

Dysport Dosing in Adult Cervical Dystonia

Dysport efficacy and safety were established in clinical trials featuring the following FDA-approved dosing ranges¹
Please see Indications and Important Safety Information, including **BOXED WARNING**, below.

500 Units () to 1000 Units ()

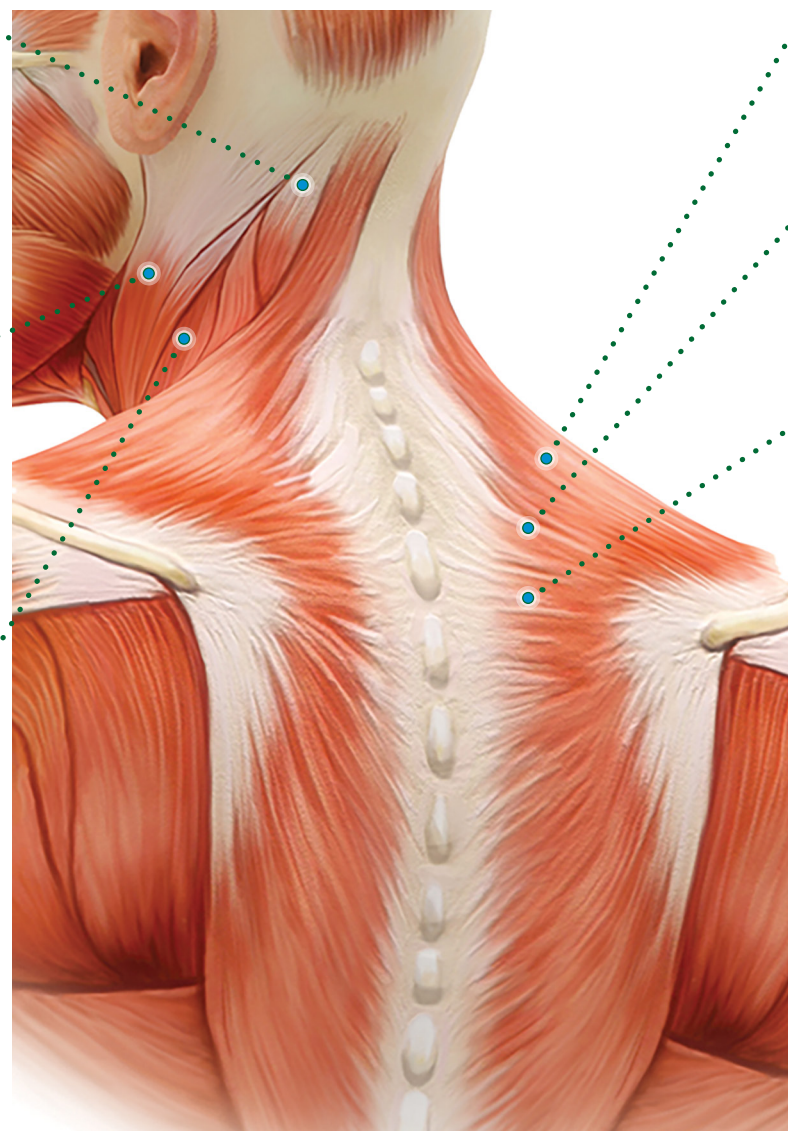
SEMI SPINALIS CAPITIS
50-250 Units

STERNOCLEIDOMASTOID (SCM)*
50-350 Units
Median: 125 Units

SPLЕНИUS CAPITIS
75-450 Units

LONGISSIMUS
100-200 Units

Located beneath the splenius capitis



TRAPEZIUS
50-300 Units

SCALENUS (MEDIUS AND ANTERIOR)
50-300 Units

LEVATOR SCAPULAE (HIDDEN)
50-200 Units

Dosing for cervical dystonia¹:

- + The recommended initial dose is Dysport 500 Units given intramuscularly as a divided dose among affected muscles
- + Titrate in 250 Unit steps according to patient's response

Median and 75th percentile dosing observed in the cervical dystonia clinical trials¹

Muscle	Median [Dysport Units] (min, max)	75th percentile [Dysport Units]
Sternocleidomastoid*	125 Units (50, 350)	150 Units
Splenius capitis	200 Units (75, 450)	250 Units
Trapezius	102.6 Units (50, 300)	150 Units
Levator scapulae	105.3 Units (50, 200)	125 Units
Scalenus (medius and anterior)	115.5 Units (50, 300)	150 Units
Semispinalis capitis	131.6 Units (50, 250)	175 Units
Longissimus	150 Units (100, 200)	200 Units

Total number of patients in combined studies 2 and 1 who received initial treatment=121.

