Capital Rx Drug Recall Report

JUNE 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. 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 **6/11/2025****

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
5/14/2025	Class 2	Artificial Tears Soln	BRS Analytical Services, LLC	50268-0043-15	126, EXP 10/26/25; 127, EXP 10/30/25; 128, EXP 11/02/25; 129, EXP 11/06/25; 162, EXP 5/09/26; 163, EXP 5/14/26; 164, EXP 5/20/26; 165, EXP 5/23/26; 166, EXP 5/29/26; 167, EXP 6/03/26; 168, EXP 6/06/26; 169, EXP 6/10/26; 170, EXP 6/13/26; 193, EXP 10/07/26; 194, EXP 10/10/26; 195, EXP 10/14/26; 196, EXP 10/17/26; 197, EXP 10/21/26; 198, EXP 10/24/26; 199, EXP 10/30/26	Deviations from the Current Good Manufacturing Practices (CGMP) and lack of assurance of sterility.

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5/14/2025	Class 2	Lubricant Eye Drops 0.4-0.3 % Soln	BRS Analytical Services, LLC	50268-0126-15	117, EXP 9/20/25; 118, EXP 9/25/25; 119, EXP 9/27/25; 121, EXP 10/05/25; 161, EXP 5/01/26; 171, EXP 6/18/26; 172, EXP 6/24/26; 174, EXP 7/01/26; 175, EXP 7/08/26; 200, EXP 11/05/26; 201, EXP 11/10/26; 202, EXP 11/13/26; 203, EXP 11/18/26; 204, EXP 11/21/26; 205, EXP 11/25/26; 206, EXP 12/02/26; 219, EXP 2/24/27; 221, EXP 3/02/27; 222, EXP 3/05/27	Deviations from the Current Good Manufacturing Practices (CGMP) and lack of assurance of sterility
5/14/2025	Class 2	Polyvinyl Alcohol 1.4 % Soln	BRS Analytical Services, LLC	50268-0678-15	120, EXP 10/02/25; 122, EXP 10/09/25; 123, EXP 10/12/25; 124, EXP 10/16/25; 138, EXP 1/08/26; 142, EXP 1/29/26; 143, EXP 2/01/26; 144, EXP 2/07/26; 145, EXP 2/12/26; 146, EXP 2/15/26; 147, EXP 2/21/26; 148, EXP 2/27/26; 149, EXP 3/04/26; 150, EXP 3/11/26; 158, EXP 4/15/26; 159, EXP 4/22/26; 176, EXP 7/24/26; 177, EXP 7/28/26; 178, EXP 7/31/26; 179, EXP 8/05/26	Deviations from the Current Good Manufacturing Practices (CGMP) and lack of assurance of sterility

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5/14/2025	Class 2	Timolol Maleate 0.5 % Soln	FDC Limited	64980-0514-01	083I098, EXP 08/31/2025	A defective container. The spike of the cap was lodged in the nozzle of the product bottle preventing solution from coming out of the bottle.
5/28/2025	Class 2	Airsupra 90-80 Mcg/Act Aero	AstraZeneca Pharmaceuticals LP	00310-9080-12, 00310-9080-28	A) 6270044C00, 6270040D00; 6270034E00, EXP 10/2026; 6270053C00, 6270045C00, 6270047C00, 6270056C00, 6270052C00, 6270063E00 EXP 11/30/2026; 6270064C00, 6270071D00, 6270075D00, 6270075F00 EXP 12/31/2026; 6270107C00, EXP 9/30/2027; B) 6270019E00, EXP 7/31/2025; 6270021D00, EXP 8/31/2025; 6270095C00, EXP 2/28/2026	A defect found in the mouthpiece of the inhaler that might stop it from giving the right amount of medicine needed to help control asthma
5/28/2025	Class 2	Esomeprazole Magnesium 20 Mg Pack	Zydus Pharmaceuticals (USA) Inc	68382-0848-94	M402147, EXP 10/2025; M311637, EXP 07/2025; M402495, EXP 02/2026; M407997, EXP 05/2026; M502246, EXP11/2026	Failing to meet impurity and degradation standards
5/28/2025	Class 2	Esomeprazole Magnesium 40 Mg Pack	Zydus Pharmaceuticals (USA) Inc	68382-0849-94	M311638, EXP 07/2025; M400374, EXP 10/2025; M402496, EXP 02/2026; M407998, EXP 05/2026; M502247, EXP 11/2026 M414770, M414512, EXP 09/2026	Failing to meet impurity and degradation standards
5/28/2025	Class 2	Indomethacin Er 75 Mg Cpcr	KVK Tech, Inc.	10702-0016-01	18400A, EXP 7/31/2027	Deviations from the Current Good Manufacturing Practices (CGMP)

