In the treatment of adults with spasticity

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

Start Dysport first-line for lasting symptom* relief[1]

In some patients, results with Dysport lasted beyond the minimum retreatment time of 12 weeks

- In clinical trials, Dysport was proven effective at reducing muscle tone at Week 4 as assessed by the Modified Ashworth Scale (MAS) and Physician's Global Assessment (PGA)
- A majority of patients were retreated between 12 and 16 weeks; however, some patients had a longer duration of response

*Symptoms of spasticity include abnormal increase in muscle tone.

INDICATIONS

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

- Lower and upper limb spasticity in adults
- Lower limb spasticity in pediatric patients 2 years of age and older
- Upper limb spasticity in pediatric patients 2 years of age and older, excluding spasticity caused by cerebral palsy
- 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.

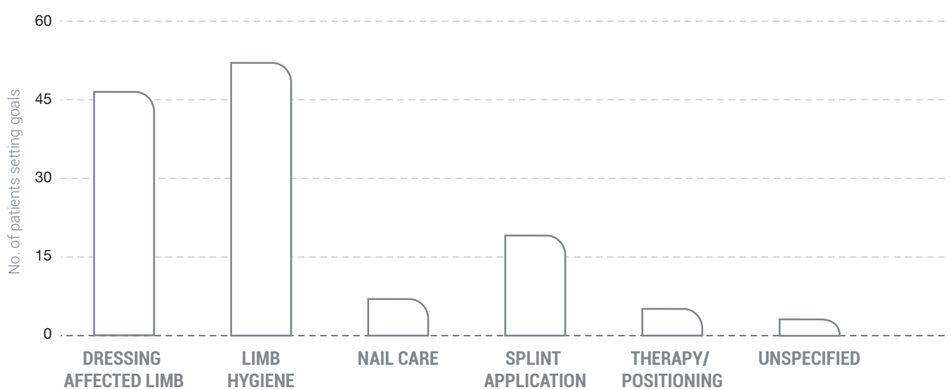
Please see accompanying full Prescribing Information, including **Boxed Warning** and Medication Guide.

Dysport®
(abobotulinumtoxinA)

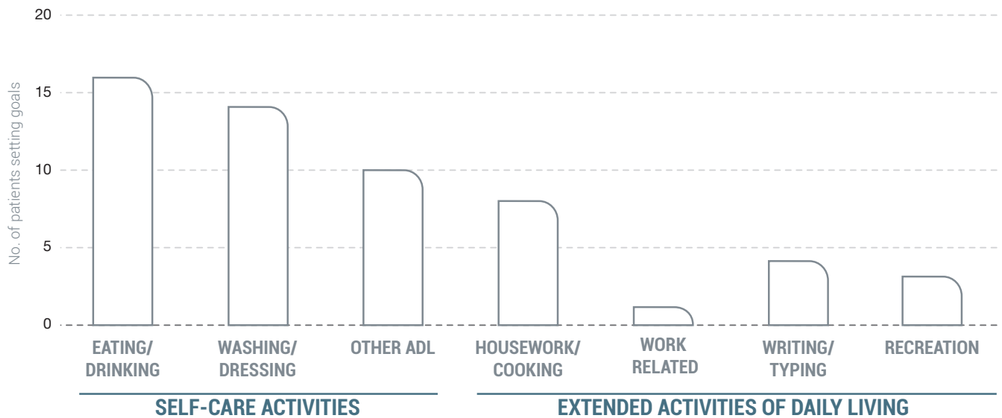
It's Time

Patients listed a number of passive and active goals of treatment in an observational study of adult patients with upper limb spasticity[2]

PASSIVE FUNCTION PRIMARY GOAL CATEGORY[2]



ACTIVE FUNCTION PRIMARY GOAL CATEGORY[3]



ADL=activities of daily living; ULIS-II=Upper Limb International Spasticity Study-II.

