

ANTHRAX VACCINE ADSORBED

Anthrax Vaccine Adsorbed

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Introduction

Anthrax vaccine adsorbed (BioThrax[®]) and anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) are used to stimulate active immunity to *Bacillus anthracis*.^{1,100}

Uses

■ Prevention of Anthrax

Anthrax vaccine adsorbed (BioThrax[®]) and anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) are used in combination with recommended antibacterial agents for postexposure prophylaxis following suspected or confirmed *Bacillus anthracis* exposure in adults 18–65 years of age.^{1,100} The efficacy of both vaccines for postexposure prophylaxis is based solely on studies in animal models of inhalational anthrax.^{1,100}

Anthrax vaccine adsorbed (BioThrax[®]) is also used for pre-exposure prophylaxis against anthrax in adults 18–65 years of age who are at high risk of exposure.¹

Anthrax is a severe infectious disease caused by the spore-forming bacterium *B. anthracis*.¹⁰¹ The spores of *B. anthracis* are highly resilient and can be readily disseminated through the air.¹⁰¹ In certain regions, *B. anthracis* is endemic in soil, where spores may infect grazing livestock (e.g., cattle, sheep, and goats) following ingestion.¹⁰¹ Human infection occurs when spores enter the body, most commonly through cutaneous exposure or inhalation.¹⁰¹ Although uncommon, naturally acquired human cases may arise from contact with infected animals or contaminated animal-derived products.¹⁰¹ In the U.S., anthrax in humans is rare; however, it is regarded as a potential agent for bioterrorism.¹⁰¹

Cutaneous anthrax represents the most frequent form of infection in humans and typically occurs when spores enter through breaks in the skin during handling of infected animals or contaminated products such as wool, hides, or hair.¹⁰¹ Gastrointestinal anthrax, though rarely reported in the U.S., may result from ingestion of raw or undercooked meat from infected animals, affecting the oropharynx, esophagus, stomach, or intestinal tract.¹⁰¹ Inhalation anthrax develops following the inhalation of aerosolized spores, often in occupational settings involving exposure to contaminated animal products (e.g., wool processing facilities or slaughterhouses).¹⁰¹ Mortality rates for untreated disease vary depending on the exposure route (approximately 20% for cutaneous anthrax, over 50% for GI anthrax, and nearly 100% for inhalational anthrax).¹⁰¹ All types of anthrax can be treated with appropriate anti-infective therapy.¹⁰¹

Anthrax vaccines have been procured by the U.S. federal government and are maintained within the Strategic National Stockpile (SNS) for use in postexposure prophylaxis in conjunction with anti-infective agents in the event of a bioterrorism incident.¹⁰¹ Additionally, due to the risk of biological warfare, the U.S. military implements an active vaccination program for personnel deployed to high-risk regions.¹⁰¹

Clinical Experience

Preexposure Prophylaxis

A pivotal controlled field study conducted between 1955 and 1959 in mill workers in the northeastern US demonstrated that vaccination with an earlier version of a protective antigen-based anthrax vaccine substantially reduced the incidence of disease, with a calculated efficacy of 92.5% against both cutaneous and inhalational anthrax.¹ The vaccine was administered subcutaneously at weeks 0, 2, and 4 and months 6, 12, and 18.¹ During the study, most anthrax cases occurred in unvaccinated or incompletely vaccinated individuals, with few cases observed among vaccine recipients (generally prior to completion of the full vaccination series).¹

Additional supportive surveillance data on the occurrence of anthrax in mill workers or those living near mills in the US were collected by the Centers for Disease Control and Prevention (CDC) between 1962 and 1974.¹ During this time period, individuals received either anthrax vaccine adsorbed (BioThrax[®]) or the earlier antigen-based anthrax vaccine used in the field trial described above.¹ Data showed that nearly all reported anthrax cases occurred in unvaccinated individuals, whereas no cases were observed in persons who had completed at least 3 doses of the originally licensed 6-dose series.¹

