IPSEN

PATIENTS WITH
PAEDIATRIC SPASTICITY

MORE MOMENTS WORTH SHARING

Dosing guide

Dysport® is indicated for focal spasticity, including for the:[1]

- Treatment of dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients, 2 years of age or older.
- Symptomatic treatment of focal spasticity affecting the upper limbs in paediatric cerebral palsy patients, 2 years of age or older.

Dysport®
CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

This handbook is intended for use by healthcare professionals only.
Prescribing Information and adverse event reporting can be found on the relevant tab.

Dysport®
CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Indication in paediatric spasticity[1]

Dysport® is indicated for:[1]

Symptomatic treatment **of focal spasticity of upper limbs** in paediatric cerebral palsy patients, 2 years of age or older

Treatment of **dynamic equinus foot deformity** in ambulant paediatric cerebral palsy patients, 2 years of age or older

For the full list of indications, please consult the Dysport® Summary of Product Characteristics.[1]

Dysport® provides:

SYMPTOM RELIEF that can last UP TO 34 WEEKS or more for upper limb spasticity and UP TO 28 WEEKS for lower limb spasticity[1]

Treatment should be repeated when the effect of a previous injection has diminished[1]

(but not before 12 weeks for dynamic equinus foot deformity and 16 weeks for upper limb spasticity)[1]*

*The degree and pattern of muscle spasticity at the time of re-injection may necessitate alterations in the dose of Dysport® and muscles to be injected.[1]

Dosing principles[1]

For every Dysport® injection, dosing should be TAILORED TO THE INDIVIDUAL BASED ON:[1]

- **Size** of muscle
- **Number and location** of muscles
- **Patient's response** to previous treatment and/or adverse event history with **botulinum toxins**
- **Severity of spasticity** or the condition in general
- Any local **muscle weakness**

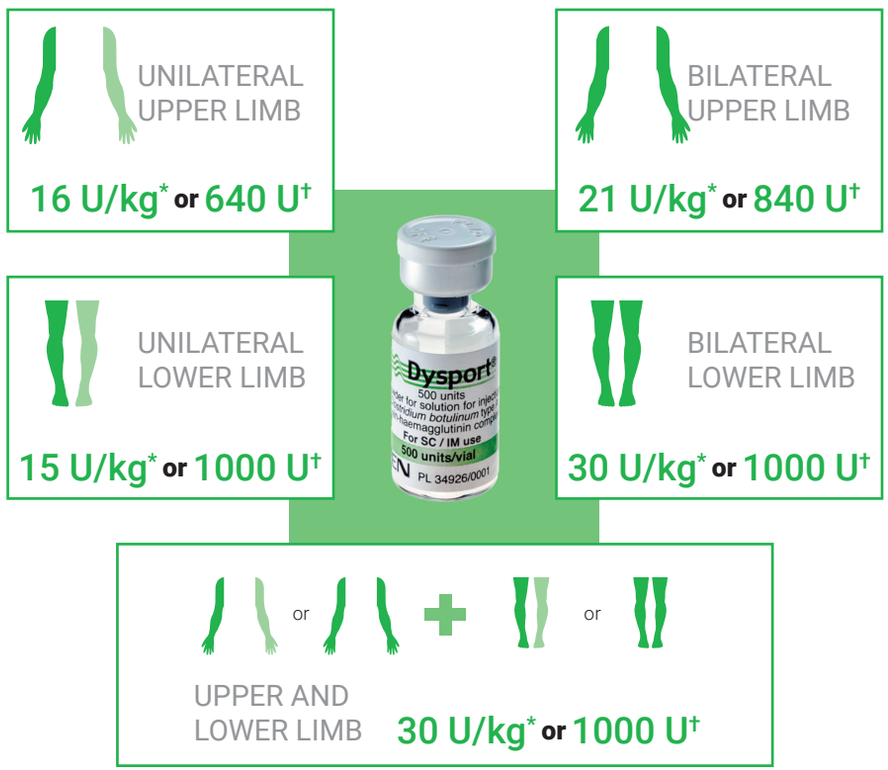
The dosing recommendations in the Dysport® SmPC should also be followed.

SmPC, Summary of Product Characteristics.

