Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zolnod 10 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 10 mg of zolpidem tartrate.

Excipients with known effect:
Each film-coated tablet contains 54 mg of lactose (as monohydrate) .

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

White, shining film-coated tablets, oblong, biconvex, (10.2 mm x 2.8 mm), with a score line on one side.
The tablet can be divided into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Zolpidem is indicated for short-term treatment of insomnia in adults. Treatment is indicated only when the disorder is severe, disabling or subjecting the individual to extreme distress.

4.2 Posology and method of administration

The duration of treatment should be as short as possible. It should not exceed 4 weeks, including the gradual discontinuation phase.
In certain cases treatment beyond this period may be necessary; if so, it should not take place without re-evaluation of the patient's condition, as the risk of abuse and dependency increases with the duration of the treatment (see section 4.4).

Posology

Adults
The treatment should be taken in a single intake and not be re-administered during the same night.
The recommended daily dose for adultsis 10 mg to be taken immediately at bedtime. The lowest effective daily dose of zolpidem should be used andmust not exceed 10 mg.

Elderly and debilitated patients

In elderly or debilitated patients who may be especially sensitive to the effects of zolpidem a daily dose of 5 mg is recommended (1/2 tablet).
This dose should only be increased to 10 mg where the clinical response is inadequate and the medicinal product is well tolerated.

Hepatic impairment
Due to reduced clearance and delayed metabolism the dose in patients with impaired liver function should only be 5 mg zolpidem tartrate (see section 4.3). Special care should be taken with elderly patients.
Severe hepatic impairment is a contraindication (see section 4.3).

Chronic respiratory impairment

A lower dose is recommended for patients with chronic respiratory impairment due to the risk of respiratory depression (see section 4.4).

Paediatric population
Zolpidem is not recommended for use in children and adolescents below 18 years of age, due to insufficient data to support use in this age group. The available evidence from placebo-controlled clinical trials is presented in section 5.1.

Method of administration

For oral administration.
The film-coated tablet is to be taken together with some liquid (water) just before going to bed, or in bed.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Severe hepatic impairment
- Sleep apnoea syndrome
- Myasthenia gravis
- Acute and/or severe respiratory impairment
- Previously known complex sleep behaviours after taking zolpidem, see section 4.4

4.4 Special warnings and precautions for use

Warnings

Respiratory impairment
As hypnotics have the capacity to depress respiratory drive, precautions should be observed if zolpidem is prescribed to patients with compromised respiratory function (see section 4.2).

Hepatic impairment
In patients with hepatic impairment dose recommendations given in section 4.2 are to be respected.
Zolpidem is contraindicated in patients with severe hepatic impairment due to the risk of encephalopathy (see section 4.2, 4.3 and 4.8).

Precautions

General
Prior to initiation of treatment with zolpidem, specific treatable causes of insomnia should be clarified and treated. If there is no improvement in insomnia after 7-14 days of treatment with zolpidem, the patient should be re-evaluated (repeatedly, if necessary) for possible primary psychiatric or physical disorders.

Elderly and debilitated patients

In elderly and debilitated patients, dose recommendations given in section 4.2 are to be respected. Caution is required in elderly patients as there is a risk of falls, especially in association with nocturnal getting up.

Severe injuries
The use of zolpidem can cause falls which can lead to severe injuries. Possibly the fall is caused by adverse reactions of zolpidem such as ataxia, muscle weakness, dizziness, somnolence and fatigue. The risk of falling is higher in elderly patients and if a higher dose than the recommended dose is used.

Psychiatric disorders

Hypnotics such as zolpidem are not recommended for the primary treatment of psychoses.

Risks from concomitant use with opioids
Concomitant use of zolpidem and opioids may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing of sedative medicinal products such as benzodiazepines or related medicinal products such as zolpidem with opioids should be reserved for patients for whom alternative treatment options are not possible.

If a decision is made to prescribe zolpidem concomitantly with opioids, the lowest effective dose should be used, and the duration of treatment should be as short as possible (see also section 4.2).

The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers (where applicable) to be aware of these symptoms (see section 4.5).

