

*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.*

Dr. Reddy's Laboratories, Inc is recalling Cinacalcet Tablets 30 mg, 60 mg, and 90 mg.

This recall is being initiated due to the Nitrosamine Drug Substance Related Impurity (NDSRI) assessment in the drug product. Specifically, confirmatory testing for the N-Nitroso Cinacalcet impurity was conducted on Cinacalcet Tablets, 90 mg strength, as per guidance. The results showed that the levels of N-Nitroso Cinacalcet Tablets (30 mg, 60 mg, and 90 mg) in distribution are being recalled.

Please refer to the table below:

<b>Product Name</b>	<b>Lot Number</b>	<b>Expiration date</b>	<b>NDC Number</b>
Cinacalcet Tablets 30 mg, 30 Count	T2200120	11/2024	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2200121	11/2024	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2200119	11/2024	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2200116	11/2024	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2200118	11/2024	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2200117	11/2024	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2200695	01/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2200694	01/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2200696	01/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2200697	01/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2201426	03/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2201428	03/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2201432	03/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2201427	03/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2201430	03/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2201429	03/2025	43598-367 -30
Cinacalcet Tablets 30 mg, 30 Count	T2201431	03/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2202743	06/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2202742	06/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2202741	06/2025	

Cinacalcet Tablets 30 mg, 30 Count	T2202740	06/2025	43598-367-30
			43590-367 -30
Cinacalcet Tablets 30 mg, 30 Count	T2203081	07/2025	43598-367 -30
Cinacalcet Tablets 30 mg, 30 Count	T2203079	07/2025	43598-367-30
Cinacalcet Tablets 30 mQ, 30 Count	T2203080	07/2025	43598-367 -30
Cinacalcet Tablets 30 mQ, 30 Count	T2203082	07/2025	43598-367 30
Cinacalcet Tablets 30 mg, 30 Count	T2203083	07/2025	43598-367 -30
Cinacalcet Tablets 30 mg, 30 Count	T2203084	07/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2300770	12/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2300771	12/2025	43598-367 -30
Cinacalcet Tablets 30 mg, 30 Count	T2300769	12/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2300766	12/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2300767	12/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2300768	12/2025	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2301663	02/2026	43598-367 -30
Cinacalcet Tablets 30 mg, 30 Count	T2301665	02/2026	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2301662	02/2026	43598-367 -30
Cinacalcet Tablets 30 mg, 30 Count	T2301664	02/2026	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2301667	02/2026	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2301661	02/2026	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2301666	02/2026	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2301660	02/2026	43598-367-30

Cinacalcet Tablets 30 mg, 30 Count	T2301658	02/2026	43598-367-30
Cinacalcet Tablets 30 mQ, 30 Count	T2301659	02/2026	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2304704	08/2026	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2304703	08/2026	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2304705	08/2026	43598-367-30
Cinacalcet Tablets 30 mg, 30 Count	T2304706	08/2026	43598-367 -30
Cinacalcet Tablets 30 mg, 30 Count	T2400468	11/2026	43598-367 -30
Cinacalcet Tablets 30 mg, 30 Count	T2400469	11/2026	43598-367 -30
Cinacalcet Tablets 30 mg, 30 Count	T2400473	11/2026	43598-367 -30
Cinacalcet Tablets 30 mg, 30 Count	T2400474	11/2026	43598-367-30
Cinacalcet Tablets 60 mg, 30 Count	T2200698	01/2025	43598-368-30
Cinacalcet Tablets 60 mg, 30 Count	T2201444	03/2025	43598-368-30
Cinacalcet Tablets 60 mg, 30 Count	T2202827	06/2025	43598-368-30
Cinacalcet Tablets 60 mg, 30 Count	T2300531	12/2025	43598-368-30
Cinacalcet Tablets 60 mg, 30 Count	T2301696	02/2026	43598-368-30
Cinacalcet Tablets 60 mg, 30 Count	T2304726	08/2026	43598-368-30
Cinacalcet Tablets 60 mg, 30 Count	T2400480	11/2026	43598-368-30
Cinacalcet Tablets 90 mg, 30 Count	T2201443	03/2025	43598-369-30
Cinacalcet Tablets 90 mg, 30 Count	T2300664	12/2025	43598-369-30

**Risk Assessment:** The dosing of Cinacalcet may depend on the severity of the condition and the patient's response to treatment. Guidelines recommend initiating treatment and evaluating the patient's response continuously over the period for titration and dose adjustments as necessary.

Lower doses of Cinacalcet (30-60 mg/day) appear to be effective for many patients, but higher doses may be required for those with more severe disease or when lower doses are insufficient to achieve the desired response. The duration of Cinacalcet treatment can vary, with some studies employing shorter treatment durations (12-26 weeks), while others involve longer treatment durations and follow-up periods beyond 52 weeks. The optimal dosing and duration of Cinacalcet treatment is determined on an individual patient basis, considering the severity of the condition, patient response, and the potential side effects. Overall, the intake of N-nitroso-Cinacalcet due to its presence in the final product formulation at the calculated interim limits up to 7.44 ppm (MDD: 360 mg/day) as per the LTL approach for 1-10 years, it is not expected to increase the theoretical excess cancer risk above 1 in 100,000 and thus, should not be considered to represent a significant safety concern to patients if exposed for period and the treatment duration as discussed above.

The product Distribution Dates: February 24th, 2022 - August 22nd, 2024