Dysport®
CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Approved doses[1]

Approved maximum total doses for paediatric cerebral palsy patients (2 years and older) with focal spasticity:[1]



E.g. If a child weighs 10 kg, the total approved dose would be 300 U (30 U x 10 kg)

For concomitant treatment of upper and lower limb spasticity

When treating upper and lower limb spasticity in children aged 2 years and older, please refer to the posology section of the Dysport® SmPC for the individual indication, e.g. treatment of focal spasticity of the upper limb or lower limb in children aged 2 years and older.[1]

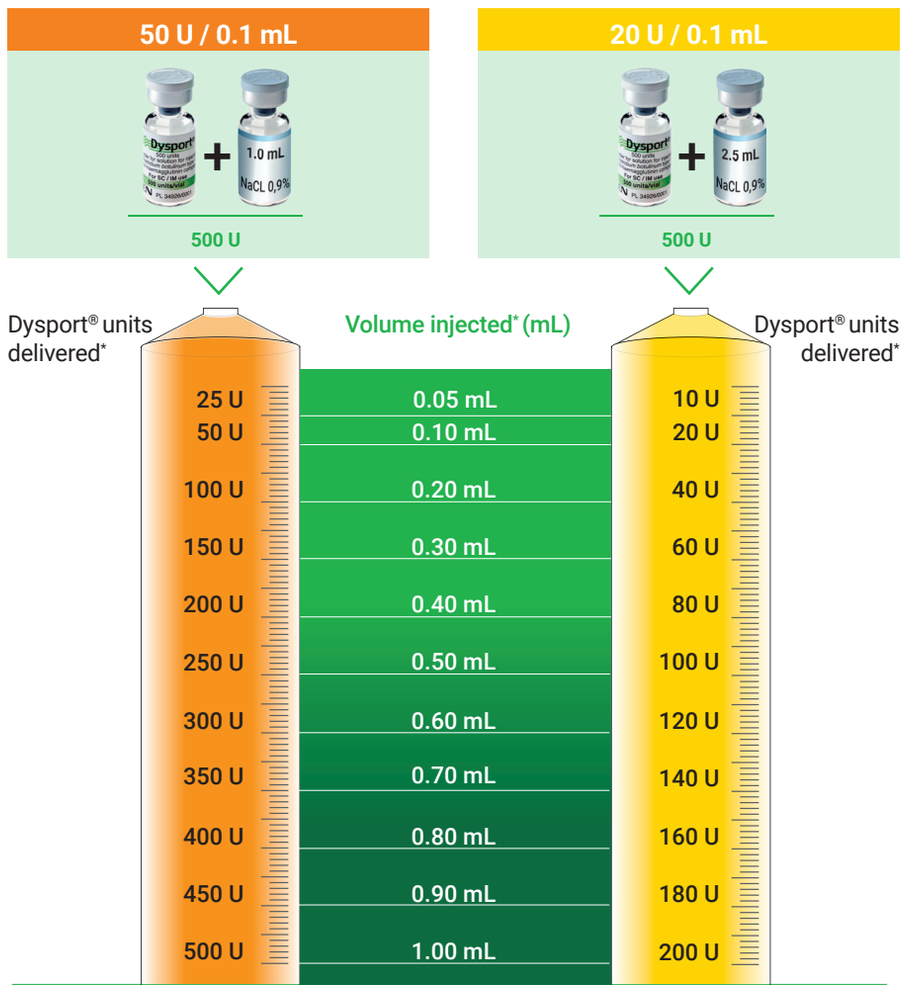
*kg refers to the patient's total body weight in kilograms.[1] †Whichever is lower.

SmPC, Summary of Product Characteristics; U, unit.

Dilution ruler[1]

Dysport® is available in 500 U vials and can be diluted to offer the flexibility needed[1]

Dysport® is diluted and reconstituted with NaCl injection B.P. (0.9% w/v) preservation-free diluent for a solution containing either:

