PATIENT SAFETY BLOG

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Diabetes drug Avandia will be gone from retail shelves by November

Diabetes medication Avandia will be pulled from pharmacy shelves in November because it poses a major risk of heart attack, the Food and Drug Administration has announced.

Under a new program effective Nov. 18, 2011, only certified physicians will be allowed to prescribe the drug, and then only to patients who've been informed of the risks and who will fill their prescriptions by mail order through specific pharmacies.

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The new FDA guidelines limit the drug to patients already successfully treated with it or to those for whom it's pretty much a last-ditch effort to control blood glucose medically. In addition, healthcare providers and patients have to enroll in the Avandia-Rosiglitazone Medicines Access Program to prescribe and receive rosiglitazone medicines.

The restrictions to access are so tough that virtually no one will be able to obtain the drug, says Dr. Steven Nissen, chief of cardiovascular medicine at the Cleveland Clinic, who has long advocated more restrictions on the use of rosiglitazone (Avandia's generic name).

Avandia is also sold as a component in the combination drugs Avandamet and Avandaryl. It was approved in 1999 to lower blood-sugar levels in patients with type 2 diabetes. In 2007, Nissen published an analysis showing that the drug increased heart attack risk by about 40% in people with type 2 diabetes, who are already much more prone to heart attacks than people without the disease.

Subsequent studies confirmed the greater heart attack risk. In June 2010, more than half of the members of an FDA advisory committee recommended pulling Avandia from the market or tightening restrictions on its use, and in September, the FDA decided to impose restrictions.

Source: TheHeart.org

You can read the FDA's decision here.

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