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Serious Breathing Difficulty Risk with Gabapentinoids

The Issue: The FDA issued a Drug Safety Communication (DSC) that highlights a new warning for gabapentinoid medications. Reports to the FDA through the MedWatch Adverse Drug Event reporting program and clinical trials show that gabapentinoids can cause serious breathing difficulties (e.g., respiratory depression) in patients who have respiratory risk factors. Respiratory risk factors include:

- Co-administration with an opioid
- Co-administration with other central nervous system depressants (e.g., benzodiazepines, antihistamines, anti-anxiety medications, and antidepressants)
- Underlying respiratory disease
- Elderly patients

Gabapentinoids: Gabapentinoids include the medications:

- Gabapentin (Neurontin®, Galise®, Horizant®)
- Pregabalin (Lyrica®, Lyrica CR®)

What should health care professionals do?

Initiate gabapentinoids at the lowest dose when prescribing with an opioid or CNS depressant, in patients with underlying respiratory impairment, or elderly patients.

Adjust the dose of both gabapentin and pregabalin in patients with renal impairment and patients undergoing hemodialysis, because both drugs are excreted by the kidneys.

Monitor for symptoms of respiratory depression and sedation, especially when prescribing with an opioid or CNS depressant, in patients with underlying respiratory impairment, or elderly patients.

The management of respiratory depression may include close observation, supportive measures, and reduction or withdrawal of CNS depressants, including the gabapentinoid.

Gabapentinoids used for analgesia or seizure control should be tapered prior to discontinuation. See the prescribing information for specific tapering guidance.

Encourage patients to read the Medication Guide they receive with each gabapentinoid prescription and to watch for symptoms of respiratory problems:

- Confusion or disorientation
- Unusual dizziness or lightheadedness
- Extreme sleepiness or lethargy
- Slowed, shallow, or difficult breathing
- Unresponsiveness
- Bluish-colored or tinted skin, especially on the lips, fingers, and toes

The full drug safety communication can be attached and can be found on the FDA website at:
<https://www.fda.gov/BLAHBLAHBLAH>