Public Communication -
Health Canada Endorsed Important Safety Information TEMODAL® (temozolomide)

MERCK

May 7, 2014

Subject: Association of TEMODAL® (temozolomide) with the risk of liver problems

Merck Canada Inc., in consultation with Health Canada, would like to inform you of new important safety information about TEMODAL® (temozolomide) and risk of liver problems.

TEMODAL® is an antitumor agent used in combination with radiotherapy in the treatment and maintenance therapy of some brain cancers.

- TEMODAL® may cause liver problems which may, in some cases, result in death. Liver problems may occur several weeks after starting treatment with TEMODAL® or after treatment has been stopped.
- If you are using TEMODAL®, your doctor will be monitoring you for signs of liver problems with blood tests as appropriate for your condition. It is important to tell your doctor if you already have liver problems.
- Contact your doctor if your skin or the whites of your eyes turn yellow, you feel tired or have flu-like symptoms, your urine is dark or brown, your stools are discoloured and/or pale, you experience itching, you have nausea or vomiting, you have pain on the right side of your stomach just below the ribs, or you do not have an appetite. These may be signs of liver problems.

Merck Canada Inc. has sent a letter to health care professionals informing them of this important safety information. You may view this letter on Health Canada's website at: http://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php?cat=3

The TEMODAL® product information has been updated to include this new information. A copy may be obtained on the Merck Canada website (www.merck.ca) or on the Health Canada website (http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp).

If you have questions regarding your TEMODAL® prescription, please contact your doctor.

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing side effects are generally presumed to underestimate the risks associated with health product treatments. Any case of serious liver injury or other serious or unexpected side effects in patients receiving TEMODAL® should be reported to Merck Canada Inc. or Health Canada.

Merck Canada Inc., Pharmacovigilance
16750 Trans-Canada Hwy.
Kirkland, Québec H9H 4M7
Fax: 1-800-369-3090

You can report any suspected side effect associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax

For other health product inquiries related to this communication, contact Health Canada at:
Marketed Health Products Directorate
E-mail: mhpd_dpsc.public@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Sincerely,

Mauricio Ede, M.D.
Executive Director, Medical Affairs

® Registered trademark of Schering-Plough Canada Inc. Used under license.