PHARMACODE

Zolpi - Z

PHARMACODE

SCHEDULING STATUS
NS3

PROPRIETARY NAME (AND DOSAGE FORM):
ZOLPI-Z 10 film coated tablets

COMPOSITION
Each tablet contains 10 mg of zolpidem tartrate, equivalent to 8,038 mg zolpidem.

Product also contains the following inactive ingredients:
Hypromellose, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, purified water, sodium starch glycolate, titanium dioxide

PHARMACOLOGICAL CLASSIFICATION
A 2.2 Sedatives, hypnotics.

PHARMACOLOGICAL ACTION
Pharmacodynamic properties
Zolpidem is an imidazopyridine compound and has sedative/hypnotic effects. These sedative/hypnotic effects are contributed to a specific agonist action at central receptors belonging to GABA-omega benzodiazepine-1 and benzodiazepine-2 macromolecular receptor complex, modulating the opening of the chloride ion channel. Zolpidem acts primarily upon the omega-1 (benzodiazepine-1) receptor subtypes.

Pharmacokinetic properties
Absorption
After oral administration, zolpidem is absorbed readily from the gastrointestinal tract. The bioavailability of zolpidem is about 70 %, and peak plasma concentration is reached between 0,5 and 3 hours after dosing.
Distribution
The pharmacokinetics are linear at therapeutic dose levels. The degree of plasma protein binding is about 92 %. The plasma elimination half-life is about 2,5 hours (1,4 – 3,8 hours). The distribution volume in adults is 0,54 ± 0,02 l/kg. The distribution volume decreases to 0,34 ± 0,05 l/kg in the very elderly.
Metabolism
The bioavailability of zolpidem is approximately 72 % ± 7 %, and is increased in patients with hepatic insufficiency. Clearance is reduced and the elimination half-life prolonged to about 10 hours.
Elimination
Zolpidem is eliminated in the form of inactive metabolites (hepatic metabolism), mainly in the urine (56 %) and faeces (37 %). It has no inducing effects on hepatic enzymes. Clearance is reduced in elderly subjects. Peak concentration is increased by about 50 % and elimination half-life by 32 %.
There is a moderate reduction in clearance in patients with renal insufficiency, whether dialysed or not. The other pharmacokinetic parameters are unaffected.

INDICATIONS
• **ZOLPI-Z** is indicated for the short-term treatment of insomnia.
• **ZOLPI-Z** or a short acting hypnotic is only indicated when the disorder is severe, debilitating or subjecting the individual to extreme distress.

CONTRAINDICATIONS
· Hypersensitivity to zolpidem or any of the ingredients of **ZOLPI-Z**, including the excipients.
· Pregnancy and lactation (see **PREGNANCY AND LACTATION**).
· Myasthenia gravis.
· Sleep apnoea syndrome.
· Acute and severe pulmonary insufficiency.
· Severe hepatic insufficiency (see **WARNINGS AND SPECIAL PRECAUTIONS**).
· Paediatric population under the age of 18.

