



Gamunex® / IGIVnex® Immune Globulin Intravenous (Human) 10%

APPLICABILITY: This document applies to APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.				OTHER NAMES: <i>Intravenous Immune Globulin, IVIG</i>		
				Company: <i>Grifols Therapeutics</i>		
				Class: <i>Manufactured blood product, derived from human plasma</i>		
	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:						
<ul style="list-style-type: none"> ▪ Gamunex® and IGIVnex®* are sterile solutions of human immunoglobulin protein made from large pools of human plasma by a combination of cold ethanol fractionation, caprylate precipitation and filtration, and anion-exchange chromatography. ▪ Viral inactivation/removal steps include caprylate incubation, column chromatography, and final container low pH incubation. ▪ Contains 9-11% protein, 98% of which is gamma globulin ▪ Average immunoglobulin A (IgA) concentration is 0.046g/L, and not more than 0.084 g/L ▪ Solution is colourless, free of particulate matter and not turbid ▪ Available in 2.5g, 5g, 10g, and 20g vials (1 gram = 10 mL) ▪ pH is 4.0 – 4.5 ▪ Also contains glycine ▪ Preservative-free ▪ Latex-free 						
*Note: CBS IGIV-nex™ is made from plasma supplied to Grifols from Canadian Blood Services (CBS). It is made by the same process as Gamunex® and the two brands can therefore be used interchangeably.						
AVAILABILITY:						
<ul style="list-style-type: none"> ▪ Canadian Blood Services (CBS) provides IVIG products from multiple manufacturers at predetermined percentages. Local availability of a particular IVIG brand is based on provincial alignment with CBS availability. ▪ Requests for IVIG must meet approved indications. An IVIG request form must be completed for initial approval and for renewal http://www.albertahealthservices.ca/frm-20549.pdf unless ordered through Connect Care. 						
INDICATIONS FOR USE:						
<ul style="list-style-type: none"> ▪ IVIG may be appropriate in a number of clinical indications. Refer to the Prairie Collaborative Criteria for the Clinical Use of Immune Globulin 						

CONTRAINDICATIONS:

- Patients who are hypersensitive to human immune globulin, or any ingredient in the formulation or component of the container.
- IgA deficiency when the patient has antibodies against IgA **and** a history of hypersensitivity (can result in severe anaphylactic reaction).

WARNINGS:

- May impair the efficacy of live attenuated virus vaccines. Refer to the Canadian National Advisory Committee on Immunization for further recommendations.
- IVIG has been reported to be associated with renal dysfunction. The minimum concentration and the minimum rate of infusion practicable should be used.
- There is evidence of an association between IVIG administration and thromboembolic events in patients with pre-existing risk factors for thrombotic events including: obesity, advanced age, diabetes mellitus, history of vascular disease or thrombotic episodes, acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilization, severe hypovolemia and patients with disease states that increase blood viscosity.
- IVIG can contain blood group antibodies which may act as hemolysins and induce in vivo coating of red blood cells with immunoglobulin, causing a positive direct antiglobulin reaction and, rarely, clinically significant hemolysis.

DOSE:

- Use the lowest dose for the shortest duration required to achieve clinical efficacy
- Use adjusted body weight dosing for adult patients with a height of greater than 152 cm and a weight of 20 – 200 kg. Body weight adjusted dose calculator is available at https://www.albertahealthservices.ca/webapps/labservices/IVIG_Dosing_Calculator.htm
- If IVIG is being used for immune replacement therapy (primary or secondary), monitoring trough levels is recommended
- IVIG dose will be rounded to the nearest available vial size.
- Refer to the [Prairie Collaborative Criteria for the Clinical Use of Immune Globulin](#) for dosing recommendations.

ADMINISTRATION:

Confirm written (signed) consent has been obtained and documented prior to requesting blood component from lab/transfusion service where possible.

Pre-Infusion:

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

Access: Gamunex®/IVIGnex® can be given via CVAD or peripheral venous line.

Compatible IV Solutions:

- Compatible with D5W.
- Do not mix with other products, medications, or solutions.
- Normal saline may be used to prime and flush the line.

Administration Set:

- Gamunex®/IVIGnex® should be given using a vented, unfiltered set.
- Note: a filter is not necessary, but if used, a pore size of 15 microns or larger will be less likely to slow infusion. 0.2 micron filters may be used.

