

Zileze® 3.75 mg & 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 Zileze is and what it is used for
2. What you need to know before you take Zileze
3. How to take Zileze
4. Possible side effects
5. How to store Zileze
6. Contents of the pack and other information

1. What Zileze is and what it is used for

Zileze Film-Coated Tablets contain zopiclone which belongs to a group of medicines called hypnotics that act on your brain. Zileze has been prescribed by your doctor to help you sleep. Your doctor will only prescribe these tablets if he/she considers your sleep problem to be severe, disabling or distressful. Sleeping problems do not usually last for a long time and therefore most people only need a short course of treatment. The length of time for which your doctor will prescribe you to take Zileze will vary from a few days to three weeks, with a maximum of four weeks. You should contact your doctor again if you still have problems sleeping after you have finished your course of tablets.

2. What you need to know before you take Zileze

Do not take Zileze:

- if you are under the age of 18. The safety and efficacy of Zileze in children and adolescents aged less than 18 years have not been established
- if you are allergic to zopiclone or any of the other ingredients in Zileze, listed in Section 6 (Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue)
- if you have a problem that causes severe muscle weakness (myasthenia gravis)
- if you have a problem where you stop breathing for short periods at night (sleep apnoea)
- if you suffer from breathing difficulties
- if you have severe liver problems

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Zileze.

Warnings and precautions:

- you suffer from mild breathing problems, your doctor will decide if you should receive Zileze
- Before taking Zileze, it is important to make sure that you can have at least 7 to 8 hours of uninterrupted sleep to help reduce the risk of some side effects (see section 4 – Possible side effects)
- you have been told by a doctor that you have a personality disorder
- you have any liver or kidney problems, your doctor may need to give you a lower dose of Zileze
- you have recently taken Zileze or other similar medicines for more than four weeks
- you do not feel you will ever be able to stop taking Zileze or other medicines used to treat sleep problems
- you have a history of alcohol or drug abuse.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Zileze.

Other considerations for when taking Zileze 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 Zileze 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 Zileze 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 Zileze can cause memory loss. To avoid this make sure that when you take Zileze you will be able to have uninterrupted sleep
- Psychiatric and ‘paradoxical’ reactions – Zileze 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 Zileze.

Other medicines and Zileze

Before starting treatment, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is because Zileze can affect the way some other medicines work. Also some medicines can affect the way Zileze works. If you have to go to a doctor, dentist or hospital for any reason, tell them that you are taking Zileze.

In particular, tell your doctor if you are taking:

- medicines for mental problems (antipsychotics)
- medicines for depression
- medicines to calm or reduce anxiety or for sleep problems (hypnotics)
- medicines for epilepsy (anticonvulsants), such as carbamazepine, phenobarbital or phenytoin
- medicines for moderate to severe pain (narcotic analgesics) such as codeine, methadone, morphine, oxycodone, pethidine or tramadol
- medicines used in surgery (anaesthetics)
- medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines) such as chlorphenamine or promethazine
- ritonavir (a protease inhibitor), used to treat HIV infections
- rifampicin, an antibiotic to treat tuberculosis
- St John’s Wort, a herbal medicine for mood swings and depression
- medicines to treat fungal infections, such as ketoconazole and itraconazole
- antibiotics, such as clarithromycin or erythromycin

Taking Zileze with alcohol

You should not drink alcohol while being treated with this medicine, because this may increase the sedative effect of Zileze so that you do not breathe properly or have difficulty waking. This may persist to the following morning and affect your ability to drive.

Pregnancy, breast-feeding and fertility

- Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant
- Do not take Zileze during the last 3 months of pregnancy or during labour because it may be harmful to your baby
- Do not breast-feed if you are taking Zileze. This is because small amounts may pass into mother’s milk. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines:

Like other medicines used for sleep problems, Zileze can cause slowing of your normal brain function (central nervous system depression). The risk of psychomotor impairment including driving ability, is increased if:

- You take Zileze within 12 hours of performing activities that require mental alertness
- You take higher than the recommended dose of Zileze
- You take Zileze while already taking another central nervous system depressant or another medicine that increases levels of Zileze in your blood, or while drinking alcohol.

Do not engage in hazardous activities requiring complete mental alertness such as driving or operating machinery after taking Zileze, and in particular during the 12 hours after taking your medicine.

For more information about possible side effects which could affect your driving see section 4 of this leaflet.

Important information about some of the ingredients of Zileze

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

3. How to take Zileze

Always take Zileze exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The label on the carton will tell you how many tablets you should take and when. **Do not stop taking or change the prescribed dose** without talking to your doctor first.

How to take your tablets

- Take this medicine by mouth
- Swallow the tablet whole with a glass of water
- Do not crush or chew your tablets
- Take your tablet 30 to 60 minutes before bedtime and do not take again during the same night

Dosage

Adults

The usual dose is 7.5mg 30 to 60 minutes before bedtime.

Elderly

The usual starting dose 3.75mg just before bedtime. Your doctor may decide to increase your dose to 7.5mg if needed.

Please read the back of this leaflet

Patients with liver, kidney or respiratory problems

The usual starting dose is 3.75mg just before bedtime.

