

A CHANCE TO GIVE CHILDREN
LIVING WITH SPASTICITY



Consider Dysport for lasting symptom relief:

- The minimum retreatment interval for pediatric upper limb is 16 weeks; however, most children in the trial did not receive their next injection for 5-7 months, giving them a chance for less frequent injections
- The minimum retreatment interval for pediatric lower limb is 12 weeks; however, most children in the trial did not receive their next injection for 4-5 months, giving them a chance for less frequent injections

What is Dysport?

Dysport is a prescription medicine that is injected into muscles and used to treat:

- increased muscle stiffness in patients 2 years of age and older with upper and lower limb spasticity
- cervical dystonia (CD) in adults

Select Important Safety Information

Dysport may cause serious side effects, including problems breathing or swallowing and/or spread of toxin effects, that can be life threatening and death can happen as a complication. These problems can happen within hours, or days to weeks after an injection of Dysport.

Please see Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#) with Important Warning.

**Dysport**[®]
(abobotulinumtoxinA)

IMPORTANT SAFETY INFORMATION

What is the most important safety information I should know about Dysport?

Dysport may cause serious side effects, including problems breathing or swallowing and/or spread of toxin effects, that can be life threatening and death can happen as a complication. These problems can happen within hours, or days to weeks after an injection of Dysport.

- **Problems swallowing, breathing, or speaking.** Treatment with Dysport can result in swallowing or breathing problems. People with pre-existing swallowing or breathing problems may be at greater risk following treatment with Dysport. Swallowing problems may last for several weeks; you may need a feeding tube to receive food or water. If swallowing problems are severe, food or liquids may go into your lungs.
- **Spread of toxin effects.** The effects of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism which include: loss of strength and muscle weakness all over the body, double or blurred vision, and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, and trouble breathing or swallowing. The risk of these symptoms is probably greatest in children treated for spasticity. These problems could make it unsafe for you to drive a car, operate machinery, or do other dangerous activities.

Call your doctor or get medical help right away if you experience these problems after treatment with Dysport.

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Consider Dysport on this journey

Managing a chronic condition is difficult, not to mention managing one in a young child or adolescent. Whether your child has been newly diagnosed with spasticity, or you are deciding which treatment is best for them, making a decision involving their care can be overwhelming.

We recognize that spasticity may not be the only condition your child is managing, but that it still has a significant impact on their life.

We are here to give you helpful information about spasticity and to let you know about available treatment options.

Our goal is to help you and your child's doctor choose a treatment approach that best suits you and your child.

This guide will walk you through:

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- **Pediatric spasticity and treatment options**
 - **Realistic goals for treatment**
 - **A treatment called Dysport, how it works, and what you can expect from treatment**
 - **Resources and support groups that are available to you**
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What is spasticity?

Spasticity is caused by damage to parts of the brain that control movement. This damage can cause some of your child's muscles to be uncontrollably tight or stiff.

The damage can be caused by a traumatic injury (a head injury) or by another condition. One of the most common causes of spasticity in children is cerebral palsy; nearly two-thirds of children with cerebral palsy will present with upper or lower limb spasticity.

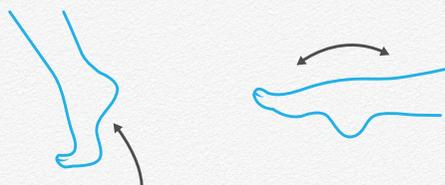
Spasticity can interfere with things like everyday movement, speech, and even the ability to walk.

Spasticity can occur in the upper limbs and/or the lower limbs

Upper limb spasticity involves muscles in the arms, hands, and fingers. The tightness in those muscles may cause hands, arms, and fingers to contract like this:



Lower limb spasticity involves the muscles in the legs, feet, and toes. The tightness in those muscles may cause legs, ankles, and feet to bend or turn like this:



How is it managed?

There are several different treatment options that can help manage spasticity in children:

- Baclofen pump
- Occupational and/or physical therapy
- Oral medicines
- Botulinum toxin injections
- Surgery on nerves near the spinal cord
- Splints or casts for arms or legs

Work with your child's doctor to decide which management option (or combination of management options) best suits you and your child's needs.

Note: It is common to use more than one management option for spasticity in children.

What are common goals and expectations when managing spasticity?



- **Improved ability to care for your child's affected limb/limbs**

Clenched fists or curled toes can be difficult to clean under/in between.



- **Improved every day (active) function**

Ideally, you want your child to participate in their daily activities without as much pain or difficulty moving.



- **Pain relief**

A goal of management is to be able to relax muscles and lessen painful spasms.



