Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: October 9, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Hospira, Inc. [Drug]

AFFECTED PRODUCT: **Vancomycin Hydrochloride for Injection, USP**

SUMMARY: **Unclassified Recall; This recall has been initiated because the product may have experienced temperature excursions during shipment to a customer and then was further distributed by the customer.**

The recalled product is Vancomycin Hydrochloride for Injection, USP, Equivalent to 1 g Vancomycin (Sterile Powder), NDC 0409-6533-01, Lot 35-315-DD with expiration date of 01 NOV 2015.

The product was distributed nationwide.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-844-861-6215 between the hours of 8am to 5pm ET, Monday through Friday.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Hospira Issues a Voluntary Nationwide Recall of One Lot of Vancomycin Hydrochloride for Injection USP, Equivalent to 1 G Vancomycin (Sterile Powder) Due to Uncontrolled Storage During Transit

Contact
Consumer:
1-800-615-0187

Media:
224-212-2357

FOR IMMEDIATE RELEASE - October 7, 2014 - Hospira, Inc. (NYSE: HSP), announced today it is initiating a voluntary nationwide user-level recall of one lot of Vancomycin Hydrochloride for Injection, USP, Equivalent to 1 g Vancomycin (Sterile Powder), NDC 0409-6533-01, Lot 35-315-DD with expiration date of 01 NOV 2015. This action is because the product may have experienced temperature excursions during shipment to a customer and then was further distributed by the customer. There have been no adverse events or complaints reported for the affected lot. Hospira is undertaking the recall out of an abundance of caution.

Due to lack of information on the effect of uncontrolled temperatures on vancomycin and toxicological and clinical characterization of potential degradants, a meaningful medical risk assessment cannot be performed.

Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. This recall is being carried out to the medical facility/retail level (both human and veterinary). Please notify all users in your facility. If you have further distributed the recalled product please notify any accounts or additional locations which may have received the recalled product from you and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the medical facility/retail level. In addition, customers should inform potential users of this product in their organizations of this notification. Hospira will be notifying its direct customers via a recall letter and will arrange for impacted product to be returned to Stericycle. For additional assistance, call Stericycle at 1-844-861-6215 between the hours of 8am to 5pm ET, Monday through Friday.

For clinical inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Global Complaint Management	1-800-441-4100 (8am-5pm CT, M-F) (ProductComplaintsPP@hospira.com)	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 or medcom@hospira.com (Available 24 hours a day/7 days per week)	Medical inquiries

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 conducted with the knowledge of the U.S. Food and Drug Administration.

About Hospira
Hospira, Inc. is the world's leading provider of injectable drugs and infusion technologies, and a global leader in biosimilars. Through its broad, integrated portfolio, Hospira is uniquely positioned to Advance Wellness™ by improving patient and caregiver safety while reducing healthcare costs. The company is headquartered in Lake Forest, Ill., and has approximately 17,000 employees. Learn more at www.hospira.com.

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