

Biotech Laboratories (Pty) Ltd
BIO ZOPICLONE 7,5, film-coated tablets 420537
Each tablet contains zopiclone 7,5 mg

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

BIO ZOPICLONE 7,5 film-coated tablets

Zopiclone

Contains sugar (mannitol 53,70 mg and sucrose 0,45 mg per tablet).

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

- 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.
- BIO ZOPICLONE 7,5 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 BIO ZOPICLONE 7,5 is and what it is used for
2. What you need to know before you take BIO ZOPICLONE 7,5
3. How to take BIO ZOPICLONE 7,5
4. Possible side effects
5. How to store BIO ZOPICLONE 7,5
6. Contents of the pack and other information

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

Zopiclone belongs to the group of medicines called central nervous system (CNS) depressants (medicines that slow down the nervous system). It works by acting on your brain to help you sleep.

BIO ZOPICLONE 7,5 is used for the short-term treatment of insomnia (trouble in sleeping) in adults, when the problem is severe or causing too much stress.

Biotech Laboratories (Pty) Ltd

BIO ZOPICLONE 7,5, film-coated tablets 420537

Each tablet contains zopiclone 7,5 mg

2. What you need to know before you take BIO ZOPICLONE 7,5**Do not take BIO ZOPICLONE 7,5:**

- If you are hypersensitive (allergic) to zopiclone or any of the other ingredients of BIO ZOPICLONE 7,5 (listed in section 6).
- If your lungs do not work properly (respiratory failure)
- If your liver function is severely impaired.
- If you are suffering from sleep apnoea (temporary stopping of breathing during sleep).
- If you have ever experienced sleepwalking or other unusual behaviour (while not being fully awake after taking BIO ZOPICLONE 7,5).
- If you have emphysema, asthma, bronchitis or other lung disease.
- If you have myasthenia gravis (disorder characterised by muscle weakness).
- If you are pregnant or breastfeeding a baby.
- If you have suffered from central nervous system depression or have been in a coma.
- If you are under the age of 18 years.

Warnings and precautions

Take special care with BIO ZOPICLONE 7,5:

Tell your doctor:

- If you have recently taken BIO ZOPICLONE 7,5 or other similar medicines for more than four weeks.
- If you have any liver problems (see also 'Do not take this medicine and tell your doctor if:' section above).
- If you have any kidney problems, your doctor may need to give you a lower dose of BIO ZOPICLONE 7,5.
- If you have a history of alcohol or drug abuse.
- If you are suffering from depression or anxiety.
- If you are elderly, your doctor may need to give you a lower dose of BIO ZOPICLONE 7,5.
- BIO ZOPICLONE 7,5 may sometimes provoke seizures in patients with a disease called epilepsy. You may experience seizures if you stop taking BIO ZOPICLONE 7,5 suddenly.
- If lack of sleep is not treated after 7-10 days of treatment, there might be other conditions.

Biotech Laboratories (Pty) Ltd

BIO ZOPICLONE 7,5, film-coated tablets 420537

Each tablet contains zopiclone 7,5 mg

- Before taking BIO 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.
- If BIO ZOPICLONE 7,5 is taken with strong pain medicines called opioids, it can cause drowsiness, problems in breathing, coma and death.
- BIO ZOPICLONE 7,5 and opioids should only be used together, when other treatment options are not enough.

Sleep-Driving and other strange behaviour

BIO ZOPICLONE 7,5 may cause sleepwalking or other unusual behaviour (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake. The next morning, you may not remember that you did anything during the night. These activities may occur whether or not you drink alcohol or take other medicines that make you drowsy with BIO ZOPICLONE 7,5.

Dependence

BIO ZOPICLONE 7,5 may be habit-forming (causing mental or physical dependence), especially when taken for a long time or in high doses.

Some signs of dependence are:

- ♦ A strong desire or need to continue taking BIO ZOPICLONE 7,5
- ♦ A need to increase the dose to receive the same effect of the medicine.

Withdrawal

Withdrawal symptoms such as irritability, nervousness, trouble in sleeping, trembling or shaking, occurring after the medicine is stopped.

