

**Health Canada Endorsed Important Safety Information on
INTELENCE* (etravirine)**



October 19, 2009

New safety information regarding INTELENCE* (etravirine) and severe skin reactions

Tibotec, a division of Janssen-Ortho Inc. ("Tibotec"), in collaboration with Health Canada, would like to inform patients of important safety information regarding severe skin reactions in patients receiving HIV combination therapy including INTELENCE (etravirine) tablets. Reports have included severe allergic reactions sometimes accompanied by liver failure, and one report of death.

INTELENCE, in combination with other antiretroviral agents, is used to treat human immunodeficiency virus (HIV) in treatment-experienced adult patients who have been unsuccessfully treated with prior therapy and who are resistant to multiple antiretroviral agents including Non-nucleoside Reverse Transcriptase Inhibitors (NNRTIs).

- **Patients who develop a rash should contact their doctor immediately. A doctor will advise on how to manage symptoms and decide whether or not treatment with INTELENCE should be stopped.**
- Severe, potentially life-threatening, and fatal skin reactions have been reported. Symptoms of these reactions can include severe rash, blistering of the skin, fever, general unwell feeling, fatigue and muscle or joint pain. Some of these reactions have been accompanied by liver failure.

Tibotec is currently working with Health Canada to incorporate this new safety information in the Canadian Product Monograph for INTELENCE. Tibotec has also sent a letter to healthcare professionals to inform them of this new safety information. A copy of that letter is available on the Health Canada website.

This information is also available at <http://www.janssen-ortho.com>. For further information on Janssen-Ortho Inc.: call Suzanne Frost, Janssen-Ortho Inc., (416) 449-9444. Should you have any questions or require additional information regarding the use of INTELENCE, please contact Janssen-Ortho Inc. Medical Information Department at 1-800-567-3331 from 8:30 am to 4:30 pm Monday to Friday Eastern Standard Time (EST), by facsimile at 416-449-2658 or by email at medinfocanada@joica.jnj.com.

Managing marketed health product-related adverse reactions depends on healthcare 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 hypersensitivity reactions, or other serious or unexpected adverse reactions in patients receiving INTELENCE should be reported to Tibotec or Health Canada at the following addresses:

Tibotec, a division of Janssen-Ortho Inc.
Drug Safety Department
19 Green Belt Drive
Toronto, Ontario M3C 1L9
Tel: (800) 567-3331 or Fax: (866) 767-5865
dsscan@its.jnj.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/guide/2008-ar-ei_guide-ldir/index-eng.php

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

Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)
E-mail: BGIVD_Enquiries@hc-sc.gc.ca
Tel: 613-941-2566
Fax: 613-941-1183

Sincerely,

A handwritten signature in black ink, appearing to be 'Cathy Lau', written over a horizontal line.

Cathy Lau, PhD.

Vice President
Regulatory Affairs
JANSSEN-ORTHO Inc.

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