

Package leaflet: Information for the user
Zolpidem 5 mg and 10 mg film-coated tablets
Zolpidem tartrate

This medicine contains Zolpidem tartrate, which can cause dependence, tolerance and addiction. You can get withdrawal symptoms if you stop taking it or reduce the dose suddenly.

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 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

This medicine has been prescribed to you for short-term treatment of insomnia.

It contains the Zolpidem tartrate which belongs to a class of medicines called Z-drugs.

The active substance zolpidem tartrate is a hypnotic. The drug has a calming, sedative, hypnotic, muscle relaxant, and anticonvulsant effect. Zolpidem is used for short-term treatment of insomnia in adults in situations where the insomnia is severe, disabling or subjecting the individual to extreme distress.

This medicine has been prescribed to you and should not be given to anyone else.

Z-drugs can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking it or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

2. What you need to know before you take Zolpidem

Please notice that your doctor may have prescribed the medicinal product for a different therapeutic indication and/or at a different dosage than stated in the package leaflet. Always follow the doctor's prescription and the instructions on the dosage label.

Do not take Zolpidem:

- if you suffer from myasthenia gravis (a special form of muscle fatigue).
- if you suffer from sleep apnoea (short periods without breathing, while asleep), or suffer from irregular snoring.
- if you suffer from severe hepatic insufficiency.
- if you suffer from acute or severe respiratory insufficiency.
- if you are allergic to zolpidem tartrate or any of the other ingredients of this medicine (listed in section 6).
- if you have ever experienced sleep walking or exhibited other abnormal behaviors (eg driving, eating, making phone calls or having sex, etc.) while not fully awake after taking Zolpidem or another medicine containing zolpidem.

Zolpidem must not be given to children and adolescents under 18 years of age.

Warnings and precautions

Contact your doctor or pharmacist before taking Zolpidem if you

- are elderly
- have renal insufficiency/ impaired kidney function

- have chronic respiratory problems
- have a psychiatric disease
- have a history of alcohol or drug abuse
- have a depression
- have hepatic insufficiency/ impaired liver function
- have hereditary long QT syndrome. Risks and benefits of Zolpidem should be carefully considered if you have hereditary long QT syndrome (fast-paced, irregular heart rhythm disorder).
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Zolpidem to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Zolpidem should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of Zolpidem, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Contact your doctor or pharmacist before taking Zolpidem if any of the following applies to you:

Children and adolescents

The safety of Zolpidem has not been established in patients younger than 18 years. Zolpidem should therefore not be used in children and adolescents younger than 18 years of age.

Tolerance (decreased effect)

The effect of Zolpidem might be reduced after repeated use for a few weeks.

Dependence

In some cases physical or psychological dependence can occur, when taking Zolpidem or other benzodiazepines. The risk increases with the dose and length of treatment period. The risk is greater if you have had an alcohol or drug abuse.

If you have developed physical dependence of Zolpidem, abrupt termination of treatment will be accompanied by withdrawal symptoms such as: headaches, muscle pain, extreme anxiety or tension, restlessness, confusion, irritability, or insomnia. In severe cases the following symptoms may occur: derealisation, depersonalization, hyperacusis, numbness and tingling of the extremities, hypersensitivity to light, noise, and physical contact, hallucinations or epileptic seizures.

Tell your doctor if you have a history of mental illness or have abused or been addicted to alcohol, drugs or medication.

Rebound effect

Might occur at the end of the treatment. The symptoms, which lead to the prescription of Zolpidem, will recur in an enhanced form. These symptoms will disappear again. Other symptoms may occur simultaneously, such as mood changes, anxiety, and restlessness.

It is recommended that you gradually reduce treatment with zolpidem in order to avoid withdrawal symptoms and rebound effects. Your doctor will tell you about this.

Duration of treatment

The duration of treatment with Zolpidem should be as short as possible and should not exceed 4 weeks including the tapering off process.

If you still experience insomnia after a 1-2 week treatment period, your insomnia may have mental or physical causes that you should talk to your doctor about.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include:

- feeling anxious, shaky, irritable, agitated, confused, having panic attacks, sweating, headache, faster heartbeat or uneven heartbeat (palpitations), lower level of awareness or problems with focusing or concentrating, nightmares, seeing of 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.

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

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 the recommended dose
- You take zolpidem while you are already taking another central nervous system depressants or another 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.

Amnesia

Use of Zolpidem might cause amnesia. This is observed several hours after ingesting the tablets. In order to reduce the risk, you should ensure to get 8 hours uninterrupted sleep.

Serious injuries

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

Psychiatric and “paradoxical” reactions

Reactions like restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, hallucinations, psychosis, sleepwalking, inappropriate behavior, aggravated insomnia and other adverse behavioral effects might occur, especially if you are older. You should stop taking Zolpidem if you experience these reactions.

