

Dysport®
(abobotulinumtoxinA)

Treatment for **Adult Spasticity**



What is Dysport®?

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

- increased muscle stiffness in adults with spasticity
- 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.

Please see accompanying Full Prescribing Information, including Medication Guide with **important warnings about the spread of toxin, which can be life threatening.**

What is Adult Spasticity?

If you have suffered a stroke, traumatic brain or spinal cord injury, or if you have been diagnosed with multiple sclerosis (MS) or cerebral palsy, you may have spasms and stiffness in your arms, legs, or both. These spasms and stiffness may be due to a condition known as spasticity.

Spasticity can occur when the nerve cells that carry messages from your brain to different parts of your body are damaged. When this happens, the affected muscles in your limbs may receive the wrong signals. This can cause your muscles to contract or tense up, leading to stiffness and tightness.

Developing spasticity can be a turning point in your life, because the extreme stiffness can be painful. It can also interfere with movement and your ability to perform simple tasks. If you think you might have adult spasticity, it's important to identify it and discuss treating it with your doctor right away. Together, you and your healthcare team can create a plan that's right for you.

Limb spasticity at a glance:

- Caused by: stroke, brain injury, multiple sclerosis, cerebral palsy, spinal cord injury, or other medical conditions

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.

Please see accompanying Full Prescribing Information, including Medication Guide with **important warnings**.

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Adult Upper Limb Spasticity



Flexed elbow



Clenched fist



Flexed wrist

Adult Lower Limb Spasticity



Equinovarus foot



Plantar flexed foot/ankle



Flexed toes



Ask your doctor about Dysport for spasticity

In the United States, approximately 2.4 million adults experience some form of lower limb spasticity related to various medical conditions, including

- Stroke - 1,495,000
- Cerebral Palsy - 649,400
- Multiple Sclerosis - 268,000

Talk to your doctor about how you may benefit from treatment with Dysport.

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

- 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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Reduce muscle stiffness with Dysport®



How Dysport works

- Dysport (*DIS-port*) is a type of prescription medicine called botulinum toxin type A that works by temporarily blocking the signals that cause muscles to tighten (contract)
- It is an injection in your arm or leg muscles right in your doctor's office
- In a clinical study, most patients needed treatment again between 3 and 4 months. In the same study, some patients had a longer response to Dysport and were treated again at 5 months

The next Dysport treatment should not be given sooner than 12 weeks after the last Dysport treatment session. Your healthcare professional will assess your spasticity at each treatment session and may adjust the dose and muscles injected.



A history of FDA-approved indications

2015

Adults with upper limb spasticity

2016

Children with lower limb spasticity (ages 2 and older)

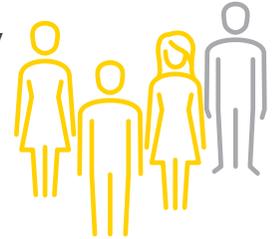
2017

Expanded indication for adult spasticity to include lower limb

How Dysport worked in clinical trials

Effective for the majority of patients with adult upper limb spasticity who showed improvement in muscle tone at Week 4.

For adults with upper limb spasticity, approximately 3 out of 4 patients had a response to treatment at Week 4 as measured by a reduction in stiffness in the elbow, wrist, or finger muscles.



- For some patients, improvement was seen 1 week after treatment

Study design: In a study of 238 adults with upper limb spasticity due to stroke or traumatic brain injury were treated with either Dysport or placebo. 4 weeks later, doctors assessed improvement in muscle tone, as well as reduction in stiffness (elbow, wrist, and finger muscles), and overall response to treatment. About half of the patients had never been treated with a botulinum toxin while the rest had previously received botulinum toxin treatment.

For adults with lower limb spasticity, nearly half of patients treated with Dysport had a response to treatment at Week 4 as measured by a reduction in muscle stiffness at the ankle joint.



- For some patients, improvement was seen 1 week after treatment

Study design: In a study of 381 adults with lower limb spasticity, after stroke or traumatic brain injury, about 2 out of 3 were new to treatment while the rest had received treatment before; patients received Dysport or placebo for 4 weeks. At Week 4, doctors checked the ankle for improvement in muscle tone.

