Smallpox Vaccine Live (Lexi-Drugs)

ALERT: US Boxed Warning

Collapse All

Myopericarditis, pericarditis:

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 to 13.3) receiving smallpox vaccine.

Other serious adverse reactions:

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 vaccinia virus smallpox vaccines.

These risks are increased in vaccinees 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

Transmission of virus:

Smallpox vaccine 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 for the vaccinee.

Appropriate use:

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

Pronunciation

Vm

P

(SMAL poks vak SEEN)

Brand Names: US

ACAM2000

Pharmacologic Category

Vaccine; Vaccine, Live (Viral)

Dosing: Adult

Collapse All

Monkeypox disease prevention

Monkeypox disease prevention (off-label use):

Percutaneous: Vaccination by scarification (multiple-puncture technique) only; **not** for IM, intradermal, IV, or SUBQ injection. **Note:** A trace of blood should appear at vaccination site after 15 to 20 seconds; if no trace of blood is visible, an additional 3 insertions should be made using the same needle, without reinserting the needle into the vaccine bottle.

Use a single drop of vaccine suspension and 15 needle punctures (using the same bifurcated needle) into the superficial skin; if the patient does not have a major cutaneous reaction after the first dose (by day 6 to 8), a second dose (revaccination) from another vial or vaccine lot may be administered. If there is not a reaction to the second dose, consult the CDC or the state or local health department for further guidance.

Note: For postexposure prophylaxis, administration within 4 days of monkeypox exposure is the most effective. If given 4 to 14 days after exposure, then the vaccine may reduce symptoms but not prevent disease (CDC 2022a).

Smallpox disease prevention

Smallpox disease prevention:

Primary vaccination: Vaccination by scarification (multiple-puncture technique) only; **not** for IM, intradermal, IV, or SUBQ injection. **Note:** A trace of blood should appear at vaccination site after 15 to 20 seconds; if no trace of blood is visible, an additional 3 insertions should be made using the same needle, without reinserting the needle into the vaccine bottle.

Use a single drop of vaccine suspension and 15 needle punctures (using the same bifurcated needle) into the superficial skin; if the patient does not have a major cutaneous reaction after the first dose (by day 6 to 8), a second dose (revaccination) from another vial or vaccine lot may be administered. If there is not a reaction to the second dose, consult the CDC or the state or local health department for further guidance.

Booster dose: The Advisory Committee on Immunization Practices recommends routine nonemergency revaccination every 3 to 10 years, depending on type of exposure (ACIP [Petersen 2016]). Additional information can be obtained from the Department of Defense and the CDC.

Interchangeability: Smallpox and monkeypox vaccine (Jynneos or Imvamune [Canadian product]) may be used as a booster dose for those persons who received a primary series with the smallpox vaccine (ACAM2000) and who are at continued risk for exposure (CDC/ACIP [Rao 2022]; NACI 2022).

* See Dosage and Administration in AHFS Essentials for additional information.

Dosing: Older Adult

Refer to adult dosing.

Dosing: Altered Kidney Function: Adult

There are no dosage adjustments provided in the manufacturer's labeling.

Dosing: Hepatic Impairment: Adult

There are no dosage adjustments provided in the manufacturer's labeling.

Dosing: Pediatric

Note: Dose is administered percutaneously requiring multiple skin punctures; not for IM, intradermal, IV, or SUBQ injection.

Monkeypox disease prevention: Limited data available (CDC 2022a; CDC 2022b; manufacturer's labeling):

Note: Use available for this indication under an expanded access investigational new drug (EA-IND).

Postexposure prophylaxis: **Note:** Administration within 4 days of monkeypox exposure is the most effective. If administered 4 to 14 days after exposure, the vaccine may reduce symptoms but not prevent disease.

Children and Adolescents: ACAM2000: Percutaneous: Vaccination by scarification (multiple-puncture technique): Use a single drop of vaccine suspension (0.0025 mL) and rapidly administer 15 needle punctures using the same bifurcated needle into the superficial skin. A trace of blood should appear at vaccination site.

If the patient does not have a major cutaneous reaction after the first dose (by day 6 to 8), a second dose (revaccination) from another vial or vaccine lot may be administered. If there is not a reaction to the second dose, consult the CDC or the state or local health department for further guidance.

Smallpox disease prevention:

Note: Although only FDA approved in ages ≥16 years, the smallpox vaccine may be used in all ages for postevent exposure or risk of exposure regardless of age. For routine preexposure prophylaxis, smallpox vaccine is not recommended in individuals <18 years of age and is contraindicated in individuals <1 year of age (CDC [Petersen 2015]; CDC/ACIP [Wharton 2003]; manufacturer's labeling).

Primary immunization following exposure or event (CDC [Petersen 2015]; manufacturer's labeling):

Infants, Children, and Adolescents: Limited data available in ages <16 years: ACAM2000: Percutaneous: Vaccination by scarification (multiple-puncture technique): Use a single drop of vaccine suspension (0.0025 mL) and rapidly administer 15 needle punctures using the same bifurcated needle into the superficial skin. A trace of blood should appear at vaccination site.

If the patient does not have a major cutaneous reaction after the first dose (by day 6 to 8), a second dose (revaccination) from another vial or vaccine lot may be administered. If there is not a reaction to the second dose, consult the CDC or the state or local health department for further guidance.

Dosing: Altered Kidney Function: Pediatric

There are no dosage adjustments provided in the manufacturer’s labeling.

Dosing: Hepatic Impairment: Pediatric

There are no dosage adjustments provided in the manufacturer’s labeling.

Use: Labeled Indications

Smallpox disease prevention: Active immunization against smallpox disease in persons determined to be at high risk for smallpox infection.

The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination for the following (ACIP [Petersen 2016]):

• Laboratory workers who directly handle cultures or animals who are contaminated or infected with replication-competent vaccinia virus, recombinant vaccinia viruses derived from replication-competent vaccinia strains or related orthopoxviruses capable of causing infections in humans (eg, monkeypox, cowpox, variola).

