

Rx

For the use of registered medical practitioner or a hospital or a laboratory only

Abbreviated Prescribing Information – Botulinum Toxin

BOTOX® (botulinum toxin type A) purified neurotoxin complex is a prescription medicine available as 50 units, 100 units and 200 units pack sizes containing of botulinum toxin type A for injection. **Indications:** BOTOX® is indicated for the management of: blepharospasm, cervical dystonia, hemifacial spasm and associated focal dystonias. BOTOX® is indicated for the treatment of focal spasticity: 1) Associated with dynamic equinus foot deformity due to spasticity in ambulant pediatric cerebral palsy patients, two years of age or older. 2) In adult post stroke patients. BOTOX® is indicated for the treatment of Glabellar lines and Hyperkinetic facial lines. BOTOX® is also indicated for the treatment of Hyperhidrosis. BOTOX® is indicated for prophylaxis of headaches in adults with chronic migraine. BOTOX® is indicated for the treatment of adults with urinary incontinence due to detrusor overactivity e.g., spinal cord injury (SCI) or multiple sclerosis (MS) (Neurogenic Detrusor Overactivity [NDO]) and adults with urinary incontinence due to Overactive Bladder (OAB) who have an inadequate response to or are intolerant of an anticholinergic medication. **Reconstitution:** Single-use, sterile 50 Units, 100 Units or 200 Units vacuum-dried powder for reconstitution only with sterile, non-preserved 0.9% Sodium Chloride Injection USP prior to injection. **Contraindications:** Known Hypersensitivity to Botulinum Toxin- BOTOX® is contraindicated in patients who are hypersensitive to any botulinum toxin preparation or any of the components in the formulation. Infection at the Injection Site(s)- BOTOX® is contraindicated in the presence of infection at the proposed injection site(s). Urinary Tract Infection or Urinary Retention- Intradetrusor injection of BOTOX® is contraindicated in patients with overactive bladder or neurogenic detrusor overactivity (NDO) who have a urinary tract infection. Intradetrusor injection of BOTOX® is also contraindicated in patients with urinary retention and in patients with post-void residual (PVR) urine volume > 200 mL, who are not routinely performing clean intermittent self-catheterization (CIC). **Warning and Precautions:** The relevant anatomy, and any alterations to the anatomy due to prior surgical procedures, must be understood prior to administering BOTOX®. Caution should be exercised when BOTOX® is used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle. As is expected for any injection procedure, localized pain, inflammation, paresthesia, hypoesthesia, tenderness, swelling/edema, erythema, localized infection, bleeding and/or bruising have been associated with the injection. Needle-related pain and/or anxiety have resulted in vasovagal responses, including transient symptomatic hypotension and syncope. Lack of Interchangeability between Botulinum Toxin Products- They are not interchangeable with other preparations of botulinum toxin products; Spread of Toxin Effect- Postmarketing safety data from BOTOX® and other approved botulinum toxins suggest that botulinum toxin effects may, in some cases, be observed beyond the site of local injection; Injections In or Near Vulnerable Anatomic Structures - Care should be taken when injecting in or near vulnerable anatomic structures. Serious adverse events including fatal outcomes have been reported in patients who had received BOTOX® injected directly into salivary glands, the oro-lingual-pharyngeal region, esophagus and stomach; Hypersensitivity Reactions - Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea; 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; Dysphagia and Breathing Difficulties in Treatment of Cervical Dystonia - Treatment with BOTOX® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with preexisting swallowing or breathing difficulties may be more susceptible to these complications; Pulmonary Effects of BOTOX® in Patients with Compromised Respiratory Status Treated for Neurogenic Detrusor Overactivity (NDO) Corneal Exposure and Ulceration in Patients Treated with BOTOX® for Blepharospasm- Reduced blinking from BOTOX® injection of the orbicularis muscle can lead to corneal exposure, persistent epithelial defect, and corneal ulceration, especially in patients with VII nerve disorders; Patients with compromised respiratory status treated with BOTOX for spasticity should be monitored closely. Glabellar Lines and Hyperkinetic Lines: Reduced blinking from BOTOX® injection of the orbicularis oculi muscle can lead to corneal exposure, persistent epithelial defects and corneal ulceration, especially in patients with cranial nerve VII disorders. Bronchitis and Upper Respiratory Tract Infections in Patients Treated for Spasticity - Bronchitis was reported more frequently as an adverse reaction in patients treated for upper limb spasticity with BOTOX® compared to placebo; Focal Spasticity associated with Pediatric Cerebral Palsy and Focal Spasticity associated with Stroke in Adults BOTOX® is a treatment of focal spasticity that has only been studied in association with usual standard of care regimens, and is not intended as a replacement for

