

Grifols - Withdrawal of Gamunex® -C (immune globulin [human]) 10% injection

- On February 19, 2025, <u>Grifols Therapeutics announced</u> a voluntary, consumer level withdrawal of one lot of <u>Gamunex-C (immune globulin [human])</u> 10% injection because of an increased rate of allergic/hypersensitivity type reactions.
- Gamunex-C was distributed nationwide.

Product Description	NDC#	Lot# (Expiration Date)
Gamunex -C 10% injection, 40 gram vial	13533-800-40	B01J112733 (11/8/2027)

- Gamunex-C is approved for the following indications:
 - Treatment of primary humoral immunodeficiency in patients 2 years of age and older
 - Treatment of adults and children with idiopathic thrombocytopenic purpura (ITP) to raise platelet counts to prevent bleeding or to allow a patient with ITP to undergo surgery
 - Treatment of chronic inflammatory demyelinating polyneuropathy in adults to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse.
- A small number of the reactions have been reported and were considered medically significant.
 Hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with immune globulin products.
- Anyone with the affected lot on hand should stop distribution and discard product.
- Contact US Clinical Communications by phone at 1-800-520-2807 for questions regarding this withdrawal.



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