

# PATIENT INJECTION RECORD: ADULT CERVICAL DYSTONIA<sup>1</sup>

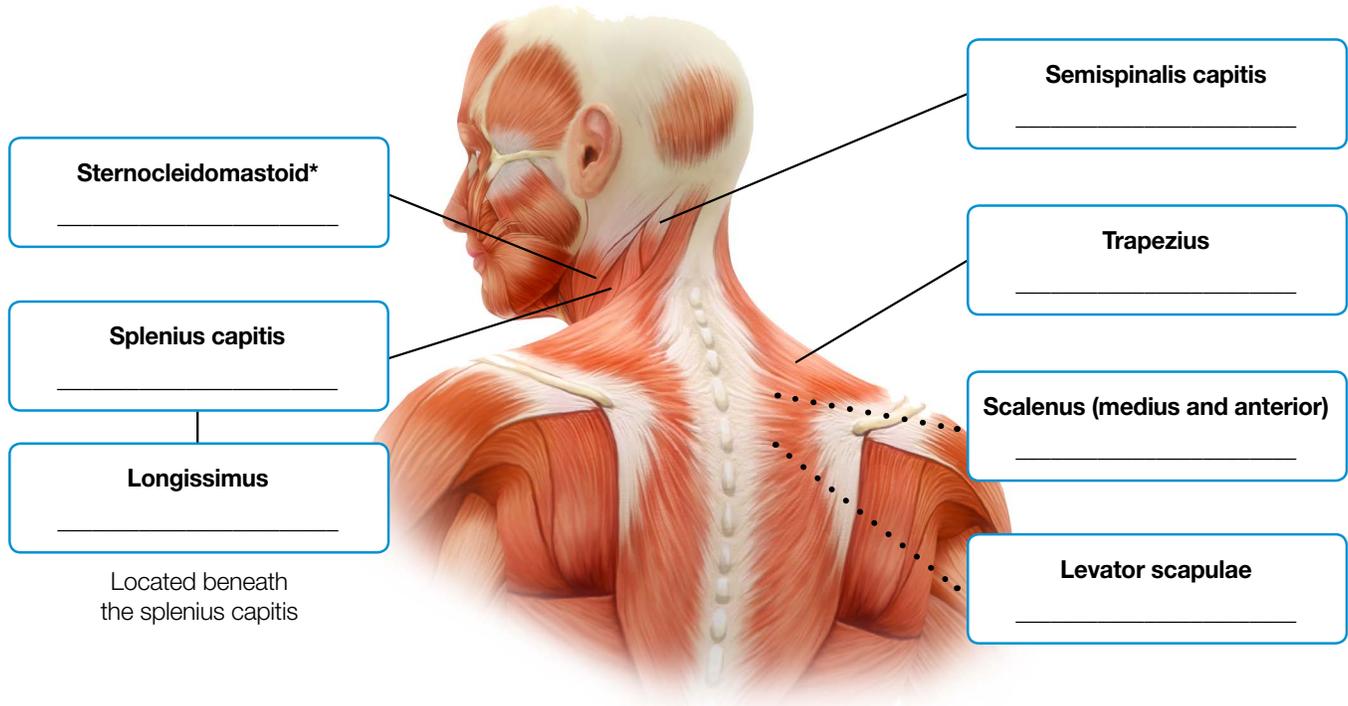
Patient: \_\_\_\_\_ Chart #: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_

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

## Dysport® Injection Tracker

Total Dose: \_\_\_\_\_ Units



\*Dosing considerations for the **sternocleidomastoid (SCM)**: Limiting the dose injected unilaterally into the SCM to 150 U or less may reduce the occurrence of dysphagia.<sup>2</sup>

## Indications

Dysport® (abobotulinumtoxinA) for injection is indicated for the treatment of:

- Spasticity in adult patients
- Adults with cervical dystonia

The safety and effectiveness of Dysport® injected into upper limb muscles or proximal muscles of the lower limb for the treatment of spasticity in pediatric patients has not been established.

Safety and effectiveness in pediatric patients with lower limb spasticity below 2 years of age have not been evaluated.

Safety and effectiveness in pediatric patients with cervical dystonia or upper limb spasticity have not been established.

## 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, including upper limb spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to lower than the maximum recommended total dose.

Please see additional Important Safety Information on next page, and [click here](#) for Full Prescribing Information, including **Boxed Warning** regarding distant spread of toxin effect.

*Additional record keeping information on next page.*

 **Dysport**<sup>®</sup>  
(abobotulinumtoxinA)

**What's your next move?**

## Was EMG guidance performed?

Yes  No Other method performed: \_\_\_\_\_

## Dysport® Product Tracking

Lot number	Expiration date

Additional notes: \_\_\_\_\_

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## Contraindications

Dysport® is contraindicated in patients with known hypersensitivity to any botulinum toxin preparation or to any of the components; or in the presence of infection at the proposed injection site(s); or in patients known to be allergic to cow's milk protein. Hypersensitivity reactions including anaphylaxis have been reported.

## 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 (see Boxed Warning). 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 (eg, 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.

### Adverse Reactions

Most common adverse reactions ( $\geq 2\%$  and greater than placebo in either Dysport® group) in adults with upper limb spasticity for Dysport® 500 Units, Dysport® 1000 Units, and Placebo, respectively, were: nasopharyngitis (4%, 1%, 1%), urinary tract infection (3%, 1%, 2%), muscular weakness (2%, 4%, 1%), musculoskeletal pain (3%, 2%, 2%), dizziness (3%, 1%, 1%), fall (2%, 3%, 2%), and depression (2%, 3%, 1%).

Most common adverse reactions ( $\geq 5\%$  and greater than placebo in either Dysport® group) in adults with lower limb spasticity for Dysport® 1000 Units, Dysport® 1500 Units, and Placebo, respectively, were: falls (9%, 6%, 3%), muscular weakness (2%, 7%, 3%), pain in extremity (6%, 6%, 2%). Muscular weakness was reported more frequently in women (10%) treated with 1500 units of Dysport® compared to men (5%).

Most common adverse reactions ( $\geq 5\%$  and greater than placebo) in adults with cervical dystonia for Dysport® 500 Units and Placebo, respectively, were: muscular weakness (16%, 4%), dysphagia (15%, 4%), dry mouth (13%, 7%), injection site discomfort (13%, 8%), fatigue (12%, 10%), headache (11%, 9%), musculoskeletal pain (7%, 3%), dysphonia (6%, 2%), injection site pain (5%, 4%), and eye disorders (7%, 2%).

### 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®.

### Pediatric Use

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.

### Use in Pregnancy

Based on animal data Dysport® may cause fetal harm. 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.

### 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% versus 6% and 4% versus 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](http://www.fda.gov/medwatch).

Please [click here](#) for Full Prescribing Information, including **Boxed Warning** regarding distant spread of toxin effect.

**References:** 1. Dysport® (abobotulinumtoxinA) [Prescribing Information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc; June 2017. 2. Hauser RA, Truong D, Hubble J, et al. AbobotulinumtoxinA (Dysport) dosing in cervical dystonia: an exploratory analysis of two large open-label extension studies. *J Neural Transm*. 2013;120(2):299-307; doi:10.1007/s00702-012-0872-1.



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

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What's your next move?