Capital Rx Drug Recall Report

MARCH 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 **3/19/2025****

Privacy Statement:

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RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
2/26/2025	Class 1	Fentanyl 25 Mcg/Hr Patch	Alvogen, Inc	47781-0424-47	108319, EXP 04/30/2027	A potential that patches could be multi-stacked, adhered one on top of the other, in a single product pouch
2/26/2025	Class 2	Atomoxetine Hcl 10 Mg Capsules	Glenmark Pharmaceuticals Inc., USA	68462-0265-30, 16714-0755-01	A) 19232368, EXP 5/2025; 19235088, EXP 11/2025; 19241447, EXP 3/2026; 19243146, EXP 7/2026 B) 19232356, EXP 5/2025; 19233198, EXP 7/2025; 19234213, 19234232, EXP 9/2025; 19241445, EXP 3/2026; 19243033, 19243121, EXP 7/2026	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
2/26/2025	Class 2	Atomoxetine Hcl 18 Mg Capsules	Glenmark Pharmaceuticals Inc., USA	68462-0266-30, 16714-0756-01	A) 19233756, EXP 8/2025; 19235111, EXP 11/2025; 19242167, EXP 5/2026; 19242180, EXP 5/2026 B) 19233228, 19233227, EXP 7/2025; 19233757, EXP 8/2025; 19234229, EXP 9/2025; 19235090, EXP 11/2025; 19241471, EXP 3/2026; 19242180, EXP 5/2026	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Atomoxetine Impurity above the FDA recommended limit.
2/26/2025	Class 2	Atomoxetine Hcl 25 Mg Capsules	Glenmark Pharmaceuticals Inc., USA	16714-0757-01, 68462-0267-30	A) 19232506, 19232397, 19232415, EXP 5/2025; 19233791, EXP 8/2025; 19234248, EXP 9/2025; 19240909, EXP 2/2026; 19242598, EXP 6/2026; 19243163, 19243122, EXP 7/2026; 19243884, EXP 9/2026 B) 19233792, EXP 8/2025; 19233795, EXP 8/2025; 19234258, EXP 9/2025; 19240912, EXP 2/2026; 19241476, 19241477, EXP 3/2026; 19242599, EXP 6/2026; 19243163, 19243162, EXP 7/2026; 19243884, 19243887, EXP 9/2026	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Atomoxetine Impurity above the FDA recommended limit.
2/26/2025	Class 2	Atomoxetine Hcl 40 Mg Capsules	Glenmark Pharmaceuticals Inc., USA	68462-0268-30, 16714-0758-01	A) 19234109, EXP 9/2025; 19234897, EXP 11/2025; 19240501, EXP 1/2026; 19241489, EXP 3/2026; 19241806, EXP 4/2026 B) 19232540, 19232524, 19232553, EXP 5/2025; 19240510, EXP 1/2026; 19241489, EXP 3/2026; 19243905, 19243935, EXP 9/2026	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Atomoxetine Impurity above the FDA recommended limit.

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
2/26/2025	Class 2	Atomoxetine Hcl 60 Mg Capsules	Glenmark Pharmaceuticals Inc., USA	68462-0269-30, 16714-0759-01	A) 19234630, EXP 10/2025; 19240528, 19240529, EXP 1/2026 B) 19234630, EXP 10/2025; 19240529, EXP 1/2026	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Atomoxetine Impurity above the FDA recommended limit.
2/26/2025	Class 2	Atomoxetine Hcl 80 Mg Capsules	Glenmark Pharmaceuticals Inc., USA	68462-0270-30, 16714-0760-01	A) 19234153, EXP 9/2025; 19234900, 19234929, EXP 11/2025; 19240936, 19240942, EXP 2/2026; 19243199, 19243190, EXP 7/2026; 19244013, 19244014, EXP 9/2026 B) 19233234, 19233253, EXP 7/2025; 19234154, EXP 9/2025; 19243185, EXP 7/2026; 19243951, 19243974, EXP 9/2026	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Atomoxetine Impurity above the FDA recommended limit.
2/26/2025	Class 2	Atomoxetine Hcl 100 Mg Capsules	Glenmark Pharmaceuticals Inc., USA	68462-0271-30, 16714-0761-01	A) 19234955, 19234956, EXP 11/2025; 19240971, EXP 2/2026; 19241864, EXP 4/2026 B) 19233270, 19233278, 19233285, EXP 7/2025; 19233806, EXP 8/2025; 19240954, EXP 2/2026; 19241854, EXP 4/2026	Deviations from the Current Good Manufacturing Practices (CGMP). N-Nitroso Atomoxetine Impurity above the FDA recommended limit.
2/26/2025	Class 2	Lorazepam 0.5 Mg Tablets	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories	00904-6007-61	N01424, N01425, EXP 03/31/2025; N01659, N01660, EXP 08/31/2025; N01668, EXP 09/2025; N01679, N01704, N01745, EXP 10/31/2025; N01856, EXP 02/28/2026; N01973, EXP 05/31/2026; N02079, EXP 08/31/2026	Failing to meet impurity and degradation standards

