COMMUNICATION

COM-2024-050

22 July 2024

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:

07/22/2024

Drug Information:

National Drug Code

0143-9386-10

0143-9386-01

Product Description:

Acetaminophen Injection 1,000mg per 100mL (10mg/mL), 100mL bag

Lot Number

24070381

Expiration Date

September 2025

Company:

Hikma Pharmaceuticals PLC

QUESTIONS

Call Inmar at 877-890-0765, Monday - Friday, 9:00 a.m. – 5:00 p.m. EST.

Acetaminophen Injection, 1000mg/100mL, (10mg/mL)

It is for this reason that we are notifying you that on 07.22.2024 the U.S. Food and Drug Administration published a drug recall for the following product(s): Acetaminophen Injection 1,000mg per 100mL (10mg/mL).

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:

The product is being recalled due to the potential presence of a bag labelled Dexmedetomidine HCL Injection (400mcg/100mL) inside the overwrap that is labelled Acetaminophen Injection, 1000mg/100mL, (10mg/mL). The product was distributed to Hikma's direct customers nationwide.

Risk Statement:

If the provider does not identify the drug inside the acetaminophen overwrap as dexmedetomidine and administers the drug to a patient, there are multiple potential adverse outcomes that may result including varying degrees of sedation, bradypnea, bradycardia, hypertension, and hypotension or more serious and potentially life-threatening outcomes. To date, Hikma has received one report of an adverse event.

CLINICAL PEARLS BY PHARMPIX

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 Recall Communication Number COM-2024-050 July 2024

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REFERENCES:

1. U.S. Food and Drug Administration. (2024). Hikma Pharmaceuticals USA Inc. Extends Voluntary Nationwide Recall of One Lot of Acetaminophen Injection, 1000mg/100mL, (10mg/mL) Bags Due to an Individual Unit of Acetaminophen Overwrap Found to Have Contained a Labelled Bag of Dexmedetomidine HCL Injection (400mcg/100mL). Retrieved July 23,2024 from: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hikma-pharmaceuticals-usa-inc-extends-voluntary-nationwide-recall-one-lot-acetaminophen-injection
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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