

## MEDICATION GUIDE

### Zolpidem Tartrate Sublingual Tablets CIV

#### (ZÒL-PÍ-DUM TAR-TRA-ATE)

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 tablets?**

**Follow the Instructions for Use at the end of this Medication Guide when you take zolpidem tartrate sublingual tablets. 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 tablets if you have at least 4 hours of bedtime left.**

**Zolpidem tartrate sublingual tablets may cause serious side effects, including:**

- **Complex sleep behaviors that have caused serious injury and death.** After taking zolpidem tartrate sublingual 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 sublingual 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 sublingual 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 sublingual tablets.**

**Important:**

- 1. Take zolpidem tartrate sublingual tablets exactly as prescribed**
- 2. Do not take zolpidem tartrate sublingual tablets if you:**
  - have ever experienced a complex sleep behavior (such as driving a car, making and eating food, talking on the phone or having sex while not fully awake) after taking zolpidem tartrate sublingual tablets.
  - 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 are zolpidem tartrate sublingual tablets?**

Zolpidem tartrate sublingual tablets are a sedative-hypnotic (sleep) medicine. Zolpidem tartrate sublingual tablets are 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 tablets are designed to specifically treat this problem.

It is not known if zolpidem tartrate sublingual tablets are safe and effective in children.

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

- Do not take zolpidem tartrate sublingual tablets if you have ever had a complex sleep behavior happen after taking zolpidem tartrate sublingual tablets.
- Do not take zolpidem tartrate sublingual tablets if you are allergic to zolpidem or any other ingredients in zolpidem tartrate sublingual tablets. See the end of this Medication Guide for a complete list of ingredients in zolpidem tartrate sublingual tablets.
- Do not take zolpidem tartrate sublingual tablets 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 tablets can include:**

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

**Zolpidem tartrate sublingual tablets may not be right for you. Before starting zolpidem tartrate sublingual tablets, 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 tablets 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 tablets?**

- See **“What is the most important information I should know about zolpidem tartrate sublingual tablets”**
- Read the **“Instructions for Use”** at the end of this Medication Guide for detailed instructions on how to take zolpidem tartrate sublingual tablets.
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- Do not take zolpidem tartrate sublingual tablets 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 tablets with or right after a meal. Zolpidem tartrate sublingual tablets 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 tablets or overdose, get emergency treatment.

**What are the possible side effects of zolpidem tartrate sublingual tablets?**

Zolpidem tartrate sublingual 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 sublingual 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, trouble breathing, and nausea and vomiting. Get emergency medical help if you get these symptoms after taking zolpidem tartrate sublingual tablets.

**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 tablets.**

**The most common side effects of zolpidem tartrate sublingual tablets 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 tablets. Do not drive or do other dangerous activities after taking zolpidem tartrate sublingual tablets until you are fully awake.

These are not all the side effects of zolpidem tartrate sublingual tablets. 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 tablets?**

- Store zolpidem tartrate sublingual tablets at room temperature, 68° to 77°F (20° to 25°C). Protect from moisture.
- Only open the pouch when you are ready to use zolpidem tartrate sublingual tablets.

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

**General Information about zolpidem tartrate sublingual tablets**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use zolpidem tartrate sublingual tablets for a condition for which it was not prescribed. Do not give zolpidem tartrate sublingual tablets 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 tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about zolpidem tartrate sublingual tablets that is written for healthcare professionals. For more information about zolpidem tartrate sublingual tablets, call Par Pharmaceutical at 1-800-828-9393 or visit www.parpharm.com

**What are the ingredients in zolpidem tartrate sublingual tablets?**

**Active Ingredient:** Zolpidem tartrate

**Inactive Ingredients:** Each zolpidem tartrate sublingual tablets include the following inactive ingredients: colloidal silicon dioxide, crospovidone, magnesium stearate, pregelatinized starch, mannitol, peppermint flavor, saccharin sodium, corn starch.

**Rx only**

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Revised: 10/2019

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**INSTRUCTIONS FOR USE**  
**Zolpidem Tartrate Sublingual Tablets CIV**  
**(ZÒL-PÌ-DUM TAR-TRA-ATE)**

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**What is the most important information I should know about zolpidem tartrate sublingual tablets?**

Follow these Instructions for Use when you take zolpidem tartrate sublingual tablets. 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 tablets if you have at least 4 hours of bedtime left

**Using zolpidem tartrate sublingual tablets the wrong way can make you drowsy in the morning.**

**Before you go to bed:**

- Place only 1 zolpidem tartrate sublingual tablets pouch by your bed, and have a clock or watch nearby (see Figure A).



Figure A

- Store all other unopened zolpidem tartrate sublingual tablets pouches with your other medicines away from your bedside.
- Only open the zolpidem tartrate sublingual tablets pouch when you are ready to use it.
- You can either use the **zolpidem tartrate sublingual tablets Dosing Time Chart** (see Figure B) or the **Dosing Time Tool** (see Figure C) that comes with zolpidem tartrate sublingual tablets to find the latest time during the night you can take zolpidem tartrate sublingual tablets.

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

- You can take zolpidem tartrate sublingual tablets 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 tablets on the same line in the column on the right.

