Dysport®

500 units
Powder for solution for injection

Clostridium botulinum type A
toxin-haemagglutinin complex

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

Dysport should only be administered by appropriately trained physicians.

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. 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, except for the indication of urinary incontinence due to neurogenic detrusor overactivity for which there are specific instructions.

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

*Preservative-free sodium chloride 9 mg/mL (0.9%) solution for 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.

Dilution instructions for 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 medicinal product should be used immediately.

Dilution instructions using 500 U vials
- **For a dose of 600 U:** Reconstitute two 500 U vials each with 2.5 mL of preservative-free sodium chloride 9 mg/mL solution for injection. 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 sodium chloride 9 mg/mL solution for injection into both syringes and mix gently.
  This will result in two 10 mL syringes, each containing 7.5 mL, providing a total of 600 U of reconstituted Dysport.
- **For a dose of 800 U:** Reconstitute two 500 U vials each with 2.5 mL of preservative-free sodium chloride 9 mg/mL solution for injection. 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 sodium chloride 9 mg/mL solution for injection into both syringes and mix gently.
  This will result in two 10 mL syringes, each containing 7.5 mL, providing a total of 800 U of reconstituted Dysport.

Appearance of product after reconstitution:
A clear, colourless solution, free from particulate matter, otherwise it must not be injected.

Instructions for use

Review the full SmPC available on the HPRA website for further information on posology and method of administration.

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Incompatibilities
This medicinal product should not be mixed with other medicinal products except those listed in section 6.6 of 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.

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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 nurse.
- 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 nurse. 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

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:
- In the arm and shoulders
- In the lower leg affecting the ankle joint
- In the neck
- Around the eyes
- In the face.

Dysport is also used in adults to treat:
- Hyperhidrosis. This is a condition where the body produces excessive 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 for patients regularly performing clean intermittent catheterisation.

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.

Dysport injected into the underarm areas will block the nerves that stimulate sweating.

2. What you need to know before you use Dysport

Do not use Dysport
- if you are allergic to botulinum toxin or any of the other ingredients of this medicine (see section 6 for a list of ingredients)
- 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 in some circumstances.
Talk to your doctor, pharmacist or nurse 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 inflammed
- The muscles at the proposed site of injection show signs of wasting.

When Dysport is used in the muscles around the eye, your eyes may become dry (see section 4) which may harm the surface of your eyes. In order ro prevent this, you may need treatment with protective drops, ointments or protective covering which closes the eye. Your doctor will tell you if this is required.

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).

Other medicines and Dysport
Tell your doctor if you are taking, have recently taken or might take any other medicines, including the following medicines, as these may change the effects of Dysport:
- Any antibiotics for an infection, called aminoglycosides, such as gentamicin or amikacin.
- Any muscle relaxing drugs.

Pregnancy and breast-feeding
Dysport is not recommended during pregnancy, unless clearly necessary.
Dysport is not recommended in breast-feeding women.

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

Use in children
For the treatment of spasms in the legs in patients with cerebral palsy, Dysport should only be used in children 2 years of age or over.

Driving and using machines
Dysport may cause muscle weakness or problems with your vision.

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

Dysport contains albumin:
Dysport contains a small amount of albumin which has been obtained from human blood. The risk of passing on infections from blood cannot be eliminated completely when using human blood or products made from human blood.

3. How Dysport is given

Your doctor 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 and the Elderly

For treatment of muscle spasms in your *arm and shoulder:*
The dose of Dysport will usually be between 500 and 1000 units. The doctor may divide this amount between the affected arm muscles. If you are also being injected in your shoulder muscles, the dose can be increased to 1500 units. The total dose you may be given in the shoulder muscles should not exceed 500 units. Your muscle spasms should normally improve within 1 week and may last up to 20 weeks.
Further injections will be given about every 12 to 16 weeks, depending on how long the effect lasts.

For treatment of muscle spasms in your leg affecting your *ankle joint:*
The dose of Dysport will usually be 1500 units and should not exceed this dose.
The doctor may divide the amount between the affected leg muscles.

Injections will usually be given about every 12 to 16 weeks, or longer as necessary.

