MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Rosiglitazone

[02/22/2010]

第二型糖尿病治療藥物thiazolidinedione（TZD）類藥物rosiglitazone maleate（商品名Avandia，梵帝雅膜衣錠或Avandamet，梵帝美錠）有增加充血性心衰竭之風險。美國食品藥物管理局（FDA）曾於96年7月30日與藥物安全專家及臨床醫師召開會議，共同討論該藥品之風險與臨床效益問題，其討論結果建議該藥品之臨床效益仍高於風險，應可繼續供病患治療用，惟需加註警語提醒Avandia有引發缺血性心臟病發作之風險。美國FDA評估藥品上市後安全性報告後，遂於8月15日發布新聞，提醒醫療專業人員以thiazolidinedione類藥物治療第二型糖尿病病人時，應監測病人心臟衰竭的徵兆或症狀，例如過度、快速的體重增加，呼吸困難，及水腫等，一但發現上述徵兆或症狀，應考慮停用或降低劑量。此外，美國FDA亦提醒有限行動力或臥床等狀況之嚴重心衰竭病患，應避免使用此類藥物。

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Audience: Endocrinology, cardiology healthcare professionals, patients

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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.