



**Public Communication -  
Health Canada Endorsed Important Safety Information on <sup>Pr</sup>ARZERRA™ (ofatumumab)**

August 6, 2014

**Subject: ARZERRA™ (ofatumumab) – Fatal Infusion Reaction in a patient with Chronic Lymphocytic Leukemia (CLL)**

GlaxoSmithKline Inc., in consultation with Health Canada, has informed health care professionals of important new updates to safety information regarding infusion reactions related to ARZERRA™.

ARZERRA™ is a medication that is administered into the veins to treat chronic lymphocytic leukemia (CLL), a type of blood cancer.

- A severe infusion reaction resulting in death was reported in a patient with CLL who was given ARZERRA™.
  - Signs and symptoms of an infusion reaction may include the following: swelling of face or mouth, fever, chills, difficulty breathing, tightness of the chest and/or throat, light headedness, nausea, diarrhea, and rash.
  - These symptoms can occur during or shortly after the infusion of ARZERRA™. If you experience these or any other symptoms, please notify your health care provider immediately.
- The prescribing information for ARZERRA™ is being revised to include new information regarding the potential for fatal infusion reactions.
- Patients are reminded that it is important to be closely monitored during and after the infusion by a health care professional, especially if you have a heart condition.

GSK has sent a letter to health care professionals informing them of this important safety information. This information may be obtained on the Canadian website of GlaxoSmithKline Inc. ([www.gsk.ca](http://www.gsk.ca)) or on the Health Canada website.

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of serious hypersensitivity or infusion reactions or other serious or unexpected side effects in patients receiving ARZERRA™ should be reported to GlaxoSmithKline or Health Canada.

GlaxoSmithKline Inc.  
7333 Mississauga Road  
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Tel: 1-800-387-7374

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>)  
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:  
Marketed Health Products Directorate  
E-mail: [mhpd\\_dpssc@hc-sc.gc.ca](mailto:mhpd_dpssc@hc-sc.gc.ca)  
Telephone: 1-613-954-6522  
Fax: 1-613-952-7738

If you have any questions about this new information, please contact GlaxoSmithKline Medical Information Department at 1-800-387-7374.

***Original signed by***

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