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

FDA Drug Safety Communication

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

Additional Information for Health Care Professionals

en Español

Drug Safety Communication (PDF - 69KB)

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

Contact FDA

For More Info

855-543-DRUG (3784) and press 4
druginfo@fda.hhs.gov

Report a Serious Problem to MedWatch
Complete and submit the report Online.
Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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