BIO ZOPICLONE 7,5

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

BIO ZOPICLONE 7,5 film-coated tablets
Zopiclone
Contains sugar (mannitol 53,70 mg and sucrose 0,45 mg per tablet).

Read all of this leaflet carefully before you start taking BIO ZOPICLONE 7,5
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- BIO ZOPICLONE 7,5 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 BIO ZOPICLONE 7,5 is and what it is used for
2. What you need to know before you take BIO ZOPICLONE 7,5
3. How to take BIO ZOPICLONE 7,5
4. Possible side effects
5. How to store BIO ZOPICLONE 7,5
6. Contents of the pack and other information

1. What BIO ZOPICLONE 7,5 is and what it is used for
Zopiclone belongs to the group of medicines called central nervous system (CNS) depressants (medicines that slow down the nervous system). It works by acting on your brain to help you sleep.
BIO ZOPICLONE 7,5 is used for the short-term treatment of insomnia (trouble in sleeping) in adults, when the problem is severe or causing too much stress.

2. What you need to know before you take BIO ZOPICLONE 7,5
Do not take BIO ZOPICLONE 7,5:
- If you are hypersensitive (allergic) to zopiclone or any of the other ingredients of BIO ZOPICLONE 7,5 (listed in section 6).
- If your lungs do not work properly (respiratory failure)
- If your liver function is severely impaired.
- If you are suffering from sleep apnoea (temporary stopping of breathing during sleep).
- If you have ever experienced sleepwalking or other unusual behaviour (while not being fully awake after taking BIO ZOPICLONE 7,5).
- If you have emphysema, asthma, bronchitis or other lung disease.
- If you have myastenia gravis (disorder characterised by muscle weakness).
- If you are pregnant or breastfeeding a baby.
- If you have suffered from central nervous system depression or have been in a coma.
- If you are under the age of 18 years.

Warnings and precautions
Take special care with BIO ZOPICLONE 7,5:
Tell your doctor:
- If you have recently taken BIO ZOPICLONE 7,5 or other similar medicines for more than four weeks.
- If you have any liver problems (see also 'Do not take this medicine 'and' tell your doctor if:' section above).
- If you have any kidney problems, your doctor may need to give you a lower dose of BIO ZOPICLONE 7,5.
- If you have a history of alcohol or drug abuse.
- If you are suffering from depression or anxiety.
- If you are elderly, your doctor may need to give you a lower dose of BIO ZOPICLONE 7,5.
- BIO ZOPICLONE 7,5 may sometimes provoke seizures in patients with a disease called epilepsy. You may experience seizures if you stop taking BIO ZOPICLONE 7,5 suddenly.
- If lack of sleep in not treated after 7-10 days of treatment, there might be other conditions.
- Before taking BIO ZOPICLONE 7,5 it is important to make sure that you can have at least 7 to 8 hours of sleep to help reduce the risk of some side effects.
- If BIO ZOPICLONE 7,5 is taken with strong pain medicines called opioids, it can cause drowsiness, problems in breathing, coma and death.
- BIO ZOPICLONE 7,5 and opioids should only be used together, when other treatment options are not enough.

Sleep-Driving and other strange behaviour
BIO ZOPICLONE 7,5 may cause sleepwalking or other unusual behaviour (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake. The next morning, you may not remember that you did anything during the night. These activities may occur whether or not you drink alcohol or take other medicines that make you drowsy with BIO ZOPICLONE 7,5.

Dependence
BIO ZOPICLONE 7,5 may be habit-forming (causing mental or physical dependence), especially when taken for a long time or in high doses.
Some signs of dependence are:
- A strong desire or need to continue taking BIO ZOPICLONE 7,5
- A need to increase the dose to receive the same effect of the medicine.

Withdrawal
Withdrawal symptoms such as irritability, nervousness, trouble in sleeping, trembling or shaking, occurring after the medicine is stopped.
If you think you may have become mentally or physically dependent on this medicine, check with your doctor. Do not stop taking it suddenly. Treatment should be gradually withdrawn.

