PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

ZOPISLEEP, 7,5 mg (tablets)

Zopiclone

Contains sugar (lactose monohydrate 30,8 mg) per tablet

Read all of this leaflet carefully before you start taking ZOPISLEEP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ZOPISLEEP 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.

WHAT IS IN THIS LEAFLET

1. What ZOPISLEEP is and what it is used for
2. What you need to know before you take ZOPISLEEP
3. How to take ZOPISLEEP
4. Possible side effects
5. How to store ZOPISLEEP
6. Contents of the pack and other information

1. What ZOPISLEEP is and what it is used for

ZOPISLEEP is used for the short-term (a few days to two weeks) treatment of sleeplessness in adult patients who for example have difficulty in falling asleep upon retiring, or who have frequent awakenings after falling asleep, and/or early awakenings.

2. What you need to know before you take ZOPISLEEP

Do not take ZOPISLEEP if:

- you are hypersensitive (allergic) to zopiclone or any of the other ingredients ZOPISLEEP (listed in section 6).
- you have breathing difficulties
- you have a problem where you stop breathing for short periods at night (sleep apnoea)
- you have severe liver problems
- you have a problem that causes severe muscle weakness (myasthenia gravis)
- you are under the age of 18 years
- you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with ZOPISLEEP:

- If you have a history of alcohol or drug abuse
- If you have any liver problems (see also 'Do not take ZOPISLEEP' section above). Your doctor may need to give you a lower dose of ZOPISLEEP
- If you have any kidney problems. Your doctor may need to give you a lower dose of ZOPISLEEP
- If your breathing is slower (respiratory depression)
- If you are elderly
- If you do not feel you will ever be able to stop taking ZOPISLEEP or other medicines used to treat sleep problems
- If you have depression or have had another mental illness in the past
- If you have been told by a doctor that you have a personality disorder

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- If you have recently taken ZOPISLEEP or other similar medicines for more than four weeks
- If you are taking ZOPISLEEP together with opioids, drowsiness, difficulties breathing, coma and death may occur. ZOPISLEEP and opioids should only be used concomitantly, when other treatment options are inadequate.
- Avoid the use of Central Nervous System Depressants while you are taking ZOPISLEEP.
- If clumsiness or unsteadiness occurs, especially in older patients.
- To avoid memory problems, take ZOPISLEEP only when you are able to get a full night's sleep (7 to 8 hours). Check with your doctor if unusual or strange thoughts or behaviour develops while taking ZOPISLEEP.
- Check with your doctor before stopping this medicine, as gradual dosage reduction may be necessary to avoid withdrawal symptoms.

Some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including ZOPISLEEP. However, it has not been established whether this is caused by the medicine or if there may be other reasons. If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice.

Use of ZOPISLEEP may lead to the development of abuse and /or physical and psychological dependence. The risk of dependence increases with dose and duration of treatment and is greater when ZOPISLEEP is used for longer than 4 weeks, and in patients with a history of mental disorders and/or alcohol, illicit substance or drug abuse. Tell your healthcare provider if you have ever had a mental disorder, or have abused or have been dependent on alcohol, substance or drugs.

Other medicines and ZOPISLEEP

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking ZOPISLEEP, it is especially important that your doctor and pharmacist know if you are taking any of the following:

- Alcohol
- Medicines for mental problems (antipsychotics)
- Medicines for depression
- Medicines for epilepsy (anticonvulsants)
- Medicines used in surgery (anaesthetics)
- Medicines to calm or reduce anxiety or for sleep problems (hypnotics)
- Medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines) such as chlorphenamine or promethazine
- Some medicines for moderate to severe pain (narcotic analgesics) such as codeine, methadone, morphine, oxycodone, pethidine or tramadol

The following medicines can increase the chance of you getting side effects when taken with ZOPISLEEP. To make this less likely, your doctor may decide to lower your dose of ZOPISLEEP:

- Some antibiotics such as clarithromycin or erythromycin
- Some medicines for fungal infections such as ketaconazole and itraconazole
- Ritonavir (a protease inhibitor) – for HIV infections
- Concomitant use of ZOPISLEEP and opioids increases the risk of drowsiness, difficulties breathing, coma and death. Follow your doctor's dosage recommendations closely.