Suicidal thoughts/suicide attempt/suicide and depression
Some epidemiological studies suggest an increased incidence of suicidal ideation, suicide attempt and suicide in patients with or without depression, and treated with benzodiazepines and other hypnotics, including zolpidem. However, a causal relationship has not been established.

Concomitant use of SSRIs did not demonstrate any clinically relevant pharmacokinetic or pharmacodynamic interactions (see section 4.5). As with other hypnotic/sedative medicinal products, zolpidem should be administered with caution in patients exhibiting symptoms of depression. Suicidal tendencies may be present. The lowest dose of zolpidem that is feasible should be supplied to these patients to prevent the possibility of intentional overdose by the patient.

Pre-existing depression may be unmasked during use of hypnotics/sedatives like zolpidem. Since insomnia may be a symptom of depression, the patient should be re-evaluated if insomnia persists.

As with other hypnotics/sedatives, zolpidem should not be used without appropriate treatment for existing depression or anxiety accompanied by depression (in these patients this can increase the risk of suicide).

Next-day psychomotor impairment
Like other hypnotics/sedatives, zolpidem has a central depressant effect. The risk of next-day psychomotor impairment, including impaired driving ability, is increased if:

- zolpidem is taken within less than 8 hours before performing activities that require increased mental alertness(see section 4.7);
- a higher than the recommended dose is taken;
- zolpidem is co-administered with other CNS depressants or with other medicinal products that increase the blood levels of zolpidem, or with concomitant use of alcohol or illicit drugs (see section 4.5).

Zolpidem should be taken in a single intake immediately at bedtime and not be re-administered during the same night.

Amnesia

Hypnotics/sedatives like zolpidem may induce anterograde amnesia (memory gaps over a certain period of time) especially during the first hours after intake. In order to reduce the risk, patients should ensure that they will be able to have an uninterrupted sleep of 8 hours (see section 4.8).

Somnambulism and associated behaviours

Complex sleep behaviours, including sleepwalking and other associated behaviours such as "sleep driving", preparing and eating food, making phone calls or having sexual intercourse, with amnesia for the event, have been reported in patients who had taken zolpidem and were not fully awake. These events may occur after the first or any subsequent use of zolpidem. The use of alcohol and other CNS depressants with zolpidem appears to increase the risk of such behaviours, as does the use of zolpidem at doses exceeding the maximum recommended dose. Treatment should be discontinued immediately if the patient develops unusual sleep behaviour, due to the risk to the patient and others (see section 4.3).

Other psychiatric and "paradoxical" reactions

With the use of hypnotics/sedatives such as zolpidem, especially by the elderly patients, other psychiatric and so called "paradoxical reactions" like inner restlessness, increased insomnia, agitation, irritability, aggression, delusions, tantrums, nightmares, hallucinations, abnormal behaviour and other adverse behavioural disorders are known to occur. In these cases, treatment with zolpidem should be discontinued (see section 4.8).

Tolerance development

After repeated intake of hypnotics/sedatives over a few weeks, loss of efficacy (tolerance) may occur.

Dependence

Use of zolpidem may lead to the development of abuse and/or physical and psychological dependence. The risk of dependence increases with dose and duration of treatment. The risk of abuse and dependence is also greater in patients with a history of psychiatric disorders and/or alcohol, substance or drug abuse. Zolpidem should be used with extreme caution in patients who are or have been abusing or dependent on alcohol, medicinal products or drugs.

If physical dependence is developed, a sudden discontinuation of treatment will be accompanied by withdrawal symptoms. These may consist of headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability.

In severe cases the following symptoms may occur: loss of reality, depersonalisation, hyperacusis, numbness and tingling of the extremities, hypersensitivity to light, noise and physical contact, hallucinations or epileptic seizures.

With the use of short-acting hypnotics/sedatives such as zolpidem, withdrawal symptoms can also occur within the dosing interval.

Use in patients with a history of alcohol, drug or medicinal product abuse

Zolpidem should be used with extreme caution in patients with alcohol, drug or medicinal product abuse in their anamnesis.

