# Duloxetine Delayed Release Capsules, USP, 20mg, 30mg, 30mg, and 60mg Class II - Retail Level Recall - CUSTOMER CARE TALK TRACK

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**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** |
| Duloxetine Delayed-Release Capsules USP, 20 mg | 51991-0746-05 | 240098C exp. 01/2027 |
| Duloxetine Delayed-Release Capsules USP, 30 mg | 51991-0747-10 | 240225C exp. 01/2027 |
| Duloxetine Delayed-Release Capsules USP, 60 mg | 51991-0748-10 | 240301C exp. 01/2027 |

# 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:**

96380

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Product Type:**

Drugs

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

Letter

**Status:**

Ongoing

**Distribution Pattern:**

Nationwide

**Recalling Firm:**

Breckenridge Pharmaceutical, Inc.  
200 Connell Dr Ste 4200  
Berkeley Heights, NJ 07922-2805  
United States

**Press Release URL(s):**

Press Release Not Issued For This Recall

**Recall Initiation Date:**

2/28/2025

**Center Classification Date:**

3/11/2025

**Date Terminated:**

N/A

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

Product Details

| **#** | **Product Description** | **Recall Number** | **Classification** | **Code Information** | **Product Quantity** | **Reason for Recall** |
| --- | --- | --- | --- | --- | --- | --- |
| 1 | Duloxetine Delayed-Release Capsules, USP, 60mg, Rx Only, 1000-count bottles, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922. NDC 51991-748-10 | D-0269-2025 | Class II | Lot#: 240301C, Expiration: 01/2027. | 11,100 bottles. | CGMP Deviations: Presence of N-nitroso-duloxetine impurity above FDA recommended interim limit. |
| 2 | Duloxetine Delayed-Release Capsules, USP, 30mg, Rx Only, 1000-count bottles, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922. NDC 51991-747-10 | D-0270-2025 | Class II | Lot#: 240225C, Expiration: 01/2027 | 14,749 bottles. | CGMP Deviations: Presence of N-nitroso-duloxetine impurity above FDA recommended interim limit. |
| 3 | Duloxetine Delayed-Release Capsules, USP, 20mg, Rx Only, 500-count bottles, Mfr. by: Towa Pharmaceutical Europe, S.L. Martorelles, (Barcelona), Spain, Dist. by: Breckenridge Pharmaceuticals, Inc., Berkeley Heights, NJ 07922. NDC 51991-746-05 | D-0271-2025 | Class II | Lot#: 240098C, Expiration: 01/2027. | 11,125 bottles. | CGMP Deviations: Presence of N-nitroso-duloxetine impurity above FDA recommended interim limit. |

Update History

[Top of the Document](#_top)

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