

U.S. Food & Drug Administration

Drugs



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FDA Drug Safety Communication: Updated drug labels for pioglitazone-containing medicines

This update provides a follow-up to the [Drug Safety Communication: Update to ongoing safety review of Actos \(pioglitazone\) and increased risk of bladder cancer](#) issued on 6/15/2011.

[8-4-2011] The U.S. Food and Drug Administration (FDA) is informing the public that the Agency has approved updated drug labels for the pioglitazone-containing medicines to include safety information that the use of pioglitazone for more than one year may be associated with an increased risk of bladder cancer. FDA previously communicated these labeling changes to the public on [June 15, 2011 \(Drug Safety Communication\)](#).

The updated drug labels recommend that healthcare professionals should:

- Not use pioglitazone in patients with active bladder cancer.
- Use pioglitazone with caution in patients with a prior history of bladder cancer.

The updated drug labels recommend that patients should:

- Contact their healthcare professional if they experience any sign of blood in the urine or a red color in the urine or other symptoms such as new or worsening urinary urgency or pain on urination since starting pioglitazone, as these may be due to bladder cancer.

Healthcare professionals and patients can access the latest drug labels for pioglitazone-containing medicines at:

[Actos \(pioglitazone\)](#)

[Actoplus Met \(pioglitazone/metformin\)](#)

[Actoplus Met XR \(pioglitazone/metformin extended-release\)](#)

[Duetact \(pioglitazone/glimepiride\)](#)

Related Information

- [FDA Drug Safety Communication: Update to ongoing safety review of Actos \(pioglitazone\) and increased risk of bladder cancer 6/15/2011](#)
- [Pioglitazone HCl \(marketed as Actos, Actoplus Met, and Duetact\) Information](#)
- [Comunicado de la FDA sobre la seguridad de los medicamentos: Actualización de las etiquetas de los medicamentos que contienen pioglitazona](#)

Labeling and Regulatory History from Drugs@FDA

- [Pioglitazone HCL \(marketed as Actos\) Prescribing and Labeling Information](#)
- [Pioglitazone HCl and Metformin HCl \(marketed as Actos Met\) Prescribing and Labeling Information](#)
- [Pioglitazone HCl and Metformin HCl\(marketd as Actos Met XR\) Prescribing and Labeling Information](#)
- [Pioglitazone HCl and Glimepride\(marketd as Duetact\) Prescribing and Labeling Information](#)

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