



Quality Tip: Actos (pioglitazone) and Bladder Cancer

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The U.S. Food and Drug Administration (FDA) is informing the public that use of the diabetes medication Actos (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer. Information about this risk will be added to the *Warnings and Precautions* section of the label for pioglitazone-containing medicines. The patient Medication Guide for these medicines will also be revised to include information on the risk of bladder cancer.

This safety information is based on FDA's review of data from a planned five-year interim analysis of an ongoing, ten-year epidemiological study¹, described in FDA's September 2010 ongoing safety review¹ and in the Data Summary below. The five-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 pioglitazone.

FDA is also aware of a recent epidemiological study conducted in France² which suggests an increased risk of bladder cancer with pioglitazone. Based on the results of this study, France has suspended the use of pioglitazone and Germany has recommended not to start pioglitazone in new patients.

FDA recommends that healthcare professionals should:

- Not use pioglitazone in patients with active bladder cancer.
- Use pioglitazone with caution in patients with a prior history of bladder cancer. The benefits of blood sugar control with pioglitazone should be weighed against the unknown risks for cancer recurrence.

FDA will continue to evaluate data from the ongoing ten-year epidemiological study. The Agency will also conduct a comprehensive review of the results from the French study. FDA will update the public when more information becomes available.

You will be sent a patient list if you have a patient who is taking a pioglitazone product and has a history of bladder cancer.

Population management within Connected is powerful when we have current problem lists and medication lists. I encourage our healthcare teams to continue their diligence in keeping these current and accurate.

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<http://www.fda.gov/Drugs/DrugSafety/ucm259150.htm>

¹ Lewis JD, Ferrara A, PengHedderon M, Bilker WB, QuesenberryJr, et al. *Diabetes Care*. 2011; 34: 916-22.

² SDI, Vector One[®] : Total Patient Tracker (TPT). January 2010-October 2010. Data extracted 12-15-10.

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