

Approval Date: [May 2, 2017](#)

Product: ACAM2000

Proper Name: Smallpox (Vaccinia) Vaccine, Live

Manufacturer: Emergent Product Development Gaithersburg, Inc.

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

Description of Product:

ACAM2000, Smallpox (Vaccinia) Vaccine, Live, is a live vaccinia virus derived from plaque purification cloning from Dryvax® (Wyeth Laboratories, Marietta, PA, calf lymph vaccine, New York City Board of Health Strain) and grown in African Green Monkey kidney (Vero) cells and tested to be free of adventitious agents.

BLA: BL 125158

Regulatory Milestone: No data available

PDUFA Goal Date: No data available

Package Insert: [ACAM 2000](#)

Summary Basis for Regulatory Approval: [BLA Clinical Review Memorandum](#)

European Public Assessment Report: No data available

Advisory Committee: No data available

Safety: No data available

NCT Numbers:

- NCT00005916
- NCT00189943
- NCT00042094
- NCT00038987
- NCT00046397
- NCT00050505
- NCT00053482
- NCT00053495
- NCT00053742
- NCT00189956
- NCT00063856
- NCT00189969
- NCT00079820
- NCT00032708
- NCT00189917
- NCT00082446
- NCT00466245
- NCT00189904
- NCT00258947
- NCT00133575
- NCT00261001
- NCT00316524
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- NCT00336635
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- NCT00614731
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- NCT01317238
- NCT01144637
- NCT01668537
- NCT01827371
- NCT02038881
- NCT01913353
- NCT02743455
- NCT03699124
- NCT00026611
- NCT00068198
- NCT00050518
- NCT00002261
- NCT00000767
- NCT00001043

EudraCT Numbers: No data available

Publications:

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