

## PATIENT INFORMATION LEAFLET ZOLPIDEM 5MG OR 10MG TABLETS

### Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- 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.

### In this leaflet:

1. What Zolpidem is and what it is used for
2. Before you take Zolpidem
3. How to take Zolpidem
4. Possible side effects
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### 1. What Zolpidem is and what it is used for

The name of your medicine is Zolpidem 5mg or 10mg Tablets (called Zolpidem throughout this leaflet). Zolpidem 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 is used to treat sleep problems in adults such as:

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

Zolpidem is used for temporary sleep problems. Zolpidem is not meant to be used every day for long periods of time. Ask your doctor for advice if you are unsure.

### 2. Before you take Zolpidem

#### Do not take this medicine and tell your doctor 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

- 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 breathing difficulties (hypoventilate)
- You have severe liver problems
- You are under the age of 18
- You have a severe mental illness

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.

#### Take special care and check with your doctor or pharmacist before taking Zolpidem if:

- Your lungs do not work properly
- You have any liver problems (see also 'Do not take this medicine and tell your doctor if:' section above). Your doctor may need to give you a lower dose of Zolpidem
- You have a history of drug or alcohol abuse
- You are or have been depressed
- You do not feel you will ever be able to stop taking Zolpidem or other medicines used to treat sleep problems

Zolpidem 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.

#### 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 recommended
- You take zolpidem while you are already taking other central nervous system depressants or other 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.

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines.

This is because Zolpidem can affect the way some other medicines work. Also some medicines can affect the way Zolpidem works.

## Use your doctor if you are taking any of the following medicines.

Zolpidem may increase the effect of the following medicines and 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 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
- Some medicines for moderate to severe pain (narcotic analgesics) such as codeine, methadone, morphine, oxycodone, pethidine or tramadol

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.

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

### Taking Zolpidem with food and drink

- Do not drink alcohol while you are taking Zolpidem.
- 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 and breast-feeding

- Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant.
- Do not take Zolpidem if you are in the last 3 months of pregnancy or during labour because it may be harmful to your baby. If your doctor feels it is necessary for you to keep using this medicine your baby may be born with breathing difficulties, limp or weak muscles, a low body temperature

(hypothermia) and may have withdrawal symptoms.

- Do not take Zolpidem if you are breast-feeding or planning to breast-feed. This is because small amounts may pass into mother's 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
- 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 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.

### Important information about some of the ingredients of Zolpidem

**Lactose:** This is a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before having this medicine.

## 3. How to take Zolpidem

Always take Zolpidem exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### Taking this medicine

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.
- Swallow the tablet whole with a drink of water.
- Treatment should not normally continue beyond 4 weeks.

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 10 mg per 24 hours.

## Adults

The recommended dose per 24 hours is one 10mg tablet (or two 5mg tablets) just before bedtime. A lower dose may be prescribed to some patients.

## Elderly or frail people

The usual dose is one 5mg tablet just before bedtime.

## Patients with liver problems

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

## Children

Do not give this medicine to children under the age of 18.

## 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 take more Zolpidem 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 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

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 tablet.

## If you stop taking Zolpidem

Keep taking Zolpidem until your doctor tells you to stop. Do not stop taking Zolpidem 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 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, shaky, irritable, agitated, or confused

- Feeling restless
- Headache
- Limp or weak muscles
- A 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
- Changes in your behaviour
- Fits (seizures)

## 4. Possible side effects

Like all medicines, Zolpidem 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 get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an **allergic reaction** to Zolpidem tablets

### Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

#### Common side effects (affects less than 1 in every 10 people)

- Feeling tired or agitated
- Feeling sick (nausea) or being sick (vomiting)
- Abdominal pain
- Respiratory infection
- Diarrhoea
- Feeling sleepy, drowsy or confused
- Sleeping problems
- Headache
- Feeling dizzy
- Poor memory since taking Zolpidem (amnesia)
- Seeing or hearing things that are not real (hallucinations)
- Nightmares
- Feeling irritable
- Back pain

#### Uncommon side effects (affects less than 1 in every 100 people)

- Confusion or irritability
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Tremor
- Double vision
- Blurred vision
- Changes in appetite or behaviour concerning appetite

- Muscle pain
- Muscle spasms

### **Very rare side effects (affects less than 1 in every 10,000 people)**

- Any changes in vision, in particular loss of vision

### **Other side effects:**

- Itchy, lumpy rash (urticaria)
- Excessive sweating
- Slower breathing (respiratory depression)
- Falling over
- Limp or weak muscles
- Sleep walking
- Zolpidem can change the levels of liver enzymes shown up in blood tests.
- 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
- Lack of concentration
- Speech problems
- Changes in your sex drive
- Changes in the way you walk
- Feeling aggressive or angry
- Behaving out of character
- Depression
- Feeling overly happy/confident (euphoric)
- A fixed, unreasonable idea not shared by others (delusions)
- A feeling of being out of touch with reality and being unable to think or judge clearly (psychosis)
- Becoming dependent on Zolpidem
- Needing to take more Zolpidem in order to sleep

### **“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, sleep walking, 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.

### **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:

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

## **5. How to store Zolpidem**

Keep this medicine in a safe place where children cannot see or reach it.

Do not use Zolpidem after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in a dry place below 30°C in the original packaging.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. Further Information**

### **What Zolpidem 5mg and 10mg Tablets contain**

Each 5mg tablet contains 5mg of zolpidem tartrate as the active substance.

Each 10mg tablet contains 10mg zolpidem tartrate as the active substance.

The other ingredients of Zolpidem 5mg and 10mg tablets are lactose monohydrate, microcrystalline cellulose, hypromellose, sodium starch glycollate, magnesium stearate, titanium dioxide (E171), macrogol 400.

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

Zolpidem 5mg Tablets are round, white, film-coated tablets.

Zolpidem 10mg Tablets are oblong, white to off-white, film-coated tablets, with a score line and SN10 on one side.

Zolpidem 5mg Tablets are supplied in cartons of 28 tablets.

Zolpidem 10mg Tablets are supplied in cartons of 28 tablets.

### **Marketing Authorisation Holder and Manufacturer**

#### Marketing Authorisation Holder

Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, United Kingdom

#### Manufacturer of Zolpidem 5mg Tablets

Sanofi Winthrop Industrie, 30-60 Avenue Gustave Eiffel, 37000 Tours, France

#### Manufacturer of Zolpidem 10mg Tablets

Delpharm Dijon, 6 Boulevard De L'Europe, 21800 Quetigny, France

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