FDA Drug Safety Communication: Avandia (rosiglitazone) labels now contain updated information about cardiovascular risks and use in certain patients

Safety Announcement: [2-03-2011] The U.S. Food and Drug Administration (FDA) is notifying the public that information on the cardiovascular risks (including heart attack) of the diabetes drug rosiglitazone has been added to the physician labeling and patient Medication Guide. This information was first announced by FDA on September 23, 2010[1] as part of new restrictions for prescribing and use of this drug.

Rosiglitazone is sold as a single-ingredient product under the brand name Avandia. Rosiglitazone is also sold as a combination product under the brand name Avandamet (contains rosiglitazone and metformin) and under the brand name Avandaryl (contains rosiglitazone and glimepiride).

In addition to describing the cardiovascular risks, the drug labels have been revised to state that rosiglitazone and rosiglitazone-containing medicines should only be used:

- In patients already being treated with these medicines
- In patients whose blood sugar cannot be controlled with other anti-diabetic medicines and who, after consulting with their healthcare professional, do not wish to use pioglitazone-containing medicines (Actos, Actoplus Met, Actoplus Met XR, or Duetact).

At this time, FDA has only approved these safety-related changes to the physician labeling and Medication Guides for the rosiglitazone-containing medicines. The Risk Evaluation and Mitigation Strategy (REMS), which will restrict rosiglitazone-containing medicines' availability, has not yet been approved and formally implemented.

FDA will be providing further information on this REMS program in the coming months. FDA expects to approve the REMS by Spring 2011, and for the manufacturer to complete implementation 6 months thereafter.

Additional Information for Patients

- You may continue to take a rosiglitazone-containing medicine if directed by your healthcare professional, but it is important that you understand the risks and benefits of the drug.
- Talk to your healthcare professional if you have concerns about rosiglitazone-containing medicines.
- Read the Medication Guide you get along with your rosiglitazone-containing medicine. It explains the risks associated with the use of rosiglitazone.
- Report any side effects from the use of rosiglitazone-containing medicines to the FDA MedWatch program, using the information at the bottom of the page in the "Contact Us" box.

Additional Information for Healthcare Professionals

- The REMS for rosiglitazone-containing medicines does not take effect at the time of this announcement. You may continue to prescribe and dispense rosiglitazone-containing medicines as directed in the revised drug label.
- You should begin discussing the risks and benefits of taking rosiglitazone-containing medicines versus other therapies with your patients, and make decisions about optimal treatment for your individual patients.
- Encourage patients to read the rosiglitazone Medication Guide given to them when they pick-up their prescription at the pharmacy
- Report adverse events involving rosiglitazone-containing medicines to the FDA MedWatch program, using the information at the bottom of the page in the "Contact Us" box.

Data Summary

On September 23, 2010, FDA announced that it would significantly restrict the use of rosiglitazone-containing medicines to patients with Type 2 diabetes who cannot control their blood sugar on other medicines. These new restrictions were in response to data that suggested an elevated risk of heart attacks in patients treated with rosiglitazone.