

ACAM2000[®] Smallpox (Vaccinia) Vaccine, Live Deployment Guidance - DoD

Acambis Inc.

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Information contained in this guidance will also be available through Acambis, in the event that questions, concerns, or product complaints are received from any source.

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1. CURRENT DEPLOYMENT SOP – DIFFERENCES BETWEEN ACAM2000® AND DRYVAX®

- The bifurcated needles used for the Dryvax and ACAM2000 are identical in design, production, delivery, and packaging.
- ACAM2000 bifurcated needles will have an expiration date, Dryvax bifurcated needles will not have an expiration date.
- One vial of ACAM2000 contains approximately 100 doses.
- The amount of diluent in the vial for ACAM2000 is different than the amount of diluent in the vial for Dryvax.
- Once reconstituted, ACAM2000 and Dryvax have different storage requirements.
- There may be other differences. Please read this guide, as well as the Package Insert for ACAM2000 to become familiar with the appropriate storage, shipping, reconstitution, and administration requirements.

2. RECONSTITUTION INSTRUCTIONS

Personnel preparing and administering the vaccine should wear surgical or protective gloves and avoid contact of vaccine with skin, eyes or mucous membranes.

ACAM2000 is reconstituted by addition of 0.3 mL of diluent to the vial containing lyophilized vaccine. ACAM2000 should only be reconstituted with 0.3 mL of the diluent provided.

The vaccine vial should be removed from cold storage and brought to room temperature before reconstitution.

The flip cap seals of the vaccine and diluent vials are removed, and each rubber stopper is wiped with an isopropyl alcohol swab and allowed to dry thoroughly.

Using aseptic technique and a sterile 1 mL syringe fitted with a 25 gauge x 5/8" needle (provided), draw up **0.3 mL** of diluent and transfer the entire contents of the syringe to the vaccine vial. **(Note: 0.3 mL is not the entire contents of the vial.)**

Gently swirl to mix but try not to get product on the rubber stopper.

The reconstituted vaccine should be a clear to slightly hazy, colorless to straw-colored liquid free from extraneous matter. Reconstituted vaccine should be inspected visually for particulate matter and discoloration prior to administration. If particulate matter or discoloration is observed, the vaccine should not be used and the vial should be disposed safely.

The vaccine vial, its stopper, the diluent syringe, the vented needle used for reconstitution, the bifurcated needle used for administration, and any gauze or cotton that came in contact with the vaccine should be discarded in leak-proof, puncture-proof biohazard containers. These containers should then be disposed of appropriately.

3. SHIPPING & STORAGE INSTRUCTIONS

3.1. Packaging configuration

- 50 vaccine vials (containers) per box (package)

NOTE: The bromobutyl vial stopper contains no latex material

- 8 vaccine boxes (packages) per case (carton)
- diluent
- transfer syringes
- bifurcated needles
- 1 CD per box - CD contains FDA-approved Package Insert (Prescribing Information) and Medication Guide
- Packaging Profile
 - See Table 1 Below

Table 1: ACAM2000® Vaccine Packaging Profile (note: All items are bulk packaged separately¹)

Item	No items/primary container	No. primary containers (items)Box	Box Size (inches) (L×W×H)	Box Size (cm) (L×W×H)	No. boxes (items) /Case	Case Size (inches) (L×W×H)	Case Size (cm) (L×W×H)	No. items /Pallet ²	Storage conditions
Vaccine - ACAM2000® smallpox vaccine, lyophilised, 3 ml vials	100 doses / vial	50 vials (5,000 doses)	$4^{7/8} \times 4^{7/8} \times 3^{1/2}$	12.4 × 12.4 × 8.9	8 boxes (40,000 doses)	$9^{7/8} \times 9^{7/8} \times 7^{1/4}$	25.1 × 25.1 × 18.4	96 cases (3,840,000 doses)	Minus 15°C to minus 25°C (5°F to minus 13°F) 2°C to 8°C (36°F to 46°F) at point of use)
Diluent - ACAM2000® smallpox vaccine diluent, 3 ml vials containing 0.6 ml/vial	100 doses / vial	50 vials (5,000 doses)	$4^{7/8} \times 4^{7/8} \times 3^{1/2}$	12.4 × 12.4 × 8.9	8 boxes (40,000 doses)	$9^{7/8} \times 9^{7/8} \times 7^{1/4}$	25.1 × 25.1 × 18.4	96 cases (3,840,000 doses)	15°C to 30°C (59°F to 86°F)
Bifurcated needles, sterile, individually wrapped	1 bifurcated needle	100 needles	$5^{1/8} \times 4^{3/4} \times 1$	13.0 × 12.1 × 2.5	50 boxes (5,000 needles)	$23^{5/8} \times 10^{1/2} \times 5^{3/8}$	60.0 × 26.7 × 13.7	60 cases (300,000 needles)	Room temperature (20°C to 25°C, 68°F to 77°F)
Transfer syringe ³ , 1 ml syringe, 16mm (5/8 inch) 0.51mm OD (25G) needle attached, sterile wrapped	1 transfer syringe	100 syringes	8 × 7 × 6	20.3 × 17.8 × 15.2	-	-	-	288 boxes (28,800 syringes)	Room temperature (20°C to 25°C, 68°F to 77°F)

1. The individual boxes/cases/pallets of vaccine, diluent, bifurcated needles and transfer syringes are delivered as separate units. Since storage and shipping conditions differ for individual components, the distributor must assemble the components as required for delivery to the point of use.
2. American pallet size: 1.143×1.143×1.27 meters (45×45×50 inches); maximum quantity.
3. Note: one transfer syringe is required to reconstitute 100 doses of vaccine; i.e. one box of 100 syringes suffices for 10,000 doses of vaccine, while one pallet of 28,800 syringes suffices for 2,880,000 doses of vaccine.

