Hepatitis B Immune Globulin (HBIg)

HepaGam B® **Supplier: Cangene Corporation**
HyperHEP B® S/D **Supplier: Grifols Canada Ltd.**

INDICATIONS:

- Infant born to known HBsAg positive woman
- Infant born to woman at high risk for hepatitis B infection (e.g., intravenous drug use, sex trade worker) whose infectious status is unknown or negative (possible window period)
- Infant under 12 months of age who has a mother with **acute** hepatitis B infection
- Percutaneous or mucosal exposure to HBsAg positive source
- Sex with a person who has **acute or chronic** hepatitis B infection

DOSES AND SCHEDULE: [A]

- Infants born to known HBsAg positive women and women at high risk for hepatitis B infection: Give HBIg as 0.5 mL **IM immediately after birth**, along with first dose of hepatitis B vaccine series. [B]
- Infant under 12 months of age who has a mother with acute hepatitis B: Give HBIg as 0.06 mL/kg of body weight **IM** and hepatitis B vaccine as required, considering the immune status of the infant and history of hepatitis B immunization. [B, C]
- Percutaneous or mucosal exposure to HBsAg positive source: Give HBIg as 0.06 mL/kg of body weight **IM** and hepatitis B vaccine as required, considering the client's immune status and history of hepatitis B immunization. [C]
- Sex with a person who has acute or chronic hepatitis B infection: Give HBIg as 0.06 mL/kg of body weight **IM** as soon as possible following the last sexual exposure, along with hepatitis B vaccine series. [C, D]

An at-risk known non-responder to two series of vaccine requires 2 doses of HBIg one month apart.

ADMINISTRATION:

- See Immune Globulin Preparations (HBIg, Ig, TIg, VarIg, RabIg) for administration information and maximum volume to be administered per site according to age.
- HBIg must be given at a separate anatomic site from hepatitis B vaccine.
- HBIg contains no preservatives. Vials are single dose use. Once entered discard any unused contents.

BOOSTER DOSES:

None.

[A] There is no upper limit to the volume of HBIg that can be administered.

[B] There is no outer time limit for administering HBIg to infants under 2 months of age, when the infant's exposure to the known risk factor(s) is ongoing. For infants less than 8.3 kg, give 0.5 mL HBIg.

[C] HBIg dose for all clients ≥ 8.3 kg is 0.06 mL/kg. Give HBIg as soon as possible, preferably within 48 hours of the exposure. For a percutaneous exposure, HBIg may be given up to 7 days following the exposure. If the client presents more than 7 days following a percutaneous exposure, give hepatitis B vaccine only. For permucosal or sexual exposures, HBIg may be given up to 14 days following the last exposure. If the client presents more than 14 days following a permucosal or sexual exposure, give hepatitis B vaccine only. Refer to Hepatitis B Post-Exposure Prophylaxis table.

[D] For steady, long term sexual partners of chronic hepatitis B carriers, test for HBsAg, anti-HBc and anti-HBs to determine if client is susceptible and requires HBIg, or has been infected previously.

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SEROLOGICAL TESTING:

See Communicable Disease Control Manual, Chapter 1: Hepatitis B.

CONTRAINDICATIONS:

History of anaphylactic reaction to a previous dose of any immune globulin product or any component of HepaGam B® or HyperHEP B® S/D**.**

PRODUCT COMPONENTS:

HepaGam B®:
Potential allergens: polysorbate 80.
Other components: maltose, tri-n-butyl phosphate, Triton X-100®.

HyperHEP B® S/D:
Potential allergens: none.
Other components: glycine, sodium carbonate.

PRECAUTIONS:

- Human Ig products are among the safest blood-derived products available. The method of preparation includes one or more steps that exclude or inactivate hepatitis B, C and HIV; therefore the risk of transmission is extremely low. However, it is possible that unknown infectious agents may be present in such products.
- Special measures should be considered when administering IM injections to people with bleeding disorders. A smaller gauge needle (23 gauge or smaller) should be used and steady, firm pressure should be applied to the injection site for 5 minutes. If there is concern that the injection may stimulate bleeding, the client should connect with their medical specialist.
- Persons with IgA deficiency have the potential for developing antibodies to IgA and could have an anaphylactic reaction to subsequent administration of blood products that contain IgA. Therefore, HBIg should only be given to such persons if the expected benefits outweigh the risks, and should be administered in an emergency room setting.

SPECIAL CONSIDERATIONS:

- To obtain HBIg, contact Transfusion Medicine (Blood Bank) at the nearest hospital.
- Document receipt of HBIg in the client's electronic record (e.g. Panorama, PARIS) and/or chart. The following information must be recorded: trade name of product, date, lot number, dosage, route and site(s).
- Provide a written record to individuals who receive any immune globulin product.
- Regarding HBIg and the administration of live vaccines, see Immune Globulin Preparations or Blood: Timing Intervals for Vaccines Containing Live Measles, Mumps, Rubella, or Varicella Virus.

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ADVERSE EVENTS:
HepaGam B®:
Local: soreness.
Systemic: nausea, fever, arthralgia, myalgia, headache, diarrhea (infants).

HyperHEP B® S/D:
Local: soreness.
Systemic: allergic reactions (urticaria and angioedema).

A potential increased risk of thrombosis (blood clots) has been observed within 24 hours of receipt of immune globulin products, especially when given in large doses (i.e., more than 10 mL). Additional risk factors include: age 45 years and older, history of thrombosis or those with risk factors for thrombosis (e.g., obesity, high blood pressure, diabetes, prolonged periods of immobilization, use of estrogens, a history of heart disease, blood clotting disorders, indwelling central vascular catheters, or diseases that thicken the blood). [A, B]

[A] Daniel WG, Menis M, Sridhar G, et al. Immune globulins and thrombotic events as recorded in a large administrative database in 2008 through 2010. Transfusion. 2012; 52:2113-2121.
[B] Menis M, Sridhar G, Selvam N, et al. Hyperimmune globulins and same-day thromobotic adverse events as recorded in a large healthcare database during 2008-2011. Am. J. Hematol. 2013; 88:1035-1040.