

Botox (onabotulinumtoxinA) Injection Clinical Update

Clinical Update: New Indication- FDA approves expanded Botox (onabotulinumtoxinA) label for the treatment of pediatric patients with spasticity.

FDA approval date: July 08, 2020

Botox® (onabotulinumtoxinA) is one of the most widely researched medications in the world, with a proven history as a therapeutic agent. Botox is an acetylcholine release inhibitor and a neuromuscular blocking agent. First approved by the FDA in 1989 for two rare eye muscle disorders – blepharospasm and strabismus in adults, Botox® was the world's first approved botulinum toxin type A treatment. Today, Botox® is FDA-approved for 11 therapeutic indications, including Chronic Migraine, overactive bladder, leakage of urine (incontinence) due to overactive bladder caused by a neurologic condition, cervical dystonia, spasticity, and severe underarm sweating (axillary hyperhidrosis).

Botox is a prescription medicine that is injected into muscles and used:

- To treat overactive bladder symptoms such as a strong need to urinate with leaking or wetting accidents, a strong need to urinate right away, and urinating often in adults 18 years and older when another type of medicine (anticholinergic) does not work well enough or cannot be taken
- To treat leakage of urine (incontinence) in adults 18 years and older with overactive bladder caused by a neurologic disease who still have leakage or cannot tolerate the side effects after trying an anticholinergic medication
- To prevent headaches in adults with chronic migraine who have 15 or more days each month with headache lasting 4 or more hours each day in people 18 years or older
- To treat increased muscle stiffness in people 2 years of age and older with spasticity
- To treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in people 16 years and older
- To treat certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years and older
- Botox® is also injected into the skin to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) when medicines used on the skin (topical) do not work well enough in people 18 years and older.

The safety and efficacy of Botox® as treatment for lower limb spasticity for pediatric patients is supported by a Phase 3 study with more than 300 patients two to 17 years of age with lower limb spasticity because of cerebral palsy. These trials included a 12-week, double-blind study and a one-year open-label extension study.

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