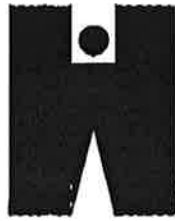


衛生署藥物辦公室
藥物註冊及進出口管制部

香港九龍南昌街 382 號公共衛生檢測中心二樓



DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
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BY FAX

15 June 2012

(來函請註明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dr. Raymond LIANG
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LIANG,

Health Canada: Theoretical Risk of Thrombotic Events with Intravenous HepaGam B
[Hepatitis B Immune Globulin (Human) Injection]

Please kindly note that the Health Canada informed healthcare professionals of the theoretical risk for arterial and venous thrombosis at the intravenous doses of HepaGam B for the liver transplantation indication.

This risk may exist because an in-house analysis detected measurable levels of procoagulant (factor XIa) activity in HepaGam B. The significance of these levels is being evaluated.

Patients should be informed of signs and symptoms of thrombotic events. And caution should be used when administering HepaGam B to patients with risk factors for thrombotic events. Patients at risk include those with a history of atherosclerosis, cardiovascular risk factors, impaired cardiac output, coagulation disorders, prolonged periods of immobilization, advanced age and/or known/suspected hyperviscosity from any cause, including dehydration.

In Canada, HepaGam B is authorized to be administered intramuscularly for hepatitis B post-exposure prophylaxis, including the treatment of acute exposure to blood containing, perinatal exposure of infants born to HBsAg-positive mothers, sexual exposure to HBsAg positive persons and household exposure to persons with acute HBV infection. HepaGam B is also indicated for the prevention of hepatitis B recurrence following liver transplantation and should be administered intravenously for this indication.

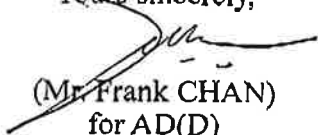
Please refer to Health Canada's website for details:

http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2012/hepagam_nth-aah-eng.php

In Hong Kong, there are two registered pharmaceutical products containing hepatitis B immunoglobulin, namely Hepatitis B Immunoglobulin P Behring Inj 200iu/ml (HK-51445) and Hyperhep B S/D Inj (HK-54263) and are prescription-only medicines. They are indicated for the prophylaxis of hepatitis B and registered for intramuscular use only.

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "Reporting an Adverse Drug Reaction": http://www.drugoffice.gov.hk/eps/root/en/healthcare_providers/adr_reporting/index.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,


(Mr. Frank CHAN)
for AD(D)

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