

IT'S TIME TO TAKE CHARGE OF YOUR SHPT



Please see Important Safety Information on pages 15-18.
Please see accompanying Brief Summary.
For Full Prescribing Information, visit www.Royaldee.com.

**Royaldee**[®]
calcifediol ER capsules
30 mg

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. It can help increase the vitamin D level in your body and decrease a hormone called parathyroid hormone (**PTH**).

This brochure was designed to answer questions about what's happening in your body and how to get the best results with Rayaldee.



The most common side effects of Rayaldee reported by patients in clinical trials were anemia, infection in the nose and/or throat, high levels of blood creatinine, shortness of breath, cough, congestive heart failure, and constipation.

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WHAT IS SHPT?

Secondary hyperparathyroidism (SHPT) is a condition associated with **chronic kidney disease (CKD)**. Your body makes too much **parathyroid hormone (PTH)**, which prevents your body from balancing minerals and hormones, such as phosphorus, calcium, and vitamin D levels, correctly.

SO WHY TREAT SHPT?

SHPT is a silent disease. It may be doing **damage inside** your body, **even when you can't feel the effects.**

Without treatment, SHPT can cause serious health issues and lead to cardiovascular events, bone fractures, and even speed up the time to dialysis or death.



Your doctor can prescribe medications to treat SHPT—more specifically, to help reduce your elevated PTH level and increase your vitamin D level.

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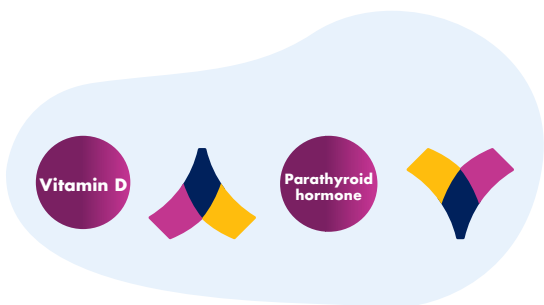
How do vitamin D levels relate to SHPT?

Some people with SHPT also have low levels of vitamin D and active vitamin D hormone (“active” means the form your body can use). When your kidneys make less active vitamin D hormone, your body has less calcium to use. People who have been diagnosed with CKD, SHPT, and low vitamin D levels have a greater risk of cardiovascular disease and bone fractures.



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HOW DOES RAYALDEE HELP YOUR SHPT?



To treat your **SHPT**, you need to help your parathyroid glands make less **PTH**, and you need to raise your low vitamin D level. **Rayaldee** helps your body do both. It works with your body to create the active form of vitamin D, which is the hormone your body can use, to lower your **PTH** level and absorb calcium.

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.

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How do you take Rayaldee?

The recommended starting dose is one capsule by mouth daily at bedtime. Your doctor may increase the dose based on how your body responds. You should take Rayaldee whole; do not chew or break the capsule. It's important to take **Rayaldee** as your doctor prescribes.



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How do you know if **Royaldee** is working?

It could take several months for your treatment to reach its full potential. Even if you do not feel any difference, it is very important that you stay on treatment as long as your doctor prescribes it for you. Your doctor will run lab tests so you can see how **Royaldee** is working for you.

Over time, **SHPT** can progress and become more difficult to treat, that is why it is very important to stay on track with your treatment. Speak to your doctor first if you plan to stop taking Royaldee.



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What happens if you forget a dose?



Like many medicines, Rayaldee needs to be taken regularly.

- If you miss a dose, take Rayaldee at the next scheduled time.
- **Do not take an extra dose to make up for the missed dose.** You can create calendar reminders on your phone or place a note near your bedside table so you can remember to **take Rayaldee every night.**

You can also install an app like **Medisafe**[®], a mobile medication management platform (iOS or Android, on your phone).



Is **Royaldee** Safe?

In clinical trials, **Royaldee** was found to be safe and generally well-tolerated. However, there are risks and important things you need to know:



- Tell your doctor about any and all medication you may be taking. While you are taking Royaldee, tell your doctor if you receive any new prescriptions or start any new over-the-counter medications.
- Talk to your doctor if you're feeling tired, have difficulty thinking clearly, loss of appetite, nausea, vomiting, constipation, increased thirst, increased urination, weight loss, or any other abnormal symptoms or side effects.

