MedWatch The FDA Safety Information and Adverse Event Reporting Program

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

[Posted 12/16/2015]

FDA 排除了第二型糖尿病中，含 rosiglitazone 成分藥物，如商品名 Avandia, Avandamet, Avandaryl 的風險評估暨管控計畫(REMS)。已不需要再確認 rosiglitazone 的治療效益是否大於潛在風險。
在 2013 年，當資料顯示 rosiglitazone 相較於標準的第二型糖尿病用藥 metformin 和 sulfonylurea 不會增加心臟病風險後，FDA 要求刪除 rosiglitazone 開立處方的限制，FDA 也要求藥物製造商須提供 rosiglitazone 心臟風險的相關知識給醫護人員當作教育訓練。製造商已達成這些要求。
FDA 會持續監測這些藥物，確定沒有新的安全訊息，一旦有新的訊息，FDA 將會再更新。
建議
風險評估暨管控計畫(REMS)已不需要再確認 rosiglitazone 的治療效益是否大於潛在風險。

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

AUDIENCE: Family Practice, Endocrinology, Cardiology

ISSUE: 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.

In 2013, FDA 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. FDA 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.

FDA has continued monitoring these medicines and identified no new pertinent safety information. FDA will update the public if any new information becomes available.

BACKGROUND: 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.

RECOMMENDATION: The REMS is no longer necessary to ensure that the benefits of rosiglitazone medicines outweigh their risks.