What if...

...your patients could have a treatment that may complement the therapy you provide?[1]

LEARN ABOUT A THERAPY OPTION FOR ADULTS WITH SPASTICITY

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 pages 10-11 and Full Prescribing Information, including **Boxed Warning** and Medication Guide.

Dysport®
(abobotulinumtoxinA)

The basics of spasticity

As a movement disorder specialist, you likely encounter many patients in your practice with spasticity, a condition in which muscles have an abnormal increase in tone. This can lead to abnormal limb positions and prevent normal limb movement.

Spasticity occurs when motor neurons in the brain or spinal cord are damaged. In the majority of cases, it is caused by a neurological condition or an external trauma.[2]

THE MOST COMMON ETIOLOGICAL CAUSES ARE[1,2]:

// Stroke
// Traumatic brain or spinal cord injury
// Multiple sclerosis
// Cerebral palsy

YOUR PATIENTS WITH SPASTICITY MAY HAVE STIFFNESS AND SPASMS in their arms (upper limb spasticity, or ULS), legs (lower limb spasticity, or LLS), or both. In most cases, spasticity limits or prevents them from performing activities of daily living.[2]

Finding the right treatment plan may help your patients reach their therapy goals.

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.

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 pages 10-11 and Full Prescribing Information, including **Boxed Warning** and Medication Guide.

How a botulinum toxin may help

As you know, physical or occupational therapy (PT/OT) can be an important part of the treatment regimen for patients with spasticity. Sometimes, patients receive oral medications along with PT/OT to help manage their condition.[1]

However, some patients do not receive sufficient symptom relief from these forms of therapy alone. In those cases, a specialist may prescribe botulinum neurotoxin injections, also known as botulinum toxin, or simply, a toxin.[1,2]

ADMINISTRATION

Toxins are given by a trained injector to improve muscle tone and help reduce stiffness and spasms[2]

HOW THEY WORK

Toxins inhibit the release of the neurotransmitter acetylcholine at the neuromuscular junction that is responsible for muscle contractions[2]

TIMEFRAME

Injections are typically administered approximately every 3 months in the affected muscles[2]

Patients may receive a different botulinum toxin even if they have been treated with a toxin in the past.[3]

Take a closer look: To learn about Dysport® and how it was shown to relieve symptoms, turn to page 6.

IMPORTANT SAFETY INFORMATION

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.

Dysport® (abobotulinumtoxinA)

The impact of spasticity

A botulinum toxin may not be right for everyone. But there may be patients in your practice who may benefit from this type of therapy. In fact, the American Academy of Neurology recommends a toxin as first-line treatment for focal spasticity—yet less than 5% of eligible patients receive it.[4,5]

To identify candidates who may be appropriate for referral for Dysport® injections, consider these example cases.

PATRICIA // AGE 45
Educator and mother of 2

Hypothetical patient and case study.

MEDICAL HISTORY

Diagnosed with multiple sclerosis 3 years ago; developed spasticity in her legs.

// Has increased plantar flexion and ankle inversion
// Experiences spasms throughout the day, often accompanied by curling of toes
// Has been receiving physical therapy 3 times a week for the past 6 months
// Takes oral medication to manage pain/symptoms

CURRENT CHALLENGES

// Spasms impede mobility, balance, and other physical functions
// Muscle tone increases and curling of toes worsens as she walks, resulting in short step lengths
// Uses a single point cane; often needs assistance from family members for mobility

TREATMENT GOAL: Reduce ankle plantar flexion/inversion and as well as toe flexion with ambulation

Patients like Patricia and Ralph may be appropriate candidates to refer to a trained toxin injector.

RALPH // AGE 59
General contractor (part time)

Hypothetical patient and case study.

MEDICAL HISTORY

Right intracerebral hemorrhage 2 years ago.

// Left spastic hemiparesis affected his dominant arm
// Reports tightness at his elbow, wrist, and fingers, which causes a posture of flexion at the elbow and fisting of his hand
// Tried an oral medication, but discontinued it due to daytime drowsiness
// Has been receiving outpatient physical and occupational therapy, which improves his symptoms slightly

CURRENT CHALLENGES

// Elbow flexes when he walks
// Can hold items in his left hand, but has difficulty letting go
// Needs help placing his clenched hand through a sleeve

TREATMENT GOAL: Reducing hypertonicity of affected left elbow, wrist, and finger flexors

Searching for a Dysport injector for referral? Use our Injector Locator to help your patients find one in your area at DysportHCP.com/FindInjector.

See the last page of this brochure for more details.

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.

Please see additional Important Safety Information on pages 10-11 and Full Prescribing Information, including **Boxed Warning** and Medication Guide.

