

ZOPICLONE 7.5mg TABLETS



Pharmaco
code
location

Read this leaflet carefully BEFORE you start taking Zopiclone Tablets because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

WHAT IS IN THIS LEAFLET

1. What Zopiclone Tablets are and what they are used for
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1. WHAT ZOPICLONE TABLETS ARE AND WHAT THEY ARE USED FOR

Zopiclone is one of a group of medicines called hypnotics (sleeping tablets). These tablets can be used for both temporary and longer lasting sleep problems (insomnia). It should help you to sleep, without leaving you drowsy the next day. However, Zopiclone is not meant to be used every day for long periods of time. If you need any further information on your condition, please ask your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZOPICLONE TABLETS

Do not take Zopiclone if:

- you are allergic to Zopiclone or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- you suffer from myasthenia gravis (a condition where the muscles easily tire and become weak)
- you suffer from sleep apnoea
- you suffer from respiratory failure (your lungs do not work properly)
- you have severe liver problems
- you are under 18 years of age. The safety and efficacy of Zopiclone in children and adolescents aged less than 18 years have not been established.
- you have ever experienced sleepwalking or other unusual behaviour (such as driving, eating, making a phone call or having sex etc.) while not being fully awake after taking Zopiclone.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Zopiclone.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zopiclone if:

- you have ever had a mental disorder (including depression and personality disorder)
- you have ever been, or are currently being treated for drug or alcohol abuse
- you have any kidney or liver problems - your doctor may need to give you a lower dose
- you feel you will not be able to stop taking Zopiclone or any medication used to treat your sleep problems
- you have recently taken Zopiclone or other similar medication for more than 4 weeks
- you are elderly as there may be a greater risk of side effects
- you suffer from mild breathing problems (your doctor will decide if you should take Zopiclone) (see also 'Do not take Zopiclone if:')

Before taking Zopiclone Tablets, ensure that you can have an uninterrupted sleep of 7 to 8 hours, to help reduce the side effect of poor memory (see section 4).

Drowsiness, difficulties breathing, coma and death may occur if Zopiclone is taken together with opioids.

Please tell your doctor about all opioid medicines you are taking and follow your doctor's dosage recommendations closely. Some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including this medicine. 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. Zopiclone and opioids should only be used concomitantly, when other treatment options are inadequate. Please tell your doctor about all opioid medicines you are taking and follow your doctor's dosage recommendations closely.

Use of Zopiclone may lead to the development of abuse and /or physical and psychological dependence. The risk of dependence increases with dose and duration of treatment and is greater when Zopiclone 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 healthcare provider if you have ever had a mental disorder, or have abused or have been dependent on alcohol, substance or drugs.

Zopiclone 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 Zopiclone.

If you experience any of the above, stop the treatment with Zopiclone immediately and contact your doctor or healthcare provider.

Children and adolescents

Do not give this medication to children or adolescents under 18 years of age as the safety has not yet been established in this group.

Other medicines and Zopiclone

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines including medicines obtained without a prescription. If you are taking any other medicines, these medicines may change the way Zopiclone Tablets work.

Example:

- another treatment to help you sleep, to calm or reduce anxiety (hypnotics)
- treatment for schizophrenia and psychotic disorders (antipsychotics)
- treatment for depression
- treatment for epilepsy such as carbamazepine, phenobarbital or phenytoin
- strong pain killers such as codeine, morphine, methadone, oxycodone, pethidine, tramadol or diamorphine
- sedative antihistamines (to treat hay fever, allergies, skin irritation or vomiting) such as chlorpheniramine or promethazine
- rifampicin, clarithromycin or erythromycin (antibiotics to treat infections)
- some medicines for fungal infections such as ketoconazole and itraconazole
- St. John's Wort (a herbal medicine) for mood swings and depression
- ritonavir (a protease inhibitor) for HIV infections
- medicines used in surgery (anaesthetics)
- treatment for pain, cough, diarrhoea and shortness of breath (opioids)

If you have to go to a doctor, dentist or hospital, for any reason, tell them that you are taking Zopiclone Tablets.

Zopiclone with alcohol

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If used during pregnancy there is a risk that the baby is affected. Some studies have shown that there may be an increased risk of cleft lip and palate (sometimes called "harelip") in the newborn baby. Reduced fetal movement and fetal heart rate variability may occur after taking Zopiclone during the second and/or third trimester of pregnancy. Do not take this medicine during the last 3 months of pregnancy or during labour because it may be harmful to your baby. If taken in late pregnancy, the baby may have muscle weakness, low body temperature, difficulty feeding, breathing difficulties and show withdrawal symptoms such as agitation or shaking after birth because of physical dependence. In this case the newborn should be closely monitored during the postnatal period.

Breast-feeding

Do not take Zopiclone if you are breast-feeding or planning to breast-feed. This is because small amounts may pass into mother's milk. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

Driving and using machines

Like other medicines used for sleep problems, Zopiclone can cause slowing of your normal brain function (central nervous system depression). The risk of psychomotor impairment including driving ability is increased if:

- You take Zopiclone within 12 hours of preforming activities that require mental alertness
- You take higher than the recommended dose of Zopiclone
- You take Zopiclone while already taking another central nervous system depressant or another medicine that increases the levels of Zopiclone in your blood, or while drinking alcohol.

On the day after taking Zopiclone 7.5mg Tablets, do not drive or use machinery or tools if you feel sleepy, dizzy or confused.

For more information about possible side effects, which could affect your driving, see section 4 of this leaflet.

Zopiclone contains Lactose

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE ZOPICLONE TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The number of tablets you need to take will depend on your condition. Zopiclone Tablets should be swallowed whole without sucking, chewing or crushing, with a small glass of water before you go to bed.

