

Botulism Emergency: Botulism Antitoxin Heptavalent (BAT) to Treat Botulism Emergency Use Instructions for Recipients

During a botulism emergency, you will be given a medicine called **Botulism Antitoxin Heptavalent (BAT®)** because you have been exposed to botulism toxin and need treatment for your illness. Botulism causes paralysis and can be deadly. Taking this medicine may reduce the progression of the illness. It is important to be treated as soon as you have symptoms. If you have questions, talk to a doctor or healthcare provider about taking BAT.

What is Botulism?

Botulism is a muscle-paralyzing disease caused by a toxin made by a germ called *Clostridium botulinum*. You can be exposed to botulism toxin through food, a wound, or air (inhaled). Botulism can cause the following symptoms:

- Double vision
- Blurred vision
- Drooping eyelids
- Slurred speech
- Difficulty swallowing
- Dry mouth
- Difficulty breathing
- Muscle weakness that spreads through the body

Botulism can also cause paralysis and death. After a person is exposed to the toxin, problems can happen within as little as 3 hours or as much as a few days. It can take weeks or months to get better. During this time, many people need special care in the hospital.

What is BAT?

BAT is a botulism antitoxin made from the plasma of horses. It contains antibodies that can help to neutralize botulism toxin(s). BAT is an FDA-approved medicine to treat symptoms of botulism after confirmed or suspected exposure to *Clostridium botulinum* in adults and children. BAT contains antitoxins against all seven toxin serotypes A, B, C, D, E, F, or G. Receiving BAT as quickly as possible from the start of illness may help to stop or lessen the progression of the illness. BAT will not reverse paralysis, but it may help to slow down or prevent the spread of paralysis, which can result in shorter hospital stays, less severe disease, and an increased chance of survival.

Who should **NOT** receive BAT?

You should not receive BAT if you have a known history of allergies to horses or horse blood products, asthma or hay fever (seasonal allergies). A severe allergic reaction may include trouble breathing, swelling of your tongue or lips, or a very fast heart rate. Talk to your doctor or public health official about other medicines available.

How is BAT given?

BAT is given as an infusion (injection through your vein). Your doctor will determine your correct dose of BAT. It may take several hours to administer BAT. Your doctor will decide if you need more than one infusion.

What are common side effects of BAT?

The most common side effects of BAT are headache, fever, rash, hives, chills, nausea and swelling. During or immediately after the infusion you may have brief pain, bleeding, bruising of the skin at the site where the needle enters, soreness and swelling at that site, and possible infection at that site. Some people feel anxious or agitated after getting BAT. Tell your doctor if you feel anxious or agitated, especially if these feelings do not go away. Also, some people have a chilly feeling, difficulty breathing, and have a quick rise in body temperature within the first 20 to 60 minutes after getting BAT. This is called a thermal reaction. If these symptoms become severe, talk to your doctor.

What are possible serious side effects of BAT?

Since BAT is made from horse plasma, there is potential for severe allergic reactions. A small number of people are allergic to horse-based products, usually without knowing it. Possible mild side effects from horse products are allergic reactions such as fever, chills and discomfort. Some people may get a really bad allergic reaction, called anaphylaxis. It causes a sudden drop in blood pressure and trouble breathing.

Seek medical care right away (go to the emergency room or call 911) if you experience:

- Closing of the throat, trouble breathing or wheezing
- Swelling of the lips, tongue or face
- Severe itching or rash, especially hives and wheals (red, swollen bumps on the skin)
- Sudden drop in blood pressure
- A weak and rapid pulse
- Dizziness, fainting or unconsciousness

Also, a small number of people (less than 5 in 100) who get horse serum may get pains in their joints and back, fever, and a rash 10–21 days after treatment. This is delayed allergic reaction called serum sickness. These problems can last a couple of weeks. You should report these problems to your doctor. Doctors can treat serum sickness with standard medicines.

What if I am taking other medicines?

BAT may interfere with some types of blood glucose testing systems and strips. This can result in false high glucose test reading. Tell your doctor if you are using these systems so you can be monitored appropriately. Tell your doctor or healthcare provider about any medications you are taking as well.

What else do I need to know about BAT?

It is not known if there are any risks from receiving BAT while pregnant or nursing. However, being pregnant is not a reason to not receive BAT. Tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding.

What are my other choices for treatment?

The only other FDA-approved antitoxin is BabyBIG[®], but it is for treatment of infant botulism caused by toxin type A or B. It is your choice whether or not to be treated with BAT. It will not change your regular medical care if you decide not to receive it. It is possible that paralysis may still progress especially if BAT treatment is not given as soon as signs or symptoms of botulism start. However, getting BAT may help to slow or stop the progression of illness and/or paralysis.

Risk-Benefit Statement

Although BAT has some potential and serious side effects, the expected benefit of BAT in helping to reduce the progression of illness associated with botulism outweighs these risks.

How do I report side effects or medication errors?

Tell your doctor or healthcare provider right away and report side effects or medication errors to MedWatch at www.fda.gov/medwatch or 1-800-FDA-1088.

A federal program called the Countermeasures Injury Compensation Program (CICP) may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by some medicines or vaccines. To learn more about this program: visit www.hrsa.gov/cicp or call 1-855-266-2427 (toll-free).

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