# Doxepin Hydrochloride Capsules, USP, 10 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 NDC # 62332-0637-31 with lot # 2305015142, exp. 9/30/2025.**

**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:**

97323

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Product Type:**

Drugs

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

N/A

**Status:**

Ongoing

**Distribution Pattern:**

Nationwide in the USA.

**Recalling Firm:**

Alembic Pharmaceuticals Limited  
Formulation Division, Village Panelav, P.O. Tajpura, Near Baska, Taluka Halol  
Panchmahal  
India

**Press Release URL(s):**

Press Release Not Issued For This Recall

**Recall Initiation Date:**

7/25/2025

**Center Classification Date:**

8/1/2025

**Date Terminated:**

N/A

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

Product Details

| **#** | **Product Description** | **Recall Number** | **Classification** | **Code Information** | **Product Quantity** | **Reason for Recall** |
| --- | --- | --- | --- | --- | --- | --- |
| 1 | Doxepin Hydrochloride Capsules, USP, 10 mg, 100 Capsules, Rx only, Manufactured by: Alembic Pharmaceuticals Limited, Panela v 389350, Gujarat, India, Manufactured for: Alembic Pharmaceuticals, Inc., Bedminster, NJ 07921, USA, NDC 62332-637-31 | D-0566-2025 | Class II | Lot: 2305015142, Exp. Date: 9/30/2025 | 9,492 bottles | CGMP Deviations: Presence of Nitrosamine Drug Substance Related Impurity above the proposed interim limit. |

Update History

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