From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@DCALISTS.CA.GOV> on behalf of Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Wednesday, December 27, 2017 8:13 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: Linezolid Injection by Auromedics Pharma: Recall - Due to Presence White Particle Matter That Has Been Identified as Mold

Linezolid Injection by Auromedics Pharma: Voluntary Recall - Due to Presence White Particle Matter That Has Been Identified as Mold

AUDIENCE: Risk Manager, Pharmacy, Nurse

ISSUE: AuroMedics Pharma is voluntarily recalling one lot of Linezolid Injection 600mg/300mL flexible bags, NDC 55150 - 242 -51 batch CLZ160007 expiration August 2018 to the hospital level. This batch was distributed May 15 through August 14, 2017. The product was found to contain white particulate matter that has been identified as mold.

BACKGROUND: Linezolid injection is an oxazolidinone-class antibacterial indicated in adults and children for the treatment of the following infections caused by susceptible Gram-positive bacteria:

- Nosocomial pneumonia
- Community-acquired pneumonia
- Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis
- Uncomplicated skin and skin structure infections
- Vancomycin-resistant Enterococcus faecium infections.

Linezolid injection is supplied as a ready-to-use sterile, clear colorless to slightly yellow color isotonic solution for intravenous infusion. Each 300 mL contains 600 mg of linezolid. Inactive ingredients are sodium citrate, citric acid, and dextrose in an aqueous vehicle for intravenous administration. The sodium (Na+) content is 0.38 mg/mL (5 mEq/300 mL bag). It is available in single-use, ready-to-use flexible plastic infusion bags in a foil laminate overwrap.

RECOMMENDATION: Healthcare professionals patients and consumers who have the product lot which is being recalled should immediately stop using and return to place of purchase/contact their doctor as appropriate.

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

Read the MedWatch Safety Alert, including a link to the FDA Drug Safety Communication, at:
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/UCM590485.htm

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.

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