

Package leaflet: Information for the patient

Zoldem 10 mg Film-coated Tablets (zolpidem tartrate)

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.

In this leaflet:

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

1. What Zoldem is and what it is used for

Zoldem contains zolpidem, which belongs to a group of medicines called hypnotics. Zoldem Tablets are sleeping pills, which work by acting on the brain to cause sleepiness.

This medicine may be used in adults for short-term treatment of insomnia which is severe, disabling or causing great distress. Insomnia is a difficulty in falling asleep or sleeping properly.

2. What you need to know before you take Zoldem

Do not take Zoldem 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 sleep apnoea (a condition where you stop breathing for very short periods whilst sleeping)
- suffer from severe muscle weakness (myasthenia gravis)
- have ever experienced sleep walking or behaviours that are unusual during sleep and that you performed without being fully awake (such as driving, eating, making a phone call, or having sex, etc.) after taking Zoldem or other medicines containing zolpidem
- have acute and/or severe breathing problems

Warnings and precautions

Talk to your doctor before taking this medicine if you:

- are elderly or frail. If you get up at night, take care. Zoldem may relax your muscles. This increases your risk of falling and consequently of hip fractures.
- have any kidney or liver problems.
- have a history of breathing problems. Whilst taking Zoldem your breathing may become less forceful
- have a history of mental illness, anxiety or psychotic illness. Zoldem may unmask or worsen symptoms

- suffer from or have a history of depression (feeling sad)
- have, or have ever had a history of, or tendency towards alcohol or drug abuse. The risk of dependence on Zoldem (physical or mental effects produced by a compulsion to keep taking the medicine) increases in these patients, and with dose and length of treatment.

Other considerations

- Tolerance – if, after a few weeks, you notice that your tablets are not working as well as they did when you first started treatment, you should see your doctor. Adjustment of 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. The risk is greater if you have a history of alcohol, substance or drug abuse. However, dependence may also occur at doses normally used for treatment and without such individual risk factors.
- Withdrawal - treatment should be withdrawn gradually. A short-lived syndrome may occur on withdrawal, where the symptoms that led to your treatment with Zoldem recur in an enhanced form. It may be accompanied by other reactions including mood changes, anxiety and restlessness.
- Amnesia - Zoldem can cause memory loss. To reduce this risk you should ensure that you are able to have 8 hours of uninterrupted sleep.
- Psychiatric and "paradoxical" reactions - Zoldem can cause behavioural side effects such as restlessness, agitation, irritability, aggressiveness, delusions (false beliefs), rages, nightmares, hallucinations (seeing, hearing or feeling things that are not there), psychoses (losing contact with reality, unable to think and judge clearly), inappropriate behaviour and increased insomnia.
- Sleep walking and other associated behaviours – Zoldem can cause people to do things whilst asleep that they do not remember when they wake up. This includes sleep walking, sleep driving, preparing and eating food, making phone calls or having sex. Alcohol and some medicines used to treat depression or anxiety or the use of Zoldem at doses larger than the maximum recommended dose can increase the risk of these side effects. If you experience any of these symptoms, discontinue treatment immediately and contact your doctor since these sleep behaviours can pose a serious risk of injury for you and other people.
- Falls and injury – zolpidem can cause you to feel drowsy or have lower levels of awareness, which may lead to falling and possible injury.
- Suicidal thoughts, suicide attempts and suicide - Some studies have shown an increased risk of suicidal thoughts, suicide attempts and suicide in patients taking certain sedative drugs and medications for insomnia, including this drug. However, it has not been established whether this is due to drug treatment or whether it may have other causes. If you have suicidal thoughts, contact a doctor for medical advice as soon as possible.
- Next-day psychomotor impairment (see also “Driving and using machines”) - The day after taking Zoldem, 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 depressant or another medicine 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 Zoldem

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Zoldem may influence the effect and/or side effects of other medicines. If you are to have an operation under general anaesthetic, 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 used to relax muscles
- Medicines for depression
- 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 (sedatives antihistamines)

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.

Concomitant use of Zoldem 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 Zoldem 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.

The following medicines may **increase the sedating effect** of Zoldem:

- medicines which inhibit liver enzymes. Ask your doctor or pharmacist which medicines have this effect (e.g. ketoconazole, a medicine used to treat fungal infections).
- Rifampicin, a medicine used to treat tuberculosis, may cause a decrease in the effect of Zoldem.
- St John's wort, a herbal medicine used to treat depression, should not be taken with zolpidem because it may cause a decrease in the effect of Zoldem.

Zoldem with alcohol

Alcohol should not be consumed when taking Zoldem, as the sedating effect may be increased.

Pregnancy and breast-feeding

Zoldem is not recommended during pregnancy. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor 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 foetal movement and foetal heart rate variability after taking zolpidem may occur during the second and/or third trimester of pregnancy.

If for urgent medical reasons, you take Zoldem during late pregnancy or during labour, your baby might suffer from low body temperature, floppy muscle, difficulty feeding and breathing difficulties, and may show withdrawal symptoms such as agitation or shaking after birth because of physical dependence. Newborns showing withdrawal symptoms should be closely monitored during the postnatal period.

Do not breast-feed your baby, as small amounts of zolpidem can pass into breast milk.

Driving and using machines

Zoldem has major influence on the ability to drive and use machines such as “sleep driving”. On the day after taking Zoldem (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 minimise the above listed effects.

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

Zoldem contains lactose

If your doctor has told you that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicinal product.

3. How to take Zoldem

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

The tablets act rapidly and should be swallowed whole with liquid immediately before going to bed, or in bed. Make sure you have at least 8 hours of sleep after taking this medicine.

The tablets can be divided into equal doses.

