

New capsule transition - FAQs

For existing **RAYALDEE**[®] patients



**NEW CAPSULE LOOK,
SAME TRUSTED SCIENCE**

1. Has the medication changed with the new capsule form?

No, the medication inside the capsule is the same. The change is only in the outer shell and color of the capsule, not the active ingredient. The new capsule is a white two-piece banded hard capsule with an "O" and "30" imprinted in blue ink.

2. Will the new hard capsule affect how I take my medication?

You should take the medication exactly as you have been doing. The capsule change does not affect the way you take your medication. Visit www.Royaldee.com for more information on dosing and management.

3. Does the new hard capsule have any new side effects?

The safety profile remains the same as the original soft capsule. Visit www.Royaldee.com for Important Safety Information and for Full Prescribing information.

4. Will the new hard capsule change the effectiveness of my treatment?

The hard capsule will deliver the same amount of medication to your body as the original soft capsule, which is 30 mcg of the active ingredient, calcifediol.

5. Are there any new storage instructions for the new hard capsule?

The storage instructions remain the same. Continue to store your medication at room temperature (at 20-25°C / 68-77° F), away from light and moisture.

6. Can I take the capsule with food?

Follow the same instructions provided with the soft capsule: take Rayaldee by mouth at bedtime.

7. Is the new hard capsule safe for individuals with difficulty swallowing?

If you have had no trouble swallowing the original soft capsules, you should not experience issues with the new hard capsules. However, if you have questions, please consult with your healthcare provider.

8. Once I receive the new white capsule, do I have an option to request the blue capsule?

No, your pharmacy will be transitioning from blue to white capsules. Once you receive the white capsule, you will continue to receive the white capsule from your pharmacy.

9. Will my insurance cover the new hard capsule form of Rayaldee?

Coverage should remain unaffected by the change in capsule form. If you have questions regarding insurance coverage, please contact your pharmacy or OPKO Connect for assistance at 1-844-414-OPKO (6756).

10. Do I need a new prescription for the new hard capsule version of Rayaldee?

No, your current prescription for Rayaldee is still valid. You will receive the new hard capsule form when you refill your prescription.

If you have additional questions or concerns, please contact your healthcare provider, your pharmacy or Rayaldee's patient hub services, OPKO Connect, at 1-844-414-OPKO (6756).

Indication and Limitations of Use:

Rayaldee is a treatment for secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease (CKD) and low vitamin D levels (25-hydroxyvitamin D less than 30 ng/mL). It is not for patients with stage 5 CKD or end-stage kidney disease on dialysis.

Important Safety Information

- Before starting Rayaldee, the level of calcium in your blood should be in the normal range (below 9.8 mg/dL). Your doctor can tell you if your calcium level is right for starting Rayaldee.
 - Rayaldee can cause hypercalcemia and hypercalciuria (high levels of calcium in your blood and urine, respectively). You should tell your doctor if you are taking any other medications, including other vitamin D medications (prescription or over-the-counter vitamin D supplements). Your doctor may tell you to stop taking them while you are taking Rayaldee, as very high calcium levels due to high vitamin D levels could cause severe changes to your heart rhythm or seizures and require emergency treatment.
 - Tell your doctor about any and all medication you may be taking. While you are taking Rayaldee, tell your doctor if you receive any new prescriptions or start any new over-the-counter medications.
 - Tell your doctor immediately if you experience any of the following symptoms of very high calcium: feeling tired, difficulty thinking clearly, loss of appetite, nausea, vomiting, constipation, increased thirst, increased urination, weight loss, or any other abnormal symptoms or side effects.
 - While you are taking Rayaldee, your doctor will order laboratory tests to see how your SHPT is doing. These lab tests will also examine your blood levels of calcium, phosphorus, 25-hydroxyvitamin D, and PTH. Based on your test results, your dose of Rayaldee may be changed or stopped until your lab results improve.
 - The most common side effects of Rayaldee reported by patients in clinical trials were anemia (low levels of red blood cells or hemoglobin), infection in the nose and/or throat, high levels of blood creatinine (a lab test for measuring kidney function), shortness of breath, cough, congestive heart failure, and constipation.
 - Take your Rayaldee at bedtime and swallow your capsules whole; do not bite or chew them.
 - If you miss a dose, take Rayaldee at your next scheduled time. Do not take an extra dose to make up for the dose you missed.
 - Be sure to follow your doctor's orders, including getting your laboratory tests done on time.
1. If you have questions regarding why you were prescribed Rayaldee, please speak with your doctor.
 2. If you have questions regarding the support programs offered by OPKO Connect, you can call 1-844-414-OPKO (1-844-414-6756), option 1.
 3. If you have questions regarding Rayaldee or the disease state it is designated to treat, you may contact a Rayaldee Clinical Pharmacist at OPKO Connect at 1-844-414-OPKO (1-844-414-6756), option 2.
 4. You are encouraged to report negative side effects to the U.S. Food and Drug Administration (FDA) at www.fda.gov/medwatch or via phone at 1-800-FDA-1088 (1-800-332-1088).
 5. For more information about Rayaldee, please contact OPKO Medical Information at 1-844-729-2539 or medicalinformation@opko.com.

Please see Important Safety Information (ISI) and Full Prescribing Information available at www.Royaldee.com.



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

