PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

ZOLPIHEXAL 10 (film-coated tablets)

Zolpidem tartrate

ZOLPIHEXAL 10 contains sugar (lactose monohydrate 57,16 mg).

Read all of this leaflet carefully before you start taking ZOLPIHEXAL 10

- 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.
- ZOLPIHEXAL 10 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 ZOLPIHEXAL 10 is and what it is used for
2. What you need to know before you take ZOLPIHEXAL 10
3. How to take ZOLPIHEXAL 10
4. Possible side effects
5. How to store ZOLPIHEXAL 10
6. Contents of the pack and other information.

1. What ZOLPIHEXAL 10 is and what it is used for

ZOLPIHEXAL 10 contains a medicine called zolpidem tartrate. This belongs to a group of medicines called hypnotics.

ZOLPIHEXAL 10 is a short-acting sedative medicine which is used for the short-term treatment of sleeplessness (insomnia).

2. What you need to know before you take ZOLPIHEXAL 10

Do not take ZOLPIHEXAL 10:

- If you are hypersensitive (allergic) to zolpidem tartrate or any of the other ingredients of ZOLPIHEXAL 10 (listed in section 6).
- If you have a muscle disorder called myasthenia gravis.
- If you have a breathing problem when you sleep.
- If you have acute and severe lung problems.
- If you have severe liver problems.
- If you are under the age of 18 years.
- If you are pregnant or are breastfeeding your baby.
- You have been told by a doctor that you have a mental illness (psychosis).

Warnings and precautions

Take special care with ZOLPIHEXAL 10:

- If your liver function is impaired.
- If you have any muscle disorder or disease.
- If you have a history of alcohol or drug abuse as the use of ZOLPIHEXAL 10 may lead to the development of abuse and/or physical and psychological dependence. Please use only as instructed by your doctor.
- If you have chronic asthma or respiratory problems.

- If you have symptoms of depression.
- If you have recently taken ZOLPIHEXAL 10 or other similar medicines for more than four weeks.
- If you are elderly.

Next-day psychomotor impairment (see also 'Driving and using machines')
The day after taking ZOLPIHEXAL 10, the risk of psychomotor impairment, including impaired driving ability may be increased if:

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

You should take the single intake immediately at bedtime and you should not take another dose during the same night.

Some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including ZOLPIHEXAL 10. However, it has not been established whether this is caused by the medicine or if there may be other reasons. If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice.

The effects for ZOLPIHEXAL 10 may be gradually reduced, following repeated use over a couple of weeks.

Use of ZOLPIHEXAL 10 may lead to the development of abuse and/or physical and psychological dependence. The risk of dependence is greater when ZOLPIHEXAL 10 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 health care provider if you have a mental disorder, or have abused or have been dependent on alcohol, substances or drugs.

ZOLPIHEXAL 10 can affect your ability to remember things (anterograde amnesia). This usually happens a few hours after taking ZOLPIHEXAL 10. In order to reduce the risk of this happening, you should ensure that you are able to sleep without interruptions for 7 – 8 hours after taking ZOLPIHEXAL 10.

Medicines like ZOLPIHEXAL 10 have been reported to cause restlessness, worsened sleeplessness (insomnia), agitation, irritability, aggression, delusion, anger, nightmares, hallucinations, psychosis (seeing and hearing things that do not exist), abnormal behaviour and other changes to your normal behaviour. If you experience any of these effects, you should speak to your doctor immediately, as your treatment with ZOLPIHEXAL 10 should be re-evaluated and may need to be withdrawn. These reactions are more likely to occur in the elderly.

Sleep walking and other associated behaviours such as “sleep driving”, preparing and eating food, making phone calls or having sex, with amnesia for the event (being unable to remember the event), have been reported in patients who had taken ZOLPIHEXAL 10 and were not fully awake. The use of alcohol and other medicines which work on the central nervous system (including strong painkillers called opioids, antidepressants, muscle relaxants, medicines for the treatment of epilepsy (fits)) appear to increase the risk of such behaviours, as does the use of ZOLPIHEXAL 10 at doses higher than those prescribed to you by your doctor. If you experience any of these behaviours, you should speak to your doctor immediately, as your

treatment with ZOLPIHEXAL 10 should be re-evaluated and may need to be withdrawn, as some of these behaviours can be very dangerous, e.g. sleep driving.