Suicidality
Risk of suicides and suicide attempts may be increased in patients treated with benzodiazepines or hypnotics, including BIO ZOPICLONE 7,5. If you develop thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

Short-term memory loss (Anterograde amnesia)
BIO ZOPICLONE 7,5 tablets may cause a short-term memory loss (anterograde amnesia). This occurs particularly a few hours after taking the medicine. In order to reduce this risk, make sure you will be able to have an uninterrupted sleep of 8 hours.

Children and adolescents
BIO ZOPICLONE 7,5 should not be used in children and adolescents less than 18 years (see section 4.3).

Other medicines and BIO ZOPICLONE 7,5
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

BIO ZOPICLONE 7,5 may increase the effect of the following medicines:
- Medicines for mental problems (antipsychotics)
- Medicines for depression
- Medicines for epilepsy (anticonvulsants)
- Other sleeping tablets or medicine for tension or anxiety (hypnotics)
- Medicine for colds, sinus problems, hay fever or allergies such as chlorphenamine or promethazine (antihistamines)
- Some medicines for moderate to severe pain (narcotic analgesics) such as codeine, methadone, morphine, oxycodone, pethidine or tramadol

The following medicines can increase the chance of you getting side effects when taken with BIO ZOPICLONE 7,5. To make this less likely, your doctor may decide to lower your dose of BIO ZOPICLONE 7,5:
- Some antibiotics such as clarithromycin or erythromycin
- Some medicines for fungal infections such as ketoconazole and itraconazole
- Some medicines used for the treatment of HIV called protease inhibitors such as ritonavir

The following medicines may reduce the effect of BIO ZOPICLONE 7,5:
- Rifampicin (medicine to treat TB)
- Some medicines for epilepsy such as carbamazepine, phenobarbital and phenytoin
- St John's wort (herbal medicine to treat depression)

BIO ZOPICLONE 7,5 with food, drink and alcohol
The tablets should be swallowed whole with a glass of water before going to bed. It is recommended that you take this medicine with food to lessen the chance of stomach upset (nausea and vomiting), unless your doctor has advised you to take it on an empty stomach.
Do not drink alcohol while you are taking BIO ZOPICLONE 7,5. Alcohol can increase the effects of BIO ZOPICLONE 7,5 and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

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 healthcare provider for advice before taking BIO ZOPICLONE 7,5.
BIO ZOPICLONE 7,5 must not be used if you are pregnant or if you are planning to get pregnant.

Do not take BIO ZOPICLONE 7,5 during pregnancy or during labour because it may be harmful to your baby.

Do not breastfeed if you are taking BIO ZOPICLONE 7,5. This is because small amounts may pass into mother's milk.

Driving and using machines
BIO ZOPICLONE 7,5 may cause some people to become drowsy, dizzy, light-headed, clumsy or less alert than they are normally. Do not drive or operate any machinery or do anything else that could be dangerous if you are not alert.

It is not always possible to predict to what extent BIO ZOPICLONE 7,5 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 BIO ZOPICLONE 7,5 affects you.

BIO ZOPICLONE 7,5 contains sugar (sucrose and mannitol)
BIO ZOPICLONE 7,5 contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take BIO ZOPICLONE 7,5.
BIO ZOPICLONE 7,5 contains mannitol and may have a mild laxative effect.

3. How to take BIO ZOPICLONE 7,5
Do not share medicines prescribed for you with any other person.
Always take BIO ZOPICLONE 7,5 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you have the impression that the effect of BIO ZOPICLONE 7,5 is too strong or too weak, tell your doctor or pharmacist, do not increase the dose.
- Treatment should be started with the lowest recommended dose.
- **The maximum dose should not be exceeded.**
- The treatment period should be as short as possible and should not be longer than 4 weeks.
- Do not take BIO ZOPICLONE 7,5 when your schedule does not permit you to get a full night's sleep (7-8 hours).