More recent evidence is derived from a prospective, randomized, double-blind, placebo- and active-controlled clinical trial conducted between 2002 and 2007 in 1,564 healthy adults.¹ This study evaluated alternative vaccination schedules and routes of administration using predefined immunogenicity endpoints, including geometric mean concentrations (mcg/mL), geometric mean titers of anti-protective antigen immunoglobulin G (IgG) antibodies, and the proportion of subjects achieving a ≥ 4 -fold rise in antibody titers from baseline.¹ The trial demonstrated that a 3-dose IM primary series (0, 1, and 6 months) was noninferior to the originally licensed 6-dose subcutaneous regimen with respect to all primary immunogenicity endpoints at designated time points (e.g., month 7 versus month 13 and 19 comparisons).¹ Similarly, a 4-dose subcutaneous primary series administered at 0, 2, and 4 weeks and 6 months demonstrated antibody responses consistent with protective immunity; this regimen is followed by booster doses at 12 and 18 months after initiation of the series and annually thereafter to maintain protective immunity.¹ Additional analyses showed that antibody levels decline in the absence of scheduled booster doses; however, administration of delayed boosters (e.g., at 42 months) resulted in an immune response that met noninferiority criteria relative to the standard regimen, although the optimal schedule for further IM booster doses among individuals administered a single booster dose at 42 months following completion of the original primary series is not known.¹

A 2009 Cochrane review identified no randomized controlled trials that assessed the ability of inactivated anthrax vaccines to protect against clinical disease.¹⁰² Four included trials reported on the safety and immunogenicity (measured using anti-protective antigen IgG antibodies) of inactivated vaccines, of which 3 were relatively small trials.¹⁰²

Postexposure Prophylaxis

Based on the toxin neutralization assay (TNA) threshold derived from a rabbit model, a pivotal, phase 3 clinical study was conducted to evaluate the immunogenicity and safety of a postexposure anthrax vaccine adsorbed (BioThrax[®]) regimen in healthy adults 18–65 years of age.^{1,103} The study assessed a 3-dose schedule administered subcutaneously at 0, 2, and 4 weeks.^{1,103} A total of 200 participants were enrolled and monitored for 128 days.^{1,103} The study evaluated immunogenicity following completion of the 3-dose vaccination series using TNA measurements.^{1,103} The primary immunogenicity endpoint was the proportion of participants achieving a TNA neutralization factor (NF₅₀) value of ≥ 0.56 on day 63, corresponding to 5 weeks after administration of the third vaccine dose.^{1,103} The predefined success criterion was met if the lower bound of the two-sided 95% confidence interval (CI) for the proportion of participants attaining the target TNA NF₅₀ threshold was $\geq 40\%$.^{1,103} Results demonstrated that 71.2% of participants achieved a TNA NF₅₀ value of ≥ 0.56 by day 63, with the lower bound of the 95% CI being 64.1%.^{1,103}

In a separate analysis of the pivotal clinical study using the threshold associated with a 70% probability of survival in nonhuman primates (NHP), 93.5% of subjects achieved an NF₅₀ value ≥ 0.29 on day 63, with the lower bound of the corresponding 95% CI being 88.9%.¹ The bridging of human immunogenicity data to the nonhuman primate study supported the primary analysis comparing human threshold data with rabbit survival.¹

The efficacy of anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) was established based on evidence from animal studies involving both anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) and anthrax vaccine adsorbed (BioThrax[®]).¹⁰⁰ Using TNA thresholds derived from anthrax vaccine adsorbed (BioThrax[®]) animal models, a pivotal multicenter, randomized, active-controlled, double-blind, parallel-group clinical trial evaluated the immunogenicity and safety of a postexposure anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) regimen in adults 18–65 years of age.^{100,104}

In this study, 3151 participants received ≥ 1 dose of anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]), while 533 participants received ≥ 1 dose of anthrax vaccine adsorbed (BioThrax[®]).^{100,104} Anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) was administered as a 2-dose series given IM at weeks 0 and 2, whereas anthrax vaccine adsorbed (BioThrax[®]) was administered as a 3-dose subcutaneous series at weeks 0, 2, and 4.^{100,104} Participants were followed for immunogenicity through day 64, corresponding to 7 and 5 weeks after the final dose of anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) and anthrax vaccine adsorbed (BioThrax[®]), respectively.^{1,104}

Two co-primary immunogenicity endpoints were assessed.^{100,104} The first primary endpoint was the proportion of subjects receiving anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) who achieved a TNA 50% neutralization factor (NF₅₀) threshold of ≥ 0.56 at day 64, with success defined as a lower bound of the 95% CI of $\geq 40\%$.^{100,104} The second primary endpoint was the difference in the proportion of participants achieving a TNA NF₅₀ threshold of ≥ 0.29 at day 64 between those who received the Cyfendus[®] vaccine and those who received the BioThrax[®] vaccine, with noninferiority established if the lower bound of the 2-sided 95% CI for the difference exceeded -15%.^{100,104}

