

Medication Guide

Zolpidem Tartrate Tablets, USP

(zole pi' dem tar' trate)



Read the Medication Guide that comes with zolpidem tartrate 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 tablets?

- Do not take more zolpidem tartrate tablets than prescribed.
- Do not take zolpidem tartrate 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 tablets right before you get in bed, not sooner.

Zolpidem tartrate tablets may cause serious side effects, including:

- After taking zolpidem tartrate 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. 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 zolpidem tartrate tablets. 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 zolpidem tartrate tablets.

Do not take zolpidem tartrate tablets if you:

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

What are zolpidem tartrate tablets?

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

It is not known if zolpidem tartrate tablets are safe and effective

in children under the age of 18 years.

Zolpidem tartrate is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep zolpidem tartrate tablets in a safe place to prevent misuse and abuse. Selling or giving away zolpidem tartrate 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 tablets?

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

Zolpidem tartrate tablets may not be right for you. Before starting zolpidem tartrate 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. It is not known if zolpidem tartrate tablets will harm your unborn baby.
- are breast-feeding or plan to breast-feed. Zolpidem tartrate can pass into your breast milk. It is not known if zolpidem tartrate tablets will harm your baby. Talk to your healthcare provider about the best way to feed your baby while you take zolpidem tartrate 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 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 tablets?

- See “**What is the most important information I should know about zolpidem tartrate tablets?**”
- Take zolpidem tartrate tablets exactly as prescribed. Only take one zolpidem tartrate tablet a night if needed.
- Do not take zolpidem tartrate tablets if you drank alcohol that evening or before bed.
- You should not take zolpidem tartrate tablets with or right after a meal. Zolpidem tartrate tablets may help you fall asleep faster if you take it on an empty stomach.
- 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 many zolpidem tartrate tablets or overdose, get emergency treatment.

What are the possible side effects of zolpidem tartrate tablets?

Zolpidem tartrate tablets may cause serious side effects, including:

- **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 zolpidem tartrate tablets?**”
- **abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts or actions.
- **memory loss**
- **anxiety**
- **severe allergic reactions.** Symptoms include swelling of the tongue or throat, and trouble breathing. Get emergency medical help if you get these symptoms after taking zolpidem tartrate tablets.
- **falls, which may lead to severe injuries**

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 tablets.

The most common side effects of zolpidem tartrate tablets are:

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

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 tablets. Ask your healthcare provider 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 zolpidem tartrate tablets?

- Store zolpidem tartrate tablets at room temperature 20° to 25°C (68° to 77°F).

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

General information about the safe and effective use of zolpidem tartrate tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use zolpidem tartrate tablets for a condition for which it was not prescribed. Do not share zolpidem tartrate 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 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 tablets that is written for healthcare professionals. For more information, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

What are the ingredients in zolpidem tartrate tablets?

Active Ingredient: Zolpidem tartrate

Inactive Ingredients: anhydrous lactose, crospovidone, D&C Red No. 30 Aluminum Lake, dibasic calcium phosphate (anhydrous), FD&C Blue No. 2 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, sodium lauryl sulfate, titanium dioxide and triacetin.

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

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Revised: 8/2016
MG:ZOLP:R6mh



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