MEDICATION GUIDE

Zolpidem Tartrate Tablets C-IV

Read the Medication Guide that comes with zolpidem tartrate 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 tablets?

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. You have a higher chance for doing these activities if you drink alcohol or take other medicines that make you sleepy with zolpidem tartrate tablets. Reported activities include:

- driving a car ("sleep-driving")
- making and eating food
- talking on the phone
- having sex
- sleep-walking

Call your doctor right away if you find out that you have done any of the above activities after taking zolpidem tartrate tablets.

Important:

1. Take zolpidem tartrate tablets exactly as prescribed

- Do not take more zolpidem tartrate tablets than prescribed.
- Take zolpidem tartrate tablets right before you get in bed, not sooner.

2. Do not take zolpidem tartrate tablets if you:

- drink alcohol
- take other medicines that can make you sleepy. Talk to your doctor about all of your medicines. Your doctor will tell you if you can take zolpidem tartrate tablets with your other medicines.
- cannot get a full night's sleep

What are zolpidem tartrate tablets?

Zolpidem tartrate tablets are a sedative-hypnotic (sleep) medicine. Zolpidem tartrate tablets are used in adults for the short-term treatment of a sleep problem called insomnia. Symptoms of insomnia include:

- trouble falling asleep

Zolpidem tartrate tablets are not for children.

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 prevent misuse and abuse. Selling or giving away zolpidem tartrate 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 tablets?

Do not take zolpidem tartrate tablets if you are allergic to anything in it.

See the end of this Medication Guide for a complete list of ingredients in zolpidem tartrate tablets.

Zolpidem tartrate tablets may not be right for you. Before starting zolpidem tartrate 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. **Do not take zolpidem tartrate tablets with other medicines that can make you sleepy.**

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 tablets?

- Take zolpidem tartrate tablets exactly as prescribed. Do not take more zolpidem tartrate tablets than prescribed for you.
- **Take zolpidem tartrate tablets right before you get into bed.**

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• Do not take zolpidem tartrate tablets unless you are able to stay in bed a full night (7-8 hours) before you must be active again.

• For faster sleep onset, zolpidem tartrate tablets should NOT be taken with or immediately after a meal.

• Call your doctor 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 tablets or overdose, call your doctor or poison control center right away, or get emergency treatment.

What are the possible side effects of zolpidem tartrate tablets?

Serious side effects of zolpidem tartrate tablets include:

• **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 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 tablets.

Call your doctor right away if you have any of the above side effects or any other side effects that worry you while using zolpidem tartrate tablets.

The most common side effects of zolpidem tartrate tablets are:

• drowsiness

• dizziness

• diarrhea

• "drugged feelings"

• You may still feel drowsy the next day after taking zolpidem tartrate tablets. **Do not drive or do other dangerous activities after taking zolpidem tartrate tablets until you feel fully awake.**

After you stop taking a sleep medicine, you may have symptoms for 1 to 2 days such as: trouble sleeping, nausea, flushing, lightheadedness, uncontrolled crying, vomiting, stomach cramps, panic attack, nervousness, and stomach area pain.

These are not all the side effects of zolpidem tartrate tablets. Ask your doctor or pharmacist for more information.

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°-25°C (68°-77°F); [See USP Controlled Room Temperature].

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

General Information about zolpidem tartrate tablets

• 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 share zolpidem tartrate tablets with 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 tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about zolpidem tartrate tablets that is written for healthcare professionals. For more information about zolpidem tartrate tablets, call 1-888-375-3784.

What are the ingredients in zolpidem tartrate tablets?

Active Ingredient: zolpidem tartrate

Inactive Ingredients: colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium starch glycolate, and titanium dioxide; the 5 mg tablet also contains iron oxide red colorant.

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

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Manufactured by:

Dr.Reddy's Laboratories Limited

Bachepalli – 502 325 INDIA

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PHARMACIST - DETACH FROM HERE

(continued from previous side)

• Do not take zolpidem tartrate tablets unless you are able to stay in bed a full night (7-8 hours) before you must be active again.

• For faster sleep onset, zolpidem tartrate tablets should NOT be taken with or immediately after a meal.

• Call your doctor 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 tablets or overdose, call your doctor or poison control center right away, or get emergency treatment.

What are the possible side effects of zolpidem tartrate tablets?

Serious side effects of zolpidem tartrate tablets include:

• **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 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 tablets.

Call your doctor right away if you have any of the above side effects or any other side effects that worry you while using zolpidem tartrate tablets.

The most common side effects of zolpidem tartrate tablets are:

• drowsiness

• dizziness

• diarrhea

• "drugged feelings"

• You may still feel drowsy the next day after taking zolpidem tartrate tablets. **Do not drive or do other dangerous activities after taking zolpidem tartrate tablets until you feel fully awake.**

After you stop taking a sleep medicine, you may have symptoms for 1 to 2 days such as: trouble sleeping, nausea, flushing, lightheadedness, uncontrolled crying, vomiting, stomach cramps, panic attack, nervousness, and stomach area pain.

These are not all the side effects of zolpidem tartrate tablets. Ask your doctor or pharmacist for more information.

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°-25°C (68°-77°F); [See USP Controlled Room Temperature].

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

General Information about zolpidem tartrate tablets

• 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 share zolpidem tartrate tablets with 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 tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about zolpidem tartrate tablets that is written for healthcare professionals. For more information about zolpidem tartrate tablets, call 1-888-375-3784.

What are the ingredients in zolpidem tartrate tablets?

Active Ingredient: zolpidem tartrate

Inactive Ingredients: colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium starch glycolate, and titanium dioxide; the 5 mg tablet also contains iron oxide red colorant.

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

Rx Only

Manufactured by:

Dr.Reddy's Laboratories Limited

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