

ZOLPIDEM TARTRATE 5 mg AND 10 mg FILM-COATED TABLETS

ZOLPIDEM TARTRATE

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

1 WHAT ZOLPIDEM IS AND WHAT IT IS USED FOR

Zolpidem belongs to a group of medicines called hypnotics. These are medicines which help you sleep.

Zolpidem is used for the short-term treatment of severe sleeping difficulties in adults, which are causing you extreme distress.

2 WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZOLPIDEM

Do NOT take Zolpidem:

- If you are allergic to zolpidem tartrate or any of the other ingredients of this medicine (listed in section 6).
- If you have myasthenia gravis (a muscle disease where the muscles become weak and tire easily)
- If you have severe breathing difficulties, including difficulty in breathing when asleep (sleep apnoea)
- If you have severe liver problems. In patients with severe liver problems, encephalopathy (a brain disorder) may develop
- If you suffer from the rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption
- If you are under the age of eighteen.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zolpidem

- If you are older people or frail. Due to the muscle relaxing effect of Zolpidem, there is a danger of falls, particularly for the older people when getting up at night.
- If you have a history of alcohol or drug related problems
- If you have psychiatric problems or mental illness including depression or anxiety (as thoughts of suicide may occur)
- If you have breathing difficulties (hypnotics can mask the symptoms of breathing difficulties such as anxiety or agitation)
- If you have kidney problems
- If you have liver problems.

Important safety messages about Zolpidem:

- Zolpidem may become less effective after repeated use for a few weeks (see section 3, How to take Zolpidem)
- Taking Zolpidem may lead to dependence. This may be physical dependence, where the body becomes used to the presence of the medicine and stopping treatment causes withdrawal symptoms (see section 3, If you stop taking Zolpidem), and/or mental dependence, where you develop a craving for the medicine. Longer treatment periods and higher doses, or a history of drug or alcohol abuse, psychiatric problems or mental illness increase the risk of dependence occurring. To stop this from happening your course of treatment should be as short as possible, at as low a dose as possible and, at the end of the treatment period, the dose should be reduced gradually
- Behavioural effects ('paradoxical reactions') may occur while taking Zolpidem (see section 4, Possible Side Effects)
- Zolpidem may cause amnesia (loss of memory). This can occur several hours after taking your medicine. To reduce the risk, you should make sure that you are able to have an uninterrupted sleep of 8 hours.

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 the recommended dose
- You take zolpidem while you are already taking another 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.

Other medicines and Zolpidem

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

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

- Medicines for mental health problems (antipsychotics)
- Medicines for sleep problems (hypnotics)
- Medicines to calm or reduce anxiety
- Muscle relaxants (e.g. baclofen), as their muscle relaxing effect may be increased
- Medicines for depressions
- Medicines for moderate to severe pain (narcotic analgesics)
- Medicines for epilepsy
- Medicines used for anaesthesia
- Medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines)

Concomitant use of zolpidem tartrate and opioids (strong pain killers, 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 tartrate together with opioids the dose 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 dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

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.

Medicines enhancing the activity of certain liver enzymes can reduce the effect of this medicine: e.g. Rifampicin (for the treatment of tuberculosis).

Tell the hospital doctor or your dentist you are taking Zolpidem if you are going to have an operation or dental treatment requiring an anaesthetic.

Zolpidem with food, drink and alcohol

- DO NOT drink alcohol whilst taking these tablets, as the sedative effect of Zolpidem may be increased.

Pregnancy, breast-feeding and fertility

- DO NOT take Zolpidem during the first three months of pregnancy, or if you are breast-feeding.
- If you are more than three months pregnant or are 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.

Driving and using machines

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

Zolpidem tartrate film-coated tablets contain lactose and sodium.

This medicine contains lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3 HOW TO TAKE ZOLPIDEM

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

Treatment with Zolpidem should be as short as possible. The treatment usually lasts from a few days to two weeks, up to a maximum of four weeks. In certain cases, treatment may last longer than four weeks, but only if your doctor thinks this is necessary.

If you do not notice any improvement after 7 to 14 days, or you should think that your tablets are not working as well as they should, contact your doctor.

