

PUBLIC COMMUNICATION

**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

**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[®]. The alcohol prep pads that are included in your package of PEGETRON[®] REDIPEN[®] have been voluntarily recalled by the manufacturer, the Triad Group, due to potential microbial contamination. The alcohol swabs are labelled **ALCO-PREP[®] Pre-injection cleansing swab**.

- You should continue to use your PEGETRON[®] REDIPEN[®] injection and capsules as directed by your health care professional.
- Do NOT use the **ALCO-PREP[®] Pre-injection cleansing swab**, that are in your package of PEGETRON[®] REDIPEN[®].
- Alternate alcohol pads are available for purchase at your local pharmacy or you can use sterile gauze pads with bottled isopropyl alcohol (70%).
- You are requested to report signs of injection site infections (such as redness, warmth, pain and/or swelling) to your healthcare professional.

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

Managing 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 case 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.

Original signed by

Michel Cimon, MD, MPH
Medical Executive Director, Medical Affairs