IMPORTANT SAFETY INFORMATION (continued)

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 additional Important Safety Information on the previous pages, and accompanying full Prescribing Information, including **Boxed Warning** and Medication Guide.

To calculate the FDA-approved dose range for each patient, download the Dysport Dosing Guide from the Apple App Store or Google Play store.

This application is not intended to diagnose, treat, cure, or prevent any disease.

Available on the App Store

Get it on Google play

References: 1. Dysport® (abobotulinumtoxinA) [prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; July 2020. **2.** Data on file. Ipsen Biopharmaceuticals, Inc. Cambridge, MA.

IPSEN Innovation for patient care

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

PATIENT INJECTION RECORD: PEDIATRIC SPASTICITY[1]

Patient: _____ **Chart #:** _____

Date: _____ **Time:** _____

Complete the Dysport Injection Tracker below. Indicate the dose used for each muscle and the specific sites of injection.

Pediatric Upper Limb Spasticity[1]

Total Dose: _____ Units

The total dose per treatment session for upper limb spasticity only must not exceed 16 Units/kg, or 640 Units (whichever is lower).

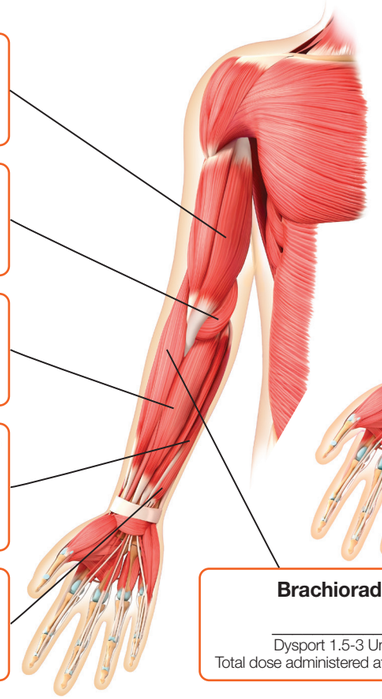
Biceps Brachii
_____ Units
Dysport 3-6 Units/kg
Total dose divided among up to 2 injection sites

Pronator Teres
_____ Units
Dysport 1-2 Units/kg
Total dose administered at 1 injection site

Flexor Carpi Radialis (FCR)
_____ Units
Dysport 2-4 Units/kg
Total dose divided among up to 2 injection sites

Flexor Digitorum Superficialis (FDS)
_____ Units
Dysport 1.5-3 Units/kg
Total dose divided among up to 4 injection sites

Flexor Carpi Ulnaris (FCU)
_____ Units
Dysport 1.5-3 Units/kg
Total dose administered at 1 injection site



Brachialis
_____ Units
Dysport 3-6 Units/kg
Total dose divided among up to 2 injection sites

Flexor Digitorum Profundus (FDP)
_____ Units
Dysport 1-2 Units/kg
Total dose administered at 1 injection site

Pronator Quadratus
_____ Units
Dysport 0.5-1 Units/kg
Total dose administered at 1 injection site

Brachioradialis
_____ Units
Dysport 1.5-3 Units/kg
Total dose administered at 1 injection site

No more than 0.5 mL should generally be administered at any single injection site.

To calculate the Dysport FDA-approved dose range for each patient, download the Dysport Dosing Guide from the Apple App Store and Google Play store. This application is not intended to diagnose, treat, cure, or prevent any disease.

Apple and the App Store are registered trademarks of Apple Inc. Google Play is a registered trademark of Google LLC.

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.

Please see additional Important Safety Information on the following page, and accompanying full Prescribing Information, including **Boxed Warning** and Medication Guide.

Dysport® (abobotulinumtoxinA)

PATIENT INJECTION RECORD: PEDIATRIC SPASTICITY[1,2]

Complete the Dysport Injection Tracker below. Indicate the dose used for each muscle and the specific sites of injection.

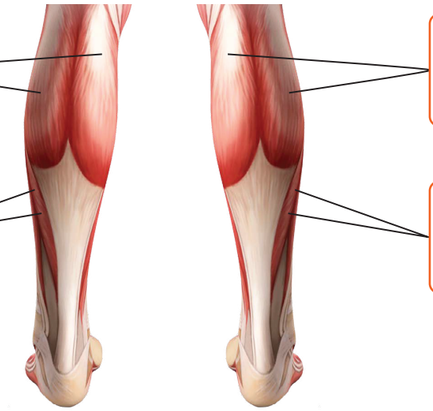
Pediatric Lower Limb Spasticity

Total Dose: _____ Units

The total dose per treatment session for lower limb spasticity only must not exceed 15 Units/kg for unilateral lower limb injections, 30 Units/kg for bilateral injections, or 1,000 Units (whichever is lower).

Gastrocnemius
_____Units
Dysport 6-9 Units/kg/leg
Total dose divided among up to 4 injection sites

Soleus
_____Units
Dysport 4-6 Units/kg/leg
Total dose divided among up to 2 injection sites



Gastrocnemius
_____Units
Dysport 6-9 Units/kg/leg
Total dose divided among up to 4 injection sites

Soleus
_____Units
Dysport 4-6 Units/kg/leg
Total dose divided among up to 2 injection sites

Steps for Injection[2]

Step 1	Obtain patient weight
Step 2	Choose unilateral/bilateral and limb(s)
Step 3	Select muscles
Step 4	Determine Dysport dose
Step 5	Achieve desired concentration

Dosing is based on Dysport Units per kilogram of body weight. The maximum recommended total dose per treatment session is 30 Units/kg or 1,000 Units, whichever is lower. No more than 0.5 mL of Dysport should be administered in any single injection site. Retreatment, based on return of clinical symptoms, should not occur in intervals of less than 3 months.[1]

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information on the following page, and accompanying full Prescribing Information, including **Boxed Warning** and Medication Guide.

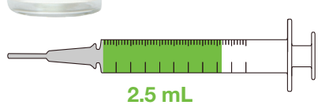
Dysport® (abobotulinumtoxinA)

TRACKING AND BILLING[2]

5 Dysport Units=1 billable Unit

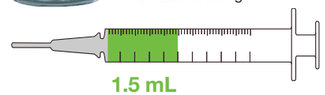
Dysport HCPCS Code	Description
J0586	Injection, abobotulinumtoxinA, 5 Units

500-Unit vial NDC 15054-0500-1*
Billing Units: 100



300-Unit vial NDC 15054-0530-6*
Billing Units: 60

*Please note that for billing purposes, the NDC number requires 11 digits. Therefore, a zero must be entered into the 10th position (eg, "15054-0530-06"). This is consistent with the Red Book and First DataBank listings.



Dysport Units	
	Injected
	Wastage
	Billable
	Total Units†

†Divide by 5=1 billable Unit.

The form is not intended to provide recommendations on clinical practice. This document represents no statement, promise, or guarantee concerning coverage or levels of reimbursement. It is always the physician's or facility's responsibility to determine and submit appropriate codes, charges, and modifiers for services that are rendered.

Dysport Product Tracking

Lot Number	Expiration Date

For CPT code information, please reference the Dysport Resource Guide.

Was guidance performed?

☐ **Yes** ☐ **No** **Note which method was used:** _____

Additional notes: _____

_____

IMPORTANT SAFETY INFORMATION

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, 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.

Please see additional Important Safety Information on the following page, and accompanying full Prescribing Information, including **Boxed Warning** and Medication Guide.

Dysport® (abobotulinumtoxinA)