

November 14, 2024

**URGENT DRUG RECALL**

Dear Customer:

This official communication is to notify you that Zydus Pharmaceuticals (USA) Inc. ("Zydus"), is voluntarily recalling one lot of the drug product mentioned below at the **RETAIL LEVEL**:

Product	Size	NDC	Lot Number	Expiry Date	Distribution
Esomeprazole Magnesium for Delayed Release Oral Suspension 40mg	30 Ct	68382-849-94 (carton pack) 68382-849-93 (unit dose packet)	M408002	05/2026	From 09/20/2024 to 10/31/2024

Zydus has decided to initiate a voluntary recall of one lot of Esomeprazole Magnesium for Delayed-Release Oral Suspension 40mg. The product is being recalled due a market complaint received for an incorrect NDC number where an incorrect NDC number (68382-848-93) was printed on a unit dose packet of Esomeprazole Magnesium for Delayed-Release Oral Suspension 40mg. Zydus' investigation is in progress and based on the preliminary investigation, the strength printed on the unit dose packet as well as the product inside the unit dose packet is correct; only the NDC number printed on the unit dose packet is incorrect. As patient safety remains our utmost priority, we are recalling this lot at the retail level.

Zydus Pharmaceuticals (USA) Inc. advises its customers that have this product in stock to discontinue the use/dispense/distribution of this lot and return it to Inmar Rx Solutions.

Through this communication, at our cost, we request you to organize the return of the above-referenced drug product in your possession. To facilitate this recall, please complete the following actions:

1. Examine your available stock of Esomeprazole Magnesium for Delayed Release Oral Suspension 40mg as per the above-mentioned lot number.
2. If you have the concerned lot number of the drug product in your stock, please discontinue further distribution, quarantine the affected product and return all units to Inmar Rx Solutions, 3845 Grand Lakes Way, Grand Prairie, TX 75050. A credit memo will be issued covering the quantity of your return to Inmar Rx Solutions.

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 | Fax: 609-730-1999

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3. Please complete the enclosed "PRODUCT RECALL RESPONSE FORM" and fax it to us at **1-817-868-5362** or email it to [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com). Even if you do not possess any inventory of the lot being recalled, we would appreciate it if you could still fill out and return the "PRODUCT RECALL RESPONSE FORM".
4. If you have further distributed this product, please notify your customers at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Please complete and return the enclosed response form as soon as possible.

If you have any questions about the logistics for returning affected lots or other issues, please call Recall Services at 866-787-5079 during business hours Monday – Friday (excluding holidays), 9 am to 5 pm EST.

If you have any questions about product safety concerns, then please call Zydus Pharmaceuticals Drug Safety/Medical Affairs at 1-877-993-8779 during business hours Monday – Friday (excluding holidays), 9 am to 5 pm EST.

This recall is being conducted with the knowledge of the US Food and Drug Administration.

We apologize for any inconvenience this voluntary recall may have caused you. Your assistance is appreciated and necessary to prevent further product usage.

Sincerely,

*Fr*  
*[Signature]*  
*11/14/2024*

Srinivas Gurram (Srini)  
Senior Vice President- Head of Regulatory Affairs and CQA Lead- Americas  
Zydus Pharmaceuticals (USA) Inc.

