Health Canada Endorsed Important Safety Information on Sutent (sunitinib malate) Capsules

September 6, 2013

Dear Healthcare Professional,

Subject: Association of Sutent (sunitinib malate) with Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)

Pfizer Canada Inc. (manufacturer of Sutent), in collaboration with Health Canada, would like to inform you about an important revision to the Product Monograph, including the consumer information section, for Sutent (sunitinib malate).

Sutent is indicated for the treatment of gastrointestinal stromal tumour (GIST) after failure of imatinib mesylate treatment due to resistance or intolerance. It is also indicated for the treatment of metastatic renal cell carcinoma (MRCC) of clear cell histology and for the treatment of patients with unresectable locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumours (pancreatic NET), whose disease is progressive. A statement has been recently added to the Product Monograph to inform Health Care Professionals and patients about a potential association between the use of Sutent and severe cutaneous reactions suggestive of Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). Early recognition is important in improving prognosis.

- Cases of Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), including fatal cases, have been very rarely reported, mostly in the post-marketing setting, in patients who have used Sutent.
- If signs or symptoms of SJS or TEN are present, Sutent treatment should be discontinued. If the diagnosis of SJS or TEN is confirmed, treatment must not be restarted.
- The Product Monograph has been updated to reflect this risk.

The potential risk of the cutaneous adverse events of Toxic Epidermal Necrolysis (TEN), and Stevens-Johnson Syndrome (SJS), with sunitinib use was evaluated using a review of currently available safety data from published literature, the Pfizer global safety database containing clinical trial serious adverse events and post-marketing reports, the US FDA Adverse Event Reporting System (AERS) database, and the Canada Vigilance database. Out of an estimated 214,848 patients exposed to sunitinib between 26 January, 2006 and 30 April, 2013, there were 4 reported cases of TEN and 5 reported cases of SJS internationally, although diagnosis was not confirmed in all cases. Two of the potential TEN cases had fatal outcomes. There

have been no Canadian cases reported as of April 30, 2013.

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 side effects are generally presumed to underestimate the risks associated with health product treatments. Any case of serious SJS or TEN or other serious or unexpected adverse reactions in patients receiving Sutent should be reported to Pfizer Canada or Health Canada.

If you have any questions concerning this information, please contact Medical Information at Pfizer Canada as per contact information below:

Pfizer Canada Inc.
17300 Trans-Canada Highway
Kirkland, QC H9J 2M5
Telephone: 1-800-463-6001

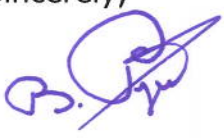
To correct your mailing address or fax number, contact Pfizer Canada.

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 (MHPD)
E-mail: mhpd_dpsc@hc-sc.gc.ca
Telephone: (613) 954-6522
Fax: (613) 952-7738

Sincerely,



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