

MEDICATION GUIDE

HALCION Tablets/ C-IV

Read this Medication Guide before you start taking HALCION 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. You and your doctor should talk about the SEDATIVE-HYPNOTIC when you start taking it and at regular checkups.

What is the most important information I should know about HALCION?

After taking a SEDATIVE-HYPNOTIC, 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 a SEDATIVE-HYPNOTIC. Reported activities include:

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

Important:

1. **Take HALCION exactly as prescribed**
 - Do not take more HALCION than prescribed.
 - Take HALCION right before you get in bed, not sooner.
2. **Do not take HALCION 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 HALCION with your other medicines
 - cannot get a full night's sleep
 - are pregnant or considering becoming pregnant
3. **Call your doctor right away if you find out that you have done any of the above activities after taking HALCION.**

What are SEDATIVE-HYPNOTICS?

SEDATIVE-HYPNOTICS are sleep medicines. SEDATIVE-HYPNOTICS are used in adults for the treatment of the symptom of trouble falling asleep due to insomnia. HALCION is not indicated for use in children. Elderly patients are especially susceptible to dose related adverse effects when taking HALCION.

HALCION is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep HALCION in a safe place to prevent misuse and abuse. Selling or giving away HALCION may harm others, and is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take HALCION?

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

SEDATIVE-HYPNOTICS may not be right for you. Before starting SEDATIVE-HYPNOTICS, 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, sometimes causing side effects. **Do not take SEDATIVE-HYPNOTICS 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.

HALCION should not be taken with potent inhibitors of CYP 3A including ketoconazole, itraconazole, nefazodone and possibly other azole-type antifungal agents.

How should I take HALCION?

- **Take HALCION exactly as prescribed.** Do not take more HALCION than prescribed for you.
- **Take HALCION right before you get into bed.** Or you can take the HALCION after you have been in bed and have trouble falling asleep.
- Do not take HALCION with or right after a meal.
- **Do not take HALCION unless you are able to get a full night's sleep before you must be active again.**
- **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 problem.
- If you take too much HALCION or overdose, call your doctor or poison control center right away, or get emergency treatment.

What are the possible side effects of SEDATIVE-HYPNOTICS?

Serious side effects of SEDATIVE-HYPNOTICS include:

- **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 SEDATIVEHYPNOTICS?")
- **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, including "traveler's amnesia"**
- **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 SEDATIVE-HYPNOTICS.

Call your doctor right away if you have any of the above side effects or any other side effects that worry you while using the SEDATIVE-HYPNOTIC.

Common side effects of HALCION include:

- drowsiness
- headache dizziness
- lightheadedness "pins and needles" feelings on your skin
- difficulty with coordination
- You may still feel drowsy the next day after taking HALCION. **Do not drive or do other dangerous activities (including operating machinery) after taking HALCION until you feel fully awake.**
- You may have withdrawal symptoms for 1 to 2 days when you stop taking the SEDATIVEHYPNOTIC suddenly. Withdrawal symptoms include trouble sleeping, unpleasant feelings, stomach and muscle cramps, vomiting, sweating, shakiness, and seizures.

These are not all the side effects of SEDATIVEHYPNOTICS. 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-FDA1088.

How should I store HALCION?

- Store HALCION at room temperature between 68° and 77° F (20° to 25°C).
- Protect from light.
- **Keep HALCION and all medicines out of the reach of children.**
- **Do not use HALCION after the expiration date on the bottle.**

General Information about SEDATIVE-HYPNOTICS

- Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide.
- Do not use the SEDATIVE-HYPNOTIC for a condition for which it was not prescribed.
- Do not give the SEDATIVE-HYPNOTIC to other people, even if they have the same condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about HALCION. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about HALCION that was written for healthcare professionals.

If you would like more information, contact 1-800-879-3477

What are the ingredients in HALCION?

Active Ingredient: Triazolam

Inactive Ingredients: 0.125 mg tablet: cellulose, corn starch, docusate sodium, lactose, magnesium stearate, silicon dioxide, sodium benzoate, 0.25 mg tablet: cellulose, corn starch, docusate sodium, FD&C Blue No. 2, lactose, magnesium stearate, silicon dioxide, sodium benzoate.

Rx only

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