FDA NEWS RELEASE

FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death

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Español (/news-events/comunicados-de-prensa/la-fda-anuncia-advertencias-mejoradas-para-los-analgesicos-opiaceos-de-liberacion-inmediata)

In a continuing effort to educate prescribers and patients about the potential risks related to opioid use, the U.S. Food and Drug Administration today announced required class-wide safety labeling changes for immediate-release (IR) opioid pain medications. Among the changes, the FDA is requiring a new boxed warning about the serious risks of misuse, abuse, addiction, overdose and death. Today's actions are among a number of steps the agency recently outlined in a plan to reassess its approach to opioid medications. The plan is focused on policies aimed at reversing the epidemic, while still providing patients in pain access to effective relief.

The FDA is also requiring several additional safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. This is part of the agency's overall effort to help inform prescribers about the importance of balancing the serious risks of opioids with their role in managing pain.

"Opioid addiction and overdose have reached epidemic levels over the past decade, and the FDA remains steadfast in our commitment to do our part to help reverse the devastating impact of the misuse and abuse of prescription opioids," said Robert Califf, M.D., FDA commissioner. "Today's actions are one of the largest undertakings for informing prescribers of risks across opioid products, and one of many steps the FDA intends to take this year as part of our comprehensive action plan to reverse this epidemic."

Opioid analgesics are powerful pain-reducing medications that include prescription oxycodone, hydrocodone and morphine, among others. Prescription opioids are divided into two main categories – IR products, usually intended for use every four to six hours; and extended-release/long-acting (ER/LA) products, which are primarily intended to be taken once or twice a day, depending on the individual product and patient. Certain opioids, such as methadone and buprenorphine, are also used as a form of treatment for opioid addiction, and in combination with behavioral therapy and counseling, are known as medication-assisted treatment, or MAT.

The updated indication clarifies that because of these risks, IR opioids should be reserved for pain severe enough to require opioid treatment and for which alternative treatment options (e.g., non-opioid analgesics or opioid combination products, as appropriate) are inadequate or not tolerated. The dosing information also provides clearer instructions regarding patient monitoring and drug administration, including initial dosage, dosage changes during therapy and a warning not to abruptly stop treatment in a physically dependent patient.

As part of the boxed warning on IR opioid analgesics, the FDA now requires a precaution that chronic maternal use of opioids during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), which may be life-threatening if not recognized and treated using protocols developed by neonatology experts. NOWS may occur in a newborn exposed to opioid drugs for a prolonged period while in utero.

In 2013, the FDA required class-wide labeling changes for ER/LA opioid analgesics (/[!--$wcmUrl('link','UCM367726')--]) that included modifications to the products' indications, limitations of use, and warnings, including boxed warnings to more effectively communicate to prescribers the serious risks associated with these drugs. Today, the FDA is requiring similar changes to the labeling of IR opioid analgesics.

"We know that there is persistent abuse, addiction, overdose mortality and risk of NOWS associated with IR opioid products," said Douglas Throckmorton, M.D., deputy center director of regulatory programs, FDA's Center for Drug Evaluation and Research. "Today, we have taken an important next step in clarifying and making more prominent the known risks of IR opioid medications."

Additionally, the FDA is requiring updated labeling for all opioids (both ER/LA and IR products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. Updated labeling will also include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (called adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). These labeling changes will also make it clear that these negative outcomes can occur whether a patient is taking an opioid to treat pain or if the product is being used for MAT. Today, the FDA issued a Drug Safety Communication (/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-warns-about-several-safety-issues-opioid-pain-medicines-requires) outlining these risks.

"The broad set of actions announced today is reflective of the FDA's efforts to improve informed prescribing of opioids across the board," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "We have been and will continue to evaluate all new data to ensure that labels of opioid drugs contain appropriate prescribing information about the benefits and risks of prescription opioids."

The FDA is also aware of, and carefully reviewing, available scientific information about potentially serious outcomes related to interactions between benzodiazepines and opioids. Once a review of all available scientific information is completed, the FDA will take necessary actions to ensure prescribers and the public are informed of the risks involved with the use of these medications.

These actions are the latest examples of the agency's commitment to combat this public health crisis and its profound impact on individuals, families and communities across our country. Health and Human Services Secretary Sylvia M. Burwell has made addressing opioid misuse, addiction and overdose a priority. Other work on this important issue is underway within HHS. The evidence-based HHS-wide opioid initiative (http://www.hhs.gov/news/press/2015pres/03/20150326a.html) focuses on three priority areas: informing opioid prescribing practices, increasing the use of naloxone (a rescue medication that can prevent death from overdose) and expanding access to and the use of MAT to treat opioid use disorder.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

New safety warnings also added to all prescription opioid medications to inform prescribers and patients of additional risks related to opioid use

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- FDA: Opioid Medications (/drugs/information-drug-class/opioid-medications)
- FDA: Fact Sheet â“ FDA Opioids Action Plan (/drugs/information-drug-class/fda-opioids-action-plan)
- FDA: Approved Drugs: Questions and Answers (/drugs/information-consumers-drugs/approved-drugs-questions-and-answers)
- CDC: Prescription Painkiller Overdoses in the US (http://www.cdc.gov/vitalsigns/PainkillerOverdoses/index.html)

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