The following medicines can make ZOPISLEEP work less well:

- Some medicines for epilepsy such as carbamazepine, phenobarbital or phenytoin
- Rifampicin (an antibiotic) - for infections
- St John's Wort (a herbal medicine) – for mood swings and depression

ZOPISLEEP with food and drink and alcohol

Do not drink alcohol while you are taking ZOPISLEEP. Alcohol can increase the effects of ZOPISLEEP and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking ZOPISLEEP.

Do not take ZOPISLEEP if you are pregnant or breastfeeding your baby.

Driving and using machines

ZOPISLEEP can cause slowing of your normal brain function (central nervous system depression). The risk of psychomotor impairment including driving ability, is increased if:

- You take ZOPISLEEP within 12 hours of performing activities that require mental alertness
- You take higher than the recommended dose of ZOPISLEEP
- You take ZOPISLEEP while already taking another central nervous system depressant or another medicine that increases levels of ZOPISLEEP in your blood, or while drinking alcohol.

It is not always possible to predict to what extent ZOPISLEEP may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or operate machines until you are aware of the measure to which ZOPISLEEP affects you.

ZOPISLEEP contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ZOPISLEEP.

3. How to take ZOPISLEEP

Do not share medicines prescribed for you with any other person.

Always take ZOPISLEEP exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage-

The usual adult dose is one tablet, immediately before retiring for the night. This dose should not be exceeded.

Your doctor may decrease this dose in older patients or if you have liver or kidney disease.

If you take more ZOPISLEEP than you should

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

If you forget to take ZOPISLEEP

If you are taking this medicine regularly and you miss a dose, take it as soon as possible. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with ZOPISLEEP is stopped

Check with your doctor before stopping ZOPISLEEP, as gradual dosage reduction may be necessary to avoid withdrawal symptoms.

4. Possible side effects

ZOPISLEEP can have side effects.

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

If any of the following happens, stop taking ZOPISLEEP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- skin rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to ZOPISLEEP. 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:

Less frequent:

- Seeing or hearing things that are not real (hallucinations)
- Poor memory since taking ZOPISLEEP (amnesia). By having 7-8 hours of uninterrupted sleep after taking ZOPISLEEP, this is less likely to cause you a problem.
- Falling, especially in the elderly

Frequency unknown:

- Thinking things that are not true (delusions)
- Feeling low or sad (depressed mood)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Dizziness
- Drowsiness and unsteadiness on waking
- Sleepiness
- Bitter taste in the mouth, indigestion, nausea, dry mouth

Less frequent side effects:

- Headache, memory problems, nightmares
- Feeling confused
- Reduced sex drive
- Irritability
- Difficulty breathing or being short of breath
- Increased liver functions
- Feeling physically or mentally tired
- Aggressiveness, inappropriate behaviour possibly associated with memory problems

Side effects with unknown frequency:

- Feeling restless or angry
- Sleepwalking

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- Becoming dependent on ZOPISLEEP
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Feeling light-headed or having problems with your coordination
- Mental problems such as poor memory
- Difficulty paying attention
- Disrupted normal speech
- Double vision
- Slower breathing (respiratory depression)
- Muscular weakness

Rebound effects: Discontinuation of treatment of ZOPISLEEP may cause you to experience anxiety, restlessness and mood changes, as well as an enhancement of symptoms that led to the treatment with ZOPISLEEP. Consult your doctor.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ZOPISLEEP.

5. How to store ZOPISLEEP

Store in a cool dry place below 25 °C protected from light.

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

Do not keep outdated or medicines no longer needed. Be sure that any discarded medicine is out of reach of children.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What ZOPISLEEP contains

Each tablet contains 7,5 mg zopiclone as the active ingredient.

Each tablet also contains the following inactive ingredients: calcium hydrogen phosphate (dihydrate), carmellose sodium, lactose monohydrate, magnesium stearate, maize starch, and Universal 05R04331 White as film coating.

What ZOPISLEEP looks like and contents of the pack

ZOPISLEEP is white, odourless, round, biconvex film coated tablets, plain on one side and a division mark on both sides.

3 x 10 tablets in a PVC/PVDC/Al blister strip packed into a carton.

7. Holder of Certificate of Registration

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The full Professional Information leaflet is available from iPharma (Pty) Ltd, please email info@ipharma.co.za to request a digital copy.

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