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AHFS Consumer Medication Information [Internet]. Bethesda (MD): American Society of Health-System Pharmacists; 2000-2011.

## Pioglitazone (pye oh gli' ta zone)

Last reviewed: October 1, 2010.

### Notice

[Posted 09/17/2010] **ISSUE:** FDA notified healthcare professionals and patients that the Agency is reviewing data from an ongoing, ten-year epidemiological study designed to evaluate whether pioglitazone (Actos) is associated with an increased risk of bladder cancer. Findings from studies in animals and humans suggest this is a potential safety risk that needs further study. At this time, FDA has not concluded that pioglitazone increases the risk of bladder cancer. Its review is ongoing, and the Agency will update the public when it has additional information.

**BACKGROUND:** The drug manufacturer, Takeda, conducted a planned analysis of the study data at the five-year mark, and submitted their results to FDA. Overall, there was no statistically significant association between pioglitazone exposure and bladder cancer risk. However, further analyses were also performed looking at how long patients were on pioglitazone and the total amount of the drug they received during that time. An increased risk of bladder cancer was observed among patients with the longest exposure to pioglitazone, as well as in those exposed to the highest cumulative dose of pioglitazone.

**RECOMMENDATIONS:** Healthcare professionals should continue to follow the recommendations in the drug label when prescribing pioglitazone. Patients should continue taking pioglitazone unless told otherwise by their healthcare professional. Patients who are concerned about the possible risks associated with using pioglitazone should talk to their healthcare professional.

Additional Information for Patients, Information for Healthcare Professionals, and a Data Summary are provided in the Drug Safety Communication. For more information visit the FDA website at: <http://www.fda.gov/Safety/MedWatch/SafetyInformation> and <http://www.fda.gov/Drugs/DrugSafety>.

### Warning

Pioglitazone and other similar medications for diabetes may cause or worsen congestive heart failure (condition in which the heart is unable to pump enough blood to the other parts of the body). Before you start to take pioglitazone, tell your doctor if you have or have ever had congestive heart failure, especially if your heart failure is so severe that you must limit your activity and are only comfortable when you are at rest or you must remain in a chair or bed. Also tell your doctor if you were born with a heart defect, and if you have or have ever had swelling of the arms, hands, feet, ankles, or lower legs; heart disease; high cholesterol or fats in the blood; high blood pressure; coronary artery disease (narrowing of the blood vessels that lead to the heart); a heart attack; or an irregular heartbeat. Your doctor may tell you not to take pioglitazone or may monitor you carefully during your treatment.

If you develop congestive heart failure, you may experience certain symptoms. Tell your doctor immediately if you have any of the following symptoms, especially when you first start taking pioglitazone or after your dose is increased: large weight gain in a short period of time; shortness of breath; swelling of the arms, hands, feet, ankles, or lower legs; swelling or pain in the stomach; waking up short of breath during the night; needing to sleep with extra pillows in order to breathe while lying down; frequent dry cough; or increased tiredness.

Talk to your doctor about the risks of taking pioglitazone.