

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 4, 2010

Dear Health Care Professional

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, would like to inform you of important new information on PEGETRON[®] (ribavirin 200 mg Capsules plus peginterferon alfa-2b Powder for Solution in REDIPEN[®] Single Dose Delivery System).

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

A manufacturing defect that has been observed at a low frequency in the glass stopper sealing flange at one end of the glass cartridge may render the seal incapable of sustaining a vacuum. This defect has the potential to compromise sterility and potentially lead to contamination and injection site infection. As a result, Schering-Plough Canada Inc. is experiencing supply constraints for all strengths of the REDIPEN[®]: 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].

Until we are able to return to uninterrupted supply of all strengths of PEGETRON[®], we recommend that:

- Patients be reminded to visually inspect the REDIPEN[®] before use. Should the cake (powder) chamber of the cartridge system show collapsed, little or no cake, it should not be used. The collapse/shrinkage/absence of this lyophilized cake is one possible indication of a defective glass cartridge seal. However, even if the appearance of the cake is normal, the defect in the glass cartridge may still be present and sterility may still not be assured.
- Patients be requested to report signs of injection site infections to their healthcare professional.
- You do NOT initiate treatment for new patients with PEGETRON[®]. This will help maximize the availability of existing supply for patients already on therapy.

The importance of adherence to therapy for treatment of hepatitis C virus (HCV) 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).

Merck is in ongoing discussions and consultation with Health Canada. Once Merck has the newly manufactured REDIPEN[®] available for patients on therapy, Merck will replace REDIPEN[®] supplies at the pharmacy/retail level.

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 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 or Health Canada at the number listed above.

original signed by



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