PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DYSPORT® 300 U Powder for solution for injection

***Clostridium botulinum* type A toxin-haemagglutinin complex**

Contains sugar (lactose monohydrate) 2,5 mg per vial

Read all of this leaflet carefully before you are given DYSPORT® 300 U

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- DYSPORT® 300 U has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- You must see a doctor if your symptoms worsen or not improve.

What is in this leaflet

1. What DYSPORT® 300 U is and what it is used for
2. What you need to know before you use DYSPORT® 300 U
3. How to use DYSPORT® 300 U
4. Possible side effects
5. How to store DYSPORT® 300 U
6. Contents of the pack and other information

1. What DYSPORT® 300 U is and what it is used for

DYSPORT® 300 U contains the active substance *Clostridium botulinum* type A toxin-haemagglutinin complex.

DYSPORT® 300 U is used for:

Children:

DYSPORT® 300 U is used in children with cerebral palsy (aged two years and older):

- to treat muscle spasms in the legs, to improve their walking;
- to treat muscle spasms in the arms.

Adults:

DYSPORT® 300 U is used in adults to treat muscle spasms:

- Around the eyes;
- In the face;
- In the neck;
- In the arm and shoulders;
- In the leg.

DYSPORT® 300 U is used in adults to treat:

- Hyperhidrosis. This is a condition where there is excess sweating of the armpits, which interferes with daily living.

How DYSPORT® 300 U works:

DYSPORT® 300 U 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.

2. What you need to know before you are given DYSPORT® 300 U

Do not use DYSPORT® 300 U:

- if you are allergic to botulinum toxin type A or any of the other ingredients of DYSPORT® 300 U (listed in section 6);

- if there is infection or inflammation at the proposed injection site(s) present;
- if you are pregnant or think you may be pregnant, or you are breastfeeding your baby.

Warnings and precautions

There are increased risks of having DYSPORT® 300 U injections under any of these circumstances.

Tell your doctor or healthcare provider before being given the injection if:

- you have other problems or diseases that affect your muscles e.g., myasthenia gravis;
- you have problems swallowing;
- you have any history of bronchitis, pneumonia or problems with breathing;
- you bleed easily;
- you have an infection where the injection will be given or if that area is swollen;
- you have had an allergic reaction to a botulinum toxin in the past;
- you have a vision disturbance after administration of DYSPORT® 300 U;
- The muscles at the proposed site of injection are weak or show signs of wasting.

When DYSPORT® 300 U is used in the treatment of persistent muscle spasms in the eyelid and face or used to improve the appearance of glabellar lines and/or lateral canthal lines, your eyes may become dry. DYSPORT® 300 U may make your eyes blink less often or produce less tears, which could harm the surface of your eyes (see section 4).

Children and adolescents

For the treatment of spasticity associated with cerebral palsy in children, DYSPORT® 300 U should only be used in children 2 years of age or over.

Other medicines and DYSPORT® 300 U

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional 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 medicines. Some of these medicines may increase the effect of DYSPORT® 300 U.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before you are given DYSPORT® 300 U. If you are pregnant or breastfeeding your baby, you cannot be given DYSPORT® 300 U.

DYSPORT® 300 U may affect fertility, when given at high doses.

Driving and using machines

DYSPORT® 300 U may cause muscle weakness or problems with your vision. If you experience any of these effects, do not drive or use any machines.

It is not always possible to predict to what extent DYSPORT® 300 U may interfere with the daily activities of a patient. Patients should ensure that they do not drive a vehicle or use machines activities until you are aware of the measure to which DYSPORT® 300 U affects you.

DYSPORT® 300 U contains human albumin and lactose monohydrate

DYSPORT® 300 U contains a small amount of albumin which 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.

DYSPORT® 300 U contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before receiving this medicine.

3. How DYSPORT® 300 U is given

Do not share medicines prescribed for you with any other person.

DYSPORT® 300 U must be injected. You will not be expected to give yourself DYSPORT® 300 U. It will be given to you by a person who is qualified to do so.

