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#### Ramelteon: Patient drug information

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(For additional information see "Ramelteon: Drug information")

#### **Brand Names: US** Rozerem

#### What is this drug used for?

· It is used to treat sleep problems.

### What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to ramelteon or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor
  about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough;
  swelling of face, lips, tongue, or throat; or any other signs.
- · If you have liver disease.
- · If you have sleep apnea.
- If you do not have time to get a full night's sleep.
- If you are taking fluvoxamine.
- If you are taking any other drugs that can make you sleepy. There are many drugs that can do this. Ask your doctor or pharmacist if you are not sure.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

## What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert after you take this drug. You may
  still feel sleepy the day after you take this drug. Avoid these tasks or actions until you feel fully awake.
- Avoid alcohol while taking this drug. Do not take this drug if you drank alcohol that evening or before bed.
- Talk with your doctor before you use other drugs and natural products that slow your actions.
- Some people have done certain tasks or actions while they were not fully awake like driving, making and eating food, and having sex. Most of the time, people do not remember doing these things. Tell your doctor if this happens to you.
- Do not take this drug unless you can get a full night's sleep (at least 7 to 8 hours) before you need to be active again.
- This drug is not approved for use in children. Talk with the doctor.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits
  and risks of using this drug while you are pregnant.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

### What are some side effects that I need to call my doctor about right away?

**WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of low mood (depression), thoughts of killing yourself, nervousness, emotional ups and downs, thinking that is not normal, anxiety, or lack of interest in life.
- · Feeling confused.
- · Change in how you act.
- · Hallucinations (seeing or hearing things that are not there).
- · Bad dreams.
- · Memory problems or loss.
- · Upset stomach or throwing up.
- For women, no period.
- · Nipple discharge.
- · Lowered interest in sex.
- Trouble getting pregnant.
- A very bad reaction called angioedema has happened with this drug. Sometimes, this may be lifethreatening. Signs may include swelling of the hands, face, lips, eyes, tongue, or throat; trouble breathing; trouble swallowing; or unusual hoarseness. Get medical help right away if you have any of these signs.

## What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- · Feeling sleepy.
- · Dizziness.
- · Feeling tired or weak.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

#### How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- · Take within 30 minutes of bedtime.
- · Avoid taking this drug with or right after high-fat meals.
- · Swallow tablet whole. Do not chew, break, or crush.
- After you take this drug, only do things needed to get ready for bed.
- If you still have trouble sleeping after 7 to 10 days, call your doctor.

#### What do I do if I miss a dose?

 Many times this drug is taken on an as needed basis. Do not take more often than every 24 hours unless told to do so by your doctor.

## How do I store and/or throw out this drug?

- Store at room temperature.
- Store in a dry place. Do not store in a bathroom.
- · Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told
  to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There
  may be drug take-back programs in your area.

# General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.

- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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