

Treating Adults with Cervical Dystonia



Learn more about Dysport

Talk to your doctor about Dysport and find out if it is right for you.

What is Dysport?

Dysport is a prescription medicine that is injected into muscles and used to treat cervical dystonia (CD) in adults.

It is not known whether Dysport is safe and effective for treating cervical dystonia in children under 18 years of age.

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.

Please see full Prescribing Information in the pocket, including **Boxed Warning** and Medication Guide.

**Dysport**[®]
(abobotulinumtoxinA)

About Adult Cervical Dystonia

Cervical Dystonia (CD), also called spasmodic torticollis, occurs when nerve signals tell the neck muscles to tighten or spasm. This can lead to abnormal head positions and/or neck pain.

In adults with CD, the abnormal position of the head may vary, depending on the muscles that are affected, as shown below.



Head tilting forward
(known as anterocollis)



Head tilting backward
(known as retrocollis)



Head turning to the side
(known as rotational torticollis)



Head tilting to the side
(known as laterocollis)

The most common form of cervical dystonia is rotational torticollis, but it is common to have a combination of different position types.

Important Safety Information (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.

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How Is Cervical Dystonia Treated?

There is no cure for CD. In some people, signs and symptoms may disappear without treatment, but recurrence is common. Treatment focuses on relieving the muscle spasms and symptoms of abnormal head position and neck pain. One of these treatments for cervical dystonia is called a botulinum toxin. It is a prescription medication that is injected directly into affected muscles to treat abnormal head position and neck pain. There are different botulinum toxins available.

Each patient may respond differently to treatment.

Important Safety Information (continued)

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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How Dysport May Help You

Dysport is a type of prescription medicine called a botulinum toxin type A that is injected into muscles of adults with CD. Dysport works by helping to temporarily block the nerve signals that tell the affected muscles to contract. The muscles injected are weakened for up to 12 to 16 weeks, or longer in some patients. This can help lessen your symptoms of muscle spasms and neck pain.

What are the potential benefits of treatment with Dysport?

Dysport has been proven to help relieve the symptoms of abnormal head position and neck pain in adults who have CD.

In clinical studies, Dysport significantly improved abnormal position of the head and reduced neck pain at **Week 4**.

Important Safety Information (continued)

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.

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Treatment With Dysport

How is Dysport treatment given?

Dysport is given as an injection into your affected muscles by your doctor. Depending on how many muscles are affected, your doctor may give you injections in a few different muscles. Your doctor will tailor the amount of Dysport given and the locations of the injections to your individual needs. Your doctor may also change your dose of Dysport until the best dose for you is found.

How long before my symptoms come back?

In clinical trials, treatment lasted for
14 weeks for most patients.

And 25% of patients were not retreated for at least 18 weeks.

Two clinical studies included 252 patients who were new to treatment and either received Dysport or placebo. At Week 4, doctors assessed how well Dysport was working by checking the change in dystonia and patient perception of disability and pain from dystonia. Most patients did not need additional treatment until 14 weeks, and about 25% were able to wait until 18 weeks.

Based on studies of patients with CD, at least 12 weeks should pass between treatments with a toxin.

Important Safety Information (continued)

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.
- **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.



Dysport[®]
(abobotulinumtoxinA)

Support When You Need It

Dysport Copay Assistance Program

Eligible* Commercially-Insured Patients Can Receive Dysport for Little or No Copay

You can save up to \$5,000 if eligible for out-of-pocket expenses every calendar year. Here is how the Dysport Copay Assistance Program works:

- Patient receives treatment with Dysport. Physician follows standard procedure for collection of patient copay
- Provider submits claim to patient's insurance company and to the program. (Instructions to submit claims to the program will be sent to the provider's office)
- IPSEN CARES® will process each claim and notify the patient and provider of the claim status
- Physician office will receive funds for approved claims directly from the program

To learn more about the Dysport Copay Assistance Program, visit www.IPSENCARES.com/dysport-patient-support

Eligible* commercially-insured patients may **save** up to

\$5,000 annually on out-of-pocket expenses for Dysport.

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 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, 2020.

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

IPSEN CARES can help:

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

**To learn more about IPSEN CARES,
visit [IpsenCares.com](https://www.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.

†Patients may be eligible to receive free drug if they are experiencing financial hardship, have no insurance coverage, are US residents, and 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 Patient Assistance Program provides Dysport product only, and does not cover the cost of previously purchased product or medical services.



More Support for Patients and Caregivers

Reach for additional help when you need it

Living with CD can be challenging. You are not alone—support and additional resources are available for you and those who care for you:

Dystonia Medical Research Foundation

1-800-377-DYST (3978)

www.dystonia-foundation.org

National Spasmodic Torticollis Association

1-800-487-8385 (HURTFUL)

www.torticollis.org

American Dystonia Society

310-237-5478



Important Safety Information (continued)

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.**

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.

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Important Safety Information (continued)

Most Common Side effects of Dysport in adults with cervical dystonia include: muscle weakness, difficulty swallowing, dry mouth, injection site discomfort, tiredness, headache, muscle pain, problems speaking, injection site pain and eye problems.

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.

**Dysport**[®]
(abobotulinumtoxinA)

Talk to Your Doctor About Dysport—Proven to Treat Adults with CD

Dysport—proven to help relieve symptoms of abnormal head position and neck pain in adults who have CD

- In clinical studies, Dysport (abobotulinumtoxinA) significantly improved abnormal position of the head and reduced neck pain **at Week 4**
 - Median time to retreatment was **14 weeks**
 - **25%** of patients were not retreated for **at least 18 weeks**

The most common side effects of Dysport in adults with cervical dystonia **include:** muscle weakness, difficulty swallowing, dry mouth, injection site discomfort, tiredness, headache, muscle pain, problems speaking, injection site pain and eye problems.



Find out if Dysport is right for you.
Talk to your doctor today or visit
www.Dysport.com for more information.

Please see full Prescribing Information in the pocket, including **Boxed Warning** on the spread of toxin effects, which can lead to death.

 **Dysport**[®]
(abobotulinumtoxinA)



Dysport[®] (abobotulinumtoxinA) for injection, for intramuscular use 300- and 500-Unit vials.
DYSPORT is a registered trademark of Ipsen Biopharm Limited.
IPSEN CARES is a registered trademark of Ipsen.
Botox[®], Xeomin[®], and Myobloc[®] are registered trademarks of their respective owners.