The dose will be different for different patients:
- *Adults:* One tablet to be taken by mouth at bedtime.
- *For elderly patients:* Half to one tablet to be taken by mouth at bedtime.

The dose can be increased to one tablet at bedtime.
- *For patients suffering from liver or kidney impairment:*

Half of a tablet to be taken by mouth at bedtime.

If you take more BIO ZOPICLONE 7,5 than you should
In the event of an 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 the doctor knows what you have taken.

Taking too much BIO ZOPICLONE 7,5 can be very dangerous.
The following effects may happen:
- Feeling drowsy, confused, sleeping deeply and possibly falling into a coma.
- Floppy muscles (hypotonia).
- Feeling dizzy, light-headed or faint. These effects are due to low blood pressure.
- Falling over or losing your balance (ataxia).
- Shallow breathing or difficulty breathing (respiratory depression).
- Feeling restless.
- Hallucinating.

If you forget to take BIO ZOPICLONE 7,5
If you missed a dose, skip the missed dose and go back to your regular dosing schedule.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking BIO ZOPICLONE 7,5
Keep taking BIO ZOPICLONE 7,5 until your doctor tells you to stop. Do not stop taking BIO ZOPICLONE 7,5 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 BIO ZOPICLONE 7,5 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, shaky, irritable, agitated, confused or having panic attacks
- Sweating
- Headache
- Faster heartbeat or uneven heartbeat (palpitations)
- A lower level of awareness and problems with focusing or concentrating
- Nightmares, seeing or hearing things that are not real (hallucinations)
- Being more sensitive to light, noise and touch than normal
- Relaxed grip on reality
- Numbness and tingling in your hands and feet
- Aching muscles
- Stomach problems
- In rare cases fits (seizures) may also occur.

4. Possible side effects
BIO ZOPICLONE 7,5 can have side effects.
Not all side effects reported for BIO ZOPICLONE 7,5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIO ZOPICLONE 7,5, please consult your health care provider for advice.

If any of the following happens, stop taking BIO ZOPICLONE 7,5 and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

These are all very serious side effects. If you have them, you may have had a serious reaction to BIO ZOPICLONE 7,5. 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:
- severe and life-threatening skin rashes (Stevens-Johnson Syndrome/ toxic epidermal necrolysis)
- skin rash with irregular red spots (erythema multiforme)
- poor memory since taking BIO ZOPICLONE 7,5 (amnesia). By having 7-8 hours of uninterrupted sleep after taking BIO ZOPICLONE 7,5, this is less likely to cause you a problem.
- seeing or hearing things that are not real (hallucinations)
- falling, especially in the elderly
- thinking things that are not true (delusions)
- feeling low or sad (depressed mood)
- abnormal behaviour
- difficulty breathing

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
- a bitter or metallic taste in your mouth or a dry mouth
- feeling drowsy or sleepy

Less frequent side effects:
- nightmares
- agitation
- aggressiveness
- confusion
- headache
- dizziness
- nausea and vomiting, diarrhoea
- skin rash, hives
- increased liver enzymes as shown in laboratory tests
- chills, sweating, tiredness

Side effects with unknown frequency:
- clumsiness or unsteadiness
- restlessness
- feeling angry
- sleepwalking (see "Take special care with BIO ZOPICLONE 7,5")
- withdrawal syndrome (see "If you stop taking BIO ZOPICLONE 7,5")
- paraesthesia (numbness/tingling of the skin)
- difficulty paying attention
- dysarthria (slowed, slurred speech)
- poor memory
- double vision
- indigestion
- muscular weakness
- slower breathing (respiratory depression)
- light-headedness or having problems with your coordination
- injury due to lack of coordination

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 BIO ZOPICLONE 7,5.

5. How to store BIO ZOPICLONE 7,5
- Store all medicines out of reach of children.
- Store in a cool dry place at or below 25 °C.
- Protect from light.
- For HDPE Container: Keep well closed.
- Do not remove blisters from outer container until required for use.
- 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 BIO ZOPICLONE 7,5 contains
The active substance is zopiclone 7,5 mg.
The other ingredients are Core: magnesium stearate, maize starch, mannitol, microcrystalline cellulose, povidone.
Film-coating: glycerine, hypromellose, polysorbate 80, sucrose and the colourant titanium dioxide.