If you think you may have become mentally or physically dependent on this medicine, check with your doctor.

Do not stop taking it suddenly. Treatment should be gradually withdrawn.

Suicidality

Biotech Laboratories (Pty) Ltd

BIO ZOPICLONE 7,5, film-coated tablets 420537

Each tablet contains zopiclone 7,5 mg

Risk of suicides and suicide attempts may be increased in patients treated with benzodiazepines or hypnotics, including BIO ZOPICLONE 7,5. If you develop thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

Short-term memory loss (Anterograde amnesia)

BIO ZOPICLONE 7,5 tablets may cause a short-term memory loss (anterograde amnesia). This occurs particularly a few hours after taking the medicine. In order to reduce this risk, make sure you will be able to have an uninterrupted sleep of 8 hours.

Children and adolescents

BIO ZOPICLONE 7,5 should not be used in children and adolescents less than 18 years (see section 4.3).

Other medicines and BIO ZOPICLONE 7,5

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

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

- Medicines for mental problems (antipsychotics)
- Medicines for depression
- Medicines for epilepsy (anticonvulsants)
- Other sleeping tablets or medicine for tension or anxiety (hypnotics)
- Medicine for colds, sinus problems, hay fever or allergies such as chlorphenamine or promethazine (antihistamines)
- 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

Biotech Laboratories (Pty) Ltd

BIO ZOPICLONE 7,5, film-coated tablets 420537

Each tablet contains zopiclone 7,5 mg

BIO ZOPICLONE 7,5. To make this less likely, your doctor may decide to lower your dose of BIO 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

The following medicines may reduce the effect of BIO ZOPICLONE 7,5:

- Rifampicin (medicine to treat TB)
- Some medicines for epilepsy such as carbamazepine, phenobarbital and phenytoin
- St John's wort (herbal medicine to treat depression)

BIO ZOPICLONE 7,5 with food, drink and alcohol

The tablets should be swallowed whole with a glass of water before going to bed. It is recommended that you take this medicine with food to lessen the chance of stomach upset (nausea and vomiting), unless your doctor has advised you to take it on an empty stomach.

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

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

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

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

Biotech Laboratories (Pty) Ltd
BIO ZOPICLONE 7,5, film-coated tablets 420537
Each tablet contains zopiclone 7,5 mg

milk.

Driving and using machines

BIO ZOPICLONE 7,5 may cause some people to become drowsy, dizzy, light-headed, clumsy or less alert than they are normally. *Do not drive or operate any machinery or do anything else that could be dangerous if you are not alert.*

It is not always possible to predict to what extent BIO ZOPICLONE 7,5 may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which BIO ZOPICLONE 7,5 affects you.

BIO ZOPICLONE 7,5 contains sugar (sucrose and mannitol)

BIO ZOPICLONE 7,5 contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take BIO ZOPICLONE 7,5.

BIO ZOPICLONE 7,5 contains mannitol and may have a mild laxative effect.

3. How to take BIO ZOPICLONE 7,5

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

Always take BIO ZOPICLONE 7,5 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you have the impression that the effect of BIO ZOPICLONE 7,5 is too strong or too weak, tell your doctor or pharmacist, do not increase the dose.

- ♦ Treatment should be started with the lowest recommended dose.
- ♦ **The maximum dose should not be exceeded.**
- ♦ The treatment period should be as short as possible and should not be longer than 4 weeks.
- ♦ Do not take BIO ZOPICLONE 7,5 when your schedule does not permit you to get a full night's sleep (7-8 hours).

The dose will be different for different patients:

Biotech Laboratories (Pty) Ltd

BIO ZOPICLONE 7,5, film-coated tablets 420537

Each tablet contains zopiclone 7,5 mg

- ♦ *Adults:* One tablet to be taken by mouth at bedtime.
- ♦ *For elderly patients:* Half to one tablet to be taken by mouth at bedtime.

The dose can be increased to one tablet at bedtime.

- ♦ *For patients suffering from liver or kidney impairment:*

Half of a tablet to be taken by mouth at bedtime.

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

In the event of an overdosage consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and any remaining tablets with you, so the doctor knows what you have taken.

