Lupin Pharmaceuticals, Inc.

May 14, 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

Cefdinir for Oral Suspension USP 125 mg/5 mL (60 mL when reconstituted)
Cefdinir for Oral Suspension USP 250 mg/5 mL (60 mL when reconstituted)

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a **voluntary recall** of lot **F305292, Expiry: August 2025** of **Cefdinir for Oral Suspension USP 125 mg/5 mL and** lot **F305442, Expiry: August 2025** of **Cefdinir for Oral Suspension USP 250 mg/5 mL to** the **retail** level. These lots are being recalled due to product complaint indicating foreign material being reported in the reconstituted bottle.

Although foreign material was not observed during reconstitution of product (at the dispensing pharmacy), out of an abundance of caution, a recall is initiated.

The health hazard associated with the reported presence of foreign material could not be conclusively assessed.

The recalled lots were distributed between October 2023 to April 2024 to wholesalers and distributors and drug chain stores nationwide.

Immediately examine your inventory and quarantine the product lots subject to recall. Wholesalers and distributors should forward this notification to retailers. Wholesalers and distributors who have the affected product lots in their inventory should contact Inmar Rx Solutions, Inc. at 877-861-5865 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 July 31, 2024. The lot number can be found on the label.

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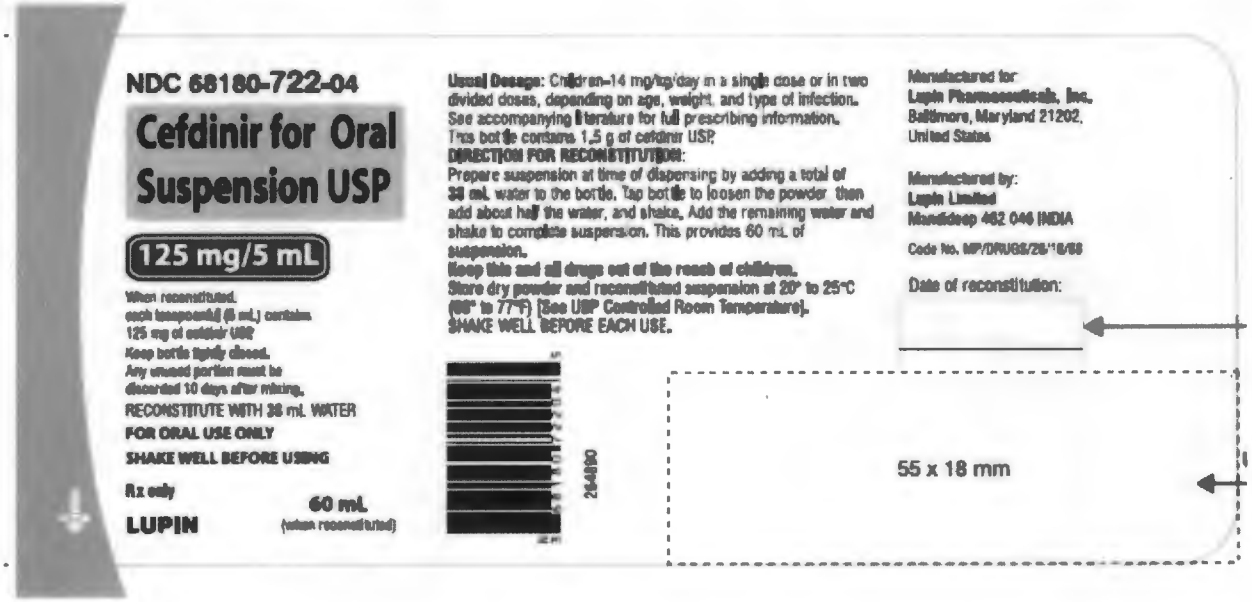
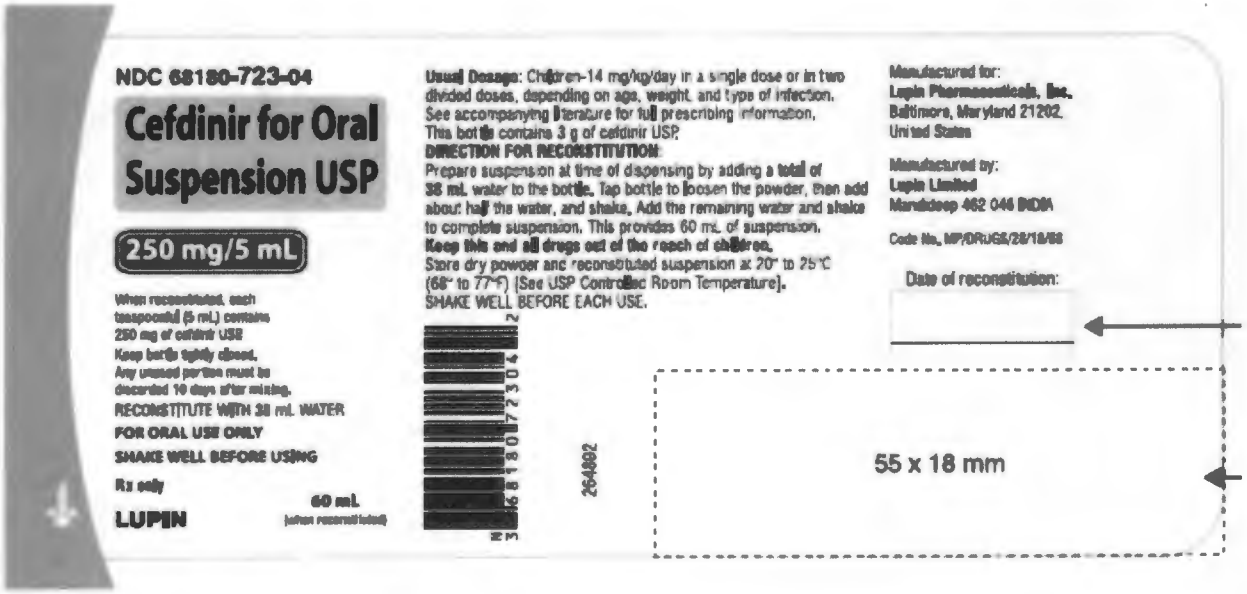
Cefdinir for Oral Suspension USP 125 mg/5 mL and Cefdinir for Oral Suspension USP 250 mg/5 mL supplied as:

Strength	Lot	Expiry	NDC	Description
125 mg/ 5 mL	F305292	August-2025	68180-722-04	Off-white to creamish powder, free from lumps and agglomerates, forming off-white to creamish suspension with characteristic odour on constitution.
250 mg/ 5 mL	F305442	August-2025	68180-723-04	

Product label(s):





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

Lupin Pharmaceuticals, Inc.

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 877-861-5865 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 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
Digitally signed by Jigar Thakkar
Date: 2024.05.14 13:54:09 -04'00'

Jigar Thakkar
Manager, Quality Assurance

INMAR intelligence

Lupin Pharmaceuticals, Inc.

RCL112-2024 N131162

Lupin Pharmaceuticals, Inc.

RECALL

Cefdinir for Oral Suspension 125 mg/5 mL (60 ml)
Cefdinir for Oral Suspension 250 mg/5 mL (60 ml)

Retail Level - 5/14/2024

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)
Cefdinir for Oral Suspension 125 mg/5 mL (60 ml)	68180-722-04	F305292	8/31/2025	
Cefdinir for Oral Suspension 250 mg/5 mL (60 ml)	68180-723-04	F305442	8/31/2025	

If you have any questions regarding this form or product return please contact Inmar at 877-861-5865 Office hours 9am to 5pm EST Mon thru Fri.

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