

Capital Rx Drug Recall Report

SEPTEMBER 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 **9/10/2025****

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RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
8/20/2025	Class 2	Amlodipine-Olmesartan 5-40 Mg Tabs	Ascend Laboratories, LLC	67877-0501-30	23121560, EXP 4/30/2026	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly
8/20/2025	Class 2	Belsomra 10 Mg Tabs	Merck & Co. Inc	00006-0033-10, 00006-0033-30	2090019, 2123744, EXP 4/30/2027	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly. This could make the release of the medication later than expected, which may delay when it starts to work to help you fall asleep

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8/20/2025	Class 2	Carvedilol 12.5 Mg Tabs	Glenmark Pharmaceuticals Inc., USA	68462-0164-05	19243202, EXP 7/31/2026; 17241257, 17241258, 17241279, EXP 6/1/2026	Deviations from the Current Good Manufacturing Practices (CGMP). NNitroso Carvedilol I impurity (NNCI-I) were found to be higher than the FDA recommended limit
8/20/2025	Class 2	Carvedilol 25 Mg Tabs	Glenmark Pharmaceuticals Inc., USA	68462-0165-05	19243104, EXP 7/31/2026; 17241213, 17241215, 17241224, EXP 6/1/2026	Deviations from the Current Good Manufacturing Practices (CGMP). NNitroso Carvedilol I impurity (NNCI-I) were found to be higher than the FDA recommended limit
8/20/2025	Class 2	Carvedilol 3.125 Mg Tabs	Glenmark Pharmaceuticals Inc., USA	68462-0162-05, 68462-0162-01	A) 19242274, 19242275, 19242272, EXP 5/31/20; B) 19242272, EXP 5/31/2026	Deviations from the Current Good Manufacturing Practices (CGMP). NNitroso Carvedilol I impurity (NNCI-I) were found to be higher than the FDA recommended limit
8/20/2025	Class 2	Levoxyl 50 Mcg Tabs	Pfizer	60793-0851-01	24C11, EXP 2/28/2026	The product being subpotent (not strong enough)
8/20/2025	Class 2	Metoprolol Tartrate 100 Mg Tabs	Westminster Pharmaceuticals LLC	69367-0355-10	R56240011, EXP 2/28/26; R56240021, R56240031, EXP 3/31/26; R56240041, R56240051, R56240061, EXP 4/30/26; R56240071, EXP 7/31/26	Deviations from the Current Good Manufacturing Practices (CGMP). Nnitroso metoprolol found to be higher than the FDA recommended limit

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8/20/2025	Class 2	Metoprolol Tartrate 50 Mg Tabs	Westminster Pharmaceuticals LLC	69367-0354-10	R55230021, R55230031, R55230041, EXP 9/30/25; R55230051, R55230061, R55230071, R55230081, R55230091, R55230101, R55230111, R55230121, R55230131, R55230141, EXP 10/31/2025; R55230151, EXP 11/30/25; R55240011, EXP 12/31/25; R55240021, R55240031, R55240041, R55240051, R55240061, EXP 6/30/26; R55240071, R55240081, R55240091, R55240101, R55240111, R55240121, EXP 7/31/26	A labeling mix up. A complaint reported that Cefazolin vials incorrectly labelled as Penicillin G Potassium were included in a carton of Cefazolin vials
8/20/2025	Class 2	Sodium Chloride 0.9 % Soln	B BRAUN MEDICAL INC	00264-7800-00	J5C919, EXP 08/31/2027	A lack of assurance of sterility, the product may be leaking fluid
8/20/2025	Class 2	Theophylline Er 400 Mg Tb24	Glenmark Pharmaceuticals Inc., USA	68462-0380-01	19243193, 19243215, 19243231, 19243248, 19243283, EXP 7/31/2026; 19244530, 19244561, EXP 10/31/2026; 19250178, EXP 12/31/2026	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly
8/27/2025	Class 2	Tavaborole 5 % Soln	VIONA PHARMACEUTICALS INC	72578-0102-04	T401968	Discoloration issues
9/03/2025	Class 2	Gnp Alcohol Swabs 70 % Pads	MEDLINE INDUSTRIES, LP - Northfield	46122-0043-78	61224070074	The product being subpotent (not strong enough)

