

**Health Canada Endorsed Important Information on PEGETRON® REDIPEN®
(peginterferon alfa-2b Powder for Solution in Single Dose Delivery System:
80 mcg per 0.5 mL, 100 mcg per 0.5 mL, 120 mcg per 0.5 mL and 150 mcg
per 0.5 mL)**



February 3, 2011

Dear Health Care Professional

**Subject: Important information regarding PEGETRON® REDIPEN®
(peginterferon alfa-2b Powder for Solution in Single Dose
Delivery System: 80 mcg per 0.5 mL, 100 mcg per 0.5 mL, 120
mcg per 0.5 mL and 150 mcg per 0.5 mL)**

Merck Canada Inc., in consultation with Health Canada, would like to inform you of important information regarding the use of PEGETRON® REDIPEN®. This follows recent announcements by Health Canada and the U.S. Food and Drug Administration regarding the market recall of alcohol prep pads, alcohol swabs, and alcohol swabsticks manufactured by the Triad Group in the United States because of potential microbial contamination. The Triad Group recall impacts alcohol prep pads that are co-packaged and distributed with PEGETRON® REDIPEN®. The alcohol swabs are labelled **ALCO-PREP® Pre-injection cleansing swab**.

PEGETRON® is indicated for the treatment of adult patients with chronic hepatitis C.

- It is important to note that PEGETRON® REDIPEN® is not contaminated, and should continue to be used in accordance with the package insert.
- Patients and healthcare providers should **not** use the alcohol prep pads, labelled **ALCO-PREP® Pre-injection cleansing swab**, packaged with PEGETRON® REDIPEN®. They should use alternative alcohol prep pads, or a sterile gauze pad and isopropyl alcohol (70%).
- Patients should be requested to report signs of injection site infections to their healthcare professional.

According to information posted on the Food and Drug Administration's (FDA) Medwatch website, <http://www.fda.gov/Safety/MedWatch/default.htm>, the recall was initiated by the Triad Group due to concerns about potential contamination of the products with the bacteria, *Bacillus cereus*. Use of the contaminated alcohol pads, alcohol swabs, and alcohol swab sticks could lead to life-threatening infection, especially in at-risk populations, including immunocompromised and surgical patients.

Upon discussion and agreement with Health Canada, Merck Canada Inc. will begin packaging orders with suitable alternative alcohol prep pads.

The management of marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any cases of serious or unexpected adverse reactions in patients using PEGETRON® should be reported to Merck Pharmacovigilance or Health Canada as follows.

Merck Canada Inc., Pharmacovigilance
16711 Trans-Canada Hwy.
Kirkland, Quebec H9H 3L1
Fax: 1-800-369-3090

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) section (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>). The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties*.

For other health product inquiries related to this communication, please contact Health Canada at:

Health Product and Food Branch Inspectorate (HPFBI)
E-mail: DCVIU_UVCEM@hc-sc.gc.ca
Telephone: 1-800-267-9675
Fax: 1-613-946-5636

To change your mailing address or fax number, contact Merck Canada Inc.

If you have any questions regarding this important information, please contact our Customer Services at 1-800-361-6550. For medical inquiries, please contact us at 1-800-567-2594 or Health Canada at the number listed above.

Original signed by

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