

MEDICATION GUIDE

Zolpidem Tartrate (zole-PI-dem TAR-trate) Extended-Release Tablets USP, 6.25 mg and 12.5 mg CIV

Rx only

Read the Medication Guide that comes with zolpidem tartrate extended-release tablets 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 zolpidem tartrate extended-release tablets?

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

Zolpidem tartrate extended-release tablets may cause serious side effects including complex sleep behaviors that have caused serious injury and death. After taking zolpidem tartrate extended-release tablets, you may get up out of bed while not being fully awake and do an activity that you do not know you are doing (complex sleep behaviors). The next morning, you may not remember that you did anything during the night. These activities may occur with zolpidem tartrate extended-release tablets whether or not you drink alcohol or take other medicines that make you sleepy. Reported activities include:

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

Stop taking zolpidem tartrate extended-release tablets and call your healthcare provider right away if you find out that you have done any of the above activities after taking zolpidem tartrate extended-release tablets.

You should not drive a car or do things that require clear thinking the day after you take zolpidem tartrate extended-release tablets.

Do not take zolpidem tartrate extended-release tablets if you:

- have ever experienced complex sleep behavior (such as driving a car, making and eating food, talking on the phone call or having sex while not being fully awake) after taking zolpidem tartrate extended-release tablets.
- drank alcohol that evening or before bed.
- take other medicines that can make you sleepy. Taking zolpidem tartrate extended-release tablets with other drugs can cause side effects. Talk to your healthcare provider about all of

your medicines. Your healthcare provider will tell you if you can take zolpidem tartrate extended-release tablets with your other medicines.

- cannot get a full night's sleep.

What is zolpidem tartrate extended-release tablet?

Zolpidem tartrate extended-release tablet is a sedative-hypnotic (sleep) medicine. Zolpidem tartrate extended-release tablets are used in adults for the treatment of a sleep problem called insomnia. Symptoms of insomnia include:

- trouble falling asleep
- waking up often during the night

Zolpidem tartrate extended-release tablets are not recommended for use in children under the age of 18 years.

Zolpidem tartrate extended-release tablets are federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep zolpidem tartrate extended-release tablets in a safe place to prevent misuse and abuse. Selling or giving away zolpidem tartrate extended-release tablets may harm others, and is against the law. Tell your healthcare provider if you have ever abused or have been dependent on alcohol, prescription medicines or street drugs.

Who should not take zolpidem tartrate extended-release tablets?

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

What should I tell my healthcare provider before taking zolpidem tartrate extended-release tablets?

Zolpidem tartrate extended-release tablets may not be right for you. Before starting zolpidem tartrate extended-release tablets, 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 a lung disease or breathing problems
- are pregnant, planning to become pregnant. Talk to your healthcare provider about the risk to your unborn baby if you take zolpidem tartrate extended-release tablets. Using zolpidem tartrate extended-release tablets in the last trimester of pregnancy may cause breathing difficulties or excess sleepiness in your newborn. Monitor for signs of sleepiness (more than usual), trouble breathing, or limpness in the newborn if zolpidem tartrate extended-release tablets are taken late in pregnancy.
- are breastfeeding or plan to breastfeed. Zolpidem tartrate passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while you take zolpidem

tartrate extended-release tablets.

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 zolpidem tartrate extended-release tablets with other medicines that can make you sleepy unless your healthcare provider tells you to.**

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 zolpidem tartrate extended-release tablets?

- See **“What is the most important information I should know about zolpidem tartrate extended-release tablets?”**
- Take zolpidem tartrate extended-release tablets exactly as prescribed. Only take 1 zolpidem tartrate extended-release tablet a night if needed.
- Do not take zolpidem tartrate extended-release tablets if you drank alcohol that evening or before bed.
- You should not take zolpidem tartrate extended-release tablets with or right after a meal. Zolpidem tartrate extended-release tablets may help you fall asleep faster if you take it on an empty stomach.
- Take zolpidem tartrate extended-release tablets whole. Do not break, crush, dissolve or chew zolpidem tartrate extended-release tablets before swallowing. If you cannot swallow zolpidem tartrate extended-release tablets whole, tell your healthcare provider. You may need a different medicine.
- 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 problems.
- If you take too much zolpidem tartrate extended-release tablets or overdose, get emergency treatment.

What are the possible side effects of zolpidem tartrate extended-release tablets?

Zolpidem tartrate extended-release tablets 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 zolpidem tartrate extended-release tablets?”**)
 - **abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, acting strangely, agitation, hallucinations, worsening of depression, and 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 zolpidem tartrate extended-release tablets.

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 zolpidem tartrate extended-release tablets.

The most common side effects of zolpidem tartrate extended-release tablets are:

- headache
- sleepiness
- dizziness
- drowsiness the next day after you take zolpidem tartrate extended-release tablets

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 zolpidem tartrate extended-release tablets. Ask your healthcare provider 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 zolpidem tartrate extended-release tablets?

Store zolpidem tartrate extended-release tablets at room temperature, 59°F to 77°F (15°C to 25°C).

Keep zolpidem tartrate extended-release tablets and all medicines out of reach of children.

General Information about the safe and effective use of zolpidem tartrate extended-release tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use zolpidem tartrate extended-release tablets for a condition for which it was not prescribed. Do not share zolpidem tartrate extended-release tablets with other people, even if 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 zolpidem tartrate extended-release tablets. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about zolpidem tartrate extended-release tablets that is written for healthcare professionals.

For more information, go to www.lupinpharmaceuticals.com or call 1-800-399-2561.

What are the ingredients in zolpidem tartrate extended-release tablets?

Active Ingredient: Zolpidem tartrate

Inactive Ingredients:

The 6.25 mg zolpidem tartrate extended-release tablets contain the following inactive ingredients: colloidal silicon dioxide, FD&C Blue # 2 aluminium lake, hypromellose, iron oxide red, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, potassium bitartrate, sodium starch glycolate and titanium dioxide.

The 12.5 mg zolpidem tartrate extended-release tablets contain the following inactive ingredients: colloidal silicon dioxide, FD&C Blue # 2 aluminium lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, potassium bitartrate, sodium starch glycolate and titanium dioxide.

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