

PACKAGE LEAFLET: INFORMATION FOR THE USER

DYSPORT®

500 units

Powder for solution for injection

Clostridium botulinum type A toxin-haemagglutinin complex

Read all of this leaflet carefully, before you start using this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist or other healthcare practitioner.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or other healthcare practitioner. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Dysport is and what it is used for**
- 2. What you need to know before you are given Dysport**
- 3. How Dysport is given**
- 4. Possible side effects**
- 5. How to store Dysport**
- 6. Contents of the pack and other information**

1. What Dysport is and what it is used for

Dysport contains the active substance *Clostridium botulinum* type A toxin-haemagglutinin complex.

What Dysport is used for:

Adults:

Dysport is used in adults to treat muscle spasms:

- Around the eyes
- In the face
- In the neck
- In the arm and shoulders
- In the leg

Dysport is also used in adults to treat:

- Hyperhidrosis. This is a condition where there is excess sweating of the armpits, which interferes with daily living.
- Leakage of urine (urinary incontinence) due to bladder problems associated with spinal cord injury or multiple sclerosis.

Children:

Dysport is used in children with cerebral palsy (aged two years or older):

- To treat muscle spasms in the legs, to improve their walking
- To treat muscle spasms in the arms.

How Dysport works:

Dysport contains a toxin produced by the bacterium *Clostridium botulinum*. It works by stopping your muscles contracting. It does this by stopping the release of a chemical which acts between the nerves and muscles that makes the muscles contract. This helps to reduce abnormal muscle contractions known as spasms.

2. What you need to know before you are given Dysport**Do not use Dysport:**

- If you are allergic to botulinum toxin type A or any of the other ingredients of this medicine (listed in section 6).
- If you have a urinary tract infection at the time of receiving treatment for leakage of urine.

Warnings and precautions:

There are increased risks of having Dysport injections under any of these circumstances.

Talk to your doctor, pharmacist or other healthcare practitioner before using Dysport if:

- You have problems swallowing
- You have any history of bronchitis, pneumonia or problems with breathing
- You have had an allergic reaction to a botulinum toxin in the past
- You have other problems or diseases that affect your muscles e.g. myasthenia gravis
- You bleed easily
- You have an infection where the injection will be given or if that area is swollen
- The muscles at the proposed site of injection are weak or show signs of wasting.

When Dysport is used in the treatment of persistent muscle spasms in the eyelid and face, your eyes may become dry. Dysport may make your eyes blink less often or produce less tears, which could harm the surface of your eyes (see section 4).

At the time of the injection into the bladder to treat urine leakage, due to the procedure by which the injection is delivered, you may possibly experience uncontrolled reflex reaction of your body (autonomic dysreflexia e.g. profuse sweating, throbbing headache, increase blood pressure or increase in pulse rate).

Children and adolescents:

For the treatment of spasticity associated with cerebral palsy in children, Dysport should only be used in children 2 years of age or over.

Other medicines and Dysport:

Please tell your doctor or healthcare practitioner if you are taking any antibiotics for an infection (e.g. aminoglycosides such as gentamicin or amikacin) or muscle relaxing drugs. Some of these medicines may increase the effect of Dysport.

Tell your doctor or pharmacist or other healthcare practitioner if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility:

Dysport is not recommended during pregnancy, unless clearly necessary.

Dysport is not recommended in breast-feeding women.

Dysport may affect fertility, when given at high doses.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist or other healthcare practitioner for advice before taking this medicine.

Driving and using machines:

Dysport may cause muscle weakness or problems with your vision.

If you experience any of these effects, do not drive or use any machines.

3. How Dysport is given

Dysport must only be injected by doctors or healthcare practitioners with specific skills and experience on how to use the medicine.

Your doctor or healthcare practitioner will choose your dose of medicine and decide how often you need treatment. This will depend on what you are being treated for.

A vial of Dysport should be used only for you and only for a single treatment session.

Adults:

For treatment of muscle spasms in your *arm and shoulder*:

The dose of Dysport will usually be between 500 and 1000 units. The doctor or healthcare practitioner may divide the amount between the affected arm and shoulder muscles. Your muscle spasms should normally improve within 1 week and this improvement may last up to 20 weeks.

