# Carvedilol Tablets USP 3.125mg, 6.25mg, 12.5mg, and 25mg 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 distributer 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. |

|  |  |  |
| --- | --- | --- |
| **Product** | **NDC** | **Lot Number / Exp. Date** |
| Carvedilol Tablets USP 3.125mg (100-count bottle) | 68462-0162-01 | 19233345 exp. 07/2025 |
| 19234275 exp. 09/2025 |
| 19240280 exp. 12/2025 |
| Carvedilol Tablets USP 3.125mg (500-count bottle) | 68462-0162-05 | 19232658 exp. 06/2025 |
| 19233328 exp. 07/2025 |
| 19233343 exp. 07/2025 |
| 19233344 exp. 07/2025 |
| 19233345 exp. 07/2025 |
| 19234275 exp. 09/2025 |
| 19234843 exp. 11/2025 |
| 19235039 exp. 11/2025 |
| 19240280 exp. 12/2025 |
| 19240296 exp. 12/2025 |
| Carvedilol Tablets USP 6.25 mg (100-count bottle) | 68462-0163-01 | 19233369 exp. 07/2025 |
| 19234162 exp. 09/2025 |
| 19240543 exp. 01/2026 |
| Carvedilol Tablets USP 6.25 mg (500-count bottle) | 68462-0163-05 | 19232736 exp. 06/2025 |
| 19232743 exp. 06/2025 |
| 19232746 exp. 06/2025 |
| 19232756 exp. 06/2025 |
| 19232757 exp. 06/2025 |
| 19233369 exp. 07/2025 |
| 19233371 exp. 07/2025 |
| 19233405 exp. 07/2025 |
| 19233416 exp. 07/2025 |
| 19234162 exp. 09/2025 |
| 19234183 exp. 09/2025 |
| 19234192 exp. 09/2025 |
| 19234204 exp. 09/2025 |
| 19234223 exp. 09/2025 |
| 19234243 exp. 09/2025 |
| 19234263 exp. 09/2025 |
| 19234165 exp. 09/2025 |
| 19234242 exp. 09/2025 |
| 19234743 exp. 11/2025 |
| 19234774 exp. 11/2025 |
| 19234993 exp. 11/2025 |
| 19240223 exp. 12/2025 |
| 19240203 exp. 12/2025 |
| 19240211 exp. 12/2025 |
| 19240214 exp. 12/2025 |
| 19240247 exp. 12/2025 |
| 19240249 exp. 12/2025 |
| 19240272 exp. 12/2025 |
| 19240319 exp. 12/2025 |
| 19240543 exp.01/2026 |
| Carvedilol Tablets USP 12.5mg (500-count bottle) | 68462-0164-05 | 19232758 exp. 06/2025 |
| 19232759 exp. 06/2025 |
| 19232762 exp. 06/2025 |
| 19232788 exp. 06/2025 |
| Carvedilol Tablets USP 25mg (500-count bottle) | 68462-0165-05 | 19234866 exp. 01/2026 |

Additional Information:

