

# Smallpox and Monkeypox Vaccine Live

**AHFS Class:** 80:12 (tofc-80) – Vaccines

## Smallpox and Monkeypox Vaccine Live (*AHFS Essentials*)

**Smallpox and Monkeypox Vaccine, Live, Non-replicating**

**Synonym:** Imvamune

**Synonym:** Imvanex

**Brands:** Jynneos®

---

### Introduction

Smallpox and monkeypox vaccine live is a live, attenuated, non-replicating virus vaccine produced using modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus.<sup>1</sup>

---

### Uses

#### ■ Smallpox and monkeypox vaccine live has the following uses:

Smallpox and monkeypox vaccine live is indicated for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.<sup>1</sup>

---

### Dosage and Administration

#### ■ General

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

Suspension, for subcutaneous use: Single-dose vial containing one 0.5-mL dose.<sup>1</sup>

#### ■ Dosage

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

## Adults

### Dosage and Administration.

For subcutaneous injection only, preferably into the deltoid.<sup>1</sup>  
Administer 2 doses (0.5 mL each) 4 weeks apart.<sup>1</sup>

---

## Cautions

### ■ **Contraindications**

None.<sup>1</sup>

### ■ **Warnings/Precautions**

#### *Severe Allergic Reactions*

Appropriate medical treatment must be available to manage possible anaphylactic reactions following administration of smallpox and monkeypox vaccine live.<sup>1</sup>

Individuals who experienced a severe allergic reaction following a previous dose of smallpox and monkeypox vaccine live or following exposure to any component of the vaccine may be at increased risk for severe allergic reactions to smallpox and monkeypox vaccine live. The risk for a severe allergic reaction should be weighed against the risk for disease due to smallpox or monkeypox.<sup>1</sup>

#### *Altered Immunocompetence*

Immunocompromised individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to smallpox and monkeypox vaccine live.<sup>1</sup>

Because smallpox and monkeypox vaccine live contains non-replicating virus, the vaccine can be used in adults with certain immunodeficiencies or conditions, such as human immunodeficiency virus (HIV) infection or atopic dermatitis.<sup>2</sup>

#### *Limitations of Vaccine Effectiveness*

Vaccination with smallpox and monkeypox vaccine live may not protect all recipients.<sup>1</sup>

For primary immunization, smallpox and monkeypox vaccine live is administered in a series of 2 doses given 4 weeks apart;<sup>1</sup> full immunity may not develop until 2 weeks after the second dose.<sup>2</sup>

#### *Specific Populations*

##### Pregnancy.

*Risk Summary:* Available human data on smallpox and monkeypox vaccine live administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively.<sup>1</sup>

The effect of smallpox and monkeypox vaccine live on embryofetal and postnatal development was evaluated in 4 developmental toxicity studies conducted in female rats and rabbits. These animal studies revealed no evidence of harm to the fetus.<sup>1</sup>

*Animal Data:* Developmental toxicity studies were conducted in female rats and rabbits. In one study, female rabbits were administered a single human dose of smallpox and monkeypox vaccine live (0.5 mL) by the subcutaneous route on three occasions (prior to mating and on gestation days 0 and 14). In three studies, female rats were administered a single human dose of smallpox and monkeypox vaccine live (0.5 mL) by the subcutaneous route on two or three occasions (prior to mating and on gestation days 0 and 14; prior to mating and on gestation day 0; or on gestation days 0 and 6). No vaccine-related fetal malformations or variations and no adverse effects on female fertility or pre-weaning development were reported in these studies.<sup>1</sup>

### **Lactation.**

*Risk Summary:* It is not known whether smallpox and monkeypox vaccine live is distributed in human milk. Data are not available to assess the effects of smallpox and monkeypox vaccine live on the breast-fed infant or on milk production/distribution.<sup>1</sup>

The developmental and health benefits of breast-feeding should be considered along with the mother's clinical need for smallpox and monkeypox vaccine live and any potential adverse effects on the breast-fed infant from the vaccine or from the underlying maternal condition. For preventive vaccines, the underlying condition is susceptibility to disease prevented by the vaccine.<sup>1</sup>

### **Pediatric Use.**

Safety and effectiveness of smallpox and monkeypox vaccine live have not been established in individuals younger than 18 years of age.<sup>1</sup>

### **Geriatric Use.**

Clinical studies of smallpox and monkeypox vaccine live did not include sufficient numbers of adults 65 years of age and older to determine whether they respond differently than younger individuals.<sup>1</sup>

In one clinical study, 42 adults 65–80 years of age previously vaccinated with a smallpox vaccine received at least one dose of smallpox and monkeypox vaccine live.<sup>1</sup>

