Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC24-017-CG
April 3, 2024

FDA announced that **AvKARE, LLC**. is voluntarily **recalling lot # AW0221A of Atovaquone Oral Suspension, USP 750mg/5mL** to the Consumer/User level, due to the potential Bacillus cereus contamination in the product found during stability testing at a 3rd party lab

RECOMMENDATIONS

1. AvKARE, LLC is notifying its distributors and wholesale customers by mailings and email communications method and is arranging for returns of all recalled Atovaquone Oral Suspension, USP.
2. Wholesalers who have Atovaquone Oral Suspension, USP 750mg/5mL, which are being recalled, should examine their inventory and cease dispensing, return any of the impacted lots to AvKARE, LLC.
3. Consumers that have product which is being recalled should stop using the product and return it to place of purchase or discard. Consumers with questions regarding this recall can contact AvKARE by phone at 1-855-361-3993 or email drugsafety@avkare.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

FDA U.S. FOOD & DRUG ADMINISTRATION

AvKARE, LLC. Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension, USP 750 mg/5 mL Due to Potential Bacillus Cereus Contamination

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SUMMARY:

Company Announcement Date:	April 1, 2024
FDA Publish Date:	April 1, 2024
Product Type:	Drugs
Reason for Announcement:	Potential Bacillus cereus contamination
Company Name:	AvKARE, LLC
Brand Name:	AVpak
Product Description:	Atovaquone Oral Suspension, USP 750mg/5mL

COMPANY ANNOUNCEMENT

FOR IMMEDIATE RELEASE – 3/29/2024 –AvKARE, LLC. is voluntarily recalling lot # AW0221A of Atovaquone Oral Suspension, USP 750mg/5mL to the Consumer/User level, due to the potential *Bacillus cereus* contamination in the product found during stability testing at a 3rd party lab.

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, AvKARE 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 between 03/18/2024 through 03/21/2024 Nationwide to Wholesalers.

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The product is packaged in a carton. The identified NDC # associated with the product is UPC # 5026808612 and the affected lot# is AW0221A with an expiration date of 08/2025.

AvKARE, LLC is notifying its distributors and wholesale customers by mailings and email communications method and is arranging for returns of all recalled Atovaquone Oral Suspension, USP.

Wholesalers who have Atovaquone Oral Suspension, USP 750mg/5mL, which are being recalled, should examine their inventory and cease dispensing, return any of the impacted lots to AvKARE, LLC.

Consumers that have product which is being recalled should stop using the product and return it to place of purchase or discard. Consumers with questions regarding this recall can contact AvKARE by phone at **1-855-361-3993** or email drugsafety@avkare.com, Monday – Friday, 9am – 5pm Eastern Time. 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.

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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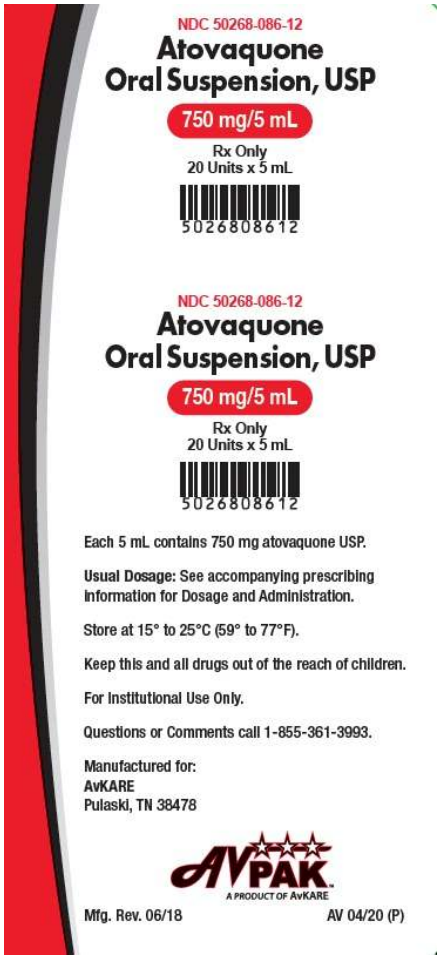

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