

MEDICATION GUIDE

Zolpidem Tartrate (ZOL-pi-dem TAR-trate or zole-PI-dem TAR-trate) Sublingual Tablet CIV

Phenylketonurics

Phenylalanine is a component of aspartame. Each 3.5 mg and 1.75 mg Zolpidem Tartrate Sublingual Tablets contains 4.48 mg and 2.24 mg of phenylalanine.

Read the Medication Guide that comes with Zolpidem Tartrate Sublingual 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 doctor about your medical condition or treatment.

What is the most important information I should know about Zolpidem Tartrate Sublingual Tablet?

Follow the Instructions for Use at the end of this Medication Guide when you take Zolpidem Tartrate Sublingual Tablet. If you do not follow the Instructions for Use, you might be drowsy in the morning without knowing it.

- **Only take one Tablet a night, if needed.**
- **Only take Zolpidem Tartrate Sublingual Tablet if you have at least 4 hours of bedtime left.**

Zolpidem Tartrate Sublingual Tablet may cause serious side effects, including:

- **After taking Zolpidem Tartrate Sublingual Tablet, 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 drank alcohol that day or take other medicines that make you sleepy with Zolpidem Tartrate Sublingual Tablet. 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 Sublingual Tablet.

Important:

1. **Take Zolpidem Tartrate Sublingual Tablet exactly as prescribed**
2. **Do not take Zolpidem Tartrate Sublingual Tablet if you:**
 - drank alcohol that day or before bed.
 - took another medicine to help you sleep.
 - do not have at least 4 hours of bedtime remaining.

What is Zolpidem Tartrate Sublingual Tablet?

Zolpidem Tartrate Sublingual Tablet is a sedative-hypnotic (sleep) medicine. Zolpidem Tartrate Sublingual Tablet is used in adults for the treatment of a sleep problem called insomnia. Many people have difficulty returning to sleep after awakening in the middle of the night. Zolpidem Tartrate Sublingual Tablet is designed to specifically treat this problem.

It is not known if Zolpidem Tartrate Sublingual Tablet is safe and effective in children.

Zolpidem Tartrate Sublingual Tablet is a federally controlled substance (CIV) because it can be abused or lead to dependence. Keep Zolpidem Tartrate Sublingual Tablet in a safe place to prevent misuse and abuse. Selling or giving away Zolpidem Tartrate Sublingual Tablet may harm others, and is against the law. Tell your doctor if you have ever abused or have been dependent on alcohol, prescription medicines, or street drugs.

Who should not take Zolpidem Tartrate Sublingual Tablet?

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

Symptoms of a serious allergic reaction to Zolpidem Tartrate Sublingual Tablet can include:

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

Zolpidem Tartrate Sublingual Tablet may not be right for you. Before starting Zolpidem Tartrate Sublingual Tablet, 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 a 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. Your doctor will tell you if you can take Zolpidem Tartrate Sublingual Tablet with your other medicines.

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 Zolpidem Tartrate Sublingual Tablet?

- See "**What is the most important information I should know about Zolpidem Tartrate Sublingual Tablet**"
- Read the "**Instructions for Use**" at the end of this Medication Guide for detailed instructions on how to take Zolpidem Tartrate Sublingual Tablet.
- Take Zolpidem Tartrate Sublingual Tablet exactly as prescribed. Only take one Zolpidem Tartrate Sublingual Tablet per night if needed.
- Do not take Zolpidem Tartrate Sublingual Tablet if you drank alcohol that evening or before bed.
- While in bed, place the tablet under your tongue and allow it to break apart completely. Do not swallow it whole.
- You should not take Zolpidem Tartrate Sublingual Tablet with or right after a meal. Zolpidem Tartrate Sublingual Tablet may help you fall asleep faster when you take it on an empty stomach.
- Call your health care 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 Zolpidem Tartrate Sublingual Tablet or overdose get emergency treatment.

What are the possible side effects of Zolpidem Tartrate Sublingual Tablet?

Zolpidem Tartrate Sublingual Tablet 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 Sublingual Tablet?")
- **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, trouble breathing, and nausea and vomiting. Get emergency medical help if you get these symptoms after taking Zolpidem Tartrate Sublingual Tablet.

Call your health care provider right away if you have any of the above side effects or any other side effects that worry you while using Zolpidem Tartrate Sublingual Tablet.

