



Managing Your Healthcare

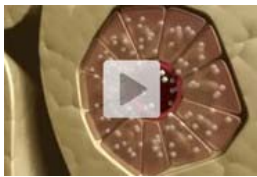
6 Things You Should Know About Avandia

Controversy over the drug is swirling again. What should you do if you're taking it?

By JANUARY W. PAYNE
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Diabetes medication Avandia



Video: What Is Diabetes?

To the chagrin of many diabetics, the medication Avandia is [back in the news](#) because of its possible link to heart problems. A Senate Finance Committee report released on Saturday says that the drug's manufacturer, GlaxoSmithKline, knew the type 2 diabetes drug had possible harmful cardiac effects several years before a 2007 *New England Journal of Medicine* study initially raised concerns about Avandia. GSK, for its part, says in a press release that it rejects the report's findings, adding that the committee's conclusions on the safety of Avandia are "based on analyses that are not consistent with the rigorous scientific evidence supporting the safety of the drug." GSK also released a 30-page rebuttal on Wednesday detailing its objections to the Senate Finance Committee's report.

The latest news has some people who take Avandia scratching their heads. "This has created a tremendous degree of uncertainty in our patients," says Robert Vigersky, president of the Endocrine Society and director of the Diabetes Institute at Walter Reed Army Medical Center. "We are recommending that nobody stop this drug precipitously on their own [and] that they speak with their [healthcare] provider." Below are some common questions about the medication, including more of what you should—and shouldn't—do if you're currently taking Avandia.

What are the concerns about heart safety and Avandia?

The Record trial, published in June 2009 in the *Lancet* and sponsored by GSK, found that Avandia seemed to increase the risk of heart failure in certain patients but didn't find any added risk of heart attack or death. That's in contrast to some, but not all, other studies. A 2007 meta-analysis, which was published in the *New England Journal of Medicine* and prompted the flurry of concern about Avandia, found that people taking the drug had a higher risk of heart attack and death from cardiovascular causes. And another study, published in November 2008 in the *Archives of Internal Medicine*, found that the risk of death and heart failure for older people with diabetes seemed to be greater in those taking Avandia than in those taking Actos, another medication in the same class.

But none of these studies have produced definitive conclusions. "We actually don't know a lot more now than we did in 2007," when the *NEJM* analysis was published, says Vigersky, who doesn't accept funding from pharmaceutical companies. But the Record study does suggest that the drug "may not be as risky as had been suggested in that [2007] study," he says, adding that it was the "only study designed as a prospective, randomized, controlled trial to ask the question, 'Is this drug safe in terms of cardiovascular effects?'" "The other studies, done retrospectively, observationally, or as a meta-analysis, "don't have the power to really make conclusions that are certain" because of how they were designed or how the data were analyzed, Vigersky says.

What should I do if I'm currently taking Avandia?

First and foremost, don't stop taking your medication without first talking to your healthcare provider. Ask your doctor any questions you have about continued use of the medicine (or, if you so desire, whether it's possible to switch to another drug), and read the medication guide that your pharmacy dispenses with your prescription to fully understand the benefits and risks of Avandia. Lastly, the Food and Drug Administration asks that you report any side effects you believe are associated with the drug to the agency's [MedWatch program](#).

Why can't I stop taking the medicine first before going to see my doctor?

There are some key reasons not to stop taking Avandia without talking to your doctor first. "What we know is that untreated or uncontrolled diabetes carries a substantial risk of complications," says David Kendall, chief scientific and medical officer at the American Diabetes Association. All medications have the potential for harmful side effects, he says, but the risks of uncontrolled diabetes mean you shouldn't chance changing your medication regimen without a doctor's OK. If left untreated, type 2 diabetes can lead to hyperglycemia (high blood sugar levels), causing frequent urination, increased thirst, and in extreme cases, diabetic coma.

Do I have other options if I want to stop taking Avandia?

Yes. Takeda Pharmaceuticals' Actos, a drug in the same class as Avandia, "works in what we think is a similar fashion," Kendall says. The labels for both Avandia and Actos contain warnings that the drugs may cause or exacerbate congestive heart failure, but there is no evidence so far that Actos causes heart attack, angina, stroke, or death, as is the concern about Avandia.

More definitive answers on the safety of Avandia and Actos may come from a large GSK-sponsored and FDA-mandated clinical trial called TIDE, for which the drugmaker is currently enrolling participants, but even that is not without controversy because of the possible heart risk for study subjects. "[We] really have to know what the risks are," says Vigersky.

When will the government know more about Avandia's safety?

The FDA says it is reviewing information on Avandia's safety and that no recommendations have been made so far. The agency plans to hold a public meeting in July when the review is finished, and at that time, it will detail the known information about Avandia's heart-related safety and update the public on the risks and benefits of the drug.

Do I need to get my heart checked out if I've been taking Avandia for some time?

Because diabetes itself carries a risk of cardiovascular problems, it's important to know where you stand on heart-related risk factors whether or not you take Avandia. In fact, for those with diabetes, the risk of a heart attack is the same as that for a person who has

already had a heart attack, according to MedlinePlus. Because of this, people with diabetes should know their blood pressure and cholesterol levels, Kendall says. [Learn how to [control your blood pressure with and without medication](#) and how to [lower LDL and raise HDL cholesterol](#).]

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