



URGENT DRUG RECALL NOTICE – RETAIL LEVEL

Recalling Firm:
 Camber Pharmaceuticals, Inc.
 1031 Centennial Ave.
 Piscataway, NJ 08854

Date: December 6th, 2022

Product Description	NDC Number	Package Size	Lot Numbers	Expiry Dates	**Distribution Dates**
Lacosamide Oral Solution, USP 10mg/mL	31722-627-26	200mL PET bottles (with FSE Wad)	E222199	05/2024	11/2019 – 1/2020
			E222200	05/2024	11/2019 – 1/2020
			E222228	06/2024	11/2019 – 1/2020

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

The recall has been initiated, due to investigative testing results of p-Hydroxybenzoic acid content, that did not meet the specifications for the Batch No's: E222200, E222199, E222228.

LEVEL: Specify the level of the recall.

This recall is being carried out to the **Retail** level and is for batch numbers E222199, E222200, and E222228 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. If you further distributed this product, please forward this notification to your **retail** customers as it is a **RETAIL LEVEL RECALL**.
5. Completed Recall Return Response form can be submitted by any of the below methods:
 Fax to: 817-868-5362
 E-mail to: rxrecalls@inmar.com
 Or mail to: Inmar, Attn: Recall Coordinator, One West Fourth Street., Suite 500Winston-Salem, NC 27101



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 877-538-8447 prompt number 1 for recall.

(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 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: Somaraju Indukuri

Title: VP, Regulatory Affairs

Signature:  _____

Date: 12/6/2022 _____



RECALL RETURN RESPONSE FORM
 Product Recall Verification/Response Form
Lacosamide Oral Solution, USP 10mg/mL

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.

Customer Name _____

Please check the appropriate box (cs) to describe your business

- wholesaler/ distributor retailer grocery corporate headquarters Repackcer
 hospital pharmacies manufacturer pharmacy –retail hospital pharmacies
 medical laboratory Hospital/ medical facility Others: _____

DEA # _____
**DEA # is required, if it is not provided, the processing of your form will be delayed.*

Address _____

City _____ State _____ Zip _____

Contact Name (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) Please indicate the # of needed box labels _____.

Product Description	NDC Number	Lot Numbers	Expiry Dates	QTY Returning (in bottles)
Lacosamide Oral Solution, USP 10mg/mL	31722-627-26	E222199	05/2024	
		E222200	05/2024	
		E222228	06/2024	

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

Purchased From: Wholesaler Name _____ DEA # _____

City _____ State _____

If you have any questions regarding this form or product return, please contact Inmar at 1-877-538-8447 prompt number 1 for recall. Office hours 9am to 5pm EST Mon thru Fri.

Please fax this form to: 1-817-868-5362 or E-mail: rxrecalls@inmar.com

Container Label of Batch No. E222199:

CAMBER
PHARMACEUTICALS, INC.

NDC 31722-627-26

Lacosamide
Oral Solution, USP
10 mg/mL

ATTENTION PHARMACIST:
Each patient is required to receive
the accompanying Medication Guide.

Rx only 200 mL

Each mL contains 10 mg of lacosamide, USP.

Phenylketonurics: A 200 mg dose of lacosamide oral solution (equivalent to 20 mL) contains 0.32 mg of phenylalanine.

USUAL DOSAGE: See package insert for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Do not freeze.

Discard any unused product remaining after seven (7) weeks of first opening the bottle.

Date Bottle Opened:

KEEP OUT OF REACH OF CHILDREN.

Dispense in the original container, or as described in USP/NF.

Medication Guide available at
<http://camberpharma.com/medication-guides>

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

LOT: E222199
EXP: 05/2024

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2066371

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

By: **HETERO™**
HETERO LABS LIMITED
Jeedimetla, Hyderabad - 500 055, India.

Mfg. Lic. No.: 22/RR/AP/2001/F/R

Handwritten notes:
02-07-2022
[Signature]

Container Label of Batch No. E222200:


NDC 31722-627-26

Lacosamide
Oral Solution, USP 
10 mg/mL

ATTENTION PHARMACIST:
Each patient is required to receive the accompanying Medication Guide.

Rx only 200 mL

Each mL contains 10 mg of lacosamide, USP.
Phenylketonurics: A 200 mg dose of lacosamide oral solution (equivalent to 20 mL) contains 0.32 mg of phenylalanine.
USUAL DOSAGE: See package insert for dosage information.
Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Do not freeze.
Discard any unused product remaining after seven (7) weeks of first opening the bottle.
Date Bottle Opened:
KEEP OUT OF REACH OF CHILDREN.
Dispense in the original container, or as described in USP/NF.
Medication Guide available at <http://camberpharma.com/medication-guides>
U.S. Contact Number: 1-866-495-1995


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Pf 03-07-2022
LOT: E222200
EXP: 05/2024
R 03-07-2022

2066371
Manufactured for:
Camber Pharmaceuticals, Inc.
Piscataway, NJ 08854

By: **HETERO™**
HETERO LABS LIMITED
Jeedimetla, Hyderabad - 500 055, India.
Mfg. Lic. No.: 22/RR/AP/2001/F/R

Container Label of Batch No. E222228:

CAMBER[®]
PHARMACEUTICALS, INC.

NDC 31722-627-26

Lacosamide
Oral Solution, USP
10 mg/mL

ATTENTION PHARMACIST:
Each patient is required to receive
the accompanying Medication Guide.

Rx only 200 mL

Each mL contains 10 mg of lacosamide, USP.

Phenylketonurics: A 200 mg dose of lacosamide oral solution (equivalent to 20 mL) contains 0.32 mg of phenylalanine.

USUAL DOSAGE: See package insert for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Do not freeze.

Discard any unused product remaining after seven (7) weeks of first opening the bottle.

Date Bottle Opened:
KEEP OUT OF REACH OF CHILDREN.

Dispense in the original container, or as described in USP/NF.

Medication Guide available at
<http://camberpharma.com/medication-guides>

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

LOT: E222228
EXP: 06/2024

06-07-2022
06-07-2022

2066371

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

By: **HETERO™**
HETERO LABS LIMITED
Jeedimetla, Hyderabad - 500 055, India.

Mfg. Lic. No.: 22/RR/AP/2001/F/R

Container Label Artwork of Lacosamide Oral Solution, USP 10mg/mL, 200ML:

CAMBER[®]
PHARMACEUTICAL, INC.

NDC 31722-627-26

Lacosamide
Oral Solution, USP 
10 mg/mL

ATTENTION PHARMACIST:
Each patient is required to receive
the accompanying Medication Guide.

Rx only **200 mL**

Each mL contains 10 mg of lacosamide, USP.

Phenylketonurics: A 200 mg dose of lacosamide oral solution (equivalent to 20 mL) contains 0.32 mg of phenylalanine.

USUAL DOSAGE: See package insert for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Do not freeze.

Discard any unused product remaining after seven (7) weeks of first opening the bottle.

Date Bottle Opened: **UVZ**

KEEP OUT OF REACH OF CHILDREN.

Dispense in the original container, or as described in USP/INF.

Medication Guide available at <http://camberpharma.com/medguide-usa>

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

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Digitally signed by rchigurupati@heterousa.com
Date: 2022.01.24 09:12:16 -05'00'

2066371

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

By: **HETERO™**
HETERO LABS LIMITED
Jeedimetla, Hyderabad - 500 055, India.

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

UVZ
40x30 mm