September 21, 2016

Subject: Pooling/Administration of Gamunex® (immune globulin intravenous [Human]) 10% and IGIVnex® (immune globulin intravenous [Human] 10%)

To Whom it May Concern:

This letter is in response to your request for information concerning Gamunex® (Immune Globulin Intravenous (Human), 10%) and IGIVnex® (immune globulin intravenous [Human] 10%, (manufactured from Canadian Blood Services (CBS) plasma)).

We are pleased to provide you with the following information regarding these immune globulin intravenous products that are distributed in Canada by Grifols Canada Ltd.

Grifols Canada Ltd. does not recommend the use of its products in any manner inconsistent with Health Canada-approved product labeling. IGIVnex® and Gamunex® should not be mixed with a different immune globulin intravenous (human) product or formulation.1,2 A risk assessment for the mixing of immune globulin intravenous products from different manufacturers has not been conducted and consequently such mixing poses a potential risk to the patient.

It is acceptable, however, for IGIVnex® (DIN 02277921) and Gamunex® (DIN 02247724) to be mixed/pooled/administered together in order to complete a required dose.3 If pooling these two specific products, the contents of vials should be pooled under aseptic conditions into sterile infusion bags and infused within 8 hours after pooling.1,2 IGIVnex® and Gamunex® are identical in formulation, characteristics and physical properties.

We trust that this information addresses your request. If you have further questions, please contact Grifols Canada Ltd medical information at 1 (866) 482-5226.

Sincerely Yours,

Steven Roblin, Ph.D.
Director, Medical Affairs
Grifols Canada Ltd.

REFERENCES (not included)

3. Internal Data