

ABBREVIATED PRESCRIBING INFORMATION

NeuroBloc® (Botulinum Toxin Type B)

Please refer to the SPC before prescribing.

Presentation: 0.5 ml, 1 ml and 2 ml vials containing 2500U, 5000U and 10000U of Botulinum Toxin Type B solution for injection.

Indication: Treatment of cervical dystonia (torticollis).

Dose and administration: For intramuscular (IM) administration only. Should only be administered by experienced physicians familiar with treatment of cervical dystonia and botulinum toxins.

Restricted to hospital use only. May be diluted with sodium chloride 9 mg/ml (0.9%) solution for injection and used immediately. Dosage units not interchangeable with units used to express potency of other botulinum toxin preparations. See SPC for instructions for use and handling.

Adults and elderly: 5000U or 10 000U divided between two to four most affected muscles. 10 000 U may increase the clinical benefit. The dose and frequency of administration should be adjusted for each patient depending on the clinical response.

Patients with renal or hepatic impairment: No dose adjustment required (see SPC).

Children and adolescents under 18 years: Not recommended

Contra-Indications: Hypersensitivity to Botulinum Toxin Type B or any excipient. Individuals with other neuromuscular diseases or neuromuscular junctional disorders.

Pregnancy: Do not use during pregnancy unless clinical condition requires treatment. Studies in animals are insufficient and potential risk in humans is unknown.

Lactation: Do not use during lactation unless clearly necessary as it is unknown whether Botulinum Toxin Type B is excreted in breast milk.

Warnings and Precautions: Caution should be exercised to prevent administration into a blood vessel. Caution should be used in patients with bleeding disorders or receiving anticoagulant therapy. Neuromuscular side effects due to toxin spread have been reported. Repeated use of NeuroBloc may be associated with development of antibodies to Botulinum Toxin Type B in some patients. An investigation showed that antibody presence did not affect clinical response or overall safety profile, However, the clinical relevance of the presence of antibodies as determined by the mouse neutralisation assay, is uncertain. Spontaneous reports of dysphagia, aspiration pneumonia and/or potentially fatal respiratory disease, after treatment with Botulinum Toxin Type A/B have been reported. There is an increased risk of side effects in patients with underlying neuromuscular disease and swallowing disorders. Close medical supervision is advised in patients with neuromuscular disorders or history of dysphagia and aspiration. Seeking medical attention for respiratory difficulties, choking or any new or worsening dysphagia is advised. Dysphagia has been reported following injection to sites other than the cervical musculature. Dosage units are specific to Botulinum Toxin Type B only and are not relevant to preparations of Botulinum Toxin Type A. Ability to drive or operate machinery may be impaired in case of adverse reactions such as muscle weakness and eye disorders.

Drug Interactions: No specific interaction studies. Effect of co-administration with other botulinum toxin types is unknown. Co-administration of Botulinum Toxin Type B and aminoglycosides or agents interfering with neuromuscular transmission (e.g. curare-like compounds) should be considered with caution.

Side effects: Adverse reactions reported with Botulinum Toxin Type B (toxin-naïve and toxin-responsive) are: Very common ($\geq 1/10$): dry mouth, dysphagia, headache and injection site pain. Common ($\geq 1/100$ to $< 1/10$): worsening of torticollis (from baseline), torticollis, taste perversion, voice alteration, dyspepsia, myasthenia, blurred vision, neck pain, dysphonia and injection site pain. Electrophysiological jitter, which is not associated with clinical weakness or other electrophysiological abnormalities, may be experienced in some distant muscles. There have been post marketing reports of exaggerated muscle weakness, dysphagia, dyspnoea, aspiration, pneumonia with fatal outcome in some cases, abnormal accommodation, ptosis, vomiting, constipation, flu-like symptoms, asthenia, angioedema, rash, urticaria and pruritis.

Shelf-life: 3 years.

Special precautions for storage: 2°C - 8°C. May be stored at a temperature not above 25°C for up to 3 months, without being refrigerated again. Do not freeze. Protect from light. For storage conditions of the diluted medicinal product, see SPC

Legal Category: POM

Basic UK NHS cost: Botulinum Toxin Type B 0.5ml vial: £111.20, Botulinum Toxin Type B 1ml vial: £148.27 and Botulinum Toxin Type B 2ml vial: £197.69

Irish price to wholesaler: Botulinum Toxin Type B 0.5ml vial: €152.55, Botulinum Toxin Type B 1ml vial: €203.40 and Botulinum Toxin Type B 2ml vial: €271.19

Marketing authorisation numbers: Botulinum Toxin Type B 0.5ml vial: EU/1/00/166/001 Botulinum Toxin Type B 1ml vial: EU/1/00/166/002 and Botulinum Toxin Type B 2ml vial: EU/1/00/166/003

Further Information from: Eisai Ltd, European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN

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Adverse events should be reported. Reporting forms and Information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Eisai Ltd on 0208 600 1400/0845 676 1400 or Lmedinfo@eisai.net