

Capital Rx Drug Recall Report

JUNE 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 **6/26/2024****

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
5/29/2024	Class 2	Haloperidol Decanoate 50 MG/ML Solution	Somerset Therapeutics LLC	70069-0381-01, 70069-0381-10	A230412A EXP. 7/2025; A230412B EXP. 7/2025	The presence of a foreign substance. This oil-based product may contain trace amounts of water.
6/5/2024	Class 2	Metoprolol Tartrate 25 Mg Tablets	Rubicon Research Private Limited	52817-0360-00	231037H1 EXP. 6/2027	The presence of a foreign substance, there may be metal in the tablet.
6/5/2024	Class 2	Zoledronic Acid 5 Mg/100 ML Solution	Dr. Reddy's Laboratories, Inc.	55111-0688-52	G3000010 EXP. 11/2025	Complaints of leaking vials and as a result, failing product stability and purity tests.
6/5/2024	Class 2	Cefdinir 250 MG/5ML Suspension	Lupin Pharmaceuticals Inc.	68180-0723-04	F305184, F305185, F305186, EXP. 7/2025	A defective container where the container may not be sealed properly.
6/12/2024	Class 2	Rizatriptan Benzoate 5 Mg Tablets	Glenmark Pharmaceuticals Inc., USA	68462-0465-99	19233788 EXP. 9/2025; 19224445 EXP. 9/2024	Deviations from the Current Good Manufacturing Practices (CGMP), the presence of an impurity above the established acceptable threshold.

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
6/12/2024	Class 2	Rizatriptan Benzoate 5 Mg Orally Disintegrating Tablets	Glenmark Pharmaceuticals Inc., USA	68462-0467-06	19224857 EXP. 11/2024; 19232493 EXP. 6/2025	Deviations from the Current Good Manufacturing Practices (CGMP), the presence of an impurity above the established acceptable threshold.
6/12/2024	Class 2	Rizatriptan Benzoate 10 Mg Tablets	Glenmark Pharmaceuticals Inc., USA	68462-0466-99	19224217 EXP. 9/2024; 19233789 EXP. 9/2025; 19224444 EXP. 9/2024	Deviations from the Current Good Manufacturing Practices (CGMP), the presence of an impurity above the established acceptable threshold.
6/12/2024	Class 2	Rizatriptan Benzoate 10 Mg Orally Disintegrating Tablets	Glenmark Pharmaceuticals Inc., USA	68462-0468-06	19223402 EXP. 6/2024; 19224858 EXP. 11/2024; 19232492 EXP. 6/2025	Deviations from the Current Good Manufacturing Practices (CGMP), the presence of an impurity above the established acceptable threshold.
6/19/2024	Class 2	Phenazopyridine HCL 100 Mg Tablets	Winder Laboratories, LLC	75826-0114-10	1142404 EXP. 2/2027	The presence of foreign tablets. A bottle labeled as Phenazopyridine HCL 100 mg tablets contained Phenobarbital 16.2 mg tablets.
6/19/2024	Class 2	Zilretta 32 Mg Extended Release Injectable Suspension	Pacira Pharmaceuticals INC	65250-0001-01, 65250-0002-01, 65250-0003-01	082657 (KIT 23-9004) EXP. 7/ 2024	Failing stability and purity tests.
6/26/2024	Class 2	Duloxetine HCL 60 Mg CPEP	Breckenridge Pharmaceutical, Inc	51991-0748-90	230035C EXP. 11/30/2025; 230101C EXP. 12/31/2025	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.
6/26/2024	Class 2	Cefixime 200 Mg/5ML Suspension	Lupin Pharmaceuticals Inc.	68180-0407-03	F201519 EXP. 11/2024	Failed content uniformity specifications, meaning the medication may not have the same amount of active ingredient throughout the batch.
6/26/2024	Class 2	Amoxicillin-Pot Clavulanate 400-57 Mg Chew	Teva Pharmaceuticals USA, Inc	00093-2272-34	100047634 EXP. 4/2025; 35449379A EXP. 7/2024	The drug being subpotent (not strong enough).

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	Haloperidol Decanoate 50 Mg/ML solution	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=207239
Class 2	Metoprolol Tartrate 25 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=207514
Class 2	Zoledronic Acid 5 Mg/100ml Solution	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=208001
Class 2	Cefdinir 250 Mg/5ml Suspension	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=207677
Class 2	Rizatriptan Benzoate 5 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=207689
Class 2	Rizatriptan Benzoate 5 Mg ODT	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=207710
Class 2	Rizatriptan Benzoate 10 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=207692
Class 2	Rizatriptan Benzoate 10 Mg ODT	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=207718
Class 2	Phenazopyridine HCL 100 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=208113
Class 2	Zilretta 32 Mg Extended Release Injectable Susp.	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=207588
Class 2	Duloxetine HCL 60 Mg CPEP	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=207727
Class 2	Cefixime 200 Mg/5ML Suspension	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=208109
Class 2	Amoxicillin-Pot Clavulanate 400-57 Mg Chew	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=208169