

PUBLIC COMMUNICATION
Health Canada Endorsed Important New Benefit-Risk Information on
PrXIGRIS® [drotrecogin alfa (activated)]



October 28, 2011

Subject: Worldwide Withdrawal of XIGRIS® [drotrecogin alfa (activated)]

Eli Lilly and Company is undertaking a worldwide withdrawal of Xigris® [drotrecogin alfa (activated)].

Xigris is used solely in hospital intensive care units in patients at a high risk of death due to serious complications of a generalized infection (called sepsis or septic shock). A recent study did not show any improvement in surviving this life-threatening illness when patients were given Xigris in addition to the usual treatment.

The withdrawal is effective immediately.

- In a recent study Xigris did not improve a patient's chances of surviving septic shock when added to the usual treatments.
- Many improvements in treatment of septic shock have taken place over the years and this may explain why Xigris is no longer seen as a useful additional treatment.
- For any questions regarding this issue, contact Eli Lilly Canada at 1-888-545-5979.

Xigris was authorized in Canada in 2003 to decrease the risk of dying from severe sepsis. This was based on the results of a study that showed that more patients survived severe sepsis when Xigris was given in addition to usual care. Since that time, many advances have been made in the treatment of patients with severe sepsis. This could explain the change in the usefulness of Xigris as an additional treatment in these patients.

A copy of the letter can be accessed at Health Canada's website <http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php> or at www.lilly.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.

Eli Lilly Canada Inc.
Toronto, Ontario
1-888-545-5972

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:

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

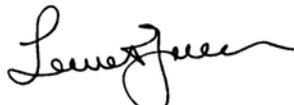
The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada website in the [Adverse Reaction Reporting](#) section.

<http://www.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:

Lead Directorate: **Marketed Health Products Directorate**
E-mail: [**MHPD_DPSC@hc-sc.gc.ca**](mailto:MHPD_DPSC@hc-sc.gc.ca)
Telephone: **613-954-6522**
Fax: **613-952-7738**

Sincerely,



Loren D. Grossman, MD, FRCPC, FACP
Vice-President, Research and Development
Eli Lilly Canada Inc.