**Esomeprazole Magnesium for Delayed-Release Oral Suspension Class II - Retail Level Recall - CUSTOMER CARE TALK TRACK**

**Background Information:** NCQA made an update to their standard requesting communication be sent to members and prescribers affected by any recall classified as a Class II by the FDA except for wholesale level recalls. Communication is being sent to members and prescribers of NCQA delegated clients to inform them of the limited recall. **The distributor is not requiring any action on the part of consumers for these recalls.**

**This recall affects:**

|  |  |  |
| --- | --- | --- |
| **Product** | **NDC** | **Lot # / Exp. Date** |
| Esomeprazole Magnesium for Delayed-Release Oral Suspension, 20 mg (Carton) | 68382-0848-94 | M402147 exp. 10/2025  M311637 exp. 07/2025 M402495 exp. 02/2026 M407997 exp. 05/2026 M502246 exp. 11/2026 |
| Esomeprazole Magnesium for Delayed-Release Oral Suspension, 20 mg (Single Dose) | 68382-0848-93 |
| Esomeprazole Magnesium for Delayed-Release Oral Suspension, 40 mg (Carton) | 68382-0849-94 | M311638 exp. 07/2025 M400374 exp. 10/2025 M402496 exp. 02/2026 M407998 exp. 05/2026 M502247 exp. 11/2026 M414770 exp. 09/2026 M414512 exp. 09/2026 |
| Esomeprazole Magnesium for Delayed-Release Oral Suspension, 40 mg (Single Dose) | 68382-0849-93 |

# Customer Care Talk Track:

\*\* Please ensure to disposition all recall calls to code “**1116**” \*\*

|  |  |  |
| --- | --- | --- |
| **Q#** | **Question** | **Answer** |
| **1** | **Why did I receive a recall notice?** | Our records indicate that you may have recently received a prescription for a product affected by a limited recall from your retail pharmacy.  For more information, call the distributor listed on the letter or visit their website. You may also call the United States Food and Drug Administration (FDA) toll-free at 1‑888‑INFO-FDA (1‑888-463-6332) or visit [www.fda.gov](http://www.fda.gov). |
| **2** | **May I return the rest of the recalled product that I have?** | The distributor is not requiring any action on the part of consumers for these recalls. |
| **3** | **Should I stop using the recalled product?** | Please contact your prescriber with any questions or concerns about this recall or your use of the product. |

Additional Information:

Event Details

**Event ID:**

96860

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Product Type:**

Drugs

**Initial Firm Notification of Consignee or Public:**

Letter

**Status:**

Ongoing

**Distribution Pattern:**

Nationwide -in the USA

**Recalling Firm:**

Zydus Pharmaceuticals (USA) Inc  
73 Route 31 N  
Pennington, NJ 08534-3601  
United States

**Press Release URL(s):**

Press Release Not Issued For This Recall

**Recall Initiation Date:**

5/13/2025

**Center Classification Date:**

5/20/2025

**Date Terminated:**

N/A

**\*N/A -***Not Available*

Product Details

| **#** | **Product Description** | **Recall Number** | **Classification** | **Code Information** | **Product Quantity** | **Reason for Recall** |
| --- | --- | --- | --- | --- | --- | --- |
| 1 | Esomeprazole Magnesium for Delayed-Release Oral Suspension, 40 mg, 30-count Single-Dose Packets per carton, Rx Only, Manufactured by: Zydus Lifesciences Ltd. Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 68382-849-94 | D-0442-2025 | Class II | Lot # M311638, Exp 07/2025, M400374, Exp 10/2025, M402496, Exp 02/2026, M407998, Exp 05/2026, M502247, Exp 11/2026, M414770, M414512, Exp 09/2026. | 30,674 30 sachets/carton | Failed Impurities/Degradation Specifications: Out-of-Specification test results obtained for any individual unknown degradation product during Related Compounds testing during long term stability. |
| 2 | Esomeprazole Magnesium for Delayed-Release Oral Suspension, 20 mg, 30-count single dose packets per carton, Rx Only, Manufactured by: Zydus Lifesciences Ltd. Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 68382-848-94 | D-0443-2025 | Class II | Lot #:M402147, Exp 10/2025; M311637, Exp 07/2025; M402495, Exp 02/2026; M407997, Exp 05/2026; M502246, Exp11/2026. | 22,152 30 sachets/carton | Failed Impurities/Degradation Specifications: Out-of-Specification test results obtained for any individual unknown degradation product during Related Compounds testing during long term stability. |

Update History

**There is no history available for products in this event**

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