**BTXPRO® Cosmetic (onabotulinumtoxinA)**

**Dosage | Dilution | Reconstitution**

BTXPRO® Cosmetic dosage is dependent on the area(s) being treated.

BTXPRO® Cosmetic dilution and reconstitution processes are the same for moderate to severe lateral canthal lines and moderate to severe glabellar lines.

### Dosage

For simultaneous treatment with glabellar lines, the dose is 24 Units for lateral canthal lines and 20 Units for glabellar lines, with a total dose of 44 Units.

### Dilution table

- BTXPRO® Cosmetic is supplied in 100-Unit and 50-Unit single-use vials
- BTXPRO® Cosmetic should be reconstituted with sterile, nonpreserved saline

<table>
<thead>
<tr>
<th>Dilution Instructions for BTXPRO® Cosmetic</th>
<th>Diluent Added</th>
<th>Resulting Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>100-Unit vial 2.50 mL 4.00 Units*</td>
<td>Preservative-free 0.9% sodium chloride injection, USP only</td>
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</tr>
<tr>
<td>50-Unit vial 1.25 mL 4.00 Units*</td>
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</table>

* Approved dose for glabellar line treatment is 4 Units per 0.1 mL at each of the 5 injection sites, for a total dose of 20 Units per 0.5 mL. Approved dose for lateral canthal line treatment is 4 Units per 0.1 mL at each of the 6 injection sites (3 on each side), for a total dose of 24 Units per 0.6 mL.

### Reconstitution

1. Using an appropriate-sized needle and syringe, draw up 1.25 mL or 2.5 mL of 0.9% nonpreserved sterile saline (see dilution table).

2. Disconnect the syringe from the needle, then gently mix BTXPRO® Cosmetic with the saline by rotating the vial. Record the date and time of reconstitution in the space on the label.

3. Insert the needle and slowly inject the saline into the BTXPRO® Cosmetic vial. Vacuum is present in the vial, which demonstrates that the sterility of the vial is intact.

4. Disconnect the syringe from the needle, then gently mix BTXPRO® Cosmetic with the saline by rotating the vial. Record the date and time of reconstitution in the space on the label.

5. Attach a new sterile syringe and draw at least 0.5 mL (for glabellar lines) or 0.6 mL (for lateral canthal lines) of the properly reconstituted BTXPRO® Cosmetic fluid into the syringe by angling the needle into the bottom corner of the vial for full extraction. Do not completely invert the vial. Expel any air bubbles in the syringe barrel.

6. Disconnect the syringe from the needle used for reconstitution and attach a 30-gauge to 33-gauge needle for injection.

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**See reverse side for injection techniques and tips.**

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**BTXPRO® Cosmetic (onabotulinumtoxinA) Important Information**

**Indications**

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

- Lateral Canthal Lines
- BTXPRO® Cosmetic is indicated for the temporary improvement in the appearance of moderate to severe lateral canthal lines associated with orbicularis oculi muscle activity in adult patients.

**IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING**

**WARNING: DISTANT SPREAD OF TOXIN EFFECT**

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

**CONTRAINDICATIONS**

- BTXPRO® 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 reverse side.
For moderate to severe lateral canthal lines:

- Injections should be given with the needle bevel tip up and oriented away from the eye.
- Inject a dose of 0.1 mL into each of 5 sites (5 injections per site) for a total dose of 20 Units.

### Crow’s feet injection pattern #1

If lines are both above and below the lateral canthus:

1. **First injection:** at least 15 mm to 2.0 mm temporal to the lateral canthus and just temporal to the lateral orbital rim.
2. **Second injection:** 1.0 cm to 1.5 cm above the first injection site and at an approximate 30° angle medially.
3. **Third injection:** 1.0 cm to 1.5 cm below the first injection site and at an approximate 30° angle medially.

### Crow’s feet injection pattern #2

If lines are primarily below the lateral canthus:

1. **First injection:** at least 15 mm to 2.0 mm temporal to the lateral canthus and just temporal to the lateral orbital rim.
2. **Inject along a line that angles from anteroinferior to superposterior.**
3. **Ensure that the most anterior injection is lateral to a line drawn vertically from the lateral canthus.**
4. **Remember to keep the most inferior injection superior to the maxillary prominence.**

For moderate to severe glabellar lines:

- Inject a dose of 0.1 mL into each of 5 sites—2 in each corrugator muscle and 1 in the procerus muscle—for a total dose of 20 Units.

### In order to reduce the complication 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/dose is accurate and, where feasible, kept to a minimum.
- Do not inject botulinum toxin closer than 1 cm above the central eyebrow.

**BTXPRO® Cosmetic (onabotulinumtoxinA)**

**IMPORTANT SAFETY INFORMATION (continued)**

**WARNINGS AND PRECAUTIONS**

**Lack of Interchangeability between Botulinum Toxin Products**

The potency Units of BTXPRO® 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 BTXPRO® 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 BTXPRO® Cosmetic at the labeled dose of 20 Units (for glabellar lines), 24 Units (for lateral canthal lines), 44 Units (for simultaneous treatment of lateral canthal lines and glabellar lines) have been reported.

**Serious Adverse Reactions With Unapproved Use**

Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with dermatologic use of BTXPRO® Cosmetic at the labeled dose of 20 Units (for glabellar lines), 24 Units (for lateral canthal lines), 44 Units (for simultaneous treatment of lateral canthal lines and glabellar lines) have been reported.

**Dysphagia and Breathing Difficulties**

Treatment with BTXPRO® 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**

**oropharyngeal muscles that control swallowing or breathing (see**

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

**Human Albumin and Transmission of Viral Diseases**

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

**ADVERSE REACTIONS**

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

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

**DRUG INTERACTIONS**

Co-administration of BTXPRO® Cosmetic and aminglycosides 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 BTXPRO® 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 BTXPRO® Cosmetic.

**USE IN SPECIFIC POPULATIONS**

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