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 may divide the dose between your arm and leg, but the overall dose must not exceed 1500 units.

For treatment of muscle spasms in your *neck:*
The first dose will usually be 500 units. The doctor may divide this amount 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 about every 16 weeks depending on how long the effect lasts, but not more often than every 12 weeks. The maximum dose you should be given is 1000 units.

For treatment of muscle spasm around your *eyes:*
The first injection will usually be about 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 will only give you injections around this eye. Your muscle spasms should normally start improving within 2 – 4 days with maximal effect within 2 weeks. Further injections (40 - 120 units) will be given about every 12 weeks depending on how long the effects last.
The maximum dose you should be given is 120 units per eye.

For treatment of muscle spasm in your *face:*
The first injection will usually be about 120 units. The doctor will give you injections on the side of your face that is affected. Your muscle spasms should normally improve within 2 weeks.
Further injections (40 - 120 units) will be given about every 12 weeks depending on how long the effects last. The maximum dose you should be given is 120 units on each side of your face.

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 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 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 medicines, 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 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 may divide this amount between the affected areas. Your symptoms should usually improve within 2 weeks and the effect can last for up to 1 year. The amount of the next dose your doctor gives you, and when you will be given a further injection will depend on how you respond. Further injections will be given not more often than every 12 weeks. The maximum dose you should be given is 200 units per armpit.

Children

For treatment of muscle spasms in the *legs* of children with cerebral palsy:
Children over 2 years: The dose is decided by your doctor. 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. Your muscle spasms should normally improve within 2 weeks and may last up to 28 weeks as observed in some patients. Your doctor 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. Dysport is injected into the affected muscles of the arms. If the treatment is injected into one arm, the dose must not be higher than 640 units or 16 units/kg at a given treatment session, whichever is lower. If the treatment is injected into both 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 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, without exceeding a total dose per treatment session of 1000 units or 30 units/kg, whichever is lower. Re-treatment of the arms and legs combined should be considered no sooner than a 12 to 16-week window 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 happens, speak to your doctor 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 who will decide when the next injection is needed.

If you stop taking Dysport
Your muscle movements will return to the way they were before treatment.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if:
- You have any problems breathing, swallowing or speaking, with or without swelling of your face, lips, tongue and/or throat.
- You get severe redness of the skin or an itchy lumpy rash (urticaria). This may mean you are having an allergic reaction to Dysport.
- You get very dry eyes.

Some side effects may occur in any patient treated with Dysport whilst other side effects may depend on your condition.
Make sure you read all the sections that apply to you.

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An MPS Company

Approval Signature
Date

Warning! We cannot accept responsibility for any errors in this proof after approval. Whilst we take extreme care at all times to ensure accuracy to our client's brief, the final responsibility must be taken by our client.
IF YOU SIGN THIS PROOF YOU ARE SIGNIFYING FULL APPROVAL OF DESIGN AND TEXT.

Customer	Ipsen		
SAP Code	1073258		
SAP Description	PIL DYSPORT 500U 2VIAL IRELAND		
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Profile Ref	-		
Size	410 x 534 mm		
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Colours Used	Fonts Used	
Black	Univers	9 pt
Keyline (Non-Printing)	Friz Quadrata	10 pt
Cirrus_Info_Box	Helvetica Neue LT Std	11 pt
	OCR B Std	7 pt
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Notes
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The chance of having a side effect is described by the following groups:

	How often it happens
Very common	May affect more than 1 in 10 people
Common	May affect up to 1 in 10 people
Uncommon	May affect up to 1 in 100 people
Rare	May affect up to 1 in 1000 people
Very rare	May affect up to 1 in 10,000 people
Not known	Frequency cannot be estimated from the available data

Treatment of any condition (*all patients*):

Side effects that have occurred include:
Common:
- Tiredness
- Flu-like symptoms
- Generalised weakness
- Bruising, redness, swelling or pain around the site where the injection was given or a burning sensation at the time the injection is given.

Uncommon:
- Itching.

Rare:
- Skin rashes and muscle weakness.

Not known:
- Numbness.
- Muscle wasting

Other side effects related to the spread of Dysport away from the site of administration have also been reported (worsened muscle weakness, difficulty with swallowing or breathing which in very rare cases have been fatal).

