

FDA Drug Recall

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

09/18/2024

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 pneumocystis 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 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

Consumers:

Drug Safety Department, Bionpharma Inc.

Phone number: 1-888-235-2466

Product Photos



LOT: 2310083
EXP: 2025-SEP

Each bottle contains 750 mg atovaquone, USP.
See accompanying prescribing information for
complete information.
Store at 25°C (77°F); excursions permitted between
15°C and 30°C (59°F and 86°F); Use USP Controlled Room Temperature
conditions. Dispense in a tight container as defined in USP.
Do not use if the seal on the bottle is broken or missing.

Manufactured by

NDC 69452-252-87

Atovaquone Oral Suspension, USP

750 mg/5 mL

Each 5 mL (1 teaspoonful) contains 750 mg atovaquone, USP.

Usual Dosage: See accompanying prescribing information for dosage and administration.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

DO NOT FREEZE. Dispense in a tight container as defined in USP.

SHAKE GENTLY BEFORE USING.

Do not use if tamper-evident seal on bottle is broken or missing.

Rx only

210 mL

BIONPHARMA

DO NOT FREEZE. Dispense in a tight
container as defined in USP.

SHAKE GENTLY BEFORE USING.

Do not use if tamper-evident seal on
bottle is broken or missing.

Rx only

210 mL

BIONPHARMA



GTIN 00369452252871

S/N 10000000059442

LOT 2310083

EXP 2025-SEP

Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bionpharma-inc-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-due-bacterial?utm_medium=email&utm_source=govdelivery