PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

APPROVED

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

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.

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

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.
    - 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

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.

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

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.

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
- 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

- 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

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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PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS

S5

ZILSUN MR Gemodifiseerde vrystellingtablet

Zolpidemtartraat

Bevat suiker: 80,687 mg Laktosemonohidraat per tablet.

Lees hierdie hele inligtingstuk noukeurig deur voordat jy begin om ZILSUN MR te neem

- Hou hierdie inligtingstuk. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het.
- ZILSUN MR is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander persone deel nie. Dit kan skadelik vir hulle wees, selfs as hulle simptome dieselfde as joune is.

Wat is in hierdie inligtingstuk

1. Wat is ZILSUN MR en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy ZILSUN MR neem
3. Hoe om ZILSUN MR te neem
4. Moontlike newe-effekte
5. Hoe om ZILSUN MR te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat is ZILSUN MR en waarvoor word dit gebruik

ZILSUN MR bevat ‘n medisyne wat zolpidemtartraat genoem word. Dit behoort aan ‘n groep medisyne wat hipnotika genoem word. Dit werk in op die brein om jou te help om te slaap.

ZILSUN MR word gebruik om slaap te inisieer by volwassenes jonger as 65 jaar met slaapprobleme, ook slapeloosheid genoem, Slegs vir korttermyn gebruik.

2. Wat jy moet weet voordat jy ZILSUN MR neem

Moenie ZILSUN MR neem nie:

- as jy hipersensitief (allergies) is vir zolpidemtartraat of enige van die ander bestanddele van ZILSUN MR (gelys in afdeling 6). Tekens van ‘n allergiese reaksie sluit uitslag, sluk- of asemhalingsprobleme, swelling van die lippe, gesig, keel of tong in
- as jy myasthenia gravis het (‘n toestand waar die spiere swak en maklik moeg word)
- as jy slaapapnee het (‘n toestand waar jy tydelik ophou om asem te haal terwyl jy slaap)
- as jy ernstige longprobleme het
- as jy ernstige lewerprobleme het
- as jy ‘n kind onder die ouderdom van 18 jaar is
- as jy swanger is, beplan om swanger te raak of as jy jou baba borsvoed (sien **Swangerskap, borsvoeding en fertiliteit**).

ZILSUN MR word nie aanbeveel vir gebruik by volwassenes ouer as 65 jaar nie.

Waarskuwings en voorsorgmaatreëls

Tref spesiale voorsorg met ZILSUN MR:

- As slaapprobleme aanhou of versleg na ‘n kort behandelingstydperk (bv. 7-14 dae van behandeling), raadpleeg jou dokter.
- As jy geringe tot matige asemhalings- of borskasprobleme het.

- As jy medisyne gebruik wat opioïede genoem word (medisyne wat gebruik word om matige tot erge pyn te behandel, soos morfien en kodeïen) aangesien dit sedasie, asemhalingsprobleme, koma, en dood kan veroorsaak.
- Jy mag tydelike geheueverlies hê (anterograde amnesie) wanneer jy ZILSUN MR neem. Dit kan gewoonlik verhoed word as jy ‘n volle nag se slaap kry (7 tot 8 uur) voordat jy weer aktief is.
- Sommige persone wat ZILSUN MR neem, mag veranderinge in gedrag en denke ervaar (sien Moontlike newe-effekte). As jy of jou familie enige veranderinge in jou gedrag opmerk, of as jy enige ongewone of ontstellende gedagtes het, raadpleeg jou dokter onmiddellik.
- As daar ‘n moontlike risiko bestaan dat jy in ‘n gereelde patroon of gewoonte verval om ZILSUN MR te neem (afhanklikheid).
- As slaapprobleme terugkeer terwyl jy ZILSUN MR neem, raadpleeg jou dokter. Wanneer medisyne om te slaap, soos ZILSUN MR, vir meer as ‘n paar weke gebruik word, kan dit die doeltreffendheid verloor om jou te help om te slaap. Dit is bekend as 'toleransie".
- As jy geringe tot matige lewerprobleme het.
- As jy aan depressie (hartseer gevoel) of geestessiekte ly

Slaapwandel en ander slaapverwante gedrag:

Daar was sommige verslae van persone wat dinge doen terwyl hulle aan die slaap is wat hulle dan nie kan onthou wanneer hulle wakker word nie, nadat hulle medisyne om te slaap geneem het. Dit sluit bestuur terwyl jy aan die slaap is, slaapwandel, voorbereiding en eet van kos en om seks te beoefen, in. Alkohol, die neem van ‘n hoër dosis as wat voorgeskryf is en sommige medisyne vir depressie of angs, kan die kans verhoog dat hierdie ernstige effek plaasvind.

