

Blepharospasm

BOTOX® (onabotulinumtoxinA) Important Information

Indications

BOTOX® is a prescription medicine that is injected into muscles and used to treat certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years and older.

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**

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 blepharospasm or strabismus.

WHAT IS BLEPHAROSPASM?

Blepharospasm (uncontrollable blinking) is a type of focal dystonia, a movement disorder that causes abnormal muscle spasms, resulting in uncontrolled blinking, narrowing and even closing of the eyelid.¹ Typically, symptoms begin in late-middle or older age, and is more than twice as frequent in women as in men.¹ It is a condition that can be difficult to understand and a challenge to live with.

Common signs of blepharospasm may include:

- Dry eyes or watering eyes²
- Light sensitivity
- Increased blinking¹
- Ocular pain²
- Soreness around the eyes²

Blepharospasm affects an estimated 20,000 to 50,000 people in the United States, with 2,000 new cases diagnosed annually.³

WHAT CAUSES BLEPHAROSPASM?

It is not known what exactly causes the muscle contractions characteristic of blepharospasm.

HOW IS BLEPHAROSPASM TREATED?

Patients with blepharospasm are generally referred to ophthalmologists or neurologists for treatment.

BOTOX® (onabotulinumtoxinA) has been used to treat blepharospasm since it was approved by the FDA in 1989.

Please see additional Important Safety Information on the following pages.

BOTOX® (onabotulinumtoxinA) 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®.

Cornea problems have been reported. Cornea (surface of the eye) problems have been reported in some people receiving BOTOX® for their blepharospasm, especially in people with certain nerve disorders. BOTOX® may cause the eyelids to blink less, which could lead to the surface of the eye being exposed to air more than is usual. Tell your doctor if you experience any problems with your eyes while receiving BOTOX®. Your doctor may treat your eyes with drops, ointments, contact lenses, or with an eye patch.

Patients treated with BOTOX® for blepharospasm may begin seeing an improvement in symptoms within the first three days, with maximum results about 1 to 2 weeks after the injection.

If a functionally impaired patient does not respond to less invasive treatments, surgical therapy to remove some or all of the muscles responsible for eyelid closure (a procedure called protractor myectomy) may be recommended. If you suffer from blepharospasm, talk to your eye care professional about treatment options.

HOW DOES BOTOX® WORK?

In patients diagnosed with blepharospasm, BOTOX® is injected by a trained medical specialist – such as a neurologist or physiatrist – using a fine needle directly into the affected muscles.⁴

BOTOX® inhibits the release of a neurotransmitter, acetylcholine, from nerve cells, blocking the signals that induce involuntary muscle contractions. The effect is temporary and when injected at labeled doses in recommended sites, BOTOX® is expected to produce results lasting up to 12 weeks, depending on the individual patient.⁵

WHAT ARE THE SIDE EFFECTS ASSOCIATED WITH BOTOX® TREATMENT?

The needles used for BOTOX® injections are very fine, but you may experience some pain, swelling, and other reactions at the injection sites. In a clinical study of patients who received BOTOX® treatment for blepharospasm, the most frequently reported adverse reactions were droopy eyelid, cornea (surface of the eye) problems, and eye dryness.

BOTOX® (onabotulinumtoxinA) 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 side 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-like products) or anticoagulants (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, 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 accompanying full Product Information including Boxed Warning and Medication Guide .

Other events reported in prior clinical studies include: irritation, tearing, eyelid disorders, sensitivity to light, inflammation of the cornea, double vision, diffuse skin rash, and local swelling of the eyelid skin lasting for several days following eyelid injection. This list does not cover all the serious possible side effects of BOTOX®. Please refer to the full Product Information, including Boxed Warning and Medication Guide, and talk with your doctor. Patients should speak to a physician to fully understand their treatment options.

REFERENCES:

1. Benign essential blepharospasm. National Institutes of Health Web site. <http://ghr.nlm.nih.gov/condition/benign-essential-blepharospasm>. Accessed June 2013.
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3. Ben Simon GJ, McCann JD. Benign essential blepharospasm. *Int Ophthalmol Clin*. 2005; 45: 49-75.
4. Facts about blepharospasm. National Eye Institute Web site. <http://www.nei.nih.gov/health/blepha/blepharospasm.asp>. Accessed June 2013.
5. BOTOX® (onabotulinumtoxinA) Prescribing Information, February 2014.

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