**Package leaflet: Information for the user**

# Zolpidem Tartrate 5mg Film-coated Tablets Zolpidem Tartrate 10mg Film-coated Tablets

zolpidem tartrate

Your medicine is called Zolpidem tartrate 5mg or 10mg Film-coated Tablets, but it will be referred to as Zolpidem tartrate tablets throughout this leaflet.
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 Zolpidem tartrate tablets 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 tartrate tablets are and what they are used for
2. What you need to know before you take Zolpidem tartrate tablets
3. How to take Zolpidem tartrate tablets
4. Possible side effects
5. How to store Zolpidem tartrate tablets
6. Contents of the pack and other information


## 1. What Zolpidem tartrate tablets are and what they are used for

Zolpidem tartrate tablets contain the active substance called zolpidem tartrate which belongs to a class of medicines called z-drugs. Zolpidem tartrate belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep.
Zolpidem tartrate tablets are 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 tartrate tablets are 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.
This medicine has been prescribed to you and should not be given to anyone else.
Zolpidem tartrate tablets 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 tartrate tablets

**Do not take Zolpidem tartrate tablets**
- 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
- If you have a problem where you stop breathing for short periods at night (sleep apnoea)
- If you have a problem that causes severe muscle weakness (myasthenia gravis)
- If you have breathing difficulties (hypoventilate)
- If you have severe liver problems
- If you have been told by a doctor that you have a mental illness (psychosis)
- If 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 tartrate tablets.

**Warnings and precautions**
Talk to your prescriber before taking this medicine 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 tartrate tablets or other similar medicines for more than 4 weeks
- 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.
- You have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- You feel you need to take more of Zolpidem tartrate 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.
Use of Zolpidem tartrate tablets may lead to the development of abuse and/or physical and psychological dependence.
The risk of dependence is greater when Zolpidem tartrate tablets are 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 tartrate tablets 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.

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 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.

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.

Zolpidem tartrate tablets 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 tartrate tablets, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

**Next-day psychomotor impairment (see also 'Driving and using machines')**
The day after taking Zolpidem tartrate tablets, 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 tartrate tablets while you are already taking other central nervous system depressants or other medicines that increase zolpidem tartrate 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 tartrate tablets**
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 tartrate tablets can affect the way some other medicines work. Also, some medicines can affect the way Zolpidem tartrate tablets work.

**Zolpidem may increase the effect of the following medicines:**
While taking Zolpidem tartrate tablets 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 tartrate tablets 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 tartrate tablets 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 tartrate tablets and opioids (strong painkillers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression) and 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 tartrate tablets 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 following medicines can increase the chance of you getting side effects when taken with Zolpidem tartrate tablets. To make this less likely, your doctor may decide to lower your dose of Zolpidem tartrate tablets:**
- Some medicines for fungal infections such as ketoconazole

**The following medicines can make Zolpidem tartrate tablets less effective:**
- Rifampicin (an antibiotic) - for infections

**Zolpidem tartrate tablets with alcohol**
Do not drink alcohol while you are taking Zolpidem tartrate tablets. Alcohol can increase the effects of Zolpidem tartrate tablets 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 are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
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 tartrate tablets 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 tartrate tablets 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 tartrate tablets, do not drive or use machinery or tools if you feel sleepy, dizzy, or confused. Zolpidem tartrate tablets have a major influence on the ability to drive and use of machines such as 'sleep

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11.5 mm
6 mm
11.5 mm
50 mm

driving'. On the day after taking Zolpidem tartrate tablets (as 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 tartrate tablets and driving, using machinery, and working at heights to minimise the above listed effects.
Do not drink alcohol or take other psychoactive substances while you are taking Zolpidem tartrate tablets, as it can increase the above listed effects.

**Zolpidem tartrate tablets contain 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 tartrate tablets contain sodium**
This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

## 3. How to take Zolpidem tartrate tablets

Always take Zolpidem tartrate tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
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.

**Taking this medicine**
- Take this medicine by mouth
- Swallow the tablet whole with a drink of water
- The 10mg tablets can be divided into equal doses
- The recommended dose per 24 hours is 10mg of Zolpidem tartrate tablets. A lower dose may be prescribed to some patients
- Zolpidem tartrate 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 Zolpidem tartrate tablet (or two 5mg Zolpidem tartrate tablets) just before bedtime. A lower dose may be prescribed to some patients.

**Elderly**
The usual dose is one 5mg Zolpidem tartrate tablet just before bedtime.

**Patients with liver problems**
The usual starting dose is one 5mg Zolpidem tartrate tablet 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**
Do not give this medicine to children and adolescents under 18 years old.

**Blood Tests**
- Zolpidem tartrate tablets 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 tartrate tablets

**If you take more Zolpidem tartrate tablets than you should**
If you take more Zolpidem tartrate tablets 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 many Zolpidem tartrate tablets 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 tartrate tablets**
Zolpidem tartrate tablets must only be taken at bedtime. If you forget to take your tablet(s) 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 tartrate tablets**
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, or confused
- Having panic attacks
- Sweating
- Feeling restless
- Headache
- Limp or weak muscles
- Faster heartbeat or uneven heartbeat (palpitations)
- 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
- 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, Zolpidem tartrate tablets can cause side effects, although not everybody gets them.

**Stop taking Zolpidem tartrate tablets and see a doctor or go to a hospital straight away if:**
You have an allergic reaction. The 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 tartrate tablets (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 tartrate tablets this is less likely to cause you a problem
- Sleeping problems that get worse after taking Zolpidem tartrate tablets
- 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'
- Change in appetite (appetite disorder)

**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 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 last 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, prickling, 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** (may affect 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 tartrate tablets in order to sleep
- Dependence and addiction (see section "How do I know if I am tolerant or addicted?")

Drug Withdrawal
When you stop taking Zolpidem tartrate tablets, 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 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 tartrate tablets, 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 Yellow Card Scheme Website: 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 tartrate tablets

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. This medicinal product does not require any special storage conditions. Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

## 6. Contents of the pack and other information

**What Zolpidem tartrate tablets contain**
The active substance is zolpidem tartrate. Each tablet contains 5mg or 10mg of zolpidem tartrate.
The other ingredients are: lactose monohydrate, microcrystalline cellulose PH101, sodium starch glycollate (Type A), hypromellose, magnesium stearate, macrogol (PEG-400), and titanium dioxide (E171).

**What Zolpidem tartrate tablets look like and contents of the pack**
Zolpidem Tartrate 5mg Film-coated Tablets are white to off-white, round, biconvex, film-coated tablets which are plain on both sides.

Zolpidem Tartrate 10mg Film-coated Tablets are white to off-white, capsule shaped, film-coated tablets with a break line on the one side and plain on the other side.

The tablets are available in blister packs of 28 tablets or tablet container of 400 tablets. Not all pack sizes may be marketed.

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