3.2. Storage and shipping temperatures - Vaccine

3.2.1. Vaccine Storage

3.2.1.1. ACAM2000 Lyophilized

ACAM2000 is to be stored frozen at -25 to -15°C (-13 to 5°F) until distributed for use. Upon distribution, product may be stored refrigerated at 2-8°C (36-46°F) for up to 18 months.

3.2.1.2. ACAM2000 Reconstituted

ACAM2000 is to be stored refrigerated at 2-8°C (36-46°F). Use within 30 days of reconstitution date.

ACAM2000 vaccine may be administered within 6 to 8 hours (i.e. one clinic day) if kept at room temperature (20-25°C, 68-77°F); it should then be discarded as a biohazardous material.

The reconstituted vaccine may be returned to refrigerated storage overnight for future use if it has been exposed to room temperature conditions for less than 6-8 hours at a time. This cycle can be repeated for as many times as is practical (so long as it is within 30 days of reconstitution date)

3.2.2. Vaccine Shelf Life (Expiration Dating)

ACAM2000 currently has a 7 year (84 month) shelf life from the date of manufacture. Stability studies will continue for the purpose of extending the shelf life, but this is not guaranteed. **Do not use after the expiration date.** This includes whether or not the 18 month refrigerated storage window or the 30 day reconstituted storage window have concluded.

3.2.3. Vaccine Shipping

Upon removal of the vial boxes from long term storage the SNS will include 18 month expiry labeling and will provide extra labels for DOD's use. Frozen ACAM2000 is to be packaged with gel packs in an insulated container and will thaw during shipment at 2-8°C (36-46°F). Product may be stored at this temperature for up to 18 months.

- **DO NOT ship on dry ice**
- **DO NOT store below -40°C (-40°F)**

3.2.4. Thaw Times for ACAM2000 Vaccine (Box of 50 Vials)

Thaw time from frozen temperature, -25 to -15°C (-13 to 5°F), to refrigerated temperature, 2-8°C (36-46°F), is 15-30 minutes.

Thaw time from refrigerated temperature, 2-8°C (36-46°F), to ambient temperature 23-27°C (73-81°F), is approximately 4 hours.

3.2.5. Vaccine Temperature Excursion Data

Un-reconstituted ACAM2000 should not be exposed to room temperature conditions (23-27°C or 73-81°F), for more than 48 hours when shipped from the SNS at 2-8°C.

For the Vaccine and the Diluent, Stability, Potency, and Chemical Integrity of the component mixtures appear to be unaffected by short duration storage and/or temperature fluctuations or excursions in the range from -20°C to +8°C.

3.3. Storage and shipping temperatures - Diluent

3.3.1. Diluent Storage

Diluent for ACAM2000 should be stored at room temperature (15-30°C, 59-86°F)

3.3.2. Diluent Shelf Life (Expiration Dating)

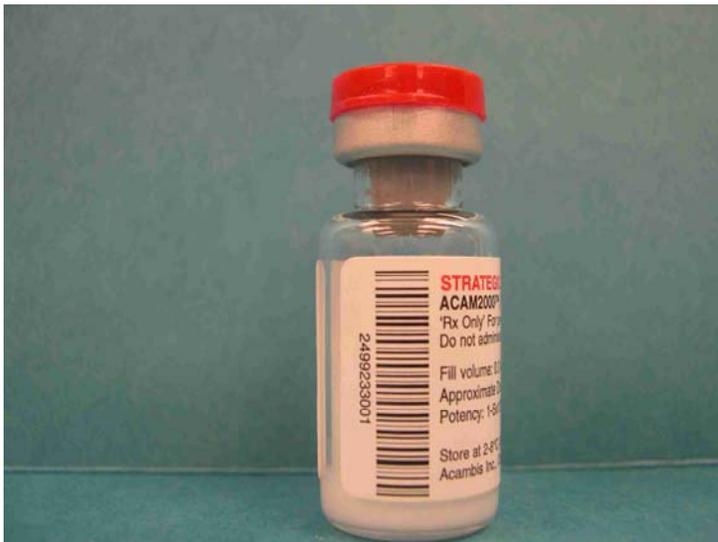
- 60 months (5 years)

3.3.3. Diluent Shipping

- 2-30°C (36-86°F)
- **DO NOT ship on dry ice**

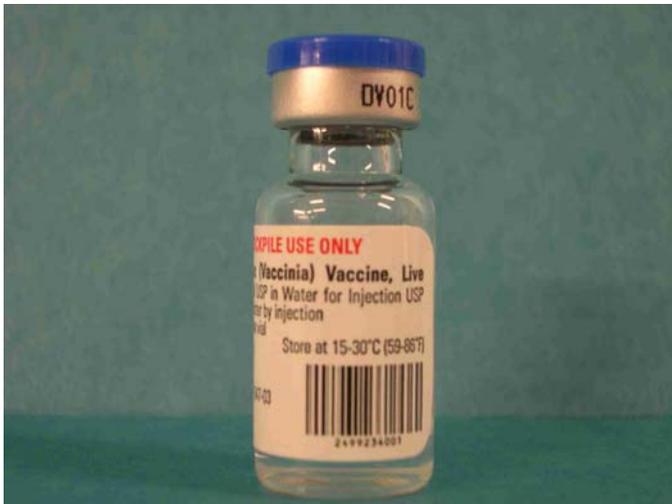
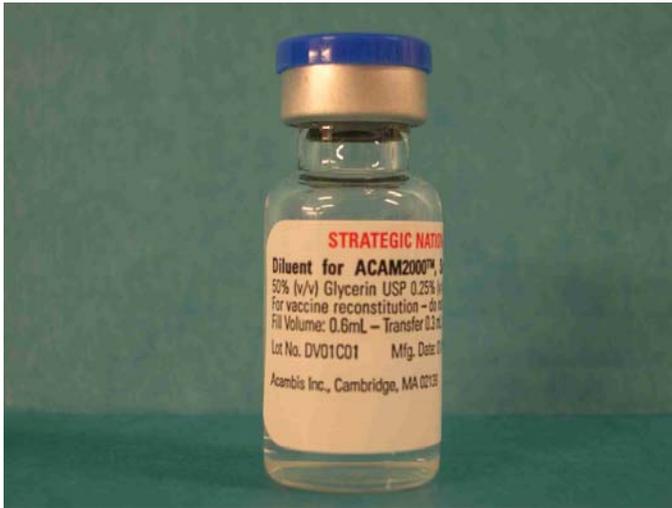
4. LIST AND PICTURES OF COMPONENTS

