Dysport® (abobotulinumtoxinA) Dosing in Adult Spasticity

Dysport efficacy and safety were established in clinical trials featuring the following FDA-approved dosing ranges[1]

Please see the Dysport Indications and Important Safety Information, including BOXED WARNING, below.

Adult Upper Limb Spasticity: 500 Units ( ) to 1000 Units ( )

BICEPS BRACHII
200 to 400 Units
Recommended: 1 to 2 injections per muscle

BRACHIALIS
200 to 400 Units
Recommended: 1 to 2 injections per muscle

BRACHIORADIALIS
100 to 200 Units
Recommended: 1 to 2 injections per muscle

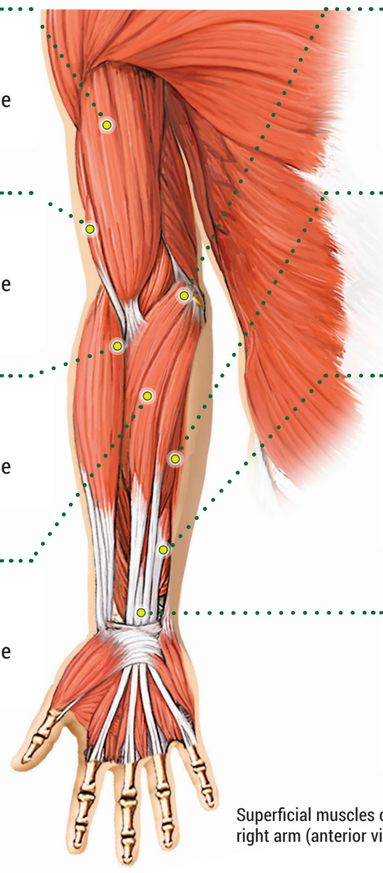
FLEXOR CARPI RADIALIS
100 to 200 Units
Recommended: 1 to 2 injections per muscle

PRONATOR TERES
100 to 200 Units
Recommended: 1 injection per muscle

FLEXOR CARPI ULNARIS
100 to 200 Units
Recommended: 1 to 2 injections per muscle

FLEXOR DIGITORUM PROFUNDUS*
100 to 200 Units
Recommended: 1 to 2 injections per muscle

FLEXOR DIGITORUM SUPERFICIALIS†
100 to 200 Units
Recommended: 1 to 2 injections per muscle



Superficial muscles of the right arm (anterior view)

*Hidden-deep.
†Hidden-intermediate.

Adult Lower Limb Spasticity: 1000 Units ( ) to 1500 Units ( )

GASTROCNEMIUS (LATERAL HEAD)
100 to 150 Units
Recommended: 1 injection site per muscle

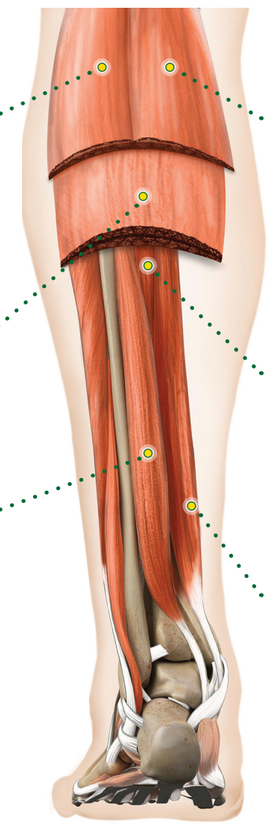
SOLEUS (HIDDEN)
330 to 500 Units
Recommended: 3 injection sites per muscle

FLEXOR HALLUCIS LONGUS
70 to 200 Units
Recommended: 1 injection site per muscle

GASTROCNEMIUS (MEDIAL HEAD)
100 to 150 Units
Recommended: 1 injection site per muscle

TIBIALIS POSTERIOR
200 to 300 Units
Recommended: 2 injection sites per muscle

FLEXOR DIGITORUM LONGUS
130 - 200 Units
Recommended: 1 to 2 injection sites per muscle



Superficial and deep muscles of the left lower leg (posterior view)

The potency units of Dysport are not interchangeable with other preparations of botulinum toxin products[1]

IN ADULT PATIENTS TREATED FOR BOTH UPPER AND LOWER LIMB SPASTICITY[1]:

If more than one limb is injected, the maximum recommended total dose per treatment session is 1500 Units. No more than 1 mL should generally be administered at any single injection site.[1]

When administering Dysport in adult spasticity, re-treatment should occur in intervals of no less than 12 weeks[1]

+ Recommended dose and frequency of administration should not be exceeded

Dosing should be tailored based on[1]:

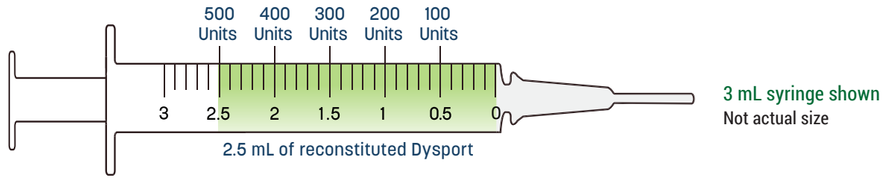
+ Size, number, and location of muscles involved
+ Severity of spasticity
+ Patient's response to previous treatment
+ Adverse event history with botulinum toxins
+ Presence of local muscle weakness

Preparation of Dysport solution for administration[1]:

+ 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:

Dysport 500-Unit vial → Reconstituted Dysport 2.5 mL → Final Concentration Dysport 0.1 mL=20 Units



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.
‡Diluent is sterile, preservative-free 0.9% Sodium Chloride Injection, USP. Dysport is given by intramuscular injection.

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.

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 Prescribing Information, including **BOXED WARNING**.

IPSEN Innovation for patient care

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

Dysport® (abobotulinumtoxinA)