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 in pediatric patients was the mean change from baseline in MAS at Week 6 for upper limb spasticity and Week 4 for lower limb spasticity. A majority of pediatric patients with spasticity did not need re-treatment until Weeks 16-28; however, some patients had a longer duration of response.[1]

MAS=Modified Ashworth Scale.

FDA APPROVED FOR
pediatric upper limb and pediatric lower limb 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.

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Dysport®
(abobotulinumtoxinA)

Meet Annika, a real pediatric patient living with spasticity

ANNIKA // AGE 9
Lives in Utah

Annika, a real Dysport patient living with spasticity

MEDICAL HISTORY

Annika was diagnosed with hemiplegic cerebral palsy at 18 months old

// Guided through her treatment journey by her mother, Wendi

// Receives occupational therapy every Thursday to complement her Dysport treatment

// Wendi discovered Dysport through her own research

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.

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How Dysport helps Annika

What Annika Wants From Treatment

"What we really needed to work on was her walking. We were determined to find a doctor who listens and is willing to partner with us to reach our goals."

– WENDI

How Dysport Helps

"Annika moves smoother and faster. Her legs don't tire as quickly, and she doesn't have to work as hard to use the muscles."

– WENDI

Efficacy That Lasts

"My doctor gives me Dysport and then she checks my flexibility about 6 weeks later. I get my injection about every 4 months."

– ANNIKA

Individual results may vary. Annika is the only Dysport patient in this image. Annika and her mother, Wendi, were compensated for their time.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Lack of Interchangeability Between Botulinum Toxin Products

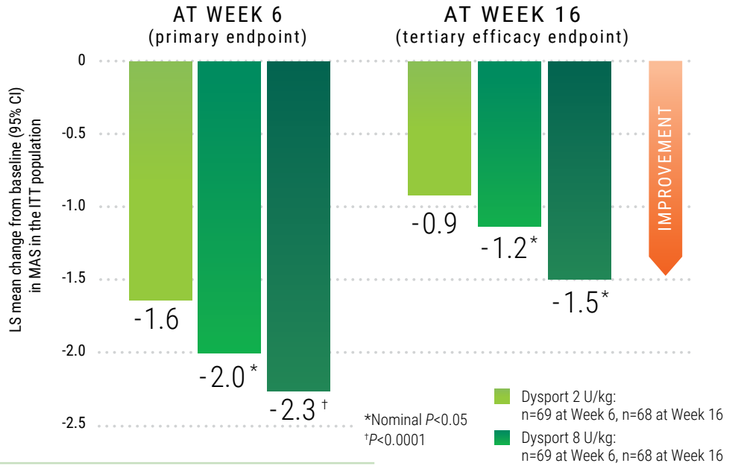
The potency Units of DYSPORT are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of DYSPORT cannot be compared to or converted into units of any other botulinum toxin products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

Dysport® (abobotulinumtoxinA)

FOR PEDIATRIC ULS

Reduced stiffness backed by proven results

High-dose Dysport significantly loosened muscles at Week 6 and produced statistically significant results vs low-dose Dysport[1]



Week 16 results may represent chance findings, as multiplicity adjustments were not applied; therefore, the results should be interpreted cautiously.

// At Week 6, patients receiving 16 Units/kg demonstrated a significant reduction in muscle tone versus those receiving 2 Units/kg

Study design: The efficacy and safety of Dysport were evaluated in a multicenter, prospective, double-blind, randomized, low-dose controlled study assessing Dysport in pediatric patients 2 to 17 years of age with upper limb spasticity because of cerebral palsy. Patients were randomized to receive Dysport 2 Units/kg (n=70), 8 Units/kg (n=70), or 16 Units/kg (n=70) for the first treatment cycle. The completion of 1 cycle occurred when the patient received the next injection. The primary efficacy endpoint was mean change from baseline in muscle tone at Week 6, assessed by MAS in the PTMG. Secondary efficacy endpoints were mean change in the PGA at Week 6, and mean GAS score at Week 6. Patients were assessed for re-treatment eligibility at Week 16. If ineligible for re-treatment, they were evaluated every 6 weeks (plus or minus 2 weeks) until eligible. There had to be a minimum of 16 weeks between each injection session, and patients could receive a maximum of 4 sessions over the course of the study, which had a duration of up to 1 year and 9 months for each patient. After completing their first treatment cycle, patients receiving Dysport 2 Units/kg were re-randomized to receive Dysport 8 Units/kg or 16 Units/kg. Patients receiving the higher doses remained at their dose unless an adjustment up (not exceeding 16 Units/kg) or down was mandated by the investigator. The study remained double blind for the remaining 3 cycles.[1,2]

CI=confidence interval; GAS=Goal Attainment Scale; ITT=intent-to-treat; LLS=lower limb spasticity; LS=least squares; PGA=Physician Global Assessment; PTMG=primary targeted muscle group; ULS=upper limb spasticity.

