

PACKAGE LEAFLET: INFORMATION FOR THE USER**Zolpidem tartrate 5 mg and 10 mg Film-coated Tablets**
(zolpidem tartrate)

This medicine contains Zolpidem, which can cause dependence, tolerance and addiction. You can get withdrawal symptoms if you stop taking it or reduce the dose suddenly. If this medicine is being used for the treatment of epilepsy you must continue to take this medicine as instructed by your doctor.

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, pharmacist or nurse.
- This medicine has been prescribed for you. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet See section 4.

What is in this leaflet:

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

1. What Zolpidem tablets are and what they are used for

The name of your medicine is Zolpidem tartrate 5mg and 10mg Film-coated Tablets. This 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 for temporary sleep problems in adults that are causing you severe distress or that are affecting your every day life.

This includes sleep problems in adults such as:

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

Zolpidem can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking it or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

2. What you need to know before taking Zolpidem tablets**Do not take this medicine if:**

- As 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 or other medicines containing zolpidem.
- You are allergic (hypersensitive) to zolpidem tartrate or any of the other ingredients of zolpidem (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 are under 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, pharmacist or nurse before taking zolpidem.

Warning and Precautions

Talk to your doctor, pharmacist or nurse before taking this medicine if:

- 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 or have ever had thoughts of harming or killing yourself
- You have ever had any heart problems including slow or uneven heartbeat
- you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake.
- you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- you feel you need to take more of zolpidem to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

- You have liver problems
- You have depression or have had another mental illnesses in the past
- You have recently taken Zolpidem or other similar medicines for more than four weeks
- You are elderly

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

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include: feeling anxious, shaky, irritable, agitated, confused, having panic attacks, sweating, headache, faster heartbeat or uneven heartbeat (palpitations), lower level of awareness or problems with focussing or concentrating, nightmares, seeing of 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, stomach problems.

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Zolpidem should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of Zolpidem, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death

Zolpidem 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 immediately and contact your doctor or health-care 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 might increase the risk of these sleep behaviours occurring.

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

The day after taking Zolpidem 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 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.

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

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

Zolpidem may increase the effect of the following medicines, drowsiness and next-day psychomotor impairment effects, including impaired driving ability

- Medicines for some mental health 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 or ciprofloxacin.

Risks from concomitant use with opioids

Concomitant use of zolpidem 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 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 tablets. To make this less likely, your doctor may decide to lower your dose of Zolpidem 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 work less well:

- 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 and St. John's Wort together is not recommended.

Zolpidem tablets with food, drink and alcohol

- Do not drink alcohol while you are being treated with these tablets. Alcohol can increase the side effects of Zolpidem tablets and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

Pregnancy and breast-feeding**Pregnancy**

Use of zolpidem is not recommended during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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 during the second and/or third trimester of pregnancy. If zolpidem 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 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 or 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 Tablets, as it can increase the above listed effects.

Zolpidem tablets contain Lactose

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

Information on sodium content:

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

3. How to take Zolpidem 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. Your prescriber should have discussed with you how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Taking this medicine

- Take this medicine by mouth.
- Swallow the tablet whole with a drink of water.
- The usual length of treatment is 2 days to 4 weeks.

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

Adults

The recommended dose per 24 hours is one 10mg tablet (or two 5mg tablets) just before bedtime.

Elderly

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

Patients with liver problems

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

Children and Adolescents

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

If you take more tablets than you should:

If you or someone else swallows a lot of the tablets or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty (A&E) or your doctor immediately. Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily.

Taking too much of this medicine 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 your tablets

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 dose.

If you stop taking these tablets

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Withdrawal symptoms such as: feeling anxious, shaky, irritable, agitated, confused, having panic attacks, sweating, headache, faster heartbeat or uneven heartbeat (palpitations), lower level of awareness or problems with focussing or concentrating, nightmares, seeing of 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, stomach problems.

In rare cases fits (seizures) may also occur.