Event Details

**Event ID:**

96861

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Product Type:**

Drugs

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

Letter

**Status:**

Ongoing

**Distribution Pattern:**

U.S. Nationwide

**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:**

2/28/2025

**Center Classification Date:**

5/28/2025

**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 3.125mg Tablets a.)100-count bottle (NDC 68462-162-01), b.) 500-count bottle (NDC 68462-162-05), Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd., Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430. | D-0448-2025 | Class II | [100-Count Bottles] Lot 19231450, Exp Mar-25, 19233345, Exp Jul-25; Lot 19234275, Exp Sep-25; Lot 19240280, Exp DEC-25 [500-Count Bottles] Lot 19231450, 19231464, 19231471, 19231493, Exp Mar-25, 19232083, 19232103 Exp Apr-25, 19232658, Exp Jun-25; Lot 19233328, 19233343, 19233344, 19233345, Exp Jul-25; Lot 19234275, Exp Sep-25; Lots 19234843, 19235039, Exp Nov-25; Lots 19240280, 19240296, Dec-25 [less...](javascript:void(0);) | [100 Tablet Bottles] 59,952 bottles; [500 Tablet Bottles] 155,976 bottles | CGMP Deviations; presence 'N-Nitroso Carvedilol I' Impurity above the recommended acceptable intake limit |
| 2 | Carvedilol Tablets USP 6.25 mg, a.)100-count bottle (NDC 68462-163-01), b.) 500-count bottle (NDC 68462-163-05) Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd., Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430. | D-0449-2025 | Class II | [*Updated*](javascript:void(0);)  [100-Count Bottles] Lot 19231618, exp Mar-25; 19232064, exp Apr-25; 19232324, May-25; 19233369, Exp Jul-25; Lot 19234162, Exp Sep-25; Lot 19240543, Exp Jan-26 [500-Count Bottles] Lots 19231174, 19231199, 19231164, Exp Feb-25, 19231517,19231527, 19231566,19231568,19231595, 19231618,19231634,19231638, 19231448, Exp Mar-25, 19232043,19232051,19232064, Apr-25, 19232322, 19232324, 19232365, 19232380, 19232389, Exp May-25; Lots 19232736, 19232743, 19232746, 19232756, 19232757, Exp Jun-25; Lots 19233369, 19233371, 19233405, 19233416, Exp Jul-25; Lots 19234162, 19234183, 19234192, 19234204, 19234223, 19234243, 19234263, 19234165, 19234242, Exp Sep-25; Lots 19234743, 19234774, 19234993, Exp Nov-25; Lots 19240223, 19240203, 19240211, 19240214, 19240247, 19240249, 19240272, 19240319, Exp Dec-25; Lot 19240543, Exp Jan-26 [less...](javascript:void(0);) | [100 Tablet Bottles] 90,000 bottles; [500 Tablet Bottles] 324,288 bottles | CGMP Deviations; presence 'N-Nitroso Carvedilol I' Impurity above the recommended acceptable intake limit |
| 3 | Carvedilol Tablets USP 12.5 mg, 500-Count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd., Manufactured for Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430. NDC: 68462-164-05 | D-0450-2025 | Class II | Lot, Exp: Lots 19231899, 19231922, 19231927, 19231967, 19231979, Exp Apr-25; Lots 19232226, 19232234, 19232265, 1923227,1 Exp May-25; Lots 19232758, 19232759, 19232762, 19232788, Exp Jun-25 | 84,048 bottles | CGMP Deviations; presence 'N-Nitroso Carvedilol I' Impurity above the recommended acceptable intake limit |
| 4 | Carvedilol Tablets USP 25 mg, 500 -Count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd., Manufactured for Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430. NDC 68462-165-05. | D-0451-2025 | Class II | Lot, expiry: Lots 19231107, 19231114, 19231152, Exp Feb-25; Lot 19234866, Exp Jan-26 | 18,696 bottles | CGMP Deviations; presence 'N-Nitroso Carvedilol I' Impurity above the recommended acceptable intake limit |

Update History

**Product 1 Update(s)**

**Code Information** (was updated on 06/03/2025):

*Previous Value:*

[100-Count Bottles] Lot 19231450, Exp Mar-25, 19233345, Exp Jul-25; Lot 19234275, Exp Sep-25; Lot 19240280, Exp DEC-25 [500-Count Bottles] Lot 19231450, 19231464, 19231471, 19231493, Exp Mar-25, 19232083, Exp Apr-25, 19232658, Exp Jun-25; Lot 19233328, 19233343, 19233344, 19233345, Exp Jul-25; Lot 19234275, Exp Sep-25; Lots 19234843, 19235039, Exp Nov-25; Lots 19240280, 19240296, Dec-25 [less...](javascript:void(0);)

*New Value:*

[100-Count Bottles] Lot 19231450, Exp Mar-25, 19233345, Exp Jul-25; Lot 19234275, Exp Sep-25; Lot 19240280, Exp DEC-25 [500-Count Bottles] Lot 19231450, 19231464, 19231471, 19231493, Exp Mar-25, 19232083, 19232103 Exp Apr-25, 19232658, Exp Jun-25; Lot 19233328, 19233343, 19233344, 19233345, Exp Jul-25; Lot 19234275, Exp Sep-25; Lots 19234843, 19235039, Exp Nov-25; Lots 19240280, 19240296, Dec-25 [less...](javascript:void(0);)

