PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
PrSEBIVO® (telbivudine)

NOVARTIS

March 12, 2008

Subject: **Risk of peripheral neuropathy in patients treated with telbivudine (SEBIVO®) in combination with interferon**

SEBIVO® (telbivudine) is an anti-viral agent used to treat adults with chronic hepatitis B (a liver disease). Novartis Pharmaceuticals Canada Inc., in consultation with Health Canada, would like to inform you of new safety information concerning the use of SEBIVO® in combination with interferon products:

- Using SEBIVO® with interferon products* may increase your risk of developing peripheral neuropathy (weakness, numbness, tingling, and/or burning sensations in the arms and/or legs).
- SEBIVO® is authorized by Health Canada for use alone (monotherapy), not for use in combination with any interferon products.

* Interferon products include standard or pegylated types of interferon alfa (marketed under brand names such as Pegasys®, Pegatron®, Intron A®, Unitron Peg®, Rebetron®, Roferon A®, and Infergen®) and of interferon beta, (marketed under brand names such as Rebif®, Betaseron® and Avonex®).

In a small clinical trial testing the use of both SEBIVO® and the interferon product Pegasys® (peginterferon alfa-2a), serious peripheral neuropathy occurred in 5 out of 48 patients (10%), and was occasionally disabling. It usually started about 3 months after treatment began. It is not yet known if this adverse event is reversible once the treatment is stopped, or whether it might also occur when SEBIVO® is used with interferon products other than Pegasys®.

Please tell your doctor if you are taking SEBIVO® and an interferon product, because taking these medicines together may increase your risk of developing peripheral neuropathy. You should not discontinue or modify your treatment with SEBIVO® without first consulting your doctor, due to the risk of worsening the hepatitis B infection.

Peripheral neuropathy has been reported in 5 out of 2000 patients (0.3%) using telbivudine alone in clinical trials. Peripheral neuropathy is a common adverse reaction of Pegasys® (reported on average in 1 to 5 out of 100 patients in clinical trials) (1-5%). The risk of developing peripheral neuropathy is increased when a patient receives telbivudine in combination with Pegasys®, compared to either treatment alone.

The Consumer Information section of the Product Monograph for telbuvidine is being updated to reflect this new safety finding. Novartis Pharmaceuticals Canada Inc. has also issued a letter to health professionals advising them of this new safety information. You may view this letter on the Canadian website of Novartis Pharmaceuticals Canada Inc., (www.Novartis.ca) or on the Health Canada website (http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2008/index_e.html).

If you have questions regarding your current treatment or prescription, talk to your doctor or pharmacist.

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 peripheral neuropathy or other serious or unexpected adverse reactions in patients receiving SEBIVO® should be reported to Novartis Pharmaceuticals Canada Inc., or Health Canada at the following addresses:

Novartis Pharmaceuticals Canada Inc.
385 Bouchard Blvd.
Dorval, Quebec H9S 1A9
Phone: 1-800-363-8883

Any suspected adverse reaction can also be reported to:
Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
Ottawa, Ontario, K1A 0K9
Tel: 613-957-0337 or Fax: 613-957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866-234-2345 or Fax: 866-678-6789 or email CanadaVigilance@hc-sc.gc.ca

The AR Reporting Form and the AR Guidelines can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties.*
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

For other inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate (MHPD)
E-mail: MHPD_DPSC@hc-sc.gc.ca
Tel: 613-954-6522 Fax: 613-952-7738

Sincerely,

Novartis Pharmaceuticals Canada Inc.

original signed by

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