PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
[Pr]Myfortic® (mycophenolate sodium) Enteric-Coated Tablets

December 23, 2009

Subject: **Reports of Pure Red Cell Aplasia in Patients Treated with Myfortic* (mycophenolate sodium)**

Novartis Pharmaceuticals Canada Inc., in consultation with Health Canada, has informed Canadian healthcare professionals of important new safety information regarding reports of a type of anaemia called pure red cell aplasia (PRCA) in patients treated with Myfortic* (mycophenolate sodium).

Myfortic*, an immunosuppressive agent, is authorized in Canada for the prevention of organ rejection in patients receiving kidney transplants, administered in combination with cyclosporine, and corticosteroids.

- Cases of PRCA have been reported worldwide in patients treated with Myfortic* (mycophenolate sodium) in combination with other anti-rejection drugs. As of October 31, 2009, there have been no Canadian cases of PRCA reported in patients receiving Myfortic*.
- In some cases, PRCA was found to be reversible when the dosage of Myfortic* was reduced or the Myfortic* therapy discontinued. There may be a risk of graft rejection to the transplanted organ if anti-rejection medications, such as Myfortic*, are reduced in dosage or discontinued.
- Patients taking Myfortic* and any other prescribed anti-rejection medications should not discontinue or change their medication without discussion with their transplant physician.

PRCA is a condition in which a patient develops severe anaemia due to failure of the bone marrow to produce red blood cells and is characterized by a severe and sudden anaemia accompanied by the feeling of tiredness or shortness of breath. It is important that you recognize the following symptoms of anaemia (decrease in red blood cells): unusual tiredness, headache, shortness of breath, dizziness, chest pain, looking pale while taking Myfortic*. You should consult your transplant physician immediately if you experience any of these symptoms. Be sure also to keep all appointments at your transplant clinic to check your blood cell counts regularly and tell your treating physician if you are feeling unusually tired or short of breath.

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 occurrence of serious and/or unexpected adverse reactions in patients receiving Myfortic* 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 (Medical Information)

Any suspected adverse reaction can also be reported to:

Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701D
Ottawa, Ontario, K1A 0K9
Tel: 613-957-0337
Fax: 613-957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866-234-2345
Fax: 866-678-6789
CanadaVigilance@hc-sc.gc.ca

The Adverse Reaction Reporting Form and the Adverse Reaction 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/ar-ei_form-eng.php
http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_fs-if/2009-ar-ei-guide-patient/index-eng.php

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,

original signed by

Jean-Marie Leclerc, M.D. FRCP (c)
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Novartis Pharmaceuticals Canada Inc.

* Myfortic is a registered trademark