



Manufactured for:

**Sunovion Pharmaceuticals Inc.**

Marlborough, MA 01752 USA

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## MEDICATION GUIDE

### LUNESTA<sup>®</sup> (lū'-nes''-tǎ) Tablets, Coated C-IV (eszopiclone)

Read the Medication Guide that comes with LUNESTA 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.

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#### **What is the most important information I should know about LUNESTA?**

**After taking LUNESTA, 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 LUNESTA. Reported activities include:

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

**Call your doctor right away if you find out that you have done any of the above activities after taking LUNESTA.**

**Important:**

**1. Take LUNESTA exactly as prescribed**

- Do not take more LUNESTA than prescribed.
- Take LUNESTA right before you get in bed, not sooner.

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

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## **WHAT IS LUNESTA?**

LUNESTA is a sedative-hypnotic (sleep) medicine. LUNESTA 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

LUNESTA is not for children.

<p>LUNESTA is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep LUNESTA in a safe place to prevent misuse and abuse. Selling or giving away LUNESTA 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.</p>
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## Who should not take LUNESTA?

Do not take LUNESTA if you are allergic to anything in it.

See the end of this Medication Guide for a complete list of ingredients in LUNESTA.

**LUNESTA may not be right for you. Before starting LUNESTA, 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 LUNESTA 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 LUNESTA?

- Take LUNESTA exactly as prescribed. Do not take more LUNESTA than prescribed for you.
- **Take LUNESTA right before you get into bed.**
- Do not take LUNESTA with or right after a meal.
- **Do not take LUNESTA 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 LUNESTA or overdose, call your doctor or poison control center right away, or get emergency treatment.

## What are the possible side effects of LUNESTA?

**Possible serious side effects of LUNESTA 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 LUNESTA?”)
- **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 LUNESTA.

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

**The most common side effects of LUNESTA 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 LUNESTA. **Do not drive or do other dangerous activities after taking LUNESTA until you feel fully awake.**

These are not all the side effects of LUNESTA. 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.

**How should I Store LUNESTA?**

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

**General Information about LUNESTA**

- Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.
- Do not use LUNESTA for a condition for which it was not prescribed.
- Do not share LUNESTA 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 LUNESTA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about LUNESTA that is written for healthcare professionals.

- For customer service, call 1-888-394-7377.
- To report side effects, call 1-877-737-7226.
- For medical information, call 1-800-739-0565.

**What are the ingredients in LUNESTA?**

**Active Ingredient:** eszopiclone

**Inactive Ingredients:** calcium phosphate, colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol,

titanium dioxide, and triacetin. 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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