



Dispense with Medication Guide available at:
<https://torrentpharma.com/pi/usa/products/>

MEDICATION GUIDE
Zolpidem Tartrate (zole-PI-dem TAR-trate)
Tablets USP, for oral use C-IV

What is the most important information I should know about zolpidem tartrate tablets? Zolpidem tartrate tablets may cause serious side effects, including:

- **Complex sleep behaviors.** 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. These activities may happen with zolpidem tartrate tablets whether or not you drink alcohol or take other medicines that make you sleepy. Some of these complex sleep behaviors have caused serious injury and death. People taking zolpidem tartrate tablets have reported:
 - o sleep-walking
 - o sleep-driving
 - o making and eating food
 - o talking on the phone
 - o having sex

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

What are zolpidem tartrate tablets?

Zolpidem tartrate tablets is a prescription sleep medicine used for the short-term treatment of adults who have trouble falling asleep (insomnia).

- It is not known if zolpidem tartrate tablets is safe and effective in children under the age of 18 years. Zolpidem tartrate tablets is not recommended for use in children under the age of 18 years.
- **Zolpidem tartrate tablets are a federally controlled substance (C-IV) because it can be abused or lead to dependence.** Keep zolpidem tartrate tablets in a safe place to protect it from theft. Never give your zolpidem tartrate tablets to anyone else because it may cause death or harm them. Selling or giving away this medicine is against the law.

Do not take zolpidem tartrate tablets if you:

- have had complex sleep behaviors that happened after taking zolpidem tartrate tablets in the past. See “What is the most important information I should know about zolpidem tartrate tablets?”
- are allergic to zolpidem or any of the ingredients in zolpidem tartrate tablets. See the end of this Medication Guide for a complete list of ingredients in zolpidem tartrate tablets.

Before taking zolpidem tartrate tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of depression, mental illness, or suicidal thoughts or actions
- have a history of drug or alcohol abuse or addiction
- have kidney or liver disease
- have a lung disease or breathing problems
- have sleep apnea
- have myasthenia gravis
- are pregnant or plan to become pregnant. Taking zolpidem tartrate tablets in the third trimester of pregnancy may harm your unborn baby.
 - o Tell your healthcare provider if you become pregnant or plan to become pregnant during treatment with zolpidem tartrate tablets.
 - o Babies born to mothers who take zolpidem tartrate tablets during the third trimester of pregnancy may have symptoms of breathing problems and sedation (such as sleepiness or low muscle tone)
- are breastfeeding or plan to breastfeed. Zolpidem tartrate passes into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with zolpidem tartrate tablets.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Zolpidem tartrate tablets and other medicines can interact with each other causing serious side effects. Zolpidem tartrate tablets may affect the way other medicines work, and other medicines may affect how zolpidem tartrate tablets works.

Especially tell your healthcare provider if you:

- take benzodiazepines
- take opioids as it may increase the risk of breathing problems (respiratory depression)
- take tricyclic antidepressants
- take other medicines that can make you sleepy or affect your breathing (including other zolpidem medicines)
- drink alcohol

You can ask your pharmacist for a list of medicines that interact with zolpidem tartrate tablets. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take zolpidem tartrate tablets?

- **Take zolpidem tartrate tablets exactly as prescribed.** Do not change your dose on your own. Tell your healthcare provider if you think zolpidem tartrate tablets is not working for you.
- **Zolpidem tartrate tablets is for short-term use only.** Treatment with zolpidem tartrate tablets should be as short as possible because the risk of dependence increases the longer you are being treated.
- Take **1** zolpidem tartrate tablet at night right before bedtime.
- **Do not take zolpidem tartrate tablets if you are not able to stay in bed a full night (7 to 8 hours) before you must be active again.**
- You should not take zolpidem tartrate tablets with or right after a meal. Zolpidem tartrate

tablet may help you fall asleep faster if you take it on an empty stomach.

