NOVARTIS

٠٠١٧١٩
١٦-١١-٧٤٦
٠١ / ربيع الاول / ١٤٣٨هـ

30/11/2016

Our ref : اشارتنا :

Date : التاريخ :

# Direct Healthcare Professional Communication on the association of systemic diclofenac with cardiovascular risk– New contraindications and warnings

Dear Healthcare professional,

This letter is sent in agreement with the Saudi Food and Drug Authority (SFDA) to inform you of important restrictions to the use of systemic diclofenac-containing medicines (e.g. tablets or suppositories) registered in Saudi Arabia. These new restrictions do not apply to topical formulations (e.g. gel) of diclofenac.

Following the review of information on cardiovascular risk in the currently approved Prescribing Information and Patient Leaflets of systemic diclofenac-containing medicines registered in Saudi Arabia, as well as the decision taken by the European Commission in the context of the European-wide safety review completed in September 2013[1], the SFDA concluded that additional risk minimization measures in the product labelling (in Contraindications and Warnings and Precautions sections) similar to the labeling changes implemented in European Union countries were required. In addition, some proposals provided by marketing authorization holder were also taken into consideration.

**Recommendations to the healthcare professionals**

- The benefits of diclofenac outweigh the risks. However, currently available data indicate a small increased risk of arterial thrombotic events, especially when diclofenac is used for long-term treatment and high doses (150 mg daily), particularly in patients who are at increased risk of vascular disease[1].
- Diclofenac is now contraindicated in patients with established congestive heart failure (NYHA class II–IV), ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease. Patients with these conditions should have their treatment reviewed.
- Patients with congestive heart failure (NYHA class I) or significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated with diclofenac after careful consideration. In addition, these patients should only be treated at doses ≤100 mg daily when treatment continues for more than 4 weeks.
- Patients should remain alert for the signs and symptoms of serious arteriothrombotic events (e.g. chest pain, shortness of breath, weakness, slurring of speech), which can occur without warnings. Patients should be instructed to see a physician immediately in case of such an event.

NOVARTIS

Our ref : اشارتنا :

Date : التاريخ :

- 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 Prescribing Information and Patient Leaflets of systemic diclofenac-containing products will be updated accordingly.

**Call for reporting of adverse reactions**

Healthcare professionals should report any suspected adverse reactions associated with the use of diclofenac in accordance with the national spontaneous reporting system:

**Novartis Consulting AG.**
Phone: +966112658100
Mobile: 0508035430
Fax: +966112658107
Email: adverse.events@novartis.com

**Saudi Food and Drug Authority National Pharmacovigilance Center**
Toll free phone: 8002490000
Fax: +966112057662
E-mail: npc.drug@sfda.gov.sa
Or by online: https://ade.sfda.gov.sa

Yours sincerely,

Malak Alowais
QPPV, Novartis

**References**

1. European Commission decision on systemic diclofenac Article 31 Referral; September 25, 2013. http://ec.europa.eu/health/documents/community-register/html/ho25010.htm

NOVARTIS