IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0711/161/001
Case No: 2053160

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Rowex Ltd

Bantry, **Co. Cork**, **Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Vedixal 25 mg Tablets

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **22/08/2008** until **22/06/2011**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vedixal 25 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablets contains 25 mg of Venlafaxine (as hydrochloride)

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Tablet.
A pale red-brown or brownish, oblong tablet, coded 2

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Vedixal is indicated for the treatment of depressive illness in both hospitalised patients and outpatients, including depression accompanied by anxiety.

Following an initial response Vedixal is indicated for the prevention of relapses of the initial episode of depression or for the prevention of the recurrence of new episodes

4.2 Posology and method of administration

Treatment with Venlafaxine should not be started until 14 days after discontinuing a monoamine oxidase inhibitor (MAOI).

Depression:

For initiation and maintenance the recommended dose for depressive illness for Venlafaxine is 75mg. If, after several weeks, further clinical improvement is required, the dose may be increased to 150mg per day given in two divided doses (75mg twice daily).

If, in the judgment of the physician, a higher dose is required, for example in more severely depressed or hospitalised patients, a starting dose of 150mg per day may be given in two divided doses (75mg twice daily). The daily dose may then be increased by up to 75mg every two or three days until the desired response is achieved. The maximum recommended dose is 375mg per day. The dose should then be gradually reduced to the usual dosage, consistent with patient response and tolerance.

Usually, the dosage for prevention of relapse or for prevention of recurrence of a new episode is similar to that used during the index episode. Patients should be re-assessed regularly in order to evaluate the benefit of long-term therapy.

It is recommended that Vedixal be taken with food.

Patients with Renal or Hepatic Impairment:

For patients with mild renal impairment (GFR >30ml/minute) or mild hepatic impairment (PT <14 seconds), no change in dosage is necessary.

For patients with moderate renal impairment (GFR 10-30ml/minute) or moderate hepatic impairment, the dose should be reduced by 50%. For patients requiring a lower daily dose than 75mg, treatment may be provided with Venlafaxine tablets.

Insufficient data are available to support the use of Venlafaxine in patients with severe renal impairment (GFR <10ml/minute) or severe hepatic impairment.

Elderly Patients:

No adjustment from the usual dosage is recommended for elderly patients. However, as with any therapy, caution should be exercised in treating the elderly (e.g. due to the possibility of renal impairment. See also dosage recommendations for renal impairment). The lowest effective dose should always be used and patients should be carefully monitored when an increase in the dose is required.

Children/Adolescents:

Controlled clinical studies in children and adolescents with major Depressive Disorder failed to demonstrate efficacy and do not support the use of Venlafaxine in these patients (see sections 4.3 Contra-indications and 4.8 Undesirable Effects).

The efficacy and safety of Venlafaxine for other indications in children and adolescents under the age of 18 have not yet been established.

Maintenance/Continuation/Extended Treatment:

The physician should periodically re-evaluate the usefulness of long-term treatment with Venlafaxine for the individual patient.

It is generally agreed that acute episodes of major depression require several months or longer of sustained pharmacological therapy. Venlafaxine has been shown to be efficacious during long-term treatment (up to 12 months in depressive illness).

In clinical trials venlafaxine was demonstrated to be effective for preventing relapse, or recurrence of new episodes, in patients responding to venlafaxine treatment during the index episode.

Discontinuing Venlafaxine:

Discontinuation effects are well known to occur with the abrupt withdrawal of other antidepressants (see section 4.8 Undesirable effects). Following treatment with daily doses of venlafaxine greater than 75mg for more than one week, it is recommended that when discontinuing treatment the dose should be gradually reduced over at least a further week. If high doses have been used for more than 6 weeks tapering over at least a 2 week period is recommended.

The period required for discontinuation may depend on the dose, duration of therapy and the individual

4.3 Contraindications

Known hypersensitivity to venlafaxine or any other component of the product.

Concomitant use of venlafaxine with monoamine oxidase inhibitors (*See Interactions with other Medicaments and Other Forms of Interactions*).