WARNINGS AND SPECIAL PRECAUTIONS
Respiratory Insufficiency:
The respiratory drive may be suppressed in patients with chronic respiratory insufficiency, and caution should be observed when prescribing **ZOLPI-Z** to these patients.
Severe Hepatic Insufficiency:
ZOLPI-Z is contraindicated in patients with severe hepatic insufficiency as it may precipitate encephalopathy (see **CONTRAINDICATIONS**).
Insomnia:
The cause of insomnia should be identified and the underlying factors treated wherever possible before **ZOLPI-Z** is prescribed. The failure of insomnia to remit after 7 – 14 days course of treatment may indicate the presence of a primary psychiatric or physical disorder, and the patient should be carefully re-evaluated at regular intervals.
Paediatric patients:
ZOLPI-Z is contraindicated in patients less than 18 years due to increased occurrence of adverse effects including dizziness, headache and hallucinations (see **CONTRAINDICATIONS**).
Elderly:
See **DOSAGE AND DIRECTIONS FOR USE.**
Psychotic illness:
ZOLPI-Z should not be used as the primary treatment of psychotic illness.
Amnesia:
ZOLPI-Z may induce anterograde amnesia. The condition occurs most often several hours after ingesting **ZOLPI-Z** and therefore, to reduce this risk, patients should ensure that they will be able to have an uninterrupted sleep of 7 to 8 hours (see **SIDE EFFECTS**).
Depression:
ZOLPI-Z should not be used as the primary treatment of depressive syndromes.
ZOLPI-Z should be administered with caution in patients exhibiting symptoms of depression. Suicidal tendencies may be present, therefore, the least amount of **ZOLPI-Z** that is feasible, should be supplied to these patients because of the possibility of intentional overdosage by the patient.
Pre-existing depression may be unmasked during use of **ZOLPI-Z**.
Since insomnia may be a symptom of depression, the patient should be re-evaluated if insomnia persists.
Psychiatric and "paradoxical" reactions:
See **SIDE EFFECTS**.
Somnambulism and associated behaviours:
Sleep walking and other associated behaviours such as "sleep driving", preparing and eating food, making phone calls or having sex, with amnesia from the event, have been reported in patients who had taken **ZOLPI-Z** and were not fully awake. The use of alcohol and other CNS-depressants with **ZOLPI-Z** appears to increase the risk of such behaviours, as does the use of **ZOLPI-Z** at doses exceeding the maximum recommended dose. Discontinuation of **ZOLPI-Z** should strongly be considered for patients who report such behaviours.
Duration of Treatment:
The duration of treatment should be as short as possible and should not exceed 4 weeks, including the tapering off process. Extensions 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, and to explain precisely how the dosage will be progressively decreased.
Tolerance:
Some loss of efficacy of the hypnotic effects of **ZOLPI-Z** may develop after repeated use for a few weeks.
Rebound Insomnia:
A transient syndrome, whereby the symptoms that led to treatment with sedative/hypnotic agents recur in an enhanced form, may occur on withdrawal of **ZOLPI-Z** treatment. It may be accompanied by other reactions including mood changes, anxiety and restlessness. The syndrome is more likely to develop if **ZOLPI-Z** is discontinued abruptly, and therefore treatment with **ZOLPI-Z** should be withdrawn gradually.
It is important that the patient should be aware of the possibility of rebound phenomena, thereby minimising anxiety over such symptoms, should they occur while the **ZOLPI-Z** is being discontinued. In the case of hypnotics with a short duration of action, such as **ZOLPI-Z**, withdrawal phenomena can become manifest within the dosage interval.
Dependence and abuse:
Use of **ZOLPI-Z** may lead to the development of physical and psychic dependence. The risk of dependence increases with the dose and duration of treatment; it is also greater in patients with a history of psychiatric disorders and/or alcohol or drug abuse. These patients should be under careful surveillance when receiving **ZOLPI-Z**.
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 and irritability. 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.
Sedatives/hypnotics including **ZOLPI-Z** have produced withdrawal signs and symptoms following abrupt discontinuation. These symptoms range from mild dysphoria and insomnia to a withdrawal syndrome that may include abdominal and muscle cramps, vomiting, sweating, tremors and convulsions. The following adverse events have been reported fatigue, nausea, flushing, light-headedness, uncontrolled crying, emesis, stomach cramps, panic attack, nervousness and abdominal discomfort.
Because persons with a history of psychiatric disorders or addiction to, or abuse of, drugs or alcohol are at increased risk of habituation and dependence, they should be under careful surveillance when receiving **ZOLPI-Z** or any other hypnotic.
History of alcohol and drug abuse:
ZOLPI-Z should not be used in patients with a history of alcohol or drug abuse.

