Medical societies respond to the FDA's safety announcement on the use of Actos

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Diabetes leaders today are responding to the announcement made by the U.S. Food and Drug Administration (FDA) yesterday that the use of the diabetes medication Actos (pioglitazone) for more than one year may be associated with an increased risk of bladder cancer. According to the FDA's Safety Announcement, 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.

In response to this important safety announcement from the FDA, The Endocrine Society, the American Association of Clinical Endocrinologists and the American Diabetes Association urge patients who are currently taking Actos or any combination of medication that includes pioglitazone, to continue taking all currently prescribed medications unless instructed otherwise by their healthcare provider. Stopping diabetes medications can result in higher levels of blood glucose that may cause serious short term health problems and could increase the risk of diabetes-related complications in the long term.

The Endocrine Society, American Association of Clinical Endocrinologists and American Diabetes Association recommend that patients adhere to the following guidance provided by the FDA:

- There may be an increased chance of having bladder cancer when taking pioglitazone;
- Do not take pioglitazone if receiving treatment for bladder cancer;
- Talk to your doctor right away if you have any of the symptoms of bladder cancer including blood or red color in urine; urgent need to urinate or pain while urinating; pain in back or lower abdomen;
- Read the Medication Guide included with pioglitazone medicine as it explains risks associated with the use of the drug; and
- Talk to your healthcare professional if you have questions of concerns about pioglitazone medicines.

According to the FDA Safety Announcement, the five-year interim analysis of an ongoing ten-year study 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 who had been on pioglitazone the longest and had been on higher doses over time.

The Endocrine Society, the American Association of Clinical Endocrinologists and the American Diabetes Association continue to support the FDA in its role as the regulatory agency that makes decisions regarding drug safety and efficacy.

Provided by The Endocrine Society