UNICHEM
PHARMACEUTICALS (USA), INC.

URGENT RECALL COMMUNICATION / CUSTOMER NOTIFICATION
Cyclobenzaprine Hydrochloride Tablets USP, 10 mg
CONSUMER LEVEL RECALL

August 27, 2025

Dear Valued Customer:

This letter is to inform you that Unichem Pharmaceuticals (USA), Inc. is voluntarily recalling the following product listed immediately below:

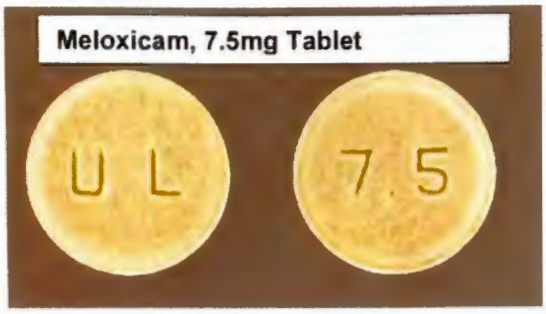
Product	Lot Number	NDC Number	Distribution Date
Cyclobenzaprine Hydrochloride Tablets USP, 10mg, 90 Count	GMML24026A	29300-415-19	April 2025 - June 2025

Unichem Pharmaceuticals (USA), Inc. is voluntarily recalling one (1) lot of Cyclobenzaprine Hydrochloride Tablets USP 10 mg, to the consumer level. The Cyclobenzaprine 10mg (90ct) label was inadvertently placed on a bottle containing Meloxicam 7.5 mg tablets. This recall is specific to "**Cyclobenzaprine Tablets, USP, 10 mg, (90ct)"** bearing Lot Number **GMML24026A** with an expiration date of **Sept 2027**. However, bottles labeled as "Meloxicam Tablets, USP, 7.5 mg, (100ct)" bearing the Lot Number GMML24026A do possess the accurate contents and are not affected by this recall.

This recall is being made with the full knowledge of the United States Food and Drug Administration and should be carried out as a **Consumer Level Recall**.

Risk Statement: For patients who unknowingly take Meloxicam there is a reasonable probability of serious adverse events including cardiovascular, gastrointestinal, renal, anaphylaxis, and skin reactions, particularly in those patients taking concomitant non-steroidal anti-Inflammatory drugs and/or blood thinners, those who have allergies to the Meloxicam, or those with underlying illness. To date, Unichem Pharmaceuticals has not received any reports of adverse events related to this recall. Should you need to report an adverse event, please call: +1 (866) 562-4616.

Meloxicam Tablets USP, 7.5 mg is a non-steroidal anti-inflammatory drug, indicated for use in Osteoarthritis, Rheumatoid Arthritis, and Juvenile Rheumatoid Arthritis. Meloxicam Tablets, USP, 7.5 mg is light yellow, round flat beveled edged, tablet with "U & L" debossed on one side and "7.5" debossed centrally on the other side.



Cyclobenzaprine Hydrochloride Tablets USP, 10mg is a muscle relaxer and indicated as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. Cyclobenzaprine Hydrochloride Tablets, USP, 10 mg, are blue colored, film coated, round shaped, biconvex tablets, debossed with "U" on one side and "12" debossed on other side.

The mislabeled bottles of Cyclobenzaprine Hydrochloride Tablets USP, 10mg but containing Meloxicam 7.5mg tablets, can be identified by the lot number GMML24026A and expiry of Sept 2027 and NDC 29300-415-19 printed on the label of the 90 count bottles.

Unichem Pharmaceuticals (USA), Inc. began shipping these batches to customers nationwide in **April 2025**.

Please complete and return the enclosed Business Response Form (Attachment I) as soon as possible and fax the form to 1-817-868-5362, or email the form to rxrecalls@inmar.com. Subsequently, please examine your inventory and quarantine the product identified in the subject recall. Additionally, if you have further distributed the recalled product, please notify your customers / patients accordingly. Your notification to your customers / patients may be enhanced by including a copy of this recall notification letter.

The product should be identified by checking the product name and lot number on the product label.

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To implement this recall, please take the following actions:

1. Immediately examine your inventory and quarantine product subject to recall.
2. Immediately discontinue use, dispensing and distribution of the identified lot numbers. A credit memo will be issued covering the quantity of your product returned.
3. Return product to:

   Inmar
   3845 Grand Lakes Way, STE 125,
   Grand Prairie, Texas 75050

   NOTE: A recall packet, inclusive of a call tag, a pre-printed, pre-paid return label will be provided to you for product return; return shipment is free of charge. For the call tag, contact 1-**877-840-5109**.

4. If you have further distributed this product and Lot Number to other **retailers and / or consumers**, please identify and notify them at once of this product recall. Your notification should include a copy of this recall notification letter and response form.

5. Please complete and return the enclosed "Customer Recall Business Response Form" as soon as possible and fax the form to us at **1-817-868-5362** or email to **rxrecalls@inmar.com**.

