PATIENT INJECTION RECORD: ADULT SPASTICITY¹

Patient:	Chart #:
Date:	Time:
Complete the Dysport Injection Tracker below. For each muscle	e, indicate the dose used and the specific sites of injection.
Dysport Injection Tracker	Total Dose: Units
When administering Dysport in adult spasticity, retreatment should not occu in intervals of less than 12 weeks. The recommended dose and frequency or administration should not be exceeded.	
Adult Upper Limb Spasticity	The potency units of Dysport are not interchangeable with other preparations of botulinum toxin products.
Brachialis	Biceps Brachii
Units	Units
Dysport 200-400 Units Recommended: 1 to 2 injections per muscle	Dysport 200-400 Units Recommended: 1 to 2 injections per muscl
Pronator Teres	Flexor Carpi Ulnaris
Units Units	Units
Dysport 100-200 Units Recommended: 1 injection per muscle	Dysport 100-200 Units Recommended: 1 to 2 injections per musc
Brachioradialis	Flexor Digitorum Profundus*
Units	Units
Dysport 100-200 Units Recommended: 1 to 2 injections per muscle	Dysport 100-200 Units Recommended: 1 to 2 injections per muscl
Flexor Carpi Radialis	Flexor Digitorum Superficialis
Units Units	Dysport 100-200 Units
Dysport 100-200 Units Recommended: 1 to 2 injections per muscle	Superficial muscles of the right arm (anterior view) Dysport 100-200 Offits Recommended: 1 to 2 injections per muscles
*Hidden-deep. †Hidden-intermediate.	

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.



TRACKING AND BILLING: ADULT SPASTICITY

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



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, "15054-0500-01"). This is consistent with the Red Book and First DataBank listings.

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. 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 Dyspor	t Resource Guide.			
Additional notes:				
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, 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.



PATIENT INJECTION RECORD: ADULT SPASTICITY

Patient:	Chart #:
Date:	Time:
Complete the Dysport Injection Tracker below. For each muscle,	ndicate the dose used and the specific sites of injection.
Dysport Injection Tracker	Total Dose: Units
When administering Dysport in adult spasticity, retreatment should not occur in intervals of less than 12 weeks. The recommended dose and frequency of administration should not be exceeded. Adult Lower Limb Spasticity	Dosing for lower limb spasticity: up to 1,500 Units The maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1,500 Units.¹ The potency units of Dysport are not interchangeable with other preparations of botulinum toxin products.
Gastrocnemius (lateral head)	Gastrocnemius (medial head)
Dysport 100-150 Units Total dose administered at 1 injection site	Dysport 100-150 Units Total dose administered at 1 injection site
Soleus Units	Tibialis Posterior Units
Dysport 330-500 Units Total dose divided among 3 injection sites	Dysport 200-300 Units Total dose divided among 2 injection sites
Flexor Hallucis Longus	Flexor Digitorum Longus
Units	Units
Dysport 70-200 Units Total dose administered at 1 injection site	Dysport 130-200 Units Total dose divided among up to 2 injection sites
Superficial and deep muscles of the left lower le (posterior view)	

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.

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.

Please see additional Important Safety Information on the next page, and accompanying full Prescribing Information, including BOXED WARNING and Medication Guide.



IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

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.

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.

Please see accompanying full <u>Prescribing Information</u>, including BOXED WARNING and <u>Medication Guide</u>.

Reference: 1. Dysport® (abobotulinumtoxinA) [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; September 2023.

Please see Important Safety Information on previous pages, and accompanying full <u>Prescribing Information</u>, including BOXED WARNING and <u>Medication Guide</u>.