• Consideration may also be given for vaccination of health care personnel who currently treat or anticipate treating patients with vaccinia virus infections or whose contact is limited to contaminated materials or administering ACAM2000 smallpox vaccine; adherence to appropriate infection prevention measures is also necessary.

In a pre-event vaccination program, the ACIP recommends vaccination for the following (CDC/ACIP [Wharton 2003):

• Persons designated by authorities (eg, smallpox response teams) to investigate and follow-up on initial smallpox cases with the likelihood of direct patient contact.

• Hospital-based health care teams who provide patient care for smallpox patients.

• Persons responsible for administering smallpox vaccine.

For post-event vaccination, the ACIP recommends vaccination for the following (CDC [Petersen 2015]):

• Persons directly exposed to an accidental or intentional release of the virus.

• Household family members of a patient with confirmed, probable or suspected smallpox or others spending ≥3 hours in the household since the onset of fever.

• Nonhousehold members with ≥3 hours of close contact (<6.5 feet or <2 meters) with a confirmed or suspected smallpox patient with a rash.

• Persons considered at high risk for smallpox infection (including healthcare workers) as defined by public health authorities.

* See Uses in AHFS Essentials for additional information.

Use: Off-Label: Adult

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Monkeypox disease prevention Level of Evidence [C]

The smallpox vaccine may be effective in preventing monkeypox disease in persons at high risk for monkeypox infection. The vaccine is allowed for use against monkeypox under an Expanded Use Access Investigational New Drug (IND) from the FDA ([Ref]).

Pre-exposure prophylaxis:

The Advisory Committee on Immunization Practices recommends vaccination for the following persons at risk for occupational exposure to orthopoxviruses ([Ref]):

- Research laboratory personnel working with orthopoxviruses

- Clinical laboratory personnel performing diagnostic testing for orthopoxviruses

- Designated public health and health care worker response team members

- Health care personnel who administer the live smallpox vaccine (ACAM2000) or who care for patients infected with orthopoxviruses (eg, monkeypox) (per shared clinical decision-making).

Postexposure prophylaxis: The CDC recommends vaccination as postexposure prophylaxis following exposure or possible exposure to monkeypox virus. See current public health updates for recommendations and details ([Ref]).

Level of Evidence Definitions

Collapse All

Level of Evidence Scale

A - Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support the off-label use. Further research is unlikely to change confidence in the estimate of benefit.

B - Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.

C - Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care), unsystematic clinical experience, or from potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.

G - Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.

Clinical Practice Guidelines

ACIP, Smallpox Vaccine in Laboratory and Health Care Personnel, March 2016

ACIP, "General Best Practice Guidelines for Immunization."

CDC, "Considerations for Monkeypox Vaccination," 2022

CDC, "Recommendations for Using Smallpox Vaccine in a Pre-Event Vaccination Program," Supplemental Recommendations April 4, 2003

IDSA, 2013 Clinical Practice Guideline for Vaccination of the Immunocompromised Host, February 2014

NACI/CATMAT, Canadian Immunization Guide, 2017

Administration: Other

Vaccination should only be performed by health care providers trained in the safe and efficacious administration of the smallpox vaccine via the percutaneous route. Do not mix with other vaccines or injections; separate needles and syringes should be used for each injection. To prevent syncope related injuries, patients should be vaccinated while seated or lying down (ACIP [Kroger 2022]).

Vaccination by scarification (multiple-puncture technique) only: Administer by percutaneous injection only; **not** for IM, intradermal, IV, or SUBQ injection. If alcohol is used to clean the skin, allow site to dry completely prior to administration to prevent the inactivation of the vaccine by the alcohol. A single-use bifurcated needle should be dipped carefully into the reconstituted vaccine (following removal of rubber stopper). Visually confirm that the needle picks up a drop of vaccine solution. Using a bifurcated needle, 1 drop of vaccine is introduced into the superficial layers of the skin using a multiple-puncture technique. The skin over the insertion of the deltoid muscle is the preferred site for vaccination. Deposit the drop of vaccine onto clean, dry skin at the vaccination site. Holding the bifurcated needle perpendicular to the skin, punctures are to be made rapidly within a diameter of about 5 mm into the superficial skin of the vaccination site. The puncture strokes should be vigorous enough to allow a trace of blood to appear after approximately 15 to 20 seconds. Wipe off any remaining vaccine with dry sterile

gauze. Dispose of all materials in a biohazard waste container; do not reuse the bifurcated needle. All materials must be burned, boiled, or autoclaved.

To prevent transmission of the virus, avoid scratching the vaccination site and cover with gauze (using first aid adhesive tape to keep gauze in place); cover gauze with a semipermeable barrier (eg, semiocclusive dressing) or clothing. Ointment or salves should not be applied to the vaccination site. Good handwashing prevents inadvertent inoculation. Vaccinees should change bandages away from others and launder their own linens separately to prevent transmission.

Administration: Pediatric

Percutaneous: Vaccination should only be performed by health care providers trained in the safe and efficacious administration of the smallpox vaccine via the percutaneous route (manufacturer's labeling). Do not mix with other vaccines or injections; separate needles and syringes should be used for each injection (ACIP [Kroger 2022]).

Vaccination by scarification (multiple-puncture technique) only: Administer by percutaneous injection only; not for IM, intradermal, IV, or SUBQ injection. If alcohol is used to clean the skin, allow site to dry completely prior to administration to prevent the inactivation of the vaccine by the alcohol. The skin over the insertion of the deltoid muscle or the posterior aspect of the arm over the triceps are the preferred sites for vaccination.

A single-use bifurcated needle should be dipped carefully into the reconstituted vaccine (following removal of rubber stopper). Visually confirm that the needle picks up a drop of vaccine solution. Using a bifurcated needle, introduce 1 drop of vaccine into the superficial layers of the skin using a multiple-puncture technique. Deposit the drop of vaccine onto clean, dry skin at the vaccination site. Holding the bifurcated needle perpendicular to the skin, 15 punctures are to be made rapidly within a diameter of about 5 mm into the superficial skin of the vaccination site. The puncture strokes should be vigorous enough to allow a trace of blood to appear after approximately 15 to 20 seconds. Wipe off any remaining vaccine with dry sterile gauze. Dispose of all materials in a biohazard waste container; do not reuse the bifurcated needle; all materials must be burned, boiled, or autoclaved.

