

Package leaflet: Information for the patient

Edluar 5 mg sublingual tablets
Edluar 10 mg sublingual 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 Edluar is and what it is used for
2. What you need to know before you take Edluar
3. How to take Edluar
4. Possible side effects
5. How to store Edluar
6. Contents of the pack and other information

1. What Edluar is and what it is used for

Edluar tablets are sleeping pills (hypnotics) which work by acting on the brain to cause sleepiness. They may be used for short-term treatment of insomnia in adults 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 Edluar

Do not take Edluar 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 acute and severe breathing problems
- 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 Edluar or other medicines containing zolpidem

Warnings and precautions

Talk to your doctor or pharmacist before taking Edluar if you:

- are elderly or frail. If you get up at night, take care. Edluar may relax your muscles. This and the sedative effect increase your risk of falling and consequently of hip fractures.
- have any kidney or liver problems.
- have a history of breathing problems. Whilst taking Edluar your breathing may become less forceful.

- have a history of mental illness, anxiety or psychotic illness. Zolpidem may unmask or worsen symptoms.
- have or have had heart problems or a condition called long QT syndrome
- suffer from or have a history of depression (feeling sad) or have suicidal thoughts.
- have, or have ever had a history of, or tendency towards alcohol or drug abuse. The risk of dependence on Edluar (physical or mental effects produced by a compulsion to keep taking the medicine) increases in these patients, and with dose and length of treatment.

Children and adolescents

Edluar shall not be used in children and adolescents under 18 years of age.

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

The day after taking Edluar, 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
- take a higher dose than the recommended dose
- 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.

Other considerations

- Habituation - 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.
- Dependence - when taking this type of medicine there is a risk of abuse and dependence, which increases with dose and length of treatment. The risk is greater if you have a history of psychiatric disorders or drug dependence, alcohol, substance or drug abuse. However, dependence may also occur at doses normally used for treatment or if you do not show risk factors such as a history of alcohol or drug abuse.
- Withdrawal - treatment should be withdrawn gradually. A short-lived syndrome may occur on withdrawal, whereby the symptoms that led to your treatment with Edluar recur in an enhanced form. It may be accompanied by other reactions including mood changes, anxiety and restlessness.
- Amnesia - Edluar can cause memory loss. To reduce this risk you should ensure that you are able to have 8 hours uninterrupted sleep.
- Psychiatric and 'paradoxical' reactions - Edluar can cause behavioural side effects such as restlessness, agitation, irritability, aggressiveness, delusions (false beliefs), rages, nightmares, hallucinations, psychoses (hallucinations; when you see, hear or feel things that are not there), inappropriate behaviour and increased insomnia.
- Edluar can cause sleep walking and other associated behaviours which are unusual while sleeping and not fully awake (such as driving, eating, making phone calls or having sex, etc.). 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 Edluar immediately and contact your doctor as these sleep behaviours might put you and others at serious risk of injury. Alcohol and some medicines used to treat depression or anxiety or the use of Edluar at doses exceeding the maximum recommended dose can increase the risk of these side effects.
- Risk of falling and severe injuries - Edluar can cause drowsiness and a decreased level of consciousness, which may increase the risk of falls and consequently to severe injuries (see also section 4 Possible side effects).

Other medicines and Edluar

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Edluar 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 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 (sedatives antihistamines)
- Muscle relaxants
- 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).

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

Concomitant use of Edluar and opioids (strong pain killers, medicines for substitution therapy and certain 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 Edluar 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.

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

Edluar may cause an increase in the effect of muscle relaxant medicines. The risk of falling may therefore be increased, especially in elderly patients and at higher dosage.

Rifampicin (a medicine used to treat tuberculosis), carbamazepine (a medicine used for example for epilepsy), phenytoin (a medicine used for example for epilepsy) and St John's Wort [(traditional) herbal medicinal product], may cause a decrease in the effect of Edluar. Concomitant use is therefore not recommended.

Edluar with food, drink and alcohol

Alcohol should not be consumed when taking Edluar, as the sedating effect may be increased. Grapefruit juice may affect the effect of this medicine, talk to your doctor for more information.

Pregnancy and breast-feeding

Pregnancy

Edluar should not be taken 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 Edluar is used during pregnancy there is a risk that it may harm the baby. Some studies have shown a potentially increased risk of cleft lip and palate (sometimes called 'harelip') in newborn babies. Reduced foetal movement and foetal heart rate variability may occur after taking zolpidem during the

second and/or third three months of pregnancy.

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

If this medicine is taken regularly in late pregnancy your baby may develop physical dependence and withdrawal symptoms such as agitation or tremors. In this case, the newborn should be closely monitored in the period right after birth.

