

Package leaflet: Information for the patient

Zolnod 10 mg Film-Coated Tablets Zolpidem tartrate

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 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 Zolnod is and what it is used for
2. Before you take Zolnod
3. How to take Zolnod
4. Possible side effects
5. How to store Zolnod
6. Contents of the pack and other information

1. What Zolnod is and what it is used for

Zolnod is a hypnotic belonging to the group of benzodiazepine-like agents.
It is indicated for short-term treatment of sleep disturbances in adults.

Treatment with benzodiazepines and benzodiazepine-like agents is only prescribed for sleep disturbances that are severe, disabling or causing extreme distress.

2. What you need to know before you take Zolnod

Do not take Zolnod

- if you are **allergic** to zolpidem or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from **severe muscle weakness** (myasthenia gravis)
- if your **breathing stops for short periods** while you are sleeping (sleep apnoea syndrome)
- if you suffer from **acute and/or severe breathing weakness** (in which the lungs cannot take in enough oxygen) (respiratory insufficiency)
- if you suffer from **severe liver damage** (hepatic insufficiency) because there is a risk of brain damage (encephalopathy).

Warnings and precautions

Talk to your doctor or pharmacist before taking Zolnod.

General

Before treatment with Zolnod

- the cause of the sleep disturbances should be clarified
- underlying diseases should be treated.

If treatment of the sleep disturbances is not successful after 7-14 days, this might point to a psychiatric or physical basic disease which should be checked. You should contact your doctor.

Effects observed after use of benzodiazepines and benzodiazepine-like agents (such as Zolnod) or other hypnotics are as follows:

- **Dependence**

Development of physical and psychological dependence is possible.

The risk increases with the dose and duration of treatment and is elevated in patients with previous alcohol or drug abuse. If physical dependence has developed, sudden discontinuation of treatment is accompanied by withdrawal symptoms.

- **Memory defects (amnesia)**

Temporarily memory loss may be induced (anterograde amnesia).

This condition generally occurs some hours after intake of Zolnod. In order to minimize this risk, you should make sure that an uninterrupted sleep of 8 hours will be possible (see section 4)

- **Psychiatric and "paradoxical" reactions**

Restlessness, inner restlessness, irritability, aggressivity, delusions (psychoses), rages, nightmares, hallucinations, sleepwalking, inappropriate behaviour, increased sleep disturbances and other adverse behavioural effects are known to occur during treatment.

If any of these effects occur you should stop taking Zolnod and contact your doctor. These reactions are more likely to occur in the elderly.

- **Sleep walking and other associated behaviours** such as "sleep driving", preparing and eating food, making phone calls or having sex, **with no recollection of the event** have been reported in patients who had taken zolpidem and were not fully awake. The risk of such events may increase if you take Zolnod with alcohol or other drugs that slow down central nervous system activity, or if you exceed the maximum recommended dose. If you experience any such event tell your doctor immediately. Your doctor may recommend that you stop your treatment.

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

The day after taking Zolnod, 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 Zolnod while you are already taking another central nervous system depressants or another medicines that increase Zolnod 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.

Benzodiazepines and benzodiazepine-like agents (such as Zolnod) should not be used as the only treatment for delusions (psychoses) and depression or anxiety accompanied by depression.

Special patient groups

- If you are **elderly or debilitated**. You should receive a lower dose (see section 3). Zolnod has a muscle-relaxant effect. For this reason, especially elderly patients are at risk of falling and consequently of hip joint fractures when getting out of bed at night.
- If you have **impaired kidney function**. It may take longer for your body to get rid of Zolnod. Although no dose adjustment is necessary, caution is required. Contact your doctor.
- If you have **breathing problems**. Your breathing problems could get worse.

- If you have a history of **alcohol or drug abuse**. You should be carefully supervised by your doctor during treatment with Zolnod, as you are at risk of habituation and psychological dependence.
- If you have **severe liver disease**. You may not use Zolnod since you are at risk of brain damage (encephalopathy). Contact your doctor.
- If you suffer from **delusions (psychoses), depression or anxiety** related to depression, Zolnod should not be the only treatment you receive.

