



Canadian Blood Services
Société canadienne du sang

MWA 08DEC 2016

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INFORMATION ONLY

Grifols' Interchangeable Products

Customer Letter # 2016-34

2016-12-08

Dear Customer:

This letter is to provide information regarding Grifols' products as follows: IGIVnex® and Gamunex® are identical in formulation, characteristics and physical properties and therefore can be pooled/administered at the same dose. Similarly, Albumin and Plasbumin® are identical in formulation. For more precise details, please refer to the attached letters from Grifols Canada Ltd.

Canadian Blood Services will fill orders for the two brands of Grifols' IG and the two brands of Grifols' Albumin products based on current inventory levels. As the brands of each type of product are interchangeable, they are not considered substitutions with respect to the "no substitution" request on the order form.

Further information and references can be obtained by contacting Grifols Canada Ltd. medical information at 1-866-482-5226.

This customer letter can also be viewed at www.blood.ca in the "Hospitals" section. If you have questions about this letter, or if you require it in an accessible format, please contact your local hospital liaison specialist.

Sincerely,

Rick Prinzen
Chief Supply Chain Officer

Share your vitality

Partagez votre vitalité

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)).

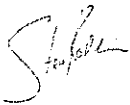
We are pleased to provide you with the following information regarding these immune globulin intravenous products that are distributed in Canada by Grifols Canada Ltd.

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)

1. **Gamunex[®]** (Immune Globulin Intravenous [Human] 10%) Manufactured by Chromatography, Product Monograph; January 26, 2016
2. **IGIVnex[®]** (Immune Globulin Intravenous [Human] 10%, CBS). Manufactured by Chromatography Product Monograph; January 26, 2016
3. Internal Data

GRIFOLS

Grifols Canada Ltd.
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Mississauga Ontario L4W 5N5
Tel 1-866-482-5226
www.grifols.com

September 21, 2016

Subject: Pooling/Administration of Grifols' Albumin (Human) 5% solution USP with Plasbumin[®]-5 and/or Pooling/Administration of Grifols' Albumin (Human) 25% solution USP with Plasbumin[®]-25

To Whom it May Concern:

This letter is in response to a request for information concerning pooling/administration of Grifols' **Albumin (Human) 5% solution USP** (manufactured from Canadian Blood Services (CBS) plasma) and **Plasbumin[®]-5** (Albumin [Human] 5% solution, USP); and/or pooling/administration of Grifols' **Albumin (Human) 25% solution USP** (manufactured from CBS plasma) and **Plasbumin[®]-25** (Albumin [Human] 25% solution, USP).

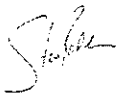
We are pleased to provide you with the following information regarding these albumin products that are distributed in Canada by Grifols Canada Ltd.

Grifols Canada Ltd. does not recommend the use of its products in any manner inconsistent with Health Canada-approved product labeling. Grifols does not recommend the pooling of our albumin products (**Plasbumin[®]-5, Plasbumin[®]-25, Albumin (Human) 5% solution USP, or Albumin (Human) 25% solution USP**), with those of other manufacturers, since Grifols has no knowledge of the manufacturing processes used for albumin products from other suppliers.

It is acceptable, however, for **Plasbumin[®]-5** (DIN 02189100) and Grifols' **Albumin (Human) 5% solution USP** (DIN 02223594) products to be pooled/administered together in order to complete a required dose. Similarly, it is acceptable for **Plasbumin[®]-25** (DIN 02189119) and Grifols' **Albumin (Human) 25% solution USP** (DIN 02223708) products to be pooled/administered together in order to complete a required dose. Grifols' **Plasbumin[®]** and **Albumin** products of the same albumin concentration 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, PhD
Director, Medical Affairs
Grifols Canada Ltd.

References:

1. Product Monograph Albumin (Human) 5% Solution, USPp, Intravenous Solution. December 19, 2011.
2. Product Monograph Albumin (Human) 25% Solution, USP, Intravenous Solution. December 19, 2011.
3. Product Monograph Plasbumin[®]-5 (Albumin (Human) 5%, USP Intravenous Solution). July 28, 2015.
4. Product Monograph Plasbumin[®]-25 (Albumin (Human) 25%, USP Intravenous Solution). July 2, 2015