**PBS Information: Section 100 Authority required (STREAMLINED). BOTOX® injection is listed on the PBS for “severe primary axillary hyperhidrosis”. Refer to PBS Schedule for full authority information.**

Before prescribing, please review Approved Product Information available on request from Allergan by phoning 1800 252 224 or from[**www.allergan.com.au/products**](http://www.allergan.com.au/products/Pages/default.aspx)

**Australian Minimum Product Information**

**BOTOX® (botulinum toxin type A) purified neurotoxin complex** is a prescription medicine containing 50 units (U), 100 units (U) or 200 units (U) of botulinum toxin type A for injection. **Indications:** Overactive bladder with symptoms of urinary incontinence, urgency and frequency, in adult patients who have an inadequate response to or are intolerant of an anticholinergic medication; urinary incontinence due to neurogenic detrusor overactivity resulting from a defined neurological illness (such as spinal cord injury or multiple sclerosis) and not controlled adequately by anticholinergic agents; prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine); strabismus; blepharospasm associated with dystonia, including benign blepharospasm & VIIth nerve disorders (hemifacial spasm) in patients 12 years & over; cervical dystonia (spasmodic torticollis); focal spasticity of the upper & lower limbs, including dynamic equinus foot deformity due to spasticity in juvenile cerebral palsy patients 2 years & older; severe primary hyperhidrosis of the axillae; focal spasticity in adults; spasmodic dysphonia; upper facial rhytides (glabellar lines, crow’s feet and forehead lines) in adults. **Contraindications:** Intradetrusor injection - acute urinary tract infection, acute urinary retention in patients who are not routinely catheterising or who are not willing and/or able to initiate catheterisation post-treatment, if required; Hypersensitivity to ingredients; Myasthenia gravis or Eaton Lambert Syndrome; Infection at injection site(s). **Precautions:** Different botulinum preparations are not therapeutically equivalent.Exercise extreme caution should substitution with another botulinum preparation be necessary. Botulinum toxin effects may be observed beyond site of local injection with symptoms consistent with mechanism of action and reported hours to weeks after injection. Symptoms may include muscular weakness, ptosis, diplopia, blurred vision, facial weakness, swallowing and speech disorders, constipation, aspiration pneumonia, difficulty breathing and respiratory depression. Risk of symptoms is greatest in children with spasticity but can also occur in adults particularly those on high doses. Swallowing/ breathing difficulties can be life threatening and there have been reports of death (relationship to BOTOX® not established). Serious adverse events including fatal outcomes have been reported in patients who had received BOTOX® injected directly into salivary glands, the oro-lingual-pharyngeal region, oesophagus and stomach. Hypersensitivity reactions such as anaphylaxis and serum sickness, as well as urticaria, soft tissue oedema and dyspnoea; inflammation at injection sites; excessive weakness in target muscle; pregnancy & lactation. Generalised weakness & myalgia may be related to systemic absorption. Blepharospasm: Reduced blinking following injection of the orbicularis muscle can lead to corneal pathology. Caution with patients at risk of angle closure glaucoma, including anatomically narrow angles. Strabismus: Inducing paralysis in extraocular muscles may produce spatial disorientation, double vision or past pointing. Use in chronic paralytic strabismus only in conjunction with surgical repair to reduce antagonist contracture. Spasticity: Not likely to be effective at a joint affected by a known fixed contracture. Not for treatment of focal lower limb spasticity in adult post-stroke patients if muscle tone reduction is not expected to result in improved function, improved symptoms or to facilitate care. To be used with caution in patients at risk of fall. Cervical Dystonia (spasmodic torticollis): Possibility of dysphagia or dyspnoea. May be decreased by limiting dose injected into the sternocleidomastoid muscle to <100U. Primary Hyperhidrosis of the Axillae: Consider causes of secondary hyperhidrosis to avoid symptomatic treatment. Spasmodic Dysphonia: Laryngoscopy in diagnostic evaluation is mandatory. Avoid treatment in patients due to have elective surgery requiring general anaesthesia. Chronic migraine: Due to difficulties in establishing a diagnosis of chronic migraine, patients being considered for prophylaxis of headaches with BOTOX® should be evaluated by a neurologist or pain management specialist prior to receiving treatment with BOTOX®. Bladder Dysfunction: The intradetrusor administration of BOTOX® is only to be conducted by a urologist/urogynaecologist trained in this technique or by a urologist/urogynaecologist under the direct supervision of a urologist/urogynaecologist who has been so