

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zopiclone 3.75 mg Tablets

Zopiclone 7.5 mg 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 further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

What is in this leaflet:

- 1. What this medicine is and what it is used for**
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1. What this medicine is and what it is used for

This medicine belongs to a group of medicines known as hypnotics or sleeping tablets, which make you feel sleepy.

This medicine is used for the short term treatment of severe sleeping difficulties (insomnia) in adults.

2. What you need to know before you take this medicine

Do not take this medicine

- if you are allergic to zopiclone or any of the other ingredients (see section 6). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- if you are allergic to any other benzodiazepines or benzodiazepine-like hypnotics, such as nitrazepam or diazepam
- if you have severe liver problems. In patients with severe liver problems encephalopathy (a brain disorder) may develop
- if you suffer from myasthenia gravis (a condition where the muscles easily tire and become weak)
- if you have any breathing problems, especially during sleep (sleep apnoea)
- if you are pregnant, planning to become pregnant or breast-feeding
- if the patient is under 18 years of age.

Warnings and precautions

Check with your doctor or pharmacist before taking zopiclone tablets if you:

- are elderly or frail. Due to the muscle relaxing effect of zopiclone, there is a danger of falls, particularly for the elderly when getting up at night

- have any kidney problems
- have mild or moderate liver problems
- have breathing difficulties
- suffer from or have a history of depression or anxiety (as suicidal thoughts may occur)
- have psychiatric problems or mental illness (including personality disorders)
- have recently taken zopiclone or other similar medicines for more than 4 weeks.

Please tell your doctor if you have any of the conditions listed above.

Please tell your doctor before taking this medicine:

- if you have any problems with your liver, kidneys or lungs
- If you have ever been, or are currently being treated for drug or alcohol abuse.

Zopiclone and other medicines:

Please tell your doctor if you are taking or have recently taken any of the following medicines including medicines obtained without a prescription:

- medicines to treat mental illness (antipsychotics)
- medicines to treat depression e.g. amitriptyline, fluoxetine, and those known as monoamine oxidase inhibitors (MAOIs) e.g. phenelzine
- other benzodiazepines or benzodiazepine-like hypnotics used to treat insomnia or anxiety e.g. nitrazepam, diazepam
- other tranquillizers e.g. chlorpromazine
- strong pain killers such as codeine, morphine. Feelings of excitement (euphoria) may increase, which in turn increase the chance of physical or mental dependence
- medicines used to treat epilepsy e.g. carbamazepine
- anaesthetics (used during surgery)
- antihistamine medicines which cause sleepiness e.g. alimemazine, chlorphenamine
- erythromycin (an antibiotic).

The following medicines may increase the risk of you getting side effects when taken with zopiclone. To make this less likely, your doctor may lower your dose of zopiclone:

- some medicines for fungal infections such as ketoconazole and itraconazole
- some antibiotics including erythromycin and clarithromycin
- ritonavir (a protease inhibitor) used to treat HIV infections.

The following medicines can make zopiclone 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.

The effect of the following medicines is increased when taken with zopiclone:

- muscle relaxants e.g. baclofen.

General information about the effects observed after the use of this medicine:

- Dependence (a need to keep taking the medicine) – when taking this type of medicine there is a risk of dependence, which increases with dose and length of treatment. This may be physical dependence, where the body becomes used to the presence of the medicine and stopping treatment causes withdrawal symptoms and/or mental dependence, where you develop a craving for the medicine. There is a greater risk in patients with a history of alcohol or drug abuse, or suffer from a personality disorder.

- Depression – this medicine should not be used as a treatment for depression. All causes of sleep disturbances should be clarified and addressed before treatment with this medicine. This is to avoid under treating the possible serious effects of depression.
- Withdrawal – treatment should be withdrawn gradually. Withdrawal effects are unlikely when duration of treatment is limited to 4 weeks. Withdrawal effects may also occur between doses, especially if you are taking a high dose of Zopiclone. See Section 3, If you stop taking Zopiclone.
- Amnesia – Zopiclone tablets can cause memory loss. To reduce this risk you should ensure that you are able to have 7-8 hours uninterrupted sleep.
- Behavioural effects may occur while taking Zopiclone (see Section 4, Possible side effects).

Zopiclone with alcohol

DO NOT drink alcohol when taking Zopiclone tablets, as the sedating effect may be increased.

Pregnancy and Breast-feeding:

- Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or think you may be pregnant
- Do not take Zopiclone during the last 3 months of pregnancy or during labour because it may be harmful to your baby
- Do not breast-feed if you are taking Zopiclone. This is because small amounts may pass into mother's milk. If you are breast-feeding or plan to breast-feed, talk to your doctor or pharmacist before taking Zopiclone.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

- Zopiclone may make you feel drowsy, cause loss of concentration or muscle weakness. DO NOT drive or operate machinery after taking a dose of Zopiclone
- DO NOT drive or operate machinery the day after taking Zopiclone until you are sure that you are not affected by Zopiclone
- If Zopiclone is taken with alcohol, the effects of Zopiclone may be increased the next morning. DO NOT drive or operate machinery until you are sure that you are not affected.

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 (See section 6).

3. How to take this medicine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

This medicine should be swallowed whole with water.

Dosage

Adults:

- the usual dose is 7.5 mg, taken in an upright position 30 to 60 minutes before you go to bed

Elderly:

- your doctor may tell you to take 3.75 mg a day at first and then gradually increase this dose to 7.5 mg per day

Children and adolescents

Zopiclone should not be used in children and adolescents less than 18 years. The safety and efficacy of zopiclone in children and adolescents aged less than 18 years have not been established.

