Lupin Pharmaceuticals, Inc.

December 20, 2023

MANUFACTURED BY:
Lupin Limited
Goa, 403 722 INDIA

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

Dear Healthcare Partner,

URGENT: VOLUNTARY DRUG RECALL – RETAIL LEVEL

Desloratadine Tablets USP 5mg (100's pack and 500's pack)

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a voluntary recall of lots: **G201822**, **Expiry**, **January 2024, G201823**, **Expiry**, **January 2024, G201824**, **Expiry**, **January 2024** of Desloratadine Tablets USP, 5mg to **retail** level. These lots are being recalled due to N-Nitroso Desloratadine impurity result exceeding acceptable intake limit.

N-Nitroso Desloratadine impurity falls into the potency category 3. Considering the levels of the impurity under discussion, potential health hazards upon continuous and/or long-term usage cannot be completely ruled out. However, the health risk associated to the exposure varies from person to person based on concurrent medication/dose regimen.

The recalled lots were distributed between May, 2022 and September, 2022 to wholesalers, distributors, drug chains, mail order and supermarkets (food) nationwide.

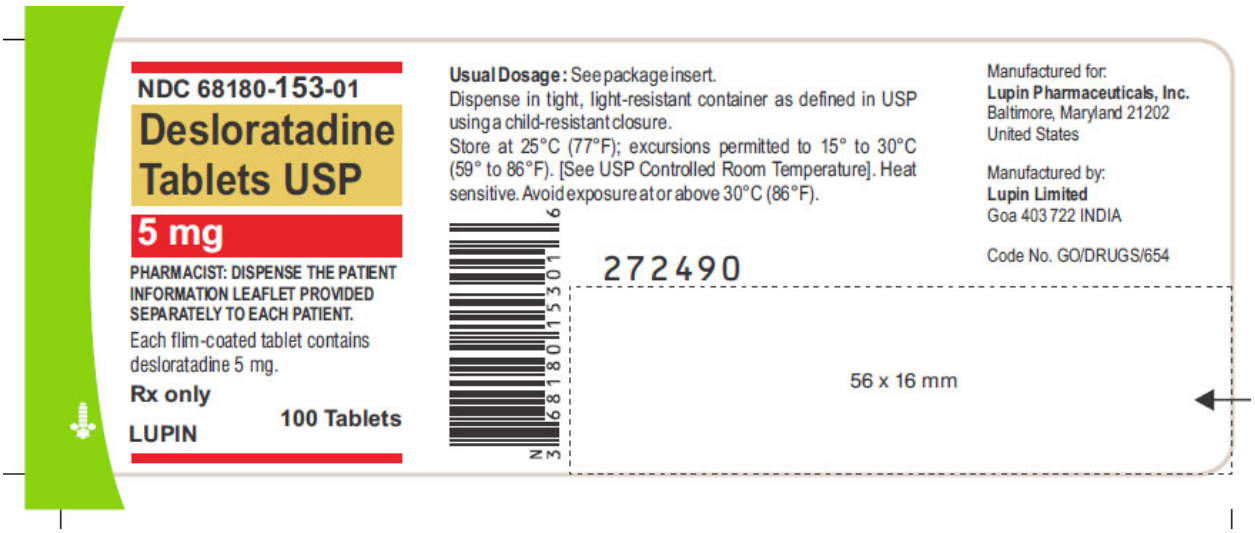
Immediately examine your inventory and quarantine the product lots subject to recall. Wholesalers and distributors should forward this notification to retailers. Wholesalers and distributors who have the affected product lots in their inventory should contact Inmar Rx Solutions, Inc. at 877-795-7587 Monday – Friday 9:00 am to 5:00 pm EST. For reimbursement, please have the recalled lots returned to Inmar Rx Solutions, Inc. on or before March 31, 2024. The lot number can be found on the side of the bottle.

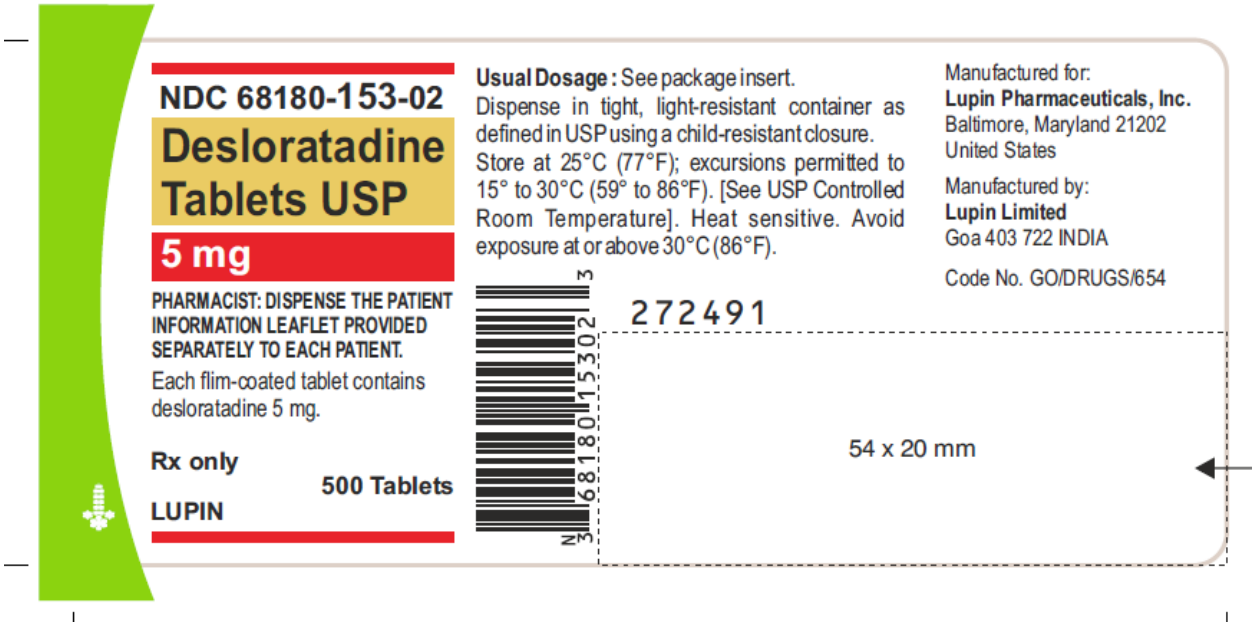
Lupin Pharmaceuticals, Inc.

Desloratadine Tablets USP are supplied as:

Strength	Lot	Expiry	NDC	Description
5mg	G201822 (100's HDPE)	Jan. 2024	68180-153-01	Light blue film coated, circular, biconvex tablet debossed 'LU' on one side and 'S71' on other side.
	G201823 (100's HDPE)	Jan. 2024	68180-153-01	
	G201824 (500's HDPE)	Jan. 2024	68180-153-02	

Product label:





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 877-795-7587 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
Manager, Quality Assurance

RCL260-2023 N131010

Lupin Pharmaceuticals, Inc.

RECALL

Desloratadine Tablets USP 5mg

Retail Level

12/20/2023

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	Tablet Count in Partial
Desloratadine Tablets USP 5mg	68180-153-01	G201822	1/2024			
Desloratadine Tablets USP 5mg	68180-153-01	G201823	1/2024			
Desloratadine Tablets USP 5mg	68180-153-02	G201824	1/2024			

If you have any questions regarding this form or product return please contact Inmar at 877-795-7587 Office hours 9am to 5pm EST Mon thru Fri.

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