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

Children and adolescents

ZOLPIHEXAL 10 should not be given to children under the age of 18.

Other medicines and ZOLPIHEXAL 10

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

If you are taking ZOLPIHEXAL 10 with any of the following substances, drowsiness and next-day psychomotor impairment effects, including impaired driving ability, may be increased.

- Anti-depressants
- Anti-psychotics and other sedatives
- Anxiolytics (medicines for anxiety and stress)
- Anti-epileptic medication (phenytoin and carbamazepine)
- Anti-histamines with a sedative effect (e.g. coughs and colds medication)
- Anaesthetics
- Narcotic analgesics (strong pain killers)

While taking ZOLPIHEXAL 10 with antidepressants including bupropion, desipramine, fluoxetine, sertraline and venlafaxine, you may see things that are not real (hallucinations).

It is not recommended to take ZOLPIHEXAL 10 with fluvoxamine (anti-depressant), ciprofloxacin (used to treat bacterial infections) or St John's Wort (herbal medicine), as these medicines my increase or decrease the blood levels of ZOLPIHEXAL 10.

Risks from concomitant use with opioids:

Concomitant use of ZOLPIHEXAL 10 and opioids (strong painkillers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, combined use should only be considered when other treatment options are not possible. However, if your doctor does prescribe ZOLPIHEXAL 10 together with opioids the dosage and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of signs and symptoms stated above. Contact your doctor when experiencing such symptoms immediately.

The following medicines can make ZOLPIHEXAL 10 work less well:

- Rifampicin (an antibiotic) – for infections.
- Some medicines for epilepsy such as carbamazepine or phenytoin.

ZOLPIHEXAL 10 with food, drink and alcohol

The tablets should be swallowed whole with a glass of water.

This medication can be taken with or without meals.

Do not use excessive amounts of alcohol while taking ZOLPIHEXAL 10 because it can worsen the sedative effects.

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.

ZOLPIHEXAL 10 is contraindicated during pregnancy or breastfeeding.

Driving and using machines

ZOLPIHEXAL 10 has major influence on the ability to drive and use machines. Driving ability impairment and behaviours such as 'sleep-driving' have occurred with medicines containing zolpidem tartrate (the active ingredient in ZOLPIHEXAL 10) alone at therapeutic doses.

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

- You may feel drowsy, sleepy or dizzy.
- 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 ZOLPIHEXAL 10 and driving, operating any machinery or working at heights in order to minimise the above listed effects. The simultaneous use of alcohol with this medicine will enhance the sedative effects.

Lacotose

ZOLPIHEXAL 10 contains lactose monohydrate. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ZOLPIHEXAL 10.

ZOLPIHEXAL 10 contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

3. How to take ZOLPIHEXAL 10

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

Always take ZOLPIHEXAL 10 exactly as your doctor has told you. Check with your doctor if you are not sure.

If you have the impression that the effect of ZOLPIHEXAL 10 is too strong or too weak, talk to your doctor or pharmacist.

ZOLPIHEXAL 10 can be habit forming, thus will only be prescribed for the short-term (a few days to two weeks) for your sleeping disorder.

The usual adult starting dose is 10 mg (one tablet) in the evening before bedtime. The elderly might be more sensitive to this medicine and may have to start with 5 mg (half a tablet).

ZOLPIHEXAL 10 should not be used by children and adolescents below 18 years of age.

If you take more ZOLPIHEXAL 10 than you should

In the event of 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 that the doctor knows what the person has taken.

Taking too much ZOLPIHEXAL 10 can be very dangerous, especially together with other medicines or agents that affect the central nervous system (e.g. strong pain medication called opioids, antidepressants, alcohol). The following effects may happen in the case of overdose:

Feeling confused, feeling drowsy, losing consciousness, sleeping deeply, falling into a coma or death.

If you forget to take ZOLPIHEXAL 10

If you missed a dose, take the next dose the following evening. Do not take a double or larger dose to make up for the forgotten individual doses.

If you stop taking ZOLPIHEXAL 10

Do not just suddenly stop taking your ZOLPIHEXAL 10. Your doctor will gradually taper off your dosage when you have recovered and do not need the medicine anymore.

