

Zolpidem tartarate 5mg/10mg Tablets

Package leaflet: information for the user

zolpidem tartrate

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

1. What Zolpidem tartarate is and what it is used for

The name of your medicine is Zolpidem tartarate 5mg/10mg film-coated Tablets (called Zolpidem tartarate in this leaflet).

Zolpidem tartarate 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 tartarate 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 tartarate 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 tartarate

Do not take Zolpidem tartarate if:

- You are allergic (hypersensitive) to zolpidem tartrate or any of the other ingredients of Zolpidem tartarate (listed in section 6).
Signs of an allergic reaction include: a rash, swallowing or breathing problems,

swelling of your lips, face, throat or tongue.

- Your lungs do not work properly (respiratory failure).
- You have severe liver problems.
- You have a problem where you stop breathing for short periods at night (sleep apnoea).
- You have a problem that causes severe muscle weakness (myasthenia gravis).
- You have been told by a doctor that you have a mental illness (psychosis).
- 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 tartarate.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zolpidem tartarate if:

- You have a history of alcohol or drug abuse.
- You have liver problems.
- You have depression or have had another mental illness in the past.
- You have recently taken Zolpidem tartarate or other similar medicines for more than four weeks.
- You are elderly.

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

dependence is greater when Zolpidem tartarate 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 tartarate 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 tartarate.

Next-day psychomotor impairment (see also 'Driving and using machines')

The day after taking Zolpidem tartarate, 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 tartarate while you are already taking other central nervous system depressants or another medicine

that increases Zolpidem tartarate 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 tartarate

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 tartarate can affect the way some other medicines work. Also some medicines can affect the way Zolpidem tartarate works.

Zolpidem tartarate may increase the effect of the following medicines:

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

- Medicines for some mental health problems (antipsychotics).
- Medicines for sleep problems (hypnotics).
- Medicines to calm or reduce anxiety.
- Medicines for depression.
- Medicines for moderate to severe pain (narcotic analgesics).
- Medicines for epilepsy (anti-convulsants).
- Medicines used for anaesthesia.

- Medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines).

While taking Zolpidem tartarate 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 tartarate 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 tartarate and opioids (strong painkillers, 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 tartarate 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 tartarate. To make this

less likely, your doctor may decide to lower your dose of Zolpidem tartarate:

- Some antibiotics such as clarithromycin or erythromycin.
- Some medicines for fungal infections such as ketoconazole and itraconazole.
- Ritonavir (a protease inhibitor) – for HIV infections.

The following medicines can make Zolpidem tartarate work less well:

- Some medicines for epilepsy such as carbamazepine, phenobarbital or phenytoin.
- Rifampicin (an antibiotic) – for infections.

Zolpidem tartarate with alcohol

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

Pregnancy, breast-feeding and fertility

Pregnancy

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

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

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

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

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

Breast-feeding

Do not take Zolpidem tartarate 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

Zolpidem tartarate has major influence on the ability to drive and use machines such as 'sleep-driving'. On the day after taking Zolpidem tartarate (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 tartarate 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 tartarate as it can increase the above listed effects.

Zolpidem tartarate contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3. How to take Zolpidem tartarate

Always take Zolpidem tartarate 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 tartarate. A lower dose may be prescribed to some patients.
- Zolpidem tartarate 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 two Zolpidem tartarate tablets (10mg) just before bedtime.

Elderly

- The usual dose is one tablet (5mg/10mg) just before bedtime.

Patients with liver problems

- The usual starting dose is one tablet (5mg/10mg) just before bedtime. Your doctor may decide to increase this to two tablets (10mg) if it is safe to do so.

Children and adolescents

Zolpidem tartarate should not be used in people under 18 years old.

If you take more Zolpidem tartarate than you should

If you take more Zolpidem tartarate 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 tartarate 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 tartarate

Zolpidem tartarate 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 tartarate

Keep taking Zolpidem tartarate until your doctor tells you to stop. Do not stop taking Zolpidem tartarate 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 tartarate 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, restless, irritable or confused
- Headache
- Faster heartbeat or uneven heartbeat (palpitations)
- Nightmares, seeing or hearing things that are not real (hallucinations)
- Being more sensitive to light, noise and touch than normal
- Relaxed grip on reality
- Feeling distant from your body or feeling 'puppet-like'

- Numbness and tingling in your hands and feet
- Aching muscles
- Stomach problems
- Sleep problems come back worse than before
- Fits (seizures)

4. Possible side effects

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

Stop taking Zolpidem tartarate 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 tartarate (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 tartarate, 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 drowsy or sleepy
- 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 (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 tartarate

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 tartarate 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zolpidem tartarate

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

Store below 30°C. Keep the blister strip in the carton in order to protect from moisture.

Do not use Zolpidem tartarate 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 protect the environment.

6. Contents of the pack and other information

What Zolpidem tartarate 5mg/10mg film-coated Tablets contain

- Each tablet of Zolpidem tartarate contains 5mg/10mg of the active substance zolpidem tartrate.
- Other ingredients are lactose monohydrate, microcrystalline cellulose,



hypromellose, titanium dioxide, sodium starch glycollate, magnesium stearate and macrogol.

What Zolpidem tartarate 5mg/10mg film-coated Tablets look like and contents of the pack

Zolpidem tartarate is a round, white, film-coated tablet contained within PVC/ foil blisters in cartons containing 4, 14, 28, or 56 tablets.

Not all pack sizes may be marketed.

7. Manufactured By:

Taj Pharmaceuticals Ltd.

at: Plot. No. 220, Mahagujarat

Industrial Estate, At & Post-Moraiya,

Tal-Sanand, Dist- Ahmedabad Gujarat (India)