Lupin Pharmaceuticals, Inc.

URGENT: DRUG RECALL

December 4, 2025

On behalf of Lupin Pharmaceuticals Inc.
Inmar Rx Solutions, Inc.,
Attn: Recall Coordinator,
One West Fourth Street, Suite 500 Winston Salem, NC 27101.

Dear Healthcare Partner,

This is to inform you of a product recall involving:

Sertraline Hydrochloride Tablets USP 100 mg (90 Tablets)

Strength	Lot	Expiry	NDC	Description
100 mg	QB00865	Feb 2028	68180-353-09	Yellow coloured, capsule shaped, biconvex, film coated tablets debossed with 'L' and 'U' on either side of the break line on one side and 'D03' on the other side.

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a **voluntary recall** of lot **QB00865 (Expiry: February 2028)** of **Sertraline Hydrochloride Tablets USP, 100 mg (90-count bottles)** at the **retail** level. This recall is being conducted due to market complaints indicating a missing seal on the bottle.

There is no immediate risk /health hazard to patients as the evaluation of complaint samples confirmed that no bottles were dispensed to patients. However, in the worst-case scenario, missing seals could lead to spillage, moisture ingress, or contamination, compromising product integrity.

The recalled lot was distributed nationwide to wholesalers, distributors, and drug chains between July 2025 and September 2025. Wholesalers and distributors should forward this notification to retailers.

See enclosed product label for ease of identifying the product.

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 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 877-268-1273 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 the recalled product lot to Inmar Rx Solutions, Inc. as instructed in recall/return packet.
7. **Pharmacies** – You do not need to contact any patients.

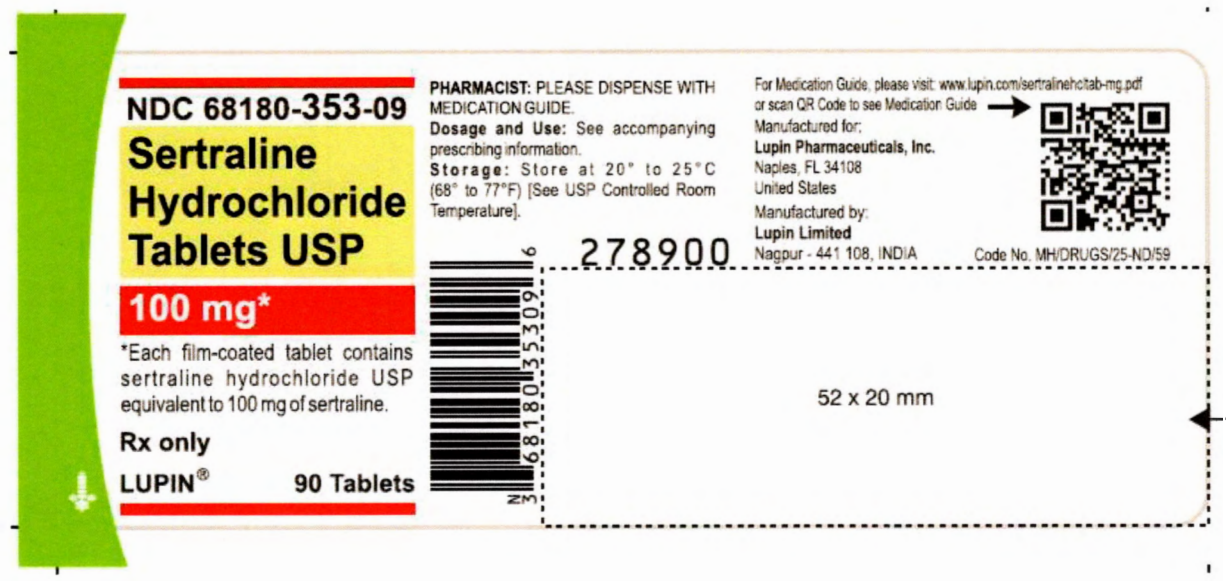
Upon receipt of the complete BRRF, a return kit will be sent including an RA form and necessary box labels.
This recall should be carried out to the **Retail** level.
We appreciate your immediate attention to this matter.
This recall is being made with the knowledge of the U.S. Food and Drug Administration.
Sincerely,

Jigar Thakkar Digitally signed by Jigar Thakkar Date: 2025.12.04 14:33:12 -05'00'

Jigar Thakkar
Manager, Quality Assurance

Label:

Sertraline Hydrochloride Tablets USP 100 mg (90 Tablets) product label:



Lupin Pharmaceuticals, Inc.

RECALL

Sertraline Hydrochloride Tablets USP, 100mg

Retail Level

12/4/2025

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. (Circle One) **YES** **YES-Corporate Notified** **NO (Why?)** _____

_____

☐ 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 Full Bottles/90 Tablets	Total Partial Bottles/Tablet Count
Sertraline Hydrochloride Tablets USP, 100mg	68180-353-09	QB00865	2/29/2028		

If you have any questions regarding this form or product return please contact Inmar at 877-268-1273 Office hours 9am to 5pm EST Mon thru Fri.

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