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 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 Zolnod is and what it is used for

Zolnod is used for the short-term treatment of insomnia in adults.
Do not use it for long-term treatment. The duration of treatment should be as short as possible because the risk of dependence increases with increasing treatment duration.
It is used only when the sleep disorders are severe, disabling or causing extreme distress for the patient.

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 certain forms of **pathologic muscle weakness** (myasthenia gravis)
- in case of **short-term respiratory arrest** while you are sleeping (sleep apnoea syndrome)
- if you suffer from **acute and/or severe breathing weakness** (respiratory impairment)
- if you suffer from **severe liver damage** (hepatic impairment
- if you have ever experienced sleepwalking or other behaviour that is unusual during sleep after taking Zolnod or other medicines containing zolpidem. This may include driving, eating, talking on the phone or having sexual intercourse during sleep without being fully awake.

Warnings and precautions
Talk to your doctor or pharmacist before taking Zolnod.

General
Before treatment with Zolnod
- the cause of the sleep disorders should be clarified and the possibility to treat them without medication
- underlying diseases should be treated.

If there is no improvement in the sleep disorder after 7-14 days of treatment with Zolnod, your doctor will carry out further investigations to clarify the causes of the sleep disorder.

<u>Tolerance</u>
Repeated use of hypnotics for a few weeks can lead to a **loss of effectiveness** (tolerance).

Dependence
Use of Zolnod may lead to the development of abuse and/or physical and psychological **dependence**. The risk of dependence increases with the dose and duration of treatment and is greater when zolpidem is used for longer than 4 weeks. The risk of abuse and dependence is greater in patients with a history of mental illness and/or alcohol, drug or medication abuse. Tell your doctor if you have or have ever had a mental illness or if you abuse or have abused alcohol, drugs or medicines or if you are or have been dependent on them.

Withdrawal
If physical dependence has developed, a sudden discontinuation of treatment is accompanied by withdrawal symptoms such as headache, muscle pain, unusual anxiety and tension, restlessness, confusion, irritability. In severe cases, loss of reality, personality disorders, auditory defects (hyperacusis), numbness and tingling of extremities, hypersensitivity to light, noise and physical contact, hallucinations or epileptic seizures may occur. Therefore it is recommended to stop treatment by gradually reducing the dose. Zolpidem may lead to withdrawal symptoms even within the dose interval.

When treatment is **terminated**, temporary **withdrawal symptoms** may occur and **the symptoms that led to treatment with Zolnod may reappear in an increased form**. Accompanying reactions include mood changes, anxiety and restlessness. Since the risk of withdrawal or discontinuation symptoms is higher after sudden cessation of treatment, it is recommended to stop the treatment by gradually reducing the dose.

When taking Zolnod in accordance with the recommendations for dose and duration of use as well as the precautions and warnings, the occurrence of withdrawal or discontinuation symptoms at the end of treatment is minimal.

Zolnod is not recommended for the basic treatment of certain mental illnesses (psychoses).

Depression
Like other hypnotic medicines or tranquilizers, Zolnod should be used with caution in patients with symptoms of **depression** or anxiety accompanied by depression. Under certain circumstances, depressive symptoms may be increased if there is no adequate treatment of the underlying disease with appropriate medicines (antidepressants). This may increase the risk of suicide for these patients. A previously unrecognized depression may appear due to Zolnod. Some studies show an increased incidence of suicide or attempted suicide in patients taking certain sleeping pills or sedatives including Zolnod.
However, it has not been established whether this is due to medicinal treatment or whether it may have other causes.
Please inform your doctor immediately if you have suicidal thoughts (thoughts about hurting yourself or killing yourself) or suicidal behaviour.

Memory gaps (amnesia)
Temporally limited **memory gaps** (anterograde amnesia) may be induced by hypnotic medicines. This means that (usually a few hours) after taking this medicine, actions may be taken, which you will not be able to remember later. This can also be inappropriate behaviour. This risk depends on the dose level. In order to minimize this risk, you should make sure that an uninterrupted sleep of 8 hours will be possible.

Psychiatric and paradoxical reactions
Zolnod can cause, especially in elderly patients, **psychiatric and so-called "paradoxical reactions"** such as inner restlessness, increased sleep disturbances, agitation, irritability, aggression, delusions (false beliefs), tantrums, nightmares, hallucinations (seeing, hearing or feeling things that are not there), abnormal behaviour and other behaviour disorders (see section 4). Should this occur, Zolnod should be discontinued (see section 4).

Sleepwalking
Sleepwalking and associated behaviours were also reported in patients who had taken zolpidem and were not fully awake. This includes "sleep driving", preparing and eating food, making phone calls or having sexual intercourse while patients cannot remember these actions when they wake up. If you notice any of the

behaviours described above, stop treatment with Zolnod immediately and contact your doctor, as this sleep behaviour may put you and others at serious risk of injury. Drinking alcohol or using other medicines at the same time that make you sleepy may increase the risk of this sleeping pattern occurring.

