



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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NeuroBloc (*botulinum toxin type B*)

An overview of NeuroBloc and why it is authorised in the EU

What is NeuroBloc and what is it used for?

NeuroBloc is a medicine used to treat cervical dystonia in adults. 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.

NeuroBloc contains the active substance botulinum toxin type B.

How is NeuroBloc used?

NeuroBloc is available as a solution for injection (5,000 units [U] per millilitre) and it can only be obtained with a prescription. It is only used in hospitals, by a doctor who 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 doses 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.

For more information about using NeuroBloc, see the package leaflet or contact your doctor or pharmacist.

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.

What benefits of NeuroBloc have been shown in studies?

NeuroBloc was more effective than placebo (a dummy treatment) at improving symptoms of cervical dystonia in four studies involving a total of 392 adults.



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).

The medicine improved the TWSTRS 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 are the risks associated with NeuroBloc?

The most common side effects with NeuroBloc (which may affect more than 1 in 10 people) are dry mouth, headache (in patients new to treatment with botulinum toxins), dysphagia (difficulty swallowing) and pain at the site of the injection. For the full list of side effects reported with NeuroBloc, see the package leaflet.

NeuroBloc must not be used in patients with other neuromuscular (nerve and muscle) disorders. For the full list of restrictions, see the package leaflet.

Why is NeuroBloc authorised in the EU?

The European Medicines Agency decided that NeuroBloc's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of NeuroBloc?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of NeuroBloc have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of NeuroBloc are continuously monitored. Side effects reported with NeuroBloc are carefully evaluated and any necessary action taken to protect patients.

Other information about NeuroBloc

NeuroBloc received a marketing authorisation valid throughout the EU on 22 January 2001.

Further information on NeuroBloc can be found on the Agency's website [ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports).

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