

Heightened Craving Precedes Smoking Relapse

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VANCOUVER, B.C. — Women appear to experience a 2- to 5-day period of heightened withdrawal and craving symptoms just prior to smoking relapse, offering what could be a golden opportunity for intervention, researchers reported at the annual meeting of the North American Primary Care Research Group.

The finding was a serendipitous discov-

ery from a larger trial investigating associations between the menstrual cycle and smoking withdrawal, explained Dr. Bruce A. Center of the department of family practice and community health at the University of Minnesota, Minneapolis.

Participants included 137 female smokers aged 18-40 years who completed an intensive, month-long study as part of a larger, longitudinal smoking cessation trial sponsored by the National Institutes of Health. At baseline and for 30 days fol-

lowing an assigned quit date, they completed daily logs of specific symptoms of withdrawal, nicotine craving, and smoking urges, as well as negative affect.

Despite education, phone counseling, and monitoring, 111 enrollees relapsed over the course of the study.

The intensity of craving, withdrawal, and smoking urges rose quite precipitously during the 2-5 days prior to relapse, when it peaked. All of the symptoms declined after relapse occurred.

“Frankly, I didn’t think there would be a window [of symptom escalation], or if there was, it would be 15 minutes,” Dr. Center said. The next step will be to design and test an intervention that educates women in how to recognize and monitor their symptoms and take steps to prevent relapse once they recognize an escalation.

More work will be necessary to determine the most effective tools for staving off relapse when an uptick in symptoms is recognized, Dr. Center said. ■

Can be used safely in patients for whom substance abuse is a concern

- Clinical studies have shown no evidence of potential abuse, dependence, or withdrawal†
- Rozerem has shown zero evidence of potential abuse at up to 20 times the recommended dose⁴
- A single 8-mg dose can be used safely in patients for whom substance abuse may be a concern and who are not actively abusing³

*Sustained efficacy has been shown over 5 weeks in clinical studies in adults and older patients.^{1,2}

†Rozerem is not a controlled substance. A clinical abuse liability study showed no differences indicative of abuse potential between Rozerem and placebo at doses up to 20 times the recommended dose (N=14). Three 35-day insomnia studies showed no evidence of rebound insomnia or withdrawal symptoms with Rozerem compared to placebo (N=2082).^{3,4}

Please visit www.rozerem.com

Rozerem is indicated for the treatment of insomnia characterized by difficulty with sleep onset. Rozerem can be prescribed for long-term use.

Important Safety Information

Rozerem should not be used in patients with hypersensitivity to any components of the formulation, severe hepatic impairment, or in combination with fluvoxamine. Failure of insomnia to remit after a reasonable period of time should be medically evaluated, as this may be the result of an unrecognized underlying medical disorder. Hypnotics should be administered with caution to patients exhibiting signs and symptoms of depression. Rozerem has not been studied in patients with severe sleep apnea, severe COPD, or in children or adolescents. The effects in these populations are unknown. Avoid taking Rozerem with alcohol. Rozerem has been associated with decreased testosterone levels and increased prolactin levels. Health professionals should be mindful of any unexplained symptoms which could include cessation of menses or galactorrhea in females, decreased libido or problems with fertility that are possibly associated with such changes in these hormone levels. Rozerem should not be taken with or immediately after a high-fat meal. Rozerem should be taken within 30 minutes before going to bed and activities confined to preparing for bed. The most common adverse events seen with Rozerem that had at least a 2% incidence difference from placebo were somnolence, dizziness, and fatigue.

Please see adjacent Brief Summary of Prescribing Information.

References: 1. Zammit G, Erman M, Wang-Weigand S, Sainati S, Zhang J, Roth T. Evaluation of the efficacy and safety of ramelteon in subjects with chronic insomnia. *J Clin Sleep Med*. 2007;3:495-504. 2. Roth T, Seiden D, Sainati S, Wang-Weigand S, Zhang J, Zee P. Effects of ramelteon on patient-reported sleep latency in older adults with chronic insomnia. *Sleep Med*. 2006;7:312-318. 3. Rozerem package insert, Takeda Pharmaceuticals America, Inc. 4. Johnson MW, Suess PE, Griffiths RR. Ramelteon: a novel hypnotic lacking abuse liability and sedative adverse effects. *Arch Gen Psychiatry*. 2006;63:1149-1157.

Visit www.rxrozerem.com/substanceabuse to learn how Rozerem may be appropriate for a variety of patients with insomnia who have difficulty falling asleep.



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