

accord

Package leaflet: Information for the patient

Zopiclone 3.75mg and 7.5mg Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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 side effects, talk to your doctor, pharmacist or nurse. 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
2. What you need to know before you take Zopiclone tablets
3. How to take Zopiclone tablets
4. Possible side effects
5. How to store Zopiclone tablets
6. Contents of the pack and other information

1. What Zopiclone tablets are and what they are used for

Zopiclone tablets are sleeping pills (hypnotics) which work by acting on the brain to cause sleepiness. They may be used for short term treatment of difficulties in falling asleep, waking up at night or early in the morning or difficulty in sleeping caused by events, situations or mental illness, which is severe, disabling or causing great distress.

Do not use long-term. Treatment should be as short as possible, because the risk of dependence increases with the duration of treatment.

2. What you need to know before you take Zopiclone tablets

Do not take Zopiclone tablets if you:

- are **allergic** to zopiclone or any of the other ingredients in the tablet (see section 6). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- have **severe liver problems**
- suffer from **breathing problems whilst sleeping** (Sleep Apnoea Syndrome)
- suffer from **severe muscle weakness** (myasthenia gravis)
- have **severe breathing problems**
- are **under the age of 18**. The safety and efficacy has not been established.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Zopiclone tablets if you:

- have depression or have had another mental illness in the past
- have any liver problems (see also Do not take this medicine and tell your doctor if: section above). Your doctor may need to give you a lower dose of Zopiclone tablets
- have any kidney problems. Your doctor may need to give you a lower dose of Zopiclone tablets
- suffer from mild breathing problems, your doctor will decide if you should receive Zopiclone tablets (see also Do not take' section above)
- have a history of alcohol or drug abuse
- have been told by a doctor that you have a personality disorder
- have recently taken Zopiclone tablets or other similar medicines for more than four weeks
- do not feel you will ever be able to stop taking Zopiclone tablets or other medicines used to treat sleep problems

Drowsiness, difficulties breathing, coma and death may occur if Zopiclone tablets are taken together with opioids. Zopiclone tablets and opioids should only be taken 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.

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.

Continued top of next column

Before taking Zopiclone tablets, it is important to make sure that you can have at least 7 to 8 hours of uninterrupted sleep to help reduce the risk of some side effects (see section 4 – Possible side effects).

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

Use of Zopiclone tablets 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 tablets are 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, substances or drugs.

Children and adolescents

Zopiclone tablets should not be used in children.

Other medicines and Zopiclone tablets

Tell your doctor or pharmacist if you are taking or have recently taken, or might take any other medicines.

The following medicines may **increase the sedating** effect of Zopiclone tablets:

- Medicines to treat mental illness (antipsychotics)
- Medicines to treat depression
- Medicines used to treat epilepsy
- Anaesthetics (used during surgery)
- Medicines to calm or reduce anxiety or for sleep problems (hypnotics)
- Medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines) such as chlorphenamine or promethazine
- Concomitant use of Zopiclone tablets and opioids (strong pain killers, 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, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Zopiclone tablets together with opioids the dose 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 dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.
- 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 Zopiclone tablets. To make this less likely, your doctor may decide to lower your dose of Zopiclone tablets:

- Some antibiotics such as clarithromycin or erythromycin
- Some medicines for fungal infections such as ketoconazole and itraconazole
- Ritonavir (a protease inhibitor) - for HIV infections

The following medicines can make Zopiclone tablets work less well:

- Some medicines for epilepsy such as carbamazepine, phenobarbital or phenytoin
- Rifampicin (an antibiotic) - for infections
- St John's Wort (a herbal medicine) - for mood swings and depression

Zopiclone tablets with alcohol

Alcohol should not be consumed when taking Zopiclone tablets, as the sedating effect may be increased.

Pregnancy, breast-feeding and fertility

Pregnancy

Use of Zopiclone tablets is not recommended during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice. 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 foetal movement and foetal heart rate variability may occur after taking Zopiclone tablets during the second and/or third trimester of pregnancy. If Zopiclone tablets are taken at the end of pregnancy or during labour, your baby may show muscle weakness, a drop in body temperature, difficulty feeding and breathing problems (respiratory depression). If this medicine is taken regularly in late pregnancy, your baby may develop physical dependence and may be at risk of developing withdrawal symptoms such as agitation or shaking. In this case the newborn should be closely monitored during the postnatal period.

Continued over page

Breast-feeding

Do not take Zopiclone tablets 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 performing 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 levels of Zopiclone in your blood, or while drinking alcohol.

Do not engage in hazardous activities requiring complete mental alertness such as driving or operating machinery after taking Zopiclone, and in particular during the 12 hours after taking your medicine.

