

The National Launch Meeting for BOTOX® in chronic migraine*

Chaired by Professor Peter Goadsby

Riverbank Park Plaza Hotel, London SE1 7TJ
9th – 10th September, 2010

Dear Colleague

On behalf of Allergan, I'm delighted to invite you to the National Launch of BOTOX® for the prophylactic treatment of chronic migraine*.

Chronic migraine* is a potentially disabling and impactful disorder, both for patients and society, but is often underdiagnosed and undertreated.

BOTOX® is the first treatment specifically licensed and labelled for the prophylaxis of headaches in adults with chronic migraine*.

This scientific meeting will include sessions on chronic migraine* management, the data supporting use of BOTOX® as prophylaxis in chronic migraine* and will address the practicalities of using BOTOX® in the clinic.

We hope that you will join me and the exemplary faculty in London for what promises to be a highly educational and exciting event.



Professor Peter Goadsby
San Francisco, CA, USA

Registration information

To request a link to the online registration page, please e-mail your name and hospital/clinic or institution address to allerganmeetings@banks-sadler.co.uk

Join us on the **9th September** for a **reception dinner** following which Professor Oliver Dolly (DCU, Ireland) will open the meeting with a presentation examining the history of the botulinum toxins.

Friday 10th September

08.30-09.15	Welcome and Introduction	Professor Peter Goadsby (Chair)
09.15-10.00	Examining the data for BOTOX® in chronic migraine*: PREEMPT	Professor David Dodick
10.00-10.15	PREEMPT Q&A	Moderated by Chair
10.15-10.45	<i>Coffee</i>	
10.45-11.30	BOTOX® in practice: experience in the clinical setting	Dr Fayyaz Ahmed
11.30-12.00	BOTOX® in practice: Q&A	Dr Fayyaz Ahmed Dr Manjit Matharu
12.00-13.00	<i>Lunch</i>	
13.00-14.00	Setting up a migraine clinic	Dr Manjit Matharu
14.00-14.45 and 14.45-15.30	Parallel Workshop 1 BOTOX® and the formulary: pharmacy perspectives	Omar Ali Angela Brewin
14.00-14.45 and 14.45-15.30	Parallel Workshop 2 BOTOX®: how to inject for chronic migraine*	Dr Fayyaz Ahmed Dr Brendan Davies Dr Paul Davies Dr Giles Elrington Dr Mark Weatherall
15.30-16.00	Concluding session: Q&A and closing remarks	Chair
16.00	Close	Chair

*Headaches on at least 15 days per month of which at least 8 days are with migraine

Prescribing information can be found on the next page


BOTOX®
Botulinum Toxin Type A

Prescribing information

BOTOX® (botulinum toxin type A)

Migraine Abbreviated Prescribing Information

Presentation: Presentation: Botulinum toxin type A (from *Clostridium botulinum*), 50 or 100 or 200 Allergan Units/vial. **Indications:** 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). **Dosage and Administration:** See Summary of Product Characteristics for full information. Reconstitute with sterile unpreserved normal saline (0.9% sodium chloride for injection). BOTOX® doses are not interchangeable with other preparations of botulinum toxin. Inject using 30 gauge, 0.5 inch needle, or 1 inch needle for thicker muscles in neck region if required. Inject 0.1ml (5U) intramuscularly to 31 (up to 39) injection sites, divided across seven specific head/neck muscle areas including frontalis, corrugator, procerus, temporalis, trapezius and cervical paraspinal muscles. Inject bilaterally, with the exception of procerus. Total dose 155U–195U. **Contra-indications:** Known hypersensitivity to any constituent. Pregnancy or lactation. Presence of infection at proposed injection site(s). **Warnings/Precautions:** Relevant anatomy and changes due to prior surgical procedures must be understood prior to administration. Adrenaline and other anti-anaphylactic measures should be available. Reports of side effects related to spread of toxin distant from injection site, sometimes resulting in death. Caution in patients with underlying neurological disorder and history of dysphagia and aspiration. Patients should seek medical help if swallowing, speech or respiratory disorders arise. Clinical fluctuations may occur during repeated use. Too frequent or excessive dosing can lead to antibody formation and treatment resistance. The previously sedentary patient should resume activities gradually. Caution in the presence of inflammation at injection site(s) or when excessive weakness/atrophy is present in target muscle. Caution when used for treatment of patients with peripheral motor neuropathic disease. Use with extreme caution and close supervision in patients with defective neuromuscular