No more than 1 mL should generally be administered at any single injection site. Simultaneous EMG-guided application of DYSPORT may be helpful in locating active muscles.¹

Immediate medical attention may be required in cases of respiratory, speech, or swallowing difficulties.

*Limiting the dose injected unilaterally into SCM to 150 Units or less may reduce the occurrence of dysphagia.¹

The potency units of Dysport are not interchangeable with other preparations of botulinum toxin products¹

Doses up to Dysport 1000 Units (divided among affected muscles) were systematically evaluated¹

When administering Dysport in adult spasticity, re-treatment should occur in intervals of no less than 12 weeks¹

- + Recommended dose and frequency of administration should not be exceeded

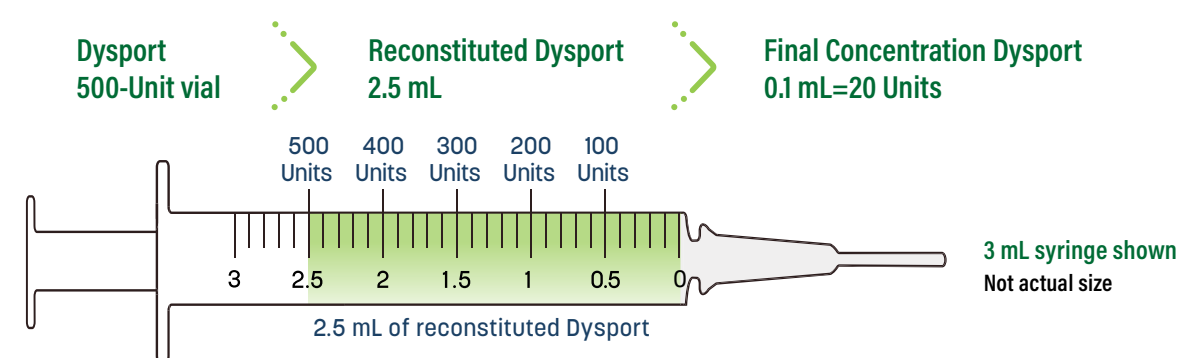
Dosing should be tailored based on¹:

- + The patient's response to treatment. Initial dose is 500 Units given intramuscularly as a divided dose among the affected muscles. Titration up or down should occur in 250-Unit steps
- + When injecting Dysport into the sternocleidomastoid, limit the dose injected unilaterally to 150 Units or less. This may reduce the occurrence of dysphagia

Preparation of Dysport solution for administration¹:

- + Once reconstituted, store in original container in a refrigerator at 2°C to 8°C (36°F to 46°F) and use within 24 hours. Do not freeze after reconstitution
- + Reconstituted Dysport is intended for intramuscular injection only. After reconstitution, Dysport should be used for only one injection session and for only one patient

When diluting[†] Dysport from a 500-Unit vial, use the following guide:



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 the course of treatment with Dysport is unknown.

[†]When reconstituting a 500-Unit vial of Dysport in preparation for dilution, no more than 2.0 mL of diluent should be used. Diluent is sterile, preservative-free 0.9% Sodium Chloride Injection, USP. Dysport is given by intramuscular injection.

To determine the Dysport FDA-approved dose range for each patient, use the Dysport Dosing Calculator.



SCAN HERE to access the Dosing Calculator or visit dosingcalculator.ipsen.com
Passcode: Dosingus

The Dysport Dosing Calculator is not intended to diagnose, treat, cure, or prevent any disease. Preferred browsers for this application are Chrome and Safari. You may experience sub-optimal experience on IE-11 and Firefox on Android devices.

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, 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.

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.

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.

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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Reference: 1. Dysport® (abobotulinumtoxinA) [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; July 2020.

Dysport[®]
(abobotulinumtoxinA)