Package leaflet: Information for the user

Dysport 500 U, powder for solution for injection
Clostridium botulinum toxin type A 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 any further questions, ask your doctor or pharmacist.
- 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 or pharmacist. 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 is a medicine that blocks the transmission of nerve impulses to the muscle or sweat glands so that spasms in the muscle or sweat production is reduced.

Dysport is used in the treatment of:
- muscle spasms in the arm and shoulder in adults
- muscle spasms in the leg in adults with equinus foot deformity
- muscle spasms that lead to dynamic equinus foot deformity in children over 2 years and thus to difficulty in walking
- muscle spasms in the arms in children aged 2 years or older with cerebral palsy
- muscle spasms in the neck region in adults
- muscle spasms in the eyelid in adults
- muscle spasms in the face in adults.

Dysport may also be used to relieve the symptoms of excessive sweating of the armpits that makes everyday activities difficult and that does not respond to local therapy.

Dysport is also used in adults to treat leakage of urine (urinary incontinence) due to bladder problems associated with spinal cord injury or multiple sclerosis for patients regularly performing clean intermittent catheterisation.

2. What you need to know before you use Dysport

Do not use Dysport
- if you are allergic to *clostridium botulinum* toxin type A haemagglutinin complex 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
Talk to your doctor before using Dysport:
- if you have swallowing or breathing difficulties
- if you have problems with nerve impulse transmission, e.g. myasthenia gravis (chronic muscle disease)
- if you have developed a permanent shortening, or contraction of a muscle (fixed contracture)
- if you have a prolonged bleeding time, infection or inflammation at the proposed injection site
- if the muscles at the proposed site of injection show signs of wasting.

Dysport contains a small amount of human albumin. The risk of transmission of a virus infection cannot be ruled out with absolute certainty when human blood or blood products are used.

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 to 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). Contact your doctor immediately or seek medical treatment immediately if you develop swallowing, speaking, or breathing difficulties.

Other medicines and Dysport
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Other medicines that affect the neuromuscular function may increase the effect of the active substance in Dysport. Your doctor will know which medicines those are.

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

Use of the product during pregnancy is not recommended, except in cases where the treatment is deemed necessary.

Use of the product during breast-feeding is not recommended.

Driving and using machines
You may experience muscle weakness and visual disorders, such as reduced visual acuity and blurred vision, after treatment with Dysport. Your ability to drive and use machines may be affected.

3. How to use Dysport

Dysport should only be administered to you by a doctor with specific skills and experience on how to use the medicine.

The dose of Dysport given depends on the type of treatment and area of use. Your doctor will decide the dose you will receive.

Dysport is given as an injection in the muscle (intramuscular), in the skin (intradermal),under the skin (subcutaneous) or into the bladder muscle after reconstitution.
When Dysport is given for the treatment of urinary incontinence, it is 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.

The syringe of Dysport should be used for you only and for one treatment only.

If you are given more Dysport than you should
If you receive more Dysport than necessary, muscles other than the ones injected may feel weak. Excessive doses may also cause muscle paralysis. This may not occur immediately. If it does happen, contact a doctor immediately. Seek emergency medical assistance if you experience breathing, swallowing, or speaking difficulties.

4. Possible side effects

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

Contact a doctor immediately if you have any problems swallowing or with your speech or if you develop breathing problems, with or without swelling of the face, lips, tongue and/or throat, redness of the skin, or an itchy skin rash (nettle-rash). This can mean that you have suffered an allergic reaction to Dysport.

Side effects generally for all indications:
Common (may affect up to 1 in 10 people): Local muscle weakness, loss of strength, tiredness, influenza-like illness, pain/tenderness at the injection site.
Uncommon (may affect up to 1 in 100 people): Itching.
Rare (may affect up to 1 in 1,000 people): Loss of muscle mass, rash.
Not known (frequency cannot be estimated from the available data): Numbness, muscle wasting.

Side effects in treatment of muscle spasms in the arm and shoulder in adults:
Common (may affect up to 1 in 10 people): Muscular weakness; musculoskeletal pain; pain, redness or swelling at the injection site; loss of strength; tiredness; influenza-like illness; pain in the hands and fingers.
Uncommon (may affect up to 1 in 100 people): Difficulty swallowing.

Side effects in treatment of muscle spasms in the leg in adults:
Common (may affect up to 1 in 10 people): Difficulty swallowing; muscle weakness; muscle pain; loss of strength; tiredness; influenza-like illness; pain, bruising, rash, itching at the site of injection; fall.

Side effects in treatment of muscle spasms that lead to dynamic equinus foot deformity in children aged 2 years and older:
Common (may affect up to 1 in 10 people): Muscle pain; generalised muscle weakness; urinary incontinence; influenza-like illness; pain, redness or bruising at the injection site; abnormal gait; tiredness; fall.
Uncommon (may affect up to 1 in 100 people): loss of strength, difficulty swallowing, localised muscle weakness.

Side effects in treatment of muscle spasms in the *arms* of children aged 2 years or older with cerebral palsy:
Common (may affect up to 1 in 10 people): Localised muscle weakness, pain in the hands and fingers, influenza-like illness, loss of strength, tiredness, bruising at the injection site, skin rash.
Uncommon (may affect up to 1 in 100 people): Muscle pain, eczema at the injection site, pain at the injection site, rash at the injection site, swelling at the injection site, generalised muscle weakness.
Not known (frequency cannot be estimated from the available data): Difficulty swallowing

Side effects in treatment of muscle spasms in the *arms* and *legs in children aged 2 years and older* with cerebral palsy:
There are no specific side effects 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.

