COMMUNICATION

COM-2024-036

28
MAY
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:

05/22/2024

Drug Information:

National Drug Code

Refer to table included in the notification

Product Description

Buprenorphine HCL Injection Carpuject Units

Labetalol HCL Injection, USP Carpujet Units

Lot Number

Refer to table included in the notification

Expiration Date

Refer to table included in the notification

Company:

Hospira, Inc

QUESTIONS

Call Sedgwick Inc at 1.800.805.3093 Monday – Friday from 8:00 a.m. to 5:00 p.m. EST

Buprenorphine HCL injection & Labetalol HCL injection, USP

It is for this reason that we are notifying you that on 05.22.2024 the US Food and Drug Administration published a drug recall for the following product(s): Buprenorphine Hydrochloride Injection Carpuject Units and Labetalol Hydrochloride Injection, USP Carpuject Units.

Pharmacy Required Action:

Identify if the product is in inventory 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:

Hospira, Inc., a Pfizer company, is voluntarily recalling the lots listed in the table below of Buprenorphine Hydrochloride Injection Carpuject™ Units and Labetalol Hydrochloride Injection, USP Carpuject™ Units to the consumer level. The recall was initiated due to the potential for incomplete crimp seals; one customer complaint has been received for one leaking unit.

In the event that impacted products are administered to a patient, there is a potential for an increased risk of lack of therapeutic effect and systemic infection that may result in the need for additional medical treatment. To date, Pfizer has not received reports of any relevant adverse events associated with this issue for these lots.

Product	Presentation	Lot Number	Expiration Date	NDS (s)	Distribution Dates
Buprenorphine Hydrochloride Injection – CIII CarpujectTM Single-dose Cartridge/Tube Unit with Luer Lock	Carton 0409-2012-32 Cartridge 0409-2012-03	HJ3965	2024/09	0.3 mg base/mL (10 cartridge units/carton)	September 2023 through April 2024
		HJ8546	2024/10	0.3 mg base/mL (10 cartridge units/carton)	
Labetalol Hydrochloride Injection, USP CarpujectTM Single-dose Cartridge Unit with Luer Lock	Bundle 0409-2339-34 Carton/Cartridge 0409-2339-24	HJ7566	2025/05	20 mg/4 mL (5 mg/mL) (10 carton/ cartridge units/bundle)	
		HN8747	2025/09	20 mg/4 mL (5 mg/mL) (10 carton/ cartridge units/bundle)	
		HN8749	2025/09	20 mg/4 mL (5 mg/mL) (10 carton/ cartridge units/bundle)	

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 116. 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-2024-036 May 2024

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REFERENCES:

1. U.S. Food and Drug Administration. (2024). Hospira Inc. Issues A Voluntary Nationwide Recall For Buprenorphine Hydrochloride Injection CarpujectTM Units and Labetalol Hydrochloride Injection, USP CarpujectTM Units Due to the Potential for Incomplete Crimp Seals Retrieved May 22,2024 from: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hospira-inc-issues-voluntary-nationwide-recall-buprenorphine-hydrochloride-injection-carpujecttm
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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