Rebound insomnia

After termination of treatment, temporary withdrawal symptoms (rebound phenomena) may occur whereby the symptoms that led to treatment with zolpidem may reappear in an enhanced form. This may be accompanied by mood changes, anxiety and restlessness.

Since the risk of withdrawal symptoms/rebound phenomena is more likely to develop after abrupt discontinuation of treatment, it is recommended that the treatment is terminated by gradually reducing the dose.

It is important that the patient is aware of the possibility of rebound phenomena, which may reduce the fear of such symptoms, should they occur when the medicinal product is being discontinued.

There are indications that, in the case of benzodiazepines and benzodiazepine-like agents with a short duration of action, withdrawal phenomena can become manifest within the dose interval.

Patients with long-QT syndrome

In a cardiac electrophysiological *in vitro* study it has been shown that zolpidem, at a very high concentration and when pluripotent stem cells are used, can reduce the potassium currents via hERG channels. The possible consequence for patients with congenital long-QT syndrome is not known. As precaution, in patients with congenital long-QT syndrome zolpidem should only be administered after careful risk benefit assessment.

Duration of treatment

The duration of treatment should be as short as possible. It should not exceed 4 weeks including the tapering off process. Extension beyond these periods should not take place without re-evaluation of the situation (see section 4.2.).

It is recommended to inform the patient when treatment is started that it will be of limited duration and of gradual dose reduction.

Zolnod contain lactose and sodium

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

This medicinal product contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium free'.

4.5 Interaction with other medicinal products and other forms of interaction

Alcohol
Alcohol should not be consumed during treatment with zolpidem, as it alters and potentiates the sedative effect of zolpidem in an unpredictable manner. This affects the ability to drive or use machines (see section 4.7).

Combination with CNS depressants
An increase of the central depressive effect may occur in cases of concomitant use with antipsychotics (neuroleptics), hypnotics, anxiolytics/sedatives, muscle relaxants, antidepressants, narcotic analgesics, antiepileptics, anaesthetics and sedative antihistamines. Therefore, concomitant use of zolpidem with these medicinal products may increase drowsiness and next-day psychomotor impairment, including impaired driving ability (see section 4.4. and section 4.7). Also, isolated cases of visual hallucinations were reported in patients taking zolpidem with antidepressants including bupropion, desipramine, fluoxetine, sertraline and venlafaxine.
Co-administration of fluvoxamine may increase blood concentrations of zolpidem, concurrent use is not recommended.

In the case of narcotic analgesics enhancement of euphoria may also occur leading to an increase in psychological dependence.

Opioids

The concomitant use of hypnotics/sedatives such as benzodiazepines or related medicinal products such as zolpidem with opioids increases the risk of sedation, respiratory depression, coma, and death because of additive CNS depressant effect. The dose and duration of concomitant use should be limited (see section 4.4).

CYP450 inhibitors and inducers
Zolpidem is metabolised via several hepatic cytochrome P450 enzymes, the main enzyme being CYP3A4 with the contribution of CYP1A2.

Inducers of the cytochrom P450 enzyme CYP3A4 (e.g. rifampicin, carbamazepine, phenytoin, St. John's wort) may reduce the hypnotic effect of zolpidem. Co-administration with St. John's wort may reduce zolpidem blood concentrations, concomitant administration is not recommended.

Compounds that inhibit hepatic enzymes (particularly CYP3A4) such as azole antifungals, macrolide antibiotics and grapefruit juice may increase plasma concentrations and enhance the efficacy of zolpidem. However, when zolpidem is administered with itraconazole (CYP3A4 inhibitor), the pharmacokinetic and pharmacodynamic effects are not significantly different. The clinical relevance of these results is unknown.

Co-administration of zolpidem with ketoconazole (200 mg twice daily), a potent CYP3A4 inhibitor, prolonged zolpidem elimination half-life, increased total AUC, and decreased apparent oral clearance when compared to zolpidem plus placebo. The total AUC for zolpidem, when co-administered with ketoconazole, increased by a factor of 1.83 when compared to zolpidem alone. A routine dose adjustment of zolpidem is not considered necessary, but patients, should be advised that use of zolpidem with ketoconazole may enhance the sedative effects.

