ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

GamaSTAN®

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:*** *Intramuscular Immune Globulin, IMIG* ***Company:*** *Grifols* ***Class:*** *Manufactured 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	No	No	No	Yes	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:

- GamaSTAN® is a sterile solution of immune globulin manufactured from large pools of human plasma.
- Manufactured by cold ethanol fractionation, caprylate precipitation and filtration, caprylate incubation, anion-exchange chromatography and nanofiltration.
- Product is a clear to slightly opalescent liquid which can range from colourless to pale yellow or light brown.
- Preservative-free.
- 15-18% protein solution at a pH of 4.1 to 4.8 in 0.16 to 0.26 M glycine.
- Available in 2mLvials.

AVAILABILITY

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

INDICATIONS FOR USE:

- Passive immunization when vaccines for active immunization are not available, contraindicated, or exposure to the infective agent has occurred prior to vaccination.
- May be used for passive immunization for Hepatitis A , Measles (Rubeola), Varicella, Rubella in specific clinical circumstances (see package insert).

CONTRAINDICATIONS:

- Patients who are hypersensitive to the product or any ingredient in the formulation or component of the container (see product insert).
- Patients with isolated immunoglobulin A (IgA) deficiency, due to the potential for developing antibodies to IgA leading to subsequent anaphylactic reactions to blood components and products containing IgA.
- Patients with severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections.

WARNINGS:

- There is clinical evidence of an association between immune globulin administration and thrombotic events. Thrombosis may occur even in the absence of known risk factors. Risk factors for thromboembolic events include: obesity, advanced age, hypertension, diabetes mellitus, history of vascular disease or thrombotic episodes, acquired or inherited thrombophilic disorders, prolonged periods of immobilization, severe hypovolemia, diseases which increase blood viscosity, hypercoagulable conditions, use of estrogens, indwelling central venous catheters, and cardiovascular risk factors.
- Antibodies in the globulin preparation may interfere with the response to live viral vaccines such as measles, mumps, polio and rubella. Use of such vaccines should be deferred until approximately 5-6 months after GamaSTAN® administration.

DOSE:

- **Hepatitis A:**
  - Household and institutional case contacts: recommended dose 0.1mL/kg
  - Travel prophylaxis recommended dose:
    - 0.1mL/kg for up to 1 month length of stay
    - 0.2 mL/kg for up to 2 month length of stay.
    - Repeat 0.2 mL/kg every two months for longer lengths of stay
- **Measles (Rubeola):**
  - Exposed less than 6 days ago: recommended dose 0.25 mL/kg
  - Immunocompromised child or patient with malignant disease: recommended dose 0.5mL/kg (max 15 mL)
- **Varicella** (if Varicella Immune Globulin not available): recommended dose 0.6 – 1.2 mL/kg
- **Rubella** (Susceptible, exposed pregnant women): recommended dose 0.55ml/kg

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 nursing protocol.

Access:

- Intramuscular injection only.
  - Preferred sites are the anterolateral aspects of the upper thigh and the deltoid muscle of the upper arm.
  - The gluteal regions should not be used routinely due to risk of injury to the sciatic nerve. If the gluteal region is used, use only the upper, outer quadrant.
  - Doses over 10mL should be divided and injected into several muscle sites to reduce local pain and discomfort.
- If Hepatitis A Vaccine is recommended along with GamaSTAN®, administer simultaneously but at separate anatomic sites.

Administration:

- Visually inspect for particulate matter and discoloration prior to administration.
- Do not administer intravenously or subcutaneously because of the potential for serious reactions.
- Administer at the minimum rate practicable.

Vials are single use. Once entered, discard any unused contents.

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.

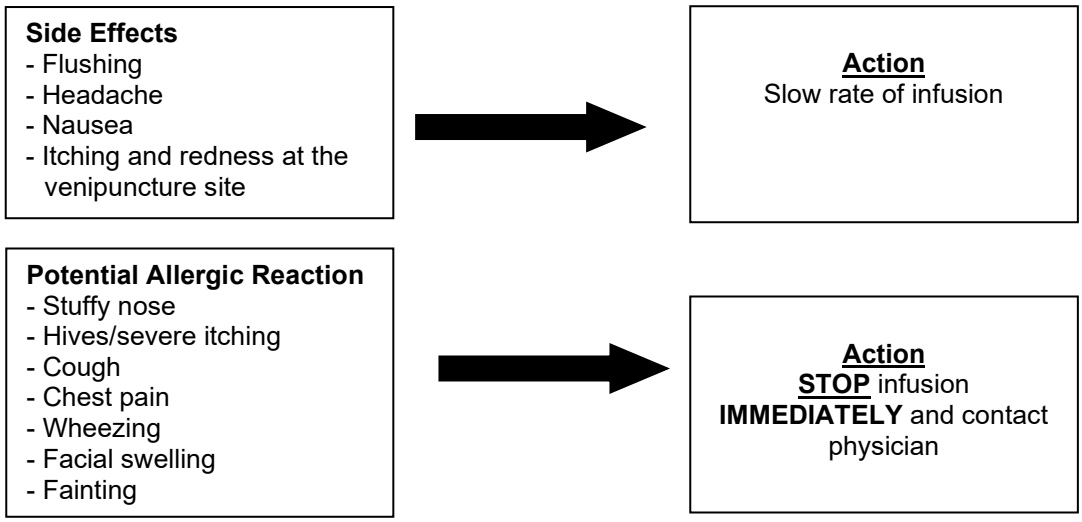
Documentation:

- 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 commonly reported adverse reactions in patients receiving GamaSTAN® include local injection-site reactions (pain, inflammation, hemorrhage), fatigue, pyrexia, headache, nausea, and allergic/anaphylactic reactions.



STORAGE & STABILITY:

- Stored at 2-8°C.
- **Do not freeze.**
- Do not use expired product.

CONTACT INFORMATION:

Approved By: APL Transfusion Medicine Discipline Council
For questions or comments regarding this document please contact: Transfusion.SafetyTeam@aplabs.ca

REFERENCES:

Grifols 13 March 2019 GamaSTAN® Product Monograph. Available from [Product Monograph Template - Standard] (hres.ca)