



URGENT: DRUG RECALL

May 3, 2021

Sterile Water for Injection, USP 100 mL Single-dose Vial

Product	NDC	Lot Number	Expiration Date	Presentation	Configuration/Count
Sterile Water for Injection, USP 100 mL Single-dose Glass Fliptop Vial	Vial: 0409-4887-25 Carton: 0409-4887-99	DN9185	01 Apr 2023	100 mL, Single-dose Glass Fliptop Vial	Tray of 25 vials

Dear Customer;

Hospira, Inc., a Pfizer Company is voluntarily recalling the above referenced lot of Sterile Water for Injection, 100 mL Single-dose Glass Fliptop Vial due to a confirmed customer report for a single vial with a visible particulate. Pfizer completed a Health Hazard Assessment, which concluded the use of the impacted product would present a very low likelihood of exposure and has an unlikely probability of being associated with potential adverse events such as anaphylaxis, fever, gastrointestinal disturbances, vein irritation, localized vein inflammation phlebitis, end-organ granuloma, tissue ischemia, pulmonary emboli, and infarction. The overall potential risk to the patient arising from this issue is considered as low.

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

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 POSTAGE-PAID BUSINESS REPLY CARD (BRC) AND RETURN IT, AS DIRECTED, WITHIN FIVE (5) BUSINESS DAYS.

If you have any questions about responding to this letter, please contact Stericycle Inc. at 800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

The recall of the above referenced lot of **Sterile Water for Injection, 100 mL Single-dose Glass Fliptop Vial** is being conducted to the **Hospital/Institution Level**.

Our records indicate that you may have received shipment of the affected lot, which was distributed between **October 2020 to December 2020**. 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 immediately and promptly return it to Stericycle Inc.; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 6957 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 BRC, require additional shipping labels, or have questions regarding the return procedure, please contact Stericycle 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. Please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request they immediately cease distribution of the affected product and promptly contact Stericycle at 800-805-3093 (Mon.-Fri. 8 am-5 pm ET) to obtain a BRC to initiate the return process.

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-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 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
Pfizer Biopharmaceutical Group

Sterile Water for Injection, USP 100 mL Single-dose Glass Fliptop Vial

