Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zoldem 10 mg film coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 10 mg zolpidem tartrate.

Excipients with known effect: Each film-coated tablet contains 47 mg lactose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

White to off-white capsule shaped tablet approximately 9.6mm x 3.9mm, marked "ZM breakline 10" on one side and "G" on the other.

The tablets can be divided into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Short term treatment of insomnia in adults.
Benzodiazepines or benzodiazepine-like agents are only indicated when the disorder is severe, disabling or subjecting the individual to extreme distress.

4.2 Posology and method of administration

Duration of treatment

Treatment should be as short as possible. Generally the duration of treatment varies from a few days to two weeks with a maximum, including the tapering off process, of four weeks. The tapering off process should be tailored to the individual.

As with all hypnotics, long-term use is not recommended and a course of treatment should not exceed four weeks. In certain cases extension beyond the maximum treatment period may be necessary; if so, it should not take place without re-evaluation of the patient's status.

The product acts rapidly and therefore should be taken with fluid just before going to bed, or in bed.

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 adults is 10 mg to be taken immediately at bedtime. The lowest effective daily dose of zolpidem should be used and must not exceed 10 mg.

Elderly (over 65 years) or debilitated patients
Elderly or debilitated patients may be especially sensitive to the effects of Zolpidem therefore a 5 mg dose is recommended. These recommended doses should not be exceeded.

Hepatic impairment

Patients with hepatic insufficiency do not clear the drug as rapidly as patients with normal hepatic function; therefore dosage should begin at 5 mg in these patients with particular caution being exercised in elderly patients. In adults (under 65 years) dosage may be increased to 10 mg only where the clinical response is inadequate and the drug is well tolerated.

The total dose of Zolpidem should not exceed 10mg in any patients.

Paediatric population
Safety and effectiveness of zolpidem in paediatric patients under the age of 18 years have not been established. Therefore, children and adolescents under 18 years of age should not be treated with Zolpidem.The available evidence from placebo-controlled clinical trials is presented in section 5.1.

Method of administration
For oral use.

4.3 Contraindications

Zolpidem is contraindicated in patients:

- with hypersensitivity to zolpidem tartrate or to any of the excipients listed in section 6.1.
- with severe hepatic insufficiency.
- with sleep apnoea syndrome.
- with myasthenia gravis.
- with acute and/or severe respiratory insufficiency.
- who have previously suffered from complex sleep behaviours after taking zolpidem; see Section 4.4.

4.4 Special warnings and precautions for use

General
The cause of insomnia should be identified wherever possible. The underlying factors should be treated before a hypnotic is prescribed. The failure of insomnia to remit after a 7-14 day course of treatment may indicate the presence of a primary psychiatric or physical disorder, which should be evaluated.

General information relating to effects seen following administration of benzodiazepines or other hypnotic agents which should be taken into account by the prescribing physician are described below.

Like other sedative/hypnotic drugs, zolpidem has CNS-depressant effects, such as sleepiness and dizziness.

Tolerance
Some loss of efficacy to the hypnotic effects of short-acting benzodiazepines and benzodiazapine-like agents may develop after repeated use for a few weeks.

Dependence
Use of benzodiazepines or benzodiazapine-like agents may lead to the development of physical and psychological dependence of these products. The risk of dependence increases with dose and duration of treatment and is also greater in patients with a history of alcohol, substance or drug abuse.

These patients should be under careful surveillance when receiving hypnotics. Dependence may also occur at therapeutic doses, and/or for subjects who do not show an individualised risk factor. Once physical dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms. These may consist of headaches or muscle pain, extreme anxiety and tension, restlessness, confusion, irritability and insomnia. In severe cases the following symptoms may occur: derealisation, depersonalisation, hyperacusis, numbness and tingling of the extremities, hypersensitivity to light, noise and physical contact, hallucinations or epileptic seizures.

Rebound insomnia
A transient syndrome whereby the symptoms that led to treatment with a benzodiazepines or benzodiazepine like agent recur in an enhanced form, may occur on withdrawal of hypnotic agent. It may be accompanied by other reactions including mood changes, anxiety and restlessness.

