Health Canada Endorsed Important Safety Information on XELODA® (capecitabine)

December 03, 2013

Dear Health Care Professional:

Subject: Association of XELODA® (capecitabine) with Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)

Hoffmann-La Roche Limited (Roche), in consultation with Health Canada, would like to inform you of the risk of severe cutaneous reactions associated with the use of XELODA.

XELODA is authorized for the following indications:

Colorectal cancer
- Adjuvant treatment of patients with stage III (Dukes' stage C) colon cancer.
- First-line treatment of patients with metastatic colorectal cancer.
- Treatment of metastatic colorectal cancer, in combination with oxaliplatin, following failure of irinotecan-containing combination chemotherapy.

Breast cancer
- Treatment of patients with advanced or metastatic breast cancer, in combination with docetaxel, after failure of prior anthracycline containing chemotherapy.
- Treatment of advanced or metastatic breast cancer after failure of standard therapy including a taxane, unless therapy with a taxane is clinically contraindicated.

- Very rare cases of severe cutaneous reactions such as Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN), in some cases with fatal outcome, have been reported during treatment with XELODA.
- XELODA should be immediately discontinued if signs and symptoms of SJS or TEN are present.
- Based on this new safety information, Roche will be working with Health Canada to implement appropriate revisions to the Product Monograph for XELODA.

The complete prescribing and adverse event information for XELODA can be found in the authorized Product Monograph available on the Health Canada Web site (http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp) and at http://www.rochecanada.com/PMs/Xeloda/Xeloda_PM_E.pdf. The revised Product Monograph for XELODA will be posted on the Health Canada and Roche Web sites.

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 SJS or TEN or any other unexpected adverse reactions in patients receiving XELODA should be reported to Hoffmann-La Roche Limited or Health Canada.

Hoffmann-La Roche Limited
Drug Safety Department
7070 Mississauga Road
Mississauga, Ontario, L5N 5M8
or call toll free at: 1-888-762-4388
or fax at: 905-542-5864
or email to: mississauga.drug_safety@roche.com

To correct your mailing address or fax number, contact Hoffmann-La Roche Limited.

You can report any suspected adverse reactions 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

Should you have any questions or require additional information regarding the use of XELODA, please contact the Drug Information Department at Hoffmann-La Roche Limited at 1-888-762-4388, Monday to Friday, between 8:30 a.m. and 4:30 p.m. (Eastern Standard Time).

Original signed by

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Hoffmann-La Roche Limited