



In the treatment of adults  
with cervical dystonia

# Do you expect symptom relief to last **between** injections?

Start Dysport first-line for lasting symptom\* relief<sup>1</sup>:

- Dysport reduces the symptoms of abnormal head position and neck pain at week 4
- Dysport provided improvement in range of motion that lasted beyond the minimum retreatment time of 12 weeks
  - A majority of adults in the trial did not need another injection for 14-18 weeks

\*Symptoms of cervical dystonia include abnormal increase in muscle tone and muscle spasm.

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

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






*It's Time*

# Meet Janice: a real patient living with cervical dystonia

Janice, 50 years old



Individual results may vary. Janice is the only Dysport patient in this image.

-  Lives in Greenbrier, TN
-  Diagnosed with cervical dystonia at 30 years old
-  First experienced symptoms (unexplained left-to-right movement of head) while expecting her first child at 22 years old
-  Symptoms subsided until she was pregnant with her second child 6 years later
-  During her second pregnancy, she decided to look for answers and met with a neurologist

## IMPORTANT SAFETY INFORMATION

### 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.

# How Dysport made a difference

## My Cervical Dystonia Diagnosis

"[By the time I was diagnosed,] the symptoms had progressed to a very obvious uncontrollable [head] movement... back and neck pain.... [Being diagnosed] was a wonderful feeling, to have a name to go with my condition. I felt vindicated, in a sense."

## How This Disease Impacted Me

"I was a young woman with high expectations.... I felt robbed of having control."

## How Dysport Worked for Me

“ [Dysport] has lived up to my expectations... it has been a reliable, effective treatment—it's comforting to know that I can count on [it] to work for me. ”



Janice -  
a real Dysport patient living  
with cervical dystonia

## IMPORTANT SAFETY INFORMATION

### 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.





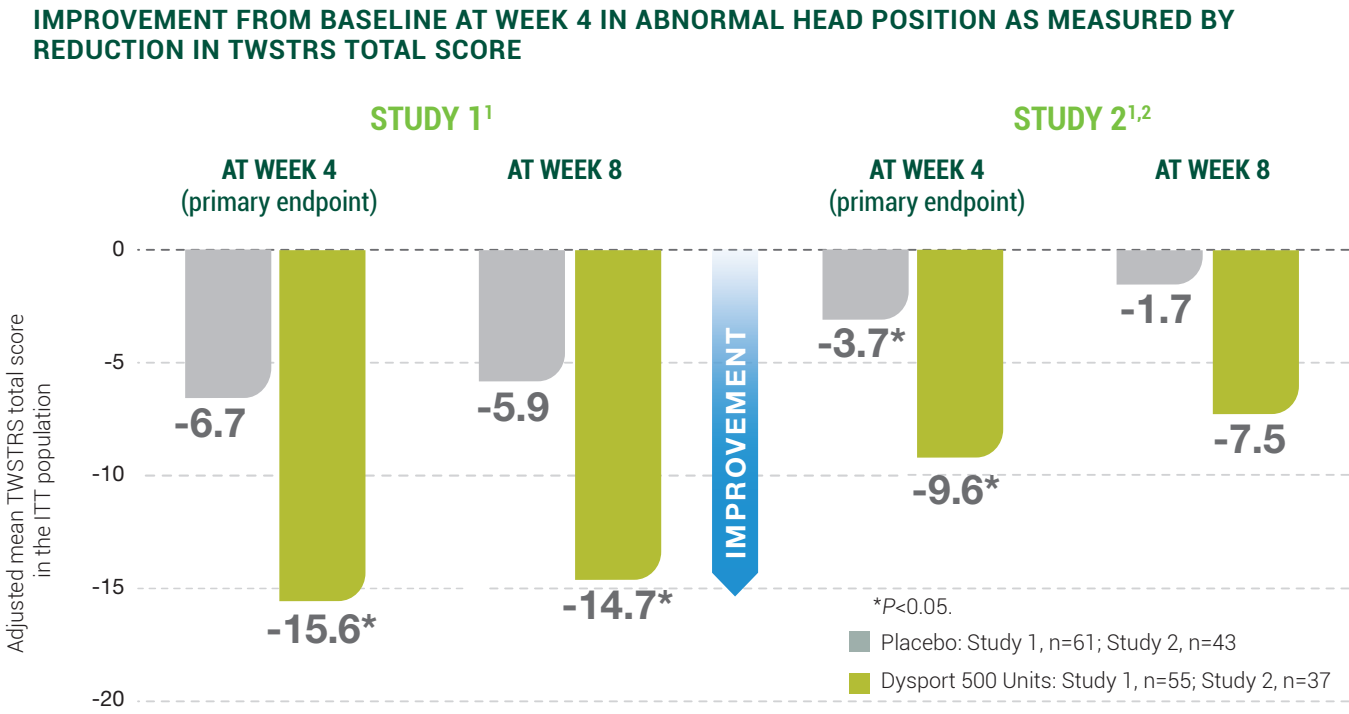
# Dysport significantly reduced abnormal head position at Week 4<sup>1,2</sup>

