



## **FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering**

### **Safety Announcement**

**[4-9-2019]** The U.S. Food and Drug Administration (FDA) has received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased. These include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.

While we continue to track this safety concern as part of our ongoing monitoring of risks associated with opioid pain medicines, we are requiring changes to the prescribing information for these medicines that are intended for use in the outpatient setting. These changes will provide expanded guidance to health care professionals on how to safely decrease the dose in patients who are physically dependent on opioid pain medicines when the dose is to be decreased or the medicine is to be discontinued.

Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, 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.

[Opioids](#) are a class of powerful prescription medicines that are used to manage pain when other treatments and medicines 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.

**Health care professionals** should not abruptly discontinue opioids in a patient who is physically dependent. When you and your patient have agreed to taper the dose of opioid analgesic, consider a variety of factors, including the dose of the drug, the duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient. No standard opioid tapering schedule exists that is suitable for all patients. Create a patient-specific plan to gradually taper the dose of the opioid and ensure ongoing monitoring and support, as needed, to avoid serious withdrawal symptoms, worsening of the patient's pain, or psychological distress (For tapering and additional recommendations, see Additional Information for Health Care Professionals).

**Patients** taking opioid pain medicines long-term should not suddenly stop taking your medicine without first discussing with your health care professional a plan for how to slowly decrease the dose of the opioid and continue to manage your pain. Even when the opioid dose is decreased gradually, you may experience symptoms of withdrawal (See Additional Information for Patients). Contact your health care professional if you experience increased pain, withdrawal symptoms, changes in your mood, or thoughts of suicide.

We are continuing to monitor this safety concern and will update the public if we have new information. Because we are constantly monitoring the safety of opioid pain medicines, we are also including new prescribing information on other side effects including central sleep apnea and drug interactions. We are also updating information on proper storage and disposal of these medicines that is currently available on our [Disposal of Unused Medicines](#) webpage.

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving opioids or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

### **Additional Information for Patients**

- If you are taking opioid pain medicines long-term, do not suddenly stop taking your medicine without first discussing with your health care professional a plan for gradually getting off the medicine. Stopping opioids abruptly or reducing the dose too quickly can result in serious problems, including withdrawal symptoms, uncontrolled pain, and thoughts of suicide.
- Even when the opioid dose is decreased gradually, you may experience symptoms of withdrawal such as:
  - Restlessness
  - Eye tearing
  - Runny nose
  - Yawning
  - Sweating
  - Chills
  - Muscle aches
- Other symptoms also may develop, including:
  - Irritability
  - Anxiety
  - Difficulty sleeping
  - Backache
  - Joint pain
  - Weakness
  - Abdominal cramp
  - Loss of appetite
  - Nausea
  - Vomiting
  - Diarrhea
  - Increased blood pressure or heart rate
  - Increased breathing rate
- Contact your health care professional if you experience increased pain, withdrawal symptoms, changes in your mood, or thoughts of suicide. Also contact them if you have any questions or concerns.

- To help FDA track safety issues with medicines, report side effects from opioids or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

### **Additional Information for Health Care Professionals**

- Do not abruptly discontinue opioid analgesics in patients physically dependent on opioids. Counsel patients not to discontinue their opioids without first discussing the need for a gradual tapering regimen.
- Abrupt or inappropriately rapid discontinuation of opioids in patients who are physically dependent has been associated with serious withdrawal symptoms, uncontrolled pain, and suicide. Abrupt or rapid discontinuation has also been associated with attempts to find other sources of opioid analgesics, which may be confused with drug-seeking for abuse. Patients may also attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances.
- It is important to ensure ongoing care of the patient and to agree on an appropriate tapering schedule and follow-up plan so that patient and provider goals and expectations are clear and realistic.
- When deciding how to discontinue or decrease therapy in an opioid-dependent patient, consider a variety of factors, including the dose of the opioid analgesic the patient has been taking, the duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient.
- There are no standard opioid tapering schedules that are suitable for all patients. A patient-specific plan should be used to taper the dose of the opioid gradually.
- In general, for patients who are physically dependent on opioids, taper by an increment of no more than 10 percent to 25 percent every 2 to 4 weeks. It may be necessary to provide the patient with lower dosage strengths to accomplish a successful taper.
- If the patient is experiencing increased pain or serious withdrawal symptoms, it may be necessary to pause the taper for a period of time, raise the opioid analgesic to the previous dose, and then once stable, proceed with a more gradual taper.
- When managing patients taking opioid analgesics, particularly those who have been treated for a long duration and/or with high doses for chronic pain, ensure that a multimodal approach to pain management, including mental health support (if needed), is in place prior to initiating an opioid analgesic taper. A multimodal approach to pain management may optimize the treatment of chronic pain, as well as assist with the successful tapering of the opioid analgesic.
- Patients who have been taking opioids for shorter time periods may tolerate a more rapid taper.
- Frequent follow-up with patients is important. Reassess the patient regularly to manage pain and withdrawal symptoms that emerge. Common withdrawal symptoms include:
 

- Restlessness	- Perspiration
- Lacrimation	- Chills
- Rhinorrhea	- Myalgia
- Yawning	- Mydriasis

- Other symptoms also may develop, including:
  - Irritability
  - Anxiety
  - Insomnia
  - Backache
  - Joint pain
  - Weakness
  - Abdominal cramps
  - Anorexia
  - Nausea
  - Vomiting
  - Diarrhea
  - Increased blood pressure or heart rate
  - Increased respiratory rate
- Patients should also be monitored for suicidal thoughts, use of other substances, or any changes in mood.
- When opioid analgesics are being discontinued due to a suspected substance use disorder, evaluate and treat the patient, or refer him/her for evaluation and treatment of the substance use disorder. Treatment should include evidence-based approaches such as medication assisted treatment of opioid use disorder. Complex patients with comorbid pain and substance use disorders may benefit from referral to a specialist.
- To help FDA track safety issues with medicines, report adverse events involving opioids or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

## **Related Information**

[Opioid Medications](#)

[Disposal of Unused Medicines: What You Should Know](#)

[Medication-Assisted Treatment \(MAT\)](#)

[The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective](#)

[Think It Through: Managing the Benefits and Risks of Medicines](#)