**Zolpidem Tartrate Sublingual Tablets Dosing Time Chart**

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 Tablets Dosing Time Tool (see Figure C):**

- Turn the zolpidem tartrate sublingual tablets Dosing Time Tool wheel to show the earliest time that you must be awake under the green arrow.
- Take zolpidem tartrate sublingual tablets before the time under the brown arrow.



Figure C

**During the night when you take zolpidem tartrate sublingual tablets:**

- Step 1.** Check the current time and use the zolpidem tartrate sublingual tablets Dosing Time Chart or the zolpidem tartrate sublingual tablets Dosing Time Tool to decide if you should take zolpidem tartrate sublingual tablets.

- Only take zolpidem tartrate sublingual tablets if you have at least 4 hours of bedtime left before you have to be awake (see Figure B).

- Step 2.** Open the zolpidem tartrate sublingual tablets pouch you placed by your bed.

- Fold the zolpidem tartrate sublingual tablets pouch along the dotted line. While the zolpidem tartrate sublingual tablets pouch are folded, tear the pouch open at the notch at the center of the dotted line (see Figure D).

**TO OPEN POUCH**  
**STEP ①:** Fold along dotted line.  
**STEP ②:** While folded, tear open at notch located at center of dotted line.

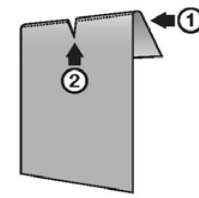


Figure D

- Step 3.** Remove the foil blister from the zolpidem tartrate sublingual tablet pouch. Push the zolpidem tartrate sublingual tablet through the foil (see Figure E).



Figure E

- Step 4.** Leave the empty zolpidem tartrate sublingual tablets pouch where you can see it. The empty pouch will help remind you that you already took your zolpidem tartrate sublingual tablets dose (see Figure F).

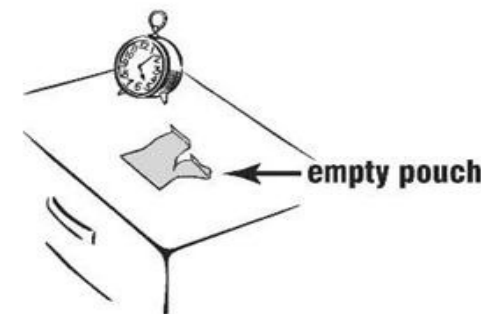


Figure F

- Step 5.** While in bed, place the zolpidem tartrate sublingual tablets 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 tablets 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 tablets and you feel fully awake before driving. Do not do dangerous activities until you know how zolpidem tartrate sublingual tablets affects you.

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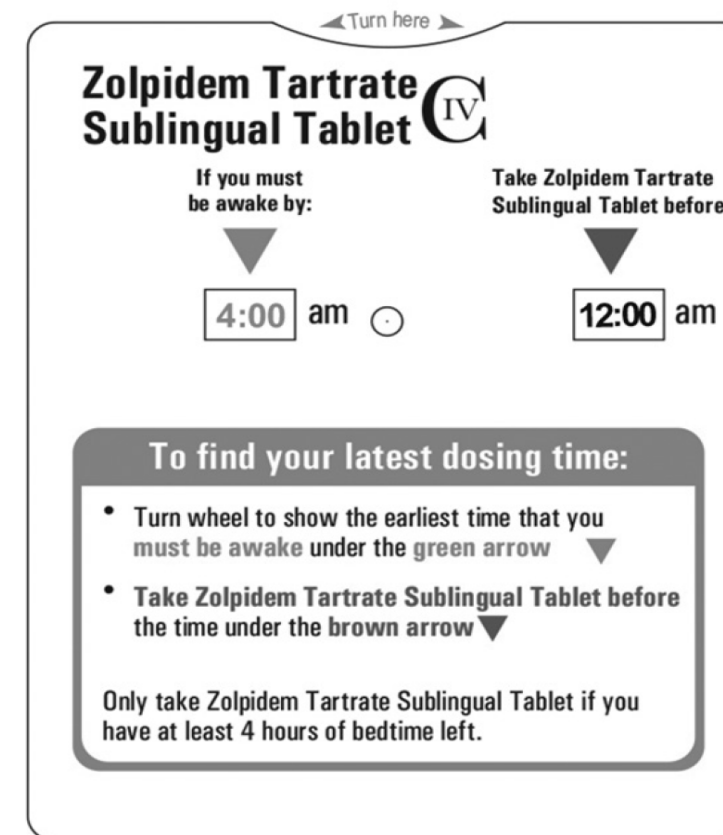


Figure C

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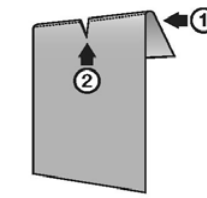


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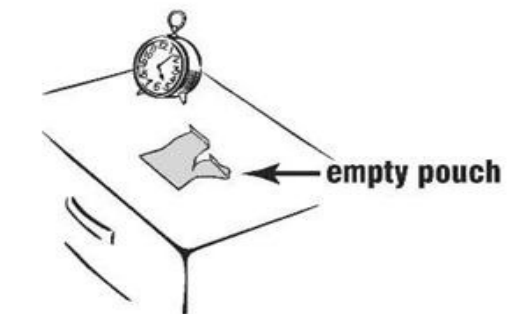


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