Unichem Issues Voluntary Nationwide Recall of Cyclobenzaprine Tablets 10 mg

Date: 08/27/2025

At Prime Therapeutics, we want to help you receive the best possible care. Visit our drug recall site for details: https://www.primetherapeutics.com/drugrecalls.

About this recall:
Unichem has voluntarily recalled one lot of cyclobenzaprine hydrochloride (HCl) tablets 10 mg (NDC 29300-0415-19) to the consumer level. The cyclobenzaprine 10 mg (90-count) label was accidentally placed on a bottle containing meloxicam 7.5 mg tablets.

Cyclobenzaprine is a muscle relaxer and is used as an add-on to rest/physical therapy for relief of muscle spasms associated with acute, painful musculoskeletal conditions. Cyclobenzaprine HCl 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. Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) and is indicated for arthritis (e.g., osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis). Meloxicam Tablets, USP, 7.5 mg are light yellow, round flat beveled edged, tablet with “U & L” debossed on one side and “7.5” debossed centrally on the other side.

What this means to you:
For patients who unknowingly take meloxicam, due to mislabeling, there is the potential for serious adverse events, especially in those who take other NSAIDs and/or blood thinners or have underlying illness. Adverse events could occur related to the following organ/organ systems: cardiac (heart), gastrointestinal (stomach/intestines), renal (kidneys) and skin. Additionally, those who have an allergy to meloxicam could potentially experience a serious allergic reaction (anaphylaxis). To date, the manufacturer has not received any reports of adverse events related to this recall.

Consumers who received the **recalled lot** should return the medication to the pharmacy they received their prescription from. The mislabeled bottles of cyclobenzaprine tablets 10 mg (but containing meloxicam 7.5 mg 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. Consumers with questions regarding this recall can Inmar at 1-877-840-5109 or via email to rxrecalls@inmar.com (Monday to Friday, 9 am to 5 pm CST). Consumers should contact their health care 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.
- Regular Mail or Fax: Download form 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.

This recall is being conducted with the knowledge of the United States (U.S.) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/unichem-pharmaceuticals-usa-inc-issues-voluntary-nationwide-recall-cyclobenzaprine-hydrochloride

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.