



JANSSEN-ORTHO

PUBLIC ADVISORY
Health Canada Endorsed Important Safety Information on
EPREX* (epoetin alfa)

Subject: Blood clot formation in cancer patients treated with EPREX (epoetin alfa) and similar medicines to higher than typical target hemoglobin levels in this population.

Toronto, October 18, 2004 - Janssen-Ortho Inc, in consultation with Health Canada, has informed Canadian healthcare professionals of important new safety information concerning EPREX (epoetin alfa) and other similar medicines. EPREX has been authorized for use in Canada since 1995 for the treatment of anemia in patients with cancer. Please note the following new safety information:

- Results of recent investigational studies using EPREX and other erythropoietin products have indicated an increased risk of blood clot formation in patients with cancer who were treated to raise their red blood cells to a level higher than the typical target in this population. In some cases, these blood clots were fatal.

Patients with cancer are generally at higher risk of blood clot formation than other patient populations as a result of known risk factors such as cancer itself, chemotherapy and radiation therapy.

Signs and symptoms of blood clot formation include:

- Weakness or numbness of the face, arms or legs and problems with speech or vision which may indicate a stroke (blood clot in the brain);
- Leg swelling, chest pain, shortness of breath or coughing up blood which may indicate a blood clot in the legs or lungs or a heart attack (blood clot in the blood vessels of the heart).

Janssen-Ortho has provided the revised prescribing information to healthcare professionals across Canada. For more information about the revisions to the prescribing information, patients should consult their healthcare professional. This information is also available at <http://www.janssen-ortho.com/>. Patients should NOT discontinue their medication without consulting their physician first.

As with all medicines, EPREX should not be used by anyone who does not require the drug to treat a disease or its symptoms.

This advisory is in addition to a letter issued to healthcare professionals discussing the above-mentioned safety information. This letter can be accessed at Health Canada's web site at:

http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_professionals_e.html - 2004

Janssen-Ortho Inc., is a research-based pharmaceutical company located in Toronto.

For further information: Simone Philogène, Janssen-Ortho Inc., (416) 449-9444. Or call the Janssen-Ortho Medical Information Department at 1-800-567-3331, from 9 a.m. to 5 p.m. Monday to Friday, EST.

The identification, characterization, and management of marketed health product-related adverse reactions are dependent on the active participation of health care professionals in adverse reaction reporting programmes. Any occurrences of blood clot formation or other serious and/or unexpected adverse reactions in patients receiving EPREX should be reported to Janssen-Ortho Inc or Health Canada at the following addresses:

Janssen-Ortho Inc.
Drug Safety and Surveillance
19 Green Belt Drive
Toronto, ON M3C 1L9 or call toll free at 1-800-567-3331
email to dsscan@joica.jnj.com

Any suspected adverse drug reactions can also be reported to:

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)

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

cadrmp@hc-sc.gc.ca

For other inquiries: please refer to contact information.

The [ADR Reporting Form](#) and the [AR Guidelines](#) can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adverse_e.pdf

www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adr_guideline_e.pdf

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Original signed by

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Regulatory, Safety and Quality