

PACKAGE LEAFLET

Package leaflet: Information for the patient
Zimovane 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. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Zimovane 7.5mg Film-Coated Tablets, which will be called Zimovane tablets through out this leaflet.

What is in this leaflet:

1. What Zimovane tablets are and what they are used for
2. What you need to know before you take Zimovane tablets
3. How to take Zimovane tablets
4. Possible side effects
5. How to store Zimovane tablets
6. Contents of the pack and further information

1. WHAT ARE ZIMOVANE TABLETS AND WHAT THEY ARE USED FOR

The active ingredient in these tablets is zopiclone. This belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep. The tablets are normally used for the short-term treatment of severe sleeping difficulties in adults.

2. WHAT YOU NEED TO KNOW BEFORE TAKING ZIMOVANE TABLETS

Do not take Zimovane tablets

- If you are allergic to zopiclone or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from myasthenia gravis (a condition where the muscles easily tire and become weak)
- If you have any severe breathing problems, if your lungs do not work properly (e.g. respiratory failure)
- If you suffer from severe sleep apnoea syndrome
- If the patient is under 18 years of age
- If you suffer from severe liver problems

Warnings and precautions

Tell your doctor or pharmacist before taking Zimovane if any of the following apply:

- If you are pregnant or think you might be pregnant
- If you are breast feeding

- If you have a history of drug or alcohol abuse
- If you are taking any other medicines.
- If you have to go to a doctor, dentist or hospital for any reason, tell them that you are taking Zimovane tablets.
- Zimovane belongs to the hypnotic group of medicines. There is a possibility that you may become physically and mentally dependant on them. The risk of dependence increases with dose and duration of treatment. It is also greater in patients with a history of alcohol and drug abuse. Abrupt termination will be accompanied by withdrawal symptoms (e.g. headache, restlessness, confusion, irritability, inability to fall asleep, or stay asleep after discontinuing your insomnia medication) anxiety, tremor, sweating, agitation, palpitations, increased heart rate, delirium, nightmares, hallucinations, and in very rare cases seizures may occur) therefore treatment should be gradually tapered off.
- There is a possibility that the medicine might lose its effectiveness at the given dosage over time (dose tolerance). If you feel that the effect of the medicine is not as good as it used to be, do not increase the dose but tell your doctor about this affect.
- Patients should ensure that they have 7-8 hours of uninterrupted sleep in order to reduce the risk of memory loss.
- Benzodiazepine and benzodiazepine-like agents are not recommended for the primary treatment of psychotic illness. Benzodiazepines and benzodiazepine-like agents should not be used alone to treat depression or anxiety associated with depression as this may lead to suicide in such patients.

Children and adolescents

Zimovane tablets are not recommended for children or adolescents under 18 years of age.

Older patients

It is generally recommended to start the treatment with Zimovane at lower doses in older patients due to better tolerability. Zimovane might increase the risk of falls and subsequent fractures in older patients as the medicine can cause muscle weakness and poor co-ordination especially after the start of treatment.

Other medicines and Zimovane tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You should tell your doctor if you are taking or have taken any of the following medicines as they may interact with your Zimovane tablets:

- Medicines for sleep problems (hypnotics)
- Medicines for mental problems (antipsychotics)
- Medicines for anxiety or depression
- Medicines for epilepsy (anticonvulsants)
- Medicines used in surgery (anaesthetics)
- Medicines for moderate to severe pain (narcotic analgesics) such as codeine, morphine or diamorphine
- Medicines to treat allergies, skin irritation or vomiting (sedative antihistamines).

The effect of zopiclone may be increased if it is taken with other drugs such as:

- Some antibiotics such as clarithromycin or erythromycin
- Some medicines for fungal infections such as ketoconazole and itraconazole
- Some Ritonavir (a protease inhibitor) – for HIV infections

In this instance a dose reduction of zopiclone may be required.

The effect of zopiclone may be decreased if it is taken with other drugs such as:

- Rifampicin (an antibiotic) – for infections
- Some medicines for epilepsy such as carbamazepine, phenobarbital or phenytoin
- St John's Wort (a herbal medicine) – for mood swings and depression

In this instance an increase in dose of zopiclone may be required.

