COMMUNICATION

COM-2023-024

09
MAY
2023

URGENT
PLEASE
REVIEW

Recall 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 recall information.

U.S. Food & Drug Administration Publication Date:

05/04/2023

Drug Information:

National Drug Code

Refer to the list attached to this notification.

Product Description

Refer to the list attached to this notification.

Batch Number

Refer to the list attached to this notification.

Expiration Date

Refer to the list attached to this notification.

Company:

AKORN OPERATING COMPANY LLC

QUESTIONS

Call AKORN at 1.800.932.5676

Monday – Friday from 8:00 a.m. to 5:00 p.m. CDT.

Several Drug Products Recalled Due to Company Shutdown

It is for this reason that we are notifying you that on 05.04.2023 the US Food and Drug Administration published a drug recall notification for various drugs because of a bankruptcy.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

Akorn Operating Company LLC filed Chapter 7 bankruptcy on February 23, 2023. As a result of the bankruptcy, the firm is removing several products from the market due to the discontinuation of the Quality program. The discontinuation of this program means the company will not be able to support or guarantee that the products meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess which render the products adulterated.

The affected products are listed in the attachment included with this notification. Please be aware that this notification is focused on the human drug products and not veterinary drugs. Products not included in the press are continuing to be monitored under a Quality Program and will remain on the market.

For a complete list of the human drug products recalled, refer to the full list published by Akorn Operating Company:

https://www.fda.gov/media/167863/download

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/.

PharmPix Drug Recall Communication Number COM-2023-024 May 2023

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ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2025

REFERENCES:

1. U.S. Food and Drug Administration. (2023). UPDATE - Akorn Issues Voluntary Nationwide Recall of Various Human and Animal Drug Products Within Expiry Due to Company Shutdown. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/update-akorn-issues-voluntary-nationwide-recall-various-human-and-animal-drug-products-within-expiry
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