

Medication Guide
Edluar[®] [ED' – loo-ahr]
(zolpidem tartrate)
sublingual tablets C-IV

Read this Medication Guide that comes with Edluar before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about Edluar?

- **Do not take more Edluar than prescribed.**
- **Do not take Edluar unless you are able to stay in bed a full night (7 to 8 hours) before you must be active again.**
- **Take Edluar right before you get in bed, not sooner**

Edluar may cause serious side effects, including:

- **After taking Edluar, you may get up out of bed while not being fully awake and do an activity that you do not know you are doing. The next morning, you may not remember that you did anything during the night.**

You have a higher chance for doing these activities if you drink alcohol or take other medicines that make you sleepy with Edluar. Reported activities include:

- driving a car (“sleep-driving”)
- making and eating food
- talking on the phone
- having sex
- sleep-walking

Call your healthcare provider right away if you find out that you have done any of the above activities after taking Edluar.

Do not take Edluar if you:

- drank alcohol that evening or before bed
- took another medicine to help you sleep

What is Edluar?

Edluar is a sedative-hypnotic (sleep) medicine. Edluar is used in adults for the short-term treatment of a sleep problem called insomnia (trouble falling asleep).

It is not known if Edluar is safe and effective in children under the age of 18 years.

Edluar is a class four (C-IV) federally controlled substance because it can be abused or lead to dependence. Keep Edluar in a safe place to prevent misuse and abuse. Selling or giving away

Edluar may harm others, and is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take Edluar?

- Do not take Edluar if you are allergic to zolpidem or any other ingredients in Edluar. See the end of this Medication Guide for a complete list of ingredients in Edluar.
- Do not take Edluar if you have had an allergic reaction to drugs containing zolpidem, such as Ambien, Ambien CR, Zolpimist, or Intermezzo.

Symptoms of a serious allergic reaction to zolpidem can include:

- swelling of your face, lips, and throat that may cause difficulty breathing or swallowing
- nausea and vomiting

What should I tell my healthcare provider before taking Edluar?

Edluar may not be right for you. Before starting Edluar, tell your healthcare provider about all of your health conditions, including if you:

- have a history of depression, mental illness or, suicidal thoughts
- have a history of drug or alcohol abuse or addiction
- have kidney or liver disease
- have lung disease or breathing problems
- are pregnant or planning to become pregnant. It is not known if Edluar will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Edluar can pass into your breast milk. It is not known if Edluar will harm your baby. Talk to your healthcare provider about the best way to feed your baby while you take Edluar.

Tell your healthcare provider about all of the medicines you take, including prescription and nonprescription medicines, vitamins and herbal supplements.

Medicines can interact with each other, sometimes causing serious side effects.

Do not take Edluar with other medicines that can make you sleepy, unless directed by your healthcare provider

Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist each time you get a new medicine.

How should I take Edluar?

- See **“What is the most important information I should know about Edluar?”**
- Take Edluar exactly as prescribed. Only take 1 Edluar tablet a night and only if needed.
- Do not take Edluar if you drank alcohol that evening or before bed.
- You should not take Edluar with or right after a meal. Edluar may help you fall asleep faster if you take it on an empty stomach.
- Do not use the tablet if the seal on the childproof blister pack is broken, or if the blister holding the tablet is broken.

- To open the blister pack, separate the individual blisters at the perforations. Peel off the top layer of paper, and push the tablet through the foil.
- Place the tablet under the tongue, where it will disintegrate. Do not swallow or take with water.
- Call your healthcare provider if your insomnia worsens or is not better within 7 to 10 days. This may mean that there is another condition causing your sleep problem.
- If you take too much Edluar or overdose, get emergency treatment.

What are the possible side effects of Edluar?

Edluar may cause serious side effects, including:

- **getting out of bed while not being fully awake and doing an activity that you do not know you are doing.** See "**What is the most important information I should know about Edluar?**"
- **abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, suicidal thoughts or actions.
- **memory loss**
- **anxiety**
- **severe allergic reactions.:** Symptoms include swelling of the tongue or throat, trouble breathing. Get emergency medical help if you get these symptoms after taking Edluar.

Call your healthcare provider right away if you have any of the above side effects or any other side effects that worry you while using Edluar.

The most common side effects of Edluar are:

- drowsiness
- dizziness
- diarrhea
- grogginess or feeling as if you have been drugged
- fatigue
- headache

You may still feel drowsy the next day after taking Edluar.

After you stop taking a sleep medicine, you may have symptoms for 1 to 2 days such as:

- trouble sleeping
- nausea
- flushing
- lightheadedness
- uncontrolled crying
- vomiting
- stomach cramps
- panic attack
- nervousness
- stomach area pain

These are not all the side effects of Edluar. Ask your doctor or pharmacist for more information.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Edluar?

- Store Edluar at room temperature, between 68°F and 77°F (20° to 25°C).
- Protect from light and moisture.

Keep Edluar and all medicines out of reach of children.

General information about the safe and effective use of Edluar

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Edluar for a condition for which it was not prescribed. Do not share Edluar with other people, even if you think they have the same symptoms that you have. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about Edluar.

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Edluar that is written for healthcare professionals.

For more information about Edluar, go to www.meda.us or call Meda Pharmaceuticals Inc. at 1-800-526-3840.

What are the ingredients in Edluar?

Active Ingredient: zolpidem tartrate

Inactive Ingredients: mannitol, colloidal silicon dioxide, silicified microcrystalline cellulose, croscarmellose sodium, saccharin sodium, and magnesium stearate.

This Medication Guide has been approved by U.S. Food and Drug Administration.

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