

**PUBLIC COMMUNICATION**  
**Health Canada Endorsed Important Safety Information on**  
**PREZISTA\* (darunavir)**



2008/05/12

**Subject: New safety information regarding PREZISTA\* (darunavir) and serious liver side effects**

Tibotec, a division of Janssen-Ortho Inc. ("Tibotec"), in cooperation with Health Canada, wishes to provide patients with important new safety information about serious liver side effects that have been reported with PREZISTA (darunavir).

PREZISTA is a medication used in combination with ritonavir, another antiretroviral medication, to treat adult patients with human immunodeficiency virus (HIV) in whom other antiretroviral therapy has failed.

- Among patients participating in clinical studies, 0.5% experienced hepatitis (inflammation of the liver) while being treated with PREZISTA.
- There have been 13 post market reports of patients taking PREZISTA who developed hepatitis during the time period from June 23, 2006 to December 23, 2007, including 2 patients who died. During that same period, there also have been 25 reports of patients who developed other liver problems, including 14 patients who died.
- It has not been established if PREZISTA contributed to these adverse liver events and deaths, or if they were due to other reasons, such as other medical problems or other medications. These reports generally involved patients with advanced HIV disease who were taking other medications, or had other illnesses such as hepatitis B or C infection, or a condition called immune reconstitution syndrome.
- Patients who have liver problems (including infection with hepatitis B or C virus) before starting treatment with PREZISTA are at greater risk for serious adverse liver events.

Your doctor will likely want to test your liver function before and during treatment with PREZISTA. If you have a liver problem before starting treatment, your doctor may choose to test your liver function more often.

If you use PREZISTA, you should consult a doctor immediately if you experience any of the following signs or symptoms suggestive of possible serious liver side effects:

- dark urine
- yellowing of the skin
- abdominal pain, especially on the right side below the ribs
- general itchiness
- decreased appetite
- nausea or vomiting
- tiredness

Patients should NOT discontinue their medication without consulting a doctor or pharmacist first.

Tibotec is working with Health Canada to update the prescribing information for PREZISTA and has sent a letter to health care professionals and pharmacists 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 more information, patients should consult their health care professionals, or call the Janssen-Ortho Medical Information Department at 1-800-567-3331, from 8:30 a.m. to 4:30 p.m. Monday to Friday, EST.

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 PREZISTA 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, ON M3C 1L9  
Tel: (800) 567-3331 or Fax: (866) 767-5865

**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/form/ar-ei\\_form\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html)

[http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei\\_guide-ldir\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html)

**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,



Cathy Lau, PhD.

Vice President  
Regulatory Affairs  
Janssen-Ortho Inc.

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