4.1. Vaccine vial





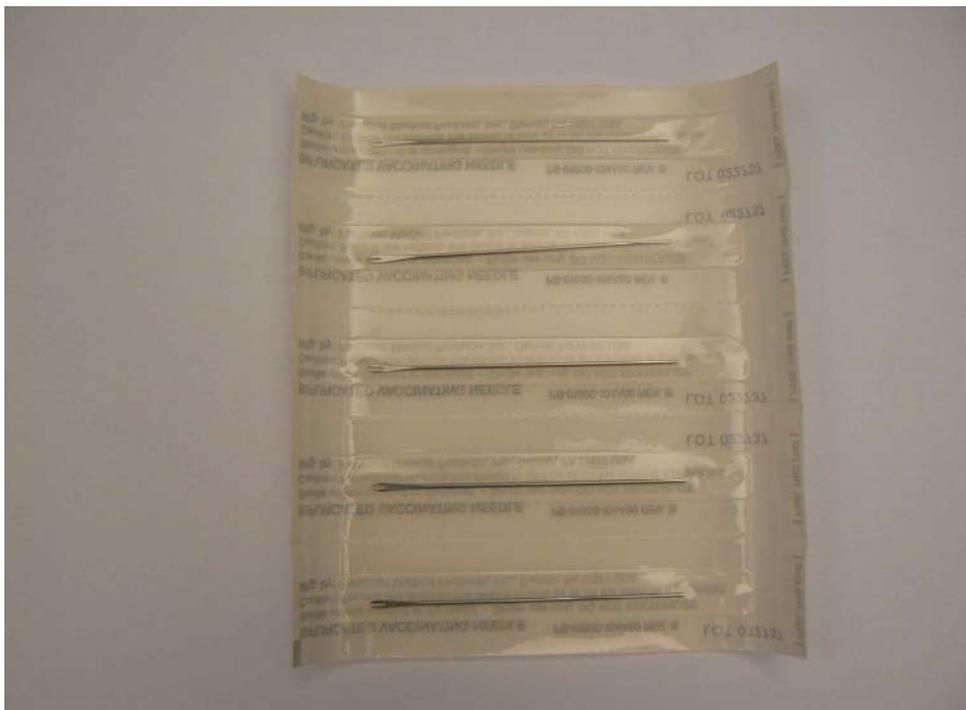
4.2. Diluent vial



4.3. Transfer syringe



4.4. Bifurcated Needle

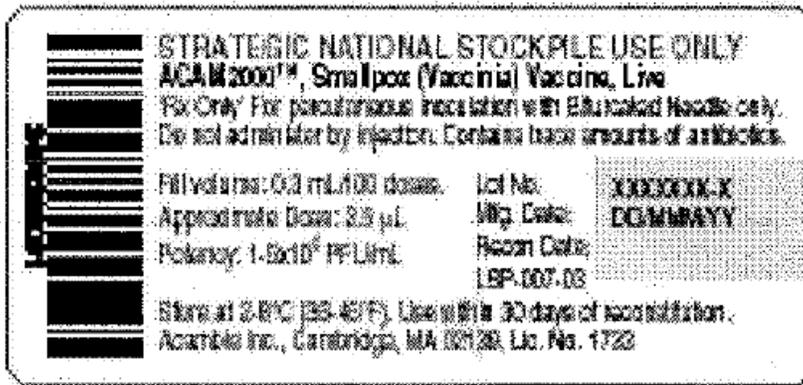




5. PICTURES/PROOFS OF FDA-APPROVED ACAM2000[®] VACCINE LABELS

5.1. Vaccine Container (Vial)

5.1.1. Vaccine Container (Vial) Label Artwork (Not to Scale)



5.1.2. Vaccine Container (Vial) Label Text

STRATEGIC NATIONAL STOCKPILE USE ONLY

ACAM2000[™], Smallpox (Vaccinia) Vaccine, Live

'Rx Only' For percutaneous inoculation with Bifurcated Needle only. Do not administer by injection. Contains trace amounts of antibiotics.

