Indication

• Dysport® (abobotulinumtoxinA) is indicated for the treatment of lower limb spasticity in pediatric patients 2 years of age and older.

Important Safety Information

Warning: Distant Spread of Toxin Effect

Postmarketing reports indicate that the effects of Dysport and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including upper limb spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to or lower than the maximum recommended total dose.

5 Steps to dosing and dilution with Dysport

Step 1: Obtain your patient’s weight
Step 2: Choose unilateral or bilateral lower limb injection
Step 3: Select muscles (gastrocnemius/soleus)
Step 4: Determine Dysport dose
Step 5: Achieve desired concentration

* Sterile preservative-free 0.9% Sodium Chloride Injection, USP. Reconstituted Dysport is for intramuscular injection only.

See pages 2 through 4 for detailed information on Dysport dosing and dilution. Please see accompanying Full Prescribing Information, including Boxed Warning regarding distant spread of toxin effect, and Medication Guide.


Dysport® (abobotulinumtoxinA) for injection, for intramuscular use 300- and 500-Unit vials. DYSPORT is a registered trademark of Ipsen Biopharm Limited.


Pediatric Lower Limb Spasticity Dosing Tool

Weight (kg)

Unilateral: Total Dysport dose per treatment session (10 to 15 Units/kg/leg)

Gastrocnemius (6 to 9 Units/kg/leg)

Soleus (4 to 6 Units/kg/leg)

Recommended total Dysport dose per treatment session:

Unilateral

• Dysport 10 to 15 Units/kg with a total dose not to exceed Dysport 15 Units/kg or Dysport 1,000 Units, whichever is lower

Bilateral

• Dysport 20 to 30 Units/kg with a total dose not to exceed Dysport 30 Units/kg or Dysport 1,000 Units, whichever is lower

SUSPECTED ADVERSE REACTIONS or product complaints, contact Ipsen at 1-855-463-5127. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
Dysport offers FDA-approved dosing recommendations

Botulinum toxins (BoNTs) are not interchangeable and the potency units are not the same.

- Units of biological activity of Dysport cannot be compared to, or converted into, units of any other BoNT

**Step 1: Obtain your patient’s weight**

Dosing is based on Dysport Units per kilogram of body weight.

- Convert from pounds to kilograms (1 kg is equal to 2.2 lb)

**Step 2: Choose unilateral or bilateral lower limb injection**

Recommended total Dysport dose per treatment session:

- **Unilateral**
  - Dysport 10 to 15 Units/kg with a total dose not to exceed Dysport 15 Units/kg or Dysport 1,000 Units, whichever is lower

- **Bilateral**
  - Dysport 20 to 30 Units/kg with a total dose not to exceed Dysport 30 Units/kg or Dysport 1,000 Units, whichever is lower

**Step 3: Select muscles (gastrocnemius/soleus)**

The total dose administered should be divided between the affected spastic muscles of the lower limb(s).

- When possible, the dose should be divided across more than 1 injection site in any single muscle
- No more than 0.5 mL should generally be administered at any single injection site
- Although actual location of the injection sites can be determined by palpation, the use of injection guiding technique, eg, ultrasound, electromyography, or electrical stimulation, is recommended to target the injection sites

**Important Safety Information (continued)**

**Contraindications**

Dysport is contraindicated in patients with known hypersensitivity to any botulinum toxin products, cow’s milk protein, components in the formulation or infection at the injection site(s). Serious hypersensitivity reactions including anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea have been reported. If such a reaction occurs, discontinue Dysport and institute appropriate medical therapy immediately.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information, including Boxed Warning.

**Step 4: Determine Dysport dose**

**Recommended Dysport dose range per muscle, per leg, of the GSC**

<table>
<thead>
<tr>
<th>Muscle</th>
<th>Dose Range (Units/kg/leg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrocnemius</td>
<td>6-9 Units/kg/leg†</td>
</tr>
<tr>
<td>Soleus</td>
<td>4-6 Units/kg/leg†</td>
</tr>
</tbody>
</table>

No more than 0.5 mL should generally be administered at any single injection site.

*Dystrocs-soleus complex.
†Do not exceed Dysport 15 Units/kg total dose for unilateral injection, or Dysport 30 Units/kg for bilateral injection, or Dysport 1,000 Units, whichever is lower.

