



## URGENT DRUG RECALL NOTICE – RETAIL LEVEL

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

Date: December 6<sup>th</sup>, 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 500 Winston-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: \_\_\_\_\_

A handwritten signature in blue ink, appearing to be "S. Indukuri", written over a horizontal line.

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](mailto:rxrecalls@inmar.com)**



**Container Label of Batch No. E222199:**



**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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3 1 7 2 2 6 2 7 2 6  
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LOT: E222199  
EXP: 05/2024

*Handwritten:* 02-07-2022


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. 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

*03-07-2022*

LOT: E222200

EXP: 05/2024


*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




3 1 7 2 2 6 2 7 2 6 9



**Container Label of Batch No. E222228:**



**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

*06-07-2022*

**LOT: E222228**

**EXP: 06/2024** *—*


*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



317221627269

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



**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/NF.

Medication Guide available at <http://camberpharma.com/medicationguide>

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'

UVZ  
40x30 mm

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