Package leaflet: Information for the patient

Zopiclone 3.75 mg 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 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

Zopiclone tablets are sleeping pills (hypnotics) which work by acting on the brain to cause sleepiness. Zopiclone may be used for the short-term treatment of difficulty in sleeping which is severe, disabling or causing great distress in adults.

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 Z-drugs.

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

Z-drugs 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 (hypersensitive) to zopiclone or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- suffer from a disease of the muscles causing drooping eyelids, double vision,

difficulty speaking and swallowing and sometimes muscle weakness in the arms and legs (myasthenia gravis)
- have severe liver problems
- suffer from irregular breathing while asleep (sleep apnoea syndrome)
- have severe breathing problems
- are under the age of 18. The safety and efficacy of zopiclone in children and adolescents aged less than 18 years have not 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:
- are elderly or at risk of becoming confused. Taking zopiclone may mean an increased risk of falling and consequential injuries
- suffer from liver or kidney problems, as your doctor may start you on a lower dose
- have a history of breathing problems. Taking zopiclone will reduce the force of your breathing
- suffer from or have a history of depression, anxiety or psychotic illness. Zopiclone may cause the symptoms to reappear or worsen
- 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 (see also 'Dependence' below)
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- have been told by a doctor that you have a personality disorder (see also 'Dependence' below)
- have recently taken zopiclone or other similar medicines for more than four weeks
- do not feel you will ever be able to stop taking zopiclone or other medicines used to treat sleep problems.
- 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.

Z-drugs 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 Z-drugs, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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.

Other considerations when taking Zopiclone are:

- Dependence – when taking this type of medicine there is a risk that you may develop some 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.
- Amnesia – taking zopiclone can cause memory loss. To avoid this make sure that when you take Zopiclone you will be able to have 7-8 hours of uninterrupted sleep.
- Drowsiness, difficulties breathing, coma and death may occur if Zopiclone is taken together with opioids. 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.

Other medicines and Zopiclone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, especially any of the following:

- Medicines used to treat certain mental and emotional conditions (antipsychotics)
- Hypnotic medicines
- Other sleeping pills (sedatives)
- Medicines used to treat depression (antidepressants)
- Medicines to treat anxiety (anxiolytics)
- Strong medicines used to relieve pain (narcotic analgesics), such as codeine and morphine, which may increase the risk of side effects and could lead to dependency
- Medicines that reduce liver function, such as erythromycin, clarithromycin, ketoconazole, fluconazole, itraconazole, tacrolimus and ritonavir. Ask your doctor or pharmacist which medicines have this effect
- Medicines that increase liver function, such as rifampicin, nefazodone, phenobarbital, phenytoin and St John's wort. Ask your doctor or pharmacist which

medicines have this effect
- Medicines used to treat epilepsy such as carbamazepine
- Antihistamine medicines which can cause sleepiness
- Anaesthetic medicines and muscle relaxants, which may be used during surgery
- Metoclopramide, used to relieve sickness
- Medicines containing atropine.

Concomitant use of zopiclone and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However, if your doctor does prescribe zopiclone together with opioids, the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Zopiclone with alcohol

You should not drink alcohol while being treated with this medicine, because this may increase the sedative effects of zopiclone. This may persist to the following morning and affect your ability to drive.

Pregnancy and breast-feeding

Pregnancy

Use of zopiclone is not recommended 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 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 take zopiclone if you are breast feeding or planning to breast feed. This is because small amounts of zopiclone may pass into breast milk.

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.

Driving and using machines

Like other medicines used for sleep problems, zopiclone 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 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.

Zopiclone contains lactose and ponceau 4R
If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine also contains ponceau 4R (E124) which may cause allergic reactions.

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.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults
2 tablets (7.5 mg) immediately before going to bed. This dose should not be exceeded.

Elderly, frail or those patients with reduced kidney, liver or lung function
A starting dose of 3.75 mg is recommended, with the tablets being taken immediately before going to bed.

Use in children and adolescents
Zopiclone should not be given to children and adolescents under the age of 18 years. The safety and efficacy of zopiclone in children and adolescents aged less than 18 years have not been established.