**Dosing in initial and subsequent treatment sessions should be tailored to the individual based on**

- Size, number, and location of muscles involved
- Severity of spasticity
- Presence of local muscle weakness
- Patient’s response to previous treatment and/or
- Adverse event history with botulinum toxin

**Retreatment**

- The majority of patients in the clinical study were retreated between 16 and 22 weeks; however, some had a longer duration of response
- Repeat administration should not occur before 12 weeks

**Dysport**
(abobotulinumtoxinA)
Time Between Treatments
Step 5: Achieve desired concentration

- Considerations for achieving desired concentration include: patient weight, limit of 0.5 mL per injection site, and recommended number of injection sites per muscle in the GSC
- Total dose per treatment session
  - Lower limb: unilateral, not to exceed Dysport 15 Units/kg; bilateral, not to exceed Dysport 30 Units/kg, or Dysport 1,000 Units, whichever is lower

Reconstitution and injection checklist

- Using a sterile syringe, needle, and aseptic technique, draw up the appropriate amount of diluent.
- Insert the needle into the Dysport vial. The partial vacuum will begin to pull the diluent into the Dysport vial. Do not use the Dysport vial if no vacuum is observed.
- Swirl gently to dissolve. The reconstituted solution should be clear, colorless, and free of particulate matter.
- Draw the required patient dose of Dysport into a sterile syringe and dilute with additional diluent, if required, to achieve the final volume for injection.
- Expel any air bubbles in the syringe barrel.
- Remove the needle used to reconstitute the product and attach an appropriately sized new sterile needle to administer the injection.
- Inject into target muscle(s) within 24 hours of reconstitution. Dysport should be used for only one injection session and for only one patient after reconstitution.

Other dilutions may be necessary to enable dosing flexibility, for example:

<table>
<thead>
<tr>
<th>Diluent* per 300-Unit Vial</th>
<th>Resulting Dose</th>
<th>Diluent* per 500-Unit Vial</th>
<th>Resulting Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.6 mL</td>
<td>50 Units/0.1 mL</td>
<td>1 mL</td>
<td>50 Units/0.1 mL</td>
</tr>
</tbody>
</table>

Adapted from Section 2.1, Table 1 of the Full Prescribing Information.

*Sterile preservative-free 0.9% Sodium Chloride Injection, USP. Reconstituted Dysport is for intramuscular injection only.

Important Safety Information (continued)

Lack of Interchangeability Between Botulinum Toxin Products

The potency Units of Dysport are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products, and, therefore, units of biological activity of Dysport cannot be compared to or converted into units of any other botulinum toxin products assessed with any other specific assay method.
For pediatric patients with lower limb spasticity 2 years of age and older

Dysport dosing scenarios*

<table>
<thead>
<tr>
<th>Step 1: Obtain weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eric, age 2</td>
</tr>
<tr>
<td>10 kg (22 lb)</td>
</tr>
<tr>
<td>John, age 10</td>
</tr>
<tr>
<td>32 kg (71 lb)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 2: Choose unilateral or bilateral lower limb injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eric (age 2)</td>
</tr>
<tr>
<td>Bilateral (Dysport 20 to 30 Units/kg)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 3: Select muscles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrocsoleus</td>
</tr>
<tr>
<td>Recommended dose range Dysport 12 to 18 Units/kg</td>
</tr>
<tr>
<td>John</td>
</tr>
<tr>
<td>Gastrocsoleus</td>
</tr>
<tr>
<td>Recommended dose range Dysport 6 to 9 Units/kg</td>
</tr>
<tr>
<td>Eric</td>
</tr>
<tr>
<td>Soleus</td>
</tr>
<tr>
<td>Recommended dose range Dysport 8 to 12 Units/kg</td>
</tr>
<tr>
<td>John</td>
</tr>
<tr>
<td>Soleus</td>
</tr>
<tr>
<td>Recommended dose range Dysport 4 to 6 Units/kg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 4: Determine Dysport dose (kg x [Dysport Units/kg])</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eric (age 2)</td>
</tr>
<tr>
<td>Total Dysport Dose per Treatment Session†</td>
</tr>
<tr>
<td>Dysport 200 to 300 Units divided between affected spastic muscles</td>
</tr>
<tr>
<td>Dysport 320 to 480 Units divided between affected spastic muscles</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 5: Achieve desired concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vial</td>
</tr>
<tr>
<td>Dysport 300 Units</td>
</tr>
<tr>
<td>Dysport 500 Units</td>
</tr>
<tr>
<td>Diluent†</td>
</tr>
<tr>
<td>1.5 mL</td>
</tr>
<tr>
<td>2.5 mL</td>
</tr>
<tr>
<td>Resulting Dose</td>
</tr>
<tr>
<td>Dysport 20 Units/0.1 mL</td>
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*Hypothetical patient examples.
†Do not exceed Dysport 15 Units/kg total dose for unilateral injection, or Dysport 30 Units/kg for bilateral injection, or Dysport 1,000 Units, whichever is lower.
‡Sterile preservative-free 0.9% Sodium Chloride Injection, USP. Reconstituted Dysport is for intramuscular injection only.

