Dysport®
CLOSTRIDIUM BOTULINUM TYPE A
TOXIN-HAEMAGGLUTININ COMPLEX

From urgency to control

Indication[1]

Dysport® is 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.

For all other indications, please refer to the Dysport® SmPC.

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.

Prescribing Information is located at the back of this booklet.
This material has been commissioned by Ipsen and is intended for Irish healthcare professionals only.

DYS-IE-000932 | January 2026

IPSEN

The challenge of urinary incontinence (UI) due to neurogenic detrusor overactivity (NDO): Widespread impact, serious consequences

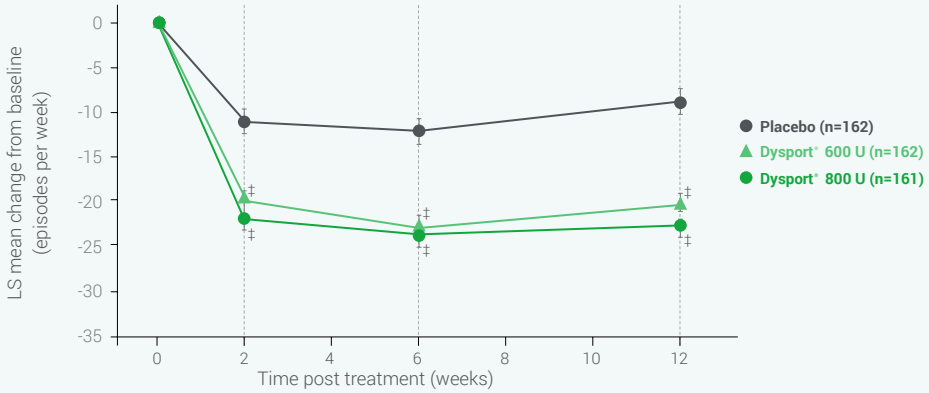
- **High prevalence:** Up to 99% of multiple sclerosis patients and 84% of spinal cord injury patients develop neurogenic detrusor overactivity (NDO)[2,3]
- **Quality of life (QoL) burden:** NDO with urinary incontinence (UI) significantly impairs daily function, social engagement, and patient wellbeing[4–6]
- **Clinical risk:** Progressive renal function deterioration represents a serious long-term complication[7]

Dysport® delivers rapid and sustained symptom relief[8]

- The CONTENT Phase III programme assessed 483 patients with UI due to NDO* who were regularly performing clean intermittent catheterisation (CIC) and were inadequately managed by oral therapy[8,†]

Dysport® significantly reduced NDO UI episodes in all patients at Weeks 2, 6 and 12 versus placebo[8]

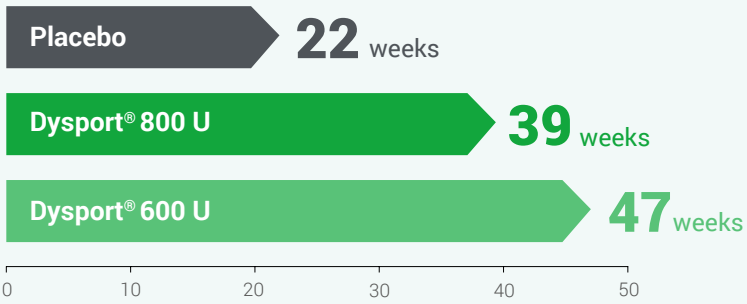
CHANGE FROM BASELINE IN WEEKLY NDO UI EPISODES OVER 12 WEEKS



Dysport® offers long-lasting symptom control, with up to 47 weeks between injections[8]

Regardless of Dysport® dose, >40% of patients were not retreated until after Week 4[8]

MEDIAN TIME TO RETREATMENT



*UI in adults with NDO due to spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who are regularly performing clean intermittent catheterisation.[8]

