Capital Rx Drug Recall Report

DECEMBER 2024

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 **12/11/2024****

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
11/27/2024	Class 2	Lisinopril 10 Mg Tablets	Evaric Pharmaceuticals Inc.	68645-0610-90	241103, EXP 05/31/2026	A pharmacist discovering a metal fragment embedded in a lisinopril 10 mg tablet.
11/27/2024	Class 2	Ramipril 2.5 Mg Capsules	Lupin Pharmaceuticals Inc.	68180-0589-09, 68180-0589-01, 68180-0589-02	A) G326781, EXP 09/30/2025 GA04468, EXP 05/31/2025 B) G326763, EXP 09/30/2025; GA03041, EXP 03/31/2025; GA03725, EXP 04/30/2025; GA04402, EXP 05/31/2026; C) G326782, EXP 09/30/2025; GA04462, EXP 05/31/2026	Deviations from the Current Good Manufacturing Practices (CGMP). The active ingredient was obtained from an unapproved vendor.

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RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
11/27/2024	Class 2	Ramipril 5 Mg Capsules	Lupin Pharmaceuticals Inc.	68180-0590-09, 68180-0590-01, 68180-0590-02	A) G326928, EXP 09/30/2025; GA00964, EXP 12/31/2025 B) G326897, G326929, EXP 09/30/2025; GA00854, GA00933, GA00954, EXP 12/31/2025 C) GA00955, EXP 12/31/2025	Deviations from the Current Good Manufacturing Practices (CGMP). The active ingredient was obtained from an unapproved vendor.
11/27/2024	Class 2	Ramipril 10 Mg Capsules	Lupin Pharmaceuticals Inc.	68180-0591-09, 68180-0591-01, 68180-0591-02	A) G327086, EXP 09/30/2025; GA01065, EXP 12/31/2025 B) G325033, G324987, EXP 07/31/25; G325110, GA00956, GA01066, GA01126, EXP 12/31/2025; GA03299, GA03288, GA03287, EXP 03/31/2026 C) GA05919, EXP 07/31/26; G327131, EXP 09/30/2025	Deviations from the Current Good Manufacturing Practices (CGMP). The active ingredient was obtained from an unapproved vendor.
11/27/2024	Class 2	Xelstrym 13.5 Mg/9hr Patch	Noven Pharmaceuticals Inc	68968-0215-03	95598, EXP 02/28/25	A defect with the product's adhesive, where it may not stick or function properly, which could affect how well the product performs.
12/11/2024	Class 2	Cinacalcet Hcl 30 Mg Tablets	Aurobindo Pharma USA Inc	65862-0831-30, 65862-0831-05	A) CFSA23001A, CFSA23002A, CFSA23003A, EXP 03/31/2025; CFSA23004A, EXP 07/31/2025; CFSA23005A, EXP 10/31/2025; B) P2300191, P2300192, P2300193, P2300194, EXP 12/31/2024;	Deviations from the Current Good Manufacturing Practices (CGMP). An impurity called N-nitroso-cinacalcet was higher than the acceptable limit.

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RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
12/11/2024	Class 2	Cinacalcet Hcl 60 Mg Tablets	Aurobindo Pharma USA Inc	65862-0832-30, 65862-0832-05	A) CFSB23001A, EXP 03/31/2025, CFSB23002A, EXP 07/31/2025; CFSB23003A, EXP 10/31/2025; CFSB23004A, EXP 10/31/2025; B) P2300196, 12/31/2024	Deviations from the Current Good Manufacturing Practices (CGMP). An impurity called N-nitroso-cinacalcet was higher than the acceptable limit.
12/11/2024	Class 2	Cinacalcet Hcl 90 Mg Tablets	Aurobindo Pharma USA Inc	65862-0833-30, 65862-0833-05	A) CFSC23001A, CFSC23001B EXP 03/31/2025 B) P2300195, EXP 12/31/2024	Deviations from the Current Good Manufacturing Practices (CGMP). An impurity called N-nitroso-cinacalcet was higher than the acceptable limit.
12/11/2024	Class 2	Diltiazem Hcl ER 120 Mg Cp12	Glenmark Pharmaceuticals Inc., USA	A) 16714-0555-01 B) 68462-0562-01	A) 17222547, EXP 11/30/2024; 17230598, EXP 02/28/2025 B) 17222470, 17230680, 17222547; EXP 11/30/2024; 17230304, EXP 12/31/2024; 17230598, EXP 02/2025	Deviations from the Current Good Manufacturing Practices (CGMP). An impurity called N-nitroso-Desmethyl-Diltiazem was higher than the acceptable limit.
12/11/2024	Class 2	Diltiazem Hcl Er 60 Mg Cp12	Glenmark Pharmaceuticals Inc., USA	A) 16714-0553-01 B) 68462-0850-01	A) 17222544, EXP 11/30/2024 B) 17222544, EXP 11/30/2024; 17230784, EXP 03/31/2025; 17231080, EXP 04/30/2025	Deviations from the Current Good Manufacturing Practices (CGMP). An impurity called N-nitroso-Desmethyl-Diltiazem was higher than the acceptable limit.
12/11/2024	Class 2	Diltiazem Hcl Er 90 Mg Cp12	Glenmark Pharmaceuticals Inc., USA	A) 16714-0554-01 B) 68462-0851-01	A) 17222452, EXP 11/30/2024; 17230607, EXP 02/28/2025 B) 17222544, EXP 11/30/2024; 17230784, EXP 03/31/2025; 17231080, EXP 04/30/2025	Deviations from the Current Good Manufacturing Practices (CGMP). An impurity called N-nitroso-Desmethyl-Diltiazem was higher than the acceptable limit.

