Rayaldee®
calcifediol ER capsules
30 mcg

NEW CAPSULE LOOK, SAME TRUSTED SCIENCE

*Bottle and pill images are for illustrative purposes only and are not actual size.

	ORIGINAL SOFT CAPSULE	**NEW HARD CAPSULE**
NDC NUMBER	70301-1001-1	**70301-1002-1**
Color	Blue	**White**
Shape	Oval	**Two-piece banded**
Imprint	"O" in white ink	**"O" and "30" in blue ink**
Strength	30 mcg	**30 mcg**
Bottle count	30 capsules	**30 capsules**

Rayaldee is the **first and only extended-release prohormone of the active form of vitamin D_3** indicated for the treatment of secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease (CKD) and serum total 25-hydroxyvitamin D levels less than 30 ng/mL. Rayaldee is not indicated in patients with stage 5 chronic kidney disease (CKD) or end-stage renal disease on dialysis.[1]

Selected Important Safety Information:

- ***Hypercalcemia:*** Excessive administration of vitamin D 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.

Please see Important Safety Information (ISI) on back. For Full Prescribing Information visit www.Rayaldee.com.

1. Rayaldee. Prescribing information. OPKO Pharmaceuticals, LLC; January, 2024

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calcifediol ER capsules
30 mcg

Dosing and Management

QD

30 mcg

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

Ca < 9.8 mg/dL

LABS @ 3 MONTHS

60 mcg

TITRATE IF PTH IS ABOVE TARGET

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.

SCAN TO ACCESS THE PRODUCT FAQs

Important Safety Information

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- 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 Full Prescribing Information available at www.Rayaldee.com.

Contact OPKO CONNECT at 1-844-414-OPKO (6756) for more information.