BOTOX® COSMETIC onabotulinumtoxinA injection

THERE'S ONLY ONE BOTOX® COSMETIC

Patient Q&A Flipchart

OWN YOUR LOOK

How to talk to your patients about FDA-approved dosing, fewer lines, facial expressions, and more.

Actual patient treated for the appearance of moderate to severe forehead lines, lateral canthal lines, and glabellar lines. ***Results may vary.***

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.

Please see additional Important Safety Information on following pages.

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TALKING ABOUT *TREATMENT AREAS*

IF A PATIENT SAYS:

"I only want to treat my forehead lines."

OR

"If I have more than one area treated, will I look overdone?"

Actual patient treated for the appearance of moderate to severe forehead lines, lateral canthal lines, and glabellar lines. ***Results may vary.***

YOU SAY

- Only BOTOX® Cosmetic is FDA approved to temporarily make moderate to severe frown lines, crow's feet lines, and forehead lines look better in adults[1]
- If you're bothered by your forehead lines, crow's feet lines, and frown lines, you're not alone. In a recent survey, men and women were asked which areas they would treat first and these 3 were among their top areas of concern[2,3,*]
- For an aesthetically desirable result and to reduce potential complications, **your specialist may treat areas together** (like the forehead and between the brows). Muscles are interrelated and balance each other[1,4-7]
- Your specialist will first perform a facial assessment. Based on your needs and the desired outcome, your specialist will then determine your optimal treatment plan

*Results from 2 separate surveys: first, of aesthetically aware women aged 30 to 65 years (N = 603), and second, of injectable-naïve, aesthetically oriented men aged 30 to 65 years (N = 600) to determine most likely treatment areas and top areas of concern.

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.

Please see additional Important Safety Information on following pages.

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THERE'S ONLY ONE BOTOX® COSMETIC

TALKING ABOUT *DOSING*

IF A PATIENT SAYS:

"How much BOTOX® Cosmetic will I need?"

Actual patient treated for the appearance of moderate to severe forehead lines, lateral canthal lines, and glabellar lines. ***Results may vary.***

YOU SAY

- Everyone is unique, so your aesthetic specialist will first perform a facial assessment and talk to you about your goals
- The FDA has approved a certain amount of BOTOX® Cosmetic to temporarily treat moderate to severe lines in 3 different areas.[1] In clinical trials, these amounts (called units) were used to achieve the desired result[1]:

FOREHEAD LINES **20 Units**

CROW'S FEET LINES **24 Units** **(12 Units each side)**

FROWN LINES **20 Units**

- Dosing is all about getting the results you want by temporarily softening these lines. In clinical trials, results lasted 4 months in frown lines with the FDA-approved dose[1,*]

*80% of patients (325/405) showed improvement vs 3% (4/132) for placebo per investigator assessment at day 30; 89% of patients (362/405) assessed improvement vs 7% (9/132) for placebo at day 30; 25% of patients (102/403) showed improvement vs 2% (2/128) for placebo per investigator assessment at day 120; 39% of patients (157/403) assessed improvement vs 1% (1/128) for placebo at day 120.

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

Please see additional Important Safety Information on following pages.

BOTOX® COSMETIC onabotulinumtoxinA injection

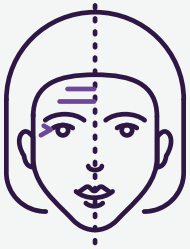
THERE'S ONLY ONE BOTOX® COSMETIC

TALKING ABOUT *FACIAL EXPRESSIONS*

IF A PATIENT SAYS:

"Will I still look like myself after treatment?"

Actual patient treated for the appearance of moderate to severe forehead lines, lateral canthal lines, and glabellar lines. ***Results may vary.***



YOU SAY

- When BOTOX® Cosmetic is administered correctly, **you'll still look like yourself**—only with less noticeable lines. No one should be able to tell you've had anything done
- It's important to be treated by someone who is licensed, trained, and a medical expert in facial anatomy
- You can see **before-and-after photos** of men and women at BotoxCosmetic.com

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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 pages.

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TALKING ABOUT *BEFORE TREATMENT*

IF A PATIENT SAYS:

"What should I expect during treatment?"

Actual patient treated for the appearance of moderate to severe forehead lines, lateral canthal lines, and glabellar lines. ***Results may vary.***

YOU SAY

- BOTOX® Cosmetic is a **quick, 10-minute treatment** that's easy to fit into your busy schedule
- First, your aesthetic specialist will discuss your **treatment goals and safety.** Then, you'll have a facial assessment to determine the appropriate treatment areas for you
- Some people say that the injections **feel like a pinch.** Your specialist may use ice or a topical numbing cream to enhance comfort

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.

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*).

Please see additional Important Safety Information on following pages.

