What about long-term side effects?

This vaccine has been used for over 40 years. Multi-year studies by independent civilian groups have found no patterns of long-term health problems due to anthrax vaccination. A vaccine, like any prescription medicine, could possibly cause significant problems but the risk of the anthrax vaccine causing serious harm or death is very small.

What if I have a health problem or adverse event after receiving a vaccination?

For severe allergic reactions persons should seek immediate medical care. For all other reactions seek care at the earliest convenience for follow-up with a medical provider.

Tell the doctor what happened, the date and time it occurred, and when the vaccination was given. Any provider or person who would like additional medical advice or consultation may contact the DoD Vaccine Clinical Call Center at 866.210.6469. All providers must report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form as noted below.

All National Guard and Reserve personnel may seek care from a civilian hospital or clinic, when unable to reach a military hospital, for treatment of an adverse event after a military-directed vaccination. Evaluation or treatment will not be denied or delayed, pending a line-of-duty (LOD) determination. However, when seeking care from a civilian provider, remember to notify your commander for the proper LOD paperwork or Notice of Eligibility determination. All Military directed vaccinations are within the LOD; therefore, you should not encounter any issues.

For assistance concerning issues with civilian health services outside a military Medical Treatment Facility call: 888.647.6676 (DSN 792.3950)

When should a VAERS report be filed?

A VAERS should be reported when a significant adverse event occurs after vaccination. An adverse event that requires medical treatment or interferes with work or recreation should be reported. Anyone may submit a report to the VAERS system. DoD requires VAERS reporting for an adverse event that results in hospitalization or loss of work/duty for 24 hours or more. A report should also be filed if contamination of a vaccine vial is suspected. Healthcare providers are encouraged to report adverse events that the provider considers unexpected in nature. Forms are available at www.vaers.hhs.gov or 800.822.7967.

More information from
Military Vaccine Agency-Vaccine Healthcare Centers Network (MILVAX-VHCN)

- **For routine 24/7 clinical consultation or exemption assistance:**
  Phone: 1.866.210.6469
  E-Mail: https://askvhc.amedd.army.mil/Questions/NewQuestionUnRegistered.aspx.
- **For information about the vaccines or policies:**
  Phone: 877.GET.VACC (877.438.8222) DSN 761.4245
  E-Mail: DoDvaccines@mail.mil
  Website: www.vaccines.mil
- **Civilian Healthcare Providers:**
  If military member presents to you for a condition that may be an adverse event caused by a military vaccination, please provide the appropriate care. For authorization and payment contact:
  The Military Treatment Facility (MTF) where the member is enrolled, OR contact the **Military Medical Support Office (MMSO)** 888.647.6676 if not enrolled in an MTF.

MILVAX VHC Vaccine Healthcare Centers Network

http://www.vaccines.mil

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TA-223-0414

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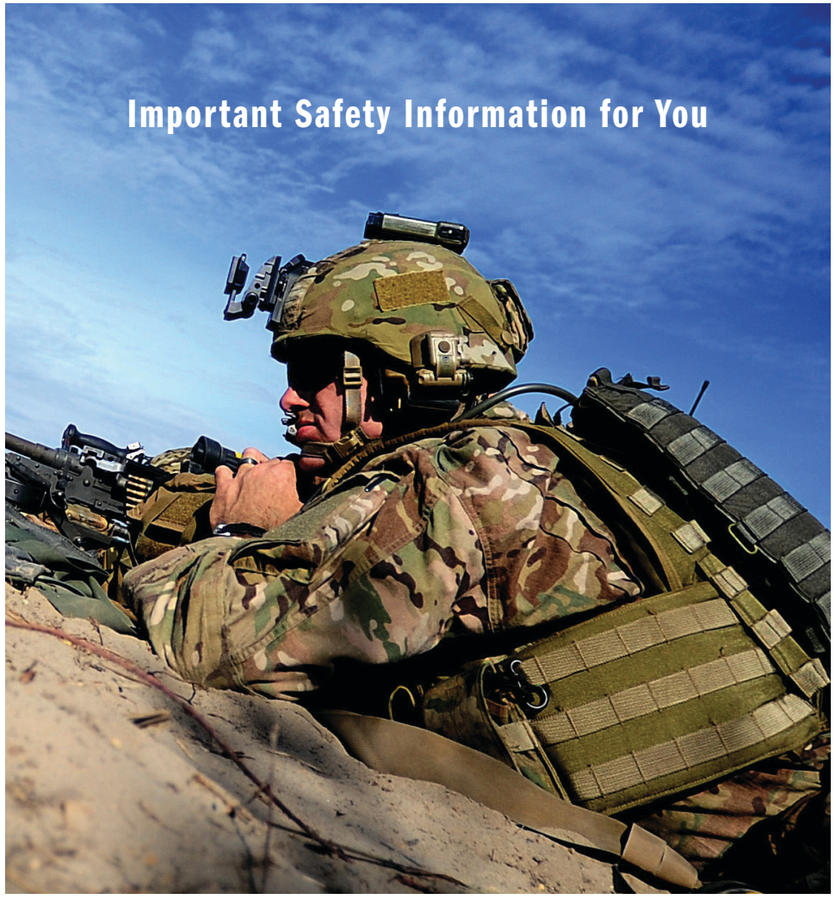
Important Safety Information for You



What You Need to Know About Anthrax Vaccine

What is Anthrax?

Anthrax is a serious disease caused by a bacterium called *Bacillus anthracis*. The small, one celled organism survives as a spore and may remain inactive for many years until it infects a human or animal. Anthrax is naturally found in soil around the world. Hoofed animals (e.g., cattle, sheep, goats, camels, antelopes) ingest the soil as they graze and are thereby infected with the spores (or disease). Humans can be infected when exposed to anthrax infected animal tissue, such as bones or hides, or when spores are used as a bioterrorist weapon.

