

PATIENT INFORMATION LEAFLET

ZOLPIDEM 5MG OR 10MG 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.
- 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 effects not listed in this leaflet. See section 4.
- Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect.

What is in this leaflet:

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

1. What zolpidem is and what it is used for

The name of your medicine is Zolpidem 5mg or 10mg Tablets (called zolpidem throughout this leaflet). Zolpidem contains a medicine called zolpidem tartrate. This belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep.

Zolpidem is used for temporary sleep problems in adults that are causing you severe distress or that are affecting your everyday life. This includes sleep problems in adults such as:

- Difficulty falling asleep
- Waking in the middle of the night
- Waking too early

Your doctor will identify your sleep problem wherever possible and the underlying factors before prescribing this medicine for you. The failure of your sleep problems to stop after a 7-14 day course of treatment may indicate you have an underlying disorder, your doctor will assess you at regular intervals.

Zolpidem 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 zolpidem

Do not take zolpidem if:

- X You are allergic (hypersensitive) to zolpidem tartrate 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.
- X You have a problem where you stop breathing for short periods at night (sleep apnoea).
- X You have a problem that causes severe muscle weakness (myasthenia gravis).
- X You have breathing difficulties (hypoventilate).

- X You have severe liver problems.
- X You have been told by a doctor that you have a mental illness (psychosis).
- X You are under the age of 18.

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 zolpidem.

Warnings and precautions

Talk to your doctor or pharmacist before taking zolpidem if:

- You have a history of alcohol or drug abuse.
- Your lungs do not work properly.
- You have any liver problems.
- You have depression or have had another mental illness in the past.
- You have recently taken zolpidem or other similar medicines for more than 4 weeks.

Use of Zolpidem may lead to the development of abuse and/or physical and psychological dependence.

The risk of dependence is greater when zolpidem 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.

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.

Zolpidem can cause drowsiness and decrease your level of alertness. This could cause you to fall, sometimes leading to severe injuries.

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

Next day psychomotor impairment (see also ‘Driving and using machines’)

The day after taking zolpidem, the risk of psychomotor impairment, including impaired driving ability may be increased if:

- You take this medicine less than 8 hours before performing activities that require your alertness.
- You take a higher dose than recommended.
- You take zolpidem while you are already taking other central nervous system depressants or other medicines that increase zolpidem in your blood, or while drinking alcohol, or while taking illicit substances.

Take the single intake immediately at bedtime.

Do not take another dose during the same night.

Other medicines and zolpidem

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because zolpidem can affect the way some other medicines work. Also some medicines can affect the way zolpidem works.

Zolpidem may increase the effect of the following medicines:

While taking zolpidem with the following medicines, drowsiness and next-day psychomotor impairment effects, including impaired driving ability, may be increased:

- Medicines for mental problems (antipsychotics).
- Medicines for depression such as sertraline.
- Some medicines for moderate to severe pain (narcotic analgesics).
- 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.

While taking zolpidem with antidepressants including bupropion, desipramine, fluoxetine, sertraline and venlafaxine, you may see things that are not real (hallucinations).

It is not recommended to take zolpidem with fluvoxamine, ciprofloxacin or St. John's Wort (a herbal medicine) used for mood swings and depression.

Risks from concomitant use with opioids

Concomitant use of zolpidem 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 zolpidem together with opioids the dosage 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 dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of sign and symptoms stated above. Contact your doctor when experiencing such symptoms.

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

- Some medicines for fungal infections such as ketoconazole.

The following medicines can make zolpidem work less well:

- Rifampicin (an antibiotic) – for infections.

Zolpidem with alcohol

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

Pregnancy and breast-feeding

Pregnancy

Use of this medicine is not recommended during pregnancy.

If you discover that you are pregnant or are planning to have a baby, consult your doctor right away to re-assess the need for treatment.

A large amount of data has not shown evidence of malformations with benzodiazepines. However, some epidemiological studies have shown a potentially increased risk of cleft lip and palate in newborn babies compared to that in the general population. Cleft lip and palate (sometimes called "harelip") is a deformation at birth caused by incomplete fusion of the palate and upper lip.

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

If taken at the end of pregnancy muscle weakness (hypotonia), a drop in body temperature (hypothermia), difficulty feeding (problems suckling causing poor weight gain) and breathing problems (respiratory depression) may occur in the newborn.

If taken regularly in late pregnancy, your baby may get withdrawal symptoms. In this case the newborn should be closely monitored during the postnatal period.

Breast-feeding

Do not take zolpidem if you are breast-feeding or planning to breast-feed. This is because small amounts may pass into mothers' milk.

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

Driving and using machines

On the day after taking zolpidem, do not drive or use machinery or tools if you feel sleepy, dizzy or confused. Zolpidem has a major influence on the ability to drive and use machines such as 'sleep driving'. On the day after taking zolpidem (as with other hypnotic medicines), you should be aware that:

- You may feel drowsy, sleepy, dizzy or confused.
- You may take longer to make quick decisions.
- You may have double or blurred vision.
- You may be less alert.

A period of at least 8 hours is recommended between taking zolpidem and driving, using machinery and working at heights to minimize the above listed effects.

Do not drink alcohol or take other psychoactive substances while you are taking zolpidem as it can increase the above listed effects.

Zolpidem contains lactose

If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before having this medicine.

