URGENT: DRUG RECALL

July 9, 2019

Milrinone Lactate Injection in 5% Dextrose Injection

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0409-2776-02	86-615-KL	1FEB2020	40 mg/200 mL (0.2mg/mL)	1 x 10; 10 overwrapped individual bags per case
	87-701-KL	1MAR2020		
	90-114-KL	1JUN2020		
0409-2776-23	85-516-KL	1JAN2020	20 mg/100 mL (0.2mg/mL)	1 x 10; 10 overwrapped individual bags per case
	85-517-KL	1JAN2020		
	86-601-KL	1FEB2020		
	86-603-KL	1FEB2020		
	86-618-KL	1FEB2020		
	87-707-KL	1MAR2020		
	91-205-KL	1JUL2020		
	92-306-KL	1AUG2020		

Dear Customer:

Hospira, Inc., a Pfizer company, ("Hospira") is voluntarily recalling the above eleven (11) lots of **Milrinone Lactate Injection in 5% Dextrose Injection,** to the hospital level, due to a molding defect in the additive ports in some units, which may lead to potential product leakage.

Pfizer completed a Health Hazard Assessment which concluded that if impacted product is administered to a patient, there is a low probability that the patient may experience adverse effects ranging from fever, chills, and sepsis or invasive systemic infections due to microbial contamination and reduced efficacy due to loss of content or drug instability. To date, Hospira 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…" 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 ATTACHED BUSINESS REPLY CARD (BRC) AND RETURN, 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 lots of **Milrinone Lactate Injection in 5% Dextrose Injection** is being conducted to the **Hospital level**.

Our records indicate that you may have received shipment of the affected product between **March 2018** and **November 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.

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 1-800-805-3093 (Mon.-Fri. 8 am-5 pm ET) to obtain a BRC to initiate the return process.

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 medical questions regarding the product you may contact Pfizer using the below information.

Contact	Contact Information	Areas of Support
Pfizer Medical Information	1-800-438-1985, option 3 (9am to 5pm 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 Biopharmaceuticals Group