Side effects in treatment of muscle spasms in the neck region in adults:
Very common (may affect more than 1 in 10 people): Difficulty swallowing, dry mouth, muscle weakness.
Common (may affect up to 1 in 10 people): Headache, dizziness, facial paresis, blurred vision, visual acuity reduced, voice changes, difficulties in breathing, neck pain, pain and stiffness in muscles and bones, pain in arms and legs.
Uncommon (may affect up to 1 in 100 people): Double vision, drooping eyelid, nausea, muscle atrophy, jaw disorder.
Rare (may affect up to 1 in 1,000 people): Aspiration (inhalation problems).

Side effects in treatment of muscle spasms in the eyelid and the face in adults:
Very common (may affect more than 1 in 10 people): Drooping eyelid.
Common (may affect up to 1 in 10 people): Weakened facial muscles, double vision, dry eyes, tear flow, swelling of the eyelid.
Uncommon (may affect up to 1 in 100 people): Facial paralysis.
Rare (may affect up to 1 in 1,000 people): Eye muscle paralysis, inward folding of the edge of the eyelid.

Side effects in treatment of excessive sweating:
Common (may affect up to 1 in 10 people): Pain in the shoulders, upper arm and neck, muscle pain in the shoulders and calves, breathing difficulties, increase in sweating in other skin areas.
Uncommon (may affect up to 1 in 100 people): Dizziness, headache, numbness and tingling in the arms and legs, nosebleeds, redness, involuntary muscle spasms in the eyelid.
Rare (may affect up to 1 in 1,000 people): Allergic reactions such as skin rash.

Side effects in 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
[To be completed nationally]

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 carton and label after EXP. The expiry date refers to the last day of that month.

The powder for injection in the unopened pack must be stored in a refrigerator (2°C - 8°C). Unopened vials of Dysport can be used following a single exposure to temperatures up to 25°C for up to 72 hours, after which time the unopened vial should be stored in a refrigerator (2°C - 8°C) for the duration of shelf-life. Do not freeze. These storage conditions also apply if you store the medicine at home.

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 substance is *clostridium botulinum* toxin type A haemagglutinin complex 500 units (U). The units given for Dysport are specific and cannot be applied to other botulinum products.
- The other ingredients are albumin and lactose monohydrate.

What Dysport looks like and contents of the pack

Dysport powder for injection is a white freeze-dried powder and is supplied in a 3 ml injection vial of colourless type I glass sealed with a rubber stopper and aluminium cap.
Packs of 1 x 1 and 2 x 1 injection vials.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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Detailed information on this medicine is available on the web site of {MA/Agency}

The following information is intended for healthcare professionals only:

Handling

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 perforation. For all indications except for the indication for the treatment of urinary incontinence, use a sterile cannula with a size 23 or 25 needle to inject the relevant saline solution (0.9%) into the injection vial and mix the contents carefully until the powder has dissolved.

After the completion of treatment all used injection vials, syringes and items with spillage must be autoclaved or any remaining botulinum toxin A must be inactivated with 0.5% hypochlorite solution. All material used must then be disposed of in accordance with the hospital's local guidelines.

Instructions for use

<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.>

The units given for Dysport are specific and cannot be applied to other botulinum toxin products.

Instructions for the use of Dysport in the symptomatic treatment of focal spasticity affecting the upper limbs in adults and/or lower limbs in adults with pes equinus, pes equinus due to spastic cerebral paralysis in ambulant paediatric patients over 2 years of age and spasticity of upper 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 solution 9 mg/ml (0.9%) to a concentration of 500 units, 200 units or 100 units Dysport per ml.
When using 1 ml or 2.5 ml of diluent the reconstitution can be performed in the Dysport powder vial.
When using 5 ml of diluent for a 500 unit vial of Dysport, complete the following steps:
1. Reconstitute a 500 unit vial of Dysport with 2.5 ml NaCl solution 9 mg/ml (0.9%), gently mix, and set the vial aside.
2. Withdraw 2.5 ml of NaCl solution 9 mg/ml (0.9%) into a 5 ml syringe.
3. Take the 5 ml syringe with 2.5 ml NaCl solution 9 mg/ml (0.9%), and draw up the Dysport solution from the reconstituted vial without inverting and mix gently. The resulting concentration will be 100 units/ml.
4. Use immediately after reconstitution in the syringe.

Dysport must be administered intramuscularly.

Instructions for the use of Dysport in the treatment of spasmodic torticollis in adults
500 units Dysport is diluted with 1 ml NaCl solution 9 mg/ml (0.9%) to a concentration of 500 units Dysport per ml. Dysport must be administered intramuscularly.

Instructions for the use of Dysport in the treatment of blepharospasm and hemifacial spasm in adults
500 units Dysport is diluted with 2.5 ml NaCl solution 9 mg/ml (0.9%) to a concentration of 200 units Dysport per ml. Dysport must be administered subcutaneously.

Instructions for the use of Dysport in the symptomatic treatment of persistent severe primary hyperhidrosis of the axillae
500 units Dysport is diluted with 2.5 ml NaCl solution 9 mg/ml (0.9%) to a concentration of 200 units Dysport per ml. Dysport must be administered intradermally.

Instructions for the use of Dysport in the management 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.

For a dose of 600 units: Two 500 unit Dysport vials each diluted with 2.5 ml of of preservative-free NaCl 9 mg/ml (0.9%) solution for injection. 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.

For a dose of 800 units: Two 500 unit Dysport vials each diluted with 2.5 ml of preservative-free NaCl 9 mg/ml (0.9%) solution for injection. 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.