The ULIS-II program was a large, international, observational cohort study, conducted across 84 centers in 22 countries. The primary objective was to assess responder rates, as defined by the achievement of the primary person-centered goal using Goal Attainment Score (GAS), and to establish a consistent and reproducible approach to the recording of goals and goal attainment, as measured by GAS. Data are from the ULIS-II observational study of patients with adult upper limb spasticity (n=456).[2]

Many patients treated with BoNT-A report a response of less than 3 months[3]

RESULTS FROM A GLOBAL INTERNET-BASED SURVEY OF 281 PEOPLE FROM 29 COUNTRIES[3]

1 in 4 patients living with spasticity (24%) reported a duration of response less than 3 months[3]

Data from a global internet-based survey (Living With Spasticity Patient Survey) collected over 13 months from 281 people and 29 countries treated with botulinum toxins. The structure and contents of the survey were designed in collaboration with World Federation for NeuroRehabilitation (WFNR). The survey was designed to be self-completed by the patients. The questions were multichoice, and 17 included a free entry format as one of the options. Survey responses were anonymous. People with spasticity were encouraged to participate in the survey by their treating healthcare professional (HCP). Other than having a diagnosis of spasticity, there were no formal inclusion or exclusion criteria for participating in this survey.[3]

Wear-off of treatment benefits can impact patient satisfaction[4]

At the time of peak effect of therapy (3.7 weeks), 98% of spasticity patients had some degree of satisfaction with their response (n=43/44)

36% of spasticity patients were “not at all satisfied” just before their next injection (n=16/44)

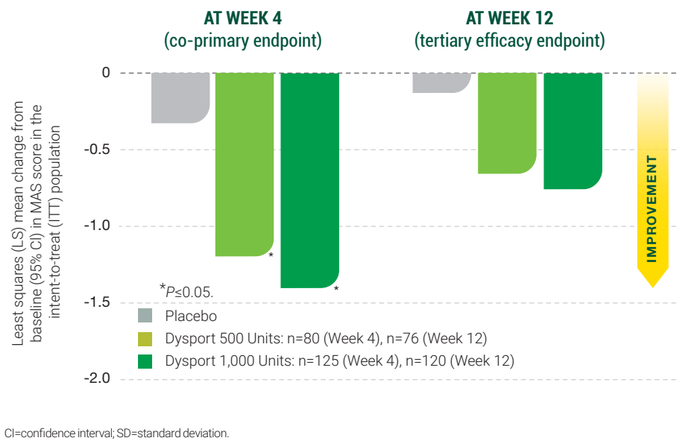
Data from 2 cross-sectional surveys conducted in Canada, France, Germany, and the US. The patient survey included patients with post-stroke spasticity who had undergone at least 2 botulinum toxin A injection cycles. Information on patients’ current and prior botulinum toxin treatment cycles and quality of life was collected. The physician survey included physicians treating post-stroke spasticity with botulinum toxins and collected information regarding physician satisfaction with botulinum toxin treatment for post-stroke spasticity. Effect of individual BoNT-A formulations not reported. Patients surveyed were receiving a range of BoNT-As. Re-treatment with a BoNT-A should not occur before 12 weeks.[4]

BoNT-A=botulinum toxin type A.

Muscle tone reduction

UPPER LIMB SPASTICITY

Patients treated with Dysport 500 Units and Dysport 1,000 Units achieved a significant reduction in muscle tone at Week 4[1,5]



Study design: The efficacy and safety of Dysport were evaluated in a randomized, multicenter, double-blind, placebo-controlled study of 238 adults with ULS. The co-primary efficacy endpoints were mean change in MAS score in the primary target muscle group (PTMG) (elbow, wrist, and finger flexors) and Physician's Global Assessment (PGA) of response to treatment between baseline and Week 4. The secondary endpoint was the effect of Dysport on passive function as measured by Disability Assessment Scale (DAS). The tertiary endpoints include upper limb passive and active function, active range of motion against the PTMG, and quality of life. MAS score at baseline (mean [SD]): placebo, 3.9 (0.4); Dysport 500 Units, 3.9 (0.5); Dysport 1,000 Units, 3.9 (0.4). Follow-up assessments occurred at Weeks 1, 4, and 12; visits were also permitted at Weeks 16, 20, and 24, as needed for retreatment.[1,5]

CI=confidence interval; SD=standard deviation.

