ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

HepaGam B®

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:*** *Hepatitis B Immunoglobulin* ***Company:*** *KI BioPharma LLC* ***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*	Yes**	Yes**	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:

- HepaGam B® is a sterile 5% solution of purified gamma globulin (IgG) containing antibodies to hepatitis B surface antigen (anti-HBs), prepared from large pools of human plasma.
- Viral reduction steps include filtration (20nm) and solvent/detergent treatment.
- Available in 1 mL and 5 mL single use vials containing >312 IU/mL of anti-HBs.
- Stabilized with 10% maltose and 0.03% polysorbate 80.
- May contain trace amounts of tri-n-butyl phosphate and Triton X-100®
- Preservative free.
- Latex free.

AVAILABILITY

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

INDICATIONS FOR USE:

- Post-exposure prophylaxis of individuals without known anti-HBs following significant exposure to HBsAg positive materials such as blood.
  - Parenteral exposure, direct mucous membrane contact, or oral ingestion involving HBsAg positive materials such as blood, plasma or serum, preferably within 48 hours and up to 7 days after exposure.
  - Prophylaxis of infants born to HBsAg positive mothers, preferably within 12 hours of birth and up to 7 days after birth.
  - Infants (less than 1 year of age) whose mother, father, or primary caregiver has or is suspected to have acute hepatitis B or is a carrier of hepatitis B
  - Sexual contacts of an acute case of hepatitis B including victims of sexual assault.
- Prevention of hepatitis B recurrence following liver transplantation in adult patients with hepatitis B who have no or low levels of HBV replication. HepaGam B® is the product of choice for liver transplant patients.

CONTRAINDICATIONS:

- History of anaphylactic or severe systemic reaction of any of the component of the product.
- IgA-deficient patients with anti-IgA antibodies (due to potential anaphylactoid reactions).
- Patients in whom IM administration is contraindicated due to severe thrombocytopenia or coagulation disorders.

WARNINGS:

- May impair the efficacy of live attenuated virus vaccines. Vaccination with live virus vaccines should be deferred until approximately 3 months after HepaGam B® administration. Refer to the Canadian National Advisory Committee on Immunization for further recommendations.
- People who receive hepatitis B vaccine might be transiently positive for HBsAg, with reports of transient positivity 18 days post-vaccination. Retesting of patients who are positive for HBsAg shortly after hepatitis B vaccination at a later time is needed to determine the true HBV infection status.
- As per manufacturer's product monograph, there is evidence of an association between IG 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.
- IG has been reported to be associated with renal dysfunction. The minimum concentration and the minimum rate of infusion practicable should be used.
- The maltose contained in HepaGam B can interfere with some types of blood glucose monitoring systems, leading to falsely increased results.

DOSE:

- For post-exposure prophylaxis, refer to the product insert and the Canadian Immunization Guide for Hepatitis B for HBIG and Hepatitis B vaccine series recommendations.
- For prevention of hepatitis B recurrence following liver transplantation in adults with hepatitis B, dose should be administered IV in order to attain serum anti-HBs levels greater than 500 mIU/mL. See recommended dose schedule in the product insert.
- If patients develop treatment-related adverse events due to immune complex formation between HBIG and circulating HBsAg, dose adjustments may be required.

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.
- Visually inspect for particulate matter and discoloration. The solution should be clear or slightly opalescent. Do not use solutions that are cloudy or have deposits.
- Allow vial to warm to room or body temperature before use
- Do not shake vial. Avoid foaming.

Access:

- For post-exposure prophylaxis, administer by intramuscular injection.
  - Administer in a separate site if given in combination with hepatitis B vaccine.
  - 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.
- For prevention of hepatitis B recurrence following liver transplantation, administer by CVC, PICC, or peripheral IV line.

Compatible IV Solutions:

- 0.9% normal saline only

Administration Supplies:

- IM administration:
  - Sterile syringe (appropriate size)
  - Injection Needle (appropriate size)
- Direct IV administration:
  - Sterile plastic luer lock syringe (large enough to contain dose)
  - Needless injection tips (as required), or
  - Filter needle (if patient DOES NOT have IV administration set with in-line or 'add-a-line' filter)
- IV Infusion:
  - Intravenous administration set with inline filter (15 micron), or 'add-a-line' filter (0.2 micron) .
  - Infusion pump
  - 50 mL normal saline mini-bag

Administration:

- **Do not** shake vial
- A separate infusion line should be used for IV administration
- **Administration Rate:**
  - Administration rate should be specified by the MRHP after patient assessment.
- Recommended direct IV and IV Infusion rate is 2 mL/min. Decrease to 1 mL/min or slower if patient develops discomfort.

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 HepaGam B are chills, fever, headaches, vomiting, allergic reactions, nausea, arthralgia and moderate low back pain.
- The most serious adverse reactions observed are anaphylactic reactions to HepaGam B.

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

STORAGE & STABILITY:

- Store at 2°C - 8°C.
- Do not freeze.
- Do not use expired product
- Protect from light.
- Keep vials in storage box until use.

Contact Information

Approved By: APL Transfusion Medicine Discipline Council

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

REFERENCES:

HepaGam B Product Monograph. Available from: HEPAGAM B - Drug and Health Products Portal (hpfb-dgpsa.ca)

Canadian Immunization Guide: Hepatitis B vaccine. Available from Hepatitis B vaccines: Canadian Immunization Guide - Canada.ca

Centers for Disease Control and Prevention. Hepatitis B, acute 2024 case definition. Available from: https://ndc.services.cdc.gov/conditions/hepatitis-b-acute/. Accessed on December 31, 2023