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

Zopiclone tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Zopiclone tablets

Always take Zopiclone tablets exactly as your doctor has told you. You should check with your doctor or pharmacist when you are not sure.

The tablet should be taken together with liquid immediately before going to bed.

The recommended dose is:

- Adults: 7.5mg before going to bed.
- Elderly: A lower dose of 3.75mg may be used initially. This dose may be increased to 7.5mg.
- Patients with liver or lung problems: Usually a lower dose of 3.75mg at night. Up to 7.5mg can be given.
- Patients with kidney problems: Treatment should be started with a dose of 3.75mg.
- Children: not recommended.

How long should you take Zopiclone tablets?

Treatment should be as short as possible. In general, it should not exceed 4 weeks including the withdrawal period. Your doctor will choose a withdrawal regime based on your individual needs.

If you take more Zopiclone tablets than you should

If you, (or someone else) swallow a lot of the tablets at the same time, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Do not go unaccompanied to seek medical help. If an overdose has been taken, you may become increasingly drowsy very quickly, with high doses probably leading to a coma.

If you forget to take Zopiclone tablets

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Never take two doses together. Take the remaining doses at the correct time.

If you stop taking Zopiclone tablets

- Treatment should be gradually withdrawn as the symptoms you are treated for will return more intensely than before (rebound insomnia), also anxiety, restlessness and mood changes may occur. These effects will disappear in time.
- If you have become physically dependent to Zopiclone tablets, sudden withdrawal of treatment will lead to side effects such as headaches, muscle pain, extreme anxiety, tension, restlessness, confusion, irritability. In severe cases other effects may appear, such as hypersensitivity to light, noise and physical contact, abnormally acute hearing and painful sensitivity to sound, hallucinations, numbness and tingling of the extremities, derealisation (feeling the world around you is not real), depersonalisation (feeling your mind is becoming separated from your body) or epileptic seizures (violent fitting or shaking).

4. Possible side effects

Like all medicines, Zopiclone tablets can cause side effects, although not everybody gets them.

Stop taking Zopiclone and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Tell your doctor as soon as possible if you have any of the following side effects:

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

- Poor memory since taking Zopiclone (amnesia). By having 7-8 hours of uninterrupted sleep after taking Zopiclone, this is less likely to cause you a problem.
- Seeing or hearing things that are not real (hallucinations)
- Falling, especially in the elderly

Not known (frequency cannot be estimated from available data)

- Thinking things that are not true (delusions)
- Feeling low or sad (depressed mood)

Tell your doctor or pharmacist if any of the following side effects get serious or lasts

longer than a few days:

Common (may affect up to 1 in 10 people)

- A mild bitter or metallic taste in your mouth or a dry mouth
- Feeling drowsy or sleepy

Uncommon (may affect up to 1 in 100 people)

- Feeling sick (nausea) or being sick (vomiting)
- Feeling dizzy or sleepy
- Headache
- Nightmares
- Feeling physically or mentally tired
- Agitation

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

- Feeling confused
- Itchy, lumpy rash (urticaria)
- Feeling irritable or aggressive
- Reduced sex drive
- Difficulty breathing or being short of breath

Not known (frequency cannot be estimated from available data)

- Feeling restless or angry
- Feeling light headed or having problems with your coordination
- Double vision
- Moving unsteadily or staggering
- Muscular weakness
- Indigestion
- Becoming dependent on Zopiclone
- Slower breathing (respiratory depression)
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Mental problems such as poor memory
- Difficulty paying attention, drowsiness
- Disrupted normal speech

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 sleep walking. 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, pharmacist or nurse. 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 out of the sight and reach of children.

Store below 25°C in a dry place and protected from light.

Do not take Zopiclone after the expiry date which is stated on the product packaging.

The expiry date refers to the last day of that month.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Zopiclone tablets contain

- The active substance (the ingredient that makes the medicine work) is zopiclone. Each tablet contains either 3.75mg or 7.5mg of the active ingredient.
- The tablets also contain lactose monohydrate, calcium hydrogen phosphate, maize starch, croscarmellose sodium, magnesium stearate, hypromellose and titanium dioxide. The 3.75mg tablets also contain iron oxide yellow, iron oxide red and macrogol.

Contents of the pack

Pack size: 28

Marketing authorisation holder

Accord, Barnstaple, EX32 8NS, UK

Manufacturer

Accord, Barnstaple, EX32 8NS, UK

Synthon Hispania SL, C/ Castelló, 1 - Poligono Las Salinas, 08830 SanBoi De Llobraegat, Barcelona

This leaflet was last revised in April 2020