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## Safety

### Avandia (rosiglitazone): REMS - Risk of Cardiovascular Events

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**AUDIENCE:** Endocrinology, Cardiology

**ISSUE:** FDA notified healthcare professionals and patients that it will significantly restrict the use of the diabetes drug Avandia (rosiglitazone) to patients with Type 2 diabetes who cannot control their diabetes on other medications. These new restrictions are in response to data that suggest an elevated risk of cardiovascular events, such as heart attack and stroke, in patients treated with Avandia.

**BACKGROUND:** Avandia is in a class of drugs known as thiazolidinediones, or TZDs. It is intended to be used in conjunction with diet and exercise to improve glucose (blood sugar) control in patients with Type 2 diabetes mellitus. Rosiglitazone also is available in combination with other diabetes medications, metformin under the brand name Avandamet or glimepiride under the brand name Avandaryl.

**RECOMMENDATION:** FDA will require that GSK develop a restricted access program for Avandia under a risk evaluation and mitigation strategy, or REMS. Under the REMS, Avandia will be available to new patients only if they are unable to achieve glucose control on other medications and are unable to take Actos (pioglitazone), the only other drug in this class. Current users of Avandia who are benefiting from the drug will be able to continue using the medication if they choose to do so.

Doctors will have to attest to and document their patients' eligibility; patients will have to review statements describing the cardiovascular safety concerns associated with this drug and acknowledge they understand the risks. The agency anticipates that the REMS will limit use of Avandia significantly.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)<sup>1</sup>
- [Download form](#)<sup>2</sup> or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[09/23/2010 - [News Release](#)<sup>3</sup> - FDA]

[09/23/2010 - [Q&As](#)<sup>4</sup> - FDA]

[09/23/2010 - [Avandia Related Information](#)<sup>5</sup> - FDA]

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1. <http://www.fda.gov/MedWatch/report.htm>
2. <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>
3. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm226975.htm>
4. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm26976.htm>
5. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm26956.htm>

