

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

Zolpidem 10 Unicorn 10 mg film-coated tablets

Zolpidem tartrate

Contains sugar (59,000 mg lactose monohydrate per film-coated tablet).

Read all of this leaflet carefully before you start taking Zolpidem 10 Unicorn:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Zolpidem 10 Unicorn 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 Zolpidem 10 Unicorn is and what it is used for
2. What you need to know before you take Zolpidem 10 Unicorn
3. How to take Zolpidem 10 Unicorn
4. Possible side effects
5. How to store Zolpidem 10 Unicorn
6. Contents of the pack and other information

1. What Zolpidem 10 Unicorn is and what it is used for

This belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep.

Zolpidem 10 Unicorn is used to initiate sleep in adults with severe sleeping difficulties, also called insomnia, for a short-term only.

2. What you need to know before you take Zolpidem 10 Unicorn

Do not take Zolpidem 10 Unicorn

- If you are allergic (hypersensitive) to zolpidem tartrate or any of the other ingredients of Zolpidem 10 Unicorn (listed in section 6).
- If you have a problem that causes severe muscle weakness (myasthenia gravis).
- If you have a problem where you stop breathing for short periods at night (sleep apnoea).
- If your lungs do not work properly (respiratory failure).
- If you have serious liver problems (liver failure).
- You are under the age of 18.
- if you are pregnant, intend to become pregnant or are breastfeeding.

Warnings and precautions

Special care should be taken with Zolpidem 10 Unicorn:

- If you have a history of alcohol or drug abuse.
- Use with caution if you have mild to moderate breathing or chest problems.
- If your sleep problems persist or worsen after a short period of treatment, consult your doctor.
- If your sleep problems return while you are taking Zolpidem 10 Unicorn, consult your doctor. When medications for sleep such as Zolpidem 10 Unicorn are used for more than a few weeks, they may lose their effectiveness to help you sleep. This is known as “tolerance”.

- You may have temporary memory loss (amnesia) when taking Zolpidem 10 Unicorn. This can usually be avoided if you get a full night sleep (7 to 8 hours) before being active again.
- Some people taking Zolpidem 10 Unicorn, may have changes in behaviour and thinking (see Possible side effects). If you or your family notice any changes in your behaviour, or if you have any unusual or disturbing thoughts, consult your doctor immediately.
- Use with caution if you have mild to moderate liver problems.
- If you suffer from depression, epilepsy or schizophrenia.
- If you may be at risk of getting into a regular pattern or habit of taking Zolpidem 10 Unicorn.
- You have recently taken Zolpidem 10 Unicorn or other similar medicines for more than four weeks.
- If you are elderly.
- If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice.

Use of Zolpidem 10 Unicorn may lead to the development of abuse and/or physical and psychological dependence and abrupt termination of treatment will cause withdrawal symptoms. The risk of dependence is greater when Zolpidem 10 Unicorn 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.

Zolpidem 10 Unicorn can cause drowsiness and decrease your level of alertness. This could cause you to fall, sometimes leading to severe injuries.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Zolpidem 10 Unicorn.

The day after taking Zolpidem 10 Unicorn, the risk of psychomotor impairment, including impaired driving ability may be increased if:

- You take this medicine less than 8 hours before performing activities that require your alertness.
- You take a higher dose than the recommended dose.
- You take Zolpidem 10 Unicorn while you are already taking other central nervous system depressants or another medicine that increases Zolpidem 10 Unicorn in your blood, or while drinking alcohol, or while taking illicit substances.

There have been reports of people doing things while asleep that they do not remember when waking up after taking Zolpidem 10 Unicorn. This includes sleep-driving, sleepwalking, preparing and eating food, and having sex. Alcohol and some medicines for depression or anxiety can increase the chance that this serious effect will happen.

Children and adolescents

You should not take ZOLPIDEM 10 UNICORN if you are under the age of 18 years (see Do not take Zolpidem 10 Unicorn).

Other medicines and Zolpidem 10 Unicorn

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

You should specifically tell you doctor if you take:

- Other medicines that act on the brain such as:
 - medicines used in the treatment of mental conditions (antipsychotics, hypnotics, anxiolytics/sedatives, antidepressants)
 - medicines used for strong pain relief (narcotic analgesics)

- medicines used for the treatment of seizures/convulsions (antiepileptic medicines)
- anaesthetics
- medicines used in the treatment of allergies (sedative antihistamines).

