

# Capital Rx Drug Recall Report

NOVEMBER 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 **11/20/2024**\*\*

### 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](http://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](http://cap-rx.com), including any services offered on or through [cap-rx.com](http://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
10/23/2024	Class 1	Atovaquone 750 Mg/5ml Suspension	Bionpharma Inc.	69452-0252-87	2310083, EXP. 9/30/2025	The product was found to be contaminated with Cohnella bacteria.
10/23/2024	Class 2	Dapsone 7.5% Gel	Viona Pharmaceuticals Inc.	72578-0094-02	T400512, EXP 2/28/2026	Crystallization, which could potentially result in incorrect dosing.
10/23/2024	Class 2	Duloxetine Hcl 20 Mg Delayed-Release Capsules	Breckenridge Pharmaceutical, Inc.	51991-0746-05	220128, EXP. DATE 12/2024	Deviations from the Current Good Manufacturing Practices (CGMP). The Nitrosamine Drug Substance Related Impurity (NDSRI) called N-nitroso-duloxetine was higher than the proposed limit.
10/30/2024	Class 2	Onelax Docusate Sodium 50 Mg/5ml Liquid	Akron Pharma, Inc.	71399-0039-06	ODS23000 1A, ODS230002 A, EXP 10/2025; ODS230003 A, EXP 11/2025	Deviations from the Current Good Manufacturing Practices (CGMP).

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
11/6/2024	Class 2	Cinacalcet Hcl 30 Mg Tabs	(A) Accord Healthcare, Inc. (B) Dr. Reddy's Laboratories, Inc.	(A) 16729-0440-10, 16729-0440-15; B) 43598-0367-30	(A) M2118190 EXP 11/2024; M2201091 EXP 11/2024; M2206241 EXP 11/2024; M2206451 EXP 04/2025; M2208674 EXP 06/2025; M2213850 EXP 08/2025; M2215221 EXP 09/2025; M2216236 EXP 11/2025; M2217098 EXP 11/2025; M2300664 EXP 11/2025; M2210808 EXP 06/2025; M2212212 EXP 08/2025; M2214435 EXP 09/2025; M2217097 EXP 11/2025; M2301921 EXP 01/2026 (B) T2200120, T2200121, T2200119, T2200116, T2200118, T2200117, EXP 11/2024; T2200695, T2200694, T2200696, T2200697, EXP 01/2025; T2201426, T2201428, T2201432, T2201427, T2201430, T2201429, T2201431, EXP 03/2025; T2202743, T2202742, T2202741, EXP 06/2025; T2203081, T2203079, T2203080, T2203082, T2203083, T2203084, EXP 07/2025; T2300770, T2300771, T2300769, T2300766, T2300767, T2300768, EXP 12/2025; T2301663, T2301665, T2301662, T2301664, T2301667, T2301661, 2301666, T2301660, T2301658, T2301659, EXP 02/2026; T2304704, T2304703, T2304705, T2304706, EXP 08/2026; T2400468, T2400469, T2400473, T2400474 EXP 11/2026	Deviations from the Current Good Manufacturing Practices (CGMP). An impurity called N-nitroso-cinacalcet was higher than the acceptable limit.

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
11/13/2024	Class 2	Cinacalcet Hcl 60 Mg Tabs	Dr. Reddy's Laboratories, Inc.	43598-0368-30	T2200698, EXP 01/2025; T2201444, EXP 03/2025; T2202827, EXP 06/2025; T2300531, EXP 12/2025; T2301696, EXP 02/2026; T2304726, EXP 08/2026; T2400480, EXP 11/2026	Deviations from the Current Good Manufacturing Practices (CGMP). An impurity called N-nitroso-cinacalcet was higher than the acceptable limit.
11/13/2024	Class 2	Morphine Sulfate Extended-Release Tablets 30 Mg	Dr. Reddy's Laboratories, Inc.	51862-0186-01	FG13996, EXP 09/30/2025	Failing to meet purity standards and dissolution specifications, which may result in the tablets not dissolving properly.
11/13/2024	Class 2	Dapsone 7.5 % Gel	Viona Pharmaceuticals Inc.	72578-0094-02	T401151, EXP 06/30/2026; T400806, EXP 03/31/2026	Crystallization, which could potentially result in incorrect dosing.
11/20/2024	Class 2	Lanthanum Carbonate 1000 Mg Chew	Cipla USA, Inc.	(A) 76282-0478-90 (B) 69097-0936-98	(A) NB240873, EXP 03/31/2026 (B) NB240316, EXP 12/31/25	Failing to meet tablet specifications, there were complaints received of crushed and broken tablets.

**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 1	Atovaquone 750 Mg/5ml Suspension	<a href="https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bionpharma-inc-is-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-due-bacterial">https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bionpharma-inc-is-issues-voluntary-nationwide-recall-atovaquone-oral-suspension-due-bacterial</a>
Class 2	Dapsone 7.5% Gel	<a href="https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210153">https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210153</a>
Class 2	Duloxetine Hcl 20 Mg Delayed Release Capsules	<a href="https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210449">https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210449</a>
Class 2	Onelax Docusate Sodium 50 Mg/5ml Liquid	<a href="https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210460">https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210460</a>
Class 2	Cinacalcet Hcl 30 Mg Tabs	(A) <a href="https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210445">https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210445</a> (B) <a href="https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210444">https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210444</a>
Class 2	Cinacalcet Hcl 60 Mg Tabs	<a href="https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210446">https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210446</a>
Class 2	Morphine Sulfate Extended-Release Tablets 30 Mg	<a href="https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210824">https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210824</a>
Class 2	Dapsone 7.5 % Gel	<a href="https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210890">https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210890</a>
Class 2	Lanthanum Carbonate 1000 Mg Chew	(A) <a href="https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211099">https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=211099</a> (B) <a href="https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210766">https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=210766</a>