

**Public Communication -
Health Canada Endorsed Important Safety Information on
Prolia®**



11/21/2012

v1.0

Subject: Prolia® (denosumab) - Risk of Unusual Thigh Bone Fractures

AMGEN Canada Inc., in association with Health Canada, would like to inform you of new important safety information related to the risk of unusual thigh bone fractures associated with the use of PROLIA.

PROLIA (denosumab) is used to decrease the risk of broken bones in women who had their menopause and suffer from osteoporosis. It is specifically prescribed for women at high risk of breaking bones or those who are unable to take other osteoporosis medicines.

Some people have developed unusual fractures in their thigh bone while receiving PROLIA. These fractures are called "atypical fractures". Atypical fractures are very rare. They can occur with minimal or no impact to the thigh area.

- Atypical fractures have been reported very rarely, in less than 1 in 10,000 patients treated with PROLIA.
- Patients with a potential fracture complain of dull, unusual aching pain in the thigh, hip or groin area.
- Contact your doctor if you experience new or unusual pain in your hip, groin, or thigh.

Amgen Canada has worked with Health Canada to update the safety information for PROLIA 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 website (www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php). This information is also available at www.amgen.ca.

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing side effects are generally presumed to underestimate the risks associated with health product treatments. Any case of serious atypical fracture or other serious or unexpected side effects in patients receiving PROLIA should be reported to Amgen Canada Inc. or Health Canada.

Amgen Canada Inc.

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Safety e-mail: safetycanada@amgen.com

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
E-mail: MHPD_DPSC@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Sincerely,



Clive Ward-Able, MD
Executive Medical Director
AMGEN Canada Inc.