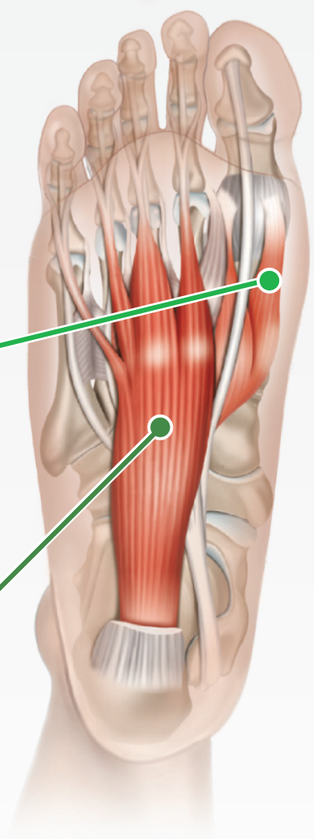
Dysport®: administration for adult focal spasticity

Dysport®
CLOSTRIDIUM BOTULINUM TYPE A
TOXIN-HAEMAGGLUTININ COMPLEX

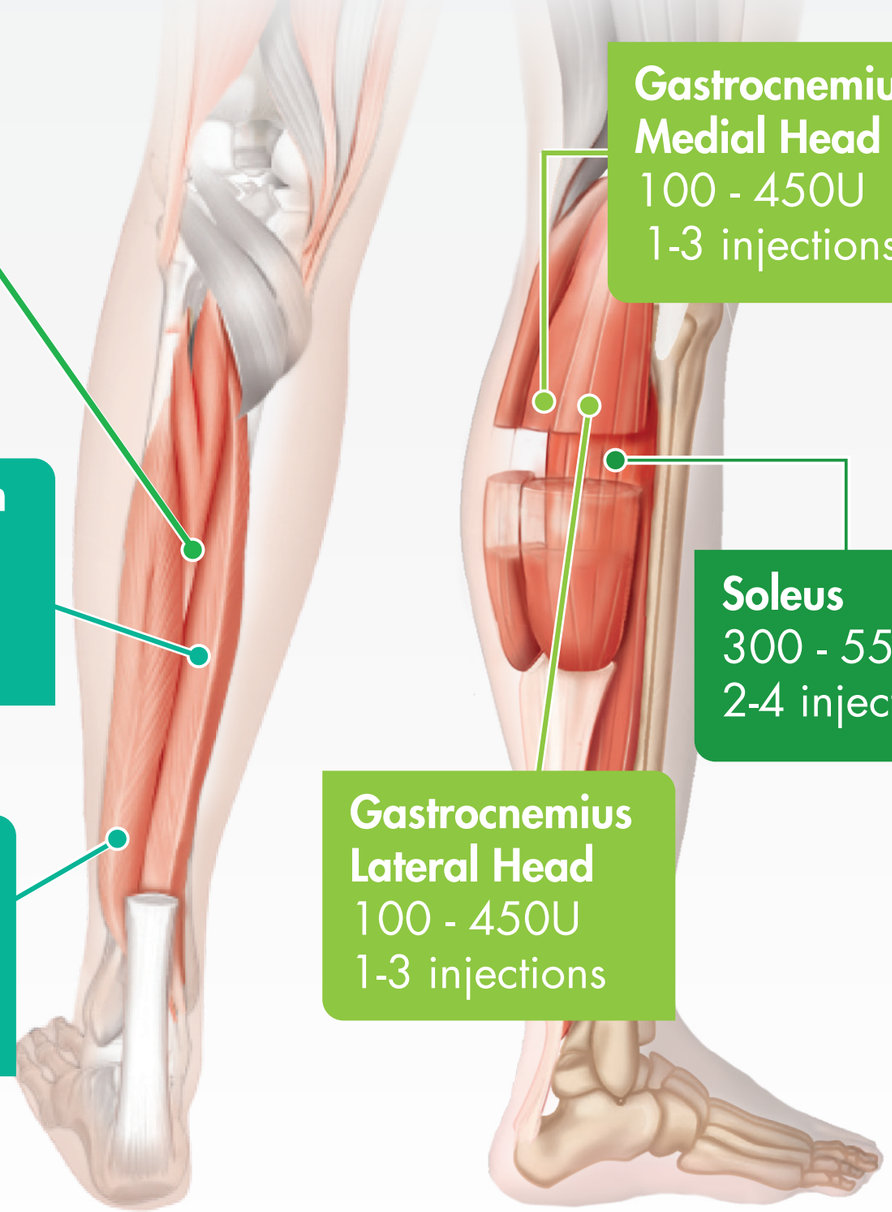
Lower limb

Dysport® is the ONLY BoNT-A licensed to treat the flexor hallucis brevis



Flexor Hallucis Brevis
50 - 100U
1-2 injections

Flexor Digitorum Brevis
50 - 200U
1-2 injections



Tibialis Posterior
100 - 250U
1-3 injections

Flexor Digitorum Longus
50 - 200U
1-2 injections

Flexor Hallucis Longus
50 - 200U
1-2 injections

Gastrocnemius Medial Head
100 - 450U
1-3 injections

Soleus
300 - 550U
2-4 injections

Gastrocnemius Lateral Head
100 - 450U
1-3 injections

Maximum combined dose across both upper and lower limbs is 1500U at a given treatment session.
No more than 1ml should generally be administered at any single injection site.

Images are for illustrative purposes only; the dots do not represent injection sites

Repeat Dysport® treatment may be **administered every 12 to 16 weeks, or longer as necessary,** based on the return of clinical symptoms but no sooner than 12 weeks after the previous injection

Abbreviations: BoNT-A: Clostridium botulinum type A toxin-haemagglutinin complex
Reference: Dysport®. Summary of Product Characteristics. www.medicines.ie Accessed October 2023

