

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on AVASTIN®
(bevacizumab)



November 14, 2011

Subject: Higher rate of ovarian failure in premenopausal women who were treated with AVASTIN® (bevacizumab)

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

- In a study of patients with colon (bowel) cancer who had surgery to remove their tumour and were then treated with anti-cancer drugs (also known as "adjuvant treatment"), more cases of ovarian failure (a loss of normal function of the ovaries) were seen in premenopausal women receiving AVASTIN and chemotherapy (anti-cancer drugs) compared to those receiving chemotherapy alone.
- AVASTIN may affect the hormonal balance of women and their ability to get pregnant as a result of ovarian failure. If you are a premenopausal woman, talk to your doctor before starting treatment with AVASTIN.

Chemotherapy alone is a known risk factor for ovarian failure in women treated for cancer. This risk is higher when AVASTIN is added to the treatment.

The Canadian Product Monograph for AVASTIN has been updated to include this new safety information.

AVASTIN is authorized, in combination with chemotherapy, for the treatment of people diagnosed with:

- colon and rectal cancer that has spread to other parts of the body,
- lung cancer that has spread to other parts of the body, and
- breast cancer that has spread to other parts of the body (this use has conditions required by Health Canada).

AVASTIN, as a single agent, is authorized for the treatment of a particular type of brain cancer called glioblastoma (this use has conditions required by Health Canada).

AVASTIN is not authorized for the treatment of colon cancer after surgical removal of the primary tumour (also known as "adjuvant treatment").

Managing marketed health product-related adverse reactions depends on health care 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 serious or unexpected adverse reactions in patients receiving AVASTIN should be reported to Hoffmann-La Roche Limited or Health Canada at the following addresses:

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 adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada Web site in the Adverse Reaction Reporting section.

<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>

For other inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate (MHPD)
E-mail: mhpd_dpssc@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, Monday to Friday, between 8:30 a.m. and 4:30 p.m. (Eastern Standard Time).

Sincerely,



Lorenzo Biondi
Vice President, Medical and Regulatory Affairs
Hoffmann-La Roche Limited