

# Human Body

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

Approved Uses in the U.S.

In 2000, BOTOX® (onabotulinumtoxinA) 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 adults.

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 2002, with dosing specific to treat the stubborn 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 adults younger than 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 after treatment with BOTOX® or BOTOX® Cosmetic:**

- **Problems swallowing, speaking, or breathing. These problems can happen hours to weeks after an injection of BOTOX® or**

**BOTOX® Cosmetic** usually because the muscles that you use to breathe and swallow can become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with BOTOX® or BOTOX® Cosmetic.

**Please see back page for additional important safety information.**

## IMPORTANT SAFETY INFORMATION

(CONTINUED)

**Call your doctor or get medical help right away if you have any of these problems after treatment with BOTOX® (onabotulinumtoxinA) or BOTOX® Cosmetic (onabotulinumtoxinA):**

- Swallowing problems may last for several months. People who already have swallowing or breathing problems before receiving BOTOX® or BOTOX® Cosmetic have the highest risk of getting these problems.
- **Spread of toxin effects.** In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include: loss of strength and muscle weakness all over the body, 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.

These symptoms can happen hours to weeks after you receive an injection of BOTOX® or BOTOX® Cosmetic.

These problems could make it unsafe for you to drive a car or do other dangerous activities. See “What should I avoid while receiving BOTOX® or BOTOX® Cosmetic” in Medication Guide.

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.

**Tell your doctor about all your medical conditions, including if you have:** a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig’s disease], myasthenia gravis or Lambert-Eaton syndrome).

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

**BOTOX® or BOTOX® Cosmetic can cause serious side effects. 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. Symptoms of an allergic reaction to BOTOX® or BOTOX® Cosmetic may 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 are wheezing or have asthma symptoms, or if you become dizzy or faint.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of BOTOX® and BOTOX® Cosmetic. For more information, ask your doctor or pharmacist.

For additional information refer to Medication Guide. This Medication Guide summarizes the most important information about BOTOX® and BOTOX® Cosmetic. If you would like more information, talk with your doctor.

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

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