

Package Leaflet: Information for the patient

Zopitan 3.75 mg Film-Coated Tablets Zopitan 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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zopitan is and what it is used for
2. What you need to know before you take Zopitan
3. How to take Zopitan
4. Possible side effects
5. How to store Zopitan
6. Contents of the pack and other information

1. What Zopitan is and what it is used for

The name of your medicine is Zopitan film-coated tablets. Zopitan tablets are part of a group of drugs known as hypnotics and sedatives.

In adults zopitan tablets are prescribed for the short-term treatment of insomnia (sleeplessness) which disrupts normal functioning or which causes extreme suffering. Zopitan tablets make you fall asleep more quickly.

2. What you need to know before you take Zopitan

Do not take Zopitan

- if you are allergic to zopiclone or any of the other ingredients of this medicine (listed in section 6)
- if you have ever had any severe problems with your liver
- if you have ever had any problems with your lungs
- if you have any difficulties with your breathing
- if you have a condition called myasthenia gravis (muscle weakness)
- if you have severe sleep apnoea syndrome caused by upper airway obstruction during sleep, associated with frequent awakening and often with daytime sleepiness.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zopitan

- if you are elderly
- if you are taking anti-depressants or drugs that act on the nervous system (for example tranquillizers)
- if you have been addicted to drugs before
- if you have ever experienced sleep walking or other events you do not remember while taking Zopitan. These events may become worse if you take Zopitan with alcohol or medicinal products used to treat psychotic disorders
- if you suffer from or have a history of depression, anxiety or psychotic illness
- if you have a history of alcohol or drug abuse

Children and adolescents

Zopiclone should not be used in children and adolescents aged less than 18 years. The safety and efficacy of zopiclone in children and adolescents aged less than 18 years have not been established.

Other considerations when taking Zopitan are

- Tolerance – If after a few weeks you notice that the tablets are not working as well as they did when you first started taking them, you should see your doctor, as an adjustment of your dosage may be required.
- 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 Zopitan and your dosage. There is also a greater risk in those patients who have history of alcohol or drug abuse.
- Withdrawal – when you stop taking Zopitan, treatment should be gradually withdrawn. For a time after stopping taking the tablets you may find that your symptoms of difficulty sleeping reoccur. This may be accompanied by other reactions such as nervousness, headaches, muscle pain, tension, confusion, restlessness and irritability.
- Amnesia – Taking Zopitan can cause memory loss. To avoid this make sure that when you take Zopitan you will be able to have uninterrupted sleep.
- Psychiatric and ‘paradoxical’ reactions – Zopitan 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 Zopitan.
- Sleepwalking and associated behaviours – Zopitan 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 Zopitan.

Other medicines and Zopitan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Please consult your doctor if you are taking:

- drugs used to treat psychotic disorders
- other drugs used to help you sleep
- drugs used to treat anxiety or depression
- strong painkillers such as codeine, morphine or diamorphine
- drugs used to treat epilepsy
- drugs used to induce anaesthesia
- sedative antihistamine (to treat allergies, skin irritation or vomiting)
- erythromycin or clarithromycin (antibiotics used to treat infections)
- ketoconazole, itraconazole (used to treat fungal infections)
- ritonavir (used to treat HIV infection)
- rifampicin (used to treat tuberculosis)
- St. John’s Wort.
- Concomitant use of Zopitan 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 Zopitan 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.

Zopitan with food, drink and alcohol

Alcohol can increase the sedative effect of Zopitan. You should not drink alcohol while taking this medicine.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Please tell your doctor if you are pregnant, think you might be pregnant or if you intend to become pregnant or are breast-feeding. Your doctor will decide if this medicine is suitable for you.

Driving and using machines

Zopitan may make you feel drowsy and occasionally this may persist until morning. If you feel drowsy you should not drive or use machinery as it may be dangerous.

Zopitan 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 dosage unit, that is to say essentially 'sodium-free'.

3. How to take Zopitan

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

Swallow the tablets whole with a glass of water.

Dosage

Adults

The recommended dose is 7.5 mg, 30 to 60 minutes before you go to bed.

Elderly

The recommended dose is 3.75 mg a day at first, and then gradually increased to 7.5 mg.

People with liver and kidney problems

The dose will be kept as low as possible. If you have mild kidney or liver problems you should not take more than 7.5 mg of Zopitan a day. If the problems are more serious, you should not take more than 3.75 mg of Zopitan a day.

