

**BOTOX<sup>®</sup>**  
**COSMETIC**  
onabotulinumtoxinA injection

# Dosing and Injection Guide

A step-by-step guide to your  
key considerations when  
assessing and treating patients

BOTOX<sup>®</sup> Cosmetic is FDA approved for the temporary improvement in the appearance of **moderate to severe platysma bands, forehead lines, lateral canthal lines, and glabellar lines in adults.**<sup>1</sup>

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

## **BOTOX<sup>®</sup> Cosmetic (onabotulinumtoxinA)**

### **Important Information**

#### **Indications**

BOTOX<sup>®</sup> 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
- Moderate to severe platysma bands associated with platysma muscle activity

## **IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING**

### **WARNING: DISTANT SPREAD OF TOXIN EFFECT**

Postmarketing reports indicate that the effects of BOTOX<sup>®</sup> 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.

# Supporting your expertise

Outlined in this guide are key considerations to support your knowledge when assessing patients and treating them with BOTOX<sup>®</sup> Cosmetic.

## START

with understanding fundamental assessment education

## ELEVATE

your consult with 6 comprehensive best practices

## UNDERSTAND

individualized anatomy and interrelated muscle anatomy prior to injections

## INDIVIDUALIZE

approved injection points to your patient's anatomy based on on-label dosing and injection

## The one & only BOTOX<sup>®</sup> Cosmetic

**BOTOX<sup>®</sup> Cosmetic is the first FDA-approved product** to temporarily improve the appearance of **3 areas—moderate to severe forehead lines, lateral canthal lines, and glabellar lines in adults**<sup>1-6</sup>

### 3 AREAS, 64 UNITS, AT LEAST 3 TIMES A YEAR<sup>1,\*</sup>

- **FDA approved for 64 Units**—20 Units in forehead lines, 24 Units in lateral canthal lines, and 20 Units in glabellar lines<sup>1</sup>
- **BOTOX<sup>®</sup> Cosmetic has** been proven to deliver **consistent results** with simultaneous treatment. See your patients at least 3 times a year and schedule treatments at least 90 days apart<sup>1,7</sup>

## The first and only product of its kind FDA approved to treat *Beyond the Face*<sup>1-6</sup>

- **FDA approved** to temporarily improve the appearance of moderate to severe platysma bands in adults<sup>1</sup>
- **FDA approved with customizable dosing** dependent on platysma band severity (26U, 31U, or 36U, for full dosing protocol, please see pages 36-37)

<sup>1</sup>Treatment should be spaced at least 90 days apart.<sup>1</sup>

moderate to severe  
**FOREHEAD LINES**  
20 Units

moderate to severe  
**GLABELLAR LINES**  
20 Units

moderate to severe  
**LATERAL CANTHAL LINES**  
24 Units (12 Units each side)

moderate to severe  
**PLATYSMA BANDS**  
26U, 31U, or 36U  
based on severity

Real patient before treatment.

#### IMPORTANT SAFETY INFORMATION (continued)

##### CONTRAINDICATIONS

BOTOX<sup>®</sup> 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.

Please see additional Important Safety Information on following pages.

## 1. BUILD TRUST with your expertise

79% of patients **receive neurotoxin treatment after a discussion** with their specialist.<sup>8,\*</sup>

## 2. KNOW what they want

**Motivators to get treated vary across ages.** 20 year olds consider the safety profile.<sup>9,\*</sup> 30 year olds want natural-looking results.<sup>9,\*</sup> 40 year olds want a brand they can trust.<sup>10,§</sup>

## 3. EDUCATE on the science

**Explain the underlying causes** of facial lines and platysma bands, and discuss how BOTOX<sup>®</sup> Cosmetic can temporarily reduce muscle activity to improve the appearance of upper facial lines and platysma bands.

**Highlight** that BOTOX<sup>®</sup> Cosmetic can provide natural-looking results in moderate to severe forehead lines, lateral canthal lines, and glabellar lines.<sup>1,10,11,11,\*</sup>

## 4. ASSURE FDA approval in 4 areas

**88% of patients (n = 526) want a product that is FDA approved**—and 91% of millennials (n = 231) say FDA approval is very or somewhat important to them.<sup>12,#</sup>

**Share** that BOTOX<sup>®</sup> Cosmetic is backed by over 20 years of published studies reviewing its safety and efficacy.<sup>13,14</sup>

## 5. EMPHASIZE FDA-approved dosing

**Talk to your patients about desired outcomes** with treatments of 3 areas, 64 Units, at least 3 times a year.<sup>1,\*\*</sup>

**Discuss** that they may see results in 1 to 2 days, with full results in 30 days, and their results may last up to 4 months for moderate to severe forehead lines, lateral canthal lines, and glabellar lines.<sup>1</sup>

**Highlight** that patients were satisfied with treatment results.<sup>1,15,††</sup>

**Explain** that BOTOX<sup>®</sup> Cosmetic is also FDA approved for moderate to severe platysma bands, with customizable dosing dependent on platysma band severity (26U, 31U, or 36U, for full dosing protocol, please see pages 36-37) with full results in 14 days.<sup>1</sup>

**Reinforce** that, for appropriate patients, BOTOX<sup>®</sup> Cosmetic can temporarily improve the appearance of moderate to severe platysma bands, forehead lines, lateral canthal lines, and glabellar lines in adults.<sup>1</sup>

## 6. ENCOURAGE booking their next assessment

**Schedule their visit** at least 90 days out and let them know you'll assess them to see if they're appropriate for another BOTOX<sup>®</sup> Cosmetic treatment.

\*Based on 2022 online survey of 242 healthcare professionals who answered how many patients received treatment after a discussion.<sup>8</sup>

†Based on a 2022 online survey of 251 neurotoxin patients, of which 40 were between the ages of 18 and 29. This subpopulation answered what drives them to BOTOX<sup>®</sup> Cosmetic.<sup>9</sup>

‡Based on a 2022 online survey of 251 neurotoxin patients, of which 82 were between the ages of 30 and 39. This subpopulation answered what drives them to BOTOX<sup>®</sup> Cosmetic.<sup>9</sup>

§Based on a 2022 online survey of 251 neurotoxin patients, of which 104 were labeled as Gen X. This subpopulation answered what drives them to BOTOX<sup>®</sup> Cosmetic.<sup>10</sup>

¶84% of pooled subjects (n = 592) who received 20U in FHL and GL, respectively, reported being "Very Satisfied" or "Mostly Satisfied" with the natural-looking results of treatment compared to 5.8% (n = 241) with placebo at day 30. This item was part of the Facial Line Satisfaction Questionnaire Follow-Up Treatment Satisfaction domain. In addition, 96% of market research subjects (n = 137) treated for LCL reported they "Completely Agree" or "Somewhat Agree" that BOTOX<sup>®</sup> Cosmetic provides natural-looking results.<sup>10,11</sup>

†In 2 clinical trials, 90% and 82% of patients (n = 260 each) who received 20 Units in forehead lines and glabellar lines, respectively, reported they were "Very Satisfied" or "Mostly Satisfied" (top 2 out of 5 responses) with their treatment results at day 60 vs 1% and 3%, respectively, for placebo (n = 6 total).<sup>1</sup>

‡Based on a 2021 online survey of 526 neurotoxin patients, of which 231 were millennials. Results from respondents who replied "Very Important" or "Somewhat Important" when asked, "How important is FDA approval in cosmetic treatments?"<sup>12</sup>

\*\*Treatment should be spaced at least 90 days apart.<sup>1</sup>

††In 2 multicenter, double-blind, placebo-controlled studies of BOTOX<sup>®</sup> Cosmetic treatment, 90% and 82% of patients (n = 260 each) who received 20 Units in forehead lines and 20 Units in glabellar lines reported they were "Very Satisfied" or "Mostly Satisfied" (top 2 out of 5 responses) with their treatment results at day 60 vs 1% and 3%, respectively, for placebo (n = 6 total). 88% of patients (n = 313) treated with 20U FHL + 24U LCL + 20U GL reported being "Very Satisfied" or "Mostly Satisfied" with BOTOX<sup>®</sup> Cosmetic compared to 3% with placebo (n = 156). This item was part of the Facial Line Satisfaction Questionnaire (FLSQ) Follow-Up Treatment Satisfaction domain, a validated scale from 1 to 5 where 1 = "Very Dissatisfied" and 5 = "Very Satisfied." In clinical trials, full results of treatment were seen at day 30.<sup>15</sup>

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS

**Lack of Equivalency Between Botulinum Toxin Products**  
The potency Units of BOTOX<sup>®</sup> Cosmetic are specific to the preparation and assay method utilized. BOTOX<sup>®</sup> Cosmetic is not equivalent to other preparations of botulinum toxin products, and therefore, Units of biological activity of BOTOX<sup>®</sup> 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.



# Take a first impression

Use the First Impression Framework to help identify areas of focus for your patients

## What is a First Impression Framework?

The First Impression Framework is a comprehensive approach to patient assessment. It provides a systematic assessment to bring focus to 3 key visual ways, or frames, a person communicates with the world, including the frame of profile.

Each frame contains elements of the face that are interrelated, and changes to one element may impact the others.

## Why is it important?

Anatomical knowledge is the foundation of this framework. Understanding the key frames helps to contextualize the various areas of the face and neck, and can help complete a full aesthetic needs evaluation.

## Be sure to use the First Impression Framework when you assess patients for:

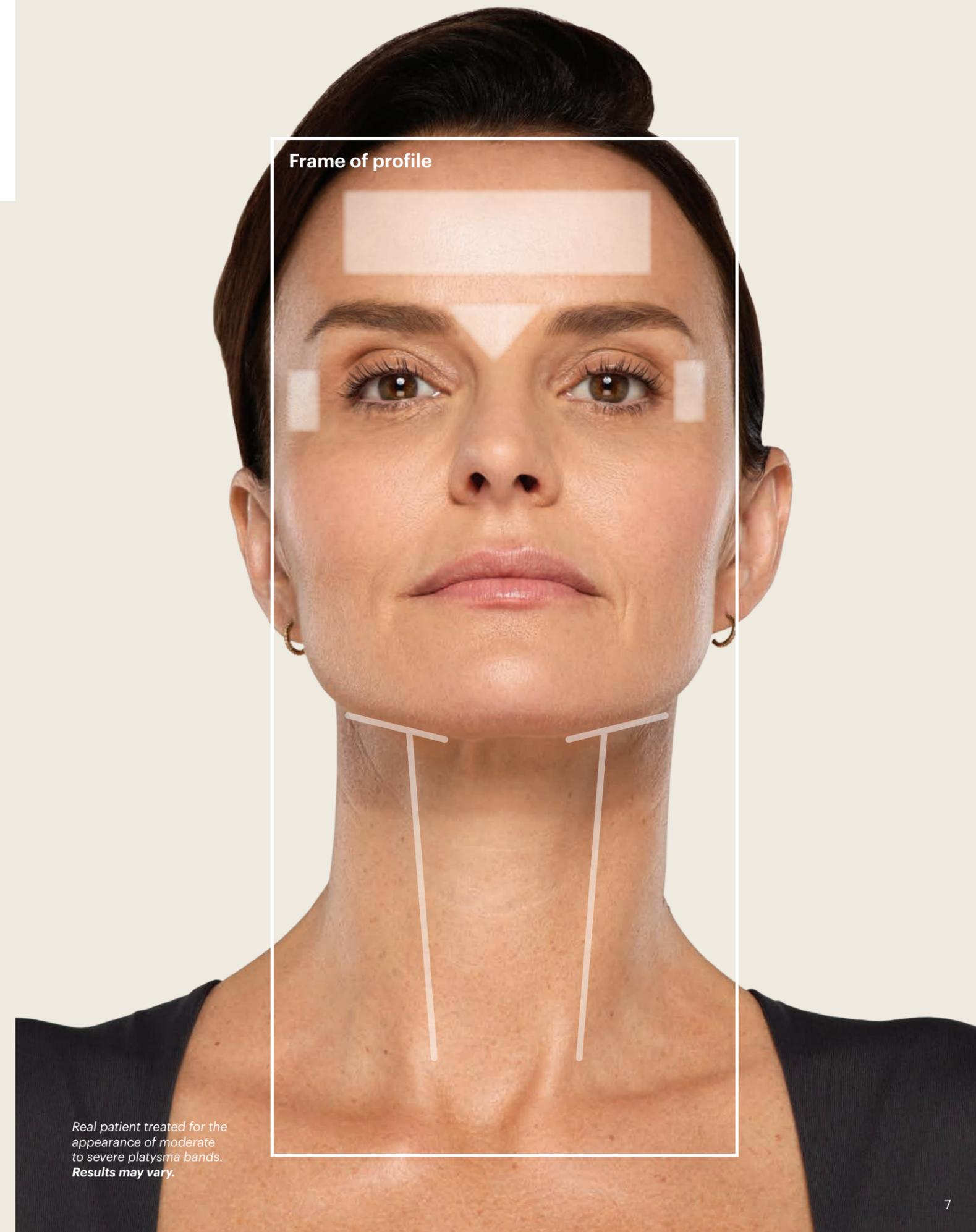
- Moderate to severe platysma bands
- Moderate to severe forehead lines
- Moderate to severe lateral canthal lines
- Moderate to severe glabellar lines

