

Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC25-021-CG **August 29, 2025**

FDA announced that, East Brunswick, NJ, 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

RECOMMENDATIONS

1. Legacy Pharmaceutical Packaging LLC is notifying its distributors and customers in writing and is arranging/assisting for return of all recalled products to:
 - a. For Distribution Center Level, please return the products to Legacy Pharmaceutical Packaging LLC;
 - b. For Retail Level, please return the products to Genco; or
 - c. For Consumer Level, please return the products to the dispensing pharmacy, whichever is applicable. Instructions for returning recalled products are provided in the recall letter.
2. Consumers with questions regarding this recall can contact Inmar at **1-877-840-5109** or via email a to rxrecalls@inmar.com; Monday – Friday (9 am – 5 pm; CST).
3. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
4. Review your inventory to identify existence of recalled products.
5. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

Unichem Pharmaceuticals (USA) Inc. Issues Voluntary Nationwide Recall of Cyclobenzaprine Hydrochloride Tablets USP 10 mg, Due to Mislabeling

SUMMARY:

Company Announcement Date:	August 27, 2025
FDA Publish Date:	August 27, 2025
Product Type:	Drugs
Reason for Announcement:	Device & Drug Safety – Mislabel
Company Name:	Unichem Pharmaceuticals
Brand Name:	Unichem Pharmaceuticals
Product Description:	Cyclobenzaprine Hydrochloride Tablets USP 10 mg

Company Announcement

FOR IMMEDIATE RELEASE – 08/27/2025– East Brunswick, NJ, 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.

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.

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.

The product was distributed Nationwide to distributors, and further downstream distribution occurred to retailers and subsequently consumers.

Unichem Pharmaceuticals (USA), Inc. is notifying its downstream trading partners, their retailers and consumers of the recall through our third party recall provider, Inmar. Inmar is arranging for the return of the subject recalled Cyclobenzaprine Hydrochloride Tablets USP, 10mg labeled with Lot # GMML24026A. Our downstream trading partners that have Cyclobenzaprine Hydrochloride Tablets USP, 10mg with Lot# GMML24026A, Exp Sept 2027, which is being recalled, should not further distribute, this medication, and notify their customers accordingly. Retail pharmacies should not dispense from this lot number, GMML24026A, and call the number provided for guidance on how to return this drug product. Any pharmacy who has dispensed this lot of Cyclobenzaprine, should notify the consumer. Consumers should return the medication to the pharmacy they received their prescription from.

Consumers with questions regarding this recall can Inmar at **1-877-840-5109** or via email **to rxrecalls@inmar.com**; Monday – Friday (9 am – 5 pm; CST). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call **1-800-332-1088** to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to **1-800-FDA-0178**.