

Grifols - Withdrawal of Gamunex-C® (immune globulin [human])

- On March 2, 2021, <u>Grif ols Therapeutics announced</u> a voluntary, consumer-level withdrawal of one lot of <u>Gamunex-C (immune globulin [human]</u>) injection due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered medically significant.
- The withdrawn Gamunex-C injection was distributed in the U.S. and had a market release date of November 30, 2020.

Product Description	NDC#	Lot# (Expiration Date)
Gamunex-C 10% (immune globulin [human])	13533-800-24	A4GLE01482 (10/22/2023)

- Gamunex-C is indicated for the treatment of primary humoral immunodeficiency in patients two
 years of age and older; idiopathic thrombocytopenic purpura in adults and children; and chronic
 inflammatory demyelinating polyneuropathy in adults.
- Per Grif ols, hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with intravenous immune globulin products.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using the withdrawn Gamunex-C injection.
- Anyone with an existing inventory of the withdrawn product should stop use and quarantine the product immediately.
- For more information regarding this withdrawal, contact Grifols US Clinical Communications at **1-800-520-2807** for further information regarding this withdrawal.



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