APPROVED PATIENT INFORMATION LEAFLET.

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MEDPLOZ 5 mg (Tablet)

MEDPLOZ 10 mg (Tablet)

Zolpidem tartrate

Read all of this leaflet carefully before you start taking MEDPLOZ.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine 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 MEDPLOZ CONTAINS

The active substance is zolpidem tartrate.

MEDPLOZ 5 mg: Each film-coated tablet contains 5 mg zolpidem tartrate.

MEDPLOZ 10 mg: Each film-coated tablet contains 10 mg zolpidem tartrate.

The other ingredients are lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, hypromellose, macrogol 400 and titanium dioxide (C.I. No: 77891).

2. WHAT MEDPLOZ IS USED FOR

Zolpidem is used to treat insomnia (trouble in sleeping). Zolpidem is only given when the disorder is severe, disabling or extremely distressing to the patient. Zolpidem should be used only for short periods of time.

3. BEFORE YOU TAKE MEDPLOZ

Do not take MEDPLOZ:

- If you have ever had an unusual or allergic reaction to zolpidem or the product.

- If you suffer from myasthenia gravis (muscle disorder causing weakness).
- If you suffer from sleep apnoea (temporary stopping of breathing during sleep).
- If you suffer from lung disease.
- If you have severe liver disease.
- If you are under the age of 18 years.
- If you are breast-feeding or pregnant. The safety of **MEDPLOZ** in pregnancy has not been established.

Take special care with MEDPLOZ:

- **MEDPLOZ** should be used for a short period of time, and generally for not longer than 4 weeks. Your doctor may want you to gradually reduce the amount you are taking before stopping completely.
- After repeated use of **MEDPLOZ** for a few weeks, some loss of the sleeping effect may develop.
- **MEDPLOZ** may cause a special type of memory loss or “amnesia”. When this occurs, a person does not remember what has happened during the several hours between use of the medicine and the time when its effects wear off.
- After taking **MEDPLOZ** for insomnia, you may have difficulty sleeping (rebound insomnia) for the first few nights after you stop taking it. Mood changes, anxiety and restlessness may also occur. Rebound insomnia is more likely to occur if MEDPLOZ is stopped suddenly, and therefore the amount you are taking should be reduced gradually.
- Do not take more of this medicine, do not take it more often, and do not take it for a longer time than your doctor ordered. If too much is taken, it may become habit-forming (causing mental or physical dependence). If you have a history of alcohol or medicine abuse, the risk of dependence increases. Once physical dependence has developed, sudden stopping of treatment will be accompanied by withdrawal symptoms. These may include headaches, muscle pain, extreme anxiety and tension, restlessness, confusion and irritability. In severe cases, the following symptoms may occur: derealisation (altered experience of the external world so that it seems unreal), depersonalisation (subjective experience of unreality in one’s sense of self), numbness

and tingling of the limbs, hypersensitivity to light, noise and physical contact, hallucinations (seeing, hearing, or feeling things that are not there) or epileptic seizures.

- In older adults, the dose of **MEDPLOZ** is reduced.
- Make sure you tell your doctor if you have breathing difficulties. Caution should be observed in these patients, since sleep tablets have been shown to impair respiratory drive.
- Make sure you tell your doctor if you suffer from depression, psychotic illness, or suicidal thoughts.
- Make sure you tell your doctor if you have a history of alcohol and medicine abuse, since **MEDPLOZ** should then not be given to you.
- Make sure you tell your doctor if you have severe liver disease, since **MEDPLOZ** should not be used to treat patients with severe liver disease.

Pregnancy and Breast-feeding:

- If **MEDPLOZ** is given during the late phase of pregnancy, or during labour, the newborn may suffer from abnormally low body temperature, hypotonia (abnormally low muscle tone) and respiratory depression (abnormally slow and/or shallow breathing). Infants born to mothers who have taken **MEDPLOZ** during pregnancy may develop physical dependence and may be at some risk of developing withdrawal symptoms.

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine .

Driving and using machinery:

MEDPLOZ may cause drowsiness, dizziness and loss of alertness. Make sure you know how you react to **MEDPLOZ** before you drive, use machines, or do anything else that could be dangerous if you are dizzy, or are not alert.

