Helping your child (2 and older) with Lower Limb Spasticity
DISCOVER **DYSPORT**

The first and only FDA-APPROVED botulinum toxin therapy to treat children with lower limb spasticity

What is Dysport?

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

- increased muscle stiffness in children 2 years of age and older with lower limb spasticity

It is not known whether Dysport is safe or effective in children under 2 years old for the treatment of lower limb spasticity; for treating other types of muscle spasms; or for treating cervical dystonia or upper limb spasticity in children under 18 years of age.

HELPING YOU GET **STARTED**

Whether your child has just been diagnosed with lower limb spasticity, a condition that causes muscle stiffness and involuntary muscle spasms, or you are looking for additional treatment options for a child who is already on therapy, you probably have a lot of questions.

At Ipsen, our goal is to help children and their caregivers learn about the overall management of lower limb spasticity and options for treatment of increased calf muscle stiffness.

This booklet contains basic information about lower limb spasticity and botulinum toxin therapy (a type of muscle injection therapy) for lower limb spasticity, as well as tips for making treatment sessions more comfortable for your child, questions to ask your healthcare team, and where to find additional information.

When it comes to what’s next, **BRING IT ON**
IMPORTANT SAFETY INFORMATION

What is the most important 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.
WHAT IS LOWER LIMB SPASTICITY?

Lower limb spasticity, or increased stiffness or tightness in lower limb muscles, is usually caused by damage to the spinal cord or parts of the brain that control movement.

Because of this damage, the nerve signals between the brain, spinal cord, and muscles are interrupted, which may lead to stiffness or muscle spasms.

As a result, the calf muscles tense up so much that the ankle cannot flex as needed, so the foot is often pointed down and in.

This is called equinus foot deformity, and it is why children with lower limb spasticity often walk on their toes.

IMPORTANT SAFETY INFORMATION

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 accompanying full Prescribing Information including Boxed Warning and Medication Guide.
TREATMENT TAKES A TEAM APPROACH

While there is no cure, there are several treatments for lower limb spasticity that can help you and your child manage his or her condition and lessen symptoms. You’ll want to form a partnership with your treatment team, and learn about all of your treatment options.

A comprehensive team approach can help you set goals and make necessary adjustments to improve your child’s overall spasticity management. His or her treatment plan will likely include work with a physical and/or occupational therapist after the injection to help loosen the affected area.

Together, you will ultimately decide which type of therapy could be right for your child.

TREATMENT WITH DYSPORT

In 2016, Dysport became the first and only botulinum toxin therapy approved by the FDA to treat increased muscle stiffness in calf muscles in children 2 years of age and older with lower limb spasticity.

For the FDA to approve its use in children, Dysport was specifically studied in a clinical trial with 235 children aged 2 to 17 years who had lower leg spasticity because of cerebral palsy, causing dynamic equinus foot deformity. Dysport was given to 158 of the children; 77 received a placebo.
HOW DYSPO RT WORKS

Dysport works by blocking the overactive nerve signals from getting to the muscles. Without receiving those signals, the muscles are weakened for up to 4 to 5 1/2 months, or possibly longer. This may help lessen your child’s symptoms.

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.

- **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.
In the clinical trial, doctors measured how well Dysport was working at Week 4 in 2 main ways:

- Change in calf muscle stiffness (muscle tone)
- The doctor's overall impression of how each patient responded to treatment

Each child (aged 2 and older) had a follow-up visit a month after their Dysport treatment session to see if they had improvement in muscle stiffness, and for the doctor to give his or her overall impression of their response to treatment.

The children also had follow-up visits starting at 3 months to see if the effects of the previous injection had lessened and if it was time for another Dysport treatment session. The next Dysport treatment should not be given sooner than 12 weeks after the last Dysport treatment session. Your healthcare professional will assess your child’s lower limb spasticity at each treatment session and may adjust the dose and muscles injected.

Treatment with Dysport can be repeated when the benefits from the previous treatment have decreased, but there should be at least 12 weeks between treatments.
CLINICAL RESULTS IN CHILDREN WITH LOWER LIMB SPASTICITY

By the first follow-up visit, 1 month after the initial Dysport treatment session, many of the children (aged 2 and older) treated with Dysport had less stiffness in their calf muscles, and doctors reported that the children had responded to treatment. These were significant improvements compared to children who did not receive Dysport treatment (placebo).

What are the possible side effects of Dysport?

The most common side effects of Dysport in children (2 to 17 years of age) with lower limb spasticity include: upper respiratory infection, stuffy or runny nose and sore throat, flu, cough, and fever.

