



## AMBIEN CR Prescription Q&As

Knowing the differences between AMBIEN® (zolpidem tartrate) CIV (or generic AMBIEN) and AMBIEN CR will help you determine which one is right for you. And once you and your healthcare provider have made that decision, it's important that you receive the right one.

Take a look through these common questions and answers that address the differences between both forms of AMBIEN, and give you tips on how to make sure you get AMBIEN CR as prescribed by your healthcare provider.

### Are there significant differences between the generic AMBIEN and AMBIEN CR?

**Answer:** Yes. Knowing the differences between AMBIEN and AMBIEN CR will help you determine which prescription is right for you.

AMBIEN (or generic AMBIEN) is approved to help you fall asleep, and is recommended for short-term use.<sup>1</sup> AMBIEN CR is different. AMBIEN CR is the only form of AMBIEN that is FDA-approved to help you fall asleep and stay asleep.<sup>2,3\*</sup> And it can be taken for as long as your healthcare provider recommends.

AMBIEN has one layer to help you fall asleep.<sup>1</sup> AMBIEN CR has two layers with a controlled-release formula. The first layer dissolves quickly to help you fall asleep fast, while the second dissolves slowly to help you stay asleep, so you can wake up ready for your day.<sup>2-6\*\*</sup>

\*Proven effective for up to 7 hours in clinical studies.

\*\*Individual results may vary.

### How can I make sure that I get AMBIEN CR as prescribed by my healthcare provider?

**Answer:** Insurers have been trying to reduce costs by insisting on cheaper alternatives to prescribed medicines. Make sure that you're receiving the right form of AMBIEN by asking your pharmacist these four questions:

#### 1. Am I getting the exact formulation of AMBIEN CR that was prescribed?

Keep in mind that AMBIEN CR works differently from generic AMBIEN<sup>1,3</sup>. And only your healthcare provider can determine which kind of AMBIEN is best for your needs, so it's important that you ask your pharmacist for exactly what was prescribed.

#### 2. If not, why have you changed my prescription?

If your prescription has been switched, make sure you understand how and why the decision was made to make a change.

AMBIEN CR is indicated to help you fall asleep and/or stay asleep.  
AMBIEN is indicated for short-term treatment to help you fall asleep.

### IMPORTANT SAFETY INFORMATION

AMBIEN and AMBIEN CR are treatment options you and your doctor can consider along with lifestyle changes. When taking either of them, don't drive or operate machinery. Plan to devote 7 to 8 hours to sleep before being active. Sleepwalking, and eating or driving while not fully awake, with memory loss for the event, as well as abnormal behaviors such as being more outgoing or aggressive than normal, confusion, agitation, and hallucinations may occur. Don't take it with alcohol as it may increase these behaviors. In patients with depression, worsening of depression, including risk of suicide may occur. If you experience any of these behaviors contact your doctor immediately.

Allergic reactions such as shortness of breath, swelling of your tongue or throat, may occur and in rare cases may be fatal. If you have an allergic reaction while using AMBIEN or AMBIEN CR, contact your doctor immediately. Side effects of AMBIEN CR may include next-day drowsiness, dizziness and headache. There is a low occurrence of side effects associated with the short-term use of AMBIEN. The most commonly observed side effects in controlled clinical trials were drowsiness, dizziness, and diarrhea. AMBIEN is taken for 7 to 10 days –or longer as advised by your provider. AMBIEN CR can be taken as long as your doctor recommends. AMBIEN and AMBIEN CR have some risk of dependency. They are non-narcotic.

Please refer to the full prescribing information at [www.AmbienCR.com](http://www.AmbienCR.com) and medication guide enclosed.

Please refer to Ambien full prescribing information at <http://products.sanofi-aventis.us/ambien/ambien.html> and medication guide enclosed.

### 3. How will this change affect my health?

Generic AMBIEN is different from AMBIEN CR and a switch means that you aren't getting the medication that your healthcare provider determined was right for you. If you are unsatisfied with the generic form of AMBIEN, please go back to your healthcare provider and inform him or her.

### 4. Have you notified my doctor that my prescription has been changed?

Your state may require pharmacists to consult with your healthcare provider before they can switch a medication. Make sure you know your rights and insist they be honored.

