



When it comes to Overactive Bladder (OAB)

Are you concerned that a leakage episode is going to come at an unpredictable time?

Visit **BOTOXOABVideo.com** to watch a video and learn if BOTOX[®] can help

If you are frustrated with OAB medications not working or can't handle the side effects, this video will help you find out:

- How well BOTOX[®] works
- How BOTOX[®] treats your OAB
- How long BOTOX[®] lasts

Talk to your doctor if you have any questions or if you think you're ready for BOTOX[®].



Indication

BOTOX[®] 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, going too often, and the strong, sudden need to go in adults 18 years and older when another type of medication (anticholinergic) does not work well enough or cannot be taken.

IMPORTANT SAFETY INFORMATION

BOTOX[®] 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[®]:

- **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, and trouble swallowing

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

Please see additional Important Safety Information on following page.

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 self-catheterization post treatment, if required, should be considered for treatment.

In clinical trials, 36 of the 552 patients had to self-catheterize for urinary retention following treatment with BOTOX[®] compared to 2 of the 542 treated with placebo. Patients with diabetes mellitus treated with BOTOX[®] were more likely to develop urinary retention than nondiabetics.

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 including 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 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 blood thinners.

Other side effects of BOTOX[®] include: dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, dry eyes; drooping eyebrows; and upper respiratory tract infection. 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](#).



Watch now at BOTOX0ABVideo.com

Summary of Information About BOTOX® (onabotulinumtoxinA) for Overactive Bladder

What is the most important information I should know about BOTOX®?

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

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

BOTOX® dosing units are not the same as, or comparable to, any other botulinum toxin product.

What is BOTOX®?

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

Who should not receive BOTOX®?

Do not receive BOTOX® if you are: allergic to any of the ingredients in BOTOX® such as botulinum toxin type A and human serum albumin; had an allergic reaction to another botulinum toxin product such as *Myobloc*® (rimabotulinumtoxinB), *Dysport*® (abobotulinumtoxinA), or *Xeomin*® (incobotulinumtoxinA); have a skin infection at the planned injection site; have a urinary tract infection (UTI); or find that you cannot empty your bladder on your own (only applies to people who are not routinely catheterizing).

What should I tell my doctor before treatment?

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.

Tell your doctor if you have or have had breathing problems such as asthma or emphysema; swallowing problems; bleeding issues; plan to or have had surgery; have symptoms of a urinary tract infection (UTI). 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.

Tell your doctor if you are pregnant, plan to become pregnant, are breastfeeding or plan to breastfeed. It is not known if BOTOX® can harm your unborn baby or if BOTOX® passes into breast milk.

What are the most common side effects?

The most common side effects include: urinary tract infection, painful urination, bacteria in urine, and the temporary inability to empty your bladder on your own. If you have difficulty fully emptying your bladder after receiving BOTOX®, you may need to use a small disposable self-catheter to empty your bladder up to a few times each day until your bladder is able to start emptying again.

Other side effects have been reported including allergic reactions (eg, itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint). These are not all of the possible side effects.

Call your doctor for medical advice if you experience any side effects after treatment with BOTOX®.

What should I tell my doctor about prescription and over-the-counter medicines I take?

Using BOTOX® with certain 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 an injection with another botulinum toxin product in the last 4 months, such as *Myobloc*®, *Dysport*®, or *Xeomin*®. Be sure your doctor knows which product you received.

Tell your doctor about all prescription, over-the-counter medicines, and supplements you take, including: vitamins and herbal supplements; recent antibiotic injections, anticholinergics; muscle relaxants; allergy or cold medicine; sleep medicine; aspirin-like products or blood thinners. **Ask your doctor if you are not sure whether your medicine is listed above.**

To learn more

If you would like more information, talk to your doctor and/or go to BOTOXforOAB.com for full Prescribing Information, including Medication Guide.

You may report side effects to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

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