

## Zolpidem Tartrate 5mg and 10mg Tablets

- **Please 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 pharmacist or doctor.
- 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 are sleeping pills (hypnotics) which work by acting on the brain to cause sleepiness.

They may be used for short term treatment of difficulty in sleeping which is severe, disabling or causing great distress.

### 2 What you need to know before you take Zolpidem Tartrate tablets

#### Do not take Zolpidem Tartrate tablets if you:

- are **allergic** to zolpidem tartrate or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- have **severe liver** problems
- suffer from **breathing problems whilst sleeping** (Sleep Apnoea Syndrome)
- suffer from severe **muscle weakness** (myasthenia gravis)
- have **severe breathing** problems
- are **under the age of 18** years.

#### Warnings and precautions:

Talk to your doctor or pharmacist before taking Zolpidem Tartrate tablets if you:

- are **elderly or frail**. If you get up at night, take care as there is an increased risk of falling and consequently of hip fractures due to the muscle relaxant effect of the tablets
- have any **kidney or liver** problems.
- have a **history of breathing problems**. Whilst taking Zolpidem Tartrate tablets your breathing may become less forceful
- have a history of **mental illness, anxiety or psychotic illness**. Zolpidem Tartrate tablets may unmask or worsen symptoms
- suffer from or have a history of **depression**
- have or have ever had a history of or tendency to **alcohol or drug abuse**. The risk of dependence to Zolpidem Tartrate tablets (physical or mental effects produced by a compulsion to keep taking the medicine) increases in these patients, and with dose and length of treatment.

**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
- take a higher dose than the recommended dose
- 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.

#### Other considerations

- Habituation – if after a few weeks you notice that the tablets are not working as well as they did when first starting treatment, you should go and see your doctor as an adjustment to your dosage may be required.
- Dependence – when taking this type of medicine there is a risk of dependence, which increases with dose and length of treatment. There is a greater risk in patients with a history of alcohol or drug abuse.
- Withdrawal – treatment should be gradually withdrawn. A transient syndrome whereby the symptoms that led to treatment with Zolpidem Tartrate tablets reoccur in an enhanced form, may happen on withdrawal. It may be accompanied by other reactions including mood changes, anxiety and restlessness.
- Amnesia – Zolpidem Tartrate tablets can cause memory loss. To reduce this risk you should ensure that you are able to have 8 hours uninterrupted sleep.
- Psychiatric and “paradoxical” reactions – Zolpidem Tartrate tablets can cause behavioural side effects such as restlessness, agitation, irritability, aggressiveness, delusions (false beliefs), rages, nightmares, hallucinations, psychoses, sleepwalking, inappropriate behaviour, increased insomnia and other adverse behavioural effects.

#### Other medicines and Zolpidem Tartrate tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Zolpidem Tartrate tablets may influence the effect and/or side effects of other medicines. If you see another doctor or go into hospital, particularly if you are having an operation under anaesthesia tell the doctor which medicines you use.

While taking zolpidem 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 (sedatives antihistamines)
- Medicines inhibiting liver enzymes. Ask your doctor or pharmacist which medicines have this 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.

The effect of the following medicine may be **increased** by Zolpidem Tartrate tablets:

- muscle relaxants

The effect the following medicine may be **decreased by** Zolpidem Tartrate tablets:

- medicine used to treat tuberculosis (rifampicin).

### **Zolpidem Tartrate tablets with alcohol**

Alcohol should not be consumed when taking Zolpidem Tartrate tablets, as the sedating effect may be increased.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Zolpidem Tartrate tablets should not be taken during pregnancy, especially in the first three months. If for urgent medical reasons, Zolpidem Tartrate tablets are taken during late pregnancy or during labour the baby may show withdrawal symptoms after birth because of physical dependence.

Zolpidem will appear in breast milk in small amounts, therefore **breast-feeding** mothers should not take this medicine.

### **Driving and using machines**

Zolpidem Tartrate tablets has major influence on the ability to drive and use machines such as “sleep 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
- 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 [Invented Name], as it can increase the above listed effects

### **Zolpidem Tartrate tablets contains lactose**

If you have been told you have an intolerance to some sugars, tell your doctor or pharmacist before taking Zolpidem Tartrate tablets as this medicine contains lactose.

## **3 How to take Zolpidem Tartrate tablets**

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

The tablet should be taken together with liquid immediately before going to bed.

### **The recommended dose is:**

Adults

The recommended dose per 24 hours is 10 mg of Zolpidem Tartrate tablets. A lower dose may be prescribed to some patients. Zolpidem Tartrate tablets 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.

*- Elderly and debilitated patients*

In elderly or debilitated a dose of 1/2 a tablet of Zolpidem Tartrate tablets 5mg (corresponding to 5mg zolpidem tartrate/day) is recommended. If the effect is insufficient and you tolerate the medicine well, your doctor may decide to increase the dose to 1 tablet of Zolpidem Tartrate tablets 10mg (corresponding to 10mg zolpidem tartrate/day).

