

# EVALUATE YOUR PATIENTS FOR SHPT<sup>1,2</sup>

## Check for

- Chronic kidney disease (CKD) stage 3 or 4
- Vitamin D insufficiency (serum 25D <30 ng/mL)
- iPTH >70 pg/mL (stage 3) or >110 pg/mL (stage 4)
- Serum calcium <9.8 mg/dL

Prescribe Rayaldee® (calcifediol) extended-release capsules, a vitamin D<sub>3</sub> analog indicated for the treatment of secondary hyperparathyroidism (SHPT) in adults.<sup>1</sup>

## 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 hypercalcemia and hypercalciuria. Severe hypercalcemia due to substantial overdose 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.

**REFERENCES:** 1. Rayaldee [prescribing information]. Miami, FL: OPKO Pharmaceuticals, LLC; June 2016.  
2. Uhlig K, Berns JS, Kestenbaum B, et al. KDOQI US Commentary on the 2009 KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of CKD-Mineral and Bone Disorder (CKD-MBD). *Am J Kidney Dis.* 2010;55(5):773-799.

For Full Prescribing Information, please visit [Rayaldee.com](http://Rayaldee.com).

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**Rayaldee**<sup>®</sup>  
calcifediol ER capsules  
30 mcg