It is important that the patient should be aware of the possibility of rebound phenomena, thereby minimising anxiety over such symptoms if 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 dosage interval, especially when the dosage is high.

As the risk of withdrawal symptoms/rebound phenomena are more likely to develop after abrupt discontinuation of treatment, it is recommended to decrease the dose gradually.

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

It may be useful to inform the patient when treatment is started that it will be of limited duration.

Amnesia
Benzodiazepines or benzodiazapine-like agents may induce anterograde amnesia. The condition usually occurs several hours after ingesting the product. 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).

Psychiatric and "paradoxical" reactions
When using benzodiazepines or benzodiazepine-like agents, reactions like restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, hallucinations, psychoses, somnambulism and other nightly unconscious behaviours, like eating and car driving, inappropriate behaviour, increased insomnia and other adverse behavioural effects are known to occur. Should this occur, use of the product should be discontinued. These reactions are more likely to occur in the elderly.

Somnambulism and associated behaviours
Complex sleep behaviours including sleep walking and other associated behaviours such as "sleep driving", preparing and eating food, making phone calls or having sex, with amnesia for the event, have been reported in patients who had taken zolpidem and were not fully awake. These events may occur the first time zolpidem is taken or after taking zolpidem at any time during the treatment. The treatment must be immediately discontinued if a patient experiences a complex sleep behaviour due to the risk to the patient and others (see Section 4.3). 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.

Serious injuries
Because of its pharmacological properties, zolpidem can cause drowsiness and reduced levels of awareness, which can lead to falls and thereby serious injury.

Next-day psychomotor impairment
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 mental alertness (see section 4.7);
- a dose higher than the recommended dose is taken;
- zolpidem is co-administered with other CNS depressants or with other drugs that increase the blood levels of zolpidem, or with 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.

Risk from concomitant use of opioids
Concomitant use of zolpidem and opioids may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing of sedative medicines such as benzodiazepines or related drugs 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 general dose recommendation in 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).

Specific patient groups
Elderly or debilitated patients should receive a lower dose: see recommended dosage (section 4.2).

Due to the myorelaxant and sedative effect there is a risk of falls and consequent injury particularly for elderly patients when they get up at night.

Although dose adjustment is not necessary, caution should be exercised in patients with renal insufficiency (see section 5.2).

Caution should be observed when prescribing zolpidem to patients with chronic respiratory insufficiency since benzodiazepines have been shown to impair respiratory drive. It should also be taken into consideration that anxiety or agitation have been described as signs of deterioration of respiratory insufficiency.

Benzodiazepines and benzodiazapine-like agents are not indicated for the treatment of patients with severe hepatic insufficiency as they may precipitate encephalopathy.

Use in patients with psychotic illness: benzodiazepines and benzodiazapine-like agents are not recommended for the primary treatment.

Suicidal ideation, 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 who are being treated with benzodiazepines and other hypnotics, including zolpidem. However, a causal relationship has not been established.

Benzodiazepine and benzodiazepine-like agents should not be used alone to treat depression or anxiety associated with depression (suicide may be precipitated in such patients).Zolpidem should be administered with caution in patients exhibiting symptoms of depression. Suicidal tendencies may be present. Due to the possibility of intentional overdose by the patient, the lowest amount of the drug that is feasible should be supplied to these patients. Pre-existing depression may be unmasked during use of zolpidem. Since insomnia may be a symptom of depression, the patient should be re-evaluated if insomnia persists.

Use in patients with a history of drug or alcohol abuse: benzodiazepines and benzodiazapine-like agents should be used with extreme caution in patients with a history of alcohol or drug abuse. These patients should be under careful surveillance when receiving zolpidem since they are at risk of habituation and psychological dependence.

Since this product contains lactose, patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interactions

Zolpidem should not be taken in combination with alcohol. The sedative effect may be enhanced when the product is used in combination with alcohol. This affects the ability to drive or use machines.