Injections will usually be given about every 12 to 16 weeks, depending on how long the effect lasts, but not more frequently than every 12 weeks.

For treatment of muscle spasms in your *leg*:

The dose of Dysport will usually be up to 1500 units and should not exceed this dose. The doctor or healthcare practitioner may divide the amount between the affected leg muscles.

Injections will usually be given about every 12 to 16 weeks, or longer as necessary, but not more frequently than every 12 weeks.

For treatment of muscle spasms in your *arm and leg*:

If you need to receive injections in your arm and leg in the same treatment session, your doctor or healthcare practitioner may divide the dose between your arm and leg in line with the approved dose recommendations, but the overall dose must not exceed 1500 units.

For treatment of muscle spasms in your *neck*:

The first dose of Dysport will usually be 500 units divided into a number of places in the neck, probably into 2 or 3 of the neck muscles most affected by the condition. A smaller amount may be given to very underweight or elderly patients. Your muscle spasms should improve within 1 week. Further injections (250 - 1000 units) will be given by your doctor or healthcare practitioner about every 16 weeks depending on how long the effect lasts or as required to maintain a response, but not more frequently than every 12 weeks. The maximum dose should not exceed 1000 units.

For treatment of muscle spasm around your *eyes*:

The first injection will usually be 40 units per eye. The medicine will be injected just under the skin at various sites around the eye. If only one eye is affected, the doctor or healthcare practitioner will only give injections of Dysport around this eye. Your muscle spasms should normally start improving within 2 - 4 days with maximal effect within 2 weeks. Injections will be given about every 12 weeks depending on

how long the effects last, but not more frequently than every 12 weeks. On the next visits, the amount of Dysport given may be increased to a maximum of 120 units per eye.

For treatment of muscle spasm in your *face*:

The doctor or healthcare practitioner will give you injections on the side of your face that is affected. The first injection will usually be 40 units. Injections will be given about every 12 weeks depending on how long the effects last, but not more frequently than every 12 weeks. On the next visits, the amount of Dysport given may be increased to a maximum of 120 units.

For treatment of urinary incontinence:

The first dose administered to your bladder muscle will be 600 units, but your doctor may decide to increase the dose to 800 units at the next injections.

Dysport will be administered by a procedure called cystoscopy. An instrument with a light source at the end will be introduced into your bladder through the opening by which you let out the urine (called urethra). This enables the doctor or healthcare practitioner to see the inside of the bladder and place Dysport injections into the bladder wall.

Dysport will only be administered to you if you are already performing clean intermittent catheterisation (CIC). CIC is a procedure during which a catheter (a soft, hollow tube that is inserted into your urethra to help empty urine from the bladder) is temporarily inserted into your bladder and removed once the bladder is empty. Please ask your doctor or healthcare practitioner to explain further details of the procedure to you.

You will be required to take antibiotics to prevent urinary infection. If you are taking blood thinning medication, your doctor will adjust your treatment before and after Dysport injections. You may be given a local or general anaesthetic or a sedative before the injections. You will be observed for at least 30 minutes after the injections. Your symptoms should usually improve within 2 weeks and improvement may last up to 48 weeks. Your doctor or healthcare practitioner will repeat the treatment as needed, but not more frequently than every 12 weeks.

For treatment of excessive sweating of your *armpits*:

The first dose will usually be 100 units per armpit. The doctor or healthcare practitioner may divide this amount between the affected areas. Your symptoms should usually improve within 2 weeks and the effect can last for up to approximately 48 weeks. The amount of the next dose your doctor or healthcare practitioner gives you, and when you will be given a further injection will depend on how you respond. The minimum time between treatments is 12 weeks. The maximum dose you should be given is 200 units per armpit.

Children with cerebral palsy (aged two years or older):

For treatment of muscle spasms in the *legs* of children with cerebral palsy:

Children over 2 years: The dose is decided by your doctor or healthcare practitioner. Dysport is injected into the affected muscles of the legs. The dose must not be higher than 1000 units or 30 units/kg at a given treatment session, whichever is lower. Your muscle spasms should normally improve within 2 weeks and this improvement may last up to 28 weeks. Your doctor or healthcare practitioner will repeat the treatment approximately every 16 - 22 weeks or as needed, but no more frequently than every 12 weeks.

