

**Public Communication**  
**Health Canada Endorsed Important Safety Information on**  
**PrEFFIENT® (prasugrel hydrochloride)**



January 17, 2014

**Subject: Association of EFFIENT® (prasugrel hydrochloride) with increased risk of bleeding in patients treated for certain types of heart attacks at the hospital.**

Eli Lilly Canada Inc. in collaboration with Health Canada would like to inform patients and their caregivers of important safety information about EFFIENT® (prasugrel hydrochloride). EFFIENT® is an antiplatelet medication which lowers the ability of blood to clot. A doctor can start EFFIENT® at the hospital around the time of a procedure to open a blocked heart artery in patients with certain types of heart attacks.

- Patients treated for certain types of heart attacks at the hospital are at an increased risk of bleeding when EFFIENT® is started before looking at the heart arteries with an angiogram (compared to when EFFIENT® was given after looking at the heart arteries).
- Doctors have been advised to consider this risk when starting treatment with EFFIENT® for certain types of heart attacks.
- There is no additional harm to people who are already taking EFFIENT®. **Do not stop taking EFFIENT® without discussing with your doctor. Stopping EFFIENT® may increase the chance of having a heart attack.**

This communication is also posted on <http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php> and on [www.lilly.ca](http://www.lilly.ca).

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of serious or unexpected side effects in patients receiving EFFIENT® should be reported to Eli Lilly Canada Inc. or Health Canada.

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

You can report any suspected side effect associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax

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

Lead Directorate: Marketed Health Products Directorate  
E-mail: (Generic e-mail address): MHPD\_DPSC@hc-sc.gc.ca  
Telephone: 613-954-6522  
Fax: 613-952-7738

Sincerely,

***Original signed by***

A handwritten signature in red ink, appearing to be 'Doron Sagman', written over a horizontal line.

Doron Sagman, MD, FRCPC  
Vice President, Research & Development  
Eli Lilly Canada Inc.