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Dear Health Care Provider,

As part of the ongoing efforts of GlaxoSmithKline (GSK) to provide updated information to health care providers, we would like to inform you of important new safety information regarding products containing rosiglitazone (i.e., Avandia®, Avandamet®, and coming soon in some markets, Avandaryl™). These products are anti diabetic therapies used in treating type 2 diabetes mellitus. To date, cumulative worldwide exposure is in excess of 5.3 million patients for Avandia and 769,000 patients for Avandamet.

GlaxoSmithKline has received very rare post-marketing reports of new onset and worsening diabetic macular edema for patients receiving rosiglitazone (Avandia or Avandamet). In the majority of these cases, the patients also reported concurrent peripheral edema. In some cases, the macular edema resolved or improved following discontinuation of therapy and in one case, macular oedema resolved after dose reduction.

Macular edema typically occurs in association with diabetic retinopathy, although it is more likely to occur as retinopathy progresses. Risk factors for macular edema include duration of diabetes, presence of retinopathy, hypertension, and poor glycemic control. Symptoms suggestive of macular edema include blurred or distorted vision, decreased color sensitivity, and decreased dark adaptation.

GSK is sending this letter in order to highlight this important new safety information and the precaution proposed by the company to be included in all rosiglitazone (i.e., Avandia, Avandamet and coming soon in some markets, Avandaryl™) product information for prescribers and patient information leaflets.

GlaxoSmithKline is committed to providing Health Care Providers and patients with the most up-to-date and accurate information regarding our products. Should you have any questions or require additional information, please contact your local GSK information line.

Sincerely,

Alexander R. Cobitz, M.D., Ph.D.
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GlaxoSmithKline