Once the business response form is received by Inmar, a Return Goods Authorization form will be sent to you. Please return your product along with the Return Authorization using the postage paid shipping label included in your recall return packet. Appropriate reimbursement for product returns will be issued on receipt of the recalled product.

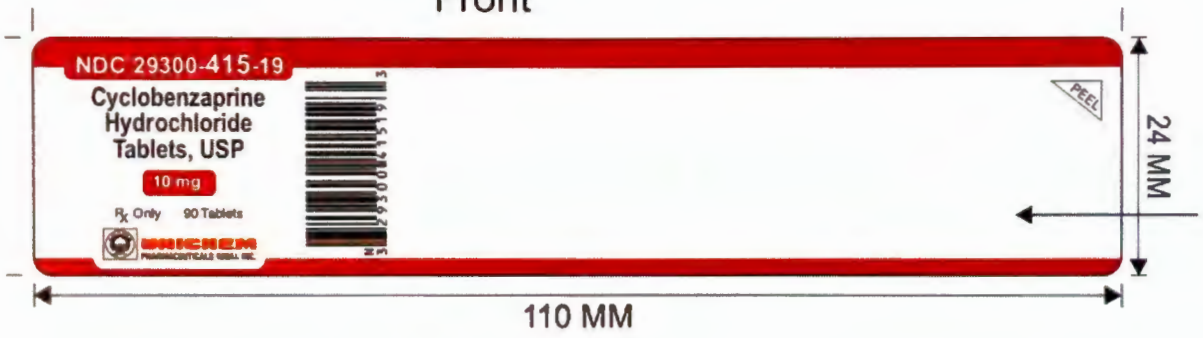
We apologize for any inconvenience this may cause you. If you should have any questions, please do not hesitate to contact Inmar at **1-877-840-5109;** Monday – Friday (9 am – 5 pm; CST).

Sincerely,

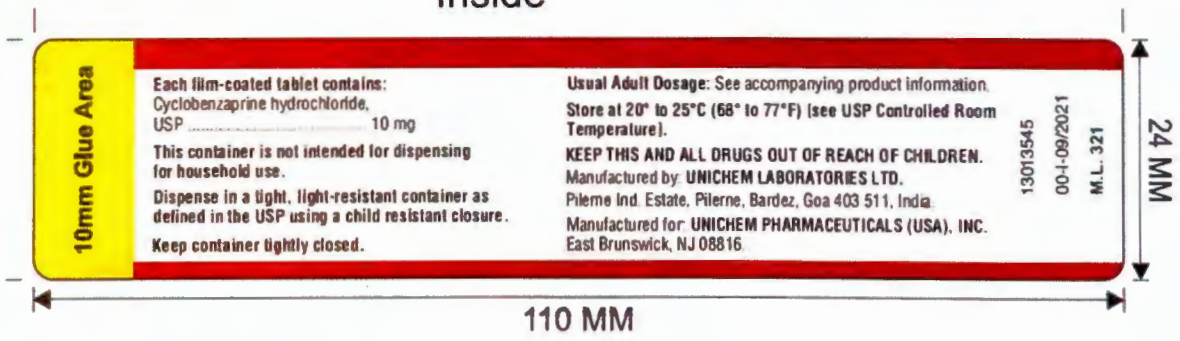
Jennifer Perry
Associate Vice President and Regional Head of Quality
Unichem Pharmaceuticals (USA), Inc.
1 Tower Center Boulevard,
East Brunswick, New Jersey 08816 (USA)
Telephone 1- (732) 253-5954

The product label is shown below:

Front



Inside



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Cyclobenzaprine Hydrochloride Tablets USP, 10mg
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Attachment 1 - BUSINESS RESPONSE FORM

Please Fill Out This Form Completely – By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Customer Name _____ *DEA #_____

DEA # is required for all Controlled Substances, if not provided, processing of your form will be delayed.

Address_____

City_____ State_____ Zip_____

Contact Name (please print)_____ Telephone #_____

Contact Signature _____ Date_____

Please Complete (check ALL applicable):

☐ I have read and understand the recall instructions provided in the recall letter and that this recall is being carried out to the Consumer level.

☐ I have checked my inventory and have quarantined the subject product, we possess _____ units of the same.

☐ I have or will contact those we further distributed the subject product regarding this recall out to the consumer level.

☐ Indicate disposition of this recalled product:

Item Description	Lot Number	NDC Number	QTY Returning

☐ Other:

_____

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Please check the appropriate box(s) to describe your business:

☐ Wholesaler/Distributor ☐ Hospital/Medical Facility ☐ Pharmacy (retail)

☐ Other:_____

If you have any questions regarding this form or product return, please contact us at: 1+ 877-840-5109. Office hours Monday – Friday (9 am – 5 pm; CST).

PLEASE SEND THIS COMPLETED RECALL RESPONSE FORM TO:

FAX: **1+ (817) 868-5362** EMAIL TO: **rxrecalls@inmar.com**

MAIL: **Inmar, 3845 Grand Lakes Way, STE 125, Grand Prairie, Texas 75050**