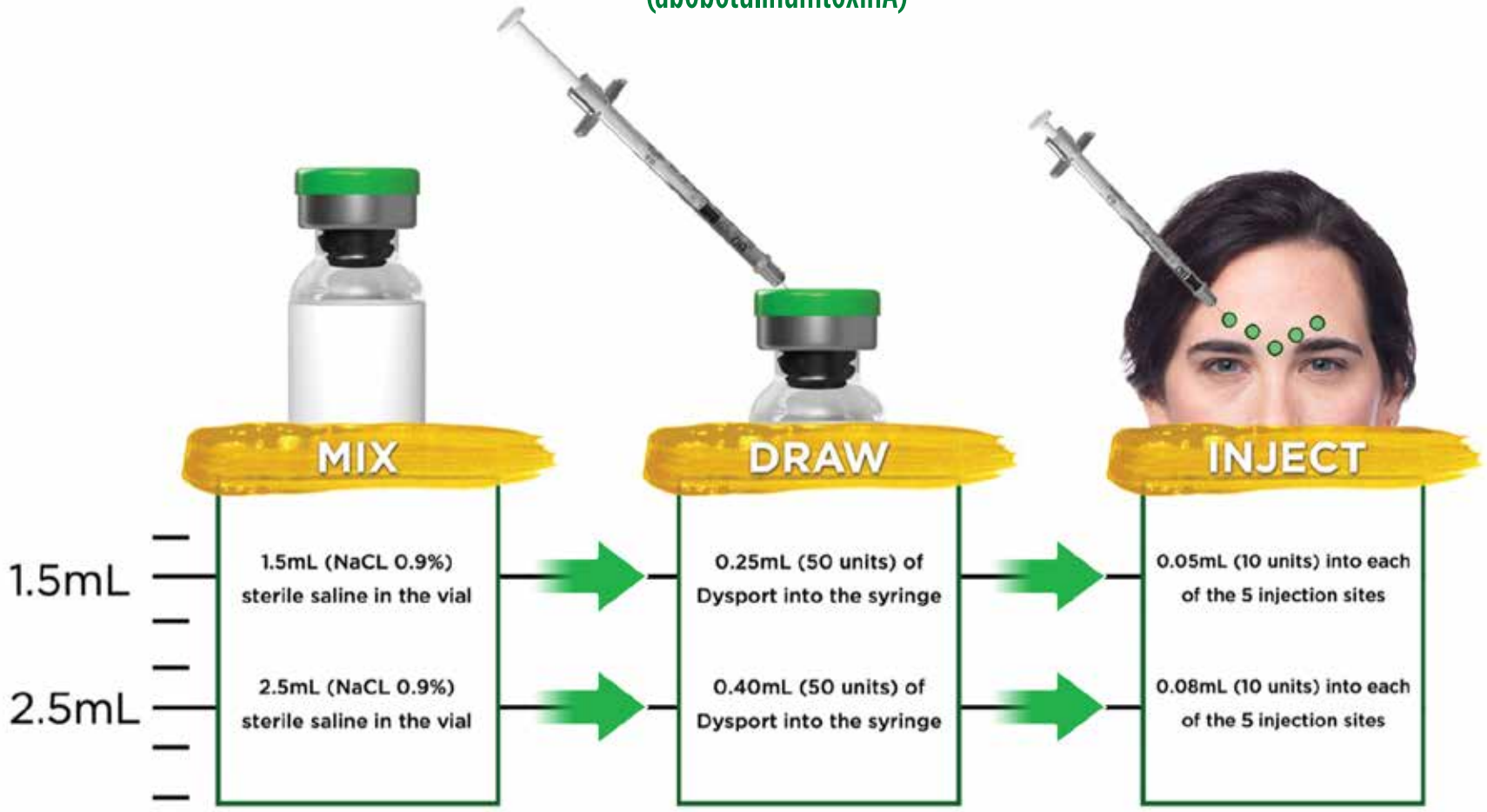
Dysport® RECONSTITUTION

(abobotulinumtoxinA)



Dysport is a prescription injection for temporary improvement in the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults less than 65 years of age.

The most common side effects are nose and throat irritation, headache, injection site pain, injection site skin reaction, upper respiratory infection, eyelid swelling, eyelid drooping, sinus inflammation and nausea.

***Please see full Important Safety Information, including Distant Spread of Toxin Effect Boxed Warning, on the next page.**

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 adults <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 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.
- Immediate medical attention may be required in cases of respiratory, speech or swallowing difficulties, or serious hypersensitivity reactions.
- Recommended dose and frequency of administration should not be exceeded.
- Dry eye may occur with glabellar line treatment, if symptoms persist, consider referring patient to an ophthalmologist.
- Concomitant neuromuscular disorder may exacerbate clinical effects of treatment.

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 or muscle relaxants, should be observed closely because effect of *Dysport* may be potentiated.
- Anticholinergic drugs may potentiate systemic anticholinergic effects.
- The effect of administering different botulinum neurotoxins during course of treatment with *Dysport* is unknown.

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 *Dysport* Full Prescribing Information including Medication Guide at DysportUSA.com

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