ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

HyperHEP B® S/D

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 Immune Globulin* ***Company:*** *Grifols Therapeutics Inc.* ***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	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:

- 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 (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.

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:

- May impair the efficacy of live attenuated virus vaccines. 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.
- 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.
- IG has been reported to be associated with renal dysfunction. The minimum concentration and the minimum rate of infusion practicable should be used.

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.

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.
- Allow to warm to room temperature before use.

Access:

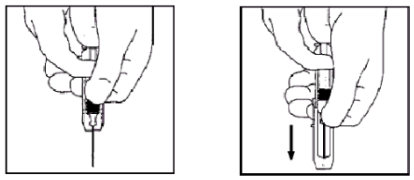
- Intramuscular injection **only.**
- Administer in a separate site if given in combination with hepatitis B vaccine.
- Preferred sites are the anterolateral aspects of the upper thigh and the deltoid muscle of the upper arm. The gluteal regions should not be used routinely due to risk of injury to the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

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 to HyperHEP® B S/D are local pain and tenderness at the injection site, urticaria and angioedema.
- The most serious adverse reactions observed are anaphylactic reactions.

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

Contact Information

Approved By: APL Transfusion Medicine Discipline Council

For questions or comments regarding 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 Hepatitis B vaccines: Canadian Immunization Guide - Canada.ca

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