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

#### Spread of Toxin Effect

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

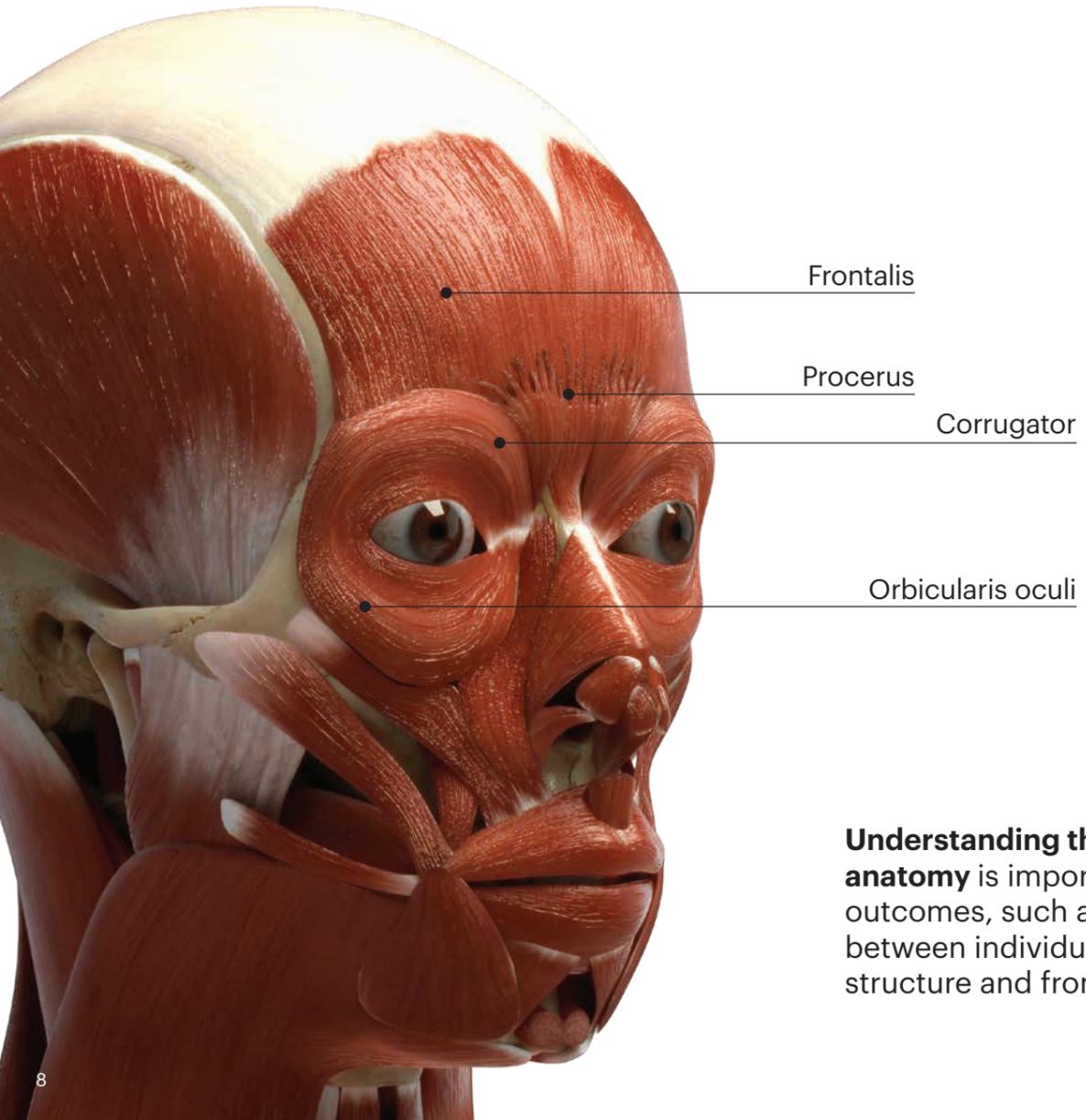
Please see additional Important Safety Information on following pages.



*Real patient treated for the appearance of moderate to severe platysma bands. Results may vary.*

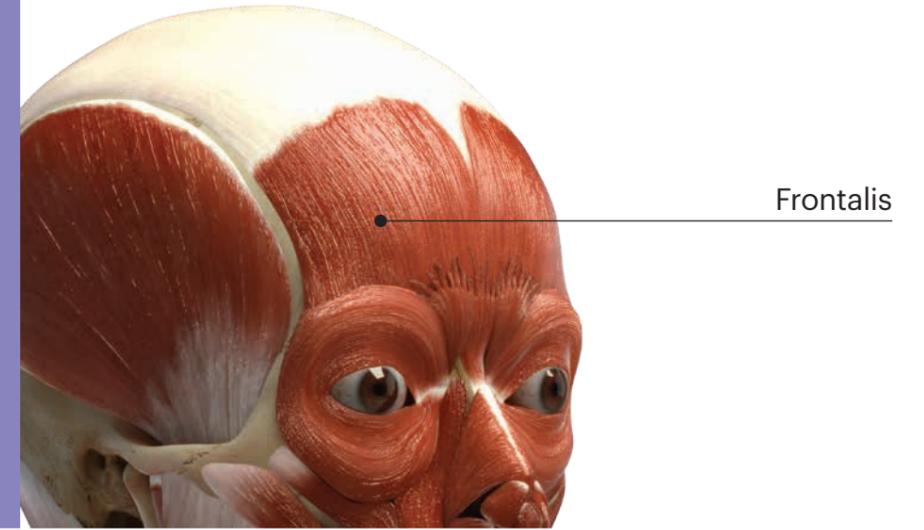
# Understand individualized anatomy and interrelated muscles for desired outcomes

Consider the functional relationship of the upper face muscles.<sup>16,17</sup>

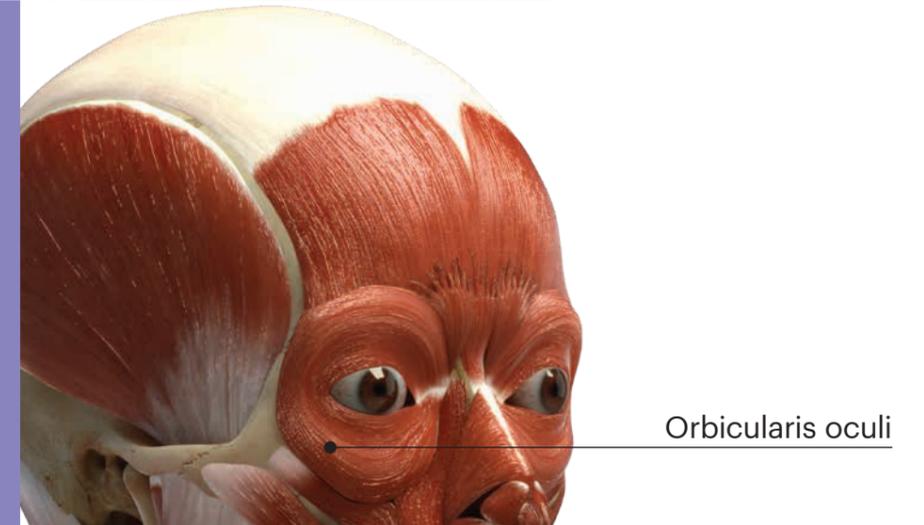


**Understanding the relevant anatomy** is important for outcomes, such as variability between individuals in frontalis structure and frontal anatomy.<sup>1,18</sup>

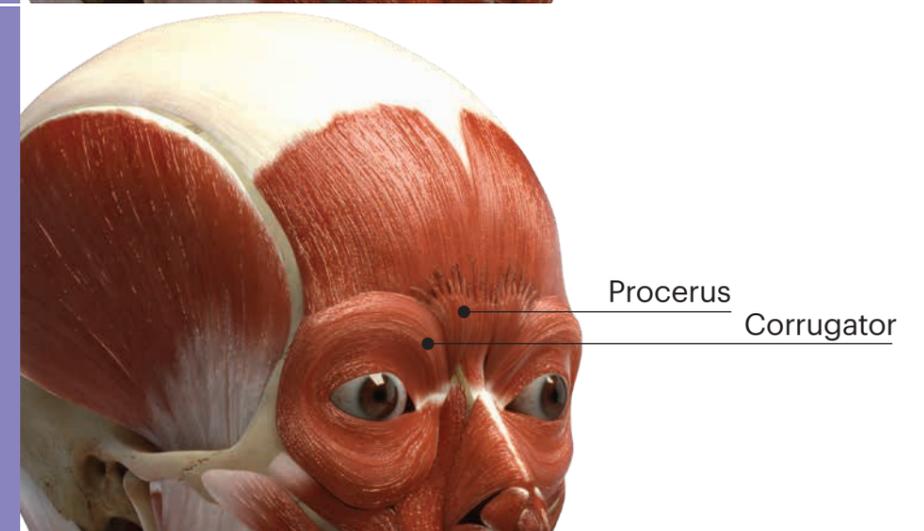
Contraction (elevation) of the frontalis draws eyebrows superiorly and creates horizontal forehead lines.<sup>19</sup>



The orbicularis oculi closes the eyelid as it contracts, producing lateral canthal lines.<sup>19</sup>



The procerus draws down the medial brow while the corrugators draw the brow toward the midline. Repeated movements contribute to vertical glabellar lines.<sup>19</sup>



**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<sup>®</sup> 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.

Please see additional Important Safety Information on following pages.

## Assess all 3 areas, every time

Ask patients to do the following to check for moderate to severe<sup>18</sup>:



Forehead lines  
**Raise your eyebrows!**

Lateral canthal lines  
**Smile!**

Glabellar lines  
**Frown!**

### Additionally, look for:

- Existing brow or lid ptosis, which may present as asymmetry in the upper face<sup>1</sup>
- Which muscles act as elevators and which act as depressors<sup>18</sup>
- The overall relationship between the size of your patient's forehead and the distribution of frontalis activity<sup>1</sup>
- The anatomy extent of the corrugator muscle<sup>18</sup>
- How the orbicularis oculi and cheek mound move during a full smile to avoid injection of the zygomatici<sup>19</sup>
- The proximity of the corrugator muscle to the levator palpebrae superioris, the muscle just beneath it<sup>1</sup>

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

#### Spread of Toxin Effect (continued)

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.



*Real patient before treatment.*

# Injecting moderate to severe forehead lines

## 3 TYPES OF LINE PATTERNS

Most common<sup>20</sup>



Full forehead lines

V-shaped forehead lines

Central forehead lines

5 Injection Sites<sup>1</sup>

Total Dosage: 20 Units<sup>1</sup>

Middle frontalis

4 Units

Left lateral frontalis

4 Units

Right lateral frontalis

4 Units

Left medial frontalis

4 Units

Right medial frontalis

4 Units



Real patients before treatment.

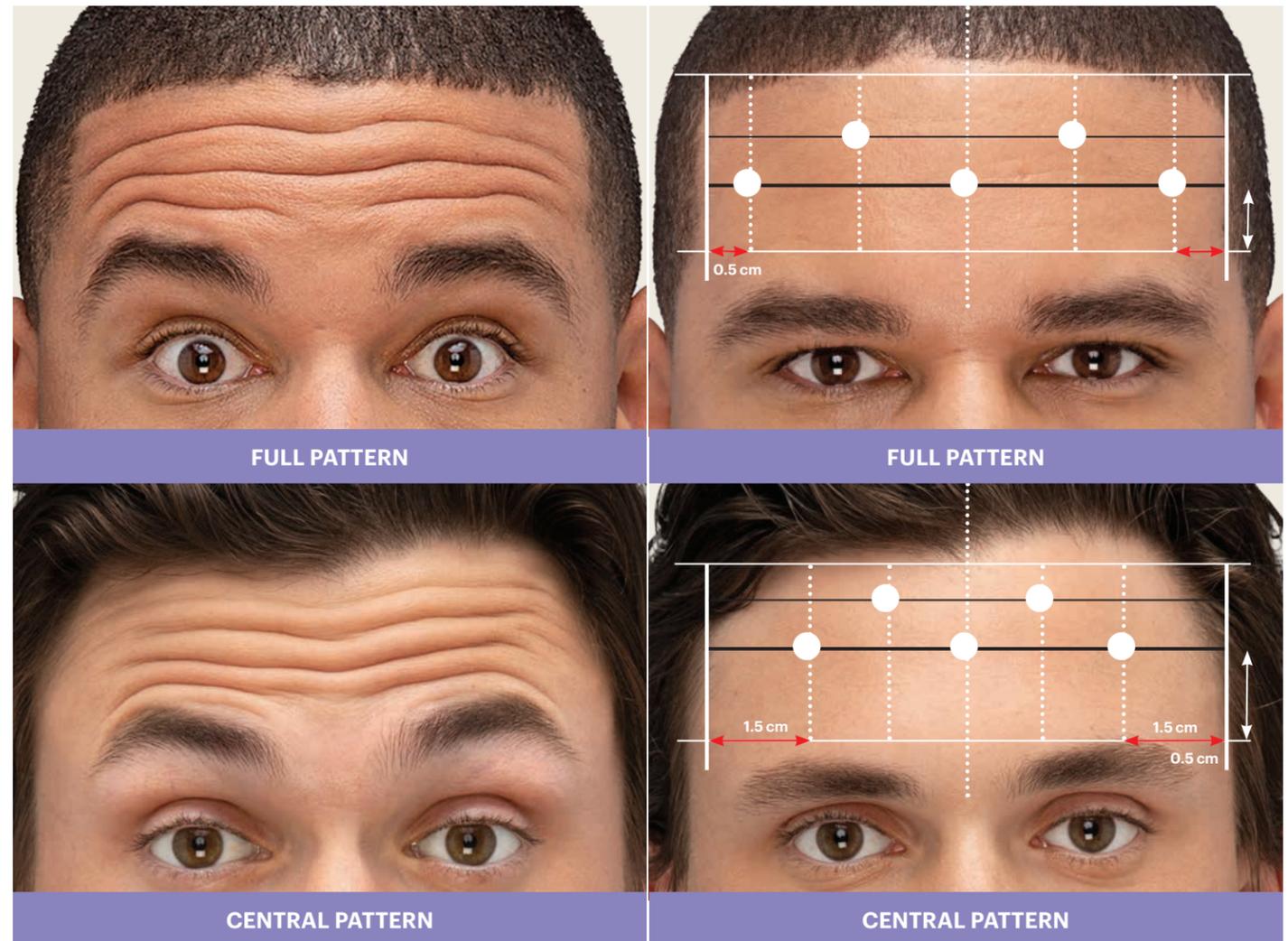
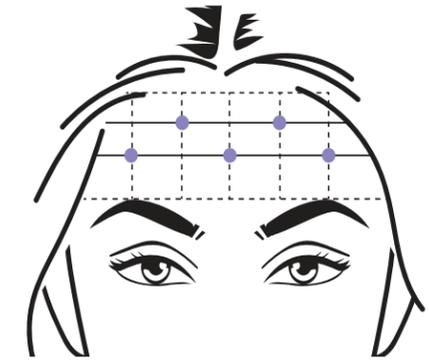
## 20 UNITS

Treatment goal: blockage of muscle activity, leading to temporarily **improved appearance of moderate to severe forehead lines.**<sup>1</sup>

## Individualize injection points to patient's anatomy<sup>1</sup>

### INJECTION PATTERN IN THE PRESCRIBING INFORMATION

These injection patterns are consistent with the approved injection pattern in the Prescribing Information, which states the lower treatment row can vary 0.5 cm to 1.5 cm medially from the palpated temporal fusion line. Injectors should assess the frontalis muscle activity when identifying the location of the appropriate injection sites.<sup>1</sup>



Real patients before treatment.

