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PACKAGE LEAFLET: INFORMATION FOR THE USER**Zopiclone 3.75 mg film-coated tablets
Zopiclone 7.5 mg film-coated tablets
Zopiclone**

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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zopiclone Tablet is and what it is 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 TABLET IS AND WHAT IT IS USED FOR

The name of your medicine is Zopiclone 3.75 mg film-coated tablets and Zopiclone 7.5 mg film-coated tablets (both called Zopiclone Tablets in this leaflet). This belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep.

Zopiclone Tablet is used to treat sleep problems in adults such as:

- Difficulty falling asleep
- Waking in the middle of the night
- Waking too early
- Severe or upsetting sleep problems that are caused by your mood or mental health problems

Zopiclone Tablets is used for short-term treatment of insomnia in adults. Do not use long-term. Treatment should be as short as possible, because the risk of dependence increases with the duration of treatment.

Ask your doctor for advice if you are unsure.

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 of Zopiclone Tablets (listed in Section 6 below)

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

- You have a problem that causes severe muscle weakness (myasthenia gravis)
- Your lungs do not work properly (respiratory failure)
- You have a problem where you stop breathing for short periods at night (sleep apnoea)
- You have severe liver problems

- You are under the age of 18. The safety and efficacy of Zopiclone Tablets in children and adolescents aged less than 18 years have not been established. Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Zopiclone Tablets.

Warnings and precautions**Talk to your doctor or pharmacist before taking Zopiclone Tablets if:**

- You have depression or have had another mental illness in the past
- You have any liver problems (see also 'Do not take this medicine and tell your doctor if:' section above). Your doctor may need to give you a lower dose of Zopiclone Tablets
- You have any kidney problems. Your doctor may need to give you a lower dose of Zopiclone Tablets
- You suffer from mild breathing problems, your doctor will decide if you should receive Zopiclone Tablets (see also 'Do not take this medicine and tell your doctor if:' section above).
- You have a history of alcohol or drug abuse
- You have been told by a doctor that you have a personality disorder
- You have recently taken Zopiclone Tablets or other similar medicines for more than four weeks
- You do not feel you will ever be able to stop taking Zopiclone Tablets or other medicines used to treat sleep problems
- Drowsiness, difficulties breathing, coma and death may occur if Zopiclone Tablet is taken together with opioids. Zopiclone Tablets and opioids should only be used concomitantly, when other treatment options are inadequate. Please tell your doctor about all opioid medicines you are taking and follow your doctor's dosage recommendations closely.

Before taking Zopiclone Tablets, 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).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Zopiclone Tablets.

Use of Zopiclone Tablets may lead to the development of abuse and/or physical and psychological dependence. The risk of dependence increases with dose and duration of treatment and is greater when Zopiclone Tablets is used for longer than 4 weeks, and in patients with a history of mental disorders and/or alcohol, illicit substance or drug abuse. Tell your healthcare provider if you have ever had a mental disorder, or have abused or have been dependent on alcohol, substance or drugs.

Other medicines and Zopiclone Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Zopiclone Tablets can affect the way some other medicines work. Also some medicines can affect the way Zopiclone Tablets works

Tell your doctor if you are taking any of the following medicines.

Zopiclone Tablets may increase the effect of the following medicines:

- Medicines for mental problems (antipsychotics)
- Medicines for depression
- Medicines for epilepsy (anticonvulsants)
- Medicines used in surgery (anaesthetics)
- Medicines to calm or reduce anxiety or for sleep problems (hypnotics)
- Medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines) such as chlorphenamine or promethazine
- Some medicines for moderate to severe pain (narcotic analgesics) such as codeine, methadone, morphine, oxycodone, pethidine or tramadol

The following medicines can increase the chance of you getting side effects when taken with Zopiclone Tablets. To make this less likely, your doctor may decide to lower your dose of Zopiclone Tablets:

- Some antibiotics such as clarithromycin or erythromycin
- Some medicines for fungal infections such as ketoconazole and itraconazole
- Ritonavir (a protease inhibitor) – for HIV infections
- Concomitant use of Zopiclone Tablets and opioids increases the risk of drowsiness, difficulties breathing, coma and death. Follow your doctor's dosage recommendations closely.

