



## **FDA Drug Safety Communication: FDA eliminates the Risk Evaluation and Mitigation Strategy (REMS) for rosiglitazone-containing diabetes medicines**

This is an update to the FDA Drug Safety Communication: FDA requires removal of some prescribing and dispensing restrictions for rosiglitazone-containing diabetes medicines issued on [November 25, 2013](#).

### **Safety Announcement**

**[12-16-2015]** The U.S. Food and Drug Administration (FDA) is eliminating the Risk Evaluation and Mitigation Strategy (REMS) for rosiglitazone-containing type 2 diabetes medicines, which are approved as Avandia, Avandamet, Avandaryl, and generics. The REMS is no longer necessary to ensure that the benefits of rosiglitazone medicines outweigh their risks.

[Type 2 diabetes](#) is a disease that can lead to serious complications such as kidney failure, blindness, and premature death. Rosiglitazone can be used along with diet and exercise to control blood sugar in adults with the disease.

In [2013](#), we required removal of the prescribing and dispensing restrictions for rosiglitazone medicines after determining that data did not demonstrate an increased risk of heart attack with rosiglitazone medicines compared to the standard type 2 diabetes medicines metformin and sulfonylurea. We also required the drug manufacturers to provide educational training to health care professionals about the current state of knowledge regarding the heart risks of rosiglitazone medicines. Manufacturers have since fulfilled these requirements.

We have continued monitoring these medicines and identified no new pertinent safety information. As a result, we have determined the REMS is no longer necessary to ensure that the benefits of rosiglitazone medicines outweigh their risks. We will update the public if any new information becomes available.