Taking too much BIO 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, light-headed 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.

If you forget to take BIO ZOPICLONE 7,5

If you missed a dose, skip the missed dose and go back to your regular dosing schedule.

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

If you stop taking BIO ZOPICLONE 7,5

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

Biotech Laboratories (Pty) Ltd

BIO ZOPICLONE 7,5, film-coated tablets 420537

Each tablet contains zopiclone 7,5 mg

If you stop taking BIO 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

BIO ZOPICLONE 7,5 can have side effects.

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

If any of the following happens, stop taking BIO ZOPICLONE 7,5 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

Biotech Laboratories (Pty) Ltd

BIO ZOPICLONE 7,5, film-coated tablets 420537

Each tablet contains zopiclone 7,5 mg

breathing,

These are all very serious side effects. If you have them, you may have had a serious reaction to BIO ZOPICLONE 7,5. 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:

- severe and life-threatening skin rashes (Stevens-Johnson Syndrome/ toxic epidermal necrolysis)
- skin rash with irregular red spots (erythema multiforme)
- poor memory since taking BIO ZOPICLONE 7,5 (amnesia). By having 7-8 hours of uninterrupted sleep after taking BIO 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
- difficulty breathing

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

- a bitter or metallic taste in your mouth or a dry mouth
- feeling drowsy or sleepy

Less frequent side effects:

- nightmares
- agitation
- aggressiveness
- confusion

Biotech Laboratories (Pty) Ltd

BIO ZOPICLONE 7,5, film-coated tablets 420537

Each tablet contains zopiclone 7,5 mg

- headache
- dizziness
- nausea and vomiting, diarrhoea
- skin rash, hives
- increased liver enzymes as shown in laboratory tests
- chills, sweating, tiredness

Side effects with unknown frequency:

- clumsiness or unsteadiness
- restlessness
- feeling angry
- sleepwalking (see “Take special care with BIO ZOPICLONE 7,5”)
- withdrawal syndrome (see “If you stop taking BIO ZOPICLONE 7,5”)
- paraesthesia (numbness/tingling of the skin)
- difficulty paying attention
- dysarthria (slowed, slurred speech)
- poor memory
- double vision
- indigestion
- muscular weakness
- slower breathing (respiratory depression)
- light-headedness or having problems with your coordination
- injury due to lack of coordination

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

Biotech Laboratories (Pty) Ltd

BIO ZOPICLONE 7,5, film-coated tablets 420537

Each tablet contains zopiclone 7,5 mg

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 BIO ZOPICLONE 7,5.

5. How to store BIO ZOPICLONE 7,5

- ♦ Store all medicines out of reach of children.
- ♦ Store in a cool dry place at or below 25 °C.
- ♦ Protect from light.
- ♦ For HDPE Container: Keep well closed.
- ♦ Do not remove blisters from outer container until required for use.
- ♦ Do not store your medicine in the bathroom.
- ♦ Do not use the tablets after the expiry date printed on the container, blister or label.
- ♦ Return all unused medicine to your pharmacist.
- ♦ Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information**What BIO ZOPICLONE 7,5 contains**

The active substance is zopiclone 7,5 mg.

The other ingredients are Core: magnesium stearate, maize starch, mannitol, microcrystalline cellulose, povidone.

Film-coating: glycerin, hypromellose, polysorbate 80, sucrose and the colourant titanium dioxide.

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

White, almost white film coated oblong, bulged tablets with breaking notch on both sides.

BIO ZOPICLONE 7,5 are packed as 30 tablets in white HDPE container with white HDPE cap or in white opaque PVC/PVDC/Aluminium blister strips, kept in an outer carton, each strip containing ten tablets.

Biotech Laboratories (Pty) Ltd

BIO ZOPICLONE 7,5, film-coated tablets 420537

Each tablet contains zopiclone 7,5 mg

Holder of Certificate of Registration

Biotech Laboratories (Pty) Ltd

Block K West, Central Park

400 16th Road, Halfway House

Midrand, 1685

South Africa

Tel: (011) 848 3053

This leaflet was last revised in

14 October 2022

Registration number

BIO ZOPICLONE 7,5: 42/2.2/053