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

- On February 21, 2019, Grifols announced a voluntary, consumer-level recall of one lot 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.
    - Hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with IVIG products.
- The recalled lot was distributed starting December 15, 2018:

Product Description	NDC#	Lot# / Expiration Date
Gamunex-C 10%, 20 gm/200 mL	13533-0800-24	A1GLC01372 / 11/2/2021

- Gamunex-C is indicated for the treatment of primary humoral immunodeficiency in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. Gamunex-C is also indicated for the 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 and for the treatment of chronic inflammatory demyelinating polyneuropathy in adults to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled Gamunex-C.
- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.
- For more information regarding this recall, contact Grifols US Clinical Communications at **1-800-520-2807**.