Smallpox (Vaccinia) Vaccine Live (AHFS DI)

Generic Name: Smallpox Vaccine Live, New York City Board of Health Live Vaccinia Strain
Brand Information: ACAM2000®

Boxed Warning:

1. Suspected cases of myocarditis and/or pericarditis have been observed in healthy adult primary vaccinees at an approximate rate of 5.7 per 1000 receiving smallpox vaccine live (ACAM2000®).[1]

2. Encephalitis, encephalomyelitis, encephalopathy, progressive vaccinia, generalized vaccinia, severe vaccinial 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, replication-competent, vaccinia virus smallpox vaccines.[1]

3. The risks listed above are increased in vaccinees with the following conditions and may result in severe disability, permanent neurological sequelae, and/or death: cardiac disease or history of cardiac disease, eye disease treated with topical steroids, congenital or acquired immune deficiency disorders or receiving immunosuppressive therapy, eczema or history of eczema or other acute or chronic exfoliative skin conditions, infants younger than 12 months of age, pregnancy.[1]

4. Smallpox vaccine live contains live vaccinia virus that can be transmitted to individuals who have close contact with the vaccinee and the risks in contacts are the same as those for the vaccinee.[1]

5. The risk for experiencing serious vaccination complications must be weighed against the risk of experiencing a potentially fatal smallpox infection.[1]

Introduction
Smallpox vaccine live is a live virus vaccine containing replication-competent vaccinia virus derived from a plaque-purified clone of the New York City Board of Health vaccinia strain.[1,2]

Uses
Smallpox
Smallpox vaccine live is indicated for active immunization against smallpox disease in individuals determined to be at high risk for smallpox infection.[1]

The US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) has issued recommendations and clinical considerations for the use of vaccines in preventing smallpox.[2] Although routine vaccination against smallpox in the US ended in the 1970s, ACIP recommends that certain populations at high risk of occupational exposure to orthopoxviruses be vaccinated.[2]

There are currently 2 licensed smallpox vaccines in the US (smallpox vaccine live [ACAM2000®] and smallpox and mpox vaccine live [JYNNEOS®]).[2] In the event of a smallpox emergency, ACIP states that ACAM2000 would be made available to persons exposed to smallpox virus or who are at high risk of smallpox infection, depending on the circumstances of the event; specific use of JYNNEOS in a smallpox emergency will be based on risk of exposure and relative contraindications to ACAM2000.[2] For additional information, consult the CDC website at https://www.cdc.gov/smallpox/clinicians/vaccines.html.

Mpox

Smallpox vaccine live (ACAM2000®) also has been used for the prevention of mpox Infection (off-label).[6,7]

The CDC ACIP has issued recommendations and clinical considerations for the use of vaccines for mpox prevention in the US.[6] There are 2 vaccines (JYNNEOS [also known internationally as Imvamune® or Imvanex®] and ACAM2000) currently available.[6,7] During the current clade II mpox outbreak that started in the US on May 17, 2022, JYNNEOS has been the main vaccine used in the US.[6] The ACAM2000 vaccine is approved for immunization against smallpox and can also be made available for use against mpox under an Expanded Access Investigational New Drug (EA-IND) protocol; however, this vaccine has not been used during the current mpox outbreak and is associated with more adverse effects and contraindications.[6]

Dosage and Administration

General

Smallpox vaccine live (ACAM2000®) is available in the following dosage form(s) and strength(s):

Multiple-dose vial containing lyophilized vaccine and vial containing diluent.1 After reconstitution with the diluent as directed by the manufacturer, each vaccine vial provides approximately 100 doses; each dose of 0.0025 mL contains 2.5×10^5 to 12.5×10^5 plaque-forming units (PFU) of vaccinia virus.[1]

Administration and Preparation

Administer smallpox vaccine live (ACAM2000®) only after being trained on the safe and effective administration of the vaccine by the percutaneous route (scarification).[1]

Do not administer intradermally, subcutaneously, IM, or IV.[1]

Provide the FDA-approved patient labeling (Medication Guide) to the vaccine recipient and provide instructions on vaccination site care.[1]

See the manufacturer's labeling for complete instructions for vaccine preparation and administration (including handling precautions and disposal instructions) and instructions for interpreting the response to vaccination (including vaccination failures).[1]

Dosage
It is essential that the manufacturer's labeling be consulted for more detailed information on dosage and administration of this drug.

