

Background

HYPERHIDROSIS

What is hyperhidrosis?

Hyperhidrosis is the medical term for severe sweating. Patients with hyperhidrosis may sweat up to four or five times more than normal, far exceeding what is needed to regulate body temperature.

What is severe primary axillary hyperhidrosis and what causes it?

Many Americans have severe primary axillary hyperhidrosis, better known as severe underarm sweating. Severe underarm sweating may be exacerbated by stress, emotion or exercise, but often occurs spontaneously. The precise mechanism that triggers symptoms is uncertain. For some individuals the eccrine glands may be over reactive or the autonomic nervous system may produce too much of the neurotransmitter that triggers the eccrine glands to produce sweat. Genetics may also play a role – many patients have a family history of the disorder.

Individuals with severe underarm sweating may find it can disrupt their daily lives. Patients often go to great lengths to cope with symptoms, such as changing clothing several times a day to conceal underarm sweat stains.

How is severe underarm sweating treated?

Patients with severe underarm sweating are generally referred to dermatologists for treatment of the condition. A number of different treatments and products are available to help people with severe underarm sweating. BOTOX[®] (onabotulinumtoxinA) injection is a minimally invasive treatment approved by the U.S. Food and Drug Administration (FDA) in 2004 to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) when medicines used on the skin do not work well enough in people 18 years and older. The effects of treatment are temporary, lasting approximately 6.7 months, and treatment is often covered by insurance.¹

Indication

BOTOX[®] is 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 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.

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.

Please see next page for additional Important Safety Information

How does BOTOX[®] treatment help to control the symptoms of severe underarm sweating?

BOTOX[®] (onabotulinumtoxinA), a purified protein derived from the bacterium *Clostridium botulinum*, is administered intradermally in tiny injections into the underarm. BOTOX[®] is believed to inhibit the release of a neurotransmitter, acetylcholine, from nerve cells, by temporarily blocking the chemical signals from the nerves that stimulate the sweat glands. When the sweat glands don't receive chemical signals, the severe sweating stops.

IMPORTANT SAFETY INFORMATION (continued)

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).

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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ⁱ Allergan Data on File