BOTOX® Cosmetic
onabotulinumtoxinA injection

FREQUENTLY ASKED QUESTIONS

Actual patients treated for moderate to severe crow's feet and glabellar lines. ***Results may vary.***

A helpful resource guide to keep near the phone when patients call about BOTOX® Cosmetic

It's important to have the right answers when patients call the office.

Be sure to let callers know that BOTOX® Cosmetic is:

- The **#1** selling product of its kind in the United States and the world[1,*]
- A **brand**, not just a treatment
- The ***only*** FDA-approved product to temporarily improve the appearance of both moderate to severe frown lines between the brows and crow's feet lines in adults.

*Data collected through December 2014.

Don't forget to tell patients about the office injector's experience with BOTOX® Cosmetic.

What is BOTOX® Cosmetic?

BOTOX® Cosmetic is the only approved treatment to temporarily improve the appearance of both moderate to severe frown lines between the brows and crow's feet lines in adults.

BOTOX® Cosmetic is a nonsurgical, injectable treatment performed in one of our treatment rooms by a healthcare professional.

Other facts to know:

- Approved in the United States for moderate to severe frown lines between the brows in 2002, for moderate to severe crow's feet in 2013, and is also approved in 79 countries[2,†]
- Well studied with 442 articles published in scientific and medical journals[3]
- Millions of people have been treated, and here in our office we treat [insert approximate number of patients treated daily] every day!

What BOTOX® Cosmetic is NOT:

- It is NOT a surgical procedure
- It is NOT a filler (a substance that is injected into certain areas of the face to "fill in" wrinkles)
- It is NOT permanent

†VISTABEL® outside of North America.

BOTOX® Cosmetic (onabotulinumtoxinA) IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of BOTOX® Cosmetic and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses, including spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and upper limb spasticity and at lower doses.

Please see full Indications and additional Important Safety Information about BOTOX® Cosmetic on following pages.

BOTOX® Cosmetic onabotulinumtoxinA injection

FREQUENTLY ASKED QUESTIONS

How does BOTOX® Cosmetic work?

BOTOX® Cosmetic **targets one of the underlying causes of frown lines and crow's feet—the repeated muscle contractions** from frowning and squinting over the years. BOTOX® Cosmetic is injected into these muscles to temporarily reduce muscle activity. After an injection, you will begin to notice a **visible smoothing of your crow's feet lines and frown lines between your brows.**[4]

When will I see results?

You may begin to notice results within 24 to 48 hours for moderate to severe frown lines, with results lasting **up to 4 months.**[4]

Will BOTOX® Cosmetic make me look like I've had work done?

BOTOX® Cosmetic is a technique-sensitive treatment. **You should not lose the ability to show expression when you are treated by someone who is licensed, trained, and a medical expert in facial anatomy.** It is important to talk to us about the results you want from treatment.

Does BOTOX® Cosmetic treatment hurt?

Some patients report that being injected with BOTOX® Cosmetic feels like a pinch. We may use ice to numb the treatment area. If you are concerned about discomfort, we may apply a topical numbing cream before administering your treatment.

What are common side effects?

Three percent of patients experienced eyelid drooping in the frown lines studies and 1% of patients experienced eyelid swelling in the crow's feet studies. Other possible side effects include: dry mouth; discomfort or pain at the injection site; tiredness; headache; neck pain; eye problems: double vision, blurred vision, decreased eyesight and dry eyes; and allergic reactions.[4] These are not all of the possible serious side effects of BOTOX® Cosmetic. **Please see the Important Safety Information including Boxed Warning and Medication Guide.**

How long does the treatment take?

We will discuss your treatment goals and perform a facial analysis to determine the appropriate treatments for you. The actual injection process **takes about 10 minutes.**

BOTOX® Cosmetic (onabotulinumtoxinA) Important Information

Indications

Glabellar Lines

BOTOX® Cosmetic (onabotulinumtoxinA) for injection is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

Lateral Canthal Lines

BOTOX® Cosmetic is indicated for the temporary improvement in the appearance of moderate to severe lateral canthal lines associated with orbicularis oculi activity in adult patients.

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

BOTOX® Cosmetic is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation.

WARNINGS AND PRECAUTIONS

Lack of Interchangeability between Botulinum Toxin Products

The potency Units of BOTOX® Cosmetic are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of BOTOX® Cosmetic cannot be compared to nor converted into units of any other botulinum toxin products assessed with any other specific assay method.

Spread of Toxin Effect

Please refer to Boxed Warning for Distant Spread of Toxin Effect.

Please see additional Important Safety Information on following pages.

BOTOX® Cosmetic onabotulinumtoxinA injection

FREQUENTLY ASKED QUESTIONS

How can I save on treatments?

