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.

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.

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
- have or ever had a history of alcohol or drug abuse (see also 'Dependence' below)
- have been told by a doctor that you have a personality disorder (see also 'Dependence' below).

Other considerations when taking Zopiclone are:
- Dependence – when taking this type of medicine there is a risk that you may develop some dependence. This risk increases with the time for which you have been taking zopiclone and your dosage. There is also a greater risk in those patients who have history of alcohol or drug abuse or personality disorders.
- 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
Do not drive, operate machinery or perform other tasks requiring mental alertness if you feel dizzy or drowsy, or you have eyesight problems while taking this medicine especially the morning after taking. If you have just started treatment with Zopiclone do not drive or use machines until you are sure that it is safe to do so. Zopiclone may make you feel drowsy, cause loss of concentration including memory problems or muscle weakness.

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

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

3. How to take Zopiclone

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.

Description	Zopiclone 3.75 mg 28			Date: 04 JUL 2019		Time: 12:29	
Component Type	Leaflet	Pharma Code	614	No. of colours	1	Page Count	1/2
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MA No.	NA	Client Market	United Kingdom	Equate CMYK with			
Packing Site/Printer	NA	Keyline/Drawing No.	NA				
Supplier Code	LT1291AK	Barcode Info	NA	Main Font	Myriad Pro	Body Text Size	10 pt
		3D Render ID	NA	Dimensions	170 x 480 mm	Min Text Size used	10 pt
Sign-offs							
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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.

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
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 anxiety, 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 and irritability. 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.

If any of the following happen, stop taking Zopiclone and tell your doctor immediately or go to your nearest hospital emergency department:
- Skin rash, itching
- Swelling of the face, lips, throat or tongue
- Difficulty breathing or swallowing.

These allergic reactions are rare but serious. You may need medical attention:

- Psychiatric and 'paradoxical' reactions – zopiclone can cause restlessness, agitation, irritability, aggression, delusion, outbursts of rage, nightmares, hallucinations, psychoses, unsuitable behaviour and other behavioural disturbances. If you experience any of these symptoms you should stop taking Zopiclone.
- Sleepwalking and associated behaviours – zopiclone can cause behaviours such as sleepwalking, 'sleep driving', preparing and eating food or making phone calls whilst not fully awake and with no memory of these actions. These can occur more commonly if you drink alcohol or take other sleeping pills or medicines to treat anxiety. If you experience any of these symptoms you should stop taking Zopiclone.
- Loss of memory (amnesia) to avoid this make sure you will be able to have 7-8 hours of uninterrupted sleep before taking this medicine
- Difficulty breathing, including very slow or shallow breathing

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

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

Rare (may affect up to 1 in 1,000 people):
- Numbed emotions
- Confusion
- Falls, which may be more likely in older people
- Irritability
- Aggressiveness
- Hallucinations (seeing, hearing and/or feeling things that are not there)
- Psychoses
- Changes in sexual drive (libido)
- Shortness of breath
- Diarrhoea
- Sweating

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

Not known (frequency cannot be estimated from the available data):
- Dependence
- Restlessness
- Fixed irrational ideas, not shared by others (delusions)
- Anger
- Depressed mood
- 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

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
Mylan,
Potters Bar,
Hertfordshire,
EN6 1TL.

Manufacturer
McDermott Laboratories Ltd t/a Gerard Laboratories,
35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13,
Ireland.

This leaflet was last revised in 07/2019

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