Effects on ability to drive or to use machines:
Sedation, drowsiness, dizziness and vertigo may adversely affect the ability to drive or to use machines in patients on **ZOLPI-Z**. If insufficient sleep duration occurs, the likelihood of impaired alertness may increase. In order to minimize this risk a full night sleep (7 – 8 hours) is recommended.

Lactose Intolerance:
Since **ZOLPI-Z** tablets contain lactose, patients with rare hereditary problems of galactose intolerance, the Lapp-lactase deficiency or glucose-galactose malabsorption, should not take this medicine.

INTERACTIONS
Alcohol:
It is not recommended to take alcohol during treatment with **ZOLPI-Z**. The sedative effect of **ZOLPI-Z** may be enhanced when used in combination with alcohol, and this will affect the ability to drive or use machines.
CNS Depressants:
Central depressive effects may be enhanced when used concomitantly with antipsychotics (neuroleptics), hypnotics, anxiolytics/sedatives, antidepressants, narcotic analgesics, antiepileptic medicines, anaesthetics and sedative antihistamines.
No clinically significant pharmacokinetic or pharmacodynamic interactions have been observed with selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine and sertraline. In the case of use of narcotic analgesics, enhancement of the euphoria may also occur, leading to an increase in psychic dependence.
CYP450 inhibitors:
The activity of **ZOLPI-Z** may be enhanced by compounds which inhibit certain hepatic enzymes (particularly cytochrome P450). **ZOLPI-Z** is metabolised via various hepatic cytochrome P450 enzymes: CYP3A4 being the main enzyme, with the contribution of CYP1A2.
The pharmacodynamic effect of **ZOLPI-Z** is decreased when administered with rifampicin (a CYP3A4 inducer). However, when **ZOLPI-Z** 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 **ZOLPI-Z** with ketoconazole (200 mg twice daily), a potent CYP3A4 inhibitor, prolonged **ZOLPI-Z** elimination half-life, increased total AUC, and decreased apparent total clearance when compared to **ZOLPI-Z** plus placebo. The total AUC for **ZOLPI-Z**, when co-administered with ketoconazole, increased by a factor of 1,83 when compared to **ZOLPI-Z** alone. A routine dosage adjustment is not considered necessary, but patients should be advised that use of **ZOLPI-Z** with ketoconazole may enhance the sedative effects.
Concomitant use of **ZOLPI-Z** with warfarin, digoxin or ranitidine or cimetidine, showed no significant pharmacokinetic interactions.

PREGNANCY AND LACTATION
Safety in pregnancy and lactation has not been demonstrated (see **CONTRAINDICATIONS**).
The use of **ZOLPI-Z** in pregnancy and breastfeeding should be avoided.
Pregnancy:
If **ZOLPI-Z** is administered during the late phase of pregnancy, or during labour, effects on the neonate such as hypothermia, hypotonia and moderate respiratory depression, can be expected due to the pharmacological action of the product.
Infants born to mothers who take **ZOLPI-Z** chronically during the latter stages of pregnancy may develop physical dependence and may be at risk of developing withdrawal symptoms in the postnatal period.
Lactation:
Small quantities of **ZOLPI-Z** appear in breast milk. The use of **ZOLPI-Z** in breastfeeding mothers is, therefore not recommended (See **CONTRAINDICATIONS**).

DOSAGE AND DIRECTIONS FOR USE
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.
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 should be taken immediately before going to bed, or in bed.
Dose:
The recommended daily dose for adults is 10 mg immediately before bedtime, or in bed.
Elderly:
Since elderly or debilitated patients may be especially sensitive to the effects of **ZOLPI-Z**, in these patients, a dose of 5 mg is recommended. The total **ZOLPI-Z** dose should not exceed 10 mg in these populations.
Children:
Safety and effectiveness of **ZOLPI-Z** in paediatric patients under the age of 18 years have not been established. **ZOLPI-Z** should not be prescribed in this population (see **CONTRAINDICATIONS**).
Hepatic impairment:
In patients with hepatic insufficiency, the recommended starting dose is 5 mg and particular caution must be exercised in elderly patients.

