Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC23-023-CG
April 3, 2023

FDA announced that Piscataway, NJ, Camber Pharmaceuticals, Inc. is voluntarily recalling lot # E220182 of Atovaquone Oral Suspension, USP 750mg/5mL to the Consumer/User level, due to the potential Bacillus cereus contamination in the product.

RECOMMENDATIONS

1. Camber Pharmaceuticals, Inc. is notifying its distributors and customers by our Reverse Logistics Company, Inmar, by mailings and emails communications method and is arranging for returns of all recalled Atovaquone Oral Suspension, USP.

2. Consumers/distributors/retailers that have product which is being recalled should stop using/return to place of purchase/discard/contact their doctor, etc.

3. Consumers with questions regarding this recall can contact Inmar by phone at **1-877-597-0878** or email rxrecalls@inmar.com, Monday – Friday, 9am – 5pm Eastern Time.

4. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this 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

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

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FDA U.S. FOOD & DRUG ADMINISTRATION

Camber Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension, USP 750mg/5mL Due to Potential Bacillus cereus Contamination in the Product.

Summary:

FDA Publish Date:	March 31, 2023
Product Type:	Drugs
Reason for Announcement:	Potential Bacillus cereus Contamination
Company Name:	Camber Pharmaceuticals, Inc.
Brand Name:	Camber
Product Description:	Device & Drug Safety / Microbial Contamination / Bacillus cereus

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Company Announcement

FOR IMMEDIATE RELEASE – 3/13/2023 – Piscataway, NJ, Camber Pharmaceuticals, Inc. is voluntarily recalling lot # E220182 of Atovaquone Oral Suspension, USP 750mg/5mL to the **Consumer/User** level, due to the potential Bacillus cereus contamination in the product.

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 endocarditis and necrotizing soft tissue infections. *To date, Camber has not received any reports of adverse events related to this recall.*

Atovaquone Oral Suspension, USP is indicated for prevention and treatment of Pneumocystis jiroveci pneumonia (PCP) in adults and children 13 years of age and older who cannot tolerate other medicines, such as trimethoprim-sulfamethoxazole.

Atovaquone Oral Suspension, USP was distributed Nationwide to Wholesalers, Distributors, Retail Pharmacies, and Mail Order Pharmacies.

The product is packaged in 210mL HDPE bottle in a mono carton. The identified NDC # associated with the product is 31722-629-21, UPC # 331722629218, and the affected lot# is E220182 with an expiration date of 12/2023.

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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: www.fda.gov/medwatch/report.htm**
- **Regular Mail or Fax:** Download form **www.fda.gov/MedWatch/getforms.htm** 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**

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