

UPDATE TO PRODUCT INFORMATION FOR
AVANDIA® (ROSIGLITAZONE)
AVANDAMET® (ROSIGLITAZONE AND METFORMIN)

Dear Healthcare Professional,

The Therapeutic Goods Administration (TGA) and GlaxoSmithKline (GSK) have made changes to the Product Information for Avandia and Avandamet. The updated Product Information for Avandia and Avandamet is available at www.gsk.com.au.

Changes to Product Information

Key changes are summarised below:

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 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

In the light of these changes

- It is important that you review the treatment of all patients currently taking Avandia or Avandamet.
- Communications by GSK to the general public via our website will advise patients currently taking Avandia or Avandamet to continue taking their medication and make an appointment with their doctor as soon as possible to review their treatment.

- In your review, you may consider that some patients may appropriately continue taking Avandia or Avandamet. However, if an alternative therapy is required, it is recommended that Healthcare Professionals refer to the Australian Diabetes Society, Diabetes Australia, their local endocrinologist or diabetes guidelines such as “Diabetes Management in General Practice: Guidelines for Type 2 Diabetes”:
<http://www.diabetesaustralia.com.au/PageFiles/763/Diabetes%20Management%20in%20General%20Practice.pdf>

Changes to Reimbursement

The Pharmaceutical Benefits Scheme (PBS) listings for Avandia and Avandamet will be changing as follows:

Removal of the following Rosiglitazone subsidies from the PBS:

- As of **01 October 2008**: Rosiglitazone for the initiation or continuation of combination therapy with insulin (streamlined authority codes 2730 and 2731)
- As of **01 November 2008**: Rosiglitazone for the initiation of triple oral combination therapy with metformin and a sulfonylurea (streamlined authority codes Avandia 2648, Avandamet 2634)

Ongoing Rosiglitazone subsidy on the PBS until further advice is sought from the PBAC:

- Continuation of therapy for patients who have previously received and been stabilised on a PBS-subsidised regimen of oral combination therapy with metformin and a sulfonylurea

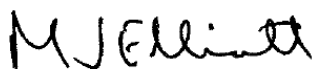
Unchanged Rosiglitazone subsidy on the PBS:

- Dual oral combination therapy with metformin or a sulfonylurea (streamlined authority codes Avandia 2635 and Avandamet 2633)

GSK is fully committed to the timely communication of safety information regarding its products to the healthcare community. You can assist GSK in monitoring the safety of our products by reporting adverse events to our Medical Information Department on 1800 033 109.

Should you have any questions or require additional information, please contact our Medical Information Department on 1800 033 109.

Sincerely,



Dr Michael Elliott
MBBS MRCP MBA
Vice President & Area Medical Director
Australasia & Asia Pacific
GlaxoSmithKline

Enclosures: Product Information for Avandia tablets
 Product Information for Avandamet tablets

® Avandia and Avandamet are registered trade marks of the GlaxoSmithKline Group of Companies.