The most common side effects of Zolpidem Tartrate Sublingual Tablet are:

- Headache
- Nausea
- Fatigue

Even if you follow the Instructions for Use, you may still feel drowsy in the morning after taking Zolpidem Tartrate Sublingual Tablet. Do not drive or do other dangerous activities after taking Zolpidem Tartrate Sublingual Tablet until you are fully awake.

These are not all the side effects of Zolpidem Tartrate Sublingual Tablet. Ask your health care provider or pharmacist for more information.

You may report side effects to FDA at 1-800-FDA-1088.

How should I store Zolpidem Tartrate Sublingual Tablet?

- Store Zolpidem Tartrate Sublingual Tablet at room temperature, 68° to 77°F (20° to 25°C). Protect from moisture.
- Only remove the blister from the pouch when you are ready to use Zolpidem Tartrate Sublingual Tablet.

Keep Zolpidem Tartrate Sublingual Tablet and all medicines out of reach of children.

General Information about Zolpidem Tartrate Sublingual Tablet

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Zolpidem Tartrate Sublingual Tablet for a condition for which it was not prescribed. Do not give Zolpidem Tartrate Sublingual Tablet to 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 Zolpidem Tartrate Sublingual Tablet. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Zolpidem Tartrate Sublingual Tablet that is written for healthcare professionals.

What are the ingredients in Zolpidem Tartrate Sublingual Tablet?

Active Ingredient: Zolpidem tartrate

Inactive Ingredients: Each Zolpidem Tartrate Sublingual Tablet includes the following inactive ingredients: Crospovidone, Povidone, Mannitol, Polyvinylacetate, colloidal silicon dioxide, sodium carbonate anhydrous, sodium bicarbonate, natural and artificial spearmint flavor, aspartame, and magnesium stearate.

Rx only

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

Manufactured by:

Novel Laboratories, Inc.

Somerset, NJ 08873

Manufactured for:

Lupin Pharmaceuticals, Inc. Baltimore, MD 21202

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Instructions for Use

Zolpidem Tartrate (ZOL-pi-dem TAR-trate or zole-PI-dem TAR-trate) Sublingual Tablet CIV

Read these Instructions for Use before you start taking Zolpidem Tartrate Sublingual Tablet and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about Zolpidem Tartrate Sublingual Tablet?

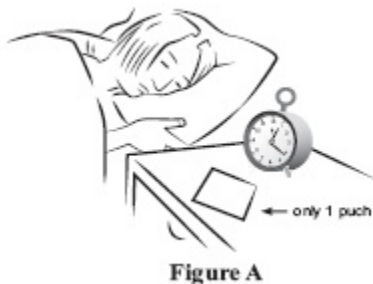
Follow these Instructions for Use when you take Zolpidem Tartrate Sublingual Tablet. If you do not follow these instructions, you might be drowsy in the morning without knowing it.

- Only take 1 tablet a night if needed
- Only take Zolpidem Tartrate Sublingual Tablet if you have at least 4 hours of bedtime left

Using Zolpidem Tartrate Sublingual Tablet the wrong way can make you drowsy in the morning.

Before you go to bed:

- Place only 1 Zolpidem Tartrate Sublingual Tablet pouch by your bed, and have a clock or watch nearby (see Figure A).



- Store all other Zolpidem Tartrate Sublingual Tablet pouches with your other medicines away from your bedside.
- Only remove the blister from the Zolpidem Tartrate Sublingual Tablet pouch when you are ready to use it.
- You can either use the **Zolpidem Tartrate Sublingual Tablet Dosing Time Chart** (see Figure B) or the **Dosing Time Tool** (see Figure C) that comes with Zolpidem Tartrate Sublingual Tablet to find the latest time during the night you can take Zolpidem Tartrate Sublingual Tablet.

Zolpidem Tartrate Sublingual Tablet Dosing Time Chart (see Figure B):

- You can take Zolpidem Tartrate Sublingual Tablet if you have at least 4 hours of bedtime left before you must be awake.
- Find the earliest time you have to be up and awake in the column on the left.

- Find the latest time you can take Zolpidem Tartrate Sublingual Tablet on the same line in the column on the right.

