AMBIEN- zolpidem tartrate 5mg tablet, film coated
Advanced Rx Pharmacy of Tennessee, LLC

Zolpidem Tartrate 5mg tablets #60

Medication Guide

MEDICATION GUIDE

Zolpidem Tartrate Tablets, USP C-IV

(zol' pi dem tar' trate)

Read the Medication Guide that comes with zolpidem tartrate 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 healthcare provider about your medical condition or treatment.

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:

complex sleep behaviors that have caused serious injury and death. 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 (complex sleep behaviors). The next morning, you may not remember that you did anything during the night. These activities may occur with zolpidem tartrate whether or not you drink alcohol or take other medicines that make you sleepy. Reported activities include:

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

Stop taking zolpidem tartrate and 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:

have ever experienced a complex sleep behavior (such as driving a car, making and eating food, talking on the phone , or having sex while not being fully awake) after taking zolpidem tartrate.
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).

Zolpidem tartrate is not recommended for use 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. Talk to your healthcare provider about the risk to your unborn baby if you take zolpidem tartrate.
Using zolpidem tartrate in the last trimester of pregnancy may cause breathing difficulties or excess sleepiness in your newborn. Monitor for signs of sleepiness (more than usual), trouble breathing, or limpness in the newborn if zolpidem tartrate is taken late in pregnancy.
are breastfeeding or plan to breastfeed. Zolpidem tartrate passes into your breast milk. 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.

What are the possible side effects of zolpidem tartrate?

Zolpidem tartrate may cause serious side effects, including:

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?”
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, and trouble breathing. Get emergency medical help if you get these symptoms after taking zolpidem tartrate.

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.

The most common side effects of zolpidem tartrate are:

drowsiness
dizziness
diarrhea
grogginess or feeling as if you have been drugged

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
stomach area pain

These are not all the side effects of zolpidem tartrate. Ask your healthcare provider 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?

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.

Manufactured for: Northstar Rx LLC
Memphis, TN 38141.
Manufactured by: Aurobindo Pharma Limited
Unit-VII (SEZ)
Mahabubnagar (Dt)-509302
India.

M.L.No.: 22/MN/AP/2009/F/R

Revised: 09/2019

Dosage and Administration Section

2 DOSAGE AND ADMINISTRATION

2.1 Dosage in Adults

Use the lowest effective dose for the patient. The recommended initial dose is 5 mg for women and either 5 or 10 mg for men, taken only once per night immediately before bedtime with at least 7 to 8 hours remaining before the planned time of awakening. If the 5 mg dose is not effective, the dose can be increased to 10 mg. In some patients, the higher morning blood levels following use of the 10 mg dose increase the risk of next-day impairment of driving and other activities that require full alertness [see WARNINGS AND PRECAUTIONS (5.2)]. The total dose of zolpidem tartrate tablets should not exceed 10 mg once daily immediately before bedtime. Zolpidem tartrate tablets should be taken as a single dose and should not be readministered during the same night.

The recommended initial doses for women and men are different because zolpidem clearance is lower in women.

2.2 Special Populations

Elderly or debilitated patients may be especially sensitive to the effects of zolpidem tartrate. The recommended dose of zolpidem tartrate in these patients is 5 mg once daily immediately before bedtime [see WARNINGS AND PRECAUTIONS (5.2), USE IN SPECIFIC POPULATIONS (8.5)].

Patients with mild to moderate hepatic impairment do not clear the drug as rapidly as normal subjects. The recommended dose of zolpidem tartrate in these patients is 5 mg once daily immediately before bedtime. Avoid zolpidem tartrate use in patients with severe hepatic impairment as it may contribute to encephalopathy [see WARNINGS AND PRECAUTIONS (5.8), USE IN SPECIFIC POPULATIONS (8.7), CLINICAL PHARMACOLOGY (12.3)].

2.3 Use with CNS Depressants

Dosage adjustment may be necessary when zolpidem tartrate tablets are combined with other CNS-depressant drugs because of the potentially additive effects [see WARNINGS AND PRECAUTIONS (5.2)].

2.4 Administration

The effect of zolpidem tartrate tablets may be slowed by ingestion with or immediately after a meal.

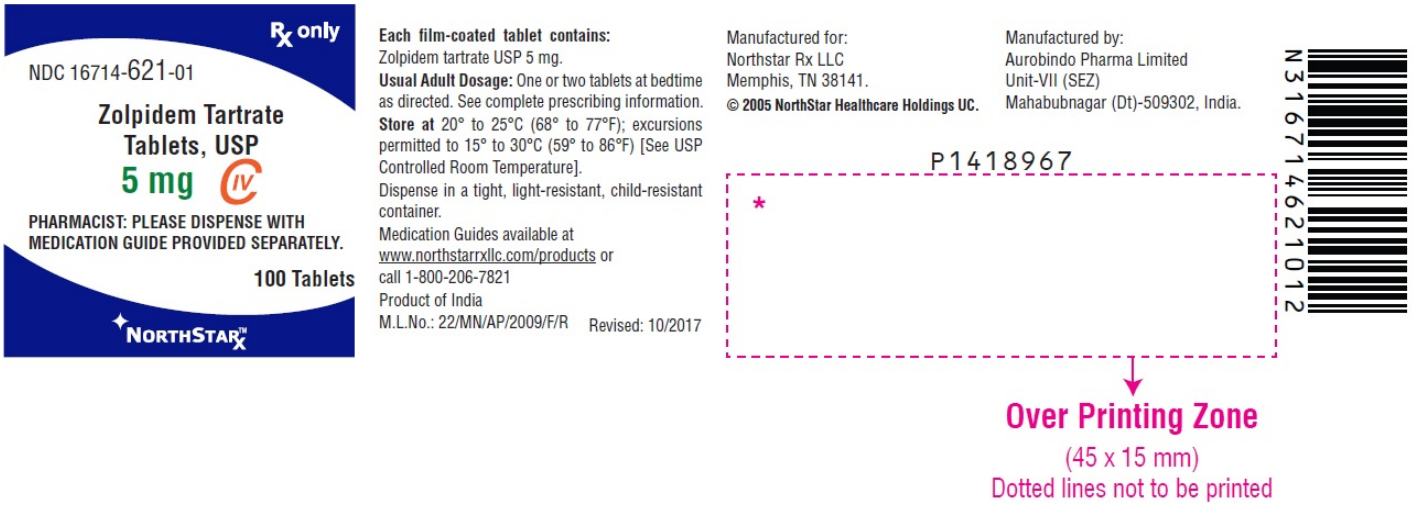
Indications and Usage Section

1 INDICATIONS AND USAGE

Zolpidem tartrate tablets are indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Zolpidem tartrate tablets have been shown to decrease sleep latency for up to 35 days in controlled clinical studies [see CLINICAL STUDIES (14)].

The clinical trials performed in support of efficacy were 4 to 5 weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.

Principal Display Panel



AMBIEN

zolpidem tartrate 5mg tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:80425-0087(NDC:16714-621)
Route of Administration	ORAL	**DEA Schedule**	CIV

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZOLPIDEM TARTRATE (UNII: WY6W63843K) (ZOLPIDEM - UNII:7K383OQI23)	ZOLPIDEM TARTRATE	5 mg

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	5mm
Flavor		**Imprint Code**	E;78
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80425-0087-2	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078413	05/04/2007	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0087)

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