Anthrax cannot be spread from one person to another. Humans must come in contact with the actual spore to be infected. The bacteria can enter the body in three different ways:

1. **Inhalation.** This exposure is caused when the spores are inhaled into the lungs. It is the deadliest form of anthrax. Symptoms include sore throat, mild fever, muscle aches, followed several days later by breathing problems, shock, meningitis, and death.
2. **Cutaneous.** The most common exposure is through a small break in the skin. It can cause skin ulcers, fever, and fatigue.
3. **Gastrointestinal.** This exposure is caused by eating raw or undercooked infected meat. Symptoms include fever, fatigue, nausea, vomiting, sore throat, abdominal pain and swelling. It may also lead to blood poisoning, shock, and death.
4. **Injection.** This exposure was recently added as another type of anthrax infection that has been identified in heroin injecting drug users in northern Europe. This type of infection has never been reported in the U.S. Symptoms may be similar to those of cutaneous anthrax, but there may be infection deep under the skin or in the muscle where the drug was injected. Injection anthrax can spread throughout the body faster and can be harder to recognize and treat.

Why is the Department of Defense vaccinating personnel?

Anthrax can and has been used as a biological weapon. Weaponized anthrax spores are known to be odorless, colorless, tasteless, and very difficult to detect. Currently the only measure available to protect personnel is pre-exposure vaccinations. Inhalation anthrax, the expected route of weaponized exposure, requires hospitalization and aggressive treatment but is often fatal. Since the DoD anthrax vaccination program began in 1998 over 2.8 million people have been vaccinated with over 11.5 million doses.

What is the anthrax vaccine?

BioThrax (Anthrax) vaccine was licensed in 1970 and is approved for use in individuals 18 to 65 years of age. The vaccine does not contain live anthrax cells and it cannot cause an anthrax infection.

The vaccine is administered as a 5-dose series over 18 months. A dose is injected into the deltoid at day 0, 4 weeks, 6 months, 12 months and 18 months followed by annual boosters. Each dose builds on the immune response from earlier doses; like climbing steps on a ladder towards full protection. The complete 5-dose series, with boosters, is needed for maximum protection. Vaccinations should never be administered earlier than the recommended due date. The series should never be restarted; if a dose was delayed just continue vaccinations as scheduled.

5-Dose Series

Dose 1	Dose 2	Dose 3	Dose 4	Dose 5
0 month	1 month	6 month	12 month	18 month

Annual boosters are recommended to sustain ongoing protection.

Who is required to receive the vaccine?

Anthrax vaccination is mandatory for uniformed personnel, emergency essential or comparable U.S. government civilian employees, and contractors traveling or assigned (or deploying within 120 days) to the U.S. CENTCOM area of responsibility (AOR) and the Korean Peninsula for 15 or more consecutive days. Anthrax vaccination is also mandatory for all special units assigned to previously approved exceptions to policy (ETP), to include members of the USPACOM Forward Deployed Naval Forces and NORTHCOM Chemical, Biological, Radiological and Nuclear (CBRN) Response Teams. Vaccination is voluntary for uniformed and civilian personnel no longer deployed to the U.S. CENTCOM AOR or Korean Peninsula who have received at least one dose previously.

Personnel and Family members traveling to the AORs noted above, who do not meet the mandatory requirement, may receive the vaccine on a voluntary basis.

Uniformed and Civilian personnel who are no longer in the AOR for mandatory vaccinations may voluntarily continue vaccinations and boosters.

Who should NOT receive the vaccine?

Anyone who:

- Had a serious allergic reaction to a prior dose of anthrax vaccine
- Had a severe allergic reaction to a vaccine component (i.e., latex)
- Is diagnosed with HIV or is immunosuppressed due to a disease or medication
- Has ever been diagnosed with Guillain-Barré Syndrome (GBS)
- Is currently pregnant

If you are unsure whether you are pregnant or not, request a pregnancy test before receiving a vaccination. The anthrax vaccine should be deferred during pregnancy unless clearly needed. Breastfeeding is not a contraindication to receiving the anthrax vaccination.

Temporary exemptions should be provided for individuals with moderate or severe illness. Medical exemptions must be evaluated and documented by a medical provider. If assistance is needed for a medical exemption, the Vaccine Healthcare Centers (VHC) Network is available for consultation at 866.210.6469.

What if the vaccine is administered to a pregnant woman?

There is little information on the safety of pregnant women and nursing mothers who have received the vaccine. However, limited studies of women who received the vaccine during pregnancy have not shown any harmful effects of pregnancy outcomes or clearly defined any possible risks to the mother or fetus. If a Service member received the vaccine while pregnant or within 4 weeks of conception, they are eligible to join the BioThrax (Anthrax) Vaccine in Pregnancy Registry. For questions about the registry, email nhrc-VaccineRegistry@med.navy.mil or call 619.553.9255 (DSN 553.9255)

What side effects may occur after vaccination?

The anthrax vaccine may cause local reactions such as tenderness, itching, redness, bruising or a small lump or burning at the injection site. These reactions usually resolve on their own after a few days.

Other side effects may include muscle or joint aches, headaches, fatigue, and fever. These symptoms are less common and usually go away in less than a week. If any symptoms persist please contact your primary care provider.

With any vaccination, serious reactions may occur. Signs of a serious allergic reaction include difficulty breathing, weakness, unconsciousness, hoarseness or wheezing, a fast heartbeat, hives, dizziness, paleness, or swelling of the throat. Seek immediate medical care for any symptoms of a serious allergic reaction.