SIDE EFFECTS
Blood and the lymphatic system disorders
Less frequent: Blood disorders

Immune system disorders
Less frequent: Hypersensitivity reaction

Psychiatric disorders
Frequent: Hallucinations, agitation, nightmares
Less frequent: Confusional state, irritability, depression, dysarthria
Frequency unknown: Restlessness, aggression, delusion, anger, abnormal behaviour, sleep walking, dependence and libido disorder

Nervous system disorders
Frequent: Somnolence, sedation, headache, dizziness, exacerbated insomnia, anterograde amnesia: (amnestic effects may be associated with inappropriate behaviour)
Less frequent: Vertigo, tremor
Frequency unknown: Depressed level of consciousness.

Eye disorders
Less frequent: Diplopia
Less frequent: Visual disturbances

Respiratory, thoracic and mediastinal disorders
Less frequent: Respiratory depression during high doses.

Gastrointestinal disorders
Frequent: Diarrhoea, nausea, vomiting, abdominal pain, changes in salivation

Hepato-biliary disorders
Less frequent: Jaundice

Skin and subcutaneous tissue disorders
Frequency unknown: Rash, angioneurotic oedema, pruritus, urticaria and hyperhidrosis

Musculoskeletal, connective tissue and bone disorders
Frequency unknown: Muscular weakness

Renal and urinary disorders
Less frequent: Urinary retention or incontinence

General disorders and administrative site conditions
Frequent: Fatigue
Frequency unknown: Gait disturbances, drug tolerance and fall
Investigations
Frequency unknown: Elevated liver enzymes

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Overdosage:
In the case of overdose with **ZOLPI-Z** alone, or with other central nervous system depressant agents (including alcohol), the symptoms may present as impairment of consciousness ranging from somnolence to coma, as well as more severe symptomatology such as fatality.
Treatment:
Gastric lavage can be used where more than 100 mg zolpidem has been ingested. Treatment should be symptomatic and supportive. Sedative medications should be avoided even if excitation occurs. The value of dialysis in the treatment of overdose has not been established, although studies done in patients with renal failure receiving therapeutic doses have demonstrated that **ZOLPI-Z** is not dialyzable. Benzodiazepine-antagonists, such as flumazenil, may be considered where serious symptoms are observed.
Flumazenil may contribute to the appearance of some neurological symptoms (e.g. convulsions).
In the management of overdose with any medicinal product, it should be borne in mind that multiple agents may have been taken.

IDENTIFICATION
ZOLPI-Z 10 mg tablets are round, white, biconvex film-coated tablets with bisection line on one side.

PRESENTATION
ZOLPI-Z 10 mg are packed in aluminium/ PVC blister packs in strips of 10 and then boxed.
Each box contains 3 blister packs of 10.

PHARMACODE

Zolpi - Z

PHARMACODE

STORAGE INSTRUCTIONS
Store at or below 25 °C. Protect from light and moisture.
Keep the blisters in the outer carton until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
18/2.2/0102

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TRINITY PHARMA (PTY) LIMITED
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DATE OF PUBLICATION OF THE PACKAGE INSERT
August 2018

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
NS3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
ZOLPI-Z 10 film coated tablets

Read all of this leaflet carefully before you start taking ZOLPI-Z
• Keep this leaflet. You may need to read it again.
• If you have further questions, please ask your doctor or your pharmacist.
• **ZOLPI-Z** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT ZOLPI-Z CONTAINS
The active substance is zolpidem tartrate.
The other ingredients are: Hypromellose, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, purified water, sodium starch glycolate, titanium dioxide

2. WHAT ZOLPI-Z IS USED FOR
ZOLPI-Z is used to initiate sleep in adults with severe sleeping difficulties, also called insomnia, for a short term only.

