Rosiglitazone REMS Program

**Date:** To be inserted locally

### Rosiglitazone Risk Update and REMS Program Changes

- Change in current state of knowledge on cardiovascular risk of rosiglitazone – containing medicines; New training available
- Elimination of the prescriber, patient and pharmacy enrollment/certification requirements in Rosiglitazone REMS Program

---

**Dear Professional Society Leader:**

The FDA has required Rosiglitazone REMS sponsors to distribute this notice to your organization. The FDA has eliminated the restricted distribution requirements of the Rosiglitazone REMS Program based on new understanding of cardiovascular risk of rosiglitazone-containing medicines. We request that you inform your members about the following update and REMS Program changes.

### New cardiovascular risk information

Training on the current state of knowledge of the cardiovascular risk of rosiglitazone-containing medicines is available at [https://www.rosiglitazonerems.com](https://www.rosiglitazonerems.com). The training includes more details on the following:

- Data from long-term, prospective, randomized, controlled clinical trials of rosiglitazone versus metformin or sulfonylureas, particularly the cardiovascular outcome trial RECORD, observed no difference in overall mortality or in major adverse cardiovascular events (MACE) and its components.
- A meta-analysis of mostly short-term trials suggested an increased risk for myocardial infarction with rosiglitazone compared to placebo.

Within the rosiglitazone Prescribing Information, the WARNINGS AND PRECAUTIONS section has been revised. Please see enclosed Prescribing Information for rosiglitazone maleate.

### What are the key changes to the REMS Program?

**Indicated Population:**

Rosiglitazone-containing medicines are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

- Rosiglitazone is no longer limited to patients already on rosiglitazone-containing medicines who are benefiting from the medicine or to new patients who are unable to be controlled on other diabetes medications.

**Prescribers:**

- No longer need to be certified within the Rosiglitazone REMS Program

**Patients:**

- No longer need to be enrolled in the Rosiglitazone REMS Program in order to receive rosiglitazone-containing medicines
Pharmacies
- No longer need to be specially certified in order to dispense rosiglitazone-containing medicines

What do patients need to know about the changes in the Rosiglitazone REMS Program?

Patients previously or currently enrolled in the Rosiglitazone REMS Program should be informed of the following:
1. The elimination of enrollment requirements
2. Availability of rosiglitazone-containing medicines through local pharmacies

What happens to records collected for the Rosiglitazone REMS Program?

Enrolled prescribers and pharmacies should maintain patient and Rosiglitazone REMS Program records in accordance with state and local records retention requirements.

Rosiglitazone product information

Approved rosiglitazone-containing medicines:
- Avandamet® (rosiglitazone maleate/metformin hydrochloride)
- Avandaryl® (rosiglitazone maleate/glimepiride)
- Avandia® (rosiglitazone maleate)
- Generic rosiglitazone products

Within the rosiglitazone Prescribing Information, the WARNINGS AND PRECAUTIONS section has been revised to include additional data on the risks. Please review the Prescribing Information for rosiglitazone maleate.

Further information

Should you have additional questions about the Rosiglitazone REMS Program, contact the Coordinating Center at 1-800-282-6342

Sincerely,

Rosiglitazone REMS Sponsors