

HepaGam B



Approved Blood Products

[Licensed Products \(BLAs\)](#)

[New Drug Applications \(NDAs\)](#)

[Premarket Approvals \(PMAs\) and Humanitarian Device Exemptions \(HDEs\)](#)

[Substantially Equivalent 510\(k\) Device Information](#)

STN: BL 125035

Proper Name: Hepatitis B Immune Globulin Intravenous (Human)

Tradename: HepaGam B

Manufacturer: Cangene Corp, License #1201

Indications:

- For the prevention of Hepatitis B recurrence following liver transplantation in HBsAg-positive liver transplant patients. Also indicated for the treatment of acute exposure to blood containing HBsAg, perinatal exposure of infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute HBV infection.
- Treatment of acute exposure to blood containing HBsAg, perinatal exposure of infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute HBV infection.

Product Information

- [Package Insert - HepaGam B](#)

Supporting Documents

- [Supporting Documents older than three years-HepaGam B](#) 

Content current as of:

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Regulated Product(s)

Biologics
Blood Products