

**PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

**AMBIEN CR 6.25 mg
AMBIEN CR 12.5 mg
Controlled-release tablets**

Active ingredient and its quantity:

Each Ambien CR 6.25 mg tablet contains: zolpidem tartrate 6.25 mg

Each Ambien CR 12.5 mg tablet contains: zolpidem tartrate 12.5 mg

Inactive and allergenic ingredients in the preparation – see in section 2 “Important information about some of the ingredients of the medicine” and section 6 “Further information”.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

WARNING: Zolpidem may be associated with unusual and potentially dangerous behaviors whilst apparently asleep. These behaviors include sleepwalking, sleep driving and other bizarre behaviors. Certain medicines may interact with zolpidem and special caution is required during treatment with other medicines that may also affect the brain; before taking zolpidem, read the section “Drug interactions” below or consult the doctor or pharmacist. Do not drink alcohol when taking zolpidem. Do not take zolpidem for more than 4 weeks. If the sleep problems persist, consult the doctor.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the short-term treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

Therapeutic group: Hypnotic and sedative substances.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient (zolpidem) or to any of the additional ingredients contained in the medicine (see section 6). Always check the ingredients to be sure that you can use this medicine.
- you have been drinking alcohol or you believe that you may have alcohol in your bloodstream.
- you have sleep apnea (a disturbance in which you temporarily stop breathing during sleep).

- you have myasthenia gravis (a disturbance in which the muscles weaken and tire easily).
- you have severe liver problems.
- you have acute and/or severe lung problems.
- you have previously experienced complex sleep behaviors after taking this medicine, including sleepwalking, sleep driving and/or engagement in other activities when you are not fully awake.

Tell the doctors, dentists and pharmacists treating you that you are taking Ambien CR.

If you are due to start treatment with a new medicine, tell the doctor and pharmacist that you are taking Ambien CR.

If you plan to undergo surgery that requires general anesthesia, tell the doctor or dentist that you are taking this medicine.

Before treatment with the medicine, tell the doctor if:

- you have any problems with your breathing or if you often snore while you are asleep.
- you have ever been addicted to alcohol or any drug or medicine, or if you have ever suffered from a mental illness. If so, you may be at risk of developing a permanent pattern or habit of taking Ambien CR.
- you are suffering or have suffered from other medical disturbances, particularly those listed below: heart, liver, kidney, or lung problems, epilepsy, depression, mental illness, e.g., schizophrenia.
- you are planning to undergo surgery.
- you suffer from allergies to one of the ingredients listed at the end of this leaflet.
- you are taking medicines for any other condition.

Talk to the doctor or pharmacist if you have ever had a mental disorder or have abused or have been dependent on alcohol or drugs.

During the course of treatment, you may be at risk of developing certain side effects. It is important that you understand these risks and know how to monitor them. See additional information in section 6.

Additional warnings

- If you are over the age of 65 and you are unwell or are taking other medicines, you may be more sensitive to some of the side effects of Ambien CR. Some patients may be particularly susceptible to the sedative effects of the medicine, which may increase the likelihood of falls.
- Ambien CR can cause drowsiness and a decreased level of consciousness. Store Ambien CR in a safe place to protect it from theft, since it may be illicitly used for criminal activities (which may be dangerous), especially in combination with alcohol, when given to a victim without his knowledge. Never give Ambien CR to other people as it may harm them.
- In most cases, sleep medicines should be used for short periods of time only. If the sleep problems persist, consult with the doctor.
- Certain medicines can cause dependence, especially when they are used regularly for more than a few weeks. People who have been dependent on alcohol or other medicines in the past may be at increased risk of addiction to sleep medicines. If you have been addicted to alcohol or medicines in the

past, it is important that you report it to the doctor before starting use of Ambien CR.

- Withdrawal symptoms may sometimes occur when treatment with a medicine is abruptly discontinued after prolonged use. Withdrawal symptoms may include abdominal and muscle cramps, vomiting and sweating. In some cases, insomnia may worsen for a short period of time, which may be accompanied by additional reactions, including mood changes, anxiety and restlessness; speak with the doctor if these effects occur. Patients who took part in trials did not experience any problems when Ambien CR was discontinued. Nonetheless, report to the doctor if you experience problems after stopping treatment with Ambien CR.