Co-administration of ciprofloxacin may increase blood levels of zolpidem, concurrent use is not recommended.

Other medicinal products
Co-administration of muscle relaxants may potentiate the muscle-relaxant effect - especially in elderly patients and at higher dose (risk of falling).
When zolpidem was administrated with ranitidine, no significant pharmacokinetic interactions were observed.

4.6 Fertility, pregnancy and lactation

Pregnancy
The use of zolpidem is not recommended during pregnancy.
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

Zolpidem crosses the placenta.

A large amount of data on pregnant women (more than 1000 pregnancy outcomes) collected from cohort studies has not demonstrated evidence of the occurrence of malformations following exposure to benzodiazepines or benzodiazepine-like substances during the first trimester of pregnancy. However, certain case-control studies reported an increased incidence of cleft lip and palate associated with use of benzodiazepines during pregnancy.

Cases of reduced foetal movement and foetal heart rate variability have been described after administration of benzodiazepines or benzodiazepine-like substances during the second and/or third trimester of pregnancy.

Administration of zolpidem, during the late phase of pregnancy or during labour has been associated with effects on the neonate, such as hypothermia, hypotonia, feeding difficulties ('floppy infant syndrome') and respiratory depression due to the pharmacological action of the product. Cases of severe neonatal respiratory depression have been reported.

Moreover, infants born to mothers who took hypnotic/sedative agents for prolonged periods of time during the later stages of pregnancy may have developed physical dependence and may be at risk of developing withdrawal symptoms in the postnatal period.
Appropriate monitoring of the newborn in the postnatal period is recommended.

If zolpidem is prescribed to a woman of childbearing potential, she should be warned to contact her physician about stopping the medicinal product if she intends to become or suspects that she is pregnant.

Breast-feeding
A small quantity of zolpidem passes into breast milk. Therefore, zolpidem should not be used by nursing mothers.

Fertility
No data are available on the effect of zolpidem on fertility.

4.7 Effects on ability to drive and use machines

Zolpidem has major influence on the ability to drive and use machines.

Vehicle drivers and machine operators should be warned that, as with other hypnotics, there may be a possible risk of drowsiness, prolonged reaction time, dizziness, sleepiness, blurred/double vision and reduced alertness and impaired driving

the morning after therapy (see section 4.8). In order to minimise this risk a resting period of at least 8 hours is recommended between taking zolpidem and driving, using machinery and working at heights.

Driving ability impairment and behaviours such as 'sleep-driving' have occurred with zolpidem alone at therapeutic doses.

Furthermore, the co-administration of zolpidem with alcohol and other CNS depressants increases the risk of such behaviours (see section 4.4 and 4.5). Patients should be warned not to drink alcohol or other psychoactive substances under any circumstances when taking zolpidem.

4.8 Undesirable effects

Daytime sleepiness, numbed emotions, reduced alertness, confusion, fatigue, headache, dizziness, muscle weakness, ataxia and double vision are all adverse reactions that occur primarily at the start of treatment and usually disappear again with repeated use. Other adverse reactions, such as gastrointestinal symptoms, changes in libido and skin reactions, are reported.
There are indications that the occurrence of adverse reactions that have been linked to the use of zolpidem is dose dependent; this applies particularly to some adverse reactions experienced in relation to the central nervous system.

The frequencies of the adverse reactions are stated using the following convention:

Very common (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1,000 to < 1/100)
Rare (≥ 1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

Infections and infestations
Common: upper respiratory tract infections, lower respiratory tract infections

Immune system disorders
Not known: angioneurotic oedema (Quincke's oedema)

Metabolism and nutrition disorders

Uncommon: appetite disorder

Psychiatric disorders
Common: hallucination[3], agitation[3], nightmares[3], worsening insomnia, depression[2] (see section 4.4)
Uncommon: confusional state, irritability[3], restlessness, aggression, somnambulism (sleepwalking or sleep driving, see section 4.4), euphoric mood
Rare: changes in libido
Very rare: delusions, dependence[4]
Not known: paradoxical reactions[3] such as anger, abnormal behaviour and psychosis, abuse[4]

