PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

Sandoz® Zopiclone 7,5 (film-coated tablets)

Zopiclone

Contains lactose monohydrate (78,5 mg per tablet)

Read all of this leaflet carefully before you start taking SANDOZ ZOPICLONE 7,5

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- SANDOZ ZOPICLONE 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 SANDOZ ZOPICLONE 7,5 is and what it is used for
2. What you need to know before you take SANDOZ ZOPICLONE 7,5
3. How to take SANDOZ ZOPICLONE 7,5
4. Possible side effects
5. How to store SANDOZ ZOPICLONE 7,5
6. Contents of the pack and other information

1. What SANDOZ ZOPICLONE 7,5 is and what it is used for

SANDOZ ZOPICLONE 7,5 belongs to group of medicines called hypnotics. It works by acting on your brain to help you sleep.

SANDOZ ZOPICLONE 7,5 is only used when the problem is severe or causing too much stress.
SANDOZ ZOPICLONE 7,5 is used to treat short term lack of sleep problems in adults.
SANDOZ ZOPICLONE 7,5 is not meant to be used every day for long periods of time or to treat depression.

2. What you need to know before you take SANDOZ ZOPICLONE 7,5

Do not take SANDOZ ZOPICLONE 7,5:

- If you are hypersensitive (allergic) to zopiclone or any of the other ingredients in SANDOZ ZOPICLONE 7,5 (listed in section 6)
- If you have a problem that causes severe muscle weakness (myasthenia gravis)
- If your lungs do not work properly (respiratory failure)
- If you have a problem where you stop breathing for short periods at night (sleep apnoea)
- If you have severe liver problems
- If you are under the age of 18. The safety and efficacy of SANDOZ ZOPICLONE 7,5 in children and adolescents aged less than 18 years have not been established
- The safety in pregnancy and lactation has not been established
- Pre-existing depression or coma and lung problems that occur for a short time

Warnings and precautions

Take special care with SANDOZ ZOPICLONE 7,5:

- If you have recently taken SANDOZ ZOPICLONE 7,5 or other similar medicines for more than four weeks.
- If you do not feel you will ever be able to stop taking SANDOZ ZOPICLONE 7,5 or other medicines used to treat sleep problems.

- If you have a history of alcohol or drug abuse.
- You have any kidney problems, your doctor may need to give you a lower dose of SANDOZ ZOPICLONE 7,5.
- You suffer from breathing problems, your doctor will decide if you should receive SANDOZ ZOPICLONE 7,5.
- If you are elderly, your doctor may need to give you a lower dose of SANDOZ ZOPICLONE 7,5.
- You have been told by a doctor that you have a personality disorder.
- Before taking SANDOZ ZOPICLONE 7,5 it is important to make sure that you can have at least 7 to 8 hours of sleep to help reduce the risk of some side effects.
- SANDOZ ZOPICLONE 7,5 may sometimes provoke seizures in patients with a disease called epilepsy. You may experience seizures if you stop taking SANDOZ ZOPICLONE 7,5 suddenly.
- If lack of sleep is not treated after 7-10 days of treatment, there might be other conditions.
- If SANDOZ ZOPICLONE 7,5 is taken with strong pain medicines called opioids, it can cause drowsiness, problems in breathing, coma and death.
- SANDOZ ZOPICLONE 7,5 and opioids should only be used together, when other treatment options are not enough.

Sleep-Driving and other strange behaviour:

There have been some reports of people doing things while asleep that they do not remember when waking up after taking a sleep medicine. This includes sleep-driving and sleep walking. Alcohol and some medicines for depression or anxiety can increase the chance that this serious effect will happen.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking SANDOZ ZOPICLONE 7,5.

Children and adolescents

SANDOZ ZOPICLONE 7,5 should not be used in children and adolescents less than 18 years. The safety and efficacy of SANDOZ ZOPICLONE 7,5 in children and adolescents aged less than 18 years have not been established.

Other medicines and SANDOZ ZOPICLONE 7,5

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

SANDOZ ZOPICLONE 7,5 may increase the effect of the following medicines:

- 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 or opioids) such as codeine, methadone, morphine, oxycodone, pethidine or tramadol

The following medicines can increase the chance of you getting side effects when taken with SANDOZ ZOPICLONE 7,5. To make this less likely, your doctor may decide to lower your dose of SANDOZ ZOPICLONE 7,5:

- Some antibiotics such as clarithromycin or erythromycin
- Some medicines for fungal infections such as ketoconazole and itraconazole
- Some medicines used for the treatment of HIV called protease inhibitors such as ritonavir
- Muscle relaxants

The following medicines can make SANDOZ ZOPICLONE 7,5 work less well:

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

SANDOZ ZOPICLONE 7,5 with food, drink and alcohol

Do not drink alcohol while you are taking SANDOZ ZOPICLONE 7,5. Alcohol can increase the effects of SANDOZ ZOPICLONE 7,5 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 this medicine.

SANDOZ ZOPICLONE 7,5 must not be used if you are pregnant or if you are planning to get pregnant.

Do not take SANDOZ ZOPICLONE 7,5 during pregnancy or during labour because it may be harmful to your baby.

Do not breastfeed if you are taking SANDOZ ZOPICLONE 7,5. This is because small amounts may pass into mother's milk.

Driving and using machines

On the day after taking SANDOZ ZOPICLONE 7,5 do not drive or use machinery or tools if you feel sleepy, dizzy or confused.

SANDOZ ZOPICLONE 7,5 contains lactose

SANDOZ ZOPICLONE 7,5 tablets contain an ingredient called lactose (milk sugar). If you have severe lactose intolerance, galactose intolerance, or glucose-galactose malabsorption, tell your doctor before taking SANDOZ ZOPICLONE 7,5 tablets.

