PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

ZOLNOREM 12,5 mg MR modified release tablets

Zolpidem tartrate

Contains sugar – lactose monohydrate: 120,85 mg

Read all of this leaflet carefully before you start taking ZOLNOREM 12,5 mg MR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ZOLNOREM 12,5 mg 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 ZOLNOREM 12,5 mg MR is and what it is used for

ZOLNOREM 12,5 mg MR contains zolpidem, one of a group of medicines called hypnotics. It works by acting on your brain to help you sleep.

ZOLNOREM 12,5 mg MR is used to treat temporary sleep problems in adults below the age of 65 years that is causing you severe distress or affecting your everyday life. This includes the following sleep problems:

- difficulty falling asleep
- waking in the middle of the night
- waking too early.

2. What you need to know before you take ZOLNOREM 12,5 mg MR

Do not take ZOLNOREM 12,5 mg MR:

- if you are hypersensitive (allergic) to zolpidem or any of the other ingredients of ZOLNOREM 12,5 mg MR (see section 6)
- 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 when you sleep)
- if you have breathing difficulties
- if you have serious liver problems

- if you are a child under 18 years of age or an adult over the age of 65 years
- if you are pregnant, intend to become pregnant or are breastfeeding.

Warnings and precautions

Take special care with ZOLNOREM 12,5 mg MR in the following cases:

- if you have a history of alcohol or drug abuse
- if you have mild to moderate breathing or chest problems
- if sleep problems persist or worsen after a short period of treatment, consult your doctor
- if sleep problems return while you are taking ZOLNOREM 12,5 mg MR, consult your doctor.

  When medicines for sleep, such as ZOLNOREM 12,5 mg MR are used for more than a few weeks,

  they may lose their effectiveness to help you sleep. This is known as “tolerance”
- if are unable to remember what you have done (amnesia) while taking ZOLNOREM 12,5 mg MR. This can usually be avoided if you get a full night’s sleep (7 - 8 hours) before being active again
- if you are sleepwalking, “sleep driving”, preparing and eating food, making phone calls or having sex, without remembering what you have done (amnesia) and you are not fully awake. Using alcohol and other medicine which is called CNS-depressants (i.e. medicine that slows down brain activity, which causes the muscles to relax and calm and soothes a person, like anxiety medication)

- some people taking ZOLNOREM 12,5 mg MR may have changes in behaviour and thinking. 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 or other mental illnesses
- you may lose the ability to drive, or less use of your limbs, if you have taken ZOLNOREM 12,5 mg MR 7-8 hours before you do activities that require being mentally awake, if you have taken a higher dose than what is recommended, or you have taken ZOLNOREM 12,5 mg MR with other products which acts on the central nervous system, alcohol or products which may increase the blood levels of ZOLNOREM 12,5 mg MR
- you may feel as if ZOLNOREM 12,5 mg MR is not working anymore after a few weeks of repeated use
- if you are at risk of becoming addicted to ZOLNOREM 12,5 mg MR as a result of previous drug/alcohol abuse or because of the dose of the tablet taken daily and the time period of use
- if you are using medicine containing opioids (i.e. pain medicine as prescribed by your doctor), please inform your doctor, as this may have severe consequences like breathing problems, coma or even death
- you may feel drowsy and not fully awake, which may lead to falls and result in injury
- if you have a heart condition called long QT-syndrome, as diagnosed by your doctor.

Other medicines and ZOLNOREM 12,5 mg MR

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

You should specifically tell your doctor if you take:

- other medicines that act on the brain in the treatment of mental conditions, such as:
  - antipsychotics e.g. chlorpromazine, fluphenazine, haloperidol
  - hypnotics/anxiolytics/sedatives, e.g. haloperidol, diazepam, lorazepam
  - antidepressants, e.g. imipramine, amitriptyline, fluoxetine, sertraline
  - medicines used for strong pain relief (narcotic analgesics), e.g. morphine, tramadol, fentanyl
  - medicines used for the treatment of seizures/convulsions (antiepileptic medicines), e.g. phenytoin, carbamazepine, sodium valproate
  - anaesthetics, e.g. propofol, lidocaine
  - medicines used in the treatment of allergies (sedative antihistamines), e.g. chlorpheniramine, promethazine.

  The combination of these medicines with ZOLNOREM 12,5 mg MR may make you drowsier than it should and lower your driving ability. In addition, you may be euphoric (feeling overly happy/confident) if narcotic analgesics are combined with ZOLNOREM 12,5 mg MR.
- medicine used to treat anxiety called benzodiazepines, and prescription pain medicine called opioids as this may cause breathing problems, coma or even death

- medicines that decrease the normal elimination of zolpidem by the liver, e.g. ketoconazole (antifungal)
- rifampicin (used to treat tuberculosis) as it may decrease the effect of ZOLNOREM 12,5 mg MR on sleep
- St. John's Wort (a herbal medicine taken for depression and anxiety) as it may decrease the effect of ZOLNOREM 12,5 mg MR on sleep
- ritonavir (antiretroviral medicine to treat HIV) as it may lead to extreme sedation and breathing problems
- fluvoxamine (used to treat other conditions including depression), may increase the effect of ZOLNOREM 12,5 mg MR
- ciprofloxacin (antibiotic to treat bacterial infections) may increase the effect of ZOLNOREM 12,5 mg MR.

