

# Is BOTOX<sup>®</sup> (onabotulinumtoxinA) Right for Me?

These questions can help you talk to your doctor about the potential benefits and side effects of BOTOX<sup>®</sup>:

## Questions for you:

1. **Are you an adult with a neurologic condition** such as multiple sclerosis or spinal cord injury?
2. **Do you have urinary incontinence** (leakage of urine that is involuntary, or not under your control)?
3. **Have you tried medication** for urinary incontinence but still have leakage or cannot tolerate side effects such as dry mouth?

## Questions for your doctor:

1. What are my treatment options?

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2. What potential benefits could I experience from treatment with BOTOX<sup>®</sup>?

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3. What are the potential side effects of treatment with BOTOX<sup>®</sup>?

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4. What is self-catheterization, and what should I know about it?

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5. How do you perform BOTOX<sup>®</sup> treatment?

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6. How soon will BOTOX<sup>®</sup> start to work?

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7. When should I come back for an appointment after treatment with BOTOX<sup>®</sup>?

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8. When should I schedule my next BOTOX<sup>®</sup> treatment?

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## BOTOX<sup>®</sup> (onabotulinumtoxinA) Important Information

### Indication

BOTOX<sup>®</sup> is a prescription medicine that is injected into the bladder muscle and used to treat leakage of urine (incontinence) in adults 18 years and older with overactive bladder caused by a neurologic disease who still have leakage or cannot tolerate the side effects after trying an anticholinergic medication.

### IMPORTANT SAFETY INFORMATION

**BOTOX<sup>®</sup> may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX<sup>®</sup>:**

- **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, trouble saying words clearly, loss of bladder control, trouble breathing, trouble swallowing

BOTOX<sup>®</sup> may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX<sup>®</sup>. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

**Please see additional Important Safety Information on following page.**



## **BOTOX® (onabotulinumtoxinA) IMPORTANT SAFETY INFORMATION (continued)**

**Do not receive 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.

**Do not receive 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 (difficulty fully emptying the bladder), only patients who are willing and able to initiate catheterization post-treatment, if required, should be considered for treatment.

In clinical trials, 30.6% of patients (33/108) who were not using clean intermittent catheterization (CIC) prior to injection, required catheterization for urinary retention following treatment with BOTOX® 200 Units as compared to 6.7% of patients (7/104) treated with placebo. The median duration of post-injection catheterization for these patients treated with BOTOX® 200 Units (n = 33) was 289 days (minimum 1 day to maximum 530 days) as compared to a median duration 358 days (minimum 2 days to maximum 379 days) for patients receiving placebo (n = 7).

Among patients not using CIC at baseline, those with MS were more likely to require CIC post-injection than those with SCI.

**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.** They include itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Get medical help right away if you experience symptoms; further injection of BOTOX® should be discontinued.

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

**Tell your doctor if you have any breathing-related problems.** Your doctor will want to monitor you for any breathing problems during your treatment with BOTOX® for detrusor overactivity associated with a neurologic condition. The risk of pulmonary effects in patients with compromised respiratory status is increased in patients receiving BOTOX®.

**Autonomic dysreflexia.** Autonomic dysreflexia associated with intradetrusor injections of BOTOX® could occur in patients treated for detrusor overactivity associated with a neurologic condition and may require prompt medical therapy. In clinical trials, the incidence of autonomic dysreflexia was greater in patients treated with BOTOX® 200 Units compared with placebo (1.5% versus 0.4%, respectively).

**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; 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. 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 (it is not known if BOTOX® passes into breast milk).

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

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 (tell your doctor 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 aspirin-like 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, and 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**Please see accompanying full [Product Information](#), including [Boxed Warning](#) and [Medication Guide](#).**



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