

April 9, 2025

Subject: Communication regarding Gamunex® 10 g (100 mL) Stopper Complaints

Dear Customers,

We are reaching out to address complaints concerning the 10 g (100 mL) vial size of Gamunex® (immunoglobulin intravenous [human], 10%), where some hospitals in Canada have reported instances of rubber stoppers becoming dislodged and pushed into the vial, when spiked with IV administration sets. No adverse events or adverse drug reactions have been received by Grifols in association with these complaints. However, we recognize the disruption this has caused for healthcare administration teams.

We wanted to inform you that Grifols is actively implementing measures to address the concerns raised. These complaints are associated with a specific stopper design that has been used for a decade at one of our manufacturing facilities for Gamunex® 10 g (100 mL) but was only recently introduced for product for Canada. In the short term, we have reverted to production of this format for Canada exclusively at the previously used manufacturing line equipped with a more robust stopper design. Longer term, Grifols is working to implement a new vial and stopper design for this product across all manufacturing facilities.

In the meantime, several lots of Gamunex® 10 g (100 mL), already manufactured and packaged for Canada, remain in the supply chain. We sincerely appreciate your support as we work through existing inventory and offer the following general recommendations as a guidance when spiking the stoppers of these vials during this period:

- Ensure needles (16-gauge) or dispensing pins are penetrated perpendicular to the plane of the stopper within the area delineated by the raised ring.¹
- Place the vial on a flat surface; and spike the exact centre of the vial stopper in one swift motion. Avoid spiking slowly, as this allows the stopper to be driven through the neck of the vial into the solution.
- If the stopper becomes dislodged during spiking, we recommend the contents be discarded and encourage you to continue to report any instance to Canadian Blood Services, for tracking and monitoring purposes.

We are committed to addressing this issue as quickly as possible and once again, apologize for the disruption and frustration caused for hospitals and healthcare administration teams.

We appreciate your understanding and ongoing support.

Should you have questions regarding this communication, or if you require this letter in an accessible format, please contact Grifols Medical Information at 1-866-482-5226 or GrifolsCanadaMedInfo@grifols.com.

Sincerely,

Gillies, Martha Digitally signed by Gillies, Martha
Date: 2025.04.10 10:38:25 -04'00'

Martha Gillies
Sr. Director, Contract Operations, Quality & Logistics

Reference:

1. Product Monograph - Gamunex® (immunoglobulin intravenous [human], 10%), November 15, 2024.