The recommended dose is:

Adults

The usual adult dose is one Zopiclone Tablet (7.5mg) per day.

Elderly

The usual starting dose is 3.75mg (½ a tablet).

Patients with liver or kidney problems

The usual starting dose is 3.75mg (½ a tablet).

Patients with Respiratory Insufficiency

A reduced dosage is recommended

Use in Children and adolescents

Zopiclone Tablets are NOT recommended for children.

Your treatment will usually be for less than 4 weeks, and the doctor may reduce your dose near the end of your course. If you take Zopiclone longer than this, the medicine may not work as well, you may become dependent and you may have withdrawal symptoms when you stop.

If you have the impression that the effect of Zopiclone Tablets is too strong or too weak talk to your doctor or pharmacist.

Blood Tests:

Zopiclone can change the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly. If you are going to have a blood test, it is important to tell your doctor that you are taking Zopiclone

If you take more of this medicine than you should

If you have taken more Zopiclone Tablets than you should, or a child swallows any tablets, go to your nearest casualty department immediately. Take the medicine pack with you so the doctor knows what you have taken. Taking too much Zopiclone can be very dangerous. The symptoms of overdose include feeling drowsy, shallow breathing or difficulties breathing and difficulty in controlling movements.

If you forget to take your medicine

Zopiclone must only be taken before going to bed. If you forget to take a dose just take the next tablet at the usual time. DO NOT take two doses at the same time.

If you stop taking this medicine

It is important to continue taking the tablets for as long as your doctor tells you to. You should not stop taking your tablets suddenly without advice from your doctor. Do not change the dose of your medicine unless you have spoken with your doctor. Your doctor will need to lower your dose before stopping your treatment to help prevent any withdrawal effects and to help prevent return of your sleep problems (rebound insomnia). Stopping treatment with Zopiclone Tablets is unlikely to be associated with withdrawal effects when duration of treatment is limited to 4 weeks.

Withdrawal symptoms

Some patients may experience withdrawal symptoms when they stop taking this medicine. See a doctor immediately if you get any of the following symptoms:

- Headaches
- Muscle pain
- Sweating
- Stomach problems
- Relaxed grip on reality
- Faster or uneven heartbeat
- Numbness and tingling sensation in hands and feet
- Increased sensitivity to light, noise and physical contact
- Feeling of watching yourself (Depersonalization)
- A lower level of awareness and problems with focusing or concentrating
- Nightmares, seeing or hearing things that are not real (hallucinations)
- Feeling anxious, shaky, irritable, agitated, confused or having panic attacks
- Epileptic Seizures

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience the following rare, but very serious side effects, stop taking Zopiclone Tablets and tell your doctor immediately or contact the casualty department at your nearest hospital:

An allergic reaction: skin rash, swelling of the face, lips, tongue or throat or difficulty breathing or swallowing or light headedness, lack of co-ordination, delusions (thinking things that are

not true), depression (feeling low or sad), and respiratory depression (slower breathing) including these signs and symptoms.

Tell your doctor or pharmacist if any of the following side effects occur or worsen:

The following side effects have been reported:

Common (may affect up to 1 in 10 people)

- Mild bitter taste or metallic taste in the mouth
- Dry mouth
- Sleepiness or drowsiness (somnia) (residual))

Uncommon (may affect up to 1 in 100 people)

- Headache
- Nightmares
- Nausea (feeling sick)
- Vomiting (being sick)
- Dizziness
- Tiredness (physically or mentally) (Fatigue)
- Agitation

Rare (may affect up to 1 in 1,000 people)

- Poor memory since taking Zopiclone
- Confusion, aggression
- Libido disorder
- Hallucinations - seeing or hearing things that are not real
- Mood changes such as irritability or aggressiveness
- Fall, especially the elderly
- Itchy, lumpy rash (urticaria), severe itching of the skin (pruritus)
- Difficult or laboured breathing (dyspnoea)

Very Rare (may affect up to 1 in 10,000 people)

- Change in blood tests (increase of liver enzymes in the blood)

Not known (frequency cannot be estimated from the available data)

- Restlessness
- Delusion
- Anger
- Muscular weakness
- Loss of co-ordination
- Loss of memory
- Double vision
- Unusual skin sensations such as numbness, burning, tingling or prickling (paraesthesia)
- Difficulty concentrating or paying attention
- Disrupted normal speech, moving unsteadily or staggering (symptom of ataxia)
- Indigestion (Dyspepsia)
- Light-headedness
- Becoming dependent on Zopiclone
- Sleepwalking

Sleep-driving and other strange behaviour

There have been some reports of people doing things while asleep that they do not remember when waking up after taking a sleep medicine. This includes sleep-driving and sleepwalking. Alcohol and some medicines for depression or anxiety can increase the chance that this serious effect will happen.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZOPICLONE TABLETS

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use this medicine after the expiry date printed on the blister and carton. The expiry date refers to the last day of that month. Do not store above 25°C. Store in the original package. Do not keep the tablets if your doctor decides to stop treatment. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF PACK AND OTHER INFORMATION

What your medicine contains

The active ingredient is zopiclone. Each tablet contains 7.5mg of zopiclone. The inactive ingredients are calcium hydrogen phosphate dihydrate, lactose monohydrate, maize starch, sodium starch, glycollate type A, magnesium stearate, hydroxypropylmethyl-cellulose, propylene glycol, titanium dioxide and talc.

What your medicine looks like and contents of the pack

Zopiclone 7.5mg Tablets are white coloured, circular, film-coated tablets with a score line on one side.

The tablets are available in a pack size of 28.

Marketing Authorisation Holder

Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland.

Manufacturer responsible for batch release

Kent Pharmaceuticals Limited, Crowbridge Road, Ashford, Kent, TN24 0GR, U.K. Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

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