MEDICATION GUIDE

ZOLPIDEM TARTRATE (zole-PI-dem TAR-trate)
EXTENDED-RELEASE TABLETS,
for oral use, C-IV

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

- **Complex sleep behaviors.** After taking zolpidem tartrate extended-release, 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 extended-release 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 extended-release have reported:
  - sleep-walking
  - sleep-driving
  - making and eating food
  - talking on the phone
  - having sex

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

What is zolpidem tartrate extended-release?
zolpidem tartrate extended-release is a prescription sleep medicine used for the treatment of adults who have trouble falling asleep or staying asleep (insomnia).

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

Do not take zolpidem tartrate extended-release if you:

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

Before taking zolpidem tartrate extended-release, 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 extended-release in the third trimester of pregnancy may harm your unborn baby.
  - Tell your healthcare provider if you become pregnant or plan to become pregnant during treatment with zolpidem tartrate extended-release.
  - Babies born to mothers who take zolpidem tartrate extended-release 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 extended-release 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.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
zolpidem tartrate extended-release and other medicines can interact with each other causing serious side effects. zolpidem tartrate extended-release may affect the way other medicines work, and other medicines may affect how zolpidem tartrate extended-release 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 extended-release.
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 extended-release?

- **Take zolpidem tartrate extended-release exactly as prescribed.** Do not change your dose on your own. Tell your healthcare provider if you think zolpidem tartrate extended-release is not working for you.
- **zolpidem tartrate extended-release is for short-term use only.** Treatment with zolpidem tartrate extended-release should be as short as possible because the risk of dependence increases the longer you are being treated.
- Take **1** zolpidem tartrate extended-release tablet a night right before bedtime.
- **Do not take zolpidem tartrate extended-release 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 extended-release with or right after a meal. zolpidem tartrate extended-release may help you fall asleep faster if you take it on an empty stomach.
- **Do not** take zolpidem tartrate extended-release if you drank alcohol that evening or before bed.
- Swallow zolpidem tartrate extended-release tablets whole. Do not divide, crush, or chew zolpidem tartrate extended-release tablets. 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 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 extended-release, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of zolpidem tartrate extended-release?
zolpidem tartrate extended-release may cause serious side effects including:

- See **"What is the most important information I should know about zolpidem tartrate extended-release?"**
- **zolpidem tartrate extended-release can make you sleepy or dizzy and can slow your thinking and motor skills.** Next-day sleepiness is common, but can be serious. Because zolpidem tartrate extended-release can make you sleepy or dizzy you are at a higher risk for falls.
  - Do not drive, operate heavy machinery, or do other dangerous activities until you know how zolpidem tartrate extended-release affects you.
  - Do not drink alcohol or take opioids or other medicines that may make you sleepy or dizzy while taking zolpidem tartrate extended-release without first talking to your healthcare provider. When taken with alcohol or other medicines that cause sleepiness or dizziness, zolpidem tartrate extended-release 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 if you get these symptoms after taking zolpidem tartrate extended-release.
- **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 extended-release. Call your healthcare provider right away if you develop any thoughts of suicide, dying, or worsening depression during treatment with zolpidem tartrate extended-release.
- **Breathing problems.** See "**Before taking zolpidem tartrate extended-release, 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 extended-release.
- **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 extended-release 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 extended-release to avoid withdrawal symptoms.

The most common side effects of zolpidem tartrate extended-release include headache and dizziness.
These are not all the side effects of zolpidem tartrate extended-release.
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?

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

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

General Information about the safe and effective use of zolpidem tartrate extended-release.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use zolpidem tartrate extended-release for a condition for which it was not prescribed. Do not give zolpidem tartrate extended-release 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 extended-release that is written for healthcare professionals.

What are the ingredients in zolpidem tartrate extended-release?
Active Ingredient: zolpidem tartrate
Inactive Ingredients:
The 6.25 mg tablets contain: colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, potassium bitartrate, red ferric oxide, sodium starch glycolate, and titanium dioxide.
The 12.5 mg tablets contain: colloidal silicon dioxide, FD&C Blue #2, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, potassium bitartrate, sodium starch glycolate, titanium dioxide, and yellow ferric oxide.

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

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