

Information for Patients BioThrax[®] (Anthrax Vaccine Adsorbed)

Please read this Patient Information summary carefully before you get this shot. This summary does not take the place of talking with your healthcare provider about BioThrax. If you have questions or would like more information, please talk with your healthcare provider.

What is BioThrax?

- BioThrax is a vaccine licensed by the FDA to protect against anthrax disease in persons 18 through 65 years of age:
 - It can be used before exposure to anthrax to protect people at high risk of getting the disease.
 - It can be used after exposure to anthrax, along with antibiotics, to protect people from getting the disease.
- BioThrax may not protect all people who get the vaccine.
- How well BioThrax works when given after exposure to anthrax has been studied only in animals. It has not been studied in humans because there are not enough people who get the disease naturally, and it is not ethical to expose people to anthrax on purpose to find out how well BioThrax works.
- The safety of BioThrax was studied in healthy adults.

Who should not get BioThrax?

You should not get BioThrax if you have a history of severe allergic reaction to any ingredient of the vaccine, including aluminum hydroxide, benzethonium chloride, and formaldehyde or had a serious reaction after getting BioThrax previously .

What should I tell my healthcare provider before getting BioThrax?

- If you may be pregnant, plan to get pregnant soon, or are nursing a baby.
- About medicines that you take, including over-the-counter medicines and supplements.
- About immune problems you have, including steroid treatments and cancer treatments.
- About blood clotting problems or if you take “blood thinners.”
- If you are allergic to latex.

What if I discover I was pregnant at the time I got BioThrax?

- Inform your healthcare provider
- You can enroll in the BioThrax (Anthrax) Vaccine in Pregnancy Registry (Phone: 1-619-553-9255), if eligible

How is BioThrax given?

BioThrax is given as a shot in your arm.

After getting the first shot, you should come back for the next shots on the schedule given to you by your health care provider. It is important that you get all your shots to get the best protection.

If you get BioThrax because you may have been exposed to anthrax, it is important that you also take antibiotics for 60 days.

What are the possible or reasonably likely side effects of BioThrax?

The most common side effects of BioThrax are:

- Pain, tenderness, redness, bruising, or problems moving the arm in which you got the shot
- Muscle aches
- Headaches
- Fatigue
- Fainting

Tell your healthcare provider about any side effects that concern you. Your healthcare provider can give you a complete list of side effects available to healthcare professionals.

You may report side effects to **FDA by calling 1-800-822-7967** or to the website www.vaers.hhs.gov. You may also report side effects directly to Emergent BioSolutions at 1-877-246-8472 or at productsafety@ebsi.com.

What are the ingredients in BioThrax?

BioThrax does not contain live bacteria. BioThrax contains non-infectious proteins, aluminum hydroxide, benzothonium chloride and formaldehyde (as preservatives).

The vial stopper contains natural rubber latex.

Manufactured by Emergent BioDefense Operations Lansing LLC
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