**INDICATIONS**

<table>
<thead>
<tr>
<th>Area</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forehead lines</td>
<td>20 UNITS</td>
</tr>
<tr>
<td>Lateral canthal lines</td>
<td>24 UNITS</td>
</tr>
<tr>
<td>Glabellar lines</td>
<td>20 UNITS</td>
</tr>
</tbody>
</table>

**DILUTION INSTRUCTIONS FOR RECONSTITUTION**

<table>
<thead>
<tr>
<th>Dose</th>
<th>Diluent added</th>
<th>Resulting dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.00 Units</td>
<td>2.50 mL preservative-free 0.9% sodium chloride injection USP</td>
<td>0.0 Units</td>
</tr>
<tr>
<td>4.00 Units</td>
<td>1.25 mL preservative-free 0.9% sodium chloride injection USP</td>
<td>0.0 Units</td>
</tr>
</tbody>
</table>

**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 reverse side.
**For moderate to severe forehead lines**

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

**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® 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 (see figure above):

- 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 crease), 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.

**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 (5 injections per side) for a total dose of 24 Units.

**For moderate to severe glabellar lines**

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 2.2 cm temporal to the lateral canthus and just temporal to the lateral orbital rim.
   - Inject along a line that angles from anterior inferior to super posterior.

- Remember to keep the most inferior injection superior to the maxillary prominence.

**For moderate to severe lateral canthal lines**

- 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 (5 injections per side) for a total dose of 24 Units.

**Two approved injection patterns**

**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 sites, or when excessive weakness or atrophy is present in the target muscle.

**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 (e.g., 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 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 human albumin or albumins contained in other licensed products.

**DRUG INTERACTIONS**

Co-administration of BOTOX® Cosmetic and anticholinergics or other agents interfering with neuromuscular transmission (e.g., 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 potentially cause 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.

**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.

**IMPORTANT SAFETY INFORMATION (continued)**

**W Warnings and Precautions (continued)**

**Spread of Toxins 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 24 Units (for glabellar 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 muscular weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with facial 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 structure. 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.

**Hyperresponsivity 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 initiated. 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 tachycardia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including 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, dysphagia, ptosis, diplopia, dysarthria, severe dysphagia, and respiratory compromise from onabotulinumtoxinA (see Warnings and Precautions).

**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 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 human albumin or albumins contained in other licensed products.

**DRUG INTERACTIONS**

Co-administration of BOTOX® Cosmetic and anticholinergics 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 potentially cause 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.

**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**


**Allergan**

© 2020 Allergan. All rights reserved. All trademarks are the property of their respective owners.

http://bboxcosmetic.com/ 1-800-BOTOXMD  Re-order: BCT118858-v4 08/20  007311