transmission (myasthenia gravis, Eaton Lambert Syndrome). Contains human serum albumin. Procedure related injury could occur. Efficacy has not been shown in prophylaxis of episodic migraine (headaches <15 days per month). May cause asthenia, muscle weakness, somnolence, dizziness and visual disturbance which could affect driving and operation of machinery. **Interactions:** Theoretically, effect may be potentiated by aminoglycoside antibiotics or other drugs that interfere with neuromuscular transmission e.g. tubocurarine-type muscle relaxants. **Adverse Effects:** See Summary of Product Characteristics for full information on side effects. *General:* Usually occur within the first few days following injection and are transient, but rarely persist for several months or longer. Local muscle weakness represents the expected pharmacological action. Localised pain, tenderness and/or bruising may be associated with the injection. Fever and flu syndrome have been reported. *Frequency defined as follows:* Very Common ($\geq 1/10$); Common ($\geq 1/100$ to $\leq 1/10$); Uncommon ($\geq 1/1,000$ to $\leq 1/100$); Rare ($\geq 1/10,000$ to $\leq 1/1,000$); Very Rare ($< 1/10,000$). *Nervous system disorders* – Common: Headache, migraine, facial paresis. *Eye Disorders* – Common: Eyelid ptosis. Uncommon: Eyelid oedema. *Skin and subcutaneous tissue disorders* – Common: Pruritis, rash. Uncommon: Pain of skin. *Musculoskeletal and connective tissue disorders* – Common: Neck pain, myalgia, musculoskeletal pain, musculoskeletal stiffness, muscle spasms, muscle tightness, muscular weakness. Uncommon: Pain in jaw. *General disorders and administration site conditions* – Common: Injection site pain. *Gastrointestinal disorders* – Uncommon: Dysphagia. *Additional Information:* Side effects related to spread of toxin distant from site of administration reported very rarely (including exaggerated muscle weakness, dysphagia, aspiration/aspiration pneumonia, with fatal outcome in some cases). Other adverse events reported include dysarthria, abdominal pain, vision blurred, pyrexia,

focal facial paralysis, hypoaesthesia, malaise, myalgia, pruritis, hyperhidrosis, diarrhoea, anorexia, hypoacusis, tinnitus, radiculopathy, syncope, myasthenia gravis, erythema multiforme, dermatitis psoriasiform, vomiting and brachial plexopathy. Also, rare reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Rare reports of serious and/or immediate hypersensitivity (including anaphylaxis, serum sickness, urticaria, soft tissue oedema and dyspnoea) associated with BOTOX® use alone or in conjunction with other agents known to cause similar reaction. Very rare reports of angle closure glaucoma following treatment for blepharospasm. New onset or recurrent seizure occurred rarely in predisposed patients, however relationship to botulinum toxin has not been established. Needle related pain and/or anxiety may result in vasovagal response. **Basic NHS Price:** 50 Units: £77.50, 100 Units: £138.20, 200 Units: £276.40. **Marketing Authorisation Number:** 50 Units: 426/0118, 100 Units: 426/0074, 200 Units: 426/0119. **Marketing Authorisation Holder:** Allergan Ltd, Marlow International, The Parkway, Marlow, Bucks, SL7 1YL, UK. **Legal Category:** POM. **Date of preparation:** July 2010. Further information is available from: Allergan Limited, Marlow International, The Parkway, Marlow, Bucks SL7 1YL.

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Allergan Ltd.
UK_Medinfo@allergan.com or **01628 494026**.