COMMUNICATION

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2023

URGENT
PLEASE
REVIEW

Safety Notification

PharmPix Clinical Department

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

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

U.S. Food & Drug Administration Publication Date:

4/13/2023

Drug Indication:

Pain

Safety Topic:

FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use

New Guidance for Opioid Pain Medications

It is for this reason that we are notifying you that on 04.13.2023 the U.S. Food and Drug Administration published a safety communication for opioid pain medications.

Reason for Communication:

As part of the ongoing efforts to address the nation's opioid crisis, the FDA is requiring several updates to the prescribing information for both immediate-release (IR) and extended release/long acting (ER/LA) opioid pain medications. The updates are the following:

- For all opioid medications: the risk of overdose increases as the dose increases.
- IR opioids: 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.

Reason for Communication (cont.):

- ER/LA opioid pain medications: should be reserved for severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine and for which alternatives treatment options are inadequate.
- Opioid-induced hyperalgesia (OIH) for both IR and ER/LA opioid medications: when opioid pain medications are taken for pain relief it causes an increase in pain or increased sensitivity to pain. New warning needs to describe the symptoms that differentiate OIH from opioid tolerance and withdrawal.

These changes to the prescribing information are designed to inform about appropriate prescribing of opioid pain medicines while also recognizing that they remain an important treatment option in appropriate situations and that undertreatment of pain carries its own risk.

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- Clinical Department. Our pharmacists will help you.

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

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REFERENCES
1. U.S. Food and Drug Administration. (2023). FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use. https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-prescribing-information-all-opioid-pain-medicines-provide-additional-guidance-safe-use
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

2 Street 1, Suite 500
Guaynabo, PR 00968
Tel. 787.522.5252
Fax 866.912.2830
www.pharmpix.com
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