## **■ Common Adverse Effects**

Healthy adults not previously vaccinated with a smallpox vaccine: Most common (>10%) solicited injection site reactions were pain (85%), redness (61%), swelling (52%), induration (45%), and itching (43%); most common solicited systemic adverse reactions were muscle pain (43%), headache (35%), fatigue (30%), nausea (17%), and chills (10%).<sup>1</sup>

Healthy adults previously vaccinated with a smallpox vaccine: Most common (>10%) solicited injection site reactions were redness (81%), pain (80%), induration (70%), swelling (67%), and itching (32%); most common solicited systemic adverse reactions were fatigue (34%), headache (28%), and muscle pain (22%).<sup>1</sup>

Adults with HIV infection or atopic dermatitis: Frequencies of solicited local and systemic adverse reactions were generally similar to those observed in healthy adults.<sup>1</sup>

---

## Interactions

### ■ Specific Drugs

**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:**

Please see product labeling for drug interaction information.

---

## Actions

### ■ Mechanism of Action

Smallpox and monkeypox vaccine live is a live, attenuated, non-replicating virus vaccine that contains a modified vaccinia virus (MVA-BN) and elicits humoral and cellular immune responses to orthopoxviruses.<sup>1</sup> Vaccinia virus, variola virus (causative agent of smallpox), and monkeypox virus are all orthopoxviruses.<sup>2</sup>

Smallpox and monkeypox vaccine live does not contain smallpox (variola) virus and cannot cause smallpox.<sup>4</sup>

Vaccinia neutralizing antibody responses in humans following vaccination with smallpox and monkeypox vaccine live were evaluated to establish the effectiveness of the vaccine for prevention of smallpox and monkeypox.<sup>1</sup>

Effectiveness of smallpox and monkeypox vaccine live against smallpox was inferred by comparing the immunogenicity of the vaccine to smallpox vaccine live (ACAM2000<sup>®</sup>) based on a plaque reduction neutralization test (PRNT) using the Western Reserve strain of vaccinia virus and was supported by efficacy data from animal challenge studies.<sup>1</sup>

Effectiveness of smallpox and monkeypox vaccine live against monkeypox was inferred from the immunogenicity of the vaccine in a clinical study and efficacy data from animal challenge studies.<sup>1</sup>

---

## Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from MedlinePlus ([https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus&query=Smallpox and Monkeypox Vaccine Live](https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus&query=Smallpox%20and%20Monkeypox%20Vaccine%20Live)) (in English and Spanish; written at a 6th- to 8th-grade reading level).

Inform vaccine recipient of the potential benefits and risks of vaccination with smallpox and monkeypox vaccine live.<sup>1</sup>

Inform vaccine recipient of the importance of completing the 2-dose vaccination series.<sup>1</sup>

Advise vaccine recipient to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System (VAERS) at 800-822-7967 or [Web] (<http://www.vaers.hhs.gov>).<sup>1</sup>

**AHFS *firstRelease*™. 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

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

Smallpox and monkeypox vaccine live is stored in the US Strategic National Stockpile (SNS).<sup>2</sup> 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).<sup>3</sup>

### **Smallpox and Monkeypox Vaccine, Live, Non-replicating**

**(<https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?>**

**sugg=NonProprietaryName&ApptName=Smallpox and Monkeypox Vaccine Live&collapse=1)**

### **Parenteral**

*Suspension, for subcutaneous use*

0.5 × 10<sup>8</sup> to 3.95 × 10<sup>8</sup> infectious units of MVA-BN live virus per 0.5 mL

**Jynneos®**, Bavarian Nordic A/S

(<https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?>

sugg=LabelerName&ApptName=Bavarian Nordic A/S&collapse=1)

---

## Related Resources

AHFS Patient Medication Information (<https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus&query=Smallpox and Monkeypox Vaccine Live>) and other related patient health topics (MedlinePlus)

ASHP Drug Shortages Resource Center (<https://www.ashp.org/Drug-Shortages>)

CCRIS (<https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+ccris:%22Smallpox and Monkeypox Vaccine Live%22>) (Chemical Carcinogenesis Research Information System)

ChemIDplus (<https://chem.nlm.nih.gov/chemidplus/name/Smallpox and Monkeypox Vaccine Live>)

Biochemical Data Summary (<http://www.drugbank.ca/unearth/q?utf8=%E2%9C%93&query=Smallpox and Monkeypox Vaccine>)

Live&searcher=drugs&approved=1&vet\_approved=1&nutraceutical=1&illicit=1&withdrawn=1&inve:  
(US and Canada)

Clinical Trials (<https://www.clinicaltrials.gov/ct/search?submit=Search&term=Smallpox and Monkeypox Vaccine Live>)

DailyMed (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?query=Smallpox and Monkeypox Vaccine Live>) (drug labels)