Fill volume: 0.3 mL /100 doses.
 Approximate Dose: 2.5µL
 Potency: 1-5x10⁸ PFU/mL

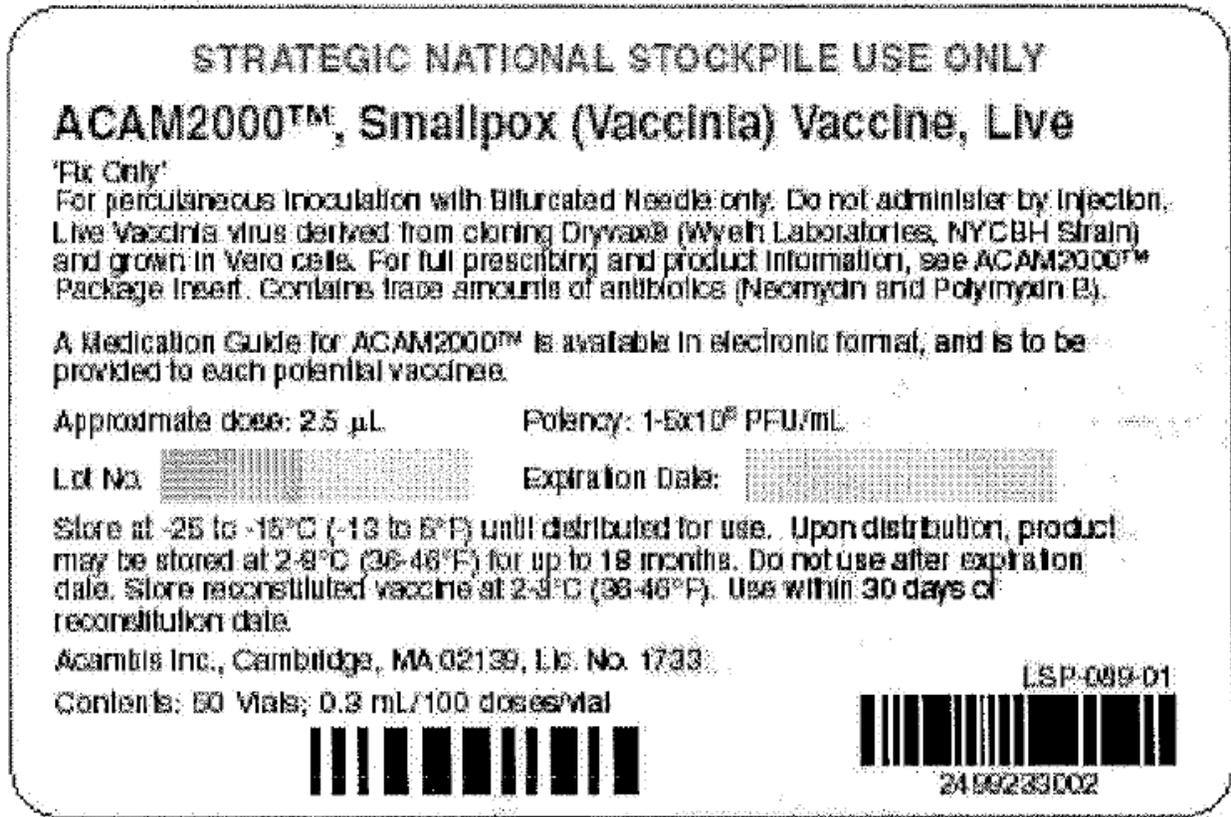
Lot No.
 Mfg. Date:
 Recon Date:
 LSP-007-03

Store at 2-8°C (36-46°F). Use within 30 days of reconstitution.
 Acambis Inc., Cambridge, MA 02139, Lic. No. 1733

[Bar Code] 2499233001 [note bar code with NDC code printed vertically on the left side of this label]

5.2. Vaccine Package (Box)

5.2.1. Vaccine Package (Box) Label Artwork (Not to Scale)



5.2.2. Vaccine Package (Box) Label Text

STRATEGIC NATIONAL STOCKPILE USE ONLY

ACAM2000™, Smallpox (Vaccinia) Vaccine, Live

'Rx Only'

For percutaneous inoculation with Bifurcated Needle only. Do not administer by injection. Live Vaccinia virus derived from cloning Dryvax® (Wyeth Laboratories, NYCBH Strain) and grown in Vero cells. For full prescribing and product information, see ACAM2000™ Package Insert. Contains trace amounts of antibiotics (Neomycin and Polymyxin B).

A Medication Guide for ACAM2000™ is available in electronic format, and is to be provided to each potential vaccinee.

Approximate dose: 2.5 µL Potency: 1-5x10⁸ PFU/mL
Lot No. Expiration Date:

Store at -25 to -15°C (-13 to 5°F) until distributed for use. Upon distribution, product may be stored at 2-8°C (36-46°F) for up to 18 months. Do not use after expiration date. Store reconstituted vaccine at 2-8°C (36-46°F). Use within 30 days of reconstitution date.

Acambis Inc., Cambridge, MA 02139, Lic. No. 1733

Contents: 50 Vials; 0.3 mL/100 doses/vial

LSP-089-01
Bar Code
2499233002

5.3. Vaccine Package (Box) Over Label

In the event of an extension of the vaccine expiry date, the following will be used to relabel the vaccine box at the SNS (vials will not be relabeled in order to avoid risk of product loss).

