

Getting Your BOTOX® (onabotulinumtoxinA) from a Specialty Pharmacy Provider (SPP)

Your BOTOX® will be shipped to our office from a **Specialty Pharmacy Provider (SPP)**. Specialty Pharmacies specialize in dispensing drugs that are not typically stocked in traditional retail pharmacies.

Our office will be contacting your insurance company to verify insurance information and obtain appropriate prior authorization for BOTOX®. Here's what you need to know:



What you need to know when using a Specialty Pharmacy:

The Specialty Pharmacy will contact you to:

- Confirm your BOTOX® order
- Verify your insurance information
- Collect your co-payment (may require credit card information)
- Schedule a date to have your BOTOX® shipped directly to our office
 - Please remind the pharmacy to send your BOTOX® directly to our office, on your behalf

Your responsibilities:

IMPORTANT: To ensure that your BOTOX® prescription is filled promptly and shipped to our office, you must speak with the Specialty Pharmacy when they call you.

- The Specialty Pharmacy may call from an unidentified toll-free number
- It is important to take this call to verify your insurance information
- Due to HIPAA privacy laws, and to assure your confidentiality, you may be asked to confirm personal information (eg, name, SSN, DOB, address)
- Your BOTOX® prescription may not be filled until you speak with the Specialty Pharmacy
- Your BOTOX® treatment may be delayed if you do not speak with the Specialty Pharmacy
- If you have not been able to take the call to verify your insurance information, you can call your Specialty Pharmacy at the contact telephone number below to complete the request

Your BOTOX® will be shipped to our office from the following Specialty Pharmacy:

Specialty Pharmacy name: _____

Telephone number: _____

Should you have any questions for our office, please call the number below:

Office name: _____

Contact person: _____ Telephone number: _____

BOTOX® Important Information

Indications

BOTOX® is a prescription medicine that is injected into muscles 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

Please see additional Indications and Important Safety Information, including Boxed Warning, on the following pages.



BOTOX® (onabotulinumtoxinA) Important Information Indications (continued)

- to treat leakage of urine (incontinence) in adults 18 years and older with overactive bladder due to neurologic disease who still have leakage or cannot tolerate the side effects after trying an anticholinergic medication
- to prevent headaches in adults with chronic migraine who have 15 or more days each month with headache lasting 4 or more hours each day in people 18 years or older
- to treat increased muscle stiffness in elbow, wrist, finger, and thumb muscles in people 18 years and older with upper limb spasticity
- to treat increased muscle stiffness in ankle and toe muscles in people 18 years and older with lower limb spasticity
- to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in people 16 years and older
- to treat certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years and older

BOTOX® is also injected into the skin to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) when medicines used on the skin (topical) do not work well enough in people 18 years and older.

It is not known whether BOTOX® is safe or effective to prevent headaches in patients with migraine who have 14 or fewer headache days each month (episodic migraine).

It is not known whether BOTOX® is safe or effective to treat increased stiffness in upper limb muscles other than those in the elbow, wrist, fingers, and thumb, or in lower limb muscles other than those in the ankle and toes. BOTOX® has not been shown to help people perform task-specific functions with their upper limbs or increase movement in joints that are permanently fixed in position by stiff muscles. Treatment with BOTOX® is not meant to replace existing physical therapy or other rehabilitation that may have been prescribed.

It is not known whether BOTOX® is safe or effective for other types of muscle spasms or for severe sweating anywhere other than your armpits.

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.

There has not been a confirmed serious case of spread of toxin effect away from the injection site when BOTOX® has been used at the recommended dose to treat chronic migraine, severe underarm sweating, blepharospasm, or strabismus.

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.

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 (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.

Patients treated for overactive bladder

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 non-diabetics.

Patients treated for overactive bladder due to neurologic disease

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 of 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.

Please see additional Important Safety Information on the following page.



IMPORTANT SAFETY INFORMATION (continued)

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 if you have any breathing-related problems. Your doctor may monitor you for breathing problems during your treatment with BOTOX® for spasticity or for detrusor overactivity associated with a neurologic condition. The risk of developing lung disease in patients with reduced lung function is increased in patients receiving BOTOX®.

Cornea problems have been reported. Cornea (surface of the eye) problems have been reported in some people receiving BOTOX® for their blepharospasm, especially in people with certain nerve disorders. BOTOX® may cause the eyelids to blink less, which could lead to the surface of the eye being exposed to air more than is usual. Tell your doctor if you experience any problems with your eyes while receiving BOTOX®. Your doctor may treat your eyes with drops, ointments, contact lenses, or with an eye patch.

Bleeding behind the eye has been reported. Bleeding behind the eyeball has been reported in some people receiving BOTOX® for their strabismus. Tell your doctor if you notice any new visual problems while receiving BOTOX®.

Bronchitis and upper respiratory tract infections (common colds) have been reported. Bronchitis was reported more frequently in people receiving BOTOX® for upper limb spasticity. Upper respiratory infections were also reported more frequently in people with prior breathing related problems with spasticity.

Autonomic dysreflexia in patients treated for overactive bladder due to neurologic disease
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 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 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, and drooping eyebrows. 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](#).