3. BEFORE YOU TAKE ZOLPI-Z
Do not take **ZOLPI-Z:**
• If you are hypersensitive (allergic) to zolpidem tartrate or any of the other ingredients of **ZOLPI-Z.**
• If you have myasthenia gravis (an auto-immune disease in which certain muscles become weak and tire easily).
• If you have sleep apnoea (a condition in which your breathing stops or you have very shallow breaths while sleeping).
• If you have severe problems with your lungs.
• If you have serious problems with your liver.
• If you are under the age of 18 years.
• If you are pregnant or you are planning to become pregnant.
• If you are breastfeeding.

Take special care with ZOLPI-Z:
• If you have a history of addiction to drugs or alcohol, as **ZOLPI-Z** is very addictive.
• If you have mild or moderate breathing or chest problems.
• If you have mild or moderate liver problems.
• If you suffer from depression (you feel down constantly).
• If you suffer from epilepsy (convulsions, associated with abnormal electrical activity in the brain).
• If you suffer from schizophrenia (a personality disorder which causes hallucinations and/or delusions.
• If you continue to have problems with sleeping, or your sleeping problems worsen after a short period of treatment, please consult your doctor.
• If your sleeping problems improved and returns while taking **ZOLPI-Z**, please consult your doctor. **ZOLPI-Z** may lose its effectiveness when used for more than a few weeks. This is known as tolerance.
• You may experience temporary memory loss (amnesia) while taking **ZOLPI-Z**. This might be avoided by assuring you sleep 7 to 8 hours before being active again.
• You might experience some changes in behaviour or thinking (see POSSIBLE SIDE EFFECTS). If you have unusual, disturbing thoughts or you or your family notice any differences in your behaviour, please consult your doctor.
• If you think that you might get into a habit or regular pattern of taking **ZOLPI-Z**.

Taking ZOLPI-Z with food and drink:
ZOLPI-Z can be taken with or without food.

Pregnancy and breastfeeding
Do not take **ZOLPI-Z** if you are pregnant, planning to become pregnant, or breastfeeding your baby.

Driving and using machinery
ZOLPI-Z may impair your ability to drive and use machinery. Do not drive, operate machinery, or do anything else that could be dangerous until you know how **ZOLPI-Z** affects you.

Important information about some of the ingredients of ZOLPI-Z:
ZOLPI-Z contains lactose monohydrate, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **ZOLPI-Z.**

Taking other medicines with ZOLPI-Z:
If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **ZOLPI-Z** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.
• Do not drink alcohol while taking **ZOLPI-Z.**
• You should specifically inform your doctor if you are taking any of the following types of medicines:
- Medicines used for treating of mental conditions (antipsychotics, hypnotics, anxiolytics/sedatives, antidepressants).
- Medicines used to relieve severe pain (narcotic analgesics).
- Medicines used in the treatment of seizures or convulsions (antiepileptic medicines).
- Medicines used in the treatment of allergies (sedative antihistamines).
The combination of these medicines with **ZOLPI-Z** might make you drowsier than you should be.
The combination of **ZOLPI-Z** with narcotic analgesics (such as morphine or opiates) may give you a euphoric feeling (increase feeling of well-being).
• Medicines that decrease the normal elimination of zolpidem by the liver (hepatic enzyme (CYP450) inhibitors).
• Rifampicin (an antibiotic) may decrease the effect of **ZOLPI-Z.**
• Ketoconazole (used to treat fungal infections) increases the effect of **ZOLPI-Z.**

4. HOW TO TAKE ZOLPI-Z
Do not share medicines prescribed for you with any other person.
Always take **ZOLPI-Z** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
The usual dose is one tablet (10 mg) at night, immediately before bedtime or in bed.
If you are over the age of 65 years, or you have liver problems, the usual dose is half a tablet (5 mg).
The total dose of 10 mg should never be exceeded in these populations.
Your doctor will tell you how long your treatment with **ZOLPI-Z** will last.
ZOLPI-Z should only be used for a few days to 2 weeks with a maximum including the tapering off process of 4 weeks.
Swallow the tablets whole with a full glass of water.
If you have the impression that the effect of **ZOLPI-Z** is too strong or too weak, tell your doctor or pharmacist.
DO NOT TAKE MORE THAN THE DOSAGE RECOMMENDED BY YOUR DOCTOR.

