Public Communication Health Canada Endorsed Important Safety Information on VOTRIENT® (pazopanib hydrochloride)



August 9, 2013

Subject: VOTRIENT® (pazopanib hydrochloride) - Important Change to Frequency of Liver Test Monitoring for Liver Toxicity

GlaxoSmithKline Inc., in consultation with Health Canada, would like to inform you of an important safety update to the Warnings & Precautions section of the Product Information for VOTRIENT®, regarding a change in frequency for monitoring liver toxicity.

- VOTRIENT® may cause liver damage. VOTRIENT® should not be used in patients with moderate or severe liver impairment (reduced function), or in patients with certain changes in liver blood tests done prior to taking VOTRIENT®.
- Testing for liver problems during treatment has increased to include monitoring during weeks 2, 4, 6, 8 and Months 3 and 4, and at the recommendation of your doctor. Regular monitoring should continue after Month 4.
- Contact your doctor if you are taking VOTRIENT® and have any questions about this safety update and how it could affect your treatment.

VOTRIENT[®] is used in the treatment of metastatic kidney cancer (when cancer cells have spread from the kidney to other parts of the body). VOTRIENT[®] is also used for certain types of advanced soft tissue sarcoma in patients who have already received chemotherapy. Soft tissue sarcoma is a type of cancer that occurs in muscles, blood vessels or other tissues that support, surround and protect the body's organs.

GlaxoSmithKline has sent a letter to healthcare professionals informing them of this new safety information. This information can be obtained on the Canadian website of GlaxoSmithKline (www.gsk.ca) or on the Health Canada Web site (healthycanadians.gc.ca/index-eng.php). If you have questions regarding your VOTRIENT® prescription, please contact your doctor.

For media inquiries, please contact GlaxoSmithKline Communications at (905) 819-3363.

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any serious or unexpected side effects in patients receiving VOTRIENT® should be reported to GlaxoSmithKline Inc. or Health Canada.

GlaxoSmithKline Inc. 7333 Mississauga Road Mississauga, Ontario L5N 6L4

Phone: 1-800-387-7374

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 <u>Adverse Reaction Reporting</u> (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, please contact Health Canada at:

Marketed Health Products Directorate E-mail: mhpd_dpsc@hc-sc.gc.ca

Telephone: 613-954-6522

Fax: 613-952-7738

Sincerely,

Original signed by

Dr. Glenn Crater Vice President, Medical and Chief Medical Officer GlaxoSmithKline Inc.

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