# Capital Rx Drug Recall Report

**DECEMBER 2023**

Capital Rx

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 **12/27/2023****

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| RECALL DATE | RECALL TYPE | DRUG RECALLED | MANUFACTURER | NDC(S) IMPACTED | IMPACTED LOT(S) | REASON FOR RECALL |
|---|---|---|---|---|---|---|
| 12/06/2023 | Class 2 | Indomethacin 25 MG Capsules | Glenmark Pharmaceuticals Inc., USA | 68462-0406-01 | 19231903, Exp. 4/2025; 19231858, Exp. 4/2025; 19231881, Exp. 4/2025; 19233484, Exp. 8/2025; 19233490, Exp. 8/2025 | A label mix-up where Indomethacin bottles may be labeled as Naproxen. |
| 12/06/2023 | Class 2 | Naproxen 250 MG Tablets | Glenmark Pharmaceuticals Inc., USA | 68462-0188-01 | 19231903, Exp. 4/2025; 19231858, Exp. 4/2025; 19231881, Exp. 4/2025; 19233484, Exp. 8/2025; 19233490, Exp. 8/2025 | A label mix-up where Indomethacin bottles may be labeled as Naproxen. |
| 12/06/2023 | Class 2 | PARoxetine HCl 10 MG Tablets | Apotex Corp. | 60505-0097-01, 60505-0097-02, 60505-0097-04 | RV2376, RV2377, RV2379, RV2380, RV2375, Exp. 08/2024 | Failing to meet impurity and degradation standards. |
| 12/06/2023 | Class 2 | PARoxetine HCl 20 MG Tablets | Apotex Corp. | 60505-0083-02, 60505-0083-04 | RV2384, RV2385, RV2396, RV2397; Exp. 08/2024 | Failing to meet impurity and degradation standards. |
| 12/06/2023 | Class 2 | PARoxetine HCl 30 MG Tablets | Apotex Corp. | 60505-0084-01, 60505-0084-02, 60505-0084-04 | RV8686, RX0119, RV2254; Exp. 08/2024 | Failing to meet impurity and degradation standards. |
| 12/06/2023 | Class 2 | PARoxetine HCl 40 MG Tablets | Apotex Corp. | 60505-0101-04 | RV0131, RV2387, RV2389, RW3296, RV2388; Exp. 08/2024 | Failing to meet impurity and degradation standards. |
| 12/13/2023 | Class 1 | SandIMMUNE (cyclosporine oral solution) 100 MG/ML Solution | Novartis Pharmaceuticals Corporation | 00078-0110-22 | FX001500, FX001582, Exp. 09/30/2024 | Crystal formation observed in some bottles, which could potentially result in incorrect dosing. |

| RECALL DATE | RECALL TYPE | DRUG RECALLED | MANUFACTURER | NDC(S) IMPACTED | IMPACTED LOT(S) | REASON FOR RECALL |
|---|---|---|---|---|---|---|
| 12/13/2023 | Class 2 | Trospium Chloride ER 60 MG Capsules | Padagis US LLC | 00574-0118-30 | 231104, 231105, 231106, exp 7/31/2025 | Failing to meet quality standards because of missing, broken, and some extra tablets found with the capsules. |
| 12/20/2023 | Class 2 | Liothyronine Sodium 5 MCG Tablets | Sun Pharmaceutical Industries, Inc. | 62756-0589-88 | DND0059A, DND0060A, DND0061A Expires 12/2023; DND0062A, DND0063A, DND0064A, DND0065A, DND0180A, DND0181A, DND0182A, DND0183A, DND0184A Expires 01/2024; DND0597A Expires 02/2024 | Failing to meet impurity and degradation standards. |
| 12/20/2023 | Class 2 | penicillAMINE 250 MG Tablets | Lupin Pharmaceuticals Inc. | 70748-0153-01 | M200498, Exp. June 2024 | Failing to meet dissolution specifications, which may result in possible issues with the tablets dissolving. |

**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 | Indomethacin 25 MG Capsules | https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=204200 |
| Class 2 | Naproxen 250 MG Tablets | https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=204201 |
| Class 2 | PARoxetine HCl 10 MG Tablets | https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=204142 |
| Class 2 | PARoxetine HCl 20 MG Tablets | https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=204288 |
| Class 2 | PARoxetine HCl 30 MG Tablets | https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=204289 |
| Class 2 | PARoxetine HCl 40 MG Tablets | https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=204290 |
| Class 1 | SandIMMUNE (cyclosporine oral solution) 100 MG/ML Solution | https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/novartis-issues-voluntary-us-nationwide-recall-two-lots-sandimmuner-oral-solution-cyclosporine-oral |
| Class 2 | Trospium Chloride ER 60 MG Capsules | https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=204052 |
| Class 2 | Liothyronine Sodium 5 MCG Tablets | https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=204693 |
| Class 2 | penicillAMINE 250 MG Tablets | https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=204481 |