Nervous system disorders
Common: numbed sensations, headache, somnolence, dizziness, exacerbated insomnia, cognitive disorders such as anterograde amnesia[1]
Uncommon: paraesthesia, tremor, disturbance in attention and speech disorder
Rare: reduced alertness and ataxia

Eye disorders
Uncommon: double vision (diplopia), blurred vision
Very rare: visual impairment

Respiratory, thoracic and mediastinal disorders
Very rare: respiratory depression (see section 4.4)

Gastrointestinal disorders
Common: diarrhoea, nausea, vomiting, abdominal pain

Hepatobiliary disorders
Uncommon: increased hepatic enzymes
Rare: hepatocellular, cholestatic or mixed forms of liver damage (see sections 4.2, 4.3 and 4.4)

Skin and subcutaneous tissue disorders
Uncommon: rash, pruritus, hyperhidrosis
Rare: urticaria

Musculoskeletal and connective tissue disorders
Common: back pain
Uncommon: arthralgia, myalgia, muscle spasms, neck pain, muscle weakness

General disorders and administration site conditions
Common: fatigue
Rare: gait disturbance
Not known: drug tolerance

Injury, poisoning and procedural complications

Not known: fall (especially in elderly patients and when zolpidem was not taken in accordance with the prescribed procedure) (see section 4.4).

1. Amnesia

Anterograde amnesia can occur with the use of therapeutic doses, the risk of which increases with higher doses. Amnesia may be associated with inappropriate behaviour (see section 4.4).

2. Depression

Pre-existing depression may be manifested during the use of benzodiazepines or benzodiazepine-like agents.

3. Psychiatric and 'paradoxical' reactions

Reactions like restlessness, agitation, irritability, aggression, delusions, rages, nightmares, hallucinations, psychoses, inappropriate behaviour and other behavioural disturbances may occur when using benzodiazepines or benzodiazepine-like substances. In rare cases, these reactions can be severe. The risk of these reactions is more likely to occur in children and the elderly.

4. Dependence

Use (even at therapeutic doses) may lead to physical dependence: discontinuation of the therapy may result in withdrawal or rebound symptoms (see section 4.4.). Psychic dependence may occur. Abuse has been reported in drug addicts who are addicted to various drugs.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system:

HPRA Pharmacovigilance; website: www.hpra.ie.

4.9 Overdose

Signs and symptoms
Intoxications with hypnotics/sedatives are usually - depending on the ingested dose – characterised by different stages of central depression, associated with somnolence, lethargy and mental confusion up to unconsciousness, central respiratory and circulatory depression and coma. Further symptoms may be blurred vision, speech disorders, dystonia, ataxia and muscle weakness as well as "paradoxical reactions" (restlessness, hallucinations).

In cases of overdose with zolpidem alone or with other CNS depressant agents (including alcohol), impairment of consciousness has ranged from somnolence to light coma, and serious symptoms, including fatal outcomes have been reported.

Management in case of overdose
Zolpidem is not dialyzable.
General symptomatic and supportive measures should be used. Patients with mild intoxication symptoms should sleep off under respiratory and circulatory control. In more severe cases, further measures (gastric lavage, administration of activated charcoal, circulatory stabilisation, intensive monitoring) should be used where appropriate.

Sedating medicinal products should be withheld even if excitation occurs.
If necessary, the specific benzodiazepine antagonist flumazenil may be used as an antidote. However, the administration of flumazenil can contribute to the occurrence of neurological symptoms (convulsions).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Psycholeptics, benzodiazepine related drugs
ATC code: N05CF02

Zolpidem is a short-acting, benzodiazepine-like hypnotic belonging to the group of imidazopyridines with sedative and hypnotic properties. In addition, zolpidem has also an anxiolytic, anticonvulsant and muscle-relaxant effect to a lower extent. Experimental studies have shown that sedative effects of zolpidem occur at lower doses than anticonvulsant, muscle relaxant or anxiolytic effects. As a specific GABA agonist, it exerts its effect predominantly via $GABA_A$-w_1-(BZ1) receptor complex and modulation of the chloride ion channel.

