# Carvedilol Tablets, USP, 3.125 mg, 12.5 mg, 25 mg 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** |
| Carvedilol Tablets, USP, 3.125 mg (500-count bottle) | 68462-0162-05 | 19242274 exp. 05/31/2026 |
| 19242275 exp. 05/31/2026 |
| 19242272 exp. 05/31/2026 |
| Carvedilol Tablets, USP, 3.125 mg (100-count bottle) | 68462-0162-01 | 19242272 exp. 05/31/2026 |
| Carvedilol Tablets, USP, 12.5 mg (500-count bottle) | 68462-0164-05 | 19243202 exp. 07/31/2026 |
| Carvedilol Tablets, USP, 25 mg (500-count bottle) | 68462-0165-05 | 19243104 exp. 07/31/2026 |

**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:**

97370

**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:**

Glenmark Pharmaceuticals Inc., USA  
750 Corporate Dr  
Mahwah, NJ 07430-2009  
United States

**Press Release URL(s):**

Press Release Not Issued For This Recall

**Recall Initiation Date:**

8/7/2025

**Center Classification Date:**

8/12/2025

**Date Terminated:**

N/A

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

Product Details

| **#** | **Product Description** | **Recall Number** | **Classification** | **Code Information** | **Product Quantity** | **Reason for Recall** |
| --- | --- | --- | --- | --- | --- | --- |
| 1 | Carvedilol Tablets, USP, 3.125 mg, Packaged as: a)500-count bottle, NDC 68462-162-05; b) 100-count bottle, NDC 68462-162-01; Rx only, Manufactured by: Glenmark Pharmaceuticals Ltd, Colvale-Bardez, Goa, 403513, India. Manufactured for Glenmark Pharmaceuticals, Inc., Mahwah, NJ, USA, NJ 07430. | D-0577-2025 | Class II | Lot#: a)19242274, 19242275, 19242272, Exp: 5/31/20; b) 19242272, Exp: 5/31/2026 | 44,328 bottles | CGMP Deviations: Presence of a nitrosamine, N-Nitroso Carvedilol I Impurity above the current Acceptable Intake Level. |
| 2 | Carvedilol Tablets, USP, 12.5 mg, 500-count bottle, Rx only, Manufactured by: Glenmark Pharmaceuticals Ltd, Colvale-Bardez, Goa, 403513, India. Manufactured for Glenmark Pharmaceuticals, Inc., USA, Mahwah, NJ 07430. NDC 68462-164-05 | D-0578-2025 | Class II | Lot#:19243202, Exp: 7/31/2026. | 6,432 bottles | CGMP Deviations: Presence of a nitrosamine, N-Nitroso Carvedilol I Impurity above the current Acceptable Intake Level. |
| 3 | Carvedilol Tablets, USP, 25 mg, 500-count bottle, Rx only, Manufactured by: Glenmark Pharmaceuticals Ltd, Colvale-Bardez, Goa, 403513, India. Manufactured for Glenmark Pharmaceuticals, Inc., USA, Mahwah, NJ 07430. NDC 68462-165-05 | D-0579-2025 | Class II | Lot#:19243104, Expires: 7/31/2026. | 4,800 bottles | CGMP Deviations: Presence of a nitrosamine, N-Nitroso Carvedilol I Impurity above the current Acceptable Intake Level. |

Update History

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