### I just realized that my prescription was filled with generic AMBIEN not AMBIEN CR. Is there anything I can do?

**Answer:** If you are unsatisfied with the generic form of AMBIEN, please go back to your healthcare provider and inform him or her. If you did not receive your prescription for AMBIEN CR and would like to get the prescription your doctor prescribed, you have a few options:

1. Call your healthcare provider to request AMBIEN CR. They may need to submit a "Prior Authorization" form to your insurance company. Many health plans require that you get Prior Authorization from your healthcare provider for some prescription medications before they will cover it. Prior to getting your prescription filled, have your healthcare provider sign and fax a "Prior Authorization" form to your insurance company.

Once you receive prior authorization (which generally occurs 95% of the time), contact your pharmacy to fill your prescription for AMBIEN CR, as approved by your plan.

2. You may be required to try generic AMBIEN first. Different insurance companies have different policies. Generally, you first need to fill your prescription for generic AMBIEN, and can then get AMBIEN CR by requesting it from your healthcare provider. This process is called a "step edit."

3. If your insurance company refuses to cover AMBIEN CR, you can pay for it, and we can help with the cost. AMBIEN CR can save you up to \$100<sup>†</sup> on five refills of AMBIEN CR. Just visit [www.ambienCR.com/getambienCR](http://www.ambienCR.com/getambienCR) to print your savings certificates.

### Why is my insurance plan only willing to pay for generic AMBIEN and not AMBIEN CR?

**Answer:** Primarily, insurance companies want you to try a generic medication first, because they usually cost less. Typically pharmacists will follow these guidelines.

### Is there anything that can help me pay for my AMBIEN CR prescription?

**Answer:** Yes. When you take advantage of our coupon offer, you can save up to \$100<sup>†</sup> on your next five AMBIEN CR refills. Just visit [www.ambienCR.com/getambienCR](http://www.ambienCR.com/getambienCR) to print your savings certificates.

<sup>†</sup>Maximum benefit is \$20 off, on up to 5 prescriptions, depending on your out-of-pocket costs. Not valid for patients participating in Medicare, Medicaid, government (public insurance) programs, or any private payor in the state of Massachusetts and where prohibited by law.

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## References

1. Ambien® (zolpidem tartrate) Prescribing Information. Bridgewater, NJ: sanofi-aventis Inc; 2009.
2. Ambien CR® Now available in the US for the Treatment of Insomnia [press release]. Paris, France: sanofi-aventis; October 7, 2005.
3. Ambien CR® (zolpidem tartrate extended release) Prescribing Information. Bridgewater, NJ: sanofi-aventis Inc; 2009.
4. Krystal, AD, Erman M, Zammit GK, Soubrane C, Roth T; on behalf of the ZOLONG Study Group. Long-term efficacy and safety of zolpidem extended-release 12.5 mg, administered 3 to 7 nights per week for 24 weeks, in patients with chronic primary insomnia: a 6-month, randomized, double-blind, placebo-controlled, parallel-group, multicenter study. *Sleep*.2008;31(1):79-90.
5. Bogan RK. Treatment options for insomnia—pharmacodynamics of zolpidem extended-release to benefit next-day performance. *Postgrad Med*. 2008;120(3):161-171.
6. Lieberman JA. Update on the safety considerations in the management of insomnia with hypnotics: incorporating modified-release formulations into primary care. *Prim Care Companion J Clin Psychiatry*. 2007;9(1):25-31.

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## 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
- 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

#### 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.

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° 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.ambienr.com](http://www.ambienr.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.

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

sanofi-aventis U.S. LLC  
Bridgewater, NJ 08807  
September 2009

## MEDICATION GUIDE

### AMBIEN® (ām'bē-ən) Tablets C-IV

(zolpidem tartrate)

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#### 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

#### 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 have been dependent on alcohol, prescription medicines or street drugs.

#### Who should not take AMBIEN?

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**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.**

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#### How should I take AMBIEN?

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- **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 you must be 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?

**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.

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?

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- **Keep AMBIEN and all medicines out of reach of children.**

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- 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.

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#### 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

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sanofi-aventis U.S. LLC  
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