Lupin Pharmaceuticals, Inc.

April 4, 2024

MANUFACTURED BY:
Lupin Limited
Aurangabad 431 210 INDIA

MANUFACTURED FOR:
Lupin Pharmaceuticals, Inc.
Baltimore, MD 21202
United States

Dear Healthcare Partner,

URGENT: DRUG RECALL – RETAIL LEVEL

Rifampin Capsules USP, 300mg (30 Count)

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a **voluntary recall** of lot **A201064, Expiry: March 2024** of Rifampin Capsules USP, 300mg to **retail** level. Above referenced lot is being recalled due to an out of specification result observed in assay testing during long term stability study.

The reduction in the assay content may result in a slight decrease of therapeutic effect (sub-therapeutic response).

Rifampin Capsules USP, 300 mg are supplied as:

Strength	Lot	Count	Expiry	NDC	Description
300 mg	A201064	30's pack	3/2024	68180-659-06	Rifampin Capsules USP, 300 mg are size '1' capsules having dark red cap, imprinted with "LU" in white ink and light red body, imprinted with "E02" in white ink, containing reddish brown powder.

The recalled lot was distributed between April 2022, and June 2022 to wholesalers, distributors, mail order pharmacies and supermarkets (food) nationwide.

Immediately examine your inventory and quarantine the product lot subject to recall. Wholesalers and distributors should forward this notification to retailers. Wholesalers and distributors who have the affected product lot in their inventory should contact Inmar Rx Solutions, Inc. at (877) 854-8490 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 June 30, 2024. The lot number can be found on the side of the bottle.

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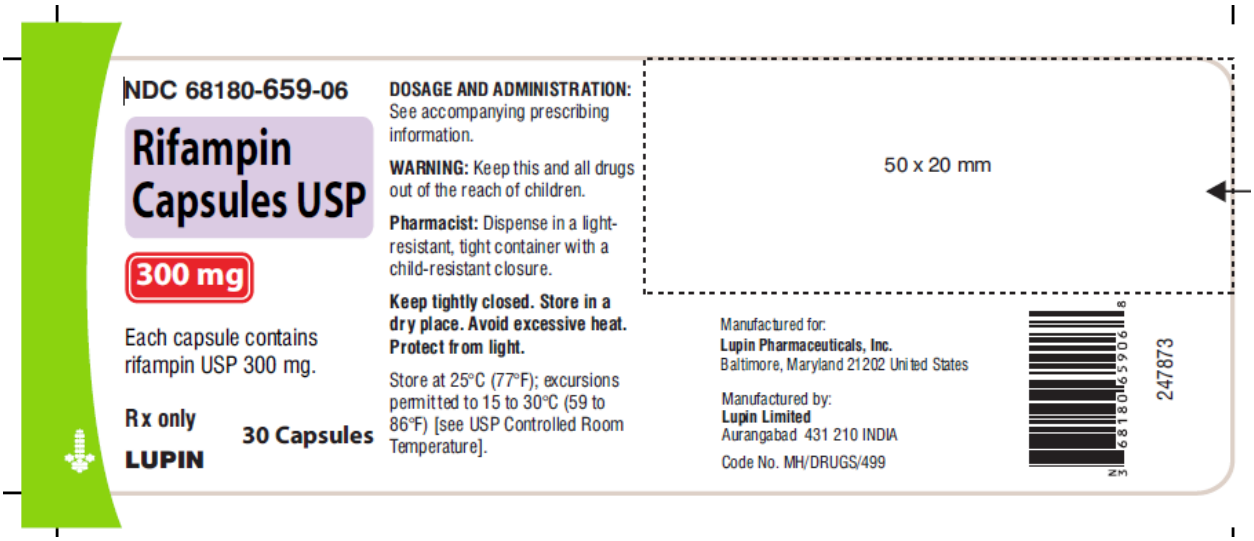
Product label:



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 **ONLY** to pharmacies that received this product lot.
4. **Pharmacies** – If you have units of the affected lot in inventory, please contact Inmar Rx Solutions, Inc. at 877-854-8490 to receive a Business Recall Response form or acquire it from clsnetlink.com.
5. Business Recall Response Form can be submitted by any of these methods.

   Fax: 817-868-5362

   Email: rxrecalls@inmar.com

   Address: Inmar Rx Solutions, Inc., Attn: Recall Coordinator – One west fourth Street, Suite 500 Winston Salem, NC 27101

Lupin Pharmaceuticals, Inc.

6. **Distributors/Pharmacies** – Return recalled product lot to Inmar Rx Solutions, Inc. as instructed in recall/return packet.
7. **Pharmacies** – You do not need to contact any patients.

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,

Anurag Mishra
Director, Quality Assurance

HARBORPLACE TOWER. 111 SOUTH CALVERT STREET. 21ST FLOOR. BALTIMORE. MD 21202. TEL: 410-576-2000 FAX: 410-576-2221
www.lupinpharmaceuticals.com

N131150 RCL082-2024

Lupin Pharmaceuticals, Inc.

RECALL

Rifampin Capsules USP 300 mg (30s)

Retail Level (4/4/2024)

3/20/2024

Please fill out this form completely. By doing so, this will acknowledge that you have read andunderstand 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 communicated to my customers at the appropriate level:

☐ I confirm that all locations that received the impacted products have been notified to the retail level _____(Initial and date)

☐ 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_____.

Product Name	NDC#	Lot#	Expiration Date	Total Quantity of Units (full and partial bottles/cartons)
Rifampin Capsules USP 300 mg (30s)	68180-659-06	A201064	3/31/2024	

If you have any questions regarding this form or product return please contact Inmar at 877-854-8490 Office hours 9am to 5pm EST Mon thru Fri.

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