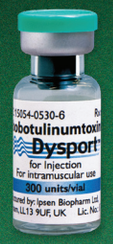
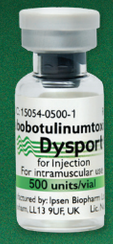
AN APPROACH FOR THE DILUTION OF DYSPORT® (abobotulinumtoxinA)



Diluent per Dysport 300-Unit Vial	Resulting Dysport Units per 0.1 mL	Resulting Dysport Units per 1.0 mL
0.6 mL	Dysport 50 Units	Dysport 500 Units
1.5 mL	Dysport 20 Units	Dysport 200 Units
2.5 mL	Dysport 12 Units	Dysport 120 Units
3.0 mL*	Dysport 10 Units	Dysport 100 Units



Diluent per Dysport 500-Unit Vial	Resulting Dysport Units per 0.1 mL	Resulting Dysport Units per 1.0 mL
1.0 mL	Dysport 50 Units	Dysport 500 Units
2.0 mL	Dysport 25 Units	Dysport 250 Units
2.5 mL	Dysport 20 Units	Dysport 200 Units
5.0 mL*	Dysport 10 Units	Dysport 100 Units

• Dysport potency units are not interchangeable with other preparations of botulinum toxin products.
• No more than 1 mL should generally be administered at any single injection site when treating adults. When treating pediatric patients, no more than 0.5 mL should generally be administered at any single injection site.
* These volumes yield concentrations specific for the use of each indication. For other dilution options, and complete dosing information for each indication, please see full Prescribing Information.

Dysport is a proven first-line treatment option

3 points to keep in mind with Dysport

1. **Vacuum.** When reconstituting Dysport, insert the needle into the vial and allow the diluent to be pulled into the vial by **partial vacuum**. Do not use the vial if no vacuum is observed.
2. **Swirl.** Swirl Dysport gently in the vial to dissolve, rather than shaking or rolling.
3. **Vent.** When using more than 2 mL of diluent, **vent the vial** to release the pressure if entering the vial again to withdraw the diluted Dysport.

- Using an appropriately sized sterile syringe, needle, and aseptic technique, draw up an appropriate amount of sterile, preservative-free 0.9% Sodium Chloride Injection USP.
- When reconstituting, do not invert the Dysport vial. Reconstituted Dysport should be a clear, colorless solution, free of particulate matter, otherwise it should not be injected.
- Once reconstituted, Dysport should be stored in the original container, in a refrigerator at 2°C to 8°C (36°F to 46°F), protected from light for up to 24 hours. It must be discarded if not used within 24 hours. Do not freeze reconstituted Dysport. Discard the vial and needle in accordance with local regulations.
- To inject, remove the needle used to reconstitute Dysport and attach an appropriately sized new sterile needle to administer the injection. Inject into target muscle(s) within 24 hours of reconstitution. Dysport should be used for only one injection session and for only one patient after reconstitution.

INDICATIONS

Dysport® (abobotulinumtoxinA) for injection is indicated for the treatment of:
• Spasticity in patients 2 years of age and older
• Cervical dystonia in adults

IMPORTANT SAFETY INFORMATION

Warning: 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

Dysport is contraindicated in patients with known hypersensitivity to any botulinum toxin products, cow's milk protein, components in the formulation or infection at the injection site(s). Serious hypersensitivity reactions including anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea have been reported. If such a reaction occurs, discontinue Dysport and institute appropriate medical therapy immediately.

Warnings and Precautions

Lack of Interchangeability Between Botulinum Toxin Products
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.

Dysphagia and Breathing Difficulties
Treatment with Dysport and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or swallowing. When distant side effects occur, additional respiratory muscles may be involved. Deaths as a complication of severe dysphagia have been reported after treatment with botulinum toxin. Dysphagia may persist for several weeks, and require use of a feeding tube to maintain adequate nutrition and hydration. Aspiration may result from severe dysphagia and is a particular risk when treating patients in whom swallowing or respiratory function is already compromised. Patients treated with botulinum toxin may require immediate medical attention should they develop problems with swallowing, speech, or respiratory disorders. These reactions can occur within hours to weeks after injection with botulinum toxin.

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 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 licensed albumin or albumin contained in other licensed products.

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. Dysport is approved only for intramuscular injection.

Most Common Adverse Reactions

Adults with lower limb spasticity (≥5%): falls, muscular weakness, and pain in extremity and with **upper limb spasticity** (≥4%): muscular weakness.

Pediatric patients with lower limb spasticity (≥10%): nasopharyngitis, cough and pyrexia and with **upper limb spasticity** (≥10%): upper respiratory tract infection and pharyngitis.

Adults with cervical dystonia (≥5%): muscular weakness, dysphagia, dry mouth, injection site discomfort, fatigue, headache, musculoskeletal pain, dysphonia, injection site pain, and eye disorders..

Drug Interactions

Co-administration 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 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 neurotoxins 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.

Special Populations

Use in Pregnancy
There are no adequate and well-controlled studies in pregnant women. Dysport should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Based on animal data, Dysport may cause fetal harm.

Pediatric Use
The safety and effectiveness of Dysport injected into proximal muscles of the lower limb for the treatment of spasticity in pediatric patients has not been established. Based on animal data Dysport may cause atrophy of injected and adjacent muscles; decreased bone growth, length, and mineral content; delayed sexual maturation; and decreased fertility.

Geriatric Use
In general, elderly patients should be observed to evaluate their tolerability of Dysport, due to the greater frequency of concomitant disease and other drug therapy. Subjects aged 65 years and over who were treated with Dysport for lower limb spasticity reported a greater percentage of fall and asthenia as compared to those younger (10% vs. 6% and 4% vs. 2%, respectively).

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact Ipsen at 1-855-463-5127. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

IPSEN Innovation for patient care

Dysport® (abobotulinumtoxinA) for injection, for intramuscular use 300- and 500-Unit vials.
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Dysport® (abobotulinumtoxinA) It's Time