

Overactive Bladder

Indication

BOTOX® (onabotulinumtoxinA) is a prescription medicine that is injected into the bladder muscle and used to treat overactive bladder symptoms such as a strong need to urinate with leaking or wetting accidents (urge urinary incontinence), a strong need to urinate right away (urgency), and urinating often (frequency) in adults 18 years and older when another type of medicine (anticholinergic) does not work well enough or cannot be taken.

IMPORTANT SAFETY INFORMATION

BOTOX® may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX®.

- **Problems swallowing, speaking, or breathing**, due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months.
- **Spread of toxin effects.** The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice (dysphonia), trouble saying words clearly (dysarthria), loss of bladder control, trouble breathing, trouble swallowing. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

Do not take BOTOX® if you: are allergic to any of the ingredients in BOTOX® (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as *Myobloc*® (rimabotulinumtoxinB), *Dysport*® (abobotulinumtoxinA), or *Xeomin*® (incobotulinumtoxinA); have a skin infection at the planned injection site.

Please see additional Important Safety Information on the following pages.

WHAT IS OVERACTIVE BLADDER?

Overactive Bladder (OAB) is a common, sometimes disabling condition often associated with a considerable impact on patients.¹ An estimated 39 million Americans currently have OAB.²

WHAT CAUSES OVERACTIVE BLADDER?

OAB occurs when nerves are affected (or damaged) and:³

- Send signals to the bladder at the wrong time, causing the muscle to squeeze without warning;
- Cause the bladder to spasm uncontrollably, creating leakage, the strong sudden need to “go,” and going too often.

HOW IS OVERACTIVE BLADDER TREATED?

Often times, treatment begins with lifestyle changes, such as reduction of fluid intake, decreased amounts of caffeine, bladder control strategies and pelvic floor muscle training. Anticholinergic medications, which are commonly prescribed as pills, and topical gels or patches are also often prescribed by physicians to manage OAB in adults.⁴ However, in one study of 1,117 patients, 73.5 percent reported that they stopped taking their OAB therapy within one year due to either side effects and/or lack of results.⁵

There are treatment options beyond pills. BOTOX® (onabotulinumtoxinA) treatment was approved in January 2013 to treat overactive bladder symptoms, such as a strong need to urinate with leakage, urgency and frequency in

IMPORTANT SAFETY INFORMATION (continued)

Do not take BOTOX® for the treatment of urinary incontinence if you: have a urinary tract infection (UTI) or cannot empty your bladder on your own and are not routinely catheterizing.

Due to the risk of urinary retention (not being able to empty the bladder), only patients who are willing and able to initiate catheterization post-treatment, if required, should be considered for treatment.

In clinical trials, 6.5% of patients (36/552) initiated clean intermittent catheterization for urinary retention following treatment with BOTOX® 100 Units as compared to 0.4% of patients (2/542) treated with placebo.

Patients with diabetes mellitus treated with BOTOX® were more likely to develop urinary retention than non-diabetics.

The dose of BOTOX® is not the same as, or comparable to, another botulinum toxin product.

Serious and/or immediate allergic reactions have been reported. These reactions include itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you experience any such symptoms; further injection of BOTOX® should be discontinued.

Tell your doctor about all your muscle or nerve conditions such as amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease), myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including severe dysphagia (difficulty swallowing) and respiratory compromise (difficulty breathing) from typical doses of BOTOX®.

Tell your doctor about all your medical conditions, including if you: have or have had bleeding problems; have plans to have surgery; had surgery on your face; weakness of forehead muscles, such as trouble raising your eyebrows; drooping eyelids; any other abnormal facial change; have symptoms of a urinary tract infection (UTI) and are being treated for urinary incontinence.

Please see additional Important Safety Information on the following pages.

adults when another type of medication (anticholinergic) does not work well enough or cannot be taken.

Other treatment options may include surgery (e.g., a peripheral or surgically-implanted neuromodulation device, or bladder augmentation surgery).⁴

HOW DOES BOTOX® WORK?

BOTOX® (onabotulinumtoxinA) is a different treatment option that takes another approach to targeting the source of OAB: the bladder muscle itself. In the body, certain chemicals travel from nerve cells to muscle cells to make the bladder contract so one can urinate. With OAB, these muscles contract uncontrollably and the person frequently feels like they have to empty their bladder.³

BOTOX® treatment works by calming the nerves that trigger the overactive bladder muscle, helping to:

- Reduce daily leakage episodes;
- Treat the strong need to urinate right away;
- Reduce the number of times needed to empty the bladder daily.