- **Improvement in mobility**

Being able to move and use the affected limb/limbs better than the child could before therapy is a common goal of spasticity treatment.

Setting management goals

Setting goals for treatment can be very helpful and is very important to include in the management of your child's spasticity.

Keeping track of goals can help you and your child's doctor monitor how well the treatment is working for your child, and adjust it as your child's treatment needs evolve.

Work together with your child and their care team when setting treatment goals. In addition to working with their doctors, try to involve your child in the discussion and allow them to contribute.

Note: When using an injection as part of a management approach for spasticity, the amount of medicine injected as well as the muscles that are injected can change. It all depends on how well your child responds to the medicine. Your doctor will monitor their progress closely to determine whether to make these adjustments. Using goals to track their progress can help this process.

Helpful hints for goal setting

- **Are the goals specific?** Tommy wants to dress himself in the mornings.
 - **Are they measurable?** Which items of clothing does he struggle to put on, and does putting them on become easier with treatment?
 - **Are they realistic?** Is this goal achievable, taking into account Tommy's level of muscle stiffness? Would a less challenging goal suit him better?
 - **Do they have an end date?** Is there a specific time by which Tommy would like to consistently dress himself in the morning?
-

What is Dysport?

Dysport is a type of muscle injection therapy called a botulinum toxin. It is a medicine that a doctor injects into muscles that are stiff.

Whether you are trying a botulinum toxin for the first time, or trying a different one, the following information can help you and your healthcare team decide if Dysport could be the right option for your child.

How is it administered?

Your doctor injects Dysport into your child's affected muscles. The goal is to reduce stiffness and improve your child's ability to move the affected limb(s).

Dysport is approved by the FDA.

2009: Dysport receives its first FDA approval in the treatment of cervical dystonia in adults.

2015: Dysport receives an FDA approval in adult spasticity.

2016: Dysport became the first FDA-approved botulinum toxin for the treatment of pediatric lower limb spasticity.

Dysport is now approved for the treatment of upper and lower limb spasticity in adult and pediatric patients 2 years of age and older, including CP patients, in addition to the treatment of cervical dystonia in adults.

IMPORTANT SAFETY INFORMATION

What is the most important safety information I should know about Dysport? (continued)

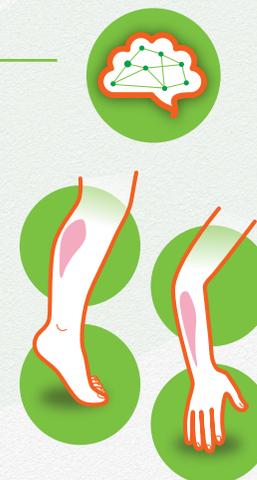
Do not receive a Dysport injection if: you are allergic to Dysport or any of its ingredients, or cow's milk protein; you had an allergic reaction to any other botulinum toxin product, such as Myobloc®, Botox®, or Xeomin®; or you have a skin infection at the planned injection site.

Please see Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#) with [Important Warning](#).

How does Dysport work?

Dysport helps to temporarily block signals from the brain from reaching the affected muscles.

By blocking these signals, Dysport prevents the brain from telling the muscles to become too tight or stiff.



This helps the muscles relax for up to 4 to 5 1/2 months in most patients (possibly longer).

Longer relief from symptoms of spasticity could mean fewer injection sessions for your child.

IMPORTANT SAFETY INFORMATION

Before you receive a Dysport injection tell your doctor:

- **About all your medical conditions**, including if you have a disease that affects your muscles and nerves (such as ALS or Lou Gehrig's disease [amyotrophic lateral sclerosis], myasthenia gravis, or Lambert-Eaton syndrome). You may be at increased risk of serious side effects, including difficulty swallowing or breathing.

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(abobotulinumtoxinA)

Dysport was studied in 2 separate studies for children

The upper limb study (2014-2018)

A total of 210 children with upper limb spasticity participated in this study. All of them received Dysport, and were divided evenly into three groups of 70. The first group were given a high dose of Dysport, the second group were given a medium dose, and the third group were given a low dose. After the first injection, doctors measured the reduction in upper limb stiffness at 1 1/2 months, and recorded their overall impression of how each child responded to treatment. They recorded their overall impression again after 4 months.

The lower limb study (2011-2014)

A total of 235 children with lower limb spasticity participated in this study. 158 were given Dysport, and 77 were given a placebo. After the first injection, doctors measured the reduction in lower limb stiffness at 1 month, and recorded their overall impression of how each child responded to treatment. They recorded their overall impression again after 3 months.

