

**Public Communication -
Health Canada Endorsed Important Safety Information on
AVASTIN® (bevacizumab)**



02 May 2013

**Subject: Cases of Severe Bacterial Infection of Skin and Soft Tissue
(Necrotizing Fasciitis) Reported With AVASTIN**

Hoffmann-La Roche Limited (Roche), in consultation with Health Canada, has informed healthcare professionals of important new safety information regarding the use of AVASTIN® (bevacizumab).

AVASTIN is used either alone to treat a particular type of brain cancer (glioblastoma), or in combination with chemotherapy to treat cancers that have spread to other parts of the body such as colon, rectal and lung cancer.

- Necrotizing fasciitis is a severe, life-threatening bacterial infection of the skin and soft tissue (tissue other than bone and cartilage). It has been reported, in rare cases, in patients treated with AVASTIN. Some of these patients have died from complications of necrotizing fasciitis.
- Symptoms can develop quickly, as early as 24 hours after a minor skin injury or surgical wound, and may include: sudden, severe pain in the affected area, fever, redness, heat, swelling, or fluid-filled blisters in the skin, scaling, peeling, or discolored skin over the affected area. Other symptoms may include confusion, fainting or dizziness.
- If you develop any of the above or any other unusual signs or symptoms, please contact your doctor or healthcare professional immediately.

If necrotizing fasciitis occurs, AVASTIN administration should be discontinued. Your healthcare professional will decide whether AVASTIN can be re-administered.

Patients suffering from diabetes and cancer have a greater risk of developing necrotizing fasciitis, because their body's natural defences are lowered.

Roche will be working with Health Canada to update the AVASTIN Product Monograph accordingly.

Managing marketed health product-related adverse reactions depends on healthcare 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. Any case of necrotizing fasciitis or other serious or unexpected adverse reactions in patients receiving AVASTIN should be reported to Roche or Health Canada.

Hoffmann-La Roche Limited
Drug Safety Department
2455 Meadowpine Boulevard
Mississauga, Ontario, L5N 6L7
or call toll free at: 1-888-762-4388
or Fax at: 905-542-5864
or email to: mississauga.drug_safety@roche.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>) 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 (MHPD)
E-mail: MHPD_DPSC@hc-sc.gc.ca
Tel: (613) 954-6522
Fax: (613) 952-7738

Should you have any questions or require additional information regarding the use of AVASTIN, please contact the Drug Information Department at Hoffmann-La Roche Limited at 1-888-762-4388 from 8:30 a.m. to 4:30 p.m. Monday to Friday Eastern Standard Time.

Original signed by



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