**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<sup>®</sup> injections for unapproved uses.

**Please see additional Important Safety Information on following pages.**

# Precise injection techniques<sup>1</sup>

## FOR MODERATE TO SEVERE FOREHEAD LINES

When identifying the location of the appropriate injection sites in the frontalis muscle, assess the overall relationship between the size of the subject's forehead and the distribution of frontalis muscle activity.



Real patient before treatment.

**LOCATE** the following horizontal treatment rows by light palpation of the forehead at rest and maximum eyebrow elevation:

- **SUPERIOR MARGIN OF FRONTALIS ACTIVITY:** approximately 1 cm above the most superior forehead crease
- **LOWER TREATMENT ROW:** midway between the superior margin of frontalis activity and the eyebrow, at least 2 cm above the eyebrow
- **UPPER TREATMENT ROW:** midway between the superior margin of frontalis activity and lower treatment row

**INJECT** 4 Units/0.1 mL of reconstituted BOTOX<sup>®</sup> Cosmetic into 5 sites in the frontalis muscle for a total of 20 Units/0.5 mL. Place the 5 injections at the intersection of the horizontal treatment rows with the following vertical landmarks:

- **ON THE LOWER TREATMENT ROW:** at the midline of the face and 0.5 cm to 1.5 cm medial to the palpated temporal fusion line (temporal crest); repeat for the other side
- **ON THE UPPER TREATMENT ROW:** midway between the lateral and medial sites on the lower treatment row; repeat for the other side



Watch step-by-step injection techniques.

## CAUTIONS AND CONSIDERATIONS

- Treat forehead lines in conjunction with glabellar lines to minimize potential for brow ptosis<sup>1</sup>
- Lateral injection sites can be 0.5 cm to 1.5 cm medial to the temporal fusion line, and the distance between the brow and lower treatment row should be no less than 2 cm<sup>1</sup>
- When targeting the corrugator, inadvertently injecting the frontalis too shallowly may lead to brow ptosis<sup>19</sup>



## REMEMBER

The reconstituted formulation of BOTOX<sup>®</sup> Cosmetic was studied in clinical trials and is critical to achieve the correct dose. Results seen in clinical trials were achieved using the FDA-approved reconstitution process.<sup>1</sup>

## START SEEING RESULTS IN 1 TO 2 DAYS WITH FULL RESULTS IN 30 DAYS<sup>1</sup>

20 Units · Moderate to severe forehead lines (FHL)



## RESULTS UP TO 4 MONTHS



Real patient treated for the appearance of moderate to severe forehead lines, lateral canthal lines, and glabellar lines. **Results may vary.** Photos taken at maximum eyebrow elevation before and after treatment with BOTOX<sup>®</sup> Cosmetic at days 2, 30, and 120. In clinical trials at day 30, 61% (178/290) and 46% (145/318) of patients demonstrated a ≥ 2-grade improvement from baseline in forehead line severity at maximum eyebrow elevation as compared to 0% (0/101) and 1% (1/156) in placebo, as assessed by both investigators and subjects. In clinical trials at day 120, approximately 40% of patients in Study 1 and approximately 32% in Study 2 achieved a grade of none or mild improvement from baseline in forehead line severity at maximum eyebrow elevation as compared to approximately 5% of patients in Study 1 and approximately 3% in Study 2 for placebo, as assessed by investigators.<sup>1</sup>

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

#### Serious Adverse Reactions With Unapproved Use (continued)

In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX<sup>®</sup> to the site of injection and/or adjacent structures. In several of the cases, patients had preexisting dysphagia or other significant disabilities.

Please see additional Important Safety Information on following pages.

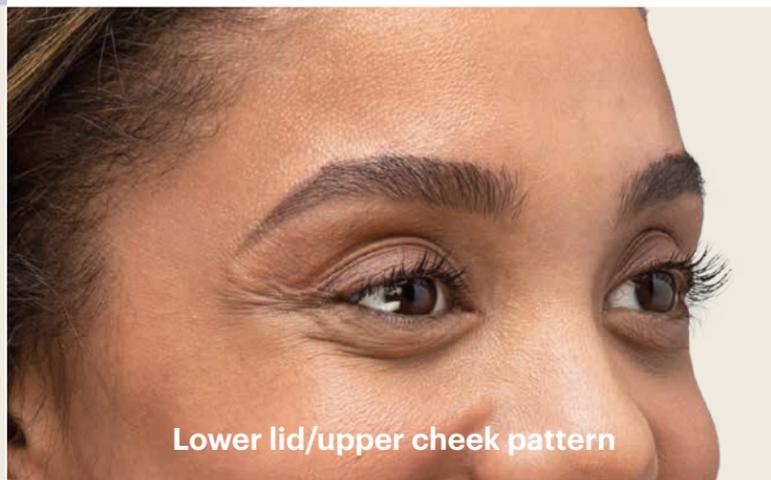
# Injecting moderate to severe lateral canthal lines

## 2 TYPES OF LINE PATTERNS

Most common<sup>21</sup>



Full-fan pattern



Lower lid/upper cheek pattern

### 3 Injection Sites<sup>1</sup>

First injection (A): 1.5 cm to 2 cm temporal to the lateral canthus and just temporal to the orbital rim

Lateral orbicularis oculi

Lateral orbicularis oculi

### Total Dosage<sup>1</sup>: 12 Units per Side

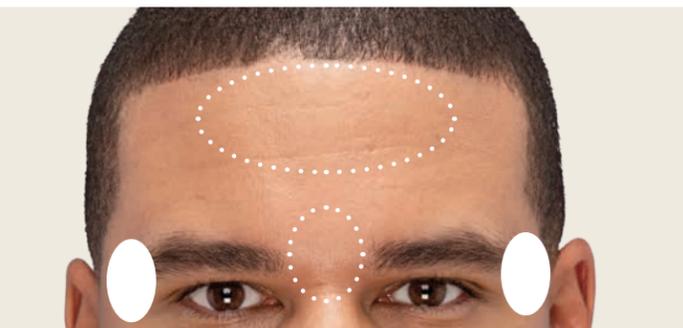
**4 Units**

**4 Units**

**4 Units**

## 24 Units

Treatment goal: temporary blockage of muscle activity, leading to **temporarily improved appearance of moderate to severe lateral canthal lines.**<sup>1</sup>



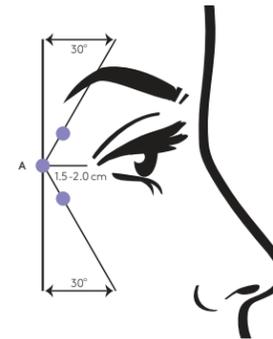
Real patients before treatment.

## Individualize injection points to patient's anatomy<sup>1</sup>

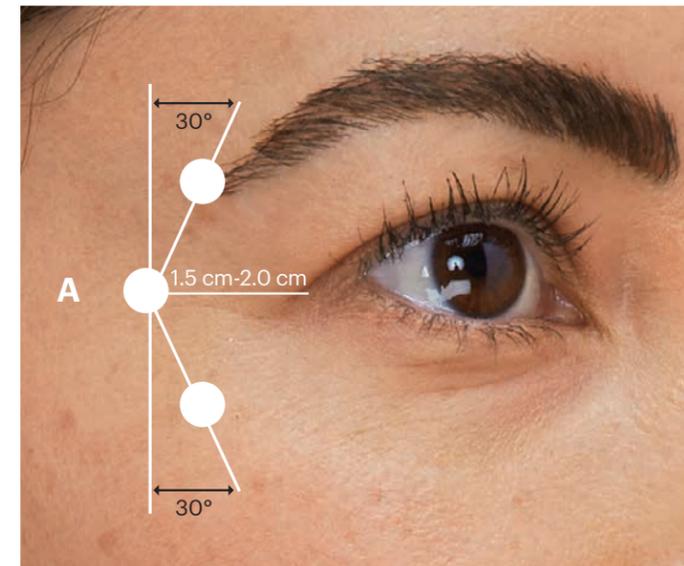
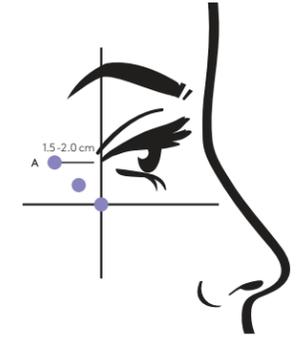
### INJECTION PATTERN IN THE PRESCRIBING INFORMATION

These injection patterns are consistent with the approved injection pattern in the Prescribing Information and have been individualized to each patient's unique anatomy. Injectors should assess the orbicularis oculi muscle activity when identifying the location of the appropriate injection sites.<sup>1</sup>

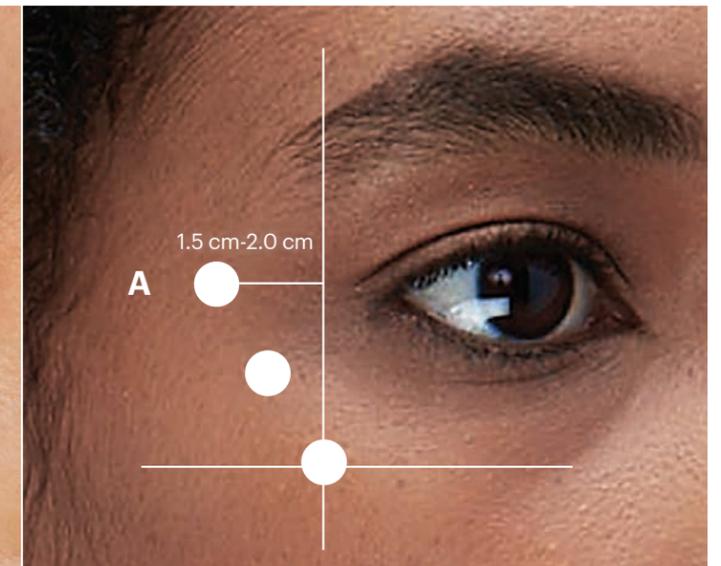
Injection pattern 1



Injection pattern 2



Injection pattern 1



Injection pattern 2

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

#### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

#### Serious Adverse Reactions With Unapproved Use (continued)

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.

Please see additional Important Safety Information on following pages.

# Precise injection techniques<sup>1</sup>

FOR MODERATE TO SEVERE LATERAL CANTHAL LINES



Real patient before treatment.

- Injections should be given with the needle bevel tip up and oriented away from the eye
- Inject 4 Units/0.1 mL into each of the 6 sites (3 injections per side) for a total dose of 24 Units

## 2 APPROVED INJECTION PATTERNS

### 1. If lines are both above and below the lateral canthus:

- First injection: at least 1.5 cm to 2.0 cm temporal to the lateral canthus and just temporal to the lateral orbital rim
- Second injection: 1.0 cm to 1.5 cm above the first injection site and at an approximate 30° angle medially
- Third injection: 1.0 cm to 1.5 cm below the first injection site and at an approximate 30° angle medially

### 2. If lines are primarily below the lateral canthus:

- First injection: at least 1.5 cm to 2.0 cm temporal to the lateral canthus and just temporal to the lateral orbital rim
- Inject along a line that angles from antero-inferior to super posterior
- Ensure that the most anterior injection is lateral to a line drawn vertically from the lateral canthus
- Remember to keep the most inferior injection superior to the maxillary prominence



Watch step-by-step injection techniques.

## CAUTIONS AND CONSIDERATIONS<sup>1</sup>

- If lateral canthal lines are above and below the lateral canthus, **use injection pattern 1**
- If lateral canthal lines are primarily below the lateral canthus, **use injection pattern 2**
- Injections should be given with the needle bevel tip up and oriented away from the eye



## REMEMBER

Achieve desired outcomes with approved dosing and injection techniques.

