

**PUBLIC COMMUNICATION**  
**Important Safety Information on <sup>Pr</sup>EXJADE\* (deferasirox)**



December 3, 2009

**SUBJECT: Use of EXJADE\* (deferasirox) in Patients Diagnosed with Myelodysplastic Syndrome (MDS) and in Elderly Patients Regarding Kidney Problems and Bleeding in the Stomach or Intestine**

EXJADE\* is used to treat chronic iron overload caused by blood transfusions for the treatment of anemias for adults, adolescents, and children aged 6 years and over; and in children aged 2 to 5 years who cannot be adequately treated with deferoxamine.

Therapy with EXJADE\* should be initiated and maintained by physicians experienced in the treatment of chronic iron overload due to blood transfusions.

Novartis has proposed changes to the Canadian Product Monograph for EXJADE\* (including the Consumer Information Section), and these changes are currently under review by Health Canada.

- There may be a greater risk of kidney problems, bleeding in the stomach or intestine (potentially fatal) and deaths in patients with myelodysplastic syndrome (MDS) and in elderly patients compared to younger patients with other anemias such as  $\beta$ -thalassemia and sickle cell disease. Many of these adverse events are common to elderly patients and patients with MDS, making it difficult to draw any conclusions about the potential relationship between EXJADE\* and the reporting of these adverse events.
- Patients should not use EXJADE\* if they have been diagnosed with myelodysplastic syndrome (MDS) in a high risk category or have an advanced cancer.
- Kidney function should be monitored before the start of treatment with Exjade and during treatment. Patients should also ensure that they are well hydrated (drink lots of fluid). Patients should tell their doctor if they produce less urine than usual.
- There have been rare reports of bleeding in the stomach or intestine (fatal in rare cases), especially in patients with advanced blood cancer and/or low blood platelet counts.

If you have any questions about the above information or about EXJADE\* please talk to your doctor, pharmacist, or contact Novartis Pharmaceuticals Canada Inc. at: 1-800-363-8883 (Medical Information).

For more information on EXJADE\* please consult the Consumer Information document available at [www.novartis.ca](http://www.novartis.ca).

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 EXJADE\* should be reported to Novartis or Health Canada at the following addresses:

Novartis Pharmaceuticals Canada Inc.  
385 Bouchard Blvd.  
Dorval, (QC) H9S 1A9  
Phone: 1-877-631-6775 x 3425 (Drug Safety & Epidemiology)

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

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- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
  - Call toll-free at 1-866-234-2345
  - Complete a Canada Vigilance Reporting Form and:
    - Fax toll-free to 1-866-678-6789, or
    - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701C  
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

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

Bureau of Metabolism, Oncology and Reproductive Sciences  
Therapeutic Products Directorate  
BMORS\_Enquiries@hc-sc.gc.ca  
Tel: (613) 941-3171 Fax: (613) 941-1365

For media inquiries, please contact Silvie Letendre at (514) 633-7872.

Sincerely,

*original signed by*

Jean-Marie Leclerc, M.D. FRCP(C)  
Chief Scientific Officer and Senior Vice-President Clinical and Regulatory Affairs

\*EXJADE is a registered trademark.