- **Do not take zolpidem tartrate tablets** if you drank alcohol that evening or before bed.
- Call your healthcare provider if your sleep problems get worse or do not get 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 tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of zolpidem tartrate tablets?

Zolpidem tartrate tablets may cause serious side effects, including:

See “What is the most important information I should know about zolpidem tartrate tablets?”

Zolpidem tartrate tablets can make you sleepy or dizzy and can slow your thinking and motor skills. Because zolpidem tartrate tablets can make you sleepy or dizzy you are at a higher risk for falls.

- o Do not drive, operate heavy machinery, or do other dangerous activities until you know how zolpidem tartrate tablets affects you.
- o Do not drink alcohol or take opioids or other medicines that may make you sleepy or dizzy while taking zolpidem tartrate tablets without first talking to your healthcare provider. When taken with alcohol or other medicines that cause sleepiness or dizziness, zolpidem tartrate tablets may make your sleepiness or dizziness much worse.

- **Severe allergic reactions.** Symptoms include swelling of the tongue or throat, trouble breathing, and nausea and vomiting. Get emergency medical help right away if you develop any of these symptoms during treatment with zolpidem tartrate tablets.

- **Abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion (delirium), acting strangely, agitation, hallucinations, worsening of depression, and suicidal thoughts or actions.

- **Risk of suicide and worsening of depression.**

Worsening of depression, including suicidal thoughts and actions can happen during treatment with medicines like zolpidem tartrate tablets. Call your healthcare provider right away if you develop any thoughts of suicide, dying, or worsening depression during treatment with zolpidem tartrate tablets.

- **Breathing problems.** See “Before taking zolpidem tartrate tablets, tell your healthcare provider about all of your medical conditions, including if you:” Call your healthcare provider or get emergency medical help right away if you develop breathing problems during treatment with zolpidem tartrate tablets.

- **Problems with your nervous system caused by severe liver disease (hepatic encephalopathy).**

- **Withdrawal symptoms.** You may have withdrawal symptoms if you stop taking zolpidem tartrate tablets suddenly. Withdrawal symptoms can be serious and include stomach and muscle cramps, vomiting, sweating, shakiness, seizures, and confusion (delirium). Talk to your healthcare provider about slowly stopping zolpidem tartrate tablets to avoid withdrawal symptoms.

The most common side effects of zolpidem tartrate tablets include sleepiness, dizziness, diarrhea, and grogginess or feeling like you have been drugged.

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

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 tablets?

- Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

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

General Information about the safe and effective use of zolpidem tartrate

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 give zolpidem tartrate tablets to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about zolpidem tartrate tablets that is written for healthcare professionals.

What are the ingredients in zolpidem tartrate tablets?

Active Ingredient: Zolpidem tartrate, USP
Inactive Ingredients: hypromellose, lactose monohydrate, microcrystalline cellulose, magnesium stearate, polyethylene glycol, sodium starch glycolate, titanium dioxide and ferric oxide red; the 10 mg tablet also contains ferric oxide yellow.

For more information call 1-800-912-9561.

Trademarks are the property of their respective owners.



Manufactured by:

Torrent Pharmaceuticals LTD., India.

Manufactured for:

Torrent Pharma INC., Basking Ridge, NJ 07920.

8097535

Revised: August 2024

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



PRODUCT NAME	Zolpidem Tartrate Tablets C-IV		COUNTRY : US		LOCATION : -		Supersedes AW No.:		V. No. : 01	
	ITEM / PACK	Medication Guide	NO. OF COLORS: 1	REMARK :	SUBSTRATE :		Name		Date	
DESIGN STYLE	Front/ Back		PANTONE SHADE NOS.:	Activities	Department	Signature	Name		Date	
CODE	8097535		Black	Prepared By	Pkg.Dev		Name		Date	
DIMENSIONS (MM)	150 x 280			Reviewed By	Pkg.Dev		Name		Date	
ART WORK SIZE	S/S			Approved By	Quality		Name		Date	
DATE	06-08-2024		Font size 10 pt				Name		Date	