SFDA SAFTEY COMMUNICATION

Apr 9th, 2012

Saudi Food and Drug Authority (SFDA) PRESS RELEASE – Metoclopramide and the Risk of Tardive Dyskinesia

The Saudi Food and Drug Authority (SFDA) would like to provide healthcare professionals (HCPs) with an important safety information about the risk of Tardive Dyskinesia (TD) associated with the use of metoclopramide. The Advisory Committee for Pharmacovigilance at SFDA reviewed the available evidence and concluded that there is a possible risk of TD development among metoclopramide users. The risk of TD might be increased among elderly, women and diabetic patients. In addition, chronic utilization of metoclopramide (more than 12 weeks) at high doses would increase the risk of TD development.

Chronic treatment with metoclopramide, for longer than 12 weeks, should be avoided unless the therapeutic benefit outweigh the risk of developing TD. Furthermore, in case if any patient develops signs or symptoms of TD, the treatment with metoclopramide should be discontinued. Tardive Dyskinesia may completely or partially disappeared within several weeks to months after metoclopramide is withdrawn.

SFDA would like to notify HCPs that the manufacturers of metoclopramide will update the Patient Information Leaflets (PIL) as well as the Summary of Product Characteristics (SPC) to include warning statement involving the risk of TD.

Report Adverse Drug Events (ADEs) to SFDA

The SFDA urges healthcare professionals and patients to report ADEs resulted from using such a medication and other medications 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: 012038222 ext. 2317, 2353, 2356, 2340, 5769
Fax: 012057662
Email: NPC.Drug@sfda.gov.sa