The combination of these medicines with Zolpidem 10 Unicorn may make you drowsier than it should and may increase the next-day psychomotor impairment effects, including impaired driving ability. In addition, you may be euphoric (increase of well-being) if narcotic analgesics morphine and opiates) are combined with Zolpidem 10 Unicorn.

- Medicines that decrease the normal elimination of zolpidem by the liver.
- Rifampicin (antibiotic used to treat infections) as it may decrease the effect of Zolpidem 10 Unicorn on sleep.
- Ketoconazole (used to treat infections) increases the effect of Zolpidem 10 Unicorn
- Fluvoxamine (an antidepressant medicine) as it may increase the effect of Zolpidem 10 Unicorn. It is not recommended to take Zolpidem 10 Unicorn with fluvoxamine.
- Ciprofloxacin (antibiotic used to treat infections) as it may increase the effect of Zolpidem 10 Unicorn. It is not recommended to take Zolpidem 10 Unicorn with ciprofloxacin.
- St John's Wort (a herbal medicine used for mood swings and depression). It is not recommended to take Zolpidem 10 Unicorn with St. John's Wort.
- Opioids (medicines used for pain relief, also contained in some cough medicines).

Concomitant use of Zolpidem 10 Unicorn and opioids increases the risk of drowsiness, difficulties in breathing, coma and may be life-threatening. Because

of this, the concomitant use with Zolpidem 10 Unicorn should only be considered when other treatment options are not possible.

Please tell your doctor about all opioid medicines you are taking.

Zolpidem 10 Unicorn with food and drink and alcohol

Do not drink alcohol while you are taking Zolpidem 10 Unicorn.

Alcohol can increase the effects of Zolpidem 10 Unicorn and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

The use of alcohol and other CNS depressants may increase the risk of sleep walking and other associated sleep behaviour such as “sleep driving”, preparing and eating food, making phone calls or having sex.

Pregnancy and, breastfeeding and fertility

You should not take Zolpidem 10 Unicorn if you are pregnant or breastfeeding. 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 health care provider for advice before taking this medicine.

Driving and using machines

Zolpidem 10 Unicorn make you sleepy, therefore caution should be exercised when operating machinery or driving motor vehicles.

Zolpidem 10 Unicorn has a major influence on the ability to drive and use machines.

On the day after taking Zolpidem 10 Unicorn, you should be aware that:

- you may feel drowsy, sleepy, dizzy or confused
- your quick decision-making may be longer
- your vision may be blurred or double
- you may be less alert

A period of at least 8 hours is recommended between taking Zolpidem 10 Unicorn and driving, using machinery and working at heights to minimise the above mentioned effects.

Do not drink alcohol or take other psychoactive substances while you are taking Zolpidem 10 Unicorn as it can increase the above-mentioned effects.

It is not always possible to predict to what extent Zolpidem 10 Unicorn 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 Zolpidem 10 Unicorn affects you.

Zolpidem 10 Unicorn contains lactose monohydrate:

Zolpidem 10 Unicorn contains lactose monohydrate, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Zolpidem 10 Unicorn. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take Zolpidem 10 Unicorn.

3. How to take Zolpidem 10 Unicorn

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

Always take Zolpidem 10 Unicorn exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The usual dose of Zolpidem 10 Unicorn is one tablet (10 mg) at night, immediately before bedtime or in bed. The dose of one tablet (10 mg) at night should not be exceeded.

If you are over 65 years of age or have liver problems, the usual dose is half of a tablet (5 mg).

The break line on the tablet allows for the division of the tablet into two equal halves which allows for the 5 mg dosage.

A total dose of 10 mg should not be exceeded in these populations.

Zolpidem 10 Unicorn should be taken in a single intake and not taken again during the same night.

Zolpidem 10 Unicorn should only be used for a few days to 2 weeks with a maximum, including the tapering off process, of 4 weeks.

Swallow the tablets whole with a full glass of water.

Your doctor will tell you how long your treatment with Zolpidem 10 Unicorn will last. Do not stop treatment early because abrupt termination of treatment will cause withdrawal symptoms. If you have the impression that the effect of Zolpidem 10 Unicorn is too strong or too weak, tell your doctor or pharmacist.

If you take more Zolpidem 10 Unicorn 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 Zolpidem 10 Unicorn with or without other CNS depressants can be very dangerous.

The following effects may happen:

Impairment of consciousness ranging from drowsiness to light coma, confusion, sleeping deeply and possibly falling into a fatal coma.

