

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
INVIRASE



02/11/2010

Subject: Updated Safety Information for INVIRASE® (saquinavir mesylate): Specific Guidance on Monitoring Heart Activity Using Electrocardiography

Hoffmann-La Roche Limited, in consultation with Health Canada, would like to inform patients of safety updates to the prescribing information for INVIRASE (saquinavir mesylate).

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

The Canadian Product Monograph, including Consumer Information, for INVIRASE has been revised to further emphasize the following safety concerns:

To inform health care professionals regarding the need to:

- Perform electrocardiogram (ECG) monitoring of patients who are starting treatment with ritonavir and INVIRASE;
- Perform ECG monitoring of patients who are taking other medications that may affect heart rhythm, while taking ritonavir and INVIRASE.

The current Canadian prescribing information for INVIRASE (Product Monograph) can be accessed at <http://www.rochecanada.com> or by performing a search in Health Canada's Drug Product Database at <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php>.

Please speak with your doctor or pharmacist if you have any related concerns or if you experience any other unexpected effects while taking INVIRASE.

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 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

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

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
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