1.3.2 PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

ZOLNOXS 10 mg TABLETS

Zolpidem tartrate 10 mg

Contains sugar: Lactose monohydrate 49,40 mg

Read all this leaflet carefully before you start taking ZOLNOXS 10 mg TABLETS

- 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.
- ZOLNOXS 10 mg TABLETS 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

6. Contents of the pack and other information

1. What ZOLNOXS 10 mg TABLETS is and what it is used for

ZOLNOXS 10 mg TABLETS contains the active substance zolpidem tartrate 10 mg.

ZOLNOXS 10 mg TABLETS 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 ZOLNOXS 10 mg TABLETS

Do not take ZOLNOXS 10 mg TABLETS:

- if you are hypersensitive (allergic) to zolpidem or any of the other ingredients of ZOLNOXS 10 mg TABLETS.
- 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 heart problems.
- if you have experienced complex sleep behaviour where you engage in activities while you are not fully awake or if you do not remember activities you have done while taking medicines to help you sleep (eszopiclone, zaleplon or zolpidem).
- if you have lung problems.
- if you have liver problems.
- if you have any psychotic illness.
- if you are a child under 18 years of age due to an incidence risk of adverse effects.
- if you are pregnant, intend to become pregnant or are breastfeeding your baby.

Warnings and precautions

Take special care with ZOLNOXS 10 mg TABLETS:

- if the cause of your sleeplessness has not been determined.
- if you still suffer from sleeplessness after 7 to 14 days of taking ZOLNOXS 10 mg TABLETS.
- if you have recently taken ZOLNOXS 10 mg TABLETS or other similar medicines for which should not exceed 4 weeks, including the tapering off process.
- if sleep problems return while you are taking ZOLNOXS 10 mg TABLETS, consult your doctor. When medicines for sleep such as ZOLNOXS 10 mg TABLETS 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 ZOLNOXS 10 mg TABLETS. This can usually be avoided if you get a full night sleep (8 hours) before being active again.
- you 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.
- if you may be at risk of getting into a regular pattern or habit of taking ZOLNOXS 10 mg TABLETS.
- if you are elderly.
- if you suffer from depression or have had another mental illness in the past.
- if you have a history of alcohol or drug abuse.
- if you feel sleepy even the next day, this may lead to falls and severe injuries.
- use with caution if you have mild to moderate breathing or chest problems.
- next day decreased mental alertness (see also Driving and using machines). The day after taking ZOLNOXS 10 mg TABLETS, the risk of decreased mental alertness,

including impaired driving ability may be increased if:

- you take ZOLNOXS 10 mg TABLETS less than 8 hours before performing activities that require your alertness.
- you take a higher dose than the recommended dose.
- you take ZOLNOXS 10 mg TABLETS while you are already taking another central nervous system depressant or another medicine that increases ZOLNOXS 10 mg TABLETS in your blood.

- due to the increased risks of suicidal thoughts and attempts and suicide in depressed or not depressed individuals.
- if you have experienced any complex sleep behaviours whilst using ZOLNOXS 10 mg TABLETS, as these can lead to serious injury or death (such as sleep walking, sleep driving). Discontinuation of the medication should be advised in such situations.

Other medicines and ZOLNOXS 10 mg TABLETS

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

Tell your doctor if you are taking any of the following medicines:

ZOLNOXS 10 mg TABLETS may increase the effect of the following medicines:

While taking ZOLNOXS 10 mg TABLETS with the following medicines, drowsiness and next day decreased mental alertness, including impaired driving ability, may be increased.

- Medicines for some mental health problems (antipsychotics)
- Medicines for sleep problems (hypnotics)
- Medicines to calm or reduce anxiety (anxiolytics)
- Medicines for depression including bupropion, desipramine, fluoxetine, sertraline

and venlafaxine, you may see things that are not real (hallucinations)

- Medicines for pain (narcotic analgesics)
- Medicine for epilepsy (carbamazepine)
- Medicines used for anaesthesia (propofol)
- Medicine for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines)

It is not recommended to take ZOLNOXS 10 mg TABLETS with fluvoxamine, ciprofloxacin or St John's Wort (a herbal medicine) used for mood swings and depression.

