

Fesoterodine Eases Overactive Bladder Symptoms

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SAVANNAH, GA. — Fesoterodine appears to significantly improve the symptoms of overactive bladder in women with an apparent dose-related response, according to a subanalysis of pooled data from two phase III clinical trials involving more than 1,500 women.

Women randomized to either 4 mg or 8 mg of fesoterodine showed significant-

ly greater improvement in the average number of micturitions per day, the average number of urgency urinary incontinence episodes per day, and perceived treatment response, Dr. Peter K. Sand reported in a poster presented at the annual meeting of the Society of Gynecologic Surgeons.

The study was funded by Schwarz Bio-Sciences, a subsidiary of Schwarz Pharma AG, and Pfizer Inc. In 2006, Schwarz Pharma transferred rights for fesoterodine

to Pfizer in exchange for an up-front payment of royalties on the combined sales of the drug, if approved. Dr. Sand disclosed that he is an adviser to and an investigator for Pfizer. In addition, another of the study authors is employed by Pfizer.

The researchers pooled data from two phase III randomized controlled trials, which involved male and female patients at least 18 years old with frequency and urgency urinary incontinence. Frequency was defined as at least eight micturitions

in 24 hours; urgency urinary incontinence was defined as at least one episode in 24 hours. This subanalysis examined efficacy and tolerability in 1,543 women.

The women were randomized to 12 weeks of treatment with 4 mg fesoterodine (434), 8 mg fesoterodine (452), or placebo (430). One trial also included a positive control arm with 4 mg tolterodine extended release (227). Patients completed 3-day bladder diaries before randomization and at 2, 8, and 12 weeks after initiating treatment.

Women on 8 mg fesoterodine showed significantly greater improvement than those on 4 mg fesoterodine in urgency urinary incontinence episodes per day, number of continent days per week, and perceived treatment response, Dr. Sand, a professor of obstetrics and gynecology at Northwestern University, Chicago, and his associates reported at the meeting,



Women on 8 mg fesoterodine showed significantly greater improvement than those on 4 mg.

DR. SAND

which was jointly sponsored by the American College of Surgeons.

The median change in number of micturitions per day from baseline to trial end (the primary end point) was significantly decreased for women on 4 mg fesoterodine (1.8), 8 mg fesoterodine (1.9), and 4 mg tolterodine (1.9), compared with placebo (1.0).

At 12 weeks, the mean decrease from baseline in the number of episodes of urgency urinary incontinence per day was 2.3 for women on 8 mg fesoterodine. Those on 4 mg fesoterodine, 4 mg tolterodine, and placebo had mean decreases from baseline of 1.9 episodes, 1.7 episodes, and 1.1 episodes per day, respectively. The difference was significantly greater for the treatment groups versus the placebo group.

Mean volume voided significantly increased from baseline in women on 4 mg fesoterodine (25.5 mL/void), 8 mg fesoterodine (32.1 mL/void), and 4 mg tolterodine (26.6 mL/void), compared with placebo (9.4 mL/void).

The researchers extrapolated the number of continent days per week from 3-day bladder diaries. The mean change from baseline was significantly increased for women taking 4 mg fesoterodine (2.5 days), 8 mg fesoterodine (3 days), and 4 mg tolterodine (2.3 days), compared with placebo (1.7 days). The change in continent days per week was significantly greater for women on 8 mg fesoterodine than for women on 4 mg tolterodine.

A positive treatment response was reported by 49%, 70%, 77%, and 74% in women receiving placebo, 4 mg fesoterodine, 8 mg fesoterodine, and 4 mg tolterodine, respectively. The most common treatment-emergent adverse events at the end of the study were dry mouth, constipation, urinary tract infection, and headache. ■

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