

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 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. This withdrawal is required to be conducted to the consumer/user level.

PRODUCT: Gamunex® -C 10%, 40G Vial

NDC NUMBER: 13533-800-40

LOT NUMBER: B01J112733

MARKET RELEASE: 12/13/2024

EXPIRATION DATE: 11/08/2027

MATERIAL NUMBER: 730807