



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



CUSTOMER RECALL RETURN RESPONSE FORM
Product Recall Verification/Response Form
Atovaquone Oral Suspension USP 750mg/5mL

If you are a wholesaler/distributor or retail pharmacy, 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: _____

Customer Name _____

Please check the appropriate box (es):

- Wholesaler/ Distributor Retailer Grocery Corporate Headquarters Repacker
- Hospital Pharmacies Manufacturer Pharmacy-Retail Medical Laboratory
- Hospital/Medical Facility Other _____

Address _____

City _____ State _____ Zip _____

Contact Name/Title (please print) _____ Telephone # _____

Contact Signature _____ Date _____

I have checked my stock and:

_____ Do not have any stock of the recalled items.

OR

I have quarantined and listed in the box below the quantity of recall units, and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s).

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 did not purchase the product directly from the Manufacturer, please complete the below section.

Purchased From: Wholesaler Name _____

City _____ State _____

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

31722-629-21

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Rx only **210 mL**

RP 27-01-2022

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

R 27-01-2022

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

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

2049495



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

1233902

27-01-2022

2022-10-12

R 27-01-2022



jay 31/11/2023

*sk
Kam Chakraborty
31/11/23*