Gabapentin, Opioids a Deadly Duo: FDA

-- Robert Preidt

THURSDAY, Dec. 19, 2019 (HealthDay News) -- New warnings about the risk of dangerous breathing difficulties when gabapentinoids are used with opioids or by certain patients must now appear on product labels, the U.S. Food and Drug Administration announced Thursday.

Serious breathing problems that can lead to death can occur in patients who use gabapentinoids with prescription opioid painkillers or other drugs that depress the central nervous system. It can also happen to the elderly or to patients who have underlying respiratory conditions such as chronic obstructive pulmonary disease (COPD), according to the FDA.

The decision to order the new warnings is based on a review of data from numerous sources, including case reports, observational studies, human trials and animal studies.

Gabapentinoids include: generic gabapentin and brand-name gabapentin marketed as Neurontin and Gralise; gabapentin enacarbil, marketed as Horizant; and generic pregabalin and pregabalin marketed as Lyrica and Lyrica CR.

These drugs are approved to treat a number of conditions: epilepsy, postherpetic neuralgia (pain following shingles), neuropathic pain associated with diabetic neuropathy, fibromyalgia, generalized anxiety disorder and restless legs syndrome.

Some doctors also prescribe gabapentinoids for unapproved off-label use to treat insomnia, migraine, social phobia, panic disorder, mania, bipolar disorder and alcohol withdrawal.

"With the evolution of the opioid crisis, getting ahead of new concerns or addressing those that are already evident requires examining signs of misuse and abuse as soon as any signal emerges," said Dr. Douglas Throckmorton, deputy director for Regulatory Programs in the FDA's Center for Drug Evaluation and Research.

"Reports of gabapentinoid abuse alone, and with opioids, have emerged and there are serious consequences of this co-use, including respiratory depression and increased risk of opioid overdose death," he warned in an agency news release.

Along with the new warnings about potential breathing dangers, the FDA ordered drugmakers to conduct clinical trials to further evaluate the abuse risk of gabapentinoids, particularly in combination with opioids, with special emphasis on assessing the breathing dangers.

Between 2012 and 2016, the number of patients who filled a gabapentin prescription increased from 8.3 million to 13.1 million a year, and the number of patients who filled a pregabalin prescription increased from 1.9 million to 2.1 million a year, according to the FDA.

In addition, 2016 data show that 14% to 19% of patient encounters with doctors that involved gabapentin and pregabalin, respectively, also involved opioids.

More information

The U.S. National Library of Medicine has more on gabapentin.

SOURCE: U.S. Food and Drug Administration, news release, Dec. 19, 2019