3. How to take SANDOZ ZOPICLONE 7,5

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

Always take SANDOZ ZOPICLONE 7,5 tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking SANDOZ ZOPICLONE 7,5:

Take SANDOZ ZOPICLONE 7,5 by mouth.

Swallow the tablet with a drink of water.

Do not crush or chew your tablets.

Take just before bedtime.

Adults:

The usual dose is one SANDOZ ZOPICLONE 7,5 tablet just before bedtime.

Elderly patients:

The usual starting dose is half a tablet (3,75 mg) just before bedtime. Your doctor may decide to increase your dose to one SANDOZ ZOPICLONE 7,5 tablet if needed.

Patients with liver, kidney or respiratory problems:

The usual starting dose is half a tablet (3,75 mg) just before bedtime.

Children and adolescents:

SANDOZ ZOPICLONE 7,5 should not be used in children and adolescents less than 18 years. The safety and efficacy of SANDOZ ZOPICLONE 7,5 in children and adolescents aged less than 18 years have not been established.

If you take more SANDOZ ZOPICLONE 7,5 than you should

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

Taking too much SANDOZ ZOPICLONE 7,5 can be very dangerous. The following effects may happen:

- Feeling drowsy, confused, sleeping deeply and possibly falling into a coma.
- Floppy muscles (hypotonia).
- Feeling dizzy, lightheaded or faint. These effects are due to low blood pressure.
- Falling over or losing your balance (ataxia).
- Shallow breathing or difficulty breathing (respiratory depression).
- Feeling restless.
- Hallucinating.

Treatment is symptomatic and supportive.

If you forget to take SANDOZ ZOPICLONE 7,5

SANDOZ ZOPICLONE 7,5 must only be taken at bedtime. If you forget to take your tablet at bedtime, then you should not take it at any other time, otherwise you may feel drowsy, dizzy and confused during the day.

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

If you stop taking SANDOZ ZOPICLONE 7,5

Keep taking SANDOZ ZOPICLONE 7,5 until your doctor tells you to stop. Do not stop taking SANDOZ ZOPICLONE 7,5 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 SANDOZ ZOPICLONE 7,5 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.

See a doctor straight away if you get any of the following effects:

- Feeling anxious, shaky, irritable, agitated, confused or having panic attacks
- Sweating
- Headache
- Faster heartbeat or uneven heartbeat (palpitations)
- A lower level of awareness and problems with focusing or concentrating
- Nightmares, seeing or hearing things that are not real (hallucinations)
- Being more sensitive to light, noise and touch than normal
- Relaxed grip on reality
- Numbness and tingling in your hands and feet
- Aching muscles
- Stomach problems
- In rare cases fits (seizures) may also occur.

4. Possible side effects

SANDOZ ZOPICLONE 7,5 can have side effects.

Not all side effects reported for SANDOZ ZOPICLONE 7,5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine please consult your doctor, pharmacist or other health care provider for advice.

Stop taking SANDOZ ZOPICLONE 7,5 and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Tell your doctor as soon as possible if you have any of the following side effects:

- Poor memory since taking SANDOZ ZOPICLONE 7,5 (amnesia). By having 7-8 hours of uninterrupted sleep after taking SANDOZ ZOPICLONE 7,5, this is less likely to cause you a problem
- Seeing or hearing things that are not real (hallucinations)
- Falling, especially in the elderly
- Thinking things that are not true (delusions)
- Feeling low or sad (depressed mood)
- Abnormal behaviour

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- A mild bitter or metallic taste in your mouth or a dry mouth
- Feeling drowsy or sleepy
- Feeling sick (nausea) or being sick (vomiting)
- Feeling dizzy
- Headache
- Nightmares
- Feeling physically or mentally tired
- Agitation
- Feeling confused
- Lacking or being without any emotions.
- Itchy, lumpy rash (urticaria)

- Feeling irritable or aggressive
- Reduced sex drive
- Feeling restless or angry
- Feeling light headed or having problems with your coordination
- Double vision
- Moving unsteadily or staggering
- Muscular weakness
- Indigestion
- Becoming dependent on SANDOZ ZOPICLONE 7,5
- Changes in blood tests that show how well your liver is working
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Difficulty paying attention
- Disrupted normal speech
- Shortness of breath
- Slower breathing (respiratory depression)
- Sleepwalking (see “Take special care with SANDOZ ZOPICLONE 7,5”)
- Withdrawal syndrome (see “If you stop taking SANDOZ ZOPICLONE 7,5”)

If you notice any side effects not listed 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 SANDOZ ZOPICLONE 7,5.

Suspected side effects can also be reported directly to the holder of the certificate of registration HCR via the link: https://pvi1j.solutions.iqvia.com, or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store SANDOZ ZOPICLONE 7,5

Store all medicines out of reach of children.

Store at or below 25 °C in well closed containers, protected from light.

6. Contents of the pack and other information

What SANDOZ ZOPICLONE 7,5 contains

The active substance is zopiclone.

Each SANDOZ ZOPICLONE 7,5 tablet contains 7,5 mg zopiclone.

The excipients are calcium hydrogen phosphate, colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, Opadry White Y-1-7000 (methocel E5 Premium EP, polyethylene glycol 400, titanium dioxide C.I. 77891), povidone K30 and sodium starch glycolate.

What SANDOZ ZOPICLONE 7,5 looks like and contents of the pack

White to off white, oval, biconvex, film-coated tablets with a break-line.

Sealed aluminium bags of 30 or 100 tablets.

Blister packs, securitainers or amber glass bottles containing 30, 100, 300 or 500 tablets.

Not all packs may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

This leaflet was last revised in

26 August 2022

Registration number

32/2.2/0487

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07