

## **Patient Education ZOLPIDEM - ORAL**

**IMPORTANT: HOW TO USE THIS INFORMATION:** This is a summary and does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

**ZOLPIDEM – ORAL COMMON BRAND NAME(S):** Ambien

### **USES:**

Zolpidem is used to treat sleep problems (insomnia) in adults. It helps you fall asleep faster, so you can get a better night's sleep. It may also help you stay asleep longer and reduce the number of times you wake up during the night. Zolpidem belongs to a class of drugs called sedative-hypnotics. It acts on your brain to produce a calming effect.

This medication is usually limited to short treatment periods of 1 to 2 weeks or less.

### **HOW TO USE:**

Read the Medication Guide and, if available, the Patient Information Leaflet provided by your pharmacist before you start taking zolpidem and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Take this medication by mouth on an empty stomach as directed by your doctor, usually once a night. Since zolpidem works quickly, take it right before you get into bed. Do not take it with or after a meal because it will not work as quickly.

Do not take a dose of this drug unless you have time for a full night's sleep of at least 7 to 8 hours. If you have to wake up before that, you may have some memory loss.

Dosage is based on your medical condition, other medications you may be taking, and response to treatment. Do not increase your dose, take it more often, or use it for longer than prescribed. Do not take more than 10 milligrams a day. Older adults are usually prescribed a lower dose to decrease the risk of side effects.

This medication may cause withdrawal reactions, especially if it has been used regularly for a long time or in high doses. In such cases, withdrawal symptoms (such as nausea, vomiting, flushing, stomach cramps, nervousness, shakiness) may occur if you suddenly stop using this medication. To prevent withdrawal reactions, your doctor may reduce your dose gradually. Consult your doctor or pharmacist for more details, and report any withdrawal reactions immediately.

Along with its benefits, this medication may rarely cause abnormal drug-seeking behavior (addiction). This risk may be increased if you have abused alcohol or drugs in the past. Take this medication exactly as prescribed to lessen the risk of addiction.

When this medication is used for a long time, it may not work as well. Talk with your doctor if this medication stops working well.

Tell your doctor if your condition persists after 7 to 10 days, or if it worsens.

You may have trouble sleeping the first few nights after you stop taking this medication. This is called rebound insomnia and is normal. It will usually go away after 1-2 nights. If this effect continues, contact your doctor.

#### **SIDE EFFECTS:**

Dizziness may occur. If this effect persists or worsens, tell your doctor or pharmacist promptly.

This medication may make you sleepy during the day. Tell your doctor if you have daytime drowsiness. Your dose may need to be adjusted.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if any of these unlikely but serious side effects occur: memory loss, mental/mood/behavior changes (such as new/worsening depression, abnormal thoughts, thoughts of suicide, hallucinations, confusion, agitation, aggressive behavior, anxiety).

Rarely, after taking this drug, people have gotten out of bed and driven vehicles while not fully awake ("sleep-driving"). People have also sleepwalked, prepared/eaten food, made phone calls, or had sex while not fully awake. Often, these people do not remember these events. This problem can be dangerous to you or to others. If you find out that you have done any of these activities after taking this medication, tell your doctor right away. Your risk is increased if you use alcohol or other medications that can make you drowsy while taking zolpidem.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

#### **PRECAUTIONS:**

Before taking zolpidem, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease, mental/mood problems (such as depression, thoughts of suicide), personal or

family history of regular use/abuse of drugs/alcohol/other substances, lung/breathing problems (such as chronic obstructive pulmonary disease-COPD, sleep apnea), a certain muscle disease (myasthenia gravis).

Since this drug makes you drowsy, do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. Avoid alcoholic beverages.

Older adults may be more sensitive to the effects of this drug, especially dizziness, confusion, unsteadiness, and excessive drowsiness.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

During pregnancy, this medication should be used only when clearly needed. Infants born to mothers who have taken sedative-hypnotics near the time of delivery may have undesirable effects such as breathing problems or withdrawal symptoms. Discuss the risks and benefits with your doctor.

A small amount of this medication passes into breast milk. Consult your doctor before breast-feeding.

#### **DRUG INTERACTIONS:**

Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

A product that may interact with this drug is: sodium oxybate.

Other medications can affect the removal of zolpidem from your body, which may affect how zolpidem works. Examples include rifampin, azole antifungals such as ketoconazole, HIV protease inhibitors such as ritonavir, among others.

Tell your doctor or pharmacist if you are taking other products that cause drowsiness including alcohol, antihistamines (such as cetirizine, diphenhydramine), other drugs for sleep or anxiety (such as alprazolam, lorazepam, diazepam), muscle relaxants, and narcotic pain relievers (such as codeine).

Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely.

#### **OVERDOSE:**

If overdose is suspected, contact a poison control center or emergency room immediately. US residents can call the US National Poison Hotline at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include slowed breathing or a deep sleep from which you cannot be awakened.

#### **NOTES:**

Do not share this medication with others. It is against the law.

As you get older, your sleep pattern may naturally change and your sleep may be interrupted several times during the night. Consult your doctor or pharmacist for ways to improve your sleep without medication, such as avoiding caffeine and alcohol close to bedtime, avoiding daytime naps, and going to bed at the same time each night.

**MISSED DOSE:**

If you miss a dose, do not take it unless you have time to sleep for 7 to 8 hours afterwards.

**STORAGE:**

Store at room temperature away from light and moisture. Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.