The TNA NF_{50} thresholds of 0.56 and 0.29 were derived from rabbit and nonhuman primate models, respectively, that were associated with a 70% probability of survival in pre-exposure prophylaxis studies.¹⁰⁰ In these studies, animals were immunized with 2 doses of the anthrax vaccine adsorbed vaccine (BioThrax[®]) given 4 weeks apart and subsequently challenged with aerosolized *B. anthracis* spores.^{100,104}

Immunogenicity results demonstrated that 66.3% of participants in the anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) group achieved a TNA NF_{50} value of ≥ 0.56 by day 64.¹⁰⁰ The lower bound of the corresponding 95% CI was 64.4%, exceeding the predefined success criterion of $\geq 40\%$.^{100,104} Additionally, 86.6% of anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) recipients achieved a TNA NF_{50} value of ≥ 0.29 at day 64, compared with 61.4% of anthrax vaccine adsorbed (BioThrax[®]) recipients, corresponding to a difference of 25.2%.¹⁰⁰ The lower bound of the associated 2-sided 95% CI was 20.5%, demonstrating noninferiority of anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) relative to anthrax vaccine adsorbed (BioThrax[®]).^{100,104}

Clinical Perspective

The U.S. Public Health Service Advisory Committee on Immunization Practices (ACIP) published guidelines on the use of anthrax vaccine in the U.S. in 2019.¹⁰⁵ ACIP recommends the use of anthrax vaccine adsorbed (BioThrax[®]) for both preexposure and postexposure prophylaxis in adults 18–65 years of age.¹⁰⁵

Preexposure prophylaxis is recommended for individuals at high risk of exposure, including military personnel deployed to high-risk areas designated by the Department of Defense, laboratory personnel handling high concentrations of *B. anthracis*, and persons such as farmers, veterinarians, and livestock handlers who may come into contact with infected animals or contaminated animal products.¹⁰⁵ The primary vaccination series for preexposure prophylaxis consists of three 0.5 mL IM doses administered at 0, 1, and 6 months, followed by booster doses at 6 and 12 months after completion of the primary series, and annually thereafter.¹⁰⁵ For individuals no longer at continuous high risk but who wish to maintain protection, booster doses may be administered every 3 years.¹⁰⁵ If the vaccination schedule is interrupted, the series does not need to be restarted.¹⁰⁵

For postexposure prophylaxis following suspected or confirmed inhalational exposure to *B. anthracis* spores, ACIP recommends administration of anthrax vaccine adsorbed (BioThrax[®]) in combination with systemic anti-infective therapy.¹⁰⁵ The vaccine should be administered as three 0.5-mL subcutaneous doses at 0, 2, and 4 weeks, unless emergency circumstances warrant IM administration or the use of dose-sparing regimens.¹⁰⁵ If the vaccine schedule is interrupted, the series does not need to be restarted; instead, subsequent doses should be administered as soon as possible, and the series should be finished.¹⁰⁵ Anti-infective therapy should be continued concurrently (typically up to 42–60 days depending on host factors and vaccine completion); consult the ACIP guidelines for specific recommendations on duration of anti-infective therapy for specific populations.¹⁰⁵ Anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) was investigational at the time of publication of the ACIP guidelines; therefore, specific recommendations are not made regarding this vaccine.¹⁰⁵

The 2023 CDC guidelines for the prevention and treatment of anthrax reaffirm the ACIP guidelines for anthrax vaccine use and do not introduce any new vaccine-specific guidance.¹⁰⁶ The guidelines discuss anthrax vaccination primarily in the context of postexposure prophylaxis, emphasizing that anthrax vaccination should be administered in conjunction with appropriate anti-infective therapy following both natural and intentional exposures (e.g., bioterrorism events, wide-area aerosol releases).¹⁰⁶ CDC acknowledges the availability of the newer anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]), which is indicated for postexposure prophylaxis in adults 18–65 years of age in conjunction with antibacterial therapy.¹⁰⁶ Anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) was designed to provide a more rapid immune response, using a 2-dose series 2 weeks apart, compared with the 3-dose anthrax vaccine adsorbed (BioThrax[®]) regimen.¹⁰⁶

Dosage and Administration

■ General

Dispensing and Administration Precautions

- Appropriate medical treatment and supervision should be available to treat potential allergic reactions.^{1,100}

Other General Considerations

- For post-exposure prophylaxis, administer in conjunction with appropriate anti-infective therapy.^{1,100,105,106}