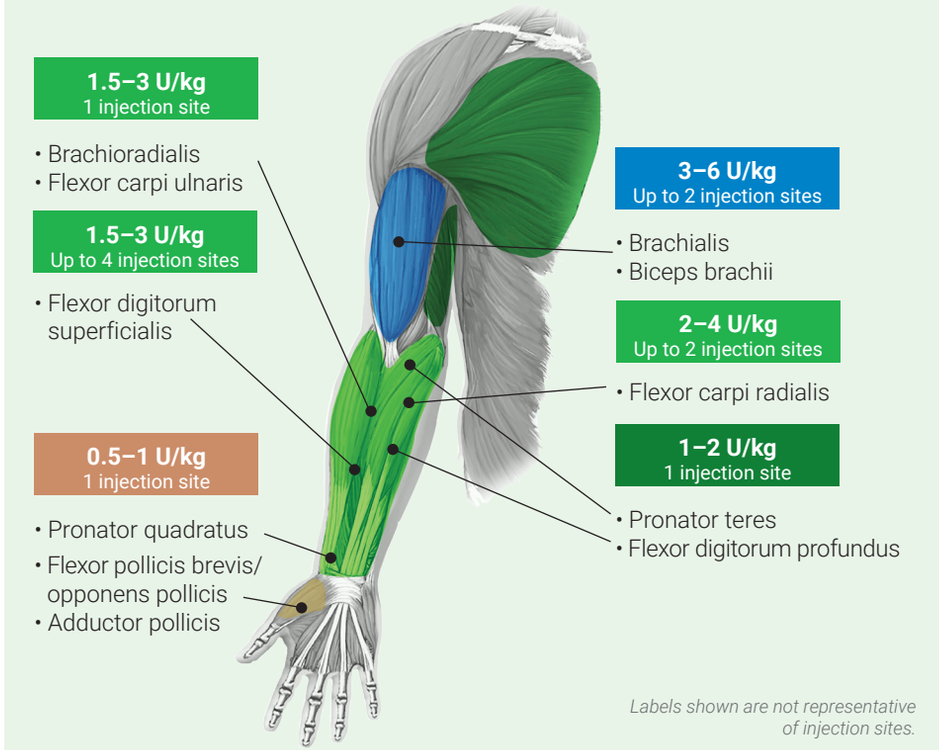


*Reconstitution instructions are specific to the 500 U vials. The volumes listed yield concentrations specific for appropriate use. Further dilutions may be required in the treatment of some patients. For full guidance, please consult the Dysport® Summary of Product Characteristics.

NaCl, sodium chloride; U, unit; w/v, weight per volume.

Dysport®
CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Recommended doses for upper limb muscles[1]



0.5 mL per muscle	As a rule, no more than 0.5 mL should be administered at a single injection site[1]
840 U or 21 U/kg total dose per session	Up to 16 U/kg or 640 U* in a single upper limb (and not exceeding 21 U/kg or 840 U* if both upper limbs injected)[1]

DIVIDE

the total dose administered between the affected spastic muscles[1]

*Whichever is lower.

U, units.

Treatment should be repeated when **the effect of a previous injection has diminished**

(But not before 16 weeks)[*1]*

The majority of patients in clinical studies received further treatment after 16–28 weeks; **however, a longer-term effect lasting 34 weeks or more occurred in some patients.**[1]

For treatment of upper and lower limbs in the same treatment session

When treating combined upper and lower spasticity in children aged 2 years or older, refer to the posology section for the individual indications. The dose of Dysport® to be injected for concomitant treatment should not exceed a total dose per treatment session of 30 U/kg or 1000 U, whichever is lower.[1]

Injection site location

Although actual location of injection sites can be determined by palpation, use of injection guiding technique, e.g. electromyography, electrical stimulation or ultrasound is recommended to target injection sites.[1]

*The degree and pattern of muscle spasticity at the time of re-injection may necessitate alterations in the dose of Dysport® and muscles to be injected.[1]

U, units.

Dysport®
CLOSTRIDIUM BOTULINUM TYPE A
TOXIN-HAEMAGGLUTININ COMPLEX

Dose ranges according to weight for upper limb muscles[1]

Weight (kg)	**0.5–1 U/kg** Pronator quadratus Flexor pollicis brevis/opponens pollicis Adductor pollicis	**1–2 U/kg** Pronator teres Flexor digitorum profundus
10	5–10 U	10–20 U
12	6–12 U	12–24 U
14	7–14 U	14–28 U
16	8–16 U	16–32 U
18	9–18 U	18–36 U
20	10–20 U	20–40 U
22	11–22 U	22–44 U
24	12 – 24 U	24–48 U
26	13 – 26 U	26–52 U
28	14–28 U	28–56 U
30	15–30 U	30–60 U
32	16–32 U	32–64 U
34	17–34 U	34–68 U
36	18–36 U	36–72 U
38	19–38 U	38–76 U
40	20–40 U	40–80 U
42	21–42 U	42–84 U
44	22–44 U	44–88 U
46	23–46 U	46–92 U
48	24–48 U	48–96 U
50	25–50 U	50–100 U
52	26–52 U	52–104 U
54	27–54 U	54–108 U
56	28–56 U	56–112 U
58	29–58 U	58–116 U
60	30–60 U	60–120 U
62	31–62 U	62–124 U
64	32–64 U	64–128 U
66	33–66 U	66–132 U
68	34–68 U	68–136 U
70	35–70 U	70–140 U

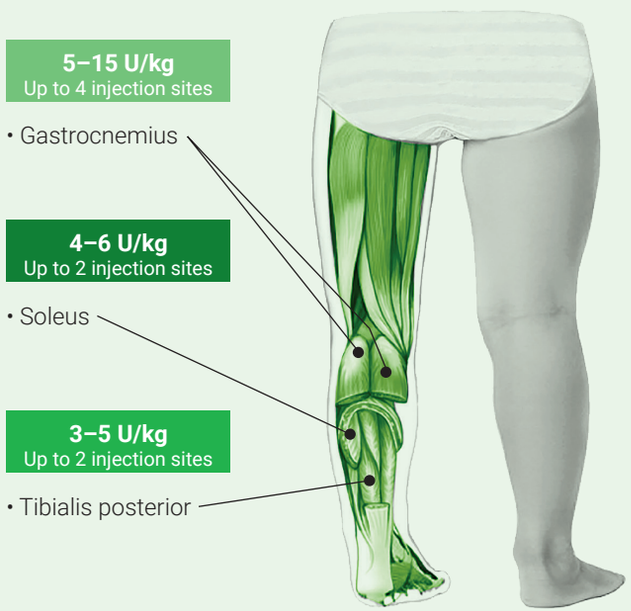
U, units.

