

# Q&A



## What is Rayaldee®?

And how can it help me?



Rayaldee® (calcifediol) extended-release 30 mcg capsules

Please see Important Safety Information on pages 12-15.

Please see accompanying Brief Summary.

For Full Prescribing Information, visit [www.Royaldee.com](http://www.Royaldee.com).



**Rayaldee**<sup>®</sup>  
calcifediol ER capsules  
30 mcg

Royaldee® is a treatment for secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease (CKD) and low vitamin D blood levels (25-hydroxyvitamin D less than 30 ng/mL). Royaldee is not for patients with stage 5 CKD or end-stage renal disease on dialysis. It can help increase the vitamin D level in your body and decrease a hormone called parathyroid hormone, or PTH. This brochure was designed to answer questions about what's happening in your body and how to get the best results with Royaldee.

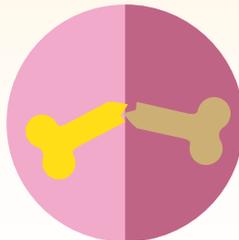
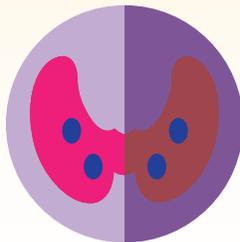
The most common side effects of Royaldee were anemia, shortness of breath, cough, congestive heart failure, and constipation.



## What is SHPT?



There are four glands located in your neck called the parathyroid glands. They help make sure your blood has the right amount of calcium. When calcium levels are too low, these glands make a hormone called parathyroid hormone, or PTH. One function of PTH is to increase the release of calcium and phosphorus from your bones. If not controlled, the parathyroid glands make too much PTH. When this happens in patients with CKD, it is called secondary hyperparathyroidism, or SHPT.



*The parathyroid glands make PTH, which removes calcium from bones.*

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## What happens when my bones lose calcium and phosphorus as a result of SHPT?



Over time, this can make your bones more brittle. And it can lead to bone pain and fractures. Calcium and phosphorus are also needed by many cells in the body to function in a healthy way. That's why SHPT is not just about your bones. Changes in calcium and phosphorus can also damage your heart, blood vessels, and body tissues.



## SHPT sounds serious. Is it?



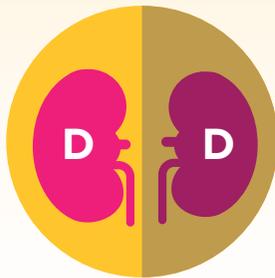
SHPT is a disorder that can lead to serious problems if not monitored and treated. Your doctor can prescribe medications to treat SHPT—more specifically, to help reduce your too-high PTH level and increase your vitamin D level.



## How does my vitamin D level 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 with CKD, SHPT, and low vitamin D levels have a greater risk of bone disease and fractures.



*Chronic kidney disease and SHPT can affect your vitamin D levels.*



## How can Rayaldee help?



To treat your SHPT, you need to help your parathyroid glands make less PTH. And you need to increase your low vitamin D level. Rayaldee helps your body do both. It is an extended-release prohormone of the active form of vitamin D that works to decrease your PTH level and increase your vitamin D level.



### 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 blood levels (25-hydroxyvitamin D less than 30 ng/mL). It is not for patients with stage 5 CKD or on dialysis.



## How is Rayaldee different?



Rayaldee is designed to lower your PTH levels and increase levels of vitamin D. And extended-release means your vitamin D level gradually increases over time. You could say Rayaldee works with your body to create the active form of vitamin D, which is the form your body can use.



### **Important Safety Information**

Before starting Rayaldee, the level of calcium in your blood should be below 9.8 mg/dL. Your doctor can tell you if your calcium level is right for starting Rayaldee.



## Can I feel it working?



SHPT is sometimes referred to as a silent disorder. It may be doing damage inside your body, even when you can't feel the effects. In the same way, you won't feel Rayaldee working. But it's still important to take Rayaldee every day just as your doctor has prescribed.



### **Important Safety Information**

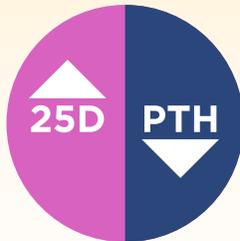
Tell your doctor immediately if you experience any of the following symptoms of very high calcium: feeling tired, difficulty thinking clearly, loss of appetite, nausea, vomiting, constipation, increased thirst, increased urination, and weight loss.



## How do I know Rayaldee is working?



You can see the effects Rayaldee has when your doctor checks your lab results. In clinical studies, Rayaldee increased vitamin D levels and decreased PTH levels in most of the people who took it. Make sure you ask your doctor about your lab tests, so you can see how Rayaldee is working for you.



*Rayaldee treats SHPT in adults with stage 3 or 4 CKD and low levels of total 25-hydroxyvitamin D (25D <30 ng/mL).*

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## Is Rayaldee safe?



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

- Be sure to take your dose at bedtime and swallow your capsule whole.
- 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.
- 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.

- 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.
- 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 about this information, be sure to talk to your healthcare provider.

# Important information about Rayaldee® (calcifediol) extended-release capsules



## 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 blood levels (25-hydroxyvitamin D less than 30 ng/mL). It is not for patients with stage 5 CKD or 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 medications 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, and weight loss.
- 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.



- 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 into 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 Rayaldee or the disease state it is designed to treat, you may contact a Rayaldee Clinical Pharmacist at OPKO Connect at **1-844-414-OPKO** (1-844-414-6756), option #1.
3. If you have questions regarding the support or programs offered by OPKO Connect you can find additional information online at **<http://www.OPKOConnect.com>** or by calling **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](http://www.fda.gov/medwatch)** or via phone at **1-800-FDA-1088** (1-800-332-1088).



## How do I take Rayaldee?



It's important to take Rayaldee as your doctor prescribed. The recommended starting dose is one 30 mcg capsule once a day. Just be sure to take your dose at bedtime and swallow the capsule whole. 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.



*Take Rayaldee once a day, at bedtime.*



# What if my insurance doesn't cover Rayaldee?



OPKO Connect is a hotline staffed with Rayaldee Support Specialists. Their job is to help patients obtain access to Rayaldee.\*

## Insurance coverage support

- They can help you understand your insurance coverage, provide you with support to try to get your prescription approved, or identify other insurance coverage options you may be eligible for.

## Free product through our Patient Assistance Program

- If you do not have insurance, your insurance policy does not cover Rayaldee, or you have exhausted your prescription benefits, the Support Specialists can work with you and your doctor's office to see if you qualify to receive Rayaldee for free.

*\*Certain eligibility and restrictions apply. Please see program terms and conditions or contact our Rayaldee Support Specialists for more information.*

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## Financial assistance

- If your prescription costs more than \$5, the OPKO Copay Assistance Program (OCAP) will help pay your out-of-pocket expenses if you meet the eligibility criteria.
- As long as your pharmacy is within the Relay Health Pharmacy Network, and you qualify, you will receive your prescription for \$5. You don't need to do anything else. To see if your pharmacy is in the Relay Health Pharmacy Network, please visit:  
**<http://www.evoucherrx.relayhealth.com/storelookup>**