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**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.

**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**

The name of your medicine is Zolpidem tartrate tablets. The tablets come in two strengths: Zolpidem tartrate 5mg tablets and Zolpidem tartrate 10mg tablets. 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 short-term treatment of insomnia **in patients over 18 years of age**, that is causing you severe distress or that is affecting your everyday life. This includes sleep problems such as:

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

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

**Do not take Zolpidem tartrate tablets:**

- As a long-term treatment. Treatment should be as short as possible, because the risk of dependence increases with the duration of treatment
- If you have ever experienced sleep walking or other behaviours which are unusual while sleeping, (such as driving, eating, making a phone call or having sex etc.) while not being fully awake after taking zolpidem tartrate tablets or other medicines containing zolpidem
- If you are allergic (hypersensitive) to zolpidem tartrate or any of the other ingredients of this medicine (listed in section 6 below). Signs of an allergic reaction

include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- If your lungs do not work properly (respiratory failure)
- If you have severe liver problems
- If you are 18 years of age

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

### **Warnings and precautions**

#### **Talk to your doctor or pharmacist before taking this medicine if:**

- You have a problem where you stop breathing for short periods during the night (sleep apnoea)
- You have a problem that causes severe muscle weakness (myasthenia gravis)
- You have liver problems
- You have depression or have had another mental illness in the past
- You have or have ever had thoughts of harming or killing yourself

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.

- You have recently taken Zolpidem tartrate tablets or other similar medicines for more than four weeks
- You are elderly (65 years of age or above)
- You have ever had any heart problems including a slow or uneven heartbeat
- You have ever had a mental disorder or have abused or have been dependent on alcohol or drugs

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

#### **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. The risk of abuse and dependence is greater in patients with a history of mental disorders and/or alcohol, illicit substance or drug abuse.

**Zolpidem tartrate tablets may cause sleep walking or other behaviours, which are unusual while sleeping**, (such as driving, eating, making a phone call or having sex etc.) while not being fully awake. The next morning, you may not remember that you did anything during the night. If you experience any of the above, stop the treatment with Zolpidem tartrate tablets immediately and contact your doctor or healthcare provider as these sleep behaviours might put you and others at serious risk of injury. Drinking alcohol or taking other medicines that make you drowsy together with Zolpidem tartrate tablets, might increase the risk of these sleep behaviours occurring.

**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 the recommended dose
- You take Zolpidem tartrate tablets while you are already taking other central nervous system depressants or medicines that increase zolpidem tartrate in your blood, or while drinking alcohol, or while taking illicit substances

Take a single intake immediately at bedtime. Do not take another dose during the same night.

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

If following a 7-14 day course of treatment, symptoms persist, contact your doctor so that your treatment can be re-evaluated.

#### **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.

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.

#### **Tell your doctor if you are taking any of the following medicines:**

When taking Zolpidem tartrate tablets 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 depressions
- Medicines for moderate to severe pain (narcotic analgesics)
- Medicines for epilepsy
- Medicines used for anesthesia

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

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 that you take Zolpidem tartrate tablets with fluvoxamine or ciprofloxacin.

**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 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 tartrate tablets less effective:**

- Some medicines for epilepsy such as carbamazepine, phenobarbital or phenytoin
- Rifampicin (an antibiotic) - for infections
- St John's Wort (a herbal medicine) – for mood swings and depression – use of Zolpidem tartrate tablets and St John's Wort together is not recommended

#### **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**

Use of Zolpidem tartrate 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 tartrate tablets during the second and/or third trimester of pregnancy.

If Zolpidem tartrate tablets are 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.

You should not breast-feed if you are taking Zolpidem tartrate tablets. This is because small amounts may pass into breast milk.

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

### **Driving and using machines**

Zolpidem tartrate tablets have a major influence on the ability to drive (such as "sleep driving") and use of machines. 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
- Your quick decision-making may take longer
- You may have blurred or double 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 effects mentioned above.