RECALL DATE	RECALL TYPE	DRUG RECALLED	MANUFACTURER	NDC(S) IMPACTED	IMPACTED LOT(S)	REASON FOR RECALL
2/26/2025	Class 2	Lorazepam 1 Mg Tablets	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories	00904-6008-61	N01419, N01420,N01421, EXP 03/31/2025; N01663, EXP 06/30/2025; N01664, EXP 08/31/2025; N01673, EXP 09/30/2025; N01688, EXP 08/31/2025; N01747, N01748, N01749, EXP 11/30/2025; N01792, EXP 12/31/2025; N01857, EXP 02/28/2026; N01974, EXP 05/31/2026; N02081, EXP 08/31/2026	Failing to meet impurity and degradation standards
2/26/2025	Class 2	Lorazepam 2 Mg Tablets	The Harvard Drug Group LLC dba Major Pharmaceuticals and Rugby Laboratories	00904-6009-61	N01422, N01423, EXP 03/31/2025; N01661, N01662, EXP 09/30/2025; N01746, N01750, EXP 10/31/2025; N01876, N01877, EXP 03/31/2026; N01899, N01900, N01975, EXP 04/30/2026	Failing to meet impurity and degradation standards
3/5/2025	Class 2	Estradiol 0.25 Mg/0.25gm Gel	Padagis US LLC	45802-0134-30	193109; EXP 07/31/2026	A defective container. Some packets may not be fully sealed, which could cause the Ethanol in the product to leak out
3/12/2025	Class 2	Morphine Sulfate Extended-Release Tablets 100 Mg	SUN PHARMACEUTICAL INDUSTRIES INC	63304-0452-01	AD16615, EXP DATE 07/2025	Failing to meet dissolution specifications, which may result in the tablets not dissolving properly
3/19/2025	Class 2	Duloxetine Hcl 20 Mg Delayed-Release Capsules	Breckenridge Pharmaceutical, Inc.	51991-0746-05	240098C, EXP 01/2027	Failing to meet purity standards, an impurity called N-nitroso-duloxetine being higher than the acceptable limit
3/19/2025	Class 2	Duloxetine Hcl 30 Mg Delayed-Release Capsules	Breckenridge Pharmaceutical, Inc.	51991-0747-10	240225C, EXP 01/2027	Failing to meet purity standards, an impurity called N-nitroso-duloxetine being higher than the acceptable limit
3/19/2025	Class 2	Duloxetine Hcl 60 Mg Delayed-Release Capsules	Breckenridge Pharmaceutical, Inc.	51991-0748-10	240301C, EXP 01/2027	Failing to meet purity standards, an impurity called N-nitroso-duloxetine being higher than the acceptable 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 1	Fentanyl 25 Mcg/Hr Patch	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/alvogen-issues-voluntary-nationwide-recall-one-lot-fentanyl-transdermal-system-25-mcgh-due-defective
Class 2	Atomoxetine Hcl 10 Mg Capsules	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212290 B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212304
Class 2	Atomoxetine Hcl 18 Mg Capsules	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212298 B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212305
Class 2	Atomoxetine Hcl 25 Mg Capsules	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212306 B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212299
Class 2	Atomoxetine Hcl 40 Mg Capsules	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212300 B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212307
Class 2	Atomoxetine Hcl 60 Mg Capsules	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212301 B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212308
Class 2	Atomoxetine Hcl 80 Mg Capsules	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212302 B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212309
Class 2	Atomoxetine Hcl 100 Mg Capsules	A) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212303 B) https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212310
Class 2	Lorazepam 0.5 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212138
Class 2	Lorazepam 1 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212139
Class 2	Lorazepam 2 Mg Tablets	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212140
Class 2	Estradiol 0.25 Mg/0.25gm Gel	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212413
Class 2	Morphine Sulfate Extended-Release Tablets 100 Mg	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212404
Class 2	Duloxetine Hcl 20 Mg Delayed-Release Capsules	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212707
Class 2	Duloxetine Hcl 30 Mg Delayed-Release Capsules	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212706
Class 2	Duloxetine Hcl 60 Mg Delayed-Release Capsules	https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=212704