

Zopiclone 3.75 mg film-coated tablets

720 mm

15 mm

Pharmacode

Package leaflet: information for the user Zopiclone 3.75 mg film-coated 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 or pharmacist.
- This medicine has been prescribed for you. 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- This medicine contains zopiclone, which can cause dependence, tolerance and addiction. You can get withdrawal symptoms if you stop taking it or reduce the dose suddenly

What is in this leaflet

1. What Zopiclone is and what it is used for
2. What you need to know before you take Zopiclone
3. How to take Zopiclone
4. Possible side effects
5. How to store Zopiclone
6. Contents of the pack and other information

1. What Zopiclone is and what it is used for

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

This medicine has been prescribed for you for the short-term treatment of insomnia in adults.

It contains the zopiclone which belongs to a class of medicines called Hypnotics (z-drugs).

Pharmacode

This medicine has been prescribed to you and should not be given to anyone else

This medicine is used for short term treatment of sleep problems (insomnia) in patients over 18 years of age, such as:

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

This medicine is not for a long-term use. 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.

Zopiclone can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking it or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

2. What you need to know before you take Zopiclone

Do not take Zopiclone

- If you are allergic to zopiclone or any of the other ingredients of this medicine (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.
- If you have a problem that causes severe muscle weakness (myasthenia gravis)
- If your lungs do not work properly (respiratory failure)
- If you have a problem where you stop breathing for short periods at night (sleep apnoea)
- If you have severe liver problems

- If you are under the age of 18. The safety and efficacy of Zopiclone in children and adolescents aged less than 18 years have not been established.
- If you have ever experienced sleepwalking or other unusual behaviour (such as driving, eating, making a phone call or having sex etc.) while not being fully awake after taking this medicine.

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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zopiclone:

- If you have any liver problems (see also 'Do not take Zopiclone'). Your doctor may need to give you a lower dose of Zopiclone.
- If you have any kidney problems. Your doctor may need to give you a lower dose of Zopiclone tablet.
- If you suffer from mild breathing problems, your doctor will decide if you should receive Zopiclone tablet (see also 'Do not take Zopiclone').
- If you have ever had a mental disorder (including depression and personality disorder)
- If you have recently taken this medicine or other similar medicines for more than four weeks.

Talk to your prescriber before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of zopiclone to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include: feeling anxious, shaky, irritable, agitated, confused, having panic attacks, sweating, headache, faster heartbeat or uneven heartbeat (palpitations), lower level of awareness or problems with focussing or concentrating, nightmares, seeing of 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.

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Zopiclone should only be used by those they are prescribed for. Do not give your me Zopiclone, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Risk of abuse and dependence

Taking Zopiclone 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 is used for longer than 4 weeks, and in patients with a history of mental disorders and/or alcohol, illicit substance or drug abuse.

Zopiclone and mental health

Some people being treated with Zopiclone can experience mental health

problems such as irrational thoughts (delusions), seeing or hearing things that are not there (hallucinations), feeling confused or disorientated (delirium), feeling angry, irritable, restless or depressed.

Additionally, some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including this medicine. However, it has not been established whether this is caused by the medicine or if there may be other reasons. If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice.

Zopiclone and unusual behaviour

Zopiclone may cause sleepwalking or other unusual behaviour (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake. The next morning, you may not remember that you did anything during the night. These activities may occur whether or not you drink alcohol or take other medicines that make you drowsy (sleepy) with Zopiclone. If you experience any of the above, stop the treatment with Zopiclone immediately and contact your doctor or healthcare provider.

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').

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

Blood Tests

- Zopiclone 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.

Children and adolescents

Zopiclone should not be used in children and adolescents less than 18 years. The safety and efficacy of Zopiclone in children and adolescents aged less

than 18 years have not been established.

Other medicines and Zopiclone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines.

This is because Zopiclone can affect the way some other medicines work. Also some medicines can affect the way Zopiclone works.

