Alberta Health Services

This document applies to all Covenant and AHS sites.

Gamunex® Immune Globulin 10%

Class: *Manufactured product, derived from human plasma*

OTHER NAMES: Intravenous Immune Globulin, IVIG, CBS IGIV-nex™

Company: Grifols

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**Intermittent Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	No	Yes	No	No	No	N/A

*** Professionals performing these restricted activities have received authorization from their regulatory college and have the knowledge and skill to perform the skill competently.**

DESCRIPTION OF PRODUCT:

- Gamunex® is manufactured from large pools of human plasma by a combination of cold alcohol fractionation, caprylate precipitation and filtration, and anion exchange chromatography.
- Viral inactivation and/or removal processes include: caprylate incubation, column chromatography, and final container low pH incubation.
- Contains 9-11% protein (98% of which is gamma globulin) in 0.16-0.24M glycine.
- pH is 4.0 – 4.5
- Contains no preservative
- Majority of gamma globulin is IgG, but contains trace amounts of IgA (avg 0.46 mg/ml) and IgM (below measurable limit of 0.002 g/L)
- Solution is colourless, free of particulate matter and not turbid.
- Dispensed in 20 g, 10 g, 5 g and 2.5 g bottles (1 gram=10 mL)

Note: CBS IGIV-nex™ is made from plasma supplied to Talecris from Canadian Blood Services (CBS). It is made by the same process as Gamunex® and can therefore be used interchangeably. Transfusion Medicine will supply either of these products based on what is available at the time.

AVAILABILITY:

- Canadian Blood Services (CBS) provides 3 different IVIG products from 3 different manufacturers: Grifols **Gamunex®**, Baxter **Gammagard Liquid®** and CSL Behring **Privigen®** at a predetermined percentage.
- Contact your local laboratory/transfusion service regarding stock availability on site.
- Please complete the IVIg request form found at http://www.albertahealthservices.ca/frm-20549.pdf where required (i.e. Edmonton zone) when IVIg is initially ordered for a patient.

Note: Baxter Gammagard S/D® (lyophilized) is also available. This preparation contains the least amount of IgA of all the IVIG products and is reserved only for patients that have IgA deficiency and documented anti-IgA.

INDICATIONS FOR USE:

- Primary and Secondary Immune Deficiency (PID, SID), Idiopathic Thrombocytopenia Purpura (ITP), Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

CONTRAINDICATIONS:

- Known hypersensitivity to Gamunex®, its formulation or ingredients or components of the container.
- Known anaphylactic or severe systemic response to human immune globulins.
- Individuals with severe, selective IgA deficiencies who have known antibody against IgA (anti-IgA antibody).

Caution: May impair the efficacy of live attenuated virus vaccines. Refer to the Canadian National Advisory Committee on Immunization for further recommendations.

DOSE:

Immune Defeciency (Primary or Secondary)

- 0.4 g/kg every 3-4 weeks

Idiopathic Thrombocytopenia Purpura:

- Highest approved dose is 1 g/kg for ITP only.

Adult Patients: All Gamunex doses should be rounded up or down to nearest 5 gram increment at time of ordering. Transfusion Medicine/lab will provide Gamunex to the nearest 5 gram increment if prescriber omits this step.

ADMINISTRATION:

Ensure patient consent has been obtained prior to requesting blood product from lab/transfusion service where possible.

Pre-Infusion: Ensure recent patient weight and height is on file, pertinent labs are available as required (ie. trough IgG, IgA, CBC), and that any premedications ordered have been given (antihistamines, antipyretics prn). Perform the appropriate pre-transfusion checks per protocol. Report any new onset acute illness to MD/authorized prescriber prior to commencing infusion.

Access: Gamunex® can be given via CVC, PICC or peripheral venous line.

Compatible IV Solutions: D5W **only**.

Administration Set: Gamunex® should be given using a vented and unfiltered set.