BOTOX® COSMETIC onabotulinumtoxinA injection

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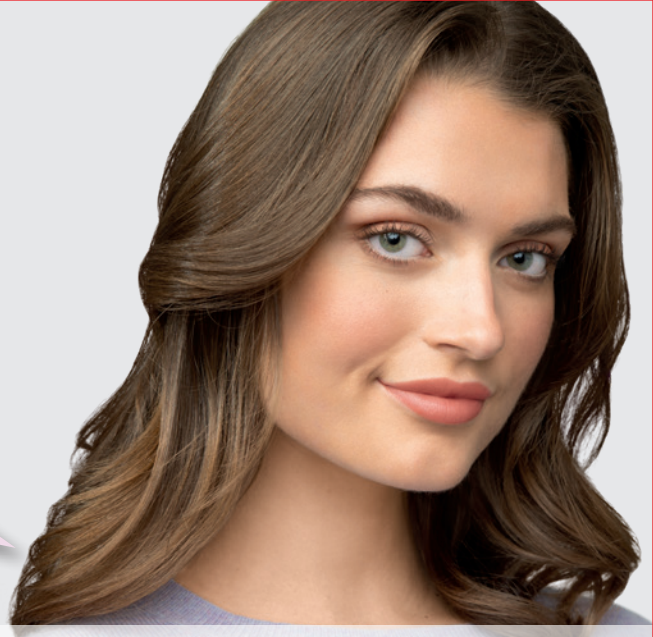
TALKING ABOUT *POST TREATMENT*

IF A PATIENT SAYS:

"What should I expect after treatment?"



Actual patient treated for the appearance of moderate to severe forehead lines, lateral canthal lines, and glabellar lines. ***Results may vary.***

YOU SAY

- Treatment requires **minimal downtime.** So you can return to your daily routine immediately after you leave your specialist's office
- You may begin to notice **results within 24 to 48 hours,** with results **lasting up to 4 months** for moderate to severe frown lines[1,]*
- **Results vary from patient to patient,** so your aesthetic specialist will plan your next appointment based on your aesthetic goals

*80% of patients (325/405) showed improvement vs 3% (4/132) for placebo per investigator assessment at day 30; 89% of patients (362/405) assessed improvement vs 7% (9/132) for placebo at day 30; 25% of patients (102/403) showed improvement vs 2% (2/128) for placebo per investigator assessment at day 120; 39% of patients (157/403) assessed improvement vs 1% (1/128) for placebo at day 120.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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.

Please see additional Important Safety Information on following pages.

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TALKING ABOUT *COST*

IF A PATIENT SAYS:

"I'm not sure I can afford treatment."

Actual patient treated for the appearance of moderate to severe forehead lines, lateral canthal lines, and glabellar lines. ***Results may vary.***

BRILLIANT DISTINCTIONS®

YOU SAY

- You can **save money on your treatments** by enrolling in the *Brilliant Distinctions*® Consumer Loyalty Program
  - It's free to join, and helps you **earn points for savings on future treatments.** With *Brilliant Distinctions*®, you can also save on other Allergan aesthetic treatments and products
- **Signing up is easy.** You can download the *Brilliant Distinctions*® app or visit BrilliantDistinctionsProgram.com

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

Please see additional Important Safety Information on following page.

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OWN YOUR LOOK

YOUR PATIENTS CAN LOOK LIKE THEMSELVES—WITH FEWER LINES.

Talk to them today about BOTOX® Cosmetic.

The ***only*** product of its kind FDA approved to temporarily make moderate to severe frown lines, crow's feet lines, and forehead lines look better in adults.

IMPORTANT SAFETY INFORMATION (continued)

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.

For more information on BOTOX® Cosmetic, please see accompanying full Prescribing Information including Boxed Warning and Medication Guide.

REFERENCES: 1. BOTOX® Cosmetic Prescribing Information, July 2020. **2.** Jagdeo J, Keaney T, Narurkar V, Kolodziejczyk J, Gallagher CJ. Facial treatment preferences among aesthetically oriented men. *Dermatol Surg.* 2016;42(10):1155-1163. **3.** Narurkar V, Shamban A, Sissins P, Stonehouse A, Gallagher C. Facial treatment preferences in aesthetically aware women. *Dermatol Surg.* 2015;41(suppl 1):153S-160S. **4.** Michaud T, Gassia V, Belhaouari L. Facial dynamics and emotional expressions in facial aging treatments. *J Cosmet Dermatol*. 2015;14(1):9-21. **5.** Bulstrode NW, Grobbelaar AO. Long-term follow-up of botulinum toxin treatment for facial rhytides. *Aesthetic Plast Surg*. 2002;26(5):356-359. **6.** Lorenc ZP, Smith S, Nestor M, Nelson D, Moradi A. Understanding the functional anatomy of the frontalis and glabellar complex for optimal aesthetic botulinum toxin type A therapy. *Aesthetic Plast Surg*. 2013;37(5):975-983. **7.** Qaqish C. Botulinum toxin use in the upper face. *Atlas Oral Maxillofac Surg Clin North Am*. 2016;24(2):95-103.

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