

DYSPORT®

(Clostridium botulinum type A toxin-haemagglutinin complex)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Dysport. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Dysport against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.

You may need to read it again.

What is Dysport

Dysport is a muscle relaxant produced by Clostridium botulinum bacteria. It acts on the junctions between the nerves and muscles, preventing the release of one of the chemical messengers called acetylcholine from the nerve endings that would normally cause the muscle to contract. If the messenger

is prevented from being released this results in a weakened muscle and helps to reduce some of the abnormal muscle contractions.

What Dysport is used for

Dysport is used for the treatment of

- upper limb spasticity in adults. Upper limb spasticity is an increased stiffness in the arm and/or hand muscles that develops in many patients after a stroke, for example, and can lead to restricted use of the arm or hand.
- lower limb spasticity in adults. Lower limb spasticity is an increased stiffness in the leg and/or foot muscles that develops in many patients after a stroke, for example, and can lead to restricted use of the leg or foot.
- spasmodic torticollis in adults. Spasmodic torticollis is where there is a turning movement of the neck leading to an unusual head and shoulder position
- upper and lower limb spasticity in children (2 years of age and older) which may be due to cerebral palsy. Cerebral palsy spasticity is a disorder in which some muscles become stiff and movement is difficult
- blepharospasm or hemifacial spasm in adults. Blepharospasm is a condition affecting the eye lid muscles causing uncontrollable blinking and closure of the eyelids. Hemifacial spasm is a condition that causes the muscles on one side of the face to contract without control from the person affected

- moderate to severe glabellar lines which are the vertical frown lines which may appear between your eyebrows
- moderate to severe lateral canthal lines (also known as 'crow's feet' lines) which are the lines that may appear near the outside corner of your eyes

Your doctor may have prescribed it for another reason. Ask your doctor if you have any questions why Dysport has been prescribed for you.

Before you are given Dysport

You must not be given Dysport if

- **you have had a previous allergic reaction to botulinum toxin or any of the ingredients listed at the end of this leaflet**
- **you have a medical condition called myasthenia gravis or a myasthenic syndrome**
- **if there is any sign of infection at the proposed injection site**
- **the package is damaged or shows signs of tampering, or if the product does not look quite right**

Before you are given Dysport

Tell your doctor if you have:

- any difficulties in swallowing

- a history of bronchitis, pneumonia or problems with your breathing
- an allergy to any of the ingredients contained in Dysport that are listed at the end of this leaflet
- any reactions such as skin rash or 'flu-like' symptoms to any injections of toxin in the past
- worsening or changes in your muscle spasms
- previous prolonged periods of muscle weakness
- you bleed easily or have a history of prolonged bleeding times
- inflammation or infection at the proposed injection site
- ever had facial surgery
- been given Dysport or another brand of botulinum toxin in the past few weeks
- received any facial cosmetic procedures recently, particularly if Dysport will be injected into your facial muscles

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without prescription from your pharmacy, supermarket or health food shop.

Some medicines can interfere with the way Dysport works such as

- muscle relaxants
- aminoglycoside antibiotics
- penicillamine, procainamide, spectinomycin, polymixins, tetracyclines and lincomycin

These drugs must be used with caution if you are receiving Dysport. Your doctor will advise you accordingly.

Dysport contains a small amount of albumin that has been obtained from human blood. The risk of a viral infection cannot be eliminated completely when using human blood or products made from human blood.

Use in Children

Dysport can be used for the treatment of upper and lower limb spasticity in children (2 years of age and older). It is not recommended for children under 2 years of age. Dysport should not be used for treatment of any other conditions in children.

Use in Elderly

A reduced dose may be appropriate in elderly patients where reduced muscle mass may exist.

Use in Pregnancy and Lactation

Tell your doctor if you are pregnant or intend to become pregnant, or if you are breastfeeding or plan to start breastfeeding.

Your doctor will advise you regarding the use of Dysport in pregnancy.

Use of Dysport during breastfeeding is not recommended.

Effect on ability to drive and use machines

Local weakness can be expected and there is a possibility of unexpected side effects such as generalised weakness. These effects can affect the ability to drive and use machines.

How Dysport is given

How to use it

Your doctor will make up and give you the injection. For the injection, Dysport will be dissolved in 0.9% sodium chloride injection. Dysport is given as an injection in the muscle (intramuscularly), or under the skin (subcutaneously) after dilution, depending on the condition for which you are being treated.

Your doctor will decide where to make the injections and for how long you need treatment. You will be given injections of your medicine in a clinic that specialises in treating your condition. The doctor who injects your medicine will have received training and be experienced in giving Dysport injections.

