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 early 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:
- are allergic to zopiclone or any of the other ingredients in the tablet (see section 6).
- have had liver problems.
- have severe breathing problems whilst sleeping (Sleep Apnoea Syndrome).
- have severe muscle weakness (myasthenia gravis).
- are under the age of 18.

Warnings and precautions
- If you are pregnant or breast-feeding, think you may be pregnant or 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.
- The following medicines may increase the sedating effect of Zopiclone tablets:
  - medicines to treat mental illness (antipsychotics)
  - medicines to treat depression
  - other sleeping pills
  - medicines to treat anxiety and other tranquillizers
  - medicines used to treat epilepsy
  - medicines to treat alcohol or drug abuse
  - medicines to treat mental illness (antipsychotics)
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  - medicines to treat alcohol or drug abuse

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

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 with liquid immediately before going to bed.

The recommended dose is:
- Adults: 3.75mg 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 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 remain 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 hypersensitivity to light, noises and physical contact, abnormally acute hearing and pain and 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 medicine, 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, 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:
- Feeling confused
- NYC (nighttime urinary frequency)
- Feeling irritable or aggressive
- Reduced sex drive
- Difficulty breathing or being short of breath

Not known (frequency cannot be estimated from available data):
- Feeling stressed or angry
- Feeling light headed or having problems with your coordination
- Double vision
- Moving unsteadily or staggering
- Muscular weakness
- Ingenuity
- Becoming dependent on Zopiclone
- Slower breathing (respiratory depression)
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paresthesia)
- Mental problems such as poor memory
- Difficulty paying attention, drowsiness
- Disrupted normal sleep

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
Synthon Hispana SL, C/ Castelló, 1–Poligono Las Salinas, 08830 SanBoi De Llobregat, Barcelona
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Zopiclone 3.75 & 7.5mg x 28’s (UK)

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Dimensions: 148x210 (Reel Fed)
Component: Leaflet for Blisters
Pharmacode: 4294
Date Sent: 23/12/16
Technologist: R.Wrey
Technically Approved
Actavis BST - Packing Technical
BSTCutterGuideReq@actavis.com