IPSEN
Innovation for patient care

Abbreviated Prescribing Information

DYSPORT® 500 units (Clostridium botulinum type A toxin-haemagglutinin complex) Powder for solution for injection
See full Summary of Product Characteristics (SmPC) before prescribing. Available at www.medicines.ie. **Presentation:** *Clostridium botulinum* type A toxin-haemagglutinin complex 500 units (U). Powder for solution for injection. **Indications:** Symptomatic treatment of focal spasticity including: Adult upper limbs, Adult ankle joint due to stroke or traumatic brain injury (TBI), Upper limbs in paediatric cerebral palsy patients ≥ 2 years of age. Treatment of: Dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients ≥ 2 years of age, Spasmodic torticollis, Blepharospasm, Hemifacial spasm, Persistent severe primary axillary hyperhidrosis (interfering with daily living and resistant to topical treatment). **Administration:** Dysport should only be administered by appropriately trained physicians. Reconstitute with preservative-free 0.9% w/v sodium chloride injection to yield a concentration as follows: Adult upper or lower limb spasticity: 100/200/500U per ml, Focal spasticity in children ≥ 2 years of age (Dynamic equinus foot deformity or upper limb spasticity associated with cerebral palsy or a combination of both): 100/200/500U per ml, further dilutions may be required. Blepharospasm, Hemifacial spasm: 200U per ml; Spasmodic torticollis: 500U per ml. Axillary hyperhidrosis: 200U per ml. *Appearance of product after reconstitution:* Reconstituted Dysport should be clear, colourless, and free of particulate matter, otherwise it must not be injected. 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:** Dosing in initial and sequential treatment sessions should be tailored to the individual. Injection guiding techniques recommended to target injection sites. Degree and pattern of muscle spasticity at the time of re-injection may necessitate alterations in dose and muscles to be injected. ***Adult upper limb spasticity and/or Adult ankle joint spasticity due to stroke/TBI:*** No more than 1 ml should generally be administered at any single injection site. Injections may be repeated approx. every 16 weeks but not more frequently than every 12 weeks. If treatment is required in the upper and lower limbs during the same treatment session, the dose of Dysport to be injected in each limb should be tailored to the individual's need, without exceeding a total dose of 1500U. *Upper limbs:* In clinical trials, intramuscular (IM) injections of 500U, 1000U and 1500U doses were divided among selected muscles at a given treatment session (see SmPC). Doses greater than 1000U and up to 1500U can be administered when the shoulder muscles are also injected. The total dose recommended in the selected shoulder muscles is up to 500U. Doses exceeding 1500U of Dysport were not investigated for the treatment of upper limb spasticity in adults. Clinical improvement may be expected 1 week after injection and may last up to 20 weeks. *Ankle joint:* In clinical trials, doses of 1000U and 1500U were divided among selected muscles. Doses of up to 1500U may be administered IM in a single treatment session (see SmPC). The total dose should not exceed 1500U. ***Paediatric cerebral palsy spasticity:*** Total dose should be divided between affected spastic muscles of upper and/ or 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 full details). ***Dynamic equinus foot deformity due to focal spasticity in ambulant paediatric cerebral palsy patients:*** Max. total dose for unilateral lower limb injections must not exceed 15U/kg or 30U/kg for bilateral injections, per treatment session. Total dose per treatment session must not exceed 30U/kg or 1000U, 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 re-treated 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 administered per treatment session when injecting unilaterally must not exceed 16U/kg or 640U whichever is lower. For bilateral injections, maximum dose per treatment session must not exceed 21U/kg or 840U, whichever is lower. Repeat treatment should be administered when the effect of a previous injection has diminished, but no sooner than 16 weeks after the previous injection. A majority of patients in the clinical study were re-treated between 16-28 weeks; however, some patients had a longer duration of response, i.e. 34 weeks or more. ***Focal spasticity of dynamic equinus foot deformity and upper limbs in paediatric cerebral palsy patients:*** refer to the posology section for individual indications above. Concomitant treatment should not exceed total dose per treatment session of 30 U/kg or 1000 U, whichever is lower. Retreatment of the upper and lower limbs combined should be considered when the effect of the previous injection has diminished, but no sooner than 