How much is given

If you are being treated for upper limb spasticity, your first dose of Dysport can be up to 1000 units in total depending on

the size, number and location of muscles involved. The doctor will give a number of injections into the affected muscles in your arm or hand. Injections will be given approximately every 12 to 16 weeks, or as required to maintain the response, but not more frequently than every 12 weeks. The maximum recommended dose is 1000 units. Doses greater than 1000 units and up to 1500 units, when the shoulder muscles were also injected, have been used in clinical trials but have not been adequately studied.

If you are being treated for lower limb spasticity, your first dose of Dysport can be up to 1500 units in total depending on the size, number and location of muscles involved, how severe the spasticity is, and taking into account any local muscle weakness and your previous response to treatment. The doctor will give a number of injections into the affected muscles in your leg or foot. Injections will be given approximately every 12 to 16 weeks, or as required to maintain the response, but not more frequently than every 12 weeks. The maximum dose must not exceed 1500 units.

If treatment is required in both the upper and lower limbs during the same treatment session, the dose of Dysport to be injected in each limb will be tailored to your needs, without exceeding a total body dose of 1500U.

If you have spasmodic torticollis, your first dose of Dysport will be 250 - 500 units in total. Your doctor will give injections into a number of places in your neck, probably into the 2 or 3 of the neck muscles most affected by the condition.

Your doctor will decide how much to give and which muscles to inject.

Injections will be given approximately every 16 weeks, or as required to maintain the response, but not more frequently than every 12 weeks. The maximum dose must not exceed 1000 units.

If your child is being treated for upper or lower limb spasticity, the first and subsequent dose will be dependent on the size, number and location of muscles involved, how severe the spasticity is, and taking into account any local muscle weakness, the previous response to treatment and/or adverse event history with botulinum toxins. When possible, the dose will be distributed across more than 1 injection site in any single muscle.

For lower limb spasticity in children, the maximum dose must not exceed 30 units /kg or 1000 units whichever is lower. Your child's doctor will repeat the treatment approximately every 16-22 weeks, or as required to maintain the response, but not more frequently than every 12 weeks.

For upper limb spasticity in children, 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 child's muscle spasms should normally improve in the weeks following treatment and this improvement may last up to 34 weeks. Your child's doctor will repeat the treatment approximately every 16

- 28 weeks or as needed, but no more frequently than every 16 weeks.

For treatment of both upper and lower limb spasticity in of children during the same treatment session, the dose of Dysport to be injected in each limb should be decided by your child's doctor, without exceeding a total body dose per treatment session of 1000 units or 30 units/kg, whichever is lower. Retreatment 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 being treated for blepharospasm affecting both eyes, your first dose will be approximately 40 units of Dysport per eye. The medicine will be injected just under the skin at certain sites around the eye. These sites and the exact amount needed will be decided by the doctor. Injections will be given approximately every twelve weeks when the relaxing effect on the muscles is wearing off, but not more frequently than every 12 weeks. On the next visits the amount of Dysport given may be increased to 60, 80 or 120 units per eye if a longer duration of effect is required. The doctor will decide what dose to administer. If only one eye is affected by blepharospasm, the doctor will only give injections of Dysport around this eye.

If you are being treated for hemifacial spasm the doctor will give injections as for blepharospasm but on the affected side of your face only.

If you are being treated for glabellar lines, the recommended dose of Dysport is 50 units to be divided equally among 5 injection sites. The effect of the treatment may last for 4 to 5

months. There should be a minimum interval of 12 weeks between treatments.

If you are being treated for lateral canthal lines, the recommended dose of Dysport is 30 units per side to be divided equally among 3 injection sites (60 units total at 6 injection sites). The treatment interval depends on the individual patient's response after assessment but should not be more frequent than every three months.

Your doctor will decide when you will need your next injection and how much of the medicine will be injected.

If you miss an injection

Nothing will happen if you miss a scheduled appointment for your injection other than some of the spasm or muscle stiffness may return. Consult your doctor and they will decide when you need your next injection.

If you stop getting injections

The relaxing effect will eventually wear off and the muscle movements will return to the way they were before treatment.

If you are given too much medicine (overdose)

As it is given to you by your doctor who has received training on administration of Dysport, it is very unlikely that you will receive an overdose. However, if you are given too much Dysport, there is an increased risk of the medicine getting into the bloodstream and causing complications associated with oral botulinum poisoning. Paralysis of your muscles may

occur and you may be placed on a respirator and other support systems if it affects your breathing. Contact the Poisons Information centre on 131126 if you believe you may have been given too much Dysport.

Which side effects can Dysport have

Along with its desired effects, Dysport may cause unwanted effects because of a weakening of muscles near the injected muscle.

General

The most common side effects are:

- Generalised weakness, fatigue (exhaustion, lethargy, tiredness, and/or asthenia), 'flu-like' symptoms, pain / bruising / swelling / reddening at injection site

Less commonly, Dysport may cause itching.

Rarely, skin rashes, including rashes at the injection site, and muscle weakness may be experienced.

