

PACKAGE LEAFLET

Package leaflet: Information for the patient

Zimoclone 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 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 Zimoclone is and what it is used for
2. What you need to know before you take Zimoclone
3. How to take Zimoclone
4. Possible side effects
5. How to store Zimoclone
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1. What Zimoclone is and what it is used for

Zimoclone tablets are sleeping pills (hypnotics) which work by acting on the brain to cause sleepiness. Zimoclone 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 Zimoclone

Do not take Zimoclone 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zimoclone 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. Zimoclone 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 Zimoclone 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 Zimoclone you will be able to have 7-8 hours of uninterrupted sleep.
- 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 medicines and Zimoclone

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 Zimoclone 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 Zimoclone 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.

Zimoclone 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

Zimoclone should not be used during pregnancy unless clearly necessary. If for urgent medical reasons, you take zopiclone during late pregnancy or during labour, your baby may show withdrawal symptoms after birth because of physical dependence.

Breast-feeding

Do not breast-feed your baby, as small amounts of zopiclone can 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 Zimoclone do not drive or use machines until you are sure that it is safe to do so. Zimoclone may make you feel drowsy, cause loss of concentration including memory problems or muscle weakness.

Zimoclone contains lactose

If your doctor has told you that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. How to take Zimoclone

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

1 tablet (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 (half a tablet) is recommended, with the tablets being taken immediately before going to bed.

Use in children and adolescents

Zimoclone 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.

How long should you take Zimoclone for

The duration of treatment with Zimoclone 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 Zimoclone 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 Zimoclone

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 Zimoclone

Treatment with zopiclone should be gradually withdrawn, as the symptoms that Zimoclone 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 Zimoclone, 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 Zimoclone 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 Zimoclone.
- 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 Zimoclone.
- 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)

- Changes in liver functions, which may be seen in blood tests
- Seizures (fits)

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

- Dependence
- Restlessness
- Fixed irrational ideas, not shared by others (delusions)
- Anger
- Depressed mood
- Sleepwalking and associated behaviours (which you may have no memory of)
- Uncontrollable movements
- Double vision
- Indigestion
- Muscle weakness
- Light-headedness
- Feeling uncoordinated
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin
- Difficulty concentrating or paying attention
- Disrupted normal speech
- Loss of memory
- Unsteadiness (often with a feeling of almost falling).

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 HPRA Pharmacovigilance, Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zimoclone

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 Zimoclone contains

The active substance is zopiclone. Each film-coated tablet contains 7.5 mg zopiclone.

The other ingredients are lactose (see section 2, 'Zimoclone contains lactose'), calcium hydrogen phosphate, maize starch, povidone, magnesium stearate and hypromellose. The tablet coating contains titanium dioxide (E171) and macrogol 400.

What Zimoclone looks like and contents of the pack

Your medicine comes as a white film-coated tablet with a breakline. The tablet can be divided into equal halves. The tablets are marked 'ZZ' on one side and '7.5' on the other.

Zimoclone is available in blisters of 5, 7, 10, 14, 20, 21, 28, 30, 56, 60, 84, 90 and 100 tablets.

Zimoclone is also available in a bulk pack of 100 or 500 tablets in a polypropylene container. Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturer

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

Madaus GmbH – 51101, Köln, Lütticher Straße 5, 53842 Troisdorf, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium - Zopiclone Mylan 7.5 mg filmomhulde tabletten

Finland - Zopiklon Mylan 7,5 mg kalvopäällysteinen tabletti

Germany - Zopiclodura 7.5 mg

Ireland - Zimoclone 7.5 mg Film-coated Tablets

The Netherlands - Zopiclon Mylan 7,5 mg filmomhulde tabletten

United Kingdom - Zopiclone 7.5 mg Film-coated Tablets

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