Weight (kg)	**1.5–3 U/kg** Brachioradialis Flexor carpi ulnaris Flexor digitorum superficialis	**1.5–3 U/kg** Flexor carpi radialis	**3–6 U/kg** Brachialis Biceps brachii
10	15–30 U	20–40 U	30–60 U
12	18–36 U	24–48 U	36–72 U
14	21–42 U	28–56 U	42–84 U
16	24–48 U	32–64 U	48–96 U
18	27–54 U	36–72 U	54–108 U
20	30–60 U	40–80 U	60–120 U
22	33–66 U	44–88 U	66–132 U
24	36–72 U	48–96 U	72–144 U
26	39–78 U	52–104 U	78–156 U
28	42–84 U	56–112 U	84–168 U
30	45–90 U	60–120 U	90–180 U
32	48–96 U	64–128 U	96–192 U
34	51–102 U	68–136 U	102–204 U
36	54–108 U	72–144 U	108–216 U
38	57–114 U	76–152 U	114–228 U
40	60–120 U	80–160 U	120–240 U
42	63–126 U	84–168 U	126–252 U
44	66–132 U	88–176 U	132–264 U
46	69–138 U	92–184 U	138–276 U
48	72–144 U	96–192 U	144–288 U
50	75–150 U	100–200 U	150–300 U
52	78–156 U	104–208 U	156–312 U
54	81–162 U	108–216 U	162–324 U
56	84–168 U	112–224 U	168–336 U
58	87–174 U	116–232 U	174–348 U
60	90–180 U	120–240 U	180–360 U
62	93–186 U	124–248 U	186–372 U
64	96–192 U	128–256 U	192–384 U
66	99–198 U	132–264 U	198–396 U
68	102–204 U	136–272 U	204–408 U
70	105–210 U	140–280 U	210–420 U

U, units.

Dysport®
CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Recommended doses for lower limb muscles[1]



Labels shown are not representative of injections sites.

0.5 mL per muscle	As a rule, no more than 0.5 mL should be administered at a single injection site[1]
1000 U or 30 U/kg total dose per session	Up to 15 U/kg in a single lower limb or 30 U/kg if both lower limbs injected and not exceeding 1000 U (whichever is lower)[1]

DIVIDE
the total dose administered between the affected spastic muscles[1]

DISTRIBUTE
the total dose across >1 injection site per muscle (if possible)[1]

U, units.

Treatment should be repeated when **the effect of a previous injection has diminished**

(But not before 12 weeks)[*1]*

The majority of patients in clinical studies received further treatment after 16–22 weeks; **however, a longer-term effect lasting up to 28 weeks occurred in some patients.**[1]

For treatment of upper and lower limbs in the same treatment session

When treating combined upper and lower spasticity in children aged 2 years or older, please refer to the posology section for the individual indications. The dose of Dysport® to be injected for concomitant treatment should not exceed a total dose per treatment session of 30 U/kg or 1000 U, whichever is lower.[1]

Injection site location

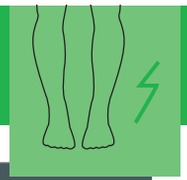
Although actual location of injection sites can be determined by palpation, use of injection guiding technique (e.g. electromyography, electrical stimulation or ultrasound) is recommended to target injection sites.[1]

*The degree and pattern of muscle spasticity at the time of re-injection may necessitate alterations in the dose of Dysport® and muscles to be injected.[1]

U, units.

Dysport®
CLOSTRIDIUM BOTULINUM TYPE A
TOXIN-HAEMAGGLUTININ COMPLEX

Dose ranges according to weight for lower limb muscles[1]



Weight (kg)	3–5 U/kg Tibialis posterior	4–6 U/kg Soleus	5–15 U/kg Gastrocnemius
10	30–50 U	40–60 U	50–150 U
12	36–60 U	48–72 U	60–180 U
14	42–70 U	56–84 U	70–210 U
16	48–80 U	64–96 U	80–240 U
18	54–90 U	72–108 U	90–270 U
20	60 –100 U	80–120 U	100–300 U
22	66–110 U	88–132 U	110–330 U
24	72–120 U	96–144 U	120–360 U
26	78–130 U	104–156 U	130–390 U
28	84–140 U	112–168 U	140–420 U
30	90–150 U	120–180 U	150–450 U
32	96–160 U	128–192 U	160–480 U
34	102–170 U	136–204 U	170–510 U
36	108–180 U	144–216 U	180–540 U
38	114–190 U	152–228 U	190–570 U
40	120–200 U	160–240 U	200–600 U
42	126–210 U	168–252 U	210–630 U
44	132–220 U	176–264 U	220–660 U
46	138–230 U	184–276 U	230–690 U
48	144–240 U	192–288 U	240–720 U
50	150–250 U	200–300 U	250–750 U
52	156–260 U	208–312 U	260–780 U
54	162–270 U	216–324 U	270–810 U
56	168–280 U	224–336 U	280–840 U
58	174–290 U	232–348 U	290–870 U
60	180–300 U	240–360 U	300–900 U
62	186–310 U	248–372 U	310–930 U
64	192–320 U	256–384 U	320–960 U
66	198–330 U	264–396 U	330–990 U
68	204–340 U	272–408 U	340–1000 U
70	210–350 U	280–420 U	350–1000 U

U, units.

