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Drugs

FDA Drug Safety Podcast: FDA significantly restricts access to the diabetes drug Avandia

Podcast ¹

On September 23, the Food and Drug Administration announced that it will significantly restrict the use of the diabetes drug Avandia to patients with Type 2 diabetes who cannot control their diabetes on other medications.

I am Yolanda Fultz-Morris from F-D-A's Center for Drug Evaluation and Research.

FDA is taking this action in response to data that suggest an elevated risk of cardiovascular events, such as heart attack and stroke, in patients treated with Avandia.

Avandia, manufactured by GlaxoSmithKline is intended to be used in conjunction with diet and exercise to improve blood sugar control in patients with Type 2 diabetes. FDA will require that GlaxoSmithKline develop a restricted access program for Avandia.

Current users of Avandia should continue taking the medication with consultation with their healthcare professional. You and your healthcare professional may decide to select an alternative medication. It is very important that patients with Type 2 diabetes continue to control their blood sugar.

If you have Type 2 diabetes and are considering taking Avandia for the first time, you should discuss the appropriate treatment with your healthcare professional. 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, the only other drug in this class.

Once in place, the restricted access program for Avandia will apply to current and new patients. Under the restricted access program, 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 program will limit use of Avandia significantly.

We urge healthcare providers and patients to report any side effects from Avandia by using the FDA's MedWatch Adverse Event Reporting program by phone at 1-800-F-D-A-ten-88 or by the Internet at W-W-W dot F-D-A dot GOV slash M-E-D-W-A-T-C-H.

Updated information about drugs with emerging safety concerns is available 24 hours a day at our Web site W-W-W dot F-D-A dot GOV slash D-R-U-G S.

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- [Rosiglitazone maleate \(marketed as Avandia, Avandamet, and Avandaryl\) Information](#)³
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