



A  Pfizer Company

**Hospira Issues A Voluntary Nationwide Recall For One Lot of
Vancomycin Hydrochloride for Injection, USP, 750 mg/vial Due to
The Presence of Particulate Matter Within a Single Vial**

Consumers Contact: 1-888-345-4680
Media Contact: 610-329-1340

For Immediate Release-LAKE FOREST, Ill., August 30, 2017 - Hospira, Inc., a Pfizer company, is voluntarily recalling one lot of Vancomycin Hydrochloride for Injection, USP, 750 mg/vial (NDC 0409-6531-02) lot 632153A, to the hospital/retailer level. The recall was due to a confirmed customer report for the presence of particulate matter, confirmed as glass, within a single vial. To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

In the event the particulate is administered to a patient, it may result in phlebitis, end-organ granuloma or micro-embolic effects, or gastrointestinal trauma. The risk is reduced by the possibility of detection, as the label contains a clear statement directing the healthcare professional to visually inspect the product for particulate matter and discoloration prior to administration.

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

Vancomycin Hydrochloride is indicated for the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant staphylococci. Vancomycin Hydrochloride is effective in the treatment of staphylococcal endocarditis, septicemia, bone infections, lower respiratory tract infections, and skin and skin-structure infections. It is used in penicillin-allergic patients, and also for patients who cannot receive or who have failed to respond to other antimicrobials, including penicillin or cephalosporin agents, and for infections caused by vancomycin-susceptible organisms that are resistant to other antimicrobials.

Vancomycin Hydrochloride USP, 750 mg/vial NDC: 0409-6531-02, Lot 632153A, Expiry Date 01 MAR 2018, is packaged in a carton containing 10 units. The lot was distributed from August 2016 through January 2017 nationwide in the United States and Puerto Rico. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine immediately. Inform Healthcare Professionals in your organization of this recall. 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 redistributed the product, they should notify their accounts, locations or facilities of the recall to the hospital level. Hospira will be notifying its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. 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.

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

Hospira Contact	Contact Information	Areas of Support
Pfizer Complaint Management	1-800-438-1985 (24 hours a day 7 days per week)	To report adverse events or product complaints
Pfizer Medical Information	1-800-615-0187 (8am to 7pm ET Monday through Friday)	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 executed with the knowledge of the U.S. Food and Drug Administration.

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