Adults and the Elderly

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

Side effects that have occurred include:
Common:
- Muscle weakness
- Musculoskeletal pain
- Pain in the hands and fingers
- Injection site reactions (e.g. pain, skin rash or redness, swelling)
- Generalised weakness, tiredness, flu-like symptoms
- Accidental injury/fall.

Uncommon
- Difficulty in swallowing.

Treatment of muscle spasms in the leg affecting your *ankle joint:*

Side effects that have occurred include:
Common:
- Difficulty in swallowing
- Leg muscle weakness
- Muscle pain
- Generalised weakness, tiredness, flu-like symptoms
- Injection site reactions (pain, bruising, skin rash, itching)
- Fall.

Treatment of muscle spasms in the *neck:*

Side effects that have occurred include:
Very common:
- Dry mouth
- Muscle weakness
- Difficulty in swallowing.

Common:
- Headache
- Dizziness
- Neck pain
- Muscle pain
- Stiff muscles
- Shortness of breath
- Musculoskeletal pain
- Face muscle weakness
- Neck muscle weakness
- Pain in the hands and feet
- A change to the tone of the voice
- Blurred vision or other problems in seeing clearly.

Uncommon:
- Jaw problems
- Double vision
- Loss of muscle tissue
- Drooping of the upper or lower eyelid
- Nausea.

Rare:
- Breathing difficulties.

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

Side effects that have occurred include:
Very common:
- Drooping eyelids.

Common:
- Dry eyes
- Double vision
- More tears than usual
- Swelling of the eyelid
- Face muscle weakness.

Uncommon:
- Facial nerves may become paralysed.

Rare:
- Difficulty in moving the eye
- The edge of the eyelid may turn in towards the eyeball and the eye muscles may become paralysed.

Treatment of excessive sweating of the *armpits:*

Side effects that have occurred include:
Common:
- Shortness of breath
- Increased sweating in other parts of the body
- Pain or muscle weakness in the shoulder, upper arm, neck or calf.

Uncommon:
- Dizziness
- Headache
- Flushing of the skin
- Nosebleeds
- Twitching of the eyelid muscles
- Numbness or tingling of the skin.

Children

Treatment of a child with cerebral palsy with muscle spasms in the *leg* (aged two years or older):

Side effects that have occurred include:
Common:
- Muscle pain
- Muscle weakness
- Urinary incontinence
- Flu-like symptoms
- Pain, redness, bruising at the injection site
- Abnormal walking
- Tiredness
- Fall.

Uncommon:
- Loss of strength and weakness.

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

Common:
- Muscle weakness
- Muscle pain
- Flu-like symptoms
- Tiredness
- Itchy skin, bruising, pain, swelling and rash at the injection site
- Skin rash.

Uncommon:
- Loss of strength and weakness

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:

Common: may affect up to 1 in 10 people
- Blood in the urine *
- Constipation
- Bacteria in urine*
- Erectile dysfunction, sometimes known as impotence
- Urinary tract infection*
- Headache
- Fever

Uncommon: may affect up to 1 in 100 people
- Numbness
- Muscle weakness
- Bladder pain*
- Uncontrolled reflex reaction of your body (autonomic dysreflexia)*
- Inability to empty the bladder (urinary retention)
- Bleeding from the bladder or from the tube that carries urine from the bladder to outside the body (urethra)

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.
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.

Dysport will be stored in a refrigerator (2°C - 8°C) at the place where the injections are carried out. This medicine should not be given to patients to store.

It is recommended that the reconstituted solution is used immediately, however it can be stored for up to 24 hours in a refrigerator (2°C - 8°C).

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 ingredients 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 container called a vial. It comes in pack sizes of 1 or 2 vials, although not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Ipsen Pharma, 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France.

Manufacturer

Ipsen Manufacturing Ireland Limited, Blanchardstown Industrial Park, Blanchardstown, Dublin 15, Ireland.

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This leaflet was last revised in July 2022

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Approval Signature	Artwork Type	Leaflet					OCR B Std	7 pt	
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Date	Size	410 x 534 mm							
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