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

September 6, 2013

Subject: Association of Sutent (sunitinib malate) with cases of severe skin reactions

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 a medication that is used to treat cancer of the stomach and bowels, kidney, and pancreas. A statement has been added in the product monograph to inform Health Care Professionals and patients about a potential association between Sutent and severe and sometimes life-threatening skin rashes such as Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). 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.

- Cases of Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), have been very rarely reported in patients who have used Sutent. Some cases resulted in death.
- Signs and symptoms of severe skin reactions may initially appear as reddish target-like spots or circular patches often with central blisters on the trunk, or elsewhere on the body. The rash may progress to widespread blistering or peeling of the skin, blisters in the mouth, and ulcers in the eyes. The skin changes happen quickly and may follow fever, tiredness, headache and cough.
- If you develop any of the above or any other unusual signs or symptoms, please contact your doctor or healthcare professional immediately.
- If a severe skin reaction occurs, Sutent needs to be stopped. A healthcare professional will decide whether to re-start Sutent or not.

Pfizer Canada is sending a letter to healthcare professionals informing them of this important safety information. This information may be obtained on the Canadian website of Pfizer Canada or on the Health Canada website.

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of serious SJS or TEN or other serious or unexpected side effects 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:

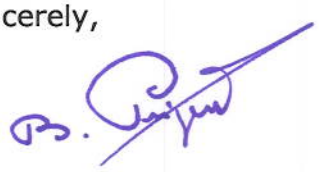
Pfizer Canada Inc.
17300 Trans-Canada Highway
Kirkland, QC H9J 2M5
Telephone: 1-800-463-6001

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
Telephone: (613) 954-6522
Fax: (613) 952-7738

Sincerely,



Bernard Prigent, MD, MBA
Vice-President and Medical Director
Pfizer Canada Inc.