



Pharmaceuticals and Medical Devices Agency

This English version is intended to be a reference material to provide convenience for users.

In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

PMDA Risk Communication

Updated information about pioglitazone and increased risk of bladder cancer

16 June 2011

Pharmaceuticals and Medical Devices Agency (PMDA)

If you are taking the following pioglitazone-containing medicines, you should NOT stop taking pioglitazone or reduce pioglitazone dosage only on your own judgment. Consult your healthcare professional if you have questions or concerns about these medications :

- ACTOS Tablets
- ACTOS OD Tablets
- METACT Combination Tablets
- SONIAS Combination Tablets

In response to the results of a recent epidemiological study which suggests an increased risk of bladder cancer with patients taking medicines containing pioglitazone as the active ingredient, on 9 June 2011, the French Medicines Agency (Afssaps) issued its decision to suspend the use of pioglitazone in new patients. At the same time, the agency urges patients who are taking pioglitazone not to stop the medication on their own judgments and to consult with their physicians if they have questions or concerns about pioglitazone medicines. Consequently, Germany has followed suit.

In addition, on 15 June 2011, the U.S. Food and Drug Administration (FDA) informed the public that use of pioglitazone for more than one year may be associated with an increased risk of bladder cancer. In this announcement, FDA has alerted healthcare professionals and patients regarding safety information on the risk of bladder cancer with pioglitazone use. ¹⁾

Please refer to the following announcements by Takeda Pharmaceuticals Company Limited who is the Marketing Authorization Holder (MAH) of the drugs.

For healthcare professionals :

- [French actions to pioglitazone-containing medicines \(Japanese text only\)](#)
- [FDA's Safety announcement regarding the risk of bladder cancer with pioglitazone use \(Japanese text only\)](#)

For Patients :

- [French actions regarding the active ingredient in ACTOS Tablets, METACT Combination Tablets, SONIAS Combination Tablets \(Japanese text only\)](#)
- [FDA's Safety announcement regarding the active ingredient in ACTOS Tablets, METACT Combination Tablets, SONIAS Combination Tablets \(Japanese text only\)](#)

The Ministry of Health, Labour and Welfare (MHLW) and PMDA have been aware of the potential risk of bladder cancer with pioglitazone use and evaluating all available data. MHLW/PMDA will conduct a comprehensive review on this matter, taking into consideration the results from the French study. At this time, PMDA does NOT recommend patients to immediately stop pioglitazone medication. PMDA will update the public as soon as further information becomes available.

European Medicines Agency (EMA) also announced that EMA will also conduct a review, and while this review is ongoing the EMA's Committee for Medicinal Products for Human Use (CHMP) is not recommending any changes to the use of pioglitazone-containing medicines. ²⁾

1) <http://www.fda.gov/Drugs/DrugSafety/ucm259150.htm>

2) http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2011/06/news_detail_001275.jsp&mid=WC0b01ac058004d5c1&murl=menus/news_and_events/news_and_events.jsp&jsenabled=true

Related information:

Safety Information Announced by MHLW:

“Safety Measures for diabetes medication ‘pioglitazone-containing products’ ”:dated 23 June 2011

[http://www.pmda.go.jp/english/service/pdf/mhlw/Safety measures for diabetes medication Pioglitazone-containing products 20110624_ag_.pdf](http://www.pmda.go.jp/english/service/pdf/mhlw/Safety%20measures%20for%20diabetes%20medication%20Pioglitazone-containing%20products%2020110624_ag_.pdf)

Original Japanese text of “Updated information about pioglitazone and increased risk of bladder cancer”:

<http://www.info.pmda.go.jp/riscommu/PDF/riscommu110803.pdf>