# URGENT DRUG RECALL

November 27, 2019

## 25% Dextrose Injection, USP

| NDC | Lot Number | Expiration Date as stated on the Carton label | Expiration Date as stated on the Product Syringe | Presentation | Configuration/Count |
|---|---|---|---|---|---|
| 0409-1775-10 | 80-292-EV* | 1AUG2019 | 1AUG2021 | 2.5 grams (250mg/mL) | Case Pack 5 X 10, 10mL Syringe |

*Lot number may be followed by -01

Dear Customer,

Hospira, Inc., a Pfizer company, ("Hospira"), is voluntarily recalling the above-referenced lot of **25% Dextrose Injection, USP** due to confirmed reports that the expiration date printed on the syringe (1AUG2021) is incorrect and does not match the expiration date on the carton (1AUG2019). The expiry on this product has been extended through FDA and the extended use date is 1DEC2019. The potential risk to patients arising from this issue is considered to be negligible. To date, Hospira has not received any reports of adverse events associated with this lot.

FDA is alerting health care professionals and patients of updated dates through which some products may be used beyond the manufacturer's labeled expiration date. The 'Search List of Extended Use Dates to Assist with Drug Shortages' communication surrounding this expiry date extension can be found on the FDA's Drug Shortage website. In this particular case, lot number 80-292-EV has an expiry date of 1AUG2019, however the approved extended use date is 1DEC2019 (https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages).

***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. 8am-5pm ET).

The recall of the above-referenced lot of **25% Dextrose Injection, USP** is being conducted to the **hospital/retail Level**.

Our records indicate that you may have received shipment of the affected product between September 2017 and September 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 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<br><br>(9am to 5pm ET Monday through Friday) | Medical inquiries |
| Pfizer Safety | 1-800-438-1985, option 1<br><br>(24 hours a day 7 days per week) | To report adverse events or product complaints |

Sincerely,

Navin Katyal
General Manager, U.S. Hospital Business Unit