09/88	20/10/88	Screen	Normal	
	54	Placebo	Female	29/11/88	26/12/88	Screen	Normal	
	55	Placebo	Male	23/01/89	20/02/89	Screen	Normal	
						Day 14	Abnormal	LEFT AXIAL DEVIATION
	56	Reboxetine	Female	24/01/89	22/02/89	Screen	Abnormal	Not relevant
	57	Placebo	Female	15/03/89	10/04/89	Screen	Normal	
	58	Reboxetine	Male	21/03/89	03/04/89	Screen	Normal	
	60	Placebo	Female	14/03/89	10/04/89	Screen	Normal	
						Day 28	Normal	
	61	Placebo	Female	09/05/89	05/06/89	Screen	Normal	

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ECG

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	E.C.G. Value	E.C.G. Abnormality
4	61	Placebo	Female	09/05/89	05/06/89	Day 28	Normal	
	62	Placebo	Female	09/05/89	11/05/89	Screen	Normal	
	63	Reboxetine	Female	16/05/89	11/06/89	Screen	Normal	
	64	Reboxetine	Male	23/05/89	19/06/89	Screen	Normal	
						Day 28	Normal	
	65	Placebo	Male	23/05/89	28/05/89	Screen	Normal	
						Day 28	Abnormal	RIPOLARIZATION DISTURBANCES
	66	Reboxetine	Female	30/05/89	26/06/89	Screen	Normal	
						Day 28	Normal	
	67	Reboxetine	Male	30/05/89	28/06/89	Screen	Normal	
5	71	Reboxetine	Female	15/05/89	12/06/89	Screen	Normal	
						Day 28	Normal	
	72	Placebo	Female	11/05/89	08/06/89	Screen	Normal	
						Day 28	Normal	
	73	Reboxetine	Male	23/05/89	21/06/89	Screen	Normal	
						Day 28	Abnormal	RIPOLARIZATION DISTURBANCES
								OTHER
	74	Placebo	Male	23/05/89	21/06/89	Screen	Normal	
						Day 28	Abnormal	RIPOLARIZATION DISTURBANCES
	75	Placebo	Female	23/05/89	21/06/89	Screen	Normal	
	76	Reboxetine	Male	23/05/89	21/06/89	Screen	Normal	
						Day 28	Normal	
	77	Reboxetine	Female	01/06/89	29/06/89	Screen	Normal	
						Day 28	Normal	

REBOXETINE - PROTOCOL 20124/ADE009
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ECG

Centre	Patient	Treatment	Sex	Treatment period Start date	Treatment period End date	E.C.G. Visit	E.C.G. Value	E.C.G. Abnormality
6	81	Reboxetine	Female	24/03/89	24/04/89	Screen	Normal	
						Day 28	Normal	
	82	Reboxetine	Male	24/03/89	24/04/89	Screen	Normal	
						Day 28	Abnormal	MYOCARDIAL ISCHEMIA LEFT ANTERIOR HEMIBLOCK
	83	Placebo	Female	15/05/89	12/06/89	Screen	Normal	
7	89	Reboxetine	Female	12/03/89	02/04/89	Screen	Normal	
						Day 28	Abnormal	LEFT VENTRICULAR HYPERTROPHY

12.2.2 CASE REPORT FORMS

Individual Patient CRFs are filed in the Study Master File.