■ Administration

Anthrax vaccine adsorbed (BioThrax[®]) is administered by IM or subcutaneous injection.¹

Anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) is administered by IM injection.^{1,100}

The vaccines should not be administered IV or intradermally.^{1,100}

Anthrax vaccine adsorbed (BioThrax[®])

Anthrax vaccine adsorbed should be inspected visually for particulate matter and discoloration prior to administration.¹ Before withdrawing a dose of anthrax vaccine adsorbed, the vial should be shaken well to obtain a homogenous, milky-white suspension; the vaccine should be discarded if it appears otherwise.¹ The vaccine is administered as supplied; no dilution or reconstitution is necessary, and the vaccine should not be admixed with other drugs or vaccines.¹ To prevent transmission of blood-borne infectious agents from one vaccinee to another, a different sterile syringe and needle must be used for each individual who is receiving anthrax vaccine adsorbed.¹ If another vaccine is administered concomitantly with anthrax vaccine adsorbed, each should be given with a different syringe and at a different injection site.¹

Anthrax vaccine adsorbed should be refrigerated at 2–8°C and should not be frozen; if freezing occurs, the vaccine should be discarded.¹ Once the stopper of the multiple-dose vial has been punctured, the vial should be discarded after 28 days.¹ Between uses, the vial should be stored as recommended and should be discarded after the expiration date on the package.¹

Anthrax vaccine adsorbed, adjuvanted (Cyfendus®)

Anthrax vaccine adsorbed, adjuvanted should be inspected visually for particulate matter and discoloration prior to administration.¹⁰⁰ Before withdrawing a dose of anthrax vaccine adsorbed, adjuvanted, the vial should be gently swirled or rolled to obtain a homogenous, milky-white suspension; the vaccine should be discarded if it appears otherwise.¹⁰⁰ The vaccine should not be shaken to avoid foaming.¹⁰⁰ The vaccine is administered as supplied; no dilution or reconstitution is necessary, and the vaccine should not be admixed with other drugs or vaccines.¹⁰⁰ To prevent transmission of blood-borne infectious agents from one vaccinee to another, a different sterile syringe and needle must be used for each individual who is receiving anthrax vaccine adsorbed, adjuvanted.¹⁰⁰

Anthrax vaccine adsorbed, adjuvanted should be refrigerated at 2–8°C and should not be frozen; if freezing occurs, the vaccine should be discarded.¹⁰⁰ The vials should be protected from light; to avoid foaming, do not shake the vials.¹⁰⁰ Once the stopper of the multiple-dose vial has been punctured, the vial should be discarded after 28 days.¹⁰⁰ Between uses, the vial should be stored as recommended and should be discarded after the expiration date on the package.¹⁰⁰

■ Dosage

Adults

Prevention of Anthrax

For preexposure prophylaxis in adults 18–65 years of age, each dose of anthrax vaccine adsorbed (BioThrax®) is 0.5 mL.¹ The manufacturer of anthrax vaccine adsorbed (BioThrax®) and the US Public Health Service Advisory Committee on Immunization Practices (ACIP) state that vaccine doses should be administered by IM injection at 0, 1, and 6 months, followed by IM booster doses 6 and 12 months after completion of the primary series, and at 12-month intervals thereafter.^{1,105} Alternatively, in patients at risk of hematoma following IM injections, a subcutaneous series can be given as follows: primary doses at 0, 2, 4 weeks, and 6 months with booster doses at 6 and 12 months after completion of the primary series and at 12-month intervals thereafter.¹ In patients who are not considered at high-risk for B. anthracis exposure, ACIP states that a booster dose may be given every 3 years instead of annually.¹⁰⁵ If the vaccines series is interrupted, the series does not need to be restarted.¹⁰⁵

For postexposure prophylaxis in adults 18–65 years of age, each dose of anthrax vaccine adsorbed (BioThrax®) is 0.5 mL.¹ The manufacturer states that a primary series should be given by subcutaneous injection at 0, 2, and 4 weeks postexposure in conjunction with antimicrobial therapy to prevent infection.^{1,105} In immunocompetent adults 18–65 years of age, ACIP and the Centers for Disease Control and Prevention (CDC) recommend administering antimicrobial therapy for a 42-day duration if started concurrently with the first dose of anthrax vaccine adsorbed (BioThrax®), or continuing antimicrobial therapy for 2 weeks after the last vaccine dose, whichever is later (not to exceed 60 days).^{105,106} In adults with immunocompromising conditions (e.g., cancer or HIV infection), adults receiving high-dose corticosteroids for >2 weeks, and adults undergoing radiation therapy, antimicrobial therapy should be continued for 60 days.^{105,106} Adults >65 years of age and pregnant or nursing mothers should also receive antimicrobial therapy for a duration of 60 days.^{105,106}