Who should not take Dysport

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.

Information to discuss with your doctor before getting started on Dysport®



Questions to ask

Your doctor is your best source of information about adult spasticity and treatment with Dysport. Whether you have just been diagnosed with spasticity or you are looking to start treatment, you probably have a lot of questions.

Here is a list of things you may want to ask during your visit:

- What should I expect from Dysport treatment?
- How will I know that Dysport therapy is working?
- When should I schedule another treatment session?
- What is the Important Safety Information I should know about Dysport?
- What are the possible side effects of Dysport?

Your medical history

Before starting treatment with Dysport, you should tell your doctor about all of your medical conditions, especially any that may affect your muscles and nerves. You should also inform your doctor if you have or have had:



- Any problems with breathing, swallowing, or bleeding
- A slow or irregular heartbeat or rhythm
- Diabetes
- Any side effect or allergy to any botulinum toxin product

These are not all the possible side effects.

Please refer to pages 14 and 15 for Full Important Safety Information.

Please see accompanying Full Prescribing Information, including Medication Guide with **important warnings**.

Prior treatment

It is important to **inform your doctor** if you have ever received any other botulinum toxin products in the past or had an allergic reaction to Botox® (onabotulinumtoxinA), Xeomin® (incobotulinumtoxinA), or Myobloc® (rimabotulinumtoxinB), or had treatment with any of these products in the last 4 months.

Also, **let your doctor know** if you have recently received an antibiotic by injection or are currently taking any prescription or nonprescription medications, muscle relaxants, sleep medicines, allergy/cold medicines, vitamins, or herbal supplements.

Before starting any new medicines, be sure to tell your doctor if you have ever had treatment with Dysport.

You can receive treatment with Dysport even if you have been treated with another botulinum toxin in the past.

Dysport was studied in adults with spasticity, including those who had:

- Already used another botulinum toxin
- Never used any botulinum toxin

Tell your doctor if you are allergic to any of the inactive ingredients in Dysport, including human albumin or cow's milk protein.

Also, let your doctor know if you are:

- Planning to have surgery
- Pregnant or plan to become pregnant; it is not known if Dysport can harm your unborn baby
- Breastfeeding or planning to breastfeed; it is not known if Dysport can pass into breast milk



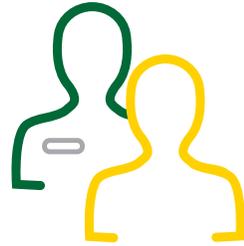
Take action! Don't hold back

It is important to be open and honest with your doctor about how you are feeling. Together, you can create a treatment plan that's right for you.



What to expect

In clinical studies, Dysport helped reduce stiffness in both upper and lower limb spasticity. Upper limb spasticity is caused by muscle spasms in the elbow, wrist, and finger muscles. Lower limb spasticity is caused by muscle spasms in the toe and ankle muscles. As a result, these spasms cause an abnormal position of these muscles.



After Dysport is injected into muscles, those muscles are weakened for up to 12 to 16 weeks or longer. This may help lessen your symptoms.

Dysport is given by a specialist...and treatment is based on your individual needs.

Here's what may happen during a typical office visit:

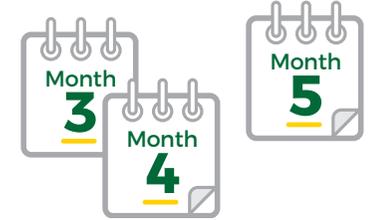
- Dysport is given as an injection into your affected muscles
- Depending on how many muscles are affected, your doctor may give you injections in a few different muscles
- Your doctor may tailor the amount of injections or dose of Dysport to your individual needs



Use the activity tracker at the back of this booklet to describe your day-to-day life while on Dysport

About treatment sessions

In a clinical trial, most patients needed treatment again between 3 and 4 months. Some had a longer response and were treated again at 5 months.



After you have an injection of Dysport, the effects of treatment will lessen over the next several weeks. Because Dysport injection therapy is not a cure, another treatment session will be needed to reduce the muscle stiffness again.

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. Your doctor will decide when you are ready for another Dysport treatment session.