## CERVICAL DYSTONIA

# Dysport significantly reduced neck pain at Week 4<sup>2,3</sup>

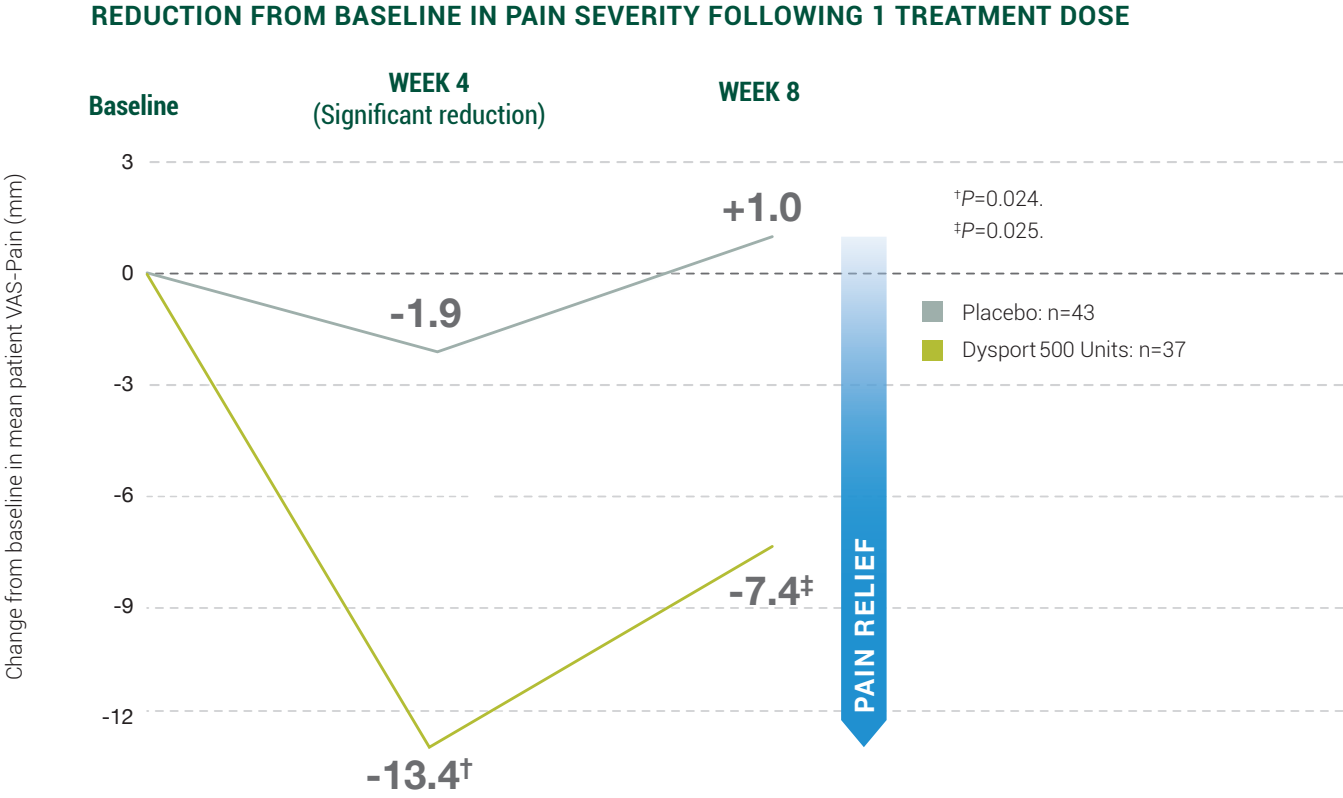


## CERVICAL DYSTONIA



**Study design:** The efficacy and safety of Dysport were evaluated in 2 randomized, double-blind, placebo-controlled, multicenter, parallel-group, single-dose studies with a 12-week follow-up in 252 patients with CD. Patients could switch to open-label extension studies. The primary endpoint was Total Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) change from baseline at Week 4 for both studies. TWSTRS total score (maximum: 85 points) is composed of 3 subscales (Severity, Disability, and Pain). The secondary endpoint was change in pain on visual analog scale (VAS) at Week 4. After a 1-week screening period, participants were randomly assigned treatment with Dysport 500 Units or placebo.<sup>1,3,4</sup>

ITT=intent to treat.



See prior page for study design. On a 100-point scale (0 [no symptoms] to 100 mm [worst possible symptoms]), baseline VAS score (patient self-rated) was 48.6 in the Dysport group and 52.9 in the placebo group. Secondary efficacy endpoint was change in patient VAS-Pain Scale at Week 4 compared with baseline.<sup>3</sup>

## IMPORTANT SAFETY INFORMATION

### 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 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.

## IMPORTANT SAFETY INFORMATION

### Warnings and Precautions (continued)

#### 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.

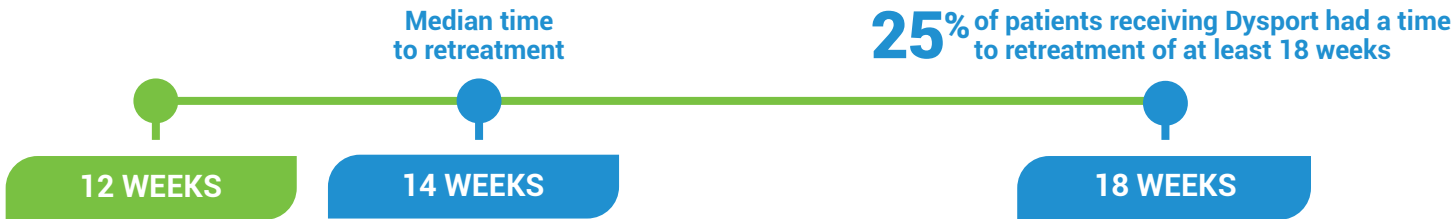
#### Human Albumin and Transmission of Viral Diseases

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.

# Dysport provided improvement in range of motion that lasted beyond the minimum retreatment time of 12 weeks

## CERVICAL DYSTONIA

### Time to retreatment<sup>1,2</sup>



- In the pivotal trials for adult CD, need for retreatment was determined by change in TWSTRS total score returning to within 10% of baseline
