

**Notice Information: - 3rd Party Publications  
05 June 2008**

**Part 1. Product Information**

- a) Title:
- b) Product Name/Type:
- c) Reference:

**Part 2. Problem/Issue**

a) Problem/Issue:

Avandia is a medicinal product authorised for use throughout the European Union through the European licensing process for the treatment of type II diabetes. Its active substance, rosiglitazone, is also available in combination with metformin as Avandamet, and in combination with glimepiride as Avaglim.

Rosiglitazone is contraindicated in patients with cardiac failure or a history of cardiac failure and this contraindication has been in place since it was first authorised in the EU in 2000. The product information for rosiglitazone also includes warnings on the risk of cardiac failure.

Since the time of first authorisation, rosiglitazone has been closely monitored, including its cardiovascular safety profile. In May 2007, the European Committee for Human Medicinal Products (CHMP) considered new information on the possible risk of ischaemic heart disease in patients taking rosiglitazone and information on possible risk of bone fractures in women and as such carried out a full re-assessment of the benefits and risks of rosiglitazone.

In October 2007, the European review concluded that the benefits of rosiglitazone continued to outweigh the risks but recommended that rosiglitazone should only be used in patients with ischaemic heart disease after careful evaluation of each patient's individual risk factors. In addition, the CHMP recommended that the product information should be updated as follows:

Inclusion of a new contraindication stating that rosiglitazone must not be used in patients with an acute coronary syndrome, such as angina or some types of myocardial infarction, because the medicine has not been studied in controlled trials in this patient group

Inclusion of a warning regarding the use of rosiglitazone in patients with peripheral artery disease.

The CHMP have recently confirmed their previous position that the benefits of rosiglitazone in the treatment of type II diabetes continue to outweigh the risks and they will continue to carefully monitor its safety.

In the meantime, the IMB would like to take this opportunity to remind h

In the meantime, the IMB would like to take this opportunity to remind healthcare professionals to closely adhere to the approved recommendations for use, warnings and precautions and contraindications when using rosiglitazone-containing products and to report all suspected adverse reactions associated with its use, particularly any cardiovascular adverse reactions, to the IMB in the usual way.

### **Part 3. Keywords**

a) Keywords:

Avandia rosiglitazone Risk of Cardiovascular Adverse Reactions