

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
TORISEL™ (temsirrolimus) concentrate for injection



2008/08/11

Subject: Association of TORISEL™ (temsirrolimus) concentrate for injection with Allergic (Hypersensitivity/Infusion) reactions

Wyeth Pharmaceuticals, a division of Wyeth Canada, in collaboration with Health Canada, wishes to inform Canadians about new safety information regarding the administration of Torisel™ (temsirrolimus) for the treatment of metastatic cancer of the kidney (i.e. when cancer cells have spread from kidney to other parts of the body).

Torisel™ (temsirrolimus) therapy may cause allergic (hypersensitivity or intravenous infusion) reactions, such as, but not limited to rash, hives, itching, pain, swelling of tissues, flushing, shortness of breath, wheezing, and cough. These allergic reactions occur in variable severity, occasionally resulting in life-threatening reactions or death. Other related side effects could include chest pain, difficulty in breathing, lower blood pressure, cessation of breathing and loss of consciousness in association with the intravenous administration of Torisel™ (temsirrolimus). There have been no serious Canadian cases reported at this time.

- Torisel™ (temsirrolimus) therapy may cause allergic reactions, often occurring within the first few minutes of receiving the first dose, although some reactions have also been reported in the course of further treatments.
- If you are currently receiving Torisel™ (temsirrolimus) therapy, you and your doctor and/or nurse should monitor for any signs of an allergic reaction.
- Your doctor and/or nurse should administer pre-medication prior to your Torisel™ (temsirrolimus) treatment to reduce the risk of an allergic reaction.
- If you have had a severe reaction to Torisel™ (temsirrolimus) treatment, speak to your doctor to ensure that you are receiving the appropriate care and ask whether you should continue therapy with Torisel™ (temsirrolimus).

If you are receiving Torisel™ (temsirrolimus) injections you should seek advice from a health care professional. Your doctor should administer pre-medication before your injection to reduce the risk of an allergic reaction.

If you have experienced a severe reaction during or after Torisel™ (temsirrolimus) therapy, speak to your doctor about whether you should continue therapy with Torisel™ (temsirrolimus). You should not use

Torisel™ (temsirolimus) if you have a history of severe allergic reaction after exposure to Torisel™ (temsirolimus) or any of its components.

Wyeth Canada has worked with Health Canada to update the safety information for Torisel™ (temsirolimus) and has sent a letter to health care professionals to inform them of this new safety information.

A copy of the healthcare professional letter and this communication are available on the Health Canada website at <http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php>. These documents can also be viewed on the Wyeth Canada website at <http://www.wyeth.ca>.

Managing marketed health product-related adverse reactions depends on the reporting of such events by health care professionals and consumers. 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 reaction, such as hypersensitivity/infusion reactions or other unexpected adverse reactions in patients receiving Torisel™ (temsirolimus) should be reported to Wyeth Canada or Health Canada at the following addresses:

Wyeth Canada
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

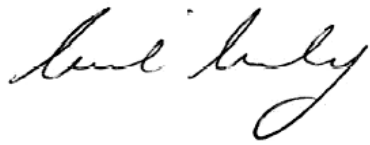
The [AR Reporting Form](#) and the [AR Guidelines](#) can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir-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

Wyeth is committed to ensuring that Torisel™ (temsirolimus) is used safely and effectively and to providing you with the most current product information.

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