

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zopiclone 3.75mg film-coated Tablets and
Zopiclone 7.5mg film-coated Tablets

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 or nurse.
- This medicine has been prescribed for you only. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect, not listed in this leaflet, please tell your doctor or pharmacist. .

What is in this leaflet:

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

1. What Zopiclone is and what it is used for

The name of your medicine is Zopiclone 3.75mg Tablets or Zopiclone 7.5mg Tablets (both called Zopiclone in this leaflet). Zopiclone belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep.

Zopiclone is used to treat sleep problems in adults such as:

- Difficulty falling asleep
- Waking in the middle of the night
- Waking too early
- Severe or upsetting sleep problems that are caused by your mood or mental health problems.

Zopiclone is used for short-term treatment of insomnia in adults. Do not use long-term. Treatment should be as short as possible, because the risk of dependence increases with the duration of treatment.

Ask your doctor for advice if you are unsure.

2. What you need to know before you take Zopiclone:

Do not take Zopiclone if:

- you are allergic to zopiclone or any of the other ingredients of this medicine (listed in Section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- you have a problem that causes severe muscle weakness (myasthenia gravis)
- your lungs do not work properly (respiratory failure)
- you have a problem where you stop breathing for short periods at night (sleep apnoea)
- you have severe liver problems
- you are under the age of 18. The safety and efficacy of Zopiclone in children and adolescents aged less than 18 years have not been established.
- you have ever experienced sleepwalking or other unusual behavior (such as driving, eating, making a phone call or having sex etc.) while not being fully awake after taking.

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 Zopiclone.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zopiclone if:

- You have any liver problems (see also 'Do not take this medicine and tell your doctor if': section above).
- Your doctor may need to give you a lower dose of Zopiclone
- You have any kidney problems. Your doctor may need to give you a lower dose of Zopiclone
- You suffer from mild breathing problems, your doctor will decide if you should receive Zopiclone (see also 'Do not take this medicine and tell your doctor if': section above).
- You have a history of alcohol or drug abuse
- You have been told by a doctor that you have a personality disorder
- You have recently taken Zopiclone or other similar medicines for more than four weeks
- You do not feel you will ever be able to stop taking Zopiclone or other medicines used to treat sleep Problems.
- Drowsiness, difficulties breathing, coma and death may occur if Zopiclone is taken together with opioids, Zopiclone and opioids should only be used concomitantly, when other treatment options are inadequate.
- You have depression or have had another mental illness in the past.

Please tell your doctor about all opioid medicines you are taking and follow your doctor's dosage recommendations closely.

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.

Before taking Zopiclone, 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).

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

Zopiclone.

Use of Zopiclone may lead to the development of abuse and /or physical and psychological

dependence. The risk of dependence increases with dose and duration of treatment and is greater when Zopiclone is used for

longer than 4 weeks, and in patients with a history of mental disorders and/or alcohol, illicit substance or drug abuse. Tell your healthcare provider if you have ever had a mental disorder, or have abused or have been dependent on alcohol, substance or drugs.

Other medicines and Zopiclone

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

This includes medicines you buy without a prescription,including herbal medicines. This is because Zopiclone can affect the way some other medicines work. Also some medicines can affect the way Zopiclone works.

Tell your doctor if you are taking any of the following medicines. Zopiclone may increase the effect of the following medicines:

- Medicines for mental problems (antipsychotics)
- Medicines for epilepsy (anticonvulsants)
- Medicines used in surgery (anaesthetics)
- Medicines to calm or reduce anxiety or for sleep problems (hypnotics)
- Medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines) such as chlorphenamine or promethazine
- Some medicines for moderate to severe pain (narcotic analgesics) such as codeine, methadone, morphine, oxycodone, pethidine or tramadol.
- Medicines for depression

The following medicines can increase the chance of you getting side effects when taken with Zopiclone. To make this less likely, your doctor may decide to lower your dose of Zopiclone:

- Some antibiotics such as clarithromycin or erythromycin
- Some medicines for fungal infections such as ketoconazole and itraconazole
- Ritonavir (a protease inhibitor) - for HIV infections.
- Concomitant use of Zopiclone and opioids increases the risk of drowsiness, difficulties breathing, coma and death. Follow your doctor's dosage recommendations closely.

The following medicines can make Zopiclone work less well:

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

Taking Zopiclone with food and drink

- **Do not drink alcohol** while you are taking Zopiclone. Alcohol can increase the effects of Zopiclone and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

Pregnancy, breast-feeding and fertility

Pregnancy

Use of Zopiclone is not recommended during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice.

If used during pregnancy there is a risk that the baby is affected. Some studies have shown that there may be an increased risk of cleft lip and palate (sometimes called "harelip") in the newborn baby.

Reduced fetal movement and fetal heart rate variability may occur after taking Zopiclone during the second and/or third trimester of pregnancy.