Dosage summary:
Pediatric Patients
Smallpox

1. One droplet of reconstituted smallpox vaccine live is administered by the percutaneous route (scarification) using 15 jabs of a bifurcated needle.[1]
2. The droplet (0.0025 mL) of smallpox vaccine live is picked up with a bifurcated needle by dipping the needle into the vial of reconstituted vaccine.[1]
3. Revaccination may be recommended (e.g., every 3 years) in individuals at continued high risk of exposure to smallpox (e.g., research laboratory workers handling variola virus).[1]

Mpox

1. In pediatric patients ≥1 year of age receiving smallpox vaccine live for prevention of mpox infection (off-label), the FDA-approved dose of one droplet (0.0025 mL) of smallpox vaccine by the percutaneous route (scarification) using 15 jabs of a bifurcated needle has been recommended.[5]
2. The droplet (0.0025 mL) of smallpox vaccine live is picked up with a bifurcated needle by dipping the needle into the vial of reconstituted vaccine.[1]

Adults
Smallpox

1. One droplet of reconstituted smallpox vaccine live is administered by the percutaneous route (scarification) using 15 jabs of a bifurcated needle.[1]
2. The droplet (0.0025 mL) of smallpox vaccine live is picked up with a bifurcated needle by dipping the needle into the vial of

reconstituted vaccine.1
3. Revaccination may be recommended (e.g., every 3 years) in individuals at continued high risk of exposure to smallpox (e.g., research laboratory workers handling variola virus).[1]

Mpox

1. In patients receiving smallpox vaccine live for prevention of mpox infection (off-label), the FDA-approved dose of one droplet (0.0025 mL) of smallpox vaccine by the percutaneous route (scarification) using 15 jabs of a bifurcated needle has been recommended.[5]
2. The droplet (0.0025 mL) of smallpox vaccine live is picked up with a bifurcated needle by dipping the needle into the vial of reconstituted vaccine.[1]

Cautions

Contraindications

1. There are very few absolute contraindications to smallpox vaccine live (ACAM2000®) for those at high risk for smallpox.[1] The risk for experiencing serious vaccination complications must be weighed against the risk of experiencing a potentially fatal smallpox infection.[1]
2. Severe localized or systemic infection with vaccinia (progressive vaccinia) may occur following receipt of smallpox vaccine live (ACAM2000®) in individuals with weakened immune systems.[1] Individuals with severe immunodeficiency who are not expected to benefit from smallpox vaccine live should not receive the vaccine. This may include individuals undergoing bone marrow transplantation and those with primary or acquired immunodeficiency who require isolation.[1]

Warnings and Precautions

Serious Vaccination Complications and Death

Smallpox vaccine live (ACAM2000®) contains live, replication-competent, vaccinia virus.[2,4] Individuals at greatest risk of experiencing serious complications following receipt of a replication-competent smallpox vaccine are often those at greatest risk for death from smallpox, and the risk for serious vaccination complications must be weighed against the risk for a potentially fatal smallpox infection.[1]

Serious complications that may occur following primary vaccination or revaccination with replication-competent smallpox vaccine live include myocarditis and/or pericarditis, encephalitis, encephalomyelitis, encephalopathy, progressive vaccinia (vaccinia necrosum), generalized vaccinia, severe vaccinial skin infections, erythema multiforme major (including Stevens-Johnson syndrome), eczema vaccinatum, and blindness.[1] These complications may rarely lead to severe disability, permanent neurological sequelae, and death.[1] Fetal death can occur if replication-competent smallpox vaccine live is administered to pregnant women.[1]

