

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

- On April 27, 2021, <u>Grifols 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- The withdrawn Gamunex-C injection was distributed in the U.S. and had a market release date of December 23, 2020.

Product Description	NDC#	Lot# (Expiration Date)
Gamunex-C 10% (immune globulin [human])	13533-800-24	A1GLE01602 (11/19/2023)

- 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contact their physician or healthcare provider if they have experienced any problems that may be related to using the withdrawn Gamunex-C injection.
- Anyone with an existing inventory of the withdrawn product should stop use and quarantine the product immediately.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.



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 $\mbox{RxNews}^{\mbox{\tiny @}}$ is published by the OptumRx Clinical Services Department.

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