Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC24-041-CG
September 20, 2024

FDA announced that Princeton, NJ, Bionpharma Inc. is voluntarily recalling (1) single Batch (2310083) of Atovaquone Oral Suspension, 750mg per mL to the consumer level. The product was manufactured by CoreRx, Inc. in Clearwater, FL and distributed by Bionpharma Inc. The product was found to be contaminated with Cohnella bacteria

RECOMMENDATIONS

1. The Company is notifying its distributors and customers by email and is arranging for return/replacement etc. of the recalled batch of the product. Distributors/retailers that have affected lot of the drug product which is being recalled should immediately cease distribution and remove it from active inventory.

2. Consumers that have the affected lot of the product should stop using the product and return to the place of purchase.

3. Consumers with questions regarding this recall can contact Bionpharma by phone at (888) 235-2466 (Mon-Fri 9AM-5PM EST) or via email to drugsafety@bionpharma.com.

4. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the affected lot of the drug product.

5. Review your inventory to identify existence of recalled products.

6. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

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Bionpharma Inc. Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension Due to Bacterial Contamination

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SUMMARY:

Company Announcement Date:	September 17, 2024
FDA Publish Date:	September 18, 2024
Product Type:	Drugs
Reason for Announcement:	Product found to be contaminated with Cohnella bacteria
Company Name:	Bionpharma Inc.
Brand Name:	Bionpharma
Product Description:	Atovaquone Oral Suspension, 750 mg/mL

COMPANY ANNOUNCEMENT:

FOR IMMEDIATE RELEASE – September 17, 2024 – Princeton, NJ, Bionpharma Inc. is voluntarily recalling (1) single Batch (2310083) of Atovaquone Oral Suspension, 750mg per mL to the consumer level. The product was manufactured by CoreRx, Inc. in Clearwater, FL and distributed by Bionpharma Inc. The product was found to be contaminated with Cohnella bacteria.

Risk Statement: In the population most at risk, immunocompromised population, there is a reasonable probability that microbial contamination of Atovaquone Oral Suspension can result in disseminated, life threatening infections such as inflammation of the heart and permanent damage to soft tissue. To date, Bionpharma has not received any reports of adverse events related to this recall.

We take these findings seriously and are taking immediate action to address the situation. We have initiated a recall of the (1) affected batch listed below and are implementing enhanced quality control measures with our manufacturer, CoreRx, Inc. to prevent recurrence. Our priority remains the safety and well-being of our consumers, and we are committed to transparency throughout this process.

This product is a quinone antimicrobial drug indicated for prevention of pneumocycstis jirovecii pneumonia (formerly known as PCP for pneumocystis carinii pneumonia) in adults and adolescents aged 13 and older. The affected batch of product was manufactured at CoreRx, Inc. and shipped

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nationwide to our customers between December 21, 2023 and June 20, 2024 and distributed through wholesalers and retailers. The recall includes the following product and batch number:

Production Date	Release Date	Product Name	NDC	Lot No.	Expiration Date
October 26, 2023	December 05, 2023	Atovaquone Oral Suspension	69452-252-87	2310083	September 2025

The product can be identified by the HDPE white bottle, picture below.

The lot number can be obtained from the side panel of the bottle or the bottom flap of the carton.

The Company is notifying its distributors and customers by email and is arranging for return/replacement etc. of the recalled batch of the product. Distributors/retailers that have affected lot of the drug product which is being recalled should immediately cease distribution and remove it from active inventory. Consumers that have the affected lot of the product should stop using the product and return to the place of purchase.

Consumers with questions regarding this recall can contact Bionpharma by phone at (888) 235-2466 (Mon-Fri 9AM-5PM EST) or via email to drugsafety@bionpharma.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the affected lot of the 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**
- Regular Mail or Fax: **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**

Reporting to Company:

- Via phone at **(888) 235-2466 (Mon-Fri 9AM-5PM EST)**
- Via email to **drugsafety@bionpharma.com**

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