Priming & infusing IVIG bottles (to minimize air bubbles):

- Allow IVIG time to come to room temperature where possible.
- Spike a minibag of D5W with vented and unfiltered set, fill drip chamber to ~2/3 full and prime entire line.
- Invert the first IVIG bottle (smallest bottle first) and spike the bottle using aseptic technique.
- Using the plastic hanger affixed to the IVIG bottle, hang the first bottle from the IV pole.
- Load the line into the IV pump, program and infuse as per guidelines below.
- **Note: Subsequent bottles can be infused at the same maximum rate as tolerated by the patient on previous bottles (ie. new bottles do not have to be restarted at initial rate).**

Infusion Rate:

- For adult infusions, please refer to the following table:
  http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-adult-rate-ivig.pdf

- For pediatric infusions, please refer to following table:
  http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-ped-rate-ivig.pdf

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Most reactions to IVIG are due to serum osmolarity changes and are rate related reactions (vs. reactions to a single donor in a pool of IVIG).
- Slower infusion rates will diminish rate related symptoms such as headache, shivering, tachycardia and blood pressure alterations.
- Some patients may require pretreatment with antihistamines, anti-inflammatories and corticosteroids, particularly if they have a past history of reaction
- Serious but rare complications of IVIG include anaphylaxis, hemolytic anemia (delayed reaction up to 10 days later), thromboembolic events, aseptic meningitis and renal failure (with older sucrose containing IVIG preparations). These reactions are reportable to Health Canada via Transfusion Medicine/lab.

Minor IVIG Reactions	
If patient experiences any of the following after starting the infusion:	**Then:**
- Skin rash - Dizziness - Mild headache (not improved with rate decrease) - Flushing - Muscle pain and arthralgias - RR 30% increase over baseline - (ie. RR of 18 increasing to 24) - HR 15% increase over baseline - (ie. HR of 60 increasing to 70) - Diastolic BP 15% change from baseline - Temperature increase less than 1.0C	1. Decrease infusion rate to highest previously tolerated 2. Recheck vitals within 5 minutes 3. Continue new rate, if tolerated 4. Recheck vital signs after 10 minutes 5. Continue at new rate and progressively increase vital signs and rate increase schedule, restarting at q15 minutes x 2, for remainder of infusion. 6. Notify MD/authorized prescriber and Transfusion Medicine/lab after completion of infusion. 7. Document reaction & care provided in patient health record and by completing the appropriate notification of reaction for the Transfsuion Service/Laboratory
Major IVIG Reactions	
If patient experiences any of the following after starting the infusion:	**Then:**
- RR 60% increase over baseline (ie. RR of 18 increasing to 28) - HR 30% increase over baseline (ie. HR of 60 increasing to 78) - SBP or DBP 30% change from baseline - Temperature increase more than 1.0 C - Chills, rigors, diaphoresis - SOB, wheezing - Severe headache + meningeal signs - Anaphylaxis - Chest or abdominal pain	**1. Stop infusion** 2. Assess vitals and ABCs (airway, breathing, circulation) 3. Notify MD/authorized prescriber and Transfusion Medicine/lab 4. Disconnect IV tubing at a point closest to patient. 5. Flush IV site with 0.9% normal saline rather than D5W 6. Infuse 0.9% normal saline at a rate equal to current IVIG rate 7. Administer emergency medications as ordered. 8. Closely monitor patient 9. Document reaction/ care provided in patient health record and by completing the appropriate notification of reaction for the Transfsuion Service/Laboratory 10. Return unused product to Transfusion Medicine/lab.

NURSING IMPLICATIONS:

Patient Vital Signs and Monitoring:

	Pre-transfusion	**At each rate increase (to assess tolerability)**	**Remainder of transfusion**	**Post transfusion**
ADULTS and PEDIATRICS	**Yes**	**Yes**	**q1h**	**20-30 min post, then PRN**

Note: Vital signs/patient monitoring may be conducted more frequently as determined by clinical condition of patient.

Patients receiving blood product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up instructions to a transfusion reaction, click http://www.albertahealthservices.ca/4240.asp.

Documentation:

- Ensure documentation is completed as per the AHS *Transfusion of Blood Components and Products* procedure.
- Patient tolerability should also be documented in appropriate flow chart or clinical record (electronic or paper) as required.
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper).

Laboratory Monitoring:

- High doses of IVIG (ie. 2 g/kg) or consecutive days of IVIG therapy may cause temporary increases in serum and urine glucose.
- False positive results in serological tests may occur (e.g. CMV serology, Direct Antiglobulin Test, etc.).

STORAGE & STABILITY of PRODUCT:

- Stored at 2-8 °C. **Do not freeze**.
- Product should be infused within 4 hours from spiking.

COMMENTS: Date Effective: 10 Mar 2017 Revised Date: 06 Mar 2017 Version: 1.1 Approved By: TM Integration Network Document Number: PTMGNR00040 *If you have any questions regarding this document please email: transfusion.safetyteam@ahs.ca*
REFERENCES Gamunex® product monograph SCN 148326
LINK to WEBSITE http://www.grifols.ca