

## Opioids – Safety update

- On April 9, 2019, the [FDA announced](#) that they are requiring changes to the prescribing information for opioids due to reports of serious harm in patients who are physically dependent on opioids suddenly having these medicines discontinued or the dose rapidly decreased.
  - Reports include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.
  - The FDA's Deputy Center Director for Regulatory Programs released an additional [announcement](#) regarding the opioid safety update.
- [Opioids](#) are used to manage pain when other therapies cannot be taken or are not able to provide enough pain relief. They have serious risks, including abuse, addiction, overdose, and death. Examples of common opioids include codeine, fentanyl, hydrocodone, hydromorphone, morphine, oxycodone, and oxymorphone.
- The opioid label changes will provide expanded guidance to healthcare providers on how to safely decrease the dose in patients who are physically dependent on opioids when the dose is to be decreased or the medicine is to be discontinued.
  - Physical dependence is different than addiction. Physical dependence means that there are withdrawal symptoms if opioid treatment suddenly stops.
  - Addiction also involves behaviors, thoughts and feelings such as: a strong desire to take the drug; difficulties in controlling drug use; persisting in drug use despite harmful consequences; and a higher priority given to drug use than to other activities and obligations.
- Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. These symptoms can lead patients to seek other sources of opioids, which may be confused with drug-seeking for abuse. Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances.
- **Opioid taper schedule recommendations:**
  - The healthcare provider and patient should agree to an appropriate tapering schedule and follow-up plan so that patient and provider goals and expectations are clear and realistic.
  - The tapering schedule should consider a variety of factors, including dosage, duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient.
  - In general, the opioid dose may be tapered by an increment of no more than 10% to 25% every 2 to 4 weeks. Lower dosage strengths may be required.
  - No standard opioid tapering schedule exists that is suitable for all patients.
- **Opioid taper monitoring recommendations:**
  - Monitoring and support should be ensured to avoid serious withdrawal symptoms, worsening of the patient's pain, or psychological distress.
  - Common withdrawal symptoms include restlessness, lacrimation, rhinorrhea, and yawning. Other symptoms may also occur such as irritability, anxiety, insomnia, and backache. Refer to the FDA press release for a more complete list of symptoms.
  - Patients should be monitored for suicidal thoughts, use of other substances, or any changes in mood.

- If the patient is experiencing increased pain or serious withdrawal symptoms, the taper may be paused for a period of time, the opioid analgesic raised to the previous dose, and then once the patient is stable, proceed with a more gradual taper.
  - A multimodal approach that may include mental health support should be in place prior to initiating an opioid taper for patients who have been treated with opioids for a long duration and/or with high doses for chronic pain. This may optimize the treatment of chronic pain, as well as assist with the successful tapering of the opioid.
  - Patients who have been taking opioids for shorter time periods may tolerate a more rapid taper.
  - Proper evaluation and treatment for substance use disorder may be warranted.
- Patients taking opioid pain medicines long-term should not suddenly stop taking their opioid therapy without first discussing with their healthcare provider a plan for how to slowly decrease the dose of the opioid while continuing to manage pain. Patients should contact their healthcare provider if they experience increased pain, withdrawal symptoms, changes in mood, or thoughts of suicide.
  - The FDA continues to monitor this safety concern and will update the public if there is new information. Opioids drug labels will also be updated with information on other side effects including central sleep apnea and drug interactions. The FDA is also updating information on proper storage and disposal of opioids ([Disposal of Unused Medicines](#)).



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