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5/28/2025	Class 2	Phentermine Hcl 30 Mg Caps	KVK Tech, Inc.	10702-0028-01	18350A, 18351A, EXP 6/30/2027	Deviations from the Current Good Manufacturing Practices (CGMP)
6/4/2025	Class 2	Bromfenac Sodium (Once-Daily) 0.09 % Soln	Alembic Pharmaceuticals Limited	62332-0508-17	7230309, EXP: 05/31/2025; 7230310, EXP: 05/31/2025; 7230311, EXP: 05/31/2025	Failing to meet impurity and degradation standards
6/4/2025	Class 2	Carvedilol 12.5 Mg Tabs	Glenmark Pharmaceuticals Inc., USA	68462-0164-05	19231899, 19231922, 19231927, 19231967, 19231979, EXP 04/2025; 19232226, 19232234, 19232265, 1923227,1 EXP 05/2025; 19232758, 19232759, 19232762, 19232788, EXP 06/2025	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Carvedilol I impurity (NNCI-I) were found to be higher than the FDA recommended limit
6/4/2025	Class 2	Carvedilol 25 Mg Tabs	Glenmark Pharmaceuticals Inc., USA	68462-0165-05	19231107, 19231114, 19231152, EXP 02/2025; 19234866, EXP 01/2026	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Carvedilol I impurity (NNCI-I) were found to be higher than the FDA recommended limit
6/4/2025	Class 2	Carvedilol 3.125 Mg Tabs	Glenmark Pharmaceuticals Inc., USA	A) 68462-0162-01, B) 68462-0162-05	A) 19231450, EXP 03/2025; 19233345, EXP 07/2025; 19234275, EXP 09/2025; 19240280, EXP 12/2025; B) 19231450, 19231464, 19231471, 19231493, EXP 03/2025; 19232083, 19232103 EXP 04/2025, 19232658, EXP 06/2025; 19233328, 19233343, 19233344, 19233345, EXP 07/2025; 19234275, EXP 09/2025; 19234843, 19235039, EXP 11/2025; 19240280, 19240296, EXP 12/2025	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Carvedilol I impurity (NNCI-I) were found to be higher than the FDA recommended limit

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
6/4/2025	Class 2	Carvedilol 6.25 Mg Tabs	Glenmark Pharmaceuticals Inc., USA	A) 68462-0163-01, B) 68462-0163-05	A) 19233369, EXP 07/2025; 19234162, EXP 09/2025; 19240543, EXP 01/2026; B) 19231174, 19231199, 19231164, EXP 02/2025; 19231517,19231527, 19231566,19231568, 19231595, 19231618, 19231634,19231638, 19231448, EXP 03/2025; 19232043,19232051,19232064, EXP 04/2025; 19232322, 19232324, 19232365, 19232380, 19232389, EXP 05/2025; 19232736, 19232743, 19232746, 19232756, 19232757, EXP 06/2025; 19233369, 19233371, 19233405, 19233416, EXP 07/2025; 19234162, 19234183, 19234192, 19234204, 19234223, 19234243, 19234263, 19234165, 19234242, EXP 09/25; 19234743, 19234774, 19234993, EXP 11/2025; 19240223, 19240203, 19240211, 19240214, 19240247, 19240249, 19240272, 19240319, EXP 12/2025; 19240543, EXP 01/2026	Deviations from the Current Good Manufacturing Practices (CGMP).
6/4/2025	Class 2	Theophylline Er 600 Mg Tb24	Glenmark Pharmaceuticals Inc., USA	68462-0356-01	19234121, 19234148, EXP 09/30/2025; 19242881, 19242899, EXP 06/30/2026	Test results that showed the tablets may not dissolve properly
6/11/2025	Class 2	Fluoxetine Hcl (Pmdd) 20 Mg Tabs	Torrent Pharma Inc.	13668-0473-30	BDX6K001; EXP 06/30/2025	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Fluoxetine were found to be higher than the FDA recommended limit

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	Artificial Tears Soln	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=213504
Class 2	Lubricant Eye Drops 0.4-0.3 % Soln	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=213536
Class 2	Polyvinyl Alcohol 1.4 % Soln	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=213537
Class 2	Timolol Maleate 0.5 % Soln	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=213500
Class 2	Airsupra 90-80 Mcg/Act Aero	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=213808
Class 2	Esomeprazole Magnesium 20 Mg Pack	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=214013
Class 2	Esomeprazole Magnesium 40 Mg Pack	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=213811
Class 2	Indomethacin Er 75 Mg Cpcr	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=213773
Class 2	Phentermine Hcl 30 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=213810
Class 2	Bromfenac Sodium (Once-Daily) 0.09 % Soln	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=213750
Class 2	Carvedilol 12.5 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=213814
Class 2	Carvedilol 25 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=213815
Class 2	Carvedilol 3.125 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=213812
Class 2	Carvedilol 6.25 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=213813
Class 2	Theophylline Er 600 Mg Tb24	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=213836
Class 2	Fluoxetine Hcl (Pmdd) 20 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=214152