

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.

Aurobindo Pharma USA, Inc. has initiated a Drug Product Recall for the product Cinacalcet Tablets 30/60/90mg from USA market due to presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Cinacalcet above acceptable intake (AI) limit.

Cinacalcet Tablets are indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis. To date, Aurobindo has not received any reports of adverse drug events that are confirmed with this recall. Patients who are prescribed Cinacalcet should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.

As per the product information leaflet, Cinacalcet tablets, 30 mg are light green, film-coated, oval shaped, biconvex tablets debossed with "80" on one side and "Y" on the other side. Cinacalcet tablets, 60 mg are light green, film-coated, oval shaped, biconvex tablets debossed with "81" on one side and "Y" on the other side. Cinacalcet tablets, 90 mg are light green, film-coated, oval shaped, biconvex tablets debossed with "82" on one side and "Y" on the other side.

Aurobindo USA began shipping impacted batches to customers nationwide from May 22, 2023 to March 14, 2024.

Batches manufactured at Aurobindo Pharma Unit VII

NDC Number	Dosage Strength	Package Size	Lot Number	Expiration Date
65862-831-30	30mg	30's HDPE Container	CFSA23001A	03/2025
			CFSA23002A	03/2025
			C.FSA23003A	03/2025
			CFSA23004A	07/2025
			CFSA23005A	10/2025
65862-832-30	60mg		CFSB23001A	03/2025
			CFSB23002A	07/2025
			CFSB23003A	10/2025

		CFSB23004A	10/2025
65862-833-30	90mg	CFSC23001A	03/2025
		CFSC23001B	03/2025

Batches manufactured at APPCO Pharma LLC, USA

NDC Number	Dosage Strength	Package Size	Lot Number	Expiration Date
			P2300191	
65862-831-05	30mg		P2300192	
		500's HDPE Container	P2300193	12/2024
			P2300194	
65862-832-05	60mg		P2300196	
65862-833-05	90mg		P2300195	