# URGENT DRUG RECALL

December 26, 2023

## 4.2% Sodium Bicarbonate Injection, USP ABBOJECT® Glass Syringe

| Product | NDC | Lot Number | Expiration Date | Strength | Configuration/Count |
|---|---|---|---|---|---|
| 4.2% Sodium Bicarbonate Injection, USP ABBOJECT® Glass Syringe | Carton: 0409-5534-24 Case: 0409-5534-14 | GX1542 | 1JAN2025 | 5 mEq/10 mL (0.5 mEq/mL) | 1 10 mL Abboject Syringe per carton 10 cartons per bundle Case Pack 5 X 10-10 mL |

## 8.4% Sodium Bicarbonate Injection, USP Lifeshield® ABBOJECT® Glass Syringe

| Product | NDC | Lot Number | Expiration Date | Strength | Configuration/Count |
|---|---|---|---|---|---|
| 8.4% Sodium Bicarbonate Injection, USP Lifeshield® ABBOJECT® Glass Syringe | Carton: 0409-6637-24 Case: 0409-6637-14 | HA7295 | 1MAR2025 | 50 mEq/50 mL (1 mEq/mL) | 1 50 mL Abboject Syringe per Carton 10 cartons per bundle Case Pack 5 X 10-50 mL |

## Atropine Sulfate Injection, USP LifeShield® Abboject® Glass Syringe

| Product | NDC | Lot Number | Expiration Date | Strength | Configuration/Count |
|---|---|---|---|---|---|
| Atropine Sulfate Injection, USP LifeShield® Abboject® Glass Syringe | Carton: 0409-4911-11 Case: 0409-4911-34 | GY2496 | 1FEB2025 | 1 mg/10 mL (0.1 mg/mL) | 1 10 mL Abboject Syringe per carton 10 cartons per bundle Case Pack 5 X 10-10 mL |

Dear Customer,

Hospira, Inc., a Pfizer company, is voluntarily recalling the above-referenced lots of **ABBOJECT® products**; **4.2% and 8.4% Sodium Bicarbonate Injection, USP and Atropine Sulfate Injection, USP** due to the potential for presence of glass particulate matter, identified during product inspection.

Should a patient receive an injectable product containing glass particulate matter as a result of this issue, the patient may experience serious adverse events. Potential complications related to injection of visible and subvisible inert particles include inflammation of a vein, granuloma, and blockage of blood vessels or life-threatening blood clot events. The frequency and severity of these adverse events could vary depending upon a variety of factors including the size and number of particles in the drug product, patient comorbidities (such as age, compromised organ function), and presence or absence of vascular anomalies. 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, Pfizer has not received reports of any adverse events associated with this issue for these lots.

***FEDERAL REGULATION 21 CFR 7.49 (d) RESPONSIBILITY OF RECIPIENT STATES: "CONSIGNEES THAT RECEIVE A RECALL COMMUNICATION SHOULD IMMEDIATELY CARRY OUT THE INSTRUCTIONS SET FORTH BY THE RECALLING FIRM …"PFIZER RECOMMENDS THAT YOU RESPOND TO THIS RECALL EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT. TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ENCLOSED BUSINESS REPLY FORM (BRF) AND RETURN IT, AS DIRECTED, WITHIN FIVE (5) BUSINESS DAYS.*** If you have any questions about responding to this letter, please contact Sedgwick Inc. at 1-800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

The recall of the above-referenced lots of **ABBOJECT® products**; **4.2% and 8.4% Sodium Bicarbonate Injection, USP and Atropine Sulfate Injection, USP** is being conducted to the **User Level**.

Our records indicate that you may have received shipment of the affected lots which was distributed between **March 14, 2023 through June 29, 2023.** Please check your stock immediately to identify whether you have cartons from the recalled lots. If you have any of the affected product in your inventory, please stop distribution, discontinue use and quarantine the product immediately. Promptly return the impacted product to Sedgwick Inc.; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 6722 using the enclosed pre-paid UPS label. **All returns are requested to be completed within one month of this notice date.** If you received this notification without the prepaid UPS label and BRF, require additional shipping labels, or have questions regarding the return procedure, please contact Sedgwick Inc. at 1-800-805-3093.

If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product from you. Further, please instruct entities that may have received the recalled product from you that if they have redistributed the product, they should notify their accounts, locations or facilities of the recall. If additional copies of the letter and/or response form are needed, please contact Sedgwick at 1-800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

Reimbursement for the returned product will be made by credit memorandum. If you have any questions regarding the reimbursement, please contact your Pfizer Customer Service Representative at 1-844-646-4398 (Mon.-Fri. 8 am-6 pm ET).

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience this action may cause you.

If you have any questions regarding this recall, please call the appropriate contact center below.

| Contact | Contact Information | Areas of Support |
|---|---|---|
| Pfizer Medical Information | 1-800-438-1985, option 3<br>(9am to 5pm ET Monday through Friday)<br>www.pfizermedinfo.com | For medical questions regarding the product |
| Pfizer Safety | 1-800-438-1985, option 1<br>(24 hours a day 7 days per week) | To report adverse events and product complaints |

Sincerely,

Masum Hossain
U.S. Hospital Lead

Pfizer Hospital

## 4.2% and 8.4% Sodium Bicarbonate Injection, USP


## Atropine Sulfate Injection, USP