

17.1 Severe anaphylactic and anaphylactoid reactions

Inform patients that severe anaphylactic and anaphylactoid reactions have occurred with zolpidem. Describe the signs/symptoms of these reactions and advise patients to seek medical attention immediately if any of them occur.

17.2 Sleep-driving and other complex behaviors

There have been reports of people getting out of bed after taking a sedative-hypnotic and driving their cars while not fully awake, often with no memory of the event. If a patient experiences such an episode, it should be reported to his or her doctor immediately, since “sleep-driving” can be dangerous. This behavior is more likely to occur when Ambien CR is taken with alcohol or other central nervous system depressants [*see Warnings and Precautions (5.3)*]. Other complex behaviors (e.g., preparing and eating food, making phone calls, or having sex) have been reported in patients who are not fully awake after taking a sedative-hypnotic. As with “sleep-driving”, patients usually do not remember these events.

In addition, patients should be advised to report all concomitant medications to the prescriber. Patients should be instructed to report events such as “sleep-driving” and other complex behaviors immediately to the prescriber.

17.3 Administration instructions

Patients should be counseled to take Ambien right before they get into bed and only when they are able to stay in bed a full night (7-8 hours) before being active again. Ambien CR tablets should not be crushed, divided, or chewed, and should not be taken with or immediately after a meal. Advise patients NOT to take Ambien CR when drinking alcohol.

17.4 Medication Guide

MEDICATION GUIDE

AMBIEN CR[®] (ām' bē-ən see ahr) **C-IV**
(zolpidem tartrate extended-release tablets)

Read the Medication Guide that comes with AMBIEN CR 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 CR?

After taking AMBIEN CR, 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 CR. Reported activities include:

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

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

Important:

1. Take AMBIEN CR exactly as prescribed

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

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

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

- trouble falling asleep
- waking up often during the night

AMBIEN CR is not for children.

AMBIEN CR is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep AMBIEN CR in a safe place to prevent misuse and abuse. Selling or giving away AMBIEN CR 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 AMBIEN CR?

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

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

- Take AMBIEN CR exactly as prescribed. Do not take more AMBIEN CR than prescribed for you.
- **Take AMBIEN CR right before you get into bed.**
- **Do not take AMBIEN CR unless you are able to stay in bed a full night (7-8 hours) before you must be active again.**
- Swallow AMBIEN CR Tablets whole. Do not chew or break the tablets. Tell your doctor if you cannot swallow tablets whole.
- For faster sleep onset, AMBIEN CR 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 problems.
- If you take too much AMBIEN CR or overdose, call your doctor or poison control center right away, or get emergency treatment.

What are the possible side effects of AMBIEN CR?

Serious side effects of AMBIEN CR 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 CR?”)
- **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 CR.

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 CR.

The most common side effects of AMBIEN CR are:

- headache
- sleepiness
- dizziness
- You may still feel drowsy the next day after taking AMBIEN CR. **Do not drive or do other dangerous activities after taking AMBIEN CR 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 CR. Ask your doctor or pharmacist for more information.

How should I store AMBIEN CR?

- Store AMBIEN CR at room temperature, 59° to 77°F (15° to 25° C).
- **Keep AMBIEN CR and all medicines out of reach of children.**

General Information about AMBIEN CR

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

What are the ingredients in AMBIEN CR?

Active Ingredient: Zolpidem tartrate

Inactive Ingredients: The 6.25 mg tablets contain: colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, potassium bitartrate, red ferric oxide, sodium starch glycolate, and titanium dioxide. The 12.5 mg tablets contain: colloidal silicon dioxide, FD&C Blue #2, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, potassium bitartrate, sodium starch glycolate, titanium dioxide, and yellow ferric oxide.

Rx Only

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

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