Patients treated with Dysport achieved significant improvement (*P*<0.05) at Week 4 as assessed by the PGA[1]

- Dysport 1,000 Units: 1.8 score
- Dysport 500 Units: 1.4 score
- Placebo: 0.7 score

Open-label phase

- In the open-label extension, the primary endpoint was long-term safety. Please see results on page 12[5,6]
- In an open-label extension study, reduction in MAS was observed over multiple injection cycles in doses up to Dysport 1,000 Units[5,6]
  - Change from baseline MAS at Week 4 in cycles 1 (-1.4), 2 (-1.6), 3 (-1.5), and 4 (-1.4)

Study design: After 3 months of on-study treatment, 258 patients continued open-label treatment with Dysport for up to 5 additional treatment cycles. The primary endpoint of the open-label extension was safety of repeated treatment cycles over 1 year. The secondary endpoint was efficacy of repeated injections over 1 year on muscle tone, determined by: MAS, passive and active range of motion (X_{v1}, X_{v2}), angle of catch (X_{v3}), DAS score, Modified Frenchay Scale (MFS) score, and PGA score. Reduction in MAS was observed over multiple injection cycles in doses up to Dysport 1,000 Units. Change from baseline MAS at Week 4 in cycles 1 (-1.4), 2 (-1.6), 3 (-1.5), and 4 (-1.4).[5,6]

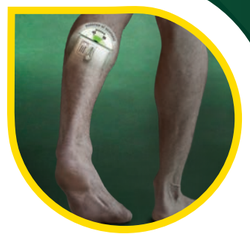
IMPORTANT SAFETY INFORMATION

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.

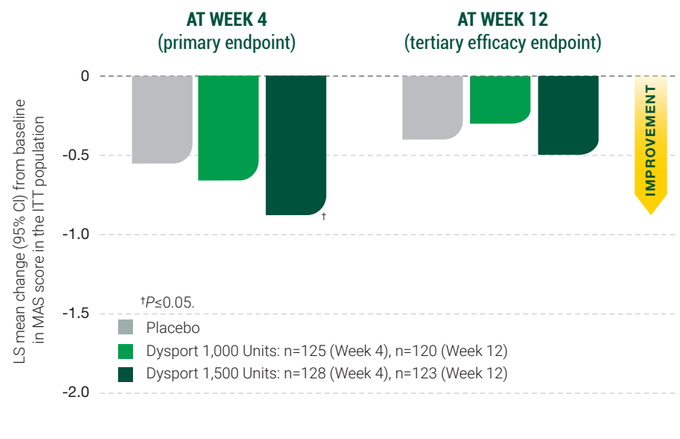
Please see accompanying full Prescribing Information, including **Boxed Warning** and Medication Guide.

Muscle tone reduction



LOWER LIMB SPASTICITY

Patients treated with Dysport 1,500 Units achieved a significant reduction in muscle tone at Week 4[1,5]



Study design: The efficacy and safety of Dysport was evaluated in a randomized, multicenter, double-blind, placebo-controlled study in 381 adults with LLS. The primary efficacy endpoint was muscle tone assessed by LS mean change from baseline in MAS score at the affected ankle joint at Week 4. The co-secondary endpoints were the PGA of treatment response at Week 4 and improvement in comfortable barefoot walking speed without walking aids at Week 4. The tertiary endpoints were impact on walking speed, scale of pain intensity, quality of life, as well as changes in MAS scores from baseline in the gastrocnemius-soleus complex (GSC) (knee extended) at additional time points. MAS score at baseline (mean [SD]): placebo, 3.9 (0.5); Dysport 1,000 Units, 3.8 (0.5); Dysport 1,500 Units, 3.7 (0.5). Follow-up assessments occurred at Weeks 1, 4, and 12; visits were also permitted at Weeks 16, 20, and 24 as needed for retreatment.[1,5]

Although the Week 12 analyses for both ULS and LLS were prespecified, being tertiary endpoints, appropriate multiplicity adjustments were not applied; therefore, the results need cautious interpretation and could represent chance findings.