Venlafaxine should not be used in children and adolescents under the age of 18 years with Major Depressive Disorder (see section 4.8 Undesirable Effects).

4.4 Special warnings and precautions for use

Venlafaxine should not be used in the treatment of children and adolescents under the age of 18 years. Suicide-related behaviours (suicide attempt and suicidal thoughts) and hostility (predominantly aggression, oppositional behaviour, and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with placebo. If, based on clinical need, a decision to treat is nevertheless taken, the patient should be carefully monitored for the appearance of suicidal symptoms. In addition, long-term safety data in children and adolescents concerning growth, maturation, and cognitive and behavioural development are lacking.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

1. **Suicide/suicidal thoughts or clinical worsening**

   Depression is associated with an increased risk of suicidal thoughts, self harm and suicide. This risk persists until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs. It is general clinical experience with all antidepressant therapies that the risk of suicide may increase in the early stages of recovery.

   Other psychiatric conditions for which venlafaxine is prescribed can also be associated with an increased risk of suicidal behaviour. In addition, these conditions may be co-morbid with major depressive disorder. The same precautions observed when treating patients with major depressive disorder should therefore be observed when treating patients with other psychiatric disorders.

   Patients with a history of suicidal behaviour or thoughts, or those exhibiting a significant degree of suicidal ideation prior to commencement of treatment, are at a greater risk of suicidal thoughts or suicide attempts, and should receive careful monitoring during treatment. A meta analysis of placebo controlled clinical trials of antidepressant drugs in adult patients with psychiatric disorders showed an increased risk of suicidal behaviour with antidepressants compared to placebo in patients less than 25 years old (see also section 5.1).

   Close supervision of patients and in particular those at high risk should accompany drug therapy especially in early treatment and following dose changes. Patients, (and caregivers of patients) should be alerted about the need to monitor for the emergence of suicidal ideation/behaviour or thoughts of harming themselves and to seek medical advice immediately if these symptoms present.

   The smallest quantity of tablets should be prescribed initially to reduce the possibility of overdose.

2. Activation of mania or hypomania has been reported rarely in patients who have received antidepressants, including venlafaxine. As with all antidepressants, Venlafaxine should be used with caution in patients with a history of mania.

3. Venlafaxine has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Therefore, it should be used with caution in these patients. Clinically significant electrocardiogram findings were observed in 1% of venlafaxine-treated patients compared with 0.2% of placebo-treated patients. Clinically significant changes in PR, QRS or QTc intervals were rarely observed in patients treated with venlafaxine during clinical trials.

4. Venlafaxine should be introduced with caution in patients with a history of seizure and should be discontinued in any patient developing a seizure.

5. Dose-related increases in blood pressure have been reported particularly in patients receiving daily doses greater than 200mg. Measurement of blood pressure is therefore recommended for patients receiving venlafaxine. The presence of treated hypertension or elevated blood pressure at baseline did not seem to predispose patients to further increases during venlafaxine therapy.

6. Due to the possibility of drug abuse with CNS-active drugs, physicians should evaluate patients for a history of drug abuse, and follow such patients closely. Clinical studies have shown no evidence of drug-seeking behaviour, development of tolerance, or dose escalation over time among patients taking venlafaxine.

7. Increases in heart rate can occur, particularly at high doses. In clinical trials the mean heart rate was increased by approximately 4 beats/minute in patients treated with venlafaxine. Caution should be exercised in patients whose underlying conditions might be compromised by increases in heart rate.

8. Dosage should be reduced in patients with moderate-severe renal impairment or hepatic cirrhosis (see sections 4.2 and 4.5).

9. Postural hypotension has been observed occasionally during venlafaxine treatment. Patients, especially the elderly, should be alerted to the possibility of dizziness or unsteadiness.

10. Hyponatraemia (usually in the elderly and possibly due to inappropriate secretion of antidiuretic hormone) has been associated with all types of antidepressants and should be considered in all patients who develop drowsiness, confusion or convulsions while taking an antidepressant.

11. Mydriasis has been reported in association with venlafaxine; therefore patients with raised intra-ocular pressure or at a risk of narrow angle glaucoma should be monitored closely.

