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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

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.

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 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.

What is in this leaflet

1. What Zopiclone is and what it is used for

The name of your medicine is Zopiclone 3.75mg and 7.5mg film-coated tablets (referred to as 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.

This medicine has been prescribed for you for insomnia. It contains the zopiclone which belongs to a class of medicines called z-drugs.

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

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.

Zopiclone is used for short term treatment of sleep problems (insomnia) in patients over 18 years of age, 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

Do not take Zopiclone tablets as long-term treatment. 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

Do not take Zopiclone if:
- You are allergic (hypersensitive) to Zopiclone or to any of the other ingredients of this medicine (listed in section 6)

  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 have ever experienced sleepwalking or other unusual behavior (such as driving, eating, making a phone call or having sex etc.) while not being fully awake after taking Zopiclone.
- You are under 18 years of age. The safety and efficacy of Zopiclone 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.

Warnings and precautions
Talk to your doctor or pharmacist before taking Zopiclone if:
- You have any liver problems (see also 'Do not take this medicine if:'). Your doctor may need to give you a lower dose of Zopiclone
- You have any kidney problems. Your doctor may need to give you a lower dose of Zopiclone
- You suffer from mild breathing problems, your doctor will decide if you should receive Zopiclone (see also 'Do not take this medicine if:').
- You have ever had a mental disorder (including depression and personality disorder) or have abused or have been dependent on alcohol or drugs.
- You have recently taken Zopiclone or other similar medicines for more than four weeks
- 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.
- You have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- You feel you need to take more of

Zopiclone tablets 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 medicine to anyone else. Taking higher doses or more frequent doses of Zopiclone , may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Risk of abuse and dependence
Use of 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 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 atleast 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.

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

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 (used for HIV infections).
- Concomitant use of Zopiclone and opioids increases the risk of drowsiness, difficulties breathing, coma and death. Zopiclone 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.

The following medicines can make Zopiclone work less well:
- Some medicines for epilepsy such as carbamazepine, phenobarbital and phenytoin
- rifampicin (an antibiotic) – for infections
- products containing St. John's wort (herb used to treat depression and mood swings).

Zopiclone with food, drink and alcohol
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.

Pregnancy, breast-feeding and fertility
Pregnancy
Use of Zopiclone is not recommended during pregnancy. If you are pregnant think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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 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.

Breast-feeding
Do not breast-feed or plan to breast-feed if you are taking Zopiclone tablets. 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 can cause slowing of your normal brain function (central nervous system depression).

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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 contain Lactose: If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

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

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.

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 this medicine exactly as your doctor or pharmacist 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 usual dose is 7.5 mg zopiclone just before bedtime (two tablets of 3.75 mg or one tablet of 7.5mg). This dose should not be exceeded.

Elderly
The usual starting is one Zopiclone tablet (3.75mg) just before bed time. Your doctor may decide to increase your dose to one Zopiclone Tablet (7.5 mg) if needed.

Patients with liver, respiratory or kidney problems
The usual starting dose is one Zopiclone Tablet (3.75mg) just before bedtime.

Use in children and adolescents:
Zopiclone should not be used 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.

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 than you should
If you take more Zopiclone tablets than you should, contact your doctor or nearest hospital casualty department immediately for advice. Take the medicine pack with you. This is so the doctor knows what you have taken.

Zopiclone overdosage can be very dangerous
The following effects may happen:
- Feeling drowsy, confused, sleeping deeply and possibly falling into 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
Zopiclone 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 the double dose to make up for a forgotten dose.

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.

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause 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 (affects 1 to 10 users in 10,000)
Tell your doctor as soon as possible if you have any of the following side effects:
- Poor memory since taking Zopiclone (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 the available data)
- Thinking things that are not true (delusions)
- Feeling low or sad (depressed mood)
- dependence and addiction (see section "How do I know if I am tolerant or addicted?").

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.

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

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 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
- 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)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Yellow Card Scheme Website: 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 blister or carton after EXP. The expiry date refers to the last day of that month.

This medicine 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 contains
- The active substance is Zopiclone. Each film-coated tablet contains 3.75 mg zopiclone.
  Each film-coated tablet contains 7.5 mg zopiclone.
- The other ingredients are:
  Tablet core: Lactose monohydrate, calcium hydrogen phosphate dihydrate, starch, pre-gelatinized (maize starch), povidone (K-30), sodium starch glycolate (Type A) and magnesium stearate.
  Tablet coat: Hypromellose (6cps), macrogol and titanium dioxide (E171).

What Zopiclone looks like and contents of the pack
Film-coated tablet.

Zopiclone 3.75 mg film-coated tablets:
White, round, biconvex film coated tablets debossed with 'Z1' on one side and plain on the other side.

Zopiclone 7.5 mg film-coated tablets:
White, round, biconvex film coated tablets debossed with 'Z & 2' separated with break line on one side and break line on the other side. The tablet can be divided into equal doses.

Zopiclone film-coated tablets are available in blister packs.

Pack sizes:
Blister packs: 5, 10, 14, 20, 28, 30, 50, 60 and 90 film-coated tablets.

Not all pack sizes may be marketed.

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