## START SEEING RESULTS IN 1 TO 2 DAYS WITH FULL RESULTS IN 30 DAYS<sup>1</sup>

24 Units · Moderate to severe lateral canthal lines (LCL)



## RESULTS UP TO 4 MONTHS



Real patient treated for the appearance of moderate to severe forehead lines, lateral canthal lines, and glabellar lines. **Results may vary.** Photos taken at maximum smile before and after treatment with BOTOX<sup>®</sup> Cosmetic at days 2, 30, and 120. In clinical trials at day 30, 26.1% (58/222) and 20.3% (62/306) of patients demonstrated a ≥ 2-grade improvement from baseline in lateral canthal line severity at maximum smile as compared to 1.3% (3/223) and 0% (0/306) in placebo, as assessed by both investigators and subjects. In clinical trials at day 120, approximately 25% of patients achieved a grade of none or mild from baseline in lateral canthal line severity at maximum smile as compared to approximately 5% in placebo, as assessed by investigators.<sup>1</sup>

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### Hypersensitivity Reactions

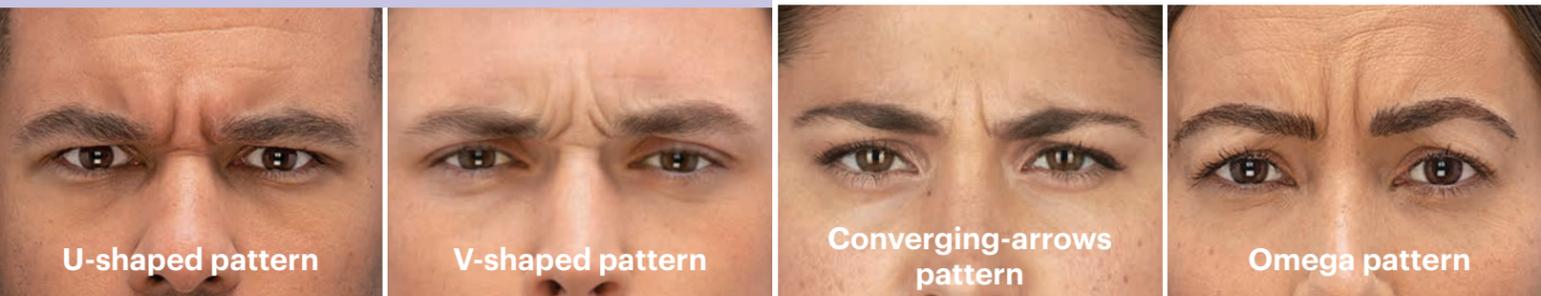
Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, and dyspnea.

Please see additional Important Safety Information on following pages.

# Injecting moderate to severe glabellar lines

## 4 TYPES OF LINE PATTERNS

Most common<sup>22</sup>



U-shaped pattern

V-shaped pattern

Converging-arrows pattern

Omega pattern

5 Injection Sites<sup>1</sup>

Total Dosage: 20 Units<sup>1</sup>

Procerus

4 Units

Left corrugator muscle—medial

4 Units

Left corrugator muscle—lateral

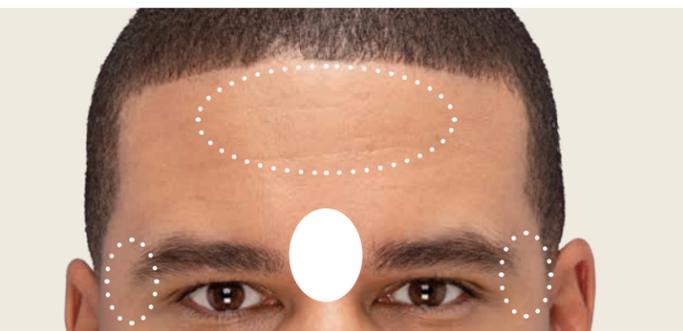
4 Units

Right corrugator muscle—medial

4 Units

Right corrugator muscle—lateral

4 Units



## 20 UNITS

Treatment goal: temporary blockage of muscle activity, leading to **temporarily improved appearance of moderate to severe glabellar lines.**<sup>1</sup>

Real patients before treatment.

**IMPORTANT SAFETY INFORMATION (continued)**

**WARNINGS AND PRECAUTIONS (continued)**

**Hypersensitivity Reactions (continued)**

If such a reaction occurs, discontinue further injection of BOTOX<sup>®</sup> Cosmetic and immediately institute appropriate medical therapy.

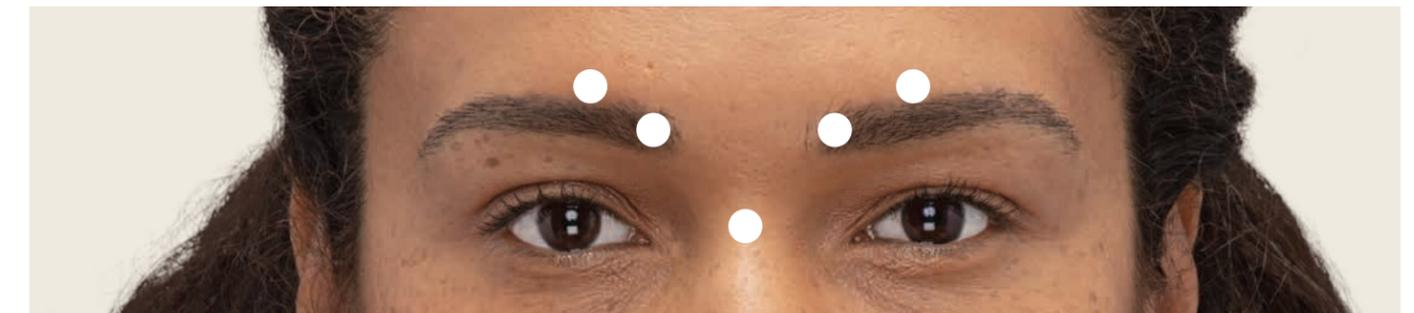
One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent and, consequently, the causal agent cannot be reliably determined.

Please see additional Important Safety Information on following pages.

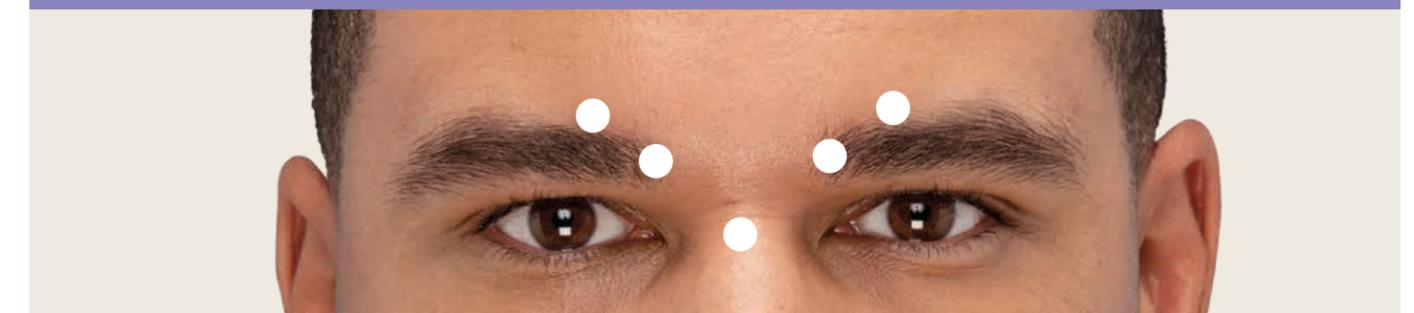
## Individualize injection points to patient's anatomy<sup>1</sup>

### INJECTION PATTERN IN THE PRESCRIBING INFORMATION

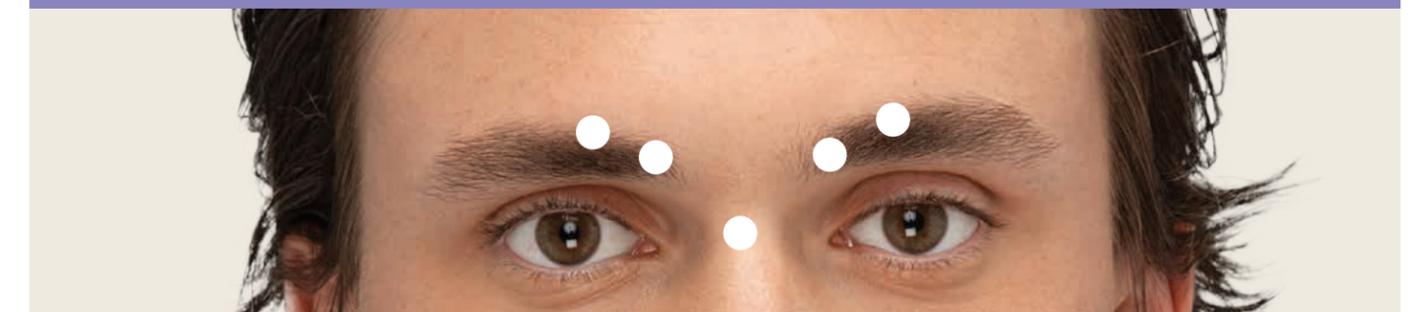
These injection patterns have been adapted from the approved injection pattern in the Prescribing Information and individualized to each patient's unique anatomy. Injectors should assess the glabellar muscle activity when identifying the location of the appropriate injection sites.<sup>1</sup>



OMEGA-SHAPED LINES



U-SHAPED LINES



V-SHAPED LINES

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

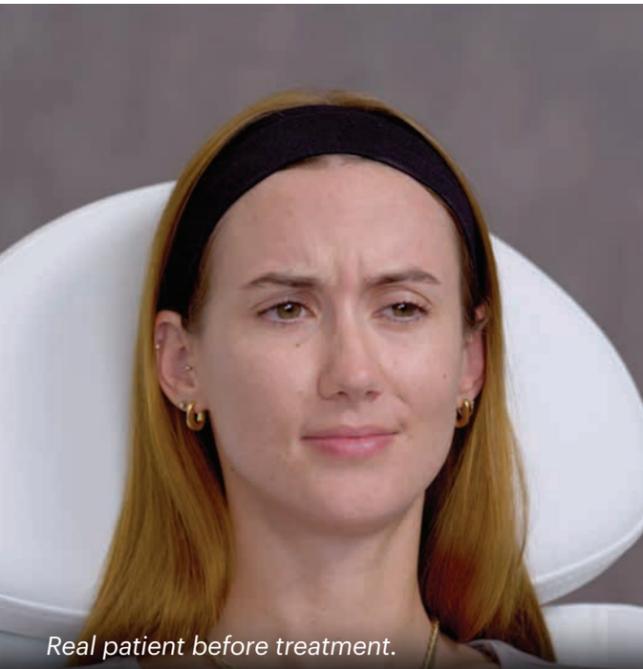
**IMPORTANT SAFETY INFORMATION (continued)**

**WARNINGS AND PRECAUTIONS (continued)**

**Cardiovascular System**

There have been reports following administration of BOTOX<sup>®</sup> of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors, including preexisting cardiovascular disease.

Please see additional Important Safety Information on following pages.



Real patient before treatment.

## Precise injection techniques<sup>1</sup>

FOR MODERATE TO SEVERE  
GLABELLAR LINES

**INJECT** 4 Units/0.1 mL into each of the 5 sites—2 in each corrugator muscle and 1 in the procerus muscle—for a total dose of 20 Units.

### TO REDUCE THE RISK OF PTOSIS:

- Avoid injection near the levator palpebrae superioris, especially in those patients with larger brow depressor complexes
- Lateral corrugator injections should be placed at least 1 cm above the bony supraorbital ridge
- Ensure the injected volume and dose are accurate and, where feasible, kept to a minimum
- Do not inject botulinum toxin closer than 1 cm above the central eyebrow



Watch step-by-step injection techniques.

## CAUTIONS AND CONSIDERATIONS<sup>1</sup>

- Avoid injection near the levator palpebrae superioris, particularly in patients with larger brow depressor complexes
- Lateral corrugator injections should be placed at least 1 cm above the bony supraorbital ridge
- Ensure the injected volume/dose is accurate and, where feasible, kept to a minimum
- Do not inject neurotoxin closer than 1 cm above the central eyebrow



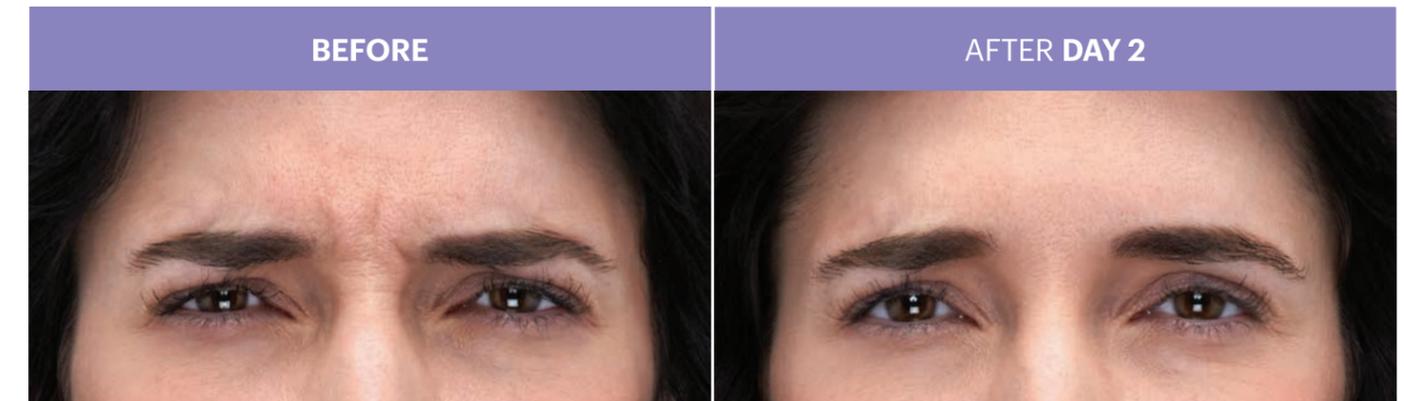
## REMEMBER

60% of patients say that they wish they had started treatment with BOTOX<sup>®</sup> Cosmetic sooner to temporarily improve the appearance of their moderate to severe lines.<sup>23,\*</sup>

