Adverse Effects

1- Immediate reactions:

The reactions liable to be observed are anaphylactoid reactions with hypotension, dyspnea, and urticaria. More serious reactions such as Quincke's edema or anaphylactic shock may occur.

2- Delayed reactions:

Reactions similar to serum sickness may occur around 6 days following the administration of proteins that are not naturally produced by the body. They consist of an inflammatory reaction due to complement activation and the formation of immune complexes (type III hypersensitivity reaction). Clinical symptoms include fever, rash or urticaria and arthralgia.

Undesirable effects must be treated as follows:

In the event of a severe anaphylactic-type reaction during the administration of the antitoxin, the injection must be stopped immediately. If the effect persists despite the discontinuation of the infusion, symptomatic treatment must be initiated.

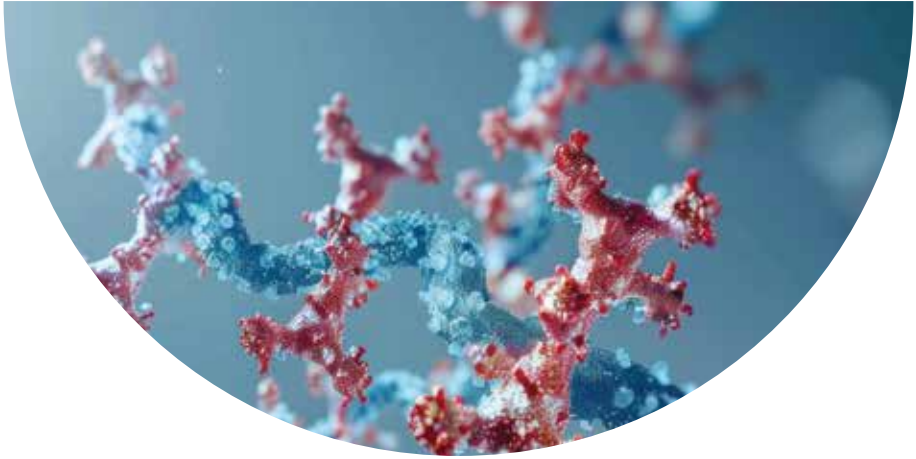
The treatment of anaphylactic-type shock essentially consists of the following:

-Intravenous fluid resuscitation

-Administering oxygen to the patient and, if necessary, intubation and mechanical ventilation.

-Injecting 0.5 ml of a 1/1000 adrenaline solution. SC until a satisfactory hemodynamic condition is obtained.

Antihistamines can be used along with corticosteroids as a complementary treatment whenever required. Serum sickness is treated by corticosteroids and antihistamines.



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Botulism Antitoxin

ZABOTRIX-ABE®

Botulinum Antitoxin, Trivalent
Type A,B,E

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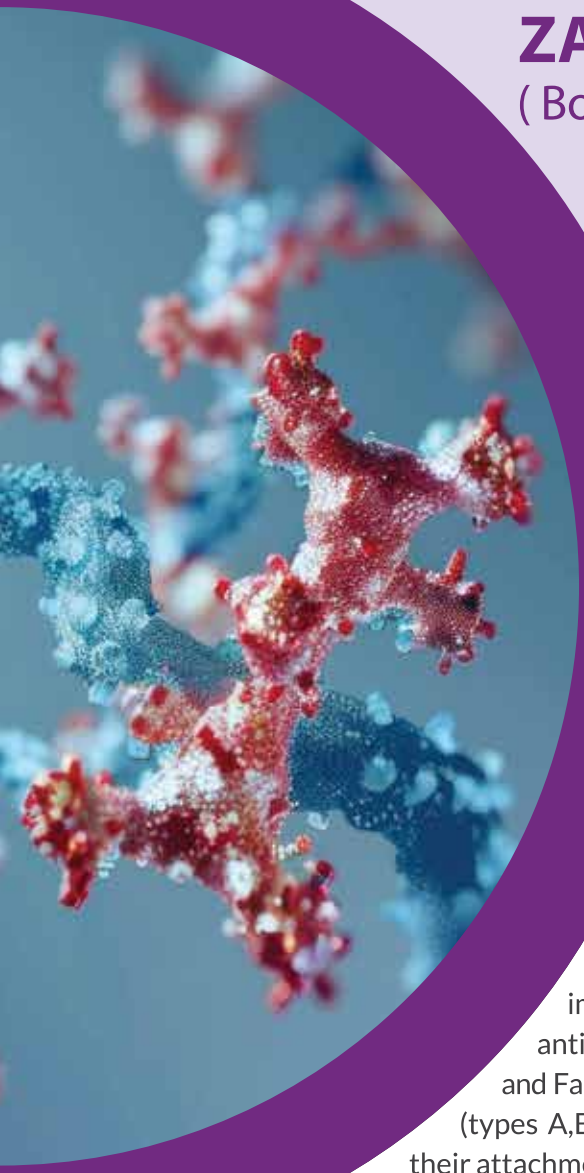

