

MEDICATION GUIDE

Estazolam (es-TAZE-oh-lam) Tablets, C-IV

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

- **Estazolam is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma and death.**
- After taking estazolam, 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 estazolam. Reported activities include:
 - driving a car (“sleep-driving”)
 - making and eating food
 - talking on the phone
 - having sex
 - sleep-walking

Call your healthcare provider right away if you find out that you have done any of the above activities after taking estazolam.

- Do not take estazolam unless you are able to stay in bed a full night (7 to 8 hours) before you must be active again.
- Do not take more estazolam than prescribed.

What is estazolam?

- Estazolam is a prescription medicine used short-term to treat certain types of insomnia including difficulty falling asleep, waking up often during the night, or waking up early in the morning.
- **Estazolam is a federal controlled substance (C-IV) because it can be abused or lead to dependence.** Keep estazolam in a safe place to prevent misuse and abuse. Selling or giving away estazolam may harm others, and is against the law. Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.
- It is not known if estazolam is safe and effective in children.
- It is not known if estazolam is safe and effective when used to treat insomnia for longer than 12 weeks.

Do not take estazolam if you:

- are allergic to estazolam, other benzodiazepines, or any of the ingredients in estazolam. See the end of this Medication Guide for a complete list of ingredients in estazolam.
- take antifungal medicines called ketoconazole and itraconazole

Before you take estazolam, tell your healthcare provider about all of your medical 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 problems
- have lung disease or breathing problems
- are pregnant or plan to become pregnant. Estazolam may cause birth defects or harm your unborn baby
- are breastfeeding, or plan to breastfeed. Estazolam may pass through your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take estazolam.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking estazolam with certain other medicines can cause side effects or affect how well estazolam or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

Do not take estazolam with other medicines that can make you sleepy unless your healthcare provider tells you to.

How should I take estazolam?

- See “**What is the most important information I should know about estazolam?**”
- Take estazolam exactly as your healthcare provider tells you to take it.
- Take estazolam right before you get into bed. Or you can take estazolam after you have been in bed and have trouble falling asleep.
- Do not take estazolam with or right after a meal.
- Do not take estazolam unless you are able to get a full night’s sleep before you must be active again.
- If you take too much estazolam, get emergency treatment right away.

What should I avoid while taking estazolam?

- Do not drive, operate machinery, do other dangerous activities or do anything that needs you to be alert until you know how estazolam affects you.
- You should not drink alcohol while you are taking estazolam.

What are the possible side effects of estazolam?

Estazolam may cause serious side effects, including:

- See “**What is the most important information I should know about estazolam?**”
- **Other conditions.** 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.
- **Severe allergic reactions.** Symptoms include swelling of the tongue or throat, and trouble breathing. Get emergency medical help right away if you have these symptoms after taking estazolam.
- **Abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts.
- **Withdrawal symptoms.** You may have withdrawal symptoms if you stop taking estazolam suddenly. Withdrawal symptoms can be serious and include seizures. Mild withdrawal symptoms include a depressed mood and trouble sleeping. Talk to your healthcare provider about slowly stopping estazolam to avoid withdrawal symptoms.
- **Abuse and dependence.** Taking estazolam can cause physical and psychological dependence. Physical and psychological dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.

The most common side effects of estazolam include:

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| • drowsiness | • headache | • fatigue |
| • dizziness | • dry mouth | • upset stomach |
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You may still feel drowsy the next day after taking ESTAZOLAM. **Do not drive or do other dangerous activities after taking ESTAZOLAM until you feel fully awake.**

These are not all the possible side effects of estazolam. 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 estazolam?

- Store estazolam tablets in a tightly closed child-resistant container at room temperature between 68° to 77°F (20° to 25°C).
- **Keep estazolam and all medicines out of the reach of children.**

General information about the safe and effective use of estazolam.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use estazolam for a condition for which it was not prescribed. Do not give estazolam to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about estazolam that is written for healthcare professionals.

What are the ingredients in estazolam?

Active Ingredient: estazolam, USP

Inactive Ingredients: docusate sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium benzoate, sodium starch glycolate and stearic acid. The 2 mg tablets also contain FD&C Red #40 aluminum lake.

Manufactured by:

Watson Pharma Private Limited
Verna, Salcette Goa 403 722 INDIA

Distributed by:

Actavis Pharma, Inc.
Parsippany, NJ 07054 USA

If you would like more information, call Actavis at 1-800-272-5525.

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

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