Botulism Antitoxin Behring

Composition
1 ml contains:

equine protein with antitoxin against Cl. botulinum	max. 100 mg
Type A	750 I.U.
Type B	500 I.U.
Type E	50 I.U.

sodium chloride, water for injections
in traces: Phenol

Presentation and contents by weight, volume or number of items
Bottle containing 250 ml

Substance or indication category
Immune sera

Name and address of the pharmaceutical entrepreneur
Novartis Vaccines and Diagnostics GmbH & Co. KG
PO Box 1630
D-35006 Marburg
Germany

Indications
Treatment of botulism
Botulism Antitoxin Behring must be given immediately on the slightest suspicion of botulism. Under no circumstances should the treatment be delayed while waiting for the results of lengthy clinical observations or of bacteriological/serological tests.

Contraindications
None as this is a vital indication (compelling indication due to life-threatening condition!)

Pregnancy and lactation
Pregnancy and lactation period are not contraindications for the treatment with Botulism Antitoxin Behring as the indication is vital.

Special precautions for use
Prior to infusion of Botulism Antitoxin Behring, the patient's history should be carefully reviewed in order to determine whether the patient is at a risk of an allergic reaction to equine protein.
Therefore the following should be considered:

General rules for the infusion/injection of immune sera of animal origin
1. Administer immune sera only after careful consideration of the indication.
2. Use only clear and particle free immune sera preparations.
3. Be prepared to treat shock.
4. Immune sera may be administered to patients with a history of allergic reactions to equine protein only in combination with a medication for the prevention of shock reactions.
5. The patient must be monitored closely for signs of the onset of shock and 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
Anaphylactoid/ anaphylactic reactions: onset within minutes to hours after start of therapy E.g. urticaria*, nausea*, headache, bronchospasm*,	• 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 + H_1- + H_2-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*	• 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 (serum sickness): Onset 7 (5 to 24) days after start of therapy Pruritus*, urticaria*, fever, arthralgia*, neurological disorders*	• Determination of clinical status • Determination of involvement of organs and any symptoms • Administration of corticosteroids, if necessary • Check potential indication for plasma separation

*** Urticaria (nettle rash), nausea (feeling of sickness), bronchospasm (narrowing of the airways), arterial hypertension (high blood pressure), pruritus (itching of the skin with obsessive scratching), arthralgia (joint pain), neurological disorders (disorders of the nervous system)**

Interactions
Botulism Antitoxin Behring must not be mixed with other medicinal products in a single container.

Dosage instructions, method and duration of administration

Dosage
Adults and children receive the same dose.
Initial dose: 500 ml
First infuse 250 ml slowly while observing the circulatory effects, then subsequently a further 250 ml as a continuous drip infusion.
A further 250 ml may be advisable 4 – 6 hours later depending on the clinical findings.

Method of administration
The antitoxin is administered preferentially at body temperature by slow intravenous injection.

Side-effects
If you develop side-effects that are not mentioned in this package insert, please inform your physician or pharmacist.
Transient elevation of body temperature may occur.
Occasionally, allergic and anaphylactic reactions (as a result of hypersensitivity) occur and, in very rare cases these may extend as far as shock.

Immediate measures depend on the nature and severity of the side-effects: see *„Special precautions for use“*
Serum sickness occurs occasionally. Delayed allergic reactions, such as in the form of serogenetic polyneuritis (inflammation of nerves triggered by serum administration) are rare, and usually the prognosis is good.
The application of sera of animal origin involves a risk of allergic sensitisation (risk of an allergic reaction after renewed contact with animal sera).

Storage and shelf-life
Botulism Antitoxin Behring should be stored at +2 to +8 °C.
Botulism Antitoxin Behring must not be used after the expiry date shown on the pack and container.
The contents of an opened bottle should be used immediately.

Keep all medicines out of reach of children!

Date of last revision
September 2006

Additional Information
Botulism Antitoxin Behring is a Fermo-Serum®.
Fermo-Serum is an immune serum "purified" by fermentative (enzymatic) treatment. By processing with pepsin the risk of sensitisation and allergic reactions as a consequence is lastingly reduced.
The procedure is based on the fact that antibody molecules are more resistant to pepsin than the other serum proteins. While other serum proteins are already degraded to peptides and peptones, the antibody globulins (7S) are only reduced by approximately a third of their molecular size (Fc-part) to the F(ab)2-fragment (5S), while their activity is largely preserved.
Botulism 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, and neutralise, the botulism toxins.
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.
All injections of immune sera should be recorded by the physician with batch No. and name of the preparation (trade name) in the International Vaccination Record.