1. WHAT ZOPICLONE TABLETS ARE AND WHAT THEY ARE USED FOR

Zopiclone belongs to a group of medicines called hypnotics (sleep producers).

Zopiclone is used for the short term treatment of insomnia (sleeplessness). This includes difficulty in getting to sleep, waking up at night or early in the morning. Zopiclone should help you sleep without making you feel drowsy the next day.

2. BEFORE YOU TAKE ZOPICLONE TABLETS

Do not take Zopiclone Tablets
- if you are allergic (hypersensitive) to zopiclone
- if you are allergic to any of the other ingredients of Zopiclone Tablets (see Section 6 – Further information)
- if you have a condition that causes muscle weakness called myasthenia gravis
- if you have any breathing problems including stopping breathing for short periods while asleep (sleep apnoea)
- if you have severe liver problems
- if you are pregnant, trying to become pregnant, or are breastfeeding.

The tablets should not be given to children.

Take special care with Zopiclone Tablets
Before treatment with Zopiclone Tablets, tell your doctor if
- you have any liver or kidney problems
- you have a personality disorder
- you have any liver or kidney problems
- you have been addicted to alcohol or any other drug.

3. HOW TO TAKE ZOPICLONE TABLETS

Tell your doctor if you are taking any of the following medicines:
- Erythromycin (an antibiotic)
- Medicines for mental illness (e.g. chlorpromazine, flupentixol, haloperidol, prochlorperazine)
- Sedatives or medicines for anxiety (e.g. nitrazepam, diazepam, lorazepam)
- Medicines for depression (e.g. amitriptyline, clomipramine, lorfenazepam)
- Medicines for epilepsy (e.g. carbamazepine, phenobarbital, phenytoin)
- Antihistamines which cause sleepiness (e.g. chlorphenamine & chlorpheniramine, hydroxyzine, promethazine)
- Strong pain-killers (e.g. codeine, morphine, dihydrocodeine)
- Medicines that affect liver enzymes (e.g. cimetidine (for digestive problems), allopurinol (for gout) and propranolol (for high blood pressure)).

If you are going into hospital for an operation, tell the doctor that you are taking Zopiclone Tablets.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you take Zopiclone tablets for longer than 4 weeks, you may become dependent on this medicine or it may not work as well. You may also have withdrawal symptoms when you stop taking the tablets (see “If you stop taking Zopiclone Tablets” in section 3).

Taking Zopiclone Tablets with food and drink
Alcohol affects the way zopiclone works and you should not drink alcohol whilst taking these tablets.

Pregnancy and breast-feeding
Do not take Zopiclone tablets if you are pregnant, trying to become pregnant or are breastfeeding.

Driving and using machines
Zopiclone may make you feel drowsy or dizzy. Make sure you are not affected before you drive or operate machinery.

Important information about some of the ingredients of Zopiclone Tablets
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 Zopiclone 7.5 mg Tablets.

4. POSSIBLE SIDE EFFECTS

When you stop taking zopiclone you may have symptoms such as headache, anxiety, sweating, shaking, muscle cramps and stomach upsets. This is more likely to happen if you have taken the tablets for a long time. You should follow the doctors instructions when you wish to stop taking this medicine.

5. HOW TO STORE ZOPICLONE TABLETS

Zopiclone 3.75 & 7.5 mg Tablets
(Zopiclone)
4. POSSIBLE SIDE EFFECTS
Like all medicines, Zopiclone Tablets can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor immediately if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The most commonly reported side effect is a bitter or metallic after-taste.

Less common side effects include:
- stomach upsets including nausea (feeling sick) and vomiting (being sick),
- dizziness
- headache
- drowsiness
- dry mouth.

Effects on mood and behaviour have been reported such as irritability, aggressiveness, confusion, depressed mood, memory loss, hallucinations, and nightmares. These reactions are more likely to occur in the elderly. Rarely, they may be severe.

Lightheadedness and poor coordination have been seen rarely.

Very rarely, changes in levels of blood enzymes have been reported.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, or you notice a change in your general health whilst taking Zopiclone Tablets please tell your doctor or pharmacist.

5. HOW TO STORE ZOPICLONE TABLETS
Keep out of the reach and sight of children.

Do not use Zopiclone Tablets after the expiry date which is stated on the carton or label after Exp. The expiry date refers to the last day of that month.

Blisters Packs: Do not store your Zopiclone Tablets above 25°C. Store in the original package.

Plastic containers (only available for 7.5 mg tablets): Do not store above 25°C. Keep the container tightly closed.

Do not use Zopiclone Tablets if you notice any visible signs of deterioration in the tablets, such as chipped, broken or discoloured tablets. Take the tablets to your pharmacist for advice.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Zopiclone Tablets contain
- The active substance is zopiclone.
- The other ingredients are calcium hydrogen phosphate; sodium starch glycolate; silicon dioxide; potato starch; magnesium stearate.

The 3.75 mg tablets are coated with Opadry II 85F2083 Blue which contains polyvinyl alcohol, titanium dioxide (E 171), macrogol, talc and Brilliant Blue FCF (E 133).

The 7.5 mg tablets are coated with Opadry II 33G28707 White which contains hypromellose, titanium dioxide (E 171), lactose monohydrate, macrogol and glycerol triacetate.

What Zopiclone Tablets look like and contents of the pack
Your medicine is available in two strengths of film-coated tablets containing 3.75 mg or 7.5 mg of zopiclone.

The 3.75 mg tablet is blue, round, film-coated tablet marked with ‘Z’ on one side and ‘Z’ on the reverse.

The 7.5 mg tablet is white, oblong, film-coated tablet marked with ‘Z / 7.5’ on one side and ‘Z / 7.5’ on the reverse.

The tablets are available in blister packs (3.75 mg and 7.5 mg) of 20, 28, 30, 50, 56, 60, 84, 100 tablets and HDPE containers (7.5 mg only) of 30 and 1000 tablets.

Not all pack sizes may be marketed.

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Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, Hertfordshire, SG1 4SZ, UK.

Manufacturer
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This leaflet was last approved in 07/2008.