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.

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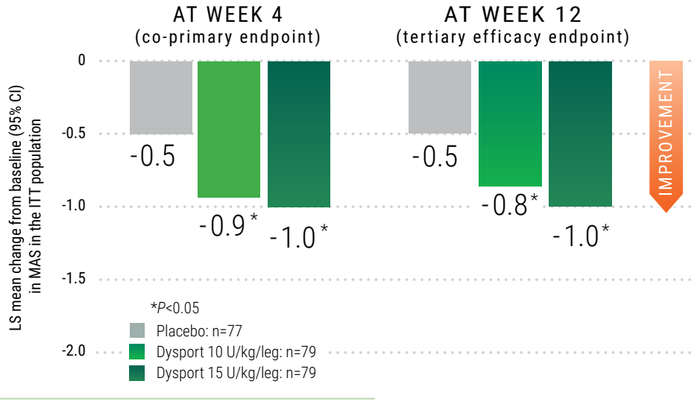
FOR PEDIATRIC LLS

Reduced stiffness backed by proven results

Dysport provided lasting relief through the minimum 12-week re-treatment time.[1]



Week 12 results may represent chance findings, as multiplicity adjustments were not applied; therefore, the results should be interpreted cautiously.

Patients on Dysport had a significantly greater response to treatment as assessed by PGA at Week 4 and Week 12[1]

// PGA score at Week 4: Dysport 10 Units/kg/leg=1.5; Dysport 15 Units/kg/leg=1.5; placebo=0.7 (*P*<0.05)

// PGA score at Week 12: Dysport 10 Units/kg/leg=0.8; Dysport 15 Units/kg/leg=1.0; placebo=0.4 (*P*<0.05)

The investigator graded muscle tone on a 6-point scale, from 0 (no increase in tone) to 4 (affected parts rigid in flexion or extension).[2]

The co-primary efficacy endpoints were the mean change in MAS score in the ankle plantar flexor and the mean PGA of response to treatment between baseline and Week 4.[1]

The secondary efficacy endpoint was mean change from baseline in GAS at Week 4.[2]

Study design: The efficacy and safety of Dysport were evaluated in a multicenter, prospective, double-blind, randomized, placebo-controlled study assessing Dysport in pediatric patients 2 to 17 years of age with lower limb spasticity because of cerebral palsy causing dynamic equinus foot deformity. In the pivotal clinical study, doses of Dysport 10 Units/kg/leg, Dysport 15 Units/kg/leg, or placebo were injected intramuscularly into the gastrocnemius and soleus muscles. The 12-week follow-up visit included assessment for re-treatment eligibility. Pediatric patients who remained in the study after Week 12 were permitted additional discretionary follow-up visits at Week 16, Week 22, and Week 28 to assess eligibility for re-treatment. Patients eligible for re-treatment were eligible for enrollment into an open-label extension study lasting up to a year or 4 treatment cycles.[1,2]

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

Pre-existing Neuromuscular Disorders

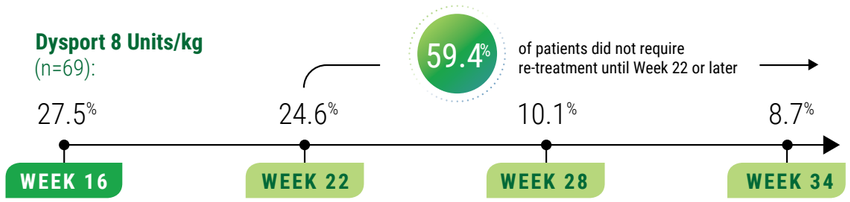
Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of DYSPORT.

