ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

HyperHEP B® S/D

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 Immune Globulin* ***Company:*** *Grifols Therapeutics Inc.* ***Class:*** *Manufactured blood product, derived from human plasma*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	No	No	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.**

DESCRIPTION OF PRODUCT:

- HyperHEP B® S/D is a sterile 15-18% solution of purified gamma globulin containing antibodies to hepatitis B surface antigen (anti-HBs), prepared from large pools of human plasma.
- Viral reduction steps include filtration, heat inactivation, and solvent/detergent treatment.
- Available in a 0.5 mL prefilled syringe, and 5 mL single use vial containing >220 IU/mL of anti-HBs.
- Also contains glycine.
- 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.

CONTRAINDICATIONS:

- History of anaphylactic or severe systemic reaction of any of the component of the product.
- Patients in whom IM administration is contraindicated due to severe thrombocytopenia or coagulation disorders.

WARNINGS:

- Immune globulin administration may impair the efficacy of live attenuated virus vaccines (ex. measles, mumps, rubella, and varicella). Vaccination with live virus vaccines should be deferred until approximately 3 months after HyperHEP B® S/D administration. Refer to the Canadian National Advisory Committee on Immunization for further recommendations.
- There is evidence of an association between immune globulin 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.

DOSE

- Refer to the product insert and the Canadian Immunization Guide for Hepatitis B for HBIG and Hepatitis B vaccine series recommendations.

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.
- Allow to warm to room temperature before use.

Access:

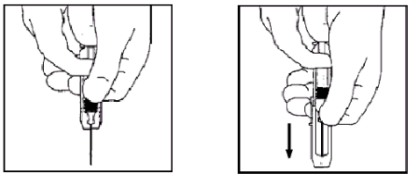
- Intramuscular injection **only.**
- Administer in a separate site if given in combination with hepatitis B vaccine.
- Preferred sites are the anterolateral aspects of the upper thigh and the deltoid muscle of the upper arm. The gluteal regions should not be used routinely due to risk of injury to the sciatic nerve. If the gluteal region is used, use only the upper, outer quadrant.

Administration Supplies:

- 0.5 mL pre-filled syringe (contained with product)
- 5mL vial: syringe and injection needle of appropriate size

Administration:

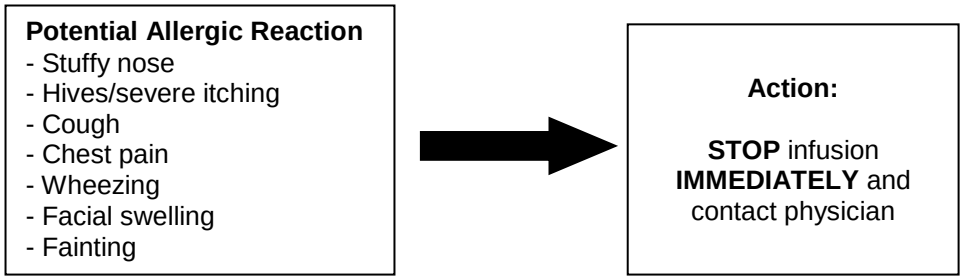
- Do not administer intravenously because of the potential for serious reactions.
- Administer at the minimum rate practicable.
- Vials are single use. Once entered, discard any unused contents.
- **Pre-filled syringe:**
  - Remove pre-filled syringe from package. Lift the syringe by the barrel, **not** the plunger.
  - Twist the plunger rod clockwise until threads are seated
  - With the rubber shield secured on the syringe tip, push the plunger rod forward a few millimeters to break any friction seal between the rubber stopper and the glass syringe barrel.
  - Immediately prior to administration, remove the needle shield and expel air bubbles.
  - Proceed with IM administration
  - Keeping your hands behind the needle, grasp the guard with your free hand and slide it forward toward the needle until it is completed covered and the guard clicks into place.



  - Dispose into an approved sharps container.

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 HyperHEP® B S/D are local pain and tenderness at the injection site, and urticaria,



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 infusion of the product for the 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:

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

COMMENTS:

Date Effective: 30 March 2021
Version: 2.10
Approved By: APL Transfusion Medicine Discipline Council
Document Number: TM40-01.02.019
For questions or comments about this document, please contact Transfusion.SafetyTeam@aplabs.ca

REFERENCES

HyperHEP B® S/D Product Monograph. Available from www.grifols.com
Canadian Immunization Guide: Hepatitis B vaccine. Available from www.canada.ca