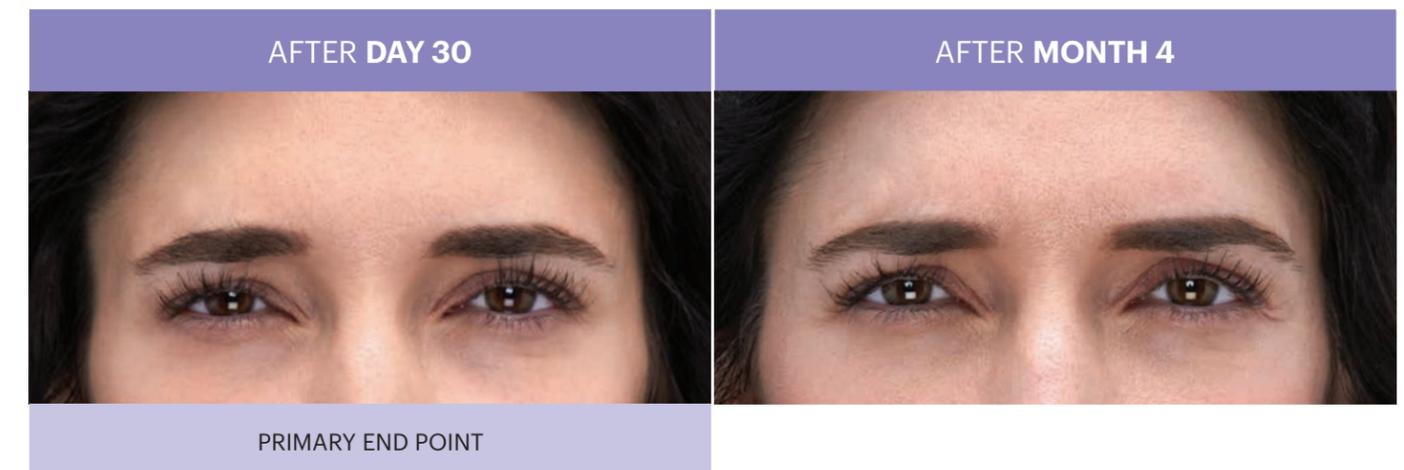
\*Based on a 2023 online survey of 258 consumers who received BOTOX<sup>®</sup> Cosmetic within the past 6 months who agreed that they wish that they had started treatment with BOTOX<sup>®</sup> Cosmetic sooner to temporarily improve the appearance of their moderate to severe lines.<sup>23</sup>

## START SEEING RESULTS IN 1 TO 2 DAYS WITH FULL RESULTS IN 30 DAYS<sup>1</sup>

20 Units · Moderate to severe glabellar lines (GL)



## RESULTS UP TO 4 MONTHS



*Real patient treated for the appearance of moderate to severe forehead lines, lateral canthal lines, and glabellar lines. Results may vary.* Photos taken at maximum frown before and after treatment with BOTOX<sup>®</sup> Cosmetic at days 2, 30, and 120. In clinical trials at day 30 as assessed by investigators, 80% (325/405) of patients demonstrated none or mild glabellar line severity at maximum frown as compared to 3% (4/132) in placebo. In clinical trials at day 30 as evaluated by patients, 89% (362/405) of patients achieved at least a moderate improvement in their glabellar line appearance compared to 7% (9/132) in placebo. In clinical trials at day 120 as assessed by investigators, 25% (102/403) of patients demonstrated none or mild glabellar line severity at maximum frown as compared to 2% (2/128) in placebo. In clinical trials at day 120 as evaluated by patients, 39% (157/403) of patients achieved at least a moderate improvement in their glabellar line appearance compared to 1% (1/128) in placebo.<sup>1</sup>

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### Cardiovascular System (continued)

Use caution when administering to patients with preexisting cardiovascular disease.

##### Increased Risk of Clinically Significant Effects With Preexisting Neuromuscular Disorders

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.

# The *one* that delivers proven results

## #1 Requested neurotoxin

BOTOX<sup>®</sup> Cosmetic is the most requested neurotoxin by patients.<sup>10,\*</sup>

## 2-day onset

Patients may start to see results within 1 to 2 days in all 3 areas.<sup>1</sup> Patients will continue to see results, with full results in 30 days.<sup>1</sup>

## 3 indications

BOTOX<sup>®</sup> Cosmetic is the first neurotoxin FDA approved for the temporary improvement in the appearance of moderate to severe forehead lines, lateral canthal lines, and glabellar lines in adults.<sup>1-6</sup>

## 4-month duration

BOTOX<sup>®</sup> Cosmetic provides long-lasting results up to 4 months in all 3 approved areas.<sup>1</sup>

\*Based on a 2022 online survey of 251 patients who had received treatment with a neurotoxin within the past 2 years. Of the 48% of patients (n = 112/235) who requested treatment with a specific brand, 83% specifically requested BOTOX<sup>®</sup> Cosmetic.<sup>10</sup>



*Real patients. Results may vary.*

**IMPORTANT SAFETY INFORMATION (continued)**  
**WARNINGS AND PRECAUTIONS (continued)**  
**Increased Risk of Clinically Significant Effects With Preexisting Neuromuscular Disorders (continued)**  
Monitor individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) when given botulinum toxin.

**Please see additional Important Safety Information on following pages.**

# The one & only neurotoxin with an FDA-approved dosing protocol<sup>1-6</sup>

The **FIRST** and only neurotoxin FDA approved to temporarily improve the appearance of moderate to severe platysma bands, forehead lines, lateral canthal lines, and glabellar lines in adults.<sup>1-6</sup>

## The **FIRST** approved for 3 indications...<sup>1-6</sup>

To temporarily improve the appearance of moderate to severe forehead lines, lateral canthal lines, and glabellar lines in adults<sup>1</sup>

## Goes Beyond the Face with the **FIRST** and only FDA approval for platysma bands<sup>1-6</sup>

To temporarily improve the appearance of moderate to severe platysma bands in adults<sup>1</sup>

## The **FIRST** and only with a customizable injection and dosing protocol<sup>1-6</sup>

FDA approved with customizable dosing dependent on platysma band severity (26U, 31U, or 36U, for full dosing protocol, please see pages 36 and 37).

*moderate to severe*  
**FOREHEAD LINES**

*moderate to severe*  
**GLABELLAR LINES**

*moderate to severe*  
**LATERAL CANTHAL LINES**

*moderate to severe*  
**PLATYSMA BANDS**

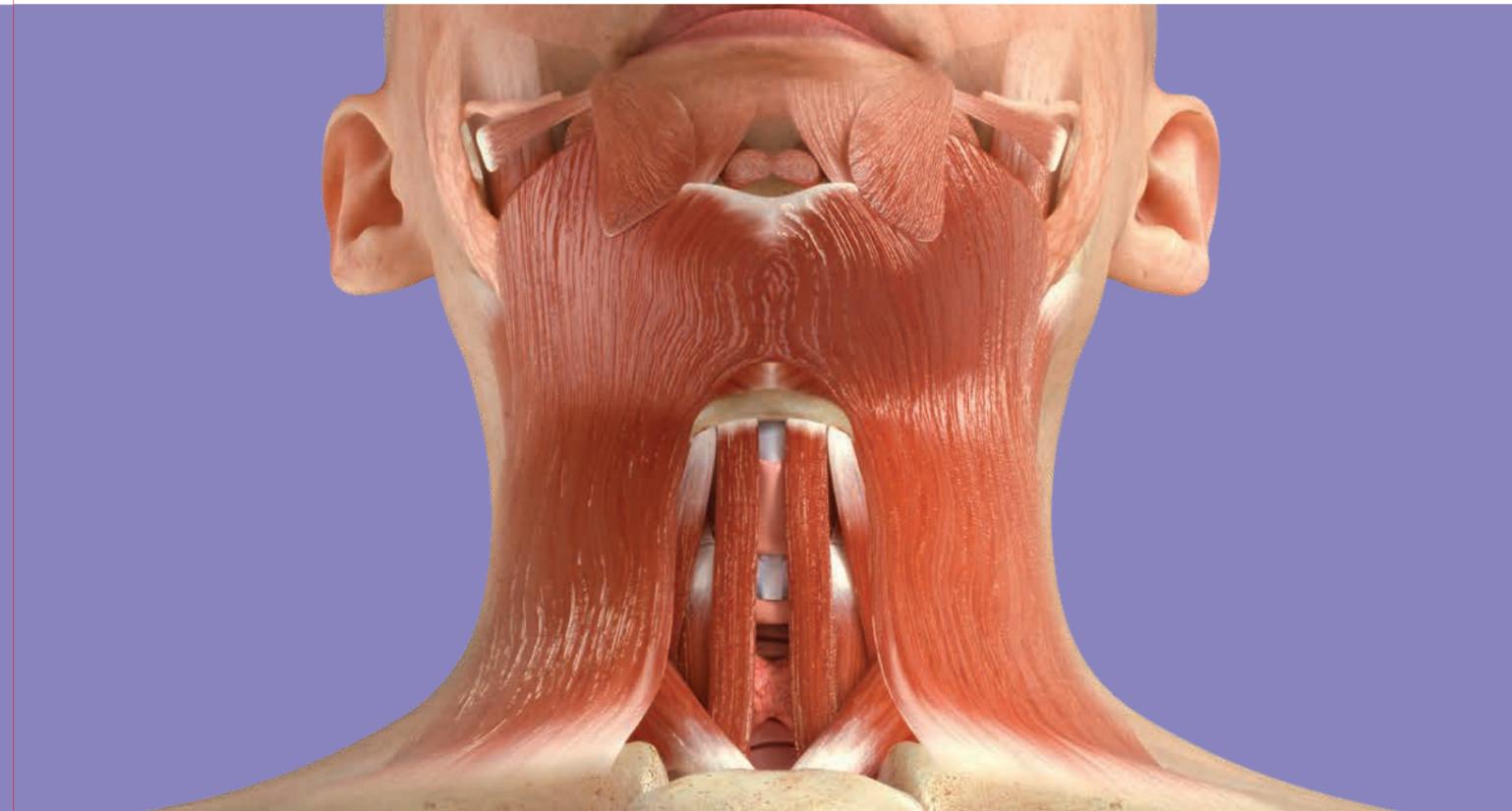
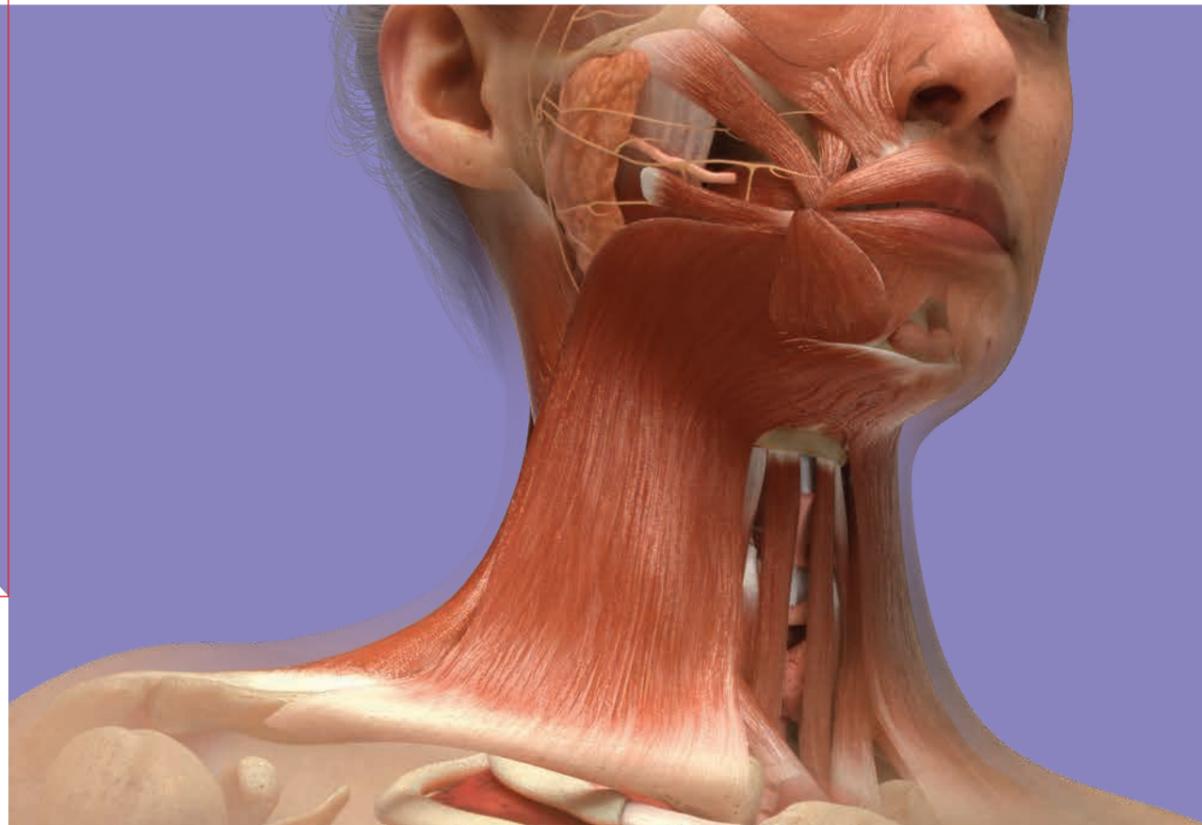
*Real patient before treatment.*



**IMPORTANT SAFETY INFORMATION (continued)**  
**WARNINGS AND PRECAUTIONS (continued)**  
**Dysphagia and Breathing Difficulties**  
Treatment with BOTOX<sup>®</sup> and other botulinum toxin products can result in swallowing or breathing difficulties.  
**Please see additional Important Safety Information on following pages.**

# Dive into the anatomy of the lower face and neck

Consider the functional relationship of the platysma region.



