## ANTHRAX VACCINE Fact Sheet for Adult Recipients (≥ 18 years of age)

#### Why Are You Being Offered the Anthrax Vaccine during this Anthrax Public Health Emergency?

Anthrax can be deadly. If you breathed in anthrax germs, you have been "exposed" to anthrax. Vaccine and antibiotics will protect you from getting anthrax. The anthrax vaccine is called BioThrax<sup>®</sup> (also known as Anthrax Vaccine Adsorbed or AVA).

- The anthrax vaccine is approved by the U.S. Food and Drug Administration (FDA) to prevent anthrax in adults 18 to 65 years of age as three doses given under the skin over 4 weeks with an oral antibiotic.
- To protect as many people as possible during this emergency, FDA is allowing different dosing under an Emergency Use Authorization. You may get either:
  - 2 full doses over 2 to 4 weeks, or 3 half doses over 4 weeks.
- FDA is also allowing the vaccine to be given either under the skin of your arm (preferred) or into an arm muscle.
- It takes a while for the vaccine to work. This is why everyone who has breathed in anthrax germs must also take antibiotics. Antibiotics work fast to keep you from getting sick.
  - Healthy adults less than 65 years of age only need to take antibiotics for 42 days after the first dose of the anthrax vaccine or 2 weeks after the last dose of the anthrax vaccine, whichever happens later.
  - Adults over 65 years of age, pregnant women, nursing mothers and people with weak immune systems need to take antibiotics for 60 days.
- Take the antibiotics as instructed. Get all of the vaccine doses to protect you from the germs that may stay in your body after you finish taking antibiotics.
- Getting the anthrax vaccine is your choice.

## What You Need to Know BEFORE You Get the Vaccine

#### What is anthrax?

Anthrax is a serious disease. You can get sick if you breathe in anthrax germs. You cannot get anthrax from another person who has anthrax.

- Early on, you could have any of the following symptoms: fever, chills, tiredness, cough, or headache.
- Later, you could have shortness of breath, chest pain, confusion, or nausea. Symptoms usually start within 7 days of breathing in anthrax germs. But, symptoms can start as soon as 24 hours or take up to 7 weeks. If you begin to feel sick or show any of these symptoms, get medical care right away.

#### Why do I need the anthrax vaccine and antibiotics?

You are being offered the vaccine to protect you because you breathed in anthrax germs. The vaccine will protect you from the germs that may stay in your body after you finish taking antibiotics.

#### Is the anthrax vaccine FDA approved?

The anthrax vaccine (also called BioThrax® or AVA) is FDA approved for adults 18 to 65 years of age for protection before or after exposure (breathe in) to anthrax germs. During this emergency, FDA has authorized certain uses of this vaccine such as different dosing (reduced doses/schedules), into an arm muscle and for all adults. This is to protect as many people as possible.

#### How will you get the anthrax vaccine?

Usually, three (3) full doses of the anthrax vaccine are given as a shot under the skin over 4 weeks along with an oral antibiotic. During this emergency, there is not enough anthrax vaccine to give 3 full doses to everyone who

needs it. Therefore, reduced vaccine doses or schedules are offered. You will get either 2 full doses over 2 to 4 weeks or 3 half doses over 4 weeks either under the skin or into the muscle of your arm. A shot under the skin may help build an immune response sooner.

Your health department will also give you antibiotics and information about how to take them. Healthy adults 18 to 65 years of age can stop taking antibiotics 42 days after the first dose of the anthrax vaccine or 2 weeks after the last dose, whichever happens later. Older adults, pregnant women, and people with certain conditions should take antibiotics for 60 days.

It is important that you get all of the shots of the vaccine and keep taking the antibiotics for as long as you have been told to take them. This is because your body needs time to build an immune response to the anthrax vaccine.

#### Who should get the anthrax vaccine?

Adults (18 years of age and older), including pregnant women and nursing mothers, should get the anthrax vaccine during this emergency. This allows public health officials to protect more people with the vaccine.

Use of AVA in children less than 18 years of age is managed by the Centers for Disease Control and Prevention (CDC). It requires informed consent from a parent or legal guardian.

#### Who should not get the anthrax vaccine?

 Those who have a severe allergy to any ingredient of the anthrax vaccine.

- Those who had a severe allergic reaction to a previous dose of the anthrax vaccine. Allergic reactions can include breathing problems or swelling of the face, lips, and tongue.
- Those who have received the complete pre-exposure AVA vaccination series (5 doses) and their annual booster doses do not have to restart the vaccination series BUT should take the recommended antibiotics.

# What should you mention before you get the anthrax vaccine?

Tell the person giving you the shot if you have:

- · ever had a latex allergy.
- ever had a bad reaction to any vaccine.
- ever had a health condition known as Guillain-Barré syndrome (GBS).
- a health problem that affects your immune system or are taking medicines that can weaken your immune system such as chemotherapy, corticosteroids, or radiation therapy.
- blood clotting problems or are currently taking "blood thinners." Be sure to mention this before you get the shot because there are ways to reduce bruising on your arm where you get the shot.
- ever received the anthrax vaccine before.

