الجـــزيـرة للصناعـــــات الدوائيـــــة
Jazeera Pharmaceutical Industries

Subject: Direct healthcare professional communication on the association of Diclofenac, (**Diclomax®** and **Oflam®**) with cardiovascular risk

11.08.2016

Dear Health Care Professional,

At Jazeera pharmaceutical industries (JPI) we are committed to provide you with updates concerning the safety of our products. We are sending this letter to update you with new information regarding Diclomax® and Oflam® (active substance: diclofenac), to reflect important safety concerns of cardiovascular risk with the use of diclofenac.

Summary

Available data indicate that the cardiovascular risk with diclofenac is similar to that of the selective COX-2 inhibitors and that consistent with COX-2 inhibitors. Diclofenac is now contraindicated in those with: Ischaemic heart disease, peripheral arterial disease, cerebrovascular disease or established congestive heart failure.

Further Information

An increased risk of heart attack and stroke with some non-selective non-steroidal anti-inflammatory drugs (NSAIDs), such as diclofenac is well recognized, particularly with long term use of high doses and in patients who are already at high risk.

Dicolfenac is now contraindicated in patients with established:

- ischaemic heart disease
- peripheral arterial disease
- cerebrovascular disease
- congestive heart failure (New York Heart Association [NYHA] classification II-IV)

Healthcare Professionals are advised that patients with these conditions should be switched to an alternative treatment. The new treatment advice applies to systemic formulations (tablets, capsules, suppositories and injection available both on prescription and via a pharmacy); it does not apply to (gel or cream) formulations of diclofenac.

It is also advised that diclofenac treatment should only be initiated after careful consideration for patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus or smoking).

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P.O. Box 106229, Riyadh 11666, Saudi Arabia, Sales Tel.: 2830245/247 - 4788034 - Fax: (+9661) 4761097 - Factory Tel.: (+9661) 4980170/0162/0158 - Fax: (+9661) 4980187
Limited Liability Company, C.R. No. 1010124373 CHAMBER OF COMMERCE MEMBERSHIP 70256 شركة ذات مسئولية محدودة - س.ت: ١٠١٠١٢٤٣٧٣ عضوية الغرفة التجارية ٧٠٢٥٦

As the cardiovascular risks of diclofenac may increase with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically.

The information in this letter has been agreed with the Saudi Food and Drug Authority (SFDA).

Call for reporting of adverse reactions

Jazeera pharmaceutical industries (JPI) is committed to global surveillance of all its products, also committed to provide you with current product information. Therefore if you have any question or received any adverse drug reaction, you can contact or send it to the National pharmacovigilance and Drug safety Centre or to the pharmacovigilance department in the Jazeera pharmaceutical industries (JPI)

National Pharmacovigilance & Drug safety Centre (NPC):

Fax: +966-11-205-7662.
Toll free phone: 8002490000.
E-mail: npc.drug@sfda.gov.sa.
Website: www.sfda.gov.sa/npc.

Pharmacovigilance department in Jazeera pharmaceutical industries (JPI):

Tel. : +966 11 2078172 Ext.277
Fax: +966 11 2078097
Email: Jpimedical@hikma.com

Sincerely,

Lama Turki

Qualified Person for Pharmacovigilance
Jazeera Pharmaceutical Industries