

# Zolpidem 10mg Film-Coated Tablets

## Zolpidem tartrate

This medicine contains the active substance 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 your 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.
- 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 full name of your medicine is Zolpidem 10mg film-coated tablets but within the leaflet it will be referred to Zolpidem.

This medicine has been prescribed for you for short-term treatment of insomnia. It works by acting on your brain to help you sleep.

It contains the active substance zolpidem tartrate which belongs to a class of medicine called z-drugs.

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.

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.

**2. What you need to know before you take Zolpidem**

**Do not take Zolpidem if:**

- 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.
- you suffer from severe liver disorders (hepatic insufficiency).
- you have a problem where you stop breathing for short periods at night (sleep apnoea syndrome)
- you have a problem that causes severe muscle weakness (myasthenia gravis)
- you have breathing difficulties (hypoventilate).
- you are under 18 years of age
- you have been told by a doctor that you have a mental illness (psychosis).

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 (respiratory failure).
- 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 four weeks.

**Talk to your prescriber before taking this medicine if you:**

- 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.

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 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.

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.

Z-drugs 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 Z-drugs, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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. If dependence develops, abrupt discontinuation of treatment will be accompanied by withdrawal symptoms which may consist of headaches or muscle pain, extreme anxiety and tension, restlessness, confusion, irritability and difficulty in sleeping (insomnia). In

severe cases the following symptoms may occur: feeling dissociated from your environment (derealisation), feeling of loss of identity/feeling detached from yourself (depersonalisation), over-sensitivity to sound (hyperacusis), numbness and tingling of the arms and/or legs, hypersensitivity to light, noise and touch, seeing or hearing things that are not real (hallucinations) or fits (epileptic seizures).

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

Where possible, the cause of insomnia (difficulty in sleeping) should be identified. Any other factors (such as psychiatric or physical disorders) should be treated before Zolpidem is prescribed. Insomnia should be relieved following a 7-14 day course of treatment.

As some loss of effectiveness (tolerance) may develop after repeated use of Zolpidem for a few weeks.

If Zolpidem is withdrawn, a temporary rebound reaction where the symptoms that led to treatment with this medicine may recur in an enhanced form. This may be accompanied by other reactions including mood changes, anxiety and restlessness. It is recommended to decrease the dose of Zolpidem gradually as the risk of withdrawal/rebound symptoms are more likely to develop following abrupt discontinuation of treatment.

As Zolpidem may induce anterograde amnesia (loss of ability to create new memories after the event that caused the original loss of memory). This usually occurs several hours after taking the medicine. In order to reduce this risk, you should ensure that you will be able to have uninterrupted sleep for 8 hours.

When using Zolpidem, reactions such as restlessness, agitation, irritability, aggressiveness, mental health disorders (delusion, psychoses), rages, nightmares, seeing or hearing things that are not real (hallucinations), sleepwalking (somnambulism), inappropriate behaviour and increased difficulty in sleeping (insomnia) are known to occur. Should any of these reactions occur, use of this medicine should be discontinued. These reactions are more likely to occur in older people.

If you suffer from a severe condition where not enough oxygen passes from the lungs into the blood (chronic respiratory insufficiency) since Zolpidem may impair your control of breathing. Anxiety or agitation have been described as signs of this condition.

If you suffer from severe mental health disorders that cause abnormal thinking/perceptions (psychotic illness) as Zolpidem is not recommended as the primary treatment.

If you suffer from depressive symptoms as you should be given the lowest possible dose of Zolpidem. Zolpidem is not intended to be used alone to treat depression or anxiety associated with depression.

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 the recommended dose.
- you take zolpidem while you are already taking another central nervous system depressant or another medicine that increases 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, including those obtained without a prescription. This includes 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.
- Medicines to calm or reduce anxiety or for sleep problems (hypnotics)
- Some medicines for moderate to severe pain (narcotic analgesics)
- Medicines for epilepsy (anti-convulsants)
- 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.

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 dose 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 dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs 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**

During treatment with Zolpidem, it is recommended **not** to drink alcohol. 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, breast-feeding and fertility**

Pregnancy

Product:	Zolpidem 10mg Film-coated Tablets
Item Code:	P3613T
Size:	172 x 620 mm
Min. Point size:	9pt
O. Artwork	06/11/25
Proof No.	3
Amendment Date:	10/11/25

Colours Used	
	Process Black
	Keyline - does not print

Use of Zolpidem 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 sucking causing poor weight gain) and breathing problems (respiratory depression) may occur in the newborn.

If this medicine is 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.
- 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.

#### Zolpidem contains lactose and sodium

This medicine contains Lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before having this medicine.

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

##### Use in children and adolescents

Zolpidem should not be used in people under 18 years of age.

##### 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 accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets 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 fatal 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 dose.

#### If you stop taking Zolpidem

Keep taking Zolpidem until your doctor tells you to stop.

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.

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

Withdrawal symptoms such as:

- Feeling anxious, shaky, irritable, agitated or confused
- Having panic attacks
- Sweating
- Headache
- Faster heartbeat or uneven heartbeat (palpitations)
- Lower level of awareness or problems with focussing 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
- Feeling restless
- Limp or weak muscles
- Changes in your behaviour
- Fits (seizures).

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.

#### 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, lips, face or throat which may cause difficulty in swallowing or breathing.

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

#### Common (may affect up to 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 (may affect up to 1 in 100 people)

- Blurred eyesight or 'seeing double'

#### Rare (may affect up to 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 (may affect up to 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 drowsy or sleepy
- Back pain

#### Uncommon (may affect up to 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 (may affect up to 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 (may affect less than 1 in 10,000 people)

- Any changes of 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

#### 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 focussing 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.

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, 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 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](http://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 this medicine after the expiry date, which is stated on the carton or blister 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 to protect the environment.

### 6. Contents of the pack and other information

#### What Zolpidem contains

- The active substance is zolpidem tartrate. Each film-coated tablet contains 10mg of zolpidem tartrate equivalent to 8.03mg of zolpidem.

• The other ingredients are:

*Tablet core:* succinic acid, sodium carboxymethyl starch (type A), microcrystalline cellulose, lactose monohydrate, magnesium stearate, colloidal silicon dioxide

*Tablet coating:* lactose monohydrate, macrogol 4000, hypromellose, colouring agent titanium dioxide (E 171).

#### What Zolpidem looks like and contents of the pack

Zolpidem are white, oblong, biconvex film-coated tablets with length of 10mm-10.4mm and height of 2.6mm-3.0mm, with a break score.

Zolpidem is available in packs of 10, 20, 28, 30, 50, 98 or 100 tablets.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

Crescent Pharma Ltd., Key House, Sarum Hill, Basingstoke, RG21 8SR, UK.



**This leaflet was last revised in November 2025.**

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