Based on clinical trials of ACAM2000®, symptoms of suspected myocarditis or pericarditis (such as chest pain, raised troponin/cardiac enzymes, or ECG abnormalities) occur in 5.7 per 1000 primary vaccinations (95% CI: 1.9-13.3).[1] This finding includes cases of acute symptomatic or asymptomatic myocarditis or pericarditis or both.[1]

Historically, death following vaccination with live vaccinia virus is a rare event; approximately 1 death per million primary vaccinations and 1 death per 4 million revaccinations have occurred after vaccination with live vaccinia virus.[1] Death is most often the result of sudden cardiac death, postvaccinial encephalitis, progressive vaccinia, or eczema vaccinatum.[1] Death has also been reported in unvaccinated contacts accidentally infected by individuals who have been vaccinated.[1]

Data on the incidence of adverse events among US military personnel and civilian first responders vaccinated with a previously available smallpox vaccine live containing replication-competent vaccinia virus (i.e., New York City Board of Health strain; Dryvax®) during vaccination programs initiated in December 2002 are shown in Table 1.[1] The incidence of preventable adverse events (eczema vaccinatum, contact transmission, and autoinoculation) reported in these programs was notably lower compared with data collected in the 1960s when smallpox vaccination was routinely recommended in the US population; this difference presumably is because of better vaccination screening procedures and routine use of protective bandages over the inoculation site.[1] Myocarditis and pericarditis were not commonly reported following smallpox vaccination in the 1960s, but emerged as a more frequent event based on more active surveillance in the military and civilian programs.[1]

Table 1. Incidence of Serious Adverse Events Reported with Smallpox Vaccine Live (Dryvax®) in 2002-2005[1]

Adverse event	N[a]	Incidence per million	N[b]	Incidence per million
Myocarditis/ pericarditis	86	117.71	21	519.52
Post-vaccinal encephalitis	1	1.37	1	24.74
Eczema vaccinatum	0	0.00	0	0.00
Generalized vaccinia	43	58.86	3	74.22
Progressive vaccinia	0	0.00	0	0.00
Fetal vaccinia	0	0.00	0	0.00
Contract transmission	52	71.18	0	0.00

Auto-inoculation (non-ocular)	62	84.86	20	494.78
Ocular vaccinia	16	21.90	3	74.22

[a]Department of Defense program as of January 2005 (n=730,580): 71% primary vaccinations; 89% male; age 28.5 years.
[b]Department of Health and Human Services program as of January 2004 (n=40,422): 36% primary vaccinations; 36% male; median age 47.1 years.

Cardiovascular Events
In clinical trials involving 2983 individuals who received smallpox vaccine live (ACAM2000®) and 868 individuals who received a previously available smallpox vaccine live (Dryvax®), 10 cases of suspected myocarditis (7 out of 2983 ACAM2000® recipients [0.2%] and 3 out of 868 Dryvax® recipients [0.3%]) were identified.[1] The mean time to onset of suspected myocarditis and/or pericarditis after vaccination was 11 days (range: 9–20 days).[1] All individuals who experienced these cardiac events were naïve to vaccinia.1 Of these 10 cases, 2 were hospitalized; none of the remaining 8 required hospitalization or treatment with medication.[1] Of the 10 cases, 8 were subclinical and detected only by ECG abnormalities with or without associated elevations of cardiac troponin I.[1] These cases resolved by 9 months, with the exception of one female in the Dryvax® group who had persistent borderline abnormal left ventricular ejection fraction on ECG.[1]

The best estimate of risk for myocarditis and pericarditis in recipients of replication competent smallpox vaccine live is derived from the phase 3 clinical trials comparing ACAM2000® and Dryvax® where there was active monitoring for potential myocarditis and pericarditis.[1] Among vaccinees naïve to vaccinia, 8 cases of suspected myocarditis and pericarditis were identified across both vaccine groups, for a total incidence rate of 6.9 per 1000 vaccinees (8 out of 1162).[1] The rate for the ACAM2000® group was 5.7 (95% CI: 1.9-13.3) per 1000 vaccinees (5 out of 873 vaccinees) and the rate for the Dryvax® group was 10.4 (95% CI: 2.1-30.0) per 1000 vaccinees (3 out of 289 vaccinees).[1] No cases of myocarditis and/or pericarditis were identified in 1819 previously vaccinated individuals. The long-term outcome of myocarditis and pericarditis following smallpox vaccine live vaccination is currently unknown.[1]