The tablets should be swallowed preferably with a drink of water immediately before going to bed.

• Adults:

The recommended dose per 24 hours is 10 mg zolpidem tartrate. A lower dose may be prescribed to some patients. *Zolpidem tartrate* film-coated 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 10 mg per 24 hours.

- **Use in children and adolescents:** Zolpidem should not be taken by children or adolescents under the age of 18 years.

- **Elderly or frail patients, and patients with liver problems:**

5 mg:

A lower dose of one 5 mg zolpidem tartrate a day is recommended.

10 mg:

For these patients other tablets of a lower strength are available. A dose of 5 mg zolpidem tartrate a day is recommended.

Your doctor may increase this to 10 mg tablet a day depending on your response to Zolpidem.

You may become tolerant to the effects of Zolpidem after you have been taking it for a few weeks. If you notice that the tablets are not working as well as they did when you first started taking them, you should go and see your doctor as an adjustment to your dose may be necessary. **DO NOT change the dose yourself.**

If you take more Zolpidem than you should
If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

An overdose is likely to cause symptoms ranging from sleepiness to a light coma. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Zolpidem

If you fall asleep without taking a dose and wake up some hours later, do not take the missed dose. Take your normal dose the following night.

If you stop taking Zolpidem

DO NOT stop taking your tablets suddenly as you may suffer from withdrawal effects or "re-bound insomnia". This means the symptoms that required you to take your tablets in the first place may reappear for a short time. When your doctor decides to stop your tablets, the dose will be reduced gradually over a period of time.

Withdrawal effects may consist of:

- headache, muscular pain, extreme anxiety, feelings of tension
- restlessness, confusion, irritability and sleeping difficulties.

In severe cases the following symptoms may occur:

- a feeling of detachment from your surroundings
- a feeling of things being unreal
- sounds seeming louder than usual (can sometimes be painful with loud noises)
- numbness and tingling in the fingers and toes
- sensitivity to light, noise and physical contact
- hallucinations
- fits.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 POSSIBLE SIDE EFFECTS

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

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

If you experience any of the following effects, you should contact your doctor immediately to discuss whether you should continue taking the tablets:

- depression
- restlessness, agitation or irritability, aggressiveness or anger, nightmares, hallucinations, increased sleeping difficulties, sleep-walking, untrue beliefs or any other change in behaviour ('paradoxical reactions'). These effects are more likely to occur in the elderly.

The following effects occur mainly at the start of treatment and usually disappear after a few days.

Common: may affect up to 1 in 10 people

- drowsiness (during the following day)
- reduced alertness
- confusion
- numbed emotions
- headache
- amnesia (loss of memory)
- dizziness
- vertigo
- stomach upsets (diarrhoea, nausea, vomiting)
- skin rashes
- problems with sight (double vision).

Uncommon: may affect up to 1 in 100 people

- muscle weakness
- fatigue
- loss of co-ordination.

Rare: may affect up to 1 in 1,000 people

- decreased sex drive
- paradoxical reactions (see above for details).

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 the Yellow Card Scheme at:

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

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the outer packaging 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 tablets contain:

- The active substance is zolpidem tartrate
- The other ingredients are lactose monohydrate, microcrystalline cellulose (E460), Type A sodium starch glycolate, magnesium stearate (E572) and hypromellose (E464). The coating contains hypromellose (E464), titanium dioxide (E171) and macrogol 400.

What Zolpidem tablets looks like and contents of the pack:

The 5 mg tablets are white, oval, biconvex, film-coated tablets. They are embossed with 'ZIM' on one side and '5' on the other side.

The 10 mg tablets are white, oval, biconvex, film-coated tablets, scored on both sides. They are embossed with 'ZIM' and '10' on one side.

The product is available in pack sizes of 4, 5, 10, 14, 15, 20, 28, 30, 50, 100, and 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder: TEVA UK Limited, Eastbourne, BN22 9AG. Company responsible for manufacture: *Merckle GmbH, Ludwig-Merckle-Strasse 3, 89143, Blaubeuren, Germany*

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