



STATEMENT

Thursday 21 August 2008

RESPONSE TO CHANGES TO PRODUCT INFORMATION FOR AVANDIA AND AVANDAMET

Diabetes Australia is advising people who are taking rosiglitazone (Avandia) or rosiglitazone/metformin (Avandamet) to manage their diabetes to not stop using this medication but to make an appointment with their doctor to review their treatment as soon as possible.

In Australia, we have a robust system whereby medications are approved and constantly reviewed by the Therapeutic Goods Administration (TGA). The TGA carries out a range of assessment and monitoring activities to ensure that therapeutic goods available in Australia are of an acceptable standard. This assessment and monitoring in turn protects the health and wellbeing of the Australian public.

The TGA has advised GlaxoSmithKline to change the product information on Avandia and Avandamet.

Changes to Avandia/Avandamet product information are as follows:

Removal of the following Indications:

- Use of rosiglitazone in combination with insulin
- Use of rosiglitazone in combination with metformin and sulfonylureas as triple therapy (Please note that rosiglitazone remains indicated for monotherapy and dual therapy with metformin or sulfonylurea.)

Addition of the following Contraindications in patients with:

- NYHA (New York Heart Association) Class I and II heart failure. Avandia and Avandamet are now contraindicated in patients with NYHA Class I to IV heart failure.
- A history of cardiac failure
- Acute Coronary Syndrome (unstable angina, NSTEMI and STEMI)

Clarification of Precaution regarding Ischaemic Heart Disease:

- Rosiglitazone is not recommended for patients with known ischaemic heart disease, particularly those who are currently being treated with nitrates. Patients with no pre-existing coronary heart disease or with known coronary heart disease but not on nitrate therapy, had no increased risk of myocardial ischaemic events with rosiglitazone versus comparator.

Addition of Statement regarding Peripheral Arterial Disease:

- As there are limited clinical trial data in patients with peripheral arterial disease, a statement has been added that, as a precaution, the use of rosiglitazone is not recommended in these patients

Diabetes Australia advises that people with diabetes take this opportunity to discuss heart disease risks with their treating doctor.