CHRONIC MIGRAINE

BOTOX® is indicated for the 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)

BOTOX® Botulinum Toxin Type A

Muscle dosage and number of sites

1. **Frontalis**[a] *20 Units (4 sites).*
2. **Procerus** *5 Units (1 site).*
3. **Corrugator**[a] *10 Units (2 sites).*
4. **Temporalis**[a] *40 Units (8 sites) no more than 50 Units (up to 10 sites).*
5. **Occipitalis**[a] *30 Units (6 sites) no more than 40 Units (up to 8 sites).*
6. **Cervical Paraspinal Muscle Group**[a] *20 Units (4 sites).*
7. **Trapezius**[a] *30 Units (6 sites) no more than 50 Units (up to 10 sites).*

Maximum recommended dose

155-195 Units of BOTOX®. 31-39 sites.
0.1 ml (5 Units) injections. 30-gauge, 0.5 inch needle.

Dilution options

50U/1 ml
100U/2 ml
200U/4 ml

Other information

Total dosage (number of sites). 1 IM injection site = 0.1 ml = 5 Units BOTOX®.

The recommended re-treatment schedule is every 12 weeks.

[a] Dose distributed bilaterally.

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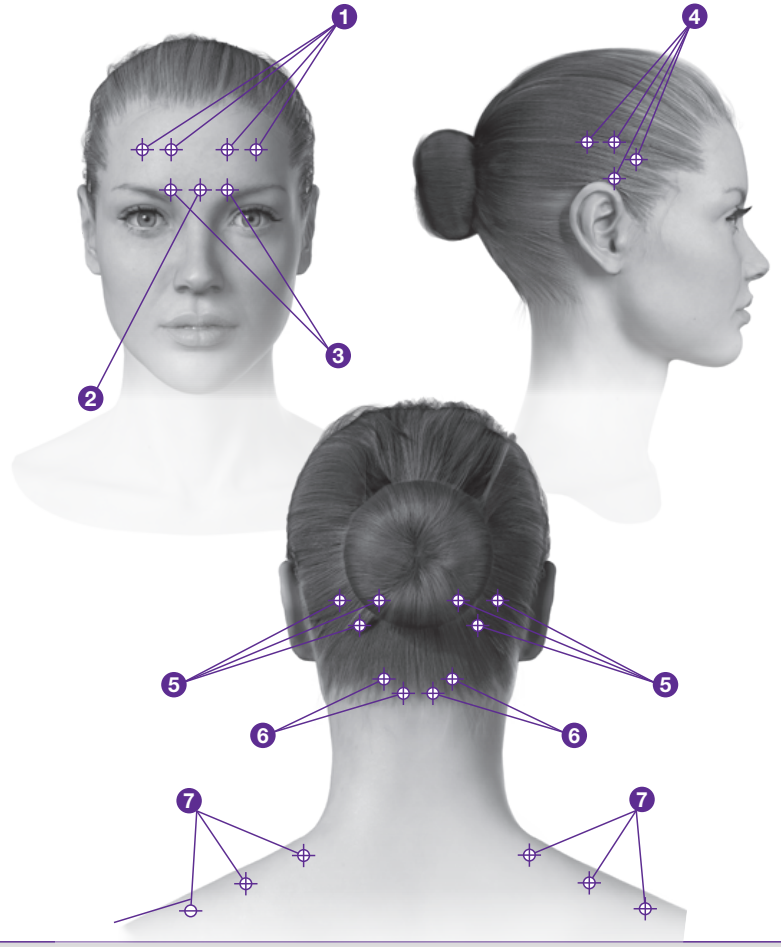
Based on a publication by Blumenfeld *et al* 2017 *(INSIGHTS into the functional anatomy behind the PREEMPT injection paradigm)* the injection points demonstrated in the images differ from the images shown in the BOTOX® product licence. Importantly these are not changes to the muscles groups identified in the licence, but simply reflect an amendment in technique to localise these muscles groups more effectively and minimise side effect profile.



Blumenfeld AM, Silberstein SD, Dodick DW, Aurora SK, Brin MF, Binder WJ (2017) Insights into the functional anatomy behind the PREEMPT injection paradigm: guidance on achieving optimal outcomes. Headache 57:766–777

BOTOX® 50/ BOTOX® 100/ BOTOX® 200

Indication: Botox is indicated for Symptom relief in adults fulfilling criteria for chronic migraine (headaches on ≥15 days per month of which at least 8 days with migraine) in patients who have responded inadequately or are intolerant of prophylactic migraine medications

Contraindications: known hypersensitivity to botulinum toxin type A or to any of the excipients (human albumin, Sodium chloride), presence of infection at the proposed injection site(s).

Safety information

Special Population: Elderly patients with significant medical history and concomitant medications should be treated with caution.

Special warnings and precautions: Botox should only be used with extreme caution and under close supervision in patients with subclinical or clinical evidence of defective neuromuscular transmission e.g. myasthenia gravis or Lambert-Eaton Syndrome in patients with peripheral motor neuropathic diseases (e.g. amyotrophic lateral sclerosis or motor neuropathy) and in patients with underlying neurological disorders.

Interactions: Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

Pregnancy, lactation and fertility: Botox should not be used during pregnancy and in women of childbearing potential not using contraception unless clearly necessary. The use of Botox during lactation cannot be recommended. Studies in male and female rats have shown fertility reductions.

Effects on ability to drive and use machines: Botox may cause asthenia, muscle weakness, dizziness and visual disturbance, which could affect driving and using machines.

Undesirable effects: In general, adverse reactions occur within the first few days following injection and, while generally transient, may have a duration of several months or, in rare cases, longer. Local muscle weakness represents the expected pharmacological action of botulinum toxin in muscle tissue. However, weakness of adjacent muscles and/or muscles remote from the site of injection has been reported. As is expected for any injection procedure, localised pain, inflammation, paraesthesia, hypoaesthesia, tenderness, swelling/oedema, erythema, localised infection, bleeding and/or bruising have been associated with the injection. Needle-related pain and/or anxiety have resulted in vasovagal responses, including transient symptomatic hypotension and syncope. Fever and flu syndrome have also been reported after injections of botulinum toxin.

* For full information please see Botox® prescribing information

Full prescribing information can be received from Allergan - Abbvie Biopharmaceutical Ltd., Israel, at 4 Hacharash Street, Hod Hasharon, 4524075. Tel: 09-7909600, Fax: 09-7909606.

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