Life-Assist
Helping Heroes Save Lives

URGENT RECALL

Monday, July 18, 2016

Dear Valued Life-Assist Customer,

According to our records you may have purchased an item that has been recalled by the manufacturer. Please examine your stock to determine if you have the following product, with the affected lot number(s) in your possession.

DIAZEPAM 10MG/2ML CARPUJECT LUER LOCK (BX/10)

Life-Assist, Inc. Product Code	NDC/UPC	Lot #(s)
PS_DR1273-32	0409-1273-32	52610LL, 57660LL

Reason for Recall: Hospira, Inc. is issuing a voluntary recall of the lot numbers listed above of Diazepam Injection due to a potential for the presence of crystallized Diazepam adhered to the plunger or wall of the Carpuject.

Complete the attached reply form and return it to Stericycle as per instructions notated on the **Response Required** form on page 3 of the manufacturer letter (enclosed). Please complete and return the form even if you have no affected lots on hand.

Credit for returned product will be applied to customer accounts once it has been issued to Life-Assist.

Contact Life-Assist Customer Service at 800-824-6016 or salesservice@life-assist.com to place your order for replacement.

We apologize for any inconvenience.

11277 Sunrise Park Drive
Rancho Cordova, CA 95742
(800) 824-6016 Phone
(800) 290-9794 Fax
customerservice@life-assist.com
www.life-assist.com

A Pfizer Company

URGENT: DRUG RECALL

June 23, 2016

Diazepam Injection, USP 10mg/2mL (5mg/mL)

10 Carpuject™ Sterile Cartridge Units with Luer Lock

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0409-1273-32	52610LL	1OCT2016	5 mg/mL, 2 mL in 2.5 mL Carpuject, Luer Lock	1 Carpuject/tube, 10 tubes/carton, 100 cartons/case (1000)
0409-1273-32	57660LL	1MAR2017	5 mg/mL, 2 mL in 2.5 mL Carpuject, Luer Lock	1 Carpuject/tube, 10 tubes/carton, 100 cartons/case (1000)

Dear Customer:

Hospira, Inc., a Pfizer company, is voluntarily recalling the above referenced lots of Diazepam Injection, USP, due to a potential for the presence of crystallized Diazepam adhered to the plunger or wall of the Carpuject. Administration of product that contains particulate may result in localized inflammation, phlebitis, low level allergic response, thromboembolic events or immune response may occur. The likelihood of serious patient harm is considered negligible.

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 RECALL REPLY FORM AND RETURN IT TO THE FAX NUMBER OR E-MAIL ADDRESS ON THE FORM, AS DIRECTED, WITHIN FIVE (5) BUSINESS DAYS. If you have any questions about responding to this letter, please contact Stericycle Inc. at 1-888-912-7089.

The recall of the above-referenced lots of **Diazepam Injection, USP**, is being conducted to the **hospital/retail level**.

Our records indicate you may have received shipment of the affected product between July 2015 and January 2016. Return affected product 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.* Please visit http://expertezlabel.com to request additional labels for returning affected product. If you have not received a return label or require additional assistance, contact Stericycle at 1-888-912-7089 (M-F, 8am to 5pm ET).

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

FA1606-01

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A Pfizer Company

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/retail level. If additional copies of the letter and/or reply form are needed, please contact Stericycle at 1-888-912-7089.

Please contact Hospira Customer Care at 1-877-946-7747 (M-F, 7am to 6pm CT) or your Hospira 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 information questions regarding the product, please contact Hospira Medical Communications at 1-800-615-0187 or via e-mail at medcom@hospira.com.

Sincerely,

Janet Stevens
Vice President, Quality Operations

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

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Urgent Drug Recall Reply Form – Response Required
Diazepam Injection, USP – Particulate
June 23, 2016

A Pfizer Company

Check your inventory and complete the information below, even if you do not have the affected product.
Failure to complete all sections of this page may result in improper, delayed or denied credit.

Fax the completed form to 1-844-782-5570 or e-mail the completed form to Hospira4977@stericycle.com.
All returns are requested to be completed within six months of this notice date. *The return label provided in this notification is for single use only, please DO NOT reproduce.* Please visit *http://expertezlabel.com* to request additional labels for returning product. If you have not received a return label or require additional assistance contact Stericycle at **1-888-912-7089,** (M-F, 8am to 5pm ET).

Required Information

Business Name _____ Phone Number _____

Address/City/State/ZIP _____ DEA # _____

Hospira Customer Number (ship to #) if applicable _____ Your reference # (e.g. PO, Debit Memo or Invoice #) _____

Completed by: Printed Name/Signature/Date _____

☐ I have **NO** affected product (fill out and return this form to Stericycle at the fax/e-mail above).

☐ **YES**, I have affected product (fill out and return this form to Stericycle via the fax/e-mail above and return the product per the instructions on the return label).

- If yes, do you intend to return the affected product? YES __ NO___

If affected product is not being returned, please explain:

- Have you distributed the product further? YES___ NO___
  - If yes, have you notified your customers? YES___ NO __ (if no, explain below)

NDC and Lot Number*	Quantity to be returned	Wholesaler/Distributor Name If you purchased from Wholesalers/Distributors include name, address, city, state, ZIP, quantity from each, and invoice number. If you purchased directly from Hospira leave this section blank.	PO, debit memo or invoice
NDC: 0409-1273-32 Lot: 52610LL			
NDC: 0409-1273-32 Lot: 57660LL			

*Note: The lot number may be followed by numbers from 01 to 99.

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FA1606-01