CIN No:

Date: July 24, 2025

URGENT: DRUG RECALL – Oral Solid

Dear Distributor,

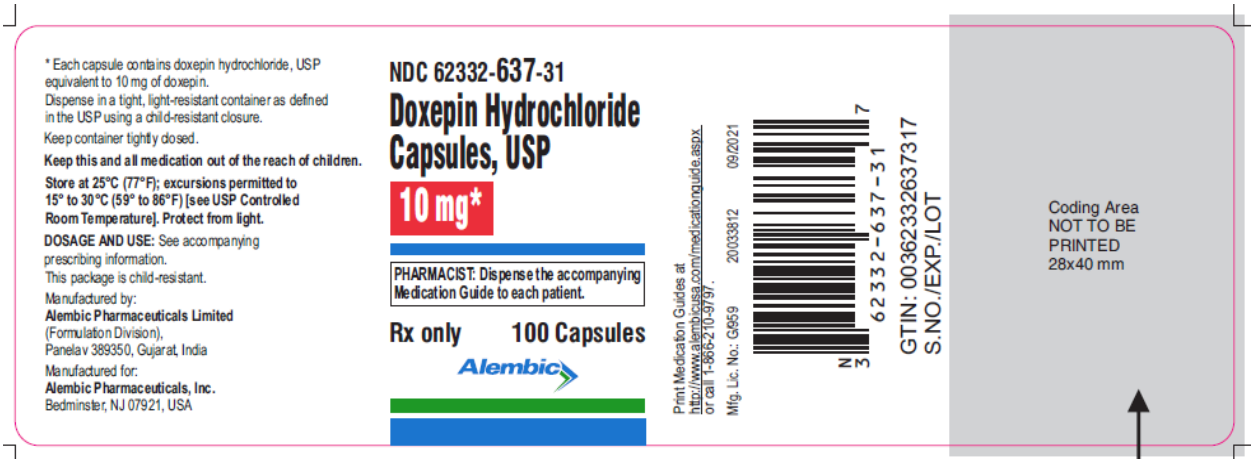
This is to inform you of a product recall involving 1 lot of Doxepin hydrochloride 10mg X 100ct:

Doxepin hydrochloride 10mg X 100ct

NDC CODE. 62332-0637-31

Lot Number 2305015142, Expiration date Sep. 2025

Doxepin hydrochloride 10mg X 100ct Label



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

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)