Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Auromedics Pharma LLC Issues Voluntary Nationwide Recall of Linezolid Injection 600mg/300ml, due to Presence White Particulate Matter that has been Identified as Mold

For Immediate Release

December 22, 2017

Contact

Consumers

866-850-2876

Announcement

View Product Photos

AuroMedics Pharma LLC 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. This problem was discovered as a result of a product complaint in which the contents of one flexible bag from one batch CLZ160007 was found to contain white particulate matter.

Use of a non-sterile injectable product could result in fatal infections in a broad array of patients. To date, AuroMedics Pharma LLC has not received reports of any adverse events or identifiable safety concerns attributed to this recall.

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 (1.1); Community-acquired pneumonia (1.1); Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis (1.2); Uncomplicated skin and skin structure infections (1.2); Vancomycin-resistant *Enterococcus faecium* infections (1.3). 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. The infusion bags and ports are latex-free.

The affected Linezolid Injection lot being recalled is CLZ160007, EXP. August 2018. The product can be identified as a single-use, ready-to-use flexible plastic infusion bag in a foil laminate overwrap. A u r o M ed i cs commenced shipping the product to customers May 15 through August 14, 2017 and was distributed to wholesalers and/or hospitals nationwide.

AuroMedics Pharma LLC is notifying its distributors and customers by recall letters and is arranging for return/replacement etc. of all recalled product.

Consumers/distributors/retailers that have the product lot which is being recalled should immediately stop using and return to place of purchase/contact their doctor as appropriate.

Consumers with questions regarding this recall can contact Aurobindo Customer Service weekdays 9:00AM to 5:00PM EST at 866-850-2876 Option 1. If you need assistance in returning your product or have questions about the recall process, contact Inmar at 800-967- 5952 weekdays Monday through Friday 8:30 AM to 5:00 PM EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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 (http://www.fda.gov/MedWatch/report.htm)**1
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)**2 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.

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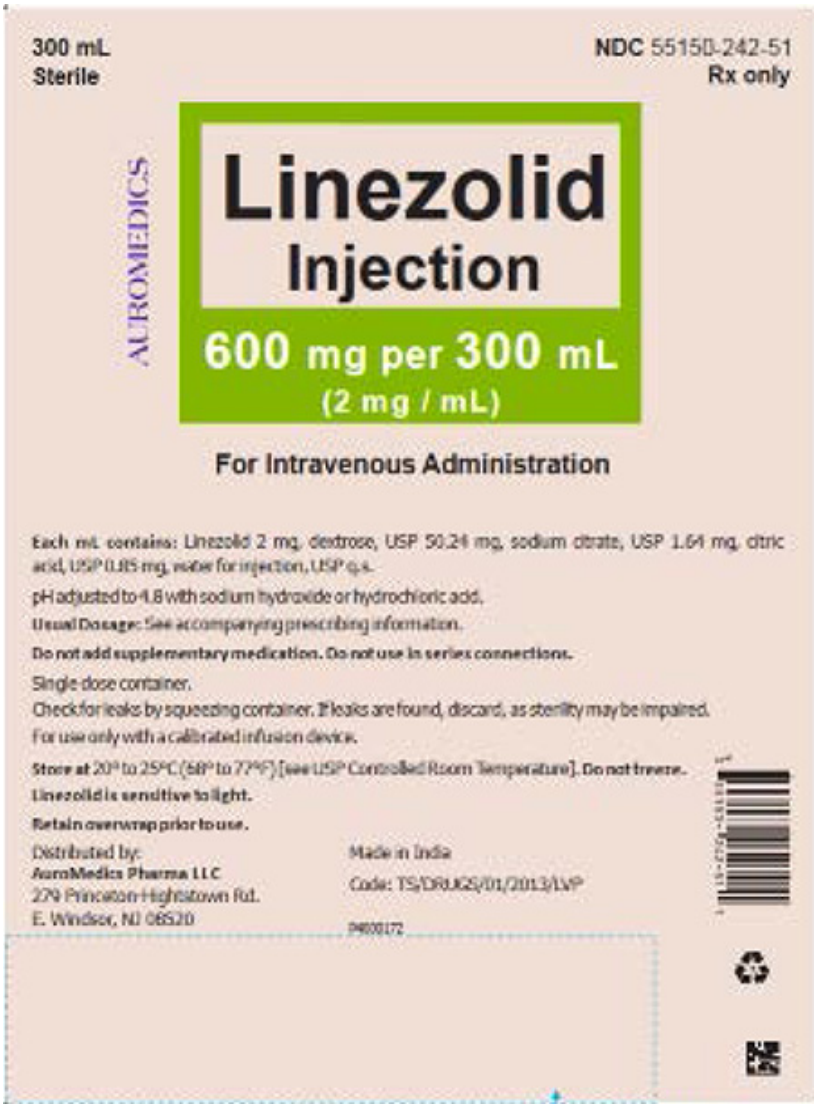

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