Psychomotor impairment
Next-day psychomotor impairment (see also "Driving and using machines")
Like other hypnotic medicines or tranquilizers, Zolnod has a depressing effect on the central nervous system. 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 zolpidem while you are already taking another central nervous system depressant or other medicines that increase zolpidem in your blood, or while drinking alcohol, or while taking drugs or medicines.

Take the entire dose immediately at bedtime.
Do not take another dose during the same night.

The use of zolpidem has been associated with an increased risk of **falling**. Falling may be caused by side effects such as coordination problems, muscle weakness, dizziness, drowsiness and fatigue. The risk of falling is higher in elderly patients and if a higher dose than recommended is used.

Impaired respiratory and liver function
Patients with chronically impaired respiratory function or **liver function disorders** should be treated with caution and your doctor may prescribe a lower dose of Zolnod (see also section 3). Due to the risk of brain damage, patients with severe liver dysfunction should not be treated with Zolnod.

Cardiac conduction disorder
Patients with a certain congenital cardiac conduction disorder (**"long-QT syndrome"**) should be treated with caution. Your doctor will carefully weigh the benefits against the risks before treatment with Zolnod.

Elderly and debilitated patients
They should receive a lower dose (see section 3). In elderly patients, caution is required due to the risk of falling, especially when getting up at night.

Children and adolescents
Zolnod is not recommended for use in children and adolescents below 18 years of age, as no sufficient clinical data are available for use in this age group.

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

The following medicines may influence the effect of Zolnod or be influenced in their effect:
While taking zolpidem with the following medicines, drowsiness and next-day psychomotor impairment effects, including impaired driving ability, may be increased on the day after the intake.

- 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 anaesthesia
- medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines).

Concomitant use of Zolnod 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 Zolnod 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 combination with opiate-type painkillers (narcotic analgesics) may also lead to an accelerated development of dependency.

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.

With simultaneous administration of muscle relaxants their effect can be increased - especially in elderly patients and at higher doses (risk of falling).

Medicines which enhance the activity of certain liver enzymes (in particular the P450 isoenzyme CYP3A4) can weaken the effect of Zolnod (e.g. rifampicin, carbamazepine, phenytoin, St. John's wort). The simultaneous use of zolpidem together with St. John's wort is not recommended.

In contrast, certain anti-fungal medicines (azole antifungals, e.g. ketoconazole) and certain antibiotics (macrolide antibiotics), which reduce the effect of these liver enzymes, can increase the effect of Zolnod.

Zolnod with food, drink and alcohol
You should not consume any alcohol during treatment, as this will change and intensify the effect of zolpidem in an unforeseeable way. The ability to perform tasks that demand an increased concentration is additionally impaired by this combination. Grapefruit juice may cause an increase in the effect of Zolnod.

Pregnancy, breast-feeding and fertility
Pregnancy
Use of Zolnod is not recommended during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice.
If used during pregnancy, there is a risk that the baby will be 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 if Zolnod is used during the second and/or third trimester of pregnancy.

If Zolnod is taken at the end of pregnancy or during labour, your baby may show muscle weakness, lower body temperature, difficulty feeding and breathing problems (respiratory depression).

If this medicine is taken regularly in later stages of 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 carefully monitored after birth.

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

Fertility
No data are available on the effect on fertility.

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 through behaviours such as sleepwalking or driving while overtired ("sleep driving"). On the day after taking Zolnod (as with other sleeping pills), you should be aware that:
- you may feel drowsy, sleepy, dizzy or confused
- your quick decision-making may take 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 machines and working at heights to minimize the above listed effects.

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

Zolnod contains lactose and sodium
If you have been told by your doctor 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 Zolnod

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

The recommended dose is:
Adults
The recommended dose per 24 hours is 10 mg of zolpidem (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 take more than 10 mg per 24 hours.

Elderly and debilitated patients
A dose of ½ film-coated tablet (5 mg) of Zolnod is recommended in elderly or debilitated patients who may be particularly sensitive to Zolnod. This dose should only be increased to 10 mg (1 film-coated tablet) if the effect is insufficient and the medicine is tolerated well.

Respiratory dysfunction or impaired liver function
In patients with respiratory dysfunction or impaired liver function, the dose should be only ½ film-coated tablet (5 mg) of Zolnod.

Children and adolescents
Zolnod is not recommended for use in children and adolescents below 18 years of age, as no sufficient clinical data are available for use in this age group.

Method of administration
Zolnod should be taken together with some liquid (water) immediately before going to bed or in bed.

The tablet can be divided into equal doses.

