SMALLPOX

CDC RECOMMENDS FOR ADULTS WITH POTENTIAL EXPOSURE TO THE VIRUS WITH A BOOSTER EVERY 3 YEARS. THE FDA HAS CURRENTLY APPROVED TWO PRODUCTS.

ACAM2000 can cause:

+ Erythema (skin redness)
+ Pruritus (itchy skin)
+ Pain/Swelling
+ Fatigue
+ Malaise (discomfort)
+ Feeling hot/Rigors
+ Exercise tolerance decreased
+ Headache
+ Limb paresthesias
+ Dizziness/Vertigo
+ **Meningitis**
+ Encephalitis/myelitis
+ Bell palsy
+ **Seizures including death**
+ Guillain-Barré syndrome
+ Accidental infection of the eye (ocular vaccinia)
+ **Blindness**
+ Photophobia
+ Myalgia (muscle pain)
+ **Back pain**
+ Arthralgia (joint pain)
+ Pain in extremity
+ Lymphadenopathy/pain
+ Nausea/Vomiting
+ Diarrhea/Constipation
+ Severe abdominal pain
+ **Toothache**
+ Dermatitis (eczema)
+ Urticaria (hives)
+ Generalized rashes
+ Inadvertent inoculation at other body sites (face, nose, mouth, lips, genitalia, and anus)
+ Keratis
+ Corneal scarring
+ Benign/Malignant lesions
+ Progressive vaccinia (vaccinia recrosum)
+ Generalized vaccinia
+ Severe vaccinial skin infections
+ Stevens-Johnson syndrome
+ Fetal vaccinia
+ **Fetal death**
+ Myocarditis
+ Pericarditis
+ **Eczema vaccinated resulting in permanent sequelae or death**

ARE THESE SAFE ADVERSE REACTIONS?

SOURCES FROM FDA + EMERGENT BIOSOLUTIONS

THE MANUFACTURER ON SMALLPOX VACCINE

ACAM2000 is a live vaccinia virus that can be transmitted to persons who have close contact with the vaccinee and the risks in contacts are the same as those stated for vaccinees. (5.10)

Inadvertent inoculation at other sites is the most frequent complication of vaccinia vaccination. The most common sites involved are the face, nose, mouth, lips, genitalia and anus.

5.6 Infants (< 12 months of Age) and Children

ACAM2000 has not been studied in infants or children. The risk of serious adverse events following vaccination with live vaccinia virus is higher in infants. Vaccinated persons who have close contact with infants, e.g., breastfeeding, must take precautions to avoid inadvertent transmission of ACAM2000 live vaccinia virus to infants.

5.7 Pregnancy

ACAM2000 has not been studied in pregnant women. Live vaccinia virus vaccines can cause fetal vaccinia and fetal death. If ACAM2000 is administered during pregnancy, the vaccinee should be apprised of the potential hazard to the fetus [See Use in Specific Populations (8.1)]. Pregnant women who are close contacts of vaccinees may be at increased risk because live vaccinia virus can shed and be transmitted to close contacts.

5.12 Limitations of Vaccine Effectiveness

ACAM2000 smallpox vaccine may not protect all persons exposed to smallpox.

THE CDC ON SMALLPOX VACCINE

Getting the Smallpox Vaccine

The smallpox vaccine is given by a special technique. It is not administered as a "shot" in the way that most other vaccines are. It is given using a two-pronged (bifurcated) needle that is dipped into the vaccine solution. When removed, the needle holds a droplet of the vaccine. The needle is used to prick the skin a number of times in a few seconds. The pricking is not deep, but it will cause a sore spot and one or two drops of blood to form. The vaccine usually is given in the upper arm.

If the vaccination is successful, a red and itchy lesion develops at the vaccine site in 3 to 4 days. In the first week, the lesion becomes a large blister, fills with pus, and begins to drain. During the second week, the lesion begins to dry and a scab forms. The scab falls off in the third week, leaving a small scar.

Because the vaccinia virus is live, it is important to follow care instructions for the vaccination site. You can spread the vaccinia virus by touching the vaccination site before it has healed or by touching bandages or clothing that have been in contact with the live virus from the vaccination site.

If you do not follow these instructions, you can spread the virus to other parts of your body or to other people.

