

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.

Product: Esomeprazole Magnesium for Delayed Release Oral Suspension								
Strength	Carton NDC Number	Sachet NDC Number	Lot Number	Exp. Date	No. of Carton Purchased	No. of Carton/Sachets Consumed	No. of Carton/Sachets in Possession	No. of Carton/Sachets to be returned
20 mg	68382-848-94	68382-848-93	M402147	10/2025				
20 mg	68382-848-94	68382-848-93	M311637	07/2025				
20 mg	68382-848-94	68382-848-93	M402495	02/2026				
20 mg	68382-848-94	68382-848-93	M407997	05/2026				
20 mg	68382-848-94	68382-848-93	M502246	11/2026				
40mg	68382-849-94	68382-849-93	M311638	07/2025				
40mg	68382-849-94	68382-849-93	M400374	10/2025				
40mg	68382-849-94	68382-849-93	M402496	02/2026				
40mg	68382-849-94	68382-849-93	M407998	05/2026				
40mg	68382-849-94	68382-849-93	M502247	11/2026				
40mg	68382-849-94	68382-849-93	M414770	09/2026				
40mg	68382-849-94	68382-849-93	M414512	09/2026				

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 _____;

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

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

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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: _____

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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