Bionpharma Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension

Date: 09/18/2024

About this recall:
Bionpharma is voluntarily recalling a single batch (lot) of Atovaquone Oral Suspension, 750 mg per 5 mL (NDC 69452-0252-87) to the consumer level due to contamination with *Cohnella* bacteria. The product was manufactured by CoreRx and distributed by Bionpharma.

This product is an antimicrobial drug indicated for prevention of a certain type of infection known as *Pneumocystis jirovecii* pneumonia (formerly known as PCP for *Pneumocystis carinii* pneumonia) in adults and adolescents aged 13 years and older. The recall is for lot #2310083 with expiration date of September 2025. The lot number is listed on the side panel of the manufacturer's bottle or the bottom flap of the manufacturer's carton.

What this means to you:
In patients with a weakened immune system (immunocompromised patients), the potential exists that microbial contamination of atovaquone oral suspension could result in serious, 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.

Consumers that have the recalled NDC and lot number 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 (Monday through Friday 9 AM to 5 PM EST) or via email at drugsafety@bionpharma.com. Consumers should contact their healthcare provider if they have experienced any problems that may be related to taking or using the recalled lot of the drug.

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-FDA0178.

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

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bionpharma-inc-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-due-bacterial

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.