

**Public Communication -
Health Canada Endorsed Important Safety Information on
ZELBORAF®(vemurafenib)**



08/20/2013

**Subject: ZELBORAF® (vemurafenib) and the Risk of Progression of
Certain Types of Cancer and the Risk of Serious Rash**

Hoffmann-La Roche Limited (Roche Canada), in collaboration with Health Canada, would like to inform you of new important safety information with ZELBORAF (vemurafenib) treatment regarding the risk of progression of certain types of cancer and the risk of serious rash.

ZELBORAF is used to treat a type of skin cancer that has a mutation in a gene called the BRAF gene and that cannot be removed by surgery or has spread to other parts of the body.

Risk of Progression of Certain Types of Cancer

- Based on how ZELBORAF works, it may cause certain cancers with a mutation in another gene called the RAS gene to spread or get worse.
- If you currently have or have had a cancer, your physician will decide if ZELBORAF is right for you.

Risk of Serious Rash

- Consult a physician right away if you develop skin rashes, fever or swelling during treatment with ZELBORAF as they may be signs of serious skin reactions.
- The physician will evaluate if you need treatment for your rash and if you need to stop taking ZELBORAF.

Roche Canada will be working with Health Canada to update the safety information for ZELBORAF.

Roche Canada has sent a letter to health care professionals informing them of this important safety information. This information may be obtained on the Web sites of Health Canada (http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2013/index-eng.php) and Roche Canada.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Any case of cancer progression,

serious rash or other serious or unexpected adverse reactions in patients receiving ZELBORAF should be reported to Roche or Health Canada.

Hoffmann-La Roche Limited
Drug Safety Department
2455 Meadowpine Boulevard
Mississauga, Ontario, L5N 6L7
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

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

Original signed by



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