



Re: pioglitazone web statement [SEC=UNCLASSIFIED]

to: Nick.Simpson

14/07/2011 02:50 PM

4 attachments



TGA advisory - pioglitazone and bladder cancer - final draft (NS 13.07.11)_EL Comments.docx



pic04472.jpg



pic07128.jpg



pic18434.gif

Dear Nick

Thank you for the opportunity to review the statement, we had a couple of suggestions which are shown in the attachment via track changes. The suggestions are primarily to align with the terminology in our dear doctor letter, please let me know if you would like to discuss any of our suggestions.

(See attached file: TGA advisory - pioglitazone and bladder cancer - final draft (NS 13.07.11)_EL Comments.docx)

Kind Regards

(Embedded image moved to file: pic04472.jpg)

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Nick.Simpson [REDACTED]

13/07/2011 01:13
PM

To
[REDACTED]
cc

Subject
pioglitazone web statement
[SEC=UNCLASSIFIED]

Dear [REDACTED]

Attached is a draft web statement regarding pioglitazone and bladder cancer risk.

Please let me know as soon as possible if you see any factual errors or have any other concerns.

kind regards

Nick

.....
Nick Simpson MBBS MPH PhD

Medical Officer | Signal Investigation | Office of Product Review |
Monitoring and Compliance Group
Therapeutic Goods Administration | Commonwealth Department of Health and
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[attachment "TGA advisory - pioglitazone and bladder cancer - final draft (NS 13.07.11).doc" deleted by XXXXXXXXXX]

Pioglitazone and risk of bladder cancer

TGA advisory

13 July 2011

The TGA is advising health professionals and consumers that use of the diabetes medicine, pioglitazone, for more than a year may be associated with an ~~increased~~ potential risk of bladder cancer.

This advice is partly based on the results of a study in the United States indicating a possible increase in bladder cancer risk among patients taking pioglitazone for more than two years, compared with diabetes patients who are not taking the medicine¹. The study found an increased ~~risk~~ incidence of bladder cancer in patients with the longest exposure to pioglitazone. The chance of developing bladder cancer in patients on pioglitazone for greater than 24 months was 1.4 times the chance in diabetic patients not on pioglitazone.

This advice is also based on a preliminary assessment of a recent study in France which suggests a similarly ~~increased~~ potential risk of bladder cancer with pioglitazone treatment for more than one year.

To put these results into context, one thing to consider is the 'normal' incidence of bladder cancer. Incidence of bladder cancer varies from group to group, depending on risk factors such as age, gender, cigarette smoking and occupational exposure to certain chemicals. The Australian Institute of Health and Welfare estimated there would be around 2500 new cases of bladder cancer in Australia for 2010, about three-quarters of these in males².

The TGA is working with the sponsors of pioglitazone medicines to update the Product Information (PI) and Consumer Medicine Information (CMI) to include the results of the United States study. The PI and CMI for the Actos brand of pioglitazone has been updated and ~~t~~ The sponsor of the Actos brand of pioglitazone has also written to health professionals advising them of the changes to the Product Information.

Pioglitazone is under review by a number of international regulators. Pending the outcome of their reviews, regulatory agencies in France, Germany and Mauritius have suspended the use of pioglitazone. Other regulators in Europe (EMA) and the US (FDA) ~~and~~ have issued safety statements.

Conclusion

The TGA is undertaking a comprehensive review of the data from the French trial and will provide further information to health professionals and consumers once this has been completed.

References

¹ Lewis JD et al (2011) Risk of bladder cancer among diabetic patients treated with pioglitazone: Interim report of a longitudinal cohort study. *Diabetes Care* 34:916-22.

² Australian Institute of Health and Welfare & Australasian Association of Cancer Registries 2010. Cancer in Australia: an overview, 2010. Cancer series no. 60. Cat. no. CAN 56. Canberra: AIHW.

Information for Health Professionals

- Do not use pioglitazone in patients with bladder cancer or a history of bladder cancer.
- Consider the risk of bladder cancer in the care of all patients treated with pioglitazone.
- Counsel patients about the possible risk of bladder cancer and ask them to report any signs or symptoms of blood in the urine, urinary urgency, pain on urination, or back or abdominal pain, as these may be due to bladder cancer.
- Report adverse events involving pioglitazone medicines to the TGA (for how to do this, see <http://www.tga.gov.au/safety/problem.htm#adr>)

Information for consumers

- There may be a small increased chance of having bladder cancer when you take pioglitazone.
- You should not take pioglitazone if you are receiving treatment for bladder cancer or have previously been treated for bladder cancer.
- Do not stop taking your pioglitazone medicine until you have talked with your doctor. This will enable your doctor to assess your diabetes and prescribe an alternative medicine if appropriate.
- Talk to your doctor if you have questions or concerns about pioglitazone medicines.
- Tell your doctor right away if you have any of the following symptoms of bladder cancer: blood or red colour in urine; urgent need to urinate or pain while urinating; pain in back or lower abdomen.
- Report side effects from the use of pioglitazone medicines to the TGA (for how to do this, see <http://www.tga.gov.au/safety/problem.htm#adr>)

Information about pioglitazone

Pioglitazone is a medicine used in the treatment of type 2 diabetes. It is used with other diabetes medicines, diet and exercise to improve the control of blood sugar. In Australia, there are several different brands, including Apotex, Acpio, Actos, Pioglitazone, Pizaccord and Vexazone.

The medicine is subsidised by the Pharmaceutical Benefits Scheme. There were over 474,000 prescriptions for pioglitazone in the 12 months to the end of May 2011.