20 February 2013
NeuroBloc: DHPC **Ireland**

Direct Healthcare Professional Communication on the risks associated with off-label use of NeuroBloc (Botulinum Toxin Type B)

Dear Healthcare Professional

Summary

- **NeuroBloc is indicated only for the treatment of cervical dystonia (torticollis) in adults**
- **The safety of NeuroBloc outside the approved indication has not been established**
- **All patients should be warned of the signs and symptoms of toxin spread and should seek medical attention immediately if they experience breathing difficulties, choking, or any new or worsening swallowing difficulties**

This communication has been endorsed by the European Medicines Agency (EMA) and the Irish Medicines Board (IMB).

Further information on the safety concern

NeuroBloc (Botulinum Toxin Type B) is indicated only for the treatment of cervical dystonia (torticollis). Individuals known to have other neuromuscular diseases (e.g. amyotrophic lateral sclerosis or peripheral neuropathy) or neuromuscular junctional disorders (e.g. myasthenia gravis or Lambert-Eaton syndrome) must not be given NeuroBloc.

Rare cases of distant toxin spread from the site of injection have been reported with NeuroBloc (and botulinum toxins as a class). Some of these cases have occurred: a) in patients with underlying neuromuscular deficits, b) in children, and c) mostly with off-label use. When used in the approved indication according to the prescribing information, the majority of adverse effects attributable to toxin spread are self-limiting events, such as dry mouth, dysphagia, blurred vision and abnormal accommodation, that do not require significant medical attention. Medically severe adverse events have occurred rarely and usually in association with incorrect clinical use or off-label use, such as the use in children or patients with significant neuromuscular disease or the use of higher than recommended doses.

Eisai Limited
European Knowledge Centre
Mosquito Way
Hatfield
Hertfordshire AL10 9SN
www.eisai.co.uk

Tel +44 (0)20 8600 1400
+44 (0)845 676 1400
Fax +44 (0)20 8600 1401

Recommendations to healthcare professionals

Healthcare Professionals are reminded to use NeuroBloc only as indicated and additional wording to this effect is being added to the SmPC for the product.
Neurobloc should not be used in children.
Neurobloc should not be used in patients with known neuromuscular disease or neuromuscular junction disorders.

Call for reporting

Healthcare professionals should report any adverse reaction suspected to be associated with the use of NeuroBloc to the Irish Medicines Board using the online form at www.imb.ie or by using the freepost yellow card system. The IMB can also be contacted on 01-6764971.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Communication information

Further information on NeuroBloc and cervical dystonia for healthcare professionals and patients is available at www.neurobloc.eu.

Should you have any questions or require further information regarding NeuroBloc, please contact Medical Information on +44 (0) 208 600 1400/+44 (0) 845 676 1400 or EUMedinfo@eisai.net.

Yours Sincerely

Dr Tony Patrikios
Medical Director
Eisai Ltd

Eisai Limited
European Knowledge Centre
Mosquito Way
Hatfield
Hertfordshire AL10 9SN
www.eisai.co.uk

Tel +44 (0)20 8600 1400
+44 (0)845 676 1400
Fax +44 (0)20 8600 1401