



Botox® (onabotulinumtoxinA) – Expanded indication

- On July 9, 2020, [AbbVie and Allergan announced](#) the FDA approval of [Botox \(onabotulinumtoxinA\)](#), 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 lower/upper limb spasticity in adult patients; treatment of upper limb spasticity in pediatric patients 2 to 17 years of age; and treatment of lower limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy.
 - Botox has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture.
- Botox is also approved for bladder dysfunction, chronic migraine, cervical dystonia, primary axillary hyperhidrosis, and blepharospasm and strabismus.
- This label expansion is based on Allergan and [another manufacturer \(Ipsen Biopharmaceuticals\)](#) 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.
- Botox carries a boxed warning for distant spread of toxin effect.
- The recommended total dose of Botox for pediatric lower limb spasticity is 4 units/kg to 8 units/kg (maximum 300 units) divided among affected muscles.
 - Refer to the Botox drug label for additional administration recommendations and for dosing for all of Botox's other indications.



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