To prevent transmission of the virus, avoid scratching the vaccination site and cover with gauze (using first aid adhesive tape to keep gauze in place); cover gauze with a semipermeable barrier (eg, semiocclusive dressing) or clothing. Ointment or salves should not be applied to the vaccination site. Good handwashing prevents inadvertent inoculation. Vaccinees should change bandages away from others and launder their own linens to prevent transmission. Soiled and contaminated bandages should be placed in plastic bag for disposal.

Storage/Stability

ACAM2000 vaccine: Prior to reconstitution, store frozen at -15°C to -25°C (5°F to -13°F); may also be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 18 months. Following reconstitution, stable for 6 to 8 hours at room temperature of 20°C to 25°C (68°F to 77°F) or for up to 30 days when refrigerated at 2°C to 8°C (36°F to 46°F). The provided diluent should be stored at room temperature of 15°C to 30°C (59°F to 86°F).

Smallpox vaccine (Sanofi Pasteur) (Canadian product): Prior to reconstitution, store frozen at <5°C (<41°F). Following reconstitution, store at 2°C to 8°C (36°F to 46°F) for up to 1 week; do not freeze. The provided diluent should be stored at 2°C to 8°C (36°F to 46°F); do not freeze.

Preparation for Administration: Adult

ACAM2000 vaccine: Bring to room temperature prior to reconstitution. Using the syringe provided, inject 0.3 mL of provided diluent into the vaccine vial. Swirl gently until the solution becomes a slightly hazy, colorless to straw-colored liquid free from particulate matter; avoid contact between the solution and the rubber stopper.

Smallpox vaccine (Sanofi Pasteur) (Canadian product): Add 0.25 mL diluent slowly to the vaccine vial; shake until a uniform, cloudy, off-white to pale yellow suspension results. Slowly inject the reconstituted vaccine into the administration vial.

Preparation for Administration: Pediatric

Percutaneous:

ACAM2000 vaccine: Bring to room temperature prior to reconstitution. Using the syringe provided, inject 0.3 mL of provided diluent into the vaccine vial. Swirl gently until the solution becomes a slightly hazy, colorless to straw-colored liquid; do not use if solution contains particulate matter or is discolored; avoid contact between the solution and the rubber stopper.

Smallpox vaccine (Sanofi Pasteur) (Canadian product): Add 0.25 mL diluent slowly to the vaccine vial; shake until a uniform, cloudy, off-white to pale yellow suspension results; do not use if solution contains particulate matter or is discolored. Slowly inject the reconstituted vaccine into the administration vial.

Medication Patient Education with HCAHPS Considerations

What is this drug used for?

• It is used to prevent smallpox infection.

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

• Pain, redness, or swelling where the shot was given

• Irritation where the shot is given

• Itching

• Feeling tired or weak

• Feeling hot

• Fever or chills

• Headache

• Constipation, diarrhea, throwing up, or upset stomach

• Swollen gland

• Muscle pain

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

• Heart problems like chest pain or pressure, fast heartbeat, a heartbeat that does not feel normal, or breathing problems

• Change in eyesight

• Loss of eyesight

• Seizures

• A burning, numbness, or tingling feeling that is not normal

• If bright lights bother your eyes

• Severe skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes

• Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

Note: This is not a comprehensive list of all side effects. Talk to your doctor if you have questions.

Consumer Information Use and Disclaimer: This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a limited summary of general information about the medicine's uses from the patient education leaflet and is not intended to be comprehensive. This limited summary does NOT include all information available about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not intended to provide medical advice, diagnosis or treatment and does not replace information you receive from the healthcare provider. For a more detailed summary of information about the risks and benefits of using this medicine, please speak with your healthcare provider and review the entire patient education leaflet.

Prescribing and Access Restrictions

Smallpox vaccine is not available for general public use. Supplies are part of the US federal government's Strategic National Stockpile. See the following for additional information:

CDC Drug Service Formulary: https://www.cdc.gov/laboratory/drugservice/formulary.html.

FDA Smallpox Preparedness and Response Updates: https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/smallpox-preparedness-and-response-updates-fda.

CDC Considerations for Monkeypox Vaccination: https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html.

Medication Guide and/or Vaccine Information Statement (VIS)

An FDA-approved patient medication guide, which is available with the product information and at http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142576.pdf, must be dispensed with this medication.

Contraindications

There are very few absolute contraindications regarding vaccination of individuals at high risk for exposure to smallpox. The decision to vaccinate must be based on a careful analysis of potential benefits and possible risks.

US labeling: Severe immune deficiency (eg, persons undergoing bone marrow transplant, individuals with primary or acquired immunodeficiency requiring isolation) not expected to benefit from the vaccine.

Canadian labeling: Hypersensitivity to the vaccine or any component of the formulation; persons <18 years of age, eczema or other significant exfoliative skin conditions, immunosuppression, pregnancy, breastfeeding, heart disease or ≥3 major cardiac risk factors (ie, hypertension, diabetes, hypercholesterolemia, heart disease at 50 years of age in a first-degree relative, smoking), persons with household or other close contacts with eczema or other exfoliative skin conditions (Smallpox vaccine [Sanofi Pasteur] Canadian product monograph).

ACIP contraindications in a pre-event vaccination program: Serious hypersensitivity to the vaccine or any component of the formulation; history or presence of atopic dermatitis, eczema or other acute, chronic or exfoliative skin conditions (or persons with household contacts with these conditions); immunosuppression (or persons with household contacts who are immunosuppressed); pregnancy or breastfeeding (or persons with household contacts who are pregnant); infants <1 year of age (CDC/ACIP [Wharton 2003]).

