

MEDICATION GUIDE

Rx Only

AMBIEN CR® (ām'bě-ən see ahr)

(zolpidem tartrate) **extended-release tablets C-IV**

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 healthcare provider about your medical condition or treatment.

What is the most important information I should know about AMBIEN CR?

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

AMBIEN CR may cause serious side effects including complex sleep behaviors that have caused serious injury and death. 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 (complex sleep behaviors). The next morning, you may not remember that you did anything during the night. These activities may occur with AMBIEN CR 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 AMBIEN CR and call your healthcare provider right away if you find out that you have done any of the above activities after taking AMBIEN CR.

You should not drive a car or do things that require clear thinking the day after you take AMBIEN CR.

Do not take AMBIEN CR 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 AMBIEN CR.
- drank alcohol that evening or before bed.
- take other medicines that can make you sleepy. Taking AMBIEN CR with other drugs can cause side effects. Talk to your healthcare provider about all of your medicines. Your healthcare provider will tell you if you can take AMBIEN CR with your other medicines.
- cannot get a full night's sleep.

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 recommended for use in children under the age of 18 years.

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 healthcare provider 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 zolpidem or any other ingredients in AMBIEN CR. See the end of this Medication Guide for a complete list of ingredients in AMBIEN CR.
- Do not take AMBIEN CR if you have had an allergic reaction to drugs containing zolpidem, such as Ambien, 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 AMBIEN CR?

AMBIEN CR may not be right for you. Before starting AMBIEN CR, 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 AMBIEN CR.
- Using AMBIEN CR 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 AMBIEN CR is taken late in pregnancy.
- are breastfeeding or plan to breastfeed. AMBIEN CR passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while you take AMBIEN CR.

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 AMBIEN CR 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 AMBIEN CR?

- See "What is the most important information I should know about AMBIEN CR?"
- Take AMBIEN CR exactly as prescribed. Only take 1 AMBIEN CR tablet a night if needed.
- Do not take AMBIEN CR if you drank alcohol that evening or before bed.
- You should not take AMBIEN CR with or right after a meal. AMBIEN CR may help you fall asleep faster if you take it on an empty stomach.
- Take AMBIEN CR Tablets whole. Do not break, crush, dissolve or chew AMBIEN CR tablets before swallowing. If you cannot swallow AMBIEN CR tablets whole, tell your healthcare provider. You may need a different medicine.
- 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 problems.
- If you take too much AMBIEN CR or overdose, get emergency treatment.

What are the possible side effects of AMBIEN CR?

AMBIEN CR may cause serious side effects including:

- **getting out of bed while not being fully awake and doing 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, acting strangely, 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 healthcare provider 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
- drowsiness the next day after you take AMBIEN CR

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 AMBIEN CR. 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 AMBIEN CR?

Store AMBIEN CR at room temperature, 59°F to 77°F (15°C to 25°C).

Keep AMBIEN CR and all medicines out of reach of children.

General Information about the safe and effective use of 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 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 healthcare provider. You can ask your healthcare provider or pharmacist for information about AMBIEN CR that is written for healthcare professionals.

For more information, go to www.ambienr.com or call 1-800-633-1610.

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.

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

sanofi-aventis U.S. LLC
Bridgewater, NJ 08807
A SANOFI COMPANY

Revised: August 2019

©2019 sanofi-aventis U.S. LLC

ACR-MG-SL-AUG19