12. There have been reports of cutaneous bleeding abnormalities, such as ecchymosis and purpura, with serotonin-reuptake inhibitors (SSRIs). Other bleeding manifestations (e.g. gastrointestinal bleeding and mucous membrane bleeding) have been reported. Caution is advised in patients predisposed to bleeding due to factors such as age, underlying medical conditions or concomitant medications.

13. Clinically relevant increases in serum cholesterol were recorded in 5.3% of venlafaxine-treated patients and 0.0% of placebo-treated patients treated for at least 3 months in placebo-controlled trials. Measurement of serum cholesterol levels should be considered during long-term treatment.

14. The safety and efficacy of venlafaxine therapy in combination with weight loss agents, including phentermine, have not been established. Co-administration of venlafaxine hydrochloride and weight loss agents is not recommended. Venlafaxine hydrochloride is not indicated for weight loss alone or in combination with other products.

15. As with SSRIs, venlafaxine should be used with caution in patients already receiving neuroleptics, since symptoms suggestive of Neuroleptic Malignant Syndrome cases have been reported with this combination.

16. **Withdrawal effects** are well known to occur with antidepressants, and it is therefore recommended that the dosage of either formulation of venlafaxine be tapered gradually and the patient monitored (see section 4.2 and 4.8).

4.5 Interaction with other medicinal products and other forms of interaction

MAOIs: Adverse reactions, some serious, have been reported when venlafaxine therapy is initiated soon after discontinuation of an MAOI, and when an MAOI is initiated soon after discontinuation of venlafaxine. These reactions have included tremor, myoclonus, diaphoresis, nausea, vomiting, flushing, dizziness and hyperthermia with features resembling neuroleptic malignant syndrome, seizures and death. Do not use Venlafaxine in combination with an MAOI, or within at least 14 days of discontinuing MAOI treatment. Allow at least 7 days after stopping Venlafaxine before starting an MAOI (see also Contra-indications).

Serotonergic drugs: Based on the known mechanism of action of venlafaxine and the potential for serotonergic syndrome, caution is advised when venlafaxine is co-administered with drugs that may affect the serotonergic neurotransmitter systems (such as triptans, SSRIs or lithium).

Lithium:
Venlafaxine had no effect on the pharmacokinetics of lithium.

Imipramine/desipramine: The metabolism of imipramine and its metabolite 2-OH-imipramine were unaffected by venlafaxine although the total renal clearance of 2-hydroxydesipramine was reduced and desipramine AUC and C_{max} were increased by approximately 35%.

Haloperidol: In a pharmacokinetic study co-administration of venlafaxine with a single 2mg oral dose of haloperidol resulted in a 42% decrease in renal clearance, a 70% increase in AUC and an 88% increase in C_{max} for haloperidol. The elimination half-life remained unchanged.

Diazepam: The pharmacokinetic profiles of venlafaxine and ODV were not significantly altered by the administration of diazepam. Venlafaxine has no effect on the pharmacokinetic profile of diazepam or on the psychomotor or psychometric effects induced by diazepam.

Clozapine: Increased levels of clozapine, that were temporally associated with adverse events, including seizures, have been reported following the addition of venlafaxine.

Alcohol: Venlafaxine has been shown not to increase the impairment of mental or motor skills caused by ethanol. However, as with all CNS-active drugs, patients should be advised to avoid alcohol consumption while taking Venlafaxine.

ECT: There is little clinical experience of the concurrent use of venlafaxine with ECT. As prolonged seizure activity has been reported with concomitant SSRI antidepressants, caution is advised.

Drugs metabolised by Cytochrome P450 isoenzymes: Venlafaxine is primarily metabolised to its equally active metabolite, ODV, by the cytochrome P450 enzyme CYP2D6.

However, unlike many other antidepressants, no dosage adjustment is necessary when Venlafaxineis administered concomitantly with drugs that inhibit CYP2D6, or when used in patients who are poor CYP2D6 metabolisers, since the total concentration of active compound (venlafaxine and ODV) is not affected.