TIME UNTIL THE NEXT TREATMENT SESSION

Your healthcare professional will look at your child’s level of spasticity and spasms to figure out when to schedule another Dysport treatment session after at least 3 months or longer.

In the Dysport clinical trial, many patients were retreated between 4 and 5 ½ months. Some patients may have a longer time to retreatment.

Approximately 6 out of 10 children were retreated between 4 and 5 1/2 months
The office visit could last several hours or even the whole day. If your child goes to school, he or she will probably miss school or any other activities usually planned for that day. Prepare yourself with books, soft toys, crayons, and other comforts from home to help the day go as smoothly as possible.

Getting injections during a treatment session is no fun for anyone, especially kids. As a parent, it can be difficult to see your child in distress.

Your treatment team will likely know what you’re going through and may be able to help.

IMPORTANT SAFETY INFORMATION

Before you receive a Dysport injection tell your doctor:

- **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.

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

- **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.**
THE DAYS AHEAD

For the first few days or weeks, you may not really see a difference in the stiffness in your child’s leg(s). In the study, results were typically seen in children (aged 2 or older) by 4 weeks after their treatment session. However, the time to see results can vary for each child. After Dysport is injected into muscles, those muscles are weakened for up to 16 to 22 weeks or longer. This may help lessen your child’s symptoms. After the injection, your child can continue with physical or occupational therapy.

The most common side effects of Dysport are upper respiratory infection, stuffy or runny nose, sore throat, flu, cough, and fever.

Talk to your doctor if your child has any side effects. For more information about the possible side effects, ask your doctor.

IMPORTANT SAFETY INFORMATION

Before you receive a Dysport injection tell your doctor:

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.
Dysport injection therapy is not a cure. The effects of each Dysport treatment session will lessen over time, and another treatment session will be needed to reduce the calf muscle stiffness again.

In the Dysport clinical trial, many patients were retreated between 4 and 5½ months. Some patients may have a longer time to retreatment. Treatment with Dysport can be repeated when the benefits from the previous treatment have decreased, but there should be at least 12 weeks between treatments.

Work with your child’s healthcare team to evaluate your child’s progress, and ask them to teach you how to know when it’s time for the next treatment session.

Remember, you may need time to schedule your child’s next appointment, to take time off from work, and to arrange for travel to and from your child’s doctor’s office or clinic. The healthcare professionals on your child’s treatment team may be able to help you plan your visits. Keep them informed about your child’s treatment and your plans.
QUESTIONS TO ASK YOUR CHILD’S HEALTHCARE TEAM ABOUT TREATMENT

The best way to advocate for your child is to ask questions of his or her healthcare team. Be sure to keep this list of questions handy when talking to any of your child’s healthcare providers, and write down any additional questions you want to discuss at your next visit.

What should I expect from Dysport therapy?

How will I know that Dysport therapy is working?

When should I schedule another treatment session?

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

What are the possible side effects of Dysport?

What can we do to make my child more comfortable during the treatment?

How do I explain Dysport therapy to my child?

Can I be in the room during the treatment?

Who do I call if I have questions between appointments?

How soon after treatment should physical or occupational therapy continue?
IMPORTANT SAFETY INFORMATION

Most Common Side effects of Dysport in:

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

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.
IPSEN CARES® is your dedicated resource

- Navigate the insurance coverage process
- Provide copay assistance for eligible* patients
- Provide free medication to financially eligible patients through the Patient Assistance Program
- Help minimize delays or interruptions in therapy

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

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

*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, 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 free starter therapy through the IPSEN CARES® program are not eligible for the copay assistance program while they are waiting for insurance prescription coverage to begin. Patients receiving assistance through another assistance program or foundation, free trial, or other similar offer or program, also are not eligible for the copay assistance program during the current enrollment year.

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®. 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. Offer expires December 31, 2019.
Cerebral Palsy Foundation
http://yourcpf.org
3 Columbus Circle, 15th Floor
New York, NY 10019
212-520-1686

Child Neurology Foundation
www.childneurologyfoundation.org
201 Chicago Avenue #200
Minneapolis, MN 55415
612-928-6325

Reaching for the Stars
www.reachingforthestars.org
3000 Old Alabama Road, Suite 119-300
Alpharetta, GA 30022
855-240-7387

United Cerebral Palsy (UCP)
www.ucp.org
1825 K Street NW, Suite 600
Washington, DC 20006
202-776-0406/800-USA-5UCP (872-5827)
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BRING IT ON

IMPORTANT SAFETY INFORMATION (continued)
Dysport® and all botulinum toxin products have a Boxed Warning which states that the effects of the botulinum toxin may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism. Those symptoms include swallowing and breathing difficulties that can be life-threatening.

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