



Pioglitazone-containing Medicines: Drug Safety Communication - Updated FDA Review, Increased Risk of Bladder Cancer

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FDA 根據更新的文獻研究，發布一則安全警訊，第二型降血糖藥物 Pioglitazone (Actos, Actoplus Met, Actoplus Met XR, Duetact, Oseni) 可能會增加罹患膀胱癌之風險。含 Pioglitazone 的藥品已於仿單上註明相關訊息，FDA 核准將新的文獻研究更新於仿單上。

建議

醫療人員對於癌細胞活躍的膀胱癌患者不應使用含 Pioglitazone 成分藥品；針對有膀胱癌病史的患者，則應同時考量 pioglitazone 控制血糖之益處與癌症復發的未知風險，以權衡利弊。病患在服用含 Pioglitazone 成分藥品後如果有血尿、急尿、小便疼痛等症狀時應該盡速與醫療人員聯繫。

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AUDIENCE: Internal Medicine, Endocrinology, Urology

ISSUE: As a result of an updated review, the FDA has concluded that use of the type 2 diabetes medicine pioglitazone (Actos, Actoplus Met, Actoplus Met XR, Duetact, Oseni) may be linked to an increased risk of bladder cancer. The labels of pioglitazone-containing medicines already contain warnings about this risk, and FDA has approved label updates to describe the additional studies reviewed. See the FDA Drug Safety Communication for more details, including a data summary.

BACKGROUND: FDA alerted the public about the possible risk of bladder cancer in September 2010 and June 2011 based on interim results from a 10-year epidemiologic study. FDA changed the labels of pioglitazone-containing medicines in August 2011 to include warnings about this risk, and required the manufacturer to modify and continue the 10-year study.

Pioglitazone is approved to improve blood sugar control, along with diet and exercise, in adults with type 2 diabetes. Pioglitazone works by increasing the body's sensitivity to insulin, a natural hormone that helps control blood sugar levels. Untreated, type 2 diabetes can lead to serious problems, including blindness, nerve and kidney damage, and heart disease.

RECOMMENDATION: Health care professionals should not use pioglitazone in patients with active bladder cancer, and should carefully consider the benefits and risks before using pioglitazone in patients with a history of bladder cancer.

Patients should contact their health care professionals if they experience any of the following signs or symptoms after starting pioglitazone, as these may be due to bladder cancer:

- Blood or a red color in the urine
- New or worsening urge to urinate
- Pain when urinating