- The median time to retreatment was 14 weeks and 18 weeks for the 75th percentile
- Repeat Dysport treatment should be administered no sooner than 12 weeks after the previous injection

## IMPORTANT SAFETY INFORMATION

### Warnings and Precautions (continued)

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





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

**Adults with cervical dystonia** (≥5%): muscular weakness, dysphagia, dry mouth, injection site discomfort, fatigue, headache, musculoskeletal pain, dysphonia, injection site pain, and eye disorders.

# Recommended Dysport doses for adults with CD

## CERVICAL DYSTONIA

### Dysport has dosing recommendations for muscles in these key CD postures<sup>1\*</sup>

	Recommended Dose Range in Dysport Units <sup>1,3</sup>	
 <b>Torticollis</b>	Sternocleidomastoid (SCM) <sup>†</sup> .....	50      350
	Trapezius.....	50      300
	Scalenus (anterior) .....	50      300
 <b>Laterocollis</b>	Levator scapulae.....	50      200
	Trapezius.....	50      300
	Scalenus (medius/anterior).....	50      300
 <b>Anterocollis</b>	Sternocleidomastoid <sup>†</sup> .....	50      350
	Scalenus (medius/anterior) .....	50      300
 <b>Retrocollis</b>	Levator scapulae.....	50      200
	Trapezius.....	50      300
	Longissimus.....	100      200
	Splenius capitis.....	75      450
	Semispinalis capitis .....	50      250

<sup>\*</sup>Doses up to Dysport 1,000 Units (divided among affected muscles) were systemically evaluated. The recommended initial dose is Dysport 500 Units with titration in 250-unit steps according to the patient's response.  
<sup>†</sup>Median dose: Dysport 125 Units. Dosing considerations for the sternocleidomastoid: Limiting the dose injected unilaterally into the SCM to Dysport 150 Units or less may reduce the occurrence of dysphagia.  
No more than 1 mL should generally be administered at any single injection site.



