**Dysport** (abobotulinumtoxinA) 1.5 mL Reconstitution

**Reconstitution, Dilution, and Dosing**

**Units per Injection Site**

\[ \text{Units per site} = \frac{\text{Units per vial}}{\text{Dilution in mL}} \times \text{Volume per site} \]

**Volume per Injection Site**

\[ \text{Volume per site} = \frac{\text{Volume per vial}}{\text{Units per site}} \times \text{Units per vial} \]

**Draw up volume**

\[ \text{Draw up volume} = \text{Volume per site} \times \text{number of sites} \]

**5 Sites for Injection**

\[ \text{Volume per site} = \frac{0.25 \text{ mL}}{50 \text{ U}} = 0.005 \text{ mL/site} \]

Dysport® (abobotulinumtoxinA) for Injection 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 <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 deaths. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults for treatment of conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including upper limb spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to or lower than the maximum recommended total dose.

Please see accompanying Dysport Full Prescribing Information.
Dysport® (abobotulinumtoxinA) for injection 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 <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 upper limb spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to or lower than the maximum recommended total dose.

CONTRAINDICATIONS
- Hypersensitivity to any botulinum toxin product or excipients
- Allergy to cow’s milk protein
- Infection at the proposed injection site(s)

WARNINGS AND PRECAUTIONS
- The potency Units of Dysport 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.
- Recommended dose and frequency of administration should not be exceeded.
- Immediate medical attention may be required in cases of respiratory, speech or swallowing difficulties.
- Concomitant neuromuscular disorder may exacerbate clinical effects of treatment.
- Dysport contains human albumin. There is a risk for transmission of Creutzfeldt-Jakob disease (CJD) however, no cases of transmission of viral diseases or CJD have ever been identified for albumin.

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, nausea, and blood present in urine.

DRUG INTERACTIONS
- Concomitant use of Dysport and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents); or muscle relaxants, should be observed closely because the effect of the botulinum toxin may be potentiated.
- Anticholinergic drugs may potentiate systemic anticholinergic effects.
- Excessive weakness may be exacerbated by administration of different botulinum neurotoxins and/or muscle relaxants during the course of treatment with 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 see accompanying Dysport Full Prescribing Information.

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