For postexposure prophylaxis in adults 18–65 years of age, each dose of anthrax vaccine adsorbed, adjuvanted (Cyfendus®) is 0.5 mL.¹⁰⁰ A 2-dose series should be given 2 weeks apart by IM injection, at 0 and 2 weeks postexposure in conjunction with a course of antimicrobial therapy to prevent infection.^{100,105,106}

Special Populations

Hepatic Impairment

The manufacturer makes no specific dosage recommendations for patients with hepatic impairment.^{1,100}

Renal Impairment

The manufacturer makes no specific dosage recommendations for patients with renal impairment.^{1,100}

Geriatric Patients

The manufacturer makes no specific dosage recommendations for geriatric patients; safety and efficacy have not been established in this patient population.^{1,100}

Cautions

■ Contraindications

- Anaphylactic or anaphylactoid reaction to a previous dose of the vaccine (BioThrax[®], Cyfendus[®]) or hypersensitivity to any ingredient in the formulation (including aluminum, benzethonium chloride, and formaldehyde).^{1,100,}

■ Warnings/Precautions

Management of Acute Allergic Reactions

Acute allergic reactions, including anaphylaxis, have occurred following administration of anthrax vaccines.^{1,} Appropriate medical treatment and supervision should be available to treat potential allergic reactions.^{1,100,}

Latex

Anthrax vaccine adsorbed (BioThrax[®]) should be administered with caution to individuals with latex sensitivity since some of the packaging components of the vaccine contain natural rubber latex, which may cause sensitivity reactions in susceptible individuals.^{1,} Vial stoppers of anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) are not made with natural rubber latex.^{100,}

Altered Immunocompetence

If the anthrax vaccine is administered to patients who are immunocompromised, including those receiving immunocompromising therapies, the immune response to the vaccine may be diminished.^{1,100,}

Fetal/Neonatal Morbidity and Mortality

Administration of anthrax vaccines during pregnancy may cause fetal harm.^{1,100,} One observational study found that maternal receipt of anthrax vaccine adsorbed (BioThrax[®]) in the first trimester resulted in a higher rate of birth defects in exposed infants compared with non-exposed infants.^{1,100,} The potential benefits of vaccination should be weighed against the potential fetal risk.^{1,}

If an anthrax vaccine is to be administered during pregnancy, the vaccinated individual should be informed of the potential fetal risk.^{1,100,}

History of Anthrax Disease

More severe adverse events have been reported in vaccine recipients with a history of anthrax compared with vaccinees without such a history.^{1,}

Limitations of Vaccine Effectiveness

The manufacturer of anthrax vaccine adsorbed (BioThrax[®]) states that vaccination may not protect all individuals.^{1,}

Specific Populations

Pregnancy

Administration of anthrax vaccines during pregnancy may cause fetal harm.^{1,100,} While causality has not been established, in an observational study, administration of anthrax vaccine adsorbed during the first trimester resulted in a higher number of birth defects in exposed versus non-exposed infants.^{1,100,} Pregnant women should be vaccinated against anthrax only if the potential benefits of vaccination outweigh the risks to the fetus.^{1,}

If an anthrax vaccine is to be administered during pregnancy, the individual being vaccinated should be informed of the potential fetal risk.^{1,100,}

Lactation

It is not known whether anthrax vaccines are excreted into human milk.^{1,100,} The developmental and health benefits of breast-feeding should be considered along with the mother's clinical need for the vaccine and the potential for adverse effects on the breast-fed child or from the underlying maternal condition.^{1,100,}

Pediatric Use

Because safety and efficacy of anthrax vaccine adsorbed and anthrax vaccine adsorbed, adjuvanted in pediatric patients younger than 18 years of age have not been established, the manufacturers currently do not recommend use in this age group.^{1,100,} However, the Centers for Disease Control and Prevention (CDC) states that if an anthrax event were to occur, use of anthrax vaccine adsorbed would be guided by available data at the time of the event.^{106,}

Geriatric Use

Because safety and efficacy of anthrax vaccines in geriatric adults older than 65 years of age have not been established, the manufacturer currently does not recommend use in this age group.^{1,100,}