Afhanklikheid en misbruik:

Die gebruik van ZILSUN MR kan daartoe lei dat jy afhanklik raak om ZILSUN MR te neem. Raadpleeg asseblief jou dokter as jy opmerk dat jy nie kan of wil ophou om ZILSUN MR te neem nie of as jy voel dat jy meer dikwels ZILSUN MR moet neem as wat aan jou voorgeskryf is deur jou dokter.

Ander medisyne en ZILSUN MR

Lig jou gesondheidsorgverskaffer altyd in as jy ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Dit is omdat ZILSUN MR nie geskik mag wees om saam met ander medisyne te gebruik nie.
Jy moet veral jou dokter inlig as jy die volgende neem:

- Ander medisyne wat op die brein kan inwerk, soos: -
    - medisyne wat gebruik word om geestestoestande te behandel (antipsigotika, hipnotika, angswerende middels/kalmeermiddels, antidepressante) soos risperidoon, kwetiapien (Seroquel), olansapien, diasepam en fluoksetien.
    - medisyne wat gebruik word vir sterk pynverligting (narkotiese analgetika) soos morfien en kodeïen
    - medisyne wat gebruik word vir die behandeling van aanvalle/konvulsies (anti-epileptiese medisyne) soos karbamasepien en lamotrigien
    - medisyne wat gebruik word tydens toetse en chirurgiese operasies om sensasie in sekere areas van die liggaam te verdoof of om slaap te induseer; dit voorkom pyn en ongemak (narkosemiddels)
    - medisyne wat gebruik word om allergieë te behandel (antihistamiene wat lomerigheid veroorsaak) soos chloorfeniramen en klemastien.

Die kombinasie van hierdie medisyne met ZILSUN MR mag jou meer lomerig maak as wat jy behoort te wees. Bykomend mag jy eufories wees (verhoogde gevoel van behaaglikheid en welsyn) as narkotiese analgetika (morfien en opiate) gekombineer word met ZILSUN MR.

- Medisyne wat die normale eliminasie van zolpidem deur die lewer verlaag (fluvoksamien en siprofloksasien).
- Ketokonasool (gebruik om fungusinfeksies te behandel) verhoog die effek van ZILSUN MR.
- Rifampisien (gebruik om bakteriële infeksies te behandel), aangesien dit die effek van ZILSUN MR op slaap verlaag.

ZILSUN MR saam met voedsel, drinkgoed en alkohol

ZILSUN MR moet met of onmiddellik ná ‘n maaltyd geneem word.

Moenie alkohol gebruik terwyl jy ZILSUN MR neem nie.

Swangerskap, borsvoeding en vrugbaarheid

As jy swanger is of borsvoed, dink dat jy swanger mag wees of as jy beplan om ‘n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne neem.

As jy swanger is of jou baba borsvoed, moet jy nie ZILSUN MR neem nie (sien Wat jy moet weet voordat jy ZILSUN MR neem).

Bestuur en gebruik van masjinerie

ZILSUN MR 12,5 kan jou slaperig maak, daarom moet versigtigheid uitgeoefen word wanneer masjinerie hanteer of motorvoertuie bestuur word.

ZILSUN MR bevat laktose

As jy deur jou dokter ingelig is dat jy ‘n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat hierdie medisyne gebruik word.

3. Hoe om ZILSUN MR te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem ZILSUN MR altyd presies soos wat jou dokter of apteker jou ingelig het. Kontroleer met jou dokter of apteker as jy nie seker is nie.

Die normale dosis vir volwassenes jonger as 65 jaar is een tablet (12,5 mg) saans, onmiddellik voor slaaptyd of as jy reeds in die bed is.
ZILSUN MR moet slegs vir 4 dae tot 2 weke gebruik word, met ‘n maksimum, insluitend die afskaalperiode, van 4 weke.
Sluk die tablette heel in met ‘n vol glas water.