12 to 16 weeks after the previous treatment session. The optimal time to retreatment should be selected based on an individual's progress and response to treatment. ***Spasmodic torticollis:*** Initial recommended dose is 500U IM as a divided dose into the 2 or 3 most active neck muscles. The split amongst muscles varies according to the type of torticollis diagnosed (see SmPC). Lower dose may be appropriate in markedly underweight patients or the elderly, where reduced muscle mass may exist. Subsequent doses may be adjusted according to clinical response and side-effects observed. Doses within the range of 250-1000U are recommended, although the higher doses may be accompanied by an increase in side effects, particularly dysphagia. Max. dose must not exceed 1000U. Symptom relief may be expected within a week after injection. Injections may be repeated approx. every 16 weeks but not more frequently than every 12 weeks. Safety and efficacy in children not demonstrated for this indication. ***Blepharospasm and hemifacial spasm:*** 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. However, the incidence of local adverse events, specifically ptosis, was dose related. Max. dose must not exceed 120U/eye. Injections are given subcutaneously, medially and laterally into the junction between preseptal and orbital parts of both the upper and lower orbicularis oculi muscles of the eyes. In order to reduce the risk of ptosis, injections near the levator palpebrae superioris should be avoided. Relief of symptoms may be expected to begin within 2-4 days with maximal effect within 2 weeks. Repeat injections as required, to prevent recurrence of symptoms but not more frequently than every 12 weeks. For cases of unilateral blepharospasm, the injections should be confined to the affected eye. Patients with hemifacial spasm should be treated as for unilateral blepharospasm. Safety and efficacy in children not demonstrated for this indication. ***Axillary hyperhidrosis:*** The initial recommended dose is 100U per axilla (10U to 10 sites), given intradermally. If desired effect is not attained with this dose, up to 200U/axilla can be administered, for subsequent injections. Max. dose must not exceed 200U/axilla. The maximum effect should be seen by week 2 after injection. Injections should not be repeated more frequently than every 12 weeks. Safety and efficacy in children not demonstrated for this indication. See SmPC for full dosing information. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions:** Adverse effects resulting from the distribution of the effects of the toxin to sites remote from the site of administration have been reported. Patients treated with therapeutic doses may present with excessive muscle weakness; risk of occurrence of such side effects may be reduced by using lowest effective possible dose and not exceeding the recommended dose. 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. 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. Exercise caution when treating adult lower limb spasticity especially in elderly patients, who may be at increased risk of fall. Dry eye has been reported with the use of Dysport in the treatment of blepharospasm and hemifacial spasm. Reduced tear production, reduced blinking, and corneal disorders may occur. The recommended posology and frequency of administration for Dysport must not be exceeded. Warn patients and their care-givers to seek immediate medical treatment in cases of problems with swallowing, speech or respiratory disorders. Not to be used to treat spasticity in patients who have developed a fixed contracture. Antibody formation has been noted, rarely, in patients receiving Dysport. Clinically, neutralising antibodies might be suspected by a substantial deterioration in response to therapy and/or need for consistently increasing doses. In patients with prolonged bleeding times, infection/inflammation at the proposed injection site, only use if strictly necessary. Exercise caution where the targeted muscle shows excessive weakness or atrophy. Contains a small amount of human albumin, hence the risk of transmission of some viral infections cannot be excluded with certainty following the use of human blood products. Dysport should only be used to treat a single patient during a single session. *Paediatric use:* For the treatment of spasticity associated with cerebral palsy in children, Dysport should only be used in children of 2 years of age or over. Post-marketing reports of possible distant spread of toxin have been very rarely reported in paediatric patients with comorbidities, predominantly with cerebral palsy. In general, the dose used in these cases was in excess of that recommended. Rare spontaneous reports of death sometimes associated with aspiration pneumonia in children with severe cerebral palsy after treatment