What if...

...your botulinum toxin brand was devoted to you and your patients?

EXPERIENCE A DIFFERENT FOCUS

A movement disorder partner highly committed to empowering you through appropriate support along with lasting spasticity relief.[1*]

*In clinical trials, the primary endpoint for spasticity was muscle tone assessed by the Modified Ashworth Scale (MAS) at Week 4. A majority of adults with spasticity did not need re-treatment until Weeks 12-16. However, some patients had a longer duration of response.[1]

INDICATIONS

DYSPORT (abobotulinumtoxinA) for injection is indicated for the treatment of:

- spasticity in patients 2 years of age and older
- cervical dystonia in adults

FDA APPROVED FOR

adult upper limb and adult lower limb spasticity

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 14-15 and full Prescribing Information, including BOXED WARNING.

Dysport®
(abobotulinumtoxinA)

EVERY MOMENT OF RELIEF MAY MAKE A DIFFERENCE

In global surveys, people with spasticity reported their duration of response and how it impacted their satisfaction with treatment

A global internet-based survey of people with spasticity found that[2]:

1 IN 4 PATIENTS (24%) HAD A DURATION OF RESPONSE OF <3 MONTHS
after treatment with botulinum toxin

SURVEY DETAILS

The International Survey of People Living With Spasticity collected data over 13 months from 281 people in 29 countries[2]

- Designed in collaboration with the WFNR
- 204 respondents (73%) were treated with botulinum toxin injections
- Self-completed by patients (anonymous)
- Multichoice questions, including 17 with an optional free-entry format
- People with spasticity encouraged to participate by their treating healthcare provider (HCP)
- No additional inclusion/exclusion criteria

A survey of people with spasticity found that wear-off of treatment benefits can impact patient satisfaction[3]

At peak effect of therapy (3.7 weeks),

98% OF PATIENTS HAD SOME DEGREE OF SATISFACTION
with their response (n=43/44)

Just before their next injection,

36% OF PATIENTS WERE NOT AT ALL SATISFIED
with their response (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. The effects of individual botulinum toxin A formulations were not reported. Patients surveyed were receiving a range of botulinum toxin As.[3]

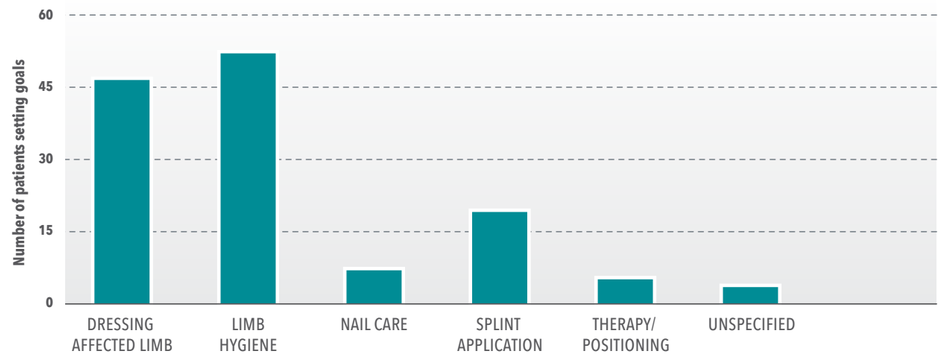
WFNR=World Federation for NeuroRehabilitation.

PATIENTS WANT TREATMENT TO HELP THEM PERFORM EVERYDAY ACTIVITIES

In an international, multicenter study, adults with upper limb spasticity selected a number of passive and active goals of treatment