Ischemic cardiac events, including fatalities, have been reported following smallpox vaccination; the relationship of these events, if any, to vaccination has not been established.[1] In addition, cases of non-ischemic, dilated cardiomyopathy have been reported following smallpox vaccination; the relationship of these cases to smallpox vaccination is unknown.[1]

There may be increased risk of adverse events following vaccination with smallpox vaccine live in individuals with known cardiac disease, including those diagnosed with previous myocardial infarction, angina, congestive heart failure, cardiomyopathy,

chest pain or shortness of breath with activity, stroke or transient ischemic attack, or other heart conditions.[1] In addition, risk of adverse events may be increased in individuals who have been diagnosed with 3 or more of the following risk factors for ischemic coronary disease: high blood pressure, elevated blood cholesterol, diabetes mellitus or high blood sugar, first degree relative (e.g., mother, father, brother, sister) who had a heart condition before 50 years of age, or history of smoking cigarettes.[1]

Ocular Complications and Blindness
Accidental infection of the eye (ocular vaccinia) following vaccination with replication competent smallpox vaccine live may result in ocular complications including keratitis, corneal scarring, and blindness.[1] Patients who are using corticosteroid eye drops may be at increased risk of ocular complications.[1]

Congenital or Acquired Immune Deficiency Disorders
Severe localized or systemic infection with vaccinia (progressive vaccinia) may occur following vaccination with replication-competent smallpox vaccine live in individuals with weakened immune systems, including those with leukemia, lymphoma, organ transplantation, generalized malignancy, HIV/AIDS, or cellular or humoral immune deficiency, and those receiving radiation therapy or treatment with antimetabolites, alkylating agents, high-dose corticosteroids (more than 10 mg of prednisone daily or equivalent for 2 weeks or longer), or other immunomodulatory drugs.[1] Smallpox vaccine live is contraindicated in individuals with severe immunodeficiency.[1] Vaccinees with close contacts who have these conditions may be at increased risk because live vaccinia virus can be shed and then transmitted from the vaccinee to these close contacts.[1]

History or Presence of Eczema and Other Skin Conditions
Individuals with eczema of any description, such as atopic dermatitis, neurodermatitis, and other eczematous conditions, regardless of severity of the condition, and individuals who have a history of these conditions at any time in the past, are at higher risk of developing eczema vaccinatum following vaccination with replication-competent smallpox vaccine live.[1] Close contacts who have eczematous conditions may be at increased risk because the live vaccinia virus can be shed and then transmitted from the vaccinee to these close contacts.[1]

Vaccinees with other active acute, chronic, or exfoliative skin disorders (e.g., burns, impetigo, varicella zoster, acne vulgaris with open lesions, Darier's disease, psoriasis, seborrheic dermatitis, erythroderma, pustular dermatitis) or household contacts having such skin disorders might also be at higher risk for eczema vaccinatum.[1]

Hypersensitivity to the Vaccine or its Components
Smallpox vaccine live contains trace amounts of neomycin and polymyxin B.[1] Individuals allergic to these components may be at higher risk for adverse events after vaccination.[1]

Management of Smallpox Vaccination Complications
The US Centers for Disease Control and Prevention (CDC) can assist clinicians in the diagnosis and management of patients with suspected complications of vaccinia (smallpox) vaccination.[1] Vaccinia immune globulin (VIG) is indicated for treatment of certain complications following vaccination with replication-competent smallpox vaccine live. If VIG and/or antivirals are needed or additional information is required, clinicians should contact the CDC emergency operations center at 770-488-7100.[1]

