# Gamunex-C10%, 40G Vial CONSUMER LEVEL WITHDRAWAL CUSTOMER CARE TALK TRACK

# 

**Background Information:** On March 21, 2025, Grifols Therapeutics issued a consumer-level withdrawal of Gamunex® -C 10%, 40G Vial NDC 13533-0800-40. This withdrawal was issued 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 affects lot number B23K001433 exp. 12/18/2027. The Market Release date is 01/28/2025.

Please note: This product is not carried by the CVS Caremark Mail Service Pharmacies.

# Customer Care Talk Track:

\*\* Please ensure to disposition all recall calls to code “**1116**” \*\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Q#** | **Question** | **Action** | **Answer** | | |
| **1** | **I heard that there is an issue with my medicine, Gamunex® -C 10%, 40G Vial. Can you give me more information?** | Note: Check PeopleSafe to determine if the medication is from Mail or Specialty Pharmacy | If the medication was dispensed from… | Then say… | |
| Mail Order | * Yes, I can. * **Proceed to Q2** | |
| Specialty | While in PeopleSafe, determine the phone number of the dispensing Specialty pharmacy and transfer the call.A: Yes, I can. Please hold while I transfer you to your Specialty Pharmacy. | |
| Customer Care/Specialty Talk Track Clinical Care Service/Specialty Pharmacy Talk Track | | | | | |
| **2** | **Why is there a recall? What is wrong with the product?** |  | On March 21, 2025, Grifols Therapeutics issued a consumer-level withdrawal of Gamunex® -C 10%, 40G Vial NDC 13533-0800-40**. This withdrawal was issued 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.  For more information, call Grifols toll-free at 1-800-243-4153 or email [customer.service@grifols.com](mailto:customer.service@grifols.com). You may also call the United States Food and Drug Administration (FDA) toll-free at 1‑888‑INFO-FDA (1‑888-463-6332) or visit [www.fda.gov](http://www.fda.gov). | | |
| **3** | **May I return the rest of the Gamunex® -C 10%, 40G Vial that I have?** | Determine if the patient is affected by this recall | First, let’s determine if you are affected by this recall: | | |
| **If the product was dispensed in…** | | **Then say...** |
| Manufacturer’s Package | | * Check the lot number. The lot number is on the manufacturer’s bottle on the label. * If your drug is not from this affected lot number, it is not affected by this recall.   **Please note: This drug is not carried by the CVS Caremark® Mail Service Pharmacies. If your drug is from this affected lot number,** CVS Specialty Pharmacy will send you replacement product and a postage-paid envelope to return the affected product. If you received any recalled product from your retail pharmacy, please contact the pharmacy that filled your prescription for more information including return instructions.  ***Please note: If the member received recalled product, please submit a damaged bottle reship order and indicate the amount of replacement product to be sent. Please make sure to request call tag.*** |
| **4** | **Should I stop using my Gamunex® -C 10%, 40G Vial?** |  | If the medication was dispensed from… | | Then say… |
| Mail Order | | **Customer Care:**  Please hold while I transfer you to one of our Clinical Counseling Clinicians.  **Clinical Care Service:** Grifols Therapeutics recommends that consumers should cease use of the product immediately. Please call your health care professional right away for advice if you may be using affected product or if you do not know if you used affected drug. Your doctor is familiar with your medical history and can suggest the best treatment option for you. |
| Specialty | | **Customer Care:**  Please hold while I transfer you to your Specialty Pharmacy.  **Clinical Care Service:**  **Grifols Therapeutics recommends that consumers should cease use of the product immediately. Please call your health care professional right away for advice if you may be using affected product or if you do not know if you used affected drug.** Your doctor is familiar with your medical history and can suggest the best treatment option for you. |
| **5** | **Will I receive credit for the product I return?** |  | Your insurance will be credited for any affected product returned to us. We will replace the affected product with unaffected product. You will not be charged any additional copayments. | | |

Additional Information:

A close-up of a letter

AI-generated content may be incorrect.

# 

[Top of the Document](#_top)

Not To Be Reproduced Or Disclosed to Others Without Prior Written Approval

**ELECTRONIC DATA = OFFICIAL VERSION / PAPER COPY = INFORMATIONAL ONLY**