PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
VIRACEPT (nelfinavir mesylate)

2007-09-10

Subject: **Safety Information related to VIRACEPT® (nelfinavir mesylate) and ethyl methanesulfonate (EMS)**

Pfizer Canada Inc., following discussions with Health Canada, is informing you of the presence of low levels of ethyl methanesulfonate (EMS), a process-related impurity in VIRACEPT (nelfinavir mesylate).VIRACEPT is a type of drug called a protease inhibitor (PI) used for the treatment of HIV/AIDS. Pfizer Canada is issuing a letter to health professionals providing them with guidance on the use of VIRACEPT in patients, including pregnant women and pediatric patients.

Ethyl methanesulfonate (EMS) is a potential human carcinogen (causes cancer). Data from animal studies indicate that EMS causes birth defects and cancer. However, no data from humans exists. Animal studies do not necessarily predict human risk.

New guidance concerning the use of VIRACEPT is as follows:

- At this time, physicians are asked to consider the risks and benefits of prescribing VIRACEPT to their HIV-infected adult patients, given the information provided below. In general, Health Canada recommends that HIV-infected patients should be switched from VIRACEPT to an alternative therapy if this can be done safely.
- **Patients should NOT stop taking VIRACEPT without first consulting with their physician.**
- The following groups of patients may be more susceptible to harm from EMS and should be switched to alternative therapy as soon as medically feasible:
  - Pregnant women
  - Children
- VIRACEPT should NOT be used for post-exposure prophylaxis (occupational or non-occupational) (This use is not an approved indication in Canada).
- VIRACEPT should NOT be prescribed for adults and children needing to initiate therapy.
- Pharmacists should notify the treating HIV physician when patients present for renewal of VIRACEPT prescriptions.

Patients taking VIRACEPT should contact their physician for discussion of whether they should continue or be switched to other treatment. VIRACEPT will remain on the market for those patients without reasonable treatment alternatives and for whom their physician has determined a positive benefit/risk for continued use of VIRACEPT.

VIRACEPT was removed by Roche Ltd from the European market in June 2007, due to detection of high levels of EMS in some product there. The levels of EMS in the VIRACEPT Canadian product are over 200 times less than that found in the European product.

Pfizer is working with Health Canada to limit EMS levels in VIRACEPT while taking into consideration the immediate needs of patients on therapy. Further relevant information will be provided as it becomes available.

Healthcare professionals and patients who have additional questions may contact Pfizer Canada's medical information line at 1-800-463-6001.

For media inquiries, please contact Ms. Julie-Catherine Racine, Pfizer Canada Inc, (514) 693-4602.

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 adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any serious or unexpected adverse reactions in patients receiving VIRACEPT should be reported to Pfizer Canada or Health Canada at the following addresses:

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

Any suspected adverse reaction can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
OTTAWA, Ontario, K1A 0K9
Tel: (613) 957-0337 or Fax: (613) 957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866 234-2345
Fax: 866 678-6789
cadrmp@hc-sc.gc.ca

The AR Reporting Form and the AR Guidelines can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

For other inquiries related to this communication, please contact Health Canada at:
Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD)
E-mail: BGIVD_Enquiries@hc-sc.gc.ca
Tel: (613) 941-3207
Fax: (613) 941-1183

Sincerely,

Dr Bernard Prigent
Vice-President and Medical Director
Pfizer Canada Inc.