June 30th , 2013

The Risk of Rhabdomylosis/Myopathy Associated with the Concomitant Use of Simvastatin and Gemfibrozil

The Saudi Food and Drug Authority (SFDA) has announced that the National Pharmacovigilance and Drug Safety Center (NPC) has completed an evaluation of the risk of rhabdomylosis/myopathy when simvastatin and gemfibrozil are used concomitantly (drug-drug interaction).

The safety review process involved evaluation of World Health Organization (WHO) adverse drug reaction database, assessment of simvastatin periodic safety update report (PSUR), analysis of the pharmacokinetic properties of both medications and actions taken by international regulatory authorities.

The NPC found an increased rate of adverse events reporting of rhabdomyolysis and myopathy in those using simvastatin and gemfibrozil concomitantly. Gemfibrozil is a potent inhibitor of CYP3A4 enzyme which is responsible for simvastatin metabolism.

The SFDA concluded that the risk of rhabdomylosis and/or myopathy increases with the concomitant use of simvastatin and gemfibrozil. Thus, the use of these medications concomitantly is now contraindicated and the NPC is working on the labeling update of both simvastatin and gemfibrozil's contraindication sections.

Report Adverse Drug Events (ADEs) to the Saudi FDA

The SFDA urges both healthcare professionals and patients to report ADEs resulted from using such a medication and other 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: 8002490000
Tel: 0112038222 ext. 2354, 2317,2340 , 2356
Fax: 0112057662
Email: NPC.Drug@sfda.gov.sa