ZOLNOREM 12,5 mg MR with food and drink alcohol

It is not recommended to take ZOLNOREM 12,5 mg MR in combination with alcohol as this may enhance the sedative (calming) effect of the product.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before using ZOLNOREM 12,5 mg MR.

If you are pregnant or breastfeeding your baby, you should not take ZOLNOREM 12,5 mg MR.

Driving and using machines

ZOLNOREM 12,5 mg MR may make you sleepy, dizzy, slow down your reaction time, make you feel drugged, have blurred or double vision, lower alertness and may affect your ability to drive a vehicle or operate machinery the morning after taking ZOLNOREM 12,5 mg MR. Try and get a full night of sleep (7-8 hours), to minimise the risk. Do not take alcohol or any other product which may affect your central nervous system when taking ZOLNOREM 12,5 mg MR.

It is not always possible to predict to what extent ZOLNOREM 12,5 mg MR 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 ZOLNOREM 12,5 mg MR affects you.

ZOLNOREM 12,5 mg MR contains lactose

ZOLNOREM 12,5 mg MR contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ZOLNOREM 12,5 mg MR.

3. How to take ZOLNOREM 12,5 mg MR

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

Always use ZOLNOREM 12,5 mg MR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults:

The usual adult (< 65 years) dose of ZOLNOREM 12,5 mg MR is one tablet (12,5 mg) at night, immediately before bedtime or in bed. ZOLNOREM 12,5 mg MR should be taken in a single intake and not be readministered during the same night.

ZOLNOREM 12,5 mg MR should only be used for a few days to 2 weeks with a maximum, including tapering off process, of 4 weeks.

Tablets should not be halved, crushed or chewed. Swallow the tablets whole with a full glass of water.

DO NOT TAKE MORE THAN THE DOSAGE RECOMMENDED BY YOUR DOCTOR.

Your doctor will tell you how long your treatment with ZOLNOREM 12,5 mg MR will last.

If you have the impression that the effect of ZOLNOREM 12,5 mg MR is too strong or too weak, tell your doctor or pharmacist.

If you take more than you should

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

Symptoms of overdose may include:

- your consciousness may be impaired, ranging from drowsiness to light coma to death.

Dependence and abuse

The use of ZOLNOREM 12,5 mg MR may lead to you becoming dependent on taking ZOLNOREM 12,5 mg MR. Please consult with your doctor if you notice that you cannot or do not want to stop taking ZOLNOREM 12,5 mg MR or if you feel that you need to take ZOLNOREM 12,5 mg MR more often than prescribed to you by your doctor.

If you forget to take ZOLNOREM 12,5 mg 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 ZOLNOREM 12,5 mg MR

Keep taking ZOLNOREM 12,5 mg MR until your doctor tells you to stop. Do not stop taking ZOLNOREM 12,5 mg 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 ZOLNOREM 12,5 mg 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
- sleep problems come back worse than before.

In rare cases fits (seizures) may also occur.

4. Possible side effects

ZOLNOREM 12,5 mg MR can have side effects.

Not all side effects reported for ZOLNOREM 12,5 mg MR are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using ZOLNOREM 12,5 mg MR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using ZOLNOREM 12,5 mg MR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZOLNOREM 12,5 mg 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:

- amnesia (memory loss)
- hallucination (seeing or hearing things that are not real), depersonalisation (your thoughts and feelings feel as though they belong to someone else)
- changes in the way your heart beats, for example, if you notice it is beating faster than normal, abnormal heart rhythms, chest pain, blood clot, heart attack, excess fluid in the lungs
- sleeping problems that get worse after taking this medicine
- suicide attempt, suicidal thoughts.

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:

- influenza (flu)

- anxiousness, confused/lack of full awareness of place, yourself and time, delayed or slowed mental and physical responses
- headache, drowsiness, dizziness, loss of attention, drugged feeling, dry mouth, light headedness, feeling overly happy/confident (euphoric), feeling sluggish
- abnormal vision, double vision
- sinusitis
- diarrhoea, nausea, constipation, stomach ache, indigestion, hiccups
- neck and back pain, muscle cramp, muscle pain
- bladder or kidney infection
- fatigue (extreme tiredness and weakness).

