

Dysport®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given Dysport?

Dysport contains the active ingredient clostridium botulinum type A toxin-haemagglutinin complex. In adults, Dysport is used to treat: muscle spasms around the eyes, in the face, in the neck; muscle stiffness and tightness (spasticity) in the arms, shoulders, and legs; and, to treat lines between the eyebrows, and lines near the outside corner of the eyes. In children, Dysport is also used to treat muscle stiffness and tightness (spasticity) in the arms and legs.

For more information, see Section [1. Why am I being given Dysport?](#) in the full CMI.

2. What should I know before I am given Dysport?

Do not use if you have ever had an allergic reaction to Dysport or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Dysport?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Dysport and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given Dysport?

- Dysport should only be given to you by a doctor who has received training and is experienced in giving Dysport injections.
- Your doctor will give you injections of Dysport into your muscle (intramuscular) or under the skin (subcutaneous).

More instructions can be found in Section [4. How am I given Dysport?](#) in the full CMI.

5. What should I know while being given Dysport?

Things you should do	<ul style="list-style-type: none">• Call your doctor straight away if you have any problems swallowing, breathing, or with your speech, have worsened muscle weakness or notice your eyes are very dry.• Remind any doctor, dentist or pharmacist you visit that you are being given Dysport injections.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Dysport affects you.
Looking after your medicine	<ul style="list-style-type: none">• Your doctor will keep the medicine at the doctor's clinic or surgery, or at the pharmacy.• If you need to store Dysport at home: Keep it in a refrigerator between

	2°C to 8°C. Do not freeze it.
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For more information, see Section [5. What should I know while being given Dysport?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, Dysport can cause side effects, although not everybody gets them. Some side effects may occur in any patient treated with Dysport, whilst other side effects may depend on the condition being treated. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Tell your doctor straight away if you notice any of the following side effects, you may need urgent medical attention:

- problems swallowing
- problems breathing or with your speech
- worsened muscle weakness
- shortness of breath
- very dry eyes

Dysport®

Active ingredient(s): *Clostridium botulinum type A toxin-haemagglutinin complex*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dysport. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Dysport.**

Where to find information in this leaflet:

- [1. Why am I being given Dysport?](#)
- [2. What should I know before I am given Dysport?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given Dysport?](#)
- [5. What should I know while being given Dysport?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Dysport?

Dysport contains the active ingredient clostridium botulinum type A toxin-haemagglutinin complex.

It works by stopping your muscles contracting. It does this by stopping the release of a chemical messenger which acts between the nerves and muscles to make the

muscles contract. This helps to reduce abnormal muscle contractions known as spasms.

Dysport is used to treat:

- **muscle stiffness or tightness in the arm, shoulders and/or hand muscles (upper limb spasticity) in adults and children 2 years and older.**
- **muscle stiffness or tightness in the leg and/or foot muscles (lower limb spasticity) in adults and children 2 years and older.**
- **a condition which causes an involuntary turning movement of the neck leading to an unusual and painful position of the head and shoulder (spasmodic torticollis, also known as cervical dystonia) in adults.**
- **a condition that causes uncontrollable blinking and closing of the eyelids (blepharospasm) in adults.**
- **a condition that causes muscles on one side of the face to uncontrollably contract or spasm (hemifacial spasm) in adults.**
- **vertical frown lines between the eyebrows (glabellar lines) in adults.**
- **lines that appear near the outside corner of your eyes ('crow's feet' or lateral canthal lines) in adults.**

2. What should I know before I am given Dysport?

Warnings

You must not be given Dysport if:

- you have a muscle disorders medical condition called myasthenia gravis or a myasthenic syndrome.
- you have any signs of infection or inflammation in the muscles where the doctor will inject Dysport.
- you are allergic to clostridium botulinum type A toxin-haemagglutinin complex, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- skin redness, rash, itching or hives on the skin

Check with your doctor if you have:

- any difficulties in swallowing.
- a history of bronchitis, pneumonia or problems with your breathing.

- had 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.
- any excessive weakness, shrinkage or wastage of muscles, or previous prolonged periods of muscle weakness.
- bleeding problems, you bleed easily or have a history of prolonged bleeding times.
- 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 your doctor will inject Dysport into your facial muscles.
- any other medical conditions.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not recommended to be given Dysport while you are breastfeeding.