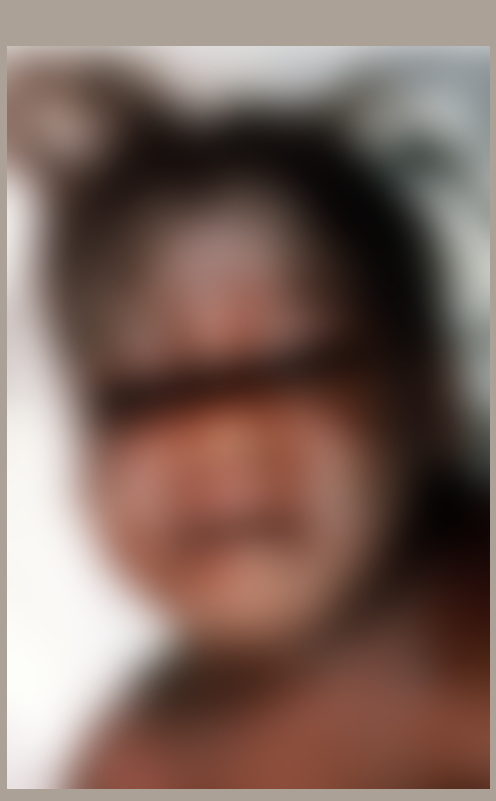
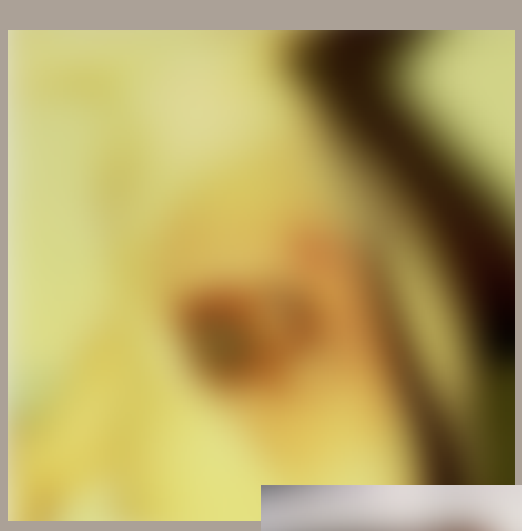
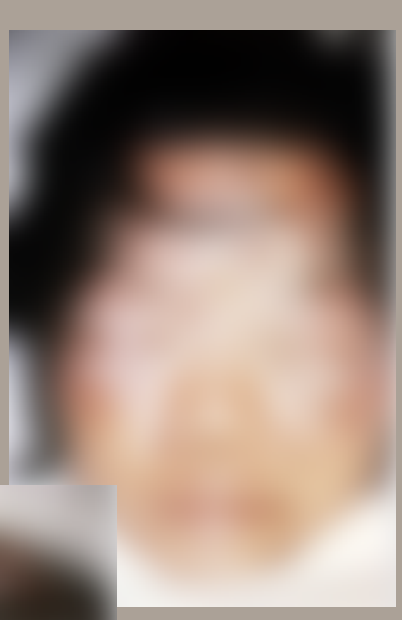
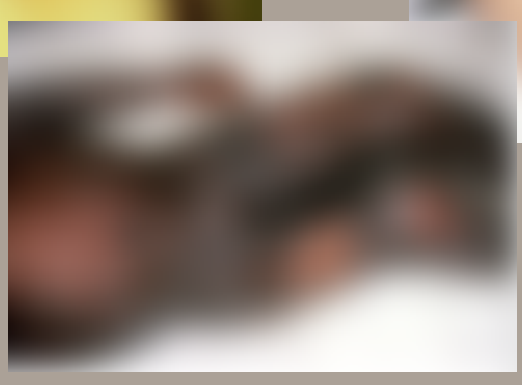
cdc.gov/smallpox/vaccine-basics/index.html

THE CDC ON VACCINE ADVERSE REACTIONS

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Vaccine Adverse Reaction Images

The following photos are blurred due to copyright limitations. Go to the below link or justtheinserts.com/smallpox to view the photos of vaccine adverse reactions

cdc.gov/smallpox/clinicians/vaccine-adverse-reaction-images.html

THE CDC ON SMALLPOX TREATMENT

Antiviral Drugs

- In July 2018, the FDA approved **tecovirimat (TPOXX)** for treatment of smallpox. In laboratory tests, tecovirimat has been shown to stop the growth of the virus that causes smallpox and to be effective in treating animals that had diseases similar to smallpox. Tecovirimat has **not** been tested in people who are sick with smallpox, but it has been given to healthy people. Test results in healthy people showed that it is safe and causes only minor side effects. In addition to treating smallpox disease, tecovirimat could also be used under an investigational new drug (IND) protocol to treat adverse reactions from vaccinia vaccination.
- In laboratory tests, **cidofovir and brincidofovir** have also been shown to stop the growth of the virus that causes smallpox and to be effective in treating animals that had diseases similar to smallpox. Cidofovir and brincidofovir have not been tested in people who are sick with smallpox, but they have been tested in healthy people and in those with other viral illnesses. These drugs continue to be evaluated for effectiveness and toxicity. Neither are FDA-approved for the treatment of variola virus infections (secondary to smallpox vaccination), but they could be used for isolated cases or during an outbreak under an appropriate regulatory mechanism (such as an investigational new drug [IND] protocol or Emergency Use Authorization) for the treatment of complications from vaccinia vaccination.

cdc.gov/smallpox/prevention-treatment/index.html