What BIO ZOPICLONE 7,5 looks like and contents of the pack
White, almost white film coated oblong, bulged tablets with breaking notch on both sides.
BIO ZOPICLONE 7,5 is packed as 30 tablets in white HDPE container with white HDPE cap or in white opaque PVC/PVDC/Aluminium blister strips, kept in an outer carton, each strip containing ten tablets.

Holder of Certificate of Registration
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BIO ZOPICLONE 7,5

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:

S5

BIO ZOPICLONE 7,5 filmbedekte tablette
Zopikloon
Bevat suiker (mannitol 53,70 mg en sukrose 0,45 mg per tablet).

Lees die hele inligtingspamflet noukeurig deur voordat jy BIO ZOPICLONE 7,5 begin neem

- Bewaar hierdie inligtingspamflet. Jy sal dit dalk weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- BIO ZOPICLONE 7,5 is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet

1. Wat BIO ZOPICLONE 7,5 is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy BIO ZOPICLONE 7,5 neem
3. Hoe om BIO ZOPICLONE 7,5 te neem
4. Moontlike newe-effekte
5. Hoe om BIO ZOPICLONE 7,5 te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat BIO ZOPICLONE 7,5 is en waarvoor dit gebruik word

Zopikloon behoort aan die groep medisyne wat sentrale senuweestelsel (SNS) onderdrukkers genoem word (medisyne wat die senuweestelsel onderdruk). Dit werk deur op jou brein in te werk om jou te help slaap.
BIO ZOPICLONE 7,5 word gebruik vir die korttermynbehandeling van slapeloosheid (slaapprobleme) by volwassenes, wanneer die probleem ernstig is of te veel spanning veroorsaak.

2. Wat jy moet weet voordat jy BIO ZOPICLONE 7,5 neem

Moenie BIO ZOPICLONE 7,5 neem:

- indien jy hipersensitief (allergies) is vir zopikloon of enige van die ander bestanddele van BIO ZOPICLONE 7,5 (gelys in afdeling 6) is nie.
- indien jou longe nie behoorlik werk nie (respiratoriese versaking)
- indien jou lewerfunksie ernstig verswak is.
- indien jy aan slaapapnee ly (tydelike ophou van asemhaling tydens slaap).
- indien jy al ooit slaaploop of ander ongewone gedrag ervaar het (terwyl jy nie heeltemal wakker was nadat jy BIO ZOPICLONE 7,5 geneem het nie).
- indien jy emfiseem, asma, brongitis of ander longsiektes het.
- indien jy myastenia gravis het (afwyking wat gekenmerk word deur spierswakheid).
- indien jy swanger is of 'n baba borsvoed.
- indien jy aan sentrale senuweestelsel depressie gely het of in 'n koma was.
- indien jy onder die ouderdom van 18 jaar is.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met BIO ZOPICLONE 7,5:

Vertel jou dokter:

