Rayaldee®
calcifediol ER capsules
30 mcg

NEW CAPSULE LOOK,
SAME TRUSTED SCIENCE

New capsule transition – FAQs

For Pharmacists

1. Why has Rayaldee changed from a soft to a hard capsule?
The change is due to OPKO's decision to bring manufacturing in-house.

2. Will the new hard capsule have different storage requirements?
No, the storage conditions for Rayaldee remain the same: store at room temperature (at 20-25°C / 68-77° F), away from moisture and direct light.

3. Is the NDC number changing for the new hard capsule form?
Yes, the new NDC number for the hard capsule is 70301-1002-1. Please ensure you're using the correct number when processing prescriptions.

4. How should I manage inventory during the transition period where both capsule forms are available?
It's important to rotate stock to ensure the soft capsules are dispensed first. Monitor your inventory closely and communicate with your suppliers to manage the transition smoothly.

5. Will the capsule change affect the medication's price or insurance coverage?
The capsule change should not affect the price or insurance coverage. However, it is always recommended to verify with the specific insurance plans.

6. How do I explain the capsule change to patients to ensure they continue their treatment without concerns?
Assure patients that although the capsule's appearance has changed, the medication inside remains the same in terms of efficacy and safety. Encourage them to continue their treatment as prescribed.

7. Is there any change to the recommended patient counseling for Rayaldee with the new capsule?
Counseling remains the same; however, it is important to inform existing patients of the new appearance to avoid confusion or potential non-adherence.

8. Will the barcodes on the packaging change?
Yes, with the new NDC numbers, the barcodes will also change. Please update your systems accordingly.

9. Are there any differences in how the hard capsule is absorbed compared to the soft capsule?
No, the absorption profile of the hard capsule has been designed to match that of the soft capsule, ensuring consistent therapeutic effects.

10. Do I need to update any pharmacy systems or records with this capsule transition?
Yes, you will need to update your pharmacy management systems with the new NDC number and ensure that the product information reflects the current form of the medication.

Remember that, as pharmacists, you play a crucial role in helping patients navigate changes in their medications. Ensuring clear communication and offering reassurance about the continuity of care is key during this transition period for Rayaldee. For questions, please contact Rayaldee's patient hub services, OPKO Connect, at 1-844-414-OPKO (6756).

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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.