IV Administration:

- Visually inspect the product prior to administration. Do not use products that are cloudy or contain particulates.
- Allow IVIG time to come to room temperature where possible.
- Be careful not to shake the IVIG vial.
- If multiple vials sizes will be infused, start with the smallest vial first.
- Ensure the vent is open to ensure a steady flow of IVIG
- Use of a syringe pump is acceptable.
- IVIG vials should be infused within 4 hours of spiking.
- Flush the line to ensure all product is infused

Infusion Rate:

- Patients should be infused at a lower infusion rate if:
 - This is their initial treatment with the particular IVIG brand.
 - It has been more than 8 weeks since the last IVIG treatment
 - The patient has renal impairment, risk of thrombosis, or is >65 years old
 - The patient does not tolerate a faster infusion rate.
- For adult infusions, refer to the following table:
<http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-adult-rate-ivig.pdf>
- For pediatric infusions, refer to following table:
<http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-ped-rate-ivig.pdf>
- Subsequent vials may be infused at the same maximum rate as tolerated by the patient on previous vials (ie. new vials do not have to be restarted at initial rate)

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 Transfusion Medicine/lab.
- Patients with antibodies to IgA or with IgA deficiencies may be at increased risk of anaphylactic reaction

Minor IVIG Reactions	
If patient experiences:	Then:
<ul style="list-style-type: none"> ▪ Skin rash ▪ Dizziness ▪ Mild headache (not improved with rate decrease) ▪ Flushing ▪ Muscle pain and arthralgia ▪ RR 30% increase over baseline (e.g. RR of 18 increasing to 24) ▪ HR 15% increase over baseline (e.g. HR of 60 increasing to 70) ▪ Diastolic BP 15% change from baseline ▪ Temperature increase less than 1.0C 	<ol style="list-style-type: none"> 1. Decrease infusion rate to highest previously tolerated rate. 2. Recheck vitals within 5 minutes. 3. Continue new rate, if tolerated. 4. Recheck vital signs after 10 minutes. 5. Continue at new rate. Progressively increase vital signs and rate increase schedule, restarting at q15 minutes x 2, for remainder of infusion. 6. Notify authorized prescriber and Transfusion Medicine lab after completion of infusion. 7. Document transfusion reaction and care provided in patient health record 8. Complete transfusion reaction notification and forward to Transfusion Medicine lab
Major IVIG Reactions	
If patient experiences:	Then:
<ul style="list-style-type: none"> ▪ RR 60% increase over baseline (e.g. RR of 18 increasing to 28) ▪ HR 30% increase over baseline (e.g. HR of 60 increasing to 78) ▪ Systolic or diastolic BP 30% change from baseline ▪ Temperature increase more than 1.0 C ▪ Chills, rigors, diaphoresis ▪ SOB, wheezing ▪ Severe headache and meningeal signs ▪ Anaphylaxis ▪ Chest or abdominal pain 	<ol style="list-style-type: none"> 1. Stop infusion 2. Assess vitals and ABCs (airway, breathing, circulation) 3. Notify 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 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 transfusion reaction and care provided in patient health record 10. Complete transfusion reaction notification 11. Forward transfusion reaction notification and remaining 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, go to <http://www.albertahealthservices.ca/lab/page4240.aspx>

Documentation:

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

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.).
- Provide patient notification documentation where required.

STORAGE & STABILITY:

- Store at 2-8°C until expiry (up to 36 months from date of manufacture).
- May be stored for up to 6 months at room temperature (up to 25°C). Product expires after 6 months RT storage.
- Do not freeze.
- Do not use expired product.

COMMENTS:

Date Effective: 22 July 2021

Revision #: 2.10

Document Number: TM40-01.02.103

Approved By: APL Transfusion Medicine Discipline Council

For questions or comments regarding this document please contact: Transfusion.SafetyTeam@aplabs.ca

REFERENCES

Gamunex® and IGIVnex® manufacturer product monographs. Available from www.grifols.ca

Prairie Collaborative Immune Globulin Utilization Management Framework Project. *Criteria for the clinical use of immune globulin*. Alberta Ministry of Health, Shared Health Manitoba, and Saskatchewan Ministry of Health; 2018. Available from www.ihe.ca

[Canadian National Advisory Committee on Immunization](http://www.cnic.gc.ca/)