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Important Drug Safety Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC23-025-CG
April 14, 2023

FDA announced that, The FDA is requiring several updates to the prescribing information for both immediate-release (IR) and extended release/long acting (ER/LA) opioid pain medicines. This includes stating for all opioid pain that the risk of overdose increases as the dose increases.

Opioid pain medicines are a class of powerful pain medicines prescribed to treat pain that does not respond well to other treatments or non-opioid pain medicines. They activate an area of nerve cells in the brain and body that block pain signals. These medicines have benefits when used appropriately, but they also have serious risks, including misuse and abuse, addiction, overdose, and death. Examples of common opioid pain medicines include codeine, hydrocodone, hydromorphone, morphine, oxycodone, oxymorphone, fentanyl, buprenorphine, and tramadol.

RECOMMENDATIONS

1. **Patients/Parents/Caregivers**

- Always take your opioid medicines exactly as prescribed. Do not take more of the medicine or take it more often than prescribed without first talking to your health care professional. Talk with them if your pain increases, you feel more sensitive to pain, or if you have new pain, especially from touch or other things that are not usually painful such as combing your hair.

- Store your opioid pain medicines securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

- Seek emergency medical help or call 911 immediately if you or someone you are caring for experiences symptoms of respiratory problems, which can be life-threatening. Signs and symptoms include serious slowed, shallow, or difficult breathing, severe sleepiness, or not being able to respond or wake up.

- Talk to your health care professionals about the benefits of naloxone, which can reverse an opioid overdose, and how to obtain it. In March 2023, FDA approved an inhaled nasal spray version of naloxone to be sold over-the-counter without a prescription while multiple forms of naloxone remain available as prescription only.

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2. **Health Care Professionals**

- In assessing the severity of pain, discuss with the patient the impact of the pain on their ability to function and their quality of life. Assessment of pain should consider both the cause of pain and individual patient factors.

- If the patient's pain is severe enough to require an opioid pain medicine and alternative treatment options are insufficient, prescribe the lowest effective dose of an IR opioid for the shortest duration of time to reduce the risks associated with these products.

- Reserve ER/LA opioid pain medicines only for severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine and for which alternative treatment options are inadequate.

- For all patients prescribed opioid pain medicines, discuss the availability of naloxone, and consider prescribing it to those at increased risk of overdose.

- Be aware that the symptoms of OIH, a condition where opioids cause an increase in pain (called hyperalgesia) or an increased sensitivity to pain (called allodynia), are distinct from opioid tolerance and withdrawal and can be difficult to recognize.

- If a patient is suspected to be experiencing OIH, carefully consider an appropriate decrease in dose of the current opioid pain medicine or safely switching them to a different opioid product, if tolerated. Advise patients about the risk of OIH and tell them to never increase the opioid dosage without first consulting a health care professional, because this could worsen the pain and increase the risk of respiratory depression.

3. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

4. Expect patients to visit your pharmacy asking for information on this safety issue and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

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All Opioid Pain Medicines: Drug Safety Communication - FDA Updates Prescribing Information to Provide Additional Guidance for Safe Use

[Posted 04/13/2023]

AUDIENCE: Patient, Health Professional, Pain Management, Pharmacy, Caregivers

ISSUE: The FDA is requiring several updates to the prescribing information for both immediate-release (IR) and extended release/long acting (ER/LA) opioid pain medicines. This includes stating for all opioid pain medicines that the risk of overdose increases as the dose increases.

- The updates to IR opioids state these products should not be used for an extended period unless the pain remains severe enough to require them and alternative treatments continue to be inadequate, and that many acute pain conditions treated in the outpatient setting require no more than a few days of an opioid pain medicine. This may include pain occurring with a number of surgical conditions or musculoskeletal injuries.

- The FDA is also updating the approved use for ER/LA opioid pain medicines to recommend they be reserved for severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine and for which alternative treatment options are inadequate.

- The FDA is also adding a new warning about opioid-induced hyperalgesia (OIH) for both IR and ER/LA opioid pain medicines. This includes information describing the symptoms that differentiate OIH from opioid tolerance and withdrawal.

- Information in the Boxed Warning, FDA's most prominent warning, for all IR and ER/LA opioid pain medicines will be updated and reordered to elevate the importance of warnings concerning life-threatening respiratory depression, and risks associated with using opioid pain medicines in conjunction with benzodiazepines or other medicines that depress the central nervous system (CNS).

- Other changes are also being required to several sections of the prescribing information, including to the Indications and Usage, Dosage and Administration, and Warnings and Precautions sections. The FDA is also requiring updates to the existing patient Medication Guides to help educate patients and caregivers about these risks.

BACKGROUND: Opioid pain medicines are a class of powerful pain medicines prescribed to treat pain that does not respond well to other treatments or non-opioid pain medicines. They activate an area of nerve cells in the brain and body that block pain signals. These medicines have benefits

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when used appropriately, but they also have serious risks, including misuse and abuse, addiction, overdose, and death. Examples of common opioid pain medicines include codeine, hydrocodone, hydromorphone, morphine, oxycodone, oxymorphone, fentanyl, buprenorphine, and tramadol.

RECOMMENDATIONS:

Patients/Parents/Caregivers

- Always take your opioid medicines exactly as prescribed. Do not take more of the medicine or take it more often than prescribed without first talking to your health care professional. Talk with them if your pain increases, you feel more sensitive to pain, or if you have new pain, especially from touch or other things that are not usually painful such as combing your hair.

- Store your opioid pain medicines securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home. Do not share these medicines with anyone else, and immediately dispose of unused or expired opioids or take them to a drug take-back site, location, or program. If provided, use the prepaid mail-back envelopes included with the prescription.

- Seek emergency medical help or call 911 immediately if you or someone you are caring for experiences symptoms of respiratory problems, which can be life-threatening. Signs and symptoms include serious slowed, shallow, or difficult breathing, severe sleepiness, or not being able to respond or wake up.

- Talk to your health care professionals about the benefits of naloxone, which can reverse an opioid overdose, and how to obtain it. Your health care professional can give you a prescription for naloxone. Additionally, in most states and the District of Columbia you can obtain naloxone from a pharmacy under a standing order that takes the place of an individual prescription. Some states also allow you to obtain naloxone without a prescription from a community-based program or pharmacy. Check with your state Health Department for more information. In March 2023, FDA approved an inhaled nasal spray version of naloxone to be sold over-the-counter without a prescription while multiple forms of naloxone remain available as prescription only.

Health Care Professionals

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- If a patient is suspected to be experiencing OIH, carefully consider an appropriate decrease in dose of the current opioid pain medicine or safely switching them to a different opioid product, if tolerated. Advise patients about the risk of OIH and tell them to never increase the opioid dosage without first consulting a health care professional, because this could worsen the pain and increase the risk of respiratory depression.

Health care professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- 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 form, or submit by fax to **1-800-FDA-0178**.

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