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

• Do not take more zolpidem tartrate than prescribed.
• Do not take zolpidem tartrate unless you are able to stay in bed a full night (7 to 8 hours) before you must be active again.
• Take zolpidem tartrate right before you get in bed, not sooner.

Zolpidem tartrate may cause serious side effects, including:

• After taking zolpidem tartrate, 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. Reported activities include:
  o driving a car (“sleep-driving”)
  o making and eating food
  o talking on the phone
  o having sex
  o sleep-walking

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

Do not take zolpidem tartrate if you:

• drank alcohol that evening or before bed
• took another medicine to help you sleep.

What is zolpidem tartrate?

Zolpidem tartrate is a sedative-hypnotic (sleep) medicine. Zolpidem tartrate is used in adults for the short-term treatment of a sleep problem called insomnia (trouble falling asleep).

It is not known if zolpidem tartrate is safe and effective in children under the age of 18 years.

Zolpidem tartrate is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep zolpidem tartrate in a safe place to prevent misuse and abuse. Selling or giving away zolpidem tartrate may harm others, and is against the law. Tell your healthcare provider if you have ever abused or have been dependent on alcohol, prescription medicines or street drugs.

Who should not take zolpidem tartrate?

• Do not take zolpidem tartrate if you are allergic to zolpidem or any other ingredients in zolpidem tartrate. See the end of this Medication Guide for a complete list of ingredients in zolpidem tartrate.
• Do not take zolpidem tartrate if you have had an allergic reaction to drugs containing zolpidem, such as Ambien CR, Edluar, Zolpimist, or Intermezzo.

Symptoms of a serious allergic reaction to zolpidem can include:

• swelling of your face, lips, and throat that may cause difficulty breathing or swallowing

What should I tell my healthcare provider before taking zolpidem tartrate?

Zolpidem tartrate may not be right for you. Before starting zolpidem tartrate, tell your healthcare provider 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. It is not known if zolpidem tartrate will harm your unborn baby.
• are breastfeeding or plan to breastfeed. Zolpidem tartrate can pass into your breast milk. It is not known if zolpidem tartrate will harm your baby. Talk to your healthcare provider about the best way to feed your baby while you take zolpidem tartrate.

Tell your healthcare provider 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 with other medicines that can make you sleepy unless your healthcare provider tells you to.

Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist each time you get a new medicine.

How should I take zolpidem tartrate?

• See “What is the most important information I should know about zolpidem tartrate?”
• Take zolpidem tartrate exactly as prescribed. Only take 1 zolpidem tartrate tablet a night if needed.
• Do not take zolpidem tartrate if you drank alcohol that evening or before bed.
• You should not take zolpidem tartrate with or right after a meal. Zolpidem tartrate may help you fall asleep faster if you take it on an empty
stomach.

- Call your healthcare 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 or overdose, get emergency treatment.

How should I store zolpidem tartrate?

- Store zolpidem tartrate at room temperature 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F).

Keep zolpidem tartrate 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 for a condition for which it was not prescribed. Do not share zolpidem tartrate with other people, even if 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. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about zolpidem tartrate that is written for healthcare professionals.

For more information, call Northstar Rx LLC at 1-800-206-7821.

What are the ingredients in zolpidem tartrate tablets?

Active Ingredient: Zolpidem tartrate

Inactive Ingredients: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, hypromellose, polyethylene glycol, and titanium dioxide.

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

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Medication Guides available at www.northstarrxllc.com/products or call 1-800-206-7821.

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