ACIP contraindications for non-emergent use in laboratory and health care personnel at risk for occupational exposure to orthopoxviruses, see guidelines for details (ACIP [Petersen 2015]):

Primary vaccines, revaccinees, and household contacts: History or presence of atopic dermatitis, other active exfoliative skin conditions, immunosuppression, pregnancy, and infants

Additional contraindications for primary vaccinees and revaccinees: Breast-feeding, serious vaccine component allergy, and known underlying heart disease.

Additional contraindications for primary vaccines only: 3 or more major cardiac risk factors

ACIP contraindications in a post-event situation: There are no absolute contraindications to vaccination (CDC/ACIP [Rotz 2001]; CDC [Petersen 2015]). The following are relative contraindications:

- Severe immunodeficiency including the following: bone marrow transplant transplantation within the previous 4 months, HIV infection with CD4 <50 cells/mm^3 (or AIDS-defining condition if recent CD4 count is unavailable; see guideline for pediatric age specific criteria), severe combined immunodeficiency, complete DiGeorge syndrome, or other severely immunocompromised states requiring isolation (CDC [Petersen 2015])

- High risk for smallpox infection but without known exposure: Hypersensitivity to the vaccine or any component of the formulation, atopic dermatitis, solid organ transplantation within the previous 3 months, bone marrow transplant transplantation within the previous 4 to 24 months, HIV infection with CD4 <50 to 199 cells/mm^3 (see guideline for pediatric age specific criteria), active graft-versus-host disease after transplantation, immunosuppressive therapy, or other immunocompromised state (CDC [Petersen 2015]).

Warnings/Precautions

Concerns related to adverse effects:

• Anaphylactoid/hypersensitivity reactions: Immediate treatment (including epinephrine 1 mg/mL) for anaphylactoid and/or hypersensitivity reactions should be available during vaccine use (ACIP [Kroger 2022]).

• Syncope: Syncope has been reported with use of injectable vaccines and may result in serious secondary injury (eg, skull fracture, cerebral hemorrhage); typically reported in adolescents and young adults and within 15 minutes of vaccination. Procedures should be in place to avoid injuries from falling and to restore cerebral perfusion if syncope occurs (ACIP [Kroger 2022]).

Disease-related concerns:

• Acute illness: The decision to administer or delay vaccination because of current or recent febrile illness depends on the severity of symptoms and the etiology of the disease. Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever) (ACIP [Kroger 2022]). The smallpox vaccine (Sanofi Pasteur) Canadian product monograph recommends postponement of vaccination in persons with acute febrile conditions if used for nonemergency (pre-event) prophylaxis.

• Eczema/exfoliative skin conditions: These patients should not be vaccinated in nonemergency situations, including laboratory and health care personnel at risk for occupational exposure to orthopoxviruses (ACIP [Petersen 2015]; CDC/ACIP [Wharton 2003]).

• Ocular conditions: In a nonemergency situation, the ACIP recommends deferring vaccination in persons with an eye condition requiring steroid treatment until the condition resolves and treatment is complete (CDC/ACIP [Wharton 2003]).

Concurrent drug therapy issues:

• Vaccines: In order to maximize vaccination rates, the ACIP generally recommends simultaneous administration (ie, >1 vaccine on the same day at different anatomic sites) of all age-appropriate vaccines (live or inactivated) for which a person is eligible at a single clinic visit, unless contraindications exist. The ACIP prefers each dose of a specific vaccine in a series come from the same manufacturer

when possible (ACIP [Kroger 2022]). For smallpox vaccine: May be given simultaneously with any inactive and most live vaccines. Varicella vaccine should be administered at least 4 weeks before or after smallpox vaccine, to help interpret any postvaccination rashes that may arise. Tuberculosis screening (PPD skin test) should be administered ≥1 month after smallpox vaccination, to avoid temporary false-negative test results.

Special populations:

• Altered immunocompetence: Use in patients with severe immune deficiency may result in progressive vaccinia and is, therefore, contraindicated by the manufacturer. The ACIP recommends that these patients not be vaccinated in nonemergency situations. In general, live vaccines should be administered ≥4 weeks prior to planned immunosuppression and avoided within 2 weeks of immunosuppression when feasible; live vaccines should not be administered for at least 3 months after immunosuppressive therapy (ACIP [Kroger 2022]; IDSA [Rubin 2014]).

Dosage form specific issues:

• Albumin: Some dosage forms may contain human albumin.

• Neomycin: Products may contain neomycin.

• Polymyxin B: Products may contain polymyxin B.

Special handling:

• Biohazard: Use appropriate precautions for handling and disposal. Personnel responsible for preparation and administration should observe appropriate contact precautions to avoid inadvertent inoculation (eg, wear surgical or protective gloves and avoid contact of vaccine with skin, eyes, or mucous membranes). Dispose of all materials for preparation and administration in a biohazard waste container. All materials must be burned, boiled, or autoclaved. Vaccinees should change bandages away from other people and launder their own linens separately to prevent transmission.

Other warnings/precautions:

• Appropriate use: Patients at greatest risk for adverse reactions from the vaccine are also at increased risk for death from smallpox infection. Recommendations for use in response to bioterrorism are periodically updated by the CDC (www.cdc.gov).

• Blood and organ donation: Patients should be advised not to donate blood or organs for 21 to 30 days following vaccination or until the scab has separated; contacts who have inadvertently contracted vaccinia should avoid donating blood for 14 days (CDC/ACIP [Wharton 2003]).

• Effective immunity: Vaccination may not result in effective immunity in all patients. Response depends upon multiple factors (eg, type of vaccine, age of patient) and may be improved by administering the vaccine at the recommended dose, route, and interval. Vaccines may not be effective if administered during periods of altered immune competence (ACIP [Kroger 2022]).

• Transmission of virus: Virus may be cultured from vaccination sites until scab separates from lesion; viral shedding ceases once the lesion is re-epithelialized (~14 to 21 days after vaccination). Individuals should be instructed to avoid contact with patients at high risk of transmission/adverse effects,

including persons who are breastfeeding and patients with eczema or immunodeficiency during this time.

* See Cautions in AHFS Essentials for additional information.

