Generic Name:
Pioglitazone
Trade Name:
Actos, ActoPlus Met, Duetact
Company:
Takeda
Notes:

A safety communication has been released by FDA that use of pioglitazone for more than 1 year may be associated with an increased risk of bladder cancer. This information is based FDA's review of data from a planned 5-year interim analysis of an ongoing, 10-year epidemiological study of pioglitazone use. The 5-year results showed that although there was no overall increased risk of bladder cancer with pioglitazone use, an increased risk of bladder cancer was noted among patients with the longest exposure to pioglitazone and in those exposed to the highest cumulative dose of the drug. An epidemiological study conducted in France also suggested that use of pioglitazone was associated with an increased risk of bladder cancer, prompting that country to suspend the use of this agent. Information about this risk will be added to the Warnings and Precautions section of the label for pioglitazone-containing medicines, and the patient Medication Guide will be revised to include information on the risk of bladder cancer. FDA noted that it will continue to evaluate data from the ongoing 10-year epidemiological study and conduct a comprehensive review of the results from the French study; updated information will be released when it becomes available.

Medication Monitor Categories:
Alerts and Recalls