


MEDICATION GUIDE
Zaleplon Capsules USP 
(zal' e plon)
Rx only

Read this Medication Guide before you start taking zaleplon 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 zaleplon when you start taking it and at regular checkups.

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

Zaleplon may cause serious side effects including complex sleep behaviors that may cause serious injury and death. After taking zaleplon, 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 zaleplon whether or not you drink alcohol or take other medicines that make you sleepy.

Reported activities include:

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

Important:

1. Take zaleplon exactly as prescribed

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

2. Do not take zaleplon 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 zaleplon
- 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 zaleplon with your other medicines
- cannot get a full night’s sleep

3. Stop taking zaleplon and call your doctor right away if you find out that you have done any of the above activities after taking zaleplon.

What is zaleplon?

Zaleplon is a sedative-hypnotic (sleep) medicine. Zaleplon is used in adults for the short-term treatment of the symptom of trouble falling asleep from insomnia. Zaleplon does not treat other symptoms of insomnia which include waking up too early in the morning and waking up often during the night.

Zaleplon is not for children.

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

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

Zaleplon may not be right for you. Before starting zaleplon, 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 zaleplon 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 zaleplon?

- **Take zaleplon exactly as prescribed.** Do not take more zaleplon than prescribed for you.
- **Take zaleplon right before you get into bed.** Or you can take zaleplon after you have been in bed and have trouble falling asleep.
- Do not take zaleplon with or right after a meal.
- **Do not take zaleplon 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 zaleplon or overdose, call your doctor or poison control center right away, or get emergency treatment.

A/s: 150 x 260 mm ■ Black

 AUROBINDO Packaging Development	Product Name	Component	Item Code	Date & Time
	Zaleplon Capsules USP	MG	P1522632	17.09.2019 & 05.00 pm
	Country	Version No.	Reason of Issue	Reviewed / Approved by
	USA - Rising Health	00	Commercial	
Team Leader	Jagan	Dimensions (mm)	Colours: 01	
Initiator	Riyaz	A/s: 150 x 260 mm		
Artist	Sree Designers			
Additional Information:	Supersede Code : P1516160			
VittalBala	Apl Ref Code: P1522410			

What are the possible side effects of zaleplon?

Serious side effects of zaleplon 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 zaleplon?”)
- **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 zaleplon.

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

Common side effects of zaleplon include:

- drowsiness
- lightheadedness
- dizziness
- “pins and needles” feeling on your skin
- difficulty with coordination
- You may still feel drowsy the next day after taking zaleplon. **Do not drive or do other dangerous activities after taking zaleplon until you feel fully awake.**
- You may have withdrawal symptoms when you stop taking zaleplon. Withdrawal symptoms include unpleasant feelings, stomach and muscle cramps, vomiting, sweating, shakiness, and rarely seizures. You may also have more trouble sleeping the first few nights after zaleplon is stopped. The problem usually goes away on its own after 1 or 2 nights.

These are not all the side effects of zaleplon. 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 zaleplon?

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

General Information about zaleplon

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

If you would like more information, contact the Rising Health, LLC at 1-833-395-6928.

What are the ingredients in zaleplon capsules?

Active Ingredient: zaleplon

Inactive Ingredients: microcrystalline cellulose, lactose monohydrate, pregelatinized starch (maize), sodium lauryl sulfate, colloidal silicon dioxide, and stearic acid. The empty hard gelatin capsule shells contain FD&C Blue #1, FD&C Green #3, FD&C Yellow #5, titanium dioxide, and gelatin. The capsules are printed with edible ink containing black iron oxide and shellac.

- **Zaleplon Capsules USP, 5 mg** are Opaque green/opaque pale green colored, size ‘4’ hard gelatin capsule filled with white to off-white powder and imprinted with ‘E19’ on opaque green cap and ‘5 mg’ on opaque pale green body with black ink.
- **Zaleplon Capsules USP, 10 mg** are Opaque green/opaque light green colored, size ‘4’ hard gelatin capsule filled with white to off-white powder and imprinted with ‘E20’ on opaque green cap and ‘10 mg’ on opaque light green body with black ink.

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

Dispense with Medication Guide available at : <http://www.risingpharma.com/med-guides.html>

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