

PRODUCT RECALL RESPONSE FORM

URGENT DRUG RECALL - RETAIL LEVEL

Please complete the required information and fax it to **1-817-868-5362**
or email to rxrecalls@inmar.com

To the Attention of Drug Safety/ Recall Services-Zydus Pharmaceuticals USA Inc.

Clomipramine Hydrochloride Capsules USP, (multiple strengths and lots as per table below)

Table:1

Sr. No.	Lot Number	Strength	Count	NDC Number	Expiry Date	Number of Bottles Purchased	Number of the Bottles Consumed	Number of Bottles in Possession	Number Bottles to be returned
1.	E408871	25 mg	30	1671484901	10/2026				
2.	E408872	25 mg	90	1671484902	10/2026				
3.	E408873	25 mg	100	1671484903	10/2026				
4.	E405280	25 mg	90	1671484902	06/2026				
5.	E405281	25 mg	100	1671484903	06/2026				
6.	E405282	25 mg	30	1671484901	06/2026				
7.	E400386	25 mg	30	1671484901	12/2025				
8.	E400387	25 mg	100	1671484903	12/2025				

Office of Regulatory Affairs

Zydus Pharmaceuticals (USA) Inc.

(A wholly owned subsidiary of Zydus Lifesciences Limited)

73 Route 31 North • Pennington, NJ 08534 | Phone: 609-730-1900





Pharmaceuticals

USA

Sr. No.	Lot Number	Strength	Count	NDC Number	Expiry Date	Number of Bottles Purchased	Number of the Bottles Consumed	Number of Bottles in Possession	Number Bottles to be returned
9.	E410157	50 mg	30	1671485001	12/2026				
10.	E410156	50 mg	90	1671485002	12/2026				
11.	E410158	50 mg	100	1671485003	12/2026				
12.	E407176	50 mg	30	1671485001	08/2026				
13.	E407128	50 mg	100	1671485003	08/2026				
14.	E405845	50 mg	30	1671485001	06/2026				
15.	E405846	50 mg	100	1671485003	06/2026				
16.	E400942	50 mg	90	1671485002	01/2026				
17.	E400943	50 mg	30	1671485001	01/2026				
18.	E400944	50 mg	100	1671485003	01/2026				
19.	E403069	75 mg	30	1671485101	04/2026				
20.	E403070	75 mg	90	1671485102	04/2026				
21.	E403071	75 mg	100	1671485103	04/2026				
22.	E406504	75 mg	30	1671485101	07/2026				
23.	E406505	75 mg	90	1671485102	07/2026				
24.	E407631	75 mg	90	1671485102	08/2026				
25.	E407632	75 mg	100	1671485103	08/2026				

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USA

Sr. No.	Lot Number	Strength	Count	NDC Number	Expiry Date	Number of Bottles Purchased	Number of the Bottles Consumed	Number of Bottles in Possession	Number Bottles to be returned
26.	E405848	75 mg	100	1671485103	07/2026				
27.	E405284	75 mg	100	1671485103	07/2026				
28.	E309177	75 mg	30	1671485101	11/2025				
29.	E400262	75 mg	30	1671485101	12/2025				
30.	E400263	75 mg	90	1671485102	12/2025				
31.	E400264	75 mg	100	1671485103	12/2025				
32.	E404200	75 mg	30	1671485101	05/2026				
33.	E404201	75 mg	100	1671485103	05/2026				
34.	E404202	75 mg	90	1671485102	05/2026				

No. of Returns kit required: _____

Please mark as applicable

We currently do not have any inventory of the above-listed Lot/bottles

We are notifying our customers

We have identified and notified my customers that were shipped or may have been shipped this product by _____;

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Pharmaceuticals

USA

Attached is the list of customers who received/ may have received this product. Please notify my customers.

Any adverse event associated with recalled product? Yes No
If yes, please explain:

Please check appropriate box to describe your business

Wholesaler/Distributor

Retailers

Repackager

Manufacturer

Pharmacy- Retail

Hospital/ Medical Facility

Hospital Pharmacies

Medical Laboratory

Other: _____

Name: _____

Title: _____

Tel Number: _____

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Pharmaceuticals

USA

Firm Name: _____

DEA# _____

Address: _____

City/ State: _____

Phone number: _____

If you have not purchased, the concerned lot directly from Zydus Pharmaceuticals USA Inc., then please provide details of your wholesaler: _____ (Name, City) DEA# _____

Signature: _____

Date: _____

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