U, units.

Reconstitution[1]

IMPORTANT NOTE:

The units of Dysport® are specific to Dysport® and are not interchangeable with other preparations of botulinum toxin type A.

EQUIPMENT required to reconstitute Dysport®:

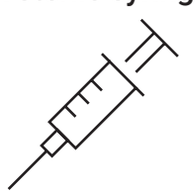
1 vial Dysport®

500 U

Diluent

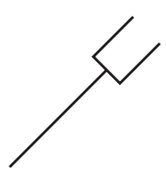
Preservative-free 0.9% w/v NaCl

1x sterile syringe



1 mL or 2.5 mL

1x sterile needle



23 or 25 gauge

U, units; w/v, weight per volume..

4-STEP reconstitution

Step 1 — Draw up the required volume of diluent*

Final concentration[1]	Diluent per Dysport® 500 U
20 U/0.1 mL	2.5 mL of NaCl 0.9%
50 U/0.1 mL	1.0 mL of NaCl 0.9%

- Based on the final concentration needed, draw up the required volume of sterile NaCl 0.9% using a 23 or 25 gauge needle syringe
- Paediatric cerebral palsy spasticity is dosed using units per body weight (in kg): further dilution may be required to achieve the final volume for injection

Step 2 — Inject the diluent into the Dysport® vial

- Remove the Dysport® vial cap and wipe the stopper with an alcohol wipe
- Insert the needle into the vial and release the diluent into the Dysport® powder

IMPORTANT NOTE:
A partial vacuum can be experienced while injecting the diluent. Extra pressure may be needed to ensure complete transfer of the diluent. Do not use the vial if no vacuum is observed.

Step 3 — Swirl gently to dissolve Dysport® powder

- **Do not shake or roll.** The solution must be colourless, clear and free of particulate matter. If not, do not use

Step 4 — Draw up the reconstituted Dysport®

- Using a new sterile needle, draw up the required volume for injection

IMPORTANT NOTE:
Vent the vial to release the pressure before detaching the reconstitution syringe and attaching the syringe that will be used to inject Dysport®

When Dysport® is ready to inject:

- Dysport® should be used immediately after reconstitution
- After injection, any residual Dysport® should be inactivated with dilute hypochlorite solution (1% available chlorine)

*Reconstitution instructions are specific to a 500 U vial. The volumes listed yield concentrations specific for appropriate use. Further dilutions may be required in the treatment of some patients.

For full guidance, please consult the Dysport® Summary of Product Characteristics.[1]

NaCl, sodium chloride; U, units; w/v, weight per volume.

Dysport®
CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Safety profile[1]

At approved doses, Dysport® has a well characterised safety profile.[1]

Across a variety of indications:[1]

- Patients treated with therapeutic doses may experience side effects related to the spread of toxin from the site of administration, such as muscle weakness, dysphagia and aspiration pneumonia[1]
- Other general side effects reported across indications include asthenia, fatigue, influenza-like illness and injection site reactions (e.g. pain, bruising)[1]
- The risk of occurrence of such undesirable effects may be reduced by administering the lowest effective possible dose and by not exceeding the maximum recommended dose[1]

REPORTING OF SUSPECTED ADVERSE REACTIONS

Adverse events should be reported. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions online via the **Health Products Regulatory Authority (HPRA) reporting service**. Reporting forms and information can be found at **www.hpra.ie**.

Adverse events should also be reported to the Ipsen Medical Information Department on +353 1 8098256 or pharmacovigilance.uk-ie@ipsen.com.

Treatment of upper and lower limbs during the same treatment session

When treating upper and lower limbs concomitantly with Dysport® at a total dose of up to 30 U/kg or 1000 U, whichever is lower, there are no safety findings in addition to those expected from treating either upper limb or lower limb muscles alone.[1]

Lower limb spasticity of paediatric (2 years and older) cerebral palsy patients[1]

System organ class	Adverse drug reaction	Frequency*
Musculoskeletal and connective tissue disorders	Myalgia, muscular weakness	Common
Renal and urinary disorders	Urinary incontinence	Common
General disorders and administration site conditions	Influenza-like illness, injection site reactions (e.g. pain, erythema, bruising, etc.), gait disturbance, fatigue	Common
	Asthenia	Uncommon
Injury, poisoning and procedural complications	Fall	Common

Upper limb spasticity of paediatric (2 years and older) cerebral palsy patients[1]

System organ class	Adverse drug reaction	Frequency*
Musculoskeletal and connective tissue disorders	Muscular weakness, myalgia	Common
General disorders and administration site conditions	Influenza-like illness, fatigue, injection site reactions (eczema, bruising, pain, swelling, rash)	Common
	Asthenia	Uncommon
Skin and subcutaneous tissue disorders	Rash	Common

*Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10,000 to <1/1000); very rare (<1/10,000); not known (cannot be estimated from the available data)

U, units.

