

## Ramelteon as a Treatment for Insomnia

Insomnia affects as many as 1 out of every 3 people. It is defined as trouble falling asleep or difficulty staying asleep. Sleeping without getting restful sleep—which can have a negative effect on work performance or social interactions—may also be considered insomnia.

With the exception of ramelteon (Rozerem), a drug that was approved by the FDA in 2005, all drugs used to treat insomnia have the potential to be abused. Ramelteon works differently from all other insomnia medications. This relatively new drug stimulates proteins in the brain called melatonin receptors. These proteins are found in a specific part of the brain that controls sleep and wakefulness. Compared with melatonin, the body's own hormone that stimulates melatonin receptors, ramelteon binds to the proteins 1000 times more strongly.

More than 1250 people have taken ramelteon in clinical trials designed to assess its effectiveness and safety. Overall, it appears that the drug decreases the time needed to fall asleep and increases the amount of time that people stay asleep.



Stimulation of melatonin receptors may alter levels of other hormones, especially hormones involved with reproduction. This could lead to breast milk production (even in men!), menstrual disturbances, decreased sex drive, and difficulty getting pregnant, but so far these issues have not been too problematic in clinical studies with ramelteon. The side effects most common with ramelteon appear to be headache, fatigue, and dizziness. Compared with other sleeping pills, ramelteon is unlikely to be abused because it does not cause euphoric feelings and patients do not become dependent upon it. This is an advantage of ramelteon over other sleeping medications. Ramelteon does not cause next-day drowsiness or impair alertness, memory, or ability to concentrate. In addition, ramelteon does not affect balance or stability, which is especially good news for elderly patients because traditional sleeping pills can make older people more prone to falls.

### FOR MORE INFORMATION

American Academy of Family Physicians  
<http://familydoctor.org/online/famdocen/home/articles/110.printinterview.html>

National Heart Lung and Blood Institute  
[www.nhlbi.nih.gov/health/dci/Diseases/inso/inso\\_what.html](http://www.nhlbi.nih.gov/health/dci/Diseases/inso/inso_what.html)

Based on "Ramelteon: A Novel Approach in the Treatment of Insomnia," by Jill Reynoldson, Ellie Elliott, Leigh Anne Nelson, *The Annals of Pharmacotherapy*, September 2008, <http://dx.doi.org/10.1345/aph.1K676>. For Our Patients is provided by *The Annals* to help explain the latest research and information relating to your medications. These summaries are for informational purposes only and are not a substitute for professional advice from your personal medical provider. If you have questions about this material, you should discuss it with your physician or pharmacist. This summary may be reproduced without permission for not-for-profit educational purposes only. Any other use must be approved by the publisher. © Copyright 2008, Harvey Whitney Books Company, [www.hwbooks.com](http://www.hwbooks.com). FOPE15 DOI 10.1345/fop.1K676

Ramelteon may not be for everyone, however. The medication should not be taken by individuals with severe chronic obstructive pulmonary disease (COPD) or severe sleep apnea because it has not been studied in patients with these conditions.

Currently, the suggested dose of ramelteon is 8 mg taken 30 minutes before bedtime. It should be

taken on an empty stomach. Meals, especially high-fat meals, cause the drug to be less effective. It is wise to avoid activities that require mental alertness (such as driving a car) after taking ramelteon. If symptoms of insomnia do not improve after taking the medication for 7–10 nights, you should talk to your healthcare provider for further evaluation.