BOTOX® COSMETIC onabotulinumtoxinA injection

THE LOOK OF 3

A TREATMENT OF
3 AREAS, 64 UNITS,
AT LEAST 3 TIMES A YEAR.

BOTOX® Cosmetic
The Look of 3: Treatments 1, 2, 3—Stefanie

Before-and-After Photo Files

INSTRUCTIONS FOR USE

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1. The Important Safety Information must be displayed whenever the branding images or photo files appear.

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3. When using images from BrandBox, make sure you download and post all 3 before-and-after photos for each of the treatment areas: frown lines, crow's feet lines, and forehead lines.

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BOTOX® Cosmetic (onabotulinumtoxinA) Important Information

Indications

BOTOX® Cosmetic (onabotulinumtoxinA) is indicated in adult patients for the temporary improvement in the appearance of:
- Moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity
- Moderate to severe lateral canthal lines associated with orbicularis oculi activity
- Moderate to severe forehead lines associated with frontalis activity

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 and approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and spasticity and at lower doses.

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.

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), 40 Units (for forehead lines with glabellar lines), 44 Units (for simultaneous treatment of lateral canthal lines and glabellar lines), and 64 Units (for simultaneous treatment of lateral canthal lines, glabellar lines, and forehead lines) have been reported. Patients or caregivers should be advised to seek immediate medical care if swallowing, speech, or respiratory disorders occur.

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.

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.

Please see additional Important Safety Information on following page.

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IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Increased Risk of Clinically Significant Effects With 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).

Dry Eye in Patients Treated With BOTOX® Cosmetic
There have been reports of dry eye associated with BOTOX® Cosmetic injection in or near the orbicularis oculi muscle. If symptoms of dry eye (eg, eye irritation, photophobia, or visual changes) persist, consider referring patients to an ophthalmologist.

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 disease and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

ADVERSE REACTIONS
The most frequently reported adverse reactions following injection of BOTOX® Cosmetic for glabellar lines were eyelid ptosis (3%), facial pain (1%), facial paresis (1%), and muscular weakness (1%).

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

The most frequently reported adverse reactions following injection of BOTOX® Cosmetic for forehead lines with glabellar lines were headache (9%), brow ptosis (2%), and eyelid ptosis (2%).

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
There are no studies or adequate data from postmarketing surveillance on the developmental risk associated with use of BOTOX® Cosmetic in pregnant women. There are no data on the presence of BOTOX® Cosmetic in human or animal milk, the effects on the breastfed child, or the effects on milk production.

Please see accompanying BOTOX® Cosmetic full Prescribing Information, including Boxed Warning, or visit https://www.rxabbvie.com/pdf/botox-cosmetic_pi.pdf

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Approved Uses
BOTOX® Cosmetic is a prescription medicine that is injected into muscles and used to temporarily improve the look of moderate to severe forehead lines, crow's feet lines, and frown lines between the eyebrows in adults.

IMPORTANT SAFETY INFORMATION
BOTOX® Cosmetic may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of 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, trouble saying words clearly, loss of bladder control, trouble breathing, and trouble swallowing.

BOTOX® Cosmetic dosing units are not the same as, or comparable to, any other botulinum toxin product.

There has not been a confirmed serious case of spread of toxin effect when BOTOX® Cosmetic has been used at the recommended dose to treat frown lines, crow's feet lines, and/or forehead lines.

BOTOX® Cosmetic may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX® Cosmetic. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

Please see additional Important Safety Information on following pages.

Treatment 1—Stefanie
Moderate to severe forehead lines

Before | After (Day 30)

Real patient. ***Results may vary.***
Photos taken at maximum eyebrow elevation before and 30 days after treatment with BOTOX® Cosmetic. In 2 clinical studies of healthy adults, 61% and 46% had a ≥ 2-grade improvement at day 30.[1,*]

Treatment 2—Stefanie
Moderate to severe forehead lines
Patient was evaluated by her specialist at least 3 months after her first treatment and considered appropriate for treatment in forehead lines with 20 Units.

Before | After (Day 30)

Real patient. ***Results may vary.***
Photos taken at maximum eyebrow elevation before and 30 days after treatment with BOTOX® Cosmetic. In 2 clinical studies of healthy adults, 61% and 46% had a ≥ 2-grade improvement at day 30.[1,*]

Treatment 3—Stefanie
Moderate to severe forehead lines
Patient was evaluated by her specialist at least 3 months after her second treatment and considered appropriate for treatment in forehead lines with 20 Units.