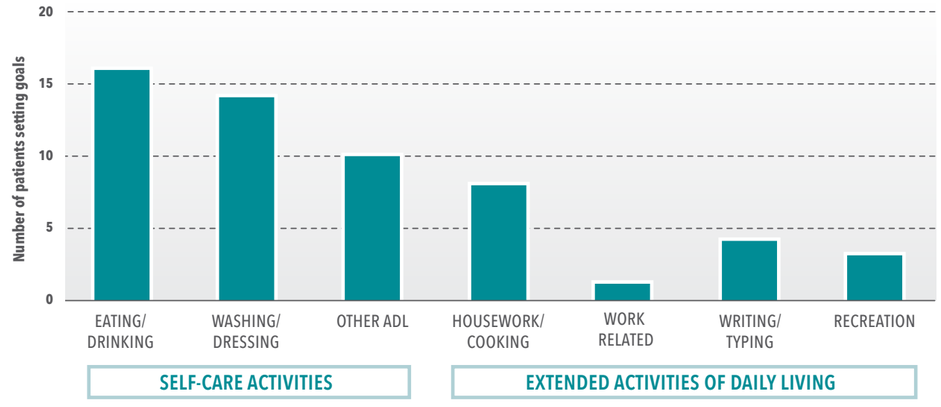
Passive Function Primary Goal Category[4]

n=132



Active Function Primary Goal Category[4]

n=56



Adapted from Fhedoroff 2015.

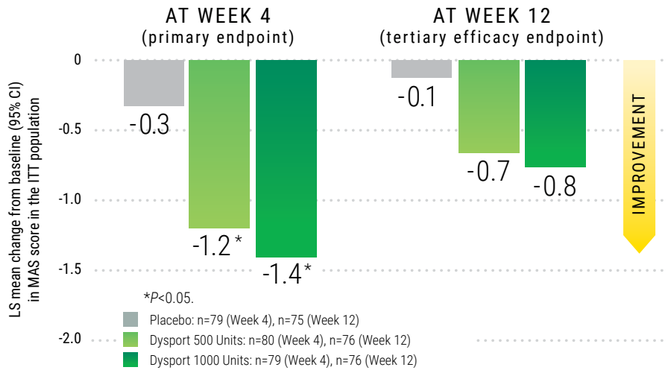
Data are from the Upper Limb International Spasticity Study-II, a large, international, observational cohort study of adults with upper limb spasticity (n=456), conducted across 84 centers in 22 countries. The primary objective was to assess responder rates, as defined by the achievement of the primary person-centered goal using Goal Attainment Scaling (GAS), and to establish a consistent and reproducible approach to the recording of goals and goal attainment, as measured by GAS.[4]

ADL=activities of daily living.

FOR ADULTS WITH ULS

Reduced stiffness, backed by proven results

Patients treated with Dysport 500 Units and Dysport 1000 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.[1] 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.[1] The second 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.[5] MAS was not measured between Week 4 and Week 12.[1,5] 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).[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 re-treatment.[5]

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

// Dysport 1000 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.[5] Please see results on page 6.

// In an open-label extension study, reduction in MAS was observed over multiple injection cycles in doses up to Dysport 1000 Units[5]
— Change from baseline MAS at Week 4 in cycles 1 (-1.4), 2 (-1.6), 3 (-1.5), and 4 (-1.4)

This was conducted as an open-label study and not placebo controlled; therefore, these results should be interpreted cautiously.

Open-label extension study design: After 3 months of on-study treatment, 258 patients continued open-label treatment with Dysport for up to 4 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_{y1}, X), angle of catch (X_{y3}), DAS score, Modified Frenchay Scale (MFS) score, and PGA score. Reduction in MAS was observed over multiple injection cycles in doses up to Dysport 1000 Units.[5]

CI=confidence interval; ITT=intent-to-treat; LLS=lower limb spasticity; LS=least squares; SD=standard deviation; ULS=upper limb spasticity.

IMPORTANT SAFETY INFORMATION

Contraindications

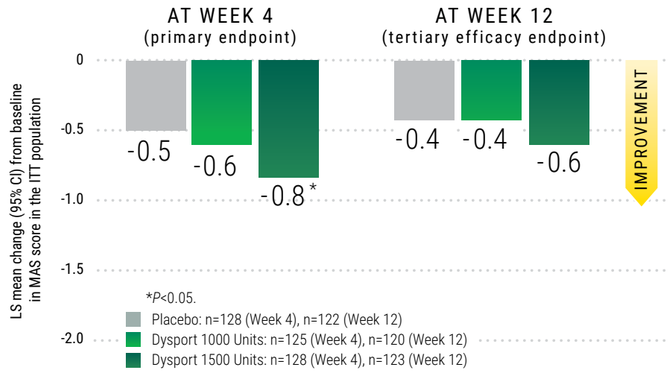
DYSPORT is contraindicated in patients with known hypersensitivity to any botulinum toxin products, cow's milk protein, or to any of the components in the formulation, or infection at the proposed injection site(s). Serious hypersensitivity reactions including anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea have been reported. If such a serious reaction occurs, discontinue DYSPORT and institute appropriate medical therapy immediately.

