URGENT: DRUG RECALL

May 20, 2024

Buprenorphine Hydrochloride Injection - CIII

Carton NDC	Cartridge NDC	Lot Number	Expiration Date	Concentration	Configuration/Count
0409-2012-32	0409-2012-03	HJ3965	2024/09	0.3 mg base/mL	Carton of 10 x 1 mL Carpuject™ Single-dose Cartridge/tube units with Luer Lock
		HJ8546	2024/10		

Labetalol Hydrochloride Injection, USP

Bundle NDC	Carton/ Cartridge NDC	Lot Number	Expiration Date	Concentration	Configuration/Count
0409-2339-34	0409-2339-24	HJ7566	2025/05	20 mg/4 mL (5 mg/mL)	Bundle containing 10 Cartons of 1 x 4 mL Carpuject™ Single-dose Cartridge units with Luer Lock
		HN8747	2025/09		
		HN8749	2025/09		

Dear Customer:

Hospira, Inc., a Pfizer company, is voluntarily recalling the above referenced lots of **Buprenorphine Hydrochloride Injection** and **Labetalol Hydrochloride Injection, USP**. Pfizer initiated this recall due to the potential for incomplete crimp seals. Pfizer completed a Health Hazard Assessment, which concluded that in the event that impacted products are administered to a patient, there is a potential of an increased risk of lack of therapeutic effect, bloodstream infections, septicemia, respiratory distress, stroke, and hypersensitivity reactions.

To date, Pfizer has not received reports of any relevant 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 …" 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 at 800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

The recall of the above referenced lots of **Buprenorphine Hydrochloride Injection** and **Labetalol Hydrochloride Injection, USP** is being conducted to the **User level**.

Our records indicate that you received shipment of one or more of the affected product lots, which were distributed from **September 2023 to April 2024**. Please check your stock immediately against the table above. If you have any of the affected lots in your inventory, please discontinue use, stop distribution, and quarantine the product immediately. Promptly return the product to Sedgwick; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 8134 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 at 800-805-3093 (Mon.-Fri. 8 am-5 pm ET).

If you have further distributed the recalled product, please notify your accounts and/or additional locations which may have received the recalled product. Please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request the accounts to immediately cease distribution and quarantine the affected product. Promptly contact Sedgwick at 800-805-3093 (Mon.-Fri. 8 am-5 pm ET) to obtain pre-paid shipping labels to initiate the return process.

Reimbursement for the returned product will be made by credit memorandum. If you have questions regarding reimbursement or product availability, please contact Pfizer Customer Service at 844-646-4398 (Mon.-Fri. 8 am-6 pm ET) or your Pfizer representative.

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, 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) www.pfizermedinfo.com	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,

Masum Hossain
U.S. Commercial Lead, Hospital

Buprenorphine Hydrochloride Injection – CIII

1 mL Carpuject™ Single-dose Cartridge units with Luer Lock

Labetalol Hydrochloride Injection, USP

4 mL Carpuject™ Single-dose Cartridge units with Luer Lock