



PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
Rapamune® (sirolimus)

2009-11-26

SUBJECT: Sirolimus Blood Level Measurement Changes

Wyeth (a Pfizer company)* in collaboration with Health Canada would like to inform patients that different ways to measure Rapamune in the blood produce results that cannot be substituted one for the other.

Rapamune belongs to a group of medicines called immunosuppressants. It is used to prevent rejection of transplanted kidneys and is often used in combination with other immunosuppressants and corticosteroids.

- There are various ways to measure Rapamune levels in the blood. These different methods produce different results, and these results cannot be substituted one for the other.
- Doctors and Health Care Professionals have been informed that they need to be aware of any changes in method used to measure Rapamune blood levels in order to properly adjust the dose as necessary. Always take the medicine as your Doctor tells you. Follow your Doctor's instructions and never change the dose yourself.[1]

Health Care Professionals will inform patients taking Rapamune exactly what dose of Rapamune to take and how often to take it. They will also monitor the quantity of the drug in patients' blood [1].

Patients taking Rapamune should always take their medicine exactly as prescribed. Rapamune should not be stopped unless advised by a physician. Rapamune doses are adjusted based on age, other medications, and medical conditions.

Rapamune should be taken once a day at about the same time each day either with or without food. Rapamune should not be taken with grapefruit or grapefruit juice. Rapamune tablets should not be crushed, chewed, or split. Patients should inform their Doctor if they have difficulty taking the tablet [1].

Wyeth Canada, in collaboration with Health Canada, issued a letter to Health Care Professionals informing them of important changes in monitoring the quantity of Rapamune in the blood. A copy of that letter is available on the Health Canada website (www.medeffect.com).

*Wyeth is now a part of Pfizer Inc. The merger of local Wyeth and Pfizer entities may be pending in various jurisdictions and is subject to completion of various local legal and regulatory obligations.



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 receiving Rapamune should be reported to Wyeth Canada or Health Canada at the following addresses:

Wyeth, a Pfizer Company
Medical Information & Pharmacovigilance
50 Minthorn Boulevard
Markham, Ontario L3T 7Y2
Tel: 1-800-461-8844
Fax: 905-470-4385

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

Fax: 866-678-6789

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/ar-ei_form_e.html

<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

Rapamune Consumer Information and a full Product Monograph can be accessed at www.wyeth.ca or on the [Health Canada website](#). Please contact Wyeth Canada Medical Information at 1-800-461-8844 with any additional questions or concerns about Rapamune.

Sincerely,

Wyeth

A handwritten signature in black ink, appearing to read "Neil Maresky". The signature is written in a cursive style with a large, looping initial "N".

Dr. Neil Maresky, M.B., B.Ch.
Vice-President
Scientific Affairs

References:

[1] Rapamune[®] - Product Monograph dated Oct. 9, 2009, Wyeth Canada.