

PUBLIC COMMUNICATION

Health Canada Endorsed Important Information on PEGETRON[®] (ribavirin 200 mg Capsules plus peginterferon alfa-2b Powder for Solution in REDIPEN[®] 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)



October 5, 2010

Subject: Important information regarding the quality, safety and supply of PEGETRON[®] (ribavirin 200 mg Capsules plus peginterferon alfa-2b Powder for Solution in REDIPEN[®] 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)

Schering-Plough Canada Inc., a subsidiary of Merck & Co., Inc., in consultation with Health Canada, has informed healthcare professionals of important new information on PEGETRON[®] (ribavirin 200 mg Capsules plus peginterferon alfa-2b Powder for Solution in REDIPEN[®] Single Dose Delivery System).

PEGETRON[®] REDIPEN[®] is a pen delivery system used to administer PEGETRON[®] for the treatment of adult patients with chronic hepatitis C virus (HCV) infection.

Merck has identified a manufacturing defect in a very small number of REDIPEN[®]s that may affect the sterility of the PEGETRON[®] product. As a result, there is reduced supply of PEGETRON[®] REDIPEN[®] for all strengths: 80 mcg per 0.5 mL [DIN 02254581], 100 mcg per 0.5 mL [DIN 02254603], 120 mcg per 0.5 mL [DIN 02254638] and 150 mcg per 0.5 mL [DIN 02254646].

Injection of a non-sterile product can lead to an infection at the site of injection. Merck monitors reports of side effects and has not seen an increase in the number or severity of infections with PEGETRON[®] REDIPEN[®].

It is expected that the supply of all strengths of PEGETRON® REDIPEN®s will return to normal within 5 weeks. During this period:

- You are reminded to visually inspect the REDIPEN® before use. Should the chamber of the cartridge system that contains the cake (powder) look unusual (collapsed, little or no cake), it should not be used. The presence of a collapsed, little or no cake is one possible sign of a defective REDIPEN®. However, even if the cake looks normal, the defect may still be present and may affect the sterility of the product. You may return a defective PEGETRON® REDIPEN® to the pharmacy where it was purchased.
- You are requested to report signs of injection site infections (such as redness, warmth, pain and/or swelling) to your healthcare professional.
- Merck is of the view that patients using PEGETRON® REDIPEN® should not stop their treatment without first consulting their doctor.

The importance of staying on therapy for treatment of hepatitis C virus infection has been well established. Merck is of the view that, patients already on therapy should continue the use of PEGETRON® REDIPEN® in light of the potential for relapse that may result from the discontinuation or interruption of therapy, the absence of any documented contamination, the low frequency of the defect and the anticipated resupply of PEGETRON® REDIPEN® products (up to 5 weeks, depending on strength). Patients already using PEGETRON® REDIPEN® should not stop their treatment without first consulting their doctor.

Merck is in ongoing discussions and consultation with Health Canada. As soon as the newly manufactured PEGETRON® REDIPEN®s become available for patients on therapy, Merck will replace these PEGETRON® REDIPEN® supplies in the pharmacies.

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 injection site infection or of serious or unexpected adverse reactions in patients using PEGETRON® should be reported to Merck Pharmacovigilance or Health Canada as follows.

Merck, 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 Frosst Canada Ltd.

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 1-800-463-5442.

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