Combination with CNS depressants
Enhancement of the central depressive effect may occur in cases of concomitant use with antipsychotics (neuroleptics), hypnotics, anxiolytics/sedatives/muscle relaxants, antidepressant agents, narcotic analgesics, antiepileptic drugs, anaesthetics and sedative antihistamines. Therefore, concomitant use of zolpidem with these drugs may increase drowsiness and next-day psychomotor impairment, including impaired driving ability (see section 4.4 and 4.7). Also, isolated cases of visual hallucinations were reported in patients taking zolpidem with antidepressants including bupropion, desipramine, fluoxetine, sertraline and venlafaxine. Therefore, caution should be exercised when Zolpidem is used in combination with other CNS depressants (see sections 4.8 and 5.1).

Co-administration of fluvoxamine may increase blood levels 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 sedative medicines such as benzodiazepines or related drugs such as zolpidem with opioids increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dosage and duration of concomitant use should be limited (see section 4.4).

CYP450 inhibitors and inducers
Zolpidem is metabolised by some enzymes of the cytochrome P450-family. The main enzyme is CYP3A4, but CYP1A2 is involved as well. Since CYP3A4 plays an important role in zolpidem tartrate metabolism, possible interactions with drugs that are substrates or inducers of CYP3A4 should be considered. CYP3A4 inducers, such as rifampicin and St John's wort can reduce the plasma concentration and therefore effect (see below).

Maximum plasma concentration and AUC has been shown to decrease when zolpidem was administered with St John's wort compared to zolpidem alone. Co-administration with St John's wort can lower levels of zolpidem in the blood and is therefore not recommended.

Rifampicin (a CYP3A4 inducer) induces the metabolism of zolpidem, resulting in approximately 60% reduction in peak plasma concentrations and possibly decreased efficacy. Similar effects might be expected also with other strong inducers of cytochrome P450-enzymes. However, when zolpidem tartrate was administered with itraconazole (a CYP3A4 inhibitor) its pharmacokinetics and pharmacodynamics were not significantly modified. The clinical relevance of these results is unknown.

Co-administration of zolpidem with ketoconazole (200mg 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 dosage 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 drugs
Caution should be observed when other psychoactive drugs are used.

When zolpidem tartrate was administered with ranitidine, no significant pharmacokinetic interactions were observed.

Zolpidem does not interact with warfarin, haloperidol, chlorpromazine, itraconazole or digoxin.

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

If, for compelling medical reason, zolpidem is administered during the late phase of pregnancy, or during labour, effects on the neonate, such as hypothermia, hypotonia, feeding difficulties ('floppy infant syndrome') and respiratory depression, can be expected due to the pharmacological action of the product. Cases of severe neonatal respiratory depression have been reported, especially when zolpidem tartrate was used with other CNS depressants at the end of pregnancy.

Infants born to mothers who took benzodiazepines or benzodiazepine-like agents chronically during the latter stages of pregnancy may develop withdrawal symptoms in the postnatal period as a result of physical dependence. Appropriate monitoring of the newborn in the postnatal period is recommended.

If zolpidem is prescribed to a woman of childbearing potential, she should be encouraged to contact her physician regarding discontinuance of the product if she intends to become or suspect that she is pregnant.

Breast-feeding
There are insufficient data to evaluate the safety of using zolpidem while breast-feeding. Zolpidem passes into breast milk in small amounts. Zolpidem should therefore not be used by breast-feeding mothers since effects on the infant are not studied.

Fertility
Effects observed were limited to irregular estrus cycles and prolonged precoital intervals at a high dose.

4.7 Effects on ability to drive and use machines

Zoldem 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 use alcohol or other psychoactive substances when taking zolpidem.

4.8 Undesirable effects

These effects seem to be related with individual sensitivity and to appear more often within the hour following the drug intake if the patient does not go to bed or does not sleep immediately (see section 4.2).

The adverse drug reactions are stated in the table below using the following convention:
Very common (≥1/10); common (≥1/100; <1/10); uncommon (≥1/1,000; <1/100); rare (≥1/10,000; <1/1,000); very rare (<1/10,000) including isolated reports; not known (cannot be estimated from available data).

