



A Pfizer Company

For immediate release
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Consumers Contact
888-345-4680

Media Contact
610-329-1340

**Hospira Issues A Voluntary Nationwide Recall For One Lot Of
Vancomycin Hydrochloride for Injection, USP Due To
The Presence of Particulate Matter Within a Single Vial**

LAKE FOREST, Ill., January 24 - Hospira, Inc., a Pfizer company, is voluntarily recalling one lot of Vancomycin Hydrochloride for Injection, USP (NDC: 0409-6510-01, Lot 591053A, Expiry Date 1NOV2017), to the hospital/retail level due to a confirmed customer report for the presence of particulate matter within a single vial.

In the unlikely event that the particulate is administered to a patient, it may result in local swelling, irritation of blood vessels or tissue, blockage of blood vessels and/or low-level allergic response to the particulate. The risk is reduced by the possibility of detection, as the label contains a clear statement directing the physician to visually inspect the product for particulate matter and discoloration prior to administration.

To date, Hospira has not received reports of any adverse events associated with this issue for this lot. 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.

The product is packaged in a carton containing 1x100 mL vial. The lot was distributed from August 2016 through September 2016 in the United States. Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Inform health care 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/retail 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 1-888-570-1678 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
Hospira Global Complaint Management	1-800-441-4100 (8am-5pm CT, M-F) (ProductComplaintsPP@hospira.com)	To report adverse events or product complaints
Pfizer Medical Information	1-800-615-0187 (7am-6pm CT, M-F)	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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