For treatment of muscle spasms in the *arms* of children with cerebral palsy:

Children 2 years or older: The dose is decided by your doctor or healthcare practitioner. Dysport is injected into the affected muscles of the arms. The dose must not be higher than 840 units or 21 units/kg at a given treatment session, whichever is lower. Your muscle spasms should normally improve in the weeks following treatment and this improvement may last up to 34 weeks. Your doctor or healthcare practitioner will repeat the treatment approximately every 16 - 28 weeks or as needed, but no more frequently than every 16 weeks.

For treatment of muscle spasms in the *arms and legs* of children with cerebral palsy:

If treatment is required in the arms and legs during the same treatment session, the dose of Dysport to be injected in each limb should be decided by your doctor or healthcare practitioner, without exceeding a total dose per treatment session of 1000 units or 30 units/kg, whichever is lower. Your doctor or healthcare practitioner will repeat the treatment as needed, but no sooner than 12 - 16 weeks after the previous treatment session.

If you are given more Dysport than you need

If you are given more Dysport than you need, muscles other than the ones that were injected may begin to feel weak. This may not happen straight away. If this does happen, speak to your doctor or healthcare practitioner immediately. Seek urgent medical help if you have difficulty breathing, swallowing or speaking.

If you forget an injection of Dysport

Nothing will happen if an injection is missed other than some of the spasm or muscle stiffness may return. Tell your doctor or healthcare practitioner and he will decide when the next injection is needed.

If you stop taking Dysport

Your muscle spasms will return to the way they were before treatment.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or other healthcare practitioner.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Dysport may in rare cases cause side effects away from its site of injection.

Seek urgent medical help if:

- You have any problems swallowing, breathing or with your speech or you have worsened muscle weakness.
- You develop difficulty in breathing with or without swelling of the face, lips, tongue and/or throat, redness of the skin or an itchy lumpy rash (urticaria). This may mean you are having an allergic reaction to Dysport.

Some side effects may occur in any patient treated with Dysport whilst other side effects may depend on the condition being treated.

Make sure you read all the sections that apply to you.

Treatment of any condition (*all patients*):

Common: may affect up to 1 in 10 people

- Bruising, or pain around the site where the injection was given
- Generalised weakness

- Tiredness
- Flu-like symptoms.

Uncommon: may affect up to 1 in 100 people

- Itching.

Rare: may affect up to 1 in 1,000 people

- Skin rashes
- Sudden severe pain and weakness in shoulder and/or arm (neuralgic amyotrophy).

Not known: (frequency cannot be estimated from the available data)

- Numbness
- Muscle wasting.

Treatment of muscle spasms in the *arm and shoulder* of adults:

Common: may affect up to 1 in 10 people

- Muscle weakness
- Musculoskeletal pain
- Pain in the hands and fingers.

Uncommon: may affect up to 1 in 100 people

- Difficulty in swallowing.

Treatment of muscle spasms in the *leg* of adults:

Common: may affect up to 1 in 10 people

- Difficulty in swallowing
- Leg muscle weakness
- Muscle pain
- Fall.

Treatment of muscle spasms in the *eyes or face*:

Very common: may affect more than 1 in 10 people

- Drooping of the upper eyelid.

Common: may affect up to 1 in 10 people

- Double vision
- Swelling of the eyelid
- Facial muscle weakness
- Dry eyes or more tears than usual.

Uncommon: may affect up to 1 in 100 people

- Facial paralysis.

Rare: may affect up to 1 in 1,000 people

- Difficulty in moving the eye
- Edge of the eyelid turning in towards the eyeball (entropion).

Treatment of muscle spasms in the *neck*:

Very common: may affect more than 1 in 10 people

- Muscle weakness
- Difficulty in swallowing. This side effect may be expected to resolve within 2 to 4 weeks
- Dry mouth.