If you must be awake by:	Take Zolpidem Tartrate Sublingual Tablets before:
4 am	12 midnight
5 am	1 am
6 am	2 am
7 am	3 am
8 am	4 am
9 am	5 am

Figure B

Zolpidem Tartrate Sublingual Tablet Dosing Time Tool (see Figure C):

- Turn the Zolpidem Tartrate Sublingual Tablet Dosing Time Tool wheel to show the earliest time that you must be awake under the green arrow.
- Take Zolpidem Tartrate Sublingual Tablet before the time under the black arrow.

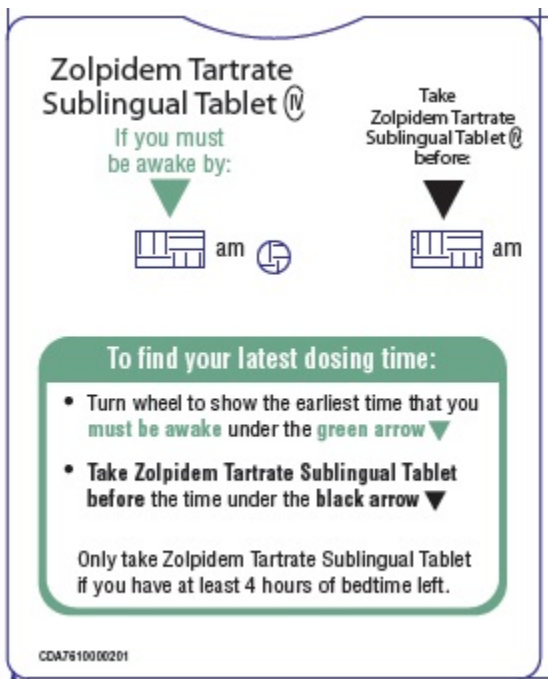


Figure C

During the night when you take Zolpidem Tartrate Sublingual Tablet:

Step 1. Check the current time and use the Zolpidem Tartrate Sublingual Tablet Dosing Time Chart or the Zolpidem Tartrate Sublingual Tablet Dosing Time Tool to decide if you should take Zolpidem Tartrate Sublingual Tablet.

- Only take Zolpidem Tartrate Sublingual Tablet if you have at least 4 hours of bedtime left before you have to be awake (see Figure B).

Step 2. Remove the blister from the Zolpidem Tartrate Sublingual Tablet pouch you placed by your bed (see Figure D).

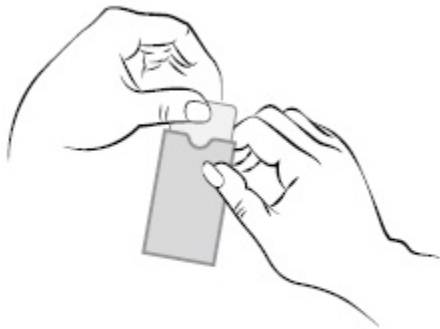


Figure D

Step 3. Cut blister with scissors at dotted line and take the Zolpidem Tartrate Sublingual Tablet out. (see Figure E).



Figure E

Step 4. Leave the empty Zolpidem Tartrate Sublingual Tablet pouch where you can see it. The empty pouch will help remind you that you already took your Zolpidem Tartrate Sublingual Tablet dose (see Figure F).

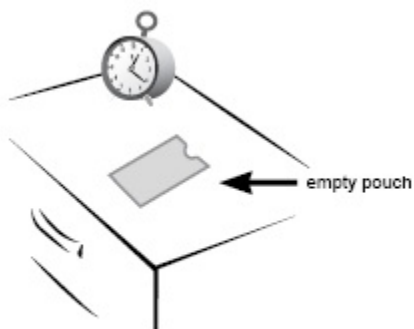


Figure F

Step 5. While in bed, place the Zolpidem Tartrate Sublingual Tablet under your tongue and allow it to break apart completely, then swallow. Do not swallow it whole. (see Figure G)



Figure G

Step 6. Throw the empty Zolpidem Tartrate Sublingual Tablet pouch away in the morning.

When you wake up in the morning, be sure that at least 4 hours have passed since you have taken Zolpidem Tartrate Sublingual Tablet and you feel fully awake before driving. Do not do dangerous activities until you know how Zolpidem Tartrate Sublingual Tablet affects you.

This Medication Guide and Instructions for Use have been approved by the U.S. Food and Drug Administration.

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