

Dysport® (abobotulinumtoxinA) - Expanded indication

- On July 9, 2020, <u>Ipsen Biopharmaceuticals announced</u> the FDA approval of <u>Dysport</u> (<u>abobotulinumtoxinA</u>), for the treatment of spasticity in patients 2 years of age and older.
 - This approval expands and streamlines the previous indication which was for the treatment of spasticity in adults; treatment of upper limb spasticity in pediatric patients 2 years of age and older, excluding spasticity caused by cerebral palsy; and treatment of lower limb spasticity in pediatric patients 2 years of age and older.
- Dysport is also approved for cervical dystonia and glabellar lines
- This label expansion is based on Ipsen Biopharmaceuticals and <u>another manufacturer (Allergan)</u> selectively waiving orphan exclusivity marketing rights each company held for the use of their respective neurotoxins in the treatment of pediatric patients with spasticity caused by cerebral palsy.
- Dysport carries a boxed warning for distant spread of toxin effect.
- The recommended total dose of Dysport for pediatric upper limb spasticity is 8 units/kg to 16 units/kg per limb. The maximum recommended total dose administered per treatment session must not exceed 16 units/kg or 640 units, whichever is lower.
- Refer to the Dysport drug label for additional administration recommendations and for dosing for all
 of Dysport's other indications.



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