Please see additional Important Safety Information on pages 14-15 and full Prescribing Information, including BOXED WARNING.

FOR ADULTS WITH LLS

Reduced stiffness, backed by proven results

Patients treated with Dysport 1500 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.[1] 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.[1] 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 Tardieu Scale (TS) scores from baseline in the gastrocnemius-soleus complex (GSC) (knee extended) at additional time points.[5] MAS was not measured between Week 4 and Week 12.[5] 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).[6] Follow-up assessments occurred at Weeks 1, 4, and 12; visits were also permitted at Weeks 16, 20, and 24 as needed for re-treatment.[5]

Week 12 results for both ULS and LLS may represent chance findings, as multiplicity adjustments were not applied; interpret appropriately

Open-label phase

// In the open-label extension, the primary endpoint was long-term safety.[5] Please see results on page 7

// In an open-label extension study in LLS, reduction in MAS was observed over multiple injection cycle in doses up to Dysport 1500 Units[5]
— Change from baseline MAS at Week 4 in cycles 1 (-0.8), 2 (-0.9), 3 (-1.0), and 4 (-1.0)

This was conducted as an open-label study and not placebo controlled; therefore, these results should be interpreted cautiously.

Open-label extension study design: After 3 months of on-study treatment, 352 patients continued open-label treatment with Dysport for up to 4 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 1500 Units.[5]

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Lack of Interchangeability Between Botulinum Toxin Products

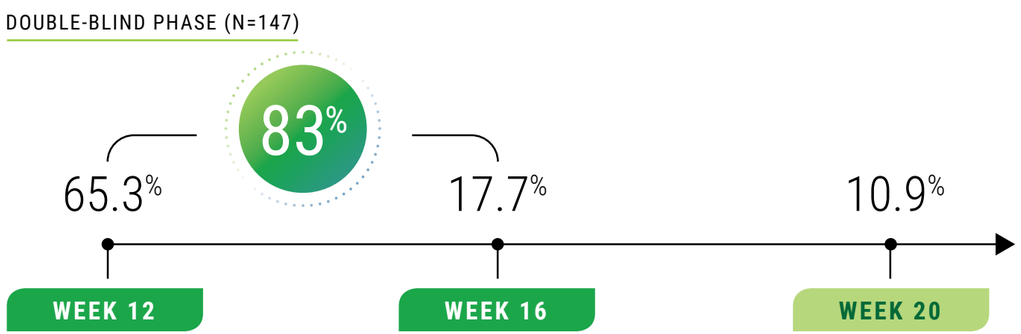
The potency Units of DYSPORT are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of DYSPORT cannot be compared to or converted into units of any other botulinum toxin products assessed with any other specific assay method.

Dysport®
(abobotulinumtoxinA)

FOR ADULTS WITH ULS

Sustained relief beyond the minimum time to re-treatment

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



Re-treatment criteria for ULS and LLS[1,5]

// Time to re-treatment was not the primary endpoint

// In the pivotal trials for adult spasticity, need for re-treatment was determined by:

- No longer demonstrating a decrease from baseline of ≥1 grade in MAS score in the primary targeted muscle group or gastrocnemius-soleus complex (knee extended)
- No improvement in PGA (ie, a score ≤0)
- No signs of unacceptable safety risk for the next treatment cycle

// Investigator discretion (based on efficacy and safety criteria) determined the need for re-treatment in 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

