



Rayaldee® Dosing Guide

Rayaldee® (calcifediol) extended-release capsules, is the only FDA-approved extended-release vitamin D₃ prohormone that safely and effectively lowers iPTH by raising 25D and 1,25D levels. ^{1,2}

Indication:

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.

Limitations of use:

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

Please see Important Safety Information (ISI) on the back of this piece and accompanying Full Prescribing Information, also available at www.rayaldee.com.

OPKO RENAL
A DIVISION OF OPKO HEALTH, INC.

How To Initiate Therapy With Rayaldee®

(calcifediol) extended-release capsules



Before treatment, ensure serum calcium is <9.8 mg/dL.



Initial dose is 30 mcg by mouth, once daily, at bedtime.



Instruct your patients to swallow the capsule whole.

If a patient misses a dose

- Instruct the patient to skip a missed dose and to resume taking the medicine at the next regularly scheduled time.
- Do not administer an extra dose.



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Monitoring And Dose Adjustments

The maintenance dose of Rayaldee® should target:

- Serum total 25-hydroxyvitamin D levels between 30 and 100 ng/mL
- PTH levels within the desired therapeutic range
- Serum calcium (corrected for low albumin) within the normal range
- Serum phosphorus <5.5 mg/dL

If PTH remains above the desired range after approximately 3 months, dosing may be increased to 60 mcg.

Before raising the dose, ensure

- Serum calcium <9.8 mg/dL
- Serum phosphorus <5.5 mg/dL
- Serum 25D <100 ng/mL



Get Started. **Prescribe Rayaldee® TODAY!**

Initiate Therapy If iPTH Is Above ULN

TARGETS:

25D
≥50 ng/mL³

Sustained
≥30% iPTH
Reduction⁴

START WITH 1 CAPSULE (30 mcg) A DAY AT BEDTIME



MONITORING AND DOSE ADJUSTMENTS

Ensure
Ca <9.8 mg/dL



CHECK LABS
@ 3 MONTHS



Titrate to 60 mcg
if iPTH is above target



Indication and Limitations of Use:

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Important Safety Information:

- **Hypercalcemia:** Excessive administration of vitamin compounds, including Rayaldee, can cause hypercalcemia 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 accompanying Full Prescribing Information, also available at www.Rayaldee.com.

References: **1.** Rayaldee® [prescribing information]. Miami, FL: OPKO Pharmaceuticals, LLC; January 2024. **2.** Sprague SM, et al. Am J Nephrol. 2016;44:316-25; **3.** Strugnell SA, Sprague SM, et al. Am J Nephrol. 2019;49:284-293; **4.** Bishop C et al. Am J Nephrol. 2024 Aug 27:1-10

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