URGENT DRUG RECALL NOTICE – RETAIL 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**
Pantoprazole Sodium Delayed Release Tablets, USP 40 mg	31722-713-10	1000	PAN22542	09/2024	1/2023 – 2/2023

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

The recall has been initiated, due to a market complaint received from a pharmacist stating that "All pills look discoloured, unsure if they are dirty, they are all a tan brown with white spots."

LEVEL: Specify the level of the recall.

This recall is being carried out to the Retail Level and is for batch PAN22542 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 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 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

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 1-855-211-6943.

(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: Raghunath Chigurupati

Title: Manager, Regulatory Affairs

Signature: _____

Date: 03/15/2023

RECALL RETURN RESPONSE FORM

Product Recall Verification/Response Form

Pantoprazole Sodium Delayed Release Tablets, USP 40 mg

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) to describe your business.

[ ] wholesaler/ distributor [ ] retailer [ ] grocery corporate headquarters [ ] Repacker

[ ] hospital pharmacies [ ] manufacturer [ ] pharmacy –retail [ ] hospital pharmacies

[ ] medical laboratory [ ] Hospital/ medical facility [ ] Others: _____

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) Please indicate the # of needed box labels _____.

Product Description	NDC Number	Package Size	Lot Numbers	Expiry Date	Qty Returning (in bottle)
Pantoprazole Sodium Delayed Release Tablets, USP 40 mg	31722-713-10	1000	PAN22542	09/2024	

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

Purchased From: Wholesaler Name _____

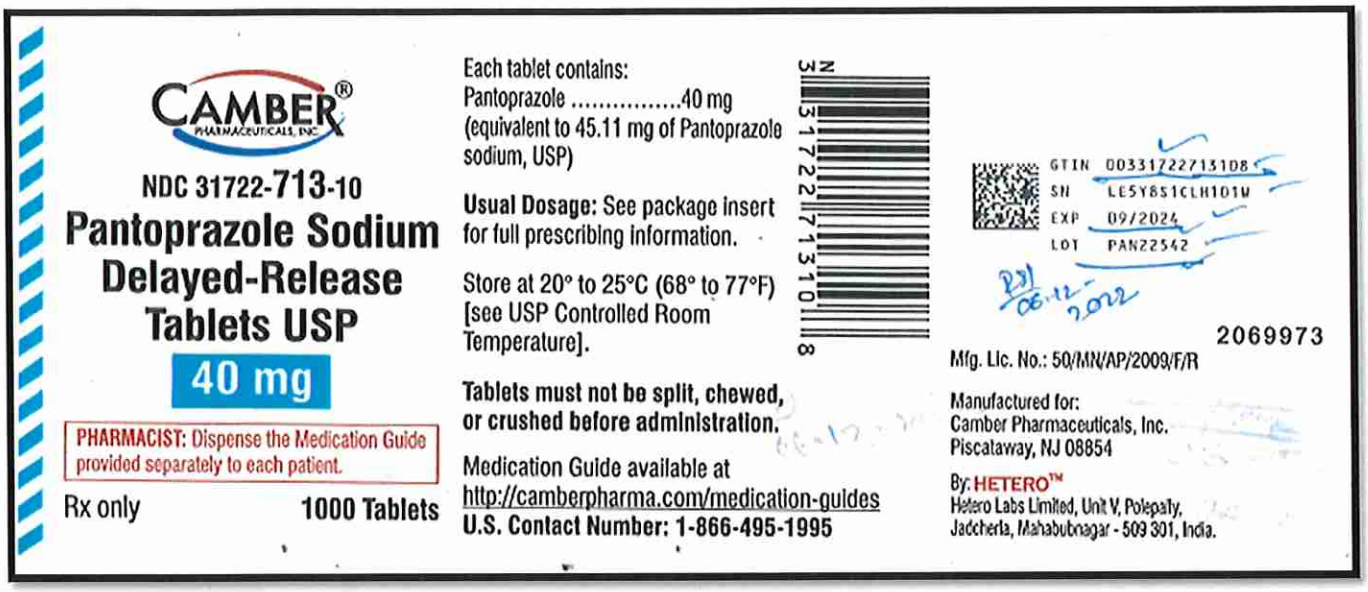
City_____ State_____

If you have any questions regarding this form or product return, please contact Inmar at 1-855-211-6943. 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.

Specimen Label

Pantoprazole Sodium Delayed Release Tablets USP 40 mg, Batch # PAN22542



CAMBER® PHARMACEUTICALS, INC

NDC 31722-713-10

Pantoprazole Sodium Delayed-Release Tablets USP

40 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

Rx only **1000 Tablets**

Each tablet contains:
Pantoprazole .....40 mg
(equivalent to 45.11 mg of Pantoprazole sodium, USP)

Usual Dosage: See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Tablets must not be split, chewed, or crushed before administration.

Medication Guide available at
http://camberpharma.com/medication-guides
U.S. Contact Number: 1-866-495-1995

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GTIN 00331722713108
SN LE5Y851CLH1D1W
EXP 09/2024
LOT PAN22542

2069973

Mfg. Lic. No.: 50/MN/AP/2009/F/R

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

By: HETERO™
Hetero Labs Limited, Unit V, Polepally,
Jadcherla, Mahabubnagar - 509 301, India.