Warnings: Additional Pediatric Considerations

In the United States, the currently available live smallpox vaccine (ACAM2000) has not been formally studied in patients <16 years of age; however, live smallpox vaccine was previously used routinely in all pediatric age groups (before the eradication of smallpox disease). Live vaccinia virus has been associated with serious complications in pediatric patients, with the highest risk occurring in ages <2 years, based on experience with the previously available vaccine (Dryvax). Complications may include central nervous system disease, including postvaccinial encephalitis. The live smallpox vaccine is not recommended for routine preexposure prophylaxis in individuals <18 years of age, and it is contraindicated in individuals <1 year of age except for emergency use following exposure (CDC [Petersen 2015]; CDC/ACIP [Wharton 2003]; manufacturer's labeling).

Reproductive Considerations

Evaluate pregnancy status prior to vaccination in patients who could become pregnant (CDC/ACIP [Wharton 2003]).

Abstinence or highly effective contraception is recommended following vaccination (CDC/ACIP [Wharton 2003]). Pregnancy should be avoided for at least 4 weeks following vaccination and until the injection site has healed, scabs have fallen off, and a new layer of intact skin has formed (CDC 2022c).

Persons should not donate sperm, oocytes, or embryos for 21 days after smallpox vaccination or until the scab separates spontaneously from the injection site, whichever occurs later. If the scab is removed but not spontaneously separated, donation should be deferred for 2 months. In case of complications from vaccination, donation should be deferred for 14 days after complete resolution of the complications (ASRM/ART 2021).

Pregnancy Considerations

Outcome data following vaccination with smallpox vaccine during pregnancy are available (Badell 2015; CDC 2003; Conlin 2015; Ryan 2008). Vaccination during any trimester of pregnancy may rarely cause fetal vaccinia which may result in fetal or neonatal death or premature birth (CDC 2003). Fetal vaccinia may present as skin lesions or eruptions resembling smallpox; lesions in the fetal lung and liver have been observed in case reports (Badell 2015). Smallpox vaccination is associated with severe adverse events (encephalitis, encephalomyelitis, encephalopathy, progressive vaccinia, generalized vaccinia, severe vaccinial skin infections, erythema multiforme major, eczema vaccinatum); these risks may be increased in patients who are pregnant.

Smallpox disease during pregnancy is also associated with adverse events. Contracting smallpox while pregnant increases the risk of severe maternal disease (including hemorrhagic smallpox) and death; the fatality rate in unvaccinated pregnant patients can be up to 70%. Pregnant health care workers should avoid direct patient care during an initial emergency response to a smallpox outbreak (CDC [Petersen 2015]).

According to the CDC, vaccination of pregnant patients is contraindicated in a pre-event setting, including laboratory and health care personnel at risk for occupational exposure to orthopoxviruses. Persons living in a household with pregnant patients should also not be vaccinated in a pre-event setting; this includes persons who might have prolonged intimate contact with a vaccinee or who have direct contact with the vaccination site (ACIP [Petersen 2016]; CDC/ACIP [Wharton 2003]). Due to the high maternal and fetal mortality associated with maternal smallpox infection, vaccination is recommended in the post-event setting for pregnant patients exposed to smallpox or at high risk for smallpox infection unless a relative contraindication exists (CDC [Petersen 2015]).

The smallpox vaccine (live) is also available for use against monkeypox under an Expanded Use Access IND from the FDA (CDC/ACIP [Rao 2022]; CDC 2022a). Infection with the monkeypox virus may lead to adverse pregnancy outcomes, including spontaneous pregnancy loss, stillbirth, and transmission of the monkeypox virus to the fetus or newborn. When a pregnant patient is diagnosed with monkeypox, neonatal health care providers should be informed of the diagnosis. When pre- or postexposure vaccination for monkeypox is needed during pregnancy, smallpox vaccine (live) should **not** be used (CDC 2022c).

Data collection to monitor pregnancy and infant outcomes following exposure to smallpox vaccine (live) is ongoing. Health care providers may enroll pregnant patients who were inadvertently vaccinated during pregnancy or from 42 days prior to conception onward, or who were a close contact of a vaccinee within the previous 4 weeks of vaccination, in the CDC pregnancy registry by calling 404-639-8253 (CDC/ACIP [Wharton 2003]). All civilian and military cases should be reported to the Department of Defense (619-553-9255 or NHRC-BirthRegistry@med.navy.mil).

Breastfeeding Considerations

It is not known if the vaccine virus or antibodies are present in breast milk.

According to the CDC, vaccination of a breastfeeding person is contraindicated in a nonemergency situation, including laboratory and health care personnel at risk for occupational exposure to orthopoxviruses (CDC/ACIP [Wharton 2003]). Vaccination is recommended in the post-event setting unless a relative contraindication exists. Following maternal vaccination, inadvertent transmission of live vaccinia virus from the vaccine site to infants is a potential risk during bottle or breastfeeding; proper infection control precautions are recommended. Breastfeeding or infant feeding with expressed breast milk should be discontinued if there is a cutaneous breast lesion suspicious for vaccinia virus infection until the lesion heals (CDC [Petersen 2015]). Persons living in a household with a breastfeeding person may be vaccinated; however, they should observe proper precautions to avoid inadvertent secondary transmission (Garde 2004).

The smallpox vaccine (live) is available for use against monkeypox under an Expanded Use Access IND from the FDA (CDC/ACIP [Rao 2022]; CDC 2022a). When pre- or postexposure vaccination for monkeypox is needed in a breastfeeding patient, smallpox vaccine (live) should not be used (CDC 2022c).

Briggs' Drugs in Pregnancy & Lactation

- Vaccine, Smallpox

Adverse Reactions (Significant): Considerations

Collapse All

Cardiovascular effects

Cardiovascular effects, including **myocarditis** and **pericarditis** potentially leading to **cardiomyopathy** (nonischemic/dilated), have been reported following smallpox vaccination ([Ref]). **Ischemic heart disease** has also been rarely reported following smallpox vaccination.

Mechanism: Unknown; potentially due to autoimmune, noninfectious processes ([Ref]).