Common: may affect up to 1 in 10 people

- Headache
- Dizziness

- Blurred vision or other problems in seeing clearly
- Weakness of face muscles
- Stiff muscles
- Shortness of breath
- A change to the tone of the voice
- Neck pain, muscle pain, pain in the hands and fingers.

Uncommon: may affect up to 1 in 100 people

- Loss of muscle tissue
- Jaw problems
- Drooping of the upper eyelid
- Double vision
- Nausea.

Rare: may affect up to 1 in 1,000 people

- Lung inflammation caused by accidentally breathing in food, drink, saliva or vomit (aspiration pneumonia).

Treatment of muscle spasms in the *legs* of children with cerebral palsy:

Common: may affect up to 1 in 10 people

- Muscle pain
- Muscle weakness
- Urinary incontinence
- Flu-like symptoms
- Pain, redness, bruising at the injection site
- Abnormal walking
- Tiredness
- Fall.

Uncommon: may affect up to 1 in 100 people

- Loss of strength and weakness.

Treatment of muscle spasms in the *arms* of children with cerebral palsy:

Common: may affect up to 1 in 10 people

- Muscle weakness
- Pain in the hands and fingers
- Flu-like symptoms
- Loss of strength and weakness
- Tiredness
- Bruising at the injection site
- Skin rash.

Uncommon: may affect up to 1 in 100 people

- Muscle pain
- Itchy skin at the injection site
- Pain at the injection site
- Rash at the injection site
- Swelling at the injection site.

Treatment of muscle spasms in the *arms and legs* of children with cerebral palsy:

There are no specific findings for the administration of Dysport at the same treatment session in the arm and leg compared to those expected from treating in the arm or the leg separately.

Treatment of urinary incontinence due to uncontrolled contractions of the bladder muscle:

Very common: may affect more than 1 in 10 people

- Urinary tract infection*

Common: may affect up to 1 in 10 people

- Blood in the urine*
- Constipation
- Bacteria in urine*
- Erectile dysfunction, sometimes known as impotence

Uncommon: may affect up to 1 in 100 people

- Tiredness
- Flu like symptoms
- Numbness
- Muscle weakness

**This side effect can be related to the procedure*

Treatment of excessive sweating of the armpits:

Common: may affect up to 1 in 10 people

- Increased sweating in other parts of the body (compensatory sweating).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or other healthcare practitioner. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Dysport

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after 'EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Chemical and physical in-use stability has been demonstrated for the reconstituted solution for 24 hours in a refrigerator (2°C - 8°C). After the solution is made up, unless the method of reconstitution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dysport contains

The active constituent of Dysport is *Clostridium botulinum* type A toxin-haemagglutinin complex (500 units).

The other excipients in Dysport are human albumin and lactose.

Before it is injected, Dysport will be dissolved in sodium chloride for injection (a solution of salt).

What Dysport looks like and contents of the pack

Dysport is a powder for solution for injection. It appears as a white powder in a glass vial. It comes in pack sizes of 1 or 2 vials, although not all pack sizes may be marketed.

Dysport is also available in 300 unit vials.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder:**

Ipsen Limited, 190 Bath Road, Slough, Berkshire, SL1 3XE, UK.

Manufacturer:

Ipsen Biopharm Limited, Ash Road, Wrexham Industrial Estate, Wrexham LL13 9UF.

Is this leaflet hard to see or read? Please phone +44 (0) 1753 627777 and ask for help.

This leaflet was last revised in July 2023.

-----DETACH HERE AND GIVE INFORMATION TO PATIENT-----

The following information is intended for healthcare professionals only.
Please refer to the Summary of Product Characteristics for complete prescribing information for Dysport:

Handling

When preparing and handling Dysport solutions, the use of gloves is recommended. If Dysport dry powder or reconstituted solution should come into contact with the skin or mucous membranes, they should be washed thoroughly with water. Reconstitution should be conducted in compliance with good practice, especially with regard to asepsis.

Dysport is supplied as a powder in a colourless injection vial and must be dissolved in sterile saline solution before use. Each vial contains 500 units of toxin-haemagglutinin complex.

The uncovered central part of the rubber stopper should be cleaned with alcohol immediately before piercing the septum. For all indications except for the indication for the treatment of urinary incontinence, a sterile 23 or 25 gauge needle should be used.