Sleepwalking and other associated behavior

Sleep walking, sleep-driving, preparing and eating food in their sleep, making phone calls or implementation of intercourse, with no recollection of it, has been reported in patients who are not fully awake after taking zolpidem. Alcohol and some medicines for depression or anxiety or use of Zolpidem at doses exceeding the maximum recommended dose may increase the risk of these side effects. Tell your doctor immediately if you experience these events. Your doctor may recommend that you stop the treatment.

Depression

Zolpidem should be given with caution to patients with symptoms of depression. Suicidal tendencies may be present. Seek medical attention immediately if you have suicidal ideation.

Other medicines and Zolpidem

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

While taking zolpidem with the following medicines, drowsiness and psychomotor impairment effects, including

impaired driving ability, may be increased the next day:

- Medicines for some mental health problems (antipsychotics)
- Medicines for sleep problems (hypnotics)
- Medicines to calm or reduce anxiety
- Medicines for depressions
- Medicines for moderate to severe pain (narcotic analgesics)
- Medicines for epilepsy
- Medicines used for full anesthesia or local anesthesia
- Medicines for hay fever, rashes or other allergies that can make you sleepy (sedatives antihistamines)
- Medicines to treat fungal infections (eg ketoconazole)
- Medicines with muscle relaxant effect

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 or ciprofloxacin.

Concomitant use of Zolpidem with strong painkillers may increase the psychological dependence on this medicine. Concomitant use of Zolpidem and opioids (strong painkillers, substitution medications and some cough medicines) increases the risk of drowsiness, impaired breathing with bluish lips and nails (respiratory depression), deep unconsciousness (coma) and may be life-threatening. Because of this, concomitant use should only be considered when no other treatment options are available.

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 signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

The concentration of Zolpidem in your blood may decrease if you concomitantly are taking rifampicin and St John's Wort.

Zolpidem with food, drink and alcohol

Concomitant intake with alcohol is not recommended. If you drink alcohol while taking Zolpidem, the risk of side effects may be increased.

Pregnancy and breast-feeding

Pregnancy

You should not take Zolpidem if you are pregnant. If you are pregnant, think you may be pregnant or are planning to become pregnant, ask your doctor for advice before taking this medicine.

If Zolpidem are 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 Zolpidem during the second and/or third trimester of pregnancy.

If Zolpidem 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 Zolpidem 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.

Breastfeeding

Zolpidem is excreted in breast milk. The use of zolpidem in nursing mothers is therefore not recommended. If you are breastfeeding, ask your doctor for advice before taking this medicine.

Driving and using machines

The package contains a red warning triangle. This means that Zolpidem can cause side effects that have major influence on the ability to drive and use machines such as “sleep driving”.

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Product :
Zolpidem 5 mg and 10 mg film-coated tablets

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On the day after taking Zolpidem (as other hypnotic medicines), you should be aware that:

- You may feel drowsy, sleepy, dizzy or confused
- Your quick decision-making may be longer
- Your vision may be blurred or double
- 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.

If you simultaneously consume alcohol, this could reduce the ability further. You should avoid driving or operating machines if you drink alcohol while you are taking Zolpidem. The risk will increase if you suffer from sleep deprivation.

Zolpidem 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.

Zolpidem contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Zolpidem

Your prescriber should have discussed with you how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

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

Zolpidem is for oral use.

As the effect of the tablet sets in rapidly it must be taken just before bedtime.

Adults:

The recommended dose per 24 hours is 10 mg of Zolpidem (corresponding to one 10 mg tablet or two 5 mg tablets). 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 10 mg per 24 hours.

Older and debilitated: 5 mg (corresponding to half a 10 mg tablet or one 5 mg tablet). This dose should only be exceeded in exceptional cases.

Hepatic impairment: The usual starting dose is 5 mg (corresponding to half a 10 mg tablet or one 5 mg tablet). If you also are older, it may be necessary to change the dose.

Use in children and adolescents: Zolpidem must not be used in children and adolescents under 18 years of age.

You should never take more than 10 mg (corresponding to 1 tablet of 10 mg or two 5 mg tablets) a day. Follow your doctor's instructions.

Your treatment with Zolpidem should be as short as possible, normally from a few days up to two weeks, a maximum of four weeks including tapering off process. If you are treated with Zolpidem longer than 4 weeks your doctor should re-examine the situation. You should take the tablets just before bedtime or in bed.

The 10 mg tablet can be divided into equal doses.

If you take more Zolpidem than you should

Contact you doctor, the hospital or pharmacy, if you have taken more Zolpidem tablets than prescribed in this information or by your doctor (and you do not feel well). In case of overdose of Zolpidem, symptoms can vary from extreme sleepiness to light

coma and possibly fatal coma.

If you forget to take Zolpidem

Do not take a double dose to make up for a forgotten dose. Continue with next dose, if you have forgotten to take Zolpidem.