Concomitant use of Zimovane 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 Zimovane 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.

Zimovane tablets with alcohol

Alcohol can affect the way Zimovane works, you should not drink alcohol whilst taking these tablets. Rarely the tablets may cause daytime drowsiness. You should not drive or operate machinery unless you are sure that you are not affected.

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. If your doctor has prescribed Zimovane during the later stages of pregnancy, then there may be some effects on the baby when it is born. Tell your doctor or midwife that you have taken Zimovane.

Driving and using machines

Zimovane tablets may affect your ability to drive or operate machinery. Make sure you are not affected before driving or operating machinery, especially if taken with alcohol.

Zimovane tablets contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. HOW TO TAKE ZIMOVANE TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Your doctor will have told you how much to take. The number of tablets you need to take will depend on your condition.

The usual adult dosage is one Zimovane 7.5mg Tablet. Your treatment will usually be for less than four weeks, and the doctor may reduce your dose near the end of your course.

Older patients and patients with liver or kidney problems

Older patients and people with liver or kidney problems, the starting dosage is usually ½ a tablet (i.e. 3.75mg) and if necessary increased to 7.5mg. The tablets should be swallowed whole with a small glass of water shortly before retiring.

Use in children and adolescents

Zopiclone should not be used in children and adolescents aged less than 18 years.

If you take more Zimovane tablets than you should

If you accidentally take too many tablets or a child swallows any tablets, contact your nearest hospital casualty department or tell your doctor immediately.

If you forget to take Zimovane tablets

Do not worry, just take your next tablet at the usual time, then go on as before.

Do not take a double dose to make up for a forgotten dose.

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 Zimovane 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.

Some side effects are serious, and you **should tell your doctor immediately if you have any of the following:**

- Mood changes such as irritability or aggressiveness
- Restlessness
- Agitation
- Delusion, rages
- Hallucinations or nightmares
- Memory loss (amnesia)
- Reoccurrence of pre-existing depression
- Dependence (where you require the medicine to function normally)

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.

Zimovane might increase the risk of falls and subsequent fractures in older patients as the medicine can cause muscle weakness and poor coordination, especially after the start of treatment.

Minor side effects of Zimovane that are well known are mild bitter or metallic taste in the mouth, dryness in mouth, dizziness, headache, drowsiness, numbed emotions, reduced alertness, confusion, forgetfulness, fatigue, muscle weakness, poor co-ordination and double vision.

Other side effects like gastrointestinal disturbances (feeling sick, indigestion), changes in libido, allergic reactions or skin reactions such as itchiness and rash have been reported occasionally.

Very rarely, changes in liver enzymes and liver function detected by a blood test were reported.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 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 ZIMOVANE TABLETS

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 carton or blister pack after "EXP". The expiry date refers to the last day of that month. Do not store above 30°C. Store in the original package in order to protect from light.

Do not keep the tablets if your doctor decides to stop treatment. Return them to your pharmacist who will arrange for their safe destruction.

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 FURTHER INFORMATION

What Zimovane tablets contains

The active ingredient in these tablets is zopiclone. Each tablet contains 7.5mg zopiclone. The tablet can be divided into equal halves.

The tablets also contain the following ingredients:

Tablet core; calcium hydrogen phosphate dihydrate, lactose monohydrate, corn starch, sodium starch, glycolate, magnesium stearate.

Tablet coat: hypromellose, titanium dioxide (E171).

What Zimovane tablets looks like and contents of the pack

Zimovane 7.5mg Film-Coated Tablets are oblong, white, film-coated scored tablets.

Pack size: 28 tablets.

Zimovane 7.5mg tablets are supplied in opaque white or clear orange PVdC coated PVC/aluminium foil blister strips packaged in outer boxes.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoyle Industrial Estate,
Dublin 13,
Ireland

Manufacturer

MEDA Manufacturing GmbH
Neurather Ring 1
51063 Cologne
Germany

Madaus GmbH
Lütticher Straße 5
53843 Troisdorf
Germany

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