ZILSUN MR werk vinnig en moet daarom verkieslik onmiddellik voor slaaptyd geneem word. As jy sou verkies om vinnig aan die slaap te raak, moet ZILSUN MR met of onmiddellik ná ‘n maaltyd geneem word.

Jou dokter sal jou inlig oor hoe lank jou behandeling met ZILSUN MR sal duur. Moenie vroeg met die behandeling ophou nie, selfs as jy beter voel, tensy jou dokter jou aangeraai het om dit te doen.
As jy onder die indruk is dat die effek van ZILSUN MR te sterk of te swak is, lig jou dokter of apteker in.

As jy meer ZILSUN MR geneem het as wat jy behoort te neem

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum en lig hulle in oor hoeveel tablette jy geneem het.

As jy te veel ZILSUN MR geneem het, kan jou bewussyn aangetas wees, wat wissel van lomerigheid tot ligte koma.

As jy vergeet het om ZILSUN MR te neem

As jy vergeet het om die tablet te neem voordat jy bed toe gaan en jy laat in die nag of vroeg in die oggend wakker word, moet jy dit nie neem nie.

As jy onseker is oor wat jy moet doen, praat met jou dokter.

Moenie ‘n dubbele dosis neem om te vergoed vir die individuele dosisse wat jy vergeet het nie.

As jy ophou om ZILSUN MR te neem

Hou aan om ZILSUN MR te neem totdat jou dokter jou aansê om dit te stop. Moenie skielik ophou om ZILSUN MR te neem nie, maar lig jou dokter in as jy wil ophou om dit te neem. Dit mag vir jou dokter moontlik wees om die dosis te verlaag en jou tablette oor ‘n tydperk te staak.

As jy skielik ophou om ZILSUN MR te neem, kan jou slaapprobleme terugkeer en jy mag ‘n ‘’ontrekkingseffek’’ ervaar. As dit gebeur, kan jy sommige van die effekte hieronder gelys, ervaar.

Besoek jou dokter dadelik indien jy enige van die volgende effekte ervaar:

- ‘n angstige, rustelose, geïrriteerde of verwarde gevoel
- hoofpyn
- vinnige of onreëlmatige hartklop (palpitasies)
- nagmerries, sien of hoor dinge wat nie werklik is nie (hallusinasies)

- meer sensitief as normaalweg vir lig, geraas en aanraking
- verloor jou greep op die werklikheid
- voel verwyder van jou liggaam of voel 'marionetagtig'
- gevoelloosheid en tinteling in jou hande en voete
- seer spiere
- maagprobleme
- slaapprobleme keer erger terug as voorheen
- in seldsame gevalle kan aanvalle (toevalle) voorkom.

4. Moontlike newe-effekte

ZILSUN MR kan newe-effekte hê.

Nie alle newe-effekte wat vir ZILSUN MR aangemeld word, is in hierdie inligtingstuk ingesluit nie. Indien jou algemene gesondheid versleg of as jy enige ongunstige reaksies ervaar terwyl jy ZILSUN MR neem, moet jy asseblief jou gesondheidsorgvoorsiener raadpleeg vir advies.

Indien enige van die volgende gebeur, staak die gebruik van ZILSUN MR en lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal:

- Uitslag of gejeuk/galbulte.

- Swelling van die gesig, lippe, mond of keel, wat probleme met sluk of asemhaling kan veroorsaak (angio-edeem).

Hierdie is baie ernstige newe-effekte. As jy dit het, kon jy ‘n ernstige allergiese reaksie teen ZILSUN MR gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- Borskasongemak

- Veranderinge in die manier waarop jou hart klop, byvoorbeeld, as jy opmerk dat dit vinniger klop
- Slaapwandeling

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag benodig.

Lig jou dokter in as jy enige van die volgende opmerk:

Dikwelse newe-effekte:

- Griep met simptome soos hoë koors, seerkeel, loopneus, hoes en koue-koors
- Angstigheid, stadige spraak, denke en liggaamsbewegings, disoriëntasie, hoofpyn, oormatige slaperigheid, duiseligheid, probleme om te onthou, aandagversteuring
- Visuele versteurings
- Voel mislik, hardlywigheid
- Spierpyn, spierkrampe, nekpyn, rugpyn, moegheid.

