

## MEDICATION GUIDE

### SEDATIVE-HYPNOTIC TABLETS / CAPSULES C-IV

Read this Medication Guide before you start taking a SEDATIVE-HYPNOTIC 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.

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#### **What is the most important information I should know about SEDATIVE-HYPNOTICS?**

**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 SEDATIVE-HYPNOTICS exactly as prescribed**

- Do not take more SEDATIVE-HYPNOTICS than prescribed.
- Take the SEDATIVE-HYPNOTIC right before you get in bed, not sooner.

##### **2. Do not take SEDATIVE-HYPNOTICS 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 SEDATIVE-HYPNOTICS with your other medicines
- cannot get a full night's sleep

##### **3. Call your doctor right away if you find out that you have done any of the above activities after taking the SEDATIVE-HYPNOTIC.**

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#### **What are SEDATIVE-HYPNOTICS?**

SEDATIVE-HYPNOTICS are sleep medicines. SEDATIVE-HYPNOTICS are used in adults for the short-term treatment of the symptom of trouble falling asleep from insomnia. SEDATIVE-HYPNOTICS do not treat other symptoms of insomnia which include waking up too early in the morning and waking up often during the night.

SEDATIVE-HYPNOTICS are not for children.

SEDATIVE-HYPNOTICS are federally controlled substances (C-IV) because they can be abused or lead to dependence. Keep SEDATIVE-HYPNOTICS in a safe place to prevent misuse and abuse. Selling or giving away SEDATIVE-HYPNOTICS 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 SEDATIVE-HYPNOTICS?**

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

**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.

### **How should I take SEDATIVE-HYPNOTICS?**

- **Take SEDATIVE-HYPNOTICS exactly as prescribed.** Do not take more SEDATIVE-HYPNOTIC than prescribed for you.
- **Take SEDATIVE-HYPNOTICS right before you get into bed.** Or you can take the SEDATIVE-HYPNOTIC after you have been in bed and have trouble falling asleep.
- Do not take SEDATIVE-HYPNOTICS with or right after a meal.
- **Do not take SEDATIVE-HYPNOTICS 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 SEDATIVE-HYPNOTIC 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 do an activity that you do not know you are doing.** (See “What is the most important information I should know about SEDATIVE-HYPNOTICS?”)
- **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 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 SEDATIVE-HYPNOTICS include:**

- drowsiness
- headache
- fatigue
- dizziness
- dry mouth
- upset stomach
- You may still feel drowsy the next day after taking the SEDATIVE-HYPNOTIC. **Do not drive or do other dangerous activities after taking the SEDATIVE-HYPNOTIC until you feel fully awake.**
- You may have withdrawal symptoms for 1 to 2 days when you stop taking the SEDATIVE-HYPNOTIC. Withdrawal symptoms include trouble sleeping, unpleasant feelings, stomach and muscle cramps, vomiting, sweating, shakiness, and seizures.

These are not all the side effects of SEDATIVE-HYPNOTICS. Ask your doctor or pharmacist for more information.

**How should I store SEDATIVE-HYPNOTICS?**

- Store SEDATIVE-HYPNOTICS at room temperature between 68° and 77° F (20° to 25°C).
- **Keep SEDATIVE-HYPNOTICS and all medicines out of the reach of children.**

**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 SEDATIVE-HYPNOTICS. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about the SEDATIVE-HYPNOTIC that was written for healthcare professionals.

If you would like more information, contact TEVA Pharmaceuticals at *[please provide contact information]*.

**What are the ingredients in the SEDATIVE-HYPNOTIC?**

**Active Ingredient:** Estazolam

**Inactive Ingredients:**

1 mg tablets - corn starch, lactose monohydrate, pregelatinized starch, and stearic acid

2 mg tablets - corn starch, FD&C Red #40 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, lactose monohydrate, pregelatinized starch, and stearic acid.

**Rx only**

Manufactured By:

TEVA PHARMACEUTICALS USA

Sellersville, PA 18960

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

Revision Date: