

MEDICATION GUIDE
ACAM2000®
Smallpox and Mpox (Vaccinia) Vaccine, Live

Please read this Medication Guide and talk to your healthcare provider before you receive ACAM2000.

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

ACAM2000 contains live vaccinia virus (a “pox”-type virus) that can be spread to individuals who have close contact with the vaccinated individual. ACAM2000 can cause serious complications in vaccinated individuals and in their close contacts to whom the vaccine virus has spread.

Serious complications of ACAM2000 include:

- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart). Most cases have occurred within 1-2 weeks after vaccination. Symptoms of myocarditis and pericarditis include:
 - Chest pain
 - Shortness of breath or difficulty breathing
 - Feelings of having a fast-beating, fluttering, or pounding heart

Symptoms of myocarditis and pericarditis may be different in children and may also include:

- Fainting
 - Unusual and persistent irritability
 - Unusual and persistent poor feeding
 - Unusual and persistent fatigue or lack of energy
 - Persistent vomiting
 - Persistent pain in the abdomen
 - Unusual and persistent cool, pale skin
- Inflammation of the brain or spinal cord
 - Serious skin infections such as a rash caused by widespread infection of the skin (known as eczema vaccinatum), buildup of inflamed tissue around the vaccination site that may at first look like a bullseye and will grow into a large, non-healing sore (known as progressive vaccinia).
 - Spreading of the vaccine virus through the blood to other parts of your body
 - Fetal death
 - 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)
 - Severe allergic reaction after vaccination

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

- have heart problems or a history of heart problems
- are taking steroid eye drops or ointment
- have a weakened immune system
- have skin problems such as eczema, atopic dermatitis, burns, impetigo, contact dermatitis, chickenpox, shingles, psoriasis, or uncontrolled acne
- are less than 1 year old
- are pregnant or become pregnant within 6 weeks after vaccination

Tell your healthcare provider if any of the above apply to you or anyone with whom you live, work or have close contact.

The risk for experiencing serious vaccination complications must be weighed against the risks for experiencing a potentially severe or fatal smallpox or mpox infection.

What is ACAM2000?

ACAM2000 is a vaccine used to prevent smallpox and mpox disease. It is for use in people of any age who have a high chance of getting smallpox or mpox disease.

If you are at a high risk for being exposed to smallpox and/or mpox, you should discuss with your healthcare provider whether you should receive ACAM2000.

Who should not get ACAM2000?

Individuals with severely weakened systems such as those undergoing bone marrow transplantation or individuals with weakened immune systems who require isolation should not get ACAM2000.

If you are unable to receive ACAM2000 because of a problem with your immune system, talk to your healthcare provider about other options to protect against smallpox and mpox.

What are the ingredients in ACAM2000?

ACAM2000 contains the following ingredients: live vaccinia virus grown in African Green Monkey kidney (Vero) cells, HEPES buffer, human serum albumin, sodium chloride, mannitol, trace amounts of the antibiotics neomycin and polymyxin B, Glycerin, and Phenol.

How is ACAM2000 given?

ACAM2000 is given “percutaneously.” Your healthcare provider will make 15 pokes in the skin of your upper arm with a two-prong needle holding a small drop of ACAM2000. The pokes are not deep but will cause a drop of blood to form. Where the 15 pokes are made is called the vaccination site.

What should I avoid after getting vaccinated with ACAM2000?

For 6 weeks after vaccination and until the vaccination site has healed, avoid:

- Getting pregnant or getting your partner pregnant.
- Spreading the vaccine virus to unvaccinated individuals, especially infants (including while breastfeeding), pregnant individuals, and individuals with a weakened immune system. The virus can be spread by physical contact (including sexual contact) and by sharing a bed, clothes, towels, linen, or toiletries with unvaccinated people.
- Donating blood or organs.
- Rubbing, scratching, or touching the vaccination site.

How do I care for the ACAM2000 vaccination site?

Your vaccination site is considered “infectious” from the time you get vaccinated until a scab forms and falls off and the skin at the vaccination site is fully healed. 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.

It is important to ALWAYS:

- Wear gauze secured loosely with first aid adhesive tape to cover the entire vaccination site.
- Wear sleeves to cover the bandage.
- Cover the vaccination site with a semipermeable dressing on top of the gauze to provide additional protection against spread of the virus if you are a healthcare worker. The dressing should allow passage of air to the vaccination site, but not allow passage of fluid.
- Wash your hands with soap and warm water or alcohol-based cleansers after contact with the vaccination site, bandages or clothes, towels, or sheets that might be contaminated with the vaccine virus. Wear gloves when changing bandages or caring for your vaccination site.
- Change your gauze when it begins to soak through (at least every 1 to 3 days).
- Throw away gloves and used gauze, semipermeable dressings, and bandages in sealed plastic bags with a small amount of bleach to kill the virus.
- Cover the vaccination site with a waterproof bandage during bathing or showering. If the vaccination site gets wet, dry the site with toilet paper and flush it. Cover the vaccination site with a loose gauze bandage after bathing or showering to allow it to dry out.
- Use a waterproof bandage on the vaccination site while exercising if you exercise enough to cause sweat to drip.
- 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.
- Throw the scab away in a sealed plastic bag with a small amount of bleach when it falls off. Wash your hands afterwards.