Risks from concomitant use with opioids

Concomitant use of ZOLNOXS 10 mg TABLETS 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. 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.

The following medicines can increase the chance of getting side effects when taking ZOLNOXS 10 mg TABLETS. To make this less likely, your doctor may decide to lower your dose of ZOLNOXS 10 mg TABLETS:

- Medicines to treat infections such as clarithromycin or erythromycin
- Medicine for fungal infections such as ketoconazole and itraconazole
- Medicine for HIV infections such as ritonavir (protease inhibitor)

The following medicines can make ZOLNOXS 10 mg TABLETS work less well:

- Medicine for epilepsy such as carbamazepine, phenobarbitone or phenytoin
- Medicine used to treat infections like TB such as rifampicin

ZOLNOXS 10 mg TABLETS with alcohol

Do not drink alcohol while you are taking ZOLNOXS 10 mg TABLETS. Alcohol can increase the effects of ZOLNOXS 10 mg TABLETS and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

Pregnancy, breastfeeding and fertility

You should not take ZOLNOXS 10 mg TABLETS if you are pregnant or breastfeeding your baby. Taking ZOLNOXS 10 mg TABLETS during pregnancy may harm your baby. You should not breastfeed if you are taking ZOLNOXS 10 mg TABLETS because small amounts may pass into mother's milk.

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 ZOLNOXS 10 mg TABLETS.

Driving and using machines

ZOLNOXS 10 mg TABLETS has a major influence on the ability to drive and use machines. Since adverse reactions such as sedation, drowsiness, dizziness and vertigo may occur in patients receiving ZOLNOXS 10 mg TABLETS, you should not drive, use machinery or perform any tasks that require concentration.

It is not always possible to predict to what extent ZOLNOXS 10 mg TABLETS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZOLNOXS 10 mg TABLETS affects them.

ZOLNOXS 10 mg TABLETS contains lactose

ZOLNOXS 10 mg TABLETS contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take ZOLNOXS 10 mg TABLETS.

3. How to take ZOLNOXS 10 mg TABLETS

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

Always take ZOLNOXS 10 mg TABLETS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Males

The usual dose is one tablet (10 mg) at night, immediately before bedtime.

Women

If you are a woman, the usual dose is half a tablet (5 mg) immediately before bedtime.

Elderly patients and patients with liver problems

If you are over 65 years of age or have liver problems, the usual dose is half a tablet (5 mg). A total dose of 10 mg should not be exceeded in these populations.

Children

You should not use this medicine if you are younger than 18 years of age.

ZOLNOXS 10 mg TABLETS should only be used for a few days to 2 weeks with a maximum including the tapering off process of 4 weeks.

Swallow the tablet with a full glass of water.

Your doctor will tell you how long your treatment with ZOLNOXS 10 mg TABLETS will last.
If you have the impression that the effect of ZOLNOXS 10 mg TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you take more ZOLNOXS 10 mg TABLETS 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.
If you take too much ZOLNOXS 10 mg TABLETS, your consciousness may be impaired, ranging from drowsiness to a light coma.

Dependence and abuse

The use of ZOLNOXS 10 mg TABLETS may lead to you becoming dependent on taking ZOLNOXS 10 mg TABLETS. Please consult with your doctor if you notice that you cannot or do not want to stop taking ZOLNOXS 10 mg TABLETS or if you feel that you need to take ZOLNOXS 10 mg TABLETS more often than prescribed to you by your doctor.

If you forget to take ZOLNOXS 10 mg TABLETS

ZOLNOXS 10 mg TABLETS must only be taken at bedtime. If you forget to take your tablet at bedtime, then you should not take it at any other time, otherwise you may feel drowsy, dizzy and confused during the day. Do not take a double dose to make up for a forgotten individual doses.

