



Lupin Pharmaceuticals, Inc.

URGENT: DRUG RECALL

November 5, 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 **wholesale** 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.

See enclosed product label for ease of identifying the product.

5801 Pelican Bay Boulevard, Suite 500, Naples, Florida, USA 34108 Tel: 239-316-1900
www.lupin.com/us



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. **Wholesalers/Distributors** – 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** – 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.
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 lot 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 complete BRRF, a return kit will be sent including an RA form and necessary box labels.

This recall should be carried out to the **Wholesale** 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: 2025.11.05 12:34:36 -05'00'

Jigar Thakkar
Manager, Quality Assurance

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Label:

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

NDC 68180-353-09

**Sertraline
Hydrochloride
Tablets USP**

100 mg*

*Each film-coated tablet contains
sertraline hydrochloride USP
equivalent to 100 mg of sertraline.

Rx only

LUPIN®

90 Tablets

6
278900
N 3

PHARMACIST: PLEASE DISPENSE WITH
MEDICATION GUIDE.
Dosage and Use: See accompanying
prescribing information.
Storage: Store at 20° to 25°C
(68° to 77°F) [See USP Controlled Room
Temperature].

For Medication Guide, please visit: www.lupin.com/sertralinehctab-mg.pdf
or scan QR Code to see Medication Guide →

Manufactured for:
Lupin Pharmaceuticals, Inc.
Naples, FL 34108
United States
Manufactured by:
Lupin Limited
Nagpur - 441 108, INDIA

Code No. MH/DRUGS/25-ND/59

52 x 20 mm

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N131390 RCL278-2025

Lupin Pharmaceuticals, Inc.**RECALL****Sertraline Hydrochloride Tablets USP, 100mg****Wholesale Level****11/5/2025**

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 _____.

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

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