

VOLUNTARY MARKET WITHDRAWAL

June 29, 2018

Daptomycin For Injection, 500mg per Vial

Product Description	Presentation	NDC Number
Daptomycin For Injection, 500 mg per Vial	1 vial/Carton 10 Cartons/bundle 10 bundles/shipper	0409-0106-01

Dear Customer:

Hospira, Inc., a Pfizer company, is voluntarily withdrawing 15 lots (refer to appendix 1) of Hospira's **Daptomycin for Injection** 500 mg, Lyophilized Powder For Solution, Single Dose Vial. Hospira's decision is based on a review of safety information regarding reported infusion reactions associated with Hospira's Daptomycin for Injection. The most common infusion reaction adverse events reported to date were chills, tremors, pyrexia and dyspnea. Other infusion reaction adverse events reported included events such as tachycardia and blood pressure changes. This decision is made out of an abundance of caution for patients while Hospira continues its investigation. This withdrawal only applies to the lots listed in the table below of Hospira's Daptomycin for Injection.

HOSPIRA RECOMMENDS THAT YOU RESPOND TO THIS MARKET WITHDRAWAL, EVEN IF YOU DO NOT HAVE THE WITHDRAWN PRODUCT. TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ENCLOSED POSTAGE-PAID, BUSINESS REPLY CARD (BRC) AND RETURN IT TO US, 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).

Our records indicate that you may have received shipment of one or more of the affected lots between January 2017 through May 2018. Please check your stock immediately against the table below. 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 8784 using the enclosed pre-paid UPS label. 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 1-800-805-3093.

If you have further distributed any of these lots to other accounts, please conduct a sub-withdrawal to those accounts and communicate this market withdrawal information immediately. Please request that they immediately cease distribution of the affected lots and promptly return the product directly to the above Stericycle Inc. address. Please contact Stericycle at 1-800-805-3093 for return instructions.

Wholesalers/distributors/hospitals/retailers/physicians and healthcare providers with an existing inventory of the lots which are being withdrawn, should stop use and distribution and quarantine immediately as well as inform other Healthcare Professionals in their organization as appropriate.

Reimbursement for the returned product will be made by credit memorandum. Please contact Pfizer Customer Service at 1-844-646-4398 (Mon.-Fri. 8 am-7 pm ET) or your Pfizer representative regarding product availability and for questions regarding this market action.

This market withdrawal 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.

Healthcare Professionals with questions regarding this withdrawal can contact Pfizer using the below information.

Contact	Contact Information	Areas of Support
Pfizer Medical Information	1-800-438-1985, option 3 (8am to 7pm 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 Essential Health

Appendix 1: Daptomycin for Injection Lots and Packaging Information

NDC Number	Lot Numbers	Expiration Date	Strength	Configuration/Count
0409-0106-01	702053A	1-Oct-18	500 mg per Vial	1 vial/Carton 10 Cartons/bundle 10 bundles/shipper
	702103A	1-Oct-18		
	702153A	1-Oct-18		
	712403A	1-Nov-18		
	712503A	1-Nov-18		
	721703A	1-Dec-18		
	721853A	1-Dec-18		
	721903A	1-Dec-18		
	742953A	1-Feb-19		
	760353A	1-Apr-19		
	770403A	1-May-19		
	770913A	1-May-19		
	772203A	1-May-19		
	791003A	1-Jul-19		
	841603A	1-Dec-19		