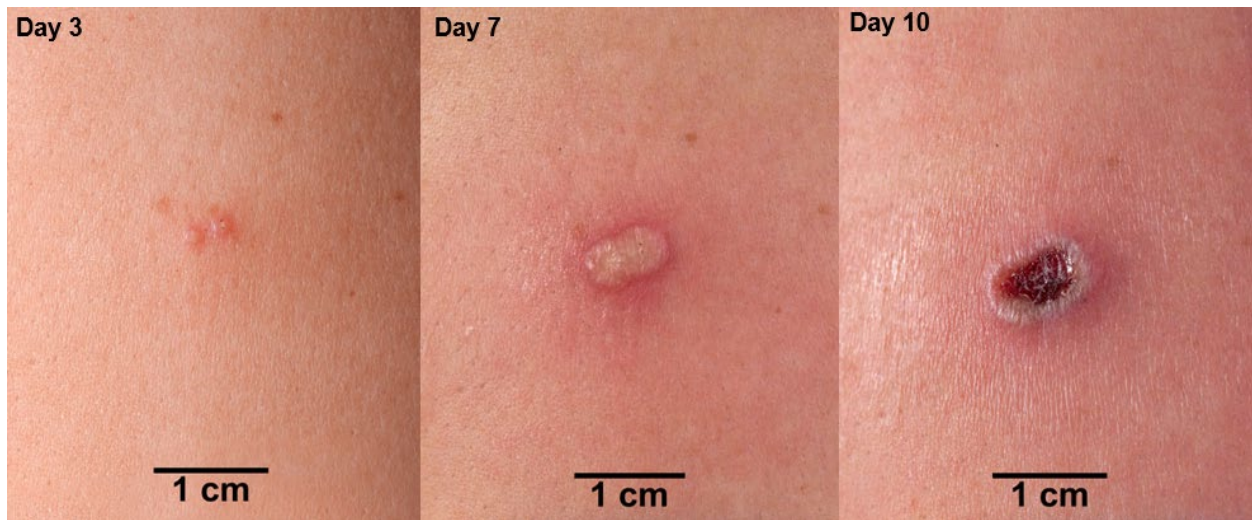
Do NOT:

- Do not use creams or ointments on the vaccination site.
- Do not scratch or pick at the vaccination site.
- Do not touch or scrub vaccination site while taking a bath or shower.
- 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.

What should I expect at the vaccination site during the weeks following vaccination with ACAM2000?

If you have never been vaccinated with a smallpox or mpox vaccine, vaccination is successful if 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. The blister then dries up and a scab forms. The scab falls off after 3 to 6 weeks, leaving a scar. The expected responses are shown below.

Expected response at ACAM2000 vaccination site in people never vaccinated with a smallpox or mpox vaccine



Note: After 6 to 11 days, check to be sure that your vaccination site looks like one of the pictures above. If it does not look like this, see your healthcare provider because you may need to be revaccinated.

If you have been previously vaccinated with a smallpox or mpox vaccine, you may have a reduced response to ACAM2000 compared to those not previously vaccinated. In most previously vaccinated individuals a red, itchy bump forms at the vaccination site in 6 to 8 days. The expected responses are shown below for individuals who were previously vaccinated with ACAM2000 or smallpox vaccines used historically.

Expected response at ACAM2000 vaccination site in people previously vaccinated with a smallpox or mpox vaccine



Note: If the expected response shown above does not occur you still may have been successfully vaccinated and you do not need another dose.

Pictures are from the United States Centers for Disease Control and Prevention (CDC). Reference to specific commercial products, manufacturers, companies, or trademarks does not constitute its endorsement or recommendation by the U.S. Government, Department of Health and Human Services, or Centers for Disease Control and Prevention. The material is otherwise available on the agency website for no charge. See also:

<https://www.cdc.gov/smallpox/clinicians/comparison-vaccinees-images.html>

If you need medical care within 6 weeks after your vaccination, tell your healthcare provider that you were vaccinated with ACAM2000.

What are other possible side effects of ACAM2000?

- redness at the vaccination site
- pain at the vaccination site
- swelling at the vaccination site
- itching at the vaccination site
- swollen lymph nodes
- fever
- headache
- muscle ache
- rash
- fatigue
- feeling unwell

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

To report SUSPECTED SIDE EFFECTS (ADVERSE REACTIONS), contact Emergent BioSolutions at 1-877-246-8472 and medicalinformation@ebsi.com or VAERS at 800-822-7967 and <https://vaers.hhs.gov>

Does ACAM2000 interfere with any laboratory tests?

ACAM2000 may cause some tests for Tuberculosis (TB) or Syphilis to give the wrong result. If you need to be tested for TB or Syphilis within **6 weeks** of receiving ACAM2000, tell your healthcare provider that you received ACAM2000.

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.

Manufactured by:

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