Public Communication -
Health Canada Endorsed Important Safety Information on
RITUXAN® (rituximab)

July 29, 2013

Subject: Hepatitis B Virus Recurrence in Patients Treated with RITUXAN® (rituximab): Updated Recommendations for Screening and Management

Hoffmann-La Roche Limited, in consultation with Health Canada, has informed health care professionals of important updates to safety information for RITUXAN.

RITUXAN is a medication that is administered into the veins to treat certain types of cancer (e.g. non-Hodgkin's lymphoma and chronic lymphocytic leukemia). RITUXAN may also be used to reduce the signs and symptoms of rheumatoid arthritis (RA) and to reduce inflammation associated with severe Granulomatosis with Polyangiitis (GPA), also known as Wegener's Granulomatosis and Microscopic Polyangiitis (MPA). GPA/MPA are disorders that cause blood vessel inflammation.

- **Use of RITUXAN has been shown to be associated with recurrence of hepatitis B virus infection in patients who show evidence of the virus in a blood test. It is advised that all patients be tested for hepatitis B virus infection before starting treatment with RITUXAN.**
- **Infection with hepatitis B virus causes inflammation of the liver which may show as mild fever, feeling of sickness, fatigue, loss of appetite, joint and/or abdominal pain and yellowing of whites of the eyes, skin and tongue.**
- **Patients who experience any of these symptoms should immediately contact their healthcare provider. Patients who show evidence of hepatitis B virus infection may be referred to a liver disease expert for ongoing monitoring and management.**
- **RITUXAN is not to be used in patients with active hepatitis B viral disease. Tell your doctor if you think you have hepatitis B.**

In the existing prescribing information for RITUXAN, hepatitis B virus screening is recommended for patients at high risk of hepatitis B infection before initiation of treatment with RITUXAN. Roche will be working with Health Canada to update the prescribing information to reflect new recommendations for management of the disease.

Hoffmann-La Roche has sent a letter to healthcare professionals informing them of this important safety information. This information may be obtained on the Canadian website of Hoffmann-La Roche Limited or on the Health Canada website.

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 hepatitis B recurrence or other serious or unexpected side effects in patients receiving RITUXAN should be reported to Hoffmann-La Roche Limited 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 RITUXAN, 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.

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Hoffmann-La Roche Limited