

Upper Limb Spasticity

Indication

BOTOX® (onabotulinumtoxinA) is a prescription medicine that is injected into muscles and used to treat increased muscle stiffness in elbow, wrist, and finger muscles in people 18 years and older with upper limb spasticity.

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, and fingers, or to treat increased stiffness in lower-limb muscles. 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 your existing physical therapy or other rehabilitation that your doctor may have prescribed.

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.**

Please see next page for additional Important Safety Information

WHAT IS UPPER LIMB SPASTICITY?

Upper limb spasticity (or ULS) is a debilitating neurological condition characterized by an abnormal increase in tone¹ in the muscles of the elbow, wrist and fingers. The condition causes affected muscles to continuously contract (stay flexed, or shortened) for long periods of time. They remain stiff and tight, and resist the normal stretching that should occur during use.²

In addition to increased muscle tone, symptoms of ULS may include rapid muscle contractions, exaggerated deep tendon reflexes and muscle spasms.¹

Upper limb spasticity can present as a bent wrist with fingers pointing downward, a fist that stays clenched or a flexed elbow that stays twisted against the chest.

WHAT CAUSES UPPER LIMB SPASTICITY?

Upper limb spasticity is usually caused by damage to the portion of the brain or spinal cord that controls voluntary movement.² The damage causes a change in the balance of signals between the nervous system and the muscles. This imbalance leads to increased activity in the muscles.² The most common disorders that result in ULS include stroke, cerebral palsy in adults, multiple sclerosis, traumatic brain injury, and spinal cord injury.²

HOW IS UPPER LIMB SPASTICITY TREATED?

Patients with symptoms of upper limb spasticity are often treated by a multi-disciplinary team of healthcare professionals that may include a neurologist, physiatrist

IMPORTANT SAFETY INFORMATION (continued)

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.

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 if you have any breathing-related problems. Your doctor will want to monitor you for any breathing problems during your treatment with BOTOX® for upper limb spasticity. The risk of pulmonary effects in patients with compromised respiratory status is increased in patients receiving BOTOX®.

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

(specializing in physical medicine and rehabilitation), physical therapist, occupational therapist, or other specialist depending on the cause of the underlying disorder. There are several ways to treat ULS depending on the severity of the condition and the patient's goals.

BOTOX® (onabotulinumtoxinA) – a prescription injectable therapy – was approved by the U.S. Food and Drug Administration (FDA) for the treatment of increased stiffness in the elbow, wrist and finger muscles in adults with upper limb spasticity in March 2010. 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 and fingers, or to treat increased stiffness in lower-limb muscles. BOTOX® has not been shown to help people perform task-specific functions of their upper limbs or increase movement by joints that are permanently fixed in position by stiff muscles. Treatment with BOTOX® is not meant to replace a patient's existing physical therapy or other rehabilitation that the doctor may have prescribed.

As is noted above, treatment for upper limb spasticity is also likely to include physical therapy requiring regular stretching and "range of motion" exercises to help prevent shrinkage or shortening of the muscles and to reduce the severity of symptoms.¹

Muscle relaxing drugs, taken orally or pumped into the spinal fluid, may also be helpful.² If the symptoms are severe and do not respond to less invasive treatments, surgery may be recommended to release tendons or to sever the nerve-muscle pathway.¹ Patients should speak to a physician to fully understand their treatment options.

*Please see next page for additional
Important Safety Information*

IMPORTANT SAFETY INFORMATION (continued)

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; 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.

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](#).

HOW DOES BOTOX® WORK?

In patients diagnosed with upper limb spasticity, BOTOX® is injected by a trained medical specialist – such as a neurologist or physiatrist – using a fine needle directly into the affected muscles.

Derived from the bacterium *Clostridium botulinum*, BOTOX® (onabotulinumtoxinA) inhibits the release of a neurotransmitter, acetylcholine, from nerve cells, blocking the signals that induce muscle contractions. The effect is temporary and the treatment needs to be administered approximately every three months, depending on the individual patient.³

BOTOX® is the first and only botulinum toxin treatment approved by the FDA for the treatment of upper limb spasticity in the elbows, wrist and fingers in adults today. In addition, BOTOX® treatment is covered under Medicare, Medicaid and most commercial insurance plans within the United States.

WHAT ARE THE SIDE EFFECTS ASSOCIATED WITH BOTOX® TREATMENT?

The most common side effects associated with 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.³ While rare, serious adverse reactions have also been reported. Patients should seek medical attention immediately if they experience problems swallowing, speaking or breathing.

The most common side effects of using BOTOX® treatment for ULS include nausea, fatigue, bronchitis, pain in extremities, and muscle weakness.

This list does not cover all the possible side effects of BOTOX®. Patients should see the Important Safety Information, including Boxed Warning, and talk to their doctor about any concerns they may have.

REFERENCES:

1. NINDS Spasticity Information Page. National Institute of Neurological Disorders and Stroke. Available at <http://www.ninds.nih.gov/disorders/spasticity/spasticity.htm>. Accessed on November 12, 2012.
2. American Association of Neurological Surgeons. Patient Information: Spasticity. Available at <http://www.aans.org/Patient%20Information/Conditions%20and%20Treatments/Spasticity.aspx>. Accessed on November 13, 2012.
3. BOTOX® Prescribing Information, updated September 2013.

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