

**PUBLIC COMMUNICATION**  
**Health Canada Endorsed Important Safety Information on**  
**INVIRASE® (saquinavir mesylate)**



April 20, 2010

**Subject: Association of INVIRASE® (saquinavir mesylate) with dose-dependent abnormal electrical activity or conduction in the heart (prolongations of QT and PR intervals) in healthy volunteers**

Hoffmann-La Roche Limited, in consultation with Health Canada, would like to inform patients of important new safety information regarding the use of INVIRASE® (saquinavir mesylate) and dose-dependent abnormal electrical activity or conduction in the heart (specifically prolongations of QT and PR intervals) in healthy volunteers.

INVIRASE is authorized for the treatment of HIV-1 infected adult patients. INVIRASE should only be given in combination with ritonavir and other antiretroviral medicinal products.

- INVIRASE should not be used if you have a history of problems with the electrical activity of the heart known as QT prolongation
- INVIRASE should not be taken with other drugs known to increase the risk of QT prolongation
- Before you use INVIRASE talk to your doctor or pharmacist if you have a history of problems with the electrical activity of the heart including QT prolongation or heart block

Changes in the heart rhythm and the electrical activity of the heart have been seen with INVIRASE. These changes may be observed on an ECG (EKG, electrocardiogram) and can lead to serious heart problems. The risk for these problems may be higher if you:

- already have a history of abnormal heart rhythm or other types of heart disease
- take other medicines that can affect your heart rhythm while you take INVIRASE.

Tell a doctor right away if you have any of these symptoms while taking INVIRASE:

- dizziness
- lightheadedness
- fainting
- sensation of abnormal heartbeats

If you are concerned about these or any other unexpected effects experienced while taking INVIRASE, talk to your doctor or pharmacist.

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 prolongations of QT and PR intervals or other serious or unexpected adverse reactions in patients receiving INVIRASE 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](mailto: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: 0701D  
Ottawa, Ontario, K1A 0K9  
Telephone: 613-957-0337 or Fax: 613-957-0335  
[CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@hc-sc.gc.ca)

To report an Adverse Reaction, consumers and health professionals may call toll free:  
Telephone: 1-866-234-2345  
Fax: 1-866-678-6789

Postage paid labels, the Canada Vigilance Reporting Forms and the Adverse Reaction Reporting Guidelines can be found on the MedEffect™ Canada Web site in the [Adverse Reaction Reporting](#) section. The Reporting Form is also in the *Canadian Compendium of Pharmaceuticals and Specialties*.

<http://hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>

**For other health product inquiries related to this communication, please contact Health Canada at:**

Marketed Health Products Directorate (MHPD)  
E-mail: [MHPD\\_DPSC@hc-sc.gc.ca](mailto:MHPD_DPSC@hc-sc.gc.ca)  
Telephone: 613-954-6522  
Fax: 613-952-7738:

**To change your mailing address or fax number, contact the Market Authorization Holder.**

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