There is evidence for a dose connection for reactions associated with use of zolpidem, especially certain CNS reactions and gastrointestinal events. Theoretically they should be less if zolpidem is taken immediately before bedtime. They occur most frequently in elderly patients.

SOC	***Frequency***				
	Common	***Uncommon***	***Rare***	***Very rare***	***Not known***
Infections and infestations	Upper respiratory tract infection, lower respiratory tract infection				
Immune system disorders					Angioneurotic disorders
Psychiatric disorders*	Hallucination, agitation, nightmare, depression (see section 4.4)	Confusion, irritability, restlessness, aggression, complex sleep behaviours (see section 4.4)	Libido disorders	Delusion, dependence (withdrawal symptoms, or rebound effects may occur after treatment discontinuation)	Anger, psychosis, abnormal behaviour
Nervous system disorders	Somnolence, headache, dizziness,		Depressed level of consciousness		Ataxia

	increased insomnia, cognitive disorders such as anterograde amnesia: (amnestic effects may be associated with inappropriate behaviour), drowsiness during the following day, reduced alertness				
Eye disorders	Double vision	Blurred vision			
Ear and labyrinth disorders	Vertigo				
Respiratory, thoracic and mediastinal disorders					Respiratory depression (see section 4.4)
Gastrointestinal disorders	Diarrhoea, nausea, vomiting, abdominal pain				
Hepatobiliary disorders		Elevated liver enzymes	Hepatocellular cholestatic or mixed liver injury		
Skin and subcutaneous tissue disorders		Rash, pruritus, hyperhidrosis	Urticaria		
Musculoskeletal and connective tissue disorders	Back pain	Muscle weakness, arthralgia, myalgia, muscle spasm, neck pain			
General disorders and administration site conditions	Fatigue		Gait disturbance, fall (predominantly in elderly patients and when zolpidem was not taken in accordance with prescribing recommendation) (see section 4.4)		Drug tolerance

*Most of these psychiatric undesirable effects are related to paradoxical reactions (see section 4.4)

These phenomena occur predominantly at the start of the therapy or in elderly patients and usually disappear with repeated administration.

Amnesia

Anterograde amnesia may occur during therapeutic dosages, the risk increasing at higher dosages. In order to reduce the risk, patients should ensure that they will be able to have an uninterrupted sleep of 8 hours. Amnestic effects may be associated with inappropriate behaviour (see section 4.4).

Depression
Pre-existing depression may become manifest during use of benzodiazepines or benzodiazepine-like agents (see section 4.4).

Psychiatric and "paradoxical" reactions
Reactions like restlessness, agitation, irritability, aggressiveness, delusions, rage, nightmares, increased insomnia, hallucinations, psychoses, inappropriate behaviour and other adverse behavioural effects may occur when using benzodiazepines and benzodiazepine-like agents. Such reactions are more likely to occur in the elderly (see section 4.4).

Dependence
Use (even at therapeutic dosages) may lead to physical dependence: discontinuation of the therapy may result in withdrawal or rebound phenomena (see section 4.4).

Psychological dependence may occur. Abuse has been reported in polydrug abusers.

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 HPRA Pharmacovigilance, website: www.hpra.ie.

4.9 Overdose

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

Individuals have fully recovered from overdoses up to 400 mg of zolpidem, 40 times the recommended dose.

General symptomatic and supportive measures should be used. Immediate gastric lavage should be used where appropriate. Intravenous fluids should be administered as needed. If there is no advantage in emptying the stomach, activated charcoal should be given to reduce absorption. Monitoring of respiratory and cardiovascular functions should be considered. Sedating medicinal products should be withheld even if excitation occurs.

Use of flumazenil may be considered when serious symptoms are observed. Flumazenil is reported to have an elimination half-life of about 40 to 80 minutes. Patients should be kept under close observation because of this short duration of action; further doses of flumazenil may be necessary. However, flumazenil administration may contribute to the appearance of neurological symptoms (convulsions).