Taking other medicines with MEDPLOZ:

- **MEDPLOZ** will add to the effects of alcohol and other CNS depressants (medicines that slow down the nervous system, possibly causing drowsiness). Some examples of CNS depressants

are antihistamines or medicine for hay fever, other allergies; sedatives, tranquilizers, or sleeping medicine; prescription pain medicine or narcotics; medicine for seizures and anaesthetics.

Check with your doctor before taking any of the above while you are using **MEDPLOZ**.

MEDPLOZ should not be taken together with alcohol.

- Tell your doctor if you are taking rifampicin – The action of **MEDPLOZ** is decreased when it is taken together with rifampicin.
- Tell your doctor if you are taking an HIV-protease inhibitor such as ritonavir – The blood level of zolpidem may be increased with a risk of extreme sedation and respiratory depression (abnormally slow and/or shallow breathing).

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **MEDPLOZ** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE MEDPLOZ

- Take **MEDPLOZ** only as directed by your doctor. Do not take it for a longer time than your doctor has ordered. The length of treatment varies from a few days to two weeks, with a maximum of four weeks.
- **MEDPLOZ** should be taken immediately before going to bed, or in bed.
- **Dose:**

  Adults – 10 mg immediately before bedtime, or in bed.

  Elderly or debilitated patients and in patients with liver disease – 5 mg immediately before bedtime, or in bed.

  The total dose of **MEDPLOZ** should not exceed 10 mg.

Always take **MEDPLOZ** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **MEDPLOZ** is too strong or too weak, talk to your doctor or pharmacist.

If you take more MEDPLOZ than you should:

Taking an overdose of zolpidem alone may lead to unconsciousness, ranging from sleepiness to light coma. Overdose cases involving taking alcohol or other CNS depressants with zolpidem have resulted in more severe symptoms, including fatal outcomes.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek contact the nearest hospital or poison center.

If you forget to take MEDPLOZ:

If you miss a dose of **MEDPLOZ**, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

5. POSSIBLE SIDE EFFECTS

MEDPLOZ can have side-effects.

Daytime drowsiness, confusion, headache, dizziness, loss of muscle co-ordination, clumsiness or unsteadiness, reduced alertness, fatigue, numbed emotions, muscle weakness, double vision.

These side-effects mentioned above occur mainly at the start of therapy and most frequently in elderly patients, but may go away during treatment as your body adjusts to the medicine.

Other side-effects include: Abdominal or stomach pain, diarrhoea, skin rashes, memory problems, mental depression, restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, hallucinations (seeing, hearing, or feeling things that are not there), psychoses, inappropriate behaviour.

Not all side-effects reported for **MEDPLOZ** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MEDPLOZ**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF MEDPLOZ

Store at or below 25 °C in a dry place.

Store away from light and moisture. Keep blisters in the original carton until required for use. Keep the HDPE container well closed.

Do not store in the bathroom, near the kitchen sink, or in other damp places. Moisture may cause the medicine to break down.

Store all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF MEDPLOZ

MEDPLOZ 5 mg, MEDPLOZ 10 mg:

1. Blister Packs:

Tablets are packed in blister packs composed of clear PVC / PVdC and printed silver-coloured aluminium foil. Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blisters of 10 tablets each.

MEDPLOZ 10 mg

2. Blister Packs:

Tablets are packed in blister packs composed comprises of clear PVC / PVdc and printed silver-coloured aluminium foil. Each blister contains 14 tablets.

Pack size: 14s - Each carton contains 1 blister of 14 tablets each.

2. HDPE Container Pack:

Tablets are packed in white opaque HDPE containers with white opaque polypropylene closure with induction sealing wad. The void space in the container is filled by Rayon coil.

Pack size: 30's: One HDPE container of 30 tablets.

8. IDENTIFICATION OF MEDPLOZ

MEDPLOZ 5 mg: White to off – white, circular, biconvex, film – coated tablets, debossed with "E" on one side and "78" on the other side.

MEDPLOZ 10 mg: White to off – white, oval shaped, biconvex film – coated tablets, debossed with "E" on one side and debossed with "80" with a score line between "8" and "0" on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

MEDPLOZ 5 mg: 43/2.2/0247

MEDPLOZ 10 mg: 43/2.2/0257

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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