

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.

This is to inform you of a product recall by Cipla USA, Inc. for 15 lots (Lot# 4PB0526, 4PB0527, 4PB0528, 5PB0173 - 30mg), (4PB0215, 4PB0216, 4PB0515, 4PB0516, 4PB0517, 5PB0167 - 60mg) and 4PB0224, 4PB0505, 4PB0506, 4PB0507, 5PB0564 - 90mg) of Cinacalcet Hydrochloride tablets. The product is labeled for and marketed by Cipla USA, Inc. bearing the NDC Numbers# 69097-410-02, 69097-411-02, 69097-412-02.

Based on statistical evaluation, Out-of-specification results are expected for 'content of N-Nitroso Cinacalcet'.

As part of the patient safety assessment, a Health Hazard Evaluation (HHE) performed and concluded that calculated patient exposure from the affected batches (maximum == 576 ng/day) remains well below both the AL x 6.7 interim threshold and the EMA-stipulated absolute upper limit of 1.5 µg/day. Therefore, no immediate or short-term risk to patient safety is anticipated. The estimated theoretical excess cancer risk at this exposure is < 1 x 10⁻⁶, consistent with international regulatory tolerability criteria.

PRODUCT DESCRIPTION	NDC#	LOT#	EXP.DATE
Cinacalcet Hydrochloride tablets 30 mg	69097-410-02	4PB0526	September-2026
Cinacalcet Hydrochloride tablets 30 mg	69097-410-02	4PB0527	September-2026
Cinacalcet Hydrochloride tablets 30 mg	69097-410-02	4PB0528	September-2026
Cinacalcet Hydrochloride tablets 30 mg	69097-410-02	5PB0173	January-2027
Cinacalcet Hydrochloride tablets 60 mg	69097-411-02	4PB0215	March-2026
Cinacalcet Hydrochloride tablets 60 mg	69097-411-02	4PB0216	March-2026
Cinacalcet Hydrochloride tablets 60 mg	69097-411-02	4PB0515	September-2026
Cinacalcet Hydrochloride tablets 60 mg	69097-411-02	4PB0516	September-2026
Cinacalcet Hydrochloride tablets 60 mg	69097-411-02	4PB0517	September-2026
Cinacalcet Hydrochloride tablets 60 mg	69097-411-02	5PB0167	January-2027
Cinacalcet Hydrochloride tablets 90 mg	69097-412-02	4PB0224	March-2026
Cinacalcet Hydrochloride tablets 90 mg	69097-412-02	4PB0505	September-2026

Cinacalcet Hydrochloride tablets 90 mg	69097-412- 02	4PB0506	September-2026
Cinacalcet Hydrochloride tablets 90 mg	69097-412- 02	4PB0507	September-2026
Cinacalcet Hydrochloride tablets 90 mg	69097-412- 02	5PB0564	April-2027