COMMUNICATION

COM-2023-019

05
APRIL
2023

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:

03/31/2023

Drug Information:

National Drug Code

31722-629-21

Product Description

ATOVAQUONE ORAL SUSPENSION, USP 750MG/5ML

Lot Number

E220182

Expiration Date

DECEMBER 2023

Company:

CAMBER PHARMACEUTICALS, INC.

QUESTIONS

Call INMAR at 1.877.597.0878

Monday – Friday from 9:00 a.m. to 5:00 p.m. ET.

Atovaquone.

It is for this reason that we are notifying you that on 03.31.2023 the US 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:

Camber Pharmaceuticals Inc. is voluntarily recalling lot #E220182 of atovaquone oral suspension 750mg/5mL to the consumer level due to the potential *Bacillus cereus* contamination in the product.

There is a reasonable probability that microbial contamination of Atovaquone Oral Suspension can result in disseminated, life-threatening infections in populations most at risk such as immunocompromised individuals. To date, Camber has not received any reports of adverse events related to this recall.

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

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. 220. 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
POWERED BY ONEARK

urac
ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2025

REFERENCES:
1. U.S. Food and Drug Administration. (2023). Camber Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Atovaquone Oral Suspension, USP 750mg/5mL Due to Potential Bacillus Cereus Contamination in the Production. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/camber-pharmaceuticals-inc-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-usp
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

2 Street 1, Suite 500
Guaynabo, PR 00968
Tel. 787.522.5252
Fax 866.912.2830
www.pharmpix.com
FRM-CL-000126-001

CLINICAL PEARLS
BY PHARMPIX