Saudi Food & Drug Authority (SFDA) Safety Communication

22/03/2020

Risk of potentially fatal respiratory depression with benzodiazepines and opioids:

The Saudi Food and Drug Authority (SFDA) would like to remind healthcare providers about the use of benzodiazepines (and benzodiazepine-like drugs) and opioid medicines (opioids) together, which can cause fatal respiratory depression.

We remind healthcare professionals to prescribe benzodiazepines (or benzodiazepine-like drugs) and opioids together if there is no alternative. Use the lowest doses possible for the shortest duration of time and closely monitor all patients for signs of respiratory depression. If co-prescribing methadone with a benzodiazepine or benzodiazepine-like drug, closely monitor for respiratory depression for at least 2 weeks following initiation or changes to prescribing because the respiratory depression effect of methadone may be delayed. If there is any change in prescribing such as new interactions or dose adjustments, re-introduce close monitoring of the patient.

Advise the Patients to inform their prescribers about any opioids or sedative medicines that they are taking and to read the leaflet for the medicines that they have been supplied. Advise patients of the symptoms of respiratory depression and sedation and the need to seek immediate medical attention if these occur.

The SFDA urges healthcare professionals to report ADEs via any of the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector

4904 Northern ring branch

Hitteen District
Riyadh 13513 - 7148

Kingdom of Saudi Arabia

Reporting hotline: 19999 Fax: +966112057662

Email: npc.drug@sfda.gov.sa

Webpage: http://ade.sfda.gov.sa