

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

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

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

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 doctor right away if you find out that you have done any of the above activities after taking Edluar.

Important
Take Edluar exactly as prescribed

- Do not take more Edluar than prescribed.
- Take Edluar right before you get in bed, not sooner.

Do not take Edluar if you:

- drink alcohol
- take other medicines that can make you sleepy. Talk to your doctor about all of your medicines. Your doctor will tell you if you can take Edluar with your other medicines.
- cannot get a full night's 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. A symptom of insomnia includes:

- trouble falling asleep

Edluar is not for children.

Edluar is a federally controlled substance (C-IV) 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 have had an allergic reaction to zolpidem (Ambien, Ambien CR, Zolpimist, Edluar).

Some signs of allergic reaction may be swelling of the face, a feeling of the throat closing, or difficulty breathing shortly after taking Zolpidem.

Do not take Edluar if you are allergic to anything in it.

See the end of this Medication Guide for a complete list of ingredients in Edluar.

Edluar may not be right for you. Before starting Edluar, tell your doctor 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, planning to become pregnant, or breastfeeding

Tell your doctor 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.

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

How should I take Edluar?

- Take Edluar exactly as prescribed. Do not take more Edluar than prescribed for you.
- **Take Edluar right before you get into bed.**
- **Do not take Edluar unless you are able to stay in bed a full night (7-8 hours) before you must be active again.**
- For faster sleep onset, Edluar should NOT be taken with or right after a meal.
- 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 doctor 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, call your doctor or poison control center right away, or get emergency treatment.

What are the possible side effects of Edluar?

Serious side effects of Edluar include:

- **getting out of bed while not being fully awake and do 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, and nausea and vomiting. Get emergency medical help if you get these symptoms after taking Edluar.

Call your doctor 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
- "drugged feelings"
- fatigue
- headache

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

Do not drive or do any dangerous activities after taking Edluar until you feel fully awake.

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, and stomach area pain

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

Call your doctor 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 between 68° 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 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 doctor. You can ask your doctor or pharmacist for information about Edluar that is written for healthcare professionals.

For more information about Edluar, call DJA Global Pharma at 1-610-558-4454
[www.orexo.com]

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.

Rx Only

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

Orexo AB, Sweden
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