ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Cytogam®

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:*** *Cytomegalovirus Immune Globulin Intravenous, CMVIg* ***Company: Saol Therapeutics / CSL Behring*** ***Class:*** *Manufactured blood product, derived from human plasma*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV 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:

- Sterile liquid gamma globulin (IgG) fraction prepared from pooled human plasma containing antibodies directed against Cytomegalovirus (CMV).
- Viral reduction steps include cold ethanol precipitation and solvent/detergent treatment.
- Solution is colorless and translucent.
- Available in a single-use 50 mL vial containing 2.5 g immune globulin.
- Also contains 5% sucrose and 1% human albumin.
- Preservative free
- **NOT** latex free

AVAILABILITY:

- Supplied by Canadian Blood Services
- Availability is limited. Contact your local laboratory/transfusion service regarding stock availability on site

INDICATIONS FOR USE:

- For the attenuation of primary (1°) CMV disease associated with kidney transplantation in recipients who are CMV seronegative, and who receive a kidney from a CMV seropositive donor.

CONTRAINDICATIONS:

- History of prior severe reactions associated with CytoGam®, or other human immune globulin preparations.
- IgA deficient patients.

WARNINGS:

- IVIG products containing sucrose as stabilizer have been associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death. Periodic monitoring of renal function tests and urine output is particularly important in patients judged to have a potential increased risk for developing acute renal failure.
- Due to the risk of thrombotic events, caution should be exercised in patients with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, and/or known or suspected hyperviscosity.
- Immune globulin administration may impair the efficacy of live attenuated virus vaccines (measles, mumps, rubella, varicella). Vaccination with live virus vaccines should be deferred until approximately 3 months after CytoGam® administration. Patients who received live virus vaccination shortly after CytoGam® administration may require re-vaccination.

DOSE (Refer to Product Insert):

- **Maximum** recommended total dosage per infusion is 150 mg/kg.
- Refer to product insert for manufacturer recommended dosing schedule

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 is on file and pertinent labs are available. Perform the appropriate pre-transfusion checks per transfusion policy and procedure.
- Ensure the patient is not volume depleted prior to Cytogam® infusion.
- Visually inspect solution for particulate matter and discoloration. Do not use if solution is not colorless, free of particulate matter, and not turbid.
- Bring to room temperature just before use. Do **NOT** shake vial. Avoid foaming.
- Do **NOT** pre-dilute.

Administration Supplies:

- Vented intravenous administration set with inline filter (15 micron), or 'add-a-line' filter (0.2 micron)
- Infusion pump

Compatible Solutions:

- 0.9% normal saline
- Dextrose solutions (with or without NaCl added): 2.5% dextrose in water, 5% dextrose in water, 10% dextrose in water, 20% dextrose in water.

Administration:

- The vial should be entered only once.
- Begin infusion within 6 hours of entering vial and complete within 12 hours of entering vial.
- A separate infusion line is preferred.
- May be 'piggybacked' into an existing line containing the above compatible solutions, but do **NOT** dilute more than 1:2 with any of the above solutions.
- Concentration: 1 mL = 50 mg anti-CMV immune globulin
- **Administration Rate :**

Initial dose :

Time	Rate
Initial (Start @)	15 mg/kg/h
@ Start + 30 min.	30 mg/kg/h
@ Start + 60 min.	**Max.** 60 mg/kg/h **(Do NOT exceed 75 mL/h)**

Subsequent doses :

Time	Rate
Initial (Start @)	15 mg/kg/h
@ Start + 15 min.	30 mg/kg/h
@ Start + 30 min.	**Max.** 60 mg/kg/h **(Do NOT exceed 75 mL/h)**

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Potential adverse events related to a blood product transfusion range in severity from minor with no sequelae to life-threatening.
- All adverse events occurring during a transfusion should be evaluated to determine whether or not the transfusion can be safely continued/restarted.
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) must be reported to your local transfusion service.
- **The most commonly reported adverse reactions are flushing, chills, muscle cramps, back pain, fever, nausea, vomiting, arthralgia, and wheezing.**

Side Effects - Flushing - Headache - Nausea - Itching and redness at the venipuncture site	→	**Action** Slow rate of infusion
Potential Allergic Reaction - Stuffy nose - Hives/severe itching - Cough - Chest pain - Wheezing - Facial swelling - Fainting	→	**Action** **STOP** infusion **IMMEDIATELY** and contact physician

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** midway, before each rate increase, and upon completion of dose and as warranted by the patient's condition.
- If the patient has experienced previous adverse reaction to product transfusion, or this is the first transfusion of product for patient, monitor for 30-60 minutes post

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:

- The transfusion documentation should be double signed (where required) to indicate infusion.
- Start and stop time of infusion and assessment of 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).
- Provide patient notification documentation where required.

STORAGE & STABILITY OF PRODUCT:

- Store at 2°C - 8°C.
- Do not freeze.
- Stable up to the expiration date indicated on the vial

COMMENTS:

Date Effective: 23 Oct 2020
Revision: 1.41
Approved By: APL Transfusion Medicine Discipline Council
Document Number: TM40-01.02.016
For questions or comments about this document, please contact Transfusion.SafetyTeam@albertaprecisionlabs.ca

REFERENCES

Cytogam® Product Monograph. Available from: www.saolrx.com