

SFDA SAFETY COMMUNICATION

12 -11-2015

Saudi Food and Drug Authority (SFDA) – Enhanced Hypoglycemic Effect of Repaglinide Due to Drug-Drug Interaction with Clopidogrel

The Saudi Food and Drug Authority (SFDA) would like to inform healthcare professional about recent safety concern regarding significant decrease in blood glucose level that may be associated with the use of repaglinide and clopidogrel concomitantly due to drug-drug interaction.

Repaglinide is a short acting insulin secretagogue, approved for the treatment of type 2 diabetes mellitus (DM). Clopidogrel is an antiplatelet agent indicated for prevention of thrombotic events.

A recent study ¹ revealed an increased risk of hypoglycemia in subjects using repaglinide with clopidogrel. The hypoglycemic risk of repaglinide seems to increase with high doses of clopidogrel. Therefore, the label of both medications will be updated to address such risk.

The SFDA advises health care professionals to prescribe repaglinide with caution if combined with clopidogrel. Patients should be advised to check blood glucose level more often when they are using repaglinide and clopidogrel together and to seek medical help when they experience symptoms of hypoglycemia.

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