IMPORTANT SAFETY INFORMATION

Human Albumin and Transmission of Viral Diseases

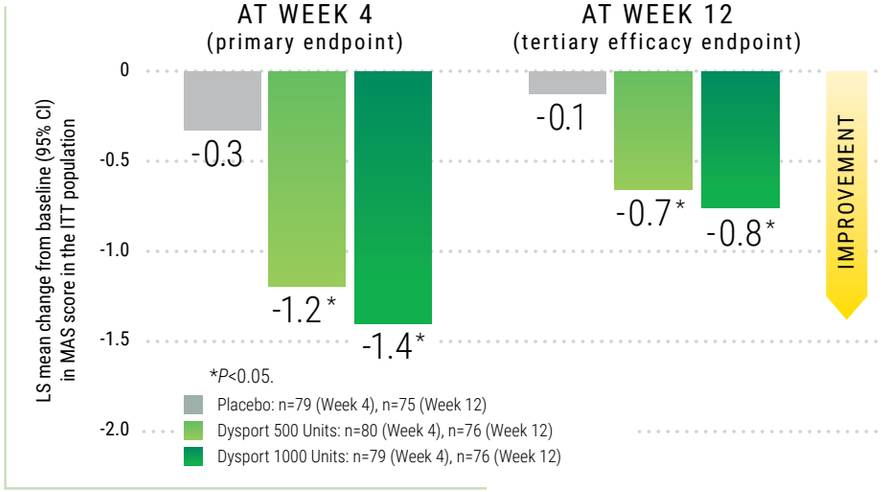
This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob 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® (abobotulinumtoxinA)

Why Dysport®?

A trained injector can help your patients determine if toxin treatment is appropriate. One option an injector may consider is Dysport (pronounced DIS-port), an FDA-approved prescription medication indicated for both adult ULS and adult LLS.[1]

In a clinical trial for adult ULS, patients treated with Dysport 500 Units and Dysport 1000 Units achieved a significant reduction in muscle tone at Week 4[1,6]



Study Design: The efficacy and safety of Dysport were evaluated in a randomized, multicenter, double-blind, placebo-controlled study in 238 adults with upper limb spasticity. The co-primary efficacy endpoints were mean change in Modified Ashworth Scale (MAS) score in the PTMG (elbow, wrist, or finger flexors) and Physician's Global Assessment (PGA) of response to treatment between baseline and week 4. MAS score at baseline (mean [SD]): placebo, 3.9 (±0.4); Dysport 500 Units, 3.9 (±0.5); Dysport 1000 Units, 3.9 (±0.4). Follow-up assessments occurred at weeks 1, 4, and 12; follow-up visits were also permitted at weeks 16, 20, and 24 as needed for retreatment. After 3 months of on-study treatment, patients were given the opportunity to continue open-label treatment with Dysport for up to 5 additional treatment cycles.[1,6]

Symptom relief that lasts between injections[1,6]

// Retreatment was between 12 and 16 weeks for **83%** of patients; however, some had a longer duration of response

// Time to retreatment was not the primary endpoint

IMPORTANT SAFETY INFORMATION

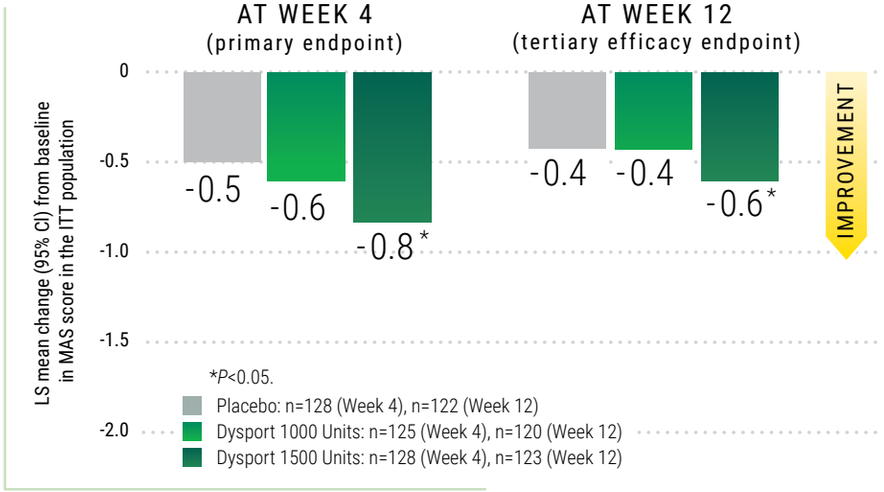
Warnings and Precautions (continued)

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.

Please see additional Important Safety Information on pages 10-11 and Full Prescribing Information, including **Boxed Warning** and Medication Guide.

In a clinical trial for adult LLS, patients treated with Dysport 1500 Units achieved a significant reduction in muscle tone at Week 4[1,6]



Study Design: The efficacy of Dysport was evaluated in a randomized, multicenter, double-blind, placebo-controlled study in 381 adults with lower limb spasticity. The primary efficacy endpoint was muscle tone assessed by LS mean change from baseline in Modified Ashworth Scale (MAS) score at the affected ankle joint at week 4. MAS score at baseline (mean [SD]): placebo, 3.9 (±0.5); Dysport 1000 Units, 3.8 (±0.5), Dysport 1500 Units, 3.7 (±0.5). Follow-up assessments occurred at weeks 1, 4, and 12; follow-up visits were also permitted at weeks 16, 20, and 24 as needed for retreatment. After 3 months of on-study treatment, patients were given the opportunity to continue open-label treatment with Dysport.[1,6]

Symptom relief that lasts between injections[1,6]

// Retreatment was between 12 and 16 weeks for **90%** of patients; however, some had a longer duration of response

// Time to retreatment was not the primary endpoint.