Prevention of Transmission of Live Vaccinia Virus
The most important measure to prevent inadvertent autoinoculation and contact transmission following vaccination with a replication-competent smallpox vaccine live is thorough hand washing after changing the bandage or after any other contact with the vaccination site.[1]

Individuals susceptible to adverse effects of vaccinia virus (i.e., those with cardiac disease, eye disease, immunodeficiency states [including HIV infection], eczema, pregnant women, infants) should be identified and measures should be taken to avoid contact between such individuals and those who have received replication-competent smallpox vaccine live and have active vaccination lesions.[1]

Recently vaccinated healthcare personnel should avoid contact with patients, particularly those with immunodeficiencies, until the scab at the vaccination site has separated from the skin.[1] However, if continued contact with patients is unavoidable, vaccinated healthcare workers should ensure that the vaccination site is well covered and follow good hand-washing technique.[1] In this setting, a more occlusive dressing may be used.[1] Semipermeable polyurethane dressings are effective barriers to shedding of vaccinia. However, exudate may accumulate beneath the dressing, and care must be taken to prevent viral spread when the dressing is changed.[1] In addition, accumulation of fluid beneath the dressing may increase skin maceration at the vaccination site.[1] Accumulation of exudate may be decreased by first covering the vaccination site with dry gauze, then applying the dressing over the gauze.[1] The dressing should be changed every 1–3 days.[1]

Blood and Organ Donation
Blood and organ donation should be avoided for at least 30 days following vaccination with replication-competent smallpox vaccine live.[1]

Laboratory Test Interference
Smallpox vaccine live (ACAM2000®) may induce false-positive tests for syphilis.[1] Positive rapid plasma reagin (RPR) test results should be confirmed using a more specific test, such as the fluorescent treponemal antibody (FTA) assay.[1]

Smallpox vaccine live (ACAM2000®) may induce temporary false-negative results for the tuberculin skin test (purified protein derivative [PPD]) and may also affect blood

tests for tuberculosis.[1] Tuberculin testing should be delayed, if possible, for 1 month following smallpox vaccination.[1]

Limitations of Vaccine Effectiveness
Vaccination with smallpox vaccine live may not protect all recipients following exposure to smallpox.[1]

Specific Populations
Pregnancy
Smallpox vaccine live (ACAM2000®) has not been studied in pregnant women. Live vaccinia virus vaccines can cause fetal harm and fetal death when administered to a pregnant woman.[1] Congenital infection, principally occurring during the first trimester, has been observed after vaccination with replication-competent smallpox vaccine live, although the risk may be low.[1] Generalized vaccinia of the fetus, early delivery of a stillborn infant, or a high risk of perinatal death has been reported.[1]

The only setting in which vaccination of pregnant women should be considered is when exposure to smallpox is considered likely.[1] If smallpox vaccine live is administered to a pregnant woman or if the vaccinee lives in the same household with or has close contact with a pregnant woman, the vaccinee should be apprised of the potential hazard to the fetus.[1] Pregnant women who are close contacts of vaccinees may be at increased risk because live vaccinia virus can be shed and then transmitted to close contacts.[1]

Healthcare providers, state health departments, and other public health staff should report to the National Smallpox Vaccine in Pregnancy Registry all pregnant women who, from 42 days prior to conception onward, received replication-competent smallpox vaccine live or had close contact with an individual who received replication-competent smallpox vaccine live within the previous 28 days.[1] Civilian women should contact their healthcare provider or state health department for help enrolling in the registry.1 All civilian and military cases should be reported to the US Department of Defense by telephone (619-553-9255), the Defense Switched Network (DSN) 553-9255, fax (619-533-7601), or e-mail (NHRC-BirthRegistry@med.navy.mil).[1]

Lactation
Smallpox vaccine live (ACAM2000®) has not been studied in lactating women.[1] It is not known whether vaccine virus or antibodies are distributed into human milk.1

Live vaccinia virus can be inadvertently transmitted from a vaccinated breast-feeding mother to her infant.[1] Infants are at high risk of developing serious complications from live vaccinia smallpox vaccination.[1]