- indien jy onlangs BIO ZOPICLONE 7,5 of ander soortgelyke medisyne vir meer as vier weke geneem het.
- indien jy enige lewerprobleme het (sien ook 'Moenie hierdie medisyne neem nie' en 'vertel jou dokter as:' afdeling hierbo).
- indien jy enige nierprobleme het, sal jou dokter dalk vir jou 'n laer dosis BIO ZOPICLONE 7,5 moet gee.
- indien jy 'n geskiedenis van alkohol- of dwelmmisbruik het.
- indien jy aan depressie of angs ly.
- indien jy bejaard is, sal jou dokter dalk vir jou 'n laer dosis BIO ZOPICLONE 7,5 moet gee.
- BIO ZOPICLONE 7,5 kan soms aanvalle uitlok by pasiënte met 'n siekte genaamd epilepsie. Jy kan aanvalle ervaar as jy skielik ophou om BIO ZOPICLONE 7,5 te neem.
- Indien gebrek aan slaap nie verbeter na 7-10 dae van behandeling nie, kan daar ander onderliggende toestande wees.
- Voordat jy BIO ZOPICLONE 7,5 neem, is dit belangrik om seker te maak dat jy ten minste 7 tot 8 uur se slaap kan hê om die risiko van sommige newe-effekte te help verminder.
- indien BIO ZOPICLONE 7,5 saam met sterk pynmedisyne genaamd opioïede geneem word, kan dit tot lomerigheid lei, probleme met asemhaling, koma en dood veroorsaak.
- BIO ZOPICLONE 7,5 en opioïede moet slegs saam gebruik word, wanneer ander behandelingsopsies nie voldoende is nie.

Slaap-bestuur en ander vreemde gedrag

BIO ZOPICLONE 7,5 kan slaaploop of ander ongewone gedrag veroorsaak (soos bestuur, eet, 'n oproep maak, of seks hê, ens.) terwyl jy nie heeltemal wakker is nie. Die volgende oggend kan jy nie onthou dat jy enigiets gedurende die nag gedoen het nie. Hierdie aktiwiteite kan voorkom of jy alkohol drink of nie of ander medisyne neem wat jou lomerig maak met BIO ZOPICLONE 7,5.

Afhanklikheid

BIO ZOPICLONE 7,5 kan gewoontevormend wees (veroorsaak geestelike of fisiese afhanklikheid), veral wanneer dit vir 'n lang tyd of in hoë dosisse geneem word.
Sommige tekens van afhanklikheid is:

- 'n Sterk begeerte of behoefte om voort te gaan om BIO ZOPICLONE 7,5 te neem
- 'n Behoefte om die dosis te verhoog om dieselfde effek van die medisyne te kry.

Ontrekking

Onttrekkingsimptome soos prikkelbaarheid, senuweeagtigheid, slaapprobleme, siddering of bewing wat voorkom nadat die medisyne gestaak is.
Indien jy dink jy het dalk geestelik of fisies afhanklik geword van hierdie medisyne, raadpleeg jou dokter. Moenie skielik ophou om dit te neem nie. Behandeling moet geleidelik gestaak word.

Selfmoord

Die risiko van selfmoord en selfmoordpogings kan verhoog word by pasiënte wat met bensodiasepiene of hipnotika behandel word, insluitend BIO ZOPICLONE 7,5. As jy enige tyd gedagtes ontwikkel om jouself te beseer of dood te maak, kontak jou dokter of gaan dadelik na 'n hospitaal.

Korttermyn geheueverlies (Anterograde amnesie)

BIO ZOPICLONE 7,5-tablette kan korttermyngeheueverlies (anterograde geheueverlies) veroorsaak. Dit gebeur veral 'n paar uur nadat die medisyne geneem is. Om hierdie risiko te verminder, maak seker dat jy 'n ononderbroke slaap van 8 uur sal kan hê.

Kinders en adolessente

BIO ZOPICLONE 7,5 moet nie by kinders en adolessente jonger as 18 jaar gebruik word nie (sien afdeling 4.3).

Ander medisyne en BIO ZOPICLONE 7,5

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

BIO ZOPICLONE 7,5 kan die effek van die volgende medisyne verhoog:

- Medisyne vir geestesprobleme (antipsigotika)
- Medisyne vir depressie
- Medisyne vir epilepsie (antikonvulsante)
- Ander slaaptablette of medisyne vir spanning of angs (hipnotika)
- Medisyne vir verkoue, sinusprobleme, hooikoors of allergieë soos chloorfenamien of prometasien (antihistamiene)
- Sommige medisyne vir matige tot erge pyn (narkotiese pynstillers) soos kodeïen, metadoon, morfien, oksikodoon, petidien of tramadol