Common side effects seen in the clinical studies

In the lower limb study

- Common cold
- Stuffy or runny nose, and sore throat
- Flu, cough, and fever

In the upper limb study

- Common cold

IMPORTANT SAFETY INFORMATION

Before you receive a Dysport injection tell your doctor: (continued)

- **If you have or have had any of the following:** a side effect from any botulinum toxin in the past; problems with breathing such as asthma or emphysema; swallowing; bleeding; diabetes; and slow heartbeat, or problems with your heart rate or rhythm.

Clinical study results



In the upper limb study, the patients with the longest-lasting results were those who received the high dose of Dysport. Most patients got another injection around 5 to 7 months after their first injection, but some patients' results lasted for up to a year.



In the lower limb study, most patients' results lasted for 4 to 5 months after their first injection, but some patients' lasted for as long as 6 to 7 months.

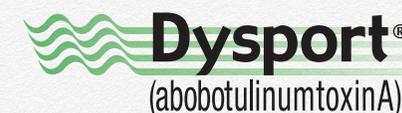
For more information on the Dysport clinical trials, please visit www.Dysport.com.

IMPORTANT SAFETY INFORMATION

Before you receive a Dysport injection tell your doctor: (continued)

- **If you have plans to have surgery,** had surgery on your face, have weakness of your forehead muscles (trouble raising your eyebrows), drooping eyelids, or any other change in the way your face normally looks.

Please see Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#) with **Important Warning**.

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If you're interested in learning more, talk to your child's doctor about Dysport today

Helpful questions

- What results can I expect with Dysport injections?
- How long do results typically last?
- What side effects should I know about?
- When do I schedule another treatment appointment?
- What is the injection experience like?
- What treatment goals should I set for my child?



See if Dysport could be right for your child.
Ask their doctor today.

IMPORTANT SAFETY INFORMATION

Before you receive a Dysport injection tell your doctor: (continued)

- **If you are pregnant or breastfeeding or plan to become pregnant or breastfeed.** It is not known if Dysport can harm your unborn baby or if it passes into breast milk.

Please see Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#) with [Important Warning](#).

IMPORTANT SAFETY INFORMATION

Before you receive a Dysport injection tell your doctor: (continued)

- **About all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal products. Using Dysport with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received Dysport in the past.**

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Once you and your doctor decide Dysport is right for your child, treatment will begin. Here's what you can expect, and some helpful tips on how to prepare

On injection day

Time

You should prepare to set aside enough time for your child's Dysport appointment. If your child is in school, he or she may miss some school or scheduled activities for that day.

Emotions

We understand that getting an injection is no fun for anyone. There are many things you can do to help minimize stress and make the day run as smoothly as possible. Consider bringing items that can make your child feel more comfortable, such as:

- A favorite toy
- Games
- Puzzles



IMPORTANT SAFETY INFORMATION

Before you receive a Dysport injection tell your doctor: (continued)

Especially tell your doctor if you have received any other injections of botulinum toxin in the last four months or ever; Myobloc®, Botox®, or Xeomin® (exactly which ones); an antibiotic recently by injection; or if you take muscle relaxants; allergy, cold or sleep medicine.

Please see Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#) with **Important Warning**.

After injection day



Results

For the first few days or weeks, you may not really see a difference in the stiffness of your child's limb(s). In the studies, results were typically seen around 4 weeks after their treatment session. However, the time can vary for each child.

Common side effects

Mild side effects such as soreness around the injection site, cough, and runny nose are common after injection with Dysport. Your child may also feel tired or fatigued afterward and want to rest. **Keep an eye out for side effects and call your child's doctor immediately if they worsen or persist.**

Additional therapy

Your child's doctor will suggest they continue with a physical therapy regimen as part of their spasticity management plan.

Does it sound like Dysport could be right for your child? Talk to their doctor.

IMPORTANT SAFETY INFORMATION

Most Common Side effects of Dysport in:

- **children (2 to 17 years of age) with upper limb spasticity include:** upper respiratory infection and sore throat.
- **children (2 to 17 years of age) with lower limb spasticity include:** upper respiratory infection, stuffy or runny nose and sore throat, cough, and fever.

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Tracking progress with Dysport

It is helpful to track your child's progress between injection sessions with a notebook or calendar. **You can also track the goals you discussed with your child and their doctor, and revisit them at the follow-up appointment.**

At each treatment session, the doctor will assess your child's progress.

Based on how your child is responding to treatment, their doctor may adjust the amount of Dysport they give your child. They may also change the muscles they inject.

