Generic Name:
OnabotulinumtoxinA
Trade Name:
Botox
Company:
Allergan
Notes:

Allergan announced FDA approval of onabotulinumtoxinA for treatment of urinary incontinence due to detrusor overactivity associated with neurologic conditions, such as a spinal cord injury or multiple sclerosis, in adults who have an inadequate response or are intolerant to an anticholinergic medication.

Approval was based on data from two Phase III trials in which 691 patients with urinary incontinence received onabotulinumtoxinA 200 units or placebo injected directly into the bladder muscle. Both studies showed significant reductions in the frequency of urinary incontinence episodes with onabotulinumtoxinA, compared with placebo (15.3 and 18 episodes/week vs. 10 and 7.9 episodes/week, respectively) within 2 weeks of treatment. The trend continued at week 6, with 19.9 and 19.6 episodes/week with active drug and 10.6 and 10.8 episodes/week with placebo in the two trials.

Retreatment with onabotulinumtoxinA was provided to study participants when the clinical effect of the previous treatment wore off. This occurred at 42-48 weeks with onabotulinumtoxinA and 13-18 weeks with placebo.

Adverse events reported following the initial injection of onabotulinumtoxinA included urinary tract infections (49%), urinary retention (17%), fatigue (6%), constipation (4%), muscular weakness (4%), dysuria (4%), fall (3%), gait disturbance (3%), insomnia (3%), and muscle spasm (2%).

Medication Monitor Categories:
Supplemental Approvals
Use:

Treatment of urinary incontinence due to detrusor overactivity associated with neurologic conditions