Fact sheet for SA Health Clinicians

Botulinum Toxin (Botox® and Xeomin®)

The South Australian Formulary Committee (SAFC) has recommended two formulations of Botulinum toxin type A for inclusion in the South Australian Medicines Formulary.

Botulinum toxin type A / Onabotulinum toxin A (Botox®) has been recommended for all Pharmaceutical Benefit Scheme (PBS) indications, for paediatric use where evidence of efficacy and safety is limited for the other brands, and as per indications below.

Incobotulinum toxin A (Xeomin®) should be used for all other indications, including Individual Patient Use (IPU) requests.

Literature supports equivalency between onabotulinum toxin A (Botox®) and incobotulinum toxin A (Xeomin®) with a comparative potency of 1:1.

Comparison between treatments

	Botox®	Xeomin®
Active ingredient	Onabotulinum toxin A Botulinum toxin type A, as a haemagglutinin complex	Incobotulinum toxin A Purified Botulinum toxin type A, free from complexing proteins
Excipients	Human albumin: 0.5 mg Sodium chloride: 0.9 mg	Human albumin: 1mg Sucrose 4.7mg
Each pack contains	1 vial of Botox® 100 units of vacuum-dried *Clostridium botulinum* toxin type A, white powder for reconstitution, sealed with a rubber stopper and tamper-proof aluminium seal.	1 vial of Xeomin® 100 units of *incobotulinum toxin A* in a type I glass vial sealed with a bromobutyl rubber stopper and tamper-proof aluminium cap.
Vial size	100 units	100 units
Dosing equivalence	Botox® and Xeomin® are given at the same doses.	Botox® and Xeomin® are given at the same doses.
Storage	Unopened vial: store between 2-8°C . Reconstitution: with preservative free sodium chloride 9 mg/mL (0.9%) solution. Reconstituted solution to be used as soon as practical once reconstituted and stored between 2-8°C for no more than 24 hours.	Unopened vial: store below 25 °C. Reconstitution: with preservative free sodium chloride 9 mg/mL (0.9%) solution. Reconstituted solution to be used as soon as practical once reconstituted and stored between 2-8°C for no more than 24 hours.

Mechanism of Action

Botulinum toxin type A is a neurotoxin complex produced from the fermentation of *Clostridium botulinum* type A. It blocks peripheral acetylcholine release at presynaptic cholinergic nerve terminals by cleaving SNAP-25, a protein integral to the docking and release of acetylcholine from vesicles located within the nerve terminals.

Botox® and Xeomin® both contain the neurotoxin produced by *Clostridium botulinum* type A.

- Botox® is a 900kD complex consisting of the neurotoxin and several complexing proteins.
- Xeomin® is a purified 150kD toxin, free of complexing proteins.
    - Xeomin's® reduced molecular size does not translate into diffusion differences.
    - Xeomin's® absence of complexing proteins may have reduced antigenicity.

Adverse Effects Botox® and Xeomin®

There are no significant differences in adverse effects between brands. The adverse effects are associated with the medications mechanism of action

- Asthenia, generalised muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties

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Precautions Botox® and Xeomin®

- Extreme caution in patients with peripheral motor neuropathic diseases

Contraindications Botox® and Xeomin®

Contraindicated in individuals with known hypersensitivity to any ingredient in the formulation

- Contraindicated in individuals with myasthenia gravis or Eaton Lambert syndrome
- Contraindicated in the presence of infection at the site of administration

South Australian Medicine Formulary Recommendations

All new patients are to follow the Formulary indications (below):

Botulinum toxin type A / Onabotulinum toxin A (Botox®) 100units injection

- For Pharmaceutical Benefit Scheme (PBS) indications **OR:**
- Paediatric use for the following indications:
  - Blepharospasm in patients less than 12 years
  - Focal Spasticity not due to cerebral palsy
  - Hypersalivation / sialorrhoea not adequately controlled with anticholinergic treatment.
  - Management of urinary incontinence due to idiopathic or neurogenic overactive bladder after failure to respond to anticholinergic treatment
  - Non-relaxing internal anal sphincter
- Urology / Gynaecology for management of urinary incontinence due to idiopathic or neurogenic overactive bladder after failure to respond to anticholinergic treatment in adult patients not fulfilling PBS criteria
- ENT or Oromaxillofacial services
  - For the management of spasmodic laryngeal dysphonia in adult patients
  - Essential voice / vocal tremor

Incobotulinum toxin A (Xeomin®) 100units Injection

Adult patients with the following indications:

- Achalasia
- Anal fissures / anal sphincter spasms / non-relaxing internal anal sphincter
- ENT or Oromaxillofacial services
  - Bruxism
  - Cricopharyngeal dysfunction with dysphagia in patients who are not candidates for surgery or endoscopic balloon dilation.
  - Focal Facial Hyperhidrosis secondary to Frey's Syndrome
  - Hypersalivation / sialorrhoea not adequately controlled with anticholinergic treatment
  - Oesophageal speech post laryngectomy
- ENT or Oromaxillofacial services for Temporomandibular Joint Disorders (includes masticatory myalgia) not responsive to pharmacological or other treatments
- Pain Units, Neurology, ENT and Oromaxillofacial services for Trigeminal neuralgia not adequately controlled with analgesia / neuropathic pain directed agents

For more information

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