Public Communication -
Health Canada Endorsed Important Safety Information on
IMURAN® and PURINETHOL®

March 26, 2014

Dear Patient,

Subject: Association of IMURAN® (azathioprine) or PURINETHOL® (mercaptopurine) with a type of blood cancer - Hepatosplenic T-Cell Lymphoma (HSTCL)

Triton Pharma Inc. and Teva Canada Ltd., in consultation with Health Canada, would like to inform you of safety information for patients receiving **IMURAN® (azathioprine) or PURINETHOL® (mercaptopurine).**

IMURAN® is a drug used to treat adult rheumatoid arthritis and help prevent kidney transplant rejection. PURINETHOL® is a drug approved to treat cancer (leukemias). IMURAN® and PURINETHOL® are not approved in Canada for the treatment of Inflammatory Bowel Disease (IBD).

Hepatosplenic T-cell lymphoma (HSTCL) is a rare[1], aggressive and often fatal cancer.

- **Cases of Hepatosplenic T-cell Lymphoma (including deaths) have been reported in IBD patients treated with IMURAN® (azathioprine) or PURINETHOL® (mercaptopurine).**
- **IMURAN® and PURINETHOL® labels have been updated to include the associated risk of HSTCL.**
- **Patients should discuss the current information regarding risks and benefits of these treatments with their doctors.**

Cases of HSTCL (including deaths) have been reported with the use of IMURAN® and PURINETHOL® in Canada and internationally mostly in patients where it is used to treat inflammatory bowel disease (IBD). A total of 238 cases of HSTCL have been reported worldwide[1], indicating this cancer is rare.

Triton Pharma Inc. and Teva Canada Ltd. have sent a letter to healthcare professionals informing them of this safety information. This letter can be obtained on the Canadian website of Triton Pharma Inc. (www.tritonpharma.ca) and Teva Canada Ltd. (www.tevacanada.com) or on the Health Canada Web site (healthycanadians.gc.ca/index-eng.php). If you have questions regarding your IMURAN® or PURINETHOL® prescriptions, please contact your doctor.

The complete prescribing and adverse event information for IMURAN® can be found in the approved Product Monograph[2] which is available on the Health Canada website and on the Triton Pharma Inc. website.

The complete prescribing and adverse event information for PURINETHOL® can be found in the approved Product Monograph[3] which is available on the Health Canada website and on the Teva Canada Ltd. website.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Any case of HSTCL or other serious or unexpected adverse reactions in patients receiving IMURAN® or PURINETHOL® should be reported to Triton Pharma Inc. or Teva Canada Ltd., respectively, or Health Canada.

Triton Pharma Inc.
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Telephone: 1-866-429-9707
E-mail: drug.safety.triton@paladinlabs.com

Teva Canada Ltd.
30 Novopharm Court
Toronto, Ontario M1B 2K9
Telephone: 1-800-268-4127 ext. 1255005
E-mail: phv@tevacanada.com

You can report any suspected adverse reactions 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
E-mail: MHPD_DPSC.public@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Sincerely,

Original signed by

Sybil Dahan
President
Triton Pharma Inc.

Bruce Valliant
Director, Medical Affairs
Teva Canada Limited

References

1) Thai, A. & Prindiville, T. Hepatosplenic T-cell lymphoma and inflammatory bowel disease. *J. Crohns Colitis* 4, 511-522 (2010).
2) IMURAN® Canadian Product Monograph. January 31st, 2013.
3) PURINETHOL® Canadian Product Monograph. September 10th, 2013.