



Lupin Pharmaceuticals, Inc.

January 25, 2024

MANUFACTURED BY:

Lupin Limited
Mandideep
462 046 INDIA

MANUFACTURED FOR:

Lupin Pharmaceuticals, Inc.
Baltimore, MD 21202
United States

Dear Healthcare Partner,

URGENT: DRUG RECALL – RETAIL LEVEL

Cefixime for Oral Suspension USP 100 mg/5 mL (50 mL Pack size)

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a **voluntary recall** of lot **F304833**, **Expiry: June 2025 of Cefixime for Oral Suspension USP 100 mg/5 mL (50 mL Pack size)** to the **retail** level. This lot is being recalled due to an out of specification (“OOS”) result observed in related substance test (any other impurity) during 3-month long term stability study.

The marginal increase of Cefixime glucose adduct impurity above specification limit is less likely to cause health hazard in the patients as Cefixime glucose adduct impurity is non-mutagenic.

The recalled lot was distributed between August 2023 to November 2023 to wholesalers and distributors and supermarkets 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 877-801-5158 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 March 31, 2024. The lot number can be found on the label.

Strength	Lot	Expiry	NDC	Description
100 mg/5 mL (50 mL)	F304833	June, 2025	68180-405-01	Off white to pale yellow colored powder forming off -white to yellow suspension with characteristic fruity odor on constitution.



Lupin Pharmaceuticals, Inc.

Cefixime for Oral Suspension USP 100 mg/5 mL Product label:

NDC 68180-405-01

Cefixime for Oral Suspension USP

100 mg/5 mL

When reconstituted, each teaspoonful (5 mL) contains 100 mg of cefixime as the trihydrate.

FOR ORAL USE ONLY
SHAKE WELL BEFORE USING
Discard any unused portion after 14 days

Rx only
50 mL (when reconstituted)
LUPIN

Net Contents: Contains 1 g cefixime as the trihydrate.
Prior to reconstitution: Store drug powder at 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature].
After reconstitution: Store at room temperature or under refrigeration. Keep tightly closed.
Usual dosage: See package insert.

TO THE PHARMACIST : IMPORTANT
Use this bottle for dispensing.
Use only if inner seal is intact.
Directions for mixing:
To reconstitute, suspend with **34 mL water**.
Method: Tap the bottle several times to loosen powder contents prior to reconstitution. Add approximately half the total amount of water for reconstitution and shake well. Add the remainder of water and shake well.
Code No. MP/DRUGS/28/18/88

Manufactured for:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States
Manufactured by:
Lupin Limited
Mandideep 462 046 INDIA.
Date of reconstitution:

52 x 16 mm

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 these lots.
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 these product lots.
4. **Pharmacies** – If you have units of the affected lots in inventory, please contact Inmar Rx Solutions, Inc. at 877-801-5158 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 lots 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



RCL261-2023 N131112

Lupin Pharmaceuticals, Inc.**RECALL****Cefixime for oral Suspension USP 100mg/5ml****Retail Level****1/24/2024**

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#	Exp Date	Full Bottle	Partial Bottle
Cefixime for oral Suspension USP 100mg/5ml	68180-405-01	F304833	6/2025		

If you have any questions regarding this form or product return please contact Inmar at 877-801-5158
Office hours 9am to 5pm EST Mon thru Fri.

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

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