



# Lupin Pharmaceuticals, Inc.

December 13, 2023

**MANUFACTURED BY:**

Lupin Limited  
Nagpur  
441108 INDIA

**MANUFACTURED FOR:**

Lupin Pharmaceuticals, Inc.  
Baltimore, MD 21202  
United States

Dear Healthcare Partner,

**URGENT: VOLUNTARY DRUG RECALL – RETAIL LEVEL**

**Penicillamine Tablets USP 250 mg**

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a voluntary recall of lot **M200498**, **Expiry: June 2024** of **Penicillamine Tablets USP 250 mg** to the **retail** level.

This lot is being recalled due to an out of specification (“OOS”) result observed in dissolution test at stability study whereas all other Quality attributes including assay met the acceptance. Further, dissolution test met acceptance criteria during retesting (as part of investigation) and subsequent interim stability time point.

Dissolution testing determines the active drug content release under specified conditions and lower dissolution, over a period of time may result in decreased bioavailability and therapeutic effectiveness, however as outlined above that dissolution test met the acceptance criteria during retesting (as part of investigation) and subsequent interim stability time point, there is a less likelihood of such occurrences.

The recalled lot was distributed between August 26, 2022 to December 22, 2022 to wholesalers and distributors nationwide.

Immediately examine your inventory and quarantine the product lot subject to recall. Wholesalers and distributors, retailers/pharmacies who have the affected product lot in their inventory should contact Inmar Rx Solutions, Inc. at 855-376-1522 Monday – Friday 9:00 am to 5:00 pm EST. For reimbursement, please have the recalled lot returned to Inmar Rx Solutions, Inc. on or before February 29, 2024. The lot number can be found on the label.



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Penicillamine Tablets USP 250 mg is supplied as:

Strength	Lot	Expiry	NDC	Description
250 mg	M200498	June, 2024	70748-153-01	White colored, oval shaped, film coated tablets with single score line on both sides. On one side, tablets are debossed with "LU" on left and "L17" on right side of the score line and plain on other side.

Product label:

**NDC 70748-153-01**

**Penicillamine Tablets, USP (Titratable Tablets)**

**250 mg**

**Rx only**

**LUPIN**

**100 Tablets**

Each film coated tablet contains 250 mg of penicillamine USP.

**Usual Dosage:** See accompanying prescribing information.

**Storage:** Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Protect from moisture. Dispense in a tight container.

Manufactured for:  
**Lupin Pharmaceuticals, Inc.**  
Baltimore, Maryland 21202, United States.

Manufactured by:  
**Lupin Limited**  
Nagpur – 441 108, INDIA

Code No.: MH/DRUGS/25-ND/59

Unvarnish Area  
54 x 20 mm

263694

This recall should be carried out to the **retail** level.

**A COMPLETE PACKAGE OF INFORMATION INCLUDING A REPLY FORM WILL BE MAILED WITHIN (5) BUSINESS DAYS. THE REPLY FORMS SHOULD BE RETURNED TO INMAR Rx SOLUTIONS, INC. THROUGH MAIL/EMAIL/FAX. ONCE RECEIVED AN RA AND NEEDED BOX LABELS WILL BE PROVIDED.**

**Upon receipt of this packet, please take the following actions:**

1. **Distributors/Pharmacies** – Immediately examine your inventory, quarantine and discontinue distribution of this lot.
2. **Distributors** – Complete the enclosed Business Response Form even if you do not have any product on hand.
3. **Distributors** – Please pass this Recall Notice on **ONLY** to pharmacies that received affected product lot.



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4. **Pharmacies** – If you have units of the affected lot in inventory, please contact Inmar Rx Solutions, Inc. at 855-376-1522 to receive a Business Recall Response form or acquire it from [clsnetlink.com](http://clsnetlink.com).
5. Business Recall Response Form can be submitted by any of these methods.  
Fax: 817-868-5362  
Email: [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com)  
Address: Inmar Rx Solutions, Inc., Attn: Recall Coordinator – One West Fourth Street, Suite 500 Winston Salem, NC 27101
6. **Distributors/Pharmacies** – Return recalled product lot to Inmar Rx Solutions, Inc. as instructed in recall/return packet.
7. **Distributors** – **You do not need to notify your customers of this event.**  
**Upon receipt of the completed BRF, a return kit will be sent including an RA form and necessary box labels.**

We appreciate your immediate attention to this matter. This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

Jigar Thakkar  
Manager, Quality Assurance



Lupin Pharmaceuticals, Inc.

RCL245-2023 N131001

**Lupin Pharmaceuticals, Inc.**

**RECALL**

**Penicillamine Tablets USP 250 mg**

**Retail Level**

**12/13/2023**

**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:

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#:

Email:

Contact Signature:

Date:

DEBIT MEMO# (If unsure, leave blank):

**Wholesaler Information if not directly purchased from Lupin:**

Wholesaler Name:

DEA#:

City:

State:

Zip:

**I have checked my stock and:**

           I do not have any stock of the recalled items.

**OR**

I have quarantined and listed in the box below the quantity of recalled 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           .

Item Description	NDC	Lot Number	Expiration Date	Full Bottle	Partial Bottle	Tablet Count in Partial
Penicillamine Tablets USP 250 mg (100's)	70748-153-01	M200498	6/30/2024			

If you have any questions regarding this form or product return please contact Inmar at 855-376-1522  
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)**

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