

*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# 5PB0465, 5PB0466, 5PB0557, 5PB0629, 5PB0630, 5PB0633, 5PB0637, 5PB0638 - 30mg), (5PB0165, 5PB0166, 5PB0552, 5PB0642, 5PB0643 , 5PB0644 - 60mg) and 5PB0563 - 90mg Cinacalcet Hydrochloride tablets.

Out-of-specification results for content of N-Nitroso Cinacalcet for two active batches in the market. Statistical projection indicates additional active batches in the market are not expected to comply with specification limits of N-Nitroso Cinacalcet through their shelf life.

This recall should be carried out to the **Retail level**.

| <b>Sr. No.</b> | <b>Product Name</b>                          | <b>FG Batch No.</b> | <b>Dates distributed</b>                  |
|----------------|----------------------------------------------|---------------------|-------------------------------------------|
| 1              | Cinacalcet<br>Hydrochloride tablets<br>30 mg | 5PB0465             | July 28, 2025 to Feb 04, 2026             |
| 2              | Cinacalcet<br>Hydrochloride tablets<br>30 mg | 5PB0466             | August 13, 2025 to<br>November 05, 2025   |
| 3              | Cinacalcet<br>Hydrochloride tablets<br>30 mg | 5PB0557             | August 21, 2025 to<br>October 24, 2025    |
| 4              | Cinacalcet<br>Hydrochloride tablets<br>30 mg | 5PB0629             | November 05, 2025 to<br>February 10, 2026 |
| 5              | Cinacalcet<br>Hydrochloride tablets<br>30 mg | 5PB0630             | November 17, 2025 to<br>February 17, 2026 |
| 6              | Cinacalcet<br>Hydrochloride tablets<br>30 mg | 5PB0633             | November 10, 2025 to<br>January 13, 2026  |
| 7              | Cinacalcet<br>Hydrochloride tablets<br>30 mg | 5PB0637             | November 17, 2025 to<br>March 03, 2026    |
| 8              | Cinacalcet<br>Hydrochloride tablets<br>30 mg | 5PB0638             | October 29, 2025 to<br>February 24, 2026  |
| 9              | Cinacalcet<br>Hydrochloride tablets<br>60 mg | *5PB0165            | May 07, 2025 to<br>September 02, 2025     |

|    |                                              |          |                                            |
|----|----------------------------------------------|----------|--------------------------------------------|
| 10 | Cinacalcet<br>Hydrochloride tablets<br>60 mg | *5PB0166 | June 03, 2025 to<br>September 25, 2025     |
| 11 | Cinacalcet<br>Hydrochloride tablets<br>60 mg | 5PB0552  | September 23, 2025 to<br>March 03, 2026    |
| 12 | Cinacalcet<br>Hydrochloride tablets<br>60 mg | 5PB0642  | October 28, 2025 to<br>January 09, 2026    |
| 13 | Cinacalcet<br>Hydrochloride tablets<br>60 mg | 5PB0643  | October 09, 2025 to<br>February 10, 2026   |
| 14 | Cinacalcet<br>Hydrochloride tablets<br>60 mg | 5PB0644  | October 31, 2025 to<br>December 17, 2025   |
| 15 | Cinacalcet<br>Hydrochloride tablets<br>90 mg | 5PB0563  | September 05, 2025 to<br>December 01, 2025 |

\*Batch# 5PB0165 and 5PB0166 are the batches that are OOS

a. The product is labeled for and marketed by Cipla USA, bearing the NDC Numbers# 69097-410-02, 69097-411-02 and 69097-412-02