

July 2023

IMPORTANT PRESCRIBING INFORMATION

Subject: Extension of expiration date for certain lots of ANTIVENIN (*Latrodectus mactans*) (Black Widow Spider Antivenin) Equine Origin

Dear Health Care Provider:

The purpose of this letter is to notify you that the U.S. Food and Drug Administration (FDA) has approved a two-year expiration date extension, from 36 months to 60 months, for the lots of ANTIVENIN (*Latrodectus mactans*) (Black Widow Spider Antivenin) Equine Origin referenced below.

Information for Providers and Distributors

Providers that have these lot numbers in stock will be able to use them through their new expiration dates. To help ensure product supply remains available until new lots of ANTIVENIN (*Latrodectus mactans*) are available, Merck is requesting that providers and distributors not return or discard product prior to expiry.

ANTIVENIN (Latrodectus mactans) (Black Widow Spider Antivenin) Equine Origin NDC 0006-5424-02			
Description	Lot Number	Current Expiry Date	Extended Expiry Date
2.5 mL Vial of Antivenin	T035013	September 22, 2023	September 22, 2025
1 mL Vial of Normal Horse Serum	U021148	September 22, 2023	September 22, 2025

The lots identified above were released prior to January 2023. Additional lots will be available in approximately the third quarter of 2023 and will reflect 60-month expiration dating on product packaging.

Reporting Adverse Events and Product Quality Complaints

Report adverse events or product quality complaints to Merck using one of the following methods:

- By phone, to the Merck National Service Center at 1-800-672-6372,
- By email, to dpoc.usa@merck.com, or
- By fax, to 1-215-616-5677.

You may also submit reports directly to FDA's MedWatch program online at www.fda.gov/medwatch/report.htm, by submitting Form FDA 3500 by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-FDA-0178). Form 3500 may be obtained at https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting, or by calling FDA at 1-800-332-1088.



If you have questions about the information contained in this letter, please contact the Merck National Service Center at 1-800-672-6372.

The Prescribing Information for ANTIVENIN (*Latrodectus mactans*) can be accessed at http://www.merck.com/product/usa/pi_circulars/a/antivenin/antivenin_pi.pdf.

Sincerely,

Richard M. Haupt, MD, MPH

Vice President, Vaccines and Infectious Diseases

Global Medical & Scientific Affairs

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