If you suddenly stop taking ZOLPIHEXAL 10 suddenly, your sleep problems may return and you may get a 'withdrawal effect'. If this happens you may experience the following effects:

- Feeling anxious, restless, tense, 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
- Fits (seizures).

If you experience these effects, speak to your doctor.

If ZOLPIHEXAL 10 is to be withdrawn, it is recommended that this should be done gradually. Your doctor will advise you on the best way to stop treatment with ZOLPIHEXAL 10 when required.

4. Possible side effects

ZOLPIHEXAL 10 can have side effects.

Not all side effects reported for ZOLPIHEXAL 10 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZOLPIHEXAL 10, please consult your health care provider for advice.

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

- You have an allergic reaction. These signs may include: an itchy, lumpy rash (hives) or nettle rash (urticaria), swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing.
- Poor memory (amnesia) while taking ZOLPIHEXAL 10 and strange behaviour during this time. This is more likely to affect you in the few hours after you take this medicine. By having 7-8 hours' sleep after taking ZOLPIHEXAL 10, this is less likely to cause you a problem.
- Sleeping problems that get worse after taking this medicine.
- Seeing or hearing things that are not real (hallucinations).
- Blurred eyesight, impaired vision or 'seeing double'.
- Falling, especially in the elderly.

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

Sleep-driving 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 and some medicines for depression or anxiety can increase the chance that this serious effect will happen. If you experience any of these behaviour changes, you should speak to your doctor.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Agitation
- Nightmares
- Depression
- Drowsiness or sleepiness
- Tiredness
- Headache
- Dizziness
- Diarrhoea
- Feeling sick (nausea) or being sick (vomiting)
- Abdominal pain
- Back pain
- Respiratory infection.

Less frequent side effects:

- Confusion
- Restlessness
- Irritability

- Aggressiveness
- Sleepwalking
- Feeling overly happy/confident (euphoric)
- Changes in libido
- Thinking and believing things that are not true/real (delusion)
- Becoming dependent on ZOLPIHEXAL 10 (sudden discontinuation of treatment may result in withdrawal effects and recurrence of sleeping difficulty)
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Tremor (uncontrollable shaking)
- Lack of concentration
- Speech problems
- Reduced alertness
- Slower and difficult breathing (respiratory depression)
- Changes in the amount of liver enzymes – shown up in the results of blood tests
- Yellow discolouration of the skin or eyes (jaundice), pain in the abdomen (stomach) or a bloated feeling, severe itching, pale or bloody stools, extreme weakness, nausea or loss of appetite. This could be caused by an infection or injury to the liver
- An illness where removal of bile from the liver is blocked (cholestasis). Signs include jaundice, rash or fever and the colour of your water (urine) becomes darker
- Changes in appetite or behaviour concerning appetite
- Excessive sweating
- Muscle pain
- Muscle spasms
- Muscle weakness
- Changes in the way you walk.

The frequency of the following side effects are unknown:

- Anger
- A feeling of being out of touch with reality and being unable to think or judge clearly (psychoses)
- Inappropriate behaviour
- The need to take increasingly higher doses of a medicine to gain the same effect.

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 ZOLPIHEXAL 10. Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store ZOLPIHEXAL 10

- Store in a dry place, at or below 25 ˚C.
- Protect from light.
- Do not remove the blisters from the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- 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 ZOLPIHEXAL 10 contains

Active ingredient: Each tablet contains zolpidem tartrate 10 mg.

Inactive ingredients: Colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, purified water, sodium starch glycollate type A and succinic acid.

Film-coating:

Opadry II white

Lactose monohydrate

Hydroxypropylmethyl-cellulose

Titanium dioxide

Macrogol 4000.

What ZOLPIHEXAL 10 looks like and contents of the pack

ZOLPIHEXAL 10 is a white, shining tablet, bi-convex, oblong, scored in half on one side.

Length: 10,0 ± 0,2 mm

Height: 2,8 ± 0,2 mm

ZOLPIHEXAL 10 is packed in PVC/Aluminium blister strips containing 10 tablets each.

3 (10) blister strips are packed into a carton i.e. 30 tablets per carton or

30 (10) blister strips are packed into a carton i.e. 300 tablets per carton.

Not all pack sizes will be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Not applicable.

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