



URGENT DRUG RECALL

October 3, 2018

Magnesium Sulfate in Water For Injection (0.325 mEq Mg⁺⁺/mL) 40 mg/mL

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0409-6729-03	87904FW	1MAR2020	40mg/mL	Case Pack 1 X 24-500 mL

Dear Customer,

Hospira, Inc., a Pfizer company, (“Hospira”), is voluntarily recalling the above-referenced lot of Magnesium Sulfate in Water For Injection due to a confirmed report involving a single unit of Heparin in 0.45% Sodium Chloride for Injection NDC 0409-7651-03, Lot 87903FW that was found inside a case of Magnesium Sulfate in Water for Injection.

Hospira has completed a health hazard assessment which concluded the potential hazards arising from the properly labeled Heparin Sodium bag mixed in a case of properly labeled Magnesium Sulfate bags of the same volume. Although the likelihood of finding a bag of Heparin Sodium in a case of Magnesium sulfate is remote, unintentional use of Heparin Sodium in the place of Magnesium Sulfate has a reasonable probability of being associated with moderate to severe adverse events, such as bleeding, placental abruption, seizure or stroke. There have been no reports of relevant adverse events associated with the Magnesium Sulfate in Water for Injection Lot 87904FW. The potential risk to the patient administered Heparin rather than Magnesium Sulfate is considered to be high.

To date, Hospira 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...” HOSPIRA 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 CARD AND RETURN IT VIA USPS, 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. 8 am-5 pm ET).

The recall of the above-referenced lot of **Magnesium Sulfate in Water For Injection** is being conducted to the **hospital/institution level**.

Hospira, Inc., a Pfizer company
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.pfizerinjectables.com

Our records indicate that you may have received shipment of the affected product between April 2018 through June 2018. 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 using the label provided with this letter. **All returns are requested to be completed within six months of this notice date.** To ensure proper and timely credit, follow the instructions on the return label for returning the product.

The return label provided in this notification is for single use only, please DO NOT reproduce. If you have not received a return label or require additional assistance, please contact Stericycle 1-800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

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 to the hospital/institution. If additional copies of the letter and/or reply card are needed, please contact Stericycle at 1-800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

Please contact Pfizer Customer Service at 1-844-646-4398 (Mon.-Fri. 8am - 7pm ET) or your Pfizer representative regarding product availability and for questions regarding this market action.

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 you may contact Pfizer using the below information.

Contact	Contact Information	Areas of Support
Pfizer Medical Information	1-800-438-1985, option 3 (8am to 7pm ET Monday through Friday)	Medical inquiries
Pfizer Safety	1-800-438-1985, option 1 (24 hours a day 7 days per week)	To report adverse events or product complaints

Sincerely,



Navin Katyal
General Manager, Pfizer Injectables
Pfizer Essential Health

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