URGENT DRUG RECALL

October 4, 2023

4.2% Sodium Bicarbonate Injection, USP

Product	NDC	Lot Number	Expiration Date	Strength	Configuration/Count
4.2% Sodium Bicarbonate Injection, USP Glass ABBOJECT® Syringe	Carton 0409-5534-24 Case 0409-5534-14	GJ5007	1AUG2024	5 mEq/10mL (0.5 mEq/mL)	1 vial and injector per carton; 10 cartons per bundle; Case Pack 5 X 10 –10mL

1% Lidocaine HCl Injection, USP

Product	NDC	Lot Number	Expiration Date	Strength	Configuration/Count
1% Lidocaine HCl Injection, USP LIFESHIELD® Glass ABBOJECT® Syringe	Carton 0409-4904-11 Case 0409-4904-34	42290DK	1JUN2024	50 mg /5mL (10 mg/mL)	1 vial and injector per carton; 10 cartons per bundle; Case Pack 5 X 10 – 5mL

2% Lidocaine HCl Injection, USP

Product	NDC	Lot Number	Expiration Date	Strength	Configuration/Count
2% Lidocaine HCl Injection, USP LIFESHIELD® Glass ABBOJECT® Syringe	Carton 0409-4903-11 Case 0409-4903-34	GH6567	1JUL2024	100 mg/5mL (20 mg/mL)	1 vial and injector per carton; 10 cartons per bundle; Case Pack 5 X 10 – 5mL

Dear Customer,

Hospira, Inc., a Pfizer company, is voluntarily recalling the above-referenced lots of **ABBOJECT® products**; **4.2% Sodium Bicarbonate Injection, USP, 1% and 2% Lidocaine HCl Injection, USP** due to the possibility of glass particulates in the products. Pfizer completed a Health Hazard Assessment which concluded that the use of the impacted product has an unlikely probability of occurrence of adverse effects such as myocardial infarction, stroke, pulmonary embolism, deep vein thrombosis, and thrombophlebitis or mild pain. The potential risk to the patient arising from this issue is considered to be low.

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 800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

The recall of the above-referenced lots of **ABBOJECT® products**; **4.2% Sodium Bicarbonate Injection, USP, 1% and 2% Lidocaine HCl 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 **October 13, 2022 through October 26, 2022.** 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 7162 using the enclosed pre-paid UPS label. **All returns are requested to be completed within six months 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 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 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 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.

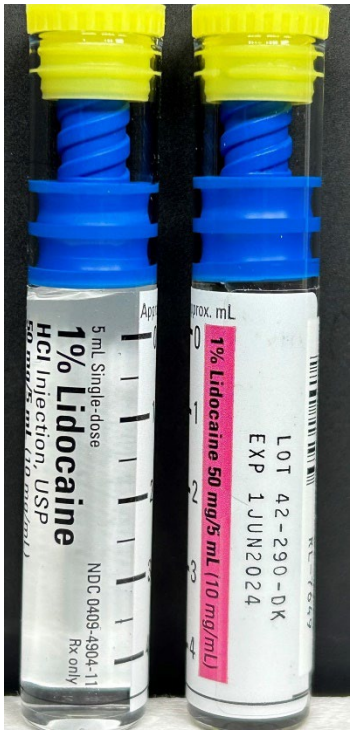
Contact	Contact Information	Areas of Support
Pfizer Medical Information	800-438-1985, option 3 (8am to 7pm ET Monday through Friday) www.pfizermedinfo.com	For medical questions regarding the product
Pfizer Safety	800-438-1985, option 1 (24 hours a day 7 days per week)	To report adverse events and product complaints