Open-label phase

- In the open-label extension, the primary endpoint was long-term safety. Please see results on page 13[5,7]
- In an open-label extension study in LLS, reduction in MAS was observed over multiple injection cycle in doses up to Dysport 1,500 Units[5,7]
  - Change from baseline MAS at Week 4 in cycles 1 (-0.7), 2 (-1.2), 3 (-0.9), and 4 (-1.0)

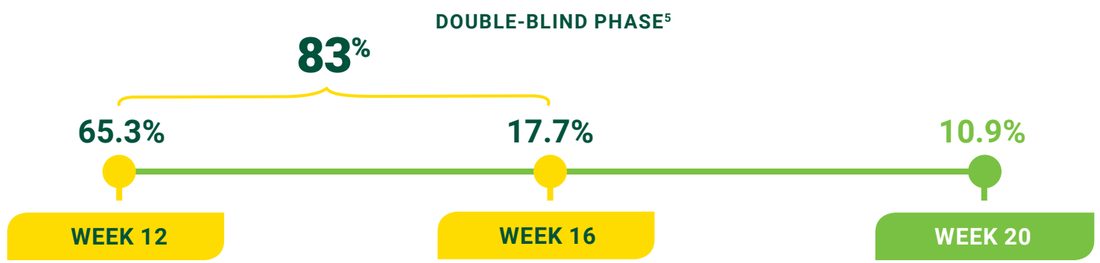
Study design: After 3 months of on-study treatment, 352 patients continued open-label treatment with Dysport for up to 5 additional treatment cycles. Safety of repeated treatment cycles over 1 year was the open-label primary endpoint. The secondary efficacy endpoint was the effect of Dysport on MAS in the GSC, PGA, comfortable barefoot walking speed, and pain (exploratory endpoint). Reduction in MAS was observed over multiple injection cycles in doses up to Dysport 1,500 Units. Change from baseline MAS at Week 4 in cycles 1 (-0.7), 2 (-1.2), 3 (-0.9), and 4 (-1.0).[5,7]

Dysport® (abobotulinumtoxinA) It's Time

Time to retreatment

UPPER LIMB SPASTICITY

Retreatment was between 12 and 16 weeks for 83% of patients; however, some patients had a longer duration of response[1,5]



OPEN-LABEL PHASE[6]

Across open-label cycles, a significant proportion of patients did not require reinjection until Week 16 or later

At the end of Injection Cycle 2:

35% were reinjected at Week 16 or later

At the end of Injection Cycle 3:

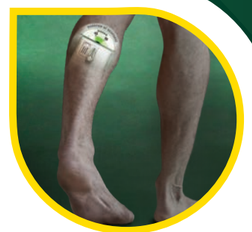
24% were reinjected at Week 16 or later

Retreatment criteria for ULS and LLS[5]

- Time to retreatment was not the primary endpoint
- In the pivotal trials for adult spasticity, need for retreatment was determined by:
  - No longer demonstrating a decrease from baseline of ≥1 grade in MAS score in the primary targeted muscle group *and*
  - No improvement in PGA (ie, a score ≤0) *and*
  - No signs of unacceptable safety risk for the next treatment cycle
- Investigator discretion (based on efficacy and safety criteria) determined the need for retreatment for patients demonstrating a decrease from baseline of ≥1 grade in MAS score and/or improvement in PGA (ie, a score ≥1)
- Repeat Dysport treatment should be administered no sooner than 12 weeks after the previous injection

