COMMUNICATION

COM-2024-027

2
April
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:

4/1/2024

Drug Information:

National Drug Code

50268-086-12

Product Description:

Atovaquone Oral Suspension, UPS 750mg/5mL

Lot Number

AW0221A

Expiration Date

August 2025

Company:

AvKARE, LLC

QUESTIONS

Call AvKAREKE, at 1 (855) 361-3993 Monday – Friday, 9:00 am – 5:00 pm ET or by email at drugsafety@avkare.com.

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Atovaquone Oral Suspension

It is for this reason that we are notifying you that on 04.01.2024 the U.S. Food and Drug Administration published a drug recall for the following product(s): Atovaquone Oral Suspension, USP 750mg/5mL.

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:

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 third-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.

Atovaquone Oral Suspension, USP was distributed between 03/18/2024 through 03/21/2024 nationwide to Wholesalers. To date, AvKARE 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-2024-027 April 2024

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REFERENCES:

1. U.S. Food and Drug Administration. (2024). AvKARE, LLC. AvKARE, LLC. Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension, USP 750 mg/5 mL Due to Potential Bacillus Cereus Contamination. from: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/avkare-llc-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-usp-750-mg5-ml-due
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

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