If after a few weeks you notice that the tablets are not working as well as they did at the start of treatment, you should see your doctor as your dose may need to be adjusted.

The tablet should be taken by mouth with a glass of liquid, immediately before going to bed.

Patients with liver, respiratory or kidney problems

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

Blood Tests
- Zopiclone can change the levels of liver enzymes shown up in the 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.

How long should you take Zopiclone for
The duration of treatment with Zopiclone should be as short as possible. Generally treatment should last from between a few days to up to two weeks. Treatment should not exceed 4 weeks, including a period of tapering off.

Your doctor will choose a withdrawal regime based on your individual needs. In some cases it may take longer than the recommended maximum time of treatment.

If you take more Zopiclone than you should
Contact your doctor or nearest hospital emergency department immediately, do not go unaccompanied to seek medical help. If an overdose has been taken you may become increasingly drowsy very quickly. Take the container and any remaining tablets with you. Symptoms of overdose can range from extreme drowsiness to coma. These symptoms can be magnified when combined with alcohol.
Taking too much zopiclone 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, lightheaded 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
If you forget to take a dose immediately before going to bed but remember during the night only take the missed dose if you are still able to have 7-8 hours uninterrupted sleep. If this is not possible, take the next dose before bed time the next night. Do not take a 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.

Treatment with zopiclone should be gradually withdrawn, as the symptoms that Zopiclone was used to treat may return with a higher intensity (rebound insomnia). Other such withdrawal symptoms could 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, restlessness and mood changes, these will however disappear with time.

If you have become physically dependent on Zopiclone, sudden withdrawal of treatment could lead to symptoms such as headaches, tension, muscle pain, confusion, anxiety, tremor, sweats, agitation, palpitation, fast heart rate, nightmares, panic attacks, muscle aches and cramps, upset stomach, restlessness, irritability and lower level of awareness and problems with focusing and concentrating. In severe cases symptoms may also include hypersensitivity to light, noise and physical contact, hallucinations, epileptic seizures, personality disturbances, numbness of the extremities and the feeling that the world around you is not real (derealisation).

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)

- 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 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?”)

Other side effects may include:
Common (may affect up to 1 in 10 people):
- Sleepiness during the following day
- Bitter taste in the mouth
- Dry mouth

Uncommon (may affect up to 1 in 100 people):
- Feeling physically or mentally tired
- Nightmares
- Agitation
- Headaches
- Feeling sick (nausea)
- Vomiting
- Dizziness

Rare (may affect up to 1 in 1,000 people):
- Confusion
- Irritability
- Aggressiveness
- Changes in sexual drive (libido)
- Shortness of breath
- Itchy, lumpy rash (urticaria)

Very rare (may affect up to 1 in 10,000 people)
- Changes in liver functions, which may be seen in blood tests

Not known (frequency cannot be estimated from the available data):
- Dependence
- Restlessness
- Anger
- Uncontrollable movements
- Double vision
- Indigestion
- Muscle weakness
- Light-headedness
- Feeling uncoordinated
- Unsteadiness
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin
- Difficulty paying attention
- Disrupted normal speech
- Slower breathing (respiratory depression)
- Mental problems such as poor memory.

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.

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 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 outer carton and blister after EXP. The expiry date refers to the last day of that month.

Do not Store above 25°C and keep in the original package.

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. The other ingredients are lactose anhydrous (see section 2, 'Zopiclone contains lactose and Ponceau 4R'), calcium hydrogen phosphate anhydrous, maize starch, povidone, magnesium stearate and hypromellose. The printing ink and tablet coating contains titanium dioxide (E171), indigo carmine (E132), ponceau 4R (E124) (see section 2, 'Zopiclone contains lactose and Ponceau 4R'), quinoline yellow (E104) and macrogol 400.

What Zopiclone looks like and contents of the pack
Your medicine comes as a blue film coated round tablet with 'ZE3' printed on one side and 'G' in the reverse.

Zopiclone is available in blisters of 5, 7, 10, 14, 20, 21, 28, 30, 56, 60, 84, 90 and 100 tablets. Zopiclone is also available in a bulk pack of 100 tablets in a polypropylene container. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Viatris,
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