URGENT DRUG RECALL

May 03, 2021

0.5% Bupivacaine Hydrochloride Injection, USP

1% Lidocaine HCl Injection, USP

Product	NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0.5% Bupivacaine Hydrochloride Injection, USP Single Dose Teartop Vial	Vial: 0409-1162-19 Tray: 0409-1162-02	EG6023	01 July 2022	0.5%, 150 mg/30 mL (5 mg/mL)	Case Pack 2 x 25 Vials
1% Lidocaine HCl Injection, USP Single Dose Teartop Vial	Vial: 0409-4279-16 Tray: 0409-4279-02	EG8933	01 Aug 2022	1%, 300 mg/30 mL (10 mg/mL)	Case Pack 2 x 25 Vials

Dear Customer,

Hospira, Inc., a Pfizer company, ("Hospira"), is voluntarily recalling the above-referenced lots of **0.5% Bupivacaine Hydrochloride Injection, USP** and **1% Lidocaine HCl Injection, USP** due to a mislabeling of the above-referenced product lots, whereby a portion of each lot was incorrectly labeled as the other product. Hospira has completed a Health Hazard Assessment, which concluded that use of the impacted products are likely to cause moderate to high severity adverse events. If 1% lidocaine is administered to the patient instead of 0.5% bupivacaine, the patient may be underdosed, leading to lack of efficacy with potential outcomes such as inadequate pain management and failure of surgical anesthesia. If 0.5% bupivacaine is administered to the patient instead of 1% lidocaine, an overdose of bupivacaine may occur, which could lead to potential outcomes such as seizures, respiratory abnormalities including hypoxia, hypercarbia, acidosis, and apnea, cardiovascular abnormalities such as myocardial depression, cardiac arrhythmias, bradycardia, asystole, ventricular fibrillation, and cardiac arrest with potentially life-threatening and/or fatal consequences. It was concluded that the overall potential risk to the patient arising from this issue is considered to be high for both mislabeling scenarios based on current information available from the investigation.

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 REQUESTS THAT YOU RESPOND TO THIS RECALL EVEN IF YOU DO NOT HAVE PRODUCT FROM THE RECALLED LOTS. TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ENCLOSED BUSINESS REPLY CARD AND RETURN IT TO THE FAX NUMBER OR E-MAIL ADDRESS ON THE CARD, 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 **0.5% Bupivacaine Hydrochloride Injection, USP** and **1% Lidocaine HCl Injection, USP** is being conducted at the **Hospital/Institution level**.

Our records indicate that you may have received shipment of the affected product which was distributed between December 29, 2020 to April 15, 2021. Please check your stock immediately to identify whether you have vials from the recalled lots. 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 3723 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 that 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 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.

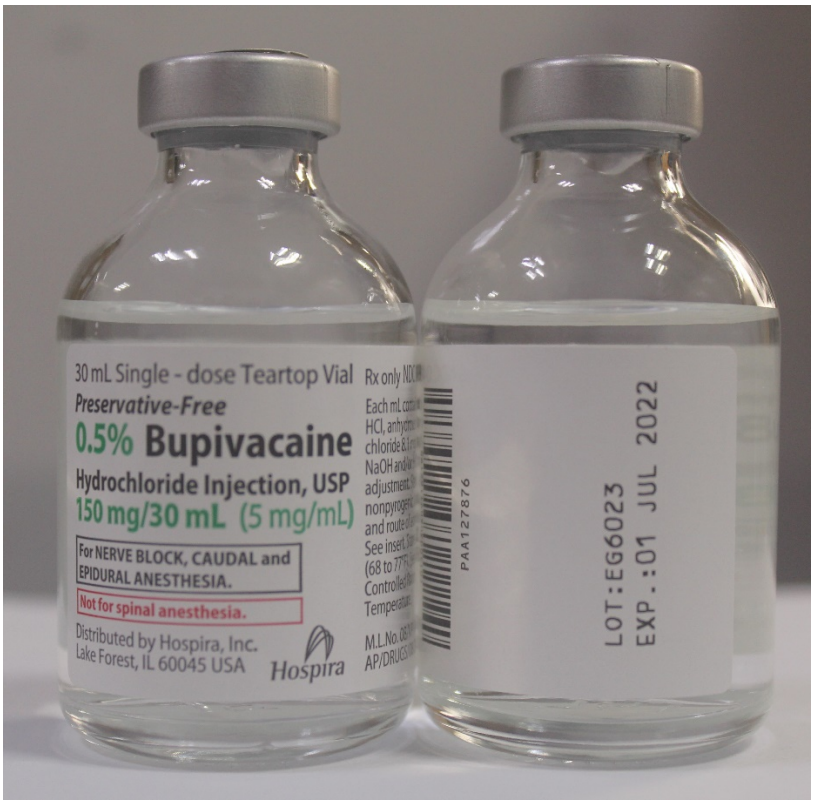
Contact Center	**Contact Information**	**Areas of Support**
Pfizer Medical Information	1-800-438-1985, option 3 (9am to 5pm ET Monday through Friday)	For medical questions regarding the product
Pfizer Safety	1-800-438-1985, option 1 (24 hours a day 7 days per week)	To report adverse events or product complaints

Sincerely,

Navin Katyal
Regional President, North America
Hospital Business Unit
Pfizer Biopharmaceutical Group

Affected Product Photos

0.5% Bupivacaine Hydrochloride Injection, USP:



1% Lidocaine HCl Injection, USP: