ALBERTA PRECISION LABORATORIES
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HepaGam B®

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:*** *Hepatitis B Immunoglobulin* ***Company:*** *Saol Therapeutics* ***Class:*** *Manufactured blood product, derived from human plasma*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	Yes***	No	No	Yes***	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.**
**** Transfusion of Blood Components and Products Learning Module Section Three: Direct IV Administration of Blood Products. RNs may administer direct IV blood products. Not to be confused with medication administration**
***** Route of administration is indication specific.**

DESCRIPTION OF PRODUCT:

- 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 (< 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.
- 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 500mIU/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 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.
- 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.

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

Compatible Solutions:

- 0.9% normal saline only

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.

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 or 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 to HepaGam B are headache, pyrexia, arthralgia, nausea, and vomiting**.**

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, during infusion at 5 min, 15 min (where applicable), 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 infusion of the product for the patient, monitor for 30-60 minutes post
- Liver transplant patients should be monitored regularly for serum anti-HBs antibody levels.

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:

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

COMMENTS:

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For questions or comments about this document, please contact Transfusion.SafetyTeam@aplabs.ca

REFERENCES

HepaGam B Product Monograph. Available from: hepagamb.ca
Canadian Immunization Guide: Hepatitis B vaccine. Available from www.canada.ca