Capital Rx Drug Recall Report

AUGUST 2024

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 **8/22/2024****

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
7/24/2024	Class 2	Cardura XL Extended Release 8mg tablets	Viatris Inc	00049-2080-10	8147041 EXP. 06/2024; 8163765 EXP. 03/2025	Failing to meet impurity and degradation standards.
7/24/2024	Class 2	Fludrocortisone Acetate 0.1 Mg Tablets	Teva Pharmaceuticals USA, Inc	00555-0997-02	CNSDH, EXP. 06/30/2024; CNWVM, CNWWH, EXP. 07/31/2024; CNXKW, CNXKY, CNXMB, CNXMH, EXP. 09/30/2024; CPBTP, CPBTV, EXP. 11/30/2024	Failing to meet impurity and degradation standards.
7/24/2024	Class 2	Nitrofurantoin Macrocrystal 100 Mg Capsules	Sun Pharmaceutical Industries, Inc	57664-0233-88	231067, 231069, EXP 04/30/2025	Failing to meet impurity and degradation standards.

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RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
7/24/2024	Class 2	Pravastatin Sodium 80 Mg Tablets	Glenmark Pharmaceuticals Inc., USA	68462-0198-90, 68462-0198-05	17211249, 17211264, 17211266, 17211286, EXP 06/30/24; 17211525, 17211535, 17211549, EXP 07/31/24; 17211787, 17211801, EXP 08/31/24; 17212041, EXP 09/30/24; 17212088, 17212106, EXP 10/31/24; 17212346, 17212345, EXP 11/30/24; 17220053, 17220054, 17220055 EXP 12/31/24; 17220309, 17220310, EXP 01/31/25; 17211290, EXP 06/30/2024	Failing to meet impurity and degradation standards.
7/24/2024	Class 1	Potassium Chloride Extended-Release 10 mEq K Capsules	Glenmark Pharmaceuticals Inc., USA	68462-0357-01, 68462-0357-05	17221197, 17221386, 17221385, EXP 05/31/24; 17221489, 17221504, 17221530, EXP 06/30/24; 17221561, 17221579, 17221568, 17221702, 17221704, EXP 07/31/24; 17221898, 17221993, 17222029, EXP 08/31/24; 17222300, 17222304, 17222278, 17222609, 17222395, EXP 10/31/24; 17222589, 17222605, 17222613, EXP 11/30/24; 17221446, 17221445, EXP 05/31/24; 17221393, 17221403, 17221405, 17221503, 17221508, EXP 06/30/24; 17221567, 17221566, 17221719, 17221731, EXP 07/31/24; 17221891, 17221892, 17221900, 17221992, 17222022, EXP 08/31/24; 17222056, 17222043, 17222068, 17222079, 17222099, 17222103, 17222114, 17222119, 17222188, 17222199, 17222209, 17222200, EXP 09/30/24; 17222265, 17222269, EXP 10/31/24; 17222527, 17222530, 17222583, 17222586, 17230051, 17230075, 17230067, EXP 11/30/24;	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly
7/31/2024	Class 2	Venlafaxine HCL ER 37.5 Mg Capsules	Zydus Pharmaceuticals (USA) Inc	68382-0034-16, 68382-0034-10	M213175, EXP 09/2024; M213176, EXP 09/2024	Failing to meet impurity and degradation standards.

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RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
8/7/2024	Class 1	Clonazepam 0.125 Mg Disintegrating Tablets	Endo Pharmaceuticals, Inc.	49884-0306-02	550147301, EXP 08/31/2026	Mislabeling where an incorrect strength appears on the cartons of some packs showing the product strength as 0.125 mg instead of 0.25 mg due to an error during packaging. The blister strips inside the product pack reflect the correct strength of 0.25 mg.
8/7/2024	Class 1	Potassium Chloride Extended-Release 10 mEq K Capsules	Amerisource Health Services LLC	68001-0396-00, 68001-0396-03	[100 COUNT BOTTLES]: 17221738, EXP 07/31/2024; 17222494, EXP 10/31/2024; 17230533, EXP 01/31/2025; 17232208, EXP 09/30/2025; [500 COUNT BOTTLES]: 17221823, 17221830, EXP 07/31/2024; 17221831, EXP 08/31/2024; 17230248, 17230253, 17230271, EXP 12/31/2024; 17230796, 17230820, EXP 02/28/2025; 17230825, 17230833, 17230840, EXP 03/31/2025; 17231537, 17231540, 17231719, 17231737, EXP 06/30/2025; 17232111, 17232164, EXP 09/30/2025	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly.
8/7/2024	Class 2	Azelaic Acid 15 % Gel	Glenmark Pharmaceuticals Inc., USA	68462-0626-52	19241453; EXP 03/2026	Deviations from Current Good Manufacturing Practices (CGMP).
8/7/2024	Class 2	Ciprofloxacin HCL 0.3% Ophthalmic Solution	FDC Limited	69315-0308-10, 69315-0308-02	084C040, EXP 02/28/2026; 084A024, EXP 12/31/2025	A defective container. The spike of the cap was blocking the product bottle opening and the solution would not drip out of the bottle.
8/7/2024	Class 2	Progesterone 50 Mg/Ml Oil	Eugia US LLC	55150-0306-10	CPR230029A	A complaint received of a glass particle in the vial.
8/14/2024	Class 2	Gabapentin 600 Mg Tablets	Granules Pharmaceuticals Inc.	70010-0227-05	1380040A, EXP DATE: 7/31/25	The presence of foreign tablets. There were three fused tablets of Metformin ER 500 mg found in a bottle of Gabapentin Tablets.
8/21/2024	Class 2	Timolol Maleate 0.5% Solution	FDC Limited	64980-0514-05	083J022, EXP DATE: 09/1/25; 083L046, EXP DATE: 11/1/25; 083H009, EXP DATE: 07/1/25	A defective container. There was a yellow-colored spike from the cap blocking the opening of the container.

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	Cardura XL Extended Release 8mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=207510
Class 2	Fludrocortisone Acetate 0.1 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=208629
Class 2	Nitrofurantoin Macrocrystal 100 Mg Capsules	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=208922
Class 2	Pravastatin Sodium 80 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=208647
Class 1	Potassium Chloride Extended Release 10 mEq K Capsule	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/glenmark-pharmaceuticals-inc-usa-issues-voluntary-nationwide-recall-potassium-chloride-extended
Class 2	Venlafaxine HCL ER 37.5 Mg Capsules	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=208488
Class 1	Clonazepam 0.125 Mg Disintegrating Tablets	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/endo-usa-inc-issues-voluntary-nationwide-recall-one-lot-clonazepam-orally-disintegrating-tablets-usp
Class 1	Potassium Chloride Extended Release 10 mEq K Capsule	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/american-health-packaging-behalf-bluepoint-laboratories-issues-voluntary-nationwide-recall-potassium
Class 2	Azelaic Acid 15% Gel	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=209119
Class 2	Ciprofloxacin HCL 0.3% Ophthalmic Solution	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=209130
Class 2	Progesterone 50 Mg/Ml Oil	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=209228
Class 2	Gabapentin 600 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=209305
Class 2	Timolol Maleate 0.5% Solution	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=209051