LS=least squares; SD=standard deviation.

IMPORTANT SAFETY INFORMATION

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.

Dysport® (abobotulinumtoxinA)

Safety of Dysport®

Dysport has a demonstrated, well-studied safety profile across indications.

Safety results in 391 adult patients with upper limb spasticity receiving Dysport up to 1000 Units.[1]

Adverse reactions observed in ≥2% of adults with ULS and reported more frequently than with placebo[1*]

Adverse Reactions	Dysport 500 Units (n=197), %	Dysport 1000 Units (n=194), %	Placebo (n=279), %
Infections and infestations			
Influenza	1	2	1
Infection	1	2	1
Musculoskeletal and connective tissue disorders			
Muscular weakness	2	4	1
Pain in extremity	0	2	1
Back pain	1	2	1
Nervous system disorders			
Headache	1	2	1
Convulsion	2	2	1
Syncope	1	2	0
Hypesthesia	0	2	<1
Partial seizures	0	2	0
General disorders and administration site conditions			
Fatigue	2	2	0
Asthenia	2	1	<1
Injury, poisoning, and procedural complications			
Fall	2	3	2
Injury	2	2	1
Contusion	1	2	<1
Gastrointestinal disorders			
Diarrhea	1	2	<1
Constipation	0	2	1
Investigation			
Blood triglycerides increased	2	1	0
Respiratory, thoracic, and mediastinal disorders			
Cough	1	2	1
Vascular disorders			
Hypertension	1	2	<1
Psychiatric disorders			
Depression	2	3	1

*Data from pooled, double-blind trials of adults with ULS.

If you would like to learn more about Dysport for the treatment of spasticity, please visit DysportHCP.com/PTOT

Please see additional Important Safety Information on pages 10-11 and Full Prescribing Information, including **Boxed Warning** and Medication Guide.

Safety results in 255 adult patients with lower limb spasticity receiving Dysport up to 1500 Units.[1]

Adverse reactions observed in ≥2% of adults with LLS and reported more frequently than with placebo[1†]

Adverse Reactions	Dysport 1000 Units (n=127), %	Dysport 1500 Units (n=128), %	Placebo (n=130), %
Musculoskeletal and connective tissue disorders			
Muscular weakness	2	7	3
Pain in extremity	6	6	2
Arthralgia	4	2	1
Injury, poisoning, and procedural complications			
Fall	9	6	3
Nervous system disorders			
Headache	0	3	1
General disorders and administration site conditions			
Fatigue	1	4	0
Influenza-like illness	2	0	0
Edema peripheral	2	0	0
Investigations			
Alanine aminotransferase increased	2	0	1
Gastrointestinal disorders			
Constipation	0	2	1
Psychiatric disorders			
Depression	2	3	0
Insomnia	0	2	0

†Data from a double-blind trial of adults with LLS.

IMPORTANT SAFETY INFORMATION

Most Common Adverse Reactions (continued)

Adults with cervical dystonia (≥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.

Dysport® (abobotulinumtoxinA)

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, 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.

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 (≥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.

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 Full Prescribing Information, including **Boxed Warning** and Medication Guide.

Dysport® (abobotulinumtoxinA)

Find a Dysport® injector

Your patient may already have a physician who treats their spasticity. However, not all physicians are trained to administer botulinum toxin injections.

If you think your patients may benefit from having a trained Dysport injector on their care team to complement the therapy you provide, you can use our Injector Locator to help them find one in your area.

SCAN HERE OR VISIT
DysportHCP.com/FindInjector

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 pages 10-11 and Full Prescribing Information, including **Boxed Warning** and Medication Guide.

References: 1. Dysport® (abobotulinumtoxinA) [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; July 2020. **2.** American Association of Neurological Surgeons. Spasticity. https://www.aans.org/Patients/Neurosurgical-Conditions-and-Treatments/Spasticity. Accessed March 10, 2022. **3.** Gracies JM, Brashear A, Jech R, et al. Safety and efficacy of abobotulinumtoxinA for hemiparesis in adults with upper limb spasticity after stroke or traumatic brain injury: a double-blind randomised controlled trial. *Lancet Neurol*. 2015;14(10):992-1001. **4.** American Academy of Neurology. Practice guideline update summary: botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. https://www.aan.com/guidelines/home/getguidelinecontent/737. Accessed March 10, 2022. **5.** de Pierrefeu A, Lamontagne A, Darhi Y. Analysis of US commercial claims to understand patient treatment pathways in spasticity. Presented at: International Society of Physical and Rehabilitation Medicine Virtual Meeting; June 12–15, 2021. Accessed March 10, 2022. **6.** Data on file. Ipsen Biopharmaceuticals, Inc. Cambridge, MA.

IPSEN
Innovation for patient care

June 2022 DYS-US-007427

Dysport®
(abobotulinumtoxinA)