NeuroBloc
botulinum toxin type B

This is a summary of the European public assessment report (EPAR) for NeuroBloc. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for NeuroBloc.

What is NeuroBloc?

NeuroBloc is a solution for injection that contains the active substance botulinum toxin type B (5000 units [U] per millilitre).

What is NeuroBloc used for?

NeuroBloc is used to treat cervical dystonia. Cervical dystonia, which is also known as torticollis, is a disorder when the neck muscles contract, causing abnormal movement and twisting of the neck and unusual positioning of the head.

The medicine can only be obtained with a prescription.

How is NeuroBloc used?

NeuroBloc is only used in hospitals, by a doctor who is familiar with and has experience in the treatment of cervical dystonia and in the use of botulinum toxins. NeuroBloc treatment starts with 10,000 U, divided into equal dosess and injected directly into the two to four muscles in the neck and shoulders that are most affected. The dose and number of injections depend on the patient’s response.

How does NeuroBloc work?

The active substance in NeuroBloc, botulinum toxin type B, is a well-known toxic substance produced by the bacterium Clostridium botulinum. The toxin is the cause of a type of food poisoning called
botulism, where patients suffer from muscle weakness and paralysis. The toxin reduces the release of acetylcholine from the nerve endings. Acetylcholine is needed to transfer electrical impulses from the nerves to the muscles in order for the muscles to contract.

In NeuroBloc, the toxin is used as a muscle relaxant. When injected directly into a muscle it reduces the release of acetylcholine and muscle contraction in the affected neck or shoulder muscles, thereby relieving the patient’s symptoms. The effect of an injection of NeuroBloc gradually wears off over time.

**How has NeuroBloc been studied?**

NeuroBloc has been compared with placebo (a dummy treatment) in four studies involving a total of 392 adults with cervical dystonia. Three of the studies included patients who had stopped responding to type A botulinum toxin (another type of botulinum toxin that may also be used to treat cervical dystonia), and the fourth only included patients who did respond to type A toxin. Effectiveness was measured by looking at the change in symptoms (severity, pain and disability) after four weeks, measured using the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS).

**What benefit has NeuroBloc shown during the studies?**

After four weeks of treatment, NeuroBloc was significantly better at improving symptoms than placebo in all studies. The medicine improved the score of the non-responders to type A botulinum toxin as well as the score of the responders. Most patients who had a response to NeuroBloc by the fourth week had returned to their original condition 12 to 16 weeks after the injection.

**What is the risk associated with NeuroBloc?**

The most common side effects with NeuroBloc (seen in more than 1 patient in 10) are dry mouth, headache (in patients new to treatment with botulinum toxins), dysphagia (difficulty swallowing) and reactions at the site of the injection (in patients previously treated with botulinum toxins). For the full list of all side effects reported with NeuroBloc, see the package leaflet.

NeuroBloc should not be used in people who may be hypersensitive (allergic) to botulinum toxin or any of the other ingredients. NeuroBloc must not be used in patients with other neuromuscular (nerve and muscle) disorders.

**Why has NeuroBloc been approved?**

The CHMP decided that NeuroBloc’s benefits are greater than its risks and recommended that it be given marketing authorisation.

**Other information about NeuroBloc**

The European Commission granted a marketing authorisation valid throughout the European Union for NeuroBloc on 22 January 2001. The marketing authorisation holder is Eisai Ltd. The marketing authorisation is valid for an unlimited period.

The full EPAR for NeuroBloc can be found on the Agency’s website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with NeuroBloc, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2010.