Hospira Issues Voluntary Nationwide Recall Of Daptomycin For Injection Lyophilized Powder For Solution, Due to Infusion Reactions

Friday, June 29, 2018 - 08:04am

FOR IMMEDIATE RELEASE-LAKE FOREST, IL., June 28, 2018 - Hospira, Inc., a Pfizer company, is voluntarily recalling 8 lots of Hospira's **Daptomycin for Injection 500 mg, Lyophilized Powder For Solution, Single Dose Vial** (NDC 0409-0106-01) to the Hospital/Retail level. The product is being recalled due to adverse event reports indicative of infusion reactions.

Daptomycin for Injection has been associated with reports of adverse events indicative of infusion reactions, including chills, tremor, pyrexia and dyspnea. Other infusion reaction adverse events, that were reported, included events such as tachycardia and blood pressure changes. This recall decision is made out of an abundance of caution for patients while Hospira continues its investigation into the reported infusion reactions.

This recall only applies to the lots listed in the table below of Hospira's Daptomycin for Injection.

Daptomycin for Injection, a lipopeptide antibacterial, is indicated for complicated skin and skin structure infections (cSSSI) in adult patients and, Staphylococcus aureus bloodstream infections (bacteremia), including those with right-sided infective endocarditis in adult patients. It is administered to adult patients intravenously in 0.9% sodium chloride, either by injection over a 2-minute period or by infusion over a 30-minute period. It is supplied as a sterile pale yellow to light brown lyophilized cake or powder in a single-dose 10 mL vial containing 500 mg of Daptomycin: Package of 1.

The NDC, Lot Numbers, Expiration Date, Strength and Configuration details for the recalled lots of Daptomycin for Injection are indicated in the table below. Product lots were distributed nationwide to wholesalers/distributors/hospitals/retailers in the United States and Puerto Rico from January 2017 through June 2018.

Daptomycin for Injection Lots and Packaging Information

NDC Number Lot Numbers Expiration Date Strength Configuration/Count 0409-0106-01 712453A 1-Nov-18 500 mg per Vial 1 vial/Carton 10 Cartons/bundle 10 bundles/shipper 771803A 1-May-19 792103A 1-July-19 800903A 1-Aug-19 810853A 1-Sep-19 841703A 1-Dec-19 841753A 1-Dec-19 850553A 1-Jan-20

Hospira places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process.

Hospira has notified wholesalers/distributors/hospitals/ retailers via recall letter to arrange for return of any recalled product.

Wholesalers/ distributors/ hospitals/ retailers/ physicians and healthcare providers with an existing inventory of the lots, which are being recalled, should stop use and distribution and quarantine immediately as well as inform other Healthcare Professionals in their organization as appropriate. Hospitals or retailers that have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product from them. For additional assistance, call Stericycle at 1-800-805-3093 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

Consumers receiving Hospira Daptomycin or experiencing problems that may be related to taking or using the product should contact their physician or healthcare provider.

Healthcare Professionals with questions regarding this recall 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

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm **Regular**

Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being executed with the knowledge of the U.S. Food and Drug Administration.

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