Prescribing information

Prescribing Information
DYSPORT® Powder for solution for injection *(Clostridium botulinum* type A toxin-haemagglutinin complex*)* 300 or 500 units

Prescribers should consult the Summary of Product Characteristics (SmPC) accessible at https://www.medicines.ie/ before treatment, to obtain more comprehensive information about Dysport. **Presentation:** Vials of 300 or 500 units (U) of *Clostridium botulinum* type A toxin-haemagglutinin complex. Powder for solution for injection. **Indications: Symptomatic treatment of focal spasticity of: Upper limbs in adults, Lower limbs in adults** affecting the ankle joint due to stroke or traumatic brain injury (TBI), and **dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients** as well as **focal spasticity affecting the upper limbs in paediatric cerebral palsy patients, ≥ 2 years. Symptomatic treatment of: Spasmodic torticollis, Blepharospasm, Hemifacial spasm and Severe primary hyperhidrosis of the axillae**, which does not respond to topical treatment with antiperspirants or antihidrotics. Dysport is also indicated for the **management of urinary incontinence in adults with neurogenic detrusor overactivity due to spinal cord injury (traumatic or non-traumatic) or multiple sclerosis**, who are regularly performing clean intermittent catheterisation. **Administration:** Dysport should only be administered by appropriately trained physicians. Reconstitute in sodium chloride injection B.P. (0.9 % w/v) to yield a concentration as follows: Adult and Paediatric Upper or Lower Limb spasticity: 100/200/500 units per ml; For spasticity in paediatric cerebral palsy patients, which is dosed using unit per body weight, further dilution may be required to achieve the final volume for injection. Blepharospasm, Hemifacial spasm and Axillary hyperhidrosis: 200 units per ml; Spasmodic torticollis: 500 units per ml. For further instruction on reconstitution see SmPC. **The units (U) of Dysport are specific to the preparation and are not interchangeable with other preparations of botulinum toxin**. **Posology:** ***Adult Upper and/or Lower Limb spasticity:*** Dosing in initial and sequential treatment sessions should be tailored to the individual. No more than 1 ml should generally be administered at any single injection site. Use of injection guiding techniques is recommended to target the injection sites. Injections may be repeated every 12-16 weeks or as required to maintain response, but not more frequently than every 12 weeks. The degree and pattern of muscle spasticity at the time of re-injection may necessitate alterations in the dose and muscles to be injected. If treating both upper and lower limbs during the same treatment session, the total dose must not exceed 1500U. *Upper Limb:* In clinical trials, intramuscular (IM) injections of 500U, 1000U and 1500U doses were divided among selected muscles at a given treatment session (see SmPC). Clinical improvement may be expected 1 week after injection and may last up to 20 weeks. *Lower Limb:* In clinical trials, IM injections of 1000U and 1500U doses were divided among selected muscles (see SmPC). Total dose must not exceed 1500U. ***Dynamic equinus foot deformity due to focal spasticity in ambulant paediatric cerebral palsy patients:*** Dosing in initial and sequential treatment sessions should be tailored to the individual. Use of injection guiding techniques is recommended to target the injection sites. For treatment initiation, consideration should be given to start with a lower dose. Total dose should be divided between the affected spastic muscles of the lower limb(s). If possible, the dose should be distributed across more than 1 injection site in any single muscle. No more than 0.5 ml should be administered in any single injection site (see SmPC for recommended dosing). Max. total dose for unilateral lower limb injections must not exceed 15 U/kg or 30 U/kg for bilateral injections, per treatment session. In addition, total dose per treatment session must not exceed 30 U/kg or 1000 U, whichever is the lower. Clinical improvement may be expected within 2 weeks after injection. Repeat treatment should be administered when effect of a previous injection has diminished, but no sooner than 12 weeks after the previous injection. A majority of patients in clinical studies were retreated between 16-22 weeks; however, some patients had a longer duration of response, i.e. 28 weeks. ***Focal spasticity of upper limbs in paediatric cerebral palsy patients***: The maximum dose of Dysport administered per treatment session when injecting unilaterally must not exceed 16 U/kg or 640 U whichever is lower. When injecting bilaterally, the maximum Dysport dose per treatment session must not exceed 21 U/kg or 840 U, whichever is lower. The total dose administered should be divided between the affected spastic muscles of the upper limb(s). No more than 0.5 ml of Dysport should be administered in any single injection site (please see SmPC for full details). ***Focal spasticity of dynamic foot deformity and upper limbs in paediatric cerebral palsy patients:*** The dose of Dysport to be injected for concomitant treatment should not exceed a total dose per treatment session of 30 U/kg or 1000 U, whichever is lower (please see SmPC for full details). ***Spasmodic torticollis:*** The initial recommended dose is 500U IM as a divided dose into the 2 or 3 most active neck muscles. The split amongst muscles will vary according to the type of torticollis diagnosed (see SmPC). A lower dose may be appropriate if the patient is markedly underweight or in the elderly, where a reduced muscle mass may exist. Subsequent doses may be adjusted according to clinical response and side-effects observed. Doses within the range of 250 - 1000 units are recommended, although the higher doses may be accompanied by increase in side effects, particularly dysphagia (see 'Side effects'). Relief of symptoms may be expected within 1 week after injection. Injections may be repeated approx. every 16 weeks, but not more frequently than every 12 weeks. *Children*: The safety and effectiveness of Dysport in the treatment of spasmodic torticollis in children has not been demonstrated. ***Blepharospasm and hemifacial spasm:*** The initial recommended dose is 40U per affected eye. Subsequently, if the response is insufficient from the initial treatment, the dose may be increased to 60U, 80U or up to 120U/eye. Max. dose must not exceed 120U/eye. Injections are given subcutaneously, medially and laterally into the junction between the preseptal and orbital parts of both the upper and lower *orbicularis oculi* muscles of each eye. Relief may be expected within 2-4 days with maximal effect within 2 weeks. Injections should be repeated as required to prevent recurrence of symptoms, but not more frequently than every 12 weeks. Children: The safety and effectiveness of Dysport in the treatment of blepharospasm and hemifacial spasm in children has not been demonstrated. ***Axillary hyperhidrosis:*** Initial recommended dose is 100U/axilla. Max. dose should not exceed 200U/axilla. Intradermal injections to be given at 10 sites i.e. to deliver 10U per site to equal 100U/axilla. Max. effect should be seen after 2 weeks. Injections should not be repeated more frequently than every 12 weeks. ***Urinary incontinence due to neurogenic detrusor overactivity (NDO):*** Recommended dose is 600 U but can be increased to 800 U in case of insufficient response, such as in patients with a severe disease presentation. Should be administered to patients who are regularly performing clean intermittent catheterisation. Total dose should be divided across 30 intradetrusor injections evenly