Elderly

- If you are elderly, your doctor may give you a smaller amount of Dysport.

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 to use Dysport in children under 2 years of age.
- Dysport should not be used for treatment of any other conditions in children.

Other

- 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.

3. What if I am taking other medicines?

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

Some medicines may interfere with Dysport and affect how it works:

- muscle relaxing drugs (muscle relaxants)

- antibiotics (aminoglycoside antibiotics, spectinomycin, polymyxins, tetracyclines and lincomycin)
- other medicines, in particular penicillamine and procainamide

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Dysport.

4. How am I given Dysport?

How much is given

- Your doctor will choose the correct dosage of medicine to use. This will depend on what you are being treated for.
- Your doctor may divide the dose amount between your affected muscles.
- The dose may depend on the size, number, and location of muscles affected, how severe your condition is, and taking into account any local muscle weakness or your previous response to treatment.

Upper limb spasticity:

- In adults, your dose of Dysport can be up to 1000 units in total.
- In children, your dose of Dysport can be up to 640 units or 16 units/kg for one arm or up to 840 units or 21 units/kg for both arms, whichever amount is lower.

Lower limb spasticity:

- In adults, your dose of Dysport can be up to 1500 units in total.

- In children, your dose of Dysport can be up to 1000 units or 30 units/kg, whichever amount is lower.

Upper and lower limb spasticity:

- If both your arms and legs are being treated in the same session, your dose can be up to 1500 units total in adults. For children, it can be up to 1000 units or 30 units/kg, whichever is lower, in total.

Spasmodic torticollis (cervical dystonia):

- Your first dose of Dysport will usually be 250 to 500 units in total.
- Your dose of Dysport can be up to 1000 units.

Blepharospasm or hemifacial spasm:

- Your first dose will be approximately 40 units of Dysport per eye or on the affected side of your face.
- On the next visits, your dose of Dysport can be up to 120 units per eye.

Frown lines:

- Your dose of Dysport can be up to 50 units divided equally among 5 injection sites.

Crow's feet:

- Your dose of Dysport can be up to 30 units per side divided equally among 3 injection sites per eye (equal to 60 units total at 6 injection sites).

When Dysport is given

- Your doctor will decide how often and for how long you need treatment. This will depend on what you are being treated for.

- Upper or lower limb spasticity, spasmodic torticollis/ cervical dystonia, blepharospasm/hemifacial spasm: In adults, your injections will usually be around every 12 to 16 weeks, but not less than 12 weeks.
- Upper or lower limb spasticity: In children, your injections will usually be around every 16 to 28 weeks, but not less than 12 weeks (lower limbs) or 16 weeks (upper limbs).
- Frown lines and crow's feet: Your injections will be not less than 12 weeks apart.

How Dysport is given

- Your doctor will prepare the vial and give the injection to you.
- Your doctor will inject the medicine into your muscle (intramuscular) or under your skin (subcutaneous), depending on what you are being treated for.
- Your doctor will decide where to make the injections and how many injections you will receive.
- Your doctor will have received training and be experienced in giving Dysport injections.

If you forget to get your Dysport injection

Tell your doctor if you have missed an injection.

They will decide when you need your next injection.

Nothing will happen if you miss an injection other than some of the spasm or muscle stiffness may return.

If you stop getting injections, the muscle relaxing effect will eventually wear off. The muscle movements will return to the way they were before your treatment.

If you are given too much Dysport

Dysport is given to you by a doctor or nurse, so it is unlikely that you or your child will be given too much.

If you are given too much Dysport, muscles other than the ones that were injected may begin to feel weak. There is a risk of the medicine getting into the bloodstream and causing complications (botulinum poisoning). You may experience paralysis of your muscles. If it affects your breathing, you may need to be placed on a respirator and other support systems.

If you think that you have been given too much Dysport, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given Dysport?

Things you should do

Call your doctor straight away if you:

- have any problems swallowing, breathing, or with your speech.
- have worsened muscle weakness.
- notice your eyes are very dry.

