Alberta Health Services	Hepatitis B Immune Globulin Biological Page		
Section 7:	**Biological Product Information**		**Standard #: 07.233**
Created by:	Provincial Immunization Program		
Approved by:	Provincial Immunization Program		
Approval Date:	March 1, 2013	**Revised:**	June 30, 2023

	HyperHEP B®	**HepaGam B®**
Manufacturer	Grifols Therapeutics LLC distributed by Grifols Canada Ltd.	Saol Therapeutics Research Limited distributed by Emergent BioSolutions.
Biological Classification	Immune Globulin	
Indications for Provincially Funded Vaccine	**Post exposure prophylaxis for:** • **Infants born to hepatitis B–infected mothers** (acute during pregnancy and chronic HBsAg carriers) ○ If prenatal screening has not been done prior to delivery, it should be done as soon as possible after admission in labour or for Caesarean section. Repeat testing should be considered in uninfected, susceptible women with continuing high risk factors. ○ If screening results are not available within 12 hours, administer hepatitis B vaccine and consider administration of hepatitis B immune globulin (HBIG), taking into account maternal risk factors and erring on the side of providing HBIG if any question of possible maternal hepatitis B infection exists. HBIG efficacy decreases significantly after 48 hours, but may be administered up to 7 days after birth. • **Percutaneous (needle stick) or mucosal exposure:** ○ Post-exposure follow-up and prophylaxis should be based on the immunization history and antibody status of the exposed person, and if known, the infectious nature of the source. ○ If the individual has no history of a hepatitis B vaccine series, the individual should receive HBIG as soon as possible (preferably within 48 hours) and a series of hepatitis B vaccine. HBIG may be given up to 7 days after exposure. • **Needle-sharing partners or other blood or body fluid exposure to individuals infected with hepatitis B:** ○ HBIG should be administered within 48 hours of exposure to susceptible individuals along with hepatitis B vaccine. HBIG may be given up to 7 days after the last exposure. • **Sexual exposures:** ○ HBIG should be administered within 48 hours of exposure to susceptible sexual partners along with hepatitis B vaccine. ○ HBIG may be given up to 14 days after the last exposure with the infected partner. ○ If more than 14 days since last exposure, only hepatitis B vaccine should be initiated. ○ HBIG and hepatitis B vaccine should be offered routinely to all victims of sexual assault who are unimmunized and susceptible. ○ HBIG is not recommended for non-sexual household contacts unless there is a blood or body fluid exposure (e.g., sharing needles and other	

	HyperHEP B®	HepaGam B®
	drug paraphernalia or toothbrushes or razors) with someone with hepatitis B infection. **Note:** • Refer to the information outlined in the Alberta Health Public Health Notifiable Disease Management Guidelines - Hepatitis B and the Alberta Guidelines for Post-Exposure Management and Prophylaxis: HIV, Hepatitis B, Hepatitis C and Sexually Transmitted Infections.	

Serology	**Post-immunization serology following HBIG administration:**
	• Post-immunization serology is recommended (anti-HBs) at least 6 to 9 months after HBIG administration.
	  ○ For infants born to hepatitis B positive mothers, testing should not be performed before 9 months of age to avoid detection of passive antibodies from HBIG administered at birth and to maximize the likelihood of detecting late HBV infection.
	  ○ For sexual or percutaneous/mucosal exposures, anti-HBs testing for individuals who received HBIG should be performed 6 months after administration of HBIG (after antibodies from HBIG are no longer detectable).
	• For further details refer to:
	  ○ Alberta Public Health Disease Management Guidelines - Hepatitis B
	  ○ Alberta Guidelines for Post-Exposure Management and Prophylaxis: HIV, Hepatitis B, Hepatitis C and Sexually Transmitted Infections.	

Schedule	**Infant born to hepatitis B–infected mother:**
	• One dose
	  ○ HBIG and the first dose of hepatitis B vaccine should be given as soon as possible after birth (within 12 hours).
	  ○ If there has been a delay in administration of HBIG, it may be administered up to 7 days after birth, although efficacy decreases significantly after 48 hours.
	Percutaneous (needle stick) or mucosal exposure:
	• A one-time dose of HBIG as soon as possible, after exposure (preferably within 48 hours) and begin HBV vaccine series. HBIG may be administered up to 7 days after exposure.
	Needle-sharing partners or other blood or body fluid exposure to individuals with hepatitis B infection:
	• A one-time dose of HBIG as soon as possible after exposure (preferably within 48 hours) and begin HBV vaccine series. HBIG may be administered up to 7 days after exposure.
	Sexual exposures:
	• A one-time dose of HBIG as soon as possible after exposure (preferably within 48 hours) and begin HBV vaccine series. HBIG may be administered up to 14 days of the last sexual exposure.
	Notes:
	• If exposed individual is a known vaccine non-responder, 2 doses of HBIG administered 1 month apart are required for prophylaxis.
	• The recommended interval between HBIG administration and subsequent immunization with varicella or MMR vaccines is 3 months.
	• When it is necessary to administer HBIG within 2 weeks after receiving MMR or varicella vaccine, the vaccine should be repeated 3 months after HBIG administration unless serologic testing indicates that vaccine-related antibodies were produced. If HBIG is given more than 14 days post-MMR or	