Die volgende medisyne kan die kans verhoog dat jy newe-effekte kry wanneer dit saam met BIO ZOPICLONE 7,5 geneem word. Om dit minder waarskynlik te maak, kan jou dokter besluit om jou dosis BIO ZOPICLONE 7,5 te verlaag:

- Sommige antibiotika soos klaritromisien of eritromisien
- Sommige medisyne vir swaminfeksies soos ketokonasool en itrakonasool
- Sommige medisyne wat vir die behandeling van MIV gebruik word, genaamd protease-inhibeerders soos ritonavir

Die volgende medisyne kan die effek van BIO ZOPICLONE 7,5 verminder:

- Rifampisien (medisyne om TB te behandel)
- Sommige medisyne vir epilepsie soos karbamasepien, fenobarbital en fenitoïen
- St John's wort (kruiemedisyne om depressie te behandel)

BIO ZOPICLONE 7,5 met kos, drank en alkohol

Die tablette moet heel ingesluk word met 'n glas water voor jy gaan slaap. Dit word aanbeveel dat jy hierdie medisyne saam met kos neem om die kans op maagongesteldheid (naarheid en braking) te verminder, tensy jou dokter jou aangeraai het om dit op 'n leë maag te neem.

Moenie alkohol drink terwyl jy BIO ZOPICLONE 7,5 neem nie. Alkohol kan die uitwerking van BIO ZOPICLONE 7,5 verhoog en jou baie diep laat slaap sodat jy nie behoorlik asemhaal nie of sukkel om wakker te word.

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of borsvoed dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy BIO ZOPICLONE 7,5 neem.
BIO ZOPICLONE 7,5 moet nie gebruik word as jy swanger is of as jy beplan om swanger te raak nie.

Moenie BIO ZOPICLONE 7,5 tydens swangerskap of tydens kraam neem nie, want dit kan skadelik vir jou baba wees. Moenie borsvoed as jy BIO ZOPICLONE 7,5 neem nie. Dit is omdat klein hoeveelhede in moedersmelk kan uitskei.

Bestuur en gebruik van masjiene

BIO ZOPICLONE 7,5 kan veroorsaak dat sommige mense lomerig, duiselig, lighoofdig, lomp of minder wakker word as wat hulle normaalweg is. Moenie bestuur of enige masjinerie gebruik of enigiets anders doen wat gevaarlik kan wees as jy nie wakker is nie.

Dit is nie altyd moontlik om te voorspel tot watter mate BIO ZOPICLONE 7,5 met jou daaglikse aktiwiteite kan inmeng nie. Jy moet seker maak dat jy nie by bogenoemde aktiwiteite betrokke raak voordat jy bewus is van die mate waarin BIO ZOPICLONE 7,5 jou affekteer nie.

BIO ZOPICLONE 7,5 bevat suiker (sukrose en mannitol)

BIO ZOPICLONE 7,5 bevat sukrose. Pasiënte met seldsame oorerflike probleme van fruktose-intoleransie, glukose-galaktose-wanabsorpsie of sukrase-isomaltase-ontoereikendheid moet nie BIO ZOPICLONE 7,5 neem nie. BIO ZOPICLONE 7,5 bevat mannitol en kan 'n ligte lakseermiddel effek hê.

3. Hoe om BIO ZOPICLONE 7,5 te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd BIO ZOPICLONE 7,5 presies soos jou dokter of apteker vir jou gesê het. Gaan na jou dokter of apteker as jy nie seker is nie. As jy die indruk het dat die effek van BIO ZOPICLONE 7,5 te sterk of te swak is, vertel jou dokter of apteker, moenie die dosis verhoog nie.

- Behandeling moet met die laagste aanbevole dosis begin word.
- **Die maksimum dosis moet nie oorskry word nie.**
- Die behandelingsperiode moet so kort as moontlik wees en moet nie langer as 4 weke wees nie.
- Moenie BIO ZOPICLONE 7,5 neem wanneer jou skedule jou nie toelaat om 'n volle nag se slaap te kry nie (7-8 uur).

