الشركة العربية لصناعة الأدوية المساهمة المحدودة
THE ARAB PHARMACEUTICAL MANUFACTURING CO. LTD.
RIYADH REGIONAL OFFICE

20–12–2011

Subject: Direct Health Care Professional Communication on PIOGLITAZONE and small increased risk of bladder Cancer.

Dear Health Care Professional,

APM would like to provide you with updated safety information with respect to Actos® (Pioglitazone) use. Vigilance and crisis management executive directorate at Saudi Food and Drug Authority (SFDA) along with the Pharmacovigilance advisory committee have reviewed the current safety data of Pioglitazone . Several studies showed that there is a small risk of bladder cancer associated with Pioglitazone use.

On July 30, 2011, the committees assessed the benefit-risk profile of Pioglitazone and advise that Pioglitazone remains favorable as treatment option for type 2 diabetic patients. However, the committee suggested some additional recommendations in order to help prescribers to outweigh the possible risks that might be induced by Pioglitazone administration. In addition, the SFDA has requested the Pioglitazone manufacturers to update the local package insert to reflect further contraindications, warnings and precautions linked to Pioglitazone use.

Prescribers are advised to adhere to the following points in order to minimize the possible increased risk of bladder cancer in patients treated with Pioglitazone:

1- The use of Pioglitazone is contraindicated in patients with current or a history of bladder cancer.
2- The use of Pioglitazone is contraindicated in patients with uninvestigated macroscopic haematuria. Any macroscopic haematuria should be investigated before starting Pioglitazone therapy.
3- The lowest possible dose should be used in elderly patients, as they are at a higher risk of bladder cancer.
4- Due to age-related risks (especially bladder cancer, fractures and heart failure), the balance of benefits and risks should be considered carefully both before and during treatment in the elderly.
5- Patients should be advised to promptly seek the attention of their physician if macroscopic haematuria or other symptoms such as dysuria or urinary urgency develop during treatment.
6- Prescribers should review treatment of patients on Pioglitazone within three to six months of therapy and thereafter regularly to ensure patients are deriving sufficient metabolic benefits.

APM would like to keep you assured that patients safety is a top priority. We are committed to continuously monitor the safety and tolerability of our products throughout ensuring effective and well-established Pharmacovigilance system and to keep close communication with SFDA as well as health care providers to update them with the most recent safety data about any potential risks associated with the use of Pioglitazone. Accordingly, please note that APM have revised the package insert of Actos® to include the recent safety updates on warnings and contraindications, as per SFDA request.

Call for reporting
APM will continue to monitor the safety of Actos® and notify Saudi Food and Drug Authority (SFDA) of any serious adverse events for evaluation.
You can assist us in monitoring the safety of Actos® by reporting adverse reactions to us at fax : +966-1-2151005 Or by E-mail to APM safety mail :Tariq@apmksa.com
Or to the Saudi Food and Drug Authority - National Pharmacovigilance and Drug Safety Center at fax : +966-1-2057662 or by E-mail to : NPC.Drug@sfda.gov.sa .

Yours Sincerely,

Medical Department
Health Care Manager
Dr. Yousef Herzallah

THE ARAB PHARMACEUTICAL
Manufacturing Co.