Rayaldee®
calcifediol ER capsules
30 mcg

Experience **REAL** confidence in your SHPT treatment plan with Rayaldee.

High iPTH levels are associated with faster CKD progression and increased morbidity and mortality.[1]

Uncontrolled SHPT can lead to:

- FASTER TIME TO DIALYSIS OR DEATH[2]
- CARDIOVASCULAR EVENTS[3]
- FRACTURES[4]

KDIGO Clinical Practice Guideline 2017:[1]

- Early assessment and monitoring of CKD-MBD as early as stage 3 CKD.
- Nutritional vitamin D (ergocalciferol / cholecalciferol) remains unproven, and active vitamin D (calcitriol and 1α-hydroxylated analogs) should not be routinely used in early ND-CKD due to the risk of hypercalcemia.

Rayaldee delivers REAL results by effectively managing SHPT in patients with stage 3 or 4 CKD and vitamin D levels less than 30 ng/mL.

Rayaldee has not been proven to reduce the risk of cardiovascular events, bone fractures, CKD progression, parathyroid hyperplasia, cardiovascular or all-cause mortality.

Secondary hyperparathyroidism (SHPT); chronic kidney disease (CKD); mineral bone disorder (MBD); intact parathyroid hormone (iPTH); non-dialysis (ND)

Indication and Limitations of Use

Rayaldee® (calcifediol) extended-release 30 mcg capsules is indicated for the treatment of secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease and serum total 25-hydroxyvitamin D levels less than 30 ng/mL.

Rayaldee is not indicated in patients with stage 5 chronic kidney disease or end-stage renal disease on dialysis.

Important Safety Information

• ***Hypercalcemia:*** Excessive administration of vitamin D compounds, including Rayaldee, can cause hypercalce-mia and hypercalciuria. Severe hypercalcemia due to substantial overdosage of vitamin D and its metabolites may require emergency attention. Patients should be informed about the symptoms of elevated calcium. • ***Digitalis toxicity:*** Potentiated by hypercalcemia of any cause. Monitor serum calcium and signs and symptoms of digitalis toxicity more frequently when initiating or adjusting the dose of Rayaldee. • ***Adynamic Bone Disease:*** Monitor for abnormally low levels of intact parathyroid hormone (iPTH) levels when using Rayaldee, and adjust dose if needed. • The most common adverse reactions (≥3% and more frequent than placebo) were anemia, nasopharyngitis, increased blood creatinine, dyspnea, cough, congestive heart failure and constipation. • Care should be taken while dosing Rayaldee with cytochrome P450 inhibitors, thiazides, cholestyramine or drugs stimulating microsomal hydroxylation due to the potential for drug interactions. • Serum calcium should be below 9.8 mg/dL before initiating treatment. • Monitor serum calcium, phosphorus, 25-hydroxyvitamin D and iPTH 3 months after starting therapy or changing dose.

Please see Important Safety Information (ISI) and accompanying Full Prescribing Information also available at Rayaldee.com.

Real Results. Real Benefits. That's Rayaldee®.

Rayaldee provides a different approach for REAL SHPT control.

- **FDA approved** for the treatment of SHPT in patients with stage 3 or 4 CKD [6]
- **Achieves sustained >30% iPTH reductions** associated with slower CKD progression* [7]
- **Reliably raises 25D to ≥50 ng/mL** which raises 1,25D** [8,9]
- **Produces no** clinically significant increases in serum Ca, P or FGF23*** [6,9]
- **Raises 25D up to 100 ng/mL** within accepted safety parameters [6,8,9]
- **Efficacy remains consistent** in stage 3 and 4 CKD [8]
- **Efficacy not significantly affected** by BMI or body weight [10]

*Rayaldee is not indicated to slow down CKD progression.

**Serum total 25-hydroxyvitamin D levels should be below 30 ng/mL and serum calcium should be below 9.8 mg/dL before starting Rayaldee treatment.

***Pooled data from two pivotal trials showed similar means (SE) increases in serum calcium [0.2 (0.02) vs. 0.1 (0.03) mg/dL, p<0.001] and phosphorus [0.2 (0.03) vs. 0.1 (0.04) mg/dL] for Rayaldee and placebo over 6 months. [11]

REFERENCES 1. KDIGO CKD-MBD Update Work Group. Kidney Int Suppl. 2017;7:1–59. **2.** Schumock GT et al. Curr Med Res Opin. 2008;24:3037–3048. **3.** Fisher A et al. Clin Interv Aging. 2013;8:239–256. **4.** Rix M et al. Kidney Int. 1999;56:1084–1093. **5.** Andress DL et al. Endocr Pract. 2008;14:18–27. **6.** Rayaldee® [prescribing information]. Miami, FL: OPKO Pharmaceuticals, LLC; January 2024. **7.** Bishop C et al. Am J Nephrol 2024 Aug 27:1-10. **8.** Strugnell SA et al. Am J Nephrol. 2019;49:284. **9.** Sprague SM et al. Am J Nephrol. 2016;44:316–325. **10.** Bishop CW et al. Am J Nephrol. 2022;1–9. **11.** Petkovich M, Bishop C. In: Vitamin D. 4th ed. Elsevier; 2018.