## The platysma muscle is<sup>7,24,25</sup>:

- A depressor muscle (pulling down on the soft tissue layers of the lower face and neck)
- Extremely thin and superficial
- Covers most of the anterior and lateral neck, integrating with the lower facial muscles and descends all the way to the clavicle

- **Topographical changes are caused** by the interplay of cutaneous and platysma layers<sup>26</sup>
- With repeat use, **the platysma may contribute to several aesthetic changes**—including blunted jawline, downward pull on the lower face (eg, the oral commissures), and formation of platysma bands<sup>27</sup>
- Patterns of banding **may not be bilaterally symmetric or continuous** (ie, may not extend from the jawline into the lower neck)<sup>28</sup>

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

#### Dysphagia and Breathing Difficulties (continued)

Patients with preexisting 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*).

Please see additional Important Safety Information on following pages.

# Assessing for platysma bands

Ask patients to do the following to check for moderate to severe platysma bands:



**Exaggerate your smile!**



**Make an "eek" face!**



**Check for vertical bands connecting the neck and jaw, which may also impact the jawline.**

Assessing for platysma bands is a step of the NeckOver Assessment: from the lower face to the neck

**Talk to your Allergan Aesthetics Representative to learn more about the individual steps.**

**IMPORTANT SAFETY INFORMATION (continued)**

**WARNINGS AND PRECAUTIONS (continued)**

**Preexisting Conditions at the Injection Site**

Use caution when BOTOX<sup>®</sup> 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).

**Please see additional Important Safety Information on following pages.**



*Real patient before treatment.*

# Platysma bands can present regardless of age, physical attributes, ethnicity, and gender

## Age<sup>29</sup>

In different age groups, platysma bands may present differently due to skin laxity, muscle tone loss, and overall skin quality.

## Physical Attributes<sup>28</sup>

Bands may also present differently across patients with different physical attributes.

## Ethnicity<sup>29</sup>

Keep in mind, ethnicity can also be a factor in how platysma bands are presented, and different ethnicities may require a more personalized approach considering their specific anatomical characteristics.

## Gender<sup>30</sup>

Gender can also play a role in considerations.

### IMPORTANT SAFETY INFORMATION (continued)

#### WARNINGS AND PRECAUTIONS (continued)

##### Dry Eye in Patients Treated With BOTOX<sup>®</sup> Cosmetic

There have been reports of dry eye associated with BOTOX<sup>®</sup> 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.



FEMALE, LATE 40s



FEMALE, LATE 30s



FEMALE, EARLY 40s



MALE, MID 20s



FEMALE, EARLY 50s



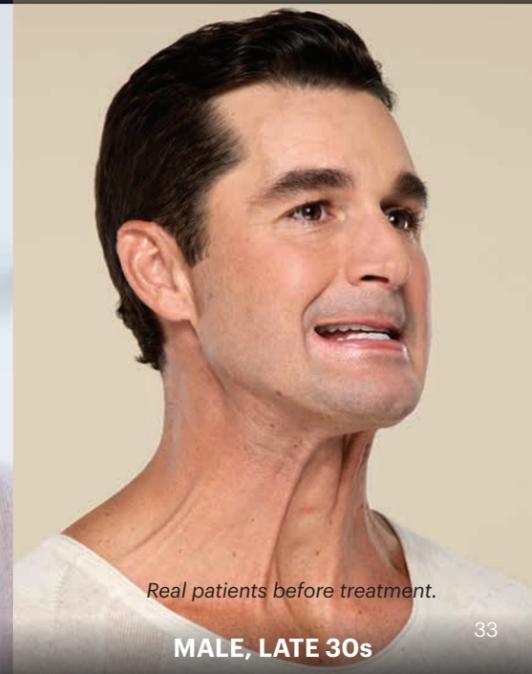
FEMALE, LATE 20s



PHYSICALLY ACTIVE



FEMALE, LATE 40s



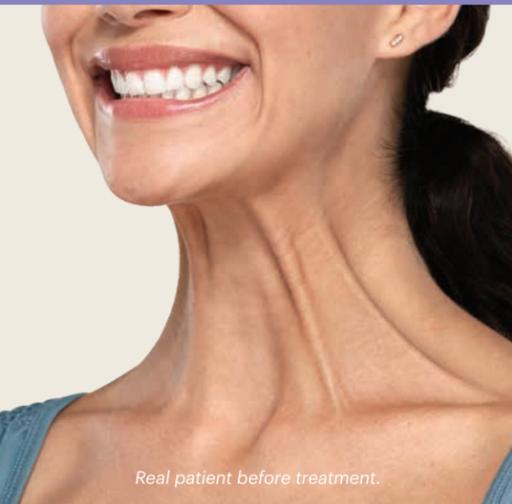
MALE, LATE 30s

Real patients before treatment.

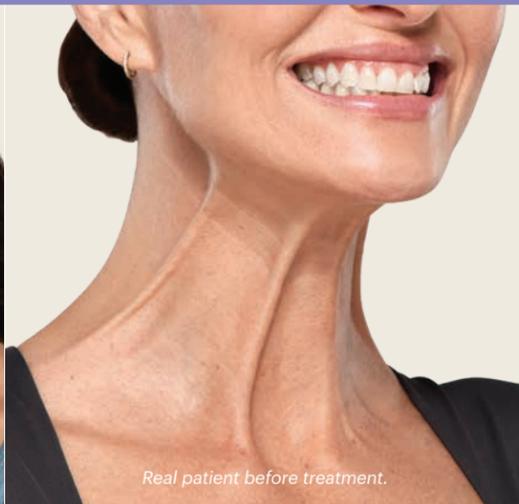
# Determining appropriate patients for platysma band treatment

Selecting appropriate candidates for platysma band treatment is crucial for achieving desired aesthetic outcomes

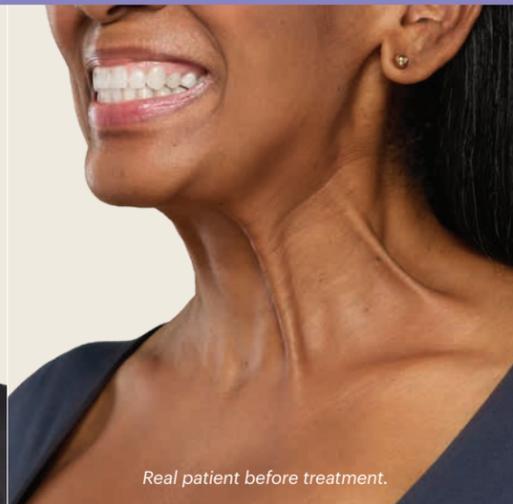
## APPROPRIATE CANDIDATES



Real patient before treatment.



Real patient before treatment.



Real patient before treatment.

### MODERATE TO SEVERE PLATYSMA BANDS<sup>1</sup>:

Vertical bands connecting the jaw and neck resulting from repeated contractions of the platysma muscle

### OTHER CONSIDERATIONS:

Past surgical interventions such as face and neck lift<sup>31</sup>

#### IMPORTANT SAFETY INFORMATION (continued)

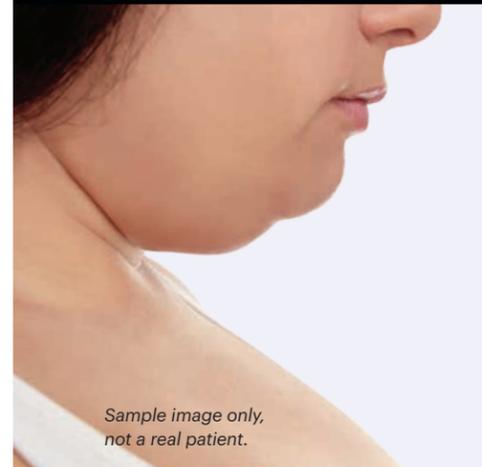
#### WARNINGS AND PRECAUTIONS (continued)

#### 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 a 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), which would also be considered 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.

Please see additional Important Safety Information on following pages.

## CONSIDER THE SEVERITY OF THE FOLLOWING CONDITIONS TO DETERMINE APPROPRIATE PATIENTS

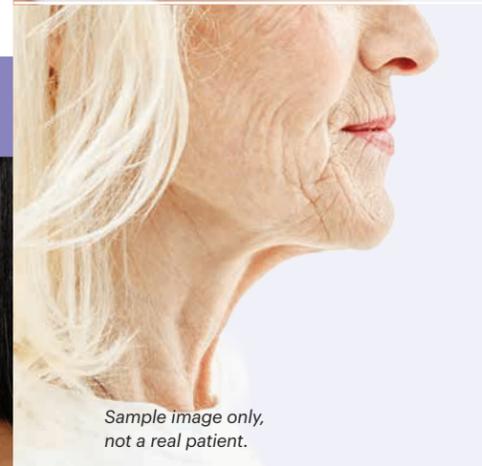


Sample image only, not a real patient.

### SUBMENTAL FAT

Exclusion Criteria:

- Excessive submental fat and deep jowls<sup>32</sup>

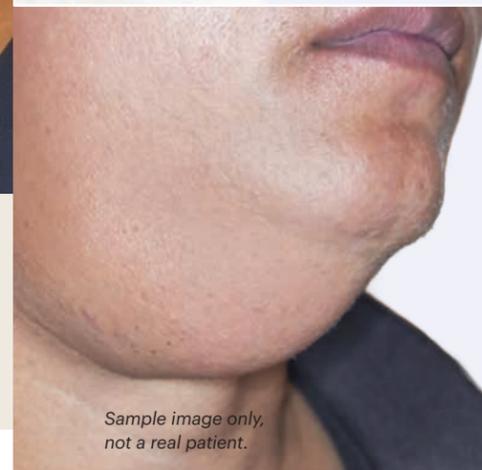


Sample image only, not a real patient.

### SKIN LAXITY

Exclusion Criteria:

- Significant skin laxity or draping, leading to loss of neck structure definition<sup>31</sup>

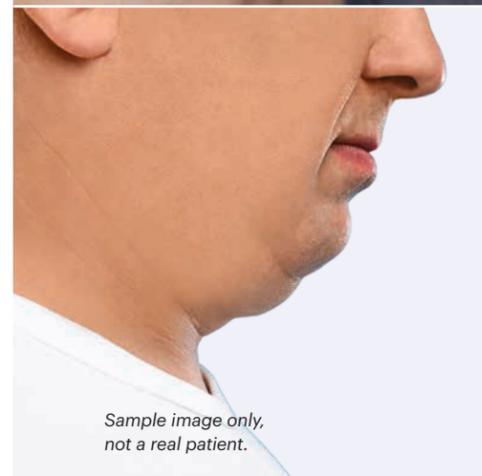


Sample image only, not a real patient.

### SUBMANDIBULAR GLANDS AND DIGASTRIC MUSCLES

Exclusion Criteria:

- Enlarged digastric muscles<sup>33</sup>
- Prominent submandibular glands<sup>32</sup>



Sample image only, not a real patient.

### BONE STRUCTURE

Exclusion Criteria:

- Low anterior hyoid bone<sup>32,34</sup>
- Microgenia (small chin)<sup>32,34</sup>
- Short, thick neck<sup>32</sup>

## Injecting moderate to severe platysma bands

BOTOX<sup>®</sup> Cosmetic is the one & only FDA-approved neurotoxin with a customizable dosing protocol to meet the individual needs of your patients<sup>1-6</sup>

**Depending on the severity** of the platysma bands<sup>1</sup>

- **26 Units** if 1 band is injected on each side
- **31 Units** if 1 band is injected on one side and 2 bands are injected on the other side
- **36 Units** if 2 bands are injected on each side

**When injecting BOTOX<sup>®</sup> Cosmetic** in the platysma band, distribute 5 injections vertically, about 1 to 2 cm apart per band. The most superior injection site should be 1 to 2 cm inferior to where the product is injected in the jawline.<sup>1</sup>

**For vertical platysma band injections**, each band should be identified while the patient is contracting their platysma. Gently pinch the band to isolate the muscle from nearby anatomical structures during administration.<sup>1</sup>

**Dilution and reconstitution processes** for BOTOX<sup>®</sup> Cosmetic are the same for moderate to severe forehead lines, lateral canthal lines, glabellar lines, and platysma bands (2.5 mL diluent for 100 Units).<sup>1</sup>

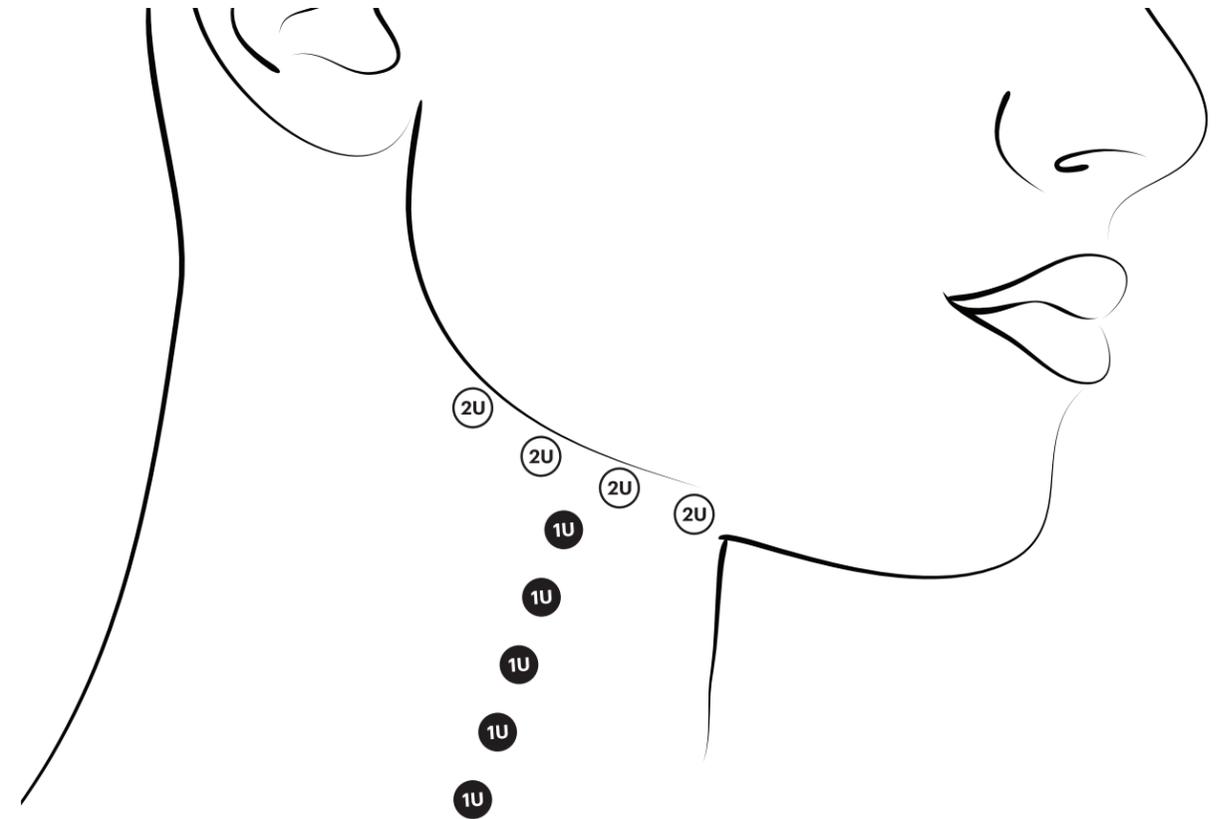
### IMPORTANT SAFETY INFORMATION (continued)

#### ADVERSE REACTIONS

The most frequently reported adverse reactions following injection of BOTOX<sup>®</sup> 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<sup>®</sup> Cosmetic for lateral canthal lines was eyelid edema (1%).