WHAT CAN OAB PATIENTS EXPECT WITH BOTOX®?

The following results were reported in two 24-week studies after patients received BOTOX® treatment for their OAB.

By week 12: ⁶

- About three times fewer accidents were experienced by patients who received BOTOX® than those who did not.
- On average, people who received BOTOX® reduced their bathroom visits by two times a day.
- The amount people urinated was increased by an average of about 25 percent per bathroom visit.

IMPORTANT SAFETY INFORMATION (continued)

Symptoms of a urinary tract infection may include pain or burning with urination, frequent urination, or fever; have problems emptying your bladder on your own and are being treated for urinary incontinence; are pregnant or plan to become pregnant (it is not known if BOTOX® can harm your unborn baby); are breastfeeding or plan to breastfeed (it is not known if BOTOX® passes into breast milk).

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal products. Using BOTOX® with certain other medicines may cause serious effects. Do not start any new medicines until you have told your doctor that you have received BOTOX® in the past.

Especially tell your doctor if you: have received any other botulinum toxin product in the last 4 months; have received injections of botulinum toxin such as *Myobloc*®, *Dysport*®, or *Xeomin*® in the past (be sure your doctor knows exactly which product you received); have recently received an antibiotic by injection; take muscle relaxants; take an allergy or cold medicine; take a sleep medicine; take anti-platelets (aspirin-line products) or anti-coagulants (blood thinners).

Other side effects of BOTOX® include: dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, and eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, or dry eyes. In people being treated for urinary incontinence other side effects include: urinary tract infection, painful urination, and/or inability to empty your bladder on your own. If you have difficulty fully emptying your bladder after receiving BOTOX®, you may need to use disposable self-catheters to empty your bladder up to a few times each day until your bladder is able to start emptying again.

For more information refer to the Medication Guide or talk with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see BOTOX® full [Product Information](#) including [Boxed Warning](#) and [Medication Guide](#).

One BOTOX® (onabotulinumtoxinA) treatment can last up to 6 months before the effects wear off.

WHAT ARE THE SIDE EFFECTS ASSOCIATED WITH BOTOX® TREATMENT?

The most common adverse reactions with BOTOX® treatment are urinary tract infections (UTI) (18 percent vs. 6 percent in placebo), dysuria (painful or difficult urination) (9 percent vs. 7 percent in placebo), and urinary retention (temporary inability to fully empty the bladder following treatment) (6 percent vs. 0 percent in placebo).⁶ This is not a complete list of side effects. Patients should see the Important Safety Information and talk to their doctor about any concerns they may have.

If a patient experiences retention, they can use a disposable self-catheter to drain the urine until the bladder starts emptying normally again. Unlike a larger hospital catheter, this catheter is about the size of a thin, short straw, like a coffee stirrer, fits in a handbag, and can be used in any bathroom. The catheter is inserted when the patient needs to drain urine and then it is removed after use. Retention is not a permanent condition and one's doctor can advise on how long it may last. In general, adverse reactions occur within the first week following injection of BOTOX® and, while generally transient, may have a duration of several months or longer.⁶

HOW ARE OAB PATIENTS TREATED WITH BOTOX®?

BOTOX® should be given by a qualified urologist or urogynecologist who has been trained to administer the treatment. Patients should not receive BOTOX® if they have a urinary tract infection. Patients will be given a preventative antibiotic to take prior to the BOTOX® appointment to help prevent infection. For patient comfort, a local anesthetic may be administered as a numbing agent and patients may also be provided with a sedative, all of which can be performed in a qualified specialist's office.

Once the bladder is numb, BOTOX® (onabotulinumtoxinA) is injected into the bladder muscle using a cystoscope, a specialized tube with an optical lens at the end that is used to see inside the bladder. A cystoscope is placed into the bladder via the urethra, the natural opening where urine comes out.

BOTOX® then goes through the cystoscope and is administered with a small needle into multiple areas of the bladder muscle. The treatment takes approximately 20-30 minutes to administer and then the patient is observed for about 30 minutes to ensure that the patient can empty the bladder before he/she leaves the office.

For patients with OAB, treatment with BOTOX® could take up to one hour in the urologist or urogynecologist's office as few as two times a year.

REFERENCES:

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3. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Nerve disease and bladder control. NIH Publication 2012; 08-4560. 1-8.
4. Gormley et al. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guidelines. *Journal of Urology*. December 2012. (Suppl)188:2455-2463.
5. D'Souza AO et al. *J Manag Care Pharm*. 2008;14(3):291-301.
6. BOTOX® Prescribing Information, updated January 2013

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