

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



December 7, 2011

Subject: Reports of cases of severe eye inflammation leading to blindness following the unauthorized use of AVASTIN® (bevacizumab) in the eye

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

- AVASTIN was not developed to be injected into the eye. The use of AVASTIN in the eye is not authorized by Health Canada.
- Clusters of cases of bacterial infection and eye inflammation in the eye resulting in blindness or near blindness have been reported in three locations in the United States in patients who were injected in the eye with AVASTIN. The cases appear to be due to contamination after repackaging single-use AVASTIN vials into several syringes.
- The following side effects may occur when AVASTIN is injected into the eye:
 - Infection or inflammation of the eye globe, which may lead to permanent blindness
 - Redness of the eye, small particles or spots in your vision (floaters), eye pain, which may lead to permanent blindness
 - Seeing flashes of light with floaters, progressing to a loss of some of your vision
 - Increased eye pressure (found on examination by your doctor)
 - Bleeding in the eye
 - Cataract formation that requires surgery
 - Other serious side effects affecting other organs, which may be severe and lead to hospitalisation, e.g. heart attack, stroke, and high blood pressure.
- It is important to see your eye doctor if you have any of these symptoms after an eye injection with AVASTIN.

A previous Health Professional Communication and Public Communication were issued in 2008 and can be found at the following address: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/public/_2008/avastin_4_pc-cp-eng.php

About AVASTIN

AVASTIN is packaged into single-use, sterile, preservative-free vials to treat cancer by injection into the veins. The practice of repackaging single-use AVASTIN vials into several syringes may contaminate the product.

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, and
- lung cancer that has spread to other parts of the body,

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

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,

original signed by

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