URGENT: DRUG RECALL

May 29, 2020

Unasyn®

(ampicillin sodium/sulbactam sodium) for Injection

NDC	Lot Number	Expiration Date	Strength and Description	Configuration/Count
Vial NDC: 0049-0013-81 Carton NDC: 0049-0013-83	33001612	02/2022	1.5g vial/Injection, powder for solution	10 X 1 Vial per Carton

Dear Customer:

Pfizer, Inc. is voluntarily recalling the above referenced lot of Unasyn due to a confirmed customer report for the presence of particulate matter identified after reconstitution, within a single vial. The use of the impacted product has an unlikely probability of being associated with adverse events such as infection or embolic events. To date, Pfizer has not received reports of any adverse events for this lot and the potential risk to the patient arising from this issue is low.

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 INC 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 POSTAGE-PAID, BUSINESS REPLY CARD (BRC) AND RETURN IT TO US, AS DIRECTED, WITHIN FIVE (5) BUSINESS DAYS. If you have any questions about responding to this letter, please contact Stericycle Inc. at 1-800-805-3093 (Mon.-Fri. 8am-5pm ET).

The recall of the above-referenced lot of Unasyn is being conducted to the **hospital/institution level**.

Our records indicate that you may have received shipment of the affected lot between August 2019 and September 2019.

Please check your stock immediately against the table above. If you have any of the affected product in your inventory, please stop distribution immediately and promptly return it to Stericycle Inc.; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 8651 using the enclosed pre-paid UPS label. If you received this notification without the prepaid UPS label and BRC, require additional shipping labels, or have questions regarding the return procedure, please contact Stericycle Inc. at 1-800-805-3093.

If you have further distributed any of this lot to other hospital/institution level accounts, please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request that they immediately cease distribution of the affected lot and promptly return the product directly to the above

Stericycle Inc. address. Your accounts do not need to fill out a BRC; however, if they have inventory of the affected product, they can contact Stericycle Inc. at 1-800-805-3093 to obtain pre-paid shipping labels for product returns. Further authorization is not required for product returns.

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. 8am - 7pm ET).

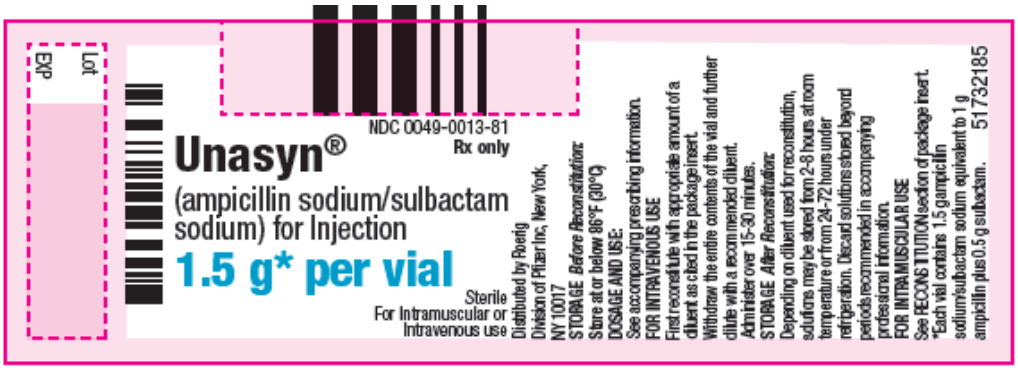
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience this action may cause you. If you have any questions regarding this recall, please call the appropriate contact center below.

Contact Center	**Contact Information**	**Area of Support**
Pfizer Medical Information	800-438-1985, option 3 (Mon.-Fri. 9 am-5 pm ET)	For medical questions regarding the product
Pfizer Drug Safety	800-438-1985, option 1 (24 hours a day; 7 days a week)	To report adverse events and product complaints

Sincerely,

Navin Katyal
Regional President,
North America, Hospital Business Unit

Vial Label for Unasyn® (ampicillin sodium/sulbactam sodium) for Injection



Carton Label for Unasyn® (ampicillin sodium/sulbactam sodium) for Injection