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## Avandia (rosiglitazone maleate) - Australian Update

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Following a review of Avandia® (rosiglitazone maleate) by the European Medicines Agency (EMA) and the US Food and Drug Administration], each agency has today informed GlaxoSmithKline (GSK) of their individual regulatory decisions and resulting actions. These decisions only apply to countries in the EU the US respectively.

Based on the totality of the data available, GSK continues to believe that Avandia is an important treatment option for patients with type 2 diabetes.

GSK Australia spokespeople are available for comment from 10.00am today.

Patients should not suddenly stop taking Avandia. If concerned, patients should speak with their doctor about their treatment and any questions they may have regarding their medicine.

Avandia remains available in Australia and may be prescribed in accordance with the label to suitable patients with type 2 diabetes.

In Australia, the safety and effectiveness of Avandia is well characterised in the label ensuring that the appropriate patients are receiving the medicine.

“GSK Australia continually works with the TGA ensuring that all relevant information on Avandia is shared in a transparent and timely manner. It is our belief that the current restricted label in Australia helps doctors to use the medicine in appropriate diabetes patients,” Dr Camilla Chong, Medical Director said.

There are approximately 15,000 patients currently taking Avandia in Australia.

In the European Union\*, the EMA has suspended the marketing authorisation for all rosiglitazone-containing medicines (Avandia, Avandamet® and Avaglim®). As a result, physicians in Europe are being advised that affected patients need to be transitioned to alternative treatment options. The EMA has stated that the suspension will remain in place unless convincing data are provided that identify a group of patients in whom the benefits of the medicine outweigh its risks.

In the US, all rosiglitazone-containing medicines (Avandia, Avandamet and Avandaryl®) will remain available with additional safety labelling and restrictions for use. The FDA will also require a Risk Evaluation and Mitigation Strategy (REMS) programme with additional measures to ensure the safe use of the medicine.

**GlaxoSmithKline** – one of the world’s leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit [www.gsk.com.au](http://www.gsk.com.au) or [www.gsk.com](http://www.gsk.com)

### References

<sup>1</sup> Avandia Product Information

\* The 27 voting members of the EMA are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal,

Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom. In addition, Norway, Iceland and Liechtenstein who are non-voting members of the EMA are also affected.

### **High Resolution Audio and Video Links: (please click to download)**

<http://streamcast.com.au/glaxosmithkline/sep10/GSK-OpeningComments.mov>

<http://streamcast.com.au/glaxosmithkline/sep10/GSK-PatientMessage.mov>

<http://streamcast.com.au/glaxosmithkline/sep10/GSK-TGA.mov>

<http://streamcast.com.au/glaxosmithkline/sep10/GSK-CurrentLabel.mov>

### **Minimum Product Information**

Avandia is used to treat patients with type 2 diabetes mellitus and can be used alone (when diet and exercise is not enough to treat your diabetes) or together with other anti-diabetic medicines. Avandia is not recommended in patients with known ischaemic heart disease, particularly in those taking nitrates. Avandia must not be used if people have had an allergic reaction to Avandia or its ingredients, heart failure, history of cardiac failure, or Acute Coronary Syndrome (unstable angina, NSTEMI and STEMI). You must tell your doctor if:

- you are breastfeeding, pregnant or trying to become pregnant. Your doctor will decide if this medicine is suitable for you.
- you have heart failure or have had heart failure in the past.
- you have breathing difficulties.
- you have a history of swelling or pain of legs and feet.
- you have a problem with your liver. The medicine may remain in your body longer than usual.
- you have visual disorders.
- you are taking insulin.
- you are taking nitrates for existing heart disease because heart problems such as angina and heart attack have been reported.
- you are taking other anti-diabetic medications. The dose of these other medications may need to be decreased to reduce any risk of hypoglycaemia (low sugar levels in the blood).
- you have polycystic ovary syndrome. Due to the way your medicine works there may be an increased risk of pregnancy.
- you are allergic to foods, dyes, preservatives or any other medicines.
- you are taking any other medicines, including medicines you buy without a prescription.

Broken bones, usually in the hand, upper arm or foot, have been seen with rosiglitazone use in women. Talk to your doctor for advice on how to keep your bones healthy. Avandia only works in the presence of the body's own insulin therefore it should not be used in patients with type 1 (or insulin dependent) diabetes mellitus.

A copy of the Avandia Consumer Medicine Information and Product Information can be accessed at <http://www.gsk.com.au/avandia>

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PBS Information (Avandia): Authority required (STREAMLINED)

Refer to PBS Schedule for full Authority Required Information

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