	HyperHEP B®	HepaGam B®
	varicella immunization, the vaccine does not need to be repeated.	
Preferred Use	There is no preference indicated: • Both biologicals are safe and immunogenic • Persons with medical contraindications should be offered the alternate product if supply is available.	
Dose	**Infants (less than 8.5 kg)** • 0.5 mL **Infants (8.5 kg or more), children and adults** • 0.06 mL/kg **Note:** • The dose may need to be divided depending upon the muscle size and the dose required. • Use a blunt fill needle to withdraw immune globulin. Withdrawal through a small-gauge needle can lead to aggregation. • Inject slowly. • Due to volume required per client, multiple vials may be needed. Whenever possible the same product and lot number should be used. If this is not possible, do not mix different products or different lot numbers in the same syringe. Once vial stopper has been entered, discard any unused contents.	
Route	IM	

Contraindications/ Precautions	**Contraindications:**
	• None known
	• Consult with zone MOH for individuals with:
	  ○ a known severe hypersensitivity to any component of the biological
	  ○ anaphylactic or other allergic reactions to a previous dose of biological containing human immune globulin preparations
	Precautions:
	• Do not administer intravenously.
	• Use with caution in individuals with a history of prior systemic allergic reactions following administration of human immunoglobulin preparations.
	• Individuals with immunoglobulin A deficiency have a potential for developing IgA antibodies and could develop anaphylactic reactions to subsequent blood products (including immune globulin preparations) that contain IgA.
	• HBIG is made from human plasma. Products made from human plasma may contain infectious agents that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, testing for the presence of certain current viral infections and inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease.
	  ○ A signed *Consent for Treatment/Procedure* is required before administering immune globulin products: http://www.albertahealthservices.ca/frm-09741.pdf.
	• Use with caution in individuals with severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections.	

Possible Reactions	**Common:** • Pain and tenderness at the injection site • Fever • Headache, malaise, arthralgia, myalgia • Nausea, diarrhea • Urticaria, angioedema	

	HyperHEP B®	HepaGam B®
	Rare: • Anaphylaxis • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.	
Pregnancy	Adequate data is not available for the use of hepatitis B immune globulin during pregnancy. However, use of this biological during pregnancy may be considered in consultation with your MOH based on the individual's risk of disease versus benefit of the product.	
Lactation	Can be administered to eligible breastfeeding women.	
Composition	• 15%-18% protein containing ≥ 220 IU/mL • glycine Contains no preservative	• Human plasma protein (greater or equal to 96% Human IgG) • Maltose • Polysorbate 80 • Trace amounts of tri-n-butyl phosphate and Triton X-100® Contains no preservative
Blood/Blood Products	Made from pooled human plasma	
Bovine/Porcine Products	Contains no bovine or porcine products	Materials that may contain or have come into contact with animal tallow derivatives are used in the manufacturing process.
Latex	There is no latex in the product or product packaging	
Interchangeability	The same product should be used. If this is not possible, do not mix different products or different lot numbers in the same syringe.	
Administration with Other Products	• The concurrent administration of HBIG and hepatitis B vaccine using separate needles/syringes and different sites/different limbs does not interfere with antibody response to the vaccine. • Measles, varicella and other live virus vaccines should not be administered until at least 3 months after the administration of HBIG. HBIG cannot be given concurrently with live virus vaccines. • When it is necessary for HBIG to be administered within 2 weeks after receiving live vaccines (i.e., MMR or varicella), the vaccine should be repeated 3 months after HBIG administration. If HBIG is given more than 2 weeks post-MMR or -varicella immunization, the vaccine does not need to be repeated. **Note:** For further information, see #03.110 Standard for Recommended Immunization Schedules.	
Appearance	Clear or slightly opalescent, and colourless or pale yellow or light brown	Clear or slightly opalescent
Storage	• Store between +2° and +8°C • Do not freeze • Do not use past the expiry date • Store in the original package	
Vaccine Code	HBIG	
Antigen Code	HBIG	
Licensed for	Persons of all ages	

	HyperHEP B®	HepaGam B®

Program Notes:

- 2023 June: Packaging of HyperHEP B® changed to reflect 1100IU/5mL which is equivalent to 220IU/mL.

Related Resources:

- Hepatitis B Immune Globulin Information Sheet

References:

1. Alberta Health. (2019, March). Alberta Guidelines for post exposure management and prophylaxis: HIV, Hepatitis B, Hepatitis C and sexually transmitted infections. https://open.alberta.ca/publications/9781460143360
2. Alberta Health. (2014, January). Alberta Immunization Policy. Adverse Event Following Immunization (AEFI) Policy for Alberta Health Services Public Health. Alberta Health.
3. Alberta Health. (2016, August 25). Alberta Immunization Policy. Hepatitis B Immune Globulin (Human) Alberta Health, Public Health and Compliance Division.
4. Alberta Health. (2018, November). *Hepatitis B: Acute Case and Chronic Carrier* . Alberta Health, Public Health Notifiable Disease Management Guidelines.
5. Centers for Disease Control and Prevention. (2011). General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices. *Morbidity and Mortality Weekly Report, 60* (2), 36-39
6. Grifols Therapeutics LLC. (2021,September 8). Product Monograph. *HyperHep B® : Hepatitis B Immune Globulin (Human)*.
7. National Advisory Committee on Immunization. (2013). Canadian Immunization Guide (Evergreen Edition). Ottawa, ON: Public Health Agency of Canada.
8. Saol Therapeutics Research Limited (2017, December 20). Product Monograph. *HepaGam B: Hepatitis B Immune Globulin (Human)*.
9. Saol Therapeutics Research Limited. Personal communication with Saol Therapeutics representative. 2019, December 2.