

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Dysport®

Clostridium botulinum type A
toxin-haemagglutinin complex

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Dysport is and what it is used for
2. Before you use Dysport
3. How Dysport is given
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1. What Dysport is and what it is used for

Dysport is a toxin produced by *Clostridium botulinum* bacteria. The toxin works by stopping muscles contracting. It does this by preventing the release of a chemical in between the nerves and muscles which would normally make the muscles contract. This helps to reduce some of the abnormal muscle contractions known as spasms.

Dysport is used in adults to treat muscle spasms

- around the eyes
- in the face
- in the neck and shoulders
- in the arm

Dysport is also used to treat spasms in the legs of children (aged two years or older) with cerebral palsy, to improve their walking.

You may also need to have physiotherapy. Dysport can also be used to prevent the muscles which cause frown lines from contracting. This muscle relaxation is temporary and gradually wears off. Some people are distressed when lines appear on their face. Dysport can be used in adults under 65 years to temporarily improve the appearance of any moderate to severe glabellar lines (these are the vertical frown lines between the eyebrows).

2. Before you use Dysport

Do not use Dysport if:

- you are aware you are allergic (hypersensitive) to *Clostridium botulinum* toxin A or to any of the ingredients of Dysport
- you have an infection at the proposed site of injection
- you have myasthenia gravis, Eaton Lambert syndrome or amyotrophic lateral sclerosis

Take special care with Dysport

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

Tell your doctor 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 had surgery on your face, or are likely to undergo facial surgery or other types of surgery soon (if you are considering treatment for glabellar lines)
- you had no significant improvement of your lines after your last treatment (if you are considering treatment for glabellar lines)

Important information about one of the ingredients of Dysport

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.

Taking other medicines:

Please tell your doctor 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.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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 you should ask your doctor for advice before taking any medicine.

Use in children

Dysport should not be used in children younger than 2 years of age. Dysport is not suitable for the treatment of glabellar lines in patients under the age of 18.

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

Your doctor will give you your injection 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.

For treatment of muscle spasms in your arm:

The dose of Dysport will normally be 1000 units and should not exceed this dose. The doctor may divide the amount between the affected arm muscles. Your muscle spasms should normally improve within 2 weeks. Injections will usually be given about every 12 to 16 weeks.

For treatment of muscle spasms in your neck and shoulder:

The first dose of Dysport will normally be 500 units. The doctor will 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 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 will only give injections of Dysport around this eye. Injections will be given about every 12 weeks depending on how long the effects last. On the next visit, 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 will give you injections on the side of your face that is affected. The first injection will usually be 120 units. Injections will be given about every 12 weeks depending on how long the effects last. Your next injections of Dysport may be reduced to 80 or 60 units.

For treatment of a child with cerebral palsy with muscle spasms in their legs:

The first dose of Dysport will be 20 units for each kg of the child's body weight. The doctor will divide the amount between both lower leg muscles. If only one leg is affected by spasms, the doctor will only give injections of 10 units per kg in this leg. Injections will be given about every 12 to 16 weeks. The dose your doctor gives the child could change depending on how they respond. The maximum dose should not exceed 1000 units.

For temporary improvement of glabellar lines:

Dysport should only be administered by physicians with appropriate qualifications and expertise in this treatment and having the required equipment.

Your doctor will prepare and give the injections. A vial of Dysport should be used only for you and only for a single treatment session.

The recommended dose is 50 units, injected as 10 units at each of 5 injection sites in your forehead in the area above your nose and eyebrows.

The units used for different botulinum toxin products are not the same.

The effect of the treatment on the severity of your glabellar lines should be noticeable in 2 to 3 days. The interval between treatments with Dysport will be decided by your doctor. You should not have treatment more often than every 12 weeks.

If you are given more Dysport than you should

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 straightaway. 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 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.

4. Possible Side Effects

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

Tell your doctor **immediately** if:

- you have any problems swallowing, breathing or with your speech
- 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.

The chance of having a side effect is described by the following groups:

	How often it occurs
Very Common	Occurs in more than 1 in 10 patients treated
Common	in less than 1 in 10 patients treated
Uncommon	in less than 1 in 100 patients treated
Rare	in less than 1 in 1000 patients treated

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)

Side effects that have occurred include:

Common:

- Bruising, or pain around the site where the injection was given or a burning sensation at the time the injection is given
- Generalised weakness
- Tiredness
- Flu-like symptoms

Uncommon:

- Itching

Rare:

- Skin rashes and muscle weakness

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).

Treatment of muscle spasms in the arm:

Side effects that have occurred include:

Common:

- Arm muscle weakness
- Accidental injury/falls
- Difficulty in swallowing

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
- Facial muscle weakness

Uncommon:

- Facial paralysis

Rare:

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

Tell your doctor **immediately** if you notice very dry eyes.

Treatment of muscle spasms in the neck or shoulders:

Side effects that have occurred include:

Very common:

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

Common:

- Headache
- Dizziness
- Blurred vision or other problems seeing clearly

- Neck pain
- Weakness of face muscles
- Musculoskeletal pain
- Muscle pain
- Pain in the hands and fingers
- Stiff muscle
- Shortness of breath
- A change to the tone of the voice

Uncommon:

- Loss of muscle tissue
- Jaw problems
- Drooping of the upper and lower eyelid
- Double vision

Rare:

- Dysport may cause breathing difficulties

Treatment of children 2 years age and older with muscle spasms in the leg:

Side effects that have occurred include:

Common:

- The muscles of the lower leg may be weakened too much. This may change the way you walk or make you fall over more
- Muscle pain
- Urinary incontinence
- Diarrhoea
- Vomiting

Temporary improvement of glabellar lines:

Side effects that have occurred include:

Very common:

- Redness, swelling, irritation, rash, itching, tingling, pain, discomfort, stinging or bruising at the site of injection

- Headache

Common:

- Tired eyes or dim vision, drooping of the upper eyelid, swelling of the eyelid, watering eyes, dry eye, twitching of muscles around the eyes

- Facial paralysis

Uncommon:

- Disturbed, blurred or double vision
- Dizziness

Rare:

- Eye movement disorder

Usually these side effects, after treatment for glabellar lines, have occurred within the first week following injections and did not last long. They were usually mild to moderate in severity.

If any of the side effects become serious or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. How to store Dysport

Keep out of the reach and sight of children.

Do not use after the expiry date shown on the box.

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.

6. Further Information

What Dysport contains

The active constituent of Dysport is *Clostridium botulinum* toxin-haemagglutinin complex (300 units). Dysport also contains 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 white powder in a glass vial. It comes in a pack size of 1 or 2 vials, though not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer

The marketing authorisation holder is: Ipsen Limited, 190 Bath Road, Slough, Berkshire, SL1 3XE, United Kingdom

Dysport is manufactured by: Ipsen Biopharm Limited, Ash Road, Wrexham Industrial Estate, Wrexham LL13 9UF United Kingdom

This leaflet was last approved in June 2012