

MEDICATION GUIDE
AMBIEN® (ām' bē-ən) **Tablets C-IV**
(zolpidem tartrate)

Read the Medication Guide that comes with AMBIEN 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 AMBIEN?

After taking AMBIEN, 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 AMBIEN. 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 AMBIEN.

Important:

1. Take AMBIEN exactly as prescribed

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

2. Do not take AMBIEN 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 AMBIEN with your other medicines.
 - cannot get a full night's sleep
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What is AMBIEN?

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

- trouble falling asleep

AMBIEN is not for children.

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

Who should not take AMBIEN?

Do not take AMBIEN if you are allergic to anything in it. See the end of this Medication Guide for a complete list of ingredients in AMBIEN.

AMBIEN may not be right for you. Before starting AMBIEN, 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 AMBIEN 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 AMBIEN?

- Take AMBIEN exactly as prescribed. Do not take more AMBIEN than prescribed for you.
- **Take AMBIEN right before you get into bed.**
- **Do not take AMBIEN unless you are able to stay in bed a full night (7-8 hours) before being active again.**
- For faster sleep onset, AMBIEN 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 AMBIEN or overdose, call your doctor or poison control center right away, or get emergency treatment.

What are the possible side effects of AMBIEN?

Possible serious side effects of AMBIEN 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 AMBIEN?”)
- **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 AMBIEN.

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

The most common side effects of AMBIEN are:

- drowsiness
- dizziness
- diarrhea
- “drugged feelings”
- You may still feel drowsy the next day after taking AMBIEN. **Do not drive or do other dangerous activities after taking AMBIEN 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 AMBIEN. Ask your doctor or pharmacist for more information.

How should I store AMBIEN?

- Store AMBIEN at room temperature, 68° to 77°F (20° to 25° C).
- **Keep AMBIEN and all medicines out of reach of children.**

General Information about AMBIEN

- Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.
- Do not use AMBIEN for a condition for which it was not prescribed.
- Do not share AMBIEN 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 AMBIEN. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about AMBIEN that is written for healthcare professionals. For more information about AMBIEN, call 1-800-633-1610.

What are the ingredients in AMBIEN?

Active Ingredient: zolpidem tartrate

Inactive Ingredients: hydroxypropyl methylcellulose, lactose, magnesium stearate, micro-crystalline cellulose, polyethylene glycol, sodium starch glycolate, and titanium dioxide. In addition, the 5 mg tablet contains FD&C Red No. 40, iron oxide colorant, and polysorbate 80.

Rx Only

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

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**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Russell Katz

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