Communicating changes and progress with your child's doctor is very important. It helps them make adjustments so that treatment is tailored to your child.



IMPORTANT SAFETY INFORMATION

Most Common Side effects of Dysport in: (continued)

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Dysport. For more information, ask your doctor or pharmacist. You may report side effects to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

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Things to keep track of for your child's doctor

- How is your child responding to the injection?
- Has their ability to move improved?
 - When did you start to see a response?
 - Has their ability to do everyday tasks improved?
- Are they experiencing any side effects?
 - What are they?
 - How long do they last?
- How long after their injection do you notice their symptoms of spasticity returning?



Annika was compensated for her appearance.

Annika, a child with spasticity who receives Dysport treatment

“ We are very pleased with how Annika is doing on Dysport. She moves smoother and faster...and she doesn't have to work as hard.... ”

—Wendi, Annika's mother

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IPSEN CARES is a support program with a team of Patient Access Specialists who can:

- Help patients navigate the insurance coverage process to determine out-of-pocket costs for treatment
- Help with copay assistance for eligible* patients
- Provide free medication to eligible† patients through the Patient Assistance Program (PAP)
- Coordinate medication deliveries through specialty pharmacies
- Help minimize delays or interruptions to treatment



To learn more about IPSEN CARES, visit www.ipsencares.com or call an IPSEN CARES Patient Access Specialist at 866-435-5677.

Representatives are available Monday through Friday from 8:00 AM to 8:00 PM ET (5:00 AM to 5:00 PM PT).

***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, Michigan, 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.

Please see Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#) with [Important Warning](#).

DYSPORT COPAY ASSISTANCE PROGRAM

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

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

Patient Eligibility & Terms and Conditions (continued)

Cash-pay patients are eligible to participate. "Cash-pay" patients are defined for purposes of this program as patients without insurance coverage or who have commercial insurance that does not cover Dysport[®]. Medicare Part D enrollees who are in the prescription drug coverage gap (the "donut hole") are not considered cash-pay patients and are not eligible for copay assistance through IPSEN CARES[®]. For patients with commercial insurance who are not considered to be cash-pay patients, the maximum copay benefit amount per prescription is an amount equal to the difference between the annual maximum copay benefit of \$5,000 and the total amount of copay benefit provided to the patient in the Dysport[®] Copay Program. In any calendar year commencing January 1, the maximum copay benefit amount paid by Ipsen Biopharmaceuticals, Inc. will be \$5,000, covering no more than four (4) Dysport[®] treatments. For cash-pay patients, the maximum copay benefit amount per eligible Dysport[®] treatment is \$1,250, subject to the annual maximum of \$5,000 in total. There could be additional financial responsibility depending on the patient's insurance plan.

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 RxCrossroads by McKesson 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.

†Patients may be eligible to receive free drug if they are experiencing financial hardship or have no insurance coverage, and have received a prescription for an on-label use of Dysport, as supported by information provided in the Program application. Eligibility does not guarantee approval for participation in the program. The PAP provides Dysport product only, and does not cover the cost of previously purchased product or medical services.

Advocacy groups and support services

There are also many different advocacy groups and support services available:

CHILD NEUROLOGY FOUNDATION

An organization that provides education and support for caregivers and parents of children with neurologic conditions

Website: www.childneurologyfoundation.org

Contact:

Child Neurology Foundation
201 Chicago Avenue #200, Minneapolis, MN 55415
info@childneurologyfoundation.org
Phone: 612-928-6325

CEREBRAL PALSY FOUNDATION

A multi-service organization that provides helpful information and resources to the cerebral palsy community. Fact sheets, videos, product recommendations, and blogs are only some of the resources they offer

Website: www.yourcpf.org

Contact:

Cerebral Palsy Foundation
3 Columbus Circle, 15th Floor, New York, NY 10019
info@yourcpf.org
Phone: 212-520-1686

CHILDREN'S CEREBRAL PALSY MOVEMENT

An organization that provides families affected by cerebral palsy with emotional, social, and academic support, including important resources designed to enhance knowledge for the long-term benefit of their child

Website: www.childrenscerebralpalsymovement.org

Contact:

Debbie Fagner, Executive Director & Founder
info@childrenscerebralpalsymovement.org
Phone: 714-746-4085

UNITED CEREBRAL PALSY

A network of affiliates working to improve the lives of caretakers and parents of children with cerebral palsy through education, research, and advocacy

Website: www.ucp.org

Contact:

United Cerebral Palsy
1825 K Street NW Suite 600, Washington, DC 20006
Phone: 202-776-0406

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**MORE
TIME
HERE**

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