Workers' Comp

Is there a new concern related to Gabapentin use and serious breathing problems?

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Sick man coughing into fist

In a drug safety communication from FDA Medwatch, the FDA warns about serious breathing difficulties related to the use of gabapentinoid (GabaP) medications in patients with other respiratory risk factors.[1] Elderly patients and others with existing respiratory ailments, such as COPD or asthma, and/or those that are co-prescribed GabaPs and central nervous system (CNS) depressants (e.g. opioids, benzodiazepines, muscle relaxants, or sedative-hypnotics) are cautioned regarding an increased risk for respiratory compromise and distress.[1] This new warning from the FDA is prompted by a number of case reports and the results of several clinical trials that indicate new awareness of serious breathing difficulties, especially when concomitant use of GabaPs and opioids or other CNS depressants is evident.

Medication info

Gabapentinoids, such as Lyrica®, Neurontin®, Gralise®, Horizant®, gabapentin, and pregabalin, are frequently prescribed in the workers' compensation setting, alone and in combination with other analgesics, for neuropathic and mixed pain conditions. There has recently been significant growth in prescription volumes, due in part to an unsatisfied need for safer, effective alternatives to opioid medications. GabaPs carry FDA-approved indications for the management of partial seizures, as well as for nerve pain from spinal cord injury, diabetic neuropathies, or post-herpetic neuralgia (shingles).[2] Fibromyalgia and restless leg syndrome are also approved uses. Common side effects of GabaPs include sleepiness, dizziness, fatigue, and tremor. More serious side effects include suicidality, angioedema, and shallow breathing.[2]

Upcoming changes

Per FDA requirements, new warnings will be added to the prescribing information for these medications. There will also be additional studies to further evaluate their additive risk for respiratory depression and abuse potential in combination with opioid medications.

What to look for

Although the euphoriant potential of GabaPs alone is thought to be minimal, they are reportedly misused on the "street premise" that they increase the effects of other substances of abuse. Misuse of GabaP in combination with other substances that inhibit respiration may carry similar risks for respiratory compromise and life-threatening emergencies. Injured workers and caregivers should be alert to symptoms of distress and seek immediate medical attention if symptoms are observed, as these can be very serious, even life-threatening. These may include:

- Confusion or disorientation
- Unusual dizziness or lightheadedness
- Extreme sleepiness or lethargy
- Slowed, shallow, or difficult breathing
- Unresponsiveness (subject doesn't respond or react normally, can't be awakened)
- Bluish-colored or tinted skin, especially on lips, fingers, and toes

Prescribers considering treatment with GabaPs should take note of existing respiratory conditions, co-prescribed CNS depressants, or other potential exposures and consider dose adjustments or treatment alternatives that mitigate this potential risk. GabaP treatment should begin at the lowest effective dose and be carefully monitored, especially for injured workers with existing respiratory risks. Tricyclic antidepressants, serotonin selective reuptake inhibitors (SSRI), serotonin norepinephrine reuptake inhibitor (SNRI) medications, duloxetine, nonsteroidal anti-inflammatory drugs (NSAIDs), and acetaminophen may all offer possibilities for added pain relief without added CNS-depressant properties. Please contact your First Script account manager or clinical pharmacist with any questions or concerns you may have regarding this new warning.

[1]FDA Drug Safety Communication – 12/19/2019 – https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-serious-breathing-problems-seizure-and-nerve-pain-medicines-gabapentinneurontin
[2]Lyrica Prescribing Information – https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021446s026,022488s005lbl.pdf



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