Capital Rx Drug Recall Report

FEBRUARY 2025

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. 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 **2/12/2025****

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
1/15/2025	Class 2	Ciprofloxacin Hcl 0.3 % Opthalmic Solution	FDC Limited	69315-0308-05	083L111, EXP. 11/30/2025; 084A032, 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.
1/15/2025	Class 2	medroxyPROGESTERone Acetate Injectable Suspension	Eugia US LLC	55150-0329-01	1MP24069, EXP 08/2026	Deviations from the Current Good Manufacturing Practices (CGMP)
1/22/2025	Class 2	Cardura XL (doxazosin) extended release tablets 8 mg	Viatris Inc	58151-0079-93	8181625, EXP 12/31/2025	Failing to meet impurity and degradation standards
1/22/2025	Class 2	Cardura XL (doxazosin) extended release tablets 4 mg	Viatris Inc	58151-0078-93	8182298, EXP 10/31/2025	Failing to meet impurity and degradation standards
2/5/2025	Class 1	Astagraf XL (tacrolimus extended-release capsules) 0.5 mg	Astellas Pharma US Inc.	00469-0647-73	0R3092A, EXP 03/31/2026	Failing to meet specifications, bottles shipped to the USA may contain empty capsules
2/5/2025	Class 1	Prograf 0.5 Mg Capsules	Astellas Pharma US Inc.	00469-0607-73	0E3353D, EXP 03/31/2026	Failing to meet specifications, bottles shipped to the USA may contain empty capsules

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2/5/2025	Class 2	Duloxetine Hcl 20 Mg Delayed-Release Capsules	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories	00904-7043-04, 00904-7043-61	A) N01530, EXP 01/2025; B) N01540, EXP 01/2025	Failing to meet purity standards, an impurity called N-nitroso-duloxetine being higher than the acceptable limit
2/5/2025	Class 2	Inflectra (infliximab-dyyb) 100 Mg Vial	McKesson	00069-0809-01	04647349, EXP 5/31/2029	Deviations from the Current Good Manufacturing Practices (CGMP). Product meant for quarantine was accidentally disturbed.
2/12/2025	Class 2	Granix (tbo-filgrastim) Injection 300 mcg/0.5 mL	Teva Pharmaceuticals USA, Inc	63459-0910-11, 63459-0910-12, 63459-0910-15, 63459-0910-17	(A) 135738, (B) 137149, (C) 137148, EXP 09/30/2025	Failing stability and purity tests
2/12/2025	Class 2	Carvedilol 25 Mg Tablets	Glenmark Pharmaceuticals Inc., USA	68462-0165-05, 68462-0165-01	A) 17230500, 17230509, 17230526, 17230546, 17230551, 17230603, 1723628, 17230642, 17230645, 17230681, EXP 02/2025; 17230829, 17230832, 17230854, 17230864, 17230874, 17230876, 17230889, 17230894, EXP 03/2025; 17230960, 17230964, 17230976, 17230981, 17230985, 17231161, 17231171, EXP 04/2025; 17231315, 17231318, 17231332, 17231333, 1723136, EXP 05/2025; 17231539, 17231563, EXP 06/2025; 17231653, 17231662, 17231663, 17231680, 17231691, 17231781, 17231782, 17231789, EXP 07/2025; 17231838, 17231880, EXP 08/2025; 17232144, 17232147, 17232151, EXP 09/2025; 17232369, 17232370, 17232408, 17232409, 17232416, 17232504, 17232522, 17232531, 17232538, 17232543, EXP 11/2025; 17240377, 17240385, 17240415, 17240422, 17240430, 17240510, EXP 02/2026 B) 17230551, 17240377, EXP 02/2025	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Carvedilol I impurity (NNCI-I) were found to be higher than the FDA recommended limit.

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
2/12/2025	Class 2	Carvedilol 12.5 Mg Tablets	Glenmark Pharmaceuticals Inc., USA	68462-0164-05, 68462-0164-01	A) 17230658, EXP 02/2025; 17230814, 17230822, EXP 03/2025; 17231004, 17231009, 17231022, EXP 04/2025; 17231393, 17231392, EXP 05/2025; 17231538, 17231541, 17231542, EXP 06/2025; 17231710, 17231718, 17231721, 17231722, 17231730, EXP 07/2025; 17232169, EXP 09/2025; 17232253, EXP 10/2025; 17240220,17240240, EXP 01/2026; 17240459, EXP 02/2026 B) 17230814, EXP 03/2025; 17231392, EXP 05/2025; 17232260, EXP 10/2025	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Carvedilol I impurity (NNCI-I) were found to be higher than the FDA recommended limit.
2/12/2025	Class 2	Potassium Chloride Extended-Release Tablets 10 mEq	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories	00904-7216-61	T05224 EXP 02/2026	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly

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	Ciprofloxacin Hcl 0.3 % Opthalmic Solution	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211762
Class 2	medroxyPROGESTERone Acetate Injectable Suspension	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211794
Class 2	Cardura XL (doxazosin) extended release tablets 8 mg	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211826
Class 2	Cardura XL (doxazosin) extended release tablets 4 mg	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211827
Class 1	Astagraf XL (tacrolimus extended-release capsules) 0.5 mg	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/astellas-pharma-us-inc-issues-voluntary-nationwide-recall-one-lot-prografr-05mg-tacrolimus-and-one
Class 1	Prograf 0.5 Mg Capsules	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/astellas-pharma-us-inc-issues-voluntary-nationwide-recall-one-lot-prografr-05mg-tacrolimus-and-one
Class 2	Duloxetine Hcl 20 Mg Delayed-Release Capsules	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212020
Class 2	Inflectra (infliximab-dyyb)100 Mg	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212202
Class 2	Granix (tbo-filgrastim) Injection 300 mcg/0.5 mL	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212029
Class 2	Carvedilol 25 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212173
Class 2	Carvedilol 12.5 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212175
Class 2	Potassium Chloride Extended-Release Tablets 10 mEq	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212297