



ACAM2000

Generic Name: **Smallpox (Vaccinia) Vaccine, Live**

Date of Approval: **August 31, 2007**

Company: **Acambis, Inc.**

Treatment for: *Smallpox Prophylaxis*

FDA Approves ACAM2000

The U.S. Food and Drug Administration has licensed ACAM2000, a new vaccine to protect against smallpox, a highly contagious disease with the potential to be used as a deadly bioterror weapon.

The vaccine, ACAM2000, is intended for the inoculation of people at high risk of exposure to smallpox and could be used to protect individuals and populations during a bioterrorist attack. It will be included in the Center for Disease Control and Prevention's (CDC) Strategic National Stockpile of medical supplies.

A worldwide vaccination program eradicated smallpox in the population. The last case of naturally occurring smallpox in the U.S. was in 1949 and the last case in the world was reported in Somalia in 1977. Known stockpiles of the virus are kept only in two approved labs in the United States and Russia. The CDC considers it a Category A agent, meaning it presents one of the greatest potential threats for harming public health.

Smallpox is caused by the variola virus, a virus that emerged in human populations thousands of years ago. It spreads through close contact with infected individuals or contaminated objects, such as bedding or clothing. There is no FDA-approved treatment for smallpox and the only prevention is vaccination.

The symptoms of smallpox typically began with high fever, head and body aches. A rash followed that spread and progressed to raised bumps and pus-filled blisters that crusted, scabbed, and fell off after about three weeks, leaving a pitted scar. The fatality rate historically was about 30 percent, according to the CDC.

ACAM2000 is made using a pox virus called vaccinia, which is related to but different from the virus that causes smallpox. The vaccine contains live vaccinia virus and works by causing a mild infection that stimulates an immune response that effectively protects against smallpox without actually causing the disease.

The vaccine is derived from the only other smallpox vaccine licensed by FDA, Dryvax, approved in 1931 and now in limited supply because it is no longer manufactured.

Although smallpox vaccination ended in the United States in 1972 because it was no longer needed for prevention, the U.S. military resumed vaccination of at-risk personnel in 1999, after concluding that the disease posed a potential bioterrorism threat.

ACAM2000 was studied in two populations: those who had never been vaccinated for smallpox and those who had received smallpox vaccination many years earlier. The percentage of unvaccinated persons who developed a successful immunization reaction was similar to that of Dryvax. ACAM2000 also was found to be acceptable as a booster in those previously vaccinated for smallpox.

Because ACAM2000 contains live vaccinia virus, care must be taken to prevent the virus from spreading from the inoculation site to other parts of the body, and to other individuals.

To minimize known risks, the vaccine licensing is subject to a Risk Minimization Action Plan (RiskMAP). The RiskMAP requires providers of the vaccine and patients to be educated about these and other risks. The RiskMAP also requires patient education through an FDA-approved Medication Guide for those who receive the vaccine.

The Medication Guide explains the proper care of the vaccination site and provides information about serious side effects that can occur with ACAM2000. In studies, about 1 in 175 healthy adults who received smallpox vaccine for the first time developed inflammation and swelling of the heart and/or surrounding tissues (myocarditis and/or pericarditis). Of the 10 affected adults, four had no symptoms and at the end of the study, all but one had their symptoms resolve.

ACAM2000 is manufactured by Acambis Inc. of Cambridge, England and Cambridge, Mass. Dryvax was made by Wyeth Laboratories Inc. based in Madison, N.J.

Source: www.fda.gov

ACAM2000 Medication Guide

Smallpox (Vaccinia) Vaccine, Live

Please read this Medication Guide before you receive a vaccination with ACAM2000. This Guide does not take the place of talking to your healthcare provider about ACAM2000 and the smallpox disease.

What is the most important information I should know about the ACAM2000 smallpox vaccine?

- If you are at a high risk for being exposed to smallpox, you should be vaccinated even if you have health problems, unless you have certain problems with your immune system. People who have health problems may have a higher chance of getting serious side effects from vaccination but are also those who have a higher chance of dying from the smallpox disease.
- ACAM2000 may cause serious heart problems called myocarditis and pericarditis, or swelling of the heart tissues. In studies, about 1 in every 175 persons who got the vaccine for the first time may have experienced myocarditis and/or pericarditis. On rare occasions these

conditions can result in an irregular heart beat and death. Your chances of getting heart problems from the vaccine are lower if you have already had this vaccine before. You can have myocarditis and/or pericarditis even if you have no symptoms. Call your healthcare provider or get emergency help right away if you have:

- chest pain or pressure
- fast or irregular heartbeat
- breathing problems

See "What are the possible side effects of ACAM2000?"

