



Grifols Therapeutics LLC
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URGENT DRUG WITHDRAWAL

March 21, 2025

This is to inform you that Grifols Therapeutics is initiating a voluntary withdrawal of one lot of Gamunex® -C 10%, 40G Vial, as detailed below.

Grifols is committed to providing the highest quality medicines in the market. This voluntary withdrawal is being conducted as a precautionary measure due to an increased rate of allergic/hypersensitivity type reactions associated with this specific lot. A small number of the reactions were considered medically significant. Hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with immune globulin products.

This withdrawal is being conducted with the knowledge of the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research.

The Gamunex® -C 10% lot affected by this withdrawal is:

<u>Lot Number</u>	<u>Material Number</u>	<u>Expiration Date</u>	<u>Market Release</u>	<u>NDC Number</u>
B23K001433	730807	12/18/2027	01/28/2025	13533-800-40

This withdrawal is required to be conducted to the consumer/user level. Please notify your subsidiary customers of this withdrawal and instruct them to return product as noted below.

Please examine your stock immediately to determine if you have any of the above-mentioned lots on hand. If you have product from this lot, cease use of the product immediately. If you have further distributed the product, you must immediately send notification of this withdrawal to your customers. This lot was distributed within the United States only. **Return product to the authorized distributor of record for this lot.** Distributors should return product to Grifols Therapeutics, 8368 Clayton Blvd, Clayton, NC 27520. **For any questions concerning return of the product, contact US Customer Service via email at customer.service@grifols.com or call (800) 243-4153.**

After receipt of returned product by Grifols, you will be credited by your distributor for the returned goods. If you have any technical or clinical questions, please contact US Clinical Communications at (800) 520-2807. Your prompt attention to this notice is appreciated.

Sincerely,

Clark Zervos
Vice President, Quality
Grifols Therapeutics