



SAFETY COMMUNICATION

24/04/2017

The Saudi Food and Drug Authority (SFDA): No strong evidence on association between proton-pump inhibitors and risk of cardiac adverse events

The Saudi Food and Drug Authority (SFDA) has concluded that there is no strong evidence to support association between the use of proton-pump inhibitors (PPIs) and risk of cardiovascular disease. PPIs are a class of medications widely used for the treatment of gastrointestinal ulcers and gastroesophageal reflux diseases (GERD).

The National Pharmacovigilance and Drug Safety center (NPC) has prepared a comprehensive review of the safety profile of PPIs and presented the findings to the Higher Pharmacovigilance Advisory Committee at the SFDA. The committee agreed that there is no sufficient evidence to support the association between PPIs and cardiovascular disease. The committee recommended that physicians should be aware about potential risk of interstitial nephritis which may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction.

Therefore, the SFDA concluded that based on available evidence the benefit from using PPIs to treat approved indications clearly outweighs potential risks. The following considerations should be taken into account when using PPI therapy:

- 1- PPIs should be only used for the approved indications.
- 2- PPIs should be used under physician supervision.
- 3- Patients on long-term treatment (particularly those treated for more than a year) should be kept under regular surveillance.

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

Call center : 19999

Tel: 01 2038222 ext. 2317, 2356, 2340

Fax: 01 2057662

Email: NPC.Drug@sfda.gov.sa