ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Cytogam®

APPLICABILITY: This document applies to all 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:*** *Kamada* ***Class:*** *Manufactured blood product, derived from human plasma*

In the event of discrepancy between APL Monograph and Manufacturer's documentation or patient resources, the APL Monograph will take precedence.

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

* Administration of blood components and blood products is a restricted activity. For specific conditions that apply to a profession's authorization to administer blood components and blood products, consult the applicable discipline-specific regulation under the Health Professions Act (Alberta). Health care professionals with this authorization require the applicable education, training and competency.

** Direct IV administration of blood products may be performed by health care professionals that have authorization of administration of blood products within their scope of practice.

DESCRIPTION:

- 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.
- Contact your local laboratory/transfusion service regarding stock availability on site.

INDICATIONS FOR USE:

- For the prophylaxis of CMV disease associated with solid organ transplantation. The use of CMVIg and the need for concomitant antiviral therapy ideally should be as recommended by Infectious Disease specialists with experience in transplantation.

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. After infusion of immunoglobulin, the transitory rise of the various passively transferred antibodies in the patient's blood may result in misleading positive results in serological testing.

DOSE:

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

ADMINISTRATION:

Confirm signed consent has been obtained and documented prior to requesting blood components or products (human-source) 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. Infuse the solution if it is 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.

Access:

- Product can be given via CVC, PICC, or peripheral IV line

Compatible IV 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 Supplies:

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

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 :

Initial Rate:	Then:	Then:
0.3 mL/kg/h x 30 min (15 mg/kg/h)	0.6mL/kg/h x 30 min (30mg/kg/h)	1.2mL/kg/h for remainder of infusion *Do not exceed 75 mL/h (60mg/kg/h)

Subsequent doses :

Initial Rate:	Then:	Then:
0.3mL/kg/h x 15min (15mg/kg/h)	0.6mL/kg/h x 15 min (30mg/kg/h)	1.2mL/kg/h for remainder of infusion *Do not exceed 75mL/h (60mg/kg/h)

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires.
- 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 to a transfusion reaction see Transfusion Reactions | Alberta Health Services. Notify the transfusion service as soon as possible that an adverse reaction has occurred.

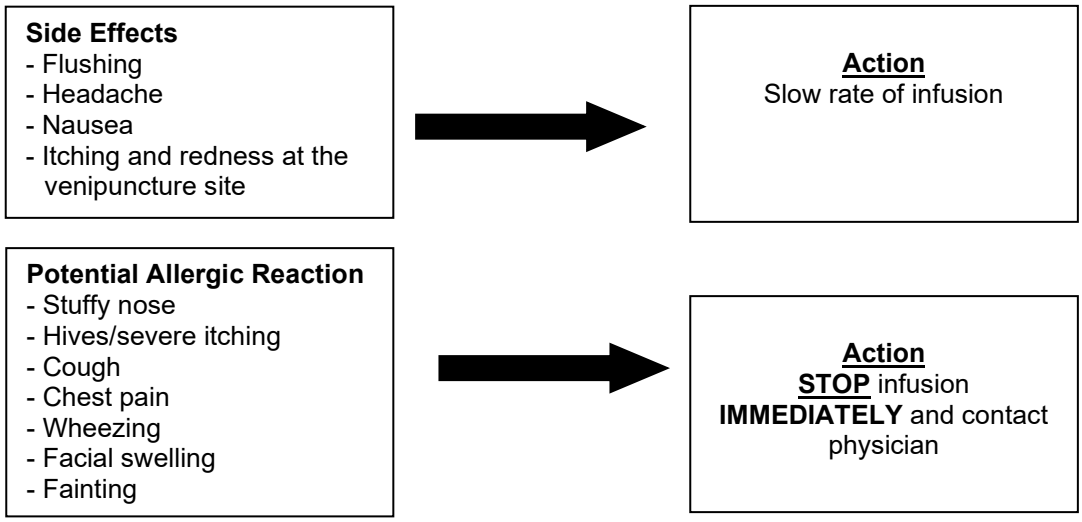
Documentation:

- Ensure documentation is completed as per the AHS Transfusion of Blood Components and Products Policy
- Start and stop time of infusion and assessment of 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 of transfusion documentation where required.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

Adverse Events

- 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 common adverse reactions observed are flushing, chills, muscle cramps, back pain, fever, nausea, vomiting, arthralgia, and wheezing.
- The most serious adverse reactions observed are angioneurotic edema and anaphylactic shock are possible.



STORAGE & STABILITY:

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

Contact Information

Approved By: APL Transfusion Medicine Discipline Council

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

REFERENCES:

Cytogam® Product Monograph. Available from Package Insert - CytoGam