The degree and pattern of muscle spasticity at the time of reinjection may necessitate alterations in the dose of Dysport and muscles to be injected<sup>1</sup>



To calculate the FDA-approved Dysport dose range for each patient, download the Dysport Dosing Calculator from the Apple App Store and Google Play store. This application is not intended to diagnose, treat, cure, or prevent any disease.

This tool allows you to

1. Select indication
  2. Select muscles
  3. Select an appropriate dose based on your clinical decision-making
4. Select dilution based on your clinical decision-making
  5. Choose type of vial and syringe based on options available
  6. Simulate syringe volume

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It's Time

# Adverse reactions as reported in patients receiving Dysport up to 500 Units

## CERVICAL DYSTONIA

Most common adverse reactions (≥5%) and greater than placebo in the pooled, double-blind phase of clinical trials<sup>1\*</sup>

Adverse Reactions	Dysport 500 Units (n=173), %	Placebo (n=182), %
Any adverse reaction	61	51
General disorders and administration site conditions		
Injection site discomfort	13	8
Fatigue	12	10
Injection site pain	5	4
Musculoskeletal and connective tissue disorders		
Muscular weakness	16	4
Musculoskeletal pain	7	3
Gastrointestinal disorders		
Dysphagia	15	4
Dry mouth	13	7
Nervous system disorders		
Headache	11	9
Respiratory, thoracic, and mediastinal disorders		
Dysphonia	6	2
Eye disorders <sup>†</sup>	7	2

<sup>\*</sup>Data from a single treatment cycle of Dysport 500 Units for adults with CD.  
<sup>†</sup>The following preferred terms were reported: vision blurred, diplopia, visual acuity reduced, eye pain, eyelid disorder, accommodation disorder, dry eye, eye pruritus.  
To reduce the recurrence of dysphagia, limit the dose injected unilaterally into the sternocleidomastoid (SCM) to 150 Units or less. Use of simultaneous EMG-guided application of Dysport may be helpful in locating these active muscles.

## IMPORTANT SAFETY INFORMATION

### Drug Interactions

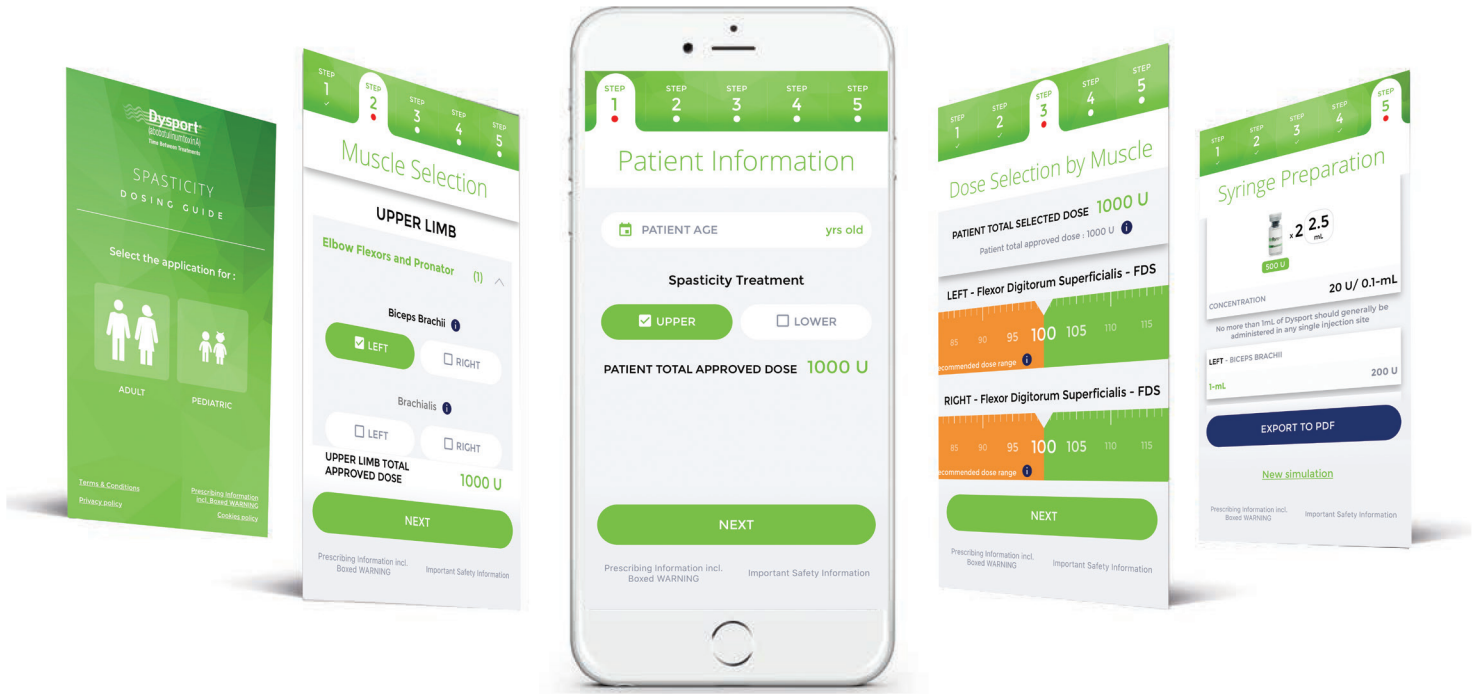
Co-administration of Dysport and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents), or muscle relaxants, should be observed closely because the effect of botulinum toxin may be potentiated. Use of anticholinergic drugs after administration of Dysport 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.