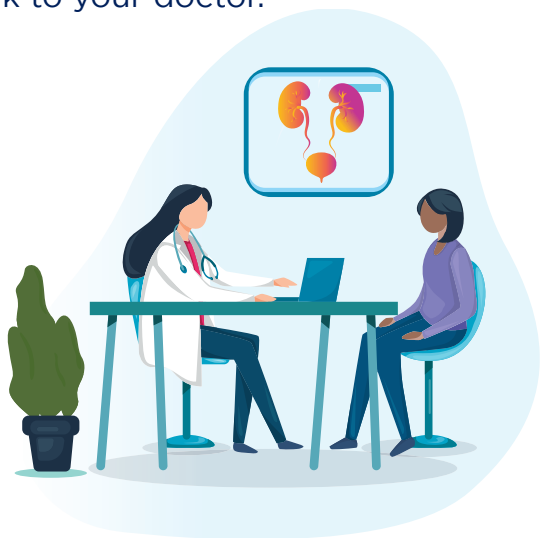
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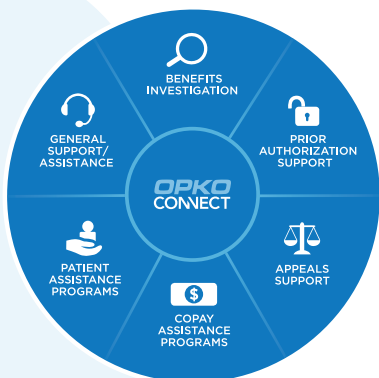
- The most common side effects of Rayaldee reported by patients in clinical trials were anemia (low levels of red blood cells or hemoglobin), infection in the nose and/or throat, high levels of blood creatinine (a substance measured by lab tests that helps determine kidney function), shortness of breath, cough, congestive heart failure, and constipation.
- 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 for 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.

If you have any questions, be sure to talk to your doctor.



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OPKO CONNECT CAN HELP



After your doctor prescribes **Royaldee**, the office can help you sign up with **OPKO Connect**, a program that can help you:

- Check on your insurance coverage and benefits
- Find help with paying for your medicine
- Get started with **Royaldee** as soon as possible.

OPKO Connect services are available Monday through Friday, 8 am to 8 pm ET, by calling **1-844-414-OPKO (6756)**.

How do you get medication coverage support?

Most patients have an out-of-pocket cost for **Royaldee** of less than \$10 per month.*



If you do not have pharmacy insurance coverage or you are unable to afford your **Royaldee** copay, please call your doctor's office. You may qualify for the patient assistance program offered only by **OPKO Connect** that offers free medication.**



*Eligible commercially-insured patients can fill their Royaldee prescription for \$0 with eVoucherRx™, a program from RelayHealth that automatically applies copay savings at the patient's pharmacy. If the patient's pharmacy does not work with RelayHealth eVoucherRx™, then OPKO Connect has a \$0 per month copay program for eligible commercially-insured patients. Out-of-pocket cost for eligible Medicare Part D Low Income Subsidy patients is typically \$0 - \$10.35 per month (source: OPKO Connect and Specialty Pharmacy case data 2023).

**Eligibility criteria apply and annual re-enrollment is required.

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How does the **Royaldee** Financial Assistance Program work?

Watch this video to learn more.

It's simple. We can help. We care.



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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.

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Important Safety Information continued

- 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.

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Important Safety Information continued

- 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 substance measured by lab tests that helps determine 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.



Important Safety Information continued

1. If you have questions regarding why you were prescribed **Royaldee**, please speak with your doctor.
2. If you have questions regarding **Royaldee** or the disease state it is designed to treat, you may contact a **Royaldee** Clinical Pharmacist at **OPKO Connect** at **1-844-414-OPKO (1-844-414-6756)**, option 1.
3. If you have questions regarding the support programs offered by **OPKO Connect**, you can call **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 **Royaldee**, please contact **OPKO** Medical Information at 1-844-729-2539 or **medicalinformation@opko.com**.

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NOTES FOR MY DOCTOR



QUESTIONS ABOUT STAYING ON TRACK?

Your healthcare provider is your best source of information about your condition, so be sure to talk to them if you have any questions about Rayaldee.



Learn how to stay on track by watching our video library



 YouTube



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