



SFDA SAFETY COMMUNICATION

23/07/2017

Risk of contrast-induced nephropathy associated with the use of metformin and contrast agents

The Saudi Food and Drug Authority (SFDA) would like to remind healthcare professionals (HCPs) about the increased risk of contrast-induced nephropathy and lactic acidosis associated with the use of metformin and contrast agents.

Metformin is a well-known oral antihyperglycemic agent indicated for the treatment of type 2 diabetes mellitus either as a monotherapy or in combination with other antihyperglycemic agents. In addition to the mild gastrointestinal side effects commonly associated with the use of metformin, there has been some reports of lactic acidosis secondary to metformin accumulation, particularly in patients with acute or chronic renal failure. For patients who are scheduled to undergo intravenous contrast-enhanced examination, the risk of renal function deterioration (contrast-induced nephropathy) is even higher. The marketing authorization holder updated the product labelling to reflect the risk and include the appropriate recommendations to ensure the safe use of metformin and minimize the possibility of metformin associated lactic acidosis (MALA).

Accordingly, the SFDA strongly recommends stopping metformin for 48 hours before intravenous contrast-enhanced examination for patients with an eGFR between 30 and 60 mL/minute/1.73 m²; in patients with a history of liver disease, alcoholism, or heart failure; or in patients who will be administered intra-arterial iodinated contrast. Renal function should be re-evaluated 48 hours after the imaging procedure; restart metformin if renal function is stable. It should be noted that metformin is contraindicated in patients with an eGFR below 30 mL/minute/1.73 m²

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

Telephone: 19999

Fax: 0112057662

Email: NPC.Drug@sfda.gov.sa