5.3.1. Vaccine Package (Box) Over Label Artwork (Not to Scale)

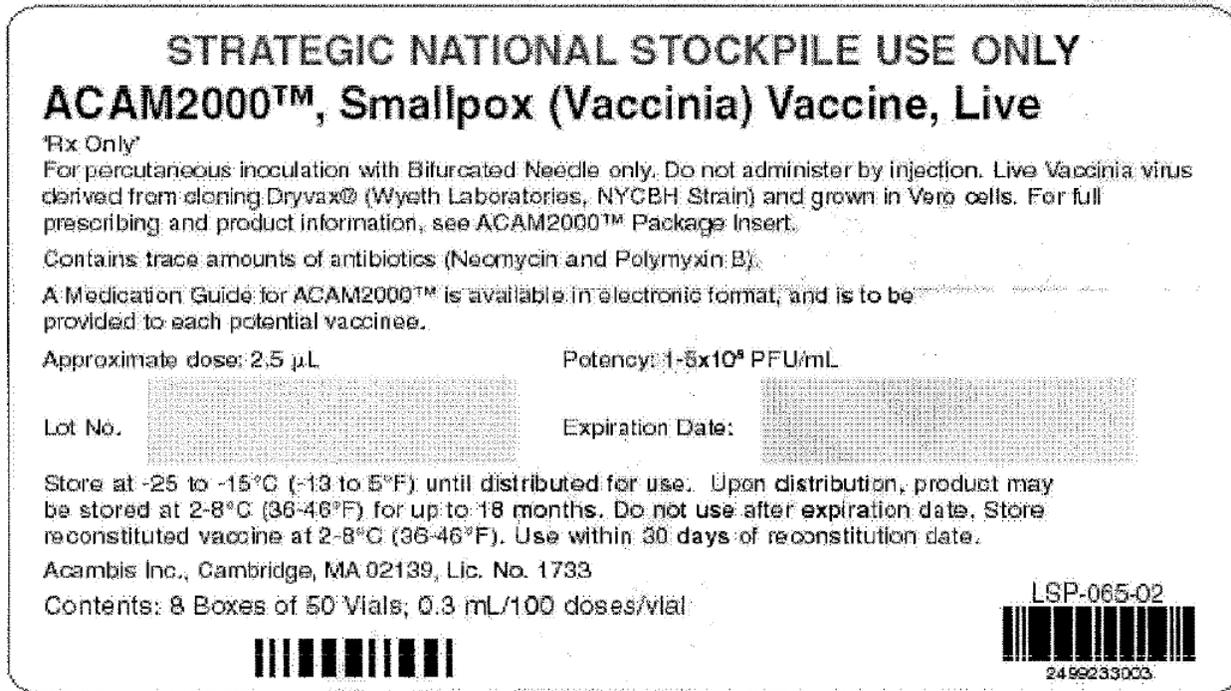
STRATEGIC NATIONAL STOCKPILE USE ONLY	
ACAM2000™, Smallpox (Vaccinia) Vaccine, Live	
'Rx Only'	
For percutaneous inoculation with Bifurcated Needle only. Do not administer by injection. Live Vaccinia virus derived from cloning Dryvax® (Wyeth Laboratories, NYCBH Strain) and grown in Vero cells. For full prescribing and product information, see ACAM2000™ Package Insert. Contains trace amounts of antibiotics (Neomycin and Polymyxin B).	
A Medication Guide for ACAM2000™ is available in electronic format, and is to be provided to each potential vaccinee.	
Approximate dose: 2.5 µL	Potency: 1-5x10 ⁸ PFU/mL
Lot No. [REDACTED]	Expiration Date: [REDACTED]
Store at -25 to -15°C (-13 to 5°F) until distributed for use. Upon distribution, product may be stored at 2-8°C (36-46°F) for up to 18 months. Do not use after expiration date. Store reconstituted vaccine at 2-8°C (36-46°F). Use within 30 days of reconstitution date.	
Acambis Inc., Cambridge, MA 02139, Lic. No. 1733	
Contents: 50 Vials; 0.3 mL/100 doses/vial	LSP-066-02  2499233002

5.3.2. Vaccine Package (Box) Over Label Text

STRATEGIC NATIONAL STOCKPILE USE ONLY	
ACAM2000™, Smallpox (Vaccinia) Vaccine, Live	
'Rx Only'	
For percutaneous inoculation with Bifurcated Needle only. Do not administer by injection. Live Vaccinia virus derived from cloning Dryvax® (Wyeth Laboratories, NYCBH Strain) and grown in Vero cells. For full prescribing and product information, see ACAM2000™ Package Insert. Contains trace amounts of antibiotics (Neomycin and Polymyxin B).	
A Medication Guide for ACAM2000™ is available in electronic format, and is to be provided to each potential vaccinee.	
Approximate dose: 2.5 µL	Potency: 1-5x10 ⁸ PFU/mL
Lot No.	Expiration Date:
Store at -25 to -15°C (-13 to 5°F) until distributed for use. Upon distribution, product may be stored at 2-8°C (36-46°F) for up to 18 months. Do not use after expiration date. Store reconstituted vaccine at 2-8°C (36-46°F). Use within 30 days of reconstitution date.	
Acambis Inc., Cambridge, MA 02139, Lic. No. 1733	
Contents: 50 Vials; 0.3 mL/100 doses/vial	LSP-066-02 Bar Code 2499233002

5.4. Vaccine Carton (Case)

5.4.1. Vaccine Carton (Case) Label Artwork (Not to Scale)



5.4.2. Vaccine Carton (Case) Label Text

STRATEGIC NATIONAL STOCKPILE USE ONLY

ACAM2000™, Smallpox (Vaccinia) Vaccine, Live

'Rx Only'

For percutaneous inoculation with Bifurcated Needle only. Do not administer by injection. Live Vaccinia virus derived from cloning Dryvax® (Wyeth Laboratories, NYCBH Strain) and grown in Vero cells. For full prescribing and product information, see ACAM2000™ Package Insert.

Contains trace amounts of antibiotics (Neomycin and Polymyxin B).

A Medication Guide for ACAM2000™ is available in electronic format, and is to be provided to each potential vaccinee.

Approximate dose: 2.5 µL Potency: 1-5x10⁸ PFU/mL

Lot No. Expiration Date:

Store at -25 to -15°C (-13 to 5°F) until distributed for use. Upon distribution, product may be stored at 2-8°C (36-46°F) for up to 18 months. Do not use after expiration date. Store reconstituted vaccine at 2-8°C (36-46°F). Use within 30 days of reconstitution date.