Pediatric Use

The safety and effectiveness of smallpox vaccine live (ACAM2000®) have not been established in the age groups from birth to 16 years of age.[1] The use of the vaccine in all pediatric age groups is supported by evidence from adequate and well controlled studies in adults and additional historical data on use of live vaccinia virus smallpox vaccines in children.[1]

Before the eradication of smallpox disease, live vaccinia smallpox vaccine was administered routinely in all pediatric age groups, including neonates and infants, and was effective in preventing smallpox disease.[1] During that time, live vaccinia virus vaccines were occasionally associated with serious complications in children, the highest risk being in infants younger than 12 months of age.[1]

Vaccinees who have close contact with infants (e.g., breast-feeding) must take precautions to avoid inadvertent transmission of live vaccinia virus to infants.[1]

Geriatric Use
Clinical studies of smallpox vaccine live (ACAM2000®) did not include sufficient numbers of individuals 65 years of age or older to determine whether they respond differently than younger individuals.[1] There are no published data to support use of the vaccine in geriatric individuals older than 65 years of age.[1]

Common Adverse Effects
Information regarding the safety of smallpox vaccine live (ACAM2000®) has been derived from clinical trials evaluating the vaccine, data compiled during the era when routine smallpox vaccination was recommended using previously available replication-competent vaccinia vaccines (e.g., Dryvax®), and adverse event data obtained from military and civilian smallpox vaccination programs during 2002–2005 that used Dryvax®.[1]

Common adverse events following vaccination with replication-competent smallpox vaccine live include inoculation site signs and symptoms, lymphadenitis, and constitutional symptoms (e.g., malaise, fatigue, fever, myalgia, headache).[1] These adverse events are less frequent in revaccinated individuals than in those receiving the vaccine for the first time.[1]

Inadvertent inoculation at other sites is the most frequent complication of replication competent vaccinia vaccination.[1] The most common sites involved are the face, nose, mouth, lips, anus, and genitalia.[1]

Self-limited skin rash (e.g., urticaria and folliculitis) not associated with vaccinia replication in skin may occur following vaccination.[1]

Drug Interactions

It is essential that the manufacturer's labeling be consulted for more detailed

information on interactions with this drug, including possible dosage adjustments.

Interaction highlights:
There are no data evaluating the simultaneous administration of smallpox vaccine live with other vaccines.[1]

Actions

Mechanism of Action

Smallpox vaccine live is a live virus vaccine containing replication-competent vaccinia virus derived from a plaque-purified clone of the New York City Board of Health vaccinia strain.[1] Vaccinia virus and variola virus (causative agent of smallpox) are both orthopoxviruses, and immunity induced by vaccinia virus cross-protects against variola virus.[1]

Smallpox vaccine live does not contain smallpox (variola) virus and cannot spread or cause smallpox.[1]

Following percutaneous administration of smallpox vaccine live (ACAM2000®) using a bifurcated needle, vaccinia virus contained in the vaccine causes a localized virus infection in the epidermis at the site of inoculation, surrounding dermal and subcutaneous tissues, and draining lymph nodes. The vaccine virus may be transiently present in blood and infects reticuloendothelial and other tissues. Langerhans cells in the epidermis are specific targets for the early stage of vaccine virus replication.r1

The formation of a pustule ('pock' or 'take') at the site of inoculation provides evidence of protective immunity.[1] The vaccinia virus replicates within cells and viral antigens are presented to the immune system.[1] Neutralizing antibodies and B and T cells provide long-term memory.[1] Although the level of neutralizing antibody to vaccinia that protects against smallpox is unknown, more than 95% of individuals who receive primary immunization develop neutralizing or hemagglutination inhibiting antibodies to vaccinia.[1]

Advice to Patients

Advise the patient to read the FDA-approved patient labeling (Medication Guide).[1]