If you take more ZOLPI-Z than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre and tell them how many tablets you have taken. Taking too much **ZOLPI-Z** may lead to impairment of your consciousness, ranging from feeling drowsy to going into a light coma.

Dependence and abuse:
The use of **ZOLPI-Z** may lead to you becoming dependent on taking **ZOLPI-Z**. Please consult with your doctor if you notice that you cannot or do not want to stop taking **ZOLPI-Z** or if you feel that you need to take **ZOLPI-Z** more often than prescribed to you by your doctor.

If you forget to take a dose of ZOLPI-Z:
If you forget to take **ZOLPI-Z** and you wake up late at night, or early the next morning, do not take the missed dose. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with ZOLPI-Z is stopped:
Keep taking **ZOLPI-Z** until your doctor tells you to stop. Do not stop taking **ZOLPI-Z** suddenly, but tell your doctor if you want to stop. Your doctor will need to lower your dose and stop your tablets over a period of time.
If you stop taking **ZOLPI-Z** suddenly, your sleep problems may come back and you may get a 'withdrawal effect'. If this happens you may get some of the effects listed below:
• Feeling anxious, restless, irritable or confused
• Headache
• Faster heartbeat or uneven heartbeat (palpitations)
• Nightmares, seeing or hearing things that are not real (hallucinations)
• Being more sensitive to light, noise and touch than normal
• Relaxed grip on reality
• Feeling distant from your body or feeling 'puppet-like'
• Numbness and tingling in your hands and feet
• Aching muscles
• Stomach problems
• Sleep problems come back worse than before
• In rare cases fits (seizures) may also occur.

5. POSSIBLE SIDE EFFECTS
ZOLPI-Z can have side effects.
Not all side effects reported for **ZOLPI-Z** are included in this leaflet. Should your general health worsen while taking **ZOLPI-Z,** please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **ZOLPI-Z** and tell your doctor immediately or go to the casualty department at your nearest hospital:
• Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
• Rash or itching
• Fainting
These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ZOLPI-Z**. You may need urgent medical attention or hospitalisation.
Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
Frequent:
• Hallucinations
Less frequent:
• Delusion
• Rage
• Blood abnormalities
• Depression (feeling down)
• Trouble breathing
• Difficulty urinating
• Liver abnormalities
These are all serious side effects. You may need urgent medical attention.
Tell your doctor as soon as possible if you notice any of the following:
Frequent:
• Drowsiness
• Dizziness
• Diarrhoea
• Nausea
• Vomiting
• Abdominal pain
• Headache
• Increased sleep problems
• Agitation
• Nightmares
• Memory difficulties (forgetfulness)
• Tiredness
Less frequent:
• Confusion
• Irritability
• Double vision or other visual disturbances
• Decreased concentration
• Restlessness
• Aggressiveness
• Abnormal behaviour
• Motion sickness
• Sleep walking
• Libido disorders
• Unsteadiness, fall (mainly in older patients and when **ZOLPI-Z** is not taken in accordance with the prescribing recommendations)
• Muscle weakness
• Tolerance (loss of effectiveness of the sleep medicine)
• Dependence (need to continue the sleep medicine associated with unpleasant symptoms when the sleep medicine is suddenly stopped)
• Slurred speech
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF ZOLPI-Z
Store at or below 25 °C
Keep the container in the outer carton until required for use.
Do not use after the expiry date printed on the label or carton.
Return all unused medicine to your pharmacist.
KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

7. PRESENTATION OF ZOLPI-Z
Zolpi-Z 10 mg are packed in aluminium/ PVC blister packs in strips of 10 and then boxed.
Each box contains 3 blister packs of 10.

8. IDENTIFICATION OF ZOLPI-Z
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