trained. Caution when performing cystoscopy. Assess post-void residual volume post-treatment. Patients treated may show increased likelihood of developing urinary retention and/or urinary infection. *Overactive Bladder:* Men with overactive bladder and signs or symptoms of urinary obstruction should not be treated with BOTOX®. *Neurogenic Detrusor Overactivity:* Autonomic dysreflexia associated with the procedure could occur, which may require prompt medical therapy. Upper facial rhytides: Caution in patients with marked facial asymmetry, ptosis, excessive dermatochalasis, deep dermal scarring, thick sebaceous skin or the inability to substantially lessen glabellar lines by physically spreading them apart. Paediatric Use: Safety & effectiveness below 18 years have not been established for urinary incontinence due to overactive bladder, neurogenic detrusor overactivity or chronic migraine and below 12 years not established for blepharospasm, hemifacial spasm, cervical dystonia, hyperhidrosis, spasmodic dysphonia or upper facial rhytides. Safety & effectiveness below 2 years not established for focal spasticity. Caution should be exercised when treating patients with significant disability & co-morbidities and elderly. Caution should be exercised after treatment of BOTOX® as it can have an effect on the ability to drive and use machines. **Interactions:** The effect of botulinum toxin may be potentiated by aminoglycoside antibiotics or any other medicines that interfere with neuromuscular transmission. Caution should be exercised when Botox® is used in patients taking any of these medicines. Excessive weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. **Adverse Reactions:** Usually transient & occur within first week of injection.≥1%Localised pain, tenderness, bruising, infection, local & general weakness, erythema, oedema, ptosis, irritation/tearing, vertical deviation, diplopia, sub-conjunctival & conjunctival haemorrhages, reversible increase in intra-ocular pressure, trigger finger, clumsiness, falling, hypokinesia, increased frequency of micturition, joint dislocation, muscle spasms, convulsions, nasopharyngitis, dyspnoea, pneumonia, dry mouth, vomiting, contusion, leg pain/cramps, fever, knee pain, ankle pain, lethargy, arm pain, hypertonia, fever/flu syndrome, accidental injury, incoordination, paraesthesia, asthenia, headache, hyperkinesia, neck pain, dysphagia, perceived increase in non-axillary sweating, vasodilation, paralytic dysphonia (breathy dysphonia), aspiration, stridor, technical failure, blepharoptosis, face pain, ecchymosis, skin tightness, nausea, temporary lateral lower eyelid droop, eyebrow ptosis, eyelid swelling, aching/itching forehead, feeling of tension, seizures, migraine, facial paresis, musculoskeletal stiffness, myalgia, musculoskeletal pain, muscle tightness, injection site pain, pruritus, rash, urinary tract infection, urinary retention, fatigue, insomnia, constipation, muscular weakness, gait disturbance, bladder diverticulum, haematuria, dysuria, autonomic dysreflexia, bacteriuria, residual urine volume, pollakiuria, lagophthalmos, dysphonia, dry eye\* and localised muscle twitching/involuntary muscle contraction\*. **Dose/Administration:** Use one vial for one patient. Store reconstituted BOTOX® in refrigerator; use within 24 hours of reconstitution. Overactive Bladder: 100U injected in the detrusor muscle. Neurogenic Detrusor Overactivity: 200 U injected in detrusor muscle. Chronic migraine: 155U to 195U administered intramuscularly (IM) divided across 7 specific head/neck muscle areas. Blepharospasm: Initially 1.25U to 2.5U injected into upper lid medial & lateral pre-tarsal orbicularis oculi & into lower lid lateral pre-tarsal orbicularis oculi. Cumulative dose over 2 months should not exceed 200U. Strabismus: Initial doses 1.25 – 2.5U to 2.5 – 5.0U per muscle. Maximum single injection for any one muscle is 25U. VIIth Nerve Disorders (hemifacial spasm): Dosing as for unilateral blepharospasm. Inject other facial muscles as needed. Focal Spasticity in Children 2 Years & Older: 0.5-2.0U/kg body weight for upper limb & 2.0-4.0U/kg body weight for lower limb. 4U/kg or 200U (the lesser amount) for equinus foot deformity. Other muscles range 3.0-8.0U/kg body weight & do not exceed 300U divided among muscles at any treatment session. Focal Spasticity in Adults: Individualise dosing. Cervical Dystonia (spasmodic torticollis): Individualise dosing. Maximum dose 360U every 2 months. Primary Hyperhidrosis of the Axillae: 50U intradermally to each axilla in 10-15 sites 1-2 cm apart. Spasmodic Dysphonia: Bilateral injections. Individualise dosing. Glabellar Lines: 2x4U in each corrugator muscle & 4U in the procerus muscle for 20U total dose. Crow’s Feet: 2-6U/injection site, 3 sites bilaterally in lateral orbicularis oculi. Forehead Lines: 2-6U/injection site, 4 sites in frontalis muscle. **Last Amended Date:** 8 February 2018

***\*Please note change(s) in Product Information***

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