INDICATIONS

BOTOX® is indicated for the temporary improvement in the appearance of:

- moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar lines) and/or;
- moderate to severe lateral canthal lines (crow's feet lines) seen at maximum smile and/or;
- moderate to severe forehead lines seen at maximum forehead elevation when the severity of the facial lines has an important psychological impact in adult patients.

WHAT YOU CAN EXPECT FROM BOTOX®

- Patients may see improvement within 2-3 days of injection;
- Recommended dosing can provide long duration* of patient satisfaction (up to 6 months);
- Interval between treatments must not be less than 3 months.

TOTAL RECOMMENDED SIMULTANEOUS DOSE = 64U BOTOX®†

<table>
<thead>
<tr>
<th>Injection Site</th>
<th>BOTOX® Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crow's Feet Lines</td>
<td>24U</td>
</tr>
<tr>
<td>Glabella Lines</td>
<td>20U</td>
</tr>
<tr>
<td>Forehead Lines</td>
<td>40U</td>
</tr>
</tbody>
</table>

SAFETY PROFILE

BOTOX® has an extensively evaluated safety profile. Please refer to the SmPC for a full range of side effects.

* Statistical significance vs. placebo and/or historical controls

† Dosage is per vial, a single vial contains 100 units of BOTOX®.
**FOREHEAD LINES**

- A volume of 0.1 ml (4 Units) is administered in each of the 5 injection sites in the frontalis muscle, for a total recommended dose of 20 Units in a total volume of 0.5 ml.

- Total recomended dose (20 Units) in conjunction with glabellar lines (20 Units) is 40 Units/1.0 ml.

- For simultaneous treatment with glabellar lines and crow's feet lines, the total recommended dose is 64 Units, comprised of 20 Units for forehead lines, 20 Units for glabellar lines and 24 Units for crow's feet lines.

**INJECTION**

To identify 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 should be assessed. The following horizontal treatment rows should be located by light palpation of the forehead at rest and maximum eyebrow elevation (see Figure 1):

- 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

The 5 injections should be placed at the intersection of the horizontal treatment rows with the following vertical landmarks (see Figure 1):

- On the lower treatment row at the midline of the face, and 0.5 – 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.

**CROW'S FEET LINES**

- Total recommended dose: 24U in 0.6 ml (12U per side)
- 0.1 ml (4U) in each of 6 injection sites
- Injected in the lateral orbicularis oculi muscle

**INJECTION**

Injections should be given with the needle tip bevel up and oriented away from the eye. The first injection (A) should be made approximately 1.5 to 2.0 cm temporal to the lateral canthus and just temporal to the orbital rim:

- If the lines in the crow’s feet region are above and below the lateral canthus, inject as shown in Figure 2
- If the lines in the crow’s feet region are primarily below the lateral canthus, inject as shown in Figure 3

**GLABELLAR LINES**

- Total recommended dose: 20U in 0.5 ml (12U in each of 5 injection sites)
- 0.1 ml (4U) in each of 6 injection sites
- 2 injections in each corrugator muscle
- 1 injection in the procerus muscle

**INJECTION**

- Before injection, place the thumb or index finger firmly below the orbit rim to prevent extravasation below the orbit rim
- Orient the needle superiorly and medially during injection

Injections near the levator palpebrae superioris muscle must be avoided particularly in patients with larger brow-depressor complexes (depressor supercilii). Injections in the corrugator muscle must be done in the central part of that muscle, at least 1 cm above the arch of the eyebrows.

**RECONSTITUTION**

BOTOX® is reconstituted with a sterile 0.9% preservative-free sodium chloride solution. Reconstitution should be performed in accordance with good practices and aseptic technique.

- For 50U BOTOX®: 1.25 ml of solvent added to 50U BOTOX® and slowly into the vial
- For 100U BOTOX®: 2.5 ml of solvent added to 100U BOTOX® slowly into the vial
- Vacuum pulled solvent into the vial, mix (discard the vac)
- Gently rotate to avoid bubble formation and denaturation
- Solution is clear, colourless to slightly yellow, and infusion packets

Diagrammatic representation for illustrative purposes only. Please refer to the BOTOX® Summary of Product Characteristics.