Humana

Pharmacy Solutions®

Drug recall notice for atovaquone oral suspension

To assist you in the care of your patients, Humana is alerting you to the recall of one lot of atovaquone oral suspension 750 mg per mL on Sept. 17, 2024.[1] We recommend you review your medical records and contact all patients for whom you have prescribed this medication to warn them of the recall.

Bionpharma Inc. is voluntarily recalling these products due to contamination of the drug with Cohnella bacteria. The affected batch of product was manufactured by CoreRx, Inc. and distributed by Bionpharma Inc.

Atovaquone is indicated to prevent pneumocystis jirovecii pneumonia in those 13 years old and older. According to the U.S. Food and Drug Administration, there is a reasonable probability that the microbial contamination of atovaquone "can result in disseminated, life threatening infections such as inflammation of the heart and permanent damage to soft tissue."

To date, Bionpharma Inc. has received no reports of adverse events related to this recall.

Medications included in this recall
Visit the FDA website for specific details about the recalled medication.

Product name	National Drug Code	Lot number	Expiration date
atovaquone oral suspension	69452-252-87	2310083	September 2025

Information for providers:[1]

- We sent a letter to your Humana-covered patients with a claim for atovaquone oral suspension and asked them to contact their providers if their medication is included in the recall and if they have experienced problems that could be related to using these drug products.
- Providers with questions can contact:
  - Bionpharma at 888-235-2466, Monday – Friday, 9 a.m. – 5 p.m., Eastern time.
- Patients can report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting Program online, by phone or by fax.
  - **Online:** Submit the report.
    - Select "Form FDA 3500 - Voluntary Reporting."
  - **Phone or fax:** Download the form.
    - Complete and submit "Form FDA 3500 - Voluntary Reporting" by phone at 800-FDA-1088 (332-1088) or by fax to 800-FDA-0178 (332-0178).

Reference

1. “Bionpharma Inc. Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension Due to Bacterial Contamination,” U.S. Food and Drug Administration, last accessed Oct. 1, 2024, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bionpharma-inc-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-due-bacterial.