Serious Complications of Vaccination

Inform vaccine recipients of the major serious adverse events associated with replication competent smallpox vaccine, including myocarditis and/or pericarditis, progressive vaccinia in immunocompromised individuals, eczema vaccinatum in individuals with skin disorders, auto and accidental inoculation, generalized vaccinia, urticaria, and erythema multiforme major (including Stevens-Johnson syndrome).[1] Inform vaccinees of the risk of fetal vaccinia if administered to pregnant women.[1]

Protecting Contacts at Highest Risk for Adverse Events
Inform vaccine recipients that they should avoid contact with individuals at high risk of serious adverse effects of vaccinia virus, including those with past or present eczema or immunodeficiency states (including HIV infection), pregnant women, and infants younger than 12 months of age.[1]

Self-inoculation and Spread to Close Contacts
Advise vaccine recipients that vaccinia virus is shed from the cutaneous lesion at the vaccination site starting from the time a papule develops (day 2–5) until the scab separates (typically day 14–21).[1] Vaccinia virus shed from the vaccination site may be transmitted by direct physical contact.[1]

Accidental infection of skin at sites other than the vaccination site (self-inoculation) may occur by trauma or scratching.[1] Contact spread may also result in accidental inoculation of household members or other close contacts.[1] The result of accidental infection in the vaccinee or a close contact is a pock lesion(s) at an unwanted site(s) that resembles that at the vaccination site.1

Self-inoculation occurs most often on the face, eyelid, nose, and mouth, but lesions at any site of traumatic inoculation can occur.[1] Self-inoculation of the eye may result in ocular vaccinia, a potentially serious complication.[1]

Care of Vaccination Site and Potentially Contaminated Materials
The vaccination site must be kept completely covered with a semipermeable bandage until the scab falls off on its own.[1]

The vaccination site must be kept dry. Normal bathing may continue, but cover the site with a waterproof bandage when bathing.[1] Do not scrub the vaccination site. Cover the site with loose gauze bandage after bathing.[1]

Do not scratch the vaccination site; do not scratch or pick at the scab.[1]

Do not touch the lesion or soiled bandage and subsequently touch other parts of the body, particularly the eyes and anal and genital areas that are susceptible to accidental autoinoculation.[1]

After changing the bandage or touching the vaccination site, wash hands thoroughly with soap and water or >60% alcohol-based hand-rub solution.[1]

To prevent transmission of the vaccinia virus to contacts, avoid physical contact with objects that have come into contact with the lesion (e.g., soiled bandages, clothing, fingers).[1]

Clothing, towels, bedding, or other items that may have come in direct contact with the

vaccination site or drainage from the site must be washed separately using hot water with detergent and/or bleach.[1] Wash hands afterwards.[1]

Soiled and contaminated bandages must be placed in plastic bags for disposal.[1]

Vaccinee must wear a shirt with sleeves that cover the vaccination site as an extra precaution to prevent spread of the vaccinia virus.[1] This is particularly important in situations of close physical contact.[1]

Vaccinee must change the bandage every 1–3 days; this will keep skin at the vaccination site intact and minimize softening.[1]

Do not put salves or ointments on the vaccination site.[1]

When the scab falls off, throw it away in a sealed plastic bag and wash hands afterwards.[1]

AHFSfirstRelease™. For additional information until a more detailed monograph is developed and published, the manufacturer's labeling should be consulted. It is essential that the manufacturer's labeling be consulted for more detailed information on usual uses, dosage and administration, cautions, precautions, contraindications, potential drug interactions, laboratory test interferences, and acute toxicity.

Preparations

Restricted Distribution

Smallpox vaccine live (ACAM2000®) is stored in the US Strategic National Stockpile (SNS) and is not commercially available in the US.[1,2] The SNS ensures that certain drugs and medical supplies are readily available to prevent or treat specific diseases, including during public health emergencies, and is managed by the US Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR).[3]

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

Smallpox (Vaccinia) Vaccine, Live
For solution, for percutaneous use
1 x 10^8 PFU per mL
ACAM2000® ,
(multiple-dose vial of lyophilized vaccine, vial of diluent, syringe and needle for reconstitution, bifurcated needles for administration)
Emergent BioSolutions

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