- Because the vaccine has a live virus, it can spread to other parts of your body or to other people if you touch the vaccination site and then touch other parts of your body or other people. The vaccine virus can spread until the vaccination scab falls off (2 to 4 weeks after vaccination). If the virus is spread to a person who should not get the vaccine, the side effects can be very serious and life-threatening.

See "How do I care for the smallpox vaccination site?"

What is the ACAM2000 smallpox vaccine?

ACAM2000 is a prescription vaccine used to protect people against smallpox disease. It is for use in people who have a high chance of getting the disease.

ACAM2000 contains live vaccinia virus (a "pox"-type virus) to protect against smallpox disease.

Who should not get the ACAM2000 smallpox vaccine?

- In an emergency, you should be vaccinated if you are at high risk for getting smallpox disease even if you have health problems (except if you have certain problems with your immune system as discussed below).
- Your healthcare provider may not give you ACAM2000 if you have problems with your immune system. You may have immune system problems if you:
 - have leukemia
 - have lymphoma
 - have had a bone marrow or organ transplant
 - have cancer that has spread
 - have HIV, AIDS
 - have cellular or humoral immune deficiency
 - are being treated with radiation
 - are being treated with steroids, prednisone, or cancer drugs

How do I receive ACAM2000?

ACAM2000 smallpox vaccine is not a shot like other vaccines. Your healthcare provider will make

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15 pokes in the skin of your upper arm with a needle containing ACAM2000. The pokes are not deep, but will cause a drop of blood to form. This is called the vaccination site.

It is important to care for the vaccination site properly so that the virus doesn't spread to other parts of your body or to other people. You can infect another part of your body or other people until the scab falls off.

How do I care for the ACAM2000 vaccination site?

It is important to ALWAYS:

1. Wear bandages or Band-Aids to cover the entire vaccination site.
 2. Wear sleeves to cover the site.
 3. Wash your hands, wash your hands, wash your hands.
- When changing bandages or caring for your vaccination site, wear gloves. Use an absorbent bandage or Band-Aid to completely cover your vaccination site.
 - Change your bandage when it begins to soak through (at least every 1 to 3 days).
 - Throw away gloves and used bandages in sealed or double plastic bags. A small amount of bleach can be added to the bag to kill the virus.
 - Wear clothes with sleeves to cover the site and prevent scratching the vaccination site. It is especially important to wear a bandage and sleeves to bed to avoid scratching.
 - Wash your hands frequently with alcohol-based cleansers or soap and water.
 - Be sure to wash your hands each time you change your bandage or if you touch the vaccination site.
 - Do not use creams or ointments on the vaccination site because they will delay healing and can spread the virus.
 - Do not scratch or pick at the vaccination site.
 - You can take a bath or shower, but don't touch or scrub the vaccination site.
 - It is best to cover the vaccination site with a waterproof bandage.
 - If the vaccination site gets wet, dry the site with toilet paper and flush it. (Do not use a cloth towel because it can spread the virus.)
 - Cover the vaccination site with a loose gauze bandage after bathing to allow it to dry out.
 - Do not use a bandage that blocks air from the vaccination site. This could cause the skin at the vaccination site to soften and wear away.
 - If you exercise enough to cause sweat to drip, use a waterproof bandage on the vaccination site when exercising.
 - Wash clothing, towels, bedding or other items that may have come in contact with the vaccination site separately from other wash. Use hot water with detergent and bleach.

- When the scab falls off, throw it away in a sealed plastic bag with a small amount of bleach. Wash your hands afterwards.

What should I expect at the vaccination site and in the weeks following vaccination?

- If vaccination is successful, a red and itchy bump forms at the vaccination site in 2 to 5 days. Over the next few days, the bump becomes a blister and fills with pus. During the second week, the blister dries up and a scab forms. The scab falls off after 2 to 4 weeks, leaving a scar. People vaccinated for the first time may have a larger reaction than those being revaccinated.
- If you need medical care in the month after your vaccination, tell your healthcare provider you just got a smallpox vaccination.
- Certain people, such as laboratory workers who work with smallpox, are at risk of being exposed to smallpox over a long period of time. These people may need a booster vaccination every 3 years to maintain protection against smallpox.

What should I avoid?

