

Public Communication
Health Canada Endorsed Important Safety Information on
^{Pr}AVANDIA[®], ^{Pr}AVANDAMET[®] and ^{Pr}AVANDARYL[™]



May 30, 2007

Subject: Cardiac Safety of ^{Pr}AVANDIA[®] (rosiglitazone maleate)

Mississauga, Ontario [May 30, 2007] – GlaxoSmithKline Inc (GSK), in conjunction with Health Canada, would like to address public concerns about the safety of Avandia[®].

An article recently published in the New England Journal of Medicine (NEJM) has raised concern about an increased risk of myocardial infarction (heart attack) and cardiovascular death in patients with type 2 diabetes treated with Avandia[®]. This article was based on a review of 42 clinical studies. The conclusions reached require confirmation. Further investigation of these results is underway and more information will be communicated when available.

Some of the studies in the NEJM article included patients using Avandia[®], in combination with other diabetic treatments. Some of these combinations are not approved for use in Canada.

In Canada, Avandia[®] is approved when diet, weight loss, and exercise are not enough to control diabetes. Avandia[®] may be used alone or in combination with other diabetes medications called metformin or a sulfonylurea.

Avandia[®] is not approved for use with insulin therapy or for use with the combination of metformin with a sulfonylurea.

Important Information for Patients

- o **Do not stop taking Avandia[®]** without first consulting your healthcare provider. Lack of control of blood sugar levels can cause serious medical problems.
- o Patients who are taking Avandia[®], especially those with underlying heart disease, mild to moderate heart failure or those who are at high risk of heart attack, should talk to their doctor.
- o Avandia[®] should not be used if you have heart problems. Avandia[®] can cause your body to keep extra fluid (fluid retention), which leads to swelling and weight gain. Extra body fluid can make some heart problems worse or lead to heart failure.

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 or pharmacist.

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. Please be reminded that any serious or unexpected adverse reactions in patients receiving Avandia® 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

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 Metabolism, Oncology and Reproductive Sciences (BMORS)

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

Tel: (613) 941-3171

Fax: (613) 941-1365

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

Sincerely,

Original signed by

Ravinder Kumar, Ph.D.
Vice President, Regulatory Affairs
GlaxoSmithKline Inc.

Avandamet® and Avandaryl™, contain the same active ingredient as Avandia®.

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