

Human Body

BOTOX® (onabotulinumtoxinA) / BOTOX® Cosmetic (onabotulinumtoxinA)

Approved Uses in the U.S.

In 2000, BOTOX® therapy was approved by the U.S. Food and Drug Administration (FDA) for the treatment of the abnormal head position and neck pain that happens with cervical dystonia (CD) in people 16 years and older.

In 2004, BOTOX® therapy was approved by the FDA 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 severe sweating anywhere other than your armpits.

In 2010, BOTOX® therapy was approved by the FDA to treat increased muscle stiffness in elbow, wrist, and finger muscles with upper limb spasticity in people 18 years and older. It is not known whether BOTOX® is safe or effective for other types of muscle spasms.

In 2002, with dosing specific to treat moderate to severe frown lines between the eyebrows (glabellar lines, also known as the '11s'), the same formulation of BOTOX® was approved to improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in people 18 to 65 years of age for a short period of time (temporary), under the name BOTOX® Cosmetic (onabotulinumtoxinA).

In 1989, BOTOX® therapy was approved by the FDA for the treatment of certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years and older.

IMPORTANT SAFETY INFORMATION

BOTOX® and BOTOX® Cosmetic 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® or BOTOX® Cosmetic:

- **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 back page for additional IMPORTANT SAFETY INFORMATION.

BOTOX® (ONABOTULINUMTOXINA) AND BOTOX® COSMETIC (ONABOTULINUMTOXINA)

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 or when BOTOX® Cosmetic has been used at the recommended dose to treat frown lines.

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® or BOTOX® Cosmetic should be discontinued.

Do not take BOTOX® or BOTOX® Cosmetic if you: are allergic to any of the ingredients in BOTOX® or BOTOX® Cosmetic (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® or BOTOX® Cosmetic.

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® or BOTOX® Cosmetic can harm your unborn baby); are breast-feeding or plan to breastfeed (It is not known if BOTOX® or BOTOX® Cosmetic passes into breast milk).

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

BOTOX® and BOTOX® Cosmetic 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® and BOTOX® Cosmetic 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®.

Please see the accompanying full Product Information, including Medication Guide, for BOTOX® Cosmetic.