*- Patients with impaired liver function*

In patients with impaired liver function a dose of 1/2 a tablet of Zolpidem Tartrate tablets 5mg (corresponding to 5mg zolpidem tartrate/day) is recommended. If the effect is insufficient and you tolerate the medicine well, your doctor may decide to increase the dose to 1 tablet of Zolpidem Tartrate tablets 10mg (corresponding to 10mg zolpidem tartrate/day).

**Maximum dose**

A daily dose of 1 tablet of Zolpidem Tartrate tablets 10mg (corresponding to 10mg zolpidem tartrate/day) should not be exceeded.

**How long should you take Zolpidem Tartrate tablets**

The duration of administration should be as short as possible. In general, it could be a few days up to 2 weeks and not exceed 4 weeks the stepwise withdrawal phase included. Your doctor will choose a withdrawal regime based on your individual needs.

Certain situations may require prolongation beyond the maximum time of treatment. Your attending doctor will decide on that after renewed evaluation of your complaints.

**Use in children and adolescents**

Zolpidem Tartrate tablets must not be used in children and adolescents of less than 18 years of age

**If you take more Zolpidem Tartrate tablets than you should**

If you, (or someone else) swallow a lot of the tablets at the same time, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately, do not go unaccompanied to seek medical help. If an overdose has been taken you may become increasingly drowsy very quickly, with high doses probably leading to a coma.

**If you forget to take Zolpidem Tartrate tablets**

If you forget to take a dose immediately before going to bed but remember during the night, only take the missed dose if you are still able to have 7-8 hours of uninterrupted sleep. If this is not possible, take the next dose before bed time the next night. **Do not** take a double dose to make up for a forgotten tablet. If you are worried ask your pharmacist or doctor for advice.

**If you stop taking Zolpidem Tartrate tablets**

- Treatment should be gradually withdrawn as the symptoms you are treated for will return more intense than before (rebound insomnia), also anxiety, restlessness and mood changes may occur. These effects will disappear in time.
- If you have become physically dependent to Zolpidem Tartrate tablets, sudden withdrawal of treatment will lead to side effects such as headaches, muscle pain, anxiety, tension, restlessness, confusion, irritability and sleeplessness. In severe cases other effects may appear, such as hypersensitivity to light, noise and physical contact, abnormally acute hearing and painful sensitivity to sound, hallucinations, numbness and tingling of the extremities, derealisation (feeling the world around you is not real), depersonalisation (feeling your mind is becoming separated from your body) or epileptic seizures (violent fitting or shaking). These symptoms may also be experienced between doses, especially if the dose is high.

#### **4 Possible side effects**

Like all medicines, this medicine 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: 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 up to 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 this medicine
- Seeing or hearing things that are not real (hallucinations)

**Uncommon: may affect up to 1 in 100**

- Blurred eyesight or 'seeing double'

**Not known: frequency cannot be estimated from the available data**

- Being less aware of your environment
- Falling, especially in the elderly

**Sleep-Driving and other strange behaviour**

There have been some reports of people doing things while asleep that they do not remember when waking up after taking a sleep medicine. This includes sleep-driving, sleep walking 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

**Uncommon: may affect up to 1 in 100**

- Feeling confused or irritable

**Not known: frequency cannot be estimated from the available data**

- Itching skin or skin rash
- Excessive sweating
- Slower breathing (respiratory depression)
- Weak muscles
- Coordination problems (ataxia)
- Abuse

- Feeling restless, aggressive, angry or showing unusual behaviour
- Depression
- Thinking things that are not true (delusions)
- Changes in sex drive (libido)
- Change in the amount of liver enzymes - shown up in the results of blood tests
- Changes in the way you walk
- Zolpidem Tartrate tablets having less effect than normal

### **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. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

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 product packaging. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Tartrate tablets contains**

The active substance is zolpidem tartrate. Each tablet contains either 5mg or 10mg of the active ingredient.

The other ingredients are:

- core: lactose monohydrate, microcrystalline cellulose, sodium starch glycollate type A, hydroxypropyl methylcellulose, magnesium stearate
- coating: hydroxypropyl methylcellulose, titanium dioxide (E171), polyethylene glycol 400.

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

- Zolpidem Tartrate Actavis 5 mg, filmcoated tablets are oval, biconvex, white tablets . One side is imprinted "ZIM", the other side is imprinted "5".
- Zolpidem Tartrate Actavis 10 mg, filmcoated tablets are oval, white tablets with a breaking line. One side is imprinted "ZIM", the other side is imprinted "10".

The tablets are packed in blisters inserted into a carton and in polyethylene containers with a child- resistant closure.

- Pack size: 28

#### **Marketing Authorisation Holder**

Actavis, Barnstaple, EX32 8NS, UK

#### **Manufacturer**

Synthon Hispania S.L., Poligono Las Salinas, 08830 Sant Boi de Llobregat, Spain

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