

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



December 03, 2013

Subject: Severe Skin Reactions Associated with the use of XELODA®

Hoffmann-La Roche Limited, in consultation with Health Canada, would like to inform you of important new safety information regarding the use of XELODA. Severe skin reactions have been reported in patients taking XELODA.

XELODA is used to treat advanced breast cancer or breast cancer that has spread to other parts of the body (metastatic), metastatic colon or rectum cancer and cancer of the colon following complete surgical removal.

- Severe skin reactions such as Stevens–Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN), in some cases with a fatal outcome, have been reported during treatment with XELODA.
- Signs and symptoms of severe skin reactions may include flu like symptoms; fever; itching of the skin; painful, red or purplish skin rash that spreads and blisters causing the top of the skin to shed; mouth sores; eye burning, itching and discharge.
- If you develop any of the above or any other unusual signs or symptoms, please contact your doctor or healthcare professional immediately. Your healthcare professional will evaluate whether you need to stop taking Xeloda.

Hoffmann-La Roche will be working with Health Canada to update the prescribing information document accordingly.

Hoffmann-La Roche has sent a letter to healthcare professionals informing them of this important safety information. This information may be obtained on the Health Canada Web site (<http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2013/index-eng.php>) or on the Canadian Web site of Hoffmann-La Roche Limited (www.roche.com).

Managing marketed health product-related adverse reactions depends on healthcare professionals and consumers reporting them. Any case of skin reactions as mentioned above or other serious or unexpected adverse reactions in patients receiving XELODA should be reported to Roche 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

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 (MHPD)
E-mail: MHPD_DPSC@hc-sc.gc.ca
Tel: (613) 954-6522
Fax: (613) 952-7738

Original signed by

A handwritten signature in black ink, appearing to be 'Lorenzo Biondi', written over the text 'Original signed by'.

Lorenzo Biondi,
Vice President, Medical and Regulatory Affairs
Hoffmann-La Roche Limited