Remind any doctor, dentist, pharmacist, or clinic staff you visit that you are using Dysport.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Dysport affects you.

Dysport may cause dizziness in some people. You may experience weakness in the muscles that are being treated, or general weakness.

Looking after your medicine

Your doctor will keep the medicine at the doctor's clinic or surgery, or at the pharmacy.

If you need to store Dysport at home:

- Keep it in a refrigerator between 2°C to 8°C.
- Do not freeze it.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine

A vial of Dysport will be used only for you, and only for a single treatment session. Your doctor or clinic staff will discard any unused medicine.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
<p>General for any condition:</p> <p>Signs of effects of Dysport away from the site of injection:</p> <ul style="list-style-type: none"> • excessive muscle weakness • difficulty swallowing • a change to the tone of the voice, shortness of breath • pneumonia <p>Signs of allergic reaction (hypersensitivity):</p> <ul style="list-style-type: none"> • shortness of breath, wheezing or difficulty breathing • swelling of the face, lips, tongue, throat or other parts of the body • skin redness, rash, itching, or hives on the skin <p>Upper & lower limb spasticity in adults:</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • difficulty in swallowing certain foods • accidental falls or injury possibly due to muscle weakness <p>Upper & lower limb spasticity in children:</p> <ul style="list-style-type: none"> • accidental falls or injury possibly due to muscle weakness <p>Spasmodic torticollis (cervical dystonia):</p> <ul style="list-style-type: none"> • difficulty in swallowing certain foods • muscle wasting, jaw disorder • breathing difficulties <p>Blepharospasm or hemifacial spasm:</p> <ul style="list-style-type: none"> • very dry eyes • facial nerve paralysis • a condition where the eyelid may turn in towards the eyeball, the eye muscles may become paralysed or 	

Serious side effects	What to do
there may be a need to avoid bright light. (rare)	

Less serious side effects

Less serious side effects	What to do
<p>General for any condition:</p> <ul style="list-style-type: none"> • general weakness • pain, bruising, swelling, reddening, rashes, weakness in the area where you had the injection • fatigue, exhaustion, lethargy, tiredness • flu-like symptoms • itching • numbness • muscle wasting <p>Upper & lower limb spasticity in adults:</p> <ul style="list-style-type: none"> • muscles may feel weaker • pain in your hands and fingers 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<p>Upper & lower limb spasticity in children:</p> <ul style="list-style-type: none"> • muscle weakness • muscle pain • pain in your hands and fingers • flu-like symptoms • loss of strength and weakness • tiredness • skin rash • urinary incontinence • abnormal walking <p>Spasmodic torticollis (cervical dystonia):</p> <ul style="list-style-type: none"> • headache, dizziness, facial weakness leading to loss of movement • blurred vision, reduced visual acuity, double vision • dry mouth • muscle weakness • neck pain, muscle or joint pain and stiffness • pain in your hands or fingers 	

Less serious side effects	What to do
<ul style="list-style-type: none"> • feeling sick <p>Blepharospasm or hemifacial spasm:</p> <ul style="list-style-type: none"> • slight eyelid droop • dry eyes • double vision • more tears than usual • swelling of the eyelid • facial muscle weakness <p>Frown lines (glabellar lines):</p> <ul style="list-style-type: none"> • headache • 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 • blurred or double vision, visual disturbances or disorders in eye movement • dizziness 	

Less serious side effects	What to do
<p>Crow's feet (lateral canthal lines):</p> <ul style="list-style-type: none"> • headache • swelling or drooping of the eyelids • bruising and swelling around the eyes (a black eye) • more tears than usual • twitching of eye muscles • temporary facial paralysis • dry eyes 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Dysport contains

Active ingredient (main ingredient)	clostridium botulinum type A toxin-haemagglutinin complex
Other ingredients (inactive ingredients)	albumin lactose

Do not take this medicine if you are allergic to any of these ingredients.

What Dysport looks like

Dysport is available in 125 units, 300 units, and 500 units (AUST R 235282, 170651, 74124).

These IPSEN units apply to Dysport only and are not the same for other medicines containing botulinum toxin.

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.

Australian Sponsor of Dysport

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