DART (<https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+dart:%22Smallpox and Monkeypox Vaccine Live%22>) (Developmental and Reproductive Toxicology Database)

Drugs@FDA (<https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&SearchType=BasicSearch&SearchTerm=Smallpox and Monkeypox Vaccine Live>) (approval information)

European Medicines Agency ([https://www.ema.europa.eu/en/search/search?search\\_api\\_views\\_fulltext=Smallpox and Monkeypox Vaccine Live](https://www.ema.europa.eu/en/search/search?search_api_views_fulltext=Smallpox and Monkeypox Vaccine Live))

FDA National Drug Code Directory (<https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=Smallpox and Monkeypox Vaccine Live&collapse=1>)

FDA Recalls, Market Withdrawals, and Safety Alerts (<https://www.fda.gov/Safety/Recalls/default.htm>)

HSDB (<https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:%22Smallpox and Monkeypox Vaccine Live%22>) (Hazardous Substances Data Bank)

Inxight Drugs (<https://drugs.ncats.io/substances?q=%22Smallpox and Monkeypox Vaccine Live%22>) (National Center for Advancing Translational Sciences)

LactMed (drug effects on breastfeeding) (<https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+lactmed:@or+%28@na+%22Smallpox and Monkeypox Vaccine Live%22+%29>)

New Drug Approvals (<http://ahfs.ashp.org/drug-assignments.aspx>)

Orange Book (<https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?panel=0&drugname=Smallpox and Monkeypox Vaccine Live>) (therapeutic equivalence)

PharmGKB (<https://www.pharmgkb.org/search?connections&gaSearch=Smallpox and Monkeypox Vaccine Live&query=Smallpox and Monkeypox Vaccine Live&type=chemical>) (Pharmacogenomic data from PharmGKB)

Pillbox (*beta*) ([https://pillbox.nlm.nih.gov/pillimage/search\\_results.php?submit=Search&splid=&getingredient=Smallpox and Monkeypox Vaccine Live](https://pillbox.nlm.nih.gov/pillimage/search_results.php?submit=Search&splid=&getingredient=Smallpox and Monkeypox Vaccine Live)) (drug identification and images)

PubMed (<https://www.ncbi.nlm.nih.gov/pubmed?DB=pubmed&term=Smallpox and Monkeypox Vaccine Live%5BAll+Fields%5D>) (scientific journals)

Safety-related Labeling Changes (<https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges>) (FDA/CDER)

ToxLine (<https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+toxline:%22Smallpox and Monkeypox Vaccine Live%22>) (Toxicology Literature Online)

AHFS<sup>®</sup> DI Essentials™. © Copyright, 2004-2022, American Society of Health-System Pharmacists<sup>®</sup>, 4500 East-West Highway, Suite 900, Bethesda, MD 20814.

Original Publication Date: March 22, 2021.

Database Extraction: 02/16/2022 02:41:30 -0500+

# References

1. Bavarian Nordic A/S. Jynneos<sup>®</sup> (smallpox and monkeypox vaccine, live, non-replicating) suspension for subcutaneous injection prescribing information. 2019 Sep.
2. US Centers for Disease Control and Prevention. Smallpox and monkeypox. From CDC website. Accessed 2021 Feb 6. [Web] (<https://www.cdc.gov/smallpox/clinicians/vaccines.html>)
3. US Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response (ASPR). Strategic National Stockpile. From Public Health Emergency website. Accessed 2021 Feb 6. [Web] (<https://www.phe.gov/about/sns/Pages/default.aspx>)
4. Petersen BW, Damon IK, Pertowski CA et al. Clinical guidance for smallpox vaccine use in a postevent vaccination program. *MMWR Recomm Rep*. 2015; 64:1-26. [PubMed] (<https://www.ncbi.nlm.nih.gov/pubmed/25695372?dopt=AbstractPlus>)

## About ASHP

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's nearly 55,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP's website (<https://www.ashp.org>), or its consumer website (<https://www.safemedication.com>).

## Contact Us


ASHP  
4500 East-West Highway, Suite 900  
Bethesda, Maryland 20814

### Customer Service

1-866-279-0681

[custserv@ashp.org](mailto:custserv@ashp.org) (<mailto:custserv@ashp.org>)

[softwaresupport@ashp.org](mailto:softwaresupport@ashp.org) (<mailto:softwaresupport@ashp.org>)

© 2022. American Society of Health-System Pharmacists. All Rights Reserved. | Copyright (<http://www.ashp.org/copyright>) | Trademark (<http://www.ashp.org/trademark>) | Privacy Policy (<http://www.ashp.org/privacy>) |  (<https://itunes.apple.com/us/app/ahfs-clinical-drug-information/id1068281731>)