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**	August 1, 2025

	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 Use of Provincially Funded HBIG	**Post exposure prophylaxis for:**
	• **Infants born to individuals infected with hepatitis B** (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 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 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 (for example, sharing needles and other drug paraphernalia or toothbrushes or razors) to someone with hepatitis B infection.	

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	Note: • Refer to 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 at least 6 months after administration of HBIG (after antibodies from HBIG are no longer detectable).
	Note:
	• Refer to 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	

Schedule	**Infant born to an individual infected with:** • 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, though 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. **Note:** • If exposed individual is a known vaccine non-responder, two doses of HBIG administered one month apart are required for prophylaxis. • The recommended interval between HBIG administration and subsequent immunization with MMR, MMR-Var, or varicella vaccines is three months. • When it is necessary to administer HBIG within two weeks after receiving MMR, MMR-Var or varicella vaccine, the vaccine should be repeated three months after HBIG administration unless serologic testing indicates that vaccine-related antibodies were produced. If HBIG is given more than 14 days post-MMR, MMR-Var or varicella immunization, the vaccine does not need to be repeated.	
Preferred Use	There is no preference indicated: • Both biologicals are safe and immunogenic.	

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	• Individuals with medical contraindications should be offered the alternate product if supply is available.	
Dose	**Infants less than 12 months of age** • 0.5 mL **Individuals 12 months of age and older (with no dose less than 0.5mL)** • 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:**
	• 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 in individuals with a history of prior systemic allergic reactions following administration of human immunoglobulin preparations.
	• Use with caution in individuals with 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.
	• Use with caution in individuals with severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections.
	• 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.
	  ○ A signed Consent for Treatment/Procedure is required before administering immune globulin products: http://www.albertahealthservices.ca/frm-09741.pdf.	

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

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	Rare: • Anaphylaxis • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.	
Pregnancy	It is not known whether HBIG can cause fetal harm when administered to pregnant individuals; however, immunoglobulins have been widely used during pregnancy for many years without any apparent negative reproductive effects. Consult with zone MOH on use of HBIG during pregnancy based on the individual's risk of disease versus benefit of the product.	
Lactation	HBIG should be given to individuals who are lactating when indicated. 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	Contains no bovine or porcine products.	Contains no bovine or porcine products.
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 attenuated replicating vaccines should not be administered until at least three months after the administration of HBIG. HBIG cannot be given concurrently with live vaccines. • When it is necessary for HBIG to be administered within two weeks after receiving live attenuated replicating vaccines (For example, MMR or varicella), the vaccine should be repeated three months after HBIG administration. If HBIG is given more than two weeks post-MMR or -varicella immunization, the vaccine does not need to be repeated. **Note:** For further information, see Standard for Recommended Immunization Schedules.	
Appearance	Clear or slightly opalescent, and colorless or pale yellow or light brown	Clear or slightly opalescent
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	

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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

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