



BOTOX[®] Fact Sheet

About BOTOX[®]

- BOTOX[®] is a simple, minimally invasive treatment that may deliver effective results to a wide range of patients suffering from certain neurological disorders (cervical dystonia, blepharospasm, strabismus, severe primary axillary hyperhidrosis and increased muscle stiffness in elbow, wrist, and finger muscles in adults with upper limb spasticity).
- BOTOX[®] is a purified protein derived from the bacterium *Clostridium botulinum*. Type A is one of the seven distinct antigenic botulinum toxins produced by different strains of the bacterium.
- BOTOX[®] decreases muscle activity by blocking overactive nerve impulses that trigger excessive muscle contractions or glandular activities and is administered in a few injections directly into the affected area.

BOTOX[®] for Therapeutic Use

- Allergan's BOTOX[®] neurotoxin is an important versatile medicine with 20 years of successful clinical experience in certain therapeutic applications.
- In the United States, BOTOX[®] therapy was granted approval in 1989 by the U.S. Food and Drug Administration (FDA) to treat certain types of eye muscle problems (strabismus) and abnormal spasm of the eyelids (blepharospasm)

Indications

BOTOX[®] is a prescription medicine that is injected into muscles and used:

- to treat increased muscle stiffness in elbow, wrist, and finger muscles with upper limb spasticity in people 18 years and older.
- to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in people 18 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 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. 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.

***Please see next page for additional
Important Safety Information***



in people 12 years and older. In December 2000, BOTOX[®] (onabotulinumtoxinA) was approved by the FDA for the treatment of the abnormal head position and neck pain that happens with cervical dystonia (CD) in people 18 years and older. In July 2004, BOTOX[®] was granted approval in the United States to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) in people 18 years and older when medicines used on the skin (topical) do not work well enough. Most recently, in March 2010, BOTOX[®] was granted approval by the FDA for the treatment of increased muscle stiffness in the elbow, wrist and finger muscles in people 18 years and older with upper limb spasticity. Around the world, BOTOX[®] is approved in approximately 80 countries.

- Today, Allergan is working in collaboration with many academic institutions, researchers, scientists and physicians to continue exploring the full therapeutic potential of this versatile medicine and to develop new medical uses for BOTOX[®] in other areas where there is a need for new treatment options.

How BOTOX[®] Works

- BOTOX[®] neurotoxin blocks overactive nerve impulses that cause excessive muscle contractions or glandular activity by selectively preventing the release of the neurotransmitter acetylcholine at the neuromuscular junction and temporarily inhibiting the targeted muscle or gland activity.
- BOTOX[®] is administered in small therapeutic doses by intramuscular or intradermal injection directly into the affected area, depending on the indication, producing a typically reversible decrease of muscle or gland activity.

IMPORTANT SAFETY INFORMATION (continued)

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 severe underarm sweating, blepharospasm, or strabismus.

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 itchy rash, swelling, and shortness of breath. Tell your doctor or get medical help right away if you experience any such symptoms, further injection of BOTOX[®] should be discontinued.

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[®]* or *Dysport[®]*; have a skin infection at the planned injection site.

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: 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 breast-feeding or plan to breastfeed (It is not known if BOTOX[®] passes into breast milk).

Please see next page for additional Important Safety Information



- The therapeutic effect of BOTOX[®] (onabotulinumtoxinA) is temporary and lasts up to approximately three to 6.7 months, depending on the individual patient and indication. Over time the nerve inhibition produced by BOTOX[®] neurotoxin is reversed as nerve endings recover and begin to release acetylcholine again, at which time another injection of BOTOX[®] may be needed to maintain therapeutic effect.

IMPORTANT SAFETY INFORMATION (continued)

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal products.

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

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.

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 the accompanying full Product Information, including Medication Guide, for BOTOX[®].

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