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

For more information about possible side effects which could affect your driving see section 4 of this leaflet.

### **Zolpidem tartrate tablets contain lactose**

If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicinal product.

## **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.

### **Taking this medicine**

- Take this medicine by mouth
- Swallow the tablet whole with a drink of water
- The 10 mg 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 10mg tablets can be divided into equal doses (5mg each) along the score line. 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

### **Adults**

The usual dose is one 10mg Zolpidem tartrate tablet (or two 5mg Zolpidem tartrate tablets) just before bedtime.

### **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. Your doctor may decide to increase this to one 10mg Zolpidem tartrate tablet (or two 5mg Zolpidem tartrate tablets) if it is safe to do so.

**Use in children and adolescents**

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

**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 much Zolpidem tartrate tablets 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 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**

Keep taking Zolpidem tartrate tablets until your doctor tells you to stop. Do not stop taking Zolpidem tartrate tablets 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 tartrate tablets 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

In rare cases fits (seizures) may also occur.

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 will have 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: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

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

**Common** (may affect less than 1 in 10 people)

- Memory disorders such as poor memory (amnesia), memory impairment, inability to recall the recent past (anterograde amnesia). 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)
- Drowsiness or a strong desire to sleep
- Dizziness

**Uncommon** (may affect less than 1 in 100 people)

- Blurred eyesight or 'seeing double'
- Change in appetite (appetite disorder)
- Sleep driving and other strange behaviour (sleep walking, having sex whilst asleep)
- Feeling of intense elation or confidence (euphoria)
- This medicine may cause sleep walking or other behaviours, which are unusual while sleeping, (such as driving, eating, making a phone call or having sex etc.) while not being fully awake, see section 'Warnings and precautions'

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

- Decreased ability to see (visual impairment)
- Being less aware of your environment
- Problems with your liver, which will show up on blood tests
- Falling, especially in the elderly

**Very Rare** (may affect less than 1 in 10,000 people)

- Dependence on Zolpidem tartrate tablets in which you feel you need to take it to feel normal
- Slower breathing (respiratory depression)

**Tell your doctor or pharmacist if any of the following side effects become serious or last longer than a few days:**

**Common** (may affect less than 1 in 10 people)

- Diarrhoea
- Feeling sick (nausea) or being sick (vomiting)
- Abdominal pain
- Infection of the lungs or airways (respiratory infection)
- Headache

- Feeling tired or agitated
- Nightmares
- Depression
- Back pain

**Uncommon** (may affect less than 1 in 100 people)

- Feeling confused or irritable
- Feeling restless or angry
- Disturbance in attention
- Speech difficulties
- Pains in your joints or muscles, muscle spasms
- Neck pain
- Unusual sensation or tingling of skin
- Tremor
- Change in the amount of liver enzymes – shown up in results of blood tests
- Itching skin or skin rash
- Excessive sweating
- Weak muscles

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

- Changes in sex drive (libido)
- Hives
- Changes in the way you walk

**Very Rare** (may affect less than 1 in 10,000 people)

- Thinking things that are not true (delusions)

**Frequency Unknown** (frequency cannot be estimated from available data)

- Feeling angry or showing unusual behaviour
- Zolpidem tartrate having less effect than normal

**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:

**Ireland**

HPRA Pharmacovigilance, website: [www.hpra.ie](http://www.hpra.ie)

**United Kingdom**

Yellow Card Scheme

Website: [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 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 glycolate (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 the 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.

### **Marketing Authorisation Holders**

UK: Key Pharmaceuticals Ltd

Galen House, 83 High Street, Somersham,  
Cambridgeshire, PE28 3JB, UK

IE: Lexon Pharmaceuticals (Ireland) Limited

Block 4, Port Tunnel Business Park, Clonshaugh, Dublin 17, Ireland

### **Manufacturer**

MEDREICH PLC

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