Before | After (Day 30)

Real patient. ***Results may vary.***
Photos taken at maximum eyebrow elevation before and 30 days after treatment with BOTOX® Cosmetic. In 2 clinical studies of healthy adults, 61% and 46% had a ≥ 2-grade improvement at day 30.[1,*]

*Side effects associated with the injection include localized pain, infection, inflammation, tenderness, swelling, redness, and/or bleeding/bruising.[1]

REFERENCE: 1. BOTOX® Cosmetic Prescribing Information, July 2020.

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IMPORTANT SAFETY INFORMATION (continued)

Serious and/or immediate allergic reactions have been reported. They include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Get medical help right away if you are wheezing or have asthma symptoms, or if you become dizzy or faint.

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

Tell your doctor about all your muscle or nerve conditions, such as ALS or Lou Gehrig's disease, myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including difficulty swallowing and difficulty breathing from typical doses of BOTOX® Cosmetic.

Tell your doctor about all your medical conditions, including: plans to have surgery; had surgery on your face; have trouble raising your eyebrows; drooping eyelids; any other abnormal facial change; are pregnant or plan to become pregnant (it is not known if BOTOX® Cosmetic can harm your unborn baby); are breast-feeding or plan to (it is not known if BOTOX® Cosmetic passes into breast milk).

Please see additional Important Safety Information on following page.

Treatment 1—Stefanie

Moderate to severe crow's feet lines

Before | After (Day 30)

Real patient. ***Results may vary.***
Photos taken at full smile before and 30 days after treatment with BOTOX® Cosmetic. In 2 clinical studies, 26.1% and 20.3% of adults had a ≥ 2-grade improvement at day 30. In one of these studies, 67.9% had mild or no crow's feet lines at day 30 after treatment.[1,*]

Treatment 2—Stefanie

Moderate to severe crow's feet lines

Patient was evaluated by her specialist at least 3 months after her first treatment and considered appropriate for treatment in crow's feet lines with 24 Units.

Before | After (Day 30)

Real patient. ***Results may vary.***
Photos taken at full smile before and 30 days after treatment with BOTOX® Cosmetic. In 2 clinical studies, 26.1% and 20.3% of adults had a ≥ 2-grade improvement at day 30. In one of these studies, 67.9% had mild or no crow's feet lines at day 30 after treatment.[1,*]

Treatment 3—Stefanie

Moderate to severe crow's feet lines

Patient was evaluated by her specialist at least 3 months after her second treatment and considered appropriate for treatment in crow's feet lines with 24 Units.

Before | After (Day 30)

Real patient. ***Results may vary.***
Photos taken at full smile before and 30 days after treatment with BOTOX® Cosmetic. In 2 clinical studies, 26.1% and 20.3% of adults had a ≥ 2-grade improvement at day 30. In one of these studies, 67.9% had mild or no crow's feet lines at day 30 after treatment.[1,*]

*Side effects associated with the injection include localized pain, infection, inflammation, tenderness, swelling, redness, and/or bleeding/bruising.[1]

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IMPORTANT SAFETY INFORMATION (continued)

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using BOTOX® Cosmetic 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® Cosmetic in the past.**

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 (tell your doctor 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 aspirin-like products or blood thinners.

Other side effects of 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 and eyebrows, swelling of your eyelids and dry eyes.

For more information refer to the Medication Guide or talk with your doctor.

To report a side effect, please call Allergan at 1-800-678-1605.

Please see accompanying Summary of Information about BOTOX® Cosmetic.

Treatment 1—Stefanie
Moderate to severe frown lines

Before | After (Day 30)

Real patient. ***Results may vary.***
Photos taken at maximum frown before and 30 days after treatment with BOTOX® Cosmetic. In clinical studies, physicians assessed 80% of adults had significant improvement at day 30; in the same studies, 89% of adults who were treated saw at least moderate improvement at day 30.[1,*]

Treatment 2—Stefanie
Moderate to severe frown lines
Patient was evaluated by her specialist at least 3 months after her first treatment and considered appropriate for treatment in frown lines with 20 Units.

Before | After (Day 30)

Real patient. ***Results may vary.***
Photos taken at maximum frown before and 30 days after treatment with BOTOX® Cosmetic. In clinical studies, physicians assessed 80% of adults had significant improvement at day 30; in the same studies, 89% of adults who were treated saw at least moderate improvement at day 30.[1,*]

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