Die dosis sal verskil vir verskillende pasiënte:

- *Volwassenes:* Een tablet moet voor slaaptyd per mond geneem word.
- *Vir bejaarde pasiënte:* Halwe tot een tablet wat voor slaaptyd per mond geneem moet word.

Die dosis kan verhoog word tot een tablet voor slaaptyd.

- *Vir pasiënte wat aan lewer- of nierversaking ly:*

Die helfte van 'n tablet moet tydens slaaptyd per mond geneem word.

As jy meer BIO ZOPICLONE 7,5 neem as wat jy moet

In die geval van 'n oordosis raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Neem hierdie inligtingspamflet en enige oorblywende tablette saam met jou, sodat die dokter weet wat jy geneem het.

Om te veel BIO ZOPICLONE 7,5 te neem kan baie gevaarlik wees. Die volgende effekte kan voorkom:

- Voel lomerig, verward, slaap diep en verval moontlik in 'n koma.
- Verswakte spiere (hipotonie).
- Voel duiselig, lighoofdig of flou. Hierdie effekte is as gevolg van lae bloeddruk.
- Omval of jou balans verloor (ataksie).
- Vlak asemhaling of moeilike asemhaling (respiratoriese onderdrukking).
- Rustelose gevoel.
- Hallusinasies.

Indien jy vergeet om BIO ZOPICLONE 7,5 te neem

Indien jy 'n dosis gemis het, slaan die gemiste dosis oor en gaan terug na jou gereelde doseringskedule.
Moenie 'n dubbeldosis neem om vergete individuele dosisse in te haal nie.

Indien jy ophou om BIO ZOPICLONE 7,5 te neem

Hou aan om BIO ZOPICLONE 7,5 te neem totdat jou dokter vir jou sê om op te hou. Moenie skielik ophou om BIO ZOPICLONE 7,5 te neem nie, maar vertel jou dokter as jy wil ophou. Jou dokter sal jou dosis moet verlaag en jou tablette oor 'n tydperk moet staak.

Indien jy skielik ophou om BIO ZOPICLONE 7,5 te neem, kan jou slaapprobleme terugkom en jy kan 'n 'onttrekkingseffek' kry.
Indien dit gebeur, kan jy van die effekte wat hieronder gelys word, kry. Gaan dadelik na 'n dokter as jy enige van die volgende effekte kry:

- Voel angstig, bewerig, geïrriteerd, opgewonde, verward of kry paniekaanvalle
- Sweet
- Hoofpyn
- Vinniger hartklop of ongelyke hartklop (kloppings)
- 'n Laer vlak van bewustheid en probleme met fokus of konsentrasie
- Nagmerries, dinge sien of hoor wat nie werklik is nie (hallusinasies)
- Om meer sensitief te wees vir lig, geraas en aanraking as normaalweg
- Verminderde greep op die werklikheid
- Gevoelloosheid en tinteling in jou hande en voete
- Pynlike spiere
- Maagprobleme
- In seldsame gevalle kan aanvalle (stuipe) ook voorkom.

4. Moontlike newe-effekte

BIO ZOPICLONE 7,5 kan newe-effekte hê.
Nie alle newe-effekte wat vir BIO ZOPICLONE 7,5 aangemeld is, is in hierdie inligtingspamflet ingesluit nie. Indien jy algemene gesondheid versleg of as jy enige nadelige effekte ervaar terwyl jy BIO ZOPICLONE 7,5 neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om BIO ZOPICLONE 7,5 te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,

Hierdie is alles baie ernstige newe-effekte. As jy dit het, het jy dalk 'n ernstige reaksie op BIO ZOPICLONE 7,5 gehad. Jy benodig dalk dringende mediese aandag of hospitalisasie.

Vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- ernstige en lewensgevaarlike veluitslag (Stevens-Johnson-sindroom/ toksiese epidermale nekrolise)
- veluitslag met onreëlmatige rooi kolle (erythema multiforme)
- swak geheue sedert die neem van BIO ZOPICLONE 7,5 (amnesie). Deur 7-8 uur se ononderbroke slaap te hê nadat jy BIO ZOPICLONE 7,5 geneem het, is dit minder geneig om jou 'n probleem te veroorsaak.
- dinge sien of hoor wat nie werklik is nie (hallusinasies)
- val, veral by bejaardes
- dinge te dink wat nie waar is nie (delusies)
- neerslagtig of hartseer voel (bedrukte bui)
- abnormale gedrag
- moeilike asemhaling

Hierdie is alles ernstige newe-effekte. Jy benodig dalk dringende mediese hulp.

Vertel jou dokter as jy enige van die volgende opmerk:

Gereelde newe-effekte

- 'n bitter of metaalagtige smaak in jou mond of 'n droë mond
- lomerig of slaperig voel

Minder gereelde newe-effekte:

- nagmerries
- agitasie
- aggressiwiteit
- verwarring
- hoofpyn
- duiseligheid
- naarheid en braking, diarree
- veluitslag, korwe
- verhoogde lewerensieme soos getoon in laboratoriumtoetse
- kouekoors, sweet, moegheid

Newe-effekte met onbekende voorkoms:

- lompheid of onbestendigheid
- rusteloosheid
- kwaad voel
- slaapwandeling (sien "Wees veral versigtig met BIO ZOPICLONE 7,5")
- onttrekkingsindroom (sien "As jy ophou om BIO ZOPICLONE 7,5 te neem")
- parestesie (gevoelloosheid/tinteling van die vel)
- probleme om aandag te gee
- disartrie (vertraagde, onduidelike spraak)
- swak geheue
- dubbelvisie
- slegte spysvertering
- spierswakheid
- stadiger asemhaling (respiratoriese onderdrukking)
- lighoofdig of probleme met jou koördinasie
- besering as gevolg van gebrek aan koördinasie

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingspamflet genoem word nie, stel asseblief jou dokter of apteker in kennis

Aanmelding van newe-effekte

As jy newe-effekte kry, praat met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA aanmeld via die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van BIO ZOPICLONE 7,5 te verskaf.

5. Hoe om BIO ZOPICLONE 7,5 te bewaar

- Bewaar alle medisyne buite bereik van kinders.
- Bewaar in 'n koel, droë plek teen of benede 25 °C.
- Beskerm teen lig.
- Vir HDPE-houer: Hou dig toe.
- Moenie stulpstroke uit die buitenste houer verwyder totdat dit benodig word vir gebruik nie.
- Moenie jou medisyne in die badkamer bewaar nie.
- Moet nie die tablette na die vervaldatum wat op die houer, stulpstrook of etiket gedruk is, gebruik nie.
- Gee alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting

Wat BIO ZOPICLONE 7,5 bevat

Die aktiewe bestanddeel is zopikloon 7,5 mg.
Die ander bestanddele is: Kern: magnesiumstearaat, mieliestysel, mannitol, mikrokristallyne sellulose, povidoon.
Filmbedekking: gliserien, hipromellose, polisorbaat 80, sukrose en die kleurstof titaandioksied.

Hoe lyk BIO ZOPICLONE 7,5 en die inhoud van die verpakking

Wit, amper wit filmbedekte langwerpige, bultende tablette met breekkerf aan beide kante.
BIO ZOPICLONE 7,5 word verpak as 30 tablette in 'n wit HDPE-houer met 'n wit HDPE-dop of in wit ondeursigtige PVC/PVDC/Aluminium stulpstroke, verpak in 'n buitekarton, elke strook bevat tien tablette.

Houer van die Registrasiesertifikaat:

Biotech Laboratories (Edms) Bpk.
Blok K Wes, Central Park
400 16de Weg, Randjespark
Midrand, 1685
Suid-Afrika
Tel: (011) 848 3053

Laaste datum van hersiening van hierdie inligtingspamflet

06 Desember 2022

Registrasienommer:

BIO ZOPICLONE 7,5: 42/2.2/0537