Previous Insert for Anthrax Vaccine Adsorbed

The following insert was redacted on January 31, 2002, to reflect a change in the systemic reaction rate from .02% to between "5-35%." The new insert can be found here: http://www.fda.gov/CBER/label/biopava0131022LB.pdf The insert was redacted thanks to the efforts of attorney Mark Zaid of the James Madison Project. See: http://www.jamesmadisonproject.org/anthraxpage.html To view Mark Zaid's petition to the FDA, see: http://www.fda.gov/ohrms/dockets/dockets/80n0208/80N-0208-EC37-Attach-1.pdf

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HOW SUPPLIED
Anthrax Vaccine is supplied in 5 mL vials containing 10 doses each.

STORAGE
THIS PRODUCT SHOULD BE STORED AT 2 TO 8º C (35.6 to 46.4ºF). Do not freeze. Do not use after the expiration date given on the package.

REFERENCES
1. Brachman, P.S., et. al. Field Evaluation of a Human Anthrax Vaccine. Amer J. Pub. Health, 52:632-645 (1962).

2. Editorial: Vaccine Against Anthrax. Brit. Med. J., 2:717-718 (1965).

3. Advisory Committee for Immunization Practices. Adult Immunization, Morbidity and Mortality Report, 33(15):33-34, 1984.

4. Committee on Immunization, Guide for Adult Immunization, 1985, Amer. Col. Physicians, Philadelphia, PA (1985).

5. Report on Committee on Infectious Diseases, 19th Edition, Amer. Acad. Pediatrics, Evanston, IL (1982).

These recommendations are prepared by the Michigan Department of Public Health only for the guidance of the physician. They do not replace the experience and judgement of the physician, who should be familiar with the pertinent medical literature before administering any biologic product.

Manufactured by

MICHIGAN DEPARTMENT OF PUBLIC HEALTH
Lansing, Michigan 48909
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ANTHRAX VACCINE ADSORBED
Anthrax Vaccine Adsorbed is a sterile product made from filtrates of microaerophilic cultures of an avirulent, nonencapsulated strain of Bacillus anthracis which elaborates the protective antigen during the growth period. The cultures are grown in a synthetic liquid

medium and the final product is prepared from the sterile filtered culture fluid. The potency of this product is confirmed according to the U. S. Food and Drug regulations (21 CFR 620.23): Additional Standards for Anthrax Vaccine Adsorbed. The final product contains no more than 2.4mg aluminum hydroxide (equivalent to 0.83 mg aluminum) per 0.5 cc dose. Formaldehyde, in a final concentration not to exceed 0.02%, and benzethonium chloride, 0.0025%, are added as preservatives.

CLINICAL PHARMACOLOGY
Anthrax Vaccine Adsorbed is used in man to promote increased resistance to Bacillus anthracis by active immunization (1, 2).

INDICATIONS AND USAGE
Immunization with Anthrax Vaccine Adsorbed is recommended for individuals who may come in contact with animal products such as hides, hair, or bones which come from anthrax endemic areas and may be contaminated with Bacillus anthracis spores; and for individuals engaged in diagnostic or investigational activities which may bring them into contact with B. anthracis spores (1-5). It is also recommended for high risk persons such as veterinarians and others handling potentially infected animals. Since the risk of exposure to anthrax infection in the general population is slight, routine immunization is not recommended.

If a person has not previously been immunized against anthrax, injection of this product following exposure to anthrax bacilli will not protect against infection.

CONTRAINDICATIONS
A history of severe reaction to a previous dose of anthrax vaccine is a contraindication to immunization with this vaccine.

WARNINGS
1. Any acute respiratory disease or other active infection is generally considered to be adequate reasons for deferring an injection.

2. Persons receiving coritco-steroid therapy or other agents which would tend to depress the immune response may not be adequately immunized with the dosage schedule recommended. If the therapy is long termed, an extra dose vaccine should be given a month or more after therapy is discontinued.

PRECAUTIONS
1. General: Epinephrine solution, 1:1000, should always be available for immediate use in case an anaphylactic reaction should occur, even though such reactions are rare.

2. Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies have not been performed to ascertain whether Anthrax Vaccine Adsorbed has carcinogenic action, or any effect on fertility.

3. Pregnancy: PREGNANCY CATEGORY C. ANTHRAX VACCINE ADSORBED

Animal reproduction studies have not been conducted with Anthrax Vaccine Adsorbed. It is also not known whether Anthrax Vaccine Adsorbed can cause fetal harm when administered

to a pregnant woman or can effect reproduction capacity Anthrax Vaccine Adsorbed should be given to pregnant women only if clearly needed.

4. Pediatric Use: This antigen should be administered only to healthy men and women from 18 to 65 years of age because investigations to date have been conducted exclusively in that population.

ADVERSE REACTIONS

Local Reactions: Mild local reactions occur in approximately thirty per cent of recipients and consist of a small ring of erythema, 1-2 cm in diameter, plus slight local tenderness (1). This reaction usually occurs within 24 hours and begins to subside by 48 hours. Occasionally, the erythema increases to 3 to 5 cm in diameter. Local reactions tend to increase in severity by the 5th injection and then may decrease in severity with subsequent doses.

These may be pruritic. Subcutaneous nodules may occur at the injection site and persist for several weeks in a few persons. A moderate local reaction can occur if the vaccine is given to anyone with a past history of anthrax infection.

More severe local reactions are less frequent and consist of extensive edema of the forarm in addition to the local inflammatory reaction.

All local reactions have been reversible.

Systemic Reactions: Systemic reactions which occur in fewer than 0.2 per cent of recipients have been characterized by malaise and lassitude. Chills and fever have been reported in only a few cases. In such cases, immunization should be discontinued.

DOSAGE AND ADMINISTRATION

Dosage

Primary immunization consists of three subcutaneous injections, 0.5mL each, given 2 weeks apart followed by three additional subcutaneous injections, 0.5mL each, given at 6, 12 and 18 months (1).

If immunity is to be maintained, subsequent booster injections of 0.5 mL of anthrax vaccine at one year intervals are recommended.

Administration

1. Use a separate sterile needle and syringe for each patient to avoid transmission of viral hepatitis and other infections agents.

2. Shake the bottle thoroughly to ensure that the suspension is homogeneous during withdrawal. The rubber stopper should be treated with an appropriate disinfectant and allowed to dry before inserting the needle.

3. This preparation must be given subcutaneously after cleansing the overlying skin with an antiseptic.

4. Follow the usual precautions to avoid intravenous injection.

5. After withdrawing the needle, the injection site may be massaged briefly and gently to promote dispersal of the vaccine.

6. The same site should not be used for more than one injection of this vaccine.

7. Do not syringe-mix with any other vaccine.

8. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

End of product information leaflet