COMMUNICATION

COM-2023-085

28
DECEMBER
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:

12/22/2023

Drug Information:

National Drug Code

61703-332-18

Product Description

Bleomycin for Injection, USP, 15 Units Single-Dose ONCO-TAIN™ Glass Fliptop Vial

Lot Number

BL12206A

Expiration Date

30/JUN/2024

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 / For medical questions call Pfizer Medical Information at 1.800.438.1985 option 3 Monday - Friday from 9 a.m. to 5 p.m. or email

www.pfizermedinfo.com

Bleomycin for Injection

It is for this reason that we are notifying you that on 12.22.2023 the U.S. Food and Drug Administration published a drug recall for the following product(s): Bleomycin for Injection, USP 15 units Single Dose ONCO-TAIN™ Glass Fliptop Vial.

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:

Hospira, Inc., a Pfizer company, is voluntarily recalling one lot of Bleomycin for Injection, USP 15 units Single Dose ONCO-TAIN™ Glass Fliptop Vial, lot BL12206A, to the user level. The recall was initiated due to a confirmed customer report for the presence of glass particulate within a single vial.

Should a patient receive injectable product containing glass particulate matter as a result of this issue, the patient may experience adverse events including injection site reaction, localized vein inflammation or phlebitis, thrombus, embolus and/or end-organ granuloma or life-threatening blood clot events. The risk is reduced by the possibility of detection, as the label contains a statement directing the healthcare professional to visually inspect the product for particulate matter and discoloration prior to administration.

To date, Pfizer has not received reports of any adverse events related to this recall.

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-2023-085 December 2023

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REFERENCES:

1. U.S. Food and Drug Administration. (2023). **Hospira, Inc. Issues A Voluntary Nationwide Recall For One Lot of Bleomycin for Injection, USP 15 Units Single Dose ONCO-TAIN™ Glass Fliptop Vial Due To The Potential For Presence of Glass Particulate Matter** Retrieved December 22, 2023, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hospira-inc-issues-voluntary-nationwide-recall-one-lot-bleomycin-injection-usp-15-units-single-dose
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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