# The Dysport dosing app may make calculating the FDA-approved dose easier




This app is not intended to diagnose, treat, or cure any disease. Consult the Terms and Conditions prior to use.



Available for adult spasticity and pediatric spasticity indications



Calculates dose per muscle



Simulates syringe preparation

This dosing tool for US healthcare professionals allows you to select the condition you're treating, then input patient information. Next, select the muscles you're treating, and then the recommended dose per muscle. The app will populate with vial selection and syringe preparation.

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## IMPORTANT SAFETY INFORMATION

### Special Populations (continued)

#### 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).





# Choose Dysport first line for symptom relief that lasts between injections

## In adult CD

- Significantly reduced abnormal head position vs placebo at Week 4 ( $P \leq 0.05$ )<sup>1,3</sup>
- Significantly relieved neck pain vs placebo at Week 4 ( $P \leq 0.05$ )<sup>1,3</sup>
- Most common adverse reactions ( $\geq 5\%$  and greater than placebo) for Dysport 500 Units and placebo were: muscular weakness, dysphagia, dry mouth, injection site discomfort, fatigue, headache, musculoskeletal pain, dysphonia, injection site pain, and eye disorders<sup>1,3</sup>
- Provided improvement in range of motion that lasted beyond the minimum retreatment time of 12 weeks, with a majority of patients not needing another injection for 14 to 18 weeks.<sup>1</sup>



**D** To calculate the FDA-approved dose range for your patient, download the Dysport Dosing Guide at the Apple App Store or Google Play store.

## Eligible\* patients can pay as little as \$0 per prescription.

- Program exhausts after 4 injection treatments, or a maximum annual copay benefit of \$5,000, whichever comes first
- Program resets every January 1st
- Patients must enroll every 12 months from the date of acceptance to remain eligible to receive a continued benefit

Visit [www.ipsencares.com](http://www.ipsencares.com) for more information.

\*Visit [www.ipsencares.com](http://www.ipsencares.com) for eligibility terms and conditions and additional copay information.

**IPSEN CARES**  
Coverage, Access, Reimbursement & Education Support

**\$0** As little as  
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## IMPORTANT SAFETY INFORMATION

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Please see Important Safety Information throughout and accompanying full Prescribing Information, including **Boxed Warning** and Medication Guide.

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).

**References:** 1. Dysport® (abobotulinumtoxinA) [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; July 2020. 2. Data on file. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. 3. Truong D, Duane DD, Jankovic J, et al. Efficacy and safety of botulinum type A toxin (Dysport) in cervical dystonia: results of the first US randomized, double-blind, placebo-controlled study. *Mov Disord.* 2005;20(7):783-791. 4. Truong D, Brodsky M, Lew M, et al. Long-term efficacy and safety of botulinum toxin type A (Dysport) in cervical dystonia. *Parkinsonism Relat Disord.* 2010;16(5):316-323.



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

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**Dysport®**  
(abobotulinumtoxinA)

**It's Time**