

Midurethral Sling May Aid Incontinence, QOL

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HOLLYWOOD, FLA. — Symptom and quality-of-life improvements were noted at 3-year follow-up by most of the women who received a midurethral sling to treat stress urinary incontinence.

Dr. John B. Gebhart reported the findings of the single-surgeon case series study at the annual meeting of the American Urogynecologic Society. Follow-up data

were available for 75 of 113 patients who received the Uretex Urethral Support device, which was introduced in 2001 by CR Bard Inc. The company provided a research grant for the study.

Dr. Gebhart, a urogynecologist and reconstructive pelvic surgeon, and a member of the obstetrics and gynecology faculty at the Mayo Clinic, Rochester, Minn., initiated the study in 2002. He or his surgery fellow implanted the Uretex device in 113 women with stress urinary in-

continence. Some of these patients also presented with pelvic organ prolapse or mixed incontinence with a predominant stress component; 16 of the 75 women (21%) had undergone prior surgery for incontinence and 43 patients (57%) had undergone prior surgery for pelvic organ prolapse. Patients' mean age at follow-up was 63 years, mean body mass index was 30 kg/m², and median parity was 3.

At baseline and follow-up, researchers assessed history, performed a physical ex-

amination, and measured quality of life using the validated Urinary Distress Inventory-6 (UDI-6) and Incontinence Impact Questionnaire-7 (IIQ-7). Median scores on quality-of-life measures had significantly improved at follow-up compared with baseline, Dr. Gebhart said.

Also, all 75 women passed a cough stress test at a comfortably full bladder; 65 had no leakage during a leak point pressure test at 300 mL; and 62 participants had a negative 1-hour pad test. ■

Patients are not likely to feel sedated, become dependent, or feel "hungover"

- Rozerem is the only prescription insomnia medication that works with the body's sleep-wake cycle to promote sleep and has not been associated with sedation³⁻⁸
- Clinical studies have shown no evidence of potential abuse, dependence, or withdrawal†
- Across several studies, no clinically relevant next-day residual effects were seen with respect to memory (Word List Memory Test), psychomotor performance (DSST), mood and feelings (VAS), or alertness and concentration (Post-sleep Questionnaire) when Rozerem was compared to placebo‡¹⁰

*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).^{3,9}

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

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. Kato K, Hirai K, Nishiyama K, et al. Neurochemical properties of ramelteon (TAK-375), a selective MT₁/MT₂ receptor agonist. *Neuropharmacology.* 2005;48:301-310. 5. Sieghart W, Sperk G. Subunit composition, distribution and function of GABA_A receptor subtypes. *Curr Top Med Chem.* 2002;2:795-816. 6. Rudolph U, Crestani F, Benke D, et al. Benzodiazepine actions mediated by specific γ -aminobutyric acid_A receptor subtypes. *Nature.* 1999;401:796-800. 7. Rowlett JK, Platt DM, Lelas S, Atack JR, Dawson GR. Different GABA_A receptor subtypes mediate the anxiolytic, abuse-related, and motor effects of benzodiazepine-like drugs in primates. *Proc Natl Acad Sci U S A.* 2005;102(suppl 3):915-920. 8. Landolt HP, Gillin JC. GABA_A receptors: involvement in sleep regulation and potential of selective agonists in the treatment of insomnia. *CNS Drugs.* 2000;13:185-199. 9. Johnson MW, Suess PE, Griffiths RR. Ramelteon: a novel hypnotic lacking abuse liability and sedative adverse effects. *Arch Gen Psychiatry.* 2006;63:1149-1157. 10. Data on file, Takeda Pharmaceuticals North America, Inc.

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

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