Treatment of upper limb spasticity in adults

Injection site reactions (e.g. pain, erythema, swelling etc.) have been commonly reported following administration of Dysport. Reports of general weakness / tiredness and 'flu-like' illness are uncommon.

The most common side effects include:

- Difficulty in swallowing certain foods
- Muscles may feel weaker
- Accidental falls or injury possibly due to muscle weakness
- Pain in extremity (such as your hands and fingers)

Treatment of lower limb spasticity in adults

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Injections into the neck muscles for the treatment of spasmodic torticollis

The most common side effects include:

- Headache, dizziness, facial weakness leading to loss of movement
- Blurred vision, reduced visual acuity
- A change to the tone of the voice, shortness of breath

- Difficulty in swallowing certain foods, dry mouth
- Muscle weakness, neck pain, muscle or joint pain and stiffness, myalgia, pain in extremities

Less common side effects are:

- Double vision
- Feeling sick
- Muscle wasting, jaw disorder

Rarely, Dysport may cause breathing difficulties. These side effects may be expected to resolve within 2 to 4 weeks.

Tell your doctor immediately if any breathing difficulties or if any difficulties in swallowing are experienced.

Treatment of upper limb spasticity in children

The most common side effects are:

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

- Skin rash

Less commonly, the following side effects are:

- 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 lower limb spasticity in children

The most common side effects are:

- Muscle pain
- Muscle weakness
- Urinary incontinence
- Flu-like illness
- Pain, redness, bruising at the injection site
- Abnormal walking
- Tiredness
- Accidental falls or injury possibly due to muscle weakness

Less commonly, loss of strength and weakness has been reported.

Injections around the eye for the treatment of blepharospasm or hemifacial spasm

The most common side effects include:

- Slight eyelid droop
- Dry eyes
- Double vision
- More tears than usual
- Swelling of the eyelid
- Facial muscle weakness

Less commonly, the facial nerves may become paralysed. On rare occasions the edge of the eyelid may turn in towards the eyeball, the eye muscles may become paralysed or there may be a need to avoid bright light.

Tell your doctor immediately if very dry eyes are noticed.

Injections for the treatment of glabellar lines

Headache and injection site reactions are very common, including pain, bruising, itchiness, a feeling of pins and needles, redness and skin rash.

Common side effects include

- swelling of the eyelids
- dry or itchy eyes
- more tears than usual
- twitching of eye muscles
- weakness in muscles close to injection site, leading to droopy upper eyelid or eye strain.
- facial numbness

Less common side effects include blurred or double vision, visual disturbances or disorders in eye movement, hypersensitivity.

Injections for the treatment of lateral canthal lines (crow's feet)

Common side effects include:

- headache
- swelling of the eyelids
- bruising and swelling around the eyes (a black eye)
- injection site reactions including, bruising, itchiness, and swelling
- more tears than usual
- twitching of eye muscles

A less common side effect is dry eyes.

If any side effect becomes troublesome or causes concern, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital. You may need medical attention.

Side effects resulting from distribution of the effects of Dysport to areas away from the site of injection have been reported (excessive muscle weakness, difficulty swallowing or pneumonia which in very rare cases may have been fatal). Hypersensitivity to Dysport has been reported occasionally.

If you have any problems with swallowing, speech or breathing following injection of Dysport, contact your doctor immediately.

After using Dysport

Your medicine will be stored in a refrigerator (2°C - 8°C - do not freeze) at the clinic where the injections are carried out. It should not be used after the date marked on the label (expiry date).

It contains no antimicrobial agent. The product is for the treatment of one patient only on one occasion. Any remaining contents should be discarded appropriately by the clinic.

Product description

What it looks like

Each pack contains 1 vial of Dysport. Each vial contains a small pellet of white powder that must be mixed with sterile sodium chloride solution before injection.

Ingredients

Each vial of Dysport 125U contains 125 IPSEN units of Clostridium botulinum type A toxin-haemagglutinin complex as the active ingredient.

Each vial of Dysport 300U contains 300 IPSEN units of Clostridium botulinum type A toxin-haemagglutinin complex as the active ingredient.

Each vial of Dysport 500U contains 500 IPSEN units of Clostridium botulinum type A toxin-haemagglutinin complex as the active ingredient.

These IPSEN units apply to Dysport only and are not the same for other medicines containing botulinum toxin. Dysport 125U, 300U and 500U both contain albumin and lactose.

Further Information

If you have any further questions on your Dysport treatment, or are unsure of the information, please see your doctor, who will be able to assist you.

Manufacturer / Sponsor

Dysport is manufactured in the UK. The Australian sponsor is:

Ipsen Pty Ltd

Level 2, Building 4

Brandon Office Park

540 Springvale Road

Glen Waverley Victoria 3150

AUST R

235282: Dysport 125U

170651: Dysport 300U

74124: Dysport 500U

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