The major elimination pathways for venlafaxine are through CYP2D6 and CYP3A4. Therefore, caution should be used with concomitant intake of drugs which inhibit both of these enzymes. Such interactions have not been studied to date.

Studies indicate that venlafaxine is a relatively weak inhibitor of CYP2D6.Venlafaxine did not inhibit CYP1A2, CYP2C9 or CYP3A4. This was confirmed by in vivo studies with the following drugs: alprazolam (CYP3A4), caffeine (CYP1A2), carbamazepine (CYP3A4) and diazepam (CYP3A4 and CYP2CI9).

Cimetidine: Cimetidine inhibited the first-pass metabolism of venlafaxine but had no significant effect on the formation or elimination of ODV, which is present in much greater quantities in the systemic circulation. No dosage adjustment therefore seems necessary when Venlafaxine is co-administered with cimetidine. For elderly patients, or patients with hepatic dysfunction the interaction could potentially be more pronounced, and for such patients clinical monitoring is indicated when Venlafaxine is administered with cimetidine.

Warfarin: Potentiation of anticoagulant effects including increases in PT or INR have been reported in patients taking warfarin following the addition of venlafaxine.

Indinavir: A pharmacokinetic study with indinavir has shown a 28% decrease in AUC and a 36% decrease in C_{max} for indinavir. Indinavir did not affect the pharmacokinetics of venlafaxine and ODV. The clinical significance of this interaction is not known.

4.6 Pregnancy and lactation

There are no adequate data from the use of venlafaxine in pregnant women. Animal studies are insufficient with respect to effects on pregnancy. The potential risk for humans is unknown. Venlafaxine should not be used during pregnancy unless clearly necessary. If venlafaxine is used until or shortly before birth, discontinuation effects in the newborn should be considered. Neonates exposed to venlafaxine late in the third trimester have developed complications requiring respiratory support or prolonged hospitalisation.

There is evidence to suggest that venlafaxine and its metabolite, ODV, transfers into breast milk. Therefore a decision should be made whether or not to breast-feed or to discontinue venlafaxine.

4.7 Effects on ability to drive and use machines

Although venlafaxine has been shown not to affect psychomotor, cognitive, or complex behaviour performance in healthy volunteers, any psychoactive drug may impair judgment, thinking or motor skills.

Therefore patients should be cautioned about their ability to drive a car or operate hazardous machinery.

4.8 Undesirable effects

See also Special Warnings and Special Precautions for Use.

The most commonly observed adverse events associated with the use of venlafaxine in clinical trials, and which occurred more frequently than those which were associated with placebo were: nausea, insomnia, dry mouth, somnolence, dizziness, constipation, sweating, nervousness, asthenia and abnormal ejaculation/orgasm.

The occurrence of most of these adverse events was dose-related, and the majority of them decreased in intensity and frequency over time. They generally did not lead to cessation of treatment.

Adverse events observed with venlafaxine, both spontaneous and clinical trials reports, are classified in body systems and listed below as very common (>1/10); common (<1/10 and >1/100); uncommon (<1/100 and >1/1000); rare (<1/1000); Very rare (>1/10,000):

Blood and lymphatic system disorders - Uncommon: ecchymosis, mucous membrane bleeding; Rare: prolonged bleeding time, haemorrhage, thrombocytopenia; Very rare: blood dyscrasias (including agranulocytosis, aplastic anaemia, neutropenia and pancytopenia.

Cardiovascular and vascular disorders (*see Special Warnings and Special Precautions for Use*) - Common: hypertension, palpitation, vasodilatation; Uncommon: hypotension/postural hypotension, syncope, arrhythmias (including tachycardia); Very rare: Torsade de Pointes, QT prolongation, ventricular tachycardia, ventricular fibrillation.

Gastrointestinal disorders - Very common: constipation, nausea *(see below);* Common: anorexia, appetite decreased, diarrhoea, dyspepsia, vomiting; Uncommon: bruxism; Rare: gastrointestinal bleeding; Very rare: pancreatitis.

General disorders - Very common: asthenia, headache; Common: abdominal pain, chills, pyrexia; Very rare: anaphylaxis.

