NABOTA

(Clostridium Botulinum Toxin Type A) Injection 100 Units

Abbreviated Prescribing Information

Name of the Medicinal Product: Clostridium Botulinum Toxin type A Injection 100 Units (NABOTA). Therapeutic Indications: Indicated in adults for the treatment of 1) strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm, hemifacial spasm or 7th nerve disorder, 2) cervical dystonia 3) severe primary hyperhidrosis that is inadequately managed with topical agents, 4) arm symptoms associated with focal spasticity in conjunction with physiotherapy, 5) for prophylaxis of chronic migraine, 6) temporary glabellar lines. **Dosage and administration:** NABOTA injections are not interchangeable with other preparations of botulinum toxin products due to differences in biological activity based on the assay method used. Indication specific dosage and administration recommendations should be followed as given in **Table 1**. While initiating treatment, lowest recommended dose should be used. In treating adults for one or more indications, the maximum cumulative dose should not exceed 360 units in 3 months interval.

Table 1 Dosage recommendations of Nabota injection based on the indication and size of the muscle

Indication	**Initial recommended units**	**Volume & Site of muscle**	**Other Comments**
Glabellar lines	4units/0.1ml administered in each of 5sites, 2 in each corrugator muscle and 1in the procerus muscle for a total of 20units.		In order to avoid ptosis, avoid injecting near levator palbebrae superioris.

Instructions for safe usage: Safe and effective use of NABOTA depends upon proper storage of product, selection of correct dose and proper re-constitution and administration techniques. Nabota injection is for single use only and any unused solution should be discarded. The exposed central portion of rubber stopper should be cleaned with alcohol immediately prior to piercing the septum. Once opened and reconstituted, store in a refrigerator and use within 24 hours. Do not freeze any reconstituted NABOTA.

Warnings and Precautions: Spread of botulinum toxin effects beyond injection sites manifesting as asthenia, generalised muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. **Contraindications:** 1) Hypersensitivity to any botulinum toxin preparation or any component in the formulation. 2) Infection at injection site. 3) Neuromuscular junctional disorders. 4) Pregnant women, women of child bearing potential or nursing mothers. **Drug interactions:** Concomitant treatment with other muscle relaxants (eg. dantrolene, tubocuraine, baclofen and benzodiazepine) and drugs with muscle relaxation activity (aminoglycoside, tetracyclines, polypeptide antibiotics and anticholinergics) may potentiate botulinum toxin activity **Adverse Reactions:** ***General*****:** There have been spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility or anaphylaxis after treatment with botulinum toxin. Localised pain, tenderness, bruising, traction, swelling, hot feeling or hypertonia at injection site, local muscle weakness and rare reports of myocardial infarction, arrhythmia, skin rash, pruritis and allergic reactions**.** ***Glabellar lines:*** ptosis, raised eyebrows and vertigo**. Over dosage:** Symptoms of over dosage include neuromuscular weakness with a variety of symptoms and are not likely to be present immediately. The person should be medically supervised for several weeks for signs and symptoms which could be local or distant from the site of injection. If the musculature of oropharynx and eosophagus are affected, may lead to aspiration pneumonia. In case of weakness of respiratory muscles or paralysis, intubation and assisted respiration may be necessary.

Further information available on request

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