

ABOUT ACAM2000

ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) is a live, vaccinia virus smallpox vaccine licensed in the U.S. by the Food and Drug Administration for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection. It was developed under a contract with the U.S. Centers for Disease Control and Prevention (CDC).

ACAM2000 vaccine was developed to be a licensed smallpox vaccine manufactured using modern cell-culture techniques complying with current Good Manufacturing Practice standards. Production of first-generation vaccines ceased in the early 1980s following a successful smallpox vaccination campaign by the World Health Organization that led to the declared eradication of smallpox in 1980.

Today, ACAM2000 vaccine is the primary smallpox vaccine designated for use in a bioterrorism emergency and forms the majority of the U.S. Government's smallpox vaccine stockpile. More than 200 million doses of ACAM2000 have been supplied to the US Government for its Strategic National Stockpile and has also been supplied under an FDA Investigational New Drug application to several other governments around the world.

IMPORTANT SAFETY INFORMATION

WARNING:

- Suspected cases of myocarditis and/or pericarditis have been observed in healthy adult primary vaccinees (at an approximate rate of 5.7 per 1000, 95% CI: 1.9-13.3) receiving ACAM2000 [see Warnings and Precautions (5.1)].
- Encephalitis, encephalomyelitis, encephalopathy, progressive vaccinia, generalized vaccinia, severe vaccinia skin infections, erythema multiforme major (including STEVENS-JOHNSON SYNDROME), eczema vaccinatum resulting in permanent sequelae or death, ocular complications, blindness, and fetal death have occurred following either primary vaccination or revaccination with live vaccinia virus smallpox vaccines [see Warnings and Precautions (5)].

These risks are increased in vaccines with the following conditions and may result in severe disability, permanent neurological sequelae and/or death:

- Cardiac disease or a history of cardiac disease
- Eye disease treated with topical steroids
- Congenital or acquired immune deficiency disorders, including those taking immunosuppressive medications
- Eczema and persons with a history of eczema or other acute or chronic exfoliative skin conditions
- Infants less than 12 months of age
- Pregnancy

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

The risk of experiencing serious vaccination complications must be weighed against the risk of experiencing a smallpox infection.

ACAM2000 vaccine may not protect all persons exposed to smallpox. ACAM2000 vaccine is contraindicated for individuals with severe immunodeficiency, and who are not expected to benefit from the vaccine who should not be administered the vaccine. These individuals may include persons who are undergoing bone marrow transplantation or persons with primary or acquired immunodeficiency states who require isolation.

- The most serious adverse events associated with smallpox vaccination are myocarditis, pericarditis, encephalitis, encephalomyelitis, encephalopathy, progressive vaccinia, generalized vaccinia, severe vaccinia skin infections, and erythema multiforme major (including STEVENS-JOHNSON SYNDROME) and eczema vaccinatum resulting in permanent sequelae or death, ocular complications, blindness and fetal death have occurred following either primary vaccination or revaccination with smallpox vaccines.
- The most common side effects following smallpox vaccination include injection site erythema, pruritus, pain, swelling, myalgia, itching, swollen lymph nodes, sore arm, fever, headache, body ache, rash and fatigue.
- Inadvertent inoculation at other sites is the most frequent complication of vaccination. The most common sites involved are the face, nose, mouth, lips, genitalia and anus.

FULL PRESCRIBING AND MEDICATION GUIDE

 Available for download at www.ebsi.com/products

Information for Health Professionals & the General Public:

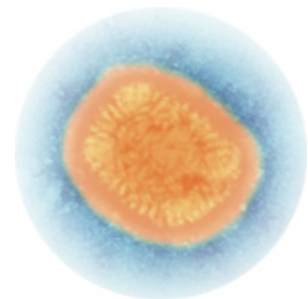
 <https://www.cdc.gov/smallpox/index.html>

ABOUT SMALLPOX

Smallpox is a highly contagious disease caused by the variola virus, a member of the Orthopox virus family. Smallpox is a serious disease with a mortality rate as high as 30%.

In 1967, the World Health Organization embarked upon an intensified vaccination campaign to eradicate smallpox, which culminated in the successful eradication of the disease globally by 1980.¹

The events in the U.S. in September and October 2001 highlighted the risk that the variola virus might be used as an agent of bioterrorism.² Governments around the world are taking precautionary measures to be ready to deal with a potential smallpox outbreak.



Notes & References:

(1) World Health Organization:

 <http://www.who.int/topics/smallpox/en/>

(2) Centers for Disease Control & Prevention:

 <https://www.cdc.gov/smallpox/about/index.html>

Intended for US Residents Only:

U.S. Department of Defense:

 <http://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Preventable-Diseases/Smallpox>