HEPAGAM B®

Hepatitis B Immune Globulin Intravenous (Human)

Indication

HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)] is an intravenous immune globulin indicated for the following:

- **Prevention of Hepatitis B recurrence following liver transplant in HBsAg-positive liver transplant patients**
- **Post-exposure prophylaxis** including:
  - Acute exposure to HBsAg-positive blood, plasma, or serum (parenteral exposure, direct mucus membrane contact, oral ingestion, etc.),
  - Perinatal exposure of infants born to HBsAg-positive mothers,
  - Sexual exposure to HBsAg-positive persons, and
  - Household exposure to persons with acute HBV infection.

Drug Administration for HBV-Related Liver Transplant Patients

Administer the first dose of HepaGam B® during the grafting of the transplanted liver (the anhepatic phase) with subsequent dosing as recommended. Calculate the dosing from the measured potency of the particular lot of HepaGam B® as stamped on the vial label.

HepaGam B® Dosing Regimen for HBV-Related Liver Transplant Patients

Anhepatic Phase	Week 1 Post Transplant	Weeks 2-12 Post Transplant	Month 4 Onwards
First dose	Daily from Day 1-7	Every 2 weeks from Day 14	Monthly

HepaGam B® Intravenous Infusion Rate

Route of Administration	Dosage	Infusion Rate
Intravenous	20,000 IU per dose	2 mL/minute
		Decrease to 1 mL/minute or slower if the patient develops discomfort or infusion-related adverse reaction(s)

HepaGam B® Dosing Regimen for Postexposure Prophylaxis (Intramuscular)

Indication	Dosage	Instructions
Acute Exposure to Blood Containing HBsAg	0.06 mL/kg	Administer HepaGam B® as soon as possible after exposure. The value after 7 days following exposure is unclear.
		For persons who refuse Hepatitis B vaccine or who are known nonresponders to vaccine, give a second dose of HepaGam B® one month after the first dose.
Perinatal Exposure of Infants Born to HBsAg-Positive Mothers	0.5 mL	Administer after physiologic stabilization of the infant and preferably within twelve hours of birth. Administer concurrently with Hepatitis B vaccine.
Sexual Exposure to HBsAg-Positive Person(s)	0.06 mL/kg	Administer HepaGam B® and Hepatitis B vaccine series within 14 days of sexual contact or if sexual contact with the infected person will continue.
Household Exposure to Person with Acute HBV Infection	0.5 mL	For infants less than 12 months of age, administer concurrently with Hepatitis B Vaccine. Prophylaxis of other household contacts of persons with acute HBV infection is not indicated unless there is an identifiable blood exposure to the index patient, such as by sharing toothbrushes or razors. Treat such exposures like sexual exposures.

Contraindications

- History of anaphylactic or severe systemic reactions to human globulins.
- IgA deficient individuals may have the potential to develop IgA antibodies and have an anaphylactoid reaction.
- IM injections may be contraindicated in patients with coagulation disorders.

Refer to full Prescribing Information.

Reimbursement Codes

HCPCS Code	Code Description
J 1573	HepaGam B® INTRAVENOUS Injection
J 1571	HepaGam B® INTRAMUSCULAR Injection

These codes are specific to HepaGam B® and should not be used for any other Hepatitis B Immune Globulin products unless directed otherwise by your payor.

HCPCS Codes available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-drugs/McrPartBDrugAvgSalesPrice/index.html, accessed November 2019.

Product Description

	NDC Code	Strength	Volume
	49591-052-51	>312 IU/mL (measured potency of each lot is stamped on the vial label)	1.0 mL single-use vial
	70257-051-51	>312 IU/mL (measured potency of each lot is stamped on the vial label)	5.0 mL single-use vial

Dosing Calculation Example

Recommended Dose of HepaGam B®	Potency	Calculation
Based on the 20,000 IU dose in the FDA-approved labeling	575 IU/mL (stamped actual potency)	Target dose ÷ potency = number of mL mL ÷ mL/vial = number of vials
		20,000 ÷ 575 = 34 mL 34 ÷ 5 = 6.8 (7 vials)

Storage and Handling

Store at 36–46° F (2–8° C). Do not freeze. Do not use after expiration date. Use within 6 hours after the vial has been entered.

Important Safety Information

Individuals known to have anaphylactic or severe systemic reactions to the parenteral administration of human globulin preparations should not receive HepaGam B®. Individuals who are deficient in IgA may have the potential to develop IgA antibodies and have severe, potentially life-threatening allergic reactions.

For post-exposure prophylaxis indications, HepaGam B® must be administered intramuscularly only. In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, HepaGam B® should be given only if the expected benefits outweigh the potential risks.

HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)] is a sterile solution of gamma globulin (IgG) made from human plasma. Products made from human plasma may carry a risk of transmitting infectious agents, e.g., viruses and, theoretically, the Creutzfeldt-Jacob disease (CJD) agent.

Severe hypersensitivity reactions may occur with HepaGam B®. Certain adverse drug reactions may be related to the rate of infusion. The recommended infusion rate given under Dosage and Administration in the prescribing information must be closely followed.

Thrombotic events may occur during or following treatment with IVIG products. Patients at risk include those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, coagulation disorders, prolonged periods of immobilization, and/or known/suspected hyperviscosity.

The maltose contained in HepaGam B® can interfere with some types of blood glucose monitoring systems. This can result in falsely elevated glucose readings that can lead to untreated hypoglycemia or to inappropriate insulin administration, resulting in life-threatening hypoglycemia.

The only adverse reactions observed in clinical trial subjects were hypotension and nausea (2% of clinical trial subjects).

To report SUSPECTED ADVERSE REACTIONS, contact Kamada at pharmacovigilance@kamada.com or 1-(866)-916-0077 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Refer to full Prescribing Information.

KAMADA