Capital Rx Drug Recall Report

NOVEMBER 2023

Capital Rx

Welcome to the Capital Rx Drug Recall Report. This report is designed to keep you up to date on the latest FDA Class 1 and Class 2 recalled drugs and market withdrawals that impact our members. It is one of the many ways we, at Capital Rx, demonstrate our commitment to providing clients and partners the tools and resources they desire.

WHO WE ARE

Capital Rx is a full-service pharmacy benefit manager (PBM) and pharmacy benefit administrator (PBA), advancing our nation's electronic healthcare infrastructure to improve drug price visibility and patient outcomes. As a Certified B Corp™, Capital Rx is executing its mission through the deployment of JUDI®, the company's cloud-native enterprise health platform, and a Single-Ledger Model™, which increases visibility and reduces variability in drug prices. JUDI connects every aspect of the pharmacy ecosystem in one efficient, scalable platform, servicing over 2.4 million members for Medicare, Medicaid, and commercial plans. Together with our clients, we are reimagining the administration of pharmacy benefits and rebuilding trust in healthcare.
The drug recall report is subject to change: information in this report is current as of 11/28/2023

Privacy Statement:
This privacy policy describes the types of information we may collect from you or that you may provide when you visit the website cap-rx.com and our practices for collecting, using, maintaining, protecting, and disclosing that information. Capital Rx, Inc. ("we," "our," or "us") is committed to ensuring that your privacy is protected. This policy applies to information we may collect through cap-rx.com, including any services offered on or through cap-rx.com such as the prescription benefit member web portal, and our mobile application accessible at the Google Play Store and iOS App Store under the name Capital Rx (collectively, our "Site").

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
11/8/2023	Class 2	Gynazole-1 (Butoconazole Nitrate) 2% Vaginal Cream	Padagis US LLC	45802-0396-01	164185, Exp. Date 4/2024	An incorrect product used during manufacturing. Hydrophilic Colloidal Silica was used to manufacture the product rather than Hydrophobic Colloidal Silica as required by the manufacturing process.
11/8/2023	Class 2	Liothyronine Sodium 5 MCG Tablets	Sun Pharmaceutical Industries Inc.	62756-0589-88	DND0058A, Exp. Date 12/2023	Failing to meet impurity and degradation standards.
11/8/2023	Class 2	Liothyronine Sodium 25 MCG Tablets	Sun Pharmaceutical Industries Inc.	62756-0590-88	DNC2204A, Exp. Date 11/2023	Failing to meet impurity and degradation standards.
11/15/2023	Class 2	Montelukast Sodium 10 MG Tablets	Dr. Reddy's Laboratories, Inc.	55111-0725-10	C2305569, Exp. date 03/31/2026	A foreign tablet identified as Metoprolol 25 mg was found in a bottle of Montelukast Sodium 10 mg tablets.

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11/15/2023	Class 2	oxyBUTYnin Chloride ER 5 MG Tablets	Zydus Pharmaceuticals (USA) Inc.	68382-0255-01	M212749, Exp. date 11/2024; M214477, Exp. date 11/2024; M214478, Exp. date 11/2024; M214479, Exp. date 11/2024; M214480, Exp. date 11/2024	Failing to meet dissolution specifications, which may result in possible issues with the tablets dissolving.
11/15/2023	Class 2	oxyBUTYnin Chloride ER 10 MG Tablets	Zydus Pharmaceuticals (USA) Inc.	68382-0256-01	M213318, Exp. date 11/2024; M213314, Exp. date 11/2024; M213315, Exp. date 11/2024; M214436, Exp. date 11/2024; M214437, Exp. date 11/2024; M214438, Exp. date 11/2024; M300653, Exp. date 12/2024; M300654, Exp. date 12/2024	Failing to meet dissolution specifications, which may result in possible issues with the tablets dissolving.
11/15/2023	Class 2	oxyBUTYnin Chloride ER 15 MG Tablets	Zydus Pharmaceuticals (USA) Inc.	68382-0257-01	M211541, Exp. date 10/2024; M211542, Exp. date 10/2024; M212746, Exp. date 10/2024; M300660, Exp. date 12/2024	Failing to meet dissolution specifications, which may result in possible issues with the tablets dissolving.
11/15/2023	Class 2	Ranolazine ER 500 MG Tablets	Glenmark Pharmaceuticals Inc., USA	68462-0319-60	17230388, Exp. 01/31/2025	Failing to meet dissolution specifications, which may result in possible issues with the tablets dissolving.

How do I find out more information about the recall?

View the FDA website URL for more information.

RECALL TYPE	DRUG RECALLED	FDA NOTIFICATION URL
Class 2	Gynazole-1 (Butoconazole Nitrate) 2% Vaginal Cream	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=203625
Class 2	Liothyronine Sodium 5 MCG Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=203773
Class 2	Liothyronine Sodium 25 MCG Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=203774
Class 2	Montelukast Sodium 10 MG Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=203703
Class 2	oxyBUTYnin Chloride ER 5 MG Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=203782
Class 2	oxyBUTYnin Chloride ER 10 MG Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=203783
Class 2	oxyBUTYnin Chloride ER 15 MG Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=203784
Class 2	Ranolazine ER 500 MG Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=203789