Hepatitis B Immune Globulin

BIOLOGICAL PAGE

Alberta Health Services
Communicable Disease Control

Section 7	Biological Product Information	**Standard # 07.233**	
Created and approved by	Provincial Immunization Program Standards and Quality		
Approval date	March 1, 2013	**Published**	March 17, 2026

	HepaGam B	HyperHEP B
Manufacturer	Ki BioPharma LLC, distributed by Accuristix	Grifols Therapeutics LLC, distributed by Grifols Canada Ltd.
Classification	Passive: Immune Globulin	

Indications for Provincially Funded HBIG	**Post exposure prophylaxis for:**
	• **Infants born to individuals with hepatitis B infection** (acute infection or chronic HBsAg carriers)
	  ○ If prenatal screening has not been done prior to delivery, complete as soon as possible upon admission. Repeat testing should be considered in uninfected, susceptible pregnant individuals 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 risk factors of the pregnant individual and erring on the side of providing HBIG if any question of possible hepatitis B infection exists for the pregnant individual. 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 with hepatitis B infection:**
	  ○ 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 (for example, sharing needles and other drug paraphernalia or toothbrushes or razors) to someone with hepatitis B infection.
	Note:	

	HepaGam B	HyperHEP B
	• Refer to Alberta public health disease management guidelines: hepatitis B-acute and chronic 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.
	  ○ Do not perform testing before 9 months of age on infants born to individuals who are hepatitis B surface antigen (HBsAg) positive. This is to avoid detection of passive antibodies from HBIG administered at birth and to maximize the likelihood of detecting late HBV infection.
	  ○ Wait at least 6 months to perform anti-HBs testing in individuals who received HBIG due to sexual or percutaneous/mucosal exposure. This ensures antibodies from HBIG are no longer detectable.
	Note:
	• Refer to Alberta public health disease management guidelines: hepatitis B-acute and chronic and the Alberta guidelines for post-exposure management and prophylaxis: HIV, hepatitis B, hepatitis C and sexually transmitted infections.	

Schedule	**Infants born to individuals with hepatitis B infection:**
	• Give a one-time dose of HBIG and the first dose of hepatitis B vaccine as soon as possible after birth (within 12 hours).
	• If there is a delay in administration of HBIG, it may be administered up to 7 days after birth. Efficacy decreases significantly after 48 hours.
	Percutaneous (needle stick) or mucosal exposure:
	• Give a one-time dose of HBIG and the first dose of hepatitis B vaccine as soon as possible after exposure (preferably within 48 hours).
	• If there is a delay in administration of HBIG, it 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:
	• Give a one-time dose of HBIG and the first dose of hepatitis B vaccine as soon as possible after exposure (preferably within 48 hours).
	• If there is a delay in administration of HBIG, it may be administered up to 7 days after exposure.
	Sexual exposures:
	• Give a one-time dose of HBIG and the first dose of hepatitis B vaccine as soon as possible after exposure (preferably within 48 hours).
	• If there is a delay in administration of HBIG, it may be administered up to 14 days of the last sexual exposure.
	Note:
	• If the exposed individual is a known vaccine non-responder, give 2 doses of HBIG for prophylaxis.
	  ○ Dose 1: day 0
	  ○ Dose 2: 1 month after dose 1
	• The recommended interval between HBIG and subsequent immunization with MMR, MMR-Var, or varicella vaccine is 3 months.
	• If HBIG is given more than 14 days post-MMR, MMR-Var or varicella immunization, do not repeat the vaccine.	

	HepaGam B	HyperHEP B
	• When it is necessary to administer HBIG within 14 days after receiving MMR, MMR-Var or varicella vaccine, repeat the vaccine 3 months after HBIG administration. ○ Do not repeat immunization if serology indicates that vaccine-related antibodies were produced.	
Preferred Use	None. • Both biologicals are safe and immunogenic. • Offer individuals with medical contraindications the alternate product.	

Dose	**Infants less than 12 months of age**
	• 0.5 mL
	Individuals 12 months of age and older
	• 0.06 mL/kg, minimum dose must be at least 0.5mL
	Note:
	• The dose may need to be divided depending upon the muscle size and required dose.
	• Use a blunt fill needle to withdraw immune globulin. Withdrawing through a small-gauge needle can lead to aggregation.
	• Due to volume required per client, multiple vials may be needed. Use the same product and lot number .
	  ○ If this is not possible, do not mix different products or different lot numbers in the same syringe.
	  ○ Once vial stopper has been punctured, discard any unused contents.
	• Inject slowly.	