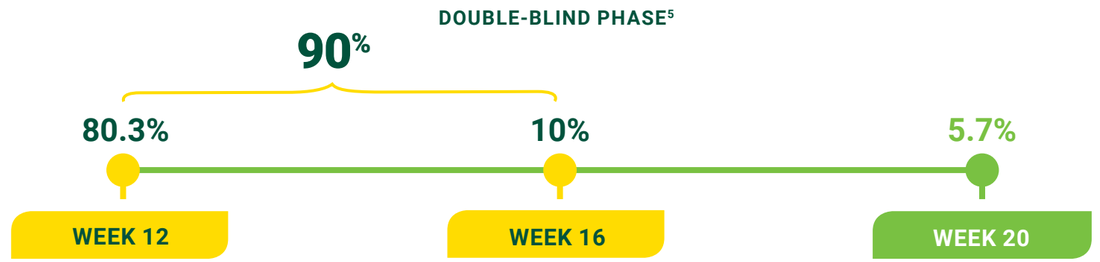
Please see accompanying full Prescribing Information, including **Boxed Warning** and Medication Guide.

Time to retreatment



LOWER LIMB SPASTICITY

Retreatment was between 12 and 16 weeks for 90% of patients; however, some patients had a longer duration of response[1,5]



OPEN-LABEL PHASE[7]

Across open-label cycles, a significant proportion of patients did not require reinjection until Week 16 or later

At the end of Injection Cycle 1:

20% were reinjected at Week 16 or later

At the end of Injection Cycle 2:

32% were reinjected at Week 16 or later

At the end of Injection Cycle 3:

15% were reinjected at Week 16 or later

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® (abobotulinumtoxinA) *It's Time*

Functional analyses measured in a placebo-controlled clinical trial

UPPER LIMB SPASTICITY

Overall DAS score change from baseline was a secondary endpoint of the study. The difference between Dysport and placebo in overall DAS score was not statistically significant[5]

Response within each DAS domain was a tertiary endpoint (data shown below)

Hygiene:
- Measured at Week 4: 34% of adults receiving Dysport 500 Units and 33% of adults receiving Dysport 1,000 Units vs 20% for placebo*
- Measured at Week 12: 30% of adults receiving Dysport 500 Units and 37% of adults receiving Dysport 1,000 Units vs 11% for placebo*

Dressing:
- Measured at Week 4: 30% of adults receiving Dysport 500 Units and 35% of adults receiving Dysport 1,000 Units vs 24% for placebo*
- Measured at Week 12: 29% of adults receiving Dysport 500 Units and 37% of adults receiving Dysport 1,000 Units vs 18% for placebo*

Pain:
- Measured at Week 4: 18% of adults receiving Dysport 500 Units and 17% of adults receiving Dysport 1,000 Units vs 9% for placebo*
- Measured at Week 12: 16% of adults receiving Dysport 500 Units and 17% of adults receiving Dysport 1,000 Units vs 11% for placebo*

Limb position:
- Measured at Week 4: 36% of adults receiving Dysport 500 Units and 50% of adults receiving Dysport 1,000 Units vs 29% for placebo*
- Measured at Week 12: 25% of adults receiving Dysport 500 Units and 46% of adults receiving Dysport 1,000 Units vs 25% for placebo*

*Changes in DAS score for the primary principle target of treatment (PTT) between baseline and Week 4 was an additional secondary endpoint. At baseline, the subject and investigator together selected 1 of the 4 DAS domains as the PTT.

IMPORTANT SAFETY INFORMATION

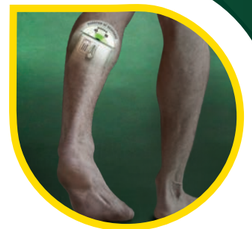
Warnings and Precautions (continued)

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.

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

Functional analyses measured in a placebo-controlled clinical trial



LOWER LIMB SPASTICITY

Single treatment with Dysport measuring GSC, walking speed, and pain[5]

Spasticity in the GSC (tertiary endpoint):
Change from baseline in the Tardieu scale was used to measure improvements in