Metabolic and nutritional disorders - Common: serum cholesterol increased (particularly with prolonged administration and possibly with higher doses; see Special warnings and special precautions for use), weight gain or loss; Uncommon: hyponatraemia including SIADH (*see Special Warnings and Special Precautions for Use*), increased liver enzymes *(see below);* Rare: hepatitis; Very rare: prolactin increased.

Musculo-skeletal disorders - Common: arthralgia, myalgia; Uncommon: muscle spasm; Very rare: rhabdomyolysis.

Neurological disorders - Very common: dizziness, dry mouth, insomnia, nervousness, somnolence; Common: abnormal dreams, agitation, anxiety, confusion, hypertonia, paraesthesia, tremor; Uncommon: apathy, hallucinations, myoclonus;

Rare: ataxia and disorders of balance and coordination, speech disorders including dysarthria, mania or hypomania *(see Special Warnings and Special Precautions for Use)*, neuroleptic malignant syndrome-like effects, seizures *(see Special Warnings and Special Precautions for Use)*, serotonergic syndrome; Very rare: delirium, extrapyramidal disorders including dyskinesia and dystonia, tardive dyskinesia.

Psychiatric disorder:
Cases of suicidal ideation and suicidal behaviours have been reported during venlafaxine therapy or early after treatment discontinuation (see section 4.4).

Renal and urinary disorders - Common: urinary frequency; Uncommon: urinary retention.

Reproductive and breast disorders - Very common: abnormal ejaculation/orgasm; Common: anorgasmia, erectile dysfuntion, decreased libido, impotence, menstrual cycle disorders; Uncommon: menorrhagia; Rare: galactorrhoea.

Respiratory system disorders - Common: dyspnoea, yawning; Very rare: pulmonary eosinophilia.

Skin and subcutaneous tissue disorders -Very common: sweating (including night sweats); Common: pruritus, rash; Uncommon: angioedema, maculopapular eruptions, urticaria, photosensitivity reactions, alopecia; Rare: erythema multiforme, Stevens Johnson syndrome.

Special senses - Common: abnormal vision/ accommodation, mydriasis, tinnitus; Uncommon: altered taste sensation.

Adverse events from paediatric clinical trials:
In paediatric Major Depressive Disorder clinical trials the following adverse events were reported at a frequency of at least 2% of patients and occurred at a rate of at least twice that of placebo: abdominal pain, chest pain, tachycardia, anorexia, weight loss, constipation, dyspepsia, nausea, ecchymosis, epistaxis, mydriasis, myalgia, dizziness, emotional liability, tremor, hostility and suicidal ideation.

Special Notes:
Nausea is most common at the start of treatment with the incidence decreasing over the first few weeks. The nausea experienced with Venlafaxine is usually mild to moderate, and infrequently results in vomiting or withdrawal. The incidence increases with higher doses particularly when the dose is increased rapidly. In clinical studies the incidence of nausea was lower, and the adaptation to nausea appeared to be improved, with Venlafaxine compared with Venlafaxine Tablets.

Reversible increases in liver enzymes are seen in a small number of patients treated with venlafaxine. These generally resolve on discontinuation of therapy.

Withdrawal reactions reported on abrupt cessation, dose reduction or tapering of venlafaxine include fatigue, somnolence, headache, nausea or vomiting, loss of appetite, dizziness, light-headedness, anorexia, dry mouth, diarrhoea, insomnia, nightmares, nervousness, agitation, anxiety, confusion, hypomania, weakness, decreased co-ordination, tinnitus, tremor, convulsions, paraesthesia, sweating and vertigo. The majority of symptoms experienced on withdrawal of Venlafaxine are non-serious and self-limiting (see also Posology and method of administration). Although withdrawal reactions may occur on stopping therapy, the available preclinical and clinical evidence does not suggest that Selective Serotonin Reuptake Inhibitors (SSRI's) cause depedence. A gradual dose reduction when stopping treatment is recommended.