If you stop taking Zolpidem

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Withdrawal symptoms such as:

- feeling anxious, shaky, irritable, agitated, confused, having panic attacks, sweating, headache, faster heartbeat or uneven heartbeat (palpitations), lower level of awareness or problems with focussing or concentrating, nightmares, seeing of 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.

If you stop treatment abruptly, the risk of your sleep problems returning in aggravated form (see section “Warnings and Precautions”) may be increased. You can also get other side effects such as mood swings, anxiety and restlessness. Your doctor will tell you how to gradually stop treatment.

If you have any further questions, ask your doctor, or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The higher the dose, the greater the risk of side effects.

Serious side effects

If you experience any of the following side effects, you should immediately stop using Zolpidem and inform your doctor or the nearest hospital emergency:

Very rare side effects (may affect less than 1 in 10,000 people):

- Impaired breathing, bluish lips and nails (respiratory depression). Call 112.

Not known (frequency cannot be estimated from available data):

- Serious allergic skin reactions, rash (hives) and swelling.

Other side effects

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

- Hallucinations
- Restless agitation
- Nightmares
- Depression.
- Feeling drowsy or sleepy
- Headache
- Feeling dizzy
- Exacerbated insomnia
- Memory loss.
- Drowsiness the following day
- Diarrhea
- Feeling sick (nausea)
- Abdominal pain
- Back pain
- Infection in the upper and lower respiratory tract
- Fatigue
- Being sick (vomiting)
- Emotional indifference
- Skin reactions

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

- Confused
- Irritable
- Threatening, possibly violent behavior.
- Sleepwalking. Zolpidem can cause sleepwalking or other behaviors that are not normal when sleeping (this includes. sleep-driving, eating food, make phone calls or having sex etc.), see section ” Warnings and precautions”.

- Feeling overly happy/confident (euphoric)
- Pricking, tingling or numbness on the skin
- Tremor
- Reduced alertness
- Speech problems
- ‘Seeing double’
- Blurred vision
- Changes in appetite
- Skin rash
- Itching skin
- Excessive sweating
- Joint pain, muscle aches, muscle spasms, neck pain, weak muscles
- Restless
- Loss of coordination of voluntary muscle movements.
- Zolpidem can also cause side effects that you do not notice. These are changes in certain laboratory samples such as blood tests for liver function.

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

- The following reactions may occur:
- Changes in sex drive (libido)
- Decreased consciousness
- Loss of vision
- Hepatic impairment
- Fall accidents (especially in the elderly and if Zolpidem not taken according to the recommended dose)
- Hives
- Gait disturbance

Not known (frequency cannot be estimated from available data):

- The following psychiatric reactions may occur: Anger, abnormal behavior, withdrawal symptoms, decreased effect of the drug, delusion and psychosis.

Unknown frequency

- dependence and addiction (see section “How do I know if I am tolerant or addicted?”).

Drug Withdrawal

When you stop taking Zolpidem, you may experience drug withdrawal symptoms, which include:

- feeling anxious, shaky, irritable, agitated, confused, having panic attacks, sweating, headache, faster heartbeat or uneven heartbeat (palpitations), lower level of awareness or problems with focusing or concentrating, nightmares, seeing of 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.

How do I know if I am tolerant or addicted?

If you notice any of the following signs whilst taking Zolpidem, it could be a sign that you have become addicted.

- You may feel the need to keep taking the medication for longer than your doctor recommended
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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.

Keep the blister in the outer carton in order to protect from light.

Do not use this medicine after the expiry date, which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

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 contains

The active substance is zolpidem tartrate (the 5 mg tablets contains 5 mg zolpidem tartrate and the 10 mg tablets contains 10 mg zolpidem tartrate).

The other ingredients are: Lactose monohydrate; cellulose, microcrystalline; hypromellose; sodium starch glycolate; magnesium stearate; titanium dioxide (E 171), macrogol 400.

What Zolpidem looks like and contents of the pack

5 mg: Zolpidem, film-coated tablets are White oval shaped, biconvex film coated tablet embossing one side with "5 mg" and other side is plain. Length 8 mm, width 4 mm and thickness 3.0-3.4 mm.

Zolpidem is sold in Alu-PVC/PVDC blister packages of 1x10 tablets, 2x10 tablets, 4x7 tablets, 3x10 tablets or 10x10 tablets.

10 mg: Zolpidem, film-coated tablets are White, oval shaped, biconvex, film-coated tablets with “ZOLPIDEM” and “10 mg” embossing and other side break line. Length 10 mm, width 7.5 mm and thickness 3.1-3.5 mm. The tablet can be divided into equal halves.

Zolpidem is sold in Alu-PVC/PVDC blister packages of 7 tablets, 1x10 tablets, 2x10 tablets, 4x7 tablets 3x10 tablets or 10x10 tablets.

Marketing Authorisation Holder

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