3. How to take zolpidem

Always take zolpidem 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 whole with a drink of water.
- The recommended dose per 24 hours is 10mg of zolpidem. A lower dose may be prescribed to some patients.
- Zolpidem should be taken as a single intake just before bedtime.
- Make sure you have a period of at least 8 hours after taking this medicine before performing activities that require your alertness.
- Do not exceed 10mg per 24 hours.
- The usual length of treatment is 2 days to 4 weeks.

How much to take

Adults

- The recommended dose is one 10mg tablet (or two 5mg tablets) just before bedtime. A lower dose may be prescribed to some patients.

Elderly

- The usual dose is one 5mg tablet just before bedtime.

Patients with liver problems

- The usual starting dose is one 5mg tablet just before bedtime. This may be increased to two 5mg tablets (or one 10mg tablet) by your doctor if necessary.

Children and adolescents

Do not give this medicine to children under 18 years old.

Blood Tests

- Zolpidem 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 zolpidem.

If you take more zolpidem than you should

If you take more zolpidem 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 zolpidem can be very dangerous. The following effects may happen:

- Feeling drowsy, confused, sleeping deeply and possibly falling into a coma.

If you forget to take zolpidem

Zolpidem 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 zolpidem

Keep taking zolpidem until your doctor tells you to stop. Do not stop taking zolpidem 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 zolpidem 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, or confused
- Feeling restless
- Headache
- Limp or weak muscles
- 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
- Changes in your behaviour
- Fits (seizures)

4. Possible side effects

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

Stop taking zolpidem and see a doctor or go to a hospital straight away if:

- You have an **allergic reaction**. These signs may include: an itchy, lumpy rash (hives) or nettle rash (urticaria), swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing

Tell your doctor as soon as possible if you have any of the following side effects:

Common side effects (may affect less than 1 in 10 people)

- Poor memory while taking zolpidem (amnesia) and strange behaviour during this time. This is more likely to affect you in the few hours after you take this medicine. By having 7-8 hours sleep after taking zolpidem this is less likely to cause you a problem
- Sleeping problems that get worse after taking this medicine
- Seeing or hearing things that are not real (hallucinations)

Uncommon side effects (may affect less than 1 in 100 people)

- Blurred eyesight or 'seeing double'

Rare side effects (may affect less than 1 in 1,000 people)

- Being less aware of your environment
- Falling, especially in the elderly

Sleep-driving and other sleep-related behaviour

There have been some reports of people doing things while asleep that they do not remember when waking up after taking a sleeping medicine. This includes sleep-driving, sleepwalking, preparing and eating food, and having sex. Alcohol and some medicines for depression or anxiety can increase the chance that this serious effect will happen.

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

Common side effects (may affect less than 1 in 10 people)

- Diarrhoea
- Feeling sick (nausea) or being sick (vomiting)
- Abdominal pain
- Respiratory infection
- Headache
- Feeling tired or agitated
- Nightmares
- Depression
- Feeling dizzy
- Feeling sleepy or drowsy
- Back pain

Uncommon side effects (may affect less than 1 in 100 people)

- Itching skin or skin rash
- Excessive sweating
- Feeling restless, aggressive, confused or irritable
- Feeling overly happy/confident (euphoric)

- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Tremor
- Sleepwalking (see ‘Sleep-driving and other sleep-related behaviour’)
- Lack of concentration
- Speech problems
- Blurred vision
- Changes in the amount of liver enzymes – shown up in the results of blood tests
- Changes in appetite or behaviour concerning appetite
- Muscle pain
- Muscle spasms
- Limp or weak muscles

Rare side effects (may affect less than 1 in 1,000 people)

- Itchy, lumpy rash (urticaria)
- Thinking things that are not true (delusions)
- Changes in sex drive (libido)
- You have discolouration of the skin or eyes, pain in the abdomen (stomach) or a bloated feeling, severe itching, pale or bloody stools, extreme weakness, nausea or loss of appetite. This could be caused by an infection or injury to the liver
- An illness where removal of bile from the liver is blocked (cholestasis). Signs include jaundice, rash or fever and the colour of your water (urine) becomes darker
- Changes in the way you walk

Very rare side effects (affects less than 1 in 10,000 people)

- Any changes in vision, in particular loss of vision
- Slower breathing (respiratory depression)
- Becoming dependent on zolpidem

Not known (frequency cannot be estimated from available data)

- A feeling of being out of touch with reality and being unable to think or judge clearly (psychosis)
- Feeling angry or showing unusual behaviour
- Needing to take more zolpidem in order to sleep

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 zolpidem

Keep this medicine out of the sight and reach of children.

Do not use zolpidem after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in a dry place below 30°C in the original packaging.

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 Zolpidem 5mg and 10mg Tablets contain

Each 5mg tablet contains 5mg of zolpidem tartrate as the active substance.

Each 10mg tablet contains 10mg zolpidem tartrate as the active substance.

The other ingredients of Zolpidem 5mg and 10mg Tablets are lactose monohydrate, microcrystalline cellulose, hypromellose, sodium starch glycollate, magnesium stearate, titanium dioxide (E171), macrogol 400.

What Zolpidem 5mg and 10mg Tablets look like and contents of the pack

Zolpidem 5mg Tablets are round, white to off-white, film-coated tablets.

Zolpidem 10mg Tablets are oblong, white to off-white, film-coated tablets, with a score line and SN10 on one side.

Zolpidem 5mg Tablets are supplied in cartons of 28 tablets.

Zolpidem 10mg Tablets are supplied in cartons of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, United Kingdom

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