

Hormone Combo Eased Vasomotor Symptoms

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WASHINGTON — Postmenopausal women who took a low-dose estrogen/progestin medication reported significant improvements in vasomotor symptoms and quality of life after 6 months, according to findings from an open-label efficacy study.

The therapy caused a significant increase in triglycerides, from an average of 129 mg/dL at baseline to an average of 168

mg/dL after 6 months. But the women had no other significant changes in their lipid profiles or in their body weight, body mass index, or blood glucose during the study period, Dr. Fernando Ayala Aguilera of the Hospital Universitario, Monterrey (Mexico), and colleagues reported in a poster presentation at the annual meeting of the American Society for Reproductive Medicine.

In the study, sponsored by Wyeth Pharmaceuticals, 68 postmenopausal women aged 45-55 years who reported at least four

hot flashes a day received a combination of 1 mg 17 β -estradiol and 0.125 mg trimegestone orally each day for 6 months. Women without an intact uterus, with known or suspected breast cancer, or with abnormal bleeding were excluded.

Patient scores on the MENQOL (a questionnaire designed to evaluate the quality of life symptoms in menopausal women) dropped from an average of 78 at baseline to an average of 5 after 6 months of treatment. Scores on the Blatt-Kupperman

menopausal index dropped from an average of 40 at baseline to an average of 8 after 6 months. The average total cholesterol was stable between baseline and 6 months. Blood glucose, body weight, and body mass index were essentially also unchanged.

The preliminary results suggest the combination may provide enough relief from menopausal symptoms to outweigh the potential risks of increased triglycerides in the absence of other adverse effects on lipid profiles. ■

Rozerem did not impair balance or memory in older adults[†]

- Rozerem improves sleep in older adults, significantly reducing time to fall asleep and demonstrating sustained efficacy through 5 weeks²
- Rozerem has not been shown to impair middle-of-the-night balance or memory in older adults with chronic insomnia compared with placebo^{†4}
- A single 8-mg dose can be used safely in older adults³

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

†Patients should be advised to avoid engaging in hazardous activities (such as operating a motor vehicle or heavy machinery) after taking Rozerem.³

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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. Wang-Weigand S, Zammit G, Peng X. Placebo-controlled, double-blind trial examining the effects of ramelteon vs placebo with zolpidem as a reference on balance in older adults after middle-of-the-night awakening. Poster presented at: American Psychiatric Association Annual Meeting; May 19-24, 2007; San Diego, Calif. Poster NR604.

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



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