

**Public Communication –  
Health Canada Endorsed Important Safety Information on  
VECTIBIX® (panitumumab)**



27 May 2014

**Subject: Rare cases of severe skin reactions called Stevens-Johnson syndrome and Toxic Epidermal Necrolysis have been reported in patients treated with VECTIBIX® (panitumumab)**

Amgen Canada Inc., in consultation with Health Canada, would like to inform you of important new safety information related to severe skin reactions called Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) reported in regard to VECTIBIX®.

VECTIBIX is used to treat certain types of cancer of the colon and/or rectum that have spread to other parts of the body. VECTIBIX has been approved with conditions, pending the results of studies to verify its clinical benefit.

Stevens-Johnson Syndrome (SJS) and TEN are severe body surface reactions which may extend from the skin to involve the lining of the mouth, the anal and genital area, as well as the inside lining of the eyelids. These reactions can sometimes lead to death.

- Cases of SJS and TEN have been reported rarely ( $\geq 1/10,000$  patients and  $< 1/1000$  patients) in patients treated with VECTIBIX.
- Signs and symptoms of SJS and TEN may include blistering of the skin, mouth, eyes and genitals. One or many of these symptoms may occur up to 7-14 days after an infusion of VECTIBIX.
- If you experience any of these symptoms, or if you have any questions regarding SJS or TEN, please contact your doctor immediately.

Amgen Canada is working with Health Canada to update the safety information for VECTIBIX and has sent a letter to health care professionals to inform them of this new important safety information. A copy of that letter is available on the Health Canada Web site (<http://www.hc-sc.gc.ca>). This information is also available at [www.amgen.ca](http://www.amgen.ca).

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of serious skin reactions called Stevens-Johnson syndrome and Toxic Epidermal Necrolysis or other serious or unexpected side effects in patients receiving VECTIBIX should be reported to Amgen Canada Inc. or Health Canada.

**Amgen Canada Inc.**

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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:

Marketed Health Products Directorate

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Sincerely,



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