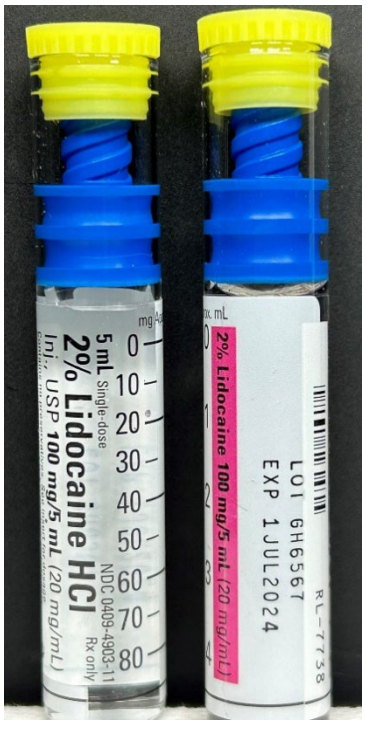
Sincerely,

Masum Hossain
U.S. Commercial Lead, Hospital

4.2% Sodium Bicarbonate Injection, USP

1% and 2% Lidocaine HCl Injection, USP





PLEASE COMPLETE THIS FORM AND RETURN VIA FAX TO 888-345-0241 OR EMAIL TO PFIZER7162@SEDGWICK.COM
EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT.
MAKE A COPY OF THIS FORM TO INCLUDE WITH YOUR PRODUCT RETURN.

BUSINESS REPLY FORM/PACKING SLIP

4.2% Sodium Bicarbonate Injection, USP; 5 mEq/10mL, (0.5 mEq/mL)
1% Lidocaine HCl Injection, USP; 50 mg /5mL, (10 mg/mL)
2% Lidocaine HCl Injection, 100 mg/5mL, (20 mg/mL)

NDC #	Lot #	Product	Expiration Date	SEALED CARTONS 1 vial and injector per carton	UNSEALED CARTONS 1 vial and injector per carton
Carton 0409-5534-24 Case 0409-5534-14	GJ5007	4.2% Sodium Bicarbonate Injection, USP Glass ABBOJECT®Syringe	1AUG2024		
Carton 0409-4904-11 Case 0409-4904-34	42290DK	1% Lidocaine HCl Injection, USP LIFESHIELD® Glass ABBOJECT® Syringe	1JUN2024		
Carton 0409-4903-11 Case 0409-4903-34	GH6567	2% Lidocaine HCl Injection, USP LIFESHIELD® Glass ABBOJECT® Syringe	1JUL2024		

Your timely response to this notification is requested. Please complete and fax this Business Reply Form/Packing Slip within five (5) business days **even if you do not have the recalled product.** Thank you.

- ☐ We have read and understand the urgent drug recall information.
- ☐ We have/will further notify our accounts who may have received the affected product lots, to the Hospital/Institution level.
- ☐ We do not have any of the affected product lots on hand.

To report any adverse events or product complaints, please contact Pfizer Safety at 1-800-438-1985, option 1.

The below information will help us ensure you are correctly credited in compliance with all applicable regulations, including 340b reporting.

Company/Institution/Practice Name: _____

Signature: _____ Title: _____

Print Name: _____ Phone: _____

Please provide as applicable:

Direct Acct #: _____ Indirect Acct #: _____

Your DEA# _____

Your HIN # _____

Your 340b identifier # _____ Your Debit Memo/Reference #: _____

(Pfizer will use your DM/Reference number on the credit documents for your convenience)

If purchased from a wholesaler, wholesaler Name and DEA #:

_____

The below shipping label is not intended for multiple shipments. Please DO NOT duplicate or re-distribute.

Ship SEDGWICK
To:
2670 EXECUTIVE DRIVE SUITE A
INDIANAPOLIS IN 46241

RS
ID: 77356108
Event: 7162
Seq.# 1

IN 462 8-01

SAMPLE

UPS GROUND
TRACKING: 1Z E38 010 90 2373 0116

SAMPLE

PACKING INSTRUCTIONS:

1. Fill out this packing slip and photocopy it for your records. Return this original packing slip with your product shipment.

2. Affix prepaid UPS RS shipping label to shipping container (if reusing a shipping container, remove or mark out all labels, stickers, hazmat and ORM markings). Give directly to any UPS driver or deliver to UPS. (Do not enter this shipment in a UPS log book or apply any other UPS shipping label or bar code.)

3. Keep this for your records. All follow-up will be based on this shipping information.

TRACKING: 1Z E38 010 90 2373 0116

ID 77356108 Event 7162
Any Business Name

LTR 1 OF 1

SEDGWICK
(855)-215-4970
2670 EXECUTIVE DR SUITE A
INDIANAPOLIS IN 46241

SHIP TO:
DEAR CUSTOMER:
N/A
ANY BUSINESS NAME
ANY STREET

ANY CITY XX 12345

NY 122 9-02

SAMPLE

UPS GROUND

TRACKING: 1Z A0Y 770 03 2288 3155

SAMPLE

BILLING: P/P

N77356108D7162-1

URC38.5V 09/2023

URGENT: DRUG RECALL