Other medicines and Zolnod

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

Other medicines may be affected by Zolnod. They, in turn, may affect how well Zolnod works. You may feel an increased sleepiness when Zolnod is used in combination with the medicines listed below.

Zolnod can interact with:

- **strong pain killers** (narcoanalgesics). Increased euphoria may occur which can result in increased psychological dependence.
- **muscle relaxants**
- medicines to treat a variety of fungal infections such as itraconazole and ketoconazole. Taking ketoconazole with Zolnod may increase the drowsiness effect.
- clarythromycin and erythromycin (antibiotics)
- ritonavir (an antiretroviral drug used to treat HIV and AIDS).

While taking Zolnod 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).

While taking Zolnod with antidepressants including bupropion, desipramine, fluoxetine, sertraline and venlafaxine, you may see things that are not real (hallucinations).

It is not recommended to take Zolnod with fluvoxamine or ciprofloxacin.

Medicines which strongly enhance the activity of certain liver enzymes can possibly reduce the effect of Zolnod e.g. rifampicin (an **antibacterial** used to treat for example, tuberculosis).

Zolnod with food and drink

You should not consume any alcohol during treatment, as this can increase the sedating effect of Zolnod, making you more sleepy or drowsy. The ability to perform tasks that demand an increased concentration such as driving or operating machinery will also be affected.

Pregnancy, breast-feeding and lactation

Pregnancy

Zolnod should **not be taken during pregnancy and breast-feeding**, especially not in the first 3 months because insufficient data is available to evaluate safe administration of Zolnod during pregnancy and breast-feeding.

However, if the benefit to the mother outweighs the risk to the child, your doctor may decide to treat you with Zolnod. If Zolnod is taken for a longer period during the last months of pregnancy, withdrawal symptoms may occur in the child after birth.

Breast-feeding

Since zolpidem passes into mother's milk in low quantities, Zolnod **should not be taken during 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.

Driving and using machines

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

Zolnod contains lactose

If you have been told by your doctor that you have **an intolerance to some sugars**, contact your doctor before taking this medicinal product.

3. How to take Zolnod

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

The film-coated 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 (1 film coated tablet of Zolnod). A lower dose may be prescribed to some patients. Zolnod 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 and patients with impaired liver function

A dose of 1/2 tablet of Zolnod (5 mg) is recommended.

The dose should only be increased to 1 tablet of Zolnod (10 mg) if the effect is insufficient and the medicinal product is tolerated well.

Children and adolescents

Zolnod must not be used in children and adolescents of less than 18 years of age.

How long should you take Zolnod?

After repeated intake over several weeks the sleep-promoting (hypnotic) effect can be reduced. The duration of treatment should be as short as possible. In general, it could be a few days up to 2 weeks and should not exceed 4 weeks including the gradual reduction in dosage. Your doctor will tell you how to gradually reduce your dosage in order to prevent withdrawal effects.

In certain cases, treatment beyond 4 weeks may be required. Your doctor will review your response to treatment and decide if this is necessary.

If you take more Zolnod than you should

In case of over-dosage, a doctor's advice is to be asked without delay. Take any leftover tablets in the carton or the leaflet with you, so that the staff will know exactly what has been taken.

In case of over-dosage, symptoms could vary from extreme sleepiness to light coma and possibly fatal coma.

If you forget to take Zolnod

Do not take a double dose to make up for a forgotten dose.

If you miss a dose, you may take it provided that you are still able to sleep 7 or 8 hours. If this is not possible, you should not take a tablet until going to bed the next day.

Then continue intake of Zolnod as prescribed by your doctor.

If you stop taking Zolnod

Do not stop taking Zolnod suddenly. The risk of withdrawal symptoms (see section 2 under "Withdrawal symptoms") is higher after abrupt discontinuation of treatment. Your doctor will advise you how to stop treatment by gradual reduction in the dose.

