

FACT SHEET – Chronic Migraine

What is the difference between a headache and a migraine?

A headache is pain felt anywhere in the head or neck and can be caused by a wide range of contributing factors including stress, exercise and food intake/missing meals, changes in weather and hormonal changes.¹ It is normal for people to experience headaches in one form or another.²

Typical characteristics of the migraine (without aura) are unilateral location, pulsating quality, moderate or severe intensity, aggravation by routine physical activity and association with nausea and/or photophobia and phonophobia. Migraines are characterised by recurrent moderate to severe headaches and the duration can vary from a couple of hours through to multiple days.³

What is Chronic Migraine?

There are two types of migraine – Episodic Migraine (EM) and Chronic Migraine (CM) – each determined by frequency of headache days.^{1,4}

- CM is a debilitating condition where patients suffer headaches for 15 days or more per month, with migraine on at least eight of those days.^{2,5}
- Some symptoms may include:¹
 - Visual disturbances (such as flashing lights, blind spots in vision, zig zag patterns)
 - Nausea and vomiting
 - Sensitivity to light (photophobia)
 - Sensitivity to noise (phonophobia)
 - Sensitivity to smells (osmophobia)
 - Tingling/pins and needles/weakness/numbness in the limbs

The Impact of Chronic Migraine

- People with CM may experience substantial physical, social, psychological and economic burden as a result of their condition.⁶
 - Patients can be very disabled due to Chronic Migraine. As reported in the World Health Organisation (WHO) Bulletin, a day lived with severe migraine is as disabling or more so as a day lived with dementia, active psychosis, paraplegia or blindness.⁸
 - Chronic migraine patients are twice as likely to have severe anxiety or depression, due to missed days at work and loss of income which further contributes to the burden of the disease.⁴
 - Many people with CM find it hard to work or may have difficulties with everyday tasks such as household chores or participating in family activities.⁴

The Statistics

Migraine

- Two million – The approximate number of Australians who suffer from migraine, close to 10 per cent of the total population.¹
 - More people suffer from migraine in Australia than diabetes, asthma, or coronary heart disease.¹

- 1.5 Million - The number of women in Australia who suffer from migraine, compared with 500,000 men.¹

Chronic Migraine

- 450,000* – Approximate number of Australians (aged 18 years and over) who suffer from CM, equating to about 2 per cent of the total population.^{6,7}
- 80% – The estimated percentage of Australians experiencing CM who are not aware that they suffer from the condition, and thus are uninformed of the specialist care available.⁶

* <http://www.abs.gov.au/> Australian Bureau of Statistics. Estimate extrapolated from Australian population data.

Diagnosis and Treatment

- There are several treatment options for CM management¹:
 - Non-medicinal (such as complementary therapies or understanding - and then avoiding - potential triggers)
 - Medicinal (acute or preventative therapies).
- Medicinal treatments for chronic migraine include¹:
 - *Analgesics* which are used for pain relief (e.g. aspirin, paracetamol or ibuprofen)
 - *Triptans* which are used as abortive treatments for migraine (e.g. sumatriptan and zolmitriptan)
 - *Anti-emetics* that stop nausea and vomiting (e.g. metoclopramide)
 - Preventative medications (e.g. topiramate).
- A headache diary tracks everyday life disruptions from migraine and may help frequent migraine sufferers identify chronic migraine. Those who experience headaches for 15 days or more per month (with at least 8 of these being with migraine) should ask their doctor for a referral to a neurologist for assessment and appropriate treatment.

BOTOX® for the Prevention of Chronic Migraine

- From 1 March 2014, BOTOX® (botulinum toxin type A) treatment will be available on the Pharmaceutical Benefits Scheme (PBS) for the prevention of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least eight are with migraine).
- BOTOX® treatment works by temporarily blocking the release of chemicals in the brain associated with the cause of chronic migraine and is administered as an injection.⁹
- When injected at the correct dose and in the recommended locations in the head and neck, BOTOX® is expected to produce results lasting up to three months depending on the individual patient.¹⁰

Date of preparation: February, 2014

Further information:

For more information about BOTOX[®], including further safety information, please see the TGA-approved Consumer Medicine Information (CMI) and Product Information (PI) available at www.allergan.com.au/Products/Overview.

**PBS Information: Section 100 restriction.
Refer to PBS schedule for full information.**

Before prescribing, please review Approved Product Information available on request from Allergan.

Australian Minimum Product Information

BOTOX[®] (botulinum toxin type A) purified neurotoxin complex is a prescription medicine containing 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. 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. *Overactive Bladder: Patients treated may show increased likelihood of developing urinary retention and/or urinary infection. 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. Paediatric Use: Safety & effectiveness below 18 years have not been established for urinary incontinence due to *overactive bladder or neurogenic detrusor overactivity, 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, subconjunctival & 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. **Dose/Administration**: Use one



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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. VIIIth 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. Date of TGA approval: 06 August 2013

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

Issued by Cube on behalf of Allergan.

The information in this media fact sheet is not intended to be a substitute for professional medical advice, diagnosis or treatment. Questions about medical conditions and treatment options should be answered by a medical practitioner or other qualified health providers. This media fact sheet is intended to be used by media alongside the Allergan media release for the PBS listing of BOTOX® (botulinum toxin type A) for the prevention of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 are with migraine). A copy of the media release is available from Allergan.

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