Generic Name:
Opioids
Trade Name:
Multiple trade names
Company:
Multiple manufacturers
Notes:

FDA announced that it has received reports of serious harm in patients who are physically dependent on opioid pain medications when these medications are discontinued or the dose is rapidly decreased. Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms, psychological distress, and suicide. Patients may seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse, or attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances.

Health professionals should not discontinue opioids abruptly in a patient who is physically dependent. When tapering, consider a variety of factors, including the dose, treatment duration, type of pain being treated, and a patient's physical and psychological attributes. No standard opioid tapering schedule exists that is suitable for all patients. Create a patient-specific plan to gradually taper the dose, and ensure ongoing monitoring and support, as needed, to avoid serious withdrawal symptoms, worsening of the patient?s pain, or psychological distress.

FDA is tracking this safety concern as part of its ongoing monitoring of risks associated with opioid pain medications. In addition, it is requiring changes to the prescribing information that will provide expanded guidance to health professionals on how to safely decrease the dose in patients who are physically dependent on opioids. The new labeling will include additional information on other adverse effects of opioids, such as central sleep apnea and drug interactions, and on proper storage and disposal of these medications.

The agency is urging patients and health professionals to report adverse effects involving opioids to the FDA MedWatch program.

Medication Monitor Categories:
Alerts and Recalls