Route	IM	

Contraindications/ Precautions	**Contraindications:**
	• Known severe hypersensitivity to any component of HBIG or its container.
	• 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 because of the potential for serious reactions.
	• Use with caution for individuals with:
	  ○ History of prior systemic allergic reactions following administration of human immune globulin preparations.
	  ○ Immunoglobulin A (IgA) deficiencies. These individuals have the potential to develop anti-IgA antibodies and could have anaphylactic reactions to subsequent administration of blood products containing IgA.
	  ○ Severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections.
	• A signed Consent for Treatment/Procedure is required before administering immune globulin products: http://www.albertahealthservices.ca/frm-09741.pdf.
	  HBIG is made from human plasma. Measures to reduce the risk of transmission of viral diseases from HBIG include screening plasma donors for prior exposure to certain viruses, testing for the presence of certain current virus infections and by inactivating and/or removing certain viruses. Despite these measures, such products could still potentially transmit disease.	

	HepaGam B	HyperHEP B
Possible Reactions	**Common:** • Pain and tenderness at the injection site • Fever • Headache, malaise, arthralgia, myalgia • Nausea, diarrhea • Urticaria, angioedema. **Rare:** • Anaphylaxis • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.	
Pregnancy	Consult with the zone MOH/designate. • It is not known whether HBIG can cause fetal harm when administered to individuals during pregnancy. However, immune globulins have been widely used during pregnancy for many years without any apparent negative reproductive effects. • MOH/designate will make an individual recommendation based on the risk of disease versus benefit of the product.	
Lactation	May use for people who are lactating and feeding their milk to infants or children. • It is not known if anti-HBs antibodies are excreted in human milk.	
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	Does not contain bovine or porcine products.	Does not contain bovine or porcine products.
Latex	Does not contain latex.	
Interchangeability	Use the same product. • If this is not possible, do not mix different products or different lot numbers in the same syringe.	

Administration with Other Products	• May be given at the same time as hepatitis B vaccine.
	  ○ 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.
	• Do not give HBIG at the same time as live vaccines.
	  ○ The recommended interval between HBIG and subsequent immunization with MMR, MMR-Var, or varicella vaccine is 3 months.
	• If HBIG is given more than 14 days post-MMR, MMR-Var or varicella immunization, do not repeat the vaccine.
	• When it is necessary to administer HBIG within 14 days after receiving MMR, MMR-Var or varicella vaccine, repeat the vaccine 3 months after HBIG administration.
	  ○ Do not repeat immunization if serology indicates that vaccine-related antibodies were produced.
	Note:
	For further information, see Standard for Recommended Immunization Schedules.	

	HepaGam B	HyperHEP B
Additional Preparation Instructions	• Product should be brought to room or body temperature before use. • Do not shake vial, avoid foaming.	None. Follow the Standard for the Administration of Immunizations
Appearance	Clear or slightly opalescent.	Clear or slightly opalescent, and colorless or pale yellow or light brown.
Storage	• Store between +2°C and +8°C. • Do not freeze. • Do not use past the expiry date. • Store in the original packaging.	
Vaccine Code	HBIG	
Antigen Code	HBIG	
Licensed for	Individuals of all ages	
Program Notes	• 2023 June: Packaging of HyperHEP B changed to reflect 1100IU/5mL which is equivalent to 220IU/mL. • 2025 August 1: Updated to use inclusive language when referring to pregnant individuals.	
Related Resources	Hepatitis B Immune Globulin Information Sheet	

References

Alberta Health. (2019, March). Alberta Guidelines for Post-Exposure Management and Prophylaxis: HIV, Hepatitis B, Hepatitis C and Sexually Transmitted Infections. In *Alberta Public Health Disease Management Guidelines*. Government of Alberta.

Alberta Health. (2025, August 01). Hepatitis B Immune Globulin (Human) – HBIG. In *Alberta Immunization Policy: Biological Products*. Government of Alberta.

Alberta Health. (2024, June 28). Alberta Public Health Disease Management Guidelines: Hepatitis B – Acute and Chronic. In *Alberta Public Health Disease Management Guidelines*. Government of Alberta.

Alberta Health. (2024, April). Adverse Events Following Immunization (AEFI) policy for Alberta immunization providers. In *Alberta Immunization Policy: Adverse events – immunization* (2019). Government of Alberta.

Grabenstein JD. ImmunoFacts: Vaccines and Immunologic Drugs. St. Louis, MO: Wolters Kluwer Health; 2013.

Grifols Therapeutics LLC (2021, September 08). HyperHEP B ® Hepatitis B Immunoglobulin (Human) Injection. Health Canada Drug Product Database. https://pdf.hres.ca/dpd_pm/00062962.PDF.

KI BioPharma LLC. (2025, January 09). HepaGam B® Hepatitis B Immunoglobulin (Human) Injection. Health Canada Drug Product Database. https://pdf.hres.ca/dpd_pm/00078242.PDF.

Public Health Agency of Canada. (2022, May). Hepatitis B vaccines. In *Canadian Immunization Guide*. Government of Canada.