If Zopiclone is taken at the end of pregnancy or during labour, your baby may show muscle weakness, a drop in body temperature, difficulty feeding and breathing problems (respiratory depression)

If this medicine is taken regularly in late pregnancy, your baby may develop physical dependence and may be at risk of developing withdrawal symptoms such as agitation or shaking. In this case the newborn should be closely monitored during the postnatal period.

Breast-feeding

Do not take Zopiclone if you are breast-feeding or planning to breast-feed. 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, Zopiclone 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 Zopiclone within 12 hours of performing activities that require mental alertness
- You take higher than the recommended dose of Zopiclone
- You take Zopiclone while already taking another central nervous system depressant or another medicine that increases levels of Zopiclone 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 Zopiclone, 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.

Zopiclone contains lactose

Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine product.

3. How to take Zopiclone

Treatment should be as short as possible and should not exceed four weeks including a period of tapering off.

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

Taking this medicine

- Take this medicine by mouth
- Swallow the tablet with a drink of water
- Do not crush or chew your tablets
- Take just before bedtime in a single intake and do not take again during the same night
- The usual length of treatment is 2 days to 3 weeks

Adults

The usual dose is one Zopiclone 7.5mg tablet just before bedtime.

Elderly

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

Use in children and adolescents

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

Patients with liver, respiratory or kidney problems

The usual starting dose is one Zopiclone 3.75mg tablet just before bedtime.

Blood Tests

- Zopiclone 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 Zopiclone.

If you take more Zopiclone than you should

If you take more Zopiclone than you should, tell a doctor or go to a hospital casualty department straight

away. Take the medicine pack with you. This is so the doctor knows what you have taken. Taking too much Zopiclone 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 Zopiclone

Zopiclone must only be taken at bedtime. If you forget to take your tablet at bedtime, then you should not take it at any other time, otherwise you may feel drowsy, dizzy and confused during the day.

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

If you stop taking Zopiclone

Keep taking Zopiclone until your doctor tells you to stop. Do not stop taking Zopiclone suddenly, but tell your doctor if you want to stop. Your doctor will need to lower your dose and stop your tablets over a period of time.

If you stop taking Zopiclone suddenly, your sleep problems may come back and you may get a

'withdrawal effect'. If this happens you may get some of the effects listed below.

See a doctor straight away if you get any of the following effects:

- Feeling anxious, shaky, irritable, agitated, confused or having panic attacks
- Sweating
- Headache
- Faster heartbeat or uneven heartbeat (palpitations)
- A lower level of awareness and problems with focusing or concentrating
- Nightmares, seeing or hearing things that are not real (hallucinations)
- Being more sensitive to light, noise and touch than normal
- Relaxed grip on reality
- Numbness and tingling in your hands and feet
- Aching muscles
- Stomach problems.

In rare cases fits (seizures) may also occur.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Zopiclone 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 (affects 1 to 10 users in 10,000)

- Poor memory since taking Zopiclone (amnesia). By having 7-8 hours of uninterrupted sleep after taking Zopiclone, 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 dependant on Zopiclone
- 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.
- Sleepwalking

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA

Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zopiclone

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

Store below 25°C. Keep the blister in the outer carton in order to protect from light and moisture.

Do not use this medicine if you notice any visible signs of deterioration to the tablets. 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 Zopiclone contains

- Each tablet of Zopiclone 3.75mg contains 3.75 mg of the active substance zopiclone
- Each tablet of Zopiclone 7.5mg contains 7.5 mg of the active substance zopiclone.

Other ingredients are calcium hydrogen phosphate dihydrate, starch pregelatinised, hydroxyl propyl cellulose, lactose monohydrate, maize starch, magnesium stearate, hypromellose, titanium dioxide and macrogol 400.

What Zopiclone looks like and contents of the pack

Zopiclone 3.75mg film-coated tablets - white to off white, round, biconvex film-coated tablet.

Zopiclone 7.5mg film-coated tablets - white to off white, oval, biconvex film-coated tablet with a breakline on one side.

Zopiclone 3.75mg film-coated tablets are available in PVC/ aluminium foil blisters containing 10, 28, 30 tablets.

Zopiclone 7.5mg film-coated tablets are available in PVC/ aluminium foil blisters containing 14, 28, 30 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

RIA Generics Limited, 36 Ingleby Way, Wallington, Surrey SM6 9LR, United Kingdom

Manufacturer

Wave Pharma Limited

4th floor, Cavendish House, 369 Burnt Oak, Broadway, Edgware, Middlesex HA8 5AW, UK

RIA Generics Limited

36 Ingleby Way, Wallington SM6 9LR, United Kingdom

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

If you would like to have any further information or want to report any side effects, please email at info@riagenerics.com.

This leaflet was last revised in September 2021.



Description	Zopiclone 3.75mg and 7.5mg		
Client	RIA Generic	Market	UK
Component	Leaflet	Version	05
Actual Size	180 mm x 430 mm	Font Size	9pt
Colors	BLACK	Font Style	Arial
Track Date	SS 06/08/2020		

Artwork Same Size
Size : 180 x 430 mm

Kaypee Design
(kaypeedesign@gmail.com)
21 09 20 / 03 09 21/24 09 21