

Hepatitis B Immune Globulin (Human) - HBIG

Revision Date: August 25, 2016

Rational for Policy Update: Updated to be consistent with CIG indications for HBIG.

Please consult the appropriate Product Monograph ^{1,2} for further information about this product.		
	HepaGam B®	HyperHEP B® S/D
Manufacturer	Aptevo BioTherapeutics LLC distributed by Cangene Corporation	Talecris Biotherapeutics, Inc. distributed by Bayer Inc.
Off-license use	None	
Authorization and access	<p>Accessed by Alberta Health Services (AHS) from Canadian Blood Services</p> <ul style="list-style-type: none"> Alberta prenatal screening program identifies women infected with hepatitis B. Infants born to these women need to receive HBIG and hepatitis B vaccine promptly following delivery. Local AHS processes need to be in place to ensure that HBIG has been ordered from Canadian Blood Services and is on hand approximately three weeks before the expected date of delivery. Community exposures/household contacts/sexual partners: HBIG required for hepatitis B prophylaxis for susceptible individuals is ordered by AHS from Canadian Blood Services. 	
Indications for use of provincially funded HBIG	<p>Infants: Born to hepatitis B-infected mothers (acute during pregnancy and chronic HBsAg carriers)</p> <ul style="list-style-type: none"> Should receive HBIG and the first dose of hepatitis B vaccine as soon as possible after birth (within 12 hours).³ <p>Notes:</p> <ul style="list-style-type: none"> ➤ 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 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 seven days after birth.³ <p>For disease information and reporting requirements refer to <i>Public Health Notifiable Disease Management Guidelines – Hepatitis B</i>⁴ and <i>Alberta Prenatal Screening Program for Selected Communicable Diseases Public Health Guidelines – Hepatitis B</i>.⁵</p> <p>Percutaneous (needle stick) or mucosal exposure:</p> <ul style="list-style-type: none"> 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.³ If the individual has no history of a hepatitis B vaccine series, the individual should receive HBIG as soon as possible (preferable within 48 hours) and a series of hepatitis B vaccine. HBIG may be given up to seven days after exposure.³ 	

	<p>Needle-sharing partners or other blood or body fluid exposure to individuals infected with hepatitis B:</p> <ul style="list-style-type: none"> HBIG should be administered within 48 hours of exposure to susceptible individuals along with hepatitis B vaccine. HBIG may be given up to seven days after the last exposure.³ <p>Sexual exposures:</p> <ul style="list-style-type: none"> 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 of the last exposure with the infected partner.³ If more than 14 days since last exposure, hepatitis B vaccine only 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 drug paraphernalia or toothbrushes or razors) with someone with hepatitis B infection. <p>Refer to <i>Public Health Notifiable Disease Management Guidelines – Hepatitis B⁴</i> and <i>Alberta Guidelines for Non-Occupational, Occupational and Mandatory Testing and Disclosure Act Post-Exposure Management and Prophylaxis: HIV, Hepatitis B, Hepatitis C and Sexually Transmitted Infections.</i>⁶</p>
<p>Dose</p>	<p>0.5 mL – Infants (less than 8.5 kg) 0.06 mL/kg – Infants (8.5 kg or more), children and adults</p>
<p>Route</p>	<p>Intramuscular injection</p> <p>Note: The dose may need to be divided depending upon the muscle size and the dose required.</p>
<p>Schedule</p>	<p>Infant born to hepatitis B-infected mother:</p> <ul style="list-style-type: none"> ❖ HBIG and the first dose of hepatitis B vaccine should be administered 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 seven days after birth, though efficacy decreases significantly after 48 hours.³ <p>Percutaneous (needle stick or mucosal) exposure:</p> <ul style="list-style-type: none"> ❖ A one-time dose of HBIG as soon as possible after exposure (preferable within 48 hours) and begin hepatitis B vaccine series. HBIG may be administered up to seven days after exposure. <p>Needle-sharing partners or other blood or body fluid exposure to individuals with hepatitis B infection:</p> <ul style="list-style-type: none"> ❖ A one-time dose of HBIG as soon as possible after exposure (preferable within 48 hours) and begin hepatitis B vaccine series. HBIG may be administered up to seven days after exposure.³ <p>Sexual exposures:</p> <ul style="list-style-type: none"> ❖ A one-time dose as soon as possible after exposure (preferable within 48 hours) and begin a hepatitis B vaccine series. HBIG may be administered up to 14 days of the last sexual exposure.³

	<p>See Biological Products - Hepatitis B Vaccine.</p> <p>Notes:</p> <ul style="list-style-type: none"> • If the exposed person is a known non-vaccine responder, two doses of HBIG administered one month apart are required for prophylaxis.³ • The recommended interval between HBIG administration and subsequent immunization with varicella or MMR vaccines is three months.³ • When it is necessary to administer HBIG within two weeks after receiving MMR 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 or -varicella immunization, the vaccine does not need to be repeated.³
Contraindications	Known severe hypersensitivity to any component of HBIG or its container.
Precautions	<ul style="list-style-type: none"> • Use with caution in individuals with 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.^{2,3,7} • Use with caution in individuals with a history of prior systemic allergic reactions following administration of human immune globulin preparations.¹ • Do not administer intravenously because of the potential for serious reactions.¹ • 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.¹ • Use with caution in those with severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections. See General Guidelines.
Possible reactions following receipt of HBIG	<p>Local reactions:</p> <ul style="list-style-type: none"> • Local pain and tenderness at the injection site.¹ <p>Systemic reactions:</p> <ul style="list-style-type: none"> • Urticaria and angioedema may occur.¹ • Headache, malaise, myalgia, nausea and diarrhea.^{1,2,7} • Anaphylactic reactions, although rare, have been reported.¹ <p>Refer to <i>Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers</i>.⁸</p>
Pregnancy	HBIG should be administered to pregnant women who have been exposed to hepatitis B virus when indicated. Clinical experience suggests there are no known adverse effects on the fetus from immune globulins. ^{1,2,7}
Lactation	HBIG should be given to breastfeeding women when indicated. It is not known if anti-HBs antibodies are excreted in breast milk. ^{1,2,7}

References

- ¹ Talecris Biotherapeutics. (2005, June 2). HyperHEP B® S/D: Hepatitis B immune globulin (human). *Product Monograph*.
- ² Aptevo BioTherapeutics. (2016, May 20). HepaGam B®: Hepatitis B immune globulin (human). *Product Monograph*.
- ³ National Advisory Committee on Immunization. (2013). *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. www.canada.ca/en/public-health/services/canadian-immunization-guide.html
- ⁴ Alberta Health. Hepatitis B. In *Public Health Notifiable Disease Management Guidelines*. www.health.alberta.ca/professionals/notifiable-diseases-guide.html
- ⁵ Alberta Health. (2007, July). Prenatal hepatitis B screening. In *Alberta Prenatal Screening Program for Selected Communicable Diseases: Public Health Guidelines*.
- ⁶ Alberta Health. (2015, February). *Alberta Guidelines for Non-Occupational, Occupational and Mandatory Testing and Disclosure Act Post-Exposure Management and Prophylaxis: HIV, Hepatitis B, Hepatitis C, and Sexually Transmitted Infections*. www.health.alberta.ca/professionals/notifiable-diseases-guide.html
- ⁷ Grabenstein, J. D. (2012). *ImmunoFacts: Vaccines and Immunologic Drugs - 2013*. St. Louis, MO: Wolters Kluwer Health.
- ⁸ Alberta Health. (2016, December). *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers*. www.health.alberta.ca/documents/AIP-Adverse-Events-Following-Immunization-Policy.pdf