

Capital Rx Drug Recall Report

MARCH 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 **3/27/2024****

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
2/28/2024	Class 2	Acthar 80 UNIT/ML gel	Mallinckrodt Hospital Products Inc.	63004-8710-01	1564-103 Exp. 9/30/2024	Deviations from the Current Good Manufacturing Practices (CGMP). Due to shipping delays from the manufacturer to the distributor, the medication was exposed to temperatures outside the required storage temperature range.
2/28/2024	Class 2	Clobazam 10 MG tablets	Micro Labs Limited	42571-0315-01	ZOAG043	Deviations from the Current Good Manufacturing Practices (CGMP), failing to meet impurity and degradation standards.
2/28/2024	Class 2	Fluticasone Propionate 50 MCG Nasal Spray	Apotex Corp.	60505-0829-01	TX5274 Exp. 09/30/2026	A potential bacterial contamination of Burkholderia cepacia complex (BCC). This recall is being initiated out of an abundance of caution and as a precautionary measure. There have been no reports of relevant adverse events or complaints received as of February 4, 2024.

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
2/28/2024	Class 2	Fosfomycin Tromethamine 3 GM pack	Ascend Laboratories, LLC	67877-0749-57	22121458, 22121459, 22121460, 22121461, 22121462, 22121463, 22121464 Exp. 4/2024; 22121176, 22121407, 22121465 Exp. 3/2024; 22121761, 22121762, 22121763, 22121764, 22121766, 22121968, 22121969 Exp. 5/2024	Failing to meet impurity and degradation standards.
2/28/2024	Class 2	Oseltamivir Phosphate 6 MG/ML Suspension	Amneal Pharmaceuticals of New York, LLC	69238-1273-06	BF22722A Exp. 08/31/2024; BJ15122A Exp. 09/30/2024	Failing to meet impurity and degradation standards.
3/6/2024	Class 2	Mesalamine ER 500 MG Capsule Extended Release	SUN PHARMACEUTICAL INDUSTRIES INC	63304-0089-13	MHD0606A, MHD0612A, Exp. 04/30/2024; MHD0613A, MHD0652A, MHD0657A, MHD0672A, MHD0673A, Exp. 05/31/2024; MHD0767A, MHD0768A, MHD0769A, MHD0785A, MHD0799A, MHD0800A, MHD0801A, Exp. 06/30/2024; MHD0827A, MHD0828A, MHD0875A, MHD0876A, MHD0898A, MHD0901A, Exp. 07/31/2024; MHD1081A, MHD1082A, MHD1087A Exp. 09/30/2024.	Failing to meet dissolution specifications, which may result in possible issues with the tablets dissolving.
3/6/2024	Class 2	Omeprazole-Sodium Bicarbonate 40-1680 MG Packet	Bausch Health Companies, Inc.	68682-0991-30	0013R, Exp. 01/2026	Failing testing that showed the drug was subpotent (not strong enough). This tests the amount of the active ingredient in the liquid suspension.
3/20/2024	Class 2	Betimol 0.5 % Solution	Thea Pharma, Inc.	82584-0002-15	435019, EXP. DATE 11/2024	Failing the stability and purity tests. Unable to guarantee the solution was pure, due to the volume and the container closure not meeting testing requirements.
3/20/2024	Class 2	Bicillin L-A 1.2, MMU / 2 mL Injection	Mckesson Medical-Surgical Inc. Corporate Office	60793-0701-10	567951	Failing the stability and purity tests. Out of specification for blend uniformity.

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
3/20/2024	Class 2	Febuxostat 40 Mg Tablets	SUN PHARMACEUTICAL INDUSTRIES INC	16714-0059-01	DNE0865A, DNE0866A, EXP 06/30/2025	Deviations from the Current Good Manufacturing Practices (CGMP). Contamination was reported in stagnant water in the duct of the manufacturing equipment.
3/20/2024	Class 2	Febuxostat 80 Mg Tablets	SUN PHARMACEUTICAL INDUSTRIES INC	16714-0060-01	DNE0894A, EXP 07/31/2025	Deviations from the Current Good Manufacturing Practices (CGMP). Contamination was reported in stagnant water in the duct of the manufacturing equipment.
3/20/2024	Class 2	Telmisartan 40 Mg Tablets	Micro Labs Limited	42571-0227-30	SFBG024, SFBG025, EXP. 05/31/2024	Failing the stability and purity tests. Out of specification for blend uniformity.

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	Acthar 80 UNIT/ML gel	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=205979
Class 2	Clobazam 10 MG tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=206036
Class 2	Fluticasone Propionate 50 MCG Nasal Spray	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=206035
Class 2	Fosfomycin Tromethamine 3 GM pack	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=205516
Class 2	Oseltamivir Phosphate 6 MG/ML Suspension	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=206003
Class 2	Mesalamine ER 500 MG Capsule Extended Release	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=205863
Class 2	Omeprazole-Sodium Bicarbonate 40-1680 MG Packet	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=205878
Class 2	Betimol 0.5 % Solution	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=206449
Class 2	Bicillin L-A 1200000 Unit 2ml Suspension	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=205967
Class 2	Febuxostat 40 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=206423
Class 2	Febuxostat 80 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=206424
Class 2	Telmisartan 40 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=206019