

MEDICATION GUIDE

Eszopiclone (ES-zoe-PIK-lone)

Tablets USP[®]

R_x only

Read the Medication Guide that comes with eszopiclone tablets before you start taking it 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.

What is the most important information I should know about eszopiclone tablets?

- **Do not take more eszopiclone tablets than prescribed.**
- **Do not take eszopiclone tablets unless you are able to stay in bed a full night (7 to 8 hours) before you must be active again.**
- **Take eszopiclone tablets right before you get in bed, not sooner.**

Eszopiclone tablets may cause serious side effects, including:

Complex sleep behaviors that have caused serious injury and death. After taking eszopiclone tablets, you may get up out of bed while not being fully awake and do an activity that you do not know you are doing (complex sleep behaviors). The next morning, you may not remember that you did anything during the night. These activities may occur with eszopiclone tablets whether or not you drink alcohol or take other medicines that make you sleepy.

Reported activities and behaviors include:

- doing activities when you are asleep like:
 - making and eating food
 - talking on the phone
 - having sex
 - driving a car (“sleep-driving”)
 - sleep walking

Stop taking eszopiclone tablets and call your healthcare provider right away if you find out that you have done any of the above activities after taking eszopiclone tablets.

The morning after you take eszopiclone tablets your ability to drive safely and think clearly may be decreased. You also may experience sleepiness during the day.

Do not take eszopiclone tablets if you:

- have ever experienced a complex sleep behavior (such as driving a car, making and eating food, talking on the phone or having sex while not fully awake) after taking eszopiclone tablets.
- drank alcohol that evening or before bed
- 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 eszopiclone tablets with your other medicines.

- cannot get a full night's sleep
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WHAT IS ESZOPICLONE TABLET?

Eszopiclone tablet is a sedative-hypnotic (sleep) medicine. Eszopiclone tablet is used in adults for the treatment of a sleep problem called insomnia. Symptoms of insomnia include:

- trouble falling asleep
- waking up often during the night

Eszopiclone tablets are not for children.

Eszopiclone tablet is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep eszopiclone tablets in a safe place to prevent misuse and abuse. Selling or giving away eszopiclone tablets 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 eszopiclone tablets?

- Do not take eszopiclone tablets if you have ever had a complex sleep behavior happen after taking eszopiclone tablets.
- Do not take eszopiclone tablets if you are allergic to anything in it. See the end of this Medication Guide for a complete list of ingredients in eszopiclone tablets.

Eszopiclone tablets may not be right for you. Before starting eszopiclone tablets, 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 liver disease
- 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 with each other, sometimes causing serious side effects. **Do not take eszopiclone tablets 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 eszopiclone tablets?

- Take eszopiclone tablets exactly as prescribed. Do not take more eszopiclone tablets than prescribed for you.
- **Take eszopiclone tablets right before you get into bed.**
- Do not take eszopiclone tablets with or right after a meal.
- **Do not take eszopiclone tablets unless you are able to get a full night's sleep before you must be active again.**

- **Call your doctor if your insomnia worsens or is not better within 7 to 10 days.** This may mean that there is another condition causing your sleep problems.
- If you take too much eszopiclone tablets or overdose, call your doctor or poison control center right away, or get emergency treatment.

What are the possible side effects of eszopiclone tablets?

Possible serious side effects of eszopiclone tablets 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 eszopiclone tablets?”)
- **abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, acting strangely, 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 eszopiclone tablets.

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

The most common side effects of eszopiclone tablets are:

- unpleasant taste in mouth, dry mouth
- drowsiness
- dizziness
- headache
- symptoms of the common cold
- You may still feel drowsy the next day after taking eszopiclone tablets. **Do not drive or do other dangerous activities after taking eszopiclone tablets until you feel fully awake.**

These are not all the side effects of eszopiclone tablets. 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-FDA-1088. You may also report side effects to Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

How should I store eszopiclone tablets?

- Store eszopiclone tablets at room temperature, between 59° F to 86° F (15° C to 30° C).
- Do not use eszopiclone tablets after the expiration date.
- **Keep eszopiclone tablets and all medicines out of reach of children.**

General Information about eszopiclone tablets

- Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.
- Do not use eszopiclone tablets for a condition for which it was not prescribed.

- Do not share eszopiclone tablets with other people, even if you think they have the same symptoms that you have. It may harm them and is against the law.

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

- To report side effects, call 1-800-399-2561.

What are the ingredients in eszopiclone tablets?

Active Ingredient: eszopiclone

Inactive Ingredients: colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, hypromellose, lactose monohydrate, polyethylene glycol, povidone, pregelatinized starch, magnesium stearate and titanium dioxide. In addition, both the 1 mg and 3 mg tablets contain FD&C Blue #2.

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

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Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

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Manufactured by:

Lupin Limited

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