

What You Need to Know Before You Get ACAM2000® [Smallpox (Vaccinia) Vaccine, Live] Emergency Use Instructions for Recipients

During a smallpox public health emergency, you may be offered a smallpox vaccine. Getting the smallpox vaccine can protect you from getting smallpox, which is a serious, life-threatening and contagious disease. This fact sheet contains key facts about ACAM2000.

You are being offered the smallpox vaccine (ACAM2000) because your healthcare provider or a public health official has determined that your risk of getting smallpox may be greater than your risk of experiencing serious side effects from the vaccine. If you have more questions about ACAM2000, ask a doctor or public health official.

What is smallpox?

Smallpox is a serious infectious disease caused by the **variola** virus that can kill about 3 out of 10 people who get it. People with smallpox have a distinctive and progressive rash with high fevers and head and body aches. For survivors it can cause significant and long-lasting complications such as severe scarring and blindness after the rash has healed. Smallpox is spread by humans primarily through direct, fairly prolonged face-to-face contact between people but can also be spread through contaminated objects such as bedding or clothing.



Before the smallpox vaccine was developed in 1796, smallpox used to kill millions of people worldwide. As a result of the vaccine, smallpox was declared eradicated from the world in 1980.

What is ACAM2000?

ACAM2000 is a FDA-approved smallpox vaccine made from a living virus called "**vaccinia**" to protect people against smallpox. Vaccinia virus is in the same family as smallpox but it CANNOT give you smallpox.

What should I expect when I get the ACAM2000 vaccine?

The ACAM2000 smallpox vaccine is not a shot like some other vaccines. You will get 15 needle pricks onto the skin of your upper arm with a needle containing the vaccine (called a bifurcated needle). The pricks are not deep but should cause a drop of blood to form. Where the skin has been pricked is called the **vaccination site**. In about a week, a bump or blister will develop at the vaccination site with a successful vaccination.



What are common side effects?

Common side effects are usually temporary and may include itching or a rash at the vaccination site, swollen lymph nodes, sore arm, fever, headache or body aches, and/or fatigue.

What are possible serious side effects?

ACAM2000 may cause serious side effects. Some people with skin or immune system problems may have uncontrolled spread of the vaccine virus, which may include other parts of their body. Some people may also get serious heart problems after vaccination, including *myocarditis* (inflammation of the heart muscle) and/or *pericarditis* (inflammation of tissue covering the heart), which can cause chest pain or pressure, fast or irregular heartbeats, and/or breathing problems. This can happen up to 4 weeks after getting the vaccine.

Although rare, other possible serious side effects include:

- swelling of the brain or spinal cord
- problems with the vaccination site blister such as infections
- multiple blisters or bad rash developing all over the body
- severe allergic reactions such as breathing problems
- swelling of the face, lips, and tongue
- trouble swallowing

Most people who have side effects get better after a few weeks, but sometimes side effects can last longer and in very rare cases may cause death.

Because the vaccine virus is live, the virus may spread to others and/or to other parts of your body if you do not follow good hand washing and proper care of your vaccination site. For example, spread of the vaccine virus to your eyes could cause an accidental eye infection with watery, painful eyes and blurred vision, scarring of the cornea, and/or blindness; and this risk may be higher if you are using steroid eye products. It could also spread onto other people which may cause them to have serious side effects especially in people with weak immune systems or skin problems.

If you have any of these serious side effects then seek medical help right away.

Go to the emergency room or call 911.

Who are at higher risk for serious side effects or poor outcomes?

The risks for serious side effects or poor outcomes from the vaccine are greater for people who:

- Have any type of immune system problems, conditions that affect the immune system, or are taking any medication that weakens the immune system
- Have skin problems such as eczema, atopic dermatitis, burns, impetigo, contact dermatitis, chickenpox, shingles, psoriasis, or uncontrolled acne
- Have or had heart or blood vessel problems
- Have 3 or more risk factors for heart disease such as high blood pressure, high blood cholesterol, high blood sugar (diabetes), first degree relative (example: mom, dad, sister, or brother) who had a heart condition before the age of 50, or currently smoke
- Are pregnant (the vaccine may cause infection in an unborn baby, which can result in death or stillbirth)
- Are children less than 1 year old
- Are using steroid eye drops or ointment
- Have had problems after a previous dose of ACAM2000 or other smallpox vaccines or are allergic to any parts of the vaccine such as the antibiotics neomycin or polymyxin B

But remember, people at higher risk for serious side effects from the vaccine are usually also at higher risk for severe disease and death from smallpox.

Who should not be vaccinated?

The vaccine may not be able to protect you if your immune system is very weak and cannot respond to the vaccine at this time. Be sure to tell the healthcare provider or public health official, if you have any serious immune system problems such as:

- Bone marrow transplant (especially within the past 4 months)
- HIV (especially with CD4 cell count of less than 50 cells/mm³)
- Severe combined immunodeficiency, complete DiGeorge syndrome, or other serious condition that affects your immune system (especially if it requires isolation)

Tell your healthcare provider or a public health official if you have any of the above conditions. They will then inform you whether or not you should receive the vaccine based on your medical condition and risk of getting smallpox.

What are other vaccines for preventing smallpox?

ACAM2000 is the only FDA-approved smallpox vaccine. Public health officials will tell you if other vaccines (such as APSV or IMVAMUNE) are available. The risks and benefits of other available vaccines will be explained in separate fact sheets.

What if I decide not to get vaccinated?

It is your choice to get vaccinated or not. If you do not get vaccinated and are exposed to the smallpox virus, you can develop smallpox. *Getting sick with smallpox is much worse than most side effects of the vaccine.*

How do I report vaccine side effects?

