COMPANY ANNOUNCEMENT

AuroMedics Pharma LLC Issues Voluntary Nationwide Recall of Levofloxacin in 5% Dextrose 250mg/50mL Due to Presence of Visible Particulate Matter Tentatively Identified as Mold

Summary

Company Announcement Date:

January 11, 2018

FDA Publish Date:

April 14, 2020

Product Type:

Drugs

Reason for Announcement:

Due to the Presence of Particulate Matter

Company Name:

AuroMedics Pharma LLC

Brand Name:

AuroMedics

Product Description:

Levofloxacin in 5% Dextrose Injection 250mg/50mL

Company Announcement

AuroMedics Pharma LLC is voluntarily recalling one lot of Levofloxacin in 5% Dextrose Injection 250mg/50mL in a Single-Use flexible container NDC 55150-243-46, Lot CLF160003, Expiry date May 2018, to the hospital level. The product has been found to contain visible

particulate matter tentatively identified as mold. This problem was discovered as a result of a product complaint in which the contents of one flexible bag was found to contain white particulate matter.

Risk Statement: 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.

Levofloxacin injection is indicated for the treatment of adults (≥18 years of age) with mild, moderate, and severe infections caused by susceptible isolates of the designated microorganisms in the specified conditions. Levofloxacin injection is indicated when intravenous administration offers a route of administration advantageous to the patient (e.g., patient cannot tolerate an oral dosage form). The affected Levofloxacin in 5% Dextrose Injection 250mg/50mL lot being recalled is CLF160003, Expiry date May 2018. This recall is being carried out to the hospital level. It is packaged in a carton containing 24 bags, NDC: 55150-243-46. The product can be identified as a single-use, ready-to-use flexible plastic infusion bag in a foil laminate overwrap. AuroMedics shipped the lot to wholesalers and/or hospitals nationwide September 19 through October 31, 2017.

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 AuroMedics Customer Service Monday through Friday from 9:00AM to 5:00PM EST at 888-238-7880 Option 1. If you need assistance in returning your product or have questions about the recall process, contact Inmar at 800-967-5952, Monday through Friday from 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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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.

Company Contact Information

Consumers:

Inmar

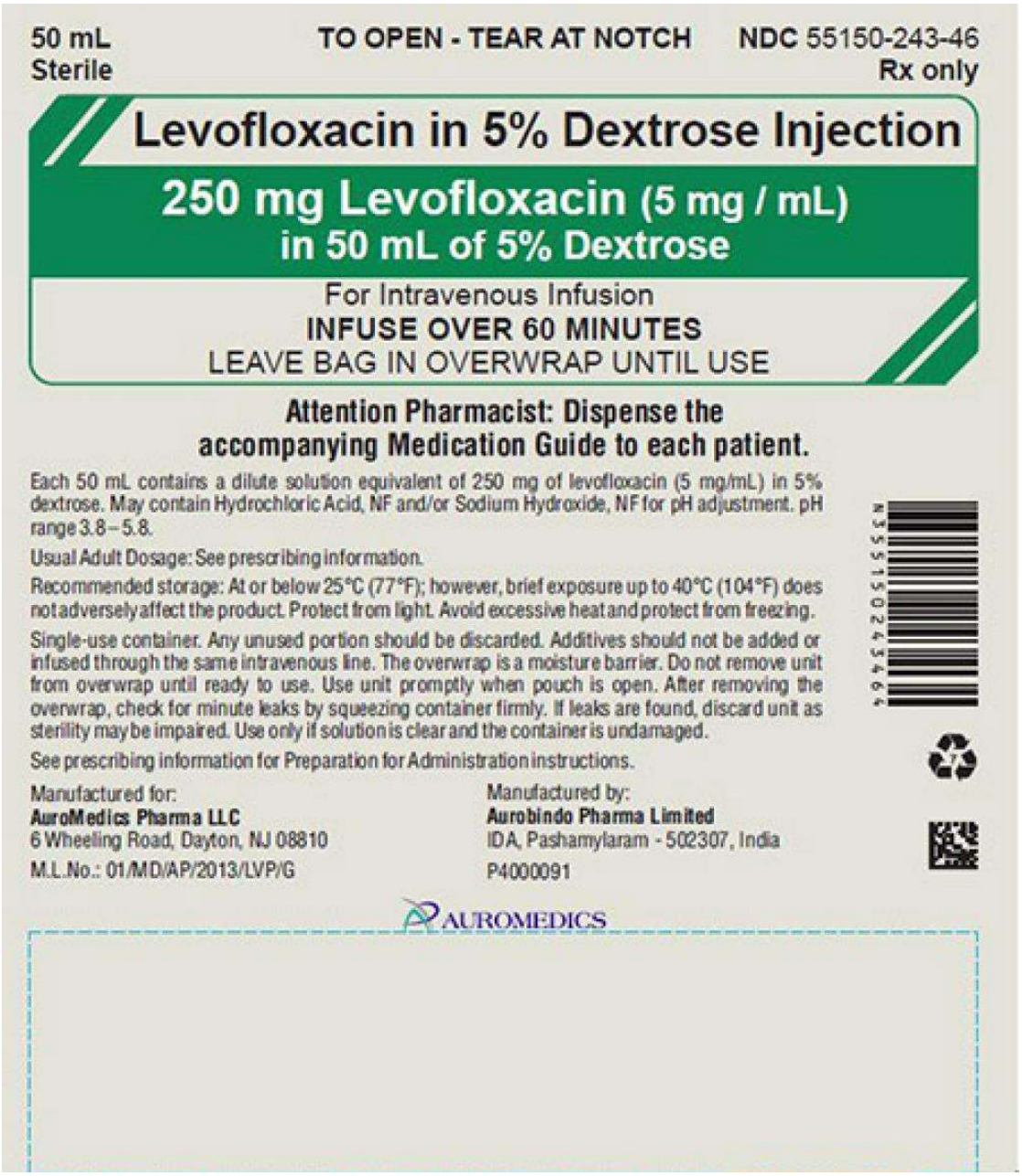
888-238-7880; 800-967-5952

Media:

Steve Lucas

732-823-4122

Product Photos



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