

June 28, 2007

**Important Information  
about Avandia®**

Dear Healthcare Prescriber,

You have likely heard about the results from the recent meta-analysis in the *New England Journal of Medicine* that suggests a higher risk of heart attacks with Avandia®.<sup>1</sup> There is much controversy over the significance of this meta-analysis and the impact it should have on clinical practice.<sup>2-4</sup> While many limitations and shortcomings are pointed out with this analysis,<sup>2-4</sup> the report raises awareness about the need to consider the risks and benefits in selecting diabetes medications for patients.

Our desire is that you and your patient make the most informed decision possible in selection of diabetes medication. When prescribing diabetes medications, including Avandia, please consider the following:

- All diabetes medications carry risk of adverse effects.
- It's still unknown if the increased risk of heart attacks suggested with Avandia is a class effect and would apply to Actos®. Switching a patient who is well-controlled on Avandia to Actos has an unknown safety benefit.
- Both Avandia and Actos have proven benefit of improving glycemic control in type 2 diabetes, but at the expense of known side effects of edema and/or heart failure.

The American Diabetes Association states:

- Generic metformin as the first-line for treatment of type 2 diabetes.<sup>5</sup>
- “The overall level of (cardiovascular) risk associated with Avandia appears to be small, but nonetheless one that must be considered carefully.”<sup>5</sup>

The FDA has issued the following:

- a safety alert on the potential cardiovascular risk with Avandia and is currently analyzing all data available to determine the significance of the risk and if any regulatory action should be made.
- the intention to require a black-box warning on both Avandia and Actos regarding the risk of congestive heart failure.

For more information on Avandia and details related to this topic, please see the:

- FDA website at <http://www.fda.gov/cder/drug/infopage/rosiglitazone/default.htm>
- GlaxoSmithKline website at [www.gsk.com](http://www.gsk.com).
- Regence website at [www.regence.com/policy/medication/](http://www.regence.com/policy/medication/) for our medication policies for Avandia, Avandamet® and Avandaryl® that supports generic metformin first-line treatment for type 2 diabetes.

Sincerely,

Pharmacy Services

<sup>1</sup> Nissen SE, Wolski K. Effect of rosiglitazone on the risk of myocardial infarction and death from cardiovascular causes. *New Eng J Med* 2007;356:1-15.

<sup>2</sup> Psaty BM, Furberg CD. Rosiglitazone and cardiovascular risk (editorial). *New Eng J Med* 2007;356: 1-3.

<sup>3</sup> Rosiglitazone maleate (marketed as Avandia, Avandamet, and Avandaryl) Information. FDA Alert. May 21, 2007. <http://www.fda.gov/cder/drug/infopage/rosiglitazone/default.htm> (accessed May 29, 2007).

<sup>4</sup> Rosiglitazone: seeking a balanced perspective. *Lancet* May 23, 2007. DOI:10.1016/S0140-6736(07)60787-9.

<sup>5</sup> American Diabetes Association. Standards of Medical Care in Diabetes – 2007. *Diabetes Care* 2007 Jan;30 Suppl 1:S4-41. Available at: [http://care.diabetesjournals.org/content/vol30/suppl\\_1/](http://care.diabetesjournals.org/content/vol30/suppl_1/). (Accessed 1/12/2007).