

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
Avandia® and Avandamet®

December 20, 2005

Subject: An association between Avandia® and Avandamet® and vision problems in diabetics

Mississauga, Ontario (December 20, 2005) — Avandia® (rosiglitazone maleate) tablets and Avandamet® (rosiglitazone maleate/metformin hydrochloride) tablets are medications authorized for use in Canada to control blood sugar levels in diabetic patients whose blood sugar levels have not been controlled by diet, exercise or other medications. GlaxoSmithKline Inc. (GSK), after discussions with Health Canada, wishes to provide Canadians with important new safety information regarding rare reports of a specific vision problem called macular edema occurring in diabetic patients who were taking Avandia or Avandamet.

Macular edema is a swelling of the retina due to fluid at the back of the eye and may be more likely to occur in people with diabetic retinopathy (a disease of the retina caused by diabetes), high blood pressure, and/or poor control of their blood sugar levels.

Advice to patients using Avandia or Avandamet:

- Your doctor may send you to an eye doctor for a consultation and may consider stopping your Avandia or Avandamet therapy. You should see your doctor if you have any of the following symptoms of visual impairment: blurred or distorted vision, decreased colour sensitivity, and/or decreased ability to adapt to darker surroundings.
- If you have already been diagnosed with macular edema or diabetic retinopathy, you should see your doctor to assess whether Avandia or Avandamet treatment should be continued.
- It is very important that you do not stop taking your medication without first consulting with your doctor as an increase in blood sugar levels can cause medical problems.
- As part of a comprehensive diabetes management plan, you should get regular eye checkups.

GSK has sent a letter to Canadian health-care 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 website of the Therapeutic Products Directorate of Health Canada (<http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2005/14308a-eng.php>). GSK is working with Health Canada to revise the Canadian prescribing information for Avandia and Avandamet. If patients have questions regarding their current prescription, they are asked to contact their doctor or pharmacist. Health Canada will review this new safety information for Avandia and Avandamet and will do so for other similar drugs used for the treatment of diabetes.

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 serious or unexpected adverse reactions in patients receiving Avandia or Avandamet should be reported to GlaxoSmithKline Inc. or Health Canada at the following addresses:

GlaxoSmithKline Inc.
7333 Mississauga Road North
Mississauga (Ontario) L5N 6L4
Telephone: 1 800 387-7374

Any suspected adverse reaction can 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:

Marketed Health Products Directorate (MHPD)

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

Tel: (613) 954-6522

Fax: (613) 952-7738

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For media inquiries, please contact Alison Steeves, (905) 819-3363.