If you forget to take Zolpidem 10 Unicorn

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

Zolpidem 10 Unicorn must only be taken at bedtime. If you forget to take the tablet before you go to bed, and you wake up late in the night or very early in the morning, do not take it. If you are not sure what to do, ask your doctor.

If you stop taking Zolpidem 10 Unicorn

Keep taking Zolpidem 10 Unicorn until your doctor tells you to stop. Do not stop taking Zolpidem 10 Unicorn 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 Zolpidem 10 Unicorn 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, restless, irritable or confused
- Headache, light headedness
- Faster heartbeat or uneven heartbeat (palpitations)
- Nightmares, seeing or hearing things that are not real (hallucinations)
- Being more sensitive to light, noise and touch than normal
- Relaxed grip on reality
- Feeling distant from your body or feeling 'puppetlike'
- Numbness and tingling in your hands and feet
- Aching muscles
- Stomach problems including nausea, vomiting and cramps
- Sleep problems come back worse than before
- Fits (seizures)
- Fatigue
- Uncontrolled crying
- Uncontrolled movements (tremor and convulsions)

4. Possible side effects

Zolpidem 10 Unicorn can have side effects.

Not all side effects reported for Zolpidem 10 Unicorn are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking Zolpidem 10 Unicorn, please consult your health care provider for advice.

If any of the following happens, stop taking Zolpidem 10 Unicorn and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or hives (an itchy, lumpy rash)
- fainting
- discolouration of the skin or eyes, pain in the abdomen (stomach) or a bloated feeling, severe itching, pale or bloody stools, extreme weakness, nausea or loss of appetite. This may be signs of a problem with your liver.
- slower breathing or difficulty breathing (respiratory depression)

These are all very serious side effects. If you have them, you may have had a serious reaction to Zolpidem 10 Unicorn. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- drowsiness
- dizziness
- diarrhoea
- nausea
- vomiting
- abdominal pain
- headache
- increased sleep problems

- hallucination
- agitation
- nightmares
- memory difficulties
- tiredness
- nose, throat or lung infections (respiratory infection)
- back pain

Less frequent side effects:

- confusion
- irritability
- double vision, blurred vision
- decreased concentration
- restlessness
- aggressiveness
- delusion
- rage
- abnormal behaviour
- sleep walking (see “sleep-driving and other sleep-related behaviour”)
- libido disorders (changes in sex drive)
- unsteadiness, fall (mainly in older patients and when Zolpidem 10 Unicorn is not taken in accordance with the prescribing recommendations)
- muscle weakness, muscle spasms, limp or weak muscles, muscle pain, joint pain
- tolerance (loss of effectiveness of the sleep medicine)
- dependence (need to continue the sleep medicine associated with unpleasant symptoms when the sleep medicine is suddenly stopped)

Applicant: Unicorn Pharmaceuticals (Pty) Ltd.
Product Name: Zolpidem 10 Unicorn
Dosage form and strength: Each film coated tablet contains 10 mg zolpidem
(as zolpidem tartrate)

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- depression
- tremor
- feeling overly happy or confident (euphoric)
- unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- changes in appetite

Frequency Unknown:

- Disturbance in attention and speech
- Rash, itchy skin
- Pain and swelling under the skin
- Difficulty in breathing
- Liver disorder

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website By reporting side effects, you can help provide more information on the safety of Zolpidem 10 Unicorn.

Adverse reactions must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za.

5. How to store Zolpidem 10 Unicorn

Store all medicines out of reach of children.

Store at or below 25 °C

Do not use this medicine after the 'EXPIRY' date shown on the pack

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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 Zolpidem 10 Unicorn contains

- The active substance is zolpidem tartrate. Each Zolpidem 10 Unicorn tablet contains 10 mg zolpidem tartrate.
- The other ingredients are:

Tablet core: lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch (maize starch), silica colloidal anhydrous and sodium starch glycolate (type A)

Film Coating: hypromellose (5 cps), macrogol 6000, purified talc and titanium dioxide

Contains sugar (59,000 mg lactose monohydrate per tablet).

What Zolpidem 10 Unicorn looks like and contents of the pack

White to almost white, caplet shaped, biconvex, film coated tablets with break line on one side and "10" embossed on other side.

Tablets are packed in blisters of 10 tablets. The blisters are then packaged in an outer carton containing 30 tablets.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd
4th Floor Offices, Block A, The District Building,
41 Sir Lowry Road, Woodstock, Cape Town,
Western Cape, 7925, Republic of South Africa

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