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

- On February 19, 2025, Grifols Therapeutics announced a voluntary, consumer level withdrawal of one lot of Gamunex-C (immune globulin [human]) 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.