
SUMMARY OF PRODUCT CHARACTERISTICS

BOTULISM-ANTITOXIN BEHRING

1. Name of the medicinal product

Botulismus-Antitoxin Behring

2. Qualitative and quantitative composition

1 ml contains:

Equine protein	max. 100 mg
with antitoxin against Cl. botulinum	
Type A	750 IU
Type B	500 IU
Type E	50 IU

3. Pharmaceutical form

Botulismus-Antitoxin Behring is a clear, colourless to pale yellow solution for infusion.

4. Clinical particulars

4.1 Therapeutic indications

Treatment of botulism

Botulismus-Antitoxin Behring must be given immediately on suspicion of botulism. Under no circumstances should the treatment be delayed by waiting for results of lengthy clinical observations or of bacteriological / serological tests.

4.2 Posology and method of administration

4.2.1 Dosage

Adults and children receive the same dose.

Initial dose: 500 ml

First infuse 250 ml slowly while observing the circulatory effects. Follow with a continuous drip infusion of a further 250 ml.

Depending on the degree of clinical improvement, a further 250 ml may be advisable 4 - 6 hours later.

4.2.2 Method of administration

The antitoxin is to be administered slowly intravenously and preferably at body temperature.

The application of immune sera must be recorded by the physician with batch no. and name of the preparation (trade name) in the International Vaccination Record.

4.3 Contraindications

None (vital indication!)

4.4 Special warnings and special precautions for use

Precautions:

Before administering Botulism-Antitoxin Behring the patient's history should be carefully reviewed whether the patient has been sensitised to equine protein.

General rules for injections of Heterologous Immune Sera

1. Administer immune sera only when clearly necessary.
2. Use only clear and particle free immune sera.
3. Be prepared to treat shock.
4. Administration of immune sera to patients with a history of allergic reactions to equine proteine, may only be done together with a medication for the prevention of shock reactions.
5. The patient must be monitored closely for signs of the onset of shock and be kept under medical supervision for 2 hours after the administration of the immune serum.

Management of adverse drug reactions

Clinical manifestation, symptoms and signs	Measures
Anaphylaxis, anaphylactoid reactions:	
Onset within minutes to hours after administration	
Symptoms such as urticaria, nausea, headache, bronchospasm, symptoms of shock may occur	<ul style="list-style-type: none">▪ Immediate interruption of administration of the antigenic material▪ Shock recovery position▪ Administration of oxygen▪ Rapid intravenous volume substitution (CAVE: antigenic plasma expanders!)▪ If necessary, intravenous administration of catecholamines + corticosteroids + H₁- + H₂-receptor antagonists▪ Monitoring of vital signs (respiration, pulse, blood pressure)
Pyretic reactions:	
Onset 1 to 2 hours after start of therapy	
Fever, chills, arterial hypertension	<ul style="list-style-type: none">▪ Monitoring of the circulatory system▪ Antipyretic treatment, including, if appropriate, physical measures (wet compresses)▪ In case of severe chills Pethidine may be administered, if necessary
Late reactions (e.g. serum sickness):	
Onset 7 (5 to 24) days after start of therapy	
Pruritus, urticaria, fever, arthralgia, neurological disorders	<ul style="list-style-type: none">▪ Determination of clinical status▪ Determination of involvement of organs and any symptoms▪ Administration of corticosteroids, if necessary▪ Check potential indication for plasma separation

4.5 Interactions with other medicaments and other forms of interaction

None known.

4.6 Pregnancy and lactation

Pregnancy or lactation period are no contraindication to the use of Botulismus-Antitoxin Behring (vital indication!).

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Transient elevations in temperature may occur.

Allergic and anaphylactic reactions occur occasionally and, in very rare cases, may extend as far as a shock.

Immediate measures depend on the nature and degree of the clinical symptoms: see "Special warnings and special precautions for use"

Serum sickness occurs occasionally. Delayed allergic reactions such as serogenetic polyneuritis rarely occur and usually the prognosis is good.

The application of heterologous sera involves a risk of allergic sensitisation.

4.9 Overdose

No symptoms of overdosage are known

5. Pharmacological properties

Pharmacodynamic properties

Botulismus-Antitoxin Behring is a Fermo-Serum®.

Fermo-Serum® is enzymatically treated (with pepsin) „purified“ serum. This procedure reduces the risk of sensitisation and allergic reactions are persistently reduced.

The procedure is based on the fact that antibody molecules are more resistant to pepsin as the remaining serum proteins. As the latter are readily splitted to peptides and peptones, the antibody globulines (7S) are degraded only about one third of their size (Fc-fragment) to F(ab)2-fragment(5S) and they keep their activity to a large extent.

Botulismus-Antitoxin Behring is a clear, colourless to pale yellow solution and is obtained from horses immunised with the toxins of Cl. botulinum Types A, B and E. The antibodies react specifically with the botulismus toxins and neutralise them.

To verify the clinical diagnosis, the patient's serum (collected before the administration of antitoxin), vomit, stool, or stomach contents is tested for toxin in the laboratory animal test. After administering the antitoxin a further sample of the patient's serum should be collected and tested for toxin by the same method in order to ensure that all the toxin has been neutralised.

In infant botulism antitoxin is not used.

Pharmacokinetic properties

When administered intravenously, the antibodies take immediate effect.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium chloride, water for injections.

In traces: Phenol

6.2 Incompatibilities

Botulismus-Antitoxin Behring must not be mixed with other drugs in a single syringe.

6.3 Shelf life

The shelf life of Botulismus-Antitoxin Behring is 48 months.

This preparation should not be used after the expiry date printed on the package and container.

Once the bottle has been opened, its contents is to be used immediately.

6.4 Special precautions for storage

Botulismus-Antitoxin Behring should be stored at +2 to +8°C.

6.5 Nature and contents of container

250 ml infusion bottle

6.6 Instructions for use/handling

Dispose any unused solution appropriately.

7. Marketing authorisation holder

Novartis Vaccines and Diagnostics GmbH & Co. KG
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D-35006 Marburg
Germany

8. Marketing authorisation number

9. Date of first authorisation/renewal of the authorisation

10. Date of (partial) revision of the text.

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