The following medicines can make Zopiclone Tablets 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

Zopiclone Tablets with food, drink and alcohol

Do not drink alcohol while you are taking Zopiclone Tablets. Alcohol can increase the effects of Zopiclone Tablets and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

Pregnancy, breast-feeding and fertility**Pregnancy**

Use of Zopiclone Tablets is not recommended during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice. If used during pregnancy there is a risk that the baby is affected. Some studies have shown that there may be an increased risk of cleft lip and palate (sometimes called "harelip") in the newborn baby.

Reduced fetal movement and fetal heart rate variability may occur after taking Zopiclone Tablets during the second and/or third trimester of pregnancy.

If Zopiclone Tablets is taken at the end of pregnancy or during labour, your baby may show muscle weakness, a drop in body temperature, difficulty feeding and breathing problems (respiratory depression).

If this medicine is taken regularly in late pregnancy, your baby may develop physical dependence and may be at risk of developing withdrawal symptoms such as agitation or shaking. In this case the newborn should be closely monitored during the postnatal period.

Breast-feeding

Do not take Zopiclone Tablets if you are breast-feeding or planning to breast-feed. This is because small amounts may pass into mother's milk.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

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

Driving and using machines

Like other medicines used for sleep problems, Zopiclone Tablets 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 Tablets within 12 hours of performing activities that require mental alertness
- You take higher than the recommended dose of Zopiclone Tablets
- You take Zopiclone Tablets while already taking another central nervous system depressant or another medicine that increases levels of Zopiclone in your blood, or while drinking alcohol.

Do not engage in hazardous activities requiring complete mental alertness such as driving or operating machinery after taking Zopiclone Tablets, and in particular during the 12 hours after taking your medicine.

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

Important information about some of the ingredients of Zopiclone Tablets**Zopiclone Tablets contains:**

Lactose monohydrate. This is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sodium: This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE ZOPICLONE TABLETS

Treatment should be as short as possible and should not exceed four weeks including period of tapering off your doctor will give you the lowest effective dose.

Always take Zopiclone Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablet with a drink of water
- Do not crush or chew your tablets
- Take just before bedtime in a single intake and do not take again during the same night
- The usual length of treatment is 2 days to 3 weeks

Dosage

Adults: The usual dose is one Zopiclone Tablet (7.5 mg) just before bedtime.

Elderly: The usual starting dose is one Zopiclone Tablet (3.75 mg) just before bedtime.

Your doctor may decide to increase your dose to one Zopiclone Tablet (7.5 mg) if needed.

Use in children and adolescents

Zopiclone Tablets should not be used in children and adolescents less than 18 years.

The safety and efficacy of Zopiclone Tablets in children and adolescents aged less than 18 years have not been established.

Patients with liver, respiratory or kidney problems

The usual starting dose is one Zopiclone Tablet (3.75 mg) just before bedtime.

Blood Tests

- Zopiclone Tablets can change the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly
- If you are going to have a blood test, it is important to tell your doctor that you are taking Zopiclone Tablets

If you take more Zopiclone Tablets than you should

If you take more Zopiclone Tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

Taking too much Zopiclone Tablets can be very dangerous. The following effects may happen:

- Feeling drowsy, confused, sleeping deeply and possibly falling in to a coma
- Floppy muscles (hypotonia)
- Feeling dizzy, light headed or faint. These effects are due to low blood pressure
- Falling over or losing your balance (ataxia)
- Shallow breathing or difficulty breathing (respiratory depression)

If you forget to take Zopiclone Tablets

Zopiclone Tablets must only be taken at bedtime. If you forget to take your tablet at bedtime, then you should not take it at any other time, otherwise you may feel drowsy, dizzy and confused during the day. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Zopiclone Tablets

Keep taking Zopiclone Tablets until your doctor tells you to stop. Do not stop taking Zopiclone Tablets suddenly, but tell your doctor if you want to stop. Your doctor will need to lower your dose and stop your tablets over a period of time.

