

**URGENT DRUG RECALL NOTICE – CONSUMER LEVEL**

Recalling Firm:
Camber Pharmaceuticals, Inc.
800 Centennial Ave.
Piscataway, NJ 08854

Date: March 15th, 2023

Product Description	NDC Number	Package Size	Lot Numbers	Expiry Dates	**Distribution Dates**
Atovaquone Oral Suspension USP 750mg/5mL	31722-629-21	210mL HDPE Bottle	E220182	12/2023	6/2022

REASON: Provide a description of the reason and health hazard for the recall.

The recall has been initiated due to the potential *Bacillus Cereus* contamination in the Product for Batch No: E220182.

LEVEL: Specify the level of the recall.

This recall is being carried out to the Consumer level and is for batch E220182 which is referenced above. This recall is being conducted with the knowledge of the Food and Drug Administration.

ACTION: Describes actions to be taken by direct customers

1. Immediately examine your inventory, stop dispensing, and quarantine the batch subject to recall.
2. Please carry out a physical count and record this data on the verification response form included with this letter.
3. Complete and return the attached response form ***even if you do not have the recalled product.***
4. Notifications of this recall are being sent to all direct distributor accounts of Camber through Inmar. If you further distributed this product, please forward this notification to your retail and consumer customers as it is a **CONSUMER LEVEL RECALL.**
5. Completed Recall Return Response form can be submitted by any of the below methods:

Fax to 1-817-868-5362

E-mail to: rxrecalls@inmar.com

Or mail to:

Inmar, Attn: Recall Coordinator, One West Fourth Street., Suite 500 Winston-Salem, NC 27101.

*****If you are a Consumer, we are providing reimbursement for returned product. To qualify for reimbursement, the product must be returned to Inmar, along with the proof of purchase.*****



Other Information: Provide necessary contact information for distributor, retailer, and consumer for recall, including contact for medical and product questions and cost recovery information.

If you have any questions about the return of the product, please contact Inmar at 1-877-597-0878.

(Operation time is, Mon -Fri 9:00am to 5:00pm EST; outside of those operating hours we have voicemail and email that will be responded to in the next business day).

If you have medical questions call 1-866-495-1995 or Customer Service-related questions, please contact Camber at 1-732-529-0433.

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

We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience caused by this action.

AUTHORIZED BY:

Name: Raghunath Chigurupati

Title: Manager, Regulatory Affairs

Signature: _____

Date: _____

03/15/2023

**CONSUMER RECALL RETURN RESPONSE FORM**

Product Recall Verification/Response Form
Atovaquone Oral Suspension USP 750mg/5mL

If you are a Consumer, complete the form below.

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Any adverse events associated with recalled product? ☐ Yes ☐ No

If Yes, please explain: _____

Please check the appropriate box(es):

☐ Consumer ☐ Other _____

Contact Name (please print) _____

Address _____

City _____ State _____ Zip _____

Telephone # _____

Contact Signature _____ Date _____

Product Description	NDC Number	Package Size	Lot Numbers	Expiry Date	QTY Returning (in bottles)
Atovaquone Oral Suspension USP 750mg/5mL	31722-629-21	210mL HDPE Bottle	E220182	12/2023	

If you are a Consumer, we are providing reimbursement for returned product. To qualify for reimbursement, **the product must be returned to Inmar, along with the proof of purchase.**

Purchased From: _____

Address _____

City _____ State _____ Zip _____

If you have any questions regarding this form or product return, please contact Inmar at 1-877-597-0878. Office hours 9am to 5pm EST Mon thru Fri.

Please fax this form to: 1-817-868-5362 or e-mail this form to: rxrecalls@inmar.com or mail to: Inmar, Attn: Recall Coordinator, One West Fourth Street., Suite 500 Winston-Salem, NC 27101.

Container Label of Batch No. E220182

Each 5 mL (1 teaspoonful) contains 750 mg atovaquone USP.

Usual Dosage: See accompanying prescribing information for Dosage and Administration.

Store at 15°C to 25°C (59°F to 77°F).

DO NOT FREEZE. Dispense in tight container as defined in USP.

SHAKE GENTLY BEFORE USING.

U.S. Contact Number:
1-866-495-1995

Manufactured for:
Camber Pharmaceuticals, Inc.
Piscataway, NJ 08854

CAMBER™
PHARMACEUTICALS, INC.

NDC 31722-629-21

Atovaquone Oral Suspension, USP
750 mg/5 mL

Rx only 210 mL

3 31722-629-21 8

Handwritten: KP 27-01-2022

BATCH NO.: E220182
MFG DATE: 01/2022
EXP DATE: 12/2023

Handwritten: R 27-01-2022

Mfg. Lic. No.: 22/RR/AP/2001/FR

By: **HETERO™**
Hetero Labs Limited,
Jeedimetla, Hyderabad - 500 055, India.

2049459

Mono Carton of Batch No. E220182

Atovaquone Oral Suspension, USP
750 mg/5 mL

NDC 31722-629-21

CAMBER™
PHARMACEUTICALS, INC.

210 mL

Rx only

Handwritten: 27-01-2022

Handwritten: R 27-01-2022

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2049459

Handwritten: Jay 31/11/2023

Handwritten: K. V. S. 31/11/23