



CIN No:

Date: July 24, 2025

**URGENT: DRUG RECALL – Oral Solid**

Dear Distributor,

This is to inform you of a product recall involving 1 lot of Doxepin hydrochloride 10mg X 100ct:

**Doxepin hydrochloride 10mg X 100ct**

**NDC CODE. 62332-0637-31**

**Lot Number 2305015142, Expiration date Sep. 2025**

**Doxepin hydrochloride 10mg X 100ct Label**

The image shows a rectangular product label for Doxepin Hydrochloride Capsules, USP. The label is divided into several sections. On the left, there is a block of text containing usage instructions, storage information, and manufacturer details. In the center, the product name and strength (10 mg\*) are prominently displayed in a red box. Below this, there is a box for the pharmacist's instruction. To the right of the product name, there is a barcode with the NDC number 62332-637-31 and the lot number 2305015142. Further right, there is a section for the expiration date and a unique identifier (GTIN). On the far right, there is a grey rectangular area labeled 'Coding Area NOT TO BE PRINTED 28x40 mm' with an arrow pointing to it.

\* Each capsule contains doxepin hydrochloride, USP equivalent to 10 mg of doxepin. Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Keep container tightly closed. **Keep this and all medication out of the reach of children.** Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from light. **DOSAGE AND USE:** See accompanying prescribing information. This package is child-resistant. Manufactured by: **Alembic Pharmaceuticals Limited** (Formulation Division), Panelav 389350, Gujarat, India. Manufactured for: **Alembic Pharmaceuticals, Inc.** Bedminsiher, NJ 07921, USA

**NDC 62332-637-31**  
**Doxepin Hydrochloride Capsules, USP**  
**10 mg\***

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

**Rx only 100 Capsules**

**Alembic**

Print Medication Guides at <http://www.alembicusa.com/medicationguide.aspx>, or call 1-866-270-9797.  
Mfg. Lic. No.: G659 20/033812 09/2021

62332-637-31  
3 7

GTIN: 00362332637317  
S.NO./EXP./LOT

Coding Area  
NOT TO BE  
PRINTED  
28x40 mm

This recall has been initiated due to the product being out of specification at the time of testing. CDER recommended to Alembic to recall the batch due to levels of 'N-Nitroso-Desmethyl-Doxepin (e) Impurity' exceeding USFDA published acceptable Intake of 26.5 ng/day (i.e. the limit of NMT 0.088 ppm is derived considering published acceptable Intake with maximum daily dose of 300 mg).

There have been no known reported adverse events associated product being recalled and the recall is limited to the 1 identified lot of Doxepin hydrochloride 10mg.

Please examine your stocks immediately to determine if you have any of the units of Lot 2305015142 on hand. If so, please discontinue dispensing (distribution) the lot and promptly return via parcel post to Inmar Rx Solutions, 3845 Grand Lakes Way, Suite 125, Grand Prairie, TX 75050.

ATTENTION: RETURNED GOODS.

If you have further distributed any units of Lots **2305015142**, please immediately contact your accounts, advise them of the recall situation, and have them return their outstanding recalled stocks to you. Return these stocks as indicated above. This distribution of the batch was carried out from 3/7/2024 to 6/11/2024.

Based on the extent of the distribution, the depth of the recall is considered up to pharmacy level.

Please return the enclosed card immediately, providing the requested information. Your assistance is appreciated and necessary to prevent consumer illness.

**STOCK RESPONSE FORM**

**Recall of Doxepin Hydrochloride 10mg X 100ct**  
**Lots 2305015142**  
**Retail Level**  
**(07/24/2025)**

**Please fill out this form completely.** By doing so, this will acknowledge that you have read and understand the withdraw instructions and have taken the appropriate action.

Customer Name \_\_\_\_\_ DEA # \_\_\_\_\_  
*\*DEA # is required, if it is not provided, the processing of your form will be delayed.*

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Contact Name (please print) \_\_\_\_\_ Telephone # \_\_\_\_\_

Contact Signature \_\_\_\_\_ Date \_\_\_\_\_

**I have checked my stock and:**

\_\_\_\_\_ Do not have any stock of the **recall product**.

**OR**

I have quarantined and listed in the box below the quantity of withdrawn units and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s) Please indicate the # of needed box labels \_\_\_\_\_.

Item Description	NDC	Lot #	Qty returning
Doxepin hydrochloride 10mg X 100ct	62332-0637-31	2305015142	

**If you did not purchase the product directly from the Manufacturer, please complete the below section.**

Purchased From: Wholesaler Name \_\_\_\_\_ DEA # \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_

If you have any questions regarding this form or product return please contact Inmar at 1-877-296-5632. Office hours 9am to 5pm EST Mon thru Fri.

**Please fax this form to: 1-817-868-5362 or E-mail [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com)**

**EVENT ID: RCL174-25 / N131334**



**Product Name: Doxepin hydrochloride 10mg X 100ct**

**Lot No.: 2305015142**

**Expiration date: 9/30/2025**

**Please check ALL appropriate boxes.**

I have read and understand the recall instructions provided in the recall letter dated July 24, 2025.

I have checked my stock and have quarantined inventory consisting of \_\_\_\_\_ <units or cases>.

Indicate disposition of recalled product:

returned (**specify quantity, date and method**)/held for return;

destroyed (**specify quantity, date and method**);

relabeled (**specify quantity and date**);

quarantined pending correction (**specify quantity**);

transfused – Blood or blood products (**specify date and quantity**);

implanted (**specify date and quantity**)

I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**); <or>



Attached is a list of customers who received/may have received this product. Please notify my customers.

Any adverse events associated with recalled product?  Yes  NO

If yes, please explain: \_\_\_\_\_

Please check the appropriate box(es) to describe your business

Wholesaler/distributor  Retailer

Grocery corporate headquarters  Food service/restaurant

Repacker  Manufacturer

Pharmacy  Retail  Hospital/Medical facility  Hospital Pharmacies  Medical Laboratory

Other: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Tel. number: ( ) \_\_\_\_\_ Name

Title

Enclosure(s)