Humana
Pharmacy Solutions®

Drug recall notice for Gamunex-C

To assist you in the care of your patients, Humana is alerting you to the recall of Gamunex-C on Oct. 28, 2025.[1] We recommend you review your medical records and contact all patients for whom you have prescribed this medication to warn them of the recall.

The drug manufacturer, Grifols Therapeutics LLC, is voluntarily recalling multiple lots of Gamunex-C to the consumer level as a precautionary measure due to an increased rate of allergic/hypersensitivity type reactions associated with the affected vials, some of which are considered medically significant. This is an expansion of similar recalls due to the same safety concern for Gamunex-C earlier this year.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA) and the Center for Biologics Evaluation and Research.

Medications included in this recall
Visit the FDA website for specific details about the recalled medication.

Information for providers:[1]

- We sent a letter to your Humana-covered patients with a claim for Gamunex-C and asked them to contact their providers if their medication is included in the recall and if they have experienced problems that could be related to using these drug products.
- Providers with questions can contact:
  - Grifols Therapeutics at 800-520-2807, Monday – Friday, 8:30 a.m. – 5 p.m., Eastern time.
- Patients can report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting Program online, by phone or by fax.
  - **Online:** Submit the report.
    - Select "FDA Form 3500."
  - **Phone or fax:** Download the form.
    - Report by phone at 800-FDA-1088 (332-1088), Monday – Friday, 8 a.m. – 4:30 p.m., Eastern time, or by fax to 800-FDA-0178 (332-0178).

Note: A reporting form also can be requested by calling 800-FDA-1088 (332-1088). Complete and return to the address on the pre-addressed form or by fax to 800-FDA-0178 (332-0178).

Reference

1. "Voluntary Lot Withdrawals of Immune Globulin Intravenous (IGIV) and Immune Globulin Subcutaneous (IGSC) for Increased Reports of Allergic/Hypersensitivity Reactions," U.S. Food and Drug Administration, last accessed Dec. 9, 2025, https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/voluntary-lot-withdrawals-immune-globulin-intravenous-igiv-and-immune-globulin-subcutaneous-igsc-0.