4.9 Overdose

Electrocardiogram changes (e.g. prolongation of QT interval, bundle branch block, QRS prolongation), sinus and ventricular tachycardia, bradycardia, seizures, hypotension, vertigo and changes in level of consciousness have been reported in association with overdosage of venlafaxine usually when in combination with alcohol and/or other CNS drugs.

There have been reports of fatalities in patients taking overdoses of Venlafaxine, predominantly in combination with alcohol and/or other CNS drugs.

Management of Overdose - Ensure an adequate airway, oxygenation and ventilation. Monitoring of cardiac rhythm and vital signs is recommended, as are general supportive and symptomatic measures. Use of activated charcoal or gastric lavage should be considered. Induction of emesis is not recommended. No specific antidotes for venlafaxine are known.

The haemodialysis clearance of venlafaxine and its main active metabolite are low, therefore, they are not considered dialysable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antidepressant; other depressants. ATC Code: NO6A X16

Venlafaxine is a structurally novel antidepressant which is chemically unrelated to tricyclic, tetracyclic, or other available antidepressant agents. It is a racemate with two active enantiomers.

The mechanism of Venlafaxines antidepressant action in humans is believed to be associated with its potentiation of neurotransmitter activity in the central nervous system. Preclinical studies have shown that venlafaxine and its major metabolite, O-desmethylvenlafaxine, are potent neuronal serotonin and noradrenaline re-uptake inhibitors (SNRI) and weak inhibitors of dopamine reuptake. In addition, venlafaxine and O-desmethylvenlafaxine reduce b-adrenergic responsiveness in animals after both acute (single dose) and chronic administration. Venlafaxine and its major metabolite appear to be equipotent with respect to their overall action on neurotransmitter re-uptake.

Venlafaxine has virtually no affinity for rat brain muscarinic, histaminergic or adrenergic receptors *in vitro*. Pharmacologic activity at these receptors may be related to various side effects seen with other antidepressant drugs, such as anticholinergic, sedative and cardiovascular effects

5.2 Pharmacokinetic properties

Venlafaxine is well absorbed and undergoes extensive first-pass metabolism. Mean peak plasma concentrations of venlafaxine range from approximately 33 to 172ng/ml after 25 to 150mg single doses, and are reached in approximately 2.4 hours. Venlafaxine is extensively metabolised in the liver. O-desmethylvenlafaxine is the major active metabolite of venlafaxine. The mean disposition half-life of venlafaxine and O-desmethylvenlafaxine is approximately 5 and 11 hours, respectively. Mean peak O-desmethyl -venlafaxine plasma concentrations range from approximately 61 to 325ng/ml and are reached in approximately 4.3 hours. Plasma concentrations of venlafaxine and O-desmethylvenlafaxine generally correlated well with dose levels. Venlafaxine and O-desmethylvenlafaxine are 27% and 30% bound to plasma proteins respectively. O-desmethylvenlafaxine, other minor venlafaxine metabolites, and non-metabolised venlafaxine are excreted primarily through the kidneys.

5.3 Preclinical safety data

The oral LD_{50} of venlafaxine in mice was 405mg/kg in female rats and 673mg/kg in male rats. These values are equivalent to 45-90 times the maximum recommended human dose.

Studies with venlafaxine in rats and mice revealed no evidence of carcinogenesis. Venlafaxine was not mutagenic in a wide range of *in-vitro* and *in-vivo* tests.

Reduced fertility was observed in a study in which both male and female rats were exposed to the major metabolite of venlafaxine (ODV). This exposure was approximately 2 to 3 times that of a human dose of 225mg/day.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Brown ferric oxide (E172)
Microcrystalline cellulose
Sodium starch glycolate (type A)
Colloidal anhydrous silica
Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

30 months

6.4 Special precautions for storage

This medicinal product does not require any special precautions for storage

6.5 Nature and contents of container

PVC/aluminium foil blisters (pack size of 28)

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7 MARKETING AUTHORISATION HOLDER

Rowex Ltd
Newtown
Bantry
Co. Cork

8 MARKETING AUTHORISATION NUMBER

PA 711/161/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 23rd June 2006

10 DATE OF REVISION OF THE TEXT

August 2008