Adults: The recommended dose per 24 hours is 10 mg of Zoldem. A lower dose may be prescribed to some patients. Zoldem 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.

Elderly (over 65 years) or debilitated patients: The recommended dose is 5 mg.

Patients with liver problems: The recommended starting dose is 5 mg. Your doctor may decide to increase this to 10 mg if it is safe to do so.

The maximum dose of 10 mg must not be exceeded in any patients.

Use in children and adolescents: Zoldem should not be taken by patients under 18 years of age.

If 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.

Duration of treatment

The duration of administration should be as short as possible. This usually varies from a few days to two weeks. The maximum treatment period, including the stepwise withdrawal process, is four weeks.

Your doctor will choose a stepwise withdrawal regime for you based on your individual needs. In certain situations you may be required to take Zoldem for longer than 4 weeks.

If you take more Zoldem 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 doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you. Do not go unaccompanied to seek medical help. If an overdose has been taken you may become increasingly drowsy very quickly, with high doses possibly leading to a coma or even death.

If you forget to take Zoldem

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 8 hours of uninterrupted sleep. If this is not possible, take the next dose before bed time the next night. You should not take this medicine at another time of the day because it may make you feel drowsy, dizzy or confused. Do not take a double dose to make up for a forgotten dose. If you are worried ask your pharmacist or doctor for advice.

If you stop taking Zoldem

Keep taking your medicine until your doctor tells you to stop. Do not stop taking your medicine suddenly, but tell your doctor if you want to stop. Treatment should be withdrawn gradually, otherwise the sleep problems you are treated for may return more intensely 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 Zoldem, 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.

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 any of the following happen, **stop taking** Zoldem and tell your doctor immediately or go to your nearest hospital emergency department:

Common (may affect up to 1 in 10 people):

- amnesia (which may be associated with inappropriate behaviours (see section 2, 'Other considerations')

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

- itchy skin with yellowing of the skin or eyes, abdominal pain, dark urine, fever or chills. These may be signs of a problem with your liver
- feeling very sleepy or tired, unable to concentrate or carry out normal activities

Very rare (may affect up to 1 in 10,000 people):

- physical dependence: use (even at therapeutic dosages) may lead to physical dependence; sudden discontinuation of treatment may result in withdrawal effects and recurrence of problems
- psychological dependence: this is when you think that you cannot ever sleep without taking Zoldem

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

- allergic reactions such as skin rash, itching, swelling of the face, lips, throat or tongue, difficulty breathing or swallowing
- difficulty breathing
- psychosis (losing contact with reality, unable to think and judge clearly)

These side effects are serious. You may need medical attention.

The risk of amnesia is higher at higher doses. If you make sure that you can have 8 hours of uninterrupted sleep the risk of amnesia is reduced.

Tell your doctor or pharmacist if any of the following side effects occur or worsen:

Common (may affect up to 1 in 10 people):

- hallucinations, agitation, nightmares
- drowsiness, headache, dizziness, increased insomnia
- 'spinning' sensation
- drowsiness the following day, reduced alertness
- diarrhoea, nausea, vomiting
- skin reactions
- back pain
- fatigue
- abdominal pain
- infections in the nose or throat
- double vision
- depression (feeling sad)

Uncommon (may affect up to 1 in 100 people):

- confusion
- irritability
- blurred vision
- muscle weakness, co-ordination disturbances, tingling or numbness, shaking, muscular pain, muscle spasm, joint pain, neck pain
- restlessness, aggression
- sleep walking, and other behaviors that are unusual during sleep and which you perform without being fully awake (such as driving a car, eating, making phone calls or having sex, etc.) can happen. See section 2 "Warnings and Precautions"
- increased levels of some liver enzymes (which would be detected by your doctor during a blood test)
- skin rash, itching,
- excessive sweating

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

- changes in sexual drive (libido)
- hives
- changes in the way you walk
- falls, particularly in the elderly.

Very rare (may affect up to 1 in 10,000 people):

- delusion (false beliefs)

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

- co-ordination disturbances
- feeling angry, inappropriate behaviour.

- the need to take increasingly higher doses of a medicine to gain the same effect

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 HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Zoldem

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep your medicine 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 to protect the environment.

6. Contents of the pack and other information

What Zoldem contains

The active substance is zolpidem tartrate. Each tablet contains 10 mg of zolpidem tartrate.

The other ingredients are lactose monohydrate (see section 2, 'Zoldem contains lactose'), microcrystalline cellulose, pregelatinised maize starch, magnesium stearate. The coating includes hypromellose, titanium dioxide (E171), polysorbate 80 (E433), macrogol 400.

What Zoldem looks like and contents of the pack

Your medicine comes as a white to off-white capsule shaped film-coated tablet, marked "ZM breakline 10" on one side and "G" on the other. The tablets can be divided into equal doses.

Zoldem Tablets are available in blister packs or in plastic containers containing 4, 7, 10, 14, 20, 28, 30, 50, 100 or 250 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Manufacturer

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Mylan B.V., Dieselweg 25, 3752 LB Bunschoten, Netherlands

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This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium – Zolpidem Mylan 10 mg filmomhulde tabletten

Denmark – Zolpidem "Mylan" fillovertrukne tabletter 10 mg

Germany – Zolpidem dura 10 mg filmtabletten

Ireland – Zoldem 10 mg Film-coated Tablets

Luxembourg – Dodocest 10 mg filmomhulde tabletten

Netherlands – Zolpidemtartraat Mylan 10 mg, filmomhulde tabletten

Sweden – Zolpidem Mylan 10 mg filmdragerade tablett
United Kingdom – Zolpidem 10 mg Film-coated Tablets

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