Package leaflet: Information for the user

Zorclone™ 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 Zorclone™ is and what it is used for

Zorclone™ is a sleeping tablet belonging to a group of medicines known as benzodiazepine-like agents.

Zorclone™ is prescribed for the short-term treatment of sleeplessness (insomnia) which disrupts normal functioning or which causes extreme suffering in adults. Zopiclone makes you fall asleep more quickly.

2. What you need to know before you take Zorclone™

Do not take Zorclone™ if you**:**
- are **allergic (hypersensitive) to zopiclone or any of the other ingredients** of Zorclone™ (listed in section 6).
- suffer from a specific **muscle weakness** disease called myasthenia gravis.
- have **severe breathing problems**.
- suffer from **sleep apnoea syndrome** (severe snoring with long pauses between two breaths).
- have severe **liver problems**.
- are **under the age of 18** years.

Warnings and precautions
Talk to your doctor or pharmacist before taking Zorclone™ if you:

- have chronic (long-lasting) breathing problems. Zopiclone can sometimes depress breathing. Your doctor may prescribe a lower dose.
- have any liver or kidney problems (see also "Do not take Zorclone™ if you:"). Your doctor may prescribe a lower dose.
- suffer from depression or anxiety related to depression. Zopiclone should not be the only treatment you receive as you may be sensitive to suicidal thoughts.
- have a history of alcohol or drug abuse. You should be carefully supervised by your doctor during treatment with zopiclone, as you are at risk of habituation and psychological dependence.
- have recently taken zopiclone or other similar medicines for more than four weeks.

- do not feel you will be able to stop taking zopiclone or other similar medicines used to treat sleep problems.
- are elderly. Your doctor may prescribe a lower dose.
- Suffer from a psychotic illness. Zopiclone is not recommended as the primary treatment in these cases.

Other considerations when taking Zorclone™
Taking Zopiclone can cause memory loss. To avoid this make sure that when you take Zopiclone, an uninterrupted sleep of 7-8 hours will be possible

The effect of zopiclone can decrease when it is taken for a longer period.

Upon stopping the treatment with zopiclone, the symptoms you were treated for (sleeplessness) may return temporarily and more severely (rebound insomnia). They can be accompanied by mood changes, anxiety and restlessness. To minimise the risk of these symptoms, zopiclone treatment should not be stopped abruptly; the dosage should be decreased gradually.

Zopiclone can cause restlessness, inner restlessness, irritability, aggressiveness, delusions (psychoses), rages, nightmares, hallucinations, inappropriate behaviour, increased sleep disturbances. These and other adverse behavioural effects are known to occur during treatment. If any of these occur, you should stop taking zopiclone and contact your doctor.

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.

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 o medicines to treat anxiety. If you experience any of these symptoms you should stop taking Zorclone™.

Before treatment with Zorclone™:
- the cause of the sleep disturbances should be clarified.
- underlying diseases should be treated.

Dependence
Development of physical and psychological dependence is possible. Therefore treatment with Zorclone™ should be as short as possible and should **not exceed four weeks at the lowest effective dose** (including the time to decrease the dosage before stopping treatment).
The risk of dependence increases with the dose and duration of treatment and is increased in patients with previous alcohol or drug abuse. If physical dependence has developed, sudden stop of treatment is accompanied by withdrawal symptoms (see also "If you stop taking Zorclone™").

Children and adolescents
Zorclone™ should not be used by children and adolescents less than 18 years.

Other medicines and Zorclone™
Tell your doctor or pharmactist if you are taking, have recently taken or might take any other medicines.
Please consult your doctor if you are taking:
– medicines to treat mental illness (psychosis/schizophrenia)
– medicines to treat anxiety and depression
– medicines to treat epilepsy (anticonvulsants)
– medicines used in surgery (anaesthetics)

– medicines to treat allergies, skin irritations or vomiting (sedatives anti-histamines such as chlorphenamide or promethazine)
– medicines for moderate to severe pain (narcotic analgesics) such as codeine, morphine or diamorphine

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
- Ritonavir (a protease inhibitor) – for HIV infections

In this instance, a dose reduction of Zorclone™ 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 Zorclone™ may be required.

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 Zorclone™ 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.

Please **tell your doctor or pharmacist** if you are taking or have recently taken any of the medicines listed above or any other medicines, including medicines obtained without a prescription.

Zorclone™ with food, drink and alcohol
You should not drink **alcohol** while taking zopiclone, as alcohol may increase the sedative effect of zopiclone. This may have a negative effect on your ability to drive or operate machines.
Grapefruit and grapefruit juice should be avoided when taking Zorclone™. Grapefruit may increase the effect of zopiclone.

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.

