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 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 in the morning or difficulty in sleeping 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 (hypersensitive) to zopiclone or any of the other ingredients in the tablet (see section 6).
- if you have any kidney or liver problems.
- if you have a history of mental illness.
- if you have or have ever had a history of, or tendancy to alcohol or drug abuse or personality disorders.
- if you have low body temperature or breathing difficulties and breathing problems whilst sleeping (Sleep Apnoea Syndrome)
- if you suffer from severe muscle weakness (myasthenia gravis).
- if you have severe breathing problems.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Zopiclone tablets:
- if you have any kidney or liver problems.
- if you have a history of mental illness.
- if you have or have ever had a history of, or tendency to alcohol or drug abuse or personality disorders.
- if you 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.

Other considerations
- Habituation - if after a few weeks you notice that the tablets are not working as well as they did when first starting treatment, you should go and see your doctor 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 - treatment 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 restlessness.
- 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.

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.

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.

3. How to take Zopiclone tablets

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 in the morning or difficulty in sleeping caused by events, situations or mental illness, which is severe, disabling or causing great distress.

4. Possible side effects

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.

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.

5. How to store Zopiclone tablets

Keep this medicine in the original package, away from direct sunlight. If you have any questions, ask your doctor, pharmacist or nurse.

6. Contents of the pack and other information

- This medicine is available in blister packs containing 28 tablets.
- Each tablet contains Zopiclone 3.75mg or 7.5mg.
- The tablets may be taken with or without food.
- The pack contains information about the medicine and its possible side effects.
Zopiclone tablets contain lactose
If you have been told you have an intolerance to some sugars, tell your doctor or pharmacist before taking Zopiclone tablets as this medicine contains lactose.

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 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 you forget to take Zopiclone tablets
If you forget to take a tablet, take one as soon as you remember, without taking 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 if treatment is stopped too soon.
• 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.

4. Possible side effects
Like all medicines, Zopiclone tablets can cause unwanted 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 nearest department at your nearest hospital:
• allergic reaction: skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

Tell your doctor or pharmacist if any of the following side effects occur or worsen:
• effects on the gastrointestinal system: a bitter or metallic taste in the mouth, dry mouth and feeling sick or being sick.
• effects on the nervous system: headache, dizziness, light headedness, lack of co-ordination.
• psychiatric effects: drowsiness, irritability, aggressiveness, confusion, depression, amnesia, hallucinations or nightmares.

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

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 use 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
Actavis, Barnstaple, EX32 8NS, UK
Manufacturer
Actavis, Barnstaple, EX32 8NS, UK
Synthony Hispana SL, C/ Castelló, 1- Poligono Las Salinas, 08830 San Blas de Llobrera, Barcelona
Date of last Revision: August 2016

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

JDE No.: 50896351
Dimensions: 148x210 (Reel Fed)
Component: Leaflet for Blisters
Pharmacode: 7246
Date Sent: 05/04/16
Technologist: R.Wrey
Technically Approved
Actavis BST - Packing Technical
BSTCutterGuideReq@actavis.com

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