

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Accord Healthcare, Inc. (“Accord Healthcare”) is recalling **multiple batches of Cinacalcet Tablets 30 mg, 60 mg and 90 mg, at the Pharmacy Level.**

This recall is being initiated due to the presence of a nitrosamine impurity, N-nitroso-cinacalcet, at or above the acceptable daily intake (ADI) limits established by regulatory authorities. During testing, the presence of **N-nitroso-cinacalcet** above ADI limits was detected, a type of nitrosamine impurity in certain batches of Cinacalcet Tablets. Nitrosamines are classified as probable human carcinogens based on laboratory studies and long-term exposure above the ADI may increase the risk of cancer. As patient safety is its highest priority, Accord Healthcare is taking immediate action to recall the affected product batches. To date, Accord Healthcare has not received any reports of adverse events related to the presence of a nitrosamine impurity in the medicine.

Cinacalcet Tablets

Strength	Bottle Pack size	Product NDC	Batch No.	Expiry Date
30MG	30 Tablets	16729-440-10	M2118190	11/2024
30MG	30 Tablets	16729-440-10	M2201091	11/2024
30MG	30 Tablets	16729-440-10	M2206241	11/2024
30MG	30 Tablets	16729-440-10	M2206451	04/2025
30MG	30 Tablets	16729-440-10	M2208674	06/2025
30MG	30 Tablets	16729-440-10	M2213850	08/2025
30MG	30 Tablets	16729-440-10	M2215221	09/2025
30MG	30 Tablets	16729-440-10	M2216236	11/2025
30MG	30 Tablets	16729-440-10	M2217098	11/2025
30MG	30 Tablets	16729-440-10	M2300664	11/2025
30MG	90 Tablets	16729-440-15	M2210808	06/2025
30MG	90 Tablets	16729-440-15	M2212212	08/2025
30MG	90 Tablets	16729-440-15	M2214435	09/2025
30MG	90 Tablets	16729-440-15	M2217097	11/2025
30MG	90 Tablets	16729-440-15	M2301921	01/2026
60MG	30 Tablets	16729-441-10	M2204481	02/2025
60MG	30 Tablets	16729-441-10	M2212389	08/2025
60MG	30 Tablets	16729-441-10	M2214271	09/2025
60MG	30 Tablets	16729-441-10	M2215970	10/2025
60MG	30 Tablets	16729-441-10	M2216458	10/2025

60MG	90 Tablets	16729-441-15	M2212869	08/2025
60MG	90 Tablets	16729-441-15	M2216362	09/2025
60MG	90 Tablets	16729-441-15	M2215969	10/2025
90MG	30 Tablets	16729-442-10	M2303264	01/2026
90MG	90 Tablets	16729-442-15	M2306979	04/2026