**PATIENT INFORMATION LEAFLET FOR**

**ZOPIVANE**

**Scheduling Status**

**S5**

**ZOPIVANE (7,5 mg film-coated tablets)**

**Zopiclone**

**Contains sugar: lactose monohydrate 40,000 mg per tablet**

**Read all of this leaflet carefully before you start using ZOPIVANE**

- Keep this leaflet. You may need to read it again.
- if you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- if you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. (See **section 4**)
- ZOPIVANE 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 ZOPIVANE is and what it is used for
2. What you need to know before you take ZOPIVANE
3. How to take ZOPIVANE
4. Possible side effects
5. How to store ZOPIVANE

6. Contents of the pack and other information.

## 1. What ZOPIVANE is and what it is used for

ZOPIVANE (zopiclone) belongs to a class of medicine known as sedatives, hypnotics.

ZOPIVANE 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 ZOPIVANE

**Do not take ZOPIVANE if you:**

- are hypersensitive (allergic) to zopiclone or any of the other ingredients of ZOPIVANE (listed in **Section 6**).
- have a problem that causes severe muscle weakness (myasthenia gravis)
- have breathing difficulties
- have severe liver problems
- have a problem where you stop breathing for short periods at night (sleep apnoea)
- have pre-existing reduced heart rate, low breathing rate of fewer than 10 breaths per minute, extreme confusion or memory loss, nausea and vomiting, poor judgment, blue lips or fingertips, irritability and aggression and clammy or cold skin (pre-existing CNS depression)
- are under the age of 18 years
- are pregnant or breastfeeding your baby.

**Warnings and Precautions**

Take special care with **ZOPIVANE**:

- if you have a history of alcohol or drug abuse
- Avoid driving motor vehicles or operating machinery as drowsiness and inco-ordination on waking may occur
- if you have any liver problems (see also '**Do not take ZOPIVANE**' section above). Your doctor may need to give you a lower dose of ZOPIVANE
- if you have any kidney problems. Your doctor may need to give you a lower dose of ZOPIVANE
- if your breathing is slower (respiratory depression)
- if you are elderly
- if you do not feel you will ever be able to stop taking ZOPIVANE 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.
- if you have recently taken ZOPIVANE or other similar medicines for more than four weeks
- if you are taking ZOPIVANE together with opioids, drowsiness, difficulties breathing, coma and death may occur. ZOPIVANE 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 ZOPIVANE.
- if clumsiness or unsteadiness occurs, especially in older patients
- to avoid memory problems, take ZOPIVANE 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 ZOPIVANE
- 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 ZOPIVANE. 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 ZOPIVANE 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 ZOPIVANE 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.

**Children and adolescents**

ZOPIVANE should not be used by children younger than 18 years old.

**Other medicines and ZOPIVANE**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

When you are taking ZOPIVANE, 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 ZOPIVANE. To make this less likely, your doctor may decide to lower your dose of ZOPIVANE:

- 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 ZOPIVANE and opioids increases the risk of drowsiness, difficulties breathing, coma and death. Follow your doctor's dosage recommendations closely

The following medicines can make ZOPIVANE 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.

**ZOPIVANE with food, drink and alcohol**

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

**Pregnancy, breastfeeding and fertility**

Do not use ZOPIVANE if you are pregnant or breastfeeding your baby.

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

**Driving and using machines**

ZOPIVANE can cause slowing of your normal brain function (central nervous system depression) (see '**Warnings and Precautions**' section above). The risk of psychomotor impairment including driving ability, is increased if:

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

It is not always possible to predict to what extent ZOPIVANE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZOPIVANE affects them.

**ZOPIVANE contains lactose monohydrate**

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

**3. How to take ZOPIVANE**

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

Always take ZOPIVANE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

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.

Your doctor will tell you how long your treatment with ZOPIVANE will last.

If you have the impression that the effect of ZOPIVANE is too strong or too weak, tell your doctor or pharmacist.

**If you take more ZOPIVANE than you should**

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

**If you forget to take ZOPIVANE**

Do not take a double dose to make up for forgotten individual doses.

**If you stop taking ZOPIVANE**

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

**4. Possible Side Effects**

ZOPIVANE can have side effects

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

If any of the following happens, stop taking ZOPIVANE 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZOPIVANE. 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 ZOPIVANE (amnesia). By having 7- 8 hours of uninterrupted sleep after taking ZOPIVANE, 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 mount

*Less frequent side effects:*

- headache, memory problems, nightmares
- felling 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
- becoming dependent on ZOPIVANE.
- unusual skin sensation 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 ZOPIVANE may cause you to experience anxiety, restlessness and mood changes, as well as an enhancement of symptoms that led to the treatment with ZOPIVANE. 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 or by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of ZOPIVANE.

## 5. How to store ZOPIVANE

Store in a cool, dry place at or below 25 °C. Protect from light. (1.5.5.1, line 511)

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

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 ZOPIVANE contains**

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

The other ingredients are colloidal silicon dioxide (Aerosil 200), lactose monohydrate, magnesium stearate, maize starch, opadry QX321A180025 (glycerol monocaprylocaprate, macrogol (PEG) polyvinyl alcohol graft copolymer, polyvinyl alcohol, talc and titanium dioxide) and sodium starch glycolate.

**What ZOPIVANE looks like and contents of the pack**

ZOPIVANE: White, film coated, oblong-shaped, shallow convex tablets with central breakline on one side and plain on the other side.

**ZOPIVANE** tablets are supplied in blister strips of 10 tablets, packed in 30's in a carton.

**Holder of Certificate of Registration**

**CIPLA MEDPRO (PTY) LTD**.

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