these treatment modalities; Autonomic Dysreflexia in Patients Treated for Neurogenic Detrusor Overactivity (NDO)- Autonomic dysreflexia associated with intradetrusor injections of BOTOX® could occur in patients treated for neurogenic detrusor overactivity and may require prompt medical therapy; Urinary Tract Infections in Patients with Overactive Bladder (OAB)- BOTOX® increases the incidence of urinary tract infection; Urinary Retention in Patients Treated for Overactive Bladder (OAB) and Neurogenic Detrusor Overactivity (NDO) - Due to the risk of urinary retention, treat only patients who are willing and able to initiate catheterization post-treatment, if required, for urinary retention. Primary Hyperhidrosis of the Axillae - Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism or pheochromocytoma) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease. **Dose/Administration:** BOTOX® is supplied in single-use 50 units, 100 Units and 200 Units per vial. Overactive Bladder (OAB): An intravesical instillation of diluted local anesthetic with or without sedation may be used prior to injection, per local site practice. If a local anesthetic instillation is performed, the bladder should be drained and irrigated with sterile saline before injection. The recommended dose is 100 Units of BOTOX® and is the maximum recommended dose. The recommended dilution is 100 Units/10 mL with 0.9% non-preserved saline solution. Dispose of any unused saline. Neurogenic Detrusor Overactivity (NDO)- The recommended dose is 200 Units of BOTOX® per treatment and should not be exceeded. Reconstituted BOTOX® (200 Units/30 mL) is injected into the detrusor muscle via a flexible or rigid cystoscope, avoiding the trigone. Chronic Migraine-The recommended dilution is 200 Units/4 mL or 100 Units/2 mL, with a final concentration of 5 Units per 0.1 mL. The recommended dose for treating chronic migraine is 155 Units administered intramuscularly using a sterile 30-gauge, 0.5-inch needle as 0.1 mL (5 Units) injections per site. Cervical Dystonia-A double-blind, placebo-controlled study enrolled patients who had extended histories of receiving and tolerating BOTOX® injections, with prior individualized adjustment of dose. The mean BOTOX® dose administered to patients in this study was 236 Units (25th to 75th percentile range of 198 Units to 300 Units). The BOTOX® dose was divided among the affected muscles. The recommended dilution is 200 Units/2 mL, 200 Units/4 mL, 100 Units/1 mL, or 100 Units/2 mL with 0.9% non-preserved sterile saline, depending on volume and number of injection sites desired to achieve treatment objectives. In general, no more than 50 Units per site should be administered. An appropriately sized needle (e.g., 25-30 gauge) may be used for superficial muscles, and a longer 22-gauge needle may be used for deeper musculature. Localization of the involved muscles with electromyographic guidance may be useful. Hyperhidrosis-The recommended dose is 50 Units per axilla. The hyperhidrotic area to be injected should be defined using standard staining techniques, e.g., Minor's Iodine-Starch Test. The recommended dilution is 100 Units/4 mL with 0.9% preservative-free sterile saline. Using a 30-gauge needle, 50 Units of BOTOX® (2 mL) is injected intradermally in 0.1 to 0.2 mL aliquots to each axilla evenly distributed in multiple sites (10-15) approximately 1-2 cm apart. Blepharospasm- For blepharospasm, reconstituted BOTOX® is injected using a sterile, 27-30-gauge needle without electromyographic guidance. The initial recommended dose is 1.25 Units-2.5 Units (0.05 mL to 0.1 mL volume at each site) injected into the medial and lateral pretarsal orbicularis oculi of the upper lid and into the lateral pre-tarsal orbicularis oculi of the lower lid. Avoiding injection near the levator palpebrae superioris may reduce the complication of ptosis. Avoiding medial lower lid injections, and thereby reducing diffusion into the inferior oblique, may reduce the complication of diplopia. Ecchymosis occurs easily in the soft eyelid tissues. This can be prevented by applying pressure at the injection site immediately after the injection. The recommended dilution to achieve 1.25 Units is 100 Units/8 mL; for 2.5 Units it is 100 Units/4 mL. The cumulative dose of BOTOX® treatment for blepharospasm in a 30-day period should not exceed 200 Units. Hemifacial Spasm- Patients with hemifacial spasm or VII nerve disorder should be treated as for unilateral blepharospasm. Further injections may be necessary into the corrugator, zygomaticus major, orbicularis oris and/or other facial muscles according to the extent of spasm. Electromyographical control may be useful to identify small circumoral muscles. The cumulative dose of BOTOX® in a two-month period should not exceed 200 U. Spasticity (due to juvenile cerebral palsy)-For the treatment of equinus foot deformity due to spasticity in juvenile cerebral palsy, diluted BOTOX® is injected using a sterile 27 gauge needle. The recommended total dose is 4 U/kg administered by injecting 2 cc of reconstituted BOTOX® into each of two sites in the medial and lateral heads of the gastrocnemius of the affected lower limbs. Spasticity (in adult post-stroke patients)-Injection of BOTOX® for this indication needs to be administered either by a qualified Neurologist or a physical medicine specialist (Physiatrist) in a hospital setting. An informed consent should be obtained from the parents/guardian. Glabellar Lines-Using a 30-33-gauge needle, inject a dose of 0.1 mL (4 Units) intramuscularly into each of 5 sites, 2 in each corrugator muscle and 1 in the procerus muscle for a total dose of 20 Units. Typically, the initial doses of reconstituted BOTOX® induce chemical denervation of the injected muscles one to two days after injection, increasing in intensity during the first week. Crow's Feet Lines Injection technique: Injections for Crow's Feet Lines should be given with the needle tip bevel up and oriented away from the eye. Using a 30-33-gauge needle, inject 4 Units/0.1 mL of reconstituted BOTOX® into 3 sites per side (6 total injection points) in the lateral orbicularis oculi muscle for a total of 24 Units/0.6 mL (12 Units per side). The first injection (A) should be made at approximately

1.5-2.0 cm temporal to the lateral canthus and just temporal to the orbital rim. The median time to onset of crow's feet lines treatment effect is three to four days.

Source: Prescribing Information version dated Oct 2023

Date of updation: Oct 2023

For complete prescribing information please contact **AbbVie Healthcare India Pvt. Ltd., Level 6 & 7, Prestige Obelisk, No. 3, Kasturba Road, Bangalore 560001.**