ZABOTRIX-ABE®

(Botulinum Antitoxin)

Botulinum Antitoxin contains antitoxic globulins derived from horse serum immunized against Clostridium botulinum types A, B, and E toxins, which commonly cause human botulism through contaminated food, wounds, or infant colonization. It is available as monovalent, divalent, or trivalent forms for different uses. The antitoxin works by passive immunization; equine polyclonal antibody fragments (mainly $F(ab')_2$ and Fab) bind free botulinum neurotoxins (types A,B,E) in the bloodstream, blocking their attachment and entry into nerve cells, and facilitating clearance of antibody-toxin complexes by the immune system.

Dosage forms

Botulinum Antitoxin is a sterile, clear and colorless solution supplied in 10 ml vials. It is available as Monovalent Type A (5000 IU/vial), Monovalent Type B (500 IU/vial), Monovalent Type E (1000 IU/vial), and Trivalent Type A+B+E (Type A: 5000 IU, Type B: 500 IU, Type E: 1000 IU per vial). Each vial contains highly purified antitoxin serum with immunoglobulin $F(ab)_2$ fragments as the active ingredient, and phenol as a preservative.

Ingredient

Each Vial of Clostridium Botulinum Antitoxin contains:

highly purified antitoxin serum containing immunoglobulin $F(ab)_2$ fragments as active ingredient.

It also contains phenol as preservative.

Uses

Botulinum antitoxins are used in the post-exposure prophylaxis and treatment of botulism. Treatment should be given as early as possible in the course of the disease. If the type of botulinum toxiN is known the related monovalent antitoxin should be used, but in the cases with unknown type of botulinum toxin divalent or trivalent antitoxin shall be administered. Since the type of botulinum toxin is seldom known the trivalent or divalent antitoxin is usually given. In patients that treatment started with multivalent antitoxin, after recognition of toxin type treatment should be continued with related monovalent antitoxin. Individuals who have eaten food suspected of being contaminated and in botulism epidemics should receive prophylaxis.

Administration

The treatment of botulism is with antitoxin and intensive respiratory and supportive therapy. The administration of antitoxins should occur as soon as possible during the treatment process, and they can still be effective even if treatment is delayed. For the treatment of botulism, 0.5 ml/kg of antitoxin should be administered, with half diluted to 100 ml using 0.9% sodium chloride, via slow IV infusion over at least 30 minutes, and the other half given by IM injection. A second dose of antitoxin, equivalent to 2/3 of the initial dose, should be administered 12-24 hours after initial dose, half by IV and half by IM injection. Further doses equivalent to 1/3 of the initial dose at 12-24 hour intervals shall be administered. Persons who have been exposed to the toxin and in whom symptoms have not developed should be given 20 ml IM as a prophylactic measure.

Precautions & Contraindications

Like all medicines, Botulinum Antitoxins may cause side effects, including hypersensitivity reactions such as anaphylaxis and delayed allergic reactions like serum sickness. Infusion reactions can also occur, so patients should be closely monitored during and after administration, with emergency treatments such as adrenaline and resuscitation equipment on hand. Sensitivity testing should be performed before use, especially in patients with a history of allergies, asthma, eczema, drug allergies, or previous injections of animal-derived sera. Botulinum Antitoxins can interfere with some blood sugar tests, so only glucose-specific systems should be used. As the product is made from horse plasma, there is a potential risk of transmitting infectious agents. Use in pregnancy only if clearly needed and if the benefits outweigh the risks; use caution in nursing women.

Benefits of Botulinum Antitoxin

Safe and effective post-exposure therapy: Early administration reduces mortality and decreases the severity of illness in patients exposed to the botulinum toxin.

Quick therapeutic outcomes: Timely administration, especially within 48 hours of symptom onset, leads to improved clinical outcomes—such as reduced risk of death, shortened illness duration, and decreased need for mechanical ventilation.

High quality and regulatory compliance: Manufacturing under cGMP ensures the product is consistently safe, pure, and potent. cGMP compliance meets rigorous U.S. FDA and European standards for biological medical products.