Rayaldee®
calcifediol ER capsules
30 mcg

New capsule transition – FAQs

For Healthcare professionals

NEW CAPSULE LOOK,
SAME TRUSTED SCIENCE

1. **Why has the Rayaldee capsule changed from a soft capsule to a hard capsule?**
   OPKO decided to bring manufacturing capabilities in-house, which led to a change in the capsule's appearance.

2. **Will the new hard capsule formulation affect the pharmacokinetics of Rayaldee?**
   No, the pharmacokinetic profile remains the same. The new hard capsule has been tested to ensure it delivers the same amount of active ingredient in the body as the original soft capsule.

3. **Are there any differences in the stability or shelf life of the hard capsule compared to the soft capsule?**
   There are no changes in the stability or the expiration date of the product. The hard capsule meets the same stability criteria as the soft capsule.

4. **Does the capsule material change impact any known allergies or sensitivities in patients?**
   The components of the hard capsule are the same as the soft capsule. The only difference is that the hard capsule contains gellan gum which the soft capsule does not. However, you should always check the full list of excipients if your patient has known allergies.

5. **Should we expect any changes in the administration recommendations for Rayaldee with the new capsule form?**No, there are no changes in how Rayaldee should be administered. The dosing and administration instructions remain consistent with the soft capsule.

6. **How should patients be counseled regarding the change in capsule appearance?**
   Patients should be informed that although the capsule's appearance has changed, the efficacy, safety, and dosing remain the same. It's important to reassure them that they will receive the same therapeutic benefits.

7. **Will the new capsule form alter the way Rayaldee interacts with other medications?**
   No, there are no new interactions expected due to the change in capsule form. The interaction profile for Rayaldee remains the same.

8. **Is there any impact on the absorption rate of the medication with the hard capsule?**
   The absorption rate of Rayaldee with the new hard capsule has been shown to be equivalent to the original soft capsule.

9. **Has there been any change in the recommended storage conditions for Rayaldee with the new hard capsule?**
   No, Rayaldee should be stored in the same conditions as before: at room temperature (at 20-25°C / 68-77° F), away from light and moisture.

10. **Are there any new contraindications or precautions we should be aware of with the new hard capsule?**
    There are no new contraindications or precautions specific to the hard capsule form. The prescribing information remains consistent with the previous formulation. Visit www.Rayaldee.com for Important Safety Information and Full Prescribing information.

HCPs should always refer to the latest prescribing information provided by OPKO for the most up-to-date product details. If there are further questions or if additional clarification is needed, please contact OPKO's Medical Affairs department (phone: 1-844-729-2539 / email: medicalinformation@opko.com).

Rayaldee®
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.

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.
- 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.