If you stop taking ZOLNOXS 10 mg TABLETS

Keep taking ZOLNOXS 10 mg TABLETS until your doctor tells you to stop. Do not stop

taking ZOLNOXS 10 mg TABLETS 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 ZOLNOXS 10 mg TABLETS 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
- Fits (seizures) may also occur.

4. Possible side effects

ZOLNOXS 10 mg TABLETS can have side effects.

Not all side effects reported for ZOLNOXS 10 mg TABLETS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking ZOLNOXS 10 mg TABLETS, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking ZOLNOXS 10 mg TABLETS 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 ZOLNOXS 10 mg TABLETS. 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:

- liver problems with symptoms such as skin and eyes that appear yellowish (jaundice), dark urine, stomach pain and swelling, swelling in the legs and ankles and a tendency to bruise easily,
- respiratory depression (slower breathing),
- suicidal thoughts and behaviours,
- falls and injuries.

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:

- hallucinations (seeing or hearing things that are not real),

  agitation, nightmares (bad dreams), depression (low mood),
- somnolence (sleepiness), headache, dizziness, exacerbated insomnia (worsening of

sleeplessness), anterograde amnesia (loss of memory),

- diarrhoea, nausea (feeling sick), vomiting, abdominal pain (stomach ache),
- back pain,
- upper and lower respiratory tract infection (infection of the nose, throat or chest),
- fatigue (tiredness).

Less frequent side effects:

- changes in appetite or behaviour concerning appetite,
- confusional state, irritability, restlessness, aggression, delusion (thinking things that are not true), unrealistic feeling of well-being (euphoric mood), anger, psychosis (being unable to think or judge clearly), abnormal behaviour, somnambulism (sleep walking), dependence, libido disorder (sex drive disorder), insomnia (inability to sleep),
- numbness and tingling in the skin (paraesthesia), tremor, lack of concentration, speech disorder, low level of consciousness, day time drowsiness, vertigo (dizziness), light-headedness,
- vision abnormalities (inability to see properly), blurred vision, diplopia (double vision),
- liver enzymes elevated (changes in amount of liver enzymes shown in blood tests),
- increased sweating,
- muscle pain, muscle spasms, muscular weakness,
- gait disturbance (problem whilst walking), medicine tolerance (needing more medicine to get the same effect), fall, malaise (general feeling of being unwell).

Side effects with frequency unknown:

- Sleep behaviours which include: sleepwalking, sleep driving and engaging in other activities while not fully awake.

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: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of ZOLNOXS 10 mg TABLETS.

5. How to store ZOLNOXS 10 mg TABLETS

Store all medicines out of reach of children.

Store in a dry place at or below 25℃.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

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

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 ZOLNOXS 10 mg TABLETS contains

The active substance in ZOLNOXS 10 mg TABLETS is zolpidem tartrate 10 mg.

The other ingredients are lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch.

Coating: HMPC 2910/Hypromellose, Macrogol/PEG, titanium dioxide.

What ZOLNOXS 10 mg TABLETS looks like and contents of the pack

White to off-white capsule-shaped film coated tablet with a breakline on one side.

Blister strips composed of clear, transparent PVC backed with aluminium foil containing 10 tablets each. Blister strips are packed into cardboard cartons containing either 30 tablets (3 blister strips of 10 tablets each) or 100 tablets (10 blister strips of 10 tablets each).
Grey, cylindrical, plastic securitainer containing 30 or 100 tablets held down by white, plastic ullage filler with collapsible prongs. The container is sealed with a white snap-on polyethylene cap.

Not all packs and pack sizes are necessarily marketed.

HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

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Woodlands Drive

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Hotline: 0800 122 912 (South Africa)

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Access to the corresponding Professional Information SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://ww.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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