

ACAM2000[™] (smallpox and mpox (vaccinia) vaccine, live) – New indication

- On August 29, 2024, [Emergent BioSolutions announced](#) the [FDA approval](#) of [ACAM2000 \(smallpox and mpox \(vaccinia\) vaccine, live\)](#), for active immunization for the prevention of smallpox and mpox disease in individuals determined to be at high risk for smallpox or mpox (previously called monkeypox) infection.
 - ACAM2000 was previously approved only for the prevention of smallpox disease.
- The approval of ACAM2000 for the new indication was based on its effectiveness for the prevention of smallpox and efficacy in animal challenge studies. Animals were administered placebo (ACAM2000 diluent component), ACAM2000 or Dryvax (previously available smallpox vaccine) percutaneously (approximately 0.0025 mL each via scarification) on day 0. On day 61, all animals were challenged with an intravenous injection of mpox virus (3.8×10^7 PFU).
 - All of the animals vaccinated with ACAM2000 or Dryvax survived vs. 0% of animals that received placebo.
- ACAM2000 carries a boxed warning for serious complications including myocarditis, pericarditis, encephalitis, severe skin reactions, and other serious reactions. The risk for experiencing severe vaccination complications must be weighed against the risk for experiencing a potentially severe or fatal smallpox or mpox infection. ACAM2000 use is contraindicated in individuals with severe immunodeficiency
- The recommended dose of ACAM2000 for the prevention of smallpox or mpox disease should be administered as follows: the bifurcated end of the needle should be submerged in the reconstituted vaccine solution. The needle will pick up a droplet of vaccine (approximately 0.0025 mL) within the fork of the bifurcation. The droplet of vaccine should be deposited onto the clean, dry skin of the arm prepared for vaccination. The vaccinator should rapidly make 15 jabs of the needle perpendicular to the skin through the vaccine droplet to puncture the skin, within a diameter of about 5 mm.
 - Refer to the [ACAM2000's drug label](#) for additional administration instructions.
- Currently, ACAM2000 is not available to the general public, and is supplied to the [U.S. Strategic National Stockpile](#).