Reconstitution instructions for 500 unit vial. These volumes yield concentrations specific for the use for each indication.

Resulting Dose Unit per ml	Diluent* per 500U vial
500U	1 ml
200U	2.5 ml
100U	5 ml

*Preservative-free 0.9 % sodium chloride injection

For paediatric cerebral palsy spasticity, which is dosed using unit per body weight, further dilution may be required to achieve the final volume for injection.

Appearance of product after reconstitution:

A clear, colourless solution, free from particulate matter

Instructions for use

The units given for Dysport are specific to the preparation and are not interchangeable with other preparations of botulinum toxin.

Instructions for the use of Dysport in the symptomatic treatment of focal spasticity affecting the upper limbs in adults, lower limbs in adults affecting the ankle joint, dynamic equinus foot deformity due to spastic cerebral palsy in ambulant paediatric patients two years of age or older and focal spasticity of upper limbs or upper and lower limbs in paediatric cerebral palsy patients, 2 years of age or older

500 units Dysport is diluted with 1 ml, 2.5 ml or 5 ml NaCl injection B.P. (0.9% w/v) to a concentration of 500 units, 200 units or 100 units Dysport per ml, respectively.

Dysport must be administered intramuscularly.

Treatment of Spasmodic torticollis in adults

When treating spastic torticollis, Dysport 500 units is diluted with 1 ml of 0.9% sodium chloride injection to yield a solution of Dysport with a concentration equivalent to 500 units in 1 ml.

Treatment of blepharospasm and hemifacial spasm in adults

When treating blepharospasm and hemifacial spasm, Dysport 500 units is diluted with 2.5 ml of 0.9% sodium chloride injection to yield a solution of Dysport with a concentration equivalent to 200 units in 1 ml.

Dysport is administered by subcutaneous injection medially and laterally into the junction between the preseptal and orbital parts of both the upper and lower *orbicularis oculi* muscles of the eyes.

Treatment of Severe primary hyperhidrosis of the axillae When treating excessive sweating, Dysport 500 units is diluted with 2.5 ml of 0.9% sodium chloride injection to yield a solution of Dysport with a concentration equivalent to 200 units in 1 ml.

Treatment of urinary incontinence due to neurogenic detrusor overactivity

The overall result following preparation is to have the required 15 mL of reconstituted Dysport for injection equally divided between two 10 mL syringes, with each syringe containing 7.5 mL of reconstituted Dysport at the same concentration.

After reconstitution in the syringe the product should be used immediately and any unused product remaining in the vials should be disposed of.

Dilution instructions for a dose of 600 units:

Two 500 unit Dysport vials each diluted with 2.5 ml of sodium chloride solution 9 mg/ml (0.9%). The following steps should be followed:

- Into the first 10 mL syringe draw 1.5 mL from the first vial and into the second 10 mL syringe draw 1.5 mL from the second vial.
- Complete the reconstitution by adding 6 mL of preservative-free saline solution into both syringes and mix gently.

This will result in two 10 mL syringes, each containing 7.5 mL, providing a total of 600 unit of reconstituted Dysport.

Dilution instructions for a dose of 800 units:

Two 500 unit Dysport vials each diluted with 2.5 ml of sodium chloride solution 9 mg/ml (0.9%). The following steps should be followed:

- Into the first 10 mL syringe draw 2 mL from the first vial and into the second 10 mL syringe draw 2 mL from the second vial.
- Complete the reconstitution by adding 5.5 mL of preservative-free saline solution into both syringes and mix gently.

This will result in two 10 mL syringes, each containing 7.5 mL, providing a total of 800 unit of reconstituted Dysport.

For further information see Section 4.2, Posology and method of administration, and Section 6.6, Special precautions for disposal and other handling, in the Summary of Product Characteristics.

Disposal

Immediately after treatment of the patient, any residual Dysport which may be present in either vial or syringe should be inactivated with dilute hypochlorite solution (1 % available chlorine).

Spillage of Dysport should be wiped up with an absorbent cloth soaked in dilute hypochlorite solution. Any unused product or waste material should be disposed of appropriately.