

Public Communication
Health Canada Endorsed Important Safety Information on fosamprenavir
(^{PR}TELZIR[®])



July 17, 2009

Subject: Potential association of myocardial infarction (heart attack) in patients treated with ^{PR}TELZIR[®] (fosamprenavir).

GlaxoSmithKline Inc. (GSK), in consultation with Health Canada, would like to inform you of important safety information regarding a potential association between myocardial infarction (heart attack) and exposure to fosamprenavir (^{PR}TELZIR[®]) in HIV-infected patients.

Fosamprenavir is a protease inhibitor (PI) used in combination with low-dose ritonavir and other antiretrovirals in the treatment of HIV-1 infection.

Recent data has suggested a potential association between fosamprenavir and myocardial infarction (heart attack) in HIV-infected adults¹.

Important Information for Patients

- Results from a study suggest that exposure to fosamprenavir may be associated with an increased risk of myocardial infarction (heart attack) in HIV-infected patients¹.
- Do not stop taking ^{PR}TELZIR[®] without first consulting your healthcare provider.
- You should talk to your doctor about how to help manage risk factors for heart disease (such as high blood pressure, diabetes and smoking)

Myocardial infarction (heart attack) has already been identified as being potentially associated with the PI class in an ongoing population study².

Healthcare professionals thoroughly consider the overall benefit versus the risk of a medication for each individual patient before prescribing. If patients have questions regarding their current prescription, they should contact their doctor.

It is recommended that patients taking ^{PR}TELZIR[®] consult with their healthcare provider before making any change to their medication, as HIV infection can lead to complications, if left untreated.

GlaxoSmithKline is working with Health Canada to update the prescribing information for ^{PR}TELZIR[®] and has, in consultation with Health Canada, sent a letter to relevant Canadian healthcare professionals informing them of this new safety information. You may view this letter on the Canadian website of GSK (www.gsk.ca) or on the Health Canada website (www.medeffect.com).

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 case of myocardial infarction (heart attack) or other serious or unexpected adverse reactions in patients receiving **TELZIR® Tablets and Oral Solution** should be reported to GlaxoSmithKline Inc. or Health Canada at the following addresses:

GlaxoSmithKline Inc.
7333 Mississauga Road
Mississauga, Ontario
L5N 6L4
Tel.: 1-800-387-7374
www.gsk.ca

Any suspected adverse reaction can also be reported to:

Canada Vigilance National Office
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

CanadaVigilance@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/ar-ei_form-eng.php

<http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/fs-if/2009-ar-ei-guide-patient/index-eng.php>

For other inquiries related to this communication, please contact Health Canada at:

Marketed Health Products Directorate

E-mail: MHPD_DPSC@hc-sc.gc.ca

Tel: (613) 954-6522

Fax: (613) 952-7738

For media inquiries, please contact GSK Corporate Communications, (905) 819-3363.

Sincerely,

original signed by

Dr. Tjark Reblin, MD, MBA
Vice President, Medical Division and Chief Medical Officer
GlaxoSmithKline Inc.

REFERENCES

1. Lang S, Mary-Krause M, Cotte L et al. Impact of Specific NRTI and PI Exposure on the Risk of Myocardial Infarction: A Case-Control Study Nested within FHDH ANRS CO4. 16th Conference on Retroviruses and Opportunistic Infections (CROI 2009) February 8 - 11, 2009, Montreal, Canada. Abstract #43LB. (Slides and audio from the oral presentation by D Costagliola in session “Oral Abstract: Pharmacogenetics, Pharmacoenhancement, and Complications of ART” on Monday, Feb 9, 2009 10:00 AM available from the CROI webpage at:
<http://app2.capitalreach.com/esp1204/servlet/tc?c=10164&cn=retro&e=10649&m=1&s=20415&&espmt=2&mp3file=10649&m4bfile=10649&br=80&audio=false>)
2. DAD Study Group. Class of antiretroviral drugs and the risk of myocardial infarction. N Engl J Med. 2007;356(17):1723-35.

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