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

- On August 6, 2021, Grifols Therapeutics announced a voluntary, consumer-level withdrawal of several lots of Gamunex-C (immune globulin [human]) 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- The withdrawn Gamunex-C injection products were distributed in the U.S. and had market release dates from November 2020 through March 2021.

Product Description	NDC#	Lot# (Expiration Date)
Gamunex-C 10% (immune globulin [human])	13533-800-71	A1GKF00022 (1/2024); A1GKF00032 (1/2024); A1GKF00042 (1/2024); A4GKE01012 (10/2023); A4GKE01092 (10/2023);
	13533-800-24	A3GKE01432 (10/2023); A4GLE01512 (10/2023); A1GLE01582 (11/2023); A1GLE01642 (12/2023)

- 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 Grifols, 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contact their physician or healthcare provider if they have experienced any problems that may be related to using the withdrawn Gamunex-C injection.

- Anyone with an existing inventory of the withdrawn product should stop use and quarantine the product immediately.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 U.S. Clinical Communications at **1-800-520-2807** for further information regarding this withdrawal.