

UPDATED EXPIRATION DATE EXTENSION NOTICE FOR PEMGARDA™ (PEMIVIBART)



Audience

Healthcare facilities and healthcare professionals including physicians, pharmacists, nurse practitioners, nurses, and public health officials.

Key messages for healthcare professionals

- On November 12, 2024 and January 8, 2025, the FDA granted an extension of the shelf-life (from 24 months to 30 months) for all packaged lots of PEMGARD A™ (pemivibart) injection.
- Invivyd, Inc. is now correcting the expiry dates for all packaged lots of PEMGARD A to ensure that appropriate action is taken. Please refer to the table below for the corrected expiry dates.
- The approved storage conditions remain unchanged.
- Healthcare professionals are advised that:
 - PEMGARD A can still be used after the printed expiration date, which can be found on both the carton and the individual vials.
 - The expiration date of PEMGARD A must be verified against the below table prior to dispensing. Check the expiration date ("EXP") and lot number ("LOT") on the label and refer to the below table for detailed date extensions.
 - See full [Fact Sheet for Healthcare Providers](#) and [Fact Sheet for Patients, Parents, and Caregivers](#).

What is the issue?

On November 12, 2024, and January 8, 2025, the FDA granted an extension of the shelf-life (from 24 months to 30 months) for all packaged lots of PEMGARD A. FDA allows updates to expiration dates for products authorized under emergency use without the need to re-label. Accordingly, Invivyd is now extending the expiration dates of all packaged lots of PEMGARD A and ensuring appropriate action is taken through this communication. The FDA has approved the extension of the expiration dates as summarized in the table below.

If you have a PEMGARD A carton or vial with an expiration date listed in the table below, please see the right column to find the updated extended expiration date.

Lot Number	Labeled Expiry Date*	Approved Extended Expiry Date*
2053018	October 2024	October 2025
2053020	October 2024	October 2025
2053022	October 2024	October 2025
2066667	April 2025	October 2025
2066670	April 2025	October 2025
2066671	July 2025	January 2026
2098979	July 2025	January 2026
2068066	July 2025	January 2026

Lot Number	Labeled Expiry Date*	Approved Extended Expiry Date*
2068071	December 2025	June 2026
2069568	January 2026	July 2026
2070221	February 2026	August 2026
2072055	February 2026	August 2026
2120203	February 2026	August 2026
2072056	February 2026	August 2026
2072227	February 2026	August 2026
2072228	February 2026	August 2026

*Note that the labelled expiration date is valid until the last day of the month.

PEMGARDA is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of PEMGARDA under section 564(b)(1) of the FD&C Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

See full [Fact Sheet for Healthcare Providers](#) and [Fact Sheet for Patients, Parents, and Caregivers](#)

Report health or safety concerns

Submit serious adverse event and medication error reports using FDA Form 3500 to FDA MedWatch using one of the following methods:

- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Complete and submit a postage-paid [FDA Form 3500](#) and return by:
 - Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or
 - Fax to 1-800-FDA (332)-0178, or
- Call 1-800-FDA (332)-1088 to request a reporting form.

In addition, please provide a copy of all FDA MedWatch forms to:

Invivyd, Inc.

Email: pv@invivyd.com

Or call Invivyd, Inc. at 1-800-890-3385 to report serious adverse events.

You may report side effects related to Invivyd, Inc. products by sending an email to medinfo@invivyd.com.

INVIVYD RETURN POLICY

Invivyd will only accept expired, unopened product returned during the period commencing upon the product's expiration date and ending six (6) months after the product's expiration date as defined as the last day of the month for that Lot as shown in the Approved Extended Expiry Date in the table above. For a full list of terms and conditions and the process for requesting Invivyd product returns, please visit www.invivyd.com/returnspolicy.