Generic Name:
Oxybutynin
Trade Name:
No trade name
Company:
Antares, Watson
Notes:

Topical oxybutynin gel 3% has received FDA approval for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, according to a news release from Antares and Watson. The gel is available in a metered-dose pump that is applied once daily to the thigh, abdomen, upper arm, or shoulder.

Approval was based on a 12-week, multicenter, placebo-controlled Phase III clinical study in which patients were randomized to either oxybutynin gel 3% (84 mg) or placebo. Data from this trial showed that patients treated with oxybutynin gel daily achieved steady state drug concentrations within 3 days and experienced a statistically significant decrease in overactive bladder symptoms compared with placebo. In addition, the gel was well tolerated, with the most frequently reported treatment-related adverse events being dry mouth (12.1% versus 5% with placebo), application site erythema (3.7% versus 1.0% with placebo), and application site rash (3.3% versus 0.5% with placebo).

This new formulation is expected to launch in 2012.

Medication Monitor Categories:
Supplemental Approvals
Use:

Treatment of overactive bladder