Rosiglitazone Risk Evaluation and Mitigation Strategy (REMS) Program

What is the Rosiglitazone REMS (Risk Evaluation and Mitigation Strategy)?

The Rosiglitazone REMS is a training program designed to inform prescribers of the current state of knowledge concerning the cardiovascular risk of rosiglitazone-containing medicines. This program is required by The Food and Drug Administration (FDA) to ensure the benefits of rosiglitazone containing medicines outweigh the risks.

Approved Rosiglitazone Products and Manufacturers

To review the training materials for healthcare providers, please click here.

- TRAINING MATERIALS: US Prescribers click here
- TRAINING MATERIALS: If you are not a US Prescriber click here
- Dear Healthcare Provider Letter
- Frequently Asked Questions
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Dear Healthcare Provider Letter

Frequently Asked Questions

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

This section is intended for U.S. residents only.

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Frequently Asked Questions

Do I have to be enrolled in the Rosiglitazone REMS in order to prescribe rosiglitazone-containing medicines?
No. Prescribers do not need to enroll in the Rosiglitazone REMS in order to prescribe rosiglitazone-containing medicines.

Do I need to enroll my patients in the Rosiglitazone REMS Program for them to receive rosiglitazone-containing medicines?
No. Patients do not need to be enrolled in the Rosiglitazone REMS Program to receive rosiglitazone containing medicines.

Do I have to review the training materials before I can prescribe rosiglitazone containing medicines?
Healthcare providers are encouraged to complete the Prescriber Training to be informed about the current state of knowledge concerning the cardiovascular risk of rosiglitazone-containing medicines.

Will my patients be able to receive rosiglitazone-containing medicines through their local pharmacies?
Rosiglitazone-containing medicines are no longer under restricted distribution and are available for order by local pharmacies.

Who do I contact if I have additional questions about the Rosiglitazone REMS Program?
Contact the Rosiglitazone REMS Coordinating Center at 1-800-282-6342 if you have additional questions about the Rosiglitazone REMS Program.
Rosiglitazone REMS Program

Please call the Rosiglitazone REMS Program Coordinating Center with questions about the Rosiglitazone REMS Program.

Phone: 1-800-282-6342

Hours of Operation:

Monday through Friday from 8:30 AM to 5:00 PM ET

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PDFs to be accessed through the Rosiglitazone REMS Program website:

1. Dear Healthcare Provider Letter
2. Prescriber Training Materials
3. Prescribing Information for approved rosiglitazone medicines:
   a. AVANDIA®
   b. AVANDAMET®
   c. AVANDARYL®
   d. ROSIGLITAZONE MALEATE
   e. ROSIGLITAZONE MALEATE AND METFORMIN HYDROCHLORIDE
4. Medication Guide for approved rosiglitazone medicines:
   a. AVANDIA®
   b. AVANDAMET®
   c. AVANDARYL®
   d. ROSIGLITAZONE MALEATE
   e. ROSIGLITAZONE MALEATE AND METFORMIN HYDROCHLORIDE
5. Contact Information for Manufacturers of approved rosiglitazone medicines
6. Important Safety Information
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JEAN-MARC P GUETTIER
05/07/2014