Use of zopiclone is not recommended during pregnancy.
If you take zopiclone during the last three months of your pregnancy or during labour (only in case of clear medical benefit as decided by your doctor) your new born child may temporarily have a low body temperature, low muscle strength (hypotonia), feeding difficulties and decreased breathing function.
If you have taken zopiclone for a longer time during the last months of your pregnancy, your new born child may have developed a dependency and may show withdrawal symptoms (see section 3 'If you stop taking Zorclone™').

Zopiclone passes into breast milk. You **should not take zopiclone** while you are breast-feeding.

Driving and using machines
Zopiclone is meant to make you sleepy. Therefore you should not drive or operate machines while you take zopiclone.

Zorclone™ 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 Zorclone™

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

The recommended dose is 7.5 mg, taken just before going to bed. This dose should not be exceeded.
You can take zopiclone with or without food or (non-alcoholic) drink.

Elderly patients, patients with decreased liver or kidney function and patients with long-lasting (chronic) breathing difficulties should start with a dose of 3.75 mg.

If necessary the 7.5 mg tablets can be split in two (3.75 mg). The easiest way to break the tablet is illustrated below:

Press forefinger and thumb of the same hand on either side of the division mark and push.

Treatment with zopiclone should be as short as possible. Generally the duration of treatment varies from a few days to two weeks. The duration of treatment should not exceed four weeks; this includes the time needed to decrease the dose towards the end of treatment.
In certain cases the treatment may be extended beyond the maximum period of four weeks, if necessary.

This can only be decided by your doctor after a re-evalutaion of your status.

If you take more Zorclone™ than you should
If you take more zopiclone than you should, **contact you doctor immediatel**y. You may experience dizziness, difficulty in co-ordinating movements and fatigue. A large overdose or an overdose combined with other medicines acting directly on the brain (central nervous system depressants) including alcohol may lead to coma.
You doctor can try to empty your stomach and may monitor your heart and breathing.

If you forget to take Zorclone™
Do not take a double dose to make up for a forgotten dose. Skip the missed dose and take the next tablet at the usual time.

If you stop taking Zorclone™
You should not stop zopiclone treatment abruptly.
You may develop physical and psychological dependence when taking zopiclone, even at the normal dose. Stopping treatment abruptly may lead to withdrawal symptoms like headaches, muscle pain, extreme anxiety, feelings of tension, restlessness, confusion and irritability. In severe cases you may also experience

loss of reality, depersonalisation, sensitivity to certain sounds, numbness and tingling in arms and legs, hypersensitivity to light, noise and physical contact, hallucinations or seizures.
To minimise the risk of withdrawal symptoms the dosage should be decreased gradually towards the end of 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 Zorclone™ 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.

The following side effects have been observed for zopiclone:

Common *(may affect up to 1 in 10 people):*
Drowsiness • Decreased alertness • Bitter taste or metallic after taste.

Uncommon *(may affect up to 1 in 100 people):*
• Headache • Dizziness

Rare *(may affect up to 1 in 1,000 people):*
• Confusion • Depression • Restlessness • Agitation • Irritability • Aggression • False beliefs (delusions) • Rage • Nightmares • Hallucinations • Mental disturbances (psychoses) • Inappropriate behaviour • Behavioural disturbances • Memory loss (see also Section 2 'Before you take zopiclone') • Double vision (occurs mainly at the beginning of treatment and generally disappears after repeated administration) • Sleep driving and walking (alcohol and some medicines for depression or anxiety can increase the chance that this effect will happen) • Lightheadiness • Dry mouth • Indigestion • Gastrointestinal problems including feeling and being sick • Tiredness • Muscle weakness • Falling • Poor memory • Allergic reactions, including skin reactions like rash and hives

Very rare *(may affect up to 1 in 10,000 people):*
Severe allergic (hypersensitivity) reactions (anaphylactic reactions) • Serious allergic reaction which causes swelling of the face or throat (angioedema) • Change in sexual need • Changes in liver enzymes and liver function detected by a blood test

Not known *(frequency cannot be estimated from the available data):*
Dependence (see also Section 2 'What you need to know before you take Zorclone™) • Numbed emotions • Difficulty in co-ordinating movements (occurs mainly at the beginning of treatment and generally disappears after repeated administration)

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 Zorclone™

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 packaging after 'EXP'. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

Do not store above 25 °C.
Store 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 Zorclone™ contains
- The active substance is zopiclone (7.5 mg).
- The other ingredients are lactose monohydrate, calcium hydrogen phosphate dihydrate, maize starch, croscarmellose sodium, magnesium stearate (core) and titanium dioxide (E171) and hydroxypropylmethylcellulose (E464) (coating).

What Zorclone™ looks like and contents of the pack
The 7.5 mg tablets are white, round, biconvex film-coated tablets, debossed with 'ZOC 7.5' and a narrow division mark on one side and a wide division mark on the other side.

The film-coated tablets are available in blister packs of 10, 14, 20, 28, 30, 56, 60 tablets per carton box and as hospital blister of 50 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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