Summary of Product Characteristics of Botulinum Toxin Type A for Injection Ph. Eur.

Brand Name: Boto Genie®

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Summary of Product Characteristics

(As per Annexure C of Module 1 of Guidance for industry by CDSCO)

1. Name of the Medicinal Product :-

Botulinum Toxin Type A for Injection Ph. Eur.

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.....500 unit Purified Neurotoxin complex
- Lactose (Stabilizer).....5 mg

C. Diluent

- Sodium chloride injection I.P.

3. Pharmaceutical Form :-

Injection in freeze dried form.

4. Clinical Particulars :-

4.1 Therapeutic Indications:

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.

Indication	Reference
• Strabismus, Blepherospasm, 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

References :

1. Akoi, K.R. - Evidence of antinociceptive activity of Botulinum Toxin type A in pain management, Headache (2003), 43 (Suppl.) 9-15.
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4. Clinical use of Botulinum toxin-National Institute of Health Consensus Development Conference Statement (1990) Nov. 12-14 pg. 2-18.
5. Klein, A.W. - Cosmetic therapy with Botulinum toxin, Dermatal, Surg. (1996) 22, 757-759.
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7. Pasricha, P.J. Ravich. W.J., Henrichs, T.R. et al. - Intrasphincteric Botulinum toxin for treatment of achlasia. N. Engi. J. Med (1995) 322, 774-778.
8. Scott, A.B. - Botulinum toxin injection into extraocular muscles as an alternative to Strabismus Surgery. Opthal (1980) 89, 1044-1049.
9. Shelly W.B. et al. - Botulinum toxin therapy for palmer hyperhydrosis. J. Amer. Acad Dermatol (1998) 38, 227-229.
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11. Maneksha, et al.- Outcomes of regional variant of botulinum toxin type A in the treatment of essential blepharospasm and hemifacial spasms: A retrospective study. Indian Journal of Ophthalmology: October 2021-Volume 69- Issue 10- p 2777-2781.
12. Timilsina et al.- Randomized Clinical Trial Comparing Botulinum Toxin Injection with Nitroglycerine Ointment for Treatment of Chronic Anal Fissure. JBPKIHS 2018;1(2),88-94.

4.2 Physiology and method of administration:

Administer the drug by intramuscular/subcutaneous/intradermal route depending on the indication.

4.3 Contra indications:

The vaccine must not be used in the following cases:-

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

4.4 Special warnings:

- **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.

4.5 Interaction with other medicinal products and other forms of interaction :

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

4.6 Pregnancy & Lactation:

- **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.

4.7 Effects on ability to drive and use machines:

The Boto Genie® has no effects after administration on ability to drive and use machines. No separate study was done.

4.8 Undesirable 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, pruritis, 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 supportive care is advised.

5. Pharmacological Properties:-

5.1 Pharmacodynamics Properties:

Not applicable as doses are too less for Pharmacodynamics studies.

5.2 Pharmacokinetic Properties:

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

5.3 Preclinical Safety Data:

In the preclinical safety Data the Boto Genie® is found safe and a wide margin range of safety.

The final lots used in safety assessment studies was well characterized & evaluated for identity, potency, purity & stability.

6. Pharmaceutical Particulars:-

6.1 List of excipients :

Lactose I.P. (stabilizer)

6.2 Incompatibilities:

No compatibility studies of Boto Genie® with other drug 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°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.

6.5 Nature & contents of container:

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

- Glass Vials :-
  8 ml, 20 mm USP type I clear tubular glass vial.

- Rubber closures :-
  20 mm Grey Butyl Slotted Rubber Stopper (Sterile ready for use).

- Aluminium Seals :-
  20 mm flip off Pink aluminium seals (PK-1)for 100 units.

  20 mm flip off Blue aluminium seals (BE-11) for 50 units.

Materials used for the final packing of vaccine diluent are as follows:

- Glass vial :-

  8 ml, 13 mm USP type I clear tubular glass vial

- Rubber Closures: -

  13 mm Grey butyl, 'Bioclean RFU' Rubber stopper.

- Aluminium Seals :-

  13 mm flip off white aluminium seals(WE-1).

6.6 Special precautions for disposal:

No special requirements

7. Marketing authorization Holder :-

BIO-MED (P) LTD.
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8. Marketing authorization number :-

Manufacturing License No. 08/SC/P of 2006 on Form 28 dated 04 January, 2007.

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

a) **Date of First authorization** License No. 08/SC/P of 2006 on Form 28 dated 04 January, 2007.

b) **Amendment of authorization** License No. 08/SC/P of 2006 on Form 26 dated 20 June 2012.

10. Date of Revision of the text :-

January 2024.