Enroll in the *Brilliant Distinctions*® Rewards Program to save money on BOTOX® Cosmetic treatments. You earn points on each BOTOX® Cosmetic treatment that you can redeem for savings on future treatments. You can also earn and redeem points on other selected treatments that your doctor may determine are right for you.

In addition, you can earn points when you shop online at your favorite retailers participating in the *Brilliant Distinctions*® Mall. As a member you will receive treatment reminders and information about your points balance.

How many injections will I receive?

For the crow's feet area, 3 areas of the muscle that frames the side of the eye (orbicularis oculi) will be injected. This will be repeated on the orbicularis oculi muscle on the side of the other eye.[4]

For the frown lines area, there are 5 injections into muscles in your forehead—1 in the procerus muscle and 4 in the corrugator muscles.[4]

How long is the recovery time after treatment?

After your treatment, you can resume your day. There is minimal downtime and we may give you specific aftercare instructions.

Do men receive BOTOX® Cosmetic treatment?

Yes. BOTOX® Cosmetic has also been clinically evaluated in male patients. In clinical studies for moderate to severe frown lines, 17.5% of patients treated with BOTOX® Cosmetic were men.[5] In the clinical studies for moderate to severe crow's feet, male patients comprised approximately 12% of patients treated with BOTOX® Cosmetic.[6,7]

BOTOX® Cosmetic onabotulinumtoxinA injection

There's only one BOTOX® Cosmetic

BOTOX® Cosmetic (onabotulinumtoxinA) IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Spread of Toxin Effect (continued)

No definitive serious adverse event reports of distant spread of toxin effect associated with dermatologic use of BOTOX® Cosmetic at the labeled dose of 20 Units (for glabellar lines), 24 Units (for lateral canthal lines), 44 Units (for simultaneous treatment of lateral canthal lines and glabellar lines) have been reported.

Serious Adverse Reactions With Unapproved Use

Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX® injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX® to the site of injection and/or adjacent structures. In several of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX®. The safety and effectiveness of BOTOX® for unapproved uses have not been established.

Hypersensitivity Reactions

Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, and dyspnea. If such reactions occur, further injection of BOTOX® Cosmetic should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent and, consequently, the causal agent cannot be reliably determined.

Please see additional Important Safety Information on following page.

BOTOX® Cosmetic (onabotulinumtoxinA) IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Cardiovascular System

There have been reports following administration of BOTOX® of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease. Use caution when administering to patients with pre-existing cardiovascular disease.

Pre-existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including generalized muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from onabotulinumtoxinA (see *Warnings and Precautions*).

Dysphagia and Breathing Difficulties

Treatment with BOTOX® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing (see *Boxed Warning*).

Pre-existing Conditions at the Injection Site

Caution should be used when BOTOX® Cosmetic treatment is used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle(s).

Human Albumin and Transmission of Viral Diseases

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

ADVERSE REACTIONS

The most frequently reported adverse event following injection of BOTOX® Cosmetic for glabellar lines was eyelid ptosis (3%).

The most frequently reported adverse event following injection of BOTOX® Cosmetic for lateral canthal lines was eyelid edema (1%).

DRUG INTERACTIONS

Co-administration of BOTOX® Cosmetic and aminoglycosides or other agents interfering with neuromuscular transmission (eg, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX® Cosmetic may potentiate systemic anticholinergic effects.

The effect of administering different botulinum neurotoxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of BOTOX® Cosmetic.

USE IN SPECIFIC POPULATIONS

BOTOX® Cosmetic is not recommended for use in children or pregnant women. It is not known whether BOTOX® Cosmetic is excreted in human milk. Caution should be exercised when BOTOX® Cosmetic is administered to a nursing woman.

Please see accompanying full Prescribing Information including Boxed Warning and Medication Guide.

References:
1. Data on file, Allergan, Inc., December 2014. **2.** Data on file, Allergan, Inc.; May 2015; BOTOX® and BOTOX® Cosmetic Country Approvals. **3.** Data on file, Allergan, Inc., June 17, 2015. **4.** BOTOX® Cosmetic Prescribing Information, August 2015. **5.** Carruthers A, Carruthers J, Lowe NJ, et al; for BOTOX® Glabellar Lines I & II Study Groups. One-year, randomised, multicenter, two-period study of the safety and efficacy of repeated treatments with botulinum toxin type A in patients with glabellar lines. *J Clin Res.* 2004;7:1-20. **6.** Data on file, Allergan, Inc.; Clinical Study Report 191622-098; March 28, 2012. **7.** Data on file, Allergan, Inc.; Clinical Study Report 191622-099.

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