European Medicines Agency
Post authorisation Evaluation of Medicines for Human Use

London, 24 January 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
AVANDAMET

International Nonproprietary Name (INN): ***rosiglitazone / metformin***

On 24 January 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion** to recommend the variation to the terms of the marketing authorisation for the medicinal product Avandamet. The Marketing Authorisation Holder for this medicinal product is SmithKline Beecham Plc.

The CHMP adopted a new contraindication as follows:
"an Acute Coronary Syndrome (unstable angina, NSTEMI and STEMI) (see section 4.4)"

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full contraindications for Avandamet will be as follows***:

- hypersensitivity to rosiglitazone, metformin hydrochloride or to any of the excipients
- cardiac failure or history of cardiac failure (NYHA stages I to IV)
- **an Acute Coronary Syndrome (unstable angina, NSTEMI and STEMI) (see section 4.4)**
- acute or chronic disease which may cause tissue hypoxia such as:
    - cardiac or respiratory failure
    - recent myocardial infarction
    - shock
- hepatic impairment
- acute alcohol intoxication, alcoholism (see section 4.4)
- diabetic ketoacidosis or diabetic pre-coma
- renal failure or renal dysfunction e.g. serum creatinine levels > 135 µmol/l in males and > 110 µmol/l in females and/or creatinine clearance < 70 ml/min (see section 4.4)
- acute conditions with the potential to alter renal function such as:
    - dehydration
    - severe infection
    - shock
    - intravascular administration of iodinated contrast agents (see section 4.4)
    - lactation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

** Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

*** The text in bold represents the new or the amended contraindication.

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