In the treatment of overdose with any medicinal product, it should be borne in mind that multiple agents may have been taken.

Due to the high distribution volume and protein binding of zolpidem, haemodialysis and forced diuresis are not effective measures.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Hypnotics and Sedatives, Benzodiazepine related drugs

ATC Code: N05C F02

Zolpidem, an imidazopyridine, is a benzodiazepine-like hypnotic agent. In experimental studies it was shown that it has sedative effects at lower dosages than those required to exert anticonvulsant, myorelaxant or anxiolytic effects. These effects are related to a specific agonist action at central receptors belonging to the "GABA-omega" (BZ1 & BZ2) macromolecular receptor complex, modulating the opening of the chloride ion channel. Zolpidem acts primarily upon omega (BZ1) receptor subtypes.

The randomised trials only showed convincing evidence of efficacy of 10 mg zolpidem.

In a randomised double-blind trial in 462 non-elderly healthy volunteers with transient insomnia, zolpidem 10 mg decreased the mean time to fall asleep by 10 minutes compared to placebo, while for 5 mg zolpidem this was 3 minutes.

In a randomised double-blind trial in 114 non-elderly patients with chronic insomnia, zolpidem 10 mg 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 effective.

Paediatric population: Safety and efficacy of zolpidem have not been established in children aged less than 18 years. A randomised placebo-controlled study in 201 children 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 comprised the most frequent treatment emergent adverse events observed 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 section 4.2).

5.2 Pharmacokinetic properties

Absorption
Zolpidem has both a rapid absorption and onset of hypnotic effect. Bioavailability is 70% following oral administration. It demonstrates linear kinetics in the therapeutic dose range. The therapeutic plasma level is between 80 and 200 ng/ml. Peak plasma concentration is reached at between 0.5 and 3 hours after administration.

Distribution
The distribution volume in adults is 0.54 l/kg and decreases to 0.34 l/kg in the elderly.

Protein binding amounts to 92%. First pass metabolism by the liver amounts to approximately 35%. Repeated administration has been shown not to modify protein binding, indicating a lack of competition between zolpidem and its metabolites for binding sites.

Elimination
The elimination half-life is short, with a mean of 2.4 hours and a duration of action up to 6 hours.

All metabolites are pharmacologically inactive and are eliminated in the urine (56%) and in the faeces (37%).

Zolpidem has been shown in trials to be non-dialysable.

Special populations
In patients with renal insufficiency, including patients on dialysis a moderate reduction in clearance is observed. The other pharmacokinetic parameters remain unaffected.

In elderly patients and in patients with hepatic insufficiency, the bio-availability of zolpidem is increased. Clearance is reduced and the elimination half-life is prolonged (approximately 10 hours).

In patients with liver cirrhosis a 5-fold increase in AUC and a 3-fold increase in half-life was observed.

5.3 Preclinical safety data

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

Fertility
Oral administration of zolpidem doses of 4, 20, and 100 mg base/kg or approximately 5, 24, and 120 times the maximum recommended human dose (MRHD) on a mg/m2 basis to rats prior to and during mating, and continuing in females through postpartum day 25, resulted in irregular estrus cycles and prolonged precoital intervals, but did not produce a decline in fertility. No effects on other fertility parameters were noted. The no-effect dose was 20 mg base/kg/day (approximately 24 times the MRHD on a mg/m2 basis).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Lactose monohydrate
Microcrystalline cellulose
Maize starch, pregelatinised
Magnesium stearate.

Film-coating
Hypromellose
Titanium dioxide (E l71)
Polysorbate 80 (E 433)
Macrogol 400

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25^{o}C. Store in the original package.

6.5 Nature and contents of container

4, 7, 10, 14, 20, 28, 30, 50, 100 or 250 film-coated tablets in PVC/aluminium blisters or Polypropylene tablet containers with polyethylene caps.

Not all packs sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

McDermott Laboratories Ltd., T/A Gerard Laboratories
35/36 Baldoyle Industrial Estate
Grange Road
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA0577/048/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT