

PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

ZILSUN MR Modified Release tablet

Zolpidem tartrate

Contains sugar: Lactose monohydrate 80,687 mg per tablet.

Read all of this leaflet carefully before you start taking ZILSUN MR

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

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1. What ZILSUN MR is and what it is used for

ZILSUN MR contains a medicine called zolpidem tartrate. This belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep.

ZILSUN MR is used to initiate sleep in adults below the age of 65 years with sleeping difficulties, also called insomnia, for a short-term use only.

2. What you need to know before you take ZILSUN MR

Do not take ZILSUN MR:

- If you are hypersensitive (allergic) to zolpidem tartrate or any of the other ingredients of ZILSUN MR (listed in section 6). Signs of an allergic reaction include rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue
- if you have myasthenia gravis (a condition in which the muscles become weak and tire easily)
- if you have sleep apnoea (a condition where you temporarily stop breathing while you sleep)
- if you have severe lung problems
- if you have serious liver problems
- if you are a child under 18 years of age
- if you are pregnant, intend to become pregnant or are breastfeeding your baby (see **Pregnancy, breastfeeding and fertility**).

ZILSUN MR is not recommended for use in an adult over the age of 65 years.

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Warnings and precautions

Take special care with ZILSUN MR:

- If sleep problems persist or worsen after a short period of treatment (e.g 7-14 days of treatment), consult your doctor.
- If you have mild to moderate breathing or chest problems.
- If you are taking medicines called opioids (medicines used to treat moderate to severe pain, such as morphine and codeine) as it may cause sedation, breathing difficulties, coma, and death.
- You may have temporary memory loss (anterograde amnesia) when taking ZILSUN MR. This can usually be avoided if you get a full night sleep (7 to 8 hours) before being active again.
- Some people taking ZILSUN MR 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.
- If you may be at risk of getting into a regular pattern or habit of taking ZILSUN MR (dependence).
- If sleep problems return while you are taking ZILSUN MR consult your doctor. When medications for sleep such as ZILSUN MR are used for more than a few weeks, they may lose their effectiveness to help you sleep. This is known as 'tolerance'.
- If you have mild to moderate liver problems.
- If you suffer from depression (feeling sad) or mental illness

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Sleep-walking and other sleep-related behaviour:

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

Dependence and abuse:

The use of ZILSUN MR may lead to you becoming dependent on taking ZILSUN MR. Please consult with your doctor if you notice that you cannot or do not want to stop taking ZILSUN MR or if you feel that you need to take ZILSUN MR more often than prescribed to you by your doctor.

Other medicines and ZILSUN MR

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

This is because ZILSUN MR may not be suitable to be taken with some other medicines.

You should specifically tell your 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) such as risperidone, quetiapine (Seroquel), olanzapine, diazepam and fluoxetine.

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- medicines used for strong pain relief (narcotic analgesics) such as morphine and codeine
- medicines used for the treatment of fits/convulsions (antiepileptic medicines) such as carbamazepine and lamotrigine
- medicines used during tests and surgical operations to numb sensation in certain areas of the body or induce sleep; this prevents pain and discomfort (anaesthetics)
- medicines used in the treatment of allergies (sedative antihistamines) such Chlorphenamine and clemastine.

The combination of these medicines with ZILSUN MR may make you more drowsy than you should. In addition, you may be euphoric (increase of wellbeing) if narcotic analgesics (morphine and opiates) are combined with ZILSUN MR.

- Medicines that decrease the normal elimination of zolpidem by the liver (Fluvoxamine and Ciprofloxacin).
- Ketoconazole (used to treat fungal infections) increases the effect of ZILSUN MR.
- Rifampicin (used for treating bacterial infections), as it may decrease the effect of ZILSUN MR on sleep.

ZILSUN MR with food, drink and alcohol

ZILSUN MR should not be taken with or immediately after a meal.

Do not drink alcohol while you are taking ZILSUN MR.

Pregnancy, breastfeeding and fertility

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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.

If you are pregnant or breastfeeding your baby, do not take ZILSUN MR (see what you need to know before you take ZILSUN MR).

Driving and using machines

ZILSUN MR 12,5 may make you sleepy, therefore caution should be exercised when operating machinery or driving motor vehicles.

ZILSUN MR contains lactose

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

3. How to take ZILSUN MR

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

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

The usual dose for adults below 65 years of age is one tablet (12,5 mg) at night, immediately before bedtime or in bed.

ZILSUN MR should only be used for 4 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.

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ZILSUN MR acts rapidly and therefore should be taken immediately before bedtime. Should you desire to sleep fast, ZILSUN MR should not be administered with or immediately after a meal.

Your doctor will tell you how long your treatment with ZILSUN MR will last. Do not stop treatment early even if you feel better unless told to do so by your doctor.

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

If you take more ZILSUN MR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre and tell them how many tablets have been taken.

If you take too much ZILSUN MR, your consciousness may be impaired, ranging from drowsiness to light coma.

If you forget to take ZILSUN MR

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.

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

If you stop taking ZILSUN MR

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Keep taking ZILSUN MR until your doctor tells you to stop. Do not stop taking ZILSUN MR 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 ZILSUN MR 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
- 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 'puppet-like'
- numbness and tingling in your hands and feet
- aching muscles
- stomach problems
- sleep problems come back worse than before.
- In rare cases fits (seizures) may also occur.

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4. Possible side effects

ZILSUN MR can have side effects.

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

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

- Rash or itching/hives.
- Swelling the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing (angioedema).

These are very serious side effects. If you have them, you may have had a serious allergic reaction to ZILSUN MR. 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:

- Chest discomfort
- Changes in the way your heart beats, for example, if you notice it beating faster.
- Sleep-walking

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:

- Flu with symptoms, such as high temperature, sore throat, runny nose, cough and chills
- Anxiety, slowing of speech, thinking and body movements, disorientation, headache, excessive sleepiness, dizziness, memory difficulties, disturbance in attention

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- Visual disturbance
- Feeling sick, constipation
- Muscle pain, muscle cramp, neck pain, back pain, tiredness.

Less frequent side effects:

- Stomach and intestinal infections
- Infections of the inner ear and outer ear
- Lung infections
- Infections of the mouth, nose, sinus, throat and voice box (often referred to as "colds"),
- Depression, seeing or hearing things that are not real, lack of interest, confusion, experience of feeling unreal and detached, depressed mood, loss of inhibition, feeling overly happy/confident, frequent mood changes, nightmares, feeling stressed, feeling of unsteadiness or dizziness when standing or walking,
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin
- Unsteadiness when walking, burning sensation, dizziness with change in posture, tremor
- Taste disturbances
- Muscle cramp
- Eye redness, blurred vision, other vision problems like difficulty in assessing depth, eye strain
- A feeling of dizziness or "spinning", ringing in the ears
- Cough, dryness in throat, throat irritation
- Being sick, abdominal discomfort, excessive gas in the stomach or bowel, passing stools frequently, heartburn (acidity problem)
- Skin allergy, wrinkling of skin

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- Joint pain
- Pain when passing urine, pain during periods, heavy menstrual periods, dryness of vulva and vagina
- Unusual weakness, feeling drunk, flu-like illness, lack of energy, pain, fever, high blood pressure, increased heart rate.
- Symptoms related to nervous system have been reported frequently in elderly patients.

If any of the side effects become serious, or 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 ZILSUN MR.

5. How to store ZILSUN MR

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not remove the strips or blisters from the carton until required for use.

Do not take ZILSUN MR after the expiry date stated on the carton.

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

6. Contents of the pack and other information

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WHAT ZILSUN MR CONTAINS

The active substance is zolpidem tartrate.

Each film coated two layer tablet contains :

Zolpidem Tartrate USP 12,5 mg

The other ingredients are: ferric oxide yellow, hypromellose (methocel E-5LV premium), hypromellose 2910 (methocel E15 premium LV), hypromellose 2208 (methocel K4M CR premium), isopropyl alcohol, lactose monohydrate, magnesium stearate, microcrystalline cellulose, opadry II clear 85F19250, opacode black S-1-17823, sodium starch glycolate type A, tartaric acid.

Contains sugar: lactose monohydrate 80,687 mg per tablet.

What ZILSUN MR looks like and contents of the pack

ZILSUN MR is available in a pack of 30 tablets, each Alu-PVC coated with PVDC blister pack or Alu/Alu strip containing 10 tablets, packed in carton along with pack insert.

Holder of certificate of registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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South Africa

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Ranbaxy Pharmaceuticals (Pty) Ltd
MASTER: ZILSUN MR
DUPLICATE: ZOLPIDEM SUN MR

Each modified Release Tablet contains 12,5 mg
Zolpidem tartrate

Version:04-2023

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