



EGYPTIAN INTERNATIONAL PHARMACEUTICAL INDUSTRIES CO.
Research, Development and Quality sector
Registration department
Pharmacovigilance department



Date: 19/03/2014

Direct healthcare professional communication on the association of diclofenac, Epifenac[®] with cardiovascular risk

Dear Health Care Professional,

At EIPICO 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 Epifenac[®] ampoule (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.

Diclofenac 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 topical (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).

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.



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

Call for reporting of adverse reactions

EIPICO 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 our Scientific Office in Saudi Arabia.

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.

EIPICO Scientific Office (Saudi Arabia, Riyadh):

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Sincerely,

Dr. Magda Abd El-Gawad

Qualified person of Pharmacovigilance (QP/PA)