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
12/11/2024	Class 2	Duloxetine Hcl 20 Mg Delayed-Release Capsules	A) Rising Pharma Holding, Inc. B) Amerisource Health Services LLC	A) 57237-0017-60 B) 68001-0413-06	A) DT2022023A, DT2022024A, DT2022025A, DT2022026A, DT2022027A, EXP 11/2024; DT2023001B, DT2023004A, DT2023005A, DT2023006A, EXP 01/2025; B) DT2023001A, DT2023009A, EXP 01/31/2025;	Deviations from the Current Good Manufacturing Practices (CGMP). An impurity called N-nitroso-duloxetine was higher than the acceptable limit.
12/11/2024	Class 2	Duloxetine Hcl 30 Mg Delayed-Release Capsules	A) Rising Pharma Holding, Inc. B) Amerisource Health Services LLC	A) 57237-0018-30, 57237-0018-90, 57237-0018-99 B) 68001-0414-04, 68001-0414-08	A) DT3023019A, EXP 01/2025; DT3023050A, EXP 04/2025; DT3023022A, EXP 01/2025; DT3022108A, DT3022107A, DT3022106A, DT3022111A, DT3022109A, EXP 11/2024; DT3023001A, DT3023003A, EXP 12/2024; DT3023024A, DT3023020B, EXP 01/2025; DT3023027A, DT3023028A, EXP 02/2025; DT3023034A, EXP 03/2025; DT3023049A, EXP 04/2025; DT3023095A, EXP 07/2025; B) DT3023019B, DT3023020A, EXP 01/31/2025; DTB23098A, EXP 08/31/2025	Deviations from the Current Good Manufacturing Practices (CGMP). An impurity called N-nitroso-duloxetine was higher than the acceptable limit.

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
12/11/2024	Class 2	Duloxetine Hcl 60 Mg Delayed-Release Capsules	A) Rising Pharma Holding, Inc. B) Amerisource Health Services LLC	A) 57237-0019-30, 57237-0019-90, 57237-0019-99 B) 68001-0415-08	A) DT6023059A, DT6023060A, DT6023065A, DT6023069A, DT6023070A, EXP 01/2025; DT6023080A, EXP 02/2025; DT6023093A, EXP 03/2025; DTC24012A, EXP 12/2025; DT6023108A, EXP 04/2025; DTC23201A, EXP 10/2025; DT6022160A, DT6022165A, DT6022162A, DT6022164A, DT6022163A, DT6022171A, DT6022169A, DT6022170A, DT6022173A, EXP 11/2024; DT6023009A, DT6023007A, DT6023008A, DT6023011A, DT6023034B, EXP 12/2024; DT6023067C, EXP 01/2025; DT6023114A, EXP 04/2025; DTC23243A, EXP 10/2025; DTC24040A, EXP 12/2025 B) DT6022159A, DT6022167A, DT6022168A, EXP 11/30/2024; DT6023034A, EXP 12/31/2024; DT6023050A, DT6023051A, DT6023063A, DT6023067A, EXP 01/31/2025; DT6023073A, DT6023072A, EXP 02/28/2025	Deviations from the Current Good Manufacturing Practices (CGMP). An impurity called N-nitroso-duloxetine was higher than the acceptable limit.
12/11/2024	Class 2	Levothyroxine Sodium 75 Mcg Tablets	ACCORD HEALTHCARE, INC.	16729-0449-17	D2300191, EXP 12/31/2025	The product being subpotent (not strong enough).
12/11/2024	Class 2	Lisdexamfetamine Dimesylate 10 Mg Capsules	Lannett Company Inc.	00527-4661-37	23274856A, EXP 04/30/2025	Failed content uniformity specifications, meaning the medication may not have the same amount of active ingredient throughout the batch.
12/11/2024	Class 2	Venofer 20 Mg/Ml Solution	American Regent, Inc.	00517-2340-01, 00517-2340-10, 00517-2340-25	4205, EXP 05/31/2026; 24229, 24233, 24239, EXP 07/31/2026	Potential for glass particle in the vial.

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	Lisinopril 10 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211098
Class 2	Ramipril 2.5 Mg Capsules	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210765
Class 2	Ramipril 5 Mg Capsules	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210788
Class 2	Ramipril 10 Mg Capsules	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210789
Class 2	Xelstrym 13.5 Mg/9hr Patch	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210957
Class 2	Cinacalcet Hcl 30 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211025
Class 2	Cinacalcet Hcl 60 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211048
Class 2	Cinacalcet Hcl 90 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211365
Class 2	Diltiazem Hcl ER 120 Mg Cp12	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211274 B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211138
Class 2	Diltiazem Hcl Er 60 Mg Cp12	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211272 B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210908
Class 2	Diltiazem Hcl Er 90 Mg Cp12	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211273 B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211137
Class 2	Duloxetine Hcl 20 Mg Delayed-Release Capsules	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211116 B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211366
Class 2	Duloxetine Hcl 30 Mg Delayed-Release Capsules	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211117 B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211430
Class 2	Duloxetine Hcl 60 Mg Delayed-Release Capsules	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211120 B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211431
Class 2	Levothyroxine Sodium 75 Mcg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211095
Class 2	Lisdexamfetamine Dimesylate 10 Mg Capsules	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210842
Class 2	Venofer 20 Mg/Ml Solution	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211007