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® 300 U should be used only for you and only for a single treatment session.

If you have the impression that the effect of DYSPORT® 300 U is too strong or too weak, talk to your doctor or pharmacist.

Adults:

For treatment of muscle spasms in your *arm and shoulder*:

The dose of DYSPORT® 300 U will usually be between 500 and 1 000 units. The doctor or other healthcare professional may divide the amount between the affected arm and shoulder muscles. Your muscle spasms should normally improve within 1 week and this improvement may last up to 20 weeks.

Injections will usually be given about every 12 to 16 weeks, depending on how long the effect last, but not more frequently than every 12 weeks.

For treatment of muscle spasms in your *leg*:

The dose of DYSPORT® 300 U will usually be up to 1500 units and should not exceed this dose. The doctor or other healthcare professional may divide the amount between the affected leg muscles. Injections will usually be given about every 12 to 16 weeks, or longer as necessary, but not more frequently than every 12 weeks.

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 or other healthcare professional may divide the dose between your arm and leg in line with the approved dose recommendations, but the overall dose must not exceed 1 500 units.

For treatment of muscle spasms in your *neck*:

The first dose of DYSPORT® 300 U will usually be 500 units divided 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 – 1 000 units) will be given about every 16 weeks, depending on how long the effect lasts or as required to maintain the response, but not more frequently than every 12 weeks. The maximum dose must not exceed 1 000 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® 300 U around this eye. Your muscle spasms should normally start improving within 2 - 4 days with maximal effect within 2 weeks. Injections will be given about every 12 weeks depending on how long the effects last, but not more frequently than every 12 weeks. On the next visits, the amount of DYSPORT® 300 U 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 40 units. Injections will be given about every 12 weeks depending on how long the effects last, but not more frequently than every 12 weeks. On the next visits, the amount of DYSPORT® 300 U given may be increased to a maximum of 120 units.

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 approximately 48 weeks.

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. The minimum time between treatments is 12 weeks. The maximum dose you should be given is 200 units per armpit.

Children with cerebral palsy (aged two years or older):

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® 300 U is injected into the affected muscles of the legs. The dose must not be higher than 1 000 units or 30 units/kg at a given treatment session, whichever is lower. Your muscle spasms should normally improve within 2 weeks and this improvement may last up to 28 weeks. Your doctor or other healthcare professional 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® 300 U is injected into the affected muscles of the 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 or other healthcare provider 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® 300 U to be injected in each limb should be decided by your doctor or healthcare practitioner, without exceeding a total dose per treatment session of 1 000 units or 30 units/kg, whichever is lower. Your doctor or healthcare practitioner will repeat the treatment as needed, but no sooner than 12 - 16 weeks after the previous treatment session.

If you are given more DYSPORT® 300 U than you should

Since a healthcare provider will administer DYSPORT® 300 U, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you are given more DYSPORT® 300 U than you need, muscles other than the ones that were injected may begin to feel weak. This may not happen straight away. If this does happen, speak to your doctor immediately. Seek urgent medical help if you have difficulty breathing, swallowing, or speaking.

If you forget an injection of DYSPORT® 300 U

Since a healthcare provider will administer DYSPORT® 300 U, it is unlikely that the dose will be missed.

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® 300 U

Your muscle spasms will return to the way they were before treatment.

4. Possible side effects

DYSPORT® 300 U can have side effects.

Not all side effects reported for DYSPORT® 300 U are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DYSPORT® 300 U, please consult your healthcare provider for advice.

DYSPORT® 300 U may in less frequent cases cause side effects away from its site of injection.

Seek urgent medical help if:

If any of the following happens, tell your doctor immediately and seek urgent medical help:

- Problems swallowing, breathing or with your speech or you have worsened muscle weakness.

- 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® 300 U.

These are all very serious side effects. If you have them, you may have had a serious reaction to DYSPORT® 300 U. You may need urgent medical attention or hospitalisation.

Some side effects may occur in any patient treated with DYSPORT® 300 U 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*):

Frequent side effects:

- bruising, or pain around the site where the injection was given;
- generalised weakness;
- tiredness;
- flu-like symptoms.

