Saudi Food & Drug Authority (SFDA)
SAFETY COMMUNICATION

20/01/2020

Concern on Potential Risk of Respiratory Depression Associated with Gabapentinoids (pregabalin and gabapentin) medications

The Saudi Food and Drug Authority (SFDA) would like to warn healthcare providers about the serious, life-threatening, and fatal respiratory depression during treatment with gabapentinoids including gabapentin or pregabalin for seizures or nerve pain in patients with respiratory risk factors.

Risk factors include older age, chronic obstructive pulmonary disease, and use of opioid analgesics and other CNS depressants such as antidepressants, anxiolytics and antihistamines.

Healthcare professionals should start patients on the lowest dose of gabapentinoids and monitor them for symptoms of respiratory depression and sedation if an opioid or other CNS depressant is co-prescribed, and in elderly patients and those with underlying respiratory disease.

Patients and caregivers are advised to seek immediate medical attention for symptoms of potentially life-threatening respiratory problems such as slow or shallow breathing, confusion, dizziness, extreme sleepiness, unresponsiveness, or bluish skin colour.

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 re- 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