- Angle of arrest:
  - Measured at Week 4: Dysport 1,000 Units 0.7 and Dysport 1,500 Units 1.4 vs 1.3 for placebo
  - Measured at Week 12: Dysport 1,000 Units 0.4 and Dysport 1,500 Units 0.4 vs 0.5 for placebo
- Angle of catch:
  - Measured at Week 4: Dysport 1,000 Units 4.8 and Dysport 1,500 Units 5.3 vs 3.4 for placebo
  - Measured at Week 12: Dysport 1,000 Units 3.0 and Dysport 1,500 Units 2.9 vs 2.6 for placebo
- Spasticity angle:
  - Measured at Week 4: Dysport 1,000 Units -4.0 and Dysport 1,500 Units -4.0 vs -2.5 for placebo
  - Measured at Week 12: Dysport 1,000 Units -2.4 and Dysport 1,500 Units -2.8 vs -2.3 for placebo
- Spasticity grade:
  - Measured at Week 4: Dysport 1,000 Units -0.3 and Dysport 1,500 Units -0.4 vs -0.1 for placebo
  - Measured at Week 12: Dysport 1,000 Units -0.3 and Dysport 1,500 Units -0.4 vs -0.1 for placebo

Comfortable barefoot walking speed (tertiary endpoint):
- Measured at Week 4: Dysport 1,000 Units 0.07 and Dysport 1,500 Units 0.04 vs 0.05 for placebo
- Measured at Week 12: Dysport 1,000 Units 0.09 and Dysport 1,500 Units 0.06 vs 0.06 for placebo

Pain (tertiary endpoint):
Reductions in lower limb pain at each treatment cycle
- Measured at Week 4: Dysport 1,000 Units -0.1 and Dysport 1,500 Units -0.2 vs -0.1 for placebo
- Measured at Week 12: Dysport 1,000 Units -0.2 and Dysport 1,500 Units -0.1 vs 0.1 for placebo

Although these analyses for both ULS and LLS were prespecified, appropriate multiplicity adjustments were not applied, so the results on the individual components need cautious interpretation and could represent chance findings.

Dysport® (abobotulinumtoxinA) *It's Time*

Dysport dosing

UPPER LIMB SPASTICITY

Dysport has dosing recommendations for muscles in these key ULS postures[1,5]

	Recommended Dose Range in Dysport Units		Median Number of Injection Sites
Flexed elbow			
Brachialis	200	400	2
Brachioradialis	100	200	1
Biceps brachii	200	400	2
Pronator teres	100	200	1
Clenched fist			
Flexor digitorum profundus	100	200	1-2
Flexor digitorum superficialis	100	200	2
Flexed wrist			
Flexor carpi radialis	100	200	1
Flexor carpi ulnaris	100	200	1

Dysport is not interchangeable with other botulinum toxins. Dysport Units are not the same as other botulinum toxins[1]

Select dose based on muscles affected, severity of muscle spasticity, prior response, and adverse reaction history following treatment with Dysport[1]

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

Pre-existing Neuromuscular Disorders

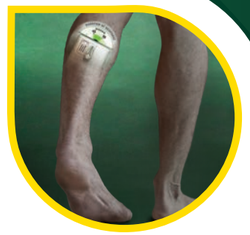
Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased 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.

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

Dysport dosing



LOWER LIMB SPASTICITY

Dysport has dosing recommendations for muscles in these key LLS postures[1,5]

	Recommended Dose Range in Dysport Units		Median Number of Injection Sites
Equinovarus foot			
Gastrocnemius:			
Medial head	100	150	1
Lateral head	100	150	1
Soleus	330	500	3
Tibialis posterior	200	300	2
Flexor digitorum longus	130	200	1-2
Flexor hallucis longus	70	200	1
Plantar flexed foot/ankle			
Gastrocnemius:			
Medial head	100	150	1
Lateral head	100	150	1
Soleus	330	500	3
Tibialis posterior	200	300	2
Flexor digitorum longus	130	200	1-2
Flexor hallucis longus	70	200	1
Flexed toes			
Flexor digitorum longus	130	200	1-2
Flexor hallucis longus	70	200	1

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[1]

Dysport® (abobotulinumtoxinA) *It's Time*

Adverse reactions as reported in patients receiving Dysport up to 1,000 Units

UPPER LIMB SPASTICITY

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

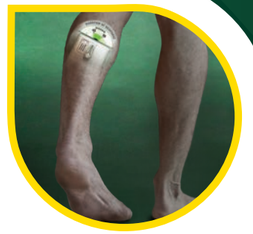
Adverse Reactions	Dysport 500 Units (n=197), %	Dysport 1,000 Units (n=194), %	Placebo (n=279), %
Infections and infestations			
Influenza	1	2	1
Infection	1	2	1
Musculoskeletal and connective tissue disorders			
Muscular weakness	2	4	1
Pain in extremity	0	2	1
Back pain	1	2	1
Nervous system disorders			
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.