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Important Safety Information (continued)

Warnings and Precautions (continued)

Dysphagia and Breathing Difficulties

Treatment with Dysport and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or swallowing. When distant side effects occur, additional respiratory muscles may be involved. Deaths as a complication of severe dysphagia have been reported after treatment with botulinum toxin. Dysphagia may persist for several weeks, and require use of a feeding tube to maintain adequate nutrition and hydration. Aspiration may result from severe dysphagia and is a particular risk when treating patients in whom swallowing or respiratory function is already compromised. Patients treated with botulinum toxin may require immediate medical attention should they develop problems with swallowing, speech, or respiratory disorders. These reactions can occur within hours to weeks after injection with botulinum toxin.

Pre-existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of Dysport.
Important Safety Information (continued)

Warnings and Precautions (continued)

Human Albumin and Transmission of Viral Diseases

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD, or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

Intradermal Immune Reaction

The possibility of an immune reaction when injected intradermally is unknown. The safety of Dysport for the treatment of hyperhidrosis has not been established. Dysport is approved only for intramuscular injection.

Most Common Adverse Reactions

Adults with upper limb spasticity (≥2% and greater than placebo): nasopharyngitis, urinary tract infection, muscular weakness, musculoskeletal pain, dizziness, fall, and depression.

Adults with lower limb spasticity (≥5% and greater than placebo): falls, muscular weakness, and pain in extremity.

Adults with cervical dystonia (≥5% and greater than placebo): muscular weakness, dysphagia, dry mouth, injection site discomfort, fatigue, headache, musculoskeletal pain, dysphonia, injection site pain, and eye disorders.

Pediatric patients with lower limb spasticity (≥10% and greater than placebo): upper respiratory tract infection, nasopharyngitis, influenza, pharyngitis, cough, and pyrexia.

Drug Interactions

Co-administration of Dysport and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents), or muscle relaxants, should be observed closely because the effect of botulinum toxin may be potentiated. Use of anticholinergic drugs after administration of Dysport may potentiate systemic anticholinergic effects such as blurred vision. The effect of administering different botulinum neurotoxins at the same time or within several months of each other is unknown. Excessive weakness may be exacerbated by another administration of botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of Dysport.

Please see additional Important Safety Information throughout and accompanying Full Prescribing Information, including Boxed Warning.

Important Safety Information (continued)

Special Populations

Use in Pregnancy

Based on animal data, Dysport may cause fetal harm. There are no adequate and well-controlled studies in pregnant women. Dysport should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pediatric Use

Based on animal data Dysport may cause atrophy of injected and adjacent muscles; decreased bone growth, length, and mineral content; delayed sexual maturation; and decreased fertility.

Geriatric Use

In general, elderly patients should be observed to evaluate their tolerability of Dysport, due to the greater frequency of concomitant disease and other drug therapy. Subjects aged 65 years and over who were treated with Dysport for lower limb spasticity reported a greater percentage of fall and asthenia as compared to those younger (10% vs. 6% and 4% vs. 2%, respectively).

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Important Safety Information (continued)
**Pediatric Lower Limb Spasticity Dosing Tool**

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**Recommended total Dysport dose per treatment session:**

**Unilateral**
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**Bilateral**
- Dysport 20 to 30 Units/kg with a total dose not to exceed Dysport 30 Units/kg or Dysport 1,000 Units, whichever is lower.

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