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

Dysphagia and Breathing Difficulties

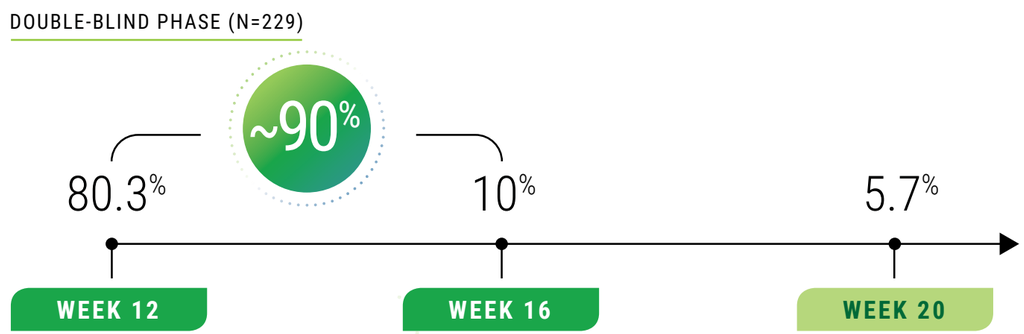
Treatment with DYSPORT and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or swallowing. When distant 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.

Please see additional Important Safety Information on pages 14-15 and full Prescribing Information, including BOXED WARNING.

FOR ADULTS WITH LLS

Sustained relief beyond the minimum time to re-treatment

Re-treatment was between 12 and 16 weeks for ~90% of patients; however, some patients had a longer duration of response[5]



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.

Dysport® (abobotulinumtoxinA)

FOR ADULTS WITH ULS

An analysis of physical function at Week 4 and Week 12

Patient responders in the individual DAS domains (tertiary endpoint)[5]

The difference between Dysport and placebo in these analyses was not statistically significant

	Dysport 500 Units (n=80)	Dysport 1000 Units (n=79)	Placebo (n=79)
HYGIENE			
Week 4	34%	33%	20%
Week 12	30%	37%	11%
DRESSING			
Week 4	30%	35%	24%
Week 12	29%	37%	18%
LIMB POSITION			
Week 4	36%	51%	29%
Week 12	25%	46%	25%
PAIN			
Week 4	18%	17%	9%
Week 12	16%	17%	11%

Results on individual components may represent chance findings, as multiplicity adjustments were not applied; interpret appropriately.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

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.

Please see additional Important Safety Information on pages 14-15 and full Prescribing Information, including BOXED WARNING.

FOR ADULTS WITH LLS

An analysis of physical function and related factors at Week 4

Comfortable barefoot walking speed (secondary endpoint) and spasticity in the GSC and pain (tertiary endpoints)[5]

Secondary endpoints for the study included PGA of treatment response at Week 4 and change in comfortable barefoot walking speed without walking aids at Week 4[1,5]

		Dysport 1000 Units (n=125)	Dysport 1500 Units (n=128)	Placebo (n=128)
Physician Global Assessment[1] (secondary endpoint)	At Week 4	0.9	0.9	0.7
Comfortable barefoot walking speed (m/s)[5] (secondary endpoint)	At Week 4	0.05	0.05	0.05
Spasticity in the GSC[5] (tertiary endpoint) Change from baseline in the Tardieu Scale was used to measure improvements at Week 4	**ANGLE OF ARREST**	0.7	1.4	1.3
	ANGLE OF CATCH	4.8	5.3	3.4
	SPASTICITY ANGLE	−4.0	−4.0	−2.5
	SPASTICITY GRADE	−0.3	−0.4	−0.1
Lower limb pain[5]* (tertiary endpoint)	At Week 4	−0.1	−0.2	−0.1

Results on individual components may represent chance findings, as multiplicity adjustments were not applied; interpret appropriately.

*Lower limb pain was evaluated using the Scale of Pain Intensity (SPIN).

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.

