Lupin Pharmaceuticals, Inc.

January 05, 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, 150mg (30 Count)
Rifampin Capsules USP, 300mg (30 Count)

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a **voluntary recall** of lots **A200816**, **Expiry: January 2024** and **A201248**, **Expiry: March 2024** of Rifampin Capsules USP, 150mg and lot **A200817**, **Expiry: January 2024** of Rifampin Capsules USP, 300mg to retail level.

Above lots are being recalled due to out of specification result observed in assay testing of all above lots and related substance testing (N-Methyl Rifampin impurity) in lot A200816, Expiry: January 2024 during stability study.

The reduction in the assay content may result in slight decrease in therapeutic effect (sub-therapeutic response). The toxicological properties of N-Methyl Rifampin impurity have not been extensively studied; thus, the health hazards cannot be conclusively assessed.

Rifampin Capsules USP, 150mg and 300 mg are supplied as:

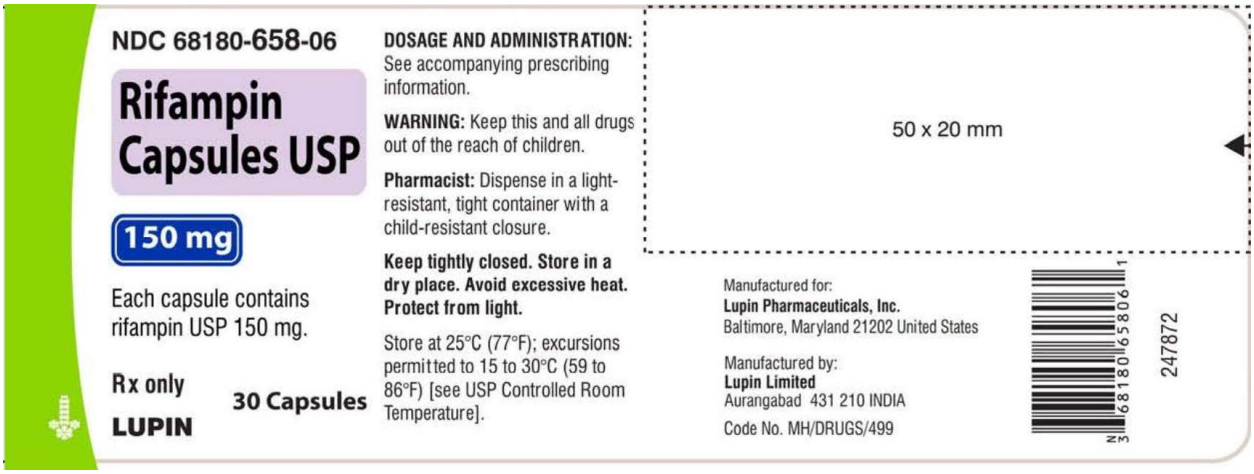
Strength	Lot	Count	Expiry	NDC	Description
150 mg	A200816	30 count	01/2024	68180-658-06	Rifampin Capsules USP, 150 mg are size '2' capsules having dark red cap, imprinted with "LU" in white ink and light red body, imprinted with "E01" in white ink, containing reddish brown powder.
	A201248		03/2024		
300 mg	A200817		01/2024	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.

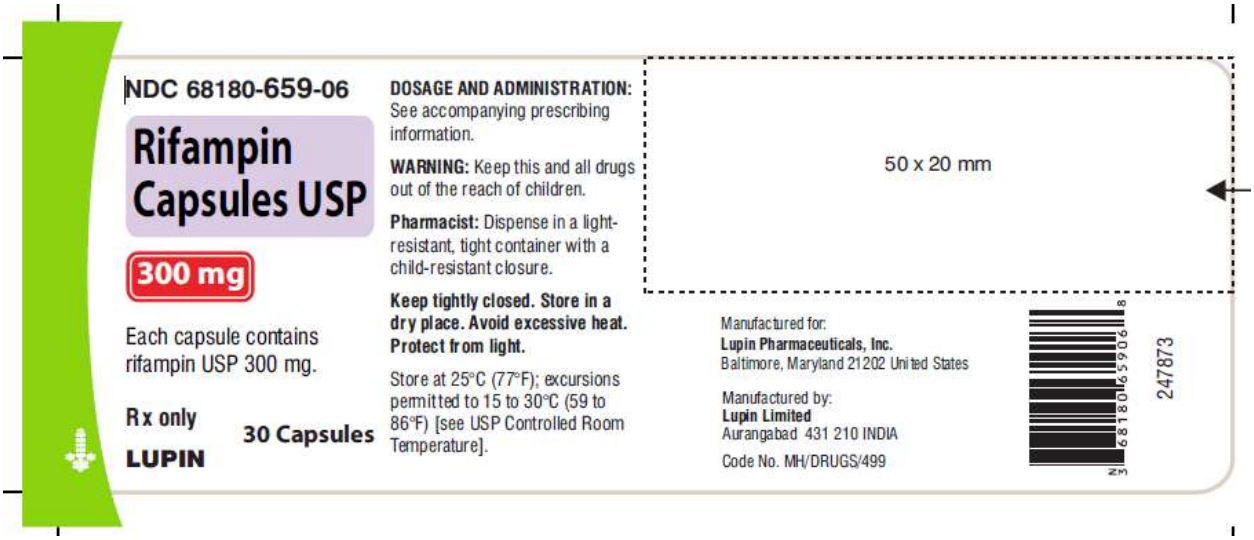
The recalled lots were distributed between February 2022, and June 2022 to wholesalers, distributors, and mail order pharmacies and supermarkets (food) nationwide.

Lupin Pharmaceuticals, Inc.

Immediately examine your inventory and quarantine the product lot(s) subject to recall. Wholesalers and distributors should forward this notification to retailers. Wholesalers and distributors who have the affected product(s) lot in their inventory should contact Inmar Rx Solutions, Inc. at (877) 738-4309 Monday – Friday 9:00 am to 5:00 pm EST. For reimbursement, please have the recalled lot(s) returned to Inmar Rx Solutions, Inc. on or before March 31, 2024. The lot number can be found on the side of the bottle.

Product label(s):





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.

Lupin Pharmaceuticals, Inc.

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

1. **Wholesalers/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 this product lot.
4. **Pharmacies** – If you have units of the affected lot in inventory, please contact Inmar Rx Solutions, Inc. at (877) 738-4309 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
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,

Jigar Thakkar
Manager, Quality Assurance

RCL002-2024 N131121

Lupin Pharmaceuticals, Inc.

RECALL

Rifampin Capsules USP 150mg & 300mg

Retail Level

1/5/2024

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:

_____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 authorizationlabel(s) Please indicate the # of needed box labels_____.

Item Description	NDC#	Lot#	Exp Date	Full Bottle	Partial Bottle	Capsule Count in Partial
Rifampin Capsules USP 150 mg (30's)	68180-658-06	A200816	1/2024			
Rifampin Capsules USP 150 mg (30's)	68180-658-06	A201248	3/2024			
Rifampin Capsules USP 300 mg (30's)	68180-659-06	A200817	1/2024			

If you have any questions regarding this form or product return please contact Inmar at 877-738-4309 Office hours 9am to 5pm EST Mon thru Fri.

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