

AuroMedics Pharma - Recall of Linezolid Injection

- On December 26, 2017, the <u>FDA announced</u> a voluntary recall of one lot of AuroMedics Pharma's <u>linezolid</u> injection due to a product complaint in which the contents of one flexible bag from the recalled lot was found to contain white particulate matter identified as mold.
- The recalled lot was distributed May 15, 2017 through August 14, 2017.

Product Description	NDC #	Lot # (expiration date)
Linezolid injection 600 mg/300 mL flexible bags	55150-242-51	CLZ160007 (August 2018)

- Linezolid injection is indicated for the treatment of infections caused by susceptible strains of certain microorganisms of various conditions, including pneumonia, skin and skin structure infections, and vancomycin-resistant *Enterococcus faecium* infections.
- Use of a non-sterile injectable product could result in fatal infections in a broad array of patients. To date, AuroMedics Pharma has not received reports of any adverse events or identifiable safety concerns attributed to this recall.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to taking or using the recalled linezolid injection.
- Anyone with recalled product should stop use and distribution, quarantine the product, and return to the place of purchase. Contact Inmar at 1-800-967-5952 for return information. For general questions regarding this recall, contact Aurobindo (affiliate of AuroMedics) at 1-866-850-2876.



optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.