Less frequent side effects:

- respiratory tract infection (lower and upper), gastroenteritis, earache with discharge from the ear, shingles (a viral infection) (herpes simplex)
- anaemia, abnormal blood test results, low white blood cell count, thrombosis (blood clot)
- infection, middle ear infection, outer ear infection, abscess, shingles
- eating disorders, high blood glucose levels, thirst, gout, high cholesterol, puffy eyes, abnormal blood test results, higher appetite, weight loss

- depressed feeling, lack of interest or concern, binge eating, confusion, mood swings, nightmares, feeling very happy, mood swings, nightmares, stress symptoms, a sensation of impending threat, feelings of suffocation, and sensations of floating, spinning, or falling when falling asleep
- unsteadiness/tendency to fall, numbness, pins and needles, a lack of muscle control or coordination of voluntary movements, such as walking or picking up objects, burning sensation, dizziness when standing up, altered taste, muscle spasm, tremor, agitation, trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life, feeling detached, slurred speech, exaggerated mood swings (uncontrollable laughing or crying, or heightened irritability or temper), poor concentration, nervousness, abnormal thinking, memory loss/forgetfulness, illusion, leg cramps, migraine, sleeping (after daytime dosing), yawning, increased sweating, unhealthy pale appearance
- speech disorder, a state of near-unconsciousness or insensibility, unable to walk in the usual way, aggressive reaction, lack of interest, enthusiasm, or concern, lower sex drive, a belief of altered reality, memory loss, feeling that you're observing yourself from outside your body, a stabbing, burning, and often severe pain due to an irritated or damaged nerve, inflammation of a nerve, damage to the nerves, poor ability to adapt to your environment, panic attacks, weakened muscle movements, personality disorder, sleepwalking, involuntary muscle contractions, fainting, hot flushes, cramping rectal pain with a feeling that bowel needs to be emptied even if you already had complete bowel movement, increased or altered saliva, weakness, loss of movement, impotence (sexual dysfunction)

- eye redness, vision blurred, altered visual depth perception, eye irritation, eye pain, eye inflammation, conjunctivitis (pink eye), abnormal secretion of tears, seeing flashes of light, increased pressure in the eye, a problem with focusing, an open sore in the eye
- ringing or buzzing in the ears (tinnitus), sense of spinning (vertigo)
- rapid heartbeats, low blood pressure (including when getting up from a lying down), position conditions that affect blood flow and the blood vessels in the brain, high blood pressure and worsening of high blood pressure, artery or vein inflammation, varicose veins
- cough, dry throat, throat irritation, bronchitis (inflammation of the lining of bronchial tubes), laryngitis (throat infection), pneumonia (lung infection), difficulty or shallow breathing, nose bleeds
- vomiting, abdominal discomfort, flatulence, frequent bowel movements, acid reflux, inflammation of the small intestine, burping, inflammation of the stomach, haemorrhoids, obstruction in the intestines, bleeding from your rectum, tooth cavities
- blood disorders, including low blood cell count, abnormal lymph node size, unusual large red blood cells, purple-coloured spots and patches that occur on the skin, and in mucus membranes, including the lining of the mouth, porphyria (a rare hereditary blood disease)
- abnormal liver test results, liver infection
- skin rashes, hives, contact eczema, acne, light sensitivity, skin wrinkles, itching skin, forming of blisters, boils
- arthritis (joint inflammation), sciatica (compressed nerve in the lower back causing back, leg and hip pain), osteoarthritis, tendon inflammation, joint pain

- painful or difficult urination, bladder infection, passing more or less urine than is normal for you, inability to pass urine, frequent urination at night, kidney infection, kidney pain
- breast pain, menstrual changes or disorder, painful menstruation, inflammation or dryness of the vagina, breast tumour
- weakness, chest discomfort, feeling drunk, influenza-like illness, tiredness, pain, fever, swelling, falling, general discomfort, trauma, swelling in the face, hot flashes, restless legs, higher tolerance
- higher body temperature, higher heart rate, abnormal blood test results.

The following side effects have been reported but the frequency for them to occur is not known:

- sleepwalking, restlessness, aggression, delusion, anger, abnormal behaviour, dependence/addiction
- liver injury
- muscle weakness
- medicine tolerance.

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. T You can also report any side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ZOLNOREM 12,5 mg MR. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store ZOLNOREM 12,5 mg MR

Store all medicines out of reach of children.

Store at or below 30 °C in original container.

Keep the blisters in the carton until required for use.

Keep the HDPE bottle tightly closed.

Do not use after the expiry date stated on the carton.

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 ZOLNOREM 12,5 mg MR contains

The active substance is zolpidem tartrate.

ZOLNOREM 12,5 mg MR modified release tablet contains 12,5 mg zolpidem tartrate.

ZOLNOREM 12,5 mg MR contains sugar (lactose monohydrate).

The other ingredients are:

Cores: Colloidal silicon dioxide, FD and C blue aluminium lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, potassium bitartrate, sodium starch glycolate.

Film coating 12,5 mg: FD and C blue/indigo carmine aluminium lake, hypromellose, polyethylene glycol 400, titanium dioxide

What ZOLNOREM 12,5 mg MR looks like and contents of the pack

ZOLNOREM 12,5 mg MR are blue coloured, round, biconvex, film coated tablets debossed with “E62” on one side and “LU” on the other side.

ZOLNOREM 12,5 mg MR is packed into:
Round opaque white HDPE bottle with child resistant closure along with one silica gel sachet 1 g. Pack sizes of 30 or 100 film coated tablets.

PVC/aclar blister consisting of clear PVC/aclar film forming base material and hard tampered aluminium foil, one side bright, and other side dull and lacquered. Pack size of 3 x 10 film coated tablets.

Holder of Certificate of Registration

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