# Carvedilol Tablets, USP, 12.5 mg and 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.**

**A complete list of the affected products can be found at the end of this document.**

# 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:

**This recall affects:**

|  |  |  |
| --- | --- | --- |
| **Product Name** | **NDC #** | **Affected Lots** |
| Carvedilol tablets, USP 25 mg, 500 bottle pack | 68462-0165-05 | 17230500 exp. 02/2025  17230509 exp. 02/2025  17230526 exp. 02/2025  17230546 exp. 02/2025  17230551 exp. 02/2025  17230603 exp. 02/2025  17230628 exp. 02/2025  17230642 exp. 02/2025  17230645 exp. 02/2025  17230681 exp. 02/2025  17230829 exp. 03/2025  17230832 exp. 03/2025  17230854 exp. 03/2025  17230864 exp. 03/2025  17230874 exp. 03/2025  17230876 exp. 03/2025  17230889 exp. 03/2025  17230894 exp. 03/2025  17230960 exp. 04/2025  17230964 exp. 04/2025  17230976 exp. 04/2025  17230981 exp. 04/2025  17230985 exp. 04/2025  17231161 exp. 04/2025  17231171 exp. 04/2025  17231315 exp. 05/2025  17231318 exp. 05/2025  17231332 exp. 05/2025  17231333 exp. 05/2025  17231365 exp. 05/2025  17231539 exp. 06/2025  17231563 exp. 06/2025  17231653 exp. 07/2025  17231662 exp. 07/2025  17231663 exp. 07/2025  17231680 exp. 07/2025  17231691 exp. 07/2025  17231781 exp. 07/2025  17231782 exp. 07/2025  17231789 exp. 07/2025  17231838 exp. 08/2025  17231880 exp. 08/2025  17232144 exp. 09/2025  17232147 exp. 09/2025  17232151 exp. 09/2025  17232369 exp. 11/2025  17232370 exp. 11/2025  17232408 exp. 11/2025  17232409 exp. 11/2025  17232416 exp. 11/2025  17232504 exp. 11/2025  17232522 exp. 11/2025  17232531 exp. 11/2025  17232538 exp. 11/2025  17232543 exp. 11/2025  17240377 exp. 02/2026  17240385 exp. 02/2026  17240415 exp. 02/2026  17240422 exp. 02/2026  17240430 exp. 02/2026  17240510 exp. 02/2026 |
| Carvedilol tablets, USP 25 mg, 100 bottle pack | 68462-0165-01 | 17230551 exp. 02/2025  17240377 exp. 02/2026 |
| Carvedilol tablets, USP 12.5 mg, 500 bottle pack | 68462-0164-05 | 17230658 exp. 02/2025  17230814 exp. 03/2025  17230822 exp. 03/2025  17231004 exp. 04/2025  17231009 exp. 04/2025  17231022 exp. 04/2025  17231393 exp. 05/2025  17231392 exp. 05/2025  17231538 exp. 06/2025  17231541 exp. 06/2025  17231542 exp. 06/2025  17231710 exp. 07/2025  17231718 exp. 07/2025  17231721 exp. 07/2025  17231722 exp. 07/2025  17231730 exp. 07/2025  17232169 exp. 09/2025  17232253 exp. 10/2025  17240220 exp. 01/2026  17240240 exp. 01/2026  17240459 exp. 02/2026 |
| Carvedilol tablets, USP 12.5 mg, 100 bottle pack | 68462-0164-01 | 17230814 exp. 03/2025  17231392 exp. 05/2025  17232260 exp. 10/2025 |

Event Details

**Event ID:**

96162

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Product Type:**

Drugs

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

Letter

**Status:**

Ongoing

**Distribution Pattern:**

Nationwide in the U.S

**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:**

1/22/2025

**Center Classification Date:**

2/3/2025

**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, 25 mg, Rx only, a)500 Tablets, NDC 68462-165-05; b) 100 Tablets, NDC 68462-165-01, Manufactured for Glenmark Pharmaceuticals, NJ. | D-0215-2025 | Class II | Lot numbers: a) 17230500, 17230509,17230526,17230546,17230551,17230603,17230628, 17230642,17230645,17230681, Exp.:02/2025; 17230829,17230832,17230854, 17230864,17230874,17230876,17230889,17230894, Exp.: 03/2025; 17230960, 17230964,17230976,17230981,17230985,17231161,17231171, Exp.: 04/2025 17231315,17231318,17231332,17231333,17231365, Exp.: 05/2025; 17231539, 17231563, Exp.: 06/2025; 17231653,17231662,17231663,17231680,17231691, 17231781,17231782,17231789, Exp.: 07/2025;17231838,17231880, Exp.: 08/2025; 17232144,17232147,17232151, Exp.: 09/2025; 17232369,17232370,17232408,17232409, 17232416,17232504,17232522,17232531,17232538,17232543, Exp.: 11/2025; 17240377,17240385,17240415,17240422,17240430,17240510, Exp.: 02/2026. b) 17230551, 17240377, Exp.:02/2025 | N/A | CGMP Deviations:N-Nitroso Carvedilol I impurity (NNCI-I) were found to be failing per current FDA recommended limit. |
| 2 | Carvedilol Tablets, USP, 12.5 mg, Rx only, a)500 Tablets, NDC 68462-164-05; b) 100 Tablets, NDC 68462-164-01, Manufactured for Glenmark Pharmaceuticals, NJ. | D-0216-2025 | Class II | Lot numbers: a) 17230658, Exp.: 02/2025; 17230814,17230822, Exp.: 03/2025; 17231004,17231009,17231022, Exp.: 04/2025; 17231393,17231392, Exp.: 05/2025; 17231538, 17231541,17231542, Exp.: 06/2025; 17231710,17231718,17231721,17231722,17231730, Exp': 07/2025; 17232169, Exp.: 09/2025; 17232253, Exp.: 10/2025; 17240220,17240240, Exp.: 01/2026; 17240459, Exp.: 02/2026 b) 17230814, Exp.: 03/2025; 17231392, Exp.:05/2025; 17232260, Exp.: 10/2025. | N/A | CGMP Deviations:N-Nitroso Carvedilol I impurity (NNCI-I) were found to be failing per current FDA recommended limit. |

Update History

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

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