BiO-MeD PREVENT DISEASES BY VACCINATION
PRIVATE LIMITED In Service Since 1974

BOTULINUM TOXIN TYPE A FOR INJECTION Ph. Eur.
PURIFIED NEUROTOXIN COMPLEX
BOTO GENIE®

DESCRIPTION & PHARMACOLOGY

BOTO GENIE® (Botulinum toxin Type A) is produced from fermentation of *Clostridium botulinum* type A and purification of neurotoxin complex. It has unique pharmacological properties as a neuromuscular blocking agent by inhibiting the release of acetylcholine resulting in partial, local, flaccid muscle paralysis, which helps to reduce some of the abnormal muscle contractions. The action of BOTO GENIE® is reversible and can sustain partial chemical denervation for 3 to 6 months. Recovery of impulse transmission occurs gradually as new nerve terminals develop. One unit is defined as the median lethal intraperitoneal dose in mice estimated relative to the reference preparation assayed in parallel. The units of BOTO GENIE® are product specific and not applicable to other preparations, due to specific testing method such as vehicle dilution scheme, laboratory protocols and differences in species sensitivities. The specific activity of BOTO GENIE® is approximately 20 units/nanogram of purified neurotoxin complex.

COMPOSITION

(A) BOTO GENIE® 100 unit vial (Freeze dried)
- Botulinum toxin type A Purified Neurotoxin complex.....100 unit
- Lactose (Stabilizer).....5 mg

(B) BOTO GENIE® 50 unit vial (Freeze dried)
- Botulinum toxin type A Purified Neurotoxin complex.....50 unit
- Lactose (Stabilizer).....5 mg

(C) Diluent
- Sodium chloride injection I.P.

DILUTION PROCEDURE

Reconstitute lyophilized BOTO GENIE® with the diluent provided as per dilution chart below:

Volume of diluent used for reconstitution	Resulting units per 0.1 ml** for 100 unit vial	Resulting units per 0.1 ml** for 50 unit vial
1 ml	10.0 U	5.0 U
2 ml	5.0 U	2.5 U
4 ml	2.5 U	1.25 U
5 ml	2.0 U	1.0 U

** Injection volume may be increased to 0.15 ml (50% increase in dose) or reduced 0.05 ml (50% decrease in dose).

INDICATIONS AND USAGE

Botulinum toxin type A is one of the most effective drug for treatment of variety of indications. Safe and effective use of BOTO GENIE® depends on selection of correct dose and administration techniques. Clinicians are advised to update their understanding of neuromuscular anatomy of the area being considered for treatment and take into consideration of any alteration to the anatomy due to prior surgical procedures. References of journal article for specific treatment with Botulinum toxin type A shall be of help.

Indications	Reference
• Strabismus, Blepharospasm, Hemifacial spasm, Tremors	8
• Cerebral palsy, Dystonia, Spasticity	3
• Migraine, Chronic facial pain, Neck pain etc.	1
• Hyperhydrosis-Palmer, Axilla etc.	6, 9
• Spasmodic dysphonia, Drooling Saliva, Speech & voice disorders	2, 4
• Achlasia	7
• Cosmetic enhancer – Glabeller frown lines, Crow feet & other Facial wrinkles	4, 5

CLINICAL STUDY

Studies have been published on use of Botogenie® in patients of infantile esotropia [10], blepharospasm & hemifacial spasms [11] and chronic anal fissures [12].

PHARMACOKINETICS

At recommended dosage of Botulinum toxin type A, systemic clinical effects and measurable levels in peripheral blood are not expected.

INTERACTION WITH OTHER DRUGS

Effect of Botulinum toxin type A may be potentiated on simultaneous administration with aminoglycosides or other drugs affecting neuromuscular transmission.

CONTRA-INDICATIONS

- Hypersensitivity to any ingredient in the formulation.
- Infection at the proposed site of inoculation

CAUTION DURING ADMINISTRATION

- **Nursing mother:** In view of lack of availability of data on excretion of this drug in human milk, caution should be exercised for administration of BOTO GENIE® in nursing mothers.
- **Pregnancy:** In view of inadequate data on effect of Botulinum toxin type A in pregnant woman and reported abortions/fetal malformations in animal studies. BOTO GENIE® should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- **In Individuals** with peripheral motor neuropathic diseases or neuromuscular junction disorder BOTO GENIE® should be administered with caution.
- **Necessary equipment** & medicines should be available to doctors to take care of rare possibilities of severe allergic/anaphylactic reactogenicity.

ADVERSE EFFECTS/SIDE EFFECTS

- Localized weakness of the injected muscle(s) represents the expected desirable action of the drug, however weakness of adjacent muscles may also occur due to spread of toxin e.g.
  -Dysphagia and subsequent pneumonia in patients treated local cervical dystonia.
  -Ptosis, keratitis, eye dryness, diplopia in patients treated for blepharospasm and strabismus.
- Skin rash, pruritus, allergic reaction, localized pain, bruising may be associated with the injection which may occur rarely.
- **Overdose:** Excessive doses may cause distant and profound neuromuscular paralysis. There is no specific antidote. General supportive care is advised.

STORAGE

- Unopened vials of BOTO GENIE® shall be stored in refrigerator at 2°C to 8°C. BOTO GENIE® is not affected by freezing, stability is even better at lower temperatures.
- Once reconstituted BOTO GENIE® shall preferably be used immediately.
- BOTO GENIE® reconstituted in aseptic conditions can be stored at 2°C to 8°C for 4 hours.

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