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

Zopiclone 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. To make this less likely, your doctor may decide to lower your dose of Zopiclone:

- Some antibiotics such as clarithromycin or erythromycin
- Some medicines for fungal infections such as ketoconazole and itraconazole
- Ritonavir (a protease inhibitor) - for HIV infections
- Taking Zopiclone with opioids increases the risk of drowsiness (sleepiness), difficulties breathing, coma and death. Zopiclone and opioids should only be used at the same time, 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.

The following medicines can decrease the effect of Zopiclone:

- 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

Taking Zopiclone with food and drink

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take this medicine during pregnancy. 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 this medicine during the second and/or third trimester of pregnancy.

If Zopiclone 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.

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Pharmacode: Dummy

Pharmacode

Size: 720 x 150 mm Black

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720 mm

150 mm

Breast-feeding

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

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 can slow down 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
- You take Zopiclone 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, 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.

Zopiclone contains lactose

This medicine contains lactose which 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 medicine.

3. How to take Zopiclone

Your prescriber should have discussed with you how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

The treatment with this medicine must be as short as possible and must not exceed four weeks including period of tapering off. Your doctor will give you the lowest effective dose.

Always take this medicine exactly as your doctor has told you. 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

Adults

The recommended dose is two tablets (7.5 mg) just before bedtime.

Use in elderly

The recommended starting dose is one tablet (3.75 mg) just before bedtime. Your doctor may decide to increase your dose to two tablets (7.5 mg) if needed.

Use in patients with liver, respiratory or kidney problems

The recommended starting dose is one tablet (3.75 mg) just before bedtime.

If you take more Zopiclone than you should

If you take more of this medicine than you should, tell your 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 can be very dangerous. The following effects may happen:

- Feeling drowsy (sleepy), 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

This medicine 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

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Withdrawal symptoms such as: feeling anxious, shaky, irritable, agitated, confused, having panic attacks, sweating, headache, faster heartbeat or uneven heartbeat (palpitations), lower level of awareness or problems with focussing or concentrating, nightmares, seeing of 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine 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 (may affect up to 1 in 1,000 people)

- Poor memory since taking this medicine (amnesia). By having 7-8 hours of uninterrupted sleep after taking Zopiclone, 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 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 (may affect up to 1 in 10 people)

- A mild bitter or metallic taste in your mouth or a dry mouth
- Feeling drowsy or sleepy

Uncommon (may affect up to 1 in 100 people)

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

Rare (may affect up to 1 in 1,000 people)

- 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 available data)

- Feeling restless or angry
- Feeling light headed or having problems with your coordination

- Double vision
- Moving unsteadily or staggering
- Muscular weakness
- Indigestion
- Dependence and addiction (see section "How do I know if I am tolerant or addicted?")
- 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
- Zopiclone may cause sleepwalking or other unusual behaviour (such as driving, eating, making a phone call, or having sex etc.) while not being fully awake.
- Delirium (a sudden and severe change in mental state that can cause a combination of confusion, disorientation and/or attention deficit)

Drug Withdrawal

When you stop taking zopiclone, you may experience drug withdrawal symptoms, which include: feeling anxious, shaky, irritable, agitated, confused, having panic attacks, sweating, headache, faster heartbeat or uneven heartbeat (palpitations), lower level of awareness or problems with focussing or concentrating, nightmares, seeing of 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.

How do I know if I am tolerant or addicted?

If you notice any of the following signs whilst taking zopiclone, it could be a sign that you have become addicted.

- You may feel the need to keep taking the medication for longer than your doctor recommended
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed

- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

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 search for 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

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label, carton or bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 contains

- The active substance is zopiclone. Each tablet contains 3.75 mg of zopiclone.
- Other ingredients are calcium hydrogen phosphate dihydrate (E341), lactose monohydrate, sodium starch glycolate (Type A), polyvinylpyrrolidone PVP K-30 (E1201), maize starch, colloidal anhydrous silica, magnesium stearate

Film Coating: opadry white 03B58965 consisting of hypromellose (E464), titanium dioxide (E171), talc (E553b), macrogol (E1521)

What Zopiclone looks like and contents of the pack

Zopiclone is white to off-white, round shaped, filmcoated tablets plain on both sides packed in a PVC/PVDC blister with pack size of 10, 28, 30, 50, 90, 100 tablets.

Not all pack sizes may be marketed.

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