Children and adolescents

Do not give Ambien CR to a child or adolescent under the age of 18; there is no experience with its use in children or adolescents under the age of 18.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. **Certain medicines may disrupt the effect of Ambien CR and affect how it works.**

Medicines that may increase the effect of Ambien CR include:

- alcohol
- medicines to treat depression, anxiety and mental illness
- medicines used to produce calmness or to help you sleep
- medicines to treat epilepsy
- pain relievers
- muscle relaxants
- antihistamines
- ciprofloxacin, a medicine used to treat infections
- ketoconazole, a medicine to treat fungal infections
- opioids

These medicines may increase drowsiness. This may affect ability to drive a car or to operate dangerous machinery. You may need to use different amounts of the medicine or to take different medicines. The doctor will advise you.

Medicines that may reduce the effect of Ambien CR include:

- St. John's wort (also known as *Hypericum*), a herbal medicine used to treat depression
- rifampicin, a medicine used to treat infection

Check with the doctor or pharmacist if you are not sure about the medicines, vitamins or supplements you are taking and about their possible effect on Ambien CR.

Use of the medicine and alcohol consumption

Do not drink alcohol before or after taking this medicine. This may increase the risk of side effects or the effects of alcohol may worsen while taking Ambien CR.

Tell the doctor if you drink alcohol.

Pregnancy and breastfeeding

Consult the doctor if you are pregnant, suspect that you are pregnant, or intend to become pregnant.

Like most medicines of this kind, Ambien CR is not recommended to be used during pregnancy. The doctor will discuss the risks and benefits of taking it if you are pregnant.

If you become pregnant or suspect that you are pregnant while taking this medicine, stop taking it and report to the doctor or pharmacist immediately.

Talk to the doctor if you are breastfeeding or intend to breastfeed.

Ambien CR can pass into breast milk. The doctor will discuss the risks and benefits of using it if you are breastfeeding or planning to breastfeed.

Driving and operating machinery

Since Ambien CR may cause drowsiness, do not operate dangerous machinery or drive a car for 8 hours after taking it. You should also be careful when you wake up the next morning.

Before driving or operating machinery, make sure that you know how you react to Ambien CR. This is very important if you are taking other medicines which also cause drowsiness.

Important information regarding some of the ingredients of the medicine

The medicine contains **lactose**. Consult your doctor before starting to use the medicine if you have an intolerance to certain sugars.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally:

If needed, take only one Ambien CR tablet at night, just before bedtime.

The usual starting dosage is generally: For women – a 6.25 mg tablet. For men – 6.25-12.5 mg.

In the elderly and patients with liver function problems, the dosage is one 6.25 mg tablet, once at night, at bedtime. Do not use if you have been diagnosed with severe liver failure.

Do not exceed a dosage of 12.5 mg once a day, at bedtime.

Make sure that you will be able to sleep for at least 7-8 hours after taking the medicine.

Do not exceed the recommended dose.

Do not take Ambien CR if you drank alcohol that evening or before bedtime.

Do not take Ambien CR with or immediately after a meal. Ambien CR can help you fall asleep faster if taken on an empty stomach.

Duration of treatment:

Ambien CR is intended for short-term use only. Treatment with Ambien CR must be as short as possible since the risk of dependence increases with more prolonged treatment.

The usual duration of treatment with the medicine is two days to four weeks.

In some patients, the higher levels of the medicine in the blood in the morning, after taking 12.5 mg at bedtime, increase the risk of impaired alertness, ability to drive and ability to concentrate.

Refer to your doctor if your insomnia worsens or does not improve within 7-10 days. This may indicate that there is another medical condition that is causing your sleep problems.

The tablets are not intended for children and adolescents under 18 years of age.

Method of administration:

Swallow the tablet whole. Do not chew, halve or crush the tablet. The tablet comprises two layers that release the active ingredient in a controlled manner. If you are unable to swallow the Ambien CR tablet whole, tell the doctor. You may need to receive a different medicine.

If you accidentally took a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine:

Take the medicine immediately before you go to bed only if you will be able to sleep for at least 7-8 hours. If you forgot to take the medicine before going to sleep, do not take a dose at any other time as you may feel drowsy, dizzy and confused during the day.

