**Indication:** Dysport is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients less than 65 years of age.

**Important Safety Information**

**Distant Spread of Toxin Effect**

Postmarketing reports indicate that the effects of Dysport 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, blurred vision, 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 underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and at lower doses.

Please see complete Important Safety Information on page 3 and full prescribing information at dysportusa.com.

**Recommended dosing**

- **Units per Injection Site =**
  - 300U Dysport ÷ 1.5mL Saline*
  - x 0.05 mL/site = 10 U/site
  - (units per vial ÷ dilution in mL) x mL per site

- **Volume per Injection Site =**
  - 1.5mL Saline* ÷ 300U Dysport
  - x 10 U/site = 0.05 mL/site
  - (dilution in mL ÷ units per vial) x units per site

*Preservative-free, 0.9% sterile saline.

**Draw up volume =** 0.25 mL

- mL per site x number of sites

- 0.25 mL 50 U

- 1 mL Norm-Ject® Tuberkulin syringe

- 3/10 mL (0.33 mL) Insulin-type syringe

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**Recommended dosing**

**Units per Injection Site =**

\[
\frac{300 \text{ U}}{2.5 \text{ mL}} \times 0.08 \text{ mL/site} = 10 \text{ U/site}
\]

(units per vial ÷ dilution in mL) x mL per site

**Volume per Injection Site =**

\[
\frac{2.5 \text{ mL}}{300 \text{ U}} \times 10 \text{ U/site} = 0.08 \text{ mL/site}
\]

(dilution in mL ÷ units per vial) x units per site

*Preservative-free, 0.9% sterile saline.

**Draw up volume** = 0.40 mL

- 1 mL Norm-Ject® Tuberkulin syringe
- 5/10 mL (0.50 mL) Insulin-type syringe

- mL per site x number of sites

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**CONTRAINDICATIONS**

- *Dysport* is contraindicated in patients with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation.
- This product may contain trace amounts of cow's milk protein. Patients known to be allergic to cow's milk protein should not be treated with *Dysport*.
- *Dysport* is contraindicated for use in patients with infection at the proposed injection site(s).

**DOSAGE AND ADMINISTRATION**

The potency Units of *Dysport* 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 *Dysport* cannot be compared to or converted into units of any other botulinum toxin products assessed with any other specific assay method.

**WARNINGS AND PRECAUTIONS**

**Facial Anatomy in the Treatment of Glabellar Lines**

- Caution should be exercised when administering *Dysport* to patients with surgical alterations to the facial anatomy, excessive weakness or atrophy in the target muscle(s), marked facial asymmetry, inflammation at the injection site(s), ptosis, excessive dermatochalasis, deep dermal scarring, thick sebaceous skin or the inability to substantially lessen glabellar lines by physically spreading them apart.
- Do not exceed the recommended dosage and frequency of administration of *Dysport*. In clinical trials, subjects who received a higher dose of *Dysport* had an increased incidence of eyelid ptosis.

**Pre-existing Neuromuscular Disorders**

- Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis or neuromuscular junction disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin.
- Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of *Dysport*.
Human Albumin

• 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) is also considered extremely remote. No cases of transmission of viral diseases or CJD have ever been reported for albumin.

Intradermal Immune Reaction

• The possibility of an immune reaction when injected intradermally is unknown.

• The safety of Dysport for the treatment of hyperhidrosis has not been established.

ADVERSE REACTIONS

• In clinical studies, the most frequently reported adverse events (≥2%) were nasopharyngitis, headache, injection site pain, injection site reaction, upper respiratory tract infection, eyelid edema, eyelid ptosis, sinusitis and nausea.

DRUG INTERACTIONS

• Patients treated concomitantly with botulinum toxins and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents) should be observed closely because the effect of the botulinum toxin may be potentiated. Use of anticholinergic drugs after administration of Dysport may potentiate systemic anticholinergic effects such as blurred vision.

• The effect of administering different botulinum neurotoxin products at the same time or within several months of each other is unknown. Excessive weakness may be exacerbated by another administration of 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 Dysport.

USE IN SPECIFIC POPULATIONS

• Dysport is not recommended for use in children or pregnant women.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please visit dysportusa.com for Full Prescribing Information including Medication Guide.