In case treatment is stopped suddenly, your sleep may temporarily be worsened (rebound phenomenon). It may be accompanied by mood changes, anxiety and restlessness. The withdrawal symptoms consist of headache or muscle pain, extreme anxiety and tension, restlessness, confusion, irritability and sleep disturbances and in severe cases loss of perception of reality (derealisation), alienation of oneself (depersonalisation), abnormal sensitivity to sound (hyperacusis), numbness and tingling of extremities, hypersensitivity to light, noise and physical contact, hallucinations or fits (epileptic seizures) may occur.

It is important that you are aware of the possibility of such symptoms in order to minimise your anxiety.

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. These effects seem to be related with individual sensitivity and to appear more often within the hour after taking the tablet if you do not go to bed or sleep immediately.

These side effects occur most frequently in elderly patients.

Stop taking Zolnod 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

- Respiratory infection
- Sensing things that are not real (hallucinations), agitation, nightmares
- Sleepiness during the following day, numbed emotions, reduced alertness, tiredness, headache, dizziness, difficulty remembering things, which may be associated with inappropriate behaviour, ataxia (loss of coordination of the muscles), worsening insomnia
- Sensation of spinning with loss of balance (vertigo), ataxia
- Diarrhoea, feeling sick, vomiting, stomach pain
- Back pain
- Fatigue.

Uncommon: may affect up to 1 in 100 people

- State of confusion, irritability
- Double vision
- Rash, nettle rash, itching, excessive sweating.

Not known: frequency cannot be estimated from the available data

- Restlessness, aggression, delusions, anger, mental disturbances (psychosis), sleepwalking, inappropriate behaviour and other adverse behavioural effects, which may be associated with inappropriate behaviour (see section 2). Such reactions are more likely to occur in the elderly. Pre-existing depression may be unmasked during use of Zolnod or other sleeping tablets (hypnotics). Taking Zolnod for a long period of time may lead to physical or psychological dependence. If you suddenly stop taking Zolnod, you may suffer from withdrawal symptoms (see section 2).
- Misuse of Zolnod by drug abusers has been reported
- Decrease in sexual need (libido)
- Being less aware of your environment
- Slower breathing (respiratory depression)
- Muscle weakness
- Abnormal posture when walking (abnormal gait), drug tolerance, falls (mainly in elderly patients and when Zolnod was not taken as prescribed)

- Increased liver enzymes.

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 HPRA

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zolnod

Keep out of the sight and reach of children.

Store in the original container to protect from light.

Do not use Zolnod after the expiry date which is stated on the carton and the blister.

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

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. Contents of the pack and other information

What Zolnod contains

The **active substance** is zolpidem tartrate.

Each tablet contains 10 mg zolpidem tartrate.

The **other ingredients** are:

Tablet core: succinic acid, sodium starch glycollate (type A), microcrystalline cellulose, lactose monohydrate, magnesium stearate, colloidal silicon dioxide.

Tablet coating: lactose monohydrate, macrogol 4000, hypromellose, titanium dioxide (E171).

What Zolnod looks like and contents of the pack

Zolnod film-coated tablets are white, oblong, biconvex with a break score.

The film-coated tablets are packed in blisters in a carton containing 10, 20, 28, 30, 30 x 1, 50, 98, 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.

Rowa Pharmaceuticals Ltd., Newtown, Bantry, Co. Cork, Ireland.

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

NL:	Zolpidemtartraat Sandoz 10 mg, filmomhulde tabletten
UK:	Zolpidem 10 mg tablets
SE:	Zolpidem HEXAL
ES:	ZOLPIDEM Sandoz 10 mg comprimidos recubiertos con película EFG
DE:	Zolpidem Hexal 10 mg Filmtabletten
IE:	Zolnod 10 mg Film-Coated Tablets
BE:	Zolpidem Sandoz 10 mg filmomhulde tabletten
FI:	Zolpidem Hexal 10 mg tabletti, kalvopäällysteinen
DK:	Zolpidem HEXAL 10 mg filmcoated tablets
IT:	Zolpidem Sandoz 10 mg compresse rivestite con film

This leaflet was last approved in 04/2017.