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9/03/2025	Class 2	Lisdexamfetamine Dimesylate 40 Mg Caps	Lannett Company Inc.	00527-4664-37	25280726A, EXP 03/2027	A labeling mixup. A bottle labeled as Lisdexamfetamine Dimesylate Capsules 40mg, contained Lisdexamfetamine Dimesylate Capsules 30mg
9/10/2025	Class 1	Sodium Chloride 0.9 % Soln	B BRAUN MEDICAL INC	00264-7800-09	V3K770, EXP 1/31/2026	The presence of particulate matter, tiny particles in the product
9/10/2025	Class 2	Chlorpromazine Hcl 100 Mg Tabs	Amneal Pharmaceuticals, LLC	69238-1060-01	AM240334, AM240335, EXP 02/28/2027; AM241031, EXP 06/30/2027	The presence of a foreign substance. A specific lot of auxiliary polyester coil, used in product packaging was found to contain a micro-organism. Although no contamination was found on any tablets, the recall was issued as a precaution.
9/10/2025	Class 2	Chlorpromazine Hcl 200 Mg Tabs	Amneal Pharmaceuticals, LLC	69238-1062-01	AM240336, AM240337, EXP 02/28/2027	The presence of a foreign substance. A specific lot of auxiliary polyester coil, used in product packaging was found to contain a micro-organism. Although no contamination was found on any tablets, the recall was issued as a precaution.
9/10/2025	Class 2	Chlorpromazine Hcl 25 Mg Tabs	Amneal Pharmaceuticals, LLC	69238-1056-01	AM240617, AM240618, EXP 04/30/2027	The presence of a foreign substance. A specific lot of auxiliary polyester coil, used in product packaging was found to contain a micro-organism. Although no contamination was found on any tablets, the recall was issued as a precaution.
9/10/2025	Class 2	Chlorpromazine Hcl 50 Mg Tabs	Amneal Pharmaceuticals, LLC	69238-1058-01	AM240147, AM240148, EXP 01/31/2027; AM240664, AM240665, EXP 04/30/2027	The presence of a foreign substance. A specific lot of auxiliary polyester coil, used in product packaging was found to contain a micro-organism. Although no contamination was found on any tablets, the recall was issued as a precaution.

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9/10/2025	Class 2	Sulfamethoxazole -Trimethoprim 800-160 Mg Tabs	Amneal Pharmaceuticals, LLC	65162-0272-10, 65162-0272-50	AM240173, EXP 01/31/2027, AM240680, EXP 05/31/2027, AM 240921, EXP 06/30/2027, AM241191, EXP 08/31/2027 B) AM240176, AM240177, EXP 01/31/2027, AM240301, AM240300, EXP 02/28/2027, AM240676, AM240677, EXP 04/30/2027, AM240678, AM240679, EXP 05/30/2027 AM240922, AM240923, AM240924, AM240925, EXP 6/30/27, AM241086, EXP 7/31/27, AM241087, AM241088, EXP 8/31/27	The presence of a foreign substance. A specific lot of auxiliary polyester coil, used in product packaging was found to contain a micro-organism. Although no contamination was found on any tablets, the recall was issued as a precaution

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	Amlodipine-Olmesartan 5-40 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215105
Class 2	Belsomra 10 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=214973
Class 2	Carvedilol 12.5 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215396
Class 2	Carvedilol 25 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215397
Class 2	Carvedilol 3.125 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215395
Class 2	Levoxyl 50 Mcg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215245
Class 2	Metoprolol Tartrate 100 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215492
Class 2	Metoprolol Tartrate 50 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215491
Class 2	Sodium Chloride 0.9 % Soln	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215410
Class 2	Theophylline Er 400 Mg Tb24	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215521
Class 2	Tavaborole 5 % Soln	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215561
Class 2	Gnp Alcohol Swabs 70 % Pads	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215480
Class 2	Lisdexamfetamine Dimesylate 40 Mg Caps	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215500

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Class 1	Sodium Chloride 0.9 % Soln	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/b-braun-medical-issues-voluntary-nationwide-recall-lactated-ringers-injection-usp-1000-ml-and-09
Class 2	Chlorpromazine Hcl 100 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215900
Class 2	Chlorpromazine Hcl 200 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215901
Class 2	Chlorpromazine Hcl 25 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215602
Class 2	Chlorpromazine Hcl 50 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215891
Class 2	Sulfamethoxazole-Trimethoprim 800-160 Mg Tabs	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=215601