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## Drug Safety Communication: New Safety Warnings Added to Prescription Opioids

Opioids are powerful prescription medications that can help manage pain when other treatments and medicines are not able to provide enough pain relief. However, opioids also carry serious risks, including misuse and abuse, addiction, overdose, and death.

On March 22, 2016, the United States Food and Drug Administration (FDA) announced several safety issues with the entire class of prescription opioid medications and are requiring changes to opioid labels to warn about the following:

- Opioids can interact with antidepressants and migraine medicines to cause serotonin syndrome, in which high levels of the chemical serotonin build up in the brain and cause toxicity.
  - Patients taking an opioid along with a serotonergic medicine should seek medical attention immediately if they develop symptoms such as agitation, hallucinations, rapid heart rate, fever, excessive sweating, shivering or shaking, muscle twitching or stiffness, trouble with coordination, and/or nausea, vomiting, or diarrhea.
  - Health care providers should discontinue opioid treatment and/or use of the other medicine if serotonin syndrome is suspected.
- Taking opioids may lead to a rare but serious condition called adrenal insufficiency in which the adrenal glands do not produce adequate amounts of the hormone cortisol.
  - Patients should seek medical attention if they experience symptoms of adrenal insufficiency such as nausea, vomiting, loss of appetite, fatigue, weakness, dizziness, or low blood pressure.
  - Health care providers should perform diagnostic testing if adrenal insufficiency is suspected. If diagnosed, treat with corticosteroids and wean the patient off of the opioid if appropriate. If the opioid can be discontinued, a follow-up assessment of adrenal function should be performed to determine if treatment with corticosteroids can be discontinued.
- Long-term use of opioids may be associated with decreased sex hormone levels and symptoms such as reduced interest in sex, impotence, or infertility.
  - Patients should inform their health care providers if they experience symptoms of low libido, impotence, erectile dysfunction, lack of menstruation, or infertility.
  - Health care providers should conduct laboratory evaluations in patients presenting with such signs or symptoms.

To read the full MedWatch safety alert, refer to the “FDA Drug Safety Communication: FDA warns about several safety issues with opioid pain medicines; requires label changes” article found on the [Drug Safety and Availability](#) Web page of the FDA website.