- In the open-label phase of the study, the most commonly observed system organ classes (SOCs) during Cycle 1 were musculoskeletal and connective tissue disorders followed by infections and infestations; general disorders and administration site conditions; and injury, poisoning, and procedural complications. The nature of the most common SOCs and preferred terms (regardless of causality) was similar across all treatment cycles, but the frequency decreased with repeated doses of Dysport. The overall incidence of treatment-emergent adverse events decreased across cycles and was lower in Cycle 2 (27.1%) than in Cycle 1 (40.2%). The corresponding incidence was 26.9% during Cycle 3 and 13.6% during Cycle 4[5]

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

Adverse reactions as reported in patients receiving Dysport up to 1,500 Units



LOWER LIMB SPASTICITY

Adverse reactions observed in ≥5% of adults with LLS and reported more frequently than with placebo[1†]

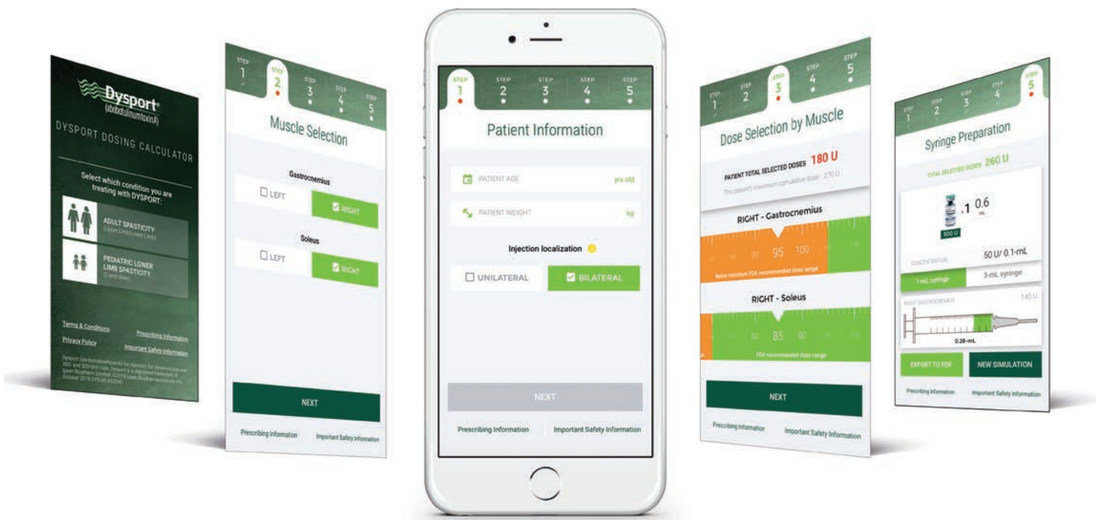
Adverse Reactions	Dysport 1,000 Units (n=127), %	Dysport 1,500 Units (n=128), %	Placebo (n=130), %
Musculoskeletal and connective tissue disorders			
Muscular weakness	2	7	3
Pain in extremity	6	6	2
Arthralgia	4	2	1
Injury, poisoning, and procedural complications			
Fall	9	6	3
Nervous system disorders			
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.
In the efficacy and safety studies of Dysport for the treatment of LLS in adults, muscular weakness was reported more frequently in women (10%) treated with Dysport 1,500 Units than in men (5%). Falls were reported more frequently in patients 65 years of age and over.

