DOCTORS HEALTHCARE PLANS, INC.

FDA warns about serious breathing problems with seizure and nerve pain medicines gabapentin (Neurontin, Gralise, Horizant) and pregabalin (Lyrica, Lyrica CR)

When used with CNS depressants or in patients with lung problems

12-19-2019 FDA Drug Safety Communication

The U.S. Food and Drug Administration (FDA) is warning that serious breathing difficulties may occur in patients using gabapentin (Neurontin, Gralise, Horizant) or pregabalin (Lyrica, Lyrica CR) who have respiratory risk factors. These include the use of opioid pain medicines and other drugs that depress the central nervous system, and conditions such as chronic obstructive pulmonary disease (COPD) that reduce lung function. The elderly are also at higher risk.

Gabapentin and pregabalin are FDA-approved for a variety of conditions, including seizures, nerve pain, and restless legs syndrome.

Our evaluation shows that the use of these medicines, often referred to as gabapentinoids, has been growing for prescribed medical use, as well as misuse and abuse. Gabapentinoids are often being combined with CNS depressants, which increases the risk of respiratory depression. CNS depressants include opioids, anti-anxiety medicines, antidepressants, and antihistamines. There is less evidence supporting the risk of serious breathing difficulties in healthy individuals taking gabapentinoids alone. FDA will continue to monitor these medicines as part of its routine monitoring of all FDA-approved drugs.

Health care professionals should start gabapentinoids at the lowest dose and monitor patients for symptoms of respiratory depression and sedation when co-prescribing gabapentinoids with an opioid or other central nervous system (CNS) depressant such as a benzodiazepine. Patients with underlying respiratory disease and elderly patients are also at increased risk and should be managed similarly.

We recognize that incorporating one or more medications with non-drug therapies is the prevailing approach for optimizing analgesia. However, pairing an opioid with any CNS depressant – a gabapentinoid, benzodiazepine, sedating antidepressant, sedating antipsychotic, antihistamine, or other product – will increase the risk of respiratory depression. Shifting treatment from one CNS depressant to another may pose similar risks. Be aware of the potential additive effects of all these CNS depressants and plan accordingly, by starting with low doses, titrating carefully, and informing patients of the potential for CNS and respiratory depression and their symptoms. The gabapentinoid prescribing information already includes guidance for health care professionals to caution patients about dizziness, somnolence, and the potential for impaired ability to operate a car or complex machinery.

Reference:

https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-serious-breathing-problems-seizure-and-nerve-pain-medicines-gabapentin-neurontin