



Lupin Pharmaceuticals, Inc.

February 05, 2024

MANUFACTURED BY:

Novel Laboratories Inc.
Somerset, NJ 08873
United States

MANUFACTURED FOR:

Lupin Pharmaceuticals, Inc.
Baltimore, MD 21202
United States

Dear Healthcare Partner,

URGENT: DRUG RECALL – WHOLESALE LEVEL

Voriconazole for Oral Suspension 40 mg/mL (75 mL when reconstituted)

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a **voluntary recall** of lots **S200756 Expiry: October 2024, S300218 Expiry: April 2025, and S300633 Expiry: September 2025** of **Voriconazole for Oral Suspension 40 mg/mL (75 mL when reconstituted)** to the **wholesale** level. These lots are being recalled due to a minor error identified in the reconstitution volume (water quantity) in the package insert. Product carton and product label state to reconstitute with 50mL while the package insert states to reconstitute with 46mL. 50mL is the correct reconstitution volume.

The erroneous reconstitution of Voriconazole for oral Suspension 40mg/mL (if reconstituted per pack insert instruction) would increase the potency of drug product which might lead to labelled adverse drug experience.

The recalled lots were distributed between November 2022 to January 2024 to wholesalers and distributors nationwide.

Immediately examine your inventory and quarantine the product lots subject to recall. Wholesalers and distributors who have the affected product lots in their inventory should contact Inmar Rx Solutions, Inc. at 877-815-4881 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 April 30, 2024. The lot number can be found on the bottle label and carton.

Voriconazole for Oral Suspension 40 mg/mL (75 mL when reconstituted) supplied as:

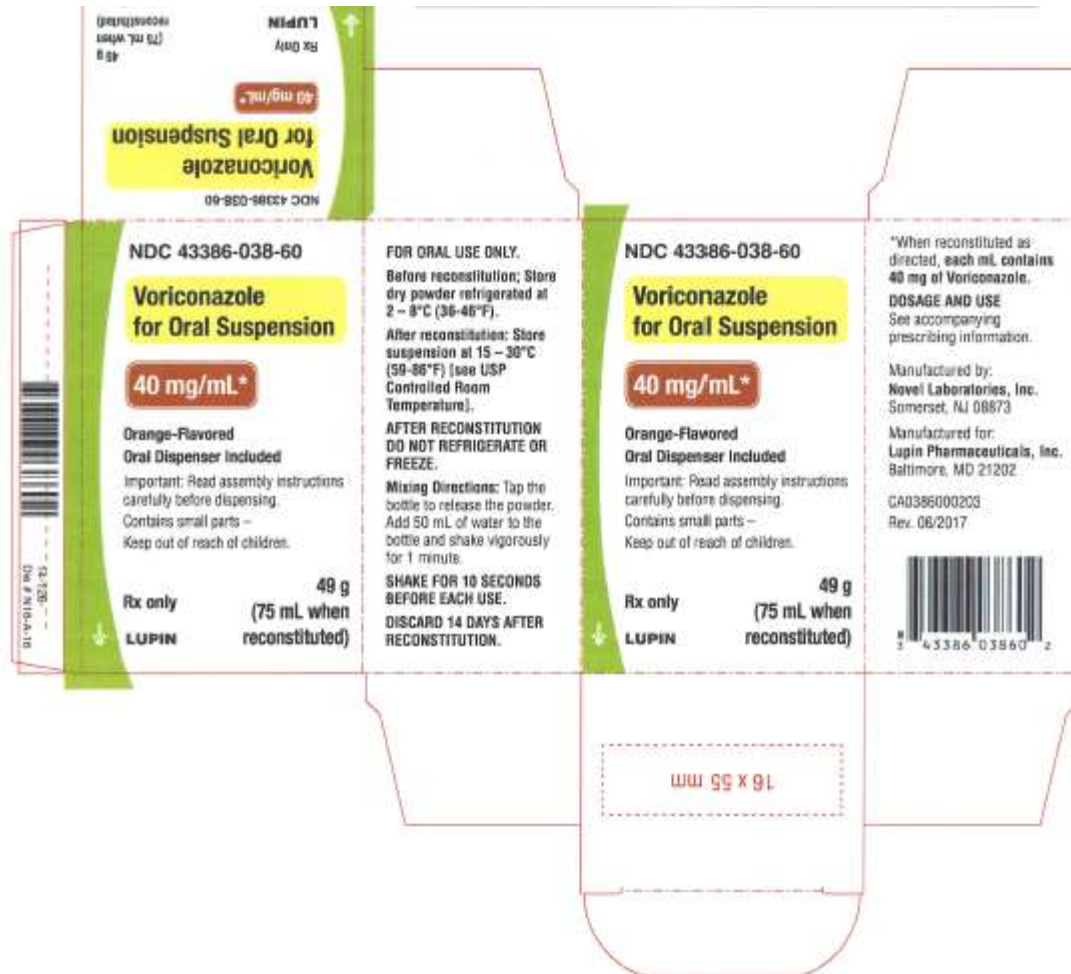
Strength	Lot(s)	Expiry	NDC	Description
40 mg/ mL (75 mL)	S300633	September 2025	43386-038-60	<u>Before reconstitution:</u> Orange flavored, white to off -white granular powder.
	S300218	April 2025		<u>After reconstitution:</u> White to off-white suspension with orange flavor.
	S200756	October 2024		



Lupin Pharmaceuticals, Inc.

Product label(s):

a) Carton label:



b) Bottle label:





Lupin Pharmaceuticals, Inc.

This recall should be carried out to the **Wholesale** 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. **Wholesalers/Distributors** – 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** – If you have units of the affected lots in inventory, please contact Inmar Rx Solutions, Inc. at 877-815-4881 to receive a Business Recall Response form or acquire it from clsnetlink.com.
4. 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
5. **Distributors/Wholesalers** – Return recalled product lots to Inmar Rx Solutions, Inc. as instructed in recall/return packet.
6. **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.

RECALL

Voriconazole For Oral Suspension 40mg/mL

Wholesale Level

2/1/2024

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 communicated to my customers at the appropriate level:

- _____ 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
Voriconazole For Oral Suspension 40mg/mL	43386-038-60	S300633	9/2025		
Voriconazole For Oral Suspension 40mg/mL	43386-038-60	S300218	4/2025		
Voriconazole For Oral Suspension 40mg/mL	43386-038-60	S200756	10/2024		

If you have any questions regarding this form or product return please contact Inmar at 877-815-4881 Office hours 9am to 5pm EST Mon thru Fri.

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