distributed throughout the detrusor muscle, avoiding the trigone. Dysport is injected via a flexible or rigid cystoscope and each injection should be to a depth of approximately 2 mm with the delivery of 0.5 ml to each site. For the final injection, approximately 0.5 ml of sterile normal saline should be injected to ensure the full dose is delivered. **Contraindications:** (See SmPC for full dosing information): Known hypersensitivity to any component of Dysport. Urinary tract infection at the time of treatment for the management of urinary incontinence due to neurogenic detrusor overactivity. **Warnings and precautions:** Side effects related to the spread of toxin, distant from the injection site, have been reported (see 'Undesirable effects). Patients treated with therapeutic doses may present with excessive muscle weakness. The risk of occurrence of such side effects may be reduced by using the lowest effective possible dose and by not exceeding the maximum recommended dose. Exercise caution, with close medical supervision, in patients with subclinical/clinical evidence of marked defective neuromuscular transmission (e.g. myasthenia gravis), where excessive muscle weakness may occur, with therapeutic doses of Dysport. Patients with underlying neurological disorders are at increased risk of this side effect. Exercise caution when treating lower limb spasticity in adults especially in elderly patients, who may be at increased risk of fall. Very rare cases of death, occasionally in the context of dysphagia, pneumopathy (including but not limited to dyspnoea, respiratory failure, respiratory arrest) and/or in patients with significant asthenia, have been reported following treatment with botulinum toxin A or B. Patients with disorders resulting in defective neuromuscular transmission, difficulty in swallowing or breathing are more at risk of experiencing these effects. In these patients, treatment must be administered under the control of a specialist and only if the benefit of treatment outweighs the risk. Administer with caution to patients with pre-existing swallowing/breathing problems as these can worsen following the distribution of the effect of toxin into the relevant muscles. Aspiration has occurred in rare cases and is a risk when treating patients who have a chronic respiratory disorder. The recommended posology and frequency of administration for Dysport must not be exceeded. Not to be used to treat spasticity in patients who have developed a fixed contracture. Careful consideration should be given before the injection of patients with a history of allergic reaction to a product containing botulinum toxin type A or in patients with prolonged bleeding times, infection/inflammation at the proposed injection site(s). Antibody formation to botulinum toxin has been noted rarely in patients receiving Dysport. Clinically, neutralising antibodies might be suspected by substantial deterioration in response to therapy and/or the need for consistent use of increased doses. Dysport should only be used to treat a single patient during a single session. **Interactions:** Drugs affecting neuromuscular transmission may potentiate the effect of botulinum toxin and should be used with caution. **Fertility, pregnancy and lactation:** Safety in pregnancy has not been demonstrated and Dysport should be used only if the benefit justifies any potential risk to the foetus. Exercise caution when prescribing to pregnant women. Use during lactation cannot be recommended. Studies in male and female rats have shown effects on fertility (see SmPC). **Effects on ability to drive and use machines:** May impair the ability to drive or operate machinery in case of adverse reactions such as muscle weakness and eye disorders. **Undesirable effects:** Undesirable effects related to spread of toxin distant from the injection site have been reported, such as dry mouth, excessive muscle weakness, dysphagia, aspiration/aspiration pneumonia, with fatal outcome (death) in some very rare cases. Hypersensitivity reactions have