with botulinum toxin, including following off-label use (e.g. neck area). Extreme caution should be exercised when treating paediatric patients with significant neurologic debility, dysphagia, or have recent history of aspiration pneumonia or lung disease Treatment in patients with poor underlying health status should be administered only if the potential benefit to the individual patient outweighs the risks. *Traceability:* the name and the batch number of the administered product should be clearly recorded. **Interactions:** Drugs affecting neuromuscular transmission may potentiate the effect of botulinum toxin and should be used with caution. **Pregnancy and lactation:** Safety in pregnancy has not been demonstrated; 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. **Effects on the ability to drive and use machines:** May temporarily impair ability to drive or operate machinery in case of adverse reactions such as muscle weakness and eye disorders. **Undesirable effects:** Adverse reactions (ADRs) related to spread of toxin distant from the injection site, have rarely been reported (excessive muscle weakness, dysphagia, aspiration pneumonia that may be fatal). The risk of occurrence of such undesirable effects may be reduced by using the lowest effective possible dose and by not exceeding the maximum recommended dose. Hypersensitivity reactions have also been reported post-marketing. In general, the following ADRs were reported in clinical trials, ***across all indications:*** *Common:* asthenia, fatigue, influenza-like illness, injection site pain/bruising. These reactions usually disappear within a few weeks of treatment. *Rare:* includes neuralgic amyotrophy. ADRs vary across the indications. ***Adult upper limb spasticity:*** *Common:* injection site reactions (e.g. pain, erythema, swelling etc.), asthenia, fatigue, influenza-like illness, muscular weakness, musculoskeletal pain, pain in extremity, accidental lesions/fall. Ankle joint due to stroke/TBI: Common: dysphagia, muscular weakness, myalgia, asthenia, fatigue, influenza-like illness, injection site reactions (pain, bruising, rash, pruritus), fall. ***Dynamic equinus foot deformity in ambulant paediatric cerebral palsy patients:*** *Common:* myalgia, muscular weakness, urinary incontinence, influenza-like illness, injection site reaction (e.g. pain, erythema, bruising etc.), gait disturbance, fatigue, fall. ***Focal spasticity of upper limbs in paediatric cerebral palsy patients:*** *Common:* muscular weakness, myalgia, influenza-like illness, fatigue, injection site reactions (eczema, bruising, pain, swelling, rash), rash. ***Concomitant treatment of dynamic equinus foot deformity and of upper limbs in ambulant paediatric cerebral palsy patients:*** No data of placebo-controlled clinical trials are available, according to the existing data the number of treatment-related side effects is not higher in doses of up to 30 U/kg or 1000 U whichever is lower in comparison to treating either upper limb or lower limb muscles alone. ***Spasmodic torticollis:*** *Very common:* dysphagia, dry mouth, muscle weakness; *Common:* headache, dizziness, facial paresis, vision blurred, visual acuity reduced, dysphonia, dyspnoea, neck pain, musculoskeletal pain or stiffness, myalgia, pain in extremity. *Rare:* includes aspiration. Dysphagia appeared to be dose-related, occurring 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. *Uncommon:* includes VIIth nerve paralysis, *Rare:* includes ophthalmoplegia. Side effects may occur due to deep or misplaced injections, temporarily paralysing other nearby muscle groups. ***Axillary hyperhidrosis:*** *Common:* dyspnoea, compensatory sweating, pain in the shoulder, upper arm and neck, myalgia of the shoulder and calf. **Post-marketing experience:** *Not known:* hypersensitivity, hypoaesthesia, muscle atrophy. See SmPC for full side-effect profile including all uncommon and rare events for each indication. **Overdose:** Respiratory support may be required where excessive doses cause paralysis of respiratory muscles. General supportive care is advised. Symptoms of overdose may not present immediately following injection; monitor patients for several weeks for symptoms of systemic weakness or muscle paralysis. **Pharmaceutical precautions:** 3 ml glass vial containing 500U of toxin complex. Pack size: 2 vials/box. *Unopened vials:* Store at 2 - 8ºC. Do not freeze. Refer to the SmPC for further details on the reconstituted solution. **Legal category:** POM. **Marketing Authorisation Number:** PA 1613/002/001. **MA Holder:** Ipsen Pharma, 65 quai Georges Gorse, 92100 Boulogne-Billancourt, 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 preparation:** March 2022 **Ref: DYS-IE 000430**

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

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