Acambis Inc., Cambridge, MA 02139, Lic. No. 1733

Contents: 8 Boxes of 50 Vials; 0.3 mL/100 doses/vial

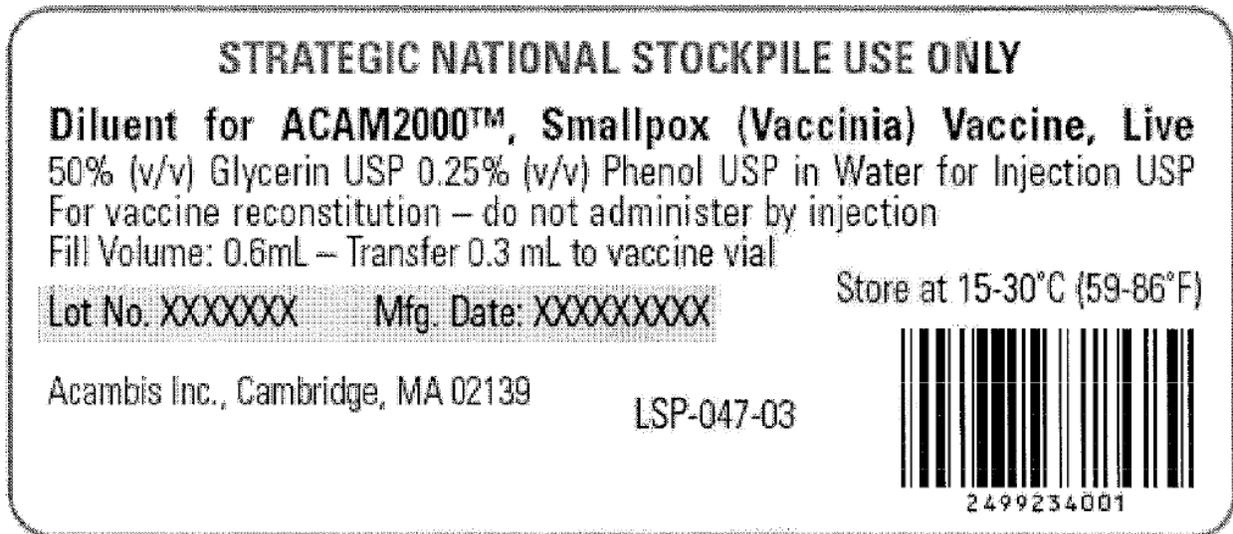
LSP-065-02

Bar Code
2499233003

6. PICTURES/PROOFS OF FDA-APPROVED ACAM2000 DILUENT LABELS

6.1. Diluent Container (Vial)

6.1.1. Diluent Container (Vial) Label Artwork (Not to Scale)



6.1.2. Diluent Container (Vial) Label Text

STRATEGIC NATIONAL STOCKPILE USE ONLY

Diluent for ACAM2000™, Smallpox (Vaccinia) Vaccine, Live

50% (v/v) Glycerin USP 0.25% (v/v) Phenol USP in Water for Injection USP

For vaccine reconstitution - do not administer by injection

Fill Volume: 0.6mL – Transfer 0.3 mL to vaccine vial

Lot No.

Mfg. Date:

Store at 15-30°C (59-86°F)

