COMMUNICATION

COM-2025-070

10 NOVEMBER 2025

URGENT PLEASE REVIEW

Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date:

10/28/2025

Drugs Indication:

Indicated for the treatment of primary humoral immunodeficiency (PI)

Safety Topic:

Immune Globulin Intravenous (IGIV) and/or Immune Globulin Subcutaneous (IGSC) Lots with Increased Reports of Allergic/Hypersensitivity Reactions

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It is for this reason that we are notifying you that on 10/28/2025, the U.S. Food and Drug Administration (FDA) published a safety communication for the following product(s): Asceniv and Bivigam.

Reason for Communication:

The FDA Adverse Event Reporting System (FAERS) has received increased reporting of allergic/hypersensitivity type reactions following infusion of specific lots of Immune Globulin Intravenous (IGIV) and/or Immune Globulin Subcutaneous (IGSC). Reports included serious adverse events, some of which were considered severe, requiring treatment with epinephrine, steroids, and/or admission to the emergency room or hospital. Though hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with immune globulin products, the increased reporting of hypersensitivity reactions to these lots presents heightened safety risks for patients.

While the FDA investigates this safety issue, the following is recommended:

- Please examine your stock immediately to determine if you have any vials from these lots.
- If you have a product from these lots, please cease use immediately.
- If you have questions about a lot, please contact the manufacturer.

Product	Lot	Expiration Date	Manufacturer
Asceniv	# 239825	31-Aug-2027	ADMA Biologics
Bivigam	# 237452	31-Oct-2027	

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- ext. 219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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REFERENCES:
1. U.S. Food and Administration (2025). *Immune Globulin Intravenous (IGIV) and/or Immune Globulin Subcutaneous (IGSC) Lots with Increased Reports of Allergic/Hypersensitivity Reactions.* https://www.fda.gov/vaccines-blood-biologics/immune-globulin-intravenous-igiv-andor-immune-globulin-subcutaneous-igsc-lots-increased-reports

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