The randomized trials only showed convincing evidence of efficacy of 10 mg zolpidem
In a randomized double-blind trial in 462 non-elderly healthy volunteers with transient insomnia,
10 mg zolpidem decreased the average time to fall asleep by 10 minutes compared to placebo, while for 5 mg zolpidem this was 3 minutes.

In a randomized double-blind trial in 114 non-elderly patients with chronic insomnia, 10 mg zolpidem decreased the mean time to fall asleep by 30 minutes compared to placebo, while for 5 mg zolpidem this was 15 minutes.
In some patients, a lower dose of 5 mg could be enough.

Paediatric population
Safety and efficacy of zolpidem have not been established in children aged less than 18 years. A randomized placebo-controlled 8 week trail in 201 patients aged 6-17 years with insomnia associated with Attention Deficit Hyperactivity Disorder (ADHD) failed to demonstrate efficacy of zolpidem 0.25 mg/kg/day (with a maximum of 10 mg/day) as compared to placebo. Psychiatric and nervous system disorders were observed as the most common treatment-related adverse events during treatment with zolpidem versus placebo and included dizziness (23.5% versus 1.5%), headache (12.5% versus 9.2%), and hallucinations (7.4% versus 0%) (see sections 4.2 and 4.3.).

5.2 Pharmacokinetic properties

Absorption
After oral administration, zolpidem is rapidly and almost completely absorbed, maximum plasma levels are reached between 0.5 and 3 hours.
The absolute bioavailability is approx. 70% due to a first-pass effect.

Distribution
Zolpidem is rapidly distributed in organism from the central compartment. Zolpidem is strongly bound to plasma proteins (92%); the volume of distribution is 0.54 l/kg.
Therapeutic plasma levels are between 80 and 200 ng/ml.

Biotransformation
Zolpidem is metabolised via several hepatic cytochrome P450 enzymes, the main enzyme being CYP3A4 with the contribution of CYP1A2. The metabolites are pharmacologically inactive.

Elimination
The elimination half-life is relatively short and is approx. 2.4 (2-4) hours.
Zolpidem is excreted in the form of its metabolites both via the kidneys (approx. 56 %) and with the faeces (approx. 37 %). Only approx. 1% is excreted in unchanged form.

Linearity/non-linearity
Pharmacokinetics are linear at therapeutic doses.

Special populations
In elderly patients, the bioavailability of zolpidem is increased, clearance and volume of distribution (0.34 l/kg) are reduced, the dose should be adjusted accordingly.

In hepatic impairment, zolpidem plasma concentration is increased, elimination half-life prolonged and plasma clearance significantly reduced. For this reason, the dose should be reduced in these patients as well. In patients with liver cirrhosis, a four-fold increase in exposure and a three-fold increase in the elimination half-life were observed.

In patients with renal impairment (including dialysis-dependent patients), clearance is only slightly reduced, and no dose adjustment is usually necessary.

5.3 Preclinical safety data

Based on conventional studies of safety pharmacology, acute and chronic toxicity, reproductive toxicity, genotoxicity and cancerogenic potential, preclinical data do not reveal any specific risk for humans.

Preclinical effects were only observed at doses well above the maximum human exposure levels and are therefore of little significance for clinical use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Magnesium stearate
Microcrystalline cellulose
Lactose monohydrate
Colloidal silicon dioxide
Sodium starch glycollate (Type A)
Succinic acid

Tablet coating:
Lactose monohydrate
Macrogol 4000
Hypromellose
Titanium dioxide (colouring agent E171)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Store in the original package in order to protect from light.
This medicinal product does not require any special temperature storage conditions.

6.5 Nature and contents of container

The film-coated tablets are packed in polyvinylchloride/aluminium blisters and inserted into a carton.
The packages contain 10, 14, 20, 28, 30, 30x1, 50, 98, 100 film-coated tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Rowex Ltd
Newtown
Bantry
Co. Cork
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0711/039/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8 March 2002
Date of last renewal: 6 February 2011

10 DATE OF REVISION OF THE TEXT

September 2023