Dysport® (abobotulinumtoxinA)

FOR ADULTS WITH ULS

Flexiblity to customize dosing for each patient

Recommended dosage and administration for adults with ULS[1]

	Recommended Dose Range in Dysport Units		Recommended Number of Injections per Muscle
FLEXED ELBOW			
Brachialis	200	400	1-2
Brachioradialis	100	200	1-2
Biceps brachii	200	400	1-2
Pronator teres	100	200	1

CLENCHED FIST			
Flexor digitorum profundus	100	200	1-2
Flexor digitorum superficialis	100	200	1-2

FLEXED WRIST			
Flexor carpi radialis	100	200	1-2
Flexor carpi ulnaris	100	200	1-2

IMPORTANT SAFETY INFORMATION

Adverse Reactions

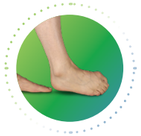
- The most common adverse reactions (≥4%) in adults with upper limb spasticity include muscular weakness; in adults with lower limb spasticity (≥5%) include falls, muscular weakness, and pain in extremity
- The most common adverse reactions (≥10%) in pediatric patients with upper limb spasticity include 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

Please see additional Important Safety Information on pages 14-15 and full Prescribing Information, including BOXED WARNING.

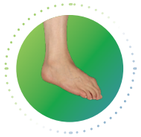
FOR ADULTS WITH LLS

Flexiblity to customize dosing for each patient

Recommended dosage and administration for adults with LLS[1]



	Recommended Dose Range in Dysport Units		Recommended Number of Injections per Muscle
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

Additional dosing guidance for ULS and LLS[1]

1. In adults with upper and lower limb spasticity, the maximum recommended total dose per treatment session is 1500 Units.
2. No more than 1 mL should generally be administered at any given injection site.
3. Re-treatment of adult spasticity should not occur in intervals of less than 12 weeks.
4. The potency units of Dysport are not interchangeable with other preparations of botulinum toxin products.

Dysport® (abobotulinumtoxinA)

FOR ADULTS WITH ULS

A demonstrated, well-studied safety profile across all doses

Most common adverse reactions observed in ≥2% of adults with ULS who received Dysport (up to 1000 Units) 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.

Open-label study adverse events

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 additional Important Safety Information on pages 14-15 and full Prescribing Information, including BOXED WARNING.

FOR ADULTS WITH LLS

A demonstrated, well-studied safety profile across all doses

Adverse reactions observed in ≥2% of adults with LLS who received Dysport (up to 1500 Units) 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

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 1500 Units than in men (5%). Falls were reported more frequently in patients 65 years of age and over.[1]

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

Open-label study adverse events

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 (TEAEs). 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 TEAEs in subjects who received 500 Units Dysport in the upper limb alongside 1000 Units in the lower limb were fall (7.7% [8/104] of subjects) and muscular weakness (4.8% [5/104]).[5]

Dysport® (abobotulinumtoxinA)

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.

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.

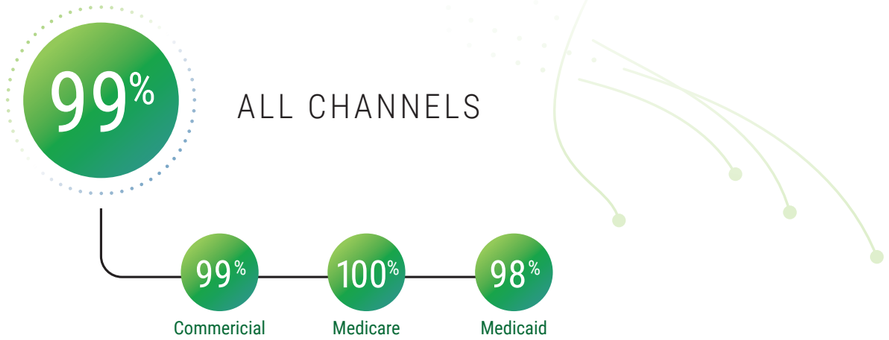
Please see full Prescribing Information, including BOXED WARNING.

Dysport® (abobotulinumtoxinA)

Favorable access for nearly all of your patients

Nearly 100% of patient lives covered for the treatment of spasticity

National Total | SPASTICITY COVERAGE WITHOUT RESTRICTIONS



This document represents no promise or guarantee concerning coverage or levels of reimbursement. It is recommended that you contact your local payers with regard to local reimbursement policies and practices. Please consult your counsel or reimbursement specialist on reimbursement or billing questions specific to your practice.

