



## SFDA SAFETY COMMUNICATION

18-10-2015

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### **Saudi Food And Drug Authority (SFDA) – Increased risk of heart attack or stroke associated with the use of non-steroidal anti-inflammatory drugs (NSAIDs)**

The Saudi Food and Drug Authority (SFDA) would like to remind health care professionals that the use of non-aspirin, non-steroidal anti-inflammatory drugs (NSAIDs), including selective cyclooxygenase-2 (COX-2) inhibitors (coxibs), might increase the risk of major cardiovascular diseases such as heart attack and stroke. The cardiovascular risk appears to increase with high doses and with longer use of NSAIDs

On 2012, the SFDA reviewed all available evidence on the association of registered COX-II inhibitors (etoricoxib, celecoxib) and diclofenac with cardiovascular disease and gastrointestinal bleeding. The SFDA advised that coxibs should be contraindicated in patients with coronary heart disease, cerebrovascular disease, peripheral arterial disease and congestive heart failure, and should be used with caution in patients with risk factors for cardiovascular disease, such as hypertension, diabetes mellitus, hyperlipidemia or smoking. In addition, the SFDA emphasized that etoricoxib is contraindicated in patients with uncontrolled high blood pressure. The SFDA also advised that coxibs and diclofenac should only be used when the benefits outweigh the risks and the lowest effective dose for the shortest period of time should be considered.

In 2013, the SFDA evaluated new evidences regarding cardiovascular risk associated with diclofenac use compared with many NSAIDs, including COX-2 inhibitors. Diclofenac has been found to be associated with cardiovascular risk comparable to COX-2 inhibitors, especially in high-risk patients, with long duration use and at high doses (150mg/day or higher). Therefore, a dear health care professional communication (DHPC) was requested to inform doctors about such risk.

The SFDA continues to monitor the safety of all registered NSAIDs. The SFDA advises health care professionals (HCPs) to consider the existing cardiovascular risk factors before prescribing or recommending any NSAID for the long-term use. In

addition, the SFDA advises that higher doses of some of NSAIDs such as ibuprofen (at or above 2,400 mg per day) and diclofenac (150mg/day or higher) should be avoided in patients with existing heart diseases. Patients should be advised to seek medical help if they experience symptoms of heart disease when using NSAIDs for a long period of time.

**Report Adverse Drug Events (ADRs) to the SFDA**

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)

Saudi Food and Drug Authority-Drug sector

3292 Northern Ring Road

Al Nafal District

Riyadh 13312 – 6288

Kingdom of Saudi Arabia

Toll free number: 8002490000

Tel: 01 2038222 ext. 2317, 2356, 2340, 5769

Fax: 01 2057662

Email: [NPC.Drug@sfd.gov.sa](mailto:NPC.Drug@sfd.gov.sa)