Minder dikwelse newe-effekte:

- Maag- en intestinale infeksies
- Infeksies van die binne- en buite-oor
- Longinfeksies
- Infeksies van die mond, neus, sinus, keel en stembande (dikwels verwys na as ‘’verkoues’’),
- Depressie, sien en hoor dinge wat nie bestaan nie, verlies aan belangstelling, verwarring, ervaring van onwerklike en verwyderde gevoel, onderdrukte gemoed, verlies van inhibisie, voel oormatig gelukkig/selfversekerd, dikwelse gemoedsveranderinge, nagmerries, voel gespanne, voel onvas of duiselig as jy staan of loop,
- Ongewone velsensasies soos gevoelloosheid, tinteling, prikkeling, branderigheid of gevoel of iets oor jou vel kruip

- Onstandvastigheid wanneer jy loop, branderige sensasie, duiseligheid met verandering in postuur, bewerigheid
- Smaakversteurings
- Spierkrampe
- Oogrooiheid, dowwe visie, ander visuele probleme soos probleme om diepte te bepaal, ooginspanning
- ‘n Gevoel van duiseligheid of “dat jy in die rondte draai”, gesuis in die ore
- Hoes, droogheid in keel, keelirritasie
- Gooi op, abdominale ongemak, oormatige gas in die maag of ingewande, passeer dikwels stoelgange, sooibrand (suurprobleme)
- Velallergie, verrimpeling van die vel
- Gewrigspyn
- Pyn wanneer urine passeer word, pyn tydens maandstonde, swaar maandstondes, droogheid van die vulva en vagina
- Ongewone swakheid, dronkgevoel, griepagtige siekte, verlies aan energie, pyn, koors, hoë bloeddruk, verhoogde hartritme.
- Simptome verwant aan senuweestelsel is dikwels aangemeld by bejaarde pasiënte.

As enige van die newe-effekte ernstig raak, of as jy opmerk dat enige newe-effekte nie in hierdie inligtingstuk genoem word nie, moet jy asseblief jou dokter of apteker inlig.

Aanmelding van newe-effekte

Praat met jou dokter, apteker of verpleegkundige as jy newe-effekte ervaar. Jy kan ook newe-effekte by SAHPRA aanmeld *via* die “6.04 Adverse Drug Reaction Reporting Form”, wat aanlyn onder SAHPRA se publikasies beskikbaar is: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van ZILSUN MR te verskaf.

5. Hoe om ZILSUN MR te bewaar

Bewaar alle medisyne buite die bereik van kinders.

Bewaar by of benede 25 °C.

Moenie die stroke of stulpstroke uit die karton verwyder tot benodig vir gebruik nie.

Moenie ZILSUN MR ná die vervaldatum, soos aangedui op die karton, gebruik nie.

Moenie van ongebruikte medisyne in dreinering- of rioleringstelsels (bv. toilette) ontslae raak nie.

6. Inhoud van die verpakking en ander inligting

WAT ZILSUN MR BEVAT

Die aktiewe bestanddeel is zolpidemtartraat.

Elke filmbedekte twee-lagige tablet bevat:

Zolpidemtartraat USP 12,5 mg

Die ander besonderhede is: geel ysteroksied, hipromellose (methocel E-5LV premium), hipromellose 2910 (methocel E15 premium LV), hipromellose 2208 (methocel K4M CR premium), isopropielalkohol, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, Opadry II helder 85F19250, Opacode swart S-1-17823, natrium-styselglikolaat tipe A, wynsteensuur.

Bevat suiker: 80,687 mg laktosemonohidraat per tablet.

Hoe ZILSUN MR lyk en inhoud van die verpakking

ZILSUN MR is beskikbaar in ‘n pakkie van 30 tablette, elke Alu-PVC-stulpstrook, bedek met PVDC, of Alu/Alu-strook bevat 10 tablette, verpak in ‘n karton saam met ‘n inligtingstuk.

Houer van die registrasiesertifikaat

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14

Stormill, Uitbreiding 1

Roodepoort, 1724

Suid-Afrika

Hierdie inligtingstuk was laas hersien in