



# Food and Drugs Authority

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Dear Healthcare Professional,

## **UPDATE ON SAFETY OF PIOGLITAZONE**

The Food and Drugs Authority (FDA) would like to update healthcare professionals on the outcome of the recent review of the benefit-risk profile of pioglitazone by the Technical Advisory Committee on Safety of Medicines (TAC-SM) taking into consideration the findings of the association of pioglitazone with small increased risk of bone fracture in women and bladder cancer.

Pioglitazone is an oral anti-diabetic drug registered by the FDA as an adjunct to decrease blood glucose levels not controlled by diet and exercise alone in patients with type 2 diabetes mellitus. Pioglitazone is also indicated in combination with a sulfonylurea or metformin when diet and exercise plus the single agent do not result in adequate glycemic control.

The FDA's Technical Advisory Committee on Safety of Medicines concluded that the benefit-risk profile of pioglitazone remains favourable but recommended the underlisted actions to guide healthcare professionals on the use of pioglitazone to minimize the risk of fracture in women and bladder cancer in patients who are prescribed this medication.

1. Pioglitazone should not be used as the first choice for the treatment of type 2 diabetes mellitus but used only in patients in whom other therapies (sulphonylureas and metformin) are contraindicated or ineffective.
2. The use of pioglitazone is contraindicated in patients with active, or history of, bladder cancer and in patients with uninvestigated macroscopic haematuria.
3. Risk factors for bladder cancer should be assessed before initiating pioglitazone treatment. Some of the risk factors include: current or past history of smoking, family history of bladder cancer, exposure to chemicals in the workplace or to certain cancer treatments such as cyclophosphamide and radiation therapy to the abdomen or pelvis.
4. Bladder cancer occurs more commonly in elderly patients and in men compared to women. Caution should be exercised when pioglitazone is prescribed for this group of patients.

5. Studies-to-date suggest that use of pioglitazone for more than a year may be associated with a small increased risk of bladder cancer. Doctors and other healthcare professionals are therefore advised to review the treatment of patients on pioglitazone after three to six months (and regularly thereafter) to ensure that only patients with a favourable benefit-risk profile continue treatment with pioglitazone.
6. All patients prescribed pioglitazone should be counselled to seek medical attention if they experience blood in the urine, urinary urgency, pain on urination, or back or abdominal pain, as these may be signs and symptoms of bladder cancer.

In Ghana, pioglitazone is registered by the FDA with the following brand names; Diavista, LG-Glizone, Nilgar, Pilgat and Piotex.

Although the Food and Drugs Authority has not received any report of bone fracture and bladder cancer from the spontaneous reporting system, healthcare professionals are encouraged to report adverse drug reactions to pioglitazone and any other medications to FDA by completing the Adverse Reaction Reporting Form or call **024 431 0297** or send an email to [\*\*drug.safety@fdaghana.gov.gh\*\*](mailto:drug.safety@fdaghana.gov.gh) or online at [\*\*http://adr.fdaghana.gov.gh/\*\*](http://adr.fdaghana.gov.gh/)

Yours sincerely,



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AG. CHIEF EXECUTIVE OFFICER

References

1. <https://www.fda.gov/Drugs/DrugSafety/ucm259150.htm>
2. <http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2012/15854a-eng.php>