Use in children and adolescents

Zopiclone should not be used in children and adolescents aged less than 18 years. The safety and efficacy of zopiclone in children and adolescents aged less than 18 years have not been established.

How long should you take Zopitan for

The duration of treatment should be as short as possible. In general, it should not exceed 4 weeks including the withdrawal period. Your doctor will choose a withdrawal regime based on your individual needs.

If you take more Zopitan than you should

It is important not to take too many tablets.

Contact your nearest hospital casualty department or your doctor for advice if you have swallowed too many tablets or if you think a child has swallowed any.

Take this leaflet, and any tablets that you still have to show the doctor.

If you take too many tablets you may feel tired or sleepy and have jerking movements.

If you forget to take Zopitan

If you forget to take a dose at the right time, take it as soon as you remember. If it is almost time to take the next dose, wait until then and then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Zopitan

It can be dangerous to stop taking your tablets without your doctor's advice. See section 4, "Possible side effects" for more information on the possible withdrawal symptoms when stopping treatment.

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 Zopitan 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 (may affect up to 1 in 1,000 people)

- Poor memory since taking Zopitan (amnesia). By having 7-8 hours of uninterrupted sleep after taking Zopitan, this is less likely to cause you a problem.

Not known (frequency cannot be estimated from available data)

- Believing, seeing or hearing things that are not real (delusion or hallucinations)
- Feeling low or sad (depressed mood)

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days

Common (may affect up to 1 in 10 people)

- A mild bitter or metallic taste in your mouth or a dry mouth

Uncommon (may affect up to 1 in 100 people)

- Feeling sick (nausea) or being sick (vomiting)
- Feeling dizzy or sleepy
- Headache
- Nightmares
- Feeling physically or mentally tired

Rare (may affect up to 1 in 1,000 people)

- Feeling confused
- Itchy, lumpy rash (urticaria)
- Feeling irritable or aggressive
- Reduced sex drive

Not known (frequency cannot be estimated from available data)

- Feeling restless or angry
- Feeling light headed or having problems with your coordination
- Double vision

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.

If you stop taking Zopitan

The use of Zopitan may lead to physical and mental dependence. When physical dependence has developed abrupt termination of treatment will be accompanied by withdrawal symptoms. If this affects you, the withdrawal symptoms may be similar to the symptoms you were originally given the tablets for. Withdrawal symptoms may include:

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|-------------|------------------------|
| • insomnia | • palpitations |
| • anxiety | • increased heart rate |
| • tremor | • delirium |
| • sweating | • nightmares |
| • agitation | • hallucinations |
| • confusion | • irritability |
| • headache | |

To reduce the risk of these symptoms, the treatment with Zopitan should not be terminated abruptly but gradually tapered off. The risk of dependence increases with dose and duration of treatment. In order to avoid the above mentioned symptoms, the use of Zopitan will normally not exceed two weeks with a maximum, including the tapering-off, of four weeks.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zopitan

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

Do not store above 25°C.

Store in the original package to protect from moisture.

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 Zopitan film-coated tablets contain

The active substance is zopiclone.

Each Zopitan 3.75 mg film-coated tablet contains 3.75 mg of zopiclone.

Each Zopitan 7.5 mg film-coated tablet contains 7.5 mg of zopiclone.

The other ingredients are:

Lactose monohydrate, calcium hydrogen phosphate dihydrate, maize starch, carmellose sodium, magnesium stearate, titanium dioxide (E171), hypromellose.

The 3.75 mg tablets, only, also contain iron oxide yellow (E172), iron oxide red (E172) and macrogol.

What Zopitan looks like and contents of the pack

Zopitan 3.75 mg film-coated tablets are orange, round, biconvex film-coated tablet marked ZOC 3.75 on one side.

Zopitan 7.5 mg film-coated tablets are white, round, biconvex film-coated tablet marked ZOC 7.5 on one side and a breakline on both sides.

Zopitan film-coated tablets are available in packs containing 10, 14, 28, 30, 56 and 60 tablets in PVC/PVDC/Al blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Clonmel Healthcare Ltd, Clonmel, Co. Tipperary, Ireland

Manufacturer:

Clonmel Healthcare Ltd, Clonmel, Co. Tipperary, Ireland

And

Synthon BV, Microweg 22, 6545 CM Nijmegen, The Netherlands

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