Blood Tests

- Zileze can change the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly
- If you are going to have a blood test, it is important to tell your doctor that you are taking Zileze

Children and adolescents

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

Length of treatment

The usual length of treatment is 2 days to 3 weeks. This includes the time for your doctor to gradually reduce your dose, if it is necessary.

The risk of zopiclone becoming 'habit forming' is low but can increase if the length of treatment lasts longer than four weeks.

If you take more Zileze than you should

If you take more Zileze than you should, contact your nearest casualty department or tell your doctor or pharmacist immediately. Remember to take the pack and any remaining tablets with you.

Taking too much Zileze can be very dangerous. The following effects may happen:

- Feeling drowsy, confused, sleeping deeply and possibly falling in to a coma
- Floppy muscles (hypotonia)
- Feeling dizzy, light headed or faint. These effects are due to low blood pressure
- Falling over or losing your balance (ataxia)
- Shallow breathing or difficulty breathing (respiratory depression)

If you forget to take Zileze

If you forget to take your tablet before going to bed but remember during the night, only take the missed dose if you are still able to have 7 to 8 hours of uninterrupted sleep. If this is not possible, take the next dose before bedtime the next night otherwise you may feel drowsy, dizzy and confused during the day. **Do not** take a double dose to make up for a missed dose.

If you stop taking Zileze

If you stop taking Zileze suddenly, your sleep problems may come back and you may get a 'withdrawal effect'. Contact your doctor straightaway if you get any of the following effects:

- aching muscles
- feeling anxious, tense, irritable, confused or having panic attacks
- numbness and tingling in your hands and feet
- fits (seizures)
- being more sensitive to light, noise and touch than normal
- seeing or hearing things that are not real
- restlessness
- relaxed grip on reality
- tremor
- sweating
- nightmares
- faster heartbeat or uneven heartbeat (palpitations)
- headache
- a lower level of awareness and problems with focusing or concentrating
- stomach problems

4. Possible side effects

Like all medicines, Zileze can cause side effects, although not everyone gets them.

Allergic reactions, although serious, have been reported in rare cases. If you experience any of the following, **stop** taking your tablets and contact your doctor or casualty department immediately.

- rashes
- severe wheezing
- itching
- shortness of breath
- swallowing problems
- swelling of your lips, face, throat or tongue

The following side effects have also been reported, tell your doctor or pharmacist immediately if you notice any of these:

Rare (affects 1 to 10 users in 10,000)

- Poor memory since taking Zileze (amnesia). By having 7-8 hours of uninterrupted sleep after taking Zileze, this is less likely to cause you a problem.
- Seeing or hearing things that are not real (hallucinations)
- Falling, especially in the elderly

Not known (frequency cannot be estimated from available data)

- Thinking things that are not true (delusions)
- 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 (affects 1 to 10 users in 100)

- A mild bitter or metallic taste in your mouth or a dry mouth
- Feeling drowsy or sleepy
- Dry mouth

Uncommon (affects 1 to 10 users in 1,000)

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

Rare (affects 1 to 10 users in 10,000)

- Feeling confused
- Itchy, lumpy rash (urticaria)
- Feeling irritable or aggressive
- Reduced sex drive
- Difficulty breathing or being short of breath

Not known (frequency cannot be estimated from available data)

- Feeling restless or angry
- Feeling light headed or having problems with your coordination
- Double vision
- Moving unsteadily or staggering
- Muscular weakness
- Indigestion
- Becoming dependent on Zileze
- Slower breathing (respiratory depression)
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Mental problems such as poor memory
- Difficulty paying attention
- Disrupted normal speech

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.

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 Zileze

- Keep this medicine out of the sight and reach of children
- Do not store above 25°C. Keep the blister in outer carton in order to protect the tablets from light.
- Do not use Zileze after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Zileze contains:

- The active substance in your tablets is zopiclone. Each tablet contains either 3.75mg or 7.5mg of zopiclone.
- The other ingredients are lactose monohydrate, calcium hydrogen phosphate, maize starch, croscarmellose sodium, magnesium stearate, titanium dioxide (E171), hypromellose (E464). Yellow iron oxide (E172), red iron oxide (E172) and macrogol [3.75mg tablets only].

What Zileze looks like and contents of the pack:

Zileze Film-Coated Tablets are round and biconvex in shape and are available in blister packs of 28 tablets. Each strength can be identified by its colour and marking.

3.75mg tablets are orange and marked with "ZOC 3.75"

7.5mg tablets are white and marked with "ZOC 7.5"

Marketing Authorisation Holder: Chiesi Limited, 333 Styal Road, Manchester, M22 5LG, UK.

Manufacturer: Chiesi Limited, 333 Styal Road, Manchester, M22 5LG, UK and Synthon BV, Microveg 22, 6545 CM Nijmegen, The Netherlands.

Distributed by: Pinewood Laboratory Limited, Ballymacarbry, Clonmel, Co. Tipperary.

Is this leaflet hard to see or read? Phone + 44 161 488 5555 for help

This leaflet was last revised 01/2017