

FDA gives nod to botox to treat overactive bladder

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Injections of the drug into bladder muscle appear to ease incontinence, agency says.

(HealthDay)—The U.S. Food and Drug Administration on Friday gave its approval for the use of Botox against a form of urinary incontinence known as overactive bladder.

"Clinical studies have demonstrated Botox's ability to significantly reduce the frequency of urinary incontinence," Dr. Hylton Joffe, director of the Division of Reproductive and Urologic Products in the FDA's Center for [Drug Evaluation](#) and Research, said in an agency news release.

"Today's approval provides an important additional treatment option for patients with [overactive bladder](#), a condition that affects an estimated 33 million men and women in the United States," he added.

Overactive bladder is a condition where the bladder contracts too frequently or without warning, causing incontinence, sudden/urgent urge to urinate and frequent urination.

However, injections of Botox (onabotulinumtoxinA) into the [bladder muscle](#) can trigger a relaxation of the bladder, boost the organ's [storage capacity](#) and make incontinence episodes less frequent, the

FDA said.

Physicians inject the drug while using cystoscopy, a procedure that allows the doctor to visualize the interior of the bladder as injection occurs.

The FDA said the safety and effectiveness of Botox for this use was verified in two clinical trials involving more than 1,100 patients with overactive bladder, with patients receiving either 100 units of Botox (20 injections of 5 units each) or a placebo.

Lasting more than three months, the trials found that Botox patients experienced close to two fewer bouts of [urinary incontinence](#) a day compared to those on a placebo, had fewer urinations per day, and an average of 30 milliliters more urine expelled each day, compared to those on a placebo.

Side effects included [urinary tract infections](#), painful urination and incomplete emptying of the bladder, the FDA said. People who already have a urinary tract infection should not take Botox for overactive bladder, and people who do take the drug should take antibiotics before, during and for a few days after the procedure, the agency added.

Botox, best known for its ability to temporarily smooth away facial lines and wrinkles, is made by Allergan Inc. of Irvine, Calif.

More information: Find out more about overactive bladder at the [American Urological Association](#).

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