**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.

Zopiclone 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).
- if you suffer from a specific muscle disease called **myasthenia gravis**.
- if you have severe **breathing problems**.
- if you suffer from **sleep apnoea syndrome** (severe snoring with long pauses between two breaths).
- if your **liver function** is severely decreased.

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Zorclone™

**Children and adolescents**
Zopiclone should not be used by children and adolescents less than 18 years.
**Take special care with Zorclone™**
- if you have **chronic** (long-lasting) **breathing problems**. Zopiclone can sometimes depress breathing. Your doctor may prescribe a lower dose.
- if you 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.
- if you 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.

- if you suffer from a **psychotic illness**. Zopiclone is not recommended as the primary treatment in these cases.
- if you are about to **stop the treatment**. 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.
- if you take zopiclone for **several weeks**. The effect of zopiclone can decrease when it is taken for a longer period.
- if you foresee you **cannot get an uninterrupted sleep of 7 to 8 hours**. Zopiclone may cause loss of memory (amnesia). This generally occurs some hours after intake of zopiclone. In order to minimize this risk, you should make sure that an uninterrupted sleep of 7-8 hours will be possible.
- if you **experience any of the following behavioural reactions**: 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. These reactions are more likely to occur in children and the elderly.

Before treatment with zopiclone:
- 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 zopiclone should be as short as possible and should **not exceed four weeks** (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.

**Other medicines and Zorclone™**
Other medicines may be affected by zopiclone. They, in turn, may affect how well zopiclone works.
Zopiclone can interact with:
- **medicines acting directly on the brain** (Central Nervous System depressants) like drugs to treat psychosis/schizophrenia, drugs to treat anxiety, antidepressants, painkillers, anti-epileptic drugs, anaesthetics, sedatives and sedative anti-allergic medicines (anti-histamines). These medicines may increase the effect of zopiclone.
- **painkillers** (narcotic analgesics). Zopiclone may increase the feeling of intense happiness (euphoric effect) caused by these medicines, thereby increasing the risk of psychological dependence to these medicines.
- medicines which **decrease the activity of certain liver enzymes** (such as erythromycin, clarithromycin, ketoconazole, itraconazole and ritonavir). They may increase the effect of zopiclone.
- medicines which **increase the activity of certain liver enzymes** (such as rifampicin, carbamazepine, phenobarbital, phenytoin and St. John's wort). They may decrease the effect of zopiclone

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 can take zopiclone with or without food or (non-alcoholic) drink.
You should not drink **alcohol** while taking zopiclone, as alcohol may increase the effect of zopiclone. This may have a negative effect on your ability to drive or operate machines.

**Pregnancy and breast-feeding**

There are insufficient data to assess the safety of zopiclone use during pregnancy.
You **should not take zopiclone** while you are pregnant, unless it is clearly necessary. Your doctor will make this decision for you.
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) 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 'How to take Zorclone™').

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

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

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

**Zorclone™ contains sodium**
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.

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.

The following side effects have been observed for zopiclone:

***Very Common side effects*** *(may affect more than 1 in 10 people):*
Bitter after taste

***Common side effects*** *(may affect more than 1 in 100, but less than 1 in 10 people):*
Drowsiness • Decreased alertness • Headache • Dizziness • Gastrointestinal problems

***Uncommon*** *side effects (may affect more than 1 in 1000, but less than 1 in 100 people):*
Tiredness

***Rare side effects*** *(may affect more than 1 in 10,000, but less than 1 in 1000 people):*
Allergic reactions, including skin reactions like rash and hives • Numbed emotions • 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') • Difficulty in co-ordinating movements (occurs mainly at the beginning of treatment and generally disappears after repeated administration) • Double vision (occurs mainly at the beginning of treatment and generally disappears after repeated administration) • Muscle weakness

***Very rare side effects*** *(may affect less than 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

***Side effects with unknown frequency:***
Dependence (see also Section 2 'What you need to know before you take Zorclone™) • Falling • Skin reactions

**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**

*Marketing Authorisation Holder:*
Teva B.V.
Swensweg 5
2031GA Haarlem
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*Manufacturers:*
Synthon BV
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**This leaflet was last revised in October 2020.**