**Please see additional Important Safety Information on following pages.**



## Follow the **8/5 Rule**

### ● **8 UNITS IN THE JAWLINE PER SIDE**<sup>1</sup>

- 2 Units/0.05 mL into 4 sites on each side
- 16 Units in 8 sites total



### ● **5 UNITS PER PLATYSMA BAND**<sup>1</sup>

- 1 Unit/0.025 mL into 5 sites per band on each side
- 10 to 20 Units in 10 to 20 sites total (1 to 2 bands per side)



### **TOTAL DOSING**<sup>1</sup>

- 26 Units if 1 band is injected on each side
- 31 Units if 1 band is injected on one side and 2 bands are injected on the other side
- 36 Units if 2 bands are injected on each side

# Precise injection techniques

## JAWLINE INJECTIONS<sup>1</sup>

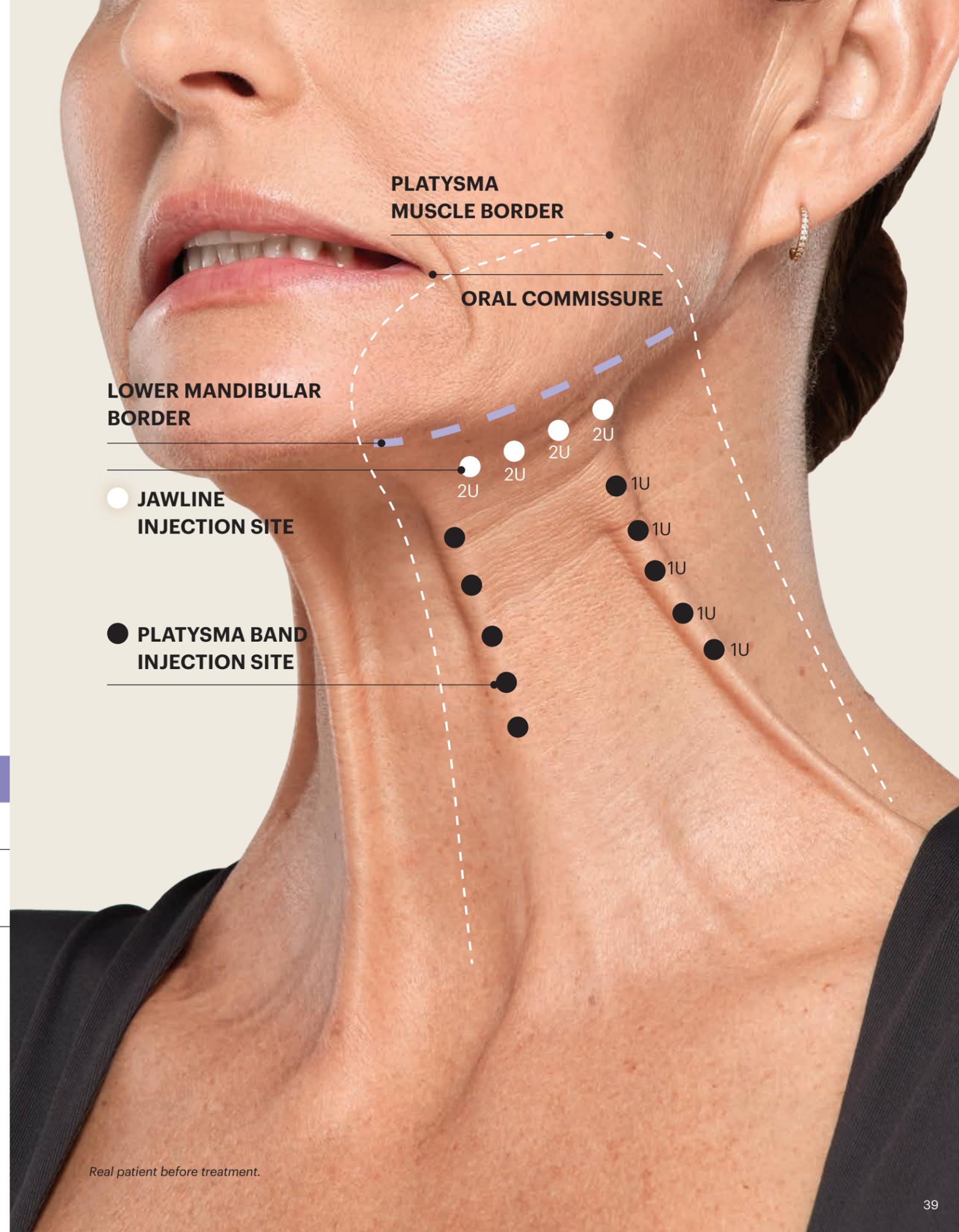
8 Units must be injected perpendicular to the surface of the skin in the upper segment of the platysma muscle along the mandibular border (approximately 1 cm apart)

- The first injection site should be in line with the oral commissure
- The last injection site should be slightly anterior to the angle of the mandible
- The remaining 2 middle injections should be equidistant between the first and last injection points
- Injections should be at least 1 cm inferior to the lower mandibular border

## PLATYSMA BAND INJECTIONS<sup>1</sup>

Inject 5 Units along each continuous vertical platysma band on each side of the neck (1 to 2 bands per side, approximately 1 to 2 cm apart)

- The most superior injection site should be 1 to 2 cm inferior to where the product is injected in the jawline



Jawline <sup>1</sup>	Number of Platysma Bands <sup>1</sup>	Units <sup>1</sup>	Total Dose <sup>1</sup>
Inject 4 sites on both sides of jawline (2 Units in 4 sites for a total of 16 Units)	1 band on both sides	10 Units in 10 sites	26 Units
	1 band on one side and 2 bands on the other side	15 Units in 15 sites	31 Units
	2 bands on both sides	20 Units in 20 sites	36 Units

**IMPORTANT SAFETY INFORMATION (continued)**

**ADVERSE REACTIONS (continued)**

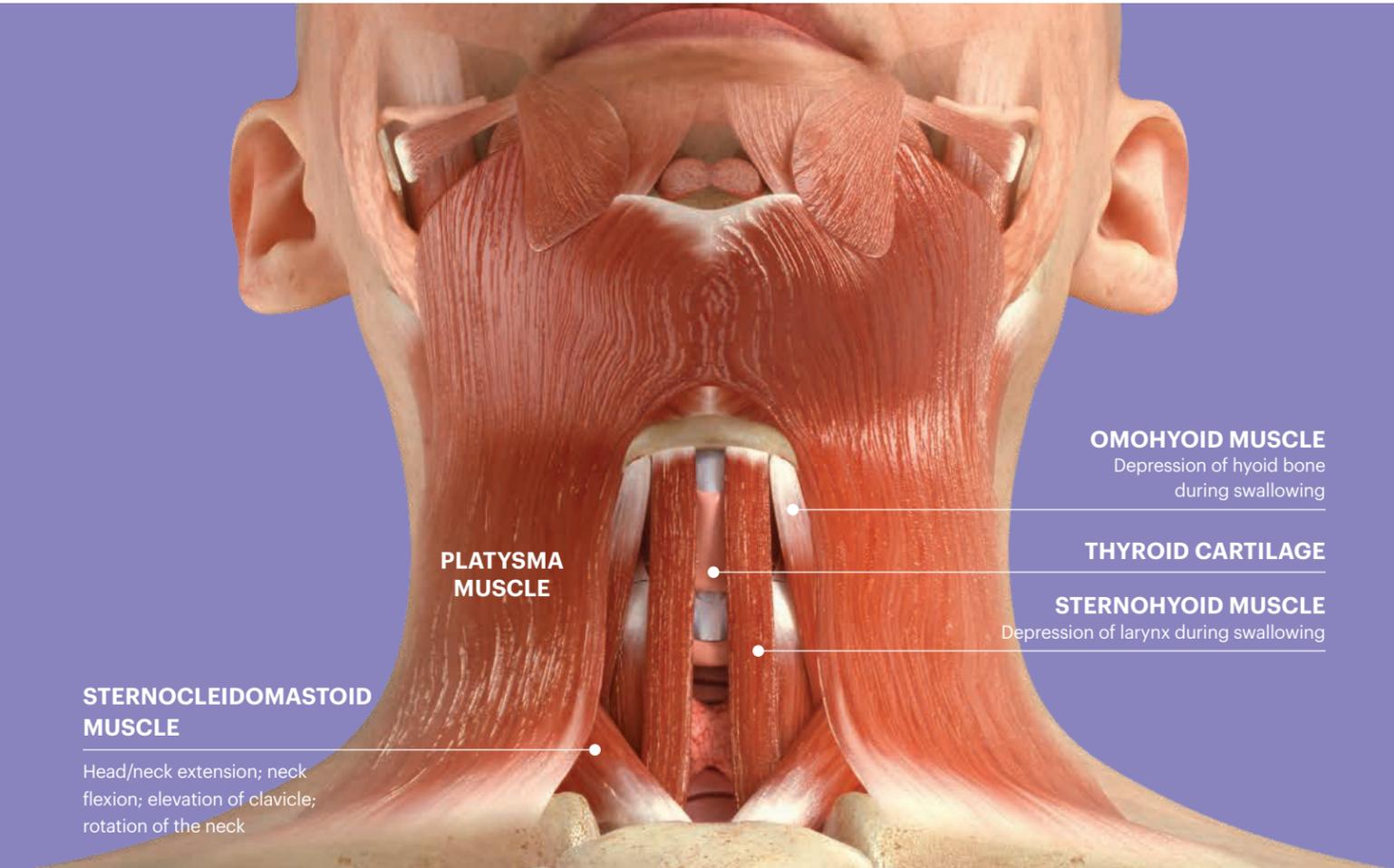
The most frequently reported adverse reactions following injection of BOTOX<sup>®</sup> Cosmetic for forehead lines with glabellar lines were headache (9%), brow ptosis (2%), and eyelid ptosis (2%).

Please see additional Important Safety Information on following pages.

Real patient before treatment.

## Areas of caution in the jawline and neck

For safety reasons, BOTOX<sup>®</sup> Cosmetic injections should be avoided in areas near the arteries, veins, sensory nerves, and submandibular glands<sup>35-37</sup>



### CAUTIONS AND CONSIDERATIONS<sup>1</sup>

- The platysma muscle is a thin muscle sheet just below the surface of the skin. Therefore, all platysma muscle injections should be administered superficially and intramuscularly with the needle perpendicular to the surface of the skin
- Do not inject into structures deep to the platysma muscle, particularly in the lower anterior region of the neck
- Injecting into the structures deep to the platysma may impact the patient's neck and head mobility, as well as swallowing and speech<sup>1</sup>



### REMEMBER

The platysma muscle should be contracted in order to identify each platysma band, and the band should be gently pinched to isolate the muscle during administration.<sup>1</sup>

**Learn more from AMI Online.**

#### IMPORTANT SAFETY INFORMATION (continued)

#### ADVERSE REACTIONS (continued)

The safety profile of BOTOX<sup>®</sup> Cosmetic treatment of platysma bands is consistent with the known safety profile of BOTOX<sup>®</sup> Cosmetic for other indications.

Please see additional Important Safety Information on following pages.

