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MEDICATION GUIDE

RAMELTEON TABLETS (ram-EL-tee-on)

Read the Medication Guide that comes with ramelteon 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 ramelteon tablets?

Ramelteon tablets may cause 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 ramelteon tablets.

After taking ramelteon 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. 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 ramelteon tablets. Activities may 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 ramelteon tablets.

Important:

1. Take ramelteon tablets exactly as prescribed

- Do not take more ramelteon tablets than prescribed.
- Take ramelteon tablets within 30 minutes of going to bed, not sooner.

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

What are ramelteon tablets?

Ramelteon tablets are a hypnotic (sleep) medicine. Ramelteon tablets are used in adults for the treatment of the symptom of trouble falling asleep from insomnia.

Ramelteon tablets are not for children.

Who should not take ramelteon tablets?

Do not take ramelteon tablets if you are allergic to anything in it. See the end of this Medication Guide for a complete list of ingredients in ramelteon tablets.

Do not take ramelteon tablets if you are currently taking Luvox (fluvoxamine).

Ramelteon tablets may not be right for you. Before starting ramelteon tablets, tell your doctor about all of your health conditions, including if you:

- have a history of depression, mental illness, or suicidal thoughts
- have liver disease
- have a lung disease or breathing problems
- are pregnant, or planning to become pregnant
- are breastfeeding or plan to breastfeed. Ramelteon tablets may cause somnolence in a breastfed infant. You may consider interrupting breastfeeding and pumping and discarding breastmilk during treatment and for 25 hours after administration of ramelteon tablets.

Tell your doctor about all of the medicines you take including prescription and non-prescription medicines, vitamins and herbal supplements. Medicines can interact with each other, sometimes causing serious side effects.

Do not take ramelteon tablets with:

- **other medicines that can make you sleepy**
- **Luvox (fluvoxamine)**

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 ramelteon tablets?

- Take ramelteon tablets exactly as prescribed. Do not take more ramelteon tablets than prescribed for you.
- Do not break the tablets. They should be swallowed whole.
- **Take ramelteon tablets within 30 minutes of going to bed.** After taking ramelteon tablets only do activities to get ready for bed.
- Do not take ramelteon tablets with or right after a meal.
- **Do not take ramelteon 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 ramelteon tablets or overdose, call your doctor or poison control center right away, or get emergency treatment.

What are the possible side effects of ramelteon tablets?

Possible serious side effects of ramelteon tablets include:

- **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 ramelteon tablets.
- **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 ramelteon tablets?"")
- **abnormal thoughts and behavior.** Symptoms include worsening of depression, suicidal thoughts or actions, nightmares, and hallucinations.
- **hormone effects.** Ramelteon tablets can decrease testosterone levels and increase prolactin levels in the blood. Symptoms of low testosterone or high prolactin levels are:
 - **decreased interest in sex**
 - **problems getting pregnant**
 - **irregular menstrual periods or no menstrual periods**
 - **leakage of milk from the nipples of a person who is not breast feeding**

Call your doctor right away if you have any of the above side effects or any other side effects that worry you while using ramelteon tablets. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

The most common side effects of ramelteon tablets are:

- drowsiness
- tiredness
- dizziness
- You may still feel drowsy the next day after taking ramelteon tablets. **Do not drive or do other dangerous activities after taking ramelteon tablets until you feel fully awake.**

These are not all the side effects of ramelteon tablets. Ask your doctor or pharmacist for more information.

How should I Store ramelteon tablets?

- Store ramelteon tablets at room temperature, 59° to 86°F (15° to 30°C). Keep the container tightly closed and protected from moisture and humidity.
- **Keep ramelteon tablets and all medicines out of reach of children.**

General Information about ramelteon tablets

- Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.
- Do not use ramelteon tablets for a condition for which it was not prescribed.
- Do not share ramelteon tablets with other people, even if you think they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about ramelteon tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ramelteon tablets that is written for healthcare professionals. For more information about ramelteon tablets, please contact Granules Pharmaceuticals Inc. at 1-877-770-3183 or visit www.granulesindia.com.

What are the ingredients in ramelteon tablets?

Active Ingredient: ramelteon

Inactive Ingredients: copovidone, corn starch, hydroxypropyl cellulose, iron oxide yellow, lactose monohydrate, magnesium stearate, polyethylene glycol, and titanium dioxide.

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

Manufactured by:

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Chantilly, VA 20151

Rev. 05/2023