†Adult patients were randomised to receive either Dysport® 600 U (n=162), Dysport® 800 U (n=161), or placebo (n=162). Patients recorded the number of UI episodes they experienced per day over a 7-day period in an eDiary at baseline and at Weeks 2, 6, and 12, and every 12 weeks thereafter. The primary endpoint was the mean change from baseline in NDO UI episodes per week at Week 6. Secondary endpoints were the proportion of patients with no NDO UI episodes, the volume per void, urodynamic parameters, and quality of life. Safety was also assessed.[8]

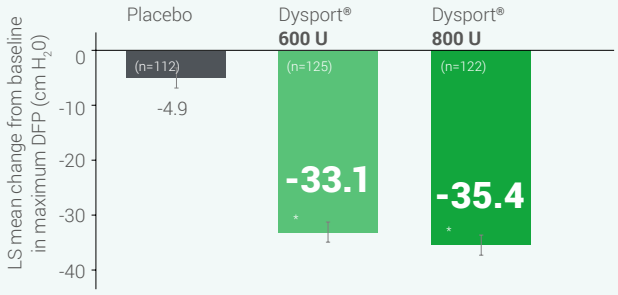
‡p<0.001 versus placebo.[8]

Dysport® provides a comprehensive improvement in neurogenic bladder function across key parameters[8]

Relief in detrusor filling pressure (DFP)[8]

Dysport® achieved a significant decrease in DFP at Week 6 versus placebo[8]

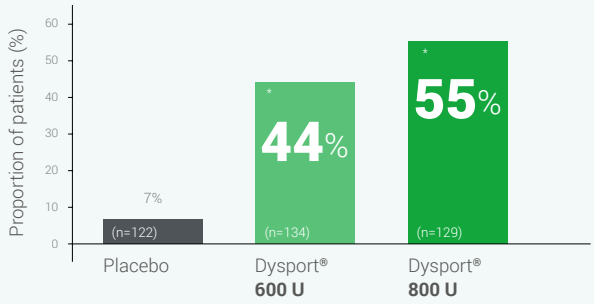
CHANGE IN MAXIMUM DFP FROM BASELINE AT WEEK 6



Suppression of involuntary detrusor contractions (IDCs)[8]

>40% of Dysport® patients had no IDCs during bladder storage at Week 6[8]

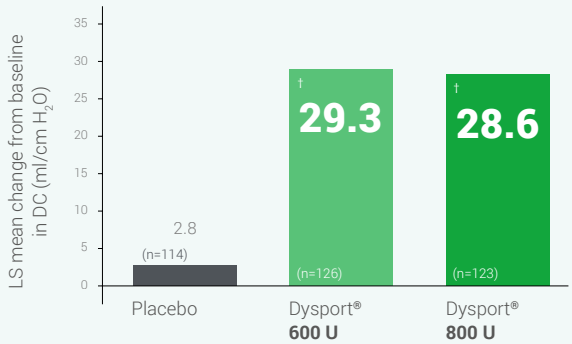
PROPORTION OF PATIENTS WITH NO IDCs DURING BLADDER STORAGE AT WEEK 6



Enhanced detrusor compliance (DC)[8]

Dysport® significantly improved DC at Week 6 versus placebo[8]

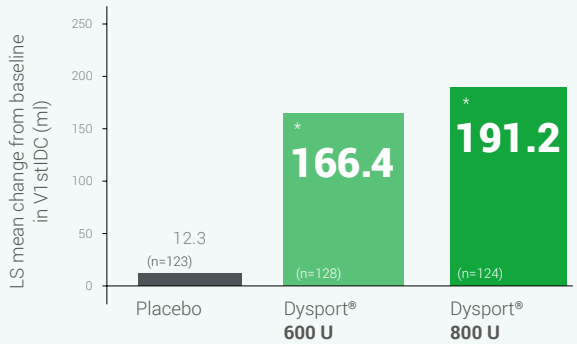
CHANGE IN DC FROM BASELINE AT WEEK 6



Improved bladder storage[8]

Dysport® significantly increased the volume at first IDC (V1stIDC) at Week 6 versus placebo[8]