Tell your doctor right away if you have side effects that are bothersome or that do not go away. Report any side effects of the smallpox vaccine to the Vaccine Adverse Event Reporting System (VAERS) at 800-822-7967 or <https://vaers.hhs.gov>.

What else should I know?

The [Countermeasures Injury Compensation Program \(CICP\)](#) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines. To learn more about this program, visit: <http://www.hrsa.gov/cicp> or call 1-855-266-2427 (toll-free).

How can I learn more about ACAM2000?

- Talk to a healthcare provider
- Contact your local or state health department
- Visit CDC's smallpox webpage <http://www.cdc.gov/smallpox>
- Refer to ACAM2000's package insert and medication guide <https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm180810.htm>

After your ACAM2000 smallpox vaccination, remember to:

Wash your hands often when touching the site or if you've touched anything that has touched the vaccination site (ex: bandages, clothing, bedding, towels, etc.) and keep the entire vaccination site covered until the scab falls off.

The vaccine virus can be spread to other parts of your body and to other people until the scab falls off the vaccination site (2 to 4 weeks after you get the vaccine). If the virus is spread to infants or someone with health problems, it can cause serious illness.

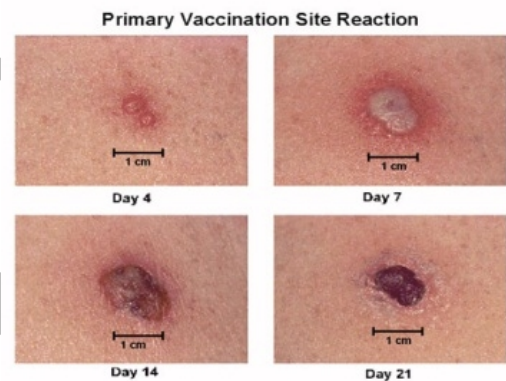
This is why it is **very important** that you follow all the steps on this sheet to protect yourself and your family.

What to expect in the weeks after getting the vaccine

Following a successful vaccination your body will build immunity to protect you from smallpox and you will see these signs:

- 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 2 to 4 weeks after getting the vaccine. This will leave a scar.

After 6 to 8 days, check to be sure that your vaccination site looks like these pictures. If it does not, then see a healthcare provider or public health official because you may need to get the vaccine again.

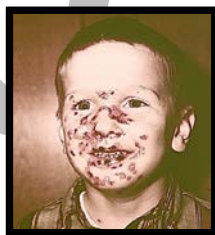


The vaccination site reaction may be larger for people who have never gotten a smallpox vaccine. You can find more pictures of what the vaccination site should look like at <https://www.cdc.gov/smallpox/clinicians/comparison-vaccinees-images.html>

Avoid these things until your scab falls off (approximately 2 to 4 weeks):

- ✘ **DO NOT** rub, scratch, pick at, or touch the vaccination site.
 - Wear long-sleeve clothing to cover the site and prevent scratching, especially when sleeping.
- ✘ **DO NOT** touch your eyes, other parts of your body, or others while caring for your site and until after you wash your hands.

These pictures below show what can happen when you touch the site and then other parts of your body.



- ✘ **DO NOT** let others touch the vaccination site or items that have touched the site such as bandages and/or clothing.
- ✘ **DO NOT** share clothes, towels, or linens with other people.
- ✘ **DO NOT** have close contact with others or handle infants/children (including breastfeeding) without making sure the entire vaccination site is first covered.

- Women can continue to breastfeed and/or express breast milk. But women should stop and contact a healthcare provider if any red bump or blister (like the pictures shown above) develops on the breast after vaccination.
- ✘ **DO NOT** get pregnant.
- ✘ **DO NOT** get the site wet.
 - Use a waterproof bandage during activities such as swimming, bathing, or exercising.
 - Cover the site with a loose bandage afterwards to let the site dry out.
 - If the site gets wet, dry it with toilet paper and flush it. Do not use a cloth towel because it can spread the virus.
- ✘ **DO NOT** use creams or ointments (including topical antibiotics) on the vaccination site.
- ✘ **DO NOT** donate blood.
- ✘ **DO NOT** get a tuberculin (TB) test (a test that checks for tuberculosis infection). The vaccine may cause a wrong result.
- ✘ **DO NOT** let your pet near the vaccination site.
 - It is not known if the vaccine virus can spread to household pets, or whether pets can spread the vaccine virus to people.

Follow these steps to protect you and your family

- ✓ **DO** wash your hands often.
 - Use soap and water or an alcohol-based cleanser.
 - Always wash your hands after caring for your vaccination site.
- ✓ **DO** cover the entire vaccination site with a loose bandage.
 - Use loose bandages that do not block air from the site, such as a gauze bandage held in place with medical adhesive tape.
 - Change your bandage every 3 days or sooner if it gets dirty or wet.
 - Put used bandages in a sealed or double plastic bag. Add a small amount of bleach to kill the virus and throw it away.
 - If you are a healthcare worker or caretaker, cover the gauze with another additional semi-permeable dressing while at work (this type of dressing allows air to flow through but not fluids) and wear long-sleeves to cover the site.
- ✓ **DO** your own laundry. Wash clothes, towels, bedding, or other items that may have touched the vaccination site separately from other items.
 - Use hot water with detergent and/or bleach.
- ✓ **DO** throw the scab away when it falls off.
 - Put it in a sealed plastic bag with a small amount of bleach and throw it away.
- ✓ **DO** wear gloves when caring for your vaccination site, if you have them.
 - Throw away used gloves. Place them in a sealed or double plastic bag. Add a small amount of bleach to kill the virus and throw it away.

Space Reserved for State/Local Public Health Information