

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

This is to inform you that Grifols Therapeutics is initiating a withdrawal of four lots of Gamunex® -C 10%, as detailed below. This withdrawal is required to be conducted to the consumer/user level.

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 these specific lots. 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% lots affected by this withdrawal are:

<u>Lot Number</u>	<u>Material Number</u>	<u>Expiration Date</u>	<u>Market Release</u>	<u>NDC Number</u>	<u>Lot Format</u>
B03J086043	730806	08/31/2027	10/07/2024	13533- 800-24	20 G Vial
B03J077152	729688	10/10/2027	12/4/2024	13533- 800-24	20 G Vial
B03J079503	730807	08/16/2027	9/17/2024	13533- 800-40	40 G Vial
B01J100623	730807	10/03/2027	11/13/2024	13533- 800-40	40 G Vial