CHANGE FROM BASELINE IN V1STIDC AT WEEK 6

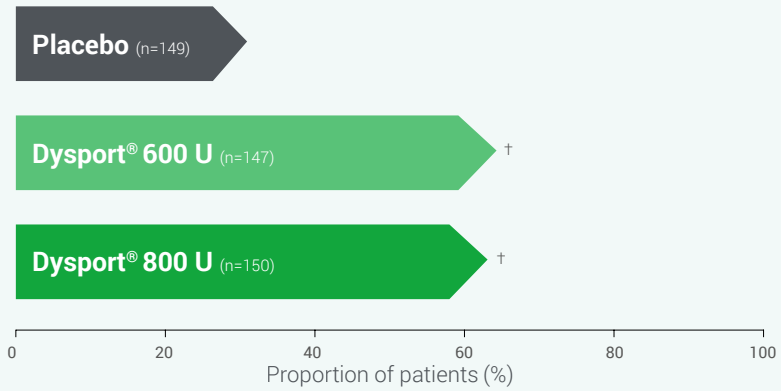


*p<0.001 versus placebo.[8]
†p<0.01 versus placebo.[8]

Patients with UI due to NDO* reported a significant improvement in their QoL following treatment with Dysport®[8]

More than 6 out of 10 patients achieved a clinically meaningful improvement in QoL[8]

PROPORTION OF PATIENTS ACHIEVING ≥11-POINT IMPROVEMENT IN THE TOTAL SUMMARY SCORE OF THE INCONTINENCE-RELATED QOL QUESTIONNAIRE AT WEEK 6



Dysport® has a well-characterised safety profile[1]

Dysport® was well tolerated among patients in the CONTENT Phase III programme[8]

TREATMENT-EMERGENT ADVERSE EVENTS (TEAEs) UP TO WEEK 12 AND OVER THE FULL DOUBLE-BLIND PLACEBO-CONTROLLED (DBPC) TREATMENT CYCLE REPORTED IN ≥5% OF PATIENTS ACROSS GROUPS

	Placebo (n=161)	Dysport® **600 U** (n=160)	Dysport® **800 U** (n=162)
During first 12 weeks of DBPC cycle, n (%)			
Any TEAE	66 (41)	74 (46)	68 (42)
Any serious TEAE	4 (3)	9 (6)	6 (4)
TEAEs with incidence ≥5% in ≥1 Dysport® group, n (%)			
UTI‡	27 (17)	23 (14)	24 (15)
During full DBPC cycle, n (%)			
Any TEAE	78 (49)	88 (55)	88 (54)
Any serious TEAE	8 (5)	18 (11)	14 (9)
TEAEs with incidence ≥5% in ≥1 Dysport® group			
UTI‡	32 (20)	33 (21)	44 (27)
Haematuria	5 (3)	9 (6)	6 (4)

UTI incidence comparable *vs* placebo

UTI was the most frequently reported TEAE among patients in all groups

For the full list of adverse events, please refer to the Dysport® Summary of Product Characteristics.[1]

*UI in adults with NDO due to spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who are regularly performing clean intermittent catheterisation.

†p<0.001 versus placebo.[8]

‡UTI was defined as a positive urine culture result with a bacteria count of >105 colony-forming units/ml, leukocyturia of >5 cells per high-power field, and symptoms suggestive of a UTI (may be atypical symptoms in the population with NDO UI). If a patient experienced more than one event in a category, the patient is counted only once in that category.[8]

With two dosing options, Dysport® offers treatment flexibility and individualised care for patients with UI due to NDO*,[1]

Recommended doses[1]

600 U
per session

OR

800 U
per session in cases of insufficient response or severe disease

Contraindications[1]

- Patients with a UTI at the time of treatment
- Patients with known hypersensitivity to the active substance or any of the excipients

Dilution guide[1]