Recognize possible side effects

The most common side effects of Dysport in adults with upper limb spasticity include: urinary tract infection, muscle weakness, musculoskeletal pain, fall, depression, stuffy or runny nose and sore throat, and dizziness.

The most common side effects of Dysport in adults with lower limb spasticity include: muscle weakness, pain in arms or legs, and fall.

Please refer to pages 14 and 15 for Full Important Safety Information.



Stick to your treatment plan

Everyone responds to treatment differently, so remember to ask your doctor if you have any concerns. Your doctor might adjust your treatment plan accordingly.

The Dysport® Copay Assistance Program



Patient savings on private insurance copay, deductible, and coinsurance costs

Savings may be applied for up to **four injections*** per calendar year.

Savings

Eligible^{††} patients may receive up to \$5,000:

- Beginning or currently receiving treatment with Dysport®
- Being treated for an approved indication for Dysport®
- Currently have commercial insurance that covers the medication and associated cost of Dysport®, or uninsured patients who pay their entire out-of-pocket cost

*In any calendar year commencing January 1, the maximum copay benefits paid by Ipsen Biopharmaceuticals, Inc. will be \$5,000, covering no more than (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 Eligibility

†Patients who are eligible to participate (i.e. prescriptions or coverage could be paid in part or in full) in any state or federally funded programs, including, but not limited to, Medicare or Medicaid, VA, DOD, or TRICARE (collectively, "Government Programs") are not eligible for copay assistance through IPSEN CARES®. 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 current enrollment year.

Please see accompanying Full Prescribing Information, including Medication Guide with **important warnings**.

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IPSEN CARES®
Coverage, Access, Reimbursement & Education Support



IPSEN CARES® is dedicated to helping you receive your treatment with Dysport®

The IPSEN CARES® program was designed to help you:

- Navigate the insurance coverage process
- Provide copay assistance for eligible^{††} patients
- Provide free medication to financially eligible patients through the Copay Assistance Program
- Avoid delays or interruptions in therapy



To learn more about IPSEN CARES®, visit IpsenCares.com

or call **(866) 435-5677** to speak to an IPSEN CARES® Patient Access Specialist.



Terms and Conditions

†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 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 TrialCard, Incorporated are not responsible for any transactions processed under this program where Medicaid, Medicare, or Medigap payment in part or full has been applied. Cash-paying 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 the copay benefit. Data related to your 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 you. 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, 2018.

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Treatment Tracker



Tracking your experience after a Dysport® injection can be a helpful tool in your discussions with your doctor about treatment for adult spasticity. Take notes on how your symptoms have changed and how you are feeling, and start a discussion with your doctor on your next appointment about how Dysport may have helped those symptoms.

1 What is your expectation while on treatment?

2 What changes have you noticed in your muscle stiffness since your first injection?

3 Have you noticed anything different about how you are able to move your arms or legs?



4 What improvements have you seen since your last Dysport injection?

5 Have you experienced any side effects?

6 Are you experiencing any new symptoms?

7 What is your typical day like?

Important Safety Information



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

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- **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.

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.

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.

- **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 breastfeed.** 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.**
- **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.

Most common side effects of Dysport in:

- **adults with upper limb spasticity include:** urinary tract infection, muscle weakness, musculoskeletal pain, fall, depression, stuffy or runny nose and sore throat, and dizziness.
- **adults with lower limb spasticity include:** muscle weakness, pain in your arms or legs, and fall.
- **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.

Please see accompanying Full Prescribing Information, including Medication Guide with **important warnings.**



Treatment for **Adult Spasticity**



Additional information and support are also available through these organizations:

- ◆ **Caregiver Action Network**
1-202-454-3970
caregiveraction.org
- ◆ **Alliance for Patient Access**
1-202-499-4114
allianceforpatientaccess.org
- ◆ **American Stroke Association**
1-888-4-STROKE (1-888-478-7653)
strokeassociation.org
- ◆ **National Stroke Association**
1-800-STROKES (1-800-787-6537)
stroke.org
- ◆ **Brain Injury Association of America**
1-800-444-6443
biausa.org
- ◆ **Paralyzed Veterans of America**
1-800-424-8200
pva.org

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For more information on Dysport,
visit www.dysport.com



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