

Paricap Capsule

Composition : Paricalcitol USP 1 mcg.

Indication : It is indication for the treatment and prevention of secondary hyperparathyroidism associated with Chronic Kidney Disease (CKD) stages 3 and 4, stage 5 in patients on hemodialysis (HD) or peritoneal dialysis (PD).

Dosage & Administration : Chronic Kidney Disease Stages 3 and 4 : Paricalcitol capsules may be administered daily or three times a week. When dosing three times weekly, the dose should be administered not more frequently than every other day.

Initial Dose : The initial dose of this capsules for CKD stage 3 and 4 patients is based on baseline intact parathyroid hormone (iPTH) levels.

Baseline iPTH Level	Daily Dose	Three Times a Week Dose
≤ 500pg/ml	1mcg	2mcg
≥500pg/ml	2mcg	4mcg

Chronic Kidney Disease Stages 5 :

This capsules are to be administered three times a week.

Or, as directed by the registered physicians.

Side effects : The most common side effects of the medicine are: diarrhea, hypertension, dizziness and vomiting.

Contraindication : Paricalcitol is contraindicated in patients with a history of hypersensitivity to paricalcitol or any other components of paricalcitol. It should not be given to patients with evidence of hypercalcemia or vitamin D toxicity.

Precautions : Excessive administration

of vitamin D compounds, including Paricalcitol capsule, can cause over suppression of PTH, hypercalcemia, hypercalciuria, hyperphosphatemia, and a dynamic bone disease. Monitor serum calcium, serum phosphorus or plasma iPTH during initial dosing or following any dose adjustment. Avoid excessive use of aluminium containing compounds.

Use in Pregnancy and Lactation :

There are no adequate and well-controlled clinical studies in pregnant women. This capsules should be used during pregnancy only if the potential

benefit to the mother justifies the potential risk to the fetus. It is not known whether paricalcitol is excreted in human milk.

Drug-Interactions : Strong CYP3A inhibitors (e.g. ketoconazole) will increase the exposure of paricalcitol. Cholestyramine, Intestinal adsorption of Paricalcitol may be reduced if administered simultaneously with mineral oil or chilestyramine.

Packing : Paricap : 1 x 10's soft capsules in blister pack.