



URGENT DRUG RECALL

September 27, 2022

Aminophylline Injection, USP

Vial NDC	Carton NDC	Lot Number	Expiration Date	Description	Configuration/Count
0409-5921-16	0409-5921-01	30-137-DK	1-DEC-2022	250 mg/10mL (25 mg/mL) Single-Dose Vial	2 X 25, 10 mL Fill in 20 mL Fliptop Vials

Dear Customer,

Hospira, Inc., a Pfizer company, is voluntarily recalling the above-referenced lot of **Aminophylline Injection, USP**, to the **User level**, due to a confirmed report of a visible particulate observed in a single vial. Pfizer completed a Health Hazard Assessment which concluded that the use of the impacted product has an unlikely probability of being associated with limited adverse events such as end-organ granuloma or tissue ischemia, tissue inflammation or phlebitis, decreased blood flow to the brain, heart attack, tissue necrosis, hypersensitivity reactions and infections. The overall potential risk to patients 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 this lot.

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 lot of **Aminophylline Injection, USP** is being conducted to the **User Level**.

Our records indicate that you may have received shipment of the affected lot which was distributed between **October 25, 2021 through April 01, 2022**. Please check your stock immediately to identify whether you have vials from the recalled lot. If you have any of the affected product in your inventory, please stop distribution and use of the product immediately and promptly return it to Sedgwick Inc.; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 8585 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 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-7 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 (8am to 9pm ET Monday through Friday) www.pfizermedinfo.com	For medical questions regarding the product
Pfizer Safety	1-800-438-1985, option 1 (24 hours a day 7 days per week)	To report adverse events and product complaints

Sincerely,

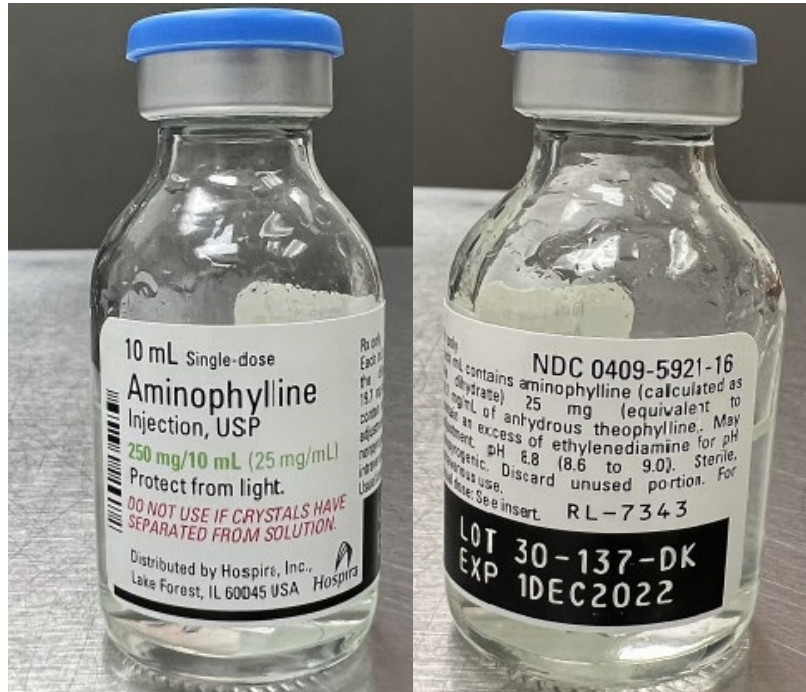
A handwritten signature in black ink, appearing to read 'Masum Hossain', written over a light grey background.

Masum Hossain

U.S. Commercial Lead, Hospital

Aminophylline Injection, USP

10 mL Single-Dose Vial





PLEASE COMPLETE THIS FORM AND RETURN VIA FAX TO 866-808-1159 OR EMAIL TO PFIZER8585@SEDGWICK.COM EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT.

MAKE A COPY OF THIS FORM AND INCLUDE IT WITH YOUR PRODUCT RETURN.

BUSINESS REPLY FORM/PACKING SLIP

Vial NDC	Carton NDC	Product Description	Lot #	Expiration Date	Vials on Hand
0409-5921-16	0409-5921-01	250 mg/10mL (25 mg/mL) Single-Dose Vial	30-137-DK	1-DEC-2022	

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 lot, to the user Level.
- We do not have any of the affected product lot on hand.

To report any adverse events or product complaints, please contact Pfizer Drug Safety at 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:

Pfizer Direct Account # _____

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 #:
