



Patient Information Sheet

Ramelteon tablets (marketed as Rozerem®)

This is a summary of the most important information about Rozerem. For details, talk to your healthcare professional.

What Is Rozerem?

Rozerem is a prescription medicine for adults to treat insomnia where the problem is trouble falling asleep.

Rozerem has not been studied in children. It is not known if Rozerem is safe and effective for children.

Who Should Not Take Rozerem?

You should not take Rozerem if you have any of the following conditions:

- are allergic to ramelteon or any of its ingredients
- have severe liver disease

What Are The Risks?

The following are the major potential risks and side effects of Rozerem therapy. However, this list is not complete. The following are the major potential risks and side effects of Rozerem therapy:

- **Worsening of insomnia, mental, or behavior changes.** These may happen if your insomnia is caused by a mental or medical problem. Your healthcare professional should check you carefully for other health problems before prescribing Rozerem. Tell your healthcare professional if you develop:
 - worse insomnia
 - mental problems including thoughts of harming yourself
 - behavior changes
- **Drowsiness.** Rozerem may affect your ability to drive or do other dangerous activities. Do not do these activities after taking Rozerem. After taking Rozerem, do only activities needed to get ready for bed.
- **Affect reproductive hormones.** Rozerem may affect the reproductive hormones by increasing prolactin and potentially decreasing testosterone levels. This may cause missed monthly periods, nipple drainage, decreased sex drive, or problems getting pregnant. Your healthcare professional may do blood tests to check your hormone levels if you have any of these symptoms.

- **Some common side effects** that may occur with Rozerem include:
 - headache
 - daytime sleepiness
 - dizziness
 - tiredness
 - nausea
 - worsening insomnia
 - colds

What Should I Tell My Healthcare Professional?

Before you start taking Rozerem, tell your healthcare professional if you:

- have or had liver disease
- have breathing problems when you sleep (severe sleep apnea) or a lung disease called severe chronic obstructive pulmonary disease (COPD). Rozerem is not recommended if you have these problems.
- are trying to become pregnant, already pregnant, or are breastfeeding

Can Other Medicines or Food Affect Rozerem?

Rozerem and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how Rozerem works or Rozerem may affect how your other medicines work. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

Especially, tell your healthcare professional if you take:

- fluvoxamine (Luvox®)
- rifampin (Rifadin®)
- ketoconazole (Nizoral®)
- fluconazole (Diflucan®)

Tell your healthcare provider if you drink alcohol. Alcohol may increase the side effects with Rozerem.





Patient Information Sheet

Ramelteon tablets (marketed as Rozerem®)

How Should I Take Rozerem?

- Take Rozerem by mouth within 30 minutes of going to bed.
- Do not take Rozerem with or right after a high fat meal.

Rozerem Approved 2005