- In the open-label phase of the study, in subjects only treated in the lower limb with Dysport, fall and muscular weakness were the most commonly reported treatment-emergent adverse events. In subjects treated in the lower limb only, fall was reported in 4.9% of subjects during Cycle 1, 5.7% during Cycle 2, 1.6% during Cycle 3, and 5.6% during Cycle 4. In subjects treated in the lower limb only, muscular weakness was reported in 6.4% of subjects during Cycle 1, 4.0% during Cycle 2, 2.4% during Cycle 3, and 1.4% during Cycle 4. Similarly, the most frequently reported treatment-emergent adverse events (TEAEs) in subjects who received 500 Units Dysport in the upper limb alongside 1,000 Units in the lower limb were fall (7.7% [8/104] of subjects) and muscular weakness (4.8% [5/104])[5]

Dysport® (abobotulinumtoxinA) *It's Time*

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.

Available on the App Store

Get it on Google play

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

IMPORTANT SAFETY INFORMATION

Intradermal Immune Reaction

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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 benefi t justifi es 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.

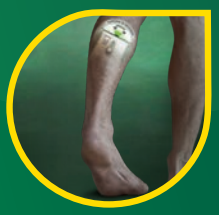
Please see full Prescribing Information, including **Boxed Warning** and Medication Guide.

Dysport® (abobotulinumtoxinA) *It's Time*

Start Dysport first-line for lasting symptom relief

In adult ULS[1,5]

- Significantly reduced muscle tone vs placebo at Week 4 when dosed at 500 Units and 1,000 Units ($P \leq 0.05$)
- A duration of response that lasts through to the next injection: 12 to 16 weeks for a majority of patients
- The most common adverse reaction (≥4%) was muscular weakness



In adult LLS[1]

- Significantly reduced muscle tone vs placebo at Week 4 when given the 1,500 Unit dose ($P<0.05$)
- A duration of response that lasts through to the next injection: 12 to 16 weeks for a majority of patients
- The most common adverse reactions (≥5%) were falls, muscular weakness, and pain in extremity

In clinical trials, retreatment was between 12 and 16 weeks or longer[1]

To calculate the FDA-approved dose range for your patient, download the Dysport Dosing Calculator from the Apple App Store or the Google Play store.

IPSEN CARES® Coverage, Access, Reimbursement & Education Support

IPSEN CARES® is a program that offers support to your patients, including services such as benefits verification in as little as 1 business day. IPSEN CARES also provides copay assistance to eligible* patients, **up to a maximum annual benefi t of $5,000**, and for as little as $0 per prescription. Visit www.ipsencares.com for more information.

*Visit www.ipsencares.com for eligibility terms and conditions and additional copay information.

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.

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

References: 1. Dysport® (abobotulinumtoxinA) [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; September 2019. **2.** Fheodoroff K, Ashford S, Jacinto J, et al. Factors influencing goal attainment in patients with post-stroke upper limb spasticity following treatment with botulinum toxin A in real-life clinical practice: sub-analyses from the Upper Limb International Spasticity (ULIS)-II Study. *Toxins.* 2015;7(4):1192-1205. **3.** Barnes M, Kocer S, Fernandez MM, Balcaitiene J, Fheodoroff K. An international survey of patients living with spasticity. *Disabil Rehabil.* 2016;39(14):1428-1434. **4.** Bensmail D, Hanschmann A, Wissel J. Satisfaction with botulinum toxin treatment in post-stroke spasticity: results from two cross-sectional surveys (patients and physicians). *J Med Econ.* 2014;17(9):618-625. **5.** Data on file. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. **6.** Gracies J-M, O'Dell M, Vecchio M, et al. Effects of repeated abobotulinumtoxinA injections in upper limb spasticity. *Muscle Nerve.* 2018;57(2):245-254. **7.** Gracies J-M, Esquenazi A, Brashear A, et al. Efficacy and safety of abobotulinumtoxinA in spastic lower limb: randomized trial and extension. *Neurology.* 2017;89(22):2245-2253.

IPSEN Innovation for patient care

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

Dysport® (abobotulinumtoxinA)

It's Time