COMMUNICATION

COM-2024-060

19 SEPTEMBER 2024

URGENT
PLEASE
REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

9/18/2024

Drug Information:

National Drug Code

69452-252-87

Product Description:

Atovaquone Oral Suspension, 750mg/mL

Lot Number

2310083

Expiration Date

September-2025

Company:

Bionpharma Inc.

QUESTIONS

Call Bionpharma by phone at (888) 235-2466, Monday - Friday, 9:00 a.m. – 5:00 p.m. EST or via email to drugsafety@bionpharma.com

Atovaquone Oral Suspension, USP

It is for this reason that we are notifying you that on 09.17.2024 the U.S. Food and Drug Administration published a drug recall for the following product(s): Atovaquone Oral Suspension, 750 mg/mL

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

Bionpharma Inc. is voluntarily recalling one (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.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- ext.219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Recall Communication Number COM-2024-060 September2024

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REFERENCES:

1. U.S. Food and Drug Administration. (2024). Bionpharma Inc. Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension Due to Bacterial Contamination. Retrieved September 18,2024 from: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bionpharma-inc-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-due-bacterial
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

urac ACCREDITED Pharmacy Benefit Management Expires 12/01/2025

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