How long should you take Zolnod?
The duration of administration should be as short as possible. In general, it should be a few days up to 2 weeks and should not exceed 4 weeks, including the gradual discontinuation phase.

In individual cases, treatment beyond this period may be necessary. However, this should not be done without a medical reassessment of your condition.

If you take more Zolnod than you should
In case of an overdose, a doctor has to be consulted immediately.

Signs of (slight) overdose may include drowsiness, dizziness, blurred vision, slurred speech, drop in blood pressure, unsteady gait and movement, muscle weakness, mental confusion and hallucinations. In cases of severe poisoning, deep sleep to unconsciousness, agitation, respiratory dysfunction and circulatory collapse may occur. Cases of zolpidem overdose (alone or in combination with other central depressants including alcohol) have been reported with serious consequences (including fatal events).

If you forget to take Zolnod
Do not take a double dose to make up for a forgotten dose. Continue taking Zolnod as prescribed by your doctor.

If you stop taking Zolnod
If you want to interrupt the treatment, discuss this with your doctor ahead. Do not terminate the medicine on your own without medical advice. As the risk of withdrawal symptoms is higher after abrupt discontinuation of treatment, your doctor will advise you to terminate treatment by gradually reducing the dose, please see section 2. “Warnings and precautions”, “withdrawal”.

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.

Stop taking zolpidem and see a doctor or go to a hospital straight away if:
You have an **allergic reaction (angioedema).** 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.

There is evidence of a dose dependence of the occurring side effects, especially those affecting the central nervous system. To reduce these side effects, zolpidem should be taken directly before bedtime or in bed, as recommended. Side effects are more common in elderly patients.
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)
- Drowsiness
- Increased insomnia
- Nightmares
- Fatigue
- Headache
- Feeling dizzy
- Cognitive disorders such as temporary memory lapses (anterograde amnesia, which may be associated with inappropriate behaviour)
- Hallucinations
- Increased activity
- Depression
- Diarrhoea

- Feeling sick (nausea) or being sick (vomiting)
- Abdominal pain
- Infection of the upper respiratory tract
- Infection of the lower respiratory tract
- Back pain.

Uncommon (may affect up to 1 in 100 people)
- Appetite disorder
- State of confusion
- Irritability
- Restlessness
- Aggression
- Sleepwalking or other behaviour that is unusual during sleep, such as driving, eating, talking on the phone or have sexual intercourse during sleep without being fully awake (see section "Warnings and Precautions")
- Euphoric mood
- Sensory disorder such as tingling or numbness (paraesthesia)
- Tremor
- Attention deficit
- Speech disorder
- Double vision
- Blurred vision
- Elevated liver enzymes
- Rash
- Itching (pruritus)
- Excessive sweating (hyperhidrosis)
- Joint pain
- Muscle pain
- Muscle cramps
- Neck pain
- Muscle weakness.

Rare (may affect up to 1 in 1,000 people)
- Sexual dysfunction
- Deterioration of vision
- Liver damage (hepatocellular, cholestatic or mixed) (see also section 2 “What you need to know before you take Zolnod" and section 3)
- Hives (urticaria)
- Gait insecurity
- Risk of falling (especially in elderly patients or if Zolnod was not taken as prescribed)
- Clouding of consciousness.

Very rare (may affect up to 1 in 10,000 people)
- Thinking things that are not true (delusions)
- Dependence (withdrawal or discontinuation symptoms may occur after termination of treatment)
- Impaired breathing (respiratory depression).

Not known (frequency cannot be estimated from the available data)
- Tantrums
- Abnormal behaviour
- Tolerance development
- Persistent swelling of the skin and mucous membranes (angioedema)
- Abuse.

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 national reporting system: 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 Zolnod

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

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

Store in the original package in order to protect from light.
This medicine does not require any special temperature storage conditions.

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 Zolnod contains
The active substance is zolpidem tartrate.
Each film-coated tablet contains 10 mg of 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
White, shining film-coated tablets, oblong, biconvex, with a score line on one side.

The film-coated tablets are packed in polyvinylchloride/aluminium blisters and inserted into a carton.

The packages contain 10, 14, 20, 28, 30, 30x1, 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 medicine is authorised in the Member States of the European Economic Area under the following names:

Belgium	Zolpidem Sandoz 10 mg filmomhulde tabletten
Denmark	Zolpidem "Hexal"
Germany	Zolpidem HEXAL 10 mg Filmtabletten
Ireland	Zolnod 10 mg film-coated tablets
Italy	ZOLPIDEM SANDOZ
The Netherlands	ZOLPIDEMTARTRAAT SANDOZ 10 MG, FILMOMHULDE TABLETTEN
Spain	Zolpidem Sandoz 10 mg comprimidos recubiertos con película EFG
Sweden	Zolpidem Hexal 10 mg filmdragerad tablett

This leaflet was last revised in 05/2023.