Summary of Product Characteristics

of

Botulinum Toxin Type A for Injection Ph.Eur.

Brand Name: BOTO GENIE®

Manufactured By:

BIO-MED (P) LTD.
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1 Name of the Medicinal Product

Botulinum Toxin Type A for Injection Ph.Eur. Purified neurotoxin complex
Brand name: - BOTO GENIE®

2 Qualitative and Quantitative Composition

(A) BOTO GENIE® 100 Unit Vial (Freeze Dried)
Botulinum Toxin Type A……..100 unit
Purified Neurotoxin Complex
Lactose (Stabilizer)……..5 mg

(B) BOTO GENIE® 50 Unit Vial (Freeze Dried)
Botulinum Toxin Type A……..50 unit
Purified Neurotoxin Complex
Lactose (Stabilizer)……5 mg

(C) DILUENT
Sodium Chloride Injection I.P.

3 Pharmaceutical form

Lyophilized preparation with diluent for reconstitution.

4 Clinical Particulars :-

4.1 Therapeutic Indications:-

BOTO GENIE® (Botulinum toxin type A for injection) is one of the most effective drug for treatment of variety of indications.

- Strabismus, Blepharospasm, Hemifacial spasm, Tremors
- Cerebral palsy, Dystonia, Spasticity
- Migraine, Chronic facial pain, Neck pain etc.
- Hyperhydrosis-Palmer, Axilla etc.
- Spasmodic dysphonia, Drooling Saliva, Speech & voice disorders
- Achlasia
- Cosmetic enhancer - Glabeller frown lines, Crow Feet & Other Facial wrinkles

4.2 Posology and method of administration :-

Subcutaneous / Intramuscular/ intradermal depending upon the application of use.

4.3 Contra indications :-

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

4.4 Special warnings and precaution for use :-

BOTO GENIE® (Botulinum toxin type A for injection) is one of the most effective drug for treatment 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 considered of any alteration to the anatomy due to prior surgical procedures.

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.

4.5 Interaction with other medicinal :-

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

4.6 Pregnancy & Lactation :-

Nursing mothers: 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 fetus.

4.7 Effects on ability to drive and use machines :-

No studies on the effects on the ability to drive and use machines have been performed. However, BOTO GENIE® may cause asthenia, muscle weakness, somnolence, dizziness and visual disturbance, which could affect driving and the operation of machinery.

4.8 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 for 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.

4.9 Over dose :-

Excessive doses may cause distant and profound neuromuscular paralysis. There is no specific antidote. General care is advised.

5. Pharmacological Properties :-
5.1 Pharmacodynamic Properties :-

Not applicable

5.2 Pharmacokinetic Properties:-

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

5.3 Preclinical Safety Data :-

In the preclinical safety Data the BOTO GENIE® (Botulinum toxin type A for injection) is found safe and a wide margin range of safety.

6. Pharmaceutical Particulars :-

6.1 List of excipients :-

Lactose

6.2 Incompatibilities :-

No compatibility studies of BOTO GENIE® with other injection was done.In the absence of compatibility studies the medicinal product must not be mixed with other medicinal product.

6.3 Shelf life :-

Use the product within 36 months from the date of manufacture.

6.4 Special precaution for storage:-

- Unopened vials of BOTO GENIE® shall be stored in refrigerator at 2^0C to 8^0C. 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^oC to 8^oC for 4 hours.

6.5 Nature & contents of container :-

Various material used for the final packing of vaccine are as follows.

For 50 unit	For 100 unit
Glass Vials :- 5 ml, 20 mm USP Type -I clear tubular glass vial. Rubber closures :- 20mm Grey Slotted Rubber stopper. Aluminium Seals :- 20 mm flip off aluminium seals blue (BE-11)	Glass Vials :- 5 ml, 20 mm USP Type -I clear tubular glass vial. Rubber closures :- 20mm Grey Slotted Rubber stopper. Aluminium Seals :- 13mm flip off aluminium seals pink (PK-1)

6.6 Special precautions for disposal:-

No special requirements

7 Marketing authorization Holder :-

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Website: www.biomed.co.in

8 Marketing authorization number :-

Permission given on Manufacturing license No. 08/SC/P of 2006 vide 20F/837/120 Dated 04/01/2007.

9 Date of first authorization/Renewal of the authorization:-

Permission given on Manufacturing license No. 08/SC/P of 2006 vide 20F/837/120 Dated 04/01/2007 and Drug/837/3866 dated 20/06/2012.

10 Date of Revision of the text :-

July, 2012