



## **Botulinum toxin type A/B, for injection**

### **Treatment with substance of biological origin**

**Botulinum toxin (BTX) is a neurotoxic protein produced by the bacterium *Clostridium botulinum* and related species.** It is one of the most lethal substances known, that interferes with neural transmission by blocking the release of acetylcholine, the principal neurotransmitter at the neuromuscular junction, causing muscle paralysis

Injections with botulinum toxin are generally well tolerated and side effects are few. Because chemical denervation is reversible, botulinum toxin has temporary effects, the muscle being progressively reinnervated by nerve sproutings.

Botulinum toxins now play a very significant role in the management of a wide variety of medical conditions, **especially strabismus and focal dystonias, hemifacial spasm, and various spastic movement disorders, headaches, hypersalivation, hyperhidrosis**, and some chronic conditions that respond only partially to medical treatment. The list of possible new indications is rapidly expanding. The cosmetological applications include correction of lines, creases and wrinkling all over the face, chin, neck, and chest to dermatological applications such as hyperhidrosis.

**Pharmacotherapeutic group:** Other muscle relaxants, peripherally acting agents, Botulinum toxin  
ATC: M03AX01.

#### **Project description:**

The project concerned the development of methods for production and purification of botulinum toxin type A and/or B, which could be further used for the production and detailed examination of medicinal product. An innovative element of the project is a composition of culture medium used for growth of a strain of *Clostridium botulinum*, which does not contain ingredients from animal origin. Such ingredients are a potential source of virus infection and a potential source of infectious prion protein responsible for the development of neurodegenerative diseases.

#### **Project status:**

Completed stages (IP rights and know-how for the documentation):

- Detailed analysis of culture media free of any animal-derived component has been performed. The components of culture media for *Clostridium botulinum* strain have been selected.
- Procedures regarding Master and Working Cell Banks establishment for *Clostridium botulinum* have been developed.
- Research and development work for the selection of culture media free of any animal-derived component has been performed.