Breast-feeding

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

Driving and using machines

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

Edluar contains sodium

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

3. How to take Edluar

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

The tablet should be put under the tongue and should be kept there until dissolved. As the tablet acts rapidly take Edluar immediately before going to bed, or in bed. Do not take Edluar with or shortly after a meal.

Adults: The recommended dose per 24 hours is 10 mg of Edluar. A lower dose may be prescribed to some patients. Edluar 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. The recommended dose should not be exceeded.

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

Do not take Edluar if you have severe liver problems.

Patients with breathing problems: A lower dose is recommended for patients with breathing problems.

Use in children and adolescents: Edluar shall not be used in children and adolescents under 18 years of age.

If after a few weeks 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. 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 Edluar for longer than 4 weeks. If this is the case, your doctor should reassess your condition and treatment, as the risk of abuse and dependence increases with treatment duration.

If you take more Edluar 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. The following effects may happen:

- Feeling drowsy, sleepy, possibly falling into a coma and other outcomes leading to death.

If you forget to take Edluar

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. 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 Edluar

Treatment should be withdrawn gradually, otherwise the symptoms 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 Edluar, 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 Edluar and contact your doctor immediately or go to your nearest hospital emergency department:

- allergic reactions such as skin rash or itching, accompanied by swelling of the face, lips,

throat or tongue and difficulty breathing or swallowing (angioedema).

These side effects are serious, but the frequency is not known (cannot be estimated from the available data). You need medical attention.

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

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

- respiratory infection
- hallucinations, agitation, nightmares, numbed emotions, depression (feeling sad)
- sleepiness, headache, dizziness, increased insomnia, cognitive disorders such as amnesia (which may be associated with inappropriate behaviours), drowsiness during the following day
- 'spinning' sensation
- double vision
- diarrhoea, nausea, vomiting, abdominal pain
- skin reactions
- fatigue
- back pain

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

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

- confusion, irritability, restlessness, aggression
- co-ordination disturbances, tingling or numbness, shaking, muscle weakness, muscular pain, muscle spasm, joint pain, neck pain
- blurred vision
- skin rash, itching, excessive sweating
- loss of appetite
- sleep walking (see section 2 'Other considerations - Sleep walking and other associated behaviours')
- reduced alertness
- speech disorder
- euphoric mood
- increased levels of some liver enzymes (which would be detected by your doctor during a blood test)

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

- hives
- changes in sex drive (libido)
- depressed level of consciousness
- changes in the way you walk
- falls, particularly in the elderly
- problems with vision
- injury to the liver
- paradoxical reactions (restlessness, agitation, irritability, aggressiveness, delusions (false beliefs), rage, nightmares, hallucinations, psychoses, inappropriate behaviour and other adverse behavioural effects). These are more likely to occur if you are elderly.

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

- decreased breathing function (respiratory depression)

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

- delusion (false beliefs), rages, psychosis (hallucinations; when you see, hear or feel things that are not there), inappropriate behaviour
- 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 Edluar
- 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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Edluar

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

This medicinal product does not require any special 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 protect the environment.

6. Contents of the pack and other information

What Edluar contains

The active substance is zolpidem tartrate.

Edluar 5 mg:

Each sublingual tablet contains 5 mg zolpidem tartrate.

Edluar 10 mg:

Each sublingual tablet contains 10 mg zolpidem tartrate.

The other ingredients are mannitol (E421), silicified microcrystalline cellulose (mixture of microcrystalline cellulose and silica colloidal anhydrous), silica colloidal anhydrous, croscarmellose sodium, saccharin sodium, magnesium stearate.

What Edluar looks like and contents of the pack

Edluar 5 mg:

Your medicine comes as white, round, flat-faced, bevel-edged tablets approximately 7.5 mm in diameter with V debossed on one side.

Edluar 10 mg:

Your medicine comes as white, round, flat-faced, bevel-edged tablets approximately 7.5 mm in

diameter with X debossed on one side.

The medicine is available in blister packs containing 10, 14, 20, 28, 30, 60, 100 and 150 sublingual tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan Products Ltd.,
Station Close,
Potters Bar,
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Manufacturer

Recipharm Stockholm AB
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Mylan Hungary Ltd.,
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This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Bulgaria, , Denmark, Finland, France, Hungary, Iceland, Ireland, Netherlands, , Portugal, Romania, Slovenia, Spain, Sweden, Northern Ireland : Edluar
Belgium, Italy, Luxembourg: Zolpeduar

This leaflet was last revised in September 2021