Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Wednesday, January 25, 2017 8:52 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Vancomycin Hydrochloride for Injection, USP by Hospira: Recall - Particulate Matter in Vial

AUDIENCE: Pharmacy

ISSUE: Hospira, Inc. 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. 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.

If 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.

BACKGROUND: Vancomycin Hydrochloride is indicated for the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant staphylococci.

RECOMMENDATION: 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form 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

[01/24/2017 - Press Release - FDA]