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 sleep. They may be used for short-term treatment of difficulties in falling asleep, waking up at night or early in the morning, or inability to sleep caused by events, situations or mental illness, which is severe, disabling or causing great distress.

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 4).
- An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- you have a history of dependence to alcoholic or drug abuse or personality disorders.
- the risk of dependence to Zopiclone tablets (physical or mental effects produced by a compulsion to keep taking the medicine) increases as an adjustment to your dosage may be required.
- Dependence — when taking this type of medicine there is a risk of dependence, which increases with dose and length of treatment. There is a greater risk in patients with a history of alcohol or drug abuse or personality disorders.
- Withdrawal — should be gradually withdrawn. A transient syndrome whereby the symptoms that led to treatment with Zopiclone tablets recur in an enhanced form, may occur on withdrawal. It may be accompanied by other reactions including mood changes, anxiety and insomnia.
- Sleep walking and other associated behaviours such as “sleep driving”, sleep eating, with memory loss can occur if Zopiclone tablets are taken when not fully awake.
- Amnesia — Zopiclone tablets can cause memory loss. To reduce this risk you should ensure that you are able to have a full night of uninterrupted sleep.

Before taking Zopiclone, 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).

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.

Zopiclone tablets may influence the effect and/or side effects of other medicines. If you see another doctor or go into hospital, particularly if you are having an operation under anaesthesia, tell the doctor which medicines you use.

The following medicines may increase the sedating effect of Zopiclone tablets:
- medicines to treat mental illness (antipsychotics)
- medicines to treat depression
- sleeping pills
- medicines to treat anxiety and other tranquilizers.
- medicines used to treat epilepsy
- medicines used for fungal infections e.g. ketoconazole, itraconazole (CYP3A4 inhibitors)
- medicines used to treat anxiety and other tranquillizers
- medicines to treat depression
- medicines to treat mental illness (antipsychotics)
- medicines used for fungal infections e.g. ketoconazole, itraconazole (CYP3A4 inhibitors)
- medicines used to treat epilepsy
- antidepressants (sedating variety)
- antihistamine medicines which cause sleepiness
- medicines inhibiting liver enzymes e.g. cimetidine, allopurinol, propranolol. Ask your doctor or pharmacist which medicines have this effect.
- medicines used to treat bacterial infections e.g. erythromycin, clarithromycin (CYP3A4 inhibitors)
- medicines used for fungal infections e.g. ketoconazole, itraconazole (CYP3A4 inhibitors)
- medicines used to treat mental illness (antipsychotics)
- medicines to treat HIV infections e.g. Abacavir.

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
Zopiclone tablets should not be taken during pregnancy. If for urgent medical reasons, Zopiclone tablets are taken during late pregnancy or during labour the baby may have low body temperature or breathing difficulties and show withdrawal symptoms after birth because of physical dependence.

If you are planning to become pregnant or suspect you may already be pregnant, do not take Zopiclone tablets and contact your doctor as soon as possible for advice.

If you have a baby, ask your doctor or pharmacist for advice before taking this 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.

Zopiclone Tablets
3.75 & 7.5mg x 28s (UK)

JDE No.: 50949599
Dimensions: 148x210 (Reel Fed)
Component: Leaflet for Blisters
Pharmacode: 4000
Date Sent: 11/06/18
Technologist: R.Wrey
Technically Approved

Zopiclone 3.75mg & 7.5mg 28 Tablets PIL - UK

Item number: BBBA2385

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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 disease: Usually a lower dose of 3.75mg at night. Up to 7.5mg can be given.
- Patients with kidney disease: 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 period based on your individual needs.

If you take more Zopiclone tablets than you should

If you, or someone else, take too many tablets at the same time, or 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 dose 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 on 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 hyperesthesia 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 body is becoming separated from your body), or epileptic seizures.

4. Possible side effects

Like all medicines, Zopiclone tablets can cause unwanted 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, 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 effects: 1 to 10 users in 10,000
- Poor memory or taking Zopiclone for a long time
- Unusual features or changes in skin appearance
- Muscle stiffness or trembling
- Muscular weakness
- Problem sleeping
- Difficulty breathing or being short of breath

Not known (frequency cannot be estimated from available data):
- Feeling irritable or aggressive
- Difficulty breathing or being short of breath
- Difficulty yawning or being short of breath
- Difficulty becoming drowsy

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 sleeping medicine. This includes sleep-driving and other strange behaviour.

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 by calling 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 sight and reach of children.

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

Do not use Zopiclone after the expiry date which is stated on the product packaging. This expiry date refers to the last day of that month.

Do not throw away any 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, magnesium stearate, croscarmellose sodium, magnesium stearate, hypromellose and titanium dioxide. The 3.75mg tablets also contain iron oxide yellow and iron oxide red and macrogol.

Contents of the pack

Pack size: 28 tablets
Marketing authorisation holder

Actavis, Barnstaple, EX32 8NS, UK
Manufacturer

Actavis, Barnstaple, EX32 8NS, UK

SYNTHON HISPANIA SL, C/ Castelló, 1-Poligono Las Salinas, 08830 San Ildefonso De Llabrea, Barcelona

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