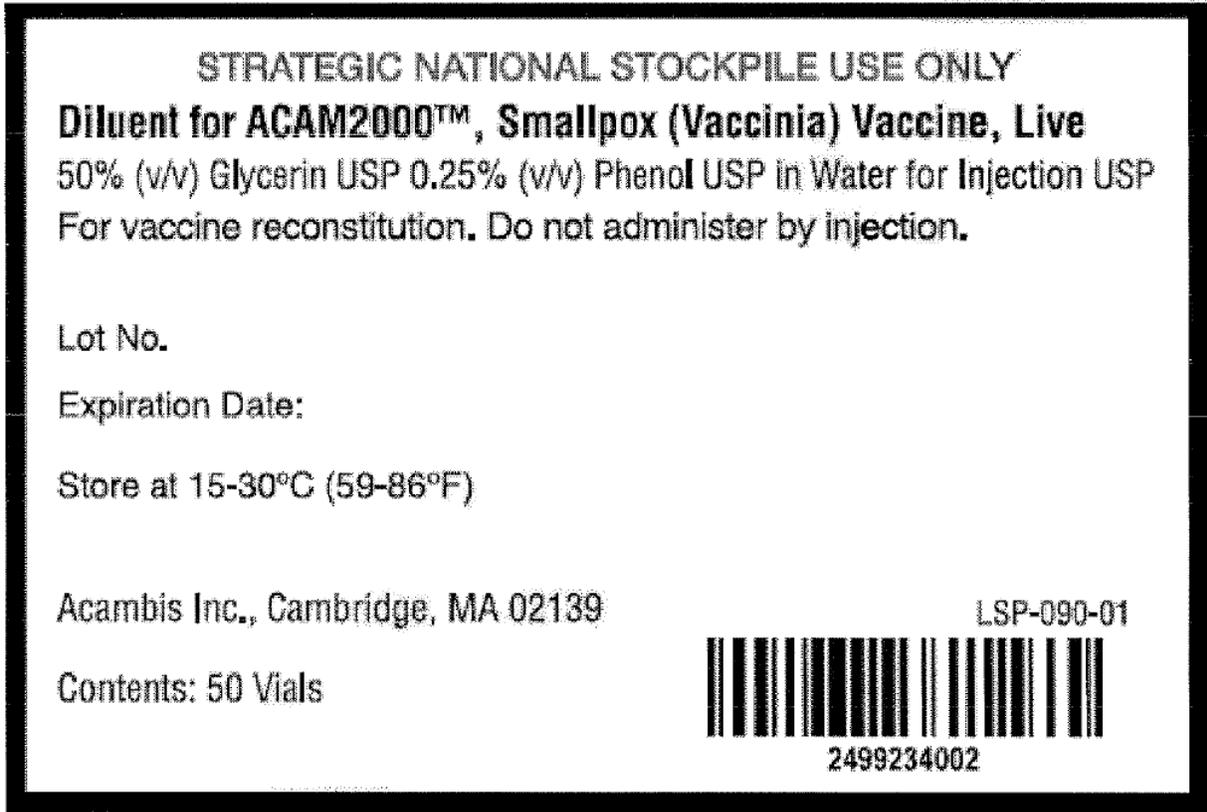
Acambis Inc., Cambridge, MA 02139

LSP-047-03

Bar Code
2499234001

6.2. Diluent Package (Box)

6.2.1. Diluent Package (Box) Label Artwork (Not to Scale)



6.2.2. Diluent Package (Box) Label Text

STRATEGIC NATIONAL STOCKPILE USE ONLY

Diluent for ACAM2000™, Smallpox (Vaccinia) Vaccine, Live
50% (v/v) Glycerin USP 0.25% (v/v) Phenol USP in Water for Injection USP
For vaccine reconstitution. Do not administer by injection.

Lot No.

Expiration Date:

Store at 15 - 30°C (59 - 86°F)

Acambis Inc., Cambridge, MA 02139

Contents: 50 Vials

LSP-090-01

[Bar Code]
2499234002

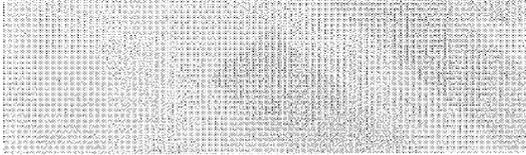
6.3. Diluent Package (Box) Over Label

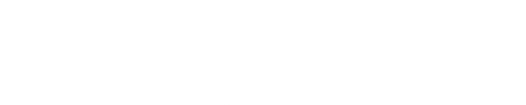
In the event of an extension of the diluent expiry date, the following will be used to relabel the diluent box at the SNS (vials will not be relabeled in order to avoid risk of product loss).

6.3.1. Diluent Package (Box) Over Label Artwork (Not to Scale)

STRATEGIC NATIONAL STOCKPILE USE ONLY

Diluent for ACAM2000™, Smallpox (Vaccinia) Vaccine, Live
 50% (v/v) Glycerin USP 0.25% (v/v) Phenol USP in Water for Injection USP
 For vaccine reconstitution. Do not administer by injection.

Lot No. 

Expiration Date: 

Store at 15-30°C
 (59-86°F)

Acambis Inc., Cambridge, MA 02139

Contents: 50 Vials

LSP-067-02

 2499234002

6.3.2. Diluent Package (Box) Over Label Text

STRATEGIC NATIONAL STOCKPILE USE ONLY

Diluent for ACAM2000™, Smallpox (Vaccinia) Vaccine, Live
 50% (v/v) Glycerin USP 0.25% (v/v) Phenol USP in Water for Injection USP
 For vaccine reconstitution. Do not administer by injection.

Lot No.

Expiration Date:

Store at 15 - 30°C (59 - 86°F)

