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

- On March 23, 2021, Grifols Therapeutics announced a voluntary, consumer-level withdrawal 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.

- The withdrawn Gamunex-C injection was distributed in the U.S. and had a market release date of December 9, 2020.

<table>
<thead>
<tr>
<th>Product Description</th>
<th>NDC#</th>
<th>Lot# (Expiration Date)</th>
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<tbody>
<tr>
<td>Gamunex-C 10%</td>
<td>13533-800-24</td>
<td>A3GLE01462 (10/19/2023)</td>
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- 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contact their physician or healthcare provider if they have experienced any problems that may be related to using the withdrawn Gamunex-C injection.

- Anyone with an existing inventory of the withdrawn product should stop use and quarantine the product immediately.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.