If you stop taking Zopiclone Tablets suddenly, your sleep problems may come back and you may get a withdrawal effect. If this happens you may get some of the effects listed below.

See a doctor straight away if you get any of the following effects:

- Feeling anxious, shaky, irritable, agitated, confused or having panic attacks
- Sweating
- Headache
- Faster heartbeat or uneven heartbeat (palpitations)
- A lower level of awareness and problems with focusing or concentrating
- Nightmares, seeing or hearing things that are not real (hallucinations)
- Being more sensitive to light, noise and touch than normal
- Relaxed grip on reality
- Numbness and tingling in your hands and feet
- Aching muscles
- Stomach problems

In rare cases fits (seizures) may also occur.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zopiclone Tablets can cause side effects, although not everybody gets them.

Stop taking Zopiclone Tablets 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** (affects 1 to 10 users in 10,000)
 - Poor memory since taking Zopiclone Tablets (amnesia). By having 7-8 hours of uninterrupted sleep after taking Zopiclone Tablets, this is less likely to cause you a problem.
 - Seeing or hearing things that are not real (hallucinations)
 - Falling, especially in the elderly

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

- Thinking things that are not true (delusions)
- Feeling low or sad (depressed mood)

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- **Common** (affects 1 to 10 users in 100)
 - A mild bitter or metallic taste in your mouth or a dry mouth
 - Feeling drowsy or sleepy
 - Dry mouth

Uncommon (affects 1 to 10 users in 1,000)

- Feeling sick (nausea) or being sick (vomiting)
- Feeling dizzy or sleepy
- Headache
- Nightmares
- Feeling physically or mentally tired
- Agitation

Rare (affects 1 to 10 users in 10,000)

- Feeling confused
- Itchy, lumpy rash (urticaria)
- Feeling irritable or aggressive
- Reduced sex drive
- Difficulty breathing or being short of breath

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

- Feeling restless or angry
- Feeling light headed or having problems with your coordination
- Double vision
- Moving unsteadily or staggering
- Muscular weakness
- Indigestion
- Becoming dependent on Zopiclone Tablets
- Slower breathing (respiratory depression)
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Mental problems such as poor memory
- Difficulty paying attention
- Disrupted normal speech
- Delirium (a sudden and severe change in mental state that can cause a combination of confusion, disorientation and/or attention deficit)

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 or 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: <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZOPICLONE TABLETS

Keep this medicine in a safe place where children cannot see or reach it.

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

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Zopiclone Tablets contains**

- Each Zopiclone 3.75 mg film-coated Tablets contains 3.75 mg of the active substance Zopiclone
- Each Zopiclone 7.5 mg film-coated Tablets contains 7.5 mg of the active substance Zopiclone

Other ingredients are lactose monohydrate, dibasic calcium phosphate dihydrate, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide (E171) and macroglol.

What Zopiclone Tablets looks like and contents of the pack

Zopiclone 3.75 mg film-coated tablets are white to off white approx 5.5 mm round shaped film coated tablets plain on both sides. They are available in Aluminium- PVC clear transparent blister packs of 3, 5, 7, 14, 20 and 28 with a leaflet in each carton.

Zopiclone 7.5 mg film-coated tablets are white to off white approx. 10 × 5 mm oval shaped film coated tablets with breakline on one side and plain on other side. The tablet can be divided into equal halves. They are available in Aluminium- PVC clear transparent blister packs of 3, 7, 14, 20 and 28 with a leaflet in each carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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