- When treating UI due to NDO*, Dysport® is reconstituted with sodium chloride 9 mg/ml (0.9%) solution to yield a 15-ml solution containing either 600 U or 800 U
- The 15 ml of reconstituted Dysport® should be divided equally into two 10-ml syringes

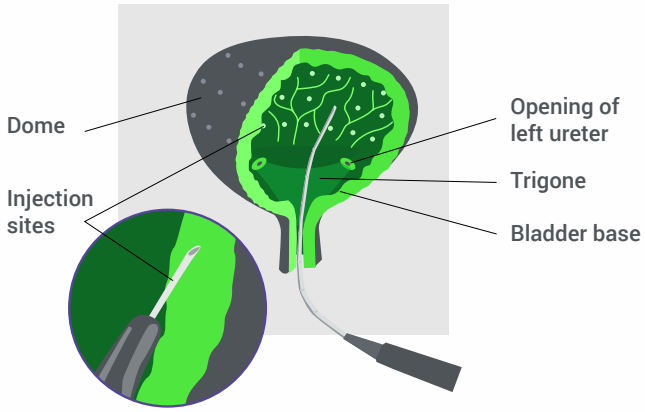
Dilution instructions using 300 U vials

No. of vials to be used	Diluent* per 300 U vial	Mixing	Reconstitution	Resulting dose concentration
2	1.5 ml	Into the first 10-ml syringe, draw 1.5 ml from the first vial. Into the second 10-ml syringe, draw 1.5 ml from the second vial.	Add 6 ml of diluent† into both syringes and mix gently	600 U
3	1.5 ml	Into the first 10-ml syringe, draw 1.5 ml from the first vial and 0.5 ml from the second vial. Into the second 10-ml syringe, draw 0.5 m from the second vial and 1.5 ml from the third vial.	Add 5.5 ml of diluent* into both syringes and mix gently.	800 U

*UI in adults with NDO due to spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who are regularly performing clean intermittent catheterisation.[8]
†Diluent: preservative-free sodium chloride 9 mg/ml solution for injection.

Administration[1]

- Dysport® should only be administered by an appropriately qualified healthcare practitioner with expertise in the treatment of the relevant indication and the use of the required equipment, in accordance with national guidelines
- Dysport® is administered by **subcutaneous injection into the detrusor muscle with a cystoscope**



- 30 sites should be injected, with the sites evenly distributed throughout the detrusor muscle
- Inject 0.5 ml of Dysport® per site at a depth of ~2 mm
- Avoid the trigone

Dysport® 300 U provides an additional vial size option that complements the existing Dysport® 500[1]

- This new vial size option may support more efficient use of Dysport® by:

Providing greater dosing flexibility alongside Dysport® 500

Optimising vial utilisation

Offering a convenient choice

References

1. Dysport® 300 Summary of Product Characteristics IE. July 2025.
2. Mehnert U, et al. *SN Compr Clin Med*. 2019;1:160–182.
3. Alsulihem A, Corcos J. *Neuroimmunol Neuroinflammation*. 2019;6:13.
4. Ginsberg, D. *Am J Manag Care*. 2013;19(10)191–196.
5. Tang D, et al. *BMC Neurol*. 2014;14:74.
6. Chen G, et al. *Health Qual Life Outcomes*. 2014;12:133.
7. Madhuvrata P, et al. *Eur Urol*. 2012;62:816–830.
8. Kennelly M, et al. *Eur Urol*. 2022;82(2):223–232.

Prescribing Information

DYSPORT® Powder for solution for injection (*Clostridium botulinum* type A toxin-haemagglutinin complex) 300 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 units 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. 28weeks. ***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. A***xillary 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:* Store at 2 - 8ºC. Do not freeze. Refer to the SmPC for further details on the reconstituted solution. **Marketing authorisation numbers:** PA 1613/002/002 **MA Holder:** Ipsen Pharma 70 rue Balard 75015 Paris France. Tel: +353 (0)1 809 8256.

Dysport® is a registered trademark. **Date of PI preparation:** November 2025.
Ref. DYS-IE-001050

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

IPSEN