- For 4 weeks after vaccination AND until the vaccination site has healed, you should avoid:
 - getting pregnant. Smallpox vaccine may rarely cause infection in an unborn baby if the mother is vaccinated during pregnancy. This infection usually results in stillbirth or death.
 - handling babies or breastfeeding.
 - swimming or hot tub use.
 - donating blood
 - Tuberculin (TB) testing. Smallpox vaccine may cause the TB test to give the wrong result.
- Avoid rubbing, scratching or touching the vaccination site.
- Until the vaccination scab falls off, do NOT:
 - have contact with people who cannot get the vaccine to prevent accidental spread of the vaccine virus. This includes physical contact and household contact. If there is someone in your household who should not get the vaccine, such as a pregnant woman, an infant, or someone who has an illness, you should not stay in the house until the vaccination scab falls off.
 - share a bed, clothes, towels, linen, or toiletries with unvaccinated people
- We don't know if the vaccine virus can be spread to cats, dogs, or other household pets, or whether pets can spread the virus to other people in the household. Try to keep the vaccine virus from reaching your pet. See "How do I care for the smallpox vaccination site?"

What are the possible side effects of ACAM2000?

ACAM2000 may cause serious heart problems, including myocarditis and pericarditis. This can

ACAM2000 may cause serious heart problems, including myocarditis and pericarditis. This can happen within 3 to 4 weeks after you get the vaccine.

Call your healthcare provider or get emergency help right away if you have:

- chest pain or pressure
- fast or irregular heartbeat
- breathing problems

Most people who get myocarditis and/or pericarditis seem to get better after a few weeks. But heart problems may last longer in some people, and in rare cases, could lead to death.

Other serious side effects include:

- swelling of the brain or spinal cord
- problems with the vaccination site blister, such as it becoming infected
- spreading of the vaccine virus to other parts of your body or to another person
- severe allergic reaction after vaccination
- accidental infection of the eye (which may cause swelling of the cornea causing watery painful eyes and blurred vision, scarring of the cornea, and blindness)

Common side effects include:

- itching
- swollen lymph nodes
- sore arm
- fever
- headache
- body ache
- mild rash
- fatigue

The risks for serious vaccine side effects are greater for people who:

- have skin problems called eczema or atopic dermatitis
- have skin problems, such as burns, impetigo, contact dermatitis, chickenpox, shingles, psoriasis, or uncontrolled acne
- have had heart problems
- have serious heart or blood vessel problems including angina, previous heart attack, artery disease, congestive heart failure, stroke, or other cardiac problems

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- smoke or have high blood pressure, high cholesterol, diabetes, high blood sugar, or a family history of heart problems
- are breastfeeding
- are pregnant, could be pregnant, or plan to become pregnant
- are less than 1 year old
- are taking steroid eye drops or ointment
- have had problems after previous doses or are allergic to ACAM2000 or any part of ACAM2000 such as antibiotics neomycin or polymixin B

Tell your healthcare provider if you have any of the above conditions.

The virus from your vaccination can spread to other people and cause serious side effects. It is important to tell your healthcare provider if you:

- live or work with a person who has skin problems (like eczema, dermatitis, burns, psoriasis, bad acne) or is suffering from impetigo, chicken pox or shingles
- live or have close contact with a baby, or a person who is pregnant or breastfeeding
- live or have close contact with a person who has an immune deficiency or cardiac disease

See "How do I care for the ACAM2000 vaccination site?"

Tell your healthcare provider about any side effect that bothers you or that does not go away.

To report SUSPECTED ADVERSE REACTIONS, contact your health provider and Acambis Inc. at 866-440-9440 (toll free) or 617-866-4500 or VAERS at 800-822-7967 and <http://vaers.hhs.gov>

See also:

Side effects (in more detail)

General information about the safe and effective use of ACAM2000

This Medication Guide provides a summary of the most important information about ACAM2000. Medicines are sometimes prescribed for purposes other than those listed in the Medication Guide. If you would like more information or have any questions, talk to your healthcare provider. You can ask your healthcare provider for information about ACAM2000 that is written for healthcare professionals. The vaccine should not be used for a condition other than that for which it is prescribed.

What are the ingredients in ACAM2000?

ACAM2000: live vaccinia virus derived from plaque purification cloning from Dryvax® (Wyeth Laboratories, Marietta, PA, calf lymph vaccine, New York City Board of Health Strain) and grown

in African Green Monkey kidney (Vero) cells

Inactive ingredients: 6-8 mM HEPES (pH 6.5-7.5), 2% human serum albumin USP, 0.5 - 0.7% sodium chloride USP, 5% mannitol USP, and trace amounts of the antibiotics neomycin and polymyxin B

Diluent for ACAM2000: 50% (v/v) Glycerin USP, 0.25% (v/v) Phenol USP in Water for Injection USP

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.