# Has the anthrax vaccine been used safely before? Yes. BioThrax® (AVA) is an FDA-approved anthrax vaccine that has been safely given to millions of adults for more than 40 years. These include U.S. military personnel and workers at risk for anthrax.

Although the anthrax vaccine has not yet been given to children, breastfeeding mothers, or the elderly, the CDC believes that the vaccine is safe to give to these groups during this emergency. Pregnant women have received the anthrax vaccine in the past with no known serious health problems for them or their babies.

#### What are the benefits of the anthrax vaccine?

Anyone who has breathed in (exposed) anthrax germs needs to take the antibiotics provided by public health officials. If you have been exposed, some germs may remain inside your body even **after** you've taken all your antibiotics. Therefore, the vaccine can help protect you against remaining germs **after** you finish your antibiotics. Reduced dosing or schedules of anthrax vaccine given during this emergency have shown to protect against anthrax germs. However, the information is limited.

#### What are the risks of the anthrax vaccine?

Like any vaccine, the anthrax vaccine can cause some side effects. Mild side effects should go away within a few days. Anthrax is much worse than any side effects you might experience from the vaccine. Mild side effects can include:

- At the injection site: tenderness, redness, itching, a lump, or bruise.
  - About 1 in 10 people have these side effects.
- Temporary problems moving the arm.
  - About 1 in 10 people have this side effect.
- Muscle aches, headache or tiredness.
  - About 1 in 20 people have these side effects.

As with any vaccine, there is a small risk for severe allergic reaction known as anaphylaxis or anaphylactic shock. These reactions are very rare. For every 100,000 shots of vaccine that are given, less than 1 case of anaphylaxis happens. See below for possible serious side effects.

#### Will the anthrax vaccine give me anthrax?

No. The anthrax vaccine does **not** have any anthrax germs in it and **cannot** give you anthrax.

What if I decide NOT to get the anthrax vaccine? Anthrax is a serious disease that can be deadly. The anthrax vaccine is recommended for you in addition to antibiotics. If you choose not to get the vaccine, it is possible that you may develop anthrax from germs that are still in your body after you finish your antibiotics.

# Are other choices available for preventing anthrax besides the anthrax vaccine?

Yes, antibiotics alone (without anthrax vaccine) can help to prevent anthrax as soon as you start taking them and while you continue to take them.

The vaccine can help protect you against anthrax germs that may remain in your body **after** you finish the antibiotics. It is important that you finish all of your antibiotics whether you choose to get the anthrax vaccine or not. Any adults who choose not to get the vaccine or do not get all of the vaccine doses must take 60 days of antibiotics.

### What you need to know AFTER you get your first shot

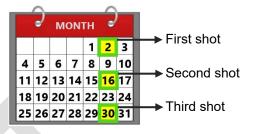
- You need all of the shots to be protected.
  - Once you have received your first shot, it is **very important** that you return to get:

• If you have been told to get 2 full doses:

• The second shot 2 weeks after the first shot but no more than 4 weeks after the first shot.



- If you have been told to get 3 half doses:
  Once you have received your first shot, it's very important that you return to get:
  - The second shot 2 weeks after the first shot
  - The third shot 4 weeks after the first shot



#### AND

• Take your antibiotics for **60 days** unless a healthcare provider tells you otherwise. If you are a healthy adult between 18 to 65 years of age, you may be told you can stop taking antibiotics 42 days after the first dose of the anthrax vaccine or 2 weeks after the last dose of the anthrax vaccine, whichever happens later. When you receive your antibiotic, you will receive a Fact Sheet about how to take them.

#### Keep your vaccination card.

When you get your first shot, you will get a vaccination card to show you when to come back. Remember to bring your card when you return.

#### Serious side effects are rare, but know the signs and know what to do.

A severe allergic reaction is very rare. It would usually occur within a few minutes to 1 hour after getting a shot of the anthrax vaccine. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

#### What should I do about side effects?

- If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.
- Tell a healthcare provider right away that you have just received the anthrax vaccine.
- Report vaccine side effects to the Vaccine Adverse Event Reporting System: 1-800-822-7967 or www.vaers.hhs.gov.
- Report antibiotic side effects to MedWatch: 1-800-FDA-1088 or <a href="www.fda.gov/medwatch">www.fda.gov/medwatch</a>.
  Also be aware of the Countermeasures Injury Compensation Program. This is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines. To learn more about this program, visit <a href="www.hrsa.gov/cicp/">www.hrsa.gov/cicp/</a> or call 1-888-266-2427.

#### How can I learn more?

Contact your doctor or local health department.

- Contact your doctor or local health department.
- Visit cdc.gov/anthrax or call CDC at 1-800-232-4636 (1-800-CDC-INFO).

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