Onset: Myocarditis/pericarditis: Intermediate; in clinical trials, mean time to symptom onset was 11 days (range: 9 to 20 days).

Risk factors:

• Known cardiac disease (ie, previous myocardial infarction, angina, heart failure, cardiomyopathy, chest pain or shortness of breath with activity, stroke or TIA, other heart conditions)

• Risk factors for ischemic coronary disease (ie, hypertension, hyperlipidemia, diabetes mellitus, first-degree relative diagnosed with heart condition before age 50, current smoker)

• History of myopericarditis of any etiology ([Ref])

CNS effects

CNS effects, including post-vaccination **encephalopathy** and **encephalitis** have been reported following smallpox vaccination. Symptoms may include **headache**, **fever**, **vomiting**, **seizures**, and coma. Encephalopathy (cerebral damage due to vascular changes) is more frequently reported in patients <2 years of age, while encephalitis more commonly impacts patients ≥2 years of age ([Ref]). In clinical trials, **Guillain-Barré syndrome** and **Bell palsy** have also been rarely reported following smallpox vaccination ([Ref]).

Mechanism: Unknown; potentially due to autoimmune process ([Ref]).

Onset: Encephalopathy: Intermediate (6 to 10 days post-vaccination) ([Ref]). Encephalitis: Intermediate (11 to 15 days post-vaccination) ([Ref]).

Risk factors:

• Primary vaccination (as compared to revaccination) ([Ref])

Ocular effects

Ocular complications, including **keratitis**, corneal scarring, and **blindness** have been reported following smallpox vaccination secondary to accidental infection of the eye (ocular vaccinia). Most uncomplicated

accidental inoculation lesions are self-limiting within ~3 weeks, although severe manifestations may require treatment with topical antivirals or vaccinia immune globulin ([Ref]).

Mechanism: Autoinoculation ([Ref]).

Onset: Varied; 7 days to 3 months post-vaccination ([Ref]).

Risk factors:

• Use of corticosteroid eye drops

• Vaccinee or close contact touching eye and/or immunization site ([Ref])

• Contact lens use ([Ref])

• History of pruritic eye disease (eg, allergic conjunctivitis, eyelid eczema) ([Ref])

Skin and systemic reactions

Dermatologic complications, including generalized **vaccinia**, **eczema** vaccinatum, **erythema multiforme,** and **Stevens-Johnson syndrome**, have been reported following smallpox vaccination. Symptoms may include localized or generalized maculopapular, vesicular, pustular, or erosive **skin rash**. Though most cases are self-limiting, severe cases may be life-threatening and require treatment with vaccinia immune globulin ([Ref]).

Onset: Intermediate; 4 to 19 days following vaccination ([Ref])

Risk factors:

• Primary vaccination (as compared to revaccination) ([Ref])

• Eczema vaccinatum: History of atopic dermatitis, neurodermatitis, eczema, or other active acute, chronic or exfoliative skin disorders (eg, burns, impetigo, varicella zoster, acne vulgaris with open lesions, Darier disease, psoriasis, seborrheic dermatitis, erythroderma, pustular dermatitis), or vaccinee with close contact having such skin disorders.

Adverse Reactions

The following adverse drug reactions and incidences are derived from product labeling unless otherwise specified. Adverse reactions reported in adults.

>10%:

Dermatologic: Erythema of skin (18% to 24%), skin rash (6% to 11%; including contact dermatitis [<1%] and urticaria [<1%])

Gastrointestinal: Diarrhea (12% to 16%), nausea (10% to 19%)

Immunologic: Lymph node pain (19% to 57%)

Local: Erythema at injection site (61% to 74%), injection-site pruritus (82% to 92%), pain at injection site (37% to 67%), swelling at injection site (28% to 48%)

Nervous system: Fatigue (34% to 48%), feeling hot (20% to 32%), headache (32% to 50%), malaise (28% to 37%), rigors (12% to 21%)

Neuromuscular & skeletal: Myalgia (27% to 46%)

Miscellaneous: Decreased exercise tolerance (8% to 11%)

1% to 10%:

Gastrointestinal: Constipation (6%), vomiting (3% to 5%)

Hematologic & oncologic: Lymphadenopathy (6% to 8%)

Neuromuscular & skeletal: Arthralgia (≤2%), back pain (≤2%), limb pain (≤2%)

Respiratory: Dyspnea (3% to 4%)

Frequency not defined:

Cardiovascular: Cardiomyopathy (nonischemic/dilated), ischemic heart disease

Gastrointestinal: Abdominal pain, toothache

Local: Injection-site lesion (benign and malignant)

Nervous system: Dizziness, meningitis, pain, peripheral paresthesia, vertigo

Neuromuscular & skeletal: Myelitis

Ophthalmic: Corneal injury (scarring), photophobia

Postmarketing:

Cardiovascular: Myocarditis (Cassimatis 2004), pericarditis (Cassimatis 2004)

Dermatologic: Eczema (vaccinatum) (CDC [Cono 2003]), erythema multiforme (CDC [Cono 2003]), Stevens-Johnson syndrome (CDC [Cono 2003])

Infection: Vaccinia (including generalized, ocular, progressive, skin infection) (CDC [Cono 2003]; Semba 2003)

Nervous system: Bell palsy (Sejvar 2005), encephalitis (Sejvar 2005), encephalopathy (Sejvar 2005), Guillain-Barre syndrome (Sejvar 2005), seizure (Sejvar 2005)

Ophthalmic: Blindness (Semba 2003), keratitis (Semba 2003)

Miscellaneous: Fever (Sejvar 2005)

* See Cautions in AHFS Essentials for additional information.

Allergy and Idiosyncratic Reactions

- Aminoglycoside Allergy

Metabolism/Transport Effects

None known.

Drug Interactions Open Interactions

Note: Interacting drugs may **not be individually listed below** if they are part of a group interaction (eg, individual drugs within "CYP3A4 Inducers [Strong]" are NOT listed). For a complete list of drug interactions by individual drug name and detailed management recommendations, use the Lexicomp drug interactions program by clicking on the "Open Interactions" button above.

