

PATIENT INJECTION RECORD: ADULT CERVICAL DYSTONIA¹

Patient: _____ Chart #: _____

Date: _____ Time: _____

Complete the Dysport Injection Tracker below. For each muscle, indicate the dose used and the specific sites of injection.

Dysport Injection Tracker

When administering Dysport in cervical dystonia, retreatment should not occur in intervals of less than 12 weeks. The recommended dose and frequency of administration should not be exceeded.

Total Dose: _____ Units

Dosing for cervical dystonia: 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. Doses up to Dysport 1,000 Units (divided among affected muscles) injected intramuscularly were systematically evaluated. The potency units of Dysport are not interchangeable with other preparations of botulinum toxin products.

Sternocleidomastoid (SCM)*
 _____ Units
 Dysport 50-350 Units
 Median: 125 Units

Splenius Capitis
 _____ Units
 Dysport 75-450 Units

Longissimus
 _____ Units
 Located beneath the splenius capitis

Semispinalis Capitis
 _____ Units
 Dysport 50-250 Units

Trapezius
 _____ Units
 Dysport 50-300 Units

Scalenus (medius and anterior)
 _____ Units
 Dysport 50-300 Units

Levator Scapulae
 _____ Units
 Dysport 50-200 Units

Simultaneous EMG guided application of Dysport may be helpful in locating active muscles

*Dosing for the **sternocleidomastoid (SCM)**: Limiting the dose injected unilaterally into SCM to 150 Units or less may reduce the occurrence of dysphagia.¹ No more than 1 mL should generally be administered at any single injection site.

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.

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 next page, and accompanying full Prescribing Information, including **Boxed Warning** and Medication Guide.

Dysport[®]
 (abobotulinumtoxinA)

It's Time

TRACKING AND BILLING: ADULT CERVICAL DYSTONIA

5 Dysport Units Is 1 Billable Unit

Dysport HCPCS Code	Description
J0586	Injection, abobotulinumtoxinA, 5 Units



**500-Unit vial NDC
15054-0500-1***

Billing Units: 100

*Please note that for billing purposes, the NDC number requires 11 digits. Therefore, a zero must be entered into the 10th position (eg, "15054-0500-01"). This is consistent with the Red Book and First DataBank listings.



**300-Unit vial NDC
15054-0530-6***

Billing Units: 60

Dysport Units	
_____	Injected Units
_____	Wastage
_____	Billable Units
_____	Total Units [†]

[†]Divide by 5 = 1 Billable Unit.

- 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

The form is not intended to provide recommendations on clinical practice or legal advice. 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 electromyography (EMG) guidance performed?

Yes No Other method performed: _____

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.

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IMPORTANT SAFETY INFORMATION (continued)

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 ($\geq 5\%$): falls, muscular weakness, and pain in extremity and with **upper limb spasticity** ($\geq 4\%$): muscular weakness.

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

Adults with cervical dystonia ($\geq 5\%$): 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.

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

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