SFDA SAFETY COMMUNICATION

17-03-2016

Saudi Food and Drug Authority (SFDA) –Potential Risk of Severe Hyperkalemia Associated with the Concomitant Use of Spironolactone with Renin –Angiotensin System Drugs in Heart Failure

The Saudi Food and Drug Authority (SFDA) would like to remind health care professionals (HCPs) that the concomitant use of potassium sparing diuretic (spironolactone) with an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin receptor blocker (ARB) for heart failure might increase risk of severe hyperkalemia.

The risk of hyperkalemia appears to increase in patients with renal insufficiency and diabetes mellitus. Although the risk is well communicated through the products' Summary of Product Characteristics, the reporting rate of hyperkalemia with these products is still increasing globally leading to fatalities in some cases.

SFDA is emphasizing that the concomitant use of spironolactone with ACEI or ARB is not advisable. If spironolactone therapy is essential, the lowest effective dose of spironolactone should be considered with regular monitoring of potassium level and kidney function.

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@sfda.gov.sa