Dysport® (abobotulinumtoxinA)

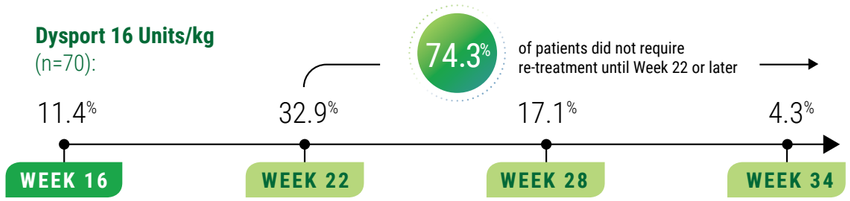
FOR PEDIATRIC ULS AND LLS

Extended symptom relief may mean fewer injections

A majority of patients with ULS did not need re-treatment until Weeks 16-28; some experienced an even longer duration of response[1,2*]

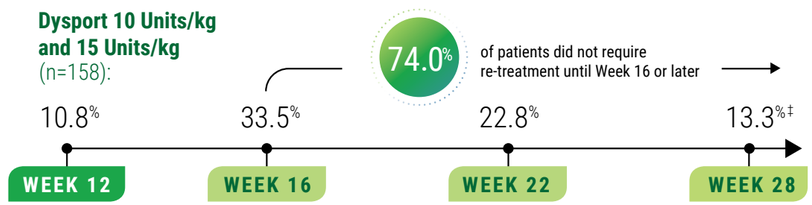


// Out of the patients receiving Dysport 8 Units/kg, 15.8% were retreated between Weeks 34 and 52; data was missing for a total of 9 patients[2]



// Out of the patients receiving Dysport 16 Units/kg, 20% were retreated between Weeks 34 and 52; data was missing for a total of 10 patients[2]

A majority of patients with LLS did not need re-treatment until Weeks 16-22; some experienced an even longer duration of response[1,2†]



Additional Dosing Guidance for ULS and LLS

1. The optimal dose of Dysport, muscles to be injected, and re-treatment eligibility should be selected based on the patient's progress and response to treatment[1]
2. Re-treatment should occur no sooner than 16 weeks after the previous injection for ULS, and no sooner than 12 weeks after the previous injection for LLS[1]
3. Eligibility for re-treatment was assessed by the investigator at every visit onward from Week 12 for LLS or Week 16 for ULS[2]

*Patients who remained in the ULS study after Week 16 were permitted additional discretionary follow-up visits at Week 22, Week 28, Week 34, or beyond.[2]
†Patients who remained in the LLS study after Week 12 were permitted additional discretionary follow-up visits at Week 16, Week 22, and Week 28 to assess eligibility for re-treatment.[3]
‡4.4% of patients were retreated after Week 28.[2]

FOR PEDIATRIC LLS

Significant improvement in Goal Attainment Scale

GAS results at Week 4 (secondary endpoint) and Week 12 (tertiary endpoint)[2]

// Both Dysport doses (10 U/kg/leg and 15 U/kg/leg; n=158) achieved statistically significant improvement in GAS vs placebo (n=77)[2]

Responder analyses for achievement of primary goal and for the 5 most commonly chosen individual goals[4§]

	Placebo (n=77), %	Dysport 10 U/kg/leg (n=79), %	Dysport 15 U/kg/leg (n=79), %
Primary goal achievement	62	79	76
Individual goal analysis			
Improved walking pattern			
Responder rate Week 4	40	79	60
Responder rate Week 12	39	72	63
Improved balance			
Responder rate Week 4	53	62	39
Responder rate Week 12	56	62	56
Decreased frequency of falling			
Responder rate Week 4	56	82	69
Responder rate Week 12	42	90	71
Decreased frequency of tripping			
Responder rate Week 4	46	56	77
Responder rate Week 12	62	64	88
Improved endurance			
Responder rate Week 4	55	72	64
Responder rate Week 12	46	88	91

GAS=Goal Attainment Scale.
§Best goal attainment total score for each patient was assessed using the best score attained for each goal at any time during the study. Patients who completed the study or withdrew are counted as missing at subsequent visits.

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.