Acetaminophen: May diminish the therapeutic effect of Vaccines. Management: Consider avoiding routine prophylactic use of acetaminophen before or during vaccine administration when possible. Acetaminophen is still recommended to treat fevers and/or pain that occurs after vaccination. *Risk D: Consider therapy modification*

Brincidofovir: May diminish the therapeutic effect of Smallpox Vaccine Live. *Risk C: Monitor therapy*

Cladribine: May enhance the adverse/toxic effect of Vaccines (Live). Specifically, the risk of vaccine-associated infection may be increased. Cladribine may diminish the therapeutic effect of Vaccines (Live). *Risk X: Avoid combination*

Corticosteroids (Systemic): May enhance the adverse/toxic effect of Vaccines (Live). Specifically, the risk of vaccine-associated infection may be increased. Corticosteroids (Systemic) may diminish the therapeutic effect of Vaccines (Live). Management: Avoid live vaccines during and for 1 month after therapy with immunosuppressive doses of corticosteroids (equivalent to prednisone > 2 mg/kg or 20 mg/day in persons over 10 kg for at least 2 weeks). Give live vaccines prior to therapy whenever possible. *Risk D: Consider therapy modification*

COVID-19 Vaccine (mRNA): Smallpox Vaccine Live may enhance the adverse/toxic effect of COVID-19 Vaccine (mRNA). Specifically, the risk for myocarditis may be increased. Management: Consider waiting 4 weeks after receipt of the smallpox vaccine before receiving an mRNA COVID-19 vaccine. No minimum interval is necessary between receipt of an mRNA COVID-19 vaccine and the smallpox vaccine. *Risk D: Consider therapy modification*

Dimethyl Fumarate: May enhance the adverse/toxic effect of Vaccines (Live). Specifically, Dimethyl Fumarate may increase the risk of vaccinal infection. Dimethyl Fumarate may diminish the therapeutic effect of Vaccines (Live). Management: Non-US labeling for dimethyl fumarate states that live attenuated vaccine administration is not recommended during treatment. US labeling states that safety and effectiveness of live vaccines administered with dimethyl fumarate has not been assessed. *Risk C: Monitor therapy*

Dupilumab: May enhance the adverse/toxic effect of Vaccines (Live). *Risk X: Avoid combination*

Elivaldogene Autotemcel: May enhance the adverse/toxic effect of Vaccines. Specifically, there may be a greater risk for contracting an infection from any live vaccine. Elivaldogene Autotemcel may diminish the therapeutic effect of Vaccines. Management: Administration of vaccines is not recommended in the 6 weeks before myeloablative conditioning, and until hematologic recovery after elivaldogene autotemcel treatment. *Risk X: Avoid combination*

Immune Globulins: May diminish the therapeutic effect of Vaccines (Live). Management: Live organism vaccination should be withheld for as long as 6 to 11 months following immune globulin administration. Recommendations vary by product and immune globulin dose, see full monograph for details. *Risk D: Consider therapy modification*

Immunosuppressants (Cytotoxic Chemotherapy): May enhance the adverse/toxic effect of Vaccines (Live). Specifically, the risk of vaccine-associated infection may be increased. Vaccines (Live) may diminish the therapeutic effect of Immunosuppressants (Cytotoxic Chemotherapy). *Risk X: Avoid combination*

Immunosuppressants (Miscellaneous Oncologic Agents): May enhance the adverse/toxic effect of Vaccines (Live). Specifically, the risk of vaccine-associated infection may be increased. Immunosuppressants (Miscellaneous Oncologic Agents) may diminish the therapeutic effect of Vaccines (Live). *Risk X: Avoid combination*

Immunosuppressants (Therapeutic Immunosuppressant Agents): Vaccines (Live) may enhance the adverse/toxic effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). Specifically, the risk of vaccine-associated infection may be increased. Vaccines (Live) may diminish the therapeutic effect of Immunosuppressants (Therapeutic Immunosuppressant Agents). *Risk X: Avoid combination*

Methotrexate: May enhance the adverse/toxic effect of Vaccines (Live). Methotrexate may diminish the therapeutic effect of Vaccines (Live). Management: Low-dose methotrexate (0.4 mg/kg/week or less) is not considered sufficiently immunosuppressive to create vaccine safety concerns. Higher doses of methotrexate should be avoided. *Risk D: Consider therapy modification*

Propacetamol: May diminish the therapeutic effect of Vaccines. Management: Consider avoiding routine prophylactic use of propacetamol before or during vaccine administration when possible. Propacetamol is still recommended to treat fevers and/or pain that occurs after vaccination. *Risk D: Consider therapy modification*

Rabies Immune Globulin (Human): May diminish the therapeutic effect of Vaccines (Live). Management: Avoid administering the measles vaccine within 4 months after administration of rabies immune globulin. Avoid administering other live vaccines within 3 months after administration of rabies immune globulin. *Risk D: Consider therapy modification*

RiTUXimab: May enhance the adverse/toxic effect of Vaccines (Live). Specifically, the risk of vaccine-associated infection may be increased. RiTUXimab may diminish the therapeutic effect of Vaccines (Live). *Risk X: Avoid combination*

Tecovirimat: May diminish the therapeutic effect of Smallpox Vaccine Live. *Risk C: Monitor therapy*

Tezepelumab: May enhance the adverse/toxic effect of Vaccines (Live). *Risk X: Avoid combination*

Tildrakizumab: May enhance the adverse/toxic effect of Vaccines (Live). The risk for contracting an infection from the vaccine may be increased. Tildrakizumab may diminish the therapeutic effect of Vaccines (Live). *Risk X: Avoid combination*

Tralokinumab: May enhance the adverse/toxic effect of Vaccines (Live). *Risk X: Avoid combination*

Tuberculin Tests: Vaccines (Live) may diminish the diagnostic effect of Tuberculin Tests. Management: It is preferable to administer live vaccines simultaneously with tuberculin tests. If a live vaccine has been recently administered, the tuberculin skin test should be administered 4 to 6 weeks following the administration of the vaccine. *Risk D: Consider therapy modification*

Vaccines (Live): May diminish the therapeutic effect of other Vaccines (Live). Management: Two or more injectable or nasally administered live vaccines not administered on the same day should be separated by at least 28 days (ie, 4 weeks). If not, the vaccine administered second should be repeated at least 4 week later. *Risk C: Monitor therapy*

Varicella Virus Vaccine: Smallpox Vaccine Live may enhance the adverse/toxic effect of Varicella Virus Vaccine. It may be difficult to determine which vaccine caused skin lesions or other adverse effects. Management: Separate the administration of smallpox and varicella vaccines by at least 4 weeks. *Risk D: Consider therapy modification*

Test Interactions

Rapid plasma reagin (RPR) test: Smallpox vaccine may induce false-positive RPR test for syphilis; confirm positive RPR test using a more specific test (eg, FTA assay).

