COMMUNICATION

COM-2025-054

6 AUGUST 2025

Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date:

07/31/2025

Drug Indication:

Management of severe pain.

Safety Topic:

The FDA is requiring opioid pain medicine manufacturers to update labeling to better reflect the risks of long-term use.

Labeling Update for Opioids

It is for this reason that we are notifying you that on 07/31/2025 the U.S. Food and Drug Administration (FDA) published a safety communication for long-term opioid analgesic (also referred to as opioid pain medicine) therapy.

Reason for Communication

The FDA convened a joint meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee to discuss two recently completed observational studies examining the risks of misuse, abuse, addiction, and fatal and non-fatal overdose in patients on long-term opioid analgesic therapy. These studies provided new, quantitative data on risks of these serious adverse outcomes in patients prescribed opioid pain medicines long term.

After reviewing the findings, the FDA has determined that this new information should be included in drug labeling to help health care professionals and patients better understand the benefit-risk profile of opioid pain medicines when prescribed long-term and to make more informed decisions. Among the various labeling changes, the FDA is also requiring labeling updates to further clarify that extended-release/long-acting opioid pain medicines should only be used when alternative therapies, including immediate-release opioid pain medicines, are inadequate to manage severe and persistent pain, and to emphasize the importance of avoiding rapid dose reduction or abrupt discontinuation in patients who may be physically dependent on opioid pain medicines.

Pharmacy Required Action:

Advise patients that they should not discontinue using the medication without contacting their healthcare provider.

Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- ext. 219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Safety Communication Number COM-2025-054 August 2025

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REFERENCES:
1. U.S. Food and Drug Administration. (2025). *FDA is requiring opioid pain medicine manufacturers to update prescribing information regarding long-term use* https://www.fda.gov/drugs/drug-safety-and-availability/fda-requiring-opioid-pain-medicine-manufacturers-update-prescribing-information-regarding-long-term

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FRM-CL-000127-001

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