

Public Communication

Health Canada Endorsed Important Safety Information on abacavir-containing medicinal products (PrZIAGEN[®] Tablets and Oral Solution; PrKIVEXA[®] Tablets; PrTRIZIVIR[®] Tablets)



June 23, 2008

Subject: Potential risk of cardiac events associated with ZIAGEN[®], KIVEXA[®] and TRIZIVIR[®]

GlaxoSmithKline, in consultation with Health Canada, would like to provide you with new safety information regarding a potential increased risk of myocardial infarction (heart attack) associated with abacavir-containing medicinal products (ZIAGEN[®], KIVEXA[®] and TRIZIVIR[®]).

Abacavir is an antiretroviral medication used in combination with other antiretrovirals in the treatment of human immune deficiency syndrome virus (HIV) infection.

A study recently published in *The Lancet*¹ has raised concern about a potential increased risk of myocardial infarction (heart attack) in HIV-infected patients receiving abacavir-containing medicinal products. Further investigation of this study is necessary to confirm the association between the use of abacavir and an increased risk of myocardial infarction.

Important Information for Patients

- Results from a study suggest that abacavir-containing products may be associated with a potential increased risk of myocardial infarction (heart attack) in HIV-infected patients.
- Do not stop taking ZIAGEN[®], KIVEXA[®] or TRIZIVIR[®] without first consulting your healthcare provider.
- You should talk to your doctor if you have had pre-existing serious cardiovascular disease.

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 are asked to contact their doctor.

At this time, Health Canada has undertaken the review of this safety data and will advise Canadians if further risk measures are deemed necessary.

In the interim, it is recommended that patients taking abacavir-containing medicinal products (ZIAGEN[®], KIVEXA[®] and TRIZIVIR[®]) consult with their healthcare professional before making any change to their medication, as HIV infection can lead to complications, if left untreated.

GlaxoSmithKline has 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.

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. As always, any serious or unexpected adverse reactions in patients receiving ZIAGEN[®], KIVEXA[®] and TRIZIVIR[®] should be reported to GlaxoSmithKline 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 Program
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/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

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

Marketed Health Products Directorate (MHPD)
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

¹D:A:D Study Group, Sabin CA, Worm SW, Weber R, *et al.* (2008) Use of nucleoside reverse transcriptase inhibitors and risk of myocardial infarction in HIV-infected patients enrolled in the D:A:D study: a multi-cohort collaboration. *Lancet*. Apr 26; **371(9622)**:1417-26.

Comment in:

Lancet. 2008 Apr 26; 371(9622):1391-2.

Lancet. 2008 Apr 26; 371(9622):1413.

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