Dosing guidelines for HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)] – an intravenously administered HBIg with high levels of anti-HBs

A potency of 550 IU/mL of anti-HBs is targeted at the time of manufacture.

- Targeting this potency at manufacture ensures a minimum anti-HBs potency of > 312 IU/mL is maintained over product shelf life (36 months).
- As with all immune globulins, the potency of HepaGam B varies from lot to lot.

Dosage volume consistent with published protocols.1,2

- The FDA approval of HepaGam B for the prevention of hepatitis B recurrence following liver transplantation is based on the dose of 20,000 IU used in the pivotal clinical trial.
- Calculate total dose based on the measured potency stamped on each vial label; this provides a dose that is consistent with published protocols.

**Comparative Dosing Calculation Example**

<table>
<thead>
<tr>
<th>Recommended dose of HBIg</th>
<th>Potency</th>
<th>Calculation</th>
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<tbody>
<tr>
<td>Based on the 20,000 IU dose of HepaGam B in the FDA approved labeling.†</td>
<td>575 IU/mL (stamped actual potency)</td>
<td>Target dose ÷ potency = number of mL/mL ÷ mL/vial = number of vials</td>
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</tbody>
</table>
| HBIg published dose: 10,000 IU2 | >312 IU/mL (assumed minimum potency) | 20,000 ÷ 575 = 34 mL  
34 ÷ 5 ≈ 7 vials |

Do NOT use the measured potency on the vial of HepaGam B to calculate a 10,000 IU dose. This will result in significant underdosing as compared to published protocols.

- At 2 mL/minute, the infusion of HepaGam B takes less than 20 minutes per patient††
HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)]

Dosing Schedule and Patient Record

**HepaGam B Dosing Regimen**

<table>
<thead>
<tr>
<th>Anhepatic Phase</th>
<th>Week 1 post-operative</th>
<th>Weeks 2-12 post-operative</th>
<th>Month 4 Onward</th>
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<tbody>
<tr>
<td>First Dose</td>
<td>Daily from day 1-7</td>
<td>Every 2 weeks from day 14</td>
<td>Monthly</td>
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**Patient ID ___________________**  **Date of LT __________________**

<table>
<thead>
<tr>
<th>Date</th>
<th>Anti-HBs titer</th>
<th># of 5 mL vials</th>
<th>Start</th>
<th>End</th>
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Dosing calculation: 20,000 ÷ stamped potency = total mL
Total mL ÷ 5 mL = number of vials

**Specific J codes for reimbursement**
- HepaGam B Intravenous injection: J1573†
- HepaGam B Intramuscular injection: J1571†

Available in 5 mL and 1 mL vials

For more information, please contact the customer service line at 1-877-HepaGam B (437-2426) or visit www.HepaGamB.com. For medical inquiries, please contact Medical Affairs at 1-800-768-2304.

**Important Risk information**

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, eg, viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Individuals known to have severe, potentially life-threatening reaction to human globulin preparations should not receive HepaGam B or any other immune globulin (human). Individuals who are deficient in IgA may have the potential to develop IgA antibodies and have severe, potentially life-threatening allergic reactions.

The maltose contained in HepaGam B can interfere with some types of blood glucose monitoring systems. Only testing systems that are glucose-specific should be used in patients receiving HepaGam B. This interference can result in falsely elevated glucose readings that can lead to untreated hypoglycemia or to inappropriate insulin administration, resulting in life-threatening hypoglycemia.

The most common expected adverse drug reactions for immune globulins like HepaGam B are chills, fever, headaches, vomiting, allergic reactions, nausea, arthralgia, and moderate low back pain.

HepaGam B must be administered only intramuscularly for post-exposure prophylaxis. 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.

Please see accompanying full Prescribing Information for full prescribing details.


†As of July 2008, HepaGam B qualifies for pass-through status under the hospital OPPS Update. Some payers use ASP methodology to calculate reimbursement (eg, Medicare, some Medicaid, and some private insurers).

These codes are specific to HepaGam B and should not be used for any other HBIG unless directed otherwise by your payer.