

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
[MABCAMPATH® (alemtuzumab)]



November 18, 2008

Bayer HealthCare and Genzyme, in collaboration with Health Canada, has informed Canadian healthcare professionals of important safety information concerning the use of MABCAMPATH® (alemtuzumab) following treatment with other anti-leukemia drugs which also suppress the body's immune system.

Subject: Infection-related deaths were reported with the use of MABCAMPATH® (alemtuzumab) following initial combination therapy with anti-leukemia drugs which also suppress the body's immune response

MABCAMPATH is currently used to treat patients with B-cell chronic lymphocytic leukemia (B-CLL), a blood cancer affecting a certain type of white blood cells called B-lymphocytes, when other drugs to treat this type of cancer have been unsuccessful. Please note the following important safety information for the use of MABCAMPATH:

- **MABCAMPATH is not authorized to be used in patients who have responded but not relapsed following combination treatment with other drugs which also suppress the immune system.**
- **Early safety information from a clinical trial conducted in the United States, reported six infection-related deaths out of 51 patients who were taking anti-leukemia drugs, which also suppress the immune system, followed by MABCAMPATH.**
- **The possibility for an increased risk of infection-related problems may be present following treatment with many drugs that suppress the body's immune system.**

In a study done in the United States, leukemia patients were treated with a combination of two drugs, fludarabine + rituximab followed approximately four months later by MABCAMPATH. This study reported six infection-related deaths out of 51 patients who received these three drugs. The six fatal infections were said to be due to either bacteria, viruses or fungus.

A number of factors may increase the risk of infections in leukemia patients under the above treatment regimen. These may include the specific initial treatment plan, dose of drugs used, and the time interval between initial combination therapy followed by the use of MABCAMPATH. All three drugs used in the study discussed above are known to reduce the activity of the immune system which makes the treated individual more susceptible to infection. Therefore, the role that each drug plays with respect to the outcomes in that study remains unclear. MABCAMPATH is not authorized to be used in patients who have responded but not relapsed following combination treatment with other drugs which also suppress the immune system.

Additional information

Bayer HealthCare and Genzyme were also informed of an additional non-infection related death which was believed to be related to a reaction of donated blood cells against the patient's own tissues. This happened in a patient who received blood products that were not treated with radiation prior to the transfusion. Irradiation of blood products is thought to remove the possibility of such reactions from happening. As of this posting, no new significant safety information regarding this study has been received by Bayer HealthCare or Genzyme.

If you are participating in a clinical trial, report any adverse events to your doctor.

The prescribing information for MABCAMPATH will be updated to reflect this safety information.

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 occurrence of serious and/or unexpected adverse reactions in patients receiving MABCAMPATH should be reported to Bayer HealthCare, or Health Canada at the following addresses:

Bayer HealthCare
77 Belfield Road
Toronto ON M9W 1G6
Tel: 1-800-265-7382
Fax: 1-866-232-0565
E-mail: DSI_Canada@bayer.com

Any suspected adverse reaction can also be reported to:

Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
Ottawa, Ontario, K1A 0K9
Tel: 613-957-0337 or Fax: 613-957-0335

To report an Adverse Reaction, consumers and health professionals may call toll free:

Tel: 866-234-2345
Fax: 866-678-6789

CanadaVigilance@hc-sc.gc.ca

The AR Reporting Form and the AR Guidelines can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

For other inquiries related to this communication, please 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

Sincerely,

Original signed by

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