■ Common Adverse Effects

The most common injection-site adverse reactions occurring in at least 10% of patients receiving anthrax vaccine adsorbed include tenderness, pain, erythema, edema, and arm motion limitation.¹ The most common systemic adverse reactions occurring in at least 5% of patients receiving anthrax vaccine adsorbed include muscle aches, fatigue, and headache.¹

The most common injection-site adverse reactions occurring in at least 10% of patients receiving anthrax vaccine adsorbed, adjuvanted were tenderness, pain, arm motion limitation, warmth, induration, itching, swelling, and erythema/redness.¹⁰⁰ The most common systemic adverse reactions occurring in at least 10% of patients receiving anthrax vaccine adsorbed, adjuvanted were muscle aches, tiredness, and headache.¹⁰⁰

Drug Interactions

■ Ciprofloxacin

Concomitant administration of anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) IM did not have a clinically significant impact on the pharmacokinetics of oral ciprofloxacin, or on the immunogenicity of the vaccine, as measured by the toxin neutralization assay (TNA).¹⁰⁰

Concomitant administration of anthrax vaccine adsorbed (BioThrax[®]) subcutaneously did not alter the pharmacokinetics of oral ciprofloxacin, and did not impact the immunogenicity of the vaccine, as measured by the anthrax lethal TNA.¹

■ Doxycycline

Concomitant administration of anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) IM did not have a clinically significant impact on the pharmacokinetics of oral doxycycline or on the immunogenicity of the vaccine, as measured by the TNA assay.¹⁰⁰

■ Immunosuppressive Drugs

Immunosuppression may reduce the immune response to anthrax vaccines.^{1,100}

■ Vaccines

Safety and effectiveness of concomitant administration of anthrax vaccine adsorbed (BioThrax[®]) with other vaccines has not been evaluated.¹ Anthrax vaccine adsorbed (BioThrax[®]) should not be mixed with any other vaccine in the same vial or syringe.¹ If given at the same time as another vaccine, anthrax vaccine adsorbed should be administered at a separate injection site from other injectable vaccines.¹

Description

Anthrax vaccine adsorbed (BioThrax[®]) and anthrax vaccine adsorbed, adjuvanted (Cyfendus[®]) are inactivated vaccines derived from cell-free filtrates of microaerophilic cultures of an avirulent, nonencapsulated strain of *Bacillus anthracis*.^{1,100} Production cultures are grown in a chemically defined, protein-free medium; the final product contains proteins, including the protective antigen (PA) protein, that are released during the bacterial growth period only (no dead or live bacteria).^{1,100} Both vaccines contain aluminum hydroxide as an adjuvant, as well as formaldehyde and benzethonium chloride as preservatives; anthrax vaccine adsorbed, adjuvanted additionally contains an adjuvant known as CPG 7909.^{1,100}

Anthrax vaccine adsorbed and anthrax vaccine adsorbed, adjuvanted stimulate active immunity to Gram-positive, spore-forming *B. anthracis* by inducing specific antibodies against the bacterium.^{1,100} Anthrax vaccines induce antibodies against the PA protein that may contribute to protection by neutralizing the activities of the cytotoxic lethal toxin and edema toxin of *B. anthracis*.^{1,100}

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from [MedlinePlus](#) (in English and Spanish; written at a 6th- to 8th-grade reading level).

- Instruct patients to report any serious adverse reactions to their healthcare provider.^{1,100}
- Advise patients to inform their clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs and dietary and herbal supplements, as well as any concomitant illnesses.^{1,100}
- Advise patients to inform their clinician if they are or plan to become pregnant or plan to breast-feed.^{1,100}
- Advise patients of other important precautionary information.^{1,100}

Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The manufacturer's

labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

Currently, anthrax vaccine adsorbed is not commercially available. The vaccine is available for military use. A limited supply of the vaccine is available under an investigational new drug application (IND) through the US Department of Health and Human Services (HHS) for certain individuals exposed to inhalational anthrax for postexposure prophylaxis combined with anti-infective therapy.

Anthrax Vaccine Adsorbed

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER
Parenteral	Injectable suspension, for IM or subcutaneous use	5 mL multiple-dose vial containing 10 doses	Biothrax [®]	Emergent BioSolutions

Anthrax Vaccine Adsorbed, Adjuvanted

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER
Parenteral	Injectable suspension, for IM use	5 mL multiple-dose vial containing 10 doses	Cyfundus [®]	Emergent BioSolutions

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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