

Avandia (rosiglitazone): FDA reviewing a large, long-term clinical study on possible risks for cardiovascular outcomes with use of rosiglitazone

Avandia (rosiglitazone): Ongoing Review of Cardiovascular Safety

Audience: Endocrinology, cardiology healthcare professionals, patients

FDA notified healthcare professional and patients that it is reviewing the primary data from a large, long-term clinical study, RECORD, on possible cardiovascular risks with the diabetes drug, Avandia (rosiglitazone). In addition to the clinical trial, a number of observational studies of the cardiovascular safety of rosiglitazone have been published and FDA has been reviewing these on an ongoing basis.

These reviews are ongoing and no new conclusions or recommendations about the use of rosiglitazone in the treatment of type 2 diabetes have been made at this time. Once FDA completes its review of the data from the RECORD study, the agency will present the totality of new and existing cardiovascular safety data on rosiglitazone at a public meeting in July 2010. The Agency will provide an updated assessment of the risks and benefits of rosiglitazone in the treatment of type 2 diabetes.

FDA recommends that healthcare professionals follow the recommendations in the drug label when prescribing rosiglitazone. This includes a Boxed Warning. Patients should continue taking rosiglitazone unless told by their healthcare professional to stop. Patients who are concerned about the possible risks associated with using rosiglitazone should talk to their healthcare professional.

Read the complete MedWatch 2010 Safety summary, including a link to the Drug Safety communication, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm201446.htm>

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