

02/2025

IMPORTANT PRESCRIBING INFORMATION

Subject: ACAM2000® [Smallpox and Mpox (Vaccinia) Vaccine, Live] supplied in vials, cartons and cases with previously approved labels

Dear Health Care Provider:

The purpose of this letter is to notify you that you have received ACAM2000 supplied in vials, cartons, and cases with previously approved labels.

The previously approved labels do not include:

- The revised nonproprietary name for ACAM2000: Smallpox and Mpox (Vaccinia) Vaccine, Live
- The revised names for the two components of ACAM2000 (i.e., Lyophilized Antigen Component, Live and Diluent Component).

The previously approved labels include the previous nonproprietary name for ACAM2000: Smallpox (Vaccinia) Vaccine, Live and refer to the Diluent Component as “Diluent for Smallpox (Vaccinia) Vaccine, Live, ACAM2000®.”

The components of ACAM2000 have not changed despite the revised names. The revised names for the vaccine components are used in the US Prescribing Information (USPI) including in the Dosage and Administration and the How Supplied/Storage and Handling sections. Complete reconstitution instructions and storage and handling are described in the USPI.

You will continue to receive ACAM2000 components packaged with the previously approved vial, carton, and case labels until this supply is depleted or expired.

The ACAM2000 nonproprietary name was revised when the indication for ACAM2000 vaccine was expanded on August 29, 2024, to include the prevention of mpox disease in individuals determined to be at high risk for mpox infection. This required revisions to the USPI and Medication Guide to include the new nonproprietary name and indication. Updates were also made to the Dosage and Administration and How Supplied/Storage and Handling sections of the USPI. Changes were made to the product packaging labelling (vial, carton and case labels) to make them consistent with the USPI.

Indications and Usage

ACAM2000 is a vaccine indicated for active immunization for the prevention of smallpox and mpox disease in individuals determined to be at high risk for smallpox or mpox infection.

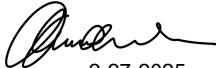
Reporting Adverse Events

Report adverse events following use of ACAM2000 to Emergent BioSolutions at 1-877-246-8472 and medicalinformation@ebsi.com or to VAERS at 800-822-7967 and <https://vaers.hhs.gov>.

You may contact our medical information department if you have any questions about the information contained in this letter or the safe and effective use of ACAM2000 at 1-877-246-8472 or medicalinformation@ebsi.com

This letter is not intended as a complete description of the benefits and risks related to the use of ACAM2000; please refer to the enclosed full prescribing information and Medication Guide.

Sincerely,



2-27-2025

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Director, Safety Physician

Emergent BioSolutions