



New advice on risk of bladder cancer with the anti-diabetic drug pioglitazone (Actos ▼, Competact ▼)

Pioglitazone (Actos ▼) is used to treat type 2 diabetes, either on its own or in combination with other anti-diabetic medicines. Pioglitazone is also available as a combination tablet with metformin (Competact ▼). A review of pioglitazone and a possible increased risk of bladder cancer conducted by the European Medicines Agency (EMA) concluded on 21 July 2011.

Risk of bladder cancer

The review found that there is a small increased risk of bladder cancer associated with pioglitazone use. It is not clear if the risk increases early in treatment or only after prolonged administration. However, with careful patient selection, the benefits of pioglitazone continue to outweigh the risks.

New recommendations

It is advised that pioglitazone should not be used in patients with a history of bladder cancer or in patients with uninvestigated visible blood in the urine. This applies to those being considered for pioglitazone treatment and those already receiving it.

Before starting pioglitazone treatment the following known risk factors for bladder cancer should be assessed in individual patients: age; current or past history of smoking; exposure to some occupational or chemotherapy agents such as cyclophosphamide; or previous radiation therapy to the pelvic region. Such risk factors should also be considered in those already receiving treatment as part of an overall evaluation of the safety and effectiveness of pioglitazone treatment in individual patients. Use in elderly patients should be considered carefully before and during treatment because the risk of bladder cancer increases with age.

Advice for healthcare professionals

Prescribers should review the safety and efficacy of pioglitazone in individuals after 3–6 months of treatment to ensure that only patients who are deriving benefit continue to be treated. Patients who are already receiving pioglitazone should also commence a similar programme of monitoring. Pioglitazone should be stopped in patients who do not respond adequately to treatment (eg, reduction in glycosylated haemoglobin, HbA1c).

A Direct Healthcare Professional Communication on the risk of bladder cancer with pioglitazone will be circulated shortly to healthcare professionals in the UK.

Advice for patients

Patients should not stop taking pioglitazone without consulting their doctor. Patients receiving pioglitazone should immediately report any visible blood in their urine or bladder problems such as pain while urinating or urgency to urinate, to their doctor. Patients receiving pioglitazone will have their treatments evaluated by their doctor at their next scheduled appointment.

Further information

[EMA press release](#) (external link).