

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
ACCUTANE™ ROCHE® (isotretinoin)

February 16, 2010

Subject: Association of ACCUTANE™ ROCHE® (isotretinoin) with cases of severe skin reactions

Hoffmann-La Roche Limited, in consultation with Health Canada, would like to inform you of important new safety information regarding the use of ACCUTANE™ ROCHE® (isotretinoin).

ACCUTANE is a medicine used to treat severe acne (nodular and/or inflammatory) that cannot be cleared up by other acne treatments, including antibiotics. Acne is a skin condition mainly affecting adolescents with lesions (pimples, cysts, nodules) appearing most often on the face, chest and back.

- There have been very rare reports of severe skin reactions associated with the use of ACCUTANE. These events may be serious in nature and can result in hospitalization, disability or death.
- If you are taking or have recently been taking ACCUTANE and you develop any of the following:
 - rash, especially if associated with fever and/or malaise or conjunctivitis (red or inflamed eyes, like “pink eye”);
 - blisters on legs, arms or face and/or sores in mouth, throat, nose or eyes;
 - peeling skin,stop ACCUTANE and see a doctor immediately.
- Severe skin reactions can start with mild non-specific symptoms such as fever, malaise, chills, aching muscles, headache, sore throat or stinging eyes. It can take up to 3 days for the skin lesions to develop.

Over the past 25 years, ACCUTANE has been prescribed worldwide to approximately 16 million patients. A total of 66 cases of severe skin reactions (e.g. erythema multiforme [EM], Stevens-Johnson syndrome [SJS] and toxic epidermal necrolysis [TEN]) have been reported in both adults and children worldwide. While there were other factors involved for the majority of these reports, an association between ACCUTANE and these severe skin reactions cannot be ruled out.

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 serious skin reactions or other serious or unexpected adverse reactions in patients receiving ACCUTANE should be reported to Hoffmann-La Roche Limited or Health Canada at the following addresses:

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

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/pubs/medeff/_fs-if/2009-ar-ei-guide-prof/index-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

Should you have any questions or require additional information regarding the use of ACCUTANE, 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.

Sincerely,



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