

**INFORMATION ONLY**

**HepaGam B<sup>®</sup> (Hepatitis B Immune Globulin (Human) Injection)**

Customer Letter #2010-04

2010-02-08

Dear Customer,

This Customer Letter pertains to the following Cangene Corporation updates for HepaGam B<sup>®</sup> (Hepatitis B Immune Globulin (Human) Injection):

- HepaGam B<sup>®</sup> is now available for a second indication: Post Exposure Prophylaxis of the Hepatitis B Infection and
- HepaGam B<sup>®</sup> Regulatory Status Update for approval of HepaGam B<sup>®</sup> Notice of Compliance with Conditions (NOC/c).

Please find enclosed the following:

1. Dear Healthcare Professional letter from Cangene Corporation dated October 01, 2009 announcing that HepaGam B<sup>®</sup> (Hepatitis B Immune Globulin (Human) Injection) can now be used for a second indication.
2. Dear Healthcare Professional letter from Cangene Corporation dated December 11, 2009 providing a Regulatory Status Update of HepaGam B<sup>®</sup> NOC/c.
3. Hepatitis B Immune Globulin Comparison Table (2009-10-21) presenting product characteristics compiled from the Product Monographs.

**HepaGam B<sup>®</sup> (Hepatitis B Immune Globulin (Human) Injection) Now Available for Post-Exposure Prophylaxis of the Hepatitis B Infection**

HepaGam B<sup>®</sup> has been approved by Health Canada to be used for a second indication, Post Exposure Prophylaxis of the Hepatitis B Infection in the following settings:

- Acute Exposure to Blood Containing HBsAg,
- Perinatal Exposure of Infants Born to HBsAg-positive Mothers
- Sexual Exposure to HBsAg-positive Persons
- Household Exposure to Persons with Acute HBV Infection

Additionally, Cangene Corporation has indicated that HepaGam B<sup>®</sup> will feature new peel off labels, which can be inserted onto a patient's chart for permanent traceability. Inventory with the new peel off labels should start to appear in customer deliveries from Canadian Blood Services throughout the first quarter of 2010.

The HepaGamB<sup>®</sup> packaging components and package insert will be updated to include details of the post exposure prophylaxis indication. These changes should be expected for deliveries from Canadian Blood Services by the second quarter of 2010.

The Product Monograph for HepaGam B<sup>®</sup> can be viewed on the Health Canada website <http://www.hc-sc.gc.ca/dhp-mps/index-eng.php>. Please refer to Drugs & Health Products>Drug Products>Drug Product Database>Drug Product Database Online Query or at [www.cangene.com](http://www.cangene.com).

If you have questions about HepaGam B<sup>®</sup> (Hepatitis B Immune Globulin (Human) Injection) please contact Cangene at 1-877-226-4363.

.../2

**HepaGam B® (Hepatitis B Immune Globulin (Human) Injection) For The Prevention of Hepatitis B Recurrence Following Liver Transplantation – Regulatory Status Update**

**Background**

In January 2007, Health Canada approved HepaGam B Hepatitis B Immune Globulin (HBIG), for the prevention of hepatitis B recurrence following liver transplantation under the Notice of Compliance with Conditions (NOC/c) policy and as such HepaGam B was made available to Canadian Blood Services for distribution. Please refer to Customer Letter 2007-39 for more details at [www.blood.ca](http://www.blood.ca) in the “Hospitals” section.

Cangene Corporation has provided the regulatory status update as required under the conditions for approval of HepaGam B® NOC/c. The status update covers the period from January 2007 to present which includes:

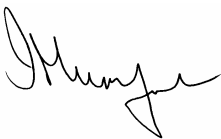
- Annual Status Report of Confirmatory Studies
- Post marketing Surveillance Commitments.

If you have questions regarding this regulatory update, please contact Christopher Fredric at 416-675-8281, fax 416-675-8301 or email: [cfredric@cangene.com](mailto:cfredric@cangene.com).

This Customer Letter and the enclosures can also be viewed at [www.blood.ca](http://www.blood.ca) in the “Hospitals” section. As well, the Hepatitis B Immune Globulin Comparison Table (2009-10-21) may be viewed in the aforementioned section, under Plasma Protein Products.

If you have questions about this Customer Letter, please contact Canadian Blood Services Plasma Products and Services Department at 613-739-2392.

Sincerely,



Ian Mumford  
Chief Operating Officer

encl.