COMMUNICATION

COM-2023-086

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:

12/26/2023

Drug Information:

National Drug Code

Refer to the table included in the notification

Product Description

4.2% Sodium Bicarbonate Injection, 8.4% Sodium Bicarbonate Injection, Atropine Sulfate Injection

Lot Number

Refer to the table included in the notification

Expiration Date

Refer to the 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 / 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

Sodium Bicarbonate and Atropine for Injection

It is for this reason that we are notifying you that on 12.26.2023 the U.S. Food and Drug Administration published a drug recall for the following product(s): 4.2% Sodium Bicarbonate Injection, 8.4% Sodium Bicarbonate Injection, and Atropine Sulfate Injection

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 the lots listed in the table below of 4.2% Sodium Bicarbonate Injection, USP ABBOJECT® Glass Syringe, 5 mEq/10 mL; 8.4% Sodium Bicarbonate Injection, USP Lifeshield® ABBOJECT® Glass Syringe, 50 mEq/50 mL; and Atropine Sulfate Injection, USP Lifeshield® ABBOJECT® Glass Syringe, 1 mg/10 mL to the user level. The recall was initiated due to the potential presence of glass particulate matter, identified during product inspection.

The risk is reduced by the possibility of detection, as the label contains a clear statement directing the healthcare professional to visually inspect the product for particulate matter and discoloration prior to administration.

To date, Hospira, Inc. has not received reports of any adverse events associated with this issue for these lots.

Recalled Lots:

Product	Presentation	Lot Number	Expiration Date	NDC (s)	Distribution Dates
4.2% Sodium Biocarbonate Injection, USP ABBOJECT™ Glass Syringe	5 mEq/10 mL (0.5 mEq/mL)	GX1542	1JAN2025	Carton: 0409-5534-24 Case: 0409-5534-14	March 14, 2023, to June 29, 2023.
8.4% Sodium Biocarbonate Injection, USP Lifeshield™ ABBOJECT™ Glass Syringe	50 mEq/50 mL (1 mEq/mL)	HA7295	1MAR2025	Carton: 0409-6637-24 Case: 0409-6637-14	March 14, 2023, to June 29, 2023.
Atropine Sulfate Injection, USP Lifeshield™ ABBOJECT™ Glass Syringe	1 mg/10 mL (0.1 mg/mL)	GY2496	1FEB2025	Carton: 0409-4911-11 Case: 0409-4911-34	March 14, 2023, to June 29, 2023.

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-2023-086 December 2023

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REFERENCES:

1. U.S. Food and Drug Administration. (2023). **Hospira, Inc. Issues A Voluntary Nationwide Recall For 4.2% Sodium Bicarbonate Injection, 8.4% Sodium Bicarbonate Injection, and Atropine Sulfate Injection Due to the Potential Presence of Glass Particulate Matter.** Retrieved December 26, 2023, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hospira-inc-issues-voluntary-nationwide-recall-42-sodium-bicarbonate-injection-84-sodium-bicarbonate
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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