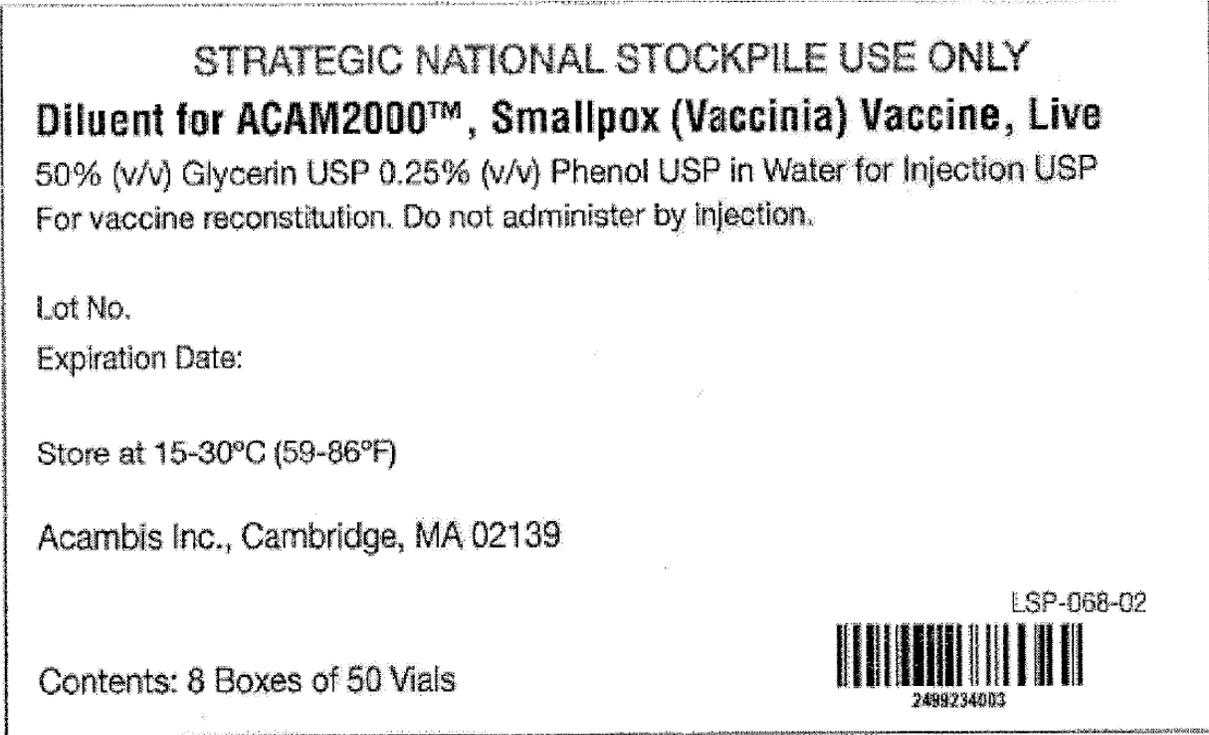
Acambis Inc., Cambridge, MA 02139

Contents: 50 Vials

LSP-067-02
 [Bar Code]
 2499234002

6.4. Diluent Carton (Case)

6.4.1. Diluent Carton (Case) Label Artwork (Not to Scale)



6.4.2. Diluent Carton (Case) Label Text

STRATEGIC NATIONAL STOCKPILE USE ONLY

Diluent for ACAM2000™, Smallpox (Vaccinia) Vaccine, Live

50% (v/v) Glycerin USP 0.25% (v/v) Phenol USP in Water for Injection USP
For vaccine reconstitution. Do not administer by injection.

Lot No.

Expiration Date:

Store at 15 - 30°C (59 - 86°F)

Acambis Inc., Cambridge, MA 02139

LSP-068-02

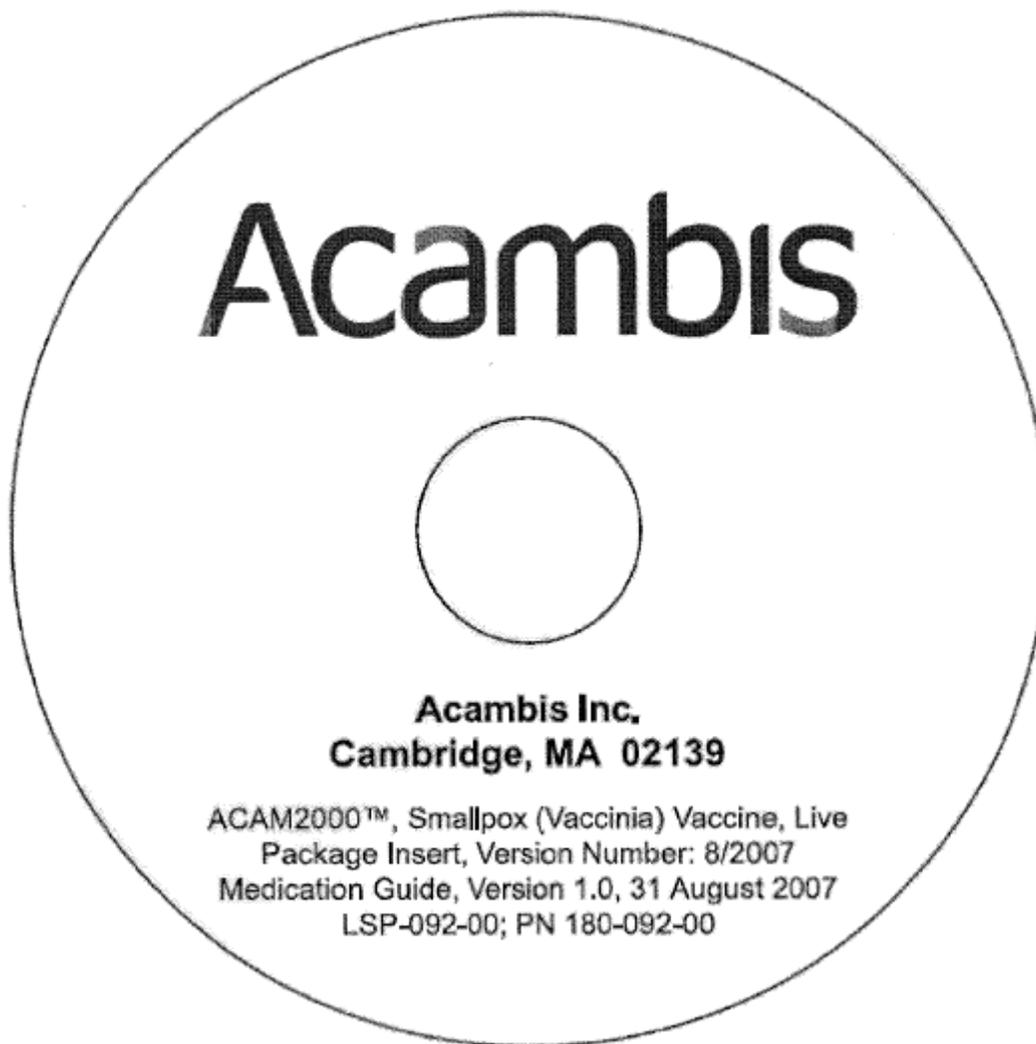
Contents: 8 Boxes of 50 Vials

[Bar Code]
2499234003

7. ADDITIONAL, MISCELLANEOUS LABELS ON OR ACCOMPANYING PRODUCT AT SNS

7.1. CD Label

blackPMS320



8. ACAM2000[®] PACKAGE INSERT AND MEDICATION GUIDE

The most current Package Insert and Medication Guide can be found at the following web pages:

- Acambis Inc. Website: <http://www.Acambis.com/Acam2000>
- FDA Website: <http://www.fda.gov/cber/products/acam2000.htm>

For questions regarding ACAM2000, you can contact Acambis Inc. at 866-440-9440 (toll free) or 617-866-4500.