DYS-US-005044 V2.0 Product Fact Sheet - Print Schematic

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Product Fact Sheet

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

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 abobotulinumtoxinA	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	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 after the expiration date on the vial. All vials, including expired vials, or equipment used with Dysport should be disposed of carefully as is done with all medical waste. Dysport contains a unique hologram on the carton. If you do not see the hologram, do not use the product. Instead contact 1-855-463-5127.
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 and accompanying full Prescribing Information, including BOXED WARNING.

Dysport® (abobotulinumtoxinA)

Dysport® (abobotulinumtoxinA)

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Dysport® (abobotulinumtoxinA) for injection, for intramuscular use 300- and 500-unit vials.
Dysport is a registered trademark of Ipsen Biopharm Limited.
IPSEN CARES is a registered trademark of Ipsen S.A.
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October 2023 DYS-US-005044 V2.0

IPSEN Innovation for patient care

Product Fact Sheet

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	Credit for returns is subject to Ipsen's current Return Goods Policy. Please contact Returns.USA@ipsen.com for more information or to receive a Return Goods Authorization.
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 for patient and providers.
Patient Support Program	IPSEN CARES®: 1-866-435-5677 Monday through Friday 8:00 AM to 8:00 PM ET
J-Code	J0585 - Injection, abobotulinumtoxinA, 5 units
Important Safety Information (Continued)	**Contraindications** DYSPORT is contraindicated in patients with known hypersensitivity to any botulinum toxin products, cow's milk protein, or to any of the components in the formulation, or infection at the proposed injection site(s). Serious hypersensitivity reactions including anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea have been reported. If such a serious 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 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. Treatment of cervical dystonia with botulinum toxins may weaken accessory muscles of ventilation, which may result in a critical loss of breathing capacity in patients with respiratory disorders who may have become dependant upon these muscles. 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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including BOXED WARNING.

Dysport® (abobotulinumtoxinA)

Product Fact Sheet

Important Safety Information (Continued)	**Warnings and Precautions (Continued)** **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, vCJD, or CJD 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. **Pre-existing Conditions at the Injection Site** Caution should be exercised when DYSPORT is used where the targeted muscle shows excessive weakness or atrophy. **Adverse Reactions** • The most common adverse reactions (>4%) in adults with upper limb spasticity include muscular weakness; in adults with lower limb spasticity (>5%) include falls, muscular weakness, and pain in extremity • The most common adverse reactions (≥10%) in pediatric patients with upper limb spasticity include upper respiratory tract infection and pharyngitis; in pediatric patients with lower limb spasticity include nasopharyngitis, cough, and pyrexia • The most common adverse reactions (≥5%) in adults with cervical dystonia include 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) should only be performed with caution 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 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 and after administration of DYSPORT. 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.

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Dysport® (abobotulinumtoxinA)

Product Fact Sheet

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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
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Product Information

NDC	Description	Dispensing/Sale Pack Quantity
15054-0500-01	500 Unit Vial Each Vial Contains 500 Units of Freeze-Dried abobotulinuntoxinA	1
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Product Availability

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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

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 after the expiration date on the vial. All vials, including expired vials, or equipment used with Dysport should be disposed of carefully as is done with all medical waste. Dysport contains a unique hologram on the carton. If you do not see the hologram, do not use the product. Instead contact 1-855-463-5127.

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.

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Dysport® (abobotulinumtoxinA)

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Product Returns	Credit for returns is subject to Ipsen's current Return Goods Policy. Please contact Returns.USA@Ipsen.com for more information or to receive a Return Goods Authorization.
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 for patient and providers.
Patient Support Program	IPSEN CARES®: 1-866-435-5677 Monday through Friday 8:00 AM to 8:00 PM ET
J-Code	J0586 - Injection, abobotulinumtoxinA, 5 units

Important Safety Information (Continued)

Contraindications

DYSPORT is contraindicated in patients with known hypersensitivity to any botulinum toxin products, cow's milk protein, or to any of the components in the formulation, or infection at the proposed injection site(s). Serious hypersensitivity reactions including anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea have been reported. If such a serious 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 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. Treatment of cervical dystonia with botulinum toxins may weaken accessory muscles of ventilation, which may result in a critical loss of breathing capacity in patients with respiratory disorders who may have become dependent upon these muscles. 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.

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Dysport® (abobotulinumtoxinA)

Product Fact Sheet

Important Safety Information (Continued)

Warnings and Precautions (Continued)

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, vCJD, or CJD 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.

Pre-existing Conditions at the Injection Site

Caution should be exercised when DYSPORT is used where the targeted muscle shows excessive weakness or atrophy.

Adverse Reactions

- The most common adverse reactions (≥4%) in adults with upper limb spasticity include muscular weakness; in adults with lower limb spasticity (≥5%) include falls, muscular weakness, and pain in extremity
- The most common adverse reactions (≥10%) in pediatric patients with upper limb spasticity include upper respiratory tract infection and pharyngitis; in pediatric patients with lower limb spasticity include nasopharyngitis, cough, and pyrexia
- The most common adverse reactions (≥5%) in adults with cervical dystonia include 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) should only be performed with caution 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 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 and after administration of DYSPORT.

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Dysport® (abobotulinumtoxinA)

Dysport®
(abobotulinumtoxinA)

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Dysport® (abobotulinumtoxinA) for injection, for intramuscular use 300- and 500-unit vials.
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IPSEN CARES is a registered trademark of Ipsen S.A.

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Innovation for patient care