Do not take a double dose to compensate for the forgotten dose. Take the next dose at the usual time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with Ambien CR without consulting the doctor or pharmacist and even then, only gradually.

If you stop taking the medicine:

The following reactions may occur one or two days after you stop taking the medicine: sleep problems, nausea, flushing, dizziness, uncontrollable crying, vomiting, abdominal cramps, anxiety attack, nervousness and pain in the stomach area.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Ambien CR may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

If you do not feel well while taking Ambien CR, tell the doctor as soon as possible.

Ambien CR may cause serious side effects, including:

Allergic reactions:

- swelling of the face, lips, mouth or throat, which may cause difficulty swallowing or breathing
- hives
- fainting

Sleepwalking and associated behaviors:

Sleepwalking, driving vehicles and other unusual, and on some occasions dangerous, behaviors whilst apparently asleep. These behaviors have also included preparing and eating food, making phone calls or having sexual intercourse. People who experienced these effects had no memory of the events.

Refer to a doctor immediately or proceed to the closest hospital emergency room if you notice any of these serious side effects.

Alcohol can increase the risk of sleepwalking and other related behaviors. These side effects can also occur without the presence of alcohol. Even though these side effects can occur at the usual recommended dosages, the risk of these behaviors occurring may be increased if you take more than the recommended dosage.

Some sleep medicines may cause a short-term memory loss. When this occurs, a person may not remember what has happened for several hours after taking the medicine. This is usually not a problem since most people fall asleep after taking this medicine.

Less serious side effects:

Head- and neurology-related:

- drowsiness
- dizziness
- headache
- fatigue
- anxiety
- disorientation
- hallucinations
- nightmares
- slowness in thinking and movement
- poor attention and concentration
- memory impairment and loss
- unexpected changes in behavior. These have included rage reactions, worsened insomnia, confusion, agitation, hallucinations, delirium and other forms of unwanted behavior

Gastrointestinal system-related:

- stomach discomfort, indigestion, wind, frequent bowel movements
- diarrhea, nausea and vomiting
- constipation
- changes in appetite

Musculoskeletal system-related:

- muscle pain, muscle weakness or tenderness not caused by exertion
- muscle cramps

- neck and back pain

Infection-related:

- influenza or flu-like symptoms, such as high fever, sore throat, runny nose, cough and chills

Eye-related:

- vision disturbances

Although these side effects can occur at the usual recommended dosages, the risk of onset of these behaviors may be increased if you take a dosage higher than the recommended dosage.

Speak to the doctor if you experience one of these less serious side effects and it concerns you.

Tell the doctor or pharmacist if you notice another side effect that may cause you to feel unwell. Additional side effects that are not listed here may occur in some people. If any questions arise, refer to the doctor.

If a side effect occurs, if one of the side effects worsens, or persists for more than a few days, or if you suffer from side effects not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be stored in a safe place, out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor!

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Do not take the medicine if the package is damaged or shows signs of tampering.

Storage conditions: Store at a temperature below 30°C.

If you have no further need for this medicine or if it has expired, bring it to the pharmacy for safe disposal.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Ambien CR 6.25 mg: lactose monohydrate 138.913 mg, microcrystalline cellulose, hypromellose, potassium hydrogen tartrate, sodium starch glycolate (type A), magnesium stearate, titanium dioxide, macrogol 3350, colloidal anhydrous silica, red iron oxide.

Ambien CR 12.5 mg: lactose monohydrate 138.913 mg, microcrystalline cellulose, hypromellose, potassium hydrogen tartrate, sodium starch glycolate

(type A), magnesium stearate, titanium dioxide, macrogol 3350, indigotine (E132)-aluminium lake, colloidal anhydrous silica, yellow iron oxide.

What the medicine looks like and the contents of the package:

Ambien CR 6.25 mg controlled-release tablets – round pink tablets.

Ambien CR 12.5 mg controlled-release tablets – round blue tablets.

There are packages of 14 or 28 controlled-release tablets. Not all package sizes may be marketed.

Registration holder and importer and address: Sanofi Israel Ltd., Greenwork Park, P.O. box 47, Yakum.

Revised in September 2025 in accordance with the MOH guidelines.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Ambien CR 6.25 mg: 1420531833

Ambien CR 12.5 mg: 1420631834

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