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

4. Possible side effects

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

Stop taking Zolpidem tablets and see a doctor or go to 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 (may affect up to 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, 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)
- Drowsiness or a strong desire to sleep
- Dizziness

Uncommon (may affect up to 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)

- Zolpidem 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 side effects (may affect less than 1 in 1,000 people)

- Being less aware of your environment
- Falling, especially in the elderly when zolpidem was not taken in accordance with prescribing recommendation.
- Decreased ability to see (visual impairment)
- Problems with your liver, which will show up on blood tests

Very Rare

- Slower breathing (respiratory depression)

Not known: frequency cannot be estimated from the available data

- Delirium (a sudden and severe change in mental state that causes a person to appear confused or disoriented)

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 (Infection of the lungs or airways)
- Headache
- Feeling tired or agitated
- Nightmares
- Depression
- Back pain

Uncommon (may affect up to 1 in 100 people)

- Itching skin or skin rash
- Excessive sweating
- Feeling restless, aggressive, angry
- Feeling overly happy/ confident (euphoric). Most of these psychiatric undesirable effects are related to paradoxical reactions.
- Lack of concentration
- Neck pain
- Disturbance in attention
- Speech problems
- Change in the amount of liver enzymes-shown up in the results of blood tests
- Limp or weak muscles
- Feeling confused or irritable
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Tremor
- Blurred vision
- Changes in appetite or behaviour concerning appetite
- Pains in your joints or muscles, muscle spasms

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

- Pains in your joints or muscles, muscle spasms
- 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
- Hives

Very rare (affects less than 1 in 10,000 people)

- Thinking things that are not true (delusions)

Not known (frequency cannot be estimated from the available data)

- Feeling angry or showing unusual behaviour
- Zolpidem having less effect than normal
- dependence and addiction (see section "How do I know if I am tolerant or addicted?").

Drug Withdrawal

When you stop taking Zolpidem, you may experience drug withdrawal symptoms, which include: feeling anxious, shaky, irritable, agitated, confused, having panic attacks, sweating, headache, faster heartbeat or uneven heartbeat (palpitations), lower level of

awareness or problems with focussing or concentrating, nightmares, seeing of 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, stomach problems.

How do I know if I am tolerant or addicted?

If you notice any of the following signs whilst taking <product name>, it could be a sign that you have become addicted.

- You may feel the need to keep taking the medication for longer than your doctor recommended
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

Reporting 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 Yellow Card Scheme website: 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 tablets

- Keep this medicine out of sight and reach of children.
- Do not use this medicine after the expiry date (EXP.) which is stated on the carton. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- 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 5 mg and 10 mg tablets contains:

- The active ingredient is Zolpidem tartrate
- The other ingredients are lactose monohydrate, microcrystalline cellulose, pregelatinised starch, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, hypromellose, titanium dioxide (E171), purified talc, macrogol 6000.

What the tablets look like and contents of the pack

- There are two strengths of Zolpidem tartrate tablets, 5mg and 10mg
- Zolpidem 5mg tablets are white to almost white, round, biconvex, film-coated tablets '5' debossed on one side and plain on the other side.
- Zolpidem 10mg tablets are white to almost white, caplet shaped, biconvex, film-coated tablets with break line on one side and 'BL 10' debossed on other side.
- This medicine is available in packs of 7, 14, 28, 56 or 84 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name and address: Bristol Laboratories Limited,
Unit 3, Canalside, Northbridge Road,
Berkhamsted, Hertfordshire, HP4 1EG.

Telephone: 0044 (0) 1442 200922
Email: info@bristol-labs.co.uk

Manufacturer

Bristol Laboratories Ltd.
Laporte Way, Luton, LU4 8WL, United Kingdom

Manufacturer

Bristol Laboratories Ltd.
Unit 5, Traynor Way, Whitehouse Business Park,
Peterlee, SR8 2RU, United Kingdom.

Zolpidem tartrate 5mg film-coated Tablets; PL 17907/0123

Zolpidem tartrate 10mg film-coated Tablets; PL 17907/0124

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