Dysport® (abobotulinumtoxinA)

Adverse reactions observed in ≥3% of pediatric patients with ULS treated with Dysport (up to 16 Units/kg) in the double-blind study that were reported more frequently than in the control group[1]

Adverse Reactions	Dysport 2 Units/kg* (n=70), %	Dysport 8 Units/kg (n=70), %	Dysport 16 Units/kg (n=70), %
Infections and infestations			
Upper respiratory tract infection	7	9	11
Influenza	1	1	3
Pharyngitis†	9	6	10
Gastrointestinal disorders			
Nausea	0	3	1
Musculoskeletal and connective tissue disorders			
Muscular weakness	1	4	6
Nervous system disorders			
Headache	0	6	3
Epilepsy	1	0	4

*Low dose active comparator arm.
†Includes pharyngitis, pharyngitis streptococcal, pharyngotonsillitis.

// Additional adverse reactions occurring below 3% and considered to be drug related include: myalgia, pain in extremity, fatigue, influenza-like illness, injection site eczema, injection site bruising, injection site rash, injection site pain, and injection site swelling.

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.

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

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When it comes to your pediatric patients,
we know safety is important

Adverse reactions observed in ≥4% of pediatric patients with LLS treated with Dysport (up to 30 Units/kg) in the double-blind trial that were reported more frequently than with placebo[1]

Adverse Reactions	Placebo (n=79), %	UNILATERAL INJECTIONS Dysport 10 Units/kg (n=43), %	UNILATERAL INJECTIONS Dysport 15 Units/kg (n=50), %	BILATERAL INJECTIONS Dysport 20 Units/kg (n=37), %	BILATERAL INJECTIONS Dysport 30 Units/kg (n=30), %
Infections and infestations					
Nasopharyngitis	5	9	12	16	10
Bronchitis	3	0	0	8	7
Respiratory, thoracic, and mediastinal disorders					
Cough	6	7	6	14	10
General disorders and administration site conditions					
Pyrexia	5	7	12	8	7
Musculoskeletal and connective tissue disorders					
Pain in extremity	5	0	2	5	7
Nervous system disorders					
Convulsion/epilepsy‡	0	7	4	0	7

Open-label study safety results

// In the open label study, the SOCs and PTs most frequently associated with TEAEs (in ≥5% of subjects in any treatment group by total dose) were infections and infestations, followed by general disorders and administration site conditions, respiratory, thoracic and mediastinal disorders, gastrointestinal disorders and musculoskeletal and connective tissue disorders.[2]

*Convulsion/Epilepsy: Five patients reported seizures in the double-blind study. Two of the cases occurred in the Dysport 10 Units/kg/leg group, and 3 occurred in the 15 Units/kg/leg group. Of the 5 reported cases, only 1 was a new occurrence of epilepsy (in the 10 Units/kg/leg group). All cases were considered unrelated to study treatment.[3]

PT=preferred term; SOC=system organ class; TEAE=treatment emergent adverse event.

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.

Dysport® (abobotulinumtoxinA)

INDICATIONS

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

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Warnings and Precautions

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Dysphagia and Breathing Difficulties

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Dysport® (abobotulinumtoxinA)

EXPERIENCE A DIFFERENT FOCUS

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

Reduces stiffness, backed by proven results

Reduction in MAS at Week 6* and through Week 16† for children with ULS, and at Week 4* and through Week 12† for children with LLS.[1,2]

Extended symptom relief may mean fewer injections

A majority of patients did not need re-treatment until Weeks 16-28 in ULS and 16-22 in LLS; however, some patients had a longer duration of response.[1]

We know safety is important for your pediatric patients

The most common adverse reactions (≥10% of patients) in ULS were upper respiratory tract infection and pharyngitis; in LLS, they were nasopharyngitis, cough, and pyrexia.[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

*Primary endpoint.
†Tertiary endpoint.

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

Discover more at **DysportHCP.com**

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References: **1.** Dysport® (abobotulinumtoxinA) [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; July 2020. **2.** Data on file. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. **3.** Delgado MR, Tilton A, Russman B, et al. AbobotulinumtoxinA for equinus foot deformity in cerebral palsy: a randomized controlled trial. *Pediatrics*. 2016;137(2): e20152830. doi: 10.1542/peds.2015-2830 **4.** Tilton A, Russman B, Aydin R, et al. AbobotulinumtoxinA (Dysport) improves function according to goal attainment in children with dynamic equinus due to cerebral palsy. *J Child Neurol*. 2017;32(5):482-487.

IPSEN Innovation for patient care

Dysport® (abobotulinumtoxinA)