

Avandia Black Box Warning Revised

GlaxoSmithKline has revised the black box warning for Avandia (rosiglitazone maleate) tablets. The revised warning states that a meta-analysis of 52 clinical trials showed Avandia to be associated with a statistically significant increased risk of myocardial infarction. Three other trials that compared Avandia with other approved oral antidiabetic agents or placebo showed a statistically nonsignificant increased risk of myocardial infarction and a statistically nonsignificant decreased risk of death. No clinical trials exist directly comparing cardiovascular risk of Avandia and Actos (pioglitazone, another thiazolidinedione), but in a separate trial, Actos did not show an increased risk of myocardial infarction or death.