

FDA Drug Recall

Voluntary Lot Withdrawals of Immune Globulin Intravenous (IGIV) and Immune Globulin Subcutaneous (IGSC) for Increased Reports of Allergic/Hypersensitivity Reactions

3/10/2025

FOR IMMEDIATE RELEASE – As a precautionary measure, the following lots of Immune Globulin Intravenous (IGIV) and Immune Globulin Subcutaneous (IGSC) have been voluntarily withdrawn by the manufacturers due to a higher rate of allergic/hypersensitivity type reactions, some of which were considered medically significant. Hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with immune globulin products.

1. Please examine your stock immediately to determine if you have any vials from these lots.
2. If you have product from these lots, please cease use immediately.
3. Return the affected product to the point of purchase to receive replacement product.

Product Lot	Date of Voluntary Withdrawal	Expiration Date	Manufacturer
Xembify Lot # B01J108133	10-Jan-2025	30-Oct-2027	Grifols
Xembify Lot # B01J107803	13-Jan-2025	29-Oct-2027	Grifols
Bivigam Lot # 321524	31-Jan-2025	31-Jul-2027	ADMA Biologics
Panzyga Lot #L319C8261	12-Feb-2025	14-May-2026	Octapharma
Gamunex-C Lot #B01J112733	19-Feb-2025	8-Nov-2027	Grifols
Bivigam Lot # 321724	27-Feb-2025	31-Aug-2027	ADMA Biologics

Source: <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/voluntary-lot-withdrawals-immune-globulin-intravenous-igiv-and-immune-globulin-subcutaneous-igsc-0>