Capital Rx Drug Recall Report

DECEMBER 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. 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 **12/17/2025****

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
2025-11-26	Class 2	Bromocriptine Mesylate 5 Mg Caps	Zydus Pharmaceuticals	68382-0110-06	M313934, M313935, M315615, EXP NOV 2025; M316809, EXP DEC-25; M405765, M405763, M405764, EXP APR-26; M414999, M414241, M414307, M414305, EXP OCT-26	Failing to meet impurity and degradation standards
2025-12-03	Class 1	Famotidine (PF) 20 Mg/2ml Solution	Fresenius Kabi USA, LLC	63323-0739-11, 63323-0739-12	6133156, 6133194, EXP 08/2026; 6133388, EXP 10/2026	Out-of-specification (OOS) endotoxin results of certain reserve samples
2025-12-10	Class 2	Duloxetine HCL 60 Mg CPEP	Breckenridge Pharmaceutical, Inc.	51991-0748-10	240534C, EXP 01/2027; 240977C, EXP 04/2027	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-nitroso-duloxetine being higher than the acceptable limit

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
2025-12-10	Class 2	Haloperidol Lactate 5 Mg/Ml Solution	Safecor Health, LLC	67457-0426-12	25381993, 25391516 EXP 12/31/2026	Incorrect RFID tag labels applied to the product by the repackaging firm
2025-12-10	Class 2	Zinc Oxide 20% Oint	Blossom Pharmaceuticals	A) 75834-0170-01 B) 75834-0170-02	A) A352405 B) A352505	Deviations from the Current Good Manufacturing Practices (CGMP)
2025-12-17	Class 2	Cinacalcet HCL 30 Mg Tabs	Cipla USA, Inc.	69097-0410-02	4PB0109, EXP 1/31/2026; 5PB0172, EXP 1/31/2027	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-nitroso-cinacalcet being higher than the acceptable limit
2025-12-17	Class 2	Cinacalcet HCL 60 Mg Tabs	Cipla USA, Inc.	69097-0411-02	5PB0164, EXP 1/31/2027	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-nitroso-cinacalcet being higher than the acceptable limit
2025-12-17	Class 2	Cinacalcet HCL 90 Mg Tabs	Cipla USA, Inc.	69097-0412-02	5PB0183, EXP 1/31/2027	Deviations from the Current Good Manufacturing Practices (CGMP), an impurity called N-nitroso cinacalcet being higher than the acceptable limit
2025-12-17	Class 2	Ganirelix Acetate 250 Mcg/0.5ml Sosy	Lupin Pharmaceuticals	70748-0274-01	WB00006, EXP 12/31/2026	Failing to meet impurity and degradation standards
2025-12-17	Class 2	Sertraline HCL 100 Mg Tabs	Lupin Pharmaceuticals	68180-0353-09	QB00865, EXP FEB 2028	A defective container, the seal did not stick to the bottles

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	Bromocriptine Mesylate 5 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=216745
Class 1	Famotidine (PF) 20 Mg/2ml Soln	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fresenius-kabi-issues-voluntary-nationwide-recall-three-lots-famotidine-injection-usp-20-mg-2-ml-10
Class 2	Duloxetine HCL 60 Mg CPEP	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=217502
Class 2	Haloperidol Lactate 5 Mg/Ml Soln	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=217357
Class 2	Zinc Oxide 20 % Oint	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=217284 B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=217285
Class 2	Cinacalcet HCL 30 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=217353
Class 2	Cinacalcet HCL 60 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=217354
Class 2	Cinacalcet HCL 90 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=217355
Class 2	Ganirelix Acetate 250 Mcg/0.5ml Sosy	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=217391
Class 2	Sertraline HCL 100 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=217276