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FDA Joins France and Germany With Actos Bladder Cancer Warning But Stops Short of Recall

Actos (pioglitazone) is a blockbuster diabetes medication produced by the Japanese drug company Takeda Pharmaceuticals. Actos belongs to the thiazolidinedione (TZD) drug class and works by decreasing insulin resistance in type 2 diabetic patients. In the last year, the medication had global sales of $4.8 billion and accounted for 27% of Takeda's revenue. In 2008, Actos was the tenth best selling medication in the United States. From January 2010 through October 2010, there were an estimated 2.3 million prescriptions filled by diabetic patients that had a pioglitazone containing product from pharmacies in the United States. In preclinical *in vivo* studies, bladder cancer was observed in male rats receiving clinical equivalent doses of pioglitazone. In addition, two clinical studies of Actos (the PROactive study and a liver safety study) showed a high percentage of bladder cancer cases in patients taking Actos. As a result, the Food and Drug Administration (FDA) has included these findings in the precautions section of the Actos drug label. To address the concerns regarding the possible association with bladder cancer, Takeda is conducting a ten-year observational cohort study and a nested case control study in diabetic patients from the Kaiser Permanente Northern California (KPNC) health plan. Preliminary data from this epidemiological study suggests a possible link between pioglitazone and bladder cancer, and the FDA ordered a safety review in September of 2010. Recently, on June 9, 2011 the French Agency for the Safety of Health Products pulled the product from their market because of safety concerns over the association with bladder cancer. This action was the result of a clinical study conducted by the French National Health Insurance Plan using 1.5 million diabetic patients treated with pioglitazone. It was show that there was a statistically significant increase in the risk for bladder cancer in patients using pioglitazone, and that risk increased with exposure longer than one year. Shortly thereafter, on June 10, 2011 the German Federal Institute for Drugs and Medical Devices advised physicians not to prescribe the medication to their diabetic patients based upon the French data. There have been no other countries that have withdrawn the medication from their markets. At a five-year interim analysis of the KPNC study, the FDA found that there was no significant increase in the risk for bladder cancer in patients taking pioglitazone. However, it was found that the risk for bladder cancer did increase with increasing dose and use longer than one year. Pioglitazone treatment for over 12 months carried a 40% increased risk of bladder cancer. Today, June 15, 2011 the FDA has released a drug safety communication to inform the public of these results. The FDA will include this information on the warnings and precautions section of the drug label. The FDA is recommending that physicians not prescribe pioglitazone to patients with active bladder cancer, and to use caution in patients with a prior history of bladder cancer. The drug was not pulled from the market in the United States. There will be continued analysis of the KPNC data as well as the data from the French study. There will be future updates as additional results are obtained.

Tags: Actos, bladder cancer, French Agency for the Safety of Health Products, German Federal Institute for Drugs and Medical Devices, Kaiser Permanente Northern California health plan, pioglitazone, Takeda Pharmaceuticals, the PROactive study, type 2 diabetes

This entry was posted on Wednesday, June 15th, 2011 at 6:00 pm and is filed under Uncategorized. You can follow any responses to this entry through the RSS 2.0 feed. You can leave a response, or trackback from your own site.

2 Comments

- *Hany S. Girgis* says:
  June 16, 2011 at 1:48 pm

  Pick your poison: diabetes or cancer. Type 2 diabetes is treatable by altering one's lifestyle, but Americans would prefer maintain an unhealthy lifestyle and take a drug that may cause cancer. The FDA understands this preference, otherwise they would have banned Actos in the United States. I presume bladder cancer is curable and is the lesser of the two poisons.

  Reply

- *Chris Bergstrom* says:
  June 17, 2011 at 8:42 am

  Obviously cancer is a terrible disease, but I think it's an oversimplification to say that type 2 diabetes is treatable by altering one's lifestyle. Some cases are, but some cases are not. My grandmother had type 2 diabetes when she got older and was extremely conscientious about her health and eating habits but still required medication. I also want to point out that this is not a story about the FDA coddling Americans too lazy to make lifestyle changes, since no other country besides Germany has withdrawn the drug either.

  In short, diabetes is a real disease, which sometimes requires medication. I don't know enough about diabetes to say whether there are other medications available which could be substituted for pioglitazone without the increased cancer risk (if someone knows this I'd be interested to hear their perspective), but if not it may be worth it to keep the medicine available for patients who are informed of the risks and who are without another option to manage their diabetes.

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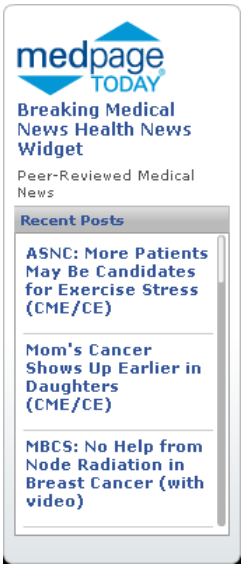
- 

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