

EVALUATE YOUR STAGE 3 AND 4 CKD PATIENTS FOR SHPT^{1,2}

- ☐ eGFR 30-59 (CKD Stage 3)
- ☐ eGFR 15-29 (CKD Stage 4)
- ☐ Serum 25D <30 ng/mL
- ☐ Serum calcium <9.8 mg/dL
- ☐ iPTH progressively rising or persistently above the upper limit of normal

ICD-10 DIAGNOSIS CODES³

- ☐ N18.3 Chronic kidney disease (CKD) stage 3
- ☐ N18.4 Chronic kidney disease (CKD) stage 4
- ☐ N25.81 Secondary hyperparathyroidism (SHPT)
- ☐ E55.9 Vitamin D deficiency

Royaldee: the next generation in SHPT care

Indication and Limitations of Use

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

Please see Important Safety Information on back and Full Prescribing Information available at [Royaldee.com](https://www.opko.com).

REFERENCES: **1.** Royaldee® [prescribing information]. Miami, FL: OPKO Pharmaceuticals, LLC; April 2021. **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. **3.** <https://www.cms.gov/medicare/icd-10/2023-icd-10-cm>

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 **Royaldee®**
calcifediol ER capsules
30 mcg

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Important Safety Information

- **Hypercalcemia:** Excessive administration of vitamin D compounds, including Royaldee, 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 Royaldee.
- **Adynamic Bone Disease:** Monitor for abnormally low levels of intact parathyroid hormone (iPTH) levels when using Royaldee, and adjust dose if needed.
- The most common adverse reactions ($\geq 3\%$ and more frequent than placebo) were anemia, nasopharyngitis, increased blood creatinine, dyspnea, cough, congestive heart failure and constipation.
- Care should be taken while dosing Royaldee 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.

For Full Prescribing Information, please visit Royaldee.com.