ZOLPIDEM TARTRATE

**INDICATIONS AND USAGE**

Zolpidem tartrate extended-release tablets, a nonbenzodiazepine hypnotic agent, are a Schedule IV controlled substance. Zolpidem tartrate extended-release tablets are indicated for the treatment of insomnia characterized by difficulty with sleep maintenance.

**CONTRAINDICATIONS**

Zolpidem tartrate extended-release tablets are contraindicated in patients with known hypersensitivity to zolpidem or any of the ingredients in the formulation.

**WARNINGS AND PRECAUTIONS**

5.3 Severe Anaphylactic and Anaphylactoid Reactions

There have been reports of serious anaphylactic and anaphylactoid reactions following administration of zolpidem tartrate extended-release tablets. Patients with a history of drug allergies, especially to sedatives or hypnotics, are at increased risk for this type of reaction. Patients should be observed overnight if zolpidem tartrate extended-release tablets are to be used in those with a history of drug allergies.

5.4 Next-Day Psychomotor Impairment

The risk of next-day psychomotor impairment is increased if zolpidem tartrate extended-release tablets is taken with any ethanol-containing beverages, or if zolpidem tartrate extended-release tablets is taken with other CNS depressants. Children born to mothers taking sedative-hypnotic drugs may also be affected by CNS depression, including respiratory depression, hypotension, and hypothermia. Zolpidem tartrate extended-release tablets are not recommended for use in women within 6 weeks of labor and delivery, in the postpartum period, and in women who are breastfeeding.

5.5 Safety and Abuse

5.5.1 Dependence and/or Physical and/or Psychological Dependence

Zolpidem tartrate extended-release tablets are physically and psychologically dependent. Zolpidem tartrate extended-release tablets may be habit forming. Children born to mothers taking sedative-hypnotic drugs may also be affected by CNS depression, including respiratory depression, hypotension, and hypothermia. Zolpidem tartrate extended-release tablets are not recommended for use in women within 6 weeks of labor and delivery, in the postpartum period, and in women who are breastfeeding.

5.5.2 Misuse and Abuse

In 3-week clinical trials in adults and elderly patients (>65 years), 3.5% of patients who received zolpidem tartrate extended-release tablets reported an increase in sleepiness or drowsiness. Tolerance may occur with chronic use.

5.5.3 Substance Use/Use Disorder

**DRUG INTERACTIONS**

Zolpidem is extensively metabolized in the liver by various CYP enzymes as well as by aldehyde dehydrogenase and is rapidly excreted in the urine (60-80%). Zolpidem tartrate extended-release tablets are not recommended for use in women within 6 weeks of labor and delivery, in the postpartum period, and in women who are breastfeeding.

**ADVERSE REACTIONS**

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The following tables enumerate treatment-emergent adverse events and laboratory abnormalities in controlled clinical trials involving zolpidem tartrate extended-release tablets treated patients. The frequency and severity of adverse events were similar in controlled clinical trials of zolpidem tartrate extended-release tablets and placebo.

**INFORMATION FOR PATIENTS**

The patient information leaflet should be provided with every new prescription. The information contained in the patient information leaflet is not intended to replace the information provided by your healthcare provider. It does not take the place of talking to your healthcare provider about your medical condition or treatment.

**REPRESENTATIVE PRESCRIBING INFORMATION**

**PHARMACOTHERAPY**

**Zolpidem Tartrate (brand names) Extended-Release Tablets, USP**

**MEDICATION GUIDE**

Zolpidem Tartrate (brand names) Extended-Release Tablets, USP

Read the Medication Guide before you start taking 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 treatment.

**Zolpidem Tartrate**

Do not take zolpidem tartrate extended-release tablets if*

- you are allergic to zolpidem or any of the ingredients in the formulation.
- you are pregnant or plan to become pregnant.
- you are breastfeeding.

**What is zolpidem tartrate extended-release tablets?**

Zolpidem tartrate extended-release tablets are a nonbenzodiazepine hypnotic (sleep) medicine. Zolpidem tartrate extended-release tablets are used to treat the symptoms of insomnia (difficulty falling asleep). Zolpidem tartrate extended-release tablets are not recommended for use in women within 6 weeks of labor and delivery, in the postpartum period, and in women who are breastfeeding.

**Who should not take zolpidem tartrate extended-release tablets?**

Do not take zolpidem tartrate extended-release tablets if you are allergic to zolpidem or any of the ingredients in the formulation.

**Who should avoid zolpidem tartrate extended-release tablets?**

Zolpidem tartrate extended-release tablets are a Schedule IV controlled substance (CSII) because it can be abused or lead to dependence. Keep zolpidem tartrate extended-release tablets in a safe place to prevent misuse and abuse. Selling or giving away zolpidem tartrate extended-release tablets may result in serious harm or death to a person adding zolpidem tartrate extended-release tablets to a prescription, such as zolpidem tartrate, Edipraz, Zolpidem, or Intezos.

**How should I take zolpidem tartrate extended-release tablets?**

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

**What is the most important information I should know about zolpidem tartrate extended-release tablets?**
Take zolpidem tartrate extended-release tablets exactly as prescribed. Only take 1 zolpidem tartrate extended-release tablet at night. Do not take zolpidem tartrate extended-release tablets if you drink alcohol that evening or before bed. Do not take zolpidem tartrate extended-release tablets if you think you are an alcoholic. Take zolpidem tartrate extended-release tablets whole. Do not break, crush, dissolve, chew zolpidem tartrate extended-release tablets. If you break, crush, dissolve, or chew extended-release tablets, you may have side effects that are not as expected. You may need a different medicine.

Zolpidem tartrate extended-release 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 extended-release 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
- abnormal dreams
- 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 extended-release tablets.

The most common side effects of zolpidem tartrate extended-release tablets are:

- drowsiness
- dizziness
- ringing in the ears
- trouble sleeping
- headaches
- gas or stomach pain
- nausea or vomiting
- stomach area pain
- dry mouth
- constipation
- diarrhea
- indigestion
- increased appetite
- heartburn
- chest discomfort
- back area pain
- nervousness
- muscle cramps
- panic attack
- abnormal dreams
- nightmares
- unusual tiredness or weakness
- loss of balance
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