# Real patients, real results



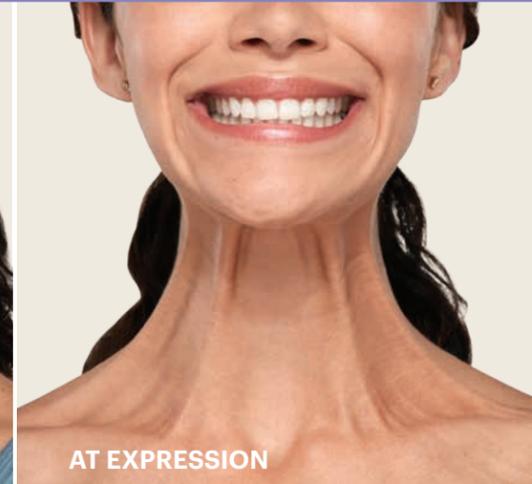
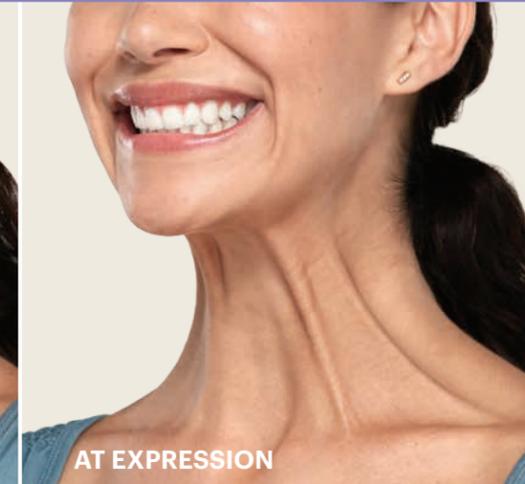
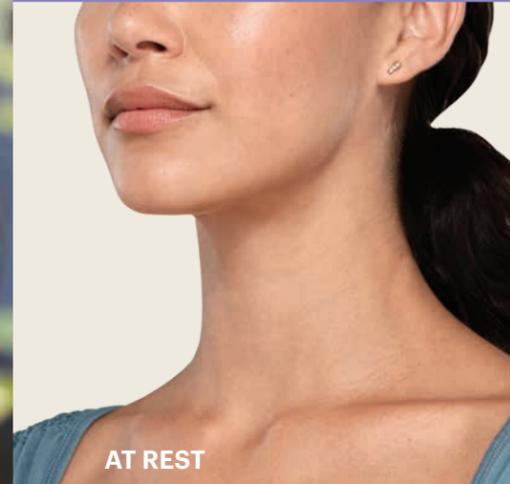
*Real patient treated for the appearance of moderate to severe platysma bands.*  
**Results may vary.**

## Vanessa

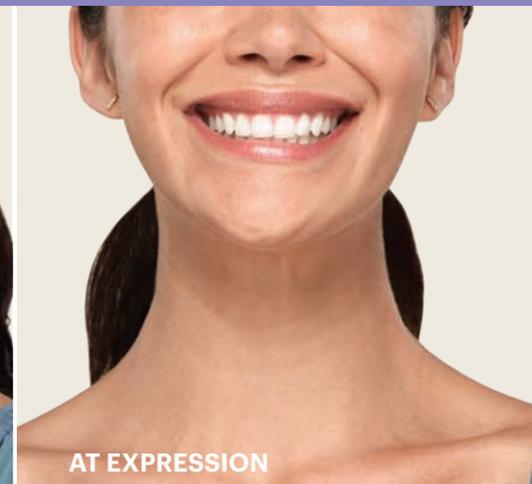
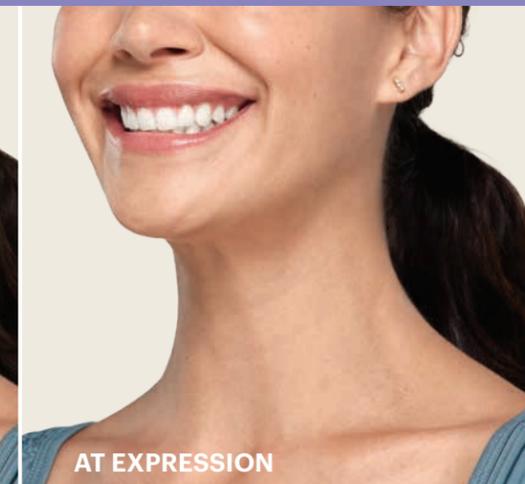
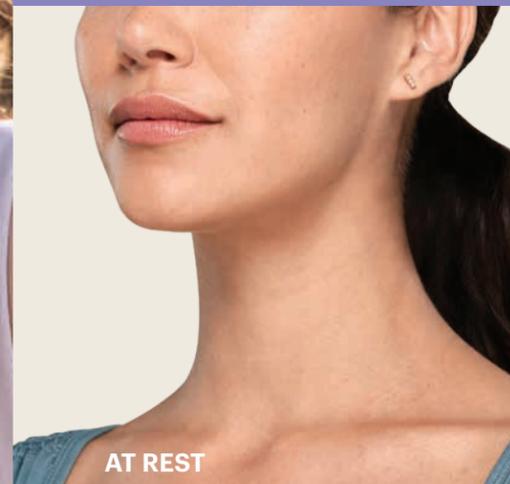
AGE: 27

Results for treatment of moderate to severe platysma bands.

BEFORE



AFTER DAY 14



*Real patient treated for the appearance of moderate to severe platysma bands with 36 Units. **Results may vary.***

Photos taken at rest and maximum expression before and after treatment with BOTOX<sup>®</sup> Cosmetic (onabotulinumtoxinA) at day 14. In clinical trials at day 14, 32% (63/199) and 31% (64/209) of patients demonstrated a  $\geq 2$ -grade improvement from baseline in platysma band severity at maximum expression as compared to 2% (4/209) and 0% (0/217) in placebo, as assessed by both investigators and subjects.<sup>1</sup>

### IMPORTANT SAFETY INFORMATION (continued)

#### DRUG INTERACTIONS

Coadministration of BOTOX<sup>®</sup> 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<sup>®</sup> Cosmetic may potentiate systemic anticholinergic effects.

**Please see additional Important Safety Information on following pages.**

# Real patients, real results



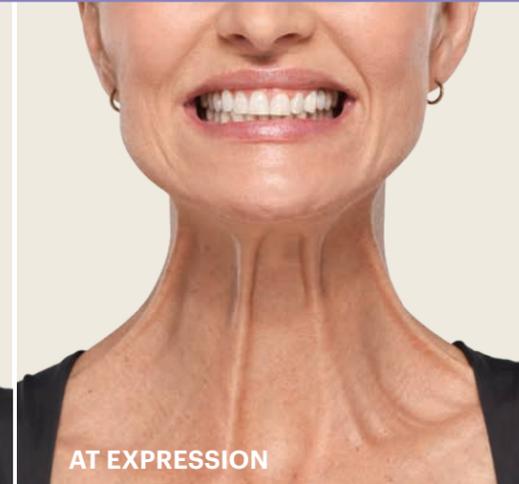
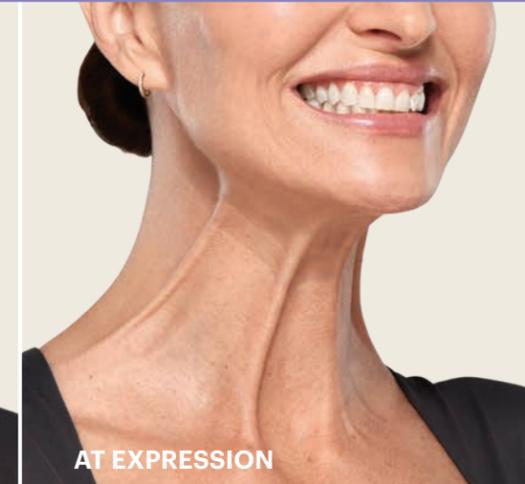
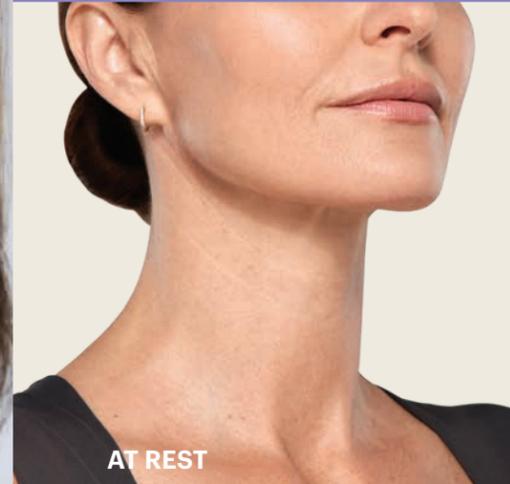
*Real patient treated for the appearance of moderate to severe platysma bands.*  
**Results may vary.**

## Ana

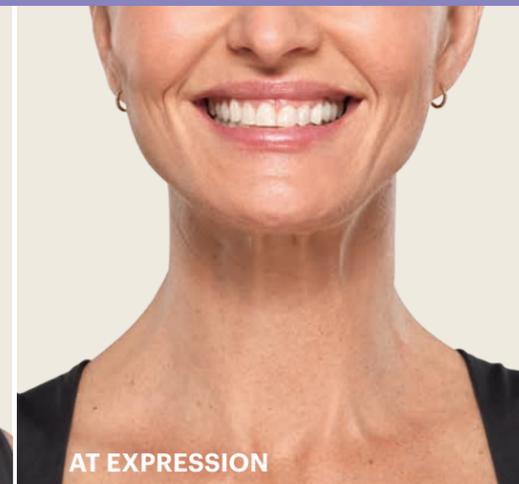
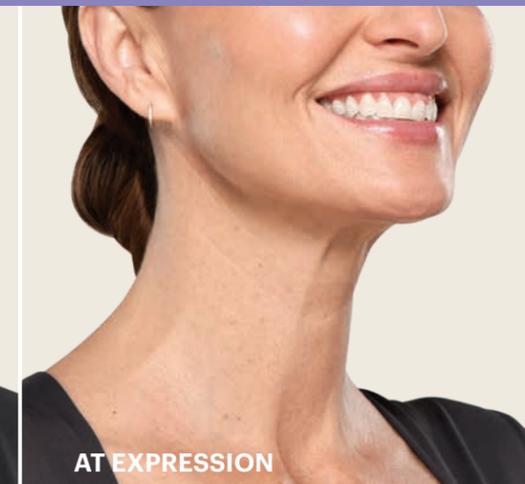
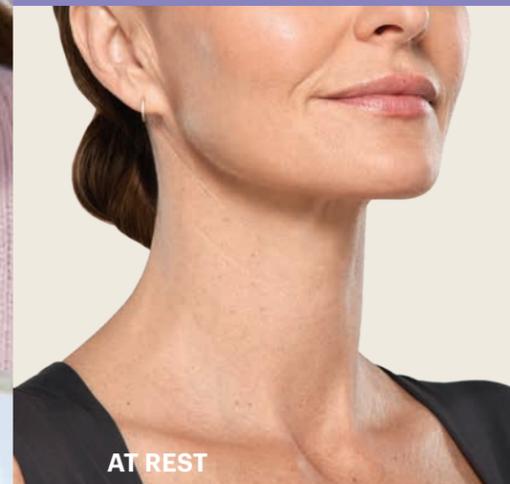
AGE: 48

Results for treatment of moderate to severe platysma bands.

### BEFORE



### AFTER DAY 14



*Real patient treated for the appearance of moderate to severe platysma bands with 36 Units. **Results may vary.***

Photos taken at rest and maximum expression before and after treatment with BOTOX<sup>®</sup> Cosmetic (onabotulinumtoxinA) at day 14. In clinical trials at day 14, 32% (63/199) and 31% (64/209) of patients demonstrated a  $\geq 2$ -grade improvement from baseline in platysma band severity at maximum expression as compared to 2% (4/209) and 0% (0/217) in placebo, as assessed by both investigators and subjects.<sup>1</sup>

#### **IMPORTANT SAFETY INFORMATION (continued)**

##### **DRUG INTERACTIONS (continued)**

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.

**Please see additional Important Safety Information on following pages.**

# BOTOX<sup>®</sup> Cosmetic

The one neurotoxin with the most neurotoxin experience<sup>1</sup>

## #1 REQUESTED NEUROTOXIN

BOTOX<sup>®</sup> Cosmetic is the most requested neurotoxin by patients<sup>10,\*</sup>

## 30+ YEARS OF EXPERIENCE ENSURING QUALITY PRODUCT

AbbVie owns end-to-end development, from drug substance development to manufacturing and distribution, and has been manufacturing BOTOX<sup>®</sup> (onabotulinumtoxinA) since its therapeutic approval in 1989<sup>1,38</sup>

## MOST STUDIED NEUROTOXIN

Over 6400 publications featuring BOTOX<sup>®</sup> or BOTOX<sup>®</sup> Cosmetic<sup>13,†</sup>

## MORE FDA APPROVALS THAN ANY OTHER NEUROTOXIN

4 BOTOX<sup>®</sup> Cosmetic aesthetic uses, 12 BOTOX<sup>®</sup> therapeutic uses, approved in over 100 countries<sup>1-6,39,40</sup>

<sup>\*</sup>Based on a 2022 online survey of 251 patients who had received treatment with a neurotoxin within the past 2 years. Of the 48% of patients (n = 112/235) who requested treatment with a specific brand, 83% specifically requested BOTOX<sup>®</sup> Cosmetic.<sup>10</sup>

<sup>†</sup>For therapeutic and aesthetic use.



## The one that *continues to innovate*

- **The first and only with 4 indications**—moderate to severe platysma bands, forehead lines, lateral canthal lines, and glabellar lines in adults<sup>1-6</sup>
- **The first and only to go Beyond the Face**, BOTOX<sup>®</sup> Cosmetic is clinically proven to deliver full results in moderate to severe platysma bands in 2 weeks<sup>1-6</sup>



**Scan the QR Code** for more information on precise injection techniques and platysma bands training.

**Or visit [BOTOXCOSMETICHCP.com](https://www.botoxcosmetichcp.com)**

### IMPORTANT SAFETY INFORMATION (continued)

#### DRUG INTERACTIONS (continued)

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

**Please see additional Important Safety Information on following pages.**



**BOTOX<sup>®</sup>**  
COSMETIC  
onabotulinumtoxinA injection

# Own the vial

Treatment in all 4 areas—  
from a single 100 Unit vial<sup>1</sup>

For the temporary improvement in the appearance of moderate to severe platysma bands (26U, 31U, and 36U), forehead lines (20U), lateral canthal lines (24U), and glabellar lines (20U) in adults.<sup>1</sup>

## **IMPORTANT SAFETY INFORMATION (continued)** **USE IN SPECIFIC POPULATIONS**

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

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

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