Tuberculin skin (PPD) and blood tests: Smallpox vaccine may diminish the diagnostic utility of tuberculin skin (PPD) and blood tests; avoid skin test for ≥1 month after vaccine to prevent false-negative results.

Monitoring Parameters

Monitor for anaphylaxis and syncope for 15 minutes following administration (ACIP [Kroger 2022]). If seizure-like activity associated with syncope occurs, maintain patient in supine or Trendelenburg position to reestablish adequate cerebral perfusion.

Evaluate pregnancy status prior to vaccination in females of reproductive potential (CDC/ACIP [Wharton 2003]).

Primary vaccination: Monitor vaccination site; inspect after 6 to 8 days. Evidence of a major reaction (vesicular or pustular lesion or an area of palpable induration surrounding a central lesion) confirms success of vaccination. An equivocal reaction (all responses other than a major reaction) requires revaccination in patients undergoing primary vaccination only.

Booster dose: Successful vaccination is confirmed when a major cutaneous reaction is observed 6 to 8 days postvaccination. Prior vaccination may reduce the cutaneous response and does not necessarily indicate a vaccination failure.

Advanced Practitioners Physical Assessment/Monitoring

US federal law requires entry into the patient's medical record. State and local governments are encouraged to keep a list of those “first responders” vaccinated against smallpox. Instruct patient regarding vaccine site care until scabbed over. Observe for syncope for 15 minutes after administration. Monitor injection site: the site will initially have some blood drops, then develop into a red bump, then become a blister with purulent drainage that will drain. Monitor patient for symptoms of encephalitis, myocarditis, pericarditis, vision changes, and severe skin reactions.

Nursing Physical Assessment/Monitoring

US federal law requires entry into the patient's medical record. State and local governments are encouraged to keep a list of those “first responders” vaccinated against smallpox. Instruct patient regarding vaccine site care until scabbed over. Monitor injection site: the site will initially have some blood drops, then develop into a red bump, then become a blister with purulent drainage that will drain. Instruct patients to report any of these signs or symptoms severe skin reactions, vision changes, abnormal heartbeat, breathing problems, seizures, or numbness or tingling.

Dosage Forms: US

Excipient information presented when available (limited, particularly for generics); consult specific product labeling. [DSC] = Discontinued product

Injection, powder for reconstitution [purified monkey cell source]:

ACAM2000: 1-5 x 10^8 plaque-forming units per mL [contains polymyxin B, neomycin (trace amounts) and human albumin; packed with diluent, tuberculin syringes for reconstitution, and 100 bifurcated needles for administration]

Generic Available (US)

No

Mechanism of Action

Vaccinia virus is similar in some respects to the variola (smallpox) virus. By inducing a localized infection with vaccinia virus, immunity to both vaccinia and variola is achieved. Vaccination results in viral replication, production of neutralizing antibodies, immunity, and cellular hypersensitivity.

Efficacy: Neutralizing or hemagglutination-inhibiting antibodies against vaccinia develop in more than 95% of individuals after primary vaccination and may be boosted on revaccination (CDC/ACIP [Rotz 2001]).

Pharmacokinetics

Onset of action: Neutralizing antibodies appear 15-20 days after vaccination; time to appearance of neutralizing antibodies may be shorter (~7 days) following revaccination (CDC/ACIP [Rotz 2001]).

Duration of action: For 75% of patients, neutralizing antibody titers (>1:10) persisted for 10 years after receiving second doses and <30 years after receiving 3 doses of vaccine (CDC/ACIP [Rotz 2001]).

Dental: Local Anesthetic/Vasoconstrictor Precautions

No information available to require special precautions

Dental: Effects on Dental Treatment

No significant effects or complications reported

Dental: Effects on Bleeding

No information available to require special precautions

Related Information

- Centers for Disease Control and Prevention (CDC) and Other Links
- Immunization Administration Recommendations

Pharmacotherapy Pearls

Initial reaction of the percutaneously administered vaccine includes formation of a papule (2 to 5 days following vaccination). The papule forms a vesicle on day 5 or day 6, which becomes pustular, with surrounding erythema and induration. The maximal area of erythema usually occurs between day 8 and day 10, and crusting of the lesion normally occurs between day 14 and day 21. Formation of a major cutaneous reaction in patients undergoing primary vaccination by day 6 to 8 is indicative of successful acquisition of protective immunity. In patients previously vaccinated, the major cutaneous reaction typically seen by day 6 to 8 may be modified and/or reduced. At the peak of the reaction, systemic symptoms (fever, malaise) and lymphadenopathy may occur. All materials used in vaccination must be burned, boiled, or autoclaved. Vaccination can decrease the rate of severe or fatal smallpox if administered during the first 4 days of exposure.

Vaccinia immune globulin (VIG) is available from the CDC for the treatment of severe adverse reactions; administration of VIG does not blunt response to vaccination.

Index Terms

Live Smallpox Vaccine; Vaccinia Vaccine

FDA Approval Date

August 31, 2007

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Brand Names: International

ACAM2000 (AU); En Zai Shi (CN); Imvanex (CZ, DE, DK, EE, HR, LT, LV, MT, NL, PL, PT, SK); Ospavir (RU); TEOVac (RU)

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