**Product 2 Update(s)**

**Code Information** (was updated on 06/10/2025):

*Previous Value:*

[100-Count Bottles] Lot 19233369, Exp Jul-25; Lot 19234162, Exp Sep-25; Lot 19240543, Exp Jan-26 [500-Count Bottles] Lots 19231174, 19231199, 19231164, Exp Feb-25, 19231517,19231527, 19231566,19231568,19231595, 19231618,19231634,19231638, 19231448, Exp Mar-25, 19232043,19232051,19232064, Apr-25, 19232322, 19232324, 19232365, 19232380, 19232389, Exp May-25; Lots 19232736, 19232743, 19232746, 19232756, 19232757, Exp Jun-25; Lots 19233369, 19233371, 19233405, 19233416, Exp Jul-25; Lots 19234162, 19234183, 19234192, 19234204, 19234223, 19234243, 19234263, 19234165, 19234242, Exp Sep-25; Lots 19234743, 19234774, 19234993, Exp Nov-25; Lots 19240223, 19240203, 19240211, 19240214, 19240247, 19240249, 19240272, 19240319, Exp Dec-25; Lot 19240543, Exp Jan-26 [less...](javascript:void(0);)

*New Value:*

[100-Count Bottles] Lot 19231618, exp Mar-25; 19232064, exp Apr-25; 19232324, May-25; 19233369, Exp Jul-25; Lot 19234162, Exp Sep-25; Lot 19240543, Exp Jan-26 [500-Count Bottles] Lots 19231174, 19231199, 19231164, Exp Feb-25, 19231517,19231527, 19231566,19231568,19231595, 19231618,19231634,19231638, 19231448, Exp Mar-25, 19232043,19232051,19232064, Apr-25, 19232322, 19232324, 19232365, 19232380, 19232389, Exp May-25; Lots 19232736, 19232743, 19232746, 19232756, 19232757, Exp Jun-25; Lots 19233369, 19233371, 19233405, 19233416, Exp Jul-25; Lots 19234162, 19234183, 19234192, 19234204, 19234223, 19234243, 19234263, 19234165, 19234242, Exp Sep-25; Lots 19234743, 19234774, 19234993, Exp Nov-25; Lots 19240223, 19240203, 19240211, 19240214, 19240247, 19240249, 19240272, 19240319, Exp Dec-25; Lot 19240543, Exp Jan-26 [less...](javascript:void(0);)

**Code Information** (was updated on 06/03/2025):

*Previous Value:*

[100-Count Bottles] Lot 19233369, Exp Jul-25; Lot 19234162, Exp Sep-25; Lot 19240543, Exp Jan-26 [500-Count Bottles] Lots 19231174, 19231199, Exp Feb-25, 19231517,19231527, 19231566,19231568,19231595, 19231618,19231634,19231638, Exp Mar-25, 19232043,19232051,19232064, Apr-25, 19232322, 19232324, 19232365, 19232380, 19232389, Exp May-25; Lots 19232736, 19232743, 19232746, 19232756, 19232757, Exp Jun-25; Lots 19233369, 19233371, 19233405, 19233416, Exp Jul-25; Lots 19234162, 19234183, 19234192, 19234204, 19234223, 19234243, 19234263, 19234165, 19234242, Exp Sep-25; Lots 19234743, 19234774, 19234993, Exp Nov-25; Lots 19240223, 19240203, 19240211, 19240214, 19240247, 19240249, 19240272, 19240319, Exp Dec-25; Lot 19240543, Exp Jan-26 [less...](javascript:void(0);)

*New Value:*

[100-Count Bottles] Lot 19233369, Exp Jul-25; Lot 19234162, Exp Sep-25; Lot 19240543, Exp Jan-26 [500-Count Bottles] Lots 19231174, 19231199, 19231164, Exp Feb-25, 19231517,19231527, 19231566,19231568,19231595, 19231618,19231634,19231638, 19231448, Exp Mar-25, 19232043,19232051,19232064, Apr-25, 19232322, 19232324, 19232365, 19232380, 19232389, Exp May-25; Lots 19232736, 19232743, 19232746, 19232756, 19232757, Exp Jun-25; Lots 19233369, 19233371, 19233405, 19233416, Exp Jul-25; Lots 19234162, 19234183, 19234192, 19234204, 19234223, 19234243, 19234263, 19234165, 19234242, Exp Sep-25; Lots 19234743, 19234774, 19234993, Exp Nov-25; Lots 19240223, 19240203, 19240211, 19240214, 19240247, 19240249, 19240272, 19240319, Exp Dec-25; Lot 19240543, Exp Jan-26 [less...](javascript:void(0);)

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