Coverage data provided by Breakaway Partners and current as of May 2022.

IMPORTANT SAFETY INFORMATION

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 additional Important Safety Information on pages 14-15 and full Prescribing Information, including BOXED WARNING.

Support for eligible and enrolled patients

IPSENCARES®
Coverage, Access, Reimbursement & Education Support

The Copay Assistance Program: Assistance With Private Insurance Copay or Coinsurance Costs for Dysport

// In any calendar year commencing January 1, the maximum copay benefit amount paid by Ipsen Biopharmaceuticals, Inc. will be $5,000

// IPSEN CARES® will confirm every 12 months that eligible* patients meet the criteria for the program

As little as
$0 PER PRESCRIPTION
for eligible* patients

Annual maximum of $5,000 per calendar year in copay assistance

To learn more,
visit IpsenCares.com

*Patient Eligibility & Terms and Conditions: Patients are not eligible for copay assistance through IPSEN CARES® if they are enrolled in any state or federally funded programs for which drug prescriptions or coverage could be paid in part or in full, including, but not limited to, Medicare Part B, Medicare Part D, Medicaid, Medigap, VA, DoD, or TRICARE (collectively, "Government Programs"), or where prohibited by law. Patients residing in Massachusetts, Minnesota, or Rhode Island can only receive assistance with the cost of Ipsen products but not the cost of related medical services (injection). Patients receiving assistance through another assistance program or foundation, free trial, or other similar offer or program, are not eligible for the copay assistance program during the current enrollment year.

In any calendar year commencing January 1, the maximum copay benefit amount paid by Ipsen Biopharmaceuticals, Inc. will be $5,000.

Patient or guardian is responsible for reporting receipt of copay savings benefit to any insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled through the program, as may be required. Additionally, patients may not submit any benefit provided by this program for reimbursement through a Flexible Spending Account, Health Savings Account, or Health Reimbursement Account. Ipsen reserves the right to rescind, revoke, or amend these offers without notice at any time. Ipsen and/or CoverMyMeds are not responsible for any transactions processed under this program where Medicaid, Medicare, or Medigap payment in part or full has been applied. Data related to patient participation may be collected, analyzed, and shared with Ipsen for market research and other purposes related to assessing the program. Data shared with Ipsen will be de-identified, meaning it will not identify the patient. Void outside of the United States and its territories or where prohibited by law, taxed, or restricted. This program is not health insurance. No other purchase is necessary.

Dysport®
(abobotulinumtoxinA)

EXPERIENCE A DIFFERENT FOCUS

Highly committed to empowering you through appropriate support along with lasting spasticity relief.[1]

Reduced stiffness, backed by proven results

Significantly reduced muscle tone vs placebo at Week 4 when given at 500 Units and 1000 Units ($P \leq 0.05$) for adults with ULS, and at 1500 Units ($P < 0.05$) for adults with LLS[1]

Relief between the time to re-treatment

Re-treatment was between 12 and 16 weeks for the majority of patients; however, some patients had a longer duration of response (up to 20 weeks)[1,5]

A demonstrated, well-studied safety profile

The most common adverse reactions were muscular weakness in adult ULS (≥4%), and falls, muscular weakness, and pain in extremity in adult LLS (≥5%)[1]

Appropriate support for you and your patients

- // C.L.I.M.B.® online learning continuum with injection education and training
- // In-person, virtual, and on-demand peer-to-peer education
- // Clinical tools and patient materials
- // IPSEN CARES® patient coverage and access support

SCAN HERE to access the Dysport Resource Catalogue or visit DysportHCP.com/CatalogueAS

Discover more at **DysportHCP.com**

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 14-15 and full Prescribing Information, including BOXED WARNING.

References: **1.** Dysport® (abobotulinumtoxinA) [prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; July 2020. **2.** Barnes M, Kocer S, Fernandez MM, et al. An international survey of patients living with spasticity. *Disabil Rehabil*. 2017;39(14):1428-1434. **3.** 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. **4.** Fhedoroff 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. **5.** Data on file. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. **6.** 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.

January 2023 DYS-US-007636

Dysport® (abobotulinumtoxinA)