Patients with kidney and liver problems:

- if you suffer from mild kidney or liver problems, you should not take more than 7.5 mg a day
- If you suffer from more serious kidney or liver problems, you should not take more than 3.75 mg a day

This medicine should not be given to children.

Treatment with this medicine usually lasts up to a maximum of four weeks, including the period of gradual dose reduction. Extended use is not recommended.

It is important to continue taking the tablets for as long as your doctor tells you to. You should not suddenly stop taking your tablets without advice from your doctor. Do not change the dose of your medicine unless you have spoken with your doctor.

If you forget to take this medicine:

- if you forget to take a dose before you go to bed, take it as soon as you remember. Only take the dose if it is still possible to get a full night's sleep, if this is not possible take the next dose before you go to bed the following day. If your sleep is interrupted or delayed you may suffer from memory loss of recent events (anterograde amnesia), this does not affect your long term memory only new and most recent events.
- **Do not take two doses at the same time**

If you take more of this medicine than you should:

- if you have accidentally taken too many tablets, contact your nearest casualty department or tell your doctor/pharmacist immediately symptoms may include ataxia, hypotonia, hypotension, respiratory depression, rarely coma.

If you stop taking this medicine:

Some patients may experience withdrawal symptoms when they stop taking this medicine, these symptoms may include:

- headaches
- muscle pain
- extreme anxiety
- tension
- restlessness
- confusion and irritability.

In severe cases the following symptoms may occur:

- derealisation
- depersonalisation
- increased sensitivity in hearing (hyperacusis)
- numbness and tingling sensation of hands and feet
- increased sensitivity to light, noise and physical contact
- hallucinations or epileptic fits.

In rare cases reports of abuse have been reported.

Although it is unlikely patients will suffer from withdrawal symptoms using this medicine, patients may benefit from tapering of the dose before stopping treatment.

4. Possible side effects

Like all medicines, Zopiclone tablets can cause side effects, although not everybody gets them. Side effects are most common at the beginning of treatment, during the first hour after taking your tablet.

If you experience the following rare, but very serious side effect, 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.
- signs of potentially life-threatening skin rashes (Stevens-Johnson, erythema multiforme, necrolysis), initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs may include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.

This is a very serious but very rare side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you have any of the following side effects. He may want to stop your treatment with Zopiclone.

Rare (affects less than 1 in 1,000 patients taking the medicine):

- poor memory (amnesia) since taking Zopiclone
- hallucinations (seeing or hearing things that are not real).

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

- depressed mood (feeling low or sad)
- untrue beliefs (delusions).

These effects are more likely to occur in the elderly.

Tell your doctor or pharmacist if any of the following side effects last more than a few days or become serious:

Very common (affects more than 1 in 10 patients taking the medicine)

- a bitter (metallic) taste in the mouth.

Common (affects less than 1 in 10 patients taking the medicine):

- stomach upsets (including feeling sick (nausea) or being sick)
- drowsiness (during the following day)
- reduced alertness
- headache
- dizziness.

Rare (affects less than 1 in 1,000 patients taking the medicine):

- confusion

- tiredness
- numbed emotions
- dry mouth
- light-headedness
- loss of co-ordination
- difficulty in controlling movements (predominantly at the beginning of treatment; generally disappears after repeated administration)
- problems with sight (double vision)
- sleep walking (somnambulism)
- fall (predominantly in older people)
- indigestion (dyspepsia)
- muscle weakness
- skin rashes
- abnormal blood test results for liver function
- restlessness, agitation or irritability
- aggressiveness or anger
- nightmares.

Very rare (affects less than 1 in 10,000 patients taking the medicine):

- reduced sex drive.

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

- physical and mental dependence.

Sleep-walking and other strange behaviours

There have been some reports of people (when asleep) performing tasks that they do not remember on waking up after taking a sleep medicine. This includes sleep-driving, eating and sleep walking. Alcohol and some medicines for depression or anxiety can increase the likelihood of this serious effect happening. If you are concerned this side effect may have happened to you after taking Zopiclone, tell your doctor as soon as possible.

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

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this medicine

Keep out of the sight and reach of children.

This medicine should not be stored above 25°C. Store in the original container.

The expiry date of this product is printed on the carton and blister foil. Do not use this medicine after this date.

6. Contents of the pack and other information

Your doctor has prescribed Zopiclone Tablets. Your medicine is available in two strengths:

- Zopiclone 3.75 mg Tablets: orange, round tablets, embossed with 'ZOC 3.75' on one side, and containing 3.75 mg zopiclone, which is the active ingredient.

- Zopiclone 7.5 mg Tablets: white, round tablets, scored on both sides and embossed with ‘ZOC 7.5’ on one side, and containing 7.5 mg zopiclone, which is the active ingredient.

- Zopiclone Tablets also contain the following other ingredients: lactose monohydrate, calcium hydrogen phosphate, maize starch, pregelatinised starch, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, titanium dioxide (E171) and hypromellose. In addition, the 3.75 mg tablets contain: iron oxide yellow (E172) and iron oxide red (E172).

Both strengths are available in blister packs containing 28 tablets.

Marketing Authorisation Holder:

ratiopharm GmbH, Graf-Arco-Strasse 3, D-89079 Ulm, Germany.

Manufacturer:

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