

11/2025

IMPORTANT PRESCRIBING INFORMATION

Subject: Important Labeling Update for BioThrax[®] (Anthrax Vaccine Adsorbed): 28-Day Discard After Vial Puncture Instructions

Dear Healthcare Provider:

The purpose of this letter is to inform you of an important update to the labeling of BioThrax[®] (Anthrax Vaccine Adsorbed), specifically regarding the storage and handling of the multiple-dose vial once it has been pierced.

Effective immediately, the following information has been added to the United States Prescribing Information (USPI), **Section 2.2 Administration** to state:
Once the stopper of the multiple-dose vial has been pierced, discard the vial within 28 days.

Additional information on the 28-day discard date has been included in **Section 16.2 Storage and Handling**, to state:

- Once the stopper of the multiple-dose vial has been pierced, discard the vial within 28 days.
- Between uses, store the multiple-dose vial at 2°C to 8°C (36°F to 46°F).
- The date of discard should not exceed the manufacturer's expiration date printed on the label.

Information has also been added to **Section 16.2 Storage and Handling** to clarify that product should be discarded if it has been frozen.

Healthcare Provider Action

To ensure proper storage and handling of BioThrax[®], healthcare providers are instructed to:

- Ensure that the multiple-dose vial is stored at 2°C to 8°C (36°F to 46°F) between uses
- Discard the vial within 28 days of first puncture
- Ensure that the discard date does not exceed the expiration date printed on the vial
- Ensure all clinical staff are informed and trained on these instructions

Reporting Adverse Events

Report adverse events following BioThrax® administration to FDA by calling 1-800-822-7967 or to the website www.vaers.hhs.gov. You may also report side effects directly to Emergent BioSolutions at 1-800-768-2304 or at medicalinformation@ebsi.com.

If you require further guidance regarding the information contained in this letter, please contact medicalinformation@ebsi.com or call 1-888-483-9053.

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

Sincerely,

Electronically signed by: Scott White
Reason: Approved
Date: Nov 10, 2025 09:19:37 EST



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