also been reported post-marketing. In general, the following ADRs (Adverse drug reactions) were reported in clinical trials, ***across all indications***: *Common:* asthenia, fatigue, influenza like illness, injection site reactions. ADRs vary across the indications. ***Adult Upper Limb spasticity:*** *Common:* muscular weakness, musculoskeletal pain, pain in the extremity. ***Adult Lower Limb spasticity***: *Common:* dysphagia, muscular weakness, myalgia, asthenia, fatigue, influenza-like illness, injection site reactions (pain, bruising, rash, pruritus), fall. When treating combined upper and lower spasticity in children aged 2 years or older refer to the posology section of the SmPC for the individual indication. The dose of Dysport to be injected for concomitant treatment should not exceed a total dose per treatment session of 30 U/kg or 1000 U, whichever is lower. **Focal spasticity in paediatric cerebral palsy patients, two years of age or older:** ***Dynamic equinus foot deformity due to focal spasticity:*** *Common:* myalgia, muscular weakness, urinary incontinence, influenza-like illness, injection site reaction (e.g. pain, erythema, bruising etc.), gait disturbance, fatigue, fall. ***Upper limbs in paediatric cerebral palsy patients*:** *Common:* Musculoskeletal and connective tissue disorders, General disorders and administration site conditions, Skin and subcutaneous tissue disorders. Adverse reactions: Muscular weakness, myalgia, Influenza-like illness, fatigue, injection site reactions (eczema, bruising, pain, swelling, rash), Asthenia, Rash. ***Spasmodic torticollis:*** *Very common*: dysphagia, dry mouth, muscle weakness; *Common*: dysphonia, dyspnoea, headache, dizziness, facial paresis, vision blurred, visual acuity reduced, neck pain, musculoskeletal pain or stiffness, myalgia, pain in extremity. Dysphagia appeared to be dose related and occurred most frequently following injection into the *sternomastoid* muscle. A soft diet may be required until symptoms resolve. ***Blepharospasm and hemifacial spasm***: *Very common*: ptosis; *Common:* facial paresis, diplopia, dry eye, lacrimation increased, eyelid oedema. ***Axillary hyperhidrosis:*** *Common:* compensatory sweating. See SmPC for full side-effect profile including uncommon and rare events for each indication. Adverse Drug Reactions: Urinary tract infection, Bacteriuria, Headache, Hypoaesthesia, Constipation, Muscle weakness, Haematuria, Urinary retention, Urethral haemorrhage, Bladder haemorrhage, Erectile dysfunction, Pyrexia, Bladder pain, Autonomic dysreflexia. **Overdose:** Respiratory support may be required where excessive doses cause paralysis of respiratory muscles. Patients should be monitored for several weeks for symptoms of systemic weakness or muscle paralysis. **Pharmaceutical precautions:** *Unopened vials:* Can be used following a single exposure to temperatures up to 25°C for up to 72 hours. Store at 2°C - 8°C. Do not freeze. *Reconstituted solution:* may be stored at 2°C - 8°C for up to 24 hours prior to use. Refer to the SmPC for further details on the reconstituted solution. **Marketing authorisation numbers:** 300U: PA 1613/002/002; 500U: PA 1613/002/001. **MA Holder:** Ipsen Pharma 70 rue Balard 75015 Paris France. Further information is available on request from: Ipsen Pharmaceuticals Limited, Blanchardstown Industrial Park, Blanchardstown, Dublin 15, Ireland. Tel: +353 1 809 8256. Dysport® is a registered trademark. **Date of PI preparation:** May 2026. **Ref. DYS-IE-001019**

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to the Ipsen Medical Information Department on +353 1 8098256 or pharmacovigilance.uk-ie@ipsen.com

Dysport®
CLOSTRIDIUM BOTULINUM TYPE A
TOXIN-HAEMAGGLUTININ COMPLEX

CONTINUE BUILDING YOUR EXPERIENCE with Dysport®

If you'd like additional training with Dysport®, please contact your local Ipsen representative.

REFERENCE

1. Dysport® 300/500 Summary of Product Characteristics.

DYS-IE-001161 | June 2026

Dysport®

CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX