Product Fact Sheet

Internet: www.IpsenUS.com | www.dysport.com

Supplied and Marketed by: IPSEN Biopharmaceuticals, Inc.

Product Name

Dysport®

Established Name

abobotulinumtoxinA

Indications

Dysport® (abobotulinumtoxinA) for injection is indicated for the treatment of:

- Spasticity in patients 2 years of age and older
- Cervical dystonia in adults

Product Information

NDC	Description	Dispensing/Sale Pack Quantity
15054-0500-01	500 Unit Vial Each Vial Contains 500 Units of Freeze-Dried abobotulinuntoxinA	1
15054-0530-06	300 Unit Vial Each Vial Contains 300 Units of Freeze-Dried abobotulinumtoxinA	1

Product Availability

Dysport is available through your Specialty Distributor or Wholesaler. Please contact your supplier or refer to the Ipsen Product Acquisition Guide found on the Ipsen US Website (www.IpsenUS.com) for a list of Specialty Distributors.

A limited number of Specialty Pharmacies are also authorized to dispense the medication; please call IPSEN CARES® at 1-866-435-5677 for a list of Specialty Distributors or Specialty Pharmacy Providers who have access to Dysport.

Dispensing Pack Dimensions

Dysport Approximate Dimensions - Unit
Depth: 1”, Height: 1 7/8”, Width: 3”

Handling and Storage Information

Dysport for Injection is supplied in a sterile, single-use, 3 mL glass vial. Dysport must be stored under refrigeration at 2–8°C (36–46°F). Protect from light. Each vial is intended for single use. Do not use beyond the expiration date on the vial and packaging.

Sales Unit to Trade

One dispensing pack.

Product Expiration

The expiration date is printed on each dispensing pack and the vial.

Prescription Legend

Prescription only.

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.

Please see additional Important Safety Information throughout this document, and accompanying full Prescribing Information, including **Boxed Warning**.

Dysport® (abobotulinumtoxinA)

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Special Shipping Requirements	Dysport is labeled with specific transportation and storage requirements. Care should be taken to ensure that temperature control at 2° to 8 C° (36° to 46° F) is maintained during these activities. Ipsen will ship Dysport in a manner that maintains its temperature to meet the requirements stated above during transport from Ipsen to the product destination. Specialty Distributors and Specialty Pharmacies should also package and ship Dysport in a manner that maintains this same environment. Customers should call 1-855-463-5127 if they have any questions pertaining to proper shipping.
Product Returns	For questions regarding returns, please contact Ipsen Customer Service at 1-844-944-7736
Order Information	Ipsen Customer Service: 1-844-944-7736
Product Information	Ipsen Medical Affairs Phone: 1-855-463-5127 Fax: 1-866-681-1063 Email: medinfo.USA@ipsen.com
Reimbursement Information	IPSEN CARES®: 1-866-435-5677 Monday through Friday 8:00 AM to 8:00 PM ET Program provides coverage, access, reimbursement, and educational support to patients and their healthcare professionals.
Patient Support Program	IPSEN CARES®: 1-866-435-5677 Monday through Friday 8:00 AM to 8:00 PM ET
J-Code	J0586

Important Safety Information (Continued)

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.

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Product Fact Sheet

Important Safety Information (Continued)

Warnings and Precautions (Continued)

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 spasticit**y (≥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.

Dysport®
(abobotulinumtoxinA)

Please see accompanying full Prescribing Information, including **Boxed Warning**.

Dysport® (abobotulinumtoxinA) for injection, for intramuscular use 300- and 500-unit vials.

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