Less frequent side effects:

- itching;
- skin rashes;
- sudden severe pain and weakness in shoulder and/or arm (neuralgic amyotrophy).

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

Frequent side effects:

- muscle weakness;
- musculoskeletal pain;
- pain in the hands and fingers.

Less frequent side effects:

- difficulty in swallowing.

Treatment of muscle spasms in the *leg* of adults:

Frequent side effects:

- difficulty in swallowing;
- leg muscle weakness;
- muscle pain;
- fall.

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

Frequent side effects:

- drooping of the upper eyelid;
- double vision;
- swelling of the eyelid;
- facial muscle weakness;
- dry eyes or more tears than usual.

Less frequent side effects:

- facial paralysis;
- difficulty in moving the eye;
- edge of the eyelid turning in towards the eyeball (entropion).

Treatment of muscle spasms in the *neck*:

Frequent side effects:

- muscle weakness;
- difficulty in swallowing. This side effect may be expected to resolve within 2 to 4 weeks;
- dry mouth;
- headache;
- dizziness;
- blurred vision or other problems in seeing clearly;
- weakness of face muscles;
- stiff muscles;
- shortness of breath;
- a change to the tone of the voice;

- neck pain, muscle pain, pain in the hands and fingers.

Less frequent side effects:

- loss of muscle tissue;
- jaw problems;
- drooping of the upper eyelid;
- double vision;
- nausea;
- lung inflammation caused by accidentally breathing in food, drink, saliva or vomit (aspiration pneumonia).

Treatment of excessive sweating of the *armpits*:

Frequent side effects:

- increased sweating in other parts of the body (compensatory sweating).

Not Known: (frequency cannot be estimated from the available data)

- Numbness;
- Muscle wasting;

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

Frequent side effects:

- muscle pain;
- muscle weakness;
- urinary incontinence;
- flu-like symptoms;
- pain, redness, bruising at the injection site;
- abnormal walking;
- tiredness;
- fall.

Less frequent side effects:

- loss of strength and weakness.

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

- Frequent side effects:
- 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 frequent side effects:

- 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 muscle spasms in the arms and *legs* of children with cerebral palsy:

- There are no specific findings for the administration of DYSPORT® 300 U at the same treatment session in the arm and leg compared to those expected from treating in the arm or the leg separately.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to effects to Acino Pharma (Pty) Ltd: E-mail: drugsafety_ZA@acino.swiss OR to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of DYSPORT® 300 U.

5. How to store DYSPORT® 300 U

- Store all medicines out of reach of children.
- Store in a refrigerator (2 °C – 8 °C). Do not freeze the vial.
- Do not use the medicine after the expiry date which is stated on the label after 'EXP'. The expiry date refers to the last day of the [than] month.
- Chemical and physical in-use stability has been demonstrated for the reconstituted solution for 24 hours in a refrigerator (2 °C – 8 °C). After the solution is made up, unless the method of reconstitution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What DYSPORT® 300 U contains

The active substance of DYSPORT® 300 U is *Clostridium botulinum* type A toxin-haemagglutinin complex (500 units per vial).

The other ingredients in DYSPORT® 300 U are human albumin and lactose.

Before it is injected, DYSPORT® 300 U will be dissolved in sodium chloride for injection (a solution of salt).

What DYSPORT® 300 U looks like and contents of the pack

DYSPORT® 300 U is a powder for solution for injection. It appears as a white freeze-dried pellet with no foreign matter in a glass vial.

DYSPORT® 300 U is filled into a 3 ml Type I clear neutral glass vial sealed with a rubber closure and self-coloured aluminium seal with flip top.

Pack sizes of 1 or 2 vials. Not all pack sizes may be marketed.

Holder of Certificate of Registration

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1686

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This leaflet was last revised in

13 June 2025

Registration number

49/30.5/0246

Access to the corresponding Professional Information

The professional information for DYSPORT 300 U can be accessed by scanning the QR-code below:

AA4941 07/2025