

#### Home

2. Ramelteon

## Ramelteon

**Generic name:** ramelteon [ ram-EL-tee-on ]

Brand name: Rozerem

Dosage form: oral tablet (8 mg)

Drug class: Miscellaneous anxiolytics, sedatives and hypnotics



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Uses Side effects Warnings Before taking Dosage Interactions FAQ

## What is ramelteon?

Ramelteon is a sedative, also called a hypnotic. It works by affecting certain substances in your body that help regulate your "sleep-wake cycle."

Ramelteon is used to treat insomnia that is associated with having trouble falling asleep.

Ramelteon may also be used for purposes not listed in this medication guide.

## Ramelteon side effects

Ramelteon may cause a severe allergic reaction. Get emergency medical help if you have signs of an allergic reaction: hives; difficult breathing; nausea and vomiting; swelling of your face, lips, tongue, or throat.

Some people using ramelteon have engaged in activity while not fully awake and later had no memory of it. This may include walking, driving, eating, having sex, or making phone calls. If this happens to you, call your doctor right away.

Ramelteon may cause serious side effects. Call your doctor at once if you have:

- unusual thoughts or behavior, hallucinations, worsening depression, thoughts about hurting yourself;
- a missed menstrual period;
- · nipple discharge; or
- · loss of interest in sex.

### Common side effects of ramelteon may include:

- drowsiness, tired feeling;
- dizziness;

- · nausea; or
- worsening sleep problems.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

• Ramelteon side effects (more detail)

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## Warnings

You should not use ramelteon if you are also taking fluvoxamine, or if you have ever had a severe allergic reaction to ramelteon.

Ramelteon may cause a severe allergic reaction. Get emergency medical help if you have hives; difficult breathing; nausea and vomiting; swelling of your face, lips, tongue, or throat.

Some people using this medicine have engaged in activity while not fully awake and later had no memory of it. If this happens to you, call your doctor right away.

## Before taking this medicine

Ramelteon will make you fall asleep. Never take ramelteon during your normal waking hours, unless you have at least 7 to 8 hours to dedicate to sleeping.

You should not use ramelteon if you are allergic to it, or if:

- you have severe liver disease; or
- · you also take fluvoxamine.

Tell your doctor if you have ever had:

- · liver disease;
- · breathing problems;
- sleep apnea (breathing stops while you are asleep); or
- depression, mental illness, or suicidal thoughts.

Tell your doctor if you are pregnant or breastfeeding.

You should not breastfeed within 25 hours after using ramelteon. If you use a breast pump during this time, throw out any milk you collect. Do not feed it to your baby.

Ramelteon may affect the levels of male or female hormones (testosterone or prolactin). This may affect menstrual periods in women, sexual desire in men, or fertility (ability to have children) in either a man or a woman.

Ramelteon is not approved for use by anyone younger than 18 years old.

## How should I take ramelteon?

Follow all directions on your prescription label and read all medication guides or instruction sheets. Use the medicine exactly as directed.

Take ramelteon 30 minutes before your normal bedtime.

Swallow the tablet whole and do not crush, chew, or break it.

Ramelteon should not be taken with or after a high-fat meal. This will make it harder for your body to absorb the medication.

Call your doctor if your symptoms do not improve after 7 to 10 days of using ramelteon.

Store at room temperature away from moisture and heat. Keep the bottle tightly closed when not in use.

## Ramelteon dosing information

**Usual Adult Dose for Insomnia:** 

8 mg orally within 30 minutes of going to bed

Maximum Dose: 8 mg per day

Comments: This drug should not be taken with or immediately after a high-fat meal.

Use: Treatment of insomnia characterized by difficulty with sleep onset

Detailed Ramelteon dosage information

# What happens if I miss a dose?

Since ramelteon is taken only at bedtime if needed, you are not likely to miss a dose. **Never take this medication if you do not have 7 to 8 hours to sleep before being active again.** 

Do not take two doses at one time.

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

## What should I avoid while taking ramelteon?

#### Do not drink alcohol with ramelteon.

Avoid driving or hazardous activity until you know how this medicine will affect you. Your reactions could be impaired.

## What other drugs will affect ramelteon?

Using ramelteon with other drugs that make you drowsy can worsen this effect. Ask your doctor before using opioid medication, a sleeping pill, a muscle relaxer, or medicine for anxiety or seizures.

Sometimes it is not safe to use certain medications at the same time. Some drugs can affect your blood levels of other drugs you take, which may increase side effects or make the medications less effective.

Other drugs may affect ramelteon, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all your current medicines and any medicine you start or stop using.

• Ramelteon drug interactions (more detail)

## Does ramelteon interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.



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## **Further information**

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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### **DRUG STATUS**

### **Availability**

Rx Prescription only

### **Pregnancy & Lactation**

ം Risk data available

### **CSA Schedule\***

N/A Not a controlled drug

### Approval History

The Drug history at FDA

## **User Reviews & Ratings**

## **Images**

## Ramelteon 8 mg (AC 414)





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